2014 Edition
Test Procedure for §170.314(b)(3) Electronic prescribing
Approved Test Procedure Version 1.4 ■ June 10, 2013

The Office of the National Coordinator for
Health Information Technology

Test Procedure for §170.314(b)(3) Electronic prescribing

This document describes the test procedure for evaluating conformance of 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 CRITERIA

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(b)(3) Electronic prescribing. Enable a user to electronically create prescriptions and prescription-related information for electronic transmission in accordance with:
    (i) The standard specified in §170.205(b)(2); and
    (ii) At a minimum, the version of the standard specified in §170.207(d)(2).

---

[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 for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule.

2014 Edition
Test Procedure for §170.314(b)(3) Electronic prescribing
Approved Test Procedure Version 1.4 ■ June 10, 2013

The Office of the National Coordinator for
Health Information Technology

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), the 2014 Edition of this certification criterion is classified as new in the inpatient setting and revised in the ambulatory setting from the 2011 Edition. This certification criterion meets at least one of the two factors of new certification criteria in the inpatient setting: (1) the certification criterion only specifies capabilities that have never been included in previously adopted certification criteria; or (2) the certification criterion was previously adopted as "mandatory" for a particular setting and subsequently adopted as "mandatory" or "optional" for a different setting. This certification criterion meets at least one of the three factors of revised certification criteria in the ambulatory setting: (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 electronic prescribing certification criterion is discussed:

- "We proposed the use of the February 2012 monthly version of RxNorm, but have adopted the August 2012 monthly version of RxNorm." "We proposed to require the use of RxNorm as the vocabulary standard and NCPDP SCRIPT version 10.6 as the only content exchange standard for this certification criterion. In our discussion of this certification criterion for the ambulatory setting, we proposed to not include the NCPDP SCRIPT version 8.1 in the 2014 Edition EHR certification criterion."
- "CMS has recently proposed (77 FR 45022) to retire version 8.1 and only permit version 10.6 as of 11/1/2013. More importantly, NCPDP SCRIPT 10.6 is backwards compatible with version 8.1, so 10.6 users will be able to communicate with version 8.1 users."
- "The use of RxNorm as the sole vocabulary standard would entail its use to represent medications within an electronic prescription formatted according to the SCRIPT 10.6 standard. We intend for the RxNorm concept unique identifiers (RXCUIs) to be used as drug qualifiers. Mappings are not something within the scope of this rulemaking…"
- "We acknowledge that all medications may not yet have an equivalent RxNorm code. We do not believe it is necessary to modify the standard to explicitly state that RxNorm "be utilized when there is an equivalent concept mapping" because certification is meant to verify that EHR technology can properly use this standard. This certification criterion requires the capability to use RxNorm, specifically RXCUIs as noted in our prior response. Thus, where no RxNorm code exists, nothing prohibits another code from being used. However, where corresponding RxNorm codes exist, EHR technology must be able to use those codes."

2014 Edition
Test Procedure for §170.314(b)(3) Electronic prescribing
Approved Test Procedure Version 1.4 ■ June 10, 2013

The Office of the National Coordinator for
Health Information Technology

- "Given the flexibility provided by CMS, we believe this [a clear way to differentiate whether a prescription is merely sent "in house" (scenarios 1 and 2 in the Stage 2 proposed rule or "transmitted" (scenario 3))] will need to be determined on an implementation-by-implementation basis and would be difficult to assess for the purpose of certification in a simulated testing laboratory environment."

- "…we believe it is premature to include controlled substances in the 2014 edition of the certification requirements."

- "This suggested capability [a capability in the certification criterion that ensures a provider is actively alerted when an e-prescription fails] is beyond the scope of the proposed certification criterion and we decline to modify the certification criterion."

- "A commenter recommended that there be a way for patients to review e-prescriptions and participate in medication reconciliation with both their doctors and pharmacists via a patient portal...This suggested capability is beyond the scope of the proposed certification criterion and we decline to modify the certification criterion."

