

# **Implementation Guide for CDA Release 2 IHE Patient Care Coordination (PCC)**



**Revision 5.0**

**DRAFT: FOR DEVELOPMENT USE ONLY  
(Consolidated Developer Documentation)**



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# Acknowledgments

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## Revision History

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Rev	Date	By Whom	Changes
New	July 2010	Dave Carlson	
First draft for posting	August 31, 2010	Dave Carlson	Updated model content and publication format



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# Chapter 1

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## INTRODUCTION

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### Topics:

- [Overview](#)
- [Approach](#)
- [Scope](#)
- [Audience](#)
- [Organization of This Guide](#)
- [Use of Templates](#)
- [Conventions Used in This Guide](#)

## Overview

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This implementation guide is generated from UML models developed in the Open Health Tools (OHT) Model-Driven Health Tools (MDHT) project. The IHE Patient Care Coordination (PCC) specification has 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.

Integrating the Healthcare Enterprise (IHE) is an initiative designed to stimulate the integration of the information systems that support modern healthcare institutions. Its fundamental objective is to ensure that in the care of patients all required information for medical decisions is both correct and available to healthcare professionals. The IHE initiative is both a process and a forum for encouraging integration efforts. It defines a technical framework for the implementation of established messaging standards to achieve specific clinical goals. It includes a rigorous testing process for the implementation of this framework. And it organizes educational sessions and exhibits at major meetings of medical professionals to demonstrate the benefits of this framework and encourage its adoption by industry and users.

The approach employed in the IHE initiative is not to define new integration standards, but rather to support the use of existing standards, HL7, DICOM, IETF, and others, as appropriate in their respective domains in an integrated manner, defining configuration choices when necessary. When clarifications or extensions to existing standards are necessary, IHE refers recommendations to the relevant standards bodies.

## Approach

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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

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TODO: scope of this implementation guide.

## Audience

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

## Organization of This Guide

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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](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

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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

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### 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](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.





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# Chapter

# 2

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## DOCUMENT TEMPLATES

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### Topics:

- [\*Discharge Summary\*](#)
- [\*Medical Document\*](#)
- [\*Medical Summary\*](#)
- [\*PHR Extract\*](#)
- [\*PHR Update\*](#)
- [\*Scanned Document\*](#)

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

## Discharge Summary

---

[ClinicalDocument: templateId 1.3.6.1.4.1.19376.1.5.3.1.1.4]

1. Conforms to [CDA Clinical Document](#)
2. Conforms to [CDT General Header Constraints](#) template (templateId: 2.16.840.1.113883.10.20.3)
3. Conforms to [Medical Document](#) template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.1)
4. Conforms to [Medical Summary](#) template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.2)
5. [CDT] **CONF-HP-17: 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.
6. [IHE] **SHALL** contain [1..1] code (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC 2.26)
7. [CDT] **CONF-HP-23: 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.
8. [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.
9. [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.
10. [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.
11. [CDA] Contains [1..1] component, where its type is [CDA Component2](#)
12. [CDT] **CONF-HP-24: SHALL** contain [1..1] languageCode
13. [CDT] **CONF-HP-15: SHALL** contain [1..1] realmCode/@code = "US"
14. [CDT] **CONF-HP-22: 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.
15. [CDT] **CONF-HP-16: 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.
16. [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.

17. [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.

18. [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.

19. [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.

20. [IHE] **SHALL** contain [1..1] component, such that it

a. contains *Active Problems Section* (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.6)

21. [CDT] **CONF-HP-6: SHALL** satisfy: All patient, guardianPerson, assignedPerson, maintainingPerson, relatedPerson, intendedRecipient/informationRecipient, associatedPerson, and relatedSubject/subject elements have a name.

- [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]

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

- [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]

23. [CDT] **CONF-HP-8: SHOULD** satisfy: All guardian, dataEnterer/assignedEntity, relatedEntity, intendedRecipient, relatedSubject and participantRole elements have an addr and telecom element.
- [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]
24. [CDT] **CONF-HP-9: SHALL** satisfy: All guardianOrganization, providerOrganization, wholeOrganization, representedOrganization, representedCustodianOrganization, receivedOrganization, scopingOrganization and serviceProviderOrganization elements have name, addr and telecom elements.
- 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]
25. [CDT] **CONF-HP-10: 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.
- [OCL]: -- implemented in Java using XPath selector
  - [XPath]: /cda:ClinicalDocument/cda:effectiveTime | //cda:author/cda:time | //cda:dataEnterer/cda:time | //cda:encompassingEncounter/cda:effectiveTime
26. [CDT] **CONF-HP-11: 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.
- [OCL]: -- implemented in Java using XPath selector
27. [CDT] **CONF-HP-12: SHALL** satisfy: Telephone numbers match the regular expression pattern tel:\+?[-0-9().]+
- The telecom element is used to provide a contact telephone number for the various participants that require it. The value attribute of this element 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]
28. [CDT] **CONF-HP-13: SHALL** satisfy: At least one dialing digit is present in the phone number after visual separators are removed.
- [OCL]: -- implemented in Java using XPath selector
  - [XPath]: //\*[self::cda:telecom]
29. [CDT] **CONF-HP-14: SHALL** satisfy: If the telephone number is unknown it is represented using the appropriate flavor of null.
- 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]`

30. [CDT] **CONF-HP-16: SHALL** satisfy: The extension attribute of the typeId element is POCD\_HD000040.

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

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

32. [CDT] **CONF-HP-18: 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].

33. [CDT] **CONF-HP-19: 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  $((0-2)(.[1-9][0-9]^*(0))+)$ .

- 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.

34. [CDT] **CONF-HP-20: SHALL** satisfy: OIDs are no more than 64 characters in length.

- 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.ocIsUndefined()) and id.root.size() > 64 )`

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

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

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

38. [CDT] **CONF-HP-28: SHALL** satisfy: Both setId and versionNumber SHALL be present or both SHALL be absent.

- 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.ocIsUndefined() and self.versionNumber.ocIsUndefined()) xor (not self.setId.ocIsUndefined() and not self.versionNumber.ocIsUndefined())`

39. [CDT] **CONF-HP-29: SHALL** satisfy: The @extension and/or @root of setId and id SHALL be different when both are present.

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

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

- The ClinicalDocument/copyTime element has been deprecated in CDA R2.
- [OCL]: `self.copyTime.ocIsUndefined()`

**41. [CDT] CONF-HP-31: SHALL** satisfy: At least one recordTarget/patientRole element is present.

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

**42. [CDT] CONF-HP-32: 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.

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

**43. [CDT] CONF-HP-33: 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.

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

**44. [CDT] CONF-HP-34: 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.

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

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

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

**47. [CDT] CONF-HP-37: SHALL** satisfy: The author/time element is present.

- 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.ocIsUndefined())`

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

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

**49. [CDT] CONF-HP-39: SHALL** satisfy: An assignedAuthor element contains at least one assignedPerson or assignedAuthoringDevice elements.

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

**50. [CDT] CONF-HP-40: SHALL** satisfy: When dataEnterer is present, an assignedEntity/assignedPerson element is present.

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

**51. [CDT] CONF-HP-41: MAY** satisfy: The dataEnterer/time element MAY be present. If present, it represents the starting time of entry of the data.

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

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

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

**53. [CDT] CONF-HP-43: SHALL** satisfy: When informant is present, an assignedEntity/assignedPerson or relatedEntity/relatedPerson element SHALL be present.

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

**54. [CDT] CONF-HP-44: SHALL** satisfy: When the informant is a healthcare provider with an assigned role, the informant SHALL be represented using the assignedEntity element

- 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

**55. [CDT] CONF-HP-45: SHALL** satisfy: Allowable values for informant/relatedEntity/@classCode SHALL be CON, PRS, CAREGIVER, AGNT or PROV from the RoleClass vocabulary.

- 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.

**56. [CDT] CONF-HP-46: 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).

**57. [CDT] CONF-HP-47: 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.

- 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.

**58. [CDT] CONF-HP-48: 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.

- 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.

**59. [CDT] CONF-HP-49: SHOULD** satisfy: When the informant is a healthcare provider, the value of relatedEntity/code SHOULD be present and indicate the type of healthcare provider.

**60. [CDT] CONF-HP-50: 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.

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

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

**62. [CDT] CONF-HP-52: SHALL** satisfy: The assignedEntity/assignedPerson element SHALL be present in an authenticator element.

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

**63. [CDT] CONF-HP-10: 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.

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

**64. [IHE] SHALL** satisfy: MedicalSummaryProblemConcernEntry

- [OCL]: self.getSections()->exists(sect : cda::Section | sect.getActs()->exists(act : cda::Act | act.ocIsKindOf(ihe::ProblemConcernEntry)))

**65. [IHE] SHALL** satisfy: MedicalSummaryAllergyConcernEntry

- [OCL]: self.getSections()->exists(sect : cda::Section | sect.getActs()->exists(act : cda::Act | act.ocIsKindOf(ihe::AllergyIntoleranceConcern)))

**66. [IHE] SHALL** satisfy: MedicalSummaryMedications

- [OCL]: self.getSections()->exists(sect : cda::Section | sect.getSubstanceAdministrations()->exists(sub : cda::SubstanceAdministration | sub.ocIsKindOf(ihe::Medication)))

```
<?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="1.3.6.1.4.1.19376.1.5.3.1.1.2" assigningAuthorityName="IHE
  Medical Summary"/>
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.1.4" assigningAuthorityName="IHE
  Discharge Summary"/>
  <id root="21c8e61f-f296-4a79-9fc8-ad9f853a9c9d"/>
  <code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
  <title/>
  <effectiveTime/>
  <confidentialityCode/>
  <languageCode/>
  <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"/>
          <code code="11450-4" codeSystem="2.16.840.1.113883.6.1"
          codeSystemName="LOINC" displayName="Problem list"/>
          <title>Problem list</title>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

**Figure 5: Discharge Summary example**

## Medical Document

[ClinicalDocument: templateId 1.3.6.1.4.1.19376.1.5.3.1.1.1]

1. Conforms to [CDA Clinical Document](#)



2. Conforms to *CDT General Header Constraints* template (templateId: 2.16.840.1.113883.10.20.3)
3. [CDT] **CONF-HP-17: 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.
4. [CDT] **CONF-HP-21: SHALL** contain [1..1] `code`
  - Specifies the type of the clinical document.
5. [CDT] **CONF-HP-23: 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.
6. [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.
7. [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.
8. [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.
9. [CDA] Contains [1..1] `component`, where its type is *CDA Component2*
10. [CDT] **CONF-HP-24: SHALL** contain [1..1] `languageCode`
11. [CDT] **CONF-HP-15: SHALL** contain [1..1] `realmCode/@code = "US"`
12. [CDT] **CONF-HP-22: 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.
13. [CDT] **CONF-HP-16: 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.
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. [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.

**16. [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.

**17. [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.

**18. [CDT] CONF-HP-6: SHALL** satisfy: All patient, guardianPerson, assignedPerson, maintainingPerson, relatedPerson, intendedRecipient/informationRecipient, associatedPerson, and relatedSubject/subject elements have a name.

- [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]

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

- [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]

**20. [CDT] CONF-HP-8: SHOULD** satisfy: All guardian, dataEnterer/assignedEntity, relatedEntity, intendedRecipient, relatedSubject and participantRole elements have an addr and telecom element.

- [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]

**21. [CDT] CONF-HP-9: SHALL** satisfy: All guardianOrganization, providerOrganization, wholeOrganization, representedOrganization, representedCustodianOrganization, receivedOrganization, scopingOrganization and serviceProviderOrganization elements have name, addr and telecom elements.

- 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]

**22. [CDT] CONF-HP-10: 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.

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

**23. [CDT] CONF-HP-11: 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.

- [OCL]: -- implemented in Java using XPath selector

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

- The telecom element is used to provide a contact telephone number for the various participants that require it. The value attribute of this element 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]

**25. [CDT] CONF-HP-13: SHALL** satisfy: At least one dialing digit is present in the phone number after visual separators are removed.

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

**26. [CDT] CONF-HP-14: SHALL** satisfy: If the telephone number is unknown it is represented using the appropriate flavor of null.

- 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]

**27. [CDT] CONF-HP-16: SHALL** satisfy: The extension attribute of the typeId element is POCD\_HD000040.

- [OCL]: self.typeId.extension = 'POCD\_HD000040'

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

**29. [CDT] CONF-HP-18: 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].

**30. [CDT] CONF-HP-19: 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  $((0-2)([1-9][0-9]^*(0))+)$ .

- 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.

**31. [CDT] CONF-HP-20: SHALL** satisfy: OIDs are no more than 64 characters in length.

- 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.ocIsUndefined()) and id.root.size() > 64 )`

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

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

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

**35. [CDT] CONF-HP-28: SHALL** satisfy: Both setId and versionNumber SHALL be present or both SHALL be absent.

- 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.ocIsUndefined() and self.versionNumber.ocIsUndefined()) xor (not self.setId.ocIsUndefined() and not self.versionNumber.ocIsUndefined())`

**36. [CDT] CONF-HP-29: SHALL** satisfy: The @extension and/or @root of setId and id SHALL be different when both are present.

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

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

- The ClinicalDocument/copyTime element has been deprecated in CDA R2.
- [OCL]: `self.copyTime.ocIsUndefined()`

**38. [CDT] CONF-HP-31: SHALL** satisfy: At least one recordTarget/patientRole element is present.

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

**39. [CDT] CONF-HP-32: 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.

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

- ```

        or not
        target.patientRole.patient.birthTime.nullFlavor.ocIsUndefined())

```
40. [CDT] **CONF-HP-33: 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.
- TODO: add OCL test for terminology
  - [OCL]: self.recordTarget->forall(target : cda::RecordTarget | not target.patientRole.ocIsUndefined() implies (not target.patientRole.patient.administrativeGenderCode.code.ocIsUndefined() or not target.patientRole.patient.administrativeGenderCode.nullFlavor.ocIsUndefined()))
41. [CDT] **CONF-HP-34: 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.
42. [CDT] **CONF-HP-35: SHOULD** satisfy: The guardian element is present when the patient is a minor child.
43. [CDT] **CONF-HP-36: MAY** satisfy: The providerOrganization element is present.
- [OCL]: self.recordTarget->exists(target : cda::RecordTarget | not target.patientRole.providerOrganization.ocIsUndefined())
44. [CDT] **CONF-HP-37: SHALL** satisfy: The author/time element is present.
- 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.ocIsUndefined())
45. [CDT] **CONF-HP-38: SHALL** satisfy: The assignedAuthor/id element is present.
- [OCL]: self.author->forall(author : cda::Author | author.assignedAuthor.id->size() > 0)
46. [CDT] **CONF-HP-39: SHALL** satisfy: An assignedAuthor element contains at least one assignedPerson or assignedAuthoringDevice elements.
- [OCL]: self.author->forall(author : cda::Author | not author.assignedAuthor.assignedPerson.ocIsUndefined() or not author.assignedAuthor.assignedAuthoringDevice.ocIsUndefined())
47. [CDT] **CONF-HP-40: SHALL** satisfy: When dataEnterer is present, an assignedEntity/assignedPerson element is present.
- [OCL]: not self.dataEnterer.ocIsUndefined() implies not self.dataEnterer.assignedEntity.assignedPerson.ocIsUndefined()
48. [CDT] **CONF-HP-41: MAY** satisfy: The dataEnterer/time element MAY be present. If present, it represents the starting time of entry of the data.
- [OCL]: not self.dataEnterer.ocIsUndefined() implies not self.dataEnterer.time.ocIsUndefined()
49. [CDT] **CONF-HP-42: MAY** satisfy: The informant element is present.
- [OCL]: self.informant->size() > 0
50. [CDT] **CONF-HP-43: SHALL** satisfy: When informant is present, an assignedEntity/assignedPerson or relatedEntity/relatedPerson element SHALL be present.
- [OCL]: self.informant->forall(i : cda::Informant12 | not i.assignedEntity.assignedPerson.ocIsUndefined() or not i.relatedEntity.relatedPerson.ocIsUndefined())
51. [CDT] **CONF-HP-44: SHALL** satisfy: When the informant is a healthcare provider with an assigned role, the informant SHALL be represented using the assignedEntity element
- 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 determine if informant is a healthcare provider? condition for implementing OCL
- 52. [CDT] CONF-HP-45: SHALL** satisfy: Allowable values for informant/relatedEntity/@classCode SHALL be CON, PRS, CAREGIVER, AGNT or PROV from the RoleClass vocabulary.
- 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.
- 53. [CDT] CONF-HP-46: 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).
- 54. [CDT] CONF-HP-47: 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.
- 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.
- 55. [CDT] CONF-HP-48: 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.
- 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.
- 56. [CDT] CONF-HP-49: SHOULD** satisfy: When the informant is a healthcare provider, the value of relatedEntity/code SHOULD be present and indicate the type of healthcare provider.
- 57. [CDT] CONF-HP-50: 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.
- 58. [CDT] CONF-HP-51: SHALL** satisfy: The assignedEntity/assignedPerson element SHALL be present in legalAuthenticator.
- [OCL]: not self.legalAuthenticator.oclIsUndefined() implies not self.legalAuthenticator.assignedEntity.assignedPerson.oclIsUndefined()
- 59. [CDT] CONF-HP-52: SHALL** satisfy: The assignedEntity/assignedPerson element SHALL be present in an authenticator element.
- [OCL]: self.authenticator->forAll(auth : cda::Authenticator | auth.assignedEntity->forAll(entity : cda::AssignedEntity | not entity.assignedPerson.oclIsUndefined()))
- 60. [CDT] CONF-HP-10: 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.
- [OCL]: -- implemented in Java using XPath selector
  - [XPath]: /cda:ClinicalDocument/cda:effectiveTime | //cda:author/cda:time | //cda:dataEnterer/cda:time | //cda:encompassingEncounter/cda:effectiveTime

```
<?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"/>
  <id root="b62b8dd5-43bc-4f74-acda-d680cb0a3b07" />
  <code/>
  <title/>
```

