IMPL_CDAR2_LEVEL1-2REF_US_2006JUN

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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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, Personal 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

This guide is a conformance profile, as described in the Refinement and Localization section of the HL7 Version 3 standards. The base standard for this guide is the HL7 Clinical Document Architecture, Release 2.0. As defined in that document, this guide is both an annotation profile and a localization profile.

1.4.1 Explanatory Statements

As an annotation profile, portions of this guide summarize or explain the base standard.

Explanatory statements will appear in this style.

1.4.2 Conformance Requirements

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

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

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

1.4.3 XPath Notation

Instead of the traditional dotted notation used by HL7 to represent RIM classes, this guide uses XPath notation in conformance statements and elsewhere to identify the XML elements and attributes within the CDA document instance to which various constraints are applied. The implicit context of these expressions is the root of the document. The purpose of using this notation is to provide a mechanism which will be familiar to developers for identifying parts of an XML document.

1.4.4 Key Words

The key words "**SHALL**", "**SHALL NOT**", "**SHOULD**", "**SHOULD NOT**", "**MAY**", and "**NEED NOT**" in this document are to be interpreted as described in the HL7 Version 3 Publishing Facilitator's Guide.

1.4.5 XML Samples

XML Samples appear in various figures in this document in a `fixed font.` Portions of the XML content may be elided from the content for brevity. These are marked by a vertical ellipses, as shown in the example below.

```
<ClinicalDocument xmlns='urn:hl7-org:v3'>
        :
        .
</ClinicalDocument>
```

Within the narrative, XML element and attribute names in the text will appear in this font. Literal attribute values will appear in *this* font.

XPath expressions are used in the narrative and conformance requirements to identify elements. These were chosen because they are familiar to many XML implementers.

1.4.6 Content of the Ballot Package

The ballot package contains the following files:

Filename	Description
crs3.pdf	This guide
crs.sch	The Schematron schema found in Appendix A.
crs.xsl	An XSLT stylesheet that performs the same Schematron processing as the Schematron schema.
sample.xml	The sample CDA document found in Appendix B and C.
voc.xml	A vocabulary data file used by both the Schematron schema and the display stylesheet.
IMPL_CDAR2.xsl	A stylesheet for displaying the content of the sample document in HTML.
POCD_HD000040CRS.xls	A hierarchical description for a Care Record Summary.

Table 1 Contents of the Ballot Package

1.4.6.1 Schematron Schema

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. Schematron processors typically work by translating the schema into a stylesheet that can then be used to validate instances. More information on Schematron is available from the Schematron resource directory at http://xml.ascc.net/schematron/.

The constraints in the guide are expressed formally in an appendix as a Schematron schema that **SHALL NOT** produce errors when the CDA document is evaluated with schema. The ballot package includes this in the file schema.sch. The XSLT stylesheet schema.xsl has been produced by a Schematron processor running over schema.sch to support validating instances. This stylesheet is provided for users without access to, or familiarity with Schematron. It 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.

1.4.6.2 Sample XML

A sample document is provided which conforms to the level 1 and level 2 constraints of this guide. This document is the source of many of the examples provided in this guide.

1.4.6.3 Hierarchical Description

The CDA Release 2.0 specification includes a spreadsheet the describes the model of a CDA Document, known as the Hierarchical Description or HD[1]. These are described more fully in the HL7 Version 3 Guide. Changes from the original CDA hierarchical description are marked in red in the attached spreadsheet.

The **No.** column of this spreadsheet contains the same numbers as the CDA spreadsheet so that users can compare the two.

Elements derived from *InfrastructureRoot* (see the **Rim Source** column) do not usually appear in an HD. However, this implementation guide specifies constraints on a few of these, and so these are included.

The templateId element appears three times under ClinicalDocument, because there is one required and one optional templateId specified by this guide. In addition there **MAY** be other templateId elements present in the ClinicalDocument. There is no specified order in which these may appear, even though the HD might seem to imply that the template identifiers defined in this guide must appear first.

[1] Many HL7 specifications call this an HMD or Hierarchical Message Description. CDA uses the more general term because CDA Documents are not messages.

The **Conformance** column of this spreadsheet has one value not usually found in an HD. We use *C* in this column to indicate cases where the item is required depending upon particular conditions, which are then documented in the column labeled **Nt** (for Note). For example, the setId and versionNumber fields must either both be sent or omitted. One cannot be sent without the other. In other cases, at least one of two elements must be present, and these are also both marked with *C*, with a note that one or the other must be present.

Finally, the format of an HD allows message elements previously defined to be reused, to avoid repetition. In certain cases, the constraints on these message elements differ from one use to another (for example, the constraints for the addr and telecom fields for an assignedEntity for the dataEnterer are different than for an author). In these cases, a new message element type is defined for these (see the **of Message Element Type** column in the spreadsheet), and the lines in the spreadsheet where these message elements have been reused have been altered appropriately.

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.

CDA provides 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 level 1 and level 2 constraints specified in this implementation guide.

```
<ClinicalDocument xmlns='urn:hl7-org:v3'>
    <typeId extension='POCD_HD000040' root='2.16.840.1.113883.1.3'/>
    <templateId extension='IMPL_CDAR2_LEVEL1' root='2.16.840.1.113883.10'/>
    <templateId extension='IMPL_CDAR2_LEVEL2' root='2.16.840.1.113883.10'/>
    <id extension='999021' root='1.3.6.4.1.4.1.2835.2'/>
        :
        .
</ClinicalDocument>
```

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.

1.5.1 Future Work

Future work includes the definition of increasing refined (granular) machine-verifiable processing structures. This work will be performed in conjunction other HL7 technical committees and in cooperation with the ASTM Healthcare Informatics committee using E2369-05 Standard for the Continuity of Care Record (CCR) data set. The Structured Documents Technical Committee is beginning to work on a Continuity of Care Document (CCD) implementation guide which will incorporate the constraints of this guide and of CCR.

2 CDA Header

2.1 ClinicalDocument

The namespace for CDA Release 2.0 is urn:hl7-org:v3. *Appropriate namespace declarations* ***SHALL*** *be used in the XML instance of the Clinical Document. In the examples in this specification, all elements are shown un-prefixed, assuming that the default namespace is declared to be* urn:hl7-org:v3. *This guide does not require use of any specific namespace prefix. Instances* ***SHOULD NOT*** *include the* xsi:schemaLocation[2] *element.*

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

```
<ClinicalDocument xmlns='urn:hl7-org:v3'>
    <typeId extension='POCD_HD000040' root='2.16.840.1.113883.1.3'/>
    <templateId extension='IMPL_CDAR2_LEVEL1' root='2.16.840.1.113883.10'/>
    <templateId extension='IMPL_CDAR2_LEVEL2' 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' displayName='SUMMARIZATION OF EPISODE NOTE'/>
    <effectiveTime value='20050329224411+0500'/>
    <confidentialityCode code='N' codeSystem='2.16.840.1.113883.5.25'/>
    <languageCode code='en-US'/>
    <title>Good Health Clinic Care Record Summary</title>
    <setId extension='999021' root='1.3.6.4.1.4.1.2835.1'/>
    <versionNumber value='1'/>
        :
        .
</ClinicalDocument>
```

Figure 2 ClinicalDocument Example

2.1.1 General Constraints

Within the clinical document header[3], the following general guidelines have been applied:

To support communication between the receiver of the Care Record Summary and the patient or any other person or organization mentioned within it, the elements representing them **SHALL** provide a name. All persons **SHOULD**, and the patient, assigned healthcare providers and other persons or organizations associated with the healthcare of the patient **SHALL** supply addr and telecom elements. Although the

[2] The xsi:schemaLocation element is not recommended by the XML ITS because of security risks. Receivers who choose to perform validation should use a locally cached schema.
[3] Constraints on elements within structured entries in the structuredBody are not within the scope of this implementation guide.

dataEnterer represents an assigned person, they are not (usually) an assigned healthcare provider, and are therefore not included by this constraint.

L1-1: All patient, guardianPerson, assignedPerson, maintainingPerson, relatedPerson, intendedRecipient/informationRecipient, associatedPerson, and relatedSubject/subject elements **SHALL** have a name.

L1-2: All patientRole, assignedAuthor, assignedEntity[not(parent::dataEnterer)] and associatedEntity elements **SHALL** have an addr and telecom element.

L1-3: All guardian, dataEnterer/assignedEntity, relatedEntity, intendedRecipient, relatedSubject and participantRole elements **SHOULD** have an addr and telecom element.

L1-4: All guardianOrganization, providerOrganization, wholeOrganization, representedOrganization, representedCustodianOrganization, recievedOrganization, scopingOrganization and serviceProviderOrganization elements **SHALL** have name, addr and telecom elements.

*When name, addr or telecom information is unknown and where these elements are required to be present, the fact that the information is unknown **SHALL** be represented using an appropriate value for the nullFlavor attribute on the element. Legal values according to this specification come from the HL7 NullFlavor vocabulary. Use of nullFlavor is shown below in Figure 3.*

```
<assignedEntity>
    <id extension='3' root='1.3.6.4.1.4.1.2835.1'/>
    <addr nullFlavor='UNK'/>
    <telecom nullFlavor='ASKU' use='WP'/>
    <assignedPerson>
        <name nullFlavor='NAV'/>
    </assignedPerson>
</assignedEntity>
```

Figure 3 Various Uses of nullFlavor

Events occurring at a single point in time which are represented in the in the Clinical Document header will in general be precise to the day. An exception is made for the patient birth time (which may only be approximately known). These point in time events are the time of creation of the document, or the starting time of a participation by an author, data enterer, authenticator or legal authenticator, or the starting and ending time of an encounter. Other times or intervals in time represented in the Clinical Document header **SHALL** be precise at least to the year, **SHOULD** be precise to the day, and **MAY** omit time zone.

L1-5: Times or time intervals found in the ClinicalDocument/effectiveTime, author/time, dataEnterer/time, legalAuthenticator/time, authenticator/time and encompassingEncounter/effectiveTime elements **SHALL** be precise to the day, **SHALL** include a time zone if more precise than to the day[4], and **SHOULD** be precise to the second.

L1-6: The patient/birthTime element **SHALL** be precise at least to the year, and **SHOULD** be precise at least to the day, and **MAY** omit time zone.

L1-7: Times or time intervals found in the patient/birthTime, asOrganizationPartOf/effectiveTime, asMaintainedEntity/effectiveTime, relatedEntity/effectiveTime, serviceEvent/effectiveTime,

[4] The XML ITS precludes the use of time zone unless the precision of the timestamp is more than to the day.

ClinicalDocument/participant/time, serviceEvent/performer/time and encounterParticipant/time **SHALL** be precise at least to the year, **SHOULD** be precise to the day, and **MAY** omit time zone.

All telephone numbers **SHALL** be encoded using a restricted form of the tel: URL scheme, described in the section on Telephone Numbers below.

2.1.1.1 Telephone Numbers

*The telecom element **SHALL** be used to provide a contact telephone number for the various participants that require them. The value attribute of this element is a URL that specifies the telephone number, as specified by the TEL data type.*

Within the specification all telephone numbers **SHALL** be encoded using the grammar of Figure 4 below. The grammar in Figure 4 is a restriction on the TEL data type and RFC 2806[5]. It simplifies interchange between applications, as it removes optional URL components found in RFC 2806 that applications typically do not know how to process, such as ISDN sub-address, phone context, or other dialing parameters.

*A telephone number used for voice calls begins with the URL scheme tel:. If the number is a global phone number, it starts with a plus sign. The remainder is made up of the dialing digits and an optional extension, and **MAY** also contain visual separators.*

```
telephone-url  = telephone-scheme ':' telephone-subscriber
telephone-scheme   = 'tel'
telephone-subscriber   = (global-phone-number | phone-number ) [ extension ]
global-phone-number    = '+' phone-number
phone-number   = digits
digits = phonedigit | digits phonedigit
phonedigit = DIGIT | visual-separator
extension = ';ext=' digits
visual-separator   = '-' | '.' | '(' | ')'
```

Figure 4 Restricted URL grammar for telephone communications

L1-8: Telephone numbers **SHALL** match the regular expression pattern *tel:\+?[-0-9().]+*

L1-9: At least one dialing digit **SHALL** 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 e-mail or other telecommunications address. Therefore, the following convention will be used. Any telecom element that uses a flavor of null (has a nullFlavor attribute) is assumed to be a telephone number, as these are the only required telecommunications address elements within this implementation guide. In cases where the telephone number is not known, it **SHALL** be represented using a flavor of null, as shown below.

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

Figure 5 Unknown Telephone number example.

[5] Note that RFC 3966 obsoletes RFC 2806, but is backwards compatible. The restricted grammar is compatible with both RFC 3966 and 2806 by virtue of section 2.5.11 of RFC 2806 which provides for additional parameters (e.g., ';ext=') to be added as future extensions.

2.1.2 Rendering Information from the CDA Header for Human Presentation

Rendering the information in the header for human presentation is optional.

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 their roles, participations, participation date ranges, identifiers, address and telecom information
- Selected organizations named along with roles, participations, participation date ranges, identifiers, address and telecom information
- Record Target(s) date-of-birth
- Other Insurance and guarantor information as appropriate

2.1.3 ClinicalDocument/realmCode

This value identifies the realm[6].

The ClinicalDocument/realmCode element **SHALL** be present. It **SHALL** use the fixed value *US*.

```
<realmCode code='US'/>
```

Figure 6 ClinicalDocument/realmCode Example

2.1.4 ClinicalDocument/typeId

*The ClinicalDocument/typeId element **SHALL** be present. It identifies the constraints imposed by CDA Release 2.0 on the content, essentially acting as a version identifier. The @root and @extension values of this element **SHALL** be specified as shown below in Figure 7.*

```
<typeId extension='POCD_HD000040' root='2.16.840.1.113883.1.3'/>
```

Figure 7 ClinicalDocument/typeId Example

L1-10: The extension attribute of the typeId element **SHALL** be *POCD_HD000040*.

2.1.5 ClinicalDocument/templateId

The ClinicalDocument/templateId elements identify the templates that impose constraints on the content.

At least one ClinicalDocument/templateId **SHALL** be present with the content shown below in Figure 8. This indicates conformance to the level one features of this guide.

L1-11: A ClinicalDocument/templateId element **SHALL** be present where the value of @extension is *IMPL_CDAR2_LEVEL1* and the value of @root is *.2.16.840.1.113883.10*.

[6] 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.

```
<templateId extension='IMPL_CDAR2_LEVEL1' root='2.16.840.1.113883.10' />
```

Figure 8 ClinicalDocument/templateId Example conforming to Level 1 only

To indicate conformance to level 2 features of this guide, ClinicalDocument/templateId elements **SHALL** be present with values show in Figure 9.

```
<templateId extension='IMPL_CDAR2_LEVEL1' root='2.16.840.1.113883.10' />
<templateId extension='IMPL_CDAR2_LEVEL2' root='2.16.840.1.113883.10' />
```

Figure 9 ClinicalDocument/templateId Example conforming to Level 1 and Level 2

2.1.6 ClinicalDocument/id

*The ClinicalDocument/id element **SHALL** be present. It is an instance identifier data type (see HL7 Version 3 Abstract Data Types). The root attribute is a UUID or OID. The root uniquely identifies the scope of the extension. The root and extension attributes uniquely identify the document.*

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

L1-12: *The ClinicalDocument/id/@root attribute **SHALL** be a syntactically correct UUID or OID.*

L1-13: *UUIDs **SHALL** be represented in the form* XXXXXXXX-XXXX-XXXX-XXXX-XXXXXXXXXXXX*, where each X is a character from the set [A-Fa-f0-9].*

L1-14: *OIDs **SHALL** be represented in dotted decimal notation, where each decimal number is either 0, or starts with a non-zero digit. More formally, an OID **SHALL** be in the form ([0-2])(.([1-9][0-9]*|0))+.*

L1-15: OIDs **SHALL** be no more than 64 characters in length.

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

Figure 10 ClinicalDocument/id Example

*Organizations that wish to use OIDs **SHALL** 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

*The ClinicalDocument/code element **SHALL** be present and 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 **SHALL** be used as the value for ClinicalDocument/code in the CDA Header. These codes are shown below in Table 2.

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 2 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*.

L1-16: *For /ClinicalDocument/code, @code **SHALL** come from the appropriate LOINC code subset listed in Table 2, @codeSysem **SHALL** be the OID for LOINC, and @codeSystemName, if present **SHALL** be* LOINC.

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

Figure 11 ClinicalDocument/code Example

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 **SHALL** be used for a Care Record Summary.

2.1.7.1 Use of Local Document Type Codes

*Implementations **MAY** use local codes in translation elements to specify a local code that is equivalent to the document type. An example of this is shown below in Figure 12.*

```
<code code='34133-9' displayName='SUMMARIZATION OF EPISODE NOTE'
    codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'>
    <translation code='46239-0GISOE' displayName='GI SUMMARIZATION OF EPISODE NOTE'
        codeSystem='2.16.840.1.113883.6.1'/>
</code>
```

Figure 12 Use of a translation to include local equivalents for document type

2.1.7.2 Precoordinated Document Type Codes

*Some LOINC codes listed above also indicate the practice setting or the training or professional level of the author. These are pre-coordinated document type codes. When these codes are used, any coded values describing the author or performer of the service act or the practice setting **SHALL** be consistent with the LOINC document type.*

The LOINC document hierarchy listed in Table 2 is a complete list of all document type codes supported under this specification. Some of these codes (those not marked in boldface type), are pre-coordinated with either the practice setting, or the training or professional level of the author. Use of these codes is not recommended, as this duplicates information potentially present with the CDA document header. When these codes are used, they **SHALL NOT** conflict with the other information present in the document.

L1-17: *If pre-coordinated document type codes are used, values used in the assignedAuthor/code and assignedAuthor/author/functionCode elements **SHALL NOT** conflict with ClinicalDocument/code.*

L1-18: *If pre-coordinated document type codes are used, values used in encompassingEncounter/location/healthCareFacility/code **SHALL NOT** conflict with ClinicalDocument/code.*

Figure 13 below illustrates the various codes found in the header that need to be consistent when using pre-coordinated document type codes.

```
<ClinicalDocument xmlns='urn:hl7-org:v3'>
        :
        .
    <code code='34106-5' codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'
        displayName='ATTENDING PHYSICIAN HOSPITAL DISCHARGE SUMMARIZATION NOTE'/>
        .
        :
    <author>
        <functionCode code='ATTPHYS' codeSystem='2.16.840.1.113883.5.88'
            codeSystemName='ParticipationFunction'/>
        <assignedAuthor>
                :
                .
            <code code='59058001' codeSystem='2.16.840.1.113883.6.96'
                codeSystemName='SNOMED CT'/>
                .
                :
        </assignedAuthor>
    </author>
        .
        :
    <componentOf>
        <encompassingEncounter>
                .
                :
            <healthCareFacility>
                <code code='HOSP' codeSystem='2.16.840.1.113883.5.111'
                    codeSystemName='RoleCode'/>
            </healthCareFacility>
        </encompassingEncounter>
    </componentOf>
</ClinicalDocument>
```

Figure 13 Use of Precoordinated of Document Type Codes in the CDA

Using document type codes that are not precoordinated eliminates the necessity to ensure consistency between the document type and other codes found in the document. In the example shown above, changing the document type code to that found in Figure 14 shown below eliminates the need to ensure consistency of the document type code with the codes assigned to an author or healthcare facility.

```
<ClinicalDocument xmlns='urn:hl7-org:v3'>
        :
        .
    <code code='18842-5' codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'
        displayName='DISCHARGE SUMMARIZATION NOTE'/>
        .
        :
</ClinicalDocument>
```

Figure 14 Precoordination of Document Type Codes in the CDA

2.1.8 ClinicalDocument/title

The title *element* ***MAY*** *be present and specifies the local name used for the document.*

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

Figure 15 ClinicalDocument/title *Example*

2.1.9 ClinicalDocument/effectiveTime

*The ClinicalDocument/effectiveTime element **SHALL** be present and specifies the creation time of the document.*

All Care Record Summaries authored by direct input to a computer system **SHOULD** record an effectiveTime that is precise to the second. When authored in other ways, for example, by filling out a paper form that is then transferred into an EHR system, the precision of effectiveTime may be less than to the second.

```
<effectiveTime value='20050303171504+0500'/>
```

Figure 16 ClinicalDocument/effectiveTime Example

2.1.10 ClinicalDocument/confidentialityCode

*The ClinicalDocument/confidentialityCode **SHALL** be present. It 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 17 ClinicalDocument/confidentialityCode Example

2.1.11 ClinicalDocument/languageCode

The ClinicalDocument/languageCode element **SHALL** be present. It specifies the language of the Care Record Summary. Care Record Summaries **SHALL** be in a human language readable by medical practitioners, care givers and patients. The encoding of the language **SHALL** be present, and **SHALL** be in the form *nn* (see Figure 18) or *nn-CC* (see Figure 19), 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.

