





§170.315(b)(11) Electronic prescribing				
Testing Components:				
				ONC Supplied Test Data
NPRM Draft				

Please consult the Notice of Proposed Rulemaking (NPRM) entitled: *21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program* for a detailed description of the certification criterion with which these testing steps are associated.

### Revision History

Version #	Description of Change	Version Date
1.0	NPRM Draft	04-05-2019

### Regulation Text

§170.315 (b)(11) *Electronic prescribing*—

- (i) Enable a user to perform all of the following prescription-related electronic transactions in accordance with the standard specified in § 170.205(b)(1) and, at a minimum, the version of the standard specified in § 170.207(d)(3) as follows:
  - (A) Ask mailbox (GetMessage).
  - (B) Relay acceptance of transaction (Status).
  - (C) Error response (Error).
  - (D) Create new prescriptions (NewRx, NewRxRequest, NewRxResponseDenied).
  - (E) Change prescriptions (RxChangeRequest, RxChangeResponse).
  - (F) Renew prescriptions (RxRenewalRequest, RxRenewalResponse).
  - (G) Resupply (Resupply).
  - (H) Return receipt (Verify)
  - (I) Cancel prescriptions (CancelRx, CancelRxResponse).
  - (J) Receive fill status notifications (RxFill, RxFillIndicatorChange).
  - (K) Drug administration (DrugAdministration).

- (L) Transfer (RxTransferRequest, RxTransferResponse, RxTransferConfirm).
- (M) Recertify (Recertification).
- (N) Request and receive medication history (RxHistoryRequest, RxHistoryResponse).
- (O) Complete Risk Evaluation and Mitigation Strategy transactions (REMSInitiationRequest, REMSInitiationResponse, REMSRequest, and REMSResponse).
- (ii) For each transaction listed in paragraph (b)(11)(i) of this section, the technology must be able to receive and transmit the reason for the prescription using the <Diagnosis><Primary> or <Secondary> elements.
- (iii) *Optional*. For each transaction listed in paragraph (b)(11)(i) of this section, the technology must be able to receive and transmit the reason for the prescription using the <IndicationForUse> element, and be consistent with the ICDs sent in the diagnosis element(s).
- (iv) Limit a user's ability to prescribe all oral liquid medications in only metric standard units of mL (*i.e.*, not cc).
- (v) 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)(11)(i)

§ 170.205(b)(1) [National Council for Prescription Drug Programs \(NCPDP\), Script Standard Implementation Guide, Version 2017071](#)

§ 170.207(d)(3) [RxNorm, September 8, 2015 Full Release Update](#)

## Required Tests

Paragraph (b)(11)(i)(A)

System Under Test	Test Lab Verification
The user tests Ask Mailbox (b)(11)(i)(A) transaction (GetMessage).	The tester verifies that the Health IT Module sends and receives the following transaction and completes ALL required test tool interaction steps and verifies the validation reports for the following required transaction: <ul style="list-style-type: none"> <li>• GetMessage (see Implementation Guide)</li> </ul>

Paragraphs (b)(11)(i)(B), (C), (D), (E), (F), (H), (I), (J)

System Under Test	Test Lab Verification
<ol style="list-style-type: none"> <li>1. The user tests (b)(11)(i)(D) create new prescriptions (NewRx, NewRxResponseDenied), (b)(3)(i)(E) change prescriptions (RxChangeRequest, RxChangeResponse), and (b)(11)(i)(J) fill status notifications (RxFill, RxFillIndicatorChange).</li> <li>2. The user tests (b)(3)(i)(D) create new prescription (NewRx) and (b)(11)(i)(I) cancel prescription transactions (CancelRx, CancelRxResponse).</li> <li>3. The user tests (b)(11)(i)(D) create new prescription (NewRx) and (b)(11)(i)(F) renewal prescription transactions (RxRenewalRequest, RxRenewalResponse).</li> <li>4. The user tests (b)(11)(i)(B) Status message.</li> <li>5. The user tests (b)(11)(i)(C) Error message.</li> <li>6. The user tests (b)(11)(i)(H) Verify message.</li> </ol>	<ol style="list-style-type: none"> <li>1. The tester verifies that 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 in the scenario:               <ul style="list-style-type: none"> <li>○ Create and send New Prescription (NewRx);</li> <li>○ Create and send a deny response to NewRxRequest (NewRxResponseDenied);</li> <li>○ Receive Change Request (RxChangeRequest);</li> <li>○ Create and send Change Response (RxChangeResponse);</li> <li>○ Receive Fill Status Notification (RxFill); and</li> <li>○ Send RxFill change (RxFillIndicatorChange).</li> </ul> </li> <li>2. The tester verifies that 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:               <ul style="list-style-type: none"> <li>○ Create and send New Prescription (NewRx);</li> <li>○ Receive New Rx Request (NewRxRequest) and send NewRxResponseDenied;</li> <li>○ Send Cancel Request (CancelRx); and</li> <li>○ Receive Cancel Response (CancelRxResponse).</li> </ul> </li> <li>3. The tester verifies that 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:               <ul style="list-style-type: none"> <li>○ Create and send New Prescription (NewRx);</li> <li>○ Receive Renewal Request (RxRenewalRequest); and</li> <li>○ Create and send Renewal Response (RxRenewalResponse).</li> </ul> </li> <li>4. The tester verifies that the Health IT Module supports, as applicable,</li> </ol>

System Under Test	Test Lab Verification
	Status, Error, and Verify messages.

