Document Change History

Version Number	Description of Change	Date Published
0.5	Updated typographical error in certification criteria on page 2	May 11, 2010

Test Procedure for §170.306 (c) Clinical decision support

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

§170.306 (c) Clinical decision support.

(1) Implement rules. Implement automated, electronic clinical decision support rules (in addition to drug-drug and drug-allergy contraindication checking) according to a high priority hospital condition that use demographic data, specific patient diagnoses, conditions, diagnostic test results and/or patient medication list.
(2) Alerts. Automatically and electronically generate and indicate in real-time, alerts and care suggestions based upon clinical decision support rules and evidence grade.
(3) 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 Module[1] to:

- Configure automated, electronic clinical decision support rules (in addition to drug-drug and drug-allergy contraindication checking) that use patient demographic data, specific patient diagnoses, conditions, diagnostic test results and/or patient medication list
- Automatically and electronically generate and indicate, in real-time, alerts and care suggestions based upon clinical decision support rules; and
- Automatically and electronically track, record, and generate reports on the number of alerts responded to by a user during the test

The Vendor supplies the test data for this test procedure.

[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.

Per the IFR, there are no specific clinical decision support rules which should be evaluated in the test procedure. The Vendor will identify the rules configured in the EHR which can be used for this test. In the IFR there are no specific requirements identified for the clinical validity or accuracy of the algorithms implemented by the Vendor. The test procedure is intentionally silent on evaluating those aspects of the rules implemented by the Vendor.

This test procedure is organized into three sections:

- Implement rules – evaluates the capability to implement automated, electronic clinical decision support rules (in addition to drug-drug and drug-allergy contraindication checking) that use patient demographic data, specific patient diagnoses, conditions, diagnostic test results and/or patient medication list
    - The Tester validates that two or more electronic clinical decision support rules (in addition to drug-drug and drug-allergy contraindication checking) that use patient demographic data, specific patient diagnoses, conditions, diagnostic test results and/or patient medication list are configured in the EHR

- Generate and indicate alerts – evaluates the capability to generate, indicate, and respond to alerts and care suggestions, in real-time, based upon clinical decision support rules configured by the Vendor
    - The Tester performs the Vendor-identified EHR functions and generates two or more alerts and care suggestions based on the clinical decision support rules examined in the Implement Rules test
    - 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 Alerts Statistics Reports
    - The Tester validates that the alerts and care suggestions examined in the Implement Rules test:
        - are generated and indicated to the user in real-time
        - are based on the clinical decision support rules that use patient demographic data, specific patient diagnoses, conditions, diagnostic test results and/or patient medication list
        - are displayed as described by the Vendor

- Track, record, and report alert statistics – evaluates the capability to track, record, and generate reports on the number of clinical decision support alerts responded to by a user
    - The Tester validates that the responses to the alerts generated and responded to in the Generate and Indicate Alerts test are tracked, recorded, and reported accurately and completely

REFERENCED STANDARDS

None

NORMATIVE TEST PROCEDURES

Derived Test Requirements

DTR170.306.c – 1: Implement clinical decision support rules

DTR170.306.c – 2: Automatically generate and indicate alerts and care suggestions

DTR170.306.c – 3: Track, record, and generate reports on alert statistics

DTR170.306.c – 1: Implement clinical decision support rules

Required Vendor Information

VE170.306.c – 1.01: Vendor shall configure and identify two or more automated, electronic clinical decision support rules (in addition to drug-drug and drug-allergy contraindication checking) to be used for this test

VE170.306.c – 1.02: Vendor shall identify the EHR function(s) that are available to: 1) examine the configured clinical decision support rules, 2) select the patient, 3) generate, indicate, and respond to real-time alerts and care suggestions based on patient demographic data, specific patient diagnoses, conditions, diagnostic test results and/or patient medication list, 4) automatically and electronically track, record, and generate reports on the number of clinical decision support alerts responded to by a user

Required Test Procedure:

TE170.306.c – 1.01: Using EHR functions identified by the Vendor, the Tester shall examine the electronic clinical decision support rules which are configured in the EHR

TE170.306.c – 1.02: Using the NIST-supplied Inspection Test Guide, the Tester shall verify that the electronic clinical decision support rules configured in the EHR support the types of rules identified in the criteria

Inspection Test Guide

IN170.306.c – 1.01: Tester shall verify that two or more electronic clinical decision support rules (in addition to drug-drug and drug-allergy contraindication checking) that use patient demographic data, specific patient diagnoses, conditions, diagnostic test results and/or patient medication list are configured in the EHR. There is no requirement for the Tester to validate the algorithm or clinical validity of the rules provided by the Vendor for this test

DTR170.306.c – 2: Automatically generate and indicate alerts and care suggestions

Required Vendor Information

- Information as defined in DTR170.306.c – 1 and the following additional information is required

VE170.306.c – 2.01: Vendor shall identify a patient with an existing record in the EHR to be used for this test

VE170.306.c – 2.02: Vendor shall configure the test data for this test including patient demographic data, specific patient diagnoses, conditions, diagnostic test results and/or patient medication list

Required Test Procedure:

TE170.306.c – 2.01: Using the EHR function(s) identified by the Vendor, the Tester shall select the patient's existing record and perform the actions that automatically generate and indicate, in real-time, alerts and care suggestions based on the clinical decision support rules validated in the Implement Clinical Decision Support Rules test

TE170.306.c – 2.02: Using the EHR function(s) identified by the Vendor, the Tester shall respond to all but one of the generated alerts and care suggestions and shall record the number of alerts to which they responded

TE170.306.c – 2.03: Using the NIST-supplied Inspection Test Guide, the Tester shall verify that the alerts and care suggestions validated in the Implement Clinical Decision Support Rules test are generated, indicated, and responded to in real-time, and are displayed as described by the Vendor in VE170.306.c – 1.01

Inspection Test Guide

IN170.306.c – 2.01: Tester shall verify that the alerts and care suggestions validated in the Implement Clinical Decision Support Rules test are generated, indicated, and responded to in real-time; are displayed as described by the Vendor in VE170.306.c – 1.01; and are based on patient demographic data, specific patient diagnoses, conditions, diagnostic test results and/or patient medication list

DTR170.306.c – 3: Track, record, and generate reports on alert statistics

Required Vendor Information

- As defined in DTR170.306.c – 1 and DTR170.306.c – 2, no additional information is required

Required Test Procedure:

TE170.306.c – 3.01: Using the EHR function(s) identified by the Vendor, the Tester shall generate reports on the number of clinical decision support alerts and care suggestions responded to in the Generate and Indicate Alerts and Care Suggestions test

TE170.306.c – 3.02: Using the NIST-supplied Inspection Test Guide, the Tester shall verify that the reports are accurate and complete

Inspection Test Guide

IN170.306.c – 3.01: Tester shall verify that the number of user responses to clinical decision support alerts and care suggestions from the Generate and Indicate Alerts and Care Suggestions test 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