Test Procedure for §170.302 (e) Maintain active medication allergy list

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.

§170.302 (e) Maintain active medication allergy list. Enable a user to electronically record, modify, and retrieve a patient's active medication allergy list as well as medication allergy history for longitudinal care.

[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.

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 maintain active medication allergy list certification criterion is discussed:

- "The reference to longitudinal care is intended to convey that the problem list must be comprehensive in the sense that it must be capable of including entries provided over an extended period of time. Consequently, for Complete EHRs and EHR Modules to be certified for an ambulatory setting, they will need to be designed to enable the user to electronically record, modify, and retrieve a patient's problem list over multiple encounters. For an inpatient setting, they will need to enable the user to electronically record, modify, and retrieve a patient's problem list for the duration of an entire hospitalization. This clarification was also requested in relation to the medication list and medication allergy list certification criteria and we have not repeated our response. We clarify that for this certification criterion, and all other certification criteria, the term "retrieve" means the retrieval of information directly stored and managed by Certified EHR Technology and that it does not mean the retrieval of information from external sources, unless explicitly stated otherwise."

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 Modules to enable a user to electronically record, modify, and retrieve a patient's active medication allergy list and medication allergy history for longitudinal care.

Based on the text referenced above from the Final Rule, the longitudinal care requirement in this criteria shall be evaluated in the context of the care setting supported by the EHR. Specifically, for EHRs designed for an ambulatory setting, access to the medication allergy information gathered during multiple patient visits to a single Eligible Provider shall be available to the provider. There is no requirement that allergy information gathered by other providers or hospitals be accessible. For EHRs designed for an inpatient care setting, access to medication allergy information gathered during the current hospitalization episode of care shall be available to users in the inpatient care setting. There is no requirement that allergy information gathered during prior hospitalizations or by Eligible Providers in the ambulatory settings be accessible.

This test procedure is organized into three sections:

- Record - evaluates the capability to enter patient active medication allergy data into the EHR to create the patient active medication allergy list
    - The Tester enters the NIST-supplied active medication allergies

- Modify – evaluates the capability to modify patient medication allergy data that have been previously entered into the EHR

- The Tester displays the patient active medication allergy list data entered during the Record Patient Active Medication Allergy test
- The Tester modifies the previously entered active medication allergy data using NIST-supplied medication allergy data, for example, changing an allergy status from active to inactive and changing or entering additional allergy reactions for an existing allergy

- Retrieve – evaluates the capability to display the patient medication allergy list data that have been previously entered into the EHR, including the capability to display the patient medication allergy history list as recorded during multiple ambulatory visits with the same provider or during a single inpatient visit
  - The Tester displays the patient active medication allergy data entered during the test
  - The Tester displays the patient medication allergy history including modified patient medication allergy data
  - The Tester validates that the displayed medication allergy list data and medication allergy history data are accurate and complete including the medication allergy list data that were modified during the Modify test

For complete EHR or EHR modules targeted to the ambulatory setting, the following derived test requirements apply:

- DTR170.302.e – 1: Electronically Record Patient Active Medication Allergy List in an Ambulatory Setting
- DTR170.302.e – 2: Electronically Modify Patient Active Medication Allergy List in an Ambulatory Setting
- DTR170.302.e – 3: Electronically Retrieve Patient Active Medication Allergy List and Medication Allergy History in an Ambulatory Setting

For complete EHR or EHR modules targeted to the inpatient setting, the following derived test requirements apply:

- DTR170.302.e – 4: Electronically Record Patient Active Medication Allergy List in an Inpatient Setting
- DTR170.302.e – 5: Electronically Modify Patient Active Medication Allergy List in an Inpatient Setting
- DTR170.302.e – 6: Electronically Retrieve Patient Active Medication Allergy List and Medication Allergy History in an Inpatient Setting

For complete EHR or EHR modules targeted to both settings, the following derived test requirements apply:

- DTR170.302.e – 1: Electronically Record Patient Active Medication Allergy List in an Ambulatory Setting
- DTR170.302.e – 2: Electronically Modify Patient Active Medication Allergy List in an Ambulatory Setting
- DTR170.302.e – 3: Electronically Retrieve Patient Active Medication Allergy List and Medication Allergy History in an Ambulatory Setting

