

Quick Start Guide for Care Record Summary Documents Using CDA Release 2.0

CRS Ballot 3 (Pre-reconciliation) Version 1.1

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Revision History

Date	Version	Comment
January 6, 2006	1.0	Preliminary - CRS Ballot 3 Pre-reconciliation Release
March 6, 2006	1.1	Preliminary – revised acknowledgements, fix typo in Appendix B.

Introduction

The purpose of this Quick Start Guide is to aid implementers in developing applications to produce Care Record Summary (CRS) documents based on HL7's **Clinical Document Architecture (CDA) Release 2** specification and the **Implementation Guide for CDA Release 2 – Level 1 and 2 – Care Record Summary (US realm) – Third Informative Ballot, November 17, 2005** (hereafter referred to in this document as the CRS IG). It is recommended that implementers and developers refer to these documents for additional information. All documents and specifications are available from HL7 (see the references section below for links to other documents and information sources that may be helpful.)

Note also that the CRS IG is in ballot at the time this Quick Start Guide was created. This guide will be modified when the CRS IG completes the balloting process, and any changes that affect this guide will be incorporated and a new version made available. Users are strongly encouraged to monitor the CRS ballot activity for critical issues raised during review that may impact their implementations.

As defined in the CRS IG, a CRS "... document contains a patient's relevant health history for some time period. It is intended for communication between healthcare providers." As such, it defines a number of constraints and requirements on the basic CDA to meet that objective. Note that while the authoritative reference documents may be required, this CRS Quick Start Guide is intended as a stand-alone guide and reiterates all relevant information also found in the CDA Quick Start Guide.

This document is broken into two main sections. The first presents information on the required elements of the CRS header – globally-unique identifier, document type code, timestamp, confidentiality code, patient, author and custodian – which support retrieval by the most common parameters with no further refinement or qualification needed. These are the basic requirements for distributed access to portable records.

The second section deals with the body of the document. CRS requires that every document contain at least three sections in the body: medications, allergies and adverse reactions, and conditions. If the CRS is created as a discharge summary then a forth section – hospital course – is also required.

This guide presupposes no consensus on coding beyond the CDA specification itself except where explicitly defined in the CRS IG. Aspects of CDA and/or CRS may be further constrained through local, regional or national guidelines and agreements.

Rendering Considerations

The CDA itself guarantees that legally required, human-readable content can be rendered with a single style sheet. The same applies to CRS, which is a constraint on CDA.

CRS, CCD and the SDTC Roadmap

Starting in December, 2005, the HL7 Structured Documents Technical Committee, in conjunction with ASTM E31.28, launched a project to create a "Continuity of Care Document" or CCD. The CCD will reiterate the clinical content of the ASTM Continuity of Care Record (CCR) as a CDA application. The outcome will be an implementation guide, similar to the one for CRS. Simultaneously, CRS is entering its third ballot cycle for Level 1 and Level 2 summary documents.

The outcome of this activity will be a merged set of implementation specifications covering “continuity of care” such that implementers can work off of a single set of requirements and can implement to the highest level of which they are capable. To achieve this, CRS may be modified to accommodate the CCD and the CCD may be influenced by the design of CRS. This reconciliation must be addressed before the spring ballot cycle in HL7, approximately April 1, 2006.

About this Quick Start Guide

Document Notational Conventions

Narrative text will appear as Times Roman, plain face text in Word, and plain face in HTML versions.

element is bold when an XML element is discussed in narrative text

attribute is bold italic when an XML attribute is discussed in narrative text

Coding examples will appear as monospaced font (typically Courier or Courier New) with color to identify optional and fixed content for clarity where applicable.

```
<requiredElement required="fixedValue" optional="variableValue">  
<optionalElement required="variableValue" optional="variableValue">
```

References are made throughout this document to the CRS Implementation Guide and to the normative HL7 Clinical Document Architecture (CDA), Release 2.0 documentaton set. To improve readability, all references to these documents will appear at the end of each topic as:

[*CRS Implementation Guide, Section X.x.x.x – Section Title*] – note that references to this document will not be hyperlinks.

[*CDA Release 2.0, Section X.x.x.x – Section Title*].

Additional references to other HL7 specifications will include the title of the document in addition to the section number and title, i.e.:

[*HL7 Reference Information Model, Section 3.4.1.3 – InfrastructureRoot.typeId*]

NOTE: Some references are active links if you have installed a local copy of the web version of the HL7 Clinical Document Architecture (CDA), Release 2.0 specification. For proper functioning of the links, place this document in the root directory of the specification created when unzipping the specification. By default it will be `..\CDA_R2_NormativeWebEdition`.

If you do not have a local copy, then please navigate to www.hl7.org/memonly/downloads to obtain a copy. Please note that you must have HL7 member log-in privileges to access and download the specification.

CRS IG - Key Words

The CRS implementation guide places constraints on the generality of CDA therefore that document makes use of key phrases to indicate such constraints.

The key words “**shall**”, “**shall not**”, “**should**”, “**should not**”, “**may**”, and “**neednot**” in this document are to be interpreted as described the [HL7 Version 3 Publishing Facilitator's Guide](#).

Essentially, “**shall**” means that the item, subject or article is an absolute requirement, whereas “**shall not**” indicates an absolute prohibition against inclusion.

“Should” means that valid reasons may exist in particular circumstances to ignore a particular item, but the full implications must be understood and carefully weighed by the author.

Conversely, “should not” means that valid reasons may exist in particular circumstances when the particular behavior is acceptable or useful, but the full implications should be understood and carefully weighed before implementing any behavior described with this label.

“May” and “neednot” mean that the item is truly optional and can be included or omitted as the author decides with no implications. Note that this can potentially be overridden by local business practices or other external requirements; local implementations should verify whether or not something is truly optional in local practice.

