

Clinical Documents

Provincial CDA Header Implementation Guide

Version: 1.0

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1. Introduction

1.1 Purpose

The purpose of this Implementation Guide is to provide formal, implementable specifications for the construction of a Clinical Document Header using the Clinical Document Architecture (CDA) standard, in compliance with profiles and templates from National and International Standards

1.2 Open Issue

- 1.) Currently the value set for the code for author is set to HealthcareProviderRoleType. However this value set does not allow for the possibility of non-clinical authors, or for the cases where the author is an authoring device. eHealth Ontario invites reviewers of this document to comment on both the need for either of these author types, or a suitable value set should they be included.
- 2.) Currently the value set for the code for dataEnterer is set to HealthcareProviderRoleType. However this value set does not allow for the possibility of non-clinical people entering data into a document. eHealth Ontario invites reviewers of this document to comment on a suitable value set for this class.
- 3.) The informant class contains two related code systems, classCode and code. If the value of classCode taken from the value set RoleClassMutualRelationship is PRS, for personal relationship, we use PersonalRelationshipRoleType, usually, for the code. However, if the classCode is something other than PRS, that value set for code is not sufficient. eHealth Ontario invites reviewers of this document to comment on the need for classCode values other than PRS in this case, and appropriate value sets for code, should they be needed.

1.3 Background

This guide contains information about the format of the CDA Header as it should be implemented, including the appropriate value sets for Ontario. For general background information about CDA, please refer to the HL7 International website (URL: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7).

There are three levels of CDA documents. A level one CDA document contains human readable information only in the document body as some kind of non-structured, non-XML content. A level two document adds structure to the information, dividing the human readable content into sections. Level three incorporates the addition of coded, machine readable entries to the sections, adding semantic interoperability.

All CDA documents, regardless of level have a fully coded, structured header. This guide contains detailed instructions as to how to construct this header for use in the Ontario EHR.

1.3.1 Ontario vs. Pan-Canadian and International Standards

If pan-Canadian and International standards are available, why does Ontario create their own standards?

- Pan-Canadian and International standards have been developed in a number of clinical and administrative domains. These standards are intended to cover the needs and requirements of jurisdictions across the country and around the world. As such, there are elements of these standards that are not appropriate in Ontario and need to be removed / constrained. We would expect jurisdictional differences to be small and manageable, primarily focused on legislative and practice differences amongst the jurisdictions.
- Standards being developed/proposed for use in Ontario by eHealth Ontario are subsets of pan-Canadian and International standards and are quite closely aligned, taking into account Ontario constraints.
- Where there are no pan-Canadian or International standards, the eHealth Standards Program works with projects to develop Ontario standards which are subsequently proposed for consideration as pan-Canadian standards.
- For all Ontario standards, the eHealth Standards Program works with Infoway Standards Collaborative working groups to ensure that Ontario requirements are incorporated into relevant pan-Canadian standards.

1.4 Audience

The audience for this document includes eHealth Ontario Programs and any organizations implementing the specifications contained in this Implementation Guide.

The intended audience includes technical and business audiences who will use the guide to develop implementations and validate that these implementations conform to the specifications and to the requirements of stakeholder organizations. Readers are expected to have some basic understanding of CDA methodology and implementations.

1.5 Scope

This document provides guidance for implementations supporting the electronic transfer of Clinical Document information between devices, systems, and applications in the Health Care space, leveraging international standards, enhancing and constraining as required for use in Ontario.

The scope of this implementation guide is the specification of the constraints required in Ontario for the CDA Header. The specification for body of individual document types and the specification of section and entry level templates are out of scope.

1.6 Release Mechanism and Updates

1.6.1 Distribution

A copy of this implementation guide and related documentation are available in electronic format upon request from the eHealth Ontario Architecture Program Office. (email: architecture@ehealthontario.on.ca)

1.6.2 Update frequency

Future updates will be made on an as-needed basis.

1.7 Referenced Documents

In the development of this Implementation Guide, the Project team referenced material from various sources. (See [Table 1: Reference Document](#))

Document Name	Version	Comments
CDA R2 Normative Standard	R2, 2005	http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7
The CDA Book by Keith W. Boone		Springer; ISBN 978-0-85729-335-0
Pan-Canadian CDA Header Implementation Guide	1.1	https://infocentral.infoway-inforoute.ca/2_Standards/1_pan-Canadian_Standards/Messaging/3_Clinical_Document_Architecture_(CDA)/CDA_Header
pan-Canadian Data Type Specification	R02.04.05	https://infocentral.infoway-inforoute.ca/2_Standards/1_pan-Canadian_Standards/Messaging/s_Common_Services_%28HL7_v3%29/Data_Types_-_Current_Releases/MR_02.05_-_Data_Types
IHE Patient Care Coordination Technical Framework, Volume 2, section 4.1	Revision 8.0, August 2012	http://www.ihe.net/Technical_Framework/upload/IHE_PCC_TF_Vol2.pdf
US Consolidated CDA guide	May 2012	http://www.hl7.org/implement/standards/product_brief.cfm?product_id=258
eHealth Ontario CDA Header Vocabulary Guide	Dec 2013	Included with this Implementation Guide

Table 1: Reference Documents

1.8 Acronyms

Acronym	Description
CDA	Clinical Document Architecture
c-CDA	Consolidated CDA
ebXML	Electronic Business eXtensible Markup Language
HL7	Health Level Seven
iEHR	Interoperable Electronic Health Record
IHE	Integrating the Health Care Enterprise
LOINC	Logical Observation Identifiers Names and Codes
OID	Object Identifier
PCC	Patient Care Coordination (domain at IHE)
RIM	Reference Information Model
SNOMED CT	Systematized Nomenclature Of Medicine Clinical Terms

Table 2: Acronyms

1.9 Assumptions

The following assumptions have been identified as applicable to this Implementation Guide Volume.

Subject Area	Additional Considerations
CDA R2	The specifications have been developed following the HL7 CDA R2 (Health Level 7 Clinical Document Architecture Release 2) development methodology. It is assumed that readers of this specification have a basic understanding of HL7 CDA R2 development methodology. Refer to the HL7 Release documentation (available to HL7 members at www.hl7.org) and Canada Health Infoway Draft CDA Header Implementation Guide (available to members at https://svn.emri.infoway-inforoute.ca/2_Standards) to augment this document.
OID	Object Identifiers (OID), except for those pertaining to terminology / vocabulary systems, are expected to be addressed across all specifications and are not specifically called out in this document.
Privacy & Security	Privacy and security policy implications are typically addressed across all specifications but are not specifically called out in this document. It is assumed that the definition of a CDA Header does not have any privacy or security implications until it is implemented as part of a complete system. It is assumed that any privacy or security implications will be addressed in other systems' implementation guides.

Table 3: Assumptions

1.10 Risks

None identified.

2. Business-based Considerations

The following sections identify business-based considerations.



The developers of this Implementation Guide do not assert that the set of implementation considerations and guidelines are complete.

2.1 Security and Privacy Considerations

Prior to implementing, an organization should appropriately complete an analysis of privacy and security issues in their environment, including Threat Risk Assessment (TRA) and Privacy Impact Assessment (PIA) and implement the recommendations of those assessments. Care should be taken to ensure that the confidentiality and integrity of Personal Health Information in transit and at rest can be maintained at a level that is appropriate for the implementing organization.

2.2 Code sets

Any value or code sets mentioned in this document are found in the referenced document eHealth Ontario CDA Header Vocabulary Guide. See also Section 4 Vocabulary-based considerations.

2.3 OID

There are many places in this implementation guide that the use of OIDs is required. OIDs are object identifiers that serve as worldwide unique names for objects. All OIDs used in eHealth Ontario projects must conform to eHealth Ontario's OIDs Policy. eHealth Ontario maintains a registry of OIDs for use in Ontario. eHealth projects and all OIDs to be used within these projects should be obtained from this registry.

For more information, or to obtain the proper OIDs for use in the Clinical Documents project, please refer to the **Object Identifier Service** section in the **Ontario EHR Interoperability Standards** webpage (URL: <http://www.ehealthontario.on.ca/en/why-standards>). The OID Registration Form is also available for download on this webpage.

2.4 Requests for change

Change requests for this implementation guide can be directed to the eHealth Ontario Architecture Program Office-email address at:
architecture@ehealthontario.on.ca

3. Implementation Considerations



The developers of this Standard do not assert that the set of implementation considerations and guidelines are complete.

3.1 Conformance Conventions Used in This Guide

3.1.1 Open and Closed Templates

CDA supports two kinds of templates, open and closed.

In open templates, all of the features of the CDA R2 base specification are allowed except as constrained by the templates. The sender and receiver agree on a certain set of content to be exchanged, and it is understood that the sender can include extra information, but that the receiver does not have to be able to interpret that information. Anything extra that is sent must be able to be safely discarded. This is the most common type of template.

