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

PROTOTYPE: FOR DISCUSSION AND DEMONSTRATION USE ONLY

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Acknowledgments

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

This demonstration document contains informtion from the following sources:

Chapter 1

DOCUMENT TEMPLATES

Topics:

- *General Header Constraints*

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

General Header Constraints

[ClinicalDocument: templateId `2.16.840.1.113883.10.20.21.1.1`]

This section describes constraints that apply to CDA documents defined for general exchange in the US realm. The template defined here should be reused wherever these general header constraints are applied.

To support communication between the receiver of the document and the patient or any other person or organization mentioned within it, the elements representing them will be named.

When name, address, or telecom information is unknown and where these elements are required to be present, as with CDA conformance if the information is unknown, these elements will be represented using an appropriate value for the nullFlavor attribute on the element.

Events occurring at a single point in time that are represented in the Clinical Document header will in general be precise to the day. These point-in-time events are the time of creation of the document; the starting time of a participation by an author, data enterer, authenticator, or legal authenticator; or the starting and ending time of an encounter.

Within the specification, all telephone numbers are to be encoded using a grammar which is a restriction on the TEL data type and RFC 2806. It simplifies interchange between applications as it removes optional URL components found in RFC 2806 that applications typically do not know how to process, such as ISDN sub-address, phone context, or other dialing parameters.

Organizations that wish to use OIDs should properly register their OID root and ensure uniqueness of the OID roots used in identifiers. A large number of mechanisms exist for obtaining OID roots for free or for a reasonable fee. HL7 maintains an OID registry page from which organizations may request an OID root under the HL7 OID root. This page can be accessed at: http://www.hl7.org/oid.

Another useful resource lists the many ways to obtain a registered OID Root for free or a small fee anywhere in the world and is located at:

http://www.dclunie.com/medical-image-faq/html/part8.html#UIDRegistration.

The manner in which the OID root is obtained is not constrained by this DSTU.

There are constraints on templateId which are not included. The templateId SHALL NOT use `templateId.extension`. The templateId SHALL be a syntactically correct OID, REGEX (egrep syntax) "[0-2].[0-9](\.[0-9]+)+", the templateId SHALL include (several OIDS which the new template may or may not conform) 2.16.840.1.113883.10.20.3, 1.3.6.1.4.1.19376.1.5.3.1.1.1, and (presumably) 2.16.840.1.113883.10.20.1.

1. **SHALL** contain exactly one [1..1] **`realmCode/@code`**`="US"` (CONF-CONSOL-49)
2. **SHALL** contain exactly one [1..1] **`typeId`**, where its data type is II (CONF-CONSOL-51)
   - The clinical document type ID identifies the constraints imposed by CDA R2 on the content, essentially acting as a version identifier.

     This value is fixed to `root="2.16.840.1.113883.1.3" extension="POCD_HD000040"`
3. **SHALL** contain exactly one [1..1] **`id`** (CONF-CONSOL-47)
   - The ClinicalDocument/id element is an instance identifier data type (see HL7 Version 3 Abstract Data in Section 5 REFERENCES). The root attribute is a UUID or OID. The root uniquely identifies the scope of the extension. The root and extension attributes uniquely identify the document.
4. **SHALL** contain exactly one [1..1] **`code`** (CONF-CONSOL-45)
   - Specifies the type of the clinical document.
5. **SHALL** contain exactly one [1..1] **`title`** (CONF-CONSOL-50)
   - Specifies the local name used for the document. Note that the title does not need to be the same as the display name provided with the document type code. For example, the display name provided by LOINC® as an aid in debugging may be "HISTORY AND PHYSICAL." The title can be localized, as appropriate.
6. **SHALL** contain exactly one [1..1] **`effectiveTime`** (CONF-CONSOL-46)

- Specifies the creation time of the document. All documents authored by direct input to a computer system should record an effectiveTime that is precise to the second. When authored in other ways, for example, by filling out a paper form that is then transferred into an EHR system, the precision of effectiveTime may be less than to the second.

7. **SHALL** contain exactly one [1..1] **`confidentialityCode`**
   - Specifies the confidentiality assigned to the document. This specification provides no further guidance beyond CDA R2 on documents with respect to the vocabulary used for confidentialityCode, nor treatment or implementation of confidentiality.
8. **SHALL** contain exactly one [1..1] **`languageCode`** (CONF-CONSOL-48)
   - Each IG has a different method to constrain how the language code is to be expressed, including something which resembles regular expressions. All reference use of ISO 639-1 and ISO 3166.
9. Contains at least one [1..*] **`recordTarget`**, such that it
   a. **SHALL** contain CDA Record Target
10. Contains at least one [1..*] **`author`**, such that it
    a. **SHALL** contain CDA Author
    - The author element represents the creator of the clinical document. If the role of the actor is the entry of information from his or her own knowledge or application of skills, that actor is the author. If one actor provides information to another actor who filters, reasons, or algorithmically creates new information, then that second actor is also an author, having created information from his or her own knowledge or skills. However, that determination is independent from the determination of the first actor's authorship.
11. Contains exactly one [1..1] **`custodian`**, such that it
    a. **SHALL** contain CDA Custodian
    - Based on the CDA R2 constraints (Section 4.2.2.3 of the CDA Normative Web Edition. See Section 5 REFERENCES), the custodian element is required and is the custodian of the clinical document.
12. Contains exactly one [1..1] **`component`**, such that it
    a. **SHALL** contain CDA Component2
13. Contains zero or one [0..1] **`dataEnterer`**, such that it
    a. **SHALL** contain CDA Data Enterer
    - The dataEnterer element represents the person who transferred the information from other sources into the clinical document, where the other sources wrote the content of the note. The guiding rule of thumb is that an author provides the content found within the header or body of the document, subject to their own interpretation. The dataEnterer adds information to the electronic system. A person can participate as both author and dataEnterer.

      If the role of the actor is to transfer information from one source to another (e.g., transcription or transfer from paper form to electronic system), that actor is considered a dataEnterer.
14. Contains zero or one [0..1] **`informationRecipient`**, such that it
    a. **SHALL** contain CDA Information Recipient
    - informationRecipient, when used in the context of a referral or request for consultation, this records the intended recipient of the information at the time the document is created. The intended recipient may also be the health chart of the patient, in which case the receivedOrganization is the scoping organization of that chart.
15. Contains zero or one [0..1] **`legalAuthenticator`**, such that it
    a. **SHALL** contain CDA Legal Authenticator
    - The legalAuthenticator element identifies the legal authenticator of the document and must be present if the document has been legally authenticated. Based on local practice, clinical documents may be released before legal authentication. This implies that a clinical document that does not contain this element has not been legally authenticated.

The act of legal authentication requires a certain privilege be granted to the legal authenticator depending upon local policy. All clinical documents have the potential for legal authentication, given the appropriate credentials.

Local policies may choose to delegate the function of legal authentication to a device or system that generates the clinical document. In these cases, the legal authenticator is a person accepting responsibility for the document, not the generating device or system.

16. Contains zero or one [0..1] **`authenticator`**, such that it

    a. **SHALL** contain CDA Authenticator

    - The authenticator identifies the participant who attested to the accuracy of the information in the document.

      Automated systems, such as a PHR, that allow a clinical document to be generated need to give special consideration to authentication permissions because the information contained in the document may come from sources or contain information that the author cannot validate.

