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

Chapter 4: CLINICAL STATEMENT TEMPLATES............................. 63

Chapter 5: OTHER CLASSES...99

Chapter 6: VALUE SETS... 103

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*
- *Approach*
- *Scope*
- *Audience*
- *Organization of This Guide*
- *Use of Templates*
- *Conventions Used in This Guide*

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 `templateIds` 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 `templateIds`).

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:

- *Patient Summary*
- *Unstructured Document*

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

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 *CDA Clinical Document*
3. **SHALL** conform to *CDT General Header Constraints* template (templateId: `2.16.840.1.113883.10.20.3`)
4. **SHALL** conform to *IHE Medical Document* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.1.1`)
5. [CCD] **SHOULD** contain [1..1] component, such that it
   a. contains *CCD Problem Section* (templateId: `2.16.840.1.113883.10.20.1.11`)
   (CONF-140)
6. [CCD] **SHOULD** contain [1..1] component, such that it
   a. contains *CCD Family History Section* (templateId: `2.16.840.1.113883.10.20.1.4`)
7. [CCD] **SHOULD** contain [1..1] component, such that it
   a. contains *CCD Social History Section* (templateId: `2.16.840.1.113883.10.20.1.15`)
8. [CCD] **SHOULD** contain [1..1] component, such that it
   a. contains *CCD Alerts Section* (templateId: `2.16.840.1.113883.10.20.1.2`)
9. [HITSP] **MAY** contain [0..1] component, such that it
   a. contains *Medications Section* (templateId: `2.16.840.1.113883.3.88.11.83.112`)
   (C32-[CT1-11])
10. [CCD] **SHOULD** contain [1..1] component, such that it
    a. contains *CCD Results Section* (templateId: `2.16.840.1.113883.10.20.1.14`)
    (CONF-388)
11. [CCD] **SHOULD** contain [1..1] component, such that it
    a. contains *CCD Procedures Section* (templateId: `2.16.840.1.113883.10.20.1.12`)
12. [HITSP] **MAY** contain [0..1] component, such that it
    a. contains *Encounters Section* (templateId: `2.16.840.1.113883.3.88.11.83.127`)
    (C32-[CT1-5])
13. [HITSP] **MAY** contain [0..1] component, such that it
    a. contains *Plan Of Care Section* (templateId: `2.16.840.1.113883.3.88.11.83.124`)
    (C32-[CT1-13])
14. [HITSP] **MAY** contain [0..1] component, such that it
    a. contains *Immunizations Section* (templateId: `2.16.840.1.113883.3.88.11.83.117`)
    (C32-[CT1-7])
15. [HITSP] **MAY** contain [0..1] component, such that it
    a. contains *Vital Signs Section* (templateId: `2.16.840.1.113883.3.88.11.83.119`)
    (C32-[CT1-17])
16. [CCD] **SHOULD** contain [1..1] component, such that it

    a. contains *CCD Medical Equipment Section* (templateId: `2.16.840.1.113883.10.20.1.7`)

17. [CCD] **SHOULD** contain [1..1] `component`, such that it

    a. contains *CCD Functional Status Section* (templateId: `2.16.840.1.113883.10.20.1.5`)

18. [HITSP] **MAY** contain [0..1] `component`, such that it

    a. contains *Advance Directives Section* (templateId: `2.16.840.1.113883.3.88.11.83.116`)

    (C32-[CT1-1])

19. [HITSP] **MAY** contain [0..1] `component`, such that it

    a. contains *Payers Section* (templateId: `2.16.840.1.113883.3.88.11.83.101`)

    (C32-[CT1-9])

20. [CDT] **SHALL** contain [1..1] `code`

    • Specifies the type of the clinical document.

    (CONF-HP-21)

21. [CDT] **SHALL** contain [1..1] `languageCode` (CONF-HP-24)

22. [CCD] **MAY** contain [1..1] `component`, such that it

    a. contains *CCD Purpose Section* (templateId: `2.16.840.1.113883.10.20.1.13`)

    (CONF-15)

23. [CDT] **SHALL** contain [1..1] `id`

    • 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.

    (CONF-HP-17)

24. [CDT] **SHALL** contain [1..1] `effectiveTime`

    • 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.

    (CONF-HP-23)

25. [CDT] Contains [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.

26. [CDT] Contains [1..*] `author`, such that it

    a. contains *CDA Author*

    • The author element represents the creator of the clinical document. If the role of the actor is the entry of information from his or her own knowledge or application of skills, that actor is the author. If one actor provides information to another actor who filters, reasons, or algorithmically creates new information, then that second actor is also an author, having created information from his or her own knowledge or skills. However, that determination is independent from the determination of the first actor's authorship.

27. [CDT] Contains [1..1] `custodian`, such that it

    a. contains *CDA Custodian*

    • Based on the CDA R2 constraints (Section 4.2.2.3 of the CDA Normative Web Edition. See Section 5 REFERENCES), the custodian element is required and is the custodian of the clinical document.

28. [CDA] Contains [1..1] `component`, where its type is *CDA Component2*

29. [CDT] **SHALL** contain [1..1] `realmCode/@code` = "US" (CONF-HP-15)

30. [CDT] **SHALL** contain [1..1] `title`

- 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.

(CONF-HP-22)

31. [CDT] **SHALL** contain [1..1] `typeId`

- The clinical document type ID identifies the constraints imposed by CDA R2 on the content, essentially acting as a version identifier.

(CONF-HP-16)

32. [CDT] Contains [0..1] `dataEnterer`, such that it

   a. contains *CDA Data Enterer*

- The dataEnterer element represents the person who transferred the information from other sources into the clinical document, where the other sources wrote the content of the note. The guiding rule of thumb is that an author provides the content found within the header or body of the document, subject to their own interpretation. The dataEnterer adds information to the electronic system. A person can participate as both author and dataEnterer.

   If the role of the actor is to transfer information from one source to another (e.g., transcription or transfer from paper form to electronic system), that actor is considered a dataEnterer.

33. [CDT] Contains [0..*] `informationRecipient`, such that it

   a. contains *CDA Information Recipient*

- informationRecipient, when used in the context of a referral or request for consultation, this records the intended recipient of the information at the time the document is created. The intended recipient may also be the health chart of the patient, in which case the receivedOrganization is the scoping organization of that chart.

34. [CDT] Contains [0..1] `legalAuthenticator`, such that it

   a. contains *CDA Legal Authenticator*

- The legalAuthenticator element identifies the legal authenticator of the document and must be present if the document has been legally authenticated. Based on local practice, clinical documents may be released before legal authentication. This implies that a clinical document that does not contain this element has not been legally authenticated.

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

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

35. [CDT] Contains [0..*] `authenticator`, such that it

   a. contains *CDA Authenticator*

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

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

36. [HITSP] **MAY** contain [0..1] `component`, such that it

   a. contains *Allergies Reactions Section* (templateId: `2.16.840.1.113883.3.88.11.83.102`)

(C32-[CT1-2])

37. [HITSP] **MAY** contain [0..*] `component`, such that it

   a. contains *Comment* (templateId: `2.16.840.1.113883.3.88.11.83.11`)

(C32-[CT1-3])

38. [HITSP] **MAY** contain [0..1] `component`, such that it

  a. contains *Problem List Section* (templateId: `2.16.840.1.113883.3.88.11.83.103`)

  (C32-[CT1-4])

39. [HITSP] **MAY** contain [0..1] `component`, such that it

  a. contains *IHE Pregnancy History Section* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.1.5.3.4`)

  (C32-[CT1-14])

40. [HITSP] **MAY** contain [0..1] `component`, such that it

  a. contains *Surgeries Section* (templateId: `2.16.840.1.113883.3.88.11.83.108`)

  (C32-[CT1-15])

41. [HITSP] **SHOULD** contain [1..*] `supportHeaders`, such that it

  a. contains *Support*

  (C32-[CT1-16])

42. [HITSP] **MAY** contain [0..1] `component`, such that it

  a. contains *Diagnostic Results Section* (templateId: `2.16.840.1.113883.3.88.11.83.122`)

  (C32-[CT1-18])

43. [CCD] **SHALL** satisfy: Contains exactly one documentationOf / serviceEvent (CONF-2)

  - `[OCL]: self.documentationOf->one(doc : cda::DocumentationOf | not doc.serviceEvent.oclIsUndefined())`

44. [CCD] **SHALL** satisfy: documentationOf / serviceEvent / @classCode SHALL be 'PCPR' (CONF-3)

  - `[OCL]: self.documentationOf->one(doc : cda::DocumentationOf | doc.serviceEvent.classCode = vocab::ActClassRoot::PCPR)`

45. [CCD] **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())`

46. [CCD] **SHALL** satisfy: 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)

47. [CCD] **SHALL** satisfy: 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())`

48. [CCD] **SHALL** satisfy: effectiveTime is expressed with precision to include seconds (CONF-9)

49. [CCD] **SHALL** satisfy: effectiveTime includes an explicit time zone offset (CONF-10)

50. [CCD] **SHALL** satisfy: Contains one or two recordTarget (CONF-11)

  - `[OCL]: self.recordTarget->size() = 1 or self.recordTarget->size() =2`

51. [CCD] **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())`

52. [CCD] **SHALL** satisfy: 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))
```

53. [CCD] **MAY** satisfy: Contains one or more informationRecipient (CONF-14)

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

54. [CCD] **MAY** satisfy: 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)

55. [CCD] **SHOULD** satisfy: 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)

56. [CDT] **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]`

57. [CDT] **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]`

58. [CDT] **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]`

59. [CDT] **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]`

60. [CDT] **SHALL** satisfy: 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`

61. [CDT] **SHALL** satisfy: 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))
```

62. [CDT] **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]`

63. [CDT] **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]`

64. [CDT] **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]`

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

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

66. [CDT] **SHALL** satisfy: The id/@root attribute is a syntactically correct UUID or OID. (CONF-HP-17)

67. [CDT] **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)

68. [CDT] **SHALL** satisfy: 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.

69. [CDT] **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 )`

70. [CDT] **SHALL** satisfy: languageCode has the form nn, or nn-CC. (CONF-HP-25)

71. [CDT] **SHALL** satisfy: The nn portion of languageCode is a legal ISO-639-1 language code in lowercase. (CONF-HP-26)

72. [CDT] **SHALL** satisfy: The CC portion languageCode, if present, SHALL be an ISO-3166 country code in uppercase. (CONF-HP-27)

73. [CDT] **SHALL** satisfy: 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())`

74. [CDT] **SHALL** satisfy: 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)`

75. [CDT] **SHALL** satisfy: A copyTime element SHALL NOT be present. (CONF-HP-30)

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

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

76. [CDT] **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())
  ```

77. [CDT] **SHALL** satisfy: 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()))
  ```

78. [CDT] **SHALL** satisfy: 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()))
  ```

79. [CDT] **MAY** satisfy: 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)

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

81. [CDT] **MAY** satisfy: The providerOrganization element is present. (CONF-HP-36)

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

82. [CDT] **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())
  ```

83. [CDT] **SHALL** satisfy: The assignedAuthor/id element is present. (CONF-HP-38)

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

84. [CDT] **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())
  ```

85. [CDT] **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()
  ```

86. [CDT] **MAY** satisfy: 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()`

87. [CDT] **MAY** satisfy: The informant element is present. (CONF-HP-42)

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

88. [CDT] **SHALL** satisfy: 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())`

89. [CDT] **SHALL** satisfy: 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

90. [CDT] **SHALL** satisfy: 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.

91. [CDT] **SHALL** satisfy: 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)

92. [CDT] **SHALL** satisfy: 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.

93. [CDT] **SHALL** satisfy: 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.

94. [CDT] **SHOULD** satisfy: 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)

95. [CDT] **MAY** satisfy: 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)

96. [CDT] **SHALL** satisfy: The assignedEntity/assignedPerson element SHALL be present in legalAuthenticator. (CONF-HP-51)

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

97. [CDT] **SHALL** satisfy: 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()))`

98. [CDT] **SHOULD** satisfy: 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`

99. [CDT] **SHOULD** satisfy: 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 constraitn
- ```
  [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))
  ```

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

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

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

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

```xml
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <realmCode code="US"/>
  <templateId root="2.16.840.1.113883.10.20.1" assigningAuthorityName="CCD
 Continuity Of Care Document"/>
```

```
 <templateId root="2.16.840.1.113883.10.20.3" assigningAuthorityName="CDT
General Header Constraints"/>
 <templateId root="1.3.6.1.4.1.19376.1.5.3.1.1.1" assigningAuthorityName="IHE
Medical Document"/>
 <templateId root="2.16.840.1.113883.3.88.11.32.1"
assigningAuthorityName="HITSP Patient Summary"/>
 <id root="69c4cc4c-ac90-4722-88e9-25fd08d9d3c1"/>
 <code code="34133-9" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Summarization of episode note"/>
 <title/>
 <effectiveTime/>
 <confidentialityCode/>
 <languageCode/>
 <component>
   <structuredBody>
     <component>
       <section>
         <templateId root="2.16.840.1.113883.10.20.1.1"
assigningAuthorityName="CCD Advance Directives Section"/>
         <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.34"
assigningAuthorityName="IHE Advance Directives Section"/>
         <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.35"
assigningAuthorityName="IHE Coded Advance Directives Section"/>
         <templateId root="2.16.840.1.113883.3.88.11.83.116"
assigningAuthorityName="HITSP Advance Directives Section"/>
         <code code="42348-3" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Advance directives"/>
         <title>Advance directives</title>
       </section>
     </component>
     <component>
       <section>
         <templateId root="2.16.840.1.113883.10.20.1.2"
assigningAuthorityName="CCD Alerts Section"/>
         <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.13"
assigningAuthorityName="IHE Allergies Reactions Section"/>
         <templateId root="2.16.840.1.113883.3.88.11.83.102"
assigningAuthorityName="HITSP Allergies Reactions Section"/>
         <code code="48765-2" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Allergies, adverse reactions, alerts"/>
         <title>Allergies, adverse reactions, alerts</title>
       </section>
     </component>
     <component>
       <section>
         <templateId root="2.16.840.1.113883.10.20.1.11"
assigningAuthorityName="CCD Problem Section"/>
         <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.6"
assigningAuthorityName="IHE Active Problems Section"/>
         <templateId root="2.16.840.1.113883.3.88.11.83.103"
assigningAuthorityName="HITSP Problem List Section"/>
         <code code="11450-4" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Problem list"/>
         <title>Problem list</title>
       </section>
     </component>
     <component>
       <section>
         <templateId root="2.16.840.1.113883.10.20.1.3"
assigningAuthorityName="CCD Encounters Section"/>
         <templateId root="1.3.6.1.4.1.19376.1.5.3.1.1.5.3.3"
assigningAuthorityName="IHE Encounter History Section"/>
         <templateId root="2.16.840.1.113883.3.88.11.83.127"
assigningAuthorityName="HITSP Encounters Section"/>
```

```
        <code code="46240-8" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="History of encounters"/>
          <title>History of encounters</title>
        </section>
      </component>
      <component>
        <section>
          <templateId root="2.16.840.1.113883.10.20.1.6"
assigningAuthorityName="CCD Immunizations Section"/>
          <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.23"
assigningAuthorityName="IHE Immunizations Section"/>
          <templateId root="2.16.840.1.113883.3.88.11.83.117"
assigningAuthorityName="HITSP Immunizations Section"/>
          <code code="11369-6" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="History of immunizations"/>
          <title>History of immunizations</title>
        </section>
      </component>
      <component>
        <section>
          <templateId root="2.16.840.1.113883.10.20.1.9"
assigningAuthorityName="CCD Payers Section"/>
          <templateId root="1.3.6.1.4.1.19376.1.5.3.1.1.5.3.7"
assigningAuthorityName="IHE Payers Section"/>
          <templateId root="2.16.840.1.113883.3.88.11.83.101"
assigningAuthorityName="HITSP Payers Section"/>
          <code code="48768-6" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Payment sources"/>
          <title>Payment sources</title>
        </section>
      </component>
      <component>
        <section>
          <templateId root="2.16.840.1.113883.10.20.1.8"
assigningAuthorityName="CCD Medications Section"/>
          <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.19"
assigningAuthorityName="IHE Medications Section"/>
          <templateId root="2.16.840.1.113883.3.88.11.83.112"
assigningAuthorityName="HITSP Medications Section"/>
          <code code="10160-0" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="History of medication use"/>
          <title>History of medication use</title>
        </section>
      </component>
      <component>
        <section>
          <templateId root="2.16.840.1.113883.10.20.1.10"
assigningAuthorityName="CCD Plan Of Care Section"/>
          <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.31"
assigningAuthorityName="IHE Care Plan Section"/>
          <templateId root="2.16.840.1.113883.3.88.11.83.124"
assigningAuthorityName="HITSP Plan Of Care Section"/>
          <code code="18776-5" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Treatment plan"/>
          <title>Treatment plan</title>
        </section>
      </component>
      <component>
        <section>
          <templateId root="1.3.6.1.4.1.19376.1.5.3.1.1.5.3.4"
assigningAuthorityName="IHE Pregnancy History Section"/>
          <code code="10162-6" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="HISTORY OF PREGNANCIES"/>
          <title>HISTORY OF PREGNANCIES</title>
```

```
            </section>
        </component>
        <component>
          <section>
            <templateId root="2.16.840.1.113883.10.20.1.12"
  assigningAuthorityName="CCD Procedures Section"/>
            <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.11"
  assigningAuthorityName="IHE Surgeries Section"/>
            <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.12"
  assigningAuthorityName="IHE Coded Surgeries Section"/>
            <templateId root="2.16.840.1.113883.3.88.11.83.108"
  assigningAuthorityName="HITSP Surgeries Section"/>
            <code code="47519-4" codeSystem="2.16.840.1.113883.6.1"
  codeSystemName="LOINC" displayName="History of procedures"/>
            <title>History of procedures</title>
          </section>
        </component>
        <component>
          <section>
            <templateId root="2.16.840.1.113883.10.20.1.16"
  assigningAuthorityName="CCD Vital Signs Section"/>
            <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.25"
  assigningAuthorityName="IHE Vital Signs Section"/>
            <templateId root="1.3.6.1.4.1.19376.1.5.3.1.1.5.3.2"
  assigningAuthorityName="IHE Coded Vital Signs Section"/>
            <templateId root="2.16.840.1.113883.3.88.11.83.119"
  assigningAuthorityName="HITSP Vital Signs Section"/>
            <code code="8716-3" codeSystem="2.16.840.1.113883.6.1"
  codeSystemName="LOINC" displayName="Vital signs"/>
            <title>Vital signs</title>
          </section>
        </component>
        <component>
          <section>
            <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.28"
  assigningAuthorityName="IHE Coded Results Section"/>
            <templateId root="2.16.840.1.113883.3.88.11.83.122"
  assigningAuthorityName="HITSP Diagnostic Results Section"/>
            <code code="30954-2" codeSystem="2.16.840.1.113883.6.1"
  codeSystemName="LOINC" displayName="STUDIES SUMMARY"/>
            <title>STUDIES SUMMARY</title>
          </section>
        </component>
      </structuredBody>
    </component>
</ClinicalDocument>
```

