Implementation Guide for CDA Release 2
CDA Tools Design Pilot
(U.S. Realm)

Draft Standard for Trial Use
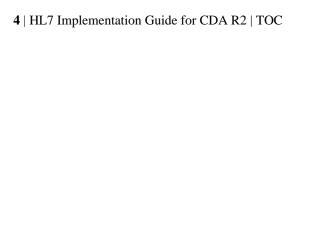## First Ballot
May 2010
CDAR2_IG_TBPN_R1_O1_2010MAY

Contents

Authors

Co-Chair	Robert H. Dolin, MD Semantically Yours, LLC bobdolin@gmail.com
Co-Chair	Liora Alschuler Alschuler Associates, LLC liora@alschulerassociates.com
Co-Chair	Calvin Beebe Mayo Clinic cbeebe@mayo.edu
Co-Chair	Keith W. Boone GE Healthcare keith.boone@ge.com
Primary Editor	Amnon Shabo, Ph.D. IBM Research SHABO@il.ibm.com
Co-Editor	Dave Carlson, Ph.D. U.S. Department of Veterans Affairs David.Carlson@va.gov
Current Working Group also includes:	Kate Conrad, Bobby George, Andy Spooner, David Muraco, Diane Ward, Celeste Milton, Jean Millar, Ann Watt, Shaun Shakib, Sandy Stuart, Brett Marquard, Jingdong (JD) Li, Anneke Goossen, William Goossen, Teresa Finitzo

Acknowledgments

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

Chapter

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.XX.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:hl7-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

Chapter

2

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 `2.16.840.1.113883.10.20.15.2.6.1.1.1.1.1.2.3`]

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** *CDA Clinical Document*
2. **SHALL** contain [1..1] `component`, such that it

   a. contains *TB Results Section* (templateId: `2.16.840.1.113883.10.20.15.2.6`)
3. **SHALL** satisfy: There can be any number of patient names, but at least one of them must include a given and family name.

```xml
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 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"
 assigningAuthorityName="PILOT Tuberculosis Follow Up Progress Note"/>
  <component>
    <structuredBody>
      <component>
        <section>
          <templateId root="2.16.840.1.113883.10.20.1.14"
 assigningAuthorityName="CCD Results Section"/>
          <templateId root="2.16.840.1.113883.10.20.15.2.6"
 assigningAuthorityName="PILOT TB Results Section"/>
          <code code="30954-2" codeSystem="2.16.840.1.113883.6.1"
 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

Chapter

3

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 *CCD Results Section* template (templateId: `2.16.840.1.113883.10.20.1.14`)
2. **MAY** contain [0..*] `entry`, such that it

    a. has @typeCode="DRIV" *DRIV (is derived from)*
    b. contains *TB Result Organizer* (templateId: `2.16.840.1.113883.10.20.15.3.21`)
3. **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)
4. **SHALL** contain [1..1] `text`
5. **SHALL** contain [1..1] `title` = "Relevant diagnostic tests and/or laboratory data"
6. **MAY** contain [0..*] `entry`, such that it

    a. has @typeCode="DRIV" *DRIV (is derived from)*
    b. contains *TB Result Observation* (templateId: `2.16.840.1.113883.10.20.15.3.13`)

```xml
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 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"
 assigningAuthorityName="CCD Results Section"/>
          <templateId root="2.16.840.1.113883.10.20.15.2.6"
 assigningAuthorityName="PILOT TB Results Section"/>
          <code code="30954-2" codeSystem="2.16.840.1.113883.6.1"
 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"
 assigningAuthorityName="CCD Result Organizer"/>
              <templateId root="2.16.840.1.113883.10.20.15.3.21"
 assigningAuthorityName="PILOT TB Result Organizer"/>
              <id root="9e26a1ae-c327-4033-8a47-3c6d53d8115f"/>
              <code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/
>
              <statusCode/>
            </organizer>
          </entry>
          <entry>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.31"
 assigningAuthorityName="CCD Result Observation"/>
              <templateId root="2.16.840.1.113883.10.20.15.3.13"
 assigningAuthorityName="PILOT TB Result Observation"/>
              <id root="af1370e2-a85b-4abc-8c78-b7657e30a2d4"/>
              <code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/
>
              <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

