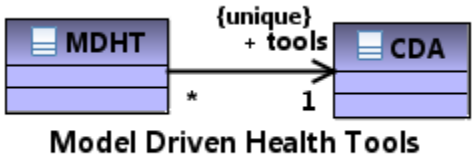
Implementation Guide for CDA Release 2

MEDICATION THERAPY MANAGEMENT PROGRAM

MEDICARE PART D



Model Driven Health Tools

Contents

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:

Revision History

Rev	Date	By Whom	Changes
Draft	January 2012	Sean Muir	

Chapter 1

INTRODUCTION

Topics:

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:

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

MTM

[ClinicalDocument: templateId `111.222.333.444.111`]

1. **SHALL** conform to *Consol General Header Constraints* template (templateId: `2.16.840.1.113883.10.20.22.1.1`)
2. **SHALL** contain exactly one [1..1] **`component`**
   a. Contains exactly one [1..1] *Consol Allergies Section* (templateId: `2.16.840.1.113883.10.20.22.2.6.1`)
3. **SHALL** contain exactly one [1..1] **`component`**
   a. Contains exactly one [1..1] *MTM Medication Section* (templateId: `111.222.333.444.333`)
4. **MAY** contain zero or one [0..1] **`component`**
   a. Contains exactly one [1..1] *Other Information Section* (templateId: `111.222.333.444.444`)

mtm::MTM							
cda::clinicaldocument[cda:templateId/@root =]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
classCode	@classCode	0..1		NO	ActClinicalDocument		DOCCLIN
moodCode	@moodCode	0..1		NO	ActMood		EVN
nullFlavor	@nullFlavor	0..1		NO	NullFlavor		ASKU
code	code	1..1	SHALL	YES	CE	CONF:5253	
confidentialityCode	confidentialityCode	1..1	SHALL	YES	CE	CONF:5259	null
copyTime	copyTime	0..1		YES	TS		
effectiveTime	effectiveTime	1..1	SHALL	YES	TS	CONF:5256	
id	id	1..1	SHALL	YES	II	CONF:5363	
languageCode	languageCode	1..1	SHALL	YES	CS	CONF:5372	
realmCode	realmCode	1..1	SHALL	YES	CS	CONF:5249	null null US
setId	setId	0..1	MAY	YES	II	CONF:5261	
templateId	templateId	0..*		YES	II		
title	title	1..1	SHALL	YES	ST	CONF:5254	
versionNumber	versionNumber	0..1	MAY	YES	INT	CONF:5264	
allergiesSection	allergiesSection	1..1	SHALL	YES	AllergiesSection		
authenticator	authenticator	0..*	MAY	YES	Authenticator	CONF:5607	
author	author	1..*	SHALL	YES	Author	CONF:5444	
authorization	authorization	0..*		YES	Authorization		
component	component	1..1		YES	Component2		
componentOf	componentOf	1..1	MAY	YES	ComponentOf	CONF:9955	
custodian	custodian	1..1	SHALL	YES	Custodian	iv.CONF:5519	
dataEnterer	dataEnterer	0..1	MAY	YES	DataEnterer	CONF:5441	

mtm::MTM							
cda::clinicaldocument[cda:templateId/@root =]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
documentationOf	documentationOf	0..*		YES	DocumentationOf		
informant	informant	0..1	MAY	YES	Informant	CONF:8001	
informationRecipient	informationRecipient	0..*	MAY	YES	InformationRecipient	CONF:5565	
inFulfillmentOf	inFulfillmentOf	0..*	MAY	YES	InFulfillmentOf	CONF:9952	
legalAuthenticator	legalAuthenticator	0..1	SHOULD	YES	LegalAuthenticator	CONF:5579	
medicationsSection	medicationsSection	1..1	SHALL	YES	MTMMedicationSection		
otherInformationSection	otherInformationSection	0..1	MAY	YES	OtherInformationSection		
participant	participant	0..*		YES	Participant1		
recordTarget	recordTarget	1..*	SHALL	YES	RecordTarget	CONF:5266	
relatedDocument	relatedDocument	0..*		YES	RelatedDocument		
supportParticipant	supportParticipant	0..*	MAY	YES	ParticipantSupport	CONF:10003	
typeId	typeId	1..1	SHALL	YES	InfrastructureRootTypeId	CONF:5361	