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), 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:

- "We proposed to require the use of RxNorm as the vocabulary standard and NCPDP SCRIPT version 10.6 as the only content exchange standard for this certification criterion. In our discussion of this certification criterion for the ambulatory setting, we proposed to not include the NCPDP SCRIPT version 8.1 in the 2014 Edition EHR certification criterion."

- "We proposed to adopt for the inpatient setting the same revised electronic prescribing certification criterion that we proposed to adopt for the ambulatory setting"

2014 Edition
Test Procedure for §170.314(b)(3) Electronic prescribing
Approved Test Procedure Version 1.4 ■ June 10, 2013

The Office of the National Coordinator for
Health Information Technology

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.

ONC supplies the test data for this test procedure.

This test evaluates the capability for an EHR technology to electronically create prescriptions and prescription-related information for electronic transmission using the NCPCP SCRIPT version 10.6; and using the RxNorm vocabulary standard. The test procedure incorporates both the EDIFACT and XML versions of NCPDP SCRIPT.

During the process of building the ePrescribing Validation Tool, NIST discovered additional errata as well as conformance requirements that were either conflicting or unclear in the named standards documents. The "NCPDP Script Implementation Recommendations Document" clarifies these issues and indicates how they are interpreted in the test tool. This document can be accessed via the NCPDP homepage at: http://www.ncpdp.org/eprescribing.aspx.

The medications vocabulary requirement must be met by providing RxNorm codes or medication vocabulary codes from any of the source vocabularies incorporated within RxNorm, when an RxNorm code exists. (2011 EHR Certification and Meaningful Use Stage 1 permitted the use of other source vocabularies – for 2014 EHR Certification and Meaningful Use Stage 2, these source vocabularies are not permitted as RxNorm must be used.)

The SCRIPT standard allows use of any version of the External Code List (ECL) from the one published October 2008 to the current version. For the purpose of meaningful use testing, all values contained in any of those ECL versions will be considered valid.

The test procedure is organized into one section:

- Create—evaluates the capability of the EHR technology to electronically generate conformant NCPDP and RxNorm prescriptions and prescription related information for electronic transmission
    - o Using the Vendor-identified EHR function(s), the Tester inputs the provided prescription information test data for the test patients (input can be performed using a manual or automated process)
    - o Using the Vendor-identified EHR function(s) and the ONC-supplied test data, the Tester causes the EHR to generate the indicated prescription information message using the NCPDP SCRIPT version 10.6 and the RxNorm vocabulary standard
    - o The Tester verifies that the NCPDP SCRIPT version 10.6 conformance requirements tested are met and that the RxNorm codes are appropriate for the prescription information message

2014 Edition
Test Procedure for §170.314(b)(3) Electronic prescribing
Approved Test Procedure Version 1.4 ■ June 10, 2013

The Office of the National Coordinator for
Health Information Technology

REFERENCED STANDARDS

§170.205 Content exchange standards and implementation specifications for exchanging electronic health information.	Regulatory Referenced Standard
The Secretary adopts the following content exchange standards and associated implementation specifications:	
(b) Electronic prescribing.	
(2) Standard. NCPDP SCRIPT Standard, Implementation Guide, Version 10.6 (incorporated by reference in §170.299).	

§170.207 Vocabulary standards for representing electronic health information.	Regulatory Referenced Standard
The Secretary adopts the following code sets, terminology, and nomenclature as the vocabulary standards for the purpose of representing electronic health information:	
(d) Medications.	
(2) Standard. RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine, August 6, 2012 Release (incorporated by reference in §170.299).	