17. **SHALL** satisfy: All patient, guardianPerson, assignedPerson, maintainingPerson, relatedPerson, intendedRecipient/informationRecipient, associatedPerson, and relatedSubject/subject elements have a name. (CONF-CONSOL-1)

    - **`Person.name`** **SHALL** follow the convention of having each name part (e.g. given name, family name) represented as a discrete **`ENXP`**. These **SHALL** be in the same order which the name normally would be written. The name SHALL convey at least one **`EntityName.use`** `(SET<CS>)` drawn from `EntityNamePartQualifier` Concept Domain / Value Set (2.16.840.1.113883.1.11.15888) based on *`EntityNamePartQualifier`* HL7 code system (2.16.840.1.113883.5.43). In cases where the name has not been the full and legal name for the individual, (for example the patient changed their name when married, a "John Doe" name for a patient was retired after determining their actual identity) the **`EntityName.validTime`**`( IVL<TS>)` **SHOULD** be used. This is particularly useful in matching records after such name changes, and in cases such as emergency care and referalls using a health record summary such as the Continuity of Care Document (CCD).

      The other use case often encountered regards healthcare professionals, particularly physicians. Because of the importance of correctly indentifying an individual and linking them to their credendials (history of specialty and other certificiations), women (and less often, men) may change their names meaning the legal name now reflects taking on the family name of a spouse. Often a physician will keep their previous name for professional matters.

      The various parts of the name are captured and represented as **`EntityNamePart (ENXP)`** . The various parts of the name are represented with the name of the part, and **MAY** include the part type as an attribute, although it is redundant. Individual name parts **MAY** use **`EntityNamePart.qualifier`** `SET<CS>` drawn from Concept Domain / Value Set `EntityNamePartQualifier (2.16.840.1.113883.1.11.15888)` based upon the HL7 Code System *`EntityNamePartQualifier`* `(2.16.840.1.113883.5.43)` to clairify complex circumstance, such as use of a spouses name. In particular noting that a name part was given at the time of adoption (code ***`AD`***), birth (code ***`BR`***), and marrried name from a spouse (code ***`SP`***) can be particularly relevant.

      Finally, the name of the person **MAY** have the name as it should appear with proper spacing as the **`PersonName.formatted`** `ST`

18. **SHALL** satisfy: All patientRole, assignedAuthor, assignedEntity[not(parent::dataEnterer)] and associatedEntity elements have an addr and telecom element. (CONF-CONSOL-2)
19. **SHOULD** satisfy: All guardian, dataEnterer/assignedEntity, relatedEntity, intendedRecipient, relatedSubject and participantRole elements have an addr and telecom element. (CONF-CONSOL-3)
20. **SHALL** satisfy: All guardianOrganization, providerOrganization, wholeOrganization, representedOrganization, representedCustodianOrganization, receivedOrganization, scopingOrganization and serviceProviderOrganization elements have name, addr and telecom elements. (CONF-CONSOL-4)

    - When name, address, or telecom information is unknown nullFlavor = "UNK" or a specialization / subtype of unknown, (ASKU, NAV, NASK) drawn from the HL7 valueset 2.16.840.1.113883.1.11.10609 which uses HL7 code system NullFlavor 2.16.840.1.113883.5.1008.

21. Times or time intervals found in the ClinicalDocument/effectiveTime, author/time, dataEnterer/time, legalAuthenticator/time, authenticator/time and encompassingEncounter/effectiveTime elements **SHALL** be precise to the day, **SHALL** include a time zone if more precise than to the day, and **SHOULD** be precise to the minute. (CONF-CONSOL-5)
22. Times or time intervals found in the asOrganizationPartOf/effectiveTime, asMaintainedEntity/effectiveTime, relatedEntity/effectiveTime, serviceEvent/effectiveTime, ClinicalDocument/participant/time, serviceEvent/performer/time and encounterParticipant/time **SHALL** be precise at least to the year, **SHOULD** be precise to the day, and **MAY** omit time zone. (CONF-CONSOL-6)
23. **SHALL** satisfy: Telephone numbers match the regular expression pattern !FIXME! (CONF-CONSOL-7)

    - The telecom element is used to provide a contact telephone number for the various participants that require it. The value attribute ofthis elements is a URL that specifies the telephone number, as indicated by the TEL data type.

      All telephone numbers are to be encoded using a restricted form of the tel: URL scheme. A telephone number used for voice calls begins with the URL scheme tel:. If the number is a global phone number, it starts with a plus (+) sign. The remaining number is made up of the dialing digits and an optional extension and may also contain visual separators.

      Need to update REGEX to allow for extensions
24. **SHALL** satisfy: At least one dialing digit is present in the phone number after visual separators are removed. (CONF-CONSOL-8)
25. **SHALL** satisfy: If the telephone number is unknown it is represented using nullFlavor of UNK (CONF-CONSOL-9)

    - There is no way to distinguish between an unknown phone number and an unknown e-mail or other telecommunications address. Therefore, the following convention will be used: Any telecom element that uses a flavor of null (has a nullFlavor attribute) is assumed to be a telephone number, which is the only required telecommunications address element within this DSTU.
26. **SHALL** satisfy: The extension attribute of the typeId element is POCD_HD000040. (CONF-CONSOL-10)
27. **SHALL** satisfy: The id/@root attribute is a syntactically correct UUID or OID. (CONF-CONSOL-11)
28. **SHALL** satisfy: UUIDs are represented in the form XXXXXXXX-XXXX-XXXX-XXXXXXXXXXXXXXXX, where each X is a character from the set [A-Fa-f0-9]. UUIDs fit the REGEX ...[0-9a-fA-F] (CONF-CONSOL-12)
29. OIDs are represented in dotted decimal notation, where each decimal number is either 0, or starts with a nonzero digit. More formally, an OID **SHALL** be in the form ([0-2])(.([1-9][0-9]*|0))+. (CONF-CONSOL-13)

    - Organizations that wish to use OIDs should properly register their OID root and ensure uniqueness of the OID roots used in identifiers. A large number of mechanisms exist for obtaining OID roots for free or for a reasonable fee. HL7 maintains an OID registry page from which organizations may request an OID root under the HL7 OID root. This page can be accessed at: http://www.hl7.org/oid.

      Another useful resource lists the many ways to obtain a registered OID Root for free or a small fee anywhere in the world and is located at: http://www.dclunie.com/medical-image-faq/html/part8.html#UIDRegistration.

      The manner in which the OID root is obtained is not constrained by this DSTU.
30. **SHALL** satisfy: OIDs are no more than 64 characters in length. (CONF-CONSOL-14)

    - OIDs are limited by this specification to no more than 64 characters in length for compatibility with other standards and Implementation Guides.
31. **SHALL** satisfy: languageCode has the form nn, or nn-CC. (CONF-CONSOL-15)
32. **SHALL** satisfy: The nn portion of languageCode is a legal ISO-639-1 language code in lowercase. (CONF-CONSOL-16)
33. The CC portion languageCode, if present, **SHALL** be an ISO-3166 country code in uppercase. (CONF-CONSOL-17)
34. Both setId and versionNumber **SHALL** be present or both **SHALL** be absent. (CONF-CONSOL-18)

    - The ClinicalDocument/setId element uses the instance identifier (II) data type. The root attribute is a UUID or OID that uniquely identifies the scope of the identifier, and the extension attribute is a value that is unique within the scope of the root for the set of versions of the document. See Document Identification, Revisions,

and Addenda in Section 4.2.3.1 of the CDA Specification for some examples showing the use of the setId element.

