

# Implementation Guide for CDA Release 2

## ToC Reference Implementation (RI)

### Document Type Specification



**PROTOTYPE: FOR DISCUSSION  
AND DEMONSTRATION USE ONLY  
(Consolidated Developer Documentation)**



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# Acknowledgments

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

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# Revision History

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Rev	Date	By Whom	Changes
New	August 26, 2011	Dave Carlson	





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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 data specifications have been formalized into computational models expressed in UML. These models are used by automated tooling to generate this publication, plus validation tools and Java libraries for implementers.

## Approach

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Working with specifications generated from formal UML models 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:hl7-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:

- [\*Consultation Request\*](#)
- [\*Consultation Summary\*](#)
- [\*Discharge Instructions\*](#)
- [\*Discharge Summary\*](#)

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

## Consultation Request

---

[ClinicalDocument: templateId 1.2.3.4.5.103]

1. **SHALL** conform to *CDT General Header Constraints* template (templateId: 2.16.840.1.113883.10.20.3)
2. **SHALL** contain exactly one [1..1] **realmCode/@code**="US" (CONF-HP-15)
3. **SHALL** contain exactly one [1..1] **typeId** (CONF-HP-16)
  - The clinical document type ID identifies the constraints imposed by CDA R2 on the content, essentially acting as a version identifier.
4. **SHALL** contain exactly one [1..1] **id** (CONF-HP-17)
  - The ClinicalDocument/id element is an instance identifier data type (see HL7 Version 3 Abstract Data in Section 5 REFERENCES). The root attribute is a UUID or OID. The root uniquely identifies the scope of the extension. The root and extension attributes uniquely identify the document.
5. **SHALL** contain exactly one [1..1] **code** (CONF-HP-21)
  - Specifies the type of the clinical document.
6. **SHALL** contain exactly one [1..1] **title** (CONF-HP-22)
  - Specifies the local name used for the document. Note that the title does not need to be the same as the display name provided with the document type code. For example, the display name provided by LOINC® as an aid in debugging may be "HISTORY AND PHYSICAL." The title can be localized, as appropriate.
7. **SHALL** contain exactly one [1..1] **effectiveTime** (CONF-HP-23)
  - Specifies the creation time of the document. All documents authored by direct input to a computer system should record an effectiveTime that is precise to the second. When authored in other ways, for example, by filling out a paper form that is then transferred into an EHR system, the precision of effectiveTime may be less than to the second.
8. Contains exactly one [1..1] **confidentialityCode**
  - Specifies the confidentiality assigned to the document. This specification provides no further guidance beyond CDA R2 on documents with respect to the vocabulary used for confidentialityCode, nor treatment or implementation of confidentiality.
9. **SHALL** contain exactly one [1..1] **languageCode** (CONF-HP-24)
10. Contains at least one [1..\*] **recordTarget**, where its type is *Record Target*
11. Contains at least one [1..\*] **author**, where its type is *Author*
12. Contains exactly one [1..1] **custodian**, where its type is *Custodian*
13. Contains exactly one [1..1] **component**, where its type is *Component2*
14. Contains at least one [1..\*] **author**, such that
  - The author element represents the creator of the clinical document. If the role of the actor is the entry of information from his or her own knowledge or application of skills, that actor is the author. If one actor provides information to another actor who filters, reasons, or algorithmically creates new information, then that second actor is also an author, having created information from his or her own knowledge or skills. However, that determination is independent from the determination of the first actor's authorship.
15. Contains zero or one [0..1] **dataEnterer**, such that
  - The dataEnterer element represents the person who transferred the information from other sources into the clinical document, where the other sources wrote the content of the note. The guiding rule of thumb is that an author provides the content found within the header or body of the document, subject to their own interpretation. The dataEnterer adds information to the electronic system. A person can participate as both author and dataEnterer.  
  
If the role of the actor is to transfer information from one source to another (e.g., transcription or transfer from paper form to electronic system), that actor is considered a dataEnterer.
16. Contains exactly one [1..1] **custodian**, such that

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

**17. Contains zero or more [0..\*] `informationRecipient`, such that**

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

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

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

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

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

**19. Contains zero or more [0..\*] `authenticator`, such that**

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

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

**20. SHALL contain exactly one [1..1] `component`, such that**

- a. Contains exactly one [1..1] [HITSP Allergies Reactions Section](#) (templateId: 2.16.840.1.113883.3.88.11.83.102)

**21. SHALL contain exactly one [1..1] `component`, such that**

- a. Contains exactly one [1..1] [HITSP Medications Section](#) (templateId: 2.16.840.1.113883.3.88.11.83.112)

**22. SHALL contain exactly one [1..1] `component`, such that**

- a. Contains exactly one [1..1] [HITSP Problem List Section](#) (templateId: 2.16.840.1.113883.3.88.11.83.103)

**23. SHALL contain exactly one [1..1] `component`, such that**

- a. Contains exactly one [1..1] [HITSP Surgeries Section](#) (templateId: 2.16.840.1.113883.3.88.11.83.108)

**24. SHALL contain exactly one [1..1] `component`, such that**

- a. Contains exactly one [1..1] [HITSP Diagnostic Results Section](#) (templateId: 2.16.840.1.113883.3.88.11.83.122)

**25. SHALL contain exactly one [1..1] `component`, such that**

- a. Contains exactly one [1..1] [HITSP Advance Directives Section](#) (templateId: 2.16.840.1.113883.3.88.11.83.116)

**26. SHOULD contain zero or one [0..1] `component`, such that**

- a. Contains exactly one [1..1] [HITSP Assessment And Plan Section](#) (templateId: 2.16.840.1.113883.3.88.11.83.123)

**27. SHOULD contain zero or one [0..1] `component`, such that**

- a. Contains exactly one [1..1] [HITSP History Of Present Illness](#) (templateId: 2.16.840.1.113883.3.88.11.83.107)

**28. SHOULD contain zero or one [0..1] `component`, such that**

- a. Contains exactly one [1..1] *HITSP Physical Exam Section* (templateId: 2.16.840.1.113883.3.88.11.83.118)
- 29. **SHOULD** contain zero or one [0..1] **component**, such that
  - a. Contains exactly one [1..1] *HITSP Reason For Referral Section* (templateId: 2.16.840.1.113883.3.88.11.83.106)
- 30. **SHOULD** contain zero or one [0..1] **component**, such that
  - a. Contains exactly one [1..1] *HITSP Encounters Section* (templateId: 2.16.840.1.113883.3.88.11.83.127)
- 31. **SHOULD** contain zero or one [0..1] **component**, such that
  - a. Contains exactly one [1..1] *HITSP Family History Section* (templateId: 2.16.840.1.113883.3.88.11.83.125)
- 32. **SHOULD** contain zero or one [0..1] **component**, such that
  - a. Contains exactly one [1..1] *HITSP Functional Status Section* (templateId: 2.16.840.1.113883.3.88.11.83.109)
- 33. **SHOULD** contain zero or one [0..1] **component**, such that
  - a. Contains exactly one [1..1] *HITSP Immunizations Section* (templateId: 2.16.840.1.113883.3.88.11.83.117)
- 34. **SHOULD** contain zero or one [0..1] **component**, such that
  - a. Contains exactly one [1..1] *HITSP Medical Equipment Section* (templateId: 2.16.840.1.113883.3.88.11.83.128)
- 35. **SHOULD** contain zero or one [0..1] **component**, such that
  - a. Contains exactly one [1..1] *HITSP Plan Of Care Section* (templateId: 2.16.840.1.113883.3.88.11.83.124)
- 36. **SHOULD** contain zero or one [0..1] **component**, such that
  - a. Contains exactly one [1..1] *HITSP Social History Section* (templateId: 2.16.840.1.113883.3.88.11.83.126)
- 37. **SHOULD** contain zero or one [0..1] **component**, such that
  - a. Contains exactly one [1..1] *HITSP Vital Signs Section* (templateId: 2.16.840.1.113883.3.88.11.83.119)
- 38. **SHOULD** contain zero or one [0..1] **component**, such that
  - a. Contains exactly one [1..1] *HITSP Chief Complaint Section* (templateId: 2.16.840.1.113883.3.88.11.83.105)
- 39. **SHOULD** contain zero or one [0..1] **component**, such that
  - a. Contains exactly one [1..1] *CDT General Status Section* (templateId: 2.16.840.1.113883.10.20.2.5)
- 40. **SHOULD** contain zero or one [0..1] **component**, such that
  - a. Contains exactly one [1..1] *HITSP History Of Past Illness Section* (templateId: 2.16.840.1.113883.3.88.11.83.104)
- 41. **SHOULD** contain zero or one [0..1] **component**, such that
  - a. Contains exactly one [1..1] *HITSP Payers Section* (templateId: 2.16.840.1.113883.3.88.11.83.101)
- 42. **SHALL** satisfy: All patient, guardianPerson, assignedPerson, maintainingPerson, relatedPerson, intendedRecipient/informationRecipient, associatedPerson, and relatedSubject/subject elements have a name. (CONF-HP-6)
  - [OCL]: -- implemented in Java using XPath selector
  - [XPath]: \*[self::cda:patient or self::cda:guardianPerson or self::cda:assignedPerson or self::cda:maintainingPerson or self::cda:relatedPerson or self::cda:associatedPerson]



```
or self::cda:intendedRecipient/cda:informationRecipient or
self::cda:relatedSubject/cda:subject]
```

