

Mapping of ONC § 170.315(f)(1) Transmission to immunization registries NIST Test Tool to the CDC Immunization Related Requirements Test Plan (CNI) v5.1

March 28, 2017

Required Tests

(f)(1) Transmission to immunization registries

ONC 2015 Requirement	CDC Immunization Related Requirement Mapping
<p>(i) Create immunization information for electronic transmission in accordance with:</p> <p>(A) The standard and applicable implementation specifications specified in § 170.205(e)(4);</p> <p>(B) At a minimum, the version of the standard specified in § 170.207(e)(3) for historical vaccines; and</p> <p>(C) At a minimum, the version of the standard specified in § 170.207(e)(4) for administered vaccines.</p>	<p>Transmit Standard Patient Immunization History Report: The EHR or other clinical software system directly or indirectly through an intermediary creates and transmits a report of a patient's immunization history to public health immunization registries.</p>
<p>Standard(s): §170.205(e)(4) - HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.5, October 2014; and HL7 Version 2.5.1 Implementation Guide for Immunization Messaging (Release 1.5)—Addendum, July 2015 (incorporated by reference in § 170.299)</p>	<p>All products evaluated provide an HL7 2.5.1 patient immunization report to the immunization registry. Vendors should take care to avoid conformance errors with respect to HL7 Implementation Guide for Immunization Messaging version 1.4 (used for Meaningful Use Stage 2) and the newer HL7 version 1.5.</p>
<p>§170.207(e)(3) - HL7 Standard Code Set CVX—Vaccines Administered, updates through August 17, 2015;</p>	<p>All messages are evaluated to verify that CVX is used for historical vaccinations.</p>
<p>§170.207(e)(4) - National Drug Code Directory— Vaccine Codes, updates through August 17, 2015;</p>	<p>All messages are evaluated to verify that NDC is used for new vaccinations.</p>

<p>ONC Test Tools and Test Data :</p> <p>NIST HL7 v2 Immunization Test Suite</p>	<p>CNI Test Tool and Test Data</p> <p>TestPlan: CDC Immunization Related Requirements Test Plan (CNI) v5.1</p> <p>The CNI Test Plan uses the same underlying NIST test tool used for the ONC 2015 Immunization Test Plan, but CNI has generated a test plan and supporting test data that tests for a robust set of EMR Functional Requirements. Included in these requirements is the ability of the EMR to request, access, and display the Immunization History and Forecast from an</p>
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<p>Immunization Registry using the HL7 v2.5.1 Implementation Guide for Immunization Messaging, Release 1.5, and the requirement to create and transmit immunization information to the Immunization Registry using this same standard.</p> <p>The CNI Test Plan uses Context-based testing for these transactions using the NIST Immunization Test Suite tool and the CNI generated test data.</p>
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[Normative Test Processing Document](#)

