Implementation Guide for CDA Release 2
ONC/HL7/IHE Consolidation Project
Problems Section (working draft)

DRAFT: FOR DEVELOPMENT USE ONLY
(Consolidated Developer Documentation)

Contents

Acknowledgments

Chapter 1

DOCUMENT TEMPLATES

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

Chapter 2

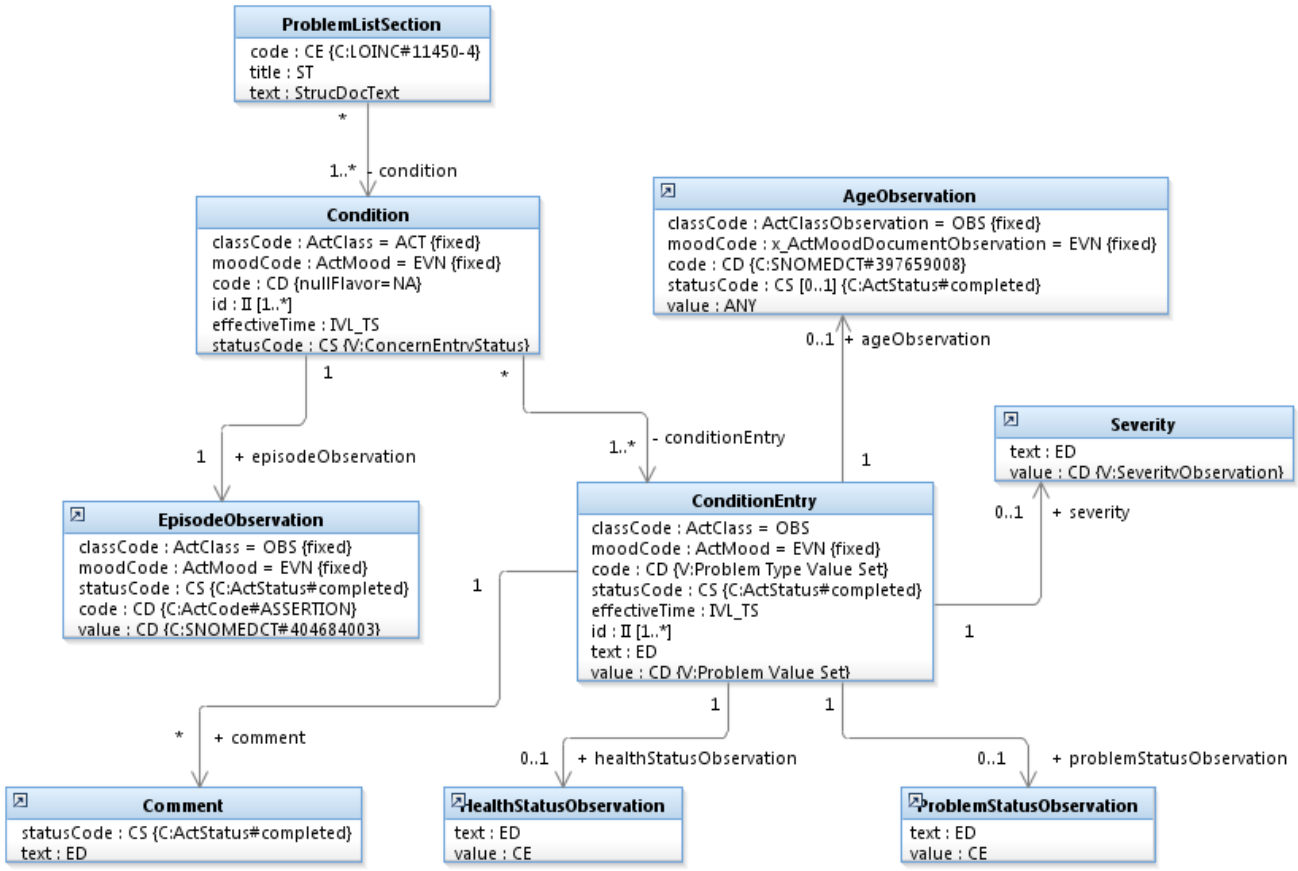
SECTION TEMPLATES

Topics:

Problem List Section

[Section: templateId `2.16.840.1.113883.3.88.11.83.103`]

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



1. **SHALL** conform to CDA Section
2. **SHALL** conform to *CCD Problem Section* template (templateId: `2.16.840.1.113883.10.20.1.11`)
3. **SHALL** conform to *IHE Active Problems Section* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.3.6`)
4. **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)
5. **SHALL** contain exactly one [1..1] `title` (CONF-143)
6. **SHALL** contain exactly one [1..1] `text` (CONF-140)
7. **SHOULD** contain at least one [1..*] `entry`, such that it
   a. contains *CCD Problem Act* (templateId: `2.16.840.1.113883.10.20.1.27`) (CONF-140)
8. **SHALL** contain at least one [1..*] `entry`, such that it
   a. contains *HITSP Condition* (templateId: `2.16.840.1.113883.3.88.11.83.7`) (C83-[CT-103-1])
9. **SHOULD** satisfy: Contains a case-insensitive language-insensitive string containing 'problems'. (CONF-144)

Problem List Section 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">
  <component>
```

```
    <structuredBody>
      <component>
        <section>
          <templateId root="2.16.840.1.113883.10.20.1.11"
 assigningAuthorityName="CCD Problem Section"/>
          <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.6"
 assigningAuthorityName="IHE Active Problems Section"/>
          <templateId root="2.16.840.1.113883.3.88.11.83.103"
 assigningAuthorityName="HITSP Problem List Section"/>
          <code code="11450-4" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="Problem list"/>
          <title>Problem list</title>
          <entry>
            <act classCode="ACT" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.27"
 assigningAuthorityName="CCD Problem Act"/>
              <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.5.1"
 assigningAuthorityName="IHE Concern Entry"/>
              <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.5.2"
 assigningAuthorityName="IHE Problem Concern Entry"/>
              <templateId root="2.16.840.1.113883.3.88.11.83.7"
 assigningAuthorityName="HITSP Condition"/>
              <id root="cf1da32c-1d43-43c7-817b-6f8565b5240b"/>
              <code nullFlavor="NA"/>
              <statusCode/>
              <effectiveTime>
                <low value="1972"/>
                <high value="2008"/>
              </effectiveTime>
            </act>
          </entry>
          <entry>
            <act classCode="ACT" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.27"
 assigningAuthorityName="CCD Problem Act"/>
              <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.5.1"
 assigningAuthorityName="IHE Concern Entry"/>
              <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.5.2"
 assigningAuthorityName="IHE Problem Concern Entry"/>
              <id root="09222de9-8883-41e8-92ef-737f3a782441"/>
              <code nullFlavor="NA"/>
              <statusCode/>
              <effectiveTime>
                <low value="1972"/>
                <high value="2008"/>
              </effectiveTime>
            </act>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

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** conform to CDA Clinical Statement
2. **SHALL** conform to CDA Observation
3. **SHALL** contain exactly one [1..1] `@classCode` = "OBS" (CONF-226)
4. **SHALL** contain exactly one [1..1] `@moodCode` = "EVN" (CONF-227)
5. **SHALL** contain exactly one [1..1] `code/@code` = "397659008" *Age* (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT) (CONF-228)
6. **SHALL** contain zero or one [0..1] `statusCode/@code` = "completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus) (CONF-229, CONF-230)
7. **SHALL** contain exactly one [1..1] `value` (CONF-231)
   - Valued using appropriate datatype.
8. **SHOULD** satisfy: subject/relatedSubject/subject contains exactly one birthTime (CONF-219)
9. **MAY** satisfy: subject/relatedSubject/subject contains exactly one sdtc:deceasedInd (CONF-220)
10. **MAY** satisfy: subject/relatedSubject/subject contains exactly one sdtc:deceasedTime (CONF-221)
11. **SHOULD** satisfy: The age of a relative at the time of observation is inferred by comparing subject/relatedSubject/subject/birthTime with effectiveTime (CONF-222)
12. **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"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.38"
 assigningAuthorityName="CCD Age Observation"/>
              <code code="397659008" codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMEDCT" displayName="Age"/>
              <statusCode code="completed"/>
            </observation>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Comment

[Act: templateId `1.3.6.1.4.1.19376.1.5.3.1.4.2`]

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.