Figure 5: Patient 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 *CDA Clinical Document*
4. **SHALL** conform to *IHE Scanned Document* template (templateId: `1.3.6.1.4.1.19376.1.2.20`)

5. [IHE] **SHALL** contain [1..1] `code`

   - Entered by operator or appropriately fixed for scanned content.

6. [IHE] **SHALL** contain [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.

7. [IHE] **SHALL** contain [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.

8. [IHE] **SHALL** contain [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.

9. [IHE] **SHALL** contain [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.

10. [CDT] **SHALL** contain [1..1] `realmCode/@code` = "US" (CONF-HP-15)

11. [IHE] **SHOULD** contain [1..1] `title`

    - Entered by operator, or possibly can be taken from the scanned content.

12. [IHE] **SHALL** contain [1..1] `typeId`

13. [CDA] Contains [1..*] `author`, where its type is *CDA Author*

14. [CDT] Contains [0..1] `dataEnterer`, such that it

    a. contains *CDA Data Enterer*

    - The dataEnterer element represents the person who transferred the information from other sources into the clinical document, where the other sources wrote the content of the note. The guiding rule of thumb is that an author provides the content found within the header or body of the document, subject to their own interpretation. The dataEnterer adds information to the electronic system. A person can participate as both author and dataEnterer.

      If the role of the actor is to transfer information from one source to another (e.g., transcription or transfer from paper form to electronic system), that actor is considered a dataEnterer.

15. [CDA] Contains [1..1] `custodian`, where its type is *CDA Custodian*

16. [CDT] Contains [0..*] `informationRecipient`, such that it

    a. contains *CDA Information Recipient*

    - informationRecipient, when used in the context of a referral or request for consultation, this records the intended recipient of the information at the time the document is created. The intended recipient may also be the health chart of the patient, in which case the receivedOrganization is the scoping organization of that chart.

17. [IHE] **MAY** contain [0..1] `legalAuthenticator`, such that it

    a. contains *CDA Legal Authenticator*

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

18. [CDT] Contains [0..*] `authenticator`, such that it

    a. contains *CDA Authenticator*

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

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

19. [CDA] Contains [1..1] `component`, where its type is *CDA Component2*
20. [IHE] **SHOULD** contain [1..*] `scanOriginalAuthor`, such that it

    a. contains *IHE Scan Original Author* (templateId: `1.3.6.1.4.1.19376.1.2.20.1`)

21. [IHE] **SHALL** contain [1..*] `scanningDevice`, such that it

    a. contains *IHE Scanning Device* (templateId: `1.3.6.1.4.1.19376.1.2.20.2`)

22. [IHE] **SHALL** contain [1..1] `scanDataEnterer`, such that it

    a. contains *IHE Scan Data Enterer* (templateId: `1.3.6.1.4.1.19376.1.2.20.3`)

23. [IHE] **MAY** contain [0..1] `documentationOf`, such that it

    a. contains *CDA Documentation Of*

    • 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.

24. [CDT] **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]`

25. [CDT] **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]`

26. [CDT] **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]`

27. [CDT] **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]
```

28. [CDT] **SHALL** satisfy: 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

29. [CDT] **SHALL** satisfy: 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))
```

30. [CDT] **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]

**31.** [CDT] **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]`

**32.** [CDT] **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]`

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

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

**34.** [CDT] **SHALL** satisfy: The id/@root attribute is a syntactically correct UUID or OID. (CONF-HP-17)

**35.** [CDT] **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)

**36.** [CDT] **SHALL** satisfy: 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.

**37.** [CDT] **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 )`

**38.** [CDT] **SHALL** satisfy: languageCode has the form nn, or nn-CC. (CONF-HP-25)

**39.** [CDT] **SHALL** satisfy: The nn portion of languageCode is a legal ISO-639-1 language code in lowercase. (CONF-HP-26)

**40.** [CDT] **SHALL** satisfy: The CC portion languageCode, if present, SHALL be an ISO-3166 country code in uppercase. (CONF-HP-27)

**41.** [CDT] **SHALL** satisfy: 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())`

**42.** [CDT] **SHALL** satisfy: 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)`

**43.** [CDT] **SHALL** satisfy: A copyTime element SHALL NOT be present. (CONF-HP-30)

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

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

**44.** [CDT] **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())`

**45.** [CDT] **SHALL** satisfy: 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()))`

**46.** [CDT] **SHALL** satisfy: 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()))`

**47.** [CDT] **MAY** satisfy: 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)

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

**49.** [CDT] **MAY** satisfy: The providerOrganization element is present. (CONF-HP-36)

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

**50.** [CDT] **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())`

**51.** [CDT] **SHALL** satisfy: The assignedAuthor/id element is present. (CONF-HP-38)

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

**52.** [CDT] **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())`

**53.** [CDT] **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()
  ```

54. [CDT] **MAY** satisfy: 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()
  ```

55. [CDT] **MAY** satisfy: The informant element is present. (CONF-HP-42)

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

56. [CDT] **SHALL** satisfy: 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())
  ```

57. [CDT] **SHALL** satisfy: 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

58. [CDT] **SHALL** satisfy: 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.

59. [CDT] **SHALL** satisfy: 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)

60. [CDT] **SHALL** satisfy: 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.

61. [CDT] **SHALL** satisfy: 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.

62. [CDT] **SHOULD** satisfy: 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)

63. [CDT] **MAY** satisfy: 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)

64. [CDT] **SHALL** satisfy: The assignedEntity/assignedPerson element SHALL be present in legalAuthenticator. (CONF-HP-51)

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

65. [CDT] **SHALL** satisfy: 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())))
  ```

66. [CDT] **SHOULD** satisfy: 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
  ```

67. [CDT] **SHOULD** satisfy: 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 constraitn

- ```
  [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))
  ```

68. [IHE] **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'
  ```

69. [IHE] **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`

70. [IHE] **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())
  ```

71. [IHE] **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()))
  ```

72. [IHE] **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)))
  ```

73. [IHE] **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()))
  ```

74. [IHE] **SHALL** satisfy: The recordTarget/patientRole/patient/ administrativeGenderCode element is present.
- ```
  [OCL]: self.recordTarget->one(target : cda::RecordTarget |
     not
  target.patientRole.patient.administrativeGenderCode.oclIsUndefined())
  ```

75. [IHE] **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())
  ```

76. [IHE] **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))
  ```

77. [IHE] **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))
  ```

78. [IHE] **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)
  ```

79. [IHE] **SHALL** satisfy: custodian/assignedCustodian/representedCustodianOrganization/name is present.
- ```
  [OCL]: not
  self.custodian.assignedCustodian.representedCustodianOrganization.name.oclIsUndefir
  ```

80. [IHE] **SHALL** satisfy: custodian/assignedCustodian/representedCustodianOrganization/addr is present and includes at least the country sub element.

- ```
  [OCL]: not
  self.custodian.assignedCustodian.representedCustodianOrganization.addr.oclIsUndefin
     and
  self.custodian.assignedCustodian.representedCustodianOrganization.addr.country-
  >exists(c : datatypes::ADXP |
         not c.oclIsUndefined() and c.getText().size() > 0)
  ```

81. [IHE] **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()))
  ```

82. [IHE] **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()`

83. [IHE] **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.

84. [IHE] **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()`

85. [IHE] **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'
  ```

86. [IHE] **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
  ```

87. [HITSP] **SHOULD** satisfy: This construct should not be used when the data are structured.

- `[OCL]: self.component.structuredBody.oclIsUndefined()`

88. [HITSP] **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())
  ```

```xml
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <realmCode code="US"/>
  <templateId root="2.16.840.1.113883.10.20.3" assigningAuthorityName="CDT
General Header Constraints"/>
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.1.1" assigningAuthorityName="IHE
Medical Document"/>
  <templateId root="1.3.6.1.4.1.19376.1.2.20" assigningAuthorityName="IHE
Scanned Document"/>
  <templateId root="2.16.840.1.113883.3.88.11.62.1"
assigningAuthorityName="HITSP Unstructured Document"/>
```

```
  <id root="f6b6e576-af38-4cfe-a7da-9d10d62dfb35"/>
  <code/>
  <title/>
  <effectiveTime/>
  <confidentialityCode/>
  <languageCode/>
  <author>
    <templateId root="1.3.6.1.4.1.19376.1.2.20.2" assigningAuthorityName="IHE
 Scanning Device"/>
    <time/>
  </author>
  <dataEnterer>
    <templateId root="1.3.6.1.4.1.19376.1.2.20.3" assigningAuthorityName="IHE
 Scan Data Enterer"/>
    <time/>
  </dataEnterer>
</ClinicalDocument>
```

Figure 6: Unstructured 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 *CDA Section*
2. **SHALL** conform to *IHE Admission Medication History Section* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.3.20`)
3. [IHE] **SHALL** contain [1..1] `code/@code` = "42346-7" *MEDICATIONS ON ADMISSION* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC)

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.20"
 assigningAuthorityName="IHE Admission Medication History Section"/>
          <templateId root="2.16.840.1.113883.3.88.11.83.113"
 assigningAuthorityName="HITSP Admission Medication History Section"/>
          <code code="42346-7" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="MEDICATIONS ON ADMISSION"/>
          <title>MEDICATIONS ON ADMISSION</title>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 7: 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 *CDA Section*
2. **SHALL** conform to *CCD Advance Directives Section* template (templateId: `2.16.840.1.113883.10.20.1.1`)
3. **SHALL** conform to *IHE Advance Directives Section* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.3.34`)
4. **SHALL** conform to *IHE Coded Advance Directives Section* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.3.35`)
5. [CCD] **SHALL** contain [1..1] `code/@code` = "42348-3" *Advance directives* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC)
6. [CCD] **SHALL** contain [1..1] `title`
7. [CCD] **SHALL** contain [1..*] `entry`, such that it
   a. contains *CCD Advance Directive Observation* (templateId: `2.16.840.1.113883.10.20.1.17`)

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

```
    <structuredBody>
      <component>
        <section>
          <templateId root="2.16.840.1.113883.10.20.1.1"
 assigningAuthorityName="CCD Advance Directives Section"/>
          <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.34"
 assigningAuthorityName="IHE Advance Directives Section"/>
          <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.35"
 assigningAuthorityName="IHE Coded Advance Directives Section"/>
          <templateId root="2.16.840.1.113883.3.88.11.83.116"
 assigningAuthorityName="HITSP Advance Directives Section"/>
          <code code="42348-3" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="Advance directives"/>
          <title>Advance directives</title>
          <entry>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.17"
 assigningAuthorityName="CCD Advance Directive Observation"/>
              <id root="f1ec61cd-a144-42e3-8660-80ce11721e9d"/>
              <code/>
              <statusCode code="completed"/>
              <effectiveTime>
                <low value="1972"/>
                <high value="2008"/>
              </effectiveTime>
            </observation>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 8: 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 *CDA Section*
2. **SHALL** conform to *CCD Alerts Section* template (templateId: `2.16.840.1.113883.10.20.1.2`)
3. **SHALL** conform to *IHE Allergies Reactions Section* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.3.13`)
4. [CCD] **SHALL** contain [1..1] `code/@code` = "48765-2" *Allergies, adverse reactions, alerts* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC)
5. [CCD] **SHALL** contain [1..1] `title`
6. [CCD] **SHALL** contain [1..1] `text`
7. [CCD] **SHOULD** contain [1..*] `entry`, such that it

    a. contains *CCD Problem Act* (templateId: `2.16.840.1.113883.10.20.1.27`)
8. [CCD] **SHOULD** satisfy: Contains a case-insensitive language-insensitive string containing "alert" and/or "allergies and adverse reactions".
9. [CCD] **SHALL** satisfy: The absence of known allergies, adverse reactions or alerts SHALL be explicitly asserted.

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

```
  <component>
    <structuredBody>
      <component>
        <section>
          <templateId root="2.16.840.1.113883.10.20.1.2"
assigningAuthorityName="CCD Alerts Section"/>
          <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.13"
assigningAuthorityName="IHE Allergies Reactions Section"/>
          <templateId root="2.16.840.1.113883.3.88.11.83.102"
assigningAuthorityName="HITSP Allergies Reactions Section"/>
          <code code="48765-2" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Allergies, adverse reactions, alerts"/>
          <title>Allergies, adverse reactions, alerts</title>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 9: 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 *CDA Section*
2. **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`)
3. [IHE] **SHALL** contain [1..1] `code/@code` = "51847-2" *ASSESSMENT AND PLAN* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC)

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <templateId root="1.3.6.1.4.1.19376.1.5.3.1.1.13.2.5"
assigningAuthorityName="IHE Assessment And Plan Section"/>
          <templateId root="2.16.840.1.113883.3.88.11.83.123"
assigningAuthorityName="HITSP Assessment And Plan Section"/>
          <code code="51847-2" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="ASSESSMENT AND PLAN"/>
          <title>ASSESSMENT AND PLAN</title>
        </section>
      </component>
    </structuredBody>
  </component>
```

