Implementation Guide for CDA Release 2

MEDICATION THERAPY MANAGEMENT PROGRAM

MEDICARE PART D

(Consolidated Developer Documentation)

Contents

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	

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.

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.

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`]

The Medicare Part D Medication Therapy Management (MTM) Program Standardized Format (Format) is a written summary of a comprehensive medication review (CMR). A 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.

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] **`realmCode/@code`**`="US"` (CONF:5249)
3. **SHALL** contain exactly one [1..1] **`typeId`** (CONF:5361)
4. **SHALL** contain exactly one [1..1] **`id`** (CONF:5363)
5. **SHALL** contain exactly one [1..1] **`code`** (CONF:5253)
6. **SHALL** contain exactly one [1..1] **`title`** (CONF:5254)
7. **SHALL** contain exactly one [1..1] **`effectiveTime`** (CONF:5256)
8. **SHALL** contain exactly one [1..1] **`confidentialityCode`**, where the @code **SHALL** be selected from ValueSet *`HL7 BasicConfidentialityKind`* `2.16.840.1.113883.1.11.16926` **STATIC** (CONF:5259)
9. **SHALL** contain exactly one [1..1] **`languageCode`**, where the @code **SHALL** be selected from ValueSet *`Language`* `2.16.840.1.113883.1.11.11526` **DYNAMIC** (CONF:5372)
10. **MAY** contain zero or one [0..1] **`setId`** (CONF:5261)
11. **MAY** contain zero or one [0..1] **`versionNumber`** (CONF:5264)
12. Contains at least one [1..*] **`author`**
    a. Such authors Contains zero or one [0..1] **`@typeCode`**`="AUT"`
13. Contains exactly one [1..1] **`component`**, where its type is *Component2*
14. **SHALL** contain at least one [1..*] **`recordTarget`** (CONF:5266)

    The recordTarget records the patient whose health information is described by the clinical document; it must contain at least one patientRole element.

    a. Such recordTargets **SHALL** contain exactly one [1..1] **`patientRole`** (CONF:5268)
       a. This patientRole **SHALL** contain at least one [1..*] **`addr`** (CONF:5271)
       b. This patientRole **SHALL** contain at least one [1..*] **`id`** (CONF:5268)
       c. This patientRole **SHALL** contain at least one [1..*] **`telecom`** (CONF:5280)
       d. This patientRole **SHALL** contain exactly one [1..1] **`patient`** (CONF:5283)
          a. This patient **SHALL** contain exactly one [1..1] **`administrativeGenderCode`**, where the @code **SHALL** be selected from ValueSet *`Administrative Gender (HL7 V3)`* `2.16.840.1.113883.1.11.1` **DYNAMIC** (CONF:6394)
          b. This patient **SHALL** contain exactly one [1..1] **`birthTime`**
          c. This patient **MAY** contain zero or one [0..1] **`ethnicGroupCode`**, where the @code **SHALL** be selected from ValueSet *`HITSP Ethnicity Value Set`* `2.16.840.1.113883.1.11.15836` **STATIC** (CONF:5323)
          d. This patient **SHOULD** contain zero or one [0..1] **`maritalStatusCode`**, where the @code **SHOULD** be selected from ValueSet *`HL7 Marital Status`* `2.16.840.1.113883.1.11.12212` **STATIC** 1
          e. This patient **SHALL** contain exactly one [1..1] **`name`** (CONF:5284)
          f. This patient **MAY** contain zero or one [0..1] **`raceCode`**, where the @code **MAY** be selected from ValueSet *`Race`* `2.16.840.1.113883.1.11.14914` **STATIC** 1
          g. This patient **MAY** contain zero or one [0..1] **`religiousAffiliationCode`**, where the @code **MAY** be selected from ValueSet *`HL7 Religious Affiliation`* `2.16.840.1.113883.1.11.19185` **STATIC** 1

h. This patient **MAY** contain zero or more [0..*] **guardian** (CONF:5325)

a. Such guardians **SHOULD** contain zero or more [0..*] **addr**

b. Such guardians **SHOULD** contain zero or one [0..1] **code**, where the @code **SHALL** be selected from ValueSet *Personal Relationship Role Type* 2.16.840.1.113883.1.11.19563 **STATIC** 1 (CONF:5326)

c. Such guardians **MAY** contain zero or more [0..*] **telecom**

d. Such guardians **SHALL** contain zero or one [0..1] **guardianPerson** (CONF:5385)

