

Implementation Guide for CDA Release 2 Continuity of Care Document (CCD) (U.S. Realm)



DRAFT: FOR DEVELOPMENT USE ONLY

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Revision History

Rev	Date	By Whom	Changes
New	July 2010	Dave Carlson	
First draft for posting	August 31, 2010	Dave Carlson	Updated model content and publication format

Chapter 1

INTRODUCTION

Topics:

- *Overview*
- *Approach*
- *Scope*
- *Audience*
- *Organization of This Guide*
- *Use of Templates*
- *Conventions Used in This Guide*

Overview

This implementation guide is generated from UML models developed in the Open Health Tools (OHT) Model-Driven Health Tools (MDHT) project. The HL7 CCD specification has 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.

The purpose of this document is to describe constraints on the HL7 Clinical Document Architecture, Release 2 (CDA) specification in accordance with requirements set forward in ASTM E2369-05 Standard Specification for Continuity of Care Record (CCR).

The CCR is a core data set of the most relevant administrative, demographic, and clinical information facts about a patient's healthcare, covering one or more healthcare encounters. It provides a means for one healthcare practitioner, system, or setting to aggregate all of the pertinent data about a patient and forward it to another practitioner, system, or setting to support the continuity of care. The primary use case for the CCR is to provide a snapshot in time containing the pertinent clinical, demographic, and administrative data for a specific patient.

The HL7 Clinical Document Architecture (CDA) is a document markup standard that specifies the structure and semantics of clinical documents for the purpose of exchange. From its inception, CDA has supported the ability to represent professional society recommendations, national clinical practice guidelines, and standardized data sets. From the perspective of CDA, the CCR is a standardized data set that can be used to constrain CDA specifically for summary documents.

The resulting specification, known as the Continuity of Care Document (CCD), is developed as a collaborative effort between ASTM and HL7. It is intended as an alternate implementation to the one specified in ASTM ADJE2369 for those institutions or organizations committed to implementation of the HL7 Clinical Document Architecture.

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
 - a. **SHALL** contain [1..1] Reporting Parameters section (templateId:2.16.840.1.113883.10.20.17.2.1) (CONF:4131).
 - b. This component/structuredBody **SHALL** contain [1..1] component (CONF:4132) such that it
 - a. **SHALL** contain [1..1] Patient data section - NCR (templateId:2.16.840.1.113883.10.20.17.2.5) (CONF:4133).

Figure 2: Template-based conformance statements example

CCD templates are included within this implementation guide for ease of reference. CCD templates contained within this implementation guide are formatted **WITHOUT** typical **KEYWORD** and **XML** element styles. A WIKI site is available if you would like to make a comment to be considered for the next release of CCD: http://wiki.hl7.org/index.php?title=CCD_Suggested_Enhancements The user name and password are: wiki/wikiwiki. You will need to create an account to edit the page and add your suggestion.

1. The value for "Observation / @moodCode" in a problem observation **SHALL** be "EVN" 2.16.840.1.113883.5.1001 ActMood **STATIC**. (CONF: 814).
2. A problem observation **SHALL** include exactly one Observation / statusCode. (CONF: 815).
3. The value for "Observation / statusCode" in a problem observation **SHALL** be "completed" 2.16.840.1.113883.5.14 ActStatus **STATIC**. (CONF: 816).
4. A problem observation **SHOULD** contain exactly one Observation / effectiveTime, to indicate the biological timing of condition (e.g. the time the condition started, the onset of the illness or symptom, the duration of a condition). (CONF: 817).

Figure 3: CCD conformance statements example

Keywords

The keywords SHALL, SHALL NOT, SHOULD, SHOULD NOT, MAY, and NEED NOT in this document are to be interpreted as described in the [HL7 Version 3 Publishing Facilitator's Guide](#):

- **SHALL**: an absolute requirement
- **SHALL NOT**: an absolute prohibition against inclusion
- **SHOULD/SHOULD NOT**: valid reasons to include or ignore a particular item, but must be understood and carefully weighed
- **MAY/NEED NOT**: truly optional; can be included or omitted as the author decides with no implications

XML Examples

XML samples appear in various figures in this document in a fixed-width font. Portions of the XML content may be omitted from the content for brevity, marked by an ellipsis (...) as shown in the example below.

```
<ClinicalDocument xmlns='urn:h17-org:v3'>
  ...
</ClinicalDocument>
```

Figure 4: ClinicalDocument example

XPath expressions are used in the narrative and conformance requirements to identify elements because they are familiar to many XML implementers.

Chapter

2

DOCUMENT TEMPLATES

Topics:

- [*Continuity Of Care Document*](#)

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

Continuity Of Care Document

[ClinicalDocument: templateId 2.16.840.1.113883.10.20.1]

1. **SHALL** conform to CDA Clinical Document
2. **SHOULD** contain [1..1] component, such that it
 - a. contains *CCD Problem Section* (templateId: 2.16.840.1.113883.10.20.1.11) (CONF-140)
3. **SHOULD** contain [1..1] component, such that it
 - a. contains *CCD Family History Section* (templateId: 2.16.840.1.113883.10.20.1.4)
4. **SHOULD** contain [1..1] component, such that it
 - a. contains *CCD Social History Section* (templateId: 2.16.840.1.113883.10.20.1.15)
5. **SHOULD** contain [1..1] component, such that it
 - a. contains *CCD Alerts Section* (templateId: 2.16.840.1.113883.10.20.1.2)
6. **SHOULD** contain [1..1] component, such that it
 - a. contains *CCD Medications Section* (templateId: 2.16.840.1.113883.10.20.1.8) (CONF-298)
7. **SHOULD** contain [1..1] component, such that it
 - a. contains *CCD Results Section* (templateId: 2.16.840.1.113883.10.20.1.14) (CONF-388)
8. **SHOULD** contain [1..1] component, such that it
 - a. contains *CCD Procedures Section* (templateId: 2.16.840.1.113883.10.20.1.12)
9. **SHOULD** contain [1..1] component, such that it
 - a. contains *CCD Encounters Section* (templateId: 2.16.840.1.113883.10.20.1.3)
10. **SHOULD** contain [1..1] component, such that it
 - a. contains *CCD Plan Of Care Section* (templateId: 2.16.840.1.113883.10.20.1.10)
11. **SHOULD** contain [1..1] component, such that it
 - a. contains *CCD Immunizations Section* (templateId: 2.16.840.1.113883.10.20.1.6)
12. **SHOULD** contain [1..1] component, such that it
 - a. contains *CCD Vital Signs Section* (templateId: 2.16.840.1.113883.10.20.1.16)
13. **SHOULD** contain [1..1] component, such that it
 - a. contains *CCD Medical Equipment Section* (templateId: 2.16.840.1.113883.10.20.1.7)
14. **SHOULD** contain [1..1] component, such that it
 - a. contains *CCD Functional Status Section* (templateId: 2.16.840.1.113883.10.20.1.5)
15. **SHOULD** contain [1..1] component, such that it
 - a. contains *CCD Advance Directives Section* (templateId: 2.16.840.1.113883.10.20.1.1)
16. **SHOULD** contain [1..1] component, such that it
 - a. contains *CCD Payers Section* (templateId: 2.16.840.1.113883.10.20.1.9)
17. **SHALL** contain [1..1] code/@code = "34133-9" *Summarization of episode note* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC) (CONF-1)
18. **SHALL** contain [1..1] languageCode (CONF-5)
19. **MAY** contain [1..1] component, such that it
 - a. contains *CCD Purpose Section* (templateId: 2.16.840.1.113883.10.20.1.13) (CONF-15)
20. **SHALL** satisfy: Contains exactly one documentationOf / serviceEvent (CONF-2)
 - [OCL]: self.documentationOf->one(doc : cda::DocumentationOf | not doc.serviceEvent.oclIsUndefined())

21. SHALL satisfy: documentationOf / serviceEvent / @classCode SHALL be 'PCPR' (CONF-3)

- [OCL]: self.documentationOf->one(doc : cda::DocumentationOf | doc.serviceEvent.classCode = vocab::ActClassRoot::PCPR)

22. SHALL satisfy: documentationOf / serviceEvent contains exactly one serviceEvent / effectiveTime / low and exactly one serviceEvent / effectiveTime / high (CONF-4)

- [OCL]: self.documentationOf->one(doc : cda::DocumentationOf | not doc.serviceEvent.effectiveTime.low.ocIsUndefined() and not doc.serviceEvent.effectiveTime.high.ocIsUndefined())

23. SHALL satisfy: 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)

24. SHALL satisfy: SHALL NOT contain templateId / @extension (CONF-8)

- [OCL]: self.templateId->forAll(id : datatypes::II | id.root = '2.16.840.1.113883.10.20.1' implies id.extension.ocIsUndefined())

25. SHALL satisfy: effectiveTime is expressed with precision to include seconds (CONF-9)

26. SHALL satisfy: effectiveTime includes an explicit time zone offset (CONF-10)

27. SHALL satisfy: Contains one or two recordTarget (CONF-11)

- [OCL]: self.recordTarget->size() = 1 or self.recordTarget->size() = 2

28. SHOULD satisfy: Contains one or more author / assignedAuthor / assignedPerson and/or author / assignedAuthor / representedOrganization (CONF-12)

- [OCL]: self.author->exists(author : cda::Author | not author.assignedAuthor.assignedPerson.ocIsUndefined() or not author.assignedAuthor.representedOrganization.ocIsUndefined())

29. SHALL satisfy: If author has an associated representedOrganization with no assignedPerson or assignedAuthoringDevice, then the value for author / assignedAuthor / id / @NullFlavor SHALL be 'NA' (CONF-13)

- [OCL]: self.author->exists(author : cda::Author | (not author.assignedAuthor.representedOrganization.ocIsUndefined() and author.assignedAuthor.assignedPerson.ocIsUndefined() and author.assignedAuthor.assignedAuthoringDevice.ocIsUndefined()) implies author.assignedAuthor.id->one(id : datatypes::II | id.nullFlavor = vocab::NullFlavor::NA))

30. MAY satisfy: Contains one or more informationRecipient (CONF-14)

- [OCL]: self.informationRecipient->size() > 0

31. MAY satisfy: 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)

32. SHOULD satisfy: 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)

```
<?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">
  <templateId root="2.16.840.1.113883.10.20.1" assigningAuthorityName="CCD
  Continuity Of Care Document"/>
  <code code="34133-9" codeSystem="2.16.840.1.113883.6.1"
  codeSystemName="LOINC" displayName="Summarization of episode note"/>
  <languageCode/>
  <component>
    <structuredBody>
      <component>
        <section>
          <templateId root="2.16.840.1.113883.10.20.1.11"
  assigningAuthorityName="CCD Problem Section"/>
          <code code="11450-4" codeSystem="2.16.840.1.113883.6.1"
  codeSystemName="LOINC" displayName="Problem list"/>
          <title>Problem list</title>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

```

    </component>
  <component>
    <section>
      <templateId root="2.16.840.1.113883.10.20.1.4"
assigningAuthorityName="CCD Family History Section"/>
      <code code="10157-6" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="History of family member diseases"/>
      <title>History of family member diseases</title>
    </section>
  </component>
  <component>
    <section>
      <templateId root="2.16.840.1.113883.10.20.1.15"
assigningAuthorityName="CCD Social History Section"/>
      <code code="29762-2" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Social history"/>
      <title>Social history</title>
    </section>
  </component>
  <component>
    <section>
      <templateId root="2.16.840.1.113883.10.20.1.2"
assigningAuthorityName="CCD Alerts Section"/>
      <code code="48765-2" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Allergies, adverse reactions, alerts"/>
      <title>Allergies, adverse reactions, alerts</title>
    </section>
  </component>
  <component>
    <section>
      <templateId root="2.16.840.1.113883.10.20.1.8"
assigningAuthorityName="CCD Medications Section"/>
      <code code="10160-0" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="History of medication use"/>
      <title>History of medication use</title>
    </section>
  </component>
  <component>
    <section>
      <templateId root="2.16.840.1.113883.10.20.1.14"
assigningAuthorityName="CCD Results Section"/>
      <code code="30954-2" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Relevant diagnostic tests and/or
laboratory data"/>
      <title>Relevant diagnostic tests and/or laboratory data</title>
    </section>
  </component>
  <component>
    <section>
      <templateId root="2.16.840.1.113883.10.20.1.12"
assigningAuthorityName="CCD Procedures Section"/>
      <code code="47519-4" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="History of procedures"/>
      <title>History of procedures</title>
    </section>
  </component>
  <component>
    <section>
      <templateId root="2.16.840.1.113883.10.20.1.3"
assigningAuthorityName="CCD Encounters Section"/>
      <code code="46240-8" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="History of encounters"/>
      <title>History of encounters</title>
    </section>
  </component>

```

```

    </component>
  <component>
    <section>
      <templateId root="2.16.840.1.113883.10.20.1.10"
assigningAuthorityName="CCD Plan Of Care Section"/>
      <code code="18776-5" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Treatment plan"/>
      <title>Treatment plan</title>
    </section>
  </component>
  <component>
    <section>
      <templateId root="2.16.840.1.113883.10.20.1.6"
assigningAuthorityName="CCD Immunizations Section"/>
      <code code="11369-6" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="History of immunizations"/>
      <title>History of immunizations</title>
    </section>
  </component>
  <component>
    <section>
      <templateId root="2.16.840.1.113883.10.20.1.16"
assigningAuthorityName="CCD Vital Signs Section"/>
      <code code="8716-3" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Vital signs"/>
      <title>Vital signs</title>
    </section>
  </component>
  <component>
    <section>
      <templateId root="2.16.840.1.113883.10.20.1.7"
assigningAuthorityName="CCD Medical Equipment Section"/>
      <code code="46264-8" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="History of medical device use"/>
      <title>History of medical device use</title>
    </section>
  </component>
  <component>
    <section>
      <templateId root="2.16.840.1.113883.10.20.1.5"
assigningAuthorityName="CCD Functional Status Section"/>
      <code code="47420-5" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Functional status assessment"/>
      <title>Functional status assessment</title>
    </section>
  </component>
  <component>
    <section>
      <templateId root="2.16.840.1.113883.10.20.1.1"
assigningAuthorityName="CCD Advance Directives Section"/>
      <code code="42348-3" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Advance directives"/>
      <title>Advance directives</title>
    </section>
  </component>
  <component>
    <section>
      <templateId root="2.16.840.1.113883.10.20.1.9"
assigningAuthorityName="CCD Payers Section"/>
      <code code="48768-6" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Payment sources"/>
      <title>Payment sources</title>
    </section>
  </component>

```

```
<component>
  <section>
    <templateId root="2.16.840.1.113883.10.20.1.13"
      assigningAuthorityName="CCD Purpose Section"/>
    <code code="48764-5" codeSystem="2.16.840.1.113883.6.1"
      codeSystemName="LOINC" displayName="Summary purpose"/>
    <title>Summary purpose</title>
  </section>
</component>
</structuredBody>
</component>
</ClinicalDocument>
```

Figure 5: Continuity Of Care Document example

Chapter

3

SECTION TEMPLATES

Topics:

- *Advance Directives Section*
- *Alerts Section*
- *Encounters Section*
- *Family History Section*
- *Functional Status Section*
- *Immunizations Section*
- *Medical Equipment Section*
- *Medications Section*
- *Payers Section*
- *Plan Of Care Section*
- *Problem Section*
- *Procedures Section*
- *Purpose Section*
- *Results Section*
- *Social History Section*
- *Vital Signs Section*

Advance Directives Section

[Section: templateId 2.16.840.1.113883.10.20.1.1]

1. **SHALL** conform to CDA Section
2. **SHALL** contain [1..1] code/@code = "42348-3" *Advance directives* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC)
3. **SHALL** contain [1..1] title
4. **SHALL** contain [1..*] entry, such that it
 - a. contains *CCD Advance Directive Observation* (templateId: 2.16.840.1.113883.10.20.1.17)

```
<?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">
  <component>
    <structuredBody>
      <component>
        <section>
          <templateId root="2.16.840.1.113883.10.20.1.1"
            assigningAuthorityName="CCD Advance Directives Section"/>
          <code code="42348-3" codeSystem="2.16.840.1.113883.6.1"
            codeSystemName="LOINC" displayName="Advance directives"/>
          <title>Advance directives</title>
          <entry>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.17"
                assigningAuthorityName="CCD Advance Directive Observation"/>
              <id root="99cbca15-74b3-4242-9367-14f17b8fc198"/>
              <code/>
              <statusCode code="completed"/>
              <effectiveTime>
                <low value="1972"/>
                <high value="2008"/>
              </effectiveTime>
            </observation>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 6: Advance Directives Section example

Alerts Section

[Section: templateId 2.16.840.1.113883.10.20.1.2]

This section is used to list and describe any allergies, adverse reactions, and alerts that are pertinent to the patient's current or past medical history. At a minimum, currently active and any relevant historical allergies and adverse reactions should be listed.

