Implementation Guide for CDA Release 2
HITSP Summary Documents using CCD and CDA Content Modules
C32, C83, and C80

C32 Version 2.5, C83 Version 2.0.1
DRAFT: FOR DEVELOPMENT USE ONLY
(Consolidated Developer Documentation)

Contents

Acknowledgments

Revision History

Rev	Date	By Whom	Changes
First draft for posting	August 31, 2010	Dave Carlson	Updated model content and publication format
First draft for IG consolidation project	December 29, 2010	Dave Carlson	

Notes on draft status

December 29, 2010: This is a first draft of HITSP/IHE/HL7 implementation guide consolidation for C32 and CCD. This draft includes all template sections defined in C83, some of which are not part of C32 summaries. The next draft will limit content to templates used in C32.

Chapter 1

INTRODUCTION

Topics:

Overview

This implementation guide is generated from UML models developed in the Open Health Tools (OHT) Model-Driven Health Tools (MDHT) project. The HITSP specifications have been formalized into computational models expressed in UML. These models are used by automated tooling to generate this publication, plus validation tools and Java libraries for implementers.

This document combines specifications from several HITSP documents, as summarized in the following sections. For the authoritative source, please refer to the approved specifications from HITSP.

C32 Patient Summary

The HITSP Summary Documents Using HL7 Continuity of Care Document (CCD) Component describes the document content summarizing a consumer's medical status for the purpose of information exchange. The content may include administrative (e.g., registration, demographics, insurance, etc.) and clinical (problem list, medication list, allergies, test results, etc) information. Any specific use of this Component by another HITSP specification may constrain the content further based upon the requirements and context of the document exchange. This specification defines content in order to promote interoperability between participating systems. Any given system creating or consuming the document may contain much more information than conveyed by this specification. Such systems may include Personal Health Record Systems (.1.s), Electronic Health Record Systems (EHRs), Practice Management Applications and other persons and systems as identified and permitted.

This Component is essentially a subset of the healthcare data that has been developed for specific business Use Cases. This subset contains the minimum critical or pertinent medical information sections as specified by the business case. Information conveyed according to the Component Construct is a representative extract of the information available on the creating system. The information in the HITSP Summary Documents Using HL7 Continuity of Care Document (CCD) Component and the creating systems must be consistent. Furthermore there should be no data elsewhere in the creating systemthat would contradict the meaning of any data in this construct. The expectation is that consuming systems will be able to use this specification as a source of information to input and/or update information in their instantiation of the healthcare record. This specification does not define the policies applicable to the import of this information.

It is anticipated and desirable that some implementers of the HITSP Summary Documents Using HL7 Continuity of Care Document (CCD) Component will want to add data and sections to permit greater communication between systems. The underlying standards (primarily HL7 CCD – Continuity of Care Document) have additional modules that may serve such purposes. This practice is beyond the scope of this HITSP Component. Implementers should be aware that they must assume that receivers of the document may only be able to view or process content modules as described in this specification, and may not be able to use the additional modules in the document. This means that the HITSP Summary Documents Using HL7 Continuity of Care Document (CCD) Component must be able to stand-alone. Applications may wish to display the document in two different user-selected views, one of which is restricted to the minimal dataset contents of this component. Adding optional sections and data elements should not generate errors. Optional data should be used if understood by the receiving system, but must not change the meaning of the document.

This Component refers to the HITSP 2008 work cycle. It expands upon the prior version of the specification for a consumer’s registration/medication history information to include content to support the consumer's access to clinical information, medication management activities and supportive information for quality of care assessment.

C83 Content Modules

The purpose of the Healthcare Information Technology Standards Panel (HITSP) CDA Content Modules Component is to define the library of Components that may be used by CDA-based constructs developed by HITSP and others in standards based exchanges. The Components are organized into modules to simplify navigation. These modules are organized along the same principals as the HL7 Continuity of Care Document.

The data elements found in these modules are based on HL7 CDA Implementation Guides and the IHE PCC Technical Framework Volume II, Release 5 and its related supplements. These guides contain specifications for document sections that are consistent with all clinical documents currently selected for HITSP constructs.

C80 Clinical Document and Message Terminology

The purpose of the Health Information Technology Standards Panel (HITSP) Clinical Document and Message Terminology Component is to define the vocabulary for either document-based or message-based HITSP constructs such as Clinical Document Architecture (CDA) documents, HL7 V2 messages, etc. For more in-depth information about how this Component relates to other HITSP constructs, see HITSP/TN901 Clinical Documents.

Approach

Working with an initial portion of the data provides the opportunity to work with the data from the perspective of the underlying model and electronic format and to explore many design issues thoroughly. Taking this as an initial step ensures that the data set developers and standards community can reach consensus prior to the larger commitment of time that would be required to bring the full data set into standard format.

This project supports reusability and ease of data collection through a standard data representation harmonized with work developed through Health Information Technology Expert Panel (HITEP), balloted through Health Level Seven (HL7) and/or recognized by the Health Information Technology Standards Panel (HITSP).

This implementation guide (IG) specifies a standard for electronic submission of NCRs in a Clinical Document Architecture (CDA), Release 2 format.

Scope

TODO: scope of this implementation guide.

Audience

The audience for this document includes software developers and implementers who wish to develop...

Organization of This Guide

The requirements as laid out in the body of this document are subject to change per the policy on implementation guides (see section 13.02" Draft Standard for Trial Use Documents" within the HL7 Governance and Operations Manual, *http://www.hl7.org/documentcenter/public/membership/HL7_Governance_and_Operations_Manual.pdf*).

Templates

Templates are organized by document (see Document Templates), by section (see Section Templates), and by clinical statements (see Clinical Statement Templates). Within a section, templates are arranged hierarchically, where a more specific template is nested under the more generic template that it conforms to. See Templates by Containment for a listing of the higher level templates by containment; the appendix Templates Used in This Guide includes a table of all of the templates Organized Hierarchically.

Vocabulary and Value Sets

Vocabularies recommended in this guide are from standard vocabularies. When SNOMED codes are used, rules defined in Using SNOMED CT in HL7 Version 3 are adhered to. In many cases, these vocabularies are further constrained into value sets for use within this guide. Value set names and OIDs are summarized in the table Summary of Value Sets. Each named value set in this summary table is stored in a template database that will be maintained by CHCA.

Use of Templates

When valued in an instance, the template identifier (`templateId`) signals the imposition of a set of template-defined constraints. The value of this attribute provides a unique identifier for the templates in question.

Originator Responsibilities

An originator can apply a `templateId` to assert conformance with a particular template.

In the most general forms of CDA exchange, an originator need not apply a `templateId` for every template that an object in an instance document conforms to. This implementation guide asserts when `templateId`s are required for conformance.

Recipient Responsibilities

A recipient may reject an instance that does not contain a particular `templateId` (e.g., a recipient looking to receive only CCD documents can reject an instance without the appropriate `templateId`).

A recipient may process objects in an instance document that do not contain a `templateId` (e.g., a recipient can process entries that contain Observation acts within a Problems section, even if the entries do not have `templateId`s).

Conventions Used in This Guide

Conformance Requirements

Conformance statements are grouped and identified by the name of the template, along with the templateId and the context of the template (e.g., ClinicalDocument, section, observation), which specifies the element under constraint. If a template is a specialization of another template, its first constraint indicates the more general template. In all cases where a more specific template conforms to a more general template, asserting the more specific template also implies conformance to the more general template. An example is shown below.

Template name

`[<type of template>: templateId <XXXX.XX.XXX.XXX>]`

Description of the template will be here .....

1. Conforms to <The template name> Template (templateId: XXXX<XX>XXX>YYY).
2. **SHALL** contain [1..1] @classCode = <AAA> <code display name> (CodeSystem: 123.456.789 <XXX> Class) **STATIC** (CONF:<number>).
3. .....

Figure 1: Template name and "conforms to" appearance

The conformance verb keyword at the start of a constraint (**SHALL** , **SHOULD** , **MAY**, etc.) indicates business conformance, whereas the cardinality indicator (0..1, 1..1, 1..*, etc.) specifies the allowable occurrences within an instance. Thus, " **MAY** contain 0..1" and " **SHOULD** contain 0..1" both allow for a document to omit the particular component, but the latter is a stronger recommendation that the component be included if it is known.

The following cardinality indicators may be interpreted as follows:

0..1 as zero to one present
1..1 as one and only one present
2..2 as two must be present
1..* as one or more present
0..* as zero to many present

Value set bindings adhere to HL7 Vocabulary Working Group best practices, and include both a conformance verb (**SHALL** , **SHOULD** , **MAY,** etc.) and an indication of **DYNAMIC** vs. **STATIC** binding. The use of **SHALL** requires that the component be valued with a member from the cited value set; however, in every case any HL7 "null" value such as other (OTH) or unknown (UNK) may be used.

Each constraint is uniquely identified (e.g., "CONF:605") by an identifier placed at or near the end of the constraint. These identifiers are not sequential as they are based on the order of creation of the constraint.

1. **SHALL** contain [1..1] component/structuredBody (CONF:4082).
    a. This component/structuredBody **SHOULD** contain [0..1] component (CONF:4130) such that it
        a. **SHALL** contain [1..1] Reporting Parameters section (templateId:2.16.840.1.113883.10.20.17.2.1) (CONF:4131).
    b. This component/structuredBody **SHALL** contain [1..1] component (CONF:4132) such that it
        a. **SHALL** contain [1..1] Patient data section - NCR (templateId:2.16.840.1.113883.10.20.17.2.5) (CONF:4133).

Figure 2: Template-based conformance statements example

CCD templates are included within this implementation guide for ease of reference. CCD templates contained within this implementation guide are formatted WITHOUT typical **KEYWORD** and **XML** element styles. A WIKI site is available if you would like to make a comment to be considered for the next release of CCD: *http://wiki.hl7.org/index.php?title=CCD_Suggested_Enhancements* The user name and password are: wiki/wikiwiki. You will need to create an account to edit the page and add your suggestion.

1. The value for "Observation / @moodCode" in a problem observation SHALL be "EVN" 2.16.840.1.113883.5.1001 ActMood STATIC. (CONF: 814).
2. A problem observation SHALL include exactly one Observation / statusCode. (CONF: 815).
3. The value for "Observation / statusCode" in a problem observation SHALL be "completed" 2.16.840.1.113883.5.14 ActStatus STATIC. (CONF: 816).
4. A problem observation SHOULD contain exactly one Observation / effectiveTime, to indicate the biological timing of condition (e.g. the time the condition started, the onset of the illness or symptom, the duration of a condition). (CONF: 817).

Figure 3: CCD conformance statements example

Keywords

The keywords SHALL, SHALL NOT, SHOULD, SHOULD NOT, MAY, and NEED NOT in this document are to be interpreted as described in the *HL7 Version 3 Publishing Facilitator's Guide*:

- **SHALL**: an absolute requirement
- **SHALL NOT**: an absolute prohibition against inclusion
- **SHOULD/SHOULD NOT**: valid reasons to include or ignore a particular item, but must be understood and carefully weighed
- **MAY/NEED NOT**: truly optional; can be included or omitted as the author decides with no implications

XML Examples

XML samples appear in various figures in this document in a fixed-width font. Portions of the XML content may be omitted from the content for brevity, marked by an ellipsis (…) as shown in the example below.

```
<ClinicalDocument xmlns='urn:h17-org:v3'>
  ...
</ClinicalDocument>
```

Figure 4: ClinicalDocument example

XPath expressions are used in the narrative and conformance requirements to identify elements because they are familiar to many XML implementers.

Chapter 2

DOCUMENT TEMPLATES

Topics:

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

Discharge Summary

[ClinicalDocument: templateId `2.16.840.1.113883.3.88.11.48.2`]

1. **SHALL** conform to *CDT General Header Constraints* template (templateId: `2.16.840.1.113883.10.20.3`)
2. **SHALL** conform to *IHE Medical Document* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.1.1`)
3. **SHALL** conform to *IHE Medical Summary* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.1.2`)
4. **SHALL** contain exactly one [1..1] **`realmCode/@code="US"`** (CONF-HP-15)
5. **SHALL** contain exactly one [1..1] **`typeId`** (CONF-HP-16)
   - The clinical document type ID identifies the constraints imposed by CDA R2 on the content, essentially acting as a version identifier.
6. **SHALL** contain exactly one [1..1] **`id`** (CONF-HP-17)
   - 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.
7. **SHALL** contain exactly one [1..1] **`code`** (CodeSystem:)
8. **SHALL** contain exactly one [1..1] **`title`** (CONF-HP-22)
   - 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.
9. **SHALL** contain exactly one [1..1] **`effectiveTime`** (CONF-HP-23)
   - 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.
10. Contains exactly one [1..1] **`confidentialityCode`**
    - Specifies the confidentiality assigned to the document. This specification provides no further guidance beyond CDA R2 on documents with respect to the vocabulary used for confidentialityCode, nor treatment or implementation of confidentiality.
11. **SHALL** contain exactly one [1..1] **`languageCode`** (CONF-HP-24)
12. Contains at least one [1..*] **`recordTarget`**, where its type is *Record Target*
13. Contains at least one [1..*] **`author`**, where its type is *Author*
14. Contains exactly one [1..1] **`custodian`**, where its type is *Custodian*
15. Contains exactly one [1..1] **`component`**, where its type is *Component2*
16. 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.
17. 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.
18. 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.

19. Contains zero or more [0..*] **`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.

20. 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.

21. Contains zero or more [0..*] **`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.

22. **SHALL** contain exactly one [1..1] **`component`** (C48-[CT2-1]), such that

a. Contains exactly one [1..1] *Problem List Section* (templateId: `2.16.840.1.113883.3.88.11.83.103`)

23. **SHOULD** contain exactly one [1..1] **`component`** (C48-[CT2-2]), such that

a. Contains exactly one [1..1] *Admission Medication History Section* (templateId: `2.16.840.1.113883.3.88.11.83.113`)

24. **SHALL** contain exactly one [1..1] **`component`** (C48-[CT2-3]), such that

a. Contains exactly one [1..1] *Hospital Admission Diagnosis Section* (templateId: `2.16.840.1.113883.3.88.11.83.110`)

25. **MAY** contain zero or one [0..1] **`component`** (C48-[CT2-4]), such that

a. Contains exactly one [1..1] *Advance Directives Section* (templateId: `2.16.840.1.113883.3.88.11.83.116`)

26. **SHALL** contain exactly one [1..1] **`component`** (C48-[CT2-5]), such that

a. Contains exactly one [1..1] *Allergies Reactions Section* (templateId: `2.16.840.1.113883.3.88.11.83.102`)

27. **SHALL** contain exactly one [1..1] **`component`** (C48-[CT2-6]), such that

a. Contains exactly one [1..1] *Discharge Diagnosis Section* (templateId: `2.16.840.1.113883.3.88.11.83.111`)

28. **MAY** contain zero or one [0..1] **`component`** (C48-[CT2-7]), such that

a. Contains exactly one [1..1] *IHE Discharge Diet* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.3.33`)

29. **SHALL** contain exactly one [1..1] **`component`** (C48-[CT2-8]), such that

a. Contains exactly one [1..1] *Hospital Discharge Medications Section* (templateId: `2.16.840.1.113883.3.88.11.83.114`)

30. **MAY** contain zero or one [0..1] **`component`** (C48-[CT2-9]), such that

a. Contains exactly one [1..1] *Diagnostic Results Section* (templateId: `2.16.840.1.113883.3.88.11.83.122`)

31. **MAY** contain zero or one [0..1] **`component`** (C48-[CT2-10]), such that
    a. Contains exactly one [1..1] *Functional Status Section* (templateId: `2.16.840.1.113883.3.88.11.83.109`)
32. **SHOULD** contain exactly one [1..1] **`component`** (C48-[CT2-11]), such that
    a. Contains exactly one [1..1] *History Of Present Illness* (templateId: `2.16.840.1.113883.3.88.11.83.107`)
33. **SHALL** contain exactly one [1..1] **`component`** (C48-[CT2-12]), such that
    a. Contains exactly one [1..1] *Hospital Course Section* (templateId: `2.16.840.1.113883.3.88.11.83.121`)
34. **SHOULD** contain exactly one [1..1] **`component`** (C48-[CT2-13]), such that
    a. Contains exactly one [1..1] *Medical Equipment Section* (templateId: `2.16.840.1.113883.3.88.11.83.128`)
35. **MAY** contain zero or one [0..1] **`component`** (C48-[CT2-15]), such that
    a. Contains exactly one [1..1] *Physical Exam Section* (templateId: `2.16.840.1.113883.3.88.11.83.118`)
36. **SHALL** contain exactly one [1..1] **`component`** (C48-[CT2-16]), such that
    a. Contains exactly one [1..1] *Plan Of Care Section* (templateId: `2.16.840.1.113883.3.88.11.83.124`)
37. **SHALL** contain exactly one [1..1] **`component`** (C48-[CT2-17]), such that
    a. Contains exactly one [1..1] *History Of Past Illness Section* (templateId: `2.16.840.1.113883.3.88.11.83.104`)
38. **MAY** contain zero or one [0..1] **`component`** (C48-[CT2-18]), such that
    a. Contains exactly one [1..1] *Review Of Systems Section* (templateId: `2.16.840.1.113883.3.88.11.83.120`)
39. **SHOULD** contain exactly one [1..1] **`component`** (C48-[CT2-19]), such that
    a. Contains exactly one [1..1] *Medications Administered Section* (templateId: `2.16.840.1.113883.3.88.11.83.115`)
40. **SHOULD** contain exactly one [1..1] **`component`** (C48-[CT2-20]), such that
    a. Contains exactly one [1..1] *Vital Signs Section* (templateId: `2.16.840.1.113883.3.88.11.83.119`)
41. **SHALL** satisfy: All patient, guardianPerson, assignedPerson, maintainingPerson, relatedPerson, intendedRecipient/informationRecipient, associatedPerson, and relatedSubject/subject elements have a name. (CONF-HP-6)
    - `[OCL]: -- implemented in Java using XPath selector`
    - ```
      [XPath]: *[self::cda:patient or self::cda:guardianPerson or
       self::cda:assignedPerson
         or self::cda:maintainingPerson or self::cda:relatedPerson or
       self::cda:associatedPerson
         or self::cda:intendedRecipient/cda:informationRecipient or
       self::cda:relatedSubject/cda:subject]
      ```
42. **SHALL** satisfy: All patientRole, assignedAuthor, assignedEntity[not(parent::dataEnterer)] and associatedEntity elements have an addr and telecom element. (CONF-HP-7)
    - `[OCL]: -- implemented in Java using XPath selector`
    - ```
      [XPath]: *[self::cda:patientRole or self::cda:assignedAuthor
       or self::cda:assignedEntity[not(parent::cda:dataEnterer)]  or
       self::cda:associatedEntity]
      ```

43. **SHOULD** satisfy: All guardian, dataEnterer/assignedEntity, relatedEntity, intendedRecipient, relatedSubject and participantRole elements have an addr and telecom element. (CONF-HP-8)

    - `[OCL]: -- implemented in Java using XPath selector`
    - ```
      [XPath]: *[self::cda:guardian or
       self::cda:assignedEntity[parent::cda:dataEnterer] or
       self::cda:relatedEntity or self::cda:intendedRecipient or
       self::cda:relatedSubject or self::cda:participantRole]
      ```

44. **SHALL** satisfy: All guardianOrganization, providerOrganization, wholeOrganization, representedOrganization, representedCustodianOrganization, receivedOrganization, scopingOrganization and serviceProviderOrganization elements have name, addr and telecom elements. (CONF-HP-9)

    - 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. Legal values according to this specification come from the HL7 NullFlavor vocabulary.

    - `[OCL]: -- implemented in Java using XPath selector`
    - ```
      [XPath]: *[self::cda:guardianOrganization or
       self::cda:providerOrganization or self::cda:wholeOrganization or
       self::cda:representedOrganization or
       self::cda:representedCustodianOrganization or
       self::cda:receivedOrganization or self::cda:scopingOrganization or
       self::cda:serviceProviderOrganization]
      ```

45. 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 second. (CONF-HP-10)

    - `[OCL]: -- implemented in Java using XPath selector`
    - ```
      [XPath]: /cda:ClinicalDocument/cda:effectiveTime | //cda:author/
      cda:time | //cda:dataEnterer/cda:time | //cda:encompassingEncounter/
      cda:effectiveTime
      ```

46. 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-HP-11)

    - ```
      [OCL]: cda::OrganizationPartOf.allInstances()-
      >select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject)-
      > union(  cda::MaintainedEntity.allInstances()-
      >select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject) )-
      >union( cda::RelatedEntity.allInstances()-
      >select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject) )-
      >union(cda::RelatedEntity.allInstances()-
      >select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject) )-
      >union(cda::RelatedEntity.allInstances()-
      >select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject) )-
      >union(cda::ServiceEvent.allInstances()-
      >select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject) )-
      >union(cda::EncounterParticipant.allInstances()-
      >select( time.oclIsUndefined()).oclAsType( ecore::EObject))-
      >union(self.participant-
      >select( time.oclIsUndefined()).oclAsType( ecore::EObject))-
      >union(cda::OrganizationPartOf.allInstances().effectiveTime-
      >union(cda::MaintainedEntity.allInstances().effectiveTime)-
      >union( cda::RelatedEntity.allInstances().effectiveTime)-
      >union(cda::RelatedEntity.allInstances().effectiveTime)-
      >union(cda::RelatedEntity.allInstances().effectiveTime)-
      >union(cda::ServiceEvent.allInstances().effectiveTime)-
      >union(cda::EncounterParticipant.allInstances().time)-
      >union(self.participant.time)->select(current :
      ```

```
datatypes::IVL_TS  |  ((not current.low.oclIsUndefined()) and
(current.low.value.oclIsUndefined() or current.low.value.size()
< 4)) or ((not current.center.oclIsUndefined()) and
(current.center.value.oclIsUndefined() or current.center.value.size()
< 4)) or ((not current.high.oclIsUndefined()) and
(current.high.value.oclIsUndefined() or current.high.value.size() < 4))
or (current.low.oclIsUndefined() and current.center.oclIsUndefined() and
current.high.oclIsUndefined()) ).oclAsType( ecore::EObject))
```

47. **SHALL** satisfy: Telephone numbers match the regular expression pattern tel:\+?[-0-9().]+ (CONF-HP-12)

    - 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.
    - `[OCL]: -- implemented in Java using XPath selector`
    - `[XPath]: //*[self::cda:telecom]`

48. **SHALL** satisfy: At least one dialing digit is present in the phone number after visual separators are removed. (CONF-HP-13)

    - `[OCL]: -- implemented in Java using XPath selector`
    - `[XPath]: //*[self::cda:telecom]`

49. **SHALL** satisfy: If the telephone number is unknown it is represented using the appropriate flavor of null. (CONF-HP-14)

    - 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.
    - `[OCL]: -- implemented in Java using XPath selector`
    - `[XPath]: //*[self::cda:telecom]`

50. **SHALL** satisfy: The extension attribute of the typeId element is POCD_HD000040. (CONF-HP-16)

    - `[OCL]: self.typeId.extension = 'POCD_HD000040'`

51. **SHALL** satisfy: The id/@root attribute is a syntactically correct UUID or OID. (CONF-HP-17)
52. **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]. (CONF-HP-18)
53. 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-HP-19)

    - 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.

54. **SHALL** satisfy: OIDs are no more than 64 characters in length. (CONF-HP-20)

    - OIDs are limited by this specification to no more than 64 characters in length for compatibility with other standards and Implementation Guides.
    - `[OCL]: self.id->select((not id.root.oclIsUndefined()) and id.root.size() > 64 )`

55. **SHALL** satisfy: languageCode has the form nn, or nn-CC. (CONF-HP-25)

56. **SHALL** satisfy: The nn portion of languageCode is a legal ISO-639-1 language code in lowercase. (CONF-HP-26)
57. The CC portion languageCode, if present, **SHALL** be an ISO-3166 country code in uppercase. (CONF-HP-27)
58. Both setId and versionNumber **SHALL** be present or both **SHALL** be absent. (CONF-HP-28)

    - 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.
    - ```
      [OCL]: (self.setId.oclIsUndefined() and
       self.versionNumber.oclIsUndefined())
         xor (not self.setId.oclIsUndefined() and not
       self.versionNumber.oclIsUndefined())
      ```
59. The @extension and/or @root of setId and id **SHALL** be different when both are present. (CONF-HP-29)

    - ```
      [OCL]: (not self.setId.oclIsUndefined() and not self.id.oclIsUndefined())
         implies (self.setId.root <> self.id.root or self.setId.extension <>
       self.id.extension)
      ```
60. A copyTime element **SHALL NOT** be present. (CONF-HP-30)

    - The ClinicalDocument/copyTime element has been deprecated in CDA R2.
    - ```
      [OCL]: self.copyTime.oclIsUndefined()
      ```
61. **SHALL** satisfy: At least one recordTarget/patientRole element is present. (CONF-HP-31)

    - ```
      [OCL]: self.recordTarget->size() > 0 and self.recordTarget-
      >exists(target : cda::RecordTarget | not
       target.patientRole.oclIsUndefined())
      ```
62. 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-HP-32)

    - ```
      [OCL]: self.recordTarget->forAll(target : cda::RecordTarget | not
       target.patientRole.oclIsUndefined()
         implies (not
       target.patientRole.patient.birthTime.value.oclIsUndefined()
            or not
       target.patientRole.patient.birthTime.nullFlavor.oclIsUndefined()))
      ```
63. 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-HP-33)

    - TODO: add OCL test for terminology
    - ```
      [OCL]: self.recordTarget->forAll(target : cda::RecordTarget | not
       target.patientRole.oclIsUndefined()
         implies (not
       target.patientRole.patient.administrativeGenderCode.code.oclIsUndefined()
            or not
       target.patientRole.patient.administrativeGenderCode.nullFlavor.oclIsUndefined()))
      ```
64. 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-HP-34)
65. **SHOULD** satisfy: The guardian element is present when the patient is a minor child. (CONF-HP-35)
66. **MAY** satisfy: The providerOrganization element is present. (CONF-HP-36)

    - ```
      [OCL]: self.recordTarget->exists(target : cda::RecordTarget | not
       target.patientRole.providerOrganization.oclIsUndefined())
      ```
67. **SHALL** satisfy: The author/time element is present. (CONF-HP-37)
      ```

- The author/time element represents the start time of the author's participation in the creation of the clinical document.
- `[OCL]: self.author->forAll(author : cda::Author | not author.time.oclIsUndefined())`

68. **SHALL** satisfy: The assignedAuthor/id element is present. (CONF-HP-38)

- `[OCL]: self.author->forAll(author : cda::Author | author.assignedAuthor.id->size() > 0)`

69. **SHALL** satisfy: An assignedAuthor element contains at least one assignedPerson or assignedAuthoringDevice elements. (CONF-HP-39)

- `[OCL]: self.author->forAll(author : cda::Author | not author.assignedAuthor.assignedPerson.oclIsUndefined() or not author.assignedAuthor.assignedAuthoringDevice.oclIsUndefined())`

70. **SHALL** satisfy: When dataEnterer is present, an assignedEntity/assignedPerson element is present. (CONF-HP-40)

- `[OCL]: not self.dataEnterer.oclIsUndefined() implies not self.dataEnterer.assignedEntity.assignedPerson.oclIsUndefined()`

71. The dataEnterer/time element **MAY** be present. If present, it represents the starting time of entry of the data. (CONF-HP-41)

- `[OCL]: not self.dataEnterer.oclIsUndefined() implies not self.dataEnterer.time.oclIsUndefined()`

72. **MAY** satisfy: The informant element is present. (CONF-HP-42)

- `[OCL]: self.informant->size() > 0`

73. When informant is present, an assignedEntity/assignedPerson or relatedEntity/relatedPerson element **SHALL** be present. (CONF-HP-43)

- `[OCL]: self.informant->forAll(i : cda::Informant12 | not i.assignedEntity.assignedPerson.oclIsUndefined() or not i.relatedEntity.relatedPerson.oclIsUndefined())`

74. When the informant is a healthcare provider with an assigned role, the informant **SHALL** be represented using the assignedEntity element (CONF-HP-44)

- Assigned health care providers may be a source of information when a document is created. (e.g., a nurse's aide who provides information about a recent significant health care event that occurred within an acute care facility.) In these cases, the assignedEntity element is used.
- TODO: how to determin if informant is a healthcare provider? condition for implementing OCL

75. Allowable values for informant/relatedEntity/@classCode **SHALL** be CON, PRS, CAREGIVER, AGNT or PROV from the RoleClass vocabulary. (CONF-HP-45)

- 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.

76. 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-HP-46)

77. 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-HP-47)

- 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.

78. 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-HP-48)

- 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.

79. When the informant is a healthcare provider, the value of relatedEntity/code **SHOULD** be present and indicate the type of healthcare provider. (CONF-HP-49)

80. 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-HP-50)

81. The assignedEntity/assignedPerson element **SHALL** be present in legalAuthenticator. (CONF-HP-51)

- ```
  [OCL]: not self.legalAuthenticator.oclIsUndefined() implies not
   self.legalAuthenticator.assignedEntity.assignedPerson.oclIsUndefined()
  ```

82. The assignedEntity/assignedPerson element **SHALL** be present in an authenticator element. (CONF-HP-52)

- ```
  [OCL]: self.authenticator->forAll(auth : cda::Authenticator |
   auth.assignedEntity->forAll(entity : cda::AssignedEntity |
     not entity.assignedPerson.oclIsUndefined()))
  ```

83. 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 second. (CONF-HP-10)

- Should portion of CON-HP-10 constraitn
- ```
  [OCL]: -- implemented in Java using XPath selector
  ```
- ```
  [XPath]: /cda:ClinicalDocument/cda:effectiveTime | //cda:author/
  cda:time | //cda:dataEnterer/cda:time | //cda:encompassingEncounter/
  cda:effectiveTime
  ```

84. 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-HP-11)

- Should portion of CON-HP-11 constraint
- ```
  [OCL]: cda::OrganizationPartOf.allInstances()-
  >select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject)-
  > union(  cda::MaintainedEntity.allInstances()-
  >select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject) )-
  >union( cda::RelatedEntity.allInstances()-
  >select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject) )-
  >union(cda::RelatedEntity.allInstances()-
  >select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject) )-
  >union(cda::RelatedEntity.allInstances()-
  >select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject) )-
  >union(cda::ServiceEvent.allInstances()-
  >select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject) )-
  >union(cda::EncounterParticipant.allInstances()-
  >select( time.oclIsUndefined()).oclAsType( ecore::EObject))-
  >union(self.participant-
  >select( time.oclIsUndefined()).oclAsType( ecore::EObject))-
  >union(cda::OrganizationPartOf.allInstances().effectiveTime-
  >union(cda::MaintainedEntity.allInstances().effectiveTime)-
  >union( cda::RelatedEntity.allInstances().effectiveTime)-
  >union(cda::RelatedEntity.allInstances().effectiveTime)-
  >union(cda::RelatedEntity.allInstances().effectiveTime)-
  >union(cda::ServiceEvent.allInstances().effectiveTime)-
  >union(cda::EncounterParticipant.allInstances().time)-
  >union(self.participant.time)->select(current :
   datatypes::IVL_TS  |  ((not current.low.oclIsUndefined()) and
   (current.low.value.oclIsUndefined() or current.low.value.size()
   < 8)) or ((not current.center.oclIsUndefined()) and
   (current.center.value.oclIsUndefined() or current.center.value.size()
   < 8)) or ((not current.high.oclIsUndefined()) and
  ```
  ```