a. This guardianPerson **SHALL** contain at least one [1..*] **name** (CONF:5470)

i. This patient **MAY** contain zero or one [0..1] **birthplace** (CONF:5395)

a. This birthplace **SHALL** contain zero or one [0..1] **place** (CONF:5396)

a. This place **SHALL** contain zero or one [0..1] **addr** (CONF:5397)

j. This patient **SHOULD** contain zero or one [0..1] **languageCommunication** (CONF:5406)

a. This languageCommunication **SHALL** contain exactly one [1..1] **languageCode**, where the @code **SHALL** be selected from ValueSet *Language* 2.16.840.1.113883.1.11.11526 **DYNAMIC** (CONF:5407)

b. This languageCommunication **MAY** contain zero or one [0..1] **preferenceInd** (CONF:5414)

c. This languageCommunication **SHOULD** contain zero or one [0..1] **proficiencyLevelCode**, where the @code **SHALL** be selected from ValueSet *LanguageAbilityProficiency* 2.16.840.1.113883.1.11.12199 **STATIC** (CONF:9965)

d. This languageCommunication **MAY** contain zero or one [0..1] **modeCode**, where the @code **SHALL** be selected from ValueSet *HL7 LanguageAbilityMode* 2.16.840.1.113883.1.11.12249 **STATIC** 1 (CONF:5409)

k. This patient **SHALL** satisfy: BirthTime precise to year

l. This patient **SHOULD** satisfy: BirthTime precise to day

e. This patientRole Contains zero or one [0..1] **providerOrganization**

a. This providerOrganization **SHALL** contain at least one [1..*] **addr** (CONF:5422)

b. This providerOrganization **SHALL** contain at least one [1..*] **id** (CONF:5417)

c. This providerOrganization **SHALL** contain at least one [1..*] **name** (CONF:5419)

d. This providerOrganization **SHALL** contain at least one [1..*] **telecom** (CONF:5420)

e. This providerOrganization The id **SHOULD** include zero or one [0..1] id where id/@root ="2.16.840.1.113883.4.6" National Provider Identifier (CONF:9996) (CONF:9996)

15. **MAY** contain exactly one [1..1] **componentOf** (CONF:9955)

a. This componentOf **SHALL** contain exactly one [1..1] **encompassingEncounter** (CONF:9956)

a. This encompassingEncounter **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:9958)

b. This encompassingEncounter **SHALL** contain at least one [1..*] **id** (CONF:9959)

16. **MAY** contain zero or one [0..1] **dataEnterer** (CONF:5441)

a. This dataEnterer **SHALL** contain exactly one [1..1] **assignedEntity** (CONF:5442)

a. This assignedEntity **SHALL** contain at least one [1..*] **addr** (CONF:5460)

b. This assignedEntity **MAY** contain zero or one [0..1] **code**, where the @code **SHOULD** be selected from (CodeSystem: 2.16.840.1.113883.6.101 NUCC Health Care Provider Taxonomy) (CONF:9944)

c. This assignedEntity **SHALL** contain at least one [1..*] **id** (CONF:5443)

d. This assignedEntity **SHALL** contain at least one [1..*] **telecom** (CONF:5466)

e. This assignedEntity **SHALL** contain exactly one [1..1] **assignedPerson** (CONF:5469)

a. This assignedPerson **SHALL** contain at least one [1..*] **name** (CONF:5470)

f. This assignedEntity id **SHOULD** include zero or one [0..1] id where id/@root ="2.16.840.1.113883.4.6" National Provider Identifier (CONF:9943)

