

Implementation Guide for CDA Release 2

ONC/HL7/IHE Consolidation Project

Problems Section (working draft)



DRAFT: FOR DEVELOPMENT USE ONLY
(Consolidated Developer Documentation)

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Acknowledgments

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HITSP Problems List

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. [CCD] **SHALL** contain [1..1] code/@code = "11450-4" *Problem list* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC) (CONF-141, CONF-142)
5. [CCD] **SHALL** contain [1..1] title (CONF-143)
6. [CCD] **SHOULD** contain [1..*] entry, such that it
 - a. contains [CCD Problem Act](#) (templateId: 2.16.840.1.113883.10.20.1.27) (CONF-140)
7. [CCD] **SHALL** contain [1..1] text (CONF-140)
8. [IHE] **SHALL** contain [1..*] entry, such that it
 - a. contains [IHE Problem Concern Entry](#) (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.5.2)
9. [HITSP] **SHALL** contain [1..*] entry, such that it
 - a. contains [Condition](#) (templateId: 2.16.840.1.113883.3.88.11.83.7)
10. [CCD] **SHOULD** satisfy: Contains a case-insensitive language-insensitive string containing 'problems'. (CONF-144)

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
  xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <templateId root="2.16.840.1.113883.10.20.1.11"
            assigningAuthorityName="CCD Problem Section"/>
          <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="c7872239-7116-45e9-8aab-be05b9a47a6f"/>
              <code nullFlavor="NA"/>
              <statusCode/>
            </act>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

```

        <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="814fb477-4df4-4b7b-bbf3-20ff5ffe637c"/>
        <code nullFlavor="NA"/>
        <statusCode/>
        <effectiveTime>
          <low value="1972"/>
          <high value="2008"/>
        </effectiveTime>
      </act>
    </entry>
  </section>
</component>
</structuredBody>
</component>
</ClinicalDocument>

```

Figure 1: Problem List Section example

Condition

[Act: templateId 2.16.840.1.113883.3.88.11.83.7]

1. **SHALL** conform to *CCD Clinical Statement*
2. **SHALL** conform to *CCD 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. [CCD] **SHALL** contain [1..1] @classCode = "ACT" (CONF-146)
7. [CCD] **SHALL** contain [1..1] @moodCode = "EVN" (CONF-147)
8. [CCD] **SHALL** contain [1..1] code/@nullFlavor = "NA" *NA (not applicable)* (CONF-149)
9. [CCD] **SHALL** contain [1..*] id (CONF-148)
10. [IHE] **SHALL** contain [1..1] effectiveTime
 - The effectiveTime element records the starting and ending times during which the concern was active.
11. [CCD] **MAY** contain [1..1] entryRelationship, such that it
 - a. contains *CCD Episode Observation* (templateId: 2.16.840.1.113883.10.20.1.41) (CONF-168)
12. [CCD] **Contains** [0..*] entryRelationship, such that it
 - a. contains *CCD Problem Observation* (templateId: 2.16.840.1.113883.10.20.1.28)
13. [IHE] **SHALL** contain [1..1] statusCode, which **SHALL** be selected from ValueSet *ConcernEntryStatus* STATIC
14. [IHE] **SHALL** contain [1..*] entryRelationship, such that it
 - a. has @typeCode="SUBJ" *SUBJ (has subject)*

