Test Procedure for §170.314(f)(3) Transmission to public health agencies – syndromic surveillance

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(f)(3) Transmission to public health agencies – syndromic surveillance.[3] EHR technology must be able to electronically create syndrome-based public health surveillance information for electronic transmission in accordance with:

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

[3] This test procedure document addresses part (i)(A) of the §170.314(f)(3) criterion and parts (i)(B) and (ii) of the §170.314(f)(3) criterion in separate sections of the document.

(i) Ambulatory setting only.

(A) The standard specified in §170.205(d)(2).

(B) Optional. The standard (and applicable implementation specifications) specified in §170.205(d)(3).

(ii) Inpatient setting only. The standard (and applicable implementation specifications) specified in §170.205(d)(3).

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.

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 transmission to public health agencies – syndromic surveillance certification criterion is discussed:

- "It is our understanding that EPs, EHs, and CAHs will not necessarily be recording, accessing, and capturing separate kinds of "syndromic surveillance" information to facilitate the transmission of syndrome-based public health surveillance information to public health agencies. Rather, they will simply be "passing on" or reporting the information that already exists in their CEHRT to public health agencies."
- "In regard to the commenters assertion that HIE should not be required to be certified, we note that there is no such requirement. However, if an HIE performs a capability for which certification is required and an EP, EH, or CAH uses that capability for MU, then that capability must be certified."
- "We are adopting only the 2.5.1 standard because…public health agencies are rapidly moving to this standard and all stakeholders would benefit from focusing on a single standard for public health surveillance."
- "We believe it is appropriate to specifically adopt this standard and not just the implementation guide that references this standard to provide clarity around the certification requirements for this certification criterion. In particular, the implementation guide is optional for the ambulatory

setting. Therefore, clearly specifying the standard will ensure that EHR technology designed for the ambulatory setting will be certified to the HL7 2.5.1 standard."

- "Several commenters recommended replacing "Inpatient" with "Hospital or urgent care." The commenters asserted that such a change more appropriately reflects the clinical settings that transmit syndromic surveillance data to health departments…While we appreciate the commenters' recommendation, the designation "inpatient" is a general designation that we use to distinguish certification criteria and capabilities that apply to a particular setting for certification. We currently designate only two settings for certification, the inpatient setting and the ambulatory setting without variation. EHs use "inpatient-certified" EHR technology for their inpatient department and emergency departments. For urgent care settings that are not the emergency department, the providers would be non-hospital-based EPs and would require "ambulatory-certified" EHR technology. Therefore, we are retaining the "inpatient" designation."
- "We want to make clear that we do not require EHR technology to be certified to any transport standard, including Direct, to meet this certification criterion. There is no consensus transport standard that states and public health agencies use for the reporting of syndrome-based public health surveillance information. Therefore, we believe that it is appropriate for EHR technology developers to have the flexibility to include in their EHR technology and implement the transport standards that permit EPs, EHs, and CAHs to report in their states and to local public health agencies."

2011 Edition Preamble Language

Per Section III.D of the preamble of the Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, Final Rule (July 28, 2010) where the public health surveillance certification criterion is discussed:

- "…we have, consistent with our rationale in the immunization submission certification criterion, removed our reference to "public health agencies" as the recipient of information. Also, consistent with the certification criterion above, we have replaced the term "transmit" with "submit.""
- "We permit a Complete EHR or EHR Module to be tested and certified to either HL7 2.3.1 or HL7 2.5.1. No other versions will be considered compliant with the adopted standards or certification criterion."

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) where the transmission to public health agencies – syndromic surveillance certification criterion is discussed:

- "We proposed two certification criteria…that were essentially a split of the 2011 Edition EHR certification criterion…(§ 170.302(l))
    - We proposed one certification criterion that focused just on the capabilities to electronically record, change, and access syndrome-based public health surveillance information (data capture) and another that focused on the capability to electronically create syndrome-based public health surveillance information for transmission in accordance with specified standards.
    - We discussed these two proposed certification criteria together in the Proposed Rule for simplicity and to prevent confusion, but noted that we did not consider the certification criterion we proposed to focus on data capture to be a revised certification criterion. Rather, we stated that we believed that the certification criterion would constitute an unchanged certification criterion because all the capabilities included in the criterion were the same as the capabilities included in the corresponding 2011 Edition EHR certification criterion (§ 170.302(l))."
- "Commenters supported our proposed "two certification criteria approach.""

