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

DRAFT: FOR DEVELOPMENT USE ONLY

Contents

Acknowledgments

We acknowledge the foundational work on HL7 Version 3 and the Reference Information Model (RIM), the HL7 domain committees, especially Patient Care, and the work done on Clinical Document Architecture (CDA) itself.

We also acknowledge the collaborative effort of the American Society for Standards and Materials (ASTM) and HL7, which produced the Continuity of Care Document (CCD). All these efforts were critical ingredients to the development of this Draft Standard for Trial Use (DSTU), and the degree to which the DSTU reflects these efforts will foster interoperability across the spectrum of health care.

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

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 `templateId`s are required for conformance.

Recipient Responsibilities

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

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

Conventions Used in This Guide

Conformance Requirements

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

Template name

```
[<type of template>: templateId <XXXX.XX.XXX.XXX>]
```

Description of the template will be here .....

1. Conforms to <The template name> Template (templateId: XXXX<XX>XXX>YYY).
2. **SHALL** contain [1..1] @classCode = <AAA> <code display name> (CodeSystem: 123.456.789 <XXX> Class) **STATIC** (CONF:<number>).
3. .....

Figure 1: Template name and "conforms to" appearance

The conformance verb keyword at the start of a constraint (**SHALL** , **SHOULD** , **MAY**, etc.) indicates business conformance, whereas the cardinality indicator (0..1, 1..1, 1..*, etc.) specifies the allowable occurrences within an instance. Thus, " **MAY** contain 0..1" and " **SHOULD** contain 0..1" both allow for a document to omit the particular component, but the latter is a stronger recommendation that the component be included if it is known.

The following cardinality indicators may be interpreted as follows:

0..1 as zero to one present
1..1 as one and only one present
2..2 as two must be present
1..* as one or more present
0..* as zero to many present

Value set bindings adhere to HL7 Vocabulary Working Group best practices, and include both a conformance verb (**SHALL** , **SHOULD** , **MAY,** etc.) and an indication of **DYNAMIC** vs. **STATIC** binding. The use of **SHALL** requires that the component be valued with a member from the cited value set; however, in every case any HL7 "null" value such as other (OTH) or unknown (UNK) may be used.

Each constraint is uniquely identified (e.g., "CONF:605") by an identifier placed at or near the end of the constraint. These identifiers are not sequential as they are based on the order of creation of the constraint.

1. **SHALL** contain [1..1] component/structuredBody (CONF:4082).
    a. This component/structuredBody **SHOULD** contain [0..1] component (CONF:4130) such that it
        a. **SHALL** contain [1..1] Reporting Parameters section (templateId:2.16.840.1.113883.10.20.17.2.1) (CONF:4131).
    b. This component/structuredBody **SHALL** contain [1..1] component (CONF:4132) such that it
        a. **SHALL** contain [1..1] Patient data section - NCR (templateId:2.16.840.1.113883.10.20.17.2.5) (CONF:4133).

Figure 2: Template-based conformance statements example

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

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

Figure 3: CCD conformance statements example

Keywords

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

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

XML Examples

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

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

Figure 4: ClinicalDocument example

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

Chapter 2

DOCUMENT TEMPLATES

Topics:

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

Continuity Of Care Document

[ClinicalDocument: templateId `2.16.840.1.113883.10.20.1`]

1. **SHOULD** contain exactly one [1..1] **`component`** (CONF-140), such that
   a. Contains exactly one [1..1] *Problem Section* (templateId: `2.16.840.1.113883.10.20.1.11`)
2. **SHOULD** contain exactly one [1..1] **`component`**, such that
   a. Contains exactly one [1..1] *Family History Section* (templateId: `2.16.840.1.113883.10.20.1.4`)
3. **SHOULD** contain exactly one [1..1] **`component`**, such that
   a. Contains exactly one [1..1] *Social History Section* (templateId: `2.16.840.1.113883.10.20.1.15`)
4. **SHOULD** contain exactly one [1..1] **`component`**, such that
   a. Contains exactly one [1..1] *Alerts Section* (templateId: `2.16.840.1.113883.10.20.1.2`)
5. **SHOULD** contain exactly one [1..1] **`component`** (CONF-298), such that
   a. Contains exactly one [1..1] *Medications Section* (templateId: `2.16.840.1.113883.10.20.1.8`)
6. **SHOULD** contain exactly one [1..1] **`component`** (CONF-388), such that
   a. Contains exactly one [1..1] *Results Section* (templateId: `2.16.840.1.113883.10.20.1.14`)
7. **SHOULD** contain exactly one [1..1] **`component`**, such that
   a. Contains exactly one [1..1] *Procedures Section* (templateId: `2.16.840.1.113883.10.20.1.12`)
8. **SHOULD** contain exactly one [1..1] **`component`**, such that
   a. Contains exactly one [1..1] *Encounters Section* (templateId: `2.16.840.1.113883.10.20.1.3`)
9. **SHOULD** contain exactly one [1..1] **`component`**, such that
   a. Contains exactly one [1..1] *Plan Of Care Section* (templateId: `2.16.840.1.113883.10.20.1.10`)
10. **SHOULD** contain exactly one [1..1] **`component`**, such that
    a. Contains exactly one [1..1] *Immunizations Section* (templateId: `2.16.840.1.113883.10.20.1.6`)
11. **SHOULD** contain exactly one [1..1] **`component`** (CONF-381), such that
    a. Contains exactly one [1..1] *Vital Signs Section* (templateId: `2.16.840.1.113883.10.20.1.16`)
12. **SHOULD** contain exactly one [1..1] **`component`**, such that
    a. Contains exactly one [1..1] *Medical Equipment Section* (templateId: `2.16.840.1.113883.10.20.1.7`)
13. **SHOULD** contain exactly one [1..1] **`component`**, such that
    a. Contains exactly one [1..1] *Functional Status Section* (templateId: `2.16.840.1.113883.10.20.1.5`)
14. **SHOULD** contain exactly one [1..1] **`component`**, such that
    a. Contains exactly one [1..1] *Advance Directives Section* (templateId: `2.16.840.1.113883.10.20.1.1`)
15. **SHOULD** contain exactly one [1..1] **`component`**, such that
    a. Contains exactly one [1..1] *Payers Section* (templateId: `2.16.840.1.113883.10.20.1.9`)
16. **SHALL** contain exactly one [1..1] **`code/@code`**`="34133-9"` *Summarization of episode note* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`) (CONF-1)
17. **SHALL** contain exactly one [1..1] **`languageCode`** (CONF-5)
    a. 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)
18. **MAY** contain exactly one [1..1] **`component`** (CONF-15), such that
    a. Contains exactly one [1..1] *Purpose Section* (templateId: `2.16.840.1.113883.10.20.1.13`)
19. **SHALL** satisfy: Contains exactly one documentationOf / serviceEvent (CONF-2)

- ```
  [OCL]: self.documentationOf->one(doc : cda::DocumentationOf | not
   doc.serviceEvent.oclIsUndefined())
  ```
  ```

20. documentationOf / serviceEvent / @classCode **SHALL** be 'PCPR' (CONF-3)

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

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

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

22. **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.oclIsUndefined())`

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

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

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

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

26. **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.oclIsUndefined() or not author.assignedAuthor.representedOrganization.oclIsUndefined())`

27. 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.oclIsUndefined() and author.assignedAuthor.assignedPerson.oclIsUndefined() and author.assignedAuthor.assignedAuthoringDevice.oclIsUndefined()) implies author.assignedAuthor.id->one(id : datatypes::II | id.nullFlavor = vocab::NullFlavor::NA))`

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

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

29. 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)

30. 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)

31. A section **MAY** contain one or more comments, either as a clinical statement or nested under another clinical statement. (CONF-502)

Continuity Of Care Document example

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <typeId root="2.16.840.1.113883.1.3"/>
  <templateId root="2.16.840.1.113883.10.20.1"/>
  <id root="1622479886"/>
  <code code="34133-9" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="Summarization of episode note"/>
  <title/>
  <effectiveTime/>
  <confidentialityCode code="Value"/>
  <languageCode/>
  <recordTarget/>
  <author/>
  <custodian/>
  <component>
```

```
    <structuredBody>
      <component>
        <section>
          <templateId root="2.16.840.1.113883.10.20.1.11"/>
          <id root="2030179321"/>
          <code code="11450-4" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="Problem list"/>
          <title/>
          <languageCode/>
          <entry>
            <act/>
          </entry>
        </section>
      </component>
      <component>
        <section/>
      </component>
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      <component>
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      </component>
      <component>
        <section/>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Chapter 3

SECTION TEMPLATES

Topics:

Advance Directives Section

[Section: templateId `2.16.840.1.113883.10.20.1.1`]

1. **SHALL** contain exactly one [1..1] **`code/@code`**`="42348-3"` *Advance directives* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`)
2. **SHALL** contain exactly one [1..1] **`title`**
3. **SHALL** contain at least one [1..*] **`entry`**, such that
   a. Contains exactly one [1..1] *Advance Directive Observation* (templateId: `2.16.840.1.113883.10.20.1.17`)
4. **SHALL** contain exactly one [1..1] **`text`**
5. **SHOULD** satisfy: Contains a case-insensitive language-insensitive text string containing 'advance directives'.

Advance Directives Section example

```
<?xml version="1.0" encoding="UTF-8"?>
<section xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-
org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <templateId root="2.16.840.1.113883.10.20.1.1"/>
  <id root="753009024"/>
  <code code="42348-3" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="Advance directives"/>
  <title/>
  <text/>
  <entry>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.1.17"/>
      <id root="1717697110"/>
      <code code="520371600"/>
      <text/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2011"/>
        <high value="2011"/>
      </effectiveTime>
    </observation>
  </entry>
</section>
```

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** contain exactly one [1..1] **`code/@code`**`="48765-2"` *Allergies, adverse reactions, alerts* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`) (CONF-258, CONF-259)
2. **SHALL** contain exactly one [1..1] **`title`** (CONF-260)
   a. **SHOULD** satisfy: Contains a case-insensitive language-insensitive string containing "alert" and/or "allergies and adverse reactions". (CONF-261)
3. **SHALL** contain exactly one [1..1] **`text`** (CONF-256)
4. **SHOULD** contain at least one [1..*] **`entry`** (CONF-256), such that
   a. Contains exactly one [1..1] *Problem Act* (templateId: `2.16.840.1.113883.10.20.1.27`)
5. The absence of known allergies, adverse reactions or alerts **SHALL** be explicitly asserted.

Alerts Section example

```
<?xml version="1.0" encoding="UTF-8"?>
<section xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-
org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <templateId root="2.16.840.1.113883.10.20.1.2"/>
  <id root="1382775424"/>
  <code code="48765-2" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="Allergies, adverse reactions, alerts"/>
  <title/>
  <text/>
  <entry>
    <act classCode="ACT" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.1.27"/>
      <id root="1945624370"/>
      <code nullFlavor="NA"/>
      <text/>
      <effectiveTime>
        <low value="2011"/>
        <high value="2011"/>
      </effectiveTime>
      <entryRelationship>
        <observation/>
      </entryRelationship>
    </act>
  </entry>
</section>
```

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** contain exactly one [1..1] **`code/@code`**`="46240-8"` *History of encounters* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`)
2. **SHALL** contain exactly one [1..1] **`title`**
3. **SHALL** contain exactly one [1..1] **`text`**
4. **SHOULD** contain at least one [1..*] **`entry`**, such that
   a. Contains exactly one [1..1] *Encounters Activity* (templateId: `2.16.840.1.113883.10.20.1.21`)
5. **SHOULD** be valued with a case-insensitive language-insensitive text string containing 'encounters'.

Encounters Section example

