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

PROTOTYPE: FOR DISCUSSION AND DEMONSTRATION USE ONLY

Contents

Acknowledgments

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

This demonstration document contains informtion from the following sources:

Chapter 1

DOCUMENT TEMPLATES

Topics:

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

General Header Constraints

[ClinicalDocument: templateId `2.16.840.1.113883.10.20.21.1.1`]

This template 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. Contains zero or one [0..1] **`setId`**
   a. 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.

   b. The @extension and/or @root of setId and id **SHALL** be different when both are present. (CONF-CONSOL-19)
3. **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"`

   a. **SHALL** satisfy: The extension attribute of the typeId element is POCD_HD000040. (CONF-CONSOL-10)
4. **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.

a. **SHALL** satisfy: The id/@root attribute is a syntactically correct UUID or OID. (CONF-CONSOL-11)

5. **SHALL** contain exactly one [1..1] **`code`** (CONF-CONSOL-45)

- Specifies the type of the clinical document.

6. **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.

7. **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.

8. **SHALL** contain exactly one [1..1] **`confidentialityCode`** (CONF-CONSOL-558)

- 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.

9. **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.

a. **SHALL** satisfy: languageCode has the form nn, or nn-CC. (CONF-CONSOL-15)

b. **SHALL** satisfy: The nn portion of languageCode is a legal ISO-639-1 language code in lowercase. (CONF-CONSOL-16)

c. The CC portion languageCode, if present, **SHALL** be an ISO-3166 country code in uppercase. (CONF-CONSOL-17)

10. Contains at least one [1..*] **`recordTarget`**, such that

a. **SHALL** satisfy: At least one recordTarget/patientRole element is present. (CONF-CONSOL-21)

b. 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)

c. 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)

d. **SHOULD** satisfy: The guardian element is present when the patient is a minor child. (CONF-CONSOL-25)

e. **MAY** satisfy: The providerOrganization element is present. (CONF-CONSOL-26)

11. Contains at least one [1..*] **`author`**, such that

- 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.

a. **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.

b. **SHALL** satisfy: The assignedAuthor/id element is present. (CONF-CONSOL-28)

c. **SHALL** satisfy: An assignedAuthor element contains at least one assignedPerson or assignedAuthoringDevice elements. (CONF-CONSOL-29)

12. Contains zero or one [0..1] **`dataEnterer`**, such that

- 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.

a. **SHALL** satisfy: When dataEnterer is present, an assignedEntity/assignedPerson element is present. (CONF-CONSOL-30)

b. The dataEnterer/time element **MAY** be present. If present, it represents the starting time of entry of the data. (CONF-CONSOL-31)

13. Contains zero or one [0..1] **`informant`**, such that

a. **MAY** satisfy: The informant element is present. (CONF-CONSOL-32)

b. When informant is present, an assignedEntity/assignedPerson or relatedEntity/relatedPerson element **SHALL** be present. (CONF-CONSOL-33)

c. 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.

d. 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.

e. 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)

f. 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.

g. 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.

h. 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)

14. Contains exactly one [1..1] **`custodian`**, such that

- 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.

15. Contains zero or one [0..1] **`informationRecipient`**, such that

- 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.

a. 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)

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

- 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.

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

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

- 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.

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

18. Contains exactly one [1..1] **`component`**, such that

19. **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

20. **SHALL** satisfy: All patientRole, assignedAuthor, assignedEntity[not(parent::dataEnterer)] and associatedEntity elements have an addr and telecom element. (CONF-CONSOL-2)
21. **SHOULD** satisfy: All guardian, dataEnterer/assignedEntity, relatedEntity, intendedRecipient, relatedSubject and participantRole elements have an addr and telecom element. (CONF-CONSOL-3)
22. **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.

23. 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)
24. 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)
25. **SHALL** satisfy: Telephone numbers match the regular expression pattern "tel:\\+?[-0-9().]+(;ext=[0-9]+|)" (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.

26. **SHALL** satisfy: At least one dialing digit is present in the phone number after visual separators are removed. (CONF-CONSOL-8)
27. **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.

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. A copyTime element **SHALL NOT** be present. (CONF-CONSOL-20)

    - The ClinicalDocument/copyTime element has been deprecated in CDA R2.

32. 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)

33. 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)

34. 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

Chapter 2

SECTION TEMPLATES

Topics:

Diagnostic Results Narrative Section

[Section: templateId `2.16.840.1.113883.10.20.21.2.3`]

1. **SHALL** contain exactly one [1..1] **`code/@code`**`="30954-2"` *STUDIES SUMMARY* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`) (CONF-CONSOL-559)
2. **SHOULD** satisfy: Contains a case-insensitive language-insensitive string containing 'results'. (CONF-392)

Diagnostic Results Narrative Section example

Diagnostic Results Section

[Section: templateId `2.16.840.1.113883.10.20.21.2.3.1`]

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** conform to *Diagnostic Results Narrative Section* template (templateId: `2.16.840.1.113883.10.20.21.2.3`)
2. **SHOULD** contain at least one [1..*] **`entry`** (CONF-388), such that
   a. Contains exactly one [1..1] *Result Organizer* (templateId: `2.16.840.1.113883.10.20.21.4.1`)
3. **SHOULD** contain at least one [1..*] **`entry`** (CONF-CONSOL-550), such that
   a. Contains exactly one [1..1] *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
   a. Contains exactly one [1..1] *Result* (templateId: `2.16.840.1.113883.10.20.21.4.2`)

Diagnostic Results Section example

Immunizations Narrative Section

[Section: templateId `2.16.840.1.113883.10.20.21.2.2`]

1. **SHALL** contain exactly one [1..1] **`code/@code`**`="11369-6"` *History of immunizations* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`) (CONF-377)

2. **SHALL** contain exactly one [1..1] **`title`** (CONF-379)
3. **SHALL** contain exactly one [1..1] **`text`** (CONF-376)
4. **SHOULD** satisfy: Contains a case-insensitive language-insensitive string containing 'immunization'. (CONF-380)

Immunizations Narrative Section example

Immunizations Section

[Section: templateId `2.16.840.1.113883.10.20.21.2.2.1`]

The Immunizations section defines a patient's current immunization status and pertinent immunization history. The primary use case for the Immunization section is to enable communication of a patient's immunization status. The section should include current immunization status, and may contain the entire immunization history that is relevant to the period of time being summarized.

This section is optional, however it is strongly recommended that it be present in cases of pediatric care and in other cases when such information is available.

The immunizations section shall contain a narrative description of the immunizations administered to the patient in the past. It shall include entries for medication administration as described in the Entry Content Modules.

The Immunizations Section contains information describing the immunizations administered to the patient.

1. **SHALL** conform to *Immunizations Narrative Section* template (templateId: `2.16.840.1.113883.10.20.21.2.2`)
2. Contains at least one [1..*] **`entry`**, such that
   a. Contains exactly one [1..1] *Immunization* (templateId: `2.16.840.1.113883.3.88.11.83.13`)

Immunizations Section example

Medications Narrative Section

[Section: templateId `2.16.840.1.113883.10.20.21.2.1`]

1. **SHALL** contain exactly one [1..1] **`code/@code`**`="10160-0"` *History of medication use* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`) (CONF-300, CONF-301)
2. **SHALL** contain exactly one [1..1] **`title`** (CONF-302)
   a. **SHOULD** satisfy: Valued with a case-insensitive language-insensitive string containing 'medication'. (CONF-303)
3. **SHALL** contain zero or one [0..1] **`text`** (CONF-298)

Medications Narrative Section example

Medications Section

[Section: templateId `2.16.840.1.113883.10.20.21.2.1.1`]

The Medications section defines a patient's current medications and pertinent medication history. At a minimum, the currently active medications should be listed, with an entire medication history as an option, particularly when the summary document is used for comprehensive data export. The section may also include a patient's prescription history, and enables the determination of the source of a medication list (e.g. from a pharmacy system vs. from the patient).

Reconciliation of conflicting medication information from various sources is enabled both by indicating the source of information and by indicating whether the source is reporting intended or actual medication use. For instance, a physician may intend for a patient to be on a particular dose, but the patient may actually be taking a different

dose; a pharmacy may fill a prescription for a particular dose only to then have the patient's physician lower the dose without notifying the pharmacy. Therefore, medication and supply activities can be expressed in CCD in either the "EVN" (event) mood or the "INT" (intent) mood. Medication activities in "INT" mood are not orders (which are represented in the Plan of Care section), but rather are reflections of what a clinician intends a patient to be taking. Medication activities in "EVN" mood reflect actual use. A pharmacy system will typically report what was actually filled (supply event), along with intended use (substance administration intent). A physician will often report intended use (substance administration and supply intent). A patient or family member will typically report actual use (substance administration event).

