

HL7 CDA & C-CDA Primer

Clinical Data Architecture & Consolidated Clinical Data Architecture

Prepared for Washington State B&T Workgroup

November 2019

Page 1 of 32

Ver: 111919a

TABLE OF CONTENTS

Chapter	Page
TABLE OF CONTENTS	2
Clinical Document Architecture (CDA) – Overview	3
Consolidated Clinical Document Architecture (C-CDA) – Overview	6
Clinical Document Architecture (CDA) – Structure Overview.....	9
Clinical Document Architecture (CDA) – Structure Detail	25
References:	34

I. Clinical Document Architecture (CDA) - Overview

What is a CDA?

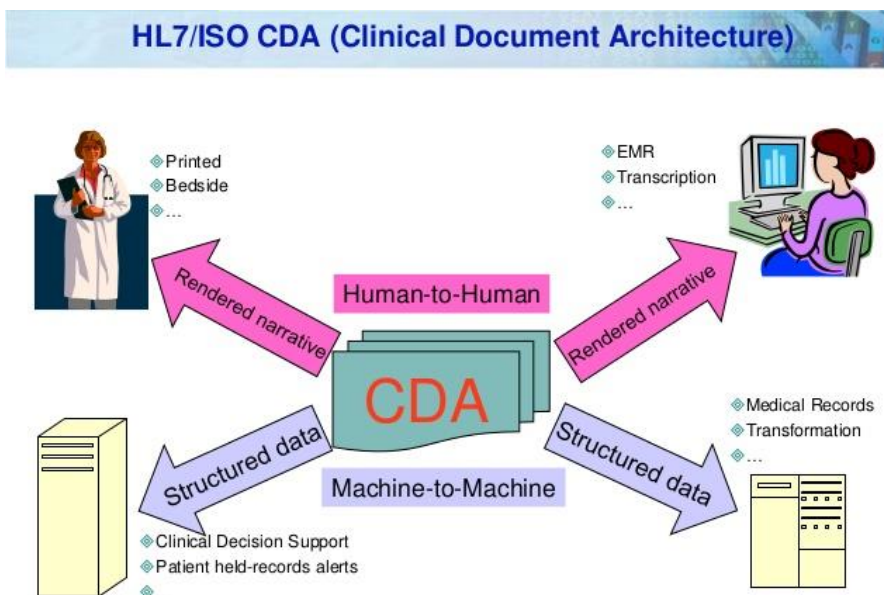
- Specification which defines how to structure clinical data as XML. The CDA provides a foundation for developing electronic documents. It is based on the HL7 Reference Implementation Model (RIM) which is an integral piece of HL7 Version 3 .
- CDA documents are stable and persist over time. (As opposed to HL7 Version 2/3 messaging which defines how to send transactions between clinical systems that are only valid during the time between when the sending system transmits that message and the receiving message has processed and integrated that message into its database).
- CDA is a broad class of artifacts. A CDA may be as simple as an electronic envelope, containing an image, or it may be as complex as a complete Transfer of Care Summary that contains the data in a format that can be displayed, but also in a computer readable format.

The importance and Purpose of CDA

- Transmit a snapshot of a patient's health record from point A to point B
- Compliant with Meaningful Use.
 - Requires participants to be able to create, transmit, receive, and incorporate HL7 Consolidated CDA documents of several types.
 - Optionally, participants must be able to report quality measures using HL7 Quality Reporting Document Architecture (QRDA) format

When to use CDA Documents

- The focus is on persistence of the document (artifact) – can be retrieved in the condition that it was originally sent
- Need tight control over authenticated content; signed and not edited when received
- When human readability across platforms is desirable; can be viewed in a browser




When to avoid using CDA Documents

- When the workflow requires rapid back-and-forth exchange, such as requesting information from a decision support engine or service or evoking a request response query.
- When the data are more dynamic, and persistence is not required—for example, when you only want to see how the data look in the moment, or when more than one person or entity will be contributing data over time.
- When the data need to be acquired from multiple sources and integrated, in which case HL7 messages may be simpler or otherwise more appropriate.