```
<?xml version="1.0" encoding="UTF-8"?>
<section xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-
org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <templateId root="2.16.840.1.113883.10.20.1.3"/>
  <id root="774902062"/>
  <code code="46240-8" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="History of encounters"/>
  <title/>
  <text/>
</section>
```

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** contain exactly one [1..1] **`code/@code`**`="10157-6"` *History of family member diseases* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`)
2. **SHALL** contain exactly one [1..1] **`title`**
3. **SHALL** contain exactly one [1..1] **`text`**
4. **MAY** contain at least one [1..*] **`entry`**, such that
   a. Contains exactly one [1..1] *Family History Organizer* (templateId: `2.16.840.1.113883.10.20.1.23`)
5. **SHOULD** satisfy: Contains a case-insensitive language-insensitive text string containing 'family history'.
6. Family History Section **SHOULD** include one or more family history observations (templateId 2.16.840.1.113883.10.20.1.22), which **MAY** be contained within family history organizers (templateId 2.16.840.1.113883.10.20.1.23)
7. The family history section **SHALL NOT** contain Section / subject.

Family History Section example

```
<?xml version="1.0" encoding="UTF-8"?>
<section xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-
org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <templateId root="2.16.840.1.113883.10.20.1.4"/>
  <id root="1212364277"/>
  <code code="10157-6" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="History of family member diseases"/>
  <title/>
  <text/>
</section>
```

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** contain exactly one [1..1] **`code/@code`**`="47420-5"` *Functional status assessment* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`)
2. **SHALL** contain exactly one [1..1] **`title`**
3. **SHALL** contain exactly one [1..1] **`text`**
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`
5. **SHOULD** satisfy: Contains a case-insensitive language-insensitive string containing 'functional status'.
6. problem observation or result observation in the functional status section **SHALL** contain exactly one observation / code (CONF-128)
7. The value for Observation / code in a problem observation or result observation in the functional status section **MAY** be selected from ValueSet 2.16.840.1.113883.1.11.20.6 FunctionalStatusTypeCode STATIC 20061017
8. If the functional status was collected using a standardized assessment instrument, then the instrument itself **SHOULD** be represented in the Organizer / code of a result organizer, with a value selected from LOINC (codeSystem 2.16.840.1.113883.6.1) or SNOMED CT (codeSystem 2.16.840.1.113883.6.96)
9. If the functional status was collected using a standardized assessment instrument, then the question within that instrument **SHOULD** be represented in the Observation / code of a result observation, with a value selected from LOINC (codeSystem 2.16.840.1.113883.6.1) or SNOMED CT (codeSystem 2.16.840.1.113883.6.96).
10. If the functional status was collected using a standardized assessment instrument containing questions with enumerated values as answers, then the answer **SHOULD** be represented in the Observation / value of a result observation
11. If Observation / value in a result observation in the functional status section is of data type CE or CD, then it **SHOULD** use the same code system used to code the question in Observation / code.
12. Observation / value in a result observation in the functional status section **MAY** be of datatype CE or CD and **MAY** contain one or more Observation / value / translation, to represent equivalent values from other code systems.
13. A problem observation or result observation in the functional status section **MAY** use codes from the International Classification of Functioning, Disability, and Health (ICF, http://www.who.int/classifications/icf/en/) (codeSystem 2.16.840.1.113883.6.254).
14. A problem observation in the functional status section **SHALL** contain exactly one status of functional status observation
15. A result observation in the functional status section **SHALL** contain exactly one status of functional status observation.

Functional Status Section example

```
<?xml version="1.0" encoding="UTF-8"?>
<section xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-
org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <templateId root="2.16.840.1.113883.10.20.1.5"/>
  <id root="301136135"/>
  <code code="47420-5" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="Functional status assessment"/>
  <title/>
  <text/>
</section>
```

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 *Medications Section* template (templateId: `2.16.840.1.113883.10.20.1.8`)
2. **SHALL** contain exactly one [1..1] **`code/@code`**`="11369-6"` *History of immunizations* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`) (CONF-377)
3. **SHALL** contain exactly one [1..1] **`title`** (CONF-379)
4. **SHALL** contain exactly one [1..1] **`text`** (CONF-376)
5. **SHOULD** satisfy: Contains a case-insensitive language-insensitive string containing 'immunization'. (CONF-380)

Immunizations Section example

```
<?xml version="1.0" encoding="UTF-8"?>
<section xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-
org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <templateId root="2.16.840.1.113883.10.20.1.6"/>
  <id root="815605609"/>
  <code code="11369-6" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="History of immunizations"/>
  <title/>
  <text/>
</section>
```

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** contain exactly one [1..1] **`code/@code`**`="46264-8"` *History of medical device use* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`) (CONF-CCD-520)
2. **SHALL** contain exactly one [1..1] **`title`** (CONF-CCD-521)
3. **SHALL** contain exactly one [1..1] **`text`**
4. **SHOULD** contain zero or more [0..*] **`entry`**, such that
   a. Contains exactly one [1..1] *Supply Activity* (templateId: `2.16.840.1.113883.10.20.1.34`)
5. **MAY** contain zero or more [0..*] **`entry`**, such that
   a. Contains exactly one [1..1] *Medication Activity* (templateId: `2.16.840.1.113883.10.20.1.24`)
6. **SHOULD** satisfy: Contains a a case-insensitive language-insensitive text string containing "equipment"

Medical Equipment Section example

```
<?xml version="1.0" encoding="UTF-8"?>
<section xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-
org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <templateId root="2.16.840.1.113883.10.20.1.7"/>
  <id root="388710208"/>
  <code code="46264-8" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="History of medical device use"/>
  <title/>
  <text/>
</section>
```

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** contain exactly one [1..1] **`code/@code`**`="10160-0"` *History of medication use* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`) (CONF-300, CONF-301)
2. **SHALL** contain exactly one [1..1] **`title`** (CONF-302)
    a. **SHOULD** satisfy: Valued with a case-insensitive language-insensitive string containing 'medication'. (CONF-303)
3. **SHALL** contain zero or one [0..1] **`text`** (CONF-298)
4. **SHOULD** contain zero or more [0..*] **`entry`** (CONF-298), such that
    a. Contains exactly one [1..1] *Medication Activity* (templateId: `2.16.840.1.113883.10.20.1.24`)
5. **SHOULD** contain zero or more [0..*] **`entry`** (CONF-298), such that
    a. Contains exactly one [1..1] *Supply Activity* (templateId: `2.16.840.1.113883.10.20.1.34`)
6. **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))
      ```
7. **SHALL** satisfy: The absence of known medications is explicitly asserted. (CONF-299)

Medications Section example

```
<?xml version="1.0" encoding="UTF-8"?>
<section xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-
org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <templateId root="2.16.840.1.113883.10.20.1.8"/>
  <id root="1917380016"/>
  <code code="10160-0" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="History of medication use"/>
  <title/>
  <text/>
</section>
```
```

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

Payers Section example

```
<?xml version="1.0" encoding="UTF-8"?>
<section xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-
org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <templateId root="2.16.840.1.113883.10.20.1.9"/>
  <id root="1855519892"/>
  <code code="48768-6" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="Payment sources"/>
  <title/>
  <text/>
  <entry>
    <act classCode="ACT" moodCode="DEF">
      <templateId root="2.16.840.1.113883.10.20.1.20"/>
      <id root="1632934169"/>
      <code code="48768-6" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="Payment sources"/>
      <text/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2011"/>
        <high value="2011"/>
      </effectiveTime>
      <entryRelationship>
        <act/>
      </entryRelationship>
    </act>
  </entry>
</section>
```

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** contain exactly one [1..1] **`code/@code`**`="18776-5"` *Treatment plan* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`)
2. **SHALL** contain exactly one [1..1] **`title`**
3. **SHALL** contain exactly one [1..1] **`text`**
4. **MAY** contain zero or one [0..1] **`entry`**, such that
   a. Contains exactly one [1..1] *Plan Of Care Activity Act* (templateId: `2.16.840.1.113883.10.20.1.25`)
5. **MAY** contain zero or one [0..1] **`entry`**, such that
   a. Contains exactly one [1..1] *Plan Of Care Activity Encounter* (templateId: `2.16.840.1.113883.10.20.1.25`)
6. **MAY** contain zero or one [0..1] **`entry`**, such that
   a. Contains exactly one [1..1] *Plan Of Care Activity Observation* (templateId: `2.16.840.1.113883.10.20.1.25`)
7. **MAY** contain zero or one [0..1] **`entry`**, such that
   a. Contains exactly one [1..1] *Plan Of Care Activity Procedure* (templateId: `2.16.840.1.113883.10.20.1.25`)
8. **MAY** contain zero or one [0..1] **`entry`**, such that
   a. Contains exactly one [1..1] *Plan Of Care Activity Substance Administration* (templateId: `2.16.840.1.113883.10.20.1.25`)
9. **MAY** contain zero or one [0..1] **`entry`**, such that
   a. Contains exactly one [1..1] *Plan Of Care Activity Supply* (templateId: `2.16.840.1.113883.10.20.1.25`)
10. **SHALL** contain exactly one [1..1] **`planOfCareActivity`**, such that
11. **SHOULD** contain a case-insensitive language-insensitive text string containing 'plan'.

Plan Of Care Section example

```
<?xml version="1.0" encoding="UTF-8"?>
<section xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-
org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <templateId root="2.16.840.1.113883.10.20.1.10"/>
  <id root="269094429"/>
  <code code="18776-5" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="Treatment plan"/>
  <title/>
  <text/>
  <entry>
    <act>
      <templateId root="2.16.840.1.113883.10.20.1.25"/>
      <id root="1004577796"/>
      <code code="1497290539"/>
      <text/>
```

```
      <effectiveTime>
        <low value="2011"/>
        <high value="2011"/>
      </effectiveTime>
    </act>
  </entry>
  <entry>
    <encounter/>
  </entry>
  <entry>
    <observation/>
  </entry>
  <entry>
    <procedure/>
  </entry>
  <entry>
    <substanceAdministration/>
  </entry>
  <entry>
    <supply/>
  </entry>
</section>
```

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** contain exactly one [1..1] **`code/@code`**`="11450-4"` *Problem list* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`) (CONF-141, CONF-142)
2. **SHALL** contain exactly one [1..1] **`title`** (CONF-143)
   a. **SHOULD** contain a case-insensitive language-insensitive string containing 'problems'. (CONF-144)
3. **SHOULD** contain at least one [1..*] **`entry`** (CONF-140), such that
   a. Contains exactly one [1..1] *Problem Act* (templateId: `2.16.840.1.113883.10.20.1.27`)
4. **SHALL** contain exactly one [1..1] **`text`** (CONF-140)

Problem Section example

```
<?xml version="1.0" encoding="UTF-8"?>
<section xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-
org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <templateId root="2.16.840.1.113883.10.20.1.11"/>
  <id root="1197391935"/>
  <code code="11450-4" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="Problem list"/>
  <title/>
  <text/>
  <entry>
    <act classCode="ACT" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.1.27"/>
      <id root="343956487"/>
      <code nullFlavor="NA"/>
      <text/>
      <effectiveTime>
        <low value="2011"/>
        <high value="2011"/>
      </effectiveTime>
      <entryRelationship>
        <observation/>
```

```
      </entryRelationship>
    </act>
  </entry>
</section>
```

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** contain exactly one [1..1] **code/@code**="47519-4" *History of procedures* (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF-423, CONF-424)
2. **SHALL** contain exactly one [1..1] **title** (CONF-425)
3. **SHALL** contain exactly one [1..1] **text** (CONF-422)
    a. **SHOULD** satisfy: title is valued with a case-insensitive language-insensitive text string containing "procedures". (CONF-426)
        a. **SHOULD** satisfy: include one or more of the following: ProcedureActivityAct, ProcedureActivityObservation, ProcedureActivityProcedure (CONF-422)

Procedures Section example

```
<?xml version="1.0" encoding="UTF-8"?>
<section xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-
org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <templateId root="2.16.840.1.113883.10.20.1.12"/>
  <id root="239443064"/>
  <code code="47519-4" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="History of procedures"/>
  <title/>
  <text/>
</section>
```

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

Purpose Section example

```
<?xml version="1.0" encoding="UTF-8"?>
<section xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-
org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <templateId root="2.16.840.1.113883.10.20.1.13"/>
```

```
  <id root="1735659204"/>
  <code code="48764-5" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="Summary purpose"/>
  <title/>
  <text/>
  <entry>
    <act classCode="ACT" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.1.30"/>
      <id root="1156222443"/>
      <code code="23745001" codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMEDCT" displayName="Documentation procedure"/>
      <text/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2011"/>
        <high value="2011"/>
      </effectiveTime>
    </act>
  </entry>
</section>
```

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** contain exactly one [1..1] **`code/@code`**`="30954-2"` *Relevant diagnostic tests and/or laboratory data* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`) (CONF-389)
2. **SHALL** contain exactly one [1..1] **`title`** (CONF-391)
    a. **SHOULD** satisfy: Contains a case-insensitive language-insensitive string containing 'results'. (CONF-392)
3. **SHOULD** contain at least one [1..*] **`entry`** (CONF-388), such that
    a. Contains exactly one [1..1] *Result Organizer* (templateId: `2.16.840.1.113883.10.20.1.32`)
4. **SHALL** contain exactly one [1..1] **`text`** (CONF-388)

Results Section example

```
<?xml version="1.0" encoding="UTF-8"?>
<section xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-
org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <templateId root="2.16.840.1.113883.10.20.1.14"/>
  <id root="1527940618"/>
  <code code="30954-2" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="Relevant diagnostic tests and/or
 laboratory data"/>
  <title/>
```

```
  <text/>
  <entry>
    <organizer moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.1.32"/>
      <id root="73261711"/>
      <code code="802519608"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2011"/>
        <high value="2011"/>
      </effectiveTime>
      <component>
        <observation/>
      </component>
    </organizer>
  </entry>
</section>
```

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.