1. **SHALL** conform to CDA Section
2. **SHALL** contain [1..1] code/@code = "48765-2" *Allergies, adverse reactions, alerts* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC)
3. **SHALL** contain [1..1] title
4. **SHALL** contain [1..1] text
5. **SHOULD** contain [1..*] entry, such that it
 - a. contains *CCD Problem Act* (templateId: 2.16.840.1.113883.10.20.1.27)

6. **SHOULD** satisfy: Contains a case-insensitive language-insensitive string containing "alert" and/or "allergies and adverse reactions".
7. **SHALL** satisfy: The absence of known allergies, adverse reactions or alerts **SHALL** be explicitly asserted.

```
<?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">
  <component>
    <structuredBody>
      <component>
        <section>
          <templateId root="2.16.840.1.113883.10.20.1.2"
            assigningAuthorityName="CCD Alerts Section"/>
          <code code="48765-2" codeSystem="2.16.840.1.113883.6.1"
            codeSystemName="LOINC" displayName="Allergies, adverse reactions, alerts"/>
          <title>Allergies, adverse reactions, alerts</title>
          <entry>
            <act classCode="ACT" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.27"
                assigningAuthorityName="CCD Problem Act"/>
              <id root="65b4fcb0-a016-4031-a76c-dbf9f445d489"/>
              <code nullFlavor="NA"/>
              <effectiveTime>
                <low value="1972"/>
                <high value="2008"/>
              </effectiveTime>
            </act>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 7: Alerts Section example

Encounters Section

[Section: templateId 2.16.840.1.113883.10.20.1.3]

This section is used to list and describe any healthcare encounters pertinent to the patient's current health status or historical health history. An Encounter is an interaction, regardless of the setting, between a patient and a practitioner who is vested with primary responsibility for diagnosing, evaluating, or treating the patient's condition. It may include visits, appointments, as well as non face-to-face interactions. It is also a contact between a patient and a practitioner who has primary responsibility for assessing and treating the patient at a given contact, exercising independent judgment. This section may contain all encounters for the time period being summarized, but should include notable encounters.

1. **SHALL** conform to CDA Section
2. **SHALL** contain [1..1] code/@code = "46240-8" *History of encounters* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC)
3. **SHALL** contain [1..1] title

```
<?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">
  <component>
    <structuredBody>
      <component>
        <section>
          <templateId root="2.16.840.1.113883.10.20.1.3"
            assigningAuthorityName="CCD Encounters Section"/>
```

```

        <code code="46240-8" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="History of encounters"/>
        <title>History of encounters</title>
    </section>
</component>
</structuredBody>
</component>
</ClinicalDocument>

```

Figure 8: Encounters Section example

Family History Section

[Section: templateId 2.16.840.1.113883.10.20.1.4]

This section contains data defining the patient's genetic relatives in terms of possible or relevant health risk factors that have a potential impact on the patient's healthcare risk profile.

1. **SHALL** conform to CDA Section
2. **SHALL** contain [1..1] code/@code = "10157-6" *History of family member diseases* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC)
3. **SHALL** contain [1..1] title

```

<?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">
    <component>
        <structuredBody>
            <component>
                <section>
                    <templateId root="2.16.840.1.113883.10.20.1.4"
assigningAuthorityName="CCD Family History Section"/>
                    <code code="10157-6" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="History of family member diseases"/>
                    <title>History of family member diseases</title>
                </section>
            </component>
        </structuredBody>
    </component>
</ClinicalDocument>

```

Figure 9: Family History Section example

Functional Status Section

[Section: templateId 2.16.840.1.113883.10.20.1.5]

Functional Status describes the patient's status of normal functioning at the time the Care Record was created. Functional statuses include information regarding the patient relative to:

- Ambulatory ability
- Mental status or competency
- Activities of Daily Living (ADLs), including bathing, dressing, feeding, grooming
- Home / living situation having an effect on the health status of the patient
- Ability to care for self
- Social activity, including issues with social cognition, participation with friends and acquaintances other than family members
- Occupation activity, including activities partly or directly related to working, housework or volunteering, family and home responsibilities or activities related to home and family
- Communication ability, including issues with speech, writing or cognition required for communication
- Perception, including sight, hearing, taste, skin sensation, kinesthetic sense, proprioception, or balance

Any deviation from normal function that the patient displays and is recorded in the record should be included. Of particular interest are those limitations that would in any way interfere with self care or the medical therapeutic process. In addition, an improvement, any change in or noting that the patient has normal functioning status is also valid for inclusion.

Functional Statuses can be expressed in 3 different forms. They can occur as a Problem, a Result or as text. Text can be employed if and only if the Functional Status is neither a Problem nor a Result. Functional Statuses expressed as Problems include relevant clinical conditions, diagnoses, symptoms and findings. Results are the interpretation or conclusion derived from a clinical assessment or test battery, such as the Instrumental Activities of Daily Living (IADL) scale or the Functional Status Index (FSI).

1. **SHALL** conform to CDA Section
2. **SHALL** contain [1..1] code/@code = "47420-5" *Functional status assessment* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC)
3. **SHALL** contain [1..1] title
4. **SHOULD** satisfy: Contains one or more Problem Act and/or Result Organizer (CONF-123)

- [OCL]: self.getEntryTargets(ccd::ProblemAct)->size() > 0
or self.getEntryTargets(ccd::ResultOrganizer)->size() > 0

```
<?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">
  <component>
    <structuredBody>
      <component>
        <section>
          <templateId root="2.16.840.1.113883.10.20.1.5"
            assigningAuthorityName="CCD Functional Status Section"/>
          <code code="47420-5" codeSystem="2.16.840.1.113883.6.1"
            codeSystemName="LOINC" displayName="Functional status assessment"/>
          <title>Functional status assessment</title>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 10: Functional Status Section example

Immunizations Section

[Section: templateId 2.16.840.1.113883.10.20.1.6]

The Immunizations section defines a patient's current immunization status and pertinent immunization history. The primary use case for the Immunization section is to enable communication of a patient's immunization status. The section should include current immunization status, and may contain the entire immunization history that is relevant to the period of time being summarized.

This section is optional, however it is strongly recommended that it be present in cases of pediatric care and in other cases when such information is available.

1. **SHALL** conform to CDA Section
2. **SHALL** contain [1..1] code/@code = "11369-6" *History of immunizations* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC)
3. **SHALL** contain [1..1] title
4. **SHALL** contain [1..1] text
5. **SHOULD** satisfy: Contains a case-insensitive language-insensitive string containing 'immunization'.
6. **SHOULD** satisfy: Contains one or more Medication Activity and/or Supply Activity (CONF-376)

- [OCL]: self.getEntryTargets(ccd::MedicationActivity)->size() > 0
or self.getEntryTargets(ccd::SupplyActivity)->size() > 0

```
<?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">
  <component>
    <structuredBody>
      <component>
        <section>
          <templateId root="2.16.840.1.113883.10.20.1.6"
            assigningAuthorityName="CCD Immunizations Section"/>
          <code code="11369-6" codeSystem="2.16.840.1.113883.6.1"
            codeSystemName="LOINC" displayName="History of immunizations"/>
          <title>History of immunizations</title>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 11: Immunizations Section example

Medical Equipment Section

[Section: templateId 2.16.840.1.113883.10.20.1.7]

The Medical Equipment section defines 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. This section is also used to itemize any pertinent current or historical durable medical equipment (DME) used to help maintain the patient's health status. All pertinent equipment relevant to the diagnosis, care, and treatment of a patient should be included.

1. **SHALL** conform to CDA Section
2. **SHALL** contain [1..1] code/@code = "46264-8" *History of medical device use* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC)
3. **SHALL** contain [1..1] title

```
<?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">
  <component>
    <structuredBody>
      <component>
        <section>
          <templateId root="2.16.840.1.113883.10.20.1.7"
            assigningAuthorityName="CCD Medical Equipment Section"/>
          <code code="46264-8" codeSystem="2.16.840.1.113883.6.1"
            codeSystemName="LOINC" displayName="History of medical device use"/>
          <title>History of medical device use</title>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 12: Medical Equipment Section example

Medications Section

[Section: templateId 2.16.840.1.113883.10.20.1.8]

The Medications section defines a patient's current medications and pertinent medication history. At a minimum, the currently active medications should be listed, with an entire medication history as an option, particularly when the summary document is used for comprehensive data export. The section may also include a patient's prescription history, and enables the determination of the source of a medication list (e.g. from a pharmacy system vs. from the patient).

Reconciliation of conflicting medication information from various sources is enabled both by indicating the source of information and by indicating whether the source is reporting intended or actual medication use. For instance, a physician may intend for a patient to be on a particular dose, but the patient may actually be taking a different dose; a pharmacy may fill a prescription for a particular dose only to then have the patient's physician lower the dose without notifying the pharmacy. Therefore, medication and supply activities can be expressed in CCD in either the "EVN" (event) mood or the "INT" (intent) mood. Medication activities in "INT" mood are not orders (which are represented in the Plan of Care section), but rather are reflections of what a clinician intends a patient to be taking. Medication activities in "EVN" mood reflect actual use. A pharmacy system will typically report what was actually filled (supply event), along with intended use (substance administration intent). A physician will often report intended use (substance administration and supply intent). A patient or family member will typically report actual use (substance administration event).

1. **SHALL** conform to CDA Section
2. **SHALL** contain [1..1] code/@code = "10160-0" *History of medication use* (CodeSystem: STATIC) (CONF-300, CONF-301)
3. **SHALL** contain [1..1] title (CONF-302)
4. **SHALL** contain [0..1] text
5. Contains [0..*] entry, such that it
 - a. contains *CCD Medication Activity* (templateId: 2.16.840.1.113883.10.20.1.24)
6. Contains [0..*] entry, such that it
 - a. contains *CCD Supply Activity* (templateId: 2.16.840.1.113883.10.20.1.34)
7. **SHOULD** satisfy: Clinical statements include one or more Medication Activity and/or one or more Supply Activity. (CONF-298)
 - [OCL]: self.getSubstanceAdministrations()->exists(activity : cda::SubstanceAdministration | activity.oclIsKindOf(ccd::MedicationActivity)) or self.getSupplies()->exists(activity : cda::Supply | activity.oclIsKindOf(ccd::SupplyActivity))
8. **SHALL** satisfy: The absence of known medications is explicitly asserted. (CONF-299)
9. **SHOULD** satisfy: Valued with a case-insensitive language-insensitive string containing 'medication'. (CONF-303)

```
<?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">
  <component>
    <structuredBody>
      <component>
        <section>
          <templateId root="2.16.840.1.113883.10.20.1.8"
            assigningAuthorityName="CCD Medications Section"/>
          <code code="10160-0" codeSystem="2.16.840.1.113883.6.1"
            codeSystemName="LOINC" displayName="History of medication use"/>
          <title>History of medication use</title>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 13: Medications Section example

Payers Section

[Section: templateId 2.16.840.1.113883.10.20.1.9]

Payers contains data on the patient's payers, whether a 'third party' insurance, self-pay, other payer or guarantor, or some combination of payers, and is used to define which entity is the responsible fiduciary for the financial aspects of a patient's care.

Each unique instance of a payer and all the pertinent data needed to contact, bill to, and collect from that payer should be included. Authorization information that can be used to define pertinent referral, authorization tracking number, procedure, therapy, intervention, device, or similar authorizations for the patient or provider, or both should be included. At a minimum, the patient's pertinent current payment sources should be listed.

The CCD represents the sources of payment as a coverage act, which identifies all of the insurance policies or government or other programs that cover some or all of the patient's healthcare expenses. The policies or programs are sequenced by order of preference. Each policy or program identifies the covered party with respect to the payer, so that the identifiers can be recorded.

1. **SHALL** conform to CDA Section
2. **SHALL** contain [1..1] `code/@code = "48768-6" Payment sources` (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC) (CONF-31, CONF-32)
3. **SHALL** contain [1..1] `title` (CONF-33)
4. **SHOULD** contain [1..*] `entry`, such that it
 - a. contains *CCD Coverage Activity* (templateId: 2.16.840.1.113883.10.20.1.20) (CONF-30)
5. **SHALL** contain [1..1] `text` (CONF-30)
6. **SHOULD** satisfy: Contains a case-insensitive language-insensitive string containing 'insurance' or 'payers'. (CONF-34)

```
<?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">
  <component>
    <structuredBody>
      <component>
        <section>
          <templateId root="2.16.840.1.113883.10.20.1.9"
            assigningAuthorityName="CCD Payers Section"/>
          <code code="48768-6" codeSystem="2.16.840.1.113883.6.1"
            codeSystemName="LOINC" displayName="Payment sources"/>
          <title>Payment sources</title>
          <entry>
            <act classCode="ACT" moodCode="DEF">
              <templateId root="2.16.840.1.113883.10.20.1.20"
                assigningAuthorityName="CCD Coverage Activity"/>
              <id root="99be346b-4cf7-4c9f-9lcc-4d84f97d2b1d"/>
              <code code="48768-6" codeSystem="2.16.840.1.113883.6.1"
                codeSystemName="LOINC" displayName="Payment sources"/>
              <statusCode code="completed"/>
            </act>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 14: Payers Section example

Plan Of Care Section

[Section: templateId 2.16.840.1.113883.10.20.1.10]

The plan of care section contains data defining pending orders, interventions, encounters, services, and procedures for the patient. It is limited to prospective, unfulfilled, or incomplete orders and requests only. All active, incomplete, or pending orders, appointments, referrals, procedures, services, or any other pending event of clinical significance to the current and ongoing care of the patient should be listed, unless constrained due to issues of privacy.

The plan of care section also contains information regarding goals and clinical reminders. Clinical reminders are placed here for purposes of providing prompts that may be used for disease prevention, disease management, patient safety, and healthcare quality improvements, including widely accepted performance measures.