- DTR170.302.e – 4: Electronically Record Patient Active Medication Allergy List in an Inpatient Setting
- DTR170.302.e – 5: Electronically Modify Patient Active Medication Allergy List in an Inpatient Setting
- DTR170.302.e – 6: Electronically Retrieve Patient Active Medication Allergy List and Medication Allergy History in an Inpatient Setting

REFERENCED STANDARDS

None

NORMATIVE TEST PROCEDURES – AMBULATORY SETTING

Derived Test Requirements

DTR170.302.e – 1: Electronically Record Patient Active Medication Allergy List in an Ambulatory Setting

DTR170.302.e – 2: Electronically Modify Patient Active Medication Allergy List in an Ambulatory Setting

DTR170.302.e – 3: Electronically Retrieve Patient Active Medication Allergy List and Medication Allergy History in an Ambulatory Setting

DTR170.302.e – 1: Electronically Record Patient Active Medication Allergy List in an Ambulatory Setting

Required Vendor Information

VE170.302.e – 1.01: Vendor shall identify a patient with an existing record in the EHR containing patient medication allergies entered during multiple ambulatory visits to the same provider to be used for this test (for testing purposes at least three visits over a multiple month timeframe)

VE170.302.e – 1.02: Vendor shall identify the EHR function(s) that are available to: 1) select the patient, 2) enter patient medication allergies, 3) modify patient medication allergies, and 4) retrieve patient active medication allergy list and medication allergy history for longitudinal care

Required Test Procedure:

TE170.302.e – 1.01: Tester shall select patient active medication allergy data from NIST-supplied Test Data set TD170.302.e – 1

TE170.302.e – 1.02: Using the EHR function(s) identified by the Vendor, the Tester shall select the patient's existing record and enter patient active medication allergy data from the Test Data set TD170.302.e – 1

TE170.302.e – 1.03: Using the NIST-supplied Inspection Test Guide, the Tester shall verify that the patient active medication allergy test data have been entered correctly and without omission

Inspection Test Guide

IN170.302.e – 1.01: Using the data in the NIST-supplied Test Data set TD170.302.e – 1, Tester shall verify that the patient active medication allergy list test data are entered correctly and without omission

IN170.302.e – 1.02: Tester shall verify that the patient medication allergy list data are stored in the patient's record

DTR170.302.e – 2: Electronically Modify Patient Active Medication Allergy List in an Ambulatory Setting

Required Vendor Information

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

Required Test Procedure:

TE170.302.e – 2.01: Tester shall select patient medication allergy test data from NIST-supplied test data set TD170.302.e – 2

TE170.302.e – 2.02: Using the EHR function(s) identified by the Vendor , the Tester shall select the patient's existing record, shall display the patient active medication allergy list data entered during the DTR170.302.e – 1: Electronically Record Patient Medication Allergy List in an Ambulatory Setting test, and shall modify the previously entered patient medication allergy list data

TE170.302.e – 2.03: Using the NIST-supplied Inspection Test Guide, the Tester shall verify that the patient medication allergy list data modified in TE170.302.e – 2.02 have been entered correctly and without omission

Inspection Test Guide:

IN170.302.e – 2.01: Tester shall verify that the patient medication allergy data entered during the DTR170.302.e – 1: Record Patient Medication Allergy List test are accessed and modified

IN170.302.e – 2.02: Using the data in the NIST-supplied Test Data set TD170.302.e – 2 , Tester shall verify that the modified medication allergy list data are stored in the patient's record correctly and without omission

DTR170.302.e – 3: Electronically Retrieve Patient Active Medication Allergy List and Medication Allergy History in an Ambulatory Setting

Required Vendor Information

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

Required Test Procedure:

TE170.302.e – 3.01: Using the EHR function(s) identified by the Vendor, the Tester shall select the patient's existing record and shall display the patient active medication allergy list and medication allergy history data entered during the DTR170.302.e – 1: Electronically Record Patient Active Medication Allergy List in an Ambulatory