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

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

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

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

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

- When name, address, or telecom information is unknown and where these elements are required to be present, as with CDA conformance if the information is unknown, these elements will be represented using an appropriate value for the nullFlavor attribute on the element. Legal values according to this specification come from the HL7 NullFlavor vocabulary.
- [OCL]: -- implemented in Java using XPath selector
- [XPath]: \*[self::cda:guardianOrganization or self::cda:providerOrganization or self::cda:wholeOrganization or self::cda:representedOrganization or self::cda:representedCustodianOrganization or self::cda:receivedOrganization or self::cda:scopingOrganization or self::cda:serviceProviderOrganization]

**46.** Times or time intervals found in the ClinicalDocument/effectiveTime, author/time, dataEnterer/time, legalAuthenticator/time, authenticator/time and encompassingEncounter/effectiveTime elements **SHALL** be precise to the day, **SHALL** include a time zone if more precise than to the day, and **SHOULD** be precise to the second. (CONF-HP-10)

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

**47.** Times or time intervals found in the asOrganizationPartOf/effectiveTime, asMaintainedEntity/effectiveTime, relatedEntity/effectiveTime, serviceEvent/effectiveTime, ClinicalDocument/participant/time, serviceEvent/performer/time and encounterParticipant/time **SHALL** be precise at least to the year, **SHOULD** be precise to the day, and **MAY** omit time zone. (CONF-HP-11)

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

```

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

```

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

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

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

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

• [XPath]: `//*[self::cda:telecom]`

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

- There is no way to distinguish between an unknown phone number and an unknown e-mail or other telecommunications address. Therefore, the following convention will be used: Any telecom element that uses a flavor of null (has a nullFlavor attribute) is assumed to be a telephone number, which is the only required telecommunications address element within this DSTU.

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

• [XPath]: `//*[self::cda:telecom]`

**51. SHALL** satisfy: The extension attribute of the typeId element is POCD\_HD000040. (CONF-HP-16)

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

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

**53. 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]. (CONF-HP-18)

**54. OIDs** are represented in dotted decimal notation, where each decimal number is either 0, or starts with a nonzero digit. More formally, an OID **SHALL** be in the form ([0-2])(.[1-9][0-9]\*[0])+. (CONF-HP-19)

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

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

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

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

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

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

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

**58.** The CC portion languageCode, if present, **SHALL** be an ISO-3166 country code in uppercase. (CONF-HP-27)

**59.** Both setId and versionNumber **SHALL** be present or both **SHALL** be absent. (CONF-HP-28)

- The ClinicalDocument/setId element uses the instance identifier (II) data type. The root attribute is a UUID or OID that uniquely identifies the scope of the identifier, and the extension attribute is a value that is unique within the scope of the root for the set of versions of the document. See Document Identification, Revisions, and Addenda in Section 4.2.3.1 of the CDA Specification for some examples showing the use of the setId element.
- [OCL]: `(self.setId.ocIsUndefined() and self.versionNumber.ocIsUndefined()) xor (not self.setId.ocIsUndefined() and not self.versionNumber.ocIsUndefined())`

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

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

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

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

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

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

**63.** A patient/birthTime element **SHALL** be present. The patient/birthTime element **SHALL** be precise at least to the year, and **SHOULD** be precise at least to the day, and **MAY** omit time zone. If unknown, it **SHALL** be represented using a flavor of null. (CONF-HP-32)

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

**64.** A patient/administrativeGenderCode element **SHALL** be present. If unknown, it **SHALL** be represented using a flavor of null. Values for administrativeGenderCode **SHOULD** be drawn from the HL7 AdministrativeGender vocabulary. (CONF-HP-33)

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

**65.** The maritalStatusCode, religiousAffiliationCode, raceCode and ethnicGroupCode **MAY** be present. If maritalStatusCode, religiousAffiliationCode, raceCode and ethnicGroupCode elements are present, they **SHOULD** be encoded using the appropriate HL7 vocabularies. (CONF-HP-34)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The relationship between the informant and the patient needs to be described to help the receiver of the clinical document understand the information in the document.

**77.** When relatedEntity/@classCode is PRS, values in relatedEntity/code **SHALL** come from the HL7 PersonalRelationshipRoleType vocabulary or from SNOMED, any subtype of "Person in the family" (303071001). (CONF-HP-46)

78. When an informant is an unrelated person not otherwise specified, the value relatedEntity/@classCode **SHALL** be set to CON to indicate that this person is a contact. (CONF-HP-47)
- Individuals with no prior personal relationship to the patient (e.g., a witness to a significant health care event) may provide information about the patient.
79. When the informant is a healthcare provider without an assigned role, the informant **SHALL** be represented using the relatedEntity element and the value of relatedEntity/@classCode **SHALL** be set to PROV. (CONF-HP-48)
- A health care provider who does not have an assigned role at the institution may provide information. To record an informant that does not have an assigned role that can be represented within the context of the document, the information will be represented using the relatedEntity element and the value of relatedEntity/@classCode will be set to PROV.
80. When the informant is a healthcare provider, the value of relatedEntity/code **SHOULD** be present and indicate the type of healthcare provider. (CONF-HP-49)
81. The ClinicalDocument/informationRecipient element **MAY** be present. When informationRecipient is used, at least one informationRecipient/intendedRecipient/informationRecipient or informationRecipient/intendedRecipient/receivedOrganization **SHALL** be present. (CONF-HP-50)
82. The assignedEntity/assignedPerson element **SHALL** be present in legalAuthenticator. (CONF-HP-51)
- [OCL]: not self.legalAuthenticator.ocIsUndefined() implies not self.legalAuthenticator.assignedEntity.assignedPerson.ocIsUndefined()
83. The assignedEntity/assignedPerson element **SHALL** be present in an authenticator element. (CONF-HP-52)
- [OCL]: self.authenticator->forAll(auth : cda::Authenticator | auth.assignedEntity->forAll(entity : cda::AssignedEntity | not entity.assignedPerson.ocIsUndefined()))
84. Times or time intervals found in the ClinicalDocument/effectiveTime, author/time, dataEnterer/time, legalAuthenticator/time, authenticator/time and encompassingEncounter/effectiveTime elements **SHALL** be precise to the day, **SHALL** include a time zone if more precise than to the day, and **SHOULD** be precise to the second. (CONF-HP-10)
- Should portion of CON-HP-10 constraint
  - [OCL]: -- implemented in Java using XPath selector
  - [XPath]: /cda:ClinicalDocument/cda:effectiveTime | //cda:author/cda:time | //cda:dataEnterer/cda:time | //cda:encompassingEncounter/cda:effectiveTime
85. Times or time intervals found in the asOrganizationPartOf/effectiveTime, asMaintainedEntity/effectiveTime, relatedEntity/effectiveTime, serviceEvent/effectiveTime, ClinicalDocument/participant/time, serviceEvent/performer/time and encounterParticipant/time **SHALL** be precise at least to the year, **SHOULD** be precise to the day, and **MAY** omit time zone. (CONF-HP-11)
- Should portion of CON-HP-11 constraint
  - [OCL]: cda::OrganizationPartOf.allInstances()->select( effectiveTime.ocIsUndefined()).oclAsType( ecore::EObject)->union( cda::MaintainedEntity.allInstances()->select( effectiveTime.ocIsUndefined()).oclAsType( ecore::EObject) )->union( cda::RelatedEntity.allInstances()->select( effectiveTime.ocIsUndefined()).oclAsType( ecore::EObject) )->union(cda::RelatedEntity.allInstances()->select( effectiveTime.ocIsUndefined()).oclAsType( ecore::EObject) )->union(cda::ServiceEvent.allInstances()->select( effectiveTime.ocIsUndefined()).oclAsType( ecore::EObject) )->union(cda::EncounterParticipant.allInstances()->select( time.ocIsUndefined()).oclAsType( ecore::EObject))->union(self.participant->select( time.ocIsUndefined()).oclAsType( ecore::EObject))->union(cda::OrganizationPartOf.allInstances().effectiveTime->union(cda::MaintainedEntity.allInstances().effectiveTime)-

```

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