1. **SHALL** conform to CDA Section
2. **SHALL** contain [1..1] code/@code = "18776-5" *Treatment plan* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC)
3. **SHALL** contain [1..1] title
4. **SHALL** contain [1..1] text
5. **MAY** contain [0..1] entry, such that it
 - a. contains *CCD Plan Of Care Activity Act* (templateId: 2.16.840.1.113883.10.20.1.25)
6. **MAY** contain [0..1] entry, such that it
 - a. contains *CCD Plan Of Care Activity Encounter* (templateId: 2.16.840.1.113883.10.20.1.25)
7. **MAY** contain [0..1] entry, such that it
 - a. contains *CCD Plan Of Care Activity Observation* (templateId: 2.16.840.1.113883.10.20.1.25)
8. **MAY** contain [0..1] entry, such that it
 - a. contains *CCD Plan Of Care Activity Procedure* (templateId: 2.16.840.1.113883.10.20.1.25)
9. **MAY** contain [0..1] entry, such that it
 - a. contains *CCD Plan Of Care Activity Substance Administration* (templateId: 2.16.840.1.113883.10.20.1.25)
10. **MAY** contain [0..1] entry, such that it
 - a. contains *CCD Plan Of Care Activity Supply* (templateId: 2.16.840.1.113883.10.20.1.25)
11. **SHALL** contain [1..1] planOfCareActivity, such that it
 - a. contains *CCD Plan Of Care Activity*

```
<?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">
  <component>
    <structuredBody>
      <component>
        <section>
          <templateId root="2.16.840.1.113883.10.20.1.10"
            assigningAuthorityName="CCD Plan Of Care Section"/>
          <code code="18776-5" codeSystem="2.16.840.1.113883.6.1"
            codeSystemName="LOINC" displayName="Treatment plan"/>
          <title>Treatment plan</title>
          <entry>
            <act classCode="ACT" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.25"/>
              <id root="b30a637d-d9c7-409d-8d23-e80d6c26889c"/>
            </act>
          </entry>
          <entry>
            <encounter>
              <templateId root="2.16.840.1.113883.10.20.1.25"/>
              <id root="00c40f80-2ccc-415e-9bab-8abd50565da1"/>
            </encounter>
          </entry>
          <entry>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.25"/>
              <id root="7394b2fa-d35a-421f-9f1e-30885857d1c5"/>
            </observation>
          </entry>
          <entry>
            <procedure>
              <templateId root="2.16.840.1.113883.10.20.1.25"/>
              <id root="9cbdf2ee-f48c-498a-8881-3e767cb62e0e"/>
            </procedure>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

```

    <entry>
      <substanceAdministration classCode="SBADM">
        <templateId root="2.16.840.1.113883.10.20.1.25"/>
        <id root="f20113f1-5941-496d-bbbf-a0ab35c61faf"/>
      </substanceAdministration>
    </entry>
    <entry>
      <supply classCode="SPLY">
        <templateId root="2.16.840.1.113883.10.20.1.25"/>
        <id root="245b28f8-f7c9-486a-890e-d81ce0ab54cc"/>
      </supply>
    </entry>
  </section>
</component>
</structuredBody>
</component>
</ClinicalDocument>

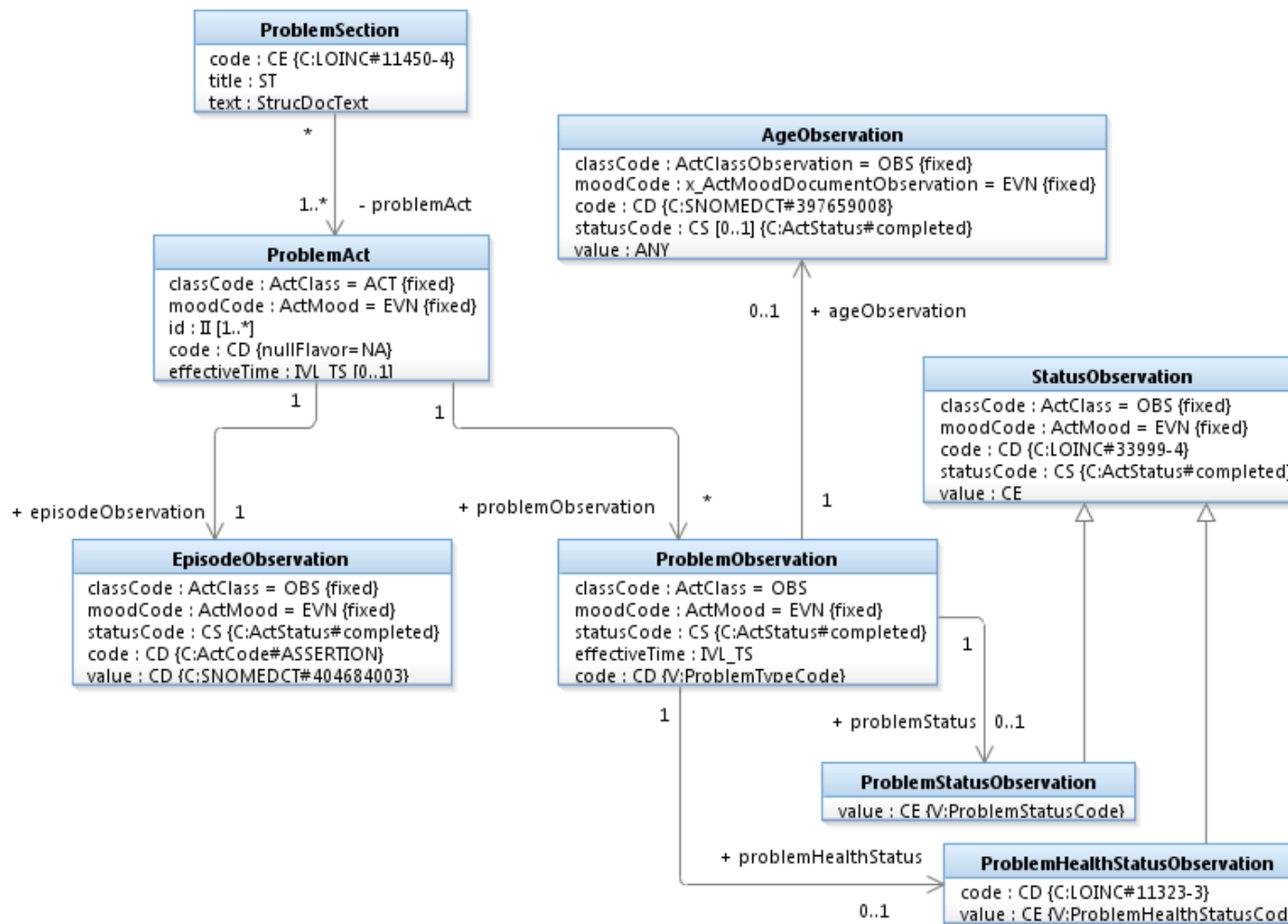
```

Figure 15: Plan Of Care Section example

Problem Section

[Section: templateId 2.16.840.1.113883.10.20.1.11]

This section lists and describes all relevant clinical problems at the time the summary is generated. At a minimum, all pertinent current and historical problems should be listed. CDA R2 represents problems as Observations.



1. **SHALL** conform to CDA Section
2. **SHALL** contain [1..1] code/@code = "11450-4" *Problem list* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC) (CONF-141, CONF-142)
3. **SHALL** contain [1..1] title (CONF-143)
4. **SHOULD** contain [1..*] entry, such that it
 - a. contains *CCD Problem Act* (templateId: 2.16.840.1.113883.10.20.1.27) (CONF-140)
5. **SHALL** contain [1..1] text (CONF-140)
6. **SHOULD** satisfy: Contains a case-insensitive language-insensitive string containing 'problems'. (CONF-144)

```

<?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">
  <component>
    <structuredBody>
      <component>
        <section>
          <templateId root="2.16.840.1.113883.10.20.1.11"
            assigningAuthorityName="CCD Problem Section"/>
          <code code="11450-4" codeSystem="2.16.840.1.113883.6.1"
            codeSystemName="LOINC" displayName="Problem list"/>
          <title>Problem list</title>
          <entry>
            <act classCode="ACT" moodCode="EVN">

```

```

        <templateId root="2.16.840.1.113883.10.20.1.27"
assigningAuthorityName="CCD Problem Act"/>
        <id root="74dbalf6-07d0-4474-b161-e810465d0f40"/>
        <code nullFlavor="NA"/>
        <effectiveTime>
            <low value="1972"/>
            <high value="2008"/>
        </effectiveTime>
    </act>
</entry>
</section>
</component>
</structuredBody>
</component>
</ClinicalDocument>

```

Figure 16: Problem Section example

Procedures Section

[Section: templateId 2.16.840.1.113883.10.20.1.12]

This section defines all interventional, surgical, diagnostic, or therapeutic procedures or treatments pertinent to the patient historically at the time the document is generated. The section may contain all procedures for the period of time being summarized, but should include notable procedures.

1. **SHALL** conform to CDA Section
2. **SHALL** contain [1..1] code/@code = "47519-4" *History of procedures* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC)
3. **SHALL** contain [1..1] title
4. **SHOULD** contain [1..*] procedureActivity, such that it
 - a. contains *CCD Procedure Activity*

```

<?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">
    <component>
        <structuredBody>
            <component>
                <section>
                    <templateId root="2.16.840.1.113883.10.20.1.12"
assigningAuthorityName="CCD Procedures Section"/>
                    <code code="47519-4" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="History of procedures"/>
                    <title>History of procedures</title>
                </section>
            </component>
        </structuredBody>
    </component>
</ClinicalDocument>

```

Figure 17: Procedures Section example

Purpose Section

[Section: templateId 2.16.840.1.113883.10.20.1.13]

Represents the specific reason for which the summarization was generated, such as in response to a request.

The general use case does not require a purpose. Purpose should be utilized when the CCD has a specific purpose such as a transfer, referral, or patient request.

1. **SHALL** conform to CDA Section

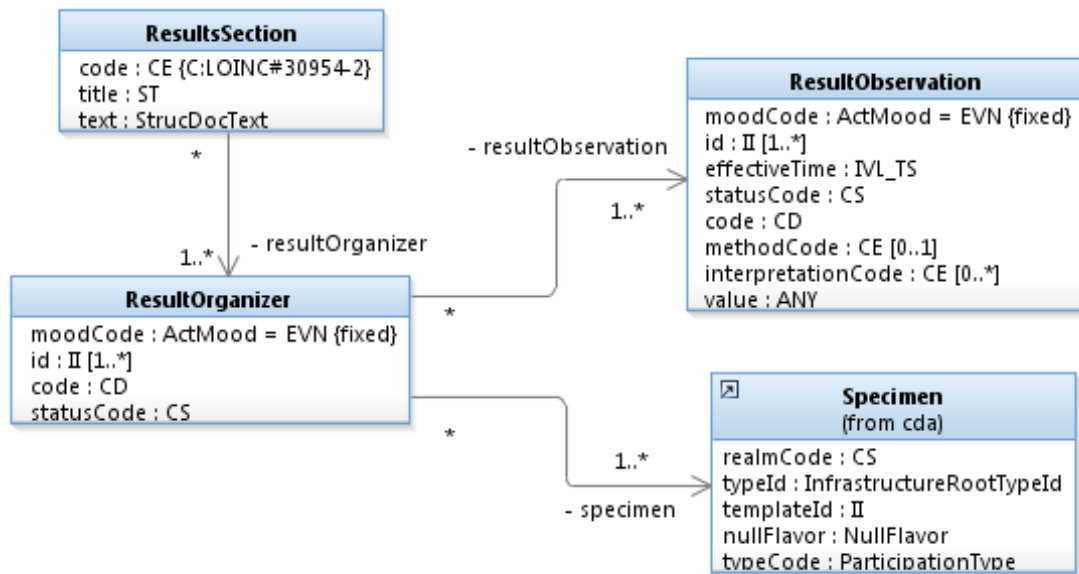
2. **SHALL** contain [1..1] code/@code = "48764-5" *Summary purpose* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC) (CONF-16, CONF-17)
3. **SHALL** contain [1..1] title (CONF-18)
4. **SHOULD** contain [1..*] entry, such that it
 - a. contains *CCD Purpose Activity* (templateId: 2.16.840.1.113883.10.20.1.30)
5. **SHALL** contain [1..1] text
6. **SHOULD** satisfy: Contains a case-insensitive language-insensitive string containing 'purpose'. (CONF-19)

```
<?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">
  <component>
    <structuredBody>
      <component>
        <section>
          <templateId root="2.16.840.1.113883.10.20.1.13"
            assigningAuthorityName="CCD Purpose Section"/>
          <code code="48764-5" codeSystem="2.16.840.1.113883.6.1"
            codeSystemName="LOINC" displayName="Summary purpose"/>
          <title>Summary purpose</title>
          <entry>
            <act classCode="ACT" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.30"
                assigningAuthorityName="CCD Purpose Activity"/>
              <code code="23745001" codeSystem="2.16.840.1.113883.6.96"
                codeSystemName="SNOMEDCT" displayName="Documentation procedure"/>
              <statusCode code="completed"/>
            </act>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 18: Purpose Section example

Results Section

[Section: templateId 2.16.840.1.113883.10.20.1.14]



This 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, cardiac echo, nuclear medicine, pathology, and procedure observations. The section may contain all results for the period of time being summarized, but should include notable results such as abnormal values or relevant trends.

Lab 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, submitted to the lab.

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 echo.

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

1. **SHALL** conform to CDA Section
2. **SHALL** contain [1..1] code/@code = "30954-2" *Relevant diagnostic tests and/or laboratory data* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC) (CONF-389)
3. **SHALL** contain [1..1] title (CONF-391)
4. **SHOULD** contain [1..*] entry, such that it
 - a. contains *CCD Result Organizer* (templateId: 2.16.840.1.113883.10.20.1.32) (CONF-388)
5. **SHALL** contain [1..1] text (CONF-388)
6. **SHOULD** satisfy: Contains a case-insensitive language-insensitive string containing 'results'. (CONF-392)

```

<?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">
  <component>
    <structuredBody>
      <component>
        <section>
          <templateId root="2.16.840.1.113883.10.20.1.14"
            assigningAuthorityName="CCD Results Section"/>
        
```

```

    <code code="30954-2" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Relevant diagnostic tests and/or
laboratory data"/>
    <title>Relevant diagnostic tests and/or laboratory data</title>
    <entry>
      <organizer moodCode="EVN">
        <templateId root="2.16.840.1.113883.10.20.1.32"
assigningAuthorityName="CCD Result Organizer"/>
        <id root="6833a9d3-4493-46a3-8933-62ed1339dbf3"/>
        <code/>
        <statusCode/>
      </organizer>
    </entry>
  </section>
</component>
</structuredBody>
</component>
</ClinicalDocument>

```

Figure 19: Results Section example

Social History Section

[Section: templateId 2.16.840.1.113883.10.20.1.15]

This section contains data defining the patient's occupational, personal (e.g. lifestyle), social, and environmental history and health risk factors, as well as administrative data such as marital status, race, ethnicity and religious affiliation. Social history can have significant influence on a patient's physical, psychological and emotional health and wellbeing so should be considered in the development of a complete record.

