Implementation Guide for CDA R2
HITSP C32, C83, and C80 Summary Documents

Acknowledgments

Revision History

Rev	Date	By Whom	Changes
First draft for posting	August 31, 2010	Dave Carlson	Updated model content and publication format
First draft for IG consolidation project	December 29, 2010	Dave Carlson	

Notes on draft status

December 29, 2010: This is a first draft of HITSP/IHE/HL7 implementation guide consolidation for C32 and CCD. This draft includes all template sections defined in C83, some of which are not part of C32 summaries. The next draft will limit content to templates used in C32.

Contents

List of Figures

Chapter 1

INTRODUCTION

Topics:

Overview

This implementation guide is generated from UML models developed in the Open Health Tools (OHT) Model-Driven Health Tools (MDHT) project. The HITSP specifications have been formalized into computational models expressed in UML. These models are used by automated tooling to generate this publication, plus validation tools and Java libraries for implementers.

This document combines specifications from several HITSP documents, as summarized in the following sections. For the authoritative source, please refer to the approved specifications from HITSP.

C32 Patient Summary

The HITSP Summary Documents Using HL7 Continuity of Care Document (CCD) Component describes the document content summarizing a consumer's medical status for the purpose of information exchange. The content may include administrative (e.g., registration, demographics, insurance, etc.) and clinical (problem list, medication list, allergies, test results, etc) information. Any specific use of this Component by another HITSP specification may constrain the content further based upon the requirements and context of the document exchange. This specification defines content in order to promote interoperability between participating systems. Any given system creating or consuming the document may contain much more information than conveyed by this specification. Such systems may include Personal Health Record Systems (.1.s), Electronic Health Record Systems (EHRs), Practice Management Applications and other persons and systems as identified and permitted.

This Component is essentially a subset of the healthcare data that has been developed for specific business Use Cases. This subset contains the minimum critical or pertinent medical information sections as specified by the business case. Information conveyed according to the Component Construct is a representative extract of the information available on the creating system. The information in the HITSP Summary Documents Using HL7 Continuity of Care Document (CCD) Component and the creating systems must be consistent. Furthermore there should be no data elsewhere in the creating systemthat would contradict the meaning of any data in this construct. The expectation is that consuming systems will be able to use this specification as a source of information to input and/or update information in their instantiation of the healthcare record. This specification does not define the policies applicable to the import of this information.

It is anticipated and desirable that some implementers of the HITSP Summary Documents Using HL7 Continuity of Care Document (CCD) Component will want to add data and sections to permit greater communication between systems. The underlying standards (primarily HL7 CCD – Continuity of Care Document) have additional modules that may serve such purposes. This practice is beyond the scope of this HITSP Component. Implementers should be aware that they must assume that receivers of the document may only be able to view or process content modules as described in this specification, and may not be able to use the additional modules in the document. This means that the HITSP Summary Documents Using HL7 Continuity of Care Document (CCD) Component must be able to stand-alone. Applications may wish to display the document in two different user-selected views, one of which is restricted to the minimal dataset contents of this component. Adding optional sections and data elements should not generate errors. Optional data should be used if understood by the receiving system, but must not change the meaning of the document.

This Component refers to the HITSP 2008 work cycle. It expands upon the prior version of the specification for a consumer’s registration/medication history information to include content to support the consumer's access to clinical information, medication management activities and supportive information for quality of care assessment.

C83 Content Modules

The purpose of the Healthcare Information Technology Standards Panel (HITSP) CDA Content Modules Component is to define the library of Components that may be used by CDA-based constructs developed by HITSP and others in standards based exchanges. The Components are organized into modules to simplify navigation. These modules are organized along the same principals as the HL7 Continuity of Care Document.

The data elements found in these modules are based on HL7 CDA Implementation Guides and the IHE PCC Technical Framework Volume II, Release 5 and its related supplements. These guides contain specifications for document sections that are consistent with all clinical documents currently selected for HITSP constructs.

C80 Clinical Document and Message Terminology

The purpose of the Health Information Technology Standards Panel (HITSP) Clinical Document and Message Terminology Component is to define the vocabulary for either document-based or message-based HITSP constructs such as Clinical Document Architecture (CDA) documents, HL7 V2 messages, etc. For more in-depth information about how this Component relates to other HITSP constructs, see HITSP/TN901 Clinical Documents.

Approach

Working with an initial portion of the data provides the opportunity to work with the data from the perspective of the underlying model and electronic format and to explore many design issues thoroughly. Taking this as an initial step ensures that the data set developers and standards community can reach consensus prior to the larger commitment of time that would be required to bring the full data set into standard format.

This project supports reusability and ease of data collection through a standard data representation harmonized with work developed through Health Information Technology Expert Panel (HITEP), balloted through Health Level Seven (HL7) and/or recognized by the Health Information Technology Standards Panel (HITSP).

This implementation guide (IG) specifies a standard for electronic submission of NCRs in a Clinical Document Architecture (CDA), Release 2 format.

Scope

TODO: scope of this implementation guide.

Audience

The audience for this document includes software developers and implementers who wish to develop...

Organization of This Guide

The requirements as laid out in the body of this document are subject to change per the policy on implementation guides (see section 13.02" Draft Standard for Trial Use Documents" within the HL7 Governance and Operations Manual, http://www.hl7.org/documentcenter/public/membership/HL7_Governance_and_Operations_Manual.pdf).

Templates

Templates are organized by document (see Document Templates), by section (see Section Templates), and by clinical statements (see Clinical Statement Templates). Within a section, templates are arranged hierarchically, where a more specific template is nested under the more generic template that it conforms to. See Templates by Containment for a listing of the higher level templates by containment; the appendix Templates Used in This Guide includes a table of all of the templates Organized Hierarchically.

Vocabulary and Value Sets

Vocabularies recommended in this guide are from standard vocabularies. When SNOMED codes are used, rules defined in Using SNOMED CT in HL7 Version 3 are adhered to. In many cases, these vocabularies are further constrained into value sets for use within this guide. Value set names and OIDs are summarized in the table Summary of Value Sets. Each named value set in this summary table is stored in a template database that will be maintained by CHCA.

Use of Templates

When valued in an instance, the template identifier (templateId) signals the imposition of a set of template-defined constraints. The value of this attribute provides a unique identifier for the templates in question.

Originator Responsibilities

An originator can apply a templateId to assert conformance with a particular template.

In the most general forms of CDA exchange, an originator need not apply a templateId for every template that an object in an instance document conforms to. This implementation guide asserts when templateIds are required for conformance.

Recipient Responsibilities

A recipient may reject an instance that does not contain a particular templateId (e.g., a recipient looking to receive only CCD documents can reject an instance without the appropriate templateId).

A recipient may process objects in an instance document that do not contain a templateId (e.g., a recipient can process entries that contain Observation acts within a Problems section, even if the entries do not have templateIds).

Conventions Used in This Guide

Conformance Requirements

Conformance statements are grouped and identified by the name of the template, along with the templateId and the context of the template (e.g., ClinicalDocument, section, observation), which specifies the element under constraint. If a template is a specialization of another template, its first constraint indicates the more general template. In all cases where a more specific template conforms to a more general template, asserting the more specific template also implies conformance to the more general template. An example is shown below.

Template name

```
[<type of template>: templateId <XXXX.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
        1. **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
        1. **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.

Discharge Summary

[ClinicalDocument: templateId 2.16.840.1.113883.3.88.11.48.2]

1. **SHALL** contain exactly one [1..1] templateId ( ) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.3.88.11.48.2"
2. **SHALL** conform to IHE Medical Summary template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.2) (C48-[CT3-1])
3. **SHALL** contain exactly one [1..1] **component** (C48-[CT2-1])
   a. Contains exactly one [1..1] Problem List Section (templateId: 2.16.840.1.113883.3.88.11.83.103)
4. **SHOULD** contain exactly one [1..1] **component** (C48-[CT2-2])
   a. Contains exactly one [1..1] Admission Medication History Section (templateId: 2.16.840.1.113883.3.88.11.83.113)
5. **SHALL** contain exactly one [1..1] **component** (C48-[CT2-3])
   a. Contains exactly one [1..1] Hospital Admission Diagnosis Section (templateId: 2.16.840.1.113883.3.88.11.83.110)
6. **MAY** contain zero or one [0..1] **component** (C48-[CT2-4])
   a. Contains exactly one [1..1] Advance Directives Section (templateId: 2.16.840.1.113883.3.88.11.83.116)
7. **SHALL** contain exactly one [1..1] **component** (C48-[CT2-5])
   a. Contains exactly one [1..1] Allergies Reactions Section (templateId: 2.16.840.1.113883.3.88.11.83.102)
8. **SHALL** contain exactly one [1..1] **component** (C48-[CT2-6])
   a. Contains exactly one [1..1] Discharge Diagnosis Section (templateId: 2.16.840.1.113883.3.88.11.83.111)
9. **MAY** contain zero or one [0..1] **component** (C48-[CT2-7])
   a. Contains exactly one [1..1] IHE Discharge Diet (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.33)
10. **SHALL** contain exactly one [1..1] **component** (C48-[CT2-8])
    a. Contains exactly one [1..1] Hospital Discharge Medications Section (templateId: 2.16.840.1.113883.3.88.11.83.114)
11. **MAY** contain zero or one [0..1] **component** (C48-[CT2-9])
    a. Contains exactly one [1..1] Diagnostic Results Section (templateId: 2.16.840.1.113883.3.88.11.83.122)
12. **MAY** contain zero or one [0..1] **component** (C48-[CT2-10])
    a. Contains exactly one [1..1] Functional Status Section (templateId: 2.16.840.1.113883.3.88.11.83.109)
13. **SHOULD** contain exactly one [1..1] **component** (C48-[CT2-11])
    a. Contains exactly one [1..1] History Of Present Illness (templateId: 2.16.840.1.113883.3.88.11.83.107)
14. **SHALL** contain exactly one [1..1] **component** (C48-[CT2-12])
    a. Contains exactly one [1..1] Hospital Course Section (templateId: 2.16.840.1.113883.3.88.11.83.121)
15. **SHOULD** contain exactly one [1..1] **component** (C48-[CT2-13])
    a. Contains exactly one [1..1] Medical Equipment Section (templateId: 2.16.840.1.113883.3.88.11.83.128)

16. **MAY** contain zero or one [0..1] **component** (C48-[CT2-15])
    a. Contains exactly one [1..1] Physical Exam Section (templateId: 2.16.840.1.113883.3.88.11.83.118)
17. **SHALL** contain exactly one [1..1] **component** (C48-[CT2-16])
    a. Contains exactly one [1..1] Plan Of Care Section (templateId: 2.16.840.1.113883.3.88.11.83.124)
18. **SHALL** contain exactly one [1..1] **component** (C48-[CT2-17])
    a. Contains exactly one [1..1] History Of Past Illness Section (templateId: 2.16.840.1.113883.3.88.11.83.104)
19. **MAY** contain zero or one [0..1] **component** (C48-[CT2-18])
    a. Contains exactly one [1..1] Review Of Systems Section (templateId: 2.16.840.1.113883.3.88.11.83.120)
20. **SHOULD** contain exactly one [1..1] **component** (C48-[CT2-19])
    a. Contains exactly one [1..1] Medications Administered Section (templateId: 2.16.840.1.113883.3.88.11.83.115)
21. **SHOULD** contain exactly one [1..1] **component** (C48-[CT2-20])
    a. Contains exactly one [1..1] Vital Signs Section (templateId: 2.16.840.1.113883.3.88.11.83.119)

1. **SHALL** conform to CDT General Header Constraints template (templateId: 2.16.840.1.113883.10.20.3)
2. **SHALL** conform to IHE Medical Document template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.1)
3. **SHALL** conform to IHE Medical Summary template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.2)
4. **SHALL** contain exactly one [1..1] **realmCode/@code**="US" (CONF-HP-15)
5. **SHALL** contain exactly one [1..1] **typeId** (CONF-HP-16)
   - *The clinical document type ID identifies the constraints imposed by CDA R2 on the content, essentially acting as a version identifier.*
6. **SHALL** contain exactly one [1..1] **id** (CONF-HP-17)
   - *The ClinicalDocument/id element is an instance identifier data type (see HL7 Version 3 Abstract Data in Section 5 REFERENCES). The root attribute is a UUID or OID. The root uniquely identifies the scope of the extension. The root and extension attributes uniquely identify the document.*
7. **SHALL** contain exactly one [1..1] **code**, where the @code **SHALL** be selected from (CodeSystem: 2.16.840.1.113883.6.1 LOINC)
8. **SHALL** contain exactly one [1..1] **title** (CONF-HP-22)
   - *Specifies the local name used for the document.*
     Note that the title does not need to be the same as the display name provided with the document type code. For example, the display name provided by LOINC® as an aid in debugging may be "HISTORY AND PHYSICAL". The title can be localized, as appropriate.
9. **SHALL** contain exactly one [1..1] **effectiveTime** (CONF-HP-23)
   - *Specifies the creation time of the document. All documents authored by direct input to a computer system should record an effectiveTime that is precise to the second. When authored in other ways, for example, by filling out a paper form that is then transferred into an EHR system, the precision of effectiveTime may be less than to the second.*
10. Contains exactly one [1..1] **confidentialityCode**
    - *Specifies the confidentiality assigned to the document. This specification provides no further guidance beyond CDA R2*
      on documents with respect to the vocabulary used for confidentialityCode, nor treatment or implementation of confidentiality.
11. **SHALL** contain exactly one [1..1] **languageCode** (CONF-HP-24)

12. Contains at least one [1..*] **`recordTarget`**, where its type is Record Target

- **a.** Contains exactly one [1..1] Record Target

13. Contains at least one [1..*] **`author`**, where its type is Author

- **a.** Contains exactly one [1..1] Author

14. Contains exactly one [1..1] **`custodian`**, where its type is Custodian

- **a.** Contains exactly one [1..1] Custodian

15. Contains exactly one [1..1] **`component`**, where its type is Component2

- **a.** Contains exactly one [1..1] Component2

16. Contains at least one [1..*] **`author`**

- **a.** Contains exactly one [1..1] CDA Author

- *The author element represents the creator of the clinical document. If the role of the actor is the entry of information from his or her own knowledge or application of skills, that actor is the author. If one actor provides information to another actor who filters, reasons, or algorithmically creates new information, then that second actor is also an author, having created information from his or her own knowledge or skills. However, that determination is independent from the determination of the first actor's authorship.*

17. Contains zero or one [0..1] **`dataEnterer`**

- **a.** Contains exactly one [1..1] CDA Data Enterer

- *The dataEnterer element represents the person who transferred the information from other sources into the clinical document, where the other sources wrote the content of the note. The guiding rule of thumb is that an author provides the content found within the header or body of the document, subject to their own interpretation. The dataEnterer adds information to the electronic system. A person can participate as both author and dataEnterer.*

  If the role of the actor is to transfer information from one source to another (e.g., transcription or transfer from paper form to electronic system), that actor is considered a dataEnterer.

18. Contains exactly one [1..1] **`custodian`**

- **a.** Contains exactly one [1..1] CDA Custodian

- *Based on the CDA R2 constraints (Section 4.2.2.3 of the CDA Normative Web Edition. See Section 5 REFERENCES), the custodian element is required and is the custodian of the clinical document.*

19. Contains zero or more [0..*] **`informationRecipient`**

- **a.** Contains exactly one [1..1] CDA Information Recipient

- *informationRecipient, when used in the context of a referral or request for consultation, this records the intended recipient of the information at the time the document is created. The intended recipient may also be the health chart of the patient, in which case the receivedOrganization is the scoping organization of that chart.*

20. Contains zero or one [0..1] **`legalAuthenticator`**

- **a.** Contains exactly one [1..1] CDA Legal Authenticator

- *The legalAuthenticator element identifies the legal authenticator of the document and must be present if the document has been legally authenticated. Based on local practice, clinical documents may be released before legal authentication. This implies that a clinical document that does not contain this element has not been legally authenticated.*

  The act of legal authentication requires a certain privilege be granted to the legal

authenticator depending upon local policy. All clinical documents have the potential for legal authentication, given the appropriate credentials.

Local policies may choose to delegate the function of legal authentication to a device or system that generates the clinical document. In these cases, the legal authenticator is a person accepting responsibility for the document, not the generating device or system.

21. Contains zero or more [0..*] **`authenticator`**
    a. Contains exactly one [1..1] CDA Authenticator

    - *The authenticator identifies the participant who attested to the accuracy of the information in the document.*

      Automated systems, such as a PHR, that allow a clinical document to be generated need to give special consideration to authentication permissions because the information contained in the document may come from sources or contain information that the author cannot validate.

22. **SHALL** contain exactly one [1..1] **`component`** (C48-[CT2-1])
    a. Contains exactly one [1..1] Problem List Section (templateId: `2.16.840.1.113883.3.88.11.83.103`)
23. **SHOULD** contain exactly one [1..1] **`component`** (C48-[CT2-2])
    a. Contains exactly one [1..1] Admission Medication History Section (templateId: `2.16.840.1.113883.3.88.11.83.113`)
24. **SHALL** contain exactly one [1..1] **`component`** (C48-[CT2-3])
    a. Contains exactly one [1..1] Hospital Admission Diagnosis Section (templateId: `2.16.840.1.113883.3.88.11.83.110`)
25. **MAY** contain zero or one [0..1] **`component`** (C48-[CT2-4])
    a. Contains exactly one [1..1] Advance Directives Section (templateId: `2.16.840.1.113883.3.88.11.83.116`)
26. **SHALL** contain exactly one [1..1] **`component`** (C48-[CT2-5])
    a. Contains exactly one [1..1] Allergies Reactions Section (templateId: `2.16.840.1.113883.3.88.11.83.102`)
27. **SHALL** contain exactly one [1..1] **`component`** (C48-[CT2-6])
    a. Contains exactly one [1..1] Discharge Diagnosis Section (templateId: `2.16.840.1.113883.3.88.11.83.111`)
28. **MAY** contain zero or one [0..1] **`component`** (C48-[CT2-7])
    a. Contains exactly one [1..1] IHE Discharge Diet (templateId: `1.3.6.1.4.1.19376.1.5.3.1.3.33`)
29. **SHALL** contain exactly one [1..1] **`component`** (C48-[CT2-8])
    a. Contains exactly one [1..1] Hospital Discharge Medications Section (templateId: `2.16.840.1.113883.3.88.11.83.114`)
30. **MAY** contain zero or one [0..1] **`component`** (C48-[CT2-9])
    a. Contains exactly one [1..1] Diagnostic Results Section (templateId: `2.16.840.1.113883.3.88.11.83.122`)
31. **MAY** contain zero or one [0..1] **`component`** (C48-[CT2-10])
    a. Contains exactly one [1..1] Functional Status Section (templateId: `2.16.840.1.113883.3.88.11.83.109`)
32. **SHOULD** contain exactly one [1..1] **`component`** (C48-[CT2-11])
    a. Contains exactly one [1..1] History Of Present Illness (templateId: `2.16.840.1.113883.3.88.11.83.107`)
33. **SHALL** contain exactly one [1..1] **`component`** (C48-[CT2-12])
    a. Contains exactly one [1..1] Hospital Course Section (templateId: `2.16.840.1.113883.3.88.11.83.121`)

34. **SHOULD** contain exactly one [1..1] **component** (C48-[CT2-13])
    a. Contains exactly one [1..1] Medical Equipment Section (templateId: 2.16.840.1.113883.3.88.11.83.128)
35. **MAY** contain zero or one [0..1] **component** (C48-[CT2-15])
    a. Contains exactly one [1..1] Physical Exam Section (templateId: 2.16.840.1.113883.3.88.11.83.118)
36. **SHALL** contain exactly one [1..1] **component** (C48-[CT2-16])
    a. Contains exactly one [1..1] Plan Of Care Section (templateId: 2.16.840.1.113883.3.88.11.83.124)
37. **SHALL** contain exactly one [1..1] **component** (C48-[CT2-17])
    a. Contains exactly one [1..1] History Of Past Illness Section (templateId: 2.16.840.1.113883.3.88.11.83.104)
38. **MAY** contain zero or one [0..1] **component** (C48-[CT2-18])
    a. Contains exactly one [1..1] Review Of Systems Section (templateId: 2.16.840.1.113883.3.88.11.83.120)
39. **SHOULD** contain exactly one [1..1] **component** (C48-[CT2-19])
    a. Contains exactly one [1..1] Medications Administered Section (templateId: 2.16.840.1.113883.3.88.11.83.115)
40. **SHOULD** contain exactly one [1..1] **component** (C48-[CT2-20])
    a. Contains exactly one [1..1] Vital Signs Section (templateId: 2.16.840.1.113883.3.88.11.83.119)
41. **SHALL** satisfy: All patient, guardianPerson, assignedPerson, maintainingPerson, relatedPerson, intendedRecipient/informationRecipient, associatedPerson, and relatedSubject/subject elements have a name. (CONF-HP-6)
42. **SHALL** satisfy: All patientRole, assignedAuthor, assignedEntity[not(parent::dataEnterer)] and associatedEntity elements have an addr and telecom element. (CONF-HP-7)
43. **SHOULD** satisfy: All guardian, dataEnterer/assignedEntity, relatedEntity, intendedRecipient, relatedSubject and participantRole elements have an addr and telecom element. (CONF-HP-8)
44. **SHALL** satisfy: All guardianOrganization, providerOrganization, wholeOrganization, representedOrganization, representedCustodianOrganization, receivedOrganization, scopingOrganization and serviceProviderOrganization elements have name, addr and telecom elements. (CONF-HP-9)
45. Times or time intervals found in the ClinicalDocument/effectiveTime, author/time, dataEnterer/time, legalAuthenticator/time, authenticator/time and encompassingEncounter/effectiveTime elements **SHALL** be precise to the day, **SHALL** include a time zone if more precise than to the day, and **SHOULD** be precise to the second. (CONF-HP-10)
46. Times or time intervals found in the asOrganizationPartOf/effectiveTime, asMaintainedEntity/effectiveTime, relatedEntity/effectiveTime, serviceEvent/effectiveTime, ClinicalDocument/participant/time, serviceEvent/performer/time and encounterParticipant/time **SHALL** be precise at least to the year, **SHOULD** be precise to the day, and **MAY** omit time zone. (CONF-HP-11)
47. **SHALL** satisfy: Telephone numbers match the regular expression pattern tel:\+?[-0-9().]+ (CONF-HP-12)
48. **SHALL** satisfy: At least one dialing digit is present in the phone number after visual separators are removed. (CONF-HP-13)
49. **SHALL** satisfy: If the telephone number is unknown it is represented using the appropriate flavor of null. (CONF-HP-14)
50. **SHALL** satisfy: The extension attribute of the typeId element is POCD_HD000040. (CONF-HP-16)
51. **SHALL** satisfy: The id/@root attribute is a syntactically correct UUID or OID. (CONF-HP-17)
52. **SHALL** satisfy: UUIDs are represented in the form XXXXXXXX-XXXX-XXXX-XXXXXXXXXXXXXXXX, where each X is a character from the set [A-Fa-f0-9]. (CONF-HP-18)
53. OIDs are represented in dotted decimal notation, where each decimal number is either 0, or starts with a nonzero digit. More formally, an OID **SHALL** be in the form ([0-2])(.([1-9][0-9]*|0))+. (CONF-HP-19)
54. **SHALL** satisfy: OIDs are no more than 64 characters in length. (CONF-HP-20)
55. **SHALL** satisfy: languageCode has the form nn, or nn-CC. (CONF-HP-25)

56. **SHALL** satisfy: The nn portion of languageCode is a legal ISO-639-1 language code in lowercase. (CONF-HP-26)
57. The CC portion languageCode, if present, **SHALL** be an ISO-3166 country code in uppercase. (CONF-HP-27)
58. Both setId and versionNumber **SHALL** be present or both **SHALL** be absent. (CONF-HP-28)
59. The @extension and/or @root of setId and id **SHALL** be different when both are present. (CONF-HP-29)
60. A copyTime element **SHALL NOT** be present. (CONF-HP-30)
61. **SHALL** satisfy: At least one recordTarget/patientRole element is present. (CONF-HP-31)
62. A patient/birthTime element **SHALL** be present. The patient/birthTime element **SHALL** be precise at least to the year, and **SHOULD** be precise at least to the day, and **MAY** omit time zone. If unknown, it **SHALL** be represented using a flavor of null. (CONF-HP-32)
63. A patient/administrativeGenderCode element **SHALL** be present. If unknown, it **SHALL** be represented using a flavor of null. Values for administrativeGenderCode **SHOULD** be drawn from the HL7 AdministrativeGender vocabulary. (CONF-HP-33)
64. The maritalStatusCode, religiousAffiliationCode, raceCode and ethnicGroupCode **MAY** be present. If maritalStatusCode, religiousAffiliationCode, raceCode and ethnicGroupCode elements are present, they **SHOULD** be encoded using the appropriate HL7 vocabularies. (CONF-HP-34)
65. **SHOULD** satisfy: The guardian element is present when the patient is a minor child. (CONF-HP-35)
66. **MAY** satisfy: The providerOrganization element is present. (CONF-HP-36)
67. **SHALL** satisfy: The author/time element is present. (CONF-HP-37)
68. **SHALL** satisfy: The assignedAuthor/id element is present. (CONF-HP-38)
69. **SHALL** satisfy: An assignedAuthor element contains at least one assignedPerson or assignedAuthoringDevice elements. (CONF-HP-39)
70. **SHALL** satisfy: When dataEnterer is present, an assignedEntity/assignedPerson element is present. (CONF-HP-40)
71. The dataEnterer/time element **MAY** be present. If present, it represents the starting time of entry of the data. (CONF-HP-41)
72. **MAY** satisfy: The informant element is present. (CONF-HP-42)
73. When informant is present, an assignedEntity/assignedPerson or relatedEntity/relatedPerson element **SHALL** be present. (CONF-HP-43)
74. When the informant is a healthcare provider with an assigned role, the informant **SHALL** be represented using the assignedEntity element (CONF-HP-44)
75. Allowable values for informant/relatedEntity/@classCode **SHALL** be CON, PRS, CAREGIVER, AGNT or PROV from the RoleClass vocabulary. (CONF-HP-45)
76. When relatedEntity/@classCode is PRS, values in relatedEntity/code **SHALL** come from the HL7 PersonalRelationshipRoleType vocabulary or from SNOMED, any subtype of "Person in the family" (303071001). (CONF-HP-46)
77. When an informant is an unrelated person not otherwise specified, the value relatedEntity/@classCode **SHALL** be set to CON to indicate that this person is a contact. (CONF-HP-47)
78. When the informant is a healthcare provider without an assigned role, the informant **SHALL** be represented using the relatedEntity element and the value of relatedEntity/@classCode **SHALL** be set to PROV. (CONF-HP-48)
79. When the informant is a healthcare provider, the value of relatedEntity/code **SHOULD** be present and indicate the type of healthcare provider. (CONF-HP-49)
80. The ClinicalDocument/informationRecipient element **MAY** be present. When informationRecipient is used, at least one informationRecipient/intendedRecipient/informationRecipient or informationRecipient/intendedRecipient/receivedOrganization **SHALL** be present. (CONF-HP-50)
81. The assignedEntity/assignedPerson element **SHALL** be present in legalAuthenticator. (CONF-HP-51)
82. The assignedEntity/assignedPerson element **SHALL** be present in an authenticator element. (CONF-HP-52)
83. Times or time intervals found in the ClinicalDocument/effectiveTime, author/time, dataEnterer/time, legalAuthenticator/time, authenticator/time and encompassingEncounter/effectiveTime elements **SHALL** be precise to the day, **SHALL** include a time zone if more precise than to the day, and **SHOULD** be precise to the second. (CONF-HP-10)
84. Times or time intervals found in the asOrganizationPartOf/effectiveTime, asMaintainedEntity/effectiveTime, relatedEntity/effectiveTime, serviceEvent/effectiveTime, ClinicalDocument/participant/time, serviceEvent/

performer/time and encounterParticipant/time **SHALL** be precise at least to the year, **SHOULD** be precise to the day, and **MAY** omit time zone. (CONF-HP-11)

85. **SHALL** satisfy: MedicalSummaryProblemConcernEntry
86. **SHALL** satisfy: MedicalSummaryAllergyConcernEntry
87. **SHALL** satisfy: MedicalSummaryMedications

hitsp::DischargeSummary							
cda::clinicaldocument[cda:templateId/@root =]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
activeProblems (problemListSection)	problemListSection	1..1	SHALL	YES	ProblemListSection	C48-[CT2-1]	
admissionMedications (admissionMedicationHistorySection)	admissionMedicationHistorySection	1..1	SHOULD	YES	AdmissionMedicationHistorySection	C48-[CT2-2]	
admittingDiagnosis (hospitalAdmissionDiagnosisSection)	hospitalAdmissionDiagnosisSection	1..1	SHALL	YES	HospitalAdmissionDiagnosisSection	C48-[CT2-3]	
advanceDirectives (advanceDirectivesSection)	advanceDirectivesSection	0..1	MAY	YES	AdvanceDirectivesSection	C48-[CT2-4]	
allergies (allergiesReactionsSection)	allergiesReactionsSection	1..1	SHALL	YES	AllergiesReactionsSection	C48-[CT2-5]	
dischargeDiagnosis (dischargeDiagnosisSection)	dischargeDiagnosisSection	1..1	SHALL	YES	DischargeDiagnosisSection	C48-[CT2-6]	
dischargeDiet	dischargeDiet	0..1	MAY	YES	DischargeDiet	C48-[CT2-7]	
dischargeMeds (hospitalDischargeMedicationsSection)	hospitalDischargeMedicationsSection	1..1	SHALL	YES	HospitalDischargeMedicationsSection	C48-[CT2-8]	
dischargeProceduresDiagnosticResults (diagnosticResultsSection)	diagnosticResultsSection	0..1	MAY	YES	DiagnosticResultsSection	C48-[CT2-9]	
functionalStatus (functionalStatusSection)	functionalStatusSection	0..1	MAY	YES	FunctionalStatusSection	C48-[CT2-10]	
historyOfPresentIllness	historyOfPresentIllness	1..1	SHOULD	YES	HistoryOfPresentIllness	C48-[CT2-11]	
hospitalCourse (hospitalCourseSection)	hospitalCourseSection	1..1	SHALL	YES	HospitalCourseSection	C48-[CT2-12]	
medicalEquipment (medicalEquipmentSection)	medicalEquipmentSection	0..1	SHOULD	YES	MedicalEquipmentSection	C48-[CT2-13]	
physicalExamination (physicalExamSection)	physicalExamSection	0..1	MAY	YES	PhysicalExamSection	C48-[CT2-15]	
planOfCare (planOfCareSection)	planOfCareSection	1..1	SHALL	YES	PlanOfCareSection	C48-[CT2-16]	
resolvedProblems (historyOfPastIllnessSection)	historyOfPastIllnessSection	1..1	SHALL	YES	HistoryOfPastIllnessSection	C48-[CT2-17]	
reviewOfSystems (reviewOfSystemsSection)	reviewOfSystemsSection	0..1	MAY	YES	ReviewOfSystemsSection	C48-[CT2-18]	
selectedMedicationsAdministered (medicationsAdministeredSection)	medicationsAdministeredSection	1..1	SHOULD	YES	MedicationsAdministeredSection	C48-[CT2-19]	
vitalSigns (vitalSignsSection)	vitalSignsSection	1..1	SHOULD	YES	VitalSignsSection	C48-[CT2-20]	

Discharge Summary 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">
  <typeId root="2.16.840.1.113883.1.3"/>
  <id root="MDHT" extension="463305664"/>
  <code code="1359823927"/>
  <title>TEXT FOR TITLE</title>
  <effectiveTime/>
  <confidentialityCode code="1103080507"/>
  <languageCode code="Code forlanguageCode"/>
  <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>
          <typeId root="2.16.840.1.113883.1.3"/>
          <id root="MDHT" extension="2086705321"/>
          <code code="615703875"/>
          <title>TEXT FOR TITLE</title>
          <languageCode code="Code forlanguageCode"/>
          <entry>
            <act>
              <typeId root="2.16.840.1.113883.1.3"/>
              <id root="MDHT" extension="552639841"/>
              <code code="1363607115"/>
              <effectiveTime>
                <low value="2012"/>
                <high value="2012"/>
              </effectiveTime>
              <languageCode code="Code forlanguageCode"/>
              <entryRelationship>
                <observation/>
              </entryRelationship>
            </act>
          </entry>
        </section>
      </component>
      <component>
        <section>
          <typeId root="2.16.840.1.113883.1.3"/>
          <id root="MDHT" extension="252666966"/>
          <code code="508267659"/>
          <title>TEXT FOR TITLE</title>
          <languageCode code="Code forlanguageCode"/>
        </section>
      </component>
      <component>
        <section>
          <typeId root="2.16.840.1.113883.1.3"/>
          <id root="MDHT" extension="1596285626"/>
          <code code="53604306"/>
          <title>TEXT FOR TITLE</title>
          <languageCode code="Code forlanguageCode"/>
          <entry>
            <act>
              <typeId root="2.16.840.1.113883.1.3"/>
```

```
            <id root="MDHT" extension="1221465221"/>
            <code code="1797477443"/>
            <effectiveTime>
              <low value="2012"/>
              <high value="2012"/>
            </effectiveTime>
            <languageCode code="Code forlanguageCode"/>
            <entryRelationship>
              <observation/>
            </entryRelationship>
          </act>
        </entry>
      </section>
    </component>
    <component>
      <section>
        <typeId root="2.16.840.1.113883.1.3"/>
        <id root="MDHT" extension="1963897614"/>
        <code code="790592606"/>
        <title>TEXT FOR TITLE</title>
        <languageCode code="Code forlanguageCode"/>
        <entry>
          <observation>
            <typeId root="2.16.840.1.113883.1.3"/>
            <id root="MDHT" extension="1294539177"/>
            <code code="785029370"/>
            <effectiveTime>
              <low value="2012"/>
              <high value="2012"/>
            </effectiveTime>
            <languageCode code="Code forlanguageCode"/>
          </observation>
        </entry>
      </section>
    </component>
    <component>
      <section>
        <typeId root="2.16.840.1.113883.1.3"/>
        <id root="MDHT" extension="1139333773"/>
        <code code="1135530843"/>
        <title>TEXT FOR TITLE</title>
        <languageCode code="Code forlanguageCode"/>
        <entry>
          <act>
            <typeId root="2.16.840.1.113883.1.3"/>
            <id root="MDHT" extension="121105268"/>
            <code code="2060278325"/>
            <effectiveTime>
              <low value="2012"/>
              <high value="2012"/>
            </effectiveTime>
            <languageCode code="Code forlanguageCode"/>
          </act>
        </entry>
      </section>
    </component>
    <component>
      <section>
        <typeId root="2.16.840.1.113883.1.3"/>
        <id root="MDHT" extension="1099244387"/>
        <code code="531027794"/>
        <title>TEXT FOR TITLE</title>
        <languageCode code="Code forlanguageCode"/>
        <entry>
```

```
            <act>
              <typeId root="2.16.840.1.113883.1.3"/>
              <id root="MDHT" extension="474531856"/>
              <code code="1713536999"/>
              <effectiveTime>
                <low value="2012"/>
                <high value="2012"/>
              </effectiveTime>
              <languageCode code="Code forlanguageCode"/>
              <entryRelationship>
                <observation/>
              </entryRelationship>
            </act>
          </entry>
        </section>
      </component>
      <component>
        <section/>
      </component>
      <component>
        <section>
          <typeId root="2.16.840.1.113883.1.3"/>
          <id root="MDHT" extension="989006245"/>
          <code code="67842718"/>
          <title>TEXT FOR TITLE</title>
          <languageCode code="Code forlanguageCode"/>
          <entry>
            <substanceAdministration classCode="SBADM">
              <typeId root="2.16.840.1.113883.1.3"/>
              <id root="MDHT" extension="274774369"/>
              <code code="1925000236"/>
              <effectiveTime xsi:type="IVL_TS">
                <low value="2012"/>
                <high value="2012"/>
              </effectiveTime>
              <consumable/>
              <entryRelationship>
                <observation/>
              </entryRelationship>
              <entryRelationship>
                <supply classCode="SPLY"/>
              </entryRelationship>
              <entryRelationship>
                <observation/>
              </entryRelationship>
            </substanceAdministration>
          </entry>
        </section>
      </component>
      <component>
        <section>
          <typeId root="2.16.840.1.113883.1.3"/>
          <id root="MDHT" extension="71863390"/>
          <code code="617208080"/>
          <title>TEXT FOR TITLE</title>
          <languageCode code="Code forlanguageCode"/>
          <entry>
            <observation>
              <typeId root="2.16.840.1.113883.1.3"/>
              <id root="MDHT" extension="523812532"/>
              <code code="1142512072"/>
              <effectiveTime>
                <low value="2012"/>
                <high value="2012"/>
```

```
            </effectiveTime>
            <languageCode code="Code forlanguageCode"/>
          </observation>
        </entry>
        <entry>
          <organizer>
            <typeId root="2.16.840.1.113883.1.3"/>
            <id root="MDHT" extension="522187267"/>
            <code code="829387387"/>
            <statusCode code="completed"/>
            <effectiveTime>
              <low value="2012"/>
              <high value="2012"/>
            </effectiveTime>
            <component>
              <observation/>
            </component>
          </organizer>
        </entry>
      </section>
    </component>
    <component>
      <section>
        <typeId root="2.16.840.1.113883.1.3"/>
        <id root="MDHT" extension="476175575"/>
        <code code="1022120952"/>
        <title>TEXT FOR TITLE</title>
        <languageCode code="Code forlanguageCode"/>
      </section>
    </component>
    <component>
      <section>
        <typeId root="2.16.840.1.113883.1.3"/>
        <id root="MDHT" extension="833806517"/>
        <code code="28217903"/>
        <title>TEXT FOR TITLE</title>
        <languageCode code="Code forlanguageCode"/>
      </section>
    </component>
    <component>
      <section>
        <typeId root="2.16.840.1.113883.1.3"/>
        <id root="MDHT" extension="1938253688"/>
        <code code="456564837"/>
        <title>TEXT FOR TITLE</title>
        <languageCode code="Code forlanguageCode"/>
      </section>
    </component>
    <component>
      <section>
        <typeId root="2.16.840.1.113883.1.3"/>
        <id root="MDHT" extension="1848944326"/>
        <code code="534226543"/>
        <title>TEXT FOR TITLE</title>
        <languageCode code="Code forlanguageCode"/>
      </section>
    </component>
    <component>
      <section>
        <typeId root="2.16.840.1.113883.1.3"/>
        <id root="MDHT" extension="1873542017"/>
        <code code="277625882"/>
        <title>TEXT FOR TITLE</title>
        <languageCode code="Code forlanguageCode"/>
```

```
          <entry>
            <act>
              <typeId root="2.16.840.1.113883.1.3"/>
              <id root="MDHT" extension="2061127625"/>
              <code code="1606829670"/>
              <effectiveTime>
                <low value="2012"/>
                <high value="2012"/>
              </effectiveTime>
              <languageCode code="Code forlanguageCode"/>
              <entryRelationship>
                <observation/>
              </entryRelationship>
            </act>
          </entry>
        </section>
      </component>
      <component>
        <section>
          <typeId root="2.16.840.1.113883.1.3"/>
          <id root="MDHT" extension="1484696858"/>
          <code code="1858791388"/>
          <title>TEXT FOR TITLE</title>
          <languageCode code="Code forlanguageCode"/>
          <entry>
            <substanceAdministration classCode="SBADM">
              <typeId root="2.16.840.1.113883.1.3"/>
              <id root="MDHT" extension="1726930784"/>
              <code code="428865982"/>
              <effectiveTime xsi:type="IVL_TS">
                <low value="2012"/>
                <high value="2012"/>
              </effectiveTime>
              <consumable/>
              <entryRelationship>
                <observation/>
              </entryRelationship>
              <entryRelationship>
                <supply classCode="SPLY"/>
              </entryRelationship>
              <entryRelationship>
                <observation/>
              </entryRelationship>
            </substanceAdministration>
          </entry>
          <entry>
            <substanceAdministration classCode="SBADM">
              <typeId root="2.16.840.1.113883.1.3"/>
              <id root="MDHT" extension="524327270"/>
              <code code="788336209"/>
              <effectiveTime value="20121102"/>
              <consumable/>
            </substanceAdministration>
          </entry>
          <entry>
            <encounter>
              <typeId root="2.16.840.1.113883.1.3"/>
              <id root="MDHT" extension="678148565"/>
              <code code="1694419607"/>
              <effectiveTime>
                <low value="2012"/>
                <high value="2012"/>
              </effectiveTime>
            </encounter>
```

```
          </entry>
        </section>
      </component>
      <component>
        <section>
          <typeId root="2.16.840.1.113883.1.3"/>
          <id root="MDHT" extension="424971753"/>
          <code code="1925217763"/>
          <title>TEXT FOR TITLE</title>
          <languageCode code="Code forlanguageCode"/>
          <entry>
            <act>
              <typeId root="2.16.840.1.113883.1.3"/>
              <id root="MDHT" extension="236631971"/>
              <code code="55920853"/>
              <effectiveTime>
                <low value="2012"/>
                <high value="2012"/>
              </effectiveTime>
              <languageCode code="Code forlanguageCode"/>
              <entryRelationship>
                <observation/>
              </entryRelationship>
            </act>
          </entry>
        </section>
      </component>
      <component>
        <section>
          <typeId root="2.16.840.1.113883.1.3"/>
          <id root="MDHT" extension="2015781679"/>
          <code code="416010380"/>
          <title>TEXT FOR TITLE</title>
          <languageCode code="Code forlanguageCode"/>
        </section>
      </component>
      <component>
        <section>
          <typeId root="2.16.840.1.113883.1.3"/>
          <id root="MDHT" extension="864461373"/>
          <code code="1485817290"/>
          <title>TEXT FOR TITLE</title>
          <languageCode code="Code forlanguageCode"/>
        </section>
      </component>
      <component>
        <section>
          <typeId root="2.16.840.1.113883.1.3"/>
          <id root="MDHT" extension="176085188"/>
          <code code="1011588017"/>
          <title>TEXT FOR TITLE</title>
          <languageCode code="Code forlanguageCode"/>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Patient Summary

[ClinicalDocument: templateId 2.16.840.1.113883.3.88.11.32.1]

This Component describes the document content that summarizes a consumer's medical status for the purpose of health information exchange. While an EHR or PHR system can contain much more information, this Component only deals with the summary information to be exchanged between such systems as established as requirements described in AHIC Use Cases.

1. **SHALL** contain exactly one [1..1] templateId (C32-[CT1-19]) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.3.88.11.32.1"
2. **SHALL** conform to IHE Medical Document template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.1)
3. **SHALL** conform to CCD Continuity Of Care Document template (templateId: 2.16.840.1.113883.10.20.1)
4. **MAY** contain zero or one [0..1] **component** (C32-[CT1-1])
   a. Contains exactly one [1..1] Advance Directives Section (templateId: 2.16.840.1.113883.3.88.11.83.116)
5. **MAY** contain zero or one [0..1] **component** (C32-[CT1-2])
   a. Contains exactly one [1..1] Allergies Reactions Section (templateId: 2.16.840.1.113883.3.88.11.83.102)
6. **MAY** contain zero or more [0..*] **component** (C32-[CT1-3])
   a. Contains exactly one [1..1] Comment (templateId: 2.16.840.1.113883.3.88.11.83.11)
7. **MAY** contain zero or one [0..1] **component** (C32-[CT1-4])
   a. Contains exactly one [1..1] Problem List Section (templateId: 2.16.840.1.113883.3.88.11.83.103)
8. **MAY** contain zero or one [0..1] **component** (C32-[CT1-5])
   a. Contains exactly one [1..1] Encounters Section (templateId: 2.16.840.1.113883.3.88.11.83.127)
9. **MAY** contain zero or one [0..1] **component** (C32-[CT1-7])
   a. Contains exactly one [1..1] Immunizations Section (templateId: 2.16.840.1.113883.3.88.11.83.117)
10. **MAY** contain zero or one [0..1] **component** (C32-[CT1-9])
    a. Contains exactly one [1..1] Payers Section (templateId: 2.16.840.1.113883.3.88.11.83.101)
11. **MAY** contain zero or one [0..1] **component** (C32-[CT1-11])
    a. Contains exactly one [1..1] Medications Section (templateId: 2.16.840.1.113883.3.88.11.83.112)
12. **MAY** contain zero or one [0..1] **component** (C32-[CT1-13])
    a. Contains exactly one [1..1] Plan Of Care Section (templateId: 2.16.840.1.113883.3.88.11.83.124)
13. **MAY** contain zero or one [0..1] **component** (C32-[CT1-14])
    a. Contains exactly one [1..1] IHE Pregnancy History Section (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.5.3.4)
14. **MAY** contain zero or one [0..1] **component** (C32-[CT1-15])
    a. Contains exactly one [1..1] Surgeries Section (templateId: 2.16.840.1.113883.3.88.11.83.108)
15. **SHOULD** contain at least one [1..*] **realmCode** (C32-[CT1-16])
16. **MAY** contain zero or one [0..1] **component** (C32-[CT1-17])
    a. Contains exactly one [1..1] Vital Signs Section (templateId: 2.16.840.1.113883.3.88.11.83.119)
17. **MAY** contain zero or one [0..1] **component** (C32-[CT1-18])
    a. Contains exactly one [1..1] Diagnostic Results Section (templateId: 2.16.840.1.113883.3.88.11.83.122)

18. **MAY** satisfy: Contains 0..* HealthcareProvider in cda:documentationOf/cda:serviceEvent/cda:performer (C32-[CT1-6])
19. **SHALL** satisfy: Contains 0..* InformationSource in ancestor-or-self::./cda:author[1] (C32-[CT1-8])
20. **SHOULD** satisfy: Contains 0..* LanguageSpoken in cda:recordTarget/cda:patientRole/cda:patient/cda:languageCommunication (C32-[CT1-10])
21. **SHALL** satisfy: Contains 1..1 Person Information in cda:recordTarget/cda:patientRole (C32-[CT1-12])

1. **SHALL** conform to CCD Continuity Of Care Document template (templateId: `2.16.840.1.113883.10.20.1`)
2. **SHALL** conform to CDT General Header Constraints template (templateId: `2.16.840.1.113883.10.20.3`)
3. **SHALL** conform to IHE Medical Document template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.1.1`)
4. **SHALL** contain exactly one [1..1] **`code`** (CONF-HP-21)
   - *Specifies the type of the clinical document.*
5. **SHALL** contain exactly one [1..1] **`languageCode`** (CONF-HP-24)
6. **SHALL** contain exactly one [1..1] **`realmCode/@code`**`="US"` (CONF-HP-15)
7. **SHALL** contain exactly one [1..1] **`typeId`** (CONF-HP-16)
   - *The clinical document type ID identifies the constraints imposed by CDA R2 on the content, essentially acting as a version identifier.*
8. **SHALL** contain exactly one [1..1] **`id`** (CONF-HP-17)
   - *The ClinicalDocument/id element is an instance identifier data type (see HL7 Version 3 Abstract Data in Section 5 REFERENCES). The root attribute is a UUID or OID. The root uniquely identifies the scope of the extension. The root and extension attributes uniquely identify the document.*
9. **SHALL** contain exactly one [1..1] **`title`** (CONF-HP-22)
   - *Specifies the local name used for the document.*
     Note that the title does not need to be the same as the display name provided with the document type code. For example, the display name provided by LOINC® as an aid in debugging may be "HISTORY AND PHYSICAL". The title can be localized, as appropriate.
10. **SHALL** contain exactly one [1..1] **`effectiveTime`** (CONF-HP-23)
    - *Specifies the creation time of the document. All documents authored by direct input to a computer system should record an effectiveTime that is precise to the second. When authored in other ways, for example, by filling out a paper form that is then transferred into an EHR system, the precision of effectiveTime may be less than to the second.*
11. Contains exactly one [1..1] **`confidentialityCode`**
    - *Specifies the confidentiality assigned to the document. This specification provides no further guidance beyond CDA R2*
      on documents with respect to the vocabulary used for confidentialityCode, nor treatment or implementation of confidentiality.
12. **SHOULD** contain exactly one [1..1] **`component`** (CONF-140)
    a. Contains exactly one [1..1] Problem Section (templateId: `2.16.840.1.113883.10.20.1.11`)
13. **SHOULD** contain exactly one [1..1] **`component`** (CONF-184)
    a. Contains exactly one [1..1] Family History Section (templateId: `2.16.840.1.113883.10.20.1.4`)
14. **SHOULD** contain exactly one [1..1] **`component`** (CONF-232)
    a. Contains exactly one [1..1] Social History Section (templateId: `2.16.840.1.113883.10.20.1.15`)
15. **SHOULD** contain exactly one [1..1] **`component`**
    a. Contains exactly one [1..1] Alerts Section (templateId: `2.16.840.1.113883.10.20.1.2`)

16. **SHOULD** contain exactly one [1..1] **component** (CONF-298)
    a. Contains exactly one [1..1] Medications Section (templateId: 2.16.840.1.113883.10.20.1.8)
17. **SHOULD** contain exactly one [1..1] **component** (CONF-388)
    a. Contains exactly one [1..1] Results Section (templateId: 2.16.840.1.113883.10.20.1.14)
18. **SHOULD** contain exactly one [1..1] **component**
    a. Contains exactly one [1..1] Procedures Section (templateId: 2.16.840.1.113883.10.20.1.12)
19. **SHOULD** contain exactly one [1..1] **component**
    a. Contains exactly one [1..1] Encounters Section (templateId: 2.16.840.1.113883.10.20.1.3)
20. **SHOULD** contain exactly one [1..1] **component**
    a. Contains exactly one [1..1] Plan Of Care Section (templateId: 2.16.840.1.113883.10.20.1.10)
21. **SHOULD** contain exactly one [1..1] **component** (CONF-376)
    a. Contains exactly one [1..1] Immunizations Section (templateId: 2.16.840.1.113883.10.20.1.6)
22. **SHOULD** contain exactly one [1..1] **component** (CONF-381)
    a. Contains exactly one [1..1] Vital Signs Section (templateId: 2.16.840.1.113883.10.20.1.16)
23. **SHOULD** contain exactly one [1..1] **component** (CONF-371)
    a. Contains exactly one [1..1] Medical Equipment Section (templateId: 2.16.840.1.113883.10.20.1.7)
24. **SHOULD** contain exactly one [1..1] **component** (CONF-123)
    a. Contains exactly one [1..1] Functional Status Section (templateId: 2.16.840.1.113883.10.20.1.5)
25. **SHOULD** contain exactly one [1..1] **component** (CONF-77)
    a. Contains exactly one [1..1] Advance Directives Section (templateId: 2.16.840.1.113883.10.20.1.1)
26. **SHOULD** contain exactly one [1..1] **component**
    a. Contains exactly one [1..1] Payers Section (templateId: 2.16.840.1.113883.10.20.1.9)
27. **MAY** contain exactly one [1..1] **component** (CONF-15)
    a. Contains exactly one [1..1] Purpose Section (templateId: 2.16.840.1.113883.10.20.1.13)
28. Contains at least one [1..*] **recordTarget**, where its type is Record Target
    a. Contains exactly one [1..1] Record Target
29. Contains at least one [1..*] **author**, where its type is Author
    a. Contains exactly one [1..1] Author
30. Contains exactly one [1..1] **custodian**, where its type is Custodian
    a. Contains exactly one [1..1] Custodian
31. Contains exactly one [1..1] **component**, where its type is Component2
    a. Contains exactly one [1..1] Component2
32. Contains at least one [1..*] **author**
    a. Contains exactly one [1..1] CDA Author
    - *The author element represents the creator of the clinical document. If the role of the actor is the entry of information from his or her own knowledge or application of skills, that actor is the author. If one actor provides information to another actor who filters, reasons, or algorithmically creates new information, then that second actor is also an author, having created information from his or her own knowledge or skills. However, that determination is independent from the determination of the first actor's authorship.*
33. Contains zero or one [0..1] **dataEnterer**
    a. Contains exactly one [1..1] CDA Data Enterer
    - *The dataEnterer element represents the person who transferred the information from*

other sources into the clinical document, where the other sources wrote the content of the note. The guiding rule of thumb is that an author provides the content found within the header or body of the document, subject to their own interpretation. The dataEnterer adds information to the electronic system. A person can participate as both author and dataEnterer.

If the role of the actor is to transfer information from one source to another (e.g., transcription or transfer from paper form to electronic system), that actor is considered a dataEnterer.

34. Contains exactly one [1..1] **`custodian`**

a. Contains exactly one [1..1] CDA Custodian

- *Based on the CDA R2 constraints (Section 4.2.2.3 of the CDA Normative Web Edition. See Section 5 REFERENCES), the custodian element is required and is the custodian of the clinical document.*

35. Contains zero or more [0..*] **`informationRecipient`**

a. Contains exactly one [1..1] CDA Information Recipient

- *informationRecipient, when used in the context of a referral or request for consultation, this records the intended recipient of the information at the time the document is created. The intended recipient may also be the health chart of the patient, in which case the receivedOrganization is the scoping organization of that chart.*

36. Contains zero or one [0..1] **`legalAuthenticator`**

a. Contains exactly one [1..1] CDA Legal Authenticator

- *The legalAuthenticator element identifies the legal authenticator of the document and must be present if the document has been legally authenticated. Based on local practice, clinical documents may be released before legal authentication. This implies that a clinical document that does not contain this element has not been legally authenticated.*

  The act of legal authentication requires a certain privilege be granted to the legal authenticator depending upon local policy. All clinical documents have the potential for legal authentication, given the appropriate credentials.

  Local policies may choose to delegate the function of legal authentication to a device or system that generates the clinical document. In these cases, the legal authenticator is a person accepting responsibility for the document, not the generating device or system.

37. Contains zero or more [0..*] **`authenticator`**

a. Contains exactly one [1..1] CDA Authenticator

- *The authenticator identifies the participant who attested to the accuracy of the information in the document.*

  Automated systems, such as a PHR, that allow a clinical document to be generated need to give special consideration to authentication permissions because the information contained in the document may come from sources or contain information that the author cannot validate.

38. **MAY** contain zero or one [0..1] **`component`** (C32-[CT1-1])

a. Contains exactly one [1..1] Advance Directives Section (templateId: `2.16.840.1.113883.3.88.11.83.116`)

39. **MAY** contain zero or one [0..1] **`component`** (C32-[CT1-2])

a. Contains exactly one [1..1] Allergies Reactions Section (templateId: `2.16.840.1.113883.3.88.11.83.102`)

40. **MAY** contain zero or more [0..*] **`component`** (C32-[CT1-3])

a. Contains exactly one [1..1] Comment (templateId: `2.16.840.1.113883.3.88.11.83.11`)

41. **MAY** contain zero or one [0..1] **component** (C32-[CT1-4])
    a. Contains exactly one [1..1] Problem List Section (templateId: 2.16.840.1.113883.3.88.11.83.103)
42. **MAY** contain zero or one [0..1] **component** (C32-[CT1-5])
    a. Contains exactly one [1..1] Encounters Section (templateId: 2.16.840.1.113883.3.88.11.83.127)
43. **MAY** contain zero or one [0..1] **component** (C32-[CT1-7])
    a. Contains exactly one [1..1] Immunizations Section (templateId: 2.16.840.1.113883.3.88.11.83.117)
44. **MAY** contain zero or one [0..1] **component** (C32-[CT1-9])
    a. Contains exactly one [1..1] Payers Section (templateId: 2.16.840.1.113883.3.88.11.83.101)
45. **MAY** contain zero or one [0..1] **component** (C32-[CT1-11])
    a. Contains exactly one [1..1] Medications Section (templateId: 2.16.840.1.113883.3.88.11.83.112)
46. **MAY** contain zero or one [0..1] **component** (C32-[CT1-13])
    a. Contains exactly one [1..1] Plan Of Care Section (templateId: 2.16.840.1.113883.3.88.11.83.124)
47. **MAY** contain zero or one [0..1] **component** (C32-[CT1-14])
    a. Contains exactly one [1..1] IHE Pregnancy History Section (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.5.3.4)
48. **MAY** contain zero or one [0..1] **component** (C32-[CT1-15])
    a. Contains exactly one [1..1] Surgeries Section (templateId: 2.16.840.1.113883.3.88.11.83.108)
49. **SHOULD** contain at least one [1..*] **realmCode** (C32-[CT1-16])
50. **MAY** contain zero or one [0..1] **component** (C32-[CT1-17])
    a. Contains exactly one [1..1] Vital Signs Section (templateId: 2.16.840.1.113883.3.88.11.83.119)
51. **MAY** contain zero or one [0..1] **component** (C32-[CT1-18])
    a. Contains exactly one [1..1] Diagnostic Results Section (templateId: 2.16.840.1.113883.3.88.11.83.122)
52. **SHALL** satisfy: Contains exactly one documentationOf / serviceEvent (CONF-2)
53. documentationOf / serviceEvent / @classCode **SHALL** be 'PCPR' (CONF-3)
54. **SHALL** satisfy: documentationOf / serviceEvent contains exactly one serviceEvent / effectiveTime / low and exactly one serviveEvent / effectiveTime / high (CONF-4)
55. languageCode has the form nn, or nn-CC. The nn portion **SHALL** be an ISO-639-1 language code in lower case. The CC portion, if present, **SHALL** be an ISO-3166 country code in upper case (CONF-6)
56. **SHALL NOT** contain templateId / @extension (CONF-8)
57. **SHALL** satisfy: effectiveTime is expressed with precision to include seconds (CONF-9)
58. **SHALL** satisfy: effectiveTime includes an explicit time zone offset (CONF-10)
59. **SHALL** satisfy: Contains one or two recordTarget (CONF-11)
60. **SHOULD** satisfy: Contains one or more author / assignedAuthor / assignedPerson and/or author / assignedAuthor / representedOrganization (CONF-12)
61. If author has an associated representedOrganization with no assignedPerson or assignedAuthoringDevice, then the value for author / assignedAuthor / id / @NullFlavor **SHALL** be 'NA' (CONF-13)
62. **MAY** satisfy: Contains one or more informationRecipient (CONF-14)
63. The value for component / structuredBody / component / section / entry / @typeCode **MAY** be 'DRIV' "is derived from" 2.16.840.1.113883.5.1002 ActRelationshipType STATIC, to indicate that the CDA Narrative Block is fully derived from the structured entries. (CONF-28)
64. A CCD entry **SHOULD** explicitly reference its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1 <content>). (CONF-29)
65. A section **MAY** contain one or more comments, either as a clinical statement or nested under another clinical statement. (CONF-502)

66. **SHALL** satisfy: All patient, guardianPerson, assignedPerson, maintainingPerson, relatedPerson, intendedRecipient/informationRecipient, associatedPerson, and relatedSubject/subject elements have a name. (CONF-HP-6)
67. **SHALL** satisfy: All patientRole, assignedAuthor, assignedEntity[not(parent::dataEnterer)] and associatedEntity elements have an addr and telecom element. (CONF-HP-7)
68. **SHOULD** satisfy: All guardian, dataEnterer/assignedEntity, relatedEntity, intendedRecipient, relatedSubject and participantRole elements have an addr and telecom element. (CONF-HP-8)
69. **SHALL** satisfy: All guardianOrganization, providerOrganization, wholeOrganization, representedOrganization, representedCustodianOrganization, receivedOrganization, scopingOrganization and serviceProviderOrganization elements have name, addr and telecom elements. (CONF-HP-9)
70. Times or time intervals found in the ClinicalDocument/effectiveTime, author/time, dataEnterer/time, legalAuthenticator/time, authenticator/time and encompassingEncounter/effectiveTime elements **SHALL** be precise to the day, **SHALL** include a time zone if more precise than to the day, and **SHOULD** be precise to the second. (CONF-HP-10)
71. Times or time intervals found in the asOrganizationPartOf/effectiveTime, asMaintainedEntity/effectiveTime, relatedEntity/effectiveTime, serviceEvent/effectiveTime, ClinicalDocument/participant/time, serviceEvent/performer/time and encounterParticipant/time **SHALL** be precise at least to the year, **SHOULD** be precise to the day, and **MAY** omit time zone. (CONF-HP-11)
72. **SHALL** satisfy: Telephone numbers match the regular expression pattern tel:\+?[-0-9().]+ (CONF-HP-12)
73. **SHALL** satisfy: At least one dialing digit is present in the phone number after visual separators are removed. (CONF-HP-13)
74. **SHALL** satisfy: If the telephone number is unknown it is represented using the appropriate flavor of null. (CONF-HP-14)
75. **SHALL** satisfy: The extension attribute of the typeId element is POCD_HD000040. (CONF-HP-16)
76. **SHALL** satisfy: The id/@root attribute is a syntactically correct UUID or OID. (CONF-HP-17)
77. **SHALL** satisfy: UUIDs are represented in the form XXXXXXXX-XXXX-XXXX-XXXXXXXXXXXXXXXX, where each X is a character from the set [A-Fa-f0-9]. (CONF-HP-18)
78. OIDs are represented in dotted decimal notation, where each decimal number is either 0, or starts with a nonzero digit. More formally, an OID **SHALL** be in the form ([0-2])(.([1-9][0-9]*|0))+. (CONF-HP-19)
79. **SHALL** satisfy: OIDs are no more than 64 characters in length. (CONF-HP-20)
80. **SHALL** satisfy: languageCode has the form nn, or nn-CC. (CONF-HP-25)
81. **SHALL** satisfy: The nn portion of languageCode is a legal ISO-639-1 language code in lowercase. (CONF-HP-26)
82. The CC portion languageCode, if present, **SHALL** be an ISO-3166 country code in uppercase. (CONF-HP-27)
83. Both setId and versionNumber **SHALL** be present or both **SHALL** be absent. (CONF-HP-28)
84. The @extension and/or @root of setId and id **SHALL** be different when both are present. (CONF-HP-29)
85. A copyTime element **SHALL NOT** be present. (CONF-HP-30)
86. **SHALL** satisfy: At least one recordTarget/patientRole element is present. (CONF-HP-31)
87. A patient/birthTime element **SHALL** be present. The patient/birthTime element **SHALL** be precise at least to the year, and **SHOULD** be precise at least to the day, and **MAY** omit time zone. If unknown, it **SHALL** be represented using a flavor of null. (CONF-HP-32)
88. A patient/administrativeGenderCode element **SHALL** be present. If unknown, it **SHALL** be represented using a flavor of null. Values for administrativeGenderCode **SHOULD** be drawn from the HL7 AdministrativeGender vocabulary. (CONF-HP-33)
89. The maritalStatusCode, religiousAffiliationCode, raceCode and ethnicGroupCode **MAY** be present. If maritalStatusCode, religiousAffiliationCode, raceCode and ethnicGroupCode elements are present, they **SHOULD** be encoded using the appropriate HL7 vocabularies. (CONF-HP-34)
90. **SHOULD** satisfy: The guardian element is present when the patient is a minor child. (CONF-HP-35)
91. **MAY** satisfy: The providerOrganization element is present. (CONF-HP-36)
92. **SHALL** satisfy: The author/time element is present. (CONF-HP-37)
93. **SHALL** satisfy: The assignedAuthor/id element is present. (CONF-HP-38)
94. **SHALL** satisfy: An assignedAuthor element contains at least one assignedPerson or assignedAuthoringDevice elements. (CONF-HP-39)

95. **SHALL** satisfy: When dataEnterer is present, an assignedEntity/assignedPerson element is present. (CONF-HP-40)
96. The dataEnterer/time element **MAY** be present. If present, it represents the starting time of entry of the data. (CONF-HP-41)
97. **MAY** satisfy: The informant element is present. (CONF-HP-42)
98. When informant is present, an assignedEntity/assignedPerson or relatedEntity/relatedPerson element **SHALL** be present. (CONF-HP-43)
99. When the informant is a healthcare provider with an assigned role, the informant **SHALL** be represented using the assignedEntity element (CONF-HP-44)
100. Allowable values for informant/relatedEntity/@classCode **SHALL** be CON, PRS, CAREGIVER, AGNT or PROV from the RoleClass vocabulary. (CONF-HP-45)
101. When relatedEntity/@classCode is PRS, values in relatedEntity/code **SHALL** come from the HL7 PersonalRelationshipRoleType vocabulary or from SNOMED, any subtype of "Person in the family" (303071001). (CONF-HP-46)
102. When an informant is an unrelated person not otherwise specified, the value relatedEntity/@classCode **SHALL** be set to CON to indicate that this person is a contact. (CONF-HP-47)
103. When the informant is a healthcare provider without an assigned role, the informant **SHALL** be represented using the relatedEntity element and the value of relatedEntity/@classCode **SHALL** be set to PROV. (CONF-HP-48)
104. When the informant is a healthcare provider, the value of relatedEntity/code **SHOULD** be present and indicate the type of healthcare provider. (CONF-HP-49)
105. The ClinicalDocument/informationRecipient element **MAY** be present. When informationRecipient is used, at least one informationRecipient/intendedRecipient/informationRecipient or informationRecipient/intendedRecipient/receivedOrganization **SHALL** be present. (CONF-HP-50)
106. The assignedEntity/assignedPerson element **SHALL** be present in legalAuthenticator. (CONF-HP-51)
107. The assignedEntity/assignedPerson element **SHALL** be present in an authenticator element. (CONF-HP-52)
108. Times or time intervals found in the ClinicalDocument/effectiveTime, author/time, dataEnterer/time, legalAuthenticator/time, authenticator/time and encompassingEncounter/effectiveTime elements **SHALL** be precise to the day, **SHALL** include a time zone if more precise than to the day, and **SHOULD** be precise to the second. (CONF-HP-10)
109. Times or time intervals found in the asOrganizationPartOf/effectiveTime, asMaintainedEntity/effectiveTime, relatedEntity/effectiveTime, serviceEvent/effectiveTime, ClinicalDocument/participant/time, serviceEvent/performer/time and encounterParticipant/time **SHALL** be precise at least to the year, **SHOULD** be precise to the day, and **MAY** omit time zone. (CONF-HP-11)
110. **MAY** satisfy: Contains 0..* HealthcareProvider in cda:documentationOf/cda:serviceEvent/cda:performer (C32-[CT1-6])
111. **SHALL** satisfy: Contains 0..* InformationSource in ancestor-or-self::./cda:author[1] (C32-[CT1-8])
112. **SHOULD** satisfy: Contains 0..* LanguageSpoken in cda:recordTarget/cda:patientRole/cda:patient/cda:languageCommunication (C32-[CT1-10])
113. **SHALL** satisfy: Contains 1..1 Person Information in cda:recordTarget/cda:patientRole (C32-[CT1-12])

Patient Summary 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/>
  <typeId root="2.16.840.1.113883.1.3"/>
  <id root="MDHT" extension="434080292"/>
  <code code="481094242"/>
  <title>TEXT FOR TITLE</title>
  <effectiveTime/>
  <confidentialityCode code="765500573"/>
  <languageCode code="Code forlanguageCode"/>
  <recordTarget>
    <realmCode/>
```

```
    <typeId root="2.16.840.1.113883.1.3"/>
    <patientRole/>
  </recordTarget>
  <author>
    <realmCode/>
    <typeId root="2.16.840.1.113883.1.3"/>
    <time/>
    <assignedAuthor/>
  </author>
  <custodian/>
  <component>
    <structuredBody>
      <component>
        <section>
          <typeId root="2.16.840.1.113883.1.3"/>
          <id root="MDHT" extension="629915391"/>
          <code code="1622266475"/>
          <title>TEXT FOR TITLE</title>
          <languageCode code="Code forlanguageCode"/>
          <entry>
            <observation>
              <typeId root="2.16.840.1.113883.1.3"/>
              <id root="MDHT" extension="1809904912"/>
              <code code="892747877"/>
              <effectiveTime>
                <low value="2012"/>
                <high value="2012"/>
              </effectiveTime>
              <languageCode code="Code forlanguageCode"/>
            </observation>
          </entry>
        </section>
      </component>
      <component>
        <section>
          <typeId root="2.16.840.1.113883.1.3"/>
          <id root="MDHT" extension="1824874311"/>
          <code code="891140240"/>
          <title>TEXT FOR TITLE</title>
          <languageCode code="Code forlanguageCode"/>
          <entry>
            <act>
              <typeId root="2.16.840.1.113883.1.3"/>
              <id root="MDHT" extension="1507854897"/>
              <code code="501878932"/>
              <effectiveTime>
                <low value="2012"/>
                <high value="2012"/>
              </effectiveTime>
              <languageCode code="Code forlanguageCode"/>
            </act>
          </entry>
        </section>
      </component>
      <component>
        <section>
          <typeId root="2.16.840.1.113883.1.3"/>
          <id root="MDHT" extension="1782130183"/>
          <code code="1640259424"/>
          <title>TEXT FOR TITLE</title>
          <languageCode code="Code forlanguageCode"/>
          <entry>
            <act>
              <typeId root="2.16.840.1.113883.1.3"/>
```

```
            <id root="MDHT" extension="1124125615"/>
            <code code="1666956982"/>
            <effectiveTime>
              <low value="2012"/>
              <high value="2012"/>
            </effectiveTime>
            <languageCode code="Code forlanguageCode"/>
            <entryRelationship>
              <observation/>
            </entryRelationship>
          </act>
        </entry>
      </section>
    </component>
    <component>
      <section>
        <typeId root="2.16.840.1.113883.1.3"/>
        <id root="MDHT" extension="779345748"/>
        <code code="2090414859"/>
        <title>TEXT FOR TITLE</title>
        <languageCode code="Code forlanguageCode"/>
        <entry>
          <encounter>
            <typeId root="2.16.840.1.113883.1.3"/>
            <id root="MDHT" extension="1883481502"/>
            <code code="1891818161"/>
            <effectiveTime>
              <low value="2012"/>
              <high value="2012"/>
            </effectiveTime>
          </encounter>
        </entry>
      </section>
    </component>
    <component>
      <section>
        <typeId root="2.16.840.1.113883.1.3"/>
        <id root="MDHT" extension="1035180220"/>
        <code code="1935431867"/>
        <title>TEXT FOR TITLE</title>
        <languageCode code="Code forlanguageCode"/>
        <entry>
          <substanceAdministration classCode="SBADM">
            <typeId root="2.16.840.1.113883.1.3"/>
            <id root="MDHT" extension="751984249"/>
            <code code="2006090258"/>
            <effectiveTime value="20121102"/>
            <consumable/>
          </substanceAdministration>
        </entry>
      </section>
    </component>
    <component>
      <section>
        <typeId root="2.16.840.1.113883.1.3"/>
        <id root="MDHT" extension="1464438150"/>
        <code code="767659486"/>
        <title>TEXT FOR TITLE</title>
        <languageCode code="Code forlanguageCode"/>
        <entry>
          <act>
            <typeId root="2.16.840.1.113883.1.3"/>
            <id root="MDHT" extension="1732130689"/>
            <code code="730017186"/>
```

```
            <effectiveTime>
              <low value="2012"/>
              <high value="2012"/>
            </effectiveTime>
            <languageCode code="Code forlanguageCode"/>
          </act>
        </entry>
      </section>
    </component>
    <component>
      <section>
        <typeId root="2.16.840.1.113883.1.3"/>
        <id root="MDHT" extension="64640467"/>
        <code code="470646913"/>
        <title>TEXT FOR TITLE</title>
        <languageCode code="Code forlanguageCode"/>
        <entry>
          <substanceAdministration classCode="SBADM">
            <typeId root="2.16.840.1.113883.1.3"/>
            <id root="MDHT" extension="1226205619"/>
            <code code="1178592701"/>
            <effectiveTime xsi:type="IVL_TS">
              <low value="2012"/>
              <high value="2012"/>
            </effectiveTime>
            <consumable/>
            <entryRelationship>
              <observation/>
            </entryRelationship>
            <entryRelationship>
              <supply classCode="SPLY"/>
            </entryRelationship>
            <entryRelationship>
              <observation/>
            </entryRelationship>
          </substanceAdministration>
        </entry>
      </section>
    </component>
    <component>
      <section>
        <typeId root="2.16.840.1.113883.1.3"/>
        <id root="MDHT" extension="1822181818"/>
        <code code="851324300"/>
        <title>TEXT FOR TITLE</title>
        <languageCode code="Code forlanguageCode"/>
      </section>
    </component>
    <component>
      <section>
        <typeId root="2.16.840.1.113883.1.3"/>
        <id root="MDHT" extension="671140483"/>
        <code code="1231781686"/>
        <title>TEXT FOR TITLE</title>
        <languageCode code="Code forlanguageCode"/>
        <entry>
          <substanceAdministration classCode="SBADM">
            <typeId root="2.16.840.1.113883.1.3"/>
            <id root="MDHT" extension="828002019"/>
            <code code="549379785"/>
            <effectiveTime xsi:type="IVL_TS">
              <low value="2012"/>
              <high value="2012"/>
            </effectiveTime>
```

```
            <consumable/>
            <entryRelationship>
              <observation/>
            </entryRelationship>
            <entryRelationship>
              <supply classCode="SPLY"/>
            </entryRelationship>
            <entryRelationship>
              <observation/>
            </entryRelationship>
          </substanceAdministration>
        </entry>
        <entry>
          <substanceAdministration classCode="SBADM">
            <typeId root="2.16.840.1.113883.1.3"/>
            <id root="MDHT" extension="2120296509"/>
            <code code="1288752646"/>
            <effectiveTime value="20121102"/>
            <consumable/>
          </substanceAdministration>
        </entry>
        <entry>
          <encounter>
            <typeId root="2.16.840.1.113883.1.3"/>
            <id root="MDHT" extension="747715382"/>
            <code code="594899162"/>
            <effectiveTime>
              <low value="2012"/>
              <high value="2012"/>
            </effectiveTime>
          </encounter>
        </entry>
      </section>
    </component>
    <component>
      <section/>
    </component>
    <component>
      <section>
        <typeId root="2.16.840.1.113883.1.3"/>
        <id root="MDHT" extension="492805817"/>
        <code code="1254313946"/>
        <title>TEXT FOR TITLE</title>
        <languageCode code="Code forlanguageCode"/>
      </section>
    </component>
    <component>
      <section>
        <typeId root="2.16.840.1.113883.1.3"/>
        <id root="MDHT" extension="963693993"/>
        <code code="1674774547"/>
        <title>TEXT FOR TITLE</title>
        <languageCode code="Code forlanguageCode"/>
        <entry>
          <observation>
            <typeId root="2.16.840.1.113883.1.3"/>
            <id root="MDHT" extension="2019690017"/>
            <code code="1028622303"/>
            <effectiveTime>
              <low value="2012"/>
              <high value="2012"/>
            </effectiveTime>
            <languageCode code="Code forlanguageCode"/>
          </observation>
```

```
          </entry>
          <entry>
            <organizer>
              <typeId root="2.16.840.1.113883.1.3"/>
              <id root="MDHT" extension="1459282725"/>
              <code code="1622491636"/>
              <statusCode code="completed"/>
              <effectiveTime>
                <low value="2012"/>
                <high value="2012"/>
              </effectiveTime>
              <component>
                <observation/>
              </component>
            </organizer>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Referral Summary

[ClinicalDocument: templateId `2.16.840.1.113883.3.88.11.48.1`]

1. **SHALL** contain exactly one [1..1] templateId ( ) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.3.88.11.48.1"
2. **SHALL** conform to IHE Medical Summary template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.1.2`)

1. **SHALL** conform to CDT General Header Constraints template (templateId: `2.16.840.1.113883.10.20.3`)
2. **SHALL** conform to IHE Medical Document template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.1.1`)
3. **SHALL** conform to IHE Medical Summary template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.1.2`)
4. **SHALL** contain exactly one [1..1] **`realmCode/@code`**`="US"` (CONF-HP-15)
5. **SHALL** contain exactly one [1..1] **`typeId`** (CONF-HP-16)
   - *The clinical document type ID identifies the constraints imposed by CDA R2 on the content, essentially acting as a version identifier.*
6. **SHALL** contain exactly one [1..1] **`id`** (CONF-HP-17)
   - *The ClinicalDocument/id element is an instance identifier data type (see HL7 Version 3 Abstract Data in Section 5 REFERENCES). The root attribute is a UUID or OID. The root uniquely identifies the scope of the extension. The root and extension attributes uniquely identify the document.*
7. **SHALL** contain exactly one [1..1] **`code`**, where the @code **SHALL** be selected from (CodeSystem: `2.16.840.1.113883.6.1 LOINC`)
8. **SHALL** contain exactly one [1..1] **`title`** (CONF-HP-22)
   - *Specifies the local name used for the document.*
     Note that the title does not need to be the same as the display name provided with the document type code. For example, the display name provided by LOINC® as an aid in debugging may be "HISTORY AND PHYSICAL". The title can be localized, as appropriate.
9. **SHALL** contain exactly one [1..1] **`effectiveTime`** (CONF-HP-23)
   - *Specifies the creation time of the document. All documents authored by direct input to a computer system should record an effectiveTime that is precise to the second. When authored in other ways, for example, by filling out a*

paper form that is then transferred into an EHR system, the precision of effectiveTime may be less than to the second.

10. Contains exactly one [1..1] **`confidentialityCode`**
    - *Specifies the confidentiality assigned to the document. This specification provides no further guidance beyond CDA R2 on documents with respect to the vocabulary used for confidentialityCode, nor treatment or implementation of confidentiality.*
11. **SHALL** contain exactly one [1..1] **`languageCode`** (CONF-HP-24)
12. Contains at least one [1..*] **`recordTarget`**, where its type is Record Target
    a. Contains exactly one [1..1] Record Target
13. Contains at least one [1..*] **`author`**, where its type is Author
    a. Contains exactly one [1..1] Author
14. Contains exactly one [1..1] **`custodian`**, where its type is Custodian
    a. Contains exactly one [1..1] Custodian
15. Contains exactly one [1..1] **`component`**, where its type is Component2
    a. Contains exactly one [1..1] Component2
16. Contains at least one [1..*] **`author`**
    a. Contains exactly one [1..1] CDA Author
    - *The author element represents the creator of the clinical document. If the role of the actor is the entry of information from his or her own knowledge or application of skills, that actor is the author. If one actor provides information to another actor who filters, reasons, or algorithmically creates new information, then that second actor is also an author, having created information from his or her own knowledge or skills. However, that determination is independent from the determination of the first actor's authorship.*
17. Contains zero or one [0..1] **`dataEnterer`**
    a. Contains exactly one [1..1] CDA Data Enterer
    - *The dataEnterer element represents the person who transferred the information from other sources into the clinical document, where the other sources wrote the content of the note. The guiding rule of thumb is that an author provides the content found within the header or body of the document, subject to their own interpretation. The dataEnterer adds information to the electronic system. A person can participate as both author and dataEnterer.*

      If the role of the actor is to transfer information from one source to another (e.g., transcription or transfer from paper form to electronic system), that actor is considered a dataEnterer.
18. Contains exactly one [1..1] **`custodian`**
    a. Contains exactly one [1..1] CDA Custodian
    - *Based on the CDA R2 constraints (Section 4.2.2.3 of the CDA Normative Web Edition. See Section 5 REFERENCES), the custodian element is required and is the custodian of the clinical document.*
19. Contains zero or more [0..*] **`informationRecipient`**
    a. Contains exactly one [1..1] CDA Information Recipient
    - *informationRecipient, when used in the context of a referral or request for consultation, this records the intended recipient of the information at the time the document is created. The intended recipient may also be the health chart of the patient, in which case the receivedOrganization is the scoping organization of that chart.*

20. Contains zero or one [0..1] **`legalAuthenticator`**

a. Contains exactly one [1..1] CDA Legal Authenticator

- *The legalAuthenticator element identifies the legal authenticator of the document and must be present if the document has been legally authenticated. Based on local practice, clinical documents may be released before legal authentication. This implies that a clinical document that does not contain this element has not been legally authenticated.*

  The act of legal authentication requires a certain privilege be granted to the legal authenticator depending upon local policy. All clinical documents have the potential for legal authentication, given the appropriate credentials.

  Local policies may choose to delegate the function of legal authentication to a device or system that generates the clinical document. In these cases, the legal authenticator is a person accepting responsibility for the document, not the generating device or system.

21. Contains zero or more [0..*] **`authenticator`**

a. Contains exactly one [1..1] CDA Authenticator

- *The authenticator identifies the participant who attested to the accuracy of the information in the document.*

  Automated systems, such as a PHR, that allow a clinical document to be generated need to give special consideration to authentication permissions because the information contained in the document may come from sources or contain information that the author cannot validate.

22. **SHALL** satisfy: All patient, guardianPerson, assignedPerson, maintainingPerson, relatedPerson, intendedRecipient/informationRecipient, associatedPerson, and relatedSubject/subject elements have a name. (CONF-HP-6)

23. **SHALL** satisfy: All patientRole, assignedAuthor, assignedEntity[not(parent::dataEnterer)] and associatedEntity elements have an addr and telecom element. (CONF-HP-7)

24. **SHOULD** satisfy: All guardian, dataEnterer/assignedEntity, relatedEntity, intendedRecipient, relatedSubject and participantRole elements have an addr and telecom element. (CONF-HP-8)

25. **SHALL** satisfy: All guardianOrganization, providerOrganization, wholeOrganization, representedOrganization, representedCustodianOrganization, receivedOrganization, scopingOrganization and serviceProviderOrganization elements have name, addr and telecom elements. (CONF-HP-9)

26. Times or time intervals found in the ClinicalDocument/effectiveTime, author/time, dataEnterer/time, legalAuthenticator/time, authenticator/time and encompassingEncounter/effectiveTime elements **SHALL** be precise to the day, **SHALL** include a time zone if more precise than to the day, and **SHOULD** be precise to the second. (CONF-HP-10)

27. Times or time intervals found in the asOrganizationPartOf/effectiveTime, asMaintainedEntity/effectiveTime, relatedEntity/effectiveTime, serviceEvent/effectiveTime, ClinicalDocument/participant/time, serviceEvent/performer/time and encounterParticipant/time **SHALL** be precise at least to the year, **SHOULD** be precise to the day, and **MAY** omit time zone. (CONF-HP-11)

28. **SHALL** satisfy: Telephone numbers match the regular expression pattern tel:\+?[-0-9().]+ (CONF-HP-12)

29. **SHALL** satisfy: At least one dialing digit is present in the phone number after visual separators are removed. (CONF-HP-13)

30. **SHALL** satisfy: If the telephone number is unknown it is represented using the appropriate flavor of null. (CONF-HP-14)

31. **SHALL** satisfy: The extension attribute of the typeId element is POCD_HD000040. (CONF-HP-16)

32. **SHALL** satisfy: The id/@root attribute is a syntactically correct UUID or OID. (CONF-HP-17)

33. **SHALL** satisfy: UUIDs are represented in the form XXXXXXXX-XXXX-XXXX-XXXXXXXXXXXXXXXX, where each X is a character from the set [A-Fa-f0-9]. (CONF-HP-18)

34. OIDs are represented in dotted decimal notation, where each decimal number is either 0, or starts with a nonzero digit. More formally, an OID **SHALL** be in the form ([0-2])(.([1-9][0-9]*|0))+. (CONF-HP-19)

35. **SHALL** satisfy: OIDs are no more than 64 characters in length. (CONF-HP-20)

36. **SHALL** satisfy: languageCode has the form nn, or nn-CC. (CONF-HP-25)

37. **SHALL** satisfy: The nn portion of languageCode is a legal ISO-639-1 language code in lowercase. (CONF-HP-26)
38. The CC portion languageCode, if present, **SHALL** be an ISO-3166 country code in uppercase. (CONF-HP-27)
39. Both setId and versionNumber **SHALL** be present or both **SHALL** be absent. (CONF-HP-28)
40. The @extension and/or @root of setId and id **SHALL** be different when both are present. (CONF-HP-29)
41. A copyTime element **SHALL NOT** be present. (CONF-HP-30)
42. **SHALL** satisfy: At least one recordTarget/patientRole element is present. (CONF-HP-31)
43. A patient/birthTime element **SHALL** be present. The patient/birthTime element **SHALL** be precise at least to the year, and **SHOULD** be precise at least to the day, and **MAY** omit time zone. If unknown, it **SHALL** be represented using a flavor of null. (CONF-HP-32)
44. A patient/administrativeGenderCode element **SHALL** be present. If unknown, it **SHALL** be represented using a flavor of null. Values for administrativeGenderCode **SHOULD** be drawn from the HL7 AdministrativeGender vocabulary. (CONF-HP-33)
45. The maritalStatusCode, religiousAffiliationCode, raceCode and ethnicGroupCode **MAY** be present. If maritalStatusCode, religiousAffiliationCode, raceCode and ethnicGroupCode elements are present, they **SHOULD** be encoded using the appropriate HL7 vocabularies. (CONF-HP-34)
46. **SHOULD** satisfy: The guardian element is present when the patient is a minor child. (CONF-HP-35)
47. **MAY** satisfy: The providerOrganization element is present. (CONF-HP-36)
48. **SHALL** satisfy: The author/time element is present. (CONF-HP-37)
49. **SHALL** satisfy: The assignedAuthor/id element is present. (CONF-HP-38)
50. **SHALL** satisfy: An assignedAuthor element contains at least one assignedPerson or assignedAuthoringDevice elements. (CONF-HP-39)
51. **SHALL** satisfy: When dataEnterer is present, an assignedEntity/assignedPerson element is present. (CONF-HP-40)
52. The dataEnterer/time element **MAY** be present. If present, it represents the starting time of entry of the data. (CONF-HP-41)
53. **MAY** satisfy: The informant element is present. (CONF-HP-42)
54. When informant is present, an assignedEntity/assignedPerson or relatedEntity/relatedPerson element **SHALL** be present. (CONF-HP-43)
55. When the informant is a healthcare provider with an assigned role, the informant **SHALL** be represented using the assignedEntity element (CONF-HP-44)
56. Allowable values for informant/relatedEntity/@classCode **SHALL** be CON, PRS, CAREGIVER, AGNT or PROV from the RoleClass vocabulary. (CONF-HP-45)
57. When relatedEntity/@classCode is PRS, values in relatedEntity/code **SHALL** come from the HL7 PersonalRelationshipRoleType vocabulary or from SNOMED, any subtype of "Person in the family" (303071001). (CONF-HP-46)
58. When an informant is an unrelated person not otherwise specified, the value relatedEntity/@classCode **SHALL** be set to CON to indicate that this person is a contact. (CONF-HP-47)
59. When the informant is a healthcare provider without an assigned role, the informant **SHALL** be represented using the relatedEntity element and the value of relatedEntity/@classCode **SHALL** be set to PROV. (CONF-HP-48)
60. When the informant is a healthcare provider, the value of relatedEntity/code **SHOULD** be present and indicate the type of healthcare provider. (CONF-HP-49)
61. The ClinicalDocument/informationRecipient element **MAY** be present. When informationRecipient is used, at least one informationRecipient/intendedRecipient/informationRecipient or informationRecipient/intendedRecipient/receivedOrganization **SHALL** be present. (CONF-HP-50)
62. The assignedEntity/assignedPerson element **SHALL** be present in legalAuthenticator. (CONF-HP-51)
63. The assignedEntity/assignedPerson element **SHALL** be present in an authenticator element. (CONF-HP-52)
64. Times or time intervals found in the ClinicalDocument/effectiveTime, author/time, dataEnterer/time, legalAuthenticator/time, authenticator/time and encompassingEncounter/effectiveTime elements **SHALL** be precise to the day, **SHALL** include a time zone if more precise than to the day, and **SHOULD** be precise to the second. (CONF-HP-10)
65. Times or time intervals found in the asOrganizationPartOf/effectiveTime, asMaintainedEntity/effectiveTime, relatedEntity/effectiveTime, serviceEvent/effectiveTime, ClinicalDocument/participant/time, serviceEvent/

performer/time and encounterParticipant/time **SHALL** be precise at least to the year, **SHOULD** be precise to the day, and **MAY** omit time zone. (CONF-HP-11)

66. **SHALL** satisfy: MedicalSummaryProblemConcernEntry
67. **SHALL** satisfy: MedicalSummaryAllergyConcernEntry
68. **SHALL** satisfy: MedicalSummaryMedications

Referral Summary 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">
  <typeId root="2.16.840.1.113883.1.3"/>
  <id root="MDHT" extension="850325448"/>
  <code code="845564931"/>
  <title>TEXT FOR TITLE</title>
  <effectiveTime/>
  <confidentialityCode code="365807362"/>
  <languageCode code="Code forlanguageCode"/>
  <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/>
</ClinicalDocument>
```