When CRS Constrains CDA

Where an element’s behavior is constrained by CRS, this constraint will be indicated by an inset section within the element section, prefaced by the phrase “**CRS Constraint**”, and the specific behavioral difference presented. Where an element’s behavior does not deviate from the base CDA requirements, no such section will appear. However, links to both CRS IG and CDA R2 will be supplied for all elements for completeness.

Authoritative Sources

***Note:** Portions of this document are abstracted from the normative edition of the HL7 Clinical Document Architecture (CDA), Release 2.0 specification and the Care Record Summary (CRS) Implementation Guide (US Realm), Third Informative Ballot, November 17, 2005. This Guide is not a complete reference to the CDA schemas and should be used in conjunction with the full normative specification for implementation and development. Please refer to the normative edition for a complete description of the CDA and its usage. Any deviation between this Guide and the specification is an error in the Guide and the specification should be followed in all cases.*

This Quick Start Guide is based on the HL7 Care Record Summary Implementation Guide. It describes how to implement a basic CDA that will facilitate the collection of patient information as a series of CDA documents or in a mixed archive with other types of standards-based persistent objects. The resulting CDA instance will be comprised of an XML-encoded header, and a body which is either non-XML or the simple XML of the CDA Narrative block.

If, through an error, this guide deviates in any way from the CDA Release 2.0 specification or the CRS Implementation Guide (US Realm), those specifications should be followed. Note that in all cases the CDA Release 2.0 Specification is to be considered the authoritative specification.

This Guide covers all required elements of the CRS header and body and gives guidance on some optional elements. The list of CRS-required header elements is greater than the list of required header elements presented in the **CDA Quick Start Guide** because the CRS tightens some aspects of the CDA.

[\[CDA Release 2.0, Section 1.2.2 - The “A” in “CDA”\]](#)

[\[CDA Release 2.0, Section 4.3.5 - Section Narrative Block\]](#).

Assumptions

This document assumes that the reader has a thorough understanding of XML, the W3C Recommendation, as an XML applications developer. The reader should be familiar with W3C schemas, XML validation (parsing) and methods of constructing and de-constructing XML files.

Knowledge of the relevant HL7 standards and approaches are helpful. Additional information to further the readers understanding can be found in the Reference Information section of the guide.

Reference Information

Implementation Guide for CDA Release 2 – Level 1 and 2 – Care Record Summary (US realm), Third Informative Ballot, November 17, 2005

[*HL7 CDA Documentation Index*](#) – Index page for CDA Release 2 and additional HL7 documents

[*HL7 Clinical Document Architecture \(CDA\), Release 2.0*](#)

[*CDA.xsd and related schemas*](#)

[*CDA Example Documents*](#)

[*Appendix A – Sample CRS Instance*](#)

[*Appendix B – Additional Information on ISO8601 – Time and Date Stamps*](#)

Before You Begin

Constructing CRS documents imposes constraints not only on the CDA markup, but also on clinical content. As a Level 1 and Level 2 guide, however, the prescribed clinical content must be present, but need not be coded. Future Level 3 implementation guides and quick start guides will address the coding of clinical content. In absence of guidelines, implementers should follow best practice defined by the HL7 TermInfo and Clinical Statement projects.

Use of IDs and Codes

While CDA allows more than one type of unique identifier scheme, most implementations will use ISO object identifiers (OIDs) to uniquely specify the domain of a coded data value or an identifier for a person, organization, or other entity.

The identifier consists of two parts:

- **root** - a globally unique identifier composed of an OID or UUID whose root is assigned by an ISO assigning authority or obtained from HL7.
- **extension** – The value of this attribute is the responsibility of the organization, system and/or application where the document is created and stored.

In **typeID** the root and extension are fixed, but in most cases the root and extension are supplied by the application using internal OIDs or OIDs for an external organization such as HL7 or LOINC, or a third party that played some role in the event that is being documented, such as a lab, hospital, physicians office or other care setting.

Together the root and extension, when concatenated, result in a universally unique string for identification of the document, person, or organization.

Note: Throughout this document you will see references to the root “2.16.840.1.113883.19.xx”. This OID belongs to HL7 (root OID = 2.16.840.1.113883) and is specifically identified for use in example documents and has no other valid use.

To implement CRS, the identifiers you must be prepared to supply include:

- document ID: unique identifier for each CDA instance
- patient (record target)
- provider organization associated with the patient

- author and author's organization
- document custodian
- other participants such as providers performing a role in the encounter

The CDA also makes extensive use of code sets for document types, document sections, clinical procedures and clinical findings. Any code set used in the RIM, including internal RIM vocabularies and codes such as CPT, ICD, MEDCIN or SNOMED® can be used.

These vocabularies, or subsets thereof, are made available in the voc.xml file for use by Schematron for CRS rule validation. This file can be extended for local use, please refer to the CRS IG, Appendix A – Validation.

In this guide, we discuss use of Logical Observation Identifier Names and Codes (LOINC®) which is recommended for classification of document types (i.e., Discharge Summary, Transfer Note, History & Physical, etc.). LOINC codes are available for commercial use without charge, subject to the terms of a license that assures the integrity and ownership of the codes. Some commonly-used codes for CDA can be found throughout the specifications in the referenced section for each element described below.

For further information about LOINC and to obtain the latest release of the code database, please visit the LOINC site on the Web. The most current contact information can also be found there.

Internet connection required for the following links:

[[Registered HL7 OIDs](#)] – Links to HL7.org, OID registry page where you can download a .pdf or .xml file that contains information on all OIDs assigned by HL7. There is also an in-depth explanation of OIDs along with other explanatory links. USE FOR REQUEST/REGISTRATION

[[Logical Observation Identifier Names and Codes \(LOINC®\)](#)] – LOINC home page.

[[SNOMED International](#)] – SNOMED home page

[[International Classification of Diseases \(ICD\)](#)] – access page at CDC for information on ICD

[[World Health Organization – International Classification of Diseases \(ICD\)](#)] – access page at WHO for ICD

[[NCI Terminology Browser](#)] – access page for the National Cancer Institute Thesaurus, see site for scope of terminologies included in thesaurus.