1. **SHALL** conform to *Medications Narrative Section* template (templateId: `2.16.840.1.113883.10.20.21.2.1`)
2. **SHOULD** contain zero or more [0..*] **`entry`** (CONF-298), such that
   a. Contains exactly one [1..1] *Medication Order Information* (templateId: `2.16.840.1.113883.3.88.11.83.8.3`)
3. Contains at least one [1..*] **`entry`**, such that
   a. Contains exactly one [1..1] *Medication* (templateId: `2.16.840.1.113883.3.88.11.83.8`)
4. **SHOULD** satisfy: Clinical statements include one or more Medication Activity and/or one or more Supply Activity. (CONF-298)
5. **SHALL** satisfy: The absence of known medications is explicitly asserted. (CONF-299)
6. **SHALL** satisfy: Contains one dosing template to identify this as a particular type of medication event. Possible dosing templates: 1.3.6.1.4.1.19376.1.5.3.1.4.7.1 Normal Dosing, 1.3.6.1.4.1.19376.1.5.3.1.4.8, Tapered Dosing, 1.3.6.1.4.1.19376.1.5.3.1.4.9 Split Dosing, 1.3.6.1.4.1.19376.1.5.3.1.4.10 Conditional Dosing, 1.3.6.1.4.1.19376.1.5.3.1.4.11 Combination Dosing.
   - There are a variety of special cases for dosing that need to be accounted for. Most of these special cases involve changing the dosage or frequency over time, or based on some measurement. When the dosage changes, then additional entries are required for each differing dosage.
7. **MAY** satisfy: contains one or more related components (<entryRelationship typeCode='COMP'>, either to handle split, tapered or conditional dosing, or to support combination medications.
   - In the first three cases, the subordinate components shall specify only the changed <frequency> and/or <doseAmount> elements. For conditional dosing, each subordinate component shall have a <precondition> element that specifies the <observation> that must be obtained before administration of the dose. The value of the <sequenceNumber> shall be an ordinal number, starting at 1 for the first component, and increasing by 1 for each subsequent component. Components shall be sent in <sequenceNumber> order.

Medications Section example

Problem List Narrative Section

[Section: templateId `2.16.840.1.113883.10.20.21.2.5`]

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)

Problem List Narrative Section example

Problem List Section

[Section: templateId `2.16.840.1.113883.10.20.21.2.5.1`]

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 *Problem List Narrative Section* template (templateId: `2.16.840.1.113883.10.20.21.2.5`)
2. **SHALL** contain at least one [1..*] **`entry`** (CONF-CONSOL-549), such that
   a. Contains exactly one [1..1] *Condition* (templateId: `2.16.840.1.113883.10.20.21.4.3`)
3. **SHOULD** contain a case-insensitive language-insensitive string containing 'problems'. (CONF-144)

Problem List Section example

Vital Signs Narrative Section

[Section: templateId `2.16.840.1.113883.10.20.21.2.4`]

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. **SHOULD** satisfy: title Contains a case-insensitive language-insensitive string containing 'vital signs'. (CONF-385)

Vital Signs Narrative Section example

Vital Signs Section

[Section: templateId `2.16.840.1.113883.10.20.21.2.4.1`]

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.

1. **SHALL** conform to *Vital Signs Narrative Section* template (templateId: `2.16.840.1.113883.10.20.21.2.4`)
2. **SHALL** contain at least one [1..*] **`entry`** (6.3.3.4.5), such that
   a. Contains exactly one [1..1] *Vital Signs Organizer* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.13.1`)

Vital Signs Section example

Chapter 3

CLINICAL STATEMENT TEMPLATES

Topics:

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

Age Observation

[Observation: templateId `2.16.840.1.113883.10.20.1.38`]

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

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

Age Observation example

Comment

[Act: templateId `2.16.840.1.113883.10.20.21.4.10`]

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`** (CONF-CONSOL-547)
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`** (CONF-CONSOL-548), such that
7. Contains exactly one [1..1] **`author`**, such that
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

Condition

[Act: templateId `2.16.840.1.113883.10.20.21.4.3`]

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 `TEMP-OID-PROBLEM-STATUS-CODE ConcernEntryStatus` **STATIC** (CONF-CONSOL-525)
6. **SHALL** contain exactly one [1..1] **`effectiveTime`** (CONF-CONSOL-526)

   - The effectiveTime element records the starting and ending times during which the concern was active.

   a. **SHALL** contain exactly one [1..1] effectiveTime/low element (CONF-CONSOL-520)
   b. **SHALL** contain exactly one [1..1] effectiveTime/high element if statusCode@code=completed or aborted (CONF-CONSOL-521)
   c. **SHALL NOT** contain effectiveTime/high element if statusCode@code=active or suspended (CONF-CONSOL-522)
7. Contains zero or more [0..*] **`performer`**, such that

   a. 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])
   b. 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])
   c. 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])
8. Contains zero or more [0..*] **`entryRelationship`**, such that

   a. Contains exactly one [1..1] *Condition Entry* (templateId: `2.16.840.1.113883.10.20.21.4.4`)
9. **MAY** contain exactly one [1..1] **`entryRelationship`** (CONF-168), such that
   a. Contains exactly one [1..1] *Episode Observation* (templateId: `2.16.840.1.113883.10.20.1.41`)
10. Contains zero or more [0..*] **`entryRelationship`**, such that
   a. A Condition **MAY** reference a Condition Entry, Alert Observation (see section Alerts) or other clinical statement that is the subject of concern, by setting the value for entryRelationship/@typeCode to be "SUBJ" 2.16.840.1.113883.5.1002 ActRelationshipType. (CONF-152)
   b. The target of a Condition with entryRelationship/@typeCode="SUBJ" **SHOULD** be a Condition Entry (in the Problem section) or alert observation (in the Alert section), but **MAY** be some other clinical statement. (CONF-153)
   c. In Problem Section, a Condition **SHOULD** contain one or more Condition Entries (CONF-140)
   d. In Alert Section, a Condition **SHOULD** contain one or more Alert Observations. (CONF-256)
   e. 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'. (CONF-CONSOL-523)
   f. 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'. (CONF-CONSOL-524)
11. **MAY** contain exactly one Patient Awareness template (CONF-179)

Condition example

Condition Entry

[Observation: templateId `2.16.840.1.113883.10.20.21.4.4`]

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`**
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`** (CONF-CONSOL-529)
   - 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 (CONF-CONSOL-530)

5. **SHALL** contain exactly one [1..1] **`text`** (CONF-CONSOL-531)
   - 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.
   a. 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. (CONF-CONSOL-527)
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`** (CONF-CONSOL-532)
   - 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).
   a. The onset date **SHALL** be recorded in the <low> element of the <effectiveTime> element when known. (C83-[DE-7.01-1])
   b. The resolution data **SHALL** be recorded in the <high> element of the <effectiveTime> element when known. (C83-[DE-7.01-2])
   c. 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])
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 (CONF-CONSOL-533)
9. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF-160), such that
   a. Contains **`@typeCode="`**`SUBJ"` *SUBJ (has subject)*
   b. Contains exactly one [1..1] *Age Observation* (templateId: `2.16.840.1.113883.10.20.1.38`)
10. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF-CONSOL-534), such that
    a. Contains exactly one [1..1] *Severity* (templateId: `2.16.840.1.113883.10.20.21.4.8`)
11. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF-CONSOL-535), such that
    a. Contains **`@typeCode="`**`REFR"` *REFR (refers to)*
    b. Contains exactly one [1..1] *Problem Status Observation* (templateId: `2.16.840.1.113883.10.20.21.4.6`)
12. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF-CONSOL-536), such that
    a. Contains **`@typeCode="`**`REFR"` *REFR (refers to)*
    b. Contains exactly one [1..1] *Health Status Observation* (templateId: `2.16.840.1.113883.10.20.21.4.5`)
13. **MAY** contain zero or more [0..*] **`entryRelationship`** (CONF-CONSOL-537), such that
    a. Contains **`@typeCode="`**`SUBJ"` *SUBJ (has subject)*
    b. Contains exactly one [1..1] *Comment* (templateId: `2.16.840.1.113883.10.20.21.4.10`)

14. **SHALL** contain one or more sources of information. (CONF-161)
15. **MAY** contain exactly one Patient Awareness (CONF-180)
16. If entryRelationship / Comment is present, then entryRelationship **SHALL** include inversionInd = 'true'. (CONF-CONSOL-528)

Condition Entry example

Episode Observation

[Observation: templateId `2.16.840.1.113883.10.20.1.41`]