```
(current.high.value.oclIsUndefined() or current.high.value.size() < 8))
or (current.low.oclIsUndefined() and current.center.oclIsUndefined() and
current.high.oclIsUndefined()) ).oclAsType( ecore::EObject))
```

85. **SHALL** satisfy: MedicalSummaryProblemConcernEntry
    - `[OCL]: self.getSections()->exists(sect : cda::Section | sect.getActs()->exists(act : cda::Act | act.oclIsKindOf(ihe::ProblemConcernEntry)))`
86. **SHALL** satisfy: MedicalSummaryAllergyConcernEntry
    - `[OCL]: self.getSections()->exists(sect : cda::Section | sect.getActs()->exists(act : cda::Act | act.oclIsKindOf(ihe::AllergyIntoleranceConcern)))`
87. **SHALL** satisfy: MedicalSummaryMedications
    - `[OCL]: self.getSections()->exists(sect : cda::Section | sect.getSubstanceAdministrations()->exists(sub : cda::SubstanceAdministration | sub.oclIsKindOf(ihe::Medication)))`

Discharge Summary example

Patient Summary

[ClinicalDocument: templateId `2.16.840.1.113883.3.88.11.32.1`]

This Component describes the document content that summarizes a consumer's medical status for the purpose of health information exchange. While an EHR or PHR system can contain much more information, this Component only deals with the summary information to be exchanged between such systems as established as requirements described in AHIC Use Cases.

1. **SHALL** conform to *CCD Continuity Of Care Document* template (templateId: `2.16.840.1.113883.10.20.1`)
2. **SHALL** conform to *CDT General Header Constraints* template (templateId: `2.16.840.1.113883.10.20.3`)
3. **SHALL** conform to *IHE Medical Document* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.1.1`)
4. **SHALL** contain exactly one [1..1] **`code`** (CONF-HP-21)
    - Specifies the type of the clinical document.
5. **SHALL** contain exactly one [1..1] **`languageCode`** (CONF-HP-24)
6. **SHALL** contain exactly one [1..1] **`realmCode/@code`**`="US"` (CONF-HP-15)
7. **SHALL** contain exactly one [1..1] **`typeId`** (CONF-HP-16)
    - The clinical document type ID identifies the constraints imposed by CDA R2 on the content, essentially acting as a version identifier.
8. **SHALL** contain exactly one [1..1] **`id`** (CONF-HP-17)
    - 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.
9. **SHALL** contain exactly one [1..1] **`title`** (CONF-HP-22)
    - 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.
10. **SHALL** contain exactly one [1..1] **`effectiveTime`** (CONF-HP-23)
    - 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.
11. Contains exactly one [1..1] **`confidentialityCode`**

- Specifies the confidentiality assigned to the document. This specification provides no further guidance beyond CDA R2 on documents with respect to the vocabulary used for confidentialityCode, nor treatment or implementation of confidentiality.

12. **SHOULD** contain exactly one [1..1] **`component`** (CONF-140), such that
    a. Contains exactly one [1..1] *Problem Section* (templateId: `2.16.840.1.113883.10.20.1.11`)
13. **SHOULD** contain exactly one [1..1] **`component`**, such that
    a. Contains exactly one [1..1] *Family History Section* (templateId: `2.16.840.1.113883.10.20.1.4`)
14. **SHOULD** contain exactly one [1..1] **`component`**, such that
    a. Contains exactly one [1..1] *Social History Section* (templateId: `2.16.840.1.113883.10.20.1.15`)
15. **SHOULD** contain exactly one [1..1] **`component`**, such that
    a. Contains exactly one [1..1] *Alerts Section* (templateId: `2.16.840.1.113883.10.20.1.2`)
16. **SHOULD** contain exactly one [1..1] **`component`** (CONF-388), such that
    a. Contains exactly one [1..1] *Results Section* (templateId: `2.16.840.1.113883.10.20.1.14`)
17. **SHOULD** contain exactly one [1..1] **`component`**, such that
    a. Contains exactly one [1..1] *Procedures Section* (templateId: `2.16.840.1.113883.10.20.1.12`)
18. **SHOULD** contain exactly one [1..1] **`component`**, such that
    a. Contains exactly one [1..1] *Encounters Section* (templateId: `2.16.840.1.113883.10.20.1.3`)
19. **SHOULD** contain exactly one [1..1] **`component`**, such that
    a. Contains exactly one [1..1] *Plan Of Care Section* (templateId: `2.16.840.1.113883.10.20.1.10`)
20. **SHOULD** contain exactly one [1..1] **`component`**, such that
    a. Contains exactly one [1..1] *Immunizations Section* (templateId: `2.16.840.1.113883.10.20.1.6`)
21. **SHOULD** contain exactly one [1..1] **`component`** (CONF-381), such that
    a. Contains exactly one [1..1] *Vital Signs Section* (templateId: `2.16.840.1.113883.10.20.1.16`)
22. **SHOULD** contain exactly one [1..1] **`component`**, such that
    a. Contains exactly one [1..1] *Medical Equipment Section* (templateId: `2.16.840.1.113883.10.20.1.7`)
23. **SHOULD** contain exactly one [1..1] **`component`**, such that
    a. Contains exactly one [1..1] *Functional Status Section* (templateId: `2.16.840.1.113883.10.20.1.5`)
24. **SHOULD** contain exactly one [1..1] **`component`**, such that
    a. Contains exactly one [1..1] *Advance Directives Section* (templateId: `2.16.840.1.113883.10.20.1.1`)
25. **SHOULD** contain exactly one [1..1] **`component`**, such that
    a. Contains exactly one [1..1] *Payers Section* (templateId: `2.16.840.1.113883.10.20.1.9`)
26. **MAY** contain exactly one [1..1] **`component`** (CONF-15), such that
    a. Contains exactly one [1..1] *Purpose Section* (templateId: `2.16.840.1.113883.10.20.1.13`)
27. Contains at least one [1..*] **`recordTarget`**, where its type is *Record Target*
28. Contains at least one [1..*] **`author`**, where its type is *Author*
29. Contains exactly one [1..1] **`custodian`**, where its type is *Custodian*
30. Contains exactly one [1..1] **`component`**, where its type is *Component2*
31. 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.
32. 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.

33. 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.
34. Contains zero or more [0..*] **`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.
35. 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.
36. Contains zero or more [0..*] **`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.
37. **MAY** contain zero or one [0..1] **`component`** (C32-[CT1-1]), such that
    a. Contains exactly one [1..1] *Advance Directives Section* (templateId: `2.16.840.1.113883.3.88.11.83.116`)
38. **MAY** contain zero or one [0..1] **`component`** (C32-[CT1-2]), such that
    a. Contains exactly one [1..1] *Allergies Reactions Section* (templateId: `2.16.840.1.113883.3.88.11.83.102`)
39. **MAY** contain zero or more [0..*] **`component`** (C32-[CT1-3]), such that
    a. Contains exactly one [1..1] *Comment* (templateId: `2.16.840.1.113883.3.88.11.83.11`)
40. **MAY** contain zero or one [0..1] **`component`** (C32-[CT1-4]), such that
    a. Contains exactly one [1..1] *Problem List Section* (templateId: `2.16.840.1.113883.3.88.11.83.103`)
41. **MAY** contain zero or one [0..1] **`component`** (C32-[CT1-5]), such that
    a. Contains exactly one [1..1] *Encounters Section* (templateId: `2.16.840.1.113883.3.88.11.83.127`)
42. **MAY** contain zero or one [0..1] **`component`** (C32-[CT1-7]), such that
    a. Contains exactly one [1..1] *Immunizations Section* (templateId: `2.16.840.1.113883.3.88.11.83.117`)
43. **MAY** contain zero or one [0..1] **`component`** (C32-[CT1-9]), such that
    a. Contains exactly one [1..1] *Payers Section* (templateId: `2.16.840.1.113883.3.88.11.83.101`)
44. **MAY** contain zero or one [0..1] **`component`** (C32-[CT1-11]), such that
    a. Contains exactly one [1..1] *Medications Section* (templateId: `2.16.840.1.113883.3.88.11.83.112`)

45. **MAY** contain zero or one [0..1] **`component`** (C32-[CT1-13]), such that
    a. Contains exactly one [1..1] *Plan Of Care Section* (templateId: `2.16.840.1.113883.3.88.11.83.124`)
46. **MAY** contain zero or one [0..1] **`component`** (C32-[CT1-14]), such that
    a. Contains exactly one [1..1] *IHE Pregnancy History Section* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.1.5.3.4`)
47. **MAY** contain zero or one [0..1] **`component`** (C32-[CT1-15]), such that
    a. Contains exactly one [1..1] *Surgeries Section* (templateId: `2.16.840.1.113883.3.88.11.83.108`)
48. **SHOULD** contain at least one [1..*] **`supportHeaders`** (C32-[CT1-16]), such that
49. **MAY** contain zero or one [0..1] **`component`** (C32-[CT1-17]), such that
    a. Contains exactly one [1..1] *Vital Signs Section* (templateId: `2.16.840.1.113883.3.88.11.83.119`)
50. **MAY** contain zero or one [0..1] **`component`** (C32-[CT1-18]), such that
    a. Contains exactly one [1..1] *Diagnostic Results Section* (templateId: `2.16.840.1.113883.3.88.11.83.122`)
51. **SHALL** satisfy: Contains exactly one documentationOf / serviceEvent (CONF-2)
    - `[OCL]: self.documentationOf->one(doc : cda::DocumentationOf | not doc.serviceEvent.oclIsUndefined())`
52. documentationOf / serviceEvent / @classCode **SHALL** be 'PCPR' (CONF-3)
    - `[OCL]: self.documentationOf->one(doc : cda::DocumentationOf | doc.serviceEvent.classCode = vocab::ActClassRoot::PCPR)`
53. **SHALL** satisfy: documentationOf / serviceEvent contains exactly one serviceEvent / effectiveTime / low and exactly one serviveEvent / effectiveTime / high (CONF-4)
    - `[OCL]: self.documentationOf->one(doc : cda::DocumentationOf | not doc.serviceEvent.effectiveTime.low.oclIsUndefined() and not doc.serviceEvent.effectiveTime.high.oclIsUndefined())`
54. languageCode has the form nn, or nn-CC. The nn portion **SHALL** be an ISO-639-1 language code in lower case. The CC portion, if present, **SHALL** be an ISO-3166 country code in upper case (CONF-6)
55. **SHALL NOT** contain templateId / @extension (CONF-8)
    - `[OCL]: self.templateId->forAll(id : datatypes::II | id.root = '2.16.840.1.113883.10.20.1' implies id.extension.oclIsUndefined())`
56. **SHALL** satisfy: effectiveTime is expressed with precision to include seconds (CONF-9)
57. **SHALL** satisfy: effectiveTime includes an explicit time zone offset (CONF-10)
58. **SHALL** satisfy: Contains one or two recordTarget (CONF-11)
    - `[OCL]: self.recordTarget->size() = 1 or self.recordTarget->size() =2`
59. **SHOULD** satisfy: Contains one or more author / assignedAuthor / assignedPerson and/or author / assignedAuthor / representedOrganization (CONF-12)
    - `[OCL]: self.author->exists(author : cda::Author | not author.assignedAuthor.assignedPerson.oclIsUndefined() or not author.assignedAuthor.representedOrganization.oclIsUndefined())`
60. If author has an associated representedOrganization with no assignedPerson or assignedAuthoringDevice, then the value for author / assignedAuthor / id / @NullFlavor **SHALL** be 'NA' (CONF-13)
    - `[OCL]: self.author->exists(author : cda::Author | (not author.assignedAuthor.representedOrganization.oclIsUndefined() and author.assignedAuthor.assignedPerson.oclIsUndefined() and author.assignedAuthor.assignedAuthoringDevice.oclIsUndefined()) implies author.assignedAuthor.id->one(id : datatypes::II | id.nullFlavor = vocab::NullFlavor::NA))`
61. **MAY** satisfy: Contains one or more informationRecipient (CONF-14)
    - `[OCL]: self.informationRecipient->size() > 0`

62. The value for component / structuredBody / component / section / entry / @typeCode **MAY** be 'DRIV' "is derived from" 2.16.840.1.113883.5.1002 ActRelationshipType STATIC, to indicate that the CDA Narrative Block is fully derived from the structured entries. (CONF-28)
63. A CCD entry **SHOULD** explicitly reference its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1 <content>). (CONF-29)
64. A section **MAY** contain one or more comments, either as a clinical statement or nested under another clinical statement. (CONF-502)
65. **SHALL** satisfy: All patient, guardianPerson, assignedPerson, maintainingPerson, relatedPerson, intendedRecipient/informationRecipient, associatedPerson, and relatedSubject/subject elements have a name. (CONF-HP-6)

    - `[OCL]: -- implemented in Java using XPath selector`
    - ```
      [XPath]: *[self::cda:patient or self::cda:guardianPerson or
       self::cda:assignedPerson
         or self::cda:maintainingPerson or self::cda:relatedPerson or
       self::cda:associatedPerson
         or self::cda:intendedRecipient/cda:informationRecipient or
       self::cda:relatedSubject/cda:subject]
      ```
66. **SHALL** satisfy: All patientRole, assignedAuthor, assignedEntity[not(parent::dataEnterer)] and associatedEntity elements have an addr and telecom element. (CONF-HP-7)

    - `[OCL]: -- implemented in Java using XPath selector`
    - ```
      [XPath]: *[self::cda:patientRole or self::cda:assignedAuthor
       or self::cda:assignedEntity[not(parent::cda:dataEnterer)]  or
       self::cda:associatedEntity]
      ```
67. **SHOULD** satisfy: All guardian, dataEnterer/assignedEntity, relatedEntity, intendedRecipient, relatedSubject and participantRole elements have an addr and telecom element. (CONF-HP-8)

    - `[OCL]: -- implemented in Java using XPath selector`
    - ```
      [XPath]: *[self::cda:guardian or
       self::cda:assignedEntity[parent::cda:dataEnterer] or
       self::cda:relatedEntity or self::cda:intendedRecipient or
       self::cda:relatedSubject or self::cda:participantRole]
      ```
68. **SHALL** satisfy: All guardianOrganization, providerOrganization, wholeOrganization, representedOrganization, representedCustodianOrganization, receivedOrganization, scopingOrganization and serviceProviderOrganization elements have name, addr and telecom elements. (CONF-HP-9)

    - 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. Legal values according to this specification come from the HL7 NullFlavor vocabulary.

    - `[OCL]: -- implemented in Java using XPath selector`
    - ```
      [XPath]: *[self::cda:guardianOrganization or
       self::cda:providerOrganization or self::cda:wholeOrganization or
       self::cda:representedOrganization or
       self::cda:representedCustodianOrganization or
       self::cda:receivedOrganization or self::cda:scopingOrganization or
       self::cda:serviceProviderOrganization]
      ```
69. 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 second. (CONF-HP-10)

    - `[OCL]: -- implemented in Java using XPath selector`
    - ```
      [XPath]: /cda:ClinicalDocument/cda:effectiveTime | //cda:author/
      cda:time | //cda:dataEnterer/cda:time | //cda:encompassingEncounter/
      cda:effectiveTime
      ```
70. 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-HP-11)

- ```
  [OCL]: cda::OrganizationPartOf.allInstances()-
  >select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject)-
  > union(  cda::MaintainedEntity.allInstances()-
  >select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject) )-
  >union( cda::RelatedEntity.allInstances()-
  >select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject) )-
  >union(cda::RelatedEntity.allInstances()-
  >select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject) )-
  >union(cda::RelatedEntity.allInstances()-
  >select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject) )-
  >union(cda::ServiceEvent.allInstances()-
  >select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject) )-
  >union(cda::EncounterParticipant.allInstances()-
  >select( time.oclIsUndefined()).oclAsType( ecore::EObject))-
  >union(self.participant-
  >select( time.oclIsUndefined()).oclAsType( ecore::EObject))-
  >union(cda::OrganizationPartOf.allInstances().effectiveTime-
  >union(cda::MaintainedEntity.allInstances().effectiveTime)-
  >union( cda::RelatedEntity.allInstances().effectiveTime)-
  >union(cda::RelatedEntity.allInstances().effectiveTime)-
  >union(cda::RelatedEntity.allInstances().effectiveTime)-
  >union(cda::ServiceEvent.allInstances().effectiveTime)-
  >union(cda::EncounterParticipant.allInstances().time)-
  >union(self.participant.time)->select(current :
   datatypes::IVL_TS  |  ((not current.low.oclIsUndefined()) and
   (current.low.value.oclIsUndefined() or current.low.value.size()
   < 4)) or ((not current.center.oclIsUndefined()) and
   (current.center.value.oclIsUndefined() or current.center.value.size()
   < 4)) or ((not current.high.oclIsUndefined()) and
   (current.high.value.oclIsUndefined() or current.high.value.size() < 4))
   or (current.low.oclIsUndefined() and current.center.oclIsUndefined() and
   current.high.oclIsUndefined()) ).oclAsType( ecore::EObject))
  ```

71. **SHALL** satisfy: Telephone numbers match the regular expression pattern tel:\+?[-0-9().]+ (CONF-HP-12)

    - 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.
    - `[OCL]: -- implemented in Java using XPath selector`
    - `[XPath]: //*[self::cda:telecom]`

72. **SHALL** satisfy: At least one dialing digit is present in the phone number after visual separators are removed. (CONF-HP-13)

    - `[OCL]: -- implemented in Java using XPath selector`
    - `[XPath]: //*[self::cda:telecom]`

73. **SHALL** satisfy: If the telephone number is unknown it is represented using the appropriate flavor of null. (CONF-HP-14)

    - 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.
    - `[OCL]: -- implemented in Java using XPath selector`
    - `[XPath]: //*[self::cda:telecom]`
  ```

74. **SHALL** satisfy: The extension attribute of the typeId element is POCD_HD000040. (CONF-HP-16)
    - `[OCL]: self.typeId.extension = 'POCD_HD000040'`
75. **SHALL** satisfy: The id/@root attribute is a syntactically correct UUID or OID. (CONF-HP-17)
76. **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]. (CONF-HP-18)
77. 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-HP-19)
    - 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.
78. **SHALL** satisfy: OIDs are no more than 64 characters in length. (CONF-HP-20)
    - OIDs are limited by this specification to no more than 64 characters in length for compatibility with other standards and Implementation Guides.
    - `[OCL]: self.id->select((not id.root.oclIsUndefined()) and id.root.size() > 64 )`
79. **SHALL** satisfy: languageCode has the form nn, or nn-CC. (CONF-HP-25)
80. **SHALL** satisfy: The nn portion of languageCode is a legal ISO-639-1 language code in lowercase. (CONF-HP-26)
81. The CC portion languageCode, if present, **SHALL** be an ISO-3166 country code in uppercase. (CONF-HP-27)
82. Both setId and versionNumber **SHALL** be present or both **SHALL** be absent. (CONF-HP-28)
    - 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.
    - ```
      [OCL]: (self.setId.oclIsUndefined() and
       self.versionNumber.oclIsUndefined())
         xor (not self.setId.oclIsUndefined() and not
       self.versionNumber.oclIsUndefined())
      ```
83. The @extension and/or @root of setId and id **SHALL** be different when both are present. (CONF-HP-29)
    - ```
      [OCL]: (not self.setId.oclIsUndefined() and not self.id.oclIsUndefined())
         implies (self.setId.root <> self.id.root or self.setId.extension <>
       self.id.extension)
      ```
84. A copyTime element **SHALL NOT** be present. (CONF-HP-30)
    - The ClinicalDocument/copyTime element has been deprecated in CDA R2.
    - `[OCL]: self.copyTime.oclIsUndefined()`
85. **SHALL** satisfy: At least one recordTarget/patientRole element is present. (CONF-HP-31)
    - ```
      [OCL]: self.recordTarget->size() > 0 and self.recordTarget-
      >exists(target : cda::RecordTarget | not
       target.patientRole.oclIsUndefined())
      ```
86. 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-HP-32)
    - ```
      [OCL]: self.recordTarget->forAll(target : cda::RecordTarget | not
       target.patientRole.oclIsUndefined()
         implies (not
       target.patientRole.patient.birthTime.value.oclIsUndefined()
      ```

```
      or not
 target.patientRole.patient.birthTime.nullFlavor.oclIsUndefined()))
```

87. 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-HP-33)
    - TODO: add OCL test for terminology
    - ```
      [OCL]: self.recordTarget->forAll(target : cda::RecordTarget | not
       target.patientRole.oclIsUndefined()
         implies (not
       target.patientRole.patient.administrativeGenderCode.code.oclIsUndefined()
            or not
       target.patientRole.patient.administrativeGenderCode.nullFlavor.oclIsUndefined()))
      ```
88. 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-HP-34)
89. **SHOULD** satisfy: The guardian element is present when the patient is a minor child. (CONF-HP-35)
90. **MAY** satisfy: The providerOrganization element is present. (CONF-HP-36)
    - ```
      [OCL]: self.recordTarget->exists(target : cda::RecordTarget | not
       target.patientRole.providerOrganization.oclIsUndefined())
      ```
91. **SHALL** satisfy: The author/time element is present. (CONF-HP-37)
    - The author/time element represents the start time of the author's participation in the creation of the clinical document.
    - ```
      [OCL]: self.author->forAll(author : cda::Author | not
       author.time.oclIsUndefined())
      ```
92. **SHALL** satisfy: The assignedAuthor/id element is present. (CONF-HP-38)
    - ```
      [OCL]: self.author->forAll(author : cda::Author |
       author.assignedAuthor.id->size() > 0)
      ```
93. **SHALL** satisfy: An assignedAuthor element contains at least one assignedPerson or assignedAuthoringDevice elements. (CONF-HP-39)
    - ```
      [OCL]: self.author->forAll(author : cda::Author | not
       author.assignedAuthor.assignedPerson.oclIsUndefined()
         or not author.assignedAuthor.assignedAuthoringDevice.oclIsUndefined())
      ```
94. **SHALL** satisfy: When dataEnterer is present, an assignedEntity/assignedPerson element is present. (CONF-HP-40)
    - ```
      [OCL]: not self.dataEnterer.oclIsUndefined() implies not
       self.dataEnterer.assignedEntity.assignedPerson.oclIsUndefined()
      ```
95. The dataEnterer/time element **MAY** be present. If present, it represents the starting time of entry of the data. (CONF-HP-41)
    - ```
      [OCL]: not self.dataEnterer.oclIsUndefined() implies not
       self.dataEnterer.time.oclIsUndefined()
      ```
96. **MAY** satisfy: The informant element is present. (CONF-HP-42)
    - ```
      [OCL]: self.informant->size() > 0
      ```
97. When informant is present, an assignedEntity/assignedPerson or relatedEntity/relatedPerson element **SHALL** be present. (CONF-HP-43)
    - ```
      [OCL]: self.informant->forAll(i : cda::Informant12 | not
       i.assignedEntity.assignedPerson.oclIsUndefined()
         or not i.relatedEntity.relatedPerson.oclIsUndefined())
      ```
98. When the informant is a healthcare provider with an assigned role, the informant **SHALL** be represented using the assignedEntity element (CONF-HP-44)
    - Assigned health care providers may be a source of information when a document is created. (e.g., a nurse's aide who provides information about a recent significant health care event that occurred within an acute care facility.) In these cases, the assignedEntity element is used.
      ```

- TODO: how to determin if informant is a healthcare provider? condition for implementing OCL

99. Allowable values for informant/relatedEntity/@classCode **SHALL** be CON, PRS, CAREGIVER, AGNT or PROV from the RoleClass vocabulary. (CONF-HP-45)

- 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.

100. 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-HP-46)

101. 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-HP-47)

- 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.

102. 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-HP-48)

- 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.

103. When the informant is a healthcare provider, the value of relatedEntity/code **SHOULD** be present and indicate the type of healthcare provider. (CONF-HP-49)

104. 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-HP-50)

105. The assignedEntity/assignedPerson element **SHALL** be present in legalAuthenticator. (CONF-HP-51)

- ```
  [OCL]: not self.legalAuthenticator.oclIsUndefined() implies not
   self.legalAuthenticator.assignedEntity.assignedPerson.oclIsUndefined()
  ```

106. The assignedEntity/assignedPerson element **SHALL** be present in an authenticator element. (CONF-HP-52)

- ```
  [OCL]: self.authenticator->forAll(auth : cda::Authenticator |
   auth.assignedEntity->forAll(entity : cda::AssignedEntity |
     not entity.assignedPerson.oclIsUndefined()))
  ```

107. 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 second. (CONF-HP-10)

- Should portion of CON-HP-10 constraitn
- ```
  [OCL]: -- implemented in Java using XPath selector
  ```
- ```
  [XPath]: /cda:ClinicalDocument/cda:effectiveTime | //cda:author/
  cda:time | //cda:dataEnterer/cda:time | //cda:encompassingEncounter/
  cda:effectiveTime
  ```

108. 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-HP-11)

- Should portion of CON-HP-11 constraint
- ```
  [OCL]: cda::OrganizationPartOf.allInstances()-
  >select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject)-
  > union(  cda::MaintainedEntity.allInstances()-
  >select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject) )-
  >union( cda::RelatedEntity.allInstances()-
  >select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject) )-
  ```
  ```

```
>union(cda::RelatedEntity.allInstances()-
>select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject) )-
>union(cda::RelatedEntity.allInstances()-
>select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject) )-
>union(cda::ServiceEvent.allInstances()-
>select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject) )-
>union(cda::EncounterParticipant.allInstances()-
>select( time.oclIsUndefined()).oclAsType( ecore::EObject))-
>union(self.participant-
>select( time.oclIsUndefined()).oclAsType( ecore::EObject))-
>union(cda::OrganizationPartOf.allInstances().effectiveTime-
>union(cda::MaintainedEntity.allInstances().effectiveTime)-
>union( cda::RelatedEntity.allInstances().effectiveTime)-
>union(cda::RelatedEntity.allInstances().effectiveTime)-
>union(cda::RelatedEntity.allInstances().effectiveTime)-
>union(cda::ServiceEvent.allInstances().effectiveTime)-
>union(cda::EncounterParticipant.allInstances().time)-
>union(self.participant.time)->select(current :
 datatypes::IVL_TS  |  ((not current.low.oclIsUndefined()) and
 (current.low.value.oclIsUndefined() or current.low.value.size()
 < 8)) or ((not current.center.oclIsUndefined()) and
 (current.center.value.oclIsUndefined() or current.center.value.size()
 < 8)) or ((not current.high.oclIsUndefined()) and
 (current.high.value.oclIsUndefined() or current.high.value.size() < 8))
 or (current.low.oclIsUndefined() and current.center.oclIsUndefined() and
 current.high.oclIsUndefined()) ).oclAsType( ecore::EObject))
```

109 **MAY** satisfy: Contains 0..* HealthcareProvider in cda:documentationOf/cda:serviceEvent/cda:performer (C32-[CT1-6])

- `[OCL]: self.documentationOf.serviceEvent.performer->size() > 0`

110 **SHALL** satisfy: Contains 0..* InformationSource in ancestor-or-self::./cda:author[1] (C32-[CT1-8])

111 **SHOULD** satisfy: Contains 0..* LanguageSpoken in cda:recordTarget/cda:patientRole/cda:patient/cda:languageCommunication (C32-[CT1-10])

112 **SHALL** satisfy: Contains 1..1 Person Information in cda:recordTarget/cda:patientRole (C32-[CT1-12])

Patient Summary example

Referral Summary

[ClinicalDocument: templateId `2.16.840.1.113883.3.88.11.48.1`]

1. **SHALL** conform to *CDT General Header Constraints* template (templateId: `2.16.840.1.113883.10.20.3`)
2. **SHALL** conform to *IHE Medical Document* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.1.1`)
3. **SHALL** conform to *IHE Medical Summary* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.1.2`)
4. **SHALL** contain exactly one [1..1] **`realmCode/@code`**`="US"` (CONF-HP-15)
5. **SHALL** contain exactly one [1..1] **`typeId`** (CONF-HP-16)
   - The clinical document type ID identifies the constraints imposed by CDA R2 on the content, essentially acting as a version identifier.
6. **SHALL** contain exactly one [1..1] **`id`** (CONF-HP-17)
   - 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.
7. **SHALL** contain exactly one [1..1] **`code`** (CodeSystem:)
8. **SHALL** contain exactly one [1..1] **`title`** (CONF-HP-22)

- 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.

9. **SHALL** contain exactly one [1..1] **`effectiveTime`** (CONF-HP-23)
   - 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.
10. Contains exactly one [1..1] **`confidentialityCode`**
    - Specifies the confidentiality assigned to the document. This specification provides no further guidance beyond CDA R2 on documents with respect to the vocabulary used for confidentialityCode, nor treatment or implementation of confidentiality.
11. **SHALL** contain exactly one [1..1] **`languageCode`** (CONF-HP-24)
12. Contains at least one [1..*] **`recordTarget`**, where its type is *Record Target*
13. Contains at least one [1..*] **`author`**, where its type is *Author*
14. Contains exactly one [1..1] **`custodian`**, where its type is *Custodian*
15. Contains exactly one [1..1] **`component`**, where its type is *Component2*
16. 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.
17. 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.
18. 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.
19. Contains zero or more [0..*] **`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.
20. 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.
21. Contains zero or more [0..*] **`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.

22. **SHALL** satisfy: All patient, guardianPerson, assignedPerson, maintainingPerson, relatedPerson, intendedRecipient/informationRecipient, associatedPerson, and relatedSubject/subject elements have a name. (CONF-HP-6)

    - `[OCL]: -- implemented in Java using XPath selector`
    - ```
      [XPath]: *[self::cda:patient or self::cda:guardianPerson or
       self::cda:assignedPerson
         or self::cda:maintainingPerson or self::cda:relatedPerson or
       self::cda:associatedPerson
         or self::cda:intendedRecipient/cda:informationRecipient or
       self::cda:relatedSubject/cda:subject]
      ```

23. **SHALL** satisfy: All patientRole, assignedAuthor, assignedEntity[not(parent::dataEnterer)] and associatedEntity elements have an addr and telecom element. (CONF-HP-7)

    - `[OCL]: -- implemented in Java using XPath selector`
    - ```
      [XPath]: *[self::cda:patientRole or self::cda:assignedAuthor
       or self::cda:assignedEntity[not(parent::cda:dataEnterer)]  or
       self::cda:associatedEntity]
      ```

24. **SHOULD** satisfy: All guardian, dataEnterer/assignedEntity, relatedEntity, intendedRecipient, relatedSubject and participantRole elements have an addr and telecom element. (CONF-HP-8)

    - `[OCL]: -- implemented in Java using XPath selector`
    - ```
      [XPath]: *[self::cda:guardian or
       self::cda:assignedEntity[parent::cda:dataEnterer] or
       self::cda:relatedEntity or self::cda:intendedRecipient or
       self::cda:relatedSubject or self::cda:participantRole]
      ```

25. **SHALL** satisfy: All guardianOrganization, providerOrganization, wholeOrganization, representedOrganization, representedCustodianOrganization, receivedOrganization, scopingOrganization and serviceProviderOrganization elements have name, addr and telecom elements. (CONF-HP-9)

    - 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. Legal values according to this specification come from the HL7 NullFlavor vocabulary.

    - `[OCL]: -- implemented in Java using XPath selector`
    - ```
      [XPath]: *[self::cda:guardianOrganization or
       self::cda:providerOrganization or self::cda:wholeOrganization or
       self::cda:representedOrganization or
       self::cda:representedCustodianOrganization or
       self::cda:receivedOrganization or self::cda:scopingOrganization or
       self::cda:serviceProviderOrganization]
      ```

26. 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 second. (CONF-HP-10)

    - `[OCL]: -- implemented in Java using XPath selector`
    - ```
      [XPath]: /cda:ClinicalDocument/cda:effectiveTime | //cda:author/
      cda:time | //cda:dataEnterer/cda:time | //cda:encompassingEncounter/
      cda:effectiveTime
      ```

27. 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-HP-11)

- ```
  [OCL]: cda::OrganizationPartOf.allInstances()-
  >select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject)-
  > union(  cda::MaintainedEntity.allInstances()-
  >select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject) )-
  >union( cda::RelatedEntity.allInstances()-
  >select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject) )-
  >union(cda::RelatedEntity.allInstances()-
  >select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject) )-
  >union(cda::RelatedEntity.allInstances()-
  >select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject) )-
  >union(cda::ServiceEvent.allInstances()-
  >select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject) )-
  >union(cda::EncounterParticipant.allInstances()-
  >select( time.oclIsUndefined()).oclAsType( ecore::EObject))-
  >union(self.participant-
  >select( time.oclIsUndefined()).oclAsType( ecore::EObject))-
  >union(cda::OrganizationPartOf.allInstances().effectiveTime-
  >union(cda::MaintainedEntity.allInstances().effectiveTime)-
  >union( cda::RelatedEntity.allInstances().effectiveTime)-
  >union(cda::RelatedEntity.allInstances().effectiveTime)-
  >union(cda::RelatedEntity.allInstances().effectiveTime)-
  >union(cda::ServiceEvent.allInstances().effectiveTime)-
  >union(cda::EncounterParticipant.allInstances().time)-
  >union(self.participant.time)->select(current :
   datatypes::IVL_TS  |  ((not current.low.oclIsUndefined()) and
   (current.low.value.oclIsUndefined() or current.low.value.size()
   < 4)) or ((not current.center.oclIsUndefined()) and
   (current.center.value.oclIsUndefined() or current.center.value.size()
   < 4)) or ((not current.high.oclIsUndefined()) and
   (current.high.value.oclIsUndefined() or current.high.value.size() < 4))
   or (current.low.oclIsUndefined() and current.center.oclIsUndefined() and
   current.high.oclIsUndefined()) ).oclAsType( ecore::EObject))
  ```

28. **SHALL** satisfy: Telephone numbers match the regular expression pattern tel:\+?[-0-9().]+ (CONF-HP-12)

    - 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.
    - `[OCL]: -- implemented in Java using XPath selector`
    - `[XPath]: //*[self::cda:telecom]`

29. **SHALL** satisfy: At least one dialing digit is present in the phone number after visual separators are removed. (CONF-HP-13)

    - `[OCL]: -- implemented in Java using XPath selector`
    - `[XPath]: //*[self::cda:telecom]`

30. **SHALL** satisfy: If the telephone number is unknown it is represented using the appropriate flavor of null. (CONF-HP-14)

    - 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.
    - `[OCL]: -- implemented in Java using XPath selector`
    - `[XPath]: //*[self::cda:telecom]`
  ```

31. **SHALL** satisfy: The extension attribute of the typeId element is POCD_HD000040. (CONF-HP-16)
    - `[OCL]: self.typeId.extension = 'POCD_HD000040'`
32. **SHALL** satisfy: The id/@root attribute is a syntactically correct UUID or OID. (CONF-HP-17)
33. **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]. (CONF-HP-18)
34. 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-HP-19)
    - 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.
35. **SHALL** satisfy: OIDs are no more than 64 characters in length. (CONF-HP-20)
    - OIDs are limited by this specification to no more than 64 characters in length for compatibility with other standards and Implementation Guides.
    - `[OCL]: self.id->select((not id.root.oclIsUndefined()) and id.root.size() > 64 )`
36. **SHALL** satisfy: languageCode has the form nn, or nn-CC. (CONF-HP-25)
37. **SHALL** satisfy: The nn portion of languageCode is a legal ISO-639-1 language code in lowercase. (CONF-HP-26)
38. The CC portion languageCode, if present, **SHALL** be an ISO-3166 country code in uppercase. (CONF-HP-27)
39. Both setId and versionNumber **SHALL** be present or both **SHALL** be absent. (CONF-HP-28)
    - 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.
    - ```
      [OCL]: (self.setId.oclIsUndefined() and
       self.versionNumber.oclIsUndefined())
         xor (not self.setId.oclIsUndefined() and not
       self.versionNumber.oclIsUndefined())
      ```
40. The @extension and/or @root of setId and id **SHALL** be different when both are present. (CONF-HP-29)
    - ```
      [OCL]: (not self.setId.oclIsUndefined() and not self.id.oclIsUndefined())
         implies (self.setId.root <> self.id.root or self.setId.extension <>
       self.id.extension)
      ```
41. A copyTime element **SHALL NOT** be present. (CONF-HP-30)
    - The ClinicalDocument/copyTime element has been deprecated in CDA R2.
    - `[OCL]: self.copyTime.oclIsUndefined()`
42. **SHALL** satisfy: At least one recordTarget/patientRole element is present. (CONF-HP-31)
    - ```
      [OCL]: self.recordTarget->size() > 0 and self.recordTarget-
      >exists(target : cda::RecordTarget | not
       target.patientRole.oclIsUndefined())
      ```
43. 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-HP-32)
    - ```
      [OCL]: self.recordTarget->forAll(target : cda::RecordTarget | not
       target.patientRole.oclIsUndefined()
         implies (not
       target.patientRole.patient.birthTime.value.oclIsUndefined()
      ```

```
      or not
 target.patientRole.patient.birthTime.nullFlavor.oclIsUndefined()))
```

44. 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-HP-33)
    - TODO: add OCL test for terminology
    - ```
      [OCL]: self.recordTarget->forAll(target : cda::RecordTarget | not
       target.patientRole.oclIsUndefined()
         implies (not
       target.patientRole.patient.administrativeGenderCode.code.oclIsUndefined()
            or not
       target.patientRole.patient.administrativeGenderCode.nullFlavor.oclIsUndefined()))
      ```
45. 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-HP-34)
46. **SHOULD** satisfy: The guardian element is present when the patient is a minor child. (CONF-HP-35)
47. **MAY** satisfy: The providerOrganization element is present. (CONF-HP-36)
    - ```
      [OCL]: self.recordTarget->exists(target : cda::RecordTarget | not
       target.patientRole.providerOrganization.oclIsUndefined())
      ```
48. **SHALL** satisfy: The author/time element is present. (CONF-HP-37)
    - The author/time element represents the start time of the author's participation in the creation of the clinical document.
    - ```
      [OCL]: self.author->forAll(author : cda::Author | not
       author.time.oclIsUndefined())
      ```
49. **SHALL** satisfy: The assignedAuthor/id element is present. (CONF-HP-38)
    - ```
      [OCL]: self.author->forAll(author : cda::Author |
       author.assignedAuthor.id->size() > 0)
      ```
50. **SHALL** satisfy: An assignedAuthor element contains at least one assignedPerson or assignedAuthoringDevice elements. (CONF-HP-39)
    - ```
      [OCL]: self.author->forAll(author : cda::Author | not
       author.assignedAuthor.assignedPerson.oclIsUndefined()
         or not author.assignedAuthor.assignedAuthoringDevice.oclIsUndefined())
      ```
51. **SHALL** satisfy: When dataEnterer is present, an assignedEntity/assignedPerson element is present. (CONF-HP-40)
    - ```
      [OCL]: not self.dataEnterer.oclIsUndefined() implies not
       self.dataEnterer.assignedEntity.assignedPerson.oclIsUndefined()
      ```
52. The dataEnterer/time element **MAY** be present. If present, it represents the starting time of entry of the data. (CONF-HP-41)
    - ```
      [OCL]: not self.dataEnterer.oclIsUndefined() implies not
       self.dataEnterer.time.oclIsUndefined()
      ```
53. **MAY** satisfy: The informant element is present. (CONF-HP-42)
    - ```
      [OCL]: self.informant->size() > 0
      ```
54. When informant is present, an assignedEntity/assignedPerson or relatedEntity/relatedPerson element **SHALL** be present. (CONF-HP-43)
    - ```
      [OCL]: self.informant->forAll(i : cda::Informant12 | not
       i.assignedEntity.assignedPerson.oclIsUndefined()
         or not i.relatedEntity.relatedPerson.oclIsUndefined())
      ```
55. When the informant is a healthcare provider with an assigned role, the informant **SHALL** be represented using the assignedEntity element (CONF-HP-44)
    - Assigned health care providers may be a source of information when a document is created. (e.g., a nurse's aide who provides information about a recent significant health care event that occurred within an acute care facility.) In these cases, the assignedEntity element is used.
      ```

- TODO: how to determin if informant is a healthcare provider? condition for implementing OCL

56. Allowable values for informant/relatedEntity/@classCode **SHALL** be CON, PRS, CAREGIVER, AGNT or PROV from the RoleClass vocabulary. (CONF-HP-45)

- 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.

57. 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-HP-46)

58. 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-HP-47)

- 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.

59. 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-HP-48)

- 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.

60. When the informant is a healthcare provider, the value of relatedEntity/code **SHOULD** be present and indicate the type of healthcare provider. (CONF-HP-49)

61. 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-HP-50)

62. The assignedEntity/assignedPerson element **SHALL** be present in legalAuthenticator. (CONF-HP-51)

- ```
  [OCL]: not self.legalAuthenticator.oclIsUndefined() implies not
   self.legalAuthenticator.assignedEntity.assignedPerson.oclIsUndefined()
  ```

63. The assignedEntity/assignedPerson element **SHALL** be present in an authenticator element. (CONF-HP-52)

- ```
  [OCL]: self.authenticator->forAll(auth : cda::Authenticator |
   auth.assignedEntity->forAll(entity : cda::AssignedEntity |
     not entity.assignedPerson.oclIsUndefined()))
  ```

64. 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 second. (CONF-HP-10)

- Should portion of CON-HP-10 constraitn
- ```
  [OCL]: -- implemented in Java using XPath selector
  ```
- ```
  [XPath]: /cda:ClinicalDocument/cda:effectiveTime | //cda:author/
  cda:time | //cda:dataEnterer/cda:time | //cda:encompassingEncounter/
  cda:effectiveTime
  ```

65. 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-HP-11)

- Should portion of CON-HP-11 constraint
- ```
  [OCL]: cda::OrganizationPartOf.allInstances()-
  >select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject)-
  > union(  cda::MaintainedEntity.allInstances()-
  >select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject) )-
  >union( cda::RelatedEntity.allInstances()-
  >select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject) )-
  ```
  ```

```
>union(cda::RelatedEntity.allInstances()-
>select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject) )-
>union(cda::RelatedEntity.allInstances()-
>select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject) )-
>union(cda::ServiceEvent.allInstances()-
>select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject) )-
>union(cda::EncounterParticipant.allInstances()-
>select( time.oclIsUndefined()).oclAsType( ecore::EObject))-
>union(self.participant-
>select( time.oclIsUndefined()).oclAsType( ecore::EObject))-
>union(cda::OrganizationPartOf.allInstances().effectiveTime-
>union(cda::MaintainedEntity.allInstances().effectiveTime)-
>union( cda::RelatedEntity.allInstances().effectiveTime)-
>union(cda::RelatedEntity.allInstances().effectiveTime)-
>union(cda::RelatedEntity.allInstances().effectiveTime)-
>union(cda::ServiceEvent.allInstances().effectiveTime)-
>union(cda::EncounterParticipant.allInstances().time)-
>union(self.participant.time)->select(current :
 datatypes::IVL_TS  |  ((not current.low.oclIsUndefined()) and
 (current.low.value.oclIsUndefined() or current.low.value.size()
 < 8)) or ((not current.center.oclIsUndefined()) and
 (current.center.value.oclIsUndefined() or current.center.value.size()
 < 8)) or ((not current.high.oclIsUndefined()) and
 (current.high.value.oclIsUndefined() or current.high.value.size() < 8))
 or (current.low.oclIsUndefined() and current.center.oclIsUndefined() and
 current.high.oclIsUndefined()) ).oclAsType( ecore::EObject))
```

66. **SHALL** satisfy: MedicalSummaryProblemConcernEntry
    - `[OCL]: self.getSections()->exists(sect : cda::Section | sect.getActs()->exists(act : cda::Act | act.oclIsKindOf(ihe::ProblemConcernEntry)))`
67. **SHALL** satisfy: MedicalSummaryAllergyConcernEntry
    - `[OCL]: self.getSections()->exists(sect : cda::Section | sect.getActs()->exists(act : cda::Act | act.oclIsKindOf(ihe::AllergyIntoleranceConcern)))`
68. **SHALL** satisfy: MedicalSummaryMedications
    - `[OCL]: self.getSections()->exists(sect : cda::Section | sect.getSubstanceAdministrations()->exists(sub : cda::SubstanceAdministration | sub.oclIsKindOf(ihe::Medication)))`

Referral Summary example

Unstructured Document

[ClinicalDocument: templateId `2.16.840.1.113883.3.88.11.62.1`]

IMPORTANT NOTE: *The HITSP C62 specification does not include a templateId for this doument type. The id 2.16.840.1.113883.3.88.11.62.1 is included in this model to support instance validation, but we are designing a solution to allow removal of this Id.*

1. **SHALL** conform to *CDT General Header Constraints* template (templateId: `2.16.840.1.113883.10.20.3`)
2. **SHALL** conform to *IHE Medical Document* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.1.1`)
3. **SHALL** conform to *IHE Scanned Document* template (templateId: `1.3.6.1.4.1.19376.1.2.20`)
4. **SHALL** contain exactly one [1..1] **`code`**
    - Entered by operator or appropriately fixed for scanned content.
5. **SHALL** contain exactly one [1..1] **`confidentialityCode`**
    - Assigned by the operator in accordance with the scanning facility policy. The notion or level of confidentiality in the header may not be the same as that in the Affinity Domain, but in certain cases could be used to derive a

confidentiality value among those specified by the Affinity Domain. Attributes @code and @codeSystem shall be present.

6. **SHALL** contain exactly one [1..1] **`effectiveTime`**
   - Denotes the time at which the original content was scanned. At a minimum, the time shall be precise to the day and shall include the time zone offset from GMT.
7. **SHALL** contain exactly one [1..1] **`id`**
   - The root attribute shall contain the oid for the document, in which case the extension attribute shall be empty, or an oid that scopes the set of possible unique values for the extension attribute, in which case the extension shall be populated with a globally unique identifier within the scope of the root oid.
8. **SHALL** contain exactly one [1..1] **`languageCode`**
   - Denotes the language used in the character data of the wrapper CDA header. If the scanned content, when rendered, is in a language different than that of the header, the language context of the CDA will be overwritten at the body level (see ITI TF-3: 5.2.3.9 ClinicalDocument/component/nonXMLBody for an example). Attribute @code shall be present.
9. **SHOULD** contain exactly one [1..1] **`title`**
   - Entered by operator, or possibly can be taken from the scanned content.
10. **SHALL** contain exactly one [1..1] **`typeId`**
11. 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.
12. Contains zero or more [0..*] **`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.
13. 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.
14. Contains zero or more [0..*] **`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.
15. Contains at least one [1..*] **`recordTarget`**, where its type is *Record Target*
16. Contains exactly one [1..1] **`custodian`**, where its type is *Custodian*
17. Contains exactly one [1..1] **`component`**, where its type is *Component2*
18. **SHOULD** contain at least one [1..*] **`scanOriginalAuthor`**, such that
    a. Contains exactly one [1..1] *Scan Original Author* (templateId: `1.3.6.1.4.1.19376.1.2.20.1`)
19. **SHALL** contain at least one [1..*] **`scanningDevice`**, such that
    a. Contains exactly one [1..1] *Scanning Device* (templateId: `1.3.6.1.4.1.19376.1.2.20.2`)
20. **SHALL** contain exactly one [1..1] **`scanDataEnterer`**, such that

   a. Contains exactly one [1..1] *Scan Data Enterer* (templateId: `1.3.6.1.4.1.19376.1.2.20.3`)

21. **MAY** contain zero or one [0..1] **`legalAuthenticator`**, such that

    - Context is left up to the scanning facility to refine in accordance with local policies.

22. **MAY** contain zero or one [0..1] **`documentationOf`**, such that

    - Used to encode the date/time range of the original content. If the original content is representative of a single point in time then the endpoints of the date/time range shall be the same. Information regarding this date/time range shall be included, if it is known. In many cases this will have to be supplied by the operator.

23. **SHALL** satisfy: All patient, guardianPerson, assignedPerson, maintainingPerson, relatedPerson, intendedRecipient/informationRecipient, associatedPerson, and relatedSubject/subject elements have a name. (CONF-HP-6)

    - `[OCL]: -- implemented in Java using XPath selector`
    - ```
      [XPath]: *[self::cda:patient or self::cda:guardianPerson or
       self::cda:assignedPerson
         or self::cda:maintainingPerson or self::cda:relatedPerson or
       self::cda:associatedPerson
         or self::cda:intendedRecipient/cda:informationRecipient or
       self::cda:relatedSubject/cda:subject]
      ```

24. **SHALL** satisfy: All patientRole, assignedAuthor, assignedEntity[not(parent::dataEnterer)] and associatedEntity elements have an addr and telecom element. (CONF-HP-7)

    - `[OCL]: -- implemented in Java using XPath selector`
    - ```
      [XPath]: *[self::cda:patientRole or self::cda:assignedAuthor
       or self::cda:assignedEntity[not(parent::cda:dataEnterer)]  or
       self::cda:associatedEntity]
      ```

25. **SHOULD** satisfy: All guardian, dataEnterer/assignedEntity, relatedEntity, intendedRecipient, relatedSubject and participantRole elements have an addr and telecom element. (CONF-HP-8)

    - `[OCL]: -- implemented in Java using XPath selector`
    - ```
      [XPath]: *[self::cda:guardian or
       self::cda:assignedEntity[parent::cda:dataEnterer] or
       self::cda:relatedEntity or self::cda:intendedRecipient or
       self::cda:relatedSubject or self::cda:participantRole]
      ```

26. **SHALL** satisfy: All guardianOrganization, providerOrganization, wholeOrganization, representedOrganization, representedCustodianOrganization, receivedOrganization, scopingOrganization and serviceProviderOrganization elements have name, addr and telecom elements. (CONF-HP-9)

    - 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. Legal values according to this specification come from the HL7 NullFlavor vocabulary.

    - `[OCL]: -- implemented in Java using XPath selector`
    - ```
      [XPath]: *[self::cda:guardianOrganization or
       self::cda:providerOrganization or self::cda:wholeOrganization or
       self::cda:representedOrganization or
       self::cda:representedCustodianOrganization or
       self::cda:receivedOrganization or self::cda:scopingOrganization or
       self::cda:serviceProviderOrganization]
      ```

27. 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 second. (CONF-HP-10)

    - `[OCL]: -- implemented in Java using XPath selector`
    - ```
      [XPath]: /cda:ClinicalDocument/cda:effectiveTime | //cda:author/
      cda:time | //cda:dataEnterer/cda:time | //cda:encompassingEncounter/
      cda:effectiveTime
      ```
      ```

28. 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-HP-11)