MTM example

```
<?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">
  <realmCode code="US"/>
  <typeId root="2.16.840.1.113883.1.3"/>
  <templateId root="2.16.840.1.113883.10.20.22.1.1"/>
  <templateId root=""/>
  <id root="122930940"/>
  <code code="Value"/>
  <title/>
  <effectiveTime/>
  <confidentialityCode codeSystem="2.16.840.1.113883.5.25"
 codeSystemName="ConfidentialityCode"/>
  <languageCode/>
  <setId root="b9e0c7d6-c8bf-4488-9fad-27bdcf3fcd91"/>
  <versionNumber/>
  <recordTarget>
    <realmCode/>
    <typeId root="2.16.840.1.113883.1.3"/>
    <patientRole/>
  </recordTarget>
  <author>
    <realmCode/>
    <typeId root="2.16.840.1.113883.1.3"/>
    <time/>
    <assignedAuthor/>
  </author>
  <custodian/>
  <component>
    <structuredBody>
      <component>
        <section>
          <realmCode/>
          <typeId root="2.16.840.1.113883.1.3"/>
```

```
          <templateId root="2.16.840.1.113883.10.20.22.2.6"/>
          <templateId root="2.16.840.1.113883.10.20.22.2.6.1"/>
          <id root="738449840"/>
          <code code="48765-2" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Allergies, adverse reactions, alerts"/>
          <title/>
          <confidentialityCode code="Value"/>
          <languageCode/>
          <entry>
            <act classCode="ACT" moodCode="EVN">
              <realmCode/>
              <typeId root="2.16.840.1.113883.1.3"/>
              <templateId root="2.16.840.1.113883.10.20.22.4.30"/>
              <id root="2014747287"/>
              <code code="48765-2" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Allergies, adverse reactions, alerts"/>
              <effectiveTime>
                <low value="2012"/>
                <high value="2012"/>
              </effectiveTime>
              <languageCode/>
              <entryRelationship>
                <observation classCode="OBS" moodCode="EVN">
                  <realmCode/>
                  <typeId root="2.16.840.1.113883.1.3"/>
                  <templateId root="2.16.840.1.113883.10.20.22.4.7"/>
                  <id root="685136494"/>
                  <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"
codeSystemName="HL7ActCode"/>
                  <statusCode code="completed"/>
                  <effectiveTime>
                    <low value="2012"/>
                    <high value="2012"/>
                  </effectiveTime>
                  <languageCode/>
                  <entryRelationship>
                    <observation classCode="OBS" moodCode="EVN">
                      <realmCode/>
                      <typeId root="2.16.840.1.113883.1.3"/>
                      <templateId root="2.16.840.1.113883.10.20.22.4.9"/>
                      <id root="175230901"/>
                      <code code="2035019405"/>
                      <statusCode code="completed"/>
                      <effectiveTime>
                        <low value="2012"/>
                        <high value="2012"/>
                      </effectiveTime>
                      <languageCode/>
                      <entryRelationship>
                        <observation/>
                      </entryRelationship>
                      <entryRelationship>
                        <procedure/>
                      </entryRelationship>
                      <entryRelationship>
                        <substanceAdministration classCode="SBADM"/>
                      </entryRelationship>
                    </observation>
                  </entryRelationship>
                  <entryRelationship>
                    <observation/>
                  </entryRelationship>
                  <entryRelationship>
                    <observation/>
```

```
                </entryRelationship>
              </observation>
            </entryRelationship>
          </act>
        </entry>
      </section>
    </component>
    <component>
      <section>
        <realmCode/>
        <typeId root="2.16.840.1.113883.1.3"/>
        <templateId root="2.16.840.1.113883.10.20.22.2.1"/>
        <templateId root="2.16.840.1.113883.10.20.22.2.1.1"/>
        <id root="239911738"/>
        <code code="10160-0" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="History of medication use"/>
        <title>MedicationsMedications</title>
        <confidentialityCode code="Value"/>
        <languageCode/>
        <entry>
          <substanceAdministration classCode="SBADM">
            <realmCode/>
            <typeId root="2.16.840.1.113883.1.3"/>
            <templateId root="2.16.840.1.113883.10.20.22.4.16"/>
            <id root="1066918171"/>
            <code code="1766074679"/>
            <effectiveTime value="20120131"/>
            <consumable/>
            <entryRelationship>
              <observation classCode="OBS" moodCode="EVN">
                <realmCode/>
                <typeId root="2.16.840.1.113883.1.3"/>
                <templateId root="2.16.840.1.113883.10.20.22.4.19"/>
                <id root="549960095"/>
                <code codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMEDCT"/>
                <statusCode code="completed"/>
                <effectiveTime>
                  <low value="2012"/>
                  <high value="2012"/>
                </effectiveTime>
                <languageCode/>
              </observation>
            </entryRelationship>
            <entryRelationship>
              <act/>
            </entryRelationship>
            <entryRelationship>
              <act/>
            </entryRelationship>
          </substanceAdministration>
        </entry>
      </section>
    </component>
  </structuredBody>
 </component>
</ClinicalDocument>
```