By contrast, a closed template specifies everything that is allowed and nothing further may be included. If there are extra elements in the information being sent, the receiver is allowed to reject the information. This is most often done if there are legal requirements that certain data not be sent.

All templates in this guide are open templates unless specifically stated otherwise.

3.1.2 Conformance Verbs (Keywords)

The following definitions of the conformance verbs are provided in the HL7 Version 3 Publishing Facilitator's Guide (<http://www.hl7.org/v3ballot/html/help/pfg/pfg.htm>):

- **SHALL:** Required/Mandatory.
- **SHOULD:** Best Practice/Recommendation
- **MAY:** Acceptable/Permitted

The following are the definitions of the attribute conformance as defined in the Pan-Canadian Implementation Guide volume 0:

- **Mandatory (Must Exist)**
A valid instance of this message must include all mandatory content elements.
- **Populated (Expected to Exist)**
Content elements in this category must be present in all circumstances. However, on occasion, values for these elements will not be present and a Null Flavour would be provided to indicate why the data is not being provided (e.g. masked for hidden/protected data, unable to send due to regulatory constraint).
- **Required (May Exist)**
These content elements may or may not be present in the message but implementers are required to support the interchange of this information.
- **Optional (May or May Not be Supported)**
These content elements may or may not be present and there is no requirement for implementers to support the interchange of this information.

The following table summarizes the mapping between conformance verbs and attributes conformance as they are used in this document:

Conformance Verbs	Attribute conformance defined in Pan-Canadian context
SHALL	Mandatory: expressed with the keyword "SHALL". The data SHALL be sent and the use of nullFlavor is explicitly precluded. Note that any element declared to be Mandatory must have a minimum cardinality of one. Populated: expressed with the keyword "SHALL". The data SHALL be sent if available and the use of nullFlavor is explicitly required to indicate why valid data is not provided. Note that any element declared to be Populated must have a minimum cardinality of one. Required: expressed with the keyword "SHALL SUPPORT". The data SHALL be sent if available. Note that any element declared to be Required has a minimum cardinality of zero.
SHOULD	Optional: expressed with the keyword "SHOULD". The data SHOULD be sent if available, but may be omitted. Note that any element declared Optional has a minimum cardinality of zero.

Table 4: Conformance verbs and attributes mapping

Examples of use conformance verbs to convey attribute conformance

1. Example of use of the conformance verbs to express Mandatory attributes:
SHALL contain at least one [1..*] id and SHALL NOT contain nullFlavor.
`<id extension="999021" root="2.16.840.1.113883.19"/>`
2. Example of use of the conformance verbs to express Populated attributes:
SHALL contain exactly one [1..1] id and SHALL contain a nullFlavor if no value is provided.
`<id nullFlavor="NI"/>`
3. Example of use of the conformance verbs to express Required attributes:
SHALL SUPPORT up to one [0..1] effectiveTime
4. Example of use of the conformance verbs to express Optional attributes:
SHOULD contain zero or one [0..1] effectiveTime

3.1.3 Cardinality

When the conformance is Mandatory or Populated the number of allowable occurrences of an element must be at least 1. The cardinality is expressed as [1..1] or [1..*], depending on whether or not the element can repeat. Furthermore, both Mandatory and Populated use the verb SHALL. As explained above, the former prohibits the use of nullFlavor and the latter allows the use of nullFlavor when the values are not available to indicate where the data is not being provided.

If an element is Required or Optional, the number of allowable occurrences of an element may be 0; the cardinality will be expressed as [0..1] or [0..*], depending on whether or not the element can repeat.

3.1.4 Vocabulary Conformance

See Section 4. Vocabulary-base Considerations

3.1.5 Null Flavor

Sometimes data is not available to be sent in the messages or clinical documents: an item may be unknown, not relevant, or not computable. In HL7, a flavor of null, or nullFlavor, describes the reason for missing data.

Example: nullFlavor

```
<effectiveTime nullFlavor="NA"/>
```

Refer to the eHealth Ontario CDA Header Vocabulary Guide for detail.

3.1.6 XPath Notation

This document uses XML Path Language (XPath) notation in conformance statements and elsewhere to identify the Extended Markup Language (XML) elements and attributes within the CDA document instance to which various constraints are applied. The implicit context of these expressions is the root of the document. This notation provides a mechanism that will be familiar to developers for identifying parts of an XML document.

The path is constructed from node names and attribute names (prefixed by a '@') and concatenated with a '/' symbol.

Example: XML document example

```
<author>
  <assignedAuthor>
    ...
    <code codeSystem='2.16.840.1.113883.6.96' codeSystemName='SNOMED CT' code='
    310512001' displayName='Medical oncologist (occupation)' />
    ...
  </assignedAuthor>
</author>
```

In the above example, the code attribute of the code could be selected with the XPath expression below.

```
author/assignedAuthor/code/@code
```

4. Vocabulary-based Considerations



The developers of this Standard do not assert that the set of implementation considerations and guidelines are complete.

4.1 Vocabulary Conformance

The templates in this document draws vocabulary content from several terminology code systems such as LOINC® and SNOMED CT®. These vocabularies are defined in various supporting specifications and may be maintained by other bodies, as is the case for the LOINC® and SNOMED CT® vocabularies.

Note that value-set identifiers (e.g., Value Set 2.16.840.1.113883.1.11.78 Observation Interpretation (HL7) STATIC) do not appear in CDA document instances; they tie the conformance requirements of an implementation guide to the appropriate code system for validation. To uniquely identify a code used in a CDA document instance, the code system OID is used.

Value-set bindings adhere to HL7 Vocabulary Working Group best practices, and include both a conformance verb (SHALL, SHOULD, and MAY.) with an indication of STATIC binding. For Ontario implementation, the value set binding is set to STATIC value sets only. Static value sets use dates as the versioning mechanism to identify the value set required to support the specified CDA attribute for implementation.

Dynamic value sets on the other hand do not specify a particular version of a value set and implementers would be expected to check that the value set content is current prior to data transmission. This type of value set increases complexity for initial implementation and will be considered as business requirements arise.

- The conformance verb “SHALL” corresponds to the coding strength “Coded with No Extensibility (CNE)” which indicates no codes outside of the defined value set can be used for interoperability.
- The conformance verb “SHOULD” corresponds to “Coded With Extensibility (CWE)” which indicates content from the defined value set is strongly recommended to be implemented first, prior to examining inclusion of local codes. Coding strength CNE is used wherever possible to guarantee the highest level of interoperability. Use of coding strength CWE eases implementation, however interoperability will suffer as further negotiations between systems are required to transmit codes outside of the agreed upon value set content.
- The third type of vocabulary binding is a simplified constraint, used when the binding is to a single code, and includes the meaning of the code.

Example: Binding to a single code Vocabulary Conformance Statement

SHALL be fixed to the code 11405-4 (Problem List) from the code system LOINC having the OID 2.16.840.1.113883.6.1 effective 1995-04-24 and SHALL NOT contain nullFlavor.

The notation conveys the actual code (11450-4), the code’s displayName (Problem List), the OID of the codeSystem from which the code is drawn (2.16.840.1.113883.6.1), and the codeSystemName (LOINC).

HL7 Data Types Release 1 requires the codeSystem attribute unless the underlying data type is “Coded Simple” or “CS”, in which case it is prohibited. The displayName and the codeSystemName are optional, but recommended, in all cases.

The above example would be properly expressed as follows.

Example: XML expression of a single-code binding

```
<code code="11450-4" codeSystem="2.16.840.1.113883.6.1"/>
<!-- or -->
<code code="11450-4" codeSystem="2.16.840.1.113883.6.1"
  displayName="Problem List" codeSystemName="LOINC"/>
```

A full discussion of the representation of vocabulary is outside the scope of this document; for more information, see the HL7 V3 Normative Edition 2010 sections on Abstract Data Types and XML Data Types Release 1 (R1).

There is a discrepancy in the implementation of translation code versus the original code between HL7 Data Types R1 and the convention agreed upon for this specification. The R1 data type requires the original code in the root. This implementation guide specifies the standard code in the root, whether it is original or a translation. This discrepancy is resolved in HL7 Data Types R2.

Example: XML expression of Translation code example

```
<code code='206525008' displayName='neonatal necrotizing enterocolitis'
  codeSystem='2.16.840.1.113883.6.96' codeSystemName='SNOMED CT'>
  <translation code='NEC-1' displayName='necrotizing enterocolitis' codeSystem='2.16.840.1.113883.19'/>
</code>
```

5. Ontario EHR CDA Header Implementation

This template describes constraints that apply to the CDA header as it should be implemented in Ontario. This header reflects the constraints that are defined in the other CDA implementation guides (see references), in order to align as closely as possible with existing implementations.

5.1 Guiding Principles

All specifications will align with International and pan-Canadian Standards. With the four exceptions noted below, any Data Type, Cardinality, Optionality, Value Set or Fixed Value not specified will be exactly as written in the HL7 CDA R2 standard.