Paragraph (b)(11)(i)(G)

System Under Test	Test Lab Verification
The user tests Resupply (b)(11)(i)(G) transaction (Resupply).	<ol style="list-style-type: none"> <li>1. The tester verifies that the Health IT Module sends and receives the following transaction and completes ALL required test tool interaction steps and verifies the validation reports for the following required transactions: <ul style="list-style-type: none"> <li>○ Resupply.</li> </ul> </li> <li>2. The tester verifies that the Health IT Module supports, as applicable, Status, Error, and Verify messages.</li> </ol>

Paragraph (b)(11)(i)(K)

System Under Test	Test Lab Verification
The user tests DrugAdministration (b)(11)(i)(K) transaction (DrugAdministration).	<ol style="list-style-type: none"> <li>1. The tester verifies that the Health IT Module sends and receives the following transaction and completes ALL required test tool interaction steps and verifies the validation reports for the following required transaction: <ul style="list-style-type: none"> <li>○ DrugAdministration.</li> </ul> </li> <li>2. The tester verifies that the Health IT Module supports, as applicable, Status, Error, and Verify messages.</li> </ol>

Paragraph (b)(11)(i)(L)

System Under Test	Test Lab Verification
The user tests Transfer (b)(11)(i)(L) transactions (Transfer). <ul style="list-style-type: none"> <li>• RxTransferRequest</li> <li>• RxTransferResponse</li> <li>• RxTransferConfirm</li> </ul>	<ol style="list-style-type: none"> <li>1. The tester verifies that 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:</li> </ol>

System Under Test	Test Lab Verification
	<ul style="list-style-type: none"> <li>○ RxTransferRequest;</li> <li>○ RxTransferResponse; and</li> <li>○ RxTransferConfirm.</li> </ul> <p>2. The tester verifies that the Health IT Module supports, as applicable, Status, Error, and Verify messages.</p>

Paragraph (b)(11)(i)(M)

System Under Test	Test Lab Verification
<p>The user tests Recertify (b)(11)(i)(M) transaction (Recertification).</p>	<p>1. The tester verifies that the Health IT Module sends and receives the following transaction and completes ALL required test tool interaction steps and verifies the validation reports for the following required transaction:</p> <ul style="list-style-type: none"> <li>○ Recertification.</li> </ul> <p>2. The tester verifies that the Health IT Module supports, as applicable, Status, Error and Verify messages.</p>

Paragraph (b)(11)(i)(N)

System Under Test	Test Lab Verification
<p>The user tests medication history (b)(11)(i)(N) prescription transactions (RxHistoryRequest, RxHistoryResponse):</p> <ul style="list-style-type: none"> <li>• Single response;</li> <li>• No information available; and</li> <li>• Response indicating more medication history is available.</li> </ul>	<p>1. The tester verifies that 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 in the scenario:</p> <ul style="list-style-type: none"> <li>○ Send Medication History Request (RxHistoryRequest); and</li> <li>○ Receive Medication History Response (RxHistoryResponse).</li> </ul> <p>2. The tester verifies that the Health IT Module supports, as applicable, Status, Error, and Verify messages.</p>

Paragraph (b)(3)(i)(O)

System Under Test	Test Lab Verification
<p>The user tests REMS (b)(11)(i)(O) transactions (REMSInitiationRequest, REMSInitiationResponse, REMSRequest, REMSResponse).</p> <ul style="list-style-type: none"> <li>• For a standard prescription with questions, either approved or closed response.</li> <li>• For a standard prescription with no questions, either approved or closed response.</li> </ul>	<ol style="list-style-type: none"> <li>1. The tester verifies that 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: <ul style="list-style-type: none"> <li>○ REMS Initiation Request (REMSInitiationRequest);</li> <li>○ REMS Initiation Response (REMSInitiationResponse);</li> <li>○ REMS Request (REMSRequest); and</li> <li>○ REMS Response (REMSResponse).</li> </ul> </li> <li>2. The tester verifies that the Health IT Module supports, as applicable, Status, Error, and Verify messages.</li> </ol>

Paragraph (b)(11)(ii)

