# Implementation Guide for CDA Release 2
# CDA IG Consolidation
## Working Group Draft

## PROTOTYPE: FOR DISCUSSION AND DEMONSTRATION USE ONLY

# Contents

# Acknowledgments

This document contains an example of healthcare standards and specifications publication generated from UML models, using the OHT Model Driven Health Tools (MDHT). Some portions of this document may not be publicly available but are included for demonstration purposes only, therefore this version of the document is to be treated as CONFIDENTIAL by the project participants.

This demonstration document contains informtion from the following sources:

# Chapter 1

# DOCUMENT TEMPLATES

**Topics:**



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

## General Header Constraints

**General Header Constraints example**

# Chapter 2

# SECTION TEMPLATES

**Topics:**

## Diagnostic Results Section

[Section: templateId `2.16.840.1.113883.3.88.11.83.122`]

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.

The results section shall contain a narrative description of the relevant diagnostic procedures the patient received in the past. It shall include entries for procedures and references to procedure reports when known as described in the Entry Content Modules.

The Diagnostic Results Section contains information about the results from diagnostic procedures the patient received.

1. **SHALL** contain exactly one [1..1] **`code/@code`**`="30954-2"` *STUDIES SUMMARY* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`)
2. **SHOULD** contain at least one [1..*] **`entry`**, such that it
   a. **SHALL** contain *Result Organizer* (templateId: `2.16.840.1.113883.10.20.1.32`) (CONF-388)
3. **SHOULD** contain at least one [1..*] **`entry`**, such that it
   a. **SHALL** contain *External Reference* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.4`)
4. Contains at least one [1..*] **`entry`**, such that it
   a. **SHALL** contain *Result* (templateId: `2.16.840.1.113883.3.88.11.83.15`)
5. **SHOULD** satisfy: Contains a case-insensitive language-insensitive string containing 'results'. (CONF-392)

**Diagnostic Results Section example**

```
<?xml version="1.0" encoding="UTF-8"?>
<section xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-
org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <templateId root="2.16.840.1.113883.3.88.11.83.122"/>
  <id root="fb01dfca-45b1-49bc-a3eb-05ac070ae7a3"/>
  <code code="30954-2" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="STUDIES SUMMARY"/>
  <title>STUDIES SUMMARY</title>
  <entry>
    <organizer moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.1.32"/>
      <id root="db220c31-8eda-4be5-add6-62196a918dcb"/>
      <effectiveTime>
        <low value="2011"/>
        <high value="2011"/>
      </effectiveTime>
      <component>
        <observation moodCode="EVN">
          <templateId root="2.16.840.1.113883.3.88.11.83.15"/>
          <id root="a4c4e5cf-f035-42cc-9deb-09a0af00627f"/>
```

```
          <effectiveTime>
            <low value="2011"/>
            <high value="2011"/>
          </effectiveTime>
        </observation>
      </component>
    </organizer>
  </entry>
  <entry>
    <act classCode="ACT" moodCode="EVN">
      <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.4"/>
      <id root="ee89916e-8d07-4a16-a60e-eff642edea41"/>
      <effectiveTime>
        <low value="2011"/>
        <high value="2011"/>
      </effectiveTime>
    </act>
  </entry>
  <entry>
    <observation moodCode="EVN">
      <templateId root="2.16.840.1.113883.3.88.11.83.15"/>
      <id root="23cc3842-bde4-4174-8a3b-a8954861ffd7"/>
      <effectiveTime>
        <low value="2011"/>
        <high value="2011"/>
      </effectiveTime>
    </observation>
  </entry>
</section>
```

## Problem List Section

[Section: templateId `2.16.840.1.113883.3.88.11.83.103`]

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

The active problem section shall contain a narrative description of the conditions currently being monitored for the patient. It shall include entries for patient conditions as described in the Entry Content Module.

The Problem List Section contains data on the problems currently being monitored for the patient.

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)
3. **SHALL** contain exactly one [1..1] **`text`** (CONF-140)
4. Contains at least one [1..*] **`entry`**, such that it
   a. **SHALL** contain *Condition* (templateId: `2.16.840.1.113883.3.88.11.83.7`)
5. **SHOULD** contain a case-insensitive language-insensitive string containing 'problems'. (CONF-144)

