# Implementation Guide for CDA Release 2 – Level 1 and 2 – Care Record Summary (US realm)

# Based on HL7 CDA Release 2.0

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# **Revision History**

April 1, 2005 - First Release

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- 1. The two implementation guides have been merged to become one in response to a ballot comment about the fact that the content of sections shown in a Level 1 conforming CDA Document should be described, even if there is no way to verify conformance.
- 2. Two extensions have been added in an appendix that describe:
  - a. How to determine when two participants mentioned in the document are the same person.
  - b. What the relationship is between any participant and the patient.
  - c. As a consequence of 2.a an 2.b, the PolicyHolderRole vocabulary has been removed.
- 3. As a consequence of #1, their are now two levels of conformance requirements in the one document.
- 4. Examples have been added for nullFlavor.
- 5. A table has been added to help implementors assign participants to roles.
- 6. Clarifications have been added about authors, especially when the author is not a healthcare practitioner.
- 7. Clarifications have been added about the implications of legalAuthenticator, and having a "signature on file".
- 8. The section on other participating entities has been simplified.
- 9. Clarified the meaning of effectiveTime for documentationOf [the episode covered by the summary], and componentOf [the time period covered by the visit or encounter].
- 10. The sections in Level 2 have been revised.
  - a. The LOINC codes are more consistent with Claims Attachments
  - b. The sections can appear in any order.
  - c. There are no required subsections.
  - d. As a consequence of 4.c, the content describing a condition should indicate whether the condition is resolved.
- 11. Examples have been updated.
- 12. Schematron schema has been revised.

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# 1 Care Record Summary

# 1 Introduction

# 1.1 Purpose

The purpose of this document is to describe constraints on the CDA Header and Body elements for Care Record Summary documents. A Care Record Summary document contains patient's relevant health history for some time period. It is intended for communication between healthcare providers.

#### 1.2 Audience

The audience for this document is software developers and consultants responsible for implementation of Electronic Health Record (EHR) systems, Electronic Medical Record (EMR) systems, Patient Health Record (PHR) systems and local, regional and national health information exchange networks who wish to create and / or process CDA documents created according to this specification.

# 1.3 Approach

The approach taken in the development of this specification was to review existing draft and final specifications or implementation guides for similar artifacts in the US and International realms, and to review CDA Header and Body elements and attributes with domain experts, and on that basis, constrain the CDA Header and Body elements.

#### 1.4 Conventions Used in this Guide

Element and attribute names in the text will appear in this font.

Literal attribute values will appear in *this* font.

Conformance requirements appear within this guide in this format, and are sequentially numbered.

- L1-1: This is an example conformance requirement conformance to level 1 requirements.
- **L2-1:** This is an example conformance requirement for conformance to level 2 requirements.

The key words "MUST", "MUST NOT", "REQUIRED", "SHALL", "SHALL NOT", "SHOULD", "SHOULD NOT", "RECOMMENDED", "MAY", and "OPTIONAL" in this document are to be interpreted as described in Internet RFC 2119.

# 1.5 Scope

This specification defines additional constraints on CDA Header and Body elements used in a Care Record Summary document in the US realm, and provides examples of conforming fragments in the body of the document and an example of a conforming XML instance as an appendix.

This Guide specifies two levels of conformance requirements. Level 1 requirements specify constraints upon the CDA Header and the content of the document. Level 2 requirements specify constraints upon the structuredBody of the ClinicalDocument element of the CDA document.

Additional realms and/or internationalization of this document may be considered in future HL7 informative documents. The specification of workflows, messages, or procedures used to negotiate the transfer of care or referral is outside the scope of this specification.

This implementation guide uses Schematron 1.5 for validation. Schematron is a language system for specifying and declaring assertions about arbitrary patterns in XML documents. More information on Schematron is available from the Schematron resource directory at <a href="http://xml.ascc.net/schematron/">http://xml.ascc.net/schematron/</a>.

The constraints in the guide are expressed formally in an appendix as a Schematron schema that must not produce errors when the CDA document is evaluated with schema.

An XSLT stylesheet is provided that is the result of processing this schema with Schematron, and may also be used to validate the content of a CDA document to verify that it meets the guidelines described herein. This is an alternative to Schematron processing. Note that in this document, references to Schematron validation apply equally to the equivalent XSLT validation, although, for brevity, only Schematron is cited.

It is our hope that in the future, HL7 tools will be able to generate similar validation expressions automatically from a formal expression of CDA refined model (RMIM) constraints. The HL7 Template formalism, now in development within Version 3, will provide an unambiguous derivation path from the Reference Information Model (RIM) to sets of validation statements and constraints. Once such a formalism is defined, validation constraints can be generated algorithmically from the model-derived Templates in the same manner that the core CDA schema is generated from its RMIM.

While the HL7 Template formalism is still in development, CDA does provide a mechanism to reference a template or implementation guide that has been assigned a unique identifier. The following example shows how to formally assert the use of this implementation guide. Use of the templateId indicates that the CDA instance not only conforms to the CDA specification, but in addition, conforms to the constraints specified in the referenced template or implementation guide.

# NOTE TO BALLOTERS: The correct template root OID will be inserted in the final released specification.

Figure 1 Use of the templateId element to indicate use of this guide.

Within this guide, the required and optional content within the body are identified. This guide describes the information content of each section, but this cannot be verified by software. Future work will define increasing refined (granular) machine-verifiable processing structures.

# 2 CDA Header

## 2.1 ClinicalDocument

The namespace for CDA Release 2.0 is *urn:hl7-org:v3*. Appropriate namespace declarations must be used in the XML instance of the Clinical Document. This guide does not require use of any specific namespace prefix. Instances should not include the schema declaration<sup>1</sup>.

**L1-1:** The root of a Care Record Summary must be a ClinicalDocument element from the *urn:hl7-org:v3* namespace.

Figure 2 ClinicalDocument Example

#### 2.1.1 General Constraints

Within the clinical document header, the following general guidelines have been applied:

- 1. Any person represented must have a name, and should have addr and telecom information. Any assigned healthcare provider must have a name and furthermore must have addr and telecom information. If the address and/or telecommunications information is unknown, this may be indicated by using a flavor of null, as described under number 3 below.
- 2. Any organization represented must have a name, and addr and telecom information.
- 3. When name, addr or telecom information is unknown where these elements are required to be present, the fact that the information is unknown must be represented using an appropriate value for the nullFlavor attribute on the element. Legal values according to this specification are *UNK*, *NASK*, *ASKU*, or *NAV*, representing unknown, not asked, asked but unknown, or temporarily unavailable, respectively. Use of nullFlavor is shown below in Figure 3.

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<sup>&</sup>lt;sup>1</sup> The CDA Schema is a non-normative artifact. Several different schemas might be used to validate a CDA document. Sending CDA documents with a schema location defined can interfere with validation of a CDA document by the receiver.

Figure 3 Various Uses of nullFlavor

- 4. All times must have precision to the day and must include time zone, with the exception of birthTime and participant/time, which may be to the year, and may omit time zone. Times should be precise to the second where possible<sup>2</sup>.
- 5. All telephone numbers are encoded using a restricted form of the tel: URL scheme, described in the section on Telephone Numbers below.

# 2.1.1.1 Telephone Numbers

Within the specification, telecom elements must provide a contact phone number for the various participants. All telephone or fax numbers are encoded using a restricted form of the tel: or fax: URL schemes (see <a href="RFC 2806">RFC 2806</a>), using the grammar in Figure 4 below. This format simplifies interchange between applications. A telephone number used for voice calls begins with the URL scheme tel:. A facsimile number used for image transmission begins with the URL scheme fax:. If the number is a global phone number, it starts with a plus sign. The remainder is made up of the dialing digits, and may also contain visual separators.

```
telephone-url = telephone-scheme ":" telephone-subscriber
telephone-scheme = "tel" | "fax"
telephone-subscriber = global-phone-number | phone-number
global-phone-number = "+" phone-number
phone-number = 1*phonedigit
phonedigit = DIGIT | visual-separator
visual-separator = "-" | "." | "(" | ")"
```

Figure 4 Restricted URL grammar for telephone or fax communications

- **L1-2:** Telephone numbers must match the regular expression pattern tel: +?[-0-9().]+
- L1-3: At least one dialing digit must be present in the phone number after visual separators are removed.

There is no way to distinguish between an unknown phone number and an unknown email 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, as these are the only required telecommunications address elements within this implementation guide. Thus, in cases where this information is not known, it must be represented using a flavor of null, as shown below.

```
<telecom nullFlavor='UNK' use='WP'>
```

Figure 5 Unknown Telephone number example.

<sup>&</sup>lt;sup>2</sup> For example, when clinical documents are electronically authored, this information should be precise to the second. In other cases, e.g., where the Care Record Summary is transcribed from a paper form by a patient, the author participation time may only be known to the day.

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# 2.1.2 Rendering Information from the CDA Header for Human Presentation

Rendering the information in the header for human presentation is optional. However, un-rendered information cannot be assumed to be authenticated information. Therefore, the judgment of whether to render or not render information in the header should recognize the business need to authenticate the information as well as other business needs.

Recommendations for rendering information from the header include:

- Document title and document dates
- Service and encounter types and date ranges as appropriate
- All persons named along with roles, participations, participation date ranges, identifiers, address and telecom information
- Record Target(s) date-of-birth and age (when document was created)
- Selected organizations named along with roles, participations, participation date ranges, identifiers, address and telecom information
- Other Insurance and guarantor information as appropriate

#### 2.1.3 ClinicalDocument.realmCode

The realmCode is optional. When present, it identifies the realm which may impose specific constraints. It should be an ISO-3166 country code in upper case. The example below shows that this document has constraints imposed on it by the US realm<sup>3</sup>.

<realmCode code='US'/>

Figure 6 ClinicalDocument.realmCode Example

# 2.1.4 ClinicalDocument.typeId

This required element identifies the constraints imposed by CDA Release 2.0 on the content, essentially acting as a version identifier. The value is fixed<sup>4</sup> under this guide to be as shown below in Figure 7.

<typeId extension="POCD\_HD000040" root="2.16.840.1.113883.1.3"/>

Figure 7 ClinicalDocument.typeId Example

L1-4: The extension attribute of the typeId element must be *POCD\_HD000040*.

#### 2.1.5 ClinicalDocument.templateId

This optional element identifies the templates that impose constraints on the content. The example below shows how to declare that a CDA Release 2.0 document conforms to the Level 1 features specified by this guide.

<sup>&</sup>lt;sup>3</sup> This guide is, by definition, for documents in the US realm. A future guide may generalize this one, and define which constraints are imposed by virtue of the realm. There is no present utility to identification of the realm under this guide.

<sup>&</sup>lt;sup>4</sup> The schema already fixes the value of the root attribute to be 2.16.840.1.113883.1.3

Figure 8 ClinicalDocument.templateId Example

#### 2.1.6 ClinicalDocument.id

This required element must be an II data type where the root is a UUID or OSI Object Identifiers (OID). The root uniquely identifies the scope of the extension. The root and extension uniquely identifies the document.

- L1-5: The root attribute of the id element must be a syntactically correct UUID or OID.
- L1-7: OIDs must be represented in dotted decimal notation, where each decimal number is either 0, or starts with a non-zero digit. More formally, an OID must be in the form ([0-2])(.([1-9][0-9]\*|0))+.
- L1-8: OIDs must be no more than 64 characters in length.

<id extension='999021' root='1.3.6.4.1.4.1.2835.2'/>

Figure 9 ClinicalDocument.id Example

Organizations that wish to use OIDs must properly register their OID root, and ensure uniqueness of the OID roots used in identifiers. There are a large number of mechanisms to obtain 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://hl7.amg-hq.net/oid/frames.cfm

Another useful resource lists the many ways to obtain a registered OID Root for free or a small fee, anywhere in the world, 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 implementation guide.

#### 2.1.7 ClinicalDocument.code

This required element specifies the type of the clinical document. The LOINC Summarization of Episode Note document type (LOINC Document Code 34133-9) or any document type that descends from it may be used as the value for ClinicalDocument.code in the CDA Header. Episode in this guide means a period of time. These codes are shown below in Table 1.

LOINC	TYPE OF SERVICE	SETTING	TRAINING/PROFESSIONAL LEVEL
34133-9	SUMMARIZATION OF EPISODE NOTE	{SETTING}	{PROVIDER}
18842-5	DISCHARGE SUMMARIZATION NOTE	{SETTING}	{PROVIDER}
11490-0	DISCHARGE SUMMARIZATION NOTE	{SETTING}	PHYSICIAN
28655-9	DISCHARGE SUMMARIZATION NOTE	{SETTING}	ATTENDING PHYSICIAN
29761-4	DISCHARGE SUMMARIZATION NOTE	{SETTING}	DENTISTRY
34745-0	DISCHARGE SUMMARIZATION NOTE	{SETTING}	NURSING
34105-7	DISCHARGE SUMMARIZATION NOTE	HOSPITAL	{PROVIDER}
34106-5	DISCHARGE SUMMARIZATION NOTE	HOSPITAL	PHYSICIAN
18761-7	TRANSFER SUMMARIZATION NOTE	{SETTING}	{PROVIDER}
28616-1	TRANSFER SUMMARIZATION NOTE	{SETTING}	PHYSICIAN
28651-8	TRANSFER SUMMARIZATION NOTE	{SETTING}	NURSING
34755-9	TRANSFER SUMMARIZATION NOTE	{SETTING}	CRITICAL CARE
34770-8	TRANSFER SUMMARIZATION NOTE	{SETTING}	GENERAL MEDICINE

Table 1 LOINC Document Type Codes

These codes are drawn from LOINC version 2.12, February 2004 and equal the subset of LOINC whose scale is *DOC* and whose status is not *DEL*, and whose type of service is *summarization*.

Note that CDA Release 2.0 states that LOINC is the preferred vocabulary for document type specification. This implementation guide goes further, stating that only the codes listed above may be used for a Care Record Summary. Local codes may be used to further refine the document hierarchy, but if used, shall be embedded in local markup, and shall not be used in the code element of the ClinicalDocument.

- L1-9: The value of /ClinicalDocument/code/@code must come from the appropriate LOINC code subset.
- L1-10: The value of /ClinicalDocument/code/@codeSysem is the OID for LOINC.
- L1-11: The value of /ClinicalDocument/code/@codeSystemName, if present is LOINC.

The LOINC document hierarchy depicted in above is a complete list of all document type codes supported under this specification. It includes codes that are not pre-coordinated with the author training / professional level [codes in bold] and those that are. The use of pre-coordinated document type codes is not recommended, as this would duplicate information potentially present with the CDA document header. However, if pre-coordinated document codes are used, any values present for the author or performer of the service act must be consistent with the LOINC document type.

L1-12: If pre-coordinated document type codes are used, the role code and function code for the author must not conflict with the document type code.

```
<code code='34133-9' codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'
    displayName='SUMMARIZATION OF EPISODE NOTE'
/>
```

Figure 10 ClinicalDocument.code Example

#### 2.1.8 ClinicalDocument.title

The title is an optional element specifies the local name used for the document.

<title>Good Health Clinic Care Record Summary</title>

Figure 11 ClinicalDocument.title Example

#### 2.1.9 ClinicalDocument.effectiveTime

This required element specifies the creation time of the document. The precision of this must be to the day, and the time zone must be specified.

An electronically created Care Record Summary should have an effectiveTime to the second. However, 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 is likely much less.

- L1-13: The effectiveTime element must be precise at least to the day.
- L1-14: The effectiveTime element must have a time zone.

<effectiveTime value='20050303171504+0500'/>

Figure 12 CinicalDocument.effectiveTime Example

# 2.1.10 ClinicalDocument.confidentialityCode

This element is required, and specifies the confidentiality assigned to the document. This implementation guide provides no guidance on documents with respect to the vocabulary used for confidentialityCode, nor treatment or implementation of confidentiality. A CDA Release 2.0 conforming example is shown below.

<confidentialityCode code="N" codeSystem="2.16.840.1.113883.5.25"/>

Figure 13 CinicalDocument.confidentialityCode Example

# 2.1.11 ClinicalDocument.languageCode

This element is required, and specifies the language of the Care Record Summary. Care Record Summaries should be in a human language readable by medical practitioners, care givers and patients. The encoding of the language must be present, and must be in the form nn (see Figure 14) or nn-CC (see Figure 15), where nn is a two letter ISO-639-1 language code in lower case, and CC is a two letter ISO-3166 Country code in upper case. This is a subset of the values defined by RFC 3066.

- L1-15: The languageCode element must be present.
- L1-16: The language code must be in the form nn, or nn-CC.
- **L1-17:** The *nn* portion must be a legal ISO-639-1 language code in lower case.
- L1-18: The CC portion, if present must be an ISO-3166 country code in upper case.

<lanquageCode code='en'/>

Figure 14 ClinicalDocument.languageCode Example with language only

<languageCode code='en-US'/>

Figure 15 ClinicalDocument.languageCode Example with language and country.

#### 2.1.12 ClinicalDocument.setId

The setId element is optional. When present, this must be an II data type where the root is a UUID or OID that uniquely identifies the scope of the extension, and where the extension is an identifier that is unique within the scope of the root identifier for the set of versions of the document, and versionNumber must also be present.

**L1-19:** When setId is present, then versionNumber must be present.

The OID root of ClinicalDocument.id and ClinicalDocument.setId need not be the same under this guide, as these two identifiers may be in separate identifier spaces.

If these identifiers use the same identifier space as defined by the OID root, then the extension of the ClinicalDocument.id must be distinct from ClinicalDocument.setId.

L1-20: Either there is no setId, or then extension and/or root of setId and id are different.

```
<setId extension='999021' root='1.3.6.4.1.4.1.2835.1'/>
```

Figure 16 ClinicalDocument.setId Example

#### 2.1.13 ClinicalDocument.versionNumber

This element is optional unless setId is present, in which case versionNumber must be present.

```
<versionNumber value='1'/>
```

Figure 17 ClinicalDocument.versionNumber Example

#### 2.1.14 ClinicalDocument.copyTime

This has been deprecated in CDA Release 2, and must not be present in conforming instances of a Care Record Summary.

L1-21: No copyTime element is present in the ClinicalDocument.

#### 2.2 **Participants**

This section describes the constraints placed upon CDA Participants described in the CDA Header.

In the HL7 Clinical Document Architecture, Release 2.0 specification, section 4.2.2.13 describes various Participant Scenarios, where a single person can participate in several roles. In these cases, the person should be listed for each role, as described in the CDA Release 2.0 specification. Table 2 on the next page describes the various participations that can be represented in a CDA Release 2.0 document. For each participant, identify each of the roles that they can participate in, and list them in each role. Participants can be identified using an extension described in Appendix F — Extensions to CDA Release 2.0, in order to determine which participants are the same person.

Additional steps need to be taken when the author of the Care Record Summary is the patient, guardian, relation or other care-giver for the patient. Appendix E —Documents Created by Non-Practitioners discusses a these issues.

Authentication requires that the author be able to verify the accuracy of the document.

Legal Authentication requires that the author has the privilege to legally authenticate the document. The patient or other person, such as the guardian or parent may not have that privilege depending upon local regulation.

In many cases it may be desirable to record the relationship between a participant and the patient. The CDA Release 2.0 schema does not directly support this, however, an extension has been described in Appendix F — Extensions to CDA Release 2.0, which supports an element that describes the relationship between the patient and the participant.

				ator	ent			
		iterer	authenticator	egalAuthenticator	ntendedRecipient	ecordTarget	ant	pant
Description	author	dataEnterer	uther	egalA	ntend	ecord	nformant	participant
A person or system that creates the document by entry of information from their own knowledge or application of skills.	10		10	_		_	-	<u></u>
e.g., A physician who dictates a note, a patient who enters their health history information on a form or by entry into automated system, an EKG device, an information system that creates a document based upon information already recorded within its database	√							
A person or system that transfers information from one form or another without creating new information though application of their own knowledge or skills.		<b>V</b>						
e.g., A transcriptionist, a clerk copying information from a form into a document.								
A person or system that verifies the accuracy of the information contained within some portion of the document.								
e.g., A resident who verifies that the content of the document reflects what they dictated, a patient who asserts that the information they entered into a PHR is correct, an information system that asserts that the information has been verified against its data.			√					
A person with the legal right to enter the document into the patient's medical chart, and who has indicated the desire to do so by some mechanism [e.g., signing the document].				,				
i.e., a provider who indicates that the document is complete and may be added to the patient chart.				√				
A person or system that has been selected to receive the information in the document, who is known before completion of the document.					<b>V</b>			
e.g., The patient chart, an EHR system, a provider to whom the patient is being referred.								
The person or system that requested the creation of the document.					,			
e.g., The patient when requesting the creation of the document by pressing a button on form displayed by a PHR system.					√			
The patient whose care is being described within the document.						V		
A person or system that provides information contained within the document.							,	
e.g., A parent of a two-year old, describing the condition of their child, a witness to a significant healthcare event, the patient who describes their symptoms.							√	
A healthcare provider that has performed healthcare in the past for the patient whose care is being described within the document.								,
e.g., A specialist that has provided care in the past, the patient's former PCP, the surgeon who performed a prior procedure.								1
A person that provides additional support to the patient, that is not in any assigned healthcare role by any healthcare organization.								.1
e.g., A parent or other family member, a care-giver, someone who provides transportation to the patient, et cetera.								V
The guarantor for payment of healthcare services given the patient whose care is being described within the document.								<b>√</b>
e.g., A family member, an employer, or another person or organization who has agreed to be responsible for the patient's medical bills.								V
The holder of any insurance policy that may pay for the healthcare services given to the patient whose care is being described within the document.								<b>√</b>
e.g., A family member, an employer (as in the case for a workman's compensation claim), or covered party (as in the case of an automobile accident)								\ \ \

Table 2 Participant Assignment

The participants are listed below in the order they should appear.

# 2.2.1 recordTarget

This element is required and must be the patient or patients whose health history is/are described by this Care Record Summary document.

The addr and telecom elements for the postal address and contact phone number must be present. If unknown or not available, this must be explicitly stated in the elements, using a flavor of null.

- L1-22: At least one recordTarget/patientRole element exists.
- L1-23: The recordTarget/patientRole element has an addr element.
- L1-24: The recordTarget/patientRole element has a telecom element that represents a contact phone number.

The birthTime and administrativeGenderCode must be present, and if unknown must be represented using a flavor of null. Values for administrativeGenderCode should be drawn from the HL7 <u>AdministrativeGender</u> vocabulary.

- L1-25: A patient/birthTime element is present.
- L1-26: A patient/administrativeGenderCode element is present.

The maritalStatusCode, religiousAffiliationCode, raceCode and ethnicGroupCode elements are optional. If present, they should be encoding using appropriate HL7 vocabularies.

The guardian element should be present when the patient is a child.

The providerOrganization element is optional, but if present must include name, addr and telecom elements.

- L1-27: All providerOrganization elements have a name element.
- L1-28: All providerOrganization elements have an addr element.
- L1-29: All providerOrganization elements have a telecom element that is a telephone contact number.

```
<recordTarget>
   <patientRole>
       <id extension="12345" root="2.16.840.1.113883.3.933"/>
       <addr>
           <streetAddressLine>17 Daws Rd.</streetAddressLine>
           <city>Blue Bell</city>
           <state>MA</state>
           <postalCode>02368</postalCode>
           <country>USA</country>
       </addr>
       <telecom value='tel:(781)555-1212' use='HP'/>
       <patient>
           <name>
               <prefix>Mrs.</prefix></prefix>
               <given>Ellen</given>
               <family>Ross</family>
           </name>
           <administrativeGenderCode code="F" codeSystem="2.16.840.1.113883.5.1" />
           <birthTime value="19600127"/>
       </patient>
       oviderOrganization>
           <id extension="M345" root="2.16.840.1.113883.3.933"/>
           <name>Good Health Clinic</name>
           <telecom value='tel:(999)555-1212' use='WP'/>
           <addr>
               <streetAddressLine>21 North Ave</streetAddressLine>
               <city>Burlington</city>
               <state>MA</state>
               <postalCode>01803</postalCode>
               <country>USA</country>
           </addr>
       </providerOrganization>
   </patientRole>
</recordTarget>
```

Figure 18 recordTarget Example

# 2.2.2 author

The author element must be present, and represents the creator of the document. When a portal or patient-operated kiosk is used to create the document, and the end user (e.g., the patient) of the portal provides information that is entered into the document, that user must be recorded as the assignedAuthor. In addition, the application must be recorded as an assignedAuthoringDevice.

```
<author>
   <time value='20050329224411+0500'/>
   <assignedAuthor>
       <id extension='1' root='1.3.6.4.1.4.1.2835.1'/>
       <code code='SELF' codeSystem='2.16.840.1.113883.5.111'/>
           <streetAddressLine>21 North Ave</streetAddressLine>
           <city>Burlington</city>
           <state>MA</state>
           <postalCode>01803</postalCode>
           <country>USA</country>
       </addr>
       <telecom value='tel:(999)555-1212' use='WP'/>
       <assignedPerson>
           <name>
               <prefix>Dr.</prefix>
               <given>Bernard</given>
               <family>Wiseman</family>
               <suffix>Sr.</suffix>
           </name>
       </assignedPerson>
   </assignedAuthor>
</author>
<author>
   <time value='20050329224411+0500'/>
   <assignedAuthor>
       <id extension='1' root='1.3.6.4.1.4.1.2835.1'/>
       <addr>
           <streetAddressLine>21 North Ave</streetAddressLine>
           <city>Burlington</city>
           <state>MA</state>
           <postalCode>01803</postalCode>
           <country>USA</country>
       <telecom value='tel:(999)555-1212' use='WP'/>
       <assignedAuthoringDevice>
           <softwareName>Good Health Clinic System v1.0</softwareName>
       </assignedAuthoringDevice>
   </assignedAuthor>
</author>
```

Figure 19 author Example

The time element must be present, and is the starting time of the author's participation in the creation of the document. The precision of this must be at least to the day, and the time zone must be specified.

- L1-30: The author/time element must be present.
- L1-31: The author/time element must be precise at least to the day.
- L1-32: The author/time element must have a time zone.

An assignedAuthor or assignedAuthoringDevice element must be present, and is the person or device authoring the document. The id, name and a telecom address must be provided for the assignedAuthor. The postal address should be provided when known.

- L1-33: The assignedAuthor/id element must be present.
- **L1-34:** All assignedAuthors have at least one telecom element that contains a contact phone number.

Additional steps may be taken when the author of the Care Record Summary is the patient, guardian, relation or other care giver for the patient, as in the case where a portal or kiosk is used by a patient to create a Care Record Summary for their own use or the use of a care provider.

In order to represent the relationship between the author and the patient, the Patient Relationship extension described in Appendix F —Extensions to CDA Release 2.0 should be used. This is shown below in Figure 20.

```
<assignedAuthor>
       <id extension="12345" root="2.16.840.1.113883.3.933"/>
           <streetAddressLine>17 Daws Rd.</streetAddressLine>
           <city>Blue Bell</city>
           <state>MA</state>
           <postalCode>02368</postalCode>
           <country>USA</country>
       <telecom value='tel:(781)555-1212' use='WP'/>
       <assignedPerson>
           <name>
               <prefix>Mrs.</prefix></prefix>
               <given>Ellen</given>
               <family>Ross</family>
           <crs:asPatientRelationship classCode='PRS'>
               <code code='MTH' codeSystem='2.16.840.1.113883.5.111'/>
           </crs:asPatientRelationship>
</assignedPerson>
   </assignedAuthor>
```

Figure 20 asPatientRelationship example

The assignedAuthoringDevice element must be present when a device facilitates the creation of a document by a patient or other non-practitioner. It must have a softwareName element present when it occurs in the document.

L1-35: When assignedAuthoringDevice is present, the softwareName element must be present.

The use of a device is not the only way for a patient or other non-practitioner to create a Care Record Summary. For example, a patient might fill in a paper form containing the appropriate information, which would then be entered into an EHR system by another person.

#### 2.2.3 dataEnterer

This element is optional, and represents the person who transferred the information from other sources into the Care Record Summary. In portal and Kiosk systems, where the bulk of the information may come from information entered by the patient or other non-provider, the person entering the information should be considered to be both the author and the dataEnterer. 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 the information to the electronic system. A person can participate as both author and dataEnterer.

If the role of the actor is the entry of information from his or her own knowledge or application of skills, that actor should be represented as the author. If one actor provides information to another actor, which filters, reasons, or algorithmically creates new information, then that second actor is also an author, having created information

from its own knowledge or skills. However, that determination is independent from the determination of the first actor's authorship.

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 should be recorded as dataEnterer.

The time element is optional, and represents the starting time of entry of the data. If present, it must be precise to at least the day, and have the time zone. The addr and telecom elements are optional for this element, but name is required.

- L1-36: All dataEnterer/time elements must be precise at least to the day.
- L1-37: All dataEnterer/time elements must have a time zone.
- L1-38: All dataEnterer elements have an assignedEntity/assignedPerson/name element.

```
<dataEnterer>
   <time value='20050329222451+0500'/>
   <assignedEntity>
       <id extension='2' root='1.3.6.4.1.4.1.2835.2'/>
       <assignedPerson>
           <name>
               <prefix>Mrs.</prefix>
               <given>Bernice</given>
               <family>Wiseman</family>
           </name>
       </assignedPerson>
   </assignedEntity>
</dataEnterer>
```

Figure 21 dataEnterer Example

#### 2.2.4 informant

This optional element describes the source of the information in the Care Record Summary. When an informant element is present, the name element is required.