Setting and DTR170.302.e – 2: Electronically Modify Patient Active Medication Allergy List in an Ambulatory Setting tests

TE170.302.e – 3.02: Using the EHR function(s) identified by the Vendor, the Tester shall select the patient's existing record and shall display the patient medication allergy history

TE170.302.e – 3.03: Using the NIST-supplied Inspection Test Guide, the Tester shall verify that the patient active medication allergy list and medication allergy history test data display correctly and without omission

Inspection Test Guide

IN170.302.e – 3.01: Using the data in the NIST-supplied Test Data set TD170.302.e – 3a, Tester shall verify that the patient active medication allergy list data entered in the DTR170.302.e – 1: Electronically Record Patient Active Medication Allergy in an Ambulatory Setting test and modified in the DTR170.302.e – 2: Electronically Modify Patient Active Medication Allergy List in an Ambulatory Setting test display correctly and without omission

IN170.302.e – 3.02: Using the data in the NIST-supplied Test Data set TD170.302.e – 3b, Tester shall verify that medication allergies with active as well as those with inactive status, as entered in the DTR170.302.e – 1: Electronically Record Patient Active Medication Allergy in an Ambulatory Setting test and modified in the DTR170.302.e – 2: Electronically Modify Patient Active Medication Allergy List in an Ambulatory Setting test, display correctly and without omission

NORMATIVE TEST PROCEDURES – INPATIENT SETTING

Derived Test Requirements

DTR170.302.e – 4: Electronically Record Patient Active Medication Allergy List in an Inpatient Setting

DTR170.302.e – 5: Electronically Modify Patient Active Medication Allergy List in an Inpatient Setting

DTR170.302.e – 6: Electronically Retrieve Patient Active Medication Allergy List and Medication Allergy History in an Inpatient Setting

DTR170.302.e – 4: Electronically Record Patient Active Medication Allergy List in an Inpatient Setting

Required Vendor Information

VE170.302.e – 4.01: Vendor shall identify a patient with an existing record in the EHR to be used for this test (for testing purposes over the duration of a hospital visit)

VE170.302.e – 4.02: Vendor shall identify the EHR function(s) that are available to: 1) select the patient, 2) enter patient medication allergies, 3) modify patient medication allergies, and 4) retrieve patient active medication allergy list and medication allergy history for longitudinal care

Required Test Procedure:

TE170.302.e – 4.01: Tester shall select patient active medication allergy data from NIST-supplied Test Data set TD170.302.e – 4

TE170.302.e – 4.02: Using the EHR function(s) identified by the Vendor, the Tester shall select the patient's existing record and enter patient active medication allergy data from the Test Data sets

TE170.302.e – 4.03: Using the NIST-supplied Inspection Test Guide, the Tester shall verify that the patient active medication allergy test data have been entered correctly and without omission

Inspection Test Guide

IN170.302.e – 4.01: Using the data in the NIST-supplied Test Data set TD170.302.e – 4, Tester shall verify that the patient active medication allergy list test data are entered correctly and without omission

IN170.302.e – 4.02: Tester shall verify that the patient medication allergy list data are stored in the patient's record

DTR170.302.e – 5: Electronically Modify Patient Active Medication Allergy List in an Inpatient Setting

Required Vendor Information

- As defined in DTR170.302.e – 4, no additional information is required

Required Test Procedure:

TE170.302.e – 5.01: Tester shall select patient medication allergy test data from NIST-supplied test data set TD170.302.e – 5

TE170.302.e – 5.02: Using the EHR function(s) identified by the Vendor, the Tester shall select the patient's existing record, shall display the patient active medication allergy list data entered during the DTR170.302.e – 4: Electronically Record Patient Active Medication Allergy List in an Inpatient Setting test, and shall modify the previously entered patient medication allergy list data

TE170.302.e – 5.03: Using the NIST-supplied Inspection Test Guide, the Tester shall verify that the patient medication allergy list data entered in the DTR170.302.e – 5: Electronically Modify Patient Active Medication Allergy List in an Inpatient Setting test have been entered correctly and without omission

