

# §170.315(f)(1) Transmission to immunization registries

## 2015 Edition Test Procedure

Version 1.1 Updated on 10-06-2016

### Revision History

Version #	Description of Change	Version Date
1.0	Final Test Procedure	01-20-2016
1.1	Updated NIST Normative Test Process Document link.	10-06-2016

### Regulation Text

#### Regulation Text

§170.315 (f)(1) *Transmission to immunization registries*—

- (i) Create immunization information for electronic transmission in accordance with:
  - (A) The standard and applicable implementation specifications specified in §170.205(e)(4).
  - (B) At a minimum, the version of the standard specified in §170.207(e)(3) for historical vaccines.
  - (C) At a minimum, the version of the standard specified in §170.207(e)(4) for administered vaccines.
- (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).

### Standard(s) Referenced

#### Paragraph (f)(1)(i)

§ 170.205(e)(4) [HL7 2.5.1 Implementation Specifications. 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](#)

§ 170.207(e)(3) [HL7 Standard Code Set CVX— Vaccines Administered, updates through August 17, 2015](#)

§ 170.207(e)(4) [National Drug Code \(NDC\) Directory– Vaccine NDC Linker, updates through August 17, 2015](#)

#### Paragraph (f)(1)(ii)

§ 170.205(e)(4) [HL7 2.5.1 Implementation Specifications](#). [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](#)

Please consult the Final Rule entitled: 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications for a detailed description of the certification criterion with which these testing steps are associated. We also encourage developers to consult the Certification Companion Guide in tandem with the test procedure as they provide clarifications that may be useful for product development and testing.

**Note:** The order in which the test steps are listed reflects the sequence of the certification criterion and does not necessarily prescribe the order in which the test should take place.

## Testing components

				ONC Supplied Test Data
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## Paragraphs (f)(1)(i)

### System Under Test

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.

For each test case, the Health IT Module generates the indicated HL7 v2.5.1 Z22 VXU immunization information message.

For each test case, the Health IT Module consumes the associated acknowledgement message using the provided test data and according to the § 170.205(e)(4) HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.5.

The vaccines in the historical vaccine records are represented using § 170.207(e)(3) HL7 Standard Code Set CVX— Vaccines Administered.

The vaccines in the administered vaccine records are represented using § 170.207(e)(4) National Drug Code (NDC) Directory– Vaccine NDC Linker.

## Test Lab Verification

Using the Normative Test Description section of the Normative Test Process Document:

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.

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) standard.

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.

The tester uses Test Tool Validation Report from (f)(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) standard.

The tester uses Test Tool Validation Report from (f)(1)(i)(C) 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) standard.

## Paragraph (f)(1)(ii)

### System Under Test

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.
2. For each test case, the Health IT Module generates the indicated HL7 v2.5.1 Z44 QBP query message.
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 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 (f)(1)(ii) Request above, formatted according to the § 170.205(e)(4) HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.5. The Health IT Module displays the response to the user.

## Test Lab Verification

Using the Normative Test Description section of the Normative Test Process Document:

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.
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).
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:
  - 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.
  - 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.
  - c. 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.

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