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.

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Revision History

Rev	Date	By Whom	Changes
New	Feb 2011	Dave Carlson	Draft for Working Group Review

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`]

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** conform to CDA Section
2. **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)
3. **SHALL** contain exactly one [1..1] **`title`** (CONF-143)
4. **SHALL** contain exactly one [1..1] **`text`** (CONF-140)
5. Contains at least one [1..*] **`entry`**, such that it
   a. **SHALL** contain *Condition* (templateId: `2.16.840.1.113883.3.88.11.83.7`)
6. **SHOULD** contain a case-insensitive language-insensitive string containing 'problems'. (CONF-144)

Problem List Section example

```
<section>
    <templateId root="2.16.840.1.113883.3.88.11.83.103"
                assigningAuthorityName="HITSP/C83"/>
    <templateId root="2.16.840.1.113883.10.20.1.11"
                assigningAuthorityName="HL7 CCD"/>
    <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.6"
                assigningAuthorityName="IHE PCC"/>
    <!-- SHALL [1..1] @ code=11450-4 CCD -141/142-->
    <code code="11450-4" displayName="Problems"
 codeSystem="2.16.840.1.113883.6.1"
        codeSystemName="LOINC"/>
    <!-- SHALL [1..1] title CCD -143-->
    <!-- CCD - 144 Not testable  -->
    <title>Problems</title>
    <!--SHALL [1..1] text CCD -140 -->
    <text>
        ...
    </text>
    <!-- SHOULD [0..*] CCD-140, ALL ENTRIES ARE SHOULD -->
    <entry typeCode="DRIV">
        <!-- SHALL [1..1]  be represented by an ACT CCD-145 -->
        <!-- SHALL [1..1] @ classCode="ACT" CCD-146-->
        <!-- SHALL [1..1] @ moodCode="EVN" CCD -147-->
        <act classCode="ACT" moodCode="EVN">
```

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 Observation
2. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF-226)
3. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF-227)
4. **SHALL** contain exactly one [1..1] **`code/@code`**`="397659008"` *Age* (CodeSystem: `2.16.840.1.113883.6.96 SNOMEDCT`) (CONF-228)
5. **SHALL** contain zero or one [0..1] **`statusCode/@code`**`="completed"` (CodeSystem: `2.16.840.1.113883.5.14 HL7ActStatus`) (CONF-229, CONF-230)
6. **SHALL** contain exactly one [1..1] **`value`** (CONF-231)
   - Valued using appropriate datatype.
7. **SHOULD** satisfy: subject/relatedSubject/subject contains exactly one birthTime (CONF-219)
8. **MAY** satisfy: subject/relatedSubject/subject contains exactly one sdtc:deceasedInd (CONF-220)
9. **MAY** satisfy: subject/relatedSubject/subject contains exactly one sdtc:deceasedTime (CONF-221)
10. **SHOULD** satisfy: The age of a relative at the time of observation is inferred by comparing subject/relatedSubject/subject/birthTime with effectiveTime (CONF-222)
11. **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="79301981-603f-4b33-820e-46d09258c6b9"/>
  <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>.

