Implementation Guide for CDA Release 2 CDA Tools Design Pilot

(U.S. Realm)

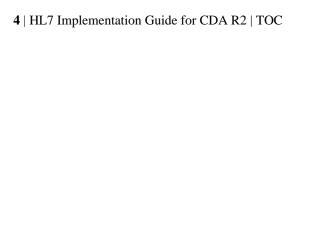


Draft Standard for Trial Use
First Ballot
May 2010
CDAR2_IG_TBPN_R1_O1_2010MAY
(Developer Documentation)



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We acknowledge the foundational work on HL7 Version 3 and the Reference Information Model (RIM), the HL7 domain committees, especially Patient Care, and the work done on Clinical Document Architecture (CDA) itself.

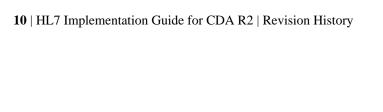
We also acknowledge the collaborative effort of the American Society for Standards and Materials (ASTM) and HL7, which produced the Continuity of Care Document (CCD). All these efforts were critical ingredients to the development of this Draft Standard for Trial Use (DSTU), and the degree to which the DSTU reflects these efforts will foster interoperability across the spectrum of health care.

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Revision History

Rev	Date	By Whom	Changes
New	7/xx/2010	Amnon Shabo	New
Draft 1		Amnon Shabo	Committee review
First draft for posting		Amnon Shabo	Tech edit/First QA completed



1

INTRODUCTION

Topics:

- Purpose
- Approach
- Scope
- Audience
- Organization of This Guide
- Use of Templates
- Conventions Used in This Guide
- Contents of the DSTU Ballot Package

Purpose

The purpose of this Implementation Guide (IG) is to specify a standard for ...

Approach

Working with an initial portion of the data provides the opportunity to work with the data from the perspective of the underlying model and electronic format and to explore many design issues thoroughly. Taking this as an initial step ensures that the data set developers and standards community can reach consensus prior to the larger commitment of time that would be required to bring the full data set into standard format.

This project supports reusability and ease of data collection through a standard data representation harmonized with work developed through Health Information Technology Expert Panel (HITEP), balloted through Health Level Seven (HL7) and/or recognized by the Health Information Technology Standards Panel (HITSP).

This implementation guide (IG) specifies a standard for electronic submission of NCRs in a Clinical Document Architecture (CDA), Release 2 format.

Scope

TODO: scope of this implementation guide.

Audience

The audience for this document includes software developers and implementers who wish to develop...

Organization of This Guide

The requirements as laid out in the body of this document are subject to change per the policy on implementation guides (see section 13.02" Draft Standard for Trial Use Documents" within the HL7 Governance and Operations Manual, http://www.hl7.org/documentcenter/public/membership/HL7_Governance_and_Operations_Manual.pdf).

Templates

Templates are organized by document (see Document Templates), by section (see Section Templates), and by clinical statements (see Clinical Statement Templates). Within a section, templates are arranged hierarchically, where a more specific template is nested under the more generic template that it conforms to. See Templates by Containment for a listing of the higher level templates by containment; the appendix Templates Used in This Guide includes a table of all of the templates Organized Hierarchically.

Vocabulary and Value Sets

Vocabularies recommended in this guide are from standard vocabularies. When SNOMED codes are used, rules defined in Using SNOMED CT in HL7 Version 3 are adhered to. In many cases, these vocabularies are further constrained into value sets for use within this guide. Value set names and OIDs are summarized in the table Summary of Value Sets. Each named value set in this summary table is stored in a template database that will be maintained by CHCA.

Use of Templates

When valued in an instance, the template identifier (templateId) signals the imposition of a set of template-defined constraints. The value of this attribute provides a unique identifier for the templates in question.

Originator Responsibilities

An originator can apply a templateId to assert conformance with a particular template.