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

1. **SHALL** 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

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`) (CONF-CONSOL-554)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF-CONSOL-555)
3. Contains exactly one [1..1] **`code`**

External Reference example

Health Status Observation

[Observation: templateId `2.16.840.1.113883.10.20.21.4.5`]

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** (CONF-CONSOL-545)
4. **SHALL** contain exactly one [1..1] **`text`** (CONF-CONSOL-546)
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. (CONF-CONSOL-544)

Health Status Observation example

Immunization

[SubstanceAdministration: templateId `2.16.840.1.113883.3.88.11.83.13`]

1. **SHALL** conform to *Medication* template (templateId: `2.16.840.1.113883.3.88.11.83.8`)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (6.3.4.17.2)
3. **SHALL** contain zero or one [0..1] **`code`** (CodeSystem: `2.16.840.1.113883.12.292 Vaccines administered (CVX)`)
4. Contains zero or more [0..*] **`approachSiteCode`**
   - The site where the medication is administered, usually used with IV or topical drugs. The <approachSiteCode> element describes the site of medication administrion. It may be coded to a controlled vocabulary that lists such sites (e.g., SNOMED-CT). In CDA documents, this 4805 element contains a URI in the value attribute of the <reference> that points to the text in the narrative identifying the site. In a message, the <originalText> element shall contain the text identifying the site.
5. Contains zero or one [0..1] **`doseQuantity`**
   - The amount of the medication given. This should be in some known and measurable unit, such as grams, milligrams, et cetera. It may be measured in "administration" units (such as tablets or each), for medications where the strength is relevant. In this case, only the unit count is specified , no units are specified. It may be a range.
6. Contains zero or one [0..1] **`rateQuantity`**
   - The rate is a measurement of how fast the dose is given to the patient over time (e.g., .5 liter / 1 hr), and is often used with IV drugs.
7. Contains zero or one [0..1] **`entryRelationship`**, such that
8. **SHALL** satisfy: Value for moodCode is "EVN" 2.16.840.1.113883.5.1001 ActMood STATIC (6.3.4.17.2)
9. **SHALL** satisfy: In a CDA document, the URI given in the value attribute of the <reference> element points to an element in the narrative content that contains the complete text describing the immunization activity.
   - In a CDA document, the URI given in the value attribute of the 'reference' element points to an element in the narrative content that contains the complete text describing the immunization activity. In an HL7 message, the content of the text element shall contain the complete text describing the immunization activity.
10. **SHALL** satisfy: The effectiveTime element shall be present and should contain a time value that indicates the date of the substance administration. If the date is unkown, this shall be recorded using the nullFlavor attribute, with the reason that the information is unknown being specified. Otherwise, the date shall be recorded, and should have precision of at least the day. (6.3.4.17.8)
11. **SHALL** satisfy: CPT-4 codes may be used for immunization procedures
12. **SHALL** satisfy: If negationInd is set to TRUE atleast one comment shall exist that provides an explanation for why the immunization did not take place. Other comments may also be present
13. The reason for refusal **SHALL** be coded as specified in HITSP/C80 Section 2.2.3.5.3 No Immunization Reason

Immunization example

Internal Reference

[Act: templateId `1.3.6.1.4.1.19376.1.5.3.1.4.4.1`]

CDA and HL7 Version 3 Entries may reference (point to) information contained in other entries within the same document or message

The act being referred to can be any CDA Clinical Statement element type (act, procedure, observation, substanceAdministration, supply, et cetera). For compatibility with the Clinical Statement model the internal reference shall always use the <act> class, regardless of the XML element type of the act it refers to.

1. Contains exactly one [1..1] **`@classCode`**
2. Contains exactly one [1..1] **`@moodCode`**
3. **SHALL** contain zero or more [0..*] **`id`**
   - This element shall be present. The root and extension attributes shall identify an element defined elsewhere in the same document.
4. **SHALL** contain exactly one [1..1] **`code`**
   - This element shall be present. It shall be valued when the internal reference is to element that has a <code> element, and shall have the same attributes as the <code> element in the act it references. If the element it references does not have a <code> element, then the nullFlavor attribute should be set to "NA".

Internal Reference example

Medication

[SubstanceAdministration: templateId `2.16.840.1.113883.3.88.11.83.8`]

A medication activity is used to describe what is administered.

An indication describes the rationale for a medication activity. The indication can be an existing problem or can be a criterion that if met would warrant the activity. Criteria are typically associated with PRN (from the Latin "pro re nata", meaning "as needed") medications (e.g. "give Medication X as needed for nausea").

A reaction represents an adverse event due to an administered substance. Significant reactions are to be listed in the Alerts section. Reactions in the Medications section can be used to track reactions associated with individual substance administrations or to track routine follow up to an administration (e.g. "no adverse reaction 30 minutes post administration").

This content module describes the general structure for a medication. All medication administration acts will be derived from this content module.

The <substanceAdministration> element may contain subordinate <substanceAdministration> elements in a related component entry to deal with special cases (see the section below on Special Cases). These cases include split, tapered, or conditional dosing, or combination medications. The use of subordinate <substanceAdministration> elements to deal with these cases is optional. The comment field should always be used in these cases to provide the same information as free text in the top level <substanceAdministration> element.

1. Contains exactly one [1..1] **`@classCode`**`="SBADM"` (CodeSystem: `2.16.840.1.113883.5.6` `HL7ActClass`)
2. Contains exactly one [1..1] **`@moodCode`**
3. **SHALL** contain at least one [1..*] **`id`** (CONF-306)
4. **MAY** contain zero or more [0..*] **`code`** (C83-[DE-8.12-CDA-1])
   - Delivery Method: A description of how the product is administered/consumed
5. **SHALL** contain exactly one [1..1] **`statusCode`** (CONF-307)
   - The status of all 'substanceAdministration' elements must be "completed". The act has either occurred, or the request or order has been placed.

6. **MAY** contain at least one [1..*] **`effectiveTime`** (CONF-308)
   - Indicate Medication Stopped: Used to express a "hard stop," such as the last Sig sequence in a tapering dose, where the last sequence is 'then D/C' or where the therapy/drug is used to treat a condition and that treatment is for a fixed duration with a hard stop, such as antibiotic treatment, etc.
   - Administration Timing: defines a specific administration or use time. Can be a text string (Morning, Evening, Before Meals, 1 Hour After Meals, 3 Hours After Meals, Before Bed) or an exact time.
   - Frequency: defines how often the medication is to be administered as events per unit of time. Often expressed as the number of times per day (e.g., four times a day), but may also include event-related information (e.g., 1 hour before meals, in the morning, at bedtime). Complimentary to Interval, although equivalent expressions may have different implications (e.g., every 8 hours versus 3 times a day).
   - Interval: defines how the product is to be administered as an interval of time. For example, every 8 hours. Complimentary to Frequency, although equivalent expressions may have different implications (e.g., every 8 hours versus 3 times a day).
   - Duration: for non-instantaneous administrations, indicates the length of time the administration should be continued. For example, (infuse) over 30 minutes.
7. **MAY** contain at least one [1..*] **`routeCode`**, which **MAY** be selected from ValueSet `2.16.840.1.113883.3.88.12.3221.8.7 Medication Route FDA` **STATIC** 1 (CONF-309, CONF-310)
   - The route is a coded value, and indicates how the medication is received by the patient (by mouth, intravenously, topically, et cetera).
8. **MAY** contain zero or more [0..*] **`approachSiteCode`**, which **MAY** be selected from ValueSet `2.16.840.1.113883.3.88.12.3221.8.9 Body Site` **STATIC** 2 (C154-[DE-8.09-1])
   - The anatomic site where the medication is administered. Usually applicable to injected or topical products
9. **MAY** contain at least one [1..*] **`doseQuantity`**
   - the amount of the product to be given. This may be a known, measurable unit (e.g., milliliters), an administration unit (e.g., tablet), or an amount of active ingredient (e.g., 250 mg). May define a variable dose, dose range or dose options based upon identified criteria (see Dose Indicator)
10. **SHOULD** contain zero or one [0..1] **`rateQuantity`**
    - The rate is a measurement of how fast the dose is given to the patient over time (e.g., .5 liter / 1 hr), and is often used with IV drugs.
11. **MAY** contain at least one [1..*] **`maxDoseQuantity`** (CONF-312)
    - defines a maximum or dose limit. This segment can repeat for more than one dose restriction
12. **MAY** contain exactly one [1..1] **`administrationUnitCode`**, which **MAY** be selected from ValueSet `2.16.840.1.113883.3.88.12.3221.8.11 Medication Product Form` **STATIC** 1 (C154-[DE-8.11-1])
    - The physical form of the product as presented to the patient. For example: tablet, capsule, liquid or ointment
13. Contains exactly one [1..1] **`consumable`**, such that
14. **MAY** contain exactly one [1..1] **`entryRelationship`** (CONF-338, CONF-339), such that
    a. Contains **`@typeCode="`**`SUBJ"` *SUBJ (has subject)*
    b. Contains exactly one [1..1] *Medication Series Number Observation* (templateId: `2.16.840.1.113883.10.20.1.46`)
15. **MAY** contain exactly one [1..1] **`entryRelationship`** (CONF-350), such that
    a. Contains exactly one [1..1] *Medication Status Observation* (templateId: `2.16.840.1.113883.10.20.1.47`)
16. **MAY** contain at least one [1..*] **`performer`** (CONF-313), such that
17. **MAY** contain at least one [1..*] **`entryRelationship`** (CONF-348, CONF-349), such that
    a. Contains **`@typeCode="`**`CAUS"` *CAUS (is etiology for)*
    b. Contains exactly one [1..1] *Reaction Observation* (templateId: `2.16.840.1.113883.10.20.21.4.9`)
18. **MAY** contain at least one [1..*] **`participant`** (CONF-368), such that