1. **SHALL** conform to CDA Section
2. **SHALL** contain [1..1] code/@code = "29762-2" *Social history* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC)
3. **SHOULD** contain [1..1] title

```

<?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">
  <component>
    <structuredBody>
      <component>
        <section>
          <templateId root="2.16.840.1.113883.10.20.1.15"
assigningAuthorityName="CCD Social History Section"/>
          <code code="29762-2" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Social history"/>
          <title>Social history</title>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>

```

Figure 20: Social History Section example

Vital Signs Section

[Section: templateId 2.16.840.1.113883.10.20.1.16]

This section contains current and historically relevant vital signs, such as blood pressure, heart rate, respiratory rate, height, weight, body mass index, head circumference, crown-to-rump length, and pulse oximetry. The section may

contain all vital signs for the period of time being summarized, but at a minimum should include notable vital signs such as the most recent, maximum and/or minimum, or both, baseline, or relevant trends.

Vital signs are represented like other results (as defined in **Results Section**), but are aggregated into their own section in order to follow clinical conventions.

1. **SHALL** conform to CDA Section
2. **SHALL** contain [1..1] code/@code = "8716-3" *Vital signs* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC)
3. **SHALL** contain [1..1] title
4. **SHOULD** contain [1..*] entry, such that it
 - a. contains *CCD Vital Signs Organizer* (templateId: 2.16.840.1.113883.10.20.1.35)
5. **SHALL** contain [1..1] text
6. **SHOULD** satisfy: Contains a case-insensitive language-insensitive string containing 'vital signs'.

```
<?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">
  <component>
    <structuredBody>
      <component>
        <section>
          <templateId root="2.16.840.1.113883.10.20.1.16"
            assigningAuthorityName="CCD Vital Signs Section"/>
          <code code="8716-3" codeSystem="2.16.840.1.113883.6.1"
            codeSystemName="LOINC" displayName="Vital signs"/>
          <title>Vital signs</title>
          <entry>
            <organizer moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.32"
                assigningAuthorityName="CCD Result Organizer"/>
              <templateId root="2.16.840.1.113883.10.20.1.35"
                assigningAuthorityName="CCD Vital Signs Organizer"/>
              <id root="acc6d0ed-8de9-412b-b62d-4a6620ff915a"/>
              <code/>
              <statusCode/>
            </organizer>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 21: Vital Signs Section example

Chapter

4

CLINICAL STATEMENT TEMPLATES

Topics:

- *Advance Directive Observation*
- *Advance Directive Status Observation*
- *Age Observation*
- *Alert Observation*
- *Alert Status Observation*
- *Authorization Activity*
- *Cause Of Death Observation*
- *Comment*
- *Coverage Activity*
- *Coverage Plan Description*
- *Encounters Activity*
- *Episode Observation*
- *Family History Observation*
- *Family History Organizer*
- *Fulfillment Instruction*
- *Functional Status Observation*
- *Medication Activity*
- *Medication Series Number Observation*
- *Medication Status Observation*
- *Patient Instruction*
- *Plan Of Care Activity Act*
- *Plan Of Care Activity Encounter*
- *Plan Of Care Activity Observation*
- *Plan Of Care Activity Procedure*
- *Plan Of Care Activity Substance Administration*
- *Plan Of Care Activity Supply*
- *Policy Activity*
- *Problem Act*
- *Problem Health Status Observation*
- *Problem Observation*
- *Problem Status Observation*
- *Procedure Activity Act*

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.

- *Procedure Activity Observation*
- *Procedure Activity Procedure*
- *Purpose Activity*
- *Reaction Observation*
- *Result Observation*
- *Result Organizer*
- *Severity Observation*
- *Social History Observation*
- *Status Observation*
- *Supply Activity*
- *Vital Signs Organizer*

Advance Directive Observation

[Observation: templateId 2.16.840.1.113883.10.20.1.17]

1. **SHALL** conform to CDA Observation
2. **SHALL** contain [1..1] @classCode = "OBS"
3. **SHALL** contain [1..1] @moodCode = "EVN"
4. **SHALL** contain [1..*] id
5. **SHALL** contain [1..1] statusCode/@code = "completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus STATIC V3NE08)
6. **SHOULD** contain [0..1] effectiveTime
7. **MAY** contain [1..1] code, which **MAY** be selected from ValueSet 2.16.840.1.113883.1.11.20.2 AdvanceDirectiveTypeCode STATIC 20061017
8. **MAY** contain [1..*] advanceDirectiveVerification, such that it
 - a. contains *CCD Advance Directive Verification* (templateId: 2.16.840.1.113883.10.20.1.58)

```
<?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">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.17"
assigningAuthorityName="CCD Advance Directive Observation"/>
              <id root="4a3ffc82-987b-435e-b1c2-f7b5ac696ec6"/>
              <code/>
              <statusCode code="completed"/>
              <effectiveTime>
                <low value="1972"/>
                <high value="2008"/>
              </effectiveTime>
            </observation>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 22: Advance Directive Observation example

Advance Directive Status Observation

[Observation: templateId 2.16.840.1.113883.10.20.1.37]

1. **SHALL** conform to *CCD Status Observation* template (templateId: 2.16.840.1.113883.10.20.1.57)
2. **SHALL** contain [1..1] value, which **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.20.1 AdvanceDirectiveStatusCode STATIC 20061017

```
<?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">
  <component>
    <structuredBody>
      <component>
```

```

    <section>
      <entry>
        <observation classCode="OBS" moodCode="EVN">
          <templateId root="2.16.840.1.113883.10.20.1.57"
            assigningAuthorityName="CCD Status Observation"/>
          <templateId root="2.16.840.1.113883.10.20.1.37"
            assigningAuthorityName="CCD Advance Directive Status Observation"/>
          <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"
            codeSystemName="LOINC" displayName="Status"/>
          <statusCode code="completed"/>
          <value xsi:type="CE"/>
        </observation>
      </entry>
    </section>
  </component>
</structuredBody>
</component>
</ClinicalDocument>

```

Figure 23: Advance Directive Status Observation example

Age Observation

[Observation: templateId 2.16.840.1.113883.10.20.1.38]

A common scenario is that a patient will know the age of a relative when they had a certain condition or when they died, but will not know the actual year (e.g. "grandpa died of a heart attack at the age of 50"). Often times, neither precise dates nor ages are known (e.g. "cousin died of congenital heart disease as an infant"). In all cases, dates and times and ages can be expressed in narrative.

1. **SHALL** conform to CDA Observation
2. **SHALL** contain [1..1] @classCode = "OBS"
3. **SHALL** contain [1..1] @moodCode = "EVN"
4. **SHALL** contain [1..1] code/@code = "397659008" Age (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT STATIC)
5. **SHALL** contain [0..1] statusCode/@code = "completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus STATIC V3NE08)
6. **SHALL** contain [1..1] value

```

<?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">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.38"
                assigningAuthorityName="CCD Age Observation"/>
              <code code="397659008" codeSystem="2.16.840.1.113883.6.96"
                codeSystemName="SNOMEDCT" displayName="Age"/>
              <statusCode code="completed"/>
            </observation>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>

```

Figure 24: Age Observation example

Alert Observation

[Observation: templateId 2.16.840.1.113883.10.20.1.18]

1. **SHALL** conform to CDA Observation
2. **SHALL** contain [1..1] @moodCode = "EVN"
3. **SHALL** contain [1..1] statusCode/@code = "completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus STATIC V3NE08)
4. **MAY** contain [0..1] effectiveTime
5. **MAY** contain [0..*] value, which **MAY** be selected from ValueSet 2.16.840.1.113883.1.11.20.4 AlertTypeCode STATIC 20061017, where its data type is CE
6. **MAY** contain [0..1] entryRelationship, such that it
 - a. contains *CCD Alert Status Observation* (templateId: 2.16.840.1.113883.10.20.1.39)
7. **MAY** contain [1..*] entryRelationship, such that it
 - a. has @typeCode="MFST" *MFST (is manifestation of)*
 - b. contains *CCD Reaction Observation* (templateId: 2.16.840.1.113883.10.20.1.54)
8. **SHOULD** satisfy: The absence of known allergies **SHOULD** be represented in an alert observation by valuing Observation / value with 160244002 "No known allergies" 2.16.840.1.113883.6.96 SNOMED CT STATIC.
9. **SHALL** satisfy: An alert observation contains one or more sources of information.
 - [OCL]: not self.informant->isEmpty()
or not self.getSection().informant->isEmpty()
or not self.getClinicalDocument().informant->isEmpty()
or self.reference->exists(ref : cda::Reference | ref.typeCode = vocab::x_ActRelationshipExternalReference::XCRPT)
or (self.entryRelationship->exists(rel : cda::EntryRelationship | rel.typeCode = vocab::x_ActRelationshipEntryRelationship::REFR and rel.observation.code.code = '48766-0'))
10. **SHOULD** satisfy: An alert observation **SHOULD** contain at least one Observation / participant, representing the agent that is the cause of the allergy or adverse reaction. The value for participant / @typeCode in an agent participation **SHALL** be "CSM" "Consumable" 2.16.840.1.113883.5.90 ParticipationType STATIC.
 - [OCL]: self.participant->exists(participant : cda::Participant2 | participant.typeCode = vocab::ParticipationType::CSM)
11. **SHALL** satisfy: Contains exactly one participant / participantRole / playingEntity. The value for participant / participantRole / playingEntity / @classCode in an agent participation **SHALL** be "MMAT" "Manufactured material" 2.16.840.1.113883.5.41 EntityClass STATIC. Contains exactly one participant / participantRole / playingEntity / code.
 - [OCL]: self.participant.participantRole.playingEntity->one(entity : cda::PlayingEntity | entity.classCode = vocab::EntityClassRoot::MMAT and not entity.code.ocIsUndefined())
12. **SHOULD** satisfy: The value for participant / participantRole / playingEntity / code in an agent participation **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 immunizations.

```
<?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">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.18"
                assigningAuthorityName="CCD Alert Observation"/>
            </observation>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

```

        <statusCode code="completed"/>
        <effectiveTime>
            <low value="1972"/>
            <high value="2008"/>
        </effectiveTime>
        <value xsi:type="CE"/>
        <entryRelationship>
            <observation classCode="OBS" moodCode="EVN">
                <templateId root="2.16.840.1.113883.10.20.1.57"
assigningAuthorityName="CCD Status Observation"/>
                <templateId root="2.16.840.1.113883.10.20.1.39"
assigningAuthorityName="CCD Alert Status Observation"/>
                <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Status"/>
                <statusCode code="completed"/>
                <value xsi:type="CE"/>
            </observation>
        </entryRelationship>
        <entryRelationship>
            <observation classCode="OBS" moodCode="EVN">
                <templateId root="2.16.840.1.113883.10.20.1.54"
assigningAuthorityName="CCD Reaction Observation"/>
                <statusCode code="completed"/>
            </observation>
        </entryRelationship>
    </observation>
</entry>
</section>
</component>
</structuredBody>
</component>
</ClinicalDocument>

```

Figure 25: Alert Observation example

Alert Status Observation

[Observation: templateId 2.16.840.1.113883.10.20.1.39]

1. **SHALL** conform to *CCD Status Observation* template (templateId: 2.16.840.1.113883.10.20.1.57)
2. **SHALL** contain [1..1] value, which **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.20.3
AlertStatusCode STATIC 20061017

```

<?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">
    <component>
        <structuredBody>
            <component>
                <section>
                    <entry>
                        <observation classCode="OBS" moodCode="EVN">
                            <templateId root="2.16.840.1.113883.10.20.1.57"
assigningAuthorityName="CCD Status Observation"/>
                            <templateId root="2.16.840.1.113883.10.20.1.39"
assigningAuthorityName="CCD Alert Status Observation"/>
                            <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Status"/>
                            <statusCode code="completed"/>
                            <value xsi:type="CE"/>
                        </observation>
                    </entry>
                </section>
            </component>
        </structuredBody>
    </component>
</ClinicalDocument>

```

```

    </component>
  </structuredBody>
</component>
</ClinicalDocument>

```

Figure 26: Alert Status Observation example

Authorization Activity

[Act: templateId 2.16.840.1.113883.10.20.1.19]

An authorization activity represents authorizations or pre-authorizations currently active for the patient for the particular payer. Authorizations are represented using an act subordinate to the policy or program that provided it. The policy or program is referred to by the authorization. Authorized treatments can be grouped into an Organizer class, where common properties, such as the reason for the authorization, can be expressed. Subordinate acts represent what was authorized.

1. **SHALL** conform to CDA Act
2. **SHALL** contain [1..1] @classCode = "ACT"
3. **SHALL** contain [1..1] @moodCode = "EVN"
4. **SHALL** contain [1..*] id

```

<?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">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <act classCode="ACT" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.19"
                assigningAuthorityName="CCD Authorization Activity"/>
              <id root="5eb3db5b-67de-46fe-9cc5-e99db738e8cf"/>
            </act>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>

```

Figure 27: Authorization Activity example

Cause Of Death Observation

[Observation: templateId 2.16.840.1.113883.10.20.1.42]

1. **SHALL** conform to *CCD Family History Observation* template (templateId: 2.16.840.1.113883.10.20.1.22)

```

<?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">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.22"
                assigningAuthorityName="CCD Family History Observation"/>
            </observation>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>

```

```

        <templateId root="2.16.840.1.113883.10.20.1.42"
assigningAuthorityName="CCD Cause Of Death Observation"/>
        <id root="c3166a6b-69f2-4ebc-810a-b166698be2a7"/>
        <statusCode code="completed"/>
    </observation>
</entry>
</section>
</component>
</structuredBody>
</component>
</ClinicalDocument>

```

Figure 28: Cause Of Death Observation example

Comment

[Act: templateId 2.16.840.1.113883.10.20.1.40]

1. **SHALL** conform to CDA Act
2. **SHALL** contain [1..1] @classCode = "ACT"
3. **SHALL** contain [1..1] @moodCode = "EVN"
4. **SHALL** contain [1..1] code/@code = "48767-8" *Annotation comment* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC)

```

<?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">
    <component>
        <structuredBody>
            <component>
                <section>
                    <entry>
                        <act classCode="ACT" moodCode="EVN">
                            <templateId root="2.16.840.1.113883.10.20.1.40"
assigningAuthorityName="CCD Comment"/>
                            <code code="48767-8" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Annotation comment"/>
                        </act>
                    </entry>
                </section>
            </component>
        </structuredBody>
    </component>
</ClinicalDocument>

```

Figure 29: Comment example

Coverage Activity

[Act: templateId 2.16.840.1.113883.10.20.1.20]

1. **SHALL** conform to CDA Act
2. **SHALL** contain [1..1] @classCode = "ACT" (CONF-36)
3. **SHALL** contain [1..1] @moodCode = "DEF" (CONF-37)
4. **SHALL** contain [1..*] id (CONF-38)
5. **SHALL** contain [1..1] statusCode/@code = "completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus STATIC V3NE08) (CONF-39, CONF-40)
6. **SHALL** contain [1..1] code/@code = "48768-6" *Payment sources* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC) (CONF-41, CONF-42)

7. **SHALL** contain [1..*] entryRelationship, such that it

- a. has @typeCode="COMP" *COMP* (has component)
- b. contains *CCD Policy Activity* (templateId: 2.16.840.1.113883.10.20.1.26) (CONF-43, CONF-45, CONF-46)

8. **SHALL** satisfy: An alert observation contains one or more sources of information. (CONF-47)

- [OCL]: not self.informant->isEmpty()
or not self.getSection().informant->isEmpty()
or not self.getClinicalDocument().informant->isEmpty()
or self.reference->exists(ref : cda::Reference | ref.typeCode =
vocab::x_ActRelationshipExternalReference::XCRPT)
or (self.entryRelationship->exists(rel : cda::EntryRelationship |
rel.typeCode = vocab::x_ActRelationshipEntryRelationship::REFR
and rel.observation.code.code = '48766-0'))

9. **MAY** satisfy: entryRelationship contains sequenceNumber, which serves to prioritize the payment sources. (CONF-44)

- [OCL]: self.entryRelationship->exists(rel : cda::EntryRelationship | not
rel.sequenceNumber.ocIsUndefined())

