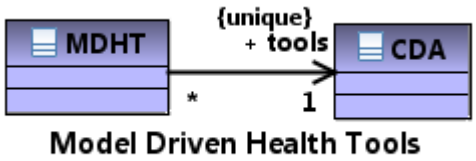

Implementation Guide for CDA® Release 2

MDHT Example Project

Optional Subtitle

HL7 Ballot

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Acknowledgments

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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

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Chapter 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 `templateId`s 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 `templateId`s).

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: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.

Chapter 2

DOCUMENT TEMPLATES

Topics:

- *emshospitaloutcomes*

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

emshospitaloutcomes

[ClinicalDocument: templateId `2.16.840.1.113883.17.3.10.3`]

A section to contain information from the patient's encounter with the Emergency Department

1. **SHALL** contain exactly one [1..1] templateId such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.17.3.10.3"
2. **MAY** contain [0..1] **`component`**
   a. Contains exactly one [1..1] *ED Outcomes Section*
3. contain [0..1] **`componentOf`**
   a. Contains exactly one [1..1] CDA Encompassing Encounter

emshospitaloutcomes example

```
Error: Missing Runtime Class
```

Chapter 3

SECTION TEMPLATES

Topics:

- *ED Chief Complaint Section*
- *ED Discharge Disposition Section*
- *ED Outcomes Section*
- *ED Procedures Section*
- *Inpatient Discharge Diagnosis Section*
- *Inpatient Outcomes Section*
- *Inpatient Procedures Section*

ED Chief Complaint Section

[Section: templateId `null`]

1. **SHALL** contain zero or one [0..1] **`code`**
2. contains zero or more [0..*] **`templateId`**
3. **SHALL** contain zero or one [0..1] **`text`**
4. **SHALL** contain zero or one [0..1] **`title`** and **SHOULD** equal "Emergency Department Chief Complaint"

ED Chief Complaint Section example

```
Error: Missing Runtime Class
```

ED Discharge Disposition Section

[Section: templateId `null`]

1. **SHALL** contain zero or one [0..1] **`code`**, which **SHALL** be selected from
2. contains zero or more [0..*] **`templateId1`** with @xsi:type="II"
3. contain zero or one [0..1] **`text`**
4. contain zero or one [0..1] **`title`**

ED Discharge Disposition Section example

```
Error: Missing Runtime Class
```

ED Outcomes Section

[Section: templateId `null`]

Contained By	Contains
ems Hospital Outcomes	

1. **SHALL** contain zero or one [0..1] **`code/@code`**="`LOINC_TBD_001`" *Emergency Department Outcomes Section* (CodeSystem: `2.16.840.1.113883.6.1` `LOINC`)
2. contains zero or more [0..*] **`templateId`**
3. **SHALL** contain zero or one [0..1] **`text`**
4. **SHALL** contain zero or one [0..1] **`title`** and **SHOULD** equal "Emergency Department Outcomes Information"

ED Outcomes Section example

```
Error: Missing Runtime Class
```

ED Procedures Section

[Section: templateId `null`]

1. contain zero or one [0..1] **code**
2. contains zero or more [0..*] **templateId1** with @xsi:type="II"
3. contain zero or one [0..1] **text**
4. contain zero or one [0..1] **title**

ED Procedures Section example

```
Error: Missing Runtime Class
```

Inpatient Discharge Diagnosis Section

[Section: templateId `null`]

1. **SHALL** contain exactly one [1..1] **code/@code**="11535-2" *Hospital Discharge Diagnosis* (CodeSystem: 2.16.840.1.113883.6.1 LOINC)
2. **SHALL** contain at least one [1..*] **templateId1** with @xsi:type="II"
3. **SHALL** contain exactly one [1..1] **text**
4. **SHALL** contain exactly one [1..1] **title** and **SHOULD** equal "Inpatient Discharge Diagnosis"

Inpatient Discharge Diagnosis Section example

```
Error: Missing Runtime Class
```

Inpatient Outcomes Section

[Section: templateId `null`]

1. **SHALL** contain at least one [1..*] **code**, which **SHALL** be selected from (CodeSystem: 2.16.840.1.113883.6.1 LOINC)
2. contains at least one [1..*] **templateId**
3. contain exactly one [1..1] **text**
4. contain exactly one [1..1] **title**

Inpatient Outcomes Section example

```
Error: Missing Runtime Class
```

Inpatient Procedures Section

[Section: templateId `null`]

1. **SHALL** contain exactly one [1..1] **code**
2. **SHALL** contain at least one [1..*] **templateId**
3. **SHALL** contain exactly one [1..1] **text**
4. **SHALL** contain exactly one [1..1] **title** and **SHOULD** equal "Inpatient Hospital Procedures"

Inpatient Procedures Section example

```
Error: Missing Runtime Class
```

Chapter 4

CLINICAL STATEMENT TEMPLATES

Topics:

- *ED Cause Of Injury Observation*
- *ED Discharge Diagnosis*
- *ED Discharge Disposition Observation*
- *ED Systolic BP Observation*
- *EMS Outcomes Procedure*
- *ICU Length Of Stay Observation*
- *Inpatient Discharge Diagnosis Act*
- *Inpatient Discharge Diagnosis Observation*
- *Patient Degree Of Disability At Discharge*
- *Ventilator Days Observation*

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.