- b. contains *IHE Problem Entry* (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.5)
- 15. [HITSP] **SHALL** contain [1..*] entryRelationship, such that it
 - a. has @typeCode="SUBJ" *SUBJ (has subject)*
 - b. contains *Condition Entry*
- 16. [CCD] **SHALL** satisfy: Contains one or more entryRelationship (CONF-151)
 - [OCL]: `not self.entryRelationship->isEmpty()`
- 17. [CCD] **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)
- 18. [CCD] **SHOULD** satisfy: The target of a problem act with Act / entryRelationship / @typeCode="SUBJ" SHOULD be a problem observation (in the Problem section) or alert observation (in the Alert section), but MAY be some other clinical statement. (CONF-153)
 - [OCL]:
`self.getEntryRelationshipTargets(vocab::x_ActRelationshipEntryRelationship::SUBJ, cda::ClinicalStatement)->forall(target : cda::ClinicalStatement | not target.ocIsUndefined() and (target.ocIsKindOf(ccd::ProblemObservation) or target.ocIsKindOf(ccd::AlertObservation)))`
- 19. [CCD] **SHOULD** satisfy: In Problem Section, a Problem Act SHOULD contain one or more Problem Observations. (CONF-140)
 - [OCL]: `self.getSection().ocIsKindOf(ccd::ProblemSection) implies self.getObservations()->exists(obs : cda::Observation | obs.ocIsKindOf(ccd::ProblemObservation))`
- 20. [CCD] **SHOULD** satisfy: In Alert Section, a ProblemAct SHOULD contain one or more Alert Observations. (CONF-256)
 - [OCL]: `self.getSection().ocIsKindOf(ccd::AlertsSection) implies self.getObservations()->exists(obs : cda::Observation | obs.ocIsKindOf(ccd::AlertObservation))`
- 21. [CCD] **MAY** satisfy: Contains exactly one Patient Awareness (CONF-179)
 - [OCL]: `self.participant->one(partic : cda::Participant2 | partic.ocIsKindOf(ccd::PatientAwareness))`
- 22. [IHE] **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.
 - [OCL]: `not self.effectiveTime.low.ocIsUndefined() and ((self.statusCode.code = 'completed' or self.statusCode.code = 'aborted') implies not self.effectiveTime.high.ocIsUndefined()) and ((self.statusCode.code <> 'completed' and self.statusCode.code <> 'aborted') implies self.effectiveTime.high.ocIsUndefined())`
- 23. [IHE] **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'.
- 24. [IHE] **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'.

```
<?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="4e22d4f3-edca-4153-9d7f-3251074cf3ed"/>
            <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"/>
                    <templateId assigningAuthorityName="HITSP Condition Entry"/>
                    <id root="c4a4367b-cbbe-4fdb-875f-c434b0e91b72"/>
                    <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="d23dc04f-70af-40b4-a2ac-fde58b8f8855"/>
                    <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>

```

Figure 2: Condition example

Condition Entry

[Observation: templateId null]

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. [CCD] Contains [1..1] @classCode = "OBS"
6. [CCD] **SHALL** contain [1..1] @moodCode = "EVN" (CONF-155)
7. [HITSP] **SHALL** contain [1..1] code, which **SHALL** be selected from ValueSet 2.16.840.1.113883.3.88.12.3221.7.2 Problem Type Value Set STATIC
8. [CCD] **SHALL** contain [1..1] statusCode/@code = "completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus STATIC V3NE08) (CONF-156, CONF-157)
9. [HITSP] **SHOULD** contain [1..1] effectiveTime
 - The problem date constraints include the onset and resolution dates for the problem. The onset date shall be recorded in the <low> element of the <effectiveTime> element when known. The resolution data shall be recorded in the <high> element of the <effectiveTime> element when known. These dates represent the clinically effective time span over which the problem existed. 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.
10. [CCD] **MAY** contain [0..1] entryRelationship, such that it
 - a. has @typeCode="REFR" *REFR (refers to)*
 - b. contains [CCD Problem Status Observation](#) (templateId: 2.16.840.1.113883.10.20.1.50) (CONF-162)
11. [CCD] **MAY** contain [0..1] entryRelationship, such that it
 - a. has @typeCode="REFR" *REFR (refers to)*
 - b. contains [CCD Problem Health Status Observation](#) (templateId: 2.16.840.1.113883.10.20.1.51) (CONF-165)
12. [CCD] **MAY** contain [0..1] entryRelationship, such that it
 - a. has @typeCode="SUBJ" *SUBJ (has subject)*
 - b. contains [CCD Age Observation](#) (templateId: 2.16.840.1.113883.10.20.1.38) (CONF-160)
13. [IHE] **SHALL** contain [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.
14. [HITSP] **SHALL** contain [1..1] text
15. [HITSP] **SHALL** contain [1..1] value, which **SHALL** be selected from ValueSet 2.16.840.1.113883.3.88.12.3221.7.4 Problem Value Set STATIC
16. [IHE] **MAY** contain [0..1] entryRelationship, such that it
 - a. contains [IHE Severity](#) (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.1)
17. [IHE] **MAY** contain [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)

18. [IHE] **MAY** contain [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)

19. [IHE] **MAY** contain [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)

20. [CCD] **SHALL** satisfy: Contains one or more sources of information. (CONF-161)

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

21. [CCD] **MAY** satisfy: Contains exactly one Patient Awareness (CONF-180)

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

22. [IHE] **SHALL** satisfy: If entryRelationship / Comment is present, then entryRelationship inversionInd = 'true'.