1. **SHALL** conform to CDA Clinical Statement
2. **SHALL** conform to CDA Act
3. **SHALL** conform to *CCD Comment* template (templateId: `2.16.840.1.113883.10.20.1.40`)
4. **SHALL** contain exactly one [1..1] `@classCode` = "ACT" (CONF-504)
5. **SHALL** contain exactly one [1..1] `@moodCode` = "EVN" (CONF-505)
6. **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)
7. **SHALL** contain exactly one [1..1] `statusCode/@code` = "completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus) (CONF-6.3.4.6.8)
8. **SHALL** contain exactly one [1..1] `text`
9. **MAY** contain zero or one [0..1] `author`, such that it
   a. contains CDA Author
10. **SHALL** satisfy: A related statement is made about another section or entry. In CDA the former shall be recorded inside an <entryRelationship> element occurring at the end of the entry. The containing entry is the subject (typeCode='SUBJ') of this comment, which is the inverse of the normal containment structure, thus inversionInd='true'. (CONF-6.3.4.6.3)
11. **SHALL** satisfy: The 'text' element contains a 'reference' element pointing to the narrative text section of the CDA, rather than duplicate text to avoid ambiguity. (CONF-6.3.4.6.7)
12. **SHALL** satisfy: The time of the comment creation is recorded in the 'time' element when the 'author' element is present. (CONF-6.3.4.6.10)
13. **SHALL** satisfy: The identifier of the author, and their address and telephone number must be present inside the 'id', 'addr' and 'telecom' elements when the 'author' element is present. (CONF-6.3.4.6.11)
14. **SHALL** satisfy: The author's and/or the organization's name must be present when the 'author' element is present. (CONF-6.3.4.6.12)

Comment 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">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <act classCode="ACT" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.40"
 assigningAuthorityName="CCD Comment"/>
              <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.2"
 assigningAuthorityName="IHE Comment"/>
              <code code="48767-8" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="Annotation comment"/>
              <text/>
              <statusCode code="completed"/>
            </act>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Condition

[Act: templateId `2.16.840.1.113883.3.88.11.83.7`]

1. **SHALL** conform to CDA Clinical Statement
2. **SHALL** conform to CDA Act

3. **SHALL** conform to *CCD Problem Act* template (templateId: `2.16.840.1.113883.10.20.1.27`)
4. **SHALL** conform to *IHE Concern Entry* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.5.1`)
5. **SHALL** conform to *IHE Problem Concern Entry* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.5.2`)
6. **SHALL** contain exactly one [1..1] `@classCode` = "ACT" (CONF-146)
7. **SHALL** contain exactly one [1..1] `@moodCode` = "EVN" (CONF-147)
8. **SHALL** contain exactly one [1..1] `code/@nullFlavor` = "NA" *NA (not applicable)* (CONF-149)
9. **SHALL** contain at least one [1..*] `id` (CONF-148)
10. **SHALL** contain exactly one [1..1] `effectiveTime`
    - The effectiveTime element records the starting and ending times during which the concern was active.
11. **SHALL** contain exactly one [1..1] `statusCode`, which **SHALL** be selected from *ConcernEntryStatus* Value Set
12. **MAY** contain exactly one [1..1] `entryRelationship`, such that it
    a. contains *CCD Episode Observation* (templateId: `2.16.840.1.113883.10.20.1.41`) (CONF-168)
13. **SHALL** contain at least one [1..*] `entryRelationship`, such that it
    a. has @typeCode="SUBJ" *SUBJ (has subject)*
    b. contains *HITSP Condition Entry* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.5`)
14. **SHALL** satisfy: Contains one or more entryRelationship (CONF-151)
15. **MAY** satisfy: A problem act MAY reference a problem observation, alert observation (see section Alerts) or other clinical statement that is the subject of concern, by setting the value for "Act / entryRelationship / @typeCode" to be "SUBJ" 2.16.840.1.113883.5.1002 ActRelationshipType STATIC. (CONF-152)
16. **SHOULD** satisfy: The target of a problem act with Act / entryRelationship / @typeCode="SUBJ" SHOULD be a problem observation (in the Problem section) or alert observation (in the Alert section), but MAY be some other clinical statement. (CONF-153)
17. **SHOULD** satisfy: In Problem Section, a Problem Act SHOULD contain one or more Problem Observations. (CONF-140)
18. **SHOULD** satisfy: In Alert Section, a ProblemAct SHOULD contain one or more Alert Observations. (CONF-256)
19. **MAY** satisfy: Contains exactly one Patient Awareness (CONF-179)
20. **SHALL** satisfy: 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.
21. **SHALL** satisfy: 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'.
22. **MAY** satisfy: 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'.
23. **SHALL** satisfy: 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])
24. **SHALL** satisfy: 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])
25. **MAY** satisfy: 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"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
```