- ```
  [OCL]: cda::OrganizationPartOf.allInstances()-
  >select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject)-
  > union(  cda::MaintainedEntity.allInstances()-
  >select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject) )-
  >union( cda::RelatedEntity.allInstances()-
  >select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject) )-
  >union(cda::RelatedEntity.allInstances()-
  >select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject) )-
  >union(cda::RelatedEntity.allInstances()-
  >select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject) )-
  >union(cda::ServiceEvent.allInstances()-
  >select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject) )-
  >union(cda::EncounterParticipant.allInstances()-
  >select( time.oclIsUndefined()).oclAsType( ecore::EObject))-
  >union(self.participant-
  >select( time.oclIsUndefined()).oclAsType( ecore::EObject))-
  >union(cda::OrganizationPartOf.allInstances().effectiveTime-
  >union(cda::MaintainedEntity.allInstances().effectiveTime)-
  >union( cda::RelatedEntity.allInstances().effectiveTime)-
  >union(cda::RelatedEntity.allInstances().effectiveTime)-
  >union(cda::RelatedEntity.allInstances().effectiveTime)-
  >union(cda::ServiceEvent.allInstances().effectiveTime)-
  >union(cda::EncounterParticipant.allInstances().time)-
  >union(self.participant.time)->select(current :
   datatypes::IVL_TS  |  ((not current.low.oclIsUndefined()) and
   (current.low.value.oclIsUndefined() or current.low.value.size()
   < 4)) or ((not current.center.oclIsUndefined()) and
   (current.center.value.oclIsUndefined() or current.center.value.size()
   < 4)) or ((not current.high.oclIsUndefined()) and
   (current.high.value.oclIsUndefined() or current.high.value.size() < 4))
   or (current.low.oclIsUndefined() and current.center.oclIsUndefined() and
   current.high.oclIsUndefined()) ).oclAsType( ecore::EObject))
  ```

29. **SHALL** satisfy: Telephone numbers match the regular expression pattern tel:\+?[-0-9().]+ (CONF-HP-12)

- 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.
- `[OCL]: -- implemented in Java using XPath selector`
- `[XPath]: //*[self::cda:telecom]`

30. **SHALL** satisfy: At least one dialing digit is present in the phone number after visual separators are removed. (CONF-HP-13)

- `[OCL]: -- implemented in Java using XPath selector`
- `[XPath]: //*[self::cda:telecom]`

31. **SHALL** satisfy: If the telephone number is unknown it is represented using the appropriate flavor of null. (CONF-HP-14)

- 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.

- `[OCL]: -- implemented in Java using XPath selector`
- `[XPath]: //*[self::cda:telecom]`

32. **SHALL** satisfy: The extension attribute of the typeId element is POCD_HD000040. (CONF-HP-16)
    - `[OCL]: self.typeId.extension = 'POCD_HD000040'`
33. **SHALL** satisfy: The id/@root attribute is a syntactically correct UUID or OID. (CONF-HP-17)
34. **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]. (CONF-HP-18)
35. 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-HP-19)
    - 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.
36. **SHALL** satisfy: OIDs are no more than 64 characters in length. (CONF-HP-20)
    - OIDs are limited by this specification to no more than 64 characters in length for compatibility with other standards and Implementation Guides.
    - `[OCL]: self.id->select((not id.root.oclIsUndefined()) and id.root.size() > 64 )`
37. **SHALL** satisfy: languageCode has the form nn, or nn-CC. (CONF-HP-25)
38. **SHALL** satisfy: The nn portion of languageCode is a legal ISO-639-1 language code in lowercase. (CONF-HP-26)
39. The CC portion languageCode, if present, **SHALL** be an ISO-3166 country code in uppercase. (CONF-HP-27)
40. Both setId and versionNumber **SHALL** be present or both **SHALL** be absent. (CONF-HP-28)
    - 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.
    - ```
      [OCL]: (self.setId.oclIsUndefined() and
       self.versionNumber.oclIsUndefined())
         xor (not self.setId.oclIsUndefined() and not
       self.versionNumber.oclIsUndefined())
      ```
41. The @extension and/or @root of setId and id **SHALL** be different when both are present. (CONF-HP-29)
    - ```
      [OCL]: (not self.setId.oclIsUndefined() and not self.id.oclIsUndefined())
         implies (self.setId.root <> self.id.root or self.setId.extension <>
       self.id.extension)
      ```
42. A copyTime element **SHALL NOT** be present. (CONF-HP-30)
    - The ClinicalDocument/copyTime element has been deprecated in CDA R2.
    - `[OCL]: self.copyTime.oclIsUndefined()`
43. **SHALL** satisfy: At least one recordTarget/patientRole element is present. (CONF-HP-31)
    - ```
      [OCL]: self.recordTarget->size() > 0 and self.recordTarget-
      >exists(target : cda::RecordTarget | not
       target.patientRole.oclIsUndefined())
      ```
      ```

44. 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-HP-32)

- ```
  [OCL]: self.recordTarget->forAll(target : cda::RecordTarget | not
  target.patientRole.oclIsUndefined()
    implies (not
  target.patientRole.patient.birthTime.value.oclIsUndefined()
       or not
  target.patientRole.patient.birthTime.nullFlavor.oclIsUndefined()))
  ```

45. 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-HP-33)

- TODO: add OCL test for terminology
- ```
  [OCL]: self.recordTarget->forAll(target : cda::RecordTarget | not
  target.patientRole.oclIsUndefined()
    implies (not
  target.patientRole.patient.administrativeGenderCode.code.oclIsUndefined()
       or not
  target.patientRole.patient.administrativeGenderCode.nullFlavor.oclIsUndefined()))
  ```

46. 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-HP-34)

47. **SHOULD** satisfy: The guardian element is present when the patient is a minor child. (CONF-HP-35)

48. **MAY** satisfy: The providerOrganization element is present. (CONF-HP-36)

- ```
  [OCL]: self.recordTarget->exists(target : cda::RecordTarget | not
  target.patientRole.providerOrganization.oclIsUndefined())
  ```

49. **SHALL** satisfy: The author/time element is present. (CONF-HP-37)

- The author/time element represents the start time of the author's participation in the creation of the clinical document.
- ```
  [OCL]: self.author->forAll(author : cda::Author | not
  author.time.oclIsUndefined())
  ```

50. **SHALL** satisfy: The assignedAuthor/id element is present. (CONF-HP-38)

- ```
  [OCL]: self.author->forAll(author : cda::Author |
  author.assignedAuthor.id->size() > 0)
  ```

51. **SHALL** satisfy: An assignedAuthor element contains at least one assignedPerson or assignedAuthoringDevice elements. (CONF-HP-39)

- ```
  [OCL]: self.author->forAll(author : cda::Author | not
  author.assignedAuthor.assignedPerson.oclIsUndefined()
    or not author.assignedAuthor.assignedAuthoringDevice.oclIsUndefined())
  ```

52. **SHALL** satisfy: When dataEnterer is present, an assignedEntity/assignedPerson element is present. (CONF-HP-40)

- ```
  [OCL]: not self.dataEnterer.oclIsUndefined() implies not
  self.dataEnterer.assignedEntity.assignedPerson.oclIsUndefined()
  ```

53. The dataEnterer/time element **MAY** be present. If present, it represents the starting time of entry of the data. (CONF-HP-41)

- ```
  [OCL]: not self.dataEnterer.oclIsUndefined() implies not
  self.dataEnterer.time.oclIsUndefined()
  ```

54. **MAY** satisfy: The informant element is present. (CONF-HP-42)

- ```
  [OCL]: self.informant->size() > 0
  ```
  ```

55. When informant is present, an assignedEntity/assignedPerson or relatedEntity/relatedPerson element **SHALL** be present. (CONF-HP-43)
    - `[OCL]: self.informant->forAll(i : cda::Informant12 | not i.assignedEntity.assignedPerson.oclIsUndefined() or not i.relatedEntity.relatedPerson.oclIsUndefined())`
56. When the informant is a healthcare provider with an assigned role, the informant **SHALL** be represented using the assignedEntity element (CONF-HP-44)
    - Assigned health care providers may be a source of information when a document is created. (e.g., a nurse's aide who provides information about a recent significant health care event that occurred within an acute care facility.) In these cases, the assignedEntity element is used.
    - TODO: how to determin if informant is a healthcare provider? condition for implementing OCL
57. Allowable values for informant/relatedEntity/@classCode **SHALL** be CON, PRS, CAREGIVER, AGNT or PROV from the RoleClass vocabulary. (CONF-HP-45)
    - 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.
58. 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-HP-46)
59. 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-HP-47)
    - 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.
60. 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-HP-48)
    - 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.
61. When the informant is a healthcare provider, the value of relatedEntity/code **SHOULD** be present and indicate the type of healthcare provider. (CONF-HP-49)
62. 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-HP-50)
63. The assignedEntity/assignedPerson element **SHALL** be present in legalAuthenticator. (CONF-HP-51)
    - `[OCL]: not self.legalAuthenticator.oclIsUndefined() implies not self.legalAuthenticator.assignedEntity.assignedPerson.oclIsUndefined()`
64. The assignedEntity/assignedPerson element **SHALL** be present in an authenticator element. (CONF-HP-52)
    - `[OCL]: self.authenticator->forAll(auth : cda::Authenticator | auth.assignedEntity->forAll(entity : cda::AssignedEntity | not entity.assignedPerson.oclIsUndefined()))`
65. 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 second. (CONF-HP-10)
    - Should portion of CON-HP-10 constraitn
    - `[OCL]: -- implemented in Java using XPath selector`
    - `[XPath]: /cda:ClinicalDocument/cda:effectiveTime | //cda:author/cda:time | //cda:dataEnterer/cda:time | //cda:encompassingEncounter/cda:effectiveTime`

66. 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-HP-11)

- Should portion of CON-HP-11 constraint
- ```
  [OCL]: cda::OrganizationPartOf.allInstances()-
  >select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject)-
  > union(  cda::MaintainedEntity.allInstances()-
  >select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject) )-
  >union( cda::RelatedEntity.allInstances()-
  >select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject) )-
  >union(cda::RelatedEntity.allInstances()-
  >select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject) )-
  >union(cda::RelatedEntity.allInstances()-
  >select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject) )-
  >union(cda::ServiceEvent.allInstances()-
  >select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject) )-
  >union(cda::EncounterParticipant.allInstances()-
  >select( time.oclIsUndefined()).oclAsType( ecore::EObject))-
  >union(self.participant-
  >select( time.oclIsUndefined()).oclAsType( ecore::EObject))-
  >union(cda::OrganizationPartOf.allInstances().effectiveTime-
  >union(cda::MaintainedEntity.allInstances().effectiveTime)-
  >union( cda::RelatedEntity.allInstances().effectiveTime)-
  >union(cda::RelatedEntity.allInstances().effectiveTime)-
  >union(cda::RelatedEntity.allInstances().effectiveTime)-
  >union(cda::ServiceEvent.allInstances().effectiveTime)-
  >union(cda::EncounterParticipant.allInstances().time)-
  >union(self.participant.time)->select(current :
   datatypes::IVL_TS  |  ((not current.low.oclIsUndefined()) and
   (current.low.value.oclIsUndefined() or current.low.value.size()
   < 8)) or ((not current.center.oclIsUndefined()) and
   (current.center.value.oclIsUndefined() or current.center.value.size()
   < 8)) or ((not current.high.oclIsUndefined()) and
   (current.high.value.oclIsUndefined() or current.high.value.size() < 8))
   or (current.low.oclIsUndefined() and current.center.oclIsUndefined() and
   current.high.oclIsUndefined()) ).oclAsType( ecore::EObject))
  ```

67. **SHALL** satisfy: The typeId root is 2.16.840.1.113883.1.3 and extension is POCD_HD000040.

- ```
  [OCL]: self.typeId.root = '2.16.840.1.113883.1.3' and
   self.typeId.extension = 'POCD_HD000040'
  ```

68. **SHALL** satisfy: Contains exactly one recordTarget.

- Contains identifying information about the patient concerned in the original content. In many cases this will have to be supplied by the operator.
- ```
  [OCL]: self.recordTarget->size() = 1
  ```

69. **SHALL** satisfy: Contains one or more author / assignedAuthor / assignedPerson and/or author / assignedAuthor / representedOrganization

- ```
  [OCL]: self.author->exists(author : cda::Author | not
   author.assignedAuthor.assignedPerson.oclIsUndefined()
     or not author.assignedAuthor.representedOrganization.oclIsUndefined())
  ```

70. **SHALL** satisfy: recordTarget/patientRole/id element includes both the root and the extension attributes.

- ```
  [OCL]: self.recordTarget->forAll(target : cda::RecordTarget | not
   target.patientRole.oclIsUndefined()
     and target.patientRole.id->forAll(roleId : datatypes::II | not
   roleId.root.oclIsUndefined()
     and not roleId.extension.oclIsUndefined()))
  ```

71. **SHALL** satisfy: At least one recordTarget/patientRole/addr element includes at least the country subelement.
  ```

- The addr element has an unbounded upper limit on occurrences. It can, and should, be replicated to include additional addresses for a patient, each minimally specified by the country sub element.
- ```
  [OCL]: self.recordTarget->exists(target : cda::RecordTarget | not
   target.patientRole.oclIsUndefined()
     and target.patientRole.addr->exists(address : datatypes::AD |
   address.country->exists(c : datatypes::ADXP |
     not c.oclIsUndefined() and c.getText().size() > 0)))
  ```

72. **SHALL** satisfy: At least one recordTarget/patientRole/patient/name element has at least one given subelement and one family subelement.
    - ```
      [OCL]: self.recordTarget->exists(target : cda::RecordTarget | not
       target.patientRole.patient.oclIsUndefined()
         and target.patientRole.patient.name->exists(name: datatypes::PN |
            not name.given->isEmpty() and not name.family->isEmpty()))
      ```
73. **SHALL** satisfy: The recordTarget/patientRole/patient/ administrativeGenderCode element is present.
    - ```
      [OCL]: self.recordTarget->one(target : cda::RecordTarget |
         not
       target.patientRole.patient.administrativeGenderCode.oclIsUndefined())
      ```
74. **SHALL** satisfy: The recordTarget/patientRole/patient/ birthTime element is present with precision to the year.
    - ```
      [OCL]: self.recordTarget->one(target : cda::RecordTarget |
         not target.patientRole.patient.birthTime.oclIsUndefined())
      ```
75. **SHOULD** satisfy: Contains author of type ScanOriginalAuthor to represent original author of this scanned document.
    - ```
      [OCL]: self.author->exists(author : cda::Author | not
       author.oclIsUndefined() and author.oclIsKindOf(ihe::ScanOriginalAuthor))
      ```
76. **SHALL** satisfy: Contains author element of type ScanningDevice to represent the scanning device and software used to produce the scanned content.
    - ```
      [OCL]: self.author->exists(author : cda::Author | not
       author.oclIsUndefined() and author.oclIsKindOf(ihe::ScanningDevice))
      ```
77. **SHALL** satisfy: Contains ScanDataEnterer element to represent the scanner operator who produced the scanned content.
    - ```
      [OCL]: not self.dataEnterer.oclIsUndefined() and
       self.dataEnterer.oclIsKindOf(ihe::ScanDataEnterer)
      ```
78. **SHALL** satisfy: custodian/assignedCustodian/representedCustodianOrganization/name is present.
    - ```
      [OCL]: not
       self.custodian.assignedCustodian.representedCustodianOrganization.name.oclIsUndefir
      ```
79. **SHALL** satisfy: custodian/assignedCustodian/representedCustodianOrganization/addr is present and includes at least the country sub element.
    - ```
      [OCL]: not
       self.custodian.assignedCustodian.representedCustodianOrganization.addr.oclIsUndefir
         and
       self.custodian.assignedCustodian.representedCustodianOrganization.addr.country-
      >exists(c : datatypes::ADXP |
           not c.oclIsUndefined() and c.getText().size() > 0)
      ```
80. **SHALL** satisfy: The legalAuthenticator/assignedEntity/id element if known shall include both the root and the extension attributes.
    - ```
      [OCL]: self.legalAuthenticator.assignedEntity.id->size() > 0 implies (
         self.legalAuthenticator.assignedEntity.id->forAll(ident : datatypes::II
       |
           not ident.root.oclIsUndefined() and not
       ident.extension.oclIsUndefined()))
      ```
81. **SHALL** satisfy: The component/nonXMLBody is present.

- Used to wrap the scanned content. The nonXMLBody element is guaranteed to be unique; thus the x-path to recover the scanned content is essentially fixed.
- `[OCL]: not self.component.nonXMLBody.oclIsUndefined()`

82. **SHALL** satisfy: If the human-readable language of the scanned content is different than that of the wrapper (specified in ClinicalDocument/languageCode), then ClinicalDocument/component/nonXMLBody/languageCode shall be present. Attribute code@code shall be present. Attribute code@codeSystem shall be IETF (Internet Engineering Task Force) RFC 3066 in accordance with the HL7 CDA R2 documentation.
83. **SHALL** satisfy: The component/nonXMLBody/text element is present and encoded using xs:base64Binary encoding. Its #CDATA will contain the scanned content.
    - `[OCL]: not self.component.nonXMLBody.text.oclIsUndefined()`
84. **SHALL** satisfy: The component/nonXMLBody/text@mediaType is 'application/pdf' for PDF, or 'text/plain' for plaintext.
    - `[OCL]: self.component.nonXMLBody.text.mediaType = 'application/pdf' or self.component.nonXMLBody.text.mediaType = 'text/plain'`
85. **SHALL** satisfy: The component/nonXMLBody/text@representation is B64.
    - The @representation for both PDF and plaintext scanned content will be "B64", because this profile requires the base-64 encoding of both formats.
    - `[OCL]: self.component.nonXMLBody.text.representation = datatypes::BinaryDataEncoding::B64`
86. **SHOULD** satisfy: This construct should not be used when the data are structured.
    - `[OCL]: self.component.structuredBody.oclIsUndefined()`
87. **SHALL** satisfy: Each document pertains to one and only one patient.
    - `[OCL]: self.recordTarget->one(record : cda::RecordTarget | not record.patientRole.oclIsUndefined() and not record.patientRole.patient.oclIsUndefined())`

Unstructured Document example

Unstructured Or Scanned Document

[ClinicalDocument: templateId `2.16.840.1.113883.10.20.19.1`]

Used for documents that implement both HL7 Unstructured Documents and HITSP C62 based on IHE Scanned Documents.

1. **SHALL** conform to *IHE Medical Document* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.1.1`)
2. **SHALL** conform to *IHE Scanned Document* template (templateId: `1.3.6.1.4.1.19376.1.2.20`)
3. **SHALL** conform to *Unstructured Document* template (templateId: `2.16.840.1.113883.3.88.11.62.1`)
4. **SHALL** conform to *CDT General Header Constraints* template (templateId: `2.16.840.1.113883.10.20.3`)
5. **SHALL** conform to *CDT Unstructured Document* template (templateId: `2.16.840.1.113883.10.20.19.1`)
6. **SHALL** contain exactly one [1..1] **`code`** (CONF-HP-21)
    - Specifies the type of the clinical document.
7. Contains exactly one [1..1] **`confidentialityCode`**
    - If the confidentialityCode cannot be determined for an Unstructured Document instance, the HL7 code "N" (normal confidentiality) is recommended.
8. **SHALL** contain exactly one [1..1] **`effectiveTime`** (CONF-UD-11)
    - The effectiveTime records the time of creation of the original document. If the referenced document is a scan, the date of scan can be recorded in dataEnterer. If the date of creation of the original document is not known, CDA allows the document effectiveTime to have a nullFlavor.

9. **SHALL** contain exactly one [1..1] **`id`** (CONF-HP-17)
    - 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.
10. **SHALL** contain exactly one [1..1] **`languageCode`** (CONF-HP-24)
11. **SHALL** contain exactly one [1..1] **`title`** (CONF-HP-22)
    - 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.
12. **SHALL** contain exactly one [1..1] **`typeId`** (CONF-HP-16)
    - The clinical document type ID identifies the constraints imposed by CDA R2 on the content, essentially acting as a version identifier.
13. **SHALL** contain exactly one [1..1] **`realmCode/@code`**`="US"` (CONF-HP-15)
14. **SHOULD** contain at least one [1..*] **`scanOriginalAuthor`**, such that
    a. Contains exactly one [1..1] *Scan Original Author* (templateId: `1.3.6.1.4.1.19376.1.2.20.1`)
15. **SHALL** contain at least one [1..*] **`scanningDevice`**, such that
    a. Contains exactly one [1..1] *Scanning Device* (templateId: `1.3.6.1.4.1.19376.1.2.20.2`)
16. **SHALL** contain exactly one [1..1] **`scanDataEnterer`**, such that
    a. Contains exactly one [1..1] *Scan Data Enterer* (templateId: `1.3.6.1.4.1.19376.1.2.20.3`)
17. **MAY** contain zero or one [0..1] **`legalAuthenticator`**, such that
    - Context is left up to the scanning facility to refine in accordance with local policies.
18. **MAY** contain zero or one [0..1] **`documentationOf`**, such that
    - Used to encode the date/time range of the original content. If the original content is representative of a single point in time then the endpoints of the date/time range shall be the same. Information regarding this date/time range shall be included, if it is known. In many cases this will have to be supplied by the operator.
19. Contains at least one [1..*] **`recordTarget`**, where its type is *Record Target*
20. Contains exactly one [1..1] **`custodian`**, where its type is *Custodian*
21. Contains exactly one [1..1] **`component`**, where its type is *Component2*
22. 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.
23. Contains zero or more [0..*] **`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.
24. 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.
25. Contains zero or more [0..*] **`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.

26. **SHALL** contain exactly one [1..1] **`custodian`** (CONF-UD-27), such that
27. **SHALL** satisfy: The typeId root is 2.16.840.1.113883.1.3 and extension is POCD_HD000040.
    - `[OCL]: self.typeId.root = '2.16.840.1.113883.1.3' and self.typeId.extension = 'POCD_HD000040'`
28. **SHALL** satisfy: Contains exactly one recordTarget.
    - Contains identifying information about the patient concerned in the original content. In many cases this will have to be supplied by the operator.
    - `[OCL]: self.recordTarget->size() = 1`
29. **SHALL** satisfy: Contains one or more author / assignedAuthor / assignedPerson and/or author / assignedAuthor / representedOrganization
    - `[OCL]: self.author->exists(author : cda::Author | not author.assignedAuthor.assignedPerson.oclIsUndefined() or not author.assignedAuthor.representedOrganization.oclIsUndefined())`
30. **SHALL** satisfy: recordTarget/patientRole/id element includes both the root and the extension attributes.
    - `[OCL]: self.recordTarget->forAll(target : cda::RecordTarget | not target.patientRole.oclIsUndefined() and target.patientRole.id->forAll(roleId : datatypes::II | not roleId.root.oclIsUndefined() and not roleId.extension.oclIsUndefined()))`
31. **SHALL** satisfy: At least one recordTarget/patientRole/addr element includes at least the country subelement.
    - The addr element has an unbounded upper limit on occurrences. It can, and should, be replicated to include additional addresses for a patient, each minimally specified by the country sub element.
    - `[OCL]: self.recordTarget->exists(target : cda::RecordTarget | not target.patientRole.oclIsUndefined() and target.patientRole.addr->exists(address : datatypes::AD | address.country->exists(c : datatypes::ADXP | not c.oclIsUndefined() and c.getText().size() > 0)))`
32. **SHALL** satisfy: At least one recordTarget/patientRole/patient/name element has at least one given subelement and one family subelement.
    - `[OCL]: self.recordTarget->exists(target : cda::RecordTarget | not target.patientRole.patient.oclIsUndefined() and target.patientRole.patient.name->exists(name: datatypes::PN | not name.given->isEmpty() and not name.family->isEmpty()))`
33. **SHALL** satisfy: The recordTarget/patientRole/patient/ administrativeGenderCode element is present.
    - `[OCL]: self.recordTarget->one(target : cda::RecordTarget | not target.patientRole.patient.administrativeGenderCode.oclIsUndefined())`
34. **SHALL** satisfy: The recordTarget/patientRole/patient/ birthTime element is present with precision to the year.
    - `[OCL]: self.recordTarget->one(target : cda::RecordTarget | not target.patientRole.patient.birthTime.oclIsUndefined())`
35. **SHOULD** satisfy: Contains author of type ScanOriginalAuthor to represent original author of this scanned document.
    - `[OCL]: self.author->exists(author : cda::Author | not author.oclIsUndefined() and author.oclIsKindOf(ihe::ScanOriginalAuthor))`
36. **SHALL** satisfy: Contains author element of type ScanningDevice to represent the scanning device and software used to produce the scanned content.
    - `[OCL]: self.author->exists(author : cda::Author | not author.oclIsUndefined() and author.oclIsKindOf(ihe::ScanningDevice))`

37. **SHALL** satisfy: Contains ScanDataEnterer element to represent the scanner operator who produced the scanned content.
    - `[OCL]: not self.dataEnterer.oclIsUndefined() and self.dataEnterer.oclIsKindOf(ihe::ScanDataEnterer)`
38. **SHALL** satisfy: custodian/assignedCustodian/representedCustodianOrganization/name is present.
    - `[OCL]: not self.custodian.assignedCustodian.representedCustodianOrganization.name.oclIsUndefir`
39. **SHALL** satisfy: custodian/assignedCustodian/representedCustodianOrganization/addr is present and includes at least the country sub element.
    - `[OCL]: not self.custodian.assignedCustodian.representedCustodianOrganization.addr.oclIsUndefir and self.custodian.assignedCustodian.representedCustodianOrganization.addr.country->exists(c : datatypes::ADXP | not c.oclIsUndefined() and c.getText().size() > 0)`
40. **SHALL** satisfy: The legalAuthenticator/assignedEntity/id element if known shall include both the root and the extension attributes.
    - `[OCL]: self.legalAuthenticator.assignedEntity.id->size() > 0 implies ( self.legalAuthenticator.assignedEntity.id->forAll(ident : datatypes::II | not ident.root.oclIsUndefined() and not ident.extension.oclIsUndefined()))`
41. **SHALL** satisfy: The component/nonXMLBody is present.
    - Used to wrap the scanned content. The nonXMLBody element is guaranteed to be unique; thus the x-path to recover the scanned content is essentially fixed.
    - `[OCL]: not self.component.nonXMLBody.oclIsUndefined()`
42. **SHALL** satisfy: If the human-readable language of the scanned content is different than that of the wrapper (specified in ClinicalDocument/languageCode), then ClinicalDocument/component/nonXMLBody/languageCode shall be present. Attribute code@code shall be present. Attribute code@codeSystem shall be IETF (Internet Engineering Task Force) RFC 3066 in accordance with the HL7 CDA R2 documentation.
43. **SHALL** satisfy: The component/nonXMLBody/text element is present and encoded using xs:base64Binary encoding. Its #CDATA will contain the scanned content.
    - `[OCL]: not self.component.nonXMLBody.text.oclIsUndefined()`
44. **SHALL** satisfy: The component/nonXMLBody/text@mediaType is 'application/pdf' for PDF, or 'text/plain' for plaintext.
    - `[OCL]: self.component.nonXMLBody.text.mediaType = 'application/pdf' or self.component.nonXMLBody.text.mediaType = 'text/plain'`
45. **SHALL** satisfy: The component/nonXMLBody/text@representation is B64.
    - The @representation for both PDF and plaintext scanned content will be "B64", because this profile requires the base-64 encoding of both formats.
    - `[OCL]: self.component.nonXMLBody.text.representation = datatypes::BinaryDataEncoding::B64`
46. **SHOULD** satisfy: This construct should not be used when the data are structured.
    - `[OCL]: self.component.structuredBody.oclIsUndefined()`
47. **SHALL** satisfy: Each document pertains to one and only one patient.
    - `[OCL]: self.recordTarget->one(record : cda::RecordTarget | not record.patientRole.oclIsUndefined() and not record.patientRole.patient.oclIsUndefined())`

48. **SHALL** satisfy: All patient, guardianPerson, assignedPerson, maintainingPerson, relatedPerson, intendedRecipient/informationRecipient, associatedPerson, and relatedSubject/subject elements have a name. (CONF-HP-6)
    - `[OCL]: -- implemented in Java using XPath selector`
    - ```
      [XPath]: *[self::cda:patient or self::cda:guardianPerson or
       self::cda:assignedPerson
         or self::cda:maintainingPerson or self::cda:relatedPerson or
       self::cda:associatedPerson
         or self::cda:intendedRecipient/cda:informationRecipient or
       self::cda:relatedSubject/cda:subject]
      ```
49. **SHALL** satisfy: All patientRole, assignedAuthor, assignedEntity[not(parent::dataEnterer)] and associatedEntity elements have an addr and telecom element. (CONF-HP-7)
    - `[OCL]: -- implemented in Java using XPath selector`
    - ```
      [XPath]: *[self::cda:patientRole or self::cda:assignedAuthor
       or self::cda:assignedEntity[not(parent::cda:dataEnterer)]  or
       self::cda:associatedEntity]
      ```
50. **SHOULD** satisfy: All guardian, dataEnterer/assignedEntity, relatedEntity, intendedRecipient, relatedSubject and participantRole elements have an addr and telecom element. (CONF-HP-8)
    - `[OCL]: -- implemented in Java using XPath selector`
    - ```
      [XPath]: *[self::cda:guardian or
       self::cda:assignedEntity[parent::cda:dataEnterer] or
       self::cda:relatedEntity or self::cda:intendedRecipient or
       self::cda:relatedSubject or self::cda:participantRole]
      ```
51. **SHALL** satisfy: All guardianOrganization, providerOrganization, wholeOrganization, representedOrganization, representedCustodianOrganization, receivedOrganization, scopingOrganization and serviceProviderOrganization elements have name, addr and telecom elements. (CONF-HP-9)
    - 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. Legal values according to this specification come from the HL7 NullFlavor vocabulary.
    - `[OCL]: -- implemented in Java using XPath selector`
    - ```
      [XPath]: *[self::cda:guardianOrganization or
       self::cda:providerOrganization or self::cda:wholeOrganization or
       self::cda:representedOrganization or
       self::cda:representedCustodianOrganization or
       self::cda:receivedOrganization or self::cda:scopingOrganization or
       self::cda:serviceProviderOrganization]
      ```
52. 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 second. (CONF-HP-10)
    - `[OCL]: -- implemented in Java using XPath selector`
    - ```
      [XPath]: /cda:ClinicalDocument/cda:effectiveTime | //cda:author/
      cda:time | //cda:dataEnterer/cda:time | //cda:encompassingEncounter/
      cda:effectiveTime
      ```
53. 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-HP-11)
    - ```
      [OCL]: cda::OrganizationPartOf.allInstances()-
      >select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject)-
      > union(  cda::MaintainedEntity.allInstances()-
      >select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject) )-
      >union( cda::RelatedEntity.allInstances()-
      >select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject) )-
      ```

