Implementation Guide for CDA Release 2
MEDICATION THERAPY MANAGEMENT PROGRAM
MEDICARE PART D

National Council for Prescription Drug Programs

Health Level Seven International

Contents

Draft Standard Use Notice

Publication of this draft standard for trial use and comment has been approved by Health Level Seven International (HL7). This draft standard is not an accredited American National Standard. The comment period for use of this draft standard shall end 12 months from the date of publication. Suggestions for revision should be submitted at *http://www.hl7.org/dstucomments/index.cfm*.

Following this 12 month evaluation period, this draft standard, revised as necessary, will be submitted to a normative ballot in preparation for approval by ANSI as an American National Standard. Implementations of this draft standard shall be viable throughout the normative ballot process and for up to six months after publication of the relevant normative standard.

Import Notes

Acknowledgments

This guide was produced and developed through the joint efforts of the National Council for Prescription Drug Programs, Health Level Seven (HL7), and the Pharmacy e-HIT Collaborative.

This project builds upon the Clinical Document Architecture (CDA) Consolidation Project within the ONC's Standards and Interoperability (S&I) Framework, which has been developed to provide a set of harmonized CDA templates for the US Realm.

The co-editors appreciate the support and sponsorship of the HL7 Pharmacy Work Group, Structured Documents Work Group (SDWG), the EHR Work Group, NCPDP Professional Pharmacy Work Group and all the volunteers, staff and contractors participating in this development.

The conformance requirements included here for review were generated from the Model-Driven Health Tools (MDHT) developed as on open source tool under the auspices of the Veterans Administration, IBM, and the ONC.

Revision History

Rev	Date	By Whom	Changes
Draft	January 2012	Sean Muir	

List of Figures

Chapter 1

INTRODUCTION

Topics:

Overview

This guide has been developed to support the documentation and communication needs of the expanding Medication Therapy Management (MTM) services arena and the CMS Medicare Part D reporting and patient information requirements for MTM. It is to be used for the exchange of medication related information including assessment results, recommendations for modifications to medication regimens, recommendations for other services (e.g., dietary or laboratory) and the results of interventions between/among providers, payers, pharmacy benefit managers (PBMs) and patients.

The MTM CDA Guide is based on the Consolidated CDA library of templates, which incorporate and harmonize previous efforts from Health Level Seven (HL7), Integrating the Healthcare Enterprise (IHE), and Health Information Technology Standards Panel (HITSP). For additional information regarding the use, structure and contents of the Consolidated CDA Guide go to *http://www.hl7.org/Special/committees/structure/index.cfm*.

This guide defines templates within this library that are used for the documentation of MTM services, specifically:

Medication Action Plan

Medication List

Comprehensive Medication Review (CMR)

Targeted Medication Review (TMR)

Medication Therapy Outcomes

Approach

In the development of this specification, the team reviewed the Consolidated CDA Implementation Guide and the CMS Medicare Part D MTM Program Standardized Format. The conformance requirements included here were generated from the Model-Driven Health Tools (MDHT) developed as an open source tool under the auspices of the Veterans Administration, IBM, and the ONC.

All major template changes are summarized in the *Change Appendix*. A full mapping of changes is anticipated to occur after ballot.

Participants in the MTM Project recognize the critical need for an intrinsic tie between the human-readable conformance requirements, the computable expression of those requirements, the production of validation test suites and application interfaces to facilitate adoption.

The consolidation of templates developed from model-based tools satisfies the full range of requirements for clinical information use and reuse through templated CDA.

Scope

The MTM Encounter supporting documentation templates are designed to provide a vehicle for reporting the results from the Medication Review (e.g. Comprehensive, (CMR) or Targeted (TMR) Medication Reviews) and/or Medication Therapy Management Services, including Clinical Documentation, Medication Therapy Outcomes and also to provide the patient-specific personal Medication Action Plan and Medication List.

This guide contains a subset of the CDA templates developed for Stage 1 Meaningful Use and for Health Story compliance to the section level that are required for implementation of MTM documents.

Additional optional CDA elements, not included here, can be included and the result will be compliant with the documents in this standard

This implementation has been developed to allow use with the Medication Therapy Management (MTM) and Query transactions defined in the NCPDP Specialized Standard Implementation Guide. Implementers in this realm should consult the NCPDP documents listed below for further information and clarification. Implementers using other HL7

or ASC X12 standards in their processing of MTM services should consult those standards for incorporating this CDA.

