# Test Procedure for §170.304 (e) Clinical Decision Support

This document describes the draft 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 (e) Clinical decision support.

(1) Implement rules. Implement automated, electronic clinical decision support rules (in addition to drug-drug and drug-allergy contraindication checking) based on the data elements included in: problem list; medication list; demographics; and laboratory test results.

[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) Notifications. Automatically and electronically generate and indicate in real-time, notifications and care suggestions based upon clinical decision support rules.

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 clinical decision support certification criterion is discussed:

- Meaningful Use Stage 1 Objective: Implement one clinical decision support rule relevant to specialty or high clinical priority along with the ability to track compliance that rule
- Meaningful Use Stage 1 Measure: Implement one clinical decision support rule
- "…we clarify that with respect to notifications, that "real-time" means at the point of clinical decision making (i.e., notifications must be provided when an eligible professional is using Certified EHR Technology and not run overnight and provided in the morning, for instance)."
- "The use of a pop-up message or sound was not a specified requirement in the regulation text. We agree with the commenters who explained that there may be better ways to provide alerts. 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. Additionally, we agree with the commenters who suggested that we replace "alert" with "notification," and we have made that change globally across all certification criteria that used the term alert."

## 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 in an ambulatory setting to:

- Provide one or more electronic clinical decision support rules (in addition to drug-drug and drug-allergy contraindication checking) that utilize data elements in a patient's problem list, medication list, demographics and laboratory test results.
- Generate and indicate automatically, electronically and in real-time notifications and care suggestions based upon clinical decision support rules

The Vendor supplies the test data for this test procedure.

The FR does not identify specific clinical decision support rules which must be implemented in the EHR. The Vendor will identify the rules provided in their EHR technology that can be used for this test. This test procedure does not specify a full evaluation of the validity of the implemented rules.

This test procedure is organized into two sections:

- Implement rules – evaluates the capability to provide one or more automated, electronic clinical decision support rules (in addition to drug-drug and drug-allergy contraindication checking) based on data elements in a patient's problem list, medication list, demographics and laboratory test results.

- The Tester validates that one or more electronic clinical decision support rules (in addition to drug-drug and drug-allergy contraindication checking) are provided in the EHR in an ambulatory setting
- The Tester validates that these rules are based on data elements in a patient's problem list, medication list, demographics and laboratory test results

- Generate and indicate notifications and care suggestions – evaluates the capability to generate and indicate in the EHR in an ambulatory setting notifications and care suggestions in real-time based upon clinical decision support rules provided by the Vendor
  - The Tester performs the Vendor-identified EHR functions and generates in real-time notifications and care suggestions based on the clinical decision support rule(s) identified by the Vendor and verified by the Tester in the Implement Rules test
  - The Tester validates that the notifications and care suggestions verified in the Implement Rules test:
    - are generated and indicated to the user in real-time
    - are based on one or more clinical decision support rules that use data elements in a patient's problem list, medication list, demographics and laboratory results
    - are displayed as described by the Vendor

## REFERENCED STANDARDS

None

## NORMATIVE TEST PROCEDURES

**Derived Test Requirements**

DTR170.304.e – 1: Implement Clinical Decision Support Rules in an Ambulatory Setting

DTR170.304.e – 2: Automatically Generate and Indicate Notifications and Care Suggestions in an Ambulatory Setting

**DTR170.304.e – 1: Implement Clinical Decision Support Rules in an Ambulatory Setting**

Required Vendor Information

VE170.304.e – 1.01: Vendor shall identify one or more automated, electronic clinical decision support rules (in addition to drug-drug and drug-allergy contraindication checking) based on data elements in a patient's problem list, medication list, demographics and laboratory test results to be used for this test

VE170.304.e – 1.02: Vendor shall identify the EHR function(s) that are available to: 1) verify the presence of identified clinical decision support rules, 2) select the patient, 3) generate and indicate real-time notifications and care suggestions

Required Test Procedure:

TE170.304.e – 1.01: Using EHR functions identified by the Vendor, the Tester shall verify that one or more clinical decision support rule(s) identified by the Vendor are present in the EHR

TE170.304.e – 1.02: Using the NIST-supplied Inspection Test Guide, the Tester shall verify that the electronic clinical decision support rule(s) identified by the Vendor in the EHR support the types of rules identified in the criteria

Inspection Test Guide

IN170.304.e – 1.01: Tester shall verify that one or more automated, electronic clinical decision support rule(s) identified by the Vendor (in addition to drug-drug and drug-allergy contraindication checking) are present in the EHR

IN170.304.e – 1.02: Tester shall verify that one or more automated, electronic clinical decision support rule(s) identified by the Vendor are based on data elements in a patient's problem list, medication list, demographics and laboratory test results

IN170.304.e – 1.03 Tester shall verify that one or more automated, electronic clinical decision support rule(s) identified by the Vendor contains a logic to initiate the rule, logic to determine action, and notification mechanism

**DTR170.304.e – 2: Automatically Generate and Indicate Notifications and Care Suggestions in an Ambulatory Setting**

Required Vendor Information

- Information as defined in DTR170.304.e – 1 and the following additional information is required

VE170.304.e – 2.01: Vendor shall identify a patient with an existing record in the ambulatory EHR to be used for this test

Required Test Procedure:

TE170.304.e – 2.01: Using the EHR function(s) identified by the Vendor, the Tester shall select the patient's existing record and perform the Vendor-identified actions that generate and indicate in real-time notifications and care suggestions based on the clinical decision support rules validated in the DTR170.304.e – 1: Implement Clinical Decision Support Rules in an Ambulatory Setting test

TE170.304.e – 2.02: Using the NIST-supplied Inspection Test Guide, the Tester shall verify that the notifications and care suggestions validated in the DTR170.304.e – 1: Implement Clinical Decision Support Rules in an Ambulatory Setting test are generated and indicated in real-time, and are displayed as described by the Vendor in VE170.304.e – 1.01

Inspection Test Guide

IN170.304.e – 2.01: Tester shall verify that the notifications and care suggestions validated in the DTR170.304.e – 1: Implement Clinical Decision Support Rules in an Ambulatory

Setting test are generated and indicated in real-time and are displayed as described by the Vendor in VE170.304.e – 1.01

## 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 |
|---|---|---|
| 0.5 | Original draft version | April 8, 2010 |
| 1.0 | Updated to reflect Final Rule | July 21, 2010 |
| 1.0 | Updated to remove “Pending” in header | August 13, 2010 |