35. The @extension and/or @root of setId and id **SHALL** be different when both are present. (CONF-CONSOL-19)
36. A copyTime element **SHALL NOT** be present. (CONF-CONSOL-20)

    - The ClinicalDocument/copyTime element has been deprecated in CDA R2.
37. **SHALL** satisfy: At least one recordTarget/patientRole element is present. (CONF-CONSOL-21)
38. A patient/birthTime element **SHALL** be present. The patient/birthTime element **SHALL** be precise at least to the year, and **SHOULD** be precise at least to the day, and **MAY** omit time zone. If unknown, it **SHALL** be represented using a flavor of null. (CONF-CONSOL-22)
39. A patient/administrativeGenderCode element **SHALL** be present. If unknown, it **SHALL** be represented using a flavor of null. Values for administrativeGenderCode **SHOULD** be drawn from the HL7 AdministrativeGender vocabulary. (CONF-CONSOL-23)

    - TODO: add OCL test for terminology
40. The maritalStatusCode, religiousAffiliationCode, raceCode and ethnicGroupCode **MAY** be present. If maritalStatusCode, religiousAffiliationCode, raceCode and ethnicGroupCode elements are present, they **SHOULD** be encoded using the appropriate HL7 vocabularies. (CONF-CONSOL-24)
41. **SHOULD** satisfy: The guardian element is present when the patient is a minor child. (CONF-CONSOL-25)
42. **MAY** satisfy: The providerOrganization element is present. (CONF-CONSOL-26)
43. **SHALL** satisfy: The author/time element is present. (CONF-CONSOL-27)

    - The author/time element represents the start time of the author's participation in the creation of the clinical document.
44. **SHALL** satisfy: The assignedAuthor/id element is present. (CONF-CONSOL-28)
45. **SHALL** satisfy: An assignedAuthor element contains at least one assignedPerson or assignedAuthoringDevice elements. (CONF-CONSOL-29)
46. **SHALL** satisfy: When dataEnterer is present, an assignedEntity/assignedPerson element is present. (CONF-CONSOL-30)
47. The dataEnterer/time element **MAY** be present. If present, it represents the starting time of entry of the data. (CONF-CONSOL-31)
48. **MAY** satisfy: The informant element is present. (CONF-CONSOL-32)
49. When informant is present, an assignedEntity/assignedPerson or relatedEntity/relatedPerson element **SHALL** be present. (CONF-CONSOL-33)
50. When the informant is a healthcare provider with an assigned role, the informant **SHALL** be represented using the assignedEntity element (CONF-CONSOL-34)

    - Assigned health care providers may be a source of information when a document is created. (e.g., a nurse's aide who provides information about a recent significant health care event that occurred within an acute care facility.) In these cases, the assignedEntity element is used.
    - TODO: how to determin if informant is a healthcare provider? condition for implementing OCL
51. Allowable values for informant/relatedEntity/@classCode **SHALL** be CON, PRS, CAREGIVER, AGNT or PROV from the RoleClass vocabulary. (CONF-CONSOL-35)

    - When the informant is a personal relation, that informant is represented in the relatedEntity element. The code element of the relatedEntity describes the relationship between the informant and the patient.

      The relationship between the informant and the patient needs to be described to help the receiver of the clinical document understand the information in the document.
52. When relatedEntity/@classCode is PRS, values in relatedEntity/code **SHALL** come from the HL7 PersonalRelationshipRoleType vocabulary or from SNOMED, any subtype of "Person in the family" (303071001). (CONF-CONSOL-36)
53. When an informant is an unrelated person not otherwise specified, the value relatedEntity/@classCode **SHALL** be set to CON to indicate that this person is a contact. (CONF-CONSOL-37)

    - Individuals with no prior personal relationship to the patient (e.g., a witness to a significant health care event) may provide information about the patient.

54. When the informant is a healthcare provider without an assigned role, the informant **SHALL** be represented using the relatedEntity element and the value of relatedEntity/@classCode **SHALL** be set to PROV. (CONF-CONSOL-38)

- A health care provider who does not have an assigned role at the institution may provide information. To record an informant that does not have an assigned role that can be represented within the context of the document, the information will be represented using the relatedEntity element and the value of relatedEntity/@classCode will be set to PROV.

55. When the informant is a healthcare provider, the value of relatedEntity/code **SHOULD** be present and indicate the type of healthcare provider. (CONF-CONSOL-39)

56. The ClinicalDocument/informationRecipient element **MAY** be present. When informationRecipient is used, at least one informationRecipient/intendedRecipient/informationRecipient or informationRecipient/intendedRecipient/receivedOrganization **SHALL** be present. (CONF-CONSOL-40)

57. The assignedEntity/assignedPerson element **SHALL** be present in legalAuthenticator. (CONF-CONSOL-41)

58. The assignedEntity/assignedPerson element **SHALL** be present in an authenticator element. (CONF-CONSOL-42)

59. Times or time intervals found in the ClinicalDocument/effectiveTime, author/time, dataEnterer/time, legalAuthenticator/time, authenticator/time and encompassingEncounter/effectiveTime elements **SHALL** be precise to the day, **SHALL** include a time zone if more precise than to the day, and **SHOULD** be precise to the minute. (CONF-CONSOL-43)

- If time is more precise than to day, it SHALL contain the offset from UTC (time zone information)

60. Times or time intervals found in the asOrganizationPartOf/effectiveTime, asMaintainedEntity/effectiveTime, relatedEntity/effectiveTime, serviceEvent/effectiveTime, ClinicalDocument/participant/time, serviceEvent/performer/time and encounterParticipant/time **SHALL** be precise at least to the year, **SHOULD** be precise to the day, and **MAY** omit time zone if only precise to day, month, or year. (CONF-CONSOL-44)

General Header Constraints 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">
  <realmCode code="US"/>
  <templateId root="2.16.840.1.113883.10.20.3"/>
  <id root="2667f561-9742-4179-bbba-fb65d9dcb05e"/>
  <code/>
  <title/>
  <effectiveTime/>
  <confidentialityCode/>
  <languageCode/>
</ClinicalDocument>
```

Chapter 2

SECTION TEMPLATES

Topics:

- *Diagnostic Results Section*
- *Problem List Section*
- *Vital Signs Section*

Diagnostic Results Section

[Section: templateId `2.16.840.1.113883.3.88.11.83.122`]

This section contains the results of observations generated by laboratories, imaging procedures, and other procedures. The scope includes hematology, chemistry, serology, virology, toxicology, microbiology, plain x-ray, ultrasound, CT, MRI, angiography, cardiac echo, nuclear medicine, pathology, and procedure observations. The section may contain all results for the period of time being summarized, but should include notable results such as abnormal values or relevant trends.

Lab results are typically generated by laboratories providing analytic services in areas such as chemistry, hematology, serology, histology, cytology, anatomic pathology, microbiology, and/or virology. These observations are based on analysis of specimens obtained from the patient, submitted to the lab.

Imaging results are typically generated by a clinician reviewing the output of an imaging procedure, such as where a cardiologist reports the left ventricular ejection fraction based on the review of a cardiac echo.

Procedure results are typically generated by a clinician wanting to provide more granular information about component observations made during the performance of a procedure, such as where a gastroenterologist reports the size of a polyp observed during a colonoscopy.

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

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

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

Diagnostic Results Section example