```

<effectiveTime/>
<confidentialityCode/>
<languageCode/>
</ClinicalDocument>

```

**Figure 6: Medical Document example**

## Medical Summary

---

[ClinicalDocument: templateId 1.3.6.1.4.1.19376.1.5.3.1.1.2]

1. Conforms to *CDA Clinical Document*
2. Conforms to *CDT General Header Constraints* template (templateId: 2.16.840.1.113883.10.20.3)
3. Conforms to *Medical Document* template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.1)
4. [CDT] **CONF-HP-17: 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.
5. [IHE] **SHALL** contain [1..1] code (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC 2.26)
6. [CDT] **CONF-HP-23: 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.
7. [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.
8. [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.
9. [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.
10. [CDA] Contains [1..1] component, where its type is *CDA Component2*
11. [CDT] **CONF-HP-24: SHALL** contain [1..1] languageCode
12. [CDT] **CONF-HP-15: SHALL** contain [1..1] realmCode/@code = "US"
13. [CDT] **CONF-HP-22: 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.
14. [CDT] **CONF-HP-16: 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.
15. [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.

**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. [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.

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

- [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]`

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

- [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]`



21. [CDT] **CONF-HP-8: SHOULD** satisfy: All guardian, dataEnterer/assignedEntity, relatedEntity, intendedRecipient, relatedSubject and participantRole elements have an addr and telecom element.
- [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]
22. [CDT] **CONF-HP-9: SHALL** satisfy: All guardianOrganization, providerOrganization, wholeOrganization, representedOrganization, representedCustodianOrganization, receivedOrganization, scopingOrganization and serviceProviderOrganization elements have name, addr and telecom elements.
- 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]
23. [CDT] **CONF-HP-10: 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.
- [OCL]: -- implemented in Java using XPath selector
  - [XPath]: /cda:ClinicalDocument/cda:effectiveTime | //cda:author/cda:time | //cda:dataEnterer/cda:time | //cda:encompassingEncounter/cda:effectiveTime
24. [CDT] **CONF-HP-11: 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.
- [OCL]: -- implemented in Java using XPath selector
25. [CDT] **CONF-HP-12: SHALL** satisfy: Telephone numbers match the regular expression pattern tel:\+?[-0-9().]+
- The telecom element is used to provide a contact telephone number for the various participants that require it. The value attribute of this element 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]
26. [CDT] **CONF-HP-13: SHALL** satisfy: At least one dialing digit is present in the phone number after visual separators are removed.
- [OCL]: -- implemented in Java using XPath selector
  - [XPath]: //\*[self::cda:telecom]
27. [CDT] **CONF-HP-14: SHALL** satisfy: If the telephone number is unknown it is represented using the appropriate flavor of null.
- 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]`

28. [CDT] **CONF-HP-16: SHALL** satisfy: The extension attribute of the typeId element is POCD\_HD000040.

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

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

30. [CDT] **CONF-HP-18: 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].

31. [CDT] **CONF-HP-19: 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  $(([0-2])(.[1-9][0-9]^*(0))^+)$ .

- 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.

32. [CDT] **CONF-HP-20: SHALL** satisfy: OIDs are no more than 64 characters in length.

- 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.ocIsUndefined()) and id.root.size() > 64 )`

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

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

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

36. [CDT] **CONF-HP-28: SHALL** satisfy: Both setId and versionNumber SHALL be present or both SHALL be absent.

- 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.ocIsUndefined() and self.versionNumber.ocIsUndefined()) xor (not self.setId.ocIsUndefined() and not self.versionNumber.ocIsUndefined())`

37. [CDT] **CONF-HP-29: SHALL** satisfy: The @extension and/or @root of setId and id SHALL be different when both are present.

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

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

- The ClinicalDocument/copyTime element has been deprecated in CDA R2.
- [OCL]: `self.copyTime.ocIsUndefined()`

39. [CDT] **CONF-HP-31: SHALL** satisfy: At least one recordTarget/patientRole element is present.

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

40. [CDT] **CONF-HP-32: 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.

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

41. [CDT] **CONF-HP-33: 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.

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

42. [CDT] **CONF-HP-34: 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.

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

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

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

45. [CDT] **CONF-HP-37: SHALL** satisfy: The author/time element is present.

- 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.ocIsUndefined())`

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

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

47. [CDT] **CONF-HP-39: SHALL** satisfy: An assignedAuthor element contains at least one assignedPerson or assignedAuthoringDevice elements.

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

48. [CDT] **CONF-HP-40: SHALL** satisfy: When dataEnterer is present, an assignedEntity/assignedPerson element is present.

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

49. [CDT] **CONF-HP-41: MAY** satisfy: The dataEnterer/time element MAY be present. If present, it represents the starting time of entry of the data.

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

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

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

**51. [CDT] CONF-HP-43: SHALL** satisfy: When informant is present, an assignedEntity/assignedPerson or relatedEntity/relatedPerson element SHALL be present.

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

**52. [CDT] CONF-HP-44: SHALL** satisfy: When the informant is a healthcare provider with an assigned role, the informant SHALL be represented using the assignedEntity element

- 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

**53. [CDT] CONF-HP-45: SHALL** satisfy: Allowable values for informant/relatedEntity/@classCode SHALL be CON, PRS, CAREGIVER, AGNT or PROV from the RoleClass vocabulary.

- 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.

**54. [CDT] CONF-HP-46: 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).

**55. [CDT] CONF-HP-47: 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.

- 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.

**56. [CDT] CONF-HP-48: 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.

- 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.

**57. [CDT] CONF-HP-49: SHOULD** satisfy: When the informant is a healthcare provider, the value of relatedEntity/code SHOULD be present and indicate the type of healthcare provider.

**58. [CDT] CONF-HP-50: 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.

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

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

**60. [CDT] CONF-HP-52: SHALL** satisfy: The assignedEntity/assignedPerson element SHALL be present in an authenticator element.

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

**61. [CDT] CONF-HP-10: 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.

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

**62. [IHE] SHALL** satisfy: MedicalSummaryProblemConcernEntry

- [OCL]: self.getSections()->exists(sect : cda::Section | sect.getActs()->exists(act : cda::Act | act.oclIsKindOf(ihe::ProblemConcernEntry)))

**63. [IHE] SHALL** satisfy: MedicalSummaryAllergyConcernEntry

- [OCL]: self.getSections()->exists(sect : cda::Section | sect.getActs()->exists(act : cda::Act | act.oclIsKindOf(ihe::AllergyIntoleranceConcern)))

**64. [IHE] SHALL** satisfy: MedicalSummaryMedications

- [OCL]: self.getSections()->exists(sect : cda::Section | sect.getSubstanceAdministrations()->exists(sub : cda::SubstanceAdministration | sub.oclIsKindOf(ihe::Medication)))

```
<?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="1.3.6.1.4.1.19376.1.5.3.1.1.2" assigningAuthorityName="IHE
  Medical Summary"/>
  <id root="7cbc4a9d-07b6-4331-8bba-582c9b64489e"/>
  <code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
  <title/>
  <effectiveTime/>
  <confidentialityCode/>
  <languageCode/>
</ClinicalDocument>
```

**Figure 7: Medical Summary example**

## PHR Extract

[ClinicalDocument: templateId 1.3.6.1.4.1.19376.1.5.3.1.1.5]

1. Conforms to [CDA Clinical Document](#)
2. Conforms to [CDT General Header Constraints](#) template (templateId: 2.16.840.1.113883.10.20.3)
3. Conforms to [Medical Document](#) template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.1)
4. Conforms to [Medical Summary](#) template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.2)
5. [CDT] **CONF-HP-17: 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.
6. [IHE] **SHALL** contain [1..1] code (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC 2.26)
7. [CDT] **CONF-HP-23: 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.
8. [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.
9. [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.
10. [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.
11. [CDA] Contains [1..1] *component*, where its type is *CDA Component2*
12. [CDT] **CONF-HP-24: SHALL** contain [1..1] *languageCode*
13. [CDT] **CONF-HP-15: SHALL** contain [1..1] *realmCode/@code = "US"*
14. [CDT] **CONF-HP-22: 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.
15. [CDT] **CONF-HP-16: 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.
16. [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.
17. [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.
18. [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.

**19. [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.

**20. [CDT] CONF-HP-6: SHALL** satisfy: All patient, guardianPerson, assignedPerson, maintainingPerson, relatedPerson, intendedRecipient/informationRecipient, associatedPerson, and relatedSubject/subject elements have a name.

- [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]`

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

- [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]`

**22. [CDT] CONF-HP-8: SHOULD** satisfy: All guardian, dataEnterer/assignedEntity, relatedEntity, intendedRecipient, relatedSubject and participantRole elements have an addr and telecom element.

- [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]`

**23. [CDT] CONF-HP-9: SHALL** satisfy: All guardianOrganization, providerOrganization, wholeOrganization, representedOrganization, representedCustodianOrganization, receivedOrganization, scopingOrganization and serviceProviderOrganization elements have name, addr and telecom elements.

- 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]`

**24. [CDT] CONF-HP-10: 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.

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

**25. [CDT] CONF-HP-11: 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.

- [OCL]: -- implemented in Java using XPath selector

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

- The telecom element is used to provide a contact telephone number for the various participants that require it. The value attribute of this element 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]

**27. [CDT] CONF-HP-13: SHALL** satisfy: At least one dialing digit is present in the phone number after visual separators are removed.

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

**28. [CDT] CONF-HP-14: SHALL** satisfy: If the telephone number is unknown it is represented using the appropriate flavor of null.

- 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]

**29. [CDT] CONF-HP-16: SHALL** satisfy: The extension attribute of the typeId element is POCD\_HD000040.

- [OCL]: self.typeId.extension = 'POCD\_HD000040'

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

**31. [CDT] CONF-HP-18: SHALL** satisfy: UUIDs are represented in the form XXXXXXXX-XXXX-XXXX-XXXXXXXXXXXXXXXXXX, where each X is a character from the set [A-Fa-f0-9].

**32. [CDT] CONF-HP-19: 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))+.

- 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.

**33. [CDT] CONF-HP-20: SHALL** satisfy: OIDs are no more than 64 characters in length.



- 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.ocIsUndefined()) and id.root.size() > 64 )`

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

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

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

37. [CDT] **CONF-HP-28: SHALL** satisfy: Both setId and versionNumber SHALL be present or both SHALL be absent.

- 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.ocIsUndefined() and self.versionNumber.ocIsUndefined()) xor (not self.setId.ocIsUndefined() and not self.versionNumber.ocIsUndefined())`

38. [CDT] **CONF-HP-29: SHALL** satisfy: The @extension and/or @root of setId and id SHALL be different when both are present.

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

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

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

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

40. [CDT] **CONF-HP-31: SHALL** satisfy: At least one recordTarget/patientRole element is present.

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

41. [CDT] **CONF-HP-32: 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.

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

42. [CDT] **CONF-HP-33: 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.

- TODO: add OCL test for terminology

- [OCL]: `self.recordTarget->forall(target : cda::RecordTarget | not target.patientRole.ocIsUndefined() implies (not target.patientRole.patient.administrativeGenderCode.code.ocIsUndefined() or not target.patientRole.patient.administrativeGenderCode.nullFlavor.ocIsUndefined()))`

43. [CDT] **CONF-HP-34: 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.

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

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

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

46. [CDT] **CONF-HP-37: SHALL** satisfy: The author/time element is present.

- 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.ocIsUndefined())`

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

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

48. [CDT] **CONF-HP-39: SHALL** satisfy: An assignedAuthor element contains at least one assignedPerson or assignedAuthoringDevice elements.

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

49. [CDT] **CONF-HP-40: SHALL** satisfy: When dataEnterer is present, an assignedEntity/assignedPerson element is present.

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

50. [CDT] **CONF-HP-41: MAY** satisfy: The dataEnterer/time element MAY be present. If present, it represents the starting time of entry of the data.

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

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

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

52. [CDT] **CONF-HP-43: SHALL** satisfy: When informant is present, an assignedEntity/assignedPerson or relatedEntity/relatedPerson element SHALL be present.

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

53. [CDT] **CONF-HP-44: SHALL** satisfy: When the informant is a healthcare provider with an assigned role, the informant SHALL be represented using the assignedEntity element

- 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

54. [CDT] **CONF-HP-45: SHALL** satisfy: Allowable values for informant/relatedEntity/@classCode SHALL be CON, PRS, CAREGIVER, AGNT or PROV from the RoleClass vocabulary.

- 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.

55. [CDT] **CONF-HP-46: 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).

**56. [CDT] CONF-HP-47: 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.

- 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.

**57. [CDT] CONF-HP-48: 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.

- 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.

**58. [CDT] CONF-HP-49: SHOULD** satisfy: When the informant is a healthcare provider, the value of relatedEntity/code SHOULD be present and indicate the type of healthcare provider.

**59. [CDT] CONF-HP-50: 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.

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

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

**61. [CDT] CONF-HP-52: SHALL** satisfy: The assignedEntity/assignedPerson element SHALL be present in an authenticator element.

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

**62. [CDT] CONF-HP-10: 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.

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

**63. [IHE] SHALL** satisfy: MedicalSummaryProblemConcernEntry

- [OCL]: self.getSections()->exists(sect : cda::Section | sect.getActs()->exists(act : cda::Act | act.ocIsKindOf(ihe::ProblemConcernEntry)))

**64. [IHE] SHALL** satisfy: MedicalSummaryAllergyConcernEntry

- [OCL]: self.getSections()->exists(sect : cda::Section | sect.getActs()->exists(act : cda::Act | act.ocIsKindOf(ihe::AllergyIntoleranceConcern)))

**65. [IHE] SHALL** satisfy: MedicalSummaryMedications

- [OCL]: self.getSections()->exists(sect : cda::Section | sect.getSubstanceAdministrations()->exists(sub : cda::SubstanceAdministration | sub.ocIsKindOf(ihe::Medication)))

```
<?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="1.3.6.1.4.1.19376.1.5.3.1.1.2" assigningAuthorityName="IHE
  Medical Summary"/>
```

```

<templateId root="1.3.6.1.4.1.19376.1.5.3.1.1.5" assigningAuthorityName="IHE
PHR Extract"/>
<id root="1b202c4d-bb6e-4ac9-a3c9-547ba919cd50"/>
<code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
<title/>
<effectiveTime/>
<confidentialityCode/>
<languageCode/>
</ClinicalDocument>

```

**Figure 8: PHR Extract example**

## PHR Update

---

[ClinicalDocument: templateId 1.3.6.1.4.1.19376.1.5.3.1.1.6]

1. Conforms to [CDA Clinical Document](#)
2. Conforms to [CDT General Header Constraints](#) template (templateId: 2.16.840.1.113883.10.20.3)
3. Conforms to [Medical Document](#) template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.1)
4. Conforms to [Medical Summary](#) template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.2)
5. [CDT] **CONF-HP-17: 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.
6. [IHE] **SHALL** contain [1..1] code (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC 2.26)
7. [CDT] **CONF-HP-23: 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.
8. [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.
9. [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.
10. [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.
11. [CDA] Contains [1..1] component, where its type is [CDA Component2](#)
12. [CDT] **CONF-HP-24: SHALL** contain [1..1] languageCode
13. [CDT] **CONF-HP-15: SHALL** contain [1..1] realmCode/@code = "US"
14. [CDT] **CONF-HP-22: 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.

**15. [CDT] CONF-HP-16: 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.

**16. [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.

**17. [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.

**18. [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.

**19. [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.

**20. [CDT] CONF-HP-6: SHALL** satisfy: All patient, guardianPerson, assignedPerson, maintainingPerson, relatedPerson, intendedRecipient/informationRecipient, associatedPerson, and relatedSubject/subject elements have a name.

- [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]

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

- [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]

**22. [CDT] CONF-HP-8: SHOULD** satisfy: All guardian, dataEnterer/assignedEntity, relatedEntity, intendedRecipient, relatedSubject and participantRole elements have an addr and telecom element.

- [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]

**23. [CDT] CONF-HP-9: SHALL** satisfy: All guardianOrganization, providerOrganization, wholeOrganization, representedOrganization, representedCustodianOrganization, receivedOrganization, scopingOrganization and serviceProviderOrganization elements have name, addr and telecom elements.

- 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]

**24. [CDT] CONF-HP-10: 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.

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

**25. [CDT] CONF-HP-11: 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.

- [OCL]: -- implemented in Java using XPath selector

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

- The telecom element is used to provide a contact telephone number for the various participants that require it. The value attribute of this element 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]

27. [CDT] **CONF-HP-13: SHALL** satisfy: At least one dialing digit is present in the phone number after visual separators are removed.

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

28. [CDT] **CONF-HP-14: SHALL** satisfy: If the telephone number is unknown it is represented using the appropriate flavor of null.

- 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]`

29. [CDT] **CONF-HP-16: SHALL** satisfy: The extension attribute of the typeId element is POCD\_HD000040.

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

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

31. [CDT] **CONF-HP-18: SHALL** satisfy: UUIDs are represented in the form XXXXXXXX-XXXX-XXXX-XXXXXXXXXXXXXXXXXX, where each X is a character from the set [A-Fa-f0-9].

32. [CDT] **CONF-HP-19: 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  $(([0-2])([1-9][0-9]^*(0))+)$ .

- 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.

33. [CDT] **CONF-HP-20: SHALL** satisfy: OIDs are no more than 64 characters in length.

- 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.ocIsUndefined()) and id.root.size() > 64 )`

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

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

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

37. [CDT] **CONF-HP-28: SHALL** satisfy: Both setId and versionNumber SHALL be present or both SHALL be absent.

- 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.ocIsUndefined() and self.versionNumber.ocIsUndefined()) xor (not self.setId.ocIsUndefined() and not self.versionNumber.ocIsUndefined())`

**38. [CDT] CONF-HP-29: SHALL** satisfy: The @extension and/or @root of setId and id SHALL be different when both are present.

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

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

- The ClinicalDocument/copyTime element has been deprecated in CDA R2.
- [OCL]: `self.copyTime.ocIsUndefined()`

**40. [CDT] CONF-HP-31: SHALL** satisfy: At least one recordTarget/patientRole element is present.

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

**41. [CDT] CONF-HP-32: 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.

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

**42. [CDT] CONF-HP-33: 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.

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

**43. [CDT] CONF-HP-34: 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.

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

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

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

**46. [CDT] CONF-HP-37: SHALL** satisfy: The author/time element is present.

- 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.ocIsUndefined())`

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

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

**48. [CDT] CONF-HP-39: SHALL** satisfy: An assignedAuthor element contains at least one assignedPerson or assignedAuthoringDevice elements.

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



49. [CDT] **CONF-HP-40: SHALL** satisfy: When dataEnterer is present, an assignedEntity/assignedPerson element is present.
- [OCL]: `not self.dataEnterer.ocIsUndefined() implies not self.dataEnterer.assignedEntity.assignedPerson.ocIsUndefined()`
50. [CDT] **CONF-HP-41: MAY** satisfy: The dataEnterer/time element MAY be present. If present, it represents the starting time of entry of the data.
- [OCL]: `not self.dataEnterer.ocIsUndefined() implies not self.dataEnterer.time.ocIsUndefined()`
51. [CDT] **CONF-HP-42: MAY** satisfy: The informant element is present.
- [OCL]: `self.informant->size() > 0`
52. [CDT] **CONF-HP-43: SHALL** satisfy: When informant is present, an assignedEntity/assignedPerson or relatedEntity/relatedPerson element SHALL be present.
- [OCL]: `self.informant->forall(i : cda::Informant12 | not i.assignedEntity.assignedPerson.ocIsUndefined() or not i.relatedEntity.relatedPerson.ocIsUndefined())`
53. [CDT] **CONF-HP-44: SHALL** satisfy: When the informant is a healthcare provider with an assigned role, the informant SHALL be represented using the assignedEntity element
- 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
54. [CDT] **CONF-HP-45: SHALL** satisfy: Allowable values for informant/relatedEntity/@classCode SHALL be CON, PRS, CAREGIVER, AGNT or PROV from the RoleClass vocabulary.
- 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.
55. [CDT] **CONF-HP-46: 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).
56. [CDT] **CONF-HP-47: 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.
- 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.
57. [CDT] **CONF-HP-48: 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.
- 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.
58. [CDT] **CONF-HP-49: SHOULD** satisfy: When the informant is a healthcare provider, the value of relatedEntity/code SHOULD be present and indicate the type of healthcare provider.
59. [CDT] **CONF-HP-50: 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.
60. [CDT] **CONF-HP-51: SHALL** satisfy: The assignedEntity/assignedPerson element SHALL be present in legalAuthenticator.
- [OCL]: `not self.legalAuthenticator.ocIsUndefined() implies not self.legalAuthenticator.assignedEntity.assignedPerson.ocIsUndefined()`

**61. [CDT] CONF-HP-52: SHALL** satisfy: The assignedEntity/assignedPerson element SHALL be present in an authenticator element.

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

**62. [CDT] CONF-HP-10: 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.

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

**63. [IHE] SHALL** satisfy: MedicalSummaryProblemConcernEntry

- [OCL]: self.getSections()->exists(sect : cda::Section | sect.getActs()->exists(act : cda::Act | act.ocIsKindOf(ihe::ProblemConcernEntry)))

**64. [IHE] SHALL** satisfy: MedicalSummaryAllergyConcernEntry

- [OCL]: self.getSections()->exists(sect : cda::Section | sect.getActs()->exists(act : cda::Act | act.ocIsKindOf(ihe::AllergyIntoleranceConcern)))

**65. [IHE] SHALL** satisfy: MedicalSummaryMedications

- [OCL]: self.getSections()->exists(sect : cda::Section | sect.getSubstanceAdministrations()->exists(sub : cda::SubstanceAdministration | sub.ocIsKindOf(ihe::Medication)))