The ASTM CCR includes 'administrative data (ADT) such as marital status, ethnicity, nationality, and religious preferences' in the Social History section. CDA R2 differentiates between administrative data and clinical observations, supporting the former in the CDA Header and the latter in the CDA Body. As a result, it is necessary at times to populate attributes in the CDA Header, and to provide richer clinical details in the CDA Body.

1. **SHALL** contain exactly one [1..1] **`code/@code`**`="29762-2"` *Social history* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`)
2. **SHALL** contain exactly one [1..1] **`title`**
3. **SHALL** contain exactly one [1..1] **`text`**
4. **SHOULD** contain zero or more [0..*] **`entry`**, such that
   a. Contains exactly one [1..1] *Social History Observation* (templateId: `2.16.840.1.113883.10.20.1.33`)
5. **SHOULD** satisfy: Contains a case-insensitive language-insensitive string containing 'social history'.
6. Marital status **SHOULD** be represented as ClinicalDocument / recordTarget / patientRole / patient / maritalStatusCode. Additional information **MAY** be represented as social history observations
7. Religious affiliation **SHOULD** be represented as ClinicalDocument / recordTarget / patientRole / patient / religiousAffiliationCode. Additional information **MAY** be represented as social history observations
8. A patient's race **SHOULD** be represented as ClinicalDocument / recordTarget / patientRole / patient / raceCode. Additional information **MAY** be represented as social history observations
9. The value for ClinicalDocument / recordTarget / patientRole / patient / raceCode **MAY** be selected from codeSystem 2.16.840.1.113883.5.104 (Race)
10. A patient's ethnicity **SHOULD** be represented as ClinicalDocument / recordTarget / patientRole / patient / ethnicGroupCode. Additional information **MAY** be represented as social history observations.
11. The value for ClinicalDocument / recordTarget / patientRole / patient / ethnicGroupCode **MAY** be selected from codeSystem 2.16.840.1.113883.5.50 (Ethnicity).

Social History Section example

```
<?xml version="1.0" encoding="UTF-8"?>
<section xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-
org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <templateId root="2.16.840.1.113883.10.20.1.15"/>
  <id root="597512114"/>
```

```
  <code code="29762-2" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="Social history"/>
  <title/>
  <text/>
</section>
```

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***) with additional vocabulary constraints, but are aggregated into their own section in order to follow clinical conventions.

1. **SHALL** contain exactly one [1..1] **`code/@code`**`="8716-3"` *Vital signs* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`) (CONF-382, CONF-383)
2. **SHALL** contain exactly one [1..1] **`title`** (CONF-384)
3. **SHOULD** contain at least one [1..*] **`entry`** (CONF-381), such that
   a. Contains exactly one [1..1] *Vital Signs Organizer* (templateId: `2.16.840.1.113883.10.20.1.35`)
4. **SHALL** contain exactly one [1..1] **`text`** (CONF-381)
5. **SHOULD** satisfy: title Contains a case-insensitive language-insensitive string containing 'vital signs'. (CONF-385)

Vital Signs Section example

```
<?xml version="1.0" encoding="UTF-8"?>
<section xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-
org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <templateId root="2.16.840.1.113883.10.20.1.16"/>
  <id root="1353337750"/>
  <code code="8716-3" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="Vital signs"/>
  <title/>
  <text/>
  <entry>
    <organizer moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.1.32"/>
      <templateId root="2.16.840.1.113883.10.20.1.35"/>
      <id root="1488529829"/>
      <code code="1707425451"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2011"/>
        <high value="2011"/>
      </effectiveTime>
    </organizer>
  </entry>
</section>
```

Chapter 4

CLINICAL STATEMENT TEMPLATES

Topics:

This section of the Implementation Guide details the clinical statement entries referenced in the document section templates. The clinical statement entry templates are arranged alphabetically.

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

Advance Directive Observation

[Observation: templateId `2.16.840.1.113883.10.20.1.17`]

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)
3. **SHALL** contain at least one [1..*] **`id`**
4. **SHALL** contain exactly one [1..1] **`statusCode/@code`**`="completed"` (CodeSystem: `2.16.840.1.113883.5.14 HL7ActStatus`)
5. **SHOULD** contain zero or one [0..1] **`effectiveTime`**
6. **SHALL** contain exactly one [1..1] **`code`**
7. **MAY** contain at least one [1..*] **`advanceDirectiveVerification`**, such that
   a. Contains exactly one [1..1] *Advance Directive Verification* (templateId: `2.16.840.1.113883.10.20.1.58`)
8. **SHALL** contain exactly one [1..1] **`entryRelationship`**, such that
   a. Contains exactly one [1..1] *Advance Directive Status Observation* (templateId: `2.16.840.1.113883.10.20.1.37`)
9. **MAY** contain zero or one [0..1] **`advanceDirectiveReference`**, such that
   a. Contains exactly one [1..1] *Advance Directive Reference* (templateId: `2.16.840.1.113883.10.20.1.36`)
10. The value for Observation / code in an advance directive observation **MAY** be selected from ValueSet 2.16.840.1.113883.1.11.20.2 AdvanceDirectiveTypeCode STATIC 20061017.
11. There **SHOULD** be an advance directive observation whose value for Observation / code is '304251008' 'Resuscitation status' 2.16.840.1.113883.6.96 SNOMED CT STATIC
12. **SHALL** satisfy: Contains one or more sources of information

Advance Directive Observation example

```
<?xml version="1.0" encoding="UTF-8"?>
<observation xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.1.17"/>
  <id root="1169380925"/>
  <code code="1265130169"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
</observation>
```

Advance Directive Status Observation

[Observation: templateId `2.16.840.1.113883.10.20.1.37`]

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

Advance Directive Status Observation example

```
<?xml version="1.0" encoding="UTF-8"?>
```

```
<observation xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.1.57"/>
  <templateId root="2.16.840.1.113883.10.20.1.37"/>
  <id root="1430803043"/>
  <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="Status"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
</observation>
```

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** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF-226)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF-227)
3. **SHALL** contain exactly one [1..1] **`code/@code`**`="397659008"` *Age* (CodeSystem: `2.16.840.1.113883.6.96 SNOMEDCT`) (CONF-228)
4. **SHALL** contain zero or one [0..1] **`statusCode/@code`**`="completed"` (CodeSystem: `2.16.840.1.113883.5.14 HL7ActStatus`) (CONF-229, CONF-230)
5. **SHALL** contain exactly one [1..1] **`value`** (CONF-231)
   - Valued using appropriate datatype.

Age Observation example

```
<?xml version="1.0" encoding="UTF-8"?>
<observation xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.1.38"/>
  <id root="719842990"/>
  <code code="397659008" codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMEDCT" displayName="Age"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
</observation>
```

Alert Observation

[Observation: templateId `2.16.840.1.113883.10.20.1.18`]

1. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF-263)
2. **SHALL** contain exactly one [1..1] **`statusCode/@code`**`="completed"` (CodeSystem: `2.16.840.1.113883.5.14 HL7ActStatus`) (CONF-264, CONF-265)

3. **MAY** contain zero or one [0..1] **`effectiveTime`** (CONF-266)
4. **MAY** contain zero or more [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 (CONF-267)
5. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF-270), such that
   a. Contains exactly one [1..1] *Alert Status Observation* (templateId: `2.16.840.1.113883.10.20.1.39`)
6. **MAY** contain at least one [1..*] **`entryRelationship`**, such that
   a. Contains **`@typeCode="MFST"`** *MFST (is manifestation of)*
   b. Contains exactly one [1..1] *Reaction Observation* (templateId: `2.16.840.1.113883.10.20.1.54`)
7. 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. (CONF-268)
8. **SHALL** satisfy: An alert observation contains one or more sources of information. (CONF-269)

```
[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. An alert observation **SHOULD** contain at least one Observation / participant, representing the agent that is the cause of the allergy or adverse reaction. (CONF-273)

```
[OCL]: self.participant->exists(participant : cda::Participant2 |
 participant.typeCode = vocab::ParticipationType::CSM )
```

10. **SHALL** satisfy: Contains exactly one participant / participantRole / playingEntity. (CONF-274)

```
[OCL]: self.participant.participantRole.playingEntity->size() > 0
```

11. The value for participant / @typeCode in an agent participation **SHALL** be "CSM" "Consumable" 2.16.840.1.113883.5.90 ParticipationType STATIC. (CONF-275)

```
[OCL]: self.participant->one(entity : cda::Participant2 |
  entity.typeCode = vocab::ParticipationType::CSM)
```

12. The value for Observation / participant / participantRole / @classCode in an agent participation **SHALL** be "MANU" "Manufactured" 2.16.840.1.113883.5.110 RoleClass STATIC. (CONF-276)

```
[OCL]: self.participant.participantRole->one(entity : cda::ParticipantRole
 |
  entity.classCode = vocab::RoleClassRoot::MANU)
```

13. 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. (CONF-277)

```
[OCL]: self.participant.participantRole.playingEntity->one(entity :
 cda::PlayingEntity |
  entity.classCode = vocab::EntityClassRoot::MMAT and not
 entity.code.oclIsUndefined())
```

14. **SHALL** satisfy: Contains exactly one participant / participantRole / playingEntity / code. (CONF-278)

```
[OCL]: self.participant.participantRole.playingEntity->one(entity :
 cda::PlayingEntity |  not entity.code.oclIsUndefined())
```

15. 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. (CONF-279)

```
[OCL]: self.participant.participantRole.playingEntity->one(entity :
 cda::PlayingEntity | not entity.code.oclIsUndefined()
 and (entity.code.codeSystem='2.16.840.1.113883.6.88' xor
 entity.code.codeSystem='2.16.840.1.113883.6.59'))
```

Alert Observation example

```
<?xml version="1.0" encoding="UTF-8"?>
<observation xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.1.18"/>
  <id root="2028949508"/>
  <code code="1343822157"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.1.57"/>
      <templateId root="2.16.840.1.113883.10.20.1.39"/>
      <id root="1091523892"/>
      <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="Status"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2011"/>
        <high value="2011"/>
      </effectiveTime>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation/>
  </entryRelationship>
</observation>
```

Alert Status Observation

[Observation: templateId `2.16.840.1.113883.10.20.1.39`]

1. **SHALL** conform to *Status Observation* template (templateId: `2.16.840.1.113883.10.20.1.57`)
2. **SHALL** contain exactly one [1..1] **`value`**, which **SHALL** be selected from ValueSet `2.16.840.1.113883.1.11.20.3 AlertStatusCode` **STATIC** 20061017 (CONF-272)

Alert Status Observation example