17. **SHALL** contain exactly one [1..1] **`custodian`** (iv., CONF:5519)
    a. This custodian **SHALL** contain exactly one [1..1] **`assignedCustodian`** (CONF:5520)
        a. This assignedCustodian **SHALL** contain zero or one [0..1] **`representedCustodianOrganization`** (CONF:5521)
            a. This representedCustodianOrganization **SHALL** contain at least one [1..*] **`addr`** (CONF:5559)
            b. This representedCustodianOrganization **SHALL** contain at least one [1..*] **`id`** (CONF:5522)
            c. This representedCustodianOrganization **SHALL** contain exactly one [1..1] **`name`** (CONF:5524)
            d. This representedCustodianOrganization **SHALL** contain exactly one [1..1] **`telecom`** (CONF:5525)
            e. This representedCustodianOrganization The id **SHOULD** include zero or one [0..1] id where id/@root ="2.16.840.1.113883.4.6" National Provider Identifier (CONF:9996)
18. **MAY** contain zero or more [0..*] **`informationRecipient`** (CONF:5565)
    a. Such informationRecipients **SHALL** contain zero or one [0..1] **`intendedRecipient`** (CONF:5566)
        a. This intendedRecipient **MAY** contain zero or one [0..1] **`informationRecipient`** (CONF:5568)
            a. This informationRecipient **SHALL** contain at least one [1..*] **`name`** (CONF:5470)
        b. This intendedRecipient **MAY** contain zero or one [0..1] **`receivedOrganization`** (CONF:5577)
            a. This receivedOrganization **SHALL** contain zero or more [0..*] **`name`** (CONF:5578)
19. **SHOULD** contain zero or one [0..1] **`legalAuthenticator`** (CONF:5579)
    a. This legalAuthenticator **SHALL** contain exactly one [1..1] **`time`** (CONF:5580)
    b. This legalAuthenticator **SHALL** contain exactly one [1..1] **`signatureCode/@code`**`="S"` (CodeSystem: `2.16.840.1.113883.5.89 Participationsignature`) (CONF:5583, CONF:5584)
    c. This legalAuthenticator Contains zero or one [0..1] **`assignedEntity`**
        a. This assignedEntity **SHALL** contain at least one [1..*] **`addr`**
        b. This assignedEntity **MAY** contain zero or one [0..1] **`code`**, where the @code **SHOULD** be selected from (CodeSystem: `2.16.840.1.113883.6.101 NUCC Health Care Provider Taxonomy`) (CONF:9949)
        c. This assignedEntity **SHALL** contain at least one [1..*] **`id`**
        d. This assignedEntity **SHALL** contain at least one [1..*] **`telecom`**
        e. This assignedEntity **SHALL** contain exactly one [1..1] **`assignedPerson`** (CONF:5597)
            a. This assignedPerson **SHALL** contain at least one [1..*] **`name`** (CONF:5470)
        f. This assignedEntity The id **SHOULD** include zero or one [0..1] id where id/@root ="2.16.840.1.113883.4.6" National Provider Identifier (CONF:9996)
20. **MAY** contain zero or more [0..*] **`authenticator`** (CONF:5607)
    a. Such authenticators **SHALL** contain exactly one [1..1] **`time`** (CONF:5608)
    b. Such authenticators **SHALL** contain exactly one [1..1] **`signatureCode/@code`**`="S"` (CodeSystem: `2.16.840.1.113883.5.89 Participationsignature`) (CONF:5610)
    c. Such authenticators **SHALL** contain zero or one [0..1] **`assignedEntity`** (CONF:5612)
        a. This assignedEntity **SHALL** contain at least one [1..*] **`addr`** (CONF:5616)
        b. This assignedEntity **MAY** contain zero or one [0..1] **`code`**, where the @code **SHOULD** be selected from (CodeSystem: `2.16.840.1.113883.6.101 NUCC Health Care Provider Taxonomy`) (CONF:9951)
        c. This assignedEntity **SHALL** contain at least one [1..*] **`id`** (CONF:5613)
        d. This assignedEntity **SHALL** contain at least one [1..*] **`telecom`** (CONF:5622)
        e. This assignedEntity Contains zero or one [0..1] **`assignedPerson`**
            a. This assignedPerson **SHALL** contain at least one [1..*] **`name`** (CONF:5470)
        f. This assignedEntity The id **SHOULD** include zero or one [0..1] id where id/@root ="2.16.840.1.113883.4.6" National Provider Identifier (CONF:9996)