```
<?xml version="1.0" encoding="UTF-8"?>
<section xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-
org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <templateId root="2.16.840.1.113883.3.88.11.83.122"/>
  <id root="f180c8c9-25ed-47e8-94c6-6d4c326916cf"/>
  <code code="30954-2" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="STUDIES SUMMARY"/>
  <title>STUDIES SUMMARY</title>
  <entry>
    <organizer moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.1.32"/>
      <id root="3159e43a-8433-4388-8f22-dd75afa8ba63"/>
      <effectiveTime>
        <low value="2011"/>
        <high value="2011"/>
      </effectiveTime>
      <component>
        <observation moodCode="EVN">
          <templateId root="2.16.840.1.113883.3.88.11.83.15"/>
          <id root="6ca15982-da7f-4a8e-a6e5-7a4ccf96c093"/>
```

```
          <effectiveTime>
            <low value="2011"/>
            <high value="2011"/>
          </effectiveTime>
        </observation>
      </component>
    </organizer>
  </entry>
  <entry>
    <act classCode="ACT" moodCode="EVN">
      <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.4"/>
      <id root="c628f2f6-9771-44fd-abde-eac385c1bc15"/>
      <effectiveTime>
        <low value="2011"/>
        <high value="2011"/>
      </effectiveTime>
    </act>
  </entry>
  <entry>
    <observation moodCode="EVN">
      <templateId root="2.16.840.1.113883.3.88.11.83.15"/>
      <id root="d95bb5ef-ba50-4674-9ecd-ebf5fea66369"/>
      <effectiveTime>
        <low value="2011"/>
        <high value="2011"/>
      </effectiveTime>
    </observation>
  </entry>
</section>
```

Problem List Section

[Section: templateId `2.16.840.1.113883.3.88.11.83.103`]

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

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

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

1. **SHALL** contain exactly one [1..1] **`code/@code`**`="11450-4"` *Problem list* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`) (CONF-141, CONF-142)
2. **SHALL** contain exactly one [1..1] **`title`** (CONF-143)
3. **SHALL** contain exactly one [1..1] **`text`** (CONF-140)
4. Contains at least one [1..*] **`entry`**, such that it
   a. **SHALL** contain *Condition* (templateId: `2.16.840.1.113883.3.88.11.83.7`)
5. **SHOULD** contain a case-insensitive language-insensitive string containing 'problems'. (CONF-144)

Problem List Section example

```
<?xml version="1.0" encoding="UTF-8"?>
<section xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-
org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <templateId root="2.16.840.1.113883.3.88.11.83.103"/>
  <id root="2b8b9750-b48e-4f6e-ba39-62765282f5a6"/>
  <code code="11450-4" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="Problem list"/>
  <title>Problem list</title>
  <entry>
    <act classCode="ACT" moodCode="EVN">
      <templateId root="2.16.840.1.113883.3.88.11.83.7"/>
```

```
      <id root="d628b0d9-ee56-49d9-9600-b456491b12ec"/>
      <code nullFlavor="NA"/>
      <effectiveTime>
        <low value="2011"/>
        <high value="2011"/>
      </effectiveTime>
      <entryRelationship>
        <observation classCode="OBS" moodCode="EVN">
          <templateId root="2.16.840.1.113883.10.20.1.41"/>
          <id root="5f9a7da3-564e-4be2-a129-f9cf783d125f"/>
          <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"
codeSystemName="HL7ActCode"/>
          <statusCode code="completed"/>
          <effectiveTime>
            <low value="2011"/>
            <high value="2011"/>
          </effectiveTime>
        </observation>
      </entryRelationship>
      <entryRelationship>
        <observation classCode="OBS" moodCode="EVN">
          <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.5"/>
          <id root="066433d8-1400-4211-99f7-13ae9f8705d5"/>
          <code codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMEDCT"/
>
          <statusCode code="completed"/>
          <effectiveTime>
            <low value="2011"/>
            <high value="2011"/>
          </effectiveTime>
          <entryRelationship>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.38"/>
              <id root="a8bb2719-973a-44c6-8c48-bcfda8a237d5"/>
              <code code="397659008" codeSystem="2.16.840.1.113883.6.96"
codeSystemName="SNOMEDCT" displayName="Age"/>
              <statusCode code="completed"/>
              <effectiveTime>
                <low value="2011"/>
                <high value="2011"/>
              </effectiveTime>
            </observation>
          </entryRelationship>
          <entryRelationship>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.1"/>
              <id root="258a0d0d-8d73-4b51-bb31-afea7f4e8d82"/>
              <code code="SEV" codeSystem="2.16.840.1.113883.5.4"
codeSystemName="HL7ActCode" displayName="Severity observation"/>
              <statusCode code="completed"/>
              <effectiveTime>
                <low value="2011"/>
                <high value="2011"/>
              </effectiveTime>
            </observation>
          </entryRelationship>
          <entryRelationship>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.57"/>
              <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.1.1"/>
              <id root="9591be24-cab8-4817-af60-aa62bd84e57d"/>
              <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Status"/>
              <statusCode code="completed"/>
```

```
              <effectiveTime>
                <low value="2011"/>
                <high value="2011"/>
              </effectiveTime>
            </observation>
          </entryRelationship>
          <entryRelationship>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.57"/>
              <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.1.2"/>
              <id root="5f40ffcd-1998-40a8-867c-14c8f332e9e6"/>
              <code code="11323-3" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Health status"/>
              <statusCode code="completed"/>
              <effectiveTime>
                <low value="2011"/>
                <high value="2011"/>
              </effectiveTime>
            </observation>
          </entryRelationship>
          <entryRelationship>
            <act classCode="ACT" moodCode="EVN">
              <templateId root="2.16.840.1.113883.3.88.11.83.11"/>
              <id root="fab7e9d6-47a6-402b-a82e-51c7eb83c1a1"/>
              <code code="48767-8" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Annotation comment"/>
              <statusCode code="completed"/>
              <effectiveTime>
                <low value="2011"/>
                <high value="2011"/>
              </effectiveTime>
            </act>
          </entryRelationship>
        </observation>
      </entryRelationship>
    </act>
  </entry>
</section>
```

Vital Signs Section

[Section: templateId `2.16.840.1.113883.3.88.11.83.119`]

This section contains current and historically relevant vital signs, such as blood pressure, heart rate, respiratory rate, height, weight, body mass index, head circumference, crown-to-rump length, and pulse oximetry. The section may contain all vital signs for the period of time being summarized, but at a minimum should include notable vital signs such as the most recent, maximum and/or minimum, or both, baseline, or relevant trends.

Vital signs are represented like other results (as defined in ***Results Section***) with additional vocabulary constraints, but are aggregated into their own section in order to follow clinical conventions.

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

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

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

1. **SHALL** contain exactly one [1..1] **`code/@code`**`="8716-3"` *Vital signs* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`) (CONF-382, CONF-383)
2. **SHALL** contain exactly one [1..1] **`title`** (CONF-384)
3. **SHALL** contain exactly one [1..1] **`text`** (CONF-381)
4. **SHALL** contain at least one [1..*] **`entry`**, such that it

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

Vital Signs Section example