Section of Test Procedure for 170.314(f)(3)(i)(A) – Ambulatory setting

§170.314(f)(3) Transmission to public health agencies – syndromic surveillance. EHR technology must be able to electronically create syndrome-based public health surveillance information for electronic transmission in accordance with:

(i) Ambulatory setting only.

(A) The standard specified in §170.205(d)(2).

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.

The test procedures are developed to be used by the ATLs in certification of EHR technology for ONC. The term 'Tester', when used in the test procedure, refers to a person (such as an ATL employee) acting on behalf of an ATL for certification testing of a Vendor's EHR technology. In addition, an EHR Vendor may use the test procedures to test their own EHR technology in preparation for certification testing by an ATL.

This test evaluates the capability for an EHR technology to electronically generate syndromic surveillance information for electronic transmission to public health agencies using the HL7 2.5.1 standard.

The Vendor supplies the test data for this test procedure.

The test procedure is organized into one section:

- Create—evaluates the capability of the ambulatory EHR technology to electronically generate conformant HL7 2.5.1 messages for syndromic surveillance information
    - Using the Vendor-identified ambulatory EHR technology function(s), the Tester verifies the presence of the Vendor-supplied test data in the EHR, causes the EHR to generate a syndromic surveillance message, and verifies that the message is conformant to the HL7 2.5.1 standard

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:	
(d)(2) *Standard.* HL7 2.5.1 (incorporated by reference in § 170.299).	

NORMATIVE TEST PROCEDURES - AMBULATORY SETTING

Derived Test Requirements

DTR170.314(f)(3)(A) – 1: Electronically Create Syndromic Surveillance Information

DTR170.314(f)(3)(A) – 1: Electronically Create Syndromic Surveillance Information

Required Vendor Information

VE170.314(f)(3)(A) – 1.01: Vendor shall identify an existing patient record in the EHR to be used for this test

VE170.314(f)(3)(A) – 1.02: Vendor shall instantiate the Vendor-supplied syndromic surveillance test data in the EHR for this test

VE170.314(f)(3)(A) – 1.03: Vendor shall identify the ambulatory EHR function(s) that are available to create HL7 2.5.1 conformant syndromic surveillance information messages using the Vendor-supplied test data

Required Test Procedures

TE170.314(f)(3)(A) – 1.01: Using the Vendor-identified ambulatory EHR function(s), the Tester shall select the existing patient record and verify the presence of the Vendor-supplied test data in the EHR

TE170.314(f)(3)(A) – 1.02: Using the Vendor-identified ambulatory EHR function(s) and the Vendor-supplied test data, the Tester shall cause the EHR to generate a syndromic surveillance information message based on the HL7 2.5.1 standard

TE170.314(f)(3)(A) – 1.03: Using the Inspection Test Guide, the Tester shall verify that the syndromic surveillance message is conformant to the HL7 2.5.1 standard and is generated with the appropriate syndromic surveillance information

Inspection Test Guide

IN170.314(f)(3)(A) – 1.01: Using the Vendor-supplied test data and the HL7 2.5.1 standard, the Tester shall verify that the syndromic surveillance message is conformant to the standard, and that the information in the message is accurate and complete. The Tester may utilize an automated test tool or may conduct a visual inspection of the message for the evaluation. The Tester shall evaluate only those items identified as Required in HL7 2.5.1

TEST DATA

The Vendor shall supply the test data for this test procedure.

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 Vendor supplied test data, the Tester shall address the following:

- Vendor-supplied test data shall ensure that the requirements identified in the criterion can be adequately evaluated for conformance.
- Vendor-supplied test data shall strictly focus on meeting the basic capabilities required of an EHR relative to the certification criterion rather than exercising the full breadth/depth of capability that an installed EHR might be expected to support.
- Tester shall record as part of the test documentation the specific Vendor-supplied test data that was utilized for testing.

CONFORMANCE TEST TOOLS

None

Section of Test Procedure for 170.314(f)(3)(i)(B) and (ii) – Inpatient setting and optional ambulatory setting

§170.314(f)(3) Transmission to public health agencies – syndromic surveillance. EHR technology must be able to electronically create syndrome-based public health surveillance information for electronic transmission in accordance with:

(i) Ambulatory setting only.

(B) Optional. The standard (and applicable implementation specifications) specified in §170.205(d)(3).

(ii) Inpatient setting only. The standard (and applicable implementation specifications) specified in §170.205(d)(3).

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.

The test procedures are developed to be used by the ATLs in certification of EHR technology for ONC. The term 'Tester', when used in the test procedure, refers to a person (such as an ATL employee) acting on behalf of an ATL for certification testing of a Vendor's EHR technology. In addition, an EHR Vendor may use the test procedures to test their own EHR technology in preparation for certification testing by an ATL.