```

### Consultation Request example

## Consultation Summary

---

[ClinicalDocument: templateId 1.2.3.4.5.102]

1. **SHALL** conform to *CDT General Header Constraints* template (templateId: 2.16.840.1.113883.10.20.3)
2. **SHALL** contain exactly one [1..1] **realmCode/@code**= "US" (CONF-HP-15)
3. **SHALL** contain exactly one [1..1] **typeId** (CONF-HP-16)
  - The clinical document type ID identifies the constraints imposed by CDA R2 on the content, essentially acting as a version identifier.
4. **SHALL** contain exactly one [1..1] **id** (CONF-HP-17)
  - The ClinicalDocument/id element is an instance identifier data type (see HL7 Version 3 Abstract Data in Section 5 REFERENCES). The root attribute is a UUID or OID. The root uniquely identifies the scope of the extension. The root and extension attributes uniquely identify the document.
5. **SHALL** contain exactly one [1..1] **code** (CONF-HP-21)
  - Specifies the type of the clinical document.
6. **SHALL** contain exactly one [1..1] **title** (CONF-HP-22)
  - Specifies the local name used for the document. Note that the title does not need to be the same as the display name provided with the document type code. For example, the display name provided by LOINC® as an aid in debugging may be "HISTORY AND PHYSICAL." The title can be localized, as appropriate.
7. **SHALL** contain exactly one [1..1] **effectiveTime** (CONF-HP-23)
  - Specifies the creation time of the document. All documents authored by direct input to a computer system should record an effectiveTime that is precise to the second. When authored in other ways, for example, by filling out a paper form that is then transferred into an EHR system, the precision of effectiveTime may be less than to the second.
8. Contains exactly one [1..1] **confidentialityCode**
  - Specifies the confidentiality assigned to the document. This specification provides no further guidance beyond CDA R2 on documents with respect to the vocabulary used for confidentialityCode, nor treatment or implementation of confidentiality.
9. **SHALL** contain exactly one [1..1] **languageCode** (CONF-HP-24)
10. Contains at least one [1..\*] **recordTarget**, where its type is *Record Target*
11. Contains at least one [1..\*] **author**, where its type is *Author*
12. Contains exactly one [1..1] **custodian**, where its type is *Custodian*
13. Contains exactly one [1..1] **component**, where its type is *Component2*
14. Contains at least one [1..\*] **author**, such that

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

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

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

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

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

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

**17. Contains zero or more [0..\*] `informationRecipient`, such that**

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

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

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

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

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

**19. Contains zero or more [0..\*] `authenticator`, such that**

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

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

**20. SHALL contain exactly one [1..1] `component`, such that**

- a. Contains exactly one [1..1] [HITSP Allergies Reactions Section](#) (templateId: 2.16.840.1.113883.3.88.11.83.102)

**21. SHALL contain exactly one [1..1] `component`, such that**

- a. Contains exactly one [1..1] [HITSP Medications Section](#) (templateId: 2.16.840.1.113883.3.88.11.83.112)

**22. SHALL contain exactly one [1..1] `component`, such that**

- a. Contains exactly one [1..1] [HITSP Problem List Section](#) (templateId: 2.16.840.1.113883.3.88.11.83.103)

**23. SHALL contain exactly one [1..1] `component`, such that**

- a. Contains exactly one [1..1] [HITSP Surgeries Section](#) (templateId: 2.16.840.1.113883.3.88.11.83.108)

**24. SHALL** contain exactly one [1..1] **component**, such that

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

**25. SHOULD** contain zero or one [0..1] **component**, such that

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

**26. SHOULD** contain zero or one [0..1] **component**, such that

- a. Contains exactly one [1..1] *HITSP Encounters Section* (templateId: 2.16.840.1.113883.3.88.11.83.127)

**27. SHOULD** contain zero or one [0..1] **component**, such that

- a. Contains exactly one [1..1] *HITSP Family History Section* (templateId: 2.16.840.1.113883.3.88.11.83.125)

**28. SHOULD** contain zero or one [0..1] **component**, such that

- a. Contains exactly one [1..1] *HITSP Functional Status Section* (templateId: 2.16.840.1.113883.3.88.11.83.109)

**29. SHOULD** contain zero or one [0..1] **component**, such that

- a. Contains exactly one [1..1] *HITSP Immunizations Section* (templateId: 2.16.840.1.113883.3.88.11.83.117)

**30. SHOULD** contain zero or one [0..1] **component**, such that

- a. Contains exactly one [1..1] *HITSP Medical Equipment Section* (templateId: 2.16.840.1.113883.3.88.11.83.128)

**31. SHOULD** contain zero or one [0..1] **component**, such that

- a. Contains exactly one [1..1] *HITSP Payers Section* (templateId: 2.16.840.1.113883.3.88.11.83.101)

**32. SHOULD** contain zero or one [0..1] **component**, such that

- a. Contains exactly one [1..1] *HITSP Plan Of Care Section* (templateId: 2.16.840.1.113883.3.88.11.83.124)

**33. SHOULD** contain zero or one [0..1] **component**, such that

- a. Contains exactly one [1..1] *HITSP Social History Section* (templateId: 2.16.840.1.113883.3.88.11.83.126)

**34. SHOULD** contain zero or one [0..1] **component**, such that

- a. Contains exactly one [1..1] *HITSP Vital Signs Section* (templateId: 2.16.840.1.113883.3.88.11.83.119)

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

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

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

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



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

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

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

- When name, address, or telecom information is unknown and where these elements are required to be present, as with CDA conformance if the information is unknown, these elements will be represented using an appropriate value for the nullFlavor attribute on the element. Legal values according to this specification come from the HL7 NullFlavor vocabulary.
- [OCL]: -- implemented in Java using XPath selector
- [XPath]: \*[self::cda:guardianOrganization or self::cda:providerOrganization or self::cda:wholeOrganization or self::cda:representedOrganization or self::cda:representedCustodianOrganization or self::cda:receivedOrganization or self::cda:scopingOrganization or self::cda:serviceProviderOrganization]

**39.** Times or time intervals found in the ClinicalDocument/effectiveTime, author/time, dataEnterer/time, legalAuthenticator/time, authenticator/time and encompassingEncounter/effectiveTime elements **SHALL** be precise to the day, **SHALL** include a time zone if more precise than to the day, and **SHOULD** be precise to the second. (CONF-HP-10)

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

**40.** Times or time intervals found in the asOrganizationPartOf/effectiveTime, asMaintainedEntity/effectiveTime, relatedEntity/effectiveTime, serviceEvent/effectiveTime, ClinicalDocument/participant/time, serviceEvent/performer/time and encounterParticipant/time **SHALL** be precise at least to the year, **SHOULD** be precise to the day, and **MAY** omit time zone. (CONF-HP-11)

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

```

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

```

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

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

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

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

• [XPath]: `//*[self::cda:telecom]`

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

- There is no way to distinguish between an unknown phone number and an unknown e-mail or other telecommunications address. Therefore, the following convention will be used: Any telecom element that uses a flavor of null (has a nullFlavor attribute) is assumed to be a telephone number, which is the only required telecommunications address element within this DSTU.