II. Consolidated Clinical Document Architecture (C-CDA) - Overview

A Implementation Guide-driven, consolidated use of HL7 templates to form a set of standard Documents

C-CDA IG Purpose: Single Source for CDA Templates



www.HealthIT.gov

<p>HL7 Implementation Guide for CDA R2: IHE Health Story Consolidation, DSTU Release 1.1 (US Realm) July 2012</p> <p>Document Templates: 9</p> <ul style="list-style-type: none"> • Continuity of Care Document (CCD) • Consultation Note • Diagnostic Imaging Report (DIR) • Discharge Summary • History and Physical (H&P) • Operative Note • Procedure Note • Progress Note • Unstructured Document <p>Section Templates: 60</p> <p>Entry Templates: 82</p>	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr style="background-color: #4F81BD; color: white;"> <th style="width: 15%;">Document Template</th> <th colspan="3" style="width: 85%;">Section Template(s)</th> </tr> </thead> <tbody> <tr> <td style="text-align: center; vertical-align: middle;">CCD</td> <td style="vertical-align: top;"> <p style="margin: 0;">Allergies</p> <p style="margin: 0;">Medications</p> <p style="margin: 0;">Problem List</p> <p style="margin: 0;">Procedures</p> <p style="margin: 0;">Results</p> <p style="margin: 0;">Advance Directives</p> <p style="margin: 0;">Encounters</p> </td> <td style="vertical-align: top;"> <p style="margin: 0;">Family History</p> <p style="margin: 0;">Functional Status</p> <p style="margin: 0;">Immunizations</p> <p style="margin: 0;">Medical Equipment</p> <p style="margin: 0;">Payers</p> <p style="margin: 0;">Plan of Care</p> </td> <td style="vertical-align: top; font-size: small;"> <p style="margin: 0;">Section templates highlighted in the two section template examples here demonstrate CDA's interoperability and reusability.</p> </td> </tr> <tr> <td style="text-align: center; vertical-align: middle;">History and Physical</td> <td style="vertical-align: top;"> <p style="margin: 0;">Allergies</p> <p style="margin: 0;">Medications</p> <p style="margin: 0;">Problem List</p> <p style="margin: 0;">Procedures</p> <p style="margin: 0;">Results</p> <p style="margin: 0;">Family History</p> <p style="margin: 0;">Immunizations</p> <p style="margin: 0;">Assessments</p> </td> <td style="vertical-align: top;"> <p style="margin: 0;">Assessment and Plan</p> <p style="margin: 0;">Plan of Care</p> <p style="margin: 0;">Social History</p> <p style="margin: 0;">Vital Signs</p> <p style="margin: 0;">History of Present Illness</p> <p style="margin: 0;">History of Present Illness</p> </td> <td style="vertical-align: top;"> <p style="margin: 0;">Chief Complaint</p> <p style="margin: 0;">Reason for Visit</p> <p style="margin: 0;">Review of Systems</p> <p style="margin: 0;">Physical Exam</p> <p style="margin: 0;">General Status</p> </td> </tr> </tbody> </table>	Document Template	Section Template(s)			CCD	<p style="margin: 0;">Allergies</p> <p style="margin: 0;">Medications</p> <p style="margin: 0;">Problem List</p> <p style="margin: 0;">Procedures</p> <p style="margin: 0;">Results</p> <p style="margin: 0;">Advance Directives</p> <p style="margin: 0;">Encounters</p>	<p style="margin: 0;">Family History</p> <p style="margin: 0;">Functional Status</p> <p style="margin: 0;">Immunizations</p> <p style="margin: 0;">Medical Equipment</p> <p style="margin: 0;">Payers</p> <p style="margin: 0;">Plan of Care</p>	<p style="margin: 0;">Section templates highlighted in the two section template examples here demonstrate CDA's interoperability and reusability.</p>	History and Physical	<p style="margin: 0;">Allergies</p> <p style="margin: 0;">Medications</p> <p style="margin: 0;">Problem List</p> <p style="margin: 0;">Procedures</p> <p style="margin: 0;">Results</p> <p style="margin: 0;">Family History</p> <p style="margin: 0;">Immunizations</p> <p style="margin: 0;">Assessments</p>	<p style="margin: 0;">Assessment and Plan</p> <p style="margin: 0;">Plan of Care</p> <p style="margin: 0;">Social History</p> <p style="margin: 0;">Vital Signs</p> <p style="margin: 0;">History of Present Illness</p> <p style="margin: 0;">History of Present Illness</p>	<p style="margin: 0;">Chief Complaint</p> <p style="margin: 0;">Reason for Visit</p> <p style="margin: 0;">Review of Systems</p> <p style="margin: 0;">Physical Exam</p> <p style="margin: 0;">General Status</p>
Document Template	Section Template(s)												
CCD	<p style="margin: 0;">Allergies</p> <p style="margin: 0;">Medications</p> <p style="margin: 0;">Problem List</p> <p style="margin: 0;">Procedures</p> <p style="margin: 0;">Results</p> <p style="margin: 0;">Advance Directives</p> <p style="margin: 0;">Encounters</p>	<p style="margin: 0;">Family History</p> <p style="margin: 0;">Functional Status</p> <p style="margin: 0;">Immunizations</p> <p style="margin: 0;">Medical Equipment</p> <p style="margin: 0;">Payers</p> <p style="margin: 0;">Plan of Care</p>	<p style="margin: 0;">Section templates highlighted in the two section template examples here demonstrate CDA's interoperability and reusability.</p>										
History and Physical	<p style="margin: 0;">Allergies</p> <p style="margin: 0;">Medications</p> <p style="margin: 0;">Problem List</p> <p style="margin: 0;">Procedures</p> <p style="margin: 0;">Results</p> <p style="margin: 0;">Family History</p> <p style="margin: 0;">Immunizations</p> <p style="margin: 0;">Assessments</p>	<p style="margin: 0;">Assessment and Plan</p> <p style="margin: 0;">Plan of Care</p> <p style="margin: 0;">Social History</p> <p style="margin: 0;">Vital Signs</p> <p style="margin: 0;">History of Present Illness</p> <p style="margin: 0;">History of Present Illness</p>	<p style="margin: 0;">Chief Complaint</p> <p style="margin: 0;">Reason for Visit</p> <p style="margin: 0;">Review of Systems</p> <p style="margin: 0;">Physical Exam</p> <p style="margin: 0;">General Status</p>										