L1-39: An informant must have either an assignedEntity/assignedPerson/name element, or a relatedEntity/relatedPerson/name element.

If it is a mutual relation, the type of relationship must be specified in relatedEntity/@classCode, and should be CON, PRS or PROV. These values comes from the RoleClass vocabulary.

The informant element supports specification of the relationship between the informant and the patient through the assignedEntity or relatedEntity elements. Therefore, the assignedPerson and relatedPerson elements should not include the extension element crs:asPatientRelationship to describe the relationship between the informant and the patient.

L1-40: An informant should not have any assignedEntity/assignedPerson/crs:asPatientRelationship elements, or relatedEntity/relatedPerson/ crs:asPatientRelationship elements.

# 2.2.4.1 Assigned Healthcare Providers

When the informant is a healthcare provider with an assigned role, the informant must be represented using the assignedEntity element (e.g., a nurse's aid who provides information about a recent significant healthcare event that occurred within an acute care facility).

Figure 22 informant Example for healthcare providers in assigned roles.

## 2.2.4.2 Personal Relations

When the informant is a personal relation, that informant must be represented in the relatedEntity element. In that case, the value of relatedEntity/classCode must be *PRS* and the specific personal relationship must be specified in relatedEntity/code using values from the PersonalRelationshipRoleType vocabulary.

**L1-41:** When relatedEntity/@classCode is *PRS*, values in relatedEntity/code shall come from the <u>PersonalRelationshipRoleType</u> vocabulary.

Figure 23 informant Example for a related person.

## 2.2.4.3 Unrelated Person

To record an informant with no (prior) personal relationship to the patient (e.g., a witness to a significant healthcare event) that is not an assigned entity, the value relatedEntity.classCode should be set to *CON*, and relatedEntity.code should not be present.

**L1-42:** When relatedEntity/@classCode is *CON*, relatedEntity/code shall not be present.

Figure 24 informant Example for an unrelated person.

#### 2.2.4.4 Healthcare Providers

To record an informant that provides healthcare to the patient (e.g., the patient primary care provider, when that provider 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, the value of relatedEntity.classCode will be set to *PROV*.

The value of relatedEntity/code should be present and indicate the type of healthcare provider. If present, the values must be drawn from SNOMED CT, using concepts that descend from the *healthcare professional* subtype hierarchy (SNOMED CT Concept ID: 223366009).

**L1-43:** When relatedEntity/@classCode is *PROV*, and relatedEntity/code is present, the value shall come from SNOMED CT.

Figure 25 informant Example for healthcare providers not in assigned roles.

#### 2.2.5 custodian

Custodian is required, and the name, id, telecom and addr elements of it must be present. This must be the custodian of the Care Record Summary document.

- L1-44: A custodian/assignedCustodian/representedCustodianOrganization/name element must be present.
- L1-45: A custodian/assignedCustodian/representedCustodianOrganization/telecom element must be present that contains a telephone contact.
- **L1-46:** A custodian/assignedCustodian/representedCustodianOrganization/addr element must be present.

Systems that allow patients to create Care Record Summaries for their own use should maintain a true and accurate copy of the document. For example, if a Regional Health Information Organization (RHIO) aggregates information from several sources, which it then makes available to the patient in a PHR system that allows the patient to construct a Care Record Summary, that PHR system should maintain a copy of the document and the RHIO should be considered the custodian of the document.

Figure 26 custodian Example

#### 2.2.6 informationRecipient

This is optional. When used in the context of a referral or request for consultation, this is 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 must be the custodian of that chart.

- **L1-47:** At least one of intendedRecipient/informationRecipient or intendedRecipient/recievedOrganization must be present.
- L1-48: All informationRecipient elements have a name element.
- L1-49: All recievedOrganization elements have a name element.
- **L1-50:** All intendedRecipient elements have at least one telecom element that contains a contact phone number.
- L1-51: All intendedRecipient elements have an addr element.

```
<informationRecipient>
   <intendedRecipient>
       <id extension='4' root='1.3.6.4.1.4.1.2835.2'/>
       <addr>
           <streetAddressLine>21 North Ave</streetAddressLine>
           <city>Burlington</city>
           <state>MA</state>
           <postalCode>01803</postalCode>
           <country>USA</country>
       </addr>
       <telecom value='tel:(999)555-1212' use='WP'/>
       <informationRecipient>
           <name>
               <prefix>Dr.</prefix>
               <given>Phil</given>
               <family>Green</family>
           </name>
       </informationRecipient>
       <receivedOrganization>
           <name>Good Health Clinic</name>
       </receivedOrganization>
   </intendedRecipient>
</informationRecipient>
```

Figure 27 informationRecipient Example

# 2.2.7 legalAuthenticator

This is the legal authenticator of the document. It is optional, as Care Record Summaries may be released before legal authentication, based on local policy. It should be present when the author or validator is available with appropriate credentials for legal authentication.

The act of legal authentication requires a certain privilege be granted to the legal authenticator depending up local regulation. In the case of a patient or other non-practitioner authored Care Record Summary document, this privilege may not be available to the author. However, all Care Record Summaries should 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 Care Record Summary. In these cases, the legal authenticator must still be a person accepting responsibility for the document, not the device or system.

The telecom and addr elements of the legalAuthenticator element must be present, as must the name of the assignedPerson.

- L1-52: All legalAuthenticator/assignedEntity elements have at least one telecom element that contains a contact phone number.
- L1-53: All legalAuthenticator/assignedEntity elements have an addr element.
- L1-54: The legalAuthenticator/assignedEntity/assignedPerson element must be present.

```
<legalAuthenticator>
   <time value='20050329224512+0500'/>
   <signatureCode code='S'/>
   <assignedEntity>
       <id extension='1' root='1.3.6.4.1.4.1.2835.1'/>
       <addr>
           <streetAddressLine>21 North Ave</streetAddressLine>
           <city>Burlington</city>
           <state>MA</state>
           <postalCode>01803</postalCode>
           <country>USA</country>
       </addr>
       <telecom value='tel:(999)555-1212' use='WP'/>
       <assignedPerson>
           <name>
               <prefix>Dr.</prefix>
               <given>Bernard</given>
               <family>Wiseman</family>
               <suffix>Sr.</suffix>
           </name>
       </assignedPerson>
   </assignedEntity>
</legalAuthenticator>
```

Figure 28 legalAuthenticator Example

#### 2.2.8 authenticator

An authenticator is optional. The authenticator is the participant who verifies the accuracy of the information in the document. The addr and telecom elements must be present, as must the name of the assignedPerson.

- L1-55: The assignedEntity/addr element of the authenticator element must be present.
- **L1-56:** An assignedEntity/telecom element must be present whose value contains a contact phone number.
- L1-57: The name element of the assignedPerson must be present.

```
<authenticator>
   <time value='20050329224512+0500'/>
   <signatureCode code='S'/>
   <assignedEntity>
       <id extension='3' root='1.3.6.4.1.4.1.2835.1'/>
       <addr>
           <streetAddressLine>21 North Ave</streetAddressLine>
           <city>Burlington</city>
           <state>MA</state>
           <postalCode>01803</postalCode>
           <country>USA</country>
       <telecom value='tel:(999)555-1212' use='WP'/>
       <assignedPerson>
           <name>
               <prefix>Dr.</prefix>
               <given>Bernard</given>
               <family>Wiseman</family>
               <suffix>Jr.</suffix>
           </name>
       </assignedPerson>
   </assignedEntity>
</authenticator>
```

Figure 29 authenticator Example

Automated systems, such as a PHR, that allow a patient or other non-practitioner to generate a Care Record Summary should give special consideration to authentication

permissions because the information contained in the document may come from sources or contain information that a non-practitioner cannot validate<sup>5</sup>.

# 2.2.9 participant

This element is used to list other supporting participants, including: parents, relatives, care givers, insurance policy holders, guarantors, and other participants related in some way to patient. See also the section on the documentationOf element below for information about healthcare providers who perform healthcare during the episode being summarized.

In general, the time element of the participant is optional, but if present, it indicates the time span over which the participation takes place. For example, in the case of an insurance policy holder, the participation time is the effective time range for the insurance policy described. For health-care providers or support persons or organizations, it indicates the time span over which care or support is provided.

This guide does not specify any use for functionCode for participants. Local policies will determine how this element should be used in implementations.

The address and contact telephone number for the participant are required.

- L1-58: The associatedEntity/addr element must be present.
- L1-59: A associatedEntity/telecom element must be present that contains a contact phone number for the participant.

If there is a scopingOrganization element present for a given participant, the name, address and telephone contact information must also be present.

- L1-60: The name element must be present in a scopingOrganization element.
- L1-61: The addr element must be present in a scopingOrganization element.
- L1-62: A telecom element must be present that contains a contact phone number in a scopingOrganization element.

Figure 30 below describes how various participants should be encoded in the Care Record Summary.

<sup>&</sup>lt;sup>5</sup> This may in fact also be the case for practitioners at various degrees of skill.

Description of the Participant	typeCode	participatingEntity/ classCode	Vocabulary Domain for participatingEntity/code	Comments
Next of Kin	IND	NOK	PersonalRelationshipRoleType	Personal relationship must be present.
Emergency Contact	IND	ECON	<u>PersonalRelationshipRoleType</u>	Personal relationship must be present.
Holder of an Insurance Policy	HLD	POLHOLD		Scoping organization must be present.
Guarantor	IND	GUAR		
Other supporting person or organization.	IND	PRS	PersonalRelationshipRoleType	Personal relationship must be present.

Figure 30 Encoding Various Participations

# 2.2.9.1 Supporting Person or Organization

The typeCode attribute must be *IND*, and participatingEntity/classCode must have a value of *PRS*, *NOK* or *ECON*. If participatingEntity/classCode is *PRS* the personal relationship between the supporting person or organization and the patient must be represented in a participatingEntity/code element, using values drawn from the <u>PersonalRelationshipRoleType</u> vocabulary domain.

A supporting person that is also an emergency contact or next of kin should be recorded as a participant for each role played.

- **L1-63:** When participant/@typeCode is *IND*, participatingEntity/@classCode must be *PRS*, *NOK*, *ECON* or *GUAR*.
- **L1-64:** When participatingEntity/@classCode is *PRS*, *NOK* or *ECON* then participatingEntity/code must be present having a value drawn from the <u>PersonalRelationshipRoleType</u> domain.

```
<participant typeCode='IND'>
   <associatedEntity classCode='NOK'>
       <code code='MTH' codeSystem='2.16.840.1.113883.5.111'/>
           <streetAddressLine>17 Daws Rd.</streetAddressLine>
           <city>Blue Bell</city>
           <state>MA</state>
           <postalCode>02368</postalCode>
           <country>USA</country>
       <telecom value='tel:(999)555-1212' use='WP'/>
       <associatedPerson>
           <name>
               <prefix>Mrs.</prefix></prefix>
               <given>Abigail</given>
               <family>Ruth</family>
           </name>
       </associatedPerson>
   </associatedEntity>
</participant>
```

Figure 31 participant Example for a Supporting Person

# 2.2.9.2 Billing Related Participants

To represent the policy holder as a participant, the typeCode attribute shall be set to *HLD*, and the participatingEntity/classCode must have a value of *POLHOLD*. To represent a guarantor, the typeCode attribute shall be set to *IND*, and the participatingEntity/classCode must have a value of *GUAR*.

When the participant being represented is a policyholder, the scopingOrganization element must be present, and represents the issuer of the insurance policy.

- **L1-65:** When participant/@typeCode is *HLD*, participatingEntity/@classCode must be *POLHOLD*.
- **L1-66:** When participant/@typeCode is *HLD*, participatingEntity/scopingOrganization must be present.

```
<participant typeCode='HLD'>
   <time>
       <low value='20050101'>
       <high value='20051231'>
   </time>
   <associatedEntity classCode='POLHOLD'>
       <code code='PHFAMDEP' codeSystem='2.16.840.1.113883.5.1095'/>
       <!-- To show that the policy holder is the patient, the above
       <code code='SELF' codeSystem='2.16.840.1.113883.5.111'/>
       <id extension='123456789'
          root='00000000-0000-0000-0000-00000000000'/>
       <addr>
           <streetAddressLine>17 Daws Rd.</streetAddressLine>
           <city>Blue Bell</city>
           <state>MA</state>
           <postalCode>02368</postalCode>
           <country>USA</country>
       </addr>
       <telecom value='tel:(999)555-1212' use='WP'/>
       <associatedPerson>
           <name>
               <prefix>Mr.</prefix></prefix>
               <given>Kenneth</given>
               <family>Ross</family>
           </name>
       </associatedPerson>
       <scopingOrganization>
           <addr>
               <streetAddressLine>3191 Broadbridge Avenue</streetAddressLine>
               <city>Stratford</city>
               <state>CT</state>
               <postalCode>06614-2559</postalCode>
               <country>USA</country>
           <telecom value='tel:(203)555-1212' use='WP'/>
           <name>Good Health Insurance Company</name>
       </scopingOrganization>
   </associatedEntity>
</participant>
```

Figure 32 participant Example for a Policy Holder

```
<participant typeCode='IND'>
   <associatedEntity classCode='GUAR'>
       <addr>
           <streetAddressLine>17 Daws Rd.</streetAddressLine>
           <city>Blue Bell</city>
           <state>MA</state>
           <postalCode>02368</postalCode>
           <country>USA</country>
       <telecom value='tel:(999)555-1212' use='WP'/>
       <associatedPerson>
           <name>
               <prefix>Mr.</prefix></prefix>
               <qiven>Kenneth</qiven>
               <family>Ross</family>
           </name>
       </associatedPerson>
   </associatedEntity>
</participant>
```

Figure 33 participant Example for a Guarantor

#### 2.2.10 documentationOf

A Care Record Summary document provides documentation of an episode of care where main service event is Care Provision. This is shown in the example below by setting the value of the classCode attribute of the serviceEvent element to *PCPR*. Additional service events or acts may have occurred, but these should be documented in the CDA Body, and might be further described within entry elements of a structuredBody.

Care Provision is a statement of responsibility. The code for this statement should apply to a commonly accepted legal/regulatory/accrediting standard scope for responsibility. It is understood that these may differ state by state in the US Realm. Examples include: JCAHO; state licensing of hospitals, nursing homes, and home health agencies; medical and nursing specialty boards; etc. For example, a hospital discharge summary would use a code for hospital care. This code is not to be interpreted as a setting code or an encounter code, but must be consistent with other related concepts, i.e. document type, encounter type, scoping organizations for licensure or accreditation of participating providers. Local needs may require extensions of any given value set depending on local regulations and accreditations. A general value set for these concepts (that is expected to be extended by local agreement) will be defined by HL7, since external vocabularies do not at this time support this concept.

L1-67: Only one ClinicalDocument/documentationOf element must be present.

Within the documentationOf element, there is one serviceEvent element. This event is some form of care provision. The type of care provided may be further described in the serviceEvent/code element. This guide makes no specific recommendations about the vocabulary to use for describing this event, however, if present, the value of serviceEvent/code must not conflict with the ClininicalDocument/code. See section 4.2.3.2 Service Event of the CDA Release 2.0 specification for more details on this requirement.

The effectiveTime for the serviceEvent covers the duration of the summary of episode being documented. This event may span several encounters, and should have one or more performers, each participating at different periods of time. However, for the summary there is a starting point and an ending point in time with respect to the content of the document. The care provision may still be ongoing (e.g., the patient may

be in the middle of treatment), but the summary of episode, by necessity, can only cover those issues that have occurred to date in the provision of care.

Implementations originating a Care Record Summary should take care to discover what the episode of care being summarized is. For example, when a patient fills out a form providing relevant health history, the episode of care being documented might be from birth to the present.

- L1-68: The effectiveTime element of the serviceEvent element must be present.
- **L1-69:** The effectiveTime element must contain only one low element. The low element is unrestricted with respect to precision or time zone<sup>6</sup>.
- **L1-70:** The effectiveTime element must contain only one high element. The high element is unrestricted with respect to precision or time zone.

A serviceEvent should have at least one performer. There are a few cases where no performers might be listed, for example, in cases where the information will not or cannot be provided by the patient.

The performer elements should list the relevant providers of healthcare during the episode being summarized. If the provider is the primary care provider for the patient during the time interval, then performer/functionCode must have a value of *PCP* from the <u>ParticipationFunction</u> vocabulary domain. The patient may also be a performer of Care Provision, as in the case of self-Care.

The specific type of provider may be listed in performer/assignedEntity/code. If present, the values must be drawn from SNOMED CT, using concepts that descend from the *healthcare professional* subtype hierarchy (SNOMED CT Concept ID: 223366009).

**L1-71:** The performer/assigneEntity/code if present must have a value drawn from the SNOMED CT *healthcare professional* subtype hierarchy.

The assignedEntity for each performer must contain at least one assignedPerson or representedOrganization. It must also contain addr and telecom elements that provide an address and telephone contact information. These elements may use a flavor of null to represent unknown values.

- **L1-72:** Every performer/assignedEntity element has at least one assignedPerson or representedOrganization.
- L1-73: All performer/assignedEntity elements have an addr element.
- L1-74: All performer/assignedEntity elements have a telecom element that is a telephone contact number.
- L1-75: All assignedPerson elements of performer/assignedEntity must have a name element.

In general, the time element of the performer element is optional, but if present, it indicates the time span over which healthcare services are provided.

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<sup>&</sup>lt;sup>6</sup> Often, specific detail is not available.

If there is a representedOrganization element present for a given assignedEntity, the name, address and telephone contact information must also be present.

- **L1-76:** The name element must be present in a performer/assignedEntity/representedOrganization element.
- **L1-77:** The addr element must be present in a performer/assignedEntity/representedOrganization element.
- **L1-78:** A telecom element must be present that contains a contact phone number in a performer/assignedEntity/representedOrganization element.

```
<documentationOf>
   <serviceEvent classCode='PCPR'>
       <effectiveTime>
           <low value='19600127'/>
           <high value='20050329'/>
       </effectiveTime>
       <performer typeCode='PRF'>
           <functionCode code='PCP' codeSystem='2.16.840.1.113883.5.88'/>
           <t.ime>
               <low value='1998'/>
               <high value='2005'/>
           </time>
           <assignedEntity>
               <id extension='1' root='1.3.6.4.1.4.1.2835.1'/>
               <code code='59058001'</pre>
                  codeSystem='2.16.840.1.113883.6.96'
                  codeSystemName='SNOMED CT'
                  displayName='General Physician'/>
                  <streetAddressLine>21 North Ave</streetAddressLine>
                   <city>Burlington</city>
                   <state>MA</state>
                   <postalCode>01803</postalCode>
                   <country>USA</country>
               </addr>
               <telecom value='tel:(999)555-1212' use='WP'/>
               <assignedPerson>
                   <name>
                       <prefix>Dr.</prefix>
                       <given>Bernard</given>
                       <family>Wiseman</family>
                       <suffix>Sr.</suffix>
                   </name>
               </assignedPerson>
           </assignedEntity>
       </performer>
   </serviceEvent>
</documentationOf>
```

Figure 34 documentationOf Example

# 2.2.11 inFullfillmentOf

These optional elements describe the prior orders that are fulfilled (in whole or part) by the service events described in this document. For example, the prior order might be a referral, and this Summarization of Episode note may be in partial fulfillment to that referral.

#### 2.2.12 authorization

These elements are optional. This document provides no guidance on the encoding of authorization elements.

# 2.2.13 componentOf

When the Care Record Summary document is a Discharge or Transfer Summarization the componentOf element is required, and describes the encounter from which the patient is being discharged or transferred. Otherwise, this element is optional.

L1-79: If the Care Record Summary is a Discharge or Transfer Summarization, then the componentOf element is required.

The id element of the encompassing Encounter must be present and represents the identifier for the encounter.

L1-80: The encompassing Encounter element must have an id element.

The effectiveTime must be present, and represents the time interval or point in time in which the encounter took place. The effectiveTime of the encompassing encounter may be shorter than the time period described by the Care Record Summary. The encompassing encounter might be that of the office visit in which the Care Record Summary was produced that describes a much longer time span. That longer time span would be recorded in the effectiveTime element used under the documentationOf element described above.

L1-81: The encompassingEncounter element must have an effectiveTime element.

If this Care Record Summary is a Discharge Summarization Note, the dischargeDispositionCode element must be present.

L1-82: If ClinicalDocument/code/@value represents a Discharge Summarization Node, then dischargeDispositionCode must be present.

The encounterParticipant elements are optional, and if present, represent only those participants in the encounter, not necessarily the entire episode of care (see related information under the sections for documentationOf or participant above).

- L1-83: The encounterParticipant/assignedEntity element must have an addr element.
- L1-84: The encounterParticipant/assignedEntity element must have a telecom element that represents a telephone contact number.
- L1-85: The encounterParticipant/assignedEntity element must have at least one assignedPerson or representedOrganization element present.

The responsibleParty element is optional. If present, it represents only the party responsible for the encounter, not necessarily the entire episode of care.

- L1-86: The responsible Party/assigned Entity element must have an addr element.
- L1-87: The responsibleParty/assignedEntity element must have a telecom element that represents a telephone contact number.
- L1-88: The responsible Party/assigned Entity element must have at least one assignedPerson or representedOrganization element present.

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```
<componentOf>
   <encompassingEncounter>
       <id extension="9937012" root="1.3.6.4.1.4.1.2835.12"/>
       <code code="99213"
           codeSystem="2.16.840.1.113883.6.12"
           displayName="Evaluation and Managment"
           codeSystemName="CPT-4"
       />
       <effectiveTime>
           <low value="20050329"/>
           <high value="20050329"/>
       </effectiveTime>
       <dischargeDispositionCode code="01"</pre>
           codeSystem="2.16.840.1.113883.6.21"
           displayName="Routine Discharge"
           codeSystemName="UB92"
    </encompassingEncounter>
</componentOf>
```

Figure 35 componentOf example

# 3 Body

A Care Record Summary must have either a structuredBody or nonXMLBody element. The content of this element makes up the human readable text of the document. This information shall be organized into sections and may have sub-sections. The order of these sections has not been prescribed by this implementation guide to allow for implementations to meet local requirements and support current practices.

A nonXMLBody element may contain the actual CDA content, or may reference it by URL, or do both.

Figure 36 Sample nonXMLBody element.

Note that the use of nonXMLBody does not eliminate the requirement that the required content be present in clearly identifiable sections according to the categories described hereafter.

To indicate that a structuredBody element conforms to the Level 2 constraints of this guide, a CDA Instance may include a templateID element, as shown below in Figure 37.

Figure 37 Indicating conformance to Level 2 Constraints

# 3.1 LOINC Section Type Codes

The LOINC Section Type codes used in this guide are described below in Table 3. All section codes shown in this table describe narrative document sections<sup>7</sup>. Where possible, the section codes have been coordinated with the Claims Attachments implementation guides to support the reuse of information found in a Care Record Summary to respond to a query for a Claims Attachment. Where no applicable LOINC code was found, an local extension code has been defined beginning with the letter X. These codes will be submitted to LOINC after close of the ballot, and will be incorporated into the final release of this document.

<sup>&</sup>lt;sup>7</sup> SCALE TYP = 'NAR' in the LOINC tables.

The column headings of this table are described below:

Category: The category column lists the general category [KWB1] of sections described

in this guide.

Use: The use column indicates that a section in a Care Record Summary is:

R – required
C – conditionally required
O – optional

Code: The code of the section in LOINC.

Component Name: The display name of the section in LOINC.

Source: The source column indicates that this LOINC code is also used in the HL7

Clinical Reports Attachment Guide; values below describe which attachment:

- Provider Unspecified History and Physical Note

DS - Physician Hospital Discharge Summary

Category	Use	Code	Component Name	Source
Conditions	R	11450-4	PROBLEM LIST	H&P
		11348-0	HISTORY OF PAST ILLNESS	H&P
		11535-2	HOSPITAL DISCHARGE DX	DS
		X-HADX	HOSPITAL ADMISSION DX	DS
Allergies and Adverse	R	10155-0	HISTORY OF ALLERGIES	
Reactions		11382-9	MEDICATION ALLERGY	H&P
Medications	R	10160-0	HISTORY OF MEDICATION USE	H&P
		10183-2	HOSPITAL DISCHARGE MEDICATIONS	DS
		X-MOA	MEDICATIONS ON ADMISSION	
Hospital Course	C <sub>8</sub>	8648-8	HOSPITAL COURSE	DS
Reason For Visit	0	X-RFVCC	REASON FOR VISIT/CHIEF COMPLAINT	
		29299-5	REASON FOR VISIT	
		10154-3	CHIEF COMPLAINT	H&P
Reason for Referral	0	X-RFR	REASON FOR REFERRAL <sup>9</sup>	
Advance Directives	0	X-ADVDIR	ADVANCE DIRECTIVES	
History of Present Illness	0	10164-2	HISTORY OF PRESENT ILLNESS	H&P
Functional Status	0	10158-4	HISTORY OF FUNCTIONAL STATUS	H&P
Family History	0	10157-6	HISTORY OF FAMILY MEMBER DISEASES	H&P
Social History	0	29762-2	SOCIAL HISTORY	H&P
Immunizations	0	11369-6	HISTORY OF IMMUNIZATIONS	H&P
Past Surgical History	0	10167-5	HISTORY OF SURGICAL PROCEDURES	H&P
Prior Encounters	0	11346-4	HISTORY OF OUTPATIENT VISITS	H&P
		11336-5	HISTORY OF HOSPITALIZATIONS	H&P
Review of Systems	0	10187-3	REVIEW OF SYSTEMS	H&P
Physical Examination	0	10210-3	GENERAL STATUS, PHYSICAL FINDINGS	H&P
		10184-0	HOSPITAL DISCHARGE PHYSICAL	DS
		8716-3	VITAL SIGNS, PHYSICAL FINDINGS	H&P
		X-FV	VITAL SIGNS, FETUS	
Studies and Reports	0	11493-4	HOSPITAL DISCHARGE STUDIES SUMMARY	DS
		X-SS	STUDIES SUMMARY	
Care Plan	0	18776-5	TREATMENT PLAN	H&P, DS

Table 3 LOINC Section Type Codes

<sup>8</sup> Required in a Discharge or Transfer Summary.

<sup>&</sup>lt;sup>9</sup> From the referring provider's perspective, this is why the patient is being referred, not necessarily why they may have visited the provider initially. From the receiving provider's perspective, this will become the reason that the patient visited them.

Additional sections or sub-sections may be inserted where necessary anywhere in the document section hierarchy, according to local policy. All sections should be coded using LOINC. Sections and sub-sections within the Care Record Summary content should have a title. A section element in a level 2 conforming Care Record Summary should have a non-empty title element.

The remainder of the examples in this section all show sample content that would appear in the structuredBody element.

For level 2 conformance, all section elements that are present in the body of the document must have a code and some non-blank text or one or more subsections, even if the purpose of the text is only to indicate that information is unknown.

- **L2-1:** A cda:section element must have a cda:code element.
- L2-2: A cda:section must contain at least one cda:text element or one or more cda:component elements.
- L2-3: All cda:text or cda:component elements must contain content.

Sections containing similar information (e.g., HISTORY OF OUTPATIENT VISITS and HISTORY OF HOSPITALIZATIONS) should use similar presentation structures (e.g., lists, tables) in the document. For example, if a tabular presentation is used in the section on HISTORY OF OUTPATIENT VISITS, it should also be used for the section describing HISTORY OF HOSPITALIZATIONS when that section is also present.

# 3.2 Required Sections

A Care Record Summary must contain sections that provides the following information:

#### 3.2.1 Conditions 11535-2/11450-4

A list of conditions for the patient. This list must include all active problems, and may include any resolved problems. This information may be presented in one or more sections within the document to further classify the conditions as preliminary or final diagnoses, reported chief complaint or reason for visit, prior illnesses or injuries, et cetera. If there are no current problems, this information must be provided. If the current problems are unknown, this information must be provided.

The reader of a Care Record Summary must be able to determine which problems are active and resolved [e.g., it is insufficient to say that the section heading provides that indication, as a DX of Diabetes may be unresolved, but one of Pneumonia will very likely be.

- **L2-4:** A Discharge or Transfer summary must include a section element whose code is *11535-2*.
- **L2-5:** A Summary of Episode note that is not a discharge or transfer summary must include a section element whose code is *11450-4*.

Implementations may include additional subsections to further identify specific conditions, for example, chief complaint or admitting diagnosis.

A sample representation for these subsections is a table containing four columns. The first column lists the problem, the second lists the date range for the problem, including onset and resolution of the problem, when known. The third column indicates the status (e.g., resolved or current), and the final column has comments. The date range for a current problem should normally include only date of onset, as the problem will have not been resolved.

Problem	Date	Status	Comments
Cholecystitis	9/28/2002 — 6/2003	Resolved	Surgery postponed until after delivery
Pregnancy	7/2001 - 4/22/2002	Resolved	Prior history of miscarriage
Ankle Sprain	3/28/2005	Current	Slipped on Ice and Fell

Figure 38 Problems Rendering

```
<component>
    <code code='11450-4' codeSystem='2.16.840.1.113883.6.1' />
     <title>Conditions</title>
     <text>
       <thead>ProblemDateComments
          Cholecystitis9/28/2002 - 6/2003Resolved
               Surgery postponed until after delivery
            Pregnancy7/2001 - 4/22/2002Resolved
               Prior history of miscarraige
            \label{lem:condition} $$ \to Ankle Sprain3/28/2005Current
              Slipped on ice and fell
            </text>
  </section>
</component>
```

Figure 39 Conditions Example

#### 3.2.2 Allergies 10155-0

A list of allergies suffered by the patient. This list must contain all known allergies, including medication, dietary and other allergies. If the patient has no known allergies, this information must be provided. If the patient's allergies are unknown, this information must be provided. If an allergy is to be removed from the patient's allergy list, this information must also be provided (e.g., in current practice, a patient may report an allergy to penicillin, but after a negative skin test, the practitioner might wish to remove that allergy from the list).

The reader of a Care Record Summary must be able to determine that an allergy is being removed from the patient allergy list. This section should contain information about the allergen and the reaction, and may provide a place for comments.

This required section will describe any allergies, adverse reactions, and intolerances. The LOINC section type code for this section is 10155-0 (HISTORY OF ALLERGIES).

#### **L2-6:** A section must be present with a code value of *10155-0*.

The sample representation for this section is a table, where the first column describes the allergen, the second describes the reaction, and the final column provides more detailed information.

Allergen	Reaction	Comments
Penicillin	Hives	Amoxicillin is OK

Figure 40 Medication Allergy Figure Rendering

```
<component>
  <section>
     <code code='10155-0' codeSystem='2.16.840.1.113883.6.1' />
     <title>Allergies and Adverse Reactions</title>
     <text>
       <thead>
             AllergenReaction
               Comments
            </thead>
          PenicillinHives
               Amoxicillin is OK
             </text>
  </section>
</component>
```

Figure 41 Allergies Example

If the patient has no known allergies, this information must be provided. This is shown in Figure 42 below.

Figure 42 No Known Allergies Example

If the patient's allergies are unknown, this information must be provided. This is shown in Figure 43 below.

Figure 43 Allergies Unknown Example

If an allergy is to be removed from the patient's allergy list, this information must also be provided (e.g., in current practice, a patient may report an allergy to penicillin, but after a negative skin test, the practitioner might wish to remove that allergy from the list). This is shown Figure 44 below.