Criteria ¶

System Under Test

Test Lab Verification

CNI Test Conformance Equivalent

<p>(i) (A)</p>	<p>1. The Health IT module creates immunization content using ONC Supplied Test data for each of the test cases from the Administration Test Group under the ONC 2015 Test Plan on the Context-Based Validation Tab of the NIST HL7 v2 Immunization Test Suite. All test cases are required. Input may be performed using manual or automated processes.</p>	<p>1. The tester verifies that the Health IT module creates the source immunization content correctly through Visual Inspection of the system under test using the test data specification of the Send Administration Message Test Step associated with the selected test case.</p>	<p>The test case immunization content is established within 5 Test Case Groups representing 4 test patients.</p> <p>The Initial Data Load Test Case Group requires the Health IT module to enter detailed demographic information for each of four patients: Juana Marian Vazquez, Juan Marcel Marina, and infant twins Juana Mariela Gonzales, and Juana Maria Gonzales. Some historical vaccines are entered during the initial data load for Juana Mariana Vazquez:</p> <ul style="list-style-type: none"> • TestCaseGroup: Initial Data Load <p>There is a Test Case Group for each patient 'Visit':</p> <ul style="list-style-type: none"> • TestCaseGroup: Juana Mariana Vazquez Visit • TestCaseGroup: Juan Marcel Marina Visit • TestCaseGroup: Juana Mariela Gonzales Morales Visit • TestCaseGroup: Juana Maria Gonzales Morales Visit <p>Under each patient visit Test Case Group, the remainder of the historical vaccines are imported during the Query Registry Test Case:</p> <ul style="list-style-type: none"> • TestCase: Query the Registry for Juana Mariana Vazquez • TestCase: Query the Registry for Juan Marcel Marina • TestCase: Query the Registry for Juana Mariela Gonzales Morales • TestCase: Query the Registry for Juana Maria Gonzales Morales. <p>New vaccinations are recorded as part of the Enter Orders and Immunizations Test Case:</p> <ul style="list-style-type: none"> • TestCase: Juana Mariana Vazquez, Enter Orders and Immunizations • TestCase: Juan Marcel Marina, Enter Orders and Immunizations • TestCase: Juana Mariela Gonzales Morales, Enter Orders and Immunizations • TestCase: Juana Maria Gonzales Morales, Enter Orders and Immunizations <p>No new immunizations are administered for Juana Mariela Gonzales Morales, but immunization deferrals are entered as part of this test case.</p>
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Criteria ¶	System Under Test	Test Lab Verification	CNI Test Conformance Equivalent
	<p>2. For each test case, the Health IT module generates the indicated HL7 v2.5.1 Z22 VXU immunization information message and</p>	<p>2. The tester imports the immunization message into the test tool for validation and uses the Validation Report produced by the test tool to verify that the Health IT module passes without error to confirm that the immunization information messages are conformant to the HL7 v2.5.1 Z22 VXU Unsolicited Vaccine Update message of the §170.205(e)(4) HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.5, October 2014; and HL7 Version 2.5.1 Implementation Guide for Immunization Messaging (Release 1.5)—Addendum, July 2015</p>	<p>The CNI Test Plan requires the Health IT Module to generate a specified HL7 v2.5.1 Z22 VXU for each of the 4 test patients. This is tested within each patient visit Test Case Group as part of the Transmit Immunization Report Test Case. These test cases include Test Steps for transmitting the vaccinations to the Immunization Registry. Content for Juana Mariana Vazquez supports testing for vaccine update functionality, and content for Juan Marcel Marina supports testing for vaccine delete functionality. Content for Juana Mariela Gonzales Morales tests for submission of vaccine deferrals to the registry. Juana Maria Gonzales Morales transmissions are used to trigger error handling responses:</p> <ul style="list-style-type: none"> • TestCase: Juana Mariana Vazquez Transmit Immunization Report <ul style="list-style-type: none"> ○ TestStep: Transmit the immunization report to the Immunization Registry ○ TestStep: Transmit the updated vaccination report with adverse reaction to the registry • TestCase: Juan Marcel Marina Transmit Immunization Report <ul style="list-style-type: none"> ○ TestStep: Transmit the Immunization Report for Juan Marcel Marina ○ TestStep: Transmit Delete from Bad Lot • TestCase: Juana Mariela Gonzales Morales Transmit Immunization Report <ul style="list-style-type: none"> ○ TestStep: Transmit the Immunization Report for Juana Mariela Gonzales Morales <p>Juana Maria Gonzales Morales transmissions are used to trigger error handling responses:</p> <ul style="list-style-type: none"> • TestCase: Juana Maria Gonzales Morales Transmit Immunization Report - Error Handling <ul style="list-style-type: none"> ○ TestStep: Transmit the Immunization Report for Juana Maria Gonzales Morales - Fatal Error Handling ○ TestStep: Transmit the Immunization Report for Juana Maria Gonzales Morales - warning handling ○ TestStep: Transmit the Immunization Report for Juana Maria Gonzales Morales - Multiple warning handling