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

• [XPath]: `//*[self::cda:telecom]`

**44. SHALL** satisfy: The extension attribute of the typeId element is POCD\_HD000040. (CONF-HP-16)

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

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

**46. 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]. (CONF-HP-18)

**47. OIDs** are represented in dotted decimal notation, where each decimal number is either 0, or starts with a nonzero digit. More formally, an OID **SHALL** be in the form `(([0-2])(.([1-9][0-9]*|0)))+`. (CONF-HP-19)

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

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

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

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

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

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

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

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

**51.** The CC portion languageCode, if present, **SHALL** be an ISO-3166 country code in uppercase. (CONF-HP-27)

**52.** Both setId and versionNumber **SHALL** be present or both **SHALL** be absent. (CONF-HP-28)

- The ClinicalDocument/setId element uses the instance identifier (II) data type. The root attribute is a UUID or OID that uniquely identifies the scope of the identifier, and the extension attribute is a value that is unique within the scope of the root for the set of versions of the document. See Document Identification, Revisions, and Addenda in Section 4.2.3.1 of the CDA Specification for some examples showing the use of the setId element.

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

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

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

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

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

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

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

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

**56.** A patient/birthTime element **SHALL** be present. The patient/birthTime element **SHALL** be precise at least to the year, and **SHOULD** be precise at least to the day, and **MAY** omit time zone. If unknown, it **SHALL** be represented using a flavor of null. (CONF-HP-32)

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

**57.** A patient/administrativeGenderCode element **SHALL** be present. If unknown, it **SHALL** be represented using a flavor of null. Values for administrativeGenderCode **SHOULD** be drawn from the HL7 AdministrativeGender vocabulary. (CONF-HP-33)

- TODO: add OCL test for terminology

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

**58.** The maritalStatusCode, religiousAffiliationCode, raceCode and ethnicGroupCode **MAY** be present. If maritalStatusCode, religiousAffiliationCode, raceCode and ethnicGroupCode elements are present, they **SHOULD** be encoded using the appropriate HL7 vocabularies. (CONF-HP-34)

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

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

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

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

- The author/time element represents the start time of the author's participation in the creation of the clinical document.
  - [OCL]: `self.author->forAll(author : cda::Author | not author.time.ocIsUndefined())`
- 62. SHALL** satisfy: The assignedAuthor/id element is present. (CONF-HP-38)
- [OCL]: `self.author->forAll(author : cda::Author | author.assignedAuthor.id->size() > 0)`
- 63. SHALL** satisfy: An assignedAuthor element contains at least one assignedPerson or assignedAuthoringDevice elements. (CONF-HP-39)
- [OCL]: `self.author->forAll(author : cda::Author | not author.assignedAuthor.assignedPerson.ocIsUndefined() or not author.assignedAuthor.assignedAuthoringDevice.ocIsUndefined())`
- 64. SHALL** satisfy: When dataEnterer is present, an assignedEntity/assignedPerson element is present. (CONF-HP-40)
- [OCL]: `not self.dataEnterer.ocIsUndefined() implies not self.dataEnterer.assignedEntity.assignedPerson.ocIsUndefined()`
- 65.** The dataEnterer/time element **MAY** be present. If present, it represents the starting time of entry of the data. (CONF-HP-41)
- [OCL]: `not self.dataEnterer.ocIsUndefined() implies not self.dataEnterer.time.ocIsUndefined()`
- 66. MAY** satisfy: The informant element is present. (CONF-HP-42)
- [OCL]: `self.informant->size() > 0`
- 67.** When informant is present, an assignedEntity/assignedPerson or relatedEntity/relatedPerson element **SHALL** be present. (CONF-HP-43)
- [OCL]: `self.informant->forAll(i : cda::Informant12 | not i.assignedEntity.assignedPerson.ocIsUndefined() or not i.relatedEntity.relatedPerson.ocIsUndefined())`
- 68.** When the informant is a healthcare provider with an assigned role, the informant **SHALL** be represented using the assignedEntity element (CONF-HP-44)
- Assigned health care providers may be a source of information when a document is created. (e.g., a nurse's aide who provides information about a recent significant health care event that occurred within an acute care facility.) In these cases, the assignedEntity element is used.
  - TODO: how to determin if informant is a healthcare provider? condition for implementing OCL
- 69.** Allowable values for informant/relatedEntity/@classCode **SHALL** be CON, PRS, CAREGIVER, AGNT or PROV from the RoleClass vocabulary. (CONF-HP-45)
- When the informant is a personal relation, that informant is represented in the relatedEntity element. The code element of the relatedEntity describes the relationship between the informant and the patient.
- The relationship between the informant and the patient needs to be described to help the receiver of the clinical document understand the information in the document.
- 70.** When relatedEntity/@classCode is PRS, values in relatedEntity/code **SHALL** come from the HL7 PersonalRelationshipRoleType vocabulary or from SNOMED, any subtype of "Person in the family" (303071001). (CONF-HP-46)
- 71.** When an informant is an unrelated person not otherwise specified, the value relatedEntity/@classCode **SHALL** be set to CON to indicate that this person is a contact. (CONF-HP-47)
- Individuals with no prior personal relationship to the patient (e.g., a witness to a significant health care event) may provide information about the patient.
- 72.** When the informant is a healthcare provider without an assigned role, the informant **SHALL** be represented using the relatedEntity element and the value of relatedEntity/@classCode **SHALL** be set to PROV. (CONF-HP-48)
- A health care provider who does not have an assigned role at the institution may provide information. To record an informant that does not have an assigned role that can be represented within the context of the

document, the information will be represented using the relatedEntity element and the value of relatedEntity/@classCode will be set to PROV.

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

74. The ClinicalDocument/informationRecipient element **MAY** be present. When informationRecipient is used, at least one informationRecipient/intendedRecipient/informationRecipient or informationRecipient/intendedRecipient/receivedOrganization **SHALL** be present. (CONF-HP-50)

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

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

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

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

77. Times or time intervals found in the ClinicalDocument/effectiveTime, author/time, dataEnterer/time, legalAuthenticator/time, authenticator/time and encompassingEncounter/effectiveTime elements **SHALL** be precise to the day, **SHALL** include a time zone if more precise than to the day, and **SHOULD** be precise to the second. (CONF-HP-10)

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

78. Times or time intervals found in the asOrganizationPartOf/effectiveTime, asMaintainedEntity/effectiveTime, relatedEntity/effectiveTime, serviceEvent/effectiveTime, ClinicalDocument/participant/time, serviceEvent/performer/time and encounterParticipant/time **SHALL** be precise at least to the year, **SHOULD** be precise to the day, and **MAY** omit time zone. (CONF-HP-11)

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

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

### Consultation Summary example

## Discharge Instructions

---

[ClinicalDocument: templateId 1.2.3.4.5.101]

