

# § 170.315(b)(3) Electronic prescribing

## **Test Procedure**

This Test Procedure illustrates the test steps required to certify a Health IT Module to this criterion. Please consult the most recent ASTP/ONC Final Rule on the <u>Certification Regulations page</u> for a detailed description of the certification criterion with which these testing steps are associated. ASTP/ONC also encourages developers to consult the Certification Companion Guide in tandem with the test procedure as it provides clarifications that may be useful for product development and testing.

**Note**: The tests step order does not necessarily prescribe the order in which the tests should take place.

## Revision History

Version #	Description of Change	Version Date
1.0	Initial publication	03-11-2024
1.1	Updated testing tool from NCPDP to new Electronic Prescribing (eRx) tool	07-08-2024
2.0	Updated test procedure to support new HTI-4 Final Rule requirements	09-05-2025

## Regulation Text

§ 170.315 (b)(3) Electronic prescribing—

- (ii) For technology certified subsequent to June 30, 2020:
  - (A) For the time period up to and including December 31, 2027, enable a user to perform the following prescription-related electronic transactions in accordance with the standards specified in § 170.205(b)(1) or (2); at a minimum, a standard adopted in § 170.207(d)(1); and the standard adopted in § 170.207(d)(2) if using the standard in § 170.205(b)(2). On and after January 1, 2028, enable a user to perform the following prescription-related electronic transactions in accordance with the standard specified in § 170.205(b)(2), at a minimum, a standard adopted in § 170.207(d)(1), and the standard in paragraph (d)(2) of this section.
    - (1) New prescriptions (NewRx).
    - (2) Request and respond to change prescriptions (RxChangeRequest, RxChangeResponse).
    - (3) Request and respond to cancel prescriptions (CancelRx, CancelRxResponse).
    - (4) Request and respond to renew prescriptions (RxRenewalRequest, RxRenewalResponse).
    - (5) Receive fill status notifications (RxFill).
    - (6) Request and receive medication history (RxHistoryRequest, RxHistoryResponse).
    - (7) Relay acceptance of transaction back to the sender (Status).
    - (8) Respond that there was a problem with the transaction (Error).
    - (9) Respond that a transaction requesting a return receipt has been received (Verify).



- (10) Electronic prior authorization transactions (PAInitiationRequest, PAInitiationResponse, PARequest, PAResponse, PAAppealRequest, PAAppealResponse, PACancelRequest, PACancelResponse, and PANotification). These transactions are required if using the standard in 170.205(b)(2).
- (B) Enable a user to exchange race and ethnicity information when performing the following prescription-related electronic transactions, if using the standard in § 170.205(b)(2):
  - (1) Receive fill status notifications (RxFill).
  - (2) Request and respond to change prescriptions (RxChangeRequest, RxChangeResponse).
  - (3) Request to cancel prescriptions (CancelRx).
  - (4) Reguest and respond to renew prescriptions (RxRenewalReguest, RxRenewalResponse).
- (C) For the following prescription-related transactions, the technology must be able to receive and transmit the diagnosis or diagnoses that are the reason for prescription:
  - (1) Required transactions
    - (i) New prescriptions (NewRx).
    - (ii) Request and respond to change prescriptions (RxChangeRequest, RxChangeResponse).
    - (iii) Cancel prescriptions (CancelRx).
    - (iv) Request and respond to renew prescriptions (RxRenewalRequest, RxRenewalResponse).
    - (v) Receive fill status notifications (RxFill).
    - (vi) [Reserved]
    - (vii) Electronic prior authorization transactions (PAInitiationRequest, PAInitiationResponse, PARequest, PAResponse, PAAppealRequest, PAAppealResponse and PACancelRequest, PACancelResponse, PANotification). These transactions are required if using the standard in § 170.205(b)(2).
  - (2) [Reserved]
- (D) [Reserved]
- (E) Limit a user's ability to prescribe all oral liquid medications in only metric standard units of mL (that is, not cc).
- (F) Always insert leading zeroes before the decimal point for amounts less than one and must not allow trailing zeroes after a decimal point when a user prescribes medications.