Unstructured Document

[ClinicalDocument: templateId `2.16.840.1.113883.3.88.11.62.1`]

IMPORTANT NOTE: *The HITSP C62 specification does not include a templateId for this doument type. The id 2.16.840.1.113883.3.88.11.62.1 is included in this model to support instance validation, but we are designing a solution to allow removal of this Id.*

1. **SHALL** contain exactly one [1..1] templateId ( ) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.3.88.11.62.1"
2. **SHALL** conform to IHE Scanned Document template (templateId: `1.3.6.1.4.1.19376.1.2.20`)
3. **SHALL** conform to IHE Medical Document template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.1.1`)
4. **SHOULD** satisfy: This construct should not be used when the data are structured.
5. **SHALL** satisfy: Each document pertains to one and only one patient.

1. **SHALL** conform to CDT General Header Constraints template (templateId: `2.16.840.1.113883.10.20.3`)
2. **SHALL** conform to IHE Medical Document template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.1.1`)
3. **SHALL** conform to IHE Scanned Document template (templateId: `1.3.6.1.4.1.19376.1.2.20`)
4. **SHALL** contain exactly one [1..1] **`code`**
   - *Entered by operator or appropriately fixed for scanned content.*

5. **SHALL** contain exactly one [1..1] **`confidentialityCode`**
   - *Assigned by the operator in accordance with the scanning facility policy. The notion or level of confidentiality in the header may not be the same as that in the Affinity Domain, but in certain cases could be used to derive a confidentiality value among those specified by the Affinity Domain. Attributes @code and @codeSystem shall be present.*
6. **SHALL** contain exactly one [1..1] **`effectiveTime`**
   - *Denotes the time at which the original content was scanned. At a minimum, the time shall be precise to the day and shall include the time zone offset from GMT.*
7. **SHALL** contain exactly one [1..1] **`id`**
   - *The root attribute shall contain the oid for the document, in which case the extension attribute shall be empty, or an oid that scopes the set of possible unique values for the extension attribute, in which case the extension shall be populated with a globally unique identifier within the scope of the root oid.*
8. **SHALL** contain exactly one [1..1] **`languageCode`**
   - *Denotes the language used in the character data of the wrapper CDA header. If the scanned content, when rendered, is in a language different than that of the header, the language context of the CDA will be overwritten at the body level (see ITI TF-3: 5.2.3.9 ClinicalDocument/component/nonXMLBody for an example). Attribute @code shall be present.*
9. **SHOULD** contain exactly one [1..1] **`title`**
   - *Entered by operator, or possibly can be taken from the scanned content.*
10. **SHALL** contain exactly one [1..1] **`typeId`**
11. Contains exactly one [1..1] **`custodian`**
    a. Contains exactly one [1..1] CDA Custodian
    - *Based on the CDA R2 constraints (Section 4.2.2.3 of the CDA Normative Web Edition. See Section 5 REFERENCES), the custodian element is required and is the custodian of the clinical document.*
12. Contains zero or more [0..*] **`informationRecipient`**
    a. Contains exactly one [1..1] CDA Information Recipient
    - *informationRecipient, when used in the context of a referral or request for consultation, this records the intended recipient of the information at the time the document is created. The intended recipient may also be the health chart of the patient, in which case the receivedOrganization is the scoping organization of that chart.*
13. Contains zero or one [0..1] **`legalAuthenticator`**
    a. Contains exactly one [1..1] CDA Legal Authenticator
    - *The legalAuthenticator element identifies the legal authenticator of the document and must be present if the document has been legally authenticated. Based on local practice, clinical documents may be released before legal authentication. This implies that a clinical document that does not contain this element has not been legally authenticated.*

      The act of legal authentication requires a certain privilege be granted to the legal authenticator depending upon local policy. All clinical documents have the potential for legal authentication, given the appropriate credentials.

      Local policies may choose to delegate the function of legal authentication to a device or system that generates the clinical document. In these cases, the legal authenticator is a person accepting responsibility for the document, not the generating device or system.
14. Contains zero or more [0..*] **`authenticator`**
    a. Contains exactly one [1..1] CDA Authenticator
    - *The authenticator identifies the participant who attested to the accuracy of the*

information in the document.

Automated systems, such as a PHR, that allow a clinical document to be generated need to give special consideration to authentication permissions because the information contained in the document may come from sources or contain information that the author cannot validate.

15. Contains at least one [1..*] **recordTarget**, where its type is Record Target
    a. Contains exactly one [1..1] Record Target
16. Contains exactly one [1..1] **custodian**, where its type is Custodian
    a. Contains exactly one [1..1] Custodian
17. Contains exactly one [1..1] **component**, where its type is Component2
    a. Contains exactly one [1..1] Component2
18. **SHOULD** contain at least one [1..*] **author**
    a. Contains exactly one [1..1] Scan Original Author (templateId: 1.3.6.1.4.1.19376.1.2.20.1)
19. **SHALL** contain at least one [1..*] **author**
    a. Contains exactly one [1..1] Scanning Device (templateId: 1.3.6.1.4.1.19376.1.2.20.2)
20. **SHALL** contain exactly one [1..1] **dataEnterer**
    a. Contains exactly one [1..1] Scan Data Enterer (templateId: 1.3.6.1.4.1.19376.1.2.20.3)
21. **MAY** contain zero or one [0..1] **legalAuthenticator**
    a. Contains exactly one [1..1] CDA Legal Authenticator
    - *Context is left up to the scanning facility to refine in accordance with local policies.*
22. **MAY** contain zero or one [0..1] **documentationOf**
    a. Contains exactly one [1..1] CDA Documentation Of
    - *Used to encode the date/time range of the original content. If the original content is representative of a single point in time then the endpoints of the date/time range shall be the same. Information regarding this date/time range shall be included, if it is known. In many cases this will have to be supplied by the operator.*
23. **SHALL** satisfy: All patient, guardianPerson, assignedPerson, maintainingPerson, relatedPerson, intendedRecipient/informationRecipient, associatedPerson, and relatedSubject/subject elements have a name. (CONF-HP-6)
24. **SHALL** satisfy: All patientRole, assignedAuthor, assignedEntity[not(parent::dataEnterer)] and associatedEntity elements have an addr and telecom element. (CONF-HP-7)
25. **SHOULD** satisfy: All guardian, dataEnterer/assignedEntity, relatedEntity, intendedRecipient, relatedSubject and participantRole elements have an addr and telecom element. (CONF-HP-8)
26. **SHALL** satisfy: All guardianOrganization, providerOrganization, wholeOrganization, representedOrganization, representedCustodianOrganization, receivedOrganization, scopingOrganization and serviceProviderOrganization elements have name, addr and telecom elements. (CONF-HP-9)
27. Times or time intervals found in the ClinicalDocument/effectiveTime, author/time, dataEnterer/time, legalAuthenticator/time, authenticator/time and encompassingEncounter/effectiveTime elements **SHALL** be precise to the day, **SHALL** include a time zone if more precise than to the day, and **SHOULD** be precise to the second. (CONF-HP-10)
28. Times or time intervals found in the asOrganizationPartOf/effectiveTime, asMaintainedEntity/effectiveTime, relatedEntity/effectiveTime, serviceEvent/effectiveTime, ClinicalDocument/participant/time, serviceEvent/performer/time and encounterParticipant/time **SHALL** be precise at least to the year, **SHOULD** be precise to the day, and **MAY** omit time zone. (CONF-HP-11)
29. **SHALL** satisfy: Telephone numbers match the regular expression pattern tel:\+?[-0-9().]+ (CONF-HP-12)
30. **SHALL** satisfy: At least one dialing digit is present in the phone number after visual separators are removed. (CONF-HP-13)
31. **SHALL** satisfy: If the telephone number is unknown it is represented using the appropriate flavor of null. (CONF-HP-14)
32. **SHALL** satisfy: The extension attribute of the typeId element is POCD_HD000040. (CONF-HP-16)

33. **SHALL** satisfy: The id/@root attribute is a syntactically correct UUID or OID. (CONF-HP-17)
34. **SHALL** satisfy: UUIDs are represented in the form XXXXXXXX-XXXX-XXXX-XXXXXXXXXXXXXXXX, where each X is a character from the set [A-Fa-f0-9]. (CONF-HP-18)
35. OIDs are represented in dotted decimal notation, where each decimal number is either 0, or starts with a nonzero digit. More formally, an OID **SHALL** be in the form ([0-2])(.([1-9][0-9]*|0))+. (CONF-HP-19)
36. **SHALL** satisfy: OIDs are no more than 64 characters in length. (CONF-HP-20)
37. **SHALL** satisfy: languageCode has the form nn, or nn-CC. (CONF-HP-25)
38. **SHALL** satisfy: The nn portion of languageCode is a legal ISO-639-1 language code in lowercase. (CONF-HP-26)
39. The CC portion languageCode, if present, **SHALL** be an ISO-3166 country code in uppercase. (CONF-HP-27)
40. Both setId and versionNumber **SHALL** be present or both **SHALL** be absent. (CONF-HP-28)
41. The @extension and/or @root of setId and id **SHALL** be different when both are present. (CONF-HP-29)
42. A copyTime element **SHALL NOT** be present. (CONF-HP-30)
43. **SHALL** satisfy: At least one recordTarget/patientRole element is present. (CONF-HP-31)
44. A patient/birthTime element **SHALL** be present. The patient/birthTime element **SHALL** be precise at least to the year, and **SHOULD** be precise at least to the day, and **MAY** omit time zone. If unknown, it **SHALL** be represented using a flavor of null. (CONF-HP-32)
45. A patient/administrativeGenderCode element **SHALL** be present. If unknown, it **SHALL** be represented using a flavor of null. Values for administrativeGenderCode **SHOULD** be drawn from the HL7 AdministrativeGender vocabulary. (CONF-HP-33)
46. The maritalStatusCode, religiousAffiliationCode, raceCode and ethnicGroupCode **MAY** be present. If maritalStatusCode, religiousAffiliationCode, raceCode and ethnicGroupCode elements are present, they **SHOULD** be encoded using the appropriate HL7 vocabularies. (CONF-HP-34)
47. **SHOULD** satisfy: The guardian element is present when the patient is a minor child. (CONF-HP-35)
48. **MAY** satisfy: The providerOrganization element is present. (CONF-HP-36)
49. **SHALL** satisfy: The author/time element is present. (CONF-HP-37)
50. **SHALL** satisfy: The assignedAuthor/id element is present. (CONF-HP-38)
51. **SHALL** satisfy: An assignedAuthor element contains at least one assignedPerson or assignedAuthoringDevice elements. (CONF-HP-39)
52. **SHALL** satisfy: When dataEnterer is present, an assignedEntity/assignedPerson element is present. (CONF-HP-40)
53. The dataEnterer/time element **MAY** be present. If present, it represents the starting time of entry of the data. (CONF-HP-41)
54. **MAY** satisfy: The informant element is present. (CONF-HP-42)
55. When informant is present, an assignedEntity/assignedPerson or relatedEntity/relatedPerson element **SHALL** be present. (CONF-HP-43)
56. When the informant is a healthcare provider with an assigned role, the informant **SHALL** be represented using the assignedEntity element (CONF-HP-44)
57. Allowable values for informant/relatedEntity/@classCode **SHALL** be CON, PRS, CAREGIVER, AGNT or PROV from the RoleClass vocabulary. (CONF-HP-45)
58. When relatedEntity/@classCode is PRS, values in relatedEntity/code **SHALL** come from the HL7 PersonalRelationshipRoleType vocabulary or from SNOMED, any subtype of "Person in the family" (303071001). (CONF-HP-46)
59. When an informant is an unrelated person not otherwise specified, the value relatedEntity/@classCode **SHALL** be set to CON to indicate that this person is a contact. (CONF-HP-47)
60. When the informant is a healthcare provider without an assigned role, the informant **SHALL** be represented using the relatedEntity element and the value of relatedEntity/@classCode **SHALL** be set to PROV. (CONF-HP-48)
61. When the informant is a healthcare provider, the value of relatedEntity/code **SHOULD** be present and indicate the type of healthcare provider. (CONF-HP-49)
62. The ClinicalDocument/informationRecipient element **MAY** be present. When informationRecipient is used, at least one informationRecipient/intendedRecipient/informationRecipient or informationRecipient/intendedRecipient/receivedOrganization **SHALL** be present. (CONF-HP-50)

63. The assignedEntity/assignedPerson element **SHALL** be present in legalAuthenticator. (CONF-HP-51)
64. The assignedEntity/assignedPerson element **SHALL** be present in an authenticator element. (CONF-HP-52)
65. Times or time intervals found in the ClinicalDocument/effectiveTime, author/time, dataEnterer/time, legalAuthenticator/time, authenticator/time and encompassingEncounter/effectiveTime elements **SHALL** be precise to the day, **SHALL** include a time zone if more precise than to the day, and **SHOULD** be precise to the second. (CONF-HP-10)
66. Times or time intervals found in the asOrganizationPartOf/effectiveTime, asMaintainedEntity/effectiveTime, relatedEntity/effectiveTime, serviceEvent/effectiveTime, ClinicalDocument/participant/time, serviceEvent/performer/time and encounterParticipant/time **SHALL** be precise at least to the year, **SHOULD** be precise to the day, and **MAY** omit time zone. (CONF-HP-11)
67. **SHALL** satisfy: The typeId root is 2.16.840.1.113883.1.3 and extension is POCD_HD000040.
68. **SHALL** satisfy: Contains exactly one recordTarget.
69. **SHALL** satisfy: Contains one or more author / assignedAuthor / assignedPerson and/or author / assignedAuthor / representedOrganization
70. **SHALL** satisfy: recordTarget/patientRole/id element includes both the root and the extension attributes.
71. **SHALL** satisfy: At least one recordTarget/patientRole/addr element includes at least the country subelement.
72. **SHALL** satisfy: At least one recordTarget/patientRole/patient/name element has at least one given subelement and one family subelement.
73. **SHALL** satisfy: The recordTarget/patientRole/patient/ administrativeGenderCode element is present.
74. **SHALL** satisfy: The recordTarget/patientRole/patient/ birthTime element is present with precision to the year.
75. **SHOULD** satisfy: Contains author of type ScanOriginalAuthor to represent original author of this scanned document.
76. **SHALL** satisfy: Contains author element of type ScanningDevice to represent the scanning device and software used to produce the scanned content.
77. **SHALL** satisfy: Contains ScanDataEnterer element to represent the scanner operator who produced the scanned content.
78. **SHALL** satisfy: custodian/assignedCustodian/representedCustodianOrganization/name is present.
79. **SHALL** satisfy: custodian/assignedCustodian/representedCustodianOrganization/addr is present and includes at least the country sub element.
80. **SHALL** satisfy: The legalAuthenticator/assignedEntity/id element if known shall include both the root and the extension attributes.
81. **SHALL** satisfy: The component/nonXMLBody is present.
82. **SHALL** satisfy: If the human-readable language of the scanned content is different than that of the wrapper (specified in ClinicalDocument/languageCode), then ClinicalDocument/component/nonXMLBody/languageCode shall be present. Attribute code@code shall be present. Attribute code@codeSystem shall be IETF (Internet Engineering Task Force) RFC 3066 in accordance with the HL7 CDA R2 documentation.
83. **SHALL** satisfy: The component/nonXMLBody/text element is present and encoded using xs:base64Binary encoding. Its #CDATA will contain the scanned content.
84. **SHALL** satisfy: The component/nonXMLBody/text@mediaType is 'application/pdf' for PDF, or 'text/plain' for plaintext.
85. **SHALL** satisfy: The component/nonXMLBody/text@representation is B64.
86. **SHOULD** satisfy: This construct should not be used when the data are structured.
87. **SHALL** satisfy: Each document pertains to one and only one patient.