L1-19: The languageCode element **SHALL** be present.

L1-20: The language code **SHALL** be in the form *nn*, or *nn-CC*.

L1-21: The *nn* portion **SHALL** be a legal ISO-639-1 language code in lower case.

L1-22: The *CC* portion, if present **SHALL** be an ISO-3166 country code in upper case.

```
<languageCode code='en'/>
```

Figure 18 ClinicalDocument/languageCode Example with language only

```
<languageCode code='en-US'/>
```

Figure 19 ClinicalDocument/languageCode Example with language and country.

2.1.12 ClinicalDocument/setId and ClinicalDocument/versionNumber

The ClinicalDocument/setId and ClinicalDocument/versionNumber elements **SHALL** either both be present or both be absent.

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

L1-23: Both ClinicalDocument/setId and ClinicalDocument/versionNumber **SHALL** be present or absent.

The 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 root, then the extension of the ClinicalDocument/id **SHALL** be distinct from ClinicalDocument/setId.

L1-24: The @extension and/or @root of ClinicalDocument/setId and ClinicalDocument/id are different when both are present.

```
<setId extension='999021'  root='1.3.6.4.1.4.1.2835.1'/>
<versionNumber value='1'/>
```

Figure 20 ClinicalDocument/setId and ClinicalDocument/versionNumber Example

2.1.13 ClinicalDocument/copyTime

The ClinicalDocument/copyTime element has been deprecated in CDA Release 2, therefore it **SHALL NOT** be present in conforming instances of a Care Record Summary.

L1-25: A ClinicalDocument/copyTime element **SHALL NOT** be present.

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 3 below describes the participations defined by CDA Release 2.0. Identify the role(s) each person participates in and list them in each role. Note that Authentication requires that the author be able to verify the accuracy of the document, and Legal Authentication requires that the author has the privilege to legally authenticate the document. Patients or other persons, such as a guardian or parent may not have these privileges depending upon local policy.

Participants **MAY** be identified using an extension described in Appendix E — Extensions to CDA Release 2.0, in order to determine which participants are the same person.

Description	*author*	*dataEnterer*	*authenticator*	*legalAuthenticator*	*intendedRecipient*	*recordTarget*	*informant*	*participant*
A person or system that creates the document by entry of information from their own knowledge or application of skills. *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 that transfers information from one form or another without creating new information though application of their own knowledge or skills. *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 verifier who attests to the accuracy of a document and provides final signature, thereby finalizing the document. *i.e. a staff physician who sees a patient and dictates a note, then later signs it. Their signature constitutes a legal authentication.*				√				
A person or system that has been selected to receive the information in the document, who is known before completion of the document. *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 recordTarget indicates whose medical record holds this document.						√		
A person 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 person that provides additional support to the patient, that is not in any assigned healthcare role by any healthcare organization. Used when other more specific participants aren't applicable to capture the type of participation.. *e.g., A parent or other family member, a care-giver, someone who provides transportation to the patient, etc.*								√
The guarantor for payment of healthcare services given the patient whose care is being described within the document. *e.g., A family member, an employer, or another person or organization who has agreed to be responsible for the patient's medical bills.*								√
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. *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 3 Participant Assignment

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

The participants are listed below in the order they appear.

2.2.1 recordTarget

*The recordTarget element **SHALL** be present. It **SHALL** be the patient or patients whose health history is/are described by this Care Record Summary document.*

L1-26: At least one recordTarget/patientRole element **SHALL** be present.

The birthTime and administrativeGenderCode **SHALL** be present as this information is needed by users of a Care Record Summary. If unknown, it **SHALL** be represented using a flavor of null. Values for administrativeGenderCode **SHOULD** be drawn from the HL7 AdministrativeGender vocabulary.

L1-27: A patient/birthTime element **SHALL** be present.

L1-28: A patient/administrativeGenderCode element **SHALL** be present.

*The maritalStatusCode, religiousAffiliationCode, raceCode and ethnicGroupCode elements **MAY** be present.*

L1-29: If maritalStatusCode, religiousAffiliationCode, raceCode and ethnicGroupCode elements are present, they **SHOULD** be encoded using appropriate HL7 vocabularies.

L1-30: The guardian element **SHOULD** be present when the patient is a minor child.

*The providerOrganization element **MAY** be present.*

```
<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>
                <given>Ellen</given>
                <family>Ross</family>
            </name>
            <administrativeGenderCode code='F' codeSystem='2.16.840.1.113883.5.1' />
            <birthTime value='19600127'/>
        </patient>
        <providerOrganization>
            <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 21 recordTarget *Example*

2.2.2 author

The author *element* ***SHALL*** *be present. It represents the creator of the document. 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, who filters, reasons, or algorithmically creates new information, then that second actor is also an* author*, having created information from his or her own knowledge or skills. However, that determination is independent from the determination of the first actor's authorship.*

```
<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'/>
        <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>
    </assignedAuthor>
</author>
```

Figure 22 author *Example*

The time *element* ***SHALL*** *be present. It* ***SHALL*** *be the starting time of the author's participation in the creation of the document.*

L1-31: The author/time element **SHALL** be present.

The assignedAuthor/id element ***SHALL*** *be present.*

L1-32: The assignedAuthor/id element **SHALL** be present.

An assignedAuthor/assignedPerson or assignedAuthor/assignedAuthoringDevice element **SHALL** be present. This is the person or device authoring the document.

L1-33: An assignedAuthor element **SHALL** contain at least one assignedPerson or assignedAuthoringDevice elements.

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

L1-34: When assignedAuthoringDevice is present, the softwareName element **SHALL** be present.

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

In order to represent the relationship between the author and the patient, the Patient Relationship extension described in Appendix E —Extensions to CDA Release 2.0 should be used. This is shown below in Figure 23.

```
        <assignedAuthor>
            <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='WP'/>
            <assignedPerson>
                <name>
                    <prefix>Mrs.</prefix>
                    <given>Ellen</given>
                    <family>Ross</family>
                </name>
                <crs:asPatientRelationship classCode='PRS' xmlns:crs='urn:hl7-org:crs'>
                    <code code='MTH' codeSystem='2.16.840.1.113883.5.111'/>
                </crs:asPatientRelationship>
            </assignedPerson>
    </assignedAuthor>
```

Figure 23 asPatientRelationship *example*

2.2.3 dataEnterer

*This element **MAY** be present. It 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*.*

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.

*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*.*

L1-35: When dataEnterer is present, an assignedEntity/assignedPerson element **SHALL** be present.

The time *element **MAY** be present. If present, it represents the starting time of entry of the data.*

```
<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 24 dataEnterer *Example*

2.2.4 informant

The informant *element **MAY** be present. It describes the source of the information in the Care Record Summary.*

L1-36: The type of relationship between the patient and the informant **SHALL** be specified in relatedEntity/@classCode and **SHALL** be *CON*, *PRS* or *PROV* from the RoleClass vocabulary.

L1-37: When informant is present, an assignedEntity/assignedPerson or relatedEntity/relatedPerson element **SHALL** be present.

2.2.4.1 Assigned Healthcare Providers

When the informant is a healthcare provider with an assigned role, the informant **SHALL** *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).*

The code *element is optional on the* assignedEntity*, since the person it identifies is already known to be in an assigned role.*

```
<!-- 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'/>
        <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>Jr.</suffix>
            </name>
        </assignedPerson>
    </assignedEntity>
</informant>
```

Figure 25 informant *Example for healthcare providers in assigned roles.*

2.2.4.2 Personal Relations

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

The relationship between the informant and the patient **SHALL** be described to assist the receiver of the Care Record Summary in understanding the information in the document.

L1-38: When relatedEntity/@classCode is *PRS*, values in relatedEntity/code **SHALL** come from the PersonalRelationshipRoleType vocabulary.

```
<!-- To represent personal relation that provides information about a patient -->
<informant>
    <relatedEntity classCode='PRS'>
        <code code='MTH' codeSystem='2.16.840.1.113883.5.111'/>
        <relatedPerson>
            <name>
                <prefix>Mrs.</prefix>
                <given>Abigail</given>
                <family>Ruth</family>
            </name>
        </relatedPerson>
    </relatedEntity>
</informant>
```

Figure 26 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 **SHALL** be set to *CON*, to indicate that this person is a contact and relatedEntity/code **SHOULD NOT** be present because there is no personal relationship to represent.

L1-39: When relatedEntity/@classCode is *CON*, relatedEntity/code **SHOULD NOT** be present.

```
<!-- To represent a witness to a signicant health event -->
<informant>
    <relatedEntity classCode='CON'>
        <relatedPerson>
            <name>
                <prefix>Mr.</prefix>
                <given>Joseph</given>
                <given>T.</given>
                <family>Jones</family>
            </name>
        </relatedPerson>
    </relatedEntity>
</informant>
```

Figure 27 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 **SHALL** be drawn from SNOMED CT, using concepts that descend from the *healthcare professional* subtype hierarchy (SNOMED CT Concept ID: 223366009).

L1-40: When relatedEntity/@classCode is *PROV*, and relatedEntity/code is present, the value **SHALL** come from SNOMED CT.

```
<!-- 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>
            <name>
                <given>Jane</given>
                <family>Queen</family>
                <suffix></suffix>
            </name>
        </relatedPerson>
    </relatedEntity>
</informant>
```

Figure 28 informant Example for healthcare providers not in assigned roles.

2.2.5 custodian

The custodian *element* ***SHALL*** be present*. This* ***SHALL*** *be the custodian of the Care Record Summary document.*

Systems that allow patients to create Care Record Summaries for their own should see Appendix D — Documents Created by Non-Practitioners for more details on this requirement.

```
<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>
```

Figure 29 custodian *Example*

2.2.6 informationRecipient

The ClinicalDocument/informationRecipient *element* ***MAY*** *be present*[7]*. When used in the context of a referral or request for consultation, this element records the intended recipient of the information at the time the document is created. The intended recipient* ***MAY*** *also be the health chart of the patient, in which case the* receivedOrganization ***SHALL*** *be the scoping organization of that chart.*

L1-41: When informationRecipient is used, at least one informationRecipient/intendedRecipient/informationRecipient or informationRecipient/intendedRecipient/recievedOrganization **SHALL** be present.

[7] Note that there are two elements in the CDA Release 2.0 schema that are named informationRecipient. The outermost of these elements is what is being discussed here. The second element with the same name may appear as a descendent of this one.

```
    <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 30 informationRecipient Example

2.2.7 legalAuthenticator

*The legalAuthenticator element **SHALL** be present if the document has been legally authenticated. It **SHALL** identify the legal authenticator of the document. Care Record Summaries **MAY** be released before legal authentication, based on local practice. This implies that a Care Record Summary that does not contain this element has not been legally authenticated.*

*The act of legal authentication requires a certain privilege be granted to the legal authenticator depending up local policy. 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 **SHALL** still be a person accepting responsibility for the document, not the device or system.*

L1-42: The assignedEntity/assignedPerson element **SHALL** be present in legalAuthenticator.

```
<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 31 legalAuthenticator Example

2.2.8 authenticator

An authenticator *MAY be present. The* authenticator *SHALL identify participant who attested to the accuracy of the information in the document.*

L1-43: The assignedEntity/assignedPerson element **SHALL** be present in an authenticator element.

```
<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>
        </addr>
        <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 32 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 the author cannot validate[8].

2.2.9 participant

The participant *element MAY be present. It MAY be used to identify 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.*

The time *element of the* participant *MAY be present. When present, it indicates the time span over which the participation takes place. For example, in the case of an insurance policy holder, the* time *element indicates 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.*

L1-44: The participant/associatedEntity element **SHALL** have an associatedPerson or scopingOrganization element.

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

[8] This may in fact also be the case for practitioners at various degrees of skill.

2.2.9.1 Supporting Person or Organization

The @typeCode attribute **SHALL** be *IND*, and participatingEntity/classCode **SHALL** 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 **SHALL** be represented in a participatingEntity/code element, using values drawn from the PersonalRelationshipRoleType 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.

L1-45: When participant/@typeCode is *IND*, participatingEntity/@classCode **SHALL** be *PRS, NOK, ECON or GUAR.*

L1-46: When participatingEntity/@classCode is *PRS, NOK or ECON* then participatingEntity/code **SHALL** be present having a value drawn from the PersonalRelationshipRoleType domain.

```
<participant typeCode='IND'>
    <associatedEntity classCode='NOK'>
        <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>
                <given>Abigail</given>
                <family>Ruth</family>
            </name>
        </associatedPerson>
    </associatedEntity>
</participant>
```

Figure 33 participant Example for a Supporting Person

2.2.9.2 Billing Related Participants

L1-47: When participant/@typeCode is *HLD*, participatingEntity/@classCode **SHALL** be *POLHOLD*.

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

L1-48: When participant/@typeCode is *HLD*, participatingEntity/scopingOrganization **SHALL** be present.

L1-49: To represent a guarantor, the @typeCode attribute **SHALL** be have a value of *IND*, and the participatingEntity/@classCode **SHALL** have a value of *GUAR*.

```
    <participant typeCode='HLD'>
        <time>
            <low value='20050101'/>
            <high value='20051231'/>
        </time>
        <associatedEntity classCode='POLHOLD'>
            <id extension='123456789' />
            <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>
                <name>
                    <prefix>Mr.</prefix>
                    <given>Kenneth</given>
                    <family>Ross</family>
                </name>
            </associatedPerson>
            <scopingOrganization>
                <name>Good Health Insurance Company</name>
                <telecom value='tel:(203)555-1212' use='WP'/>
                <addr>
                    <streetAddressLine>3191 Broadbridge Avenue</streetAddressLine>
                    <city>Stratford</city>
                    <state>CT</state>
                    <postalCode>06614-2559</postalCode>
                    <country>USA</country>
                </addr>
            </scopingOrganization>
        </associatedEntity>
    </participant>
```

Figure 34 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>
            </addr>
            <telecom value='tel:(999)555-1212' use='WP'/>
            <associatedPerson>
                <name>
                    <prefix>Mr.</prefix>
                    <given>Kenneth</given>
                    <family>Ross</family>
                </name>
            </associatedPerson>
        </associatedEntity>
    </participant>
```

Figure 35 participant *Example for a Guarantor*

The constraints listed above in sections 2.2.9.1 and 2.2.9.2 are summarized below in Figure 36.

Description of the Participant	@typeCode	participatingEntity / @classCode	Vocabulary Domain for participatingEntity / code	Comments
Next of Kin	IND	NOK	PersonalRelationshipRoleType	Personal relationship **SHALL** be present.
Emergency Contact	IND	ECON	PersonalRelationshipRoleType	Personal relationship **SHALL** be present.
Holder of an Insurance Policy	HLD	POLHOLD	Unrestricted by this guide	Scoping organization **SHALL** be present.
Guarantor	IND	GUAR	Unrestricted by this guide	
Other supporting person or organization.	IND	PRS	PersonalRelationshipRoleType	Personal relationship **SHALL** be present.

Figure 36 Encoding Various Participations

2.2.10 documentationOf

Only one documentationOf element **SHALL** be present. It **SHALL** indicate the episode of care that the provider describes in the content of the Care Record Summary. The main activity being described by this document is the provision of healthcare over a period of time. This is shown by setting the value of the @classCode attribute of the serviceEvent element to *PCPR*, and indicating the duration over which care was provided in the effectiveTime element. 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. While additional service events or acts may have occurred during the provision of care, these **SHOULD** be documented in the CDA Body, and **MAY** be further described within entry elements of a structuredBody.

L1-50: The value of the serviceEvent/@classCode attribute **SHALL** be *PCPR*.

L1-51: Only one ClinicalDocument/documentationOf element **SHALL** be present.

L1-52: If present, the value of serviceEvent/code **SHALL NOT** conflict with the ClininicalDocument/code.

*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, which **MAY** participate at the same or 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.

L1-53: The effectiveTime element of the serviceEvent element **SHALL** be present.

L1-54: The effectiveTime element **SHALL** contain both a low and a high element.

L1-55: A serviceEvent **SHOULD** have at least one performer. There are cases where no performers might be listed, for example, in cases where the information will not or cannot be provided by the patient.

L1-56: The performer elements **SHALL** list the relevant providers of healthcare during the episode being summarized.

L1-57: If the provider is the primary care provider for the patient during the time interval, then performer/functionCode **SHALL** have a value of *PCP* from the ParticipationFunction 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.

L1-58: If present, the values for performer/assignedEntity/code **SHALL** be drawn from SNOMED CT, using concepts that descend from the *healthcare professional* subtype hierarchy (SNOMED CT Concept ID: 223366009).

L1-59: The performer/assignedEntity/code if present **SHALL** have a value drawn from the SNOMED CT *healthcare professional* subtype hierarchy.

L1-60: Every performer/assignedEntity element **SHALL** have at least one assignedPerson or representedOrganization.

The time element of the performer element **MAY** be present. If present, it indicates the time span over which healthcare services are provided.

```
<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'
                    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>
                        <given>Bernard</given>
                        <family>Wiseman</family>
                        <suffix>Sr.</suffix>
                    </name>
                </assignedPerson>
            </assignedEntity>
        </performer>
    </serviceEvent>
</documentationOf>
```

Figure 37 documentationOf Example

2.2.11 inFulfillmentOf

*The inFulfillmentOf elements **MAY** be present. They 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 of that referral.*

2.2.12 authorization

*The authorization elements **MAY** be present. This document provides no guidance on the encoding of authorization elements.*

2.2.13 componentOf

When the Care Record Summary document is a Discharge Summarization the componentOf element **SHALL** be present, and describes the encounter from which the patient is being discharged, so that the receiver can query for additional information about that encounter. Otherwise, this element is optional.

L1-61: If the Care Record Summary is a Discharge Summarization, then the componentOf element **SHALL** be present.

The id element of the encompassingEncounter **SHALL** be present and represents the identifier for the encounter.

L1-62: The encompassingEncounter element **SHALL** have an id element.

*The effectiveTime **SHALL** 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.*

L1-63: The encompassingEncounter element **SHALL** have an effectiveTime element.

L1-64: If ClinicalDocument/code represents a Discharge Summarization Node, then dischargeDispositionCode **SHALL** be present.

The encounterParticipant elements **MAY** be present. If present, they 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).

L1-65: The encounterParticipant/assignedEntity element **SHALL** have at least one assignedPerson or representedOrganization element present.

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

L1-66: The responsibleParty/assignedEntity element **SHALL** have at least one assignedPerson or representedOrganization element present.

```
<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'
            codeSystem='2.16.840.1.113883.6.21'
            displayName='Routine Discharge'
            codeSystemName='UB92'/>
    </encompassingEncounter>
</componentOf>
```

Figure 38 componentOf *example*

3 Body

*A Care Record Summary **SHALL** 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. A nonXMLBody element **MAY** contain the actual CDA content, or **MAY** reference it by URL.*

It **SHOULD NOT** include both, as this is generally bad practice. If a reference is used, it **SHOULD** indicate the useable period.