- [OCL]: self.entryRelationship->forall(rel : cda::EntryRelationship | (not
rel.act.oclIsUndefined() and rel.act.oclIsKindOf(ihe::Comment)) implies
rel.inversionInd='true')

```
<?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"/>
              <templateId assigningAuthorityName="HITSP Condition Entry"/>
              <id root="3e073174-0104-414b-a722-42382887fc8b"/>
              <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>
```

Figure 3: Condition Entry example

CCD Problems

Problem Section

[Section: templateId 2.16.840.1.113883.10.20.1.11]

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

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

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
  xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <templateId root="2.16.840.1.113883.10.20.1.11"
            assigningAuthorityName="CCD Problem Section"/>
          <code code="11450-4" codeSystem="2.16.840.1.113883.6.1"
            codeSystemName="LOINC" displayName="Problem list"/>
          <title>Problem list</title>
          <entry>
            <act classCode="ACT" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.27"
                assigningAuthorityName="CCD Problem Act"/>
              <id root="db3b91d4-9f78-4098-8705-435c1a433162"/>
              <code nullFlavor="NA"/>
              <effectiveTime>
                <low value="1972"/>
                <high value="2008"/>
              </effectiveTime>
            </act>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 4: Problem Section example

Problem Act

[Act: templateId 2.16.840.1.113883.10.20.1.27]

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

1. **SHALL** conform to *CDA Clinical Statement*
2. **SHALL** conform to *CDA Act*
3. [CCD] **SHALL** contain [1..1] @classCode = "ACT" (CONF-146)
4. [CCD] **SHALL** contain [1..1] @moodCode = "EVN" (CONF-147)
5. [CCD] **SHALL** contain [1..1] code/@nullFlavor = "NA" NA (*not applicable*) (CONF-149)
6. [CCD] **SHALL** contain [1..*] id (CONF-148)
7. [CCD] **MAY** contain [0..1] effectiveTime
 - Indicates the timing of the concern (e.g. the interval of time for which the problem is a concern). (CONF-150)
8. [CCD] **MAY** contain [1..1] entryRelationship, such that it
 - a. contains *Episode Observation* (templateId: 2.16.840.1.113883.10.20.1.41) (CONF-168)
9. [CCD] Contains [0..*] entryRelationship, such that it
 - a. contains *Problem Observation* (templateId: 2.16.840.1.113883.10.20.1.28)
10. [CCD] **SHALL** satisfy: Contains one or more entryRelationship (CONF-151)
 - [OCL]: not self.entryRelationship->isEmpty()
11. [CCD] **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)
12. [CCD] **SHOULD** satisfy: The target of a problem act with Act / entryRelationship / @typeCode="SUBJ" SHOULD be a problem observation (in the Problem section) or alert observation (in the Alert section), but MAY be some other clinical statement. (CONF-153)
 - [OCL]:


```
self.getEntryRelationshipTargets(vocab::x_ActRelationshipEntryRelationship::SUBJ,
cda::ClinicalStatement)->forAll(target : cda::ClinicalStatement | not
target.ocIsKindOf(cdd::ProblemObservation) and
(target.ocIsKindOf(cdd::ProblemObservation) or
target.ocIsKindOf(cdd::AlertObservation)))
```
13. [CCD] **SHOULD** satisfy: In Problem Section, a Problem Act SHOULD contain one or more Problem Observations. (CONF-140)
 - [OCL]: self.getSection().ocIsKindOf(cdd::ProblemSection) implies


```
self.getObservations()
->exists(obs : cda::Observation |
obs.ocIsKindOf(cdd::ProblemObservation))
```
14. [CCD] **SHOULD** satisfy: In Alert Section, a ProblemAct SHOULD contain one or more Alert Observations. (CONF-256)
 - [OCL]: self.getSection().ocIsKindOf(cdd::AlertsSection) implies


```
self.getObservations()
->exists(obs : cda::Observation |
obs.ocIsKindOf(cdd::AlertObservation))
```
15. [CCD] **MAY** satisfy: Contains exactly one Patient Awareness (CONF-179)
 - [OCL]: self.participant->one(partic : cda::Participant2 |


```
partic.ocIsKindOf(cdd::PatientAwareness))
```