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

1. **SHALL** conform to CDA Act

2. **SHALL** contain exactly one [1..1] **`@classCode`**`="ACT"` *Act* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF-504)
3. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF-505)
4. **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)
5. **SHALL** contain exactly one [1..1] **`text`**
6. **SHALL** contain exactly one [1..1] **`statusCode/@code`**`="completed"` (CodeSystem: `2.16.840.1.113883.5.14 HL7ActStatus`) (CONF-6.3.4.6.8)
7. **MAY** contain zero or one [0..1] **`author`**, such that it
   a. **SHALL** contain CDA Author
8. Contains exactly one [1..1] **`author`**, such that it
   a. **SHALL** contain CDA Author
9. **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)
10. **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)
11. **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)
12. **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)
13. **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)
14. 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="1.3.6.1.4.1.19376.1.5.3.1.4.2"/>
  <id root="7904836e-db25-48dd-9d6f-030223ff1f52"/>
  <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** conform to CDA Act
2. **SHALL** contain exactly one [1..1] **`@classCode="ACT"`** *Act* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF-146)
3. **SHALL** contain exactly one [1..1] **`@moodCode="EVN"`** *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF-147)
4. **SHALL** contain at least one [1..*] **`id`** (CONF-148)
5. **SHALL** contain exactly one [1..1] **`code/@nullFlavor`** = "NA" *NA (not applicable)* (CONF-149)
6. **SHALL** contain exactly one [1..1] **`statusCode`**, which **SHALL** be selected from ValueSet `ConcernEntryStatus` **STATIC**
7. **SHALL** contain exactly one [1..1] **`effectiveTime`**
   - The effectiveTime element records the starting and ending times during which the concern was active.
8. **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)
9. 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`)
10. **SHALL** contain one or more entryRelationship (CONF-151)
11. 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. 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)
13. In Problem Section, a Problem Act **SHOULD** contain one or more Problem Observations. (CONF-140)
14. In Alert Section, a ProblemAct **SHOULD** contain one or more Alert Observations. (CONF-256)
15. **MAY** contain exactly one Patient Awareness (CONF-179)
16. 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.
17. 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'.
18. 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'.
19. 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])
20. 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])
21. 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

```
<entry typeCode="DRIV">
    <!-- SHALL [1..1]  be represented by an ACT CCD-145 -->
    <!-- SHALL [1..1] @ classCode="ACT" CCD-146-->
    <!-- SHALL [1..1] @ moodCode="EVN" CCD -147-->
    <act classCode="ACT" moodCode="EVN">
        <!-- SHOULD [0..*] templateId problem act CCD-140 -->
        <templateId root="2.16.840.1.113883.10.20.1.27"
                    assigningAuthorityName="HL7"/>
        <!-- SHALL [1..1] templateId HITSP Condition -->
        <templateId root="2.16.840.1.113883.3.88.11.83.7"
                    assigningAuthorityName="HITSP"/>
        <!-- SHALL [1..1] templateId IHE Problem Concern Entry -->
```

```
        <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.5.2"
                    assigningAuthorityName="IHE"/>
        <!-- SHALL [1..1] templateId IHE Concern Entry -->
        <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.5.1"
                    assigningAuthorityName="IHE"/>
        <!-- Problem act template -->
        <!-- SHALL [1..*] id CCD-148 -->
        <id root="6a2fa88d-4174-4909-aece-db44b60a3abb"/>
        <!-- SHALL [1..1]  actCode@null flavor = "NA" CCD-149-->
        <code nullFlavor="NA"/>

        <!-- <**> IHE PCC Requires status code with values: active, suspended,
 aborted or completed  IHE PCC-6.3.4.11.7-->
        <!--Proposed Consolidation Constraint:
            SHALL [1..1] statusCode
            SHALL [1..1] statusCode/@code from value set TEMP-OID-PROBLEM-
STATUS-CODE ProblemStatusCode   (values active, suspended, aborted or
 completed)-->
        <statusCode code="active"/>

        <!-- MAY [0..1]  act/effectiveTime CCD-150-->
        <!-- <**> SHALL [1..1] low element IHE PCC-6.3.4.11.7 -->
        <!-- SHALL [1..1] high elment if statusCode@code=completed or aborted
 IHE PCC-6.3.4.11.7-->
        <!--Proposed Consolidation Constraint:
            SHALL [1..1] low element
            SHALL [1..1] high elment if statusCode@code=completed or aborted
        -->
        <effectiveTime>
            <low value="1950"/>
        </effectiveTime>
        <!-- SHALL [1..*]  act/entryRelationship CCD-151-->
        <!-- MAY [0..1]  @typeCode="SUBJ" CCD-152-->
        <!-- SHOULD [0..1] CCD-153  The target of a problem act with
            Act / entryRelationship / @typeCode=”SUBJ” SHOULD be a problem
 observation -->
        <!-- in tdb: problem act template SHALL contain and
 [1..*]entryRelationship,
        MAY contain typeCode [0..1]SUBJ which SHOULD [0..1]problem observation
 template ID ..28
        (or whatever the new tid will be)-->
        <!-- <**> IHE Requires inversionInd=False  on template 20.1.4.5-->
        <entryRelationship typeCode="SUBJ" inversionInd="false">
            <!-- SHALL  [1..1] observation (Problem template) CCD-154-->
            <!-- SHALL  [1..1] @moodCode= "EVN" CCD-155-->
            <observation classCode="OBS" moodCode="EVN">
```