ED Cause Of Injury Observation

[Observation: templateId `null`]

1. **SHALL** contain exactly one [1..1] **`code/@code`**="`69543-7`" *Cause of injury NEMSIS* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`)
2. **SHALL** contain zero or more [0..*] **`value`** with @xsi:type="CD", which **SHALL** be selected from (CodeSystem:)
   - *NEMSIS Trace: eOutcome.08 - Emergency Department Recorded Cause of Injury*

ED Cause Of Injury Observation example

```
Error: Missing Runtime Class
```

ED Discharge Diagnosis

[Observation: templateId `null`]

1. **SHALL** contain exactly one [1..1] **`code/@code`**="`LOINC_TBD_002`" *Emergency Department Discharge Diagnosis* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`)
2. **SHALL** contain zero or more [0..*] **`value`** with @xsi:type="CD", which **SHALL** be selected from (CodeSystem:)
   - *NEMSIS trace: eOutcome.10*

ED Discharge Diagnosis example

```
Error: Missing Runtime Class
```

ED Discharge Disposition Observation

[Observation: templateId `null`]

1. **SHALL** contain exactly one [1..1] **`code/@code`**="`74285-8`" *ED discharge disposition [NTDS]* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`)
2. contains zero or more [0..*] **`templateId1`** with @xsi:type="II"
3. **SHALL** contain zero or more [0..*] **`value`** with @xsi:type="CD", which **SHALL** be selected from ValueSet *`EDDischargeDisposition`* **STATIC**

ED Discharge Disposition Observation example

```
Error: Missing Runtime Class
```

ED Systolic BP Observation

[Observation: templateId `null`]

1. **SHALL** contain exactly one [1..1] **`code/@code`**="`8480-6`" *BP Systolic* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`)
2. **SHALL** contain zero or more [0..*] **`value`** with @xsi:type="PQ"
   - *NEMSIS Trace: eOutcome.07 - First ED Systolic Blood Pressure*

ED Systolic BP Observation example

```
Error: Missing Runtime Class
```

EMS Outcomes Procedure

[Procedure: templateId `null`]

1. **SHALL** contain zero or one [0..1] **`code`**, which **SHALL** be selected from (CodeSystem:)
   - *NEMSIS Trace: eOutcome.12 - Hospital Procedures, eOutcome.09 - Emergency Department Procedures*
2. **SHALL** contain zero or more [0..*] **`templateId`**

EMS Outcomes Procedure example

```
Error: Missing Runtime Class
```

ICU Length Of Stay Observation

[Observation: templateId `null`]

1. **SHALL** contain exactly one [1..1] **`code`**, which **SHALL** be selected from ValueSet **STATIC**
   - *NEMSIS Trace: eOutcome.14 - Total ICU Length of Stay*
2. **SHALL** contain at least one [1..*] **`templateId`**
3. **SHALL** contain exactly one [1..1] **`value`** with @xsi:type="PQ"

ICU Length Of Stay Observation example

```
Error: Missing Runtime Class
```

Inpatient Discharge Diagnosis Act

[Act: templateId `null`]

1.

Inpatient Discharge Diagnosis Act example

```
Error: Missing Runtime Class
```

Inpatient Discharge Diagnosis Observation

[Observation: templateId `null`]

1. contain exactly one [1..1] **`code`**
2. contains at least one [1..*] **`templateId`**
3. **SHALL** contain zero or more [0..*] **`value`** with @xsi:type="CD", which **SHALL** be selected from (CodeSystem:)
   - *NEMSIS Trace: eOutcome.13 - Hospital Diagnosis*

Inpatient Discharge Diagnosis Observation example

```
Error: Missing Runtime Class
```

Patient Degree Of Disability At Discharge

[Observation: templateId `null`]

1. **SHALL** contain exactly one [1..1] **`code/@code`**`="75859-9"` *Modified rankin scale* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`)
2. **SHALL** contain at least one [1..*] **`templateId`**
3. **SHALL** contain exactly one [1..1] **`value`** with @xsi:type="CD", which **SHALL** be selected from ValueSet *`DegreeOfDisability (Modified rankin scale)`* **STATIC**

Patient Degree Of Disability At Discharge example

```
Error: Missing Runtime Class
```

Ventilator Days Observation

[Observation: templateId `null`]

1. **SHALL** contain exactly one [1..1] **`code/@code`**`="74201-5"` *Days on ventilator* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`)
2. contains at least one [1..*] **`templateId`**
3. contain exactly one [1..1] **`value`** with @xsi:type="PQ"