Vocabularies

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 contains these vocabularies or applicable subsets as of the release of the CRS specification. See Appendix A of the CRS IG for information on how to extend the voc.xml file for local requirements.

Null Flavor

CDA makes use of defined types of null values to indicate what way and why content may be missing from a document. The following table represents the list of defined values and their definitions.

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	<p>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.</p> <p>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.</p>
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.

[[CDA Data Types - Abstract Specification, Section 1.11.4 - Exceptional Value Detail \(CS\)](#)]

Document Design

At a minimum, all CDA documents contain a CDA header comprised of the required information elements as defined by the CDA Specification, and a body. CRS tightens the cardinality on some of the optional elements in CDA, so there are a greater number of required elements.

CRS Level 2 also stipulates that the body consist of a **structuredBody** that contains several sections, each specifically identified through the use of LOINC codes. A Level 1 CRS can use a non-XML body or a structuredBody.

As noted in the specification, CDA is scoped by the problem of exchange. Authoring applications typically use a constrained version of the general exchange standard to drive an authoring interface. Resulting documents may be compliant CDA/CRS or may be transformed to compliant CDA/CRS on output. This Guide describes the final, target CRS and does not constrain the range of authoring applications and interfaces or the XML used internally in those applications.

Another concept required for constructing CDA documents is “context”. This context is established in the header and applies to the entire document, unless specifically overridden. The specification states that the following elements propagate context throughout the document, unless overridden:

- Author
- Confidentiality
- Data enterer
- Human language
- Informant
- Legal authenticator
- Participant
- Record target

Context components that can be overridden at the level of the document body include:

- Confidentiality
- Human language

Context components that can be overridden at the level of a document section include:

- Author
- Confidentiality
- Human language
- Informant
- Subject

Context components that can be overridden at the level of a CDA entry include:

- Author
- Human language
- Informant
- Participant
- Subject

See CDA Section 4.4.1 for a full overview of the context rules.

[\[CDA Release 2.0, Section 4.4.1 - Overview of CDA Context\]](#)

Document Types

There are three primary types of CRS documents:

- Summarization of Episode Note – LOINC: 34133-9
- Discharge Summarization Note – LOINC: 18842-5
- Transfer Summarization Note – LOINC: 18761-7

Implementers may wish to refine the classification of the document by supplying data on training/professional level of the participants in the **documentationOf** element. This is accomplished by use of a **code** element on the **assignedEntity** within a participant in the **encompassingEncounter** element (see [componentOf](#)).

[*CRS Implementation Guide, Section 2.1.7 – ClinicalDocument/code*]

[[CDA Release 2.0, Section 1.2.1 – Major Components of a CDA Document](#)]

[[CDA Release 2.0, Section 1.3 – CDA Conformance](#)]

[[CDA Release 2.0, Section 4.2 - Header](#)]

[[CDA Release 2.0, Section 4.3 – Body](#)]

[[CDA Release 2.0, Section 4.4 – CDA Context](#)]

CRS Header – Required Elements

The CDA header describes the document itself (e.g. unique ID, document type classification, version), the participants (e.g. care providers, authors, patients) and the document’s relationships to other documents. CDA specifies a small set of required elements which CRS extends for completeness within the context of the CRS domain. In addition, there are a number of optional header elements that may also be included. CRS also imposes constraints on the content or usage of some of these elements (required or optional), the specifics are identified for each of these below.

The following sections describe a minimal CRS document header. Refer to the example file supplied with this guide for a complete view of a potential “shell” that shows the elements in context and that can be used to preload an editing application, or as the target for a transformation from an existing application.

Note that some elements are “parent” elements, and their inclusion results in the inclusion of required child elements, as well as allowing optional child elements. Similarly, each element may have required and optional attributes.

[*CRS Implementation Guide, Section 2.1.1 – General Constraints*]

[[CDA Release 2.0, Section 4.2 - Header](#)]

ClinicalDocument

All documents begin with the root element **ClinicalDocument** which contains one or more attributes for namespace declarations.

Note: HL7 specifications discourage the use of the `xsi:schemaLocation` attribute in exchanged documents.

Example:

```
<ClinicalDocument xmlns="urn:hl7-org:v3" xmlns:mif="urn:hl7-org:v3/mif"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">
```

[*CRS Implementation Guide, Section 2.1 – ClinicalDocument*]

[*CDA Release 2.0, Section 4.1 – Clinical Document*]

[*XML Implementable Technology Specification for V3 Structures, Section 2.7 - The Use of Schema Processors*]

typeID

The **typeID** is a technology-neutral explicit reference to the CDA, Release Two specification. The element has two attributes that must be valued as follows:

root = “2.16.840.1.113883.1.3” (which is the OID for HL7 Registered models);

extension = “POCD_HD000040” (which is the unique identifier for the CDA, Release Two Hierarchical Description).

Example:

```
<typeID root="2.16.840.1.113883.1.3" extension="POCD_HD000040"/>
```

This element must appear with these exact values to be a CDA-conforming instance.

[*CRS Implementation Guide, Section 2.1.4 – ClinicalDocument/typeID*]

[*CDA Release 2.0, Section 4.1 – Clinical Document*]

[*HL7 Reference Information Model, Section 3.4.1.3 – InfrastructureRoot.typeID*]

id

The **id** represents the unique instance identifier (UID) of a clinical document. The **id** element uniquely and universally distinguishes a document from all other documents. This allows documents to move among systems without ID collision within those systems.

