Test Procedure for §170.314(a)(6) Medication list

This document describes the test procedure for evaluating conformance of electronic health record (EHR) technology 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 http://www.healthit.gov/certification (navigation: 2014 Edition Test Method). The test procedures may be updated to reflect on-going feedback received during the certification activities.

The Department of Health and Human Services (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 Health Information Technology (HIT) Certification Program[2], is carried out by National Voluntary Laboratory Accreditation Program (NVLAP)-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 CRITERION

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. This certification criterion is included in the definition of a Base EHR.

§170.314(a)(6) Medication List. Enable a user to electronically record, change, and access a patient's active medication list as well as medication history:

(i) Ambulatory setting. Over multiple encounters; or

(ii) Inpatient setting. For the duration of an entire hospitalization.

[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.

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 unchanged without refinements from the 2011 Edition. This certification criterion meets the three factors of unchanged certification criteria: (1) the certification criterion includes only the same capabilities that were specified in previously adopted certification criteria, (2) the certification criterion's capabilities apply to the same setting as they did in previously adopted certification criteria, and (3) the certification criterion remains designated as "mandatory," or it is re-designated as "optional," for the same setting for which it was previously adopted certification criterion.

2014 Edition Preamble Language

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 (September 4, 2012) where the medication list certification criterion is discussed:

- "…we have required the use of RxNorm in instances where EHR technology would be used to perform external transmissions (e.g., for a transition of care (§ 170.314(b)(2)). Additionally, we require the capability to reconcile a patient's medication list as part of the adopted "clinical information reconciliation" certification criterion at § 170.314(b)(4) and the receipt of RxNorm codes in a summary care record should greatly facilitate this process. Thus, at this juncture, we do not believe it is necessary to require as a condition of certification that EHR technology natively record medications directly into RxNorm although such an approach may be more efficient and expeditious for some."
- "'Access' is used to mean the ability to examine or review information in or through EHR technology. We proposed to replace the term "retrieve" used in the 2011 Edition EHR certification criteria with "access" because we believe it is clearer and more accurately expresses the capability we intend for EHR technology to include. We noted that some stakeholders had interpreted "retrieve" to suggest that the EHR technology also needed to be able to obtain data from external sources. Nevertheless, we stated that we interpret both "access" and "retrieve" to have essentially the same meaning, but note that "access" should not be interpreted to include necessarily the capability of obtaining or transferring the data from an external source."

2011 Edition Preamble Language

None referenced

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 (September 4, 2012) where the medication list certification criterion is discussed:

- "We proposed to include the following unchanged certification criteria in the 2014 Edition EHR certification criteria without any substantial refinements, except, where appropriate, replacing the terms "generate," "modify," and "retrieve" with "create," "change," and "access," respectively."
- "We note that in response to comments received on our use of the term "longitudinal care" in this certification criterion and in other certification criteria, we have replaced the term…[and] refer readers to our discussion of the revised "problem list" certification criterion earlier in this preamble."
    - Per the problem list criterion in this preamble, "…for the ambulatory setting, we have replaced the term "longitudinal care" with "over multiple encounters." We believe using "encounters" instead of "office visits" is a more clinically appropriate. We note that this revision has no substantive impact on current or future testing and certification processes. For the inpatient setting, we have replaced the term "longitudinal care" with "duration of an entire hospitalization," which would continue to include situations where the patient moves to different wards or units (e.g., emergency department, intensive care, and cardiology) within the hospital during the hospitalization and continue to maintain that it would not cover multiple hospitalizations for the purpose of certification."

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 EHR technology to enable a user to electronically record, change, and access a patient's active medication list and medication history:

(i) Ambulatory setting. Over multiple encounters; or
(ii) Inpatient setting. For the duration of an entire hospitalization.

The test procedure is not prescriptive about the method used to change the medication list. For example, changing a medication list does not require changing an existing instance of a medication. Changes can be accomplished through discontinuing/inactivating an existing medication on the list and entering a new instance of the medication.

This criterion 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 information gathered during multiple encounters shall be available to the provider. There is no requirement that medication information

gathered by other hospitals be accessible. For EHRs designed for an inpatient care setting, access to medication information gathered during the duration of an entire hospitalization shall be available to users in the inpatient care setting. There is no requirement that medication information gathered during prior hospitalizations or by Eligible Providers in the ambulatory settings be accessible.

ONC supplies the test data for this test procedure.