```
<?xml version="1.0" encoding="UTF-8"?>
<observation xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.1.57"/>
  <templateId root="2.16.840.1.113883.10.20.1.39"/>
  <id root="494077633"/>
  <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="Status"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
</observation>
```

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** contain exactly one [1..1] **`@classCode`**`="ACT"` *Act* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)
3. **SHALL** contain at least one [1..*] **`id`**

Authorization Activity example

```
<?xml version="1.0" encoding="UTF-8"?>
<act xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-
org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd" classCode="ACT"
 moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.1.19"/>
  <id root="1069178672"/>
  <code code="321759196"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
</act>
```

Cause Of Death Observation

[Observation: templateId `2.16.840.1.113883.10.20.1.42`]

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

Cause Of Death Observation example

```
<?xml version="1.0" encoding="UTF-8"?>
<observation xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <templateId root="2.16.840.1.113883.10.20.1.22"/>
  <templateId root="2.16.840.1.113883.10.20.1.42"/>
  <id root="1228559340"/>
  <code code="1158919620"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
</observation>
```

Comment

[Act: templateId `2.16.840.1.113883.10.20.1.40`]

Used to contain comments associated with any of the data within the document.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="ACT"` *Act* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF-504)

2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF-505)
3. **SHALL** contain exactly one [1..1] **`code/@code`**`="48767-8"` *Annotation comment* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`) (CONF-506, CONF-507)

Comment example

Coverage Activity

[Act: templateId `2.16.840.1.113883.10.20.1.20`]

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="ACT"` *Act* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF-36)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="DEF"` (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF-37)
3. **SHALL** contain at least one [1..*] **`id`** (CONF-38)
4. **SHALL** contain exactly one [1..1] **`statusCode/@code`**`="completed"` (CodeSystem: `2.16.840.1.113883.5.14 HL7ActStatus`) (CONF-39, CONF-40)
5. **SHALL** contain exactly one [1..1] **`code/@code`**`="48768-6"` *Payment sources* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`) (CONF-41, CONF-42)
6. **SHALL** contain at least one [1..*] **`entryRelationship`** (CONF-43, CONF-45, CONF-46), such that
   a. Contains **`@typeCode="`**`COMP"` *COMP (has component)*
   b. Contains exactly one [1..1] *Policy Activity* (templateId: `2.16.840.1.113883.10.20.1.26`)
7. **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'))
```
8. **MAY** satisfy: entryRelationship contains sequenceNumber, which serves to prioritize the payment sources. (CONF-44)
   -
```
[OCL]: self.entryRelationship->exists(rel : cda::EntryRelationship | not
 rel.sequenceNumber.oclIsUndefined())
```

Coverage Activity example

```
<?xml version="1.0" encoding="UTF-8"?>
<act xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-
org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd" classCode="ACT"
 moodCode="DEF">
  <templateId root="2.16.840.1.113883.10.20.1.20"/>
  <id root="1505466167"/>
  <code code="48768-6" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="Payment sources"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
  <entryRelationship>
    <act classCode="ACT" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.1.26"/>
      <id root="212451352"/>
      <code code="875422637"/>
```

```
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2011"/>
        <high value="2011"/>
      </effectiveTime>
    </act>
  </entryRelationship>
</act>
```

Coverage Plan Description

[Act: templateId `null`]

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="ACT"` *Act* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF-67)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="DEF"` (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF-67)
3. **SHALL** contain at least one [1..*] **`id`** (CONF-68)

Coverage Plan Description example

```
<?xml version="1.0" encoding="UTF-8"?>
<act xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-
org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd" classCode="ACT"
 moodCode="DEF">
  <id root="620543764"/>
  <code code="159507710"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
</act>
```

Encounters Activity

[Encounter: templateId `2.16.840.1.113883.10.20.1.21`]

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="ENC"` (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)
3. **SHALL** contain at least one [1..*] **`id`**
4. **SHOULD** contain exactly one [1..1] **`code`**, which **SHOULD** be selected from ValueSet `2.16.840.1.113883.1.11.13955 EncounterCode` **STATIC**
5. **MAY** contain zero or one [0..1] **`effectiveTime`**
6. **MAY** contain zero or more [0..*] **`entryRelationship`**, such that
   a. Contains exactly one [1..1] *Patient Instruction* (templateId: `2.16.840.1.113883.10.20.1.49`)
7. **MAY** contain zero or one [0..1] **`entryRelationship`**, such that
   a. Contains **`@typeCode="`**`SUBJ"` *SUBJ (has subject)*
   b. Contains exactly one [1..1] *Age Observation* (templateId: `2.16.840.1.113883.10.20.1.38`)
8. **MAY** contain zero or more [0..*] **`encounterLocation`**, such that
   a. Contains exactly one [1..1] *Encounter Location* (templateId: `2.16.840.1.113883.10.20.1.45`)
9. **MAY** contain one or more [1..*] entryRelationship with @typecode='RSON' where target represents the indication for the activity
10. **MAY** contain zero or more [0..*] performer, used to define the practioners involved in an encounter
11. **MAY** contain one [0..1] performer / assignedEntity / code, to define the role of the practioner

12. **SHALL** contain one or more sources of information

Encounters Activity example

```
<?xml version="1.0" encoding="UTF-8"?>
<encounter xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 classCode="ENC" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.1.21"/>
  <id root="12691828"/>
  <code code="1756286772"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
</encounter>
```

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** contain exactly one [1..1] **`@classCode="OBS"`** *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF-170)
2. **SHALL** contain exactly one [1..1] **`@moodCode="EVN"`** *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF-171)
3. **SHALL** contain exactly one [1..1] **`statusCode/@code="completed"`** (CodeSystem: `2.16.840.1.113883.5.14 HL7ActStatus`) (CONF-172, CONF-173)
4. **SHOULD** contain exactly one [1..1] **`code/@code="ASSERTION"`** (CodeSystem: `2.16.840.1.113883.5.4 HL7ActCode`) (CONF-174)
5. **SHOULD** contain exactly one [1..1] **`value/@code="404684003"`** *Clinical finding* (CodeSystem: `2.16.840.1.113883.6.96 SNOMEDCT`), where its data type is CD (CONF-175)
6. 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)
7. **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
     ```
8. 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
     ```

Episode Observation example

```
<?xml version="1.0" encoding="UTF-8"?>
```

```
<observation xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.1.41"/>
  <id root="333049170"/>
  <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"
 codeSystemName="ActCode"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
</observation>
```

Family History Observation

[Observation: templateId `2.16.840.1.113883.10.20.1.22`]

1. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)
2. **SHALL** contain at least one [1..*] **`id`**
3. **SHALL** contain exactly one [1..1] **`statusCode/@code`**`="completed"` (CodeSystem: `2.16.840.1.113883.5.14 HL7ActStatus`)
4. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF-224), such that
   a. Contains **`@typeCode="`**`SUBJ"` *SUBJ (has subject)*
   b. Contains exactly one [1..1] *Age Observation* (templateId: `2.16.840.1.113883.10.20.1.38`)
5. **SHOULD** contain zero or one [0..1] **`effectiveTime`**
6. **MAY** contain zero or one [0..1] **`entryRelationship`**, such that
   a. Contains exactly one [1..1] *Problem Status Observation* (templateId: `2.16.840.1.113883.10.20.1.50`)
7. **SHALL** contain at least one [1..*] **`entryRelationship`**, such that
   a. Contains **`@typeCode="`**`CAUS"` *CAUS (is etiology for)*
   b. Contains exactly one [1..1] *Cause Of Death Observation* (templateId: `2.16.840.1.113883.10.20.1.42`)
8. A family history observation not contained within a family history organizer **SHALL** contain exactly one subject participant, representing the family member who is the subject of the observation
9. Where the subject of an observation is explicit in a family history observation code (e.g. SNOMED CT concept 417001009 "Family history of tuberous sclerosis"), the subject participant **SHALL** be equivalent to or further specialize the code
10. Where the subject of an observation is not explicit in a family history observation code (e.g. SNOMED CT concept 44054006 "Diabetes Mellitus type 2"), the subject participant **SHALL** be used to assert the affected relative
11. A subject participant **SHALL** contain exactly one RelatedSubject, representing the relationship of the subject to the patient
12. The value for RelatedSubject / @classCode **SHALL** be "PRS" "Personal relationship" 2.16.840.1.113883.5.110 RoleClass STATIC
13. RelatedSubject **SHALL** contain exactly one RelatedSubject / code
14. The value for "RelatedSubject / code" **SHOULD** be selected from ValueSet 2.16.840.1.113883.1.11.19579 FamilyHistoryRelatedSubjectCode DYNAMIC or 2.16.840.1.113883.1.11.20.21 FamilyHistoryPersonCode DYNAMIC
15. Representation of a pedigree graph **SHALL** be done using RelatedSubject / code values (e.g. "great grandfather") to designate a hierarchical family tree.
16. RelatedSubject **SHOULD** contain exactly one RelatedSubject / subject
17. RelatedSubject / subject **SHOULD** contain exactly one RelatedSubject / subject / administrativeGenderCode.

18. **SHOULD** satisfy: subject/relatedSubject/subject contains exactly one birthTime
    - `[OCL]: not self.subject.relatedSubject.subject.birthTime.oclIsUndefined()`
19. **MAY** satisfy: subject/relatedSubject/subject contains exactly one sdtc:deceasedInd
20. **MAY** satisfy: subject/relatedSubject/subject contains exactly one sdtc:deceasedTime
21. **SHOULD** satisfy: The age of a relative at the time of observation is inferred by comparing subject/relatedSubject/subject/birthTime with Observation/effectiveTime
22. **MAY** satisfy: The age of a relative at the time of death is inferred by comparing subject/relatedSubject/subject/birthTime with subject/relatedSubject/subject/sdtc:deceasedTime.
23. **SHALL** satisfy: Contains one or more sources of information
24. A family history cause of death observation **SHALL** contain one or more entryRelationship / @typeCode

Family History Observation example

```
<?xml version="1.0" encoding="UTF-8"?>
<observation xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <templateId root="2.16.840.1.113883.10.20.1.22"/>
  <id root="1932971121"/>
  <code code="588039367"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
</observation>
```

Family History Organizer

[Organizer: templateId `2.16.840.1.113883.10.20.1.23`]

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="CLUSTER"` (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)
3. **SHALL** contain exactly one [1..1] **`statusCode/@code`**`="completed"` (CodeSystem: `2.16.840.1.113883.5.14 HL7ActStatus`)
4. **SHOULD** contain at least one [1..*] **`component`**, such that
    a. Contains exactly one [1..1] *Family History Observation* (templateId: `2.16.840.1.113883.10.20.1.22`)
5. A family history organizer **SHALL** contain one or more Organizer / component.
6. The target of a family history organizer Organizer / component relationship **SHOULD** be a family history observation, but **MAY** be some other clinical statement
7. A family history organizer **SHALL** contain exactly one subject participant, representing the family member who is the subject of the family history observations
8. A subject participant **SHALL** contain exactly one RelatedSubject, representing the relationship of the subject to the patient
9. The value for RelatedSubject / @classCode **SHALL** be "PRS" "Personal relationship" 2.16.840.1.113883.5.110 RoleClass STATIC
10. RelatedSubject **SHALL** contain exactly one RelatedSubject / code
11. The value for "RelatedSubject / code" **SHOULD** be selected from ValueSet 2.16.840.1.113883.1.11.19579 FamilyHistoryRelatedSubjectCode DYNAMIC or 2.16.840.1.113883.1.11.20.21 FamilyHistoryPersonCode DYNAMIC
12. Representation of a pedigree graph **SHALL** be done using RelatedSubject / code values (e.g. "great grandfather") to designate a hierarchical family tree.
13. RelatedSubject **SHOULD** contain exactly one RelatedSubject / subject
14. RelatedSubject / subject **SHOULD** contain exactly one RelatedSubject / subject / administrativeGenderCode.