Criteria ¶	System Under Test	Test Lab Verification	CNI Test Conformance Equivalent
	<p>3. consumes the associated acknowledgement message using the provided test data and according to the §170.205(e)(4) HL7 v2.5.1 Immunization Guide.</p>	<p>3. The tester verifies that the Health IT module is able to receive and process a Return an Acknowledgement Z23 message (in response to a "Send Unsolicited Immunization Update Using a VXU" Z22 message) through Visual Inspection of the system under test using the Juror Document of the Consume Acknowledgement Test Step associated with the selected test cases.</p>	<p>For each of the VXU transmissions in the CNI test plan, there is a requirement to consume the Acknowledgement Z23 response.</p> <ul style="list-style-type: none"> • TestCase: Juana Mariana Vazquez Transmit Immunization Report <ul style="list-style-type: none"> ○ TestStep: Receive ACK Z23 from Immunization Registry ○ TestStep: Receive ACK Z23 from Immunization Registry for Updated Transmission • TestCase: Juan Marcel Marina Transmit Immunization Report (2 instances) <ul style="list-style-type: none"> ○ TestStep: Receive ACK Z23 from Immunization Registry • TestCase: Juana Mariela Gonzales Morales Transmit Immunization Report <ul style="list-style-type: none"> ○ TestStep: Receive ACK Z23 from Immunization Registry <p>For patient Juana Maria Gonzalez, the Acknowledgement testing also includes error handling.</p> <ul style="list-style-type: none"> • TestCase: Juana Maria Gonzales Morales Transmit Immunization Report - Error Handling <ul style="list-style-type: none"> ○ TestStep: Receive ACK Z23 Fatal Error - CVX Code ○ TestStep: Receive ACK Z23 Warning - Invalid Value ○ TestStep: Receive ACK Z23 Multiple Warnings

Criteria ¶	System Under Test	Test Lab Verification	CNI Test Conformance Equivalent
(i) B	2. The vaccines in the historical vaccine records are represented using §170.207(e)(3) CVX.	4. The tester uses Test Tool Validation Report from 1(i)(B) test cases and visual inspection of both the Test Tool Validation Report and the Health IT configuration file to verify the historical vaccine records are represented using §170.207(e)(3) CVX.	<p>All 4 test patients include transmission of historical vaccine records using CVX.</p> <p>TestCaseGroup: Juana Mariana Vazquez Visit</p> <ul style="list-style-type: none"> • TestCase: Juana Mariana Vazquez Transmit Immunization Report <ul style="list-style-type: none"> ○ TestStep: Transmit the immunization report to the Immunization Registry ○ TestStep: Transmit the updated vaccination report with adverse reaction to the registry <p>TestCaseGroup: Juan Marcel Marina Visit</p> <ul style="list-style-type: none"> • TestCase: Juan Marcel Marina Transmit Immunization Report <ul style="list-style-type: none"> ○ TestStep: Transmit the Immunization Report for Juan Marcel Marina ○ TestStep: Transmit Delete from Bad Lot <p>TestCaseGroup: Juana Mariela Gonzales Morales Visit</p> <ul style="list-style-type: none"> • TestCase: Juana Mariela Gonzales Morales Transmit Immunization Report <ul style="list-style-type: none"> ○ TestStep: Transmit the immunization report to the Immunization Registry <p>TestCaseGroup: Juana Maria Gonzales Morales Visit</p> <ul style="list-style-type: none"> • TestCase: Juana Maria Gonzales Morales Transmit Immunization Report - Error Handling <ul style="list-style-type: none"> ○ TestStep: Transmit the Immunization Report for Juana Maria Gonzales Morales - Fatal Error Handling ○ TestStep: Transmit the Immunization Report for Juana Maria Gonzales Morales - warning handling ○ TestStep: Transmit the Immunization Report for Juana Maria Gonzales Morales - Multiple warning handling