This test procedure is organized into three sections:

- Record – evaluates the capability to enter patient active medication data into the EHR to create the patient active medication list
    - The Tester enters the ONC-supplied patient active medications

- Change – evaluates the capability to change patient medication data that have been previously entered into the EHR
    - The Tester displays the patient active medication list data entered during the Record Patient Active Medication List test
    - The Tester changes the previously entered active medication data using ONC-supplied medication data, for example, changing a medication dose or frequency and discontinuing a medication

- Access – evaluates the capability to display the patient medication list data that have been previously entered into the EHR, including the capability to display the patient medication list as recorded during multiple ambulatory encounters or during the duration of an entire inpatient hospitalization
    - The Tester displays the patient active medication data entered during the test
    - The Tester displays the patient medication history, including changed medication data
    - The Tester verifies that the displayed medication list data and medication history data are accurate and complete, including the medication list data that were changed during the change test

For EHR technology **targeted to the ambulatory setting**, the following derived test requirements apply:

- DTR170.314(a)(6) – 1: Electronically Record Patient Active Medication List in an Ambulatory Setting
- DTR170.314(a)(6) – 2: Electronically Change Patient Active Medication List in an Ambulatory Setting
- DTR170.314(a)(6) – 3: Electronically Access Patient Active Medication List and Medication History in an Ambulatory Setting

For EHR technology **targeted to the inpatient setting**, the following derived test requirements apply:

- DTR170.314(a)(6) – 4: Electronically Record Patient Active Medication List in an Inpatient Setting
- DTR170.314(a)(6) – 5: Electronically Change Patient Active Medication List in an Inpatient Setting

- DTR170.314(a)(6) – 6: Electronically Access Patient Active Medication List and Medication History in an Inpatient Setting

For EHR technology **targeted to both settings**, the following derived test requirements apply:

- DTR170.314(a)(6) – 1: Electronically Record Patient Active Medication List in an Ambulatory Setting
- DTR170.314(a)(6) – 2: Electronically Change Patient Active Medication List in an Ambulatory Setting
- DTR170.314(a)(6) – 3: Electronically Access Patient Active Medication List and Medication History in an Ambulatory Setting
- DTR170.314(a)(6) – 4: Electronically Record Patient Active Medication List in an Inpatient Setting
- DTR170.314(a)(6) – 5: Electronically Change Patient Active Medication List in an Inpatient Setting
- DTR170.314(a)(6) – 6: Electronically Access Patient Active Medication List and Medication History in an Inpatient Setting

REFERENCED STANDARDS

None

NORMATIVE TEST PROCEDURES – AMBULATORY SETTING

Derived Test Requirements

DTR170.314(a)(6) – 1: Electronically Record Patient Active Medication List in an Ambulatory Setting

DTR170.314(a)(6) – 2: Electronically Change Patient Active Medication List in an Ambulatory Setting

DTR170.314(a)(6) – 3: Electronically Access Patient Active Medication List and Medication History in an Ambulatory Setting

DTR170.314(a)(6) – 1: Electronically Record Patient Active Medication List in an Ambulatory Setting

Required Vendor Information

VE170.314(a)(6) – 1.01: Vendor shall identify a patient with an existing record in the EHR containing patient medications entered during multiple ambulatory encounters to be used for this test (for testing purposes at least three encounters over a multiple month timeframe)

VE170.314(a)(6) – 1.02: Vendor shall identify the EHR function(s) that are available to: 1) select the patient, 2) enter patient active medications, 3) change patient medications, 4) access patient active medication list, and 5) access medication history for multiple ambulatory encounters

Required Test Procedure

TE170.314(a)(6) – 1.01: Tester shall select patient active medication data from one ONC-supplied test data set TD170.314(a)(6) – 1

TE170.314(a)(6) – 1.02: Using the EHR function(s) identified by the Vendor, the Tester shall select the patient's existing record and enter patient active medications data from the ONC-supplied test data set TD170.314(a)(6) – 1

TE170.314(a)(6) – 1.03: Using the Inspection Test Guide (below), the Tester shall verify that the patient active medication test data have been entered correctly and without omission

Inspection Test Guide

IN170.314(a)(6) – 1.01: Using the data in the ONC-supplied test data set TD170.314(a)(6) – 1 Tester shall verify that the patient active medication list test data are entered correctly and without omission

IN170.314(a)(6) – 1.02: Tester shall verify that the patient medication list data are stored in the patient's record

DTR170.314(a)(6) – 2: Electronically Change Patient Active Medication List in an Ambulatory Setting

Required Vendor Information

- As defined in DTR170.314(a)(6) – 1, no additional information is required

Required Test Procedure

TE170.314(a)(6) – 2.01: Tester shall select patient medication test data from one ONC-supplied test data set TD170.314(a)(6) – 2