This test evaluates the capability for an EHR technology to electronically generate syndromic surveillance information for electronic transmission to public health agencies using the HL7 2.5.1 and the PHIN Messaging Guide for Syndromic Surveillance and Conformance Clarification for EHR Certification of Electronic Syndromic Surveillance, Addendum to PHIN Messaging Guide for Syndromic Surveillance standard. Use of this standard is *optional* for ambulatory EHR technologies.

Note from the Centers for Disease Control and Prevention (CDC): "For the purposes of electronic syndromic surveillance, an ambulatory healthcare setting is understood to be one in which patient encounters always occur on an outpatient basis. Examples include non-hospital based primary care or urgent care settings. On the other hand, inpatient encounters are understood to be hospital-based settings such as emergency departments and hospital care units."

During the process of building the Conformance Test Tool, NIST (National Institute of Standards and Technology) discovered additional errata as well as conformance requirements that were either conflicting or unclear in the named standards documents. The "Conformance Clarification for EHR Certification of Electronic Syndromic Surveillance ADT MESSAGES A01, A03, A04, and A08 HL7 Version 2.5.1 Testing Clarification Document Release 1.1" clarifies these issues and indicates how they are

interpreted in the Test Tool. This document can be accessed via the "Documentation" tab on the Conformance Test Tool.

Three Test Scenarios are listed in the Test Data section for this test procedure, and each Test Scenario has three Test Cases. The test data for the Test Cases are provided in the Test Case PDF documents associated with this test procedure. For the certification test, the Tester shall select one Test Case from **each** of the three Test Scenarios. The total number of test cases an inpatient EHR product will need to pass for certification is three (3). Additional instructions for use of the provided test data are listed in the Normative Test Procedure and Test Data sections of this test procedure document.

If Vendors elect to have their ambulatory EHR products certified to the optional syndromic surveillance messaging standard, such products need only pass **one** of the Test Cases for the Urgent Care Visit Test Scenario. Inpatient EHR products will need to pass **one** Test Case for the Urgent Care Test Scenario as well as **one** Test Case for each of the two Emergency Department Test Scenarios, since the Urgent Care Test Scenario presents a kind of encounter that all certified EHR technologies need to support.

ONC supplies the test data provided for this test procedure.

The test procedure is organized into one section:

- Create—evaluates the capability of the EHR technology to electronically generate conformant HL7 messages for syndromic surveillance information
    - Using the Vendor-identified EHR technology function(s), the Tester inputs the provided syndromic surveillance information encounter test data for the test patient(s) (input can be performed using a manual or automated process)
    - Using the Vendor-identified EHR function(s) and the provided test data, the Tester causes the EHR to generate the indicated syndromic surveillance information message using the HL7 2.5.1 and the PHIN Messaging Guide for Syndromic Surveillance and Conformance Clarification for EHR Certification of Electronic Syndromic Surveillance, Addendum to PHIN Messaging Guide for Syndromic Surveillance standard
    - Using the Vendor-identified EHR function(s), the Tester imports the message into the NIST HL7v2 Syndromic Surveillance Validation Tool
    - Using the Validation Report produced by the NIST HL7v2 Syndromic Surveillance Validation Tool, the Tester verifies that the Implementation Guide conformance requirements tested are met and that the syndromic surveillance information message is conformant to the named standards

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:	
(d)(3) Standard. HL7 2.5.1 (incorporated by reference in § 170.299). Implementation specifications. PHIN Messaging Guide for Syndromic Surveillance (incorporated by reference in § 170.299) and Conformance Clarification for EHR Certification of Electronic Syndromic Surveillance, Addendum to PHIN Messaging Guide for Syndromic Surveillance (incorporated by reference in § 170.299).	