```
</ClinicalDocument>
```

Figure 10: 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 *CDA Section*
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. [IHE] **SHALL** contain [1..1] `code/@code` = "10154-3" *CHIEF COMPLAINT* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC)

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <templateId root="1.3.6.1.4.1.19376.1.5.3.1.1.13.2.1"
 assigningAuthorityName="IHE Chief Complaint Section"/>
          <templateId root="2.16.840.1.113883.3.88.11.83.105"
 assigningAuthorityName="HITSP Chief Complaint Section"/>
          <code code="10154-3" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="CHIEF COMPLAINT"/>
          <title>CHIEF COMPLAINT</title>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 11: Chief Complaint Section example

Diagnostic Results Section

[Section: templateId `2.16.840.1.113883.3.88.11.83.122`]

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

1. **SHALL** conform to *CDA Section*
2. **SHALL** conform to *IHE Coded Results Section* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.3.28`)
3. [IHE] **SHALL** contain [1..1] `code/@code` = "30954-2" *STUDIES SUMMARY* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC)
4. [IHE] **SHALL** contain [1..*] `procedureEntry`, such that it

   a. contains *IHE Procedure Entry*
5. [IHE] **SHOULD** contain [1..*] `entry`, such that it

   a. contains *IHE External Reference* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.4`)
6. [IHE] **MAY** contain [0..*] `entry`, such that it

   a. contains *IHE Simple Observation* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.13`)
7. [HITSP] **SHALL** contain [1..*] `entry`, such that it

    a. contains *Procedure* (templateId: `2.16.840.1.113883.3.88.11.83.17`)
    (C83-[CT-122-2])

8. [HITSP] **SHALL** contain [1..*] `entry`, such that it

    a. contains *Result* (templateId: `2.16.840.1.113883.3.88.11.83.15`)
    (C83-[CT-122-2])

```xml
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.28"
 assigningAuthorityName="IHE Coded Results Section"/>
          <templateId root="2.16.840.1.113883.3.88.11.83.122"
 assigningAuthorityName="HITSP Diagnostic Results Section"/>
          <code code="30954-2" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="STUDIES SUMMARY"/>
          <title>STUDIES SUMMARY</title>
          <entry>
            <procedure>
              <templateId root="2.16.840.1.113883.10.20.1.29"/>
              <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.19"/>
              <templateId root="2.16.840.1.113883.3.88.11.83.17"
 assigningAuthorityName="HITSP Procedure"/>
              <id root="9df489ae-3a42-494d-8873-9640ad829a7a"/>
              <code/>
              <text/>
              <statusCode code="completed"/>
              <effectiveTime>
                <low value="1972"/>
                <high value="2008"/>
              </effectiveTime>
              <approachSiteCode/>
              <targetSiteCode codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMEDCT"/>
            </procedure>
          </entry>
          <entry>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.31"
 assigningAuthorityName="CCD Result Observation"/>
              <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.13"
 assigningAuthorityName="IHE Simple Observation"/>
              <templateId root="2.16.840.1.113883.3.88.11.83.15"
 assigningAuthorityName="HITSP Result"/>
              <id root="d329b7d3-7b86-412e-9d10-1fa9bf4c433a"/>
              <code/>
              <statusCode code="completed"/>
              <effectiveTime>
                <low value="1972"/>
                <high value="2008"/>
              </effectiveTime>
              <interpretationCode/>
              <methodCode/>
            </observation>
          </entry>
        </section>
      </component>
    </structuredBody>
```

```
      </component>
</ClinicalDocument>
```

Figure 12: 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 *CDA Section*
2. **SHALL** conform to *IHE Discharge Diagnosis Section* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.3.7`)
3. [IHE] **SHALL** contain [1..1] `code/@code` = "11535-2" *HOSPITAL DISCHARGE DX* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC)

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.7"
 assigningAuthorityName="IHE Discharge Diagnosis Section"/>
          <templateId root="2.16.840.1.113883.3.88.11.83.111"
 assigningAuthorityName="HITSP Discharge Diagnosis Section"/>
          <code code="11535-2" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="HOSPITAL DISCHARGE DX"/>
          <title>HOSPITAL DISCHARGE DX</title>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 13: 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 *CDA Section*
2. **SHALL** conform to *CCD Encounters Section* template (templateId: `2.16.840.1.113883.10.20.1.3`)
3. **SHALL** conform to *IHE Encounter History Section* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.1.5.3.3`)
4. [CCD] **SHALL** contain [1..1] `code/@code` = "46240-8" *History of encounters* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC)
5. [CCD] **SHALL** contain [1..1] `title`
6. [HITSP] **SHALL** contain [1..*] `entry`, such that it

   a. contains *Encounter* (templateId: `2.16.840.1.113883.3.88.11.83.16`)

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

```
   <component>
     <structuredBody>
       <component>
         <section>
           <templateId root="2.16.840.1.113883.10.20.1.3"
 assigningAuthorityName="CCD Encounters Section"/>
           <templateId root="1.3.6.1.4.1.19376.1.5.3.1.1.5.3.3"
 assigningAuthorityName="IHE Encounter History Section"/>
           <templateId root="2.16.840.1.113883.3.88.11.83.127"
 assigningAuthorityName="HITSP Encounters Section"/>
           <code code="46240-8" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="History of encounters"/>
           <title>History of encounters</title>
           <entry>
             <encounter classCode="ENC" moodCode="EVN">
               <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.14"/>
               <templateId root="2.16.840.1.113883.10.20.1.21"
 assigningAuthorityName="CCD Encounters Activity"/>
               <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.14"/>
               <templateId root="2.16.840.1.113883.3.88.11.83.16"
 assigningAuthorityName="HITSP Encounter"/>
               <id root="47ececdb-ace0-4a26-b96d-61b80d9b1d4e"/>
               <code codeSystem="2.16.840.1.113883.6.12"
 codeSystemName="CPT-4"/>
               <text/>
               <effectiveTime>
                 <low value="1972"/>
                 <high value="2008"/>
               </effectiveTime>
               <priorityCode/>
             </encounter>
           </entry>
         </section>
       </component>
     </structuredBody>
   </component>
</ClinicalDocument>
```

Figure 14: 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 *CDA Section*
2. **SHALL** conform to *CCD Family History Section* template (templateId: `2.16.840.1.113883.10.20.1.4`)
3. **SHALL** conform to *IHE Family Medical History Section* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.3.14`)
4. [CCD] **SHALL** contain [1..1] `code/@code` = "10157-6" *History of family member diseases* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC)
5. [CCD] **SHALL** contain [1..1] `title`

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

```
            <templateId root="2.16.840.1.113883.10.20.1.4"
assigningAuthorityName="CCD Family History Section"/>
            <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.14"
assigningAuthorityName="IHE Family Medical History Section"/>
            <templateId root="2.16.840.1.113883.3.88.11.83.125"
assigningAuthorityName="HITSP Family History Section"/>
            <code code="10157-6" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="History of family member diseases"/>
            <title>History of family member diseases</title>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 15: 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 *CDA Section*
2. **SHALL** conform to *CCD Functional Status Section* template (templateId: `2.16.840.1.113883.10.20.1.5`)
3. [CCD] **SHALL** contain [1..1] `code`/@`code` = "47420-5" *Functional status assessment* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC)
4. [CCD] **SHALL** contain [1..1] `title`
5. [CCD] **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`

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <templateId root="2.16.840.1.113883.10.20.1.5"
assigningAuthorityName="CCD Functional Status Section"/>
          <templateId root="2.16.840.1.113883.3.88.11.83.109"
assigningAuthorityName="HITSP Functional Status Section"/>
          <code code="47420-5" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Functional status assessment"/>
          <title>Functional status assessment</title>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 16: 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 *CDA Section*
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. [IHE] **SHALL** contain [1..1] `code/@code` = "11348-0" *HISTORY OF PAST ILLNESS* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC)

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.8"
 assigningAuthorityName="IHE History Of Past Illness Section"/>
          <templateId root="2.16.840.1.113883.3.88.11.83.104"
 assigningAuthorityName="HITSP History Of Past Illness Section"/>
          <code code="11348-0" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="HISTORY OF PAST ILLNESS"/>
          <title>HISTORY OF PAST ILLNESS</title>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 17: 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 *CDA Section*
2. **SHALL** conform to *IHE History Of Present Illness* template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.4)
3. [IHE] **SHALL** contain [1..1] `code/@code` = "10164-2" *HISTORY OF PRESENT ILLNESS* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC)

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.4"
 assigningAuthorityName="IHE History Of Present Illness"/>
          <templateId root="2.16.840.1.113883.3.88.11.83.107"
 assigningAuthorityName="HITSP History Of Present Illness"/>
          <code code="10164-2" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="HISTORY OF PRESENT ILLNESS"/>
          <title>HISTORY OF PRESENT ILLNESS</title>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 18: 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 *CDA Section*
2. **SHALL** conform to *IHE Hospital Admission Diagnosis Section* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.3.3`)
3. [IHE] **SHALL** contain [1..1] `code/@code` = "46241-6" *HOSPITAL ADMISSION DX* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC)

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.3"
 assigningAuthorityName="IHE Hospital Admission Diagnosis Section"/>
          <templateId root="2.16.840.1.113883.3.88.11.83.110"
 assigningAuthorityName="HITSP Hospital Admission Diagnosis Section"/>
          <code code="46241-6" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="HOSPITAL ADMISSION DX"/>
          <title>HOSPITAL ADMISSION DX</title>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 19: 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 *CDA Section*
2. **SHALL** conform to *IHE Hospital Course Section* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.3.5`)
3. [IHE] **SHALL** contain [1..1] `code/@code` = "8648-8" *HOSPITAL COURSE* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC)

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.5"
 assigningAuthorityName="IHE Hospital Course Section"/>
          <templateId root="2.16.840.1.113883.3.88.11.83.121"
 assigningAuthorityName="HITSP Hospital Course Section"/>
          <code code="8648-8" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="HOSPITAL COURSE"/>
```

```
            <title>HOSPITAL COURSE</title>
          </section>
        </component>
      </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 20: 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 *CDA Section*
2. **SHALL** conform to *IHE Hospital Discharge Medications Section* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.3.22`)
3. [IHE] **SHALL** contain [1..1] `code/@code` = "10183-2" *HOSPITAL DISCHARGE MEDICATIONS* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC)

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.22"
 assigningAuthorityName="IHE Hospital Discharge Medications Section"/>
          <templateId root="2.16.840.1.113883.3.88.11.83.114"
 assigningAuthorityName="HITSP Hospital Discharge Medications Section"/>
          <code code="10183-2" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="HOSPITAL DISCHARGE MEDICATIONS"/>
          <title>HOSPITAL DISCHARGE MEDICATIONS</title>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 21: 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 *CDA Section*
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. [CCD] **SHALL** contain [1..1] `code/@code` = "11369-6" *History of immunizations* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC)
5. [CCD] **SHALL** contain [1..1] `title`
6. [CCD] **SHALL** contain [1..1] `text`
7. [HITSP] **SHALL** contain [1..*] `entry`, such that it
   a. contains *Immunization* (templateId: `2.16.840.1.113883.3.88.11.83.13`)
8. [CCD] **SHOULD** satisfy: Contains a case-insensitive language-insensitive string containing 'immunization'.

9. [CCD] **SHOULD** satisfy: Contains one or more Medication Activity and/or Supply Activity (CONF-376)

   - [OCL]: self.getEntryTargets(ccd::MedicationActivity)->size() > 0
     or self.getEntryTargets(ccd::SupplyActivity)->size() > 0

```xml
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <templateId root="2.16.840.1.113883.10.20.1.6"
assigningAuthorityName="CCD Immunizations Section"/>
          <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.23"
assigningAuthorityName="IHE Immunizations Section"/>
          <templateId root="2.16.840.1.113883.3.88.11.83.117"
assigningAuthorityName="HITSP Immunizations Section"/>
          <code code="11369-6" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="History of immunizations"/>
          <title>History of immunizations</title>
          <entry>
            <substanceAdministration classCode="SBADM">
              <templateId root="2.16.840.1.113883.10.20.1.24"
assigningAuthorityName="CCD Medication Activity"/>
              <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.12"
assigningAuthorityName="IHE Immunization"/>
              <templateId root="2.16.840.1.113883.3.88.11.83.13"
assigningAuthorityName="HITSP Immunization"/>
              <id root="0cd08ebf-6ccb-48c3-b03c-ccef6b3e3acd"/>
              <statusCode/>
              <effectiveTime/>
              <routeCode codeSystem="2.16.840.1.113883.5.112"
codeSystemName="HL7 RouteOfAdministration"/>
              <maxDoseQuantity/>
            </substanceAdministration>
          </entry>
          <entry>
            <substanceAdministration classCode="SBADM">
              <templateId root="2.16.840.1.113883.10.20.1.24"
assigningAuthorityName="CCD Medication Activity"/>
              <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.12"
assigningAuthorityName="IHE Immunization"/>
              <id root="b68281c9-8a3e-4004-ab3d-0b3baabbb095"/>
              <statusCode/>
              <effectiveTime/>
              <routeCode codeSystem="2.16.840.1.113883.5.112"
codeSystemName="HL7 RouteOfAdministration"/>
              <maxDoseQuantity/>
            </substanceAdministration>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 22: 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 *CDA Section*
2. **SHALL** conform to *CCD Medical Equipment Section* template (templateId: `2.16.840.1.113883.10.20.1.7`)
3. **SHALL** conform to *IHE Medical Devices Section* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.1.5.3.5`)
4. [CCD] **SHALL** contain [1..1] `code/@code` = "46264-8" *History of medical device use* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC)
5. [CCD] **SHALL** contain [1..1] `title`

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <templateId root="2.16.840.1.113883.10.20.1.7"
assigningAuthorityName="CCD Medical Equipment Section"/>
          <templateId root="1.3.6.1.4.1.19376.1.5.3.1.1.5.3.5"
assigningAuthorityName="IHE Medical Devices Section"/>
          <templateId root="2.16.840.1.113883.3.88.11.83.128"
assigningAuthorityName="HITSP Medical Equipment Section"/>
          <code code="46264-8" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="History of medical device use"/>
          <title>History of medical device use</title>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 23: 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 *CDA Section*
2. **SHALL** conform to *IHE Medications Administered Section* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.3.21`)
3. [IHE] **SHALL** contain [1..1] `code/@code` = "18610-6" *MEDICATION ADMINISTERED* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC)

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

```
            <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.21"
 assigningAuthorityName="IHE Medications Administered Section"/>
            <templateId root="2.16.840.1.113883.3.88.11.83.115"
 assigningAuthorityName="HITSP Medications Administered Section"/>
            <code code="18610-6" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="MEDICATION ADMINISTERED"/>
            <title>MEDICATION ADMINISTERED</title>
          </section>
        </component>
      </structuredBody>
    </component>
</ClinicalDocument>
```

Figure 24: 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 *CDA Section*
2. **SHALL** conform to *CCD Medications Section* template (templateId: `2.16.840.1.113883.10.20.1.8`)
3. **SHALL** conform to *IHE Medications Section* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.3.19`)
4. [CCD] **SHALL** contain [1..1] `code/@code` = "10160-0" *History of medication use* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC) (CONF-300, CONF-301)
5. [CCD] **SHALL** contain [1..1] `title` (CONF-302)
6. [CCD] **SHALL** contain [0..1] `text`
7. [CCD] Contains [0..*] `entry`, such that it
    a. contains *CCD Medication Activity* (templateId: `2.16.840.1.113883.10.20.1.24`)
8. [CCD] Contains [0..*] `entry`, such that it
    a. contains *CCD Supply Activity* (templateId: `2.16.840.1.113883.10.20.1.34`)
9. [HITSP] **SHALL** contain [1..*] `entry`, such that it
    a. contains *Medication* (templateId: `2.16.840.1.113883.3.88.11.83.8`)
    (C83-[CT-112-2])
10. [CCD] **SHALL** satisfy: The absence of known medications is explicitly asserted. (CONF-299)
11. [CCD] **SHOULD** satisfy: Valued with a case-insensitive language-insensitive string containing 'medication'. (CONF-303)
12. [CCD] **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))
```

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <templateId root="2.16.840.1.113883.10.20.1.8"
 assigningAuthorityName="CCD Medications Section"/>
          <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.19"
 assigningAuthorityName="IHE Medications Section"/>
```