TE170.314(a)(6) – 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 list data entered during the DTR170.314(a)(6) – 1: Electronically Record Patient Active Medication List in an Ambulatory Setting test, and shall change the previously entered patient medication list data

TE170.314(a)(6) – 2.03: Using the Inspection Test Guide (below), the Tester shall verify that the patient medication list data changed in TE170.314(a)(6) – 2.02 have been entered correctly and without omission

Inspection Test Guide

IN170.314(a)(6) – 2.01: Tester shall verify that the patient active medication data entered during the DTR170.314(a)(6) – 1: Electronically Record Patient Active Medication List in an Ambulatory Setting test are accessed and changed

IN170.314(a)(6) – 2.02: Using the data in the ONC-supplied test data set TD170.314(a)(6) – 2, Tester shall verify that the changed medication list data are stored in the patient's record correctly and without omission

DTR170.314(a)(6) – 3: Electronically Access Patient Active Medication List and Medication History in an Ambulatory Setting

Required Vendor Information

- As defined in DTR170.314(a)(6) – 1, no additional information is required

Required Test Procedure

TE170.314(a)(6) – 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 data entered during the DTR170.314(a)(6) – 1: Electronically Record Patient Active Medication List in an Ambulatory Setting test and changed during the DTR170.314(a)(6) – 2: Electronically Change Patient Active Medication List in an Ambulatory Setting test

TE170.314(a)(6) – 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 history

TE170.314(a)(6) – 3.03: Using the Inspection Test Guide (below), the Tester shall verify that the patient active medication test list and the medication history test data display correctly and without omission

Inspection Test Guide

IN170.314(a)(6) – 3.01: Using the data in the ONC-supplied test data set TD170.314(a)(6) – 3a, Tester shall verify that the patient active medication list data entered in the DTR170.314(a)(6) – 1: Electronically Record Patient Active Medication List in an Ambulatory Setting test display correctly and without omission

IN170.314(a)(6) – 3.02: Using the data in the ONC-supplied test data set TD170.314(a)(6) – 3b, Tester shall verify that medications with active as well as those with discontinued status, as entered in the DTR170.314(a)(6) – 1: Electronically Record Patient Active Medication List in an Ambulatory Setting test and changed in the DTR170.314(a)(6) – 2: Electronically Change Patient Active Medication List in an Ambulatory Setting test, display correctly and without omission

NORMATIVE TEST PROCEDURES – INPATIENT SETTING

Derived Test Requirements

DTR170.314(a)(6) – 4: Electronically Record Patient Active Medication List in an Inpatient Setting

DTR170.314(a)(6) – 5: Electronically Change Patient Active Medication List in an Inpatient Setting

DTR170.314(a)(6) – 6: Electronically Access Patient Active Medication List and Medication History in an Inpatient Setting

DTR170.314(a)(6) – 4: Electronically Record Patient Active Medication List in an Inpatient Setting

Required Vendor Information

VE170.314(a)(6) – 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 entire duration of a hospital visit)

VE170.314(a)(6) – 4.02: Vendor shall identify the EHR function(s) that are available to: 1) select the patient, 2) enter patient active medications, 3) change patient medications, 4) access patient active medication list, and 5) access medication history for the duration of an entire hospitalization

Required Test Procedure

TE170.314(a)(6) – 4.01: Tester shall select patient active medication data from one ONC-supplied test data set TD170.314(a)(6) – 4

TE170.314(a)(6) – 4.02: Using the EHR function(s) identified by the Vendor, the Tester shall select the patient's existing record and enter patient active medications data from the test data set TD170.314(a)(6) – 4

TE170.314(a)(6) – 4.03: Using the Inspection Test Guide (below), the Tester shall verify that the patient active medication test data have been entered correctly and without omission

Inspection Test Guide

IN170.314(a)(6) – 4.01: Using the data in the ONC-supplied test data set TD170.314(a)(6) – 4, Tester shall verify that the patient active medication list test data are entered correctly and without omission

IN170.314(a)(6) – 4.02: Tester shall verify that the patient medication list data are stored in the patient's record

DTR170.314(a)(6) – 5: Electronically Change Patient Active Medication List in an Inpatient Setting

Required Vendor Information

- As defined in DTR170.314(a)(6) – 4, no additional information is required

Required Test Procedure:

TE170.314(a)(6) – 5.01: Tester shall select patient medication test data from one ONC-supplied test data set TD170.314(a)(6) – 5

