Test Procedure for §170.302 (l) Public Health Surveillance

This document describes the draft test procedure for evaluating conformance of complete EHRs or EHR modules[1] to the certification criteria defined in 45 CFR Part 170 Subpart C of the Final Rule for Health Information Technology: Initial Set of standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology as published in the Federal Register on July 28, 2010. The document[2] 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://healthcare.nist.gov/docs/TestProcedureOverview_v1.pdf. The test procedures may be updated to reflect on-going feedback received during the certification activities.

The 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. Test procedures to evaluate conformance of EHR technology to ONC's requirements are defined by NIST. Testing of EHR technology is carried out by ONC-Authorized Testing and Certification Bodies (ATCBs), not NIST, as set forth in the final rule establishing the Temporary Certification Program (*Establishment of the Temporary Certification Program for Health Information Technology, 45 CFR Part 170; June 24, 2010*.)

Questions about the applicability of the standards, implementation guides or criteria should be directed to ONC at ONC.Certification@hhs.gov. Questions about the test procedures should be directed to NIST at hit-tst-fdbk@nist.gov. Note that NIST will automatically forward to ONC any questions regarding the applicability of the standards, implementation guides or criteria. Questions about functions and activities of the ATCBs should be directed to ONC at ONC.Certification@hhs.gov .

CERTIFICATION CRITERIA

This Certification Criterion is from the Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology Final Rule issued by the Department of Health and Human Services (HHS) on July 28, 2010.

§170.302 (l) Public health surveillance. Electronically record, modify, retrieve, and submit syndrome-based public health surveillance information in accordance with the standard (and applicable implementation specifications) specified in §170.205(d)(1) or §170.205(d)(2).

[1] Department of Health and Human Services, 45 CFR Part 170 Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, Final Rule, July 28, 2010.

[2] Disclaimer: Certain commercial products are identified in this document. Such identification does not imply recommendation or endorsement by the National Institute of Standards and Technology.

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 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."
- "Given the diversity in implementations and public health agencies' ability to receive information in a given standard, we believe that the flexibility included in this criterion is necessary for the foreseeable future. However, relative to the general comments we received regarding the adoption of implementation specifications for adopted standards, we have adopted the following implementation specifications for HL7 2.5.1: Public Health Information Network HL7 Version 2.5 Message Structure Specification for National Condition Reporting Final Version 1.0 and the Errata and Clarifications National Notification Message Structural Specification. We believe that these implementation specifications provide the additional clarity commenters were seeking and will enable Complete EHR and EHR Module developers to focus their efforts on a more specific implementation of the HL7 2.5.1 standard. We do not believe that a suitable implementation specification for HL7 2.3.1 exists for the purpose of public health surveillance and reporting."
- "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."

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.

This test evaluates the capability for a Complete EHR or EHR Module to electronically record, modify, retrieve and submit syndrome-based public health information in either HL7 2.3.1 format (no implementation guide specified), or in HL7 2.5.1 format in conformance with the Public Health Information Network HL7 Version 2.5 Message Structure Specification for National Condition Reporting Final Version 1.0 and Errata and Clarifications National Notification Message Structural Specification. The test procedure evaluates the capability to generate a new case notification message, and does not evaluate other notification functions such as updating or deleting a previously generated notification.

HL7 v2.3.1 conformance is evaluated in terms of the relevant conformance statements in the HL7.2.3.1 standard based on the specific message type(s) submitted by the Vendor. Since no implementation guide has been specified, Vendors may select the message type(s) they wish to submit. The Vendor supplies the test data for this test.

HL7 v2.5.1 conformance is evaluated in terms of the conformance statements in the Public Health Information Network HL7 Version 2.5 Message Structure Specification for National Condition Reporting Final Version 1.0 and Errata and Clarifications National Notification Message Structural Specification. For

this test, only those items whose optionality is specified as "R = Required" in the "Usage" column of Tables 3-2, 4-2, 4-3, 4-4 and 4-5 are evaluated for conformance. If a sequence number in these tables has a primary optionality code of "O=Optional" and sub-elements are labeled as "R" the entire sequence is considered to be optional, and not evaluated for conformance in this test. A few adjustments have been made to the conformance statements where CDC/PHIN-specific OIDs are specified which may not be applicable when sending information to non-CDC recipients.

The Public Health Information Network HL7 Version 2.5 Message Structure Specification for National Condition Reporting Final Version 1.0 specifies the use of Case Notification Message Mapping Guides published by the CDC at http://www.cdc.gov/phin/resources/guides/mmghomepagecasenotification.html

The Vendor is responsible for selecting a specific Case Notification Message Mapping Guide to be used during this test, and providing appropriate test data as described in the selected Case Notification Message Mapping Guide.