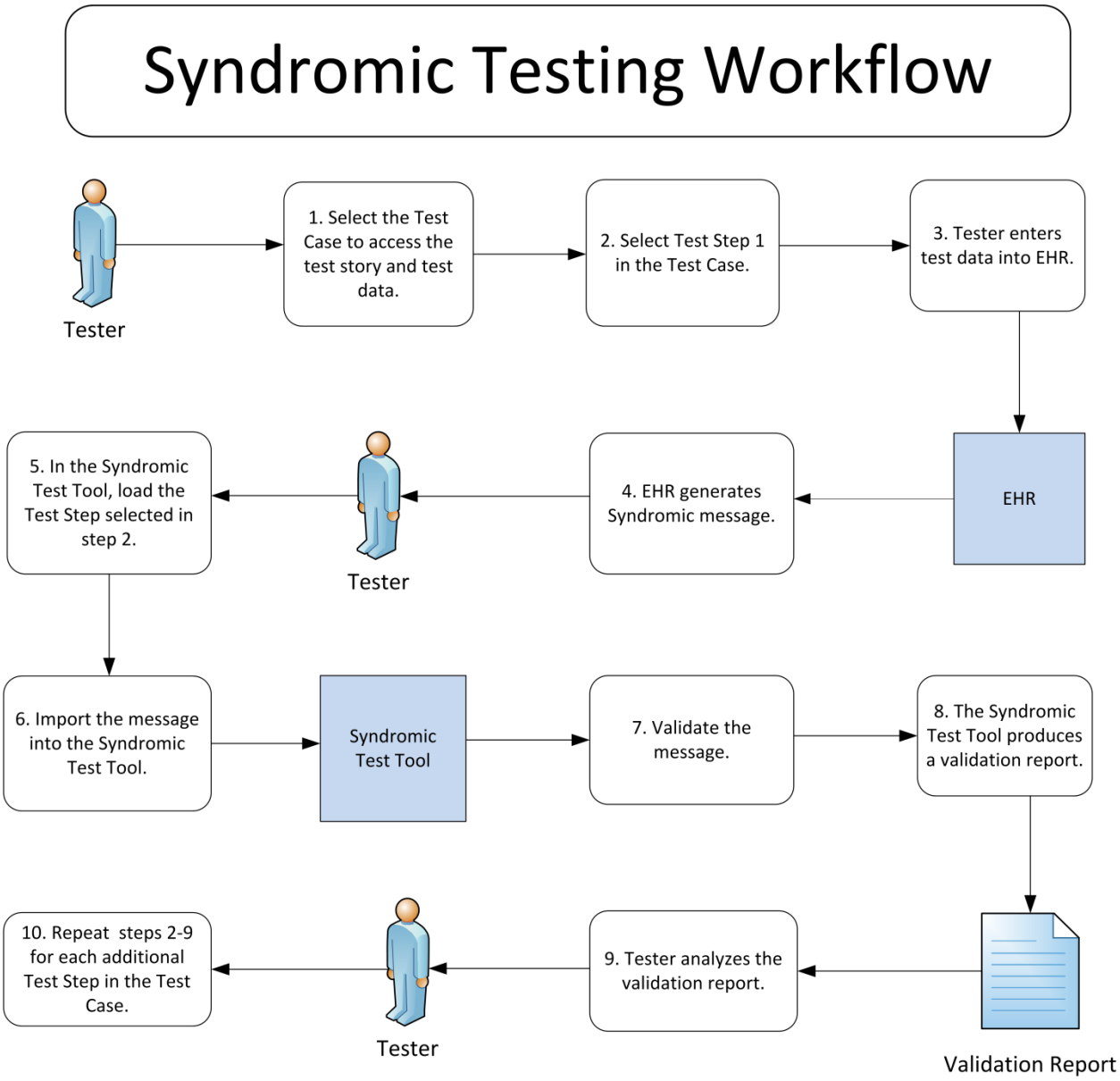
Note: As stated in §170.299(d) of 45 CFR Part 170 Subpart C of the Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule (September 4,2012): The PHIN Messaging Guide for Syndromic Surveillance and the Conformance Clarification for EHR Certification of Electronic Syndromic Surveillance, Addendum to PHIN Messaging Guide for Syndromic Surveillance specifications listed above for §170.205(d)(3) are Release 1.1.

NORMATIVE TEST PROCEDURES – AMBULATORY SETTING (OPTIONAL) (A.K.A., Urgent Care Setting in the Test Data)

Derived Test Requirements

DTR170.314(f)(3) – 2: Electronically Create Syndromic Surveillance Information

Figure 1



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

DTR170.314(f)(3) – 2: Electronically Create Syndromic Surveillance Information

Required Vendor Information

VE170.314(f)(3) – 2.01: 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 syndromic surveillance information messages using the test data, 3) import the syndromic surveillance information messages to the NIST HL7v2 Syndromic Surveillance Validation Tool, and 4) demonstrate support for any named value sets

VE170.314(f)(3) – 2.02: Vendor shall provide the mechanism necessary to capture and import syndromic surveillance messages into the NIST HL7v2 Syndromic Surveillance Validation Tool