```
<?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">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <act classCode="ACT" moodCode="DEF">
              <templateId root="2.16.840.1.113883.10.20.1.20"
assigningAuthorityName="CCD Coverage Activity"/>
              <id root="e69103f3-ce93-4093-ba03-98d81377154b"/>
              <code code="48768-6" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Payment sources"/>
              <statusCode code="completed"/>
              <entryRelationship>
                <act classCode="ACT" moodCode="EVN">
                  <templateId root="2.16.840.1.113883.10.20.1.26"
assigningAuthorityName="CCD Policy Activity"/>
                  <id root="98dc8efe-018e-436c-8b14-f5e5b91d43a3"/>
                  <code/>
                  <statusCode code="completed"/>
                </act>
              </entryRelationship>
            </act>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 30: Coverage Activity example

Coverage Plan Description

[Act: templateId null]

1. **SHALL** conform to CDA Act
2. **SHALL** contain [1..1] @classCode = "ACT" (CONF-67)
3. **SHALL** contain [1..1] @moodCode = "DEF" (CONF-67)

4. SHALL contain [1..*] id (CONF-68)

```
<?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">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <act classCode="ACT" moodCode="DEF">
              <templateId assigningAuthorityName="CCD Coverage Plan
Description" />
              <id root="2cc5b7f7-eef6-4a61-91a6-35c40cb056ed" />
            </act>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 31: Coverage Plan Description example

Encounters Activity

[Encounter: templateId 2.16.840.1.113883.10.20.1.21]

1. **SHALL** conform to CDA Encounter
2. **SHALL** contain [1..1] @classCode = "ENC"
3. **SHALL** contain [1..1] @moodCode = "EVN"
4. **SHALL** contain [1..*] id
5. **SHOULD** contain [1..1] code, which **SHOULD** be selected from ValueSet 2.16.840.1.113883.1.11.13955 EncounterCode STATIC
6. **MAY** contain [0..1] effectiveTime

```
<?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">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <encounter classCode="ENC" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.21"
assigningAuthorityName="CCD Encounters Activity" />
              <id root="ed363a21-26f3-4a12-bad6-57d30b8012c1" />
              <code />
              <effectiveTime>
                <low value="1972" />
                <high value="2008" />
              </effectiveTime>
            </encounter>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 32: Encounters Activity example

Episode Observation

[Observation: templateId 2.16.840.1.113883.10.20.1.41]

Episode observations are used to distinguish among multiple occurrences of a problem or social history item. An episode observation is used to indicate that a problem act represents a new episode, distinct from other episodes of a similar concern.

1. **SHALL** conform to CDA Observation (CONF-169)
2. **SHALL** contain [1..1] @classCode = "OBS" (CONF-170)
3. **SHALL** contain [1..1] @moodCode = "EVN" (CONF-171)
4. **SHALL** contain [1..1] statusCode/@code = "completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus STATIC V3NE08) (CONF-172, CONF-173)
5. **SHOULD** contain [1..1] code/@code = "ASSERTION" (CodeSystem: 2.16.840.1.113883.5.4 ActCode STATIC V3NE08) (CONF-174)
6. **SHOULD** contain [1..1] value/@code = "404684003" *Clinical finding* (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT STATIC), where its data type is CD (CONF-175)
7. **SHOULD** satisfy: Value in an episode observation **SHOULD** be the following SNOMED CT expression:

```
<codeblock><value xsi:type="CD" code="404684003" codeSystem="2.16.840.1.113883.6.96"
displayName="Clinical finding"> <qualifier> <name code="246456000" displayName="Episodicity"/> <value
code="288527008" displayName="New episode"/> </qualifier> </value></codeblock>
```

 (CONF-175)
8. **SHALL** satisfy: Source of exactly one entryRelationship whose typeCode is 'SUBJ'. This is used to link the episode observation to the target problem act or social history observation. (CONF-176)
 - [OCL]:

```
self.getEntryRelationshipTargets(vocab::x_ActRelationshipEntryRelationship::SUBJ,
ccd::ProblemAct)->size() = 1
or
self.getEntryRelationshipTargets(vocab::x_ActRelationshipEntryRelationship::SUBJ,
ccd::SocialHistoryObservation)->size() = 1
```
9. **MAY** satisfy: Source of one or more entryRelationship whose typeCode is 'SAS'. The target of the entryRelationship **SHALL** be a problem act or social history observation. This is used to represent the temporal sequence of episodes. (CONF-177)
 - [OCL]:

```
self.getEntryRelationshipTargets(vocab::x_ActRelationshipEntryRelationship::SAS,
ccd::ProblemAct)->size() > 0
or
self.getEntryRelationshipTargets(vocab::x_ActRelationshipEntryRelationship::SAS,
ccd::SocialHistoryObservation)->size() > 0
```

```
<?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">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.41"
assigningAuthorityName="CCD Episode Observation"/>
              <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"
codeSystemName="ActCode"/>
              <statusCode code="completed"/>
              <value xsi:type="CD"/>
            </observation>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

```

    </structuredBody>
  </component>
</ClinicalDocument>

```

Figure 33: Episode Observation example

Family History Observation

[Observation: templateId 2.16.840.1.113883.10.20.1.22]

1. **SHALL** conform to CDA Observation
2. **SHALL** contain [1..*] id
3. **SHALL** contain [1..1] statusCode/@code = "completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus STATIC V3NE08)

```

<?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">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.22"
assigningAuthorityName="CCD Family History Observation"/>
              <id root="0eac3427-517c-45a4-b5f4-a095dcca0dd4"/>
              <statusCode code="completed"/>
            </observation>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>

```

Figure 34: Family History Observation example

Family History Organizer

[Organizer: templateId 2.16.840.1.113883.10.20.1.23]

1. **SHALL** conform to CDA Organizer
2. **SHALL** contain [1..1] statusCode/@code = "completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus STATIC V3NE08)

```

<?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">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <organizer>
              <templateId root="2.16.840.1.113883.10.20.1.23"
assigningAuthorityName="CCD Family History Organizer"/>
              <statusCode code="completed"/>
            </organizer>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>

```

```

    </component>
  </structuredBody>
</component>
</ClinicalDocument>

```

Figure 35: Family History Organizer example

Fulfillment Instruction

[Act: templateId 2.16.840.1.113883.10.20.1.43]

Fulfillment instructions are additional information provided to the dispensing party (e.g. "label in spanish").

1. **SHALL** conform to CDA Act (CONF-335)
2. **SHALL** contain [1..1] @moodCode = "INT" (CONF-336)

```

<?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">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <act classCode="ACT" moodCode="INT">
              <templateId root="2.16.840.1.113883.10.20.1.43"
                assigningAuthorityName="CCD Fulfillment Instruction"/>
            </act>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>

```

Figure 36: Fulfillment Instruction example

Functional Status Observation

[Observation: templateId 2.16.840.1.113883.10.20.1.44]

1. **SHALL** conform to *CCD Status Observation* template (templateId: 2.16.840.1.113883.10.20.1.57)
2. **SHALL** contain [1..1] value, which **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.20.5
StatusOfFunctionalStatusCode STATIC 20061017

```

<?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">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.57"
                assigningAuthorityName="CCD Status Observation"/>
              <templateId root="2.16.840.1.113883.10.20.1.44"
                assigningAuthorityName="CCD Functional Status Observation"/>
              <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"
                codeSystemName="LOINC" displayName="Status"/>
              <statusCode code="completed"/>
              <value xsi:type="CE"/>
            </observation>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>

```

```

        </entry>
      </section>
    </component>
  </structuredBody>
</component>
</ClinicalDocument>

```

Figure 37: Functional Status Observation example

Medication Activity

[SubstanceAdministration: templateId 2.16.840.1.113883.10.20.1.24]

A medication activity is used to describe what is administered whereas a supply activity is used to describe what has been dispensed.

An indication describes the rationale for a medication activity. The indication can be an existing problem or can be a criterion that if met would warrant the activity. Criteria are typically associated with PRN (from the Latin "pro re nata", meaning "as needed") medications (e.g. "give Medication X as needed for nausea").

1. **SHALL** conform to CDA Substance Administration (CONF-304)
2. **SHALL** contain [1..*] id (CONF-306)
3. **SHOULD** contain [1..1] statusCode (CONF-307)
4. **MAY** contain [0..1] entryRelationship, such that it
 - a. contains *CCD Medication Series Number Observation* (templateId: 2.16.840.1.113883.10.20.1.46) (CONF-338, CONF-339)
5. **MAY** contain [0..1] entryRelationship, such that it
 - a. contains *CCD Medication Status Observation* (templateId: 2.16.840.1.113883.10.20.1.47) (CONF-350)
6. **MAY** contain [1..*] entryRelationship, such that it
 - a. has @typeCode="SUBJ" *SUBJ (has subject)*
 - b. contains *CCD Patient Instruction* (templateId: 2.16.840.1.113883.10.20.1.49) (CONF-330, CONF-333)
7. **SHOULD** contain [1..*] effectiveTime (CONF-308)
 - Used to indicate the actual or intended start and stop date of a medication, and the frequency of administration.
8. **MAY** contain [0..1] maxDoseQuantity (CONF-312)
9. **SHOULD** contain [1..1] routeCode (CodeSystem: 2.16.840.1.113883.5.112 HL7 RouteOfAdministration DYNAMIC) (CONF-309, CONF-310)
10. **MAY** contain [0..1] performer, such that it
 - a. contains CDA Performer2 (CONF-313)
 - Indicates the person administering a substance.
11. **MAY** contain [0..1] entryRelationship, such that it
 - a. has @typeCode="CAUS" *CAUS (is etiology for)*
 - b. contains *CCD Reaction Observation* (templateId: 2.16.840.1.113883.10.20.1.54) (CONF-348, CONF-349)
12. **SHALL** satisfy: Value for moodCode is "EVN" or "INT" 2.16.840.1.113883.5.1001 ActMood STATIC (CONF-305)
 - [OCL]: self.moodCode=vocab::x_DocumentSubstanceMood::EVN or self.moodCode=vocab::x_DocumentSubstanceMood::INT
13. **SHOULD** satisfy: Contains exactly one doseQuantity or rateQuantity. (CONF-311)
 - [OCL]: not self.doseQuantity.ocIsUndefined() or not self.rateQuantity.ocIsUndefined()

14. MAY satisfy: Has one or more associated consents, represented in the CCD Header as ClinicalDocument / authorization / consent. (CONF-314)

- [OCL]: `self.getClinicalDocument().authorization->exists(auth : cda::Authorization | not auth.oclIsUndefined() and not auth.consent.oclIsUndefined())`

15. SHALL satisfy: Contains one or more sources of information. (CONF-315)

- [OCL]: `not self.informant->isEmpty() or not self.getSection().informant->isEmpty() or not self.getClinicalDocument().informant->isEmpty() or self.reference->exists(ref : cda::Reference | ref.typeCode = vocab::x_ActRelationshipExternalReference::XCRPT) or (self.entryRelationship->exists(rel : cda::EntryRelationship | rel.typeCode = vocab::x_ActRelationshipEntryRelationship::REFR and rel.observation.code.code = '48766-0'))`

16. 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)

- Indicates that the medication is administered only when the associated (coded or free text) criteria are met.
- [OCL]: `self.precondition->exists(precondition : cda::Precondition | not precondition.criterion.oclIsUndefined())`

17. 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)

- The target of the relationship represents the indication for the activity.
- [OCL]: `self.entryRelationship->exists(entryRel : cda::EntryRelationship | entryRel.typeCode = vocab::x_ActRelationshipEntryRelationship::RSON)`

18. SHALL satisfy: entryRelationship / @typeCode="RSON" in a medication activity has a target of problem act, problem observation, or some other clinical statement. (CONF-329)

- [OCL]: `self.getEntryRelationshipTargets(vocab::x_ActRelationshipEntryRelationship::RSON, cda::ClinicalStatement)->forall(target : cda::ClinicalStatement | not target.oclIsUndefined() and (target.oclIsKindOf(ccd::ProblemAct) or target.oclIsKindOf(ccd::ProblemObservation)))`

19. SHALL satisfy: Contains exactly one consumable, the target of which is a Product template. (CONF-354)

- [OCL]: `self.consumable.manufacturedProduct.oclIsKindOf(ccd::Product)`

```
<?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">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <substanceAdministration classCode="SBADM">
              <templateId root="2.16.840.1.113883.10.20.1.24"
assigningAuthorityName="CCD Medication Activity"/>
              <id root="89182b26-bf47-4b78-9e8f-d188e165e3e9"/>
              <statusCode/>
              <effectiveTime/>
              <routeCode codeSystem="2.16.840.1.113883.5.112"
codeSystemName="HL7 RouteOfAdministration"/>
              <maxDoseQuantity/>
              <entryRelationship>
                <observation classCode="OBS" moodCode="EVN">
                  <templateId root="2.16.840.1.113883.10.20.1.46"
assigningAuthorityName="CCD Medication Series Number Observation"/>
```

```

        <code code="30973-2" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Dose number"/>
        <statusCode/>
        <value xsi:type="INT"/>
    </observation>
</entryRelationship>
<entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
        <templateId root="2.16.840.1.113883.10.20.1.57"
assigningAuthorityName="CCD Status Observation"/>
        <templateId root="2.16.840.1.113883.10.20.1.47"
assigningAuthorityName="CCD Medication Status Observation"/>
        <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Status"/>
        <statusCode code="completed"/>
        <value xsi:type="CE"/>
    </observation>
</entryRelationship>
<entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
        <templateId root="2.16.840.1.113883.10.20.1.54"
assigningAuthorityName="CCD Reaction Observation"/>
        <statusCode code="completed"/>
    </observation>
</entryRelationship>
</substanceAdministration>
</entry>
</section>
</component>
</structuredBody>
</component>
</ClinicalDocument>

```

Figure 38: Medication Activity example

Medication Series Number Observation

[Observation: templateId 2.16.840.1.113883.10.20.1.46]

The medication series number observation can be used to indicate which in a series of administrations a particular administration represents (e.g. "hepatitis B vaccine number 2 was administered on Feb 07, 2004).

1. **SHALL** conform to CDA Observation (CONF-340)
2. **SHALL** contain [1..1] @classCode = "OBS" (CONF-341)
3. **SHALL** contain [1..1] @moodCode = "EVN" (CONF-342)
4. **SHALL** contain [1..1] statusCode (CONF-343)
5. **SHALL** contain [1..1] code/@code = "30973-2" *Dose number* (CodeSystem: STATIC) (CONF-344, CONF-345)
6. **SHALL** contain [1..1] value, where its data type is INT (CONF-346, CONF-347)

```

<?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">
    <component>
        <structuredBody>
            <component>
                <section>
                    <entry>
                        <observation classCode="OBS" moodCode="EVN">
                            <templateId root="2.16.840.1.113883.10.20.1.46"
assigningAuthorityName="CCD Medication Series Number Observation"/>
                            <code code="30973-2" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Dose number"/>

```