# Standard(s) Referenced

Paragraph (b)(3)(ii)

- § 170.205(b)(1) NCPDP SCRIPT Standard Implementation Guide, Version 2017071, July 2017
- § 170.205(b)(2) NCPDP SCRIPT Standard Implementation Guide, Version 2023011 (This standard is required by December 31, 2027)
- § 170.207(d)(1)(i) RxNorm, July 5, 2022 Full Monthly Release



- § 170.207(d)(1)(ii) RxNorm, December 4, 2023 Full Monthly Release
- § 170.207(d)(1)(iii) RxNorm, September 8, 2015 Full Release Update
- § 170.207(d)(2) National Drug Codes (NDC) (This standard is required by December 31, 2027)

## **Required Tests**

## Paragraphs (b)(3)(ii)(A)(1-5, 7-9) Send and receive

#### System Under Test

## Expires on January 1, 2028

Complete the following steps using the NCPDP SCRIPT Standard Version 2017071.

- The health IT developer creates new prescriptions (NewRx) in accordance with (b)(3)(ii)(A)(1) and (b)(3)(ii)(A)(2) request and respond to change prescriptions (RxChangeRequest, RxChangeResponse), and (b)(3)(ii)(A)(5) fill status notifications (RxFill).
- 2. The health IT developer creates new prescriptions (NewRx) in accordance with (b)(3)(ii)(A)(1) and (b)(3)(ii)(A)(3) request and respond to cancel prescriptions (CancelRx, CancelRxResponse).
- 3. The health IT developer creates new prescriptions (NewRx) in accordance with (b)(3)(ii)(A)(1) and (b)(3)(ii)(A)(4) request and respond to renew prescriptions (RxRenewalRequest, RxRenewalResponse).
- 4. The health IT developer relays acceptance of a transaction back to the sender (Status) in accordance with (b)(3)(ii)(A)(7).
- 5. The health IT developer responds that there was a problem with the transaction (Error) in accordance with (b)(3)(ii)(A)(8).
- 6. The health IT developer responds that a transaction requesting a return receipt has been received (Verify) in accordance with (b)(3)(ii)(A)(9).

## Required by December 31, 2027

Complete the following steps using the NCPDP SCRIPT Standard Version 2023011.

 The health IT developer creates new prescriptions (NewRx) in accordance with (b)(3)(ii)(A)(1) and (b)(3)(ii)(A)(2) request and respond to change prescriptions (RxChangeRequest, RxChangeResponse), and (b)(3)(ii)(A)(5) fill status notifications (RxFill).

#### **Test Lab Verification**

## Expires on January 1, 2028

The test lab verifies the following steps in accordance with the NCPDP SCRIPT Standard Version 2017071.

- The tester verifies the Health IT Module sends and receives the following transactions and completes all required test tool interaction steps and verifies the validation report for the following required transactions:
  - a. Create and send new prescription (NewRx);
  - b. Receive prescription change request (RxChangeRequest);
  - c. Create and send prescription change response (RxChangeResponse); and
  - d. Receive fill status notification (RxFill).
- 2. The tester verifies the Health IT Module sends and receives the following transactions and completes all required test tool interaction steps and verifies the validation report for the following required transactions:
  - a. Create and send new prescription (NewRx);
  - Send request to cancel prescription (CancelRx);
  - c. Receive response to request to cancel prescription (CancelRxResponse).
- 3. The tester verifies the Health IT Module sends and receives the following transactions and completes all required test tool interaction steps and verifies the validation reports for the following required transactions:
  - a. Create and send new prescription (NewRx);
  - b. Receive request to renew prescription (RxRenewalRequest); and
  - c. Create and send response to renew prescription (RxRenewalResponse).
- 4. The tester verifies the Health IT Module supports Status, Error and Verify transactions.



#### System Under Test

- The health IT developer creates new prescriptions (NewRx) in accordance with (b)(3)(ii)(A)(1) and (b)(3)(ii)(A)(3) request and respond to cancel prescriptions (CancelRx, CancelRxResponse).
- The health IT developer creates new prescriptions (NewRx) in accordance with (b)(3)(ii)(A)(1) and (b)(3)(ii)(A)(4) request and respond to renew prescriptions (RxRenewalRequest, RxRenewalResponse).
- 4. The health IT developer relays acceptance of a transaction back to the sender (Status) in accordance with (b)(3)(ii)(A)(7).
- 5. The health IT developer responds that there was a problem with the transaction (Error) in accordance with (b)(3)(ii)(A)(8).
- 6. The health IT developer responds that a transaction requesting a return receipt has been received (Verify) in accordance with (b)(3)(ii)(A)(9).