21. **MAY** contain zero or one [0..1] **`informant`** (CONF:8001)
    a. This informant Contains zero or one [0..1] **`assignedEntity`**
        a. This assignedEntity **SHOULD** contain zero or more [0..*] **`addr`** (CONF:8220)
        b. This assignedEntity **MAY** contain zero or one [0..1] **`code`**, where the @code **SHOULD** be selected from (CodeSystem: `2.16.840.1.113883.6.101 NUCC Health Care Provider Taxonomy`) (CONF:9947)
        c. This assignedEntity **SHOULD** contain at least one [1..*] **`id`** (a., CONF:9945)
        d. This assignedEntity **SHALL** contain zero or one [0..1] **`assignedPerson`** (CONF:8221)
            a. This assignedPerson **SHALL** contain at least one [1..*] **`name`** (CONF:5470)
        e. This assignedEntity The id **SHOULD** include zero or one [0..1] id where id/@root ="2.16.840.1.113883.4.6" National Provider Identifier (CONF:9996)
    b. This informant Contains zero or one [0..1] **`relatedEntity`**
        a. This relatedEntity **SHOULD** contain zero or more [0..*] **`addr`** (CONF:8220)
        b. This relatedEntity **SHALL** contain zero or one [0..1] **`relatedPerson`** (CONF:8221)
            a. This relatedPerson **SHALL** contain at least one [1..*] **`name`** (CONF:5470)
    c. This informant **SHALL** satisfy: contain exactly one [1..1] assignedEntity OR exactly one [1..1] relatedEntity (CONF:8002)
22. **MAY** contain zero or more [0..*] **`participant`** (CONF:10003)
    a. Such participants **MAY** contain zero or one [0..1] **`time`** (CONF:10004)
    b. Such participants Such participants, if present, **SHALL** have an associatedPerson or scopingOrganization element under participant/associatedEntity.
    c. Such participants Unless otherwise specified by the document specific header constraints, when participant/@typeCode is IND, associatedEntity/@classCode **SHALL** be selected from ValueSet INDRoleclassCodes 2.16.840.1.113883.11.20.9.33 STATIC 2011-09-30.
23. **MAY** contain zero or more [0..*] **`inFulfillmentOf`** (CONF:9952)
    a. Such inFulfillmentOfs **SHALL** contain exactly one [1..1] **`order`** (CONF:9953)
        a. This order **SHALL** contain at least one [1..*] **`id`** (CONF:9954)
24. **SHALL** contain exactly one [1..1] **`component`**
    a. Contains exactly one [1..1] *Consol Allergies Section Entries Optional* (templateId: `2.16.840.1.113883.10.20.22.2.6`)

    - PML-6

25. **SHALL** contain exactly one [1..1] **`component`**
    a. Contains exactly one [1..1] *Personal Medication List Section* (templateId: `111.222.333.444.333`)

    - PML 7,8,9

26. **MAY** contain zero or one [0..1] **`component`**
    a. Contains exactly one [1..1] *Other Information Section* (templateId: `111.222.333.444.444`)

    - PML-10

27. **SHALL** contain exactly one [1..1] **`component`**
    a. Contains exactly one [1..1] *Medication Action Plan Section* (templateId: `111.222.333.444.555`)

    - MAP 6

28. **SHALL** contain at least one [1..*] **`author`** (CONF:5444)

    The author designates the primary provider developing the Medication Therapy Management Plan

    a. Such authors **SHALL** conform to *Consol Author*
    b. Such authors **SHALL** contain exactly one [1..1] **`@typeCode`**`="AUT"`

29. **SHALL** satisfy: The US Realm Clinical Document Address datatype flavor is used by US Realm Clinical Document Header for the patient or any other person or organization mentioned within it.
30. **SHALL** satisfy: The US Realm Clinical Document Date and Time datatype flavor records date and time information. If no time zone offset is provided, you can make no assumption about time, unless you have made a local exchange agreement. This data type uses the same rules as US Realm Date and Time (DTM.US.FIELDED), but is used with the effectiveTime element.
31. **SHALL** satisfy: The US Realm Patient Name datatype flavor is a set of reusable constraints that can be used for the patient or any other person. It requires a first (given) and last (family) name. If a patient or person has only one name part (e.g., patient with first name only) place the name part in the field required by the organization. Use the appropriate nullFlavor, "Not Applicable" (NA), in the other field.