```
>union(cda::RelatedEntity.allInstances()-
>select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject) )-
>union(cda::RelatedEntity.allInstances()-
>select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject) )-
>union(cda::ServiceEvent.allInstances()-
>select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject) )-
>union(cda::EncounterParticipant.allInstances()-
>select( time.oclIsUndefined()).oclAsType( ecore::EObject))-
>union(self.participant-
>select( time.oclIsUndefined()).oclAsType( ecore::EObject))-
>union(cda::OrganizationPartOf.allInstances().effectiveTime-
>union(cda::MaintainedEntity.allInstances().effectiveTime)-
>union( cda::RelatedEntity.allInstances().effectiveTime)-
>union(cda::RelatedEntity.allInstances().effectiveTime)-
>union(cda::RelatedEntity.allInstances().effectiveTime)-
>union(cda::ServiceEvent.allInstances().effectiveTime)-
>union(cda::EncounterParticipant.allInstances().time)-
>union(self.participant.time)->select(current :
 datatypes::IVL_TS  |  ((not current.low.oclIsUndefined()) and
 (current.low.value.oclIsUndefined() or current.low.value.size()
 < 4)) or ((not current.center.oclIsUndefined()) and
 (current.center.value.oclIsUndefined() or current.center.value.size()
 < 4)) or ((not current.high.oclIsUndefined()) and
 (current.high.value.oclIsUndefined() or current.high.value.size() < 4))
 or (current.low.oclIsUndefined() and current.center.oclIsUndefined() and
 current.high.oclIsUndefined()) ).oclAsType( ecore::EObject))
```

54. **SHALL** satisfy: Telephone numbers match the regular expression pattern tel:\+?[-0-9().]+ (CONF-HP-12)
    - 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.
    - `[OCL]: -- implemented in Java using XPath selector`
    - `[XPath]: //*[self::cda:telecom]`
55. **SHALL** satisfy: At least one dialing digit is present in the phone number after visual separators are removed. (CONF-HP-13)
    - `[OCL]: -- implemented in Java using XPath selector`
    - `[XPath]: //*[self::cda:telecom]`
56. **SHALL** satisfy: If the telephone number is unknown it is represented using the appropriate flavor of null. (CONF-HP-14)
    - 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.
    - `[OCL]: -- implemented in Java using XPath selector`
    - `[XPath]: //*[self::cda:telecom]`
57. **SHALL** satisfy: The extension attribute of the typeId element is POCD_HD000040. (CONF-HP-16)
    - `[OCL]: self.typeId.extension = 'POCD_HD000040'`
58. **SHALL** satisfy: The id/@root attribute is a syntactically correct UUID or OID. (CONF-HP-17)
59. **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]. (CONF-HP-18)
60. 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-HP-19)

- 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.

61. **SHALL** satisfy: OIDs are no more than 64 characters in length. (CONF-HP-20)

    - OIDs are limited by this specification to no more than 64 characters in length for compatibility with other standards and Implementation Guides.

    - ```
      [OCL]: self.id->select((not id.root.oclIsUndefined()) and id.root.size() >
       64 )
      ```

62. **SHALL** satisfy: languageCode has the form nn, or nn-CC. (CONF-HP-25)
63. **SHALL** satisfy: The nn portion of languageCode is a legal ISO-639-1 language code in lowercase. (CONF-HP-26)
64. The CC portion languageCode, if present, **SHALL** be an ISO-3166 country code in uppercase. (CONF-HP-27)
65. Both setId and versionNumber **SHALL** be present or both **SHALL** be absent. (CONF-HP-28)

    - 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.

    - ```
      [OCL]: (self.setId.oclIsUndefined() and
       self.versionNumber.oclIsUndefined())
         xor (not self.setId.oclIsUndefined() and not
       self.versionNumber.oclIsUndefined())
      ```

66. The @extension and/or @root of setId and id **SHALL** be different when both are present. (CONF-HP-29)

    - ```
      [OCL]: (not self.setId.oclIsUndefined() and not self.id.oclIsUndefined())
         implies (self.setId.root <> self.id.root or self.setId.extension <>
       self.id.extension)
      ```

67. A copyTime element **SHALL NOT** be present. (CONF-HP-30)

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

    - ```
      [OCL]: self.copyTime.oclIsUndefined()
      ```

68. **SHALL** satisfy: At least one recordTarget/patientRole element is present. (CONF-HP-31)

    - ```
      [OCL]: self.recordTarget->size() > 0 and self.recordTarget-
      >exists(target : cda::RecordTarget | not
       target.patientRole.oclIsUndefined())
      ```

69. 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-HP-32)

    - ```
      [OCL]: self.recordTarget->forAll(target : cda::RecordTarget | not
       target.patientRole.oclIsUndefined()
         implies (not
       target.patientRole.patient.birthTime.value.oclIsUndefined()
            or not
       target.patientRole.patient.birthTime.nullFlavor.oclIsUndefined()))
      ```

70. 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-HP-33)

- TODO: add OCL test for terminology
- ```
  [OCL]: self.recordTarget->forAll(target : cda::RecordTarget | not
   target.patientRole.oclIsUndefined()
     implies (not
   target.patientRole.patient.administrativeGenderCode.code.oclIsUndefined()
        or not
   target.patientRole.patient.administrativeGenderCode.nullFlavor.oclIsUndefined()))
  ```

71. 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-HP-34)
72. **SHOULD** satisfy: The guardian element is present when the patient is a minor child. (CONF-HP-35)
73. **MAY** satisfy: The providerOrganization element is present. (CONF-HP-36)

    - ```
      [OCL]: self.recordTarget->exists(target : cda::RecordTarget | not
       target.patientRole.providerOrganization.oclIsUndefined())
      ```

74. **SHALL** satisfy: The author/time element is present. (CONF-HP-37)

    - The author/time element represents the start time of the author's participation in the creation of the clinical document.
    - ```
      [OCL]: self.author->forAll(author : cda::Author | not
       author.time.oclIsUndefined())
      ```

75. **SHALL** satisfy: The assignedAuthor/id element is present. (CONF-HP-38)

    - ```
      [OCL]: self.author->forAll(author : cda::Author |
       author.assignedAuthor.id->size() > 0)
      ```

76. **SHALL** satisfy: An assignedAuthor element contains at least one assignedPerson or assignedAuthoringDevice elements. (CONF-HP-39)

    - ```
      [OCL]: self.author->forAll(author : cda::Author | not
       author.assignedAuthor.assignedPerson.oclIsUndefined()
         or not author.assignedAuthor.assignedAuthoringDevice.oclIsUndefined())
      ```

77. **SHALL** satisfy: When dataEnterer is present, an assignedEntity/assignedPerson element is present. (CONF-HP-40)

    - ```
      [OCL]: not self.dataEnterer.oclIsUndefined() implies not
       self.dataEnterer.assignedEntity.assignedPerson.oclIsUndefined()
      ```

78. The dataEnterer/time element **MAY** be present. If present, it represents the starting time of entry of the data. (CONF-HP-41)

    - ```
      [OCL]: not self.dataEnterer.oclIsUndefined() implies not
       self.dataEnterer.time.oclIsUndefined()
      ```

79. **MAY** satisfy: The informant element is present. (CONF-HP-42)

    - ```
      [OCL]: self.informant->size() > 0
      ```

80. When informant is present, an assignedEntity/assignedPerson or relatedEntity/relatedPerson element **SHALL** be present. (CONF-HP-43)

    - ```
      [OCL]: self.informant->forAll(i : cda::Informant12 | not
       i.assignedEntity.assignedPerson.oclIsUndefined()
         or not i.relatedEntity.relatedPerson.oclIsUndefined())
      ```

81. When the informant is a healthcare provider with an assigned role, the informant **SHALL** be represented using the assignedEntity element (CONF-HP-44)

    - Assigned health care providers may be a source of information when a document is created. (e.g., a nurse's aide who provides information about a recent significant health care event that occurred within an acute care facility.) In these cases, the assignedEntity element is used.
    - TODO: how to determin if informant is a healthcare provider? condition for implementing OCL

82. Allowable values for informant/relatedEntity/@classCode **SHALL** be CON, PRS, CAREGIVER, AGNT or PROV from the RoleClass vocabulary. (CONF-HP-45)
      ```

- 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.

83. 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-HP-46)

84. 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-HP-47)

- 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.

85. 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-HP-48)

- 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.

86. When the informant is a healthcare provider, the value of relatedEntity/code **SHOULD** be present and indicate the type of healthcare provider. (CONF-HP-49)

87. 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-HP-50)

88. The assignedEntity/assignedPerson element **SHALL** be present in legalAuthenticator. (CONF-HP-51)

- ```
  [OCL]: not self.legalAuthenticator.oclIsUndefined() implies not
   self.legalAuthenticator.assignedEntity.assignedPerson.oclIsUndefined()
  ```

89. The assignedEntity/assignedPerson element **SHALL** be present in an authenticator element. (CONF-HP-52)

- ```
  [OCL]: self.authenticator->forAll(auth : cda::Authenticator |
   auth.assignedEntity->forAll(entity : cda::AssignedEntity |
     not entity.assignedPerson.oclIsUndefined()))
  ```

90. 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 second. (CONF-HP-10)

- Should portion of CON-HP-10 constraitn
- ```
  [OCL]: -- implemented in Java using XPath selector
  ```
- ```
  [XPath]: /cda:ClinicalDocument/cda:effectiveTime | //cda:author/
  cda:time | //cda:dataEnterer/cda:time | //cda:encompassingEncounter/
  cda:effectiveTime
  ```

91. 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-HP-11)

- Should portion of CON-HP-11 constraint
- ```
  [OCL]: cda::OrganizationPartOf.allInstances()-
  >select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject)-
  > union(  cda::MaintainedEntity.allInstances()-
  >select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject) )-
  >union( cda::RelatedEntity.allInstances()-
  >select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject) )-
  >union(cda::RelatedEntity.allInstances()-
  >select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject) )-
  >union(cda::RelatedEntity.allInstances()-
  ```
  ```

```
>select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject) )-
>union(cda::ServiceEvent.allInstances()-
>select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject) )-
>union(cda::EncounterParticipant.allInstances()-
>select( time.oclIsUndefined()).oclAsType( ecore::EObject))-
>union(self.participant-
>select( time.oclIsUndefined()).oclAsType( ecore::EObject))-
>union(cda::OrganizationPartOf.allInstances().effectiveTime-
>union(cda::MaintainedEntity.allInstances().effectiveTime)-
>union( cda::RelatedEntity.allInstances().effectiveTime)-
>union(cda::RelatedEntity.allInstances().effectiveTime)-
>union(cda::RelatedEntity.allInstances().effectiveTime)-
>union(cda::ServiceEvent.allInstances().effectiveTime)-
>union(cda::EncounterParticipant.allInstances().time)-
>union(self.participant.time)->select(current :
 datatypes::IVL_TS  |  ((not current.low.oclIsUndefined()) and
 (current.low.value.oclIsUndefined() or current.low.value.size()
 < 8)) or ((not current.center.oclIsUndefined()) and
 (current.center.value.oclIsUndefined() or current.center.value.size()
 < 8)) or ((not current.high.oclIsUndefined()) and
 (current.high.value.oclIsUndefined() or current.high.value.size() < 8))
 or (current.low.oclIsUndefined() and current.center.oclIsUndefined() and
 current.high.oclIsUndefined()) ).oclAsType( ecore::EObject))
```

92. **SHALL** satisfy: A patientRole element contains an id element. (CONF-UD-17)

- `[OCL]: not recordTarget.patientRole.id->isEmpty()`

93. An assignedAuthor element contains an addr element. If addr is unknown it **SHALL** be represented using the appropriate flavor of null. (CONF-UD-25)

- `[OCL]: not author.assignedAuthor.addr->isEmpty()`

94. An assignedAuthor element contains a telecom element. If telecom is unknown it **SHALL** be represented using the appropriate flavor of null. (CONF-UD-26)

- `[OCL]: not author.assignedAuthor.telecom->isEmpty()`

95. The custodian element **SHALL** contain an assignedCustodian/representedCustodianOrganization element. (CONF-UD-28)

- `[OCL]: not custodian.assignedCustodian.representedCustodianOrganization.oclIsUndefined()`

96. A representedCustodianOrganization element **SHALL** contain an id element. (CONF-UD-29)

- `[OCL]: not custodian.assignedCustodian.representedCustodianOrganization.id->isEmpty()`

97. A representedCustodianOrganization element **SHALL** contain a name element. (CONF-UD-30)

- `[OCL]: not custodian.assignedCustodian.representedCustodianOrganization.name.oclIsUndefined()`

98. A representedCustodianOrganization element **SHALL** contain a telecom element. (CONF-UD-31)

- `[OCL]: not custodian.assignedCustodian.representedCustodianOrganization.telecom.oclIsUndefined`

99. A representedCustodianOrganization element **SHALL** contain an addr element. (CONF-UD-32)

- `[OCL]: not custodian.assignedCustodian.representedCustodianOrganization.addr.oclIsUndefined()`

100 **SHALL** satisfy: Contains component/nonXMLBody/text element. (CONF-UD-34)

- `[OCL]: not self.component.nonXMLBody.text.oclIsUndefined()`

101 The text element **SHALL** either contain a reference element with a value attribute, or have a representation attribute with the value of B64, a mediaType attribute, and contain the media content (CONF-UD-35)

- `[OCL]: (not self.component.nonXMLBody.text.reference.oclIsUndefined() and self.component.nonXMLBody.text.reference.isDefined('value'))`

```
or (self.component.nonXMLBody.text.representation
= datatypes::BinaryDataEncoding::B64 and
self.component.nonXMLBody.text.isDefined('mediaType') and
self.component.nonXMLBody.text.getText().size() > 0)
```

102. The value of @mediaType **SHALL** be drawn from the value set 2.16.840.1.113883.11.20.7.1 SupportedFileFormats STATIC 20100512 (CONF-UD-36)

-
```
[OCL]: self.component.nonXMLBody.text.isDefined('mediaType')
 implies (self.component.nonXMLBody.text.mediaType = 'application/
msword' or self.component.nonXMLBody.text.mediaType = 'application/
pdf' or self.component.nonXMLBody.text.mediaType = 'text/plain'
 or self.component.nonXMLBody.text.mediaType = 'text/rtf' or
 self.component.nonXMLBody.text.mediaType = 'text/html' or
 self.component.nonXMLBody.text.mediaType = 'image/gif' or
 self.component.nonXMLBody.text.mediaType = 'image/tiff' or
 self.component.nonXMLBody.text.mediaType = 'image/jpeg' or
 self.component.nonXMLBody.text.mediaType = 'image/png')
```

Unstructured Or Scanned Document example

Chapter 3

SECTION TEMPLATES

Topics:

Admission Medication History Section

[Section: templateId `2.16.840.1.113883.3.88.11.83.113`]

The Admission Medication Section contains information about the relevant medications of a patient prior to admission to a facility.

1. **SHALL** conform to *IHE Admission Medication History Section* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.3.20`)
2. **SHALL** contain exactly one [1..1] **`code/@code`**`="42346-7"` *MEDICATIONS ON ADMISSION* (CodeSystem:)

Admission Medication History Section example

Advance Directives Section

[Section: templateId `2.16.840.1.113883.3.88.11.83.116`]

The Advance Directives Section contains information that defines the patient's expectations and requests for care along with the locations of the documents.

1. **SHALL** conform to *CCD Advance Directives Section* template (templateId: `2.16.840.1.113883.10.20.1.1`)
2. **SHALL** conform to *IHE Advance Directives Section* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.3.34`)
3. **SHALL** conform to *IHE Coded Advance Directives Section* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.3.35`)
4. **SHALL** contain exactly one [1..1] **`code/@code`**`="42348-3"` *Advance directives* (CodeSystem:)
5. **SHALL** contain exactly one [1..1] **`title`**
6. **SHALL** contain exactly one [1..1] **`text`**
7. **SHALL** contain at least one [1..*] **`entry`**, such that
   a. Contains exactly one [1..1] *Advance Directive* (templateId: `2.16.840.1.113883.3.88.11.83.12`)
8. **SHOULD** satisfy: Contains a case-insensitive language-insensitive text string containing 'advance directives'.

Advance Directives Section example

Allergies Reactions Section

[Section: templateId `2.16.840.1.113883.3.88.11.83.102`]

The Allergies and Other Adverse Reactions Section contains data on the substance intolerances and the associated adverse reactions suffered by the patient. At a minimum, currently active and any relevant historical allergies and adverse reactions shall be listed.

1. **SHALL** conform to *CCD Alerts Section* template (templateId: `2.16.840.1.113883.10.20.1.2`)
2. **SHALL** conform to *IHE Allergies Reactions Section* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.3.13`)
3. **SHALL** contain exactly one [1..1] **`code/@code`**`="48765-2"` *Allergies, adverse reactions, alerts* (CodeSystem:) (CONF-258, CONF-259)
4. **SHALL** contain exactly one [1..1] **`title`** (CONF-260)
5. **SHALL** contain exactly one [1..1] **`text`** (CONF-256)
6. **SHOULD** contain at least one [1..*] **`entry`** (CONF-256), such that
   a. Contains exactly one [1..1] *Problem Act* (templateId: `2.16.840.1.113883.10.20.1.27`)

7. **SHALL** contain at least one [1..*] **`entry`**, such that
   a. Contains exactly one [1..1] *Allergy Drug Sensitivity* (templateId: `2.16.840.1.113883.3.88.11.83.6`)
8. **SHOULD** satisfy: Contains a case-insensitive language-insensitive string containing "alert" and/or "allergies and adverse reactions". (CONF-261)
9. The absence of known allergies, adverse reactions or alerts **SHALL** be explicitly asserted.

Allergies Reactions Section example

Assessment And Plan Section

[Section: templateId `2.16.840.1.113883.3.88.11.83.123`]

The Assessment and Plan Section contains information about the assessment of the patient's condition and expectations for care including proposals, goals, and order requests for monitoring, tracking, or improving the condition of the patient.

An assessment and plan section varies from the plan of care section defined later in that it includes a physician assessment of the patient condition.

NOTE : The assessments described in this section are physician assessments of the patient's current condition, and do not include assessments of functional status, or other assessments typically used in nursing. In Implementation Guides currently selected, when both the assessment and plan are documented, they are included together in a single section documenting both. When the physician assessment is not present, only the plan of care section appears. There are no cases where a physician assessment is provided without a plan.

1. **SHALL** conform to *IHE Assessment And Plan Section* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.1.13.2.5`)
2. **SHALL** contain exactly one [1..1] **`code/@code`**`="51847-2"` *ASSESSMENT AND PLAN* (CodeSystem:)

Assessment And Plan Section example

Chief Complaint Section

[Section: templateId `2.16.840.1.113883.3.88.11.83.105`]

The Chief Complaint Section contains information about the patient's chief complaint.

1. **SHALL** conform to *CDT Chief Complaint Section* template (templateId: `2.16.840.1.113883.10.20.2.8`)
2. **SHALL** conform to *IHE Chief Complaint Section* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.1.13.2.1`)
3. **SHALL** contain exactly one [1..1] **`code/@code`**`="10154-3"` *CHIEF COMPLAINT* (CodeSystem:)
4. **MAY** contain zero or one [0..1] **`entry`**, such that
   a. Contains exactly one [1..1] *Condition* (templateId: `2.16.840.1.113883.3.88.11.83.7`)

Chief Complaint Section example

Diagnostic Results Section

[Section: templateId `2.16.840.1.113883.3.88.11.83.122`]

The Results 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, echocardiography, nuclear medicine, pathology, and procedure observations. The

section often includes notable results such as abnormal values or relevant trends, and could contain all results for the period of time being documented.

Laboratory 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 and submitted to the laboratory.

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 echocardiogram.

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

1. **SHALL** conform to *IHE Coded Results Section* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.3.28`)
2. **SHALL** contain exactly one [1..1] **`code/@code`**`="30954-2"` *STUDIES SUMMARY* (CodeSystem:)
3. **SHOULD** contain at least one [1..*] **`entry`**, 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. **SHALL** contain at least one [1..*] **`entry`** (C83-[CT-122-2]), such that
   a. Contains exactly one [1..1] *Procedure* (templateId: `2.16.840.1.113883.3.88.11.83.17`)
5. **SHALL** contain at least one [1..*] **`entry`** (C83-[CT-122-2]), such that
   a. Contains exactly one [1..1] *Result* (templateId: `2.16.840.1.113883.3.88.11.83.15`)

Diagnostic Results Section example

Discharge Diagnosis Section

[Section: templateId `2.16.840.1.113883.3.88.11.83.111`]

The Discharge Diagnosis Section contains information about the conditions identified during the hospital stay that either need to be monitored after discharge from the hospital and/or where resolved during the hospital course.

1. **SHALL** conform to *IHE Discharge Diagnosis Section* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.3.7`)
2. **SHALL** contain exactly one [1..1] **`code/@code`**`="11535-2"` *HOSPITAL DISCHARGE DX* (CodeSystem:)
3. **SHALL** contain exactly one [1..1] **`entry`**, such that
   a. Contains exactly one [1..1] *Condition* (templateId: `2.16.840.1.113883.3.88.11.83.7`)

Discharge Diagnosis Section example

Encounters Section

[Section: templateId `2.16.840.1.113883.3.88.11.83.127`]

The Encounter Section contains information describing the patient history of encounters. At a minimum, current and pertinent historical encounters should be included; a full encounter history may be included.

1. **SHALL** conform to *CCD Encounters Section* template (templateId: `2.16.840.1.113883.10.20.1.3`)
2. **SHALL** conform to *IHE Encounter History Section* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.1.5.3.3`)
3. **SHALL** contain exactly one [1..1] **`code/@code`**`="46240-8"` *History of encounters* (CodeSystem:)
4. **SHALL** contain exactly one [1..1] **`title`**
5. **SHALL** contain exactly one [1..1] **`text`**

6. **SHOULD** contain at least one [1..*] **`entry`**, such that
   a. Contains exactly one [1..1] *Encounters Activity* (templateId: `2.16.840.1.113883.10.20.1.21`)
7. **SHALL** contain at least one [1..*] **`entry`**, such that
   a. Contains exactly one [1..1] *Encounter* (templateId: `2.16.840.1.113883.3.88.11.83.16`)
8. **SHOULD** be valued with a case-insensitive language-insensitive text string containing 'encounters'.

Encounters Section example

Family History Section

[Section: templateId `2.16.840.1.113883.3.88.11.83.125`]

The Family History Section contains information about the genetic family members, to the extent that they are known, the diseases they suffered from, their ages at death, and other relevant genetic information.

1. **SHALL** conform to *CCD Family History Section* template (templateId: `2.16.840.1.113883.10.20.1.4`)
2. **SHALL** conform to *IHE Family Medical History Section* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.3.14`)
3. **SHALL** contain exactly one [1..1] **`code/@code`**`="10157-6"` *History of family member diseases* (CodeSystem:)
4. **SHALL** contain exactly one [1..1] **`title`**
5. **SHALL** contain exactly one [1..1] **`text`**
6. **SHOULD** satisfy: Contains a case-insensitive language-insensitive text string containing 'family history'.
7. Family History Section **SHOULD** include one or more family history observations (templateId 2.16.840.1.113883.10.20.1.22), which **MAY** be contained within family history organizers (templateId 2.16.840.1.113883.10.20.1.23)
8. The family history section **SHALL NOT** contain Section / subject.
9. **SHALL** conform to IHE Coded Family History Section and **SHALL** contain a templateId element whose root attribute is 1.3.6.1.4.1.19376.1.5.3.1.3.15 when this section is conveying structured family history.
10. When providing structured Family History Information **SHALL** include entries conforming to the Family History module

Family History Section example

Functional Status Section

[Section: templateId `2.16.840.1.113883.3.88.11.83.109`]

The Functional Status Section provides information about the capability of the patient to perform acts of daily living.

1. **SHALL** conform to *CCD Functional Status Section* template (templateId: `2.16.840.1.113883.10.20.1.5`)
2. **SHALL** contain exactly one [1..1] **`code/@code`**`="47420-5"` *Functional status assessment* (CodeSystem:)
3. **SHALL** contain exactly one [1..1] **`title`**
4. **SHALL** contain exactly one [1..1] **`text`**
5. **SHOULD** satisfy: Contains one or more Problem Act and/or Result Organizer (CONF-123)
   -
```
[OCL]: self.getEntryTargets(ccd::ProblemAct)->size() > 0
  or self.getEntryTargets(ccd::ResultOrganizer)->size() > 0
```
6. **SHOULD** satisfy: Contains a case-insensitive language-insensitive string containing 'functional status'.
7. problem observation or result observation in the functional status section **SHALL** contain exactly one observation / code (CONF-128)
8. The value for Observation / code in a problem observation or result observation in the functional status section **MAY** be selected from ValueSet 2.16.840.1.113883.1.11.20.6 FunctionalStatusTypeCode STATIC 20061017

9. If the functional status was collected using a standardized assessment instrument, then the instrument itself **SHOULD** be represented in the Organizer / code of a result organizer, with a value selected from LOINC (codeSystem 2.16.840.1.113883.6.1) or SNOMED CT (codeSystem 2.16.840.1.113883.6.96)
10. If the functional status was collected using a standardized assessment instrument, then the question within that instrument **SHOULD** be represented in the Observation / code of a result observation, with a value selected from LOINC (codeSystem 2.16.840.1.113883.6.1) or SNOMED CT (codeSystem 2.16.840.1.113883.6.96).
11. If the functional status was collected using a standardized assessment instrument containing questions with enumerated values as answers, then the answer **SHOULD** be represented in the Observation / value of a result observation
12. If Observation / value in a result observation in the functional status section is of data type CE or CD, then it **SHOULD** use the same code system used to code the question in Observation / code.
13. Observation / value in a result observation in the functional status section **MAY** be of datatype CE or CD and **MAY** contain one or more Observation / value / translation, to represent equivalent values from other code systems.
14. A problem observation or result observation in the functional status section **MAY** use codes from the International Classification of Functioning, Disability, and Health (ICF, http://www.who.int/classifications/icf/en/) (codeSystem 2.16.840.1.113883.6.254).
15. A problem observation in the functional status section **SHALL** contain exactly one status of functional status observation
16. A result observation in the functional status section **SHALL** contain exactly one status of functional status observation.

Functional Status Section example

History Of Past Illness Section

[Section: templateId `2.16.840.1.113883.3.88.11.83.104`]

The History of Past Illness Section contains data about problems the patient suffered in the past.

1. **SHALL** conform to *CDT Past Medical History Section* template (templateId: `2.16.840.1.113883.10.20.2.9`)
2. **SHALL** conform to *IHE History Of Past Illness Section* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.3.8`)
3. **SHALL** contain exactly one [1..1] **`code/@code`**`="11348-0"` *HISTORY OF PAST ILLNESS* (CodeSystem:)
4. **SHALL** contain exactly one [1..1] **`entry`**, such that
   a. Contains exactly one [1..1] *Condition* (templateId: `2.16.840.1.113883.3.88.11.83.7`)
5. **SHOULD** satisfy: Contains clinical statements.
   - `[OCL]: not self.entry->isEmpty()`

History Of Past Illness Section example

History Of Present Illness

[Section: templateId `2.16.840.1.113883.3.88.11.83.107`]

The History of Present Illness Section contains information about the sequence of events preceding the patient's current complaints.

1. **SHALL** conform to *IHE History Of Present Illness* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.3.4`)
2. **SHALL** contain exactly one [1..1] **`code/@code`**`="10164-2"` *HISTORY OF PRESENT ILLNESS* (CodeSystem:)

History Of Present Illness example

Hospital Admission Diagnosis Section

[Section: templateId `2.16.840.1.113883.3.88.11.83.110`]

The Hospital Admitting Diagnosis Section contains information about the primary reason for admission to a hospital facility.

1. **SHALL** conform to *IHE Hospital Admission Diagnosis Section* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.3.3`)
2. **SHALL** contain exactly one [1..1] **`code/@code`**`="46241-6"` *HOSPITAL ADMISSION DX* (CodeSystem:)
3. **SHALL** contain exactly one [1..1] **`entry`**, such that
   a. Contains exactly one [1..1] *Condition* (templateId: `2.16.840.1.113883.3.88.11.83.7`)

Hospital Admission Diagnosis Section example

Hospital Course Section

[Section: templateId `2.16.840.1.113883.3.88.11.83.121`]

The Hospital Course Section contains information about of the sequence of events from admission to discharge in a hospital facility.

1. **SHALL** conform to *IHE Hospital Course Section* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.3.5`)
2. **SHALL** contain exactly one [1..1] **`code/@code`**`="8648-8"` *HOSPITAL COURSE* (CodeSystem:)

Hospital Course Section example

Hospital Discharge Medications Section

[Section: templateId `2.16.840.1.113883.3.88.11.83.114`]

The Hospital Discharge Medications Section contains information about the relevant medications of the medications ordered for the patient for use after discharge from the hospital.

1. **SHALL** conform to *IHE Hospital Discharge Medications Section* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.3.22`)
2. **SHALL** contain exactly one [1..1] **`code/@code`**`="10183-2"` *HOSPITAL DISCHARGE MEDICATIONS* (CodeSystem:)
3. **SHALL** contain exactly one [1..1] **`entry`**, such that
   a. Contains exactly one [1..1] *Medication* (templateId: `2.16.840.1.113883.3.88.11.83.8`)

Hospital Discharge Medications Section example

Immunizations Section

[Section: templateId `2.16.840.1.113883.3.88.11.83.117`]

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

1. **SHALL** conform to *CCD Medications Section* template (templateId: `2.16.840.1.113883.10.20.1.8`)
2. **SHALL** conform to *CCD Immunizations Section* template (templateId: `2.16.840.1.113883.10.20.1.6`)
3. **SHALL** conform to *IHE Immunizations Section* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.3.23`)
4. **SHALL** contain exactly one [1..1] **`code/@code`**`="11369-6"` *History of immunizations* (CodeSystem:) (CONF-377)

5. **SHALL** contain exactly one [1..1] **`title`** (CONF-379)
6. **SHALL** contain exactly one [1..1] **`text`** (CONF-376)
7. **SHOULD** contain zero or more [0..*] **`entry`** (CONF-298), such that
   a. Contains exactly one [1..1] *Supply Activity* (templateId: `2.16.840.1.113883.10.20.1.34`)
8. **SHALL** contain 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`)
9. **SHOULD** satisfy: Clinical statements include one or more Medication Activity and/or one or more Supply Activity. (CONF-298)
   - ```
     [OCL]: self.getSubstanceAdministrations()-
     >exists(activity : cda::SubstanceAdministration |
      activity.oclIsKindOf(ccd::MedicationActivity))
        or self.getSupplies()->exists(activity : cda::Supply |
      activity.oclIsKindOf(ccd::SupplyActivity))
     ```
10. **SHALL** satisfy: The absence of known medications is explicitly asserted. (CONF-299)
11. **SHOULD** satisfy: Valued with a case-insensitive language-insensitive string containing 'medication'. (CONF-303)
12. **SHOULD** satisfy: Contains a case-insensitive language-insensitive string containing 'immunization'. (CONF-380)

Immunizations Section example

Medical Equipment Section

[Section: templateId `2.16.840.1.113883.3.88.11.83.128`]

The Medical Equipment section contains information describing a patient's implanted and external medical devices and equipment that their health status depends on, as well as any pertinent equipment or device history.

1. **SHALL** conform to *CCD Medical Equipment Section* template (templateId: `2.16.840.1.113883.10.20.1.7`)
2. **SHALL** conform to *IHE Medical Devices Section* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.1.5.3.5`)
3. **SHALL** contain exactly one [1..1] **`code/@code`**`="46264-8"` *History of medical device use* (CodeSystem:) (CONF-CCD-520)
4. **SHALL** contain exactly one [1..1] **`title`** (CONF-CCD-521)
5. **SHALL** contain exactly one [1..1] **`text`**
6. **SHOULD** contain zero or more [0..*] **`entry`**, such that
   a. Contains exactly one [1..1] *Supply Activity* (templateId: `2.16.840.1.113883.10.20.1.34`)
7. **MAY** contain zero or more [0..*] **`entry`**, such that
   a. Contains exactly one [1..1] *Medication Activity* (templateId: `2.16.840.1.113883.10.20.1.24`)
8. **SHOULD** satisfy: Contains a a case-insensitive language-insensitive text string containing "equipment"

Medical Equipment Section example

Medications Administered Section

[Section: templateId `2.16.840.1.113883.3.88.11.83.115`]

The Medications Administered Section contains information about the relevant medications administered to a patient during the course of an encounter.

1. **SHALL** conform to *IHE Medications Administered Section* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.3.21`)
2. **SHALL** contain exactly one [1..1] **`code/@code`**`="18610-6"` *MEDICATION ADMINISTERED* (CodeSystem:)
     ```

Medications Administered Section example

Medications Section

[Section: templateId `2.16.840.1.113883.3.88.11.83.112`]

The Medications Section contains information about the relevant medications for the patient. At a minimum, the currently active medications should be listed.

1. **SHALL** conform to *CCD Medications Section* template (templateId: `2.16.840.1.113883.10.20.1.8`)
2. **SHALL** conform to *IHE Medications Section* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.3.19`)
3. **SHALL** contain exactly one [1..1] **`code/@code`**`="10160-0"` *History of medication use* (CodeSystem:) (CONF-300, CONF-301)
4. **SHALL** contain exactly one [1..1] **`title`** (CONF-302)
5. **SHALL** contain zero or one [0..1] **`text`** (CONF-298)
6. **SHOULD** contain zero or more [0..*] **`entry`** (CONF-298), such that
   a. Contains exactly one [1..1] *Supply Activity* (templateId: `2.16.840.1.113883.10.20.1.34`)
7. **SHALL** contain at least one [1..*] **`entry`** (C83-[CT-112-2]), such that
   a. Contains exactly one [1..1] *Medication* (templateId: `2.16.840.1.113883.3.88.11.83.8`)
8. **SHOULD** satisfy: Clinical statements include one or more Medication Activity and/or one or more Supply Activity. (CONF-298)
   - ```
     [OCL]: self.getSubstanceAdministrations()-
     >exists(activity : cda::SubstanceAdministration |
      activity.oclIsKindOf(ccd::MedicationActivity))
        or self.getSupplies()->exists(activity : cda::Supply |
      activity.oclIsKindOf(ccd::SupplyActivity))
     ```
9. **SHALL** satisfy: The absence of known medications is explicitly asserted. (CONF-299)
10. **SHOULD** satisfy: Valued with a case-insensitive language-insensitive string containing 'medication'. (CONF-303)
11. **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.
12. **MAY** 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.

Medications Section example

Payers Section

[Section: templateId `2.16.840.1.113883.3.88.11.83.101`]

The Payers Section contains data on the patient's payers, whether a 'third party' insurance, self-pay, other payer or guarantor, or some combination. At a minimum, the patient's pertinent current payment sources should be listed. If no
     ```

payment sources are supplied, the reason shall be supplied as free text in the narrative block (e.g., Not Insured, Payer Unknown, Medicare Pending, et cetera).

1. **SHALL** conform to *CCD Payers Section* template (templateId: `2.16.840.1.113883.10.20.1.9`)
2. **SHALL** conform to *IHE Payers Section* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.1.5.3.7`)
3. **SHALL** contain exactly one [1..1] **`code/@code="48768-6"`** *Payment sources* (CodeSystem:) (CONF-31, CONF-32)
4. **SHALL** contain exactly one [1..1] **`title`** (CONF-33)
5. **SHALL** contain exactly one [1..1] **`text`** (CONF-30)
6. **SHOULD** contain at least one [1..*] **`entry`**, such that
   a. Contains exactly one [1..1] *Coverage Entry* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.17`)
7. **SHOULD** satisfy: Contains a case-insensitive language-insensitive string containing 'insurance' or 'payers'. (CONF-34)

Payers Section example

Physical Exam Section

[Section: templateId `2.16.840.1.113883.3.88.11.83.118`]

The Physical Examination Section contains information describing the physical findings.

1. **SHALL** conform to *IHE Physical Exam Narrative Section* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.3.24`)
2. **SHALL** conform to *IHE Physical Exam Section* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.1.9.15`)
3. **SHALL** contain exactly one [1..1] **`code/@code="29545-1"`** *PHYSICAL EXAMINATION* (CodeSystem:)

Physical Exam Section example

Plan Of Care Section

[Section: templateId `2.16.840.1.113883.3.88.11.83.124`]

The Plan of Care Section contains information about the expectations for care to be provided including proposed interventions and goals for improving the condition of the patient.

A plan of care section varies from the assessment and plan section defined above in that it does not include a physician assessment of the patient condition.

1. **SHALL** conform to *CDT Assessment And Plan Section* template (templateId: `2.16.840.1.113883.10.20.2.7`)
2. **SHALL** conform to *CCD Plan Of Care Section* template (templateId: `2.16.840.1.113883.10.20.1.10`)
3. **SHALL** conform to *IHE Care Plan Section* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.3.31`)
4. **SHALL** contain exactly one [1..1] **`code/@code="18776-5"`** *Treatment plan* (CodeSystem:)
5. **SHALL** contain exactly one [1..1] **`title`**
6. **SHALL** contain exactly one [1..1] **`text`**
7. **MAY** contain zero or one [0..1] **`entry`**, such that
   a. Contains exactly one [1..1] *Plan Of Care Activity Act* (templateId: `2.16.840.1.113883.10.20.1.25`)
8. **MAY** contain zero or one [0..1] **`entry`**, such that
   a. Contains exactly one [1..1] *Plan Of Care Activity Encounter* (templateId: `2.16.840.1.113883.10.20.1.25`)
9. **MAY** contain zero or one [0..1] **`entry`**, such that

   a. Contains exactly one [1..1] *Plan Of Care Activity Observation* (templateId: `2.16.840.1.113883.10.20.1.25`)
10. **MAY** contain zero or one [0..1] **`entry`**, such that
   a. Contains exactly one [1..1] *Plan Of Care Activity Procedure* (templateId: `2.16.840.1.113883.10.20.1.25`)
11. **MAY** contain zero or one [0..1] **`entry`**, such that
   a. Contains exactly one [1..1] *Plan Of Care Activity Substance Administration* (templateId: `2.16.840.1.113883.10.20.1.25`)
12. **MAY** contain zero or one [0..1] **`entry`**, such that
   a. Contains exactly one [1..1] *Plan Of Care Activity Supply* (templateId: `2.16.840.1.113883.10.20.1.25`)
13. **MAY** contain zero or one [0..1] **`entry`**, such that
   a. Contains exactly one [1..1] *Medication* (templateId: `2.16.840.1.113883.3.88.11.83.8`)
14. **MAY** contain zero or one [0..1] **`entry`**, such that
   a. Contains exactly one [1..1] *Immunization* (templateId: `2.16.840.1.113883.3.88.11.83.13`)
15. **MAY** contain zero or one [0..1] **`entry`**, such that
   a. Contains exactly one [1..1] *Encounter* (templateId: `2.16.840.1.113883.3.88.11.83.16`)
16. **MAY** contain zero or one [0..1] **`entry`**, such that
   a. Contains exactly one [1..1] *Procedure* (templateId: `2.16.840.1.113883.3.88.11.83.17`)
17. **SHOULD** contain a case-insensitive language-insensitive text string containing 'plan'.

Plan Of Care Section example

Problem List Section

[Section: templateId `2.16.840.1.113883.3.88.11.83.103`]

This section lists and describes all relevant clinical problems at the time the document is generated. At a minimum, all pertinent current and historical problems should be listed.

1. **SHALL** conform to *CCD Problem Section* template (templateId: `2.16.840.1.113883.10.20.1.11`)
2. **SHALL** conform to *IHE Active Problems Section* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.3.6`)
3. **SHALL** contain exactly one [1..1] **`code/@code="11450-4"`** *Problem list* (CodeSystem:) (CONF-141, CONF-142)
4. **SHALL** contain exactly one [1..1] **`title`** (CONF-143)
5. **SHALL** contain exactly one [1..1] **`text`** (CONF-140)
6. **SHOULD** contain at least one [1..*] **`entry`** (CONF-140), such that
   a. Contains exactly one [1..1] *Problem Act* (templateId: `2.16.840.1.113883.10.20.1.27`)
7. **SHALL** contain at least one [1..*] **`entry`** (C83-[CT-103-1]), such that
   a. Contains exactly one [1..1] *Condition* (templateId: `2.16.840.1.113883.3.88.11.83.7`)
8. **SHOULD** contain a case-insensitive language-insensitive string containing 'problems'. (CONF-144)

Problem List Section example

Reason For Referral Section

[Section: templateId `2.16.840.1.113883.3.88.11.83.106`]

The Reason for Referral Section contains information about the reason that the patient is being referred.

1. **SHALL** conform to *IHE Reason For Referral Section* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.3.1`)
2. **SHALL** contain exactly one [1..1] **`code/@code`**`="42349-1"` *REASON FOR REFERRAL* (CodeSystem:)

Reason For Referral Section example

Review Of Systems Section

[Section: templateId `2.16.840.1.113883.3.88.11.83.120`]

The Review of Systems Section contains information describing patient responses to questions about the function of various body systems.

1. **SHALL** conform to *CDT Review Of Systems Section* template (templateId: `2.16.840.1.113883.10.20.4.10`)
2. **SHALL** conform to *IHE Review Of Systems Section* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.3.18`)
3. **SHALL** contain exactly one [1..1] **`code/@code`**`="10187-3"` *REVIEW OF SYSTEMS* (CodeSystem:)

Review Of Systems Section example

Social History Section

[Section: templateId `2.16.840.1.113883.3.88.11.83.126`]

The Social History Section contains information about the person's beliefs, home life, community life, work life, hobbies, and risky habits.

1. **SHALL** conform to *CCD Social History Section* template (templateId: `2.16.840.1.113883.10.20.1.15`)
2. **SHALL** conform to *IHE Social History Section* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.3.16`)
3. **SHALL** contain exactly one [1..1] **`code/@code`**`="29762-2"` *Social history* (CodeSystem:)
4. **SHALL** contain exactly one [1..1] **`title`**
5. **SHALL** contain exactly one [1..1] **`text`**
6. **SHOULD** contain zero or more [0..*] **`entry`**, such that
   a. Contains exactly one [1..1] *Social History Observation* (templateId: `2.16.840.1.113883.10.20.1.33`)
7. **MAY** contain zero or more [0..*] **`entry`**, such that
   a. Contains exactly one [1..1] *Social History* (templateId: `2.16.840.1.113883.10.20.1.33`)
8. **SHOULD** satisfy: Contains a case-insensitive language-insensitive string containing 'social history'.
9. Marital status **SHOULD** be represented as ClinicalDocument / recordTarget / patientRole / patient / maritalStatusCode. Additional information **MAY** be represented as social history observations
10. Religious affiliation **SHOULD** be represented as ClinicalDocument / recordTarget / patientRole / patient / religiousAffiliationCode. Additional information **MAY** be represented as social history observations
11. A patient’s race **SHOULD** be represented as ClinicalDocument / recordTarget / patientRole / patient / raceCode. Additional information **MAY** be represented as social history observations
12. The value for ClinicalDocument / recordTarget / patientRole / patient / raceCode **MAY** be selected from codeSystem 2.16.840.1.113883.5.104 (Race)
13. A patient’s ethnicity **SHOULD** be represented as ClinicalDocument / recordTarget / patientRole / patient / ethnicGroupCode. Additional information **MAY** be represented as social history observations.
14. The value for ClinicalDocument / recordTarget / patientRole / patient / ethnicGroupCode **MAY** be selected from codeSystem 2.16.840.1.113883.5.50 (Ethnicity).

