Preliminary ARRA IFR Stage 1 Interoperability Test Guide

Version 1.1

April 7, 2010

Table of Contents

Corrections and Clarifications: Change Control History

This section documents any minor technical corrections and clarifications to the test scripts, criteria and supporting documents since original publication in the final form for IFR Stage 1 testing. Changes are being made directly to the document and are summarized in this table. Please refer to this table to get a detailed description of any technical corrections or clarifications that have been identified since the original final publication of the document.

Item #	Version #	Date Added	Test Step Number	Type of Correction or Clarification	Issue	Clarification
1	**1.1**	2/15/10	Y.01	Technical correction	Page 13. HL7 message type for immunizations incorrectly specified VXQ/VXR.	HL7 message type for immunization messages was corrected to VXU type.
2	**1.1**	2/24/10	W.03	Technical Correction	Page 9: Requirements for terminologies did not match Table 2a of IFR	Medications terminologies updated to reflect Table 2a. Allergy terminology requirement removed, Immunization CVX terminology requirement removed
3	**1.1**	2/24/10	AA.01	Clarification	Page 15: clarification on HL7 message type	HL7 message type for Syndromic surveillance was updated to ADT
4	**1.1**	2/24/10	Y.01, Z.01, AA.01	Clarification	Page 13, 14, 15	Note added that batched patient information is not required in the file
5	**1.1**	2/24/10	K.01	Clarification	Certain conditional items may not appear in all lab result reports – clarification of expected results needed	The applicant does not have to demonstrate, and may instead describe how the system handles display of specimen source and disposition of specimens that do not meet the laboratory's criteria for acceptability
6	**1.1**	2/24/10	M.02	Clarification	Validation of generated PQRI XML report made optional	Step W.02 is an optional step that the applicant may demonstrate at their discretion
7	**1.1**	2/24/10	W.02	Clarification	Page 9: Discharge Summary section for CCD/CCR	CCHIT feels that the content section for “discharge summary” should not be included as part of the CCD/CCR patient summary document. The ability to generate a discharge summary will be tested in Component S.

Using this Guide

This guide offers additional information on CCHIT interoperability testing requirements that apply to Preliminary ARRA Stage 1 IFR Certification programs for Eligible Providers and Hospitals.

Many of the changes and additions to the program have come about as a result of the publication of the Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology (http://edocket.access.gpo.gov/2010/pdf/E9-31216.pdf). See http://healthit.hhs.gov for more information on Meaningful Use. Table 2a, of the IFR lists the standards and terminology requirements that support Meaningful Use, and is copied below.

Table 2a of 45 CFR Part 170 -Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology; Interim Final Rule

Row #	Purpose	Category	Adopted Standard(s) to Support Meaningful Use Stage 1
1	***Patient Summary Record***	Cx	HL7 CDA R2 CCD Level 2 or ASTM CCR
	• Problem List	V	Applicable HIPAA code set required by law (i.e.,ICD-9-CM); or SNOMED CT®
	•Medication List	V	Any code set by an RxNorm drug data source provider that is identified by the United States National Library of Medicine as being a complete data set integrated within RxNorm
	•Medication Allergy List	V	No standard adopted at this time.
	•Procedures	V	Applicable HIPAA code sets required by law (i.e., ICD-9-CM or CPT-4®)
	•Vital Signs	V	No standard adopted at this time.
	•Units of Measure	V	No standard adopted at this time.
	•Lab Orders and Results	V	LOINC® when LOINC® codes have been received from a laboratory
2	***Drug Formulary Check***	Cx	Applicable Part D standard required by law (i.e., NCPDP Formulary & Benefits Standard 1.0)
3	***Electronic Prescribing***	Cx	Applicable Part D standard required by law (e.g., NCPDP SCRIPT 8.1) or NCPDP SCRIPT 8.1 and NCPDP SCRIPT 10.6
		V	Any code set by an RxNorm drug data source provider that is identified by the United States National Library of Medicine as being a complete data set integrated within RxNorm+
4	***Administrative Transactions***	Cx	Applicable HIPAA transaction standards required by law
5	***Quality Reporting***	Cx	CMS PQRI 2008 Registry XML Specification#,+
6	***Submission of Lab Results to Public Health Agencies***	Cx	HL7 2.5.1
		V	LOINC® when LOINC® codes have been received from a laboratory
7	***Submission to Public Health Agencies for Surveillance or Reporting (excluding adverse event reporting)***	Cx	HL7 2.3.1 or HL7 2.5.1
		V	According to Applicable Public Health Agency Requirements
8	***Submission to Immunization Registries***	Cx	HL7 2.3.1 or HL7 2.5.1
		V	CVX

