Test Procedure for §170.314(a)(5) Problem list

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 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)(5) Problem list. Enable a user to electronically record, change, and access a patient's active problem list:

(i) Ambulatory setting. Over multiple encounters in accordance with, at a minimum, the version of the standard specified in §170.207(a)(3); or
(ii) Inpatient setting. For the duration of an entire hospitalization in accordance with, at a minimum, the version of the standard specified in §170.207(a)(3).

[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 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 problem list criterion is discussed:

- "…SNOMED CT® is the best vocabulary to use in those certification criteria that focus on electronic health information exchange. It is necessary that we specify a vocabulary for the problem list within EHR technology because it supports the current requirement that EPs, EHs, and CAHs need to meet to demonstrate MU."
- "We clarify that this certification criterion does not preclude the use of interface terms, local terms, or other terms from being displayed to a health care provider in lieu of SNOMED CT® to find, select, or view a patient's problem list. However, if such an approach is taken, the EHR technology must ultimately be able to record the semantic representation of the problem list in SNOMED CT®. For example, if a user of a given EHR technology is using a set of interface terms or any other clinical vocabulary that has been mapped to SNOMED CT®, this user may perform a search for a term that represents the patient's problem, select the appropriate term, and "save" that term to the patient's problem list, where it may be displayed. The EHR technology is required to record the problem in SNOMED CT® because this is the requirement…for alignment with the EHR Incentive Programs… SNOMED CT® codes are not required for display in the EHR technology in order for it to meet this certification criterion."
- "For information exchange, the EHR technology must send the problem in SNOMED CT®."
- "…SNOMED CT® is the appropriate standard for clinical use, and we agree that mapping from SNOMED CT® to appropriate administrative codes such as ICD-10-CM will be necessary… We do not, however, intend to require the use of mappings as part of this 2014 Edition EHR certification criterion."
- "We have established a process for adopting certain vocabulary standards, including SNOMED CT®, which permits the use of newer versions of those standards than the one adopted in regulation."

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 problem list criterion is discussed:

- "…we proposed to replace the terms "modify" and "retrieve" in the certification criterion with "change" and "access," respectively."
- "We stated that we agreed with the HITSC that the use of ICD-9-CM should no longer be required due to the pending move to ICD-10-CM, but also stated that it would be inappropriate to require the use of ICD-10-CM for problem lists."
- "We proposed to adopt the International Release January 2012 version of SNOMED CT®... We stated that SNOMED CT® (and not ICD-10-CM) would be required for calculation of CQMs and proposed only SNOMED CT® as the appropriate standard for the recording of patient problems in a problem list. We noted that this proposal did not, however, preclude the use of ICD-10-CM for the capture and/or transmission of encounter billing diagnoses."
- "…we agree with commenters that…the US Extension [to SNOMED CT®] is necessary…and, therefore, [we] have adopted it in conjunction with SNOMED CT®."
- "…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 Complete EHR or EHR Modules to enable a user to electronically record, change, and access a patient's problem list:

(i) Ambulatory setting. Over multiple encounters in accordance with, at a minimum, the version of the standard specified in §170.207(a)(3); or
(ii) Inpatient setting. For the duration of an entire hospitalization in accordance with, at a minimum, the version of the standard specified in §170.207(a)(3).

The test procedure is not prescriptive about the method used to change the problem list. For example, changing a problem list does not require changing an existing instance of a problem. Change can be accomplished through changing the status of an existing problem or entering a new problem.

For EHRs designed for an ambulatory setting, access to the problem list information gathered during multiple patient encounters with a single Eligible Provider shall be available to the provider. There is no requirement that problem list information gathered by other providers or hospitals be accessible. For EHRs designed for an inpatient care setting, access to problem list information gathered during the current hospitalization episode of care shall be available to users in the inpatient care setting. There is no requirement that problem list information gathered during prior hospitalizations or by Eligible Providers in the ambulatory settings be accessible.

The Vendor provides part of the test data and ONC provides part of the test data for this test procedure.