L1-67: A nonXMLBody/text **SHOULD** not contain both a reference element and character data.

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. 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.

Figure 39 below illustrates a nonXMLBody with the actual content.

```
<component>
    <nonXMLBody mimeType='text/plain'>
        <text>This is where the text would go.</text>
    </nonXMLBody>
 </component>
```

Figure 39 Sample nonXMLBody element with content.

Figure 40 below illustrates a nonXMLBody with a reference to a URL and a useablePeriod. Note that there is no white space or new line characters between the opening or closing tags of the text and reference elements.

```
<component xmlns:xsi='http://www.w3.org/2001/XMLSchema-instance'>
    <nonXMLBody mimeType='text/plain'>
        <text><reference value='http://www.anyhospital.org/aDocument.txt'>
                <useablePeriod xsi:type='IVL_TS' >
                    <low value='20051104'/>
                    <high value='20121104'/>
                </useablePeriod>
            </reference></text>
    </nonXMLBody>
</component>
```

Figure 40 Sample nonXMLBody element with a reference.

3.1 LOINC Section Type Codes

The LOINC Section Type codes used in this guide are described below in Table 4. All section codes shown in this table describe narrative document sections[9]. These codes **MUST** be used with the sections shown in Table 4. Other sections not appearing in this table **MAY** be included where necessary in the Care Record Summary, according to local policy. These other sections **SHOULD** be coded using the appropriate LOINC Section Type codes.

Sections **MAY** appear in any order, and **MAY** be nested under other sections. For example, a vital signs section might be nested under a physical examination section. 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 column headings of this table are described below:

Section Category:	The section category column lists the general category 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: *H&P* – Provider Unspecified History and Physical Note *DS* – Physician Hospital Discharge Summary
Summary of Episode	This column indicates whether the section is Required (R) or Optional (O) in a Summarization of Episode Note (LOINC Document Type 34133-9).
Discharge Summary	This column indicates whether the section is Required (R) or Optional (O) in a Discharge Summary (LOINC Document Type 18842-5 or its descendants – see Table 2).
Transfer Summary	This column indicates whether the section is Required (R) or Optional (O) in a Transfer Summary (LOINC Document Type 18761-5 or its descendants – see Table 2).

[9] SCALE_TYP = 'NAR' in the LOINC tables.

Section Category	Code	Component Name	Source	Summary of Episode	Discharge Summary	Transfer Summary
Conditions	11348-0	HISTORY OF PAST ILLNESS	H&P	O	O	O
	46241-6	HOSPITAL ADMISSION DX	DS	O	O	O
	11535-2	HOSPITAL DISCHARGE DX	DS	O	R[10]	R[10]
	11450-4	PROBLEM LIST	H&P	R	R[10]	R[10]
Allergies and Adverse Reactions	10155-0	HISTORY OF ALLERGIES		R[10]	R[10]	R[10]
	8658-7	HISTORY OF ALLERGIES	H&P			
	11382-9	MEDICATION ALLERGY	H&P	O	O	O
Medications	10160-0	HISTORY OF MEDICATION USE	H&P	R	O	R[10]
	10183-2	HOSPITAL DISCHARGE MEDICATIONS	DS	O	R	
	42346-7	MEDICATIONS ON ADMISSION		O	O	O
Hospital Course	8648-8	HOSPITAL COURSE	DS	O	R	O
Reason For Visit	10154-3	CHIEF COMPLAINT	H&P	These sections are all Optional		
	29299-5	REASON FOR VISIT				
	46239-0	CHIEF COMPLAINT+REASON FOR VISIT				
Reason for Referral	42349-1	REASON FOR REFERRAL[11]				
Advance Directives	42348-3	ADVANCE DIRECTIVES				
History of Present Illness	10164-2	HISTORY OF PRESENT ILLNESS	H&P			
Functional Status	10158-4	HISTORY OF FUNCTIONAL STATUS	H&P			
Family History	10157-6	HISTORY OF FAMILY MEMBER DISEASES	H&P			
Social History	29762-2	SOCIAL HISTORY	H&P			
Immunizations	11369-6	HISTORY OF IMMUNIZATIONS	H&P			
Past Surgical History	10167-5	HISTORY OF SURGICAL PROCEDURES	H&P			
Prior Encounters	46240-8	HISTORY OF HOSPITALIZATIONS+ HISTORY OF OUTPATIENT VISITS				
	11336-5	HISTORY OF HOSPITALIZATIONS	H&P			
	11346-4	HISTORY OF OUTPATIENT VISITS	H&P			
Review of Systems	10187-3	REVIEW OF SYSTEMS	H&P			
Physical Examination	10184-0	HOSPITAL DISCHARGE PHYSICAL	DS			
	22029-3	PHYSICAL EXAM.TOTAL		These sections are all Optional		
	8716-3	VITAL SIGNS, PHYSICAL FINDINGS	H&P			
	46242-2	VITAL SIGNS MEASUREMENTS, FETUS				
Studies and Reports	11493-4	HOSPITAL DISCHARGE STUDIES SUMMARY	DS			
	30954-2	RELEVANT DIAGNOSTIC TESTS AND/OR LABORATORY DATA				
Care Plan	18776-5	TREATMENT PLAN	H&P, DS			

Table 4 LOINC Section Type Codes

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

[10] At least one section of the two types shown **SHALL** be present. Both **MAY** be present.
[11] 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.

For level 2 conformance, all section elements that are present in the body of the document **SHALL** 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 section element **SHALL** have a code element.

L2-2: A section **SHALL** contain at least one text element or one or more component elements.

L2-3: All text or component elements **SHALL** contain content.

3.1.1 Claims Attachments

The section codes have been coordinated with the Additional Information Specification 0004: Clinical Reports Attachment implementation guide (ASIG0004) to support the reuse of information found in a Care Record Summary to respond to a query for a Claims Attachment. The requirements of this guide are consistent with the requirements of ASIG0004.

- The Discharge Summary requirements in this guide are consistent with the specification found in ASIG0004 for the Physician Hospital Discharge Summary.

- The Summary of Episode requirements in this guide are consistent with the general structure of notes required by ASIG0004, and are also compatible with the specific structured used for the Provider Unspecified History and Physical Note.

3.2 Required Sections

A Care Record Summary **SHALL** contain sections that provide the following information:

3.2.1 Conditions 11535-2/11450-4

A list of conditions for the patient. This list **SHALL** 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, etc. If there are no current problems, this information **SHALL** be provided. If the current problems are unknown, this information **SHALL** be provided. Problem lists **SHALL** include information about active/resolved status.

The reader of a Care Record Summary **SHALL** be able to determine which problems are active and which problems are 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 Care Record Summary **SHALL** include a section element whose code is *11450-4 or 11535-2*.

*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 five columns. The first column lists the problem, the second and third lists the date range for the problem, including onset and resolution of the problem, when known. The fourth 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. Problems Lists may also be listed as free text or list items.

Problem	Start Date	End 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 41 Problems Rendering

```
<component>
    <section>
        <code   code='11450-4' codeSystem='2.16.840.1.113883.6.1'
                displayName='PROBLEM LIST'/>
        <title>Conditions</title>
        <text>
            <table border='1'>
                <thead><tr><th>Problem</th><th>Start Date</th><th>End Date</th>
                        <th>Comments</th></tr></thead>
                <tbody>
                    <tr><td>Cholecystitis</td><td>9/28/2002</td><td>6/2003</td>
                        <td>Resolved</td><td>Surgery postponed until after delivery</td>
                    </tr>
                    <tr><td>Pregnancy</td><td>7/2001</td><td>4/22/2002</td>
                        <td>Resolved</td><td>Prior history of miscarraige</td>
                    </tr>
                    <tr><td>Ankle Sprain</td><td>3/28/2005</td><td></td>
                        <td>Current</td><td>Slipped on ice and fell</td>
                    </tr>
                </tbody>
            </table>
        </text>
    </section>
</component>
```

Figure 42 Conditions Example

3.2.2 Allergies 10155-0/8658-7

A list of allergies suffered by the patient. This list **SHALL** contain all known allergies, including medication, dietary and other allergies. When the patient has no known allergies, this **SHALL** be clearly stated in the text. If the patient's allergies are unknown, this **SHALL** be clearly stated in the text. If an allergy is to be removed from the patient's allergy list, this **SHALL** be clearly stated in the text.

The reader of a Care Record Summary **SHALL** 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 section **SHALL** be present. It **SHALL** describe any allergies, adverse reactions, and intolerances. The LOINC section type `code` for this section is *10155-0* (HISTORY OF ALLERGIES) or *8658-7* (HISTORY OF ALLERGIES).

L2-5: A section **SHALL** be present with a `code` value of *10155-0* or *8658-7*.

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. Allergies may also be recorded as free text or in lists.

Allergen	Reaction	Comments
Penicillin	Hives	Cephalexin is OK

Figure 43 Medication Allergy Figure Rendering

```
<component>
    <section>
        <code   code='10155-0' codeSystem='2.16.840.1.113883.6.1'
                displayName='HISTORY OF ALLERGIES' />
        <title>Allergies and Adverse Reactions</title>
        <text>
            <table border='1'>
                <thead>
                    <tr><th>Allergen</th><th>Reaction</th>
                        <th>Comments</th>
                    </tr>
                </thead>
                <tbody>
                    <tr><td>Penicillin</td><td>Hives</td>
                        <td>Cephalexin is OK</td>
                    </tr>
                </tbody>
            </table>
        </text>
    </section>
</component>
```

Figure 44 Allergies Example

Figure 45 below shows an example of a patient with no known allergies.

```
<component>
    <section>
        <code   code='10155-0' codeSystem='2.16.840.1.113883.6.1'
                displayName='HISTORY OF ALLERGIES' />
        <title>Allergies</title>
        <text>No known allergies.</text>
    </section>
</component>
```

Figure 45 No Known Allergies Example

Figure 46 shows an example where the patient's allergies are unknown.

```
<component>
    <section>
        <code   code='10155-0' codeSystem='2.16.840.1.113883.6.1'
                displayName='HISTORY OF ALLERGIES' />
        <title>Allergies</title>
        <text>Patient is unconcious and allergies are not known.</text>
    </section>
</component>
```

Figure 46 Allergies Unknown Example

Figure 47 shows an example where an allergy is to be removed from the patient's allergy list.

```
<component>
    <section>
        <code   code='10155-0' codeSystem='2.16.840.1.113883.6.1'
                displayName='HISTORY OF ALLERGIES' />
        <title>Allergies</title>
        <text>
            <table border='1'>
                <thead>
                    <tr><th>Allergen</th><th>Reaction</th>
                        <th>Comments</th>
                    </tr>
                </thead>
                <tbody>
                    <tr><td>Remove Penicillin from the allergy list.</td><td></td><td></td>
                    </tr>
                </tbody>
            </table>
        </text>
    </section>
</component>
```

Figure 47 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 would also be listed under allergies and intolerances.

3.2.3 Medications 10183-2/10160-2

A list of medications for the patient. This list **SHALL** 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 **SHALL** be able to determine which medications are current.

L2-6: A Discharge summary **SHALL** include a section element whose code is *10183-2*.

L2-7: A Summary of Episode note that is not also a discharge summary **SHALL** include a section element whose code is *10160-0*.

The sample representation Figure 48 is a table listing the medications. The columns of this table describe the Medication, prescription or dosage information if known, and first date and last dates of use, if known. Medications may also be recorded as free text or in lists.

Medication	Prescription or Dose	Start Date	End Date
Indomethacin	50mg bid with food	12/10/2003	
Acetaminophen with codeine	#3 1-2 tablets for pain as needed	3/28/2005	4/5/2005

Figure 48 Medications Rendering

```
<component>
    <section>
        <code   code='10160-0' codeSystem='2.16.840.1.113883.6.1'
                displayName='HISTORY OF MEDICATION USE'/>
        <title>Medications</title>
        <text>
            <table border='1'>
                <thead>
                    <tr><th>Medication</th>
                        <th>Prescription or Dose</th>
                        <th>Start Date</th><th>End Date</th>
                    </tr>
                </thead>
                <tbody>
                    <tr><td>Indomethacin</td>
                        <td>50mg bid with food </td>
                        <td>12/10/2003</td><td>present</td>
                    </tr>
                    <tr>
                        <td>Acetaminophen with codeine</td>
                        <td>#3 1-2 tablets for pain as needed</td>
                        <td>03/28/2005</td><td>4/5/2005</td>
                    </tr>
                </tbody>
            </table>
        </text>
    </section>
</component>
```

Figure 49 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 50.

```
<component>
    <section>
        <code   code='10160-0' codeSystem='2.16.840.1.113883.6.1'
                displayName='HISTORY OF MEDICATION USE'/>
        <title>Medications</title>
        <text>None</text>
    </section>
</component>
```

Figure 50 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*. When medications are partially known, as much information as is known **SHOULD** be included.

3.2.4 Hospital Course 8648-8

A Discharge Summary **SHALL** contain a section describing the Hospital Course. This section will describe the course of care provided for the inpatient stay. Figure 51 below shows a sample of a Hospital course section.

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

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

```
<component>
    <section>
        <code   code='8648-8' codeSystem='2.16.840.1.113883.6.1'
                displayName='HOSPITAL COURSE'/>
        <title>Hospital Course</title>
        <text>Some text describing the course of care provided during the inpatient stay.
        </text>
    </section>
</component>
```

Figure 51 Hospital Course Example

3.3 Optional Sections

A Care Record Summary **MAY** contain additional sections that provide additional information, such as Family History, Social History, etc. When present these sections **SHOULD** be readily identifiable by the title.

3.3.1 Reason for Visit/Chief Complaint 29299-5/10154-3/46239-0

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 complaint 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 policy. 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 46239-0 **SHALL** be used. A Care Record Summary that uses the latter code **SHALL NOT** use either of the former codes, and vise versa.

L2-9: The section type code for the section describing the reason for visit in a level 2 conforming Care Record Summary **SHALL** be either *46239-0* (REASON FOR VISIT/CHIEF COMPLAINT), or *29299-5* (REASON FOR VISIT).

L2-10: The section type code for the section describing the patient's chief complaint in a level 2 conforming Care Record Summary **SHALL** be either *46239-0* (REASON FOR VISIT/CHIEF COMPLAINT), or *10154-3* (CHIEF COMPLAINT).

L2-11: A level 2 conforming Care Record Summary that contains a section with a code value of *46239-0* (REASON FOR VISIT/CHIEF COMPLAINT) **SHALL NOT** contain sections with a code value of *29299-5* (REASON FOR VISIT) or *10154-3* (CHIEF COMPLAINT), and vice versa.

Figure 52 below shows a sample of a Reason for Visit/Chief Complaint section.

```
<component>
    <section>
        <code   code='46239-0' codeSystem='2.16.840.1.113883.6.1'
                displayName='REASON FOR VISIT/CHIEF COMPLAINT'/>
        <title>Reason for Visit/Chief Complaint</title>
        <text>Ankle Sprain</text>
    </section>
</component>
```

Figure 52 Reason for Visit/Chief Complaint Example

3.3.2 Reason for Referral 42349-1

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].

L2-12: The code for the section describing the Reason for Referral in a level 2 conforming Care Record Summary **SHALL** be *42349-1* (REASON FOR REFERRAL).

Figure 53 below shows a sample of a Reason for Referral section.

```
<component>
    <section>
        <code code='42349-1' codeSystem='2.16.840.1.113883.6.1'
            displayName='REASON FOR REFERRAL'/>
        <title>Reason for Referral</title>
        <text>Follow-up care for Ankle Sprain</text>
    </section>
</component>
```

Figure 53 Reason for Referral Example

3.3.3 Advance Directives 42348-3

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 an optional summary or description of its content.

L2-13: The code for the section describing the patient Advance Directives in a level 2 conforming Care Record Summary **SHALL** be *42348-3* (ADVANCE DIRECTIVES).

A sample representation is shown below in Figure 54. Advance Directives may also be recorded as free text or in lists.

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

Figure 54 Advance Directives Rendering

```
<component>
    <section>
        <code   code='42348-3' codeSystem='2.16.840.1.113883.6.1'
                displayName='ADVANCE DIRECTIVES'/>
        <title>Advance Directives</title>
        <text>
            <table border='1'>
                <thead>
                    <tr><th>Documentation</th><th>Contact</th>
                            <th>Effective Date</th><th>Comments</th>
                    </tr>
                </thead>
                <tbody>
                    <tr><td>Living Will</td><td>Obtain from her Husband</td>
                        <td>1994</td><td>Copy on file</td>
                    </tr>
                    <tr><td>Power of Attorney</td><td>Obtain from her Husband</td>
                        <td>1994</td><td></td>
                    </tr>
                    <tr><td>Healthcare Proxy</td><td>Obtain from her Husband</td>
                        <td>1994</td><td></td>
                    </tr>
                    <tr><td>Organ Donor</td>
                        <td>Massachusetts Registry of Motor Vehicles</td><td>1/27/2004</td>
                        <td>Registered Organ Donor</td>
                    </tr>
                </tbody>
            </table>
        </text>
    </section>
</component>
```

Figure 55 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.

L2-14: 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 56 below shows a sample of a History of Present Illness section.

```
<component>
    <section>
        <code   code='10164-2' codeSystem='2.16.840.1.113883.6.1'
                displayName='HISTORY OF PRESENT ILLNESS'/>
        <title>History of Present Illness</title>
        <text>Patient slipped and fell on ice, twisting her ankle as she fell.</text>
    </section>
</component>
```

Figure 56 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.

L2-15: 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 **MAY** indicate whether the condition was the cause of death.

L2-16: 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 shown in Figure 57 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. The section may also contain free text or lists to represent this information.

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

Figure 57 Family History Rendering

```
<component>
    <section>
        <code   code='10157-6' codeSystem='2.16.840.1.113883.6.1'
                displayName='HISTORY OF FAMILY MEMBER DISEASES' />
        <title>Family History</title>
        <text>
            <table border='1'>
                <thead>
                    <tr><th>Family Member</th><th>Problem</th><th>Cause of Death?</th></tr>
                </thead>
                <tbody>
                    <tr><td>Father</td><td>Alcoholism</td><td>No</td></tr>
                    <tr><td>Father</td><td>Liver Cancer</td><td>Yes</td></tr>
                </tbody>
            </table>
        </text>
    </section>
</component>
```

Figure 58 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 in Figure 59 is in a table with four 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 columns represent the effective date range for the risk factor. The section may also contain free text or lists to represent this information.

Social History	Comments	Start Date	End Date
Smoking	1/2 pack per day		1996
Alcohol Use	1-2 drinks per week		

Figure 59 Social History/Risk Factor Rendering

```
<component>
    <section>
        <code   code='29762-2' codeSystem='2.16.840.1.113883.6.1'
                displayName='SOCIAL HISTORY'/>
        <title>Social History</title>
        <text>
            <table border='1'>
                <thead>
                    <tr><th>Social History</th><th>Comments</th>
                        <th>Start Date</th><th>End Date</th></tr>
                </thead>
                <tbody>
                    <tr><td>Smoking</td><td>1/2 pack per day</td>
                        <td></td><td>1996</td></tr>
                    <tr><td>Alcohol Use</td><td>1-2 drinks per week</td>
                        <td></td><td></td><td></tr>
                </tbody>
            </table>
        </text>
    </section>
</component>
```

Figure 60 Social History Example

3.3.8 Immunizations 11369-6

This section lists immunizations and dates of administration.

L2-17: 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 representation in Figure 61 shows a list containing the Immunization and Date of Immunization. The section may also contain free text or tables to represent this information.

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

Figure 61 Immunization Rendering

```
    <component>
        <section>
            <code   code='11369-6' codeSystem='2.16.840.1.113883.6.1'
                    displayName='HISTORY OF IMMUNIZATION'/>
            <title>Immunizations</title>
            <text>
                <list>
                    <item>DTP - 1962</item>
                    <item>Polio Virus - 1961</item>
                    <item>MMR - 1961</item>
                </list>
            </text>
        </section>
    </component>
```

Figure 62 Immunizations Section Example

3.3.9 Past Surgical History 10167-5

This section **MAY** be present. It **SHOULD** contain relevant prior procedures, their dates and locations.

