Implementation Guide for CDA Release 2 Early Hearing Care Plan Optional Subtitle



PROTOTYPE: FOR DISCUSSION AND DEMONSTRATION USE ONLY

Contents

Acknowledgments	5
Revision History	7
	_
List of Figures	9
Chapter 1: INTRODUCTION	
Overview	
Approach	
Scope	
Audience	
Organization of This Guide	
Templates	
Vocabulary and Value Sets	
Use of Templates	
Originator Responsibilities	
Recipient Responsibilities	
Conventions Used in This Guide	
Conformance Requirements	
Keywords	
XML Examples	14
Chapter 2: DOCUMENT TEMPLATES	17
Early Hearing Care Plan Document	18
Chapter 3: SECTION TEMPLATES	21
Hearing Screening Coded Results Section	
Risk Indicators For Hearing Loss Section	
Risk indicators for flearing Loss Section.	22
Characa A. CLINICAL STATEMENT TEMPI ATES	22
Chapter 4: CLINICAL STATEMENT TEMPLATES	23
Charles 5. OTHER CLASSES	25
Chapter 5: OTHER CLASSES	25
Chantan C. VALUE CETS	27
Chapter 6: VALUE SETS	
REFERENCES	29

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Revision History

Rev	Date	By Whom	Changes
New	July 2010	Dave Carlson	
First draft for posting	December 2010	Dave Carlson	Updated model content and publication format

List of Figures

Figure 1: Template name and "conforms to" appearance	.13
Figure 2: Template-based conformance statements example.	. 14
Figure 3: CCD conformance statements example.	. 14
Figure 4: ClinicalDocument example.	. 14

1

INTRODUCTION

Topics:

- Overview
- Approach
- Scope
- Audience
- Organization of This Guide
- Use of Templates
- Conventions Used in This Guide

Overview

This implementation guide is generated from UML models developed in the Open Health Tools (OHT) Model-Driven Health Tools (MDHT) project. The data specifications have been formalized into computational models expressed in UML. These models are used by automated tooling to generate this publication, plus validation tools and Java libraries for implementers.

Approach

Working with specifications generated from formal UML models 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.

2

DOCUMENT TEMPLATES

Topics:

 Early Hearing Care Plan Document This section contains the document level constraints for CDA documents that are compliant with this implementation guide.

Early Hearing Care Plan Document

[ClinicalDocument: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.15.4.1]

- 1. SHALL conform to *IHE Medical Document* template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.1)
- 2. SHALL contain exactly one [1..1] code (CONF-HP-21)/@code="34817-7" Otorhinolaryngology Evaluation and management (CodeSystem: 2.16.840.1.113883.6.1 LOINC)
- **3.** Contains zero or one [0..1] component
 - **a.** Contains exactly one [1..1] *Risk Indicators For Hearing Loss Section* (templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.15.3.1)
- **4.** Contains zero or one [0..1] **component**
 - **a.** Contains exactly one [1..1] *IHE Active Problems Section* (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.6)
- 5. Contains zero or one [0..1] component
 - **a.** Contains exactly one [1..1] *IHE Physical Exam Section* (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.9.15)
- **6.** Contains zero or one [0..1] **component**
 - **a.** Contains exactly one [1..1] *IHE Review Of Systems Section* (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.18)
- 7. Contains zero or one [0..1] component
 - **a.** Contains exactly one [1..1] *IHE Procedures And Interventions Section* (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.13.2.11)
- **8.** Contains zero or one [0..1] **component**
 - **a.** Contains exactly one [1..1] *Hearing Screening Coded Results Section* (templateId: 1.3.6.1.4.1.19376.1.7.3.1.1.15.3.2)

Early Hearing Care Plan Document example

```
<?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">
 <typeId root="2.16.840.1.113883.1.3"/>
 <id root="MDHT" extension="1100916249"/>
 <code code="1539597524"/>
 <title>TEXT FOR TITLE</title>
 <effectiveTime/>
 <confidentialityCode code="1641224475"/>
 <languageCode code="Code forlanguageCode"/>
 <recordTarget>
    <typeId root="2.16.840.1.113883.1.3"/>
    <patientRole/>
 </recordTarget>
  <author>
    <typeId root="2.16.840.1.113883.1.3"/>
   <time/>
    <assignedAuthor/>
  </author>
  <custodian/>
  <component>
    <structuredBody>
      <component>
        <section>
          <typeId root="2.16.840.1.113883.1.3"/>
          <id root="MDHT" extension="2095020919"/>
```

```
<code code="1044247872"/>
          <title>TEXT FOR TITLE</title>
          <languageCode code="Code forlanguageCode"/>
        </section>
      </component>
      <component>
        <section/>
      </component>
      <component>
        <section/>
      </component>
      <component>
        <section/>
      </component>
      <component>
        <section/>
      </component>
      <component>
        <section>
          <typeId root="2.16.840.1.113883.1.3"/>
          <id root="MDHT" extension="250837362"/>
          <code code="1621539580"/>
          <title>TEXT FOR TITLE</title>
          <languageCode code="Code forlanguageCode"/>
          <entry>
            <act/>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

3

SECTION TEMPLATES

Topics:

- Hearing Screening Coded Results Section
- Risk Indicators For Hearing Loss Section

Hearing Screening Coded Results Section

[Section: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.15.3.2]

The Hearing Screening Code Results section SHALL include at least one observation entry describing the hearing screening results as described in the Entry Content Module.

Where there are no hearing screening results performed, then the reason SHALL be indicated.

1. SHALL conform to *IHE Coded Results Section* template (templateId:

```
1.3.6.1.4.1.19376.1.5.3.1.3.28)
```

- **2.** Contains zero or one [0..1] **entry**
 - **a.** Contains exactly one [1..1] *IHE Procedure Entry* (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.19)
- **3.** Contains zero or one [0..1] **entry**
 - **a.** Contains exactly one [1..1] *IHE External Reference* (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.4)
- **4.** Contains zero or one [0..1] **entry**
 - **a.** Contains exactly one [1..1] *IHE Simple Observation* (templateId:

```
1.3.6.1.4.1.19376.1.5.3.1.4.13)
```

Hearing Screening Coded Results Section example

Risk Indicators For Hearing Loss Section

[Section: templateId 1.3.6.1.4.1.19376.1.7.3.1.1.15.3.1]

This section SHALL include at least one entry describing hearing risk indicators for the subject.

1. Contains zero or one [0..1] code

Risk Indicators For Hearing Loss Section example

4

CLINICAL STATEMENT TEMPLATES

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.

5

OTHER CLASSES

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



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*