Social History Section example

Surgeries Section

[Section: templateId `2.16.840.1.113883.3.88.11.83.108`]

1. **SHALL** conform to *CCD Procedures Section* template (templateId: `2.16.840.1.113883.10.20.1.12`)
2. **SHALL** conform to *IHE Surgeries Section* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.3.11`)
3. **SHALL** conform to *IHE Coded Surgeries Section* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.3.12`)
4. **SHALL** contain exactly one [1..1] **`code/@code="47519-4"`** *History of procedures* (CodeSystem:) (CONF-423, CONF-424)
5. **SHALL** contain exactly one [1..1] **`title`** (CONF-425)
6. **SHALL** contain exactly one [1..1] **`text`** (CONF-422)
7. **SHOULD** contain zero or one [0..1] **`entry`**, such that
   a. Contains exactly one [1..1] *External Reference* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.4`)
8. **SHALL** contain at least one [1..*] **`entry`**, such that
   a. Contains exactly one [1..1] *Procedure Entry Procedure Activity Procedure* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.19`)
9. **SHALL** contain at least one [1..*] **`entry`** (C83-[CT-108-2]), such that
   a. Contains exactly one [1..1] *Procedure* (templateId: `2.16.840.1.113883.3.88.11.83.17`)
10. **SHOULD** satisfy: title is valued with a case-insensitive language-insensitive text string containing "procedures". (CONF-426)
11. **SHOULD** satisfy: include one or more of the following: ProcedureActivityAct, ProcedureActivityObservation, ProcedureActivityProcedure (CONF-422)

Surgeries Section example

Vital Signs Section

[Section: templateId `2.16.840.1.113883.3.88.11.83.119`]

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

1. **SHALL** conform to *CCD Vital Signs Section* template (templateId: `2.16.840.1.113883.10.20.1.16`)
2. **SHALL** conform to *IHE Vital Signs Section* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.3.25`)
3. **SHALL** conform to *IHE Coded Vital Signs Section* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.1.5.3.2`)
4. **SHALL** contain exactly one [1..1] **`code/@code="8716-3"`** *Vital signs* (CodeSystem:) (CONF-382, CONF-383)
5. **SHALL** contain exactly one [1..1] **`title`** (CONF-384)
6. **SHALL** contain exactly one [1..1] **`text`** (CONF-381)
7. **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`)
8. **SHOULD** satisfy: title Contains a case-insensitive language-insensitive string containing 'vital signs'. (CONF-385)
9. **SHALL** satisfy: Contains entries conforming to the Vital Sign module. (C83-[CT-119-2])

```
[OCL]: self.entry->exists(entry : cda::Entry |
 entry.organizer.oclIsKindOf(ihe::VitalSignsOrganizer) and
 entry.organizer.component.observation->exists(obs : cda::Observation |
 obs.oclIsKindOf(hitsp::VitalSign)))
```

Vital Signs Section example

Chapter 4

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.

Advance Directive

Advance Directive example

Allergy Drug Sensitivity

[Act: templateId `2.16.840.1.113883.3.88.11.83.6`]

This module contains the allergy or intolerance conditions and the associated adverse reactions suffered by the patient. See the HL7 Continuity of Care Document Section 3.8 for constraints applicable to this module.

1. **SHALL** conform to *CCD Problem Act* template (templateId: `2.16.840.1.113883.10.20.1.27`)
2. **SHALL** conform to *IHE Concern Entry* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.5.1`)
3. **SHALL** conform to *IHE Allergy Intolerance Concern* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.5.3`)
4. **SHALL** contain exactly one [1..1] **`@classCode="ACT"`** *Act* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF-146)
5. **SHALL** contain exactly one [1..1] **`@moodCode="EVN"`** *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF-147)
6. **SHALL** contain at least one [1..*] **`id`** (CONF-148)
7. **SHALL** contain exactly one [1..1] **`code`**`/@nullFlavor` = "NA" *NA (not applicable)* (CONF-149)
8. **SHALL** contain exactly one [1..1] **`statusCode`**, which **SHALL** be selected from ValueSet *`ConcernEntryStatus`* **STATIC**
   - The statusCode associated with any concern must be one of the following values:

     active: A concern that is still being tracked. **suspended**: A concern that is active, but which may be set aside. For example, this value might be used to suspend concern about a patient problem after some period of remission, but before assumption that the concern has been resolved. **aborted**: A concern that is no longer actively being tracked, but for reasons other than because the problem was resolved. This value might be used to mark a concern as being aborted after a patient leaves care against medical advice. **completed**: The problem, allergy or medical state has been resolved and the concern no longer needs to be tracked except for historical purposes.
9. **SHALL** contain exactly one [1..1] **`effectiveTime`**
   - The effectiveTime element records the starting and ending times during which the concern was active.
10. **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`)
11. **SHALL** contain at least one [1..*] **`entryRelationship`**, such that
    a. Contains **`@typeCode="SUBJ"`** *SUBJ (has subject)*
    b. Contains exactly one [1..1] *Allergy Intolerance* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.6`)
12. **SHALL** contain one or more entryRelationship (CONF-151)
    - `[OCL]: not self.entryRelationship->isEmpty()`
13. A problem act **MAY** reference a problem observation, alert observation (see section Alerts) or other clinical statement that is the subject of concern, by setting the value for "Act / entryRelationship / @typeCode" to be "SUBJ" 2.16.840.1.113883.5.1002 ActRelationshipType STATIC. (CONF-152)
14. The target of a problem act with Act / entryRelationship / @typeCode="SUBJ" **SHOULD** be a problem observation (in the Problem section) or alert observation (in the Alert section), but **MAY** be some other clinical statement. (CONF-153)
    - ```
      [OCL]:
      self.getEntryRelationshipTargets(vocab::x_ActRelationshipEntryRelationship::SUBJ,
      cda::ClinicalStatement)->forAll(target : cda::ClinicalStatement | not
      target.oclIsUndefined() and
      ```
      ```

```
 (target.oclIsKindOf(ccd::ProblemObservation) or
target.oclIsKindOf(ccd::AlertObservation)))
```

15. In Problem Section, a Problem Act **SHOULD** contain one or more Problem Observations. (CONF-140)

- ```
  [OCL]: self.getSection().oclIsKindOf(ccd::ProblemSection) implies
  self.getObservations()
    ->exists(obs : cda::Observation |
  obs.oclIsKindOf(ccd::ProblemObservation))
  ```

16. In Alert Section, a ProblemAct **SHOULD** contain one or more Alert Observations. (CONF-256)

- ```
  [OCL]: self.getSection().oclIsKindOf(ccd::AlertsSection) implies
  self.getObservations()
    ->exists(obs : cda::Observation |
  obs.oclIsKindOf(ccd::AlertObservation))
  ```

17. **MAY** contain exactly one Patient Awareness (CONF-179)

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

18. The effectiveTime 'low' element **SHALL** be present. The 'high' element **SHALL** be present for concerns in the completed or aborted state, and **SHALL NOT** be present otherwise.

- ```
  [OCL]: not self.effectiveTime.low.oclIsUndefined()
    and ((self.statusCode.code = 'completed' or self.statusCode.code =
  'aborted') implies not self.effectiveTime.high.oclIsUndefined())
    and ((self.statusCode.code <> 'completed' and self.statusCode.code <>
  'aborted') implies self.effectiveTime.high.oclIsUndefined())
  ```

19. This entry **SHALL** contain one or more problem or allergy entries that conform to the specification in section Problem Entry or Allergies and Intolerances.

- Each concern is about one or more related problems or allergies. This is how a series of related observations can be grouped as a single concern.
- ```
  [OCL]: self.entryRelationship.observation.templateId->exists(id :
  datatypes::II | id.root =  '1.3.6.1.4.1.19376.1.5.3.1.4.5') or
  self.entryRelationship.observation.templateId->exists(id : datatypes::II
  | id.root =  '1.3.6.1.4.1.19376.1.5.3.1.4.6')
  ```

20. This **SHALL** be represented using entryRelationship with typeCode = 'SUBJ'

- ```
  [OCL]: self.entryRelationship->select(er|er.typeCode <>
  vocab::x_ActRelationshipEntryRelationship::SUBJ)->isEmpty()
  ```

21. Each concern **MAY** have 0 or more related references. This **MAY** be any valid CDA clinical statement, and **SHOULD** be an IHE entry template.

- These may be used to represent related statements such related visits.

22. Related References **SHALL** be represented using entryRelationship with typeCode = 'REFR'.

23. **SHOULD** satisfy: the observation/effectiveTime element is present to record event date

- This is a date that expresses when this particular allergy or intolerance was known to be active for the patient
- ```
  [OCL]: self.getObservations()->exists(obs : cda::Observation
  | obs.oclIsKindOf(ccd::AlertObservation) and not
  obs.effectiveTime.oclIsUndefined())
  ```

24. **SHALL** satisfy: the observation/code element shall be present to record the adverse event type

- Describes the type of product and intolerance suffered by the patient. The type of product shall be classified with respect to whether the adverse event occurs in relationship with a medication, food, or environmental or other product. The adverse event should also be classified more specifically as an allergy, non-allergy intolerance, or just adverse reaction if that level of detail is not known
- ```
  [OCL]: self.getObservations()->exists(obs : cda::Observation |
  obs.oclIsKindOf(ccd::AlertObservation) and not obs.code.oclIsUndefined())
  ```

25. **SHALL** satisfy: the code/@code attribute value is from Allergy/Adverse Event Type Value Set, 2.16.840.1.113883.3.88.12.3221.6.2, version: 20081218, Static (C154-[DE-6.02-1])
    - `[OCL]: self.getObservations()->exists(obs : cda::Observation | obs.oclIsKindOf(ccd::AlertObservation) and not obs.code.oclIsUndefined() and obs.code.codeSystem = '2.16.840.1.113883.3.88.12.3221.6.2')`
26. the observation/participant element **SHOULD** be present
    - `[OCL]: self.getObservations()->exists(obs : cda::Observation | obs.oclIsKindOf(ccd::AlertObservation) and obs.participant->exists( par : cda::Participant2 | not par.oclIsUndefined()))`
27. **SHALL** satisfy: the participant/@typecode attribute shall be 'CSM'
    - `[OCL]: self.getObservations()->exists(obs : cda::Observation | obs.oclIsKindOf(ccd::AlertObservation) and obs.participant->exists( par : cda::Participant2 | not par.oclIsUndefined() implies par.typeCode = vocab::ParticipationType::CSM))`
28. **SHALL** satisfy: the participant/participantRole element may be present
    - `[OCL]: self.getObservations()->exists(obs : cda::Observation | obs.oclIsKindOf(ccd::AlertObservation) and obs.participant->exists(par : cda::Participant2 | not par.oclIsUndefined() implies (par.typeCode = vocab::ParticipationType::CSM and par.participantRole->exists(prole : cda::ParticipantRole | not prole.oclIsUndefined())))`
29. **SHALL** satisfy: the participant/participantRole/@classcode attribute shall be 'MANU'
    - `[OCL]: self.getObservations()->exists(obs : cda::Observation | obs.oclIsKindOf(ccd::AlertObservation) and obs.participant->exists(par : cda::Participant2 | not par.oclIsUndefined() implies (par.typeCode = vocab::ParticipationType::CSM and par.participantRole->exists(prole : cda::ParticipantRole | not prole.oclIsUndefined() and prole.classCode=vocab::RoleClassRoot::MANU))))`
30. **SHALL** satisfy: The participant/participantRole/PlayingEntity element may be present
    - `[OCL]: self.getObservations()->exists(obs : cda::Observation | obs.oclIsKindOf(ccd::AlertObservation) and obs.participant->exists(par : cda::Participant2 | not par.oclIsUndefined() implies (par.typeCode =vocab::ParticipationType::CSM and par.participantRole->exists(prole : cda::ParticipantRole | not prole.oclIsUndefined() and prole.classCode=vocab::RoleClassRoot::MANU and prole.playingEntity->exists(playe : cda::PlayingEntity | not playe.oclIsUndefined()))))))`
31. **SHALL** satisfy: the participant/participantRole/playingEntity/@classcode attribute shall be 'MMAT'
    - `[OCL]: self.getObservations()->exists(obs : cda::Observation | obs.oclIsKindOf(ccd::AlertObservation) and obs.participant->exists(par : cda::Participant2 | not par.oclIsUndefined() implies (par.typeCode =vocab::ParticipationType::CSM and par.participantRole->exists(prole : cda::ParticipantRole | not prole.oclIsUndefined() and prole.classCode=vocab::RoleClassRoot::MANU and prole.playingEntity->exists(playe : cda::PlayingEntity | not playe.oclIsUndefined() and playe.classCode =vocab::EntityClassRoot::MMAT)))))`
32. **SHALL** satisfy: the participant/participantRole/playingEntity/name element is present
    - This is the name or other description of the product or agent that causes the intolerance
    - `[OCL]: self.getObservations()->exists(obs : cda::Observation | obs.oclIsKindOf(ccd::AlertObservation) and obs.participant->exists( par : cda::Participant2 | not par.oclIsUndefined() implies (par.typeCode =`

```
 vocab::ParticipationType::CSM and par.participantRole->exists(prole :
 cda::ParticipantRole | not prole.oclIsUndefined() and
prole.classCode=vocab::RoleClassRoot::MANU and prole.playingEntity-
>exists( playe : cda::PlayingEntity | not playe.oclIsUndefined() and
 playe.classCode = vocab::EntityClassRoot::MMAT and playe.name->size() =
 1)))))
```

33. SHOULD satisfy: participant/participantRole/playingEntity/code element is present

- This value is a code describing the product
-
```
[OCL]: self.getObservations()->exists(obs : cda::Observation |
 obs.oclIsKindOf(ccd::AlertObservation) and
obs.participant->exists( par : cda::Participant2 |
 not par.oclIsUndefined() implies (par.typeCode =
 vocab::ParticipationType::CSM and par.participantRole->exists(prole :
 cda::ParticipantRole | not prole.oclIsUndefined() and
prole.classCode=vocab::RoleClassRoot::MANU and prole.playingEntity-
>exists( playe : cda::PlayingEntity | not playe.oclIsUndefined() and
 playe.classCode = vocab::EntityClassRoot::MMAT and playe.code->size() =
 1)))))
```

34. For participant/participantRole/playingEntity/code element, Food and substance allergies **SHALL** be coded as Ingredient Name Value Set, 2.16.840.1.113883.3.88.12.80.20, Dynamic (C154-[DE-6.04-1])

-
```
[OCL]: self.getObservations()->exists(obs : cda::Observation |
 obs.oclIsKindOf(ccd::AlertObservation) and
obs.participant->exists( par : cda::Participant2 |
 not par.oclIsUndefined() implies (par.typeCode =
 vocab::ParticipationType::CSM and par.participantRole->exists(prole :
 cda::ParticipantRole | not prole.oclIsUndefined() and
prole.classCode= vocab::RoleClassRoot::MANU and prole.playingEntity-
>exists( playe : cda::PlayingEntity | not playe.oclIsUndefined() and
 playe.classCode = vocab::EntityClassRoot::MMAT and playe.code->size()
 = 1 and (playe.code.codeSystem = '2.16.840.1.113883.3.88.12.80.20'
 or playe.code.codeSystem = '2.16.840.1.113883.3.88.12.80.17' or
 playe.code.codeSystem = '2.16.840.1.113883.3.88.12.80.16'))))))
```

35. For participant/participantRole/playingEntity/code element, Allergies to a class of medication **SHALL** be coded as Medication Drug Class Value Set, 2.16.840.1.113883.3.88.12.80.17, version: 20081218, Dynamic (C154-[DE-6.04-2])

-
```
[OCL]: self.getObservations()->exists(obs : cda::Observation |
 obs.oclIsKindOf(ccd::AlertObservation) and
obs.participant->exists( par : cda::Participant2 |
 not par.oclIsUndefined() implies (par.typeCode =
 vocab::ParticipationType::CSM and par.participantRole->exists(prole :
 cda::ParticipantRole | not prole.oclIsUndefined() and
prole.classCode= vocab::RoleClassRoot::MANU and prole.playingEntity-
>exists( playe : cda::PlayingEntity | not playe.oclIsUndefined() and
 playe.classCode = vocab::EntityClassRoot::MMAT and playe.code->size()
 = 1 and (playe.code.codeSystem = '2.16.840.1.113883.3.88.12.80.20'
 or playe.code.codeSystem = '2.16.840.1.113883.3.88.12.80.17' or
 playe.code.codeSystem = '2.16.840.1.113883.3.88.12.80.16'))))))
```

36. For participant/participantRole/playingEntity/code element, Allergies to a specific medication **SHALL** be coded with Medication Brand Name Value Set, 2.16.840.1.113883.3.88.12.80.16, version: 20081218, Dynamic (C154-[DE-6.04-3])

-
```
[OCL]: self.getObservations()->exists(obs : cda::Observation |
 obs.oclIsKindOf(ccd::AlertObservation) and
obs.participant->exists( par : cda::Participant2 |
 not par.oclIsUndefined() implies (par.typeCode =
 vocab::ParticipationType::CSM and par.participantRole->exists(prole :
 cda::ParticipantRole | not prole.oclIsUndefined() and
prole.classCode= vocab::RoleClassRoot::MANU and prole.playingEntity-
>exists( playe : cda::PlayingEntity | not playe.oclIsUndefined() and
 playe.classCode = vocab::EntityClassRoot::MMAT and playe.code->size()
```

```
 = 1 and (playe.code.codeSystem = '2.16.840.1.113883.3.88.12.80.20'
 or playe.code.codeSystem = '2.16.840.1.113883.3.88.12.80.17' or
 playe.code.codeSystem = '2.16.840.1.113883.3.88.12.80.16'))))))
```

37. **SHOULD** satisfy: the text element is present in the Reaction Observation entry
    - This is the reaction that may be caused by the product or agent
    - ```
      [OCL]: self.getObservations()->exists(obs : cda::Observation |
       obs.oclIsKindOf(ccd::AlertObservation) and obs.getObservations()-
      >exists(o : cda::Observation | o.oclIsKindOf(ccd::ReactionObservation) and
       not o.text.oclIsUndefined()))
      ```
38. **SHOULD** satisfy: the code element is present in the Reaction Observation entry
    - This value is a code describing the reaction
    - ```
      [OCL]: self.getObservations()->exists(obs : cda::Observation |
       obs.oclIsKindOf(ccd::AlertObservation) and obs.getObservations()-
      >exists(o : cda::Observation | o.oclIsKindOf(ccd::ReactionObservation) and
       not o.code.oclIsUndefined()))
      ```
39. **SHALL** satisfy: the code element is coded as Problem Value Set, 2.16.840.1.113883.3.88.12.3221.7.4, version: 20100125, Dynamic (C154-[DE-6.06-1])
    - ```
      [OCL]: self.getObservations()->exists(obs : cda::Observation |
       obs.oclIsKindOf(ccd::AlertObservation) and obs.getObservations()-
      >exists(o : cda::Observation | o.oclIsKindOf(ccd::ReactionObservation)
       and not o.code.oclIsUndefined() and o.code.codeSystem =
       '2.16.840.1.113883.3.88.12.3221.7.4'))
      ```
40. **SHOULD** satisfy: The text element is present in the Severity Observation template
    - This is a description of the level of severity of the allergy or intolerance
    - ```
      [OCL]: self.getObservations()->exists(obs : cda::Observation |
       obs.oclIsKindOf(ccd::AlertObservation) and obs.getObservations()-
      >exists(o : cda::Observation | o.oclIsKindOf(ccd::SeverityObservation) and
       not o.text.oclIsUndefined()))
      ```
41. **SHOULD** satisfy: the code element is present in the Severity Observation entry
    - This value is a code describing the level severity of the allergy or intolerance
    - ```
      [OCL]: self.getObservations()->exists(obs : cda::Observation |
       obs.oclIsKindOf(ccd::AlertObservation) and obs.getObservations()-
      >exists(o : cda::Observation | o.oclIsKindOf(ccd::SeverityObservation) and
       not o.code.oclIsUndefined()))
      ```
42. **SHALL** satisfy: the code element is coded as Problem Severity Value Set, 2.16.840.1.113883.3.88.12.3221.6.8, version: 20081218, Static (C154-[DE-6.08-1])
    - ```
      [OCL]: self.getObservations()->exists(obs : cda::Observation |
       obs.oclIsKindOf(ccd::AlertObservation) and obs.getObservations()-
      >exists(o : cda::Observation | o.oclIsKindOf(ccd::SeverityObservation)
       and not o.code.oclIsUndefined() and o.code.codeSystem =
       '2.16.840.1.113883.3.88.12.3221.6.8'))
      ```

Allergy Drug Sensitivity example

Comment

[Act: templateId `2.16.840.1.113883.3.88.11.83.11`]

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

1. **SHALL** conform to *CCD Comment* template (templateId: `2.16.840.1.113883.10.20.1.40`)
2. **SHALL** conform to *IHE Comment* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.2`)
3. **SHALL** contain exactly one [1..1] **`@classCode`**`="ACT"` *Act* (CodeSystem: `2.16.840.1.113883.5.6` `HL7ActClass`) (CONF-504)

4. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF-505)
5. **SHALL** contain exactly one [1..1] **`code/@code`**`="48767-8"` *Annotation comment* (CodeSystem:) (CONF-506, CONF-507)
6. **SHALL** contain exactly one [1..1] **`text`**
7. **SHALL** contain exactly one [1..1] **`statusCode/@code`**`="completed"` (CodeSystem:) (CONF-6.3.4.6.8)
8. **MAY** contain zero or one [0..1] **`author`**, such that
9. **SHALL** contain exactly one [1..1] **`author`** (C83-[DE-10-CDA-4]), such that
   - The author of a comment is recorded as specified for authors in the Information Source module.
10. **SHALL** satisfy: A related statement is made about another section or entry. In CDA the former shall be recorded inside an <entryRelationship> element occurring at the end of the entry. The containing entry is the subject (typeCode='SUBJ') of this comment, which is the inverse of the normal containment structure, thus inversionInd='true'. (CONF-6.3.4.6.3)
11. **SHALL** satisfy: The 'text' element contains a 'reference' element pointing to the narrative text section of the CDA, rather than duplicate text to avoid ambiguity. (CONF-6.3.4.6.7)
    - `[OCL]: not self.text.reference.oclIsUndefined()`
12. **SHALL** satisfy: The time of the comment creation is recorded in the 'time' element when the 'author' element is present. (CONF-6.3.4.6.10)
    - `[OCL]: not self.author->isEmpty() implies not self.effectiveTime.oclIsUndefined()`
13. **SHALL** satisfy: The identifier of the author, and their address and telephone number must be present inside the 'id', 'addr' and 'telecom' elements when the 'author' element is present. (CONF-6.3.4.6.11)
    - `[OCL]: not self.author->isEmpty() implies ( self.author.assignedAuthor.id ->size() > 0 and self.author.assignedAuthor.addr ->size() > 0 and self.author.assignedAuthor.telecom ->size() > 0)`
14. **SHALL** satisfy: The author's and/or the organization's name must be present when the 'author' element is present. (CONF-6.3.4.6.12)
    - `[OCL]: not self.author->isEmpty() implies ( self.author->exists( a : cda::Author | ( (not a.assignedAuthor.assignedPerson.oclIsUndefined()) and not a.assignedAuthor.assignedPerson.name->isEmpty()) or (not a.assignedAuthor.representedOrganization.name->isEmpty()) ) )`
15. 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 `2.16.840.1.113883.3.88.11.83.7`]

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

1. **SHALL** conform to *CCD Problem Act* template (templateId: `2.16.840.1.113883.10.20.1.27`)
2. **SHALL** conform to *IHE Concern Entry* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.5.1`)
3. **SHALL** conform to *IHE Problem Concern Entry* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.5.2`)
4. **SHALL** contain exactly one [1..1] **`@classCode`**`="ACT"` *Act* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF-146)

5. **SHALL** contain exactly one [1..1] **`@moodCode="EVN"`** *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF-147)
6. **SHALL** contain at least one [1..*] **`id`** (CONF-148)
7. **SHALL** contain exactly one [1..1] **`code`**`/@nullFlavor` = "NA" *NA (not applicable)* (CONF-149)
8. **SHALL** contain exactly one [1..1] **`statusCode`**, which **SHALL** be selected from ValueSet *`ConcernEntryStatus`* **STATIC**
   - The statusCode associated with any concern must be one of the following values:

     active: A concern that is still being tracked. **suspended**: A concern that is active, but which may be set aside. For example, this value might be used to suspend concern about a patient problem after some period of remission, but before assumption that the concern has been resolved. **aborted**: A concern that is no longer actively being tracked, but for reasons other than because the problem was resolved. This value might be used to mark a concern as being aborted after a patient leaves care against medical advice. **completed**: The problem, allergy or medical state has been resolved and the concern no longer needs to be tracked except for historical purposes.
9. **SHALL** contain exactly one [1..1] **`effectiveTime`**
   - The effectiveTime element records the starting and ending times during which the concern was active.
10. **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`)
11. **SHALL** contain at least one [1..*] **`entryRelationship`**, such that
    a. Contains **`@typeCode="SUBJ"`** *SUBJ (has subject)*
    b. Contains exactly one [1..1] *Condition Entry* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.5`)
12. **SHALL** contain one or more entryRelationship (CONF-151)
    - `[OCL]: not self.entryRelationship->isEmpty()`
13. A problem act **MAY** reference a problem observation, alert observation (see section Alerts) or other clinical statement that is the subject of concern, by setting the value for "Act / entryRelationship / @typeCode" to be "SUBJ" 2.16.840.1.113883.5.1002 ActRelationshipType STATIC. (CONF-152)
14. The target of a problem act with Act / entryRelationship / @typeCode="SUBJ" **SHOULD** be a problem observation (in the Problem section) or alert observation (in the Alert section), but **MAY** be some other clinical statement. (CONF-153)
    - ```
      [OCL]:
       self.getEntryRelationshipTargets(vocab::x_ActRelationshipEntryRelationship::SUBJ,
       cda::ClinicalStatement)->forAll(target : cda::ClinicalStatement | not
       target.oclIsUndefined() and
        (target.oclIsKindOf(ccd::ProblemObservation) or
       target.oclIsKindOf(ccd::AlertObservation)))
      ```
15. In Problem Section, a Problem Act **SHOULD** contain one or more Problem Observations. (CONF-140)
    - ```
      [OCL]: self.getSection().oclIsKindOf(ccd::ProblemSection) implies
       self.getObservations()
         ->exists(obs : cda::Observation |
       obs.oclIsKindOf(ccd::ProblemObservation))
      ```
16. In Alert Section, a ProblemAct **SHOULD** contain one or more Alert Observations. (CONF-256)
    - ```
      [OCL]: self.getSection().oclIsKindOf(ccd::AlertsSection) implies
       self.getObservations()
         ->exists(obs : cda::Observation |
       obs.oclIsKindOf(ccd::AlertObservation))
      ```
17. **MAY** contain exactly one Patient Awareness (CONF-179)
    - ```
      [OCL]: self.participant->one(partic : cda::Participant2 |
       partic.oclIsKindOf(ccd::PatientAwareness))
      ```
18. The effectiveTime 'low' element **SHALL** be present. The 'high' element **SHALL** be present for concerns in the completed or aborted state, and **SHALL NOT** be present otherwise.
    - `[OCL]: not self.effectiveTime.low.oclIsUndefined()`

```
  and ((self.statusCode.code = 'completed' or self.statusCode.code =
'aborted') implies not self.effectiveTime.high.oclIsUndefined())
  and ((self.statusCode.code <> 'completed' and self.statusCode.code <>
'aborted') implies self.effectiveTime.high.oclIsUndefined())
```

19. This entry **SHALL** contain one or more problem or allergy entries that conform to the specification in section Problem Entry or Allergies and Intolerances.
    - Each concern is about one or more related problems or allergies. This is how a series of related observations can be grouped as a single concern.
    - `[OCL]: self.entryRelationship.observation.templateId->exists(id : datatypes::II | id.root = '1.3.6.1.4.1.19376.1.5.3.1.4.5') or self.entryRelationship.observation.templateId->exists(id : datatypes::II | id.root = '1.3.6.1.4.1.19376.1.5.3.1.4.6')`
20. This **SHALL** be represented using entryRelationship with typeCode = 'SUBJ'
    - `[OCL]: self.entryRelationship->select(er|er.typeCode <> vocab::x_ActRelationshipEntryRelationship::SUBJ)->isEmpty()`
21. Each concern **MAY** have 0 or more related references. This **MAY** be any valid CDA clinical statement, and **SHOULD** be an IHE entry template.
    - These may be used to represent related statements such related visits.
22. Related References **SHALL** be represented using entryRelationship with typeCode = 'REFR'.
23. 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])
    - `[OCL]: not self.performer->isEmpty()`
24. 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])
    - `[OCL]: self.performer->exists(p : cda::Performer2 | p.assignedEntity.id->size() > 0)`
25. 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])
    - `[OCL]: self.performer->exists(p : cda::Performer2 | p.time.oclIsUndefined())`

Condition example

Condition Entry

[Observation: templateId `1.3.6.1.4.1.19376.1.5.3.1.4.5`]

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

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

1. **SHALL** conform to *CCD Problem Observation* template (templateId: `2.16.840.1.113883.10.20.1.28`)

2. **SHALL** conform to *IHE Problem Entry* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.5`)
3. Contains exactly one [1..1] **`@classCode="OBS"`** *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
4. **SHALL** contain exactly one [1..1] **`@moodCode="EVN"`** *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF-155)
5. **SHALL** contain at least one [1..*] **`id`**
   - The specific observation being recorded must have an identifier (<id>) that shall be provided for tracking purposes. If the source EMR does not or cannot supply an intrinsic identifier, then a GUID shall be provided as the root, with no extension (e.g., <id root='CE1215CD-69EC-4C7B-805F-569233C5E159'/>). At least one identifier must be present, more than one may appear.
6. **SHOULD** contain exactly one [1..1] **`code`**, which **SHOULD** be selected from ValueSet **STATIC**
7. **SHALL** contain exactly one [1..1] **`text`**
   - The <text> element is required and points to the text describing the problem being recorded; including any dates, comments, et cetera. The <reference> contains a URI in value attribute. This URI points to the free text description of the problem in the document that is being described.
8. **SHALL** contain exactly one [1..1] **`statusCode/@code="completed"`** (CodeSystem:) (CONF-156, CONF-157)
9. **SHOULD** contain exactly one [1..1] **`effectiveTime`**
   - The <effectiveTime> of this <observation> is the time interval over which the <observation> is known to be true. The <low> and <high> values should be no more precise than known, but as precise as possible. While CDA allows for multiple mechanisms to record this time interval (e.g., by low and high values, low and width, high and width, or center point and width), we are constraining Medical summaries to use only the low/high form. The <low> value is the earliest point for which the condition is known to have existed. The <high> value, when present, indicates the time at which the observation was no longer known to be true. Thus, the implication is made that if the <high> value is specified, that the observation was no longer seen after this time, and it thus represents the date of resolution of the problem. Similarly, the <low> value may seem to represent onset of the problem. Neither of these statements is necessarily precise, as the <low> and <high> values may represent only an approximation of the true onset and resolution (respectively) times. For example, it may be the case that onset occurred prior to the <low> value, but no observation may have been possible before that time to discern whether the condition existed prior to that time. The <low> value should normally be present. There are exceptions, such as for the case where the patient may be able to report that they had chicken pox, but are unsure when. In this case, the <effectiveTime> element shall have a <low> element with a nullFlavor attribute set to 'UNK'. The <high> value need not be present when the observation is about a state of the patient that is unlikely to change (e.g., the diagnosis of an incurable disease).
10. **SHALL** contain exactly one [1..1] **`value`**, which **SHALL** be selected from ValueSet **STATIC**
    - The <value> is the condition that was found. This element is required. While the value may be a coded or an un-coded string, the type is always a coded value (xsi:type='CD'). If coded, the code and codeSystem attributes shall be present. The codeSystem should reference a controlled vocabulary describing problems, complaints, symptoms, findings, diagnoses, or functional limitations, e.g., ICD-9, SNOMED-CT or MEDCIN, or others.

      It is recommended that the codeSystemName associated with the codeSystem, and the displayName for the code also be provided for diagnostic and human readability purposes, but this is not required by this profile.

      If uncoded, all attributes other than xsi:type='CD' must be absent.

      The <value> contains a <reference> to the <originalText> in order to link the coded value to the problem narrative text (minus 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.
11. **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`)
12. **MAY** contain zero or one [0..1] **`entryRelationship`**, such that
    a. Contains exactly one [1..1] *Severity* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.1`)
13. **MAY** contain zero or one [0..1] **`entryRelationship`**, such that

   a. Contains **@typeCode="**`REFR`**"** *REFR (refers to)*
   b. Contains exactly one [1..1] *Problem Status Observation* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.1.1`)
14. **MAY** contain zero or one [0..1] **entryRelationship**, such that
   a. Contains **@typeCode="**`REFR`**"** *REFR (refers to)*
   b. Contains exactly one [1..1] *Health Status Observation* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.1.2`)
15. **MAY** contain zero or more [0..*] **entryRelationship**, such that
   a. Contains **@typeCode="**`SUBJ`**"** *SUBJ (has subject)*
   b. Contains exactly one [1..1] *Comment* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.2`)
16. **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] *CCD Age Observation* (templateId: `2.16.840.1.113883.10.20.1.38`)
17. **MAY** contain zero or one [0..1] **entryRelationship**, such that
   a. Contains **@typeCode="**`CAUS`**"** *CAUS (is etiology for)*
   b. Contains exactly one [1..1] *CCD Cause Of Death Observation* (templateId: `2.16.840.1.113883.10.20.1.42`)
18. **MAY** contain zero or one [0..1] **entryRelationship**, such that
   a. Contains **@typeCode="**`REFR`**"** *REFR (refers to)*
   b. Contains exactly one [1..1] *IHE Problem Status Observation* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.1.1`)
19. **SHALL** contain one or more sources of information. (CONF-161)

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

20. **MAY** contain exactly one Patient Awareness (CONF-180)

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

21. 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.

```
[OCL]: not self.text.reference.oclIsUndefined()
```

22. If entryRelationship / Comment is present, then entryRelationship **SHALL** include inversionInd = 'true'.

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

23. The onset date **SHALL** be recorded in the <low> element of the <effectiveTime> element when known. (C83-[DE-7.01-1])

```
[OCL]: not self.effectiveTime.low.oclIsUndefined()
```

24. The resolution data **SHALL** be recorded in the <high> element of the <effectiveTime> element when known. (C83-[DE-7.01-2])

```
[OCL]: not self.effectiveTime.high.oclIsUndefined()
```

25. 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])
    - `[OCL]: not self.effectiveTime.high.oclIsUndefined()`

Condition Entry example

Encounter

[Encounter: templateId `2.16.840.1.113883.3.88.11.83.16`]

The encounter entry contains data describing the interactions between the patient and clinicians. Interaction includes both in-person and non-in-person encounters such as telephone and e-mail communication.

1. **SHALL** conform to *IHE Encounter Entry* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.14`)
2. **SHALL** contain exactly one [1..1] **`@classCode`**`="ENC"` (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
3. Contains exactly one [1..1] **`@moodCode`**, where its data type is x_DocumentEncounterMood
4. **SHALL** contain at least one [1..*] **`id`**
5. **SHOULD** contain exactly one [1..1] **`code`**, which **SHOULD** be selected from ValueSet **STATIC** (C83-[DE-16.02-1])
6. **SHALL** contain exactly one [1..1] **`text`**
7. **MAY** contain zero or one [0..1] **`priorityCode`**, which **MAY** be selected from ValueSet **STATIC** (C154-[DE-16.07-1])
8. participant/@typeCode ='ORG'/code **SHALL** be coded with ValueSet 2.16.840.1.113883.3.88.12.80.33, Admission Source Value Set, STATIC
9. ClinicalDocument/componentOf/encompassingEncounter/code/@code **SHALL** be coded with ValueSet 2.16.840.1.113883.3.88.12.80.66, Patient Class Value Set, 20090630, STATIC
10. The state part of ClinicalDocument/componentOf/encompassingEncounter/location/addr **SHALL** be coded with ValueSet 2.16.840.1.113883.3.88.12.80.1, State Value Set, 20081218, Dynamic
11. The country part of ClinicalDocument/componentOf/encompassingEncounter/location/addr **SHALL** be coded with ValueSet 2.16.840.1.113883.3.88.12.80.63, Country Value Set, 20081218, Dynamic
12. The postal code part of ClinicalDocument/componentOf/encompassingEncounter/location/addr **SHALL** be coded with ValueSet 2.16.840.1.113883.3.88.12.80.2, Postal Code Value Set, 20081218, Dynamic
13. **MAY** satisfy: The order to admit time reflects the time of participation of the provider referring the patient to an inpatient setting. The encounter type should reflect that this is an inpatient encounter.