As above, the **id** element contains a **root** and **extension** attribute

Examples:

In this first example, the value of **root** is an example code defined by HL7. In practice this should be the creating organization’s OID that has been assigned by an ISO assigning authority such as HL7. The combination of the root and the extension create the universally unique value assigned to the document.

```
<id root="2.16.840.1.113883.19.4" extension="c266"/>
```

[*CRS Implementation Guide, Section 2.1.6 – ClinicalDocument/id*]

[*Before You Begin – Use of IDs and Codes*]

[*CDA Release 2.0, Section 4.2.1.1 – ClinicalDocument.id*]

code

The **code** element at the root level of the document (i.e. a direct child of **ClinicalDocument**) specifies the particular kind of document that is being created, such as a History and Physical, Discharge Summary, or Progress Note. This is typically called a “document type code”. The value set is drawn from LOINC, and has a “Coding, With Extensions” (CWE) coding strength. CWE means that implementers should use the supplied code set, in this case from LOINC, but if none of the supplied set applies, a substitute code can be used.

The required attributes are **code** and **codeSystem**, where **code** contains the string indicating the type of document, and the **codeSystem** is the OID of the organization that defined the string. For human-readability, the optional elements are **codeSystemName** and **displayName**. Note that the LOINC display name need not match the title of the document. The LOINC name might be “Summarization of Episode Note” and the actual title might be “Outpatient Episode Note”. In the examples below, the **code** values are LOINC values, and **codeSystem** contains the OID for LOINC.

CRS Constraint: The LOINC code must be “Summarization of Episode Note” (34133-9) or any descendant type code.

Further, the set of codes permitted include pre-coordinated codes that indicate a specific setting or professional training level of the user. Use of pre-coordinated codes are NOT recommended, and place further requirements on other elements within the document, therefore are not presented in this guide. Refer to the CRS IG for a complete explanation.

Examples:

When the document is a summarization of episode note:

```
<code code="34133-9" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Summarization of Episode Note"/>
```

When the document is a discharge summarization note:

```
<code code="18842-5" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Discharge Summarization Note"/>
```

When the document is a transfer summarization note:

```
<code code="18761-7" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Transfer Summarization Note"/>
```

Note: These LOINC values are not exclusive to CRS. The value of the **templateId** declares an instance as one that could be expected to be CRS-compliant, or declares it as another kind of CDA instance.

[*CRS Implementation Guide, Section 2.1.7 – Clinical Document/code*]

[*CDA Release 2.0, Section 7.2.2 - LOINC Document Codes*] (includes list of commonly used codes)

[*Before You Begin – Use of IDs and Codes*]

[See also www.regenstrief.org to download the most current database of LOINC codes.]

effectiveTime

As a direct child of **ClinicalDocument**, signifies the document creation time, when the document first came into being. Where the CDA document is a transform from an original document in some other format, the **effectiveTime** is the time the original document is created. Date and times are coded per HL7 adoption of ISO8601.

CRS Constraint: CRS IG states “... should record an **effectiveTime** that is precise to the second.” It is recognized that some methods of manual recording (i.e. paper based) will be less precise when transferred into an EHR system.

Examples:

Known to year/month/day/hour/min/sec declared with specific offset from zero meridian

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

Known to year/month/day/hour/min declared with specific offset from zero meridian

```
<effectiveTime value="200503031715+0500"/>
```

[*CRS Implementation Guide, Section 2.1.9 – ClinicalDocument/effectiveTime*]

[*CDA Release 2.0, Section 4.2.1.4 – ClinicalDocument.effectiveTime*]

[*CDA Release 2.0, XML Implementation Technology Specification – Data Types, Section 2.32 – Point in Time (TS) specializes QTY*]

[*CDA Release 2.0, Data Types – Abstract Specification 2.36.9 – Literal Form*]

[*Appendix B – Additional Information on ISO8601 – Time and Date Stamps*]

confidentialityCode

Confidentiality is a required contextual component of CDA, where the value expressed in the header holds true for the entire document, unless overridden by a nested value. The coding strength for this element is Coded With Extensions (CWE).

Examples:

Normal Confidentiality per HL7 vocabulary

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

Restricted Confidentiality per HL7 vocabulary

```
<confidentialityCode code="R" codeSystem="2.16.840.1.113883.5.25"/>
```

Very Restricted Confidentiality per HL7 vocabulary

```
<confidentialityCode code="V" codeSystem="2.16.840.1.113883.5.25"/>
```

[*CRS Implementation Guide, Section 2.1.10 – ClinicalDocument/confidentialityCode*]

[*CDA Release 2.0, Section 4.2.1.5 – ClinicalDocument.ConfidentialityCode*]

[*HL7 Vocabulary Domains, Section 2.1 – HL7 Vocabulary Domain Values*]

recordTarget

The **recordTarget** represents the person whose chart this document belongs to. Typically this is the patient who is also the subject of the report, although the subject can be a tissue sample, fetus, etc.

A clinical document typically has exactly one **recordTarget** participant. In the uncommon case where a clinical document (such as a group encounter note) is placed into more than one patient chart, more than one **recordTarget** participants can be stated.

The **recordTarget(s)** of a document are stated in the header and propagate to nested content, where they cannot be overridden.

CRS Constraint: at least one **recordTarget** must be present in the document, and **birthTime** and **administrativeGenderCode** elements shall be present as this information is needed by the users of a Care Record Summary. If unknown, it shall be represented using a flavor of null.

The value for **birthTime** must be accurate to the day.

Values for **administrativeGenderCode** should be drawn from the HL7

AdministrativeGender vocabulary. The allowed values are presented in the following table:

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.

Example:

```

<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="19320924"/>
    </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>

```

[*CRS Implementation Guide, Section 2.2 – Participants*]

[*CRS Implementation Guide, Section 2.2.1 – recordTarget*]

[[CDA Release 2.0, Section 4.2.2 – CDA Header Participants](#)]

[[CDA Release 2.0, Section 4.2.2.11 – recordTarget](#)]

author

The **author** is a participant in a CRS document and represents the humans and/or machines that created the document content. A document may have multiple contributors in which case each

must be identified in the document. Note that in some cases the **author** and [dataEnterer](#) may be the same person.