**Problem List Section example**

```
<?xml version="1.0" encoding="UTF-8"?>
<section xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-
org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <templateId root="2.16.840.1.113883.3.88.11.83.103"/>
  <id root="e7d1ad2b-daf2-4284-b167-d7d8fa6d280f"/>
  <code code="11450-4" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="Problem list"/>
  <title>Problem list</title>
  <entry>
    <act classCode="ACT" moodCode="EVN">
      <templateId root="2.16.840.1.113883.3.88.11.83.7"/>
```

```
      <id root="6fd90641-9bfa-4b92-a2ef-184b41084e5e"/>
      <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="6d474139-0f28-40d7-9661-7317b707767e"/>
          <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"
codeSystemName="HL7ActCode"/>
          <statusCode code="completed"/>
          <effectiveTime>
            <low value="2011"/>
            <high value="2011"/>
          </effectiveTime>
        </observation>
      </entryRelationship>
      <entryRelationship>
        <observation classCode="OBS" moodCode="EVN">
          <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.5"/>
          <id root="60685fa0-e47c-49d3-84ee-f9ccf472fbad"/>
          <code codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMEDCT"/
>
          <statusCode code="completed"/>
          <effectiveTime>
            <low value="2011"/>
            <high value="2011"/>
          </effectiveTime>
          <entryRelationship>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.38"/>
              <id root="dd3fa555-b011-420e-a3dd-75bdeecdcc83"/>
              <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>
          </entryRelationship>
          <entryRelationship>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.1"/>
              <id root="4fb440a4-ff11-4fac-a2ab-a37e09e96248"/>
              <code code="SEV" codeSystem="2.16.840.1.113883.5.4"
codeSystemName="HL7ActCode" displayName="Severity observation"/>
              <statusCode code="completed"/>
              <effectiveTime>
                <low value="2011"/>
                <high value="2011"/>
              </effectiveTime>
            </observation>
          </entryRelationship>
          <entryRelationship>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.57"/>
              <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.1.1"/>
              <id root="13e7bb7a-14a2-48ec-8967-8a676d70bd87"/>
              <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 classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.57"/>
              <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.1.2"/>
              <id root="81129ab5-489a-4646-b2f9-34d40d5e210b"/>
              <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>
          </entryRelationship>
          <entryRelationship>
            <act classCode="ACT" moodCode="EVN">
              <templateId root="2.16.840.1.113883.3.88.11.83.11"/>
              <id root="cd4afe2f-3968-49c1-ba5d-9c9991d6ede7"/>
              <code code="48767-8" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Annotation comment"/>
              <statusCode code="completed"/>
              <effectiveTime>
                <low value="2011"/>
                <high value="2011"/>
              </effectiveTime>
            </act>
          </entryRelationship>
        </observation>
      </entryRelationship>
    </act>
  </entry>
</section>
```

## Vital Signs Section

[Section: templateId `2.16.840.1.113883.3.88.11.83.119`]

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.

The vital signs section shall contain a narrative description of the measurement results of a patient's vital signs.

The vital signs section contains coded measurement results of a patient's vital signs.

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

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. **SHALL** contain exactly one [1..1] **`text`** (CONF-381)
4. **SHALL** contain at least one [1..*] **`entry`**, such that it

   a. **SHALL** contain *Vital Signs Organizer* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.13.1`) (6.3.3.4.5)
5. **SHOULD** satisfy: title Contains a case-insensitive language-insensitive string containing 'vital signs'. (CONF-385)
6. **SHALL** satisfy: Contains entries conforming to the Vital Sign module. (C83-[CT-119-2])

**Vital Signs Section example**

```
<?xml version="1.0" encoding="UTF-8"?>
<section xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-
org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <templateId root="2.16.840.1.113883.3.88.11.83.119"/>
  <id root="c051e143-ff79-42de-8044-f18a86a8e5cd"/>
  <code code="8716-3" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="Vital signs"/>
  <title>Vital signs</title>
  <entry>
    <organizer classCode="CLUSTER" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.1.32"/>
      <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.13.1"/>
      <id root="ad961b7c-c3d9-4e39-abc2-b931889505c1"/>
      <code code="46680005" codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMEDCT" displayName="Vital signs"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2011"/>
        <high value="2011"/>
      </effectiveTime>
      <component>
        <observation moodCode="EVN">
          <templateId root="2.16.840.1.113883.3.88.11.83.15"/>
          <id root="293495f9-97b5-454e-b08c-024d16803748"/>
          <effectiveTime>
            <low value="2011"/>
            <high value="2011"/>
          </effectiveTime>
        </observation>
      </component>
      <component>
        <observation moodCode="EVN">
          <templateId root="2.16.840.1.113883.3.88.11.83.15"/>
          <templateId root="2.16.840.1.113883.3.88.11.83.14"/>
          <id root="08c9a9ec-4648-49ca-90e9-25bc0795dfc6"/>
          <code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
          <effectiveTime>
            <low value="2011"/>
            <high value="2011"/>
          </effectiveTime>
        </observation>
      </component>
    </organizer>
  </entry>
</section>
```

# Chapter 3

# 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.

## 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.
6. **SHOULD** satisfy: subject/relatedSubject/subject contains exactly one birthTime (CONF-219)
7. **MAY** satisfy: subject/relatedSubject/subject contains exactly one sdtc:deceasedInd (CONF-220)
8. **MAY** satisfy: subject/relatedSubject/subject contains exactly one sdtc:deceasedTime (CONF-221)
9. **SHOULD** satisfy: The age of a relative at the time of observation is inferred by comparing subject/relatedSubject/subject/birthTime with effectiveTime (CONF-222)
10. **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. (CONF-223)