C-CDA includes all templates in *Final Rules for Stage 1 Meaningful Use, 45 CFR Part 170 – Health Information Technology and Cert. Criteria for Electronic Health Record: Final Rule*

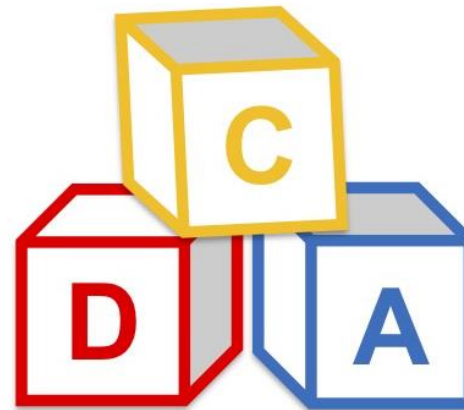
C-CDA R2.1 Document Types (12 of them)

Available in C-CDA R1.0/R1.1

- Consultation Note
- Continuity of Care (CCD)
- Diagnostic Imaging Report
- Discharge Summary
- History and Physical
- Operative Note
- Procedure Note
- Progress Note
- Unstructured Document

New as of C-CDA R2.0

- Care Plan
- Referral Note
- Transfer Summary



.....

HL7's CDA vs. C-CDA

- CDA **the schema for structured documents**

The HL7 Clinical Document Architecture (CDA) is a document markup standard that specifies the structure and semantics of "clinical documents" for the purpose of exchange.

- C-CDA **defines a set of CDA documents**

The HL7 Consolidated CDA is an implementation guide which specifies a library of templates and prescribes their use for a set of specific document types.