- All Date and Time Data Types will conform with the Canadian Realm Date and Time Data Type, except where noted.
- All Name Data Types will conform with the Canadian Realm Person Name Data Type, except where noted.
- All Address Data Types will conform with the Canadian Realm Address Data Type, except where noted.
- All Tele-communications Data Types will conform with the Canadian Realm Telecom Data Type, except where noted.

5.2 Clinical Document RIM Attributes

5.2.1 Clinical Document Header/*realmCode*

Defines the realm code for use by Ontario, Canada.

SHALL contain exactly one [1..1] *realmCode* to be fixed to the code CA-ON from the code system HL7Realm having the OID 2.16.840.1.113883.5.1124 effective 2012-08-02.

5.2.2 ClinicalDocument/*typeId*

The *typeId* is a technology-neutral explicit reference to this CDA, Release Two specification.

SHALL contain exactly one [1..1] *typeId*.

- a. This *typeId* SHALL contain exactly one [1..1] @root to be fixed to 2.16.840.1.113883.1.3 and SHALL NOT contain nullFlavor.
- b. This *typeId* SHALL contain exactly one [1..1] @extension to be fixed to "POCD_HD000040" and SHALL NOT contain nullFlavor.

5.2.3 ClinicalDocument/*templateId*

CDA provides a mechanism to reference a template that has been assigned a unique identifier using the *templateId* attribute. A ClinicalDocument that conforms to the Ontario Header specification shall contain at least the Ontario header *templateId*.

SHALL contain one or more [1..*] templateId :

- a. The first templateId SHALL contain exactly one [1..1] @root to be fixed to 2.16.840.1.113883.3.239.34.1 that represents the Ontario CDA Header and SHALL NOT contain nullFlavor.

5.2.4 ClinicalDocument/@classCode

SHALL contain exactly one [1..1] @classCode

- a. classCode SHALL be fixed to the code DOCCLIN from the code system ActClass having the OID 2.16.840.1.113883.5.6 effective 2013-03-18 and SHALL NOT contain nullFlavor.

5.2.5 ClinicalDocument/@moodCode

SHALL contain exactly one [1..1] @moodCode

- a. moodCode SHALL be fixed to the code EVN (event) from the code system ActMood having the OID 2.16.840.1.113883.5.1001 effective 2009-08-01 and SHALL NOT contain nullFlavor.

5.2.6 ClinicalDocument/id

Represents the unique instance identifier of a clinical document.

SHALL contain exactly one [1..1] globally unique id and SHALL NOT contain nullFlavor.

5.2.7 ClinicalDocument/code

The code specifies the particular type of document (e.g. Discharge Care Summary).

SHALL contain exactly one [1..1] code

- a. code SHALL comply with the following value set assertion, effective 2013-11-21: the set of codes in the value set ClinicalReportDocumentType having the OID 2.16.840.1.113883.3.239.12.34 and SHALL NOT contain nullFlavor.

5.2.8 ClinicalDocument/title

Represents the title of the document.

SHALL SUPPORT exactly one [1..1] title

5.2.9 ClinicalDocument/effectiveTime

Represents the document creation time, when the document first came into being. Where the CDA document is a transform from an original document in some other format, the ClinicalDocument.effectiveTime is the time the original document is created.

SHALL contain exactly one [1..1] effectiveTime and SHALL NOT contain nullFlavor

5.2.10 ClinicalDocument/confidentialityCode

Confidentiality code indicates the appropriate control on disclosure of information in the document. Confidentiality is a required contextual component of CDA, where the value expressed in the header holds true for the entire document, unless overridden by a nested value.

SHALL contain exactly one [1..1] confidentialityCode

- a. confidentialityCode SHALL comply with the following value set assertion, effective 2008-12-17:
 - the set of codes in the expansion of pan-Canadian value set 2.16.840.1.113883.2.20.3.139
 - x_BasicConfidentialityKind STATIC and SHALL NOT contain nullFlavor.

5.2.11 ClinicalDocument/languageCode

Specifies the primary human language the document is represented in.

SHALL contain exactly one [1..1] languageCode

- a. languageCode SHALL be fixed to the code “eng-CA” or “fra-CA” (3-letter ISO 639-3 language code and 2-letter ISO 3166-1 country code) from value set assertion, effective 2008-12-17: - the set of codes in the expansion of pan-Canadian value set 2.16.840.1.113883.2.20.3.51
- LanguageCode STATIC and SHALL NOT contain nullFlavor.

5.2.12 ClinicalDocument/setId

Represents an identifier that is common across all document revisions.

SHOULD contain zero or one [0..1] setId.

- a. If setId is present versionNumber SHALL be present and SHALL NOT contain nullFlavor.

5.2.13 ClinicalDocument/versionNumber

An integer value used to version successive replacement documents.

SHOULD contain zero or one [0..1] versionNumber.

- a. If versionNumber is present setId SHALL be present and SHALL NOT contain nullFlavor.

5.3 Participations and Roles

5.3.1 RecordTarget

The recordTarget records the information about the patient whose health information is described by the clinical document.

SHALL contain at least one [1..*] recordTarget.

- a. recordTarget SHALL contain exactly one [1..1] patientRole and SHALL NOT contain nullFlavor.
 - i. patientRole SHALL contain at least one [1..*] id which SHALL NOT contain nullFlavor.
 - ii. patientRole SHALL SUPPORT zero or more [0..*] addr
 - iii. patientRole SHALL SUPPORT zero or more [0..*] telecom
 - iv. patientRole SHALL contain exactly one [1..1] patient and SHALL NOT contain nullFlavor.
 - 1. patient SHALL contain at least one [1..*] name.
 - 2. patient SHALL contain exactly one [1..1] administrativeGenderCode and SHALL comply with the following value set assertion, effective 2008-12-17: - the set of codes in the expansion of pan-Canadian value set 2.16.840.1.113883.1.11.1
 - AdministrativeGender STATIC
 - 3. patient SHALL SUPPORT exactly one [1..1] birthTime.
 - 4. patient SHOULD contain zero or one [0..1] maritalStatusCode and SHALL comply with the following value set assertion, effective 2013-03-18: - the set of codes in the expansion of value set 2.16.840.1.113883.1.11.12212 MaritalStatus STATIC.
 - 5. patient SHOULD contain zero or more [0..*] languageCommunication.

- a. languageCommunication SHALL contain at least one [1..1] languageCode which SHALL comply with the following value set assertion, 2012-05-31: - the set of codes in the expansion of value set 2.16.840.1.113883.2.20.3.190 LanguageCode STATIC
 - b. languageCommunication SHOULD contain zero or one [0..1] modeCode and SHALL comply with the following value set assertion, effective 2008-12-17: the set of codes in the expansion of value set 2.16.840.1.113883.1.11.12249 LanguageAbilityMode STATIC.
 - c. languageCommunication SHOULD contain zero or one [0..1] proficiencyLevelCode which SHALL comply with the following value set assertion, effective 2008-12-17: the set of codes in the expansion of value set 2.16.840.1.113883.1.11.12199 LanguageAbilityProficiency STATIC
 - d. languageCommunication SHOULD contain zero or one [0..1] preferenceInd.
6. patient SHOULD contain zero or more [0..*] guardian
- a. guardian SHALL SUPPORT zero or more [0..*] id.
 - b. guardian SHALL SUPPORT zero or one [0..1] code which SHALL comply with the following value set assertion, effective 2008-12-17: the set of codes in the expansion of value set 2.16.840.1.113883.2.20.3.90 PersonalRelationshipRoleType STATIC.
 - c. guardian SHALL SUPPORT zero or more [0..*] addr
 - d. guardian SHALL SUPPORT zero or more [0..*] telecom
 - e. guardian SHALL contain exactly one [1..1] guardianPerson or exactly one [1..1] guardianOrganization
 - i. If guardianPerson is present
 - 1. guardianPerson SHALL contain at least one [1..*] name
 - ii. If guardianOrganization is present
 - 1. guardianOrganization SHALL contain at least one [1..*] id
 - a. If id contains nullFlavor then name SHALL NOT contain nullFlavor
 - 2. guardianOrganization SHALL contain at least one [1..*] name.
 - a. If name contains nullFlavor then id SHALL NOT contain nullFlavor
 - 3. guardianOrganization SHALL SUPPORT zero or more [0..*] addr.
 - 4. guardianOrganization SHALL SUPPORT zero or more [0..*] telecom.
- v. patientRole SHALL SUPPORT zero or one [0..1] providerOrganization.
- 1. providerOrganization SHALL contain at least one [1..*] id
 - a. If id contains nullFlavor then name SHALL NOT contain nullFlavor
 - 2. providerOrganization SHALL contain at least one [1..*] name.
 - a. if name contains nullFlavor then id SHALL NOT contain nullFlavor
 - 3. providerOrganization SHALL SUPPORT zero or more [0..*] addr.
 - 4. providerOrganization SHALL SUPPORT zero or more [0..*] telecom.

5.3.2 Author

The author element represents the creator of the clinical document. The Author provides demographic information on the author(s) of the document.