Unstructured Document 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">
  <typeId root="2.16.840.1.113883.1.3"/>
  <id root="MDHT" extension="1040378665"/>
  <code code="224385909"/>
  <title>TEXT FOR TITLE</title>
  <effectiveTime/>
```

```
  <confidentialityCode code="1499596825"/>
  <languageCode code="Code forlanguageCode"/>
  <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/>
</ClinicalDocument>
```

Unstructured Or Scanned Document

[ClinicalDocument: templateId 2.16.840.1.113883.10.20.19.1]

Used for documents that implement both HL7 Unstructured Documents and HITSP C62 based on IHE Scanned Documents.

1. **SHALL** contain exactly one [1..1] templateId ( ) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.19.1"
2. **SHALL** conform to CDT Unstructured Document template (templateId: 2.16.840.1.113883.10.20.19.1)
3. **SHALL** conform to Unstructured Document template (templateId: 2.16.840.1.113883.3.88.11.62.1)

1. **SHALL** conform to IHE Medical Document template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.1)
2. **SHALL** conform to IHE Scanned Document template (templateId: 1.3.6.1.4.1.19376.1.2.20)
3. **SHALL** conform to Unstructured Document template (templateId: 2.16.840.1.113883.3.88.11.62.1)
4. **SHALL** conform to CDT General Header Constraints template (templateId: 2.16.840.1.113883.10.20.3)
5. **SHALL** conform to CDT Unstructured Document template (templateId: 2.16.840.1.113883.10.20.19.1)
6. **SHALL** contain exactly one [1..1] **code** (CONF-HP-21)
   - *Specifies the type of the clinical document.*
7. Contains exactly one [1..1] **confidentialityCode**
   - *If the confidentialityCode cannot be determined for an Unstructured Document instance, the HL7 code ""N (normal confidentiality) is recommended.*
8. **SHALL** contain exactly one [1..1] **effectiveTime** (CONF-UD-11)
   - *The effectiveTime records the time of creation of the original document. If the referenced document is a scan, the date of scan can be recorded in dataEnterer. If the date of creation of the original document is not known, CDA allows the document effectiveTime to have a nullFlavor.*
9. **SHALL** contain exactly one [1..1] **id** (CONF-HP-17)
   - *The ClinicalDocument/id element is an instance identifier data type (see HL7 Version 3 Abstract Data in Section 5 REFERENCES). The root attribute is a UUID or OID. The root uniquely identifies the scope of the extension. The root and extension attributes uniquely identify the document.*
10. **SHALL** contain exactly one [1..1] **languageCode** (CONF-HP-24)
11. **SHALL** contain exactly one [1..1] **title** (CONF-HP-22)
    - *Specifies the local name used for the document.*
      Note that the title does not need to be the same as the display name provided with the

document type code. For example, the display name provided by LOINC® as an aid in debugging may be "HISTORY AND PHYSICAL". The title can be localized, as appropriate.

12. **SHALL** contain exactly one [1..1] **`typeId`** (CONF-HP-16)
    - *The clinical document type ID identifies the constraints imposed by CDA R2 on the content, essentially acting as a version identifier.*
13. **SHALL** contain exactly one [1..1] **`realmCode/@code`**`="US"` (CONF-HP-15)
14. **SHOULD** contain at least one [1..*] **`author`**
    a. Contains exactly one [1..1] Scan Original Author (templateId: `1.3.6.1.4.1.19376.1.2.20.1`)
15. **SHALL** contain at least one [1..*] **`author`**
    a. Contains exactly one [1..1] Scanning Device (templateId: `1.3.6.1.4.1.19376.1.2.20.2`)
16. **SHALL** contain exactly one [1..1] **`dataEnterer`**
    a. Contains exactly one [1..1] Scan Data Enterer (templateId: `1.3.6.1.4.1.19376.1.2.20.3`)
17. **MAY** contain zero or one [0..1] **`legalAuthenticator`**
    a. Contains exactly one [1..1] CDA Legal Authenticator
    - *Context is left up to the scanning facility to refine in accordance with local policies.*
18. **MAY** contain zero or one [0..1] **`documentationOf`**
    a. Contains exactly one [1..1] CDA Documentation Of
    - *Used to encode the date/time range of the original content. If the original content is representative of a single point in time then the endpoints of the date/time range shall be the same. Information regarding this date/time range shall be included, if it is known. In many cases this will have to be supplied by the operator.*
19. Contains at least one [1..*] **`recordTarget`**, where its type is Record Target
    a. Contains exactly one [1..1] Record Target
20. Contains exactly one [1..1] **`custodian`**, where its type is Custodian
    a. Contains exactly one [1..1] Custodian
21. Contains exactly one [1..1] **`component`**, where its type is Component2
    a. Contains exactly one [1..1] Component2
22. Contains exactly one [1..1] **`custodian`**
    a. Contains exactly one [1..1] CDA Custodian
    - *Based on the CDA R2 constraints (Section 4.2.2.3 of the CDA Normative Web Edition. See Section 5 REFERENCES), the custodian element is required and is the custodian of the clinical document.*
23. Contains zero or more [0..*] **`informationRecipient`**
    a. Contains exactly one [1..1] CDA Information Recipient
    - *informationRecipient, when used in the context of a referral or request for consultation, this records the intended recipient of the information at the time the document is created. The intended recipient may also be the health chart of the patient, in which case the receivedOrganization is the scoping organization of that chart.*
24. Contains zero or one [0..1] **`legalAuthenticator`**
    a. Contains exactly one [1..1] CDA Legal Authenticator
    - *The legalAuthenticator element identifies the legal authenticator of the document and must be present if the document has been legally authenticated. Based on local practice, clinical documents may be released before legal authentication. This implies that a clinical document that does not contain this element has not been legally authenticated.*

      The act of legal authentication requires a certain privilege be granted to the legal

authenticator depending upon local policy. All clinical documents have the potential for legal authentication, given the appropriate credentials.

Local policies may choose to delegate the function of legal authentication to a device or system that generates the clinical document. In these cases, the legal authenticator is a person accepting responsibility for the document, not the generating device or system.

25. Contains zero or more [0..*] **`authenticator`**

a. Contains exactly one [1..1] CDA Authenticator

- *The authenticator identifies the participant who attested to the accuracy of the information in the document.*

  Automated systems, such as a PHR, that allow a clinical document to be generated need to give special consideration to authentication permissions because the information contained in the document may come from sources or contain information that the author cannot validate.

26. **SHALL** contain exactly one [1..1] **`custodian`** (CONF-UD-27)

a. Contains exactly one [1..1] CDA Custodian

27. **SHALL** satisfy: The typeId root is 2.16.840.1.113883.1.3 and extension is POCD_HD000040.

28. **SHALL** satisfy: Contains exactly one recordTarget.

29. **SHALL** satisfy: Contains one or more author / assignedAuthor / assignedPerson and/or author / assignedAuthor / representedOrganization

30. **SHALL** satisfy: recordTarget/patientRole/id element includes both the root and the extension attributes.

31. **SHALL** satisfy: At least one recordTarget/patientRole/addr element includes at least the country subelement.

32. **SHALL** satisfy: At least one recordTarget/patientRole/patient/name element has at least one given subelement and one family subelement.

33. **SHALL** satisfy: The recordTarget/patientRole/patient/ administrativeGenderCode element is present.

34. **SHALL** satisfy: The recordTarget/patientRole/patient/ birthTime element is present with precision to the year.

35. **SHOULD** satisfy: Contains author of type ScanOriginalAuthor to represent original author of this scanned document.

36. **SHALL** satisfy: Contains author element of type ScanningDevice to represent the scanning device and software used to produce the scanned content.

37. **SHALL** satisfy: Contains ScanDataEnterer element to represent the scanner operator who produced the scanned content.

38. **SHALL** satisfy: custodian/assignedCustodian/representedCustodianOrganization/name is present.

39. **SHALL** satisfy: custodian/assignedCustodian/representedCustodianOrganization/addr is present and includes at least the country sub element.

40. **SHALL** satisfy: The legalAuthenticator/assignedEntity/id element if known shall include both the root and the extension attributes.

41. **SHALL** satisfy: The component/nonXMLBody is present.

42. **SHALL** satisfy: If the human-readable language of the scanned content is different than that of the wrapper (specified in ClinicalDocument/languageCode), then ClinicalDocument/component/nonXMLBody/languageCode shall be present. Attribute code@code shall be present. Attribute code@codeSystem shall be IETF (Internet Engineering Task Force) RFC 3066 in accordance with the HL7 CDA R2 documentation.

43. **SHALL** satisfy: The component/nonXMLBody/text element is present and encoded using xs:base64Binary encoding. Its #CDATA will contain the scanned content.

44. **SHALL** satisfy: The component/nonXMLBody/text@mediaType is 'application/pdf' for PDF, or 'text/plain' for plaintext.

45. **SHALL** satisfy: The component/nonXMLBody/text@representation is B64.

46. **SHOULD** satisfy: This construct should not be used when the data are structured.

47. **SHALL** satisfy: Each document pertains to one and only one patient.

48. **SHALL** satisfy: All patient, guardianPerson, assignedPerson, maintainingPerson, relatedPerson, intendedRecipient/informationRecipient, associatedPerson, and relatedSubject/subject elements have a name. (CONF-HP-6)

49. **SHALL** satisfy: All patientRole, assignedAuthor, assignedEntity[not(parent::dataEnterer)] and associatedEntity elements have an addr and telecom element. (CONF-HP-7)
50. **SHOULD** satisfy: All guardian, dataEnterer/assignedEntity, relatedEntity, intendedRecipient, relatedSubject and participantRole elements have an addr and telecom element. (CONF-HP-8)
51. **SHALL** satisfy: All guardianOrganization, providerOrganization, wholeOrganization, representedOrganization, representedCustodianOrganization, receivedOrganization, scopingOrganization and serviceProviderOrganization elements have name, addr and telecom elements. (CONF-HP-9)
52. Times or time intervals found in the ClinicalDocument/effectiveTime, author/time, dataEnterer/time, legalAuthenticator/time, authenticator/time and encompassingEncounter/effectiveTime elements **SHALL** be precise to the day, **SHALL** include a time zone if more precise than to the day, and **SHOULD** be precise to the second. (CONF-HP-10)
53. Times or time intervals found in the asOrganizationPartOf/effectiveTime, asMaintainedEntity/effectiveTime, relatedEntity/effectiveTime, serviceEvent/effectiveTime, ClinicalDocument/participant/time, serviceEvent/performer/time and encounterParticipant/time **SHALL** be precise at least to the year, **SHOULD** be precise to the day, and **MAY** omit time zone. (CONF-HP-11)
54. **SHALL** satisfy: Telephone numbers match the regular expression pattern tel:\+?[-0-9().]+ (CONF-HP-12)
55. **SHALL** satisfy: At least one dialing digit is present in the phone number after visual separators are removed. (CONF-HP-13)
56. **SHALL** satisfy: If the telephone number is unknown it is represented using the appropriate flavor of null. (CONF-HP-14)
57. **SHALL** satisfy: The extension attribute of the typeId element is POCD_HD000040. (CONF-HP-16)
58. **SHALL** satisfy: The id/@root attribute is a syntactically correct UUID or OID. (CONF-HP-17)
59. **SHALL** satisfy: UUIDs are represented in the form XXXXXXXX-XXXX-XXXX-XXXXXXXXXXXXXXXX, where each X is a character from the set [A-Fa-f0-9]. (CONF-HP-18)
60. OIDs are represented in dotted decimal notation, where each decimal number is either 0, or starts with a nonzero digit. More formally, an OID **SHALL** be in the form ([0-2])(.([1-9][0-9]*|0))+. (CONF-HP-19)
61. **SHALL** satisfy: OIDs are no more than 64 characters in length. (CONF-HP-20)
62. **SHALL** satisfy: languageCode has the form nn, or nn-CC. (CONF-HP-25)
63. **SHALL** satisfy: The nn portion of languageCode is a legal ISO-639-1 language code in lowercase. (CONF-HP-26)
64. The CC portion languageCode, if present, **SHALL** be an ISO-3166 country code in uppercase. (CONF-HP-27)
65. Both setId and versionNumber **SHALL** be present or both **SHALL** be absent. (CONF-HP-28)
66. The @extension and/or @root of setId and id **SHALL** be different when both are present. (CONF-HP-29)
67. A copyTime element **SHALL NOT** be present. (CONF-HP-30)
68. **SHALL** satisfy: At least one recordTarget/patientRole element is present. (CONF-HP-31)
69. A patient/birthTime element **SHALL** be present. The patient/birthTime element **SHALL** be precise at least to the year, and **SHOULD** be precise at least to the day, and **MAY** omit time zone. If unknown, it **SHALL** be represented using a flavor of null. (CONF-HP-32)
70. A patient/administrativeGenderCode element **SHALL** be present. If unknown, it **SHALL** be represented using a flavor of null. Values for administrativeGenderCode **SHOULD** be drawn from the HL7 AdministrativeGender vocabulary. (CONF-HP-33)
71. The maritalStatusCode, religiousAffiliationCode, raceCode and ethnicGroupCode **MAY** be present. If maritalStatusCode, religiousAffiliationCode, raceCode and ethnicGroupCode elements are present, they **SHOULD** be encoded using the appropriate HL7 vocabularies. (CONF-HP-34)
72. **SHOULD** satisfy: The guardian element is present when the patient is a minor child. (CONF-HP-35)
73. **MAY** satisfy: The providerOrganization element is present. (CONF-HP-36)
74. **SHALL** satisfy: The author/time element is present. (CONF-HP-37)
75. **SHALL** satisfy: The assignedAuthor/id element is present. (CONF-HP-38)
76. **SHALL** satisfy: An assignedAuthor element contains at least one assignedPerson or assignedAuthoringDevice elements. (CONF-HP-39)
77. **SHALL** satisfy: When dataEnterer is present, an assignedEntity/assignedPerson element is present. (CONF-HP-40)

78. The dataEnterer/time element **MAY** be present. If present, it represents the starting time of entry of the data. (CONF-HP-41)
79. **MAY** satisfy: The informant element is present. (CONF-HP-42)
80. When informant is present, an assignedEntity/assignedPerson or relatedEntity/relatedPerson element **SHALL** be present. (CONF-HP-43)
81. When the informant is a healthcare provider with an assigned role, the informant **SHALL** be represented using the assignedEntity element (CONF-HP-44)
82. Allowable values for informant/relatedEntity/@classCode **SHALL** be CON, PRS, CAREGIVER, AGNT or PROV from the RoleClass vocabulary. (CONF-HP-45)
83. When relatedEntity/@classCode is PRS, values in relatedEntity/code **SHALL** come from the HL7 PersonalRelationshipRoleType vocabulary or from SNOMED, any subtype of "Person in the family" (303071001). (CONF-HP-46)
84. When an informant is an unrelated person not otherwise specified, the value relatedEntity/@classCode **SHALL** be set to CON to indicate that this person is a contact. (CONF-HP-47)
85. When the informant is a healthcare provider without an assigned role, the informant **SHALL** be represented using the relatedEntity element and the value of relatedEntity/@classCode **SHALL** be set to PROV. (CONF-HP-48)
86. When the informant is a healthcare provider, the value of relatedEntity/code **SHOULD** be present and indicate the type of healthcare provider. (CONF-HP-49)
87. The ClinicalDocument/informationRecipient element **MAY** be present. When informationRecipient is used, at least one informationRecipient/intendedRecipient/informationRecipient or informationRecipient/intendedRecipient/receivedOrganization **SHALL** be present. (CONF-HP-50)
88. The assignedEntity/assignedPerson element **SHALL** be present in legalAuthenticator. (CONF-HP-51)
89. The assignedEntity/assignedPerson element **SHALL** be present in an authenticator element. (CONF-HP-52)
90. Times or time intervals found in the ClinicalDocument/effectiveTime, author/time, dataEnterer/time, legalAuthenticator/time, authenticator/time and encompassingEncounter/effectiveTime elements **SHALL** be precise to the day, **SHALL** include a time zone if more precise than to the day, and **SHOULD** be precise to the second. (CONF-HP-10)
91. Times or time intervals found in the asOrganizationPartOf/effectiveTime, asMaintainedEntity/effectiveTime, relatedEntity/effectiveTime, serviceEvent/effectiveTime, ClinicalDocument/participant/time, serviceEvent/performer/time and encounterParticipant/time **SHALL** be precise at least to the year, **SHOULD** be precise to the day, and **MAY** omit time zone. (CONF-HP-11)
92. **SHALL** satisfy: A patientRole element contains an id element. (CONF-UD-17)
93. An assignedAuthor element contains an addr element. If addr is unknown it **SHALL** be represented using the appropriate flavor of null. (CONF-UD-25)
94. An assignedAuthor element contains a telecom element. If telecom is unknown it **SHALL** be represented using the appropriate flavor of null. (CONF-UD-26)
95. The custodian element **SHALL** contain an assignedCustodian/representedCustodianOrganization element. (CONF-UD-28)
96. A representedCustodianOrganization element **SHALL** contain an id element. (CONF-UD-29)
97. A representedCustodianOrganization element **SHALL** contain a name element. (CONF-UD-30)
98. A representedCustodianOrganization element **SHALL** contain a telecom element. (CONF-UD-31)
99. A representedCustodianOrganization element **SHALL** contain an addr element. (CONF-UD-32)
100. **SHALL** satisfy: Contains component/nonXMLBody/text element. (CONF-UD-34)
101. The text element **SHALL** either contain a reference element with a value attribute, or have a representation attribute with the value of B64, a mediaType attribute, and contain the media content (CONF-UD-35)
102. The value of @mediaType **SHALL** be drawn from the value set 2.16.840.1.113883.11.20.7.1 SupportedFileFormats STATIC 20100512 (CONF-UD-36)

Unstructured Or Scanned Document 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">
  <typeId root="2.16.840.1.113883.1.3"/>
  <id root="MDHT" extension="2102494286"/>
  <code code="1839748251"/>
  <title>TEXT FOR TITLE</title>
  <effectiveTime/>
  <confidentialityCode code="291776330"/>
  <languageCode code="Code forlanguageCode"/>
  <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/>
</ClinicalDocument>
```

Chapter 3

SECTION TEMPLATES

Topics:

Admission Medication History Section

[Section: templateId 2.16.840.1.113883.3.88.11.83.113]

The Admission Medication Section contains information about the relevant medications of a patient prior to admission to a facility.

1. **SHALL** contain exactly one [1..1] templateId ( ) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.3.88.11.83.113"
2. **SHALL** conform to IHE Admission Medication History Section template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.20)

1. **SHALL** conform to IHE Admission Medication History Section template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.20)
2. **SHALL** contain exactly one [1..1] **code/@code**="42346-7" *MEDICATIONS ON ADMISSION* (CodeSystem: 2.16.840.1.113883.6.1 LOINC)

Admission Medication History 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">
  <id root="MDHT" extension="788871075"/>
  <title>TEXT FOR TITLE</title>
</section>
```

Advance Directives Section

[Section: templateId 2.16.840.1.113883.3.88.11.83.116]

The Advance Directives Section contains information that defines the patient's expectations and requests for care along with the locations of the documents.

1. **SHALL** contain exactly one [1..1] templateId ( ) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.3.88.11.83.116"
2. **SHALL** conform to IHE Coded Advance Directives Section template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.35)
3. **SHALL** contain at least one [1..*] **entry**
   a. Contains exactly one [1..1] Advance Directive (templateId: 2.16.840.1.113883.3.88.11.83.12)

1. **SHALL** conform to CCD Advance Directives Section template (templateId: 2.16.840.1.113883.10.20.1.1)
2. **SHALL** conform to IHE Advance Directives Section template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.34)
3. **SHALL** conform to IHE Coded Advance Directives Section template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.35)
4. **SHALL** contain exactly one [1..1] **code/@code**="42348-3" *Advance directives* (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF-78, CONF-79)
5. **SHALL** contain exactly one [1..1] **title** (CONF-80)
6. **SHALL** contain exactly one [1..1] **text**
7. **SHALL** contain at least one [1..*] **entry**
   a. Contains exactly one [1..1] Advance Directive (templateId: 2.16.840.1.113883.3.88.11.83.12)
8. **SHOULD** satisfy: Contains a case-insensitive language-insensitive text string containing 'advance directives'. (CONF-81)

Advance Directives 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">
  <id root="MDHT" extension="1712498366"/>
  <title>TEXT FOR TITLE</title>
  <text/>
  <entry>
    <observation>
      <id root="MDHT" extension="122748204"/>
      <code code="2024578559"/>
      <text>Text Value</text>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
    </observation>
  </entry>
</section>
```

Allergies Reactions Section

[Section: templateId 2.16.840.1.113883.3.88.11.83.102]

The Allergies and Other Adverse Reactions Section contains data on the substance intolerances and the associated adverse reactions suffered by the patient. At a minimum, currently active and any relevant historical allergies and adverse reactions shall be listed.

1. **SHALL** contain exactly one [1..1] templateId ( ) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.3.88.11.83.102"
2. **SHALL** conform to IHE Allergies Reactions Section template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.13) (C83-[CT-102-2])
3. **SHALL** contain at least one [1..*] **entry**
   a. Contains exactly one [1..1] Allergy Drug Sensitivity (templateId: 2.16.840.1.113883.3.88.11.83.6)

1. **SHALL** conform to CCD Alerts Section template (templateId: 2.16.840.1.113883.10.20.1.2)
2. **SHALL** conform to IHE Allergies Reactions Section template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.13)
3. **SHALL** contain exactly one [1..1] **code/@code**="48765-2" *Allergies, adverse reactions, alerts* (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF-258, CONF-259)
4. **SHALL** contain exactly one [1..1] **title** (CONF-260)
5. **SHALL** contain exactly one [1..1] **text** (CONF-256)
6. **SHOULD** contain at least one [1..*] **entry** (CONF-256)
   a. Contains exactly one [1..1] Problem Act (templateId: 2.16.840.1.113883.10.20.1.27)
7. **SHALL** contain at least one [1..*] **entry**
   a. Contains exactly one [1..1] Allergy Drug Sensitivity (templateId: 2.16.840.1.113883.3.88.11.83.6)
8. **SHOULD** satisfy: Contains a case-insensitive language-insensitive string containing "alert" and/or "allergies and adverse reactions". (CONF-261)
9. The absence of known allergies, adverse reactions or alerts **SHALL** be explicitly asserted. (CONF-257)

Allergies Reactions 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">
  <id root="MDHT" extension="1863782106"/>
  <title>TEXT FOR TITLE</title>
  <text/>
  <entry>
    <act>
      <id root="MDHT" extension="1180502789"/>
      <code code="1292751891"/>
      <text>Text Value</text>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
    </act>
  </entry>
</section>
```

Assessment And Plan Section

[Section: templateId 2.16.840.1.113883.3.88.11.83.123]

The Assessment and Plan Section contains information about the assessment of the patient's condition and expectations for care including proposals, goals, and order requests for monitoring, tracking, or improving the condition of the patient.

An assessment and plan section varies from the plan of care section defined later in that it includes a physician assessment of the patient condition.

NOTE : The assessments described in this section are physician assessments of the patient's current condition, and do not include assessments of functional status, or other assessments typically used in nursing. In Implementation Guides currently selected, when both the assessment and plan are documented, they are included together in a single section documenting both. When the physician assessment is not present, only the plan of care section appears. There are no cases where a physician assessment is provided without a plan.

1. **SHALL** contain exactly one [1..1] templateId ( ) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.3.88.11.83.123"
2. **SHALL** conform to IHE Assessment And Plan Section template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.13.2.5)
3. **SHALL** conform to CDT Assessment And Plan Section template (templateId: 2.16.840.1.113883.10.20.2.7)
4. **MAY** contain zero or more [0..*] **entry**
   a. Contains exactly one [1..1] Medication (templateId: 2.16.840.1.113883.3.88.11.83.8)
5. **MAY** contain zero or more [0..*] **entry**
   a. Contains exactly one [1..1] Immunization (templateId: 2.16.840.1.113883.3.88.11.83.13)
6. **MAY** contain zero or more [0..*] **entry**
   a. Contains exactly one [1..1] Encounter (templateId: 2.16.840.1.113883.3.88.11.83.16)
7. **MAY** contain zero or more [0..*] **entry**
   a. Contains exactly one [1..1] Procedure (templateId: 2.16.840.1.113883.3.88.11.83.17)

1. **SHALL** conform to CDT Assessment And Plan Section template (templateId: 2.16.840.1.113883.10.20.2.7)

2. **SHALL** conform to IHE Assessment And Plan Section template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.1.13.2.5`)
3. **SHALL** contain exactly one [1..1] **`code/@code`**`="51847-2"` *ASSESSMENT AND PLAN* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`)
4. **MAY** contain zero or more [0..*] **`entry`**
   a. Contains exactly one [1..1] Medication (templateId: `2.16.840.1.113883.3.88.11.83.8`)
5. **MAY** contain zero or more [0..*] **`entry`**
   a. Contains exactly one [1..1] Immunization (templateId: `2.16.840.1.113883.3.88.11.83.13`)
6. **MAY** contain zero or more [0..*] **`entry`**
   a. Contains exactly one [1..1] Encounter (templateId: `2.16.840.1.113883.3.88.11.83.16`)
7. **MAY** contain zero or more [0..*] **`entry`**
   a. Contains exactly one [1..1] Procedure (templateId: `2.16.840.1.113883.3.88.11.83.17`)

Assessment And 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">
  <id root="MDHT" extension="55722342"/>
  <title>TEXT FOR TITLE</title>
  <entry>
    <substanceAdministration>
      <id root="MDHT" extension="2068620197"/>
      <effectiveTime xsi:type="IVL_TS">
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <consumable/>
      <entryRelationship>
        <observation>
          <id root="MDHT" extension="922368536"/>
          <code code="878224847"/>
          <effectiveTime>
            <low value="2012"/>
            <high value="2012"/>
          </effectiveTime>
        </observation>
      </entryRelationship>
      <entryRelationship>
        <supply>
          <id root="MDHT" extension="1730253490"/>
          <effectiveTime value="20121102"/>
        </supply>
      </entryRelationship>
      <entryRelationship>
        <observation/>
      </entryRelationship>
    </substanceAdministration>
  </entry>
  <entry>
    <substanceAdministration>
      <id root="MDHT" extension="905355183"/>
      <effectiveTime value="20121102"/>
      <consumable/>
    </substanceAdministration>
  </entry>
  <entry>
    <encounter>
      <id root="MDHT" extension="882894764"/>
```

```
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
    </encounter>
  </entry>
</section>
```

Chief Complaint Section

[Section: templateId 2.16.840.1.113883.3.88.11.83.105]

The Chief Complaint Section contains information about the patient's chief complaint.

1. **SHALL** contain exactly one [1..1] templateId ( ) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.3.88.11.83.105"
2. **SHALL** conform to IHE Chief Complaint Section template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.13.2.1)
3. **SHALL** conform to CDT Chief Complaint Section template (templateId: 2.16.840.1.113883.10.20.2.8)
4. **MAY** contain zero or one [0..1] **entry**
   a. Contains exactly one [1..1] Condition (templateId: 2.16.840.1.113883.3.88.11.83.7)

1. **SHALL** conform to CDT Chief Complaint Section template (templateId: 2.16.840.1.113883.10.20.2.8)
2. **SHALL** conform to IHE Chief Complaint Section template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.13.2.1)
3. **SHALL** contain exactly one [1..1] **code/@code**="10154-3" *CHIEF COMPLAINT* (CodeSystem: 2.16.840.1.113883.6.1 LOINC)
4. **MAY** contain zero or one [0..1] **entry**
   a. Contains exactly one [1..1] Condition (templateId: 2.16.840.1.113883.3.88.11.83.7)

Chief Complaint 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">
  <id root="MDHT" extension="506053062"/>
  <title>TEXT FOR TITLE</title>
  <entry>
    <act>
      <id root="MDHT" extension="1419678125"/>
      <code code="442741057"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <entryRelationship>
        <observation/>
      </entryRelationship>
    </act>
  </entry>
</section>
```

Diagnostic Results Section

[Section: templateId 2.16.840.1.113883.3.88.11.83.122]

The Results section contains the results of observations generated by laboratories, imaging procedures, and other procedures. The scope includes hematology, chemistry, serology, virology, toxicology, microbiology, plain x-ray, ultrasound, CT, MRI, angiography, echocardiography, nuclear medicine, pathology, and procedure observations. The section often includes notable results such as abnormal values or relevant trends, and could contain all results for the period of time being documented.

Laboratory results are typically generated by laboratories providing analytic services in areas such as chemistry, hematology, serology, histology, cytology, anatomic pathology, microbiology, and/or virology. These observations are based on analysis of specimens obtained from the patient and submitted to the laboratory.

Imaging results are typically generated by a clinician reviewing the output of an imaging procedure, such as where a cardiologist reports the left ventricular ejection fraction based on the review of a cardiac echocardiogram.

Procedure results are typically generated by a clinician to provide more granular information about component observations made during a procedure, such as where a gastroenterologist reports the size of a polyp observed during a colonoscopy.

1. **SHALL** contain exactly one [1..1] templateId ( ) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.3.88.11.83.122"
2. **SHALL** conform to IHE Coded Results Section template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.28) (C83-[CT-122-1])
3. **SHALL** contain at least one [1..*] **entry** (C83-[CT-122-2])
   a. Contains exactly one [1..1] Procedure (templateId: 2.16.840.1.113883.3.88.11.83.17)
4. **MAY** contain zero or more [0..*] **entry**
   a. Contains exactly one [1..1] Result (templateId: 2.16.840.1.113883.3.88.11.83.15.1)
5. **MAY** contain zero or more [0..*] **entry**
   a. Contains exactly one [1..1] Result Organizer (templateId: 2.16.840.1.113883.10.20.1.32)
6. **SHALL** satisfy: Contains Result as entry within section, or within a ResultOrganizer. (C83-[CT-122-2])

1. **SHALL** conform to IHE Coded Results Section template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.28)
2. **SHALL** contain exactly one [1..1] **code/@code**="30954-2" *STUDIES SUMMARY* (CodeSystem: 2.16.840.1.113883.6.1 LOINC)
3. **SHOULD** contain at least one [1..*] **entry**
   a. Contains exactly one [1..1] External Reference (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.4)
4. **SHALL** contain at least one [1..*] **entry** (C83-[CT-122-2])
   a. Contains exactly one [1..1] Procedure (templateId: 2.16.840.1.113883.3.88.11.83.17)
5. **MAY** contain zero or more [0..*] **entry**
   a. Contains exactly one [1..1] Result (templateId: 2.16.840.1.113883.3.88.11.83.15.1)
6. **MAY** contain zero or more [0..*] **entry**
   a. Contains exactly one [1..1] Result Organizer (templateId: 2.16.840.1.113883.10.20.1.32)
7. **SHALL** satisfy: Contains Result as entry within section, or within a ResultOrganizer. (C83-[CT-122-2])

Diagnostic Results 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">
  <id root="MDHT" extension="1411033650"/>
```

```
  <title>TEXT FOR TITLE</title>
  <entry>
    <observation>
      <id root="MDHT" extension="159735242"/>
      <code code="455660218"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
    </observation>
  </entry>
  <entry>
    <organizer>
      <id root="MDHT" extension="1667141441"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <component>
        <observation>
          <id root="MDHT" extension="2074448023"/>
          <code code="2141289711"/>
          <effectiveTime>
            <low value="2012"/>
            <high value="2012"/>
          </effectiveTime>
        </observation>
      </component>
    </organizer>
  </entry>
</section>
```

Discharge Diagnosis Section

[Section: templateId 2.16.840.1.113883.3.88.11.83.111]

The Discharge Diagnosis Section contains information about the conditions identified during the hospital stay that either need to be monitored after discharge from the hospital and/or where resolved during the hospital course.

1. **SHALL** contain exactly one [1..1] templateId ( ) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.3.88.11.83.111"
2. **SHALL** conform to IHE Discharge Diagnosis Section template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.7)
3. **SHALL** contain exactly one [1..1] **entry**
   a. Contains exactly one [1..1] Condition (templateId: 2.16.840.1.113883.3.88.11.83.7)

1. **SHALL** conform to IHE Discharge Diagnosis Section template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.7)
2. **SHALL** contain exactly one [1..1] **code/@code**="11535-2" *HOSPITAL DISCHARGE DX* (CodeSystem: 2.16.840.1.113883.6.1 LOINC)
3. **SHALL** contain exactly one [1..1] **entry**
   a. Contains exactly one [1..1] Condition (templateId: 2.16.840.1.113883.3.88.11.83.7)

Discharge Diagnosis 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">
  <id root="MDHT" extension="1633777500"/>
  <title>TEXT FOR TITLE</title>
  <entry>
    <act>
      <id root="MDHT" extension="1838400974"/>
      <code code="361530497"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <entryRelationship>
        <observation/>
      </entryRelationship>
    </act>
  </entry>
</section>
```

Encounters Section

[Section: templateId 2.16.840.1.113883.3.88.11.83.127]

The Encounter Section contains information describing the patient history of encounters. At a minimum, current and pertinent historical encounters should be included; a full encounter history may be included.

1. **SHALL** contain exactly one [1..1] templateId ( ) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.3.88.11.83.127"
2. **SHALL** conform to IHE Encounter History Section template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.5.3.3)
3. **SHALL** contain at least one [1..*] **entry**
   a. Contains exactly one [1..1] Encounter (templateId: 2.16.840.1.113883.3.88.11.83.16)

1. **SHALL** conform to CCD Encounters Section template (templateId: 2.16.840.1.113883.10.20.1.3)
2. **SHALL** conform to IHE Encounter History Section template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.5.3.3)
3. **SHALL** contain exactly one [1..1] **code/@code**="46240-8" *History of encounters* (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF-454, CONF-455)
4. **SHALL** contain exactly one [1..1] **title** (CONF-456)
5. **SHALL** contain exactly one [1..1] **text** (CONF-453)
6. **SHOULD** contain at least one [1..*] **entry**
   a. Contains exactly one [1..1] Encounters Activity (templateId: 2.16.840.1.113883.10.20.1.21)
7. **SHALL** contain at least one [1..*] **entry**
   a. Contains exactly one [1..1] Encounter (templateId: 2.16.840.1.113883.3.88.11.83.16)
8. **SHOULD** be valued with a case-insensitive language-insensitive text string containing 'encounters'. (CONF-457)

Encounters 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">
  <id root="MDHT" extension="491437548"/>
  <title>TEXT FOR TITLE</title>
  <text/>
  <entry>
    <encounter>
```

```
      <id root="MDHT" extension="2146399266"/>
      <text>Text Value</text>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
    </encounter>
  </entry>
</section>
```

Family History Section

[Section: templateId 2.16.840.1.113883.3.88.11.83.125]

The Family History Section contains information about the genetic family members, to the extent that they are known, the diseases they suffered from, their ages at death, and other relevant genetic information.

1. **SHALL** contain exactly one [1..1] templateId ( ) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.3.88.11.83.125"
2. **SHALL** conform to IHE Family Medical History Section template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.14)
3. **SHALL** contain at least one [1..*] **entry**
   a. Contains exactly one [1..1] Family History (templateId: 2.16.840.1.113883.3.88.11.83.18)
4. **SHALL** conform to IHE Coded Family History Section and **SHALL** contain a templateId element whose root attribute is 1.3.6.1.4.1.19376.1.5.3.1.3.15 when this section is conveying structured family history.
5. When providing structured Family History Information **SHALL** include entries conforming to the Family History module

1. **SHALL** conform to CCD Family History Section template (templateId: 2.16.840.1.113883.10.20.1.4)
2. **SHALL** conform to IHE Family Medical History Section template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.14)
3. **SHALL** contain exactly one [1..1] **code/@code**="10157-6" *History of family member diseases* (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF-185, CONF-186)
4. **SHALL** contain exactly one [1..1] **title** (CONF-187)
5. **SHALL** contain exactly one [1..1] **text**
6. **MAY** contain at least one [1..*] **entry**
   a. Contains exactly one [1..1] Family History Organizer (templateId: 2.16.840.1.113883.10.20.1.23)
7. **SHALL** contain at least one [1..*] **entry**
   a. Contains exactly one [1..1] Family History (templateId: 2.16.840.1.113883.3.88.11.83.18)
8. **SHOULD** satisfy: Contains a case-insensitive language-insensitive text string containing 'family history'. (CONF-188)
9. Family History Section **SHOULD** include one or more family history observations (templateId 2.16.840.1.113883.10.20.1.22), which **MAY** be contained within family history organizers (templateId 2.16.840.1.113883.10.20.1.23) (CONF-184)
10. The family history section **SHALL NOT** contain Section / subject. (CONF-189)
11. **SHALL** conform to IHE Coded Family History Section and **SHALL** contain a templateId element whose root attribute is 1.3.6.1.4.1.19376.1.5.3.1.3.15 when this section is conveying structured family history.
12. When providing structured Family History Information **SHALL** include entries conforming to the Family History module

Family History 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">
  <id root="MDHT" extension="1809936439"/>
  <title>TEXT FOR TITLE</title>
  <text/>
  <entry>
    <organizer>
      <id root="MDHT" extension="576048361"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <component>
        <observation/>
      </component>
    </organizer>
  </entry>
</section>
```

Functional Status Section

[Section: templateId 2.16.840.1.113883.3.88.11.83.109]

The Functional Status Section provides information about the capability of the patient to perform acts of daily living.

1. **SHALL** contain exactly one [1..1] templateId ( ) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.3.88.11.83.109"
2. **SHALL** conform to CCD Functional Status Section template (templateId: 2.16.840.1.113883.10.20.1.5)

1. **SHALL** conform to CCD Functional Status Section template (templateId: 2.16.840.1.113883.10.20.1.5)
2. **SHALL** contain exactly one [1..1] **code/@code**="47420-5" *Functional status assessment* (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF-124, CONF-125)
3. **SHALL** contain exactly one [1..1] **title** (CONF-126)
4. **SHALL** contain exactly one [1..1] **text**
5. **SHOULD** satisfy: Contains one or more Problem Act and/or Result Organizer (CONF-123)
6. **SHOULD** satisfy: Contains a case-insensitive language-insensitive string containing 'functional status'. (CONF-127)
7. problem observation or result observation in the functional status section **SHALL** contain exactly one observation / code (CONF-128)
8. The value for Observation / code in a problem observation or result observation in the functional status section **MAY** be selected from ValueSet 2.16.840.1.113883.1.11.20.6 FunctionalStatusTypeCode STATIC 20061017 (CONF-129)
9. If the functional status was collected using a standardized assessment instrument, then the instrument itself **SHOULD** be represented in the Organizer / code of a result organizer, with a value selected from LOINC (codeSystem 2.16.840.1.113883.6.1) or SNOMED CT (codeSystem 2.16.840.1.113883.6.96) (CONF-130)
10. If the functional status was collected using a standardized assessment instrument, then the question within that instrument **SHOULD** be represented in the Observation / code of a result observation, with a value selected from LOINC (codeSystem 2.16.840.1.113883.6.1) or SNOMED CT (codeSystem 2.16.840.1.113883.6.96). (CONF-131)
11. If the functional status was collected using a standardized assessment instrument containing questions with enumerated values as answers, then the answer **SHOULD** be represented in the Observation / value of a result observation (CONF-132)

12. If Observation / value in a result observation in the functional status section is of data type CE or CD, then it **SHOULD** use the same code system used to code the question in Observation / code. (CONF-133)
13. Observation / value in a result observation in the functional status section **MAY** be of datatype CE or CD and **MAY** contain one or more Observation / value / translation, to represent equivalent values from other code systems. (CONF-134)
14. A problem observation or result observation in the functional status section **MAY** use codes from the International Classification of Functioning, Disability, and Health (ICF, http://www.who.int/classifications/icf/en/) (codeSystem 2.16.840.1.113883.6.254). (CONF-135)
15. A problem observation in the functional status section **SHALL** contain exactly one status of functional status observation (CONF-136)
16. A result observation in the functional status section **SHALL** contain exactly one status of functional status observation. (CONF-137)

Functional Status 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">
  <id root="MDHT" extension="415630315"/>
  <title>TEXT FOR TITLE</title>
  <text/>
</section>
```

History Of Past Illness Section

[Section: templateId `2.16.840.1.113883.3.88.11.83.104`]

The History of Past Illness Section contains data about problems the patient suffered in the past.

1. **SHALL** contain exactly one [1..1] templateId ( ) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.3.88.11.83.104"
2. **SHALL** conform to IHE History Of Past Illness Section template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.3.8`)
3. **SHALL** conform to CDT Past Medical History Section template (templateId: `2.16.840.1.113883.10.20.2.9`)
4. **SHALL** contain exactly one [1..1] **`entry`**
   a. Contains exactly one [1..1] Condition (templateId: `2.16.840.1.113883.3.88.11.83.7`)

1. **SHALL** conform to CDT Past Medical History Section template (templateId: `2.16.840.1.113883.10.20.2.9`)
2. **SHALL** conform to IHE History Of Past Illness Section template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.3.8`)
3. **SHALL** contain exactly one [1..1] **`code/@code`**="`11348-0`" *HISTORY OF PAST ILLNESS* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`)
4. **SHALL** contain exactly one [1..1] **`entry`**
   a. Contains exactly one [1..1] Condition (templateId: `2.16.840.1.113883.3.88.11.83.7`)
5. **SHOULD** satisfy: Contains clinical statements.

History Of Past Illness 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">
  <id root="MDHT" extension="595491630"/>
  <title>TEXT FOR TITLE</title>
```

```
  <text/>
  <entry>
    <act>
      <id root="MDHT" extension="44563498"/>
      <code code="65020950"/>
      <text>Text Value</text>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <entryRelationship>
        <observation/>
      </entryRelationship>
    </act>
  </entry>
</section>
```

History Of Present Illness

[Section: templateId 2.16.840.1.113883.3.88.11.83.107]

The History of Present Illness Section contains information about the sequence of events preceding the patient's current complaints.

1. **SHALL** contain exactly one [1..1] templateId ( ) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.3.88.11.83.107"
2. **SHALL** conform to IHE History Of Present Illness template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.4)

1. **SHALL** conform to IHE History Of Present Illness template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.4)
2. **SHALL** contain exactly one [1..1] **code/@code**="10164-2" *HISTORY OF PRESENT ILLNESS* (CodeSystem: 2.16.840.1.113883.6.1 LOINC)

History Of Present Illness 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">
  <id root="MDHT" extension="2127762912"/>
  <title>TEXT FOR TITLE</title>
</section>
```

Hospital Admission Diagnosis Section

[Section: templateId 2.16.840.1.113883.3.88.11.83.110]

The Hospital Admitting Diagnosis Section contains information about the primary reason for admission to a hospital facility.

1. **SHALL** contain exactly one [1..1] templateId ( ) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.3.88.11.83.110"
2. **SHALL** conform to IHE Hospital Admission Diagnosis Section template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.3)
3. **SHALL** contain exactly one [1..1] **entry**
   a. Contains exactly one [1..1] Condition (templateId: 2.16.840.1.113883.3.88.11.83.7)

1. **SHALL** conform to IHE Hospital Admission Diagnosis Section template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.3.3`)
2. **SHALL** contain exactly one [1..1] **`code/@code`**="`46241-6`" *HOSPITAL ADMISSION DX* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`)
3. **SHALL** contain exactly one [1..1] **`entry`**
   a. Contains exactly one [1..1] Condition (templateId: `2.16.840.1.113883.3.88.11.83.7`)

Hospital Admission Diagnosis 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">
  <id root="MDHT" extension="2003744300"/>
  <title>TEXT FOR TITLE</title>
  <entry>
    <act>
      <id root="MDHT" extension="622466745"/>
      <code code="824151355"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <entryRelationship>
        <observation/>
      </entryRelationship>
    </act>
  </entry>
</section>
```

Hospital Course Section

[Section: templateId `2.16.840.1.113883.3.88.11.83.121`]

The Hospital Course Section contains information about of the sequence of events from admission to discharge in a hospital facility.

1. **SHALL** contain exactly one [1..1] templateId ( ) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.3.88.11.83.121"
2. **SHALL** conform to IHE Hospital Course Section template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.3.5`)

1. **SHALL** conform to IHE Hospital Course Section template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.3.5`)
2. **SHALL** contain exactly one [1..1] **`code/@code`**="`8648-8`" *HOSPITAL COURSE* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`)

Hospital Course 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">
  <id root="MDHT" extension="1274730371"/>
  <title>TEXT FOR TITLE</title>
</section>
```

Hospital Discharge Medications Section

[Section: templateId 2.16.840.1.113883.3.88.11.83.114]

The Hospital Discharge Medications Section contains information about the relevant medications of the medications ordered for the patient for use after discharge from the hospital.