#### **Test Lab Verification**

#### Required by December 31, 2027

Complete the following steps using the NCPDP SCRIPT Standard Version 2023011.

- The tester verifies the Health IT Module sends and receives the following transactions and completes all required test tool interaction steps and verifies the validation report for the following required transactions:
  - e. Create and send new prescription (NewRx);
  - f. Receive prescription change request (RxChangeRequest);
  - g. Create and send prescription change response (RxChangeResponse); and
  - h. Receive fill status notification (RxFill).
- The tester verifies the Health IT Module sends and receives the following transactions and completes all required test tool interaction steps and verifies the validation report for the following required transactions:
  - d. Create and send new prescription (NewRx);
  - e. Send request to cancel prescription (CancelRx);
  - f. Receive response to request to cancel prescription (CancelRxResponse).
- 3. The tester verifies the Health IT Module sends and receives the following transactions and completes all required test tool interaction steps and verifies the validation reports for the following required transactions:
  - d. Create and send new prescription (NewRx);
  - e. Receive request to renew prescription (RxRenewalRequest); and
  - f. Create and send response to renew prescription (RxRenewalResponse).
- 4. The tester verifies the Health IT Module supports Status, Error and Verify transactions.



# Paragraph (b)(3)(ii)(A)(6) Send and receive – medication history

## System Under Test

## Expires on January 1, 2028

Complete the following steps using the NCPDP SCRIPT Standard Version 2017071.

 The health IT developer requests and receives a patient's medication history (RxHistoryRequest, RxHistoryResponse) in accordance with (b)(3)(ii)(A)(6).

## Required by December 31, 2027

Complete the following steps using the NCPDP SCRIPT Standard Version 2023011.

 The health IT developer requests and receives a patient's medication history (RxHistoryRequest, RxHistoryResponse) in accordance with (b)(3)(ii)(A)(6).

## Test Lab Verification

## Expires on January 1, 2028

Complete the following steps using the NCPDP SCRIPT Standard Version 2017071.

- The tester verifies the Health IT Module sends and receives the following transactions and completes all required test tool interaction steps and verifies the validation report for the following required transactions:
  - a. Send a request for a medication history (RxHistoryRequest); and
  - Receive a response to a request for a medication history (RxHistoryResponse); or
  - Receive a Status message (Status) in response to a request for a medication history (RxHistoryRequest) and receive a response to a request for a medication history (RxHistoryResponse).

## Required by December 31, 2027

Complete the following steps using the NCPDP SCRIPT Standard Version 2023011.

- The tester verifies the Health IT Module sends and receives the following transactions and completes all required test tool interaction steps and verifies the validation report for the following required transactions:
  - a. Send a request for a medication history (RxHistoryRequest); and
  - Receive a response to a request for a medication history (RxHistoryResponse); or
  - Receive a Status message (Status) in response to a request for a medication history (RxHistoryRequest) and receive a response to a request for a medication history (RxHistoryResponse).



## Paragraph (b)(3)(ii)(A)(10) Electronic prior authorization transactions

## System Under Test

## Required by December 31, 2027

Complete the following steps using the NCPDP SCRIPT Standard Version 2023011.

- The health IT developer completes the electronic prior authorization transactions (PAInitiationRequest, PAInitiationResponse, PARequest, PAResponse, PAAppealRequest, PAAppealResponse, PACancelRequest, PACancelResponse, PANotification) in accordance with (b)(3)(ii)(A)(10).
- 2. The Health IT Module is able to receive and transmit the diagnosis or diagnoses that are the reason for prescription.

## Test Lab Verification

## Required by December 31, 2027

Complete the following steps using the NCPDP SCRIPT Standard Version 2023011.