```
<component>
  <section>
     <code code='10155-0' codeSystem='2.16.840.1.113883.6.1' />
     <title>Allergies</title>
     <text>
       <thead>
             AllergenReaction
               Comments
             </thead>
          Not allergic to Penicillin
               Skin test shows no allergy to penecillin.
          </text>
  </section>
</component>
```

Figure 44 Allergy Removal Example

Specific conditions that require special management due to risk should be listed in the appropriate section under conditions above (e.g., Protein S Deficiency). Local policy should decide whether these should also be listed under allergies and intolerances.

#### 3.2.3 Medications 10183-2/10160-2

A list of medications for the patient. This list must include medications that the patient is currently taking or which have been prescribed. It may also include medications which were previously being used by the patient. The information may be presented in one or more sections within the document to further classify the medication as one identified on admission, given during an encounter, or prescribed or otherwise directed to take on discharge.

The reader of a Care Record Summary must be able to determine which medications are current.

- **L2-7:** A Discharge or Transfer summary must include a section element whose code is 10183-2.
- **L2-8:** A Summary of Episode note that is not also a discharge or transfer summary must include a section element whose code is 10160-0.

The sample representation is a table listing the medications, in alphabetical order. The columns of this table describe the Medication, prescription or dosage information if known, and first date and last dates of use, if known.

Medication	Prescription or Dose	Dates of Use
Indomethacin	50mg bid with food	12/10/2003 – present
Acetaminophen with codeine	#3 1-2 tablets for pain as needed	3/28/2005

Figure 45 Medications Rendering

```
<component>
     <code code='10160-0' codeSystem='2.16.840.1.113883.6.1' />
     <title>Medications</title>
     <text>
        <thead>
             Medication
               Prescription or Dose
                Dates of Use
             </thead>
             Indomethacin
                50mg bid with food 
                12/10/2003 - present
             Acetaminophen with codeine
                #3 1-2 tablets for pain as needed
                03/28/2005
             </t.r>
          </text>
  </section>
</component>
```

Figure 46 Medications

When there are no medications in section, the content of the section should clearly indicate this, for example, by using the word *None*. This is shown below in Figure 47.

Figure 47 Medications Example with no Medications Listed

When the medications for the patient are unknown, the content of the section should clearly indicate this, for example, by using the word *Unknown*.

## 3.2.4 Hospital Course 8648-8

A Discharge or Transfer Summary must contain a section describing the Hospital Course. This section will describe the course of care provided for the inpatient stay.

A level 2 conforming Discharge or Transfer Summary will use the LOINC Code 8648-8 HOSPITAL COURSE for this section.

**L2-9:** A level 2 conforming Care Record Summary that is a discharge or transfer summary shall contain a section with the code value of *8648-8*.

#### 3.3 **Optional Sections**

A Care Record Summary may contain additional sections that provide additional information, such as Family History, Social History, et cetera. When present these sections should be readily identifiable by the title.

#### 3.3.1 Reason for Visit/Chief Complaint X-RFVCC/29299-5/10154-3

These sections describe the reason for the patient's visit and/or the patient's chief complaint. The information can be divided into two sections to record the patient's chief complain in their own words separately from the provider's description of the reason for visit, or the two pieces of information may be recorded in one section serving both purposes, depending upon local requirements.

In a level 2 conforming Care Record Summary, this can be handled in one of two ways: When local requirements require that the chief complaint and the reason for visit be recorded separately, then the LOINC codes 29299-5 REASON FOR VISIT, and 10154-3 CHIEF COMPLAINT shall be used to record them. If the chief complaint and reason for visit are recorded together, then the LOINC code X-RFVCC shall be used. A Care Record Summary that uses the latter code shall not use either of the former codes, and visa versa.

- **L2-10:** The section type code for the section describing the reason for visit in a level 2 conforming Care Record Summary shall be either X-RFVCC (REASON FOR VISIT/CHIEF COMPLAINT), or 29299-5 (REASON FOR VISIT).
- L2-11: The section type code for the section describing the patient's chief complaint in a level 2 conforming Care Record Summary shall be either X-RFVCC (REASON FOR VISIT/CHIEF COMPLAINT), or 10154-3 (CHIEF COMPLAINT).
- L2-12: A level 2 conforming Care Record Summary that contains a section with a code value of X-RFVCC (REASON FOR VISIT/CHIEF COMPLAINT) shall not contain sections with a code value of 29299-5 (REASON FOR VISIT) or 10154-3 (CHIEF COMPLAINT).

```
<component>
       <code code='X-RFVCC' codeSystem='2.16.840.1.113883.6.1' />
       <title>Reason for Visit/Chief Complaint</title>
       <text>Ankle Sprain</text>
   </section>
</component>
```

Figure 48 Reason for Visit/Chief Complaint Example

#### 3.3.2 Reason for Referral X-RFR

A Care Record Summary may be used to document an episode prior to referral. To support this use case, it may include a section that indicates the reason for referral. If present, this section will describe why the patient is being referred to another provider, and this may be distinct from the reason for visit documented in the Care Record Summary [e.g., the reason for visit may be annual physical, but the reason for referral may be to follow-up on a finding from that physical].

**L2-13:** The code for the section describing the Reason for Referral in a level 2 conforming Care Record Summary shall be *X-RFR* (*REASON FOR REFERRAL*).

Figure 49 Reason for Referral Example

#### 3.3.3 Advance Directives X-ADVDIR

This section should reference documents that contain advance directives, living wills, powers of attorney, or similar information for the patient.

It should contain, a descriptive name for the document, contact information necessary to obtain access to it, possibly even a hyperlink to it, the effective dates, and optionally summary or description of its content.

**L2-14:** The code for the section describing the patient Advance Directives in a level 2 conforming Care Record Summary shall be *X-ADVDIR* (ADVANCE DIRECTIVES).

A sample	representation	is shown	below in	Figure	1.
11 Sumpic	representation	IO OIIO WII	DCIOW III	I IS UI C	т.

Documentation	Contact	Effective Date	Comments
Living Will	Obtain from her Husband	1994	Copy on file
Power of Attorney	torney Obtain from her Husband		
Healthcare Proxy	Obtain from her Husband	1994	
Organ Donor	Massachusetts Registry of Motor Vehicles	1/27/2004	Registered Organ Donor

Figure 1 Advance Directives Rendering

```
<component>
  <section>
    <code code='X-ADVDIR' codeSystem='2.16.840.1.113883.6.1'/>
    <title>Advance Directives</title>
    <text>
       <thead>
           DocumentationContact
                Effective DateComments
           </thead>
         Living WillObtain from her Husband
             1994Copy on file
           Power of AttorneyObtain from her Husband
             1994
           Healthcare ProxyObtain from her Husband
              1994
           Organ Donor
              Massachusetts Registry of Motor Vehicles1/27/2004
              Registered Organ Donor
           </text>
  </section>
</component>
```

Figure 50 Advance Directives section Example

#### 3.3.4 History of Present Illness 10164-2

This section may be included to provide information related to the present illness that the patient is being treated for.

**L2-15:** The LOINC section type code for the section describing the History of Present Illness in a level 2 conforming Care Record Summary shall be *10164-2* (HISTORY OF PRESENT ILLNESS).

Figure 51 History of Present Illness Example

#### 3.3.5 Functional Status 10158-4

This section contains information related to the functional status of the patient; such as those that would be pertinent to long-term care. Suggested sources of measures that should appear in this section are measures of Activities of Daily Living such as those found in the Long Term Care Minimum Data Set or the Barthel Index.

**L2-16:** The LOINC section type code for the section describing the patient's functional status in a level 2 conforming Care Record Summary shall be *10158-4* (HISTORY OF FUNCTIONAL STATUS).

#### 3.3.6 Family History 10157-6

This section will contain the relevant family history for the patient. The section should list the family member, the condition, and might indicate whether the condition was the cause of death.

L2-17: The LOINC section type code for the section providing family history of the patient in a level 2 conforming Care Record Summary shall be 10157-6 (HISTORY OF FAMILY MEMBER DISEASES).

The sample representation of this information is a table with three columns, where the first column gives the family member, the second is the problem, and the last indicates if the problem was the cause of death.

Family Member	Problem	Cause of Death
Father	Alcoholism	No
Father	Liver Cancer	Yes

Figure 2 Family History Rendering

```
<component>
  <section>
    <code code='10157-6' codeSystem='2.16.840.1.113883.6.1'/>
    <title>Family History</title>
    <text>
       <thead>
           Family MemberProblemCause of Death?
         </thead>
         FatherAlcoholismNo
           FatherLiver CancerYes
         </text>
  </section>
</component>
```

Figure 52 Family History Example

## 3.3.7 Social History 29762-2

This section will describe relevant social history, and should indicate relevant dates, or provide additional comments. The LOINC section type code for this section is 29762-2 (SOCIAL HISTORY).

The sample representation is in a table with three columns. The first column describes the relevant social history or risk factor (e.g., smoking). The second column comments on this item (e.g., 2 packs per day). The final column represents the effective date range for the risk factor.

Social History	Comments	Date Range
Smoking	1/2 pack per day	? – 1996
Alcohol Use	1-2 drinks per week	

Figure 53 Social History/Risk Factor Rendering

```
<component>
  <section>
    <code code='29762-2' codeSystem='2.16.840.1.113883.6.1'</pre>
    <title>Social History</title>
      <thead>
          Social HistoryCommentsDate Range
        </thead>
        Alcohol Use1-2 drinks per week
        </text>
  </section>
</component>
```

Figure 54 Social History Example

#### 3.3.8 Immunizations 11369-6

This section lists immunizations and dates of administration in reverse chronological order.

**L2-18:** The LOINC section type code for the section providing immunization history in a level 2 conforming Care Record Summary shall be *11369-6* (HISTORY OF IMMUNIZATION).

This section is optional, however, it is strongly recommended that it be present in cases of pediatric care, and it should otherwise be present when the information is available.

The sample shows a list containing the Immunization and Date of Immunization in reverse chronological order.

```
DTP - 1962Polio Virus - 1961MMR - 1961
```

Figure 55 Immunization Rendering

Figure 3 Immunizations Section Example

#### 3.3.9 Past Surgical History 10167-5

This section is optional. It should contain relevant prior procedures and their dates listed in reverse chronological order.

L2-19: The LOINC section type code for the section describing the patient's past surgical history in a level 2 conforming Care Record Summary shall be 10167-5 (PAST SURGICAL HISTORY).

The sample representation is a table, with the name of the procedure in the first column and the date of the procedure in the second column.

Procedure	Date
Laparoscopic Cholecystectomy	9/28/2002
Cesarean Section	3/22/2002

Figure 56 Procedure Rendering

```
<component>
    <code code='10167-5' codeSystem='2.16.840.1.113883.6.1' />
    <title>Procedures</title>
    <text>
       <thead>
            Procedure
               Date
          </thead>
          Laparoscopic Cholecystectomy9/28/2002
            Cesarian Section3/22/2002
          </text>
  </section>
</component>
```

Figure 57 Past Surgical History Section Example

#### 3.3.10 Prior Encounters 11346-4/11336-5

These sections should describe any relevant prior encounters in reverse chronological order.

- **L2-20:** The LOINC section code used for the section describing prior outpatient visits in a level 2 conforming Care Record Summary shall be *11346-4* (HISTORY OF OUTPATIENT VISITS).
- **L2-21:** The LOINC section code used for the section describing prior hospitalizations in a level 2 conforming Care Record Summary shall be *11336-5* (HISTORY OF HOSPITALIZATIONS).

The sample representation is a table with the date or date range of the encounter, the provider or provider organization, and a description of the reason for the encounter.

Date	Provider	Reason for Visit
3/28/2005	Community Hospital	ED Visit for Ankle Sprain
9/28/2002	City Hospital	Gall Bladder Surgery
3/21/2002	Community Hospital	Labor and Delivery
10/28/2001	Community Hospital	ED Visit for Acute Cholecystitis

Figure 4 Encounters Rendering

```
<component>
  <section>
    <code code='11336-5' codeSystem='2.16.840.1.113883.6.1' />
    <title>Prior Encounters</title>
    <text>
       DateProvider
              Description
            </thead>
          3/28/2005Community Hospital
              ED Visit for Ankle Sprain
            9/28/2002City Hospital
              Gall Bladder Surgery
            3/21/2002Community Hospital
              Labor and Delivery
            10/28/2001Community Hospital
              ED Visit for Acute Cholecystitis
          </text>
  </section>
</component>
```

Figure 58 Encounters Section Example

### 3.3.11 Review of Systems 10187-3

This section should contain relevant information from a review of systems.

Figure 59 Review of Systems Example

#### 3.3.12 Physical Examination 10210-3

This section should contain relevant information from a physical examination of the patient.

The example below shows a physical examination with the vital signs as a subsection.

```
<component>
  <section>
    <code code='10210-3' codeSystem='2.16.840.1.113883.6.1' />
     <title>Physical Examination</title>
     <text></text>
     <component>
       <section>
          <code code='29274-8' codeSystem='2.16.840.1.113883.6.1' />
          <title>Vital Signs</title>
          <text>
          <t.head>
            DateHeightWeightTemperature
               BPPulseRespiration02
            </thead>
           3/28/20055'9"215 lbs.98.7 °F
               120/80681699%
            </text>
       </section>
     </component>
  </section>
</component>
```

Figure 60 Physical Examination With Vital Signs Subsection Example

#### 3.3.13 Vital Signs 8716-3

The patient's vital signs will be listed in this section.

**L2-22:** The LOINC section **code** used for the section providing the patient vital signs in a level 2 conforming Care Record Summary shall be *8716-3* (VITAL SIGNS, PHYSICAL FINDINGS).

The sample representation is a table, where the first column indicates the date of measure, and the remaining columns list the measures for height, weight, temperature, blood pressure, pulse, respiration, and O2 saturation in that order.

Each measurement should be in the same units to make it easier to identify trends, and the units should be specified for clarity (for example, use 225 lbs. instead of 225), as shown in the table below.

Date	Height	Weight	Temperature	ВР	Pulse	Respiration	O2
3/28/2005	5'9"	215 lbs.	98.7 °F	120/80	68	16	99%

Figure 5 Vital Signs

#### 3.3.14 Studies and Reports 11493-4/X-SS

Results from, or references to various studies may be listed this section.

**L2-23:** The LOINC section code used for the section describing results or referring to other reports in a level 2 conforming Care Record Summary shall be *11493-4* (HOSPITAL DISCHARGE STUDIES SUMMARY), or *X-SS* (STUDIES SUMMARY)

Additional subsections might be used in this section for example, to allow for grouping of like results.

The sample representation is a table, where the first column of the table indicates the type of test, the second column summarizes the result, and the last column provides the date of the study or report

Study	Summary	Date of Study
X-Ray Study – Left Ankle	No Fracture	3/28/2005

Figure 6 Lab Results Rendering