**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="2f4e327e-a6c5-4250-9338-2b7add9e7f28"/>
  <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>
```

## Comment

[Act: templateId `2.16.840.1.113883.3.88.11.83.11`]

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

This entry allows for a comment to be supplied with each entry. For CDA this structure is usually included in the target act using the <entryRelationship> element defined in the CDA Schema, but can also be used in the <component> element when the comment appears within an <organizer>.

Any condition or allergy may be the subject of a comment.

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

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)
4. **SHALL** contain exactly one [1..1] **`text`**
5. **SHALL** contain exactly one [1..1] **`statusCode/@code`**`="completed"` (CodeSystem: `2.16.840.1.113883.5.14 HL7ActStatus`) (CONF-6.3.4.6.8)
6. **MAY** contain zero or one [0..1] **`author`**, such that it
   a. **SHALL** contain CDA Author
7. Contains exactly one [1..1] **`author`**, such that it
   a. **SHALL** contain CDA Author
8. **SHALL** satisfy: A related statement is made about another section or entry. In CDA the former shall be recorded inside an <entryRelationship> element occurring at the end of the entry. The containing entry is the subject (typeCode='SUBJ') of this comment, which is the inverse of the normal containment structure, thus inversionInd='true'. (CONF-6.3.4.6.3)
9. **SHALL** satisfy: The 'text' element contains a 'reference' element pointing to the narrative text section of the CDA, rather than duplicate text to avoid ambiguity. (CONF-6.3.4.6.7)
10. **SHALL** satisfy: The time of the comment creation is recorded in the 'time' element when the 'author' element is present. (CONF-6.3.4.6.10)
11. **SHALL** satisfy: The identifier of the author, and their address and telephone number must be present inside the 'id', 'addr' and 'telecom' elements when the 'author' element is present. (CONF-6.3.4.6.11)
12. **SHALL** satisfy: The author's and/or the organization's name must be present when the 'author' element is present. (CONF-6.3.4.6.12)
13. Data elements defined elsewhere in the specification **SHALL NOT** be recorded using the Comments Module. (C83-[DE-10-CDA-1])
    - Comments are free text data that cannot otherwise be recorded using data elements already defined by this specification. They are not to be used to record information that can be recorded elsewhere. For example, a free text description of the severity of an allergic reaction would not be recorded in a comment. Instead, it would be recorded using the data element defined in Allergy/Drug Sensitivity.

**Comment example**

```
<?xml version="1.0" encoding="UTF-8"?>
<act xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-
org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd" classCode="ACT"
 moodCode="EVN">
  <templateId root="2.16.840.1.113883.3.88.11.83.11"/>
  <id root="fc3d7415-18b8-4b9c-b6a8-a12e1ceff2cd"/>
  <code code="48767-8" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="Annotation comment"/>
  <text/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
</act>
```

## Condition

[Act: templateId `2.16.840.1.113883.3.88.11.83.7`]

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).

This entry is a specialization of the Concern Entry, wherein the subject of the concern is focused on a problem.

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. **SHALL** contain exactly one [1..1] **`statusCode`**, which **SHALL** be selected from ValueSet `ConcernEntryStatus` **STATIC**
6. **SHALL** contain exactly one [1..1] **`effectiveTime`**
   - The effectiveTime element records the starting and ending times during which the concern was active.
7. **MAY** contain exactly one [1..1] **`entryRelationship`**, such that it
   a. **SHALL** contain *Episode Observation* (templateId: `2.16.840.1.113883.10.20.1.41`) (CONF-168)
8. Contains at least one [1..*] **`entryRelationship`**, such that it
   a. **SHALL** contain *Condition Entry* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.5`)
9. **SHALL** contain one or more entryRelationship (CONF-151)
10. A problem act **MAY** reference a problem observation, alert observation (see section Alerts) or other clinical statement that is the subject of concern, by setting the value for "Act / entryRelationship / @typeCode" to be "SUBJ" 2.16.840.1.113883.5.1002 ActRelationshipType STATIC. (CONF-152)
11. 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)
12. In Problem Section, a Problem Act **SHOULD** contain one or more Problem Observations. (CONF-140)
13. In Alert Section, a ProblemAct **SHOULD** contain one or more Alert Observations. (CONF-256)
14. **MAY** contain exactly one Patient Awareness (CONF-179)
15. The effectiveTime 'low' element **SHALL** be present. The 'high' element **SHALL** be present for concerns in the completed or aborted state, and **SHALL NOT** be present otherwise.
16. Each concern is about one or more related problems or allergies. This entry **SHALL** contain one or more problem or allergy entries that conform to the specification in section Problem Entry or Allergies and Intolerances. This is how a series of related observations can be grouped as a single concern. This **SHALL** be represented using entryRelationship with typeCode = 'SUBJ'.
17. Each concern **MAY** have 0 or more related references. These **MAY** be used to represent related statements such related visits. This **MAY** be any valid CDA clinical statement, and **SHOULD** be an IHE entry template. This **SHALL** be represented using entryRelationship with typeCode = 'REFR'.
18. The treating provider or providers **SHALL** be recorded in a <performer> element under the <act> that describes the condition of concern (C83-[DE-7.05-CDA-3])
19. The identifier of the treating provider **SHALL** be present in the <id> element beneath the <assignedEntity>. This identifier **SHALL** be the identifier of one of the providers listed in the healthcare providers module. (C83-[DE-7.05-CDA-2])
20. The time over which this provider treated the condition **MAY** be recorded in the <time> element beneath the <performer> element (C83-[DE-7.05-CDA-1])

**Condition example**