15. **SHOULD** satisfy: subject/relatedSubject/subject contains exactly one birthTime (CONF-219)
    - `[OCL]: not self.subject.relatedSubject.subject.birthTime.oclIsUndefined()`
16. **MAY** satisfy: subject/relatedSubject/subject contains exactly one sdtc:deceasedInd
17. **MAY** satisfy: subject/relatedSubject/subject contains exactly one sdtc:deceasedTime
18. **SHOULD** satisfy: The age of a relative at the time of observation is inferred by comparing subject/relatedSubject/subject/birthTime with Observation/effectiveTime
19. **MAY** satisfy: The age of a relative at the time of death is inferred by comparing subject/relatedSubject/subject/birthTime with subject/relatedSubject/subject/sdtc:deceasedTime.

Family History Organizer example

```
<?xml version="1.0" encoding="UTF-8"?>
<organizer xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <templateId root="2.16.840.1.113883.10.20.1.23"/>
  <id root="348221111"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
</organizer>
```

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** contain exactly one [1..1] **`@moodCode`**`="INT"` (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF-336)

Fulfillment Instruction example

```
<?xml version="1.0" encoding="UTF-8"?>
<act xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-
org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd" moodCode="INT">
  <templateId root="2.16.840.1.113883.10.20.1.43"/>
  <id root="1380106664"/>
  <code code="1038494811"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
</act>
```

Functional Status Observation

[Observation: templateId `2.16.840.1.113883.10.20.1.44`]

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

Functional Status Observation example

```
<?xml version="1.0" encoding="UTF-8"?>
<observation xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.1.57"/>
```

```
  <templateId root="2.16.840.1.113883.10.20.1.44"/>
  <id root="883062809"/>
  <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="Status"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
</observation>
```

Medication Activity

[SubstanceAdministration: templateId `2.16.840.1.113883.10.20.1.24`]

A medication activity is used to describe what is administered.

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").

A reaction represents an adverse event due to an administered substance. 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** contain at least one [1..*] **`id`** (CONF-306)
2. **SHOULD** contain exactly one [1..1] **`statusCode`** (CONF-307)
3. **MAY** contain exactly one [1..1] **`entryRelationship`** (CONF-338, CONF-339), such that
   a. Contains **`@typeCode="SUBJ"`** *SUBJ (has subject)*
   b. Contains exactly one [1..1] *Medication Series Number Observation* (templateId: `2.16.840.1.113883.10.20.1.46`)
4. **MAY** contain exactly one [1..1] **`entryRelationship`** (CONF-350), such that
   a. Contains exactly one [1..1] *Medication Status Observation* (templateId: `2.16.840.1.113883.10.20.1.47`)
5. **MAY** contain at least one [1..*] **`entryRelationship`** (CONF-330, CONF-333), such that
   a. Contains **`@typeCode="SUBJ"`** *SUBJ (has subject)*
   b. Contains exactly one [1..1] *Patient Instruction* (templateId: `2.16.840.1.113883.10.20.1.49`)
6. **SHOULD** contain at least one [1..*] **`effectiveTime`** (CONF-308)
   - Used to indicate the actual or intended start and stop date of a medication, and the frequency of administration.
7. **MAY** contain exactly one [1..1] **`maxDoseQuantity`** (CONF-312)
   - represents a maximum dose limit
8. **SHOULD** contain exactly one [1..1] **`routeCode`** (CodeSystem: `2.16.840.1.113883.5.112 HL7 RouteOfAdministration`) (CONF-309, CONF-310)
9. **MAY** contain at least one [1..*] **`performer`** (CONF-313), such that
   - Indicates the person administering a substance.
10. **MAY** contain at least one [1..*] **`entryRelationship`** (CONF-348, CONF-349), such that
    a. Contains **`@typeCode="CAUS"`** *CAUS (is etiology for)*
    b. Contains exactly one [1..1] *Reaction Observation* (templateId: `2.16.840.1.113883.10.20.1.54`)
11. **MAY** contain at least one [1..*] **`participant`** (CONF-368), such that
    a. Contains exactly one [1..1] *Product Instance* (templateId: `2.16.840.1.113883.10.20.1.52`)
12. **SHOULD** contain zero or one [0..1] **`doseQuantity`**
13. **SHOULD** contain zero or one [0..1] **`rateQuantity`**

14. **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`
15. **SHOULD** satisfy: Contains exactly one doseQuantity or rateQuantity. (CONF-311)
    - `[OCL]: not self.doseQuantity.oclIsUndefined() or not self.rateQuantity.oclIsUndefined()`
16. **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())`
17. **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'))`
18. **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())`
19. **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)`
20. **SHALL** satisfy: entryRelationship / @typeCode="RSON" in a medication activity has a target of problem act (templateId 2.16.840.1.113883.10.20.1.27), problem observation (templateId 2.16.840.1.113883.10.20.1.28), or some other clinical statement. (CONF-329)
    - `[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)))`
21. **SHALL** satisfy: Contains exactly one consumable, the target of which is a Product template. (CONF-354)
    - `[OCL]: self.consumable.manufacturedProduct.oclIsKindOf(ccd::Product)`

Medication Activity example

```
<?xml version="1.0" encoding="UTF-8"?>
<substanceadministration xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <templateId root="2.16.840.1.113883.10.20.1.24"/>
  <id root="1300006842"/>
  <statusCode code="completed"/>
  <effectiveTime value="20110830"/>
  <routeCode code="Value"/>
  <doseQuantity/>
```

```
  <rateQuantity/>
  <maxDoseQuantity/>
  <consumable/>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.1.46"/>
      <id root="1290089858"/>
      <code code="30973-2" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="Dose number"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2011"/>
        <high value="2011"/>
      </effectiveTime>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation/>
  </entryRelationship>
  <entryRelationship>
    <act/>
  </entryRelationship>
</substanceadministration>
```

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** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF-341)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF-342)
3. **SHALL** contain exactly one [1..1] **`statusCode`** (CONF-343)
4. **SHALL** contain exactly one [1..1] **`code/@code`**`="30973-2"` *Dose number* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`) (CONF-344, CONF-345)
5. **SHALL** contain exactly one [1..1] **`value`**, where its data type is INT (CONF-346, CONF-347)

Medication Series Number Observation example

```
<?xml version="1.0" encoding="UTF-8"?>
<observation xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.1.46"/>
  <id root="2100155520"/>
  <code code="30973-2" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="Dose number"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
</observation>
```

Medication Status Observation

[Observation: templateId `2.16.840.1.113883.10.20.1.47`]

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

Medication Status Observation example

```
<?xml version="1.0" encoding="UTF-8"?>
<observation xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.1.57"/>
  <templateId root="2.16.840.1.113883.10.20.1.47"/>
  <id root="133870499"/>
  <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="Status"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
</observation>
```

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** contain exactly one [1..1] **`@moodCode`**`="INT"` (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF-332)

Patient Instruction example

```
<?xml version="1.0" encoding="UTF-8"?>
<act xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-
org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd" moodCode="INT">
  <templateId root="2.16.840.1.113883.10.20.1.49"/>
  <id root="689068497"/>
  <code code="1935833255"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
</act>
```

Plan Of Care Activity Act

[Act: templateId `2.16.840.1.113883.10.20.1.25`]

1. **SHALL** conform to *Plan Of Care Activity*
2. **SHALL** contain exactly one [1..1] **`@moodCode`**
   a. **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`
3. **SHALL** contain at least one [1..*] **`id`**

4. **SHALL** contain one or more sources of information

Plan Of Care Activity Act example

```
<?xml version="1.0" encoding="UTF-8"?>
<act xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-
org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <templateId root="2.16.840.1.113883.10.20.1.25"/>
  <id root="2072166787"/>
  <code code="1187379112"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
</act>
```

Plan Of Care Activity Encounter

[Encounter: templateId `2.16.840.1.113883.10.20.1.25`]

1. **SHALL** conform to *Plan Of Care Activity*
2. **SHALL** contain exactly one [1..1] **`@moodCode`**
   a. **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`
3. **SHALL** contain at least one [1..*] **`id`**
4. **SHALL** contain one or more sources of information

Plan Of Care Activity Encounter example

```
<?xml version="1.0" encoding="UTF-8"?>
<encounter xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <templateId root="2.16.840.1.113883.10.20.1.25"/>
  <id root="1040371853"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
</encounter>
```

Plan Of Care Activity Observation

[Observation: templateId `2.16.840.1.113883.10.20.1.25`]

1. **SHALL** conform to *Plan Of Care Activity*
2. **SHALL** contain exactly one [1..1] **`@moodCode`**
   a. **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`
3. **SHALL** contain at least one [1..*] **`id`**
4. **SHALL** contain one or more sources of information

Plan Of Care Activity Observation example

```
<?xml version="1.0" encoding="UTF-8"?>
<observation xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <templateId root="2.16.840.1.113883.10.20.1.25"/>
  <id root="1993154404"/>
  <code code="1790835611"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
</observation>
```

Plan Of Care Activity Procedure

[Procedure: templateId `2.16.840.1.113883.10.20.1.25`]

1. **SHALL** conform to *Plan Of Care Activity*
2. **SHALL** contain exactly one [1..1] **`@moodCode`**
   a. **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`
3. **SHALL** contain at least one [1..*] **`id`**
4. **SHALL** contain one or more sources of information

Plan Of Care Activity Procedure example

```
<?xml version="1.0" encoding="UTF-8"?>
<procedure xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <templateId root="2.16.840.1.113883.10.20.1.25"/>
  <id root="548230428"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
</procedure>
```

Plan Of Care Activity Substance Administration

[SubstanceAdministration: templateId `2.16.840.1.113883.10.20.1.25`]

1. **SHALL** conform to *Plan Of Care Activity*
2. **SHALL** contain exactly one [1..1] **`@moodCode`**
   a. **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`
3. **SHALL** contain at least one [1..*] **`id`**
4. **SHALL** contain one or more sources of information

Plan Of Care Activity Substance Administration example

```
<?xml version="1.0" encoding="UTF-8"?>
```

```
<substanceadministration xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <templateId root="2.16.840.1.113883.10.20.1.25"/>
  <id root="1476737096"/>
  <effectiveTime value="20110830"/>
  <consumable/>
</substanceadministration>
```

Plan Of Care Activity Supply

[Supply: templateId `2.16.840.1.113883.10.20.1.25`]

1. **SHALL** conform to *Plan Of Care Activity*
2. **SHALL** contain exactly one [1..1] **`@moodCode`**
   a. **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`
3. **SHALL** contain at least one [1..*] **`id`**
4. **SHALL** contain one or more sources of information

Plan Of Care Activity Supply example

```
<?xml version="1.0" encoding="UTF-8"?>
<supply xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-
org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <templateId root="2.16.840.1.113883.10.20.1.25"/>
  <id root="1397554107"/>
  <effectiveTime value="20110830"/>
</supply>
```

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** contain exactly one [1..1] **`@classCode`**`="ACT"` *Act* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF-49)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF-50)
3. **SHALL** contain at least one [1..*] **`id`** (CONF-51)
4. **SHALL** contain exactly one [1..1] **`statusCode/@code`**`="completed"` (CodeSystem: `2.16.840.1.113883.5.14 HL7ActStatus`) (CONF-52, CONF-53)
5. **SHOULD** contain exactly one [1..1] **`code`**, which **SHOULD** be selected from ValueSet `2.16.840.1.113883.1.11.19832 ActCoverageType` **DYNAMIC** (CONF-54, CONF-55)
6. **SHALL** contain exactly one [1..1] **`performer`** (CONF-56), such that
7. **SHALL** contain exactly one [1..1] **`participant`** (CONF-58), such that
8. **MAY** contain exactly one [1..1] **`participant`** (CONF-63), such that
9. **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)`

10. **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)`
11. 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)
12. 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.oclIsUndefined())`
13. 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)`
14. 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.oclIsUndefined())`
15. 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)`
16. 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.oclIsKindOf(ccd::AuthorizationActivity) or rel.act.oclIsKindOf(ccd::CoveragePlanDescription))`

