2014 Edition
Test Procedure for §170.314.a.2 Drug-drug, drug-allergy interaction checks
For Public Comment ■ September 21, 2012

The Office of the National Coordinator for
Health Information Technology

Test Procedure for §170.314 (a)(2) Drug-drug, drug-allergy interaction checks

This document describes the 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 Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule. The document[1] is organized by test procedure and derived test requirements with traceability to the normative certification criteria as described in the Overview document located at [available when final]. 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. Testing of EHR technology in the Permanent Certification Program, henceforth referred to as the ONC HIT Certification Program[2], is carried out by National Voluntary Laboratory Accreditation Program-Accredited Testing Laboratories (ATLs) as set forth in the final rule establishing the Permanent Certification Program (*Establishment of the Permanent Certification Program for Health Information Technology, 45 CFR Part 170; February 7, 2011*.)

Questions or concerns regarding the ONC HIT Certification Program should be directed to ONC at ONC.Certification@hhs.gov.

CERTIFICATION CRITERIA

This certification criterion is from the Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule issued by the Department of Health and Human Services (HHS) on September 4, 2012.

§170.314(a)(2) Drug-drug, drug-allergy interaction checks.
  (i)   Interventions. Before a medication order is completed and acted upon during computerized provider order entry (CPOE), interventions must automatically and electronically indicate to a user drug-drug and drug-allergy contraindications based on a patient's medication list and medication allergy list.
  (ii) Adjustments.

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[1] Disclaimer: Certain commercial products may be identified in this document. Such identification does not imply recommendation or endorsement by ONC.

[2] Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule

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(A) Enable the severity level of interventions provided for drug-drug interaction checks to be adjusted.

(B) Limit the ability to adjust severity levels to an identified set of users or available as a system administrative function.

Per Section III.A of the preamble of the Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule, the 2014 Edition of this certification criterion is classified as revised from the 2011 Edition. This certification criterion meets at least one of the three factors of revised certification criteria: (1) the certification criterion includes changes to capabilities that were specified in the previously adopted certification criterion, (2) the certification criterion has a new mandatory capability that was not included in the previously adopted certification criterion, or (3) the certification criterion was previously adopted as "optional" for a particular setting and is subsequently adopted as "mandatory" for that setting.

Per Section III.A of the preamble of the Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule where the drug-drug, drug-allergy interaction checks certification criterion is discussed:

- "We have modified this language in the certification criterion to reflect the recommended text by replacing 'placed' with "completed and acted upon." We believe that this revision should also address the testing timing […]"
- "The certification criterion [requires] that EHR technology include the capability to adjust the severity level of interventions provided for drug-drug interaction checks […] Unlike drug-drug alerts, the rationale we provided was that it is important for drug-allergy interventions to be indicated […] and [we] decline to include for the purposes of certification a severity adjustment requirement for drug-allergy interventions."
- "The certification criterion does not specifically address a particular drug-drug intervention," but rather that the EHR "includes a capability that permits certain users to adjust the severity level of interventions."

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)."

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- "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."

CHANGES FROM 2011 TO 2014 EDITION

Per Section III.A of the preamble of the Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule where the drug-drug, drug-allergy interaction checks certification criterion is discussed:

- "We proposed a "drug-drug, drug-allergy interaction checks" certification criterion (§ 170.314(a)(2)) that included the recommendations of the HITSC to eliminate for certification the ability for EHR technology to permit users to adjust drug-allergy interaction checks, replace the term "real-time" with "before the order is executed," revise the language to specify that notifications should happen during CPOE, specify that the level of severity of the notifications is what can be adjusted, and limit the ability to make adjustments to an identified set of users or available as a system administrative function."

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 indicate interventions for drug-drug and drug-allergy contraindications to a user before an order is completed and acted upon using computerized provider order entry (CPOE). Interventions indicated are based on information in the patient's medication list and medication allergy list
- Enable certain users to adjust the severity level of interventions provided for drug-drug interaction checking

The Vendor provides the test data for this Test Procedure.