1. **SHALL** conform to *CDT General Header Constraints* template (templateId: 2.16.840.1.113883.10.20.3)
2. **SHALL** contain exactly one [1..1] **realmCode/@code**= "US" (CONF-HP-15)
3. **SHALL** contain exactly one [1..1] **typeId** (CONF-HP-16)
  - The clinical document type ID identifies the constraints imposed by CDA R2 on the content, essentially acting as a version identifier.
4. **SHALL** contain exactly one [1..1] **id** (CONF-HP-17)
  - The ClinicalDocument/id element is an instance identifier data type (see HL7 Version 3 Abstract Data in Section 5 REFERENCES). The root attribute is a UUID or OID. The root uniquely identifies the scope of the extension. The root and extension attributes uniquely identify the document.
5. **SHALL** contain exactly one [1..1] **code** (CONF-HP-21)
  - Specifies the type of the clinical document.
6. **SHALL** contain exactly one [1..1] **title** (CONF-HP-22)
  - Specifies the local name used for the document. Note that the title does not need to be the same as the display name provided with the document type code. For example, the display name provided by LOINC® as an aid in debugging may be "HISTORY AND PHYSICAL." The title can be localized, as appropriate.
7. **SHALL** contain exactly one [1..1] **effectiveTime** (CONF-HP-23)
  - Specifies the creation time of the document. All documents authored by direct input to a computer system should record an effectiveTime that is precise to the second. When authored in other ways, for example, by filling out a paper form that is then transferred into an EHR system, the precision of effectiveTime may be less than to the second.
8. Contains exactly one [1..1] **confidentialityCode**
  - Specifies the confidentiality assigned to the document. This specification provides no further guidance beyond CDA R2 on documents with respect to the vocabulary used for confidentialityCode, nor treatment or implementation of confidentiality.
9. **SHALL** contain exactly one [1..1] **languageCode** (CONF-HP-24)
10. Contains at least one [1..\*] **recordTarget**, where its type is *Record Target*
11. Contains at least one [1..\*] **author**, where its type is *Author*
12. Contains exactly one [1..1] **custodian**, where its type is *Custodian*
13. Contains exactly one [1..1] **component**, where its type is *Component2*
14. Contains at least one [1..\*] **author**, such that
  - The author element represents the creator of the clinical document. If the role of the actor is the entry of information from his or her own knowledge or application of skills, that actor is the author. If one actor provides information to another actor who filters, reasons, or algorithmically creates new information, then that second actor is also an author, having created information from his or her own knowledge or skills. However, that determination is independent from the determination of the first actor's authorship.
15. Contains zero or one [0..1] **dataEnterer**, such that
  - The dataEnterer element represents the person who transferred the information from other sources into the clinical document, where the other sources wrote the content of the note. The guiding rule of thumb is that an author provides the content found within the header or body of the document, subject to their own

interpretation. The dataEnterer adds information to the electronic system. A person can participate as both author and dataEnterer.

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

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

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

**17. Contains zero or more [0..\*] *informationRecipient*, such that**

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

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

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

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

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

**19. Contains zero or more [0..\*] *authenticator*, such that**

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

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

**20. SHALL contain exactly one [1..1] *component*, such that**

- Contains exactly one [1..1] *HITSP Plan Of Care Section* (templateId: 2.16.840.1.113883.3.88.11.83.124)

**21. SHALL contain exactly one [1..1] *component*, such that**

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

**22. SHALL contain exactly one [1..1] *component*, such that**

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

**23. SHALL contain exactly one [1..1] *component*, such that**

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

**24. SHALL contain exactly one [1..1] *component*, such that**

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

**25. SHALL contain exactly one [1..1] *component*, such that**

- Contains exactly one [1..1] *HITSP Immunizations Section* (templateId: 2.16.840.1.113883.3.88.11.83.117)

**26. SHALL contain exactly one [1..1] *component*, such that**

- Contains exactly one [1..1] *HITSP Medical Equipment Section* (templateId: 2.16.840.1.113883.3.88.11.83.128)

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

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

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

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

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

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

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

- When name, address, or telecom information is unknown and where these elements are required to be present, as with CDA conformance if the information is unknown, these elements will be represented using an appropriate value for the nullFlavor attribute on the element. Legal values according to this specification come from the HL7 NullFlavor vocabulary.
- [OCL]: -- implemented in Java using XPath selector
- [XPath]: \*[self::cda:guardianOrganization or self::cda:providerOrganization or self::cda:wholeOrganization or self::cda:representedOrganization or self::cda:representedCustodianOrganization or self::cda:receivedOrganization or self::cda:scopingOrganization or self::cda:serviceProviderOrganization]

**31.** Times or time intervals found in the ClinicalDocument/effectiveTime, author/time, dataEnterer/time, legalAuthenticator/time, authenticator/time and encompassingEncounter/effectiveTime elements **SHALL** be precise to the day, **SHALL** include a time zone if more precise than to the day, and **SHOULD** be precise to the second. (CONF-HP-10)

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

**32.** Times or time intervals found in the asOrganizationPartOf/effectiveTime, asMaintainedEntity/effectiveTime, relatedEntity/effectiveTime, serviceEvent/effectiveTime, ClinicalDocument/participant/time, serviceEvent/performer/time and encounterParticipant/time **SHALL** be precise at least to the year, **SHOULD** be precise to the day, and **MAY** omit time zone. (CONF-HP-11)

- [OCL]: cda::OrganizationPartOf.allInstances()->select( effectiveTime.ocIsUndefined()).oclAsType( ecore::EObject)-> union( cda::MaintainedEntity.allInstances()->select( effectiveTime.ocIsUndefined()).oclAsType( ecore::EObject) )->union( cda::RelatedEntity.allInstances()->select( effectiveTime.ocIsUndefined()).oclAsType( ecore::EObject) )-



```

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

```

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

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

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

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

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

- There is no way to distinguish between an unknown phone number and an unknown e-mail or other telecommunications address. Therefore, the following convention will be used: Any telecom element that uses a flavor of null (has a nullFlavor attribute) is assumed to be a telephone number, which is the only required telecommunications address element within this DSTU.
- [OCL]: -- implemented in Java using XPath selector
- [XPath]: `//*[self::cda:telecom]`

**36. SHALL** satisfy: The extension attribute of the typeId element is POCD\_HD000040. (CONF-HP-16)

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

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

**38. 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]. (CONF-HP-18)

**39. OIDs** are represented in dotted decimal notation, where each decimal number is either 0, or starts with a nonzero digit. More formally, an OID **SHALL** be in the form ([0-2])(.([1-9][0-9]\*|0))+. (CONF-HP-19)

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

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

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

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

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

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

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

**43.** The CC portion languageCode, if present, **SHALL** be an ISO-3166 country code in uppercase. (CONF-HP-27)

**44.** Both setId and versionNumber **SHALL** be present or both **SHALL** be absent. (CONF-HP-28)

- The ClinicalDocument/setId element uses the instance identifier (II) data type. The root attribute is a UUID or OID that uniquely identifies the scope of the identifier, and the extension attribute is a value that is unique within the scope of the root for the set of versions of the document. See Document Identification, Revisions, and Addenda in Section 4.2.3.1 of the CDA Specification for some examples showing the use of the setId element.

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

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

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

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

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

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

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

**48.** A patient/birthTime element **SHALL** be present. The patient/birthTime element **SHALL** be precise at least to the year, and **SHOULD** be precise at least to the day, and **MAY** omit time zone. If unknown, it **SHALL** be represented using a flavor of null. (CONF-HP-32)

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

**49.** A patient/administrativeGenderCode element **SHALL** be present. If unknown, it **SHALL** be represented using a flavor of null. Values for administrativeGenderCode **SHOULD** be drawn from the HL7 AdministrativeGender vocabulary. (CONF-HP-33)