Lab Results Interoperability Testing Instructions (Component K)

Overview

Applicants seeking modular certification for this component are required to demonstrate the ability to process electronic lab result messages, with lab result information imported as discrete data within their system, and display a lab report with that meets the requirements specified in 42 CFR 493.1291(c). **CCHIT will not be providing sample files for tests.** It is expected that applicants will attest to the version of HL7 messaging supported and demonstrate the ability to meet the following CCHIT criteria:

- **IFR.K.1:** The system shall provide the ability to electronically receive clinical laboratory test results in a structured format and display such results in human readable format
- **IFR.K.2:** The system shall provide the ability to electronically display in human readable format any clinical laboratory tests that have been received with LOINC® codes
- **IFR.K.3:** The system shall provide the ability to electronically display all the information for a lab test report specified at 42 CFR 493.1291(c)(1) through (7)

Reference Information

The following references provide additional information relevant to lab results reporting:

- HL7 specification: http://hl7.org
- For more information about LOINC codes and the HEDIS subset: http://loinc.org
- 42 CFR 493.1291(c): http://tinyurl.com/yg2ub8l

Expected Results

The applicant is responsible for configuring the demonstration to show the processing of lab message files prior to the inspection. Lab messages should comply with the HL7 v2 standard, and encode test identifiers using LOINC. During the inspection scenario, the applicant will demonstrate to the jurors how the system can incorporate electronic lab results into a specific patient record as discrete data fields. The jurors do not need to watch the interface transaction, but do need to see the lab values within the patient record as discrete data.

CCHIT testing of lab messages is constrained to the fields needed to post a lab results to a patient's chart and the additional requirements for systems to provide the ability to electronically display all the information for a lab test report specified at 42 CFR 493.1291(c)(1) through (7). To meet certification requirements, the following data points must be displayed in the lab report:

- Either the patient's name and identification number, or a unique patient identifier and identification number for positive patient identification (PID-3, PID-5)
- The name and address of the laboratory location where the test was performed (OBX-23, OBX-24)
- The test report date (OBR-22)
- The test performed (OBR-4, OBX-3)
- Specimen source, when appropriate *
- The test result and, if applicable, the units of measurement or interpretation (OBX-5, OBX-6)
- Correct display of results flagged as Abnormal (OBX-8)
- Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.*

For the highlighted steps, it will be allowable for the applicant to describe how their system handles the following cases.

CMS Quality Reporting (M.02) - Optional

Overview

Certification testing will require applicants to meet the following criteria:

- Enable a user to electronically submit calculated quality measures in accordance with the CMS PQRI 2008 Registry XML Specification.

Reference Information

The following references provide additional information relevant to CMS Quality Reporting:

- CMS 2008 PQRI Program - http://www.cms.hhs.gov/PQRI/2008/list.asp#TopOfPage
- The zip file with the CMS 2008 PQRI Registry XML Specification can be found by following the link to titled "2008_Registry_Documents_062909" at the CMS website page above.

Expected Results

To meet the expected results for this step, the applicant will be required to demonstrate the ability to electronically submit quality measures in accordance with the specified standard. Using the results of a report created in the Test Script Step M.01, create a file using the specified standard and submit the file to the CCHIT Proctor for validation.