Inspection Test Guide:

IN170.302.e – 5.01: Tester shall verify that the patient medication allergy data entered during the DTR170.302.e – 4: Electronically Record Patient Active Medication Allergy List in an Inpatient Setting test are accessed and modified

IN170.302.e – 5.02: Using the data in the NIST-supplied Test Data set TD170.302.e – 5, Tester shall verify that the modified medication allergy list data are stored in the patient's record correctly and without omission

DTR170.302.e – 6: Electronically Retrieve Patient Active Medication Allergy List in an Inpatient Setting

Required Vendor Information

- As defined in DTR170.302.e – 4, no additional information is required

Required Test Procedure:

TE170.302.e – 6.01: Using the EHR function(s) identified by the Vendor, the Tester shall select the patient's existing record and shall display the patient active medication allergy list data entered during the DTR170.302.e – 4: Electronically Record Patient Active Medication Allergy List in an Inpatient Setting and DTR170.302.e – 5: Electronically Modify Patient Active Medication Allergy List in an Inpatient Setting tests

TE170.302.e – 6.02: Using the EHR function(s) identified by the Vendor, the Tester shall select the patient's existing record and shall display the patient medication allergy history

TE170.302.e – 6.03: Using the NIST-supplied Inspection Test Guide, the Tester shall verify that the patient active medication allergy list test data display correctly and without omission

Inspection Test Guide

IN170.302.e – 6.01: Using the data in the NIST-supplied Test Data set TD170.302.e – 6a, Tester shall verify that the patient active medication allergy list data entered in the DTR170.302.e – 4: Electronically Record Patient Active Medication Allergy List in an Inpatient Setting test and modified in the DTR170.302.e – 5: Electronically Modify Patient Active Medication Allergy List in an Inpatient Setting test display correctly and without omission

IN170.302.e – 6.02: Using the data in the NIST-supplied Test Data set TD170.302.e – 6b, Tester shall verify that medication allergies with active as well as those with inactive status, as entered in the DTR170.302.e – 4: Electronically Record Patient Active Medication Allergy List in an Inpatient Setting test and modified in the DTR170.302.e – 5: Electronically Modify Patient Active Medication Allergy List in an Inpatient Setting test, display correctly and without omission

TEST DATA

Test data is provided by NIST in this Test Procedure to ensure that the functional and interoperable requirements identified in the criteria can be adequately evaluated for conformance, as well as to provide consistency in the testing process across multiple ONC-Authorized Testing and Certification Bodies (ATCBs). The NIST-supplied test data focus on evaluating the basic capabilities required of EHR technology, rather than exercising the full breadth/depth of capability that installed EHR technology might be expected to support. The test data is formatted for readability of use within the testing process. The format is not prescribing a particular end-user view or rendering. No additional requirements should be drawn from the format.

The Tester shall use and apply the NIST-supplied test data during the test, without exception, unless one of the following conditions exist:

- The Tester determines that the Vendor product is sufficiently specialized that the NIST-supplied test data needs to be modified in order to conduct an adequate test. Having made the determination that some modification to the NIST-supplied test data is necessary, the Tester shall record the modifications made as part of the test documentation.
- The Tester determines that changes to the test data will improve the efficiency of the testing process; primarily through using consistent demographic data throughout the testing workflow. The tester shall ensure that the functional and interoperable requirements identified in the criterion can be adequately evaluated for conformance and that the test data provides a comparable level of robustness.

Any departure from the NIST-supplied test data shall strictly focus on meeting the basic capabilities required of EHR technology relative to the certification criterion rather than exercising the full breadth/depth of capability that installed EHR technology might be expected to support.

The Test Procedures require that the Tester enter the test data into the EHR technology being evaluated for conformance. The intent is that the Tester fully control the process of entering the test data in order to ensure that the data are correctly entered as specified in the test procedure. If a situation arises where it is impractical for a Tester to directly enter the test data, the Tester, at the tester's discretion, may instruct the Vendor to enter the test data, so long as the Tester remains in full control of the testing process, directly observes the test data being entered by the Vendor, and validates that the test data are entered correctly as specified in the test procedure.