- TODO: add OCL test for terminology
- [OCL]: `self.recordTarget->forall(target : cda::RecordTarget | not target.patientRole.oclIsUndefined() implies (not target.patientRole.patient.administrativeGenderCode.code.oclIsUndefined() or not target.patientRole.patient.administrativeGenderCode.nullFlavor.oclIsUndefined()))`
- 50. The maritalStatusCode, religiousAffiliationCode, raceCode and ethnicGroupCode **MAY** be present. If maritalStatusCode, religiousAffiliationCode, raceCode and ethnicGroupCode elements are present, they **SHOULD** be encoded using the appropriate HL7 vocabularies. (CONF-HP-34)
- 51. **SHOULD** satisfy: The guardian element is present when the patient is a minor child. (CONF-HP-35)
- 52. **MAY** satisfy: The providerOrganization element is present. (CONF-HP-36)
  - [OCL]: `self.recordTarget->exists(target : cda::RecordTarget | not target.patientRole.providerOrganization.oclIsUndefined())`
- 53. **SHALL** satisfy: The author/time element is present. (CONF-HP-37)
  - The author/time element represents the start time of the author's participation in the creation of the clinical document.
  - [OCL]: `self.author->forall(author : cda::Author | not author.time.oclIsUndefined())`
- 54. **SHALL** satisfy: The assignedAuthor/id element is present. (CONF-HP-38)
  - [OCL]: `self.author->forall(author : cda::Author | author.assignedAuthor.id->size() > 0)`
- 55. **SHALL** satisfy: An assignedAuthor element contains at least one assignedPerson or assignedAuthoringDevice elements. (CONF-HP-39)
  - [OCL]: `self.author->forall(author : cda::Author | not author.assignedAuthor.assignedPerson.oclIsUndefined() or not author.assignedAuthor.assignedAuthoringDevice.oclIsUndefined())`
- 56. **SHALL** satisfy: When dataEnterer is present, an assignedEntity/assignedPerson element is present. (CONF-HP-40)
  - [OCL]: `not self.dataEnterer.oclIsUndefined() implies not self.dataEnterer.assignedEntity.assignedPerson.oclIsUndefined()`
- 57. The dataEnterer/time element **MAY** be present. If present, it represents the starting time of entry of the data. (CONF-HP-41)
  - [OCL]: `not self.dataEnterer.oclIsUndefined() implies not self.dataEnterer.time.oclIsUndefined()`
- 58. **MAY** satisfy: The informant element is present. (CONF-HP-42)
  - [OCL]: `self.informant->size() > 0`
- 59. When informant is present, an assignedEntity/assignedPerson or relatedEntity/relatedPerson element **SHALL** be present. (CONF-HP-43)
  - [OCL]: `self.informant->forall(i : cda::Informant12 | not i.assignedEntity.assignedPerson.oclIsUndefined() or not i.relatedEntity.relatedPerson.oclIsUndefined())`
- 60. When the informant is a healthcare provider with an assigned role, the informant **SHALL** be represented using the assignedEntity element (CONF-HP-44)
  - Assigned health care providers may be a source of information when a document is created. (e.g., a nurse's aide who provides information about a recent significant health care event that occurred within an acute care facility.) In these cases, the assignedEntity element is used.
  - TODO: how to determine if informant is a healthcare provider? condition for implementing OCL
- 61. Allowable values for informant/relatedEntity/@classCode **SHALL** be CON, PRS, CAREGIVER, AGNT or PROV from the RoleClass vocabulary. (CONF-HP-45)

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

The relationship between the informant and the patient needs to be described to help the receiver of the clinical document understand the information in the document.

62. When relatedEntity/@classCode is PRS, values in relatedEntity/code **SHALL** come from the HL7 PersonalRelationshipRoleType vocabulary or from SNOMED, any subtype of "Person in the family" (303071001). (CONF-HP-46)
63. When an informant is an unrelated person not otherwise specified, the value relatedEntity/@classCode **SHALL** be set to CON to indicate that this person is a contact. (CONF-HP-47)
  - Individuals with no prior personal relationship to the patient (e.g., a witness to a significant health care event) may provide information about the patient.
64. When the informant is a healthcare provider without an assigned role, the informant **SHALL** be represented using the relatedEntity element and the value of relatedEntity/@classCode **SHALL** be set to PROV. (CONF-HP-48)
  - A health care provider who does not have an assigned role at the institution may provide information. To record an informant that does not have an assigned role that can be represented within the context of the document, the information will be represented using the relatedEntity element and the value of relatedEntity/@classCode will be set to PROV.
65. When the informant is a healthcare provider, the value of relatedEntity/code **SHOULD** be present and indicate the type of healthcare provider. (CONF-HP-49)
66. The ClinicalDocument/informationRecipient element **MAY** be present. When informationRecipient is used, at least one informationRecipient/intendedRecipient/informationRecipient or informationRecipient/intendedRecipient/receivedOrganization **SHALL** be present. (CONF-HP-50)
67. The assignedEntity/assignedPerson element **SHALL** be present in legalAuthenticator. (CONF-HP-51)
  - [OCL]: not self.legalAuthenticator.oclIsUndefined() implies not self.legalAuthenticator.assignedEntity.assignedPerson.oclIsUndefined()
68. The assignedEntity/assignedPerson element **SHALL** be present in an authenticator element. (CONF-HP-52)
  - [OCL]: self.authenticator->forall(auth : cda::Authenticator | auth.assignedEntity->forall(entity : cda::AssignedEntity | not entity.assignedPerson.oclIsUndefined()))
69. Times or time intervals found in the ClinicalDocument/effectiveTime, author/time, dataEnterer/time, legalAuthenticator/time, authenticator/time and encompassingEncounter/effectiveTime elements **SHALL** be precise to the day, **SHALL** include a time zone if more precise than to the day, and **SHOULD** be precise to the second. (CONF-HP-10)
  - Should portion of CON-HP-10 constraint
  - [OCL]: -- implemented in Java using XPath selector
  - [XPath]: /cda:ClinicalDocument/cda:effectiveTime | //cda:author/cda:time | //cda:dataEnterer/cda:time | //cda:encompassingEncounter/cda:effectiveTime
70. Times or time intervals found in the asOrganizationPartOf/effectiveTime, asMaintainedEntity/effectiveTime, relatedEntity/effectiveTime, serviceEvent/effectiveTime, ClinicalDocument/participant/time, serviceEvent/performer/time and encounterParticipant/time **SHALL** be precise at least to the year, **SHOULD** be precise to the day, and **MAY** omit time zone. (CONF-HP-11)
  - Should portion of CON-HP-11 constraint
  - [OCL]: cda::OrganizationPartOf.allInstances()->select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject)-> union( cda::MaintainedEntity.allInstances()->select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject) )->union( cda::RelatedEntity.allInstances()->select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject) )->union(cda::RelatedEntity.allInstances()->select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject) )->union(cda::RelatedEntity.allInstances()-

```

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

```

### Discharge Instructions example

## Discharge Summary

---

[ClinicalDocument: templateId 1.2.3.4.5.100]

1. **SHALL** conform to *CDT General Header Constraints* template (templateId: 2.16.840.1.113883.10.20.3)
2. **SHALL** contain exactly one [1..1] **realmCode/@code**= "US" (CONF-HP-15)
3. **SHALL** contain exactly one [1..1] **typeId** (CONF-HP-16)
  - The clinical document type ID identifies the constraints imposed by CDA R2 on the content, essentially acting as a version identifier.
4. **SHALL** contain exactly one [1..1] **id** (CONF-HP-17)
  - The ClinicalDocument/id element is an instance identifier data type (see HL7 Version 3 Abstract Data in Section 5 REFERENCES). The root attribute is a UUID or OID. The root uniquely identifies the scope of the extension. The root and extension attributes uniquely identify the document.
5. **SHALL** contain exactly one [1..1] **code** (CONF-HP-21)
  - Specifies the type of the clinical document.
6. **SHALL** contain exactly one [1..1] **title** (CONF-HP-22)
  - Specifies the local name used for the document. Note that the title does not need to be the same as the display name provided with the document type code. For example, the display name provided by LOINC® as an aid in debugging may be "HISTORY AND PHYSICAL." The title can be localized, as appropriate.
7. **SHALL** contain exactly one [1..1] **effectiveTime** (CONF-HP-23)
  - Specifies the creation time of the document. All documents authored by direct input to a computer system should record an effectiveTime that is precise to the second. When authored in other ways, for example, by filling out a paper form that is then transferred into an EHR system, the precision of effectiveTime may be less than to the second.
8. Contains exactly one [1..1] **confidentialityCode**

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

9. **SHALL** contain exactly one [1..1] **languageCode** (CONF-HP-24)