```
            <templateId root="2.16.840.1.113883.3.88.11.83.112"
assigningAuthorityName="HITSP Medications Section"/>
            <code code="10160-0" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="History of medication use"/>
            <title>History of medication use</title>
            <entry>
              <substanceAdministration classCode="SBADM">
                <templateId root="2.16.840.1.113883.10.20.1.24"
assigningAuthorityName="CCD Medication Activity"/>
                <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.7"
assigningAuthorityName="IHE Medication"/>
                <templateId root="2.16.840.1.113883.3.88.11.83.8"/>
                <id root="9f43af24-8aeb-45a0-b832-8ab11a5f40e6"/>
                <statusCode/>
                <effectiveTime/>
                <routeCode codeSystem="2.16.840.1.113883.5.112"
codeSystemName="HL7 RouteOfAdministration"/>
                <approachSiteCode/>
                <doseQuantity/>
                <rateQuantity/>
                <maxDoseQuantity/>
              </substanceAdministration>
            </entry>
            <entry>
              <substanceAdministration classCode="SBADM">
                <templateId root="2.16.840.1.113883.10.20.1.24"
assigningAuthorityName="CCD Medication Activity"/>
                <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.7"
assigningAuthorityName="IHE Medication"/>
                <id root="fff7217a-6e63-4dd3-8f35-0364c25c34a1"/>
                <statusCode/>
                <effectiveTime/>
                <routeCode codeSystem="2.16.840.1.113883.5.112"
codeSystemName="HL7 RouteOfAdministration"/>
                <approachSiteCode/>
                <doseQuantity/>
                <rateQuantity/>
                <maxDoseQuantity/>
              </substanceAdministration>
            </entry>
          </section>
        </component>
      </structuredBody>
    </component>
</ClinicalDocument>
```

Figure 25: 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 *CDA Section*
2. **SHALL** conform to *CCD Payers Section* template (templateId: `2.16.840.1.113883.10.20.1.9`)
3. **SHALL** conform to *IHE Payers Section* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.1.5.3.7`)
4. [CCD] **SHALL** contain [1..1] `code/@code` = "48768-6" *Payment sources* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC) (CONF-31, CONF-32)

5. [CCD] **SHALL** contain [1..1] `title` (CONF-33)
6. [CCD] **SHOULD** contain [1..*] `entry`, such that it

    a. contains *CCD Coverage Activity* (templateId: `2.16.840.1.113883.10.20.1.20`)

    (CONF-30)
7. [CCD] **SHALL** contain [1..1] `text` (CONF-30)
8. [IHE] **SHOULD** contain [1..*] `entry`, such that it

    a. contains *IHE Coverage Entry* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.17`)
9. [CCD] **SHOULD** satisfy: Contains a case-insensitive language-insensitive string containing 'insurance' or 'payers'. (CONF-34)

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <templateId root="2.16.840.1.113883.10.20.1.9"
 assigningAuthorityName="CCD Payers Section"/>
          <templateId root="1.3.6.1.4.1.19376.1.5.3.1.1.5.3.7"
 assigningAuthorityName="IHE Payers Section"/>
          <templateId root="2.16.840.1.113883.3.88.11.83.101"
 assigningAuthorityName="HITSP Payers Section"/>
          <code code="48768-6" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="Payment sources"/>
          <title>Payment sources</title>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 26: 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 *CDA Section*
2. **SHALL** conform to *IHE Physical Exam Narrative Section* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.3.24`)
3. **SHALL** conform to *IHE Physical Exam Section* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.1.9.15`)
4. [IHE] **SHALL** contain [1..1] `code/@code` = "29545-1" *PHYSICAL EXAMINATION* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC)

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.24"
 assigningAuthorityName="IHE Physical Exam Narrative Section"/>
          <templateId root="1.3.6.1.4.1.19376.1.5.3.1.1.9.15"
 assigningAuthorityName="IHE Physical Exam Section"/>
```

```
            <templateId root="2.16.840.1.113883.3.88.11.83.118"
  assigningAuthorityName="HITSP Physical Exam Section"/>
            <code code="29545-1" codeSystem="2.16.840.1.113883.6.1"
  codeSystemName="LOINC" displayName="PHYSICAL EXAMINATION"/>
            <title>PHYSICAL EXAMINATION</title>
          </section>
        </component>
      </structuredBody>
    </component>
  </ClinicalDocument>
```

Figure 27: 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 *CDA Section*
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. [CCD] **SHALL** contain [1..1] `code/@code` = "18776-5" *Treatment plan* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC)
5. [CCD] **SHALL** contain [1..1] `title`
6. [CCD] **SHALL** contain [1..1] `text`
7. [CCD] **MAY** contain [0..1] `entry`, such that it

   a. contains *CCD Plan Of Care Activity Act* (templateId: `2.16.840.1.113883.10.20.1.25`)
8. [CCD] **MAY** contain [0..1] `entry`, such that it

   a. contains *CCD Plan Of Care Activity Encounter* (templateId: `2.16.840.1.113883.10.20.1.25`)
9. [CCD] **MAY** contain [0..1] `entry`, such that it

   a. contains *CCD Plan Of Care Activity Observation* (templateId: `2.16.840.1.113883.10.20.1.25`)
10. [CCD] **MAY** contain [0..1] `entry`, such that it

    a. contains *CCD Plan Of Care Activity Procedure* (templateId: `2.16.840.1.113883.10.20.1.25`)
11. [CCD] **MAY** contain [0..1] `entry`, such that it

    a. contains *CCD Plan Of Care Activity Substance Administration* (templateId: `2.16.840.1.113883.10.20.1.25`)
12. [CCD] **MAY** contain [0..1] `entry`, such that it

    a. contains *CCD Plan Of Care Activity Supply* (templateId: `2.16.840.1.113883.10.20.1.25`)
13. [CCD] **SHALL** contain [1..1] `planOfCareActivity`, such that it

    a. contains *CCD Plan Of Care Activity*

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <templateId root="2.16.840.1.113883.10.20.1.10"
 assigningAuthorityName="CCD Plan Of Care Section"/>
```

```
            <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.31"
assigningAuthorityName="IHE Care Plan Section"/>
            <templateId root="2.16.840.1.113883.3.88.11.83.124"
assigningAuthorityName="HITSP Plan Of Care Section"/>
            <code code="18776-5" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Treatment plan"/>
            <title>Treatment plan</title>
          </section>
        </component>
      </structuredBody>
    </component>
</ClinicalDocument>
```

Figure 28: Plan Of Care Section example

Problem List Section

[Section: templateId 2.16.840.1.113883.3.88.11.83.103]

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

1. **SHALL** conform to *CDA Section*
2. **SHALL** conform to *CCD Problem Section* template (templateId: 2.16.840.1.113883.10.20.1.11)
3. **SHALL** conform to *IHE Active Problems Section* template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.6)
4. [CCD] **SHALL** contain [1..1] code/@code = "11450-4" *Problem list* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC) (CONF-141, CONF-142)
5. [CCD] **SHALL** contain [1..1] title (CONF-143)
6. [CCD] **SHOULD** contain [1..*] entry, such that it

   a. contains *CCD Problem Act* (templateId: 2.16.840.1.113883.10.20.1.27)

   (CONF-140)
7. [CCD] **SHALL** contain [1..1] text (CONF-140)
8. [IHE] **SHALL** contain [1..*] entry, such that it

   a. contains *IHE Problem Concern Entry* (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.5.2)
9. [HITSP] **SHALL** contain [1..*] entry, such that it

   a. contains *Condition* (templateId: 2.16.840.1.113883.3.88.11.83.7)
10. [CCD] **SHOULD** satisfy: Contains a case-insensitive language-insensitive string containing 'problems'. (CONF-144)

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <templateId root="2.16.840.1.113883.10.20.1.11"
assigningAuthorityName="CCD Problem Section"/>
          <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.6"
assigningAuthorityName="IHE Active Problems Section"/>
          <templateId root="2.16.840.1.113883.3.88.11.83.103"
assigningAuthorityName="HITSP Problem List Section"/>
          <code code="11450-4" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Problem list"/>
          <title>Problem list</title>
          <entry>
            <act classCode="ACT" moodCode="EVN">
```

```
              <templateId root="2.16.840.1.113883.10.20.1.27"
assigningAuthorityName="CCD Problem Act"/>
              <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.5.1"
assigningAuthorityName="IHE Concern Entry"/>
              <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.5.2"
assigningAuthorityName="IHE Problem Concern Entry"/>
              <templateId root="2.16.840.1.113883.3.88.11.83.7"
assigningAuthorityName="HITSP Condition"/>
              <id root="c7872239-7116-45e9-8aab-be05b9a47a6f"/>
              <code nullFlavor="NA"/>
              <statusCode/>
              <effectiveTime>
                <low value="1972"/>
                <high value="2008"/>
              </effectiveTime>
            </act>
          </entry>
          <entry>
            <act classCode="ACT" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.27"
assigningAuthorityName="CCD Problem Act"/>
              <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.5.1"
assigningAuthorityName="IHE Concern Entry"/>
              <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.5.2"
assigningAuthorityName="IHE Problem Concern Entry"/>
              <id root="814fb477-4df4-4b7b-bbf3-20ff5ffe637c"/>
              <code nullFlavor="NA"/>
              <statusCode/>
              <effectiveTime>
                <low value="1972"/>
                <high value="2008"/>
              </effectiveTime>
            </act>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 29: 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 *CDA Section*
2. **SHALL** conform to *IHE Reason For Referral Section* template (templateId:
   `1.3.6.1.4.1.19376.1.5.3.1.3.1`)
3. [IHE] **SHALL** contain [1..1] `code/@code` = "42349-1" *REASON FOR REFERRAL* (CodeSystem:
   2.16.840.1.113883.6.1 LOINC STATIC)

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.1"
 assigningAuthorityName="IHE Reason For Referral Section"/>
```

```
            <templateId root="2.16.840.1.113883.3.88.11.83.106"
 assigningAuthorityName="HITSP Reason For Referral Section"/>
            <code code="42349-1" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="REASON FOR REFERRAL"/>
            <title>REASON FOR REFERRAL</title>
          </section>
        </component>
      </structuredBody>
    </component>
</ClinicalDocument>
```

Figure 30: 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 *CDA Section*
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. [IHE] **SHALL** contain [1..1] `code/@code` = "10187-3" *REVIEW OF SYSTEMS* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC)

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.18"
 assigningAuthorityName="IHE Review Of Systems Section"/>
          <templateId root="2.16.840.1.113883.3.88.11.83.120"
 assigningAuthorityName="HITSP Review Of Systems Section"/>
          <code code="10187-3" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="REVIEW OF SYSTEMS"/>
          <title>REVIEW OF SYSTEMS</title>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 31: 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 *CDA Section*
2. **SHALL** conform to *CCD Social History Section* template (templateId: `2.16.840.1.113883.10.20.1.15`)
3. **SHALL** conform to *IHE Social History Section* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.3.16`)
4. [CCD] **SHALL** contain [1..1] `code/@code` = "29762-2" *Social history* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC)

5. [CCD] **SHOULD** contain [1..1] `title`

```xml
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <templateId root="2.16.840.1.113883.10.20.1.15"
 assigningAuthorityName="CCD Social History Section"/>
          <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.16"
 assigningAuthorityName="IHE Social History Section"/>
          <templateId root="2.16.840.1.113883.3.88.11.83.126"
 assigningAuthorityName="HITSP Social History Section"/>
          <code code="29762-2" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="Social history"/>
          <title>Social history</title>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 32: Social History Section example

Surgeries Section

[Section: templateId `2.16.840.1.113883.3.88.11.83.108`]

1. **SHALL** conform to *CDA Section*
2. **SHALL** conform to *CCD Procedures Section* template (templateId: `2.16.840.1.113883.10.20.1.12`)
3. **SHALL** conform to *IHE Surgeries Section* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.3.11`)
4. **SHALL** conform to *IHE Coded Surgeries Section* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.3.12`)
5. [CCD] **SHALL** contain [1..1] `code/@code` = "47519-4" *History of procedures* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC)
6. [CCD] **SHALL** contain [1..1] `title`
7. [CCD] **SHOULD** contain [1..*] `procedureActivity`, such that it

   a. contains *CCD Procedure Activity*
8. [HITSP] **SHALL** contain [1..*] `entry`, such that it

   a. contains *Procedure* (templateId: `2.16.840.1.113883.3.88.11.83.17`)

```xml
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <templateId root="2.16.840.1.113883.10.20.1.12"
 assigningAuthorityName="CCD Procedures Section"/>
          <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.11"
 assigningAuthorityName="IHE Surgeries Section"/>
          <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.12"
 assigningAuthorityName="IHE Coded Surgeries Section"/>
          <templateId root="2.16.840.1.113883.3.88.11.83.108"
 assigningAuthorityName="HITSP Surgeries Section"/>
```

```
          <code code="47519-4" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="History of procedures"/>
          <title>History of procedures</title>
          <entry>
            <procedure>
              <templateId root="2.16.840.1.113883.10.20.1.29"/>
              <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.19"/>
              <templateId root="2.16.840.1.113883.3.88.11.83.17"
 assigningAuthorityName="HITSP Procedure"/>
              <id root="efc49ad3-9896-4a78-a2ae-ee58f58824b3"/>
              <code/>
              <text/>
              <statusCode code="completed"/>
              <effectiveTime>
                <low value="1972"/>
                <high value="2008"/>
              </effectiveTime>
              <approachSiteCode/>
              <targetSiteCode codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMEDCT"/>
            </procedure>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 33: 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 *CDA Section*
2. **SHALL** conform to *CCD Vital Signs Section* template (templateId: `2.16.840.1.113883.10.20.1.16`)
3. **SHALL** conform to *IHE Vital Signs Section* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.3.25`)
4. **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`)
5. [CCD] **SHALL** contain [1..1] `code/@code` = "8716-3" *Vital signs* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC)
6. [CCD] **SHALL** contain [1..1] `title`
7. [IHE] **SHALL** contain [1..*] `entry`, such that it

   a. contains *IHE Vital Signs Organizer* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.13.1`)
8. [CCD] **SHALL** contain [1..1] `text`
9. [CCD] **SHOULD** satisfy: Contains a case-insensitive language-insensitive string containing 'vital signs'.
10. [HITSP] **SHALL** satisfy: Contains entries conforming to the Vital Sign module.