Chapter 3

SECTION TEMPLATES

Topics:

MTM Medication Section

[Section: templateId `111.222.333.444.333`]

1. **SHALL** conform to *Consol Medications Section* template (templateId: `2.16.840.1.113883.10.20.22.2.1.1`)
2. **SHALL** contain at least one [1..*] **`entry`** (CONF:7572, CONF:7573)
   - Insert generic name and brand name, strength, and dosage form for current/active medications.
   a. Contains exactly one [1..1] *MTM Medication Activity* (templateId: `111.222.333.444.222`)
3. Contains zero or one [0..1] **`component`**
   - Insert beneficiary's allergies and adverse drug reactions including the medications and their effects
   a. Contains exactly one [1..1] *Consol Allergies Section* (templateId: `2.16.840.1.113883.10.20.22.2.6.1`)

mtm::MTMMedicationSection							
/cda:ClinicalDocument/cda:component/cda:structuredBody/cda:component/cda:section[cda:templateId/@root = 2.16.840.1.113883.10.20.22.2.1.1]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
classCode	@classCode	0..1		NO	ActClass		DOCSECT
moodCode	@moodCode	0..1		NO	ActMood		EVN
nullFlavor	@nullFlavor	0..1		NO	NullFlavor		ASKU
sectionId	@sectionId	0..1		NO	String		
code	code	1..1	SHALL	YES	CE	CONF:7569	LOINC 2.16.840.1.113883.6.1LOINC 2.16.840.1.113883.6.1 10160-0
confidentialityCode	confidentialityCode	0..1		YES	CE		
id	id	0..1		YES	II		
languageCode	languageCode	0..1		YES	CS		
realmCode	realmCode	0..*		YES	CS		
templateId	templateId	0..*		YES	II		2.16.840.1.113883.10.20.22.2.1.1
title	title	1..1	SHALL	YES	ST	CONF:7793	MISSINGTYPE
allergiesSection	allergiesSection	0..1		YES	AllergiesSection		
author	author	0..*		YES	Author		
component	component	0..*		YES	Component5		
entry	entry	0..*		YES	Entry		
informant	informant	0..*		YES	Informant12		
medication	cda:entry/ cda:substanceAdministration[cda:templateId/ @root = 2.16.840.1.113883.10.20.22.4.16]	1..*	SHALL	YES	MTMMedicationActivity	CONF:7572CONF:7573	

mtm::MTMMedicationSection							
/cda:ClinicalDocument/cda:component/cda:structuredBody/cda:component/cda:section[cda:templateId/@root = 2.16.840.1.113883.10.20.22.2.1.1]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
medicationActivity	cda:entry/ cda:substanceAdministration[cda:templateId/ @root = 2.16.840.1.113883.10.20.22.4.16]	0..*	SHOULD	YES	MedicationActivity	CONF:7795CONF:7573	
subject	subject	0..1		YES	Subject		
text	text	1..1	SHALL	YES	StrucDocText	CONF:7571	
typeId	typeId	0..1		YES	InfrastructureRootTypeId		