   a. Contains exactly one [1..1] *Product Instance* (templateId: `2.16.840.1.113883.10.20.1.52`)
19. Contains at least one [1..*] **`entryRelationship`**, such that
   a. Contains exactly one [1..1] *Internal Reference* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.4.1`)
20. Contains at least one [1..*] **`entryRelationship`**, such that
   a. Contains exactly one [1..1] *Patient Medical Instructions* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.3`)
21. Contains zero or one [0..1] **`entryRelationship`**, such that
   a. Contains exactly one [1..1] *Medication Type* (templateId: `2.16.840.1.113883.3.88.11.83.8.1`)
22. Contains at least one [1..*] **`entryRelationship`**, such that
   a. Contains exactly one [1..1] *Medication Order Information* (templateId: `2.16.840.1.113883.3.88.11.83.8.3`)
23. **SHALL** satisfy: Value for moodCode is "EVN" or "INT" 2.16.840.1.113883.5.1001 ActMood STATIC (CONF-305)
24. **SHOULD** satisfy: Contains exactly one doseQuantity or rateQuantity. (CONF-311)
25. **MAY** satisfy: Has one or more associated consents, represented in the CCD Header as ClinicalDocument / authorization / consent. (CONF-314)
26. **SHALL** satisfy: Contains one or more sources of information. (CONF-315)
27. **MAY** satisfy: Contains one or more precondition / Criterion, to indicate that the medication is administered only when the associated (coded or free text) criteria are met. (CONF-327)
   - Indicates that the medication is administered only when the associated (coded or free text) criteria are met.
28. **MAY** satisfy: Contains one or more entryRelationship, where the value for @typeCode is "RSON" "Has reason" 2.16.840.1.113883.5.1002 ActRelationshipType STATIC. (CONF-328)
   - The target of the relationship represents the indication for the activity.
29. **SHALL** satisfy: entryRelationship / @typeCode="RSON" in a medication activity has a target of problem act (templateId 2.16.840.1.113883.10.20.1.27), problem observation (templateId 2.16.840.1.113883.10.20.1.28), or some other clinical statement. (CONF-329)
30. **SHALL** satisfy: Contains exactly one consumable, the target of which is a Product template. (CONF-354)
31. **SHALL** satisfy: Contains one dosing template to identify this entry as a particular type of medication event. Possible dosing templates: 1.3.6.1.4.1.19376.1.5.3.1.4.7.1 Normal Dosing, 1.3.6.1.4.1.19376.1.5.3.1.4.8, Tapered Dosing, 1.3.6.1.4.1.19376.1.5.3.1.4.9 Split Dosing, 1.3.6.1.4.1.19376.1.5.3.1.4.10 Conditional Dosing, 1.3.6.1.4.1.19376.1.5.3.1.4.11 Combination Dosing.
   - There are a variety of special cases for dosing that need to be accounted for. Most of these special cases involve changing the dosage or frequency over time, or based on some measurement. When the dosage changes, then additional entries are required for each differing dosage.
32. **SHALL** satisfy: contains one or more related components (<entryRelationship typeCode='COMP'>, either to handle split, tapered or conditional dosing, or to support combination medications.
   - n the first three cases, the subordinate components shall specify only the changed <frequency> and/or <doseAmount> elements. For conditional dosing, each subordinate component shall have a <precondition> element that specifies the <observation> that must be obtained before administration of the dose. The value of the <sequenceNumber> shall be an ordinal number, starting at 1 for the first component, and increasing by 1 for each subsequent component. Components shall be sent in <sequenceNumber> order.
33. **SHALL** satisfy: Values from SNOMED CT shall be used in the <code> element to record that a patient is either not on medications, or that medications are not known.
   - 182904002 "Drug Treatment Unknown" (To indicate lack of knowledge about drug therapy)

     182849000 "No Drug Therapy Prescribed" (To indicate the absense of any prescribed medications)

     408350003 "Patient Not On Self-Medications" (To indicate no treatment)
34. **SHALL** satisfy: The act/@classCode='ACT' and act/@moodCode='EVN' when recording reason for medication in InternalReference Template. (6.3.4.16.22)
35. **SHALL** satisfy: Contains [0..2] effectiveTime elements.

- The first <effectiveTime> element encodes the start and stop time of the medication regimen. This an interval of time (xsi:type='IVL_TS'), and must be specified as shown. This is an additional constraint placed upon CDA Release 2.0 by this profile, and simplifies the exchange of start/stop and frequency information between EMR systems.

36. **SHALL** satisfy: The <consumable> element shall be present, and shall contain a Product Entry template
37. **SHALL** satisfy: The entryRelationship/@inversionInd attribute is 'true' for Patient Medical Instructions relationship
38. **SHOULD** satisfy: The name and strength of the medication is recorded in consumable/manufacturedProduct/manufacturedMaterial/code/originalText
39. **SHALL** satisfy: Name of the substance or product is recorded in consumable/manufacturedProduct/manufacturedMaterial/name
40. **MAY** satisfy: the preconditions for use of the medication are recorded in the <precondition> element. element. The value attribute of the <reference> element is a URL that points to the CDA narrative describing those preconditions.
41. **SHALL** satisfy: The entryRelationship/@inversionInd attribute is 'false' for Supply Entry relationship
42. **SHOULD** satisfy: entryRelationship/sequenceNumber element should be present when the embedded 'supply' element has a moodCode attribute of EVN.

    - The prescription activity may have a <sequenceNumber> element to indicate the fill number. A value of 1, 2 or N indicates that it is the first, second, or Nth fill respectively of a specific prescription.

43. **SHALL** satisfy: The time at which the medication was stopped is determined based on the content of the <high> element of the first <effectiveTime> element. (2.2.2.8.3)
44. **SHALL** satisfy: The HL7 data type for PIVL_TS uses the institutionSpecified attribute to indicate whether it is the interval (time between dosing), or frequency (number of doses in a time period) that is important. If instititutionSpecified is not present or is set to false, then the time between dosing is important (every 8 hours). If true, then the frequency of administration is important (e.g., 3 times per day). (2.2.2.8.4)

    - defines a specific administration or use time. Can be a text string (Morning, Evening, Before Meals, 1 Hour After Meals, 3 Hours After Meals, Before Bed) or an exact time

45. The first <effectiveTime> **SHALL** use the IVL_TS data type unless for a single administration, in which case, it **SHALL** use the TS data type. (C83-[DE-8-CDA-3])
46. Medications that are administered based on activities of daily living **SHALL** identify the events that trigger administration in the <event> element beneath the <effectiveTime> element. The <effectiveTime> element **SHALL** be of type EIVL_TS. (C83-[DE-8.03-CDA-1])
47. Medications that are administered at a specified frequency **SHALL** record the expected interval between doses in the <period> element beneath an <effectiveTime> of type PIVL_TS. The <effectiveTime> element **SHALL** have an institutionSpecified attribute value of "true". (C83-[DE-8.04-CDA-1])

    - defines how often the medication is to be administered as events per unit of time. Often expressed as the number of times per day (e.g., four times a day), but may also include event-related information (e.g., 1 hour before meals, in the morning, at bedtime). Complimentary to Interval, although equivalent expressions may have different implications (e.g., every 8 hours versus 3 times a day)

48. Medications that are administered at a specified interval **SHALL** record interval between doses in the <period> element beneath an <effectiveTime> element of type PIVL_TS. The <effectiveTime> element **SHALL** have an institutionSpecified attribute value of "false". (C83-[DE-8.05-CDA-1])