- The quality measure file is validated by CCHIT as properly formatted and structured using the PQRI 2008 XML standard.

Insurance Eligibility Interoperability (Component Q)

Overview

Certification testing will require applicants to meet the following criteria:

- Enable a user electronically record and display patients' insurance eligibility, and submit insurance eligibility queries to public or private payers and receive an eligibility response in accordance with the applicable standards specified in Table 2A row 4.

This step relates to overall insurance eligibility for the patient and is not limited to prescription coverage through a PBM.

Reference Information

The following references provide additional information relevant to insurance eligibility:

- HIPAA X12 4010A1 (http://hhs.gov)
- CAQH CORE Phase I and Phase II (http://caqh.org)

- OR –

- HIPAA X12 5010
- CAQH CORE Phase I and Phase II (http://caqh.org)

Expected Results

To meet the expected results for this step, the applicant will be required to demonstrate the ability to check insurance eligibility from public and private payers or other transactions that are equal or greater in complexity.

- Applicants will not be submitting claims data to CCHIT. It is recommended that applicants establish a connection with any insurance carrier and use the patient of their choice to demonstrate this functionality. The applicant may submit an electronic query to the carrier and should receive a return message from the carrier indicating the coverage for the patient to demonstrate compliance. It is permissible for the return message to be blank.
- Alternatively, it is permissible to generate a compliant 270 transaction followed by a demonstration of how the system would process an inbound 271 response. The transaction would not have to be based on a "live" request or response, and establishing a connection to an external party would not be required.

Electronic Claims Submission (Component R)

Overview

Certification testing will require applicants to meet the following criteria:

- Enable a user to electronically submit claims to public or private payers in accordance with the applicable standards specified in Table 2A row 4 of 45 CFR Part 170

Reference Information

The following references provide additional information relevant to insurance eligibility:

- HIPAA X12 4010A1 (http://hhs.gov)
- CAQH CORE Phase I and Phase II (http://caqh.org)

- OR –

- HIPAA X12 5010
- CAQH CORE Phase I and Phase II (http://caqh.org)

Expected Results

To meet the expected results for this step, the applicant will be required to demonstrate the ability to submit claims information electronically to public or private payers or other transactions that are equal or greater in complexity.

- CCHIT does not provide a clearinghouse for the applicant to use for claims transmission during the inspection. Applicants will be required to show the compilation of the claim and the raw data file to the jurors, and will then describe to the jurors the process for transmission of the claim to the clearinghouse following the appropriate standard as attested to on your application.
- Connecting to a clearinghouse, submitting claims information, and receiving acknowledgement of successful transmission is preferable but not required.

CCD/CCR Patient Summary Interoperability Testing Instructions (Component W)

Overview

Applicants seeking certification are required to demonstrate the ability to file and display patient summary documents formatted to the HL7 CDA R2 CCD and ASTM Continuity of Care Record (CCR) specifications. Additionally, applicants are required to generate a valid document **per either one of the specifications** using the required terminologies.

Interoperability testing will require applicants to meet the following CCHIT criteria:

- The system shall provide the ability to display CCD documents and file them as intact documents in the EHR. Summary patient record content information will include: patient demographics, medication list, immunizations, medication allergy list, problem list, procedures, and diagnostic test results.
- The system shall provide the ability to display ASTM CCR documents and file them as intact documents in the EHR. Summary patient record content information will include: patient demographics, medication list, immunizations, medication allergy list, problem list, procedures, and diagnostic test results.
- The system shall provide the ability to generate and format patient summary documents per one of the following specifications: HITSP C32, HITSP C48, HL7 CDA R2 CCD, or ASTM CCR. Summary patient record content information will include: patient demographics, medications, immunizations, medication allergies, problem list, procedures, and diagnostic test results.
- Note: CCHIT feels that the content section for "Discharge summary" was included in the IFR under patient summary erroneously. The ability to generate a discharge summary will be tested in Component S. This changes the expected results so that information under a "Discharge Summary" section will not appear in displayed CCD and CCR documents, and the system will not be required to generate a "Discharge summary" section as part of the CCD or CCR document generated in this step.