   - [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)))`

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

```xml
      <component>
        <section>
          <templateId root="2.16.840.1.113883.10.20.1.16"
assigningAuthorityName="CCD Vital Signs Section"/>
          <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.25"
assigningAuthorityName="IHE Vital Signs Section"/>
          <templateId root="1.3.6.1.4.1.19376.1.5.3.1.1.5.3.2"
assigningAuthorityName="IHE Coded Vital Signs Section"/>
          <templateId root="2.16.840.1.113883.3.88.11.83.119"
assigningAuthorityName="HITSP Vital Signs Section"/>
          <code code="8716-3" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Vital signs"/>
          <title>Vital signs</title>
          <entry>
            <organizer classCode="CLUSTER" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.32"
assigningAuthorityName="CCD Result Organizer"/>
              <templateId root="2.16.840.1.113883.10.20.1.35"
assigningAuthorityName="CCD Vital Signs Organizer"/>
              <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.13.1"
assigningAuthorityName="IHE Vital Signs Organizer"/>
              <id root="4a70f9e9-78ec-4bbf-890f-22b8185c564b"/>
              <code code="46680005" codeSystem="2.16.840.1.113883.6.96"
codeSystemName="SNOMEDCT" displayName="Vital signs"/>
              <statusCode code="completed"/>
              <effectiveTime>
                <low value="1972"/>
                <high value="2008"/>
              </effectiveTime>
            </organizer>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 34: 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.

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 *CDA Clinical Statement*
2. **SHALL** conform to *CDA Act*
3. **SHALL** conform to *CCD Problem Act* template (templateId: 2.16.840.1.113883.10.20.1.27)
4. **SHALL** conform to *IHE Concern Entry* template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.5.1)
5. **SHALL** conform to *IHE Allergy Intolerance Concern* template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.5.3)
6. [CCD] **SHALL** contain [1..1] @classCode = "ACT" (CONF-146)
7. [CCD] **SHALL** contain [1..1] @moodCode = "EVN" (CONF-147)
8. [CCD] **SHALL** contain [1..1] code/@nullFlavor = "NA" *NA (not applicable)* (CONF-149)
9. [CCD] **SHALL** contain [1..*] id (CONF-148)
10. [IHE] **SHALL** contain [1..1] effectiveTime

    • The effectiveTime element records the starting and ending times during which the concern was active.
11. [CCD] **MAY** contain [1..1] entryRelationship, such that it

    a. contains *CCD Episode Observation* (templateId: 2.16.840.1.113883.10.20.1.41)

    (CONF-168)
12. [CCD] Contains [0..*] entryRelationship, such that it

    a. contains *CCD Problem Observation* (templateId: 2.16.840.1.113883.10.20.1.28)
13. [IHE] **SHALL** contain [1..1] statusCode, which **SHALL** be selected from ValueSet *ConcernEntryStatus* STATIC
14. [CCD] **SHALL** satisfy: Contains one or more entryRelationship (CONF-151)

    • [OCL]: not self.entryRelationship->isEmpty()
15. [CCD] **MAY** satisfy: A problem act MAY reference a problem observation, alert observation (see section Alerts) or other clinical statement that is the subject of concern, by setting the value for "Act / entryRelationship / @typeCode" to be "SUBJ" 2.16.840.1.113883.5.1002 ActRelationshipType STATIC. (CONF-152)
16. [CCD] **SHOULD** satisfy: The target of a problem act with Act / entryRelationship / @typeCode="SUBJ" SHOULD be a problem observation (in the Problem section) or alert observation (in the Alert section), but MAY be some other clinical statement. (CONF-153)

    • [OCL]:
    ```
    self.getEntryRelationshipTargets(vocab::x_ActRelationshipEntryRelationship::SUBJ,
    cda::ClinicalStatement)->forAll(target : cda::ClinicalStatement | not
    target.oclIsUndefined() and
     (target.oclIsKindOf(ccd::ProblemObservation) or
    target.oclIsKindOf(ccd::AlertObservation)))
    ```
17. [CCD] **SHOULD** satisfy: 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))
18. [CCD] **SHOULD** satisfy: 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))

19. [CCD] **MAY** satisfy: Contains exactly one Patient Awareness (CONF-179)

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

20. [IHE] **SHALL** satisfy: The effectiveTime 'low' element shall be present. The 'high' element shall be present for concerns in the completed or aborted state, and shall not be present otherwise.

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

21. [IHE] **SHALL** satisfy: Each concern is about one or more related problems or allergies. This entry shall contain one or more problem or allergy entries that conform to the specification in section Problem Entry or Allergies and Intolerances. This is how a series of related observations can be grouped as a single concern. This SHALL be represented using entryRelationship with typeCode = 'SUBJ'.

22. [IHE] **MAY** satisfy: Each concern may have 0 or more related references. These may be used to represent related statements such related visits. This may be any valid CDA clinical statement, and SHOULD be an IHE entry template. This SHALL be represented using entryRelationship with typeCode = 'REFR'.

```xml
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <act classCode="ACT" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.27"
assigningAuthorityName="CCD Problem Act"/>
              <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.5.1"
assigningAuthorityName="IHE Concern Entry"/>
              <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.5.3"
assigningAuthorityName="IHE Allergy Intolerance Concern"/>
              <templateId root="2.16.840.1.113883.3.88.11.83.6"
assigningAuthorityName="HITSP Allergy Drug Sensitivity"/>
              <id root="c685f17a-865c-43b3-98e5-6035d9642121"/>
              <code nullFlavor="NA"/>
              <statusCode/>
              <effectiveTime>
                <low value="1972"/>
                <high value="2008"/>
              </effectiveTime>
            </act>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 35: 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 *CDA Clinical Statement*
2. **SHALL** conform to *CDA Act*

3. **SHALL** conform to *CCD Comment* template (templateId: `2.16.840.1.113883.10.20.1.40`)
4. **SHALL** conform to *IHE Comment* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.2`)
5. [CCD] **SHALL** contain [1..1] `@classCode` = "ACT"
6. [CCD] **SHALL** contain [1..1] `@moodCode` = "EVN"
7. [CCD] **SHALL** contain [1..1] `code/@code` = "48767-8" *Annotation comment* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC)
8. [IHE] **SHALL** contain [1..1] `statusCode/@code` = "completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus STATIC V3NE08)
9. [IHE] **SHALL** contain [1..1] `text`
10. [HITSP] **SHALL** contain [1..1] `author`, such that it

    a. contains *CDA Author*

    (C83-[DE-10-CDA-4])
11. [IHE] **SHALL** satisfy: The 'text' elements shall contain a 'reference' element pointing to the narrative where the severity is recorded, rather than duplicate text to avoid ambiguity.

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

```xml
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <act classCode="ACT" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.40"
 assigningAuthorityName="CCD Comment"/>
              <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.2"
 assigningAuthorityName="IHE Comment"/>
              <templateId root="2.16.840.1.113883.3.88.11.83.11"
 assigningAuthorityName="HITSP Comment"/>
              <code code="48767-8" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="Annotation comment"/>
              <text/>
              <statusCode code="completed"/>
            </act>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 36: Comment example

Condition

[Act: templateId `2.16.840.1.113883.3.88.11.83.7`]

1. **SHALL** conform to *CDA Clinical Statement*
2. **SHALL** conform to *CDA Act*
3. **SHALL** conform to *CCD Problem Act* template (templateId: `2.16.840.1.113883.10.20.1.27`)
4. **SHALL** conform to *IHE Concern Entry* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.5.1`)
5. **SHALL** conform to *IHE Problem Concern Entry* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.5.2`)
6. [CCD] **SHALL** contain [1..1] `@classCode` = "ACT" (CONF-146)
7. [CCD] **SHALL** contain [1..1] `@moodCode` = "EVN" (CONF-147)

8. [CCD] **SHALL** contain [1..1] `code/@nullFlavor` = "NA" *NA (not applicable)* (CONF-149)

9. [CCD] **SHALL** contain [1..*] `id` (CONF-148)

10. [IHE] **SHALL** contain [1..1] `effectiveTime`

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

11. [CCD] **MAY** contain [1..1] `entryRelationship`, such that it

   a. contains *CCD Episode Observation* (templateId: `2.16.840.1.113883.10.20.1.41`)

   (CONF-168)

12. [CCD] Contains [0..*] `entryRelationship`, such that it

   a. contains *CCD Problem Observation* (templateId: `2.16.840.1.113883.10.20.1.28`)

13. [IHE] **SHALL** contain [1..1] `statusCode`, which **SHALL** be selected from ValueSet *ConcernEntryStatus* STATIC

14. [IHE] **SHALL** contain [1..*] `entryRelationship`, such that it

   a. has @typeCode="SUBJ" *SUBJ (has subject)*

   b. contains *IHE Problem Entry* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.5`)

15. [HITSP] **SHALL** contain [1..*] `entryRelationship`, such that it

   a. has @typeCode="SUBJ" *SUBJ (has subject)*

   b. contains *Condition Entry*

16. [CCD] **SHALL** satisfy: Contains one or more entryRelationship (CONF-151)

   - `[OCL]: not self.entryRelationship->isEmpty()`

17. [CCD] **MAY** satisfy: A problem act MAY reference a problem observation, alert observation (see section Alerts) or other clinical statement that is the subject of concern, by setting the value for "Act / entryRelationship / @typeCode" to be "SUBJ" 2.16.840.1.113883.5.1002 ActRelationshipType STATIC. (CONF-152)

18. [CCD] **SHOULD** satisfy: The target of a problem act with Act / entryRelationship / @typeCode="SUBJ" SHOULD be a problem observation (in the Problem section) or alert observation (in the Alert section), but MAY be some other clinical statement. (CONF-153)

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

19. [CCD] **SHOULD** satisfy: 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))
     ```

20. [CCD] **SHOULD** satisfy: 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))
     ```

21. [CCD] **MAY** satisfy: Contains exactly one Patient Awareness (CONF-179)

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

22. [IHE] **SHALL** satisfy: The effectiveTime 'low' element shall be present. The 'high' element shall be present for concerns in the completed or aborted state, and shall not be present otherwise.

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

23. [IHE] **SHALL** satisfy: Each concern is about one or more related problems or allergies. This entry shall contain one or more problem or allergy entries that conform to the specification in section Problem Entry or Allergies and Intolerances. This is how a series of related observations can be grouped as a single concern. This SHALL be represented using entryRelationship with typeCode = 'SUBJ'.

24. [IHE] **MAY** satisfy: Each concern may have 0 or more related references. These may be used to represent related statements such related visits. This may be any valid CDA clinical statement, and SHOULD be an IHE entry template. This SHALL be represented using entryRelationship with typeCode = 'REFR'.

```xml
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <act classCode="ACT" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.27"
assigningAuthorityName="CCD Problem Act"/>
              <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.5.1"
assigningAuthorityName="IHE Concern Entry"/>
              <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.5.2"
assigningAuthorityName="IHE Problem Concern Entry"/>
              <templateId root="2.16.840.1.113883.3.88.11.83.7"
assigningAuthorityName="HITSP Condition"/>
              <id root="4e22d4f3-edca-4153-9d7f-3251074cf3ed"/>
              <code nullFlavor="NA"/>
              <statusCode/>
              <effectiveTime>
                <low value="1972"/>
                <high value="2008"/>
              </effectiveTime>
              <entryRelationship>
                <observation classCode="OBS" moodCode="EVN">
                  <templateId root="2.16.840.1.113883.10.20.1.28"
assigningAuthorityName="CCD Problem Observation"/>
                  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.5"
assigningAuthorityName="IHE Problem Entry"/>
                  <templateId assigningAuthorityName="HITSP Condition Entry"/>
                  <id root="c4a4367b-cbbe-4fdb-875f-c434b0e91b72"/>
                  <code codeSystem="2.16.840.1.113883.6.96"
codeSystemName="SNOMEDCT"/>
                  <text/>
                  <statusCode code="completed"/>
                  <effectiveTime>
                    <low value="1972"/>
                    <high value="2008"/>
                  </effectiveTime>
                  <value xsi:type="CD"/>
                </observation>
              </entryRelationship>
              <entryRelationship>
                <observation classCode="OBS" moodCode="EVN">
                  <templateId root="2.16.840.1.113883.10.20.1.28"
assigningAuthorityName="CCD Problem Observation"/>
                  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.5"
assigningAuthorityName="IHE Problem Entry"/>
                  <id root="d23dc04f-70af-40b4-a2ac-fde58b8f8855"/>
                  <code codeSystem="2.16.840.1.113883.6.96"
codeSystemName="SNOMEDCT"/>
                  <text/>
```

```
                 <statusCode code="completed"/>
                 <effectiveTime>
                   <low value="1972"/>
                   <high value="2008"/>
                 </effectiveTime>
                 <value xsi:type="CD"/>
               </observation>
             </entryRelationship>
           </act>
         </entry>
       </section>
     </component>
   </structuredBody>
 </component>
</ClinicalDocument>
```

Figure 37: Condition example

Condition Entry

[Observation: templateId `null`]

1. **SHALL** conform to *CDA Clinical Statement*
2. **SHALL** conform to *CDA Observation*
3. **SHALL** conform to *CCD Problem Observation* template (templateId: `2.16.840.1.113883.10.20.1.28`)
4. **SHALL** conform to *IHE Problem Entry* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.5`)
5. [CCD] Contains [1..1] `@classCode` = "OBS"
6. [CCD] **SHALL** contain [1..1] `@moodCode` = "EVN" (CONF-155)
7. [HITSP] **SHALL** contain [1..1] `code`, which **SHALL** be selected from ValueSet 2.16.840.1.113883.3.88.12.3221.7.2 Problem Type Value Set STATIC
8. [CCD] **SHALL** contain [1..1] `statusCode/@code` = "completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus STATIC V3NE08) (CONF-156, CONF-157)
9. [HITSP] **SHOULD** contain [1..1] `effectiveTime`

   - The problem date constraints include the onset and resolution dates for the problem. The onset date shall be recorded in the <low> element of the <effectiveTime> element when known. The resolution data shall be recorded in the <high> element of the <effectiveTime> element when known. These dates represent the clinically effective time span over which the problem existed. If the problem is known to be resolved, but the date of resolution is not known, then the <high> element shall be present, and the nullFlavor attribute shall be set to 'UNK'. Therefore, the existence of an <high> element within a problem does indicate that the problem has been resolved.

10. [CCD] **MAY** contain [0..1] `entryRelationship`, such that it

    a. has @typeCode="REFR" *REFR (refers to)*
    b. contains *CCD Problem Status Observation* (templateId: `2.16.840.1.113883.10.20.1.50`)

    (CONF-162)

11. [CCD] **MAY** contain [0..1] `entryRelationship`, such that it

    a. has @typeCode="REFR" *REFR (refers to)*
    b. contains *CCD Problem Health Status Observation* (templateId: `2.16.840.1.113883.10.20.1.51`)

    (CONF-165)

12. [CCD] **MAY** contain [0..1] `entryRelationship`, such that it

    a. has @typeCode="SUBJ" *SUBJ (has subject)*
    b. contains *CCD Age Observation* (templateId: `2.16.840.1.113883.10.20.1.38`)

    (CONF-160)

13. [IHE] **SHALL** contain [1..*] `id`

   - The specific observation being recorded must have an identifier (<id>) that shall be provided for tracking purposes. If the source EMR does not or cannot supply an intrinsic identifier, then a GUID shall be provided as the root, with no extension (e.g., <id root='CE1215CD-69EC-4C7B-805F-569233C5E159'/>). At least one identifier must be present, more than one may appear.

14. [HITSP] **SHALL** contain [1..1] `text`

15. [HITSP] **SHALL** contain [1..1] `value`, which **SHALL** be selected from ValueSet 2.16.840.1.113883.3.88.12.3221.7.4 Problem Value Set STATIC

16. [IHE] **MAY** contain [0..1] `entryRelationship`, such that it

   a. contains *IHE Severity* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.1`)

17. [IHE] **MAY** contain [0..1] `entryRelationship`, such that it

   a. has @typeCode="REFR" *REFR (refers to)*
   b. contains *IHE Problem Status Observation* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.1.1`)

18. [IHE] **MAY** contain [0..1] `entryRelationship`, such that it

   a. has @typeCode="REFR" *REFR (refers to)*
   b. contains *IHE Health Status Observation* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.1.2`)

19. [IHE] **MAY** contain [0..*] `entryRelationship`, such that it

   a. has @typeCode="SUBJ" *SUBJ (has subject)*
   b. contains *IHE Comment* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.2`)

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

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

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

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

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

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

```xml
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.28"
assigningAuthorityName="CCD Problem Observation"/>
              <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.5"
assigningAuthorityName="IHE Problem Entry"/>
              <templateId assigningAuthorityName="HITSP Condition Entry"/>
              <id root="3e073174-0104-414b-a722-42382887fc8b"/>
              <code codeSystem="2.16.840.1.113883.6.96"
codeSystemName="SNOMEDCT"/>
              <text/>
```

```
                        <statusCode code="completed"/>
                        <effectiveTime>
                          <low value="1972"/>
                          <high value="2008"/>
                        </effectiveTime>
                        <value xsi:type="CD"/>
                      </observation>
                    </entry>
                  </section>
                </component>
              </structuredBody>
            </component>
          </ClinicalDocument>
```

Figure 38: 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** conform to *CDA Clinical Statement*
3. **SHALL** conform to *CDA Encounter*
4. **SHALL** conform to *CCD Encounters Activity* template (templateId: `2.16.840.1.113883.10.20.1.21`)
5. **SHALL** conform to *IHE Encounter Activity* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.14`)
6. [CCD] **SHALL** contain [1..1] `@classCode` = "ENC"
7. [CCD] **SHALL** contain [1..1] `@moodCode` = "EVN"
8. [HITSP] **SHOULD** contain [1..1] `code`, which **SHOULD** be selected from ValueSet 2.16.840.1.113883.3.88.12.80.32 EncounterType DYNAMIC 20081218 (C83-[DE-16.02-1])
9. [CCD] **SHALL** contain [1..*] `id`
10. [IHE] **SHALL** contain [1..1] `text`
11. [CCD] **MAY** contain [0..1] `effectiveTime`
12. [HITSP] **MAY** contain [0..1] `priorityCode`, which **MAY** be selected from ValueSet 2.16.840.1.113883.3.88.12.80.33 Admission Type (NUBC) STATIC (C154-[DE-16.07-1])

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <encounter classCode="ENC" moodCode="EVN">
              <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.14"/>
              <templateId root="2.16.840.1.113883.10.20.1.21"
 assigningAuthorityName="CCD Encounters Activity"/>
              <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.14"/>
              <templateId root="2.16.840.1.113883.3.88.11.83.16"
 assigningAuthorityName="HITSP Encounter"/>
              <id root="697db3a9-41e2-4b30-8d8f-44ab16b41b41"/>
              <code codeSystem="2.16.840.1.113883.6.12"
 codeSystemName="CPT-4"/>
              <text/>
              <effectiveTime>
                <low value="1972"/>
                <high value="2008"/>
```

```
            </effectiveTime>
            <priorityCode/>
          </encounter>
        </entry>
      </section>
    </component>
  </structuredBody>
 </component>
</ClinicalDocument>
```