    - defines how the product is to be administered as an interval of time. For example, every 8 hours. Complimentary to Frequency, although equivalent expressions may have different implications (e.g., every 8 hours versus 3 times a day)

49. doseQuantity/@unit, Dose Units **MAY** be present when needed. If present it **SHALL** be coded as 2.16.840.1.113883.3.88.12.80.29 Unit of Measure (C154-[DE-8.08-1])
50. When the coded product or brand name describes the strength or concentration of the medication, and the dosing is in administration units (e.g., 1 tablet, 2 capsules), units **SHOULD** contain the preferred name of the presentation units within braces { } using the units of presentation from the NCI Thesaurus (C154-[DE-8.08-2])
51. The free text description of the delivery method **MAY** be included within a <originalText> element beneath the <code> element (C83-[DE-8.12-CDA-2])

52. **SHALL** satisfy: Contains one consumable element which contains the Medication Information template. The name and code for the medication are recorded in the <consumable> element.
53. The medication status **MAY** be recorded using the CCD Medication Status observation using the value set defined in the CCD (C154-[DE-8.20-1])
    - If the medication is Active, Discharged, Chronic, Acute, etc
54. [0..*] indications **SHALL** be recorded using the Indication problem observation (templateID 2.16.840.1.113883.10.20.1.28) described in the CCD Implementation Guide. (C83-[DE-8.20-CDA-1])
    - The medical condition or problem intended to be addressed by the ordered product. For example: for chest pain, for pain, for high blood pressure
55. The indication problem observation **SHALL** contain a <text> element that includes a <reference> element whose value attribute points to the narrative text that is the indication for the medication (C83-[DE-8.20-CDA-2])
56. The indication **SHALL** be coded as 2.16.840.1.113883.3.88.12.3221.7.4, Problem Value Set, version: 20100125, Dynamic (C154-[DE-8.20-1])
57. Patient Instructions **SHALL** be recorded using the Patient Medication Instructions template (templateID 1.3.6.1.4.1.19376.1.5.3.1.4.3) (C83-[DE-8.22-CDA-1])
    - Instructions to the patient that are not traditionally part of the Sig. For example, "keep in the refrigerator." More extensive patient education materials can also be included

      External patient educational materials can be referenced with an appropriate URL entry in the text/ reference/ value.
58. The vehicle for administering a medication **MAY** be recorded in a <participantRole> element inside a <participant> element in the <substanceAdministration> element (C83-[DE-8.24-CDA-1])
    - Non-active ingredient(s), or substances not of therapeutic interest, in which the active ingredients are dispersed. Most often applied to liquid products where the major fluid component is considered the vehicle. For example: Normal Saline is the vehicle in "Ampicillin 150mg in 50ml NS"; Aquaphor is the vehicle in "10% LCD in Aquaphor"
59. The typeCode attribute of the <participant> element **SHALL** be CSM (C83-[DE-8.24-CDA-2])
60. The classCode of the <participantRole> **SHALL** be MANU (C83-[DE-8.24-CDA-3])
61. A <code> element for the <participantRole> **SHALL** be present and **SHALL** contain the code 412307009 from the SNOMED CT code system (C83-[DE-8.24-CDA-4])
62. The <name> element in the <playingEntity> element **SHALL** record the name of the drug vehicle (C83-[DE-8.24-CDA-5])
63. The <code> element in the <playingEntity> element **MAY** be used to supply a coded term for the drug vehicle (C83-[DE-8.24-CDA-6])
64. **SHALL** satisfy: The Medication Vehicle shall be coded as 2.16.840.1.113883.3.88.12.80.21, Medication Vehicle Value Set, version: 20081218, Dynamic (C154-[DE-8.24-1])

Medication example

Medication Combination Medication

[SubstanceAdministration: templateId `1.3.6.1.4.1.19376.1.5.3.1.4.11`]

This template identifier is used to identify medication administration events that require special processing to handle combination medications. The parent template is 1.3.6.1.4.1.19376.1.5.3.1.4.7. A combination medication is made up of two or more other medications. These may be prepackaged, such as Percocet, which is a combination of Acetaminophen and oxycodone in predefined ratios, or prepared by a pharmacist, such as a GI cocktail.

In the case of the prepackaged combination, it is sufficient to supply the name of the combination drug product, and its strength designation in a single <substanceAdministation> entry. The dosing information should then be recorded as simply a count of administration units. In the latter case of a prepared mixture, the description of the mixture should be provided as the product name (e.g., "GI Cocktail") , in the <substanceAdministration> entry. That entry may, but is not required, to have subordinate <substanceAdministration> entries included beneath it to record the components of the mixture.

1. **SHALL** conform to *Medication* template (templateId: `2.16.840.1.113883.3.88.11.83.8`)
2. **SHALL** satisfy: Subordinate <substanceAdminstration> entries are included to record the components of the prepared mixture. If medication is a prepackaged mixture, a single <substanceAdministration> entry is sufficient.

Medication Combination Medication example

Medication Conditional Dose

[SubstanceAdministration: templateId `1.3.6.1.4.1.19376.1.5.3.1.4.10`]

This template identifier is used to identify medication administration events that require special processing to handle conditional dosing. The parent template is 1.3.6.1.4.1.19376.1.5.3.1.4.7. A conditional dose is often used when the dose amount differs based on some measurement (e.g., an insulin sliding scale dose based on blood sugar level).

1. **SHALL** conform to *Medication* template (templateId: `2.16.840.1.113883.3.88.11.83.8`)
2. **SHALL** satisfy: A subordinate 'substanceAdministration' entry is required for each different dose, and the condition should be recorded

Medication Conditional Dose example

Medication Fullfillment Instructions

[Act: templateId `1.3.6.1.4.1.19376.1.5.3.1.4.3.1`]

Fulfillment instructions are additional information provided to the dispensing party (e.g. "label in spanish").

1. Contains exactly one [1..1] **`@classCode`**
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="INT"` (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF-336)
3. **SHALL** contain exactly one [1..1] **`code/@code`**`="FINSTRUCT"` (CodeSystem: `1.3.6.1.4.1.19376.1.5.3.2 IHEActCode`)
   - The <code> element indicates that this is a medication fulfillment instruction.
4. **SHALL** contain zero or one [0..1] **`text`**
   - The <text> element contains a free text representation of the instruction. For CDA this SHALL contain a provides a <reference>element to thelink text of the comment in the narrative portion of the document. The comment itself is not the act being coded, so it appears in the <text> of the <observation>, not as part of the <code>.
5. **SHALL** contain zero or one [0..1] **`statusCode`**

Medication Fullfillment Instructions example

Medication Normal Dose

[SubstanceAdministration: templateId `1.3.6.1.4.1.19376.1.5.3.1.4.7.1`]

This template identifier is used to identify medication administration events that do not require any special processing.

1. **SHALL** conform to *Medication* template (templateId: `2.16.840.1.113883.3.88.11.83.8`)
2. **SHALL** satisfy: Medications that use this template identifier shall not use subordinate 'substanceAdministation' acts.

Medication Normal Dose example

Medication Order Information

[Supply: templateId `2.16.840.1.113883.3.88.11.83.8.3`]

a supply activity is used to describe what has been dispensed.

The supply entry describes a prescription activity. The moodCode attribute shall be INT to reflect that a medication has been prescribed, or EVN to indicate that the prescription has been filled.

Order information may be recorded as part of the fulfillment history (moodcode = EVN) or as part of the administration information (moodcode = INT)

1. Contains exactly one [1..1] **`@classCode="SPLY"`** (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
2. Contains exactly one [1..1] **`@moodCode`**
3. **SHALL** contain at least one [1..*] **`id`** (CONF-318)
4. **MAY** contain exactly one [1..1] **`statusCode`**, which **MAY** be selected from ValueSet `2.16.840.1.113883.3.88.12.80.64 Medication Fill Status` **STATIC** 1 (CONF-319)
   - When supply element has a moodCode attribute set to EVN
5. **SHOULD** contain exactly one [1..1] **`effectiveTime`** (CONF-320)
   - Indicates the actual or intended time of dispensing.
6. **MAY** contain exactly one [1..1] **`repeatNumber`** (CONF-321)
   - The number of times that the ordering provider has authorized the pharmacy to dispense this medication