Ambulatory Setting Test Data

TD170.302.e – 1: Record Active Medication Allergies – Ambulatory Setting

Allergy: Codeine
Reaction: Hives
Status: Active

Allergy: Ampicillin
Reaction: Diarrhea, nausea, vomiting
Status: Active

Allergy: Sulfonamides
Reaction: Hives, photosensitivity
Status: Active

Allergy: Ibuprofen
Reaction: Hives, respiratory distress
Status: Active

TD170.302.e – 2: Modify Active Medication Allergies – Ambulatory Setting

Change the Status of the Sulfonamides allergy from Active to **Inactive**
Add the Reaction **vomiting** to the Codeine allergy
Change the Reaction for Ibuprofen from hives, respiratory distress to **nausea**

Revised Active Medication Allergies List

Allergy: Codeine
Reaction: Hives, **vomiting**
Status: Active

Allergy: Ampicillin
Reaction: Diarrhea, nausea, vomiting
Status: Active

Allergy: Ibuprofen
Reaction: **Nausea**
Status: Active

TD170.302.e – 3a: Retrieve Active Medication Allergies – Ambulatory Setting

Active Medication Allergies only

Allergy: Codeine
Reaction: Hives, vomiting
Status: Active

Allergy: Ampicillin
Reaction: Diarrhea, nausea, vomiting
Status: Active

Allergy: Ibuprofen
Reaction: Nausea
Status: Active

TD170.302.e – 3b: Retrieve Medication Allergies History - Ambulatory Setting

List of all Medication Allergies including those with active or inactive status

Allergy: Codeine
Reaction: Hives, vomiting
Status: Active

Allergy: Ampicillin
Reaction: Diarrhea, nausea, vomiting
Status: Active

Allergy: Sulfonamides
Reaction: Hives, photosensitivity
Status: Inactive

Allergy: Ibuprofen
Reaction: Nausea
Status: Active

Inpatient Setting Test Data

TD170.302.e – 4: Record Active Medication Allergies – Inpatient Setting

Allergy: Demerol
Reaction: Hives
Status: Active

Allergy: Erythomycin
Reaction: Chest pain, irregular heart rate, nausea
Status: Active

Allergy: Sulfonamides
Reaction: Hives, photosensitivity
Status: Active

Allergy: Aspirin
Reaction: Hives, swollen lips, respiratory distress
Status: Active

TD170.302.e – 5: Modify Active Medication Allergies – Inpatient Setting

Change the Status of the Sulfonamides allergy from Active to **Inactive**
Add the Reaction **vomiting** to the Demerol allergy
Change the Reaction for Aspirin from hives, swollen lips, respiratory distress to **itching**

Revised Active Medication Allergies List

Allergy: Demerol
Reaction: Hives, **vomiting**
Status: Active

Allergy: Erythomycin
Reaction: Chest pain, irregular heart rate, nausea
Status: Active

Allergy: Aspirin
Reaction: **Itching**
Status: Active

TD170.302.e – 6a: Retrieve Active Medication Allergies – Inpatient Setting

Active Medication Allergies only

Allergy: Demerol
Reaction: Hives, vomiting
Status: Active

Allergy: Erythomycin
Reaction: Chest pain, irregular heart rate, nausea
Status: Active

Allergy: Aspirin
Reaction: Itching
Status: Active

TD170.302.e – 6b: Retrieve Medication Allergies History – Inpatient Setting

List of all Medication Allergies including those with active or inactive status

Allergy: Demerol
Reaction: Hives, vomiting
Status: Active

Allergy: Erythomycin
Reaction: Chest pain, irregular heart rate, nausea
Status: Active

Allergy: Sulfonamides
Reaction: Hives, photosensitivity
Status: Inactive

Allergy: Aspirin
Reaction: Itching
Status: Active

CONFORMANCE TEST TOOLS

None

Document History

Version Number	Description	Date Published
0.7	Original draft version	February 26, 2010
1.0	Updated to reflect Final Rule	July 21, 2010
1.0	Updated to remove “Pending” from header	August 13, 2010