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="1312796362" extension="MDHT"/>
  <code code="1016179912"/>
  <title>TEXT FOR TITLE</title>
  <effectiveTime/>
  <confidentialityCode codeSystem="2.16.840.1.113883.5.25"
 codeSystemName="ConfidentialityCode"/>
  <setId root="6446989c-741e-417c-86a9-bc30a51303e2" extension="MDHT"/>
  <versionNumber value="1"/>
  <recordTarget>
    <typeId root="2.16.840.1.113883.1.3"/>
    <patientRole/>
  </recordTarget>
  <custodian/>
  <component>
    <structuredBody>
      <component>
        <section/>
      </component>
      <component>
        <section/>
      </component>
      <component>
        <section>
          <typeId root="2.16.840.1.113883.1.3"/>
          <templateId root="111.222.333.444.444"/>
          <id root="480840360" extension="MDHT"/>
          <code code="1628964776"/>
          <title>TEXT FOR TITLE</title>
        </section>
      </component>
      <component>
        <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 exactly one [1..1] **`code/@code="18776-5"`** *Treatment plan* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`) (CONF:7724)
3. **SHALL** contain exactly one [1..1] **`title`**
4. **SHALL** contain exactly one [1..1] **`text`** (CONF:7725)
5. **MAY** contain zero or one [0..1] **`entry`** (CONF:7726.CONF:8804)
   a. Contains exactly one [1..1] *Plan Of Care Activity Act* (templateId: `2.16.840.1.113883.10.20.22.4.39`)
6. **MAY** contain zero or one [0..1] **`entry`** (CONF:8808, CONF:8807)
   a. Contains exactly one [1..1] *Plan Of Care Activity Observation* (templateId: `2.16.840.1.113883.10.20.1.25`)
7. **MAY** contain zero or one [0..1] **`entry`** (CONF:8809, CONF:8810)
   a. Contains exactly one [1..1] *Plan Of Care Activity Procedure* (templateId: `2.16.840.1.113883.10.20.22.4.41`)
8. **MAY** contain zero or one [0..1] **`entry`** (CONF:8811, CONF:8812)
   a. Contains exactly one [1..1] *Plan Of Care Activity Substance Administration* (templateId: `2.16.840.1.113883.10.20.1.25`)
9. **MAY** contain zero or one [0..1] **`entry`** (CONF:8813, CONF:8814)
   a. Contains exactly one [1..1] *Plan Of Care Activity Supply* (templateId: `2.16.840.1.113883.10.20.22.4.43`)
10. **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`)

Medication Action Plan Section example

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] **`title`**
2. **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.

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="4137382" extension="MDHT"/>
  <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 Entries Optional* template (templateId: `2.16.840.1.113883.10.20.22.2.1`)
2. **SHALL** conform to *Consol Medications Section* template (templateId: `2.16.840.1.113883.10.20.22.2.1.1`)
3. **SHALL** contain exactly one [1..1] **`code/@code`**`="10160-0"` *History of medication use* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`) (CONF:7569)
4. **SHALL** contain exactly one [1..1] **`title`** = "Medications" (CONF:7793)
5. **SHALL** contain exactly one [1..1] **`text`** (CONF:7571)
6. **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`)
7. If medication use is unknown, the appropriate nullFlavor **MAY** be present (see unknown information in Section 1)
8. If medication use is unknown, the appropriate nullFlavor **MAY** be present (see unknown information in Section 1)

Personal Medication List 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.

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. (What I need to do) 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] **`@classCode`**`="ACT"` *Act* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
3. **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)
4. **SHALL** contain at least one [1..*] **`id`** (CONF:8539)
5. **SHOULD** contain exactly one [1..1] **`code`**, where the @code **SHALL** be selected from (CodeSystem: `2.16.840.1.113883.6.96 SNOMEDCT`)
6. **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

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="196873949" extension="MDHT"/>
  <code codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMEDCT"/>
  <text>Text Value</text>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <entryRelationship>
    <observation classCode="OBS" moodCode="GOL">
      <templateId root="2.16.840.1.113883.10.20.1.25"/>
      <id root="885399252" extension="MDHT"/>
      <code code="671969512"/>
      <text>Text Value</text>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS">
      <templateId root="2.16.840.1.113883.10.20.1.25"/>
      <id root="543995655" extension="MDHT"/>
      <code code="404614634"/>
      <text>Text Value</text>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
```

```
    </observation>
  </entryRelationship>
</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] **`@classCode`**`="OBS" /`**`@code`**`=""` (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF:8581)
3. **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)
4. **SHALL** contain at least one [1..*] **`id`** (CONF:8584)
5. Contains exactly one [1..1] **`code`** with data type CD
6. **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="238635218" extension="MDHT"/>
  <code code="545309257"/>
  <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`]

(What I did and when I did it) MAP 6

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] **`@classCode`**`="OBS" /`**`@code`**`=""` (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF:8581)
3. **SHALL** contain exactly one [1..1] **`@moodCode`**, 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)
4. **SHALL** contain at least one [1..*] **`id`** (CONF:8584)
5. Contains exactly one [1..1] **`code`** with data type CD
6. **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.