```

        <statusCode/>
        <value xsi:type="INT"/>
      </observation>
    </entry>
  </section>
</component>
</structuredBody>
</component>
</ClinicalDocument>

```

Figure 39: Medication Series Number Observation example

Medication Status Observation

[Observation: templateId 2.16.840.1.113883.10.20.1.47]

1. **SHALL** conform to *CCD Status Observation* template (templateId: 2.16.840.1.113883.10.20.1.57) (CONF-352)
2. **SHALL** contain [1..1] value, which **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.20.7 MedicationStatusCode STATIC 20061017 (CONF-353)

```

<?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">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.57"
                assigningAuthorityName="CCD Status Observation"/>
              <templateId root="2.16.840.1.113883.10.20.1.47"
                assigningAuthorityName="CCD Medication Status Observation"/>
              <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"
                codeSystemName="LOINC" displayName="Status"/>
              <statusCode code="completed"/>
              <value xsi:type="CE"/>
            </observation>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>

```

Figure 40: Medication Status Observation example

Patient Instruction

[Act: templateId 2.16.840.1.113883.10.20.1.49]

Patient instructions are additional information provided to a patient related to one of their medications (e.g. "take on an empty stomach").

1. **SHALL** conform to CDA Act (CONF-331)
2. **SHALL** contain [1..1] @moodCode = "INT" (CONF-332)

```

<?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">
  <component>
    <structuredBody>

```

```

    <component>
      <section>
        <entry>
          <act classCode="ACT" moodCode="INT">
            <templateId root="2.16.840.1.113883.10.20.1.49"
assigningAuthorityName="CCD Patient Instruction"/>
          </act>
        </entry>
      </section>
    </component>
  </structuredBody>
</component>
</ClinicalDocument>

```

Figure 41: Patient Instruction example

Plan Of Care Activity Act

[Act: templateId 2.16.840.1.113883.10.20.1.25]

1. **SHALL** conform to CDA Act
2. **SHALL** conform to *CCD Plan Of Care Activity*
3. **SHALL** contain [1..1] @moodCode
4. **SHALL** contain [1..*] id
5. **SHALL** satisfy: moodCodeValue

- [OCL]: self.moodCode = vocab::x_DocumentActMood::INT or self.moodCode = vocab::x_DocumentActMood::ARQ or self.moodCode = vocab::x_DocumentActMood::PRMS or self.moodCode = vocab::x_DocumentActMood::PRP or self.moodCode = vocab::x_DocumentActMood::RQO

```

<?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">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <act classCode="ACT" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.25"/>
              <id root="elef8542-c32f-4c9f-97d5-a898f177799c"/>
            </act>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>

```

Figure 42: Plan Of Care Activity Act example

Plan Of Care Activity Encounter

[Encounter: templateId 2.16.840.1.113883.10.20.1.25]

1. **SHALL** conform to CDA Encounter
2. **SHALL** conform to *CCD Plan Of Care Activity*
3. **SHALL** contain [1..1] @moodCode
4. **SHALL** contain [1..*] id

5. SHALL satisfy: moodCodeValue

- [OCL]: self.moodCode = vocab::x_DocumentEncounterMood::INT or self.moodCode = vocab::x_DocumentEncounterMood::ARQ or self.moodCode = vocab::x_DocumentEncounterMood::PRMS or self.moodCode = vocab::x_DocumentEncounterMood::PRP or self.moodCode = vocab::x_DocumentEncounterMood::RQO

```
<?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">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <encounter>
              <templateId root="2.16.840.1.113883.10.20.1.25"/>
              <id root="000c8bf3-f9ef-4492-abc5-65d9d6d5e10f"/>
            </encounter>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 43: Plan Of Care Activity Encounter example**Plan Of Care Activity Observation**

[Observation: templateId 2.16.840.1.113883.10.20.1.25]

1. **SHALL** conform to CDA Observation
2. **SHALL** conform to *CCD Plan Of Care Activity*
3. **SHALL** contain [1..1] @moodCode
4. **SHALL** contain [1..*] id
5. **SHALL** satisfy: moodCodeValue

- [OCL]: self.moodCode = vocab::x_ActMoodDocumentObservation::INT or self.moodCode = vocab::x_ActMoodDocumentObservation::GOL or self.moodCode = vocab::x_ActMoodDocumentObservation::PRMS or self.moodCode = vocab::x_ActMoodDocumentObservation::PRP or self.moodCode = vocab::x_ActMoodDocumentObservation::RQO

```
<?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">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.25"/>
              <id root="9c31222f-00d6-4fcc-b9e7-d793254bdd15"/>
            </observation>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 44: Plan Of Care Activity Observation example

Plan Of Care Activity Procedure

[Procedure: templateId 2.16.840.1.113883.10.20.1.25]

1. **SHALL** conform to CDA Procedure
2. **SHALL** conform to [CCD Plan Of Care Activity](#)
3. **SHALL** contain [1..1] @moodCode
4. **SHALL** contain [1..*] id
5. **SHALL** satisfy: moodCodeValue
 - [OCL]: self.moodCode = vocab::x_DocumentProcedureMood::INT or self.moodCode = vocab::x_DocumentProcedureMood::ARQ or self.moodCode = vocab::x_DocumentProcedureMood::PRMS or self.moodCode = vocab::x_DocumentProcedureMood::PRP or self.moodCode = vocab::x_DocumentProcedureMood::RQO

```
<?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">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <procedure>
              <templateId root="2.16.840.1.113883.10.20.1.25"/>
              <id root="75129abe-3e95-4d38-ab7c-407130e60a85"/>
            </procedure>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 45: Plan Of Care Activity Procedure example

Plan Of Care Activity Substance Administration

[SubstanceAdministration: templateId 2.16.840.1.113883.10.20.1.25]

1. **SHALL** conform to CDA Substance Administration
2. **SHALL** conform to [CCD Plan Of Care Activity](#)
3. **SHALL** contain [1..1] @moodCode
4. **SHALL** contain [1..*] id
5. **SHALL** satisfy: moodCodeValue
 - [OCL]: self.moodCode = vocab::x_DocumentSubstanceMood::INT or self.moodCode = vocab::x_DocumentSubstanceMood::RQO or self.moodCode = vocab::x_DocumentSubstanceMood::PRMS or self.moodCode = vocab::x_DocumentSubstanceMood::PRP

```
<?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">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <substanceAdministration classCode="SBADM">
```

```

        <templateId root="2.16.840.1.113883.10.20.1.25"/>
        <id root="69c2c9cf-a5ac-4cc4-8408-016198072672"/>
      </substanceAdministration>
    </entry>
  </section>
</component>
</structuredBody>
</component>
</ClinicalDocument>

```

Figure 46: Plan Of Care Activity Substance Administration example

Plan Of Care Activity Supply

[Supply: templateId 2.16.840.1.113883.10.20.1.25]

1. **SHALL** conform to CDA Supply
2. **SHALL** conform to *CCD Plan Of Care Activity*
3. **SHALL** contain [1..1] @moodCode
4. **SHALL** contain [1..*] id
5. **SHALL** satisfy: moodCodeValue
 - [OCL]: self.moodCode = vocab::x_DocumentSubstanceMood::INT or
 self.moodCode = vocab::x_DocumentSubstanceMood::RQO
 or self.moodCode = vocab::x_DocumentSubstanceMood::PRMS or self.moodCode
 = vocab::x_DocumentSubstanceMood::PRP

```

<?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">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <supply classCode="SPLY">
              <templateId root="2.16.840.1.113883.10.20.1.25"/>
              <id root="513ab25c-1116-4fb6-9999-d9bedf0fce51"/>
            </supply>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>

```

Figure 47: Plan Of Care Activity Supply example

Policy Activity

[Act: templateId 2.16.840.1.113883.10.20.1.26]

A policy activity represents the policy or program providing the coverage. The person for whom payment is being provided (i.e. the patient) is the covered party. The subscriber of the policy or program is represented as a participant that is the holder the coverage. The payer is represented as the performer of the policy activity.

1. **SHALL** conform to CDA Act
2. **SHALL** contain [1..1] @classCode = "ACT" (CONF-49)
3. **SHALL** contain [1..1] @moodCode = "EVN" (CONF-50)
4. **SHALL** contain [1..*] id (CONF-51)
5. **SHALL** contain [1..1] statusCode/@code = "completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus STATIC V3NE08) (CONF-52, CONF-53)

6. **SHOULD** contain [1..1] code, which **SHOULD** be selected from ValueSet 2.16.840.1.113883.1.11.19832 ActCoverageType DYNAMIC (CONF-54, CONF-55)
7. **SHALL** contain [1..1] performer, such that it
 - a. contains *CCD Payer Entity* (CONF-56)
8. **SHALL** contain [1..1] participant, such that it
 - a. contains *CCD Covered Party* (CONF-58)
9. **MAY** contain [1..1] participant, such that it
 - a. contains *CCD Policy Subscriber* (CONF-63)
10. **SHALL** satisfy: A policy activity contains exactly one performer [@typeCode='PRF'], representing the payer. (CONF-56)
 - [OCL]: self.performer->one(perf : cda::Performer2 | perf.typeCode = vocab::ParticipationPhysicalPerformer::PRF)
11. **SHALL** satisfy: A policy activity contains exactly one participant [@typeCode='COV'], representing the covered party. (CONF-58)
 - [OCL]: self.participant->one(part : cda::Participant2 | part.typeCode = vocab::ParticipationType::COV)
12. **MAY** satisfy: The value for participant / participantRole / code in a policy activity's covered party MAY be selected from ValueSet 2.16.840.1.113883.1.11.19809 PolicyOrProgramCoverageRoleType DYNAMIC. (CONF-61)
13. **MAY** satisfy: A covered party in a policy activity MAY contain exactly one participant / time, to represent the time period over which the patient is covered. (CONF-62)
 - [OCL]: self.participant->one(part : cda::Participant2 | part.typeCode = vocab::ParticipationType::COV
implies not part.time.ocIsUndefined())
14. **MAY** satisfy: A policy activity MAY contain exactly one participant [@typeCode='HLD'], representing the subscriber. (CONF-63)
 - [OCL]: self.participant->one(part : cda::Participant2 | part.typeCode = vocab::ParticipationType::HLD)
15. **MAY** satisfy: A subscriber in a policy activity MAY contain exactly one participant / time, to represent the time period for which the subscriber is enrolled. (CONF-65)
 - [OCL]: self.participant->one(part : cda::Participant2 | part.typeCode = vocab::ParticipationType::HLD
implies not part.time.ocIsUndefined())
16. **SHALL** satisfy: The value for entryRelationship / @typeCode in a policy activity SHALL be 'REFR' 2.16.840.1.113883.5.1002 ActRelationshipType STATIC. (CONF-66)
 - [OCL]: self.entryRelationship->forall(rel : cda::EntryRelationship | rel.typeCode = vocab::x_ActRelationshipEntryRelationship::REFR)
17. **SHALL** satisfy: The target of a policy activity with entryRelationship / @typeCode='REFR' SHALL be an Authorization Activity or an Act, with Act [@classCode = 'ACT'] and Act [@moodCode = 'DEF'], representing a description of the coverage plan. (CONF-67)
 - [OCL]: self.entryRelationship->forall(rel : cda::EntryRelationship | rel.act.ocIsKindOf(ccd::AuthorizationActivity)
or rel.act.ocIsKindOf(ccd::CoveragePlanDescription))

```
<?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">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <act classCode="ACT" moodCode="EVN">
```

```

    <templateId root="2.16.840.1.113883.10.20.1.26"
    assigningAuthorityName="CCD Policy Activity"/>
    <id root="ab4bb301-3523-42d9-9a4e-8f529e6495d2"/>
    <code/>
    <statusCode code="completed"/>
    <performer>
      <assignedEntity>
        <templateId assigningAuthorityName="CCD Payer Entity"/>
        <id root="0b037950-0892-4345-87ab-4abf21615ecf"/>
      </assignedEntity>
    </performer>
    <participant>
      <participantRole>
        <templateId assigningAuthorityName="CCD Covered Party"/>
        <id root="5f9a33d2-0756-4472-bc94-20ca15cf9869"/>
        <code/>
      </participantRole>
    </participant>
    <participant>
      <participantRole>
        <templateId assigningAuthorityName="CCD Policy Subscriber"/>
        <id root="48647217-5ec1-43ed-92e3-fa776349d5a2"/>
      </participantRole>
    </participant>
  </act>
</entry>
</section>
</component>
</structuredBody>
</component>
</ClinicalDocument>

```

Figure 48: Policy Activity example

Problem Act

[Act: templateId 2.16.840.1.113883.10.20.1.27]

A problem is a clinical statement that a clinician is particularly concerned about and 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** conform to CDA Act (CONF-145)
2. **SHALL** contain [1..1] @classCode = "ACT" (CONF-146)
3. **SHALL** contain [1..1] @moodCode = "EVN" (CONF-147)
4. **SHALL** contain [1..*] id (CONF-148)
5. **SHALL** contain [1..1] code/@nullFlavor = "NA" *NA (not applicable)* (CONF-149)
6. **MAY** contain [0..1] effectiveTime (CONF-150)
 - Indicates the timing of the concern (e.g. the interval of time for which the problem is a concern).
7. **MAY** contain [1..1] entryRelationship, such that it
 - a. contains *CCD Episode Observation* (templateId: 2.16.840.1.113883.10.20.1.41) (CONF-168)
8. Contains [0..*] entryRelationship, such that it
 - a. contains *CCD Problem Observation* (templateId: 2.16.840.1.113883.10.20.1.28)
9. **SHALL** satisfy: Contains one or more entryRelationship (CONF-151)
 - [OCL]: not self.entryRelationship->isEmpty()
10. **MAY** satisfy: 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)

11. SHOULD satisfy: 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)

- [OCL]:

```
self.getEntryRelationshipTargets(vocab:x_ActRelationshipEntryRelationship::SUBJ,
cda::ClinicalStatement)->forall(target : cda::ClinicalStatement | not
target.ocIsUndefined() and
(target.ocIsKindOf(ccd::ProblemObservation) or
target.ocIsKindOf(ccd::AlertObservation)))
```

12. SHOULD satisfy: In Problem Section, a Problem Act SHOULD contain one or more Problem Observations. (CONF-140)

- [OCL]:

```
self.getSection().ocIsKindOf(ccd::ProblemSection) implies
self.getObservations()
->exists(obs : cda::Observation |
obs.ocIsKindOf(ccd::ProblemObservation))
```

13. SHOULD satisfy: In Alert Section, a ProblemAct SHOULD contain one or more Alert Observations. (CONF-256)

- [OCL]:

```
self.getSection().ocIsKindOf(ccd::AlertsSection) implies
self.getObservations()
->exists(obs : cda::Observation |
obs.ocIsKindOf(ccd::AlertObservation))
```