```
<?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="1.3.6.1.4.1.19376.1.5.3.1.1.2" assigningAuthorityName="IHE
  Medical Summary"/>
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.1.6" assigningAuthorityName="IHE
  PHR Update"/>
  <id root="f2c191f7-216d-4d5f-aec1-811a180022ae"/>
  <code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
  <title/>
  <effectiveTime/>
  <confidentialityCode/>
  <languageCode/>
</ClinicalDocument>
```

**Figure 9: PHR Update example**

## Scanned Document

[ClinicalDocument: templateId 1.3.6.1.4.1.19376.1.2.20]

A variety of legacy paper, film, electronic and scanner outputted formats are used to store and exchange clinical documents. These formats are not designed for healthcare documentation, and furthermore, do not have a uniform mechanism to store healthcare metadata associated with the documents, including patient identifiers, demographics, encounter, order or service information. The association of structured, healthcare metadata with this kind of document is important to maintain the integrity of the patient health record as managed by the source system. It is necessary to provide a mechanism that allows such source metadata to be stored with the document.

1. Conforms to *CDA Clinical Document*

2. [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.
3. [IHE] **SHALL** contain [1..1] `code`
  - Entered by operator or appropriately fixed for scanned content.
4. [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.
5. [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.
6. [CDA] Contains [1..\*] `author`, where its type is *CDA Author*
7. [CDA] Contains [1..1] `custodian`, where its type is *CDA Custodian*
8. [CDA] Contains [1..1] `component`, where its type is *CDA Component2*
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. [IHE] **SHOULD** contain [1..1] `title`
  - Entered by operator, or possibly can be taken from the scanned content.
11. [IHE] **SHALL** contain [1..1] `typeId`
12. [IHE] **SHOULD** contain [1..\*] `scanOriginalAuthor`, such that it
  - a. contains *Scan Original Author* (templateId: 1.3.6.1.4.1.19376.1.2.20.1)
13. [IHE] **SHALL** contain [1..\*] `scanningDevice`, such that it
  - a. contains *Scanning Device* (templateId: 1.3.6.1.4.1.19376.1.2.20.2)
14. [IHE] **SHALL** contain [1..1] `scanDataEnterer`, such that it
  - a. contains *Scan Data Enterer* (templateId: 1.3.6.1.4.1.19376.1.2.20.3)
15. [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.
16. [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.
17. [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'`
18. [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`

19. [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.ocIsUndefined() or not author.assignedAuthor.representedOrganization.ocIsUndefined())

20. [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.ocIsUndefined() and target.patientRole.id->forall(roleId : datatypes::II | not roleId.root.ocIsUndefined() and not roleId.extension.ocIsUndefined()))

21. [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.ocIsUndefined() and target.patientRole.addr->exists(address : datatypes::AD | address.country->exists(c : datatypes::ADXP | not c.ocIsUndefined() and c.getText().size() > 0)))

22. [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.ocIsUndefined() and target.patientRole.patient.name->exists(name: datatypes::PN | not name.given->isEmpty() and not name.family->isEmpty()))

23. [IHE] **SHALL** satisfy: The recordTarget/patientRole/patient/ administrativeGenderCode element is present.

- [OCL]: self.recordTarget->one(target : cda::RecordTarget | not target.patientRole.patient.administrativeGenderCode.ocIsUndefined())

24. [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.ocIsUndefined())

25. [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.ocIsUndefined() and author.ocIsKindOf(ihe::ScanOriginalAuthor))

26. [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.ocIsUndefined() and author.ocIsKindOf(ihe::ScanningDevice))

27. [IHE] **SHALL** satisfy: Contains ScanDataEnterer element to represent the scanner operator who produced the scanned content.

- [OCL]: not self.dataEnterer.ocIsUndefined() and self.dataEnterer.ocIsKindOf(ihe::ScanDataEnterer)

28. [IHE] **SHALL** satisfy: custodian/assignedCustodian/representedCustodianOrganization/name is present.

- [OCL]: not self.custodian.assignedCustodian.representedCustodianOrganization.name.ocIsUndefined()

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

- [OCL]: not self.custodian.assignedCustodian.representedCustodianOrganization.addr.ocIsUndefined()

```

        and
        self.custodian.assignedCustodian.representedCustodianOrganization.addr.country-
>exists(c : datatypes::ADXP |
        not c.ocIsUndefined() and c.getText().size() > 0)

```

30. [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.ocIsUndefined() and not ident.extension.ocIsUndefined() ) )

31. [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.ocIsUndefined()

32. [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.

33. [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.ocIsUndefined()

34. [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'

35. [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

```

<?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">
  <templateId root="1.3.6.1.4.1.19376.1.2.20" assigningAuthorityName="IHE
  Scanned Document"/>
  <id root="3bc1bec8-d856-4d97-aa48-a453454cbcb4"/>
  <code/>
  <title/>
  <effectiveTime/>
  <confidentialityCode/>
  <languageCode/>
  <author>
    <templateId root="1.3.6.1.4.1.19376.1.2.20.1" assigningAuthorityName="IHE
  Scan Original Author"/>
    <time/>
  </author>
  <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 10: Scanned Document example**

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# Chapter

# 3

---

## SECTION TEMPLATES

---

### Topics:

- *Active Problems Section*
- *Admission Medication History Section*
- *Advance Directives Section*
- *Allergies Reactions Section*
- *Assessment And Plan Section*
- *Care Plan Section*
- *Chief Complaint Section*
- *Coded Advance Directives Section*
- *Coded Results Section*
- *Coded Surgeries Section*
- *Coded Vital Signs Section*
- *Discharge Diagnosis Section*
- *Encounter History Section*
- *Family Medical History Section*
- *History Of Past Illness Section*
- *History Of Present Illness*
- *Hospital Admission Diagnosis Section*
- *Hospital Course Section*
- *Hospital Discharge Medications Section*
- *Immunizations Section*
- *Intake Output Section*
- *Medical Devices Section*
- *Medications Administered Section*
- *Medications Section*
- *Payers Section*
- *Physical Exam Narrative Section*
- *Physical Exam Section*
- *Pregnancy History Section*
- *Reason For Referral Section*
- *Review Of Systems Section*
- *Social History Section*

- *Surgeries Section*
- *Vital Signs Section*





## Active Problems Section

[Section: templateId 1.3.6.1.4.1.19376.1.5.3.1.3.6]

1. Conforms to [CDA Section](#)
2. Conforms to [CCD Problem Section](#) template (templateId: 2.16.840.1.113883.10.20.1.11)
3. [CCD] **SHALL** contain [1..1] code/@code = "11450-4" *Problem list* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC 2.26)
4. [CCD] **SHALL** contain [1..1] title
5. [CCD] **SHOULD** contain [1..\*] entry, such that it
  - a. contains [CCD Problem Act](#) (templateId: 2.16.840.1.113883.10.20.1.27)
6. [CCD] **SHALL** contain [1..1] text
7. [IHE] **SHALL** contain [1..\*] entry, such that it
  - a. contains [Problem Concern Entry](#) (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.5.2)
8. [CCD] **SHOULD** satisfy: Contains a case-insensitive language-insensitive string containing 'problems'.

```
<?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"/>
          <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"/>
              <id root="adfala18-9b31-4a7b-9b22-cf1ccfb90d03"/>
              <code nullFlavor="NA"/>
              <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"/>
              <id root="9a8e3271-4f46-4e45-a3a9-0888e14f6f39"/>
              <code nullFlavor="NA"/>
              <effectiveTime>
                <low value="1972"/>
                <high value="2008"/>
              </effectiveTime>
            </act>
          </entry>
        </section>
```

```

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

```

Figure 11: Active Problems Section example

## Admission Medication History Section

[Section: templateId 1.3.6.1.4.1.19376.1.5.3.1.3.20]

The admission medication history section shall contain a narrative description of the relevant medications administered to a patient prior to admission to a facility. It shall include entries for medication administration as described in the Entry Content Module.

1. Conforms to [CDA Section](#)
2. [IHE] **SHALL** contain [1..1] code/@code = "42346-7" *MEDICATIONS ON ADMISSION* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC 2.26)

```

<?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"/>
          <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 12: Admission Medication History Section example

## Advance Directives Section

[Section: templateId 1.3.6.1.4.1.19376.1.5.3.1.3.34]

The advance directive section shall contain a narrative description of the list of documents that define the patient's expectations and requests for care along with the locations of the documents.

1. Conforms to [CDA Section](#)
2. Conforms to [CCD Advance Directives Section](#) template (templateId: 2.16.840.1.113883.10.20.1.1)
3. [CCD] **SHALL** contain [1..1] code/@code = "42348-3" *Advance directives* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC 2.26)
4. [CCD] **SHALL** contain [1..1] title
5. [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"/>
    <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="1008706c-0ble-4121-af89-7fd5f84c2d9a"/>
        <code/>
        <statusCode code="completed"/>
        <effectiveTime>
          <low value="1972"/>
          <high value="2008"/>
        </effectiveTime>
      </observation>
    </entry>
  </section>
</component>
</structuredBody>
</component>
</ClinicalDocument>

```

Figure 13: Advance Directives Section example

## Allergies Reactions Section

[Section: templateId 1.3.6.1.4.1.19376.1.5.3.1.3.13]

The adverse and other adverse reactions section shall contain a narrative description of the substance intolerances and the associated adverse reactions suffered by the patient.

1. Conforms to [CDA Section](#)
2. Conforms to [CCD Alerts Section](#) template (templateId: 2.16.840.1.113883.10.20.1.2)
3. [CCD] **SHALL** contain [1..1] code/@code = "48765-2" *Allergies, adverse reactions, alerts* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC 2.26)
4. [CCD] **SHALL** contain [1..1] title
5. [CCD] **SHALL** contain [1..1] text
6. [CCD] **SHOULD** contain [1..\*] entry, such that it
  - a. contains [CCD Problem Act](#) (templateId: 2.16.840.1.113883.10.20.1.27)
7. [CCD] **SHOULD** satisfy: Contains a case-insensitive language-insensitive string containing "alert" and/or "allergies and adverse reactions".
8. [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"/>
          <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>
          <entry>
            <act classCode="ACT" moodCode="EVN">

```

```

        <templateId root="2.16.840.1.113883.10.20.1.27"
assigningAuthorityName="CCD Problem Act"/>
        <id root="6ceal92b-2a79-437e-bf61-39bbea6f784"/>
        <code nullFlavor="NA"/>
        <effectiveTime>
            <low value="1972"/>
            <high value="2008"/>
        </effectiveTime>
    </act>
</entry>
</section>
</component>
</structuredBody>
</component>
</ClinicalDocument>

```

**Figure 14: Allergies Reactions Section example**

## Assessment And Plan Section

[Section: templateId 1.3.6.1.4.1.19376.1.5.3.1.1.13.2.5]

The assessment and plan section shall contain a narrative description of the assessment of the patient condition and expectations for care including proposals, goals, and order requests for monitoring, tracking, or improving the condition of the patient.

1. Conforms to [CDA Section](#)
2. [IHE] **SHALL** contain [1..1] code/@code = "51847-2" *ASSESSMENT AND PLAN* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC 2.26)

```

<?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"/>
          <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 15: Assessment And Plan Section example**

## Care Plan Section

[Section: templateId 1.3.6.1.4.1.19376.1.5.3.1.3.31]

The care plan section shall contain a narrative description of the expectations for care including proposals, goals, and order requests for monitoring, tracking, or improving the condition of the patient.

1. Conforms to [CDA Section](#)
2. Conforms to [CCD Plan Of Care Section](#) template (templateId: 2.16.840.1.113883.10.20.1.10)
3. [CCD] **SHALL** contain [1..1] code/@code = "18776-5" *Treatment plan* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC 2.26)
4. [CCD] **SHALL** contain [1..1] title

5. [CCD] **SHALL** contain [1..1] text
6. [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)
7. [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)
8. [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)
9. [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)
10. [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)
11. [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)
12. [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"/>
          <code code="18776-5" codeSystem="2.16.840.1.113883.6.1"
            codeSystemName="LOINC" displayName="Treatment plan"/>
          <title>Treatment plan</title>
          <entry>
            <act classCode="ACT" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.25"/>
              <id root="f1b1f7fc-4dee-400b-ace4-a65e75f54c27"/>
            </act>
          </entry>
          <entry>
            <encounter>
              <templateId root="2.16.840.1.113883.10.20.1.25"/>
              <id root="cafcecl7-0e24-48b4-94af-f8d167ae66da"/>
            </encounter>
          </entry>
          <entry>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.25"/>
              <id root="97649335-ec1b-4ae0-92a2-4b356d493fbc"/>
            </observation>
          </entry>
          <entry>
            <procedure>
              <templateId root="2.16.840.1.113883.10.20.1.25"/>
              <id root="1e7381a1-fc7e-47a4-bf9c-f147e017e033"/>
            </procedure>
          </entry>
          <entry>
            <substanceAdministration classCode="SBADM">
```

```

        <templateId root="2.16.840.1.113883.10.20.1.25"/>
        <id root="5c834bb9-5f1b-466a-a96f-c7183bba2755"/>
      </substanceAdministration>
    </entry>
    <entry>
      <supply classCode="SPLY">
        <templateId root="2.16.840.1.113883.10.20.1.25"/>
        <id root="9d724573-e060-4fc7-a6c1-dd67824ae090"/>
      </supply>
    </entry>
  </section>
</component>
</structuredBody>
</component>
</ClinicalDocument>

```

**Figure 16: Care Plan Section example**

## Chief Complaint Section

[Section: templateId 1.3.6.1.4.1.19376.1.5.3.1.1.13.2.1]

This contains a narrative description of the patient's chief complaint.

1. Conforms to [CDA Section](#)
2. [IHE] **SHALL** contain [1..1] code/@code = "10154-3" *CHIEF COMPLAINT* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC 2.26)

```

<?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"/>
          <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 17: Chief Complaint Section example**

## Coded Advance Directives Section

[Section: templateId 1.3.6.1.4.1.19376.1.5.3.1.3.35]

1. Conforms to [CDA Section](#)
2. Conforms to [CCD Advance Directives Section](#) template (templateId: 2.16.840.1.113883.10.20.1.1)
3. Conforms to [Advance Directives Section](#) template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.34)
4. [CCD] **SHALL** contain [1..1] code/@code = "42348-3" *Advance directives* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC 2.26)
5. [CCD] **SHALL** contain [1..1] title
6. [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"/>
          <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="dfa2f080-666f-4001-869b-6clda87189e2"/>
              <code/>
              <statusCode code="completed"/>
              <effectiveTime>
                <low value="1972"/>
                <high value="2008"/>
              </effectiveTime>
            </observation>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>

```

**Figure 18: Coded Advance Directives Section example**

## Coded Results Section

[Section: templateId 1.3.6.1.4.1.19376.1.5.3.1.3.28]

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

1. Conforms to [CDA Section](#)
2. [IHE] **SHALL** contain [1..1] code/@code = "30954-2" *STUDIES SUMMARY* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC 2.26)

```

<?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"/>
          <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>

```

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

**Figure 19: Coded Results Section example**

## Coded Surgeries Section

[Section: templateId 1.3.6.1.4.1.19376.1.5.3.1.3.12]

The list of surgeries section shall include entries for procedures and references to procedure reports when known as described in the Entry Content Modules.

1. Conforms to [CDA Section](#)
2. Conforms to [CCD Procedures Section](#) template (templateId: 2.16.840.1.113883.10.20.1.12)
3. Conforms to [Surgeries Section](#) template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.11)
4. [CCD] **SHALL** contain [1..1] code/@code = "47519-4" *History of procedures* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC 2.26)
5. [CCD] **SHALL** contain [1..1] title
6. [CCD] **SHOULD** contain [1..\*] procedureActivity, such that it
  - a. contains [CCD Procedure 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="2.16.840.1.113883.10.20.1.12"
            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"/>
          <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>
    </structuredBody>
  </component>
</ClinicalDocument>
```

**Figure 20: Coded Surgeries Section example**

## Coded Vital Signs Section

[Section: templateId 1.3.6.1.4.1.19376.1.5.3.1.1.5.3.2]

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

1. Conforms to [CDA Section](#)
2. Conforms to [CCD Vital Signs Section](#) template (templateId: 2.16.840.1.113883.10.20.1.16)
3. Conforms to [Vital Signs Section](#) template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.25)
4. [CCD] **SHALL** contain [1..1] code/@code = "8716-3" *Vital signs* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC 2.26)
5. [CCD] **SHALL** contain [1..1] title
6. [IHE] **SHALL** contain [1..\*] entry, such that it
  - a. contains [Vital Signs Organizer](#) (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.13.1)
7. [CCD] **SHALL** contain [1..1] text



8. [CCD] **SHOULD** satisfy: Contains a case-insensitive language-insensitive string containing 'vital signs'.

```
<?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="2.16.840.1.113883.10.20.1.16"
            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"/>
          <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="bd44cad0-d845-4367-a0d8-2dab033105c3"/>
              <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>
          <entry>
            <organizer 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"/>
              <id root="62ede68e-4759-4a2b-9bbf-c5c4856f7a29"/>
              <code/>
              <statusCode/>
            </organizer>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 21: Coded Vital Signs Section example

## Discharge Diagnosis Section

[Section: templateId 1.3.6.1.4.1.19376.1.5.3.1.3.7]

The discharge diagnosis section shall contain a narrative description of the conditions that need to be monitored after discharge from the hospital and those that were resolved during the hospital course. It shall include entries for patient conditions as described in the Entry Content Module.

1. Conforms to [CDA Section](#)

2. [IHE] **SHALL** contain [1..1] code/@code = "11535-2" *HOSPITAL DISCHARGE DX* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC 2.26)

```
<?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"/>
          <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 22: Discharge Diagnosis Section example**

## Encounter History Section

[Section: templateId 1.3.6.1.4.1.19376.1.5.3.1.1.5.3.3]

The encounter history section contains coded entries describing the patient history of encounters.