III. Clinical Document Architecture (CDA) – Structure Overview

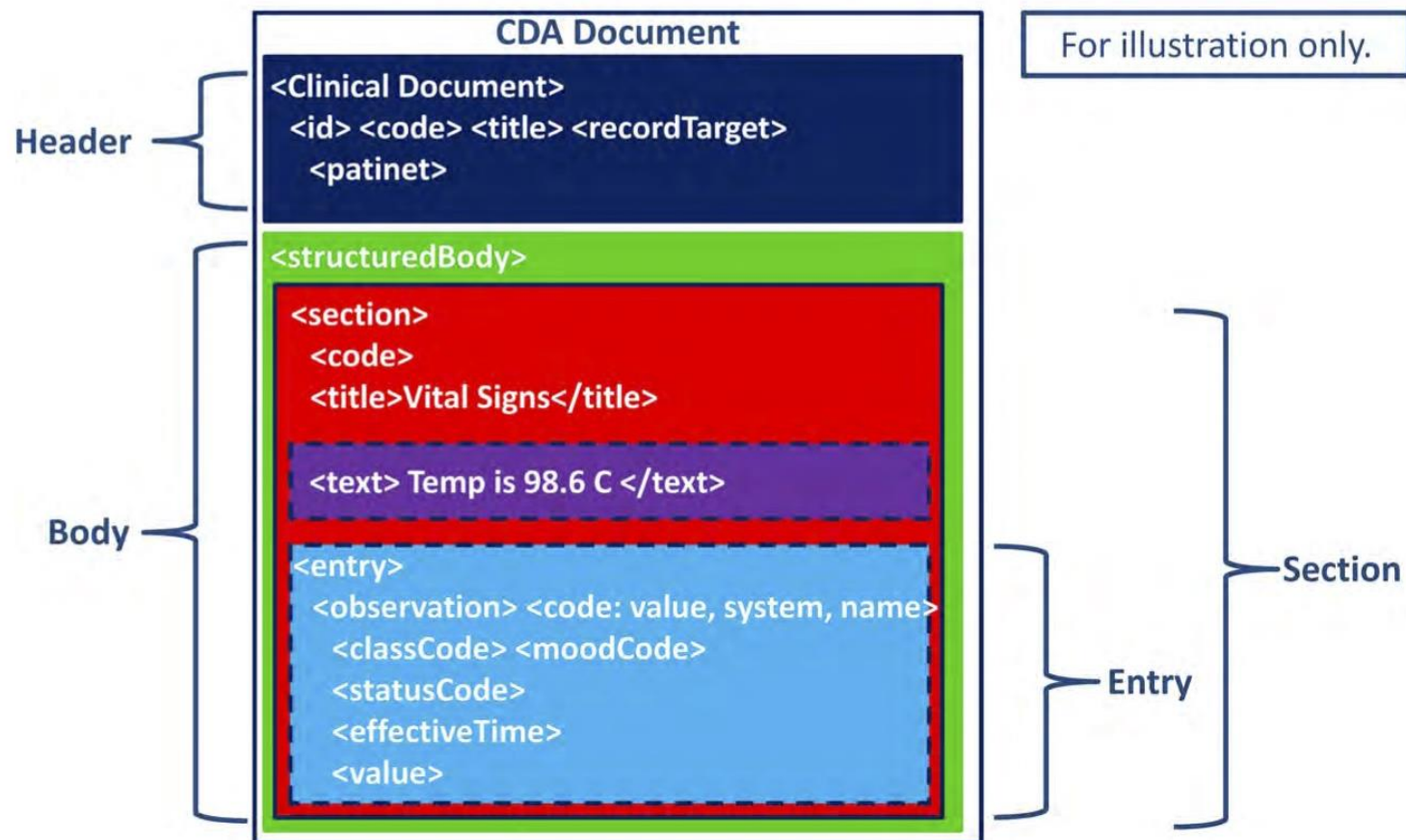
- **Header** – Demographic information about the patient along with other information about the document itself like who created it, where is it from, when was it created, what language is it in, etc.

- **Body** – Organization of one or more sections that contain information about the patient

The body contains the information about the person who is subject of the document. In a simple document, it may be a basic piece of information such as an X-ray image or a PDF document. Such basic pieces of information are called a non-XML body.