Required Test Procedures

For the Urgent Care Visit Test Scenario provided in the Test Data section of this test procedure, follow the steps below:

TE170.314(f)(3) – 2.01: Tester shall select a Test Case consisting of syndromic surveillance information, and shall select Test Step 1 from the Test Case [Figure 1, Steps1 & 2]

TE170.314(f)(3) – 2.02: Using the Vendor-identified ambulatory EHR function(s), the Tester shall input the provided syndromic surveillance test data selected in TE170.314(f)(3) – 2.01 (input can be performed using a manual or automated process) [Figure 1, Step 3]

TE170.314(f)(3) – 2.03: Using the Vendor-identified ambulatory EHR function(s) and the selected syndromic surveillance test data, the Tester shall

- Cause the EHR to generate the indicated syndromic surveillance information message for the test encounter based on HL7 2.5.1 and the PHIN Messaging Guide for Syndromic Surveillance and Conformance Clarification for EHR Certification of Electronic Syndromic Surveillance, Addendum to PHIN Messaging Guide for Syndromic Surveillance [Figure 1, Step 4]
- Import the syndromic surveillance information message to the NIST HL7v2 Syndromic Surveillance Validation Tool identified in the Conformance Test Tools section of this test procedure [Figure 1, Step 5 & 6]

TE170.314(f)(3) – 2.04: Using the Inspection Test Guide, the Tester shall verify that the syndromic surveillance messages are conformant to the named standards and are generated with the appropriate syndromic surveillance information [Figure 1, Steps 7, 8, & 9]

TE170.314(f)(3) – 2.05: Tester shall repeat Steps 2 – 9 in Figure 1, selecting the *next* Test Step specified in the Test Case selected in TE170.314(f)(3) – 2.01 until all of the specified Test Steps in the Test Case are completed [Figure 1, Step 10]

Inspection Test Guide

IN170.314(f)(3) – 2.01: After all of the specified Test Steps in the Test Case selected in TE170.314(f)(3) – 2.01 are completed, the Tester shall use the Validation Report produced for each Test Step by the NIST HL7v2 Syndromic Surveillance Validation Tool (identified in

the Conformance Test Tools section of this test procedure) and shall verify that the Syndromic Surveillance Implementation Guide conformance requirements tested are met

IN170.314(f)(3) – 2.02: Once during the certification testing for this criterion, the Tester shall inspect the EHR to verify the capability of the Vendor to support the value sets specified