```
<component>
  <section>
     <code code='X-SS' codeSystem='2.16.840.1.113883.6.1'/>
     <title>Related Reports</title>
     <text>
        <t.head>
             Study
               Summary
               Date of Study
             </thead>
          X-Ray Study - Left Ankle
               No Fracture
               3/28/2005
             </text>
  </section>
</component>
```

Figure 61 Lab Result Example

#### 3.3.15 Fetal Vital Signs X-FV

Fetal Vital signs, such as those recommended by the ACOG Guidelines for Perinatal Care, should be listed in this section.

#### 3.3.16 Plan of Care 18776-5

This section should describe the plan of care, including the patient disposition, and may provide a detailed list of planned activities, including transfers.

**L2-24:** The LOINC section **code** used for the section describing the plan of care for the patient in a level 2 conforming Care Record Summary shall be *18775-6* (TREATMENT PLAN)

This section should be present when known.

# 4 References

ACOG Guidelines	Gynecologists.  The American College of Obstetricians and				
Barthel Index	FUNCTIONAL EVALUATION: THE BARTHEL INDEX, Maryland State Medical Journal, 1965				
CDA Release 2.0	Clinical Document Architecture, Release 2.0, 2005, Health Level Seven, Inc.				
<u>ISO-3166-1</u>	Codes for the representation of names of countries and their subdivisions Part 1: Country codes, 1997, International Organization for Standardization				
<u>ISO-639-1</u>	Codes for the representation of names of languagesPart 1: Alpha-2 code, 2002, International Organization for Standardization				
<u>LOINC®</u>	Logical Observation Identifiers Names and Codes, Regenstrief Institute				
Long Term Care I	Minimum Data Set Long-Term Care Resident Assessment Instrument User's Manual, Release 2.0, 2004, Centers For Medicare & Medicaid Services				
RFC 2806	URLs for Telephone Calls, 2000, A. Vaha-Sipila, The Internet Society				
RFC 2119	Key words for use in RFCs to Indicate Requirement Levels				
RFC 3066	Tags for the Identification of Languages, 2001, H. Alvestrand, The Internet Society				
Schematron	The Schematron Assertion Language 1.5, 2002, Rick Jelliffe, Academia Sinica Computing Centre				
SNOMED CT	SNOMED Clinical Terms, 2002, SNOMED International Organization				

# Appendix A — Validation

## Introduction

This appendix describes the vocabularies used or defined by this specification, and the Schematron schema that may be used to validate the content of the CDA Header for Care Record Summary documents.

# Vocabulary

A number of controlled vocabularies are referenced in this document. These controlled vocabularies are defined in various supporting specifications, and may be maintained by other bodies, as is the case for the LOINC and SNOMED CT. The Schematron schema makes use a supporting file (voc.xml) that contain these vocabularies or applicable subsets as of the release of this specification.

# **Extending the Vocabulary Tables for Local Use**

NOTE: An implementation that uses an extended vocabulary file to validate instances may<sup>10</sup> no longer conform to this guide.

The structure of this file is shown Figure 62. To extend the controlled vocabularies in voc.xml, simply add new entries to it.

Figure 62 voc.xml Structure

The file is a collection of coding systems. Each system has a name (codeSystemName). The root of a system represents the registered OID for that coding system. Within each system are code elements which provide the code value and a displayName for the code.

# **Administrative Contact Role Type**

Certain Administrative Contact Role Type codes are used to described emergency contacts and next of kin. These codes are drawn from the <u>RoleCode</u> vocabulary. The OID of this vocabulary domain is *2.16.840.1.113883.5.111*.

<sup>&</sup>lt;sup>10</sup> An implementation may add new vocabularies to support restriction of other elements not specified by this guide, or may restrict existing vocabularies by removing terms and still produce valid instances. Adding new terms to the listed vocabularies will result in non-conformance to this guide.

Code	Display Name	Description	
ECON	emergency contact	A contact designated for contact in emergent situations.	
NOK	next of kin	Played by an individual who is designated as the next of kin for another individual which scopes the role.	

#### **Administrative Gender**

Administrative Gender codes used to describe the gender of the patient should come from the HL7 AdministrativeGender vocabulary. The OID for this vocabulary domain is 2.16.840.1.113883.5.1.

Code	Display Name	Description
F	Female	Female
М	Male	Male
UN	Undifferentiated	The gender of a person could not be uniquely defined as male or female, such as hermaphrodite.

Table 4 Administrative Gender

# **Ethnicity**

Ethnicity codes used to describe the ethnicity of the patient should come from the HL7 Ethnicity vocabulary. The OID for this vocabulary domain is 2.16.840.1.113883.5.50. This vocabulary is listed below.

In the United States, federal standards for classifying data on ethnicity determine the categories used by federal agencies and exert a strong influence on categorization by state and local agencies and private sector organizations. The federal standards do not conceptually define ethnicity, and they recognize the absence of an anthropological or scientific basis for ethnicity classification. Instead, the federal standards acknowledge that ethnicity is a social-political construct in which an individual's own identification with a particular ethnicity is preferred to observer identification.

The standards specify two minimum ethnicity categories: Hispanic or Latino, and Not Hispanic or Latino. The standards define a Hispanic or Latino as a person of "Mexican, Puerto Rican, Cuban, South or Central America, or other Spanish culture or origin, regardless of race." The standards stipulate that ethnicity data need not be limited to the two minimum categories, but any expansion must be collapsible to those categories. In addition, the standards stipulate that an individual can be Hispanic or Latino or can be Not Hispanic or Latino, but cannot be both.

Category	Code	Display Name or Mnemonic
EthnicityHispanic	2135-2	EthnicityHispanic
	2182-4	Cuban
	2184-0	Dominican
EthnicityHispanicCentralAmerican	2155-0	EthnicityHispanicCentralAmerican
	2163-4	Canal Zone
	2162-6	Central American Indian
	2156-8	Costa Rican
	2157-6	Guatemalan
	2158-4	Honduran
	2159-2	Nicaraguan
	2160-0	Panamanian
	2161-8	Salvadoran
EthnicityHispanicMexican	2148-5	EthnicityHispanicMexican
	2151-9	Chicano
	2152-7	La Raza
	2149-3	Mexican American
	2153-5	Mexican American Indian
	2150-1	Mexicano
EthnicityHispanicSouthAmerican	2165-9	EthnicityHispanicSouthAmerican
	2166-7	Argentinean
	2167-5	Bolivian
	2168-3	Chilean
	2169-1	Colombian
	2176-6	Criollo
	2170-9	Ecuadorian
	2171-7	Paraguayan
	2172-5	Peruvian
	2175-8	South American Indian
	2173-3	Uruguayan
	2174-1	Venezuelan
EthnicityHispanicSpaniard	2137-8	EthnicityHispanicSpaniard
	2138-6	Andalusian
	2139-4	Asturian
	2142-8	Belearic Islander
	2145-1	Canarian
	2140-2	Castillian
	2141-0	Catalonian
	2143-6	Gallego
	2146-9	Spanish Basque
	2144-4	Valencian
	2178-2	Latin American
	2180-8	Puerto Rican
	2186-5	Not Hispanic or Latino

Table 5 Ethnicity

## **LOINC**

LOINC Codes are used to describe the types of documents within this guide. The following section lists the applicable LOINC codes at the time of publication. After publication, the maintainer of LOINC may update this list. The OID for LOINC is 2.16.840.1.113883.6.1.

Code	Display Name		
34133-9	SUMMARIZATION OF EPISODE NOTE		
18842-5	DISCHARGE SUMMARIZATION NOTE		
11490-0	DISCHARGE SUMMARIZATION NOTE		
28655-9	DISCHARGE SUMMARIZATION NOTE		
29761-4	DISCHARGE SUMMARIZATION NOTE		
34745-0	DISCHARGE SUMMARIZATION NOTE		
34105-7	DISCHARGE SUMMARIZATION NOTE		
34106-5	DISCHARGE SUMMARIZATION NOTE		
18761-7	TRANSFER SUMMARIZATION NOTE		
28616-1	TRANSFER SUMMARIZATION NOTE		
28651-8	TRANSFER SUMMARIZATION NOTE		
34755-9	TRANSFER SUMMARIZATION NOTE		
34770-8	TRANSFER SUMMARIZATION NOTE		

Table 6 LOINC Document Type Codes

#### **Marital Status**

Marital status codes used to describe the marital status of the patient should come from the HL7 MaritalStatus vocabulary. This vocabulary is listed below. The OID for this vocabulary domain is 2.16.840.1.113883.5.2.

Code	Display Name	Description		
A	Annulled	Marriage contract has been declared null and to not have existed		
D	Divorced	Marriage contract has been declared dissolved and inactive		
Т	Domestic partner	Person declares that a domestic partner relationship exists.		
I	Interlocutory	Subject to an Interlocutory Decree.		
L	Legally Separated			
М	Married A current marriage contract is active			
S	Never Married	er Married No marriage contract has ever been entered		
Р	Polygamous	More than 1 current spouse		
W	Widowed The spouse has died			

Table 7 Marital Status

# **Participation Function**

Participating function codes used to describe the exact function of a healthcare providers should come from the HL7 <a href="ParticipatingFunction">ParticipatingFunction</a> vocabulary. This vocabulary is listed below. The OID for this vocabulary domain is 2.16.840.1.113883.5.88.

Code	Display Name	Description		
ADMPHYS	admitting physician	A physician who admitted a patient to a hospital or other care unit that is the context of this service.		
ANRS	anesthesia nurse	In a typical anesthesia setting the nurse principally assisting the anesthesiologist during the critical periods.		
ANEST	anesthesist	In a typical anesthesia setting an anesthesiologist or anesthesia resident in charge of the anesthesia and life support, but only a witness to the surgical procedure itself. To clarify responsibilities anesthesia should always be represented as a separate service related to the surgery.		
ATTPHYS	attending physician	A physician who is primarily responsible for a patient during the hospitalization, which is the context of the service.		
DISPHYS	discharging physician	A physician who discharged a patient from a hospital or other care unit that is the context of this service.		
FASST	first assistant surgeon	In a typical surgery setting the assistant facing the primary surgeon. The first assistant performs parts of the operation and assists in others (e.g., incision, approach, electrocoutering, ligatures, sutures).		
MDWF	midwife	A person (usually female) helping a woman deliver a baby. Responsibilities vary locally, ranging from a mere optional assistant to a full required participant, responsible for (normal) births and pre- and post-natal care for both mother and baby.		
NASST	nurse assistant	In a typical surgery setting the non-sterile nurse handles material supply from the stock, forwards specimen to pathology, and helps with other non-sterile tasks (e.g., phone calls, etc.).		
PCP	primary care physician	The healthcare provider that holds primary responsibility for the overall care of a patient.		
PRISURG	primary surgeon	In a typical surgery setting the primary performing surgeon.		
RNDPHYS	rounding physician	A physician who made rounds on a patient in a hospital or other care center.		
SNRS	scrub nurse	In a typical surgery setting the nurse in charge of the instrumentation.		
SASST	second assistant surgeon	In a typical surgery setting the assistant who primarily holds the hooks.		
TASST	third assistant	In a typical surgery setting there is rarely a third assistant (e.g., in some Hip operations the third assistant postures the affected leg).		

Table 8 Participating Function Codes

# **Personal Relationship Role Type**

The Personal Relationship Role Type provides more information about the link between two people in a personal relationship. These codes are drawn from the RoleCode vocabulary. The OID of this vocabulary domain is 2.16.840.1.113883.5.111. As used within this guide the scoping person is the patient.

Category Code Display Name Descripti		Display Name	Description
FamilyMember			
Child	CHILD	Child	The player of the role is a child of the scoping entity.
AdoptedChild	CHLDADOPT	adopted child	The player of the role is a child taken into a family through legal means and raised by the scoping person (parent) as his or her own child.
	DAUADOPT	adopted daughter	The player of the role is a female child taken into a family through legal means and raised by the scoping person (parent) as his or her own child.
	SONADOPT	adopted son	The player of the role is a male child taken into a family through legal means and raised by the scoping person (parent) as his or her own child.
ChildInLaw	CHLDINLAW	child in-law	The player of the role is the spouse of scoping person's child.
	DAUINLAW	daughter in-law	The player of the role is the wife of scoping person's son.
	SONINLAW	son in-law	The player of the role is the husband of scoping person's daughter.
FosterChild	CHLDFOST	foster child	The player of the role is a child receiving parental care and nurture from the scoping person (parent) but not related to him or her through legal or blood ties.
	DAUFOST	foster daughter	The player of the role is a female child receiving parental care and nurture from the scoping person but not related to him or her through legal or blood ties.
	SONFOST	foster son	The player of the role is a male child receiving parental care and nurture from the scoping person (parent) but not related to him or her through legal or blood ties.
NaturalChild	NCHILD	natural child	The player of the role is an offspring of the scoping entity as determined by birth.
	DAU	natural daughter	The player of the role is a female offspring of the scoping entity (parent).
	SON	natural son	The player of the role is a male offspring of the scoping entity (parent).
StepChild	STPCHLD	step child	The player of the role is a child of the scoping person's spouse by a previous union.
	STPDAU	stepdaughter	The player of the role is a daughter of the scoping person's spouse by a previous union.
	STPSON	stepson	The player of the role is a son of the scoping person's spouse by a previous union.
GrandChild	GRNDCHILD	grandchild	The player of the role is a child of the scoping person's son or daughter.
	GRNDDAU	granddaughter	The player of the role is a daughter of the scoping person's son or daughter.
	GRNDSON	grandson	The player of the role is a son of the scoping person's son or daughter.

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Category	Code	Display Name	Description
Grandparent	GRPRN	Grandparent	The player of the role is a parent of the scoping person's mother or father.
	GRFTH	Grandfather	The player of the role is the father of the scoping person's mother or father.
	GRMTH	Grandmother	The player of the role is the mother of the scoping person's mother or father.
GreatGrandparent	GGRPRN	great grandparent	The player of the role is a parent of the scoping person's grandparent.
	GGRFTH	great grandfather	The player of the role is the father of the scoping person's grandparent.
	GGRMTH	great grandmother	The player of the role is the mother of the scoping person's grandparent.
NieceNephew	NIENEPH	niece/nephew	The player of the role is a child of scoping person's brother or sister or of the brother or sister of the scoping person's spouse.
	NEPHEW	nephew	The player of the role is a son of the scoping person's brother or sister or of the brother or sister of the scoping person's spouse.
	NIECE	niece	The player of the role is a daughter of the scoping person's brother or sister or of the brother or sister of the scoping person's spouse.
Parent	PRN	Parent	The player of the role is one who begets, gives birth to, or nurtures and raises the scoping entity (child).
NaturalParent	NPRN	natural parent	
	NFTH	natural father	The player of the role is a male who begets the scoping entity (child).
	NMTH	natural mother	The player of the role is a female who conceives or gives birth to the scoping entity (child).
ParentInLaw	PRNINLAW	parent in-law	The player of the role is the parent of scoping person's husband or wife.
	FTHINLAW	father-in-law	The player of the role is the father of the scoping person's husband or wife.
	MTHINLOAW	mother-in-law	The player of the role is the mother of the scoping person's husband or wife.
StepParent	STPPRN	step parent	The player of the role is the spouse of the scoping person's parent and not the scoping person's natural parent.
	STPFTH	stepfather	The player of the role is the husband of scoping person's mother and not the scoping person's natural father.
	STPMTH	stepmother	The player of the role is the wife of scoping person's father and not the scoping person's natural mother.
	FTH	Father	The player of the role is a male who begets or raises or nurtures the scoping entity (child).
	MTH	Mother	The player of the role is a female who conceives, gives birth to, or raises and nurtures the scoping entity (child).
Sibling	SIB	Sibling	The player of the role shares one or both parents in common with the scoping entity.
HalfSibling	HSIB	half-sibling	The player of the role is related to the scoping entity by sharing only one biological parent.
	HBRO	half-brother	The player of the role is a male related to the scoping entity by sharing only one biological parent

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Category	Code	Display Name	Description
			sharing only one biological parent.
	HSIS	half-sister	The player of the role is a female related to the scoping entity by sharing only one biological parent.
NaturalSibling	NSIB	natural sibling	The player of the role has both biological parents in common with the scoping entity.
	NBRO	natural brother	The player of the role is a male having the same biological parents as the scoping entity.
	NSIS	natural sister	The player of the role is a female having the same biological parents as the scoping entity.
SiblingInLaw	SIBINLAW	sibling in-law	The player of the role is: (1) a sibling of the scoping person's spouse, or (2) the spouse of the scoping person's sibling, or (3) the spouse of a sibling of the scoping person's spouse.
	BROINLAW	brother-in-law	The player of the role is: (1) a brother of the scoping person's spouse, or (2) the husband of the scoping person's sister, or (3) the husband of a sister of the scoping person's spouse.
	SISLINLAW	sister-in-law	The player of the role is: (1) a sister of the scoping person's spouse, or (2) the wife of the scoping person's brother, or (3) the wife of a brother of the scoping person's spouse.
StepSibling	STPSIB	step sibling	The player of the role is a child of the scoping person's stepparent.
	STPBRO	stepbrother	The player of the role is a son of the scoping person's stepparent.
	STPSIS	stepsister	The player of the role is a daughter of the scoping person's stepparent.
	BRO	Brother	The player of the role is a male sharing one or both parents in common with the scoping entity.
	SIS	Sister	The player of the role is a female sharing one or both parents in common with the scoping entity.
SignificantOther RoleType	SIGOTHR	significant other	A person who is important to one's well being; especially a spouse or one in a similar relationship. (The player is the one who is important)
Spouse	SPS	spouse	The player of the role is a marriage partner of the scoping person.
	HUSB	husband	The player of the role is a man joined to a woman (scoping person) in marriage.
	WIFE	wife	The player of the role is a woman joined to a man (scoping person) in marriage.
	AUNT	aunt	The player of the role is a sister of the scoping person's mother or father.
	COUSN	cousin	The player of the role is a relative of the scoping person descended from a common ancestor, such as a grandparent, by two or more steps in a diverging line.
	DOMPART	domestic partner	The player of the role cohabits with the scoping person but is not the scoping person's spouse.
	ROOM	Roomate	One who shares living quarters with the subject.
	UNCLE	uncle	The player of the role is a brother of the scoping person's mother or father.
	FRND	unrelated friend	The player of the role is a person who is known, liked, and trusted by the scoping person.
	NBOR	neighbor	The player of the role lives near or next to the scoping person.

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#### Race

Race codes used to describe the race of the patient should come from the HL7 Race vocabulary. This vocabulary is too extensive to list in this document. The OID for this vocabulary domain is 2.16.840.1.113883.5.104.

In the United States, federal standards for classifying data on race determine the categories used by federal agencies and exert a strong influence on categorization by state and local agencies and private sector organizations. The federal standards do not conceptually define race, and they recognize the absence of an anthropological or scientific basis for racial classification. Instead, the federal standards acknowledge that race is a social-political construct in which an individual's own identification with one more race categories is preferred to observer identification. The standards use a variety of features to define five minimum race categories. Among these features are descent from "the original peoples" of a specified region or nation. The minimum race categories are American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and White. The federal standards stipulate that race data need not be limited to the five minimum categories, but any expansion must be collapsible to those categories.

#### **SNOMED CT**

<u>SNOMED Clinical Terms</u> is a dynamic and scientifically validated ontology of clinical healthcare terminology. It is published by SNOMED International, and is made available free of charge in the United States by the US National Library of Medicine.

This guide uses SNOMED CT to classify providers of healthcare. The OID for SNOMED CT is 2.16.840.1.113883.6.96.

#### Schematron Validation

The Schematron schema below will validate a CDA Document instance against the conformance requirements of this specification, and report the failed validation constraints. It uses version 1.5 of Schematron.

#### How to Read the Schema

Schematron schemas are collections of patterns. Each pattern contains one or more rules which provide the context in which the rule is triggered. The first rule from each pattern will be triggered for each element in the instance that matches the context of the rule. Each rule may assert that a test has passed, or report that a test has failed and can provide one or more diagnostic messages. The test attributes found in assert and report elements are XPath expressions executed in the context of the parent rule.

Schematron can be implemented using a two phase XSL Transformation. The first phase uses the Schematron stylesheet to process the schema, producing a second XSL transformation. That transformation is executed over the instance to be validated, producing the validation output.

For more information, see the Schematron 1.5 specification.

## The Schema

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<?xml version="1.0" encoding="UTF-8" standalone="yes"?>
<!DOCTYPE schema [
< ! --
Replace baseURI below with a reference to the published Implementation Guide HTML.
<!ENTITY baseURI "">
]>
<schema xmlns="http://www.ascc.net/xml/schematron" xmlns:cda="urn:hl7-org:v3">
  <title>
   Schematron schema for validating conformance to IMPL_CDAR2_LEVEL1REF_US_I1_2005MAY
  </title>
  <ns prefix="cda" uri="urn:hl7-org:v3" />
  <pattern name='ClinicalDocument' see='&baseURI;#ClinicalDocument'>
   This schema applies to CDA Release 2.0 documents.
   <rule id='cda-root' context='/*'>
     <assert diagnostics="CNF-1" test='self::cda:ClinicalDocument'>
       The root of a Care Record Summary must be a <emph>ClinicalDocument</emph> element from
       the <emph>urn:h17-org-v3</emph> namespace.
     </assert>
   </rule>
  </pattern>
  <rule id='cda-id-uuid' context="/cda:ClinicalDocument/cda:id[contains(@root, '-')]">
     <assert diagnostics='CNF-2 CNF-3' test="string-length(@root) = 37" >
       A properly formatted UUID has only 37 characters.
     </assert>
     <assert diagnostics='CNF-2 CNF-3'</pre>
       test="translate(substring(@root, 1, 8), 'ABCDEFabcdef0123456789','') = ''">
       The first four data bytes of the UUID should be represented using hexidecimal
       digits ([A-Fa-f0-9]).
     </assert>
     <assert diagnostics='CNF-2 CNF-3'</pre>
       test="translate(substring(@root, 10, 4),'ABCDEFabcdef0123456789','') = ''" >
       The fifth and sixth data bytes of the UUID should be represented using hexidecimal
       digits ([A-Fa-f0-9]).
     </assert>
     <assert diagnostics='CNF-2 CNF-3'</pre>
       test="translate(substring(@root, 15, 4), 'ABCDEFabcdef0123456789','') = ''">
       The seventh and eighth data bytes of the UUID should be represented using hexidecimal
       digits ([A-Fa-f0-9]).
     </assert>
     <assert diagnostics='CNF-2 CNF-3'</pre>
       test="translate(substring(@root, 20, 4),'ABCDEFabcdef0123456789','') = ''">
       The ninth and tenth data bytes of the UUID should be represented using hexidecimal
       digits ([A-Fa-f0-9]).
     </assert>
     <assert diagnostics='CNF-2 CNF-3'</pre>
       test="translate(substring(@root, 25, 12), 'ABCDEFabcdef0123456789','') = ''">
       The eleventh through sixteenth data bytes of the UUID should be represented using
       hexidecimal digits ([A-Fa-f0-9]).
     <assert diagnostics='CNF-2 CNF-3' test="substring(@root, 9, 1) = '-'">
       A hyphen should separate the first four data bytes from the remainder of the UUID.
     </assert>
     <assert diagnostics='CNF-2 CNF-3' test="substring(@root, 14, 1) = '-'">
       A hyphen should separate the fifth and sixth data byte from the remainder of the UUID.
     <assert diagnostics='CNF-2 CNF-3' test="substring(@root, 19, 1) = '-'">
      A hyphen should separate the seventh and eighth data byte from the remainder of the UUID.
     <assert diagnostics='CNF-2 CNF-3' test="substring(@root, 24, 1) = '-'">
       A hyphen should separate the ninth and tenth data byte from the remainder of the UUID.
     </assert>
    </rule>
    <rule id='cda-id-oid' context="/cda:ClinicalDocument/cda:id[contains(@root, '.')]" >
     <assert test="translate(@root, '0123456789.', '') = ''" diagnostics='CNF-2 CNF-4'>
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Characters that are not in the set 0-9 or . are not present in a valid OID.
     </assert>
     <assert diagnostics='CNF-2 CNF-4'</pre>
       test="not(substring(@root, 1, 1) = '.') and not(substring(@root, string-length(@root), 1)
= '.')" >
       The first and last characters of an OID must be a digit.
     </assert>
     <assert diagnostics='CNF-2 CNF-4' test="not(contains(@root,'..'))">
       A properly formatted OID should not contain two . characters without any
       intervening digits
     </assert>
     <assert diagnostics='CNF-5' test="string-length(@root) &lt; 65">
       An OID must be shorter than 65 characters.
     </assert>
   </rule>
   <rule id='cda-id' context='cda:id[not(contains(@root,".") or contains(@root,"-"))]'>
     <assert diagnostics='CNF-2' test='false()'>
       The root attribute of the id element must be a syntactically correct UUID or OID.
     </assert>
   </rule>
 </pattern>
 <pattern name='ClinicalDocument_code' see='&baseURI;#ClinicalDocument_code'>
   <rul><!rule id='clinical-document-code' context='/cda:ClinicalDocument/cda:code'>
     <assert diagnostics='CNF-6'
       test='document("voc.xml")/systems/system[@codeSystemName="LOINC"]/code[current()/@code]'>
       The value of <emph>/ClinicalDocument/code/@code</emph> must come from the
       appropriate LOINC subset.
     </assert>
     <assert test='@codeSystem = "2.16.840.1.113883.6.1"' diagnostics='CNF-7'>
       The value of <emph>/ClinicalDocument/code/@codeSystem</emph> must be
2.16.840.1.113883.6.1
     </assert>
     <assert test='count(@codeSystemName) = 0 or @codeSystemName="LOINC"' diagnostics='CNF-8'>
       The value of <emph>/ClinicalDocument/code/@codeSystemName</emph> must be
       <emph>LOINC.
     </assert>
     <assert diagnostics="CNF-9" test='true()'>
       If pre-coordinated document type codes are used, the role code and function code for the
       author must not conflict with the document type code.
     </assert>
   </rule>
 </pattern>
  <pattern name='ClinicalDocument_effectiveTime' see='&baseURI;#ClinicalDocument_effectiveTime'>
   <rule context='/cda:ClinicalDocument/cda:effectiveTime'>
     <assert diagnosics='CNF-10' test='not(contains(translate(@value,"+-","Z"),"Z")) or string-</pre>
length(substring-before(translate(@value,"+-","Z"),"Z")) > 7'>
       The <emph>effectiveTime</emph> element must be precise at least to the day.
     </assert>
     <assert diagnostics="CNF-11" test='contains(translate(@value,"+-","Z"),"Z")'>
       The emph>effectiveTime</emph> element must have a time zone.
   </rule>
 </pattern>
 <pattern name='ClinicalDocument_languageCode' see='&baseURI;#ClinicalDocument_languageCode'>
   <rule context='/cda:ClinicalDocument/cda:languageCode'>
     <assert diagnostics='CNF-12'</pre>
       test='(string-length(@value) = 5 and substring(@value,3,1) = "-") or string-
length(@value) = 2' >
       The language code must be in the form <emph>nn</emph>, or <emph>nn-CC</emph>.
     </assert>
     <assert diagnostics='CNF-13'</pre>
       test='substring(@value,1,2) = document("voc.xml")/systems/system[@codeSystemName="ISO639-
1"]/code/@value' >
       The language must be a legal ISO-639-1 language code in lower case.
     </assert>
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<assert diagnostics='CNF-14'</pre>
       test='string-length(@value) = 2 or substring(@value,4,2) =
document("voc.xml")/systems/system[@codeSystemName="ISO3166-1"]/code/@value' >
       The country code portion, if present must be an ISO-3166 country code in upper case.
     </assert>
   </rule>
 </pattern>
 <pattern name='ClinicalDocument_setId' see='&baseURI;#ClinicalDocument_setId'>
   <rule context='/cda:ClinicalDocument/cda:setId'>
     <assert diagnostics="CNF-15" test='/cda:ClinicalDocument/cda:versionNumber'>
       When <emph>setId</emph> is present, then <emph>versionNumber</emph> must be present.
     </assert>
     <assert diagnostics="CNF-16" test='@root != ../cda:id/@root or @extension !=</pre>
../cda:id/@extension or ../cda:versionNumber/@value = 1' >
       Either there is no <emph>setId</emph>, or then <emph>extension</emph> and/or
       <emph>root</emph> of <emph>setId</emph> and <emph>id</emph> are different, or the
       <emph>versionNumber</emph> of the document is <emph>1</emph>.
     </assert>
   </rule>
 </pattern>
 <pattern name='ClinicalDocument_copyTime' see='&baseURI;#ClinicalDocument_copyTime'>
   <rule context='/cda:ClinicalDocument/cda:copyTime'>
     <assert test='false()' diagnostics='CNF-17'>
       No <emph>copyTime</emph> element is present in the <emph>ClinicalDocument</emph>.
     </assert>
   </rule>
 </pattern>
 <pattern name='authenticator' see='&baseURI;#authenticator'>
   <rule context='cda:authenticator'>
     <assert diagnostics="CNF-18" test='cda:assignedEntity/cda:addr'>
       The <emph>assignedEntity/addr</emph> element of the <emph>authenticator</emph> element
       must be present.
     </assert>
     <assert diagnostics="CNF-19"</pre>
       test='cda:assignedEntity/cda:telecom[boolean(@nullFlavor) or substring-before(@value,":")
= "tel"l'>
       An <emph>assignedEntity/telecom</emph> element must be present whose value contains a
       contact phone number.
     </assert>
     <assert diagnostics='CNF-20' test='cda:assignedEntity/cda:assignedPerson'>
       The <emph>assignedPerson</emph> element must be present.
     </assert>
   </ri>
  </pattern>
 <pattern name='ClinicalDocument_General_Constraints'</pre>
see='&baseURI;#ClinicalDocument_General_Constraints'>
   <rule context='cda:addr'>
     <assert test='not(@nullFlavor) or (@nullFlavor and normalize-space(.) = "")'>
       When the <emph>addr</emph> element is null, it should not have content.
     <assert test='not(@nullFlavor) and (string-length(normalize-space(.)) &gt; 0)'>
       When the <emph>addr</emph> element is empty, it must have a value for
       <emph>nullFlavor.
     </assert>
   </rule>
   <rule context='cda:assignedPerson'>
     <assert diagnostics="CNF-20 CNF-35" test='cda:name'>
       The <emph>name</emph> of an <emph>assignedPerson</emph> must be present.
     </assert>
   </rule>
   <rule context='cda:representedOrganization'>
     <assert test='cda:name'>
       The <emph>name</emph> of a <emph>representedOrganization</emph> must be present.
     </assert>
   </rule>
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<rule context='cda:authenticator | cda:author | cda:dataEnterer | cda:legalAuthenticator'>
          <assert diagnosics='CNF-22 CNF-33' test='not(contains(translate(cda:time/@value,"+-</pre>
","Z"),"Z")) or string-length(substring-before(translate(cda:time/@value,"+-","Z"),"Z")) > 7'>
            The <emph>time</emph> element must be precise at least to the day.
         </assert>
         <assert diagnosics='CNF-23 CNF-34' test='contains(translate(cda:time/@value,"+-</pre>
","Z"),"Z")'>
            The <emph>time</emph> element must have a time zone.
         </assert>
      </rule>
   </pattern>
   <pattern name='author' see='&baseURI;#author'>
      <rule context='cda:author'>
         <assert diagnostics="CNF-21" test='cda:time'>
            The <emph>author/time</emph> element must be present.
      </rule>
      <rul><!rule context='cda:ClinicalDocument'>
         <assert diagnostics="CNF-24" test='cda:author/cda:assignedAuthor'>
            There is at least one <emph>assignedAuthor</emph>.
      </rule>
      <rule context='cda:assignedAuthor'>
         <assert diagnostics="CNF-25" test='cda:id'>
            The <emph>assignedAuthor/id</emph> element must be present.
         </assert>
         <assert diagnostics="CNF-26" test='cda:telecom[boolean(@nullFlavor) or substring-</pre>
before(@value,":") = "tel"]'>
            All <emph>assignedAuthors</emph> have at least one <emph>telecom</emph> element that
            contains a contact phone number.
         </assert>
         <assert diagnostics="CNF-27" test='cda:assignedPerson'>
            There is at least one <emph>assignedAuthor/assignedPerson</emph>.
         </assert>
         <assert diagnostics="CNF-28"</pre>
            test='not(cda:code) or (cda:code/@codeSystem = "2.16.840.1.113883.5.111" and
(cda:code/@code = "SELF" or
/cda:code/@code]))'>
            When <emph>assignedAuthor/code</emph> is present, its value comes from the