CRS Constraint: the **author** is a required element and has required child elements **time** (indicates the start time of the author's participation in the creation of the document) and **assignedAuthor** which in turn requires either the presence of an **assignedPerson** or an **assignedAuthoringDevice** element. The **assignedAuthoringDevice** element is required when a device facilitates the creation of a document by a patient or other non-practitioner (e.g. a kiosk where the patient can enter information that will become part of the document). It, in turn, requires a **softwareName** element present when it occurs in the document.

The **assignedPerson** element contains a **name**, which in turn has child elements **prefix**, **given**, **family** and **suffix**.

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. Please refer to the CRS IG, Appendix D – Documents Created by Non-Practitioners of the CRS IG which discusses these issues as they are beyond the scope of this guide.

Example:

In this example, the author is a physician using a software application to create the document

```
<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>

```

[*CRS Implementation Guide, Section 2.2 – Participants*]

[*CRS Implementation Guide, Section 2.2.2 – author*]

[*CRS Implementation Guide, Appendix D – Documents Created by Non-Practitioners*]

[[CDA Release 2.0, Section 4.2.2 – CDA Header Participants](#)]

[[CDA Release 2.0, Section 4.2.2.2 – author](#)]

custodian

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

Note that **custodian**, by inclusion, contains required child element **assignedCustodian**.

assignedCustodian requires a **representedCustodianOrganization**, which requires an **id** and may have an optional **name** element. Custodian organizations are encouraged to obtain and register their OID with HL7 to facilitate exchange of instances.

Note that systems that allow patients to create Care Record Summaries for their own use **must** maintain a true and accurate copy of the document, see the CRS IG, Appendix D – Documents Created by Non-Practitioners for more details on this requirement.

Example:

```

<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>

```

[[Use of IDs and Codes](#)]

[*CRS Implementation Guide, Section 2.2 – Participants*]

[*CRS Implementation Guide, Section 2.2.5 – custodian*]

[*CRS Implementation Guide, Appendix D – Documents Created by Non-Practitioners*]

[[CDA Release 2.0, Section 1.1 – What is the CDA](#)]

[[CDA Release 2.0, Section 4.2.2 – CDA Header Participants](#)]

[[CDA Release 2.0, Section 4.2.2.3 – custodian](#)]

documentationOf and serviceEvent

These elements describe the encounter during which the subject was seen and may include a code to describe the encounter as well as identifying the provider, location, time. It indicates the episode of care that the provider further describes in the content of the Care Record Summary

CRS Constraint: This is a required element, and only one **documentationOf** element may be present. It shall indicate the episode of care that the provider describes in the additional content of the CRS document.

Within the **documentationOf** element, there is one **serviceEvent** element, and the value of the *classCode* attribute is fixed to “PCPR”.

This event is some form of care provision and the type of care provided may be further described in the **code** element. If present, the value of the **code** element in this location shall not conflict with the values of the **code** element that is a direct child of the root **ClinicalDocument** element.

The **effectiveTime** is required and indicates the duration over which care was provided, as such it must contain both **low** and **high** elements.

The **serviceEvent** should have at least one performer, which shall list the relevant providers of healthcare during the episode being summarized.

The specific type of provider may be listed in the **performer/assignedEntity/code** element. If present, the values for the code element in this location shall be drawn from SNOMED CT using values drawn from the healthcare professional subtype hierarchy.

Each **assignedEntity** must have at least one **assignedPerson** or **representedOrganization**.

Example:

```
<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>

```

[*CRS Implementation Guide, Section 2.2.10 – documentationOf*]

[*CDA Release 2.0, Section 4.2.3 – Header Relationships*]

[*CDA Release 2.0, Section 4.2.3.2 – ServiceEvent*]

realmCode

This element identifies the realm to which this document applies.

CRS Constraint: The CRS IG was written specifically for use in the United States, therefore the element is required and the *code* value of **realmCode** is limited to “US”. Future expansion of the CRS IG may generalize and allow other realms; the current version used as the basis for this guide mandates the code value to be fixed to reflect the constraint.

Example:

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

[*CRS Implementation Guide, Section 2.1.3 – ClinicalDocument/realmCode*]

[*HL7 Reference Information Model, Section 3.4.1.2 – InfrastructureRoot.realmCode*]

templateId

A template ID is used to identify that a pre-determined template has been used as the basis for the creation of the document.

CRS Constraint: CRS requires this element be present, and that its value be fixed. CRS defines two levels of compliance, so the element would appear only once to indicate “Level 1”, or twice to indicate that the document meets both “Level 1” and “Level 2” requirements.

If additional templates are applied, additional elements may be present.

Examples:

When the document is a Level 1 document

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

When the document is a Level 2 document

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

[*CRS Implementation Guide, Section 2.1.5 – ClinicalDocument/templateId*]

[*CDA Release 2.0, Section 4.1 – Clinical Document*]

[*HL7 Reference Information Model, Section 3.4.1.4 – InfrastructureRoot.templateId*]

languageCode

The **languageCode** element indicates which human language the document is authored in.

CRS Constraint: this element is required. Further, per section 2.1.11 of the CRS IG, the document must, at a minimum, contain the language identifier drawn from [ISO-639-1](#) and optionally the country identifier drawn from [ISO-3166](#).

The format is a lowercase 2-alpha character string for the language with optionally an uppercase 2-alpha character string indicating the country.

Examples:

To specify English without indication of location of usage (dialect)

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

To specify English as used in the United States

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

To specify English as used in the United Kingdom

```
< languageCode code="en-GB"/>
```

[*CRS Implementation Guide, Section 2.1.11 – ClinicalDocument/languageCode*]

[*CDA Release 2.0, Section 4.2.1.6 – ClinicalDocument.languageCode*]

CRS Header – Optional Elements

The following sections identify a number of optional header elements that are available for use within a CRS document. Not that although they are optional, some elements have rules on how they are used if included.

title

This element is optional and represents the local title for the document. Where these display names are rendered to the clinician, or where the document has a local title, the **title** element should be used.