MTM Medication Section example

```
<?xml version="1.0" encoding="UTF-8"?>
<section xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-
org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <templateId root="2.16.840.1.113883.10.20.22.2.1"/>
  <templateId root="2.16.840.1.113883.10.20.22.2.1.1"/>
  <id root="1746084264"/>
  <code code="10160-0" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="History of medication use"/>
  <title>MedicationsMedications</title>
  <text/>
  <entry>
    <substanceAdministration classCode="SBADM">
      <templateId root="2.16.840.1.113883.10.20.22.4.16"/>
      <id root="689095874"/>
      <code code="195613943"/>
      <text/>
      <effectiveTime value="20120131"/>
      <consumable/>
      <entryRelationship>
        <observation classCode="OBS" moodCode="EVN">
          <templateId root="2.16.840.1.113883.10.20.22.4.19"/>
          <id root="881564462"/>
          <code codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMEDCT"/
>
          <text/>
          <statusCode code="completed"/>
          <effectiveTime>
            <low value="2012"/>
            <high value="2012"/>
          </effectiveTime>
        </observation>
      </entryRelationship>
      <entryRelationship>
        <act classCode="ACT" moodCode="INT">
          <templateId root="2.16.840.1.113883.10.20.22.4.20"/>
          <id root="2020788809"/>
          <code code="1532261511"/>
          <text/>
          <statusCode code="completed"/>
          <effectiveTime>
            <low value="2012"/>
            <high value="2012"/>
          </effectiveTime>
        </act>
```

```
      </entryRelationship>
      <entryRelationship>
        <act classCode="ACT" moodCode="EVN">
          <templateId root="2.16.840.1.113883.10.20.22.4.64"/>
          <id root="1771496184"/>
          <code code="48767-8" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="Annotation comment"/>
          <text/>
          <statusCode code="completed"/>
          <effectiveTime>
            <low value="2012"/>
            <high value="2012"/>
          </effectiveTime>
        </act>
      </entryRelationship>
    </substanceAdministration>
  </entry>
</section>
```

Other Information Section

[Section: templateId `111.222.333.444.444`]

1. **SHALL** contain zero or one [0..1] **`text`**
2. **SHALL** contain zero or one [0..1] **`title`**

Other Information 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.

MTM Medication Activity

[SubstanceAdministration: templateId `111.222.333.444.222`]

1. **SHALL** conform to *Consol Medication Activity* template (templateId: `2.16.840.1.113883.10.20.22.4.16`)
2. **SHALL** contain at least one [1..*] **`entryRelationship`** (CONF:7538)
   - Insert indication or intended medical use
   a. Contains **`@typeCode="`**`RSON"` *RSON*
   b. Contains exactly one [1..1] *Consol Indication* (templateId: `2.16.840.1.113883.10.20.22.4.19`)
3. **SHALL** contain exactly one [1..1] **`entryRelationship`** (CONF:7541)
   - Insert regimen, including strength, dose and frequency (e.g., 1 tablet (20 mg) by mouth daily), use of related devices and supplemental instructions as appropriate
   a. Contains **`@typeCode="`**`SUBJ"` *SUBJ*
   b. Contains exactly one [1..1] *Consol Instructions* (templateId: `2.16.840.1.113883.10.20.22.4.20`)
4. **SHALL** contain exactly one [1..1] **`author`**
   - Insert prescriber's name
5. Contains zero or more [0..*] **`effectiveTime`**
   - Start Date : May be estimated by Plan or entered based upon beneficiary-reported data, or leave blank for beneficiary to enter start date Stop Date: Leave blank for beneficiary to enter stop date >
6. **MAY** contain zero or one [0..1] **`text`** (CONF:7501)
   - Use for optional product-related information, such as additional instructions, product image/identifiers, goals of therapy, pharmacy, etc., and change field title accordingly. This field is optional and does not need to be included.
7. **MAY** contain zero or one [0..1] **`entryRelationship`**
   - This comment is used to document why the patient stopped using the drug Leave blank for beneficiary's notes
   a. Contains **`@typeCode="`**`RSON"` *RSON*
   b. Contains exactly one [1..1] *Consol Comment* (templateId: `2.16.840.1.113883.10.20.22.4.64`)

mtm::MTMMedicationActivity							
cda::substanceadministration[cda:templateId/@root = 2.16.840.1.113883.10.20.22.4.16]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
classCode	@classCode	1..1	SHALL	NO	ActClass	CONF:7496	SBADM
moodCode	@moodCode	1..1	SHALL	NO	x_DocumentSubstanceMood	CONF:7497	EVN
negationInd	@negationInd	0..1		NO	Boolean		
nullFlavor	@nullFlavor	0..1		NO	NullFlavor		ASKU
Delivery Method (code)	code	0..1	MAY	YES	CD	CONF:7506	
Dose (doseQuantity)	doseQuantity	0..1	SHOULD	YES	IVL_PQ	CONF:7516	
Dose Restriction (maxDoseQuantity)	maxDoseQuantity	0..1	MAY	YES	RTO_PQ_PQ	CONF:7518	
effectiveTime	effectiveTime	0..*		YES	SXCM_TS		