This test procedure is organized into two sections:

- Indicate – evaluates the capability for the EHR to indicate interventions for drug-drug and drug-allergy contraindications, based on a patient's medication list and medication allergy list, automatically and electronically to the user during CPOE before an order is completed and acted upon.

o The Vendor creates a patient record in their EHR and populates that patient record with Vendor-specified medications and medication allergies

o The Tester signs on to the EHR as a licensed professional, enters the Vendor-supplied medication order(s) via CPOE, and triggers at least one drug-drug contraindication intervention and at least one drug-allergy contraindication intervention

o The Tester validates that the drug-drug and drug-allergy contraindication interventions are indicated by the EHR to the user automatically and electronically before each order is completed and could be acted upon

- Adjust and limit – evaluates the capability for an identified limited set of users to make adjustments to the severity level of interventions provided for drug-drug interaction checking.
  o The Tester signs on to the EHR as a user identified by the Vendor to have the ability to adjust the severity level of interventions for drug-drug interaction checks
  o The Tester accesses the drug-drug interaction checking level of severity adjustment capabilities identified by the Vendor and adjusts the intervention severity level to allow all severities to be triggered
  o The Tester signs on to the EHR as a user who has the ability to enter orders via CPOE and enters two or more Vendor-supplied medication orders – one order that will trigger a drug-drug intervention for a low significance contraindication (e.g. minor, low severity) and one order that will trigger a drug-drug intervention for a high significance contraindication (e.g. major, high severity)
  o The Tester verifies that the Vendor-supplied medication order(s) trigger drug-drug interventions for both low significance and high significance severity levels
  o The Tester signs on to the EHR as a user identified by the Vendor to have the ability to adjust the severity level of interventions for drug-drug interaction checks and adjusts the intervention severity levels to allow only the high significance severities to be triggered
    ▪ An example of this adjustment would be changing the severity level of interventions indicated for all drug-drug interaction checks to level 5, where level 5 warns of interactions that are clinically high significance, causing the EHR to indicate only level 5 drug-drug interaction interventions
  o The Tester signs on to the EHR as a user who has the ability to enter orders via CPOE and enters two or more Vendor-supplied medication orders – one order that will trigger a drug-drug intervention for a low significance contraindication and one order that will trigger a drug-drug intervention for a high significance contraindication
  o The Tester verifies that the ONC-supplied medication orders trigger drug-drug interventions for only the high significance severity level
  o The Tester signs on to the EHR as a user identified by the Vendor **not** to have the ability to adjust the severity level of interventions for drug-drug interaction checks
  o The Tester attempts to access the severity level adjustment capability for drug-drug interaction checking identified by the Vendor
  o The Tester verifies that this user is unable to access the severity level adjustment capability

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REFERENCED STANDARDS

None

NORMATIVE TEST PROCEDURES

Derived Test Requirements

DTR170.314.a.2 – 1: Automatically and Electronically Indicate Drug-drug and Drug-allergy Interventions

DTR170.314.a.2 – 2: Adjust Severity Level of Interventions Indicated for Drug-drug Interaction Checking

DTR170.314.a.2 – 1: Automatically and Electronically Indicate Drug-drug and Drug-allergy Interventions

Required Vendor Information

VE170.314.a.2 –1.01: Vendor shall identify a patient with an existing record in the EHR to be used for this test

VE170.314.a.2 – 1.02: Vendor shall populate the patient record with Vendor-supplied test data in the medication list and the medication allergy list

VE170.314.a.2 – 1.03: Vendor shall identify the Vendor-supplied medication orders to be used for this test

VE170.314.a.2 – 1.04: Vendor shall identify the Vendor-supplied drug-drug and drug-allergy contraindication interventions that are available in the EHR for use in this test

VE170.314.a.2 – 1.05: Vendor shall identify the EHR function(s) that are available to enter orders via CPOE

VE170.314.a.2 – 1.06: Vendor shall identify 1) a user who has the ability to adjust the severity level of interventions for drug-drug interaction checks, 2) a user who does not have the ability to adjust the severity of interventions provided for drug-drug interaction checks (one without appropriate access or system administrative function), and 3) a user who has the ability to place orders via CPOE

VE170.314.a.2 – 1.07: Vendor shall identify the EHR function(s) available to adjust drug-drug interaction checking severity levels

Required Test Procedures

TE170.314.a.2 – 1.01: Using the Vendor-identified function(s), the Tester shall sign on to the EHR, select an existing patient record identified by the Vendor, and confirm that the Vendor-supplied medication and medication allergy test data are included in the medication and medication allergy lists for the patient

TE170.314.a.2 – 1.02: Using the Vendor-identified function(s) and the Vendor-supplied test data identified in VE170.314.a.2 – 1.03, the Tester shall enter medication orders into the existing patient's record via CPOE, triggering at least one of the drug-drug interventions identified by the Vendor in VE170.314.a.2 – 1.04