1. **SHALL** contain exactly one [1..1] templateId ( ) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.3.88.11.83.114"
2. **SHALL** conform to IHE Hospital Discharge Medications Section template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.22)
3. **SHALL** contain exactly one [1..1] **entry**
   a. Contains exactly one [1..1] Medication (templateId: 2.16.840.1.113883.3.88.11.83.8)

1. **SHALL** conform to IHE Hospital Discharge Medications Section template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.22)
2. **SHALL** contain exactly one [1..1] **code/@code**="10183-2" *HOSPITAL DISCHARGE MEDICATIONS* (CodeSystem: 2.16.840.1.113883.6.1 LOINC)
3. **SHALL** contain exactly one [1..1] **entry**
   a. Contains exactly one [1..1] Medication (templateId: 2.16.840.1.113883.3.88.11.83.8)

Hospital Discharge Medications 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">
  <id root="MDHT" extension="1529424038"/>
  <title>TEXT FOR TITLE</title>
  <entry>
    <substanceAdministration>
      <id root="MDHT" extension="1199336110"/>
      <effectiveTime xsi:type="IVL_TS">
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <consumable/>
      <entryRelationship>
        <observation>
          <id root="MDHT" extension="1254156196"/>
          <code code="1610886864"/>
          <effectiveTime>
            <low value="2012"/>
            <high value="2012"/>
          </effectiveTime>
        </observation>
      </entryRelationship>
      <entryRelationship>
        <supply>
          <id root="MDHT" extension="1478938526"/>
          <effectiveTime value="20121102"/>
        </supply>
      </entryRelationship>
      <entryRelationship>
        <observation/>
      </entryRelationship>
    </substanceAdministration>
  </entry>
</section>
```

Immunizations Section

[Section: templateId 2.16.840.1.113883.3.88.11.83.117]

The Immunizations Section contains information describing the immunizations administered to the patient.

1. **SHALL** contain exactly one [1..1] templateId ( ) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.3.88.11.83.117"
2. **SHALL** conform to IHE Immunizations Section template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.23)
3. **SHALL** contain at least one [1..*] **entry**
   a. Contains exactly one [1..1] Immunization (templateId: 2.16.840.1.113883.3.88.11.83.13)

1. **SHALL** conform to CCD Immunizations Section template (templateId: 2.16.840.1.113883.10.20.1.6)
2. **SHALL** conform to IHE Immunizations Section template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.23)
3. **SHALL** contain exactly one [1..1] **code/@code**="11369-6" *History of immunizations* (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF-377, CONF-378)
4. **SHALL** contain exactly one [1..1] **title** (CONF-379)
5. **SHALL** contain exactly one [1..1] **text** (CONF-376)
6. **SHOULD** contain zero or more [0..*] **entry** (CONF-298)
   a. Contains exactly one [1..1] Supply Activity (templateId: 2.16.840.1.113883.10.20.1.34)
7. **SHALL** contain at least one [1..*] **entry**
   a. Contains exactly one [1..1] Immunization (templateId: 2.16.840.1.113883.3.88.11.83.13)
8. **SHOULD** satisfy: Contains a case-insensitive language-insensitive string containing 'immunization'. (CONF-380)
9. **SHOULD** satisfy: Clinical statements include one or more Medication Activity and/or one or more Supply Activity.
10. **SHALL** satisfy: The absence of known medications is explicitly asserted.

Immunizations 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">
  <id root="MDHT" extension="1546861158"/>
  <title>TEXT FOR TITLE</title>
  <text/>
  <entry>
    <substanceAdministration>
      <id root="MDHT" extension="929183764"/>
      <text>Text Value</text>
      <effectiveTime value="20121102"/>
      <consumable/>
    </substanceAdministration>
  </entry>
</section>
```

Medical Equipment Section

[Section: templateId 2.16.840.1.113883.3.88.11.83.128]

The Medical Equipment section contains information describing a patient's implanted and external medical devices and equipment that their health status depends on, as well as any pertinent equipment or device history.

1. **SHALL** contain exactly one [1..1] templateId ( ) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.3.88.11.83.128"
2. **SHALL** conform to IHE Medical Devices Section template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.5.3.5)

1. **SHALL** conform to CCD Medical Equipment Section template (templateId: 2.16.840.1.113883.10.20.1.7)
2. **SHALL** conform to IHE Medical Devices Section template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.5.3.5)
3. **SHALL** contain exactly one [1..1] **code/@code**="46264-8" *History of medical device use* (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF-372, CONF-373)
4. **SHALL** contain exactly one [1..1] **title** (CONF-374)
5. **SHALL** contain exactly one [1..1] **text**
6. **SHOULD** contain zero or more [0..*] **entry**
   a. Contains exactly one [1..1] Supply Activity (templateId: 2.16.840.1.113883.10.20.1.34)
7. **MAY** contain zero or more [0..*] **entry**
   a. Contains exactly one [1..1] Medication Activity (templateId: 2.16.840.1.113883.10.20.1.24)
8. **SHOULD** satisfy: Contains a a case-insensitive language-insensitive text string containing 'equipment' (CONF-375)

Medical Equipment 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">
  <id root="MDHT" extension="2131495651"/>
  <title>TEXT FOR TITLE</title>
  <text/>
</section>
```

Medications Administered Section

[Section: templateId 2.16.840.1.113883.3.88.11.83.115]

The Medications Administered Section contains information about the relevant medications administered to a patient during the course of an encounter.

1. **SHALL** contain exactly one [1..1] templateId ( ) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.3.88.11.83.115"
2. **SHALL** conform to IHE Medications Administered Section template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.21)

1. **SHALL** conform to IHE Medications Administered Section template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.21)
2. **SHALL** contain exactly one [1..1] **code/@code**="18610-6" *MEDICATION ADMINISTERED* (CodeSystem: 2.16.840.1.113883.6.1 LOINC)

Medications Administered 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">
  <id root="MDHT" extension="5741405"/>
  <title>TEXT FOR TITLE</title>
```

```
</section>
```

Medications Section

[Section: templateId 2.16.840.1.113883.3.88.11.83.112]

The Medications Section contains information about the relevant medications for the patient. At a minimum, the currently active medications should be listed.

1. **SHALL** contain exactly one [1..1] templateId ( ) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.3.88.11.83.112"
2. **SHALL** conform to IHE Medications Section template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.19) (C83-[CT-112-1])
3. **SHALL** contain at least one [1..*] **entry** (C83-[CT-112-2])
   a. Contains exactly one [1..1] Medication (templateId: 2.16.840.1.113883.3.88.11.83.8)
1. **SHALL** conform to CCD Medications Section template (templateId: 2.16.840.1.113883.10.20.1.8)
2. **SHALL** conform to IHE Medications Section template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.19)
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-300, CONF-301)
4. **SHALL** contain exactly one [1..1] **title** (CONF-302)
5. **SHALL** contain zero or one [0..1] **text** (CONF-298)
6. **SHOULD** contain zero or more [0..*] **entry** (CONF-298)
   a. Contains exactly one [1..1] Supply Activity (templateId: 2.16.840.1.113883.10.20.1.34)
7. **SHALL** contain at least one [1..*] **entry** (C83-[CT-112-2])
   a. Contains exactly one [1..1] Medication (templateId: 2.16.840.1.113883.3.88.11.83.8)
8. **SHOULD** satisfy: Clinical statements include one or more Medication Activity and/or one or more Supply Activity. (CONF-298)
9. **SHALL** satisfy: The absence of known medications is explicitly asserted. (CONF-299)
10. **SHOULD** satisfy: Valued with a case-insensitive language-insensitive string containing 'medication'. (CONF-303)
11. **SHALL** satisfy: Contains one dosing template to identify this as a particular type of medication event. Possible dosing templates: 1.3.6.1.4.1.19376.1.5.3.1.4.7.1 Normal Dosing, 1.3.6.1.4.1.19376.1.5.3.1.4.8, Tapered Dosing, 1.3.6.1.4.1.19376.1.5.3.1.4.9 Split Dosing, 1.3.6.1.4.1.19376.1.5.3.1.4.10 Conditional Dosing, 1.3.6.1.4.1.19376.1.5.3.1.4.11 Combination Dosing.
12. **MAY** satisfy: contains one or more related components (<entryRelationship typeCode='COMP'>, either to handle split, tapered or conditional dosing, or to support combination medications.

Medications 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">
  <id root="MDHT" extension="1123459083"/>
  <title>TEXT FOR TITLE</title>
  <text/>
  <entry>
    <substanceAdministration>
      <id root="MDHT" extension="1190684515"/>
      <text>Text Value</text>
      <effectiveTime xsi:type="IVL_TS">
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <consumable/>
```

```
      <entryRelationship>
        <observation>
          <id root="MDHT" extension="1872877729"/>
          <code code="531440419"/>
          <text>Text Value</text>
          <effectiveTime>
            <low value="2012"/>
            <high value="2012"/>
          </effectiveTime>
        </observation>
      </entryRelationship>
      <entryRelationship>
        <supply>
          <id root="MDHT" extension="1361235024"/>
          <text>Text Value</text>
          <effectiveTime value="20121102"/>
        </supply>
      </entryRelationship>
      <entryRelationship>
        <observation/>
      </entryRelationship>
    </substanceAdministration>
  </entry>
</section>
```

Payers Section

[Section: templateId 2.16.840.1.113883.3.88.11.83.101]

The Payers Section contains data on the patient's payers, whether a 'third party' insurance, self-pay, other payer or guarantor, or some combination. At a minimum, the patient's pertinent current payment sources should be listed. If no payment sources are supplied, the reason shall be supplied as free text in the narrative block (e.g., Not Insured, Payer Unknown, Medicare Pending, et cetera).

1. **SHALL** contain exactly one [1..1] templateId (C83-[CT-101-1]) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.3.88.11.83.101"
2. **SHALL** conform to IHE Payers Section template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.5.3.7)
3. **SHALL** contain at least one [1..*] **entry** (C83-[CT-101-2])
   a. Contains exactly one [1..1] Insurance Provider (templateId: 2.16.840.1.113883.3.88.11.83.5)

1. **SHALL** conform to CCD Payers Section template (templateId: 2.16.840.1.113883.10.20.1.9)
2. **SHALL** conform to IHE Payers Section template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.5.3.7)
3. **SHALL** contain exactly one [1..1] **code/@code**="48768-6" *Payment sources* (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF-31, CONF-32)
4. **SHALL** contain exactly one [1..1] **title** (CONF-33)
5. **SHALL** contain exactly one [1..1] **text** (CONF-30)
6. **SHALL** contain at least one [1..*] **entry** (C83-[CT-101-2])
   a. Contains exactly one [1..1] Insurance Provider (templateId: 2.16.840.1.113883.3.88.11.83.5)
7. **SHOULD** satisfy: Contains a case-insensitive language-insensitive string containing 'insurance' or 'payers'. (CONF-34)

Payers 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">
  <id root="MDHT" extension="1500479924"/>
```

```
  <title>TEXT FOR TITLE</title>
  <text/>
  <entry>
    <act>
      <id root="MDHT" extension="276823535"/>
      <code code="458564697"/>
      <text>Text Value</text>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
    </act>
  </entry>
</section>
```

Physical Exam Section

[Section: templateId 2.16.840.1.113883.3.88.11.83.118]

The Physical Examination Section contains information describing the physical findings.

1. **SHALL** contain exactly one [1..1] templateId ( ) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.3.88.11.83.118"
2. **SHALL** conform to IHE Physical Exam Section template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.9.15)
3. **SHALL** conform to CDT Physical Examination Section template (templateId: 2.16.840.1.113883.10.20.2.10)
4. **SHALL** contain at least one [1..*] **entry**
   a. Contains exactly one [1..1] Condition (templateId: 2.16.840.1.113883.3.88.11.83.7)
5. **SHOULD** satisfy: Restrict the Condition Type (code) as FINDING (404684003)or FUNCTIONAL LIMITATION (248536006) from the SNOMED CT Code System

1. **SHALL** conform to CDT Physical Examination Section template (templateId: 2.16.840.1.113883.10.20.2.10)
2. **SHALL** conform to IHE Physical Exam Narrative Section template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.24)
3. **SHALL** conform to IHE Physical Exam Section template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.9.15)
4. **SHALL** contain exactly one [1..1] **code/@code**="29545-1" *PHYSICAL EXAMINATION* (CodeSystem: 2.16.840.1.113883.6.1 LOINC)
5. **MAY** contain zero or one [0..1] **component**
   a. Contains exactly one [1..1] Vital Signs Section (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.25)
6. **MAY** contain zero or one [0..1] **component**
   a. Contains exactly one [1..1] General Appearance Section (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.9.16)
7. **MAY** contain zero or one [0..1] **component**
   a. Contains exactly one [1..1] Visible Implanted Medical Devices Section (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.9.48)
8. **MAY** contain zero or one [0..1] **component**
   a. Contains exactly one [1..1] Integumentary System Section (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.9.17)
9. **MAY** contain zero or one [0..1] **component**
   a. Contains exactly one [1..1] Head Section (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.9.18)

10. **MAY** contain zero or one [0..1] **component**
    a. Contains exactly one [1..1] Eyes Section (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.9.19)
11. **MAY** contain zero or one [0..1] **component**
    a. Contains exactly one [1..1] Ears Nose Mouth Throat Section (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.9.20)
12. **MAY** contain zero or one [0..1] **component**
    a. Contains exactly one [1..1] Ears Section (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.9.21)
13. **MAY** contain zero or one [0..1] **component**
    a. Contains exactly one [1..1] Nose Section (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.9.22)
14. **MAY** contain zero or one [0..1] **component**
    a. Contains exactly one [1..1] Mouth Throat Teeth Section (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.9.23)
15. **MAY** contain zero or one [0..1] **component**
    a. Contains exactly one [1..1] Neck Section (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.9.24)
16. **MAY** contain zero or one [0..1] **component**
    a. Contains exactly one [1..1] Endocrine System Section (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.9.25)
17. **MAY** contain zero or one [0..1] **component**
    a. Contains exactly one [1..1] Thorax Lungs Section (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.9.26)
18. **MAY** contain zero or one [0..1] **component**
    a. Contains exactly one [1..1] Chest Wall Section (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.9.27)
19. **MAY** contain zero or one [0..1] **component**
    a. Contains exactly one [1..1] Breast Section (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.9.28)
20. **MAY** contain zero or one [0..1] **component**
    a. Contains exactly one [1..1] Heart Section (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.9.29)
21. **MAY** contain zero or one [0..1] **component**
    a. Contains exactly one [1..1] Respiratory System Section (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.9.30)
22. **MAY** contain zero or one [0..1] **component**
    a. Contains exactly one [1..1] Abdomen Section (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.9.31)
23. **MAY** contain zero or one [0..1] **component**
    a. Contains exactly one [1..1] Lymphatic Section (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.9.32)
24. **MAY** contain zero or one [0..1] **component**
    a. Contains exactly one [1..1] Vessels Section (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.9.33)
25. **MAY** contain zero or one [0..1] **component**
    a. Contains exactly one [1..1] Musculoskeletal System Section (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.9.34)
26. **MAY** contain zero or one [0..1] **component**
    a. Contains exactly one [1..1] Neurologic System Section (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.9.35)
27. **MAY** contain zero or one [0..1] **component**
    a. Contains exactly one [1..1] Genitalia Section (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.9.36)

28. **MAY** contain zero or one [0..1] **component**
    a. Contains exactly one [1..1] Rectum Section (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.9.37)
29. **MAY** contain zero or one [0..1] **component**
    a. Contains exactly one [1..1] Extremities Section (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.16.2.1)
30. **SHALL** contain at least one [1..*] **entry**
    a. Contains exactly one [1..1] Condition (templateId: 2.16.840.1.113883.3.88.11.83.7)
31. **SHOULD** satisfy: Restrict the Condition Type (code) as FINDING (404684003)or FUNCTIONAL LIMITATION (248536006) from the SNOMED CT Code System

Physical Exam 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">
  <id root="MDHT" extension="940844493"/>
  <title>TEXT FOR TITLE</title>
  <entry>
    <act>
      <id root="MDHT" extension="891130555"/>
      <code code="1343691164"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <entryRelationship>
        <observation/>
      </entryRelationship>
    </act>
  </entry>
</section>
```

Plan Of Care Section

[Section: templateId 2.16.840.1.113883.3.88.11.83.124]

The Plan of Care Section contains information about the expectations for care to be provided including proposed interventions and goals for improving the condition of the patient.

A plan of care section varies from the assessment and plan section defined above in that it does not include a physician assessment of the patient condition.

1. **SHALL** contain exactly one [1..1] templateId ( ) such that it
    a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.3.88.11.83.124"
2. **SHALL** conform to IHE Care Plan Section template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.31)
3. **SHALL** conform to CDT Assessment And Plan Section template (templateId: 2.16.840.1.113883.10.20.2.7)
4. **MAY** contain zero or one [0..1] **entry**
    a. Contains exactly one [1..1] Medication (templateId: 2.16.840.1.113883.3.88.11.83.8)
5. **MAY** contain zero or one [0..1] **entry**
    a. Contains exactly one [1..1] Immunization (templateId: 2.16.840.1.113883.3.88.11.83.13)
6. **MAY** contain zero or one [0..1] **entry**
    a. Contains exactly one [1..1] Encounter (templateId: 2.16.840.1.113883.3.88.11.83.16)

7. **MAY** contain zero or one [0..1] **entry**
   a. Contains exactly one [1..1] Procedure (templateId: 2.16.840.1.113883.3.88.11.83.17)

1. **SHALL** conform to CDT Assessment And Plan Section template (templateId: 2.16.840.1.113883.10.20.2.7)
2. **SHALL** conform to CCD Plan Of Care Section template (templateId: 2.16.840.1.113883.10.20.1.10)
3. **SHALL** conform to IHE Care Plan Section template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.31)
4. **SHALL** contain exactly one [1..1] **code/@code**="18776-5" *Treatment plan* (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF-481, CONF-482)
5. **SHALL** contain exactly one [1..1] **title** (CONF-483)
6. **SHALL** contain exactly one [1..1] **text** (CONF-480)
7. **MAY** contain zero or one [0..1] **entry**
   a. Contains exactly one [1..1] Plan Of Care Activity Act (templateId: 2.16.840.1.113883.10.20.1.25)
8. **MAY** contain zero or one [0..1] **entry**
   a. Contains exactly one [1..1] Plan Of Care Activity Encounter (templateId: 2.16.840.1.113883.10.20.1.25)
9. **MAY** contain zero or one [0..1] **entry**
   a. Contains exactly one [1..1] Plan Of Care Activity Observation (templateId: 2.16.840.1.113883.10.20.1.25)
10. **MAY** contain zero or one [0..1] **entry**
    a. Contains exactly one [1..1] Plan Of Care Activity Procedure (templateId: 2.16.840.1.113883.10.20.1.25)
11. **MAY** contain zero or one [0..1] **entry**
    a. Contains exactly one [1..1] Plan Of Care Activity Substance Administration (templateId: 2.16.840.1.113883.10.20.1.25)
12. **MAY** contain zero or one [0..1] **entry**
    a. Contains exactly one [1..1] Plan Of Care Activity Supply (templateId: 2.16.840.1.113883.10.20.1.25)
13. **MAY** contain zero or one [0..1] **entry**
    a. Contains exactly one [1..1] Medication (templateId: 2.16.840.1.113883.3.88.11.83.8)
14. **MAY** contain zero or one [0..1] **entry**
    a. Contains exactly one [1..1] Immunization (templateId: 2.16.840.1.113883.3.88.11.83.13)
15. **MAY** contain zero or one [0..1] **entry**
    a. Contains exactly one [1..1] Encounter (templateId: 2.16.840.1.113883.3.88.11.83.16)
16. **MAY** contain zero or one [0..1] **entry**
    a. Contains exactly one [1..1] Procedure (templateId: 2.16.840.1.113883.3.88.11.83.17)
17. **SHOULD** contain a case-insensitive language-insensitive text string containing 'plan'. (CONF-484)

Plan Of Care 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">
  <id root="MDHT" extension="481065049"/>
  <title>TEXT FOR TITLE</title>
  <text/>
  <entry>
    <substanceAdministration>
      <id root="MDHT" extension="347886061"/>
      <text>Text Value</text>
```

```
      <effectiveTime xsi:type="IVL_TS">
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <consumable/>
      <entryRelationship>
        <observation>
          <id root="MDHT" extension="416364787"/>
          <code code="1251983467"/>
          <text>Text Value</text>
          <effectiveTime>
            <low value="2012"/>
            <high value="2012"/>
          </effectiveTime>
        </observation>
      </entryRelationship>
      <entryRelationship>
        <supply>
          <id root="MDHT" extension="1619239831"/>
          <text>Text Value</text>
          <effectiveTime value="20121102"/>
        </supply>
      </entryRelationship>
      <entryRelationship>
        <observation/>
      </entryRelationship>
    </substanceAdministration>
  </entry>
  <entry>
    <substanceAdministration>
      <id root="MDHT" extension="1874983973"/>
      <text>Text Value</text>
      <effectiveTime value="20121102"/>
      <consumable/>
    </substanceAdministration>
  </entry>
  <entry>
    <encounter>
      <id root="MDHT" extension="2011412284"/>
      <text>Text Value</text>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
    </encounter>
  </entry>
</section>
```

Problem List Section

[Section: templateId 2.16.840.1.113883.3.88.11.83.103]

This section lists and describes all relevant clinical problems at the time the document is generated. At a minimum, all pertinent current and historical problems should be listed.

1. **SHALL** contain exactly one [1..1] templateId ( ) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.3.88.11.83.103"
2. **SHALL** conform to IHE Active Problems Section template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.6) (C83-[CT-103-2])

3. **SHALL** contain at least one [1..*] **entry** (C83-[CT-103-1])
   a. Contains exactly one [1..1] Condition (templateId: 2.16.840.1.113883.3.88.11.83.7)

1. **SHALL** conform to CCD Problem Section template (templateId: 2.16.840.1.113883.10.20.1.11)
2. **SHALL** conform to IHE Active Problems Section template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.6)
3. **SHALL** contain exactly one [1..1] **code/@code**="11450-4" *Problem list* (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF-141, CONF-142)
4. **SHALL** contain exactly one [1..1] **title** (CONF-143)
5. **SHALL** contain exactly one [1..1] **text** (CONF-140)
6. **SHOULD** contain at least one [1..*] **entry** (CONF-140)
   a. Contains exactly one [1..1] Problem Act (templateId: 2.16.840.1.113883.10.20.1.27)
7. **SHALL** contain at least one [1..*] **entry** (C83-[CT-103-1])
   a. Contains exactly one [1..1] Condition (templateId: 2.16.840.1.113883.3.88.11.83.7)
8. **SHOULD** contain a case-insensitive language-insensitive string containing 'problems'. (CONF-144)

Problem 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">
  <id root="MDHT" extension="1713445272"/>
  <title>TEXT FOR TITLE</title>
  <text/>
  <entry>
    <act>
      <id root="MDHT" extension="417157864"/>
      <code code="1537393332"/>
      <text>Text Value</text>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <entryRelationship>
        <observation/>
      </entryRelationship>
    </act>
  </entry>
</section>
```

Reason For Referral Section

[Section: templateId 2.16.840.1.113883.3.88.11.83.106]

The Reason for Referral Section contains information about the reason that the patient is being referred.

1. **SHALL** contain exactly one [1..1] templateId ( ) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.3.88.11.83.106"
2. **SHALL** conform to IHE Coded Reason For Referral Section template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.2)
3. **SHALL** conform to CDT Reason For Referral Section template (templateId: 2.16.840.1.113883.10.20.4.8)
4. **MAY** contain zero or more [0..*] **entry**
   a. Contains exactly one [1..1] Condition (templateId: 2.16.840.1.113883.3.88.11.83.7)

5. **MAY** contain zero or more [0..*] **entry**
   a. Contains exactly one [1..1] Result (templateId: 2.16.840.1.113883.3.88.11.83.15.1)

1. **SHALL** conform to CDT Reason For Referral Section template (templateId: 2.16.840.1.113883.10.20.4.8)
2. **SHALL** conform to IHE Reason For Referral Section template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.1)
3. **SHALL** conform to IHE Coded Reason For Referral Section template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.2)
4. **SHALL** contain exactly one [1..1] **code/@code**="42349-1" *REASON FOR REFERRAL* (CodeSystem: 2.16.840.1.113883.6.1 LOINC)
5. **SHALL** contain at least one [1..*] **entry**
   a. Contains exactly one [1..1] Problem Entry (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.5)
6. **MAY** contain zero or more [0..*] **entry**
   a. Contains exactly one [1..1] Condition (templateId: 2.16.840.1.113883.3.88.11.83.7)
7. **MAY** contain zero or more [0..*] **entry**
   a. Contains exactly one [1..1] Result (templateId: 2.16.840.1.113883.3.88.11.83.15.1)

Reason For Referral 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">
  <id root="MDHT" extension="88551914"/>
  <title>TEXT FOR TITLE</title>
  <entry>
    <act>
      <id root="MDHT" extension="607446841"/>
      <code code="332878427"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
      <entryRelationship>
        <observation/>
      </entryRelationship>
    </act>
  </entry>
  <entry>
    <observation>
      <id root="MDHT" extension="1137644475"/>
      <code code="1237655473"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
    </observation>
  </entry>
</section>
```

Review Of Systems Section

[Section: templateId 2.16.840.1.113883.3.88.11.83.120]

The Review of Systems Section contains information describing patient responses to questions about the function of various body systems.

1. **SHALL** contain exactly one [1..1] templateId ( ) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.3.88.11.83.120"
2. **SHALL** conform to IHE Review Of Systems Section template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.18)
3. **SHALL** conform to CDT Review Of Systems Section template (templateId: 2.16.840.1.113883.10.20.4.10)

1. **SHALL** conform to CDT Review Of Systems Section template (templateId: 2.16.840.1.113883.10.20.4.10)
2. **SHALL** conform to IHE Review Of Systems Section template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.18)
3. **SHALL** contain exactly one [1..1] **code/@code**="10187-3" *REVIEW OF SYSTEMS* (CodeSystem: 2.16.840.1.113883.6.1 LOINC)

Review Of Systems 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">
  <id root="MDHT" extension="1489176335"/>
  <title>TEXT FOR TITLE</title>
</section>
```

Social History Section

[Section: templateId 2.16.840.1.113883.3.88.11.83.126]

The Social History Section contains information about the person's beliefs, home life, community life, work life, hobbies, and risky habits.

1. **SHALL** contain exactly one [1..1] templateId ( ) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.3.88.11.83.126"
2. **SHALL** conform to IHE Social History Section template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.16)
3. **MAY** contain zero or more [0..*] **entry**
   a. Contains exactly one [1..1] Social History (templateId: 2.16.840.1.113883.3.88.11.83.19)

1. **SHALL** conform to CCD Social History Section template (templateId: 2.16.840.1.113883.10.20.1.15)
2. **SHALL** conform to IHE Social History Section template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.16)
3. **SHALL** contain exactly one [1..1] **code/@code**="29762-2" *Social history* (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF-233, CONF-234)
4. **SHALL** contain exactly one [1..1] **title** (CONF-235)
5. **SHALL** contain exactly one [1..1] **text**
6. **SHOULD** contain zero or more [0..*] **entry**
   a. Contains exactly one [1..1] Social History Observation (templateId: 2.16.840.1.113883.10.20.1.33)
7. **MAY** contain zero or more [0..*] **entry**
   a. Contains exactly one [1..1] Social History (templateId: 2.16.840.1.113883.3.88.11.83.19)
8. **SHOULD** satisfy: Contains a case-insensitive language-insensitive string containing 'social history'. (CONF-236)
9. Marital status **SHOULD** be represented as ClinicalDocument / recordTarget / patientRole / patient / maritalStatusCode. Additional information **MAY** be represented as social history observations (CONF-250)
10. Religious affiliation **SHOULD** be represented as ClinicalDocument / recordTarget / patientRole / patient / religiousAffiliationCode. Additional information **MAY** be represented as social history observations (CONF-251)

11. A patients race **SHOULD** be represented as ClinicalDocument / recordTarget / patientRole / patient / raceCode. Additional information **MAY** be represented as social history observations (CONF-252)
12. The value for ClinicalDocument / recordTarget / patientRole / patient / raceCode **MAY** be selected from codeSystem 2.16.840.1.113883.5.104 (Race) (CONF-253)
13. A patients ethnicity **SHOULD** be represented as ClinicalDocument / recordTarget / patientRole / patient / ethnicGroupCode. Additional information **MAY** be represented as social history observations. (CONF-254)
14. The value for ClinicalDocument / recordTarget / patientRole / patient / ethnicGroupCode **MAY** be selected from codeSystem 2.16.840.1.113883.5.50 (Ethnicity). (CONF-255)

Social History 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">
  <id root="MDHT" extension="1863621886"/>
  <title>TEXT FOR TITLE</title>
  <text/>
  <entry>
    <observation>
      <id root="MDHT" extension="1950806069"/>
      <code code="974822208"/>
      <text>Text Value</text>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
    </observation>
  </entry>
</section>
```

Surgeries Section

[Section: templateId 2.16.840.1.113883.3.88.11.83.108]

1. **SHALL** contain exactly one [1..1] templateId ( ) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.3.88.11.83.108"
2. **SHALL** conform to IHE Coded Surgeries Section template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.12) (C83-[CT-108-1])
3. **SHALL** contain at least one [1..*] **entry** (C83-[CT-108-2])
   a. Contains exactly one [1..1] Procedure (templateId: 2.16.840.1.113883.3.88.11.83.17)

1. **SHALL** conform to CCD Procedures Section template (templateId: 2.16.840.1.113883.10.20.1.12)
2. **SHALL** conform to IHE Surgeries Section template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.11)
3. **SHALL** conform to IHE Coded Surgeries Section template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.12)
4. **SHALL** contain exactly one [1..1] **code/@code**="47519-4" *History of procedures* (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF-423, CONF-424)
5. **SHALL** contain exactly one [1..1] **title** (CONF-425)
6. **SHALL** contain exactly one [1..1] **text** (CONF-422)
7. **SHOULD** contain zero or one [0..1] **entry**
   a. Contains exactly one [1..1] External Reference (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.4)
8. **SHALL** contain at least one [1..*] **entry**
   a. Contains exactly one [1..1] Procedure Entry Procedure Activity Procedure (templateId: 2.16.840.1.113883.10.20.1.29)

9. **SHALL** contain at least one [1..*] **entry** (C83-[CT-108-2])
    a. Contains exactly one [1..1] Procedure (templateId: 2.16.840.1.113883.3.88.11.83.17)
10. **SHOULD** satisfy: title is valued with a case-insensitive language-insensitive text string containing "procedures". (CONF-426)
11. **SHOULD** satisfy: include one or more of the following: ProcedureActivityAct, ProcedureActivityObservation, ProcedureActivityProcedure (CONF-419)

Surgeries 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">
  <id root="MDHT" extension="64890465"/>
  <title>TEXT FOR TITLE</title>
  <text/>
</section>
```

Vital Signs Section

[Section: templateId 2.16.840.1.113883.3.88.11.83.119]

The Vital Signs Section contains information documenting the patient vital signs.

1. **SHALL** contain exactly one [1..1] templateId ( ) such that it
    a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.3.88.11.83.119"
2. **SHALL** conform to IHE Coded Vital Signs Section template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.5.3.2) (C83-[CT-119-1])
3. **SHALL** satisfy: Contains entries conforming to the Vital Sign module. (C83-[CT-119-2])

1. **SHALL** conform to CCD Vital Signs Section template (templateId: 2.16.840.1.113883.10.20.1.16)
2. **SHALL** conform to IHE Vital Signs Section template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.25)
3. **SHALL** conform to IHE Coded Vital Signs Section template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.5.3.2)
4. **SHALL** contain exactly one [1..1] **code/@code**="8716-3" *Vital signs* (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF-382, CONF-383)
5. **SHALL** contain exactly one [1..1] **title** (CONF-384)
6. **SHALL** contain exactly one [1..1] **text** (CONF-381)
7. **SHALL** contain at least one [1..*] **entry** (6.3.3.4.5)
    a. Contains exactly one [1..1] Vital Signs Organizer (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.13.1)
8. **SHOULD** satisfy: title Contains a case-insensitive language-insensitive string containing 'vital signs'. (CONF-385)
9. **SHALL** satisfy: Contains entries conforming to the Vital Sign module. (C83-[CT-119-2])

Vital Signs 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">
  <id root="MDHT" extension="1265409268"/>
  <title>TEXT FOR TITLE</title>
  <text/>
</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.

Advance Directive

Advance Directive example

Allergy Drug Sensitivity

[Act: templateId 2.16.840.1.113883.3.88.11.83.6]

This module contains the allergy or intolerance conditions and the associated adverse reactions suffered by the patient. See the HL7 Continuity of Care Document Section 3.8 for constraints applicable to this module.

1. **SHALL** contain exactly one [1..1] templateId (C83-[DE-6-CDA-1]) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.3.88.11.83.6"
2. **SHALL** conform to IHE Allergy Intolerance Concern template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.5.3) (C83-[DE-6-CDA-2])
3. **SHOULD** satisfy: the observation/effectiveTime element is present to record event date
4. **SHALL** satisfy: the observation/code element shall be present to record the adverse event type
5. **SHALL** satisfy: the code/@code attribute value is from Allergy/Adverse Event Type Value Set, 2.16.840.1.113883.3.88.12.3221.6.2, version: 20081218, Static (C154-[DE-6.02-1])
6. the observation/participant element **SHOULD** be present
7. **SHALL** satisfy: the participant/@typecode attribute shall be 'CSM'
8. **SHALL** satisfy: the participant/participantRole element may be present
9. **SHALL** satisfy: the participant/participantRole/@classcode attribute shall be 'MANU'
10. **SHALL** satisfy: The participant/participantRole/PlayingEntity element may be present
11. **SHALL** satisfy: the participant/participantRole/playingEntity/@classcode attribute shall be 'MMAT'
12. **SHALL** satisfy: the participant/participantRole/playingEntity/name element is present
13. **SHOULD** satisfy: participant/participantRole/playingEntity/code element is present
14. For participant/participantRole/playingEntity/code element, Food and substance allergies **SHALL** be coded as Ingredient Name Value Set, 2.16.840.1.113883.3.88.12.80.20, Dynamic (C154-[DE-6.04-1])
15. For participant/participantRole/playingEntity/code element, Allergies to a class of medication **SHALL** be coded as Medication Drug Class Value Set, 2.16.840.1.113883.3.88.12.80.17, version: 20081218, Dynamic (C154-[DE-6.04-2])
16. For participant/participantRole/playingEntity/code element, Allergies to a specific medication **SHALL** be coded with Medication Brand Name Value Set, 2.16.840.1.113883.3.88.12.80.16, version: 20081218, Dynamic (C154-[DE-6.04-3])
17. **SHOULD** satisfy: the text element is present in the Reaction Observation entry
18. **SHOULD** satisfy: the code element is present in the Reaction Observation entry
19. **SHALL** satisfy: the code element is coded as Problem Value Set, 2.16.840.1.113883.3.88.12.3221.7.4, version: 20100125, Dynamic (C154-[DE-6.06-1])
20. **SHOULD** satisfy: The text element is present in the Severity Observation template
21. **SHOULD** satisfy: the code element is present in the Severity Observation entry
22. **SHALL** satisfy: the code element is coded as Problem Severity Value Set, 2.16.840.1.113883.3.88.12.3221.6.8, version: 20081218, Static (C154-[DE-6.08-1])

1. **SHALL** conform to CCD Problem Act template (templateId: 2.16.840.1.113883.10.20.1.27)
2. **SHALL** conform to IHE Concern Entry template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.5.1)
3. **SHALL** conform to IHE Allergy Intolerance Concern template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.5.3)
4. **SHALL** contain exactly one [1..1] **@classCode**="ACT" *Act* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) (CONF-146)

5. **SHALL** contain exactly one [1..1] **`@moodCode`**=**`"EVN"`** *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF-147)
6. **SHALL** contain at least one [1..*] **`id`** (CONF-148)
7. **SHALL** contain exactly one [1..1] **`code`**/`@nullFlavor` = "NA" *NA (not applicable)* (CONF-149)
8. **SHALL** contain exactly one [1..1] **`statusCode`**, where the @code **SHALL** be selected from ValueSet `ConcernEntryStatus` **STATIC**
   - *The statusCode associated with any concern must be one of the following values:*

     ***active**: A concern that is still being tracked.*
     ***suspended**: A concern that is active, but which may be set aside. For example, this value might be used to suspend concern*
     about a patient problem after some period of remission, but before assumption that the concern has been resolved.
     ***aborted**: A concern that is no longer actively being tracked, but for reasons other than because the problem was resolved.*
     This value might be used to mark a concern as being aborted after a patient leaves care against medical advice.
     ***completed**:*
     The problem, allergy or medical state has been resolved and the concern no longer needs to be tracked except for
     historical purposes.
9. **SHALL** contain exactly one [1..1] **`effectiveTime`**
   - *The effectiveTime element records the starting and ending times during which the concern was active.*
10. **MAY** contain exactly one [1..1] **`entryRelationship`** (CONF-168)
    a. Contains exactly one [1..1] Episode Observation (templateId: `2.16.840.1.113883.10.20.1.41`)
11. **SHALL** contain at least one [1..*] **`entryRelationship`**
    a. Contains **`@typeCode="`**`SUBJ`**`"`** *SUBJ*
    b. Contains exactly one [1..1] Allergy Intolerance (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.6`)
12. **SHALL** contain one or more entryRelationship (CONF-151)
13. A problem act **MAY** reference a problem observation, alert observation (see section Alerts) or other clinical statement that is the subject of concern, by setting the value for "Act / entryRelationship / @typeCode" to be "SUBJ" 2.16.840.1.113883.5.1002 ActRelationshipType STATIC. (CONF-152)
14. The target of a problem act with Act / entryRelationship / @typeCode="SUBJ" **SHOULD** be a problem observation (in the Problem section) or alert observation (in the Alert section), but **MAY** be some other clinical statement. (CONF-153)
15. In Problem Section, a Problem Act **SHOULD** contain one or more Problem Observations. (CONF-140)
16. In Alert Section, a ProblemAct **SHOULD** contain one or more Alert Observations. (CONF-256)
17. **MAY** contain exactly one Patient Awareness (CONF-179)
18. The effectiveTime 'low' element **SHALL** be present. The 'high' element **SHALL** be present for concerns in the completed or aborted state, and **SHALL NOT** be present otherwise.
19. This entry **SHALL** contain one or more problem or allergy entries that conform to the specification in section Problem Entry or Allergies and Intolerances.
20. This **SHALL** be represented using entryRelationship with typeCode = 'SUBJ'
21. Each concern **MAY** have 0 or more related references. This **MAY** be any valid CDA clinical statement, and **SHOULD** be an IHE entry template.
22. Related References **SHALL** be represented using entryRelationship with typeCode = 'REFR'.
23. **SHOULD** satisfy: the observation/effectiveTime element is present to record event date
24. **SHALL** satisfy: the observation/code element shall be present to record the adverse event type
25. **SHALL** satisfy: the code/@code attribute value is from Allergy/Adverse Event Type Value Set, 2.16.840.1.113883.3.88.12.3221.6.2, version: 20081218, Static (C154-[DE-6.02-1])

26. the observation/participant element **SHOULD** be present
27. **SHALL** satisfy: the participant/@typecode attribute shall be 'CSM'
28. **SHALL** satisfy: the participant/participantRole element may be present
29. **SHALL** satisfy: the participant/participantRole/@classcode attribute shall be 'MANU'
30. **SHALL** satisfy: The participant/participantRole/PlayingEntity element may be present
31. **SHALL** satisfy: the participant/participantRole/playingEntity/@classcode attribute shall be 'MMAT'
32. **SHALL** satisfy: the participant/participantRole/playingEntity/name element is present
33. **SHOULD** satisfy: participant/participantRole/playingEntity/code element is present
34. For participant/participantRole/playingEntity/code element, Food and substance allergies **SHALL** be coded as Ingredient Name Value Set, 2.16.840.1.113883.3.88.12.80.20, Dynamic (C154-[DE-6.04-1])
35. For participant/participantRole/playingEntity/code element, Allergies to a class of medication **SHALL** be coded as Medication Drug Class Value Set, 2.16.840.1.113883.3.88.12.80.17, version: 20081218, Dynamic (C154-[DE-6.04-2])
36. For participant/participantRole/playingEntity/code element, Allergies to a specific medication **SHALL** be coded with Medication Brand Name Value Set, 2.16.840.1.113883.3.88.12.80.16, version: 20081218, Dynamic (C154-[DE-6.04-3])
37. **SHOULD** satisfy: the text element is present in the Reaction Observation entry
38. **SHOULD** satisfy: the code element is present in the Reaction Observation entry
39. **SHALL** satisfy: the code element is coded as Problem Value Set, 2.16.840.1.113883.3.88.12.3221.7.4, version: 20100125, Dynamic (C154-[DE-6.06-1])
40. **SHOULD** satisfy: The text element is present in the Severity Observation template
41. **SHOULD** satisfy: the code element is present in the Severity Observation entry
42. **SHALL** satisfy: the code element is coded as Problem Severity Value Set, 2.16.840.1.113883.3.88.12.3221.6.8, version: 20081218, Static (C154-[DE-6.08-1])

Allergy Drug Sensitivity 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">
  <id root="MDHT" extension="2015485090"/>
  <code code="1977326979"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
</act>
```

Comment

[Act: templateId `2.16.840.1.113883.3.88.11.83.11`]

This module contains a comment to be supplied for any other entry Content Modules.

1. **SHALL** contain exactly one [1..1] templateId (C83-[DE-10-CDA-2]) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.3.88.11.83.11"
2. **SHALL** conform to IHE Comment template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.2`) (C83-[DE-10-CDA-3])
3. **SHALL** contain exactly one [1..1] **`author`** (C83-[DE-10-CDA-4])
   - *The author of a comment is recorded as specified for authors in the Information Source module.*
   a. Contains exactly one [1..1] CDA Author
4. Data elements defined elsewhere in the specification **SHALL NOT** be recorded using the Comments Module. (C83-[DE-10-CDA-1])

1. **SHALL** conform to CCD Comment template (templateId: `2.16.840.1.113883.10.20.1.40`)
2. **SHALL** conform to IHE Comment template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.2`)
3. **SHALL** contain exactly one [1..1] **`@classCode`**`="ACT"` *Act* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF-504)
4. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF-505)
5. **SHALL** contain exactly one [1..1] **`code/@code`**`="48767-8"` *Annotation comment* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`) (CONF-506, CONF-507)
6. **SHALL** contain exactly one [1..1] **`text`**
7. **SHALL** contain exactly one [1..1] **`statusCode/@code`**`="completed"` (CodeSystem: `2.16.840.1.113883.5.14 ActStatus`) (CONF-6.3.4.6.8)
8. **MAY** contain zero or one [0..1] **`author`**
   a. Contains exactly one [1..1] CDA Author
9. **SHALL** contain exactly one [1..1] **`author`** (C83-[DE-10-CDA-4])
   a. Contains exactly one [1..1] CDA Author

   - *The author of a comment is recorded as specified for authors in the Information Source module.*
10. **SHALL** satisfy: A related statement is made about another section or entry. In CDA the former shall be recorded inside an <entryRelationship> element occurring at the end of the entry. The containing entry is the subject (typeCode='SUBJ') of this comment, which is the inverse of the normal containment structure, thus inversionInd='true'. (CONF-6.3.4.6.3)
11. **SHALL** satisfy: The 'text' element contains a 'reference' element pointing to the narrative text section of the CDA, rather than duplicate text to avoid ambiguity. (CONF-6.3.4.6.7)
12. **SHALL** satisfy: The time of the comment creation is recorded in the 'time' element when the 'author' element is present. (CONF-6.3.4.6.10)
13. **SHALL** satisfy: The identifier of the author, and their address and telephone number must be present inside the 'id', 'addr' and 'telecom' elements when the 'author' element is present. (CONF-6.3.4.6.11)
14. **SHALL** satisfy: The author's and/or the organization's name must be present when the 'author' element is present. (CONF-6.3.4.6.12)
15. Data elements defined elsewhere in the specification **SHALL NOT** be recorded using the Comments Module. (C83-[DE-10-CDA-1])

Comment 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">
  <id root="MDHT" extension="4378871"/>
  <code code="661141525"/>
  <text>Text Value</text>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <author/>
</act>
```

Condition

[Act: templateId `2.16.840.1.113883.3.88.11.83.7`]

A condition is a clinical statement that a clinician is wants to track. It has important patient management use cases (e.g., health records often present the problem list as a way of summarizing a patient's medical history).

1. **SHALL** contain exactly one [1..1] templateId (C83-[DE-7-CDA-1]) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.3.88.11.83.7"
2. **SHALL** conform to IHE Problem Concern Entry template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.5.2`) (C83-[DE-7-CDA-2])
3. **SHALL** contain at least one [1..*] **`entryRelationship`**
   a. Contains **`@typeCode="SUBJ"`** *SUBJ*
   b. Contains exactly one [1..1] IHE Problem Entry (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.5`)
4. The treating provider or providers **SHALL** be recorded in a <performer> element under the <act> that describes the condition of concern (C83-[DE-7.05-CDA-3])
5. The identifier of the treating provider **SHALL** be present in the <id> element beneath the <assignedEntity>. This identifier **SHALL** be the identifier of one of the providers listed in the healthcare providers module. (C83-[DE-7.05-CDA-2])
6. The time over which this provider treated the condition **MAY** be recorded in the <time> element beneath the <performer> element (C83-[DE-7.05-CDA-1])

1. **SHALL** conform to CCD Problem Act template (templateId: `2.16.840.1.113883.10.20.1.27`)
2. **SHALL** conform to IHE Concern Entry template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.5.1`)
3. **SHALL** conform to IHE Problem Concern Entry template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.5.2`)
4. **SHALL** contain exactly one [1..1] **`@classCode`**="`ACT`" *Act* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF-146)
5. **SHALL** contain exactly one [1..1] **`@moodCode`**="`EVN`" *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF-147)
6. **SHALL** contain at least one [1..*] **`id`** (CONF-148)
7. **SHALL** contain exactly one [1..1] **`code`**`/@nullFlavor` = "NA" *NA (not applicable)* (CONF-149)
8. **SHALL** contain exactly one [1..1] **`statusCode`**, where the @code **SHALL** be selected from ValueSet `ConcernEntryStatus` **STATIC**
   - *The statusCode associated with any concern must be one of the following values:*

     ***active**: A concern that is still being tracked.*
     ***suspended**: A concern that is active, but which may be set aside. For example, this value might be used to suspend concern*
     about a patient problem after some period of remission, but before assumption that the concern has been resolved.
     ***aborted**: A concern that is no longer actively being tracked, but for reasons other than because the problem was resolved.*
     This value might be used to mark a concern as being aborted after a patient leaves care against medical advice.
     ***completed**:*
     The problem, allergy or medical state has been resolved and the concern no longer needs to be tracked except for
     historical purposes.
9. **SHALL** contain exactly one [1..1] **`effectiveTime`**
   - *The effectiveTime element records the starting and ending times during which the concern was active.*
10. **MAY** contain exactly one [1..1] **`entryRelationship`** (CONF-168)
    a. Contains exactly one [1..1] Episode Observation (templateId: `2.16.840.1.113883.10.20.1.41`)
11. **SHALL** contain at least one [1..*] **`entryRelationship`**
    a. Contains **`@typeCode="SUBJ"`** *SUBJ*
    b. Contains exactly one [1..1] Problem Entry (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.5`)

12. **SHALL** contain at least one [1..*] **`entryRelationship`**
    a. Contains **`@typeCode="`**`SUBJ"` *SUBJ*
    b. Contains exactly one [1..1] IHE Problem Entry (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.5`)
13. **SHALL** contain one or more entryRelationship (CONF-151)
14. A problem act **MAY** reference a problem observation, alert observation (see section Alerts) or other clinical statement that is the subject of concern, by setting the value for "Act / entryRelationship / @typeCode" to be "SUBJ" 2.16.840.1.113883.5.1002 ActRelationshipType STATIC. (CONF-152)
15. The target of a problem act with Act / entryRelationship / @typeCode="SUBJ" **SHOULD** be a problem observation (in the Problem section) or alert observation (in the Alert section), but **MAY** be some other clinical statement. (CONF-153)
16. In Problem Section, a Problem Act **SHOULD** contain one or more Problem Observations. (CONF-140)
17. In Alert Section, a ProblemAct **SHOULD** contain one or more Alert Observations. (CONF-256)
18. **MAY** contain exactly one Patient Awareness (CONF-179)
19. The effectiveTime 'low' element **SHALL** be present. The 'high' element **SHALL** be present for concerns in the completed or aborted state, and **SHALL NOT** be present otherwise.
20. This entry **SHALL** contain one or more problem or allergy entries that conform to the specification in section Problem Entry or Allergies and Intolerances.
21. This **SHALL** be represented using entryRelationship with typeCode = 'SUBJ'
22. Each concern **MAY** have 0 or more related references. This **MAY** be any valid CDA clinical statement, and **SHOULD** be an IHE entry template.
23. Related References **SHALL** be represented using entryRelationship with typeCode = 'REFR'.
24. The treating provider or providers **SHALL** be recorded in a <performer> element under the <act> that describes the condition of concern (C83-[DE-7.05-CDA-3])
25. The identifier of the treating provider **SHALL** be present in the <id> element beneath the <assignedEntity>. This identifier **SHALL** be the identifier of one of the providers listed in the healthcare providers module. (C83-[DE-7.05-CDA-2])
26. The time over which this provider treated the condition **MAY** be recorded in the <time> element beneath the <performer> element (C83-[DE-7.05-CDA-1])

Condition 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">
  <id root="MDHT" extension="846842173"/>
  <code code="1063249712"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <entryRelationship>
    <observation/>
  </entryRelationship>
</act>
```

Condition Entry

[Observation: templateId `1.3.6.1.4.1.19376.1.5.3.1.4.5`]

This section makes use of the linking, severity, clinical status and comment content specifications defined elsewhere in the technical framework. In HL7 RIM parlance, observations about a problem, complaint, symptom, finding, diagnosis, or functional limitation of a patient is the event (moodCode='EVN') of observing (<observation classCode='OBS'>) that problem. The <value> of the observation comes from a controlled vocabulary representing

such things. The <code> contained within the <observation> describes the method of determination from yet another controlled vocabulary.