10. Contains at least one [1..\*] **recordTarget**, where its type is *Record Target*

11. Contains at least one [1..\*] **author**, where its type is *Author*

12. Contains exactly one [1..1] **custodian**, where its type is *Custodian*

13. Contains exactly one [1..1] **component**, where its type is *Component2*

14. Contains at least one [1..\*] **author**, such that

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

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

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

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

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

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

17. Contains zero or more [0..\*] **informationRecipient**, such that

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

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

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

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

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

19. Contains zero or more [0..\*] **authenticator**, such that

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

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

20. **SHALL** contain exactly one [1..1] **component**, such that

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

21. **SHALL** contain exactly one [1..1] **component**, such that

- a. Contains exactly one [1..1] *HITSP Problem List Section* (templateId: 2.16.840.1.113883.3.88.11.83.103)
- 22. **SHALL** contain exactly one [1..1] **component**, such that
  - a. Contains exactly one [1..1] *HITSP Hospital Course Section* (templateId: 2.16.840.1.113883.3.88.11.83.121)
- 23. **SHALL** contain exactly one [1..1] **component**, such that
  - a. Contains exactly one [1..1] *HITSP Hospital Discharge Medications Section* (templateId: 2.16.840.1.113883.3.88.11.83.114)
- 24. **SHALL** contain exactly one [1..1] **component**, such that
  - a. Contains exactly one [1..1] *HITSP Discharge Diagnosis Section* (templateId: 2.16.840.1.113883.3.88.11.83.111)
- 25. **SHALL** contain exactly one [1..1] **component**, such that
  - a. Contains exactly one [1..1] *HITSP Plan Of Care Section* (templateId: 2.16.840.1.113883.3.88.11.83.124)
- 26. **SHOULD** contain zero or one [0..1] **component**, such that
  - a. Contains exactly one [1..1] *HITSP Surgeries Section* (templateId: 2.16.840.1.113883.3.88.11.83.108)
- 27. **SHOULD** contain zero or one [0..1] **component**, such that
  - a. Contains exactly one [1..1] *HITSP Chief Complaint Section* (templateId: 2.16.840.1.113883.3.88.11.83.105)
- 28. **SHOULD** contain zero or one [0..1] **component**, such that
  - a. Contains exactly one [1..1] *IHE Discharge Diet* (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.33)
- 29. **SHOULD** contain zero or one [0..1] **component**, such that
  - a. Contains exactly one [1..1] *HITSP Family History Section* (templateId: 2.16.840.1.113883.3.88.11.83.125)
- 30. **SHOULD** contain zero or one [0..1] **component**, such that
  - a. Contains exactly one [1..1] *HITSP Functional Status Section* (templateId: 2.16.840.1.113883.3.88.11.83.109)
- 31. **SHOULD** contain zero or one [0..1] **component**, such that
  - a. Contains exactly one [1..1] *HITSP History Of Present Illness* (templateId: 2.16.840.1.113883.3.88.11.83.107)
- 32. **SHOULD** contain zero or one [0..1] **component**, such that
  - a. Contains exactly one [1..1] *IHE Hospital Discharge Physical* (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.26)
- 33. **SHOULD** contain zero or one [0..1] **component**, such that
  - a. Contains exactly one [1..1] *CDT Hospital Discharge Studies Summary Section* (templateId: 2.16.840.1.113883.10.20.16.2.3)
- 34. **SHOULD** contain zero or one [0..1] **component**, such that
  - a. Contains exactly one [1..1] *HITSP Immunizations Section* (templateId: 2.16.840.1.113883.3.88.11.83.117)
- 35. **SHOULD** contain zero or one [0..1] **component**, such that
  - a. Contains exactly one [1..1] *HITSP Review Of Systems Section* (templateId: 2.16.840.1.113883.3.88.11.83.120)
- 36. **SHOULD** contain zero or one [0..1] **component**, such that
  - a. Contains exactly one [1..1] *HITSP Social History Section* (templateId: 2.16.840.1.113883.3.88.11.83.126)
- 37. **SHOULD** contain zero or one [0..1] **component**, such that

- a. Contains exactly one [1..1] *HITSP Vital Signs Section* (templateId: 2.16.840.1.113883.3.88.11.83.119)
- 38. SHALL** satisfy: All patient, guardianPerson, assignedPerson, maintainingPerson, relatedPerson, intendedRecipient/informationRecipient, associatedPerson, and relatedSubject/subject elements have a name. (CONF-HP-6)
- [OCL]: -- implemented in Java using XPath selector
  - [XPath]: \*[self::cda:patient or self::cda:guardianPerson or self::cda:assignedPerson or self::cda:maintainingPerson or self::cda:relatedPerson or self::cda:associatedPerson or self::cda:intendedRecipient/cda:informationRecipient or self::cda:relatedSubject/cda:subject]
- 39. SHALL** satisfy: All patientRole, assignedAuthor, assignedEntity[not(parent::dataEnterer)] and associatedEntity elements have an addr and telecom element. (CONF-HP-7)
- [OCL]: -- implemented in Java using XPath selector
  - [XPath]: \*[self::cda:patientRole or self::cda:assignedAuthor or self::cda:assignedEntity[not(parent::cda:dataEnterer)] or self::cda:associatedEntity]
- 40. SHOULD** satisfy: All guardian, dataEnterer/assignedEntity, relatedEntity, intendedRecipient, relatedSubject and participantRole elements have an addr and telecom element. (CONF-HP-8)
- [OCL]: -- implemented in Java using XPath selector
  - [XPath]: \*[self::cda:guardian or self::cda:assignedEntity[parent::cda:dataEnterer] or self::cda:relatedEntity or self::cda:intendedRecipient or self::cda:relatedSubject or self::cda:participantRole]
- 41. SHALL** satisfy: All guardianOrganization, providerOrganization, wholeOrganization, representedOrganization, representedCustodianOrganization, receivedOrganization, scopingOrganization and serviceProviderOrganization elements have name, addr and telecom elements. (CONF-HP-9)
- When name, address, or telecom information is unknown and where these elements are required to be present, as with CDA conformance if the information is unknown, these elements will be represented using an appropriate value for the nullFlavor attribute on the element. Legal values according to this specification come from the HL7 NullFlavor vocabulary.
  - [OCL]: -- implemented in Java using XPath selector
  - [XPath]: \*[self::cda:guardianOrganization or self::cda:providerOrganization or self::cda:wholeOrganization or self::cda:representedOrganization or self::cda:representedCustodianOrganization or self::cda:receivedOrganization or self::cda:scopingOrganization or self::cda:serviceProviderOrganization]
- 42.** Times or time intervals found in the ClinicalDocument/effectiveTime, author/time, dataEnterer/time, legalAuthenticator/time, authenticator/time and encompassingEncounter/effectiveTime elements **SHALL** be precise to the day, **SHALL** include a time zone if more precise than to the day, and **SHOULD** be precise to the second. (CONF-HP-10)
- [OCL]: -- implemented in Java using XPath selector
  - [XPath]: /cda:ClinicalDocument/cda:effectiveTime | //cda:author/cda:time | //cda:dataEnterer/cda:time | //cda:encompassingEncounter/cda:effectiveTime
- 43.** Times or time intervals found in the asOrganizationPartOf/effectiveTime, asMaintainedEntity/effectiveTime, relatedEntity/effectiveTime, serviceEvent/effectiveTime, ClinicalDocument/participant/time, serviceEvent/performer/time and encounterParticipant/time **SHALL** be precise at least to the year, **SHOULD** be precise to the day, and **MAY** omit time zone. (CONF-HP-11)
- [OCL]: cda::OrganizationPartOf.allInstances()->select( effectiveTime.ocIsUndefined()).oclAsType( ecore::EObject)-> union( cda::MaintainedEntity.allInstances()-



```

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

```

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

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

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

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

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

- There is no way to distinguish between an unknown phone number and an unknown e-mail or other telecommunications address. Therefore, the following convention will be used: Any telecom element that uses a flavor of null (has a nullFlavor attribute) is assumed to be a telephone number, which is the only required telecommunications address element within this DSTU.
- [OCL]: -- implemented in Java using XPath selector
- [XPath]: `//*[self::cda:telecom]`