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

```

<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
  xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <act classCode="ACT" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.27"
assigningAuthorityName="CCD Problem Act"/>
              <id root="da6097e5-3143-470a-a849-88e7cbfd12de"/>
              <code nullFlavor="NA"/>
              <effectiveTime>
                <low value="1972"/>
                <high value="2008"/>
              </effectiveTime>
              <entryRelationship>
                <observation classCode="OBS" moodCode="EVN">
                  <templateId root="2.16.840.1.113883.10.20.1.41"
assigningAuthorityName="CCD Episode Observation"/>
                  <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"
codeSystemName="ActCode"/>
                  <statusCode code="completed"/>
                  <value xsi:type="CD"/>
                </observation>
              </entryRelationship>
            </act>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>

```

Figure 5: Problem Act example

Problem Observation

[Observation: templateId 2.16.840.1.113883.10.20.1.28]

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

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

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
  xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.28"
assigningAuthorityName="CCD Problem Observation"/>
              <code/>
              <statusCode code="completed"/>
              <effectiveTime>
                <low value="1972"/>
                <high value="2008"/>
              </effectiveTime>
              <entryRelationship>
                <observation classCode="OBS" moodCode="EVN">
                  <templateId root="2.16.840.1.113883.10.20.1.57"
assigningAuthorityName="CCD Status Observation"/>
                  <templateId root="2.16.840.1.113883.10.20.1.50"
assigningAuthorityName="CCD Problem Status Observation"/>
                  <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Status"/>
                  <statusCode code="completed"/>
                  <value xsi:type="CE"/>
                </observation>
              </entryRelationship>
            </entryRelationship>
            <entryRelationship>
              <observation classCode="OBS" moodCode="EVN">
                <templateId root="2.16.840.1.113883.10.20.1.57"
assigningAuthorityName="CCD Status Observation"/>
                <templateId root="2.16.840.1.113883.10.20.1.51"
assigningAuthorityName="CCD Problem Health Status Observation"/>
```



```

        <code code="11323-3" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Health status"/>
        <statusCode code="completed"/>
        <value xsi:type="CE"/>
    </observation>
</entryRelationship>
<entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
        <templateId root="2.16.840.1.113883.10.20.1.38"
assigningAuthorityName="CCD Age Observation"/>
        <code code="397659008" codeSystem="2.16.840.1.113883.6.96"
codeSystemName="SNOMEDCT" displayName="Age"/>
        <statusCode code="completed"/>
    </observation>
</entryRelationship>
</observation>
</entry>
</section>
</component>
</structuredBody>
</component>
</ClinicalDocument>

```

Figure 6: Problem Observation example

Episode Observation

[Observation: templateId 2.16.840.1.113883.10.20.1.41]

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

1. **SHALL** conform to [CDA Clinical Statement](#)
2. **SHALL** conform to [CDA Observation](#)
3. [CCD] **SHALL** contain [1..1] @classCode = "OBS" (CONF-170)
4. [CCD] **SHALL** contain [1..1] @moodCode = "EVN" (CONF-171)
5. [CCD] **SHOULD** contain [1..1] code/@code = "ASSERTION" (CodeSystem: 2.16.840.1.113883.5.4 ActCode STATIC V3NE08) (CONF-174)
6. [CCD] **SHALL** contain [1..1] statusCode/@code = "completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus STATIC V3NE08) (CONF-172, CONF-173)
7. [CCD] **SHOULD** contain [1..1] value/@code = "404684003" *Clinical finding* (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT STATIC), where its data type is CD (CONF-175)
8. [CCD] **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. [CCD] **SHALL** satisfy: Source of exactly one entryRelationship whose typeCode is 'SUBJ'. This is used to link the episode observation to the target problem act or social history observation. (CONF-176)

- [OCL]:

```

self.getEntryRelationshipTargets(vocab::x_ActRelationshipEntryRelationship::SUBJ,
ccd::ProblemAct)->size() = 1
or
self.getEntryRelationshipTargets(vocab::x_ActRelationshipEntryRelationship::SUBJ,
ccd::SocialHistoryObservation)->size() = 1

```

10. [CCD] **MAY** satisfy: Source of one or more entryRelationship whose typeCode is 'SAS'. The target of the entryRelationship **SHALL** be a problem act or social history observation. This is used to represent the temporal sequence of episodes. (CONF-177)

- [OCL]:

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