- **Sections** –Each section contains a specific type of clinical data. (Similar in concept to a database table which segments the table by content type.). Within the section it contains two things called Narrative and Entries.
 - **Narratives** – Human readable versions of entries. (Unstructured)
 - **Entries** – Individual row/records within the sections. coded machine processable information This might be Prilosec or Claritin for example. (Structured)

CDA Document Structure Example



CDA Document

Header (Structured) – Document Information,
Demographics, Data Provenance

Allergy Section

Narrative (Unstructured)

Penicillin (Structured)

Shellfish (Structured)

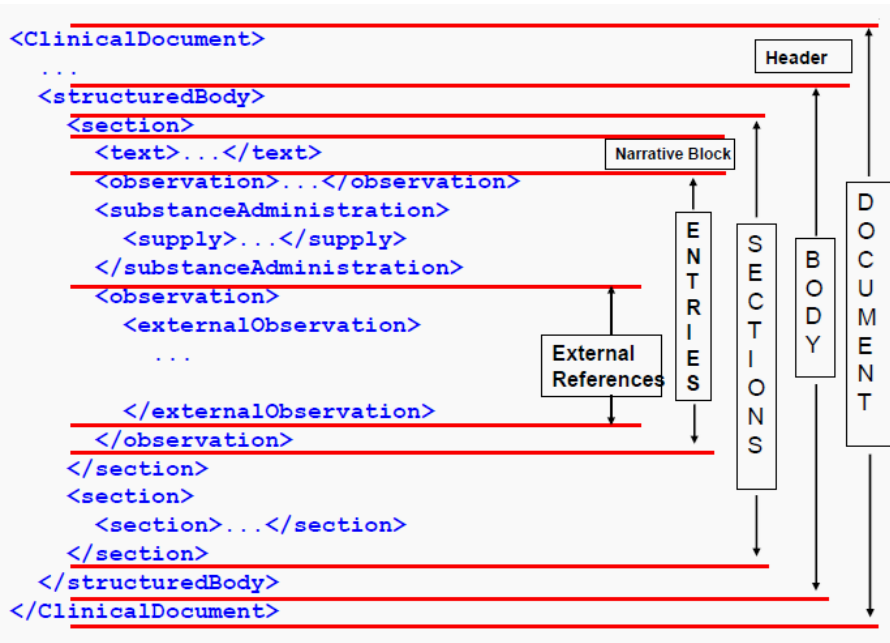
Medications Section

Narrative (Unstructured)

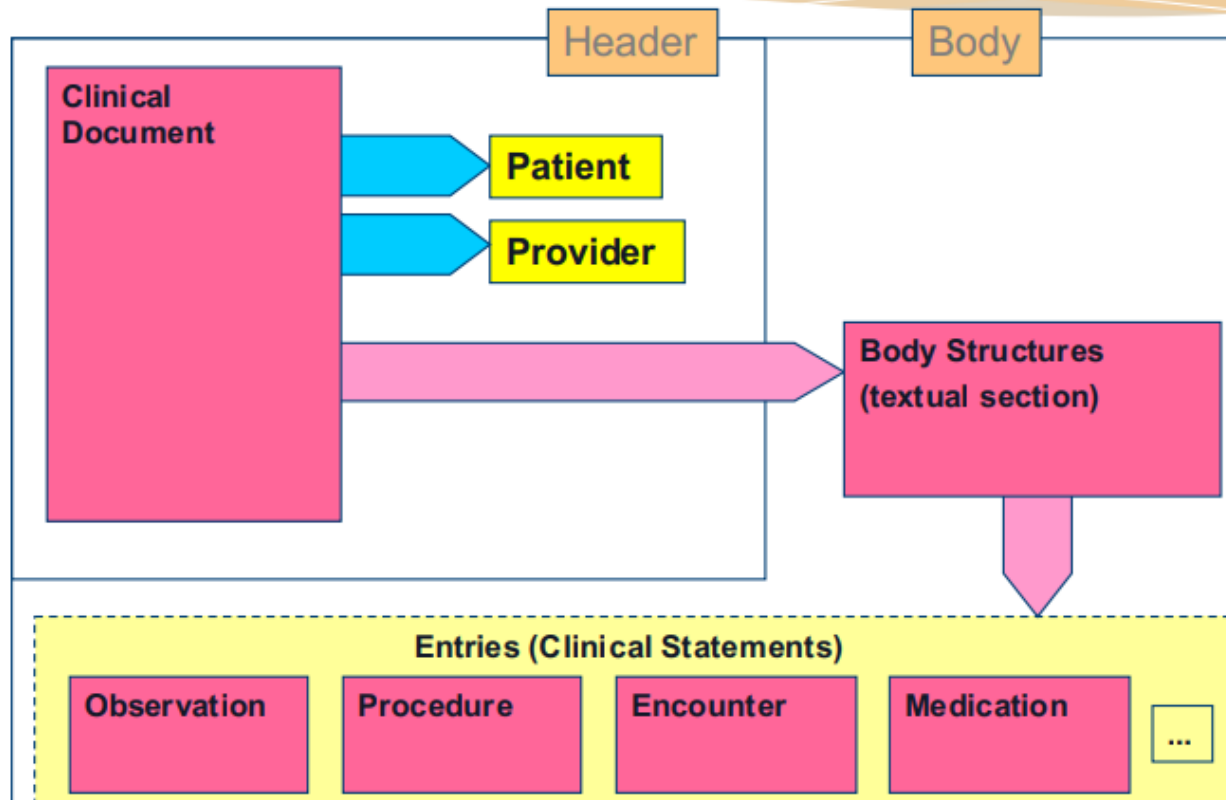
Prilosec (Structured)

