Test Procedure for §170.314(a)(10) Drug-formulary checks

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.

§170.314(a)(10) Drug-formulary checks. EHR technology must automatically and electronically check whether a drug formulary (or preferred drug list) exists for a given patient and medication.

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

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[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

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 drug-formulary checks certification criterion is discussed:

- "…CMS has issued a proposed rule (77 FR 45022) that would update Medicare Part D e-prescribing standards, including a new version of the formulary and benefit standard. We strongly encourage EHR technology developers to utilize these standards, but do not believe that it is necessary at this time to require them as a condition of certification – as having current drug formularies stored locally in the EHR technology would also be a permitted approach. Further, as we discussed in the S&CC July 2010 final rule (75 FR 44602), because some EPs, EHs, and CAHs, do not have external access to a drug formulary and would be able to satisfy the MU requirements by checking an internally managed drug formulary, we believe the flexibility provided by the certification criterion is still warranted."

- "…the ONC HIT Certification Program does not include any form of reciprocity for certification under other private sector certification programs, including Surescripts' certification program. The ONC HIT Certification Program will be a "new" certification program that will replace the temporary certification program upon the effective date of this final rule. At its onset, we believe that the best way to ensure that EHR technology has the capabilities included in the certification criteria adopted by the Secretary is to require the EHR technology to be tested and certified to the certification criteria under the provisions and procedures specified by the ONC HIT Certification Program."

Per Section III.D of the Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, Final Rule where the drug-formulary checks certification criterion is discussed:

- "…we have removed any reference to a particular [Formulary] standard because an eligible professional or eligible hospital that does not have external access to a drug formulary would be able to satisfy this meaningful use measure by checking an internally managed drug formulary. Although the Formulary and Benefits standard is no longer required as a condition of certification, we note that eligible professionals who seek to comply with the electronic prescribing requirements associated with Medicare Part D eligible individuals will need to use this standard as they do today."

2014 Edition
Test Procedure for §170.314.a.10.Drug-formulary checks
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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 drug-formulary checks certification criterion is discussed:

- "…the revision we have included specifies that EHR technology must perform an automated check for the existence of a drug formulary that is specific to a patient for the medication to be prescribed. In other words, an EHR technology would not satisfy this revised certification criterion if it provided a hyperlink to a patient's drug formulary that an EP, EH, or CAH then had to manually open and navigate."

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 to automatically and electronically check whether a drug formulary (or preferred drug list) exists for a given patient and medication. The FR criterion does not specify the context for checking if a drug is in a formulary or preferred drug list. At the Vendor's discretion, the context for performing an electronic check if a drug is in a formulary or preferred drug list may be during order entry, during eligibility checking, or other context.

This test procedure consists of one section:

- Check – evaluates the capability for a Complete EHR or EHR Module to automatically and electronically check whether a drug formulary (or preferred drug list) exists for a given patient and medication
    - The Vendor identifies the specific formulary or preferred drug list available in the EHR that can be used to initiate electronic drug checks
    - The Tester enters one or more drugs and the EHR automatically and electronically checks whether each drug is in the formulary or preferred drug list identified by the Vendor
    - The Tester verifies that at least one formulary or preferred drug list check is automatically and electronically performed as described by the Vendor

REFERENCED STANDARDS

None

NORMATIVE TEST PROCEDURES

Derived Test Requirements

DTR170.314.a.10 – 1: Automatically and Electronically Check Drug-formulary or Preferred Drug List

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Required Vendor Information

VE170.314.a.10 – 1.01: Vendor shall identify a patient with an existing record in the EHR to be used for this test

VE170.314.a.10 – 1.02: Vendor shall identify the specific drug formulary or preferred drug list available in the EHR that can be used to automatically initiate electronic checks

VE170.314.a.10 – 1.03: Vendor shall describe how the electronic check information displays to a user

VE170.314.a.10 – 1.04: Vendor shall identify the EHR function(s) that are available to: 1) select the patient, 2) enter the drug, and 3) automatically and electronically check the drug formulary or preferred drug list

Required Test Procedure:

TE170.314.a.10 – 1.01: Tester shall select drug data from an ONC-supplied test data set in TD170.314.a.10

TE170.314.a.10 – 1.02: Using the EHR function(s) and drug formulary or preferred drug list identified by the Vendor, the Tester shall select the patient's existing record, enter the drug data, and the Complete EHR or EHR module will automatically and electronically check at least one drug with the drug formulary or preferred drug list

TE170.314.a.10 – 1.03: Using the Inspection Test Guide (below), the Tester shall verify that at least one drug-formulary check is automatically and electronically performed using the specific formulary or preferred drug list identified by the Vendor in VE170.314.a.10 – 1.02

Inspection Test Guide

IN170.314.a.10 – 1.01: Using the data in an ONC-supplied test data set in TD170.314.a.10, Tester shall verify that the drug data entered in TE170.314.a.10 – 1.02 are entered correctly and without omission

IN170.314.a.10 – 1.02: Tester shall verify that:
- At least one drug check, using either the drug formulary or preferred drug list identified by the Vendor in VE170.314.a.10 – 1.02, is automatically and electronically performed

- The electronic check information is displayed to the user as described by the Vendor in VE170.314.a.10 – 1.03

CONFORMANCE TEST TOOLS

None

The Office of the National Coordinator for
Health Information Technology

Document History

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