This test procedure is organized into three sections:

- Record - evaluates the capability to enter patient health problems into the EHR to create the patient problem list
    - The Tester enters the ONC-supplied patient problem test data. The Inspection Test Guide describes several methods by which the EHR can demonstrate conformance with the vocabulary requirement

- Change – evaluates the capability to change patient problem list data which have been previously entered into the EHR
    - The Tester displays the patient problem list data entered during the Record Patient Problems test
    - The Tester changes the previously entered patient problems data using ONC-supplied patient problem list data

- Access –evaluates the capability to display the patient problem list data that have been previously entered into the EHR, including the capability to display the patient problem list as recorded during multiple ambulatory encounters with the same provider or during a single inpatient hospitalization
    - The Tester displays the patient problems data entered during the test
    - The Tester displays the patient problem list recorded during multiple ambulatory encounters or during an entire inpatient hospitalization
    - The Tester verifies that the displayed problem list data are accurate and complete, including the problem list data that were changed during the Change test

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

- DTR170.314.a.5 – 1: Electronically Record Patient Problem List in an Ambulatory Setting
- DTR170.314.a.5 – 2: Electronically Change Patient Problem List in an Ambulatory Setting
- DTR170.314.a.5 – 3: Electronically Access Patient Problem List in an Ambulatory Setting

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

- DTR170.314.a.5 – 4: Electronically Record Patient Problem List in an Inpatient Setting

- DTR170.314.a.5 – 5: Electronically Change Patient Problem List in an Inpatient Setting
- DTR170.314.a.5 – 6: Electronically Access Patient Problem List in an Inpatient Setting

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

- DTR170.314.a.5 – 1: Electronically Record Patient Problem List in an Ambulatory Setting
- DTR170.314.a.5 – 2: Electronically Change Patient Problem List in an Ambulatory Setting
- DTR170.314.a.5 – 3: Electronically Access Patient Problem List in an Ambulatory Setting
- DTR170.314.a.5 – 4: Electronically Record Patient Problem List in an Inpatient Setting
- DTR170.314.a.5 – 5: Electronically Change Patient Problem List in an Inpatient Setting
- DTR170.314.a.5 – 6: Electronically Access Patient Problem List in an Inpatient Setting

REFERENCED STANDARDS

§170.207 (a)(3)	Regulatory Referenced Standard
Standard. IHTSDO SNOMED CT® International Release July 2012 (incorporated by reference in §170.299) and US Extension to SNOMED CT® March 2012 Release (incorporated by reference in §170.299).	

NORMATIVE TEST PROCEDURES – AMBULATORY SETTING

Derived Test Requirements

DTR170.314.a.5 – 1: Electronically Record Patient Problem List in an Ambulatory Setting
DTR170.314.a.5 – 2: Electronically Change Patient Problem List in an Ambulatory Setting
DTR170.314.a.5 – 3: Electronically Access Patient Problem List in an Ambulatory Setting

DTR170.314.a.5 – 1: Electronically Record Patient Problem List in an Ambulatory Setting

Required Vendor Information

VE170.314.a.5 – 1.01: Vendor shall identify a patient with an existing record in the EHR containing patient problems entered during multiple ambulatory encounters with the same provider to be used for this test (for testing purposes at least three encounters over a multiple month timeframe)

VE170.314.a.5 – 1.02: Vendor shall identify the EHR function(s) that are available to: 1) select the patient, 2) enter patient problems, 3) change patient problems, 4) access patient problem list, and 5) access patient problem history

Required Test Procedure:

TE170.314.a.5 – 1.01: Tester shall select patient problems data from the ONC-supplied test data set TD170.314.a.5 – 1

TE170.314.a.5 – 1.02: Using the EHR function(s) identified by the Vendor, the Tester shall select the patient's existing record and enter patient problem list data from the test data set TD170.314.a.5 – 1

TE170.314.a.5 – 1.03: Using the Inspection Test Guide (below), the Tester shall verify that the patient problem test data have been entered correctly, without omission and in conformance with vocabulary standards.