             <emph>PersonalRelationshipRoleType</emph> domain, or is the value <emph>SELF</emph>
            from the RoleCode Domain.
         </assert>
      </rule>
      <rule context='cda:assignedAuthoringDevice'>
         <assert diagnostics="CNF-29" test='cda:softwareName'>
            When <emph>assignedAuthoringDevice</emph> is present, the <emph>softwareName</emph>
            element must be present.
         </assert>
         <assert diagnostics="CNF-29" test='string-length(normalize-space(cda:softwareName)) &gt;</pre>
0'>
            When <emph>assignedAuthoringDevice/softwareName</emph> must have a value.
         </assert>
      </rule>
   </pattern>
   <pattern name='custodian' see='&baseURI;#custodian'>
      <rule context='cda:custodian'>
         <assert diagnostics="CNF-30"</pre>
           test='cda:assignedCustodian/cda:representedCustodianOrganization/cda:name'>
            A <emph>custodian/assignedCustodian/representedCustodianOrganization/name</emph> element
            must be present.
         </assert>
         <assert diagnostics="CNF-31"</pre>
  \verb|test='cda:| assignedCustodian/cda:| representedCustodianOrganization/cda:| telecom[boolean(@nullFlavorganization/cda:| telecom[boolean(@nullFlavorgani
r) or substring-before(@value,":") = "tel"]'>
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element must be present that contains a telephone contact.
     </assert>
     <assert diagnostics="CNF-32"</pre>
       test='cda:assignedCustodian/cda:representedCustodianOrganization/cda:addr'>
       A <emph>custodian/assignedCustodian/representedCustodianOrganization/addr</emph> element
       must be present.
     </assert>
    </rule>
  </pattern>
  <pattern name='dataEnterer' see='&baseURI;#dataEnterer'>
    <rule context='cda:dataEnterer'>
     <assert diagnostics="CNF-35" test='cda:assignedEntity/cda:assignedPerson'>
       All <emph>dataEnterer</emph> elements have an <emph>assignedEntity/assignedPerson</emph>
     </assert>
    </rule>
  </pattern>
 <pattern name='informant' see='&baseURI;#informant'>
    <rule context='cda:informant'>
     <assert diagnostics="CNF-36"</pre>
 test='cda:assignedEntity/cda:assignedPerson/cda:name|cda:relatedEntity/cda:relatedPerson/cda:name
       An informant must have either an <emph>assignedEntity/assignedPerson/name</emph> element,
       or a <emph>relatedEntity/relatedPerson/name</emph> element.
     </assert>
    </rule>
    <rule context='cda:informant/cda:relatedEntity[@classCode = "PRS"]'>
     <assert diagnostics="CNF-37"</pre>
       test='cda:code/@codeSystem = "2.16.840.1.113883.5.111" and cda:code/@code =
When <emph>relatedEntity/@classCode</emph> is <emph>PRS</emph>, values in
       <emph>relatedEntity/code</emph> shall come from the
       <emph>PersonalRelationshipRoleType</emph> vocabulary.
     </assert>
    </rule>
    <rul>< context='cda:informant/cda:relatedEntity[@classCode = "CON"]'>
     <assert diagnostics="CNF-38" test='not(cda:code)'>
       When <emph>relatedEntity/@classCode</emph> is <emph>CON</emph>,
       <emph>relatedEntity/code</emph> shall not be present.
     </assert>
    </rule>
    <rul><!rule context='cda:informant/cda:relatedEntity[@classCode = "PROV"]/cda:code'>
     <assert diagnostics="CNF-39"
       test='@codeSystem = "2.16.840.1.113883.6.96" and @code = ^{\circ}
document("voc.xml")/systems/system[@codeSystemName="HealthcareProfessionals"]/code/@value'>
       When <emph>relatedEntity/@classCode</emph> is <emph>PROV</emph>,
       <emph>relatedEntity/code</emph> shall be descended from the
       \ensuremath{^{<}}mph\ensuremath{^{>}}healthcare professional\ensuremath{^{<}}emph\ensuremath{^{>}} concept (223366009) of SNOMED CT.
     </assert>
   </rule>
 </pattern>
  <pattern name='informationRecipient' see='&baseURI;#informationRecipient'>
    <rule context='cda:intendedRecipient/cda:informationRecipient'>
     <assert diagnostics="CNF-41" test='cda:name'>
       All <emph>informationRecipient</emph> elements have a <emph>name</emph> element.
     </assert>
   </rule>
    <rule context='cda:recievedOrganization'>
     <assert diagnostics="CNF-42" test='cda:name'>
       All <emph>recievedOrganization</emph> elements have a <emph>name</emph> element.
     </assert>
    </rule>
    <rule context='cda:ClinicalDocument/cda:informationRecipient'>
     <assert diagnostics="CNF-40"</pre>
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test='cda:intendedRecipient/cda:informationRecipient |
cda:intendedRecipient/cda:recievedOrganization'>
       At least one of <emph>intendedRecipient/informationRecipient</emph> or
       <emph>intendedRecipient/recievedOrganization</emph>
       must be present.
      </assert>
      <assert diagnostics="CNF-43"</pre>
       test='cda:intendedRecipient/cda:telecom[boolean(@nullFlavor) or substring-
before(@value,":") = "tel"]'>
       All <emph>intendedRecipient</emph> elements have at least one <emph>telecom</emph>
       element that contains a contact phone number.
     </assert>
     <assert diagnostics="CNF-44" test='cda:intendedRecipient/cda:addr'>
       All <emph>intendedRecipient</emph> elements have an <emph>addr</emph> element.
   </rule>
  </pattern>
  <pattern name='legalAuthenticator' see='&baseURI;#legalAuthenticator'>
    <rule context='cda:legalAuthenticator'>
      <assert diagnostics="CNF-45"</pre>
       test='cda:assignedEntity/cda:telecom[boolean(@nullFlavor) or substring-before(@value,":")
= "tel"]'>
       All <emph>legalAuthenticator/assignedEntity</emph> elements have at least one
       <emph>telecom</emph> element
       that contains a contact phone number.
      <assert diagnostics="CNF-46" test='cda:assignedEntity/cda:addr'>
       All <emph>legalAuthenticator/assignedEntity</emph> elements have an
       <emph>addr</emph> element.
      </assert>
      <assert diagnostics='CNF-47' test='cda:assignedEntity/cda:assignedPerson'>
       The <emph>legalAuthenticator/assignedEntity/assignedPerson</emph> element
       must be present.
      </assert>
    </rule>
  </pattern>
  <pattern name='participant' see='&baseURI;#participant'>
    <rule context='cda:participatingEntity'>
     <assert diagnostics="CNF-48" test='cda:addr'>
       The <emph>participatingEntity/addr </emph>element must be present.
     </assert>
     <assert diagnostics="CNF-49"</pre>
       test='cda:telecom[boolean(@nullFlavor) or substring-before(@value,":") = "tel"]'>
       A <emph>participatingEntity/telecom</emph> element must be present that contains a
       contact phone number
       for the participant.
     </assert>
    </rule>
    <rule context='cda:scopingOrganization'>
     <assert diagnostics='CNF-50' test='cda:name'>
       The <emph>name</emph> element must be present in a <emph>scopingOrganization</emph>
       element.
     </assert>
      <assert diagnostics='CNF-51' test='cda:addr'>
       The <emph>name</emph> element must be present in a <emph>scopingOrganization</emph>
       element.
      </assert>
     <assert diagnostics='CNF-52' test='cda:telecom[boolean(@nullFlavor) or substring-</pre>
before(@value,":") = "tel"]'>
       A <emph>telecom</emph> element must be present that contains a contact phone number
       in a <emph>scopingOrganization</emph> element.
     </assert>
    </rule>
    <rule context='cda:participant[@typeCode="IND"]'>
      <assert diagnostics="CNF-53" test='not(cda:functionCode)'>
       When <emph>participant/@typeCode</emph> is <emph>IND</emph>, <emph>functionCode</emph>
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must not be present.
     </assert>
     <assert diagnostics="CNF-54" test='cda:participatingEntity/@classCode = "PRS"'>
      When <emph>participant/@typeCode</emph> is <emph>IND</emph>,
       <emph>participatingEntity/@classCode</emph> must be <emph>PRS</emph>.
   </ri>
   <rule context='cda:participant[@typeCode="IND"]/cda:participatingEntity/cda:code'>
     <assert diagnostics="CNF-55"</pre>
 test='count(@code[.=document("voc.xml")/systems/system[@codeSystemName="PersonalRelationshipRol
eType"]/code/@value]) = 1'>
       When <emph>participant/@typeCode</emph> is <emph>IND</emph>, only one
       <emph>participatingEntity/code</emph> must be present having
       a value drawn from the PersonalRelationshipRoleType domain.
     </assert>
     <assert diagnostics="CNF-56"</pre>
 test='@code=document("voc.xml")/systems/system[@codeSystemName="PersonalRelationshipRoleType"]/
code/@value or @code = "ECON" or @code = "NOK"'>
       When <emph>participant/@typeCode</emph> is <emph>IND</emph>, other
       <emph>participatingEntity/code</emph> elements present that are not drawn from the the
       PersonalRelationshipRoleType domain must be either ECON or NOK.
     <assert diagnostics='CNF-55 CNF-56'</pre>
       test='@codeSystem="2.16.840.1.113883.5.111"'>
       When <emph>participant/@typeCode</emph> is <emph>IND</emph>, the code/@codeSystem
       must be 2.16.840.1.113883.5.111.
     </assert>
   </rule>
   <rule context='cda:participant[@typeCode="HLD"]'>
     <assert diagnostics="CNF-57" test='not(cda:functionCode)'>
       must not be present.
     </assert>
   </rule>
   <rule context='cda:participant[@typeCode="HLD"]/cda:participatingEntity'>
     <assert diagnostics="CNF-58" test='@classCode = "POLHOLD"'>
       When <emph>participant/@typeCode</emph> is <emph>HLD</emph>,
       <emph>participatingEntity/@classCode</emph> must be
       <emph>POLHOLD</emph>.
     </assert>
     <assert diagnostics="CNF-59" test='cda:scopingOrganization'>
       When <emph>participant/@typeCode</emph> is <emph>HLD</emph>,
       <assert diagnostics="CNF-60" test='count(cda:code[(@codeSystem="2.16.840.1.113883.5.111"</pre>
and @code="SELF") or (@codeSystem="2.16.840.1.113883.5.1095" and @code
document("voc.xml")/systems/system[@codeSystemName="PolicyHolderRole"]/code/@value)]) = 1'>
       When <emph>participant/@typeCode</emph> is <emph>HLD</emph>, one and only one
       <emph>participatingEntity/code</emph> must be present having a value drawn from the
       Policy Holder Role vocabulary defined by this specification, or must use the code for
       SELF drawn from the the CoverageRoleType vocabulary domain.
     </assert>
   </rule>
 </pattern>
 <pattern name='recordTarget' see='&baseURI;#recordTarget'>
   <rule context='cda:recordTarget'>
     <assert diagnostics="CNF-61" test='count(cda:patient) &gt; 0'>
      At least one <emph>recordTarget/patient</emph> element exists<emph>.</emph>
     </assert>
     <assert diagnostics="CNF-62" test='cda:patient/cda:addr'>
      The <emph>recordTarget/patient</emph> element has an <emph>addr</emph> element.
     </assert>
     <assert diagnostics="CNF-63"</pre>
       test='cda:patient/cda:telecom[boolean(@nullFlavor) or substring-before(@value,":") =
"tel"]'>
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The <emph>recordTarget/patient</emph> element has a <emph>telecom</emph> element
       that represents a contact phone number.
      </assert>
     <assert diagnostics="CNF-64" test='cda:patient/cda:patientPatient/cda:birthTime'>
       A <emph>patientPatient/birthTime</emph> element is present.
     </assert>
     <assert diagnostics="CNF-65"</pre>
test='cda:patient/cda:patientPatient/cda:administrativeGenderCode'>
       A <emph>patientPatient/administrativeGenderCode</emph> element is present.
   </rule>
    <rule context='cda:recordTarget/cda:patient/cda:providerOrganization'>
     <assert diagnostics="CNF-66" test='cda:name'>
       All <emph>providerOrganization</emph> elements have a <emph>name</emph> element.
     <assert diagnostics="CNF-67" test='cda:addr'>
       All <emph>providerOrganization</emph> elements have an <emph>addr </emph>element.
     </assert>
     <assert diagnostics="CNF-68" test='cda:telecom[boolean(@nullFlavor) or substring-</pre>
before(@value,":") = "tel"]'>
       All <emph>providerOrganization</emph> elements have a <emph>telecom </emph>element
       that is a telephone contact number.
     </assert>
    </rule>
  </pattern>
 <pattern name='documentationOf' see='&baseURI;#documentationOf'>
    <!-- TBD 70-73 -->
    <rul><rule context='cda:ClinicalDocument'>
     <assert diagnostics="CNF-69" test='cda:documentationOf'>
       There is only one <emph>documentationOf</emph> element in the
<emph>ClinicalDocument.
     </assert>
   </rule>
    <rul><rule context='cda:seviceEvent'>
     <assert diagnostics="CNF-70" test='cda:effectiveTime'>
       The <emph>effectiveTime</emph> element of the <emph>serviceEvent</emph> element must
       be present.
     </assert>
   </rule>
    <rul><!rule context='cda:seviceEvent/cda:effectiveTime'>
     <assert diagnostics="CNF-71" test='count(cda:low) = 1'>
       The <emph>effectiveTime</emph> element must contain only one <emph>low</emph> element.
       The <emph>low</emph> element is unrestricted with respect to precision or time zone.
     </assert>
     <assert diagnostics="CNF-72" test='count(cda:high) = 1'>
       The <emph>effectiveTime</emph> element must contain only one <emph>high</emph> element.
       The <emph>high</emph> element is unrestricted with respect to precision or time zone.
     </assert>
    </rule>
    <rule context='cda:performer/cda:assignedEntity'>
     <assert diagnostics="CNF-73" test='count(cda:code) = 1 and</pre>
cda:code/@codeSystem="2.16.840.1.113883.6.96"'>
       One and only one <emph>performer/assigneEntity/code</emph> must be present, and
       it must have a value drawn from the SNOMED CT healthcare professional subtype
       hierarchy.
     </assert>
     <assert diagnostics="CNF-74" test='cda:assignedPerson | cda:representedOrganization'>
       Every <emph>performer/assignedEntity</emph> element has at least one
       \verb| <emph> assignedPerson</emph> or <emph>representedOrganization</emph> element. |
     <assert diagnostics="CNF-75" test='cda:addr'>
       All <emph>performer/assignedEntity</emph> elements have an
       <emph>addr</emph> element.
     </assert>
     <assert diagnostics="CNF-76" test='cda:telecom[boolean(@nullFlavor) or substring-</pre>
before(@value,":") = "tel"]'>
       All <emph>performer</emph>/<emph>assignedEntity</emph> elements have a
       <emph>telecom </emph>element that is a telephone contact number.
```

```
</assert>
    </ri>
    <rul><!rule context='cda:performer/cda:assignedEntity/cda:assignedPerson'>
     <assert diagnostics="CNF-77" test='cda:name'>
       All <emph>assignedPerson</emph> elements of
       <emph>performer/assignedEntity</emph> must have a <emph>name</emph> element.
     </assert>
    </rule>
    <rule context='cda:performer/cda:assignedEntity/cda:representedOrganization'>
     <assert diagnostics="CNF-78" test='cda:name'>
       The <emph>name</emph> element must be present in a
       <emph>performer/assignedEntity/representedOrganization</emph> element.
     </assert>
     <assert diagnostics="CNF-79" test='cda:addr'>
       The <emph>addr</emph> element must be present in a
       <emph>performer/assignedEntity/representedOrganization</emph> element.
     <assert diagnostics="CNF-80" test='cda:telecom[boolean(@nullFlavor) or substring-</pre>
before(@value,":") = "tel"]'>
       A telecom element must be present that contains a contact phone number in a
       <emph>performer/assignedEntity/representedOrganization</emph> element.
    </ri>
  </pattern>
  <pattern name='componentOf' see='&baseURI;componentOf'>
    <rule context='/cda:ClinicalDocument/cda:code'>
      <assert diagnostics='CNF-81'
       test='/cda:ClinicalDocument/cda:componentOf or
not(document("voc.xml")/systems/system[@codeSystemName="LOINC"]/code[@value =
current()]/@displayName = "DISCHARGE SUMMARIZATION NOTE" or
document("voc.xml")/systems/system[@codeSystemName="LOINC"]/code[@value =
current()/@code]/@displayName = "TRANSFER SUMMARIZATION NOTE")'>
       If the Care Record Summary is a Discharge or Transfer Summarization,
       then the <emph>componentOf</emph> element is required.
     </assert>
    </rule>
    <rule context='cda:encompassingEncounter'>
     <assert diagnostics="CNF-82" test='cda:id'>
       \label{thm:compassingEncounter} The~<emph>encompassingEncounter</emph>~element~must~have~an~<emph>id</emph>~element~.
     <assert diagnostics="CNF-83" test='cda:effectiveTime'>
       The <emph>encompassingEncounter</emph> element must have an <emph>effectiveTime</emph>
       element.
     </assert>
     <assert diagnostics="CNF-84"</pre>
       test='cda:dischargeDisposition or
not(document("voc.xml")/systems/system[@codeSystemName="LOINC"]/code[@value =
current()/ancestor::cda:ClinicalDocument/cda:code/@code]/@displayName = "DISCHARGE SUMMARIZATION
NOTE") '>
       If <emph>ClinicalDocument/code/@value</emph> represents a Discharge Summarization Note,
       then <emph>dischargeDispositionCode</emph> must be present.
     </assert>
    </rule>
   <rul><!rule context='cda:encounterParticipant/cda:assignedEntity'>
     <assert diagnostics="CNF-85" test='cda:addr'>
       The <emph>encounterParticipant/assignedEntity</emph> element must have an
       <emph>addr</emph> element.
     </assert>
     <assert diagnostics="CNF-86" test='cda:telecom[boolean(@nullFlavor) or substring-</pre>
before(@value,":") = "tel"]'>
       The <emph>encounterParticipant/assignedEntity</emph> element must have a
        <emph>telecom</emph> element that represents a telephone contact number.
     <assert diagnostics="CNF-87" test='cda:assignedPerson | cda:representedOrganization'>
       The <emph>encounterParticipant/assignedEntity</emph> element must have at least one
       </rule>
```

```
<rule context='cda:responsibleParty/cda:assignedEntity'>
      <assert diagnostics="CNF-88" test='cda:addr'>
       The <emph>responsibleParty/assignedEntity</emph> element must have an <emph>addr</emph>
       element.
      </assert>
     <assert diagnostics="CNF-89" test='cda:telecom[boolean(@nullFlavor) or substring-</pre>
before(@value,":") = "tel"]'>
       The <emph>responsibleParty/assignedEntity</emph> element must have a <emph>telecom</emph>
       element that represents a telephone contact number.
     <assert diagnostics="CNF-90" test='cda:assignedPerson | cda:representedOrganization'>
       The <emph>responsibleParty/assignedEntity</emph> element must have at least one
       <emph>assignedPerson</emph> or <emph>representedOrganization</emph> element present.
     </assert>
   </rule>
  </pattern>
  <pattern name='Telephone_Numbers' see='&baseURI;#Telephone_Numbers'>
    <rule context='cda:telecom'>
      <assert test='@value or @nullFlavor'>
       A telecom element must have a value or a flavor of null.
     </assert>
    </rule>
    <rul><!rule context='cda:telecom/@value[substring(.,1,5) = "tel:+"]'>
     <assert diagnostics='CNF-91' test='translate(substring(.,6),"0123456789()-.","") = ""'>
       Telephone numbers must match the regular expression pattern tel:+?[-0-9().]+
     </assert>
     <assert diagnostics='CNF-92' test='string-length(translate(substring(.,6),"()-.","")) &gt;</pre>
0'>
       At least one dialing digit must be present in the phone number after visual separators
       are removed.
      </assert>
    </ri>
    <rule context='cda:telecom/@value[substring(.,1,4) = "tel:"]'>
     <assert diagnostics='CNF-91' test='translate(substring(.,5),"0123456789()-.","") = ""'>
       Telephone numbers must match the regular expression pattern tel:+?[-0-9().]+
     <assert diagnostics='CNF-92' test='string-length(translate(substring(.,5),"()-.","")) &gt;</pre>
0'>
       At least one dialing digit must be present in the phone number after visual separators
       are removed.
     </assert>
    </rule>
  </pattern>
  <diagnostics>
   <diagnostic id="CNF-1">
     The root of a Care Record Summary must be a <emph>ClinicalDocument</emph> element from
     the <emph>urn:hl7-org-v3</emph> namespace.
   </diagnostic>
   <diagnostic id="CNF-2">
     The root attribute of the id element must be a syntactically correct UUID or OID.
    </diagnostic>
   <diagnostic id="CNF-3">
     UUIDs must be represented in the form <emph>XXXXXXXXX-XXXX-XXXXX-XXXXXXXXXXXXX/emph>,
     where each X is a character from the set [A-Fa-f0-9].
    </diagnostic>
    <diagnostic id="CNF-4">
     OIDs must be represented in dotted decimal notation, where each decimal number is either
     O, or starts with a non-zero digit. More formally, an OID must be in the form
      ([1-9][0-9]*|0)(.([1-9][0-9]*|0))+.
    </diagnostic>
    <diagnostic id="CNF-5">
     OIDs must be no more than 64 characters in length.
   </diagnostic>
    <diagnostic id="CNF-6">
     The value of <emph>/ClinicalDocument/code/@code</emph> must come from the appropriate
     LOINC code subset.
    </diagnostic>
   <diagnostic id="CNF-7">
```

```
The value of <emph>/ClinicalDocument/code/@root</emph> is the OID for LOINC.
</diagnostic>
<diagnostic id="CNF-8">
   The value of <mph>/ClinicalDocument/code/@codeSystemName</emph>, if present is
   <emph>LOINC</emph>.
</diagnostic>
<diagnostic id="CNF-9">
   If pre-coordinated document type codes are used, the role code and function code for the
   author must not conflict with the document type code.
<diagnostic id="CNF-10">
   The <emph>effectiveTime</emph> element must be precise at least to the day.
</diagnostic>
<diagnostic id="CNF-11">
   The <emph>effectiveTime</emph> element must have a time zone.
</diagnostic>
<diagnostic id="CNF-12">
   The language code must be in the form <emph>nn</emph>, or <emph>nn-CC</emph>.
</diagnostic>
<diagnostic id="CNF-13">
   The <emph>nn</emph> portion must be a legal ISO-639-1 language code in lower case.
</diagnostic>
<diagnostic id="CNF-14">
   The <emph>CC</emph> portion, if present must be an ISO-3166 country code in upper case.
</diagnostic>
<diagnostic id="CNF-15">
   When <emph>setId</emph> is present, then <emph>versionNumber</emph> must be present.
</diagnostic>
<diagnostic id="CNF-16">
   Either there is no <emph>setId</emph>, or then <emph>extension</emph> and/or
   <emph>root</emph> of <emph>setId</emph> and <emph>id</emph> are different, or the
   <emph>versionNumber</emph> of the document is <emph>1</emph>.
</diagnostic>
<diagnostic id="CNF-17">
   No <emph>copyTime</emph> element is present in the <emph>ClinicalDocument</emph>.
</diagnostic>
<diagnostic id="CNF-18">
   The <emph>assignedEntity/addr</emph> element of the <emph>authenticator</emph> element
   must be present.
</diagnostic>
<diagnostic id="CNF-19">
   An <emph>assignedEntity/telecom</emph> element must be present whose value contains a
   contact phone number.
</diagnostic>
<diagnostic id="CNF-20">
   The <emph>name</emph> of the <emph>assignedPerson</emph> must be present.
</diagnostic>
<diagnostic id="CNF-21">
   The <emph>author/time</emph> element must be present.
</diagnostic>
<diagnostic id="CNF-22">
   The <emph>author/time</emph> element must be precise at least to the day.
</diagnostic>
<diagnostic id="CNF-23">
   The <emph>author/time</emph> element must have a time zone.
</diagnostic>
<diagnostic id="CNF-24">
   There is at least one <emph>assignedAuthor</emph>.
</diagnostic>
<diagnostic id="CNF-25">
   The <emph>assignedAuthor/id</emph> element must be present.
</diagnostic>
<diagnostic id="CNF-26">
   \verb|All < emph>| assigned Authors < / emph>| have at least one < emph>| telecom < / emph>| element that | emph>| element | emph>| emph>| element | emph>| element | emph>| emph>| emph>| element | emph>| emph
   contains a contact phone number.
</diagnostic>
<diagnostic id="CNF-27">
   There is at least one <emph>assignedAuthor/assignedPerson</emph>.
</diagnostic>
```

```
<diagnostic id="CNF-28">
 When <emph>assignedAuthor/code</emph> is present, its value comes from the
  <emph>PersonalRelationshipRoleType</emph> domain, or is the value <emph>SELF</emph> from
 the RoleCode Domain.
</diagnostic>
<diagnostic id="CNF-29">
 When <emph>assignedAuthoringDevice</emph> is present, the <emph>softwareName</emph>
 element must be present.
</diagnostic>
<diagnostic id="CNF-30">
 A <emph>custodian/assignedCustodian/representedCustodianOrganization/name</emph> element
 must be present.
</diagnostic>
<diagnostic id="CNF-31">
 A <emph>custodian/assignedCustodian/representedCustodianOrganization/telecom</emph>
 element must be present that contains a telephone contact.
</diagnostic>
<diagnostic id="CNF-32">
 A <emph>custodian/assignedCustodian/representedCustodianOrganization/addr</emph> element
 must be present.
</diagnostic>
<diagnostic id="CNF-33">
 All <emph>dataEnterer/time</emph> elements must be precise at least to the day.
</diagnostic>
<diagnostic id="CNF-34">
 All <emph>dataEnterer/time</emph> elements must have a time zone.
</diagnostic>
<diagnostic id="CNF-35">
 All <emph>dataEnterer</emph> elements have an
  <emph>assignedEntity/assignedPerson/name</emph> element.
</diagnostic>
<diagnostic id="CNF-36">
 An informant must have either an <emph>assignedEntity/assignedPerson/name</emph> element,
 or a <emph>relatedEntity/relatedPerson/name</emph> element.
</diagnostic>
<diagnostic id="CNF-37">
 When <emph>relatedEntity/@classCode</emph> is <emph>PRS</emph>, values in
 <emph>relatedEntity/code</emph> shall come from the
  <emph>PersonalRelationshipRoleType</emph> vocabulary.
</diagnostic>
<diagnostic id="CNF-38">
 When <emph>relatedEntity/@classCode</emph> is <emph>CON</emph>,
  <emph>relatedEntity/code</emph> shall not be present.
</diagnostic>
<diagnostic id="CNF-39">
 When <emph>relatedEntity/@classCode</emph> is <emph>PROV</emph>,
 <emph>relatedEntity/code</emph> shall be descended from the
  <emph>healthcare professional</emph> concept (223366009) of SNOMED CT.
</diagnostic>
<diagnostic id="CNF-40">
 At least one of <emph>intendedRecipient/informationRecipient</emph> or
  <emph>intendedRecipient/recievedOrganization</emph> must be present.
</diagnostic>
<diagnostic id="CNF-41">
 All <emph>informationRecipient</emph> elements have a <emph>name</emph> element.
</diagnostic>
<diagnostic id="CNF-42">
 All <emph>recievedOrganization</emph> elements have a <emph>name</emph> element.
</diagnostic>
<diagnostic id="CNF-43">
 All <emph>intendedRecipient</emph> elements have at least one <emph>telecom</emph>
 element that contains a contact phone number.
</diagnostic>
<diagnostic id="CNF-44">
 All <emph>intendedRecipient</emph> elements have an <emph>addr</emph> element.
</diagnostic>
<diagnostic id="CNF-45">
 All <emph>legalAuthenticator/assignedEntity</emph> elements have at least one
```

```
<emph>telecom</emph> element that contains a contact phone number.
   </diagnostic>
   <diagnostic id="CNF-46">
     All <emph>legalAuthenticator/assignedEntity</emph> elements have an <emph>addr</emph>
     element.
   </diagnostic>
   <diagnostic id="CNF-47">
     The <emph>legalAuthenticator/assignedEntity/assignedPerson</emph> element must be
     present.
   </diagnostic>
   <diagnostic id="CNF-48">
     The <emph>participatingEntity/addr</emph> element must be present.
   </diagnostic>
   <diagnostic id="CNF-49">
     A <emph>participatingEntity/telecom</emph> element must be present that contains a
     contact phone number for the participant.
   </diagnostic>
   <diagnostic id="CNF-50">
     The <emph>name</emph> element must be present in a <emph>scopingOrganization</emph>
element.
   </diagnostic>
   <diagnostic id="CNF-51">
     The <emph>addr</emph> element must be present in a <emph>scopingOrganization</emph>
element.
   </diagnostic>
   <diagnostic id="CNF-52">
     A emph>telecom</emph> element must be present that contains a contact phone number in a
     <emph>scopingOrganization</emph> element.
   </diagnostic>
   <diagnostic id="CNF-53">
     When <emph>participant/@typeCode</emph> is <emph>IND</emph>, <emph>functionCode</emph>
     must not be present.
   </diagnostic>
   <diagnostic id="CNF-54">
     When <emph>participant/@typeCode</emph> is <emph>IND</emph>,
     <emph>participatingEntity/@classCode</emph> must be <emph>PRS</emph>.
   </diagnostic>
   <diagnostic id="CNF-55">
     When <emph>participant/@typeCode</emph> is <emph>IND</emph>, only one
     <emph>participatingEntity/code</emph> must be present having
     a value drawn from the PersonalRelationshipRoleType domain.
   </diagnostic>
   <diagnostic id="CNF-56">
     When <emph>participant/@typeCode</emph> is <emph>IND</emph>, other
     <emph>participatingEntity/code</emph> elements present that are not drawn from the the
     PersonalRelationshipRoleType domain must be either ECON or NOK.
   </diagnostic>
   <diagnostic id="CNF-57">
     When <emph>participant/@typeCode</emph> is <emph>HLD</emph>, <emph>functionCode</emph>
     must not be present.
   </diagnostic>
   <diagnostic id="CNF-58">
     When <emph>participant/@typeCode</emph> is <emph>HLD</emph>,
     <emph>participatingEntity/@classCode</emph> must be <emph>POLHOLD</emph>.
   </diagnostic>
   <diagnostic id="CNF-59">
     When <emph>participant/@typeCode</emph> is <emph>HLD</emph>,
     <emph>participatingEntity/scopingOrganization </emph>must be present.
   </diagnostic>
   <diagnostic id="CNF-60">
     When <emph>participant/@typeCode</emph> is <emph>HLD</emph>, one and only one
     <emph>participatingEntity/code</emph> must be present having a value drawn from
     the Policy Holder Role vocabulary defined by this specification, or must use the
     code for SELF drawn from the CoverageRoleType vocabulary domain.
   </diagnostic>
   <diagnostic id="CNF-61">
     At least one <emph>recordTarget/patient</emph> element exists.
   </diagnostic>
   <diagnostic id="CNF-62">
```

```
The <emph>recordTarget/patient</emph> element has an <emph>addr</emph> element.
</diagnostic>
<diagnostic id="CNF-63">
 The <emph>recordTarget/patient</emph> element has a <emph>telecom</emph> element
 that represents a contact phone number.
</diagnostic>
<diagnostic id="CNF-64">
 A <emph>patientPatient/birthTime</emph> element is present.
</diagnostic>
<diagnostic id="CNF-65">
 A <emph>patientPatient/administrativeGenderCode</emph> element is present.
</diagnostic>
<diagnostic id="CNF-66">
 All <emph>providerOrganization</emph> elements have a <emph>name</emph> element.
</diagnostic>
<diagnostic id="CNF-67">
 All <emph>providerOrganization</emph> elements have an <emph>addr </emph>element.
</diagnostic>
<diagnostic id="CNF-68">
 All <emph>providerOrganization</emph> elements have a <emph>telecom </emph>element
 that is a telephone contact number.
</diagnostic>
<diagnostic id="CNF-69">
 Only one <emph>ClinicalDocument/documentationOf</emph> element is present.
</diagnostic>
<diagnostic id="CNF-70">
 The <emph>effectiveTime</emph> element of the <emph>serviceEvent</emph> element must
 be present.
</diagnostic>
<diagnostic id="CNF-71">
 The <emph>effectiveTime</emph> element must contain only one <emph>low</emph> element.
 The <emph>low</emph> element is unrestricted with respect to precision or time zone.
</diagnostic>
<diagnostic id="CNF-72">
 The <emph>effectiveTime</emph> element must contain only one <emph>high</emph> element.
 The <emph>high</emph> element is unrestricted with respect to precision or time zone.
</diagnostic>
<diagnostic id="CNF-73">
 One and only one performer/assigneEntity/code must be present, and it must have a
 value drawn from the SNOMED CT healthcare professional subtype hierarchy.
</diagnostic>
<diagnostic id="CNF-74">
 Every <emph>performer/assignedEntity</emph> element has at least one
 <emph>assignedPerson</emph> or <emph>representedOrganization</emph>.
</diagnostic>
<diagnostic id="CNF-75">
 All <emph>performer</emph>/<emph>assignedEntity</emph> elements have an
  <emph>addr </emph>element.
</diagnostic>
<diagnostic id="CNF-76">
 All <emph>performer</emph>/<emph>assignedEntity</emph> elements have a
  <emph>telecom</emph> element that is a telephone contact number.
</diagnostic>
<diagnostic id="CNF-77">
 All <emph>assignedPerson</emph> elements of
  <emph>performer</emph>/<emph>assignedEntity</emph> must have a <emph>name</emph> element.
</diagnostic>
<diagnostic id="CNF-78">
 The <emph>name</emph> element must be present in a
  <emph>performer/assignedEntity/representedOrganization</emph> element.
</diagnostic>
<diagnostic id="CNF-79">
 The <emph>addr</emph> element must be present in a
 <emph>performer/assignedEntity/representedOrganization</emph> element.
</diagnostic>
<diagnostic id="CNF-80">
 A telecom element must be present that contains a contact phone number in a
  <emph>performer/assignedEntity/representedOrganization/emph> element.
</diagnostic>
```

```
<diagnostic id='CNF-81'>
     If the Care Record Summary is a Discharge or Transfer Summarization,
     then the <emph>componentOf</emph> element is required.
   </diagnostic>
   <diagnostic id="CNF-82">
     The <emph>encompassingEncounter</emph> element must have an <emph>id</emph> element.
   </diagnostic>
   <diagnostic id="CNF-83">
     The <emph>encompassingEncounter</emph> element must have an <emph>effectiveTime</emph>
   </diagnostic>
   <diagnostic id="CNF-84">
     If <emph>ClinicalDocument/code/@value</emph> represents a Discharge Summarization Node,
     then <emph>dischargeDispositionCode</emph> must be present.
   <diagnostic id="CNF-85">
     The <emph>encounterParticipant/assignedEntity</emph> element must have an
     <emph>addr</emph> element.
   </diagnostic>
   <diagnostic id="CNF-86">
     The <emph>encounterParticipant/assignedEntity</emph> element must have a
     <emph>telecom</emph> element that represents a telephone contact number.
   </diagnostic>
   <diagnostic id="CNF-87">
     The <emph>encounterParticipant/assignedEntity</emph> element must have at least one
     \verb| <emph>| assigned Person < /emph>| or <emph>| represented Organization < /emph>| .element present. |
   </diagnostic>
   <diagnostic id="CNF-88">
     The <emph>responsibleParty/assignedEntity</emph> element must have an <emph>addr</emph>
     element.
   </diagnostic>
   <diagnostic id="CNF-89">
     The <emph>responsibleParty/assignedEntity</emph> element must have a <emph>telecom</emph>
     element that represents a telephone contact number.
   </diagnostic>
   <diagnostic id="CNF-90">
     The <emph>responsibleParty/assignedEntity</emph> element must have at least one
     <emph>assignedPerson</emph> or <emph>representedOrganization</emph> element present.
   </diagnostic>
   <diagnostic id="CNF-91">
     Telephone numbers must match the regular expression pattern<emph>tel:\+?[-0-9().]+</emph>
   </diagnostic>
   <diagnostic id="CNF-92">
     At least one dialing digit must be present in the phone number after visual separators
     are removed.
   </diagnostic>
 </diagnostics>
</schema>
```