SHALL contain at least one [1..*] author and SHALL NOT contain nullFlavor.

- a. author SHALL SUPPORT zero or one [0..1] functionCode and SHALL comply with the following value set assertion effective 2008-12-17: the set of codes in the expansion of value set 2.16.840.1.113883.2.20.3.87 ParticipationFunction STATIC.
- b. author SHALL contain exactly one [1..1] time.
- c. author SHALL contain exactly one [1..1] assignedAuthor and SHALL contain a nullFlavor if no value is provided.
 - i. assignedAuthor SHALL contain at least one [1..*] id
 - ii. assignedAuthor SHALL SUPPORT zero or one [0..1] code which SHALL comply with the following value set assertion effective 2008-12-17: the set of codes in the value set 2.16.840.1.113883.3.239.12.7 HealthcareProviderRoleType STATIC
 - iii. assignedAuthor SHALL SUPPORT zero or more [0..*] addr
 - iv. assignedAuthor SHALL SUPPORT zero or more [0..*] telecom
 - v. assignedAuthor SHALL contain exactly one [1..1] assignedPerson or exactly one [1..1] assignedAuthoringDevice.
 - 1. If assignedPerson is present
 - i. assignedPerson SHALL contain at least one [1..*] name
 - 2. If assignedAuthoringDevice is present
 - i. assignedAuthoringDevice SHALL contain exactly one [1..1] manufacturerModelName
 - ii. assignedAuthoringDevice SHALL contain exactly one [1..1] softwareName
 - vi. assignedAuthor SHALL SUPPORT zero or one [0..1] representedOrganization
 - 1. representedOrganization SHALL contain at least one [1..*] id
 - a. If id contains nullFlavor then name SHALL NOT contain nullFlavor
 - 2. representedOrganization SHALL contain one at least one [1..*] name.
 - a. If name contains nullFlavor then id SHALL NOT contain nullFlavor
 - 3. representedOrganization SHALL SUPPORT zero or more [0..*] addr.
 - 4. representedOrganization SHALL SUPPORT zero or more [0..*] telecom.

5.3.3 DataEnterer

The dataEnterer element represents the person who transferred the content, written or dictated by someone else, into the clinical document. 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, and the dataEnterer adds that information to the electronic system. In other words, a dataEnterer transfers information from one source to another (e.g., transcription from paper form to electronic system).

SHOULD contain zero or one [0..1] dataEnterer

- a. dataEnterer SHALL SUPPORT zero or one [0..1]time
- b. dataEnterer, SHALL contain exactly one [1..1] assignedEntity
 - i. assignedEntity SHALL contain at least one [1..*] id
 - ii. assignedEntity SHOULD contain zero or one [0..1] code which SHOULD comply with the following value set assertion, effective 2008-12-17: the set of codes in the value set 2.16.840.1.113883.3.239.12.7 HealthcareProviderRoleType STATIC
 - iii. assignedEntity SHALL SUPPORT zero or more [0..*] addr
 - iv. assignedEntity SHALL SUPPORT zero or more [0..*] telecom
 - v. assignedEntity SHALL contain exactly one [1..1] assignedPerson
 - 1. assignedPerson SHALL contain at least one [1..*] name
 - vi. assignedEntity SHALL SUPPORT zero or one [0..1] representedOrganization
 - 1. representedOrganization SHALL contain at least one [1..*] id
 - a. If id contains nullFlavor then name SHALL NOT contain nullFlavor
 - 2. representedOrganization SHALL contain at least one [1..*] name.
 - a. If name contains nullFlavor then id SHALL NOT contain nullFlavor
 - 3. representedOrganization SHALL SUPPORT zero or more [0..*] addr.
 - 4. representedOrganization SHALL SUPPORT zero or more [0..*] telecom.

5.3.4 Informant

The informant element describes the source of the information in a medical document.

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.

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.

SHOULD contain zero or more [0..*] informant

- a. SHALL contain exactly one [1..1] assignedEntity OR exactly one [1..1] relatedEntity
 - i. If assignedEntity is present
 1. assignedEntity SHALL contain one or more [1..*] id
 2. assignedEntity SHALL SUPPORT zero or more [0..*] addr
 3. assignedEntity SHALL SUPPORT zero or more [0..*] telecom
 4. assignedEntity SHOULD contain zero or one [0..1] code which SHOULD comply with the following value set assertion effective 2008-12-17: the set of codes in the value set 2.16.840.1.113883.3.239.12.7 HealthcareProviderRoleType STATIC
 5. assignedEntity SHALL contain exactly one [1..1] assignedPerson
 - a. assignedPerson SHALL contain at least one [1..*] name
 6. assignedEntity SHALL SUPPORT zero or one [0..1] representedOrganization
 - a. representedOrganization SHALL contain at least one [1..*] id
 - i. If id contains nullFlavor then name SHALL NOT contain nullFlavor
 - b. representedOrganization SHALL contain at least one [1..*] name.
 - i. If name contains nullFlavor then id SHALL NOT contain nullFlavor
 - c. representedOrganization SHALL SUPPORT zero or more [0..*] addr.
 - d. representedOrganization SHALL SUPPORT zero or more [0..*] telecom.
 - ii. If relatedEntity is present
 1. relatedEntity SHALL contain exactly one [1..1] @classCode which SHALL comply with the following value set assertion, effective 2013-03-18: the set of codes in the value set 2.16.840.1.113883.1.11.19316 RoleClassMutualRelationship STATIC.
 2. relatedEntity SHOULD contain zero or one [0..1] code which SHALL comply with the following value set assertion, effective 2013-11-25: the set of codes in the value set 2.16.840.1.113883.2.20.3.90 PersonalRelationshipRoleType STATIC
 3. relatedEntity SHALL SUPPORT zero or more [0..*] addr
 4. relatedEntity SHALL SUPPORT zero or more [0..*] telecom
 5. relatedEntity SHALL SUPPORT zero or one [0..1] effectiveTime
 6. relatedEntity SHALL contain exactly one [1..1] relatedPerson
 - a. relatedPerson SHALL contain at least one [1..*] name

5.3.5 Custodian

The custodian element represents the organization that is in charge of maintaining the document. The custodian is the steward that is entrusted with the care of the document. Every CDA document has exactly one custodian.

SHALL contain exactly one [1..1] custodian and SHALL NOT contain nullFlavor.

- a. custodian SHALL contain exactly one [1..1] assignedCustodian.
 - i. assignedCustodian SHALL contain exactly one [1..1] representedCustodianOrganization.
 - 1. representedCustodianOrganization SHALL contain at least one [1..*] id SHALL NOT be nullFlavor
 - 2. representedCustodianOrganization SHALL contain exactly one [1..1] name and SHALL NOT be nullFlavor.
 - 3. representedCustodianOrganization SHALL SUPPORT zero or one [0..1] telecom.
 - 4. representedCustodianOrganization SHALL SUPPORT zero or one [0..1] addr.

5.3.6 InformationRecipient

The informationRecipient element records the intended recipient of the information at the time the document is created.

SHALL SUPPORT zero or more [0..*] informationRecipient.

- a. informationRecipient SHALL contain exactly one [1..1] intendedRecipient.
 - i. intendedRecipient SHALL SUPPORT zero or more [0..*] id
 - ii. intendedRecipient SHALL SUPPORT zero or more [0..*] telecom.
 - iii. intendedRecipient SHALL SUPPORT zero or more [0..*] addr.
 - iv. intendedRecipient SHALL SUPPORT zero or one [0..1] informationRecipient
 - 1. If receivedOrganization is not present or contains nullFlavor, informationRecipient SHALL NOT contain nullFlavour
 - 2. informationRecipient SHALL contain at least one [1..*] name
 - v. intendedRecipient SHALL SUPPORT zero or one [0..1] receivedOrganization.
 - 1. If informationRecipient is not present or contains nullFlavor, receivedOrganization SHALL NOT contain nullFlavor.
 - 2. receivedOrganization SHALL SUPPORT at least one [1..*] id
 - a. If id contains nullFlavor then name SHALL NOT contain nullFlavor
 - 3. receivedOrganization SHALL contain at least one [1..*] name
 - a. If name contains nullFlavor then id SHALL NOT contain nullFlavor
 - 4. receivedOrganization SHOULD SUPPORT zero or more [0..*] telecom.
 - 5. receivedOrganization SHOULD SUPPORT zero or more [0..*] addr.

5.3.7 LegalAuthenticator

The legalAuthenticator identifies the person who has legally authenticated the document and must be present if the document has been legally authenticated.

SHOULD contain zero or one [0..1] legalAuthenticator.