L2-18: 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 in Figure 63 is a table, with the name of the procedure in the first column, the date of the procedure in the second column, and the location in the final column. The section may contain free text or lists to represent this information.

Procedure	Date	Location
Laparoscopic Cholecystectomy	9/28/2002	City Hospital
Cesarean Section	3/22/2002	Community Hospital

Figure 63 Procedure Rendering

```
<component>
    <section>
        <code   code='10167-5' codeSystem='2.16.840.1.113883.6.1'
                displayName='PAST SURGICAL HISTORY'/>
        <title>Procedures</title>
        <text>
            <table border='1'>
                <thead>
                    <tr>
                        <th>Procedure</th><th>Date</th><th>Location</th>
                    </tr>
                </thead>
                <tbody>
                    <tr><td>Laparoscopic Cholecystectomy</td><td>9/28/2002</td>
                        <td>City Hospital</td>
                    </tr>
                    <tr><td>Cesarian Section</td><td>3/22/2002</td>
                        <td>Community Hospital</td>
                    </tr>
                </tbody>
            </table>
        </text>
    </section>
</component>
```

Figure 64 Past Surgical History Section Example

3.3.10 Prior Encounters 11346-4/11336-5/46240-4

These sections **MAY** be present. They **SHOULD** describe any relevant prior encounters. This information **SHOULD** include the date, location, provider and type of encounter.

L2-19: The LOINC section `code` used for the section describing only prior outpatient visits in a level 2 conforming Care Record Summary **SHALL** be *11346-4* (HISTORY OF OUTPATIENT VISITS).

L2-20: The LOINC section `code` used for the section describing only prior hospitalizations in a level 2 conforming Care Record Summary **SHALL** be *11336-5* (HISTORY OF HOSPITALIZATIONS).

L2-21: The LOINC section `code` used for the section describing both prior hospitalizations and prior outpatient visits in a level 2 conforming Care Record Summary **SHALL** be *46240-4* (HISTORY OF HOSPITALIZATIONS+HISTORY OF OUTPATIENT VISITS).

Use of the code `46240-4` for a section does not preclude use of the codes `11346-4` and `11336-5` in subsections.

The sample representation in Figure 65 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. The section may contain free text or lists to represent this information.

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 65 Encounters Rendering

```
<component>
    <section>
        <code   code='11336-5' codeSystem='2.16.840.1.113883.6.1'
                displayName='HISTORY OF HOSPITALIZATIONS'/>
        <title>Prior Encounters</title>
        <text>
            <table border='1'>
                <thead>
                    <tr><th>Date</th><th>Provider</th>
                        <th>Description</th>
                    </tr>
                </thead>
                <tbody>
                    <tr><td>3/28/2005</td><td>Community Hospital</td>
                        <td>ED Visit for Ankle Sprain</td>
                    </tr>
                    <tr><td>9/28/2002</td><td>City Hospital</td>
                        <td>Gall Bladder Surgery</td>
                    </tr>
                    <tr><td>3/21/2002</td><td>Community Hospital</td>
                        <td>Labor and Delivery</td>
                    </tr>
                    <tr><td>10/28/2001</td><td>Community Hospital</td>
                        <td>ED Visit for Acute Cholecystitis</td>
                    </tr>
                </tbody>
            </table>
        </text>
    </section>
</component>
```

Figure 66 Encounters Section Example

3.3.11 Review of Systems 10187-3

This section **MAY** be present. It **SHOULD** contain relevant information from a review of systems. Figure 67 below shows an example of a Review of Systems section.

L2-22: The LOINC section code used for the section describing the Review of Systems in a level 2 conforming Care Record Summary **SHALL** be *10187-3* (REVIEW OF SYSTEMS).

```
<component>
    <section>
        <code   code='10187-3' codeSystem='2.16.840.1.113883.6.1'
                displayName='REVIEW OF SYSTEMS'/>
        <title>Review of Systems</title>
        <text>Review of systems otherwise negative</text>
    </section>
</component>
```

Figure 67 Review of Systems Example

3.3.12 Physical Examination 22029-3/10184-0

These sections **MAY** be present. They **SHOULD** contain relevant information from a physical examination of the patient[12].

L2-23: The LOINC section code used for the section describing the Physical Examination given at Discharge from a hospital in a level 2 conforming Care Record Summary **SHALL** be *10184-0* (HOSPITAL DISCHARGE PHYSICAL).

L2-24: The LOINC section code used for the section describing the Physical Examination at times other than discharge from a hospital in a level 2 conforming Care Record Summary **SHALL** be *22029-3* (PHYSICAL EXAM.TOTAL).

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

[12] Like any other section, this section may contain subsections to record more detail. This might be necessary, for example, to record various physical findings in a Provider Unspecified History and Physical Note as defined by the HL7 Additional Information Specification 0004: Clinical Reports Attachment.

```
<component>
    <section>
        <code   code='22029-3' codeSystem='2.16.840.1.113883.6.1'
                displayName='PHYSICAL EXAM.TOTAL'/>
        <title>Physical Examination</title>
        <text>Left foot and ankle are swollen profusely.</text>
        <component>
            <section>
                <code   code='29274-8' codeSystem='2.16.840.1.113883.6.1'
                        displayName='VITAL SIGNS'/>
                <title>Vital Signs</title>
                <text>
                 <table border='1'>
                  <thead>
                    <tr><th>Date</th><th>Height</th><th>Weight</th><th>Temperature</th>
                        <th>BP</th><th>Pulse</th><th>Respiration</th><th>O2</th>
                    </tr>
                  </thead>
                  <tbody>
                    <tr><th>3/28/2005</th><th>5'9"</th><th>215 lbs.</th><th>98.7 &#xB0;F</th>
                        <th>120/80</th><th>68</th><th>16</th><th>99%</th>
                    </tr>
                  </tbody>
                 </table>
                </text>
            </section>
        </component>
    </section>
</component>
```

Figure 68 Physical Examination With Vital Signs Subsection Example

3.3.13 Vital Signs 8716-3

This section **MAY** be present. The patient's vital signs **SHALL** be listed in this section.

L2-25: 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 in Figure 69 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 example below.

This section may also use free text or lists to represent the content.

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

Figure 69 Vital Signs Representation

The second `component` shown in Figure 68 in the previous section is an example of this section.

3.3.14 Fetal Vital Signs 46242-4

*This section **MAY** be present. If present, it **SHOULD** contain Fetal Vital signs, such as those recommended by the ACOG Guidelines for Perinatal Care.*

L2-26: The LOINC section `code` used for the section describing the Fetal Vital Signs in a level 2 conforming Care Record Summary **SHALL** be *46242-4* (VITAL SIGN MEASUREMENTS, FETUS)

3.3.15 Studies and Reports 11493-4/30954-2

This section **MAY** be present. Results from, or references to, various studies **MAY** be listed this section.

L2-27: 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 *30954-2* (RELEVANT DIAGNOSTIC TESTS AND/OR LABORATORY DATA)

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

The sample representation in Figure 70 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. Free text or lists may also be used.

Study	Summary	Date of Study
46239-0Ray Study – Left Ankle	No Fracture	3/28/2005

Figure 70 Lab Results Rendering

```
<component>
    <section>
        <code   code='30954-2' codeSystem='2.16.840.1.113883.6.1'
                displayName='RELEVANT DIAGNOSTIC TESTS AND/OR LABORATORY DATA'/>
        <title>Related Reports</title>
        <text>
            <table border='1'>
                <thead>
                    <tr>
                        <th>Study</th>
                        <th>Summary</th>
                        <th>Date of Study</th>
                    </tr>
                </thead>
                <tbody>
                    <tr>
                        <td>46239-0Ray Study – Left Ankle</td>
                        <td>No Fracture</td>
                        <td>3/28/2005</td>
                    </tr>
                </tbody>
            </table>
        </text>
    </section>
</component>
```

Figure 71 Lab Result Example

3.3.16 Plan of Care 18776-5

This section **MAY** be present. It **SHOULD** describe the plan of care, including the patient disposition, and **MAY** provide a detailed list of planned activities, including transfers. This section **SHOULD** be present when known. Figure 72 below shows an example Plan of Care Section in paragraph form. Tables and lists may also be used.

L2-28: 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).

```
<component>
    <section>
        <code  code='18776-5' codeSystem='2.16.840.1.113883.6.1'
               displayName='TREATMENT PLAN'/>
        <title>Plan of Care</title>
        <text>
            <paragraph>Acetaminophen with coedine prn for pain.</paragraph>
            <paragraph>Stay off the foot.  Keep foot elevated, and use
                supplied air splint and crutches.</paragraph>
            <paragraph>Advise follow-up with orthopedist if not
                significantly better in 5 days.</paragraph>
        </text>
    </section>
</component>
```

Figure 72 Plan of Care

4 References

ACOG Guidelines for Perinatal Care — The American College of Obstetricians and Gynecologists.

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.

ISO-3166-1 — Codes for the representation of names of countries and their subdivisions -- Part 1: Country codes, 1997, International Organization for Standardization

ISO-639-1 — Codes for the representation of names of languages--Part 1: Alpha-2 code, 2002, International Organization for Standardization

LOINC® — Logical Observation Identifiers Names and Codes, Regenstrief Institute

Long Term Care 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 of 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[13] no longer conform to this guide.

The structure of this file is shown Figure 73. To extend the controlled vocabularies in voc.xml, simply add new entries to it.

```
<systems>
    <system codeSystemName='LOINC' root='2.16.840.1.113883.6.1'>
        <code value='34133-9' displayName='SUMMARIZATION OF EPISODE NOTE'/>
            :
            .
    </system>
        :
        .
</systems>
```

Figure 73 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.

[13] 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.

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 RoleCode vocabulary. The OID of this vocabulary domain is *2.16.840.1.113883.5.111*.

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
M	Male	Male
UN	Undifferentiated	The gender of a person could not be uniquely defined as male or female, such as hermaphrodite.

Table 5 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 6 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 7 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
T	Domestic partner	Person declares that a domestic partner relationship exists.
I	Interlocutory	Subject to an Interlocutory Decree.
L	Legally Separated	
M	Married	A current marriage contract is active
S	Never Married	No marriage contract has ever been entered
P	Polygamous	More than 1 current spouse
W	Widowed	The spouse has died

Table 8 Marital Status

Null Flavor

Null Flavors are used to indicate why a required data element does not contain any information.

Code	Display Name	Description
NI	NoInformation	No information whatsoever can be inferred from this exceptional value. This is the most general exceptional value. It is also the default exceptional value.
OTH	other	The actual value is not an element in the value domain of a variable. (e.g., concept not provided by required code system).
NINF	negative infinity	Negative infinity of numbers.
PINF	positive infinity	Positive infinity of numbers.
UNK	unknown	A proper value is applicable, but not known.
ASKU	asked but unknown	Information was sought but not found (e.g., patient was asked but didn't know)
NAV	temporarily unavailable	Information is not available at this time but it is expected that it will be available later.
NASK	not asked	This information has not been sought (e.g., patient was not asked)
TRC	trace	The content is greater than zero, but too small to be quantified.
MSK	masked	There is information on this item available but it has not been provided by the sender due to security, privacy or other reasons. There may be an alternate mechanism for gaining access to this information. Note: using this null flavor does provide information that may be a breach of confidentiality, even though no detail data is provided. Its primary purpose is for those circumstances where it is necessary to inform the receiver that the information does exist without providing any detail.
NA	not applicable	No proper value is applicable in this context (e.g., last menstrual period for a male).
NP	not present	Value is not present in a message. This is only defined in messages, never in application data! All values not present in the message must be replaced by the applicable default, or no-information (NI) as the default of all defaults.

Table 9 Null Flavor

Participation Function

Participating function codes used to describe the exact function of a healthcare providers **SHOULD** come from the HL7 ParticipatingFunction 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 10 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	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.

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

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.