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="716410961" extension="MDHT"/>
  <code code="1864789521"/>
  <text>Text Value</text>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
</observation>
```

Medication Activity

[SubstanceAdministration: templateId `111.222.333.444.222`]

PML-7

1. **SHALL** conform to *Consol Medication Activity* template (templateId: `2.16.840.1.113883.10.20.22.4.16`)
2. **SHALL** contain exactly one [1..1] **`@classCode`**`="SBADM"` (CodeSystem: `2.16.840.1.113883.5.6` `HL7ActClass`) (CONF:7496)
3. **SHALL** contain exactly one [1..1] **`@moodCode`**, where the @code **SHALL** be selected from ValueSet *`MoodCodeEvnInt`* `2.16.840.1.113883.11.20.9.18` **STATIC** 2011-04-03 (CONF:7497)
4. **SHALL** contain at least one [1..*] **`id`** (CONF:7500)
5. **MAY** contain zero or one [0..1] **`code`** (CONF:7506)
6. **MAY** contain zero or one [0..1] **`text`** (CONF:7501)
   - Enter the medication's generic drug name (and brand name if applicable), strength, and dosage form for medications currently being used by the beneficiary, including starter supplies (e.g., samples), prescription medications, over-the-counter (OTC) drugs, herbal products, vitamins, and minerals. For brand drugs and branded generics, list both generic and brand names, such as "Generic Name (Brand Name)". An example is Furosemide (Lasix). For generic drugs, list the medication name as "Generic Name" (e.g., Furosemide). This would ensure a consistent format of: "Generic Name (Brand Name if applicable)". Information about medication-related devices should be included in the field for the applicable medication(s) where appropriate
7. **SHALL** contain exactly one [1..1] **`statusCode`** (CONF:7507)
8. Contains zero or more [0..*] **`effectiveTime`**
   - Date I started using it: The medication start date may be entered by the Part D plan if known or reasonably estimated, or entered based upon beneficiary-reported data; or the field may be left blank for the beneficiary to complete. The last prescription fill date should not be entered in this field. Date I stopped using it: This field allows the beneficiary to record the date he/she stops using the medication. Remove the italics type that states Leave blank for beneficiary to enter stop date . Leave this field blank for the beneficiary to enter the stop date. Discuss with the beneficiary that when a medication is no longer being taken, he or she should write the date that the medication was stopped and the reason why the medication was stopped. 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
9. **MAY** contain zero or one [0..1] **`repeatNumber`** (CONF:7555)
   - In "INT" (intent) mood, the repeatNumber defines the number of allowed administrations. For example, a repeatNumber of "3" means that the substance can be administered up to 3 times

     In "EVN" (event) mood, the repeatNumber is the number of occurrences. For example, a repeatNumber of "3" in a substance administration event means that the current administration is the 3rd in a series

10. **MAY** contain zero or one [0..1] **routeCode**, where the @code **SHALL** be selected from ValueSet *Medication Route FDA Value Set* 2.16.840.1.113883.3.88.12.3221.8.7 **STATIC** 1 (CONF:7514)
11. **MAY** contain zero or one [0..1] **approachSiteCode**, where the @code **SHALL** be selected from ValueSet *Body Site Value Set* 2.16.840.1.113883.3.88.12.3221.8.9 **STATIC** 2 (CONF:7515)
12. **SHOULD** contain zero or one [0..1] **doseQuantity** (CONF:7516)
    - Pre-coordinated consumable: If the consumable code is a precoordinated unit dose (e.g. metoprolol 25mg tablet) then doseQuantity is a unitless number that indicates the number of products given per administration (e.g. 2, meaning 2 x metoprolol 25mg tablet) Not pre-coordinated consumable: If the consumable code is not pre-coordinated (e.g. is simply metoprolol), then doseQuantity must represent a physical quantity with @unit, e.g. 25 and mg, specifying the amount of product given per administration
13. **MAY** contain zero or one [0..1] **rateQuantity** (CONF:7517)
14. **MAY** contain zero or one [0..1] **maxDoseQuantity** (CONF:7518)
15. **MAY** contain zero or one [0..1] **administrationUnitCode**, where the @code **MAY** be selected from ValueSet *Medication Product Form* 2.16.840.1.113883.3.88.12.3221.8.11 **STATIC** 1 (CONF:7519)
16. **MAY** contain zero or one [0..1] **performer** (CONF:7522)
17. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:7541)