Criteria ¶	System Under Test	Test Lab Verification	CNI Test Conformance Equivalent
(i) C	3. The vaccines in the administered vaccine records are represented using §170.207(e)(4) National Drug Code Directory– Vaccine Codes.	5. The tester uses Test Tool Validation Report from 1(i)(B) test cases and visual inspection of both the Test Tool Validation Report and the Health IT configuration file to verify administered vaccine records are represented using §170.207(e)(4) National Drug Code Directory– Vaccine Codes.	<p>3 of the 4 test patients include new vaccine administrations represented using NDC vaccine codes:</p> <p>TestCaseGroup: Juana Mariana Vazquez Visit</p> <ul style="list-style-type: none"> • TestCase: Juana Mariana Vazquez Transmit Immunization Report <ul style="list-style-type: none"> ○ TestStep: Transmit the immunization report to the Immunization Registry ○ TestStep: Transmit the updated vaccination report with adverse reaction to the registry <p>TestCaseGroup: Juan Marcel Marina Visit</p> <ul style="list-style-type: none"> • TestCase: Juan Marcel Marina Transmit Immunization Report <ul style="list-style-type: none"> ○ TestStep: Transmit the Immunization Report for Juan Marcel Marina ○ TestStep: Transmit Delete from Bad Lot <p>TestCaseGroup: Juana Maria Gonzales Morales Visit</p> <ul style="list-style-type: none"> • TestCase: Juana Maria Gonzales Morales Transmit Immunization Report - Error Handling <ul style="list-style-type: none"> ○ TestStep: Transmit the Immunization Report for Juana Maria Gonzales Morales - Fatal Error Handling ○ TestStep: Transmit the Immunization Report for Juana Maria Gonzales Morales - warning handling ○ TestStep: Transmit the Immunization Report for Juana Maria Gonzales Morales - Multiple warning handling

ONC 2015 Requirement	CDC Immunization Related Requirement Mapping
(ii) Enable a user to request, access, and display a patient’s evaluated immunization history and the immunization forecast from an immunization registry in accordance with the standard at § 170.205(e)(4).	The CDC Immunization Related Requirements exceed this aspect of the ONC 2015 Requirement as it also requires reconciliation in addition to access and display of the immunization history returned from the immunization registry:

	<p>Real Time Request/Receive Patient Immunization History: The system sends a request to the public health immunization registry “on demand” (e.g., those without scheduled appointments). The request includes the identifying information the immunization registry needs to match each patient with those in the registry including, if present, the mother’s maiden name, a multiple birth indicator, and the birth order. The request also is sent in a pre-determined format the registry can read and interpret (Query Response Grammar (RSP/QBP) – HL7 version 2.5.1 Implementation Guide for Immunization Messaging Release 1.5).</p> <p>Compare Public Health Immunization Registry (IIS) Immunization History to EHR Immunization History: The public health immunization registry has returned the requested immunization history for a patient. The EHR is able to display the immunization history received from the registry as well as the immunization history already present in the EHR so that a user can compare them. The EHR provides a way for the provider to view both histories, determine what is different (if anything), and update the existing EHR immunization history with new information from the public health registry if he or she chooses to do so. The system must store the new information as structured data as part of the patient’s local immunization history and include the time of the update and the source of the new information.</p> <p>Review Patient Immunization History: To assist with the ordering process, the EHR or other clinical software system allows a user to specify standard views of patient immunization information for each vaccine dose administration, including patient-specific data (e.g., age on dates of administration, etc.).</p> <p>View Immunization Forecast: The system provides a view of the immunization forecast provided by the public health immunization registry (IIS). The display includes the forecast from the registry and includes recommended vaccination dates, minimum (earliest) date, ideal date, and maximum (latest) date for each vaccine included in the forecast.</p>
<p>Standards: §170.205(e)(4) - HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.5, October 2014, and HL7 Version 2.5.1 Implementation Guide for Immunization Messaging (Release 1.5)—Addendum; available at: http://www.cdc.gov/vaccines/programs/iis/technical-guidance/downloads/hl7guide-1-5-2014-11.pdf</p>	<p>Query Response Grammar (RSP) – HL7 version 2.5.1 Implementation Guide for Immunization Messaging Release 1.5)</p>