```
<?xml version="1.0" encoding="UTF-8"?>
<section xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-
org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <templateId root="2.16.840.1.113883.3.88.11.83.119"/>
  <id root="96af48f6-b68e-4dd5-ba9a-bb3edc8a3f48"/>
  <code code="8716-3" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="Vital signs"/>
  <title>Vital signs</title>
  <entry>
    <organizer classCode="CLUSTER" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.1.32"/>
      <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.13.1"/>
      <id root="79b657ff-81f8-4684-91ae-7e144ab76b0f"/>
      <code code="46680005" codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMEDCT" displayName="Vital signs"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2011"/>
        <high value="2011"/>
      </effectiveTime>
      <component>
        <observation moodCode="EVN">
          <templateId root="2.16.840.1.113883.3.88.11.83.15"/>
          <id root="2be2f0f5-8c08-4028-8abc-21024d50f195"/>
          <effectiveTime>
            <low value="2011"/>
            <high value="2011"/>
          </effectiveTime>
        </observation>
      </component>
      <component>
        <observation moodCode="EVN">
          <templateId root="2.16.840.1.113883.3.88.11.83.15"/>
          <templateId root="2.16.840.1.113883.3.88.11.83.14"/>
          <id root="1932bd0c-7cdc-498a-b938-bedf707c9789"/>
          <code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
          <effectiveTime>
            <low value="2011"/>
            <high value="2011"/>
          </effectiveTime>
        </observation>
      </component>
    </organizer>
  </entry>
</section>
```

Chapter 3

CLINICAL STATEMENT TEMPLATES

Topics:

- *Age Observation*
- *Comment*
- *Condition*
- *Condition Entry*
- *Episode Observation*
- *External Reference*
- *Health Status Observation*
- *Problem Status Observation*
- *Result*
- *Result Organizer*
- *Severity*
- *Status Observation*
- *Vital Sign*
- *Vital Signs Organizer*

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

Age Observation

[Observation: templateId `2.16.840.1.113883.10.20.1.38`]

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

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF-226)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF-227)
3. **SHALL** contain exactly one [1..1] **`code/@code`**`="397659008"` *Age* (CodeSystem: `2.16.840.1.113883.6.96 SNOMEDCT`) (CONF-228)
4. **SHALL** contain zero or one [0..1] **`statusCode/@code`**`="completed"` (CodeSystem: `2.16.840.1.113883.5.14 HL7ActStatus`) (CONF-229, CONF-230)
5. **SHALL** contain exactly one [1..1] **`value`** (CONF-231)
   - Valued using appropriate datatype.
6. **SHOULD** satisfy: subject/relatedSubject/subject contains exactly one birthTime (CONF-219)
7. **MAY** satisfy: subject/relatedSubject/subject contains exactly one sdtc:deceasedInd (CONF-220)
8. **MAY** satisfy: subject/relatedSubject/subject contains exactly one sdtc:deceasedTime (CONF-221)
9. **SHOULD** satisfy: The age of a relative at the time of observation is inferred by comparing subject/relatedSubject/subject/birthTime with effectiveTime (CONF-222)
10. **MAY** satisfy: The age of a relative at the time of death is inferred by comparing subject/relatedSubject/subject/birthTime with subject/relatedSubject/subject/sdtc:deceasedTime. (CONF-223)

Age Observation example

```
<?xml version="1.0" encoding="UTF-8"?>
<observation xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.1.38"/>
  <id root="88f31221-cadf-491d-b593-658c6576a94a"/>
  <code code="397659008" codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMEDCT" displayName="Age"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
</observation>
```

Comment

[Act: templateId `2.16.840.1.113883.3.88.11.83.11`]

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

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

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

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

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

2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF-505)
3. **SHALL** contain exactly one [1..1] **`code/@code`**`="48767-8"` *Annotation comment* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`) (CONF-506, CONF-507)
4. **SHALL** contain exactly one [1..1] **`text`**
5. **SHALL** contain exactly one [1..1] **`statusCode/@code`**`="completed"` (CodeSystem: `2.16.840.1.113883.5.14 HL7ActStatus`) (CONF-6.3.4.6.8)
6. **MAY** contain zero or one [0..1] **`author`**, such that it
   a. **SHALL** contain CDA Author
7. Contains exactly one [1..1] **`author`**, such that it
   a. **SHALL** contain CDA Author
8. **SHALL** satisfy: A related statement is made about another section or entry. In CDA the former shall be recorded inside an <entryRelationship> element occurring at the end of the entry. The containing entry is the subject (typeCode='SUBJ') of this comment, which is the inverse of the normal containment structure, thus inversionInd='true'. (CONF-6.3.4.6.3)
9. **SHALL** satisfy: The 'text' element contains a 'reference' element pointing to the narrative text section of the CDA, rather than duplicate text to avoid ambiguity. (CONF-6.3.4.6.7)
10. **SHALL** satisfy: The time of the comment creation is recorded in the 'time' element when the 'author' element is present. (CONF-6.3.4.6.10)
11. **SHALL** satisfy: The identifier of the author, and their address and telephone number must be present inside the 'id', 'addr' and 'telecom' elements when the 'author' element is present. (CONF-6.3.4.6.11)
12. **SHALL** satisfy: The author's and/or the organization's name must be present when the 'author' element is present. (CONF-6.3.4.6.12)
13. Data elements defined elsewhere in the specification **SHALL NOT** be recorded using the Comments Module. (C83-[DE-10-CDA-1])
    - Comments are free text data that cannot otherwise be recorded using data elements already defined by this specification. They are not to be used to record information that can be recorded elsewhere. For example, a free text description of the severity of an allergic reaction would not be recorded in a comment. Instead, it would be recorded using the data element defined in Allergy/Drug Sensitivity.

Comment example