NCPDP Specialized Standard Implementation Guide

This document contains the general information needed for implementing NCPDP XML transactions used in other exchanges. The implementation guide supports the business functions of Medication Therapy Management and Queries for clinical information exchange. This document provides information to other NCPDP documents that are to be used in implementation.

NCPDP Standards Matrix

This document contains a high-level overview of the latest version/release and/or the most commonly used of those standards and implementation guides, as well as NCPDP's Data Dictionary and External Code List. Additionally, this document provides version/release/publication reference charts for approved and draft NCPDP standards/ implementation guides.

These documents are available to NCPDP members in the "Members" section of the website at *www.ncpdp.org*. Non-members may purchase the documents via membership; please see *www.ncpdp.org* or contact the NCPDP office at 48Ø-477-1ØØØ, or via Internet e-mail at *ncpdp@ncpdp.org*.

Audience

The audience for this implementation guide includes architects, developers, providers and users of healthcare information technology (HIT) systems in the US Realm that exchange patient clinical data related to MTM services. In addition, the output described in this implementation guide is intended for the patient.

Business analysts and policy managers can also benefit from a basic understanding of the use of Clinical Document Architecture (CDA) templates across multiple implementation use cases.

In the US realm, regulation requires that patients enrolled in a Medicare Part D Medication Therapy Management Program be offered a Comprehensive Medication Review, with a written or printed summary in standardized format, which includes a cover letter, Medication Action Plan, and Personal Medication List. This CDA implementation Guide is designed to fulfill that requirement for the Medication Action Plan and Personal Medication List while allowing the flexibility for use outside of Part D with modification of the viewable format and content. While the system must provide the ability to render a paper copy for the patient, the patient may chose either a paper or electronic copy and the documents may be shared electronically with providers involved in the patient's care, designated caregivers and/or the patient's personal health record.

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.

Medication Therapy Management Program

[ClinicalDocument: templateId `111.222.333.444.111`]

Medication Therapy Management Services (MTM) refers to a distinct service or group of services provided to assess and improve medication use with the goal of optimizing the patient's therapeutic outcome by improving medication use. Key components of these services are the comprehensive medication review (CMR) and condition or drug specific targeted medication reviews (TMRs). CMR is an interactive, person-to-person or telehealth medication review and consultation of a beneficiary's medications (including prescriptions, over-the-counter (OTC) medications, herbal therapies, and dietary supplements) by a pharmacist or qualified provider that is intended to aid in assessing medication therapy and optimizing patient outcomes.

This CDA implementation addresses the communication of this review and the activities the patient must complete for compliance and enhanced outcomes. These services also include services such as medication reconciliation on admission and/or discharge from a facility, assistance in planning medication schedules when several drugs must be coordinated, counseling regarding dietary requirements or restrictions to ensure the therapeutic effect of the medication and recommendations for alternative therapies. This CDA is designed to meet the requirements of the Medicare Part D Medication Therapy management (MTM) Program Standard Format. See: www.ncpdp.orghttp://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/MTM.html for the detailed requirements.

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`**
   - *PML-6*
   a. Contains exactly one [1..1] *Consol Allergies Section Entries Optional* (templateId: `2.16.840.1.113883.10.20.22.2.6`)
3. **SHALL** contain exactly one [1..1] **`component`**
   - *PML 7,8,9*
   a. Contains exactly one [1..1] *Personal Medication List Section* (templateId: `111.222.333.444.333`)
4. **MAY** contain zero or one [0..1] **`component`**
   - *PML-10*
   a. Contains exactly one [1..1] *Other Information Section* (templateId: `111.222.333.444.444`)
5. **SHALL** contain exactly one [1..1] **`component`**
   - *MAP 6*
   a. Contains exactly one [1..1] *Medication Action Plan Section* (templateId: `111.222.333.444.555`)

Medication Therapy Management Program 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="111.222.333.444.111"/>
  <id root="MDHT" extension="219765719"/>
  <code code="38134003"/>
  <title>TEXT FOR TITLE</title>
  <effectiveTime/>
  <confidentialityCode codeSystem="2.16.840.1.113883.5.25"
 codeSystemName="ConfidentialityCode"/>
  <setId root="MDHT" extension="d7061913-e5cf-47bc-a31e-46f155ba3535"/>
```