Policy Activity example

```
<?xml version="1.0" encoding="UTF-8"?>
<act xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-
org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd" classCode="ACT"
 moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.1.26"/>
  <id root="1224284175"/>
  <code code="2084076660"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
</act>
```

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** contain exactly one [1..1] **`@classCode`**`="ACT"` *Act* (CodeSystem: `2.16.840.1.113883.5.6` `HL7ActClass`) (CONF-146)

2. **SHALL** contain exactly one [1..1] **`@moodCode="EVN"`** *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF-147)
3. **SHALL** contain at least one [1..*] **`id`** (CONF-148)
4. **SHALL** contain exactly one [1..1] **`code`**`/@nullFlavor` = "NA" *NA (not applicable)* (CONF-149)
5. **MAY** contain zero or one [0..1] **`effectiveTime`** (CONF-150)
   - Indicates the timing of the concern (e.g. the interval of time for which the problem is a concern).
6. **MAY** contain exactly one [1..1] **`entryRelationship`** (CONF-168), such that
   a. Contains exactly one [1..1] *Episode Observation* (templateId: `2.16.840.1.113883.10.20.1.41`)
7. **SHALL** contain one or more entryRelationship (CONF-151)
   - `[OCL]: not self.entryRelationship->isEmpty()`
8. 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)
9. 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.oclIsUndefined() and
       (target.oclIsKindOf(ccd::ProblemObservation) or
      target.oclIsKindOf(ccd::AlertObservation)))
     ```
10. In Problem Section, a Problem Act **SHOULD** contain one or more Problem Observations. (CONF-140)
    - ```
      [OCL]: self.getSection().oclIsKindOf(ccd::ProblemSection) implies
       self.getObservations()
         ->exists(obs : cda::Observation |
       obs.oclIsKindOf(ccd::ProblemObservation))
      ```
11. In Alert Section, a ProblemAct **SHOULD** contain one or more Alert Observations. (CONF-256)
    - ```
      [OCL]: self.getSection().oclIsKindOf(ccd::AlertsSection) implies
       self.getObservations()
         ->exists(obs : cda::Observation |
       obs.oclIsKindOf(ccd::AlertObservation))
      ```
12. **MAY** contain exactly one Patient Awareness (CONF-179)
    - ```
      [OCL]: self.participant->one(partic : cda::Participant2 |
       partic.oclIsKindOf(ccd::PatientAwareness))
      ```

Problem Act example

```
<?xml version="1.0" encoding="UTF-8"?>
<act xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-
org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd" classCode="ACT"
 moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.1.27"/>
  <id root="1563494891"/>
  <code nullFlavor="NA"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.1.41"/>
      <id root="529811835"/>
      <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"
 codeSystemName="ActCode"/>
      <statusCode code="completed"/>
      <effectiveTime>
```

```
        <low value="2011"/>
        <high value="2011"/>
      </effectiveTime>
    </observation>
  </entryRelationship>
</act>
```

Problem Health Status Observation

[Observation: templateId 2.16.840.1.113883.10.20.1.51]

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

Problem Health Status Observation example

```
<?xml version="1.0" encoding="UTF-8"?>
<observation xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.1.57"/>
  <templateId root="2.16.840.1.113883.10.20.1.51"/>
  <id root="1307221718"/>
  <code code="11323-3" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="Health status"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
</observation>
```

Problem Observation

[Observation: templateId 2.16.840.1.113883.10.20.1.28]

1. Contains exactly one [1..1] **@classCode**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass)
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) (CONF-155)
3. **SHALL** contain exactly one [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) (CONF-156, CONF-157)
4. **SHOULD** contain exactly one [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).
5. **MAY** contain exactly one [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.
6. **MAY** contain zero or one [0..1] **entryRelationship** (CONF-162), such that
   a. Contains **@typeCode="**REFR" *REFR (refers to)*
   b. Contains exactly one [1..1] *Problem Status Observation* (templateId: 2.16.840.1.113883.10.20.1.50)
7. **MAY** contain zero or one [0..1] **entryRelationship** (CONF-165), such that

   a. Contains **@typeCode="**REFR" *REFR (refers to)*
   b. Contains exactly one [1..1] *Problem Health Status Observation* (templateId: 2.16.840.1.113883.10.20.1.51)
8. **MAY** contain zero or one [0..1] **entryRelationship** (CONF-160), such that
   a. Contains **@typeCode="**SUBJ" *SUBJ (has subject)*
   b. Contains exactly one [1..1] *Age Observation* (templateId: 2.16.840.1.113883.10.20.1.38)
9. **SHALL** contain 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'))
```

10. **MAY** contain exactly one Patient Awareness (CONF-180)

```
[OCL]: self.participant->one(partic : cda::Participant2 |
 partic.oclIsKindOf(ccd::PatientAwareness))
```

Problem Observation example

```
<?xml version="1.0" encoding="UTF-8"?>
<observation xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.1.28"/>
  <id root="87519447"/>
  <code code="726363952"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.1.57"/>
      <templateId root="2.16.840.1.113883.10.20.1.50"/>
      <id root="1229366830"/>
      <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="Status"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2011"/>
        <high value="2011"/>
      </effectiveTime>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation/>
  </entryRelationship>
  <entryRelationship>
    <observation/>
  </entryRelationship>
</observation>
```

Problem Status Observation

[Observation: templateId 2.16.840.1.113883.10.20.1.50]

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

Problem Status Observation example

```
<?xml version="1.0" encoding="UTF-8"?>
<observation xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.1.57"/>
  <templateId root="2.16.840.1.113883.10.20.1.50"/>
  <id root="2131731804"/>
  <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="Status"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
</observation>
```

Procedure Activity Act

[Act: templateId `2.16.840.1.113883.10.20.1.29`]

1. **SHALL** conform to *Procedure Activity*

Procedure Activity Act example

```
<?xml version="1.0" encoding="UTF-8"?>
<act xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-
org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <templateId root="2.16.840.1.113883.10.20.1.29"/>
  <id root="524782149"/>
  <code code="1683102901"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
</act>
```

Procedure Activity Observation

[Observation: templateId `2.16.840.1.113883.10.20.1.29`]

1. **SHALL** conform to *Procedure Activity*
2. contains one or more Observation / methodCode if the method isn't inherent in Observation / code or if there is a need to further specialize the method in Observation / code. Observation / methodCode **SHALL NOT** conflict with the method inherent in Observation / code. (CONF-435)
3. contains one or more Observation / targetSiteCode to indicate the anatomical site or system that is the focus of the procedure, if the site isn't inherent in Observation / code or if there is a need to further specialize the site in Observation / code. Observation / targetSiteCode **SHALL NOT** conflict with the site inherent in Observation / code (CONF-436)

Procedure Activity Observation example

```
<?xml version="1.0" encoding="UTF-8"?>
```

```
<observation xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <templateId root="2.16.840.1.113883.10.20.1.29"/>
  <id root="459681778"/>
  <code code="663651657"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
</observation>
```

Procedure Activity Procedure

[Procedure: templateId `2.16.840.1.113883.10.20.1.29`]

1. **SHALL** conform to *Procedure Activity*
2. contains one or more Procedure / methodCode if the method isn't inherent in Procedure / code or if there is a need to further specialize the method in Procedure / code. Procedure / methodCode **SHALL NOT** conflict with the method inherent in Procedure / code. (CONF-435)
3. contains one or more Procedure / targetSiteCode to indicate the anatomical site or system that is the focus of the procedure, if the site isn't inherent in Procedure / code or if there is a need to further specialize the site in Procedure / code. Procedure / targetSiteCode **SHALL NOT** conflict with the site inherent in Procedure / code (CONF-436)
4. **MAY** satisfy: has one or more Procedure / specimen, reflecting specimens that were obtained as part of the procedure. (CONF-443)
5. specimen / specimenRole / id **SHOULD** be set to equal an Organizer / specimen / specimenRole / id to indicate that the Procedure and the Results are referring to the same specimen. (CONF-444)

Procedure Activity Procedure example

```
<?xml version="1.0" encoding="UTF-8"?>
<procedure xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <templateId root="2.16.840.1.113883.10.20.1.29"/>
  <id root="892976096"/>
  <code code="1732325389"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
</procedure>
```

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** contain exactly one [1..1] **`@classCode`**`="ACT"` *Act* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF-21)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF-22)
3. **SHALL** contain exactly one [1..1] **`code/@code`**`="23745001"` *Documentation procedure* (CodeSystem: `2.16.840.1.113883.6.96 SNOMEDCT`) (CONF-25)

4. **SHALL** contain exactly one [1..1] **`statusCode/@code`**`="completed"` (CodeSystem: `2.16.840.1.113883.5.14 HL7ActStatus`) (CONF-23, CONF-24)
5. **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)`
6. 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.oclIsUndefined() and entryRelationship.encounter.oclIsUndefined() and entryRelationship.observation.oclIsUndefined() and entryRelationship.procedure.oclIsUndefined() and entryRelationship.substanceAdministration.oclIsUndefined() and entryRelationship.supply.oclIsUndefined()))`

Purpose Activity example

```
<?xml version="1.0" encoding="UTF-8"?>
<act xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-
org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd" classCode="ACT"
 moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.1.30"/>
  <id root="1631222254"/>
  <code code="23745001" codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMEDCT" displayName="Documentation procedure"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
</act>
```

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** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF-283)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF-284)
3. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF-348, CONF-288), such that
   a. Contains **`@typeCode="`**`SUBJ"` *SUBJ (has subject)*
   b. Contains exactly one [1..1] *Severity Observation* (templateId: `2.16.840.1.113883.10.20.1.55`)
4. **SHALL** contain exactly one [1..1] **`statusCode/@code`**`="completed"` (CodeSystem: `2.16.840.1.113883.5.14 HL7ActStatus`) (CONF-285, CONF-286)
5. A reaction observation **MAY** contain one or more reation interventions. (CONF-280)

6. 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)
   - `[OCL]: self.getEntryRelationshipTargets(vocab::x_ActRelationshipEntryRelationship::RSON, cda::ClinicalStatement)->exists(entry : cda::ClinicalStatement | entry.oclIsKindOf(ccd::ProcedureActivity) or entry.oclIsKindOf(ccd::MedicationActivity))`
7. 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)
   - `[OCL]: self.getEntryRelationshipTargets(vocab::x_ActRelationshipEntryRelationship::RSON, cda::ClinicalStatement)->exists(entry : cda::ClinicalStatement | entry.oclIsKindOf(ccd::ProcedureActivity) or entry.oclIsKindOf(ccd::MedicationActivity))`

Reaction Observation example

```
<?xml version="1.0" encoding="UTF-8"?>
<observation xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.1.54"/>
  <id root="235881650"/>
  <code code="1295842240"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.1.55"/>
      <id root="1791544194"/>
      <code code="SEV" codeSystem="2.16.840.1.113883.5.4"
 codeSystemName="ActCode" displayName="Severity observation"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2011"/>
        <high value="2011"/>
      </effectiveTime>
    </observation>
  </entryRelationship>
</observation>
```

Result Observation

[Observation: templateId `2.16.840.1.113883.10.20.1.31`]

1. Contains exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF-408)
3. **SHALL** contain at least one [1..*] **`id`** (CONF-409)
4. **SHOULD** contain exactly one [1..1] **`effectiveTime`** (CONF-411)
   - Represents the biologically relevant time (e.g. time the specimen was obtained from the patient).
5. **SHALL** contain exactly one [1..1] **`statusCode`** (CONF-410)
6. **SHALL** contain exactly one [1..1] **`code`** (CONF-412)
7. **MAY** contain zero or one [0..1] **`methodCode`** (CONF-414)

- Included if the method isn't inherent in code or if there is a need to further specialize the method in code.

8. **SHOULD** contain zero or more [0..*] **`interpretationCode`** (CONF-418)
   - Can be used to provide a rough qualitative interpretation of the observation, such as 'N' (normal), 'L' (low), 'S' (susceptible), etc. Interpretation is generally provided for numeric results where an interpretation range has been defined, or for antimicrobial susceptibility test interpretation.
9. **SHALL** contain exactly one [1..1] **`value`** (CONF-416)
10. 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)
    - `[OCL]: self.code.codeSystem = '2.16.840.1.113883.6.1' xor self.code.codeSystem = '2.16.840.1.113883.6.96' xor self.code.codeSystem = '2.16.840.1.113883.6.12'`
11. The methodCode **SHALL NOT** conflict with the method inherent in code (CONF-415)
12. 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 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.oclIsUndefined())`
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'))
      ```

Result Observation example

```
<?xml version="1.0" encoding="UTF-8"?>
<observation xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.1.31"/>
  <id root="1003020822"/>
  <code code="1435794802"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
  <interpretationCode code="Value"/>
  <methodCode code="Value"/>
</observation>
```

Result Organizer

[Organizer: templateId `2.16.840.1.113883.10.20.1.32`]

This clinical statement identifies set of result observations. It contains information applicable to all of the contained result observations. Result type codes categorize a result into one of several commonly accepted values (e.g.,
```

"Hematology", "Chemistry", "Nuclear Medicine"). These values are often implicit in the `Organizer/code` (e.g., an `Organizer/code` of "complete blood count" implies a `ResultTypeCode` of "Hematology"). This template requires `Organizer/code` to include a `ResultTypeCode` either directly or as a translation of a code from some other code system.