14. MAY satisfy: Contains exactly one Patient Awareness (CONF-179)

- [OCL]:

```
self.participant->one(partic : cda::Participant2 |
partic.ocIsKindOf(ccd::PatientAwareness))
```

```
<?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">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <act classCode="ACT" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.27"
assigningAuthorityName="CCD Problem Act"/>
              <id root="3c6e1621-2b4c-4d30-960c-534ba787a882"/>
              <code nullFlavor="NA"/>
              <effectiveTime>
                <low value="1972"/>
                <high value="2008"/>
              </effectiveTime>
              <entryRelationship>
                <observation classCode="OBS" moodCode="EVN">
                  <templateId root="2.16.840.1.113883.10.20.1.41"
assigningAuthorityName="CCD Episode Observation"/>
                  <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"
codeSystemName="ActCode"/>
                  <statusCode code="completed"/>
                  <value xsi:type="CD"/>
                </observation>
              </entryRelationship>
            </act>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 49: Problem Act example

Problem Health Status Observation

[Observation: templateId 2.16.840.1.113883.10.20.1.51]

1. **SHALL** conform to *CCD Status Observation* template (templateId: 2.16.840.1.113883.10.20.1.57) (CONF-166)
2. **SHALL** contain [1..1] code/@code = "11323-3" *Health status* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC) (CONF-166)
3. **SHALL** contain [1..1] value, which **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.20.12 ProblemHealthStatusCode STATIC 20061017 (CONF-167)

```
<?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">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.57"
                assigningAuthorityName="CCD Status Observation"/>
              <templateId root="2.16.840.1.113883.10.20.1.51"
                assigningAuthorityName="CCD Problem Health Status Observation"/>
              <code code="11323-3" codeSystem="2.16.840.1.113883.6.1"
                codeSystemName="LOINC" displayName="Health status"/>
              <statusCode code="completed"/>
              <value xsi:type="CE"/>
            </observation>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 50: Problem Health Status Observation example

Problem Observation

[Observation: templateId 2.16.840.1.113883.10.20.1.28]

1. **SHALL** conform to CDA Observation (CONF-154)
2. Contains [1..1] @classCode = "OBS"
3. **SHALL** contain [1..1] @moodCode = "EVN" (CONF-155)
4. **SHALL** contain [1..1] statusCode/@code = "completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus STATIC V3NE08) (CONF-156, CONF-157)
5. **SHOULD** contain [1..1] effectiveTime (CONF-158)
 - Indicates the biological timing of condition (e.g. the time the condition started, the onset of the illness or symptom, the duration of a condition).
6. **MAY** contain [1..1] code, which **MAY** be selected from ValueSet 2.16.840.1.113883.1.11.20.14 ProblemTypeCode STATIC 20061017 (CONF-159)
 - code **SHALL** be present (per CDA schema), by **MAY** use specified value set.
7. **MAY** contain [0..1] entryRelationship, such that it
 - a. has @typeCode="REFR" *REFR* (refers to)

- b. contains *CCD Problem Status Observation* (templateId: 2.16.840.1.113883.10.20.1.50) (CONF-162)
- 8. **MAY** contain [0..1] entryRelationship, such that it
 - a. has @typeCode="REFR" *REFR* (*refers to*)
 - b. contains *CCD Problem Health Status Observation* (templateId: 2.16.840.1.113883.10.20.1.51) (CONF-165)
- 9. **MAY** contain [0..1] entryRelationship, such that it
 - a. has @typeCode="SUBJ" *SUBJ* (*has subject*)
 - b. contains *CCD Age Observation* (templateId: 2.16.840.1.113883.10.20.1.38) (CONF-160)
- 10. **SHALL** satisfy: Contains one or more sources of information. (CONF-161)
 - [OCL]: not self.informant->isEmpty()
 or not self.getSection().informant->isEmpty()
 or not self.getClinicalDocument().informant->isEmpty()
 or self.reference->exists(ref : cda::Reference | ref.typeCode =
 vocab::x_ActRelationshipExternalReference::XCRPT)
 or (self.entryRelationship->exists(rel : cda::EntryRelationship |
 rel.typeCode = vocab::x_ActRelationshipEntryRelationship::REFR
 and rel.observation.code.code = '48766-0'))
- 11. **MAY** satisfy: Contains exactly one Patient Awareness (CONF-180)
 - [OCL]: self.participant->one(partic : cda::Participant2 |
 partic.ocIsKindOf(ccd::PatientAwareness))

```
<?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">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.28"
assigningAuthorityName="CCD Problem Observation"/>
              <code/>
              <statusCode code="completed"/>
              <effectiveTime>
                <low value="1972"/>
                <high value="2008"/>
              </effectiveTime>
              <entryRelationship>
                <observation classCode="OBS" moodCode="EVN">
                  <templateId root="2.16.840.1.113883.10.20.1.57"
assigningAuthorityName="CCD Status Observation"/>
                  <templateId root="2.16.840.1.113883.10.20.1.50"
assigningAuthorityName="CCD Problem Status Observation"/>
                  <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Status"/>
                  <statusCode code="completed"/>
                  <value xsi:type="CE"/>
                </observation>
              </entryRelationship>
            </entryRelationship>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.57"
assigningAuthorityName="CCD Status Observation"/>
              <templateId root="2.16.840.1.113883.10.20.1.51"
assigningAuthorityName="CCD Problem Health Status Observation"/>
              <code code="11323-3" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Health status"/>
              <statusCode code="completed"/>
            </observation>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```



```

        <value xsi:type="CE"/>
      </observation>
    </entryRelationship>
    <entryRelationship>
      <observation classCode="OBS" moodCode="EVN">
        <templateId root="2.16.840.1.113883.10.20.1.38"
assigningAuthorityName="CCD Age Observation"/>
        <code code="397659008" codeSystem="2.16.840.1.113883.6.96"
codeSystemName="SNOMEDCT" displayName="Age"/>
        <statusCode code="completed"/>
      </observation>
    </entryRelationship>
  </observation>
</entry>
</section>
</component>
</structuredBody>
</component>
</ClinicalDocument>

```

Figure 51: Problem Observation example

Problem Status Observation

[Observation: templateId 2.16.840.1.113883.10.20.1.50]

1. **SHALL** conform to *CCD Status Observation* template (templateId: 2.16.840.1.113883.10.20.1.57) (CONF-163)
2. **SHALL** contain [1..1] value, which **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.20.13 ProblemStatusCode STATIC 20061017 (CONF-164)

```

<?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">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.57"
assigningAuthorityName="CCD Status Observation"/>
              <templateId root="2.16.840.1.113883.10.20.1.50"
assigningAuthorityName="CCD Problem Status Observation"/>
              <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Status"/>
              <statusCode code="completed"/>
              <value xsi:type="CE"/>
            </observation>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>

```

Figure 52: Problem Status Observation example

Procedure Activity Act

[Act: templateId 2.16.840.1.113883.10.20.1.29]

1. **SHALL** conform to CDA Act
2. **SHALL** conform to *CCD Procedure Activity*

```
<?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">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <act classCode="ACT" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.29"/>
              <statusCode code="completed"/>
            </act>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 53: Procedure Activity Act example

Procedure Activity Observation

[Observation: templateId 2.16.840.1.113883.10.20.1.29]

1. **SHALL** conform to CDA Observation
2. **SHALL** conform to *CCD Procedure Activity*

```
<?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">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.29"/>
              <statusCode code="completed"/>
            </observation>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 54: Procedure Activity Observation example

Procedure Activity Procedure

[Procedure: templateId 2.16.840.1.113883.10.20.1.29]

1. **SHALL** conform to CDA Procedure
2. **SHALL** conform to *CCD Procedure Activity*

```
<?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">
  <component>
```

```

<structuredBody>
  <component>
    <section>
      <entry>
        <procedure>
          <templateId root="2.16.840.1.113883.10.20.1.29" />
          <statusCode code="completed" />
        </procedure>
      </entry>
    </section>
  </component>
</structuredBody>
</component>
</ClinicalDocument>

```

Figure 55: Procedure Activity Procedure example

Purpose Activity

[Act: templateId 2.16.840.1.113883.10.20.1.30]

CCD represents the ASTM CCR <Purpose> object as a relationship between two classes -- the source represents the act of creating a summary document, the target is the reason for creating the document, and the relationship type is "RSON" (has reason). The target act may be an Observation, Procedure, or some other kind of act, and it may represent an order, an event, etc.

1. **SHALL** conform to CDA Act
2. **SHALL** contain [1..1] @classCode = "ACT" (CONF-21)
3. **SHALL** contain [1..1] @moodCode = "EVN" (CONF-22)
4. **SHALL** contain [1..1] code/@code = "23745001" *Documentation procedure* (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT STATIC) (CONF-25)
5. **SHALL** contain [1..1] statusCode/@code = "completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus STATIC V3NE08) (CONF-23, CONF-24)
6. **SHALL** satisfy: Contains exactly one entryRelationship / @typeCode, with a value of 'RSON' 'Has reason' 2.16.840.1.113883.5.1002 ActRelationshipType STATIC, to indicate the reason or purpose for creating the CCD. (CONF-26)

- [OCL]: self.entryRelationship->one(entryRelationship :
cda::EntryRelationship |
entryRelationship.typeCode =
vocab::x_ActRelationshipEntryRelationship::RSON)

7. **SHALL** satisfy: The target of entryRelationship SHALL be an Act, Encounter, Observation, Procedure, SubstanceAdministration, or Supply. (CONF-27)

- [OCL]: self.entryRelationship->forAll(entryRelationship :
cda::EntryRelationship |
entryRelationship.typeCode =
vocab::x_ActRelationshipEntryRelationship::RSON implies(
not (entryRelationship.act.ocIsUndefined() and
entryRelationship.encounter.ocIsUndefined() and
entryRelationship.observation.ocIsUndefined() and
entryRelationship.procedure.ocIsUndefined() and
entryRelationship.substanceAdministration.ocIsUndefined() and
entryRelationship.supply.ocIsUndefined())))

```

<?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">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>

```

```

        <act classCode="ACT" moodCode="EVN">
            <templateId root="2.16.840.1.113883.10.20.1.30"
assigningAuthorityName="CCD Purpose Activity"/>
            <code code="23745001" codeSystem="2.16.840.1.113883.6.96"
codeSystemName="SNOMEDCT" displayName="Documentation procedure"/>
            <statusCode code="completed"/>
        </act>
    </entry>
</section>
</component>
</structuredBody>
</component>
</ClinicalDocument>

```

Figure 56: Purpose Activity example

Reaction Observation

[Observation: templateId 2.16.840.1.113883.10.20.1.54]

A reaction represents an adverse event due to an administered or exposed substance. A reaction can be defined with respect to its severity, and can have been treated by one or more interventions. Significant reactions are to be listed in the Alerts section. Reactions in the Medications section can be used to track reactions associated with individual substance administrations or to track routine follow up to an administration (e.g. "no adverse reaction 30 minutes post administration").

1. **SHALL** conform to CDA Observation (CONF-282)
2. **SHALL** contain [1..1] @classCode = "OBS" (CONF-283)
3. **SHALL** contain [1..1] @moodCode = "EVN" (CONF-284)
4. **MAY** contain [0..1] entryRelationship, such that it
 - a. has @typeCode="SUBJ" *SUBJ (has subject)*
 - b. contains *CCD Severity Observation* (templateId: 2.16.840.1.113883.10.20.1.55) (CONF-348, CONF-288)
5. **SHALL** contain [1..1] statusCode/@code = "completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus STATIC V3NE08) (CONF-285, CONF-286)
6. **MAY** satisfy: A reaction observation MAY contain one or more reaction interventions. (CONF-280)
7. **SHALL** satisfy: A reaction observation MAY contain one or more reaction interventions. A reaction intervention SHALL be represented as a procedure activity (templateId 2.16.840.1.113883.10.20.1.29), a medication activity (templateId 2.16.840.1.113883.10.20.1.24), or some other clinical statement. (CONF-297)
8. **SHALL** satisfy: The value for entryRelationship / @typeCode in a relationship between a reaction observation and reaction intervention SHALL be "RSON" "Has reason" 2.16.840.1.113883.5.1002 ActRelationshipType STATIC. (CONF-296)

```

<?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">
    <component>
        <structuredBody>
            <component>
                <section>
                    <entry>
                        <observation classCode="OBS" moodCode="EVN">
                            <templateId root="2.16.840.1.113883.10.20.1.54"
assigningAuthorityName="CCD Reaction Observation"/>
                            <statusCode code="completed"/>
                            <entryRelationship>
                                <observation classCode="OBS" moodCode="EVN">
                                    <templateId root="2.16.840.1.113883.10.20.1.55"
assigningAuthorityName="CCD Severity Observation"/>
                                    <code code="SEV" codeSystem="2.16.840.1.113883.5.4"
codeSystemName="ActCode" displayName="Severity observation"/>
                                </observation>
                            </entryRelationship>
                        </observation>
                    </entry>
                </section>
            </component>
        </structuredBody>
    </component>
</ClinicalDocument>

```

```

        <statusCode code="completed" />
      </observation>
    </entryRelationship>
  </observation>
</entry>
</section>
</component>
</structuredBody>
</component>
</ClinicalDocument>

```

Figure 57: Reaction Observation example

Result Observation

[Observation: templateId 2.16.840.1.113883.10.20.1.31]

1. **SHALL** conform to CDA Observation (CONF-407)
 2. **SHALL** contain [1..1] @moodCode = "EVN" (CONF-408)
 3. **SHALL** contain [1..*] id (CONF-409)
 4. **SHOULD** contain [1..1] effectiveTime (CONF-411)
 - Represents the biologically relevant time (e.g. time the specimen was obtained from the patient).
 5. **SHALL** contain [1..1] statusCode (CONF-410)
 6. **SHALL** contain [1..1] code (CONF-412)
 7. **MAY** contain [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.
 8. **SHOULD** contain [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.
 9. **SHALL** contain [1..1] value (CONF-416)
 10. **SHOULD** satisfy: 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)
 11. **SHALL** satisfy: The methodCode **SHALL NOT** conflict with the method inherent in code (CONF-415)
 12. **SHALL** satisfy: 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)
 13. **SHOULD** satisfy: Contain one or more referenceRange to show the normal range of values for the observation result (CONF-419)
 - [OCL]: not self.referenceRange->isEmpty()
 14. **SHALL** satisfy: **SHALL NOT** contain referenceRange / observationRange / code, as this attribute is not used by the HL7 Clinical Statement or Lab Committee models. (CONF-420)
 - [OCL]: self.referenceRange->forAll(range : cda::ReferenceRange | range.observationRange.code.code.ocIsUndefined())
 15. **SHALL** satisfy: Contains one or more sources of information. (CONF-421)
 - [OCL]: not self.informant->isEmpty()
 or not self.getSection().informant->isEmpty()
 or not self.getClinicalDocument().informant->isEmpty()
 or self.reference->exists(ref : cda::Reference | ref.typeCode = vocab::x_ActRelationshipExternalReference::XCRPT)
 or (self.entryRelationship->exists(rel : cda::EntryRelationship | rel.typeCode = vocab::x_ActRelationshipEntryRelationship::REFR and rel.observation.code.code = '48766-0'))
- <?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">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.31"
assigningAuthorityName="CCD Result Observation"/>
              <id root="e2ceed45-050c-41f6-8a9c-9745b2bfa753"/>
              <code/>
              <statusCode/>
              <effectiveTime>
                <low value="1972"/>
                <high value="2008"/>
              </effectiveTime>
              <interpretationCode/>
              <methodCode/>
            </observation>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>

```

Figure 58: Result Observation example

Result Organizer

[Organizer: templateId 2.16.840.1.113883.10.20.1.32]

The result organizer identifies an observation set, contained with the result organizer as a set of result observations. It contains information applicable to all of the contained result observations.