Generated xml documents must demonstrate use of industry-standard vocabularies/terminologies. The intent is to test the Required (R) fields both documents.

Vocabularies
Medications: Any code set by an RxNorm drug data source provider that is identified by the United States National Library of Medicine as being a complete data set integrated within RxNorm
Problem List: ICD-9-CM or SNOMED CT®
Results: LOINC®
Procedures: ICD-9-CM or CPT-4®

It is encouraged to practice validation testing prior to certification testing by making use of the Laika tool or the NIST validation site. See the Laika User's Guide available at cchit.org for more information.

There are two tests associated with demonstrating compliance to patient summary interoperability criteria: "Display & File" and "Generate & Format."

Human inspection is required to validate the results of Display & File tests as the CCHIT juror will verify that required data elements are displayed by the applicant's system. Conversely, the Generate & Format test leverages a software application in addition to human inspection, to help check that the system produced valid XML, and it contains the correct content.

Reference Information

The following provide additional information relevant to CCHIT Patient Summary interoperability testing and the referenced specifications.

- HL7 Implementation Guide: CDA Release 2 – Continuity of Care Document (CCD), Apr 1, 2007 (http://hl7.org)
- ASTM Continuity of Care Record (CCR), v.1.0 - (http://astm.org)
- NIST CDA Validation Site: http://xreg2.nist.gov/cda-validation/index.html
- NIST Validator: http://xreg2.nist.gov/cda-validation/index.html

The Display & File Test

Before the inspection begins the CCHIT proctor emails the applicant CCD and CCR documents for existing patients in their system. The following steps will be repeated to test a CCD and CCR document.

- The file is processed by the system undergoing certification testing:
    - Patient registration information from the file can be used to match to the appropriate preexisting patient chart (Note: there is no requirement to match the patient with the document automatically)
    - The document is filed into/associated with the patient chart
    - The document is then displayed
- CCHIT Jurors observe that the system displays the expected results

Expected Results

To pass this step for CCHIT certification, EHR systems must achieve these expected results:

- The system shall match the patient registration information to one of several charts created before certification testing begins, and "File" the given CCD/CCR as a document into this chart.
- Matching the patient registration information can be done manually by looking at patient demographic information or automatically by the system based on the header information.
- The system shall produce a human readable view of the CCD/CCR document, **displaying these essential elements**:
    - From the Person Information/Demographics Content Section:
        - Patient Name
        - Patient Date of Birth
        - Patient Gender
    - From the Allergy Content Section:
        - Section Title

        - Associated narrative text
          (formatted text encoded between <text> and </text> tags)
    - From the Medication Section:
        - Section Title
        - Associated narrative text
          (formatted text encoded between <text> and </text> tags)
    - From the Conditions/Problem List Section:
        - Section Title
        - Associated narrative text
          (formatted text encoded between <text> and </text> tags)
    - From the Immunization Section:
        - Section Title
        - Associated narrative text
          (formatted text encoded between <text> and </text> tags)
    - From the Results Section:
        - Section Title
        - Associated narrative text
          (formatted text encoded between <text> and </text> tags)
    - From the Procedures Section:
        - Section Title
        - Associated narrative text
          (formatted text encoded between <text> and </text> tags)

Although the system *may* display additional information (beyond that listed above) from the test file, the jurors will be scoring the step on the expected results bulleted above. One comparative basis for how human readable views of patient summary files should be displayed is through the HL7 CCD "sample" style sheet (CCD.xsl) – published with the CCD specification.

Selectively merging structured, coded clinical information from the received files to the patient chart is not required at this time.