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. **SHALL** conform to CDA Observation
2. Contains exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
3. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF-155)
4. **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.
5. **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
6. **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.
7. **SHALL** contain exactly one [1..1] **`statusCode/@code`**`="completed"` (CodeSystem: `2.16.840.1.113883.5.14 HL7ActStatus`) (CONF-156, CONF-157)
8. **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).
9. **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
10. **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)
11. **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`)
12. **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`)
13. **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`)
14. **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`)
15. **SHALL** contain one or more sources of information. (CONF-161)
16. **MAY** contain exactly one Patient Awareness (CONF-180)
17. 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.
18. If entryRelationship / Comment is present, then entryRelationship **SHALL** include inversionInd = 'true'.
19. The onset date **SHALL** be recorded in the <low> element of the <effectiveTime> element when known. (C83-[DE-7.01-1])
20. The resolution data **SHALL** be recorded in the <high> element of the <effectiveTime> element when known. (C83-[DE-7.01-2])
21. 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

```
<entryRelationship typeCode="SUBJ" inversionInd="false">
    <!-- SHALL  [1..1] observation (Problem template) CCD-154-->
    <!-- SHALL  [1..1] @moodCode= "EVN" CCD-155-->
    <observation classCode="OBS" moodCode="EVN">
        <!-- SHOULD [0..*] CCD-140 A problem act contain problem templateId-->
        <templateId root="2.16.840.1.113883.10.20.1.28"/>
        <!--<**>  IHE PCC Problem Entry-->
        <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.5"
                    assigningAuthorityName="IHE PCC"/>
        <!-- Problem observation template -->
        <id root="d11275e7-67ae-11db-bd13-0800200c9a66"/>
        <!-- SHALL [1..1] code  MAY be selected from ValueSet
2.16.840.1.113883.1.11.20.14 ProblemTypeCode CCD-159-->
        <!-- SHALL [1..1] code and selected from C83 2.2.3.1.2 Problem Type
(HITSP 7.02) -->
        <code code="64572001" codeSystem="2.16.840.1.113883.6.96"
displayName="Condition"/>
        <!-- <**> SHALL [1..1] text HITSP HITSP/C83 Table 2-11, Data Element
7.03 and Section 2.2.2.7.4 -->
        <text>
            <!-- To be discussed on 2/22-SHALL contain @value pointing to
narrative text -->
            <reference value="ASTHMA"/>
        </text>
        <!-- SHALL [1..1]  statusCode = "completed"  CCD-156-->
        <!-- SHALL [1..1]  ActStatus = "STATIC" 2.16.840.1.113883.5.14 CCD-157
-->
        <statusCode code="completed"/>
        <!-- SHOULD [0..1] effectiveTime  CCD-158-->
        <effectiveTime>
            <low value="1950"/>
        </effectiveTime>
        <!-- SHALL [1..1] observationCode (CD)(Base CDA) -->
        <!-- MAY  [0..1] observationCode from valueSet
            2.16.840.1.113883.1.11.20.14 ProblemTypeCode CCD-159 -->
        <value xsi:type="CD" code="195967001"
            codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED"
            displayName="Asthma"/>

        <!-- MAY [0..1] entryRelationship of @TypeCode SUBJ containing
            (templateId 2.16.840.1.113883.10.20.1.38 age observation template
CCD-160
```

```
        -->
        <!--SHALL [1..1]  @typeCode SUBJ CCD-160-->
        <!--SHALL [1..1]  inversionInd="true" -->
        <entryRelationship typeCode="SUBJ" inversionInd="true">
            <!--SHALL [1..1]  @alassCode="OBS" CCD-226 -->
            <!--SHALL [1..1]  @moodCode="EVN" -->
            <observation classCode="OBS" moodCode="EVN">
                <!--SHALL [1..1] templateId CCD-227-->
                <!--SHALL [1..1] @root="2.16.840.1.113883.10.20.1.38"
CCD-225-->
                <templateId root="2.16.840.1.113883.10.20.1.38"/>
                <!--SHALL [1..1] @code="397659008" CCD-228-->
                <!--SHALL [1..1] @codeSystem="2.16.840.1.113883.6.96"
CCD-228-->
                <code code="397659008" codeSystem="2.16.840.1.113883.6.96"
displayName="Age"/>
                <!--SHALL [1..1] statusCode CCD-229-->
                <!--SHALL [1..1] @code="completed" CCD-230-->
                <statusCode code="completed"/>
                <!-- SHALL [1..1] value element CCD-231-->
                <value xsi:type="INT" value="57"/>
            </observation>
        </entryRelationship>
```