```
<?xml version="1.0" encoding="UTF-8"?>
<act xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-
org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd" classCode="ACT"
 moodCode="EVN">
  <templateId root="2.16.840.1.113883.3.88.11.83.7"/>
  <id root="b641bb91-8006-4296-9c3f-f828ecc5a63e"/>
  <code nullFlavor="NA"/>
  <statusCode/>
  <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="90586b0d-484e-4f89-93e4-4c0ba7142aee"/>
     <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"
codeSystemName="HL7ActCode"/>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2011"/>
       <high value="2011"/>
     </effectiveTime>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <observation classCode="OBS" moodCode="EVN">
     <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.5"/>
     <id root="79a4acb2-af74-40cf-a004-784de8b77fbd"/>
     <code codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMEDCT"/>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2011"/>
       <high value="2011"/>
     </effectiveTime>
     <entryRelationship>
       <observation classCode="OBS" moodCode="EVN">
         <templateId root="2.16.840.1.113883.10.20.1.38"/>
         <id root="27783992-5821-47f7-a2b1-27f320067e8c"/>
         <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>
     </entryRelationship>
     <entryRelationship>
       <observation classCode="OBS" moodCode="EVN">
         <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.1"/>
         <id root="2eda6985-81b8-4482-bd48-862f05c57ce9"/>
         <code code="SEV" codeSystem="2.16.840.1.113883.5.4"
codeSystemName="HL7ActCode" displayName="Severity observation"/>
         <statusCode code="completed"/>
         <effectiveTime>
           <low value="2011"/>
           <high value="2011"/>
         </effectiveTime>
       </observation>
     </entryRelationship>
     <entryRelationship>
       <observation classCode="OBS" moodCode="EVN">
         <templateId root="2.16.840.1.113883.10.20.1.57"/>
         <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.1.1"/>
         <id root="1e2a8086-6bbe-49b4-a98b-5eea8951da5d"/>
         <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 classCode="OBS" moodCode="EVN">
         <templateId root="2.16.840.1.113883.10.20.1.57"/>
```

```
          <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.1.2"/>
          <id root="5b8cbf3d-a04c-4bc8-b05c-a15445b750f3"/>
          <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>
      </entryRelationship>
      <entryRelationship>
        <act classCode="ACT" moodCode="EVN">
          <templateId root="2.16.840.1.113883.3.88.11.83.11"/>
          <id root="db447399-7cce-40a9-a20e-e0d49237b5cd"/>
          <code code="48767-8" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Annotation comment"/>
          <statusCode code="completed"/>
          <effectiveTime>
            <low value="2011"/>
            <high value="2011"/>
          </effectiveTime>
        </act>
      </entryRelationship>
    </observation>
  </entryRelationship>
</act>
```

## Condition Entry

[Observation: templateId `1.3.6.1.4.1.19376.1.5.3.1.4.5`]

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

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

1. 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 at least one [1..*] **`id`**
   - The specific observation being recorded must have an identifier (<id>) that shall be provided for tracking purposes. If the source EMR does not or cannot supply an intrinsic identifier, then a GUID shall be provided as the root, with no extension (e.g., <id root='CE1215CD-69EC-4C7B-805F-569233C5E159'/>). At least one identifier must be present, more than one may appear.
4. **SHOULD** contain exactly one [1..1] **`code`**, which **SHOULD** be selected from ValueSet `2.16.840.1.113883.3.88.12.3221.7.2 Problem Type` **STATIC** 1
5. **SHALL** contain exactly one [1..1] **`text`**

- The <text> element is required and points to the text describing the problem being recorded; including any dates, comments, et cetera. The <reference> contains a URI in value attribute. This URI points to the free text description of the problem in the document that is being described.

6. **SHALL** contain exactly one [1..1] **`statusCode/@code`**`="completed"` (CodeSystem: `2.16.840.1.113883.5.14 HL7ActStatus`) (CONF-156, CONF-157)
7. **SHOULD** contain exactly one [1..1] **`effectiveTime`**
   - The <effectiveTime> of this <observation> is the time interval over which the <observation> is known to be true. The <low> and <high> values should be no more precise than known, but as precise as possible. While CDA allows for multiple mechanisms to record this time interval (e.g., by low and high values, low and width, high and width, or center point and width), we are constraining Medical summaries to use only the low/high form. The <low> value is the earliest point for which the condition is known to have existed. The <high> value, when present, indicates the time at which the observation was no longer known to be true. Thus, the implication is made that if the <high> value is specified, that the observation was no longer seen after this time, and it thus represents the date of resolution of the problem. Similarly, the <low> value may seem to represent onset of the problem. Neither of these statements is necessarily precise, as the <low> and <high> values may represent only an approximation of the true onset and resolution (respectively) times. For example, it may be the case that onset occurred prior to the <low> value, but no observation may have been possible before that time to discern whether the condition existed prior to that time. The <low> value should normally be present. There are exceptions, such as for the case where the patient may be able to report that they had chicken pox, but are unsure when. In this case, the <effectiveTime> element shall have a <low> element with a nullFlavor attribute set to 'UNK'. The <high> value need not be present when the observation is about a state of the patient that is unlikely to change (e.g., the diagnosis of an incurable disease).
8. **SHALL** contain exactly one [1..1] **`value`**, which **SHALL** be selected from ValueSet `2.16.840.1.113883.3.88.12.3221.7.4 Problem` **STATIC** 1
9. **MAY** contain zero or one [0..1] **`entryRelationship`**, such that it
   a. **SHALL** contain **`@typeCode="`**`SUBJ"` *SUBJ (has subject)*
   b. **SHALL** contain *Age Observation* (templateId: `2.16.840.1.113883.10.20.1.38`) (CONF-160)
10. **MAY** contain zero or one [0..1] **`entryRelationship`**, such that it
    a. **SHALL** contain *Severity* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.1`)
11. **MAY** contain zero or one [0..1] **`entryRelationship`**, such that it
    a. **SHALL** contain **`@typeCode="`**`REFR"` *REFR (refers to)*
    b. **SHALL** contain *Problem Status Observation* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.1.1`)
12. **MAY** contain zero or one [0..1] **`entryRelationship`**, such that it
    a. **SHALL** contain **`@typeCode="`**`REFR"` *REFR (refers to)*
    b. **SHALL** contain *Health Status Observation* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.1.2`)
13. **MAY** contain zero or more [0..*] **`entryRelationship`**, such that it
    a. **SHALL** contain **`@typeCode="`**`SUBJ"` *SUBJ (has subject)*
    b. **SHALL** contain *Comment* (templateId: `2.16.840.1.113883.3.88.11.83.11`)
14. **SHALL** contain one or more sources of information. (CONF-161)
15. **MAY** contain exactly one Patient Awareness (CONF-180)
16. The problem name **SHALL** be recorded in the entry by recording a <reference> where the value attribute points to the narrative text containing the name of the problem.
17. If entryRelationship / Comment is present, then entryRelationship **SHALL** include inversionInd = 'true'.
18. The onset date **SHALL** be recorded in the <low> element of the <effectiveTime> element when known. (C83-[DE-7.01-1])
19. The resolution data **SHALL** be recorded in the <high> element of the <effectiveTime> element when known. (C83-[DE-7.01-2])
20. If the problem is known to be resolved, but the date of resolution is not known, then the <high> element **SHALL** be present, and the nullFlavor attribute **SHALL** be set to 'UNK'. Therefore, the existence of an <high> element within a problem does indicate that the problem has been resolved. (C83-[DE-7.01-3])

**Condition Entry example**