In the most general forms of CDA exchange, an originator need not apply a templateId for every template that an object in an instance document conforms to. This implementation guide asserts when templateIds are required for conformance.

Recipient Responsibilities

A recipient may reject an instance that does not contain a particular templateId (e.g., a recipient looking to receive only CCD documents can reject an instance without the appropriate templateId).

A recipient may process objects in an instance document that do not contain a templateId (e.g., a recipient can process entries that contain Observation acts within a Problems section, even if the entries do not have templateIds).

Conventions Used in This Guide

Conformance Requirements

Conformance statements are grouped and identified by the name of the template, along with the templateId and the context of the template (e.g., ClinicalDocument, section, observation), which specifies the element under constraint. If a template is a specialization of another template, its first constraint indicates the more general template. In all cases where a more specific template conforms to a more general template, asserting the more specific template also implies conformance to the more general template. An example is shown below.

Template name

```
[<type of template>: templateId <XXXX.XXX.XXX.XXX>]
```

Description of the template will be here

- 1. Conforms to <The template name> Template (templateId: XXXX<XX>XXX>YYY).
- **2. SHALL** contain [1..1] @classCode = <AAA> <code display name> (CodeSystem: 123.456.789 <XXX> Class) **STATIC** (CONF:<number>).
- 3.

Figure 1: Template name and "conforms to" appearance

The conformance verb keyword at the start of a constraint (SHALL, SHOULD, MAY, etc.) indicates business conformance, whereas the cardinality indicator (0..1, 1..1, 1..*, etc.) specifies the allowable occurrences within an instance. Thus, "MAY contain 0..1" and "SHOULD contain 0..1" both allow for a document to omit the particular component, but the latter is a stronger recommendation that the component be included if it is known.

The following cardinality indicators may be interpreted as follows:

- 0..1 as zero to one present
- 1..1 as one and only one present
- 2..2 as two must be present
- 1..* as one or more present
- 0..* as zero to many present

Value set bindings adhere to HL7 Vocabulary Working Group best practices, and include both a conformance verb (SHALL, SHOULD, MAY, etc.) and an indication of DYNAMIC vs. STATIC binding. The use of SHALL requires that the component be valued with a member from the cited value set; however, in every case any HL7 "null" value such as other (OTH) or unknown (UNK) may be used.

Each constraint is uniquely identified (e.g., "CONF:605") by an identifier placed at or near the end of the constraint. These identifiers are not sequential as they are based on the order of creation of the constraint.

- 1. SHALL contain [1..1] component/structuredBody (CONF:4082).
 - a. This component/structuredBody SHOULD contain [0..1] component (CONF:4130) such that it
 - **a. SHALL** contain [1..1] Reporting Parameters section (templateId:2.16.840.1.113883.10.20.17.2.1) (CONF:4131).
 - b. This component/structuredBody SHALL contain [1..1] component (CONF:4132) such that it
 - **a. SHALL** contain [1..1] Patient data section NCR (templateId:2.16.840.1.113883.10.20.17.2.5) (CONF:4133).

Figure 2: Template-based conformance statements example

CCD templates are included within this implementation guide for ease of reference. CCD templates contained within this implementation guide are formatted WITHOUT typical **KEYWORD** and **XML** element styles. A WIKI site is available if you would like to make a comment to be considered for the next release of CCD: http://wiki.hl7.org/index.php?title=CCD_Suggested_Enhancements The user name and password are: wiki/wikiwiki. You will need to create an account to edit the page and add your suggestion.

- 1. The value for "Observation / @moodCode" in a problem observation SHALL be "EVN" 2.16.840.1.113883.5.1001 ActMood STATIC. (CONF: 814).
- 2. A problem observation SHALL include exactly one Observation / statusCode. (CONF: 815).
- **3.** The value for "Observation / statusCode" in a problem observation SHALL be "completed" 2.16.840.1.113883.5.14 ActStatus STATIC. (CONF: 816).
- **4.** A problem observation SHOULD contain exactly one Observation / effectiveTime, to indicate the biological timing of condition (e.g. the time the condition started, the onset of the illness or symptom, the duration of a condition). (CONF: 817).