```
 <versionNumber value="1"/>
 <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/>
     </component>
     <component>
       <section>
         <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"/>
         <templateId root="111.222.333.444.333"/>
         <id root="MDHT" extension="1784746715"/>
         <code code="10160-0" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="History of medication use"/>
         <title>MedicationsMedications</title>
         <entry>
           <substanceAdministration classCode="SBADM">
             <typeId root="2.16.840.1.113883.1.3"/>
             <templateId root="2.16.840.1.113883.10.20.22.4.16"/>
             <templateId root="111.222.333.444.222"/>
             <id root="MDHT" extension="1375474929"/>
             <code code="252850648"/>
             <effectiveTime value="20120718"/>
             <routeCode codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus"/>
             <approachSiteCode codeSystem="2.16.840.1.113883.6.96"
codeSystemName="SNOMEDCT"/>
             <consumable/>
             <author typeCode="AUT">
               <templateId root="null"/>
             </author>
             <entryRelationship typeCode="RSON"/>
             <entryRelationship typeCode="RSON"/>
             <entryRelationship typeCode="SPRT"/>
             <entryRelationship typeCode="SUBJ"/>
             <entryRelationship/>
           </substanceAdministration>
         </entry>
       </section>
     </component>
     <component>
       <section>
         <typeId root="2.16.840.1.113883.1.3"/>
         <templateId root="111.222.333.444.444"/>
         <id root="MDHT" extension="553688561"/>
         <code code="1782673979"/>
         <title>TEXT FOR TITLE</title>
       </section>
     </component>
     <component>
       <section>
         <typeId root="2.16.840.1.113883.1.3"/>
         <templateId root="2.16.840.1.113883.10.20.22.2.10"/>
```

```
          <templateId root="111.222.333.444.555"/>
          <id root="MDHT" extension="876247240"/>
          <code code="18776-5" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="Treatment plan"/>
          <title>TEXT FOR TITLE</title>
          <entry>
            <encounter classCode="ENC">
              <typeId root="2.16.840.1.113883.1.3"/>
              <templateId root="2.16.840.1.113883.10.20.22.4.40"/>
              <id root="MDHT" extension="1080268204"/>
              <code codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMEDCT"/>
              <effectiveTime>
                <low value="2012"/>
                <high value="2012"/>
              </effectiveTime>
              <entryRelationship>
                <act classCode="ACT" moodCode="INT">
                  <templateId root="2.16.840.1.113883.10.20.22.4.39"/>
                  <templateId root="111.222.333.444.666"/>
                  <code codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMEDCT"/>
                </act>
              </entryRelationship>
              <entryRelationship>
                <observation classCode="OBS">
                  <templateId root="2.16.840.1.113883.10.20.1.25"/>
                </observation>
              </entryRelationship>
            </encounter>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Chapter 3

SECTION TEMPLATES

Topics:

Medication Action Plan Section

[Section: templateId `111.222.333.444.555`]

The Medication Action Plan provides the patient with documentation of the steps that they need to follow to maximize the benefits of their medication therapy. These are steps discussed during the medication review or follow-up encounter and are designed to help the patient understand and remember the needed activities, e.g., frequency and or timing of blood sugar checks or recognition of and response to a threatening change in the level. The action plan is prioritized by the provider based on the patient's concerns, the therapeutic need, and the patient's ability to understand and complete the recommended activities. It also provides a means for the patient to record their actions and thereby serves as a basis for ongoing interaction with both the MTM provider and other involved practitioners.

1. **SHALL** conform to *Consol Plan Of Care Section* template (templateId: `2.16.840.1.113883.10.20.22.2.10`)
2. **SHALL** contain at least one [1..*] **`entry`**
   a. Contains exactly one [1..1] *Medication Action Plan Encounter* (templateId: `2.16.840.1.113883.10.20.22.4.40`)
3. **SHALL** contain exactly one [1..1] **`title`**

Medication Action Plan 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="2.16.840.1.113883.10.20.22.2.10"/>
  <templateId root="111.222.333.444.555"/>
  <id root="MDHT" extension="536511903"/>
  <code code="18776-5" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="Treatment plan"/>
  <title>TEXT FOR TITLE</title>
  <text/>
  <entry>
    <encounter classCode="ENC">
      <templateId root="2.16.840.1.113883.10.20.22.4.40"/>
      <id root="MDHT" extension="290392607"/>
      <code codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMEDCT"/>
      <text>Text Value</text>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <entryRelationship>
        <act classCode="ACT" moodCode="INT">
          <templateId root="2.16.840.1.113883.10.20.22.4.39"/>
          <templateId root="111.222.333.444.666"/>
          <id root="MDHT" extension="58896223"/>
          <code codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMEDCT"/>
          <text>Text Value</text>
          <effectiveTime>
            <low value="2012"/>
            <high value="2012"/>
          </effectiveTime>
        </act>
      </entryRelationship>
      <entryRelationship>
        <observation classCode="OBS">
          <templateId root="2.16.840.1.113883.10.20.1.25"/>
          <id root="MDHT" extension="884950573"/>
          <code code="1482227533"/>
```