```
<?xml version="1.0" encoding="UTF-8"?>
<observation xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 classCode="OBS" moodCode="EVN">
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.5"/>
  <id root="281bd2cf-4dcd-4416-8a63-830c2cea40ae"/>
  <code codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMEDCT"/>
  <text/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.1.38"/>
      <id root="2fa419ca-74e3-445d-b48a-735e96511c67"/>
      <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>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.1"/>
      <id root="b06666b2-a61e-46a5-b2db-f31b1b2bcdf1"/>
      <code code="SEV" codeSystem="2.16.840.1.113883.5.4"
 codeSystemName="HL7ActCode" displayName="Severity observation"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2011"/>
        <high value="2011"/>
      </effectiveTime>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.1.57"/>
      <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.1.1"/>
      <id root="7f2941d9-e351-4689-aaa6-8062ef4f0716"/>
      <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 classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.1.57"/>
      <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.1.2"/>
      <id root="63eb15dc-0c4c-4cd6-a00d-6eeb60c6c865"/>
      <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>
  </entryRelationship>
  <entryRelationship>
    <act classCode="ACT" moodCode="EVN">
      <templateId root="2.16.840.1.113883.3.88.11.83.11"/>
      <id root="b5f56f0e-75f3-4d67-9297-e775a0003a40"/>
      <code code="48767-8" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="Annotation comment"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2011"/>
        <high value="2011"/>
      </effectiveTime>
    </act>
  </entryRelationship>
</observation>
```

## 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. **SHOULD** contain exactly one [1..1] **`code/@code="ASSERTION"`** (CodeSystem: `2.16.840.1.113883.5.4 HL7ActCode`) (CONF-174)
4. **SHALL** contain exactly one [1..1] **`statusCode/@code="completed"`** (CodeSystem: `2.16.840.1.113883.5.14 HL7ActStatus`) (CONF-172, CONF-173)
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)
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)

**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="2265b183-90ce-46cf-ba91-c2bceccaff6d"/>
  <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"
 codeSystemName="HL7ActCode"/>
  <statusCode code="completed"/>
  <effectiveTime>
```

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

## External Reference

[Act: templateId `1.3.6.1.4.1.19376.1.5.3.1.4.4`]

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. Contains exactly one [1..1] **`code`**

**External Reference 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="1.3.6.1.4.1.19376.1.5.3.1.4.4"/>
  <id root="892739c7-72cd-4386-89cc-b49cf8fc2dc3"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
</act>
```

## Health Status Observation

[Observation: templateId `1.3.6.1.4.1.19376.1.5.3.1.4.1.2`]

The health status observation records information about the current health status of the patient.

1. **SHALL** conform to *Status Observation* template (templateId: `2.16.840.1.113883.10.20.1.57`)
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 `HealthStatusValue` **STATIC**
4. **SHALL** contain exactly one [1..1] **`text`**
5. The 'text' elements **SHALL** contain a 'reference' element pointing to the narrative where the severity is recorded, rather than duplicate text to avoid ambiguity.

**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="1.3.6.1.4.1.19376.1.5.3.1.4.1.2"/>
  <id root="06b2843c-ee22-4fac-8710-eac6940429db"/>
  <code code="11323-3" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="Health status"/>
  <text/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
```

```
  </effectiveTime>
</observation>
```

## Problem Status Observation

[Observation: templateId `1.3.6.1.4.1.19376.1.5.3.1.4.1.1`]

Any problem or allergy observation may reference a problem status observation. The clinical status observation records information about the current status of the problem or allergy, for example, whether it is active, in remission, resolved, et cetera.

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 `ProblemStatusValue` **STATIC**
3. **SHALL** contain exactly one [1..1] **`text`**
4. The 'text' elements **SHALL** contain a 'reference' element pointing to the narrative where the severity is recorded, rather than duplicate text to avoid ambiguity.