Figure 39: Encounter example

Immunization

[SubstanceAdministration: templateId `2.16.840.1.113883.3.88.11.83.13`]

1. **SHALL** conform to *CDA Clinical Statement*
2. **SHALL** conform to *CDA Substance Administration*
3. **SHALL** conform to *CCD Medication Activity* template (templateId: `2.16.840.1.113883.10.20.1.24`)
4. **SHALL** conform to *IHE Immunization* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.12`)
5. [CDA] Contains [1..1] @classCode = "SBADM", where its data type is ActClass
6. [CDA] Contains [1..1] @moodCode, where its data type is x_DocumentSubstanceMood
7. [CDA] Contains [1..1] consumable, where its type is *CDA Consumable*
8. [CCD] **SHALL** contain [1..*] id (CONF-306)
9. [CCD] **SHOULD** contain [1..1] statusCode (CONF-307)
10. [CCD] **MAY** contain [0..1] entryRelationship, such that it

    a. contains *CCD Medication Series Number Observation* (templateId: `2.16.840.1.113883.10.20.1.46`)
11. [CCD] **MAY** contain [0..1] entryRelationship, such that it

    a. contains *CCD Medication Status Observation* (templateId: `2.16.840.1.113883.10.20.1.47`)
12. [CCD] **MAY** contain [1..*] entryRelationship, such that it

    a. has @typeCode="SUBJ" *SUBJ (has subject)*
    b. contains *CCD Patient Instruction* (templateId: `2.16.840.1.113883.10.20.1.49`)

    (CONF-330, CONF-333)
13. [CCD] **SHOULD** contain [1..*] effectiveTime

    •   Used to indicate the actual or intended start and stop date of a medication, and the frequency of administration.

    (CONF-308)
14. [CCD] **MAY** contain [0..1] maxDoseQuantity (CONF-312)
15. [CCD] **SHOULD** contain [1..1] routeCode (CodeSystem: 2.16.840.1.113883.5.112 HL7 RouteOfAdministration DYNAMIC) (CONF-309, CONF-310)
16. [CCD] **MAY** contain [0..1] performer, such that it

    a. contains *CDA Performer2*
    •   Indicates the person administering a substance.

    (CONF-313)
17. [CCD] **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`
18. [CCD] **SHOULD** satisfy: Contains exactly one doseQuantity or rateQuantity. (CONF-311)

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

19. [CCD] **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())`

20. [CCD] **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'))`

21. [CCD] **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())`

22. [CCD] **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)`

23. [CCD] **SHALL** satisfy: entryRelationship / @typeCode="RSON" in a medication activity has a target of problem act, problem observation, 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)))`

```xml
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <substanceAdministration classCode="SBADM">
              <templateId root="2.16.840.1.113883.10.20.1.24"
assigningAuthorityName="CCD Medication Activity"/>
              <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.12"
assigningAuthorityName="IHE Immunization"/>
              <templateId root="2.16.840.1.113883.3.88.11.83.13"
assigningAuthorityName="HITSP Immunization"/>
              <id root="7aad62c2-0cbc-42cc-9b0f-47d579a7c87f"/>
              <statusCode/>
              <effectiveTime/>
              <routeCode codeSystem="2.16.840.1.113883.5.112"
codeSystemName="HL7 RouteOfAdministration"/>
              <maxDoseQuantity/>
            </substanceAdministration>
          </entry>
        </section>
```

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

Figure 40: Immunization example

Insurance Provider

[Act: templateId `2.16.840.1.113883.3.88.11.83.5`]

1. **SHALL** conform to *CDA Clinical Statement*
2. **SHALL** conform to *CDA Act*
3. **SHALL** conform to *CCD Coverage Activity* template (templateId: `2.16.840.1.113883.10.20.1.20`)
4. **SHALL** conform to *IHE Coverage Entry* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.17`)
5. [CCD] **SHALL** contain [1..1] `@classCode` = "ACT" (CONF-36)
6. [CCD] **SHALL** contain [1..1] `@moodCode` = "DEF" (CONF-37)
7. [CCD] **SHALL** contain [1..1] `code/@code` = "48768-6" *Payment sources* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC) (CONF-41, CONF-42)
8. [CCD] **SHALL** contain [1..*] `id` (CONF-38)
9. [CCD] **SHALL** contain [1..1] `statusCode/@code` = "completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus STATIC V3NE08) (CONF-39, CONF-40)
10. [CCD] **SHALL** contain [1..*] `entryRelationship`, such that it
    a. has @typeCode="COMP" *COMP (has component)*
    b. contains *CCD Policy Activity* (templateId: `2.16.840.1.113883.10.20.1.26`)
    (CONF-43, CONF-45, CONF-46)
11. [CCD] **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'))
      ```
12. [CCD] **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())
      ```

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <act classCode="ACT" moodCode="DEF">
              <templateId root="2.16.840.1.113883.10.20.1.20"
 assigningAuthorityName="CCD Coverage Activity"/>
              <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.17"
 assigningAuthorityName="IHE Coverage Entry"/>
              <templateId root="2.16.840.1.113883.3.88.11.83.5"
 assigningAuthorityName="HITSP Insurance Provider"/>
              <id root="cdc0d4b9-d438-461f-8e67-98f05b603c40"/>
              <code code="48768-6" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="Payment sources"/>
```

```
              <statusCode code="completed"/>
              <entryRelationship>
                <act classCode="ACT" moodCode="EVN">
                  <templateId root="2.16.840.1.113883.10.20.1.26"
 assigningAuthorityName="CCD Policy Activity"/>
                  <id root="b42a075e-dc17-4e08-80ae-e3c20e1b2fa7"/>
                  <code/>
                  <statusCode code="completed"/>
                </act>
              </entryRelationship>
            </act>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 41: Insurance Provider example

Medication

[SubstanceAdministration: templateId `2.16.840.1.113883.3.88.11.83.8`]

1. **SHALL** conform to *CDA Clinical Statement*
2. **SHALL** conform to *CDA Substance Administration*
3. **SHALL** conform to *CCD Medication Activity* template (templateId: `2.16.840.1.113883.10.20.1.24`)
4. **SHALL** conform to *IHE Medication* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.7`)
5. [CDA] Contains [1..1] `@classCode` = "SBADM", where its data type is ActClass
6. [CDA] Contains [1..1] `@moodCode`, where its data type is x_DocumentSubstanceMood
7. [CDA] Contains [1..1] `consumable`, where its type is *CDA Consumable*
8. [CCD] **SHALL** contain [1..*] id (CONF-306)
9. [CCD] **SHOULD** contain [1..1] `statusCode` (CONF-307)
10. [CCD] **MAY** contain [0..1] `entryRelationship`, such that it

    a. contains *CCD Medication Series Number Observation* (templateId: `2.16.840.1.113883.10.20.1.46`)
11. [CCD] **MAY** contain [0..1] `entryRelationship`, such that it

    a. contains *CCD Medication Status Observation* (templateId: `2.16.840.1.113883.10.20.1.47`)
12. [CCD] **MAY** contain [1..*] `entryRelationship`, such that it

    a. has @typeCode="SUBJ" *SUBJ (has subject)*
    b. contains *CCD Patient Instruction* (templateId: `2.16.840.1.113883.10.20.1.49`)

    (CONF-330, CONF-333)
13. [HITSP] **SHOULD** contain [1..*] `effectiveTime`

    • 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.

(CONF-308)

14. [CCD] **MAY** contain [0..1] `maxDoseQuantity` (CONF-312)

15. [HITSP] **SHOULD** contain [1..1] `routeCode` (CodeSystem: 2.16.840.1.113883.5.112 HL7 RouteOfAdministration DYNAMIC)

- The route is a coded value, and indicates how the medication is received by the patient (by mouth, intravenously, topically, et cetera).

(CONF-309, CONF-310)

16. [CCD] **MAY** contain [0..1] `performer`, such that it

   a. contains *CDA Performer2*

- Indicates the person administering a substance.

(CONF-313)

17. [IHE] **MAY** contain [0..*] `approachSiteCode`

- The site where the medication is administered, usually used with IV or topical drugs.

18. [IHE] **SHOULD** contain [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.

19. [IHE] **SHOULD** contain [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.

20. [CCD] **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`

21. [CCD] **SHOULD** satisfy: Contains exactly one doseQuantity or rateQuantity. (CONF-311)

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

22. [CCD] **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())`

23. [CCD] **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'))`

24. [CCD] **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())`

25. [CCD] **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)

26. [CCD] **SHALL** satisfy: entryRelationship / @typeCode="RSON" in a medication activity has a target of problem act, problem observation, 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)))

27. [IHE] **SHALL** satisfy: Contains the consumable name. If the name of the medication is unknown, the type, purpose or other description may be supplied.

   - The name of the substance or product. This should be sufficient for a provider to identify the kind of medication. It may be a trade name or a generic name. This information is required in all medication entries. If the name of the medication is unknown, the type, purpose or other description may be supplied. The name should not include packaging, strength or dosing information. Note: Due to restrictions of the CDA schema, there is no way to explicitly link the name to the narrative text.

   - [OCL]: not
     self.consumable.manufacturedProduct.manufacturedLabeledDrug.name.oclIsUndefined()
       or not
     self.consumable.manufacturedProduct.manufacturedMaterial.name.oclIsUndefined()

28. [HITSP] **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.

29. [HITSP] **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 institutionSpecified 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).

30. [HITSP] **SHALL** satisfy: 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])

31. [HITSP] **SHALL** satisfy: 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])

32. [HITSP] **SHALL** satisfy: 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])

33. [HITSP] **SHALL** satisfy: 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])

```xml
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <substanceAdministration classCode="SBADM">
              <templateId root="2.16.840.1.113883.10.20.1.24"
 assigningAuthorityName="CCD Medication Activity"/>
              <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.7"
 assigningAuthorityName="IHE Medication"/>
```

```
              <templateId root="2.16.840.1.113883.3.88.11.83.8"/>
              <id root="3dfea78d-5d9f-4d08-9296-8da3e09dc1d9"/>
              <statusCode/>
              <effectiveTime/>
              <routeCode codeSystem="2.16.840.1.113883.5.112"
 codeSystemName="HL7 RouteOfAdministration"/>
              <approachSiteCode/>
              <doseQuantity/>
              <rateQuantity/>
              <maxDoseQuantity/>
          </substanceAdministration>
        </entry>
      </section>
    </component>
  </structuredBody>
 </component>
</ClinicalDocument>
```

Figure 42: Medication example

Medication Combination Medication

[SubstanceAdministration: templateId `null`]

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 *CDA Clinical Statement*
3. **SHALL** conform to *CDA Substance Administration*
4. **SHALL** conform to *CCD Medication Activity* template (templateId: `2.16.840.1.113883.10.20.1.24`)
5. **SHALL** conform to *IHE Medication* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.7`)
6. **SHALL** conform to *Medication* template (templateId: `2.16.840.1.113883.3.88.11.83.8`)
7. [CDA] Contains [1..1] @classCode = "SBADM", where its data type is ActClass
8. [CDA] Contains [1..1] @moodCode, where its data type is x_DocumentSubstanceMood
9. [CDA] Contains [1..1] consumable, where its type is *CDA Consumable*
10. [CCD] **SHALL** contain [1..*] id (CONF-306)
11. [CCD] **SHOULD** contain [1..1] statusCode (CONF-307)
12. [CCD] **MAY** contain [0..1] entryRelationship, such that it

    a. contains *CCD Medication Series Number Observation* (templateId: `2.16.840.1.113883.10.20.1.46`)
13. [CCD] **MAY** contain [0..1] entryRelationship, such that it

    a. contains *CCD Medication Status Observation* (templateId: `2.16.840.1.113883.10.20.1.47`)
14. [CCD] **MAY** contain [1..*] entryRelationship, such that it

    a. has @typeCode="SUBJ" *SUBJ (has subject)*
    b. contains *CCD Patient Instruction* (templateId: `2.16.840.1.113883.10.20.1.49`)

    (CONF-330, CONF-333)
15. [HITSP] **SHOULD** contain [1..*] effectiveTime

    • 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.

(CONF-308)

16. [CCD] **MAY** contain [0..1] `maxDoseQuantity` (CONF-312)

17. [HITSP] **SHOULD** contain [1..1] `routeCode` (CodeSystem: 2.16.840.1.113883.5.112 HL7 RouteOfAdministration DYNAMIC)

- The route is a coded value, and indicates how the medication is received by the patient (by mouth, intravenously, topically, et cetera).

(CONF-309, CONF-310)

18. [CCD] **MAY** contain [0..1] `performer`, such that it

   a. contains *CDA Performer2*

- Indicates the person administering a substance.

(CONF-313)

19. [IHE] **MAY** contain [0..*] `approachSiteCode`

- The site where the medication is administered, usually used with IV or topical drugs.

20. [IHE] **SHOULD** contain [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.

21. [IHE] **SHOULD** contain [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.

22. [CCD] **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`

23. [CCD] **SHOULD** satisfy: Contains exactly one doseQuantity or rateQuantity. (CONF-311)

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

24. [CCD] **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())`

25. [CCD] **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'))`

26. [CCD] **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())

27. [CCD] **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)

28. [CCD] **SHALL** satisfy: entryRelationship / @typeCode="RSON" in a medication activity has a target of problem act, problem observation, 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)))
  ```

29. [IHE] **SHALL** satisfy: Contains the consumable name. If the name of the medication is unknown, the type, purpose or other description may be supplied.

- The name of the substance or product. This should be sufficient for a provider to identify the kind of medication. It may be a trade name or a generic name. This information is required in all medication entries. If the name of the medication is unknown, the type, purpose or other description may be supplied. The name should not include packaging, strength or dosing information. Note: Due to restrictions of the CDA schema, there is no way to explicitly link the name to the narrative text.
- [OCL]: not
  self.consumable.manufacturedProduct.manufacturedLabeledDrug.name.oclIsUndefined()
    or not
  self.consumable.manufacturedProduct.manufacturedMaterial.name.oclIsUndefined()

30. [HITSP] **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.

31. [HITSP] **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).

32. [HITSP] **SHALL** satisfy: 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])

33. [HITSP] **SHALL** satisfy: 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])

34. [HITSP] **SHALL** satisfy: 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])

35. [HITSP] **SHALL** satisfy: 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])

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

```
            <templateId root="2.16.840.1.113883.10.20.1.24"
assigningAuthorityName="CCD Medication Activity"/>
            <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.7"
assigningAuthorityName="IHE Medication"/>
            <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.11"
assigningAuthorityName="IHE Combination Medication"/>
            <templateId root="2.16.840.1.113883.3.88.11.83.8"/>
            <templateId assigningAuthorityName="HITSP Medication Combination
Medication"/>
            <id root="94fdf38b-682c-4049-ba45-001a0152bd98"/>
            <statusCode/>
            <effectiveTime/>
            <routeCode codeSystem="2.16.840.1.113883.5.112"
codeSystemName="HL7 RouteOfAdministration"/>
            <approachSiteCode/>
            <doseQuantity/>
            <rateQuantity/>
            <maxDoseQuantity/>
          </substanceAdministration>
        </entry>
      </section>
    </component>
  </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 43: Medication Combination Medication example

Medication Conditional Dose

[SubstanceAdministration: templateId `null`]

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 *CDA Clinical Statement*
3. **SHALL** conform to *CDA Substance Administration*
4. **SHALL** conform to *CCD Medication Activity* template (templateId: `2.16.840.1.113883.10.20.1.24`)
5. **SHALL** conform to *IHE Medication* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.7`)
6. **SHALL** conform to *Medication* template (templateId: `2.16.840.1.113883.3.88.11.83.8`)
7. [CDA] Contains [1..1] @`classCode` = "SBADM", where its data type is ActClass
8. [CDA] Contains [1..1] @`moodCode`, where its data type is x_DocumentSubstanceMood
9. [CDA] Contains [1..1] `consumable`, where its type is *CDA Consumable*
10. [CCD] **SHALL** contain [1..*] `id` (CONF-306)
11. [CCD] **SHOULD** contain [1..1] `statusCode` (CONF-307)
12. [CCD] **MAY** contain [0..1] `entryRelationship`, such that it

    a. contains *CCD Medication Series Number Observation* (templateId: `2.16.840.1.113883.10.20.1.46`)
13. [CCD] **MAY** contain [0..1] `entryRelationship`, such that it

    a. contains *CCD Medication Status Observation* (templateId: `2.16.840.1.113883.10.20.1.47`)
14. [CCD] **MAY** contain [1..*] `entryRelationship`, such that it

    a. has @typeCode="SUBJ" *SUBJ (has subject)*
    b. contains *CCD Patient Instruction* (templateId: `2.16.840.1.113883.10.20.1.49`)

    (CONF-330, CONF-333)
15. [HITSP] **SHOULD** contain [1..*] `effectiveTime`
    • 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.