1. Conforms to [CDA Section](#)
2. Conforms to [CCD Encounters Section](#) template (templateId: 2.16.840.1.113883.10.20.1.3)
3. [CCD] **SHALL** contain [1..1] code/@code = "46240-8" *History of encounters* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC 2.26)
4. [CCD] **SHALL** contain [1..1] title
5. [IHE] **SHALL** contain [1..\*] entry, such that it
  - a. contains [Encounter Entry](#) (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.14)

```
<?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"/>
          <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>
    </structuredBody>
  </component>
</ClinicalDocument>
```

**Figure 23: Encounter History Section example**

## Family Medical History Section

[Section: templateId 1.3.6.1.4.1.19376.1.5.3.1.3.14]

The family history section shall contain a narrative description of 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. Conforms to [CDA Section](#)
2. Conforms to [CCD Family History Section](#) template (templateId: 2.16.840.1.113883.10.20.1.4)
3. [CCD] **SHALL** contain [1..1] code/@code = "10157-6" *History of family member diseases* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC 2.26)
4. [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"/>
          <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 24: Family Medical History Section example

## History Of Past Illness Section

[Section: templateId 1.3.6.1.4.1.19376.1.5.3.1.3.8]

The History of Past Illness section shall contain a narrative description of the conditions the patient suffered in the past. It shall include entries for problems as described in the Entry Content Modules.

1. Conforms to [CDA Section](#)
2. [IHE] **SHALL** contain [1..1] code/@code = "11348-0" *HISTORY OF PAST ILLNESS* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC 2.26)

```
<?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"/>
          <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>
```

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

**Figure 25: History Of Past Illness Section example**

## History Of Present Illness

[Section: templateId 1.3.6.1.4.1.19376.1.5.3.1.3.4]

The history of present illness section shall contain a narrative description of the sequence of events preceding the patient's current complaints.

1. Conforms to [CDA Section](#)
2. [IHE] **SHALL** contain [1..1] code/@code = "10164-2" *HISTORY OF PRESENT ILLNESS* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC 2.26)

```
<?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"/>
          <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 26: History Of Present Illness example**

## Hospital Admission Diagnosis Section

[Section: templateId 1.3.6.1.4.1.19376.1.5.3.1.3.3]

The hospital admitting diagnosis section shall contain a narrative description of the primary reason for admission to a hospital facility. It shall include entries for observations as described in the Entry Content Modules.

1. Conforms to [CDA Section](#)
2. [IHE] **SHALL** contain [1..1] code/@code = "46241-6" *HOSPITAL ADMISSION DX* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC 2.26)

```
<?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"/>
          <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 27: Hospital Admission Diagnosis Section example**

## Hospital Course Section

[Section: templateId 1.3.6.1.4.1.19376.1.5.3.1.3.5]

The hospital course section shall contain a narrative description of the sequence of events from admission to discharge in a hospital facility.

1. Conforms to [CDA Section](#)
2. [IHE] **SHALL** contain [1..1] code/@code = "8648-8" *HOSPITAL COURSE* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC 2.26)

```
<?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"/>
          <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 28: Hospital Course Section example**

## Hospital Discharge Medications Section

[Section: templateId 1.3.6.1.4.1.19376.1.5.3.1.3.22]

The hospital discharge medications section shall contain a narrative description of the medications requested (ordered) to be administered to the patient after discharge from the hospital. It shall include entries for medication requests as described in the Entry Content Module.

1. Conforms to [CDA Section](#)
2. [IHE] **SHALL** contain [1..1] code/@code = "10183-2" *HOSPITAL DISCHARGE MEDICATIONS* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC 2.26)

```
<?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"/>
          <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>
```

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

**Figure 29: Hospital Discharge Medications Section example**

## Immunizations Section

[Section: templateId 1.3.6.1.4.1.19376.1.5.3.1.3.23]

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

1. Conforms to [CDA Section](#)
2. Conforms to [CCD Immunizations Section](#) template (templateId: 2.16.840.1.113883.10.20.1.6)
3. [CCD] **SHALL** contain [1..1] code/@code = "11369-6" *History of immunizations* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC 2.26)
4. [CCD] **SHALL** contain [1..1] title
5. [CCD] **SHALL** contain [1..1] text
6. [IHE] **SHALL** contain [1..\*] entry, such that it
  - a. contains [Immunization](#) (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.12)
7. [CCD] **SHOULD** satisfy: Contains a case-insensitive language-insensitive string containing 'immunization'.
8. [CCD] **CONF-376: SHOULD** satisfy: Contains one or more Medication Activity and/or Supply Activity

- [OCL]: self.getEntryTargets(ccd::MedicationActivity)->size() > 0  
or self.getEntryTargets(ccd::SupplyActivity)->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="2.16.840.1.113883.10.20.1.6"
            assigningAuthorityName="CCD Immunizations Section"/>
          <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.23"
            assigningAuthorityName="IHE 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"/>
              <id root="clb4d531-2a3f-43a1-a013-d0ec3312a6c6"/>
              <statusCode/>
              <effectiveTime/>
              <routeCode codeSystem="2.16.840.1.113883.5.112"
                codeSystemName="HL7 RouteOfAdministration"/>
              <maxDoseQuantity/>
            </substanceAdministration>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

**Figure 30: Immunizations Section example**

## Intake Output Section

---

[Section: templateId 1.3.6.1.4.1.19376.1.5.3.1.1.20.2.3]

1. Conforms to [CDA Section](#)
- 2.

```
<?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="1.3.6.1.4.1.19376.1.5.3.1.1.20.2.3"
            assigningAuthorityName="IHE Intake Output Section"/>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

**Figure 31: Intake Output Section example**

## Medical Devices Section

---

[Section: templateId 1.3.6.1.4.1.19376.1.5.3.1.1.5.3.5]

The medical devices section contains narrative text describing the patient history of medical device use.

1. Conforms to [CDA Section](#)
2. Conforms to [CCD Medical Equipment Section](#) template (templateId: 2.16.840.1.113883.10.20.1.7)
3. [CCD] **SHALL** contain [1..1] code/@code = "46264-8" *History of medical device use* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC 2.26)
4. [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"/>
          <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 32: Medical Devices Section example**

## Medications Administered Section

[Section: templateId 1.3.6.1.4.1.19376.1.5.3.1.3.21]

The medications administered section shall contain a narrative description of the relevant medications administered to a patient during the course of an encounter. It shall include entries for medication administration as described in the Entry Content Module.

1. Conforms to [CDA Section](#)
2. [IHE] **SHALL** contain [1..1] code/@code = "18610-6" *MEDICATION ADMINISTERED* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC 2.26)

```
<?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"/>
          <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 33: Medications Administered Section example

## Medications Section

[Section: templateId 1.3.6.1.4.1.19376.1.5.3.1.3.19]

The medications section shall contain a description of the relevant medications for the patient, e.g. an ambulatory prescription list. It shall include entries for medications as described in the Entry Content Module.

1. Conforms to [CDA Section](#)
2. Conforms to [CCD Medications Section](#) template (templateId: 2.16.840.1.113883.10.20.1.8)
3. [CCD] **CONF-300, CONF-301: SHALL** contain [1..1] code/@code = "10160-0" *History of medication use* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC 2.26)
4. [CCD] **CONF-302: SHALL** contain [1..1] title
5. [CCD] **SHALL** contain [0..1] text
6. [CCD] Contains [0..\*] entry, such that it
  - a. contains [CCD Medication Activity](#) (templateId: 2.16.840.1.113883.10.20.1.24)
7. [CCD] Contains [0..\*] entry, such that it
  - a. contains [CCD Supply Activity](#) (templateId: 2.16.840.1.113883.10.20.1.34)
8. [IHE] **SHALL** contain [1..\*] entry, such that it
  - a. contains [Medication](#) (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.7)
9. [CCD] **CONF-299: SHALL** satisfy: The absence of known medications is explicitly asserted.
10. [CCD] **CONF-303: SHOULD** satisfy: Valued with a case-insensitive language-insensitive string containing 'medication'.



11. [CCD] **CONF-298: SHOULD** satisfy: Clinical statements include one or more Medication Activity and/or one or more Supply Activity.

- [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"/>
          <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"/>
              <id root="d2ba2346-4df9-4d97-b1be-478c9d6dcce3"/>
              <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 34: Medications Section example

## Payers Section

[Section: templateId 1.3.6.1.4.1.19376.1.5.3.1.1.5.3.7]

The Payers section contains data on the patient's payers, whether a 'third party' insurance, self-pay, other payer or guarantor, or some combination.

1. Conforms to [CDA Section](#)
2. Conforms to [CCD Payers Section](#) template (templateId: 2.16.840.1.113883.10.20.1.9)
3. [CCD] **CONF-31, CONF-32: SHALL** contain [1..1] code/@code = "48768-6" *Payment sources* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC 2.26)
4. [CCD] **CONF-33: SHALL** contain [1..1] title
5. [CCD] **CONF-30: SHOULD** contain [1..\*] entry, such that it
  - a. contains [CCD Coverage Activity](#) (templateId: 2.16.840.1.113883.10.20.1.20)

6. [CCD] **CONF-30: SHALL** contain [1..1] text
7. [IHE] **SHOULD** contain [1..\*] entry, such that it
  - a. contains [Coverage Entry](#) (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.17)
8. [CCD] **CONF-34: SHOULD** satisfy: Contains a case-insensitive language-insensitive string containing 'insurance' or 'payers'.

```
<?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"/>
          <code code="48768-6" codeSystem="2.16.840.1.113883.6.1"
            codeSystemName="LOINC" displayName="Payment sources"/>
          <title>Payment sources</title>
          <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"/>
              <id root="e81f5e07-8dc7-438d-bb02-2721a9c4a255"/>
              <code code="48768-6" codeSystem="2.16.840.1.113883.6.1"
                codeSystemName="LOINC" displayName="Payment sources"/>
              <statusCode code="completed"/>
            </act>
          </entry>
          <entry>
            <act classCode="ACT" moodCode="DEF">
              <templateId root="2.16.840.1.113883.10.20.1.20"
                assigningAuthorityName="CCD Coverage Activity"/>
              <id root="58c7c07a-d61b-4ef4-9ebd-a152d36935c2"/>
              <code code="48768-6" codeSystem="2.16.840.1.113883.6.1"
                codeSystemName="LOINC" displayName="Payment sources"/>
              <statusCode code="completed"/>
            </act>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

**Figure 35: Payers Section example**

## Physical Exam Narrative Section

[Section: templateId 1.3.6.1.4.1.19376.1.5.3.1.3.24]

The physical exam section shall contain a narrative description of the patient's physical findings.

1. Conforms to [CDA Section](#)
2. [IHE] **SHALL** contain [1..1] code/@code = "29545-1" *PHYSICAL EXAMINATION* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC 2.26)

```
<?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"/>
        <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 36: Physical Exam Narrative Section example**

## Physical Exam Section

[Section: templateId 1.3.6.1.4.1.19376.1.5.3.1.1.9.15]

The physical exam section shall contain only the required and optional subsections performed.

1. Conforms to [CDA Section](#)
2. Conforms to [Physical Exam Narrative Section](#) template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.24)
3. [IHE] **SHALL** contain [1..1] code/@code = "29545-1" *PHYSICAL EXAMINATION* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC 2.26)

```

<?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"/>
          <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 37: Physical Exam Section example**

## Pregnancy History Section

[Section: templateId 1.3.6.1.4.1.19376.1.5.3.1.1.5.3.4]

The pregnancy history section contains coded entries describing the patient history of pregnancies.

1. Conforms to [CDA Section](#)
2. [IHE] **SHALL** contain [0..1] code/@code = "10162-6" *HISTORY OF PREGNANCIES* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC 2.26)
3. [IHE] **SHALL** contain [1..\*] entry, such that it
  - a. contains [Pregnancy Observation](#) (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.13.5)

```
<?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="1.3.6.1.4.1.19376.1.5.3.1.1.5.3.4"
            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>
          <entry>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.13"
                assigningAuthorityName="IHE Simple Observation"/>
              <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.13.5"
                assigningAuthorityName="IHE Pregnancy Observation"/>
              <id root="bd0ald03-bd22-4d80-866c-aabecle661fe"/>
              <code/>
              <statusCode code="completed"/>
              <repeatNumber/>
              <interpretationCode/>
              <methodCode/>
              <targetSiteCode/>
            </observation>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

**Figure 38: Pregnancy History Section example**

## Reason For Referral Section

[Section: templateId 1.3.6.1.4.1.19376.1.5.3.1.3.1]

The reason for referral section shall contain a narrative description of the reason that the patient is being referred.

1. Conforms to [CDA Section](#)
2. [IHE] **SHALL** contain [1..1] code/@code = "42349-1" *REASON FOR REFERRAL* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC 2.26)

```
<?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"/>
          <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 39: Reason For Referral Section example**

## Review Of Systems Section

[Section: templateId 1.3.6.1.4.1.19376.1.5.3.1.3.18]

The review of systems section shall contain a narrative description of the responses the patient gave to a set of routine questions on the functions of each anatomic body system.

1. Conforms to [CDA Section](#)
2. [IHE] **SHALL** contain [1..1] code/@code = "10187-3" *REVIEW OF SYSTEMS* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC 2.26)

```
<?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"/>
          <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 40: Review Of Systems Section example

## Social History Section

[Section: templateId 1.3.6.1.4.1.19376.1.5.3.1.3.16]

The social history section shall contain a narrative description of the person's beliefs, home life, community life, work life, hobbies, and risky habits.

1. Conforms to [CDA Section](#)
2. Conforms to [CCD Social History Section](#) template (templateId: 2.16.840.1.113883.10.20.1.15)
3. [CCD] **SHALL** contain [1..1] code/@code = "29762-2" *Social history* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC 2.26)
4. [CCD] **SHOULD** 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="2.16.840.1.113883.10.20.1.15"
            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"/>
          <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>
```

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

**Figure 41: Social History Section example**

## Surgeries Section

[Section: templateId 1.3.6.1.4.1.19376.1.5.3.1.3.11]

The list of surgeries section shall contain a narrative description of the diagnostic and therapeutic operative procedures and associated anesthetic techniques the patient received in the past.

1. Conforms to [CDA Section](#)
2. Conforms to [CCD Procedures Section](#) template (templateId: 2.16.840.1.113883.10.20.1.12)
3. [CCD] **SHALL** contain [1..1] code/@code = "47519-4" *History of procedures* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC 2.26)
4. [CCD] **SHALL** contain [1..1] title
5. [CCD] **SHOULD** contain [1..\*] procedureActivity, such that it
  - a. contains [CCD Procedure 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="2.16.840.1.113883.10.20.1.12"
            assigningAuthorityName="CCD Procedures Section"/>
          <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.11"
            assigningAuthorityName="IHE 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>
    </structuredBody>
  </component>
</ClinicalDocument>
```

**Figure 42: Surgeries Section example**

## Vital Signs Section

[Section: templateId 1.3.6.1.4.1.19376.1.5.3.1.3.25]

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

1. Conforms to [CDA Section](#)
2. Conforms to [CCD Vital Signs Section](#) template (templateId: 2.16.840.1.113883.10.20.1.16)
3. [CCD] **SHALL** contain [1..1] code/@code = "8716-3" *Vital signs* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC 2.26)
4. [CCD] **SHALL** contain [1..1] title
5. [CCD] **SHOULD** contain [1..\*] entry, such that it
  - a. contains [CCD Vital Signs Organizer](#) (templateId: 2.16.840.1.113883.10.20.1.35)
6. [CCD] **SHALL** contain [1..1] text
7. [CCD] **SHOULD** satisfy: Contains a case-insensitive language-insensitive string containing 'vital signs'.