```
            <act classCode="ACT" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.27"
 assigningAuthorityName="CCD Problem Act"/>
              <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.5.1"
 assigningAuthorityName="IHE Concern Entry"/>
              <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.5.2"
 assigningAuthorityName="IHE Problem Concern Entry"/>
              <templateId root="2.16.840.1.113883.3.88.11.83.7"
 assigningAuthorityName="HITSP Condition"/>
              <id root="ae9e5113-b287-4f1a-839a-b9bce390f33d"/>
              <code nullFlavor="NA"/>
              <statusCode/>
              <effectiveTime>
                <low value="1972"/>
                <high value="2008"/>
              </effectiveTime>
              <entryRelationship>
                <observation classCode="OBS" moodCode="EVN">
                  <templateId root="2.16.840.1.113883.10.20.1.28"
 assigningAuthorityName="CCD Problem Observation"/>
                  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.5"
 assigningAuthorityName="IHE Problem Entry"/>
                  <id root="dbbd2290-09ac-4742-9f15-27c67e300acb"/>
                  <code codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMEDCT"/>
                  <text/>
                  <statusCode code="completed"/>
                  <effectiveTime>
                    <low value="1972"/>
                    <high value="2008"/>
                  </effectiveTime>
                  <value xsi:type="CD"/>
                </observation>
              </entryRelationship>
              <entryRelationship>
                <observation classCode="OBS" moodCode="EVN">
                  <templateId root="2.16.840.1.113883.10.20.1.28"
 assigningAuthorityName="CCD Problem Observation"/>
                  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.5"
 assigningAuthorityName="IHE Problem Entry"/>
                  <id root="447ca460-0695-469a-acb4-72a74dc3d4bd"/>
                  <code codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMEDCT"/>
                  <text/>
                  <statusCode code="completed"/>
                  <effectiveTime>
                    <low value="1972"/>
                    <high value="2008"/>
                  </effectiveTime>
                  <value xsi:type="CD"/>
                </observation>
              </entryRelationship>
            </act>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Condition Entry

[Observation: templateId `1.3.6.1.4.1.19376.1.5.3.1.4.5`]

Condition Entry is not defined as a separate template in HITSP C83, but only as additional constraints on the IHE Problem Entry when embedded in a Condition template. In this model, Condition Entry is defined as a separate class (without a template ID) that restricts the IHE Problem Entry. When these templates are consolidated in the new implementation guide, these Condition Entry constraints will be merged with Problem Entry.