(CONF-308)

16. [CCD] **MAY** contain [0..1] `maxDoseQuantity` (CONF-312)

17. [HITSP] **SHOULD** contain [1..1] `routeCode` (CodeSystem: 2.16.840.1.113883.5.112 HL7 RouteOfAdministration DYNAMIC)

- The route is a coded value, and indicates how the medication is received by the patient (by mouth, intravenously, topically, et cetera).

(CONF-309, CONF-310)

18. [CCD] **MAY** contain [0..1] `performer`, such that it

a. contains *CDA Performer2*

- Indicates the person administering a substance.

(CONF-313)

19. [IHE] **MAY** contain [0..*] `approachSiteCode`

- The site where the medication is administered, usually used with IV or topical drugs.

20. [IHE] **SHOULD** contain [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.

21. [IHE] **SHOULD** contain [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.

22. [CCD] **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
  ```

23. [CCD] **SHOULD** satisfy: Contains exactly one doseQuantity or rateQuantity. (CONF-311)

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

24. [CCD] **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())
  ```

25. [CCD] **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'))
```

26. [CCD] **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())
      ```

27. [CCD] **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)
      ```

28. [CCD] **SHALL** satisfy: entryRelationship / @typeCode="RSON" in a medication activity has a target of problem act, problem observation, 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)))
      ```

29. [IHE] **SHALL** satisfy: Contains the consumable name. If the name of the medication is unknown, the type, purpose or other description may be supplied.

    - The name of the substance or product. This should be sufficient for a provider to identify the kind of medication. It may be a trade name or a generic name. This information is required in all medication entries. If the name of the medication is unknown, the type, purpose or other description may be supplied. The name should not include packaging, strength or dosing information. Note: Due to restrictions of the CDA schema, there is no way to explicitly link the name to the narrative text.

    - ```
      [OCL]: not
       self.consumable.manufacturedProduct.manufacturedLabeledDrug.name.oclIsUndefined()
         or not
       self.consumable.manufacturedProduct.manufacturedMaterial.name.oclIsUndefined()
      ```

30. [HITSP] **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.

31. [HITSP] **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).

32. [HITSP] **SHALL** satisfy: 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])

33. [HITSP] **SHALL** satisfy: 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])

34. [HITSP] **SHALL** satisfy: 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])

35. [HITSP] **SHALL** satisfy: 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])

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

```
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <substanceAdministration classCode="SBADM">
              <templateId root="2.16.840.1.113883.10.20.1.24"
assigningAuthorityName="CCD Medication Activity"/>
              <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.7"
assigningAuthorityName="IHE Medication"/>
              <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.10"
assigningAuthorityName="IHE Conditional Dose"/>
              <templateId root="2.16.840.1.113883.3.88.11.83.8"/>
              <templateId assigningAuthorityName="HITSP Medication Conditional
Dose"/>
              <id root="dd133742-e0d1-43e8-9733-b8c0844a60c5"/>
              <statusCode/>
              <effectiveTime/>
              <routeCode codeSystem="2.16.840.1.113883.5.112"
codeSystemName="HL7 RouteOfAdministration"/>
              <approachSiteCode/>
              <doseQuantity/>
              <rateQuantity/>
              <maxDoseQuantity/>
            </substanceAdministration>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 44: Medication Conditional Dose example

Medication Normal Dose

[SubstanceAdministration: templateId `null`]

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 *CDA Clinical Statement*
3. **SHALL** conform to *CDA Substance Administration*
4. **SHALL** conform to *CCD Medication Activity* template (templateId: `2.16.840.1.113883.10.20.1.24`)
5. **SHALL** conform to *IHE Medication* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.7`)
6. **SHALL** conform to *Medication* template (templateId: `2.16.840.1.113883.3.88.11.83.8`)
7. [CDA] Contains [1..1] `@classCode` = "SBADM", where its data type is ActClass
8. [CDA] Contains [1..1] `@moodCode`, where its data type is x_DocumentSubstanceMood
9. [CDA] Contains [1..1] `consumable`, where its type is *CDA Consumable*
10. [CCD] **SHALL** contain [1..*] id (CONF-306)
11. [CCD] **SHOULD** contain [1..1] `statusCode` (CONF-307)
12. [CCD] **MAY** contain [0..1] `entryRelationship`, such that it
    a. contains *CCD Medication Series Number Observation* (templateId: `2.16.840.1.113883.10.20.1.46`)
13. [CCD] **MAY** contain [0..1] `entryRelationship`, such that it
    a. contains *CCD Medication Status Observation* (templateId: `2.16.840.1.113883.10.20.1.47`)
14. [CCD] **MAY** contain [1..*] `entryRelationship`, such that it
    a. has @typeCode="SUBJ" *SUBJ (has subject)*
    b. contains *CCD Patient Instruction* (templateId: `2.16.840.1.113883.10.20.1.49`)

(CONF-330, CONF-333)

15. [HITSP] **SHOULD** contain [1..*] `effectiveTime`

   - 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.

   (CONF-308)

16. [CCD] **MAY** contain [0..1] `maxDoseQuantity` (CONF-312)

17. [HITSP] **SHOULD** contain [1..1] `routeCode` (CodeSystem: 2.16.840.1.113883.5.112 HL7 RouteOfAdministration DYNAMIC)

   - The route is a coded value, and indicates how the medication is received by the patient (by mouth, intravenously, topically, et cetera).

   (CONF-309, CONF-310)

18. [CCD] **MAY** contain [0..1] `performer`, such that it

   a. contains *CDA Performer2*

   - Indicates the person administering a substance.

   (CONF-313)

19. [IHE] **MAY** contain [0..*] `approachSiteCode`

   - The site where the medication is administered, usually used with IV or topical drugs.

20. [IHE] **SHOULD** contain [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.

21. [IHE] **SHOULD** contain [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.

22. [CCD] **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`

23. [CCD] **SHOULD** satisfy: Contains exactly one doseQuantity or rateQuantity. (CONF-311)

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

24. [CCD] **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())
```

25. [CCD] **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'))
     ```

26. [CCD] **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())
     ```

27. [CCD] **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)
     ```

28. [CCD] **SHALL** satisfy: entryRelationship / @typeCode="RSON" in a medication activity has a target of problem act, problem observation, 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)))
     ```

29. [IHE] **SHALL** satisfy: Contains the consumable name. If the name of the medication is unknown, the type, purpose or other description may be supplied.

   - The name of the substance or product. This should be sufficient for a provider to identify the kind of medication. It may be a trade name or a generic name. This information is required in all medication entries. If the name of the medication is unknown, the type, purpose or other description may be supplied. The name should not include packaging, strength or dosing information. Note: Due to restrictions of the CDA schema, there is no way to explicitly link the name to the narrative text.

   - ```
     [OCL]: not
      self.consumable.manufacturedProduct.manufacturedLabeledDrug.name.oclIsUndefined()
        or not
      self.consumable.manufacturedProduct.manufacturedMaterial.name.oclIsUndefined()
     ```

30. [HITSP] **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.

31. [HITSP] **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).

32. [HITSP] **SHALL** satisfy: 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])

33. [HITSP] **SHALL** satisfy: 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])

34. [HITSP] **SHALL** satisfy: 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])

35. [HITSP] **SHALL** satisfy: 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])

```xml
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <substanceAdministration classCode="SBADM">
              <templateId root="2.16.840.1.113883.10.20.1.24"
assigningAuthorityName="CCD Medication Activity"/>
              <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.7"
assigningAuthorityName="IHE Medication"/>
              <templateId root="2.16.840.1.113883.3.88.11.83.8"/>
              <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.7.1"
assigningAuthorityName="IHE Normal Dose"/>
              <templateId assigningAuthorityName="HITSP Medication Normal
Dose"/>
              <id root="d4d38359-ff1b-4f65-8947-463d7fa5d756"/>
              <statusCode/>
              <effectiveTime/>
              <routeCode codeSystem="2.16.840.1.113883.5.112"
codeSystemName="HL7 RouteOfAdministration"/>
              <approachSiteCode/>
              <doseQuantity/>
              <rateQuantity/>
              <maxDoseQuantity/>
            </substanceAdministration>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 45: Medication Normal Dose example

Medication Split Dose

[SubstanceAdministration: templateId `null`]

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 *CDA Clinical Statement*
3. **SHALL** conform to *CDA Substance Administration*
4. **SHALL** conform to *CCD Medication Activity* template (templateId: `2.16.840.1.113883.10.20.1.24`)
5. **SHALL** conform to *IHE Medication* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.7`)
6. **SHALL** conform to *Medication* template (templateId: `2.16.840.1.113883.3.88.11.83.8`)
7. [CDA] Contains [1..1] @`classCode` = "SBADM", where its data type is ActClass
8. [CDA] Contains [1..1] @`moodCode`, where its data type is x_DocumentSubstanceMood
9. [CDA] Contains [1..1] `consumable`, where its type is *CDA Consumable*
10. [CCD] **SHALL** contain [1..*] id (CONF-306)
11. [CCD] **SHOULD** contain [1..1] `statusCode` (CONF-307)
12. [CCD] **MAY** contain [0..1] `entryRelationship`, such that it

    a. contains *CCD Medication Series Number Observation* (templateId: `2.16.840.1.113883.10.20.1.46`)
13. [CCD] **MAY** contain [0..1] `entryRelationship`, such that it

    a. contains *CCD Medication Status Observation* (templateId: `2.16.840.1.113883.10.20.1.47`)

14. [CCD] **MAY** contain [1..*] `entryRelationship`, such that it

    a. has @typeCode="SUBJ" *SUBJ (has subject)*

    b. contains *CCD Patient Instruction* (templateId: `2.16.840.1.113883.10.20.1.49`)

    (CONF-330, CONF-333)

15. [HITSP] **SHOULD** contain [1..*] `effectiveTime`

- 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.

    (CONF-308)

16. [CCD] **MAY** contain [0..1] `maxDoseQuantity` (CONF-312)

17. [HITSP] **SHOULD** contain [1..1] `routeCode` (CodeSystem: 2.16.840.1.113883.5.112 HL7 RouteOfAdministration DYNAMIC)

- The route is a coded value, and indicates how the medication is received by the patient (by mouth, intravenously, topically, et cetera).

    (CONF-309, CONF-310)

18. [CCD] **MAY** contain [0..1] `performer`, such that it

    a. contains *CDA Performer2*

- Indicates the person administering a substance.

    (CONF-313)

19. [IHE] **MAY** contain [0..*] `approachSiteCode`

- The site where the medication is administered, usually used with IV or topical drugs.

20. [IHE] **SHOULD** contain [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.

21. [IHE] **SHOULD** contain [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.

22. [CCD] **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
  ```

23. [CCD] **SHOULD** satisfy: Contains exactly one doseQuantity or rateQuantity. (CONF-311)

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

24. [CCD] **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())
  ```

25. [CCD] **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'))
  ```

26. [CCD] **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())
  ```

27. [CCD] **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)
  ```

28. [CCD] **SHALL** satisfy: entryRelationship / @typeCode="RSON" in a medication activity has a target of problem act, problem observation, 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)))
  ```

29. [IHE] **SHALL** satisfy: Contains the consumable name. If the name of the medication is unknown, the type, purpose or other description may be supplied.

- The name of the substance or product. This should be sufficient for a provider to identify the kind of medication. It may be a trade name or a generic name. This information is required in all medication entries. If the name of the medication is unknown, the type, purpose or other description may be supplied. The name should not include packaging, strength or dosing information. Note: Due to restrictions of the CDA schema, there is no way to explicitly link the name to the narrative text.

- ```
  [OCL]: not
  self.consumable.manufacturedProduct.manufacturedLabeledDrug.name.oclIsUndefined()
    or not
  self.consumable.manufacturedProduct.manufacturedMaterial.name.oclIsUndefined()
  ```

30. [HITSP] **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.

31. [HITSP] **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).

32. [HITSP] **SHALL** satisfy: 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])

33. [HITSP] **SHALL** satisfy: 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])

34. [HITSP] **SHALL** satisfy: 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])

35. [HITSP] **SHALL** satisfy: 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])

```xml
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <substanceAdministration classCode="SBADM">
              <templateId root="2.16.840.1.113883.10.20.1.24"
assigningAuthorityName="CCD Medication Activity"/>
              <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.7"
assigningAuthorityName="IHE Medication"/>
              <templateId root="2.16.840.1.113883.3.88.11.83.8"/>
              <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.9"
assigningAuthorityName="IHE Split Dose"/>
              <templateId assigningAuthorityName="HITSP Medication Split
Dose"/>
              <id root="2292522c-b457-46b6-af33-6cb84d18dac8"/>
              <statusCode/>
              <effectiveTime/>
              <routeCode codeSystem="2.16.840.1.113883.5.112"
codeSystemName="HL7 RouteOfAdministration"/>
              <approachSiteCode/>
              <doseQuantity/>
              <rateQuantity/>
              <maxDoseQuantity/>
            </substanceAdministration>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 46: 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 *CDA Clinical Statement*
3. **SHALL** conform to *CDA Substance Administration*
4. **SHALL** conform to *CCD Medication Activity* template (templateId: `2.16.840.1.113883.10.20.1.24`)
5. **SHALL** conform to *IHE Medication* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.7`)
6. **SHALL** conform to *Medication* template (templateId: `2.16.840.1.113883.3.88.11.83.8`)

7. [CDA] Contains [1..1] `@classCode` = "SBADM", where its data type is ActClass
8. [CDA] Contains [1..1] `@moodCode`, where its data type is x_DocumentSubstanceMood
9. [CDA] Contains [1..1] `consumable`, where its type is *CDA Consumable*
10. [CCD] **SHALL** contain [1..*] `id` (CONF-306)
11. [CCD] **SHOULD** contain [1..1] `statusCode` (CONF-307)
12. [CCD] **MAY** contain [0..1] `entryRelationship`, such that it

    a. contains *CCD Medication Series Number Observation* (templateId: `2.16.840.1.113883.10.20.1.46`)
13. [CCD] **MAY** contain [0..1] `entryRelationship`, such that it

    a. contains *CCD Medication Status Observation* (templateId: `2.16.840.1.113883.10.20.1.47`)
14. [CCD] **MAY** contain [1..*] `entryRelationship`, such that it

    a. has @typeCode="SUBJ" *SUBJ (has subject)*
    b. contains *CCD Patient Instruction* (templateId: `2.16.840.1.113883.10.20.1.49`)

    (CONF-330, CONF-333)
15. [HITSP] **SHOULD** contain [1..*] `effectiveTime`

    - 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.

    (CONF-308)
16. [CCD] **MAY** contain [0..1] `maxDoseQuantity` (CONF-312)
17. [HITSP] **SHOULD** contain [1..1] `routeCode` (CodeSystem: 2.16.840.1.113883.5.112 HL7 RouteOfAdministration DYNAMIC)

    - The route is a coded value, and indicates how the medication is received by the patient (by mouth, intravenously, topically, et cetera).