Figure 3: CCD conformance statements example

Keywords

The keywords SHALL, SHALL NOT, SHOULD, SHOULD NOT, MAY, and NEED NOT in this document are to be interpreted as described in the *HL7 Version 3 Publishing Facilitator's Guide*:

- SHALL: an absolute requirement
- SHALL NOT: an absolute prohibition against inclusion
- SHOULD/SHOULD NOT: valid reasons to include or ignore a particular item, but must be understood and carefully weighed
- MAY/NEED NOT: truly optional; can be included or omitted as the author decides with no implications

XML Examples

XML samples appear in various figures in this document in a fixed-width font. Portions of the XML content may be omitted from the content for brevity, marked by an ellipsis (...) as shown in the example below.

```
<ClinicalDocument xmlns='urn:h17-org:v3'>
    ...
</ClinicalDocument>
```

Figure 4: ClinicalDocument example

XPath expressions are used in the narrative and conformance requirements to identify elements because they are familiar to many XML implementers.

Contents of the DSTU Ballot Package

Table 1: Contents of the DSTU Ballot Package

Filename	Description
CDAR2_IG_TBPN_R1_O1_2010MAY.pdf	This guide
GeneticTestingReport.xml	The Genetic Testing Report sample
cda.xsl	A generic stylesheet for displaying the content of the sample document in HTML

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DOCUMENT TEMPLATES

Topics:

 Tuberculosis Follow Up Progress Note This section contains the document level constraints for CDA documents that are compliant with this implementation guide.

Tuberculosis Follow Up Progress Note

[ClinicalDocument: templateId 2.16.840.1.113883.10.20.15.2.6.1.1.1.1.2.3]

The CDA for Tuberculosis Follow Up Progress Note constrains CDA to express the data elements identified by the CRSWg as specific to a follow-up report of tuberculosis. Tuberculosis (TB) is a contagious and potentially life-threatening infectious disease caused by a bacterium called Mycobacterium tuberculosis. The tuberculosis bacteria are spread from person to person through the air.

- 1. Conforms to RIM Infrastructure Root
- 2. Conforms to RIM Act
- 3. Conforms to CDA Clinical Document
- 4. [TBPN] SHALL contain [1..1] component such that it
 - a. SHALL contain [1..1] TB Results Section (templateId: 2.16.840.1.113883.10.20.15.2.6)
- **5.** [TBPN] **SHALL** satisfy: There can be any number of patient names, but at least one of them must include a given and family name.

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"</pre>
xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <templateId root="2.16.840.1.113883.10.20.15.2.6.1.1.1.1.1.2.3"</pre>
assigningAuthorityName="PILOT Tuberculosis Follow Up Progress Note"/>
  <component>
    <structuredBody>
      <component>
        <section>
          <templateId root="2.16.840.1.113883.10.20.1.14"</pre>
 assigningAuthorityName="CCD Results Section"/>
          <templateId root="2.16.840.1.113883.10.20.15.2.6"</pre>
assigningAuthorityName="PILOT TB Results Section"/>
          <code code="30954-2" codeSystem="2.16.840.1.113883.6.1"</pre>
 codeSystemName="LOINC" displayName="Relevant diagnostic tests and/or
 laboratory data"/>
          <title>Relevant diagnostic tests and/or laboratory data</title>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 5: Tuberculosis Follow Up Progress Note example

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SECTION TEMPLATES

Topics:

• TB Results Section

TB Results Section

```
[Section: templateId 2.16.840.1.113883.10.20.15.2.6]
```

The tuberculosis results section represents the name of the laboratory tests, the date that the specimens for the laboratory tests were taken from the subject of the case report, and the date that the tests were performed on the specimen. It represents the result of the laboratory tests and observation ranges and susceptibility results. In addition, it captures the name of organization where the specimens were collected.