mtm::MTMMedicationActivity							
cda::substanceadministration[cda:templateId/@root = 2.16.840.1.113883.10.20.22.4.16]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
id	id	1..*	SHALL	YES	II	CONF:7500	
priorityCode	priorityCode	0..1		YES	CE		
Product Form (administrationUnitCode)	administrationUnitCode	0..1	MAY	YES	CE	CONF:7519	
rateQuantity	rateQuantity	0..1	MAY	YES	IVL_PQ	CONF:7517	
realmCode	realmCode	0..*		YES	CS		
repeatNumber	repeatNumber	0..1	MAY	YES	IVL_INT	CONF:7555	
Route (routeCode)	routeCode	0..1	MAY	YES	CE	CONF:7514	
Site (approachSiteCode)	approachSiteCode	0..1	MAY	YES	CD	CONF:7515	
statusCode	statusCode	1..1	SHALL	YES	CS	CONF:7507	
templateId	templateId	0..*		YES	II		2.16.840.1.113883.10.20.22.4.16
text	text	0..1	MAY	YES	ED	CONF:7501	
author	author	1..1	SHALL	YES	Author		
comment	comment	0..1	MAY	YES	Comment		
drugVehicle	drugVehicle	0..*	MAY	YES	DrugVehicle	CONF:7523	
entryRelationship	entryRelationship	0..*		YES	EntryRelationship		
Fulfillment Instructions (medicationDispense)	medicationDispense	0..1	MAY	YES	MedicationDispense	CONF:7554	
indication	indication	1..*	SHALL	YES	Indication	CONF:7538	
informant	informant	0..*		YES	Informant12		
instructions	instructions	1..1	SHALL	YES	Instructions	CONF:7541	
Medication Information (consumable)	consumable	1..1	SHALL	YES	MedicationInformation	CONF:7520	
Order Information (medicationSupplyOrder)	medicationSupplyOrder	1..*	MAY	YES	MedicationSupplyOrder	CONF:7545	
participant	participant	0..*		YES	Participant2		
performer	performer	0..1	MAY	YES	Performer2	CONF:7522	
precondition	precondition	0..*	MAY	YES	PreconditionForSubstanceAdministration	CONF:7546	
Reaction (reactionObservation)	reactionObservation	0..1	MAY	YES	ReactionObservation	CONF:7548	
reference	reference	0..*		YES	Reference		

mtm::MTMMedicationActivity							
cda::substanceadministration[cda:templateId/@root = 2.16.840.1.113883.10.20.22.4.16]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
specimen	specimen	0..*		YES	Specimen		
subject	subject	0..1		YES	Subject		
typeId	typeId	0..1		YES	InfrastructureRootTypeId		

MTM Medication Activity example

```
<?xml version="1.0" encoding="UTF-8"?>
<substanceadministration xmlns:xsi="http://www.w3.org/2001/XMLSchema-
instance" xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 classCode="SBADM">
  <templateId root="2.16.840.1.113883.10.20.22.4.16"/>
  <id root="14178473"/>
  <code code="2069820992"/>
  <text/>
  <statusCode code="completed"/>
  <effectiveTime value="20120131"/>
  <repeatNumber/>
  <routeCode code="Value"/>
  <approachSiteCode code="125593159"/>
  <doseQuantity/>
  <rateQuantity/>
  <maxDoseQuantity/>
  <administrationUnitCode code="Value"/>
  <consumable/>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.22.4.19"/>
      <id root="635116279"/>
      <code codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMEDCT"/>
      <text/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <repeatNumber/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <act classCode="ACT" moodCode="INT">
      <templateId root="2.16.840.1.113883.10.20.22.4.20"/>
      <id root="880643382"/>
      <code code="1464805276"/>
      <text/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
    </act>
  </entryRelationship>
  <entryRelationship>
    <act classCode="ACT" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.22.4.64"/>
      <id root="1883683750"/>
```

```
      <code code="48767-8" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="Annotation comment"/>
      <text/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
    </act>
  </entryRelationship>
</substanceadministration>
```

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*