- a. legalAuthenticator SHALL contain exactly one [1..1] time.
- b. legalAuthenticator SHALL contain exactly one [1..1] signatureCode which SHALL be fixed to the code S from the code system ParticipationSignature having the OID 2.16.840.1.113883.5.89 effective 2012-08-02
- c. legalAuthenticator SHALL contain exactly one [1..1] assignedEntity.
 - i. assignedEntity SHALL contain at least one [1..*] id
 - ii. assignedEntity SHALL SUPPORT zero or one [0..1] code and SHALL comply with the following value set assertion effective 2008-12-17: the set of codes in the value set 2.16.840.1.113883.3.239.12.7 HealthcareProviderRoleType STATIC.
 - iii. assignedEntity SHALL SUPPORT zero or more [0..*] addr
 - iv. assignedEntity SHALL SUPPORT zero or more [0..*] telecom
 - v. assignedEntity SHALL contain exactly one [1..1] assignedPerson.
 - 1. assignedPerson SHALL contain at least one [1..*] name

- vi. assignedEntity SHALL SUPPORT zero or one [0..1] representedOrganization.
 - 1. representedOrganization SHALL contain at least one [1..*] id.
 - a. If id contains nullFlavor then name SHALL NOT contain nullFlavor
 - 2. representedOrganization SHALL contain at least one [1..*] name.
 - a. If name contains nullFlavor then id SHALL NOT contain nullFlavor
 - 3. representedOrganization SHALL SUPPORT zero or more [0..*] addr.
 - 4. representedOrganization SHALL SUPPORT zero or more [0..*] telecom.

5.3.8 Authenticator

The authenticator identifies a participant or participants who attested to the accuracy of the information in the document.

SHOULD contain zero or more [0..*] authenticator.

- a. authenticator SHALL contain exactly one [1..1] time
- b. authenticator SHALL contain exactly one [1..1] signatureCode which SHALL be fixed to the code S from the code system Participationsignature having the OID 2.16.840.1.113883.5.89 effective 2013-03-18.
- c. authenticator SHALL contain exactly one [1..1] assignedEntity
 - i. assignedEntity SHALL contain at least one [1..*] id
 - ii. assignedEntity SHALL SUPPORT zero or one [0..1] code which SHALL comply with the following value set assertion effective 2012-05-31: the set of codes in the expansion of value set 2.16.840.1.113883.3.239.12.7 HealthcareProviderRoleType STATIC
 - iii. assignedEntity SHALL SUPPORT zero or more [0..*] addr
 - iv. assignedEntity SHALL SUPPORT zero or more [0..*] telecom
 - v. assignedEntity SHALL contain exactly one [1..1] assignedPerson
 - 1. assignedPerson SHALL contain at least one [1..*] name
- vii. assignedEntity SHALL SUPPORT zero or one [0..1] representedOrganization
 - 1. representedOrganization SHALL contain at least one [1..*] id
 - a. If id contains nullFlavor then name SHALL NOT contain nullFlavor
 - 2. representedOrganization SHALL contain at least one [1..*] name.
 - a. If name contains nullFlavor then id SHALL NOT contain nullFlavor
 - 3. representedOrganization SHALL SUPPORT zero or more [0..*] addr.
 - 4. representedOrganization SHALL SUPPORT zero or more [0..*] telecom.

5.3.9 Participant

The participant element identifies other supporting participants, including parents, relatives, caregivers, insurance policyholders, guarantors, and other participants related in some way to the patient.

A supporting person or organization is an individual or an organization with a relationship to the patient. A supporting person who is playing multiple roles would be recorded in multiple participants (e.g., emergency contact and next-of-kin)

SHOULD contain zero or more [0..*] participant

- a. participant SHALL contain exactly one [1..1] @typeCode and SHALL comply with the following value set assertion effective 2013-03-18: the set of codes in the expansion of value set 2.16.840.1.113883.1.11.10901 ParticipationType STATIC.
- b. participant SHALL SUPPORT zero or one [0..1] functionCode and SHALL comply with the following value set assertion effective 2008-12-17: the set of codes in the expansion of value set 2.16.840.1.113883.2.20.3.87 ParticipationFunction STATIC.
- c. participant SHALL SUPPORT zero or one [0..1] time
- d. participant SHALL contain exactly one [1..1] associatedEntity

- i. associatedEntity SHALL SUPPORT zero or more [0..*] id
- ii. associatedEntity SHALL SUPPORT zero or one [0..1] code which SHALL comply with the following value set assertion, effective 2013-11-25: the set of codes in the value set 2.16.840.1.113883.2.20.3.90 PersonalRelationshipRoleType STATIC
- iii. associatedEntity SHALL SUPPORT zero or more [0..*] addr
- iv. associatedEntity SHALL SUPPORT zero or more [0..*] telecom
- v. associatedEntity SHALL SUPPORT zero or one [0..1] associatedPerson
 - 1. associatedPerson SHALL contain at least one [1..*] name
- vi. associatedEntity SHALL SUPPORT zero or one [0..1] scopingOrganization
 - 1. scopingOrganization SHALL contain at least one [1..*] id
 - a. If id contains nullFlavor then name SHALL NOT contain nullFlavor
 - 2. scopingOrganization SHALL contain at least one [1..*] name.
 - a. If name contains nullFlavor then id SHALL NOT contain nullFlavor
 - 3. scopingOrganization SHALL SUPPORT zero or more [0..*] addr.
 - 4. scopingOrganization SHALL SUPPORT zero or more [0..*] telecom.
- e. Unless otherwise specified by the document specific header constraints, when participant/@typeCode is IND, associatedEntity/@classCode SHALL be selected from ValueSet 2.16.840.1.113883.11.20.9.33 INDRoleclassCodes STATIC 2011-09-30

5.4 Related Acts and Related Documents

5.4.1 InFulfillmentOf

The inFulfillmentOf element represents orders that are fulfilled by this document.

SHOULD contain zero or more [0..*] inFulfillmentOf.

- a. inFulfillmentOf SHALL contain exactly one [1..1] order and SHALL NOT contain null flavour.
 - i. order SHALL contain exactly one [1..1] @classCode and SHALL comply with the following value set assertion, effective 2012-08-02: - the set of codes in the expansion of value set 2.16.840.1.113883.1.11.13856 ActClassRoot STATIC
 - ii. order SHALL contain one or more [1..*] id
 - iii. order SHALL SUPPORT zero or one [0..1] code
 - iv. order SHOULD contain zero or one [0..1] priorityCode and SHALL comply with the following value set assertion, effective 2012-08-02: - the set of codes in the expansion of value set 2.16.840.1.113883.1.11.16866 ActPriority STATIC

5.4.2 DocumentationOf

The documentationOf element represents the main act, such as a colonoscopy or a cardiac stress study, being documented.

SHOULD contain zero or more [0..*] documentationOf.

- a. documentationOf SHALL contain exactly one [1..1] serviceEvent.
 - i. serviceEvent SHALL contain exactly one [1..1] @classCode and SHALL comply with the following value set assertion, effective 2012-08-02: - the set of codes in the expansion of value set 2.16.840.1.113883.1.11.13856 ActClassRoot STATIC
 - ii. serviceEvent SHALL SUPPORT zero or more [0..*] id
 - iii. serviceEvent SHALL SUPPORT zero or one [0..1] code,
 - iv. serviceEvent SHALL SUPPORT zero or one [0..1] effectiveTime.
 - v. serviceEvent SHALL SUPPORT zero or more [0..*] performer
 - 1. performer SHALL contain one [1..1] @typeCode and SHALL comply with the following value set assertion effective 2012-08-02: the set of codes in the expansion of value set 2.16.840.1.113883.1.11.19601 x_ServiceEventPerformer STATIC.

2. performer SHALL SUPPORT zero or one [0..1] functionCode and SHALL comply with the following value set assertion effective 2012-08-02: the set of codes in the expansion of value set 2.16.840.1.113883.2.20.3.87 ParticipationFunction STATIC.
3. performer SHALL SUPPORT zero or one [0..1] time
4. performer SHALL contain exactly one [1..1] assignedEntity.
 - a. assignedEntity SHALL contain at least one [1..*] id
 - b. assignedEntity SHALL SUPPORT zero or one [0..1] code and SHALL comply with the following value set assertion effective 2008-12-17: the set of codes in the value set 2.16.840.1.113883.3.239.12.7 HealthcareProviderRoleType STATIC.
 - c. assignedEntity SHALL SUPPORT zero or more [0..*] addr
 - d. assignedEntity SHALL SUPPORT zero or more [0..*] telecom
 - e. assignedEntity SHALL contain exactly one [1..1] assignedPerson.
 - i. assignedPerson SHALL contain at least one [1..*] name
 - f. assignedEntity SHALL SUPPORT zero or one [0..1] representedOrganization.
 - i. representedOrganization SHALL contain at least one [1..*] id.
 1. If id contains nullFlavor then name SHALL NOT contain nullFlavor
 - ii. representedOrganization SHALL contain at least one [1..*] name.
 1. If name contains nullFlavor then id SHALL NOT contain nullFlavor
 - iii. representedOrganization SHALL SUPPORT zero or more [0..*] addr.
 - iv. representedOrganization SHALL SUPPORT zero or more [0..*] telecom.