# Appendix B — Validation

### Introduction

This appendix describes the vocabularies used or defined by this specification, and the Schematron schema that may be used to validate the content of the CDA Header for Care Record Summary documents.

## Vocabulary

A number of controlled vocabularies are referenced in this document. These controlled vocabularies are defined in various supporting specifications, and may be maintained by other bodies, as is the case for the LOINC Document Type Codes. The Schematron schema makes use of several supporting files that contain these vocabularies. To extend the controlled vocabularies, simply add new entries to these files.

Ed Note: <bob>The use of voc.xml should be described, including how it factors in to conformance requirements of section 1.1.5. For instance, if voc.xml contains extensible vocabulary domains, it's possible that the document originator will have added values. The recipient would than generate schematron errors, which, per section 1.1.5, would mean that the instance doesn't conform to this implementation guide.</bob>

### **Schematron Validation**

The Schematron schema below will validate a CDA Document instance against the conformance requirements of this specification, and report the failed validation constraints. It uses version 1.5 of Schematron.

#### How to Read the Schema

Schematron schemas are collections of patterns. Each pattern contains one or more rules which provide the context in which the rule is triggered. The first rule from each pattern will be triggered for each element in the instance that matches the context of the rule. Each rule may assert that a test has passed, or report that a test has failed and can provide one or more diagnostic messages. The test attributes found in assert and report elements are XPath expressions executed in the context of the parent rule.

Schematron can be implemented using a two phase XSL Transformation. The first phase uses the Schematron stylesheet to process the schema, producing a second XSL transformation. That transformation is executed over the instance to be validated, producing the validation output.

For more information, see the <u>Schematron 1.5 specification</u>.

#### The Schema

```
<?xml version="1.0" encoding="UTF-8" standalone="yes"?>
<!DOCTYPE schema [
Replace baseURI below with a reference to the published Implementation Guide HTML.
<!ENTITY baseURI "">
<schema xmlns="http://www.ascc.net/xml/schematron" xmlns:cda="urn:h17-org:v3" xmlns:crs='urn:h17-org:crs'>
  <title>Schematron schema for validating conformance to IMPL_CDAR2_LEVEL1REF_US_I1_2005MAY</title>
  <ns prefix="cda" uri="urn:h17-org:v3" />
<ns prefix="crs" uri="urn:h17-org:crs" />
  <pattern name='ClinicalDocument' see='&baseURI;#ClinicalDocument'>
    This schema applies to CDA Release 2.0 documents.
    <rule id='cda-root' context='/*'>
      <assert diagnostics="L1-1" test='self::cda:ClinicalDocument'>
        The root of a Care Record Summary must be a <emph>ClinicalDocument</emph> element from
        the <emph>urn:h17-org-v3</emph> namespace.
      </assert>
    </rule>
  </pattern>
  <pattern name='ClinicalDocument_General_Constraints' see='&baseURI;#ClinicalDocument_General_Constraints'>
    <rule id='general-addr' context='cda:addr'>
      <assert id='null-or-no-content' test='not(@nullFlavor) or (@nullFlavor and normalize-space(.) = "")'>
        When the <emph>addr</emph> element is null, it should not have content.
      <assert id='empty-implies-null' test='not(@nullFlavor) and (string-length(normalize-space(.)) &gt; 0)'>
        When the <emph>addr</emph> element is empty, it must have a value for
        <emph>nullFlavor.
      </assert>
    </rule>
    <rule id='general-person' context='cda:assignedPerson'>
      <assert diagnostics="L1-38 L1-57" test='cda:name'>
        The <emph>name</emph> of an <emph>assignedPerson</emph> must be present.
      </assert>
    </rule>
    <rule id='general-org' context='cda:representedOrganization'>
      <assert test='cda:name'>
        The <emph>name</emph> of a <emph>representedOrganization</emph> must be present.
      </assert>
    </rule>
    <rul><!rule id='general-time-reg'</li>
        context='cda:authenticator | cda:author | cda:dataEnterer | cda:legalAuthenticator'>
      <assert diagnostics='L1-31 L1-36'</pre>
        test='(not(contains(translate(cda:time/@value,"+-","Z"),"Z")) and
                string-length(cda:time/@value) > 7
               ) or
               string-length(substring-before(translate(cda:time/@value,"+-","Z"),"Z")) > 7'
        The <emph>time</emph> element must be precise at least to the day.
      </assert>
      <assert diagnostics='L1-32 L1-37' test='contains(translate(cda:time/@value,"+-","Z"),"Z")'>
        The <emph>time</emph> element must have a time zone.
      </assert>
    </ri>
  </pattern>
  <pattern name='Telephone_Numbers' see='&baseURI;#Telephone_Numbers'>
    <rule id='telcom-null-or-valued' context='cda:telecom'>
      <assert test='@value or @nullFlavor'>
        A telecom element must have a value or a flavor of null.
      </assert>
      <assert id='telcom-regex' diagnostics='L1-2'</pre>
        test="not(substring(@value,1,4) = "tel:") or
            string-length(
             concat (
               translate(substring(@value,5,1),"+0123456789()-.",""),
               translate(substring(@value,6),"0123456789()-.","")
        Telephone numbers must match the regular expression pattern tel:\+?[-0-9().]+
       </assert>
```

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<assert id='telcom-has-digit' diagnostics='L1-3'
  test='not(substring(@value,1,4) = "tel:") or</pre>
          string-length(
          concat (
             translate(substring(@value, 5, 1), "+()-.", ""),
             translate(substring(@value,6),"()-.","")
          ) > 0'
      At least one dialing digit must be present in the phone number after visual separators
    </assert>
  </rule>
</pattern>
<pattern name='ClinicalDocument_typeId' see='&baseURI;#ClinicalDocument_typeId'>
  <rule id='cda-typeid' context="/cda:ClinicalDocument/cda:typeId">
    <assert id='typeId-extension' diagnostics='L1-4' test='@extension = "POCD_HD000040"'>
      The <emph>extension</emph> attribute of the <emph>typeId</emph> element must be
      <emph>POCD_HD000040</emph>.
    </assert>
  </rule>
</pattern>
<pattern name='ClinicalDocument_id' see='&baseURI;#ClinicalDocument_id'>
  <rule id='cda-id-uuid' context="/cda:ClinicalDocument/cda:id[contains(@root, '-')]">
    <assert diagnostics='L1-5 L1-6' test="string-length(@root) = 37" >
      A properly formatted UUID has only 37 characters.
    <assert diagnostics='L1-5 L1-6'</pre>
      test="translate(substring(@root, 1, 8),'ABCDEFabcdef0123456789','') = ''">
      The first four data bytes of the UUID should be represented using hexidecimal
      digits ([A-Fa-f0-9]).
    <assert diagnostics='L1-5 L1-6'
      test="translate(substring(@root, 10, 4),'ABCDEFabcdef0123456789','') = ''" >
      The fifth and sixth data bytes of the UUID should be represented using hexidecimal
      digits ([A-Fa-f0-9]).
    <assert diagnostics='L1-5 L1-6'</pre>
      test="translate(substring(@root, 15, 4),'ABCDEFabcdef0123456789','') = ''">
      The seventh and eighth data bytes of the UUID should be represented using hexidecimal
      digits ([A-Fa-f0-9]).
    <assert diagnostics='L1-5 L1-6'</pre>
      test="translate(substring(@root, 20, 4),'ABCDEFabcdef0123456789','') = ''">
      The ninth and tenth data bytes of the UUID should be represented using hexidecimal
      digits ([A-Fa-f0-91).
    <assert diagnostics='L1-5 L1-6'
      test="translate(substring(@root, 25, 12),'ABCDEFabcdef0123456789','') = ''">
      The eleventh through sixteenth data bytes of the UUID should be represented using
      hexidecimal digits ([A-Fa-f0-9]).
    </assert>
    <assert diagnostics='L1-5 L1-6' test="substring(@root, 9, 1) = '-'">
      A hyphen should separate the first four data bytes from the remainder of the UUID.
    <assert diagnostics='L1-5 L1-6' test="substring(@root, 14, 1) = '-'">
      A hyphen should separate the fifth and sixth data byte from the remainder of the UUID.
    </assert>
    <assert diagnostics='L1-5 L1-6' test="substring(@root, 19, 1) = '-'">
      A hyphen should separate the seventh and eighth data byte from the remainder of the UUID.
    </assert>
    <assert diagnostics='L1-5 L1-6' test="substring(@root, 24, 1) = '-'">
      A hyphen should separate the ninth and tenth data byte from the remainder of the UUID.
  </rule>
  <rule id='cda-id-oid' context="/cda:ClinicalDocument/cda:id[contains(@root, '.')]" >
    <assert test="translate(@root, '0123456789.', '') = ''" diagnostics='L1-5 L1-7'>
      Characters that are not in the set 0-9 or . are not present in a valid OID.
    <assert diagnostics='L1-5 L1-7'</pre>
      test="not(substring(@root, 1, 1) = '.') and not(substring(@root, string-length(@root), 1) = '.')" >
      The first and last characters of an OID must be a digit.
    </assert>
    <assert diagnostics='L1-5 L1-7' test="not(contains(@root,'..'))">
      A properly formatted OID should not contain two . characters without any
      intervening digits
    </assert>
```

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<assert diagnostics='L1-8' test="string-length(@root) &lt; 65">
        An OID must be shorter than 65 characters
      </assert>
    </rule>
    <rule id='cda-id' context='cda:id[not(contains(@root,".") or contains(@root,"-"))]'>
      <assert diagnostics='L1-5' test='false()'>
        The root attribute of the id element must be a syntactically correct UUID or OID.
      </assert>
    </rule>
  </pattern>
  <pattern name='ClinicalDocument_code' see='&baseURI;#ClinicalDocument_code'>
    <rule id='clinical-document-code' context='/cda:ClinicalDocument/cda:code'>
      <assert diagnostics='L1-9'</pre>
        test='document("voc.xml")/systems/system[@codeSystemName="LOINC"]/code[@value = current()/@code]'>
        The value of <emph>/ClinicalDocument/code/@code</emph> must come from the
        appropriate LOINC subset.
      <assert test='@codeSystem = "2.16.840.1.113883.6.1"' diagnostics='L1-10'>
        The value of <emph>/ClinicalDocument/code/@codeSystem</emph> must be 2.16.840.1.113883.6.1
      <assert test='count(@codeSystemName) = 0 or @codeSystemName="LOINC"' diagnostics='L1-11'>
        The value of <emph>/ClinicalDocument/code/@codeSystemName</emph> must be
        <emph>LOINC</emph>.
      <assert diagnostics="L1-12" test='true()'>
        TBD: If pre-coordinated document type codes are used, the role code and function code for the
        author must not conflict with the document type code.
      </assert>
    </rule>
  </pattern>
  <pattern name='ClinicalDocument_effectiveTime' see='&baseURI;#ClinicalDocument_effectiveTime'>
    <rule id='cda-effectiveTime' context='/cda:ClinicalDocument/cda:effectiveTime</pre>
      <assert diagnostics='L1-13'</pre>
        test='(not(contains(translate(@value,"+-","Z"),"Z")) and string-length(@value) > 7) or
             string-length(substring-before(translate(@value,"+-","Z"),"Z")) > 7
        The <emph>effectiveTime</emph> element must be precise at least to the day.
      <assert diagnostics="L1-14" test='contains(translate(@value,"+-","Z"),"Z")'>
        The <emph>effectiveTime</emph> element must have a time zone.
    </rule>
  </pattern>
  <pattern name='ClinicalDocument_languageCode' see='&baseURI;#ClinicalDocument_languageCode'>
    <rule id='cda-languageCode' context='/cda:ClinicalDocument'>
      <assert diagnostics='L1-15' test='cda:languageCode'>
        The <emph>languageCode</emph> element must be present.
      </assert>
    <rule id='cda-languageCode-format' context='/cda:ClinicalDocument/cda:languageCode'>
      <assert diagnostics='L1-16'</pre>
        test='(string-length(@code) = 5 and substring(@code,3,1) = "-") or string-length(@code) = 2' >
        The language code must be in the form emph>nn-emph>, or emph>nn-CC</emph>.
      <assert diagnostics='L1-17'</pre>
        test='substring(@code,1,2) = document("voc.xml")/systems/system[@codeSystemName="ISO639-
1"]/code/@value' >
        The language must be a legal ISO-639-1 language code in lower case.
      </assert>
      <assert diagnostics='L1-18'</pre>
        test='string-length(@code) = 2 or substring(@code, 4, 2) =
document("voc.xml")/systems/system[@codeSystemName="ISO3166-1"]/code/@value' >
        The country code portion, if present must be an ISO-3166 country code in upper case.
      </assert>
    </rule>
  </pattern>
  <pattern name='ClinicalDocument_setId' see='&baseURI;#ClinicalDocument_setId'>
    <rul><rule context='/cda:ClinicalDocument/cda:setId'>
      <assert diagnostics="L1-19" test='/cda:ClinicalDocument/cda:versionNumber'>
        When <emph>setId</emph> is present, then <emph>versionNumber</emph> must be present.
      </assert>
      <assert diagnostics="L1-20" test='@root != ../cda:id/@root or @extension != ../cda:id/@extension' >
        Either there is no <emph>setId</emph>, or the <emph>extension</emph> and/or
         <emph>root</emph> of <emph>setId</emph> and <emph>id</emph> are different.
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</rule>
  <pattern name='ClinicalDocument_copyTime' see='&baseURI;#ClinicalDocument_copyTime'>
    <rule id='cda-copyTime' context='/cda:ClinicalDocument/cda:copyTime'>
      <assert test='false()' diagnostics='L1-21'>
        No <emph>copyTime</emph> element is present in the <emph>ClinicalDocument</emph>.
      </assert>
    </rule>
  </pattern>
  <pattern name='recordTarget' see='&baseURI;#recordTarget'>
    <rule id='cda-recordTarget' context='cda:recordTarget'>
      <assert diagnostics="L1-22" test='count(cda:patientRole) &gt; 0'>
        At least one <emph>recordTarget/patientRole</emph> element exists.
      <assert diagnostics="L1-23" test='cda:patientRole/cda:addr'>
        \label{thm:local_condition} The <emph>recordTarget/patientRole</emph> element has an <emph>addr</emph> element.
      </assert>
      <assert diagnostics="L1-24"
        test='cda:patientRole/cda:telecom[boolean(@nullFlavor) or substring-before(@value,":") = "tel"]'>
        The <emph>recordTarget/patientRole</emph> element has a <emph>telecom</emph> element that represents a
contact phone number.
      </assert>
      <assert diagnostics="L1-25" test='cda:patientRole/cda:patient/cda:birthTime'>
        A <emph>patient/birthTime</emph> element is present.
      <assert diagnostics="L1-26" test='cda:patientRole/cda:patient/cda:administrativeGenderCode'>
        A <emph>patient/administrativeGenderCode</emph> element is present.
    </rule>
    <rule id='cda-providerOrg' context='cda:recordTarget/cda:patientRole/cda:providerOrganization'>
      <assert diagnostics="L1-27" test='cda:name'>
        All <emph>providerOrganization</emph> elements have a <emph>name</emph> element.
      <assert diagnostics="L1-28" test='cda:addr'>
        All <emph>providerOrganization</emph> elements have an <emph>addr </emph>element.
      <assert diagnostics="L1-29" test='cda:telecom[boolean(@nullFlavor) or substring-before(@value,":") =</pre>
"tel"]'>
        All <emph>providerOrganization</emph> elements have a <emph>telecom </emph>element
        that is a telephone contact number.
      </assert>
    </rule>
  </pattern>
  <pattern name='author' see='&baseURI; #author'>
    <rule id='cda-author' context='cda:author'>
      <assert diagnostics="L1-30" test='cda:time'>
        The <emph>author/time</emph> element must be present.
      </assert>
    <rule id='cda-assignedAuthor' context='cda:assignedAuthor'>
      <assert diagnostics="L1-33" test='cda:id'>
        The <emph>assignedAuthor/id</emph> element must be present.
      </assert>
      <assert diagnostics="L1-34" test='cda:telecom[boolean(@nullFlavor) or substring-before(@value,":") =</pre>
"tel"]'>
        All <emph>assignedAuthors</emph> have at least one <emph>telecom</emph> element that
        contains a contact phone number.
      </assert>
    </rule>
    <rule id='cda-assignedAuthoringDevice' context='cda:assignedAuthoringDevice'>
      <assert diagnostics="L1-35" test='cda:softwareName'>
        When <emph>assignedAuthoringDevice</emph> is present, the <emph>softwareName</emph>
        element must be present.
      </assert>
      <assert diagnostics="L1-35" test='string-length(normalize-space(cda:softwareName)) &gt; 0'>
        When <emph>assignedAuthoringDevice/softwareName</emph> must have a value.
      </assert>
    </rule>
  </pattern>
  <pattern name='dataEnterer' see='&baseURI;#dataEnterer'>
    <rule id='cda-dataEnterer' context='cda:dataEnterer'>
      <assert diagnostics="L1-38" test='cda:assignedEntity/cda:assignedPerson/cda:name'>
        All <emph>dataEnterer</emph> elements have an <emph>assignedEntity/assignedPerson/name</emph> element.
      </assert>
  </pattern>
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<pattern name='informant' see='&baseURI;#informant'>
    <rule id='cda-informant' context='cda:informant'>
      <assert diagnostics="L1-39"
        test='cda:assignedEntity/cda:assignedPerson/cda:name | cda:relatedEntity/cda:relatedPerson/cda:name'>
        An <emph>informant</emph> must have either an <emph>assignedEntity/assignedPerson/name</emph>
        element, or a <emph>relatedEntity/relatedPerson/name</emph> element.
      <assert test='not(descendant::crs:asPatientRelationship)' diagnostics='L1-40'>
        An <emph>informant</emph> should not have any
<emph>assignedEntity/assignedPerson/crs:asPatientRelationship </emph>elements, or
<emph>relatedEntity/relatedPerson/ crs:asPatientRelationship</emph> elements.
      </assert>
    </rule>
    <rule id='cda-relatedEntity-PRS' context='cda:informant/cda:relatedEntity[@classCode = "PRS"]'>
      <assert diagnostics="L1-41"</pre>
        test='cda:code/@codeSystem = "2.16.840.1.113883.5.111" and cda:code/@code =
When <emph>relatedEntity/@classCode</emph> is <emph>PRS</emph>, values in
        <emph>relatedEntity/code</emph> shall come from the
        \verb|<emph>| Personal Relationship Role Type < | emph>| vocabulary. |
      </assert>
    </rule>
    <rule id='cda-relatedEntity-CON' context='cda:informant/cda:relatedEntity[@classCode = "CON"]'>
      <assert diagnostics="L1-42" test='not(cda:code)'>
        When <emph>relatedEntity/@classCode</emph> is <emph>CON</emph>,
        <emph>relatedEntity/code</emph> shall not be present.
    </rule>
    <rule id='cda-relatedEntity-PROV' context='cda:informant/cda:relatedEntity[@classCode = "PROV"]/cda:code'>
      <assert diagnostics="L1-43"</pre>
        test='@codeSystem = "2.16.840.1.113883.6.96" and @code =
document("voc.xml")/systems/system[@codeSystemName="HealthcareProfessionals"]/code/@value'>
        When <emph>relatedEntity/@classCode</emph> is <emph>PROV</emph>,
        <emph>relatedEntity/code</emph> shall be descended from the
        <emph>healthcare professional</emph> concept (223366009) of SNOMED CT.
      </assert>
    </rule>
  </pattern>
  <pattern name='custodian' see='&baseURI;#custodian'>
    <rule id='cda-custodian' context='cda:custodian'>
      <assert diagnostics="L1-44"</pre>
        test='cda:assignedCustodian/cda:representedCustodianOrganization/cda:name'>
        \verb|A < emph> custodian/assignedCustodian/representedCustodianOrganization/name</emph> element
        must be present.
      </assert>
      <assert diagnostics="L1-45"
        substring-before (@value, ":") = "tel"] '>
        A <emph>custodian/assignedCustodian/representedCustodianOrganization/telecom</emph>
        element must be present that contains a telephone contact.
      </assert>
      <assert diagnostics="L1-46"</pre>
        test='cda:assignedCustodian/cda:representedCustodianOrganization/cda:addr'>
        {\tt A < emph> custodian/assignedCustodian/representedCustodianOrganization/addr</emph> \ {\tt element}} \\
        must be present.
      </assert>
    </rule>
  <pattern name='informationRecipient' see='&baseURI;#informationRecipient'>
    <rule id='cda-intendedRecipient' context='cda:intendedRecipient/cda:informationRecipient'>
      <assert diagnostics="L1-48" test='cda:name'>
        All <emph>informationRecipient</emph> elements have a <emph>name</emph> element.
      </assert>
    <rule id='cda-receivedOrganization' context='cda:receivedOrganization'>
      <assert diagnostics="L1-49" test='cda:name'>
       All <emph>receivedOrganization</emph> elements have a <emph>name</emph> element.
      </assert>
    <rule id='cda-informationRecipient' context='cda:ClinicalDocument/cda:informationRecipient'>
      <assert diagnostics="L1-47"
        test='cda:intendedRecipient/cda:informationRecipient |
cda:intendedRecipient/cda:receivedOrganization'>
        At least one of <emph>intendedRecipient/informationRecipient</emph> or
        <emph>intendedRecipient/receivedOrganization</emph>
        must be present.
      </assert>
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<assert diagnostics="L1-50"
  test='cda:intendedRecipient/cda:telecom[boolean(@nullFlavor) or substring-before(@value,":") =</pre>
"tel"l'>
        All <emph>intendedRecipient</emph> elements have at least one <emph>telecom</emph>
        element that contains a contact phone number.
      <assert diagnostics="L1-51" test='cda:intendedRecipient/cda:addr'>
        All <emph>intendedRecipient</emph> elements have an <emph>addr</emph> element.
    </rule>
  </pattern>
  <pattern name='legalAuthenticator' see='&baseURI;#legalAuthenticator'>
    <rule id='cda-legalAuthenticator' context='cda:legalAuthenticator'>
      <assert diagnostics="L1-52"</pre>
        test='cda:assignedEntity/cda:telecom[boolean(@nullFlavor) or substring-before(@value,":") = "tel"]'>
        All <emph>legalAuthenticator/assignedEntity</emph> elements have at least one
         <emph>telecom</emph> element
        that contains a contact phone number.
      <assert diagnostics="L1-53" test='cda:assignedEntity/cda:addr'>
        All <emph>legalAuthenticator/assignedEntity</emph> elements have an
         <emph>addr</emph> element.
      <assert diagnostics='L1-54' test='cda:assignedEntity/cda:assignedPerson'>
        The < emph>legal Authenticator/assigned Entity/assigned Person < / emph> element
        must be present.
      </assert>
    </rule>
  </pattern>
  <pattern name='authenticator' see='&baseURI;#authenticator'>
    <rule id='cda-authenticator' context='cda:authenticator'>
      <assert diagnostics="L1-55" test='cda:assignedEntity/cda:addr'>
        The <emph>assignedEntity/addr</emph> element of the <emph>authenticator</emph> element
        must be present.
      </assert>
      <assert diagnostics="L1-56"
        test='cda:assignedEntity/cda:telecom[boolean(@nullFlavor) or substring-before(@value,":") = "tel"]'>
        An <emph>assignedEntity/telecom</emph> element must be present whose value contains a
        contact phone number.
      <assert diagnostics='L1-57' test='cda:assignedEntity/cda:assignedPerson/cda:name'>
        The <emph>name</emph> element of the <emph>assignedPerson</emph> must be present.
      </assert>
    </rule>
  </pattern>
  <pattern name='participant' see='&baseURI;#participant'>
    <rule id='cda-associatedEntity' context='cda:participant/cda:associatedEntity'>
      <assert diagnostics="L1-58" test='cda:addr'>
        The <emph>associatedEntity/addr </emph>element must be present.
      </assert>
      <assert diagnostics="L1-59"</pre>
        test='cda:telecom[boolean(@nullFlavor) or substring-before(@value,":") = "tel"]'>
        A emph>associatedEntity/telecom</emph> element must be present that contains a
        contact phone number
        for the participant.
      </assert>
      <assert diagnostics="L1-63"</pre>
          test='not(../@typeCode = "IND") or
               @classCode = "PRS" or @classCode = "NOK" or @classCode = "ECON" or @classCode = "GUAR"'
        When <emph>participant/@typeCode</emph> is <emph>IND</emph>, <emph>associatedEntity/@classCode</emph>
        must be <emph>PRS, NOK, ECON or GUAR.</emph>
      <assert diagnostics="L1-64"</pre>
        test='not(../@typeCode = "IND") or
             @classCode = "GUAR" or
count(cda:code/@code[.=document("voc.xml")/systems/system[@codeSystemName="PersonalRelationshipRoleType"]/code/
@value]) = 1'
        When <emph>associatedEntity/@classCode</emph> is <emph>PRS, NOK or ECON</emph> then
<emph>associatedEntity/code</emph>
        must be present having a value drawn from the <emph>PersonalRelationshipRoleType</emph> domain.
      </assert>
      <assert diagnostics="L1-65" test='not(../@typeCode="HLD") or @classCode = "POLHOLD"'>
        When <emph>participant/@typeCode</emph> is <emph>HLD</emph>,
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<emph>associatedEntity/@classCode</emph> must be
         <emph>POLHOLD</emph>
      </assert>
      <assert diagnostics="L1-66" test='not(../@typeCode="HLD") or cda:scopingOrganization'>
        When <emph>participant/@typeCode</emph> is <emph>HLD</emph>,
        <emph>associatedEntity/scopingOrganization</emph> must be present.
    </rule>
    <rule id='cda-scopingOrg' context='cda:scopingOrganization'>
      <assert diagnostics='L1-60' test='cda:name'>
        The <emph>name</emph> element must be present in a <emph>scopingOrganization</emph>
      <assert diagnostics='L1-61' test='cda:addr'>
        The <emph>addr</emph> element must be present in a <emph>scopingOrganization</emph>
        element.
      </assert>
      <assert diagnostics='L1-62' test='cda:telecom[boolean(@nullFlavor) or substring-before(@value,":") =</pre>
"tel"l'>
        A <emph>telecom</emph> element must be present that contains a contact phone number
        in a <emph>scopingOrganization</emph> element.
    </rule>
  </pattern>
  <pattern name='documentationOf' see='&baseURI;#documentationOf'>
    Only one <emph>ClinicalDocument/documentationOf</emph> element must be present.
    </rule>
    <rule id='cda-serviceEvent' context='cda:serviceEvent'>
      <assert diagnostics="L1-68" test='cda:effectiveTime'>
        \label{thm:comph} The~\mbox{\tt <emph>effectiveTime</emph>~element~of~the~\mbox{\tt <emph>serviceEvent</emph>~element~must}
        be present.
      </assert>
    </rule>
    <rule id='cda-effectiveTime' context='cda:serviceEvent/cda:effectiveTime'>
      <assert diagnostics="L1-69" test='count(cda:low) = 1'>
        The <emph>effectiveTime</emph> element must contain only one <emph>low</emph> element.
        The <emph>low</emph> element is unrestricted with respect to precision or time zone.
      </assert>
      <assert diagnostics="L1-70" test='count(cda:high) = 1'>
        \label{thm:contain} The <emph>effectiveTime</emph> \ element \ must \ contain \ only \ one \ <emph>high</emph> \ element.
        The <emph>high</emph> element is unrestricted with respect to precision or time zone.
      </assert>
    </rule>
    <rule id='cda-performer' context='cda:performer/cda:assignedEntity'>
       <assert diagnostics="L1-71" test='count(cda:code) = 1 and</pre>
cda:code/@codeSystem="2.16.840.1.113883.6.96"'>
        The <emph>performer/assigneEntity/code</emph> if present must have a value
        drawn from the SNOMED CT <emph>healthcare professional </emph>subtype hierarchy.
      </assert>
      <assert diagnostics="L1-72" test='cda:assignedPerson | cda:representedOrganization'>
        Every <emph>performer/assignedEntity</emph> element has at least one <emph>assignedPerson</emph>
        or <emph>representedOrganization</emph>.
      <assert diagnostics="L1-73" test='cda:addr'>
        All <emph>performer/assignedEntity</emph> elements have an
        <emph>addr</emph> element.
      <assert diagnostics="L1-74" test='cda:telecom[boolean(@nullFlavor) or substring-before(@value,":") =</pre>
"tel"]'>
        All <emph>performer/assignedEntity</emph> elements have a
         <emph>telecom </emph>element that is a telephone contact number.
      </assert>
    </rule>
    <rule id='cda-performer-person' context='cda:performer/cda:assignedEntity/cda:assignedPerson'>
      <assert diagnostics="L1-75" test='cda:name'</pre>
        All <emph>assignedPerson</emph> elements of
        <emph>performer/assignedEntity</emph> must have a <emph>name</emph> element.
      </assert>
    </rule>
    <rule id='cda-performer-org' context='cda:performer/cda:assignedEntity/cda:representedOrganization'>
      <assert diagnostics="L1-76" test='cda:name'>
        The <emph>name</emph> element must be present in a
         <emph>performer/assignedEntity/representedOrganization</emph> element.
      </assert>
```

```
<assert diagnostics="L1-77" test='cda:addr'>
                  addr</emph> element must be present in a
        <emph>performer/assignedEntity/representedOrganization</emph> element.
      </assert>
      <assert diagnostics="L1-78" test='cda:telecom[boolean(@nullFlavor) or substring-before(@value,":") =</pre>
"tel"]'>
        A emph>telecom</emph> element must be present that contains a contact phone number in a
        <emph>performer/assignedEntity/representedOrganization</emph> element.
      </assert>
    </ri>
  </pattern>
  <pattern name='componentOf' see='&baseURI;componentOf'>
    <rule id='cda-componentOf' context='/cda:ClinicalDocument/cda:code'>
      <assert diagnostics='L1-79'</pre>
        test='/cda:ClinicalDocument/cda:componentOf or
        = "DISCHARGE SUMMARIZATION NOTE" or document("voc.xml")/systems/system[@codeSystemName="LOINC"]/code[@value =
current()/@code]/@displayName = "TRANSFER SUMMARIZATION NOTE")'>
        If the Care Record Summary is a Discharge or Transfer Summarization,
        then the <emph>componentOf</emph> element is required.
    </rule>
    <rule id='cda-encompassingEncounter' context='cda:encompassingEncounter'>
      <assert diagnostics="L1-80" test='cda:id'>
        The <emph>encompassingEncounter</emph> element must have an <emph>id</emph> element.
      <assert diagnostics="L1-81" test='cda:effectiveTime'>
        The <emph>encompassingEncounter</emph> element must have an <emph>effectiveTime</emph>
      </assert>
      <assert diagnostics="L1-82"
        test='cda:dischargeDispositionCode or
not(document("voc.xml")/systems/system[@codeSystemName="LOINC"]/code[@value =
current()/ancestor::cda:ClinicalDocument/cda:code/@code]/@displayName = "DISCHARGE SUMMARIZATION NOTE")'>
        If <emph>ClinicalDocument/code/@value</emph> represents a Discharge Summarization Note,
        then <emph>dischargeDispositionCode</emph> must be present.
    <rule id='cda-encounterParticipant' context='cda:encounterParticipant/cda:assignedEntity'>
      <assert diagnostics="L1-83" test='cda:addr'>
        \label{thm:counterParticipant} The~\mbox{\tt <emph>encounterParticipant/assignedEntity<\tt/emph>~element~must~have~an}
        <emph>addr</emph> element.
      <assert diagnostics="L1-84" test='cda:telecom[boolean(@nullFlavor) or substring-before(@value,":") =</pre>
"tel"]'>
        The <emph>encounterParticipant/assignedEntity</emph>element must have a
        <emph>telecom</emph> element that represents a telephone contact number.
      <assert diagnostics="L1-85" test='cda:assignedPerson | cda:representedOrganization'>
        The <emph>encounterParticipant/assignedEntity</emph> element must have at least one
        <emph>assignedPerson</emph> or <emph>representedOrganization</emph> element present.
      </assert>
    </rule>
    <rule id='cda-responsibleParty' context='cda:responsibleParty/cda:assignedEntity'>
      <assert diagnostics="L1-86" test='cda:addr'>
        The <emph>responsibleParty/assignedEntity</emph> element must have an <emph>addr</emph>
        element.
      </assert>
      <assert diagnostics="L1-87" test='cda:telecom[boolean(@nullFlavor) or substring-before(@value,":") =</pre>
"tel"]'>
        The <emph>responsibleParty/assignedEntity</emph> element must have a <emph>telecom</emph>
        element that represents a telephone contact number.
      <assert diagnostics="L1-88" test='cda:assignedPerson | cda:representedOrganization'>
        The <emph>responsibleParty/assignedEntity</emph> element must have at least one
        <emph>assignedPerson</emph> or <emph>representedOrganization</emph> element present.
      </assert>
    </rule>
  </pattern>
  <pattern name='Body' see='&baseURI;Body'>
    <rule id='sectionRequirements' context='cda:section'>
      <assert diagnostics='L2-1' test='cda:code'>
        A <emph>cda:section</emph> element must have a <emph>cda:code</emph> element.
      </assert>
      <assert diagnostics="L2-2" test='cda:text | cda:component'>
        A <emph>cda:section</emph> must contain at least one <emph>cda:text </emph>element or one or more
<emph>cda:component</emph> elements.
```

```
</assert>
      assert diagnostics="L2-3" test='string-length(string(cda:text)) > 0'>
        All <emph>cda:text</emph> or <emph>cda:component</emph> elements must contain content.
      </assert>
    </rule>
    <rule id='RequiredSections' context='/cda:ClinicalDocument/cda:component/cda:structuredBody'>
      <assert diagnostics="L2-4"</pre>
        test='/cda:ClinicalDocument/cda:code/@code = "34133-9" or descendant-or-
self::cda:section/cda:code/@code="11535-2"'>
       A Discharge or Transfer summary must include a <emph>section</emph> element whose code is <emph>11535-
      <assert diagnostics="L2-5"</pre>
        test='not(/cda:ClinicalDocument/cda:code/@code = "34133-9") or descendant-or-
self::cda:section/cda:code/@code="11450-4"'>
        A Summary of Episode note that is not a discharge or transfer summary must include a
<emph>section</emph>
        element whose code is <emph>11450-4</emph>.
      <assert diagnostics="L2-6" test='descendant-or-self::cda:section/cda:code/@code="10155-0"'>
        A <emph>section</emph> must be present with a <emph>code</emph> value of <emph>10155-0</emph>.
      <assert diagnostics="L2-7"</pre>
        test='/cda:ClinicalDocument/cda:code/@code = "34133-9" or descendant-or-
self::cda:section/cda:code/@code="10183-2"'>
       A Discharge or Transfer summary must include a <emph>section</emph> element whose code is <emph>10183-
      <assert diagnostics="L2-8"
        test='not(/cda:ClinicalDocument/cda:code/@code = "34133-9") or descendant-or-
self::cda:section/cda:code/@code="10160-0"'>
       A Summary of Episode note that is not also a discharge or transfer summary must include a
<emph>section</emph>
        element whose code is emph>10160-0</emph>.
      <assert diagnostics="L2-9"</pre>
        test='/cda:ClinicalDocument/cda:code/@code = "34133-9" or descendant-or-
self::cda:section/cda:code/@code="8648-8"'>
        A level 2 conforming Care Record Summary that is a discharge or transfer summary shall contain a
        <emph>section</emph> with the <emph>code</emph> value of <emph>8648-8</emph>.
      </assert>
    <rule id='RequiredSections' context='cda:section/cda:code[@code="X-RFVCC"]'>
      <assert diagnostics="L2-9"</pre>
        test='count(//cda:section/cda:code[@code="29299-5" or @code="10154-3"])=0'>
        A level 2 conforming Care Record Summary that contains a <emph>section</emph> with a <emph>code</emph>
        value of <emph>X-RFVCC</emph> (REASON FOR VISIT/CHIEF COMPLAINT) shall not contain sections with a
        value of <emph>29299-5</emph> (REASON FOR VISIT) or <emph>10154-3</emph> (CHIEF COMPLAINT).
      </assert>
    </rule>
  </pattern>
  <diagnostics>
    <diagnostic id="L1-1">
      The root of a Care Record Summary must be a <emph>ClinicalDocument</emph> element from the
<emph>urn:h17-org:v3</emph> namespace.
    </diagnostic>
    <diagnostic id="L1-2">
      Telephone numbers must match the regular expression pattern<emph>tel:\+?[-0-9().]+</emph>
    </diagnostic>
    <diagnostic id="L1-3">
      At least one dialing digit must be present in the phone number after visual separators are removed.
    </diagnostic>
    <diagnostic id="L1-4">
      The <emph>extension</emph> attribute of the <emph>typeId</emph> element must be
<emph>POCD_HD000040</emph>.
    </diagnostic>
    <diagnostic id="L1-5">
      The root attribute of the id element must be a syntactically correct UUID or OID.
    </diagnostic>
    <diagnostic id="L1-6">
      a character from the set [A-Fa-f0-9].
    </diagnostic>
    <diagnostic id="L1-7">
      OIDs must be represented in dotted decimal notation, where each decimal number is either 0, or starts
with a non-zero digit. More formally, an OID must be in the form ([0-2])(.([1-9][0-9]*|0))+.
```

```
</diagnostic>
       <diagnostic id="L1-8">
          OIDs must be no more than 64 characters in length.
       </diagnostic>
       <diagnostic id="L1-9">
          The value of <emph>/ClinicalDocument/code/@code</emph> must come from the appropriate LOINC code subset.
       </diagnostic>
       <diagnostic id="L1-10">
          The value of <emph>/ClinicalDocument/code/@codeSysem</emph> is the OID for LOINC.
       <diagnostic id="L1-11">
          The value of <emph>/ClinicalDocument/code/@codeSystemName</emph>, if present is <emph>LOINC</emph>.
       </diagnostic>
       <diagnostic id="L1-12">
          If pre-coordinated document type codes are used, the role code and function code for the author must not
conflict with the document type code.
       </diagnostic>
       <diagnostic id="L1-13">
          The <emph>effectiveTime</emph> element must be precise at least to the day.
       </diagnostic>
       <diagnostic id="L1-14">
          The <emph>effectiveTime</emph> element must have a time zone.
       </diagnostic>
       <diagnostic id="L1-15">
          The <emph>languageCode</emph> element must be present.
       </diagnostic>
       <diagnostic id="L1-16">
          The language code must be in the form emph>nn-emph>n, or emph>nn-CC</emph>.
       </diagnostic>
       <diagnostic id="L1-17">
          The <emph>nn</emph> portion must be a legal ISO-639-1 language code in lower case.
       <diagnostic id="L1-18">
          The <emph>CC</emph> portion, if present must be an ISO-3166 country code in upper case.
       </diagnostic>
       <diagnostic id="L1-19">
          When <emph>setId</emph> is present, then <emph>versionNumber</emph> must be present.
       <diagnostic id="L1-20">
          Either there is no <emph>setId</emph>, or then <emph>extension</emph> and/or <emph>root</emph> of
<emph>setId</emph> and <emph>id</emph> are different.
       </diagnostic>
       <diagnostic id="L1-21">
          No <emph>copyTime</emph> element is present in the <emph>ClinicalDocument</emph>.
       </diagnostic>
       <diagnostic id="L1-22">
          At least one <emph>recordTarget/patientRole</emph> element exists.
       </diagnostic>
       <diagnostic id="L1-23">
          The <emph>recordTarget/patientRole</emph> element has an <emph>addr</emph> element.
       </diagnostic>
       <diagnostic id="L1-24">
          \label{thm:cond} The \ensuremath{\,^{<}}\xspace emph> record Target/patient Role </emph> \ensuremath{\,^{<}}\xspace emph> telecom </emph> \ensuremath{\,^{<}}\xspace emph> telecom </emph> \ensuremath{\,^{<}}\xspace emph> telecom </emph> \ensuremath{\,^{<}}\xspace emph> \ensuremath{\,^{<}}\xspace emph> telecom </emph> \ensuremath{\,^{<}}\xspace emph> \ens
contact phone number.
       </diagnostic>
       <diagnostic id="L1-25">
          A <emph>patient/birthTime</emph> element is present.
       </diagnostic>
       <diagnostic id="L1-26">
          A <emph>patient/administrativeGenderCode</emph> element is present.
       </diagnostic>
       <diagnostic id="L1-27">
          All emph>providerOrganization</emph> elements have a <math>emph>name</emph> element.
       </diagnostic>
       <diagnostic id="L1-28">
          All <emph>providerOrganization</emph> elements have an <emph>addr </emph>element.
       </diagnostic>
       <diagnostic id="L1-29">
          All <emph>providerOrganization</emph> elements have a <emph>telecom </emph>element that is a telephone
contact number.
       </diagnostic>
       <diagnostic id="L1-30">
          The <emph>author/time</emph> element must be present.
       </diagnostic>
       <diagnostic id="L1-31">
          The <emph>author/time</emph> element must be precise at least to the day.
       </diagnostic>
       <diagnostic id="L1-32">
          The <emph>author/time</emph> element must have a time zone.
```

```
</diagnostic>
    <diagnostic id="L1-33">
      The <emph>assignedAuthor/id</emph> element must be present.
    </diagnostic>
    <diagnostic id="L1-34">
      All <emph>assignedAuthors</emph> have at least one <emph>telecom</emph> element that contains a contact
phone number.
    </diagnostic>
    <diagnostic id="L1-35">
      When <emph>assignedAuthoringDevice</emph> is present, the <emph>softwareName</emph> element must be
    </diagnostic>
    <diagnostic id="L1-36">
      All <emph>dataEnterer/time</emph> elements must be precise at least to the day.
    </diagnostic>
    <diagnostic id="L1-37">
      All <emph>dataEnterer/time</emph> elements must have a time zone.
    <diagnostic id="L1-38">
      \verb|All <= mph> dataEnterer</emph> elements have an <= mph> assignedEntity/assignedPerson/name</emph> element. |
    </diagnostic>
    <diagnostic id="L1-39">
      An <emph>informant</emph> must have either an <emph>assignedEntity/assignedPerson/name</emph> element,
or a <emph>relatedEntity/relatedPerson/name</emph> element.
    <diagnostic id="L1-40">
      An <emph>informant</emph> should not have any
<emph>assignedEntity/assignedPerson/crs:asPatientRelationship </emph>elements, or
<emph>relatedEntity/relatedPerson/ crs:asPatientRelationship</emph> elements.
    </diagnostic>
    <diagnostic id="L1-41">
      When <emph>relatedEntity/@classCode</emph> is <emph>PRS</emph>, values in
<emph>relatedEntity/code</emph> shall come from the
    </diagnostic>
    <diagnostic id="L1-42">
      When <emph>relatedEntity/@classCode</emph> is <emph>CON</emph>, <emph>relatedEntity/code</emph> shall
not be present.
    </diagnostic>
    <diagnostic id="L1-43">
      present, the value shall come from SNOMED CT.
    </diagnostic>
    <diagnostic id="L1-44">
      A <emph>custodian/assignedCustodian/representedCustodianOrganization/name</emph> element must be
present.
    </diagnostic>
    <diagnostic id="L1-45">
      A <emph>custodian/assignedCustodian/representedCustodianOrganization/telecom</emph> element must be
present that contains a telephone contact.
    </diagnostic>
    <diagnostic id="L1-46">
      A <emph>custodian/assignedCustodian/representedCustodianOrganization/addr/emph> element must be
present.
    </diagnostic>
    <diagnostic id="L1-47">
      At least one of <emph>intendedRecipient/informationRecipient</emph> or
<emph>intendedRecipient/recievedOrganization</emph> must be present.
    </diagnostic>
    <diagnostic id="L1-48">
      All <emph>informationRecipient</emph> elements have a <emph>name</emph> element.
    </diagnostic>
    <diagnostic id="L1-49">
      All <emph>receivedOrganization</emph> elements have a <emph>name</emph> element.
    </diagnostic>
    <diagnostic id="L1-50">
      All <emph>intendedRecipient</emph> elements have at least one <emph>telecom</emph> element that contains
a contact phone number.
    </diagnostic>
    <diagnostic id="L1-51">
      All <emph>intendedRecipient</emph> elements have an <emph>addr</emph> element.
    </diagnostic>
    <diagnostic id="L1-52">
     All <emph>legalAuthenticator/assignedEntity</emph> elements have at least one <emph>telecom</emph>
element that contains a contact phone number.
    </diagnostic>
    <diagnostic id="L1-53">
      All <emph>legalAuthenticator/assignedEntity</emph> elements have an <emph>addr</emph> element.
    </diagnostic>
    <diagnostic id="L1-54">
```