Encounter example

Family History

[Organizer: templateId `2.16.840.1.113883.3.88.11.83.18`]

1. **SHALL** conform to *CCD Family History Organizer* template (templateId: `2.16.840.1.113883.10.20.1.23`)
2. **SHALL** conform to *IHE Family History Organizer* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.15`)
3. **SHALL** contain exactly one [1..1] **`@classCode`**`="CLUSTER"` (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
4. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)
5. **SHALL** contain exactly one [1..1] **`code`** (CodeSystem:)
6. **SHALL** contain exactly one [1..1] **`statusCode/@code`**`="completed"` (CodeSystem:)
7. **SHALL** contain at least one [1..*] **`component`**, such that

   a. Contains exactly one [1..1] *Family History Observation* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.13.3`)
8. **SHOULD** contain zero or more [0..*] **`component`**, such that
   a. Contains exactly one [1..1] *IHE Problem Status Observation* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.1.1`)
9. A family history organizer **SHALL** contain one or more Organizer / component.
10. The target of a family history organizer Organizer / component relationship **SHOULD** be a family history observation, but **MAY** be some other clinical statement
11. A family history organizer **SHALL** contain exactly one subject participant, representing the family member who is the subject of the family history observations
12. A subject participant **SHALL** contain exactly one RelatedSubject, representing the relationship of the subject to the patient
13. The value for RelatedSubject / @classCode **SHALL** be "PRS" "Personal relationship" 2.16.840.1.113883.5.110 RoleClass STATIC
14. RelatedSubject **SHALL** contain exactly one RelatedSubject / code
15. The value for "RelatedSubject / code" **SHOULD** be selected from ValueSet 2.16.840.1.113883.1.11.19579 FamilyHistoryRelatedSubjectCode DYNAMIC or 2.16.840.1.113883.1.11.20.21 FamilyHistoryPersonCode DYNAMIC
16. Representation of a pedigree graph **SHALL** be done using RelatedSubject / code values (e.g. "great grandfather") to designate a hierarchical family tree.
17. RelatedSubject **SHOULD** contain exactly one RelatedSubject / subject
18. RelatedSubject / subject **SHOULD** contain exactly one RelatedSubject / subject / administrativeGenderCode.
19. **SHOULD** satisfy: subject/relatedSubject/subject contains exactly one birthTime (CONF-219)
    - `[OCL]: not self.subject.relatedSubject.subject.birthTime.oclIsUndefined()`
20. **MAY** satisfy: subject/relatedSubject/subject contains exactly one sdtc:deceasedInd
21. **MAY** satisfy: subject/relatedSubject/subject contains exactly one sdtc:deceasedTime
22. **SHOULD** satisfy: The age of a relative at the time of observation is inferred by comparing subject/relatedSubject/subject/birthTime with Observation/effectiveTime
23. **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.
24. One RelatedSubject/subject/sdtc:id element **SHOULD** be present. It is used to identify the patient relation to create a pedigree graph.
25. The participant element **MAY** be present to record the relationship of the subject to other family members to create a pedigree graph.
26. **SHALL** satisfy: Participant shall contain a participantRole/@classCode = "PRS" element showing the relationship of the subject to other family members
27. **SHALL** satisfy: The Participant/ParticipantRole/code element shall be present, and gives the relationship of the participant to the subject. The code attribute shall be present, and shall contain a value from the HL7 FamilyMember vocabulary
28. **SHALL** satisfy: The Participant/ParticipantRole/PlayingEntity element shall be present with @classCode = 'PSN'
29. **SHALL** satisfy: The Participant/ParticipantRole/PlayingEntity/sdtc:id shall be present. It must have the same root and extension attributes of the subject element of a separate family history organizer.
30. A pedigree image **MAY** be included in an observationMedia element in an entry under the Family History section
31. value/@mediaType element of the observationMedia element **SHALL** be application/pdf, image/jpeg or image/png
32. value/@representation element of the observationMedia element **SHALL** be B64, and the data for the image **SHALL** be included within the value element
33. RelatedSubject/Code (Family Member Relationship to Patient) **SHALL** be coded as 2.16.840.1.113883.1.11.19579, Family Member Value Set, STATIC, V3NE08
34. One RelatedSubject/subject/sdtc:id element **SHALL** be present.
    - Each family member in a family history must be identified to allow for reconciliation of updated family histories when exchanged between providers

35. RelatedSubject/subject/name **SHOULD** be present.
    - The family member name need not be the actual name of the family member. It may be a string (such as aunt1 or aunt2) to help the patient and providers distinguish between different family members with the same relationship to the patient
36. RelatedSubject/subject/administrationGenderCode **SHALL** be code as 2.16.840.1.113883.1.11.1, Adminstrative Gender Value Set, STATIC, 20081218
37. The race of the family member, when recorded, **SHALL** appear in an RelatedSubject/subject/sdtc:raceCode element.
38. raceCode **SHALL** be coded as 2.16.840.1.113883.1.11.14914, Race Value Set, Dynamic
39. The ethnicity of the family member, when recorded, **SHALL** appear in an RelatedSubject/subject/ sdtc:ethnicGroupCode element
40. Ethnicity **SHALL** be coded as 2.16.840.1.113883.1.11.15836, Ethnicity Value Set, Dynamic
41. Family History Condition data elements **SHALL** declare conformance to the IHE Family History Observation entry by including a <templateID> element with the root attribute set to the value 1.3.6.1.4.1.19376.1.5.3.1.4.13.3
42. **SHOULD** satisfy: The age of onset of disease or age at death of a family member should be computable from the family member date of birth and the effective time of the observation of the disease or the death. When that data are not available, the age of the patient at the time of the observation shall be recorded within a condition or test result observation using the CCD Age Observation
43. **SHOULD** satisfy: When a condition is one of the causes of death for the patient, that fact is related using the CCD Cause of Death Observation
44. **MAY** satisfy: The biological sex may be recorded as a IHE Family History Observation to identify the biological sex of the subject where it differs from the administrative gender
45. **MAY** satisfy: Multiple birth status is may be recorded as a IHE Family History observation on the subject when it is relevant for a family member (18.17 Family Member Multiple Birth Status) or the patient (1.13 Multiple Birth Indicator).
46. **MAY** satisfy: Multiple birth order is may be recorded as a IHE Family History observation on the subject when it is relevant for a family member (18.26 - Family Member Multiple Birth Order) or the patient (1.14 - Birth Order). Family Member Age
47. **MAY** satisfy: The age may be recorded as a CCD Age Observation on the subject when it is relevant for a family member (18.23 - Family Member Age) or the patient (1.14 - Age)
48. **MAY** satisfy: Genetic test results may be recorded as Family History observations on the subject
49. Components of a Genetic Laboratory Test **SHALL** be coded as specified in HITSP/C80 Section 2.2.3.11 Genetic Testing

Family History example

Immunization

[SubstanceAdministration: templateId `2.16.840.1.113883.3.88.11.83.13`]

1. **SHALL** conform to *CCD Medication Activity* template (templateId: `2.16.840.1.113883.10.20.1.24`)
2. **SHALL** conform to *IHE Immunization* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.12`)
3. Contains exactly one [1..1] **`@classCode`**`="SBADM"` (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`), where its data type is ActClass
4. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (6.3.4.17.2)
5. **SHALL** contain at least one [1..*] **`id`** (CONF-306)
6. **SHALL** contain zero or one [0..1] **`code`**, which **SHALL** be selected from ValueSet **STATIC**
7. **SHALL** contain exactly one [1..1] **`statusCode`** (6.3.4.17.7)
8. **SHALL** contain exactly one [1..1] **`effectiveTime`** (CONF-308)
9. **SHOULD** contain exactly one [1..1] **`routeCode`** (CodeSystem: `2.16.840.1.113883.5.112 HL7 RouteOfAdministration`) (CONF-309, CONF-310)

10. 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.
11. 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.
12. 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.
13. **MAY** contain exactly one [1..1] **`maxDoseQuantity`** (CONF-312)
    - represents a maximum dose limit
14. Contains exactly one [1..1] **`consumable`**, where its type is *Consumable*
15. **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`)
16. **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`)
17. **MAY** contain at least one [1..*] **`entryRelationship`** (CONF-330, CONF-333), such that
    a. Contains **`@typeCode="SUBJ"`** *SUBJ (has subject)*
    b. Contains exactly one [1..1] *Patient Instruction* (templateId: `2.16.840.1.113883.10.20.1.49`)
18. **MAY** contain at least one [1..*] **`performer`** (CONF-313), such that
    - Indicates the person administering a substance.
19. **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: `2.16.840.1.113883.10.20.1.54`)
20. **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`)
21. **SHALL** satisfy: Value for moodCode is "EVN" or "INT" 2.16.840.1.113883.5.1001 ActMood STATIC (CONF-305)
    - `[OCL]: self.moodCode=vocab::x_DocumentSubstanceMood::EVN or self.moodCode=vocab::x_DocumentSubstanceMood::INT`
22. **SHOULD** satisfy: Contains exactly one doseQuantity or rateQuantity. (CONF-311)
    - `[OCL]: not self.doseQuantity.oclIsUndefined() or not self.rateQuantity.oclIsUndefined()`
23. **MAY** satisfy: Has one or more associated consents, represented in the CCD Header as ClinicalDocument / authorization / consent. (CONF-314)
    - `[OCL]: self.getClinicalDocument().authorization->exists(auth : cda::Authorization | not auth.oclIsUndefined() and not auth.consent.oclIsUndefined())`
24. **SHALL** satisfy: Contains one or more sources of information. (CONF-315)
    - `[OCL]: not self.informant->isEmpty()`

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

25. **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.
    - `[OCL]: self.precondition->exists(precondition : cda::Precondition | not precondition.criterion.oclIsUndefined())`
26. **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.
    - `[OCL]: self.entryRelationship->exists(entryRel : cda::EntryRelationship | entryRel.typeCode = vocab::x_ActRelationshipEntryRelationship::RSON)`
27. **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)
    - ```
      [OCL]:
       self.getEntryRelationshipTargets(vocab::x_ActRelationshipEntryRelationship::RSON,
       cda::ClinicalStatement)->forAll(target :

      cda::ClinicalStatement | not target.oclIsUndefined() and
        (target.oclIsKindOf(ccd::ProblemAct) or
       target.oclIsKindOf(ccd::ProblemObservation)))
      ```
28. **SHALL** satisfy: Contains exactly one consumable, the target of which is a Product template. (CONF-354)
    - `[OCL]: self.consumable.manufacturedProduct.oclIsKindOf(ccd::Product)`
29. **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.
30. **SHALL** satisfy: CPT-4 codes may be used for immunization procedures
31. **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
    - `[OCL]: self.negationInd=true implies not self.entryRelationship.act->select( act | act.oclIsKindOf(ccd::Comment) )->isEmpty()`
32. The reason for refusal **SHALL** be coded as specified in HITSP/C80 Section 2.2.3.5.3 No Immunization Reason
    - ```
      [OCL]: self.entryRelationship->select(er |   er.typeCode
       = vocab::x_ActRelationshipEntryRelationship::RSON and
       er.act.code.codeSystem <> '2.16.840.1.113883.1.11.19717' )->isEmpty()
      ```

Immunization example

Insurance Provider

[Act: templateId `2.16.840.1.113883.3.88.11.83.5`]

1. **SHALL** conform to *CCD Coverage Activity* template (templateId: `2.16.840.1.113883.10.20.1.20`)
2. **SHALL** conform to *IHE Coverage Entry* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.17`)

3. **SHALL** contain exactly one [1..1] **`@classCode`**`="ACT"` *Act* (CodeSystem: `2.16.840.1.113883.5.6` `HL7ActClass`) (CONF-36)
4. **SHALL** contain exactly one [1..1] **`@moodCode`**`="DEF"` (CodeSystem: `2.16.840.1.113883.5.1001` `HL7ActMood`) (CONF-37)
5. **SHALL** contain at least one [1..*] **`id`** (CONF-38)
6. **SHALL** contain exactly one [1..1] **`code/@code`**`="48768-6"` *Payment sources* (CodeSystem:) (CONF-41, CONF-42)
7. **SHALL** contain exactly one [1..1] **`statusCode/@code`**`="completed"` (CodeSystem:) (CONF-39, CONF-40)
8. **SHALL** contain at least one [1..*] **`entryRelationship`** (CONF-43, CONF-45, CONF-46), such that
   a. Contains **`@typeCode="`**`COMP"` *COMP (has component)*
   b. Contains exactly one [1..1] *Policy Activity* (templateId: `2.16.840.1.113883.10.20.1.26`)
9. **SHALL** satisfy: An alert observation contains one or more sources of information. (CONF-47)
   -
```
[OCL]: not self.informant->isEmpty()
  or not self.getSection().informant->isEmpty()
  or not self.getClinicalDocument().informant->isEmpty()
  or self.reference->exists(ref : cda::Reference | ref.typeCode =
 vocab::x_ActRelationshipExternalReference::XCRPT)
  or (self.entryRelationship->exists(rel : cda::EntryRelationship |
   rel.typeCode = vocab::x_ActRelationshipEntryRelationship::REFR
   and rel.observation.code.code = '48766-0'))
```
10. **MAY** satisfy: entryRelationship contains sequenceNumber, which serves to prioritize the payment sources. (CONF-44)
    -
```
[OCL]: self.entryRelationship->exists(rel : cda::EntryRelationship | not
 rel.sequenceNumber.oclIsUndefined())
```

Insurance Provider example

Medication

[SubstanceAdministration: templateId `2.16.840.1.113883.3.88.11.83.8`]

1. **SHALL** conform to *CCD Medication Activity* template (templateId: `2.16.840.1.113883.10.20.1.24`)
2. **SHALL** conform to *IHE Medication* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.7`)
3. Contains exactly one [1..1] **`@classCode`**`="SBADM"` (CodeSystem: `2.16.840.1.113883.5.6` `HL7ActClass`), where its data type is ActClass
4. Contains exactly one [1..1] **`@moodCode`**, where its data type is x_DocumentSubstanceMood
5. **SHALL** contain at least one [1..*] **`id`** (CONF-306)
6. **MAY** contain zero or more [0..*] **`code`** (C83-[DE-8.12-CDA-1])
   - Delivery Method: A description of how the product is administered/consumed
7. **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.
8. **MAY** contain at least one [1..*] **`effectiveTime`**, where its data type is IVL_TS (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.

9. **MAY** contain at least one [1..*] **`routeCode`**, which **MAY** be selected from ValueSet **STATIC** (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).
10. **MAY** contain zero or more [0..*] **`approachSiteCode`**, which **MAY** be selected from ValueSet **STATIC** (C154-[DE-8.09-1])
    - The anatomic site where the medication is administered. Usually applicable to injected or topical products
11. **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)
12. **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.
13. **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
14. **MAY** contain exactly one [1..1] **`administrationUnitCode`**, which **MAY** be selected from ValueSet **STATIC** (C154-[DE-8.11-1])
    - The physical form of the product as presented to the patient. For example: tablet, capsule, liquid or ointment
15. Contains exactly one [1..1] **`consumable`**, where its type is *Consumable*
16. **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`)
17. **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`)
18. **MAY** contain at least one [1..*] **`performer`** (CONF-313), such that
    - Indicates the person administering a substance.
19. **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: `2.16.840.1.113883.10.20.1.54`)
20. **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`)
21. 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`)
    - Entry may indicate one or more reasons for the use of the medication. The extension and root of each observation present must match the identifier of a concern entry contained elsewhere within the CDA document. A consumer of the Medical Summary is encouraged, but not required to maintain these links on import.
22. 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`)

   - At most one instruction may be provided for each <substanceAdministration> entry. The instructions shall contain any special case dosing instructions (e.g., split, tapered, or conditional dosing), and may contain other information (take with food, et cetera).

23. 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`)

24. 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`)

25. Contains zero or one [0..1] **`entryRelationship`**, such that

   a. Contains exactly one [1..1] *CCD Reaction Observation* (templateId: `2.16.840.1.113883.10.20.1.54`)

   - Any noted intended or unintended effects of the product. For example: full body rash, nausea, rash resolved

26. **SHALL** satisfy: Value for moodCode is "EVN" or "INT" 2.16.840.1.113883.5.1001 ActMood STATIC (CONF-305)

   - ```
     [OCL]: self.moodCode=vocab::x_DocumentSubstanceMood::EVN or
      self.moodCode=vocab::x_DocumentSubstanceMood::INT
     ```

27. **SHOULD** satisfy: Contains exactly one doseQuantity or rateQuantity. (CONF-311)

   - ```
     [OCL]: not self.doseQuantity.oclIsUndefined() or not
      self.rateQuantity.oclIsUndefined()
     ```

28. **MAY** satisfy: Has one or more associated consents, represented in the CCD Header as ClinicalDocument / authorization / consent. (CONF-314)

   - ```
     [OCL]: self.getClinicalDocument().authorization->exists(auth :
      cda::Authorization |
        not auth.oclIsUndefined() and not auth.consent.oclIsUndefined())
     ```

29. **SHALL** satisfy: Contains one or more sources of information. (CONF-315)

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

30. **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.

   - ```
     [OCL]: self.precondition->exists(precondition : cda::Precondition | not
      precondition.criterion.oclIsUndefined())
     ```

31. **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.

   - ```
     [OCL]: self.entryRelationship->exists(entryRel : cda::EntryRelationship |
      entryRel.typeCode = vocab::x_ActRelationshipEntryRelationship::RSON)
     ```

32. **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)

    - ```
      [OCL]:
       self.getEntryRelationshipTargets(vocab::x_ActRelationshipEntryRelationship::RSON,
       cda::ClinicalStatement)->forAll(target :

      cda::ClinicalStatement | not target.oclIsUndefined() and
        (target.oclIsKindOf(ccd::ProblemAct) or
       target.oclIsKindOf(ccd::ProblemObservation)))
      ```

33. **SHALL** satisfy: Contains exactly one consumable, the target of which is a Product template. (CONF-354)

    - ```
      [OCL]: self.consumable.manufacturedProduct.oclIsKindOf(ccd::Product)
      ```

34. **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.

    - ```
      [OCL]: self.templateId->exists(id : datatypes::II | id.root =
       '1.3.6.1.4.1.19376.1.5.3.1.4.7.1') xor self.templateId->exists(id :
       datatypes::II | id.root = '1.3.6.1.4.1.19376.1.5.3.1.4.8')
       xor self.templateId->exists(id : datatypes::II | id.root =
       '1.3.6.1.4.1.19376.1.5.3.1.4.9') xor self.templateId->exists(id :
       datatypes::II | id.root = '1.3.6.1.4.1.19376.1.5.3.1.4.10')
       xor self.templateId->exists(id : datatypes::II | id.root =
       '1.3.6.1.4.1.19376.1.5.3.1.4.11')
      ```

35. **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.

    - ```
      [OCL]: self.templateId->exists(id : datatypes::II | id.root =
       '1.3.6.1.4.1.19376.1.5.3.1.4.8') xor
      self.templateId->exists(id : datatypes::II | id.root =
       '1.3.6.1.4.1.19376.1.5.3.1.4.9') xor
      self.templateId->exists(id : datatypes::II | id.root =
       '1.3.6.1.4.1.19376.1.5.3.1.4.10') xor
      self.templateId->exists(id : datatypes::II | id.root =
       '1.3.6.1.4.1.19376.1.5.3.1.4.11') implies self.entryRelationship-
      >exists(er | er.typeCode=vocab::x_ActRelationshipEntryRelationship::COMP)
      ```

36. **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)

    - ```
      [OCL]: true
      ```

37. **SHALL** satisfy: The act/@classCode='ACT' and act/@moodCode='EVN' when recording reason for medication in InternalReference Template. (6.3.4.16.22)

    - self.internalReference->exists(ir : ihe::InternalReference | ar.classCode <> 'ACT' or ar.moodCode <> 'EVN')
      ```

- OCL Issue - What is the internalReference relationship? unable to get OCL to reference
- `[OCL]: true`

38. **SHALL** satisfy: The <consumable> element shall be present, and shall contain a Product Entry template
    - `[OCL]: self.consumable.manufacturedProduct.templateId->exists(id : datatypes::II | id.root = '1.3.6.1.4.1.19376.1.5.3.1.4.7.2')`
39. **SHALL** satisfy: The entryRelationship/@inversionInd attribute is 'true' for Patient Medical Instructions relationship
    - OCL Issue - What is the patientInstructions relationship? unable to get OCL to reference
    - `[OCL]: not self.entryRelationship->exists( er : cda::EntryRelationship | er.inversionInd <> true and er.act.templateId->exists(id : datatypes::II | id.root = '1.3.6.1.4.1.19376.1.5.3.1.4.3') )`
40. **SHOULD** satisfy: The name and strength of the medication is recorded in consumable/manufacturedProduct/manufacturedMaterial/code/originalText
    - `[OCL]: not self.consumable.manufacturedProduct.manufacturedMaterial.code.oclIsUndefined() implies not self.consumable.manufacturedProduct.manufacturedMaterial.code.originalText.oclIsUnd`
41. **SHALL** satisfy: Name of the substance or product is recorded in consumable/manufacturedProduct/manufacturedMaterial/name
    - `[OCL]: not self.consumable.manufacturedProduct.manufacturedMaterial.name.oclIsUndefined()`
42. **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.
    - `[OCL]: not self.precondition.criterion.text->exists (t | t.reference.oclIsUndefined())`
43. **SHALL** satisfy: The entryRelationship/@inversionInd attribute is 'false' for Supply Entry relationship
    - `[OCL]: not self.entryRelationship->exists(er : cda::EntryRelationship | (not er.supply->isEmpty()) and er.inversionInd<>false )`
44. **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.
    - `[OCL]: not self.entryRelationship->exists(er| (not er.supply->isEmpty()) and er.sequenceNumber.value.oclIsUndefined() )`
45. **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)
46. **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
47. 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])
    - `[OCL]: self.effectiveTime->exists (ef : datatypes::SXCM_TS | not ef.oclIsUndefined())`
48. 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])

49. 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)

50. 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)

51. 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])

- `[OCL]: self.doseQuantity->exists(dq : datatypes::IVL_PQ | dq.unit='2.16.840.1.113883.3.88.12.80.29')`

52. 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])

53. 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])

- `[OCL]: not self.code.originalText.oclIsUndefined()`

54. **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.

- `[OCL]: self.consumable.manufacturedProduct->exists(mp : cda::ManufacturedProduct | mp.oclIsKindOf(hitsp::MedicationInformation))`

55. 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
- `[OCL]: self.getObservations()->exists(po : cda::Observation | po.oclIsKindOf(ccd::MedicationStatusObservation))`

56. [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
- `[OCL]: self.getObservations()->exists(po : cda::Observation | po.oclIsKindOf(ccd::ProblemObservation))`

57. 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])

- `[OCL]: self.getObservations()->exists(po : cda::Observation | po.oclIsKindOf(ccd::ProblemObservation) and not po.text.reference.oclIsUndefined())`

58. 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])

- `[OCL]: self.getObservations()->exists(po : cda::Observation | po.oclIsKindOf(ccd::ProblemObservation) and po.code.codeSystem = '2.16.840.1.113883.3.88.12.3221.7.4')`

59. 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.

- ```
  [OCL]: self.getActs()->exists(po : cda::Act |
   po.oclIsKindOf(ihe::PatientMedicalInstructions))
  ```

60. 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"

- ```
  [OCL]: self.getSubstanceAdministrations()->exists(sa :
   cda::SubstanceAdministration | sa.participant.participantRole->size() >
   0)
  ```

61. The typeCode attribute of the <participant> element **SHALL** be CSM (C83-[DE-8.24-CDA-2])

- ```
  [OCL]: self.getSubstanceAdministrations()->exists(sa :
   cda::SubstanceAdministration | sa.participant->exists(par :
   cda::Participant2 | par.typeCode = vocab::ParticipationType::CSM))
  ```

62. The classCode of the <participantRole> **SHALL** be MANU (C83-[DE-8.24-CDA-3])

- ```
  [OCL]: self.getSubstanceAdministrations()->exists(sa :
   cda::SubstanceAdministration | sa.participant->exists(par :
   cda::Participant2 | par.typeCode = vocab::ParticipationType::CSM and
   par.participantRole->exists(pr : cda::ParticipantRole | pr.classCode =
   vocab::RoleClassRoot::MANU)))
  ```

63. 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])

- ```
  [OCL]: self.getSubstanceAdministrations()->exists(sa :
   cda::SubstanceAdministration | sa.participant->exists(par :
   cda::Participant2 | par.typeCode = vocab::ParticipationType::CSM and
   par.participantRole->exists(pr : cda::ParticipantRole | pr.classCode
   = vocab::RoleClassRoot::MANU and pr.code.code = '412307009' and
   pr.code.codeSystem = '2.16.840.1.113883.6.96')))
  ```

64. The <name> element in the <playingEntity> element **SHALL** record the name of the drug vehicle (C83-[DE-8.24-CDA-5])

- ```
  [OCL]: self.getSubstanceAdministrations()->exists(sa :
   cda::SubstanceAdministration | sa.participant->exists(par :
   cda::Participant2 | par.typeCode = vocab::ParticipationType::CSM and
   par.participantRole->exists(pr : cda::ParticipantRole | pr.classCode
   = vocab::RoleClassRoot::MANU and pr.code.code = '412307009' and
   pr.code.codeSystem = '2.16.840.1.113883.6.96' and pr.playingEntity.name-
  >size() > 0)))
  ```

65. 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])

- ```
  [OCL]: self.getSubstanceAdministrations()->exists(sa :
   cda::SubstanceAdministration | sa.participant->exists(par :
   cda::Participant2 | par.typeCode =vocab::ParticipationType::CSM and
   par.participantRole->exists(pr : cda::ParticipantRole | pr.classCode
   = vocab::RoleClassRoot::MANU and pr.code.code = '412307009' and
   pr.code.codeSystem = '2.16.840.1.113883.6.96' and pr.playingEntity.code-
  >size() > 0)))
  ```
  ```

66. **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])
    - `[OCL]: self.getSubstanceAdministrations()->exists(sa : cda::SubstanceAdministration | sa.participant->exists(par : cda::Participant2 | par.typeCode = vocab::ParticipationType::CSM and par.participantRole->exists(pr : cda::ParticipantRole | pr.classCode = vocab::RoleClassRoot::MANU and pr.code.code = '412307009' and pr.code.codeSystem = '2.16.840.1.113883.6.96' and pr.playingEntity.code->size() > 0 and pr.playingEntity.code.codeSystem = '2.16.840.1.113883.3.88.12.80.21')))`

Medication example

Medication Combination Medication

[SubstanceAdministration: templateId `2.16.840.1.113883.3.88.11.83.8`]

1. **SHALL** conform to *IHE Combination Medication* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.11`)
2. **SHALL** conform to *CCD Medication Activity* template (templateId: `2.16.840.1.113883.10.20.1.24`)
3. **SHALL** conform to *IHE Medication* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.7`)
4. **SHALL** conform to *Medication* template (templateId: `2.16.840.1.113883.3.88.11.83.8`)
5. Contains exactly one [1..1] **`@classCode="SBADM"`** (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`), where its data type is ActClass
6. Contains exactly one [1..1] **`@moodCode`**, where its data type is x_DocumentSubstanceMood
7. **SHALL** contain at least one [1..*] **`id`** (CONF-306)
8. **MAY** contain zero or more [0..*] **`code`** (C83-[DE-8.12-CDA-1])
    - Delivery Method: A description of how the product is administered/consumed
9. **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.
10. **MAY** contain at least one [1..*] **`effectiveTime`**, where its data type is IVL_TS (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.
11. **MAY** contain at least one [1..*] **`routeCode`**, which **MAY** be selected from ValueSet **STATIC** (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).
12. **MAY** contain zero or more [0..*] **`approachSiteCode`**, which **MAY** be selected from ValueSet **STATIC** (C154-[DE-8.09-1])

- The anatomic site where the medication is administered. Usually applicable to injected or topical products

13. **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)
14. **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.
15. **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
16. **MAY** contain exactly one [1..1] **`administrationUnitCode`**, which **MAY** be selected from ValueSet **STATIC** (C154-[DE-8.11-1])
    - The physical form of the product as presented to the patient. For example: tablet, capsule, liquid or ointment
17. Contains exactly one [1..1] **`consumable`**, where its type is *Consumable*
18. **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`)
19. **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`)
20. **MAY** contain at least one [1..*] **`performer`** (CONF-313), such that
    - Indicates the person administering a substance.
21. **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: `2.16.840.1.113883.10.20.1.54`)
22. **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`)
23. 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`)
    - Entry may indicate one or more reasons for the use of the medication. The extension and root of each observation present must match the identifier of a concern entry contained elsewhere within the CDA document. A consumer of the Medical Summary is encouraged, but not required to maintain these links on import.
24. 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`)
    - At most one instruction may be provided for each <substanceAdministration> entry. The instructions shall contain any special case dosing instructions (e.g., split, tapered, or conditional dosing), and may contain other information (take with food, et cetera).
25. 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`)
26. 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`)
27. Contains zero or one [0..1] **`entryRelationship`**, such that

a. Contains exactly one [1..1] *CCD Reaction Observation* (templateId: `2.16.840.1.113883.10.20.1.54`)

- Any noted intended or unintended effects of the product. For example: full body rash, nausea, rash resolved

28. **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.
    - `[OCL]: not self.entryRelationship.substanceAdministration->isEmpty()`
29. **SHALL** satisfy: Value for moodCode is "EVN" or "INT" 2.16.840.1.113883.5.1001 ActMood STATIC (CONF-305)
    - `[OCL]: self.moodCode=vocab::x_DocumentSubstanceMood::EVN or self.moodCode=vocab::x_DocumentSubstanceMood::INT`
30. **SHOULD** satisfy: Contains exactly one doseQuantity or rateQuantity. (CONF-311)
    - `[OCL]: not self.doseQuantity.oclIsUndefined() or not self.rateQuantity.oclIsUndefined()`
31. **MAY** satisfy: Has one or more associated consents, represented in the CCD Header as ClinicalDocument / authorization / consent. (CONF-314)
    - `[OCL]: self.getClinicalDocument().authorization->exists(auth : cda::Authorization | not auth.oclIsUndefined() and not auth.consent.oclIsUndefined())`
32. **SHALL** satisfy: Contains one or more sources of information. (CONF-315)
    - `[OCL]: not self.informant->isEmpty() or not self.getSection().informant->isEmpty() or not self.getClinicalDocument().informant->isEmpty() or self.reference->exists(ref : cda::Reference | ref.typeCode = vocab::x_ActRelationshipExternalReference::XCRPT) or (self.entryRelationship->exists(rel : cda::EntryRelationship | rel.typeCode = vocab::x_ActRelationshipEntryRelationship::REFR and rel.observation.code.code = '48766-0'))`
33. **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.
    - `[OCL]: self.precondition->exists(precondition : cda::Precondition | not precondition.criterion.oclIsUndefined())`
34. **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.
    - `[OCL]: self.entryRelationship->exists(entryRel : cda::EntryRelationship | entryRel.typeCode = vocab::x_ActRelationshipEntryRelationship::RSON)`
35. **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)
    - `[OCL]: self.getEntryRelationshipTargets(vocab::x_ActRelationshipEntryRelationship::RSON, cda::ClinicalStatement)->forAll(target : cda::ClinicalStatement | not target.oclIsUndefined() and (target.oclIsKindOf(ccd::ProblemAct) or target.oclIsKindOf(ccd::ProblemObservation)))`
36. **SHALL** satisfy: Contains exactly one consumable, the target of which is a Product template. (CONF-354)
    - `[OCL]: self.consumable.manufacturedProduct.oclIsKindOf(ccd::Product)`
37. **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.

- `[OCL]: self.templateId->exists(id : datatypes::II | id.root = '1.3.6.1.4.1.19376.1.5.3.1.4.7.1') xor self.templateId->exists(id : datatypes::II | id.root = '1.3.6.1.4.1.19376.1.5.3.1.4.8') xor self.templateId->exists(id : datatypes::II | id.root = '1.3.6.1.4.1.19376.1.5.3.1.4.9') xor self.templateId->exists(id : datatypes::II | id.root = '1.3.6.1.4.1.19376.1.5.3.1.4.10') xor self.templateId->exists(id : datatypes::II | id.root = '1.3.6.1.4.1.19376.1.5.3.1.4.11')`

38. **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.

    - `[OCL]: self.templateId->exists(id : datatypes::II | id.root = '1.3.6.1.4.1.19376.1.5.3.1.4.8') xor self.templateId->exists(id : datatypes::II | id.root = '1.3.6.1.4.1.19376.1.5.3.1.4.9') xor self.templateId->exists(id : datatypes::II | id.root = '1.3.6.1.4.1.19376.1.5.3.1.4.10') xor self.templateId->exists(id : datatypes::II | id.root = '1.3.6.1.4.1.19376.1.5.3.1.4.11') implies self.entryRelationship->exists(er | er.typeCode=vocab::x_ActRelationshipEntryRelationship::COMP)`

39. **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)

    - `[OCL]: true`

40. **SHALL** satisfy: The act/@classCode='ACT' and act/@moodCode='EVN' when recording reason for medication in InternalReference Template. (6.3.4.16.22)

    - self.internalReference->exists(ir : ihe::InternalReference | ar.classCode <> 'ACT' or ar.moodCode <> 'EVN')
    - OCL Issue - What is the internalReference relationship? unable to get OCL to reference

    - `[OCL]: true`

41. **SHALL** satisfy: The <consumable> element shall be present, and shall contain a Product Entry template

    - `[OCL]: self.consumable.manufacturedProduct.templateId->exists(id : datatypes::II | id.root = '1.3.6.1.4.1.19376.1.5.3.1.4.7.2')`

42. **SHALL** satisfy: The entryRelationship/@inversionInd attribute is 'true' for Patient Medical Instructions relationship

    - OCL Issue - What is the patientInstructions relationship? unable to get OCL to reference

    - `[OCL]: not self.entryRelationship->exists( er : cda::EntryRelationship | er.inversionInd <> true and er.act.templateId->exists(id : datatypes::II | id.root = '1.3.6.1.4.1.19376.1.5.3.1.4.3') )`

43. **SHOULD** satisfy: The name and strength of the medication is recorded in consumable/manufacturedProduct/manufacturedMaterial/code/originalText
    - `[OCL]: not self.consumable.manufacturedProduct.manufacturedMaterial.code.oclIsUndefined() implies not self.consumable.manufacturedProduct.manufacturedMaterial.code.originalText.oclIsUnd`
44. **SHALL** satisfy: Name of the substance or product is recorded in consumable/manufacturedProduct/manufacturedMaterial/name
    - `[OCL]: not self.consumable.manufacturedProduct.manufacturedMaterial.name.oclIsUndefined()`
45. **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.
    - `[OCL]: not self.precondition.criterion.text->exists (t | t.reference.oclIsUndefined())`
46. **SHALL** satisfy: The entryRelationship/@inversionInd attribute is 'false' for Supply Entry relationship
    - `[OCL]: not self.entryRelationship->exists(er : cda::EntryRelationship | (not er.supply->isEmpty()) and er.inversionInd<>false )`
47. **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.
    - `[OCL]: not self.entryRelationship->exists(er| (not er.supply->isEmpty()) and er.sequenceNumber.value.oclIsUndefined() )`
48. **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)
49. **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
50. 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])
    - `[OCL]: self.effectiveTime->exists (ef : datatypes::SXCM_TS | not ef.oclIsUndefined())`
51. 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])
52. 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)
53. 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)

54. 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])

- `[OCL]: self.doseQuantity->exists(dq : datatypes::IVL_PQ | dq.unit='2.16.840.1.113883.3.88.12.80.29')`

55. 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])

56. 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])

- `[OCL]: not self.code.originalText.oclIsUndefined()`

57. **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.

- `[OCL]: self.consumable.manufacturedProduct->exists(mp : cda::ManufacturedProduct | mp.oclIsKindOf(hitsp::MedicationInformation))`

58. 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
- `[OCL]: self.getObservations()->exists(po : cda::Observation | po.oclIsKindOf(ccd::MedicationStatusObservation))`

59. [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
- `[OCL]: self.getObservations()->exists(po : cda::Observation | po.oclIsKindOf(ccd::ProblemObservation))`

60. 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])

- `[OCL]: self.getObservations()->exists(po : cda::Observation | po.oclIsKindOf(ccd::ProblemObservation) and not po.text.reference.oclIsUndefined())`

61. 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])

- `[OCL]: self.getObservations()->exists(po : cda::Observation | po.oclIsKindOf(ccd::ProblemObservation) and po.code.codeSystem = '2.16.840.1.113883.3.88.12.3221.7.4')`

62. 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.