```
<?xml version="1.0" encoding="UTF-8"?>
<act xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-
org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd" classCode="ACT"
 moodCode="EVN">
  <templateId root="2.16.840.1.113883.3.88.11.83.11"/>
  <id root="2f0fb6c6-7981-4e69-aeac-fcca5c64be5a"/>
  <code code="48767-8" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="Annotation comment"/>
  <text/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
</act>
```

Condition

[Act: templateId `2.16.840.1.113883.3.88.11.83.7`]

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

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

1. **SHALL** contain exactly one [1..1] **`@classCode="ACT"`** *Act* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF-146)
2. **SHALL** contain exactly one [1..1] **`@moodCode="EVN"`** *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF-147)
3. **SHALL** contain at least one [1..*] **`id`** (CONF-148)
4. **SHALL** contain exactly one [1..1] **`code`**`/@nullFlavor` = "NA" *NA (not applicable)* (CONF-149)
5. **SHALL** contain exactly one [1..1] **`statusCode`**, which **SHALL** be selected from ValueSet `ConcernEntryStatus` **STATIC**
6. **SHALL** contain exactly one [1..1] **`effectiveTime`**
   - The effectiveTime element records the starting and ending times during which the concern was active.
7. **MAY** contain exactly one [1..1] **`entryRelationship`**, such that it
   a. **SHALL** contain *Episode Observation* (templateId: `2.16.840.1.113883.10.20.1.41`) (CONF-168)
8. Contains at least one [1..*] **`entryRelationship`**, such that it
   a. **SHALL** contain *Condition Entry* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.5`)
9. **SHALL** contain one or more entryRelationship (CONF-151)
10. A problem act **MAY** reference a problem observation, alert observation (see section Alerts) or other clinical statement that is the subject of concern, by setting the value for "Act / entryRelationship / @typeCode" to be "SUBJ" 2.16.840.1.113883.5.1002 ActRelationshipType STATIC. (CONF-152)
11. The target of a problem act with Act / entryRelationship / @typeCode="SUBJ" **SHOULD** be a problem observation (in the Problem section) or alert observation (in the Alert section), but **MAY** be some other clinical statement. (CONF-153)
12. In Problem Section, a Problem Act **SHOULD** contain one or more Problem Observations. (CONF-140)
13. In Alert Section, a ProblemAct **SHOULD** contain one or more Alert Observations. (CONF-256)
14. **MAY** contain exactly one Patient Awareness (CONF-179)
15. The effectiveTime 'low' element **SHALL** be present. The 'high' element **SHALL** be present for concerns in the completed or aborted state, and **SHALL NOT** be present otherwise.
16. Each concern is about one or more related problems or allergies. This entry **SHALL** contain one or more problem or allergy entries that conform to the specification in section Problem Entry or Allergies and Intolerances. This is how a series of related observations can be grouped as a single concern. This **SHALL** be represented using entryRelationship with typeCode = 'SUBJ'.
17. Each concern **MAY** have 0 or more related references. These **MAY** be used to represent related statements such related visits. This **MAY** be any valid CDA clinical statement, and **SHOULD** be an IHE entry template. This **SHALL** be represented using entryRelationship with typeCode = 'REFR'.
18. The treating provider or providers **SHALL** be recorded in a <performer> element under the <act> that describes the condition of concern (C83-[DE-7.05-CDA-3])
19. The identifier of the treating provider **SHALL** be present in the <id> element beneath the <assignedEntity>. This identifier **SHALL** be the identifier of one of the providers listed in the healthcare providers module. (C83-[DE-7.05-CDA-2])
20. The time over which this provider treated the condition **MAY** be recorded in the <time> element beneath the <performer> element (C83-[DE-7.05-CDA-1])

Condition example

```
<?xml version="1.0" encoding="UTF-8"?>
<act xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-
org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd" classCode="ACT"
 moodCode="EVN">
  <templateId root="2.16.840.1.113883.3.88.11.83.7"/>
  <id root="9d0dd18a-476a-46f4-ba76-a7b6baf56423"/>
  <code nullFlavor="NA"/>
  <statusCode/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
```

```
     <templateId root="2.16.840.1.113883.10.20.1.41"/>
     <id root="731be3ec-d7c7-435f-bb02-913de3bc21e4"/>
     <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"
codeSystemName="HL7ActCode"/>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2011"/>
       <high value="2011"/>
     </effectiveTime>
   </observation>
 </entryRelationship>
 <entryRelationship>
   <observation classCode="OBS" moodCode="EVN">
     <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.5"/>
     <id root="d4ac63d4-918d-485f-b510-6a67c91a2fc4"/>
     <code codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMEDCT"/>
     <statusCode code="completed"/>
     <effectiveTime>
       <low value="2011"/>
       <high value="2011"/>
     </effectiveTime>
     <entryRelationship>
       <observation classCode="OBS" moodCode="EVN">
         <templateId root="2.16.840.1.113883.10.20.1.38"/>
         <id root="e721b5f1-a903-435c-883c-9375d99145d1"/>
         <code code="397659008" codeSystem="2.16.840.1.113883.6.96"
codeSystemName="SNOMEDCT" displayName="Age"/>
         <statusCode code="completed"/>
         <effectiveTime>
           <low value="2011"/>
           <high value="2011"/>
         </effectiveTime>
       </observation>
     </entryRelationship>
     <entryRelationship>
       <observation classCode="OBS" moodCode="EVN">
         <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.1"/>
         <id root="04bd7481-532a-47fb-963c-ecd0ab44a0b5"/>
         <code code="SEV" codeSystem="2.16.840.1.113883.5.4"
codeSystemName="HL7ActCode" displayName="Severity observation"/>
         <statusCode code="completed"/>
         <effectiveTime>
           <low value="2011"/>
           <high value="2011"/>
         </effectiveTime>
       </observation>
     </entryRelationship>
     <entryRelationship>
       <observation classCode="OBS" moodCode="EVN">
         <templateId root="2.16.840.1.113883.10.20.1.57"/>
         <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.1.1"/>
         <id root="19cb7dac-43fb-43b8-8c4b-6a979b3882d1"/>
         <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Status"/>
         <statusCode code="completed"/>
         <effectiveTime>
           <low value="2011"/>
           <high value="2011"/>
         </effectiveTime>
       </observation>
     </entryRelationship>
     <entryRelationship>
       <observation classCode="OBS" moodCode="EVN">
         <templateId root="2.16.840.1.113883.10.20.1.57"/>
```

```
          <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.1.2"/>
          <id root="a630b1ba-7411-4761-9182-baccd4483d46"/>
          <code code="11323-3" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Health status"/>
          <statusCode code="completed"/>
          <effectiveTime>
            <low value="2011"/>
            <high value="2011"/>
          </effectiveTime>
        </observation>
      </entryRelationship>
      <entryRelationship>
        <act classCode="ACT" moodCode="EVN">
          <templateId root="2.16.840.1.113883.3.88.11.83.11"/>
          <id root="4369acc4-a132-4f31-8d88-b772b96d5cef"/>
          <code code="48767-8" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Annotation comment"/>
          <statusCode code="completed"/>
          <effectiveTime>
            <low value="2011"/>
            <high value="2011"/>
          </effectiveTime>
        </act>
      </entryRelationship>
    </observation>
  </entryRelationship>
</act>
```

Condition Entry

[Observation: templateId `1.3.6.1.4.1.19376.1.5.3.1.4.5`]

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

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

1. Contains exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF-155)
3. **SHALL** contain at least one [1..*] **`id`**
   - The specific observation being recorded must have an identifier (<id>) that shall be provided for tracking purposes. If the source EMR does not or cannot supply an intrinsic identifier, then a GUID shall be provided as the root, with no extension (e.g., <id root='CE1215CD-69EC-4C7B-805F-569233C5E159'/>). At least one identifier must be present, more than one may appear.
4. **SHOULD** contain exactly one [1..1] **`code`**, which **SHOULD** be selected from ValueSet `2.16.840.1.113883.3.88.12.3221.7.2 Problem Type` **STATIC** 1
5. **SHALL** contain exactly one [1..1] **`text`**

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

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

Condition Entry example

```
<?xml version="1.0" encoding="UTF-8"?>
<observation xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 classCode="OBS" moodCode="EVN">
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.5"/>
  <id root="ef03a7d2-1ec4-4504-9a6b-6331ca018c27"/>
  <code codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMEDCT"/>
  <text/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.1.38"/>
      <id root="5b43cc94-6f00-4dab-8a29-5acd05b1b453"/>
      <code code="397659008" codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMEDCT" displayName="Age"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2011"/>
        <high value="2011"/>
      </effectiveTime>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.1"/>
      <id root="07bd9d6d-8852-4143-b492-a87dcddcdd00"/>
      <code code="SEV" codeSystem="2.16.840.1.113883.5.4"
 codeSystemName="HL7ActCode" displayName="Severity observation"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2011"/>
        <high value="2011"/>
      </effectiveTime>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.1.57"/>
      <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.1.1"/>
      <id root="92859780-ef91-4ac8-9573-136869be9744"/>
      <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="Status"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2011"/>
        <high value="2011"/>
      </effectiveTime>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.1.57"/>
      <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.1.2"/>
      <id root="d173ef8a-bd2f-4a14-83a6-88d76fd285f9"/>
      <code code="11323-3" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="Health status"/>
      <statusCode code="completed"/>
      <effectiveTime>
```