Inspection Test Guide

IN170.314.a.5 – 1.01: Using the data in the ONC-supplied Test Data set TD170.314.a.5 – 1, Tester shall verify that the patient problem list test data are entered correctly and without omission

IN170.314.a.5 – 1.02: Tester shall verify that the patient problem list data entered during the test are associated with the required standard terminology. Verification methods include, but are not limited to:

- verifying that the appropriate vocabulary code is displayed along with the patient problem description when the user is recording patient problems; or
- verifying that the EHR includes the capability to cross-reference (map) the user-displayed problem descriptions to the appropriate vocabulary codes; or
- verifying that the patient problem list data stored in the EHR contains the appropriate vocabulary codes

IN170.314.a.5 – 1.03: Tester shall verify the patient problem list data and the correct values from the standard terminology are stored in the patient's record

DTR170.314.a.5 – 2: Electronically Change Patient Problem List in an Ambulatory Setting

Required Vendor Information

- As defined in DTR170.314.a.5 – 1, no additional information is required

Required Test Procedure:

TE170.314.a.5 – 2.01: Tester shall select patient problem test data from ONC-supplied test data set TD170.314.a.5 – 2

TE170.314.a.5 – 2.02: Using the EHR function(s) identified by the Vendor, the Tester shall select the patient's existing record, shall display the patient problem list data entered during the DTR170.314.a.5 – 1: Electronically Record Patient Problem List in an Ambulatory Setting test, and shall change the previously entered patient problem list data

TE170.314.a.5 – 2.03: Using the Inspection Test Guide (below), the Tester shall verify that the patient problem list data changed in TE170.314.a.5 – 2.02 have been entered correctly and without omission

Inspection Test Guide:

IN170.314.a.5 – 2.01: Tester shall verify that the patient problems entered during the DTR170.314.a.5 – 1: Electronically Record Patient Problem List in an Ambulatory Setting test are accessed and changed

IN170.314.a.5 – 2.02: Using the data in the ONC-supplied Test Data set TD170.314.a.5 – 2, Tester shall verify that the changed patient problem list data and the correct values from the standard terminology are stored in the patient's record

DTR170.314.a.5 – 3: Electronically Access Patient Problem List and Problem List History in an Ambulatory Setting

Required Vendor Information

- As defined in DTR170.314.a.5 – 1, no additional information is required

Required Test Procedure:

TE170.314.a.5 – 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 problems entered during the DTR170.314.a.5 – 1: Electronically Record Patient Problem List in an Ambulatory Setting test and changed during the DTR170.314.a.5 – 2: Electronically Change Patient Problem List in an Ambulatory Setting test

TE170.314.a.5 – 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 problem history

TE170.314.a.5 – 3.03: Using the Inspection Test Guide (below), the tester shall verify that the patient problem list test data and the patient problem history display correctly and without omission

Inspection Test Guide

IN170.314.a.5 – 3.01: Using the data in the ONC-supplied Test Data set TD170.314.a.5 – 3a, Tester shall verify that the patient problem list data entered in the DTR170.314.a.5 – 1: Electronically Record Patient Problem List in an Ambulatory Setting test and DTR170.314.a.5 – 2: Electronically Change Patient Problem List in an Ambulatory Setting test display correctly and without omission

IN170.314.a.5 – 3.02: Using the data in the ONC-supplied Test Data set TD170.314.a.5 – 3b, Tester shall verify that the patient problem history data and the correct values from the standard terminology display correctly and without omission

NORMATIVE TEST PROCEDURES – INPATIENT SETTING

Derived Test Requirements

DTR170.314.a.5 – 4: Electronically Record Patient Problem List in an Inpatient Setting

DTR170.314.a.5 – 5: Electronically Change Patient Problem List in an Inpatient Setting

DTR170.314.a.5 – 6: Electronically Access Patient Problem List in an Inpatient Setting

DTR170.314.a.5 – 4: Electronically Record Patient Problem List in an Inpatient Setting

Required Vendor Information

VE170.314.a.5 – 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.5 – 4.02: Vendor shall identify the EHR function(s) that are available to: 1) select the patient, 2) enter patient problems, 3) change patient problems, 4) access patient problem list, and 5) access patient problem history

Required Test Procedure:

TE170.314.a.5 – 4.01: Tester shall select patient problems data from ONC-supplied test data set TD170.314.a.5 – 4

TE170.314.a.5 – 4.02: Using the EHR function(s) identified by the Vendor, the Tester shall select the patient's existing record and enter patient problem list data from the test data set TD170.314.a.5 – 4

TE170.314.a.5 – 4.03: Using the Inspection Test Guide (below), the Tester shall verify that the patient problem test data have been entered correctly, without omission and in conformance with vocabulary standards.