- `[OCL]: self.getActs()->exists(po : cda::Act | po.oclIsKindOf(ihe::PatientMedicalInstructions))`

63. 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"

- ```
  [OCL]: self.getSubstanceAdministrations()->exists(sa :
   cda::SubstanceAdministration | sa.participant.participantRole->size() >
   0)
  ```

64. The typeCode attribute of the <participant> element **SHALL** be CSM (C83-[DE-8.24-CDA-2])

- ```
  [OCL]: self.getSubstanceAdministrations()->exists(sa :
   cda::SubstanceAdministration | sa.participant->exists(par :
   cda::Participant2 | par.typeCode = vocab::ParticipationType::CSM))
  ```

65. The classCode of the <participantRole> **SHALL** be MANU (C83-[DE-8.24-CDA-3])

- ```
  [OCL]: self.getSubstanceAdministrations()->exists(sa :
   cda::SubstanceAdministration | sa.participant->exists(par :
   cda::Participant2 | par.typeCode = vocab::ParticipationType::CSM and
   par.participantRole->exists(pr : cda::ParticipantRole | pr.classCode =
   vocab::RoleClassRoot::MANU)))
  ```

66. 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])

- ```
  [OCL]: self.getSubstanceAdministrations()->exists(sa :
   cda::SubstanceAdministration | sa.participant->exists(par :
   cda::Participant2 | par.typeCode = vocab::ParticipationType::CSM and
   par.participantRole->exists(pr : cda::ParticipantRole | pr.classCode
   = vocab::RoleClassRoot::MANU and pr.code.code = '412307009' and
   pr.code.codeSystem = '2.16.840.1.113883.6.96')))
  ```

67. The <name> element in the <playingEntity> element **SHALL** record the name of the drug vehicle (C83-[DE-8.24-CDA-5])

- ```
  [OCL]: self.getSubstanceAdministrations()->exists(sa :
   cda::SubstanceAdministration | sa.participant->exists(par :
   cda::Participant2 | par.typeCode = vocab::ParticipationType::CSM and
   par.participantRole->exists(pr : cda::ParticipantRole | pr.classCode
   = vocab::RoleClassRoot::MANU and pr.code.code = '412307009' and
   pr.code.codeSystem = '2.16.840.1.113883.6.96' and pr.playingEntity.name-
  >size() > 0)))
  ```

68. 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])

- ```
  [OCL]: self.getSubstanceAdministrations()->exists(sa :
   cda::SubstanceAdministration | sa.participant->exists(par :
   cda::Participant2 | par.typeCode =vocab::ParticipationType::CSM and
   par.participantRole->exists(pr : cda::ParticipantRole | pr.classCode
   = vocab::RoleClassRoot::MANU and pr.code.code = '412307009' and
   pr.code.codeSystem = '2.16.840.1.113883.6.96' and pr.playingEntity.code-
  >size() > 0)))
  ```

69. **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])

- ```
  [OCL]: self.getSubstanceAdministrations()->exists(sa :
   cda::SubstanceAdministration | sa.participant->exists(par :
   cda::Participant2 | par.typeCode = vocab::ParticipationType::CSM
   and par.participantRole->exists(pr : cda::ParticipantRole |
   pr.classCode = vocab::RoleClassRoot::MANU and pr.code.code =
   '412307009' and pr.code.codeSystem = '2.16.840.1.113883.6.96' and
   pr.playingEntity.code->size() > 0 and pr.playingEntity.code.codeSystem =
   '2.16.840.1.113883.3.88.12.80.21')))
  ```

Medication Combination Medication example
  ```

Medication Conditional Dose

[SubstanceAdministration: templateId `2.16.840.1.113883.3.88.11.83.8`]

1. **SHALL** conform to *IHE Conditional Dose* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.10`)
2. **SHALL** conform to *CCD Medication Activity* template (templateId: `2.16.840.1.113883.10.20.1.24`)
3. **SHALL** conform to *IHE Medication* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.7`)
4. **SHALL** conform to *Medication* template (templateId: `2.16.840.1.113883.3.88.11.83.8`)
5. Contains exactly one [1..1] **`@classCode="SBADM"`** (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`), where its data type is ActClass
6. Contains exactly one [1..1] **`@moodCode`**, where its data type is x_DocumentSubstanceMood
7. **SHALL** contain at least one [1..*] **`id`** (CONF-306)
8. **MAY** contain zero or more [0..*] **`code`** (C83-[DE-8.12-CDA-1])
   - Delivery Method: A description of how the product is administered/consumed
9. **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.
10. **MAY** contain at least one [1..*] **`effectiveTime`**, where its data type is IVL_TS (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.
11. **MAY** contain at least one [1..*] **`routeCode`**, which **MAY** be selected from ValueSet **STATIC** (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).
12. **MAY** contain zero or more [0..*] **`approachSiteCode`**, which **MAY** be selected from ValueSet **STATIC** (C154-[DE-8.09-1])
    - The anatomic site where the medication is administered. Usually applicable to injected or topical products
13. **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)
14. **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.
15. **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

16. **MAY** contain exactly one [1..1] **`administrationUnitCode`**, which **MAY** be selected from ValueSet **STATIC** (C154-[DE-8.11-1])
    - The physical form of the product as presented to the patient. For example: tablet, capsule, liquid or ointment
17. Contains exactly one [1..1] **`consumable`**, where its type is *Consumable*
18. **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`)
19. **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`)
20. **MAY** contain at least one [1..*] **`performer`** (CONF-313), such that
    - Indicates the person administering a substance.
21. **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: `2.16.840.1.113883.10.20.1.54`)
22. **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`)
23. 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`)
    - Entry may indicate one or more reasons for the use of the medication. The extension and root of each observation present must match the identifier of a concern entry contained elsewhere within the CDA document. A consumer of the Medical Summary is encouraged, but not required to maintain these links on import.
24. 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`)
    - At most one instruction may be provided for each <substanceAdministration> entry. The instructions shall contain any special case dosing instructions (e.g., split, tapered, or conditional dosing), and may contain other information (take with food, et cetera).
25. 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`)
26. 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`)
27. Contains zero or one [0..1] **`entryRelationship`**, such that
    a. Contains exactly one [1..1] *CCD Reaction Observation* (templateId: `2.16.840.1.113883.10.20.1.54`)
    - Any noted intended or unintended effects of the product. For example: full body rash, nausea, rash resolved
28. **SHALL** satisfy: A subordinate 'substanceAdministration' entry is required for each different dose, and the condition should be recorded
    - `[OCL]: not self.entryRelationship.substanceAdministration->isEmpty()`
29. **SHALL** satisfy: Value for moodCode is "EVN" or "INT" 2.16.840.1.113883.5.1001 ActMood STATIC (CONF-305)
    - ```
      [OCL]: self.moodCode=vocab::x_DocumentSubstanceMood::EVN or
       self.moodCode=vocab::x_DocumentSubstanceMood::INT
      ```
      ```

30. **SHOULD** satisfy: Contains exactly one doseQuantity or rateQuantity. (CONF-311)

    - `[OCL]: not self.doseQuantity.oclIsUndefined() or not self.rateQuantity.oclIsUndefined()`

31. **MAY** satisfy: Has one or more associated consents, represented in the CCD Header as ClinicalDocument / authorization / consent. (CONF-314)

    - `[OCL]: self.getClinicalDocument().authorization->exists(auth : cda::Authorization | not auth.oclIsUndefined() and not auth.consent.oclIsUndefined())`

32. **SHALL** satisfy: Contains one or more sources of information. (CONF-315)

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

33. **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.
    - `[OCL]: self.precondition->exists(precondition : cda::Precondition | not precondition.criterion.oclIsUndefined())`

34. **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.
    - `[OCL]: self.entryRelationship->exists(entryRel : cda::EntryRelationship | entryRel.typeCode = vocab::x_ActRelationshipEntryRelationship::RSON)`

35. **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)

    - `[OCL]: self.getEntryRelationshipTargets(vocab::x_ActRelationshipEntryRelationship::RSON, cda::ClinicalStatement)->forAll(target : cda::ClinicalStatement | not target.oclIsUndefined() and (target.oclIsKindOf(ccd::ProblemAct) or target.oclIsKindOf(ccd::ProblemObservation)))`

36. **SHALL** satisfy: Contains exactly one consumable, the target of which is a Product template. (CONF-354)

    - `[OCL]: self.consumable.manufacturedProduct.oclIsKindOf(ccd::Product)`

37. **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.
    - `[OCL]: self.templateId->exists(id : datatypes::II | id.root = '1.3.6.1.4.1.19376.1.5.3.1.4.7.1') xor self.templateId->exists(id : datatypes::II | id.root = '1.3.6.1.4.1.19376.1.5.3.1.4.8') xor self.templateId->exists(id : datatypes::II | id.root = '1.3.6.1.4.1.19376.1.5.3.1.4.9') xor self.templateId->exists(id : datatypes::II | id.root = '1.3.6.1.4.1.19376.1.5.3.1.4.10')`

```
xor self.templateId->exists(id : datatypes::II | id.root =
'1.3.6.1.4.1.19376.1.5.3.1.4.11')
```

38. **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.
    - ```
      [OCL]: self.templateId->exists(id : datatypes::II | id.root =
       '1.3.6.1.4.1.19376.1.5.3.1.4.8') xor
      self.templateId->exists(id : datatypes::II | id.root =
       '1.3.6.1.4.1.19376.1.5.3.1.4.9') xor
      self.templateId->exists(id : datatypes::II | id.root =
       '1.3.6.1.4.1.19376.1.5.3.1.4.10') xor
      self.templateId->exists(id : datatypes::II | id.root =
       '1.3.6.1.4.1.19376.1.5.3.1.4.11') implies self.entryRelationship-
      >exists(er | er.typeCode=vocab::x_ActRelationshipEntryRelationship::COMP)
      ```
39. **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)
    - ```
      [OCL]: true
      ```
40. **SHALL** satisfy: The act/@classCode='ACT' and act/@moodCode='EVN' when recording reason for medication in InternalReference Template. (6.3.4.16.22)
    - self.internalReference->exists(ir : ihe::InternalReference | ar.classCode <> 'ACT' or ar.moodCode <> 'EVN')
    - OCL Issue - What is the internalReference relationship? unable to get OCL to reference
    - ```
      [OCL]: true
      ```
41. **SHALL** satisfy: The <consumable> element shall be present, and shall contain a Product Entry template
    - ```
      [OCL]: self.consumable.manufacturedProduct.templateId->exists(id :
       datatypes::II | id.root = '1.3.6.1.4.1.19376.1.5.3.1.4.7.2')
      ```
42. **SHALL** satisfy: The entryRelationship/@inversionInd attribute is 'true' for Patient Medical Instructions relationship
    - OCL Issue - What is the patientInstructions relationship? unable to get OCL to reference
    - ```
      [OCL]: not self.entryRelationship->exists( er : cda::EntryRelationship |
       er.inversionInd <> true and er.act.templateId->exists(id : datatypes::II
       | id.root = '1.3.6.1.4.1.19376.1.5.3.1.4.3')  )
      ```
43. **SHOULD** satisfy: The name and strength of the medication is recorded in consumable/manufacturedProduct/manufacturedMaterial/code/originalText
    - ```
      [OCL]: not
       self.consumable.manufacturedProduct.manufacturedMaterial.code.oclIsUndefined()
       implies not
       self.consumable.manufacturedProduct.manufacturedMaterial.code.originalText.oclIsUnd
      ```
44. **SHALL** satisfy: Name of the substance or product is recorded in consumable/manufacturedProduct/manufacturedMaterial/name
    - ```
      [OCL]: not
       self.consumable.manufacturedProduct.manufacturedMaterial.name.oclIsUndefined()
      ```
      ```

45. **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.
    - `[OCL]: not self.precondition.criterion.text->exists (t | t.reference.oclIsUndefined())`
46. **SHALL** satisfy: The entryRelationship/@inversionInd attribute is 'false' for Supply Entry relationship
    - `[OCL]: not self.entryRelationship->exists(er : cda::EntryRelationship | (not er.supply->isEmpty()) and er.inversionInd<>false )`
47. **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.
    - `[OCL]: not self.entryRelationship->exists(er| (not er.supply->isEmpty()) and er.sequenceNumber.value.oclIsUndefined() )`
48. **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)
49. **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
50. 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])
    - `[OCL]: self.effectiveTime->exists (ef : datatypes::SXCM_TS | not ef.oclIsUndefined())`
51. 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])
52. 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)
53. 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)
54. 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])
    - `[OCL]: self.doseQuantity->exists(dq : datatypes::IVL_PQ | dq.unit='2.16.840.1.113883.3.88.12.80.29')`
55. 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])

56. 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])

- `[OCL]: not self.code.originalText.oclIsUndefined()`

57. **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.

- `[OCL]: self.consumable.manufacturedProduct->exists(mp : cda::ManufacturedProduct | mp.oclIsKindOf(hitsp::MedicationInformation))`

58. 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
- `[OCL]: self.getObservations()->exists(po : cda::Observation | po.oclIsKindOf(ccd::MedicationStatusObservation))`

59. [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
- `[OCL]: self.getObservations()->exists(po : cda::Observation | po.oclIsKindOf(ccd::ProblemObservation))`

60. 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])

- `[OCL]: self.getObservations()->exists(po : cda::Observation | po.oclIsKindOf(ccd::ProblemObservation) and not po.text.reference.oclIsUndefined())`

61. 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])

- `[OCL]: self.getObservations()->exists(po : cda::Observation | po.oclIsKindOf(ccd::ProblemObservation) and po.code.codeSystem = '2.16.840.1.113883.3.88.12.3221.7.4')`

62. 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.

- `[OCL]: self.getActs()->exists(po : cda::Act | po.oclIsKindOf(ihe::PatientMedicalInstructions))`

63. 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"
- `[OCL]: self.getSubstanceAdministrations()->exists(sa : cda::SubstanceAdministration | sa.participant.participantRole->size() > 0)`

64. The typeCode attribute of the <participant> element **SHALL** be CSM (C83-[DE-8.24-CDA-2])

- `[OCL]: self.getSubstanceAdministrations()->exists(sa : cda::SubstanceAdministration | sa.participant->exists(par : cda::Participant2 | par.typeCode = vocab::ParticipationType::CSM))`

65. The classCode of the <participantRole> **SHALL** be MANU (C83-[DE-8.24-CDA-3])

- ```
  [OCL]: self.getSubstanceAdministrations()->exists(sa :
   cda::SubstanceAdministration | sa.participant->exists(par :
   cda::Participant2 | par.typeCode = vocab::ParticipationType::CSM and
   par.participantRole->exists(pr : cda::ParticipantRole | pr.classCode =
   vocab::RoleClassRoot::MANU)))
  ```

66. 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])

- ```
  [OCL]: self.getSubstanceAdministrations()->exists(sa :
   cda::SubstanceAdministration | sa.participant->exists(par :
   cda::Participant2 | par.typeCode = vocab::ParticipationType::CSM and
   par.participantRole->exists(pr : cda::ParticipantRole | pr.classCode
   = vocab::RoleClassRoot::MANU and pr.code.code = '412307009' and
   pr.code.codeSystem = '2.16.840.1.113883.6.96')))
  ```

67. The <name> element in the <playingEntity> element **SHALL** record the name of the drug vehicle (C83-[DE-8.24-CDA-5])

- ```
  [OCL]: self.getSubstanceAdministrations()->exists(sa :
   cda::SubstanceAdministration | sa.participant->exists(par :
   cda::Participant2 | par.typeCode = vocab::ParticipationType::CSM and
   par.participantRole->exists(pr : cda::ParticipantRole | pr.classCode
   = vocab::RoleClassRoot::MANU and pr.code.code = '412307009' and
   pr.code.codeSystem = '2.16.840.1.113883.6.96' and pr.playingEntity.name-
  >size() > 0)))
  ```

68. 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])

- ```
  [OCL]: self.getSubstanceAdministrations()->exists(sa :
   cda::SubstanceAdministration | sa.participant->exists(par :
   cda::Participant2 | par.typeCode =vocab::ParticipationType::CSM and
   par.participantRole->exists(pr : cda::ParticipantRole | pr.classCode
   = vocab::RoleClassRoot::MANU and pr.code.code = '412307009' and
   pr.code.codeSystem = '2.16.840.1.113883.6.96' and pr.playingEntity.code-
  >size() > 0)))
  ```

69. **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])

- ```
  [OCL]: self.getSubstanceAdministrations()->exists(sa :
   cda::SubstanceAdministration | sa.participant->exists(par :
   cda::Participant2 | par.typeCode = vocab::ParticipationType::CSM
   and par.participantRole->exists(pr : cda::ParticipantRole |
   pr.classCode = vocab::RoleClassRoot::MANU and pr.code.code =
   '412307009' and pr.code.codeSystem = '2.16.840.1.113883.6.96' and
   pr.playingEntity.code->size() > 0 and pr.playingEntity.code.codeSystem =
   '2.16.840.1.113883.3.88.12.80.21')))
  ```

Medication Conditional Dose example

Medication Normal Dose

[SubstanceAdministration: templateId `2.16.840.1.113883.3.88.11.83.8`]

1. **SHALL** conform to *IHE Normal Dose* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.7.1`)
2. **SHALL** conform to *CCD Medication Activity* template (templateId: `2.16.840.1.113883.10.20.1.24`)
3. **SHALL** conform to *IHE Medication* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.7`)
4. **SHALL** conform to *Medication* template (templateId: `2.16.840.1.113883.3.88.11.83.8`)
5. Contains exactly one [1..1] **`@classCode`**`="SBADM"` (CodeSystem: `2.16.840.1.113883.5.6` `HL7ActClass`), where its data type is ActClass
6. Contains exactly one [1..1] **`@moodCode`**, where its data type is x_DocumentSubstanceMood
  ```

7. **SHALL** contain at least one [1..*] **`id`** (CONF-306)
8. **MAY** contain zero or more [0..*] **`code`** (C83-[DE-8.12-CDA-1])
   - Delivery Method: A description of how the product is administered/consumed
9. **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.
10. **MAY** contain at least one [1..*] **`effectiveTime`**, where its data type is IVL_TS (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.
11. **MAY** contain at least one [1..*] **`routeCode`**, which **MAY** be selected from ValueSet **STATIC** (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).
12. **MAY** contain zero or more [0..*] **`approachSiteCode`**, which **MAY** be selected from ValueSet **STATIC** (C154-[DE-8.09-1])
    - The anatomic site where the medication is administered. Usually applicable to injected or topical products
13. **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)
14. **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.
15. **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
16. **MAY** contain exactly one [1..1] **`administrationUnitCode`**, which **MAY** be selected from ValueSet **STATIC** (C154-[DE-8.11-1])
    - The physical form of the product as presented to the patient. For example: tablet, capsule, liquid or ointment
17. Contains exactly one [1..1] **`consumable`**, where its type is *Consumable*
18. **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`)
19. **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`)
20. **MAY** contain at least one [1..*] **`performer`** (CONF-313), such that

- Indicates the person administering a substance.

21. **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: `2.16.840.1.113883.10.20.1.54`)
22. **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`)
23. 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`)
    - Entry may indicate one or more reasons for the use of the medication. The extension and root of each observation present must match the identifier of a concern entry contained elsewhere within the CDA document. A consumer of the Medical Summary is encouraged, but not required to maintain these links on import.
24. 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`)
    - At most one instruction may be provided for each <substanceAdministration> entry. The instructions shall contain any special case dosing instructions (e.g., split, tapered, or conditional dosing), and may contain other information (take with food, et cetera).
25. 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`)
26. 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`)
27. Contains zero or one [0..1] **`entryRelationship`**, such that
    a. Contains exactly one [1..1] *CCD Reaction Observation* (templateId: `2.16.840.1.113883.10.20.1.54`)
    - Any noted intended or unintended effects of the product. For example: full body rash, nausea, rash resolved
28. **SHALL** satisfy: Medications that use this template identifier shall not use subordinate 'substanceAdministation' acts.
    - `[OCL]: self.entryRelationship.substanceAdministration->isEmpty()`
29. **SHALL** satisfy: Value for moodCode is "EVN" or "INT" 2.16.840.1.113883.5.1001 ActMood STATIC (CONF-305)
    - `[OCL]: self.moodCode=vocab::x_DocumentSubstanceMood::EVN or self.moodCode=vocab::x_DocumentSubstanceMood::INT`
30. **SHOULD** satisfy: Contains exactly one doseQuantity or rateQuantity. (CONF-311)
    - `[OCL]: not self.doseQuantity.oclIsUndefined() or not self.rateQuantity.oclIsUndefined()`
31. **MAY** satisfy: Has one or more associated consents, represented in the CCD Header as ClinicalDocument / authorization / consent. (CONF-314)
    - `[OCL]: self.getClinicalDocument().authorization->exists(auth : cda::Authorization | not auth.oclIsUndefined() and not auth.consent.oclIsUndefined())`
32. **SHALL** satisfy: Contains one or more sources of information. (CONF-315)
    - `[OCL]: not self.informant->isEmpty() or not self.getSection().informant->isEmpty() or not self.getClinicalDocument().informant->isEmpty() or self.reference->exists(ref : cda::Reference | ref.typeCode = vocab::x_ActRelationshipExternalReference::XCRPT)`

```
or (self.entryRelationship->exists(rel : cda::EntryRelationship |
   rel.typeCode = vocab::x_ActRelationshipEntryRelationship::REFR
   and rel.observation.code.code = '48766-0'))
```

33. **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.
    - `[OCL]: self.precondition->exists(precondition : cda::Precondition | not precondition.criterion.oclIsUndefined())`
34. **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.
    - `[OCL]: self.entryRelationship->exists(entryRel : cda::EntryRelationship | entryRel.typeCode = vocab::x_ActRelationshipEntryRelationship::RSON)`
35. **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)
    - ```
      [OCL]:
      self.getEntryRelationshipTargets(vocab::x_ActRelationshipEntryRelationship::RSON,
      cda::ClinicalStatement)->forAll(target :

      cda::ClinicalStatement | not target.oclIsUndefined() and
        (target.oclIsKindOf(ccd::ProblemAct) or
      target.oclIsKindOf(ccd::ProblemObservation)))
      ```
36. **SHALL** satisfy: Contains exactly one consumable, the target of which is a Product template. (CONF-354)
    - `[OCL]: self.consumable.manufacturedProduct.oclIsKindOf(ccd::Product)`
37. **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.
    - ```
      [OCL]: self.templateId->exists(id : datatypes::II | id.root =
      '1.3.6.1.4.1.19376.1.5.3.1.4.7.1') xor self.templateId->exists(id :
      datatypes::II | id.root = '1.3.6.1.4.1.19376.1.5.3.1.4.8')
      xor self.templateId->exists(id : datatypes::II | id.root =
      '1.3.6.1.4.1.19376.1.5.3.1.4.9') xor self.templateId->exists(id :
      datatypes::II | id.root = '1.3.6.1.4.1.19376.1.5.3.1.4.10')
      xor self.templateId->exists(id : datatypes::II | id.root =
      '1.3.6.1.4.1.19376.1.5.3.1.4.11')
      ```
38. **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.
    - ```
      [OCL]: self.templateId->exists(id : datatypes::II | id.root =
      '1.3.6.1.4.1.19376.1.5.3.1.4.8') xor
      self.templateId->exists(id : datatypes::II | id.root =
      '1.3.6.1.4.1.19376.1.5.3.1.4.9') xor
      self.templateId->exists(id : datatypes::II | id.root =
      '1.3.6.1.4.1.19376.1.5.3.1.4.10') xor
      ```
      ```

```
self.templateId->exists(id : datatypes::II | id.root =
 '1.3.6.1.4.1.19376.1.5.3.1.4.11') implies self.entryRelationship-
>exists(er | er.typeCode=vocab::x_ActRelationshipEntryRelationship::COMP)
```

39. **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)
    - `[OCL]: true`
40. **SHALL** satisfy: The act/@classCode='ACT' and act/@moodCode='EVN' when recording reason for medication in InternalReference Template. (6.3.4.16.22)
    - self.internalReference->exists(ir : ihe::InternalReference | ar.classCode <> 'ACT' or ar.moodCode <> 'EVN')
    - OCL Issue - What is the internalReference relationship? unable to get OCL to reference
    - `[OCL]: true`
41. **SHALL** satisfy: The <consumable> element shall be present, and shall contain a Product Entry template
    - `[OCL]: self.consumable.manufacturedProduct.templateId->exists(id :
      datatypes::II | id.root = '1.3.6.1.4.1.19376.1.5.3.1.4.7.2')`
42. **SHALL** satisfy: The entryRelationship/@inversionInd attribute is 'true' for Patient Medical Instructions relationship
    - OCL Issue - What is the patientInstructions relationship? unable to get OCL to reference
    - `[OCL]: not self.entryRelationship->exists(er : cda::EntryRelationship |
      er.inversionInd <> true and er.act.templateId->exists(id : datatypes::II
      | id.root = '1.3.6.1.4.1.19376.1.5.3.1.4.3'))`
43. **SHOULD** satisfy: The name and strength of the medication is recorded in consumable/manufacturedProduct/manufacturedMaterial/code/originalText
    - `[OCL]: not
      self.consumable.manufacturedProduct.manufacturedMaterial.code.oclIsUndefined()
      implies not
      self.consumable.manufacturedProduct.manufacturedMaterial.code.originalText.oclIsUnd`
44. **SHALL** satisfy: Name of the substance or product is recorded in consumable/manufacturedProduct/manufacturedMaterial/name
    - `[OCL]: not
      self.consumable.manufacturedProduct.manufacturedMaterial.name.oclIsUndefined()`
45. **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.
    - `[OCL]: not self.precondition.criterion.text->exists (t |
      t.reference.oclIsUndefined())`
46. **SHALL** satisfy: The entryRelationship/@inversionInd attribute is 'false' for Supply Entry relationship
    - `[OCL]: not self.entryRelationship->exists(er : cda::EntryRelationship |
      (not er.supply->isEmpty()) and er.inversionInd<>false)`
47. **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.
    - `[OCL]: not self.entryRelationship->exists(er| (not er.supply->isEmpty())
      and er.sequenceNumber.value.oclIsUndefined())`
48. **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)

49. **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
50. 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])
    - `[OCL]: self.effectiveTime->exists (ef : datatypes::SXCM_TS | not ef.oclIsUndefined())`
51. 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])
52. 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)
53. 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)
54. 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])
    - `[OCL]: self.doseQuantity->exists(dq : datatypes::IVL_PQ | dq.unit='2.16.840.1.113883.3.88.12.80.29')`
55. 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])
56. 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])
    - `[OCL]: not self.code.originalText.oclIsUndefined()`
57. **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.
    - `[OCL]: self.consumable.manufacturedProduct->exists(mp : cda::ManufacturedProduct | mp.oclIsKindOf(hitsp::MedicationInformation))`
58. 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
    - `[OCL]: self.getObservations()->exists(po : cda::Observation | po.oclIsKindOf(ccd::MedicationStatusObservation))`
59. [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
    - `[OCL]: self.getObservations()->exists(po : cda::Observation | po.oclIsKindOf(ccd::ProblemObservation))`

60. 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])

- ```
  [OCL]: self.getObservations()->exists(po : cda::Observation
   | po.oclIsKindOf(ccd::ProblemObservation) and not
   po.text.reference.oclIsUndefined())
  ```

61. 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])

- ```
  [OCL]: self.getObservations()->exists(po : cda::Observation |
   po.oclIsKindOf(ccd::ProblemObservation) and po.code.codeSystem =
   '2.16.840.1.113883.3.88.12.3221.7.4')
  ```

62. 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.

- ```
  [OCL]: self.getActs()->exists(po : cda::Act |
   po.oclIsKindOf(ihe::PatientMedicalInstructions))
  ```

63. 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"

- ```
  [OCL]: self.getSubstanceAdministrations()->exists(sa :
   cda::SubstanceAdministration | sa.participant.participantRole->size() >
   0)
  ```

64. The typeCode attribute of the <participant> element **SHALL** be CSM (C83-[DE-8.24-CDA-2])

- ```
  [OCL]: self.getSubstanceAdministrations()->exists(sa :
   cda::SubstanceAdministration | sa.participant->exists(par :
   cda::Participant2 | par.typeCode = vocab::ParticipationType::CSM))
  ```

65. The classCode of the <participantRole> **SHALL** be MANU (C83-[DE-8.24-CDA-3])

- ```
  [OCL]: self.getSubstanceAdministrations()->exists(sa :
   cda::SubstanceAdministration | sa.participant->exists(par :
   cda::Participant2 | par.typeCode = vocab::ParticipationType::CSM and
   par.participantRole->exists(pr : cda::ParticipantRole | pr.classCode =
   vocab::RoleClassRoot::MANU)))
  ```

66. 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])

- ```
  [OCL]: self.getSubstanceAdministrations()->exists(sa :
   cda::SubstanceAdministration | sa.participant->exists(par :
   cda::Participant2 | par.typeCode = vocab::ParticipationType::CSM and
   par.participantRole->exists(pr : cda::ParticipantRole | pr.classCode
   = vocab::RoleClassRoot::MANU and pr.code.code = '412307009' and
   pr.code.codeSystem = '2.16.840.1.113883.6.96')))
  ```

67. The <name> element in the <playingEntity> element **SHALL** record the name of the drug vehicle (C83-[DE-8.24-CDA-5])

- ```
  [OCL]: self.getSubstanceAdministrations()->exists(sa :
   cda::SubstanceAdministration | sa.participant->exists(par :
   cda::Participant2 | par.typeCode = vocab::ParticipationType::CSM and
   par.participantRole->exists(pr : cda::ParticipantRole | pr.classCode
   = vocab::RoleClassRoot::MANU and pr.code.code = '412307009' and
  ```

```
 pr.code.codeSystem = '2.16.840.1.113883.6.96' and pr.playingEntity.name-
>size() > 0)))
```

68. 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])

- ```
  [OCL]: self.getSubstanceAdministrations()->exists(sa :
   cda::SubstanceAdministration | sa.participant->exists(par :
   cda::Participant2 | par.typeCode =vocab::ParticipationType::CSM and
   par.participantRole->exists(pr : cda::ParticipantRole | pr.classCode
   = vocab::RoleClassRoot::MANU and pr.code.code = '412307009' and
   pr.code.codeSystem = '2.16.840.1.113883.6.96' and pr.playingEntity.code-
  >size() > 0)))
  ```

69. **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])

- ```
  [OCL]: self.getSubstanceAdministrations()->exists(sa :
   cda::SubstanceAdministration | sa.participant->exists(par :
   cda::Participant2 | par.typeCode = vocab::ParticipationType::CSM
   and par.participantRole->exists(pr : cda::ParticipantRole |
   pr.classCode = vocab::RoleClassRoot::MANU and pr.code.code =
   '412307009' and pr.code.codeSystem = '2.16.840.1.113883.6.96' and
   pr.playingEntity.code->size() > 0 and pr.playingEntity.code.codeSystem =
   '2.16.840.1.113883.3.88.12.80.21')))
  ```

Medication Normal Dose example

Medication Order Information

[Supply: templateId `2.16.840.1.113883.3.88.11.83.8.3`]

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

1. **SHALL** conform to *CCD Supply Activity* template (templateId: `2.16.840.1.113883.10.20.1.34`)
2. **SHALL** conform to *IHE Supply Entry* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.7.3`)
3. Contains exactly one [1..1] **`@classCode`**`="SPLY"` (CodeSystem: `2.16.840.1.113883.5.6` `HL7ActClass`), where its data type is ActClassSupply
4. Contains exactly one [1..1] **`@moodCode`**, where its data type is x_DocumentSubstanceMood
5. **SHALL** contain at least one [1..*] **`id`** (CONF-318)
6. **MAY** contain exactly one [1..1] **`statusCode`**, which **MAY** be selected from ValueSet **STATIC** (CONF-319)
   - When supply element has a moodCode attribute set to EVN
7. **SHOULD** contain exactly one [1..1] **`effectiveTime`** (CONF-320)
   - Indicates the actual or intended time of dispensing.
8. **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.
9. **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.
10. **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`)
11. **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`)
12. 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`)
13. **SHALL** satisfy: Value for moodCode is 'EVN' or 'INT' 2.16.840.1.113883.5.1001 ActMood STATIC (CONF-317)
   - `[OCL]: self.moodCode=vocab::x_DocumentSubstanceMood::EVN or self.moodCode=vocab::x_DocumentSubstanceMood::INT`
14. **MAY** satisfy: Contains one or more author. (CONF-323)
   - Indicates the prescriber.
   - `[OCL]: not self.author->isEmpty()`
15. **MAY** satisfy: Contains one or more performer. (CONF-324)
   - Indicates the person dispensing the product.
   - `[OCL]: not self.performer->isEmpty()`
16. **MAY** satisfy: Contains exactly one participant / @typeCode = "LOC". (CONF-325)
   - Iindicates the supply location.
   - `[OCL]: self.participant->one(part : cda::Participant2 | part.typeCode = vocab::ParticipationType::LOC)`
17. **SHALL** satisfy: Contains one or more sources of information. (CONF-326)
   - ```
     [OCL]: not self.informant->isEmpty()
     or not self.getSection().informant->isEmpty()
     or not self.getClinicalDocument().informant->isEmpty()
     or self.reference->exists(ref : cda::Reference | ref.typeCode = vocab::x_ActRelationshipExternalReference::XCRPT)
     or (self.entryRelationship->exists(rel : cda::EntryRelationship |
        rel.typeCode = vocab::x_ActRelationshipEntryRelationship::REFR
        and rel.observation.code.code = '48766-0'))
     ```
18. **MAY** satisfy: Contains exactly one product, the target of which is a Product template. (CONF-355)
   - `[OCL]: not self.product.oclIsUndefined() and self.product.oclIsKindOf(cda::Product)`
19. 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.
20. **MAY** satisfy: A supply entry that describes an intent (<supply classCode='SPLY' moodCode='INT'>) may include an <author> element to identify the prescribing provider.
21. **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.
22. **SHALL** satisfy: The <assignedAuthor> element shall be present in author, and identifies the author.
23. **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.
24. **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.
25. **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.
26. **SHOULD** satisfy: The <time> element should be present to indicate when the prescription is intended to be filled (moodCode='INT').
27. **SHALL** satisfy: The performer/assignedEntity element shall be present, and identifies the filler of the prescription.
28. **SHOULD** satisfy: One or more <id> elements should be present. These identify the performer.
     ```

29. **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.
30. 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')
    - `[OCL]: self.moodCode = vocab::x_DocumentSubstanceMood::INT implies self.id->size() > 0`
31. **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
    - `[OCL]: self.moodCode = vocab::x_DocumentSubstanceMood::INT implies not self.effectiveTime->select(et | et.value.oclIsUndefined())->isEmpty()`
32. 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
    - `[OCL]: not self.quantity.value.oclIsUndefined()`
33. **SHALL** satisfy: the @unit attribute of quantity element is present (C83-[DE-8.26-CDA-2])
    - `[OCL]: not self.quantity.unit.oclIsUndefined()`
34. 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])
35. 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])
36. 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
    - `[OCL]: self.moodCode = vocab::x_DocumentSubstanceMood::EVN implies not self.id->isEmpty()`
37. 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.
    - `[OCL]: self.id.root->size() > 0`
38. A GUID **MAY** be used in place of the OID of the assigning authority (C83-[DE-8.34-CDA-3])
39. **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
    - `[OCL]: self.moodCode = vocab::x_DocumentSubstanceMood::EVN implies self.effectiveTime->size() > 0`
40. **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
    - `[OCL]: self.moodCode = vocab::x_DocumentSubstanceMood::EVN implies self.performer->select(p | p.assignedEntity.addr->isEmpty())->isEmpty()`
41. 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])

42. 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])
43. 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])
44. 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
    - `[OCL]: self.moodCode = vocab::x_DocumentSubstanceMood::EVN implies not self.quantity.value.oclIsUndefined()`
45. 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.
    - `[OCL]: self.entryRelationship->select(er | er.typeCode = vocab::x_ActRelationshipEntryRelationship::COMP and er.sequenceNumber.oclIsUndefined())->isEmpty()`

Medication Order Information example

Medication Split Dose

[SubstanceAdministration: templateId `2.16.840.1.113883.3.88.11.83.8`]

1. **SHALL** conform to *IHE Split Dose* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.9`)
2. **SHALL** conform to *CCD Medication Activity* template (templateId: `2.16.840.1.113883.10.20.1.24`)
3. **SHALL** conform to *IHE Medication* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.7`)
4. **SHALL** conform to *Medication* template (templateId: `2.16.840.1.113883.3.88.11.83.8`)
5. Contains exactly one [1..1] **`@classCode="SBADM"`** (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`), where its data type is ActClass
6. Contains exactly one [1..1] **`@moodCode`**, where its data type is x_DocumentSubstanceMood
7. **SHALL** contain at least one [1..*] **`id`** (CONF-306)
8. **MAY** contain zero or more [0..*] **`code`** (C83-[DE-8.12-CDA-1])
    - Delivery Method: A description of how the product is administered/consumed
9. **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.
10. **MAY** contain at least one [1..*] **`effectiveTime`**, where its data type is IVL_TS (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.

11. **MAY** contain at least one [1..*] **routeCode**, which **MAY** be selected from ValueSet **STATIC** (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).
12. **MAY** contain zero or more [0..*] **approachSiteCode**, which **MAY** be selected from ValueSet **STATIC** (C154-[DE-8.09-1])
    - The anatomic site where the medication is administered. Usually applicable to injected or topical products
13. **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)
14. **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.
15. **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
16. **MAY** contain exactly one [1..1] **administrationUnitCode**, which **MAY** be selected from ValueSet **STATIC** (C154-[DE-8.11-1])
    - The physical form of the product as presented to the patient. For example: tablet, capsule, liquid or ointment
17. Contains exactly one [1..1] **consumable**, where its type is *Consumable*
18. **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)
19. **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)
20. **MAY** contain at least one [1..*] **performer** (CONF-313), such that
    - Indicates the person administering a substance.
21. **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: 2.16.840.1.113883.10.20.1.54)
22. **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)
23. 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)
    - Entry may indicate one or more reasons for the use of the medication. The extension and root of each observation present must match the identifier of a concern entry contained elsewhere within the CDA document. A consumer of the Medical Summary is encouraged, but not required to maintain these links on import.
24. 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)
    - At most one instruction may be provided for each <substanceAdministration> entry. The instructions shall contain any special case dosing instructions (e.g., split, tapered, or conditional dosing), and may contain other information (take with food, et cetera).
25. 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`)
26. 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`)
27. Contains zero or one [0..1] **`entryRelationship`**, such that
   a. Contains exactly one [1..1] *CCD Reaction Observation* (templateId: `2.16.840.1.113883.10.20.1.54`)

- Any noted intended or unintended effects of the product. For example: full body rash, nausea, rash resolved

28. **SHALL** satisfy: A subordinate <substanceAdministration> entry is required for each separate dosage.
- `[OCL]: not self.entryRelationship.substanceAdministration->isEmpty()`

29. **SHALL** satisfy: Value for moodCode is "EVN" or "INT" 2.16.840.1.113883.5.1001 ActMood STATIC (CONF-305)
- `[OCL]: self.moodCode=vocab::x_DocumentSubstanceMood::EVN or self.moodCode=vocab::x_DocumentSubstanceMood::INT`

30. **SHOULD** satisfy: Contains exactly one doseQuantity or rateQuantity. (CONF-311)
- `[OCL]: not self.doseQuantity.oclIsUndefined() or not self.rateQuantity.oclIsUndefined()`

31. **MAY** satisfy: Has one or more associated consents, represented in the CCD Header as ClinicalDocument / authorization / consent. (CONF-314)
- `[OCL]: self.getClinicalDocument().authorization->exists(auth : cda::Authorization | not auth.oclIsUndefined() and not auth.consent.oclIsUndefined())`

32. **SHALL** satisfy: Contains one or more sources of information. (CONF-315)
- `[OCL]: not self.informant->isEmpty() or not self.getSection().informant->isEmpty() or not self.getClinicalDocument().informant->isEmpty() or self.reference->exists(ref : cda::Reference | ref.typeCode = vocab::x_ActRelationshipExternalReference::XCRPT) or (self.entryRelationship->exists(rel : cda::EntryRelationship | rel.typeCode = vocab::x_ActRelationshipEntryRelationship::REFR and rel.observation.code.code = '48766-0'))`

33. **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.
- `[OCL]: self.precondition->exists(precondition : cda::Precondition | not precondition.criterion.oclIsUndefined())`

34. **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.
- `[OCL]: self.entryRelationship->exists(entryRel : cda::EntryRelationship | entryRel.typeCode = vocab::x_ActRelationshipEntryRelationship::RSON)`

35. **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)
- `[OCL]: self.getEntryRelationshipTargets(vocab::x_ActRelationshipEntryRelationship::RSON, cda::ClinicalStatement)->forAll(target : cda::ClinicalStatement | not target.oclIsUndefined() and (target.oclIsKindOf(ccd::ProblemAct) or target.oclIsKindOf(ccd::ProblemObservation)))`

36. **SHALL** satisfy: Contains exactly one consumable, the target of which is a Product template. (CONF-354)
    - `[OCL]: self.consumable.manufacturedProduct.oclIsKindOf(ccd::Product)`
37. **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.
    - ```
      [OCL]: self.templateId->exists(id : datatypes::II | id.root =
       '1.3.6.1.4.1.19376.1.5.3.1.4.7.1') xor self.templateId->exists(id :
       datatypes::II | id.root = '1.3.6.1.4.1.19376.1.5.3.1.4.8')
       xor self.templateId->exists(id : datatypes::II | id.root =
       '1.3.6.1.4.1.19376.1.5.3.1.4.9') xor self.templateId->exists(id :
       datatypes::II | id.root = '1.3.6.1.4.1.19376.1.5.3.1.4.10')
       xor self.templateId->exists(id : datatypes::II | id.root =
       '1.3.6.1.4.1.19376.1.5.3.1.4.11')
      ```
38. **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.
    - ```
      [OCL]: self.templateId->exists(id : datatypes::II | id.root =
       '1.3.6.1.4.1.19376.1.5.3.1.4.8') xor
      self.templateId->exists(id : datatypes::II | id.root =
       '1.3.6.1.4.1.19376.1.5.3.1.4.9') xor
      self.templateId->exists(id : datatypes::II | id.root =
       '1.3.6.1.4.1.19376.1.5.3.1.4.10') xor
      self.templateId->exists(id : datatypes::II | id.root =
       '1.3.6.1.4.1.19376.1.5.3.1.4.11') implies self.entryRelationship-
      >exists(er | er.typeCode=vocab::x_ActRelationshipEntryRelationship::COMP)
      ```
39. **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)
    - `[OCL]: true`
40. **SHALL** satisfy: The act/@classCode='ACT' and act/@moodCode='EVN' when recording reason for medication in InternalReference Template. (6.3.4.16.22)
    - self.internalReference->exists(ir : ihe::InternalReference | ar.classCode <> 'ACT' or ar.moodCode <> 'EVN')
    - OCL Issue - What is the internalReference relationship? unable to get OCL to reference
    - `[OCL]: true`
41. **SHALL** satisfy: The <consumable> element shall be present, and shall contain a Product Entry template
    - ```
      [OCL]: self.consumable.manufacturedProduct.templateId->exists(id :
       datatypes::II | id.root = '1.3.6.1.4.1.19376.1.5.3.1.4.7.2')
      ```
42. **SHALL** satisfy: The entryRelationship/@inversionInd attribute is 'true' for Patient Medical Instructions relationship
      ```

- OCL Issue - What is the patientInstructions relationship? unable to get OCL to reference
- ```
  [OCL]: not self.entryRelationship->exists( er : cda::EntryRelationship |
   er.inversionInd <> true and er.act.templateId->exists(id : datatypes::II
   | id.root = '1.3.6.1.4.1.19376.1.5.3.1.4.3')  )
  ```

43. **SHOULD** satisfy: The name and strength of the medication is recorded in consumable/manufacturedProduct/manufacturedMaterial/code/originalText
    - ```
      [OCL]: not
       self.consumable.manufacturedProduct.manufacturedMaterial.code.oclIsUndefined()
       implies not
       self.consumable.manufacturedProduct.manufacturedMaterial.code.originalText.oclIsUnd
      ```
44. **SHALL** satisfy: Name of the substance or product is recorded in consumable/manufacturedProduct/manufacturedMaterial/name
    - ```
      [OCL]: not
       self.consumable.manufacturedProduct.manufacturedMaterial.name.oclIsUndefined()
      ```
45. **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.
    - ```
      [OCL]: not self.precondition.criterion.text->exists (t |
       t.reference.oclIsUndefined())
      ```
46. **SHALL** satisfy: The entryRelationship/@inversionInd attribute is 'false' for Supply Entry relationship
    - ```
      [OCL]: not self.entryRelationship->exists(er : cda::EntryRelationship |
       (not er.supply->isEmpty()) and er.inversionInd<>false )
      ```
47. **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.
    - ```
      [OCL]: not self.entryRelationship->exists(er| (not er.supply->isEmpty())
       and er.sequenceNumber.value.oclIsUndefined() )
      ```
48. **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)
49. **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
50. 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])
    - ```
      [OCL]: self.effectiveTime->exists (ef : datatypes::SXCM_TS | not
       ef.oclIsUndefined())
      ```
51. 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])
52. 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)
      ```

53. 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)

54. 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])

- `[OCL]: self.doseQuantity->exists(dq : datatypes::IVL_PQ | dq.unit='2.16.840.1.113883.3.88.12.80.29')`

55. 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])

56. 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])

- `[OCL]: not self.code.originalText.oclIsUndefined()`

57. **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.

- `[OCL]: self.consumable.manufacturedProduct->exists(mp : cda::ManufacturedProduct | mp.oclIsKindOf(hitsp::MedicationInformation))`

58. 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
- `[OCL]: self.getObservations()->exists(po : cda::Observation | po.oclIsKindOf(ccd::MedicationStatusObservation))`

59. [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
- `[OCL]: self.getObservations()->exists(po : cda::Observation | po.oclIsKindOf(ccd::ProblemObservation))`

60. 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])

- `[OCL]: self.getObservations()->exists(po : cda::Observation | po.oclIsKindOf(ccd::ProblemObservation) and not po.text.reference.oclIsUndefined())`

61. 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])

- `[OCL]: self.getObservations()->exists(po : cda::Observation | po.oclIsKindOf(ccd::ProblemObservation) and po.code.codeSystem = '2.16.840.1.113883.3.88.12.3221.7.4')`

62. 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.

- `[OCL]: self.getActs()->exists(po : cda::Act | po.oclIsKindOf(ihe::PatientMedicalInstructions))`

63. 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"
- ```
  [OCL]: self.getSubstanceAdministrations()->exists(sa :
   cda::SubstanceAdministration | sa.participant.participantRole->size() >
   0)
  ```

64. The typeCode attribute of the <participant> element **SHALL** be CSM (C83-[DE-8.24-CDA-2])