Example:

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

[*CRS Implementation Guide, Section 2.1.8 – ClinicalDocument/title*]

[*CDA Release 2.0, Section 4.2.1.3 – ClinicalDocument.title*]

setId and versionNumber

As with the **id** element, these two elements are related to document management. They are used together to indicate that the document is a member of a set where all the members of the set are multiple revisions of the same document. The **setId** is a unique string that is common across all the members of the set (the revisions), where the **versionNumber** is an integer value indicating the specific revision.

CRS Constraint: this element pair is optional, although if present, both elements must be present. Additionally, the **root** attribute of **setId** must be different from the value of the **root** attribute of the **id** element that is the globally unique identifier.

Examples:

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

[*CRS Implementation Guide, Section 2.1.12 – ClinicalDocument/setId and ClinicalDocument/versionNumber*]

[*CDA Release 2.0, Section 4.2.1.7 – ClinicalDocument.setId*]

[*CDA Release 2.0, Section 4.2.1.8 – ClinicalDocument.versionNumber*]

[*CDA Release 2.0, Section 4.2.3 – Header Relationships*]

[*CDA Release 2.0, Section 4.2.3.1 – ParentDocument*]

copyTime

CRS Constraint: this element is deprecated in CDA, therefore it is prohibited from appearing in a CRS document.

[*CRS Implementation Guide, Section 2.1.13 – ClinicalDocument/copyTime*]

dataEnterer

The **dataEnterer** is an optional element and identifies a participant in a CRS document. A **dataEnterer** is defined as a person or system that transfers information from one form or another (e.g. from paper to an electronic system) without creating new information through application of their knowledge or skills. A **dataEnterer** is usually but not always a transcriptionist or clerk copying information from a form into a document without interpretation or extrapolation from the source. In some cases the [author](#) and **dataEnterer** may be the same person.

CRS Constraint: If present requires an **assignedEntity** and optionally a **time** element which, if present, indicates the starting time of data entry.

Example:

```
<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>
```

[*CRS Implementation Guide, Section 2.2 – Participants*]

[*CRS Implementation Guide, Section 2.2.3 – dataEnterer*]

[*CDA Release 2.0, Section 4.2.2 – CDA Header Participants*]

[*CDA Release 2.0, Section 4.2.2.4 – dataEnterer (Transcriptionist)*]

informant

The **informant** is an optional element and identifies a participant in a CRS document who is a source of the information in the CRS. The **code** element of the **assignedEntity** or **relatedEntity**, if present, describes the relationship between the informant and the patient.

CRS Constraint: If present must contain either an **assignedEntity** or **relatedEntity**. There are a number of possible informants, please refer to the CRS IG for a complete description of the rules for each one as they vary by type. The examples below are provided to demonstrate the range of types.

CRS requires that the informant identified in **relatedEntity** must be specified in the *classCode*. The allowable values are CON (contact), PRS (personal relationship) or PROV (healthcare provider) from the [RoleClass](#) vocabulary.

Examples:

To represent a healthcare provider with a specific assigned healthcare role where the role 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>
    <telecom value="tel:(999)555-1212" use="WP"/>
    <name>
      <prefix>Dr.</prefix>
      <given>Bernard</given>
      <family>Wiseman</family>
      <suffix>Sr.</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 significant 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>
      </name>
    </relatedPerson>
  </relatedEntity>
</informant>

```

```
</relatedEntity>
</informant>
```

Note: the RoleCode and RoleClass vocabularies contain mnemonics for a large number of relationships. Some common ones are:

MTH – mother
FTH – father
SON – natural son
SONADOPT – adopted son
DAU - natural daughter
DAUADOPT – adopted daughter
CON – contact
PROV – health care provider

[*CRS Implementation Guide, Section 2.2 – Participants , 2.2.4 – informant, and sub sections 1-4 on Assigned Healthcare Providers, Personal Relations, Unrelated Person and Healthcare Providers*]

[[CDA Release 2.0, Section 4.2.2 – CDA Header Participants](#)]

[[CDA Release 2.0, Section 4.2.2.6 – informant](#)]

[[HL7 Vocabulary Domains - RoleCode & RoleClass](#)]

informationRecipient

The **informationRecipient** is a participant in a CRS document in the context of a referral or request for consultation. This element is optional and is used to record the intended recipient of the document at the time the document is created. The intended recipient may be the health chart of the patient, in which case the **receivedOrganization** shall be the scoping organization of that chart.

Example:

```
<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"/>
  </intendedRecipient>
  <informationRecipient>
    <name>
      <prefix>Dr.</prefix>
      <given>Phil</given>
      <family>Green</family>
    </name>
  </informationRecipient>
  <receivedOrganization>
    <name>Good Health Clinic</name>
  </receivedOrganization>
```



```
</intendedRecipient>
</informationRecipient>
```

[*CRS Implementation Guide, Section 2.2 – Participants*]

[*CRS Implementation Guide, Section 2.2.6 – informationRecipient*]

[*CDA Release 2.0, Section 4.2.2 – CDA Header Participants*]

[*CDA Release 2.0, Section 4.2.2.7 – informationRecipient*]

legalAuthenticator

The **legalAuthenticator** is an optional element and identifies a participant in a CRS document who is the legal authenticator of the document. The act of legal authentication requires privileges be granted to the authenticator depending on local policy. In the case of a patient or other non-practitioner authored document, this privilege may not be available to the author. CRS documents should have the potential to be legally authenticated by an assigned person or entity with the proper credentials. When present, the **legalAuthenticator** must refer to a person who is accepting responsibility for the document.

CRS Constraint: This constraint is a non-validating rule (from an XML perspective) in that this element is optional **UNLESS** the document has been legally authenticated, in which case it is required (this is a fact known only to the creating organization). CRS documents may be released before legal authentication has occurred based on local practice, in which case the absence of this element implies that the CRS has not been legally authenticated.

Example:

```
<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"/>
    <name>
      <prefix>Dr.</prefix>
      <given>Phil</given>
      <family>Green</family>
    </name>
  </assignedEntity>
</legalAuthenticator>
```

[*CRS Implementation Guide, Section 2.2 – Participants*]

[*CRS Implementation Guide, Section 2.2.7 – legalAuthenticator*]

[*CDA Release 2.0, Section 4.2.2 – CDA Header Participants*]

[*CDA Release 2.0, Section 4.2.2.8 – legalAuthenticator*]

authenticator

The **authenticator** is an optional element and identifies a participant in a CRS document that has verified the accuracy of the information in the document, but who does not have privileges to legally authenticate the document. A document may have 0 to many authenticators.

Example:

```
<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>Phil</given>
        <family>Green</family>
      </name>
    </assignedPerson>
  </assignedEntity>
</authenticator>
```

[*CRS Implementation Guide, Section 2.2 – Participants*]

[*CRS Implementation Guide, Section 2.2.8 – authenticator*]

[[CDA Release 2.0, Section 4.2.2 – CDA Header Participants](#)]

[[CDA Release 2.0, Section 4.2.2.1 – authenticator](#)]

participant

The **participant** is an optional element and identifies other supporting participants in a CRS document including: parents, relatives, care givers, insurance policy holders, guarantors and others related in some way to the patient. See the entry for [documentationOf](#) for information about healthcare providers who are involved in patient care during the episode being summarized.

Example:

When the participant is the guarantor

```
<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"/>
  </associatedEntity>
</participant>
```

```

    <associatedPerson>
      <name>
        <prefix>Mr.</prefix>
        <given>Kenneth</given>
        <family>Ross</family>
      </name>
    </associatedPerson>
  </associatedEntity>
</participant>

```

[*CRS Implementation Guide, Section 2.2 – Participants*]

[*CRS Implementation Guide, Section 2.2.9 – participant*]

[[CDA Release 2.0, Section 4.2.2 – CDA Header Participants](#)]

[[CDA Release 2.0, Section 4.2.2.9 – participant](#)]

inFulfillmentOf

This element is optional and describes the prior orders that are fulfilled in whole or part by events described in the CRS. It is anticipated that CRS documents will rarely be created in response to an order, which is the type of information **inFulfillmentOf** is intended to convey.

[*CRS Implementation Guide, Section 2.2 – Participants*]

[*CRS Implementation Guide, Section 2.2.11 – inFullfillmentOf*]

[[CDA Release 2.0, Section 4.2.3 – Header Relationships](#)]

[[CDA Release 2.0, Section 4.2.3.3 – Order](#)]

authorization

This element is optional and represents the consents associated with this document, e.g. the consent to perform the service related in the **serviceEvent**, consent to release the information in the document to a third party, etc. CDA states “Consents referenced in the CDA Header have been finalized (Consent.statusCode must equal "completed") and should be on file.” The OID indicates this value is from the HL7 ActStatus vocabulary.

Example:

```

<authorization>
  <consent>
    <statusCode code="completed" codeSystem="2.16.840.1.113883.5.14"/>
  </consent>
</authorization>

```

[*CRS Implementation Guide, Section 2.2 – Participants*]

[*CRS Implementation Guide, Section 2.2.12 – authorization*]

[[CDA Release 2.0, Section 4.2.3 – Header Relationships](#)]

[[CDA Release 2.0, Section 4.2.3.4 – Consent](#)]

componentOf

This is an optional element that identifies the encounter to which this document pertains.

CRS Constraint: If the CRS document is coded as a Discharge Summarization, then the **componentOf** element must be present. It shall describe the encounter from which the patient is being discharged.

The **componentOf** has a required **encompassingEncounter** element, which in turn contains a required **id** element and a required **effectiveTime** element.

In the following example, the value for **dischargeDispositionCode** is drawn from a common reimbursement form (UB92). Neither CDA nor CRS currently specify or place constraints on the vocabulary for these values.

Example:

In the case where the document is coded as a Discharge Summarization

```
<componentOf>
  <encompassingEncounter>
    <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>
```

[*CRS Implementation Guide, Section 2.2 – Participants*]

[*CRS Implementation Guide, Section 2.2.13 – componentOf*]

[[CDA Release 2.0, Section 4.2.3 – Header Relationships](#)]

[[CDA Release 2.0, Section 4.2.3.5 – EncompassingEncounter](#)]

CRS Body Elements

The CDA body can be represented using a **nonXMLBody** or a **structuredBody** element. The former is used when the content is an external file such as a TIFF image, text file, etc. The latter is used when the body will be XML structured content. XML structured content is always inserted into the **structuredBody** element, never as an external file.

structuredBody

CDA with a structured (XML) body stipulates the use of the **structuredBody** element. A structured body may be coded as a Level 1 or Level 2.

CRS Constraints: A CRS **structuredBody** has the following required sections with permissible LOINC values:

Conditions – 11535-2 or 11450-4

Allergies – 10155-0 or 8658-7

Medications – 10183-2 or 10160-2

Additionally, if the CRS is coded as a Discharge Summary, it must contain a section coded Hospital Course – 8648-8

A **section** must have a **code** element, and must contain at least one **text** element or one or more **component** elements; **text** and **component** elements, if present, must contain content.

The conditions section shall include all active problems, and may include resolved problems. This information may be presented in one or more sections within the document to further classify the conditions as preliminary or final diagnoses, reported chief complaint or reason for visit, prior illnesses or injuries, et cetera. If there are no current problems, this information must be provided. If the current problems are unknown, this information must be provided. Problem lists shall include information about active/resolved status of each item.

The allergies section shall describe any and all allergies, adverse reactions and intolerances whether medicinal, dietary, or other. If the patient has no known allergies, or if unknown to be allergic to any substances, that information shall be provided.

The medications section shall list all medications that the patient is currently taking or which have been prescribed. It may also include medications previously used by the patient, in which case the information must be clearly identified such that a reader of the document can determine which medications are current. Medications may appear in one or more locations in the document to distinguish medications identified on admission, given during the encounter, or prescribed for later use by the patient.

These sections must be identified by the use of a LOINC value. CRS describes the appropriate contents, but imposes no further requirements on markup beyond those for any CDA. Note that some values in the examples begin with the letter X, these are values that are not currently found in LOINC but are to be submitted for inclusion in the LOINC database at the close of the CRS ballot.

The CRS body defines a number of optional sections as well: Reason for Visit/Chief Complaint, Reason for Referral, Advance Directives, History of Present Illness, Functional Status, Family History, Social History, Immunizations, Past Surgical History, Prior Encounters, Review of

Systems, Physical Examinations, Vital Signs, Studies and Reports, Fetal Vital Signs, and Plan of Care. These sections should be identified by the use of a LOINC value.

Section codes have been coordinated with other domains, such as Claims Attachments, for content reuse in a response to a query.

Sections may appear in any order, and may be nested as appropriate, e.g. vital signs may be nested within a physical examination section.

Level 1 and Level 2 are distinguished by the presence of the **code** element, and the values and code system it declares. A Level 1 instance would contain the required sections but without the use of the **code** and the additional information it conveys via LOINC values. An instance where these elements are present and their values adhere to the guidelines set forth in the CRS IG may be considered Level 2 instances. The examples below would indicate a Level 2 instance.

Example:

The examples given are for the three required sections, please refer to the populated example file for other sections. Note the section codes are showing as **variable** but in this context it is variable between the two possible codes for each section as listed above.