System Under Test	Test Lab Verification
<p>The Health IT Module is able to transmit and receive the reason for the prescription using the &lt;Diagnosis&gt;&lt;Primary&gt; or &lt;Secondary&gt;diagnosis elements for all transactions:</p> <ul style="list-style-type: none"> <li>• Create new prescriptions (NewRx);</li> <li>• Change prescriptions (RxChangeRequest, RxChangeResponse); <ul style="list-style-type: none"> <li>○ The pharmacy requests authorization to dispense a generic when the medication prescribed was “dispense as written”</li> <li>○ The pharmacy requests authorization to dispense a different medication in the same therapeutic class</li> <li>○ The pharmacy requests a change of medication due to a patient allergy</li> <li>○ The pharmacy requests the prescriber obtain prior authorization for the prescribed medication</li> <li>○ The pharmacy requests clarification of a prescription that appears to contain a dosing error</li> </ul> </li> </ul>	<p>The tester verifies that the Health IT Module sends and receives the reason for the prescription using the &lt;Diagnosis&gt;&lt;Primary&gt; or &lt;Secondary&gt; diagnosis elements for all transactions, using the test data specified with the selected test case via the test tool:</p> <ul style="list-style-type: none"> <li>• Create new prescriptions (NewRx);</li> <li>• Change prescriptions (RxChangeRequest, RxChangeResponse);</li> <li>• Cancel prescriptions (CancelRx);</li> <li>• Renew prescriptions (RxRenewalRequest, RxRenewalResponse);</li> <li>• Receive fill status notifications (RxFill); and</li> <li>• Receive medication history information (RxHistoryResponse).</li> </ul>

System Under Test	Test Lab Verification
<ul style="list-style-type: none"> <li>• Cancel prescriptions (CancelRx);               <ul style="list-style-type: none"> <li>○ Cancel before any product is dispensed</li> <li>○ Remaining refills canceled</li> <li>○ Current regimen canceled but no refills remaining</li> <li>○ Prescription has been transferred to a different pharmacy</li> </ul> </li> <li>• Renew prescriptions (RxRenewalRequest, RxRenewalResponse);               <ul style="list-style-type: none"> <li>○ Prescriber authorizes number of refills requested</li> <li>○ Prescriber authorizes a different number of refills than requested (approve with changes)</li> <li>○ Prescriber denies the request and sends a replacement NewRx</li> <li>○ Prescriber denies the request</li> <li>○ Pharmacy does not specify number of refills but prescriber authorizes X number of refills.</li> </ul> </li> <li>• Receive fill status notifications (RxFill)</li> <li>• Send fill status indicator change (RxFillIndicatorChange)               <ul style="list-style-type: none"> <li>○ Request fill status notifications only for certain medications for a given patient</li> </ul> </li> <li>• Receive medication history information (RxHistoryResponse).               <ul style="list-style-type: none"> <li>○ Single response</li> </ul> </li> </ul>	

Paragraph (b)(11)(iii) *Optional*

System Under Test	Test Lab Verification
<p>The Health IT Module transmits and receives the reason for the prescription using the &lt;IndicationForUse&gt; element and it is consistent with the diagnoses sent in the diagnosis element(s) for all transactions.</p>	<p>The tester verifies that the Health IT Module sends and receives the reason for the prescription using the &lt;IndicationForUse&gt; element and it is consistent with the diagnoses sent in the diagnosis element(s) for all transactions using the test data specified with the selected test case via the test tool.</p>

Paragraph (b)(11)(iv)

System Under Test	Test Lab Verification
<ol style="list-style-type: none"> <li>1. The user is able to prescribe all oral liquid medications in only the metric standard, i.e. milliliter (mL).</li> <li>2. Negative Testing: The user attempts to prescribe an oral liquid medication using non-metric standard units.</li> </ol>	<ol style="list-style-type: none"> <li>1. The tester verifies that users are able to prescribe all oral liquid medications in only the metric standard, i.e. milliliter (mL).</li> <li>2. Negative Testing: The tester verifies through visual inspection of the system under test that users are not able to prescribe oral liquid medications using non-metric standard units, i.e. cc, teaspoon.</li> </ol>

Paragraph (b)(11)(v)

System Under Test	Test Lab Verification
<ol style="list-style-type: none"> <li>1. The Health IT Module inserts leading zeroes before the decimal point for all amounts less than one when a user prescribes medication.</li> <li>2. The Health IT Module does not allow trailing zeroes after a decimal point when a user prescribes medication.</li> </ol>	<ol style="list-style-type: none"> <li>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 user prescribes medication.</li> <li>2. The tester verifies through visual inspection of the system under test that there are no trailing zeroes after a decimal point when a user prescribes medication.</li> </ol>

## Testing tab

### Testing Tool

[NCPDP Electronic Prescribing \(eRx\)](#)

### Test Tool Data

Criterion Subparagraph	Test Data
(b)(11)	Refer to <a href="#">NCPDP Electronic Prescribing (eRx)</a>