```
<?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="2.16.840.1.113883.10.20.1.16"
            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"/>
          <code code="8716-3" codeSystem="2.16.840.1.113883.6.1"
            codeSystemName="LOINC" displayName="Vital signs"/>
          <title>Vital signs</title>
          <entry>
            <organizer 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"/>
              <id root="cf2b79e7-05e0-4d9a-85ce-049da7d76976" />
              <code/>
              <statusCode/>
            </organizer>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>

```

**Figure 43: Vital Signs Section example**





---

# Chapter

# 4

---

## CLINICAL STATEMENT TEMPLATES

---

### Topics:

- *Allergy Intolerance*
- *Allergy Intolerance Concern*
- *Combination Medication*
- *Comment*
- *Concern Entry*
- *Conditional Dose*
- *Coverage Entry*
- *Encounter Activity*
- *Encounter Entry*
- *Encounter Plan Of Care*
- *Immunization*
- *Medication*
- *Normal Dose*
- *Observation Request Entry*
- *Payer Entry*
- *Pregnancy Observation*
- *Problem Concern Entry*
- *Problem Entry*
- *Procedure Entry Plan Of Care*
- *Activity Procedure*
- *Procedure Entry Procedure*
- *Activity Procedure*
- *Simple Observation*
- *Split Dose*
- *Supply Entry*
- *Tapered Dose*
- *Vital Sign Observation*
- *Vital Signs Organizer*

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

## Allergy Intolerance

[Observation: templateId 1.3.6.1.4.1.19376.1.5.3.1.4.6]

1. Conforms to [CDA Clinical Statement](#)
2. Conforms to [CDA Observation](#)
3. Conforms to [CCD Problem Observation](#) template (templateId: 2.16.840.1.113883.10.20.1.28)
4. Conforms to [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"
7. [CCD] **MAY** contain [1..1] code, which **MAY** be selected from ValueSet 2.16.840.1.113883.1.11.20.14 ProblemTypeCode STATIC 20061017
8. [CCD] **SHALL** contain [1..1] statusCode/@code = "completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus STATIC V3NE08)
9. [CCD] **SHOULD** contain [0..1] effectiveTime
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)
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)
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)
13. [IHE] **SHALL** contain [1..1] text
14. [IHE] **SHALL** contain [1..1] value, where its data type is CD
15. [CCD] **SHALL** satisfy: Contains one or more sources of information.
  - [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'))

16. [CCD] **MAY** satisfy: Contains exactly one Patient Awareness

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

```
<?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 root="1.3.6.1.4.1.19376.1.5.3.1.4.6"
```

```
assigningAuthorityName="IHE Allergy Intolerance"/>
```

```
            <code/>
```

```
            <text/>
```

```

        <statusCode code="completed"/>
        <effectiveTime>
          <low value="1972"/>
          <high value="2008"/>
        </effectiveTime>
        <value xsi:type="CD"/>
        <entryRelationship>
          <observation classCode="OBS" moodCode="EVN">
            <templateId root="2.16.840.1.113883.10.20.1.57"
assigningAuthorityName="CCD Status Observation"/>
            <templateId root="2.16.840.1.113883.10.20.1.50"
assigningAuthorityName="CCD Problem Status Observation"/>
            <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Status"/>
            <statusCode code="completed"/>
            <value xsi:type="CE"/>
          </observation>
        </entryRelationship>
        <entryRelationship>
          <observation classCode="OBS" moodCode="EVN">
            <templateId root="2.16.840.1.113883.10.20.1.57"
assigningAuthorityName="CCD Status Observation"/>
            <templateId root="2.16.840.1.113883.10.20.1.51"
assigningAuthorityName="CCD Problem Health Status Observation"/>
            <code code="11323-3" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Health status"/>
            <statusCode code="completed"/>
            <value xsi:type="CE"/>
          </observation>
        </entryRelationship>
        <entryRelationship>
          <observation classCode="OBS" moodCode="EVN">
            <templateId root="2.16.840.1.113883.10.20.1.38"
assigningAuthorityName="CCD Age Observation"/>
            <code code="397659008" codeSystem="2.16.840.1.113883.6.96"
codeSystemName="SNOMEDCT" displayName="Age"/>
            <statusCode code="completed"/>
          </observation>
        </entryRelationship>
      </observation>
    </entry>
  </section>
</component>
</structuredBody>
</component>
</ClinicalDocument>

```

**Figure 44: Allergy Intolerance example**

## Allergy Intolerance Concern

[Act: templateId 1.3.6.1.4.1.19376.1.5.3.1.4.5.3]

This entry is a specialization of the Concern Entry, wherein the subject of the concern is focused on an allergy or intolerance.

1. Conforms to *CDA Clinical Statement*
2. Conforms to *CDA Act*
3. Conforms to *CCD Problem Act* template (templateId: 2.16.840.1.113883.10.20.1.27)
4. Conforms to *Concern Entry* template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.5.1)
5. [CCD] **SHALL** contain [1..1] @classCode = "ACT"
6. [CCD] **SHALL** contain [1..1] @moodCode = "EVN"

7. [CCD] **SHALL** contain [1..1] code/@nullFlavor = "NA" NA (*not applicable*)
8. [CCD] **SHALL** contain [1..\*] id
9. [IHE] **SHALL** contain [1..1] effectiveTime
10. [CCD] **MAY** contain [0..1] entryRelationship, such that it
  - a. contains *CCD Episode Observation* (templateId: 2.16.840.1.113883.10.20.1.41)
11. [CCD] **SHALL** satisfy: Contains one or more entryRelationship
  - [OCL]: `not self.entryRelationship->isEmpty()`
12. [CCD] **CONF-152: 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.
13. [CCD] **CONF-153: 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.
  - [OCL]:
 

```
self.getEntryRelationshipTargets(vocab::x_ActRelationshipEntryRelationship::SUBJ,
cda::ClinicalStatement)->forall(target : cda::ClinicalStatement | not
target.ocIsUndefined() and
(target.ocIsKindOf(ccd::ProblemObservation) or
target.ocIsKindOf(ccd::AlertObservation)))
```
14. [CCD] **SHOULD** satisfy: In Problem Section, a Problem Act SHOULD contain a Problem Observation.
  - [OCL]: `self.getSection().ocIsKindOf(ccd::ProblemSection) implies self.getObservations()->exists(obs : cda::Observation | obs.ocIsKindOf(ccd::ProblemObservation))`
15. [CCD] **SHOULD** satisfy: In Alert Section, a ProblemAct SHOULD contain an Alert Observation.
  - [OCL]: `self.getSection().ocIsKindOf(ccd::AlertsSection) implies self.getObservations()->exists(obs : cda::Observation | obs.ocIsKindOf(ccd::AlertObservation))`
16. [CCD] **MAY** satisfy: Contains exactly one Patient Awareness
  - [OCL]: `self.participant->one(partic : cda::Participant2 | partic.ocIsKindOf(ccd::PatientAwareness))`

```
<?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"/>
              <id root="9d876718-4bfd-4691-aa35-5dedfa37e3ab"/>
              <code nullFlavor="NA"/>
              <effectiveTime>
                <low value="1972"/>
                <high value="2008"/>
              </effectiveTime>
              <entryRelationship>
                <observation classCode="OBS" moodCode="EVN">
                  <templateId root="2.16.840.1.113883.10.20.1.41"
assigningAuthorityName="CCD Episode Observation"/>

```

```

        <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"
codeSystemName="ActCode"/>
        <statusCode code="completed"/>
        <value xsi:type="CD"/>
    </observation>
</entryRelationship>
</act>
</entry>
</section>
</component>
</structuredBody>
</component>
</ClinicalDocument>

```

**Figure 45: Allergy Intolerance Concern example**

## Combination Medication

[SubstanceAdministration: templateId 1.3.6.1.4.1.19376.1.5.3.1.4.11]

1. Conforms to [CDA Clinical Statement](#)
2. Conforms to [CDA Substance Administration](#)
3. Conforms to [CCD Medication Activity](#) template (templateId: 2.16.840.1.113883.10.20.1.24)
4. Conforms to [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] **CONF-306: SHALL** contain [1..\*] id
9. [CCD] **CONF-307: SHOULD** contain [1..1] statusCode
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] **CONF-330, CONF-333: 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)
13. [CCD] **CONF-308: SHOULD** contain [1..\*] effectiveTime
  - Used to indicate the actual or intended start and stop date of a medication, and the frequency of administration.
14. [CCD] **CONF-312: MAY** contain [0..1] maxDoseQuantity
15. [IHE] **SHOULD** contain [1..1] routeCode
  - The route is a coded value, and indicates how the medication is received by the patient (by mouth, intravenously, topically, et cetera).
16. [CCD] **CONF-313: MAY** contain [0..1] performer, such that it
  - a. contains [CDA Performer2](#)
  - Indicates the person administering a substance.
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] CONF-305: SHALL** satisfy: Value for moodCode is "EVN" or "INT" 2.16.840.1.113883.5.1001 ActMood STATIC

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

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

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

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

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

**23. [CCD] CONF-315: SHALL** satisfy: Contains one or more sources of information.

- [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] CONF-327: 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.

- 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.ocIsUndefined())`

**25. [CCD] CONF-328: 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.

- 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] CONF-329: SHALL** satisfy: entryRelationship / @typeCode="RSON" in a medication activity has a target of problem act, problem observation, or some other clinical statement.

- [OCL]: `self.getEntryRelationshipTargets(vocab::x_ActRelationshipEntryRelationship::RSON, cda::ClinicalStatement)->forall(target : cda::ClinicalStatement | not target.ocIsUndefined() and (target.ocIsKindOf(ccd::ProblemAct) or target.ocIsKindOf(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.ocIsUndefined()`

```

    or not
    self.consumable.manufacturedProduct.manufacturedMaterial.name.ocIsUndefined()
<?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"/>
              <id root="5977d1e8-a19b-47a9-884e-ffd7e05394c9"/>
              <statusCode/>
              <effectiveTime/>
              <routeCode codeSystem="2.16.840.1.113883.5.112"
codeSystemName="HL7 RouteOfAdministration"/>
              <approachSiteCode/>
              <doseQuantity/>
              <rateQuantity/>
              <maxDoseQuantity/>
              <entryRelationship>
                <observation classCode="OBS" moodCode="EVN">
                  <templateId root="2.16.840.1.113883.10.20.1.46"
assigningAuthorityName="CCD Medication Series Number Observation"/>
                  <code code="30973-2" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Dose number"/>
                  <statusCode/>
                  <value xsi:type="INT"/>
                </observation>
              </entryRelationship>
              <entryRelationship>
                <observation classCode="OBS" moodCode="EVN">
                  <templateId root="2.16.840.1.113883.10.20.1.57"
assigningAuthorityName="CCD Status Observation"/>
                  <templateId root="2.16.840.1.113883.10.20.1.47"
assigningAuthorityName="CCD Medication Status Observation"/>
                  <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Status"/>
                  <statusCode code="completed"/>
                  <value xsi:type="CE"/>
                </observation>
              </entryRelationship>
            </substanceAdministration>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>

```

**Figure 46: Combination Medication example**

## Comment

[Act: templateId 1.3.6.1.4.1.19376.1.5.3.1.4.2]

1. Conforms to *CDA Clinical Statement*
2. Conforms to *CDA Act*
3. [IHE] **SHALL** contain [1..1] @classCode = "ACT"
4. [IHE] **SHALL** contain [1..1] @moodCode = "EVN"
5. [IHE] **SHALL** contain [1..1] code/@code = "48767-8" *Annotation Comment* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC 2.26)
6. [IHE] **SHALL** contain [0..1] statusCode/@code = "completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus STATIC V3NE08)
7. [IHE] **SHALL** contain [0..1] text

```
<?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="1.3.6.1.4.1.19376.1.5.3.1.4.2"
assigningAuthorityName="IHE 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 47: Comment example**

## Concern Entry

[Act: templateId 1.3.6.1.4.1.19376.1.5.3.1.4.5.1]

1. Conforms to *CDA Clinical Statement*
2. Conforms to *CDA Act*
3. Conforms to *CCD Problem Act* template (templateId: 2.16.840.1.113883.10.20.1.27)
4. [CCD] **SHALL** contain [1..1] @classCode = "ACT"
5. [CCD] **SHALL** contain [1..1] @moodCode = "EVN"
6. [CCD] **SHALL** contain [1..1] code/@nullFlavor = "NA" *NA (not applicable)*
7. [CCD] **SHALL** contain [1..\*] id
8. [IHE] **SHALL** contain [1..1] effectiveTime
9. [CCD] **MAY** contain [0..1] entryRelationship, such that it
  - a. contains *CCD Episode Observation* (templateId: 2.16.840.1.113883.10.20.1.41)
10. [CCD] **SHALL** satisfy: Contains one or more entryRelationship
  - [OCL]: not self.entryRelationship->isEmpty()
11. [CCD] **CONF-152: 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.



**12. [CCD] CONF-153: 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.

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

**13. [CCD] SHOULD** satisfy: In Problem Section, a Problem Act SHOULD contain a Problem Observation.

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

**14. [CCD] SHOULD** satisfy: In Alert Section, a ProblemAct SHOULD contain an Alert Observation.

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

**15. [CCD] MAY** satisfy: Contains exactly one Patient Awareness

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

```
<?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"/>
              <id root="2cc4f4fe-e8c5-4690-a6ac-11a6181aceb5"/>
              <code nullFlavor="NA"/>
              <effectiveTime>
                <low value="1972"/>
                <high value="2008"/>
              </effectiveTime>
              <entryRelationship>
                <observation classCode="OBS" moodCode="EVN">
                  <templateId root="2.16.840.1.113883.10.20.1.41"
assigningAuthorityName="CCD Episode Observation"/>
                  <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"
codeSystemName="ActionCode"/>
                  <statusCode code="completed"/>
                  <value xsi:type="CD"/>
                </observation>
              </entryRelationship>
            </act>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

**Figure 48: Concern Entry example**

## Conditional Dose

[SubstanceAdministration: templateId 1.3.6.1.4.1.19376.1.5.3.1.4.10]

1. Conforms to [CDA Clinical Statement](#)
2. Conforms to [CDA Substance Administration](#)
3. Conforms to [CCD Medication Activity](#) template (templateId: 2.16.840.1.113883.10.20.1.24)
4. Conforms to [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] **CONF-306: SHALL** contain [1..\*] id
9. [CCD] **CONF-307: SHOULD** contain [1..1] statusCode
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] **CONF-330, CONF-333: 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)
13. [CCD] **CONF-308: SHOULD** contain [1..\*] effectiveTime
  - Used to indicate the actual or intended start and stop date of a medication, and the frequency of administration.
14. [CCD] **CONF-312: MAY** contain [0..1] maxDoseQuantity
15. [IHE] **SHOULD** contain [1..1] routeCode
  - The route is a coded value, and indicates how the medication is received by the patient (by mouth, intravenously, topically, et cetera).
16. [CCD] **CONF-313: MAY** contain [0..1] performer, such that it
  - a. contains [CDA Performer2](#)
    - Indicates the person administering a substance.
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] **CONF-305: SHALL** satisfy: Value for moodCode is "EVN" or "INT" 2.16.840.1.113883.5.1001 ActMood STATIC
  - [OCL]: self.moodCode=vocab::x\_DocumentSubstanceMood::EVN or self.moodCode=vocab::x\_DocumentSubstanceMood::INT
21. [CCD] **CONF-311: SHOULD** satisfy: Contains exactly one doseQuantity or rateQuantity.
  - [OCL]: not self.doseQuantity.ocIsUndefined() or not self.rateQuantity.ocIsUndefined()

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

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

**23. [CCD] CONF-315: SHALL** satisfy: Contains one or more sources of information.

- [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] CONF-327: 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.

- 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.ocIsUndefined())`

**25. [CCD] CONF-328: 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.

- 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] CONF-329: SHALL** satisfy: entryRelationship / @typeCode="RSON" in a medication activity has a target of problem act, problem observation, or some other clinical statement.

- [OCL]: `self.getEntryRelationshipTargets(vocab::x_ActRelationshipEntryRelationship::RSON, cda::ClinicalStatement)->forall(target : cda::ClinicalStatement | not target.ocIsUndefined() and (target.ocIsKindOf(ccd::ProblemAct) or target.ocIsKindOf(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.ocIsUndefined() or not self.consumable.manufacturedProduct.manufacturedMaterial.name.ocIsUndefined()`

```
<?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"/>
            </substanceAdministration>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

```

        <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"/>
        <id root="366cd322-3615-4cbe-b089-110ec65410c4"/>
        <statusCode/>
        <effectiveTime/>
        <routeCode codeSystem="2.16.840.1.113883.5.112"
codeSystemName="HL7 RouteOfAdministration"/>
        <approachSiteCode/>
        <doseQuantity/>
        <rateQuantity/>
        <maxDoseQuantity/>
        <entryRelationship>
            <observation classCode="OBS" moodCode="EVN">
                <templateId root="2.16.840.1.113883.10.20.1.46"
assigningAuthorityName="CCD Medication Series Number Observation"/>
                <code code="30973-2" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Dose number"/>
                <statusCode/>
                <value xsi:type="INT"/>
            </observation>
        </entryRelationship>
        <entryRelationship>
            <observation classCode="OBS" moodCode="EVN">
                <templateId root="2.16.840.1.113883.10.20.1.57"
assigningAuthorityName="CCD Status Observation"/>
                <templateId root="2.16.840.1.113883.10.20.1.47"
assigningAuthorityName="CCD Medication Status Observation"/>
                <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Status"/>
                <statusCode code="completed"/>
                <value xsi:type="CE"/>
            </observation>
        </entryRelationship>
    </substanceAdministration>
</entry>
</section>
</component>
</structuredBody>
</component>
</ClinicalDocument>

```

**Figure 49: Conditional Dose example**

## Coverage Entry

[Act: templateId 1.3.6.1.4.1.19376.1.5.3.1.4.17]

1. Conforms to [CDA Clinical Statement](#)
2. Conforms to [CDA Act](#)
3. Conforms to [CCD Coverage Activity](#) template (templateId: 2.16.840.1.113883.10.20.1.20)
4. [CCD] **CONF-36: SHALL** contain [1..1] @classCode = "ACT"
5. [CCD] **CONF-37: SHALL** contain [1..1] @moodCode = "DEF"
6. [CCD] **CONF-41, CONF-42: SHALL** contain [1..1] code/@code = "48768-6" *Payment sources* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC 2.26)
7. [CCD] **CONF-38: SHALL** contain [1..\*] id
8. [CCD] **CONF-39, CONF-40: SHALL** contain [1..1] statusCode/@code = "completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus STATIC V3NE08)
9. [CCD] **CONF-43, CONF-45, CONF-46: 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)
10. [CCD] **CONF-47: SHALL** satisfy: An alert observation contains one or more sources of information.
- [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'))
11. [CCD] **CONF-44: MAY** satisfy: entryRelationship contains sequenceNumber, which serves to prioritize the payment sources.
- [OCL]: self.entryRelationship->exists(rel : cda::EntryRelationship | not  
 rel.sequenceNumber.ocIsUndefined())
- ```
<?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"/>
              <id root="2d24c373-0c7b-4fc2-915c-383f5957e09c"/>
              <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="1f31addd-fdel-4cf7-a343-e09df1054e1c"/>
                  <code/>
                  <statusCode code="completed"/>
                </act>
              </entryRelationship>
            </act>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

**Figure 50: Coverage Entry example**

## Encounter Activity

[Encounter: templateId 1.3.6.1.4.1.19376.1.5.3.1.4.14]

1. Conforms to *Encounter Entry* template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.14)
2. Conforms to *CDA Clinical Statement*
3. Conforms to *CDA Encounter*
4. Conforms to *CCD Encounters Activity* template (templateId: 2.16.840.1.113883.10.20.1.21)

5. [CCD] **SHALL** contain [1..1] @classCode = "ENC"
6. [CCD] **SHALL** contain [1..1] @moodCode = "EVN"
7. [CCD] **SHOULD** contain [1..1] code, which **SHOULD** be selected from ValueSet 2.16.840.1.113883.1.11.13955 EncounterCode STATIC
8. [CCD] **SHALL** contain [1..\*] id
9. [IHE] **SHALL** contain [1..1] text
10. [CCD] **MAY** contain [0..1] effectiveTime

```
<?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"/>
              <id root="a487b802-6cc3-4ff0-acf9-a216db092aaf"/>
              <code codeSystem="2.16.840.1.113883.5.4"
codeSystemName="ActEncounterCode"/>
              <text/>
              <effectiveTime>
                <low value="1972"/>
                <high value="2008"/>
              </effectiveTime>
            </encounter>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

**Figure 51: Encounter Activity example**

## Encounter Entry

[Encounter: templateId 1.3.6.1.4.1.19376.1.5.3.1.4.14]

1. Conforms to [CDA Clinical Statement](#)
2. Conforms to [CDA Encounter](#)
3. [IHE] **SHALL** contain [1..1] @classCode = "ENC"
4. [CDA] Contains [1..1] @moodCode, where its data type is x\_DocumentEncounterMood
5. [IHE] **SHOULD** contain [0..1] code (CodeSystem: 2.16.840.1.113883.5.4 ActEncounterCode STATIC)
  - Developers should take care to check that rational combinations of encounter.code and encounter.moodCode are used , but this profile does not restrict any combination.
6. [IHE] **SHALL** contain [1..\*] id
7. [IHE] **SHALL** contain [1..1] text

**Figure 52: Encounter Entry example**

## Encounter Plan Of Care

[Encounter: templateId 1.3.6.1.4.1.19376.1.5.3.1.4.14]