Chapter

4

CLINICAL STATEMENT TEMPLATES

Topics:

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 *CCD Result Observation* template (templateId: `2.16.840.1.113883.10.20.1.31`)
2. **SHALL** contain [1..1] @classCode = "OBS"
3. **SHALL** contain [1..1] code, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.3205 Lab Test Result Name (TB) STATIC 1
4. **SHALL** contain [1..1] statusCode/@code = "completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus STATIC V3NE08)

```xml
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.31"
 assigningAuthorityName="CCD Result Observation"/>
              <templateId root="2.16.840.1.113883.10.20.15.3.13"
 assigningAuthorityName="PILOT TB Result Observation"/>
              <id root="69ea4254-1d28-4a31-8db5-9838121d3a34"/>
              <code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/
>
              <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 *CCD Result Organizer* template (templateId: `2.16.840.1.113883.10.20.1.32`)
2. **SHALL** contain [1..1] code, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.3205 Lab Test Result Name (TB) STATIC 1

3. **SHALL** contain [1..1] `component`, such that it

    a. contains *TB Result Observation* (templateId: `2.16.840.1.113883.10.20.15.3.13`)

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 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"
 assigningAuthorityName="CCD Result Organizer"/>
              <templateId root="2.16.840.1.113883.10.20.15.3.21"
 assigningAuthorityName="PILOT TB Result Organizer"/>
              <id root="d2a5530c-552f-4f39-bf3b-4a8b46b80372"/>
              <code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/
>
              <statusCode/>
              <component>
                <observation classCode="OBS" moodCode="EVN">
                  <templateId root="2.16.840.1.113883.10.20.1.31"
 assigningAuthorityName="CCD Result Observation"/>
                  <templateId root="2.16.840.1.113883.10.20.15.3.13"
 assigningAuthorityName="PILOT TB Result Observation"/>
                  <id root="5f51898f-48c9-4ccf-977b-8a01f8f4225b"/>
                  <code codeSystem="2.16.840.1.113883.6.1"
 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

Chapter

5

OTHER CLASSES

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

Chapter

6

VALUE SETS

The following tables summarize the value sets used in this Implementation Guide.

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* .
- HL7 Implementation Guide for CDA Release 2 Quality Reporting Document Architecture (QRDA) Draft Standard for Trial Use March 2009. Available at: *Quality Reporting Document Architecture (QRDA)*
- HL7 Implementation Guide for CDA Release 2 CDA for Public Health Case Reports (PHCR) Informative Standard October 2009. Available through *HL7* .
- HL7 Implementation Guide for CDA Release 2: NHSN Healthcare Associated Infection (HAI) Reports, Release 2 Draft Standard for Trial Use January 2009 Available at: *NHSN Healthcare Associated Infection (HAI) Reports*
- Dolin RH, Alschuler L, Boyer S, Beebe C, Behlen FM, Biron PV, Shabo A, (Editors). HL7 Clinical Document Architecture, Release 2.0. ANSI-approved HL7 Standard; May 2005. Ann Arbor, Mich.: Health Level Seven, Inc. Available through *HL7* or if an HL7 member with the following link: *CDA Release 2 Normative Web Edition.*
- *LOINC®* : Logical Observation Identifiers Names and Codes, Regenstrief Institute.
- *SNOMED CT®* : SNOMED Clinical Terms SNOMED International Organization.
- Extensible Markup Language, *www.w3.org/XML* .
- Dolin RH, Alschuler L, Boyer S, Beebe C, Behlen FM, Biron PV, Shabo A., HL7 Clinical Document Architecture, Release 2. J Am Med Inform Assoc. 2006;13:30-39. Available at: *http://www.jamia.org/cgi/reprint/13/1/30* .
- Using SNOMED CT in HL7 Version 3; Implementation Guide, Release 1.5. Available through *HL7* or if an HL7 member with the following link: *Using SNOMED CT in HL7 Version 3*