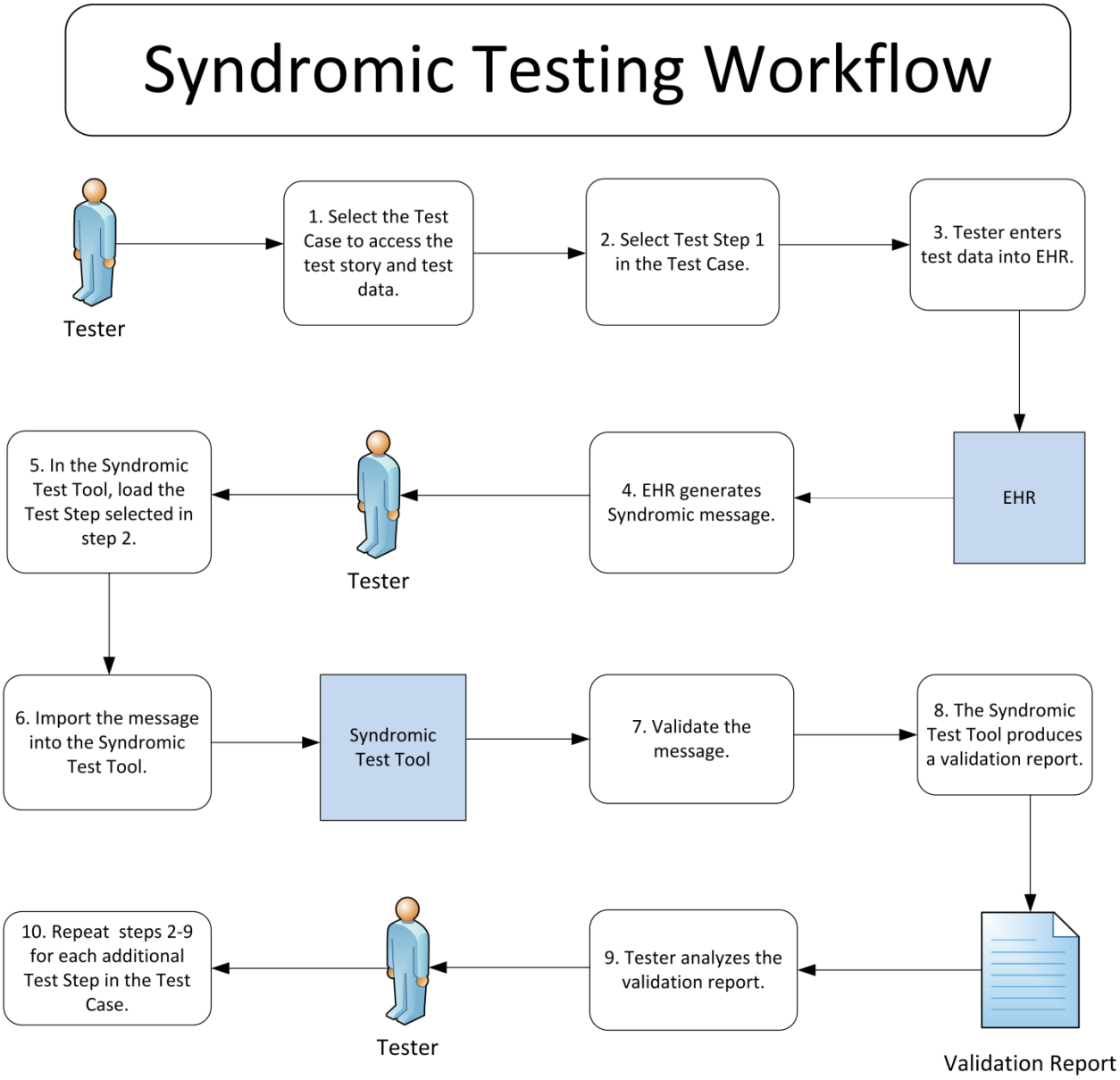
- Using the Vendor-identified EHR function(s) and the HL7v2 Syndromic Surveillance Validation Tool, the Vendor shall demonstrate to the Tester that their EHR supports any of the value sets (selected at the Tester's discretion) specified in the PHIN Messaging Guide for Syndromic Surveillance and Conformance Clarification for EHR Certification of Electronic Syndromic Surveillance, Addendum to PHIN Messaging Guide for Syndromic Surveillance

NORMATIVE TEST PROCEDURES – INPATIENT SETTING (A.K.A., Emergency Department Setting in the Test Data)

Derived Test Requirements

DTR170.314(f)(3) – 3: Electronically Create Syndromic Surveillance Information

Figure 2



The instructions in the derived test procedure listed below reference the numbered test steps in Figure 2 above

DTR170.314(f)(3) – 3: Electronically Create Syndromic Surveillance Information

Required Vendor Information

VE170.314(f)(3) – 3.01: 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 syndromic surveillance information messages using the test data, 3) import the syndromic surveillance information messages to the NIST HL7v2 Syndromic Surveillance Validation Tool, and 4) demonstrate support for any named value sets

VE170.314(f)(3) – 3.02: Vendor shall provide the mechanism necessary to capture and import syndromic surveillance messages into the NIST HL7v2 Syndromic Surveillance Validation Tool

Required Test Procedures

For three Test Cases (that is, one Test Case from each of the three Test Scenarios), provided in the Test Data section of this test procedure, follow the steps below:

TE170.314(f)(3) – 3.01: Tester shall select a Test Scenario and one of the associated Test Cases consisting of syndromic surveillance information, and shall select Test Step 1 from the Test Case [Figure 2, Steps1 & 2]

TE170.314(f)(3) – 3.02: Using the Vendor-identified inpatient EHR function(s), the Tester shall input the provided syndromic surveillance test data selected in TE170.314(f)(3) – 3.01 (input can be performed using a manual or automated process) [Figure 2, Step 3]

TE170.314(f)(3) – 3.03: Using the Vendor-identified inpatient EHR function(s) and the selected syndromic surveillance test data, the Tester shall

- Cause the EHR to generate the indicated syndromic surveillance information message for the test encounter based on the PHIN Messaging Guide for Syndromic Surveillance and Conformance Clarification for EHR Certification of Electronic Syndromic Surveillance, Addendum to PHIN Messaging Guide for Syndromic Surveillance [Figure 2, Step 4]
- Import the syndromic surveillance information message to the NIST HL7v2 Syndromic Surveillance Validation Tool identified in the Conformance Test Tools section of this test procedure [Figure 2, Step 5 & 6]