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The <emph>legalAuthenticator/assignedEntity/assignedPerson</emph> element must be present.
    <diagnostic id="L1-55">
      \label{thm:comph} The~\mbox{emph}\mbox{-authenticator}\mbox{-/emph}\mbox{- element~must~be~present.}
    </diagnostic>
      An <emph>assignedEntity/telecom</emph> element must be present whose value contains a contact phone
number
    </diagnostic>
    <diagnostic id="L1-57">
      The <emph>name</emph> element of the <emph>assignedPerson</emph> must be present.
    <diagnostic id="L1-58">
      The <emph>associatedEntity/addr</emph> element must be present.
    </diagnostic>
    <diagnostic id="L1-59">
      A <emph>associatedEntity/telecom</emph> element must be present that contains a contact phone number for
the participant.
    </diagnostic>
    <diagnostic id="L1-60">
      The <emph>name</emph> element must be present in a <emph>scopingOrganization</emph> element.
    <diagnostic id="L1-61">
      The <emph>addr</emph> element must be present in a <emph>scopingOrganization</emph> element.
    </diagnostic>
    <diagnostic id="L1-62">
      A <emph>telecom</emph> element must be present that contains a contact phone number in a
<emph>scopingOrganization</emph> element.
    </diagnostic>
    <diagnostic id="L1-63">
      When <emph>participant/@typeCode</emph> is <emph>IND</emph>, <emph>associatedEntity/@classCode</emph>
must be <emph>PRS, NOK, ECON or GUAR.</emph>
    </diagnostic>
    <diagnostic id="L1-64">
      When <emph>associatedEntity/@classCode</emph> is <emph>PRS, NOK or ECON</emph> then
<emph>associatedEntity/code</emph> must be present having a value drawn from the
    </diagnostic>
    <diagnostic id="L1-65">
      When <emph>participant/@typeCode</emph> is <emph>HLD</emph>, <emph>associatedEntity/@classCode</emph>
must be <emph>POLHOLD</emph>.
    </diagnostic>
    <diagnostic id="L1-66">
      </emph>must be present.
    </diagnostic>
    <diagnostic id="L1-67">
      Only one <emph>ClinicalDocument/documentationOf</emph> element must be present.
    <diagnostic id="L1-68">
      The <emph>effectiveTime</emph> element of the <emph>serviceEvent</emph> element must be present.
    </diagnostic>
    <diagnostic id="L1-69">
      The <emph>effectiveTime</emph> element must contain only one <emph>low</emph> element. The
<emph>low</emph> element is unrestricted with respect to precision or time zone.
    <diagnostic id="L1-70">
      The <emph>effectiveTime</emph> element must contain only one <emph>high</emph> element. The
<emph>high</emph> element is unrestricted with respect to precision or time zone.
    </diagnostic>
    <diagnostic id="L1-71">
      The <emph>performer/assigneEntity/code</emph> if present must have a value drawn from the SNOMED CT
<emph>healthcare professional </emph>subtype hierarchy.
    </diagnostic>
    <diagnostic id="L1-72">
      Every <emph>performer/assignedEntity</emph> element has at least one <emph>assignedPerson</emph> or
<emph>representedOrganization</emph>.
    </diagnostic>
    <diagnostic id="L1-73">
      All <emph>performer/assignedEntity</emph> elements have an <emph>addr </emph>element.
    </diagnostic>
    <diagnostic id="L1-74">
      All <emph>performer/assignedEntity</emph> elements have a <emph>telecom </emph>element that is a
telephone contact number.
    </diagnostic>
    <diagnostic id="L1-75">
      All <emph>assignedPerson</emph> elements of <emph>performer/assignedEntity</emph> must have a
<emph>name</emph> element.
    </diagnostic>
    <diagnostic id="L1-76">
```

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The <emph>name</emph> element must be present in a
<emph>performer/assignedEntity/representedOrganization</emph> element.
    </diagnostic>
    <diagnostic id="L1-77">
      The <emph>addr</emph> element must be present in a
<emph>performer/assignedEntity/representedOrganization</emph> element.
    </diagnostic>
    <diagnostic id="L1-78">
      A <emph>telecom</emph> element must be present that contains a contact phone number in a
<emph>performer/assignedEntity/representedOrganization</emph> element.
    <diagnostic id="L1-79">
      If the Care Record Summary is a Discharge or Transfer Summarization, then the <emph>componentOf</emph>
element is required.
    </diagnostic>
    <diagnostic id="L1-80">
      The <emph>encompassingEncounter</emph> element must have an <emph>id</emph> element.
    </diagnostic>
    <diagnostic id="L1-81">
      \label{thm:compassingEncounter} The~\mbox{\tt <emph>encompassingEncounter</emph>~element~must~have~an~\mbox{\tt <emph>effectiveTime</emph>~element~.}
    </diagnostic>
    <diagnostic id="L1-82">
      If <emph>ClinicalDocument/code/@value</emph> represents a Discharge Summarization Node, then
<emph>dischargeDispositionCode</emph> must be present.
    </diagnostic>
    <diagnostic id="L1-83">
      The <emph>encounterParticipant/assignedEntity</emph> element must have an <emph>addr</emph> element.
    <diagnostic id="L1-84">
      The <emph>encounterParticipant/assignedEntity</emph> element must have a <emph>telecom</emph> element
that represents a telephone contact number.
     </diagnostic>
    <diagnostic id="L1-85">
      The <emph>encounterParticipant/assignedEntity</emph> element must have at least one
\\ <emph>assigned Person</emph> or <emph>represented Organization</emph> element present. \\
    <diagnostic id="L1-86">
      The <emph>responsibleParty/assignedEntity</emph> element must have an <emph>addr</emph> element.
    <diagnostic id="L1-87">
      The <emph>responsibleParty/assignedEntity</emph> element must have a <emph>telecom</emph> element that
represents a telephone contact number.
    </diagnostic>
    <diagnostic id="L1-88">
      The <emph>responsibleParty/assignedEntity</emph> element must have at least one
<emph>assignedPerson</emph> or <emph>representedOrganization</emph> element present.
    </diagnostic>
    <diagnostic id="L2-1">
      A <emph>cda:section</emph> element must have a <math><emph>cda:code</emph> element.
    </diagnostic>
    <diagnostic id="L2-2">
      A <emph>cda:section</emph> must contain at least one <emph>cda:text </emph>element or one or more
<emph>cda:component</emph> elements.
    </diagnostic>
    <diagnostic id="L2-3">
      All <emph>cda:text</emph> or <emph>cda:component</emph> elements must contain content.
    <diagnostic id="L2-4">
      A Discharge or Transfer summary must include a <emph>section</emph> element whose code is <emph>11535-
2</emph>.
    </diagnostic>
    <diagnostic id="L2-5">
      A Summary of Episode note that is not a discharge or transfer summary must include a
<emph>section</emph> element whose code is <emph>11450-4</emph>.
    </diagnostic>
    <diagnostic id="L2-6">
      A <emph>section</emph> must be present with a <emph>code</emph> value of <emph>10155-0</emph>.
    </diagnostic>
    <diagnostic id="L2-7">
      A Discharge or Transfer summary must include a <emph>section</emph> element whose code is <emph>10183-
2</emph>.
    </diagnostic>
    <diagnostic id="L2-8">
      A Summary of Episode note that is not also a discharge or transfer summary must include a
<emph>section</emph> element whose code is <emph>10160-0</emph>.
    </diagnostic>
    <diagnostic id="L2-9">
      A level 2 conforming Care Record Summary that is a discharge or transfer summary shall contain a
<emph>section</emph> with the <emph>code</emph> value of <emph>8648-8</emph>.
```

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</diagnostic>
    <diagnostic id="L2-10">
      The section type code for the section describing the reason for visit in a level 2 conforming Care
Record Summary shall be either <emph>X-RFVCC</emph> (REASON FOR VISIT/CHIEF COMPLAINT), or <emph>29299-5</emph>
(REASON FOR VISIT).
    </diagnostic>
    <diagnostic id="L2-11">
      The section type code for the section describing the patient's chief complaint in a level 2 conforming
Care Record Summary shall be either <emph>X-RFVCC</emph> (REASON FOR VISIT/CHIEF COMPLAINT), or <emph>10154-
3</emph> (CHIEF COMPLAINT).
    </diagnostic>
    <diagnostic id="L2-12">
      A level 2 conforming Care Record Summary that contains a <emph>section</emph> with a <emph>code</emph>
value of <emph>X-RFVCC</emph> (REASON FOR VISIT/CHIEF COMPLAINT) shall not contain sections with a code value
of <emph>29299-5</emph> (REASON FOR VISIT) or <emph>10154-3</emph> (CHIEF COMPLAINT).
    </diagnostic>
    <diagnostic id="L2-13">
     The <emph>code</emph> for the <emph>section</emph> describing the Reason for Referral in a level 2
conforming Care Record Summary shall be <emph>X-RFR (REASON FOR REFERRAL)</emph>.
    <diagnostic id="L2-14">
      The <emph>code</emph> for the <emph>section</emph> describing the patient Advance Directives in a level
2 conforming Care Record Summary shall be <emph>X-ADVDIR</emph> (ADVANCE DIRECTIVES).
    </diagnostic>
    <diagnostic id="L2-15">
      The LOINC section type <emph>code</emph> for the section describing the History of Present Illness in a
level 2 conforming Care Record Summary shall be <emph>10164-2</emph> (HISTORY OF PRESENT ILLNESS).
    <diagnostic id="L2-16">
      The LOINC section type <emph>code</emph> for the section describing the patient's functional status in a
level 2 conforming Care Record Summary shall be <emph>10158-4</emph> (HISTORY OF FUNCTIONAL STATUS).
    </diagnostic>
    <diagnostic id="L2-17">
      The LOINC section type <emph>code</emph> for the section providing family history of the patient in a
level 2 conforming Care Record Summary shall be <emph>10157-6</emph> (HISTORY OF FAMILY MEMBER DISEASES).
    </diagnostic>
    <diagnostic id="L2-18">
      a level 2 conforming Care Record Summary shall be <emph>11369-6</emph> (HISTORY OF IMMUNIZATION).
    </diagnostic>
    <diagnostic id="L2-19">
      The LOINC section type <emph>code</emph> for the section describing the patient's past surgical history
in a level 2 conforming Care Record Summary shall be <emph>10167-5</emph> (PAST SURGICAL HISTORY).
    </diagnostic>
    <diagnostic id="L2-20">
      The LOINC section <emph>code</emph> used for the section describing prior outpatient visits in a level 2
conforming Care Record Summary shall be <emph>11346-4</emph> (HISTORY OF OUTPATIENT VISITS).
    </diagnostic>
    <diagnostic id="L2-21">
      The LOINC section <emph>code</emph> used for the section describing prior hospitalizations in a level 2
conforming Care Record Summary shall be <emph>11336-5</emph> (HISTORY OF HOSPITALIZATIONS).
    <diagnostic id="L2-22">
      The LOINC section <emph>code</emph> used for the section providing the patient vital signs in a level 2
conforming Care Record Summary shall be <emph>8716-3</emph> (VITAL SIGNS, PHYSICAL FINDINGS).
    </diagnostic>
    <diagnostic id="L2-23">
      The LOINC section <emph>code</emph> used for the section describing results or referring to other
reports in a level 2 conforming Care Record Summary shall be <emph>11493-4 </emph>(HOSPITAL DISCHARGE STUDIES
SUMMARY), or <emph>X-SS</emph> (STUDIES SUMMARY)
    </diagnostic>
    <diagnostic id="L2-24">
      The LOINC section <emph>code</emph> used for the section describing the plan of care for the patient in
a level 2 conforming Care Record Summary shall be <emph>18775-6 </emph>(TREATMENT PLAN)
    </diagnostic>
  </diagnostics>
</schema>
```

# Appendix C — Sample Level 1 Conforming CDA Document

The document below is a non-normative example of a Care Record Summary that conforms to this specification.