Table 11 Personal Relationship Role Type

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

SNOMED Clinical Terms 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

```
<?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_LEVEL1-2REF_US_2006JUN</title>
    <ns prefix="cda" uri="urn:hl7-org:v3" />
    <ns prefix="crs" uri="urn:hl7-org:crs" />

    <phase id='errors'>
        <active pattern='ClinicalDocument'/>
        <active pattern='ClinicalDocument_General_Constraints'/>
        <active pattern='ClinicalDocument_typeId'/>
        <active pattern='ClinicalDocument_templateId'/>
        <active pattern='ClinicalDocument_id'/>
        <active pattern='ClinicalDocument_code'/>
        <active pattern='ClinicalDocument_setId'/>
        <active pattern='ClinicalDocument_copyTime'/>
        <active pattern='recordTarget'/>
        <active pattern='author'/>
        <active pattern='dataEnterer'/>
        <active pattern='informant'/>
        <active pattern='informant-2'/>
        <active pattern='informationRecipient'/>
        <active pattern='legalAuthenticator'/>
        <active pattern='authenticator'/>
        <active pattern='participant'/>
        <active pattern='ClinicalDocument_copyTime'/>
        <active pattern='documentationOf'/>
        <active pattern='componentOf'/>
        <active pattern='Body'/>
    </phase>
    <phase id='warning'>
        <active pattern='ClinicalDocument_General_Constraints_Warnings'/>
        <active pattern='recordTarget_warnings'/>
        <active pattern='informant_warnings'/>
        <active pattern='documentationOf_warnings'/>
        <active pattern='nonXMLBody_warnings'/>
    </phase>
    <phase id='manual'>
        <active pattern='Body_manual'/>
        <active pattern='ClinicalDocument_code_manual'/>
    </phase>

    <pattern id='ClinicalDocument' name='ClinicalDocument' see='&baseURI;#ClinicalDocument'>
        <p>This schema applies to CDA Release 2.0 documents.</p>
        <rule id='cda-root' context='/*'>
            <assert test='self::cda:ClinicalDocument'>
                Error: The root of a Care Record Summary must be a <emph>ClinicalDocument</emph> element from
                the <emph>urn:hl7-org-v3</emph> namespace.
            </assert>
        </rule>
    </pattern>

    <pattern id='ClinicalDocument_General_Constraints_Warnings'
         name='ClinicalDocument_General_Constraints_Warnings'
        see='&baseURI;#ClinicalDocument_General_Constraints'>
        <rule id='assigned-person-warnings'
            context='cda:guardian|cda:dataEnterer/cda:assignedEntity|cda:relatedEntity|cda:intendedRecipient|
            cda:relatedSubject|cda:participantRole'>
            <assert diagnostics="L1-3" test='cda:addr'>
                Warning: Missing addr element.
            </assert>
            <assert diagnostics="L1-3" test='cda:telecom'>
                Warning: Missing telecom element.
            </assert>
        </rule>
```

```
        <rule id='general-time-req-warnings'
            context='cda:authenticator/cda:time |
            cda:author/cda:time |
            cda:dataEnterer/cda:time |
            cda:legalAuthenticator/cda:time |
            cda:ClinicalDocument/cda:effectiveTime |
            cda:encompassingEncounter/cda:effectiveTime |
            cda:encompassingEncounter/cda:effectiveTime/cda:low |
            cda:encompassingEncounter/cda:effectiveTime/cda:center |
            cda:encompassingEncounter/cda:effectiveTime/cda:high'>
            <assert diagnostics='L1-5' test='not(@value) or string-length(@value) &gt; 18'>
                Warning: This should be precise to the second.
            </assert>
        </rule>
        <rule id='general-time-req-2-warnings'
            context='cda:patient/cda:birthTime |

            cda:ClinicalDocument/cda:participant/cda:time |
            cda:encompassingEncounter/cda:effectiveTime |
            cda:asOrganizationPartOf/cda:effectiveTime |
            cda:asMaintainedEntity/cda:effectiveTime |
            cda:relatedEntity/cda:effectiveTime |
            cda:serviceEvent/cda:effectiveTime |

            cda:ClinicalDocument/cda:participant/cda:time/cda:low |
            cda:encompassingEncounter/cda:effectiveTime/cda:low |
            cda:asOrganizationPartOf/cda:effectiveTime/cda:low |
            cda:asMaintainedEntity/cda:effectiveTime/cda:low |
            cda:relatedEntity/cda:effectiveTime/cda:low |
            cda:serviceEvent/cda:effectiveTime/cda:low |

            cda:ClinicalDocument/cda:participant/cda:time/cda:center |
            cda:encompassingEncounter/cda:effectiveTime/cda:center |
            cda:asOrganizationPartOf/cda:effectiveTime/cda:center |
            cda:asMaintainedEntity/cda:effectiveTime/cda:center |
            cda:relatedEntity/cda:effectiveTime/cda:center |
            cda:serviceEvent/cda:effectiveTime/cda:center |

            cda:ClinicalDocument/cda:participant/cda:time/cda:high |
            cda:encompassingEncounter/cda:effectiveTime/cda:high |
            cda:asOrganizationPartOf/cda:effectiveTime/cda:high |
            cda:asMaintainedEntity/cda:effectiveTime/cda:high |
            cda:relatedEntity/cda:effectiveTime/cda:high |
            cda:serviceEvent/cda:effectiveTime/cda:high

            '>
            <assert diagnostics='L1-7' test='not(@value) or string-length(@value) &gt; 7'>
                Warning: This should be precise to the day.
            </assert>
        </rule>
    </pattern>

    <pattern name='ClinicalDocument_General_Constraints'  id='ClinicalDocument_General_Constraints'
             see='&baseURI;#ClinicalDocument_General_Constraints'>
        <rule id='general-addr-null' context='cda:addr[@nullFlavor != ""]'>
            <assert id='null-or-no-content' test='normalize-space(.) = ""'>
                Error: When the <emph>addr</emph> element is null, it must not have content.
            </assert>
        </rule>
        <rule id='general-addr-not-null' context='cda:addr[@nullFlavor = ""]'>
            <assert id='empty-implies-null' test='string-length(normalize-space(.)) &gt; 0'>
                Error: When the <emph>addr</emph> element is empty, it must have a value for
                <emph>nullFlavor</emph>.
            </assert>
        </rule>
        <rule id='general-person'
            context='cda:patient|cda:guardianPerson|cda:assignedPerson|cda:maintainingPerson|
            cda:relatedPerson|cda:intendedRecipient/cda:informationRecipient|cda:associatedPerson|
            cda:relatedSubject/cda:subject'>
            <assert diagnostics="L1-1" test='cda:name'/>
        </rule>
```

```
        <rule id='assigned-person'
            context='cda:patientRole|cda:assignedAuthor|cda:assignedEntity|cda:associatedEntity'>
            <assert diagnostics="L1-2" test='cda:addr or ../self::cda:dataEnterer'>
                Error: Missing addr element.
            </assert>
            <assert diagnostics="L1-2" test='cda:telecom or ../self::cda:dataEnterer'>
                Error: Missing telecom element.
            </assert>
        </rule>
        <rule id='general-org'
            context='cda:guardianOrganization|cda:providerOrganization|cda:wholeOrganization|
            cda:representedOrganization|cda:recievedOrganization|cda:scopingOrganization|
            cda:serviceProviderOrganization'>
            <assert diagnostics='L1-4' test='cda:name'>
                Error: Missing name element.
            </assert>
            <assert diagnostics='L1-4' test='cda:addr'>
                Error: Missing addr element.
            </assert>
            <assert diagnostics='L1-4' test='cda:telecom'>
                Error: Missing telecom element.
            </assert>
        </rule>
        <rule id='general-time-req'
            context='cda:authenticator/cda:time |
            cda:author/cda:time |
            cda:dataEnterer/cda:time |
            cda:legalAuthenticator/cda:time |
            cda:ClinicalDocument/cda:effectiveTime |
            cda:encompassingEncounter/cda:effectiveTime |
            cda:encompassingEncounter/cda:effectiveTime/cda:low |
            cda:encompassingEncounter/cda:effectiveTime/cda:center |
            cda:encompassingEncounter/cda:effectiveTime/cda:high'>
            <assert diagnostics='L1-5' test='not(@value) or string-length(@value) &gt; 7'>
                Error: This must be precise to the day.
            </assert>
            <assert diagnostics='L1-5'
                test='not(@value) or
                (not(contains(translate(@value,"+-","ZZ"),"Z")) and string-length(@value) &gt; 7) or
                string-length(substring-before(translate(@value,"+-","ZZ"),"Z")) &gt; 7'
                >
                Error: If precision is to less than the hour, no time zone shall be present.
            </assert>
            <assert diagnostics='L1-5'
                test='contains(translate(@value,"+-","ZZ"),"Z") or string-length(@value) &lt; 9'/>
        </rule>
        <rule id='general-time-effectiveTime-IVL_TS' context='cda:encompassingEncounter | cda:serviceEvent'>
            <assert diagnostics='L1-7'
                test='count(cda:effectiveTime/@value |
                cda:effectiveTime/cda:low/@value |
                cda:effectiveTime/cda:high/@value |
                cda:effectiveTime/cda:center/@value) &gt; 0'
                >
                Error: An effectiveTime value must be present.
            </assert>
        </rule>
```

```
        <rule id='general-time-req-2'
            context='cda:patient/cda:birthTime |

            cda:ClinicalDocument/cda:participant/cda:time |
            cda:encompassingEncounter/cda:effectiveTime |
            cda:asOrganizationPartOf/cda:effectiveTime |
            cda:asMaintainedEntity/cda:effectiveTime |
            cda:relatedEntity/cda:effectiveTime |
            cda:serviceEvent/cda:effectiveTime |

            cda:ClinicalDocument/cda:participant/cda:time/cda:low |
            cda:encompassingEncounter/cda:effectiveTime/cda:low |
            cda:asOrganizationPartOf/cda:effectiveTime/cda:low |
            cda:asMaintainedEntity/cda:effectiveTime/cda:low |
            cda:relatedEntity/cda:effectiveTime/cda:low |
            cda:serviceEvent/cda:effectiveTime/cda:low |

            cda:ClinicalDocument/cda:participant/cda:time/cda:center |
            cda:encompassingEncounter/cda:effectiveTime/cda:center |
            cda:asOrganizationPartOf/cda:effectiveTime/cda:center |
            cda:asMaintainedEntity/cda:effectiveTime/cda:center |
            cda:relatedEntity/cda:effectiveTime/cda:center |
            cda:serviceEvent/cda:effectiveTime/cda:center |

            cda:ClinicalDocument/cda:participant/cda:time/cda:high |
            cda:encompassingEncounter/cda:effectiveTime/cda:high |
            cda:asOrganizationPartOf/cda:effectiveTime/cda:high |
            cda:asMaintainedEntity/cda:effectiveTime/cda:high |
            cda:relatedEntity/cda:effectiveTime/cda:high |
            cda:serviceEvent/cda:effectiveTime/cda:high'
            >
            <assert diagnostics='L1-7' test='not(@value) or string-length(@value) &gt; 4'>
                Error: This must be precise to the year.
            </assert>
            <assert diagnostics='L1-7'
                test='not(@value) or contains(translate(@value,"+-","ZZ"),"Z") or string-length(@value) &lt; 9'>
                Error: If precision is to less than the hour, no time zone shall be present.
            </assert>
            <assert diagnostics='L1-7' test='not(@value) or string-length(@value) &gt; 7'>
                Warning: This should be precise to the day.
            </assert>
        </rule>
    </pattern>

    <pattern id='Telephone_Numbers' 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='L1-8'
                test='not(substring(@value,1,4) = "tel:") or
                string-length(
                concat(translate(substring(@value,5,1),"+0123456789()-.",""),
                translate(substring(@value,6),"0123456789()-.","") )
                ) = 0'/>
            <assert id='telcom-has-digit' diagnostics='L1-9'
                test='not(substring(@value,1,4) = "tel:") or
                string-length(
                concat(
                translate(substring(@value,5,1),"+()-.",""),
                translate(substring(@value,6),"()-.","")
                ) ) &gt; 0' />
        </rule>
    </pattern>

    <pattern id='ClinicalDocument_typeId' name='ClinicalDocument_typeId' see='&baseURI;#ClinicalDocument_typeId'>
        <rule id='cda-typeid' context="/cda:ClinicalDocument/cda:typeId">
            <assert id='typeId-extension' diagnostics='L1-10' test='@extension = "POCD_HD000040"'/>
        </rule>
    </pattern>
    <pattern id='ClinicalDocument_templateId' name='ClinicalDocument_templateId'
see='&baseURI;#ClinicalDocument_templateId'>
        <rule id='cda-templateid' context="/cda:ClinicalDocument">
            <assert id='templateId-extension' diagnostics='L1-11'
                test='cda:templateId[@extension = "IMPL_CDAR2_LEVEL1" and @root="2.16.840.1.113883.10"]'/>
        </rule>
    </pattern>
```

```
    <pattern id='ClinicalDocument_id' name='ClinicalDocument_id' see='&baseURI;#ClinicalDocument_id'>
        <rule id='cda-id-uuid' context="/cda:ClinicalDocument/cda:id[contains(@root, '-')]">
            <assert diagnostics='L1-12 L1-13' test="string-length(@root) = 37" >
                A properly formatted UUID has only 37 characters.
            </assert>
            <assert diagnostics='L1-12 L1-13'
                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='L1-12 L1-13'
                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='L1-12 L1-13'
                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='L1-12 L1-13'
                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='L1-12 L1-13'
                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='L1-12 L1-13' test="substring(@root, 9, 1) = '-'">
                A hyphen should separate the first four data bytes from the remainder of the UUID.
            </assert>
            <assert diagnostics='L1-12 L1-13' test="substring(@root, 14, 1) = '-'">
                A hyphen should separate the fifth and sixth data byte from the remainder of the UUID.
            </assert>
            <assert diagnostics='L1-12 L1-13' test="substring(@root, 19, 1) = '-'">
                A hyphen should separate the seventh and eighth data byte from the remainder of the UUID.
            </assert>
            <assert diagnostics='L1-12 L1-13' 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='L1-14'>
                Characters that are not in the set 0-9 or . are not present in a valid OID.
            </assert>
            <assert diagnostics='L1-12 L1-14'
                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='L1-12 L1-14' test="not(contains(@root,'..'))">
                A properly formatted OID should not contain two . characters without any
                intervening digits
            </assert>
            <assert diagnostics='L1-15' test="string-length(@root) &lt; 65"/>
        </rule>

        <rule id='cda-id' context='/cda:ClinicalDocument/cda:id[not(contains(@root,".") or contains(@root,"-"))]'>
            <assert diagnostics='L1-12' test='false()'/>
        </rule>
    </pattern>

    <pattern id='ClinicalDocument_code' name='ClinicalDocument_code' see='&baseURI;#ClinicalDocument_code'>
        <rule id='clinical-document-code' context='/cda:ClinicalDocument/cda:code'>
            <assert diagnostics='L1-16'
                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>
            <assert test='@codeSystem = "2.16.840.1.113883.6.1"' diagnostics='L1-16'>
                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='L1-16'>
                The value of <emph>/ClinicalDocument/code/@codeSystemName</emph> must be
                <emph>LOINC</emph>.
            </assert>
        </rule>
    </pattern>
```

```
    <pattern id='ClinicalDocument_code_manual' name='ClinicalDocument_code_manual'
see='&baseURI;#ClinicalDocument_code'>
        <rule id='clinical-document-code-role' context='//cda:author/cda:assignedAuthor/cda:code'>
            <assert diagnostics="L1-17"
                test='/cda:ClinicalDocument/cda:code[@code = "34133-9" or @code = "18842-5" or @code = "18761-7"]' >
                Manual: Verify that the the role code for the author does not conflict with the document type code.
            </assert>
        </rule>
        <rule id='clinical-document-code-function' context='//cda:author/cda:functionCode'>
            <assert diagnostics="L1-18"
                test='/cda:ClinicalDocument/cda:code[@code = "34133-9" or @code = "18842-5" or @code = "18761-7"]' >
                Manual: Verify that the the function code for author does not conflict with the document type code.
            </assert>
        </rule>
        <rule id='clinical-document-code-service-event' context='//cda:serviceEvent/cda:code'>
            <assert diagnostics="L1-52"
                test='/cda:ClinicalDocument/cda:code[@code = "34133-9" or @code = "18842-5" or @code = "18761-7"]' >
                Manual: Verify that the code for the serviceEventdoes not conflict with the document type code.
            </assert>
        </rule>
    </pattern>

    <pattern id='ClinicalDocument_languageCode' name='ClinicalDocument_languageCode'
see='&baseURI;#ClinicalDocument_languageCode'>
        <rule id='cda-languageCode' context='/cda:ClinicalDocument'>
            <assert diagnostics='L1-19' test='cda:languageCode'>
                The <emph>languageCode</emph> element must be present.
            </assert>
        </rule>
        <rule id='cda-languageCode-format' context='/cda:ClinicalDocument/cda:languageCode'>
            <assert diagnostics='L1-20'
                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>
            <assert diagnostics='L1-21'
                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='L1-22'
                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 id='ClinicalDocument_setId' name='ClinicalDocument_setId' see='&baseURI;#ClinicalDocument_setId'>
        <rule context='/cda:ClinicalDocument'>
            <assert diagnostics="L1-23" test='count(cda:versionNumber) = count(cda:setId)'/>
            <assert diagnostics="L1-24"
                test='cda:setId/@root != cda:id/@root or cda:setId/@extension != cda:id/@extension'/>
        </rule>
    </pattern>

    <pattern id='ClinicalDocument_copyTime' name='ClinicalDocument_copyTime' see='&baseURI;#ClinicalDocument_copyTime'>
        <rule id='cda-copyTime' context='/cda:ClinicalDocument/cda:copyTime'>
            <assert test='false()' diagnostics='L1-25'/>
        </rule>
    </pattern>

    <pattern id='recordTarget' name='recordTarget' see='&baseURI;#recordTarget'>
        <rule id='cda-recordTarget' context='cda:recordTarget'>
            <assert diagnostics="L1-26" test='count(cda:patientRole) &gt; 0'/>
        </rule>
        <rule id='cda-patient' context='cda:recordTarget/cda:patientRole/cda:patient'>
            <assert diagnostics="L1-27" test='cda:birthTime'/>
            <assert diagnostics="L1-28" test='cda:administrativeGenderCode'/>
        </rule>
    </pattern>

    <pattern id='recordTarget_warnings' name='recordTarget_warnings' see='&baseURI;#recordTarget'>
        <rule id='cda-recordTarget-warnings' context='cda:recordTarget/cda:patientRole/cda:patient'>
            <assert diagnostics="L1-29"
                test='not(cda:maritalStatusCode) or cda:maritalStatusCode/@codeSystem = ""'/>
            <assert diagnostics="L1-29"
                test='not(cda:religiousAffiliationCode) or cda:religiousAffiliationCode/@codeSystem = ""'/>
            <assert diagnostics="L1-29" test='not(cda:raceCode) or cda:raceCode/@codeSystem = ""'/>
            <assert diagnostics="L1-29" test='not(cda:ethnicGroupCode) or cda:ethnicGroupCode/@codeSystem = ""'/>
```

```
            <!-- Take the effectiveTime of the document, and subtract 18 years.  If the birthTime of the
            patient (padded to 8 digits of precision) is greater than the effective time of the document
            (which must be to the day), then the guardian element must be present.
            -->
            <assert diagnostics="L1-30"
                test='concat(number(substring(/cda:ClinicalDocument/cda:effectiveTime/@value,1,4)) - 18,
                substring(/cda:ClinicalDocument/cda:effectiveTime/@value, 5, 4)) &gt;
                substring(concat(substring(cda:birthTime/@value, 1, 8),"00000000"), 1, 8) or
                count(cda:guardian) &gt; 1'/>
        </rule>
    </pattern>

    <pattern id='author' name='author' see='&baseURI;#author'>
        <rule id='cda-author' context='cda:author'>
            <assert diagnostics="L1-31" test='cda:time'/>
        </rule>
        <rule id='cda-assignedAuthor' context='cda:assignedAuthor'>
            <assert diagnostics="L1-32" test='cda:id'/>
            <assert diagnostics="L1-33" test='cda:assignedPerson | cda:assignedAuthoringDevice'/>
        </rule>
        <rule id='cda-assignedAuthoringDevice' context='cda:assignedAuthoringDevice'>
            <assert diagnostics="L1-34" test='cda:softwareName'>
                When <emph>assignedAuthoringDevice</emph> is present, the <emph>softwareName</emph>
                element must be present.
            </assert>
            <assert diagnostics="L1-34" test='string-length(normalize-space(cda:softwareName)) &gt; 0'>
                When <emph>assignedAuthoringDevice/softwareName</emph> must have a value.
            </assert>
        </rule>
    </pattern>

    <pattern id='dataEnterer' name='dataEnterer' see='&baseURI;#dataEnterer'>
        <rule id='cda-dataEnterer' context='cda:dataEnterer'>
            <assert diagnostics="L1-35" test='cda:assignedEntity/cda:assignedPerson'/>
        </rule>
    </pattern>

    <pattern id='informant' name='informant' see='&baseURI;#informant'>
        <rule id='cda-informant' context='cda:informant/cda:relatedEntity'>
            <assert diagnostics='L1-36' test='@classCode = "CON" or @classCode = "PRS" or @classCode = "PROV"' />
        </rule>
        <rule id='cda-informant-person' context='cda:informant'>
            <assert diagnostics='L1-37'
                test='cda:relatedEntity/cda:relatedPerson | cda:assignedEntity/cda:assignedPerson' />
            <assert test='not(descendant::crs:asPatientRelationship)' diagnostics='L1-69'/>
        </rule>
    </pattern>
    <pattern id='informant-2' name='informant-2' see='&baseURI;#informant'>
        <rule id='cda-relatedEntity-PRS' context='cda:informant/cda:relatedEntity[@classCode = "PRS"]'>
            <assert diagnostics="L1-38"
                test='cda:code/@codeSystem = "2.16.840.1.113883.5.111" and cda:code/@code =
document("voc.xml")/systems/system[@codeSystemName="PersonalRelationshipRoleType"]/code/@value'/>
        </rule>
        <rule id='cda-relatedEntity-PROV' context='cda:informant/cda:relatedEntity[@classCode = "PROV"]/cda:code'>
            <assert diagnostics="L1-40"
                test='@codeSystem = "2.16.840.1.113883.6.96" and @code =
document("voc.xml")/systems/system[@codeSystemName="HealthcareProfessionals"]/code/@value'/>
        </rule>
    </pattern>
    <pattern id='informant_warnings' name='informant_warnings' see='&baseURI;#informant'>
        <rule id='cda-relatedEntity-CON-warnings' context='cda:informant/cda:relatedEntity[@classCode = "CON"]'>
            <assert diagnostics="L1-39" test='not(cda:code)'/>
        </rule>
    </pattern>

    <pattern id='informationRecipient' name='informationRecipient' see='&baseURI;#informationRecipient'>
        <rule id='cda-informationRecipient' context='cda:ClinicalDocument/cda:informationRecipient'>
            <assert diagnostics="L1-41"
                test='cda:intendedRecipient/cda:informationRecipient|cda:intendedRecipient/cda:receivedOrganization'/>
        </rule>
    </pattern>

    <pattern id='legalAuthenticator' name='legalAuthenticator' see='&baseURI;#legalAuthenticator'>
        <rule id='cda-legalAuthenticator' context='cda:legalAuthenticator'>
            <assert diagnostics='L1-42' test='cda:assignedEntity/cda:assignedPerson'/>
        </rule>
    </pattern>
```

```
    <pattern id='authenticator' name='authenticator' see='&baseURI;#authenticator'>
        <rule id='cda-authenticator' context='cda:authenticator'>
            <assert diagnostics='L1-43' test='cda:assignedEntity/cda:assignedPerson'/>
        </rule>
    </pattern>

    <pattern id='participant' name='participant' see='&baseURI;#participant'>
        <rule id='cda-associatedEntity' context='cda:participant/cda:associatedEntity'>
            <assert diagnostics="L1-44" test='cda:associatedPerson | cda:scopingOrganization'/>
            <assert diagnostics="L1-45"
                test='not(../@typeCode = "IND") or
                @classCode = "PRS" or @classCode = "NOK" or @classCode = "ECON" or @classCode = "GUAR"'
                />
            <assert diagnostics="L1-46"
                test='not(../@typeCode = "IND") or
                @classCode = "GUAR" or
                count(cda:code/@code[.=document("voc.xml")/systems/system
                [@codeSystemName="PersonalRelationshipRoleType"]/code/@value]) = 1'
                />
            <assert diagnostics="L1-47" test='not(../@typeCode="HLD") or @classCode = "POLHOLD"'/>
            <assert diagnostics="L1-48" test='not(../@typeCode="HLD") or cda:scopingOrganization'/>
        </rule>
    </pattern>

    <pattern id='documentationOf' name='documentationOf' see='&baseURI;#documentationOf'>
        <rule id='cda-serviceEvent' context='cda:serviceEvent'>
            <assert diagnostics="L1-50" test='@classCode = "PCPR"'/>
            <assert diagnostics="L1-53" test='cda:effectiveTime'/>
        </rule>
        <rule id='cda-documentationOf' context='cda:ClinicalDocument'>
            <assert diagnostics="L1-51" test='count(cda:documentationOf) = 1'>
                Only one <emph>ClinicalDocument/documentationOf</emph> element must be present.
            </assert>
        </rule>
        <rule id='cda-effectiveTime' context='cda:serviceEvent/cda:effectiveTime'>
            <assert diagnostics="L1-54" test='count(cda:low) = 1'/>
            <assert diagnostics="L1-54" test='count(cda:high) = 1'/>
        </rule>
        <rule id='cda-performer' context='cda:performer/cda:assignedEntity'>
            <assert diagnostics="L1-59"
                test='count(cda:code) = 0 or cda:code/@codeSystem="2.16.840.1.113883.6.96"'/>
            <assert diagnostics="L1-60" test='cda:assignedPerson | cda:representedOrganization'/>
        </rule>
    </pattern>
    <pattern id='documentationOf_warnings' name='documentationOf_warnings' see='&baseURI;#documentationOf'>
        <rule id='cda-serviceEvent-warnings' context='cda:serviceEvent'>
            <assert diagnostics="L1-55" test='cda:performer'/>
        </rule>
    </pattern>

    <pattern id='componentOf' name='componentOf' see='&baseURI;componentOf'>
        <rule id='cda-componentOf' context='/cda:ClinicalDocument/cda:code'>
            <assert diagnostics='L1-61'
                test='/cda:ClinicalDocument/cda:componentOf or
                not(document("voc.xml")/systems/system
                [@codeSystemName="LOINC"]/code[@value = current()]/@displayName = "DISCHARGE SUMMARIZATION NOTE")'/>
        </rule>
        <rule id='cda-encompassingEncounter' context='cda:encompassingEncounter'>
            <assert diagnostics="L1-62" test='cda:id'/>
            <assert diagnostics="L1-63" test='cda:effectiveTime'/>
            <assert diagnostics="L1-64"
                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")'/>
        </rule>
        <rule id='cda-encounterParticipant' context='cda:encounterParticipant/cda:assignedEntity'>
            <assert diagnostics="L1-65" test='cda:assignedPerson | cda:representedOrganization'/>
        </rule>
        <rule id='cda-responsibleParty' context='cda:responsibleParty/cda:assignedEntity'>
            <assert diagnostics="L1-66" test='cda:assignedPerson | cda:representedOrganization'/>
        </rule>
    </pattern>

    <pattern id='nonXMLBody_warnings' name='nonXMLBody_warnings' see='&baseURI;nonXMLBody'>
        <rule id='nonXMLBody-warnings' context='cda:nonXMLBody'>
            <assert diagnostics='L1-67' test='(cda:text = "" and cda:reference) or not(cda:reference)'/>
        </rule>
    </pattern>
```

```
    <pattern id='Body' name='Body' see='&baseURI;Body'>
        <rule id='sectionRequirements' context='cda:section'>
            <assert diagnostics='L2-1' test='cda:code'/>
            <assert diagnostics="L2-2" test='cda:text | cda:component'/>
            <assert diagnostics="L2-3"
                test='string-length(string(cda:text)) &gt; 0 or count(cda:component) &gt; 0'/>
        </rule>

        <rule id='Level2AndRequiredSections' context='/cda:ClinicalDocument/cda:component/cda:structuredBody'>
            <assert test='/cda:ClinicalDocument/cda:templateId[@extension = "IMPL_CDAR2_LEVEL2" and
            @root="2.16.840.1.113883.10"]'>
                This document contains a structured body.  It should also conform to Level 2 requirements.
            </assert>
            <assert diagnostics="L2-4"
                test='descendant-or-self::cda:section/cda:code/@code="11535-2" or
                descendant-or-self::cda:section/cda:code/@code="11450-4"'/>
            <assert diagnostics="L2-5"
                test='descendant-or-self::cda:section/cda:code/@code="10155-0" or
                descendant-or-self::cda:section/cda:code/@code="8658-7"'/>
        </rule>
        <rule id='DischargeSections'
context='/cda:ClinicalDocument[document("voc.xml")/systems/system[@codeSystemName="LOINC"]/code[
            @displayName = "DISCHARGE SUMMARIZATION NOTE"]/@value = cda:code/@code]/cda:component'>
            <!-- rules applicable to discharge summary
               Either it's not a discharge summary, or it has the required section.
            -->
            <assert diagnostics="L2-6" test='descendant-or-self::cda:section/cda:code/@code="10183-2"'/>
            <assert diagnostics="L2-7" test='descendant-or-self::cda:section/cda:code/@code="10160-0"'/>
            <assert diagnostics="L2-8" test='descendant-or-self::cda:section/cda:code/@code="8648-8"'/>
        </rule>
        <rule id='ConflictingSections' context='cda:section/cda:code[@code="46239-0"]'>
            <assert diagnostics="L2-11"
                test='count(//cda:section/cda:code[@code="29299-5" or @code="10154-3"])=0'/>
        </rule>
    </pattern>

    <pattern id='Body_manual' name='Body_manual' see='&baseURI;Body'>
        <rule context='cda:section/cda:code[@code="29299-5"]'>
            <assert diagnostics='L2-9' test='false()'>
                Manually verify that this section contains a chief complaint.
            </assert>
        </rule>
        <rule context='cda:section/cda:code[@code="46239-0"]'>
            <assert diagnostics='L2-9 L2-10' test='false()'>
                Manually verify that this section contains both a chief complaint and the reason for visit.
            </assert>
        </rule>
        <rule context='cda:section/cda:code[@code="10154-3"]'>
            <assert diagnostics='L2-10' test='false()'>
                Manually verify that this section contains both a chief complaint and the reason for visit.
            </assert>
        </rule>
        <rule context='cda:section/cda:code[@code="10154-3"]'>
            <assert diagnostics='L2-10' test='false()'>
                Manually verify that this section contains both a chief complaint and the reason for visit.
            </assert>
        </rule>
        <rule context='cda:section/cda:code[@code="42349-1"]'>
            <assert diagnostics='L2-12' test='false()'>
                Manually verify that this section contains the reason for referral.
            </assert>
        </rule>
        <rule context='cda:section/cda:code[@code="42348-3"]'>
            <assert diagnostics='L2-13' test='false()'>
                Manually verify that this section contains the patient's Advance Directives.
            </assert>
        </rule>
        <rule context='cda:section/cda:code[@code="10164-2"]'>
            <assert diagnostics='L2-14' test='false()'>
                Manually verify that this section contains the History of Present Illness.
            </assert>
        </rule>
        <rule context='cda:section/cda:code[@code = "10158-4"]'>
            <assert diagnostics="L2-15" test="false()">
                Manually verify that this section contains the patient's functional status
            </assert>
        </rule>
        <rule context='cda:section/cda:code[@code = "10157-6"]'>
```

