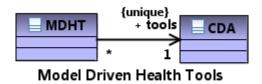
Implementation Guide for CDA Release 2 MDHT Example Project Optional Subtitle



PROTOTYPE: FOR DISCUSSION AND DEMONSTRATION USE ONLY



Contents

Acknowledgments	
Revision History	
Chapter 1: INTRODUCTION	9
Overview	10
Approach	10
Scope	10
Audience	10
Organization of This Guide	10
Templates	10
Vocabulary and Value Sets	
Use of Templates	11
Originator Responsibilities	
Recipient Responsibilities	11
Conventions Used in This Guide	
Conformance Requirements	11
Keywords	
XML Examples	
Chapter 2: DOCUMENT TEMPLATES	13
Chapter 3: SECTION TEMPLATES	
Chapter 4: CLINICAL STATEMENT TEMPLATES	
•	
Chapter 5: OTHER CLASSES	
•	
Chapter 6: VALUE SETS	2 1
REFERENCES	
<u></u>	



Acknowledgments

This document contains an example of healthcare standards and specifications publication generated from UML models, using the OHT Model Driven Health Tools (MDHT). Some portions of this document may not be publicly available but are included for demonstration purposes only, therefore this version of the document is to be treated as CONFIDENTIAL by the project participants.

This demonstration document contains informtion from the following sources:

©2010 ANSI. This material may be copied without permission from ANSI only if and to the extent that the text is not altered in any fashion and ANSI's copyright is clearly noted.

SNOMED CT® is the registered trademark of the International Health Terminology Standard Development Organization (IHTSDO).

This material contains content from LOINC® (http://loinc.org). The LOINC table, LOINC codes, and LOINC panels and forms file are copyright © 1995-2010, Regenstrief Institute, Inc. and the Logical Observation Identifiers Names and Codes (LOINC) Committee and available at no cost under the license at http://loinc.org/terms-of-use.

Certain materials contained in this Interoperability Specification are reproduced from Health Level Seven (HL7) HL7 Implementation Guide: CDA Release 2 – Continuity of Care Document (CCD), HL7 Implementation Guide for CDA Release 2: History and Physical (H&P) Notes, HL7 Implementation Guide for CDA Release 2: Consult Notes, or HL7 Implementation Guide for CDA Release 2: Operative Notes with permission of Health Level Seven, Inc. No part of the material may be copied or reproduced in any form outside of the Interoperability Specification documents, including an electronic retrieval system, or made available on the Internet without the prior written permission of Health Level Seven, Inc. Copies of standards included in this Interoperability Specification may be purchased from the Health Level Seven, Inc. Material drawn from these standards is credited where used.



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



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>
```

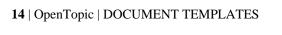
Figure 4: ClinicalDocument example

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

2

DOCUMENT TEMPLATES

This section contains the document level constraints for CDA documents that are compliant with this implementation guide.



3

SECTION TEMPLATES

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*