TE170.314(a)(6) – 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 list data entered during the DTR170.314(a)(6) – 4: Electronically Record Patient Active Medication List in an Inpatient Setting test, and shall change the previously entered patient medication list data

TE170.314(a)(6) – 5.03: Using the Inspection Test Guide (below), the Tester shall verify that the patient medication list data changed in TE170.314(a)(6) – 5.02 have been entered correctly and without omission

Inspection Test Guide:

IN170.314(a)(6) – 5.01: Tester shall verify that the patient medication data entered during the DTR170.314(a)(6) – 4: Electronically Record Patient Active Medication List in an Inpatient Setting test are accessed and changed

IN170.314(a)(6) – 5.02: Using the data in the ONC-supplied test data set TD170.314(a)(6) – 5, Tester shall verify that the changed medication list data are stored in the patient's record correctly and without omission

DTR170.314(a)(6) – 6: Electronically Access Patient Active Medication List and Medication History in an Inpatient Setting

Required Vendor Information

- As defined in DTR170.314(a)(6) – 4, no additional information is required

Required Test Procedure

TE170.314(a)(6) – 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 data entered during the DTR170.314(a)(6) – 4: Electronically Record Patient Active Medication List in an Inpatient Setting test and changed during the DTR170.314(a)(6) – 5: Electronically Change Patient Active Medication List in an Inpatient Setting test

TE170.314(a)(6) – 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 history

TE170.314(a)(6) – 6.03: Using the Inspection Test Guide (below), the Tester shall verify that the patient active medication list test data and the medication history display correctly and without omission

Inspection Test Guide

IN170.314(a)(6) – 6.01: Using the data in the ONC-supplied test data set TD170.314(a)(6) – 6a, Tester shall verify that the patient active medication list data entered in the DTR170.314(a)(6) – 4: Electronically Record Patient Active Medication List in an Inpatient Setting test display correctly and without omission

IN170.314(a)(6) – 6.02: Using the data in the ONC-supplied test data set TD170.314(a)(6) – 6b, Tester shall verify that medications with active as well as those with discontinued status, as entered in the DTR170.314(a)(6) – 4: Electronically Record Patient Active Medication List in an Inpatient Setting test and changed in the DTR170.314(a)(6) – 5: Electronically Change Patient Active Medication List in an Inpatient Setting test, display correctly and without omission

TEST DATA

ONC-supplied test data are provided with the test procedure to ensure that the applicable requirements identified in the criteria can be adequately evaluated for conformance, as well as to provide consistency in

the testing process across multiple National Voluntary Laboratory Accreditation Program (NVLAP)-Accredited Testing Labs (ATLs). The provided test data focus on evaluating the basic capabilities of required EHR technology, rather than exercising the full breadth/depth of capability that installed EHR technology might be expected to support. The test data are 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 provided test data during the test, without exception, unless one of the following conditions exists:

- The Tester determines that the Vendor product is sufficiently specialized that the provided test data needs to be modified in order to conduct an adequate test. Having made the determination that some modification to the provided 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 applicable requirements identified in the criterion can be adequately evaluated for conformance and that the test data provides a comparable level of robustness. Having made the determination that some modification to the provided test data is necessary, the Tester shall record the modifications made as part of the test documentation.

Any departure from the provided 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 applicable test data into the EHR technology being evaluated for conformance. The intent is that the Tester fully controls 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.

For additional information regarding the provided test data for use in this test procedure:

- Test Data for §170.314(a)(6) Medication list available at http://www.healthit.gov/certification (navigation: 2014 Edition Test Method)

CONFORMANCE TEST TOOLS

None

Document History

Version Number	Description of Change	Date
1.0	Released for public comment	September 7, 2012
1.1	Delivered for National Coordinator Approval	December 4, 2012
1.2	Posted Approved Test Procedure	December 14, 2012
1.3	DTR170.314(a)(6) – 3: Electronically Access Patient Active Medication List and Medication History in an Ambulatory Setting, Inspection Test Guide • IN170.314(a)(6) – 3.02 o Changed "…verify that the patient active medication list data entered…" to "verify that medications with active as well as those with discontinued status, as entered…" o Changed DTR170.314(a)(6) – 1 to DTR170.314(a)(6) – 2 DTR170.314(a)(6) – 6: Electronically Access Patient Active Medication List and Medication History in an Inpatient Setting, Inspection Test Guide • IN170.314(a)(6) – 6.02 o Changed "…verify that the patient active medication list data entered…" to "verify that medications with active as well as those with discontinued status, as entered…"	June 28, 2013