```
          <text>Text Value</text>
          <effectiveTime>
            <low value="2012"/>
            <high value="2012"/>
          </effectiveTime>
        </observation>
      </entryRelationship>
    </encounter>
  </entry>
</section>
```

Other Information Section

[Section: templateId `111.222.333.444.444`]

The section is used to convey information that might support the patient's compliance with the action plan and medication list, but not explicitly included, e.g., condition lists, primary provider information, primary pharmacy information and emergency contact information.

PML-10:

1. **SHALL** contain exactly one [1..1] **`text`**
   - *This field may be personalized for the beneficiary, such as including a list of the beneficiary's medical conditions, primary care provider, primary pharmacy provider, or emergency contact information.*
2. **SHALL** contain exactly one [1..1] **`title`**

Other Information 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="111.222.333.444.444"/>
  <id root="MDHT" extension="1522382057"/>
  <title>TEXT FOR TITLE</title>
  <text/>
</section>
```

Personal Medication List Section

[Section: templateId `111.222.333.444.333`]

The Personal Medication List (PML) is a reconciled list of all the medications in use (i.e., active medications) by the beneficiary at the time of a CMR. Information for this section may be pre-populated by the Part D plan and must be completed and updated with information provided by the beneficiary and/or caregiver during the consultation. Part D plans must also collect and report the purpose and instructions for the beneficiary's use of his/her medications. The use of over-the-counter medications is important for drug utilization review and should be captured during the interactive CMR and reported in the PML by the Part D plan.

The PML is intended to help beneficiaries understand their medications and how they relate to their treatment plans; to engage beneficiaries in the management of their drug therapy; and to improve both communication about medications and tracking of all medications, including self-prescribed medicines, with their healthcare providers. The PML assists the beneficiary with managing his/her medications by allowing the beneficiary to add new medications and their start dates, redacting discontinued products, and indicating the stop dates and reasons for stopping. The PML is not considered marketing material and should not include any marketing messages, marketing disclaimers, or other sales information.

The PML is not a wallet card. Some MTM programs may also provide supplemental wallet cards, such as the one prepared by AHRQ: http://www.ahrq.gov/consumer/safemeds/walletform.pdf.

Order of medications: MTM programs may select the sort order for the medications to be listed, such as alphabetically, by purpose, by prescriber, or by product type (e.g., prescription, OTC, vitamin, herbal supplement).

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)
   a. Contains exactly one [1..1] *Medication Activity* (templateId: `111.222.333.444.222`)

Personal Medication List 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"/>
  <templateId root="111.222.333.444.333"/>
  <id root="MDHT" extension="1662475502"/>
  <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"/>
      <templateId root="111.222.333.444.222"/>
      <id root="MDHT" extension="1177189832"/>
      <text>Text Value</text>
      <effectiveTime value="20120718"/>
      <routeCode codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
 Thesaurus"/>
      <approachSiteCode codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMEDCT"/>
      <consumable/>
      <author typeCode="AUT">
        <templateId root="null"/>
        <time/>
        <assignedAuthor/>
      </author>
      <entryRelationship typeCode="RSON">
        <observation/>
      </entryRelationship>
      <entryRelationship typeCode="RSON">
        <act classCode="ACT" moodCode="EVN" negationInd="true"/>
      </entryRelationship>
      <entryRelationship typeCode="SPRT">
        <act/>
      </entryRelationship>
      <entryRelationship typeCode="SUBJ">
        <act/>
      </entryRelationship>
      <entryRelationship>
        <observation/>
      </entryRelationship>
    </substanceAdministration>
  </entry>
</section>
```

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.

Instructions

[Act: templateId `111.222.333.444.222.2`]

1. **SHALL** conform to *Consol Instructions* template (templateId: `2.16.840.1.113883.10.20.22.4.20`)
2. **SHALL** contain exactly one [1..1] **`text`**

Instructions example