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            <assert diagnostics="L2-16" test="false()">
                Manually verify that this section contains family history of the patient
            </assert>
        </rule>
        <rule context='cda:section/cda:code[@code = "11369-6"]'>
            <assert diagnostics="L2-17" test="false()">
                Manually verify that this section contains immunization history
            </assert>
        </rule>
        <rule context='cda:section/cda:code[@code = "10167-5"]'>
            <assert diagnostics="L2-18" test="false()">
                Manually verify that this section contains the patient's past surgical history
            </assert>
        </rule>
        <rule context='cda:section/cda:code[@code = "11346-4"]'>
            <assert diagnostics="L2-19" test="false()">
                Manually verify that this section contains only prior outpatient visits
            </assert>
        </rule>
        <rule context='cda:section/cda:code[@code = "11336-5"]'>
            <assert diagnostics="L2-20" test="false()">
                Manually verify that this section contains only prior hospitalizations
            </assert>
        </rule>
        <rule context='cda:section/cda:code[@code = "46240-8"]'>
            <assert diagnostics="L2-21" test="false()">
                Manually verify that this section contains both prior hospitalizations and prior outpatient visits
            </assert>
        </rule>
        <rule context='cda:section/cda:code[@code = "10187-3"]'>
            <assert diagnostics="L2-22" test="false()">
                Manually verify that this section contains the Review of Systems
            </assert>
        </rule>
        <rule context='cda:section/cda:code[@code = "10184-0"]'>
            <assert diagnostics="L2-23" test="false()">
                Manually verify that this section contains the Physical Examination given at Discharge from a hospital
            </assert>
        </rule>
        <rule context='cda:section/cda:code[@code = "22029-3"]'>
            <assert diagnostics="L2-24" test="false()">
                Manually verify that this section contains the Physical Examination at times other than discharge
                from a hospital
            </assert>
        </rule>
        <rule context='cda:section/cda:code[@code = "8716-3"]'>
            <assert diagnostics="L2-25" test="false()">
                Manually verify that this section contains the patient vital signs
            </assert>
        </rule>
        <rule context='cda:section/cda:code[@code = "46242-4"]'>
            <assert diagnostics="L2-26" test="false()">
                Manually verify that this section contains the Fetal Vital Signs
            </assert>
        </rule>
        <rule context='cda:section/cda:code[@code = "11493-4"]'>
            <assert diagnostics="L2-27" test="false()">
                Manually verify that this section contains results or referring to other reports </assert>
        </rule>
        <rule context='cda:section/cda:code[@code = "30954-2"]'>
            <assert diagnostics="L2-27" test="false()">
                Manually verify that this section contains results or referring to other reports </assert>
        </rule>
        <rule context='cda:section/cda:code[@code = "18775-6"]'>
            <assert diagnostics="L2-28" test="false()">
                Manually verify that this section contains the plan of care for the patient
            </assert>
        </rule>
    </pattern>

    <diagnostics>
        <diagnostic id="L1-1">
            Error: All <emph>patient</emph>, <emph>guardianPerson</emph>, <emph>assignedPerson</emph>,
            <emph>maintainingPerson</emph>, <emph>relatedPerson</emph>,
            <emph>intendedRecipient/informationRecipient</emph>, <emph>associatedPerson</emph>, and
            <emph>relatedSubject/subject</emph> elements shall have a <emph>name</emph>.
        </diagnostic>
```

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        <diagnostic id="L1-2">
            Error: All <emph>patientRole</emph>, <emph>assignedAuthor</emph>,
            <emph>assignedEntity[not(parent::dataEnterer)]</emph> and <emph>associatedEntity</emph> elements shall
            have an <emph>addr</emph> and <emph>telecom</emph> element<emph>.</emph>
        </diagnostic>
        <diagnostic id="L1-3">
            Warning: All <emph>guardian</emph>, <emph>dataEnterer/assignedEntity</emph>, <emph>relatedEntity</emph>,
            <emph>intendedRecipient</emph>, <emph>relatedSubject</emph> and <emph>participantRole </emph>elements
            should have an <emph>addr</emph> and <emph>telecom</emph> element<emph>.</emph>
        </diagnostic>
        <diagnostic id="L1-4">
            Error: All <emph>guardianOrganization</emph>, <emph>providerOrganization</emph>,
            <emph>wholeOrganization</emph>, <emph>representedOrganization</emph>,
            <emph>representedCustodianOrganization</emph>, <emph>recievedOrganization</emph>,
<emph>scopingOrganization</emph> and <emph>serviceProviderOrganization</emph> elements shall have <emph>name</emph>,
<emph>addr</emph> and <emph>telecom</emph> elements<emph>.</emph>
        </diagnostic>
        <diagnostic id="L1-5">
            Times or time intervals found in the <emph>ClinicalDocument/effectiveTime</emph>,
            <emph>author/time</emph>, <emph>dataEnterer/time</emph>, <emph>legalAuthenticator/time</emph>,
            <emph>authenticator/time </emph>and <emph>encompassingEncounter/effectiveTime</emph> elements shall be
            precise to the day, shall include a time zone if more precise than to the day, and should be precise to
            the second.
        </diagnostic>
        <diagnostic id="L1-6">
            The <emph>patient/birthTime</emph> element shall be precise at least to the year, and should be precise
            at least to the day, and may omit time zone.
        </diagnostic>
        <diagnostic id="L1-7">
            Times or time intervals found in the <emph>patient/birthTime</emph>,
            <emph>asOrganizationPartOf/effectiveTime</emph>, <emph>asMaintainedEntity/effectiveTime</emph>,
            <emph>relatedEntity</emph>/<emph>effectiveTime</emph>,
            <emph>serviceEvent</emph>/<emph>effectiveTime</emph>, <emph>ClinicalDocument/participant/time</emph>,
            <emph>serviceEvent/performer/time</emph> and <emph>encounterParticipant/time</emph> shall be precise at
            least to the year, should be precise to the day, and may omit time zone.
        </diagnostic>
        <diagnostic id="L1-8">
            Error: Telephone numbers shall match the regular expression pattern<emph>tel:\+?[-0-9().]+</emph>
        </diagnostic>
        <diagnostic id="L1-9">
            Error: At least one dialing digit shall be present in the phone number after visual separators are
            removed.
        </diagnostic>
        <diagnostic id="L1-10">
            Error: The <emph>extension</emph> attribute of the <emph>typeId</emph> element shall be
            <emph>POCD_HD000040</emph>.
        </diagnostic>
        <diagnostic id="L1-11">
            Error: A <emph>ClinicalDocument/templateId</emph> element shall be present where the value of
            <emph>@extension</emph> is <emph>IMPL_CDAR2_LEVEL1</emph> and the value of <emph>@root</emph> is
            <emph>2.16.840.1.113883.10</emph>.
        </diagnostic>
        <diagnostic id="L1-12">
            Error: The <emph>ClinicalDocument/id/@root</emph> attribute shall be a syntactically correct UUID
            or OID.
        </diagnostic>
        <diagnostic id="L1-13">
            Error: UUIDs shall be represented in the form <emph>XXXXXXXX-XXXX-XXXX-XXXX-XXXXXXXXXXXX</emph>,
            where each X is a character from the set [A-Fa-f0-9].
        </diagnostic>
        <diagnostic id="L1-14">
            Error: OIDs shall be represented in dotted decimal notation, where each decimal number is either 0,
            or starts with a non-zero digit.  More formally, an OID shall be in the form ([0-2])(.([1-9][0-9]*|0))+.
        </diagnostic>
        <diagnostic id="L1-15">
            Error: OIDs shall be no more than 64 characters in length.
        </diagnostic>
        <diagnostic id="L1-16">
            Error: For <emph>/ClinicalDocument/code, @code</emph> shall come from the appropriate LOINC code subset
            listed in Table 2, <emph>@codeSysem</emph> shall be the OID for LOINC, and <emph>@codeSystemName</emph>,
            if present is LOINC.
        </diagnostic>
        <diagnostic id="L1-17">
            Manual: If pre-coordinated document type codes are used, values used in the
            <emph>assignedAuthor/code</emph> and <emph>assignedAuthor/author/functionCode</emph> elements shall not
            conflict with <emph>ClinicalDocument/code</emph>.
        </diagnostic>
        <diagnostic id="L1-18">
            Manual: If pre-coordinated document type codes are used, values used in
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            <emph>encompassingEncounter/location/healthCareFacility/code</emph> shall not conflict with
            <emph>ClinicalDocument/code</emph>.
        </diagnostic>
        <diagnostic id="L1-19">
            Error: The <emph>languageCode</emph> element shall be present.
        </diagnostic>
        <diagnostic id="L1-20">
            Error: The language code shall be in the form <emph>nn</emph>, or <emph>nn-CC</emph>.
        </diagnostic>
        <diagnostic id="L1-21">
            Error: The <emph>nn</emph> portion shall be a legal ISO-639-1 language code in lower case.
        </diagnostic>
        <diagnostic id="L1-22">
            Error: The <emph>CC</emph> portion, if present shall be an ISO-3166 country code in upper case.
        </diagnostic>
        <diagnostic id="L1-23">
            Error: Both <emph>ClinicalDocument/setId</emph> and <emph>ClinicalDocument/versionNumber</emph> shall be
            present or absent.
        </diagnostic>
        <diagnostic id="L1-24">
            Error: The <emph>@extension</emph> and/or <emph>@root</emph> of <emph>ClinicalDocument/setId</emph> and
            <emph>ClinicalDocument/id</emph> are different when both are present.
        </diagnostic>
        <diagnostic id="L1-25">
            Error: A<emph> ClinicalDocument/copyTime</emph> element shall not be present.
        </diagnostic>
        <diagnostic id="L1-26">
            Error: At least one <emph>recordTarget/patientRole</emph> element shall be present.
        </diagnostic>
        <diagnostic id="L1-27">
            Error: A <emph>patient/birthTime</emph> element shall be present.
        </diagnostic>
        <diagnostic id="L1-28">
            Error: A <emph>patient/administrativeGenderCode</emph> element shall be present.
        </diagnostic>
        <diagnostic id="L1-29">
            Warning: If <emph>maritalStatusCode</emph>, <emph>religiousAffiliationCode</emph>, <emph>raceCode</emph>
            and <emph>ethnicGroupCode</emph> elements are present, they should be encoded using appropriate HL7
            vocabularies.
        </diagnostic>
        <diagnostic id="L1-30">
            Warning: The <emph>guardian</emph> element should be present when the patient is a minor child.
        </diagnostic>
        <diagnostic id="L1-31">
            Error: The <emph>author/time</emph> element shall be present.
        </diagnostic>
        <diagnostic id="L1-32">
            Error: The <emph>assignedAuthor/id</emph> element shall be present.
        </diagnostic>
        <diagnostic id="L1-33">
            Error: An <emph>assignedAuthor</emph> element shall contain at least one <emph>assignedPerson</emph> or
            <emph>assignedAuthoringDevice</emph> elements.
        </diagnostic>
        <diagnostic id="L1-34">
            Error: When <emph>assignedAuthoringDevice</emph> is present, the <emph>softwareName</emph> element shall
            be present.
        </diagnostic>
        <diagnostic id="L1-35">
            Error: When <emph>dataEnterer </emph>is present, an <emph>assignedEntity/assignedPerson</emph> element
            shall be present.
        </diagnostic>
        <diagnostic id="L1-36">
            Error: If the <emph>informant</emph> is a mutual relation, the type of relationship shall be specified
            in <emph>relatedEntity/@classCode</emph>, and shall be <emph>CON</emph>, <emph>PRS</emph> or
            <emph>PROV</emph> from the <emph>RoleClass</emph> vocabulary.
        </diagnostic>
        <diagnostic id="L1-37">
            Error: When <emph>informant</emph> is present, an <emph>assignedEntity/assignedPerson</emph> or
            <emph>relatedEntity/relatedPerson</emph> element shall be present.
        </diagnostic>
        <diagnostic id="L1-38">
            Error: 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="L1-39">
            Warning: When <emph>relatedEntity/@classCode</emph> is <emph>CON</emph>, <emph>relatedEntity/code</emph>
            should not be present.
        </diagnostic>
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        <diagnostic id="L1-40">
            Error: When <emph>relatedEntity/@classCode</emph> is <emph>PROV</emph>, and
            <emph>relatedEntity/code</emph> is present, the value shall come from SNOMED CT.
        </diagnostic>
        <diagnostic id="L1-41">
            Error: When <emph>informationRecipient</emph> is used, at least one
            <emph>informationRecipient/intendedRecipient/informationRecipient</emph> or
            <emph>informationRecipient/intendedRecipient/recievedOrganization</emph> shall be present.
        </diagnostic>
        <diagnostic id="L1-42">
            Error: The <emph>assignedEntity/assignedPerson</emph> element shall be present in a legalAuthenticator.
        </diagnostic>
        <diagnostic id="L1-43">
            Error: The <emph>assignedEntity/assignedPerson</emph> element shall be present in an
            <emph>authenticator</emph> element.
        </diagnostic>
        <diagnostic id="L1-44">
            Error: The <emph>participant/associatedEntity</emph> element shall have an <emph>associatedPerson</emph>
            or <emph>scopingOrganization</emph> element.
        </diagnostic>
        <diagnostic id="L1-45">
            Error: When <emph>participant/@typeCode</emph> is <emph>IND</emph>,
            <emph>participatingEntity/@classCode</emph> shall be <emph>PRS, NOK, ECON or GUAR.</emph>
        </diagnostic>
        <diagnostic id="L1-46">
            Error: When <emph>participatingEntity/@classCode</emph> is <emph>PRS, NOK or ECON</emph> then
            <emph>participatingEntity/code</emph> shall be present having a value drawn from the
            <emph>PersonalRelationshipRoleType</emph> domain.
        </diagnostic>
        <diagnostic id="L1-47">
            Error: When <emph>participant/@typeCode</emph> is <emph>HLD</emph>,
            <emph>participatingEntity/@classCode</emph> shall be <emph>POLHOLD</emph>.
        </diagnostic>
        <diagnostic id="L1-48">
            Error: When <emph>participant/@typeCode</emph> is <emph>HLD</emph>,
            <emph>participatingEntity/scopingOrganization </emph>shall be present.
        </diagnostic>
        <diagnostic id="L1-49">
            Manual: To represent a guarantor, the <emph>@typeCode</emph> attribute shall be have a value of
            <emph>IND</emph>, and the <emph>participatingEntity/@classCode</emph> shall have a value of
            <emph>GUAR</emph>.
        </diagnostic>
        <diagnostic id="L1-50">
            Error: The value of the <emph>serviceEvent/@classCode</emph> attribute shall be <emph>PCPR</emph>.
        </diagnostic>
        <diagnostic id="L1-51">
            Error: Only one <emph>ClinicalDocument/documentationOf</emph> element shall be present.
        </diagnostic>
        <diagnostic id="L1-52">
            Manual: If present, the value of <emph>serviceEvent/code</emph> shall not conflict with the
            <emph>ClininicalDocument/code</emph>.
        </diagnostic>
        <diagnostic id="L1-53">
            Error: The <emph>effectiveTime</emph> element of the <emph>serviceEvent</emph> element shall be present.
        </diagnostic>
        <diagnostic id="L1-54">
            Error: The <emph>effectiveTime</emph> element shall contain both a <emph>low</emph> and a
            <emph>high</emph> element.
        </diagnostic>
        <diagnostic id="L1-55">
            Warning: A <emph>serviceEvent</emph> should have at least one <emph>performer</emph>.
        </diagnostic>
        <diagnostic id="L1-56">
            Manual: The <emph>performer</emph> elements shall list the relevant providers of healthcare during the
            episode being summarized.
        </diagnostic>
        <diagnostic id="L1-57">
            Error: If the provider is the primary care provider for the patient during the time interval, then
            <emph>performer</emph>/<emph>functionCode</emph> shall have a value of <emph>PCP</emph> from the
            <emph>ParticipationFunction</emph> vocabulary domain
        </diagnostic>
        <diagnostic id="L1-58">
            Error: If present, the values for <emph>performer/assignedEntity/code</emph> shall be drawn from SNOMED
            CT, using concepts that descend from the <emph>healthcare professional </emph>subtype hierarchy (SNOMED
            CT Concept ID: 223366009).
        </diagnostic>
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        <diagnostic id="L1-59">
            Error: The <emph>performer/assigneEntity/code</emph> if present shall have a value drawn from the SNOMED
            CT <emph>healthcare professional </emph>subtype hierarchy.
        </diagnostic>
        <diagnostic id="L1-60">
            Error: Every <emph>performer/assignedEntity</emph> element shall have at least one
            <emph>assignedPerson</emph> or <emph>representedOrganization</emph>.
        </diagnostic>
        <diagnostic id="L1-61">
            Error: If the Care Record Summary is a Discharge Summarization, then the <emph>componentOf</emph>
            element is required.
        </diagnostic>
        <diagnostic id="L1-62">
            Error: The <emph>encompassingEncounter</emph> element shall have an <emph>id</emph> element.
        </diagnostic>
        <diagnostic id="L1-63">
            Error: The <emph>encompassingEncounter</emph> element shall have an <emph>effectiveTime</emph> element.
        </diagnostic>
        <diagnostic id="L1-64">
            Error: If <emph>ClinicalDocument/code </emph>represents a Discharge Summarization Node, then
            <emph>dischargeDispositionCode</emph> shall be present.
        </diagnostic>
        <diagnostic id="L1-65">
            Error: The <emph>encounterParticipant/assignedEntity</emph> element shall have at least one
            <emph>assignedPerson</emph> or <emph>representedOrganization</emph> element present.
        </diagnostic>
        <diagnostic id="L1-66">
            Error: The <emph>responsibleParty/assignedEntity</emph> element shall have at least one
            <emph>assignedPerson</emph> or <emph>representedOrganization</emph> element present.
        </diagnostic>
        <diagnostic id="L1-67">
            Warning: A <emph>nonXMLBody/text</emph> should not contain both a <emph>reference</emph> element and
            character data.
        </diagnostic>
        <diagnostic id="L1-68">
            Manual: 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 shall be
            recorded as the <emph>assignedAuthor</emph> and the application shall be recorded as an
            <emph>assignedAuthoringDevice</emph>.
        </diagnostic>
        <diagnostic id="L1-69">
            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="L2-1">
            Error: A <emph>section</emph> element shall have a <emph>code</emph> element.
        </diagnostic>
        <diagnostic id="L2-2">
            Error: A <emph>section</emph> shall contain at least one <emph>text </emph>element or one or more
            <emph>component</emph> elements.
        </diagnostic>
        <diagnostic id="L2-3">
            Error: All <emph>text</emph> or <emph>component</emph> elements shall contain content.
        </diagnostic>
        <diagnostic id="L2-4">
            Error: A Care Record Summary shall include a <emph>section</emph> element whose code is <emph>11450-4
            or 11535-2</emph>.
        </diagnostic>
        <diagnostic id="L2-5">
            Error: A <emph>section</emph> shall be present with a <emph>code</emph> value of <emph>10155-0</emph>
            or <emph>8658-7</emph>.
        </diagnostic>
        <diagnostic id="L2-6">
            Error: A Discharge summary shall include a <emph>section</emph> element whose code is
            <emph>10183-2</emph>.
        </diagnostic>
        <diagnostic id="L2-7">
            Error: A Summary of Episode note that is not also a discharge summary shall include a
            <emph>section</emph> element whose code is <emph>10160-0</emph>.
        </diagnostic>
        <diagnostic id="L2-8">
            Error: A level 2 conforming Care Record Summary that is a discharge summary shall contain a
            <emph>section</emph> with the <emph>code</emph> value of <emph>8648-8</emph>.
        </diagnostic>
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        <diagnostic id="L2-9">
            Manual: The section type code for the section describing the reason for visit in a level 2
            conforming Care Record Summary shall be either <emph>46239-0</emph> (REASON FOR VISIT/CHIEF COMPLAINT),
            or <emph>29299-5</emph> (REASON FOR VISIT).
        </diagnostic>
        <diagnostic id="L2-10">
            Manual: 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>46239-0</emph> (REASON FOR VISIT/CHIEF COMPLAINT),
            or <emph>10154-3</emph> (CHIEF COMPLAINT).
        </diagnostic>
        <diagnostic id="L2-11">
            Error: A level 2 conforming Care Record Summary that contains a <emph>section</emph> with a
            <emph>code</emph> value of <emph>46239-0</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), and vice versa.
        </diagnostic>
        <diagnostic id="L2-12">
            Manual: 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>42349-1</emph> (REASON FOR REFERRAL).
        </diagnostic>
        <diagnostic id="L2-13">
            Manual: The <emph>code</emph> for the <emph>section</emph> describing the patient's Advance Directives
            in a level 2 conforming Care Record Summary SHALL be <emph>42348-3</emph> (ADVANCE DIRECTIVES).
        </diagnostic>
        <diagnostic id="L2-14">
            Manual: The <emph>code</emph> for the <emph>section</emph> 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>
        <diagnostic id="L2-15">
            Manual: 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="L2-16">
            Manual: 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="L2-17">
            Manual: The LOINC section type <emph>code</emph> for the <emph>section</emph> providing immunization
            history in a level 2 conforming Care Record Summary shall be <emph>11369-6</emph> (HISTORY OF
            IMMUNIZATION).
        </diagnostic>
        <diagnostic id="L2-18">
            Manual: 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="L2-19">
            Manual: The LOINC section <emph>code</emph> used for the section describing only prior outpatient visits
            in a level 2 conforming Care Record Summary shall be <emph>11346-4</emph> (HISTORY OF OUTPATIENT
            VISITS).
        </diagnostic>
        <diagnostic id="L2-20">
            Manual: The LOINC section <emph>code</emph> used for the section describing only prior hospitalizations
            in a level 2 conforming Care Record Summary shall be <emph>11336-5</emph> (HISTORY OF HOSPITALIZATIONS).
        </diagnostic>
        <diagnostic id="L2-21">
            Manual: The LOINC section <emph>code</emph> used for the section describing both prior hospitalizations
            and prior outpatient visits in a level 2 conforming Care Record Summary shall be <emph>46240-8</emph>
            (HISTORY OF HOSPITALIZATIONS+HISTORY OF OUTPATIENT VISITS).
        </diagnostic>
        <diagnostic id="L2-22">
            Manual: The LOINC section <emph>code</emph> used for the section describing the Review of Systems in a
            level 2 conforming Care Record Summary shall be <emph>10187-3</emph> (REVIEW OF SYSTEMS).
        </diagnostic>
        <diagnostic id="L2-23">
            Manual: The LOINC section <emph>code</emph> used for the section describing the Physical Examination
            given at Discharge from a hospital in a level 2 conforming Care Record Summary shall be
            <emph>10184-0</emph> (HOSPITAL DISCHARGE PHYSICAL).
        </diagnostic>
        <diagnostic id="L2-24">
            Manual: The LOINC section <emph>code</emph> used for the section describing the Physical Examination at
            times other than discharge from a hospital in a level 2 conforming Care Record Summary shall be
            <emph>22029-3 </emph>(PHYSICAL EXAM.TOTAL).
        </diagnostic>
```

```
        <diagnostic id="L2-25">
            Manual: 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="L2-26">
            Manual: The LOINC section <emph>code</emph> used for the section describing the Fetal Vital Signs in a
            level 2 conforming Care Record Summary shall be <emph>46242-4</emph> (VITAL MEASUREMENTS, FETUS)
        </diagnostic>
        <diagnostic id="L2-27">
            Manual: 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>30954-2</emph> (RELEVANT DIAGNOSTIC TESTS AND/OR LABORATORY DATA)
        </diagnostic>
        <diagnostic id="L2-28">
            Manual: 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 B — Sample Level 1 Conforming CDA Header

The document below is a non-normative example of the header of a Care Record Summary that conforms to this specification. Appendix C — Sample Level 2 Conforming Structured Body following this appendix contains a conforming structuredBody that can be included in this header to produce a conforming Care Record Summary. The file sample.xml included in this distribution with this specification is a complete Care Record Summary made up of these two appendices.