2014 Edition
Test Procedure for §170.314(b)(3) Electronic prescribing
Approved Test Procedure Version 1.4 ■ June 10, 2013

The Office of the National Coordinator for
Health Information Technology

NORMATIVE TEST PROCEDURES

Derived Test Requirements

DTR170.314(b)(3) – 1: Electronically Create Prescriptions

Figure 1
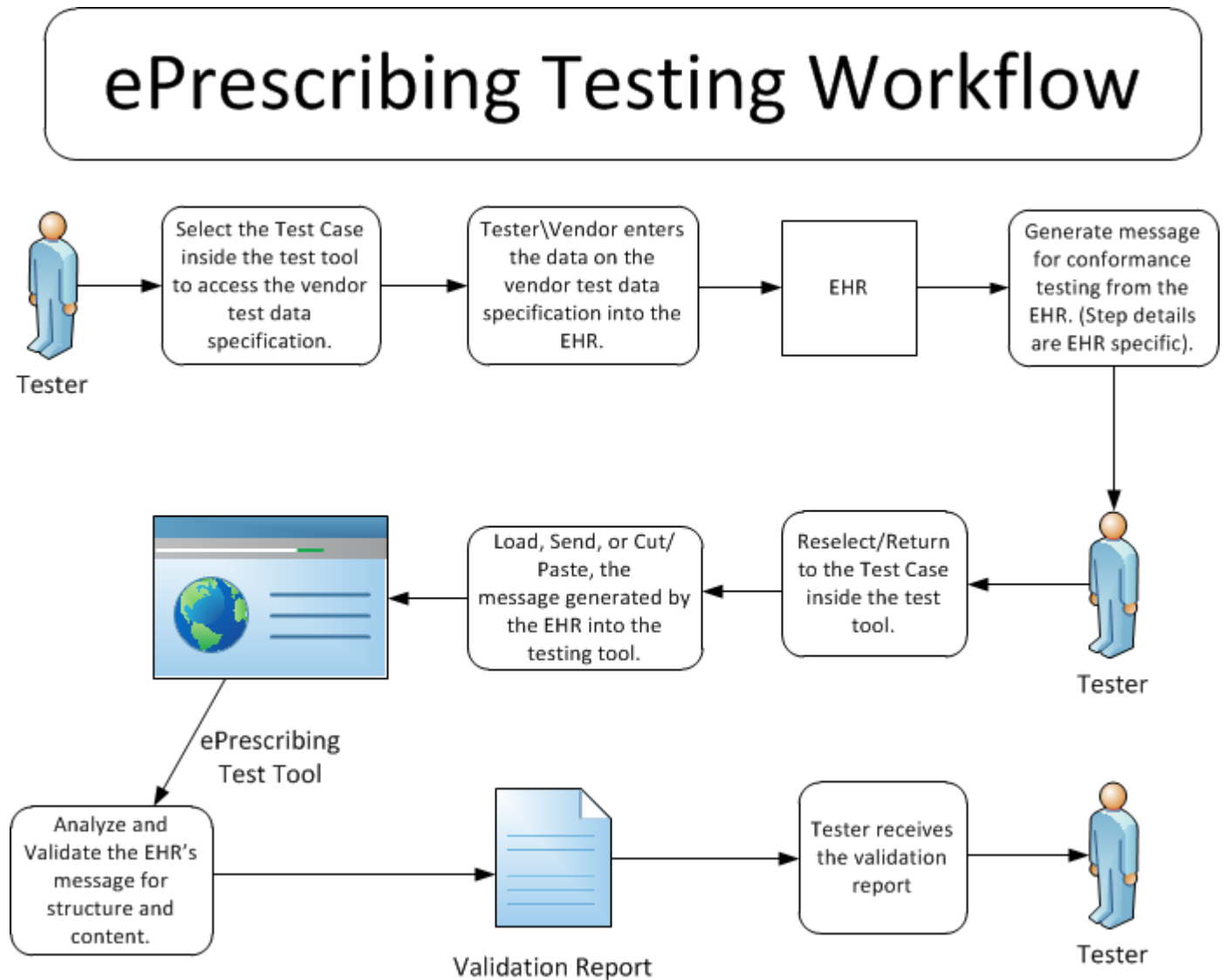
The instructions in the derived test procedure listed below reference the numbered test steps in Figure 1 above.