```
        <low value="2011"/>
        <high value="2011"/>
      </effectiveTime>
    </observation>
  </entryRelationship>
  <entryRelationship>
    <act classCode="ACT" moodCode="EVN">
      <templateId root="2.16.840.1.113883.3.88.11.83.11"/>
      <id root="6650032f-d40e-4e1d-bae0-5f0049391141"/>
      <code code="48767-8" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="Annotation comment"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2011"/>
        <high value="2011"/>
      </effectiveTime>
    </act>
  </entryRelationship>
</observation>
```

Episode Observation

[Observation: templateId `2.16.840.1.113883.10.20.1.41`]

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

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF-170)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF-171)
3. **SHOULD** contain exactly one [1..1] **`code/@code`**`="ASSERTION"` (CodeSystem: `2.16.840.1.113883.5.4 HL7ActCode`) (CONF-174)
4. **SHALL** contain exactly one [1..1] **`statusCode/@code`**`="completed"` (CodeSystem: `2.16.840.1.113883.5.14 HL7ActStatus`) (CONF-172, CONF-173)
5. **SHOULD** contain exactly one [1..1] **`value/@code`**`="404684003"` *Clinical finding* (CodeSystem: `2.16.840.1.113883.6.96 SNOMEDCT`), where its data type is CD (CONF-175)
6. Value in an episode observation **SHOULD** be the following SNOMED CT expression: <codeblock><value xsi:type="CD" code="404684003" codeSystem="2.16.840.1.113883.6.96" displayName="Clinical finding"> <qualifier> <name code="246456000" displayName="Episodicity"/> <value code="288527008" displayName="New episode"/> </qualifier> </value></codeblock> (CONF-175)
7. **SHALL** satisfy: Source of exactly one entryRelationship whose typeCode is 'SUBJ'. This is used to link the episode observation to the target problem act or social history observation. (CONF-176)
8. Source of one or more entryRelationship whose typeCode is 'SAS'. The target of the entryRelationship **SHALL** be a problem act or social history observation. This is used to represent the temporal sequence of episodes. (CONF-177)

Episode Observation example

```
<?xml version="1.0" encoding="UTF-8"?>
<observation xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.1.41"/>
  <id root="ac025325-b4d7-42ea-8a75-dcb4be2f859b"/>
  <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"
 codeSystemName="HL7ActCode"/>
  <statusCode code="completed"/>
  <effectiveTime>
```

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

External Reference

[Act: templateId `1.3.6.1.4.1.19376.1.5.3.1.4.4`]

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

External Reference example

```
<?xml version="1.0" encoding="UTF-8"?>
<act xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-
org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd" classCode="ACT"
 moodCode="EVN">
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.4"/>
  <id root="12d0ece2-8ec0-440a-a4fe-74d73333214d"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
</act>
```

Health Status Observation

[Observation: templateId `1.3.6.1.4.1.19376.1.5.3.1.4.1.2`]

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

1. **SHALL** conform to *Status Observation* template (templateId: `2.16.840.1.113883.10.20.1.57`)
2. **SHALL** contain exactly one [1..1] **`code/@code`**`="11323-3"` *Health status* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`) (CONF-166)
3. **SHALL** contain exactly one [1..1] **`value`**, which **SHALL** be selected from ValueSet `HealthStatusValue` **STATIC**
4. **SHALL** contain exactly one [1..1] **`text`**
5. The 'text' elements **SHALL** contain a 'reference' element pointing to the narrative where the severity is recorded, rather than duplicate text to avoid ambiguity.

Health Status Observation example

```
<?xml version="1.0" encoding="UTF-8"?>
<observation xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.1.57"/>
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.1.2"/>
  <id root="3d4bc754-1501-4d42-aff4-3feb48667ca9"/>
  <code code="11323-3" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="Health status"/>
  <text/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
```

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

Problem Status Observation

[Observation: templateId `1.3.6.1.4.1.19376.1.5.3.1.4.1.1`]

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

1. **SHALL** conform to *Status Observation* template (templateId: `2.16.840.1.113883.10.20.1.57`)
2. **SHALL** contain exactly one [1..1] **`value`**, which **SHALL** be selected from ValueSet `ProblemStatusValue` **STATIC**
3. **SHALL** contain exactly one [1..1] **`text`**
4. The 'text' elements **SHALL** contain a 'reference' element pointing to the narrative where the severity is recorded, rather than duplicate text to avoid ambiguity.

Problem Status Observation example

```
<?xml version="1.0" encoding="UTF-8"?>
<observation xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.1.57"/>
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.1.1"/>
  <id root="d155def3-0787-49f9-960e-94e90991f1c0"/>
  <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="Status"/>
  <text/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
</observation>
```

Result

[Observation: templateId `2.16.840.1.113883.3.88.11.83.15`]

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

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

1. Contains exactly one [1..1] **`@classCode`**
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF-408)
3. **SHALL** contain at least one [1..*] **`id`** (CONF-409)
4. **SHALL** contain exactly one [1..1] **`code`**
5. **SHALL** contain exactly one [1..1] **`statusCode`** (CONF-410)
6. **SHALL** contain exactly one [1..1] **`effectiveTime`**
7. **SHALL** contain exactly one [1..1] **`value`**
   - The Result value records the desired result in a goal or recorded event, and will not present when recording an intent, request or proposal to measure a result.

8. **SHOULD** contain zero or more [0..*] **`interpretationCode`** (CONF-418)
   - Can be used to provide a rough qualitative interpretation of the observation, such as 'N' (normal), 'L' (low), 'S' (susceptible), etc. Interpretation is generally provided for numeric results where an interpretation range has been defined, or for antimicrobial susceptibility test interpretation.
9. **MAY** contain zero or one [0..1] **`methodCode`** (CONF-414)
   - Included if the method isn't inherent in code or if there is a need to further specialize the method in code.
10. The value for 'code' **SHOULD** be selected from LOINC (codeSystem 2.16.840.1.113883.6.1) or SNOMED CT (codeSystem 2.16.840.1.113883.6.96), and **MAY** be selected from CPT-4 (codeSystem 2.16.840.1.113883.6.12). (CONF-413)
11. The methodCode **SHALL NOT** conflict with the method inherent in code (CONF-415)
12. Where value is a physical quantity, the unit of measure **SHALL** be expressed using a valid Unified Code for Units of Measure (UCUM) expression. (CONF-417)
13. **SHOULD** satisfy: Contain one or more referenceRange to show the normal range of values for the observation result (CONF-419)
14. **SHALL NOT** contain referenceRange / observationRange / code, as this attribute is not used by the HL7 Clinical Statement or Lab Committee models. (CONF-420)
15. **SHALL** satisfy: Contains one or more sources of information. (CONF-421)
16. Result Type **SHOULD** be selected from LOINC (codeSystem 2.16.840.1.113883.6.1) or SNOMED CT (codeSystem 2.16.840.1.113883.6.96) (C154-[DE-15.03-1])
17. Result Type for laboratory results **SHOULD** be coded as specified in HITSP/C80 Section 2.2.3.6.1 Laboratory Observations. (C154-[DE-15.03-2])
18. Result Value **SHALL** be present when the observation/@moodCode is EVN or GOL, and **SHALL NOT** be present when observation/@moodCode is INT or PRP. (C83-[DE-15.05-CDA-1])

Result example