- 1. Conforms to RIM Infrastructure Root
- 2. Conforms to RIM Act
- **3.** Conforms to *CDA Section*
- **4.** Conforms to *CCD Results Section* template (templateId: 2.16.840.1.113883.10.20.1.14)
- 5. [TBPN] SHALL contain [1..1] code/@code = "30954-2" Relevant diagnostic tests and/or laboratory data (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC 2.26)
- 6. [TBPN] SHALL contain [1..1] title = "Relevant diagnostic tests and/or laboratory data"
- 7. [CCD] **SHOULD** contain [1..*] entry such that it
 - **a. SHALL** contain [1..1] *CCD Result Organizer* (templateId: 2.16.840.1.113883.10.20.1.32)
- 8. [TBPN] SHALL contain [1..1] text
- **9.** [TBPN] **MAY** contain [0..*] entry such that it
 - **a. SHALL** contain [1..1] @typeCode="DRIV" *DRIV* (is derived from)
 - **b. SHALL** contain [1..1] *TB Result Organizer* (templateId: 2.16.840.1.113883.10.20.15.3.21)
- 10. [TBPN] MAY contain [0..*] entry such that it
 - **a. SHALL** contain [1..1] @typeCode="DRIV" *DRIV* (is derived from)
 - **b. SHALL** contain [1..1] *TB Result Observation* (templateId: 2.16.840.1.113883.10.20.15.3.13)
- 11. [CCD] SHOULD satisfy: Contains a case-insensitive language-insensitive string containing 'results'.

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"</pre>
xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <templateId root="2.16.840.1.113883.10.20.1.14"</pre>
 assigningAuthorityName="CCD Results Section"/>
          <templateId root="2.16.840.1.113883.10.20.15.2.6"</pre>
 assigningAuthorityName="PILOT TB Results Section"/>
          <code code="30954-2" codeSystem="2.16.840.1.113883.6.1"</pre>
 codeSystemName="LOINC" displayName="Relevant diagnostic tests and/or
 laboratory data"/>
          <title>Relevant diagnostic tests and/or laboratory data</title>
          <entry>
            <organizer moodCode="EVN">
               <templateId root="2.16.840.1.113883.10.20.1.32"</pre>
 assigningAuthorityName="CCD Result Organizer"/>
              <templateId root="2.16.840.1.113883.10.20.15.3.21"</pre>
assigningAuthorityName="PILOT TB Result Organizer"/>
              <id root="79d4f586-1641-43cb-b65d-8f0772ce34ac"/>
              <code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/</pre>
              <statusCode/>
            </organizer>
          </entry>
          <entry>
            <observation classCode="OBS" moodCode="EVN">
               <templateId root="2.16.840.1.113883.10.20.1.31"</pre>
assigningAuthorityName="CCD Result Observation"/>
```