**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="1.3.6.1.4.1.19376.1.5.3.1.4.1.1"/>
  <id root="b924e421-3703-4f67-9e74-b5fd395abd9a"/>
  <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="Status"/>
  <text/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
</observation>
```

## Result

[Observation: templateId `2.16.840.1.113883.3.88.11.83.15`]

The simple observation entry is meant to be an abstract representation of many of the observations used in this specification. It can be made concrete by the specification of a few additional constraints, namely the vocabulary used for codes, and the value representation. A simple observation may also inherit constraints from other specifications (e.g., ASTM/HL7 Continuity of Care Document).

This module contains current and relevant historical result observations for the patient. The scope of "observations" is broad with the exception of "vital signs" which are contained in the Vital Signs section.

1. Contains exactly one [1..1] **`@classCode`**
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. **SHALL** contain exactly one [1..1] **`code`**
5. **SHALL** contain exactly one [1..1] **`statusCode`** (CONF-410)
6. **SHALL** contain exactly one [1..1] **`effectiveTime`**
7. **SHALL** contain exactly one [1..1] **`value`**
   - The Result value records the desired result in a goal or recorded event, and will not present when recording an intent, request or proposal to measure a result.

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. **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.
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)
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)
14. **SHALL NOT** contain referenceRange / observationRange / code, as this attribute is not used by the HL7 Clinical Statement or Lab Committee models. (CONF-420)
15. **SHALL** satisfy: Contains one or more sources of information. (CONF-421)
16. Result Type **SHOULD** be selected from LOINC (codeSystem 2.16.840.1.113883.6.1) or SNOMED CT (codeSystem 2.16.840.1.113883.6.96) (C154-[DE-15.03-1])
17. Result Type for laboratory results **SHOULD** be coded as specified in HITSP/C80 Section 2.2.3.6.1 Laboratory Observations. (C154-[DE-15.03-2])
18. Result Value **SHALL** be present when the observation/@moodCode is EVN or GOL, and **SHALL NOT** be present when observation/@moodCode is INT or PRP. (C83-[DE-15.05-CDA-1])

**Result example**

```
<?xml version="1.0" encoding="UTF-8"?>
<observation xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 moodCode="EVN">
  <templateId root="2.16.840.1.113883.3.88.11.83.15"/>
  <id root="55bb9877-cf08-49e2-9717-9e64385776c3"/>
  <code/>
  <statusCode/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
  <interpretationCode/>
  <methodCode/>
</observation>
```

## Result Organizer

[Organizer: templateId `2.16.840.1.113883.10.20.1.32`]

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

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

1. Contains exactly one [1..1] **`@classCode`**
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF-394)
3. **SHALL** contain at least one [1..*] **`id`** (CONF-395)

4. **SHALL** contain exactly one [1..1] **`code`** (CONF-397)
5. **SHALL** contain exactly one [1..1] **`statusCode`** (CONF-396)
6. Contains at least one [1..*] **`component`**, such that it
   a. **SHALL** contain *Result* (templateId: `2.16.840.1.113883.3.88.11.83.15`)
7. Contains at least one [1..*] **`specimen`**, such that it
   a. **SHALL** contain CDA Specimen
8. The value for 'code' in a result organizer **SHOULD** be selected from LOINC (codeSystem 2.16.840.1.113883.6.1) or SNOMED CT (codeSystem 2.16.840.1.113883.6.96), and **MAY** be selected from CPT-4 (codeSystem 2.16.840.1.113883.6.12) or ValueSet 2.16.840.1.113883.1.11.20.16 ResultTypeCode STATIC. (CONF-398)
9. The specimen element **SHALL NOT** conflict with the specimen inherent in code (CONF-400)
10. specimen / specimenRole / id **SHOULD** be set to equal a Procedure / specimen / specimenRole / id to indicate that the Results and the Procedure are referring to the same specimen. (CONF-401)
11. **SHALL** satisfy: Contains one or more component (CONF-402)
12. The target of one or more result organizer component relationships **MAY** be a procedure, to indicate the means or technique by which a result is obtained, particularly if the means or technique isn't inherent in code or if there is a need to further specialize the code value. (CONF-403)
13. A result organizer component / procedure **MAY** be a reference to a procedure described in the Procedure section. (CONF-404)
14. **SHALL** satisfy: Contains one or more sources of information. (CONF-406)

**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="31b07c74-619f-4fe9-87c9-e94b220b9a0a"/>
  <code/>
  <statusCode/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
  <component>
    <observation moodCode="EVN">
      <templateId root="2.16.840.1.113883.3.88.11.83.15"/>
      <id root="b20e4d9f-bfb8-4b5b-a0f8-f05f789af3e7"/>
      <effectiveTime>
        <low value="2011"/>
        <high value="2011"/>
      </effectiveTime>
    </observation>
  </component>
</organizer>
```

## Severity

[Observation: templateId `1.3.6.1.4.1.19376.1.5.3.1.4.1`]

This specification models a severity observation as a separate observation from the condition. While this model is different from work presently underway by various organizations (i.e., SNOMED, HL7, TermInfo), it is not wholly incompatible with that work. In that work, qualifiers may be used to identify severity in the coded condition observation, and a separate severity observation is no longer necessary. The use of qualifiers is not precluded by this specification. However, to support semantic interoperability between EMR systems using different vocabularies, this specification does require that severity information also be provided in a separate observation. This ensures that all EMR systems have equal access to the information, regardless of the vocabularies they support.

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] **`text`**
5. **SHALL** contain exactly one [1..1] **`statusCode/@code`**`="completed"` (CodeSystem: `2.16.840.1.113883.5.14 HL7ActStatus`) (CONF-291, CONF-292)
6. **SHALL** contain exactly one [1..1] **`value`**, which **SHALL** be selected from ValueSet `SeverityObservation` **STATIC**, where its data type is CD
   - Value code representing high, moderate and low severity depending upon whether the severity is life threatening, presents noticeable adverse consequences, or is unlikely substantially effect the situation of the subject.
7. The 'text' elements **SHALL** contain a 'reference' element pointing to the narrative where the severity is recorded, rather than duplicate text to avoid ambiguity.