DTR170.314(b)(3) – 1: Electronically Create Prescriptions

<u>Required Vendor Information</u>

VE170.314(b)(3) – 1.01: Vendor shall identify the EHR function(s) that are available to 1) input the test data into the EHR for the test patients, 2) create prescription messages using the

2014 Edition
Test Procedure for §170.314(b)(3) Electronic prescribing
Approved Test Procedure Version 1.4 ■ June 10, 2013

The Office of the National Coordinator for
Health Information Technology

test data, 3) import the prescription messages to the NIST ePrescribing Validation Tool, and 4) demonstrate support for the named standard vocabulary value sets

VE170.314(b)(3) – 1.02: Vendor shall provide the mechanism necessary to capture and import prescription messages into the ePrescribing Validation Tool

Required Test Procedures

TE170.314(b)(3) – 1.01: Tester shall select two or more data sets consisting of prescription information [Figure 1, Step 1]

TE170.314(b)(3) – 1.02: Using the Vendor-identified EHR function(s), the Tester shall input the provided prescription information test data selected in TE170.314(b)(3) – 1.01 [Figure 1, Step 2]

TE170.314(b)(3) – 1.03: Using the Vendor-identified EHR function(s) and the selected prescription test data, the Tester shall

- Cause the EHR to generate the indicated prescription message for the test patient based on the NCPDP SCRIPT version 10.6 Implementation Guide for Electronic Prescribing using either XML or EDIFACT implementation [Figure 1, Step 3]
- Import the prescription message to the NIST ePrescribing Validation Tool identified in the Conformance test tools section of this test procedure [Figure 1, Steps 4 & 5]

TE170.314(b)(3) – 1.04: Using the Inspection Test Guide, the Tester shall verify that the prescription message is conformant to the named standards and is generated with the appropriate prescription information

TE170.314(b)(3) – 1.05: Using the Inspection Test Guide, the Tester shall perform visual inspection to verify that the information in the prescription message is complete and accurate

Inspection Test Guide

IN170.314(b)(3) – 1.01: Using the message Validation Report produced by the NIST ePrescribing Validation Tool identified in the Conformance test tools section of this test procedure, the Tester shall verify that the NCPDP SCRIPT version 10.6 Implementation Guide conformance requirements tested are met [Figure 1, Steps 6 & 7]

IN170.314(b)(3) – 1.02: The Tester shall inspect the EHR to verify the capability of the Vendor to support the named RxNorm vocabulary standard

- Using the Vendor-identified EHR function(s) and the NIST ePrescribing Validation Tool, the Vendor shall demonstrate to the Tester that their EHR supports the RxNorm vocabulary standard

IN170.314(b)(3) – 1.03: The Tester shall perform a visual inspection of items noted within the ePrescribing Conformance Tool's Test Cases within the "Test Story" Tab as "Notes to Testers"

2014 Edition
Test Procedure for §170.314(b)(3) Electronic prescribing
Approved Test Procedure Version 1.4 ■ June 10, 2013

The Office of the National Coordinator for
Health Information Technology

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 need 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 provide 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 this test procedure the Tester shall select two or more Data Sets of the 16 Data Sets provided.

NAVIGATING A TEST CASE

A test case consists of a test story and a test data specification. The test story gives a real world scenario that provides the context for the test case. The test data specification provides the data associated with

2014 Edition
Test Procedure for §170.314(b)(3) Electronic prescribing
Approved Test Procedure Version 1.4 ■ June 10, 2013

The Office of the National Coordinator for
Health Information Technology

the test story and is what is typically available in the clinical setting. Together the test story and the test data specification provide sufficient information that is to be entered into the EHR for a particular test case. Using this data and the EHR functions, a message is to be generated.

Another artifact called the message content data sheet is provided that shows a conformant message instance for the test case. The message content is organized in a table format that provides the NCPCP SCRIPT version 10.6 message elements and the data associated with the message elements for a given test case. If necessary, the message content may be used to help the Vendor select the correct option provided by the EHR technology. It may also be used to provide assistance to the Tester and Vendor to resolve issues discovered in conformance testing. In short, the message content data sheet can be thought of as the "answer" to the scenario ("question") provided by the test story and the test data specification.