The basic pattern for reporting a problem uses the CDA <observation> element, setting the classCode='OBS' to represent that this is an observation of a problem, and the moodCode='EVN', to represent that this is an observation that has in fact taken place. The negationInd attribute, if true, specifies that the problem indicated was observed to not have occurred (which is subtly but importantly different from having not been observed). The value of negationInd should not normally be set to true. Instead, to record that there is "no prior history of chicken pox", one would use a coded value indicated exactly that. However, it is not always possible to record problems in this manner, especially if using a controlled vocabulary that does not supply pre-coordinated negations , or which do not allow the negation to be recorded with post-coordinated coded terminology.

1. **SHALL** contain exactly one [1..1] templateId ( ) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="1.3.6.1.4.1.19376.1.5.3.1.4.5"
2. **SHALL** conform to IHE Problem Entry template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.5`)
3. **SHOULD** contain exactly one [1..1] **`code`**, where the @code **SHALL** be selected from ValueSet `Problem Type 2.16.840.1.113883.3.88.12.3221.7.2` **STATIC** 1 (C154-[DE-7.02-1])
4. **SHALL** contain exactly one [1..1] **`text`**
   - *The <text> element is required and points to the text describing the problem being recorded; including any dates, comments, et cetera. The <reference> contains a URI in value attribute. This URI points to the free text description of the problem in the document that is being described.*
5. **SHALL** contain exactly one [1..1] **`value`**, where the @code **SHALL** be selected from ValueSet `Problem 2.16.840.1.113883.3.88.12.3221.7.4` **STATIC** 1
   - *The <value> is the condition that was found. This element is required. While the value may be a coded or an un-coded string, the type is always a coded value (xsi:type='CD'). If coded, the code and codeSystem attributes shall be present. The codeSystem should reference a controlled vocabulary describing problems, complaints, symptoms, findings, diagnoses, or functional limitations, e.g., ICD-9, SNOMED-CT or MEDCIN, or others.*

     It is recommended that the codeSystemName associated with the codeSystem, and the displayName for the code also be provided for diagnostic and human readability purposes, but this is not required by this profile.

     If uncoded, all attributes other than xsi:type='CD' must be absent.

     The <value> contains a <reference> to the <originalText> in order to link the coded value to the problem narrative text (minus any dates, comments, et cetera). The <reference> contains a URI in value attribute. This URI points to the free text description of the problem in the document that is being described.
6. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF-160)
   a. Contains **`@typeCode="SUBJ"`** *SUBJ*
   b. Contains exactly one [1..1] CCD Age Observation (templateId: `2.16.840.1.113883.10.20.1.38`)
7. **MAY** contain zero or one [0..1] **`entryRelationship`**
   a. Contains **`@typeCode="CAUS"`** *CAUS*
   b. Contains exactly one [1..1] CCD Cause Of Death Observation (templateId: `2.16.840.1.113883.10.20.1.42`)
8. **MAY** contain zero or one [0..1] **`entryRelationship`**
   a. Contains **`@typeCode="REFR"`** *REFR*
   b. Contains exactly one [1..1] IHE Problem Status Observation (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.1.1`)
9. The onset date **SHALL** be recorded in the <low> element of the <effectiveTime> element when known. (C83-[DE-7.01-1])
10. The resolution data **SHALL** be recorded in the <high> element of the <effectiveTime> element when known. (C83-[DE-7.01-2])

11. If the problem is known to be resolved, but the date of resolution is not known, then the <high> element **SHALL** be present, and the nullFlavor attribute **SHALL** be set to 'UNK'. Therefore, the existence of an <high> element within a problem does indicate that the problem has been resolved. (C83-[DE-7.01-3])

1. **SHALL** conform to CCD Problem Observation template (templateId: `2.16.840.1.113883.10.20.1.28`)
2. **SHALL** conform to IHE Problem Entry template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.5`)
3. Contains exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
4. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF-155)
5. **SHALL** contain at least one [1..*] **`id`**
    - *The specific observation being recorded must have an identifier (<id>) that shall be provided for tracking purposes. If the source EMR does not or cannot supply an intrinsic identifier, then a GUID shall be provided as the root, with no extension (e.g., <id root='CE1215CD-69EC-4C7B-805F-569233C5E159'/>). At least one identifier must be present, more than one may appear.*
6. **SHOULD** contain exactly one [1..1] **`code`**, where the @code **SHALL** be selected from ValueSet `Problem Type 2.16.840.1.113883.3.88.12.3221.7.2` **STATIC** 1 (C154-[DE-7.02-1])
7. **SHALL** contain exactly one [1..1] **`text`**
    - *The <text> element is required and points to the text describing the problem being recorded; including any dates, comments, et cetera. The <reference> contains a URI in value attribute. This URI points to the free text description of the problem in the document that is being described.*
8. **SHALL** contain exactly one [1..1] **`statusCode/@code`**`="completed"` (CodeSystem: `2.16.840.1.113883.5.14 ActStatus`) (CONF-156, CONF-157)
9. **SHOULD** contain exactly one [1..1] **`effectiveTime`**
    - *The <effectiveTime> of this <observation> is the time interval over which the <observation> is known to be true. The <low> and <high> values should be no more precise than known, but as precise as possible. While CDA allows for multiple mechanisms to record this time interval (e.g., by low and high values, low and width, high and width, or center point and width), we are constraining Medical summaries to use only the low/high form. The <low> value is the earliest point for which the condition is known to have existed. The <high> value, when present, indicates the time at which the observation was no longer known to be true. Thus, the implication is made that if the <high> value is specified, that the observation was no longer seen after this time, and it thus represents the date of resolution of the problem. Similarly, the <low> value may seem to represent onset of the problem. Neither of these statements is necessarily precise, as the <low> and <high> values may represent only an approximation of the true onset and resolution (respectively) times. For example, it may be the case that onset occurred prior to the <low> value, but no observation may have been possible before that time to discern whether the condition existed prior to that time. The <low> value should normally be present. There are exceptions, such as for the case where the patient may be able to report that they had chicken pox, but are unsure when. In this case, the <effectiveTime> element shall have a <low> element with a nullFlavor attribute set to 'UNK'. The <high> value need not be present when the observation is about a state of the patient that is unlikely to change (e.g., the diagnosis of an incurable disease).*
10. **SHALL** contain exactly one [1..1] **`value`**, where the @code **SHALL** be selected from ValueSet `Problem 2.16.840.1.113883.3.88.12.3221.7.4` **STATIC** 1
    - *The <value> is the condition that was found. This element is required. While the value may be a coded or an un-coded string, the type is always a coded value (xsi:type='CD'). If coded, the code and codeSystem attributes shall be present. The codeSystem should reference a controlled vocabulary describing problems, complaints, symptoms, findings, diagnoses, or functional limitations, e.g., ICD-9, SNOMED-CT or MEDCIN, or others.*

      It is recommended that the codeSystemName associated with the codeSystem, and the displayName for the code also be provided for diagnostic and human readability purposes, but this is not required by this profile.

      If uncoded, all attributes other than xsi:type='CD' must be absent.

The <value> contains a <reference> to the <originalText> in order to link the coded value to the problem narrative text (minus any dates, comments, et cetera). The <reference> contains a URI in value attribute. This URI points to the free text description of the problem in the document that is being described.

11. **MAY** contain zero or one [0..1] **entryRelationship** (CONF-160)
    a. Contains **@typeCode="SUBJ"** *SUBJ*
    b. Contains exactly one [1..1] Age Observation (templateId: 2.16.840.1.113883.10.20.1.38)
12. **MAY** contain zero or one [0..1] **entryRelationship**
    a. Contains exactly one [1..1] Severity (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.1)
13. **MAY** contain zero or one [0..1] **entryRelationship**
    a. Contains **@typeCode="REFR"** *REFR*
    b. Contains exactly one [1..1] Problem Status Observation (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.1.1)
14. **MAY** contain zero or one [0..1] **entryRelationship**
    a. Contains **@typeCode="REFR"** *REFR*
    b. Contains exactly one [1..1] Health Status Observation (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.1.2)
15. **MAY** contain zero or more [0..*] **entryRelationship**
    a. Contains **@typeCode="SUBJ"** *SUBJ*
    b. Contains exactly one [1..1] Comment (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.2)
16. **MAY** contain zero or one [0..1] **entryRelationship** (CONF-160)
    a. Contains **@typeCode="SUBJ"** *SUBJ*
    b. Contains exactly one [1..1] CCD Age Observation (templateId: 2.16.840.1.113883.10.20.1.38)
17. **MAY** contain zero or one [0..1] **entryRelationship**
    a. Contains **@typeCode="CAUS"** *CAUS*
    b. Contains exactly one [1..1] CCD Cause Of Death Observation (templateId: 2.16.840.1.113883.10.20.1.42)
18. **MAY** contain zero or one [0..1] **entryRelationship**
    a. Contains **@typeCode="REFR"** *REFR*
    b. Contains exactly one [1..1] IHE Problem Status Observation (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.1.1)
19. **SHALL** contain one or more sources of information. (CONF-161)
20. **MAY** contain exactly one Patient Awareness (CONF-180)
21. The problem name **SHALL** be recorded in the entry by recording a <reference> where the value attribute points to the narrative text containing the name of the problem.
22. If entryRelationship / Comment is present, then entryRelationship **SHALL** include inversionInd = 'true'.
23. The onset date **SHALL** be recorded in the <low> element of the <effectiveTime> element when known. (C83-[DE-7.01-1])
24. The resolution data **SHALL** be recorded in the <high> element of the <effectiveTime> element when known. (C83-[DE-7.01-2])
25. If the problem is known to be resolved, but the date of resolution is not known, then the <high> element **SHALL** be present, and the nullFlavor attribute **SHALL** be set to 'UNK'. Therefore, the existence of an <high> element within a problem does indicate that the problem has been resolved. (C83-[DE-7.01-3])

Condition Entry 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">
```

```
  <id root="MDHT" extension="21995079"/>
  <code code="1177870445"/>
  <text>Text Value</text>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <value xsi:type="CD" code="1672686798"/>
  <entryRelationship>
    <observation/>
  </entryRelationship>
  <entryRelationship>
    <observation/>
  </entryRelationship>
  <entryRelationship>
    <observation/>
  </entryRelationship>
</observation>
```

Encounter

[Encounter: templateId `2.16.840.1.113883.3.88.11.83.16`]

The encounter entry contains data describing the interactions between the patient and clinicians. Interaction includes both in-person and non-in-person encounters such as telephone and e-mail communication.

1. **SHALL** contain exactly one [1..1] templateId (C83-[DE-16-CDA-1]) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.3.88.11.83.16"
2. **SHALL** conform to IHE Encounter Entry template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.14`)
3. **SHOULD** contain exactly one [1..1] **`code`**, where the @code **SHOULD** be selected from ValueSet `EncounterType 2.16.840.1.113883.3.88.12.80.32` **DYNAMIC** (C83-[DE-16.02-1])
4. **MAY** contain zero or one [0..1] **`priorityCode`**, where the @code **MAY** be selected from ValueSet `Admission Type (NUBC) 2.16.840.1.113883.3.88.12.80.33` **STATIC** (C154-[DE-16.07-1])
5. participant/@typeCode ='ORG'/code **SHALL** be coded with ValueSet 2.16.840.1.113883.3.88.12.80.33, Admission Source Value Set, STATIC
6. ClinicalDocument/componentOf/encompassingEncounter/code/@code **SHALL** be coded with ValueSet 2.16.840.1.113883.3.88.12.80.66, Patient Class Value Set, 20090630, STATIC
7. The state part of ClinicalDocument/componentOf/encompassingEncounter/location/addr **SHALL** be coded with ValueSet 2.16.840.1.113883.3.88.12.80.1, State Value Set, 20081218, Dynamic
8. The country part of ClinicalDocument/componentOf/encompassingEncounter/location/addr **SHALL** be coded with ValueSet 2.16.840.1.113883.3.88.12.80.63, Country Value Set, 20081218, Dynamic
9. The postal code part of ClinicalDocument/componentOf/encompassingEncounter/location/addr **SHALL** be coded with ValueSet 2.16.840.1.113883.3.88.12.80.2, Postal Code Value Set, 20081218, Dynamic
10. **MAY** satisfy: The order to admit time reflects the time of participation of the provider referring the patient to an inpatient setting. The encounter type should reflect that this is an inpatient encounter.

1. **SHALL** conform to IHE Encounter Entry template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.14`)
2. **SHALL** contain exactly one [1..1] **`@classCode`**`="ENC"` (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
3. Contains exactly one [1..1] **`@moodCode`** with data type x_DocumentEncounterMood
4. **SHALL** contain at least one [1..*] **`id`**
5. **SHOULD** contain exactly one [1..1] **`code`**, where the @code **SHOULD** be selected from ValueSet `EncounterType 2.16.840.1.113883.3.88.12.80.32` **DYNAMIC** (C83-[DE-16.02-1])
6. **SHALL** contain exactly one [1..1] **`text`**
7. **MAY** contain zero or one [0..1] **`priorityCode`**, where the @code **MAY** be selected from ValueSet `Admission Type (NUBC) 2.16.840.1.113883.3.88.12.80.33` **STATIC** (C154-[DE-16.07-1])

8. participant/@typeCode ='ORG'/code **SHALL** be coded with ValueSet 2.16.840.1.113883.3.88.12.80.33, Admission Source Value Set, STATIC
9. ClinicalDocument/componentOf/encompassingEncounter/code/@code **SHALL** be coded with ValueSet 2.16.840.1.113883.3.88.12.80.66, Patient Class Value Set, 20090630, STATIC
10. The state part of ClinicalDocument/componentOf/encompassingEncounter/location/addr **SHALL** be coded with ValueSet 2.16.840.1.113883.3.88.12.80.1, State Value Set, 20081218, Dynamic
11. The country part of ClinicalDocument/componentOf/encompassingEncounter/location/addr **SHALL** be coded with ValueSet 2.16.840.1.113883.3.88.12.80.63, Country Value Set, 20081218, Dynamic
12. The postal code part of ClinicalDocument/componentOf/encompassingEncounter/location/addr **SHALL** be coded with ValueSet 2.16.840.1.113883.3.88.12.80.2, Postal Code Value Set, 20081218, Dynamic
13. **MAY** satisfy: The order to admit time reflects the time of participation of the provider referring the patient to an inpatient setting. The encounter type should reflect that this is an inpatient encounter.

Encounter example

```
<?xml version="1.0" encoding="UTF-8"?>
<encounter xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <id root="MDHT" extension="928176417"/>
  <code code="770748247"/>
  <text>Text Value</text>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
</encounter>
```

Family History

[Organizer: templateId `2.16.840.1.113883.3.88.11.83.18`]

1. **SHALL** contain exactly one [1..1] templateId ( ) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.3.88.11.83.18"
2. **SHALL** conform to IHE Family History Organizer template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.15`)
3. **SHOULD** contain zero or more [0..*] **`component`**
   a. Contains exactly one [1..1] IHE Problem Status Observation (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.1.1`)
4. A pedigree image **MAY** be included in an observationMedia element in an entry under the Family History section
5. value/@mediaType element of the observationMedia element **SHALL** be application/pdf, image/jpeg or image/png
6. value/@representation element of the observationMedia element **SHALL** be B64, and the data for the image **SHALL** be included within the value element
7. subject/RelatedSubject/Code (Family Member Relationship to Patient) **SHALL** be coded as 2.16.840.1.113883.1.11.19579, Family Member Value Set, STATIC, V3NE08
8. One RelatedSubject/subject/sdtc:id element **SHALL** be present.
9. RelatedSubject/subject/name **SHOULD** be present.
10. RelatedSubject/subject/administrativeGenderCode **SHALL** be code as 2.16.840.1.113883.1.11.1, Adminstrative Gender Value Set, STATIC, 20081218
11. The race of the family member, when recorded, **SHALL** appear in an RelatedSubject/subject/sdtc:raceCode element.
12. raceCode **SHALL** be coded as 2.16.840.1.113883.1.11.14914, Race Value Set, Dynamic

13. The ethnicity of the family member, when recorded, **SHALL** appear in an RelatedSubject/subject/sdtc:ethnicGroupCode element
14. Ethnicity **SHALL** be coded as 2.16.840.1.113883.1.11.15836, Ethnicity Value Set, Dynamic
15. Family History Condition data elements **SHALL** declare conformance to the IHE Family History Observation entry by including a <templateID> element with the root attribute set to the value 1.3.6.1.4.1.19376.1.5.3.1.4.13.3
16. **SHOULD** satisfy: The age of onset of disease or age at death of a family member should be computable from the family member date of birth and the effective time of the observation of the disease or the death. When that data are not available, the age of the patient at the time of the observation shall be recorded within a condition or test result observation using the CCD Age Observation
17. **SHOULD** satisfy: When a condition is one of the causes of death for the patient, that fact is related using the CCD Cause of Death Observation
18. **MAY** satisfy: The biological sex may be recorded as a IHE Family History Observation to identify the biological sex of the subject where it differs from the administrative gender
19. **MAY** satisfy: Multiple birth status is may be recorded as a IHE Family History observation on the subject when it is relevant for a family member (18.17 Family Member Multiple Birth Status) or the patient (1.13 Multiple Birth Indicator).
20. **MAY** satisfy: Multiple birth order is may be recorded as a IHE Family History observation on the subject when it is relevant for a family member (18.26 - Family Member Multiple Birth Order) or the patient (1.14 - Birth Order). Family Member Age
21. **MAY** satisfy: The age may be recorded as a CCD Age Observation on the subject when it is relevant for a family member (18.23 - Family Member Age) or the patient (1.14 - Age)
22. **MAY** satisfy: Genetic test results may be recorded as Family History observations on the subject
23. Components of a Genetic Laboratory Test **SHALL** be coded as specified in HITSP/C80 Section 2.2.3.11 Genetic Testing

1. **SHALL** conform to CCD Family History Organizer template (templateId: `2.16.840.1.113883.10.20.1.23`)
2. **SHALL** conform to IHE Family History Organizer template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.15`)
3. **SHALL** contain exactly one [1..1] **`@classCode`**`="CLUSTER"` (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF-201)
4. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF-202)
5. **SHALL** contain exactly one [1..1] **`code`**, where the @code **SHALL** be selected from (CodeSystem: `2.16.840.1.113883.5.111 RoleCode`)
6. **SHALL** contain exactly one [1..1] **`statusCode/@code`**`="completed"` (CodeSystem: `2.16.840.1.113883.5.14 ActStatus`) (CONF-203, CONF-204)
7. **SHALL** contain at least one [1..*] **`component`**
   a. Contains exactly one [1..1] Family History Observation (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.13.3`)
8. **SHOULD** contain zero or more [0..*] **`component`**
   a. Contains exactly one [1..1] IHE Problem Status Observation (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.1.1`)
9. A family history organizer **SHALL** contain one or more Organizer / component. (CONF-205)
10. The target of a family history organizer Organizer / component relationship **SHOULD** be a family history observation, but **MAY** be some other clinical statement
11. A family history organizer **SHALL** contain exactly one subject participant, representing the family member who is the subject of the family history observations (CONF-208)
12. A subject participant **SHALL** contain exactly one RelatedSubject, representing the relationship of the subject to the patient (CONF-212)
13. The value for RelatedSubject / @classCode **SHALL** be "PRS" "Personal relationship" 2.16.840.1.113883.5.110 RoleClass STATIC (CONF-213)
14. RelatedSubject **SHALL** contain exactly one RelatedSubject / code

15. The value for "RelatedSubject / code" **SHOULD** be selected from ValueSet 2.16.840.1.113883.1.11.19579 FamilyHistoryRelatedSubjectCode DYNAMIC or 2.16.840.1.113883.1.11.20.21 FamilyHistoryPersonCode DYNAMIC (CONF-215)
16. Representation of a pedigree graph **SHALL** be done using RelatedSubject / code values (e.g. "great grandfather") to designate a hierarchical family tree. (CONF-216)
17. RelatedSubject **SHOULD** contain exactly one RelatedSubject / subject (CONF-217)
18. RelatedSubject / subject **SHOULD** contain exactly one RelatedSubject / subject / administrativeGenderCode. (CONF-218)
19. **SHOULD** satisfy: subject/relatedSubject/subject contains exactly one birthTime (CONF-219)
20. **MAY** satisfy: subject/relatedSubject/subject contains exactly one sdtc:deceasedInd
21. **MAY** satisfy: subject/relatedSubject/subject contains exactly one sdtc:deceasedTime
22. **SHOULD** satisfy: The age of a relative at the time of observation is inferred by comparing subject/relatedSubject/subject/birthTime with Observation/effectiveTime
23. **MAY** satisfy: The age of a relative at the time of death is inferred by comparing subject/relatedSubject/subject/birthTime with subject/relatedSubject/subject/sdtc:deceasedTime.
24. One subject/RelatedSubject/subject/sdtc:id element **SHOULD** be present. It is used to identify the patient relation to create a pedigree graph.
25. The participant element **MAY** be present to record the relationship of the subject to other family members to create a pedigree graph.
26. **SHALL** satisfy: Participant shall contain a participantRole/@classCode = "PRS" element showing the relationship of the subject to other family members
27. **SHALL** satisfy: The Participant/ParticipantRole/code element shall be present, and gives the relationship of the participant to the subject. The code attribute shall be present, and shall contain a value from the HL7 FamilyMember vocabulary
28. **SHALL** satisfy: The Participant/ParticipantRole/PlayingEntity element shall be present with @classCode = 'PSN'
29. **SHALL** satisfy: The Participant/ParticipantRole/PlayingEntity/sdtc:id shall be present. It must have the same root and extension attributes of the subject element of a separate family history organizer.
30. A pedigree image **MAY** be included in an observationMedia element in an entry under the Family History section
31. value/@mediaType element of the observationMedia element **SHALL** be application/pdf, image/jpeg or image/png
32. value/@representation element of the observationMedia element **SHALL** be B64, and the data for the image **SHALL** be included within the value element
33. subject/RelatedSubject/Code (Family Member Relationship to Patient) **SHALL** be coded as 2.16.840.1.113883.1.11.19579, Family Member Value Set, STATIC, V3NE08
34. One RelatedSubject/subject/sdtc:id element **SHALL** be present.
35. RelatedSubject/subject/name **SHOULD** be present.
36. RelatedSubject/subject/administrativeGenderCode **SHALL** be code as 2.16.840.1.113883.1.11.1, Adminstrative Gender Value Set, STATIC, 20081218
37. The race of the family member, when recorded, **SHALL** appear in an RelatedSubject/subject/sdtc:raceCode element.
38. raceCode **SHALL** be coded as 2.16.840.1.113883.1.11.14914, Race Value Set, Dynamic
39. The ethnicity of the family member, when recorded, **SHALL** appear in an RelatedSubject/subject/sdtc:ethnicGroupCode element
40. Ethnicity **SHALL** be coded as 2.16.840.1.113883.1.11.15836, Ethnicity Value Set, Dynamic
41. Family History Condition data elements **SHALL** declare conformance to the IHE Family History Observation entry by including a <templateID> element with the root attribute set to the value 1.3.6.1.4.1.19376.1.5.3.1.4.13.3
42. **SHOULD** satisfy: The age of onset of disease or age at death of a family member should be computable from the family member date of birth and the effective time of the observation of the disease or the death. When that data are not available, the age of the patient at the time of the observation shall be recorded within a condition or test result observation using the CCD Age Observation
43. **SHOULD** satisfy: When a condition is one of the causes of death for the patient, that fact is related using the CCD Cause of Death Observation

44. **MAY** satisfy: The biological sex may be recorded as a IHE Family History Observation to identify the biological sex of the subject where it differs from the administrative gender
45. **MAY** satisfy: Multiple birth status is may be recorded as a IHE Family History observation on the subject when it is relevant for a family member (18.17 Family Member Multiple Birth Status) or the patient (1.13 Multiple Birth Indicator).
46. **MAY** satisfy: Multiple birth order is may be recorded as a IHE Family History observation on the subject when it is relevant for a family member (18.26 - Family Member Multiple Birth Order) or the patient (1.14 - Birth Order). Family Member Age
47. **MAY** satisfy: The age may be recorded as a CCD Age Observation on the subject when it is relevant for a family member (18.23 - Family Member Age) or the patient (1.14 - Age)
48. **MAY** satisfy: Genetic test results may be recorded as Family History observations on the subject
49. Components of a Genetic Laboratory Test **SHALL** be coded as specified in HITSP/C80 Section 2.2.3.11 Genetic Testing

hitsp::FamilyHistory							
cda::organizer[cda:templateId/@root =]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
familyHistory	familyHistory	1..*	SHALL	YES	FamilyHistory		
problemStatusObservation	problemStatusObservation	0..*	SHOULD	YES	ProblemStatusObservation		

Family History example

```
<?xml version="1.0" encoding="UTF-8"?>
<organizer xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <id root="MDHT" extension="158773266"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <component>
    <observation/>
  </component>
</organizer>
```

Immunization

[SubstanceAdministration: templateId `2.16.840.1.113883.3.88.11.83.13`]

1. **SHALL** contain exactly one [1..1] templateId ( ) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.3.88.11.83.13"
2. **SHALL** conform to IHE Immunization template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.12`)
3. The reason for refusal **SHALL** be coded as specified in HITSP/C80 Section 2.2.3.5.3 No Immunization Reason
4. Immunizations **SHALL** be coded using CVX as specified in HITSP/C80 Section 2.2.3.5.1 Vaccines Administered. (C154-[DE-13.06-1])

1. **SHALL** conform to CCD Medication Activity template (templateId: `2.16.840.1.113883.10.20.1.24`)
2. **SHALL** conform to IHE Immunization template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.12`)
3. Contains exactly one [1..1] **`@classCode`**=`"SBADM"` with data type ActClass (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)

4. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) (6.3.4.17.2)
5. **SHALL** contain at least one [1..*] **id** (CONF-306)
6. **SHALL** contain zero or one [0..1] **code/@code**="IMMUNIZ" (CodeSystem: 2.16.840.1.113883.5.4 HL7ActCode) (6.3.4.17.5)
7. **SHALL** contain exactly one [1..1] **statusCode** (6.3.4.17.7)
8. **SHALL** contain exactly one [1..1] **effectiveTime** (6.3.4.17.8)
9. **SHOULD** contain exactly one [1..1] **routeCode**, where the @code **SHOULD** be selected from (CodeSystem: 2.16.840.1.113883.5.112 HL7 RouteOfAdministration) (CONF-309, CONF-310)
10. Contains zero or more [0..*] **approachSiteCode**
    - *The site where the medication is administered, usually used with IV or topical drugs. The <approachSiteCode> element describes the site of medication administrion. It may be coded to a controlled vocabulary that lists such sites (e.g., SNOMED-CT). In CDA documents, this 4805 element contains a URI in the value attribute of the <reference> that points to the text in the narrative identifying the site. In a message, the <originalText> element shall contain the text identifying the site.*
11. Contains zero or one [0..1] **doseQuantity**
    - *The amount of the medication given. This should be in some known and measurable unit, such as grams, milligrams, et cetera. It may be measured in "administratio"n units (such as tablets or each), for medications where the strength is relevant. In this case, only the unit count is specified , no units are specified. It may be a range.*
12. Contains zero or one [0..1] **rateQuantity**
    - *The rate is a measurement of how fast the dose is given to the patient over time (e.g., .5 liter / 1 hr), and is often used with IV drugs.*
13. **MAY** contain exactly one [1..1] **maxDoseQuantity** (CONF-312)
    - *represents a maximum dose limit*
14. Contains exactly one [1..1] **consumable**, where its type is Consumable
    a. Contains exactly one [1..1] Consumable
15. **MAY** contain exactly one [1..1] **entryRelationship** (CONF-338, CONF-339)
    a. Contains **@typeCode="SUBJ"** *SUBJ*
    b. Contains exactly one [1..1] Medication Series Number Observation (templateId: 2.16.840.1.113883.10.20.1.46)
16. **MAY** contain exactly one [1..1] **entryRelationship** (CONF-350)
    a. Contains exactly one [1..1] Medication Status Observation (templateId: 2.16.840.1.113883.10.20.1.47)
17. **MAY** contain at least one [1..*] **entryRelationship** (CONF-330, CONF-333)
    a. Contains **@typeCode="SUBJ"** *SUBJ*
    b. Contains exactly one [1..1] Patient Instruction (templateId: 2.16.840.1.113883.10.20.1.49)
18. **MAY** contain at least one [1..*] **performer** (CONF-313)
    a. Contains exactly one [1..1] CDA Performer2
    - *Indicates the person administering a substance.*
19. **MAY** contain at least one [1..*] **entryRelationship** (CONF-348, CONF-349)
    a. Contains **@typeCode="CAUS"** *CAUS*
    b. Contains exactly one [1..1] Reaction Observation (templateId: 2.16.840.1.113883.10.20.1.54)
20. **MAY** contain at least one [1..*] **participant** (CONF-368)
    a. Contains exactly one [1..1] Product Instance (templateId: 2.16.840.1.113883.10.20.1.52)
21. **SHALL** satisfy: Value for moodCode is "EVN" or "INT" 2.16.840.1.113883.5.1001 ActMood STATIC (CONF-305)

22. **SHOULD** satisfy: Contains exactly one doseQuantity or rateQuantity. (CONF-311)
23. **MAY** satisfy: Has one or more associated consents, represented in the CCD Header as ClinicalDocument / authorization / consent. (CONF-314)
24. **SHALL** satisfy: Contains one or more sources of information. (CONF-315)
25. **MAY** satisfy: Contains one or more precondition / Criterion, to indicate that the medication is administered only when the associated (coded or free text) criteria are met. (CONF-327)
26. **MAY** satisfy: Contains one or more entryRelationship, where the value for @typeCode is "RSON" "Has reason" 2.16.840.1.113883.5.1002 ActRelationshipType STATIC. (CONF-328)
27. **SHALL** satisfy: entryRelationship / @typeCode="RSON" in a medication activity has a target of problem act (templateId 2.16.840.1.113883.10.20.1.27), problem observation (templateId 2.16.840.1.113883.10.20.1.28), or some other clinical statement. (CONF-329)
28. **SHALL** satisfy: Contains exactly one consumable, the target of which is a Product template. (CONF-354)
29. **SHALL** satisfy: In a CDA document, the URI given in the value attribute of the <reference> element points to an element in the narrative content that contains the complete text describing the immunization activity.
30. **SHALL** satisfy: CPT-4 codes may be used for immunization procedures
31. **SHALL** satisfy: If negationInd is set to TRUE atleast one comment shall exist that provides an explanation for why the immunization did not take place. Other comments may also be present
32. The reason for refusal **SHALL** be coded as specified in HITSP/C80 Section 2.2.3.5.3 No Immunization Reason
33. Immunizations **SHALL** be coded using CVX as specified in HITSP/C80 Section 2.2.3.5.1 Vaccines Administered. (C154-[DE-13.06-1])

Immunization 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">
  <id root="MDHT" extension="1569290250"/>
  <statusCode code="completed"/>
  <effectiveTime value="20121102"/>
  <doseQuantity/>
  <rateQuantity/>
  <maxDoseQuantity/>
  <consumable/>
</substanceadministration>
```

Insurance Provider

[Act: templateId `2.16.840.1.113883.3.88.11.83.5`]

1. **SHALL** contain exactly one [1..1] templateId ( ) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.3.88.11.83.5"
2. **SHALL** conform to IHE Coverage Entry template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.17`)
3. **SHALL** contain exactly one [1..1] **`code/@code`**="`48768-6`" *Payment sources* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`) (CONF-41, CONF-42)
4. Information for payment providers **SHALL** be recorded as a policy act inside the coverage act.
5. All Insurance Provider modules **SHALL** declare conformance to the IHE Payer Entry by including a <templateID> element with the root attribute set to the value 1.3.6.1.4.1.19376.1.5.3.1.4.18
6. The id/@root attribute of a Payer Entry **SHOULD** be the OID of the assigning authority for the identifier; however, determining the assigning authority is not feasible in all settings. A GUID **MAY** be used in place of the OID of the assigning authority. Implementers **SHOULD** use the same GUID for each instance of the same group or contract number

7. The code/@code element **SHOULD** be present in a Payer Entry and **SHALL** be coded as 2.16.840.1.113883.3.88.12.3221.5.2, Health Insurance Type Value Set, 20081218, STATIC
8. performer/@typeCode='PRF'/assignedEntity **SHALL** be present to record Payer Information/Health Insurance Information
9. performer/@typeCode='PRF'/assignedEntity/id elements **MAY** be present. The ID element corresponds to the RxBIN and RxPCN fields found on pharmacy benefit cards. When a national payer identifier is standardized, it would also go in this field. The OID for RxBIN is 2.16.840.1.113883.3.88.3.1. The OID for an RxPCN is 2.16.840.1.113883.3.88.3.1 plus the numeric identifier used in the RxBIN.
10. The performer/@typeCode='PRF'/assignedEntity/addr **MAY** be present.
11. The state part of performer/@typeCode='PRF'/assignedEntity/addr **SHALL** be recorded using 2.16.840.1.113883.3.88.12.80.1, State Value Set, 20081218, Dynamic
12. The country part of performer/@typeCode='PRF'/assignedEntity/addr **SHALL** be recorded using 2.16.840.1.113883.3.88.12.80.63, Country Value Set, 20081218, Dynamic
13. The state part of performer/@typeCode='PRF'/assignedEntity/addr **SHALL** be recorded using 2.16.840.1.113883.3.88.12.80.2, Postal Code Value Set, 20081218, Dynamic
14. The date when the plan began covering the member **SHOULD** be recorded in the <low> element of the <time> element beneath the participant/@typeCode='COV' element
15. The date when the plan stops covering the member **SHOULD** be recorded in the <high> element of the <time> element beneath the participant/@typeCode='COV' element
16. participant/@typeCode='COV'/participantRole/@classCode='PAT' **SHALL** be present to record Patient information.
17. The member identifier number **SHALL** be recorded in the extension attribute of the <id> element found in the <participant/@typeCode='COV'/participantRole/@classCode='PAT'> element
18. The root attribute of a participant/@typeCode='COV'/participantRole/@classCode='PAT'/id element **SHOULD** be the OID of the assigning authority for the identifier; however, determining the assigning authority is not feasible in all settings
19. A GUID **MAY** be used in place of the OID of the assigning authority
20. Implementers **SHOULD** use the same GUID for each instance of a member identifier from the same health plan
21. The relationship to the subscriber **SHALL** be present and **SHALL** be recorded in the <code> element underneath the <participantRole> element recording the member information
22. The Patient Relationship to Subscriber **SHALL** be coded as 2.16.840.1.113883.1.11.18877, Coverage Role Type Value, V3NE08, STATIC
23. The state part of participant/@typeCode='COV'/participantRole/@classCode='PAT'/addr element **SHALL** be coded as 2.16.840.1.113883.3.88.12.80.1, State Value Set, 20081218, Dynamic
24. The state part of participant/@typeCode='COV'/participantRole/@classCode='PAT'/addr element **SHALL** be coded as 2.16.840.1.113883.3.88.12.80.63, Country Value Set, 20081218, Dynamic
25. The state part of participant/@typeCode='COV'/participantRole/@classCode='PAT'/addr element **SHALL** be coded as 2.16.840.1.113883.3.88.12.80.2, Postal Code Value Set, 20081218, Dynamic
26. If the member name as recorded by the health plan differs from the patient name as recorded in the registration/medication summary (e.g., due to marriage or for other reasons), then the member name **SHALL** be recorded in the <name> element of the <playingEntity> element beneath the <participant/@typeCode='COV'/participantRole/@classCode='PAT'> element
27. If the member date of birth as recorded by the health plan differs from the patient date of birth as recorded in the registration/medication summary, then the member date of birth **SHALL** be recorded in the <sdtc:birthTime> element of the <playingEntity> element beneath the <participant/@typeCode='COV'/participantRole/@classCode='PAT'> element
28. The <participant/@typeCode='HLD'> element **SHOULD** be present to record Subscriber Information.
29. When the Subscriber is the patient, the <participant/@typeCode='HLD'> element describing the subscriber **SHALL NOT** be present. This information will be recorded instead in the data elements used to record member information
30. The participant/@typeCode='HLD'/participantRole/id element **SHALL** be present.
31. The root attribute **SHOULD** be the OID of the assigning authority for the identifier; however, determining the assigning authority is not feasible in all settings. A GUID **MAY** be used in place of the OID of the assigning

authority. Implementers **SHOULD** use the same GUID for each instance of a subscriber identifier from the same health plan

32. The participant/@typeCode='HLD'/participantRole/addr element **SHALL** be present to record the Subscriber Address.
33. The state part of participant/@typeCode='HLD'/participantRole/addr element **SHALL** be coded as 2.16.840.1.113883.3.88.12.80.1, State Value Set, 20081218, Dynamic
34. The country part of participant/@typeCode='HLD'/participantRole/addr element **SHALL** be coded as 2.16.840.1.113883.3.88.12.80.63, Country Value Set, 20081218, Dynamic
35. The postal code part of participant/@typeCode='HLD'/participantRole/addr element **SHALL** be coded as 2.16.840.1.113883.3.88.12.80.2, Postal Code Value Set, 20081218, Dynamic
36. The subscriber date of birth **SHALL** be recorded in the <sdtc:birthTime> element of the <playingEntity> element beneath the <performer/@typeCode='HLD'/participantRole> element.
37. **SHALL** satisfy: performer/assignedEntity/code element is used to denote the financial Responsibility Party Type.
38. performer/assignedEntity/code/@code attribute **SHALL** be coded as 2.16.840.1.113883.1.11.10416, Financially Responsible Party Type Value Set, V3NE08, STATIC
39. When the code of the encompassing act is PP, the code attribute value **SHALL** be set to GUAR or PAT to represent a guarantor or self-paying patient respectively
40. The code attribute **SHALL** be set to PAYOR when the code of the encompassing act is other than PP
41. performer/assignedEntity/addr **SHOULD** be present to record Financial Responsibility Party Address
42. The state part of a performer/assignedEntity/addr/ element **SHALL** be coded as 2.16.840.1.113883.3.88.12.80.1, State Value Set, 20081218, Dynamic
43. The country part of a performer/assignedEntity/addr/ element **SHALL** be coded as 2.16.840.1.113883.3.88.12.80.63, Country Value Set, 20081218, Dynamic
44. The postal code part of a performer/assignedEntity/addr/ element **SHALL** be coded as 2.16.840.1.113883.3.88.12.80.2, Postal Code Value Set, 20081218, Dynamic

1. **SHALL** conform to CCD Coverage Activity template (templateId: `2.16.840.1.113883.10.20.1.20`)
2. **SHALL** conform to IHE Coverage Entry template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.17`)
3. **SHALL** contain exactly one [1..1] **`@classCode`**=`"ACT"` *Act* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF-36)
4. **SHALL** contain exactly one [1..1] **`@moodCode`**=`"DEF"` (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF-37)
5. **SHALL** contain at least one [1..*] **`id`** (CONF-38)
6. **SHALL** contain exactly one [1..1] **`code/@code`**=`"48768-6"` *Payment sources* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`) (CONF-41, CONF-42)
7. **SHALL** contain exactly one [1..1] **`statusCode/@code`**=`"completed"` (CodeSystem: `2.16.840.1.113883.5.14 ActStatus`) (CONF-39, CONF-40)
8. **SHALL** contain at least one [1..*] **`entryRelationship`**
   a. Contains **`@typeCode="`**`COMP`**`"`** *COMP*
   b. Contains exactly one [1..1] Payer Entry (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.18`)
9. **SHALL** satisfy: An alert observation contains one or more sources of information. (CONF-47)
10. **MAY** satisfy: entryRelationship contains sequenceNumber, which serves to prioritize the payment sources. (CONF-44)
11. Information for payment providers **SHALL** be recorded as a policy act inside the coverage act.
12. All Insurance Provider modules **SHALL** declare conformance to the IHE Payer Entry by including a <templateID> element with the root attribute set to the value 1.3.6.1.4.1.19376.1.5.3.1.4.18
13. The id/@root attribute of a Payer Entry **SHOULD** be the OID of the assigning authority for the identifier; however, determining the assigning authority is not feasible in all settings. A GUID **MAY** be used in place of the OID of the assigning authority. Implementers **SHOULD** use the same GUID for each instance of the same group or contract number
14. The code/@code element **SHOULD** be present in a Payer Entry and **SHALL** be coded as 2.16.840.1.113883.3.88.12.3221.5.2, Health Insurance Type Value Set, 20081218, STATIC

15. performer/@typeCode='PRF'/assignedEntity **SHALL** be present to record Payer Information/Health Insurance Information
16. performer/@typeCode='PRF'/assignedEntity/id elements **MAY** be present. The ID element corresponds to the RxBIN and RxPCN fields found on pharmacy benefit cards. When a national payer identifier is standardized, it would also go in this field. The OID for RxBIN is 2.16.840.1.113883.3.88.3.1. The OID for an RxPCN is 2.16.840.1.113883.3.88.3.1 plus the numeric identifier used in the RxBIN.
17. The performer/@typeCode='PRF'/assignedEntity/addr **MAY** be present.
18. The state part of performer/@typeCode='PRF'/assignedEntity/addr **SHALL** be recorded using 2.16.840.1.113883.3.88.12.80.1, State Value Set, 20081218, Dynamic
19. The country part of performer/@typeCode='PRF'/assignedEntity/addr **SHALL** be recorded using 2.16.840.1.113883.3.88.12.80.63, Country Value Set, 20081218, Dynamic
20. The state part of performer/@typeCode='PRF'/assignedEntity/addr **SHALL** be recorded using 2.16.840.1.113883.3.88.12.80.2, Postal Code Value Set, 20081218, Dynamic
21. The date when the plan began covering the member **SHOULD** be recorded in the <low> element of the <time> element beneath the participant/@typeCode='COV' element
22. The date when the plan stops covering the member **SHOULD** be recorded in the <high> element of the <time> element beneath the participant/@typeCode='COV' element
23. participant/@typeCode='COV'/participantRole/@classCode='PAT' **SHALL** be present to record Patient information.
24. The member identifier number **SHALL** be recorded in the extension attribute of the <id> element found in the <participant/@typeCode='COV'/participantRole/@classCode='PAT'> element
25. The root attribute of a participant/@typeCode='COV'/participantRole/@classCode='PAT'/id element **SHOULD** be the OID of the assigning authority for the identifier; however, determining the assigning authority is not feasible in all settings
26. A GUID **MAY** be used in place of the OID of the assigning authority
27. Implementers **SHOULD** use the same GUID for each instance of a member identifier from the same health plan
28. The relationship to the subscriber **SHALL** be present and **SHALL** be recorded in the <code> element underneath the <participantRole> element recording the member information
29. The Patient Relationship to Subscriber **SHALL** be coded as 2.16.840.1.113883.1.11.18877, Coverage Role Type Value, V3NE08, STATIC
30. The state part of participant/@typeCode='COV'/participantRole/@classCode='PAT'/addr element **SHALL** be coded as 2.16.840.1.113883.3.88.12.80.1, State Value Set, 20081218, Dynamic
31. The state part of participant/@typeCode='COV'/participantRole/@classCode='PAT'/addr element **SHALL** be coded as 2.16.840.1.113883.3.88.12.80.63, Country Value Set, 20081218, Dynamic
32. The state part of participant/@typeCode='COV'/participantRole/@classCode='PAT'/addr element **SHALL** be coded as 2.16.840.1.113883.3.88.12.80.2, Postal Code Value Set, 20081218, Dynamic
33. If the member name as recorded by the health plan differs from the patient name as recorded in the registration/medication summary (e.g., due to marriage or for other reasons), then the member name **SHALL** be recorded in the <name> element of the <playingEntity> element beneath the <participant/@typeCode='COV'/participantRole/@classCode='PAT'> element
34. If the member date of birth as recorded by the health plan differs from the patient date of birth as recorded in the registration/medication summary, then the member date of birth **SHALL** be recorded in the <sdtc:birthTime> element of the <playingEntity> element beneath the <participant/@typeCode='COV'/participantRole/@classCode='PAT'> element
35. The <participant/@typeCode='HLD'> element **SHOULD** be present to record Subscriber Information.
36. When the Subscriber is the patient, the <participant/@typeCode='HLD'> element describing the subscriber **SHALL NOT** be present. This information will be recorded instead in the data elements used to record member information
37. The participant/@typeCode='HLD'/participantRole/id element **SHALL** be present.
38. The root attribute **SHOULD** be the OID of the assigning authority for the identifier; however, determining the assigning authority is not feasible in all settings. A GUID **MAY** be used in place of the OID of the assigning authority. Implementers **SHOULD** use the same GUID for each instance of a subscriber identifier from the same health plan

39. The participant/@typeCode='HLD'/participantRole/addr element **SHALL** be present to record the Subscriber Address.
40. The state part of participant/@typeCode='HLD'/participantRole/addr element **SHALL** be coded as 2.16.840.1.113883.3.88.12.80.1, State Value Set, 20081218, Dynamic
41. The country part of participant/@typeCode='HLD'/participantRole/addr element **SHALL** be coded as 2.16.840.1.113883.3.88.12.80.63, Country Value Set, 20081218, Dynamic
42. The postal code part of participant/@typeCode='HLD'/participantRole/addr element **SHALL** be coded as 2.16.840.1.113883.3.88.12.80.2, Postal Code Value Set, 20081218, Dynamic
43. The subscriber date of birth **SHALL** be recorded in the <sdtc:birthTime> element of the <playingEntity> element beneath the <performer/@typeCode='HLD'/participantRole> element.
44. **SHALL** satisfy: performer/assignedEntity/code element is used to denote the financial Responsibility Party Type.
45. performer/assignedEntity/code/@code attribute **SHALL** be coded as 2.16.840.1.113883.1.11.10416, Financially Responsible Party Type Value Set, V3NE08, STATIC
46. When the code of the encompassing act is PP, the code attribute value **SHALL** be set to GUAR or PAT to represent a guarantor or self-paying patient respectively
47. The code attribute **SHALL** be set to PAYOR when the code of the encompassing act is other than PP
48. performer/assignedEntity/addr **SHOULD** be present to record Financial Responsibility Party Address
49. The state part of a performer/assignedEntity/addr/ element **SHALL** be coded as 2.16.840.1.113883.3.88.12.80.1, State Value Set, 20081218, Dynamic
50. The country part of a performer/assignedEntity/addr/ element **SHALL** be coded as 2.16.840.1.113883.3.88.12.80.63, Country Value Set, 20081218, Dynamic
51. The postal code part of a performer/assignedEntity/addr/ element **SHALL** be coded as 2.16.840.1.113883.3.88.12.80.2, Postal Code Value Set, 20081218, Dynamic