    a. Contains **@typeCode="**SUBJ" *SUBJ*
    b. Contains exactly one [1..1] *Instructions* (templateId: 2.16.840.1.113883.10.20.22.4.20)
18. **MAY** contain at least one [1..*] **entryRelationship** (CONF:7545)
    a. Contains **@typeCode="**REFR" *REFR*
    b. Contains exactly one [1..1] *Medication Supply Order* (templateId: 2.16.840.1.113883.10.20.22.4.17)
19. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:7548)
    a. Contains **@typeCode="**CAUS" *CAUS*
    b. Contains exactly one [1..1] *Reaction Observation* (templateId: 2.16.840.1.113883.10.20.22.4.9)
20. **MAY** contain zero or more [0..*] **entryRelationship** (CONF:7538)
    a. Contains **@typeCode="**RSON" *RSON*
    b. Contains exactly one [1..1] *Indication* (templateId: 2.16.840.1.113883.10.20.22.4.19)
21. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:7554)
    a. Contains **@typeCode="**REFR" *REFR*
    b. Contains exactly one [1..1] *Medication Dispense* (templateId: 2.16.840.1.113883.10.20.22.4.18)
22. **MAY** contain zero or more [0..*] **precondition** (CONF:7546)
    a. Contains exactly one [1..1] *Precondition For Substance Administration* (templateId: 2.16.840.1.113883.10.20.22.4.25)
23. **MAY** contain zero or more [0..*] **participant** (CONF:7523)
    a. Contains exactly one [1..1] *Drug Vehicle* (templateId: 2.16.840.1.113883.10.20.22.4.24)
24. **SHALL** contain exactly one [1..1] **consumable** (CONF:7520)
    a. This consumable **SHALL** contain exactly one [1..1] **manufacturedProduct**, where its type is *Medication Information* (CONF:7521)
        a. Contains exactly one [1..1] *Medication Information* (templateId: 2.16.840.1.113883.10.20.22.4.23)
25. **SHALL** contain exactly one [1..1] **author**

    Presciber of the medication is recorded here
    a. This author **SHALL** contain exactly one [1..1] **@typeCode**="AUT"
    b. This author **SHALL** contain exactly one [1..1] **assignedAuthor**
        a. This assignedAuthor **SHALL** contain zero or one [0..1] **assignedPerson**

   a. This assignedPerson **SHOULD** contain exactly one [1..1] **`name`**

      Enter the name of the authorized practitioner who ordered the medication for the beneficiary. This field may also include other prescriber data, such as designation of practitioner type (e.g., MD, PA, or NP), telephone number, address, site, etc., such as J. Johnson-Smith, NP. For non-prescribed OTCs, enter "self" or leave this field blank.

26. **SHALL** contain exactly one [1..1] **`entryRelationship`**

    Use this entry relationship definition to document the medications instructions or Sig

    a. This entryRelationship **SHALL** contain exactly one [1..1] **`@typeCode`**`="SUBJ"`
    b. This entryRelationship **SHALL** contain exactly one [1..1] **`act`**
       a. This act **SHALL** conform to *Consol Instructions* template (templateId: `2.16.840.1.113883.10.20.22.4.20`)
       b. This act **SHALL** contain exactly one [1..1] **`text`**
       a. Contains exactly one [1..1] *Instructions* (templateId: `2.16.840.1.113883.10.20.22.4.20`)

27. **SHALL** contain exactly one [1..1] **`entryRelationship`**

    Use this entry relationship definition to document the reason for taking the medication

    a. This entryRelationship **SHALL** contain exactly one [1..1] **`@typeCode`**`="RSON"`
    b. This entryRelationship **SHALL** contain exactly one [1..1] **`observation`**, where its type is *Consol Indication*
       a. Contains exactly one [1..1] *Consol Indication* (templateId: `2.16.840.1.113883.10.20.22.4.19`)

28. **MAY** contain zero or one [0..1] **`entryRelationship`**

    Use this entry relationship definition to document the reason for stopping the medication

    a. This entryRelationship **SHALL** contain exactly one [1..1] **`@typeCode`**`="RSON"`
    b. This entryRelationship Contains zero or one [0..1] **`act`**
       a. This act **SHALL** contain exactly one [1..1] **`@classCode`**`="ACT"` *Act* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
       b. This act Contains exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)
       c. This act **SHALL** contain zero or one [0..1] **`@negationInd`**`="true"`
       d. This act Contains zero or one [0..1] **`text`**

          This field allows the beneficiary to record the reason he/she stops using the medication.

29. **MAY** contain zero or one [0..1] **`entryRelationship`**

    Use this entry relationship definition to document any reminders associated with the medication