The Generate & Format Test

- As outlined in the CCHIT Test Scripts, the CCHIT Proctor will have the applicant update information in a patient chart.
- The data being updated in the chart will be constrained to the basic **Required (R) fields** of the specifications.
- The applicant will then generate ***either*** a CCD or CCR file that reflects the updated information and email the file to the CCHIT proctor
- CCHIT will validate the xml for proper structure using LAIKA and will verify the display of the required data elements of the document using a standard stylesheet.

Expected Results

Before the scenario starts, applicants must inform the proctor as to the version of the document being created.

To pass the Generate & Format test, EHR systems must achieve these expected results:

- The system shall properly format a patient summary document according to either the HL7 CDA R2 CCD , HITSP C32, HITSP C48 or ASTM CCR v1.0 specification.
- The applicant's generated file shall contain patient registration and clinical information from the appropriate patient charts, including the updated patient information supplied by the proctor during the inspection. The content of the document will be checked by applying the xml to a stylesheet to visually inspect the document for the required elements.

- Required sections include Person Information (Demographics), Medications, Allergies, Conditions (Problem List), Immunizations, Results, and Procedures.

Immunization Registries Interoperability Testing Instructions (Component Y)

Overview

Certification testing will require applicants to meet the following criteria:

- Electronically record, retrieve, and transmit immunization information to immunization registries in accordance with the standards specified in Table 2A row 8 or in accordance with the applicable state-designated standard format.

Reference Information

The following references provide additional information relevant to immunization messaging standards:

- HL7 v2.3.1 or v.2.5.1 VXU messages (HL7.org)
- CVX vocabulary (CDC, http://www.cdc.gov/vaccines/programs/iis/stds/cvx.htm)

The CDC's National Center of Immunization and Respiratory Diseases (NCIRD) maintains the HL7 external code set CVX. The implementation of the HL7 standard for immunization data exchange is described in Chapter 4 of the HL7 standard. The codes in HL7 Version 2.3 table 0292, represented the initial content of the external CVX code set.

Expected Results

It is expected that applicants will meet the requirement to submit immunization data to registries by:

- Demonstrating the ability to generate a valid data file containing immunization information using one of the approved standard formats (HL7 2.3.1 or HL7 2.5.1) and;
- Submitting the file to CCHIT for validation.
- Note is not required to send batched patient information in the file generated

Reportable Lab Submission Interoperability Testing Instructions (Component Z)

Overview

Note: **Hospitals only**

Certification testing will require applicants to meet the following criteria:

- Electronically record, retrieve, and transmit reportable clinical lab results to public health agencies in accordance with the standards specified in Table 2A row 6.

Reference Information

The following references provide additional information relevant to standards for submitting reportable lab results to public health agencies:

- HL7 v2.5.1 ORU (HL7.org)
- CDC Resource Guide: http://www.cdc.gov/phin/resources/guides.html
- PHIN: http://www.cdc.gov/PHIN/library/documents/pdf/PHIN%20requirements%20V2.0.pdf

Expected Results

It is expected that applicants will meet the requirement to transmit reportable clinical lab results to public health agencies by:

- Demonstrating the ability to generate a valid data file containing reportable clinical lab results information using the approved standard format (HL7 2.5.1) and;
- Submitting the file to CCHIT for validation.
- Note is not required to send batched patient information in the file generated

Electronic Syndromic Surveillance Interoperability Testing Instructions (Component AA)

Overview

Certification testing will require applicants to meet the following criteria:

- Electronically record, retrieve, and transmit syndrome-based (e.g., influenza like illness) public health surveillance information to public health agencies in accordance with the standards specified in Table 2A row 7.

Reference Information

The following references provide additional information relevant to electronic syndromic surveillance data submission standards:

- HL7 v2.5.1 or v2.3.1 ADT encounter message (HL7.org)

Expected Results

It is expected that applicants will meet the requirement to submit syndromic surveillance data to public health agencies by:

- Demonstrating the ability to generate a valid data file containing syndromic surveillance information using one of the approved standard formats (HL7 2.3.1 or HL7 2.5.1) and;
- Submitting the file to CCHIT for validation.
- Note is not required to send batched patient information in the file generated