```
<?xml version='1.0' encoding='UTF-8'?>
<?xml-stylesheet type='text/xsl' href='IMPL_CDAR2.xsl'?>
<ClinicalDocument xmlns='urn:hl7-org:v3' xmlns:crs='urn:hl7-org:crs'
xmlns:xsi='http://www.w3.org/2001/XMLSchema-instance'>
  <realmCode code='US'/>
  <typeId extension='POCD_HD000040' root='2.16.840.1.113883.1.3'/>
  <templateId extension='IMPL_CDAR2_LEVEL1' root='2.16.840.1.113883.10' />
  <templateId extension='IMPL_CDAR2_LEVEL2' root='2.16.840.1.113883.10' />
  <id extension='999021'  root='1.3.6.4.1.4.1.2835.2'/>
  <code code='34133-9' displayName='SUMMARIZATION OF EPISODE NOTE'
    codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
  <title>Good Health Clinic Care Record Summary</title>
  <effectiveTime value='20050303171504+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'/>
      <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>
          <given>Ellen</given>
          <family>Ross</family>
        </name>
        <administrativeGenderCode code='F' codeSystem='2.16.840.1.113883.5.1' />
        <birthTime value='19600127'/>
      </patient>
      <providerOrganization>
        <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>
  <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'/>
      <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>
    </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>
      </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>
          <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>
        <addr>
          <streetAddressLine>21 North Ave</streetAddressLine>
          <city>Burlington</city><state>MA</state><postalCode>01803</postalCode>
          <country>USA</country>
        </addr>
```

```
      <name>
        <prefix>Dr.</prefix>
        <given>Bernard</given>
        <family>Wiseman</family>
        <suffix>Jr.</suffix>
      </name>
    </assignedPerson>
  </assignedEntity>
</informant>
<!-- To represent personal relation that provides information about a patient -->
<informant>
  <relatedEntity classCode='PRS'>
    <code code='MTH' codeSystem='2.16.840.1.113883.5.111'/>
    <relatedPerson>
      <name>
        <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>
        <given>Joseph</given>
        <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>
      <name>
        <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'/>
    <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>
<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>
<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>
    </addr>
    <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>
```

```
  <participant typeCode='IND'>
    <associatedEntity classCode='NOK'>
      <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>
          <given>Abigail</given>
          <family>Ruth</family>
        </name>
      </associatedPerson>
    </associatedEntity>
  </participant>
  <participant typeCode='HLD'>
    <time>
      <low value='20050101'/>
      <high value='20051231'/>
    </time>
    <associatedEntity classCode='POLHOLD'>
      <id extension='123456789' />
      <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>
        <name>
          <prefix>Mr.</prefix>
          <given>Kenneth</given>
          <family>Ross</family>
        </name>
      </associatedPerson>
      <scopingOrganization>
        <name>Good Health Insurance Company</name>
        <telecom value='tel:(203)555-1212' use='WP'/>
        <addr>
          <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>
        <name>
          <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' 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>
              <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'
        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'
        displayName='Routine Discharge'
        codeSystemName='UB92'/>
    </encompassingEncounter>
  </componentOf>
  <component>
      :
      .
  </component>
</ClinicalDocument>
```

Appendix C — 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. Appendix B — Sample Level 1 Conforming CDA Header preceding this appendix contains a conforming CDA Header that could be wrapped around this structuredBody to produce a conforming Care Record Summary. The file sample.xml included in this distribution with this specification is a complete Care Record Summary made up of these two appendices.

```
<structuredBody>
  <component>
    <section>
      <code code='46239-0' codeSystem='2.16.840.1.113883.6.1'
        displayName='REASON FOR VISIT/CHIEF COMPLAINT'/>
      <title>Reason for Visit/Chief Complaint</title>
      <text>Ankle Sprain</text>
    </section>
  </component>
  <component>
    <section>
      <code code='42349-1' codeSystem='2.16.840.1.113883.6.1'
        displayName='REASON FOR REFERRAL'/>
      <title>Reason for Referral</title>
      <text>Follow-up care for Ankle Sprain</text>
    </section>
  </component>
  <component>
    <section>
      <code  code='42348-3' codeSystem='2.16.840.1.113883.6.1'
        displayName='ADVANCE DIRECTIVES'/>
      <title>Advance Directives</title>
      <text>
        <table border='1'>
          <thead>
            <tr><th>Documentation</th><th>Contact</th>
              <th>Effective Date</th><th>Comments</th>
            </tr>
          </thead>
          <tbody>
            <tr><td>Living Will</td><td>Obtain from her Husband</td>
              <td>1994</td><td>Copy on file</td>
            </tr>
            <tr><td>Power of Attorney</td><td>Obtain from her Husband</td>
              <td>1994</td><td></td>
            </tr>
            <tr><td>Healthcare Proxy</td><td>Obtain from her Husband</td>
              <td>1994</td><td></td>
            </tr>
            <tr><td>Organ Donor</td>
              <td>Massachusetts Registry of Motor Vehicles</td><td>1/27/2004</td>
              <td>Registered Organ Donor</td>
            </tr>
          </tbody>
        </table>
      </text>
    </section>
  </component>
```

```
      <component>
        <section>
          <code code='10164-2' codeSystem='2.16.840.1.113883.6.1'
            displayName='HISTORY OF PRESENT ILLNESS'/>
          <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'
            displayName='HISTORY OF FAMILY MEMBER DISEASES' />
          <title>Family History</title>
          <text>
            <table border='1'>
              <thead>
                <tr><th>Family Member</th><th>Problem</th><th>Cause of Death?</th></tr>
              </thead>
              <tbody>
                <tr><td>Father</td><td>Alcoholism</td><td>No</td></tr>
                <tr><td>Father</td><td>Liver Cancer</td><td>Yes</td></tr>
              </tbody>
            </table>
          </text>
        </section>
      </component>
      <component>
        <section>
          <code  code='29762-2' codeSystem='2.16.840.1.113883.6.1'
            displayName='SOCIAL HISTORY'/>
          <title>Social History</title>
          <text>
            <table border='1'>
              <thead>
                <tr><th>Social History</th><th>Comments</th>
                  <th>Start Date</th><th>End Date</th></tr>
              </thead>
              <tbody>
                <tr><td>Smoking</td><td>1/2 pack per day</td>
                  <td></td><td>1996</td></tr>
                <tr><td>Alcohol Use</td><td>1-2 drinks per week</td>
                  <td></td><td></td><td></tr>
              </tbody>
            </table>
          </text>
        </section>
      </component>
      <component>
        <section>
          <code code='11450-4' codeSystem='2.16.840.1.113883.6.1'
              displayName='PROBLEM LIST'/>
          <title>Conditions</title>
          <text>
            <table border='1'>
              <thead><tr><th>Problem</th><th>Start Date</th><th>End Date</th>
                  <th>Comments</th></tr></thead>
              <tbody>
                <tr><td>Cholecystitis</td><td>9/28/2002</td><td>6/2003</td>
                  <td>Resolved</td><td>Surgery postponed until after delivery</td>
                </tr>
                <tr><td>Pregnancy</td><td>7/2001</td><td>4/22/2002</td>
                  <td>Resolved</td><td>Prior history of miscarraige</td>
                </tr>
                <tr><td>Ankle Sprain</td><td>3/28/2005</td><td></td>
                  <td>Current</td><td>Slipped on ice and fell</td>
                </tr>
              </tbody>
            </table>
          </text>
        </section>
      </component>
      <component>
        <section>
          <code  code='10155-0' codeSystem='2.16.840.1.113883.6.1'
            displayName='HISTORY OF ALLERGIES' />
          <title>Allergies and Adverse Reactions</title>
          <text>
```

```
          <table border='1'>
            <thead>
              <tr><th>Allergen</th><th>Reaction</th>
                <th>Comments</th>
              </tr>
            </thead>
            <tbody>
              <tr><td>Penicillin</td><td>Hives</td>
                <td>Cephalexin is OK</td>
              </tr>
            </tbody>
          </table>
        </text>
      </section>
    </component>
    <component>
      <section>
        <code  code='10160-0' codeSystem='2.16.840.1.113883.6.1'
          displayName='HISTORY OF MEDICATION USE'/>
        <title>Medications</title>
        <text>
          <table border='1'>
            <thead>
              <tr><th>Medication</th>
                <th>Prescription or Dose</th>
                <th>Start Date</th><th>End Date</th>
              </tr>
            </thead>
            <tbody>
              <tr><td>Indomethacin</td>
                <td>50mg bid with food </td>
                <td>12/10/2003</td><td>present</td>
              </tr>
              <tr>
                <td>Acetaminophen with codeine</td>
                <td>#3 1-2 tablets for pain as needed</td>
                <td>03/28/2005</td><td>4/5/2005</td>
              </tr>
            </tbody>
          </table>
        </text>
      </section>
    </component>
    <component>
      <section>
        <code  code='11369-6' codeSystem='2.16.840.1.113883.6.1'
          displayName='HISTORY OF IMMUNIZATION'/>
        <title>Immunizations</title>
        <text>
          <list>
            <item>DTP - 1962</item>
            <item>Polio Virus - 1961</item>
            <item>MMR - 1961</item>
          </list>
        </text>
      </section>
    </component>
```

```
      <component>
        <section>
          <code code='10167-5' codeSystem='2.16.840.1.113883.6.1'
            displayName='PAST SURGICAL HISTORY'/>
          <title>Procedures</title>
          <text>
            <table border='1'>
              <thead>
                <tr>
                  <th>Procedure</th><th>Date</th><th>Location</th>
                </tr>
              </thead>
              <tbody>
                <tr><td>Laparoscopic Cholecystectomy</td><td>9/28/2002</td>
                  <td>City Hospital</td>
                </tr>
                <tr><td>Cesarian Section</td><td>3/22/2002</td>
                  <td>Community Hospital</td>
                </tr>
              </tbody>
            </table>
          </text>
        </section>
      </component>
      <component>
        <section>
          <code  code='11336-5' codeSystem='2.16.840.1.113883.6.1'
            displayName='HISTORY OF HOSPITALIZATIONS'/>
          <title>Prior Encounters</title>
          <text>
            <table border='1'>
              <thead>
                <tr><th>Date</th><th>Provider</th>
                  <th>Description</th>
                </tr>
              </thead>
              <tbody>
                <tr><td>3/28/2005</td><td>Community Hospital</td>
                  <td>ED Visit for Ankle Sprain</td>
                </tr>
                <tr><td>9/28/2002</td><td>City Hospital</td>
                  <td>Gall Bladder Surgery</td>
                </tr>
                <tr><td>3/21/2002</td><td>Community Hospital</td>
                  <td>Labor and Delivery</td>
                </tr>
                <tr><td>10/28/2001</td><td>Community Hospital</td>
                  <td>ED Visit for Acute Cholecystitis</td>
                </tr>
              </tbody>
            </table>
          </text>
        </section>
      </component>
      <component>
        <section>
          <code  code='10187-3' codeSystem='2.16.840.1.113883.6.1'
            displayName='REVIEW OF SYSTEMS'/>
          <title>Review of Systems</title>
          <text>Review of systems otherwise negative</text>
        </section>
      </component>
```

```
      <component>
        <section>
          <code  code='22029-3' codeSystem='2.16.840.1.113883.6.1'
            displayName='PHYSICAL EXAM.TOTAL'/>
          <title>Physical Examination</title>
          <text>Left foot and ankle are swollen profusely.</text>
          <component>
            <section>
              <code    code='29274-8' codeSystem='2.16.840.1.113883.6.1'
                displayName='VITAL SIGNS'/>
              <title>Vital Signs</title>
              <text>
                <table border='1'>
                  <thead>
                    <tr><th>Date</th><th>Height</th><th>Weight</th><th>Temperature</th>
                        <th>BP</th><th>Pulse</th><th>Respiration</th><th>O2</th>
                    </tr>
                  </thead>
                  <tbody>
                    <tr><th>3/28/2005</th><th>5'9"</th><th>215 lbs.</th><th>98.7 &#xB0;F</th>
                        <th>120/80</th><th>68</th><th>16</th><th>99%</th>
                    </tr>
                  </tbody>
                </table>
              </text>
            </section>
          </component>
        </section>
      </component>
      <component>
        <section>
          <code  code='30954-2' codeSystem='2.16.840.1.113883.6.1'
            displayName='RELEVANT DIAGNOSTIC TESTS AND/OR LABORATORY DATA'/>
          <title>Related Reports</title>
          <text>
            <table border='1'>
              <thead>
                <tr>
                  <th>Study</th>
                  <th>Summary</th>
                  <th>Date of Study</th>
                </tr>
              </thead>
              <tbody>
                <tr>
                  <td>46239-0Ray Study - Left Ankle</td>
                  <td>No Fracture</td>
                  <td>3/28/2005</td>
                </tr>
              </tbody>
            </table>
          </text>
        </section>
      </component>
      <component>
        <section>
          <code  code='18776-5' codeSystem='2.16.840.1.113883.6.1'
            displayName='TREATMENT PLAN'/>
          <title>Plan of Care</title>
          <text>
            <paragraph>Acetaminophen with coedine prn for pain.</paragraph>
            <paragraph>Stay off the foot.  Keep foot elevated, and use
              supplied air splint and crutches.</paragraph>
            <paragraph>Advise follow-up with orthopedist if not
              significantly better in 5 days.</paragraph>
          </text>
        </section>
      </component>
    </structuredBody>
```

Appendix D — 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 authentication	A clinical document is an assemblage of information that is intended to be legally authenticated.
Context	A clinical document establishes the default context for its contents.
Wholeness	Authentication of a clinical document applies to the whole and does not apply to portions of the document without the full context of the document.
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 organization 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 person 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 legal authenticator 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 (DOCCLIN). 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 authenticator). 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, and would not have this privilege in other cases.

One 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.

L1-68: 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 **SHALL** be recorded as the assignedAuthor and the application **SHALL** be recorded as an assignedAuthoringDevice.