- The tester verifies the Health IT Module sends and receives the following transactions and completes all required test tool interaction steps and verifies the validation report for the following transactions:
  - a. Create and send PA Initiation Request (PAInitiationRequest);
  - b. Receive PA Initiation Response (PAInitiationResponse);
  - c. Create and send PA Request (PARequest);
  - d. Receive PA Response (PAResponse);
  - e. Create and send PA Appeal Request (PAAppealRequest);
  - f. Receive PA Appeal Response (PAAppealResponse);
  - g. Create and send PA Cancel Request (PACancelRequest);
  - h. Receive PA Cancel Response (PACancelResponse);
  - i. Receive PA Notification (PANotification)
- The tester verifies the Health IT Module receives and transmits the diagnosis or diagnoses that are the reason for prescription.

## Paragraph (b)(3)(ii)(B)(1-4) Exchange race and ethnicity information

## System Under Test

## Required by December 31, 2027

- The health IT developer enables a user to exchange race and ethnicity information when performing the following prescription-related electronic transactions, if using the standard in § 170.205(b)(2):
  - a. Receive fill status notifications (RxFill).
  - b. Request and respond to change prescriptions (RxChangeRequest, RxChangeResponse).
  - c. Request to cancel prescriptions (CancelRx).
  - d. Request and respond to renew prescriptions (RxRenewalRequest, RxRenewalResponse).

## **Test Lab Verification**

## Required by December 31, 2027

- The tester verifies the Health IT Module enables a user to exchange race and ethnicity information when performing the following transactions:
  - a. Receive fill status notifications (RxFill).
  - b. Request and respond to change prescriptions (RxChangeRequest, RxChangeResponse).
  - c. Request to cancel prescriptions (CancelRx).
  - Request and respond to renew prescriptions (RxRenewalRequest, RxRenewalResponse).



## Paragraph (b)(3)(ii)(C)(1)(i-v) Transmit and receive – diagnosis

## System Under Test

## Expires on January 1, 2028

Complete the following steps using the NCPDP SCRIPT Standard Version 2017071.

- 1. The Health IT Module is able to transmit and receive the reason for the prescription using the <Diagnosis><Primary> or <Secondary> diagnosis elements for the following transactions in accordance with (b)(3)(ii)(C)(1):
  - a. Create new prescriptions (NewRx);
  - b. Request and respond to change prescriptions (RxChangeRequest, RxChangeResponse);
  - c. Request to cancel prescriptions (CancelRx);
  - d. Request and respond to renew prescriptions (RxRenewalRequest, RxRenewalResponse); and
  - e. Receive fill status notifications (RxFill);

## Required by December 31, 2027

Complete the following steps using the NCPDP SCRIPT Standard Version 2023011.

- 1. The Health IT Module is able to transmit and receive the diagnosis or diagnoses that are the reason for the prescription for the following transactions in accordance with (b)(3)(ii)(C)(1):
  - a. Create new prescriptions (NewRx);
  - b. Request and respond to change prescriptions (RxChangeRequest, RxChangeResponse);
  - c. Request to cancel prescriptions (CancelRx);
  - d. Request and respond to renew prescriptions (RxRenewalReguest, RxRenewalResponse);
  - e. Receive fill status notifications (RxFill)

## Test Lab Verification

## Expires on January 1, 2028

Complete the following steps using the NCPDP SCRIPT Standard Version 2017071.

- The tester verifies the Health IT Module sends and receives the reason for the prescription using the <Diagnosis><Primary> or <Secondary> diagnosis elements for all transactions, using the test data specified with the selected test case via the test tool:
  - a. Create new prescriptions (NewRx);
  - b. Request and respond to change prescriptions (RxChangeRequest, RxChangeResponse);
  - c. Request to cancel prescriptions (CancelRx);
  - d. Request and respond to renew prescriptions (RxRenewalRequest, RxRenewalResponse); and
  - e. Receive fill status notifications (RxFill)

## Required by December 31, 2027

Complete the following steps using the NCPDP SCRIPT Standard Version 2023011.