    (CONF-309, CONF-310)
18. [CCD] **MAY** contain [0..1] `performer`, such that it

    a. contains *CDA Performer2*
    - Indicates the person administering a substance.

    (CONF-313)
19. [IHE] **MAY** contain [0..*] `approachSiteCode`

    - The site where the medication is administered, usually used with IV or topical drugs.
20. [IHE] **SHOULD** contain [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.
21. [IHE] **SHOULD** contain [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.

22. [CCD] **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`

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

24. [CCD] **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())`

25. [CCD] **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'))`

26. [CCD] **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())`

27. [CCD] **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)`

28. [CCD] **SHALL** satisfy: entryRelationship / @typeCode="RSON" in a medication activity has a target of problem act, problem observation, 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)))`

29. [IHE] **SHALL** satisfy: Contains the consumable name. If the name of the medication is unknown, the type, purpose or other description may be supplied.
    - The name of the substance or product. This should be sufficient for a provider to identify the kind of medication. It may be a trade name or a generic name. This information is required in all medication entries. If the name of the medication is unknown, the type, purpose or other description may be supplied. The name should not include packaging, strength or dosing information. Note: Due to restrictions of the CDA schema, there is no way to explicitly link the name to the narrative text.
    - `[OCL]: not`
      `self.consumable.manufacturedProduct.manufacturedLabeledDrug.name.oclIsUndefined()`
      `or not`
      `self.consumable.manufacturedProduct.manufacturedMaterial.name.oclIsUndefined()`

30. [HITSP] **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.

31. [HITSP] **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 institutionSpecified 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).

32. [HITSP] **SHALL** satisfy: 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])

33. [HITSP] **SHALL** satisfy: 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])

34. [HITSP] **SHALL** satisfy: 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])

35. [HITSP] **SHALL** satisfy: 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])

```xml
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <substanceAdministration classCode="SBADM">
              <templateId root="2.16.840.1.113883.10.20.1.24"
 assigningAuthorityName="CCD Medication Activity"/>
              <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.7"
 assigningAuthorityName="IHE Medication"/>
              <templateId root="2.16.840.1.113883.3.88.11.83.8"/>
              <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.8"
 assigningAuthorityName="IHE Tapered Dose"/>
              <templateId root="null" assigningAuthorityName="HITSP Medication
Tapered Dose"/>
              <templateId assigningAuthorityName="HITSP Medication Tapered
Dose"/>
              <id root="74454b50-bab2-4d2d-a186-818d277cf597"/>
              <statusCode/>
              <effectiveTime/>
              <routeCode codeSystem="2.16.840.1.113883.5.112"
 codeSystemName="HL7 RouteOfAdministration"/>
              <approachSiteCode/>
              <doseQuantity/>
              <rateQuantity/>
              <maxDoseQuantity/>
            </substanceAdministration>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 47: Medication Tapered Dose 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*
2. **SHALL** conform to *CCD Procedure Activity*
3. **SHALL** conform to *CDA Clinical Statement*
4. **SHALL** conform to *CDA Procedure*
5. **SHALL** conform to *CCD Procedure Activity Procedure* template (templateId: `2.16.840.1.113883.10.20.1.29`)
6. **SHALL** conform to *IHE Procedure Entry Procedure Activity Procedure* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.19`)
7. [CDA] Contains [1..1] `@classCode`, where its data type is ActClass
8. [CDA] Contains [1..1] `@moodCode`, where its data type is x_DocumentProcedureMood
9. [IHE] **SHALL** contain [1..*] `id`
10. [IHE] **SHALL** contain [1..1] `statusCode`
    - The <statusCode> element shall be present when used to describe a procedure event. It shall have the value 'completed' for procedures that have been completed, and 'active' for procedures that are still in progress. Procedures that were stopped prior to completion shall use the value 'aborted', and procedures that were cancelled before being started shall use the value 'cancelled'.
11. [IHE] **SHOULD** contain [1..1] `effectiveTime`
12. [IHE] **SHALL** contain [1..1] `code`
    - Contains a code describing the type of procedure.
13. [IHE] **MAY** contain [0..*] `approachSiteCode`
    - This element may be present to indicate the procedure approach.
14. [HITSP] **SHOULD** contain [1..1] `targetSiteCode`, which **SHOULD** be selected from ValueSet 2.16.840.1.113883.3.88.12.3221.8.9 Body Site Value Set STATIC 2 (C83-[DE-17-CDA-3])
15. [IHE] **SHALL** contain [1..1] `text`
16. [IHE] **SHALL** satisfy: The <text> element shall contain a reference to the narrative text describing the procedure.
    - `[OCL]: not self.text.reference.oclIsUndefined()`
17. [IHE] **MAY** satisfy: entryRelationship with typeCode='COMP' may be present to point to the encounter in which the procedure was performed, and shall contain an internal reference to the encounter.
18. [IHE] **MAY** satisfy: entryRelationship with typeCode='RSON' may be present. A <procedure> act may indicate one or more reasons for the procedure. These reasons identify the concern that was the reason for the procedure via an Internal Reference to the concern. The extension and root of each observation present must match the identifier of a concern entry contained elsewhere within the CDA document.
19. [HITSP] **SHOULD** satisfy: The code/@code attribute is present.
    - `[OCL]: not self.code.code.oclIsUndefined()`
20. [HITSP] **SHALL** satisfy: The code/originalText/reference/@value is present.
    - `[OCL]: not self.code.originalText.reference.value.oclIsUndefined()`
21. [HITSP] **SHOULD** satisfy: Contains the procedure provider in performer / assignedEntity.
    - `[OCL]: self.performer->forAll(perf : cda::Performer2 | not perf.oclIsUndefined() and perf.assignedEntity->size() > 0)`

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

```
        <section>
          <entry>
            <procedure>
              <templateId root="2.16.840.1.113883.10.20.1.29"/>
              <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.19"/>
              <templateId root="2.16.840.1.113883.3.88.11.83.17"
 assigningAuthorityName="HITSP Procedure"/>
              <id root="5ab0e01d-831a-4170-8e28-058d6956fdf9"/>
              <code/>
              <text/>
              <statusCode code="completed"/>
              <effectiveTime>
                <low value="1972"/>
                <high value="2008"/>
              </effectiveTime>
              <approachSiteCode/>
              <targetSiteCode codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMEDCT"/>
            </procedure>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 48: Procedure example

Result

[Observation: templateId `2.16.840.1.113883.3.88.11.83.15`]

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

1. **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 *CDA Clinical Statement*
3. **SHALL** conform to *CDA Observation*
4. **SHALL** conform to *CCD Result Observation* template (templateId: `2.16.840.1.113883.10.20.1.31`)
5. [CDA] Contains [1..1] @classCode, where its data type is ActClassObservation
6. [CCD] **SHALL** contain [1..1] @moodCode = "EVN" (CONF-408)
7. [CCD] **SHALL** contain [1..*] id (CONF-409)
8. [CCD] **SHALL** contain [1..1] statusCode (CONF-410)
9. [HITSP] **SHALL** contain [1..1] code
10. [HITSP] **SHALL** contain [1..1] effectiveTime
11. [CCD] **MAY** contain [0..1] methodCode

   • Included if the method isn't inherent in code or if there is a need to further specialize the method in code.

   (CONF-414)
12. [CCD] **SHOULD** contain [0..*] interpretationCode

   • 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.

   (CONF-418)
13. [HITSP] **SHALL** contain [1..1] value

   • The Result value records the desired result in a goal or recorded CDA event, and will not present when recording an intent, request or proposal to measure a result.

14. [CCD] **SHOULD** satisfy: 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)

15. [CCD] **SHALL** satisfy: The methodCode SHALL NOT conflict with the method inherent in code (CONF-415)

16. [CCD] **SHALL** satisfy: 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. [CCD] **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. [CCD] **SHALL** satisfy: 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. [CCD] **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. [HITSP] **SHOULD** satisfy: 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])

21. [HITSP] **SHOULD** satisfy: 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])

22. [HITSP] **SHALL** satisfy: 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())`

```xml
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.31"
 assigningAuthorityName="CCD Result Observation"/>
              <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.13"
 assigningAuthorityName="IHE Simple Observation"/>
              <templateId root="2.16.840.1.113883.3.88.11.83.15"
 assigningAuthorityName="HITSP Result"/>
              <id root="4010cd7d-f139-4fc5-a1f7-d74197a42474"/>
              <code/>
              <statusCode code="completed"/>
              <effectiveTime>
                <low value="1972"/>
                <high value="2008"/>
              </effectiveTime>
              <interpretationCode/>
              <methodCode/>
```

```
                </observation>
              </entry>
            </section>
          </component>
      </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 49: Result example

Vital Sign

[Observation: templateId `2.16.840.1.113883.3.88.11.83.14`]

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 *CDA Clinical Statement*
3. **SHALL** conform to *CDA Observation*
4. **SHALL** conform to *CCD Result Observation* template (templateId: `2.16.840.1.113883.10.20.1.31`)
5. **SHALL** conform to *IHE Vital Sign Observation* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.13.2`)
6. [CDA] Contains [1..1] `@classCode`, where its data type is ActClassObservation
7. [CCD] **SHALL** contain [1..1] `@moodCode` = "EVN" (CONF-408)
8. [CCD] **SHALL** contain [1..*] `id` (CONF-409)
9. [IHE] Contains [1..1] `statusCode`

   • The observations have all been completed.

10. [HITSP] **SHALL** contain [1..1] `code`, which **SHALL** be selected from ValueSet 2.16.840.1.113883.3.88.12.80.62 Vital Sign Result Value Set STATIC 1
11. [CCD] **SHOULD** contain [1..1] `effectiveTime`

   • Represents the biologically relevant time (e.g. time the specimen was obtained from the patient).

   (CONF-411)
12. [IHE] **MAY** contain [0..*] `methodCode`

   • 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. [IHE] **MAY** contain [0..*] `interpretationCode`

   • The interpretation code may be present to provide an interpretation of the vital signs measure (e.g., High, Normal, Low, et cetera).
14. [IHE] **SHALL** contain [1..1] `value`, where its data type is PQ
15. [IHE] **MAY** contain [0..*] `targetSiteCode`

   • The target site of the measure may be identified in the targetSiteCode element (e.g., Left arm [blood pressure], oral [temperature], et cetera).
16. [CCD] **SHOULD** satisfy: 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)
17. [CCD] **SHALL** satisfy: The methodCode SHALL NOT conflict with the method inherent in code (CONF-415)
18. [CCD] **SHALL** satisfy: 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)
19. [CCD] **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()`

20. [CCD] **SHALL** satisfy: 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())
  ```

21. [CCD] **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'))
  ```

```xml
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.31"
assigningAuthorityName="CCD Result Observation"/>
              <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.13"
assigningAuthorityName="IHE Simple Observation"/>
              <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.13.2"
assigningAuthorityName="IHE Vital Sign Observation"/>
              <templateId root="2.16.840.1.113883.3.88.11.83.14"
assigningAuthorityName="HITSP Vital Sign"/>
              <id root="24c63891-f2a3-42fd-8693-c688baed866b"/>
              <code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/
>
              <statusCode code="completed"/>
              <effectiveTime>
                <low value="1972"/>
                <high value="2008"/>
              </effectiveTime>
              <value xsi:type="PQ"/>
              <interpretationCode/>
              <methodCode/>
              <targetSiteCode/>
            </observation>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 50: Vital Sign example

Chapter

5

OTHER CLASSES

Topics:

- *Healthcare Provider*
- *Language Spoken*
- *Medication Information*
- *Support*
- *Support Guardian*
- *Support Participant*

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 *CDA Performer1*
2. **SHALL** conform to *IHE Healthcare Providers Pharmacies* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.2.3`)
3. [CDA] Contains [1..1] `@typeCode`, where its data type is x_ServiceEventPerformer
4. [CDA] Contains [1..1] `assignedEntity`, where its type is *CDA Assigned Entity*

Figure 51: Healthcare Provider example

Language Spoken

[LanguageCommunication: templateId `2.16.840.1.113883.3.88.11.83.2`]

1. **SHALL** conform to *CDA Language Communication*
2. **SHALL** conform to *IHE Language Communication* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.2.1`)
3. [HITSP] **SHALL** contain [1..1] `languageCode`, which **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.11526 Language DYNAMIC 200609 (C154-[DE-2.01-1])
4. [HITSP] **SHALL** contain [0..1] `modeCode`, which **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.12249 LanguageAbilityMode Value Set STATIC 1

   • 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.

   (C83-[DE-2.01-CDA-4])
5. [HITSP] **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])
6. [HITSP] **SHALL** satisfy: Sign language is treated as a separate language. (C154-[DE-2.01-2])
7. [HITSP] **SHOULD** satisfy: 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()`

Figure 52: Language Spoken example

Medication Information

[ManufacturedProduct: templateId `2.16.840.1.113883.3.88.11.83.8.2`]

1. **SHALL** conform to *CDA Manufactured Product*
2. **SHALL** conform to *CCD Product* template (templateId: `2.16.840.1.113883.10.20.1.53`)
3. **SHALL** conform to *IHE Product Entry* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.7.2`)
4. [CDA] **SHALL** satisfy: manufacturedDrugOrOtherMaterial

   • `[OCL]: self.manufacturedLabeledDrug.oclIsUndefined() xor`
     `self.manufacturedMaterial.oclIsUndefined()`

Figure 53: 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.

Figure 54: 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 *CDA Guardian*
5. **SHALL** conform to *CCD Support Guardian*
6. **SHALL** conform to *IHE Patient Contact Guardian* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.2.4`)
7. [IHE] **SHALL** contain [1..1] @classCode = "GUAR"
8. [IHE] **SHOULD** contain [0..*] addr
9. [IHE] **SHALL** contain [0..1] code (CodeSystem: 2.16.840.1.113883.5.111 RoleCode STATIC)
10. [IHE] **SHOULD** contain [0..*] telecom
11. [CDA] **SHALL** satisfy: guardianChoice

   - [OCL]: self.guardianPerson.oclIsUndefined() xor
     self.guardianOrganization.oclIsUndefined()

Figure 55: 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 *CDA Participant1*
5. **SHALL** conform to *CCD Support Participant*

6. **SHALL** conform to *IHE Patient Contact Participant* template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.2.4)
7. [IHE] **SHALL** contain [1..1] @typeCode = "IND"
8. [CDA] Contains [1..1] associatedEntity, where its type is *CDA Associated Entity*
9. [IHE] **MAY** contain [0..1] time

   • Indicates the time of the participation.

Figure 56: 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* .
- HL7 Implementation Guide for CDA Release 2 Quality Reporting Document Architecture (QRDA) Draft Standard for Trial Use March 2009. Available at: *Quality Reporting Document Architecture (QRDA)*
- HL7 Implementation Guide for CDA Release 2 CDA for Public Health Case Reports (PHCR) Informative Standard October 2009. Available through *HL7* .
- HL7 Implementation Guide for CDA Release 2: NHSN Healthcare Associated Infection (HAI) Reports, Release 2 Draft Standard for Trial Use January 2009 Available at: *NHSN Healthcare Associated Infection (HAI) Reports*
- Dolin RH, Alschuler L, Boyer S, Beebe C, Behlen FM, Biron PV, Shabo A, (Editors). HL7 Clinical Document Architecture, Release 2.0. ANSI-approved HL7 Standard; May 2005. Ann Arbor, Mich.: Health Level Seven, Inc. Available through *HL7* or if an HL7 member with the following link: *CDA Release 2 Normative Web Edition.*
- *LOINC®* : Logical Observation Identifiers Names and Codes, Regenstrief Institute.
- *SNOMED CT®* : SNOMED Clinical Terms SNOMED International Organization.
- Extensible Markup Language, *www.w3.org/XML* .
- Dolin RH, Alschuler L, Boyer S, Beebe C, Behlen FM, Biron PV, Shabo A., HL7 Clinical Document Architecture, Release 2. J Am Med Inform Assoc. 2006;13:30-39. Available at: *http://www.jamia.org/cgi/reprint/13/1/30* .
- Using SNOMED CT in HL7 Version 3; Implementation Guide, Release 1.5. Available through *HL7* or if an HL7 member with the following link: *Using SNOMED CT in HL7 Version 3*