1. **SHALL** conform to CDA Clinical Statement
2. **SHALL** conform to CDA Observation
3. **SHALL** conform to *CCD Problem Observation* template (templateId: `2.16.840.1.113883.10.20.1.28`)
4. **SHALL** conform to *IHE Problem Entry* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.5`)
5. Contains exactly one [1..1] `@classCode` = "OBS"
6. **SHALL** contain exactly one [1..1] `@moodCode` = "EVN" (CONF-155)
7. **SHOULD** contain exactly one [1..1] `code`, which **SHOULD** be selected from Problem Type Value Set (2.16.840.1.113883.3.88.12.3221.7.2)
8. **SHALL** contain exactly one [1..1] `statusCode/@code` = "completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus) (CONF-156, CONF-157)
9. **SHOULD** contain exactly one [1..1] `effectiveTime`
   - The <effectiveTime> of this <observation> is the time interval over which the <observation> is known to be true. The <low> and <high> values should be no more precise than known, but as precise as possible. While CDA allows for multiple mechanisms to record this time interval (e.g., by low and high values, low and width, high and width, or center point and width), we are constraining Medical summaries to use only the low/high form. The <low> value is the earliest point for which the condition is known to have existed. The <high> value, when present, indicates the time at which the observation was no longer known to be true. Thus, the implication is made that if the <high> value is specified, that the observation was no longer seen after this time, and it thus represents the date of resolution of the problem. Similarly, the <low> value may seem to represent onset of the problem. Neither of these statements is necessarily precise, as the <low> and <high> values may represent only an approximation of the true onset and resolution (respectively) times. For example, it may be the case that onset occurred prior to the <low> value, but no observation may have been possible before that time to discern whether the condition existed prior to that time. The <low> value should normally be present. There are exceptions, such as for the case where the patient may be able to report that they had chicken pox, but are unsure when. In this case, the <effectiveTime> element shall have a <low> element with a nullFlavor attribute set to 'UNK'. The <high> value need not be present when the observation is about a state of the patient that is unlikely to change (e.g., the diagnosis of an incurable disease).
10. **SHALL** contain 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.
11. **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.
12. **SHALL** contain exactly one [1..1] `value`, which **SHALL** be selected from Problem Value Set (2.16.840.1.113883.3.88.12.3221.7.4)
13. **MAY** contain zero or one [0..1] `entryRelationship`, such that it
    a. has @typeCode="SUBJ" *SUBJ (has subject)*
    b. contains *CCD Age Observation* (templateId: `2.16.840.1.113883.10.20.1.38`) (CONF-160)
14. **MAY** contain zero or one [0..1] `entryRelationship`, such that it
    a. contains *IHE Severity* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.1`)
15. **MAY** contain zero or one [0..1] `entryRelationship`, such that it

   a. has @typeCode="REFR" *REFR (refers to)*
   b. contains *IHE Problem Status Observation* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.1.1`)
16. **MAY** contain zero or one [0..1] `entryRelationship`, such that it
   a. has @typeCode="REFR" *REFR (refers to)*
   b. contains *IHE Health Status Observation* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.1.2`)
17. **MAY** contain zero or more [0..*] `entryRelationship`, such that it
   a. has @typeCode="SUBJ" *SUBJ (has subject)*
   b. contains *IHE Comment* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.2`)
18. **SHALL** satisfy: Contains one or more sources of information. (CONF-161)
19. **MAY** satisfy: Contains exactly one Patient Awareness (CONF-180)
20. **SHALL** satisfy: 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.
21. **SHALL** satisfy: If entryRelationship / Comment is present, then entryRelationship inversionInd = 'true'.
22. **SHOULD** satisfy: The onset date SHALL be recorded in the <low> element of the <effectiveTime> element when known. (C83-[DE-7.01-1])
23. **SHOULD** satisfy: The resolution data SHALL be recorded in the <high> element of the <effectiveTime> element when known. (C83-[DE-7.01-2])
24. **SHOULD** satisfy: 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"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.28"
 assigningAuthorityName="CCD Problem Observation"/>
              <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.5"
 assigningAuthorityName="IHE Problem Entry"/>
              <id root="68e0d602-6ffa-48dd-b574-e49cdd2f8039"/>
              <code codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMEDCT"/>
              <text/>
              <statusCode code="completed"/>
              <effectiveTime>
                <low value="1972"/>
                <high value="2008"/>
              </effectiveTime>
              <value xsi:type="CD"/>
            </observation>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Episode Observation