**Severity 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="1.3.6.1.4.1.19376.1.5.3.1.4.1"/>
  <id root="c7553946-3a9a-4334-a665-025ae51bc79e"/>
  <code code="SEV" codeSystem="2.16.840.1.113883.5.4"
 codeSystemName="HL7ActCode" displayName="Severity observation"/>
  <text/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
</observation>
```

## 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)
7. **SHALL NOT** contain any additional Observation attributes. (CONF-517)
8. **SHALL NOT** contain any Observation participants. (CONF-518)
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="336e4e24-9017-45e0-84be-465e3c580e4a"/>
  <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>
```

## Vital Sign

[Observation: templateId `2.16.840.1.113883.3.88.11.83.14`]

A vital signs observation is a simple observation that uses a specific vocabulary, and inherits constraints from CCD.

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

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

1. **SHALL** conform to *Result* template (templateId: `2.16.840.1.113883.3.88.11.83.15`)
2. **SHALL** contain exactly one [1..1] **`code`**, which **SHALL** be selected from ValueSet `2.16.840.1.113883.3.88.12.80.62 Vital Sign Result` **STATIC** 1 (C154-[DE-14.03-1])
3. **MAY** contain zero or more [0..*] **`interpretationCode`** (6.3.4.22.5)
   - The interpretation code may be present to provide an interpretation of the vital signs measure (e.g., High, Normal, Low, et cetera).
4. **MAY** contain zero or one [0..1] **`methodCode`** (6.3.4.22.6)
   - The method code element may be present to indicate the method used to obtain the measure. Note that method used is distinct from, but possibly related to the target site.
5. **MAY** contain zero or more [0..*] **`targetSiteCode`** (6.3.4.22.7)
   - The target site of the measure may be identified in the targetSiteCode element (e.g., Left arm [blood pressure], oral [temperature], et cetera).
6. **SHALL** contain exactly one [1..1] **`value`**, where its data type is PQ (6.3.4.22.4)
7. **SHALL** satisfy: Data Element Definitions for Results [Placeholder]
   - Vital Signs are a subset of Results Section, but are reported in this section to follow clinical conventions.

**Vital Sign example**

```
<?xml version="1.0" encoding="UTF-8"?>
<observation xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 moodCode="EVN">
  <templateId root="2.16.840.1.113883.3.88.11.83.15"/>
  <templateId root="2.16.840.1.113883.3.88.11.83.14"/>
  <id root="2ae892ef-9afc-45d3-99e8-bc8379a072aa"/>
  <code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
  <statusCode/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
```

```
  <interpretationCode/>
  <methodCode/>
  <targetSiteCode/>
</observation>
```

## Vital Signs Organizer

[Organizer: templateId `1.3.6.1.4.1.19376.1.5.3.1.4.13.1`]

A vital signs organizer collects vital signs observations.

1. **SHALL** conform to *Result Organizer* template (templateId: `2.16.840.1.113883.10.20.1.32`)
2. **SHALL** contain exactly one [1..1] **`@classCode`**`="CLUSTER"` (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (6.3.4.21.2)
   - The vital signs organizer is a cluster of vital signs observations.
3. **SHALL** contain exactly one [1..1] **`code/@code`**`="46680005"` *Vital signs* (CodeSystem: `2.16.840.1.113883.6.96 SNOMEDCT`) (6.3.4.21.5)
4. **SHALL** contain exactly one [1..1] **`effectiveTime`** (6.3.4.21.7)
   - The effective time element shall be present to indicate when the measurement was taken.
5. **SHALL** contain exactly one [1..1] **`statusCode/@code`**`="completed"` (CodeSystem: `2.16.840.1.113883.5.14 HL7ActStatus`) (6.3.4.21.6)
   - The observations have all been completed.
6. **SHALL** contain exactly one [1..1] **`id`** (6.3.4.21.4)
   - The organizer shall have an <id> element.
7. Contains at least one [1..*] **`component`**, such that it
   a. **SHALL** contain *Vital Sign* (templateId: `2.16.840.1.113883.3.88.11.83.14`)
8. Contains exactly one [1..1] **`author`**, such that it
   a. **SHALL** contain CDA Author
9. **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***.
10. **SHALL** satisfy: ccd::ResultOrganizer template ID (2.16.840.1.113883.10.20.1.32) is included (6.3.4.21.3)

**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"
 classCode="CLUSTER" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.1.32"/>
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.13.1"/>
  <id root="9031e2e3-55d3-4557-a3ec-0cec6a15cc0f"/>
  <code code="46680005" codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMEDCT" displayName="Vital signs"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
  <component>
    <observation moodCode="EVN">
      <templateId root="2.16.840.1.113883.3.88.11.83.15"/>
      <id root="7f82bae8-d35a-47e9-978d-4075909835b0"/>
      <effectiveTime>
        <low value="2011"/>
        <high value="2011"/>
```