```
<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>
        </addr>
        <telecom value='tel:(999)555-1212' use='WP'/>
        <assignedAuthoringDevice>
            <softwareName>Good Health Clinic System v1.0</softwareName>
        </assignedAuthoringDevice>
    </assignedAuthor>
</author>
```

Figure 74 Recording the Authoring Device

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 E — 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 document and provide a link between the author and the patient using the mechanism described in the Patient Relationship extension described in Appendix E — Extensions to CDA Release 2.0.

Appendix E — 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 **NEED NOT** 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 **SHALL** be *urn:hl7-org:crs*.
- This namespace **SHALL** be used as the namespace for any extension elements or attributes that are defined by this implementation guide.
- Each extension element **SHALL** use the same HL7 vocabularies and data types used by CDA Release 2.0.
- Each extension element **SHALL** use the same conventions for order and naming as is used by the current HL7 tooling.
- An extension element **SHALL** 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 75 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 75.
- 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 75.

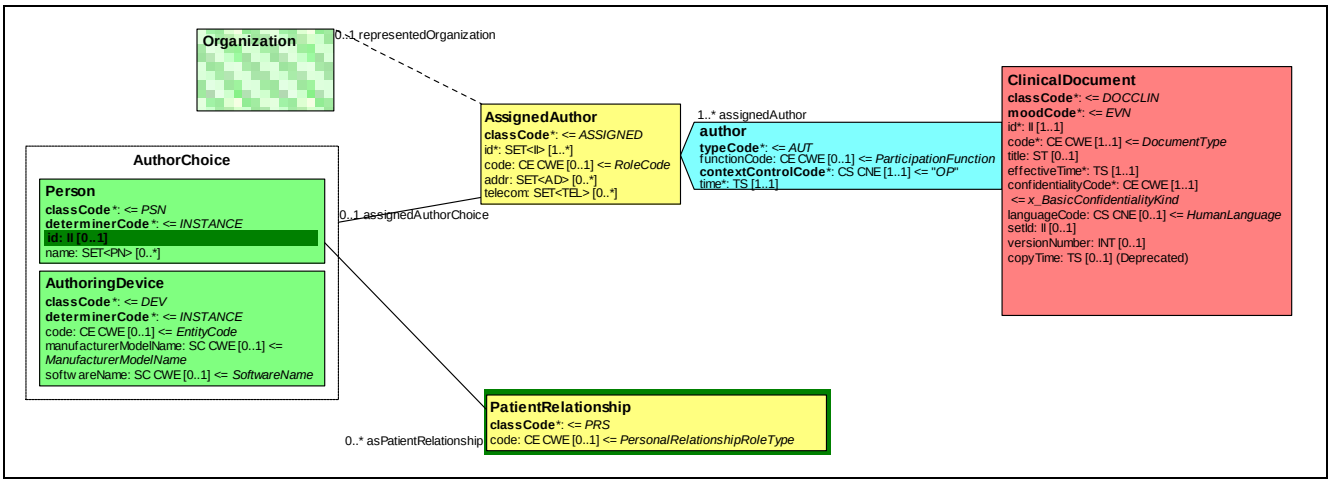

Figure 75 Extensions to CDA

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 to 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. In this case, when two participants have the same role identifier, they are the same person.

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. The identifier **MAY** be provided in an id element from the urn:hl7-org:crs namespace. This element **SHALL** be an instance identifier (II) and **SHALL** appear 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 76.

```
<ClinicalDocument xmlns='urn:hl7-org:v3' xmlns:crs='urn:hl7-org:crs'>
        :
        .
    <author>
        <time value='20050329224411+0500'/>
        <assignedAuthor>
        :
        .
        <assignedPerson>
            <crs:id extension='67890' root='2.16.840.1.113883.3.933'/>
            <name>
                <prefix>Mrs.</prefix><given>Ellen</given><family>Ross</family>
            </name>
        </assignedPerson>
        </assignedAuthor>
    </author>
        :
        .
    <recordTarget>
        <patientRole>
        :
        .
        <patient>
            <id extension='67890' root='2.16.840.1.113883.3.933'>
            <name>
                <prefix>Mrs.</prefix><given>Ellen</given><family>Ross</family>
            </name>
            <administrativeGenderCode code='F'
                    codeSystem='2.16.840.1.113883.5.1'/>
            <birthTime value='19600127'/>
        </patient>
        :
        .
        </patientRole>
    </recordTarget>
    .
    :
</ClinicalDocument>
```

Figure 76 Using crs:id when the patient is the author

Patient Relationship

CDA Release 2.0 does not provide a mechanism to relate participants other than an informant 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. 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 other than an informant **MAY** have zero or more relationship roles with the patient. Each of these roles can be 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>
                <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 77 crs:asPatientRelationship relating the author to the patient

The informant element already 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.

L1-69: An informant **SHOULD NOT** have any assignedEntity/assignedPerson/crs:asPatientRelationship elements, or relatedEntity/relatedPerson/ crs:asPatientRelationship elements.

Appendix F — Level 1 and Level 2 Constraints

This appendix lists all of the Level 1 and Level 2 constraints contained within the body of this document.

1 Level 1 Constraints

L1-1: All patient, guardianPerson, assignedPerson, maintainingPerson, relatedPerson, intendedRecipient/informationRecipient, associatedPerson, and relatedSubject/subject elements **SHALL** have a name.

L1-2: All patientRole, assignedAuthor, assignedEntity[not(parent::dataEnterer)] and associatedEntity elements **SHALL** have an addr and telecom element.

L1-3: All guardian, dataEnterer/assignedEntity, relatedEntity, intendedRecipient, relatedSubject and participantRole elements **SHOULD** have an addr and telecom element.

L1-4: All guardianOrganization, providerOrganization, wholeOrganization, representedOrganization, representedCustodianOrganization, recievedOrganization, scopingOrganization and serviceProviderOrganization elements **SHALL** have name, addr and telecom elements.

L1-5: Times or time intervals found in the ClinicalDocument/effectiveTime, author/time, dataEnterer/time, legalAuthenticator/time, authenticator/time and encompassingEncounter/effectiveTime elements **SHALL** be precise to the day, **SHALL** include a time zone if more precise than to the day, and **SHOULD** be precise to the second.

L1-6: The patient/birthTime element **SHALL** be precise at least to the year, and **SHOULD** be precise at least to the day, and **MAY** omit time zone.

L1-7: Times or time intervals found in the patient/birthTime, asOrganizationPartOf/effectiveTime, asMaintainedEntity/effectiveTime, relatedEntity/effectiveTime, serviceEvent/effectiveTime, ClinicalDocument/participant/time, serviceEvent/performer/time and encounterParticipant/time **SHALL** be precise at least to the year, **SHOULD** be precise to the day, and **MAY** omit time zone.

L1-8: Telephone numbers **SHALL** match the regular expression pattern *tel:\+?[-0-9().]+*

L1-9: At least one dialing digit **SHALL** be present in the phone number after visual separators are removed.

L1-10: The extension attribute of the typeId element **SHALL** be *POCD_HD000040*.

L1-11: A ClinicalDocument/templateId element **SHALL** be present where the value of @extension is *IMPL_CDAR2_LEVEL1* and the value of @root is *.2.16.840.1.113883.10*.

L1-12: *The ClinicalDocument/id/@root attribute **SHALL** be a syntactically correct UUID or OID.*

L1-13: *UUIDs **SHALL** be represented in the form* XXXXXXXX-XXXX-XXXX-XXXX-XXXXXXXXXXXX*, where each X is a character from the set [A-Fa-f0-9].*

L1-14: *OIDs **SHALL** be represented in dotted decimal notation, where each decimal number is either 0, or starts with a non-zero digit. More formally, an OID **SHALL** be in the form ([0-2])(.([1-9][0-9]*|0))+.*

L1-15: OIDs **SHALL** be no more than 64 characters in length.

L1-16: *For /ClinicalDocument/code, @code **SHALL** come from the appropriate LOINC code subset listed in Table 2, @codeSysem **SHALL** be the OID for LOINC, and @codeSystemName, if present **SHALL** be* LOINC.

L1-17: *If pre-coordinated document type codes are used, values used in the assignedAuthor/code and assignedAuthor/author/functionCode elements **SHALL NOT** conflict with ClinicalDocument/code.*

L1-18: *If pre-coordinated document type codes are used, values used in encompassingEncounter/location/healthCareFacility/code **SHALL NOT** conflict with ClinicalDocument/code.*

L1-19: The languageCode element **SHALL** be present.

L1-20: The language code **SHALL** be in the form *nn*, or *nn-CC*.

L1-21: The *nn* portion **SHALL** be a legal ISO-639-1 language code in lower case.

L1-22: The *CC* portion, if present **SHALL** be an ISO-3166 country code in upper case.

L1-23: Both ClinicalDocument/setId and ClinicalDocument/versionNumber **SHALL** be present or absent.

L1-24: The @extension and/or @root of ClinicalDocument/setId and ClinicalDocument/id are different when both are present.

L1-25: A ClinicalDocument/copyTime element **SHALL NOT** be present.

L1-26: At least one recordTarget/patientRole element **SHALL** be present.

L1-27: A patient/birthTime element **SHALL** be present.

L1-28: A patient/administrativeGenderCode element **SHALL** be present.

L1-29: If maritalStatusCode, religiousAffiliationCode, raceCode and ethnicGroupCode elements are present, they **SHOULD** be encoded using appropriate HL7 vocabularies.

L1-30: The guardian element **SHOULD** be present when the patient is a minor child.

L1-31: The author/time element **SHALL** be present.

L1-32: The assignedAuthor/id element **SHALL** be present.

L1-33: An assignedAuthor element **SHALL** contain at least one assignedPerson or assignedAuthoringDevice elements.

L1-34: When assignedAuthoringDevice is present, the softwareName element **SHALL** be present.

L1-35: When dataEnterer is present, an assignedEntity/assignedPerson element **SHALL** be present.

L1-36: The type of relationship between the patient and the informant **SHALL** be specified in relatedEntity/@classCode and **SHALL** be *CON*, *PRS* or *PROV* from the RoleClass vocabulary.

L1-37: When informant is present, an assignedEntity/assignedPerson or relatedEntity/relatedPerson element **SHALL** be present.

L1-38: When relatedEntity/@classCode is *PRS*, values in relatedEntity/code **SHALL** come from the PersonalRelationshipRoleType vocabulary.

L1-39: When relatedEntity/@classCode is *CON*, relatedEntity/code **SHOULD NOT** be present.

L1-40: When relatedEntity/@classCode is *PROV*, and relatedEntity/code is present, the value **SHALL** come from SNOMED CT.

L1-41: When informationRecipient is used, at least one informationRecipient/intendedRecipient/informationRecipient or informationRecipient/intendedRecipient/recievedOrganization **SHALL** be present.

L1-42: The assignedEntity/assignedPerson element **SHALL** be present in legalAuthenticator.

L1-43: The assignedEntity/assignedPerson element **SHALL** be present in an authenticator element.

L1-44: The participant/associatedEntity element **SHALL** have an associatedPerson or scopingOrganization element.

L1-45: When participant/@typeCode is *IND*, participatingEntity/@classCode **SHALL** be *PRS, NOK, ECON or GUAR.*

L1-46: When participatingEntity/@classCode is *PRS, NOK or ECON* then participatingEntity/code **SHALL** be present having a value drawn from the PersonalRelationshipRoleType domain.

L1-47: When participant/@typeCode is *HLD*, participatingEntity/@classCode **SHALL** be *POLHOLD*.

L1-48: When participant/@typeCode is *HLD*, participatingEntity/scopingOrganization **SHALL** be present.

L1-49: To represent a guarantor, the @typeCode attribute **SHALL** be have a value of *IND*, and the participatingEntity/@classCode **SHALL** have a value of *GUAR*.

L1-50: The value of the serviceEvent/@classCode attribute **SHALL** be *PCPR*.

L1-51: Only one ClinicalDocument/documentationOf element **SHALL** be present.

L1-52: If present, the value of serviceEvent/code **SHALL NOT** conflict with the ClininicalDocument/code.

L1-53: The effectiveTime element of the serviceEvent element **SHALL** be present.

L1-54: The effectiveTime element **SHALL** contain both a low and a high element.

L1-55: A serviceEvent **SHOULD** have at least one performer. There are cases where no performers might be listed, for example, in cases where the information will not or cannot be provided by the patient.

L1-56: The performer elements **SHALL** list the relevant providers of healthcare during the episode being summarized.

L1-57: If the provider is the primary care provider for the patient during the time interval, then performer/functionCode **SHALL** have a value of *PCP* from the ParticipationFunction vocabulary domain.

L1-58: If present, the values for performer/assignedEntity/code **SHALL** be drawn from SNOMED CT, using concepts that descend from the *healthcare professional* subtype hierarchy (SNOMED CT Concept ID: 223366009).

L1-59: The performer/assignedEntity/code if present **SHALL** have a value drawn from the SNOMED CT *healthcare professional* subtype hierarchy.

L1-60: Every performer/assignedEntity element **SHALL** have at least one assignedPerson or representedOrganization.

L1-61: If the Care Record Summary is a Discharge Summarization, then the componentOf element **SHALL** be present.

L1-62: The encompassingEncounter element **SHALL** have an id element.

L1-63: The encompassingEncounter element **SHALL** have an effectiveTime element.

L1-64: If ClinicalDocument/code represents a Discharge Summarization Node, then dischargeDispositionCode **SHALL** be present.

L1-65: The encounterParticipant/assignedEntity element **SHALL** have at least one assignedPerson or representedOrganization element present.

L1-66: The responsibleParty/assignedEntity element **SHALL** have at least one assignedPerson or representedOrganization element present.

L1-67: A nonXMLBody/text **SHOULD** not contain both a reference element and character data.

L1-68: 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 **SHALL** be recorded as the assignedAuthor and the application **SHALL** be recorded as an assignedAuthoringDevice.

L1-69: An informant **SHOULD NOT** have any assignedEntity/assignedPerson/crs:asPatientRelationship elements, or relatedEntity/relatedPerson/ crs:asPatientRelationship elements.

2 Level 2 Constraints

L2-1: A section element **SHALL** have a code element.

L2-2: A section **SHALL** contain at least one text element or one or more component elements.

L2-3: All text or component elements **SHALL** contain content.

L2-4: A Care Record Summary **SHALL** include a section element whose code is *11450-4 or 11535-2*.

L2-5: A section **SHALL** be present with a code value of *10155-0* or *8658-7*.

L2-6: A Discharge summary **SHALL** include a section element whose code is *10183-2*.

L2-7: A Summary of Episode note that is not also a discharge summary **SHALL** include a section element whose code is *10160-0*.

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

L2-9: The section type code for the section describing the reason for visit in a level 2 conforming Care Record Summary **SHALL** be either *46239-0* (REASON FOR VISIT/CHIEF COMPLAINT), or *29299-5* (REASON FOR VISIT).

L2-10: The section type code for the section describing the patient's chief complaint in a level 2 conforming Care Record Summary **SHALL** be either *46239-0* (REASON FOR VISIT/CHIEF COMPLAINT), or *10154-3* (CHIEF COMPLAINT).

L2-11: A level 2 conforming Care Record Summary that contains a section with a code value of *46239-0* (REASON FOR VISIT/CHIEF COMPLAINT) **SHALL NOT** contain sections with a code value of *29299-5* (REASON FOR VISIT) or *10154-3* (CHIEF COMPLAINT), and vice versa.

L2-12: The code for the section describing the Reason for Referral in a level 2 conforming Care Record Summary **SHALL** be *42349-1* (REASON FOR REFERRAL).

Figure 53 below shows a sample of a Reason for Referral section.

L2-13: The code for the section describing the patient Advance Directives in a level 2 conforming Care Record Summary **SHALL** be *42348-3* (ADVANCE DIRECTIVES).

L2-14: 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 56 below shows a sample of a History of Present Illness section.

L2-15: 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).

L2-16: 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).

L2-17: 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).

L2-18: 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).

L2-19: The LOINC section code used for the section describing only prior outpatient visits in a level 2 conforming Care Record Summary **SHALL** be *11346-4* (HISTORY OF OUTPATIENT VISITS).

L2-20: The LOINC section `code` used for the section describing only prior hospitalizations in a level 2 conforming Care Record Summary **SHALL** be *11336-5* (HISTORY OF HOSPITALIZATIONS).

L2-21: The LOINC section `code` used for the section describing both prior hospitalizations and prior outpatient visits in a level 2 conforming Care Record Summary **SHALL** be *46240-4* (HISTORY OF HOSPITALIZATIONS+HISTORY OF OUTPATIENT VISITS).

L2-22: The LOINC section `code` used for the section describing the Review of Systems in a level 2 conforming Care Record Summary **SHALL** be *10187-3* (REVIEW OF SYSTEMS).

L2-23: The LOINC section `code` used for the section describing the Physical Examination given at Discharge from a hospital in a level 2 conforming Care Record Summary **SHALL** be *10184-0* (HOSPITAL DISCHARGE PHYSICAL).

L2-24: The LOINC section `code` used for the section describing the Physical Examination at times other than discharge from a hospital in a level 2 conforming Care Record Summary **SHALL** be *22029-3* (PHYSICAL EXAM.TOTAL).

L2-25: 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).

L2-26: The LOINC section `code` used for the section describing the Fetal Vital Signs in a level 2 conforming Care Record Summary **SHALL** be *46242-4* (VITAL SIGN MEASUREMENTS, FETUS)

L2-27: 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 *30954-2* (RELEVANT DIAGNOSTIC TESTS AND/OR LABORATORY DATA)

L2-28: 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).