     Please note that the number of fills requested is what is recorded in the document, not the number of refills. The number of refills is simply one less than the number of fills.
7. **SHOULD** contain exactly one [1..1] **`quantity`** (CONF-322)
   - The supply entry should indicate the quantity supplied. The value attribute shall be present and indicates the quantity of medication supplied. If the medication is supplied in dosing units (tablets or capsules), then the unit attribute need not be present (and should be set to 1 if present). Otherwise, the unit element shall be present to indicate the quantity (e.g., volume or mass) of medication supplied.
8. **MAY** contain exactly one [1..1] **`entryRelationship`** (CONF-351), such that
   a. Contains exactly one [1..1] *Medication Status Observation* (templateId: `2.16.840.1.113883.10.20.1.47`)
9. **MAY** contain at least one [1..*] **`participant`** (CONF-369), such that
   a. Contains exactly one [1..1] *Product Instance* (templateId: `2.16.840.1.113883.10.20.1.52`)
10. Contains zero or one [0..1] **`entryRelationship`**, such that
    a. Contains exactly one [1..1] *Medication Fullfillment Instructions* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.3.1`)
11. **SHALL** satisfy: Value for moodCode is 'EVN' or 'INT' 2.16.840.1.113883.5.1001 ActMood STATIC (CONF-317)
12. **MAY** satisfy: Contains one or more author. (CONF-323)
    - Indicates the prescriber.
13. **MAY** satisfy: Contains one or more performer. (CONF-324)
    - Indicates the person dispensing the product.
14. **MAY** satisfy: Contains exactly one participant / @typeCode = "LOC". (CONF-325)
    - Iindicates the supply location.
15. **SHALL** satisfy: Contains one or more sources of information. (CONF-326)
16. **MAY** satisfy: Contains exactly one product, the target of which is a Product template. (CONF-355)
17. Supply / participant / participantRole / id **SHOULD** be set to equal a [Act | Observation | Procedure] / participant / participantRole / id to indicate that the Supply and the Procedure are referring to the same product instance.

18. **MAY** satisfy: A supply entry that describes an intent (<supply classCode='SPLY' moodCode='INT'>) may include an <author> element to identify the prescribing provider.
19. **SHALL** satisfy: The <time> element must be present to indicate when the author created the prescription. If this information is unknown, it shall be recorded by setting the nullFlavor attribute to UNK.
20. **SHALL** satisfy: The <assignedAuthor> element shall be present in author, and identifies the author.
21. **SHOULD** satisfy: One or more <id> elements should be present in assignedAuthor
    - These identifiers identify the author of the act. When the author is the prescribing physician they may include local identifiers or regional identifiers necessary for prescribing.
22. **SHALL** satisfy: An <assignedPerson> and/or <representedOriganization> element shall be present in assignedAuthor. This element shall contain a <name> element to identify the prescriber or their organization.
23. **SHALL** satisfy: The <time> element shall be present in performer to indicate when the prescription was filled (moodCode='EVN'). If this information is unknown, it shall be recorded by setting the nullFlavor attribute to UNK.
24. **SHOULD** satisfy: The <time> element should be present to indicate when the prescription is intended to be filled (moodCode='INT').
25. **SHALL** satisfy: The performer/assignedEntity element shall be present, and identifies the filler of the prescription.
26. **SHOULD** satisfy: One or more <id> elements should be present. These identify the performer.
27. **SHALL** satisfy: An <assignedPerson> and/or <representedOriganization> element shall be present. This element shall contain a <name> element to identify the filler or their organization.
28. The order number, i.e., the identifier from the perspective of the ordering provider, **SHOULD** be recorded in the id element within the supply element with moodcode = 'INT' (C83-[DE-8.26-CDA-1])
    - The order identifier from the perspective of the ordering clinician. Also known as the 'placer number' versus the pharmacies prescription number (or 'filler number')
29. **SHOULD** satisfy: The effectiveTime/high element is present to record the order expiration date and time when supply/@moodcode = INT
    - The date, including time if applicable, when the order is no longer valid. Dispenses and administrations are not continued past this date for an order instance
30. The quantity ordered **SHALL** be recorded in the value attribute of quantity element inside a supply element used to record order information (C83-[DE-8.26-CDA-1])
    - The amount of product indicated by the ordering provider to be dispensed. For example, number of dosage units or volume of a liquid substance. Note: this is comprised of both a numeric value and a unit of measure
31. **SHALL** satisfy: the @unit attribute of quantity element is present (C83-[DE-8.26-CDA-2])
32. When the quantity ordered or dispensed is in other than administration units (e.g., when the quantity ordered is a volume of liquid or mass of substance) units **SHALL** be coded as 2.16.840.1.113883.3.88.12.80.29, Unit of Measure, Dynamic (C83-[DE-8.26-CDA-3], C83-[DE-8.38-CDA-2])
33. When the quantity ordered or dispensed is in administration units, the unit attribute **SHOULD** contain the preferred name of the presentation units within braces { } using the units of presentation as 2.16.840.1.113883.3.88.12.3221.8.11, Medication Product Form Value Set, Dynamic (C83-[DE-8.26-CDA-4], C83-[DE-8.38-CDA-3])
34. The prescription number **SHALL** be recorded in the extension attribute of the <id> element within a supply element having a moodCode attribute of EVN (C83-[DE-8.34-CDA-1])
    - The prescription identifier assigned by the pharmacy
35. The root attribute of the id element **SHOULD** be the OID of the assigning authority for the identifier. (C83-[DE-8.34-CDA-2])
    - determining the assigning authority is not feasible in all settings.
36. A GUID **MAY** be used in place of the OID of the assigning authority (C83-[DE-8.34-CDA-3])
37. **SHALL** satisfy: The dispense date is recorded in effectiveTime element within a supply element with a moodCode attribute set to EVN
    - The date of this dispense
38. **MAY** satisfy: The dispensing pharmacy's location is present in the addr element in performer/assignEntity element inside a supply element with a moodCode attribute set to EVN

39. The state element of the performer/assignedEntity/addr element in the United States **SHALL** be recorded using 2.16.840.1.113883.3.88.12.80.1, State Value Set, version: 20081218, Dynamic (C154-[DE-8.36-1])

40. The postalCode element of the performer/assignedEntity/addr element in the United States **SHALL** be recorded using 2.16.840.1.113883.3.88.12.80.2, Postal Code Value Set, version: 20081218, Dynamic (C154-[DE-8.36-2])

41. The country element of the performer/assignedEntity/addr element in the United States **SHALL** be recorded using 2.16.840.1.113883.3.88.12.80.3, Country Value Set, version: 20081218, Dynamic (C154-[DE-8.36-3])

42. The quantity dispensed **SHALL** be recorded in the value attribute of quantity element inside a supply element with a moodCode attribute set to EVN

- The actual quantity of product supplied in this dispense. Note: This is comprised of both a numeric value and a unit of measure

43. The fill number **SHOULD** be recorded in the sequenceNumber attribute of a entryRelationship element with a typeCode attribute set to COMP (C83-[DE-8.39-CDA-1])

- The fill number for the history entry. The fill number identifies the supply (dispense) event as a distinct activities against the prescription.

Medication Order Information example

Medication Series Number Observation

[Observation: templateId `2.16.840.1.113883.10.20.1.46`]

The medication series number observation can be used to indicate which in a series of administrations a particular administration represents (e.g. "hepatitis B vaccine number 2 was administered on Feb 07, 2004).

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF-341)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF-342)
3. **SHALL** contain exactly one [1..1] **`code/@code`**`="30973-2"` *Dose number* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`) (CONF-344, CONF-345)
4. **SHALL** contain exactly one [1..1] **`statusCode`** (CONF-343)
5. **SHALL** contain exactly one [1..1] **`value`**, where its data type is INT (CONF-346, CONF-347)

Medication Series Number Observation example

Medication Split Dose

[SubstanceAdministration: templateId `1.3.6.1.4.1.19376.1.5.3.1.4.9`]

This template identifier is used to identify medication administration events that require special processing to handle split dosing. The parent template is 1.3.6.1.4.1.19376.1.5.3.1.4.7. A split dose is often used when different dosages are given at different times (e.g., at different times of day, or on different days). This may be to account for different metabolism rates at different times of day, or to simply address drug packaging deficiencies (e.g., and order for Coumadin 2mg on even days, 2.5mg on odd days is used because Coumadin does not come in a 2.25mg dose form).

1. **SHALL** conform to *Medication* template (templateId: `2.16.840.1.113883.3.88.11.83.8`)
2. **SHALL** satisfy: A subordinate <substanceAdministration> entry is required for each separate dosage.

Medication Split Dose example

Medication Status Observation

[Observation: templateId `2.16.840.1.113883.10.20.1.47`]

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 `2.16.840.1.113883.1.11.20.7 MedicationStatusCode` **STATIC** 20061017 (CONF-353)

Medication Status Observation example

Medication Tapered Dose

[SubstanceAdministration: templateId `1.3.6.1.4.1.19376.1.5.3.1.4.8`]

This template identifier is used to identify medication administration events that require special processing to handle tapered dosing. The parent template is 1.3.6.1.4.1.19376.1.5.3.1.4.7. A tapered dose is often used for certain medications where abrupt termination of the medication can have negative consequences. Tapered dosages may be done by adjusting the dose frequency, the dose amount, or both.