- The tester verifies the Health IT Module sends and receives the diagnosis or diagnoses that are the reason for the prescription for all transactions, using the test data specified with the selected test case via the test tool:
  - a. Create new prescriptions (NewRx);
  - b. Request and respond to change prescriptions (RxChangeRequest, RxChangeResponse);
  - c. Request to cancel prescriptions (CancelRx);
  - d. Request and respond to renew prescriptions (RxRenewalReguest, RxRenewalResponse); and
  - Receive fill status notifications (RxFill)

# Paragraph (b)(3)(ii)(C)(1)(vii) Transmit and receive – diagnosis – electronic prior authorization

# transactions

# System Under Test

## Required by December 31, 2027

1. The Health IT Module is able to receive and transmit the diagnosis or diagnoses that are the reason for prescription for the electronic prior authorization transactions (PAInitiationRequest, PAInitiationResponse, PARequest, PAResponse, PAAppealRequest, PAAppealResponse, PACancelRequest, PACancelResponse, PANotification).

#### **Test Lab Verification**

## Required by December 31, 2027

1. The tester verifies the Health IT Module receives and transmits the diagnosis or diagnoses that are the reason for prescription for the electronic prior authorization transactions (PAInitiationRequest, PAInitiationResponse, PARequest, PAResponse, PAAppealRequest, PAAppealResponse, PACancelRequest, PACancelResponse, PANotification).



# Paragraph (b)(3)(ii)(E) Liquid medications

# System Under Test

## Expires on January 1, 2028

- The Health IT Module is able to prescribe all oral liquid medications in only the metric standard units of milliliter (mL) (i.e., not cubic centimeter (cc) or teaspoon) in accordance with (b)(3)(ii)(E).
- Negative Testing: The health IT developer attempts to prescribe an oral liquid medication using non-metric standard units.

## Required by December 31, 2027

- The Health IT Module is able to prescribe all oral liquid medications in only the metric standard units of milliliter (mL) (i.e., not cubic centimeter (cc) or teaspoon) in accordance with (b)(3)(ii)(E).
- Negative Testing: The health IT developer attempts to prescribe an oral liquid medication using non-metric standard units.

#### **Test Lab Verification**

## Expires on January 1, 2028

- 1. The tester verifies the Health IT Module limits the ability to prescribe all oral liquid medications in metric standard units of milliliter (mL).
- Negative Testing: The tester verifies through visual inspection of the System Under Test that the Health IT Module does not have the ability to prescribe oral liquid medications using non-metric standard units (i.e., cubic centimeter (cc), teaspoon).

## Required by December 31, 2027

- 1. The tester verifies the Health IT Module limits the ability to prescribe all oral liquid medications in metric standard units of milliliter (mL).
- Negative Testing: The tester verifies through visual inspection of the System Under Test that the Health IT Module does not have the ability to prescribe oral liquid medications using non-metric standard units (i.e., cubic centimeter (cc), teaspoon).

## Paragraph (b)(3)(ii)(F) e-Prescriptions

## System Under Test

## Expires on January 1, 2028

- The Health IT Module inserts leading zeroes before the decimal point for all amounts less than one when a prescriber prescribes medication in accordance with (b)(3)(ii)(F).
- The Health IT Module does not allow trailing zeroes after a decimal point when a prescriber prescribes medication.

## Required by December 31, 2027

- 1. The Health IT Module inserts leading zeroes before the decimal point for all amounts less than one when a prescriber prescribes medication in accordance with (b)(3)(ii)(F).
- The Health IT Module does not allow trailing zeroes after a decimal point when a prescriber prescribes medication.

#### **Test Lab Verification**

## Expires on January 1, 2028

- 1. The tester verifies through visual inspection of the System Under Test that leading zeroes are inserted before the decimal point for all amounts less than one when a prescriber prescribes medication.
- The tester verifies through visual inspection of the System Under Test that there are no trailing zeroes after a decimal point when a prescriber prescribes medication.

#### Required by December 31, 2027

- The Health IT Module inserts leading zeroes before the decimal point for all amounts less than one when a prescriber prescribes medication in accordance with (b)(3)(ii)(F).
- The Health IT Module does not allow trailing zeroes after a decimal point when a prescriber prescribes medication.

# **Testing Tool**

Electronic Prescribing (eRx) Testing Tool (tool has not yet been finalized to support new standards in testing)