Insurance Provider 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">
  <id root="MDHT" extension="875389452"/>
  <code code="384508013"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
</act>
```

Medication

[SubstanceAdministration: templateId `2.16.840.1.113883.3.88.11.83.8`]

1. **SHALL** contain exactly one [1..1] templateId (C83-[DE-8-CDA-1]) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.3.88.11.83.8"
2. **SHALL** conform to IHE Medication template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.7`) (C83-[DE-8-CDA-2])
3. **MAY** contain at least one [1..*] **`effectiveTime`** with data type IVL_TS (CONF-308)

   - *Indicate Medication Stopped: Used to express a "hard stop", such as the last Sig sequence in a tapering dose, where the last sequence is 'then D/C' or where the therapy/drug is used to treat a condition and that treatment is for a fixed duration with a hard stop, such as antibiotic treatment, etc.*
   - *Administration Timing: defines a specific administration or use time. Can be a text string (Morning, Evening, Before Meals, 1 Hour After Meals, 3 Hours After Meals, Before Bed) or an exact time.*
   - *Frequency: defines how often the medication is to be administered as events per unit of time. Often expressed as the number of times per day (e.g., four times a day), but may also include event-related information (e.g.,*

1 hour before meals, in the morning, at bedtime). Complimentary to Interval, although equivalent expressions may have different implications (e.g., every 8 hours versus 3 times a day).

- *Interval: defines how the product is to be administered as an interval of time. For example, every 8 hours. Complimentary to Frequency, although equivalent expressions may have different implications (e.g., every 8 hours versus 3 times a day).*
- *Duration: for non-instantaneous administrations, indicates the length of time the administration should be continued. For example, (infuse) over 30 minutes.*

4. **MAY** contain at least one [1..*] **routeCode** (CONF-309, CONF-310), where the @code **SHALL** be selected from ValueSet `Medication Route FDA 2.16.840.1.113883.3.88.12.3221.8.7` **STATIC** 1

   - *The route is a coded value, and indicates how the medication is received by the patient (by mouth, intravenously, topically, et cetera).*

5. **MAY** contain at least one [1..*] **doseQuantity**

   - *the amount of the product to be given. This may be a known, measurable unit (e.g., milliliters), an administration unit (e.g., tablet), or an amount of active ingredient (e.g., 250 mg). May define a variable dose, dose range or dose options based upon identified criteria (see Dose Indicator)*

6. **MAY** contain exactly one [1..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 (C154-[DE-8.11-1])

   - *The physical form of the product as presented to the patient. For example: tablet, capsule, liquid or ointment*

7. **MAY** contain at least one [1..*] **maxDoseQuantity** (CONF-312)

   - *defines a maximum or dose limit. This segment can repeat for more than one dose restriction*

8. **MAY** contain zero or more [0..*] **approachSiteCode** (C154-[DE-8.09-1]), where the @code **SHALL** be selected from ValueSet `Body Site 2.16.840.1.113883.3.88.12.3221.8.9` **STATIC** 2

   - *The anatomic site where the medication is administered. Usually applicable to injected or topical products*

9. **MAY** contain zero or more [0..*] **code** (C83-[DE-8.12-CDA-1])

   - *Delivery Method: A description of how the product is administered/consumed*

10. Contains zero or one [0..1] **entryRelationship**

    a. Contains exactly one [1..1] Medication Type (templateId: `2.16.840.1.113883.3.88.11.83.8.1`)

11. Contains at least one [1..*] **entryRelationship**

    a. Contains exactly one [1..1] Medication Order Information (templateId: `2.16.840.1.113883.3.88.11.83.8.3`)

12. Contains zero or one [0..1] **entryRelationship**

    - *Any noted intended or unintended effects of the product. For example: full body rash, nausea, rash resolved*

    a. Contains exactly one [1..1] CCD Reaction Observation (templateId: `2.16.840.1.113883.10.20.1.54`)

13. **SHALL** satisfy: The time at which the medication was stopped is determined based on the content of the <high> element of the first <effectiveTime> element. (2.2.2.8.3)

14. **SHALL** satisfy: The HL7 data type for PIVL_TS uses the institutionSpecified attribute to indicate whether it is the interval (time between dosing), or frequency (number of doses in a time period) that is important. If instititutionSpecified is not present or is set to false, then the time between dosing is important (every 8 hours). If true, then the frequency of administration is important (e.g., 3 times per day). (2.2.2.8.4)
15. The first <effectiveTime> **SHALL** use the IVL_TS data type unless for a single administration, in which case, it **SHALL** use the TS data type. (C83-[DE-8-CDA-3])
16. Medications that are administered based on activities of daily living **SHALL** identify the events that trigger administration in the <event> element beneath the <effectiveTime> element. The <effectiveTime> element **SHALL** be of type EIVL_TS. (C83-[DE-8.03-CDA-1])
17. Medications that are administered at a specified frequency **SHALL** record the expected interval between doses in the <period> element beneath an <effectiveTime> of type PIVL_TS. The <effectiveTime> element **SHALL** have an institutionSpecified attribute value of "true". (C83-[DE-8.04-CDA-1])
18. Medications that are administered at a specified interval **SHALL** record interval between doses in the <period> element beneath an <effectiveTime> element of type PIVL_TS. The <effectiveTime> element **SHALL** have an institutionSpecified attribute value of "false". (C83-[DE-8.05-CDA-1])
19. doseQuantity/@unit, Dose Units **MAY** be present when needed. If present it **SHALL** be coded as 2.16.840.1.113883.3.88.12.80.29 Unit of Measure (C154-[DE-8.08-1])
20. When the coded product or brand name describes the strength or concentration of the medication, and the dosing is in administration units (e.g., 1 tablet, 2 capsules), units **SHOULD** contain the preferred name of the presentation units within braces { } using the units of presentation from the NCI Thesaurus (C154-[DE-8.08-2])
21. The free text description of the delivery method **MAY** be included within a <originalText> element beneath the <code> element (C83-[DE-8.12-CDA-2])
22. **SHALL** satisfy: Contains one consumable element which contains the Medication Information template. The name and code for the medication are recorded in the <consumable> element.
23. The medication status **MAY** be recorded using the CCD Medication Status observation using the value set defined in the CCD (C154-[DE-8.20-1])
24. **MAY** contain [0..*] indications which **SHALL** be recorded using the Indication problem observation (templateID 2.16.840.1.113883.10.20.1.28) described in the CCD Implementation Guide. (C83-[DE-8.20-CDA-1])
25. The indication problem observation **SHALL** contain a <text> element that includes a <reference> element whose value attribute points to the narrative text that is the indication for the medication (C83-[DE-8.20-CDA-2])
26. The indication **SHALL** be coded as 2.16.840.1.113883.3.88.12.3221.7.4, Problem Value Set, version: 20100125, Dynamic (C154-[DE-8.20-1])
27. **MAY** contain Patient Instructions which **SHALL** be recorded using the Patient Medication Instructions template (templateID 1.3.6.1.4.1.19376.1.5.3.1.4.3) (C83-[DE-8.22-CDA-1])
28. The vehicle for administering a medication **MAY** be recorded in a <participantRole> element inside a <participant> element in the <substanceAdministration> element (C83-[DE-8.24-CDA-1])
29. The typeCode attribute of the <participant> element **SHALL** be CSM (C83-[DE-8.24-CDA-2])
30. The classCode of the <participantRole> **SHALL** be MANU (C83-[DE-8.24-CDA-3])
31. A <code> element for the <participantRole> **SHALL** be present and **SHALL** contain the code 412307009 from the SNOMED CT code system (C83-[DE-8.24-CDA-4])
32. The <name> element in the <playingEntity> element **SHALL** record the name of the drug vehicle (C83-[DE-8.24-CDA-5])
33. The <code> element in the <playingEntity> element **MAY** be used to supply a coded term for the drug vehicle (C83-[DE-8.24-CDA-6])
34. **SHALL** satisfy: The Medication Vehicle shall be coded as 2.16.840.1.113883.3.88.12.80.21, Medication Vehicle Value Set, version: 20081218, Dynamic (C154-[DE-8.24-1])

1. **SHALL** conform to CCD Medication Activity template (templateId: `2.16.840.1.113883.10.20.1.24`)
2. **SHALL** conform to IHE Medication template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.7`)
3. Contains exactly one [1..1] **`@classCode`**`="SBADM"` with data type ActClass (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
4. Contains exactly one [1..1] **`@moodCode`** with data type x_DocumentSubstanceMood
5. **SHALL** contain at least one [1..*] **`id`** (CONF-306)

6. **MAY** contain zero or more [0..*] **`code`** (C83-[DE-8.12-CDA-1])
   - *Delivery Method: A description of how the product is administered/consumed*
7. **SHALL** contain exactly one [1..1] **`statusCode`** (CONF-307)
   - *The status of all 'substanceAdministration' elements must be "complete"d. The act has either occurred, or the request or order has been placed.*
8. **MAY** contain at least one [1..*] **`effectiveTime`** with data type IVL_TS (CONF-308)
   - *Indicate Medication Stopped: Used to express a "hard stop", such as the last Sig sequence in a tapering dose, where the last sequence is 'then D/C' or where the therapy/drug is used to treat a condition and that treatment is for a fixed duration with a hard stop, such as antibiotic treatment, etc.*
   - *Administration Timing: defines a specific administration or use time. Can be a text string (Morning, Evening, Before Meals, 1 Hour After Meals, 3 Hours After Meals, Before Bed) or an exact time.*
   - *Frequency: defines how often the medication is to be administered as events per unit of time. Often expressed as the number of times per day (e.g., four times a day), but may also include event-related information (e.g., 1 hour before meals, in the morning, at bedtime). Complimentary to Interval, although equivalent expressions may have different implications (e.g., every 8 hours versus 3 times a day).*
   - *Interval: defines how the product is to be administered as an interval of time. For example, every 8 hours. Complimentary to Frequency, although equivalent expressions may have different implications (e.g., every 8 hours versus 3 times a day).*
   - *Duration: for non-instantaneous administrations, indicates the length of time the administration should be continued. For example, (infuse) over 30 minutes.*
9. **MAY** contain at least one [1..*] **`routeCode`** (CONF-309, CONF-310), where the @code **SHALL** be selected from ValueSet `Medication Route FDA 2.16.840.1.113883.3.88.12.3221.8.7` **STATIC** 1
   - *The route is a coded value, and indicates how the medication is received by the patient (by mouth, intravenously, topically, et cetera).*
10. **MAY** contain zero or more [0..*] **`approachSiteCode`** (C154-[DE-8.09-1]), where the @code **SHALL** be selected from ValueSet `Body Site 2.16.840.1.113883.3.88.12.3221.8.9` **STATIC** 2
    - *The anatomic site where the medication is administered. Usually applicable to injected or topical products*
11. **MAY** contain at least one [1..*] **`doseQuantity`**
    - *the amount of the product to be given. This may be a known, measurable unit (e.g., milliliters), an administration unit (e.g., tablet), or an amount of active ingredient (e.g., 250 mg). May define a variable dose, dose range or dose options based upon identified criteria (see Dose Indicator)*
12. **SHOULD** contain zero or one [0..1] **`rateQuantity`**
    - *The rate is a measurement of how fast the dose is given to the patient over time (e.g., .5 liter / 1 hr), and is often used with IV drugs.*
13. **MAY** contain at least one [1..*] **`maxDoseQuantity`** (CONF-312)
    - *defines a maximum or dose limit. This segment can repeat for more than one dose restriction*
14. **MAY** contain exactly one [1..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 (C154-[DE-8.11-1])
    - *The physical form of the product as presented to the patient. For example: tablet, capsule, liquid or ointment*

15. Contains exactly one [1..1] **`consumable`**, where its type is Consumable
    a. Contains exactly one [1..1] Consumable
16. **MAY** contain exactly one [1..1] **`entryRelationship`** (CONF-338, CONF-339)
    a. Contains **`@typeCode="`**`SUBJ`**`"`** *SUBJ*
    b. Contains exactly one [1..1] Medication Series Number Observation (templateId: `2.16.840.1.113883.10.20.1.46`)
17. **MAY** contain exactly one [1..1] **`entryRelationship`** (CONF-350)
    a. Contains exactly one [1..1] Medication Status Observation (templateId: `2.16.840.1.113883.10.20.1.47`)
18. **MAY** contain at least one [1..*] **`performer`** (CONF-313)
    a. Contains exactly one [1..1] CDA Performer2

    - *Indicates the person administering a substance.*
19. **MAY** contain at least one [1..*] **`entryRelationship`** (CONF-348, CONF-349)
    a. Contains **`@typeCode="`**`CAUS`**`"`** *CAUS*
    b. Contains exactly one [1..1] Reaction Observation (templateId: `2.16.840.1.113883.10.20.1.54`)
20. **MAY** contain at least one [1..*] **`participant`** (CONF-368)
    a. Contains exactly one [1..1] Product Instance (templateId: `2.16.840.1.113883.10.20.1.52`)
21. Contains at least one [1..*] **`entryRelationship`**
    a. Contains exactly one [1..1] Internal Reference (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.4.1`)

    - *Entry may indicate one or more reasons for the use of the medication. The extension and root of each observation present must match the identifier of a concern entry contained elsewhere within the CDA document.*
      A consumer of the Medical Summary is encouraged, but not required to maintain these links on import.
22. Contains at least one [1..*] **`entryRelationship`**
    a. Contains exactly one [1..1] Patient Medical Instructions (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.3`)

    - *At most one instruction may be provided for each <substanceAdministration> entry. The instructions shall contain any special case dosing instructions (e.g., split, tapered, or conditional dosing), and may contain other information (take with food, et cetera).*
23. Contains zero or one [0..1] **`entryRelationship`**
    a. Contains exactly one [1..1] Medication Type (templateId: `2.16.840.1.113883.3.88.11.83.8.1`)
24. Contains at least one [1..*] **`entryRelationship`**
    a. Contains exactly one [1..1] Medication Order Information (templateId: `2.16.840.1.113883.3.88.11.83.8.3`)
25. Contains zero or one [0..1] **`entryRelationship`**
    a. Contains exactly one [1..1] CCD Reaction Observation (templateId: `2.16.840.1.113883.10.20.1.54`)

    - *Any noted intended or unintended effects of the product. For example: full body rash, nausea, rash resolved*
26. **SHALL** satisfy: Value for moodCode is "EVN" or "INT" 2.16.840.1.113883.5.1001 ActMood STATIC (CONF-305)
27. **SHOULD** satisfy: Contains exactly one doseQuantity or rateQuantity. (CONF-311)
28. **MAY** satisfy: Has one or more associated consents, represented in the CCD Header as ClinicalDocument / authorization / consent. (CONF-314)
29. **SHALL** satisfy: Contains one or more sources of information. (CONF-315)

30. **MAY** satisfy: Contains one or more precondition / Criterion, to indicate that the medication is administered only when the associated (coded or free text) criteria are met. (CONF-327)
31. **MAY** satisfy: Contains one or more entryRelationship, where the value for @typeCode is "RSON" "Has reason" 2.16.840.1.113883.5.1002 ActRelationshipType STATIC. (CONF-328)
32. **SHALL** satisfy: entryRelationship / @typeCode="RSON" in a medication activity has a target of problem act (templateId 2.16.840.1.113883.10.20.1.27), problem observation (templateId 2.16.840.1.113883.10.20.1.28), or some other clinical statement. (CONF-329)
33. **SHALL** satisfy: Contains exactly one consumable, the target of which is a Product template. (CONF-354)
34. **SHALL** satisfy: Contains one dosing template to identify this entry as a particular type of medication event. Possible dosing templates: 1.3.6.1.4.1.19376.1.5.3.1.4.7.1 Normal Dosing, 1.3.6.1.4.1.19376.1.5.3.1.4.8, Tapered Dosing, 1.3.6.1.4.1.19376.1.5.3.1.4.9 Split Dosing, 1.3.6.1.4.1.19376.1.5.3.1.4.10 Conditional Dosing, 1.3.6.1.4.1.19376.1.5.3.1.4.11 Combination Dosing.
35. **SHALL** satisfy: contains one or more related components (<entryRelationship typeCode='COMP'>, either to handle split, tapered or conditional dosing, or to support combination medications.
36. **SHALL** satisfy: Values from SNOMED CT shall be used in the <code> element to record that a patient is either not on medications, or that medications are not known.
37. **SHALL** satisfy: The act/@classCode='ACT' and act/@moodCode='EVN' when recording reason for medication in InternalReference Template. (6.3.4.16.22)
38. **SHALL** satisfy: The <consumable> element shall be present, and shall contain a Product Entry template
39. **SHALL** satisfy: The entryRelationship/@inversionInd attribute is 'true' for Patient Medical Instructions relationship
40. **SHOULD** satisfy: The name and strength of the medication is recorded in consumable/manufacturedProduct/manufacturedMaterial/code/originalText
41. **SHALL** satisfy: Name of the substance or product is recorded in consumable/manufacturedProduct/manufacturedMaterial/name
42. **MAY** satisfy: the preconditions for use of the medication are recorded in the <precondition> element. element. The value attribute of the <reference> element is a URL that points to the CDA narrative describing those preconditions.
43. **SHALL** satisfy: The entryRelationship/@inversionInd attribute is 'false' for Supply Entry relationship
44. **SHOULD** satisfy: entryRelationship/sequenceNumber element should be present when the embedded 'supply' element has a moodCode attribute of EVN.
45. **SHALL** satisfy: The time at which the medication was stopped is determined based on the content of the <high> element of the first <effectiveTime> element. (2.2.2.8.3)
46. **SHALL** satisfy: The HL7 data type for PIVL_TS uses the institutionSpecified attribute to indicate whether it is the interval (time between dosing), or frequency (number of doses in a time period) that is important. If instititutionSpecified is not present or is set to false, then the time between dosing is important (every 8 hours). If true, then the frequency of administration is important (e.g., 3 times per day). (2.2.2.8.4)
47. The first <effectiveTime> **SHALL** use the IVL_TS data type unless for a single administration, in which case, it **SHALL** use the TS data type. (C83-[DE-8-CDA-3])
48. Medications that are administered based on activities of daily living **SHALL** identify the events that trigger administration in the <event> element beneath the <effectiveTime> element. The <effectiveTime> element **SHALL** be of type EIVL_TS. (C83-[DE-8.03-CDA-1])
49. Medications that are administered at a specified frequency **SHALL** record the expected interval between doses in the <period> element beneath an <effectiveTime> of type PIVL_TS. The <effectiveTime> element **SHALL** have an institutionSpecified attribute value of "true". (C83-[DE-8.04-CDA-1])
50. Medications that are administered at a specified interval **SHALL** record interval between doses in the <period> element beneath an <effectiveTime> element of type PIVL_TS. The <effectiveTime> element **SHALL** have an institutionSpecified attribute value of "false". (C83-[DE-8.05-CDA-1])
51. doseQuantity/@unit, Dose Units **MAY** be present when needed. If present it **SHALL** be coded as 2.16.840.1.113883.3.88.12.80.29 Unit of Measure (C154-[DE-8.08-1])
52. When the coded product or brand name describes the strength or concentration of the medication, and the dosing is in administration units (e.g., 1 tablet, 2 capsules), units **SHOULD** contain the preferred name of the presentation units within braces { } using the units of presentation from the NCI Thesaurus (C154-[DE-8.08-2])

53. The free text description of the delivery method **MAY** be included within a <originalText> element beneath the <code> element (C83-[DE-8.12-CDA-2])
54. **SHALL** satisfy: Contains one consumable element which contains the Medication Information template. The name and code for the medication are recorded in the <consumable> element.
55. The medication status **MAY** be recorded using the CCD Medication Status observation using the value set defined in the CCD (C154-[DE-8.20-1])
56. **MAY** contain [0..*] indications which **SHALL** be recorded using the Indication problem observation (templateID 2.16.840.1.113883.10.20.1.28) described in the CCD Implementation Guide. (C83-[DE-8.20-CDA-1])
57. The indication problem observation **SHALL** contain a <text> element that includes a <reference> element whose value attribute points to the narrative text that is the indication for the medication (C83-[DE-8.20-CDA-2])
58. The indication **SHALL** be coded as 2.16.840.1.113883.3.88.12.3221.7.4, Problem Value Set, version: 20100125, Dynamic (C154-[DE-8.20-1])
59. **MAY** contain Patient Instructions which **SHALL** be recorded using the Patient Medication Instructions template (templateID 1.3.6.1.4.1.19376.1.5.3.1.4.3) (C83-[DE-8.22-CDA-1])
60. The vehicle for administering a medication **MAY** be recorded in a <participantRole> element inside a <participant> element in the <substanceAdministration> element (C83-[DE-8.24-CDA-1])
61. The typeCode attribute of the <participant> element **SHALL** be CSM (C83-[DE-8.24-CDA-2])
62. The classCode of the <participantRole> **SHALL** be MANU (C83-[DE-8.24-CDA-3])
63. A <code> element for the <participantRole> **SHALL** be present and **SHALL** contain the code 412307009 from the SNOMED CT code system (C83-[DE-8.24-CDA-4])
64. The <name> element in the <playingEntity> element **SHALL** record the name of the drug vehicle (C83-[DE-8.24-CDA-5])
65. The <code> element in the <playingEntity> element **MAY** be used to supply a coded term for the drug vehicle (C83-[DE-8.24-CDA-6])
66. **SHALL** satisfy: The Medication Vehicle shall be coded as 2.16.840.1.113883.3.88.12.80.21, Medication Vehicle Value Set, version: 20081218, Dynamic (C154-[DE-8.24-1])

Medication 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">
  <id root="MDHT" extension="548148719"/>
  <code code="60979804"/>
  <statusCode code="completed"/>
  <effectiveTime xsi:type="IVL_TS">
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <routeCode code="2081109094"/>
  <approachSiteCode code="157334026"/>
  <doseQuantity/>
  <rateQuantity/>
  <maxDoseQuantity/>
  <consumable/>
  <entryRelationship>
    <observation>
      <id root="MDHT" extension="1690080166"/>
      <code code="1704534059"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
    </observation>
  </entryRelationship>
  <entryRelationship>
```

```
    <supply>
      <id root="MDHT" extension="417057100"/>
      <code code="306638536"/>
      <statusCode code="completed"/>
      <effectiveTime value="20121102"/>
    </supply>
  </entryRelationship>
  <entryRelationship>
    <observation/>
  </entryRelationship>
</substanceadministration>
```

Medication Combination Medication

[SubstanceAdministration: templateId 2.16.840.1.113883.3.88.11.83.8]

1. **SHALL** contain exactly one [1..1] templateId ( ) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.3.88.11.83.8"
2. **SHALL** conform to Medication template (templateId: 2.16.840.1.113883.3.88.11.83.8)
3. **SHALL** conform to IHE Combination Medication template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.11)

1. **SHALL** conform to IHE Combination Medication template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.11)
2. **SHALL** conform to CCD Medication Activity template (templateId: 2.16.840.1.113883.10.20.1.24)
3. **SHALL** conform to IHE Medication template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.7)
4. **SHALL** conform to Medication template (templateId: 2.16.840.1.113883.3.88.11.83.8)
5. Contains exactly one [1..1] **@classCode**="SBADM" with data type ActClass (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)
6. Contains exactly one [1..1] **@moodCode** with data type x_DocumentSubstanceMood
7. **SHALL** contain at least one [1..*] **id** (CONF-306)
8. **MAY** contain zero or more [0..*] **code** (C83-[DE-8.12-CDA-1])
   - *Delivery Method: A description of how the product is administered/consumed*
9. **SHALL** contain exactly one [1..1] **statusCode** (CONF-307)
   - *The status of all 'substanceAdministration' elements must be "complete"d. The act has either occurred, or the request or order has been placed.*
10. **MAY** contain at least one [1..*] **effectiveTime** with data type IVL_TS (CONF-308)
    - *Indicate Medication Stopped: Used to express a "hard stop", such as the last Sig sequence in a tapering dose, where the last sequence is 'then D/C' or where the therapy/drug is used to treat a condition and that treatment is for a fixed duration with a hard stop, such as antibiotic treatment, etc.*
    - *Administration Timing: defines a specific administration or use time. Can be a text string (Morning, Evening, Before Meals, 1 Hour After Meals, 3 Hours After Meals, Before Bed) or an exact time.*
    - *Frequency: defines how often the medication is to be administered as events per unit of time. Often expressed as the number of times per day (e.g., four times a day), but may also include event-related information (e.g., 1 hour before meals, in the morning, at bedtime). Complimentary to Interval, although equivalent expressions may have different implications (e.g., every 8 hours versus 3 times a day).*
    - *Interval: defines how the product is to be administered as an interval of time. For example, every 8 hours. Complimentary to Frequency, although equivalent expressions may have different implications (e.g., every 8 hours versus 3 times a day).*
    - *Duration: for non-instantaneous administrations, indicates the length of time the administration should be continued. For example, (infuse) over 30 minutes.*

11. **MAY** contain at least one [1..*] **routeCode** (CONF-309, CONF-310), where the @code **SHALL** be selected from ValueSet `Medication Route FDA 2.16.840.1.113883.3.88.12.3221.8.7` **STATIC** 1
    - *The route is a coded value, and indicates how the medication is received by the patient (by mouth, intravenously, topically, et cetera).*
12. **MAY** contain zero or more [0..*] **approachSiteCode** (C154-[DE-8.09-1]), where the @code **SHALL** be selected from ValueSet `Body Site 2.16.840.1.113883.3.88.12.3221.8.9` **STATIC** 2
    - *The anatomic site where the medication is administered. Usually applicable to injected or topical products*
13. **MAY** contain at least one [1..*] **doseQuantity**
    - *the amount of the product to be given. This may be a known, measurable unit (e.g., milliliters), an administration unit (e.g., tablet), or an amount of active ingredient (e.g., 250 mg). May define a variable dose, dose range or dose options based upon identified criteria (see Dose Indicator)*
14. **SHOULD** contain zero or one [0..1] **rateQuantity**
    - *The rate is a measurement of how fast the dose is given to the patient over time (e.g., .5 liter / 1 hr), and is often used with IV drugs.*
15. **MAY** contain at least one [1..*] **maxDoseQuantity** (CONF-312)
    - *defines a maximum or dose limit. This segment can repeat for more than one dose restriction*
16. **MAY** contain exactly one [1..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 (C154-[DE-8.11-1])
    - *The physical form of the product as presented to the patient. For example: tablet, capsule, liquid or ointment*
17. Contains exactly one [1..1] **consumable**, where its type is Consumable
    a. Contains exactly one [1..1] Consumable
18. **MAY** contain exactly one [1..1] **entryRelationship** (CONF-338, CONF-339)
    a. Contains **@typeCode="**`SUBJ`**"** *SUBJ*
    b. Contains exactly one [1..1] Medication Series Number Observation (templateId: `2.16.840.1.113883.10.20.1.46`)
19. **MAY** contain exactly one [1..1] **entryRelationship** (CONF-350)
    a. Contains exactly one [1..1] Medication Status Observation (templateId: `2.16.840.1.113883.10.20.1.47`)
20. **MAY** contain at least one [1..*] **performer** (CONF-313)
    a. Contains exactly one [1..1] CDA Performer2
    - *Indicates the person administering a substance.*
21. **MAY** contain at least one [1..*] **entryRelationship** (CONF-348, CONF-349)
    a. Contains **@typeCode="**`CAUS`**"** *CAUS*
    b. Contains exactly one [1..1] Reaction Observation (templateId: `2.16.840.1.113883.10.20.1.54`)
22. **MAY** contain at least one [1..*] **participant** (CONF-368)
    a. Contains exactly one [1..1] Product Instance (templateId: `2.16.840.1.113883.10.20.1.52`)

23. Contains at least one [1..*] **entryRelationship**
    a. Contains exactly one [1..1] Internal Reference (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.4.1)
    - *Entry may indicate one or more reasons for the use of the medication. The extension and root of each observation present must match the identifier of a concern entry contained elsewhere within the CDA document.*
      A consumer of the Medical Summary is encouraged, but not required to maintain these links on import.
24. Contains at least one [1..*] **entryRelationship**
    a. Contains exactly one [1..1] Patient Medical Instructions (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.3)
    - *At most one instruction may be provided for each <substanceAdministration> entry. The instructions shall contain any special case dosing instructions (e.g., split, tapered, or conditional dosing), and may contain other information (take with food, et cetera).*
25. Contains zero or one [0..1] **entryRelationship**
    a. Contains exactly one [1..1] Medication Type (templateId: 2.16.840.1.113883.3.88.11.83.8.1)
26. Contains at least one [1..*] **entryRelationship**
    a. Contains exactly one [1..1] Medication Order Information (templateId: 2.16.840.1.113883.3.88.11.83.8.3)
27. Contains zero or one [0..1] **entryRelationship**
    a. Contains exactly one [1..1] CCD Reaction Observation (templateId: 2.16.840.1.113883.10.20.1.54)
    - *Any noted intended or unintended effects of the product. For example: full body rash, nausea, rash resolved*
28. **SHALL** satisfy: Subordinate <substanceAdminstration> entries are included to record the components of the prepared mixture. If medication is a prepackaged mixture, a single <substanceAdministration> entry is sufficient.
29. **SHALL** satisfy: Value for moodCode is "EVN" or "INT" 2.16.840.1.113883.5.1001 ActMood STATIC (CONF-305)
30. **SHOULD** satisfy: Contains exactly one doseQuantity or rateQuantity. (CONF-311)
31. **MAY** satisfy: Has one or more associated consents, represented in the CCD Header as ClinicalDocument / authorization / consent. (CONF-314)
32. **SHALL** satisfy: Contains one or more sources of information. (CONF-315)
33. **MAY** satisfy: Contains one or more precondition / Criterion, to indicate that the medication is administered only when the associated (coded or free text) criteria are met. (CONF-327)
34. **MAY** satisfy: Contains one or more entryRelationship, where the value for @typeCode is "RSON" "Has reason" 2.16.840.1.113883.5.1002 ActRelationshipType STATIC. (CONF-328)
35. **SHALL** satisfy: entryRelationship / @typeCode="RSON" in a medication activity has a target of problem act (templateId 2.16.840.1.113883.10.20.1.27), problem observation (templateId 2.16.840.1.113883.10.20.1.28), or some other clinical statement. (CONF-329)
36. **SHALL** satisfy: Contains exactly one consumable, the target of which is a Product template. (CONF-354)
37. **SHALL** satisfy: Contains one dosing template to identify this entry as a particular type of medication event. Possible dosing templates: 1.3.6.1.4.1.19376.1.5.3.1.4.7.1 Normal Dosing, 1.3.6.1.4.1.19376.1.5.3.1.4.8, Tapered Dosing, 1.3.6.1.4.1.19376.1.5.3.1.4.9 Split Dosing, 1.3.6.1.4.1.19376.1.5.3.1.4.10 Conditional Dosing, 1.3.6.1.4.1.19376.1.5.3.1.4.11 Combination Dosing.
38. **SHALL** satisfy: contains one or more related components (<entryRelationship typeCode='COMP'>, either to handle split, tapered or conditional dosing, or to support combination medications.
39. **SHALL** satisfy: Values from SNOMED CT shall be used in the <code> element to record that a patient is either not on medications, or that medications are not known.
40. **SHALL** satisfy: The act/@classCode='ACT' and act/@moodCode='EVN' when recording reason for medication in InternalReference Template. (6.3.4.16.22)

41. **SHALL** satisfy: The <consumable> element shall be present, and shall contain a Product Entry template
42. **SHALL** satisfy: The entryRelationship/@inversionInd attribute is 'true' for Patient Medical Instructions relationship
43. **SHOULD** satisfy: The name and strength of the medication is recorded in consumable/manufacturedProduct/manufacturedMaterial/code/originalText
44. **SHALL** satisfy: Name of the substance or product is recorded in consumable/manufacturedProduct/manufacturedMaterial/name
45. **MAY** satisfy: the preconditions for use of the medication are recorded in the <precondition> element. element. The value attribute of the <reference> element is a URL that points to the CDA narrative describing those preconditions.
46. **SHALL** satisfy: The entryRelationship/@inversionInd attribute is 'false' for Supply Entry relationship
47. **SHOULD** satisfy: entryRelationship/sequenceNumber element should be present when the embedded 'supply' element has a moodCode attribute of EVN.
48. **SHALL** satisfy: The time at which the medication was stopped is determined based on the content of the <high> element of the first <effectiveTime> element. (2.2.2.8.3)
49. **SHALL** satisfy: The HL7 data type for PIVL_TS uses the institutionSpecified attribute to indicate whether it is the interval (time between dosing), or frequency (number of doses in a time period) that is important. If instititutionSpecified is not present or is set to false, then the time between dosing is important (every 8 hours). If true, then the frequency of administration is important (e.g., 3 times per day). (2.2.2.8.4)
50. The first <effectiveTime> **SHALL** use the IVL_TS data type unless for a single administration, in which case, it **SHALL** use the TS data type. (C83-[DE-8-CDA-3])
51. Medications that are administered based on activities of daily living **SHALL** identify the events that trigger administration in the <event> element beneath the <effectiveTime> element. The <effectiveTime> element **SHALL** be of type EIVL_TS. (C83-[DE-8.03-CDA-1])
52. Medications that are administered at a specified frequency **SHALL** record the expected interval between doses in the <period> element beneath an <effectiveTime> of type PIVL_TS. The <effectiveTime> element **SHALL** have an institutionSpecified attribute value of "true". (C83-[DE-8.04-CDA-1])
53. Medications that are administered at a specified interval **SHALL** record interval between doses in the <period> element beneath an <effectiveTime> element of type PIVL_TS. The <effectiveTime> element **SHALL** have an institutionSpecified attribute value of "false". (C83-[DE-8.05-CDA-1])
54. doseQuantity/@unit, Dose Units **MAY** be present when needed. If present it **SHALL** be coded as 2.16.840.1.113883.3.88.12.80.29 Unit of Measure (C154-[DE-8.08-1])
55. When the coded product or brand name describes the strength or concentration of the medication, and the dosing is in administration units (e.g., 1 tablet, 2 capsules), units **SHOULD** contain the preferred name of the presentation units within braces { } using the units of presentation from the NCI Thesaurus (C154-[DE-8.08-2])
56. The free text description of the delivery method **MAY** be included within a <originalText> element beneath the <code> element (C83-[DE-8.12-CDA-2])
57. **SHALL** satisfy: Contains one consumable element which contains the Medication Information template. The name and code for the medication are recorded in the <consumable> element.
58. The medication status **MAY** be recorded using the CCD Medication Status observation using the value set defined in the CCD (C154-[DE-8.20-1])
59. **MAY** contain [0..*] indications which **SHALL** be recorded using the Indication problem observation (templateID 2.16.840.1.113883.10.20.1.28) described in the CCD Implementation Guide. (C83-[DE-8.20-CDA-1])
60. The indication problem observation **SHALL** contain a <text> element that includes a <reference> element whose value attribute points to the narrative text that is the indication for the medication (C83-[DE-8.20-CDA-2])
61. The indication **SHALL** be coded as 2.16.840.1.113883.3.88.12.3221.7.4, Problem Value Set, version: 20100125, Dynamic (C154-[DE-8.20-1])
62. **MAY** contain Patient Instructions which **SHALL** be recorded using the Patient Medication Instructions template (templateID 1.3.6.1.4.1.19376.1.5.3.1.4.3) (C83-[DE-8.22-CDA-1])
63. The vehicle for administering a medication **MAY** be recorded in a <participantRole> element inside a <participant> element in the <substanceAdministration> element (C83-[DE-8.24-CDA-1])
64. The typeCode attribute of the <participant> element **SHALL** be CSM (C83-[DE-8.24-CDA-2])
65. The classCode of the <participantRole> **SHALL** be MANU (C83-[DE-8.24-CDA-3])

66. A <code> element for the <participantRole> **SHALL** be present and **SHALL** contain the code 412307009 from the SNOMED CT code system (C83-[DE-8.24-CDA-4])
67. The <name> element in the <playingEntity> element **SHALL** record the name of the drug vehicle (C83-[DE-8.24-CDA-5])
68. The <code> element in the <playingEntity> element **MAY** be used to supply a coded term for the drug vehicle (C83-[DE-8.24-CDA-6])
69. **SHALL** satisfy: The Medication Vehicle shall be coded as 2.16.840.1.113883.3.88.12.80.21, Medication Vehicle Value Set, version: 20081218, Dynamic (C154-[DE-8.24-1])

Medication Combination Medication 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">
  <id root="MDHT" extension="1594223488"/>
  <code code="1861484405"/>
  <statusCode code="completed"/>
  <effectiveTime value="20121102"/>
  <routeCode code="1410875891"/>
  <approachSiteCode code="541685163"/>
  <doseQuantity/>
  <rateQuantity/>
  <maxDoseQuantity/>
  <consumable/>
</substanceadministration>
```

Medication Conditional Dose

[SubstanceAdministration: templateId `2.16.840.1.113883.3.88.11.83.8`]

1. **SHALL** contain exactly one [1..1] templateId ( ) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.3.88.11.83.8"
2. **SHALL** conform to Medication template (templateId: `2.16.840.1.113883.3.88.11.83.8`)
3. **SHALL** conform to IHE Conditional Dose template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.10`)

1. **SHALL** conform to IHE Conditional Dose template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.10`)
2. **SHALL** conform to CCD Medication Activity template (templateId: `2.16.840.1.113883.10.20.1.24`)
3. **SHALL** conform to IHE Medication template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.7`)
4. **SHALL** conform to Medication template (templateId: `2.16.840.1.113883.3.88.11.83.8`)
5. Contains exactly one [1..1] **`@classCode`**="`SBADM`" with data type ActClass (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
6. Contains exactly one [1..1] **`@moodCode`** with data type x_DocumentSubstanceMood
7. **SHALL** contain at least one [1..*] **`id`** (CONF-306)
8. **MAY** contain zero or more [0..*] **`code`** (C83-[DE-8.12-CDA-1])
   - *Delivery Method: A description of how the product is administered/consumed*
9. **SHALL** contain exactly one [1..1] **`statusCode`** (CONF-307)
   - *The status of all 'substanceAdministration' elements must be "complete"d. The act has either occurred, or the request or order has been placed.*

10. **MAY** contain at least one [1..*] **`effectiveTime`** with data type IVL_TS (CONF-308)
    - *Indicate Medication Stopped: Used to express a "hard stop", such as the last Sig sequence in a tapering dose, where the last sequence is 'then D/C' or where the therapy/drug is used to treat a condition and that treatment is for a fixed duration with a hard stop, such as antibiotic treatment, etc.*
    - *Administration Timing: defines a specific administration or use time. Can be a text string (Morning, Evening, Before Meals, 1 Hour After Meals, 3 Hours After Meals, Before Bed) or an exact time.*
    - *Frequency: defines how often the medication is to be administered as events per unit of time. Often expressed as the number of times per day (e.g., four times a day), but may also include event-related information (e.g., 1 hour before meals, in the morning, at bedtime). Complimentary to Interval, although equivalent expressions may have different implications (e.g., every 8 hours versus 3 times a day).*
    - *Interval: defines how the product is to be administered as an interval of time. For example, every 8 hours. Complimentary to Frequency, although equivalent expressions may have different implications (e.g., every 8 hours versus 3 times a day).*
    - *Duration: for non-instantaneous administrations, indicates the length of time the administration should be continued. For example, (infuse) over 30 minutes.*
11. **MAY** contain at least one [1..*] **`routeCode`** (CONF-309, CONF-310), where the @code **SHALL** be selected from ValueSet `Medication Route FDA 2.16.840.1.113883.3.88.12.3221.8.7` **STATIC** 1
    - *The route is a coded value, and indicates how the medication is received by the patient (by mouth, intravenously, topically, et cetera).*
12. **MAY** contain zero or more [0..*] **`approachSiteCode`** (C154-[DE-8.09-1]), where the @code **SHALL** be selected from ValueSet `Body Site 2.16.840.1.113883.3.88.12.3221.8.9` **STATIC** 2
    - *The anatomic site where the medication is administered. Usually applicable to injected or topical products*
13. **MAY** contain at least one [1..*] **`doseQuantity`**
    - *the amount of the product to be given. This may be a known, measurable unit (e.g., milliliters), an administration unit (e.g., tablet), or an amount of active ingredient (e.g., 250 mg). May define a variable dose, dose range or dose options based upon identified criteria (see Dose Indicator)*
14. **SHOULD** contain zero or one [0..1] **`rateQuantity`**
    - *The rate is a measurement of how fast the dose is given to the patient over time (e.g., .5 liter / 1 hr), and is often used with IV drugs.*
15. **MAY** contain at least one [1..*] **`maxDoseQuantity`** (CONF-312)
    - *defines a maximum or dose limit. This segment can repeat for more than one dose restriction*
16. **MAY** contain exactly one [1..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 (C154-[DE-8.11-1])
    - *The physical form of the product as presented to the patient. For example: tablet, capsule, liquid or ointment*
17. Contains exactly one [1..1] **`consumable`**, where its type is Consumable
    a. Contains exactly one [1..1] Consumable
18. **MAY** contain exactly one [1..1] **`entryRelationship`** (CONF-338, CONF-339)
    a. Contains **`@typeCode="`**`SUBJ`**`"`** *SUBJ*
    b. Contains exactly one [1..1] Medication Series Number Observation (templateId: `2.16.840.1.113883.10.20.1.46`)

19. **MAY** contain exactly one [1..1] **`entryRelationship`** (CONF-350)
    a. Contains exactly one [1..1] Medication Status Observation (templateId: `2.16.840.1.113883.10.20.1.47`)
20. **MAY** contain at least one [1..*] **`performer`** (CONF-313)
    a. Contains exactly one [1..1] CDA Performer2

    - *Indicates the person administering a substance.*
21. **MAY** contain at least one [1..*] **`entryRelationship`** (CONF-348, CONF-349)
    a. Contains **`@typeCode="`**`CAUS`**`"`** *CAUS*
    b. Contains exactly one [1..1] Reaction Observation (templateId: `2.16.840.1.113883.10.20.1.54`)
22. **MAY** contain at least one [1..*] **`participant`** (CONF-368)
    a. Contains exactly one [1..1] Product Instance (templateId: `2.16.840.1.113883.10.20.1.52`)
23. Contains at least one [1..*] **`entryRelationship`**
    a. Contains exactly one [1..1] Internal Reference (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.4.1`)

    - *Entry may indicate one or more reasons for the use of the medication. The extension and root of each observation present must match the identifier of a concern entry contained elsewhere within the CDA document.*
      A consumer of the Medical Summary is encouraged, but not required to maintain these links on import.
24. Contains at least one [1..*] **`entryRelationship`**
    a. Contains exactly one [1..1] Patient Medical Instructions (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.3`)

    - *At most one instruction may be provided for each <substanceAdministration> entry. The instructions shall contain any special case dosing instructions (e.g., split, tapered, or conditional dosing), and may contain other information (take with food, et cetera).*
25. Contains zero or one [0..1] **`entryRelationship`**
    a. Contains exactly one [1..1] Medication Type (templateId: `2.16.840.1.113883.3.88.11.83.8.1`)
26. Contains at least one [1..*] **`entryRelationship`**
    a. Contains exactly one [1..1] Medication Order Information (templateId: `2.16.840.1.113883.3.88.11.83.8.3`)
27. Contains zero or one [0..1] **`entryRelationship`**
    a. Contains exactly one [1..1] CCD Reaction Observation (templateId: `2.16.840.1.113883.10.20.1.54`)

    - *Any noted intended or unintended effects of the product. For example: full body rash, nausea, rash resolved*
28. **SHALL** satisfy: A subordinate 'substanceAdministration' entry is required for each different dose, and the condition should be recorded
29. **SHALL** satisfy: Value for moodCode is "EVN" or "INT" 2.16.840.1.113883.5.1001 ActMood STATIC (CONF-305)
30. **SHOULD** satisfy: Contains exactly one doseQuantity or rateQuantity. (CONF-311)
31. **MAY** satisfy: Has one or more associated consents, represented in the CCD Header as ClinicalDocument / authorization / consent. (CONF-314)
32. **SHALL** satisfy: Contains one or more sources of information. (CONF-315)
33. **MAY** satisfy: Contains one or more precondition / Criterion, to indicate that the medication is administered only when the associated (coded or free text) criteria are met. (CONF-327)
34. **MAY** satisfy: Contains one or more entryRelationship, where the value for @typeCode is "RSON" "Has reason" 2.16.840.1.113883.5.1002 ActRelationshipType STATIC. (CONF-328)

35. **SHALL** satisfy: entryRelationship / @typeCode="RSON" in a medication activity has a target of problem act (templateId 2.16.840.1.113883.10.20.1.27), problem observation (templateId 2.16.840.1.113883.10.20.1.28), or some other clinical statement. (CONF-329)
36. **SHALL** satisfy: Contains exactly one consumable, the target of which is a Product template. (CONF-354)
37. **SHALL** satisfy: Contains one dosing template to identify this entry as a particular type of medication event. Possible dosing templates: 1.3.6.1.4.1.19376.1.5.3.1.4.7.1 Normal Dosing, 1.3.6.1.4.1.19376.1.5.3.1.4.8, Tapered Dosing, 1.3.6.1.4.1.19376.1.5.3.1.4.9 Split Dosing, 1.3.6.1.4.1.19376.1.5.3.1.4.10 Conditional Dosing, 1.3.6.1.4.1.19376.1.5.3.1.4.11 Combination Dosing.
38. **SHALL** satisfy: contains one or more related components (<entryRelationship typeCode='COMP'>, either to handle split, tapered or conditional dosing, or to support combination medications.
39. **SHALL** satisfy: Values from SNOMED CT shall be used in the <code> element to record that a patient is either not on medications, or that medications are not known.
40. **SHALL** satisfy: The act/@classCode='ACT' and act/@moodCode='EVN' when recording reason for medication in InternalReference Template. (6.3.4.16.22)
41. **SHALL** satisfy: The <consumable> element shall be present, and shall contain a Product Entry template
42. **SHALL** satisfy: The entryRelationship/@inversionInd attribute is 'true' for Patient Medical Instructions relationship
43. **SHOULD** satisfy: The name and strength of the medication is recorded in consumable/manufacturedProduct/manufacturedMaterial/code/originalText
44. **SHALL** satisfy: Name of the substance or product is recorded in consumable/manufacturedProduct/manufacturedMaterial/name
45. **MAY** satisfy: the preconditions for use of the medication are recorded in the <precondition> element. element. The value attribute of the <reference> element is a URL that points to the CDA narrative describing those preconditions.
46. **SHALL** satisfy: The entryRelationship/@inversionInd attribute is 'false' for Supply Entry relationship
47. **SHOULD** satisfy: entryRelationship/sequenceNumber element should be present when the embedded 'supply' element has a moodCode attribute of EVN.
48. **SHALL** satisfy: The time at which the medication was stopped is determined based on the content of the <high> element of the first <effectiveTime> element. (2.2.2.8.3)
49. **SHALL** satisfy: The HL7 data type for PIVL_TS uses the institutionSpecified attribute to indicate whether it is the interval (time between dosing), or frequency (number of doses in a time period) that is important. If instititutionSpecified is not present or is set to false, then the time between dosing is important (every 8 hours). If true, then the frequency of administration is important (e.g., 3 times per day). (2.2.2.8.4)
50. The first <effectiveTime> **SHALL** use the IVL_TS data type unless for a single administration, in which case, it **SHALL** use the TS data type. (C83-[DE-8-CDA-3])
51. Medications that are administered based on activities of daily living **SHALL** identify the events that trigger administration in the <event> element beneath the <effectiveTime> element. The <effectiveTime> element **SHALL** be of type EIVL_TS. (C83-[DE-8.03-CDA-1])
52. Medications that are administered at a specified frequency **SHALL** record the expected interval between doses in the <period> element beneath an <effectiveTime> of type PIVL_TS. The <effectiveTime> element **SHALL** have an institutionSpecified attribute value of "true". (C83-[DE-8.04-CDA-1])
53. Medications that are administered at a specified interval **SHALL** record interval between doses in the <period> element beneath an <effectiveTime> element of type PIVL_TS. The <effectiveTime> element **SHALL** have an institutionSpecified attribute value of "false". (C83-[DE-8.05-CDA-1])
54. doseQuantity/@unit, Dose Units **MAY** be present when needed. If present it **SHALL** be coded as 2.16.840.1.113883.3.88.12.80.29 Unit of Measure (C154-[DE-8.08-1])
55. When the coded product or brand name describes the strength or concentration of the medication, and the dosing is in administration units (e.g., 1 tablet, 2 capsules), units **SHOULD** contain the preferred name of the presentation units within braces { } using the units of presentation from the NCI Thesaurus (C154-[DE-8.08-2])
56. The free text description of the delivery method **MAY** be included within a <originalText> element beneath the <code> element (C83-[DE-8.12-CDA-2])
57. **SHALL** satisfy: Contains one consumable element which contains the Medication Information template. The name and code for the medication are recorded in the <consumable> element.

58. The medication status **MAY** be recorded using the CCD Medication Status observation using the value set defined in the CCD (C154-[DE-8.20-1])
59. **MAY** contain [0..*] indications which **SHALL** be recorded using the Indication problem observation (templateID 2.16.840.1.113883.10.20.1.28) described in the CCD Implementation Guide. (C83-[DE-8.20-CDA-1])
60. The indication problem observation **SHALL** contain a <text> element that includes a <reference> element whose value attribute points to the narrative text that is the indication for the medication (C83-[DE-8.20-CDA-2])
61. The indication **SHALL** be coded as 2.16.840.1.113883.3.88.12.3221.7.4, Problem Value Set, version: 20100125, Dynamic (C154-[DE-8.20-1])
62. **MAY** contain Patient Instructions which **SHALL** be recorded using the Patient Medication Instructions template (templateID 1.3.6.1.4.1.19376.1.5.3.1.4.3) (C83-[DE-8.22-CDA-1])
63. The vehicle for administering a medication **MAY** be recorded in a <participantRole> element inside a <participant> element in the <substanceAdministration> element (C83-[DE-8.24-CDA-1])
64. The typeCode attribute of the <participant> element **SHALL** be CSM (C83-[DE-8.24-CDA-2])
65. The classCode of the <participantRole> **SHALL** be MANU (C83-[DE-8.24-CDA-3])
66. A <code> element for the <participantRole> **SHALL** be present and **SHALL** contain the code 412307009 from the SNOMED CT code system (C83-[DE-8.24-CDA-4])
67. The <name> element in the <playingEntity> element **SHALL** record the name of the drug vehicle (C83-[DE-8.24-CDA-5])
68. The <code> element in the <playingEntity> element **MAY** be used to supply a coded term for the drug vehicle (C83-[DE-8.24-CDA-6])
69. **SHALL** satisfy: The Medication Vehicle shall be coded as 2.16.840.1.113883.3.88.12.80.21, Medication Vehicle Value Set, version: 20081218, Dynamic (C154-[DE-8.24-1])

Medication Conditional Dose 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">
  <id root="MDHT" extension="808166210"/>
  <code code="1345678732"/>
  <statusCode code="completed"/>
  <effectiveTime value="20121102"/>
  <routeCode code="113866143"/>
  <approachSiteCode code="888371020"/>
  <doseQuantity/>
  <rateQuantity/>
  <maxDoseQuantity/>
  <consumable/>
</substanceadministration>
```