The message content data sheet indicates the location and data of the message for a particular test case. The message content data sheet can be used to assist the Tester in loading the EHR with the test case data and provides a classification of the data. The message validation is examining the message element for the presence of data and for exact content. The Message Validation Result will indicate whether the SCRIPT v10.6 message validated successfully or is invalid.

The test cases and the context-based validation test tool are tightly coupled. In addition to validating conformance, the test tool performs selective content validation based on the test data provided, and deviation from the test data may cause the test tool to issue Errors. For additional information, refer to the ePrescribing Validation Tool documentation.

CONFORMANCE TEST TOOLS

The following testing tools are available to evaluate conformance to the standards referenced in this test procedure:

- o ePrescribing Validation Tool: SCRIPT 10.6 – NIST provides an SCRIPT 10.6 validation tool using XML or EDI designed specifically to support this test procedure. The tool is available as a Web Application
- o The application can be downloaded for local installation
- o The web application validation service is available at: http://erx-testing.nist.gov

Support for these tools is available by submitting questions to the following user's group: https://groups.google.com/d/forum/erx-testing-tool.

Multiple browsers may be used to access this tool; if the tool does not load completely using Internet Explorer 8 or Internet Explorer 9, alternative browsers such as Firefox, Google Chrome, or Safari are recommended. The Transport Testing Tool uses non-standard ports. If your firewall blocks HTTP traffic

2014 Edition
Test Procedure for §170.314(b)(3) Electronic prescribing
Approved Test Procedure Version 1.4 ■ June 10, 2013

The Office of the National Coordinator for
Health Information Technology

on non-standard ports, this tool may not be accessible. Please retry access from a location without a firewall that blocks non-standard ports. Alternatively users may download and run a local version of the tool.

The following information is provided to assist the Tester in interpreting the conformance reports generated by the NIST conformance testing tools.

The NIST ePrescribing Conformance Tool evaluates conformance requirements which are specified or have been derived from the standards and implementation guides identified in the Final Rule and the test data provided in this test procedure. The conformance test tool evaluates the submitted SCRIPT 10.6 message for each conformance requirement, and then produces a conformance report. The Tester should consider that a report containing only Affirmative and Warning messages indicates a sufficient level of conformance to the standard and test data expectations. If reported, Errors should be considered as significant departures from the standard or test data requirements which need to be corrected in order to claim conformance. ATLs will need to further analyze each error to determine if, in the context of meeting the criterion and overall meaningful use objective, the error results in a failure of the test procedure by the EHR technology.

As noted in the Informative Test Description section above, the SCRIPT standard allows use of any version of the External Code List (ECL) from the one published October 2008 to the current version. However, the SCRIPT 10.6 XML schema published by NCPDP has not been updated to contain all values present in recent ECL versions. Because the ePrescribing Conformance Tool uses the published SCRIPT schema as a basis for XML message validation, erroneous conformance report errors will be caused by use of these values. The Tester should refer to the set of allowed, non-schema values when evaluating errors in the conformance report, and should disregard errors resulting from their use. The list of such values, titled Additional Allowed SCRIPT 10.6 Code Values, will be updated quarterly as NCPDP releases new ECL versions.

2014 Edition
Test Procedure for §170.314(b)(3) Electronic prescribing
Approved Test Procedure Version 1.4 ■ June 10, 2013

The Office of the National Coordinator for
Health Information Technology

Document History

Version Number	Description of Change	Date Published
1.0	Released for public comment	November 19, 2012
1.1	Delivered for National Coordinator Approval	December 3, 2012
1.2	Posted Approved Test Procedure	December 14, 2012
1.3	Updated Approved Test Procedure Updates: • Removed "ambulatory setting only" to reflect that the test procedure applies to the ambulatory and inpatient settings	February 22, 2013
1.4	Updated Approved Test Procedure Updates: • Test Data section: Changed 'three or more data sets' to 'two or more data sets' to conform to the normative test procedure	June 10, 2013