```
<ClinicalDocument xmlns='urn:hl7-org:v3'>
  <realmCode code='US'/>
  <typeId extension="POCD_HD000040" root="2.16.840.1.113883.1.3"/>
  <templateId extension="IMPL_CDAR2_LEVEL1-2REF_US_12_2005SEP" root="2.16.840.1.113883.10"/>
  <id extension='999021' root='1.3.6.4.1.4.1.2835.2'/>
  <code code='34133-9' codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'</pre>
displayName='SUMMARIZATION OF EPISODE NOTE'/>
  <title>Good Health Clinic Care Record Summary</title>
  <effectiveTime value='20050329224411+0500'/>
  <confidentialityCode code="N" codeSystem="2.16.840.1.113883.5.25"/>
  <languageCode code='en-US'/>
  <setId extension='999021' root='1.3.6.4.1.4.1.2835.1'/>
  <versionNumber value='1'/>
  <recordTarget>
   <patientRole>
      <id extension="12345" root="2.16.840.1.113883.3.933"/>
       <streetAddressLine>17 Daws Rd.</streetAddressLine>
       <city>Blue Bell</city>
       <state>MA</state>
       <postalCode>02368</postalCode>
       <country>USA</country>
     </addr>
     <telecom value='tel:(781)555-1212' use='HP'/>
     <patient>
         <prefix>Mrs.</prefix>
         <given>Ellen</given>
         <family>Ross</family>
       </name>
       <administrativeGenderCode code="F" codeSystem="2.16.840.1.113883.5.1"/>
       <birthTime value="19600127"/>
      oroviderOrganization>
       <id extension="M345" root="2.16.840.1.113883.3.933"/>
       <name>Good Health Clinic</name>
       <telecom value='tel:(999)555-1212' use='WP'/>
         <streetAddressLine>21 North Ave</streetAddressLine>
         <city>Burlington</city>
         <state>MA</state>
         <postalCode>01803</postalCode>
         <country>USA</country>
       </addr>
      </providerOrganization>
    </patientRole>
  </recordTarget>
```

```
<author>
 <time value='20050329224411+0500'/>
 <assignedAuthor>
   <id extension='1' root='1.3.6.4.1.4.1.2835.1'/>
   <code code='SELF' codeSystem='2.16.840.1.113883.5.111'/>
     <streetAddressLine>21 North Ave</streetAddressLine>
     <city>Burlington</city>
     <state>MA</state>
     <postalCode>01803</postalCode>
     <country>USA</country>
   </addr>
   <telecom value='tel:(999)555-1212' use='WP'/>
   <assignedPerson>
     <name>
       <prefix>Dr.</prefix></prefix>
       <given>Bernard</given>
       <family>Wiseman</family>
       <suffix>Sr.</suffix>
     </name>
   </assignedPerson>
 </assignedAuthor>
</author>
<author>
 <time value='20050329224411+0500'/>
 <assignedAuthor>
   <id extension='1' root='1.3.6.4.1.4.1.2835.1'/>
   <addr>
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     <city>Burlington</city>
     <state>MA</state>
     <postalCode>01803</postalCode>
     <country>USA</country>
   </addr>
   <telecom value='tel:(999)555-1212' use='WP'/>
   <assignedAuthoringDevice>
     <softwareName>Good Health Clinic System v1.0</softwareName>
   </assignedAuthoringDevice>
 </assignedAuthor>
</author>
<dataEnterer>
 <time value='20050329222451+0500'/>
 <assignedEntity>
   <id extension='2' root='1.3.6.4.1.4.1.2835.2'/>
   <assignedPerson>
     <name>
       <prefix>Mrs.</prefix></prefix>
       <given>Bernice</given>
       <family>Wiseman</family>
     </name>
   </assignedPerson>
 </assignedEntity>
</dataEnterer>
```

```
<!-- To represent a healthcare provider with a specific assigned healthcare role that can be
identified by the author and authoring system.
  <informant>
   <assignedEntity>
     <id extension='3' root='1.3.6.4.1.4.1.2835.2'/>
     <assignedPerson>
       <name>
         <prefix>Dr.</prefix>
         <given>Bernard</given>
         <family>Wiseman</family>
         <suffix>Jr.</suffix>
       </name>
     </assignedPerson>
   </assignedEntity>
 </informant>
  <!-- To represent a mother who provides information about her child -->
 <informant>
   <relatedEntity classCode='PRS'>
     <code code='MTH' codeSystem='2.16.840.1.113883.5.111'/>
     <relatedPerson>
         <prefix>Mrs.</prefix>
         <given>Abigail</given>
         <family>Ruth</family>
       </name>
     </relatedPerson>
   </relatedEntity>
 </informant>
 <!-- To represent a witness to a signicant health event -->
  <informant>
   <relatedEntity classCode='CON'>
     <relatedPerson>
       <name>
         <prefix>Mr.</prefix>
         <qiven>Joseph</qiven>
         <given>T.</given>
         <family>Jones</family>
       </name>
     </relatedPerson>
   </relatedEntity>
 </informant>
 <!-- To represent a healthcare provider in a healthcare role without an assigned role known or
representable to the author. The example below represents a physician who was the patient's
primary care provider. -->
 <informant>
   <relatedEntity classCode='PROV'>
     <code code='59058001' codeSystem='2.16.840.1.113883.6.96'/>
     <relatedPerson>
         <given>Jane</given>
         <family>Queen</family>
         <suffix></suffix>
       </name>
     </relatedPerson>
   </relatedEntity>
  </informant>
```

```
<custodian>
 <assignedCustodian>
   <representedCustodianOrganization>
     <id extension='1' root='1.3.6.4.1.4.1.2835.3'/>
     <name>Good Health Clinic</name>
     <telecom value='tel:(999)555-1212' use='WP'/>
     <addr>
       <streetAddressLine>21 North Ave</streetAddressLine>
       <city>Burlington</city>
       <state>MA</state>
       <postalCode>01803</postalCode>
       <country>USA</country>
     </addr>
   </representedCustodianOrganization>
  </assignedCustodian>
</custodian>
<informationRecipient>
  <intendedRecipient>
   <id extension='4' root='1.3.6.4.1.4.1.2835.2'/>
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     <city>Burlington</city>
     <state>MA</state>
     <postalCode>01803</postalCode>
     <country>USA</country>
   </addr>
   <telecom value='tel:(999)555-1212' use='WP'/>
   <informationRecipient>
     <name>
       <prefix>Dr.</prefix>
       <given>Phil</given>
       <family>Green</family>
     </name>
    </informationRecipient>
    <receivedOrganization>
     <name>Good Health Clinic</name>
   </receivedOrganization>
  </intendedRecipient>
</informationRecipient>
<legalAuthenticator>
  <time value='20050329224512+0500'/>
 <signatureCode code='S'/>
  <assignedEntity>
   <id extension='1' root='1.3.6.4.1.4.1.2835.1'/>
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     <city>Burlington</city>
     <state>MA</state>
     <postalCode>01803</postalCode>
     <country>USA</country>
   </addr>
   <telecom value='tel:(999)555-1212' use='WP'/>
    <assignedPerson>
     <name>
       <prefix>Dr.</prefix>
       <given>Bernard</given>
       <family>Wiseman</family>
       <suffix>Sr.</suffix>
     </name>
   </assignedPerson>
  </assignedEntity>
</legalAuthenticator>
```

```
<authenticator>
 <time value='20050329224512+0500'/>
 <signatureCode code='S'/>
 <assignedEntity>
   <id extension='3' root='1.3.6.4.1.4.1.2835.1'/>
     <streetAddressLine>21 North Ave</streetAddressLine>
     <city>Burlington</city>
     <state>MA</state>
     <postalCode>01803</postalCode>
     <country>USA</country>
   </addr>
   <telecom value='tel:(999)555-1212' use='WP'/>
   <assignedPerson>
     <name>
       <prefix>Dr.</prefix></prefix>
       <given>Bernard</given>
       <family>Wiseman</family>
       <suffix>Jr.</suffix>
     </name>
   </assignedPerson>
 </assignedEntity>
</authenticator>
<participant typeCode='IND'>
 <time>-</time>
 <associatedEntity classCode='PRS'>
   <code code='MTH' codeSystem='2.16.840.1.113883.5.111'/>
   <addr>
     <streetAddressLine>17 Daws Rd.</streetAddressLine>
     <city>Blue Bell</city>
     <state>MA</state>
     <postalCode>02368</postalCode>
     <country>USA</country>
   </addr>
   <telecom value='tel:(999)555-1212' use='WP'/>
   <associatedPerson>
     <name>
       <prefix>Mrs.</prefix></prefix>
       <given>Abigail</given>
       <family>Ruth</family>
     </name>
   </associatedPerson>
 </associatedEntity>
</participant>
<participant typeCode='HLD'>
```

```
<time>
   <low value='20050101'/>
   <high value='20051231'/>
 </t.ime>
 <associatedEntity classCode='POLHOLD'>
   <id extension='123456789' root='00000000-0000-0000-0000-00000000000'/>
   <code code='PHFAMDEP' codeSystem='2.16.840.1.113883.5.1095'/>
   <!-- To show that the policy holder is the patient, the above would be:
   <code code='SELF' codeSystem='2.16.840.1.113883.5.111'/>
   <addr>
     <streetAddressLine>17 Daws Rd.</streetAddressLine>
     <city>Blue Bell</city>
     <state>MA</state>
     <postalCode>02368</postalCode>
     <country>USA</country>
   </addr>
   <telecom value='tel:(999)555-1212' use='WP'/>
   <associatedPerson>
       <prefix>Mr.</prefix></prefix>
       <qiven>Kenneth</qiven>
       <family>Ross</family>
     </name>
   </associatedPerson>
   <scopingOrganization>
     <name>Good Health Insurance Company</name>
     <telecom value='tel:(203)555-1212' use='WP'/>
       <streetAddressLine>3191 Broadbridge Avenue</streetAddressLine>
       <city>Stratford</city>
       <state>CT</state>
       <postalCode>06614-2559</postalCode>
       <country>USA</country>
     </addr>
   </scopingOrganization>
 </associatedEntity>
</participant>
<participant typeCode='IND'>
 <associatedEntity classCode='GUAR'>
   <addr>
     <streetAddressLine>17 Daws Rd.</streetAddressLine>
     <city>Blue Bell</city>
     <state>MA</state>
     <postalCode>02368</postalCode>
     <country>USA</country>
   </addr>
   <telecom value='tel:(999)555-1212' use='WP'/>
   <associatedPerson>
       <prefix>Mr.</prefix>
       <given>Kenneth</given>
       <family>Ross</family>
     </name>
   </associatedPerson>
 </associatedEntity>
</participant>
```

```
<documentationOf>
    <serviceEvent classCode='PCPR'>
     <effectiveTime>
       <low value='19600127'/>
       <high value='20050329'/>
      </effectiveTime>
      <performer typeCode='PRF'>
       <functionCode code='PCP' codeSystem='2.16.840.1.113883.5.88'/>
       <time>
         <low value='1998'/>
         <high value='2005'/>
       </time>
       <assignedEntity>
         <id extension='1' root='1.3.6.4.1.4.1.2835.1'/>
         <code code='59058001'</pre>
           codeSystem='2.16.840.1.113883.6.96'
           codeSystemName='SNOMED CT'
           displayName='General Physician'/>
         <addr>
           <streetAddressLine>21 North Ave</streetAddressLine>
           <city>Burlington</city>
           <state>MA</state>
           <postalCode>01803</postalCode>
           <country>USA</country>
         </addr>
         <telecom value='tel:(999)555-1212' use='WP'/>
         <assignedPerson>
           <name>
             <prefix>Dr.</prefix></prefix>
             <given>Bernard</given>
             <family>Wiseman</family>
             <suffix>Sr.</suffix>
           </name>
         </assignedPerson>
       </assignedEntity>
      </performer>
   </serviceEvent>
  </documentationOf>
  <componentOf>
   <encompassingEncounter>
     <id extension='9937012' root='1.3.6.4.1.4.1.2835.12'/>
     <code code='99213' codeSystem='2.16.840.1.113883.6.12'</pre>
           displayName='Evaluation and Managment' codeSystemName='CPT-4'/>
     <effectiveTime>
       <low value='20050329'/>
       <high value='20050329'/>
     </effectiveTime>
     <dischargeDispositionCode code='01' codeSystem='2.16.840.1.113883.6.21'</pre>
           displayName='Routine Discharge' codeSystemName='UB92'/>
    </encompassingEncounter>
  </componentOf>
 <component>
     :
 </component>
</ClinicalDocument>
```

# Appendix D — Sample Level 2 Conforming Structured Body

The document below is a non-normative example of a Care Record Summary structuredBody that conforms to this specification.

```
<structuredBody>
 <templateId extension="IMPL_CDAR2_LEVEL1-2REF_US_I2_2005SEP" root="2.16.840.1.113883.10"/>
 <component>
  <section>
   <code code='11450-4' codeSystem='2.16.840.1.113883.6.1' />
   <title>Conditions</title>
     <thead>
       ProblemDateComments
       </thead>
      Cholecystitis9/28/2002 - 6/2003
        Resolved
        Surgery postponed until after delivery
       Pregnancy7/2001 - 4/22/2002
        Resolved
        Prior history of miscarraige
       Ankle Sprain3/28/2005
        Current
        Slipped on ice and fell
       </text>
  </section>
 </component>
 <component>
   <code code='10155-0' codeSystem='2.16.840.1.113883.6.1' />
   <title>Allergies and Adverse Reactions</title>
     AllergenReaction
        Comments
       </thead>
       PenicillinHives
        Amoxicillin is OK
       </text>
  </section>
 </component>
```

```
<component>
 <section>
   <code code='10160-0' codeSystem='2.16.840.1.113883.6.1' />
   <title>Medications</title>
   <text>
    <t.head>
       Medication
         Prescription or Dose
         Dates of Use
       </thead>
      Indomethacin
         50mg bid with food 
         12/10/2003 - present
        <t.r>
         Acetaminophen with codeine
         #3 1-2 tablets for pain as needed
         03/28/2005
        </text>
 </section>
</component>
<component>
 <section>
   <code code='X-RFVCC' codeSystem='2.16.840.1.113883.6.1' />
   <title>Reason for Visit/Chief Complaint</title>
   <text>Ankle Sprain</text>
 </section>
</component>
<component>
 <section>
   <code code='X-RFR' codeSystem='2.16.840.1.113883.6.1' />
   <title>Reason for Referral</title>
   <text>Follow-up care for Ankle Sprain</text>
 </section>
</component>
```

```
<component>
 <section>
  <code code='X-ADVDIR' codeSystem='2.16.840.1.113883.6.1'/>
  <title>Advance Directives</title>
  <text>
    <t.head>
      DocumentationContact
       Effective DateComments
     </thead>
     Living Will
        Obtain from her Husband1994
        Copy on file
      </t.r>
      Power of Attorney
       Obtain from her Husband1994<
      Healthcare Proxy
       Obtain from her Husband1994<
      Organ Donor
       Massachusetts Registry of Motor Vehicles
       1/27/2004 - Registered Organ Donor
      </text>
 </section>
</component>
<component>
 <section>
  <code code='10164-2' codeSystem='2.16.840.1.113883.6.1' />
  <title>History of Present Illness</title>
  <text>Patient slipped and fell on ice, twisting her ankle as she fell.</text>
 </section>
</component>
<component>
 <section>
  <code code='10157-6' codeSystem='2.16.840.1.113883.6.1'/>
  <title>Family History</title>
  <text>
    <thead>
      Family Member
        Problem
        Cause of Death?
      </thead>
     FatherAlcoholismNo
      FatherLiver CancerYes
     </text>
 </section>
</component>
```

```
<component>
 <section>
   <code code='29762-2' codeSystem='2.16.840.1.113883.6.1' />
  <title>Social History</title>
  <text>
    <t.head>
       Social History
        Comments
        Date Range
       </thead>
     Smoking1/2 pack per day? - 1996
       <t.r>
        Alcohol Use1-2 drinks per week
       </text>
 </section>
</component>
<component>
 <section>
  <code code='11369-6' codeSystem='2.16.840.1.113883.6.1' />
  <title>Immunizations</title>
  <text>
    st>
     <item>DTP - 1962</item>
     <item>Polio Virus - 1961</item>
     <item>MMR - 1961</item>
    </list>
   </text>
 </section>
</component>
<component>
  <code code='10167-5' codeSystem='2.16.840.1.113883.6.1' />
  <title>Procedures</title>
  <text>
    <thead>
       <+r>
        Procedure
        Date
       </thead>
     Laparoscopic Cholecystectomy9/28/2002
       Cesarian Section3/22/2002
    </text>
 </section>
</component>
```

```
<component>
  <section>
     <code code='11336-5' codeSystem='2.16.840.1.113883.6.1' />
     <title>Prior Encounters</title>
     <text>
       <t.head>
            DateProvider
               Description
            </thead>
          3/28/2005Community Hospital
              ED Visit for Ankle Sprain
            \t  td > 9/28/2002  td > City Hospital 
               Gall Bladder Surgery
            </t.r>
            \label{localization} $$ \tr>3/21/2002Community Hospital
               Labor and Delivery
            10/28/2001Community Hospital
              ED Visit for Acute Cholecystitis
            </t.ext.>
  </section>
</component>
<component>
  <section>
    <code code='10187-3' codeSystem='2.16.840.1.113883.6.1' />
     <title>Review of Systems</title>
     <text></text>
  </section>
</component>
<component>
  <section>
     <code code='10210-3' codeSystem='2.16.840.1.113883.6.1' />
     <title>Physical Examination</title>
     <text></text>
     <component>
       <section>
          <code code='29274-8' codeSystem='2.16.840.1.113883.6.1' />
          <title>Vital Signs</title>
          <text>
            <thead>
                 DateHeightWeightTemperature
                      BPPulseRespiration02
                 </thead>
               \label{th>3/28/20055'9"215 lbs.98.7 & $xB0;F215 lbs.4xB0;F215 lbs.3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F3xB0;F</th
                      120/80681699%
                 </text>
       </section>
     </component>
  </section>
</component>
```

```
<component>
      <section>
        <code code='X-SS' codeSystem='2.16.840.1.113883.6.1'/>
        <title>Related Reports</title>
         <thead>
            Study
              Summary
              Date of Study
            </thead>
           X-Ray Study - Left Ankle
              No Fracture
              3/28/2005
            </text>
      </section>
     </component>
    <component>
      <section>
       <code code='18776-5' codeSystem='2.16.840.1.113883.6.1' />
       <title>Plan of Care</title>
         <paragraph>Acetaminophen with codiene prn for pain.
         <paragraph>Stay off the foot. Keep foot elevated, and use supplied air splint and
crutches.</paragraph>
         <paragraph>Follow-up with orthopedist in next 5 days./paragraph>
       </text>
      </section>
    </component>
   </structuredBody>
```

# Appendix E — Documents Created by Non-Practitioners

A number of issues must be addressed for CDA Documents created by persons other than healthcare practitioners. These issues are raised by the CDA Release 2.0 definition of a clinical document. According to CDA Release 2.0, a clinical document has six attributes:

**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** A clinical document is an assemblage of information that is

**authentication** 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.

Human readability A clinical document is human readable.

If a document has all of these attributes, and meets the other requirements of the CDA Release 2.0 specification, then it is a valid CDA document.

The last three attributes can be met by any document that meets the technical requirements of the CDA Release 2.0 Specification, as they will always establish the default context, are authenticated as a whole, and through use of a style sheet, can be made human readable.

The first three attributes are non-technical, perhaps even philosophical in nature, and these are the attributes that raise the most difficult issues to resolve.

#### **Persistence**

A clinical document continues to exist in an unaltered state, for a time period defined by local and regulatory requirements. The exact wording of the CDA Specification ensures persistence of a clinical document by using local and regulatory requirements. A patient maintained CDA document may in fact meet this test as there may be no local or regulatory requirements that a patient maintain a copy of this document. However, the intention of this attribute was to ensure that a true copy of the document is accessible to healthcare practitioners for a reasonable period of time in order to provide healthcare. That reasonable period of time is already defined by local laws and regulations for documentation that a practitioner maintains. The CDA Specification did not consider the issue that there may in fact be no local law or regulation requiring that a clinical document be persistent because it might have been created by a non-practitioner.

Our advice on this issue is to follow the more restrictive intent, as well as the exact wording of the specification regarding documents created by a non-practitioner.

## Stewardship

A clinical document must be maintained by an organization. CDA is based on the RIM. The RIM defines an <u>organization</u> as "An Entity representing a formalized group of entities with a common purpose (e.g. administrative, legal, political) and the infrastructure to carry out that purpose. "A <u>person</u> is distinct from an organization in the RIM, and so a person cannot be a steward of a clinical document.

This attribute then prevents a patient or guardian from being a steward of a clinical document, but does not prevent authorship.

#### **Potential for Authentication**

A clinical document is an assemblage of information that is intended to be legally authenticated. According to the CDA and the RIM, a <u>legal authenticator</u> is: "A verifier who legally authenticates the accuracy of an act. An example would be a staff physician who sees a patient and dictates a note, then later signs it. Their signature constitutes a legal authentication." The Act in this case is the clinical document act (<u>DOCCLIN</u>). According to CDA Release 2.0, legal authentication is the final state during the creation of a clinical document.

This raises the question of whether a non-practitioner can legally authenticate a clinical document. There are several opinions on this issue. It is clear that CDA and the RIM intend to limit the authority for legal authentication to privileged persons (see <a href="authenticator"><u>authenticator</u></a>). However, no definition or limits are placed on who can be a legal authenticator within either the RIM or the CDA. Secondly, it seems clear that the organization responsible for maintenance of the patient's chart is the one who can delegate the legal responsibility to individuals to enter material into that chart.

Thus, a non-practitioner would only be allowed to enter information into their chart in special cases.

One such special case might be covered by a PHR system provided by a third party which would allow persons to maintain personal health records for themselves and their dependents. Such a system might allow only the patient or guardian, or designated healthcare providers to update the patient's PHR information.

#### **Use Cases**

Four use cases follow to illustrate the points discussed above.

#### **Patient Created and Maintained Document**

A patient creates a document in CDA format, and maintains it on their home computer system. Is such a document in fact a CDA according to the specification? The answer to this question is clearly no as the patient is not an organization that can provide stewardship. Secondly, according to the intent [but not necessarily the definition] required for persistence, this document may not be persistent for a reasonable period of time.

### Patient Created Document Maintained by Third Party Organization

A patient creates a document in CDA format, and maintains it through a third party repository or PHR system. In this case, the document is persistent, and the third party steward is an organization (that will likely be required by local law or regulation to make the document available for a reasonable period of time). The third party may grant the patient the authority to legally sign the document to become part of that patient's chart in the repository or PHR system.

### Non-Patient Created Document Maintained by Third Party Organization

A guardian or other party creates a document in CDA format, and maintains it through a third party repository or PHR system. In this case, the document is persistent, and the third party steward is an organization (that will likely be required by local law or regulation to make the document available for a reasonable period of time). The third party may grant the guardian of the patient the authority to legally sign the document to become part of that patient's chart in the repository or PHR system. This is not very different from a patient created document described above, save that the person creating it is other than the patient.

## **Patient Created Document Maintained by Healthcare Practice**

In the final case, a patient or guardian creates a document in CDA format, as directed by their health care practitioner. The document is then reviewed by the practitioner, who signs it an adds it to the patient chart. This use case is meant to cover the case where a patient fills out a health history form, and signs it.

In this case the steward is the health care organization, which has requirements under local law and regulation to maintain the document, and the legal authenticator is the healthcare practitioner. The only difference is that the patient or guardian is the author. This use case raises a technical issue in using the CDA Release 2.0 specification. The issue is that in order to attest authorship, the organization allowing the document creation must be able to assert the identity for the role ID of the assigned author of the document.

To put it simply, the application that allows patients to create documents must be able to record information about the creator, and assign a distinct user ID to each creator. This applies whether the creator of the document is the patient, a relative or other guardian.

### Recording the Author Relationship to the Patient

In several of the cases described above, the author of the document may not be the patient, but may have some relationship (e.g., parent or guardian) to the patient. Appendix F — Extensions to CDA Release 2.0 below describes an extension that will allow this relationship to be recorded.

The basic mechanism is to record the author of the and provide a link between the author and the patient using the mechanism described in the Patient Relationship extension described below.

# Appendix F — Extensions to CDA Release 2.0

During development of this implementation guide, some limitations of CDA Release 2.0 were discovered. Local extensions to the CDA Release 2.0 specification have been developed and are described below to help alleviate these issues.

To resolve issues that need to be addressed by extension, the developers of this guide chose to approach extensions as follows:

- An extension is a collection of element or attribute declarations and rules for their application to the CDA Release 2.0.
- All extensions are optional. An extension may be used, but is not required to be under this guide.
- A single namespace for all extension elements or attributes that may be used by this guide will be defined.
- The namespace for Care Record Summaries is TBD<sup>11</sup>.
- This namespace will be used as the namespace for any extension elements or attributes that are defined by this implementation guide.
- Each extension element will use the same HL7 vocabularies and data types used by CDA Release 2.0.
- Each extension element will use the same conventions for order and naming as is used by the current HL7 tooling.
- An extension element must appear in the XML where the expected RIM element of the same name would have appeared had that element not been otherwise constrained from appearing in the CDA XML schema.

The extensions defined by this guide are briefly described below and illustrated in Figure 63 on the next page. A more detailed description of each extension follows the illustration.

- The Entity Identifier extension allows for participants to be uniquely identified so that users of this implementation guide can identify all of a given entity's participations in a CDA Document. This is reflected by the addition of an id attribute on the person in Figure 63.
- The Patient Relationship extension allows the relationship between any participant and the patient. This is reflected by the PatientRelationship role association connected to the person in Figure 63.

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<sup>&</sup>lt;sup>11</sup> While I would propose urn:hl7-org:crs, in fact, HL7 must propose hl7-org as a URN Namespace ID to IANA, which it apparently has not. Therefore, I would propose http://www.hl7.org/URL\_PATH\_TO\_SPECIFICATION for the final balloted CRS Specification.

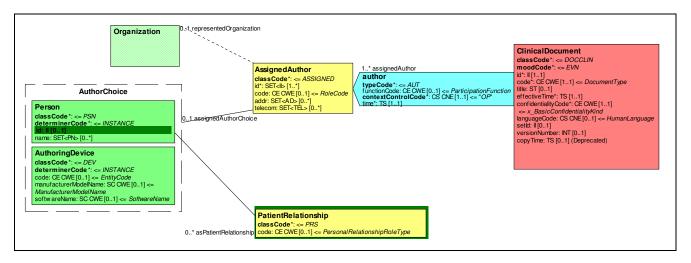


Figure 63 Extensions to CDA

## **Entity Identifier**

CDA Release 2.0 does not provide a mechanism to determine when two participants in different roles are in fact the same entity (i.e., an entity can be a person, organization or device). A CDA Document identifies each participant through the application of a role identifier. This identifier can be used to trace the participation of an entity in a given role, but cannot necessarily be used to determine that two entities are the same. While more role identities could be provided whose intended use is to unify the entities, this is better modeled through the use of an entity identifier. Therefore, to facilitate this capability, this guide defines an extension to CDA Release 2.0 which allows the person or organization playing the role to be uniquely identified; by the inclusion of an identifier on the entity.

An entity identifier opaquely represents the entity referenced in a clinical document. It has no required relationship between the entity and the role that they play in that document. Use of an entity identifier therefore gives CDA producing and consuming applications a mechanism to unite the various entities represented in the CDA document, and thereby expose relationships that would otherwise be obscured when entities cannot be recognized as being identical. When two participants have the same entity identifier, they can be assumed to be the same entity.

An example of an entity identifier is one provided from a government issued ID, such as those found on a passport, driver's license, or other ID card. A universal patient identifier, or universal provider identifier are similar examples of an entity identifier, although the assigning authority of these identifiers does have a more limited intent for their use [attainment of care, and provision of care]. Other identifiers could also be used as entity identifiers (e.g., SSN), but these also convey additional information, and are not just used for general identification purposes.

Conversely, an entity identifier may also be used as a role identifier. For example, a given EHR system may use the Universal Provider Identifier identify the providers that use it. This is a scenario likely to be encountered when identities must be managed across a wide variety of organizations, and there is already a uniform process for managing these identities that need not be duplicated by the application or

organizations that use it. An example use case where this might be a reasonable approach would be in a regional health information network where numerous providers need to be identified. A reasonable assumption that can be made is that if two participants have the same role identifier, that they are also the same person. This assumption can only be made if the assigning authority for the role identifiers follows good practices in its assignment.

The key fact raised by both of these points is that the assigning authority of an identifier (e.g., the government) may have an intent for the use of the identifier that is different from the actual use of it in an EHR system. This is not really material to the discussion of the need for an entity identifier. While the intended purpose of an identifier may be other than uniquely identifying an entity, it does also service this need, and applications may use it in that fashion.

In the CDA Release 2.0 schema, organizations and the patient already carry an identifier on the entity, and devices can have only one form of participation (as assignedAuthoringDevice). Therefore, only those elements describing participant persons that are not the patient need to support an element to identify the person. To state it simply, each person that is represented by the CDA document that does not already have an id element may now generate one if necessary using this extension. This identifier may be provided in an id element from the urn:hl7-org:crs of type II, appearing just before name element of any person described by any role in the CDA Release 2.0 schema.

A document that identifies one person in this fashion should identify all persons in this way, otherwise there will be unidentified persons described by the document, and the utility of this extension will be negated.

Because the patient already supports an identifier element according to the CDA schema, an additional id element is not necessary and should not be provided in the patient element. However, to represent the patient in any other role, the identifier used in the corresponding id element should be the same as the identifier used to represent the patient. This is shown below in Figure 64.

```
<ClinicalDocument xmlns='urn:h17-org:v3' xmlns:crs='urn:h17-org:crs'>
   <author>
      <time value='20050329224411+0500'/>
      <assignedAuthor>
      <assignedPerson>
          <crs:id extension="67890" root="2.16.840.1.113883.3.933"/>
             </name>
      </assignedPerson>
      </assignedAuthor>
   </author>
      :
   <recordTarget>
      <patientRole>
          <id extension="67890" root="2.16.840.1.113883.3.933">
          <name>
             <prefix>Mrs.</prefix><given>Ellen</given><family>Ross</family>
          <administrativeGenderCode code="F"
                 codeSystem="2.16.840.1.113883.5.1"/>
          <birthTime value="19600127"/>
      </patient>
      </patientRole>
   </recordTarget>
</ClinicalDocument>
```

Figure 64 Using crs:id when the patient is the author

## **Patient Relationship**

CDA Release 2.0 does not provide a mechanism to relate any participant<sup>12</sup> to the patient. Often useful information, such as the relationship between the patient and the policy holder, or the patient and the author, cannot be easily determined by traversal of the CDA document. Therefore, to facilitate this capability, this guide defines an extension to CDA Release 2.0 which allows the relationship to the patient to be expressed for any participant.

Each participant can have zero or more relationship roles with the patient. Each of these roles is expressed by an asPatientRelationship element which further describes the type of role in a code element.

```
<ClinicalDocument xmlns='urn:hl7-org:v3' xmlns:crs='urn:hl7-org:crs'>
   <author>
       <time value='20050329224411+0500'/>
       <assignedAuthor>
       <assignedPerson>
           <crs:id extension="12345" root="2.16.840.1.113883.3.933"/>
           <name>
               <prefix>Mrs.</prefix></prefix>
               <given>Abigail</given>
               <family>Ruth</family>
           </name>
           <crs:asPatientRelationship classCode='PRS'>
               <code code='MTH' codeSystem='2.16.840.1.113883.5.111'/>
           </crs:asPatientRelationship>
       </assignedPerson>
       </assignedAuthor>
   </author>
       :
</ClinicalDocument>
```

Figure 65 Using crs:asPatientRelationship to describe the author's relationship to the patient.

<sup>&</sup>lt;sup>12</sup> Only the informant can be related expressly to the patient.

[KWB1]Category. Make display names different in example, comment on language.