1. Conforms to *Encounter Entry* template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.14)
2. Conforms to *CCD Plan Of Care Activity*
3. Conforms to *CDA Clinical Statement*
4. Conforms to *CDA Encounter*
5. Conforms to *CCD Plan Of Care Activity Encounter* template (templateId: 2.16.840.1.113883.10.20.1.25)
6. [CDA] Contains [1..1] @classCode, where its data type is ActClass
7. [CCD] **SHALL** contain [1..1] @moodCode
8. [IHE] **SHOULD** contain [0..1] code (CodeSystem: 2.16.840.1.113883.5.4 ActEncounterCode STATIC)
  - Developers should take care to check that rational combinations of encounter.code and encounter.moodCode are used , but this profile does not restrict any combination.
9. [CCD] **SHALL** contain [1..\*] id
10. [IHE] **SHALL** contain [1..1] text
11. [CCD] **SHALL** satisfy: moodCodeValue
  - [OCL]: self.moodCode = vocab::x\_DocumentEncounterMood::INT or self.moodCode = vocab::x\_DocumentEncounterMood::ARQ or self.moodCode = vocab::x\_DocumentEncounterMood::PRMS or self.moodCode = vocab::x\_DocumentEncounterMood::PRP or self.moodCode = vocab::x\_DocumentEncounterMood::RQO
12. [IHE] **SHALL** satisfy: moodCodeValue
  - [OCL]: self.moodCode = vocab::x\_DocumentEncounterMood::ARQ or self.moodCode = vocab::x\_DocumentEncounterMood::PRMS

```
<?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">
              <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.14"/>
              <templateId root="2.16.840.1.113883.10.20.1.25"/>
              <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.14"/>
              <id root="196f78e6-89a3-45d7-97a9-8d292adf3b34"/>
              <code codeSystem="2.16.840.1.113883.5.4"
codeSystemName="ActEncounterCode"/>
              <text/>
            </encounter>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 53: Encounter Plan Of Care example

## Immunization

[SubstanceAdministration: templateId 1.3.6.1.4.1.19376.1.5.3.1.4.12]

1. Conforms to *CDA Clinical Statement*
2. Conforms to *CDA Substance Administration*
3. Conforms to *CCD Medication Activity* template (templateId: 2.16.840.1.113883.10.20.1.24)
4. [CDA] Contains [1..1] @classCode = "SBADM", where its data type is ActClass
5. [CDA] Contains [1..1] @moodCode, where its data type is x\_DocumentSubstanceMood

6. [CDA] Contains [1..1] consumable, where its type is *CDA Consumable*
7. [CCD] **CONF-306: SHALL** contain [1..\*] id
8. [CCD] **CONF-307: SHOULD** contain [1..1] statusCode
9. [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)
10. [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)
11. [CCD] **CONF-330, CONF-333: 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)
12. [CCD] **CONF-308: SHOULD** contain [1..\*] effectiveTime
  - Used to indicate the actual or intended start and stop date of a medication, and the frequency of administration.
13. [CCD] **CONF-312: MAY** contain [0..1] maxDoseQuantity
14. [CCD] **CONF-309, CONF-310: SHOULD** contain [1..1] routeCode (CodeSystem: 2.16.840.1.113883.5.112 HL7 RouteOfAdministration DYNAMIC)
15. [CCD] **CONF-313: MAY** contain [0..1] performer, such that it
  - a. contains *CDA Performer2*
    - Indicates the person administering a substance.
16. [CCD] **CONF-305: SHALL** satisfy: Value for moodCode is "EVN" or "INT" 2.16.840.1.113883.5.1001 ActMood STATIC
  - [OCL]: `self.moodCode=vocab::x_DocumentSubstanceMood::EVN or self.moodCode=vocab::x_DocumentSubstanceMood::INT`
17. [CCD] **CONF-311: SHOULD** satisfy: Contains exactly one doseQuantity or rateQuantity.
  - [OCL]: `not self.doseQuantity.ocIsUndefined() or not self.rateQuantity.ocIsUndefined()`
18. [CCD] **CONF-314: MAY** satisfy: Has one or more associated consents, represented in the CCD Header as ClinicalDocument / authorization / consent.
  - [OCL]: `self.getClinicalDocument().authorization->exists(auth : cda::Authorization | not auth.ocIsUndefined() and not auth.consent.ocIsUndefined())`
19. [CCD] **CONF-315: SHALL** satisfy: Contains one or more sources of information.
  - [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. [CCD] **CONF-327: 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.
  - 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.ocIsUndefined())`
21. [CCD] **CONF-328: 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.
  - The target of the relationship represents the indication for the activity.
  - [OCL]: `self.entryRelationship->exists(entryRel : cda::EntryRelationship | entryRel.typeCode = vocab::x_ActRelationshipEntryRelationship::RSON)`



**22. [CCD] CONF-329: SHALL** satisfy: entryRelationship / @typeCode="RSON" in a medication activity has a target of problem act, problem observation, or some other clinical statement.

- [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 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"/>
              <id root="271176bb-f633-48f5-9129-8483ad20427b"/>
              <statusCode/>
              <effectiveTime/>
              <routeCode codeSystem="2.16.840.1.113883.5.112"
codeSystemName="HL7 RouteOfAdministration"/>
              <maxDoseQuantity/>
              <entryRelationship>
                <observation classCode="OBS" moodCode="EVN">
                  <templateId root="2.16.840.1.113883.10.20.1.46"
assigningAuthorityName="CCD Medication Series Number Observation"/>
                  <code code="30973-2" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Dose number"/>
                  <statusCode/>
                  <value xsi:type="INT"/>
                </observation>
              </entryRelationship>
              <entryRelationship>
                <observation classCode="OBS" moodCode="EVN">
                  <templateId root="2.16.840.1.113883.10.20.1.57"
assigningAuthorityName="CCD Status Observation"/>
                  <templateId root="2.16.840.1.113883.10.20.1.47"
assigningAuthorityName="CCD Medication Status Observation"/>
                  <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Status"/>
                  <statusCode code="completed"/>
                  <value xsi:type="CE"/>
                </observation>
              </entryRelationship>
            </substanceAdministration>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

**Figure 54: Immunization example**

## Medication

[SubstanceAdministration: templateId 1.3.6.1.4.1.19376.1.5.3.1.4.7]

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

1. Conforms to [CDA Clinical Statement](#)
2. Conforms to [CDA Substance Administration](#)
3. Conforms to [CCD Medication Activity](#) template (templateId: 2.16.840.1.113883.10.20.1.24)
4. [CDA] Contains [1..1] @classCode = "SBADM", where its data type is ActClass
5. [CDA] Contains [1..1] @moodCode, where its data type is x\_DocumentSubstanceMood
6. [CDA] Contains [1..1] consumable, where its type is [CDA Consumable](#)
7. [CCD] **CONF-306: SHALL** contain [1..\*] id
8. [CCD] **CONF-307: SHOULD** contain [1..1] statusCode
9. [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)
10. [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)
11. [CCD] **CONF-330, CONF-333: 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)
12. [CCD] **CONF-308: SHOULD** contain [1..\*] effectiveTime
  - Used to indicate the actual or intended start and stop date of a medication, and the frequency of administration.
13. [CCD] **CONF-312: MAY** contain [0..1] maxDoseQuantity
14. [IHE] **SHOULD** contain [1..1] routeCode
  - The route is a coded value, and indicates how the medication is received by the patient (by mouth, intravenously, topically, et cetera).
15. [CCD] **CONF-313: MAY** contain [0..1] performer, such that it
  - a. contains [CDA Performer2](#)
  - Indicates the person administering a substance.
16. [IHE] **MAY** contain [0..\*] approachSiteCode
  - The site where the medication is administered, usually used with IV or topical drugs.
17. [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.
18. [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.
19. [CCD] **CONF-305: SHALL** satisfy: Value for moodCode is "EVN" or "INT" 2.16.840.1.113883.5.1001  
ActMood STATIC
  - [OCL]: self.moodCode=vocab::x\_DocumentSubstanceMood::EVN or self.moodCode=vocab::x\_DocumentSubstanceMood::INT
20. [CCD] **CONF-311: SHOULD** satisfy: Contains exactly one doseQuantity or rateQuantity.
  - [OCL]: not self.doseQuantity.ocIsUndefined() or not self.rateQuantity.ocIsUndefined()

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

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

**22. [CCD] CONF-315: SHALL** satisfy: Contains one or more sources of information.

- [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'))`

**23. [CCD] CONF-327: 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.

- 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.ocIsUndefined())`

**24. [CCD] CONF-328: 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.

- The target of the relationship represents the indication for the activity.
- [OCL]: `self.entryRelationship->exists(entryRel : cda::EntryRelationship | entryRel.typeCode = vocab::x_ActRelationshipEntryRelationship::RSON)`

**25. [CCD] CONF-329: SHALL** satisfy: entryRelationship / @typeCode="RSON" in a medication activity has a target of problem act, problem observation, or some other clinical statement.

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

**26. [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.ocIsUndefined() or not self.consumable.manufacturedProduct.manufacturedMaterial.name.ocIsUndefined()`

```
<?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"/>
            </substanceAdministration>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

```

        <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.7"
assigningAuthorityName="IHE Medication"/>
        <id root="a6136d63-bafc-4908-820a-db0a7f09f514"/>
        <statusCode/>
        <effectiveTime/>
        <routeCode codeSystem="2.16.840.1.113883.5.112"
codeSystemName="HL7 RouteOfAdministration"/>
        <approachSiteCode/>
        <doseQuantity/>
        <rateQuantity/>
        <maxDoseQuantity/>
        <entryRelationship>
            <observation classCode="OBS" moodCode="EVN">
                <templateId root="2.16.840.1.113883.10.20.1.46"
assigningAuthorityName="CCD Medication Series Number Observation"/>
                <code code="30973-2" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Dose number"/>
                <statusCode/>
                <value xsi:type="INT"/>
            </observation>
        </entryRelationship>
        <entryRelationship>
            <observation classCode="OBS" moodCode="EVN">
                <templateId root="2.16.840.1.113883.10.20.1.57"
assigningAuthorityName="CCD Status Observation"/>
                <templateId root="2.16.840.1.113883.10.20.1.47"
assigningAuthorityName="CCD Medication Status Observation"/>
                <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Status"/>
                <statusCode code="completed"/>
                <value xsi:type="CE"/>
            </observation>
        </entryRelationship>
    </substanceAdministration>
</entry>
</section>
</component>
</structuredBody>
</component>
</ClinicalDocument>

```

Figure 55: Medication example

## Normal Dose

[SubstanceAdministration: templateId 1.3.6.1.4.1.19376.1.5.3.1.4.7.1]

1. Conforms to [CDA Clinical Statement](#)
2. Conforms to [CDA Substance Administration](#)
3. Conforms to [CCD Medication Activity](#) template (templateId: 2.16.840.1.113883.10.20.1.24)
4. Conforms to [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] **CONF-306: SHALL** contain [1..\*] id
9. [CCD] **CONF-307: SHOULD** contain [1..1] statusCode
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] **CONF-330, CONF-333: 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)
- 13. [CCD] **CONF-308: SHOULD** contain [1..\*] effectiveTime
  - Used to indicate the actual or intended start and stop date of a medication, and the frequency of administration.
- 14. [CCD] **CONF-312: MAY** contain [0..1] maxDoseQuantity
- 15. [IHE] **SHOULD** contain [1..1] routeCode
  - The route is a coded value, and indicates how the medication is received by the patient (by mouth, intravenously, topically, et cetera).
- 16. [CCD] **CONF-313: MAY** contain [0..1] performer, such that it
  - a. contains *CDA Performer2*
  - Indicates the person administering a substance.
- 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] **CONF-305: SHALL** satisfy: Value for moodCode is "EVN" or "INT" 2.16.840.1.113883.5.1001 ActMood STATIC
  - [OCL]: self.moodCode=vocab::x\_DocumentSubstanceMood::EVN or self.moodCode=vocab::x\_DocumentSubstanceMood::INT
- 21. [CCD] **CONF-311: SHOULD** satisfy: Contains exactly one doseQuantity or rateQuantity.
  - [OCL]: not self.doseQuantity.ocIsUndefined() or not self.rateQuantity.ocIsUndefined()
- 22. [CCD] **CONF-314: MAY** satisfy: Has one or more associated consents, represented in the CCD Header as ClinicalDocument / authorization / consent.
  - [OCL]: self.getClinicalDocument().authorization->exists(auth : cda::Authorization | not auth.ocIsUndefined() and not auth.consent.ocIsUndefined())
- 23. [CCD] **CONF-315: SHALL** satisfy: Contains one or more sources of information.
  - [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] **CONF-327: 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.
  - 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.ocIsUndefined())

**25. [CCD] CONF-328: 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.

- 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] CONF-329: SHALL** satisfy: entryRelationship / @typeCode="RSON" in a medication activity has a target of problem act, problem observation, or some other clinical statement.

- [OCL]: `self.getEntryRelationshipTargets(vocab::x_ActRelationshipEntryRelationship::RSON, cda::ClinicalStatement)->forall(target : cda::ClinicalStatement | not target.ocIsUndefined() and (target.ocIsKindOf(ccd::ProblemAct) or target.ocIsKindOf(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.ocIsUndefined() or not self.consumable.manufacturedProduct.manufacturedMaterial.name.ocIsUndefined()`

```
<?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="1.3.6.1.4.1.19376.1.5.3.1.4.7.1"
assigningAuthorityName="IHE Normal Dose"/>
              <id root="422b6f92-ffe7-4fdb-9062-dbd95b180823"/>
              <statusCode/>
              <effectiveTime/>
              <routeCode codeSystem="2.16.840.1.113883.5.112"
codeSystemName="HL7 RouteOfAdministration"/>
              <approachSiteCode/>
              <doseQuantity/>
              <rateQuantity/>
              <maxDoseQuantity/>
              <entryRelationship>
                <observation classCode="OBS" moodCode="EVN">
                  <templateId root="2.16.840.1.113883.10.20.1.46"
assigningAuthorityName="CCD Medication Series Number Observation"/>
                  <code code="30973-2" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Dose number"/>
                  <statusCode/>
                  <value xsi:type="INT"/>
                </observation>
              </entryRelationship>
            </substanceAdministration>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

```

        <entryRelationship>
          <observation classCode="OBS" moodCode="EVN">
            <templateId root="2.16.840.1.113883.10.20.1.57"
assigningAuthorityName="CCD Status Observation"/>
            <templateId root="2.16.840.1.113883.10.20.1.47"
assigningAuthorityName="CCD Medication Status Observation"/>
            <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Status"/>
            <statusCode code="completed"/>
            <value xsi:type="CE"/>
          </observation>
        </entryRelationship>
      </substanceAdministration>
    </entry>
  </section>
</component>
</structuredBody>
</component>
</ClinicalDocument>

```

Figure 56: Normal Dose example

## Observation Request Entry

[Observation: templateId 1.3.6.1.4.1.19376.1.5.3.1.1.20.3.1]

1. Conforms to [CCD Plan Of Care Activity](#)
2. Conforms to [CDA Clinical Statement](#)
3. Conforms to [CDA Observation](#)
4. Conforms to [CCD Plan Of Care Activity Observation](#) template (templateId: 2.16.840.1.113883.10.20.1.25)
5. [CDA] Contains [1..1] @classCode, where its data type is ActClassObservation
6. [CCD] **SHALL** contain [1..1] @moodCode
7. [CDA] Contains [1..1] code, where its data type is CD
8. [CCD] **SHALL** contain [1..\*] id
9. [CCD] **SHALL** satisfy: moodCodeValue
  - [OCL]: self.moodCode = vocab::x\_ActMoodDocumentObservation::INT or self.moodCode = vocab::x\_ActMoodDocumentObservation::GOL or self.moodCode = vocab::x\_ActMoodDocumentObservation::PRMS or self.moodCode = vocab::x\_ActMoodDocumentObservation::PRP or self.moodCode = vocab::x\_ActMoodDocumentObservation::RQO

```

<?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="2.16.840.1.113883.10.20.1.25"/>
              <templateId root="1.3.6.1.4.1.19376.1.5.3.1.1.20.3.1"
assigningAuthorityName="IHE Observation Request Entry"/>
              <id root="f9f6a54c-6216-4eb4-bfe3-b702d33d7ba0"/>
            </observation>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>

```

&lt;/ClinicalDocument&gt;

**Figure 57: Observation Request Entry example**

## Payer Entry

[Act: templateId 1.3.6.1.4.1.19376.1.5.3.1.4.18]

1. Conforms to *CDA Clinical Statement*
2. Conforms to *CDA Act*
3. Conforms to *CCD Policy Activity* template (templateId: 2.16.840.1.113883.10.20.1.26)
4. [CCD] **CONF-49: SHALL** contain [1..1] @classCode = "ACT"
5. [CCD] **CONF-50: SHALL** contain [1..1] @moodCode = "EVN"
6. [CCD] **CONF-54, CONF-55: SHOULD** contain [1..1] code, which **SHOULD** be selected from ValueSet 2.16.840.1.113883.1.11.19832 ActCoverageType DYNAMIC
7. [CCD] **CONF-51: SHALL** contain [1..\*] id
8. [CCD] **CONF-52, CONF-53: SHALL** contain [1..1] statusCode/@code = "completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus STATIC V3NE08)
9. [CCD] **CONF-56: SHALL** contain [1..1] performer, such that it
  - a. contains *CCD Payer Entity*
10. [CCD] **CONF-58: SHALL** contain [1..1] participant, such that it
  - a. contains *CCD Covered Party*
11. [CCD] **CONF-63: MAY** contain [1..1] participant, such that it
  - a. contains *CCD Policy Subscriber*
12. [CCD] **CONF-56: SHALL** satisfy: A policy activity contains exactly one performer [@typeCode='PRF'], representing the payer.
  - [OCL]: self.performer->one(perf : cda::Performer2 | perf.typeCode = vocab::ParticipationPhysicalPerformer::PRF)
13. [CCD] **CONF-58: SHALL** satisfy: A policy activity contains exactly one participant [@typeCode='COV'], representing the covered party.
  - [OCL]: self.participant->one(part : cda::Participant2 | part.typeCode = vocab::ParticipationType::COV)
14. [CCD] **CONF-61: MAY** satisfy: The value for participant / participantRole / code in a policy activity's covered party MAY be selected from ValueSet 2.16.840.1.113883.1.11.19809 PolicyOrProgramCoverageRoleType DYNAMIC.
15. [CCD] **CONF-62: MAY** satisfy: A covered party in a policy activity MAY contain exactly one participant / time, to represent the time period over which the patient is covered.
  - [OCL]: self.participant->one(part : cda::Participant2 | part.typeCode = vocab::ParticipationType::COV implies not part.time.oclIsUndefined())
16. [CCD] **CONF-63: MAY** satisfy: A policy activity MAY contain exactly one participant [@typeCode='HLD'], representing the subscriber.
  - [OCL]: self.participant->one(part : cda::Participant2 | part.typeCode = vocab::ParticipationType::HLD)
17. [CCD] **CONF-65: MAY** satisfy: A subscriber in a policy activity MAY contain exactly one participant / time, to represent the time period for which the subscriber is enrolled.
  - [OCL]: self.participant->one(part : cda::Participant2 | part.typeCode = vocab::ParticipationType::HLD implies not part.time.oclIsUndefined())



**18. [CCD] CONF-66: SHALL** satisfy: The value for entryRelationship / @typeCode in a policy activity SHALL be 'REFR' 2.16.840.1.113883.5.1002 ActRelationshipType STATIC.

- [OCL]: self.entryRelationship->forAll(rel : cda::EntryRelationship | rel.typeCode = vocab::x\_ActRelationshipEntryRelationship::REFR)

**19. [CCD] CONF-67: SHALL** satisfy: The target of a policy activity with entryRelationship / @typeCode='REFR' SHALL be an Authorization Activity or an Act, with Act [@classCode = 'ACT'] and Act [@moodCode = 'DEF'], representing a description of the coverage plan.

- [OCL]: self.entryRelationship->forAll(rel : cda::EntryRelationship | rel.act.ocIsKindOf(ccd::AuthorizationActivity) or rel.act.ocIsKindOf(ccd::CoveragePlanDescription))

```
<?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="2.16.840.1.113883.10.20.1.26"
assigningAuthorityName="CCD Policy Activity"/>
              <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.18"
assigningAuthorityName="IHE Payer Entry"/>
              <id root="74202b65-1fbd-40d6-97f8-2ec397e77bee"/>
              <code/>
              <statusCode code="completed"/>
              <performer>
                <assignedEntity>
                  <templateId assigningAuthorityName="CCD Payer Entity"/>
                  <id root="81e03076-d6ef-437c-899a-501e72085bfd"/>
                </assignedEntity>
              </performer>
              <participant>
                <participantRole>
                  <templateId assigningAuthorityName="CCD Covered Party"/>
                  <id root="975ae069-d366-47a3-a17e-be689897c0be"/>
                </participantRole>
              </participant>
              <participant>
                <participantRole>
                  <templateId assigningAuthorityName="CCD Policy Subscriber"/>
                  <id root="0e7cbe99-316c-42fb-ada7-394de8345ffd"/>
                </participantRole>
              </participant>
            </act>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

**Figure 58: Payer Entry example**

## Pregnancy Observation

[Observation: templateId 1.3.6.1.4.1.19376.1.5.3.1.4.13.5]

A pregnancy observation is a Simple Observation that uses a specific vocabulary to record observations about a patient's current or historical pregnancies.