TE170.314(f)(3) – 3.04: Using the Inspection Test Guide, the Tester shall verify that the syndromic surveillance messages are conformant to the named standards and are generated with the appropriate syndromic surveillance information [Figure 2, Steps 7, 8, & 9]

TE170.314(f)(3) – 3.05: Tester shall repeat Steps 2 – 9 in Figure 2, selecting the *next* Test Step specified in the Test Case selected in TE170.314(f)(3) – 3.01 until all of the specified Test Steps in the Test Case are completed [Figure 2, Step 10]

Inspection Test Guide

IN170.314(f)(3) – 3.01: After all of the specified Test Steps in the Test Case selected in TE170.314(f)(3) – 3.01 are completed, the Tester shall use the Validation Report produced for each Test Step by the NIST HL7v2 Syndromic Surveillance Validation Tool (identified in the Conformance Test Tools section of this test procedure), and shall verify that the Syndromic Surveillance Implementation Guide conformance requirements tested are met

IN170.314(f)(3) – 3.02: Once during the certification testing for this criterion, the Tester shall inspect the EHR to verify the capability of the Vendor to support the value sets specified in the PHIN Messaging Guide for Syndromic Surveillance and Conformance Clarification for EHR Certification of Electronic Syndromic Surveillance, Addendum to PHIN Messaging Guide for Syndromic Surveillance

- Using the Vendor-identified EHR function(s) and the NIST HL7v2 Syndromic Surveillance Validation Tool, the Vendor shall demonstrate to the Tester that their EHR supports any of the value sets (selected at the Tester's discretion) specified in the PHIN Messaging Guide for Syndromic Surveillance and Conformance Clarification for EHR Certification of Electronic Syndromic Surveillance, Addendum to PHIN Messaging Guide for Syndromic Surveillance

TEST DATA

ONC supplied test data is 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-Accredited Testing Laboratories (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 is 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 needs 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. See Table 2 below for guidance on allowable changes to data.
- 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 functional and interoperable requirements identified in the

criterion can be adequately evaluated for conformance and that the test data provides 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 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 ONC EHR certification testing, the primary purpose of the provided test data is to assist the Tester in verifying that the vendors' EHR technologies are capable of supporting the required functions; verifying the ability to support the specific content is not the primary purpose of the test data. Such testing and verification is more appropriate for local installations of the EHR technologies. The clinical test data are relevant for the given test stories; however, these data should not be expected to represent standards of practice.

For this test procedure the Tester shall select one Test Case from **each** of the three Test Scenarios listed.

1. Urgent Care Visit
2. Emergency Department Visit – Patient Dies
3. Emergency Department Visit – Patient Admit

If Vendors elect to have their ambulatory EHR products certified to the optional syndromic surveillance messaging standard, such products need only pass **one** of the Test Cases for the Urgent Care Visit Test Scenario. Inpatient EHR products will need to pass **one** Test Case for the Urgent Care Test Scenario as well as **one** Test Case for each of the two Emergency Department Test Scenarios, since the Urgent Care Test Scenario presents a kind of encounter that all certified EHR technologies need to support. The total number of test cases an inpatient EHR product will need to pass for certification is three (3).

The Tester shall follow the normative test procedure to conduct these tests. Table 1 (Syndromic Surveillance Test Scenarios and Associated Test Cases) lists three Test Scenarios and identifies three Test Cases for each scenario. Each Test Case contains multiple test steps with test data for each step. Details of the Test Cases are provided in PDF files and are also accessible in the test tool (See the Context-based Validation tab). The test data provided for this test procedure have been verified by the

CDC. For the ADT messages generated during certification testing with this test procedure, the specifics regarding message profile requirements can be found in the HL7v2 Syndromic Surveillance Validation Tool under the message "Profile Viewer" tab.

Table 1: Syndromic Surveillance Test Scenarios and Associated Test Cases

Test Scenario	Test Case 1	Test Case 2	Test Case 3
Urgent Care Visit	SS_1_1.1-A04_Step1	SS_1_1.2-A04_Step1	SS_1_1.3-A04_Step1
	SS_1_2.1-A03_Step2	SS_1_2.2-A03_Step2	SS_1_2.3-A03_Step2
Emergency Department Visit -Patient Dies	SS_2_1.1-A04_Step1	SS_2_1.2-A04_Step1	SS_2_1.3-A04_Step1
	SS_2_2.1-A08_Step2	SS_2_2.2-A08_Step2	SS_2_2.3-A08_Step2
	SS_2_3.1-A03_Step3	SS_2_3.2-A03_Step3	SS_2_3.3-A03_Step3
Emergency Department Visit – Patient Admit	SS_3_1.1-A04_Step1	SS_3_1.2-A04_Step1	SS_3_1.3-A04_Step1
	SS_3_2.1-A08_Step2	SS_3_2.2-A08_Step2	SS_3_2.3-A08_Step2
	SS_3_3.1-A03_Step3	SS_3_3.2-A03_Step3	SS_3_3.3-A03_Step3
	SS_3_4.1-A01_Step4	SS_3_4.2-A01_Step4	SS_3_4.3-A01_Step4