Criteria ¶	System Under Test	Test Lab Verification	CNI Test Conformance Equivalent
(ii)	<p>1. The Health IT module creates immunization query content using ONC Supplied Test data for each of the test cases from the Evaluate History and Forecast Test Group under the ONC 2015 Test Plan on the Context-Based Validation Tab of the NIST HL7 v2 Immunization Test Suite. All test cases are required. Input may be performed using manual or automated processes.</p>	<p>1. The tester verifies that the Health IT module creates the source immunization query content correctly through Visual Inspection of the system under test using the test data specification of the Send Query Test Step associated with the selected test case.</p>	<p>The test case query content is established in the Initial Data Load Test Case Group. .</p> <p>The Initial Data Load Test Case Group requires the Health IT module to enter detailed demographic information for each of four patients: Juana Marian Vazquez, Juan Marcel Marina, and infant twins Juana Mariela Gonzales, and Juana Maria Gonzales:</p> <ul style="list-style-type: none"> • TestCaseGroup: Initial Data Load

Criteria ¶	System Under Test	Test Lab Verification	CNI Test Conformance Equivalent
	<p>2. For each test case, the Health IT module generates the indicated HL7 v2.5.1 Z44 QBP query message.</p>	<p>2. The tester imports the query message into the test tool for validation and uses the Validation Report produced by the test tool to verify that the Health IT module passes without error to confirm that the query message is conformant to the HL7 v2.5.1 Z44 QBP Query for Evaluated History and Forecast message profile of the §170.205(e)(4) HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.5, October 2014; and HL7 Version 2.5.1 Implementation Guide for Immunization Messaging (Release 1.5)—Addendum, July 2015.</p>	<p>The CNI Test Plan requires the Health IT Module to generate a specified HL7 v2.5.1 Z44 QBP query message for each of the 4 test patients. This is tested within each patient visit Test Case Group as part of the Query Registry Test Case. These test cases include Test Steps for querying the Immunization Registry for vaccine history and forecast, which is validated using the context-based testing specific to this test data in the NIST Immunization Test Suite:</p> <ul style="list-style-type: none"> • TestCase: Query the Registry for Juana Mariana Vazquez <ul style="list-style-type: none"> ○ TestStep: Query Registry for vaccination history and forecast for Juana Mariana Vazquez • TestCase: Query the Registry for Juan Marcel Marina <ul style="list-style-type: none"> ○ TestStep: Query Registry for vaccination history and forecast for Juan Marcel Marina • TestCase: Query the Registry for Juana Mariela Gonzales Morales <ul style="list-style-type: none"> ○ TestStep: Query Registry for vaccination history and forecast for Juana Mariela Gonzales Morales <p>Juana Maria Gonzales Morales queries are used to trigger error handling responses:</p> <ul style="list-style-type: none"> • TestCase: Query the Registry for Juana Maria Gonzales Morales. <ul style="list-style-type: none"> ○ TestStep: Query Registry for vaccination history and forecast too many matches found response ○ TestStep: Query Registry for vaccination history and forecast no persons found response ○ TestStep: Query Registry for vaccination history and forecast for Juana Maria Gonzales Morales

Criteria ¶	System Under Test	Test Lab Verification	CNI Test Conformance Equivalent
	<p>3. The Health IT module electronically receives HL7 evaluated immunization history and forecast HL7 v2.5.1 Z42 RSP or HL7 v2.5.1 Z33 RSP response messages returned for each of the test cases from the Evaluated History and Forecast Test Group under</p>	<p>3. The Tester verifies that the Health IT module can process each of the following Test Case responses through Visual Inspection of the system under test using the Juror Document of the second Test Step (the Return response) associated with the selected test case from the NIST HL7 v2 Immunization Test Suite:</p>	<p>The CNI test plan uses the NIST Immunization Test Suite providing a Juror Document for each the test patients to evaluate that the SUT correctly receives, accesses, and views the response to the forecast HL7 v2.5.1 Z42 RSP or HL7 v2.5.1 Z33 RSP request for immunization history and forecast.</p>