[Observation: templateId `2.16.840.1.113883.10.20.1.41`]

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

1. **SHALL** conform to CDA Clinical Statement
2. **SHALL** conform to CDA Observation
3. **SHALL** contain exactly one [1..1] `@classCode` = "OBS" (CONF-170)
4. **SHALL** contain exactly one [1..1] `@moodCode` = "EVN" (CONF-171)
5. **SHOULD** contain exactly one [1..1] `code/@code` = "ASSERTION" (CodeSystem: 2.16.840.1.113883.5.4 ActCode) (CONF-174)
6. **SHALL** contain exactly one [1..1] `statusCode/@code` = "completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus) (CONF-172, CONF-173)
7. **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)
8. **SHOULD** satisfy: Value in an episode observation SHOULD be the following SNOMED CT expression: <codeblock><value xsi:type="CD" code="404684003" codeSystem="2.16.840.1.113883.6.96" displayName="Clinical finding"> <qualifier> <name code="246456000" displayName="Episodicity"/> <value code="288527008" displayName="New episode"/> </qualifier> </value></codeblock> (CONF-175)
9. **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)
10. **MAY** satisfy: Source of one or more entryRelationship whose typeCode is 'SAS'. The target of the entryRelationship SHALL be a problem act or social history observation. This is used to represent the temporal sequence of episodes. (CONF-177)

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

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 CDA Clinical Statement
2. **SHALL** conform to CDA Observation
3. **SHALL** conform to *CCD Status Observation* template (templateId: `2.16.840.1.113883.10.20.1.57`)
4. **SHALL** conform to *CCD Problem Health Status Observation* template (templateId: `2.16.840.1.113883.10.20.1.51`)
5. **SHALL** contain exactly one [1..1] `@classCode` = "OBS" (CONF-510)
6. **SHALL** contain exactly one [1..1] `@moodCode` = "EVN" (CONF-511)
7. **SHALL** contain exactly one [1..1] `code/@code` = "11323-3" *Health status* (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF-166)
8. **SHALL** contain exactly one [1..1] `statusCode/@code` = "completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus) (CONF-514, CONF-515)
9. **SHALL** contain exactly one [1..1] `value`, which **SHALL** be selected from HealthStatusValue Value Set
10. **SHALL** contain exactly one [1..1] `text`
11. **SHALL** satisfy: Target of an entryRelationship whose value for "entryRelationship / @typeCode" SHALL be "REFR" 2.16.840.1.113883.5.1002 ActRelationshipType STATIC. (CONF-509)
12. **SHALL** satisfy: SHALL NOT contain any additional Observation attributes. (CONF-517)
13. **SHALL** satisfy: SHALL NOT contain any Observation participants. (CONF-518)
14. **SHALL** satisfy: SHALL NOT be the source of any Observation relationships. (CONF-519)
15. **SHALL** satisfy: 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"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.57"
 assigningAuthorityName="CCD Status Observation"/>
              <templateId root="2.16.840.1.113883.10.20.1.51"
 assigningAuthorityName="CCD Problem Health Status Observation"/>
              <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.1.2"
 assigningAuthorityName="IHE Health Status Observation"/>
              <code code="11323-3" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="Health status"/>
              <text/>
              <statusCode code="completed"/>
              <value xsi:type="CE"/>
            </observation>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

