Test Procedure for §170.302 (b) Drug-formulary checks

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 (b) Drug-formulary checks. Enable a user to electronically check if drugs are in a formulary or preferred drug list.

[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 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."

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 enable a user to electronically check if drugs are in a formulary or preferred drug list. 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 to check if a drug is in a formulary or preferred drug list
  - 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 checks if each drug is in the formulary or preferred drug list identified by the Vendor
  - The Tester validates that at least one formulary or preferred drug list check is performed as described by the Vendor

REFERENCED STANDARDS

None

NORMATIVE TEST PROCEDURES

Derived Test Requirements

DTR170.302.b – 1: Electronically Check Drug-formulary or Preferred Drug List

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Required Vendor Information

VE170.302.b – 1.01: Vendor shall identify a patient with an existing record in the EHR to be used for this test

VE170.302.b – 1.02: Vendor shall identify the specific formulary or preferred drug list available in the EHR that can be used to initiate electronic checks

VE170.302.b – 1.03: Vendor shall describe how the electronic check information displays to a user

VE170.302.b – 1.04: Vendor shall identify the EHR function(s) that are available to: 1) select the patient, 2) enter the drug, and 3) check the drug formulary or preferred drug list

Required Test Procedure:

TE170.302.b – 1.01: Tester shall select drug data from a NIST-supplied test data set in TD170.302.b

TE170.302.b – 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 check at least one drug with the drug formulary or preferred drug list

TE170.302.b – 1.03: Using the NIST-supplied Inspection Test Guide, the Tester shall verify that at least one drug-formulary check is performed using the specific formulary or preferred drug list identified by the Vendor in VE170.302.b – 1.02

Inspection Test Guide

IN170.302.b – 1.01: Using the data in a NIST-supplied Test Data set in TD170.302.b, Tester shall verify that the drug data entered in TE170.302.b – 1.02 are entered correctly and without omission

IN170.302.b – 1.02: Tester shall verify that:

- At least one drug check, using either the formulary or preferred drug list identified by the Vendor in VE170.302.b – 1.02, is performed
- The electronic check information is displayed to the user as described by the Vendor in VE170.302.b – 1.03

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.

TD170.302.b: Check Drug Formulary or Preferred Drug List

The certification criterion does not specify order entry as the context for checking the drug formulary or preferred drug list. The Test Data, by listing medication orders, are intended to support this context if the Vendor chooses order entry as the context. The drug names in the Test Data may be used alone if the Vendor chooses a different context.

Drug Test Data - Set 1

- Diabeta (glyburide) 2.5 mg tablet by mouth every morning
- Erythromycin (erythromycin ethylsuccinate) oral suspension 400 mg by mouth every 6 hours
- Norvasc (amlodipine) 5 mg tablet by mouth daily

Drug Test Data - Set 2

- Macrobid (nitrofurantoin) 100 mg tablet by mouth daily
- Catapres (clonidine hydrochloride) 0.1 mg tablet by mouth 2 times per day
- Milk of Magnesia (magnesium hydroxide) 30 ml by mouth once daily at bedtime

Drug Test Data - Set 3

- Lipitor (atorvastatin calcium) 10 mg tablet by mouth daily
- Lasix (furosemide) 20 mg tablet by mouth 2 times per day
- Klor-Con (potassium chloride) 10 mEq tablet by mouth 2 times per day

Drug Test Data - Set 4

- HydroDiuril (hydrochlorothiazide) 25 mg tablet by mouth 2 times per day
- Cefzil (cefprozil) oral suspension 250 mg by mouth every 12 hours
- Albuterol inhaler (albuterol sulfate) aerosol 2 puffs by oral inhalation every 4 hours

CONFORMANCE TEST TOOLS

None

Document History

Version Number	Description	Date Published
0.8	Original draft version	March 22, 2010
1.0	Updated to reflect Final Rule	July 21, 2010
1.0	Updates include: • removed “Pending” in header • updated medication from Esidrix to HydroDiuril	August 13, 2010