5.4.3 ComponentOf

The componentOf element contains the encompassing encounter for this document. The encompassing encounter represents the setting of the clinical encounter during which the document act(s) or ServiceEvent occurred.

In order to represent providers associated with a specific encounter, they are recorded within the encompassingEncounter as participants.

SHOULD contain zero or one [0..1] componentOf

- a. componentOf SHALL contain exactly one [1..1] encompassingEncounter
 - i. encompassingEncounter SHALL SUPPORT zero or more [0..*] id
 - ii. encompassingEncounter SHALL SUPPORT zero or one [0..1] code and SHALL comply with the following value set assertion, effective 2008-12-17: the set of codes in the expansion of value set 2.16.840.1.113883.2.20.3.2 ActCareEventType STATIC
 - iii. encompassingEncounter SHALL contain exactly one [1..1] effectiveTime
 - iv. encompassingEncounter SHALL SUPPORT zero or one [0..1] dischargeDispositionCode and SHALL comply with the following value set assertion, effective 2008-12-17: the set of codes in the expansion of value set 2.16.840.1.113883.2.20.3.43 EncounterDischargeDisposition STATIC
 - v. encompassingEncounter SHALL SUPPORT zero or more [0..*] encounterParticipant
- a. encounterParticipant SHALL contain exactly one [1..1]@ typeCode and SHALL comply with the following value set assertion, effective 2008-12-17: the set of codes in the expansion of the value set 2.16.840.1.113883.1.11.19600 x_EncounterParticipant STATIC
 - b. encounterParticipant SHALL SUPPORT zero or one [0..1] time
 - c. encounterParticipant SHALL contain exactly one [1..1] assignedEntity
 - i. assignedEntity SHALL contain at least one [1..*] id
 - ii. assignedEntity SHALL SUPPORT zero or one [0..1] code and SHALL comply with the following value set assertion effective 2008-12-17: the set of codes in the value set 2.16.840.1.113883.3.239.12.7 HealthcareProviderRoleType STATIC.
 - iii. assignedEntity SHALL SUPPORT zero or more if available [0..*] addr
 - iv. assignedEntity SHALL SUPPORT zero or more [0..*] telecom
 - v. assignedEntity SHALL contain exactly one [1..1] assignedPerson.

1. assignedPerson SHALL contain at least one [1..*] name
- vi. assignedEntity SHALL SUPPORT zero or one [0..1] representedOrganization.
 1. representedOrganization SHALL contain at least one [1..*] id.
 - a. If id contains nullFlavor then name SHALL NOT contain nullFlavor
 2. representedOrganization SHALL contain at least one [1..*] name.
 - a. If name contains nullFlavor then id SHALL NOT contain nullFlavor
 3. representedOrganization SHALL SUPPORT zero or more [0..*] addr.
 4. representedOrganization SHALL SUPPORT zero or more [0..*] telecom.
- vii. encompassingEncounter SHALL SUPPORT zero or one [0..1] responsibleParty
 - a. responsibleParty SHALL contain exactly one [1..1] assignedEntity
 - i. assignedEntity SHALL contain at least one [1..*] id
 - ii. assignedEntity SHALL SUPPORT zero or one [0..1] code and SHALL comply with the following value set assertion effective 2008-12-17: the set of codes in the value set 2.16.840.1.113883.3.239.12.7 HealthcareProviderRoleType STATIC.
 - iii. assignedEntity SHALL SUPPORT zero or more if available [0..*] addr
 - iv. assignedEntity SHALL SUPPORT zero or more [0..*] telecom
 - v. assignedEntity SHALL contain exactly one [1..1] assignedPerson.
 1. assignedPerson SHALL contain at least one [1..*] name
 - vi. assignedEntity SHALL SUPPORT zero or one [0..1] representedOrganization.
 1. representedOrganization SHALL contain at least one [1..*] id.
 - a. If id contains nullFlavor then name SHALL NOT contain nullFlavor
 2. representedOrganization SHALL contain at least one [1..*] name.
 - a. If name contains nullFlavor then id SHALL NOT contain nullFlavor
 3. representedOrganization SHALL SUPPORT zero or more [0..*] addr.
 4. representedOrganization SHALL SUPPORT zero or more [0..*] telecom.
- viii. encompassingEncounter SHOULD contain zero or more [0..*] location.
 - a. location SHOULD contain zero or one [0..1] healthCareFacility.
 - i. healthCareFacility SHALL SUPPORT zero or more [0..*] id.
 - ii. healthCareFacility SHOULD contain zero or one [0..1] code and SHALL comply with the following value set assertion effective 2008-12-17: the set of codes in the expansion of 2.16.840.1.113883.2.20.3.182 ServiceDeliveryLocationRoleType STATIC.
 - iii. healthCareFacility SHOULD contain zero or one [0..1] location.
 1. location SHOULD contain zero or one [0..1] name
 2. location SHOULD contain zero or one [0..1] addr
 - iv. healthCareFacility SHOULD contain zero or one [0..1] serviceProviderOrganization.
 1. serviceProviderOrganization SHALL contain at least one [1..*] id.
 1. If id contains nullFlavor then name SHALL NOT contain nullFlavor
 - a. serviceProviderOrganization SHALL contain at least one [1..*] name.
 2. If name contains nullFlavor then id SHALL NOT contain nullFlavor
 - a. serviceProviderOrganization SHALL SUPPORT zero or more [0..*] addr.
 - b. serviceProviderOrganization SHALL SUPPORT zero or more [0..*] telecom.

5.4.4 RelatedDocument

The relatedDocument section identifies and is required any related parent documents, such as an earlier version, or a document being replaced.

SHOULD contain zero or one [0..1] relatedDocument

- a. relatedDocument SHALL contain exactly one [1..1] typeCode and SHALL comply with the following value set assertion, effective 2012-08-02: the set of codes in the value set 2.16.840.1.113883.1.11.11610 x_ActRelationshipDocument
- b. relatedDocument SHALL contain exactly one [1..1] parentDocument
 - i. parentDocument SHALL contain exactly one [1..1]@ classCode and SHALL be fixed to the code DOCCLIN from the code system ActClass having the OID 2.16.840.1.113883.5.6 effective 2009-08-01
 - ii. parentDocument SHALL contain exactly one [1..1]@ moodCode and SHALL be fixed to the code EVN (event) from the code system ActMood having the OID 2.16.840.1.113883.5.1001 effective 2009-08-01
 - iii. parentDocument SHALL contain one or more [1..*] id which SHALL NOT contain nullFlavor.
 - iv. parentDocument SHALL SUPPORT zero or one [0..1] code and SHALL comply with the following value set assertion, effective 2013-11-21: the set of codes in the value set 2.16.840.1.113883.3.239.12.30 ClinicalReportDocumentType
 - v. parentDocument SHALL SUPPORT zero or one [0..1] text
 - vi. parentDocument SHOULD contain zero or one [0..1] setId.
 - a. If setId is present versionNumber SHALL be present and SHALL NOT contain nullFlavor.
 - vii. parentDocument SHOULD contain zero or one [0..1] versionNumber.
 - a. If versionNumber is present setId SHALL be present and SHALL NOT contain nullFlavor.

5.5 Canadian Realm Data Types

Please refer to the pan-Canadian Data Type Specification (R02.04.05) for complete definitions of the Canadian Realm Data Types.

5.5.1 Canadian Realm Address Data Type

The Canadian Realm Address data type is based on AD.FULL flavor defined in the pan-Canadian Data Type Specification.

- a. SHALL SUPPORT use, which SHALL comply with the following value set assertion, effective 2008-12-17: - the set of codes in the expansion of pan- Canadian value set 2.16.840.1.113883.2.20.3.143 which SHOULD be selected from value set x_BasicPostalAddressUse STATIC
- b. SHOULD contain zero to four [0..4] lines of address information sent as plain text and separated by delimiter tag.
- c. SHALL SUPPORT zero or one [0..1] postalCode.
- d. SHALL SUPPORT zero or one [0..1] city.
- e. SHALL SUPPORT zero or one [0..1] state, which SHOULD be selected from the code system ISO 3166-2 alpha codes having the OID 1.0.3166.2.
- f. SHALL SUPPORT address parts (part types), which SHOULD comply with the following value set assertion, effective 2008-12-17: the set of codes in the expansion of 2.16.840.1.113883.2.20.3.143 x_BasicAddressPartType STATIC.

5.5.2 Canadian Realm Date Time Data Type

The Canadian Realm Date and Time data type is based on TS.DATETIME flavor defined in the pan-Canadian Data Type Specification.

This flavour constrains the timestamp to permit the “date”, “time” and “timezone” portions of the timestamp to be specified. Partial dates may be specified only if no time component is specified. Time may be omitted, and partial times may be specified. If a time is specified, the “timezone” portion of the timestamp must be specified. Local time is calculated as an offset of GMT (e.g. “- 0800” for Pacific Time Zone, -0500 for Eastern Time Zone).