```
      </effectiveTime>
    </observation>
  </component>
  <component>
    <observation moodCode="EVN">
      <templateId root="2.16.840.1.113883.3.88.11.83.15"/>
      <templateId root="2.16.840.1.113883.3.88.11.83.14"/>
      <id root="f4b19690-42c7-46aa-a8df-c4721722bb41"/>
      <code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
      <effectiveTime>
        <low value="2011"/>
        <high value="2011"/>
      </effectiveTime>
    </observation>
  </component>
</organizer>
```

# Chapter 4

# OTHER CLASSES

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

# Chapter 5

# VALUE SETS

**Topics:**



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

## Concern Entry Status

| | |
|---|---|
| Value Set | ConcernEntryStatus - (OID not specified) |
| Description | A concern in the "active" state represents one for which some ongoing clinical activity is expected, and that no activity is expected in other states. Specific uses of the suspended and aborted states are left to the implementation. |

| Concept Code | Concept Name | Code System | Description |
|---|---|---|---|
| active | | | |
| suspended | | | |
| aborted | | | |
| completed | | | |

## Health Status Value

| | |
|---|---|
| Value Set | HealthStatusValue - (OID not specified) |
| Code System | SNOMEDCT - 2.16.840.1.113883.6.96 |

| Concept Code | Concept Name | Code System | Description |
|---|---|---|---|
| 81323004 | Alive and well | SNOMEDCT | |
| 313386006 | In remission | SNOMEDCT | |
| 162467007 | Symptom free | SNOMEDCT | |
| 161901003 | Chronically ill | SNOMEDCT | |
| 271593001 | Severely ill | SNOMEDCT | |
| 21134002 | Disabled | SNOMEDCT | |
| 161045001 | Severely disabled | SNOMEDCT | |
| 419099009 | Deceased | SNOMEDCT | |

## Problem Type

| | |
|---|---|
| Value Set | Problem Type - 2.16.840.1.113883.3.88.12.3221.7.2 |
| Code System | SNOMEDCT - 2.16.840.1.113883.6.96 |
| Version | 1 |
| Source | HITSP |
| Definition | The SNOMED CT has been limited by HITSP to the value set reproduced below in Table 2-60 Problem Type Value Set Definition. This indicates the level of medical judgment used to determine the existence of a problem |

| Concept Code | Concept Name | Code System | Description |
|---|---|---|---|
| 404684003 | Finding | SNOMEDCT | |
| 409586006 | Complaint | SNOMEDCT | |
| 282291009 | Diagnosis | SNOMEDCT | |
| 64572001 | Condition | SNOMEDCT | |
| 248536006 | Functional limitation | SNOMEDCT | |
| 418799008 | Symptom | SNOMEDCT | |
| 55607006 | Problem | SNOMEDCT | |

## Problem

| | |
|---|---|
| Value Set | Problem - 2.16.840.1.113883.3.88.12.3221.7.4 |
| Code System | SNOMEDCT - 2.16.840.1.113883.6.96 |
| Version | 1 |
| Source | Veterans Administration/Kaiser Permanente (VA/KP) |
| Source URL | http://evs.nci.nih.gov/ftp1/FDA/ProblemList/ |
| Definition | This describes the problem. Diagnosis/Problem List is broadly defined as a series of brief statements that catalog a patient s medical, nursing, dental, social, preventative and psychiatric events and issues that are relevant to that patient s healthcare (e.g., signs, symptoms, and defined conditions) |

## Problem Status Value

| | |
|---|---|
| Value Set | ProblemStatusValue - (OID not specified) |
| Code System | SNOMEDCT - 2.16.840.1.113883.6.96 |

| Concept Code | Concept Name | Code System | Description |
|---|---|---|---|
| 55561003 | Active | SNOMEDCT | |
| 73425007 | Inactive | SNOMEDCT | |
| 90734009 | Chronic | SNOMEDCT | |
| 7087005 | Intermittent | SNOMEDCT | |
| 255227004 | Recurrent | SNOMEDCT | |
| 415684004 | Rule out | SNOMEDCT | |
| 410516002 | Ruled out | SNOMEDCT | |
| 413322009 | Resolved | SNOMEDCT | |

## Severity Observation

| | |
|---|---|
| Value Set | SeverityObservation - (OID not specified) |

| | |
|---|---|
| Code System | SeverityObservation - 2.16.840.1.113883.5.1063 |

| Concept Code | Concept Name | Code System | Description |
|---|---|---|---|
| H | High | SeverityObservation | |
| M | Moderate | SeverityObservation | |
| L | Low | SeverityObservation | |

## Vital Sign Result

| | |
|---|---|
| Value Set | Vital Sign Result - 2.16.840.1.113883.3.88.12.80.62 |
| Code System | LOINC - 2.16.840.1.113883.6.1 |
| Version | 1 |
| Source | HITSP |
| Definition | This identifies the vital sign result type |

| Concept Code | Concept Name | Code System | Description |
|---|---|---|---|
| 8310-5 | Body temperature:Temp:Pt:^Patient:Qn: | LOINC | |
| 8462-4 | Intravascular diastolic:Pres:Pt:Arterial system:Qn: | LOINC | |
| 8480-6 | Intravascular systolic:Pres:Pt:Arterial system:Qn: | LOINC | |
| 8287-5 | Circumference.occipital-frontal:Len:Pt:Head:Qn:Tape measure | LOINC | |
| 8867-4 | Heart beat:NRat:Pt:XXX:Qn: | LOINC | |
| 8302-2 | Body height:Len:Pt:^Patient:Qn: | LOINC | |
| 8306-3 | Body height^lying:Len:Pt:^Patient:Qn: | LOINC | |
| 2710-2 | Oxygen saturation:SFr:Pt:BldC:Qn:Oximetry | LOINC | |
| 9279-1 | Breaths:NRat:Pt:Respiratory system:Qn: | LOINC | |
| 3141-9 | Body weight:Mass:Pt:^Patient:Qn:Measured | LOINC | |

# 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*