Ventilator Days Observation example

```
Error: Missing Runtime Class
```

Chapter 5

OTHER CLASSES

Topics:

- *EMS Outcomes Encompassing Encounter*
- *Outcomes Prior Document*

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

EMS Outcomes Encompassing Encounter

[EncompassingEncounter: templateId `null`]

1. **SHALL** contain exactly one [1..1] **`dischargeDispositionCode`**, which **SHALL** be selected from ValueSet *`InpatientDischargeDisposition`* **STATIC**
   - *NEMSIS Trace: eOutcome.02 - Hospital Disposition*
2. **SHALL** contain exactly one [1..1] **`effectiveTime`**
   - *NEMSIS Trace: eOutcome.11 - Date/Time of Hospital Admission, eOutcome.16 - Date/Time of Hospital Discharge*

EMS Outcomes Encompassing Encounter example

```
Error: Missing Runtime Class
```

Outcomes Prior Document

[ExternalDocument: templateId `null`]

1. **SHALL** contain exactly one [1..1] **`code`**, which **SHALL** be selected from ValueSet **STATIC**
   - *NEMSIS Trace: eOutcome.03 - External Report ID/Number Type, eOutcome.05 - Other Report Registry Type. If the type is not found, the type code may be null and the other type text placed in the code original text attribute.*
2. **SHALL** contain exactly one [1..1] **`id`**
   - *NEMSIS Trace: eOutcome.04 - External Report ID/Number. This will typically be placed in the extension, as NEMSIS will not maintain an OID registry for all responder and healthcare organizations. The vendor or implementer may discover or assign OIDS.*
3. contains at least one [1..*] **`templateId1`** with @xsi:type="II"

Outcomes Prior Document example

```
Error: Missing Runtime Class
```

Chapter 6

CLASS REFERENCES

This section of the Implementation Guide describes classes from other implementation guides.

Chapter 7

VALUE SETS

Topics:

- *CMS-1450 Data Set (UB-04)*
- *DegreeOfDisability (Modified rankin scale)*
- *Inpatient Discharge Disposition*
- *LOINC*

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

CMS-1450 Data Set (UB-04)

Value Set	CMS-1450 Data Set (UB-04)

DegreeOfDisability (Modified rankin scale)

Value Set	DegreeOfDisability (Modified rankin scale) - (OID not specified)
Code System	LOINC - 2.16.840.1.113883.6.1

Code	Code System	Print Name
LA6111-4	LOINC	No symptoms
LA6112-2	LOINC	No significant disability despite symptoms; able to carry out all usual duties and activities
LA6113-0	LOINC	Slight disability; unable to carry out all previous activities, but able to look after own affairs without assistance
LA6114-8	LOINC	Moderate disability; requiring some help, but able to walk without assistance
LA6115-5	LOINC	Moderately severe disability; unable to walk without assistance and unable to attend to own bodily needs without assistance
LA10137-0	LOINC	Severe disability; bedridden, incontinent and requiring constant nursing care and attention
LA10138-8	LOINC	Dead

Inpatient Discharge Disposition

Value Set	InpatientDischargeDisposition - (OID not specified)

Code	Code System	Print Name
01		Discharged to home or self care (routine discharge)
02		Discharged/transferred to another short term general hospital for inpatient care
03		Discharged/transferred to a skilled nursing facility (SNF)
04		Discharged/transferred to an intermediate care facility (ICF)
05		Discharged/transferred to another type of institution not defined elsewhere in this code list
06		Discharged/transferred to home under care of organized home health service organization in anticipation of covered skills care
07		Left against medical advice or discontinued care

Code	Code System	Print Name
20		Deceased/Expired (or did not recover - Religious Non Medical Health Care Patient)
21		Discharged/transferred to court/law enforcement
30		Still a patient or expected to return for outpatient services
43		Discharged/transferred to a Federal Health Care Facility (e.g., VA or federal health care facility)
50		Discharged/transferred to Hospice - home
51		Discharged/transferred to Hospice - medical facility
61		Discharged/transferred within this institution to a hospital based Medicare approved swing bed
62		Discharged/transferred to a inpatient rehabilitation facility including distinct part units of a hospital
63		Discharged/transferred to long term care hospitals
64		Discharged/transferred to a nursing facility certified under Medicaid but not certified under Medicare
65		Discharged/transferred to a psychiatric hospital or psychiatric distinct part unit of a hospital
66		Discharged/transferred to a Critical Access Hospital (CAH)
70		Discharged/transferred to another type of health care institution not defined elsewhere in the code list

LOINC

Value Set	LOINC

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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- *LOINC®* : Logical Observation Identifiers Names and Codes, Regenstrief Institute.
- *SNOMED CT®* : SNOMED Clinical Terms SNOMED International Organization.
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