	<p>the ONC 2015 Test Plan on the Context-Based Validation Tab of the NIST HL7 v2 Immunization Test Suite, which is in the Return response to the HL7 v2.5.1 Z44 QBP query message initiated in 1(ii) Request above, formatted according to the §170.205(e)(4) HL7 v2.5.1 Immunization Guide. The Health IT Module displays the response to the user.</p>	<p>a. The Tester verifies that the Health IT module is able to display a response that contains evaluated history and forecast information for the test patient, through Visual Inspection of the system under test using the Juror Document of the Return response Test Step associated with the selected test case.</p>	<p>The CNI test plan includes separate test steps to view the vaccine history and to review the vaccine forecast returned from the registry in order to test conformance to these separate requirements. Patient Juana Mariana Vazquez also includes testing for comparison and reconciliation of the vaccine history returned from the registry with vaccines in the EMR. This test patient also includes a post-reconciliation vaccine forecast which is allowed to be EMR generated. All patients include a test step to view and import of the historical vaccines returned from the registry.</p> <p>TestCaseGroup: Juana Mariana Vazquez Visit</p> <ul style="list-style-type: none"> • TestCase: Query the Registry for Juana Mariana Vazquez <ul style="list-style-type: none"> ○ TestStep: View and Compare response to request for vaccination history for Juana Mariana Vazquez ○ View the vaccination forecast for Juana Mariana Vazquez ○ TestStep: Reconcile and import vaccinations from Evaluated History and Forecast for Juana Mariana Vazquez ○ TestStep: View the updated vaccination forecast for Juana Mariana Vazquez <p>TestCaseGroup: Juan Marcel Marina Visit</p> <ul style="list-style-type: none"> • TestCase: Query the Registry for Juan Marcel Marina <ul style="list-style-type: none"> ○ TestStep: View and import response to request for vaccination history for Juan Marcel Marina ○ TestStep: View the vaccination forecast for Juan Marcel Marina <p>TestCaseGroup: Juana Mariela Gonzales Morales Visit</p> <ul style="list-style-type: none"> • TestCase: Query the Registry for Juana Mariela Gonzales Morales <ul style="list-style-type: none"> ○ TestStep: View and import response to request for vaccination history for Juana Mariela Gonzales Morales ○ TestStep: View the vaccination forecast for Juana Mariela Gonzales Morales <p>TestCaseGroup: Juana Maria Gonzales Morales Visit</p> <ul style="list-style-type: none"> • TestCase: Query the Registry for Juana Maria Gonzales Morales.
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Criteria ¶	System Under Test	Test Lab Verification	CNI Test Conformance Equivalent
			<ul style="list-style-type: none"> ○ TestStep: View and import response to request for vaccination history for Juana Maria Gonzales Morales ○ TestStep: View the vaccination forecast for Juana Maria Gonzales Morales
		<p>b. The tester verifies that the Health IT module can process a response with a notification indicating that the query for the Evaluated Immunization History and Immunization Forecast is complete but no matching records were found for the person in the query, through Visual Inspection of the system under test using the Juror Document of the Return response Test Step associated with the selected test case.</p>	<p>TestCaseGroup: Juana Maria Gonzales Morales Visit</p> <ul style="list-style-type: none"> ● TestCase: Query the Registry for Juana Maria Gonzales Morales. <ul style="list-style-type: none"> ○ TestStep: Error Handling - No persons found
		<p>b. The tester verifies that the Health IT module can process a response with a notification indicating that the query for the Evaluated Immunization History and Immunization Forecast is complete but too many matches were found for the patient requested through Visual Inspection of the system under test using the Juror Document of the Return response Test Step associated with the selected test case.</p>	<p>TestCaseGroup: Juana Maria Gonzales Morales Visit</p> <ul style="list-style-type: none"> ● TestCase: Query the Registry for Juana Maria Gonzales Morales. <ul style="list-style-type: none"> ○ TestStep: Error Handling - Too many matches found