Inspection Test Guide

IN170.314.a.5 – 4.01: Using the data in the ONC-supplied Test Data set TD170.314.a.5 – 4, Tester shall verify that the patient problem list test data are entered correctly and without omission

IN170.314.a.5 – 4.02: Tester shall verify that the patient problem list data entered during the test are associated with the required standard terminology. Verification methods include, but are not limited to:

- verifying that the appropriate terminology code is displayed along with the patient problem description when the user is recording patient problems; or
- verifying that the EHR includes the capability to cross-reference (map) the user-displayed problem descriptions to the appropriate vocabulary codes; or
- verifying that the patient problem list data stored in the EHR contains the appropriate vocabulary codes

IN170.314.a.5 – 4.03: Tester shall verify the patient problem list data and the correct values from the standard terminology are stored in the patient's record

DTR170.314.a.5 – 5: Electronically Change Patient Problem List in an Inpatient Setting

Required Vendor Information

- As defined in DTR170.314.a.5 – 4, no additional information is required

Required Test Procedure:

TE170.314.a.5 – 5.01: Tester shall select patient problem test data from ONC-supplied test data set TD170.314.a.5 – 5

TE170.314.a.5 – 5.02: Using the EHR function(s) identified by the Vendor, the Tester shall select the patient's existing record, shall display the patient problem list data entered during the DTR170.314.a.5 – 4: Electronically Record Patient Problem List in an

Inpatient Setting test, and shall change the previously entered patient problem list data

TE170.314.a.5 – 5.03: Using the Inspection Test Guide (below), the Tester shall verify that the patient problem list data changed in TE170.314.a.5 – 5.02 have been entered correctly and without omission

Inspection Test Guide:

IN170.314.a.5 – 5.01: Tester shall verify that the patient problems entered during the DTR170.314.a.5 – 4: Electronically Record Patient Problem List in an Inpatient Setting test are accessed and changed

IN170.314.a.5 – 5.02: Using the data in the ONC-supplied Test Data set TD170.314.a.5 – 5, Tester shall verify that the changed patient problem list data and the correct values from the standard terminology are stored in the patient's record

DTR170.314.a.5 – 6: Electronically Access Patient Problem List and Problem List History in an Inpatient Setting

Required Vendor Information

- As defined in DTR170.314.a.5 – 4, no additional information is required

Required Test Procedure:

TE170.314.a.5 – 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 problems entered during the DTR170.314.a.5 – 4: Electronically Record Patient Problem List in an Inpatient Setting test and changed during the DTR170.314.a.5 – 5: Electronically Change Patient Problem List in an Inpatient Setting test

TE170.314.a.5 – 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 problem history

TE170.314.a.5 – 6.03: Using the Inspection Test Guide (below), the tester shall verify that the patient problem list test data and the patient problem history display correctly and without omission

Inspection Test Guide

IN170.314.a.5 – 6.01: Using the data in the ONC-supplied Test Data set TD170.314.a.5 – 6a, Tester shall verify that the patient problem list data entered in the DTR170.314.a.5 – 4: Electronically Record Patient Problem List in an Inpatient Setting test and DTR170.314.a.5 – 5: Electronically Change Patient Problem List in an Inpatient Setting test display correctly and without omission

IN170.314.a.5 – 6.02: Using the data in the ONC-supplied Test Data set TD170.314.a.5 – 6b, Tester shall verify that the patient problem history data and the correct values from the standard terminology display correctly and without omission

CONFORMANCE TEST TOOLS

None

Document History

Version Number	Description	Date
1.0	Released for public comment	September 7, 2012