```
<?xml version="1.0" encoding="UTF-8"?>
<act xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-
org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd" classCode="ACT"
 moodCode="INT">
  <templateId root="2.16.840.1.113883.10.20.22.4.20"/>
  <templateId root="111.222.333.444.222.2"/>
  <id root="MDHT" extension="1957406616"/>
  <code codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMEDCT"/>
  <text>Text Value</text>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
</act>
```

Medication Action Plan Activity

[Act: templateId `111.222.333.444.666`]

The medication action plan activity describes the specific action that the patient is to take or has taken.

MAP 6

1. **SHALL** conform to *Consol Plan Of Care Activity Act* template (templateId: `2.16.840.1.113883.10.20.22.4.39`)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="INT"` , where the @code **SHALL** be selected from ValueSet `Plan of Care moodCode (Act/Encounter/Procedure) 2.16.840.1.113883.11.20.9.23` **STATIC** (CONF:8539)
3. **SHALL** contain exactly one [1..1] **`text`**
   - *WHAT I NEED TO DO*

     Enter recommendations on what the beneficiary should be doing (e.g., Check your blood pressure every morning. Record your blood pressure reading in your log book.). In some cases, it may be appropriate to tell the beneficiary to take no action pending outcome of the MTM provider's follow up with the physician or other practitioner.

     See MAP 6
4. **SHOULD** contain exactly one [1..1] **`code`**, where the @code **SHALL** be selected from (CodeSystem: `2.16.840.1.113883.6.96 SNOMEDCT`)

Medication Action Plan Activity example

```
<?xml version="1.0" encoding="UTF-8"?>
<act xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-
org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd" classCode="ACT"
 moodCode="INT">
```

```
  <templateId root="2.16.840.1.113883.10.20.22.4.39"/>
  <templateId root="111.222.333.444.666"/>
  <id root="MDHT" extension="1055947189"/>
  <code codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMEDCT"/>
  <text>Text Value</text>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
</act>
```

Medication Action Plan Encounter

Medication Action Plan Encounter example

Medication Action Plan Goal

[Observation: templateId `2.16.840.1.113883.10.20.1.25`]

1. **SHALL** conform to *Consol Plan Of Care Activity Observation* template (templateId: `2.16.840.1.113883.10.20.1.25`)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="GOL"` , where the @code **SHALL** be selected from ValueSet `Plan of Care moodCode (Observation) 2.16.840.1.113883.11.20.9.25` **STATIC** (CONF:8582)
3. **SHALL** contain exactly one [1..1] **`text`**

Medication Action Plan Goal example

```
<?xml version="1.0" encoding="UTF-8"?>
<observation xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 classCode="OBS" moodCode="GOL">
  <templateId root="2.16.840.1.113883.10.20.1.25"/>
  <id root="MDHT" extension="1106270322"/>
  <code code="451237588"/>
  <text>Text Value</text>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
</observation>
```

Medication Action Plan Observation

[Observation: templateId `2.16.840.1.113883.10.20.1.25`]

This defines the issues that were discussed between the MTM provider and the patient/caregiver

1. **SHALL** conform to *Consol Plan Of Care Activity Observation* template (templateId: `2.16.840.1.113883.10.20.1.25`)
2. **SHALL** contain exactly one [1..1] **`text`**
   - *WHAT I DID AND WHEN I DID IT*

This field is for the beneficiary to use after the CMR is complete. Discuss with the beneficiary that the box is for his/her use and to write in this box as appropriate. For example, the MTM provider may educate the beneficiary to take the medication with a meal to increase absorption (e.g., calcium carbonate) and then the beneficiary can note when they started doing this and the effects if any.

3. **MAY** contain exactly one [1..1] **`effectiveTime`**
   - *Capture the date the that the patient reports the activity was completed*

Medication Action Plan Observation example

```
<?xml version="1.0" encoding="UTF-8"?>
<observation xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 classCode="OBS">
  <templateId root="2.16.840.1.113883.10.20.1.25"/>
  <id root="MDHT" extension="1737215327"/>
  <code code="2130974772"/>
  <text>Text Value</text>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
</observation>
```

Medication Activity

Medication Activity example

Reminder

[Act: templateId `111.222.333.444.222.1`]

Documents a reminder for the medication activity

1. **SHALL** conform to *Consol Instructions* template (templateId: `2.16.840.1.113883.10.20.22.4.20`)
2. **SHALL** contain exactly one [1..1] **`text`**

Reminder example

```
<?xml version="1.0" encoding="UTF-8"?>
<act xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-
org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd" classCode="ACT"
 moodCode="INT">
  <templateId root="2.16.840.1.113883.10.20.22.4.20"/>
  <templateId root="111.222.333.444.222.1"/>
  <id root="MDHT" extension="764438099"/>
  <code codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMEDCT"/>
  <text>Text Value</text>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
</act>
```

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*