    a. This entryRelationship **SHALL** contain exactly one [1..1] **`@typeCode`**`="SPRT"`
    b. This entryRelationship **SHALL** contain exactly one [1..1] **`act`**
       a. This act **SHALL** conform to *Consol Instructions* template (templateId: `2.16.840.1.113883.10.20.22.4.20`)
       b. This act **SHALL** contain exactly one [1..1] **`text`**
       a. Contains exactly one [1..1] *Reminder* (templateId: `2.16.840.1.113883.10.20.22.4.20`)

30. **SHOULD** contain at least one [1..*] **`entryRelationship`**

    Use this entry relationship definition to document the goals for using the medication

    a. Such entryRelationships **SHALL** contain exactly one [1..1] **`observation`**, where its type is *Medication Action Plan Goal*
       a. Contains exactly one [1..1] *Medication Action Plan Goal* (templateId: `2.16.840.1.113883.10.20.1.25`)

31. Medication Activity **SHOULD** include doseQuantity OR rateQuantity
32. text, if present, **SHOULD** contain zero or one [0..1] reference/@value (CONF:7502)
33. reference/@value **SHALL** begin with a '#' and **SHALL** point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:7503)
34. **SHALL** contain exactly one [1..1] effectiveTime such that it **SHALL** contain exactly one [1..1] @xsi:type = "IVL_TS" (CONF:7508, CONF:9104)
35. effectiveTime with @xsi:type="IVL_TS" **SHALL** contain exactly one [1..1] low
36. effectiveTime with @xsi:type="IVL_TS" **SHALL** contain exactly one [1..1] high
37. **SHOULD** contain zero or one [0..1] effectiveTime such that it **SHALL** contain exactly one [1..1] @xsi:type = "PIVL_TS" or "EIVL_TS" (CONF:7513, CONF:9105)
38. effectiveTime with @xsi:type = "PIVL_TS" or "EIVL_TS" **SHALL** contain exactly one [1..1] @operator="A" and (CONF:9106)
39. doseQuantity, if present, **SHOULD** contain zero or one [0..1] @unit, which **SHALL** be selected from ValueSet UCUM Units of Measure (case sensitive) 2.16.840.1.113883.1.11.12839 DYNAMIC (CONF:7526)
40. participant with target entry Drug Vehicle **SHALL** contain exactly one [1..1] @typeCode="CSM" (CodeSystem: HL7ParticipationType 2.16.840.1.113883.5.90) (CONF:7524)
41. entryRelationship with target entry Instructions **SHALL** contain exactly one [1..1] @inversionInd="true" True (CONF:7542)
42. Precondition for Substance Administration **SHALL** contain exactly one [1..1] @typeCode="PRCN" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:7550)

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"/>
  <templateId root="111.222.333.444.222"/>
  <id root="811105851" extension="MDHT"/>
  <code code="1710302509"/>
  <text>Text Value</text>
  <statusCode code="completed"/>
  <effectiveTime value="20120618"/>
  <repeatNumber value="1"/>
  <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"/>
  <doseQuantity/>
  <rateQuantity/>
  <maxDoseQuantity/>
  <consumable/>
  <author typeCode="AUT">
    <templateId root="null"/>
    <time/>
    <assignedAuthor>
      <id root="783010618" extension="MDHT"/>
      <assignedPerson/>
    </assignedAuthor>
  </author>
  <entryRelationship>
    <observation>
      <id root="1605553788" extension="MDHT"/>
      <code code="427001740"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <value xsi:type="CD" code="577447036"/>
```

```
    </observation>
  </entryRelationship>
  <entryRelationship>
    <act>
      <code code="1926950046"/>
    </act>
  </entryRelationship>
  <entryRelationship>
    <act>
      <code code="1131988263"/>
      <text>Text Value</text>
    </act>
  </entryRelationship>
  <entryRelationship>
    <act>
      <code code="1253098762"/>
      <text>Text Value</text>
    </act>
  </entryRelationship>
  <entryRelationship>
    <observation>
      <id root="2072760804" extension="MDHT"/>
      <code code="119566679"/>
      <text>Text Value</text>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation/>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS" moodCode="GOL">
      <templateId root="2.16.840.1.113883.10.20.1.25"/>
      <id root="1953327193" extension="MDHT"/>
      <code code="964541820"/>
      <text>Text Value</text>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <repeatNumber value="1"/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <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)*
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- 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.
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- 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*