```
<templateId root="2.16.840.1.113883.10.20.15.3.13"</pre>
assigningAuthorityName="PILOT TB Result Observation"/>
              <id root="e83e311e-d3ec-41a6-9b9a-79431fdf7f0a"/>
              <code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/</pre>
              <statusCode code="completed"/>
              <effectiveTime>
                <low value="1972"/>
                <high value="2008"/>
              </effectiveTime>
              <interpretationCode/>
              <methodCode/>
            </observation>
          </entry>
        </section>
      </component>
    </structuredBody>
 </component>
</ClinicalDocument>
```

Figure 6: TB Results Section example

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CLINICAL STATEMENT TEMPLATES

Topics:

- TB Result Observation
- TB Result Organizer

This section of the Implementation Guide details the clinical statement entries referenced in the document section templates. The clinical statement entry templates are arranged alphabetically.

TB Result Observation

[Observation: templateId 2.16.840.1.113883.10.20.15.3.13]

This clinical statement represents the name of the laboratory test, the date that the specimen for the laboratory test was taken from the subject of the case report, the date that the laboratory test was performed on the specimen, and the result of the laboratory test. If applicable, it may capture the physical body location from where the specimen for the lab report was taken from the subject. In addition, it captures the name of organization where the specimen was collected. This tuberculosis result observation also contains a susceptibility clinical statement.

- 1. Conforms to RIM Infrastructure Root
- 2. Conforms to RIM Act
- 3. Conforms to CDA Clinical Statement
- 4. Conforms to CDA Observation
- 5. Conforms to CCD Result Observation template (templateId: 2.16.840.1.113883.10.20.1.31)
- 6. [TBPN] SHALL contain [1..1] @classCode = "OBS"
- 7. [CCD] SHALL contain [1..1] @moodCode = "EVN"
- 8. [CCD] SHALL contain [1..*] id
- 9. [CCD] SHOULD contain [1..1] effectiveTime
 - Represents the biologically relevant time (e.g. time the specimen was obtained from the patient).
- 10. [TBPN] SHALL contain [1..1] statusCode/@code = "completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus STATIC V3NE08)
- 11. [TBPN] SHALL contain [1..1] code, which SHALL be selected from ValueSet 2.16.840.1.114222.4.11.3205 Lab Test Result Name (TB) DYNAMIC
- 12. [CCD] MAY contain [0..1] methodCode
 - Included if the method isn't inherent in code or if there is a need to further specialize the method in code.
- 13. [CCD] SHOULD contain [0..*] interpretationCode
 - Can be used to provide a rough qualitative interpretation of the observation, such as 'N' (normal), 'L' (low), 'S' (susceptible), etc. Interpretation is generally provided for numeric results where an interpretation range has been defined, or for antimicrobial susceptibility test interpretation.
- 14. [CCD] SHALL contain [1..1] value
- **15.** [CCD] **SHOULD** satisfy: The value for 'code' SHOULD be selected from LOINC (codeSystem 2.16.840.1.113883.6.1) or SNOMED CT (codeSystem 2.16.840.1.113883.6.96), and MAY be selected from CPT-4 (codeSystem 2.16.840.1.113883.6.12).
- 16. [CCD] SHALL satisfy: The methodCode SHALL NOT conflict with the method inherent in code
- **17.** [CCD] **SHALL** satisfy: Where value is a physical quantity, the unit of measure SHALL be expressed using a valid Unified Code for Units of Measure (UCUM) expression.
- **18.** [CCD] **SHOULD** satisfy: Contain one or more referenceRange to show the normal range of values for the observation result
- **19.** [CCD] **SHALL** satisfy: SHALL NOT contain referenceRange / observationRange / code, as this attribute is not used by the HL7 Clinical Statement or Lab Committee models.
- 20. [CCD] SHALL satisfy: Contains one or more sources of information.

```
<templateId root="2.16.840.1.113883.10.20.15.3.13"</pre>
assigningAuthorityName="PILOT TB Result Observation"/>
              <id root="be05bc88-0c34-4794-83b5-80c371191272"/>
              <code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/</pre>
              <statusCode code="completed"/>
              <effectiveTime>
                <low value="1972"/>
                <high value="2008"/>
              </effectiveTime>
              <interpretationCode/>
               <methodCode/>
            </observation>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 7: TB Result Observation example

TB Result Organizer

```
[Organizer: templateId 2.16.840.1.113883.10.20.15.3.21]
```

The tuberculosis result organizer identifies an observation set, contained within the result organizer as a set of result observations. It contains information applicable to all of the contained result observations. It is particularly useful to group a number of tests, such as culture results, that are performed on a common specimen.