NAVIGATING A TEST CASE

A test case contains multiple test steps each consisting of a test story and a test data specification. The test story gives a real world scenario that provides the context for the test step with the test case. The test data specification provides the data associated with 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 step. 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 step. The message content is organized in a table format that provides the HL7 V2 message elements and the data associated with the message elements for a given test case step. 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.

HOW TO INTERPRET THE MESSAGE CONTENT DATA SHEET

The message content data sheet indicates the location and data of the message for a particular test case step. The message content data sheet can be used to assist the Tester in loading the EHR with the test case step data and provides a classification of the data. This classification indicates the type and the

expected source of the data. How the data is classified is directly related to how the message content is validated. In some cases the validator is examining the message element for the presence of data whereas in other cases it is examining the message element for the presence of data and for exact content.

The information in the ***Location*** column indicates the canonical element location in the HL7 V2 message. For example, MSH-9.3 represents the 3rd component in the 9th field of the MSH segment. The ***Data Element*** column indicates the name of the data element as specified by the HL7 2.5.1 standard and/or the PHIN Messaging Guide for Syndromic Surveillance.

The ***Test Data*** column provides the expected data (if applicable) for that message element. The ***Data Classification*** column indicates the classification of the data. See the table below for a description of the data classification and how it is being validated.

Table 2 Description of Data Classification and Validation

Data Classification	Description	Validation
Configurable	Data typically that is configured by the system (customer-definable). Example data is provided.	Validate for the presence of data
System Generated	Data typically generated automatically by system, for example, message time. Example data is provided.	Validate for the presence of data
IG Fixed	Data that is fixed by the implementation guide; data can't be changed. Specific data is provided.	Validate for the presence and data content
Test Case Fixed	Data that is specific and fixed by the test case; data should not be changed. Specific data is provided.	Validate for the presence and selectively validate for data content.
Changeable	Data where the exact content is not relevant for the test case and can be changed for the purposes of testing. Example data is provided.	Validate for the presence of data

The test cases and the context-based validation test tool are tightly-coupled. In addition to validating message conformance, the test tool performs selective content validation based on the test story and test data provided, and deviation from the test data may cause the test tool to issue errors. For this reason, the Tester should use the test data as specified.

The HL7 V2 standard provides flexibility in messaging—many different message instances for a given test case step can be considered conformant. The test tool is designed to support such instances; however, it is not a certainty. If the test tool issues an error for a message instance, the Vendor shall provide evidence of equivalency to the Tester.

The test data for 170.314(f)(3)Transmission to Public Health Agencies - Syndromic Surveillance is available through the conformance tool (reference Conformance Tool Section for tool access).

CONFORMANCE TEST TOOLS

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

- HL7v2 Syndromic Surveillance Validation Tool – The HL7 V2 validation tool is designed specifically to support this test procedure. The tool is available as a Web Application.
- The application can be downloaded for local installation
- The web application validation service is available at: http://hl7v2-ss-testing.nist.gov

Support for these tools is available by submitting questions to the following user's group:
http://groups.google.com/d/forum/hl7v2-syndromic-testing

Inquiries may also be sent to this user group via email: hl7v2-syndromic-testing@googlegroups.com.

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 HL7v2 Syndromic Surveillance Validation Tool uses non-standard ports. If your firewall blocks HTTP traffic 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 HL7v2 Syndromic Surveillance Validation 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 HL7 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.

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	Posted Updated Approved Test Procedure Updates to 170.314(f)(3)(i)(A) – Ambulatory setting: • Informative Test Description updated to indicate test data is Vendor-supplied • Sentence indicating that Vendor-supplied data should direct the basic capabilities of EHR technology removed in Test Data section Updates to 170.314(f)(3)(i)(B) and (ii) – Inpatient setting and optional ambulatory setting: • Reference to Table 2 added to first bullet of Test Data section • Added paragraph to Test Data section about primary purpose of test data • Link to Google Group and email address changed to hl7v2-syndromic-testing from hl7v2-lab-testing in Conformance Tools section	January 16, 2013