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TE170.314.a.2 – 1.03: Using the Vendor-identified function(s) and the Vendor-supplied test data identified in VE170.314.a.2 – 1.03, the Tester shall enter medication orders into the existing patient's record via CPOE, triggering at least one of the drug-allergy interventions identified by the Vendor in VE170.314.a.2 – 1.04

TE170.314.a.2 – 1.04: Using the Inspection Test Guide, the Tester shall verify that the drug-drug contraindication intervention(s) and the drug-allergy contraindication intervention(s) are triggered during CPOE before the medication orders are completed and acted upon and based on the information in the patient's medication list and medication allergy list

Inspection Test Guide

IN170.314.a.2 – 1.01: Using the Vendor-supplied test data, the Tester shall verify that at least one drug-drug contraindication intervention is electronically and automatically indicated to the user during CPOE before a medication order is completed and acted upon based on the patient's medication list

IN170.314.a.2 – 1.02: Using the Vendor-supplied test data, the Tester shall verify that at least one drug-allergy contraindication intervention is electronically and automatically indicated to the user during CPOE before a medication order is completed and acted upon based on the patient's medication allergy list

DTR170.314.a.2 – 2: Adjust Severity Level of Interventions Indicated for Drug-drug Interaction Checking

Required Vendor Information

- As defined in DTR170.314.a.2 – 1, no additional information is required

Required Test Procedures

TE170.314.a.2 – 2.01: Using the Vendor-identified EHR function(s), the Tester shall sign on to the EHR as a user who has the ability to adjust the severity level of interventions for drug-drug interaction checks and access the level of severity adjustment capabilities

TE170.314.a.2 – 2.02: Using the Vendor-identified EHR function(s), the Tester shall adjust the intervention severity level to allow all drug-drug interaction checking severity levels to be triggered

TE170.314.a.2 – 2.03: Using the Vendor-identified EHR function(s), the Tester shall sign on to the EHR as a user who does not have the ability to adjust drug-drug contraindication intervention severity levels and shall verify that this user is unable to access the adjustment capabilities

TE170.314.a.2 – 2.04: Using the Vendor-identified EHR function(s) and the Vendor-supplied test data, the Tester shall sign on to the EHR as a user who has the ability to place orders via CPOE, select a test patient identified by the Vendor, enter at least one medication order that will cause an intervention to be indicated for a low significance drug-drug interaction, and enter at least one other medication order

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that will cause an intervention to be indicated for a high significance drug-drug interaction

TE170.314.a.2 – 2.05: Using the Inspection Test Guide, the Tester shall verify that the low significance and high significance drug-drug interaction interventions are indicated to the user and that that those interventions are indicated during CPOE before the medication orders are completed and acted upon

TE170.314.a.2 – 2.06: Using the Vendor-identified EHR function(s), the Tester shall sign on to the EHR as a user who has the ability to adjust the severity level of interventions for drug-drug interaction checks, access the drug-drug interaction checking level of severity adjustment capabilities, and adjust the severity levels to allow only the high significance interventions to be triggered

TE170.314.a.2 – 2.07: Using the Vendor-identified EHR function(s), the Tester shall sign on to the EHR as a user who has the ability to place orders via CPOE, select the patient selected in TE170.314.a.2 – 2.04, and enter the medication orders entered in TE170.314.a.2 – 2.04

TE170.314.a.2 – 2.08: Using the Inspection Test Guide, the Tester verifies that only the drug-drug interaction intervention for the high significance contraindication is indicated to the user and that the intervention is indicated during CPOE before the medication order is completed and acted upon

Inspection Test Guide

IN170.314.a.2 – 2.01: Tester shall verify that the ability to adjust the severity level of interventions for drug-drug interaction checks is only accessible by authorized users

IN170.314.a.2 – 2.02: Tester shall verify that the severity level of interventions provided for drug-drug interaction checks are adjustable by an authorized user

IN170.314.a.2 – 2.03: Tester shall verify that:

- When the intervention severity level is adjusted to allow only high significance severity interventions to be indicated to the CPOE user, that low significance severity interventions are not indicated when orders are entered for low significance drug-drug contraindications
- When the intervention severity level is adjusted to allow all interventions, including low significance severity interventions, to be indicated to the CPOE user, that severity interventions are indicated when orders are entered for both low significance and high significance drug-drug contraindications

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 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

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- Tester shall record as part of the test documentation the specific Vendor-supplied test data that was utilized for testing

CONFORMANCE TEST TOOLS

None

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Document History

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1.0	Released for public comment	September 21, 2012