- 1. Conforms to RIM Infrastructure Root
- 2. Conforms to RIM Act
- 3. Conforms to CDA Clinical Statement
- 4. Conforms to CDA Organizer
- 5. Conforms to CCD Result Organizer template (templateId: 2.16.840.1.113883.10.20.1.32)
- **6.** [CCD] **SHALL** contain [1..1] @moodCode = "EVN"
- 7. [CCD] SHALL contain [1..*] component such that it
 - a. SHALL contain [1..1] CCD Result Observation (templateId: 2.16.840.1.113883.10.20.1.31)
- 8. [CCD] SHOULD contain [1..*] specimen such that it
 - a. SHALL contain [1..1] CDA Specimen
- **9.** [CCD] **SHALL** contain [1..*] id
- 10. [TBPN] SHALL contain [1..1] code, which SHALL be selected from ValueSet 2.16.840.1.114222.4.11.3205 Lab Test Result Name (TB) DYNAMIC
- 11. [CCD] SHALL contain [1..1] statusCode
- 12. [TBPN] SHALL contain [1..1] component such that it
 - **a. SHALL** contain [1..1] *TB Result Observation* (templateId: 2.16.840.1.113883.10.20.15.3.13)
- 13. [CCD] SHOULD satisfy: The value for 'code' in a result organizer SHOULD be selected from LOINC (codeSystem 2.16.840.1.113883.6.1) or SNOMED CT (codeSystem 2.16.840.1.113883.6.96), and MAY be selected from CPT-4 (codeSystem 2.16.840.1.113883.6.12) or ValueSet 2.16.840.1.113883.1.11.20.16 ResultTypeCode STATIC.
- 14. [CCD] SHOULD satisfy: Contains one or more Specimen if the specimen isn't inherent in code value.
- 15. [CCD] SHALL satisfy: The specimen element SHALL NOT conflict with the specimen inherent in code
- 16. [CCD] SHALL satisfy: Contains one or more component
- 17. [CCD] MAY satisfy: The target of one or more result organizer component relationships MAY be a procedure, to indicate the means or technique by which a result is obtained, particularly if the means or technique isn't inherent in code or if there is a need to further specialize the code value.

- **18.** [CCD] **MAY** satisfy: A result organizer component / procedure MAY be a reference to a procedure described in the Procedure section.
- 19. [CCD] SHALL satisfy: Contains one or more sources of information.

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"</pre>
xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <organizer moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.32"</pre>
assigningAuthorityName="CCD Result Organizer"/>
              <templateId root="2.16.840.1.113883.10.20.15.3.21"</pre>
assigningAuthorityName="PILOT TB Result Organizer"/>
              <id root="0dfe5a89-d87b-40f4-bb11-06eaebf69e2f"/>
              <code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/</pre>
              <statusCode/>
              <component>
                 <observation classCode="OBS" moodCode="EVN">
                   <templateId root="2.16.840.1.113883.10.20.1.31"</pre>
assigningAuthorityName="CCD Result Observation"/>
                   <templateId root="2.16.840.1.113883.10.20.15.3.13"</pre>
 assigningAuthorityName="PILOT TB Result Observation"/>
                   <id root="1704e90b-dd2a-4395-885c-4dc9c952940e"/>
                   <code codeSystem="2.16.840.1.113883.6.1"</pre>
 codeSystemName="LOINC"/>
                   <statusCode code="completed"/>
                   <effectiveTime>
                     <low value="1972"/>
                     <high value="2008"/>
                   </effectiveTime>
                   <interpretationCode/>
                   <methodCode/>
                </observation>
              </component>
            </organizer>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 8: TB Result Organizer example

5

OTHER CLASSES

This section of the Implementation Guide describes other classes that are not CDA Clinical Documents, Sections, or Clinical Statements.

REFERENCES

- HL7 Implementation Guide: CDA Release 2 Continuity of Care Document (CCD) A CDA implementation of ASTM E2369-05 Standard Specification for Continuity of Care Record[©] (CCR) April 01, 2007 available through HL7.
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