Results in ASTM CCR and CCD are structured similarly to the HL7 Version 2 ORU Observation message, where there is an outer result organizer (templateId 2.16.840.1.113883.10.20.1.32), analogous to the HL7 Version 2 OBR Observation Result Segment, which contains one or more result observations (templateId 2.16.840.1.113883.10.20.1.31), analogous to the HL7 Version 2 OBX Observation/Result Segment.

1. **SHALL** conform to CDA Organizer (CONF-393)
2. **SHALL** contain [1..1] @moodCode = "EVN" (CONF-394)
3. **SHALL** contain [1..*] component, such that it
 - a. contains *CCD Result Observation* (templateId: 2.16.840.1.113883.10.20.1.31) (CONF-405)
4. **SHOULD** contain [1..*] specimen, such that it
 - a. contains CDA Specimen (CONF-399)
 - Should be included if the specimen isn't inherent in code value.
5. **SHALL** contain [1..*] id (CONF-395)
6. **SHALL** contain [1..1] code (CONF-397)
7. **SHALL** contain [1..1] statusCode (CONF-396)
8. **SHOULD** satisfy: 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)
9. **SHALL** satisfy: The specimen element **SHALL NOT** conflict with the specimen inherent in code (CONF-400)
10. **SHOULD** satisfy: 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)

11. SHALL satisfy: Contains one or more component (CONF-402)

- [OCL]: `not self.component->isEmpty()`

12. MAY satisfy: 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)

13. MAY satisfy: A result organizer component / procedure MAY be a reference to a procedure described in the Procedure section. (CONF-404)

14. SHALL satisfy: Contains one or more sources of information. (CONF-406)

- [OCL]: `not self.informant->isEmpty()`
or `not self.getSection().informant->isEmpty()`
or `not self.getClinicalDocument().informant->isEmpty()`
or `self.reference->exists(ref : cda::Reference | ref.typeCode = vocab::x_ActRelationshipExternalReference::XCRPT)`

```
<?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">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <organizer moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.32"
assigningAuthorityName="CCD Result Organizer"/>
              <id root="01799eef-ef50-433d-a2d3-02f528elfc19"/>
              <code/>
              <statusCode/>
              <component>
                <observation classCode="OBS" moodCode="EVN">
                  <templateId root="2.16.840.1.113883.10.20.1.31"
assigningAuthorityName="CCD Result Observation"/>
                  <id root="f924d292-9c0b-4212-ab3f-2a1910df3571"/>
                  <code/>
                  <statusCode/>
                  <effectiveTime>
                    <low value="1972"/>
                    <high value="2008"/>
                  </effectiveTime>
                  <interpretationCode/>
                  <methodCode/>
                </observation>
              </component>
            </organizer>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 59: Result Organizer example

Severity Observation

[Observation: templateId 2.16.840.1.113883.10.20.1.55]

1. **SHALL** conform to CDA Observation (CONF-287)
2. **SHALL** contain [1..1] @classCode = "OBS" (CONF-289)
3. **SHALL** contain [1..1] @moodCode = "EVN" (CONF-290)

4. **SHALL** contain [1..1] code/@code = "SEV" *Severity observation* (CodeSystem: 2.16.840.1.113883.5.4 ActCode STATIC V3NE08) (CONF-293, CONF-294)
5. **SHALL** contain [1..1] statusCode/@code = "completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus STATIC V3NE08) (CONF-291, CONF-292)
6. **SHALL** contain [1..1] value (CONF-295)

```
<?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">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.55"
assigningAuthorityName="CCD Severity Observation"/>
              <code code="SEV" codeSystem="2.16.840.1.113883.5.4"
codeSystemName="ActCode" displayName="Severity observation"/>
              <statusCode code="completed"/>
            </observation>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 60: Severity Observation example

Social History Observation

[Observation: templateId 2.16.840.1.113883.10.20.1.33]

1. **SHALL** conform to CDA Observation

```
<?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">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.33"
assigningAuthorityName="CCD Social History Observation"/>
            </observation>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 61: Social History Observation example

Status Observation

[Observation: templateId 2.16.840.1.113883.10.20.1.57]

1. **SHALL** conform to CDA Observation (CONF-508)
2. **SHALL** contain [1..1] @classCode = "OBS" (CONF-510)
3. **SHALL** contain [1..1] @moodCode = "EVN" (CONF-511)
4. **SHALL** contain [1..1] code/@code = "33999-4" *Status* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC) (CONF-512, CONF-513)
5. **SHALL** contain [1..1] statusCode/@code = "completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus STATIC V3NE08) (CONF-514, CONF-515)
6. **SHALL** contain [1..1] value, where its data type is CE (CONF-516)
7. **SHALL** satisfy: Target of an entryRelationship whose value for "entryRelationship / @typeCode" **SHALL** be "REFR" 2.16.840.1.113883.5.1002 ActRelationshipType STATIC. (CONF-509)
8. **SHALL** satisfy: **SHALL NOT** contain any additional Observation attributes. (CONF-517)
9. **SHALL** satisfy: **SHALL NOT** contain any Observation participants. (CONF-518)

- [OCL]: self.participant->isEmpty()

10. **SHALL** satisfy: **SHALL NOT** be the source of any Observation relationships. (CONF-519)

```
<?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">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.57"
assigningAuthorityName="CCD Status Observation"/>
              <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Status"/>
              <statusCode code="completed"/>
              <value xsi:type="CE"/>
            </observation>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 62: Status Observation example

Supply Activity

[Supply: templateId 2.16.840.1.113883.10.20.1.34]

A medication activity is used to describe what is administered whereas a supply activity is used to describe what has been dispensed.

1. **SHALL** conform to CDA Supply (CONF-316)
2. **SHALL** contain [1..*] id (CONF-318)
3. **SHOULD** contain [1..1] statusCode (CONF-319)
4. **MAY** contain [0..1] entryRelationship, such that it
 - a. contains *CCD Medication Status Observation* (templateId: 2.16.840.1.113883.10.20.1.47) (CONF-351)
5. **MAY** contain [0..*] entryRelationship, such that it
 - a. has @typeCode="SUBJ" *SUBJ (has subject)*
 - b. contains *CCD Fulfillment Instruction* (templateId: 2.16.840.1.113883.10.20.1.43) (CONF-334, CONF-337)

6. SHOULD contain [1..1] effectiveTime (CONF-320)

- Indicates the actual or intended time of dispensing.

7. MAY contain [0..1] quantity (CONF-322)

- Indicates the actual or intended supply quantity.

8. MAY contain [0..1] repeatNumber (CONF-321)

- Indicates the number of fills. (Note that repeatNumber corresponds to the number of "fills", as opposed to the number of "refills").

9. SHALL satisfy: Value for moodCode is 'EVN' or 'INT' 2.16.840.1.113883.5.1001 ActMood STATIC (CONF-317)

- [OCL]: self.moodCode=vocab::x_DocumentSubstanceMood::EVN or
self.moodCode=vocab::x_DocumentSubstanceMood::INT

10. MAY satisfy: Contains one or more author. (CONF-323)

- Indicates the prescriber.

- [OCL]: not self.author->isEmpty()

11. MAY satisfy: Contains one or more performer. (CONF-324)

- Indicates the person dispensing the product.

- [OCL]: not self.performer->isEmpty()

12. MAY satisfy: Contains exactly one participant / @typeCode = "LOC". (CONF-325)

- Indicates the supply location.

- [OCL]: self.participant->one(part : cda::Participant2 | part.typeCode =
vocab::ParticipationType::LOC)

13. SHALL satisfy: Contains one or more sources of information. (CONF-326)

- [OCL]: not self.informant->isEmpty()
or not self.getSection().informant->isEmpty()
or not self.getClinicalDocument().informant->isEmpty()
or self.reference->exists(ref : cda::Reference | ref.typeCode =
vocab::x_ActRelationshipExternalReference::XCRPT)
or (self.entryRelationship->exists(rel : cda::EntryRelationship |
rel.typeCode = vocab::x_ActRelationshipEntryRelationship::REFR
and rel.observation.code.code = '48766-0'))

14. MAY satisfy: Contains exactly one product, the target of which is a Product template. (CONF-355)

- [OCL]: not self.product.oclIsUndefined() and
self.product.oclIsKindOf(ccd::Product)

```
<?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">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <supply classCode="SPLY">
              <templateId root="2.16.840.1.113883.10.20.1.34"
assigningAuthorityName="CCD Supply Activity"/>
              <id root="ed0a01ca-8943-40aa-8fea-c8f6940ead0c"/>
              <statusCode/>
              <effectiveTime/>
              <repeatNumber/>
              <quantity/>
            </supply>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

```

    </component>
  </structuredBody>
</component>
</ClinicalDocument>

```

Figure 63: Supply Activity example

Vital Signs Organizer

[Organizer: templateId 2.16.840.1.113883.10.20.1.35]

1. **SHALL** conform to *CCD Result Organizer* template (templateId: 2.16.840.1.113883.10.20.1.32)
2. **SHALL** satisfy: Contains one or more sources of information.

- [OCL]: not self.informant->isEmpty()
or not self.getSection().informant->isEmpty()
or not self.getClinicalDocument().informant->isEmpty()
or self.reference->exists(ref : cda::Reference | ref.typeCode =
vocab::x_ActRelationshipExternalReference::XCRPT)

```

<?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">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <organizer moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.32"
                assigningAuthorityName="CCD Result Organizer"/>
              <templateId root="2.16.840.1.113883.10.20.1.35"
                assigningAuthorityName="CCD Vital Signs Organizer"/>
              <id root="586f5bc6-6c8d-47f1-8030-a0fde1396889"/>
              <code/>
              <statusCode/>
              <component>
                <observation classCode="OBS" moodCode="EVN">
                  <templateId root="2.16.840.1.113883.10.20.1.31"
                    assigningAuthorityName="CCD Result Observation"/>
                  <id root="1b9161a9-2b9b-48f4-b86e-3449fe03861a"/>
                  <code/>
                  <statusCode/>
                  <effectiveTime>
                    <low value="1972"/>
                    <high value="2008"/>
                  </effectiveTime>
                  <interpretationCode/>
                  <methodCode/>
                </observation>
              </component>
            </organizer>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>

```

Figure 64: Vital Signs Organizer example

Chapter

5

OTHER CLASSES

Topics:

- [*Advance Directive Verification*](#)
- [*Covered Party*](#)
- [*Encounter Location*](#)
- [*Patient Awareness*](#)
- [*Payer Entity*](#)
- [*Plan Of Care Activity*](#)
- [*Policy Subscriber*](#)
- [*Procedure Activity*](#)
- [*Product*](#)
- [*Product Instance*](#)
- [*Support*](#)
- [*Support Guardian*](#)
- [*Support Participant*](#)

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

Advance Directive Verification

[Participant2: templateId 2.16.840.1.113883.10.20.1.58]

1. **SHALL** conform to CDA Participant2
2. **SHALL** contain [1..1] @typeCode = "VRF"
3. **SHOULD** contain [0..1] time, where its data type is TS

Figure 65: Advance Directive Verification example

Covered Party

[ParticipantRole: templateId null]

1. **SHALL** conform to CDA Participant Role
2. **SHOULD** contain [1..*] id (CONF-59)
3. **SHOULD** contain [1..1] code (CONF-60)

Figure 66: Covered Party example

Encounter Location

[Participant2: templateId 2.16.840.1.113883.10.20.1.45]

1. **SHALL** conform to CDA Participant2
2. **SHALL** contain [1..1] @typeCode = "LOC"

Figure 67: Encounter Location example

Patient Awareness

[Participant2: templateId 2.16.840.1.113883.10.20.1.48]

1. **SHALL** conform to CDA Participant2 (CONF-178)
2. **SHALL** contain [1..1] @typeCode = "SBJ" (CONF-181)
3. **SHALL** contain [1..1] awarenessCode (CONF-182)
4. **SHALL** satisfy: Patient awareness SHALL contain exactly one participant / participantRole / id, which SHALL have exactly one value, which SHALL also be present in ClinicalDocument / recordTarget / patientRole / id. (CONF-183)
 - [OCL]: self.participantRole.id->one(id : datatypes::II | not id.root.ocIsUndefined())
-- TODO compare with ClinicalDocument/recordTarget/patientRole/id

Figure 68: Patient Awareness example

Payer Entity

[AssignedEntity: templateId null]

1. **SHALL** conform to CDA Assigned Entity

2. **SHALL** contain [1..*] id (CONF-57)

Figure 69: Payer Entity example

Plan Of Care Activity

- 1.

Figure 70: Plan Of Care Activity example

Policy Subscriber

[ParticipantRole: templateId null]

1. **SHALL** conform to CDA Participant Role
2. **SHOULD** contain [0..*] id (CONF-64)

Figure 71: Policy Subscriber example

Procedure Activity

1. **SHALL** contain [1..1] moodCode, where its data type is ActMood
2. **SHALL** contain [1..*] id, where its data type is II
3. **SHALL** contain [1..1] statusCode/@code = "completed" (CodeSystem: 2.16.840.1.113883.1.11.20.15 ProcedureStatusCode STATIC 20061017), where its data type is CS
4. **SHOULD** contain [0..1] effectiveTime, where its data type is IVL_TS
5. **SHALL** contain [1..1] code, where its data type is CD

Figure 72: Procedure Activity example

Product

[ManufacturedProduct: templateId 2.16.840.1.113883.10.20.1.53]

1. **SHALL** conform to CDA Manufactured Product (CONF-356)
2. **SHALL** satisfy: Contain exactly one manufacturedMaterial. (CONF-357)
 - [OCL]: not self.manufacturedMaterial.ocIsUndefined()
3. **SHALL** satisfy: Contain exactly one manufacturedMaterial / code. (CONF-358)
 - [OCL]: not self.manufacturedMaterial.code.ocIsUndefined()
4. **SHOULD** satisfy: 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)
5. **MAY** satisfy: 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)
6. **SHALL** satisfy: 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)

7. **SHALL** satisfy: 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)
8. **SHALL** satisfy: A manufacturedMaterial in a product template contains exactly one code / originalText, which represents the generic name of the product. (CONF-363)
 - [OCL]: `not self.manufacturedMaterial.code.originalText.ocIsUndefined()`
9. **MAY** satisfy: A manufacturedMaterial in a product template contains exactly one name, which represents the brand name of the product. (CONF-364)
 - [OCL]: `not self.manufacturedMaterial.name.ocIsUndefined()`

Figure 73: Product example

Product Instance

[ParticipantRole: templateId 2.16.840.1.113883.10.20.1.52]

1. **SHALL** conform to CDA Participant Role
2. **SHALL** contain [1..1] @classCode = "MANU"

Figure 74: Product Instance example

Support

Represents the patient's sources of support such as immediate family, relatives, and guardian at the time the summarization is generated. Support information also includes next of kin, caregivers, and support organizations. At a minimum, key support contacts relative to healthcare decisions, including next of kin, should be included.

CDA R2 represents a patient's guardian with the CDA Header Guardian class. Other Supporters are represented as participant participations in the CDA Header.

- 1.

Figure 75: Support example

Support Guardian

[Guardian: templateId null]

1. **SHALL** conform to CDA Guardian
2. **SHALL** conform to *CCD Support*

Figure 76: Support Guardian example

Support Participant

[Participant1: templateId null]

1. **SHALL** conform to CDA Participant1
2. **SHALL** conform to *CCD Support*

Figure 77: Support Participant example

Chapter

6

VALUE SETS

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

REFERENCES

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