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 CDA Clinical Statement
2. **SHALL** conform to CDA Observation
3. **SHALL** conform to *CCD Status Observation* template (templateId: `2.16.840.1.113883.10.20.1.57`)
4. **SHALL** conform to *CCD Problem Status Observation* template (templateId: `2.16.840.1.113883.10.20.1.50`)
5. **SHALL** contain exactly one [1..1] `@classCode` = "OBS" (CONF-510)
6. **SHALL** contain exactly one [1..1] `@moodCode` = "EVN" (CONF-511)
7. **SHALL** contain exactly one [1..1] `code/@code` = "33999-4" *Status* (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF-512, CONF-513)
8. **SHALL** contain exactly one [1..1] `statusCode/@code` = "completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus) (CONF-514, CONF-515)
9. **SHALL** contain exactly one [1..1] `value`, which **SHALL** be selected from ProblemStatusValue Value Set
10. **SHALL** contain exactly one [1..1] `text`
11. **SHALL** satisfy: Target of an entryRelationship whose value for "entryRelationship / @typeCode" SHALL be "REFR" 2.16.840.1.113883.5.1002 ActRelationshipType STATIC. (CONF-509)
12. **SHALL** satisfy: SHALL NOT contain any additional Observation attributes. (CONF-517)
13. **SHALL** satisfy: SHALL NOT contain any Observation participants. (CONF-518)
14. **SHALL** satisfy: SHALL NOT be the source of any Observation relationships. (CONF-519)
15. **SHALL** satisfy: 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"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.57"
 assigningAuthorityName="CCD Status Observation"/>
              <templateId root="2.16.840.1.113883.10.20.1.50"
 assigningAuthorityName="CCD Problem Status Observation"/>
              <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.1.1"
 assigningAuthorityName="IHE Problem Status Observation"/>
              <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="Status"/>
              <text/>
              <statusCode code="completed"/>
              <value xsi:type="CE"/>
            </observation>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

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** conform to CDA Clinical Statement
2. **SHALL** conform to CDA Observation
3. **SHALL** conform to *CCD Severity Observation* template (templateId: `2.16.840.1.113883.10.20.1.55`)
4. **SHALL** contain exactly one [1..1] `@classCode` = "OBS" (CONF-289)
5. **SHALL** contain exactly one [1..1] `@moodCode` = "EVN" (CONF-290)
6. **SHALL** contain exactly one [1..1] `code/@code` = "SEV" *Severity observation* (CodeSystem: 2.16.840.1.113883.5.4 ActCode) (CONF-293, CONF-294)
7. **SHALL** contain exactly one [1..1] `statusCode/@code` = "completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus) (CONF-291, CONF-292)
8. **SHALL** contain exactly one [1..1] `value`, which **SHALL** be selected from SeverityObservation Value Set, 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.
9. **SHALL** contain exactly one [1..1] `text`
10. **SHALL** satisfy: 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"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.55"
 assigningAuthorityName="CCD Severity Observation"/>
              <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.1"
 assigningAuthorityName="IHE Severity"/>
              <code code="SEV" codeSystem="2.16.840.1.113883.5.4"
 codeSystemName="ActCode" displayName="Severity observation"/>
              <text/>
              <statusCode code="completed"/>
              <value xsi:type="CD"/>
            </observation>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

VALUE SETS

Concern Entry Status

[OID null]

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.

OID: null

Name: null

Code	Display Name	Code System	Code System Name
active	null		
suspended	null		
aborted	null		
completed	null		

Health Status Value

[OID null from code system: SNOMEDCT]

OID: null

Name: null

Code System: 2.16.840.1.113883.6.96

Code System Name: SNOMEDCT

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

Problem Status Value

[OID null from code system: SNOMEDCT]

OID: null

Name: null

Code System: 2.16.840.1.113883.6.96

Code System Name: SNOMEDCT

Code	Display Name	Code System	Code System Name
55561003	Active		
73425007	Inactive		
90734009	Chronic		
7087005	Intermittent		
255227004	Recurrent		
415684004	Rule out		
410516002	Ruled out		
413322009	Resolved		

Severity Observation

[OID `null` from code system: SeverityObservation]

OID: null

Name: null

Code System: 2.16.840.1.113883.5.1063

Code System Name: SeverityObservation

Code	Display Name	Code System	Code System Name
H	High		
M	Moderate		
L	Low		