```
<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>Date</th>
            <th>Comments</th>
          </tr>
        </thead>
        <tbody>
          <tr>
            <td>Cholecystitis</td>
            <td>9/28/2002 - 6/2003</td>
            <td>Resolved</td>
            <td>Surgery postponed until after delivery</td>
          </tr>
          <tr>
            <td>Pregnancy</td>
            <td>7/2001 - 4/22/2002</td>
            <td>Resolved</td>
            <td>Prior history of miscarriage</td>
          </tr>
          <tr>
            <td>Ankle Sprain</td>
            <td>3/28/2005</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>Amoxicillin 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>Dates of Use</th>
          </tr>
        </thead>
        <tbody>
          <tr>
            <td>Indomethacin</td>
            <td>50mg bid with food </td>
            <td>12/10/2003 - present</td>
          </tr>
          <tr>
            <td>Acetaminophen with codeine</td>
            <td>#3 1-2 tablets for pain as needed</td>
            <td>03/28/2005</td>
          </tr>
        </tbody>
      </table>
    </text>
  </section>
</component>

```

If the document is a Discharge Summary, the following section will be present:

```
<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.</text>
  </section>
</component>
```

nonXMLBody

A **nonXMLBody** contains a **text** element, which has an optional *mediaType* attribute which identifies the encoding of the encapsulated data and identifies a method to interpret or render the data. Preferred *mediaType* values include "image/gif", "image/tiff", "text/rtf", "application/pdf", "image/g3fax", "text/html", "image/jpeg", "image/png", and "text/plain".

A **text** element may contain a **reference** or **thumbnail** element. The **reference** has a required attribute of **value**, which contains a URL pointing to the external object. It should contain an optional **useablePeriod** that can declare the length of time the object will be available.

CRS Constraint: Use of a **nonxmlBody** does not eliminate the requirement for required content in clearly identified sections as stipulated [above](#). These sections must be present but may be in any order.

Examples:

A non-XML body with text content

```
<component>
  <nonXMLBody mimeType="text/plain">
    <text>This is a care record summary</text>
  </nonXMLBody>
</component>
```

A non-XML body with a reference to a URL with a usable period:

```
<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>
```

[CRS Implementation Guide, Section 3 – Body]

[[CDA Release 2.0, Section 1.2.1 - Major Components of a CDA Document](#)]

[[CDA Release 2.0, Section 4.3.4.1 – component](#)]

[Additional Information Specification 0004: Clinical Reports Attachment Implementation Guide (ASIG0004)]

Appendix A – Sample CRS Instance

Example files are supplied that incorporate the examples above, see the CRSsample.xml for a sample of a fully populated instance. Note that this file is the same sample supplied with the CRS Ballot 3 package.

An empty version of this file is also supplied with this guide as EmptySampleCRS.xml.

The method of rendering .xml files is not part of the normative CDA or HL7 specifications. Example style sheets are available as part of the CDA R2 distribution (cda.xsls) as well as the CRS Implementation Guide (impl_cdar2.xsls). The sample style sheet with the CRS IG is supplied with this Quick Start Guide (IMPL_CDAR2.xsl). Note that any instance of a style sheet may not render all of the content of the CDA/CRS header, depending on the application environment, but must render the section title and section.text field of the CDA body. For complete receiver rendering requirements, see CDA 1.3.1.

[\[CDA Release 2.0, Section 1.3.1 – Recipient Responsibilities\]](#)

Appendix B – Additional Information on ISO8601 – Time and Date Stamps

HL7 time declarations use ISO8601 format with modifications – the use of the T for delimiting date and time and the use of a “Z” to indicate Zulu are prohibited. Likewise, the use of dashes or other separators within the string are prohibited. The time and dates are structured as:

CCYYMMDDHHMMSS.UUUU([+|-]HHMM)

Where:

CC – century

YY – year

MM – month

DD – day

HH – hour (24 hour format)

MM – minute

SS – second

UUUU – fractions of a second, may be any number of fractional digits

+|- – indicates the offset from UTC where + indicates the zone is east of the zero meridian (up to the international dateline) and – indicates the zone is west of the zero meridian.

HH – hours offset

MM – minutes of offset

See also:

[\[CDA Release 2.0, Section 4.2.1.4 – ClinicalDocument.effectiveTime\]](#)

[\[CDA Release 2.0, XML Implementation Technology Specification – Data Types, Section 2.32 – Point in Time \(TS\) specializes QTY\]](#)

[\[CDA Release 2.0, Data Types – Abstract Specification 2.36.9 – Literal Form\]](#)