When merely the dose frequency is adjusted, (e.g., Prednisone 5mg b.i.d. for three days, then 5mg. daily for three days, and then 5mg every other day), then only one medication entry is needed, multiple frequency specifications recorded in <effectiveTime> elements. When the dose varies (eg. Prednisone 15mg daily for three days, then 10 mg daily for three days, the 5 mg daily for three days), subordinate medication entries should be created for each distinct dosage.

1. **SHALL** conform to *Medication* template (templateId: `2.16.840.1.113883.3.88.11.83.8`)
2. **SHALL** satisfy: Subordinate Medication entries should be created for each distinct dosage.

Medication Tapered Dose example

Medication Type

[Observation: templateId `2.16.840.1.113883.3.88.11.83.8.1`]

A classification based on how the medication is marketed (e.g., prescription, over the counter drug)

1. Contains exactly one [1..1] **`@classCode`**
2. Contains exactly one [1..1] **`@moodCode`**
3. **SHALL** contain exactly one [1..1] **`code`**, which **SHALL** be selected from ValueSet `2.16.840.1.113883.3.88.12.3221.8.19 Medication Type` **STATIC** 1 (C83-[DE-8.19-CDA-5], C154-[DE-8.19-1])

Medication Type example

Patient Medical Instructions

[Act: templateId `1.3.6.1.4.1.19376.1.5.3.1.4.3`]

Patient instructions are additional information provided to a patient related to one of their medications (e.g. "take on an empty stomach").

Any medication may be the subject of further instructions to the patient, for example to indicate that it should be taken with food, et cetera. This structure is included in the target substance administration or supply act using the <entryRelationship> element defined in the CDA Schema.

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`**`="INT"` (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF-332)
3. **SHALL** contain exactly one [1..1] **`code/@code`**`="PINSTRUCT"` (CodeSystem: `1.3.6.1.4.1.19376.1.5.3.2 IHEActCode`)

4. **SHALL** contain zero or one [0..1] **`text`**
   - The <text> element indicates the text of the comment. For CDA, this SHALL be represented as a <reference> element that points at the narrative portion of the document. The comment itself is not the act being coded, so it appears in the <text> of the <observation>, not as part of the <code>.
5. **SHALL** contain zero or one [0..1] **`statusCode`**
   - The code attribute of <statusCode> for all comments must be completed

Patient Medical Instructions example

Problem Status Observation

[Observation: templateId `2.16.840.1.113883.10.20.21.4.6`]

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** (CONF-CONSOL-542)
3. **SHALL** contain exactly one [1..1] **`text`** (CONF-CONSOL-543)
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. (CONF-CONSOL-541)

Problem Status Observation example

Reaction Observation

[Observation: templateId `2.16.840.1.113883.10.20.21.4.9`]

A reaction represents an adverse event due to an administered or exposed substance. A reaction can be defined with respect to its severity, and can have been treated by one or more interventions. Significant reactions are to be listed in the Alerts section. Reactions in the Medications section can be used to track reactions associated with individual substance administrations or to track routine follow up to an administration (e.g. "no adverse reaction 30 minutes post administration").

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF-283)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF-284)
3. Contains exactly one [1..1] **`code`**
4. **SHALL** contain exactly one [1..1] **`statusCode/@code`**`="completed"` (CodeSystem: `2.16.840.1.113883.5.14 HL7ActStatus`) (CONF-285, CONF-286)
5. Contains zero or one [0..1] **`entryRelationship`**, such that
   a. Contains exactly one [1..1] *Severity* (templateId: `2.16.840.1.113883.10.20.21.4.8`)
6. A reaction observation **MAY** contain one or more reation interventions. (CONF-280)
7. A reaction observation **MAY** contain one or more reation interventions. A reaction intervention **SHALL** be represented as a procedure activity (templateId 2.16.840.1.113883.10.20.1.29), a medication activity (templateId 2.16.840.1.113883.10.20.1.24), or some other clinical statement. (CONF-297)
8. The value for entryRelationship / @typeCode in a relationship between a reaction observation and reaction intervention **SHALL** be "RSON" "Has reason" 2.16.840.1.113883.5.1002 ActRelationshipType STATIC. (CONF-296)

Reaction Observation example

Result

[Observation: templateId `2.16.840.1.113883.10.20.21.4.2`]

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`** (CONF-CONSOL-551)
    a. 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])
    b. 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])
5. **SHALL** contain exactly one [1..1] **`statusCode`** (CONF-410)
6. **SHALL** contain exactly one [1..1] **`effectiveTime`** (CONF-CONSOL-552)
7. **SHALL** contain exactly one [1..1] **`value`** (CONF-CONSOL-553)
    - 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.
    a. 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])
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)

Result example

Result Organizer

[Organizer: templateId `2.16.840.1.113883.10.20.21.4.1`]

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)
    a. 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)
5. **SHALL** contain exactly one [1..1] **`statusCode`** (CONF-396)
6. Contains at least one [1..*] **`component`**, such that
    a. Contains exactly one [1..1] *Result* (templateId: `2.16.840.1.113883.10.20.21.4.2`)
7. Contains at least one [1..*] **`specimen`**, such that
8. The specimen element **SHALL NOT** conflict with the specimen inherent in code (CONF-400)
9. 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)
10. **SHALL** satisfy: Contains one or more component (CONF-402)
11. 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)
12. A result organizer component / procedure **MAY** be a reference to a procedure described in the Procedure section. (CONF-404)
13. **SHALL** satisfy: Contains one or more sources of information. (CONF-406)

Result Organizer example

Severity

[Observation: templateId `2.16.840.1.113883.10.20.21.4.8`]

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`** (CONF-CONSOL-539)
    a. The 'text' elements **SHALL** contain a 'reference' element pointing to the narrative where the severity is recorded, rather than duplicate text to avoid ambiguity. (CONF-CONSOL-538)
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 (CONF-CONSOL-540)
    - 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.

Severity example

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

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: `2.16.840.1.113883.10.20.21.4.2`)
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] (CONF-CONSOL-557)
   - Vital Signs are a subset of Results Section, but are reported in this section to follow clinical conventions.

Vital Sign example

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: `2.16.840.1.113883.10.20.21.4.1`)
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. **SHALL** contain at least one [1..*] **`component`**, such that
   a. Contains exactly one [1..1] *Vital Sign* (templateId: `2.16.840.1.113883.3.88.11.83.14`)
8. Contains exactly one [1..1] **`author`**, such that
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

Chapter 4

OTHER CLASSES

Topics:

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

Medication Information

[ManufacturedProduct: templateId `2.16.840.1.113883.3.88.11.83.8.2`]

The product entry describes a medication or immunization used in a 'substanceAdministration' or 'supply' act

In a CDA document, the name and strength of the medication are specified in the elements under the 'manufacturedMaterial' element.

The 'code' element of the 'manufacturedMaterial' describes the medication. This may be coded using a controlled vocabulary, such as RxNorm, First Databank, or other vocabulary system for medications, and should be the code that represents the generic medication name and strength (e.g., acetaminophen and oxycodone -5/325), or just the generic medication name alone if strength is not relevant (Acetaminophen). In a CDA document, the <originalText> shall contain a 'reference' whose URI value points to the generic name and strength of the medication, or just the generic name alone if strength is not relevant.

The product concentration is determined from the coded product or brand name using knowledge base information in the vocabularies specified for these fields, and therefore this information is not explicitly included.