1. **SHALL** contain exactly one [1..1] **`@moodCode="EVN"`** *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF-394)
2. **SHALL** contain at least one [1..*] **`component`** (CONF-405), such that
   a. Contains exactly one [1..1] *Result Observation* (templateId: `2.16.840.1.113883.10.20.1.31`)
3. **SHOULD** contain at least one [1..*] **`specimen`** (CONF-399), such that
   - Should be included if the specimen isn't inherent in code value.
4. **SHALL** contain at least one [1..*] **`id`** (CONF-395)
5. **SHALL** contain exactly one [1..1] **`code`** (CONF-397)
   a. 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)
   - `[OCL]: self.code.codeSystem = '2.16.840.1.113883.6.1' xor self.code.codeSystem = '2.16.840.1.113883.6.96' xor self.code.codeSystem = '2.16.840.1.113883.6.12' xor self.code.codeSystem = '2.16.840.1.113883.1.11.20.16'`
6. **SHALL** contain exactly one [1..1] **`statusCode`** (CONF-396)
7. The specimen element **SHALL NOT** conflict with the specimen inherent in code (CONF-400)
8. 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)
9. **SHALL** satisfy: Contains one or more component (CONF-402)
   - `[OCL]: not self.component->isEmpty()`
10. 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)
11. A result organizer component / procedure **MAY** be a reference to a procedure described in the Procedure section. (CONF-404)
12. **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)`

Result Organizer example

```
<?xml version="1.0" encoding="UTF-8"?>
<organizer xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.1.32"/>
  <id root="19380331"/>
  <code code="1171601615"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
  <component>
    <observation moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.1.31"/>
```

```
      <id root="1849825358"/>
      <code code="784448220"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2011"/>
        <high value="2011"/>
      </effectiveTime>
    </observation>
  </component>
</organizer>
```

Severity Observation

[Observation: templateId `2.16.840.1.113883.10.20.1.55`]

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF-289)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF-290)
3. **SHALL** contain exactly one [1..1] **`code/@code`**`="SEV"` *Severity observation* (CodeSystem: `2.16.840.1.113883.5.4 HL7ActCode`) (CONF-293, CONF-294)
4. **SHALL** contain exactly one [1..1] **`statusCode/@code`**`="completed"` (CodeSystem: `2.16.840.1.113883.5.14 HL7ActStatus`) (CONF-291, CONF-292)
5. **SHALL** contain exactly one [1..1] **`value`** (CONF-295)

Severity Observation example

```
<?xml version="1.0" encoding="UTF-8"?>
<observation xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.1.55"/>
  <id root="419897184"/>
  <code code="SEV" codeSystem="2.16.840.1.113883.5.4" codeSystemName="ActCode"
 displayName="Severity observation"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
</observation>
```

Social History Observation

[Observation: templateId `2.16.840.1.113883.10.20.1.33`]

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)
3. **SHALL** contain at least one [1..*] **`id`**
4. **SHALL** contain exactly one [1..1] **`statusCode/@code`**`="completed"` (CodeSystem: `2.16.840.1.113883.5.14 HL7ActStatus`)
5. **MAY** contain zero or one [0..1] **`entryRelationship`**, such that
   a. Contains exactly one [1..1] *Social History Status Observation* (templateId: `2.16.840.1.113883.10.20.1.56`)
6. **MAY** contain zero or one [0..1] **`entryRelationship`**, such that

   a. Contains exactly one [1..1] *Episode Observation* (templateId: `2.16.840.1.113883.10.20.1.41`)
7. The value for Observation / code in a social history observation **SHOULD** be selected from LOINC (codeSystem 2.16.840.1.113883.6.1) or SNOMED CT (codeSystem 2.16.840.1.113883.6.96), or **MAY** be selected from ValueSet 2.16.840.1.113883.1.11.20.18 SocialHistoryTypeCode STATIC 20061017
8. Observation / value can be any datatype. Where Observation / value is a physical quantity, the unit of measure **SHALL** be expressed using a valid Unified Code for Units of Measure (UCUM) expression
9. **SHALL** satisfy: Contains one or more sources of information

Social History Observation example

```
<?xml version="1.0" encoding="UTF-8"?>
<observation xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <templateId root="2.16.840.1.113883.10.20.1.33"/>
  <id root="1548090314"/>
  <code code="1875043274"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
</observation>
```

Social History Status Observation

[Observation: templateId `2.16.840.1.113883.10.20.1.56`]

1. **SHALL** conform to *Status Observation* template (templateId: `2.16.840.1.113883.10.20.1.57`)
2. **SHALL** contain exactly one [1..1] **`value`** (CodeSystem: `2.16.840.1.113883.1.11.20.17 SocialHistoryStatusCode`) (CONF-516)

Social History Status Observation example

Status Observation

[Observation: templateId `2.16.840.1.113883.10.20.1.57`]

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF-510)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF-511)
3. **SHALL** contain exactly one [1..1] **`code/@code`**`="33999-4"` *Status* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`) (CONF-512, CONF-513)
4. **SHALL** contain exactly one [1..1] **`statusCode/@code`**`="completed"` (CodeSystem: `2.16.840.1.113883.5.14 HL7ActStatus`) (CONF-514, CONF-515)
5. **SHALL** contain exactly one [1..1] **`value`**, where its data type is CE (CONF-516)
6. Target of an entryRelationship whose value for "entryRelationship / @typeCode" **SHALL** be "REFR" 2.16.840.1.113883.5.1002 ActRelationshipType STATIC. (CONF-509)
   - `[OCL]: self.entryRelationship->exists(entry : cda::EntryRelationship | entry.typeCode = vocab::x_ActRelationshipEntryRelationship::REFR)`
7. **SHALL NOT** contain any additional Observation attributes. (CONF-517)
8. **SHALL NOT** contain any Observation participants. (CONF-518)
   - `[OCL]: self.participant->isEmpty()`
9. **SHALL NOT** be the source of any Observation relationships. (CONF-519)

Status Observation example

```
<?xml version="1.0" encoding="UTF-8"?>
<observation xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.1.57"/>
  <id root="1124854514"/>
  <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="Status"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
</observation>
```

Supply Activity

[Supply: templateId `2.16.840.1.113883.10.20.1.34`]

a supply activity is used to describe what has been dispensed.

1. **SHALL** contain at least one [1..*] **`id`** (CONF-318)
2. **SHOULD** contain exactly one [1..1] **`statusCode`** (CONF-319)
3. **MAY** contain exactly one [1..1] **`entryRelationship`** (CONF-351), such that
   a. Contains exactly one [1..1] *Medication Status Observation* (templateId: `2.16.840.1.113883.10.20.1.47`)
4. **MAY** contain at least one [1..*] **`entryRelationship`** (CONF-334, CONF-337), such that
   a. Contains **`@typeCode="`**`SUBJ"` *SUBJ (has subject)*
   b. Contains exactly one [1..1] *Fulfillment Instruction* (templateId: `2.16.840.1.113883.10.20.1.43`)
5. **SHOULD** contain exactly one [1..1] **`effectiveTime`** (CONF-320)
   - Indicates the actual or intended time of dispensing.
6. **MAY** contain exactly one [1..1] **`quantity`** (CONF-322)
   - Indicates the actual or intended supply quantity.
7. **MAY** contain exactly one [1..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").
8. **MAY** contain at least one [1..*] **`participant`** (CONF-369), such that
   a. Contains exactly one [1..1] *Product Instance* (templateId: `2.16.840.1.113883.10.20.1.52`)
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)

- Iindicates 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(cda::Product)`
15. Supply / participant / participantRole / id **SHOULD** be set to equal a [Act | Observation | Procedure] / participant / participantRole / id to indicate that the Supply and the Procedure are referring to the same product instance.

Supply Activity example

```
<?xml version="1.0" encoding="UTF-8"?>
<supply xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-
org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <templateId root="2.16.840.1.113883.10.20.1.34"/>
  <id root="598950337"/>
  <statusCode code="completed"/>
  <effectiveTime value="20110830"/>
  <repeatNumber/>
  <quantity/>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.1.57"/>
      <templateId root="2.16.840.1.113883.10.20.1.47"/>
      <id root="1740535824"/>
      <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="Status"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2011"/>
        <high value="2011"/>
      </effectiveTime>
      <repeatNumber/>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <act/>
  </entryRelationship>
</supply>
```

Vital Signs Organizer

[Organizer: templateId `2.16.840.1.113883.10.20.1.35`]

1. **SHALL** conform to *Result Organizer* template (templateId: `2.16.840.1.113883.10.20.1.32`) (CONF-386)
2. **SHALL** satisfy: Contains one or more sources of information. (CONF-387)
    - A vital signs organizer SHALL contain one or more sources of information, as defined in section ***Source***.
    - `[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)
```

Vital Signs Organizer example

```
<?xml version="1.0" encoding="UTF-8"?>
<organizer xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.1.32"/>
  <templateId root="2.16.840.1.113883.10.20.1.35"/>
  <id root="233902799"/>
  <code code="2136000344"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
</organizer>
```

Chapter 5

OTHER CLASSES

Topics:

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

Advance Directive Reference

[ExternalDocument: templateId `2.16.840.1.113883.10.20.1.36`]

1. **SHALL** contain at least one [1..*] **`id`**
2. An advance directive reference (templateId 2.16.840.1.113883.10.20.1.36) **SHALL** be represented with Observation / reference / ExternalDocument
3. The value for Observation / reference / @typeCode in an advance directive reference **SHALL** be 'REFR' 2.16.840.1.113883.5.1002 ActRelationshipType STATIC.
4. The URL of a referenced advance directive document **MAY** be present, and **SHALL** be represented in Observation / reference / ExternalDocument / text / reference. A <linkHTML> element containing the same URL **SHOULD** be present in the associated CDA Narrative Block
5. The MIME type of a referenced advance directive document **MAY** be present, and **SHALL** be represented in Observation / reference / ExternalDocument / text / @mediaType
6. Where the value of Observation / reference / seperatableInd is "false", the referenced advance directive document **SHOULD** be included in the CCD exchange package. The exchange mechanism **SHOULD** be based on Internet standard RFC 2557 "MIME Encapsulation of Aggregate Documents, such as HTML (MHTML)" (http://www.ietf.org/rfc/rfc2557.txt)

Advance Directive Reference example

Advance Directive Verification

[Participant2: templateId `2.16.840.1.113883.10.20.1.58`]

1. **SHALL** contain exactly one [1..1] **`@typeCode`**`="VRF"`
2. **SHOULD** contain exactly one [1..1] **`time`**

Advance Directive Verification example