Medication Normal Dose

[SubstanceAdministration: templateId `2.16.840.1.113883.3.88.11.83.8`]

1. **SHALL** contain exactly one [1..1] templateId ( ) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.3.88.11.83.8"
2. **SHALL** conform to Medication template (templateId: `2.16.840.1.113883.3.88.11.83.8`)
3. **SHALL** conform to IHE Normal Dose template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.7.1`)

1. **SHALL** conform to IHE Normal Dose template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.7.1`)
2. **SHALL** conform to CCD Medication Activity template (templateId: `2.16.840.1.113883.10.20.1.24`)
3. **SHALL** conform to IHE Medication template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.7`)
4. **SHALL** conform to Medication template (templateId: `2.16.840.1.113883.3.88.11.83.8`)

5. Contains exactly one [1..1] **`@classCode`**="`SBADM`" with data type ActClass (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
6. Contains exactly one [1..1] **`@moodCode`** with data type x_DocumentSubstanceMood
7. **SHALL** contain at least one [1..*] **`id`** (CONF-306)
8. **MAY** contain zero or more [0..*] **`code`** (C83-[DE-8.12-CDA-1])
   - *Delivery Method: A description of how the product is administered/consumed*
9. **SHALL** contain exactly one [1..1] **`statusCode`** (CONF-307)
   - *The status of all 'substanceAdministration' elements must be "complete"d. The act has either occurred, or the request or order has been placed.*
10. **MAY** contain at least one [1..*] **`effectiveTime`** with data type IVL_TS (CONF-308)
    - *Indicate Medication Stopped: Used to express a "hard stop", such as the last Sig sequence in a tapering dose, where the last sequence is 'then D/C' or where the therapy/drug is used to treat a condition and that treatment is for a fixed duration with a hard stop, such as antibiotic treatment, etc.*
    - *Administration Timing: defines a specific administration or use time. Can be a text string (Morning, Evening, Before Meals, 1 Hour After Meals, 3 Hours After Meals, Before Bed) or an exact time.*
    - *Frequency: defines how often the medication is to be administered as events per unit of time. Often expressed as the number of times per day (e.g., four times a day), but may also include event-related information (e.g., 1 hour before meals, in the morning, at bedtime). Complimentary to Interval, although equivalent expressions may have different implications (e.g., every 8 hours versus 3 times a day).*
    - *Interval: defines how the product is to be administered as an interval of time. For example, every 8 hours. Complimentary to Frequency, although equivalent expressions may have different implications (e.g., every 8 hours versus 3 times a day).*
    - *Duration: for non-instantaneous administrations, indicates the length of time the administration should be continued. For example, (infuse) over 30 minutes.*
11. **MAY** contain at least one [1..*] **`routeCode`** (CONF-309, CONF-310), where the @code **SHALL** be selected from ValueSet `Medication Route FDA 2.16.840.1.113883.3.88.12.3221.8.7` **STATIC** 1
    - *The route is a coded value, and indicates how the medication is received by the patient (by mouth, intravenously, topically, et cetera).*
12. **MAY** contain zero or more [0..*] **`approachSiteCode`** (C154-[DE-8.09-1]), where the @code **SHALL** be selected from ValueSet `Body Site 2.16.840.1.113883.3.88.12.3221.8.9` **STATIC** 2
    - *The anatomic site where the medication is administered. Usually applicable to injected or topical products*
13. **MAY** contain at least one [1..*] **`doseQuantity`**
    - *the amount of the product to be given. This may be a known, measurable unit (e.g., milliliters), an administration unit (e.g., tablet), or an amount of active ingredient (e.g., 250 mg). May define a variable dose, dose range or dose options based upon identified criteria (see Dose Indicator)*
14. **SHOULD** contain zero or one [0..1] **`rateQuantity`**
    - *The rate is a measurement of how fast the dose is given to the patient over time (e.g., .5 liter / 1 hr), and is often used with IV drugs.*
15. **MAY** contain at least one [1..*] **`maxDoseQuantity`** (CONF-312)
    - *defines a maximum or dose limit. This segment can repeat for more than one dose restriction*

16. **MAY** contain exactly one [1..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 (C154-[DE-8.11-1])
    - *The physical form of the product as presented to the patient. For example: tablet, capsule, liquid or ointment*
17. Contains exactly one [1..1] **`consumable`**, where its type is Consumable
    a. Contains exactly one [1..1] Consumable
18. **MAY** contain exactly one [1..1] **`entryRelationship`** (CONF-338, CONF-339)
    a. Contains **`@typeCode="SUBJ"`** *SUBJ*
    b. Contains exactly one [1..1] Medication Series Number Observation (templateId: `2.16.840.1.113883.10.20.1.46`)
19. **MAY** contain exactly one [1..1] **`entryRelationship`** (CONF-350)
    a. Contains exactly one [1..1] Medication Status Observation (templateId: `2.16.840.1.113883.10.20.1.47`)
20. **MAY** contain at least one [1..*] **`performer`** (CONF-313)
    a. Contains exactly one [1..1] CDA Performer2
    - *Indicates the person administering a substance.*
21. **MAY** contain at least one [1..*] **`entryRelationship`** (CONF-348, CONF-349)
    a. Contains **`@typeCode="CAUS"`** *CAUS*
    b. Contains exactly one [1..1] Reaction Observation (templateId: `2.16.840.1.113883.10.20.1.54`)
22. **MAY** contain at least one [1..*] **`participant`** (CONF-368)
    a. Contains exactly one [1..1] Product Instance (templateId: `2.16.840.1.113883.10.20.1.52`)
23. Contains at least one [1..*] **`entryRelationship`**
    a. Contains exactly one [1..1] Internal Reference (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.4.1`)
    - *Entry may indicate one or more reasons for the use of the medication. The extension and root of each observation present must match the identifier of a concern entry contained elsewhere within the CDA document.*
      A consumer of the Medical Summary is encouraged, but not required to maintain these links on import.
24. Contains at least one [1..*] **`entryRelationship`**
    a. Contains exactly one [1..1] Patient Medical Instructions (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.3`)
    - *At most one instruction may be provided for each <substanceAdministration> entry. The instructions shall contain any special case dosing instructions (e.g., split, tapered, or conditional dosing), and may contain other information (take with food, et cetera).*
25. Contains zero or one [0..1] **`entryRelationship`**
    a. Contains exactly one [1..1] Medication Type (templateId: `2.16.840.1.113883.3.88.11.83.8.1`)
26. Contains at least one [1..*] **`entryRelationship`**
    a. Contains exactly one [1..1] Medication Order Information (templateId: `2.16.840.1.113883.3.88.11.83.8.3`)
27. Contains zero or one [0..1] **`entryRelationship`**
    a. Contains exactly one [1..1] CCD Reaction Observation (templateId: `2.16.840.1.113883.10.20.1.54`)
    - *Any noted intended or unintended effects of the product. For example: full body rash, nausea, rash*

resolved

28. **SHALL** satisfy: Medications that use this template identifier shall not use subordinate 'substanceAdministation' acts.
29. **SHALL** satisfy: Value for moodCode is "EVN" or "INT" 2.16.840.1.113883.5.1001 ActMood STATIC (CONF-305)
30. **SHOULD** satisfy: Contains exactly one doseQuantity or rateQuantity. (CONF-311)
31. **MAY** satisfy: Has one or more associated consents, represented in the CCD Header as ClinicalDocument / authorization / consent. (CONF-314)
32. **SHALL** satisfy: Contains one or more sources of information. (CONF-315)
33. **MAY** satisfy: Contains one or more precondition / Criterion, to indicate that the medication is administered only when the associated (coded or free text) criteria are met. (CONF-327)
34. **MAY** satisfy: Contains one or more entryRelationship, where the value for @typeCode is "RSON" "Has reason" 2.16.840.1.113883.5.1002 ActRelationshipType STATIC. (CONF-328)
35. **SHALL** satisfy: entryRelationship / @typeCode="RSON" in a medication activity has a target of problem act (templateId 2.16.840.1.113883.10.20.1.27), problem observation (templateId 2.16.840.1.113883.10.20.1.28), or some other clinical statement. (CONF-329)
36. **SHALL** satisfy: Contains exactly one consumable, the target of which is a Product template. (CONF-354)
37. **SHALL** satisfy: Contains one dosing template to identify this entry as a particular type of medication event. Possible dosing templates: 1.3.6.1.4.1.19376.1.5.3.1.4.7.1 Normal Dosing, 1.3.6.1.4.1.19376.1.5.3.1.4.8, Tapered Dosing, 1.3.6.1.4.1.19376.1.5.3.1.4.9 Split Dosing, 1.3.6.1.4.1.19376.1.5.3.1.4.10 Conditional Dosing, 1.3.6.1.4.1.19376.1.5.3.1.4.11 Combination Dosing.
38. **SHALL** satisfy: contains one or more related components (<entryRelationship typeCode='COMP'>, either to handle split, tapered or conditional dosing, or to support combination medications.
39. **SHALL** satisfy: Values from SNOMED CT shall be used in the <code> element to record that a patient is either not on medications, or that medications are not known.
40. **SHALL** satisfy: The act/@classCode='ACT' and act/@moodCode='EVN' when recording reason for medication in InternalReference Template. (6.3.4.16.22)
41. **SHALL** satisfy: The <consumable> element shall be present, and shall contain a Product Entry template
42. **SHALL** satisfy: The entryRelationship/@inversionInd attribute is 'true' for Patient Medical Instructions relationship
43. **SHOULD** satisfy: The name and strength of the medication is recorded in consumable/manufacturedProduct/manufacturedMaterial/code/originalText
44. **SHALL** satisfy: Name of the substance or product is recorded in consumable/manufacturedProduct/manufacturedMaterial/name
45. **MAY** satisfy: the preconditions for use of the medication are recorded in the <precondition> element. element. The value attribute of the <reference> element is a URL that points to the CDA narrative describing those preconditions.
46. **SHALL** satisfy: The entryRelationship/@inversionInd attribute is 'false' for Supply Entry relationship
47. **SHOULD** satisfy: entryRelationship/sequenceNumber element should be present when the embedded 'supply' element has a moodCode attribute of EVN.
48. **SHALL** satisfy: The time at which the medication was stopped is determined based on the content of the <high> element of the first <effectiveTime> element. (2.2.2.8.3)
49. **SHALL** satisfy: The HL7 data type for PIVL_TS uses the institutionSpecified attribute to indicate whether it is the interval (time between dosing), or frequency (number of doses in a time period) that is important. If instititutionSpecified is not present or is set to false, then the time between dosing is important (every 8 hours). If true, then the frequency of administration is important (e.g., 3 times per day). (2.2.2.8.4)
50. The first <effectiveTime> **SHALL** use the IVL_TS data type unless for a single administration, in which case, it **SHALL** use the TS data type. (C83-[DE-8-CDA-3])
51. Medications that are administered based on activities of daily living **SHALL** identify the events that trigger administration in the <event> element beneath the <effectiveTime> element. The <effectiveTime> element **SHALL** be of type EIVL_TS. (C83-[DE-8.03-CDA-1])

52. Medications that are administered at a specified frequency **SHALL** record the expected interval between doses in the <period> element beneath an <effectiveTime> of type PIVL_TS. The <effectiveTime> element **SHALL** have an institutionSpecified attribute value of "true". (C83-[DE-8.04-CDA-1])
53. Medications that are administered at a specified interval **SHALL** record interval between doses in the <period> element beneath an <effectiveTime> element of type PIVL_TS. The <effectiveTime> element **SHALL** have an institutionSpecified attribute value of "false". (C83-[DE-8.05-CDA-1])
54. doseQuantity/@unit, Dose Units **MAY** be present when needed. If present it **SHALL** be coded as 2.16.840.1.113883.3.88.12.80.29 Unit of Measure (C154-[DE-8.08-1])
55. When the coded product or brand name describes the strength or concentration of the medication, and the dosing is in administration units (e.g., 1 tablet, 2 capsules), units **SHOULD** contain the preferred name of the presentation units within braces { } using the units of presentation from the NCI Thesaurus (C154-[DE-8.08-2])
56. The free text description of the delivery method **MAY** be included within a <originalText> element beneath the <code> element (C83-[DE-8.12-CDA-2])
57. **SHALL** satisfy: Contains one consumable element which contains the Medication Information template. The name and code for the medication are recorded in the <consumable> element.
58. The medication status **MAY** be recorded using the CCD Medication Status observation using the value set defined in the CCD (C154-[DE-8.20-1])
59. **MAY** contain [0..*] indications which **SHALL** be recorded using the Indication problem observation (templateID 2.16.840.1.113883.10.20.1.28) described in the CCD Implementation Guide. (C83-[DE-8.20-CDA-1])
60. The indication problem observation **SHALL** contain a <text> element that includes a <reference> element whose value attribute points to the narrative text that is the indication for the medication (C83-[DE-8.20-CDA-2])
61. The indication **SHALL** be coded as 2.16.840.1.113883.3.88.12.3221.7.4, Problem Value Set, version: 20100125, Dynamic (C154-[DE-8.20-1])
62. **MAY** contain Patient Instructions which **SHALL** be recorded using the Patient Medication Instructions template (templateID 1.3.6.1.4.1.19376.1.5.3.1.4.3) (C83-[DE-8.22-CDA-1])
63. The vehicle for administering a medication **MAY** be recorded in a <participantRole> element inside a <participant> element in the <substanceAdministration> element (C83-[DE-8.24-CDA-1])
64. The typeCode attribute of the <participant> element **SHALL** be CSM (C83-[DE-8.24-CDA-2])
65. The classCode of the <participantRole> **SHALL** be MANU (C83-[DE-8.24-CDA-3])
66. A <code> element for the <participantRole> **SHALL** be present and **SHALL** contain the code 412307009 from the SNOMED CT code system (C83-[DE-8.24-CDA-4])
67. The <name> element in the <playingEntity> element **SHALL** record the name of the drug vehicle (C83-[DE-8.24-CDA-5])
68. The <code> element in the <playingEntity> element **MAY** be used to supply a coded term for the drug vehicle (C83-[DE-8.24-CDA-6])
69. **SHALL** satisfy: The Medication Vehicle shall be coded as 2.16.840.1.113883.3.88.12.80.21, Medication Vehicle Value Set, version: 20081218, Dynamic (C154-[DE-8.24-1])

Medication Normal Dose 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">
  <id root="MDHT" extension="1258642930"/>
  <code code="1000094995"/>
  <statusCode code="completed"/>
  <effectiveTime value="20121102"/>
  <routeCode code="398792138"/>
  <approachSiteCode code="1769444303"/>
  <doseQuantity/>
  <rateQuantity/>
  <maxDoseQuantity/>
  <consumable/>
</substanceadministration>
```

Medication Order Information

[Supply: templateId 2.16.840.1.113883.3.88.11.83.8.3]

Order information may be recorded as part of the fulfillment history (moodcode = EVN) or as part of the administration information (moodcode = INT)

1. **SHALL** contain exactly one [1..1] templateId (C83-[DE-8-CDA-6]) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.3.88.11.83.8.3"
2. **SHALL** conform to IHE Supply Entry template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.7.3) (C83-[DE-8-CDA-7])
3. **MAY** contain exactly one [1..1] **repeatNumber** (CONF-321)
   - *The number of times that the ordering provider has authorized the pharmacy to dispense this medication*

     Please note that the number of fills requested is what is recorded in the document, not the number of refills. The number of refills is simply one less than the number of fills.
4. **MAY** contain exactly one [1..1] **statusCode** (CONF-319), where the @code **SHALL** be selected from ValueSet Medication Fill Status 2.16.840.1.113883.3.88.12.80.64 **STATIC** 1
   - *When supply element has a moodCode attribute set to EVN*
5. The order number, i.e., the identifier from the perspective of the ordering provider, **SHOULD** be recorded in the id element within the supply element with moodcode = 'INT' (C83-[DE-8.26-CDA-1])
6. **SHOULD** satisfy: The effectiveTime/high element is present to record the order expiration date and time when supply/@moodcode = INT
7. The quantity ordered **SHALL** be recorded in the value attribute of quantity element inside a supply element used to record order information (C83-[DE-8.26-CDA-1])
8. **SHALL** satisfy: the @unit attribute of quantity element is present (C83-[DE-8.26-CDA-2])
9. When the quantity ordered or dispensed is in other than administration units (e.g., when the quantity ordered is a volume of liquid or mass of substance) units **SHALL** be coded as 2.16.840.1.113883.3.88.12.80.29, Unit of Measure, Dynamic (C83-[DE-8.26-CDA-3], C83-[DE-8.38-CDA-2])
10. When the quantity ordered or dispensed is in administration units, the unit attribute **SHOULD** contain the preferred name of the presentation units within braces { } using the units of presentation as 2.16.840.1.113883.3.88.12.3221.8.11, Medication Product Form Value Set, Dynamic (C83-[DE-8.26-CDA-4], C83-[DE-8.38-CDA-3])
11. The prescription number **SHALL** be recorded in the extension attribute of the <id> element within a supply element having a moodCode attribute of EVN (C83-[DE-8.34-CDA-1])
12. The root attribute of the id element **SHOULD** be the OID of the assigning authority for the identifier. (C83-[DE-8.34-CDA-2])
13. A GUID **MAY** be used in place of the OID of the assigning authority (C83-[DE-8.34-CDA-3])
14. **SHALL** satisfy: The dispense date is recorded in effectiveTime element within a supply element with a moodCode attribute set to EVN
15. **MAY** satisfy: The dispensing pharmacy's location is present in the addr element in performer/assignEntity element inside a supply element with a moodCode attribute set to EVN
16. The state element of the performer/assignedEntity/addr element in the United States **SHALL** be recorded using 2.16.840.1.113883.3.88.12.80.1, State Value Set, version: 20081218, Dynamic (C154-[DE-8.36-1])
17. The postalCode element of the performer/assignedEntity/addr element in the United States **SHALL** be recorded using 2.16.840.1.113883.3.88.12.80.2, Postal Code Value Set, version: 20081218, Dynamic (C154-[DE-8.36-2])
18. The country element of the performer/assignedEntity/addr element in the United States **SHALL** be recorded using 2.16.840.1.113883.3.88.12.80.3, Country Value Set, version: 20081218, Dynamic (C154-[DE-8.36-3])
19. The quantity dispensed **SHALL** be recorded in the value attribute of quantity element inside a supply element with a moodCode attribute set to EVN

20. The fill number **SHOULD** be recorded in the sequenceNumber attribute of a entryRelationship element with a typeCode attribute set to COMP (C83-[DE-8.39-CDA-1])

1. **SHALL** conform to CCD Supply Activity template (templateId: `2.16.840.1.113883.10.20.1.34`)
2. **SHALL** conform to IHE Supply Entry template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.7.3`)
3. Contains exactly one [1..1] **`@classCode`**`="SPLY"` with data type ActClassSupply (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
4. Contains exactly one [1..1] **`@moodCode`** with data type x_DocumentSubstanceMood
5. **SHALL** contain at least one [1..*] **`id`** (CONF-318)
6. **MAY** contain exactly one [1..1] **`statusCode`** (CONF-319), where the @code **SHALL** be selected from ValueSet `Medication Fill Status 2.16.840.1.113883.3.88.12.80.64` **STATIC** 1
   - *When supply element has a moodCode attribute set to EVN*
7. **SHOULD** contain exactly one [1..1] **`effectiveTime`** (CONF-320)
   - *Indicates the actual or intended time of dispensing.*
8. **MAY** contain exactly one [1..1] **`repeatNumber`** (CONF-321)
   - *The number of times that the ordering provider has authorized the pharmacy to dispense this medication*

     Please note that the number of fills requested is what is recorded in the document, not the number of refills. The number of refills is simply one less than the number of fills.
9. **SHOULD** contain exactly one [1..1] **`quantity`** (CONF-322)
   - *The supply entry should indicate the quantity supplied. The value attribute shall be present and indicates the quantity of medication supplied. If the medication is supplied in dosing units (tablets or capsules), then the unit attribute need not be present (and should be set to 1 if present). Otherwise, the unit element shall be present to indicate the quantity (e.g., volume or mass) of medication supplied.*
10. **MAY** contain exactly one [1..1] **`entryRelationship`** (CONF-351)
    a. Contains exactly one [1..1] Medication Status Observation (templateId: `2.16.840.1.113883.10.20.1.47`)
11. **MAY** contain at least one [1..*] **`participant`** (CONF-369)
    a. Contains exactly one [1..1] Product Instance (templateId: `2.16.840.1.113883.10.20.1.52`)
12. **MAY** contain zero or one [0..1] **`entryRelationship`**
    a. Contains **`@typeCode="`**`SUBJ`**`"`** *SUBJ*
    b. Contains exactly one [1..1] Medication Fullfillment Instructions (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.3.1`)
13. **SHALL** satisfy: Value for moodCode is 'EVN' or 'INT' 2.16.840.1.113883.5.1001 ActMood STATIC (CONF-317)
14. **MAY** satisfy: Contains one or more author. (CONF-323)
15. **MAY** satisfy: Contains one or more performer. (CONF-324)
16. **MAY** satisfy: Contains exactly one participant / @typeCode = "LOC". (CONF-325)
17. **SHALL** satisfy: Contains one or more sources of information. (CONF-326)
18. **MAY** satisfy: Contains exactly one product, the target of which is a Product template. (CONF-355)
19. Supply / participant / participantRole / id **SHOULD** be set to equal a [Act | Observation | Procedure] / participant / participantRole / id to indicate that the Supply and the Procedure are referring to the same product instance. (CONF-370)
20. **MAY** satisfy: A supply entry that describes an intent (<supply classCode='SPLY' moodCode='INT'>) may include an <author> element to identify the prescribing provider.
21. **SHALL** satisfy: The <time> element must be present to indicate when the author created the prescription. If this information is unknown, it shall be recorded by setting the nullFlavor attribute to UNK.
22. **SHALL** satisfy: The <assignedAuthor> element shall be present in author, and identifies the author.

23. **SHOULD** satisfy: One or more <id> elements should be present in assignedAuthor
24. **SHALL** satisfy: An <assignedPerson> and/or <representedOriganization> element shall be present in assignedAuthor. This element shall contain a <name> element to identify the prescriber or their organization.
25. **SHALL** satisfy: The <time> element shall be present in performer to indicate when the prescription was filled (moodCode='EVN'). If this information is unknown, it shall be recorded by setting the nullFlavor attribute to UNK.
26. **SHOULD** satisfy: The <time> element should be present to indicate when the prescription is intended to be filled (moodCode='INT').
27. **SHALL** satisfy: The performer/assignedEntity element shall be present, and identifies the filler of the prescription.
28. **SHOULD** satisfy: One or more <id> elements should be present. These identify the performer.
29. **SHALL** satisfy: An <assignedPerson> and/or <representedOriganization> element shall be present. This element shall contain a <name> element to identify the filler or their organization.
30. **SHALL** satisfy: The supply entry should indicate the quantity supplied. The value attribute shall be present and indicates the quantity of medication supplied. If the medication is supplied in dosing units (tablets or capsules), then the unit attribute need not be present (and should be set to 1 if present). Otherwise, the unit element shall be present to indicate the quantity (e.g., volume or mass) of medication supplied.
31. The order number, i.e., the identifier from the perspective of the ordering provider, **SHOULD** be recorded in the id element within the supply element with moodcode = 'INT' (C83-[DE-8.26-CDA-1])
32. **SHOULD** satisfy: The effectiveTime/high element is present to record the order expiration date and time when supply/@moodcode = INT
33. The quantity ordered **SHALL** be recorded in the value attribute of quantity element inside a supply element used to record order information (C83-[DE-8.26-CDA-1])
34. **SHALL** satisfy: the @unit attribute of quantity element is present (C83-[DE-8.26-CDA-2])
35. When the quantity ordered or dispensed is in other than administration units (e.g., when the quantity ordered is a volume of liquid or mass of substance) units **SHALL** be coded as 2.16.840.1.113883.3.88.12.80.29, Unit of Measure, Dynamic (C83-[DE-8.26-CDA-3], C83-[DE-8.38-CDA-2])
36. When the quantity ordered or dispensed is in administration units, the unit attribute **SHOULD** contain the preferred name of the presentation units within braces { } using the units of presentation as 2.16.840.1.113883.3.88.12.3221.8.11, Medication Product Form Value Set, Dynamic (C83-[DE-8.26-CDA-4], C83-[DE-8.38-CDA-3])
37. The prescription number **SHALL** be recorded in the extension attribute of the <id> element within a supply element having a moodCode attribute of EVN (C83-[DE-8.34-CDA-1])
38. The root attribute of the id element **SHOULD** be the OID of the assigning authority for the identifier. (C83-[DE-8.34-CDA-2])
39. A GUID **MAY** be used in place of the OID of the assigning authority (C83-[DE-8.34-CDA-3])
40. **SHALL** satisfy: The dispense date is recorded in effectiveTime element within a supply element with a moodCode attribute set to EVN
41. **MAY** satisfy: The dispensing pharmacy's location is present in the addr element in performer/assignEntity element inside a supply element with a moodCode attribute set to EVN
42. The state element of the performer/assignedEntity/addr element in the United States **SHALL** be recorded using 2.16.840.1.113883.3.88.12.80.1, State Value Set, version: 20081218, Dynamic (C154-[DE-8.36-1])
43. The postalCode element of the performer/assignedEntity/addr element in the United States **SHALL** be recorded using 2.16.840.1.113883.3.88.12.80.2, Postal Code Value Set, version: 20081218, Dynamic (C154-[DE-8.36-2])
44. The country element of the performer/assignedEntity/addr element in the United States **SHALL** be recorded using 2.16.840.1.113883.3.88.12.80.3, Country Value Set, version: 20081218, Dynamic (C154-[DE-8.36-3])
45. The quantity dispensed **SHALL** be recorded in the value attribute of quantity element inside a supply element with a moodCode attribute set to EVN
46. The fill number **SHOULD** be recorded in the sequenceNumber attribute of a entryRelationship element with a typeCode attribute set to COMP (C83-[DE-8.39-CDA-1])

Medication Order Information example

```
<?xml version="1.0" encoding="UTF-8"?>
<supply xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <id root="MDHT" extension="1000719543"/>
  <statusCode code="completed"/>
  <effectiveTime value="20121102"/>
  <repeatNumber value="1"/>
  <quantity/>
</supply>
```

Medication Split Dose

[SubstanceAdministration: templateId 2.16.840.1.113883.3.88.11.83.8]

1. **SHALL** contain exactly one [1..1] templateId ( ) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.3.88.11.83.8"
2. **SHALL** conform to Medication template (templateId: 2.16.840.1.113883.3.88.11.83.8)
3. **SHALL** conform to IHE Split Dose template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.9)

1. **SHALL** conform to IHE Split Dose template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.9)
2. **SHALL** conform to CCD Medication Activity template (templateId: 2.16.840.1.113883.10.20.1.24)
3. **SHALL** conform to IHE Medication template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.7)
4. **SHALL** conform to Medication template (templateId: 2.16.840.1.113883.3.88.11.83.8)
5. Contains exactly one [1..1] **@classCode**="SBADM" with data type ActClass (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)
6. Contains exactly one [1..1] **@moodCode** with data type x_DocumentSubstanceMood
7. **SHALL** contain at least one [1..*] **id** (CONF-306)
8. **MAY** contain zero or more [0..*] **code** (C83-[DE-8.12-CDA-1])
   - *Delivery Method: A description of how the product is administered/consumed*
9. **SHALL** contain exactly one [1..1] **statusCode** (CONF-307)
   - *The status of all 'substanceAdministration' elements must be "complete"d. The act has either occurred, or the request or order has been placed.*
10. **MAY** contain at least one [1..*] **effectiveTime** with data type IVL_TS (CONF-308)
    - *Indicate Medication Stopped: Used to express a "hard stop", such as the last Sig sequence in a tapering dose, where the last sequence is 'then D/C' or where the therapy/drug is used to treat a condition and that treatment is for a fixed duration with a hard stop, such as antibiotic treatment, etc.*
    - *Administration Timing: defines a specific administration or use time. Can be a text string (Morning, Evening, Before Meals, 1 Hour After Meals, 3 Hours After Meals, Before Bed) or an exact time.*
    - *Frequency: defines how often the medication is to be administered as events per unit of time. Often expressed as the number of times per day (e.g., four times a day), but may also include event-related information (e.g., 1 hour before meals, in the morning, at bedtime). Complimentary to Interval, although equivalent expressions may have different implications (e.g., every 8 hours versus 3 times a day).*
    - *Interval: defines how the product is to be administered as an interval of time. For example, every 8 hours. Complimentary to Frequency, although equivalent expressions may have different implications (e.g., every 8 hours versus 3 times a day).*
    - *Duration: for non-instantaneous administrations, indicates the length of time the administration should be continued. For example, (infuse) over 30 minutes.*

11. **MAY** contain at least one [1..*] **routeCode** (CONF-309, CONF-310), where the @code **SHALL** be selected from ValueSet `Medication Route FDA 2.16.840.1.113883.3.88.12.3221.8.7` **STATIC** 1
    - *The route is a coded value, and indicates how the medication is received by the patient (by mouth, intravenously, topically, et cetera).*
12. **MAY** contain zero or more [0..*] **approachSiteCode** (C154-[DE-8.09-1]), where the @code **SHALL** be selected from ValueSet `Body Site 2.16.840.1.113883.3.88.12.3221.8.9` **STATIC** 2
    - *The anatomic site where the medication is administered. Usually applicable to injected or topical products*
13. **MAY** contain at least one [1..*] **doseQuantity**
    - *the amount of the product to be given. This may be a known, measurable unit (e.g., milliliters), an administration unit (e.g., tablet), or an amount of active ingredient (e.g., 250 mg). May define a variable dose, dose range or dose options based upon identified criteria (see Dose Indicator)*
14. **SHOULD** contain zero or one [0..1] **rateQuantity**
    - *The rate is a measurement of how fast the dose is given to the patient over time (e.g., .5 liter / 1 hr), and is often used with IV drugs.*
15. **MAY** contain at least one [1..*] **maxDoseQuantity** (CONF-312)
    - *defines a maximum or dose limit. This segment can repeat for more than one dose restriction*
16. **MAY** contain exactly one [1..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 (C154-[DE-8.11-1])
    - *The physical form of the product as presented to the patient. For example: tablet, capsule, liquid or ointment*
17. Contains exactly one [1..1] **consumable**, where its type is Consumable
    a. Contains exactly one [1..1] Consumable
18. **MAY** contain exactly one [1..1] **entryRelationship** (CONF-338, CONF-339)
    a. Contains **@typeCode="**`SUBJ`**"** *SUBJ*
    b. Contains exactly one [1..1] Medication Series Number Observation (templateId: `2.16.840.1.113883.10.20.1.46`)
19. **MAY** contain exactly one [1..1] **entryRelationship** (CONF-350)
    a. Contains exactly one [1..1] Medication Status Observation (templateId: `2.16.840.1.113883.10.20.1.47`)
20. **MAY** contain at least one [1..*] **performer** (CONF-313)
    a. Contains exactly one [1..1] CDA Performer2
    - *Indicates the person administering a substance.*
21. **MAY** contain at least one [1..*] **entryRelationship** (CONF-348, CONF-349)
    a. Contains **@typeCode="**`CAUS`**"** *CAUS*
    b. Contains exactly one [1..1] Reaction Observation (templateId: `2.16.840.1.113883.10.20.1.54`)
22. **MAY** contain at least one [1..*] **participant** (CONF-368)
    a. Contains exactly one [1..1] Product Instance (templateId: `2.16.840.1.113883.10.20.1.52`)

23. Contains at least one [1..*] **entryRelationship**
    a. Contains exactly one [1..1] Internal Reference (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.4.1)
    - *Entry may indicate one or more reasons for the use of the medication. The extension and root of each observation present must match the identifier of a concern entry contained elsewhere within the CDA document.*
      A consumer of the Medical Summary is encouraged, but not required to maintain these links on import.
24. Contains at least one [1..*] **entryRelationship**
    a. Contains exactly one [1..1] Patient Medical Instructions (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.3)
    - *At most one instruction may be provided for each <substanceAdministration> entry. The instructions shall contain any special case dosing instructions (e.g., split, tapered, or conditional dosing), and may contain other information (take with food, et cetera).*
25. Contains zero or one [0..1] **entryRelationship**
    a. Contains exactly one [1..1] Medication Type (templateId: 2.16.840.1.113883.3.88.11.83.8.1)
26. Contains at least one [1..*] **entryRelationship**
    a. Contains exactly one [1..1] Medication Order Information (templateId: 2.16.840.1.113883.3.88.11.83.8.3)
27. Contains zero or one [0..1] **entryRelationship**
    a. Contains exactly one [1..1] CCD Reaction Observation (templateId: 2.16.840.1.113883.10.20.1.54)
    - *Any noted intended or unintended effects of the product. For example: full body rash, nausea, rash resolved*
28. **SHALL** satisfy: A subordinate <substanceAdministration> entry is required for each separate dosage.
29. **SHALL** satisfy: Value for moodCode is "EVN" or "INT" 2.16.840.1.113883.5.1001 ActMood STATIC (CONF-305)
30. **SHOULD** satisfy: Contains exactly one doseQuantity or rateQuantity. (CONF-311)
31. **MAY** satisfy: Has one or more associated consents, represented in the CCD Header as ClinicalDocument / authorization / consent. (CONF-314)
32. **SHALL** satisfy: Contains one or more sources of information. (CONF-315)
33. **MAY** satisfy: Contains one or more precondition / Criterion, to indicate that the medication is administered only when the associated (coded or free text) criteria are met. (CONF-327)
34. **MAY** satisfy: Contains one or more entryRelationship, where the value for @typeCode is "RSON" "Has reason" 2.16.840.1.113883.5.1002 ActRelationshipType STATIC. (CONF-328)
35. **SHALL** satisfy: entryRelationship / @typeCode="RSON" in a medication activity has a target of problem act (templateId 2.16.840.1.113883.10.20.1.27), problem observation (templateId 2.16.840.1.113883.10.20.1.28), or some other clinical statement. (CONF-329)
36. **SHALL** satisfy: Contains exactly one consumable, the target of which is a Product template. (CONF-354)
37. **SHALL** satisfy: Contains one dosing template to identify this entry as a particular type of medication event. Possible dosing templates: 1.3.6.1.4.1.19376.1.5.3.1.4.7.1 Normal Dosing, 1.3.6.1.4.1.19376.1.5.3.1.4.8, Tapered Dosing, 1.3.6.1.4.1.19376.1.5.3.1.4.9 Split Dosing, 1.3.6.1.4.1.19376.1.5.3.1.4.10 Conditional Dosing, 1.3.6.1.4.1.19376.1.5.3.1.4.11 Combination Dosing.
38. **SHALL** satisfy: contains one or more related components (<entryRelationship typeCode='COMP'>, either to handle split, tapered or conditional dosing, or to support combination medications.
39. **SHALL** satisfy: Values from SNOMED CT shall be used in the <code> element to record that a patient is either not on medications, or that medications are not known.
40. **SHALL** satisfy: The act/@classCode='ACT' and act/@moodCode='EVN' when recording reason for medication in InternalReference Template. (6.3.4.16.22)
41. **SHALL** satisfy: The <consumable> element shall be present, and shall contain a Product Entry template

42. **SHALL** satisfy: The entryRelationship/@inversionInd attribute is 'true' for Patient Medical Instructions relationship
43. **SHOULD** satisfy: The name and strength of the medication is recorded in consumable/manufacturedProduct/manufacturedMaterial/code/originalText
44. **SHALL** satisfy: Name of the substance or product is recorded in consumable/manufacturedProduct/manufacturedMaterial/name
45. **MAY** satisfy: the preconditions for use of the medication are recorded in the <precondition> element. element. The value attribute of the <reference> element is a URL that points to the CDA narrative describing those preconditions.
46. **SHALL** satisfy: The entryRelationship/@inversionInd attribute is 'false' for Supply Entry relationship
47. **SHOULD** satisfy: entryRelationship/sequenceNumber element should be present when the embedded 'supply' element has a moodCode attribute of EVN.
48. **SHALL** satisfy: The time at which the medication was stopped is determined based on the content of the <high> element of the first <effectiveTime> element. (2.2.2.8.3)
49. **SHALL** satisfy: The HL7 data type for PIVL_TS uses the institutionSpecified attribute to indicate whether it is the interval (time between dosing), or frequency (number of doses in a time period) that is important. If instititutionSpecified is not present or is set to false, then the time between dosing is important (every 8 hours). If true, then the frequency of administration is important (e.g., 3 times per day). (2.2.2.8.4)
50. The first <effectiveTime> **SHALL** use the IVL_TS data type unless for a single administration, in which case, it **SHALL** use the TS data type. (C83-[DE-8-CDA-3])
51. Medications that are administered based on activities of daily living **SHALL** identify the events that trigger administration in the <event> element beneath the <effectiveTime> element. The <effectiveTime> element **SHALL** be of type EIVL_TS. (C83-[DE-8.03-CDA-1])
52. Medications that are administered at a specified frequency **SHALL** record the expected interval between doses in the <period> element beneath an <effectiveTime> of type PIVL_TS. The <effectiveTime> element **SHALL** have an institutionSpecified attribute value of "true". (C83-[DE-8.04-CDA-1])
53. Medications that are administered at a specified interval **SHALL** record interval between doses in the <period> element beneath an <effectiveTime> element of type PIVL_TS. The <effectiveTime> element **SHALL** have an institutionSpecified attribute value of "false". (C83-[DE-8.05-CDA-1])
54. doseQuantity/@unit, Dose Units **MAY** be present when needed. If present it **SHALL** be coded as 2.16.840.1.113883.3.88.12.80.29 Unit of Measure (C154-[DE-8.08-1])
55. When the coded product or brand name describes the strength or concentration of the medication, and the dosing is in administration units (e.g., 1 tablet, 2 capsules), units **SHOULD** contain the preferred name of the presentation units within braces { } using the units of presentation from the NCI Thesaurus (C154-[DE-8.08-2])
56. The free text description of the delivery method **MAY** be included within a <originalText> element beneath the <code> element (C83-[DE-8.12-CDA-2])
57. **SHALL** satisfy: Contains one consumable element which contains the Medication Information template. The name and code for the medication are recorded in the <consumable> element.
58. The medication status **MAY** be recorded using the CCD Medication Status observation using the value set defined in the CCD (C154-[DE-8.20-1])
59. **MAY** contain [0..*] indications which **SHALL** be recorded using the Indication problem observation (templateID 2.16.840.1.113883.10.20.1.28) described in the CCD Implementation Guide. (C83-[DE-8.20-CDA-1])
60. The indication problem observation **SHALL** contain a <text> element that includes a <reference> element whose value attribute points to the narrative text that is the indication for the medication (C83-[DE-8.20-CDA-2])
61. The indication **SHALL** be coded as 2.16.840.1.113883.3.88.12.3221.7.4, Problem Value Set, version: 20100125, Dynamic (C154-[DE-8.20-1])
62. **MAY** contain Patient Instructions which **SHALL** be recorded using the Patient Medication Instructions template (templateID 1.3.6.1.4.1.19376.1.5.3.1.4.3) (C83-[DE-8.22-CDA-1])
63. The vehicle for administering a medication **MAY** be recorded in a <participantRole> element inside a <participant> element in the <substanceAdministration> element (C83-[DE-8.24-CDA-1])
64. The typeCode attribute of the <participant> element **SHALL** be CSM (C83-[DE-8.24-CDA-2])
65. The classCode of the <participantRole> **SHALL** be MANU (C83-[DE-8.24-CDA-3])

66. A <code> element for the <participantRole> **SHALL** be present and **SHALL** contain the code 412307009 from the SNOMED CT code system (C83-[DE-8.24-CDA-4])
67. The <name> element in the <playingEntity> element **SHALL** record the name of the drug vehicle (C83-[DE-8.24-CDA-5])
68. The <code> element in the <playingEntity> element **MAY** be used to supply a coded term for the drug vehicle (C83-[DE-8.24-CDA-6])
69. **SHALL** satisfy: The Medication Vehicle shall be coded as 2.16.840.1.113883.3.88.12.80.21, Medication Vehicle Value Set, version: 20081218, Dynamic (C154-[DE-8.24-1])

Medication Split Dose 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">
  <id root="MDHT" extension="1817529014"/>
  <code code="1698061638"/>
  <statusCode code="completed"/>
  <effectiveTime value="20121102"/>
  <routeCode code="423433373"/>
  <approachSiteCode code="330213623"/>
  <doseQuantity/>
  <rateQuantity/>
  <maxDoseQuantity/>
  <consumable/>
</substanceadministration>
```

Medication Tapered Dose

[SubstanceAdministration: templateId `null`]

1. **SHALL** contain exactly one [1..1] templateId ( ) such that it
   a. **SHALL** contain exactly one [1..1] **@root**=""
2. **SHALL** conform to Medication template (templateId: `2.16.840.1.113883.3.88.11.83.8`)
3. **SHALL** conform to IHE Tapered Dose template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.8`)

1. **SHALL** conform to IHE Tapered Dose template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.8`)
2. **SHALL** conform to CCD Medication Activity template (templateId: `2.16.840.1.113883.10.20.1.24`)
3. **SHALL** conform to IHE Medication template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.7`)
4. **SHALL** conform to Medication template (templateId: `2.16.840.1.113883.3.88.11.83.8`)
5. Contains exactly one [1..1] **`@classCode`**=`"SBADM"` with data type ActClass (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
6. Contains exactly one [1..1] **`@moodCode`** with data type x_DocumentSubstanceMood
7. **SHALL** contain at least one [1..*] **`id`** (CONF-306)
8. **MAY** contain zero or more [0..*] **`code`** (C83-[DE-8.12-CDA-1])
   - *Delivery Method: A description of how the product is administered/consumed*
9. **SHALL** contain exactly one [1..1] **`statusCode`** (CONF-307)
   - *The status of all 'substanceAdministration' elements must be "complete"d. The act has either occurred, or the request or order has been placed.*

10. **MAY** contain at least one [1..*] **`effectiveTime`** with data type IVL_TS (CONF-308)
    - *Indicate Medication Stopped: Used to express a "hard stop", such as the last Sig sequence in a tapering dose, where the last sequence is 'then D/C' or where the therapy/drug is used to treat a condition and that treatment is for a fixed duration with a hard stop, such as antibiotic treatment, etc.*
    - *Administration Timing: defines a specific administration or use time. Can be a text string (Morning, Evening, Before Meals, 1 Hour After Meals, 3 Hours After Meals, Before Bed) or an exact time.*
    - *Frequency: defines how often the medication is to be administered as events per unit of time. Often expressed as the number of times per day (e.g., four times a day), but may also include event-related information (e.g., 1 hour before meals, in the morning, at bedtime). Complimentary to Interval, although equivalent expressions may have different implications (e.g., every 8 hours versus 3 times a day).*
    - *Interval: defines how the product is to be administered as an interval of time. For example, every 8 hours. Complimentary to Frequency, although equivalent expressions may have different implications (e.g., every 8 hours versus 3 times a day).*
    - *Duration: for non-instantaneous administrations, indicates the length of time the administration should be continued. For example, (infuse) over 30 minutes.*
11. **MAY** contain at least one [1..*] **`routeCode`** (CONF-309, CONF-310), where the @code **SHALL** be selected from ValueSet `Medication Route FDA 2.16.840.1.113883.3.88.12.3221.8.7` **STATIC** 1
    - *The route is a coded value, and indicates how the medication is received by the patient (by mouth, intravenously, topically, et cetera).*
12. **MAY** contain zero or more [0..*] **`approachSiteCode`** (C154-[DE-8.09-1]), where the @code **SHALL** be selected from ValueSet `Body Site 2.16.840.1.113883.3.88.12.3221.8.9` **STATIC** 2
    - *The anatomic site where the medication is administered. Usually applicable to injected or topical products*
13. **MAY** contain at least one [1..*] **`doseQuantity`**
    - *the amount of the product to be given. This may be a known, measurable unit (e.g., milliliters), an administration unit (e.g., tablet), or an amount of active ingredient (e.g., 250 mg). May define a variable dose, dose range or dose options based upon identified criteria (see Dose Indicator)*
14. **SHOULD** contain zero or one [0..1] **`rateQuantity`**
    - *The rate is a measurement of how fast the dose is given to the patient over time (e.g., .5 liter / 1 hr), and is often used with IV drugs.*
15. **MAY** contain at least one [1..*] **`maxDoseQuantity`** (CONF-312)
    - *defines a maximum or dose limit. This segment can repeat for more than one dose restriction*
16. **MAY** contain exactly one [1..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 (C154-[DE-8.11-1])
    - *The physical form of the product as presented to the patient. For example: tablet, capsule, liquid or ointment*
17. Contains exactly one [1..1] **`consumable`**, where its type is Consumable
    a. Contains exactly one [1..1] Consumable
18. **MAY** contain exactly one [1..1] **`entryRelationship`** (CONF-338, CONF-339)
    a. Contains **`@typeCode="`**`SUBJ`**`"`** *SUBJ*
    b. Contains exactly one [1..1] Medication Series Number Observation (templateId: `2.16.840.1.113883.10.20.1.46`)

19. **MAY** contain exactly one [1..1] **`entryRelationship`** (CONF-350)
    a. Contains exactly one [1..1] Medication Status Observation (templateId: `2.16.840.1.113883.10.20.1.47`)
20. **MAY** contain at least one [1..*] **`performer`** (CONF-313)
    a. Contains exactly one [1..1] CDA Performer2

    - *Indicates the person administering a substance.*
21. **MAY** contain at least one [1..*] **`entryRelationship`** (CONF-348, CONF-349)
    a. Contains **`@typeCode="`**`CAUS`**`"`** *CAUS*
    b. Contains exactly one [1..1] Reaction Observation (templateId: `2.16.840.1.113883.10.20.1.54`)
22. **MAY** contain at least one [1..*] **`participant`** (CONF-368)
    a. Contains exactly one [1..1] Product Instance (templateId: `2.16.840.1.113883.10.20.1.52`)
23. Contains at least one [1..*] **`entryRelationship`**
    a. Contains exactly one [1..1] Internal Reference (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.4.1`)

    - *Entry may indicate one or more reasons for the use of the medication. The extension and root of each observation present must match the identifier of a concern entry contained elsewhere within the CDA document.*
      A consumer of the Medical Summary is encouraged, but not required to maintain these links on import.
24. Contains at least one [1..*] **`entryRelationship`**
    a. Contains exactly one [1..1] Patient Medical Instructions (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.3`)

    - *At most one instruction may be provided for each <substanceAdministration> entry. The instructions shall contain any special case dosing instructions (e.g., split, tapered, or conditional dosing), and may contain other information (take with food, et cetera).*
25. Contains zero or one [0..1] **`entryRelationship`**
    a. Contains exactly one [1..1] Medication Type (templateId: `2.16.840.1.113883.3.88.11.83.8.1`)
26. Contains at least one [1..*] **`entryRelationship`**
    a. Contains exactly one [1..1] Medication Order Information (templateId: `2.16.840.1.113883.3.88.11.83.8.3`)
27. Contains zero or one [0..1] **`entryRelationship`**
    a. Contains exactly one [1..1] CCD Reaction Observation (templateId: `2.16.840.1.113883.10.20.1.54`)

    - *Any noted intended or unintended effects of the product. For example: full body rash, nausea, rash resolved*
28. **SHALL** satisfy: Subordinate Medication entries should be created for each distinct dosage.
29. **SHALL** satisfy: Value for moodCode is "EVN" or "INT" 2.16.840.1.113883.5.1001 ActMood STATIC (CONF-305)
30. **SHOULD** satisfy: Contains exactly one doseQuantity or rateQuantity. (CONF-311)
31. **MAY** satisfy: Has one or more associated consents, represented in the CCD Header as ClinicalDocument / authorization / consent. (CONF-314)
32. **SHALL** satisfy: Contains one or more sources of information. (CONF-315)
33. **MAY** satisfy: Contains one or more precondition / Criterion, to indicate that the medication is administered only when the associated (coded or free text) criteria are met. (CONF-327)
34. **MAY** satisfy: Contains one or more entryRelationship, where the value for @typeCode is "RSON" "Has reason" 2.16.840.1.113883.5.1002 ActRelationshipType STATIC. (CONF-328)

35. **SHALL** satisfy: entryRelationship / @typeCode="RSON" in a medication activity has a target of problem act (templateId 2.16.840.1.113883.10.20.1.27), problem observation (templateId 2.16.840.1.113883.10.20.1.28), or some other clinical statement. (CONF-329)
36. **SHALL** satisfy: Contains exactly one consumable, the target of which is a Product template. (CONF-354)
37. **SHALL** satisfy: Contains one dosing template to identify this entry as a particular type of medication event. Possible dosing templates: 1.3.6.1.4.1.19376.1.5.3.1.4.7.1 Normal Dosing, 1.3.6.1.4.1.19376.1.5.3.1.4.8, Tapered Dosing, 1.3.6.1.4.1.19376.1.5.3.1.4.9 Split Dosing, 1.3.6.1.4.1.19376.1.5.3.1.4.10 Conditional Dosing, 1.3.6.1.4.1.19376.1.5.3.1.4.11 Combination Dosing.
38. **SHALL** satisfy: contains one or more related components (<entryRelationship typeCode='COMP'>, either to handle split, tapered or conditional dosing, or to support combination medications.
39. **SHALL** satisfy: Values from SNOMED CT shall be used in the <code> element to record that a patient is either not on medications, or that medications are not known.
40. **SHALL** satisfy: The act/@classCode='ACT' and act/@moodCode='EVN' when recording reason for medication in InternalReference Template. (6.3.4.16.22)
41. **SHALL** satisfy: The <consumable> element shall be present, and shall contain a Product Entry template
42. **SHALL** satisfy: The entryRelationship/@inversionInd attribute is 'true' for Patient Medical Instructions relationship
43. **SHOULD** satisfy: The name and strength of the medication is recorded in consumable/manufacturedProduct/manufacturedMaterial/code/originalText
44. **SHALL** satisfy: Name of the substance or product is recorded in consumable/manufacturedProduct/manufacturedMaterial/name
45. **MAY** satisfy: the preconditions for use of the medication are recorded in the <precondition> element. element. The value attribute of the <reference> element is a URL that points to the CDA narrative describing those preconditions.
46. **SHALL** satisfy: The entryRelationship/@inversionInd attribute is 'false' for Supply Entry relationship
47. **SHOULD** satisfy: entryRelationship/sequenceNumber element should be present when the embedded 'supply' element has a moodCode attribute of EVN.
48. **SHALL** satisfy: The time at which the medication was stopped is determined based on the content of the <high> element of the first <effectiveTime> element. (2.2.2.8.3)
49. **SHALL** satisfy: The HL7 data type for PIVL_TS uses the institutionSpecified attribute to indicate whether it is the interval (time between dosing), or frequency (number of doses in a time period) that is important. If instititutionSpecified is not present or is set to false, then the time between dosing is important (every 8 hours). If true, then the frequency of administration is important (e.g., 3 times per day). (2.2.2.8.4)
50. The first <effectiveTime> **SHALL** use the IVL_TS data type unless for a single administration, in which case, it **SHALL** use the TS data type. (C83-[DE-8-CDA-3])
51. Medications that are administered based on activities of daily living **SHALL** identify the events that trigger administration in the <event> element beneath the <effectiveTime> element. The <effectiveTime> element **SHALL** be of type EIVL_TS. (C83-[DE-8.03-CDA-1])
52. Medications that are administered at a specified frequency **SHALL** record the expected interval between doses in the <period> element beneath an <effectiveTime> of type PIVL_TS. The <effectiveTime> element **SHALL** have an institutionSpecified attribute value of "true". (C83-[DE-8.04-CDA-1])
53. Medications that are administered at a specified interval **SHALL** record interval between doses in the <period> element beneath an <effectiveTime> element of type PIVL_TS. The <effectiveTime> element **SHALL** have an institutionSpecified attribute value of "false". (C83-[DE-8.05-CDA-1])
54. doseQuantity/@unit, Dose Units **MAY** be present when needed. If present it **SHALL** be coded as 2.16.840.1.113883.3.88.12.80.29 Unit of Measure (C154-[DE-8.08-1])
55. When the coded product or brand name describes the strength or concentration of the medication, and the dosing is in administration units (e.g., 1 tablet, 2 capsules), units **SHOULD** contain the preferred name of the presentation units within braces { } using the units of presentation from the NCI Thesaurus (C154-[DE-8.08-2])
56. The free text description of the delivery method **MAY** be included within a <originalText> element beneath the <code> element (C83-[DE-8.12-CDA-2])
57. **SHALL** satisfy: Contains one consumable element which contains the Medication Information template. The name and code for the medication are recorded in the <consumable> element.