1. Conforms to [CDA Clinical Statement](#)
2. Conforms to [CDA Observation](#)
3. Conforms to [Simple Observation](#) template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.13)
4. [CDA] Contains [1..1] @classCode, where its data type is ActClassObservation
5. [CDA] Contains [1..1] @moodCode, where its data type is x\_ActMoodDocumentObservation
6. [IHE] **SHALL** contain [1..1] code
7. [IHE] **SHALL** contain [1..\*] id
8. [IHE] **SHALL** contain [1..1] statusCode/@code = "completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus STATIC V3NE08)
9. [IHE] **SHALL** contain [0..0] interpretationCode
10. [IHE] **SHALL** contain [0..0] methodCode
11. [IHE] **SHALL** contain [0..0] repeatNumber
12. [IHE] **SHALL** contain [0..0] targetSiteCode
13. [IHE] **SHALL** contain [1..\*] value
  - The value of the observation shall be recording using a data type appropriate to the coded observation according to the table provided by IHE PCC specification.

```
<?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="1.3.6.1.4.1.19376.1.5.3.1.4.13"
assigningAuthorityName="IHE Simple Observation"/>
              <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.13.5"
assigningAuthorityName="IHE Pregnancy Observation"/>
              <id root="6e52328b-5321-4bc6-8eaf-eef301de6163"/>
              <code/>
              <statusCode code="completed"/>
              <repeatNumber/>
              <interpretationCode/>
              <methodCode/>
              <targetSiteCode/>
            </observation>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 59: Pregnancy Observation example

## Problem Concern Entry

[Act: templateId 1.3.6.1.4.1.19376.1.5.3.1.4.5.2]

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

1. Conforms to *CDA Clinical Statement*
  2. Conforms to *CDA Act*
  3. Conforms to *CCD Problem Act* template (templateId: 2.16.840.1.113883.10.20.1.27)
  4. Conforms to *Concern Entry* template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.5.1)
  5. [CCD] **SHALL** contain [1..1] @classCode = "ACT"
  6. [CCD] **SHALL** contain [1..1] @moodCode = "EVN"
  7. [CCD] **SHALL** contain [1..1] code/@nullFlavor = "NA" NA (not applicable)
  8. [CCD] **SHALL** contain [1..\*] id
  9. [IHE] **SHALL** contain [1..1] effectiveTime
  10. [CCD] **MAY** contain [0..1] entryRelationship, such that it
    - a. contains *CCD Episode Observation* (templateId: 2.16.840.1.113883.10.20.1.41)
  11. [IHE] **SHALL** contain [1..\*] entryRelationship, such that it
    - a. contains *Problem Entry* (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.5)
  12. [CCD] **SHALL** satisfy: Contains one or more entryRelationship
    - [OCL]: not self.entryRelationship->isEmpty()
  13. [CCD] **CONF-152: 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.
  14. [CCD] **CONF-153: 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.
    - [OCL]:
 

```
self.getEntryRelationshipTargets(vocab:x_ActRelationshipEntryRelationship::SUBJ,
cda::ClinicalStatement)->forall(target : cda::ClinicalStatement | not
target.ocIsUndefined() and
(target.ocIsKindOf(ccd::ProblemObservation) or
target.ocIsKindOf(ccd::AlertObservation)))
```
  15. [CCD] **SHOULD** satisfy: In Problem Section, a Problem Act SHOULD contain a Problem Observation.
    - [OCL]: self.getSection().ocIsKindOf(ccd::ProblemSection) implies
 

```
self.getObservations()
->exists(obs : cda::Observation |
obs.ocIsKindOf(ccd::ProblemObservation))
```
  16. [CCD] **SHOULD** satisfy: In Alert Section, a ProblemAct SHOULD contain an Alert Observation.
    - [OCL]: self.getSection().ocIsKindOf(ccd::AlertsSection) implies
 

```
self.getObservations()
->exists(obs : cda::Observation |
obs.ocIsKindOf(ccd::AlertObservation))
```
  17. [CCD] **MAY** satisfy: Contains exactly one Patient Awareness
    - [OCL]: self.participant->one(partic : cda::Participant2 |
 

```
partic.ocIsKindOf(ccd::PatientAwareness))
```
- ```
<?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"/>
            </act>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

```

<id root="edb7fe76-14d0-4103-a017-4ea0501f3243"/>
<code nullFlavor="NA"/>
<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"/>
    <code/>
    <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="2.16.840.1.113883.10.20.1.41"
assigningAuthorityName="CCD Episode Observation"/>
    <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"
codeSystemName="ActCode"/>
    <statusCode code="completed"/>
    <value xsi:type="CD"/>
  </observation>
</entryRelationship>
</act>
</entry>
</section>
</component>
</structuredBody>
</component>
</ClinicalDocument>

```

Figure 60: Problem Concern Entry example

## Problem Entry

[Observation: templateId 1.3.6.1.4.1.19376.1.5.3.1.4.5]

1. Conforms to [CDA Clinical Statement](#)
2. Conforms to [CDA Observation](#)
3. Conforms to [CCD Problem Observation](#) template (templateId: 2.16.840.1.113883.10.20.1.28)
4. [CCD] Contains [1..1] @classCode = "OBS"
5. [CCD] **SHALL** contain [1..1] @moodCode = "EVN"
6. [CCD] **MAY** contain [1..1] code, which **MAY** be selected from ValueSet 2.16.840.1.113883.1.11.20.14 ProblemTypeCode STATIC 20061017
7. [CCD] **SHALL** contain [1..1] statusCode/@code = "completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus STATIC V3NE08)
8. [CCD] **SHOULD** contain [0..1] effectiveTime
9. [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)

10. [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)

11. [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)

12. [IHE] **SHALL** contain [1..1] text

13. [IHE] **SHALL** contain [1..1] value, where its data type is CD

14. [CCD] **SHALL** satisfy: Contains one or more sources of information.

- [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'))

15. [CCD] **MAY** satisfy: Contains exactly one Patient Awareness

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

```
<?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"/>
              <code/>
              <text/>
              <statusCode code="completed"/>
              <effectiveTime>
                <low value="1972"/>
                <high value="2008"/>
              </effectiveTime>
              <value xsi:type="CD"/>
              <entryRelationship>
                <observation classCode="OBS" moodCode="EVN">
                  <templateId root="2.16.840.1.113883.10.20.1.57"
assigningAuthorityName="CCD Status Observation"/>
                  <templateId root="2.16.840.1.113883.10.20.1.50"
assigningAuthorityName="CCD Problem Status Observation"/>
                  <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Status"/>
                  <statusCode code="completed"/>
                  <value xsi:type="CE"/>
                </observation>
              </entryRelationship>
              <entryRelationship>
                <observation classCode="OBS" moodCode="EVN">
                  <templateId root="2.16.840.1.113883.10.20.1.57"
assigningAuthorityName="CCD Status Observation"/>
                  <templateId root="2.16.840.1.113883.10.20.1.51"
assigningAuthorityName="CCD Problem Health Status Observation"/>
```

```

        <code code="11323-3" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Health status"/>
        <statusCode code="completed"/>
        <value xsi:type="CE"/>
    </observation>
</entryRelationship>
<entryRelationship>
    <observation classCode="OBS" moodCode="EVN">
        <templateId root="2.16.840.1.113883.10.20.1.38"
assigningAuthorityName="CCD Age Observation"/>
        <code code="397659008" codeSystem="2.16.840.1.113883.6.96"
codeSystemName="SNOMEDCT" displayName="Age"/>
        <statusCode code="completed"/>
    </observation>
</entryRelationship>
</observation>
</entry>
</section>
</component>
</structuredBody>
</component>
</ClinicalDocument>

```

Figure 61: Problem Entry example

## Procedure Entry Plan Of Care Activity Procedure

[Procedure: templateId 1.3.6.1.4.1.19376.1.5.3.1.4.19]

1. Conforms to *Procedure Entry*
2. Conforms to *CCD Plan Of Care Activity*
3. Conforms to *CDA Clinical Statement*
4. Conforms to *CDA Procedure*
5. Conforms to *CCD Plan Of Care Activity Procedure* template (templateId: 2.16.840.1.113883.10.20.1.25)
6. [CDA] Contains [1..1] @classCode, where its data type is ActClass
7. [CCD] **SHALL** contain [1..1] @moodCode
8. [CCD] **SHALL** contain [1..\*] id
9. [CCD] **SHALL** satisfy: moodCodeValue
  - [OCL]: self.moodCode = vocab::x\_DocumentProcedureMood::INT or self.moodCode = vocab::x\_DocumentProcedureMood::ARQ or self.moodCode = vocab::x\_DocumentProcedureMood::PRMS or self.moodCode = vocab::x\_DocumentProcedureMood::PRP or self.moodCode = vocab::x\_DocumentProcedureMood::RQO

```

<?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="2.16.840.1.113883.10.20.1.25"/>
                            <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.19"/>
                            <id root="54c219ef-cc85-42e9-8baf-ee74e2763c2f"/>
                        </procedure>
                    </entry>
                </section>
            </component>

```

```

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

```

**Figure 62: Procedure Entry Plan Of Care Activity Procedure example**

## Procedure Entry Procedure Activity Procedure

[Procedure: templateId 1.3.6.1.4.1.19376.1.5.3.1.4.19]

1. Conforms to [Procedure Entry](#)
2. Conforms to [CCD Procedure Activity](#)
3. Conforms to [CDA Clinical Statement](#)
4. Conforms to [CDA Procedure](#)
5. Conforms to [CCD Procedure Activity Procedure](#) template (templateId: 2.16.840.1.113883.10.20.1.29)
6. [CDA] Contains [1..1] @classCode, where its data type is ActClass
7. [CDA] Contains [1..1] @moodCode, where its data type is x\_DocumentProcedureMood
8. [CCD] **SHALL** contain [1..\*] id, where its data type is II
9. [CCD] **SHALL** contain [1..1] statusCode/@code = "completed" (CodeSystem: 2.16.840.1.113883.1.11.20.15 ProcedureStatusCode STATIC 20061017), where its data type is CS
10. [CCD] **SHOULD** contain [0..1] effectiveTime, where its data type is IVL\_TS
11. [CCD] **SHALL** contain [1..1] code, where its data type is CD

```

<?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"/>
              <statusCode code="completed"/>
            </procedure>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>

```

**Figure 63: Procedure Entry Procedure Activity Procedure example**

## Simple Observation

[Observation: templateId 1.3.6.1.4.1.19376.1.5.3.1.4.13]

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

1. Conforms to [CDA Clinical Statement](#)
2. Conforms to [CDA Observation](#)
3. [CDA] Contains [1..1] @classCode, where its data type is ActClassObservation
4. [CDA] Contains [1..1] @moodCode, where its data type is x\_ActMoodDocumentObservation
5. [CDA] Contains [1..1] code, where its data type is CD

6. [IHE] **SHALL** contain [1..\*] id
7. [IHE] **SHALL** contain [1..1] statusCode/@code = "completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus STATIC V3NE08)

**Figure 64: Simple Observation example**

## Split Dose

[SubstanceAdministration: templateId 1.3.6.1.4.1.19376.1.5.3.1.4.9]

1. Conforms to *CDA Clinical Statement*
2. Conforms to *CDA Substance Administration*
3. Conforms to *CCD Medication Activity* template (templateId: 2.16.840.1.113883.10.20.1.24)
4. Conforms to *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] **CONF-306: SHALL** contain [1..\*] id
9. [CCD] **CONF-307: SHOULD** contain [1..1] statusCode
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] **CONF-330, CONF-333: 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)
13. [CCD] **CONF-308: SHOULD** contain [1..\*] effectiveTime
  - Used to indicate the actual or intended start and stop date of a medication, and the frequency of administration.
14. [CCD] **CONF-312: MAY** contain [0..1] maxDoseQuantity
15. [IHE] **SHOULD** contain [1..1] routeCode
  - The route is a coded value, and indicates how the medication is received by the patient (by mouth, intravenously, topically, et cetera).
16. [CCD] **CONF-313: MAY** contain [0..1] performer, such that it
  - a. contains *CDA Performer2*
  - Indicates the person administering a substance.
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] **CONF-305: SHALL** satisfy: Value for moodCode is "EVN" or "INT" 2.16.840.1.113883.5.1001 ActMood STATIC
  - [OCL]: self.moodCode=vocab::x\_DocumentSubstanceMood::EVN or self.moodCode=vocab::x\_DocumentSubstanceMood::INT



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

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

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

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

23. [CCD] **CONF-315: SHALL** satisfy: Contains one or more sources of information.

- [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] **CONF-327: 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.

- 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.ocIsUndefined())

25. [CCD] **CONF-328: 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.

- 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] **CONF-329: SHALL** satisfy: entryRelationship / @typeCode="RSON" in a medication activity has a target of problem act, problem observation, or some other clinical statement.

- [OCL]: self.getEntryRelationshipTargets(vocab::x\_ActRelationshipEntryRelationship::RSON, cda::ClinicalStatement)->forall(target : cda::ClinicalStatement | not target.ocIsUndefined() and (target.ocIsKindOf(ccd::ProblemAct) or target.ocIsKindOf(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.ocIsUndefined() or not self.consumable.manufacturedProduct.manufacturedMaterial.name.ocIsUndefined()

```
<?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="1.3.6.1.4.1.19376.1.5.3.1.4.9"
assigningAuthorityName="IHE Split Dose"/>
            <id root="f40eb716-2e17-484f-8d50-4da63fbe8150"/>
            <statusCode/>
            <effectiveTime/>
            <routeCode codeSystem="2.16.840.1.113883.5.112"
codeSystemName="HL7 RouteOfAdministration"/>
            <approachSiteCode/>
            <doseQuantity/>
            <rateQuantity/>
            <maxDoseQuantity/>
            <entryRelationship>
              <observation classCode="OBS" moodCode="EVN">
                <templateId root="2.16.840.1.113883.10.20.1.46"
assigningAuthorityName="CCD Medication Series Number Observation"/>
                <code code="30973-2" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Dose number"/>
                <statusCode/>
                <value xsi:type="INT"/>
              </observation>
            </entryRelationship>
            <entryRelationship>
              <observation classCode="OBS" moodCode="EVN">
                <templateId root="2.16.840.1.113883.10.20.1.57"
assigningAuthorityName="CCD Status Observation"/>
                <templateId root="2.16.840.1.113883.10.20.1.47"
assigningAuthorityName="CCD Medication Status Observation"/>
                <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Status"/>
                <statusCode code="completed"/>
                <value xsi:type="CE"/>
              </observation>
            </entryRelationship>
          </substanceAdministration>
        </entry>
      </section>
    </component>
  </structuredBody>
</component>
</ClinicalDocument>

```

Figure 65: Split Dose example

## Supply Entry

[Supply: templateId 1.3.6.1.4.1.19376.1.5.3.1.4.7.3]

1. Conforms to [CDA Clinical Statement](#)
2. Conforms to [CDA Supply](#)
3. Conforms to [CCD Supply Activity](#) template (templateId: 2.16.840.1.113883.10.20.1.34)
4. [CDA] Contains [1..1] @classCode = "SPLY", where its data type is ActClassSupply
5. [CDA] Contains [1..1] @moodCode, where its data type is x\_DocumentSubstanceMood
6. [CCD] **CONF-318: SHALL** contain [1..\*] id
7. [CCD] **CONF-319: SHOULD** contain [1..1] statusCode
8. [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)
- 9. [CCD] **MAY** contain [0..\*] entryRelationship, such that it
  - a. has @typeCode="SUBJ" *SUBJ (has subject)*
  - b. contains *CCD Fulfillment Instruction* (templateId: 2.16.840.1.113883.10.20.1.43)
- 10. [CCD] **CONF-320: SHOULD** contain [1..1] effectiveTime
  - Indicates the actual or intended time of dispensing.
- 11. [CCD] **CONF-322: MAY** contain [0..1] quantity
  - Indicates the actual or intended supply quantity.
- 12. [CCD] **CONF-321: MAY** contain [0..1] repeatNumber
  - Indicates the number of fills. (Note that repeatNumber corresponds to the number of "fills", as opposed to the number of "refills").
- 13. [CCD] **CONF-317: SHALL** satisfy: Value for moodCode is 'EVN' or 'INT' 2.16.840.1.113883.5.1001 ActMood STATIC
  - [OCL]: self.moodCode=vocab::x\_DocumentSubstanceMood::EVN or self.moodCode=vocab::x\_DocumentSubstanceMood::INT
- 14. [CCD] **CONF-323: MAY** satisfy: Contains one or more author.
  - Indicates the prescriber.
  - [OCL]: not self.author->isEmpty()
- 15. [CCD] **CONF-324: MAY** satisfy: Contains one or more performer.
  - Indicates the person dispensing the product.
  - [OCL]: not self.performer->isEmpty()
- 16. [CCD] **CONF-325: MAY** satisfy: Contains exactly one participant / @typeCode = "LOC".
  - Indicates the supply location.
  - [OCL]: self.participant->one(part : cda::Participant2 | part.typeCode = vocab::ParticipationType::LOC)
- 17. [CCD] **CONF-326: SHALL** satisfy: Contains one or more sources of information.
  - [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 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>
            <supply classCode="SPLY">
              <templateId root="2.16.840.1.113883.10.20.1.34"
assigningAuthorityName="CCD Supply Activity"/>
              <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.7.3"
assigningAuthorityName="IHE Supply Entry"/>
              <id root="3ce29ead-ccf9-4240-9b77-f2ca5de4227b"/>
              <statusCode/>
              <effectiveTime/>
              <repeatNumber/>

```