The grammar for the date/time is: YYYY[MM[DD[HH[MM[SS[.S[S[S[S]]]]]]][+/-ZZZZ] (24 characters) and

- a. SHALL contain the year
- b. SHOULD be precise to the month
- c. SHOULD be precise to the day
- d. SHOULD be precise to the hour
- e. SHOULD be precise to the minute
- f. SHOULD be precise to the second
- g. SHOULD be provided with up to 4 decimal places of precision if the seconds are provided.
- h. If more precise than day, SHALL include time-zone offset

5.5.3 Canadian Realm Date Time Interval Data Type

The Canadian Realm Date Time Interval data type is based on IVL<TS.DATETIME> flavor defined in the pan-Canadian Data Type Specification (R02.04.05).

- a. SHALL contain 2 of the attributes: low, high and width.
- b. The content of low and high SHALL be conformant to the Canadian Realm Data and Time Data Type.
- c. The content of width SHALL be conformant to PQ Data Type R1.

5.5.4 Canadian Realm Personal Name Data Type

- a. The Canadian Realm Personal Name data type is based on PN.FULL flavor defined in the pan-Canadian Data Type Specification (R02.04.05) with additional Ontario constraints. SHALL contain one [1..1] attribute use and the content SHOULD be selected from value set x_BasicPersonNameUse.
- b. SHOULD contain zero to two [0..2] prefix elements.
- c. SHALL contain one to two [0..2] given elements.
- d. The first occurrence of a given name is the “first name”. The requirement for a middle name is met through an additional repetition of “given name”.
- e. SHALL contain zero or one [0..1] family element.
- f. SHOULD contain zero to two [0..2] suffix elements.
- g. SHOULD contain zero or one [0..1] qualifier, if present, SHOULD comply with the following value set assertion, effective 2008-12-17: the set of codes in the expansion of 2.16.840.1.113883.2.20.3.149 x_FullPersonNamePartqualifier STATIC.
- h. The name parts SHALL comply with the following value set assertion, effective 2008-12-17: the set of codes in the expansion of 2.16.840.1.113883.2.20.3.141 x_BasicPersonNamePartType STATIC.
- i. Each part SHALL be constrained to a maximum of 75 characters.
- j. The minimal number of name parts SHALL be 1.
- k. The maximal number of name parts SHALL be 7.

5.5.5 Canadian Realm Telecom Data Type

The Canadian Realm Telecom data type is based on TEL.ALL flavor defined in the pan-Canadian Data Type Specification.

- a. SHALL contain one [1..1] attribute use and the content SHOULD be selected from value set x_BasicTelecommunicationAddressUse.

- b. SHALL contain one [1..1] attribute value and the content SHOULD follow the specifications as described in <http://www.ietf.org/rfc/rfc3966.txt>.
- c. SHOULD contain zero or one [0..1] scheme and SHOULD be selected from x_PhoneURLScheme or x_URIURLScheme Value Set.
- l. SHOULD contain zero or one [0..1] useablePeriod.

5.5.6 Canadian Realm II Data Type

The Canadian Realm II data type is based on II flavor defined in the pan-Canadian Data Type Specification (R02.04.05).

- a. SHALL contain exactly one [1..1] II.root which SHALL NOT contain nullFlavor. It is constrained to either an OID or a UUID (GUID) and has a maximum length of 200 characters.
- b. SHALL SUPPORT zero or one [0..1] II.extension which has a maximum of 50 characters. It is considered case-sensitive for comparison purposes. Non-case-sensitive identifiers should be exchanged in upper-case. There are no further restrictions on the extension component.

6. Glossary

Term	Definition	Reference
Attributes	Attributes are abstractions of the data captured about classes. Attributes capture separate aspects of the class and take their values independent of one another. Attributes assume data values that are parsed in HL7 messages. Example: 'LocationStatus' is an attribute of the 'Location' class. In an HL7 message the 'LocationStatus' attribute assumes data values such as 'ACTIVE', 'SUSPENDED' and 'TERMINATED'.	http://www.hl7.org/e/hr/documents/public/documents/Glossary%20of%20terms.pdf
Cardinality	Property of a data element (the number of times a data element may repeat within an individual occurrence of an object view) or column in the HL7 Hierarchical Message Description (the minimum and maximum number of occurrences of the message element).	http://www.hl7.org/v3ballot/html/help/glossary/glossary.htm
Clinical Document Architecture	See HL7 Clinical Document Architecture.	
Code System	Synonym for a terminology. See Terminology.	
HL7 Clinical Document Architecture (CDA)	The HL7 Clinical Document Architecture (CDA) is a document markup standard that specifies the structure and semantics of "clinical documents" for the purpose of exchange. A clinical document is a documentation of clinical observations and services, with the following characteristics: Persistence – A clinical document continues to exist in an unaltered state, for a time period defined by local and regulatory requirements (NOTE: There is a distinct scope of persistence for a clinical document, independent of the persistence of any XML-encoded CDA document instance). Stewardship – A clinical document is maintained by an organization entrusted with its care. Potential for authentication - A clinical document is an assemblage of information that is intended to be legally authenticated. Context - A clinical document establishes the default context for its contents. Wholeness - Authentication of a clinical document applies to the whole and does not apply to portions of the document without the full context of the document.	http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7

Term	Definition	Reference
	Human readability – A clinical document is human readable.	
	A CDA document is a defined and complete information object that can include text, images, sounds, and other multimedia content.	
Logical Observation Identifier Names and Codes (LOINC)	A system of names and codes for clinical observations distributed by the Regenstrief Institute of Health Care through the LOINC® database. This database consists, among other things, of a series of records intended to identify the test result, clinical observation or test requests. There are several attributes or fields that define each record. The level of detail in the LOINC® field definitions was intended to distinguish tests that are usually distinguished as separate test results within the master file of existing laboratory systems.	Infoway Glossary – (MR02.05.00) https://infocentral.infoway-inforoute.ca/2_Standards/1_pan-Canadian_Standards/v_Glossary
Query	A user's or system's request for information from a database or search engine.	http://en.wikipedia.org/wiki/Query
Systematized Nomenclature of Human and Veterinary Medicine Clinical Terms (SNOMED-CT®)	SNOMED CT is a comprehensive clinical terminology that provides clinical content and expressivity for clinical documentation and reporting. SNOMED CT contains concepts for both human and non-human medicine and some of the covered domains are: • Clinical findings, including disorders • Procedures, broadly defined as including all health related activities. • Observable entities which, when given a value, provide a specific finding or assertion about health related information. SNOMED CT can be used in health care software applications that focus on collection of clinical data, linking to clinical knowledge bases, information retrieval, as well as data aggregation and exchange. The content in SNOMED CT provides a standard for clinical information that can be used as a common reference point for improving data analysis and information access and thereby results in improved patient outcomes. The terminology is comprised of concepts; descriptions, which contain terms that explain the concepts; and relationships, which define the type of the association between two related concepts.	http://ihtsdo.org/fileadmin/user_upload/doc/en_us/faq.html
Terminology	"The terms that are characterized by special reference within a discipline are called the terms of the discipline and, collectively, they form the terminology. Terms that function in general reference over a variety of languages are simply "words," and their totality is a "vocabulary". The role of terminology is to define the meaning of the data - for example, it changes data to information through instantiation of semantic rules. It is the human readable value a user sees, it allows for intersystem interoperability by disambiguation of the message contents, is required for data aggregation, and is the single most important component for	Infoway Glossary – (MR02.05.00) https://infocentral.infoway-inforoute.ca/2_Standards/1_pan-Canadian_Standards/

Term	Definition	Reference
	interoperability.	v_Glossary
Value Set	A uniquely identifiable set of valid concept representations, where any concept representation can be tested to determine whether or not it is a member of the <i>value set</i> .	IHTSDO Glossary http://ihtsdo.org/fileadmin/user_upload/doc/en_us/gl.html
Vocabulary	A synonym for Terminology. See Terminology.	