```
<?xml version="1.0" encoding="UTF-8"?>  
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"  
xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">  
  <component>  
    <structuredBody>  
      <component>  
        <section>  
          <entry>  
            <observation classCode="OBS" moodCode="EVN">  
              <templateId root="2.16.840.1.113883.10.20.1.41"  
assigningAuthorityName="CCD Episode Observation"/>  
              <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"  
codeSystemName="ActCode"/>  
              <statusCode code="completed"/>  
              <value xsi:type="CD"/>  
            </observation>  
          </entry>  
        </section>  
      </component>  
    </structuredBody>  
  </component>  
</ClinicalDocument>
```

Figure 7: Episode Observation example

Age Observation

[Observation: templateId 2.16.840.1.113883.10.20.1.38]

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

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

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

```

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

```

Figure 8: Age Observation example

Problem Status Observation

[Observation: templateId 2.16.840.1.113883.10.20.1.50]

1. **SHALL** conform to [CDA Clinical Statement](#)
2. **SHALL** conform to [CDA Observation](#)
3. **SHALL** conform to [Status Observation](#) template (templateId: 2.16.840.1.113883.10.20.1.57)
4. [CCD] **SHALL** contain [1..1] @classCode = "OBS" (CONF-510)
5. [CCD] **SHALL** contain [1..1] @moodCode = "EVN" (CONF-511)
6. [CCD] **SHALL** contain [1..1] code/@code = "33999-4" *Status* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC) (CONF-512, CONF-513)
7. [CCD] **SHALL** contain [1..1] statusCode/@code = "completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus STATIC V3NE08) (CONF-514, CONF-515)
8. [CCD] **SHALL** contain [1..1] value, which **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.20.13 ProblemStatusCode STATIC 20061017 (CONF-164)
9. [CCD] **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)
10. [CCD] **SHALL** satisfy: **SHALL NOT** contain any additional Observation attributes. (CONF-517)
11. [CCD] **SHALL** satisfy: **SHALL NOT** contain any Observation participants. (CONF-518)

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

12. [CCD] **SHALL** satisfy: **SHALL NOT** be the source of any Observation relationships. (CONF-519)

```

<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.57"
assigningAuthorityName="CCD Status Observation"/>
              <templateId root="2.16.840.1.113883.10.20.1.50"
assigningAuthorityName="CCD Problem Status Observation"/>
              <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Status"/>
              <statusCode code="completed"/>
              <value xsi:type="CE"/>
            </observation>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>

```

```

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

```

Figure 9: Problem Status Observation example

Problem Health Status Observation

[Observation: templateId 2.16.840.1.113883.10.20.1.51]

1. **SHALL** conform to [CDA Clinical Statement](#)
2. **SHALL** conform to [CDA Observation](#)
3. **SHALL** conform to [Status Observation](#) template (templateId: 2.16.840.1.113883.10.20.1.57)
4. [CCD] **SHALL** contain [1..1] @classCode = "OBS" (CONF-510)
5. [CCD] **SHALL** contain [1..1] @moodCode = "EVN" (CONF-511)
6. [CCD] **SHALL** contain [1..1] code/@code = "11323-3" *Health status* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC) (CONF-166)
7. [CCD] **SHALL** contain [1..1] statusCode/@code = "completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus STATIC V3NE08) (CONF-514, CONF-515)
8. [CCD] **SHALL** contain [1..1] value, which **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.20.12 ProblemHealthStatusCode STATIC 20061017 (CONF-167)
9. [CCD] **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)
10. [CCD] **SHALL** satisfy: **SHALL NOT** contain any additional Observation attributes. (CONF-517)
11. [CCD] **SHALL** satisfy: **SHALL NOT** contain any Observation participants. (CONF-518)
 - [OCL]: self.participant->isEmpty()
12. [CCD] **SHALL** satisfy: **SHALL NOT** be the source of any Observation relationships. (CONF-519)

```

<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
  xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.57"
                assigningAuthorityName="CCD Status Observation"/>
              <templateId root="2.16.840.1.113883.10.20.1.51"
                assigningAuthorityName="CCD Problem Health Status Observation"/>
              <code code="11323-3" codeSystem="2.16.840.1.113883.6.1"
                codeSystemName="LOINC" displayName="Health status"/>
              <statusCode code="completed"/>
              <value xsi:type="CE"/>
            </observation>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>

```

Figure 10: Problem Health Status Observation example