1. **MAY** contain at least one [1..*] **`id`** (CONF-366)
   - uniquely represents a particular kind of product
2. **SHALL** satisfy: Contain exactly one manufacturedMaterial. (CONF-357)
3. **SHALL** satisfy: Contain exactly one manufacturedMaterial / code. (CONF-358)
4. The value for "manufacturedMaterial / code" in a product template **SHOULD** be selected from the RxNorm (2.16.840.1.113883.6.88) code system for medications, and from the CDC Vaccine Code (2.16.840.1.113883.6.59) code system for immunizations10, or **MAY** be selected from ValueSet 2.16.840.1.113883.1.11.20.8 MedicationTypeCode STATIC 20061017. (CONF-359)
5. The value for "manufacturedMaterial / code" in a product template **MAY** contain a precoordinated product strength, product form, or product concentration (e.g. "metoprolol 25mg tablet", "amoxicillin 400mg/5mL suspension"). (CONF-360)
6. If manufacturedMaterial / code contains a precoordinated unit dose (e.g. "metoprolol 25mg tablet"), then SubstanceAdministration / doseQuantity **SHALL** be a unitless number that indicates the number of products given per administration. (CONF-361)
7. If manufacturedMaterial / code does not contain a precoordinated unit dose (e.g. "metoprolol product"), then SubstanceAdministration / doseQuantity **SHALL** be a physical quantity that indicates the amount of product given per administration. (CONF-362)
8. **SHALL** satisfy: A manufacturedMaterial in a product template contains exactly one code / originalText, which represents the generic name of the product. (CONF-363)
9. **MAY** satisfy: A manufacturedMaterial in a product template contains exactly one name, which represents the brand name of the product. (CONF-364)
10. **MAY** satisfy: contains exactly one manufacturedProduct / manufacturerOrganization, which represents the manufacturer of the Material. (CONF-365)
11. If ManufacturedProduct in a product template contains manufacturedProduct / id, then ManufacturedProduct **SHOULD** also contain manufacturedProduct / manufacturerOrganization. (CONF-367)
12. The coded product name **SHALL** appear in the @code attribute of the manufacturedMaterial/code element. (C83-[DE-8.13-CDA-1])
    - A code describing the product from a controlled vocabulary
13. If the code for the generic product is unknown, the code and codeSystem attributes **MAY** be omitted (C83-[DE-8.13-CDA-2])
14. The coded product name **SHALL** be coded as 2.16.840.1.113883.3.88.12.80.17, Medication Clinical Drug Name Value Set, version: 20081218, Dynamic (C154-[DE-8.13-1])
15. When only the class of the drug is known (e.g., Beta Blocker or Sulfa Drug), it **SHALL** be coded as 2.16.840.1.113883.3.88.12.80.18, Medication Drug Class Value Set, version: 20081218, Dynamic (C154-[DE-8.13-2])
16. When only the medication ingredient name is know, the coded product name **MAY** be coded as 2.16.840.1.113883.3.88.12.80.20, Ingredient Name Value Set, Dynamic (C154-[DE-8.13-3])

17. The code for the specific brand of product **SHALL** appear in a manufacturedMaterial/translation element (C83-[DE-8.14-CDA-1])
    - A code describing the product as a branded or trademarked entity from a controlled vocabulary
18. The brand name **SHALL** be coded as 2.16.840.1.113883.3.88.12.80.16, Medication Brand Name Value Set, version: 20081218, Dynamic, OR **SHALL** be coded as 2.16.840.1.113883.3.88.12.80.19, Medication Packaged Product Value Set, Dynamic (C154-[DE-8.14-1])
19. The product (generic) name **SHALL** appear in the originalText element beneath the manufacturedMaterial/code element (C83-[DE-8.15-CDA-1])
    - The name of the substance or product without reference to a specific vendor (e.g., generic or other non-proprietary name). If a Coded Product Name is present, this is the text associated with the coded concept
20. The brand name **SHALL** appear in the <name> element of the <manufacturedMaterial> element (C83-[DE-8.14-CDA-2])
    - The branded or trademarked name of the substance or product. If a Coded Brand Name is present, this is the text associated with the coded concept

Medication Information example

Patient Awareness

[Participant2: templateId `2.16.840.1.113883.10.20.1.48`]

1. **SHALL** contain exactly one [1..1] **`@typeCode="SBJ"`** (CONF-181)
2. **SHALL** contain exactly one [1..1] **`awarenessCode`** (CONF-182)
3. Contains exactly one [1..1] **`participantRole`**, such that
4. Patient awareness **SHALL** contain exactly one participant / participantRole / id, which **SHALL** have exactly one value, which **SHALL** also be present in ClinicalDocument / recordTarget / patientRole / id. (CONF-183)

Patient Awareness example

Product Instance

[ParticipantRole: templateId `2.16.840.1.113883.10.20.1.52`]

identifes a particular product instance

1. **SHALL** contain exactly one [1..1] **`@classCode="MANU"`**
2. If participantRole in a product instance contains participantRole / id, then participantRole **SHOULD** also contain participantRole / scopingEntity. (CONF-451)

Product Instance example

Chapter 5

VALUE SETS

Topics:

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

Body Site

Value Set	Body Site - 2.16.840.1.113883.3.88.12.3221.8.9
Code System	SNOMEDCT - 2.16.840.1.113883.6.96
Version	2
Definition	Body site value set is based upon the concepts descending from the SNOMED CT Anatomical Structure (91723000) hierarchy.

Concern Entry Status

Value Set	ConcernEntryStatus - TEMP-OID-PROBLEM-STATUS-CODE
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	

Medication Fill Status

Value Set	Medication Fill Status - 2.16.840.1.113883.3.88.12.80.64

Code System	HL7ActStatus - 2.16.840.1.113883.5.14
Version	1
Definition	The HL7 ActStatus has been limited by HITSP. This identifies whether the medication has been fulfilled, such as completed and aborted

Concept Code	Concept Name	Code System	Description
aborted	Aborted	HL7ActStatus	
completed	Completed	HL7ActStatus	

Medication Product Form

Value Set	Medication Product Form - 2.16.840.1.113883.3.88.12.3221.8.11
Code System	NCI Thesaurus - 2.16.840.1.113883.3.26.1.1
Version	1
Definition	This is the physical form of the product as presented to the individual. For example: tablet, capsule, liquid or ointment. NCI concept code for pharmaceutical dosage form: C42636

Medication Route FDA

Value Set	Medication Route FDA - 2.16.840.1.113883.3.88.12.3221.8.7
Code System	NCI Thesaurus - 2.16.840.1.113883.3.26.1.1
Version	1
Definition	Route of Administration value set is based upon FDA Drug Registration and Listing Database (FDA Orange Book) which are used in FDA structured product and labelling (SPL).

Medication Type

Value Set	Medication Type - 2.16.840.1.113883.3.88.12.3221.8.19
Code System	SNOMEDCT - 2.16.840.1.113883.6.96
Version	1
Definition	This is a classification based on how the medication is marketed (e.g., prescription, over the counter drug)

Concept Code	Concept Name	Code System	Description
329505003	Over the counter products	SNOMEDCT	
73639000	Prescription Drug	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	

Concept Code	Concept Name	Code System	Description
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	

Concept Code	Concept Name	Code System	Description
8302-2	Body height:Len:Pt:^Patient:Qn:	LOINC	
8306-3	Body height^lying:Len:Pt:^Patient:Qn:	LOINC	
2710-2	Oxygen saturation:SFr:Pt:BldC:Qn:Oximetry	LOINC	
9279-1	Breaths:NRat:Pt:Respiratory system:Qn:	LOINC	
3141-9	Body weight:Mass:Pt:^Patient:Qn:Measured	LOINC	

REFERENCES

- HL7 Implementation Guide: CDA Release 2 – Continuity of Care Document (CCD) A CDA implementation of ASTM E2369-05 Standard Specification for Continuity of Care Record© (CCR) April 01, 2007 available through *HL7* .
- HL7 Implementation Guide for CDA Release 2 Quality Reporting Document Architecture (QRDA) Draft Standard for Trial Use March 2009. Available at: *Quality Reporting Document Architecture (QRDA)*
- HL7 Implementation Guide for CDA Release 2 CDA for Public Health Case Reports (PHCR) Informative Standard October 2009. Available through *HL7* .
- HL7 Implementation Guide for CDA Release 2: NHSN Healthcare Associated Infection (HAI) Reports, Release 2 Draft Standard for Trial Use January 2009 Available at: *NHSN Healthcare Associated Infection (HAI) Reports*
- Dolin RH, Alschuler L, Boyer S, Beebe C, Behlen FM, Biron PV, Shabo A, (Editors). HL7 Clinical Document Architecture, Release 2.0. ANSI-approved HL7 Standard; May 2005. Ann Arbor, Mich.: Health Level Seven, Inc. Available through *HL7* or if an HL7 member with the following link: *CDA Release 2 Normative Web Edition.*
- *LOINC®* : Logical Observation Identifiers Names and Codes, Regenstrief Institute.
- *SNOMED CT®* : SNOMED Clinical Terms SNOMED International Organization.
- Extensible Markup Language, *www.w3.org/XML* .
- Dolin RH, Alschuler L, Boyer S, Beebe C, Behlen FM, Biron PV, Shabo A., HL7 Clinical Document Architecture, Release 2. J Am Med Inform Assoc. 2006;13:30-39. Available at: *http://www.jamia.org/cgi/reprint/13/1/30* .
- Using SNOMED CT in HL7 Version 3; Implementation Guide, Release 1.5. Available through *HL7* or if an HL7 member with the following link: *Using SNOMED CT in HL7 Version 3*