

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

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<sup>1</sup> 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<sup>2</sup>, 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](mailto: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

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<sup>1</sup> Disclaimer: Certain commercial products may be identified in this document. Such identification does not imply recommendation or endorsement by ONC.

<sup>2</sup> 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.

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.

## 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 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.”

## 2011 EDITION PREAMBLE LANGUAGE

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 (July 28, 2010) 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.”

## 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 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 EHR technology to automatically and electronically check whether a drug formulary (or preferred drug list) exists for a given patient and medication. The 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.

ONC supplies the test data for this test procedure.

This test procedure consists of one section:

- Check – evaluates the capability 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

### **DTR170.314(a)(10) – 1: Automatically and Electronically Check Drug-Formulary or Preferred Drug List**

#### 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 via 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 related to the drug entered and specific patient

#### 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 EHR technology will automatically and electronically check at least one drug with the drug formulary or preferred drug list specific to that patient

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

## 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)(10) Drug-formulary checks 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