58. The medication status **MAY** be recorded using the CCD Medication Status observation using the value set defined in the CCD (C154-[DE-8.20-1])
59. **MAY** contain [0..*] indications which **SHALL** be recorded using the Indication problem observation (templateID 2.16.840.1.113883.10.20.1.28) described in the CCD Implementation Guide. (C83-[DE-8.20-CDA-1])
60. The indication problem observation **SHALL** contain a <text> element that includes a <reference> element whose value attribute points to the narrative text that is the indication for the medication (C83-[DE-8.20-CDA-2])
61. The indication **SHALL** be coded as 2.16.840.1.113883.3.88.12.3221.7.4, Problem Value Set, version: 20100125, Dynamic (C154-[DE-8.20-1])
62. **MAY** contain Patient Instructions which **SHALL** be recorded using the Patient Medication Instructions template (templateID 1.3.6.1.4.1.19376.1.5.3.1.4.3) (C83-[DE-8.22-CDA-1])
63. The vehicle for administering a medication **MAY** be recorded in a <participantRole> element inside a <participant> element in the <substanceAdministration> element (C83-[DE-8.24-CDA-1])
64. The typeCode attribute of the <participant> element **SHALL** be CSM (C83-[DE-8.24-CDA-2])
65. The classCode of the <participantRole> **SHALL** be MANU (C83-[DE-8.24-CDA-3])
66. A <code> element for the <participantRole> **SHALL** be present and **SHALL** contain the code 412307009 from the SNOMED CT code system (C83-[DE-8.24-CDA-4])
67. The <name> element in the <playingEntity> element **SHALL** record the name of the drug vehicle (C83-[DE-8.24-CDA-5])
68. The <code> element in the <playingEntity> element **MAY** be used to supply a coded term for the drug vehicle (C83-[DE-8.24-CDA-6])
69. **SHALL** satisfy: The Medication Vehicle shall be coded as 2.16.840.1.113883.3.88.12.80.21, Medication Vehicle Value Set, version: 20081218, Dynamic (C154-[DE-8.24-1])

Medication Tapered Dose 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">
  <id root="MDHT" extension="933958614"/>
  <code code="2031210411"/>
  <statusCode code="completed"/>
  <effectiveTime value="20121102"/>
  <routeCode code="1259539562"/>
  <approachSiteCode code="646640584"/>
  <doseQuantity/>
  <rateQuantity/>
  <maxDoseQuantity/>
  <consumable/>
</substanceadministration>
```

Medication Type

[Observation: templateId `2.16.840.1.113883.3.88.11.83.8.1`]

A classification based on how the medication is marketed (e.g., prescription, over the counter drug)

1. **SHALL** contain exactly one [1..1] templateId (C83-[DE-8.19-CDA-1], C83-[DE-8.19-CDA-4]) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.3.88.11.83.8.1"
2. **SHALL** contain exactly one [1..1] **`code`**, where the @code **SHALL** be selected from ValueSet `Medication Type 2.16.840.1.113883.3.88.12.3221.8.19` **STATIC** 1 (C83-[DE-8.19-CDA-5], C154-[DE-8.19-1])

1. Contains exactly one [1..1] **`@classCode`** with data type ActClassObservation

2. Contains exactly one [1..1] **@moodCode** with data type x_ActMoodDocumentObservation
3. **SHALL** contain exactly one [1..1] **code**, where the @code **SHALL** be selected from ValueSet `Medication Type 2.16.840.1.113883.3.88.12.3221.8.19` **STATIC** 1 (C83-[DE-8.19-CDA-5], C154-[DE-8.19-1])

Medication Type 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">
  <id root="MDHT" extension="1257381225"/>
  <code code="1916318240"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
</observation>
```

Past Procedure

[Procedure: templateId `2.16.840.1.113883.10.20.1.29`]

1. **SHALL** contain exactly one [1..1] templateId ( ) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.1.29"
2. **SHALL** conform to IHE Procedure Entry Procedure Activity Procedure template (templateId: `2.16.840.1.113883.10.20.1.29`)
3. **SHALL** conform to Procedure template (templateId: `2.16.840.1.113883.3.88.11.83.17`)

1. **SHALL** conform to Procedure template (templateId: `2.16.840.1.113883.3.88.11.83.17`)
2. **SHALL** conform to IHE Procedure Entry template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.19`)
3. **SHALL** conform to CCD Procedure Activity
4. **SHALL** conform to CCD Procedure Activity Procedure template (templateId: `2.16.840.1.113883.10.20.1.29`)
5. **SHALL** conform to IHE Procedure Entry Procedure Activity Procedure template (templateId: `2.16.840.1.113883.10.20.1.29`)
6. Contains exactly one [1..1] **@classCode** with data type ActClass
7. **SHALL** contain exactly one [1..1] **@moodCode**=`"EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)
8. **SHALL** contain exactly one [1..1] **code**
9. Contains exactly one [1..1] **statusCode**
   - *Need to add value set to term model for*
     The value for "[Act | Observation | Procedure] / statusCod"e in a procedure activity SHALL be selected from ValueSet 2.16.840.1.113883.1.11.20.15 ProcedureStatusCode STATIC 20061017.
10. **SHALL** contain at least one [1..*] **id**
11. **SHOULD** contain zero or one [0..1] **effectiveTime**
12. **MAY** contain zero or one [0..1] **entryRelationship**
    a. Contains **@typeCode=**`"COMP"` *COMP*
    b. Contains exactly one [1..1] Internal Reference (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.4.1`)
    - *This element may be present to point the encounter in which the procedure was performed, and shall contain an internal reference to the encounter.*

13. **MAY** contain at least one [1..*] **entryRelationship**
    a. Contains **@typeCode="**RSON**"** *RSON*
    b. Contains exactly one [1..1] Internal Reference (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.4.1)
    - *A <procedure> act may indicate one or more reasons for the procedure. These reasons identify the concern that was the reason for use via the Internal Reference entry content module. The extension and root of each observation present must match the identifier of a concern entry contained elsewhere within the CDA document.*
14. **MAY** contain at least one [1..*] **specimen** (CONF-443)
    a. Contains exactly one [1..1] CDA Specimen
15. **MAY** contain at least one [1..*] **participant**
    a. Contains exactly one [1..1] Encounter Location (templateId: 2.16.840.1.113883.10.20.1.45)
16. **MAY** contain at least one [1..*] **performer**
    a. Contains exactly one [1..1] CDA Performer2
17. **MAY** contain zero or one [0..1] **entryRelationship**
    a. Contains **@typeCode="**RSON**"** *RSON*
    b. Contains exactly one [1..1] Problem Observation (templateId: 2.16.840.1.113883.10.20.1.28)
18. **MAY** contain zero or one [0..1] **entryRelationship**
    a. Contains **@typeCode="**RSON**"** *RSON*
    b. Contains exactly one [1..1] Problem Act (templateId: 2.16.840.1.113883.10.20.1.27)
19. **MAY** contain zero or one [0..1] **entryRelationship**
    a. Contains **@typeCode="**SUBJ**"** *SUBJ*
    b. Contains exactly one [1..1] Age Observation (templateId: 2.16.840.1.113883.10.20.1.38)
20. **MAY** contain at least one [1..*] **entryRelationship**
    a. Contains **@typeCode="**COMP**"** *COMP*
    b. Contains exactly one [1..1] Medication Activity (templateId: 2.16.840.1.113883.10.20.1.24)
21. **MAY** contain at least one [1..*] **entryRelationship**
    a. Contains exactly one [1..1] Patient Instruction (templateId: 2.16.840.1.113883.10.20.1.49)
22. **SHALL** satisfy: The code/originalText/reference/@value is present.
23. **SHOULD** satisfy: Contains the procedure provider in performer / assignedEntity.
24. **SHALL** satisfy: Value for moodCode is 'INT' to indicate a planned procedure or 'EVN' to describe a procedure that has already occured.
25. **SHALL** satisfy: The <text> element shall contain a reference to the narrative text describing the procedure.
26. **SHALL** satisfy: When the procedure is in event mood (moodCode='EVN'), this entry conforms to the CCD template 2.16.840.1.113883.10.20.1.29, and when in intent mood, this entry conforms to the CCD template 2.16.840.1.113883.10.20.1.25
27. <priorityCode> **SHALL** be present in INT mood when effectiveTime is not provided, it **MAY** be present in other moods
28. **SHALL** satisfy: The entryRelationship/@inversionInd attribute is 'true' for the reference to encounter (typecode=COMP)
29. A procedure activity **MAY** have one or more associated consents, represented in the CCD Header as ClinicalDocument / authorization / consent. (CONF-442)
30. A procedure activity **SHALL** contain one or more sources of information, as defined in section 5.2 Source. (CONF-447)
31. contains one or more Procedure / methodCode if the method isn't inherent in Procedure / code or if there is a need to further specialize the method in Procedure / code. Procedure / methodCode **SHALL NOT** conflict with the method inherent in Procedure / code. (CONF-435)
32. contains one or more Procedure / targetSiteCode to indicate the anatomical site or system that is the focus of the procedure, if the site isn't inherent in Procedure / code or if there is a need to further specialize the site in

Procedure / code. Procedure / targetSiteCode **SHALL NOT** conflict with the site inherent in Procedure / code (CONF-436)

33. specimen / specimenRole / id **SHOULD** be set to equal an Organizer / specimen / specimenRole / id to indicate that the Procedure and the Results are referring to the same specimen. (CONF-444)

Past Procedure example

```
<?xml version="1.0" encoding="UTF-8"?>
<procedure xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <id root="MDHT" extension="983645078"/>
  <code code="882319637"/>
  <text>Text Value</text>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <approachSiteCode code="196239479"/>
</procedure>
```

Planned Procedure

[Procedure: templateId 2.16.840.1.113883.10.20.1.25]

1. **SHALL** contain exactly one [1..1] templateId ( ) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.1.25"
2. **SHALL** conform to IHE Procedure Entry Plan Of Care Activity Procedure template (templateId: 2.16.840.1.113883.10.20.1.25)
3. **SHALL** conform to Procedure template (templateId: 2.16.840.1.113883.3.88.11.83.17)

1. **SHALL** conform to Procedure template (templateId: 2.16.840.1.113883.3.88.11.83.17)
2. **SHALL** conform to IHE Procedure Entry template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.19)
3. Extends CCD Plan Of Care Activity
4. **SHALL** conform to CCD Plan Of Care Activity Procedure template (templateId: 2.16.840.1.113883.10.20.1.25)
5. **SHALL** conform to IHE Procedure Entry Plan Of Care Activity Procedure template (templateId: 2.16.840.1.113883.10.20.1.25)
6. Contains exactly one [1..1] **@classCode** with data type ActClass
7. **SHALL** contain exactly one [1..1] **@moodCode**="INT" (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) (CONF-487)
8. **SHALL** contain at least one [1..*] **id** (CONF-486)
9. **MAY** contain zero or one [0..1] **entryRelationship**
   a. Contains **@typeCode=**"COMP" *COMP*
   b. Contains exactly one [1..1] Internal Reference (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.4.1)
   - *This element may be present to point the encounter in which the procedure was performed, and shall contain an internal reference to the encounter.*
10. **MAY** contain at least one [1..*] **entryRelationship**
    a. Contains **@typeCode=**"RSON" *RSON*
    b. Contains exactly one [1..1] Internal Reference (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.4.1)
    - *A <procedure> act may indicate one or more reasons for the procedure. These reasons identify the concern that was the reason for use via the Internal Reference entry content module. The extension and root of*

each observation present must match the identifier of a concern entry contained elsewhere within the CDA document.

11. **SHALL** satisfy: The code/originalText/reference/@value is present.
12. **SHOULD** satisfy: Contains the procedure provider in performer / assignedEntity.
13. **SHALL** satisfy: Value for moodCode is 'INT' to indicate a planned procedure or 'EVN' to describe a procedure that has already occured.
14. **SHALL** satisfy: The <text> element shall contain a reference to the narrative text describing the procedure.
15. **SHALL** satisfy: When the procedure is in event mood (moodCode='EVN'), this entry conforms to the CCD template 2.16.840.1.113883.10.20.1.29, and when in intent mood, this entry conforms to the CCD template 2.16.840.1.113883.10.20.1.25
16. <priorityCode> **SHALL** be present in INT mood when effectiveTime is not provided, it **MAY** be present in other moods
17. **SHALL** satisfy: The entryRelationship/@inversionInd attribute is 'true' for the reference to encounter (typecode=COMP)
18. **SHALL** satisfy: moodCodeValue (CONF-488)
19. **SHALL** contain one or more sources of information (CONF-491)

Planned Procedure example

```
<?xml version="1.0" encoding="UTF-8"?>
<procedure xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <id root="MDHT" extension="1219383172"/>
  <code code="1730267267"/>
  <text>Text Value</text>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <approachSiteCode code="186196114"/>
</procedure>
```

Procedure

Abstract [Procedure: templateId `2.16.840.1.113883.3.88.11.83.17`]

Defines a coded entry describing a procedure performed on a patient.

1. **SHALL** contain exactly one [1..1] templateId (C83-[DE-17-CDA-1]) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.3.88.11.83.17"
2. **SHALL** conform to IHE Procedure Entry template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.19`)
3. **SHOULD** contain exactly one [1..1] **`targetSiteCode`**, where the @code **SHOULD** be selected from ValueSet `Body Site 2.16.840.1.113883.3.88.12.3221.8.9` **STATIC** 2 (C83-[DE-17-CDA-3])
   - *The anatomical site where a procedure is performed*
4. **SHOULD** contain exactly one [1..1] **`code`** (CONF-433)
5. **SHALL** satisfy: The code/originalText/reference/@value is present.
6. **SHOULD** satisfy: Contains the procedure provider in performer / assignedEntity.

1. **SHALL** conform to IHE Procedure Entry template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.19`)
2. **SHALL** contain exactly one [1..1] **`@classCode`**=`"PROC"` (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
3. Contains exactly one [1..1] **`@moodCode`** with data type x_DocumentProcedureMood
4. **SHOULD** contain exactly one [1..1] **`code`** (CONF-433)
5. **SHALL** contain exactly one [1..1] **`text`**

6. **SHALL** contain exactly one [1..1] **`statusCode`**, where the @code **SHALL** be selected from ValueSet `ProcedureStatusCode 2.16.840.1.113883.1.11.20.15` **STATIC** 20061017 (CONF-430, CONF-431)
   - *The <statusCode> element shall be present when used to describe a procedure event. It shall have the value 'completed' for procedures that have been completed, and 'active' for procedures that are still in progress. Procedures that were stopped prior to completion shall use the value 'aborted', and procedures that were cancelled before being started shall use the value 'cancelled'.*
7. **MAY** contain zero or more [0..*] **`approachSiteCode`**
   - *This element may be present to indicate the procedure approach.*
8. **SHOULD** contain exactly one [1..1] **`targetSiteCode`**, where the @code **SHOULD** be selected from ValueSet `Body Site 2.16.840.1.113883.3.88.12.3221.8.9` **STATIC** 2 (C83-[DE-17-CDA-3])
   - *The anatomical site where a procedure is performed*
9. **MAY** contain zero or one [0..1] **`entryRelationship`**
   a. Contains **`@typeCode="`**`COMP`**`"`** *COMP*
   b. Contains exactly one [1..1] Internal Reference (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.4.1`)
   - *This element may be present to point the encounter in which the procedure was performed, and shall contain an internal reference to the encounter.*
10. **MAY** contain at least one [1..*] **`entryRelationship`**
    a. Contains **`@typeCode="`**`RSON`**`"`** *RSON*
    b. Contains exactly one [1..1] Internal Reference (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.4.1`)
    - *A <procedure> act may indicate one or more reasons for the procedure. These reasons identify the concern that was the reason for use via the Internal Reference entry content module. The extension and root of each observation present must match the identifier of a concern entry contained elsewhere within the CDA document.*
11. **SHALL** satisfy: Value for moodCode is 'INT' to indicate a planned procedure or 'EVN' to describe a procedure that has already occured.
12. **SHALL** satisfy: The <text> element shall contain a reference to the narrative text describing the procedure.
13. **SHALL** satisfy: When the procedure is in event mood (moodCode='EVN'), this entry conforms to the CCD template 2.16.840.1.113883.10.20.1.29, and when in intent mood, this entry conforms to the CCD template 2.16.840.1.113883.10.20.1.25
14. <priorityCode> **SHALL** be present in INT mood when effectiveTime is not provided, it **MAY** be present in other moods
15. **SHALL** satisfy: The entryRelationship/@inversionInd attribute is 'true' for the reference to encounter (typecode=COMP)
16. **SHALL** satisfy: The code/originalText/reference/@value is present.
17. **SHOULD** satisfy: Contains the procedure provider in performer / assignedEntity.

Procedure example

```
Error: Missing Runtime Class
```

Result

[Observation: templateId `2.16.840.1.113883.3.88.11.83.15.1`]

This clinical statement represents details of a lab, radiology, or other study performed on a patient. The scope of result observations is broad with the exception of "vital sign"s which are contained in the Vital Signs section.

1. **SHALL** contain exactly one [1..1] templateId (C83-[DE-15-CDA-1]) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.3.88.11.83.15.1"

2. **SHALL** conform to CCD Result Observation template (templateId: `2.16.840.1.113883.10.20.1.31`) ([C83-[DE-15-CDA-3])
3. **SHALL** conform to IHE Simple Observation template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.13`) (C83-[DE-15-CDA-2])
4. **SHALL** contain exactly one [1..1] **`code`**
   a. Result Type **SHOULD** be selected from LOINC (codeSystem 2.16.840.1.113883.6.1) or SNOMED CT (codeSystem 2.16.840.1.113883.6.96) (C154-[DE-15.03-1])
   b. Result Type for laboratory results **SHOULD** be coded as specified in HITSP/C80 Section 2.2.3.6.1 Laboratory Observations. (C154-[DE-15.03-2])
5. **SHALL** contain exactly one [1..1] **`effectiveTime`**
   - *Represents clinically effective time of the measurement, which may be when the measurement was performed (e.g., a BP measurement), or may be when sample was taken (and measured some time afterwards).*
6. **SHALL** contain exactly one [1..1] **`value`**
   - *The Result value records the desired result in a goal or recorded event, and will not be present when recording an intent, request or proposal to measure a result.*
   a. Result Value **SHALL** be present when the observation/@moodCode is EVN or GOL, and **SHALL NOT** be present when observation/@moodCode is INT or PRP. (C83-[DE-15.05-CDA-1])

1. **SHALL** conform to IHE Simple Observation template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.13`)
2. **SHALL** conform to CCD Result Observation template (templateId: `2.16.840.1.113883.10.20.1.31`)
3. Contains exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
4. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF-408)
5. **SHALL** contain at least one [1..*] **`id`** (CONF-409)
6. **SHALL** contain exactly one [1..1] **`statusCode`** (CONF-410)
7. **SHALL** contain exactly one [1..1] **`code`**
   a. Result Type **SHOULD** be selected from LOINC (codeSystem 2.16.840.1.113883.6.1) or SNOMED CT (codeSystem 2.16.840.1.113883.6.96) (C154-[DE-15.03-1])
   b. Result Type for laboratory results **SHOULD** be coded as specified in HITSP/C80 Section 2.2.3.6.1 Laboratory Observations. (C154-[DE-15.03-2])
8. **SHALL** contain exactly one [1..1] **`effectiveTime`**
   - *Represents clinically effective time of the measurement, which may be when the measurement was performed (e.g., a BP measurement), or may be when sample was taken (and measured some time afterwards).*
9. **SHALL** contain exactly one [1..1] **`value`**
   a. Result Value **SHALL** be present when the observation/@moodCode is EVN or GOL, and **SHALL NOT** be present when observation/@moodCode is INT or PRP. (C83-[DE-15.05-CDA-1])
   - *The Result value records the desired result in a goal or recorded event, and will not be present when recording an intent, request or proposal to measure a result.*
10. **SHOULD** contain zero or more [0..*] **`interpretationCode`** (CONF-418)
    - *Can be used to provide a rough qualitative interpretation of the observation, such as 'N' (normal), 'L' (low), 'S' (susceptible), etc. Interpretation is generally provided for numeric results where an interpretation range has been defined, or for antimicrobial susceptibility test interpretation.*
11. **MAY** contain zero or one [0..1] **`methodCode`** (CONF-414)
    - *Included if the method isn't inherent in code or if there is a need to further specialize the method in code.*
12. The value for 'code' **SHOULD** be selected from LOINC (codeSystem 2.16.840.1.113883.6.1) or SNOMED CT (codeSystem 2.16.840.1.113883.6.96), and **MAY** be selected from CPT-4 (codeSystem 2.16.840.1.113883.6.12). (CONF-413)
13. The methodCode **SHALL NOT** conflict with the method inherent in code (CONF-415)

14. Where value is a physical quantity, the unit of measure **SHALL** be expressed using a valid Unified Code for Units of Measure (UCUM) expression. (CONF-417)
15. **SHOULD** satisfy: Contain one or more referenceRange to show the normal range of values for the observation result (CONF-419)
16. **SHALL NOT** contain referenceRange / observationRange / code, as this attribute is not used by the HL7 Clinical Statement or Lab Committee models. (CONF-420)
17. **SHALL** satisfy: Contains one or more sources of information. (CONF-421)
18. Result Type **SHOULD** be selected from LOINC (codeSystem 2.16.840.1.113883.6.1) or SNOMED CT (codeSystem 2.16.840.1.113883.6.96) (C154-[DE-15.03-1])
19. Result Type for laboratory results **SHOULD** be coded as specified in HITSP/C80 Section 2.2.3.6.1 Laboratory Observations. (C154-[DE-15.03-2])
20. Result Value **SHALL** be present when the observation/@moodCode is EVN or GOL, and **SHALL NOT** be present when observation/@moodCode is INT or PRP. (C83-[DE-15.05-CDA-1])

Result 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">
  <id root="MDHT" extension="1658410723"/>
  <code code="110993604"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <interpretationCode code="1064138996"/>
  <methodCode code="351202843"/>
</observation>
```

Result Organizer

[Organizer: templateId `2.16.840.1.113883.10.20.1.32`]

Non-template subclasss of CCD ResultOrganizer that requires entires to be HITSP Result.

1. **SHALL** contain exactly one [1..1] templateId ( ) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.1.32"
2. **SHALL** conform to CCD Result Organizer template (templateId: `2.16.840.1.113883.10.20.1.32`)
3. **SHALL** contain at least one [1..*] **`component`**
   a. Contains exactly one [1..1] Result (templateId: `2.16.840.1.113883.3.88.11.83.15.1`)

1. **SHALL** conform to CCD Result Organizer template (templateId: `2.16.840.1.113883.10.20.1.32`)
2. Contains exactly one [1..1] **`@classCode`** with data type x_ActClassDocumentEntryOrganizer
3. **SHALL** contain exactly one [1..1] **`@moodCode`**=`"EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF-394)
4. **SHALL** contain at least one [1..*] **`id`** (CONF-395)
5. **SHALL** contain exactly one [1..1] **`code`** (CONF-397)
6. **SHALL** contain exactly one [1..1] **`statusCode`** (CONF-396)
7. **SHOULD** contain at least one [1..*] **`specimen`** (CONF-399)
   a. Contains exactly one [1..1] CDA Specimen
   - *Should be included if the specimen isn't inherent in code value.*

8. **SHALL** contain at least one [1..*] **component**
    a. Contains exactly one [1..1] Result (templateId: 2.16.840.1.113883.3.88.11.83.15.1)
9. The value for 'code' in a result organizer **SHOULD** be selected from LOINC (codeSystem 2.16.840.1.113883.6.1) or SNOMED CT (codeSystem 2.16.840.1.113883.6.96), and **MAY** be selected from CPT-4 (codeSystem 2.16.840.1.113883.6.12) or ValueSet 2.16.840.1.113883.1.11.20.16 ResultTypeCode STATIC. (CONF-398)
10. The specimen element **SHALL NOT** conflict with the specimen inherent in code (CONF-400)
11. specimen / specimenRole / id **SHOULD** be set to equal a Procedure / specimen / specimenRole / id to indicate that the Results and the Procedure are referring to the same specimen. (CONF-401)
12. **SHALL** satisfy: Contains one or more component (CONF-402)
13. The target of one or more result organizer component relationships **MAY** be a procedure, to indicate the means or technique by which a result is obtained, particularly if the means or technique isn't inherent in code or if there is a need to further specialize the code value. (CONF-403)
14. A result organizer component / procedure **MAY** be a reference to a procedure described in the Procedure section. (CONF-404)
15. **SHALL** satisfy: Contains one or more sources of information. (CONF-406)

hitsp::ResultOrganizer							
cda::organizer[cda:templateId/@root =]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
result	result	1..*	SHALL	YES	Result		
resultOrganizer	resultOrganizer	0..*	MAY	YES	ResultOrganizer		

Result Organizer example

```
<?xml version="1.0" encoding="UTF-8"?>
<organizer xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <id root="MDHT" extension="1154681624"/>
  <code code="746707593"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <component>
    <observation>
      <id root="MDHT" extension="770953805"/>
      <code code="939718009"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2012"/>
        <high value="2012"/>
      </effectiveTime>
    </observation>
  </component>
</organizer>
```

Social History

[Observation: templateId 2.16.840.1.113883.3.88.11.83.19]

1. **SHALL** contain exactly one [1..1] templateId ( ) such that it
    a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.3.88.11.83.19"

2. **SHALL** conform to IHE Social History Observation template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.13.4)
3. **SHOULD** contain zero or more [0..*] **code**, where the @code **SHALL** be selected from ValueSet Social History Type 2.16.840.1.113883.3.88.12.80.60 **STATIC** 1
4. **SHOULD** contain zero or one [0..1] **effectiveTime**
5. **SHALL** contain exactly one [1..1] **text**

1. **SHALL** conform to CCD Social History Observation template (templateId: 2.16.840.1.113883.10.20.1.33)
2. **SHALL** conform to IHE Simple Observation template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.13)
3. **SHALL** conform to IHE Social History Observation template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.13.4)
4. Contains exactly one [1..1] **@classCode** with data type ActClassObservation
5. Contains exactly one [1..1] **@moodCode** with data type x_ActMoodDocumentObservation
6. **SHALL** contain at least one [1..*] **id**
7. **SHALL** contain exactly one [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus)
8. **SHOULD** contain zero or more [0..*] **code**, where the @code **SHALL** be selected from ValueSet Social History Type 2.16.840.1.113883.3.88.12.80.60 **STATIC** 1
9. **SHALL** contain exactly one [1..1] **text**
10. **SHOULD** contain zero or one [0..1] **effectiveTime**
11. **MAY** contain zero or more [0..*] **value**

    - *The data type to use for each observation should be drawn from the table below. Observations in the table above using the PQ data type have a unit in the form {xxx}/d, {xxx}/wk or {xxx}/a represent the number of items per day, week or year respectively. The value attribute indicates the number of times of the act performed, and the units represent the frequency.*

      229819007 Smoking PQ {pack}/d or {pack}/wk or {pack}/a
      256235009 Exercise PQ {times}/wk
      160573003 ETOH (Alcohol) Use PQ {drink}/d or {drink}/wk
      364393001 Diet CD N/A
      364703007 Employment CD N/A
      425400000 Toxic Exposure CD N/A
      363908000 Drug Use CD N/A
      228272008 Other Social History ANY N/A
12. **MAY** contain zero or one [0..1] **entryRelationship** (CONF-246)
    a. Contains exactly one [1..1] Social History Status Observation (templateId: 2.16.840.1.113883.10.20.1.56)
13. **MAY** contain zero or one [0..1] **entryRelationship** (CONF-249)
    a. Contains exactly one [1..1] Episode Observation (templateId: 2.16.840.1.113883.10.20.1.41)
14. The value for Observation / code in a social history observation **SHOULD** be selected from LOINC (codeSystem 2.16.840.1.113883.6.1) or SNOMED CT (codeSystem 2.16.840.1.113883.6.96), or **MAY** be selected from ValueSet 2.16.840.1.113883.1.11.20.18 SocialHistoryTypeCode STATIC 20061017 (CONF-243)
15. Observation / value can be any datatype. Where Observation / value is a physical quantity, the unit of measure **SHALL** be expressed using a valid Unified Code for Units of Measure (UCUM) expression (CONF-244)
16. **SHALL** satisfy: Contains one or more sources of information (CONF-245)
17. **SHOULD** satisfy: The <repeatNumber> element should not be used in a social history observation
18. **SHOULD** satisfy: The <interpretationCode> element should not be used in a social history observation
19. **SHOULD** satisfy: The <methodCode> element should not be used in a social history observation
20. **SHOULD** satisfy: The targetSiteCode element should not be used in a social history observation

hitsp::SocialHistory							
cda::observation[cda:templateId/@root =]/							
Name	**XPath**	**Cardinality**	**Severity**	**Nullable**	**Data Type**	**Conformance**	**Value(s)**
code	code	0..*	SHOULD	YES	CD		
effectiveTime	effectiveTime	0..1	SHOULD	YES	IVL_TS		
text	text	1..1	SHALL	YES	ED		
socialHistory	socialHistory	0..*	MAY	YES	SocialHistory		

Social History 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">
  <id root="MDHT" extension="181989624"/>
  <code code="1552210322"/>
  <text>Text Value</text>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
</observation>
```

Vital Sign

[Observation: templateId `2.16.840.1.113883.3.88.11.83.14`]

These entries are used to record current and relevant historical vital signs for the patient. Vital Signs are a subset of ***Results Section***, but are reported in this section to follow clinical conventions.

The differentiation between Vital Signs and Results varies by clinical context. Common examples of vital signs include temperature, height, weight, blood pressure, etc. However, some clinical contexts may alter these common vitals, for example in neonatology "height" may be replaced by "crown-to-rump" measurement.

1. **SHALL** contain exactly one [1..1] templateId (C83-[DE-14-CDA-1]) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.3.88.11.83.14"
2. **SHALL** conform to IHE Vital Sign Observation template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.13.2`) (C83-[DE-14-CDA-2])
3. **SHALL** contain exactly one [1..1] **`code`**, where the @code **SHALL** be selected from ValueSet `Vital Sign Result 2.16.840.1.113883.3.88.12.80.62` **STATIC** 1 (C154-[DE-14.03-1])
4. **SHALL** satisfy: Data Element Definitions for Results [Placeholder]

1. **SHALL** conform to IHE Simple Observation template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.13`)
2. **SHALL** conform to CCD Result Observation template (templateId: `2.16.840.1.113883.10.20.1.31`)
3. **SHALL** conform to IHE Vital Sign Observation template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.13.2`)
4. Contains exactly one [1..1] **`@classCode`**="`OBS`" *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
5. **SHALL** contain exactly one [1..1] **`@moodCode`**="`EVN`" *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF-408)
6. **SHALL** contain at least one [1..*] **`id`** (CONF-409)
7. **SHALL** contain exactly one [1..1] **`statusCode`** (CONF-410)

8. **SHALL** contain exactly one [1..1] **`code`**, where the @code **SHALL** be selected from ValueSet `Vital Sign Result 2.16.840.1.113883.3.88.12.80.62` **STATIC** 1 (C154-[DE-14.03-1])
9. **SHOULD** contain exactly one [1..1] **`effectiveTime`** (CONF-411)
    - *Represents the biologically relevant time (e.g. time the specimen was obtained from the patient).*
10. **SHALL** contain exactly one [1..1] **`value`** with data type PQ (6.3.4.22.4)
11. **MAY** contain zero or more [0..*] **`interpretationCode`** (6.3.4.22.5)
    - *The interpretation code may be present to provide an interpretation of the vital signs measure (e.g., High, Normal, Low, et cetera).*
12. **MAY** contain zero or one [0..1] **`methodCode`** (6.3.4.22.6)
    - *The method code element may be present to indicate the method used to obtain the measure. Note that method used is distinct from, but possibly related to the target site.*
13. **MAY** contain zero or more [0..*] **`targetSiteCode`** (6.3.4.22.7)
    - *The target site of the measure may be identified in the targetSiteCode element (e.g., Left arm [blood pressure], oral [temperature], et cetera).*
14. The value for 'code' **SHOULD** be selected from LOINC (codeSystem 2.16.840.1.113883.6.1) or SNOMED CT (codeSystem 2.16.840.1.113883.6.96), and **MAY** be selected from CPT-4 (codeSystem 2.16.840.1.113883.6.12). (CONF-413)
15. The methodCode **SHALL NOT** conflict with the method inherent in code (CONF-415)
16. Where value is a physical quantity, the unit of measure **SHALL** be expressed using a valid Unified Code for Units of Measure (UCUM) expression. (CONF-417)
17. **SHOULD** satisfy: Contain one or more referenceRange to show the normal range of values for the observation result (CONF-419)
18. **SHALL NOT** contain referenceRange / observationRange / code, as this attribute is not used by the HL7 Clinical Statement or Lab Committee models. (CONF-420)
19. **SHALL** satisfy: Contains one or more sources of information. (CONF-421)
20. **SHALL** satisfy: Data Element Definitions for Results [Placeholder]

Vital Sign 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">
  <id root="MDHT" extension="1546982211"/>
  <code code="677691929"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2012"/>
    <high value="2012"/>
  </effectiveTime>
  <interpretationCode code="1486199971"/>
  <methodCode code="1995548838"/>
  <targetSiteCode code="880415409"/>
</observation>
```

Chapter 5

OTHER CLASSES

Topics:

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

Healthcare Provider

[Performer1: templateId 2.16.840.1.113883.3.88.11.83.4]

1. **SHALL** contain exactly one [1..1] templateId ( ) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.3.88.11.83.4"
2. **SHALL** conform to IHE Healthcare Providers Pharmacies template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.2.3)

1. **SHALL** conform to IHE Healthcare Providers Pharmacies template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.2.3)
2. Contains exactly one [1..1] **@typeCode** with data type x_ServiceEventPerformer
3. Contains exactly one [1..1] **assignedEntity**, where its type is Assigned Entity
   a. Contains exactly one [1..1] Assigned Entity

Healthcare Provider example

```
<?xml version="1.0" encoding="UTF-8"?>
<performer1 xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <time>
    <low value="2012"/>
    <high value="2012"/>
  </time>
  <assignedEntity/>
</performer1>
```

Language Spoken

[LanguageCommunication: templateId 2.16.840.1.113883.3.88.11.83.2]

1. **SHALL** contain exactly one [1..1] templateId (C83-[DE-2.01-CDA-2]) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.3.88.11.83.2"
2. **SHALL** conform to IHE Language Communication template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.2.1) (C83-[DE-2.01-CDA-3])
3. **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** (C154-[DE-2.01-1])
4. **SHALL** contain zero or one [0..1] **modeCode**, where the @code **SHALL** be selected from ValueSet LanguageAbilityMode 2.16.840.1.113883.1.11.12249 **STATIC** 1 (C83-[DE-2.01-CDA-4])
   - *Mode codes SHALL be appropriate to the type of language. Thus English, as spoken in the U.S. SHOULD use the code en-US and SHOULD only use mode codes for written and verbal communications. On the other hand, American Sign Language would be represented using the code sign-US, and would only use mode codes for signed communication.*
5. **SHALL** satisfy: Languages spoken shall be recorded using the <languageCommunication> infrastructure class associated with the patient. The <languageCommunication> element describes the primary and secondary languages of communication for a person. (C83-[DE-2.01-CDA-1])
6. **SHALL** satisfy: Sign language is treated as a separate language. (C154-[DE-2.01-2])
7. CDA allows for use of proficiencyLevelCode element, but this element **SHOULD NOT** be used. (C83-[DE-2.01-CDA-5])

1. **SHALL** conform to IHE Language Communication template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.2.1)

2. **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** (C154-[DE-2.01-1])
3. **SHALL** contain zero or one [0..1] **modeCode**, where the @code **SHALL** be selected from ValueSet `LanguageAbilityMode 2.16.840.1.113883.1.11.12249` **STATIC** 1 (C83-[DE-2.01-CDA-4])
   - *Mode codes SHALL be appropriate to the type of language. Thus English, as spoken in the U.S. SHOULD use the code en-US and SHOULD only use mode codes for written and verbal communications. On the other hand, American Sign Language would be represented using the code sign-US, and would only use mode codes for signed communication.*
4. **SHALL** satisfy: Languages spoken shall be recorded using the <languageCommunication> infrastructure class associated with the patient. The <languageCommunication> element describes the primary and secondary languages of communication for a person. (C83-[DE-2.01-CDA-1])
5. **SHALL** satisfy: Sign language is treated as a separate language. (C154-[DE-2.01-2])
6. CDA allows for use of proficiencyLevelCode element, but this element **SHOULD NOT** be used. (C83-[DE-2.01-CDA-5])

Language Spoken example

```
Unable to create XML Snippet
```

Medication Information

[ManufacturedProduct: templateId `2.16.840.1.113883.3.88.11.83.8.2`]

The product concentration is determined from the coded product or brand name using knowledge base information in the vocabularies specified for these fields, and therefore this information is not explicitly included.

1. **SHALL** contain exactly one [1..1] templateId (C83-[DE-8-CDA-5]) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.3.88.11.83.8.2"
2. **SHALL** conform to IHE Product Entry template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.7.2`) (C83-[DE-8-CDA-4])
3. The coded product name **SHALL** appear in the @code attribute of the manufacturedMaterial/code element. (C83-[DE-8.13-CDA-1])
4. If the code for the generic product is unknown, the code and codeSystem attributes **MAY** be omitted (C83-[DE-8.13-CDA-2])
5. The coded product name **SHALL** be coded as 2.16.840.1.113883.3.88.12.80.17, Medication Clinical Drug Name Value Set, version: 20081218, Dynamic (C154-[DE-8.13-1])
6. When only the class of the drug is known (e.g., Beta Blocker or Sulfa Drug), it **SHALL** be coded as 2.16.840.1.113883.3.88.12.80.17, Medication Drug Class Value Set, version: 20081218, Dynamic (C154-[DE-8.13-2])
7. When only the medication ingredient name is know, the coded product name **MAY** be coded as 2.16.840.1.113883.3.88.12.80.20, Ingredient Name Value Set, Dynamic (C154-[DE-8.13-3])
8. The code for the specific brand of product **SHALL** appear in a manufacturedMaterial/translation element (C83-[DE-8.14-CDA-1])
9. The brand name **SHALL** be coded as 2.16.840.1.113883.3.88.12.80.16, Medication Brand Name Value Set, version: 20081218, Dynamic, OR **SHALL** be coded as 2.16.840.1.113883.3.88.12.80.19, Medication Packaged Product Value Set, Dynamic (C154-[DE-8.14-1])
10. The product (generic) name **SHALL** appear in the originalText element beneath the manufacturedMaterial/code element (C83-[DE-8.15-CDA-1])
11. The brand name **SHALL** appear in the <name> element of the <manufacturedMaterial> element (C83-[DE-8.14-CDA-2])

1. **SHALL** conform to CCD Product template (templateId: `2.16.840.1.113883.10.20.1.53`)
2. **SHALL** conform to IHE Product Entry template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.7.2`)

3. **MAY** contain at least one [1..*] **id** (CONF-366)
   - *uniquely represents a particular kind of product*
4. **SHALL** satisfy: Contain exactly one manufacturedMaterial. (CONF-357)
5. **SHALL** satisfy: Contain exactly one manufacturedMaterial / code. (CONF-358)
6. The value for "manufacturedMaterial / code" in a product template **SHOULD** be selected from the RxNorm (2.16.840.1.113883.6.88) code system for medications, and from the CDC Vaccine Code (2.16.840.1.113883.6.59) code system for immunizations10, or **MAY** be selected from ValueSet 2.16.840.1.113883.1.11.20.8 MedicationTypeCode STATIC 20061017. (CONF-359)
7. The value for "manufacturedMaterial / code" in a product template **MAY** contain a precoordinated product strength, product form, or product concentration (e.g. "metoprolol 25mg tablet", "amoxicillin 400mg/5mL suspension"). (CONF-360)
8. If manufacturedMaterial / code contains a precoordinated unit dose (e.g. "metoprolol 25mg tablet"), then SubstanceAdministration / doseQuantity **SHALL** be a unitless number that indicates the number of products given per administration. (CONF-361)
9. If manufacturedMaterial / code does not contain a precoordinated unit dose (e.g. "metoprolol product"), then SubstanceAdministration / doseQuantity **SHALL** be a physical quantity that indicates the amount of product given per administration. (CONF-362)
10. **SHALL** satisfy: A manufacturedMaterial in a product template contains exactly one code / originalText, which represents the generic name of the product. (CONF-363)
11. **MAY** satisfy: A manufacturedMaterial in a product template contains exactly one name, which represents the brand name of the product. (CONF-364)
12. **MAY** satisfy: contains exactly one manufacturedProduct / manufacturerOrganization, which represents the manufacturer of the Material. (CONF-365)
13. If ManufacturedProduct in a product template contains manufacturedProduct / id, then ManufacturedProduct **SHOULD** also contain manufacturedProduct / manufacturerOrganization. (CONF-367)
14. The coded product name **SHALL** appear in the @code attribute of the manufacturedMaterial/code element. (C83-[DE-8.13-CDA-1])
15. If the code for the generic product is unknown, the code and codeSystem attributes **MAY** be omitted (C83-[DE-8.13-CDA-2])
16. The coded product name **SHALL** be coded as 2.16.840.1.113883.3.88.12.80.17, Medication Clinical Drug Name Value Set, version: 20081218, Dynamic (C154-[DE-8.13-1])
17. When only the class of the drug is known (e.g., Beta Blocker or Sulfa Drug), it **SHALL** be coded as 2.16.840.1.113883.3.88.12.80.17, Medication Drug Class Value Set, version: 20081218, Dynamic (C154-[DE-8.13-2])
18. When only the medication ingredient name is know, the coded product name **MAY** be coded as 2.16.840.1.113883.3.88.12.80.20, Ingredient Name Value Set, Dynamic (C154-[DE-8.13-3])
19. The code for the specific brand of product **SHALL** appear in a manufacturedMaterial/translation element (C83-[DE-8.14-CDA-1])
20. The brand name **SHALL** be coded as 2.16.840.1.113883.3.88.12.80.16, Medication Brand Name Value Set, version: 20081218, Dynamic, OR **SHALL** be coded as 2.16.840.1.113883.3.88.12.80.19, Medication Packaged Product Value Set, Dynamic (C154-[DE-8.14-1])
21. The product (generic) name **SHALL** appear in the originalText element beneath the manufacturedMaterial/code element (C83-[DE-8.15-CDA-1])
22. The brand name **SHALL** appear in the <name> element of the <manufacturedMaterial> element (C83-[DE-8.14-CDA-2])

Medication Information example

```
<?xml version="1.0" encoding="UTF-8"?>
<manufacturedproduct xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <id root="MDHT" extension="1457460464"/>
</manufacturedproduct>
```

Support

At a minimum, key support contacts relative to healthcare decisions, including next of kin, should be included. If no healthcare providers are supplied, the reason should be supplied as free text in the narrative block (e.g., Unknown, etc).

1. **SHALL** contain exactly one [1..1] templateId ( ) such that it
   a. **SHALL** contain exactly one [1..1] **@root**=""
2. Extends IHE Patient Contact

1. Extends CCD Support
2. Extends IHE Patient Contact
3.

Support example

```
Unable to create XML Snippet
```

Support Guardian

[Guardian: templateId `2.16.840.1.113883.3.88.11.83.3`]

At a minimum, key support contacts relative to healthcare decisions, including next of kin, should be included. If no healthcare providers are supplied, the reason should be supplied as free text in the narrative block (e.g., Unknown, etc).

1. **SHALL** contain exactly one [1..1] templateId ( ) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.3.88.11.83.3"
2. **SHALL** conform to IHE Patient Contact Guardian template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.2.4`)
3. Extends Support

1. Extends Support
2. Extends IHE Patient Contact
3. Extends CCD Support
4. **SHALL** conform to CCD Support Guardian
5. **SHALL** conform to IHE Patient Contact Guardian template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.2.4`)
6. **SHALL** contain exactly one [1..1] **`@classCode`**="GUAR"
7. **SHALL** contain zero or one [0..1] **`code`**, where the @code **SHALL** be selected from (CodeSystem: `2.16.840.1.113883.5.111 RoleCode`)
8. **SHOULD** contain zero or more [0..*] **`addr`**
9. **SHOULD** contain zero or more [0..*] **`telecom`**

Support Guardian example

```
<?xml version="1.0" encoding="UTF-8"?>
<guardian xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <id root="MDHT" extension="2022308020"/>
  <addr/>
  <telecom/>
</guardian>
```

Support Participant

[Participant1: templateId `2.16.840.1.113883.3.88.11.83.3`]

At a minimum, key support contacts relative to healthcare decisions, including next of kin, should be included. If no healthcare providers are supplied, the reason should be supplied as free text in the narrative block (e.g., Unknown, etc).

1. **SHALL** contain exactly one [1..1] templateId ( ) such that it
   a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.3.88.11.83.3"
2. **SHALL** conform to IHE Patient Contact Participant template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.2.4`)
3. Extends Support

1. Extends Support
2. Extends IHE Patient Contact
3. Extends CCD Support
4. **SHALL** conform to CCD Support Participant
5. **SHALL** conform to IHE Patient Contact Participant template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.2.4`)
6. **SHALL** contain exactly one [1..1] **`@typeCode`**="`IND`"
7. **MAY** contain zero or one [0..1] **`time`**
   - *Indicates the time of the participation.*
8. Contains exactly one [1..1] **`associatedEntity`**, where its type is Associated Entity
   a. Contains exactly one [1..1] Associated Entity

Support Participant example

```
<?xml version="1.0" encoding="UTF-8"?>
<participant1 xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <time>
    <low value="2012"/>
    <high value="2012"/>
  </time>
  <associatedEntity/>
</participant1>
```

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