Table 5: Glossary

Appendix A. CDA Examples

A.1 Canadian Realm Address Data Type

```
<addr use="H">
  Apt A5 123 Some Street<delimiter/>
  <city>Edmonton</city>
  <state>AB</state>
  <postalCode>A1B2C3</postalCode>
  <country>CA</country>
</addr>
```

A.2 Canadian Realm Date Time Data Type

```
<effectiveTime value="201208021340-0500"/>
```

A.3 Personal Name Data Type

```
<name use="L">
  <prefix>Mr</prefix>
  <given>John</given>
  <given qualifier="IN">W</given>
  <family>Smith</family>
</name>
```

A.4 Canadian Realm Telecom Type

```
<telecom use="WP" xsi:type="FAX" value="tel:+1-555-555-4002"/>
```

```
<telecom use="WP" xsi:type="TEL" value="tel:+14169237867;ext=200"/>
```

A.5 Record Target Example

```
<recordTarget typeCode="RCT" contextControlCode="OP">
  <patientRole>
    <id extension="12345" root="2.16.840.1.113883.19"/>
    <addr use="H">
      17 King Street<delimiter/>
      <city>Toronto</city>
      <state>ON</state>
      <postalCode>M2K2J1</postalCode>
      <country>CA</country>
    </addr>
    <telecom value="tel:(416)555-1212" use="H"/>
    <patient classCode="PSN" determinerCode="INSTANCE">
      <id root="2.16.840.1.113883.4.20" extension="666112999"/>
      <name use="L">
        <family>Nuclear</family>
        <given>John</given>
        <prefix>Mr.</prefix>
        <suffix>II</suffix>
      </name>
    </patient>
  </patientRole>
</recordTarget>
```

```

<administrativeGenderCode code="M" codeSystem="2.16.840.1.113883.5.1"
displayName="Male"/>
<birthTime value="19441021"/>
<maritalStatusCode code="M" displayName="Married"
codeSystem="2.16.840.1.113883.5.2" codeSystemName="MaritalStatusCode"/>
<guardian classCode="GUARD">
  <addr use="H">
    Unit 20 301 Main Street<delimiter/>
    <city>Toronto</city>
    <state>ON</state>
    <postalCode>M2K1J2</postalCode>
    <country>CA</country>
  </addr>
  <telecom value="tel:(418)555-1212" use="H"/>
  <guardianPerson classCode="PSN" determinerCode="INSTANCE">
    <name>
      <prefix>Ms.</prefix>
      <given>Susan</given>
      <given qualifier="IN">S</given>
      <family>Script</family>
    </name>
  </guardianPerson>
</guardian>
</patient>
<providerOrganization classCode="ORG" determinerCode="INSTANCE">
  <id root="2.16.840.1.113883.4.284" extension="2121"/>
  <name>Good Health Clinic</name>
  <telecom use="WP" value="tel:(418)555-1212"/>
  <addr>
    21 North Ave<delimiter/>
    <city>Mississauga</city>
    <state>ON</state>
    <postalCode>M2J2H2</postalCode>
    <country>CA</country>
  </addr>
</providerOrganization>
</patientRole>
</recordTarget>

```

A.6 Custodian Example

```

<custodian>
  <assignedCustodian>
    <representedCustodianOrganization>
      <id extension="99999999" root="2.16.840.1.113883.4.6"/>
      <name>Community Health and Hospitals</name>
      <telecom value="tel: 555-555-1002" use="WP"/>
      <addr>
        1002 Healthcare Drive <delimiter/>
        <city>Toronto</city>
        <state>ON</state>
        <postalCode>M2G1X1</postalCode>
        <country>Canada</country>
      </addr>
    </representedCustodianOrganization>
  </assignedCustodian>
</custodian>

```

A.7 DocumentationOf Example

```
<documentationOf typeCode="DOC">
  <serviceEvent classCode="ACT">
    <id root="1.2.840.113619.2.62.994044785528.114289542805"/>
    <id extension="123453" root="1.2.840.113619.2.62.994044785528.26"/>
    <code code="93041" displayName="Rhythm ECG, one to three leads; tracing only without
interpretation and report" codeSystem="2.16.840.1.113883.6.12" codeSystemName="CPT4"/>
    <effectiveTime value="20080813222400"/>
    <performer typeCode="PRF">
      <templateId root="2.16.840.1.113883.10.20.6.2.1"/>
      <assignedEntity>
        <id extension="121008" root="2.16.840.1.113883.19.5"/>
        <code code="208D00000X" codeSystem="2.16.840.1.113883.6.101"
codeSystemName="NUCC" displayName="General Practice"/>
        <addr nullFlavor="NI"/>
        <telecom nullFlavor="NI"/>
        <assignedPerson>
          <name>
            <given>Matthew</given>
            <family>Care</family>
            <suffix>MD</suffix>
          </name>
        </assignedPerson>
      </assignedEntity>
    </performer>
  </serviceEvent>
</documentationOf>
```

A.8 Order Fulfillment Entry Example

```
<inFulfillmentOf typeCode="FLFS">
  <order classCode="ENC" moodCode="RQO">
    <id extension="Request1" root="2.16.840.1.113883.19.4.27 "
assigningAuthorityName="HealthCentre"/>
    <!-- {root}.27= accession number list *Note this is an example OID. -->
    <priorityCode code="A" codeSystem="2.16.840.1.113883.1.11.16866" codeSystemName="HL7 Act
Priority" displayName="ASAP"/>
  </order>
</inFulfillmentOf>
```

A.9 Participant Example for a Supporting Person

```
<participant typeCode="IND" contextControlCode="OP">
  <associatedEntity classCode="NOK">
    <code code="MTH" codeSystem="2.16.840.1.113883.5.111"/>
    <addr>
      7 King Street<delimiter/>
      <city>Toronto</city>
      <state>ON</state>
      <postalCode>M2K2J1</postalCode>
      <country>CA</country>
    </addr>
    <telecom value="tel:(416)123-2012" use="WP"/>
    <associatedPerson>
      <name>
        <prefix>Mrs.</prefix>
        <given>Martha</given>
      </name>
    </associatedPerson>
  </associatedEntity>
</participant>
```

```

        <family>Fuella</family>
      </name>
    </associatedPerson>
  </associatedEntity>
</participant>

```

A.10 Authenticator Example

```

<authenticator typeCode="AUTHEN">
  <time value="20120329100543+0500"/>
  <signatureCode code="S"/>
  <assignedEntity classCode="ASSIGNED">
    <id root="2.16.840.1.113883.19.5" extension="43252"/>
    <addr use="H">
      17 Guenette Street<delimiter/>
      <city>Montreal</city>
      <state>QC</state>
      <postalCode>H7T3L1</postalCode>
      <country>CA</country>
    </addr>
    <telecom use="H" value="tel:(514)555-1003"/>
    <assignedPerson classCode="PSN" determinerCode="INSTANCE">
      <name use="L">
        <given>Henry</given>
        <family>Seven</family>
      </name>
    </assignedPerson>
  </assignedEntity>
</authenticator>

```

A.11 Informant Example with Assigned Person

```

<informant typeCode="INF" contextControlCode="OP">
  <assignedEntity>
    <id extension="KP00017" root="2.16.840.1.113883.19.5"/>
    <addr use="H">
      17 St-Germain Street<delimiter/>
      <city>Montreal</city>
      <state>QC</state>
      <postalCode>H7T1G2</postalCode>
      <country>CA</country>
    </addr>
    <telecom use="H" value="tel:(514)111-7873"/>
    <assignedPerson classCode="PSN" determinerCode="INSTANCE">
      <name use="L">
        <given>Henry</given>
        <family>Seven</family>
      </name>
    </assignedPerson>
  </assignedEntity>
</informant>

```

A.12 Informant Example with Related Person

```

<informant typeCode="INF" contextControlCode="OP">
  <assignedEntity>
    <id extension="KP00017" root="2.16.840.1.113883.19.5"/>
    <addr use="H">

```

```

        17 St-Germain Street<delimiter/>
        <city>Montreal</city>
        <state>QC</state>
        <postalCode>H7T1G2</postalCode>
        <country>CA</country>
    </addr>
    <telecom use="H" value="tel:(514)111-7873"/>
    <relatedPerson classCode="PSN" determinerCode="INSTANCE">
        <name use="L">
            <given>Jean</given>
            <family>First</family>
        </name>
    </relatedPerson>
</assignedEntity>
</informant>

```

A.13 Author Example with Assigned Person

```

<author typeCode="AUTH" contextControlCode="OP">
    <time value="20120329224411+0500"/>
    <assignedAuthor classCode="ASSIGNED">
        <id extension="42423432" root="2.16.840.1.113883.4.390"/>
        <addr>
            Unit 20 301 Main Street N <delimiter/>
            <city>Vancouver</city>
            <state>BC</state>
            <postalCode>V5K2A1</postalCode>
            <country>CA</country>
        </addr>
        <telecom use="WP" value="tel:(604)555-1003"/>
        <assignedPerson classCode="PSN" determinerCode="INSTANCE">
            <name>
                <given>Henry</given>
                <family>Seven</family>
            </name>
        </assignedPerson>
    </assignedAuthor>
</author>

```

A.14 Author Example with Assigned Authoring Device

```

<author typeCode="AUTH" contextControlCode="OP">
    <time value="20120329224411+0500"/>
    <assignedAuthor classCode="ASSIGNED">
        <id extension="42423432" root="2.16.840.1.113883.4.390"/>
        <addr>
            Unit 20 301 Main Street N <delimiter/>
            <city>Vancouver</city>
            <state>BC</state>
            <postalCode>V5K2A1</postalCode>
            <country>CA</country>
        </addr>
        <telecom use="WP" value="tel:(604)555-1003"/>
        <assignedAuthoringDevice classCode="DEV" determinerCode="INSTANCE">
            <manufacturerModelName>New Medical Device</manufacturerModelName>
            <softwareName>Medical Device Report Generator</softwareName>
        </assignedAuthoringDevice>
    </assignedAuthor>
</author>

```