- ```
  [OCL]: self.getSubstanceAdministrations()->exists(sa :
   cda::SubstanceAdministration | sa.participant->exists(par :
   cda::Participant2 | par.typeCode = vocab::ParticipationType::CSM))
  ```

65. The classCode of the <participantRole> **SHALL** be MANU (C83-[DE-8.24-CDA-3])

- ```
  [OCL]: self.getSubstanceAdministrations()->exists(sa :
   cda::SubstanceAdministration | sa.participant->exists(par :
   cda::Participant2 | par.typeCode = vocab::ParticipationType::CSM and
   par.participantRole->exists(pr : cda::ParticipantRole | pr.classCode =
   vocab::RoleClassRoot::MANU)))
  ```

66. 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])

- ```
  [OCL]: self.getSubstanceAdministrations()->exists(sa :
   cda::SubstanceAdministration | sa.participant->exists(par :
   cda::Participant2 | par.typeCode = vocab::ParticipationType::CSM and
   par.participantRole->exists(pr : cda::ParticipantRole | pr.classCode
   = vocab::RoleClassRoot::MANU and pr.code.code = '412307009' and
   pr.code.codeSystem = '2.16.840.1.113883.6.96')))
  ```

67. The <name> element in the <playingEntity> element **SHALL** record the name of the drug vehicle (C83-[DE-8.24-CDA-5])

- ```
  [OCL]: self.getSubstanceAdministrations()->exists(sa :
   cda::SubstanceAdministration | sa.participant->exists(par :
   cda::Participant2 | par.typeCode = vocab::ParticipationType::CSM and
   par.participantRole->exists(pr : cda::ParticipantRole | pr.classCode
   = vocab::RoleClassRoot::MANU and pr.code.code = '412307009' and
   pr.code.codeSystem = '2.16.840.1.113883.6.96' and pr.playingEntity.name-
  >size() > 0)))
  ```

68. 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])

- ```
  [OCL]: self.getSubstanceAdministrations()->exists(sa :
   cda::SubstanceAdministration | sa.participant->exists(par :
   cda::Participant2 | par.typeCode =vocab::ParticipationType::CSM and
   par.participantRole->exists(pr : cda::ParticipantRole | pr.classCode
   = vocab::RoleClassRoot::MANU and pr.code.code = '412307009' and
   pr.code.codeSystem = '2.16.840.1.113883.6.96' and pr.playingEntity.code-
  >size() > 0)))
  ```

69. 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])

- ```
  [OCL]: self.getSubstanceAdministrations()->exists(sa :
   cda::SubstanceAdministration | sa.participant->exists(par :
   cda::Participant2 | par.typeCode = vocab::ParticipationType::CSM
   and par.participantRole->exists(pr : cda::ParticipantRole |
   pr.classCode = vocab::RoleClassRoot::MANU and pr.code.code =
   '412307009' and pr.code.codeSystem = '2.16.840.1.113883.6.96' and
   pr.playingEntity.code->size() > 0 and pr.playingEntity.code.codeSystem =
   '2.16.840.1.113883.3.88.12.80.21')))
  ```
  ```

Medication Split Dose example

Medication Tapered Dose

[SubstanceAdministration: templateId `null`]

1. **SHALL** conform to *IHE Tapered Dose* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.8`)
2. **SHALL** conform to *CCD Medication Activity* template (templateId: `2.16.840.1.113883.10.20.1.24`)
3. **SHALL** conform to *IHE Medication* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.7`)
4. **SHALL** conform to *Medication* template (templateId: `2.16.840.1.113883.3.88.11.83.8`)
5. Contains exactly one [1..1] **`@classCode="SBADM"`** (CodeSystem: `2.16.840.1.113883.5.6` `HL7ActClass`), where its data type is ActClass
6. Contains exactly one [1..1] **`@moodCode`**, where its data type is x_DocumentSubstanceMood
7. **SHALL** contain at least one [1..*] **`id`** (CONF-306)
8. **MAY** contain zero or more [0..*] **`code`** (C83-[DE-8.12-CDA-1])
   - Delivery Method: A description of how the product is administered/consumed
9. **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.
10. **MAY** contain at least one [1..*] **`effectiveTime`**, where its data type is IVL_TS (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.
11. **MAY** contain at least one [1..*] **`routeCode`**, which **MAY** be selected from ValueSet **STATIC** (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).
12. **MAY** contain zero or more [0..*] **`approachSiteCode`**, which **MAY** be selected from ValueSet **STATIC** (C154-[DE-8.09-1])
    - The anatomic site where the medication is administered. Usually applicable to injected or topical products
13. **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)
14. **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.
15. **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

16. **MAY** contain exactly one [1..1] **`administrationUnitCode`**, which **MAY** be selected from ValueSet **STATIC** (C154-[DE-8.11-1])
    - The physical form of the product as presented to the patient. For example: tablet, capsule, liquid or ointment
17. Contains exactly one [1..1] **`consumable`**, where its type is *Consumable*
18. **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`)
19. **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`)
20. **MAY** contain at least one [1..*] **`performer`** (CONF-313), such that
    - Indicates the person administering a substance.
21. **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: `2.16.840.1.113883.10.20.1.54`)
22. **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`)
23. 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`)
    - Entry may indicate one or more reasons for the use of the medication. The extension and root of each observation present must match the identifier of a concern entry contained elsewhere within the CDA document. A consumer of the Medical Summary is encouraged, but not required to maintain these links on import.
24. 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`)
    - At most one instruction may be provided for each <substanceAdministration> entry. The instructions shall contain any special case dosing instructions (e.g., split, tapered, or conditional dosing), and may contain other information (take with food, et cetera).
25. 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`)
26. 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`)
27. Contains zero or one [0..1] **`entryRelationship`**, such that
    a. Contains exactly one [1..1] *CCD Reaction Observation* (templateId: `2.16.840.1.113883.10.20.1.54`)
    - Any noted intended or unintended effects of the product. For example: full body rash, nausea, rash resolved
28. **SHALL** satisfy: Subordinate Medication entries should be created for each distinct dosage.
    - ```
      [OCL]: self.entryRelationship.substanceAdministration-
      >exists( substanceAdministration  |
       substanceAdministration.oclIsKindOf( ihe::Medication) )
      ```
29. **SHALL** satisfy: Value for moodCode is "EVN" or "INT" 2.16.840.1.113883.5.1001 ActMood STATIC (CONF-305)
    - ```
      [OCL]: self.moodCode=vocab::x_DocumentSubstanceMood::EVN or
       self.moodCode=vocab::x_DocumentSubstanceMood::INT
      ```

30. **SHOULD** satisfy: Contains exactly one doseQuantity or rateQuantity. (CONF-311)

    - ```
      [OCL]: not self.doseQuantity.oclIsUndefined() or not
       self.rateQuantity.oclIsUndefined()
      ```

31. **MAY** satisfy: Has one or more associated consents, represented in the CCD Header as ClinicalDocument / authorization / consent. (CONF-314)

    - ```
      [OCL]: self.getClinicalDocument().authorization->exists(auth :
       cda::Authorization |
         not auth.oclIsUndefined() and not auth.consent.oclIsUndefined())
      ```

32. **SHALL** satisfy: Contains one or more sources of information. (CONF-315)

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

33. **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.
    - ```
      [OCL]: self.precondition->exists(precondition : cda::Precondition | not
       precondition.criterion.oclIsUndefined())
      ```

34. **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.
    - ```
      [OCL]: self.entryRelationship->exists(entryRel : cda::EntryRelationship |
       entryRel.typeCode = vocab::x_ActRelationshipEntryRelationship::RSON)
      ```

35. **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)

    - ```
      [OCL]:
       self.getEntryRelationshipTargets(vocab::x_ActRelationshipEntryRelationship::RSON,
       cda::ClinicalStatement)->forAll(target :

      cda::ClinicalStatement | not target.oclIsUndefined() and
        (target.oclIsKindOf(ccd::ProblemAct) or
       target.oclIsKindOf(ccd::ProblemObservation)))
      ```

36. **SHALL** satisfy: Contains exactly one consumable, the target of which is a Product template. (CONF-354)

    - ```
      [OCL]: self.consumable.manufacturedProduct.oclIsKindOf(ccd::Product)
      ```

37. **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.
    - ```
      [OCL]: self.templateId->exists(id : datatypes::II | id.root =
       '1.3.6.1.4.1.19376.1.5.3.1.4.7.1') xor self.templateId->exists(id :
       datatypes::II | id.root = '1.3.6.1.4.1.19376.1.5.3.1.4.8')
       xor self.templateId->exists(id : datatypes::II | id.root =
       '1.3.6.1.4.1.19376.1.5.3.1.4.9') xor self.templateId->exists(id :
       datatypes::II | id.root = '1.3.6.1.4.1.19376.1.5.3.1.4.10')
      ```

```
xor self.templateId->exists(id : datatypes::II | id.root =
'1.3.6.1.4.1.19376.1.5.3.1.4.11')
```

38. **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.
    - ```
      [OCL]: self.templateId->exists(id : datatypes::II | id.root =
       '1.3.6.1.4.1.19376.1.5.3.1.4.8') xor
      self.templateId->exists(id : datatypes::II | id.root =
       '1.3.6.1.4.1.19376.1.5.3.1.4.9') xor
      self.templateId->exists(id : datatypes::II | id.root =
       '1.3.6.1.4.1.19376.1.5.3.1.4.10') xor
      self.templateId->exists(id : datatypes::II | id.root =
       '1.3.6.1.4.1.19376.1.5.3.1.4.11') implies self.entryRelationship-
      >exists(er | er.typeCode=vocab::x_ActRelationshipEntryRelationship::COMP)
      ```
39. **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)
    - ```
      [OCL]: true
      ```
40. **SHALL** satisfy: The act/@classCode='ACT' and act/@moodCode='EVN' when recording reason for medication in InternalReference Template. (6.3.4.16.22)
    - self.internalReference->exists(ir : ihe::InternalReference | ar.classCode <> 'ACT' or ar.moodCode <> 'EVN')
    - OCL Issue - What is the internalReference relationship? unable to get OCL to reference
    - ```
      [OCL]: true
      ```
41. **SHALL** satisfy: The <consumable> element shall be present, and shall contain a Product Entry template
    - ```
      [OCL]: self.consumable.manufacturedProduct.templateId->exists(id :
       datatypes::II | id.root = '1.3.6.1.4.1.19376.1.5.3.1.4.7.2')
      ```
42. **SHALL** satisfy: The entryRelationship/@inversionInd attribute is 'true' for Patient Medical Instructions relationship
    - OCL Issue - What is the patientInstructions relationship? unable to get OCL to reference
    - ```
      [OCL]: not self.entryRelationship->exists( er : cda::EntryRelationship |
       er.inversionInd <> true and er.act.templateId->exists(id : datatypes::II
       | id.root = '1.3.6.1.4.1.19376.1.5.3.1.4.3')  )
      ```
43. **SHOULD** satisfy: The name and strength of the medication is recorded in consumable/manufacturedProduct/manufacturedMaterial/code/originalText
    - ```
      [OCL]: not
       self.consumable.manufacturedProduct.manufacturedMaterial.code.oclIsUndefined()
       implies not
       self.consumable.manufacturedProduct.manufacturedMaterial.code.originalText.oclIsUnd
      ```
44. **SHALL** satisfy: Name of the substance or product is recorded in consumable/manufacturedProduct/manufacturedMaterial/name
    - ```
      [OCL]: not
       self.consumable.manufacturedProduct.manufacturedMaterial.name.oclIsUndefined()
      ```
      ```

45. **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.
    - `[OCL]: not self.precondition.criterion.text->exists (t | t.reference.oclIsUndefined())`
46. **SHALL** satisfy: The entryRelationship/@inversionInd attribute is 'false' for Supply Entry relationship
    - `[OCL]: not self.entryRelationship->exists(er : cda::EntryRelationship | (not er.supply->isEmpty()) and er.inversionInd<>false )`
47. **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.
    - `[OCL]: not self.entryRelationship->exists(er| (not er.supply->isEmpty()) and er.sequenceNumber.value.oclIsUndefined() )`
48. **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)
49. **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
50. 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])
    - `[OCL]: self.effectiveTime->exists (ef : datatypes::SXCM_TS | not ef.oclIsUndefined())`
51. 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])
52. 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)
53. 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)
54. 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])
    - `[OCL]: self.doseQuantity->exists(dq : datatypes::IVL_PQ | dq.unit='2.16.840.1.113883.3.88.12.80.29')`
55. 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])

56. 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])

- `[OCL]: not self.code.originalText.oclIsUndefined()`

57. **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.

- `[OCL]: self.consumable.manufacturedProduct->exists(mp : cda::ManufacturedProduct | mp.oclIsKindOf(hitsp::MedicationInformation))`

58. 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
- `[OCL]: self.getObservations()->exists(po : cda::Observation | po.oclIsKindOf(ccd::MedicationStatusObservation))`

59. [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
- `[OCL]: self.getObservations()->exists(po : cda::Observation | po.oclIsKindOf(ccd::ProblemObservation))`

60. 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])

- `[OCL]: self.getObservations()->exists(po : cda::Observation | po.oclIsKindOf(ccd::ProblemObservation) and not po.text.reference.oclIsUndefined())`

61. 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])

- `[OCL]: self.getObservations()->exists(po : cda::Observation | po.oclIsKindOf(ccd::ProblemObservation) and po.code.codeSystem = '2.16.840.1.113883.3.88.12.3221.7.4')`

62. 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.

- `[OCL]: self.getActs()->exists(po : cda::Act | po.oclIsKindOf(ihe::PatientMedicalInstructions))`

63. 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"
- `[OCL]: self.getSubstanceAdministrations()->exists(sa : cda::SubstanceAdministration | sa.participant.participantRole->size() > 0)`

64. The typeCode attribute of the <participant> element **SHALL** be CSM (C83-[DE-8.24-CDA-2])

- `[OCL]: self.getSubstanceAdministrations()->exists(sa : cda::SubstanceAdministration | sa.participant->exists(par : cda::Participant2 | par.typeCode = vocab::ParticipationType::CSM))`

65. The classCode of the <participantRole> **SHALL** be MANU (C83-[DE-8.24-CDA-3])

- ```
  [OCL]: self.getSubstanceAdministrations()->exists(sa :
   cda::SubstanceAdministration | sa.participant->exists(par :
   cda::Participant2 | par.typeCode = vocab::ParticipationType::CSM and
   par.participantRole->exists(pr : cda::ParticipantRole | pr.classCode =
   vocab::RoleClassRoot::MANU)))
  ```

66. 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])

- ```
  [OCL]: self.getSubstanceAdministrations()->exists(sa :
   cda::SubstanceAdministration | sa.participant->exists(par :
   cda::Participant2 | par.typeCode = vocab::ParticipationType::CSM and
   par.participantRole->exists(pr : cda::ParticipantRole | pr.classCode
   = vocab::RoleClassRoot::MANU and pr.code.code = '412307009' and
   pr.code.codeSystem = '2.16.840.1.113883.6.96')))
  ```

67. The <name> element in the <playingEntity> element **SHALL** record the name of the drug vehicle (C83-[DE-8.24-CDA-5])

- ```
  [OCL]: self.getSubstanceAdministrations()->exists(sa :
   cda::SubstanceAdministration | sa.participant->exists(par :
   cda::Participant2 | par.typeCode = vocab::ParticipationType::CSM and
   par.participantRole->exists(pr : cda::ParticipantRole | pr.classCode
   = vocab::RoleClassRoot::MANU and pr.code.code = '412307009' and
   pr.code.codeSystem = '2.16.840.1.113883.6.96' and pr.playingEntity.name-
  >size() > 0)))
  ```

68. 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])

- ```
  [OCL]: self.getSubstanceAdministrations()->exists(sa :
   cda::SubstanceAdministration | sa.participant->exists(par :
   cda::Participant2 | par.typeCode =vocab::ParticipationType::CSM and
   par.participantRole->exists(pr : cda::ParticipantRole | pr.classCode
   = vocab::RoleClassRoot::MANU and pr.code.code = '412307009' and
   pr.code.codeSystem = '2.16.840.1.113883.6.96' and pr.playingEntity.code-
  >size() > 0)))
  ```

69. **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])

- ```
  [OCL]: self.getSubstanceAdministrations()->exists(sa :
   cda::SubstanceAdministration | sa.participant->exists(par :
   cda::Participant2 | par.typeCode = vocab::ParticipationType::CSM
   and par.participantRole->exists(pr : cda::ParticipantRole |
   pr.classCode = vocab::RoleClassRoot::MANU and pr.code.code =
   '412307009' and pr.code.codeSystem = '2.16.840.1.113883.6.96' and
   pr.playingEntity.code->size() > 0 and pr.playingEntity.code.codeSystem =
   '2.16.840.1.113883.3.88.12.80.21')))
  ```

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`**, where its data type is ActClassObservation
2. Contains exactly one [1..1] **`@moodCode`**, where its data type is x_ActMoodDocumentObservation
3. **SHALL** contain exactly one [1..1] **`code`**, which **SHALL** be selected from ValueSet **STATIC** (C83-[DE-8.19-CDA-5], C154-[DE-8.19-1])

Medication Type example
  ```

Procedure

[Procedure: templateId `2.16.840.1.113883.3.88.11.83.17`]

Defines a coded entry describing a procedure performed on a patient.

1. **SHALL** conform to *IHE Procedure Entry* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.19`)
2. Contains exactly one [1..1] **`@classCode`**, where its data type is ActClass
3. Contains exactly one [1..1] **`@moodCode`**, where its data type is x_DocumentProcedureMood
4. **SHOULD** contain exactly one [1..1] **`code`** (CONF-433)
5. **SHOULD** contain exactly one [1..1] **`targetSiteCode`**, which **SHOULD** be selected from ValueSet **STATIC** (C83-[DE-17-CDA-3])
   - The anatomical site where a procedure is performed
6. **SHALL** satisfy: The code/originalText/reference/@value is present.
   - Free text describing the Procedure
   - `[OCL]: not self.code.originalText.reference.value.oclIsUndefined()`
7. **SHOULD** satisfy: Contains the procedure provider in performer / assignedEntity.
   - Name and other information for the person or organization performed or hosted the Procedure
   - `[OCL]: self.performer->forAll(perf : cda::Performer2 | not perf.oclIsUndefined() and perf.assignedEntity->size() > 0)`

Procedure example

Result

[Observation: templateId `2.16.840.1.113883.3.88.11.83.15`]

This clinical statement represents details of a lab, radiology, or other study performed on a patient. The scope of result observations is broad with the exception of "vital signs" which are contained in the Vital Signs section.

1. **SHALL** conform to *IHE Simple Observation* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.13`)
2. **SHALL** conform to *CCD Result Observation* template (templateId: `2.16.840.1.113883.10.20.1.31`)
3. Contains exactly one [1..1] **`@classCode`**, where its data type is ActClassObservation
4. **SHALL** contain exactly one [1..1] **`@moodCode="EVN"`** *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF-408)
5. **SHALL** contain at least one [1..*] **`id`** (CONF-409)
6. **SHALL** contain exactly one [1..1] **`statusCode`** (CONF-410)
7. **SHALL** contain exactly one [1..1] **`code`**
   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])
      - `[OCL]: self.code.codeSystem = '2.16.840.1.113883.6.1' or self.code.codeSystem = '2.16.840.1.113883.6.96'`
   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])
      - `[OCL]: self.code.codeSystem = '2.16.840.1.113883.6.1'`
8. **SHALL** contain exactly one [1..1] **`effectiveTime`**
   - Represents clinically effective time of the measurement, which may be when the measurement was performed (e.g., a BP measurement), or may be when sample was taken (and measured some time afterwards).
9. **SHALL** contain exactly one [1..1] **`value`**

   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])
      - `[OCL]: (self.moodCode = vocab::x_ActMoodDocumentObservation::EVN or self.moodCode = vocab::x_ActMoodDocumentObservation::EVN) implies (not self.value->isEmpty()) and (self.moodCode = vocab::x_ActMoodDocumentObservation::INT or self.moodCode = vocab::x_ActMoodDocumentObservation::PRP) implies (self.value->isEmpty())`
   - The Result value records the desired result in a goal or recorded event, and will not be present when recording an intent, request or proposal to measure a result.
10. **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.
11. **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.
12. 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)
   - `[OCL]: self.code.codeSystem = '2.16.840.1.113883.6.1' xor self.code.codeSystem = '2.16.840.1.113883.6.96' xor self.code.codeSystem = '2.16.840.1.113883.6.12'`
13. The methodCode **SHALL NOT** conflict with the method inherent in code (CONF-415)
14. 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)
15. **SHOULD** satisfy: Contain one or more referenceRange to show the normal range of values for the observation result (CONF-419)
   - `[OCL]: not self.referenceRange->isEmpty()`
16. **SHALL NOT** contain referenceRange / observationRange / code, as this attribute is not used by the HL7 Clinical Statement or Lab Committee models. (CONF-420)
   - `[OCL]: self.referenceRange->forAll(range : cda::ReferenceRange | range.observationRange.code.code.oclIsUndefined())`
17. **SHALL** satisfy: Contains one or more sources of information. (CONF-421)
   - `[OCL]: not self.informant->isEmpty() or not self.getSection().informant->isEmpty() or not self.getClinicalDocument().informant->isEmpty() or self.reference->exists(ref : cda::Reference | ref.typeCode = vocab::x_ActRelationshipExternalReference::XCRPT) or (self.entryRelationship->exists(rel : cda::EntryRelationship | rel.typeCode = vocab::x_ActRelationshipEntryRelationship::REFR and rel.observation.code.code = '48766-0'))`
18. 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])
   - `[OCL]: self.code.codeSystem = '2.16.840.1.113883.6.1' or self.code.codeSystem = '2.16.840.1.113883.6.96'`
19. 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])
   - `[OCL]: self.code.codeSystem = '2.16.840.1.113883.6.1'`
20. 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])
   - `[OCL]: (self.moodCode = vocab::x_ActMoodDocumentObservation::EVN or self.moodCode = vocab::x_ActMoodDocumentObservation::EVN)`

```
    implies (not self.value->isEmpty()) and
  (self.moodCode = vocab::x_ActMoodDocumentObservation::INT or
self.moodCode = vocab::x_ActMoodDocumentObservation::PRP)
  implies (self.value->isEmpty())
```

Result example

Social History

[Observation: templateId `2.16.840.1.113883.10.20.1.33`]

1. **SHALL** conform to *CCD Social History Observation* template (templateId: `2.16.840.1.113883.10.20.1.33`)
2. **SHALL** conform to *IHE Simple Observation* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.13`)
3. **SHALL** conform to *IHE Social History Observation* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.13.4`)
4. Contains exactly one [1..1] **`@classCode`**, where its data type is ActClassObservation
5. Contains exactly one [1..1] **`@moodCode`**, where its data type is x_ActMoodDocumentObservation
6. **SHALL** contain at least one [1..*] **`id`**
7. **SHALL** contain exactly one [1..1] **`statusCode/@code`**`="completed"` (CodeSystem:)
8. **SHOULD** contain zero or more [0..*] **`code`**, which **SHOULD** be selected from ValueSet **STATIC**
9. **SHALL** contain exactly one [1..1] **`text`**
10. **SHOULD** contain zero or one [0..1] **`effectiveTime`**
11. **MAY** contain zero or more [0..*] **`value`**
    - The data type to use for each observation should be drawn from the table below. Observations in the table above using the PQ data type have a unit in the form {xxx}/d, {xxx}/wk or {xxx}/a represent the number of items per day, week or year respectively. The value attribute indicates the number of times of the act performed, and the units represent the frequency.

      229819007 Smoking PQ {pack}/d or {pack}/wk or {pack}/a 256235009 Exercise PQ {times}/wk 160573003 ETOH (Alcohol) Use PQ {drink}/d or {drink}/wk 364393001 Diet CD N/A 364703007 Employment CD N/A 425400000 Toxic Exposure CD N/A 363908000 Drug Use CD N/A 228272008 Other Social History ANY N/A
12. **MAY** contain zero or one [0..1] **`entryRelationship`**, such that
    a. Contains exactly one [1..1] *Social History Status Observation* (templateId: `2.16.840.1.113883.10.20.1.56`)
13. **MAY** contain zero or one [0..1] **`entryRelationship`**, such that
    a. Contains exactly one [1..1] *Episode Observation* (templateId: `2.16.840.1.113883.10.20.1.41`)
14. The value for Observation / code in a social history observation **SHOULD** be selected from LOINC (codeSystem 2.16.840.1.113883.6.1) or SNOMED CT (codeSystem 2.16.840.1.113883.6.96), or **MAY** be selected from ValueSet 2.16.840.1.113883.1.11.20.18 SocialHistoryTypeCode STATIC 20061017
15. Observation / value can be any datatype. Where Observation / value is a physical quantity, the unit of measure **SHALL** be expressed using a valid Unified Code for Units of Measure (UCUM) expression
16. **SHALL** satisfy: Contains one or more sources of information
17. **SHOULD** satisfy: The <repeatNumber> element should not be used in a social history observation
18. **SHOULD** satisfy: The <interpretationCode> element should not be used in a social history observation
19. **SHOULD** satisfy: The <methodCode> element should not be used in a social history observation
20. **SHOULD** satisfy: The <targetSiteCode> element should not be used in a social history observation

Social History example

Vital Sign

[Observation: templateId `2.16.840.1.113883.3.88.11.83.14`]

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 *IHE Simple Observation* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.13`)
2. **SHALL** conform to *CCD Result Observation* template (templateId: `2.16.840.1.113883.10.20.1.31`)
3. **SHALL** conform to *IHE Vital Sign Observation* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.13.2`)
4. Contains exactly one [1..1] **`@classCode`**, where its data type is ActClassObservation
5. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF-408)
6. **SHALL** contain at least one [1..*] **`id`** (CONF-409)
7. **SHALL** contain exactly one [1..1] **`statusCode`** (CONF-410)
8. **SHALL** contain exactly one [1..1] **`code`**, which **SHALL** be selected from ValueSet **STATIC** (C154-[DE-14.03-1])
9. **SHOULD** contain exactly one [1..1] **`effectiveTime`** (CONF-411)
   - Represents the biologically relevant time (e.g. time the specimen was obtained from the patient).
10. **SHALL** contain exactly one [1..1] **`value`**, where its data type is PQ (6.3.4.22.4)
11. **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).
12. **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.
13. **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).
14. 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)
    - `[OCL]: self.code.codeSystem = '2.16.840.1.113883.6.1' xor self.code.codeSystem = '2.16.840.1.113883.6.96' xor self.code.codeSystem = '2.16.840.1.113883.6.12'`
15. The methodCode **SHALL NOT** conflict with the method inherent in code (CONF-415)
16. 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)
17. **SHOULD** satisfy: Contain one or more referenceRange to show the normal range of values for the observation result (CONF-419)
    - `[OCL]: not self.referenceRange->isEmpty()`
18. **SHALL NOT** contain referenceRange / observationRange / code, as this attribute is not used by the HL7 Clinical Statement or Lab Committee models. (CONF-420)
    - `[OCL]: self.referenceRange->forAll(range : cda::ReferenceRange | range.observationRange.code.code.oclIsUndefined())`
19. **SHALL** satisfy: Contains one or more sources of information. (CONF-421)
    - `[OCL]: not self.informant->isEmpty()`

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

20. **SHALL** satisfy: Data Element Definitions for Results [Placeholder]

- Vital Signs are a subset of Results Section, but are reported in this section to follow clinical conventions.

Vital Sign example

Chapter 5

OTHER CLASSES

Topics:

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

Healthcare Provider

[Performer1: templateId `2.16.840.1.113883.3.88.11.83.4`]

1. **SHALL** conform to *IHE Healthcare Providers Pharmacies* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.2.3`)
2. Contains exactly one [1..1] **`@typeCode`**, where its data type is x_ServiceEventPerformer
3. Contains exactly one [1..1] **`assignedEntity`**, where its type is *Assigned Entity*

Healthcare Provider example

Language Spoken

[LanguageCommunication: templateId `2.16.840.1.113883.3.88.11.83.2`]

1. **SHALL** conform to *IHE Language Communication* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.2.1`)
2. **SHALL** contain exactly one [1..1] **`languageCode`**, which **SHALL** be selected from ValueSet **STATIC** (C154-[DE-2.01-1])
3. **SHALL** contain zero or one [0..1] **`modeCode`**, which **SHALL** be selected from ValueSet **STATIC** (C83-[DE-2.01-CDA-4])
   - Mode codes SHALL be appropriate to the type of language. Thus English, as spoken in the U.S. SHOULD use the code en-US and SHOULD only use mode codes for written and verbal communications. On the other hand, American Sign Language would be represented using the code sign-US, and would only use mode codes for signed communication.
4. **SHALL** satisfy: Languages spoken shall be recorded using the <languageCommunication> infrastructure class associated with the patient. The <languageCommunication> element describes the primary and secondary languages of communication for a person. (C83-[DE-2.01-CDA-1])
5. **SHALL** satisfy: Sign language is treated as a separate language. (C154-[DE-2.01-2])
6. CDA allows for use of proficiencyLevelCode element, but this element **SHOULD NOT** be used. (C83-[DE-2.01-CDA-5])
   - Judgments about language proficiency are subjective, and could have a negative impact on consumers.
   - `[OCL]: self.proficiencyLevelCode.oclIsUndefined()`

Language Spoken example

Medication Information

[ManufacturedProduct: templateId `2.16.840.1.113883.3.88.11.83.8.2`]

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. **SHALL** conform to *CCD Product* template (templateId: `2.16.840.1.113883.10.20.1.53`)
2. **SHALL** conform to *IHE Product Entry* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.7.2`)
3. **MAY** contain at least one [1..*] **`id`** (CONF-366)
   - uniquely represents a particular kind of product
4. **SHALL** satisfy: Contain exactly one manufacturedMaterial. (CONF-357)
   - `[OCL]: not self.manufacturedMaterial.oclIsUndefined()`

5. **SHALL** satisfy: Contain exactly one manufacturedMaterial / code. (CONF-358)
   - `[OCL]: not self.manufacturedMaterial.code.oclIsUndefined()`
6. 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)
   - `[OCL]: self.manufacturedMaterial.code.codeSystem = '2.16.840.1.113883.6.88' or self.manufacturedMaterial.code.codeSystem='2.16.840.1.113883.6.59' or self.manufacturedMaterial.code.codeSystem='2.16.840.1.113883.1.11.20.8'`
7. 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)
8. 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)
9. 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)
10. **SHALL** satisfy: A manufacturedMaterial in a product template contains exactly one code / originalText, which represents the generic name of the product. (CONF-363)
    - `[OCL]: not self.manufacturedMaterial.code.originalText.oclIsUndefined()`
11. **MAY** satisfy: A manufacturedMaterial in a product template contains exactly one name, which represents the brand name of the product. (CONF-364)
    - `[OCL]: not self.manufacturedMaterial.name.oclIsUndefined()`
12. **MAY** satisfy: contains exactly one manufacturedProduct / manufacturerOrganization, which represents the manufacturer of the Material. (CONF-365)
    - `[OCL]: self.manufacturerOrganization->size() = 1`
13. If ManufacturedProduct in a product template contains manufacturedProduct / id, then ManufacturedProduct **SHOULD** also contain manufacturedProduct / manufacturerOrganization. (CONF-367)
    - `[OCL]: self.id->size() > 0 implies self.manufacturerOrganization->size() > 0`
14. 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
    - `[OCL]: not self.manufacturedMaterial.code.code.oclIsUndefined()`
15. If the code for the generic product is unknown, the code and codeSystem attributes **MAY** be omitted (C83-[DE-8.13-CDA-2])
16. 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])
    - `[OCL]: self.manufacturedMaterial.code.codeSystem = '2.16.840.1.113883.3.88.12.80.17'`
17. 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])
    - `[OCL]: self.manufacturedMaterial.code.codeSystem = '2.16.840.1.113883.3.88.12.80.18'`
18. 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])
    - `[OCL]: self.manufacturedMaterial.code.codeSystem = '2.16.840.1.113883.3.88.12.80.20'`

19. 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
    - `[OCL]: self.manufacturedMaterial.code.translation->size() > 0`
20. 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])
    - `[OCL]: self.manufacturedMaterial.code.codeSystem = '2.16.840.1.113883.3.88.12.80.16'`
21. 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
    - `[OCL]: not self.manufacturedMaterial.code.originalText.oclIsUndefined()`
22. 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
    - `[OCL]: not self.manufacturedMaterial.name.oclIsUndefined()`

Medication Information example

Support

At a minimum, key support contacts relative to healthcare decisions, including next of kin, should be included. If no healthcare providers are supplied, the reason should be supplied as free text in the narrative block (e.g., Unknown, etc).

1. **SHALL** conform to *CCD Support*
2. **SHALL** conform to *IHE Patient Contact*
3.

Support example

Support Guardian

[Guardian: templateId `2.16.840.1.113883.3.88.11.83.3`]

At a minimum, key support contacts relative to healthcare decisions, including next of kin, should be included. If no healthcare providers are supplied, the reason should be supplied as free text in the narrative block (e.g., Unknown, etc).

1. **SHALL** conform to *Support*
2. **SHALL** conform to *IHE Patient Contact*
3. **SHALL** conform to *CCD Support*
4. **SHALL** conform to *CCD Support Guardian*
5. **SHALL** conform to *IHE Patient Contact Guardian* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.2.4`)
6. **SHALL** contain exactly one [1..1] **`@classCode`**`="GUAR"`
7. **SHALL** contain zero or one [0..1] **`code`** (CodeSystem: `2.16.840.1.113883.5.111 RoleCode`)

8. **SHOULD** contain zero or more [0..*] **`addr`**
9. **SHOULD** contain zero or more [0..*] **`telecom`**

Support Guardian example

Support Participant

[Participant1: templateId `2.16.840.1.113883.3.88.11.83.3`]

At a minimum, key support contacts relative to healthcare decisions, including next of kin, should be included. If no healthcare providers are supplied, the reason should be supplied as free text in the narrative block (e.g., Unknown, etc).

1. **SHALL** conform to *Support*
2. **SHALL** conform to *IHE Patient Contact*
3. **SHALL** conform to *CCD Support*
4. **SHALL** conform to *CCD Support Participant*
5. **SHALL** conform to *IHE Patient Contact Participant* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.2.4`)
6. **SHALL** contain exactly one [1..1] **`@typeCode`**`="IND"`
7. **MAY** contain zero or one [0..1] **`time`**
   - Indicates the time of the participation.
8. Contains exactly one [1..1] **`associatedEntity`**, where its type is *Associated Entity*

Support Participant example

Chapter 6

VALUE SETS

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

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* .
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- 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*