```

        <quantity/>
      </supply>
    </entry>
  </section>
</component>
</structuredBody>
</component>
</ClinicalDocument>

```

**Figure 66: Supply Entry example**

## Tapered Dose

[SubstanceAdministration: templateId 1.3.6.1.4.1.19376.1.5.3.1.4.8]

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

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

1. Conforms to [CDA Clinical Statement](#)
2. Conforms to [CDA Substance Administration](#)
3. Conforms to [CCD Medication Activity](#) template (templateId: 2.16.840.1.113883.10.20.1.24)
4. Conforms to [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] **CONF-306: SHALL** contain [1..\*] id
9. [CCD] **CONF-307: SHOULD** contain [1..1] statusCode
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] **CONF-330, CONF-333: 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)
13. [CCD] **CONF-308: SHOULD** contain [1..\*] effectiveTime
  - Used to indicate the actual or intended start and stop date of a medication, and the frequency of administration.
14. [CCD] **CONF-312: MAY** contain [0..1] maxDoseQuantity
15. [IHE] **SHOULD** contain [1..1] routeCode
  - The route is a coded value, and indicates how the medication is received by the patient (by mouth, intravenously, topically, et cetera).
16. [CCD] **CONF-313: MAY** contain [0..1] performer, such that it
  - a. contains [CDA Performer2](#)
  - Indicates the person administering a substance.
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] CONF-305: SHALL** satisfy: Value for moodCode is "EVN" or "INT" 2.16.840.1.113883.5.1001 ActMood STATIC

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

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

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

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

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

**23. [CCD] CONF-315: SHALL** satisfy: Contains one or more sources of information.

- [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] CONF-327: 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.

- 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.ocIsUndefined())`

**25. [CCD] CONF-328: 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.

- 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] CONF-329: SHALL** satisfy: entryRelationship / @typeCode="RSON" in a medication activity has a target of problem act, problem observation, or some other clinical statement.

- [OCL]: `self.getEntryRelationshipTargets(vocab::x_ActRelationshipEntryRelationship::RSON, cda::ClinicalStatement)->forall(target : cda::ClinicalStatement | not target.ocIsUndefined() and (target.ocIsKindOf(ccd::ProblemAct) or target.ocIsKindOf(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.ocIsUndefined()`  
or not  
`self.consumable.manufacturedProduct.manufacturedMaterial.name.ocIsUndefined()`

```
<?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="1.3.6.1.4.1.19376.1.5.3.1.4.8"
assigningAuthorityName="IHE Tapered Dose"/>
              <id root="fbd87378-bd53-466e-9d1e-4e8ba7f3a59f"/>
              <statusCode/>
              <effectiveTime/>
              <routeCode codeSystem="2.16.840.1.113883.5.112"
codeSystemName="HL7 RouteOfAdministration"/>
              <approachSiteCode/>
              <doseQuantity/>
              <rateQuantity/>
              <maxDoseQuantity/>
              <entryRelationship>
                <observation classCode="OBS" moodCode="EVN">
                  <templateId root="2.16.840.1.113883.10.20.1.46"
assigningAuthorityName="CCD Medication Series Number Observation"/>
                  <code code="30973-2" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Dose number"/>
                  <statusCode/>
                  <value xsi:type="INT"/>
                </observation>
              </entryRelationship>
              <entryRelationship>
                <observation classCode="OBS" moodCode="EVN">
                  <templateId root="2.16.840.1.113883.10.20.1.57"
assigningAuthorityName="CCD Status Observation"/>
                  <templateId root="2.16.840.1.113883.10.20.1.47"
assigningAuthorityName="CCD Medication Status Observation"/>
                  <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Status"/>
                  <statusCode code="completed"/>
                  <value xsi:type="CE"/>
                </observation>
              </entryRelationship>
            </substanceAdministration>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

**Figure 67: Tapered Dose example**

## Vital Sign Observation

[Observation: templateId 1.3.6.1.4.1.19376.1.5.3.1.4.13.2]

1. Conforms to [Simple Observation](#) template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.13)
2. Conforms to [CDA Clinical Statement](#)
3. Conforms to [CDA Observation](#)
4. Conforms 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"
7. [CCD] **SHALL** contain [1..\*] id
8. [IHE] Contains [1..1] statusCode
  - The observations have all been completed.
9. [IHE] **SHALL** contain [1..1] code (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC 2.26)
10. [CCD] **SHOULD** contain [1..1] effectiveTime
  - Represents the biologically relevant time (e.g. time the specimen was obtained from the patient).
11. [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.
12. [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).
13. [IHE] **SHALL** contain [1..1] value, where its data type is PQ
14. [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).
15. [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).
16. [CCD] **SHALL** satisfy: The methodCode SHALL NOT conflict with the method inherent in code
17. [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.
18. [CCD] **SHOULD** satisfy: Contain one or more referenceRange to show the normal range of values for the observation result
  - [OCL]: not self.referenceRange->isEmpty()
19. [CCD] **SHALL** satisfy: SHALL NOT contain referenceRange / observationRange / code, as this attribute is not used by the HL7 Clinical Statement or Lab Committee models.
  - [OCL]: self.referenceRange->forall(range : cda::ReferenceRange | range.observationRange.code.code.ocIsUndefined())
20. [CCD] **SHALL** satisfy: Contains one or more sources of information.
  - [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 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"/>
            <id root="ba43e8d8-63e4-430e-b5f2-e9c873737bcb"/>
            <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 68: Vital Sign Observation example

## Vital Signs Organizer

[Organizer: templateId 1.3.6.1.4.1.19376.1.5.3.1.4.13.1]

1. Conforms to [CDA Clinical Statement](#)
2. Conforms to [CDA Organizer](#)
3. Conforms to [CCD Result Organizer](#) template (templateId: 2.16.840.1.113883.10.20.1.32)
4. Conforms to [CCD Vital Signs Organizer](#) template (templateId: 2.16.840.1.113883.10.20.1.35)
5. [IHE] **SHALL** contain [1..1] @classCode = "CLUSTER"
6. [CCD] **SHALL** contain [1..1] @moodCode = "EVN"
7. [IHE] **SHALL** contain [1..1] statusCode/@code = "completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus STATIC V3NE08)
  - The observations have all been completed.
8. [CCD] **SHALL** contain [1..\*] component, such that it
  - a. contains [CCD Result Observation](#) (templateId: 2.16.840.1.113883.10.20.1.31)
9. [CCD] **SHOULD** contain [1..\*] specimen, such that it
  - a. contains [CDA Specimen](#)
10. [CCD] **SHALL** contain [1..\*] id
11. [IHE] **SHALL** contain [1..1] code/@code = "46680005" *Vital signs* (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT STATIC 20080731)
12. [IHE] **SHALL** contain [1..1] effectiveTime
  - The effective time element shall be present to indicate when the measurement was taken.
13. [IHE] **SHALL** contain [1..\*] component, such that it



- a. contains *Vital Sign Observation* (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.13.2)
14. [IHE] **SHALL** contain [1..1] author, such that it
- a. contains *CDA Author*
15. [CCD] **SHOULD** satisfy: The value for 'code' in a result organizer **SHOULD** be selected from LOINC (codeSystem 2.16.840.1.113883.6.1) or SNOMED CT (codeSystem 2.16.840.1.113883.6.96), and **MAY** be selected from CPT-4 (codeSystem 2.16.840.1.113883.6.12) or ValueSet 2.16.840.1.113883.1.11.20.16 ResultTypeCode STATIC.
16. [CCD] **SHOULD** satisfy: Contains one or more Specimen if the specimen isn't inherent in code value.
17. [CCD] **SHALL** satisfy: The specimen element **SHALL NOT** conflict with the specimen inherent in code
18. [CCD] **SHALL** satisfy: Contains one or more component
- [OCL]: not self.component->isEmpty()
19. [CCD] **MAY** satisfy: The target of one or more result organizer component relationships **MAY** be a procedure, to indicate the means or technique by which a result is obtained, particularly if the means or technique isn't inherent in code or if there is a need to further specialize the code value.
20. [CCD] **MAY** satisfy: A result organizer component / procedure **MAY** be a reference to a procedure described in the Procedure section.
21. [CCD] **SHALL** satisfy: Contains one or more sources of information.
- [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)
22. [CCD] **SHALL** satisfy: Contains one or more sources of information.
- [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)
- ```
<?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>
            <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="04dd843a-5e79-40a7-bf1a-591b402f391d"/>
              <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>
            </component>
            <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"/>
            </observation>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

```

        <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.13.2"
assigningAuthorityName="IHE Vital Sign Observation"/>
        <id root="c72c59f2-bf2c-4355-9eae-8ab841d44cf8"/>
        <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>
</component>
<component>
    <observation classCode="OBS" moodCode="EVN">
        <templateId root="2.16.840.1.113883.10.20.1.31"
assigningAuthorityName="CCD Result Observation"/>
        <id root="0fdf217c-55b7-4a99-af07-e6fe9a13db8c"/>
        <code/>
        <statusCode/>
        <effectiveTime>
            <low value="1972"/>
            <high value="2008"/>
        </effectiveTime>
        <interpretationCode/>
        <methodCode/>
    </observation>
</component>
</organizer>
</entry>
</section>
</component>
</structuredBody>
</component>
</ClinicalDocument>

```

**Figure 69: Vital Signs Organizer example**

---

# Chapter

# 5

---

## OTHER CLASSES

---

### Topics:

- [\*Healthcare Providers\*](#)
- [\*Pharmacies\*](#)
- [\*Language Communication\*](#)
- [\*Patient Contact\*](#)
- [\*Patient Contact Guardian\*](#)
- [\*Patient Contact Participant\*](#)
- [\*Procedure Entry\*](#)
- [\*Product Entry\*](#)
- [\*Scan Data Enterer\*](#)
- [\*Scan Original Author\*](#)
- [\*Scanning Device\*](#)

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

## Healthcare Providers Pharmacies

---

[Performer1: templateId 1.3.6.1.4.1.19376.1.5.3.1.2.3]

1. Conforms to [CDA Performer1](#)
2. [CDA] Contains [1..1] @typeCode, where its data type is x\_ServiceEventPerformer
3. [CDA] Contains [1..1] assignedEntity, where its type is [CDA Assigned Entity](#)

**Figure 70: Healthcare Providers Pharmacies example**

## Language Communication

---

[LanguageCommunication: templateId 1.3.6.1.4.1.19376.1.5.3.1.2.1]

1. Conforms to [CDA Language Communication](#)
- 2.

**Figure 71: Language Communication example**

## Patient Contact

---

1. Conforms to [CCD Support](#)
- 2.

**Figure 72: Patient Contact example**

## Patient Contact Guardian

---

[Guardian: templateId 1.3.6.1.4.1.19376.1.5.3.1.2.4]

1. Conforms to [Patient Contact](#)
2. Conforms to [CCD Support](#)
3. Conforms to [CDA Guardian](#)
4. Conforms to [CCD Support Guardian](#)
5. [IHE] **SHALL** contain [1..1] @classCode = "GUAR"
6. [IHE] **SHOULD** contain [0..\*] addr
7. [IHE] **SHALL** contain [0..1] code (CodeSystem: 2.16.840.1.113883.5.111 RoleCode STATIC)
8. [IHE] **SHOULD** contain [0..\*] telecom
9. [CDA] **SHALL** satisfy: guardianChoice
  - [OCL]: self.guardianPerson.ocIsUndefined() xor self.guardianOrganization.ocIsUndefined()

**Figure 73: Patient Contact Guardian example**

## Patient Contact Participant

---

[Participant1: templateId 1.3.6.1.4.1.19376.1.5.3.1.2.4]

1. Conforms to *Patient Contact*
2. Conforms to *CCD Support*
3. Conforms to *CDA Participant1*
4. Conforms to *CCD Support Participant*
5. [IHE] **SHALL** contain [1..1] @typeCode = "IND"
6. [CDA] Contains [1..1] associatedEntity, where its type is *CDA Associated Entity*
7. [IHE] **MAY** contain [0..1] time
  - Indicates the time of the participation.

**Figure 74: Patient Contact Participant example**

## Procedure Entry

---

- 1.

**Figure 75: Procedure Entry example**

## Product Entry

---

[ManufacturedProduct: templateId 1.3.6.1.4.1.19376.1.5.3.1.4.7.2]

1. Conforms to *CDA Manufactured Product*
2. Conforms to *CCD Product* template (templateId: 2.16.840.1.113883.10.20.1.53)
3. [CDA] **SHALL** satisfy: manufacturedDrugOrOtherMaterial
  - [OCL]: self.manufacturedLabeledDrug.ocIsUndefined() xor self.manufacturedMaterial.ocIsUndefined()

**Figure 76: Product Entry example**

## Scan Data Enterer

---

[DataEnterer: templateId 1.3.6.1.4.1.19376.1.2.20.3]

Represents the scanner operator who produced the scanned content.

1. Conforms to *CDA Data Enterer*
2. [CDA] Contains [1..1] assignedEntity, where its type is *CDA Assigned Entity*
3. [IHE] **SHALL** contain [1..1] time
  - Denotes the time at which the original content was scanned.
4. [IHE] **SHALL** satisfy: The time shall be equal to that of ClinicalDocument/effectiveTime. At a minimum, the time shall be precise to the day and shall include the time zone offset from GMT.
  - [OCL]: self.time.value = self.getClinicalDocument().effectiveTime.value
5. [IHE] **SHALL** satisfy: The assignedEntity/id element has both the root and the extension attributes. The root shall be the oid of the scanning facility and the extension shall be an appropriately assigned, facility unique id of the operator.
  - [OCL]: self.assignedEntity.id->forAll(ident : datatypes::II | not ident.root.ocIsUndefined() and not ident.extension.ocIsUndefined())

**Figure 77: Scan Data Enterer example**

## Scan Original Author

---

[Author: templateId 1.3.6.1.4.1.19376.1.2.20.1]

Represents the author of the original content. It additionally can encode the original author's institution in the subelement `representedOrganization`. Information regarding the original author and his/her institution shall be included, if it is known. In many cases this will have to be supplied by the operator.

1. Conforms to [CDA Author](#)
2. [IHE] Contains [1..1] `time`
  - Represents the day and time of the authoring of the original content. This value is not restricted beyond statements made in the HL7 CDA R2 documentation.
3. [CDA] Contains [1..1] `assignedAuthor`, where its type is [CDA Assigned Author](#)
4. [IHE] **SHOULD** satisfy: The `assignedAuthor/id` element if known shall include both the root and the extension attributes. Refer to PCC TF-2: 4.1.1 for more details.
 

```
[OCL]: self.assignedAuthor.id->forAll(ident : datatypes::II |
  not ident.root.ocIsUndefined() and not
  ident.extension.ocIsUndefined())
```
5. [IHE] **SHOULD** satisfy: The `assignedAuthor/representedOrganization/id` element if known shall include both the root and the extension attributes. Refer to PCC TF-2: 4.1.1 for more details.
 

```
[OCL]: self.assignedAuthor.representedOrganization.id->forAll(ident :
  datatypes::II |
  not ident.root.ocIsUndefined() and not
  ident.extension.ocIsUndefined())
```

**Figure 78: Scan Original Author example**

## Scanning Device

---

[Author: templateId 1.3.6.1.4.1.19376.1.2.20.2]

Represents the scanning device and software used to produce the scanned content.

1. Conforms to [CDA Author](#)
2. [IHE] Contains [1..1] `time`
  - Denotes the time at which the original content was scanned.
3. [CDA] Contains [1..1] `assignedAuthor`, where its type is [CDA Assigned Author](#)
4. [IHE] **SHALL** satisfy: The time shall be equal to that of `ClinicalDocument/effectiveTime`. At a minimum, the time shall be precise to the day and shall include the time zone offset from GMT.
 

```
[OCL]: self.time.value = self.getClinicalDocument().effectiveTime.value
```
5. [IHE] **SHALL** satisfy: The `assignedAuthor/id` element shall be at least the root oid of the scanning device.
 

```
[OCL]: self.assignedAuthor.id->forAll(ident : datatypes::II | not
  ident.root.ocIsUndefined())
```
6. [IHE] **SHALL** satisfy: The `assignedAuthor/assignedAuthoringDevice/code` element is present. The values set here are taken from appropriate DICOM vocabulary. The value of `code@codeSystem` shall be set to "1.2.840.10008.2.16.4". The value of `code@code` shall be set to "CAPTURE" for PDF scanned content and "WSD" for plaintext. The value of `code@displayName` shall be set to "Image Capture" for PDF scanned content and "Workstation" for plaintext.
 

```
[OCL]: self.assignedAuthor.assignedAuthoringDevice.code.codeSystem =
  '1.2.840.10008.2.16.4'
  and not
  self.assignedAuthor.assignedAuthoringDevice.code.code.ocIsUndefined()
```

- ```

        and not
        self.assignedAuthor.assignedAuthoringDevice.code.displayName.ocIsUndefined()

```
7. [IHE] **SHALL** satisfy: The assignedAuthor/assignedAuthoringDevice/manufactureModelName element is present.
    - The mixed content shall contain string information that specifies the scanner product name and model number. From this information, features like bit depth and resolution can be inferred. In the case of virtually scanned documents (for example, print to PDF), the manufactureModelName referenced here refers to the makers of the technology that was used to produce the embedded content.
    - [OCL]: not
 

```

            self.assignedAuthor.assignedAuthoringDevice.manufacturerModelName.ocIsUndefined()
          
```
  8. [IHE] **SHALL** satisfy: The assignedAuthor/assignedAuthoringDevice/softwareName element is present.
    - The mixed content shall contain string information that specifies the scanning software name and version. In the case of virtually scanned documents, the softwareName referenced here refers to the technology that was used to produce the embedded content.
    - [OCL]: not
 

```

            self.assignedAuthor.assignedAuthoringDevice.softwareName.ocIsUndefined()
          
```
  9. [IHE] **SHALL** satisfy: The assignedAuthor/representedOrganization/id element is present. The root attribute shall be set to the oid of the scanning facility.
    - [OCL]:
 

```

            self.assignedAuthor.representedOrganization.id->forAll(ident :
            datatypes::II | not ident.root.ocIsUndefined())
          
```

**Figure 79: Scanning Device 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](http://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](#)