The test procedure is organized into one section:

- Submit – evaluates the capability of the EHR to electronically generate the Vendor-selected syndromic surveillance information in a conformant HL7 v2.3.1 or v2.5.1 message
    - The Vendor identifies the version of HL7 to be used for this test (HL7v2.3.1 or v2.5.1). If v2.5.1 is selected, the Vendor also selects a Message Mapping Guide
    - The Vendor instantiates the Vendor-supplied test data in the EHR
    - Using EHR function(s) identified by the Vendor, the Tester verifies the presence of the test data in the EHR, generates the syndromic surveillance message and verifies that the message is conformant to the selected HL7 standard and, if applicable, the PHIN implementation guide and case notification message mapping guide.

REFERENCED STANDARDS

§170.205 Content exchange and vocabulary standards for exchanging electronic health information.	Regulatory Referenced Standard
(d) Electronic submission to public health agencies for surveillance or reporting. (1)Standard. HL7 2.3.1(incorporated by reference in §170.299). (2) Standard. HL7 2.5.1(incorporated by reference in §170.299). Implementation specifications. Public Health Information Network HL7 Version 2.5 Message Structure Specification for National Condition Reporting Final Version 1.0 and Errata and Clarifications National Notification Message Structural Specification (incorporated by reference in §170.299)	

NORMATIVE TEST PROCEDURES

Derived Test Requirements

DTR170.302.l - 1: Electronically Submit Public Health Syndromic Surveillance Information

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Required Vendor Information

VE170.302.l – 1.01: Vendor shall identify the EHR function(s) that are available to record, modify retrieve and transmit syndromic surveillance information

VE170.302.l – 1.02: Vendor shall identify an existing patient record in the EHR to be used for this test

VE170.302.l – 1.03: Vendor shall select the version of HL7 (v2.3.1 or v2.5.1). If v2.5.1 is selected, the Vendor shall also select a Case Notification Message Mapping Guide to be used for this test

VE170.302.l – 1:04 Vendor shall instantiate the Vendor-supplied syndromic surveillance test data in the EHR for this test

Required Test Procedure

TE170.302.l – 1.01: Using EHR function(s) identified by the Vendor, the Tester shall select the existing patient record and verify the presence of the test data in the EHR

TE170.302.l – 1.02: Using the EHR function(s) identified by the Vendor the Tester shall generate the syndromic surveillance message

TE170.302.l – 1.03 Using the NIST-supplied Inspection Test Guide, the Tester shall verify that the generated syndromic surveillance message is conformant

Inspection Test Guide – HL7 v2.3.1

IN170.302.1 – 1.01: Tester shall verify that the message is conformant with the HL7v2.3.1 for the message type and message segments generated by the EHR. The Tester may utilize an automated test tool or conduct a visual inspection of the message to conduct the evaluation. The Tester shall only evaluate those items identified as “R=Required” in HL7v2.3.1.

Inspection Test Guide – HL7 v2.5.1

IN170.302.1 – 1.01: Tester shall verify that the message is conformant with the Public Health Information Network HL7 Version 2.5 Message Structure Specification for National Condition Reporting Final Version 1.0 and Errata and Clarifications National Notification Message Structural Specification. The Tester may utilize an automated test tool or conduct a visual inspection of the message to conduct the evaluation. Only those items whose optionality is specified as “R = Required” in the “Usage” column of Tables 3-2, 4-2, 4-3, 4-4 and 4-5 are evaluated for conformance. If a sequence number in these tables has a primary optionality code

of "O=Optional" and sub-elements are labeled as "R" the entire sequence is considered to be optional, and not evaluated for conformance in this test.

IN170.302.1 – 1.02: Modifications to the conformance statements in Public Health Information Network HL7 Version 2.5 Message Structure Specification for National Condition Reporting Final Version 1.0

- MSH 5.2 and 5.3 – specifies a static CDC-specific OID as the receiving application, which may not be appropriate when sending to a non-CDC entity. For this test, the field may be blank or populated. If populated, the value shall contain a properly formed OID
- MSH 6.2 and 6.3 – specifies a static CDC-specific OID as the receiving facility, which may not be appropriate when sending to a non-CDC entity. For this test, the field may be blank or populated. If populated, the value shall contain a properly formed OID.

IN170.302.1 – 1.03: Tester shall verify that the message is conformant with the Vendor-selected Case Notification Message Mapping Guide. The Tester may utilize an automated test tool or conduct a visual inspection of the message to conduct the evaluation. Only those items whose optionality is specified as "R = Required" in the "CDC Priority" and the "HL7 Optionality" columns of the Message Mapping Guide are evaluated for conformance.

IN170.302.1 – 1.04: Tester shall verify that the Vendor-supplied test data instantiated in the EHR is represented correctly in the message, as defined by the specified PHIN implementation guide and the Vendor-selected Case Notification Message Mapping Guide

EXAMPLE TEST DATA

This Test Procedure requires the vendor to supply the test data. The Tester shall address the following:

- Vendor-supplied test data shall ensure that the functional and interoperable 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

Document History

Version Number	Description of Change	Date Published
0.6	Original draft version	April 29, 2010
1.0	Updated to reflect Final Rule	July 21, 2010
1.0	Updated to remove “Pending” from header	August 13, 2010