**47. SHALL** satisfy: The extension attribute of the typeId element is POCD\_HD000040. (CONF-HP-16)

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

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

**49. 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]. (CONF-HP-18)

**50. OIDs** are represented in dotted decimal notation, where each decimal number is either 0, or starts with a nonzero digit. More formally, an OID **SHALL** be in the form ([0-2])(.[1-9][0-9]\*[0])+. (CONF-HP-19)

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

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

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

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

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

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

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

**54.** The CC portion languageCode, if present, **SHALL** be an ISO-3166 country code in uppercase. (CONF-HP-27)

**55.** Both setId and versionNumber **SHALL** be present or both **SHALL** be absent. (CONF-HP-28)

- The ClinicalDocument/setId element uses the instance identifier (II) data type. The root attribute is a UUID or OID that uniquely identifies the scope of the identifier, and the extension attribute is a value that is unique within the scope of the root for the set of versions of the document. See Document Identification, Revisions, and Addenda in Section 4.2.3.1 of the CDA Specification for some examples showing the use of the setId element.
- ```
[OCL]: (self.setId.ocIsUndefined() and self.versionNumber.ocIsUndefined()) xor (not self.setId.ocIsUndefined() and not self.versionNumber.ocIsUndefined())
```

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

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

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

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

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

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

**59.** A patient/birthTime element **SHALL** be present. The patient/birthTime element **SHALL** be precise at least to the year, and **SHOULD** be precise at least to the day, and **MAY** omit time zone. If unknown, it **SHALL** be represented using a flavor of null. (CONF-HP-32)

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

60. A patient/administrativeGenderCode element **SHALL** be present. If unknown, it **SHALL** be represented using a flavor of null. Values for administrativeGenderCode **SHOULD** be drawn from the HL7 AdministrativeGender vocabulary. (CONF-HP-33)
- TODO: add OCL test for terminology
  - [OCL]: `self.recordTarget->forAll(target : cda::RecordTarget | not target.patientRole.oclIsUndefined() implies (not target.patientRole.patient.administrativeGenderCode.code.oclIsUndefined() or not target.patientRole.patient.administrativeGenderCode.nullFlavor.oclIsUndefined()))`
61. The maritalStatusCode, religiousAffiliationCode, raceCode and ethnicGroupCode **MAY** be present. If maritalStatusCode, religiousAffiliationCode, raceCode and ethnicGroupCode elements are present, they **SHOULD** be encoded using the appropriate HL7 vocabularies. (CONF-HP-34)
62. **SHOULD** satisfy: The guardian element is present when the patient is a minor child. (CONF-HP-35)
63. **MAY** satisfy: The providerOrganization element is present. (CONF-HP-36)
- [OCL]: `self.recordTarget->exists(target : cda::RecordTarget | not target.patientRole.providerOrganization.oclIsUndefined())`
64. **SHALL** satisfy: The author/time element is present. (CONF-HP-37)
- The author/time element represents the start time of the author's participation in the creation of the clinical document.
  - [OCL]: `self.author->forAll(author : cda::Author | not author.time.oclIsUndefined())`
65. **SHALL** satisfy: The assignedAuthor/id element is present. (CONF-HP-38)
- [OCL]: `self.author->forAll(author : cda::Author | author.assignedAuthor.id->size() > 0)`
66. **SHALL** satisfy: An assignedAuthor element contains at least one assignedPerson or assignedAuthoringDevice elements. (CONF-HP-39)
- [OCL]: `self.author->forAll(author : cda::Author | not author.assignedAuthor.assignedPerson.oclIsUndefined() or not author.assignedAuthor.assignedAuthoringDevice.oclIsUndefined())`
67. **SHALL** satisfy: When dataEnterer is present, an assignedEntity/assignedPerson element is present. (CONF-HP-40)
- [OCL]: `not self.dataEnterer.oclIsUndefined() implies not self.dataEnterer.assignedEntity.assignedPerson.oclIsUndefined()`
68. The dataEnterer/time element **MAY** be present. If present, it represents the starting time of entry of the data. (CONF-HP-41)
- [OCL]: `not self.dataEnterer.oclIsUndefined() implies not self.dataEnterer.time.oclIsUndefined()`
69. **MAY** satisfy: The informant element is present. (CONF-HP-42)
- [OCL]: `self.informant->size() > 0`
70. When informant is present, an assignedEntity/assignedPerson or relatedEntity/relatedPerson element **SHALL** be present. (CONF-HP-43)
- [OCL]: `self.informant->forAll(i : cda::Informant12 | not i.assignedEntity.assignedPerson.oclIsUndefined() or not i.relatedEntity.relatedPerson.oclIsUndefined())`
71. When the informant is a healthcare provider with an assigned role, the informant **SHALL** be represented using the assignedEntity element (CONF-HP-44)
- Assigned health care providers may be a source of information when a document is created. (e.g., a nurse's aide who provides information about a recent significant health care event that occurred within an acute care facility.) In these cases, the assignedEntity element is used.
  - TODO: how to determine if informant is a healthcare provider? condition for implementing OCL

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

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

The relationship between the informant and the patient needs to be described to help the receiver of the clinical document understand the information in the document.

73. When relatedEntity/@classCode is PRS, values in relatedEntity/code **SHALL** come from the HL7 PersonalRelationshipRoleType vocabulary or from SNOMED, any subtype of "Person in the family" (303071001). (CONF-HP-46)

74. When an informant is an unrelated person not otherwise specified, the value relatedEntity/@classCode **SHALL** be set to CON to indicate that this person is a contact. (CONF-HP-47)

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

75. When the informant is a healthcare provider without an assigned role, the informant **SHALL** be represented using the relatedEntity element and the value of relatedEntity/@classCode **SHALL** be set to PROV. (CONF-HP-48)

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

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

77. The ClinicalDocument/informationRecipient element **MAY** be present. When informationRecipient is used, at least one informationRecipient/intendedRecipient/informationRecipient or informationRecipient/intendedRecipient/receivedOrganization **SHALL** be present. (CONF-HP-50)

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

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

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

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

80. Times or time intervals found in the ClinicalDocument/effectiveTime, author/time, dataEnterer/time, legalAuthenticator/time, authenticator/time and encompassingEncounter/effectiveTime elements **SHALL** be precise to the day, **SHALL** include a time zone if more precise than to the day, and **SHOULD** be precise to the second. (CONF-HP-10)

- Should portion of CON-HP-10 constraint

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

- [XPath]: /cda:ClinicalDocument/cda:effectiveTime | //cda:author/cda:time | //cda:dataEnterer/cda:time | //cda:encompassingEncounter/cda:effectiveTime

81. Times or time intervals found in the asOrganizationPartOf/effectiveTime, asMaintainedEntity/effectiveTime, relatedEntity/effectiveTime, serviceEvent/effectiveTime, ClinicalDocument/participant/time, serviceEvent/performer/time and encounterParticipant/time **SHALL** be precise at least to the year, **SHOULD** be precise to the day, and **MAY** omit time zone. (CONF-HP-11)

- Should portion of CON-HP-11 constraint

- [OCL]: cda::OrganizationPartOf.allInstances()->select( effectiveTime.ocIsUndefined()).oclAsType( ecore::EObject)-> union( cda::MaintainedEntity.allInstances()->select( effectiveTime.ocIsUndefined()).oclAsType( ecore::EObject) )->union( cda::RelatedEntity.allInstances()->select( effectiveTime.ocIsUndefined()).oclAsType( ecore::EObject) )->union(cda::RelatedEntity.allInstances()-

```

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

```

### Discharge Summary example



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**Chapter**

**3**

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**SECTION TEMPLATES**

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## Chapter

# 4

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## CLINICAL STATEMENT TEMPLATES

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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.



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## Chapter

# 5

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## OTHER CLASSES

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



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# Chapter

# 6

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## VALUE SETS

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



## REFERENCES

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- 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](#)
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- [LOINC®](#) : Logical Observation Identifiers Names and Codes, Regenstrief Institute.
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