Episode Observation

[Observation: templateId `2.16.840.1.113883.10.20.1.41`]

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

1. **SHALL** conform to CDA Observation
2. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF-170)
3. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF-171)
4. **SHOULD** contain exactly one [1..1] **`code/@code`**`="ASSERTION"` (CodeSystem: `2.16.840.1.113883.5.4 HL7ActCode`) (CONF-174)
5. **SHALL** contain exactly one [1..1] **`statusCode/@code`**`="completed"` (CodeSystem: `2.16.840.1.113883.5.14 HL7ActStatus`) (CONF-172, CONF-173)
6. **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)
7. Value in an episode observation **SHOULD** be the following SNOMED CT expression: <codeblock><value xsi:type="CD" code="404684003" codeSystem="2.16.840.1.113883.6.96" displayName="Clinical finding"> <qualifier> <name code="246456000" displayName="Episodicity"/> <value code="288527008" displayName="New episode"/> </qualifier> </value></codeblock> (CONF-175)
8. **SHALL** satisfy: Source of exactly one entryRelationship whose typeCode is 'SUBJ'. This is used to link the episode observation to the target problem act or social history observation. (CONF-176)
9. 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="75b4ae94-5d37-47e0-8822-16d7f02a4aa4"/>
```

```
  <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>
```

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 Observation
2. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF-510)
3. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF-511)
4. **SHALL** contain exactly one [1..1] **`code/@code`**`="11323-3"` *Health status* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`) (CONF-166)
5. **SHALL** contain exactly one [1..1] **`text`**
6. **SHALL** contain exactly one [1..1] **`statusCode/@code`**`="completed"` (CodeSystem: `2.16.840.1.113883.5.14 HL7ActStatus`) (CONF-514, CONF-515)
7. **SHALL** contain exactly one [1..1] **`value`**, which **SHALL** be selected from ValueSet `HealthStatusValue` **STATIC**
8. Target of an entryRelationship whose value for "entryRelationship / @typeCode" **SHALL** be "REFR" 2.16.840.1.113883.5.1002 ActRelationshipType STATIC. (CONF-509)
9. **SHALL NOT** contain any additional Observation attributes. (CONF-517)
10. **SHALL NOT** contain any Observation participants. (CONF-518)
11. **SHALL NOT** be the source of any Observation relationships. (CONF-519)
12. 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="1.3.6.1.4.1.19376.1.5.3.1.4.1.2"/>
  <id root="8d1b8a22-a80b-45bb-b1c6-5fee70b1fe9c"/>
  <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 CDA Observation
2. **SHALL** contain exactly one [1..1] **@classCode**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) (CONF-510)
3. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) (CONF-511)
4. **SHALL** contain exactly one [1..1] **code/@code**="33999-4" *Status* (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF-512, CONF-513)
5. **SHALL** contain exactly one [1..1] **text**
6. **SHALL** contain exactly one [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) (CONF-514, CONF-515)
7. **SHALL** contain exactly one [1..1] **value**, which **SHALL** be selected from ValueSet ProblemStatusValue **STATIC**
8. Target of an entryRelationship whose value for "entryRelationship / @typeCode" **SHALL** be "REFR" 2.16.840.1.113883.5.1002 ActRelationshipType STATIC. (CONF-509)
9. **SHALL NOT** contain any additional Observation attributes. (CONF-517)
10. **SHALL NOT** contain any Observation participants. (CONF-518)
11. **SHALL NOT** be the source of any Observation relationships. (CONF-519)
12. 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="1.3.6.1.4.1.19376.1.5.3.1.4.1.1"/>
  <id root="3312dbf7-f325-4c05-8a77-d291eff6fa4b"/>
  <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>
```

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

5. **SHALL** contain exactly one [1..1] **`text`**
6. **SHALL** contain exactly one [1..1] **`statusCode/@code`**`="completed"` (CodeSystem: `2.16.840.1.113883.5.14 HL7ActStatus`) (CONF-291, CONF-292)
7. **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.
8. 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="f6882426-6309-414e-85d9-9c9c2f3c19c4"/>
  <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>
```

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	

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