```
<?xml version="1.0" encoding="UTF-8"?>
<observation xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 moodCode="EVN">
  <templateId root="2.16.840.1.113883.3.88.11.83.15"/>
  <id root="766d1c5d-9130-4176-84d5-80eb1a93caff"/>
  <code/>
  <statusCode/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
  <interpretationCode/>
  <methodCode/>
</observation>
```

Result Organizer

[Organizer: templateId `2.16.840.1.113883.10.20.1.32`]

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

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

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

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

Result Organizer example

```
<?xml version="1.0" encoding="UTF-8"?>
<organizer xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.1.32"/>
  <id root="24d7f85c-6e62-48dc-ac45-e4ba63ec8501"/>
  <code/>
  <statusCode/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
  <component>
    <observation moodCode="EVN">
      <templateId root="2.16.840.1.113883.3.88.11.83.15"/>
      <id root="7e0d5ae2-c4c0-4cf9-97de-810c0c754734"/>
      <effectiveTime>
        <low value="2011"/>
        <high value="2011"/>
      </effectiveTime>
    </observation>
  </component>
</organizer>
```

Severity

[Observation: templateId `1.3.6.1.4.1.19376.1.5.3.1.4.1`]

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

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF-289)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF-290)
3. **SHALL** contain exactly one [1..1] **`code/@code`**`="SEV"` *Severity observation* (CodeSystem: `2.16.840.1.113883.5.4 HL7ActCode`) (CONF-293, CONF-294)
4. **SHALL** contain exactly one [1..1] **`text`**
5. **SHALL** contain exactly one [1..1] **`statusCode/@code`**`="completed"` (CodeSystem: `2.16.840.1.113883.5.14 HL7ActStatus`) (CONF-291, CONF-292)
6. **SHALL** contain exactly one [1..1] **`value`**, which **SHALL** be selected from ValueSet `SeverityObservation` **STATIC**, where its data type is CD
   - Value code representing high, moderate and low severity depending upon whether the severity is life threatening, presents noticeable adverse consequences, or is unlikely substantially effect the situation of the subject.
7. The 'text' elements **SHALL** contain a 'reference' element pointing to the narrative where the severity is recorded, rather than duplicate text to avoid ambiguity.

Severity example

```
<?xml version="1.0" encoding="UTF-8"?>
<observation xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 classCode="OBS" moodCode="EVN">
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.1"/>
  <id root="56826fe6-1481-42c3-ab0d-7aaa54f7872a"/>
  <code code="SEV" codeSystem="2.16.840.1.113883.5.4"
 codeSystemName="HL7ActCode" displayName="Severity observation"/>
  <text/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
</observation>
```

Status Observation

[Observation: templateId `2.16.840.1.113883.10.20.1.57`]

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

Status Observation example

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

```
<observation xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.1.57"/>
  <id root="3500c1cd-7a14-4845-aaac-cc56ec545291"/>
  <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="Status"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
</observation>
```

Vital Sign

[Observation: templateId `2.16.840.1.113883.3.88.11.83.14`]

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

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

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

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

Vital Sign example

```
<?xml version="1.0" encoding="UTF-8"?>
<observation xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 moodCode="EVN">
  <templateId root="2.16.840.1.113883.3.88.11.83.15"/>
  <templateId root="2.16.840.1.113883.3.88.11.83.14"/>
  <id root="f96c8603-06eb-4b00-9a26-a5284596be53"/>
  <code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
  <statusCode/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
```

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

Vital Signs Organizer

[Organizer: templateId `1.3.6.1.4.1.19376.1.5.3.1.4.13.1`]

A vital signs organizer collects vital signs observations.

1. **SHALL** conform to *Result Organizer* template (templateId: `2.16.840.1.113883.10.20.1.32`)
2. **SHALL** contain exactly one [1..1] **`@classCode`**`="CLUSTER"` (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (6.3.4.21.2)
   - The vital signs organizer is a cluster of vital signs observations.
3. **SHALL** contain exactly one [1..1] **`code/@code`**`="46680005"` *Vital signs* (CodeSystem: `2.16.840.1.113883.6.96 SNOMEDCT`) (6.3.4.21.5)
4. **SHALL** contain exactly one [1..1] **`effectiveTime`** (6.3.4.21.7)
   - The effective time element shall be present to indicate when the measurement was taken.
5. **SHALL** contain exactly one [1..1] **`statusCode/@code`**`="completed"` (CodeSystem: `2.16.840.1.113883.5.14 HL7ActStatus`) (6.3.4.21.6)
   - The observations have all been completed.
6. **SHALL** contain exactly one [1..1] **`id`** (6.3.4.21.4)
   - The organizer shall have an <id> element.
7. Contains at least one [1..*] **`component`**, such that it
   a. **SHALL** contain *Vital Sign* (templateId: `2.16.840.1.113883.3.88.11.83.14`)
8. Contains exactly one [1..1] **`author`**, such that it
   a. **SHALL** contain CDA Author
9. **SHALL** satisfy: Contains one or more sources of information. (CONF-387)
   - A vital signs organizer SHALL contain one or more sources of information, as defined in section ***Source***.
10. **SHALL** satisfy: ccd::ResultOrganizer template ID (2.16.840.1.113883.10.20.1.32) is included (6.3.4.21.3)

Vital Signs Organizer example

```
<?xml version="1.0" encoding="UTF-8"?>
<organizer xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 classCode="CLUSTER" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.1.32"/>
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.13.1"/>
  <id root="3b8ff0c6-25d7-4b57-8477-e57456208fa1"/>
  <code code="46680005" codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMEDCT" displayName="Vital signs"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
  <component>
    <observation moodCode="EVN">
      <templateId root="2.16.840.1.113883.3.88.11.83.15"/>
      <id root="242ab015-2551-483e-ae46-5c7df4fb1bbe"/>
      <effectiveTime>
        <low value="2011"/>
        <high value="2011"/>
```

```
      </effectiveTime>
    </observation>
  </component>
  <component>
    <observation moodCode="EVN">
      <templateId root="2.16.840.1.113883.3.88.11.83.15"/>
      <templateId root="2.16.840.1.113883.3.88.11.83.14"/>
      <id root="ec32986e-0b2d-41b5-abb6-3f68862ea042"/>
      <code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
      <effectiveTime>
        <low value="2011"/>
        <high value="2011"/>
      </effectiveTime>
    </observation>
  </component>
</organizer>
```

Chapter 4

OTHER CLASSES

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

Chapter 5

VALUE SETS

Topics:

- *Concern Entry Status*
- *Health Status Value*
- *Problem Type*
- *Problem*
- *Problem Status Value*
- *Severity Observation*
- *Vital Sign Result*

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

Concern Entry Status

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

Concept Code	Concept Name	Code System	Description
active			
suspended			
aborted			
completed			

Health Status Value

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

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

Problem Type

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

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

Problem

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

Problem Status Value

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

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

Severity Observation

Value Set	SeverityObservation - (OID not specified)

Code System	SeverityObservation - 2.16.840.1.113883.5.1063

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

Vital Sign Result

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

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

REFERENCES

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