```
<?xml version="1.0" encoding="UTF-8"?>
<participant2 xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 typeCode="VRF">
  <templateId root="2.16.840.1.113883.10.20.1.58"/>
  <time>
    <low value="2011"/>
    <high value="2011"/>
  </time>
  <participantRole/>
</participant2>
```

Covered Party

[ParticipantRole: templateId `null`]

1. **SHOULD** contain at least one [1..*] **`id`** (CONF-59)
2. **SHOULD** contain exactly one [1..1] **`code`** (CONF-60)

Covered Party example

```
<?xml version="1.0" encoding="UTF-8"?>
<participantrole xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <id root="1889606874"/>
  <code code="Value"/>
</participantrole>
```

Encounter Location

[Participant2: templateId `2.16.840.1.113883.10.20.1.45`]

1. **SHALL** contain exactly one [1..1] **`@typeCode`**`="LOC"` (CONF-473)
   a. **SHALL** satisfy: contains exactly one participant / participantRole (CONF-474)
      - `[OCL]: self.participantRole->size() = 1`

   a. The value for participant/participantRole/@classCode in a location participation **SHALL** be "SDLOC" "Service delivery location" 2.16.840.1.113883.5.110 RoleClass. (CONF-475)
      - `[OCL]: self.participantRole.classCode =  vocab::RoleClassRoot::SDLOC`

   a. Participant / participantRole in a location participation **MAY** contain exactly one participant / participantRole / code. (CONF-476)
      - `[OCL]: self.participantRole.code->size() = 1`

   a. The value for participant/participantRole/code in a location participation **SHOULD** be selected from ValueSet 2.16.840.1.113883.1.11.17660 ServiceDeliveryLocationRoleType 2.16.840.1.113883.5.111 RoleCode DYNAMIC. (CONF-477)
      - `[OCL]: self.participantRole.code.codeSystem = '2.16.840.1.113883.1.11.17660'`

   a. Participant / participantRole in a location participation **MAY** contain exactly one participant / participantRole / playingEntity (CONF-478)
      - `[OCL]: self.participantRole.playingEntity->size()>0`

   a. The value for participant/participantRole/playingEntity/@classCode in a location participation **SHALL** be "PLC" "Place" 2.16.840.1.113883.5.41 EntityClass. (CONF-479)
      - `[OCL]: self.participantRole.playingEntity.classCode = vocab::EntityClassRoot::PLC`

Encounter Location example

```
<?xml version="1.0" encoding="UTF-8"?>
<participant2 xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 typeCode="LOC">
  <templateId root="2.16.840.1.113883.10.20.1.45"/>
  <time>
    <low value="2011"/>
    <high value="2011"/>
  </time>
  <participantRole/>
</participant2>
```

Patient Awareness

[Participant2: templateId `2.16.840.1.113883.10.20.1.48`]

1. **SHALL** contain exactly one [1..1] **`@typeCode`**`="SBJ"` (CONF-181)
2. **SHALL** contain exactly one [1..1] **`awarenessCode`** (CONF-182)
3. 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.oclIsUndefined())
-- TODO compare with ClinicalDocument/recordTarget/patientRole/id
```

Patient Awareness example

```
<?xml version="1.0" encoding="UTF-8"?>
<participant2 xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 typeCode="SBJ">
  <templateId root="2.16.840.1.113883.10.20.1.48"/>
  <time>
    <low value="2011"/>
    <high value="2011"/>
  </time>
  <awarenessCode code="Value"/>
  <participantRole/>
</participant2>
```

Payer Entity

[AssignedEntity: templateId `null`]

1. **SHALL** contain at least one [1..*] **`id`** (CONF-57)

Payer Entity example

```
<?xml version="1.0" encoding="UTF-8"?>
<assignedentity xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <id root="1322308198"/>
</assignedentity>
```

Plan Of Care Activity

1.

Plan Of Care Activity example

```
Unable to create XML Snippet
```

Policy Subscriber

[ParticipantRole: templateId `null`]

1. **SHOULD** contain zero or more [0..*] **`id`** (CONF-64)

Policy Subscriber example

```
<?xml version="1.0" encoding="UTF-8"?>
<participantrole xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <id root="492130400"/>
</participantrole>
```

Procedure Activity

[ClinicalStatement: templateId `null`]

1. **SHALL** contain exactly one [1..1] **`code`**, where its data type is CD (CONF-433)
2. **SHOULD** contain exactly one [1..1] **`effectiveTime`**, where its data type is IVL_TS (CONF-432)
3. **SHALL** contain at least one [1..*] **`id`**, where its data type is II (CONF-429)
4. **SHALL** contain exactly one [1..1] **`moodCode`***Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`), where its data type is ActMood (CONF-428)
5. **SHALL** contain exactly one [1..1] **`statusCode`**, which **SHALL** be selected from ValueSet `2.16.840.1.113883.1.11.20.15 ProcedureStatusCode` **STATIC** 20061017, where its data type is CS
6. **MAY** contain at least one [1..*] **`encounterLocation`**, where its type is *Encounter Location* (CONF-437)
   a. Contains exactly one [1..1] *Encounter Location* (templateId: `2.16.840.1.113883.10.20.1.45`)
7. **MAY** contain at least one [1..*] **`patientInstruction`**, where its type is *Patient Instruction* (CONF-441, CONF-333)
   a. Contains **`@typeCode="`**`SUBJ"` *SUBJ (has subject)*
   b. Contains exactly one [1..1] *Patient Instruction* (templateId: `2.16.840.1.113883.10.20.1.49`)
8. **MAY** contain zero or one [0..1] **`ageObservation`**, where its type is *Age Observation* (CONF-445)
   a. Contains **`@typeCode="`**`SUBJ"` *SUBJ (has subject)*
   b. Contains exactly one [1..1] *Age Observation* (templateId: `2.16.840.1.113883.10.20.1.38`)
9. **MAY** contain at least one [1..*] **`medicationActivity`**, where its type is *Medication Activity* (CONF-446)
   a. Contains **`@typeCode="`**`COMP"` *COMP (has component)*
   b. Contains exactly one [1..1] *Medication Activity* (templateId: `2.16.840.1.113883.10.20.1.24`)
10. The value for code in a procedure activity **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), ICD9 Procedures (codeSystem 2.16.840.1.113883.6.104), ICD10 Procedure Coding System (codeSystem 2.16.840.1.113883.6.4). (CONF-434)
11. **MAY** satisfy: contain one or more performer, to represent those practioners who performed the procedure. (CONF-438)
12. **MAY** satisfy: A procedure activity contains one or more entryRelationship / @typeCode="RSON", the target of which represents the indication or reason for the procedure. (CONF-439)
13. entryRelationship / @typeCode="RSON" in a procedure activity **SHALL** have a target of problem act (templateId 2.16.840.1.113883.10.20.1.27), problem observation (templateId 2.16.840.1.113883.10.20.1.28), or some other clinical statement. (CONF-440)
14. **MAY** satisfy: have one or more associated consents, represented in the CCD Header as ClinicalDocument / authorization / consent (CONF-442)
15. **SHALL** satisfy: contains one or more sources of information (CONF-447)
16. **MAY** satisfy: have one or more participant [@typeCode="DEV"], the target of which is a product instance template (templateID: 2.16.840.1.113883.10.20.1.52) (CONF-448)
17. participant / participantRole / id **SHOULD** be set to equal a Supply / participant / participantRole / id to indicate that the Procedure and the Supply are referring to the same product instance. (CONF-452)

Procedure Activity example

```
Unable to create XML Snippet
```

Product

[ManufacturedProduct: templateId `2.16.840.1.113883.10.20.1.53`]

1. **MAY** contain at least one [1..*] **`id`** (CONF-366)
   - uniquely represents a particular kind of product
2. **SHALL** satisfy: Contain exactly one manufacturedMaterial. (CONF-357)
   - `[OCL]: not self.manufacturedMaterial.oclIsUndefined()`

3. **SHALL** satisfy: Contain exactly one manufacturedMaterial / code. (CONF-358)
   - `[OCL]: not self.manufacturedMaterial.code.oclIsUndefined()`
4. 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)
   - `[OCL]: self.manufacturedMaterial.code.codeSystem = '2.16.840.1.113883.6.88' or self.manufacturedMaterial.code.codeSystem='2.16.840.1.113883.6.59' or self.manufacturedMaterial.code.codeSystem='2.16.840.1.113883.1.11.20.8'`
5. 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. 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. 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.oclIsUndefined()`
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.oclIsUndefined()`
10. **MAY** satisfy: contains exactly one manufacturedProduct / manufacturerOrganization, which represents the manufacturer of the Material. (CONF-365)
    - `[OCL]: self.manufacturerOrganization->size() = 1`
11. If ManufacturedProduct in a product template contains manufacturedProduct / id, then ManufacturedProduct **SHOULD** also contain manufacturedProduct / manufacturerOrganization. (CONF-367)
    - `[OCL]: self.id->size() > 0 implies self.manufacturerOrganization->size() > 0`

Product example

```
<?xml version="1.0" encoding="UTF-8"?>
<manufacturedproduct xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <templateId root="2.16.840.1.113883.10.20.1.53"/>
  <id root="1147321591"/>
</manufacturedproduct>
```

Product Instance

[ParticipantRole: templateId `2.16.840.1.113883.10.20.1.52`]

identifes a particular product instance

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="MANU"`
2. If participantRole in a product instance contains participantRole / id, then participantRole **SHOULD** also contain participantRole / scopingEntity. (CONF-451)
   - `[OCL]: self.id->size() > 0 implies self.scopingEntity->size() > 0`

Product Instance example

```
<?xml version="1.0" encoding="UTF-8"?>
```

```
<participantrole xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 classCode="MANU">
  <templateId root="2.16.840.1.113883.10.20.1.52"/>
  <id root="842680767"/>
</participantrole>
```

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.

Support example

Support Guardian

[Guardian: templateId `null`]

1. **SHALL** conform to *Support*

Support Guardian example

Support Participant

[Participant1: templateId `null`]

1. **SHALL** conform to *Support*

Support Participant example

Chapter 6

VALUE SETS

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

REFERENCES

- HL7 Implementation Guide: CDA Release 2 – Continuity of Care Document (CCD) A CDA implementation of ASTM E2369-05 Standard Specification for Continuity of Care Record© (CCR) April 01, 2007 available through *HL7* .
- HL7 Implementation Guide for CDA Release 2 Quality Reporting Document Architecture (QRDA) Draft Standard for Trial Use March 2009. Available at: *Quality Reporting Document Architecture (QRDA)*
- HL7 Implementation Guide for CDA Release 2 CDA for Public Health Case Reports (PHCR) Informative Standard October 2009. Available through *HL7* .
- HL7 Implementation Guide for CDA Release 2: NHSN Healthcare Associated Infection (HAI) Reports, Release 2 Draft Standard for Trial Use January 2009 Available at: *NHSN Healthcare Associated Infection (HAI) Reports*
- Dolin RH, Alschuler L, Boyer S, Beebe C, Behlen FM, Biron PV, Shabo A, (Editors). HL7 Clinical Document Architecture, Release 2.0. ANSI-approved HL7 Standard; May 2005. Ann Arbor, Mich.: Health Level Seven, Inc. Available through *HL7* or if an HL7 member with the following link: *CDA Release 2 Normative Web Edition.*
- *LOINC®* : Logical Observation Identifiers Names and Codes, Regenstrief Institute.
- *SNOMED CT®* : SNOMED Clinical Terms SNOMED International Organization.
- Extensible Markup Language, *www.w3.org/XML* .
- Dolin RH, Alschuler L, Boyer S, Beebe C, Behlen FM, Biron PV, Shabo A., HL7 Clinical Document Architecture, Release 2. J Am Med Inform Assoc. 2006;13:30-39. Available at: *http://www.jamia.org/cgi/reprint/13/1/30* .
- Using SNOMED CT in HL7 Version 3; Implementation Guide, Release 1.5. Available through *HL7* or if an HL7 member with the following link: *Using SNOMED CT in HL7 Version 3*