Claritin (Structured)

Example of CDA XML Format Structure:



Structure of a CDA Document

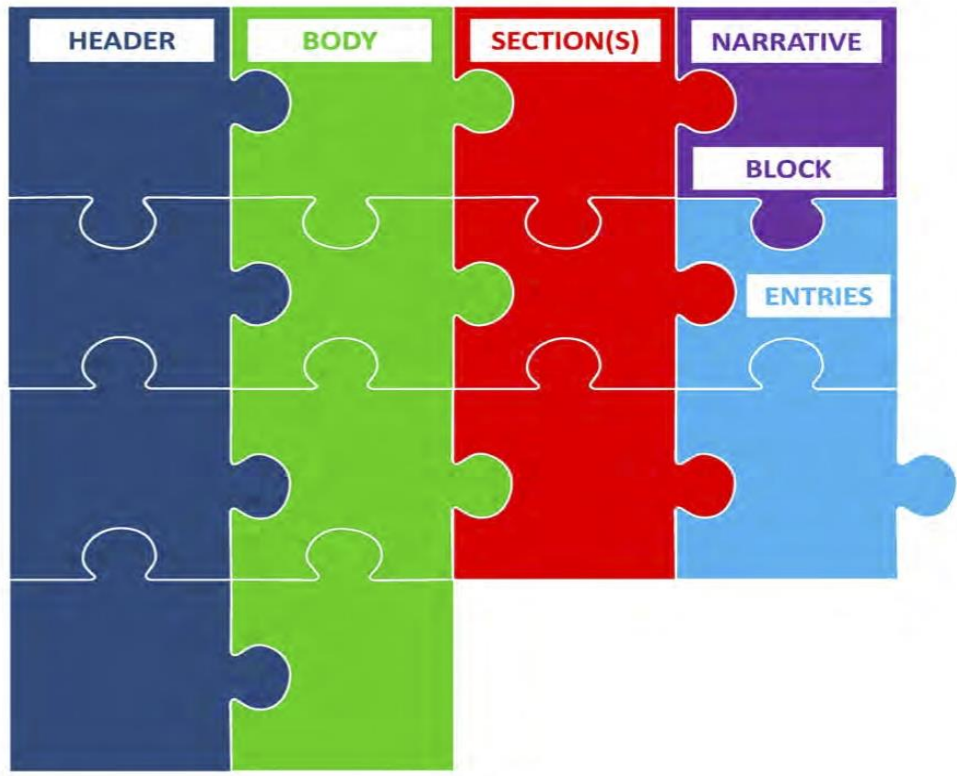


Structure of a CDA Document

- Form
 - A header providing the context:
 - To facilitate the exchanges and the management of the documents, their compilation in the patient record
 - A body
 - clinical information, ordered into sections, paragraphs, lists, tables, ...
- Encoding in XML
 - Comprehensive for the human...
 - ... and for the computers
 - can be validated by a schema



Clinical Document Architecture (CDA) – Structure Detail



Every CDA document must have AT LEAST a **Header** AND a One **Section**.

XML enables both human and machine readability.

The XML structure for a CDA document nests data in the following way:

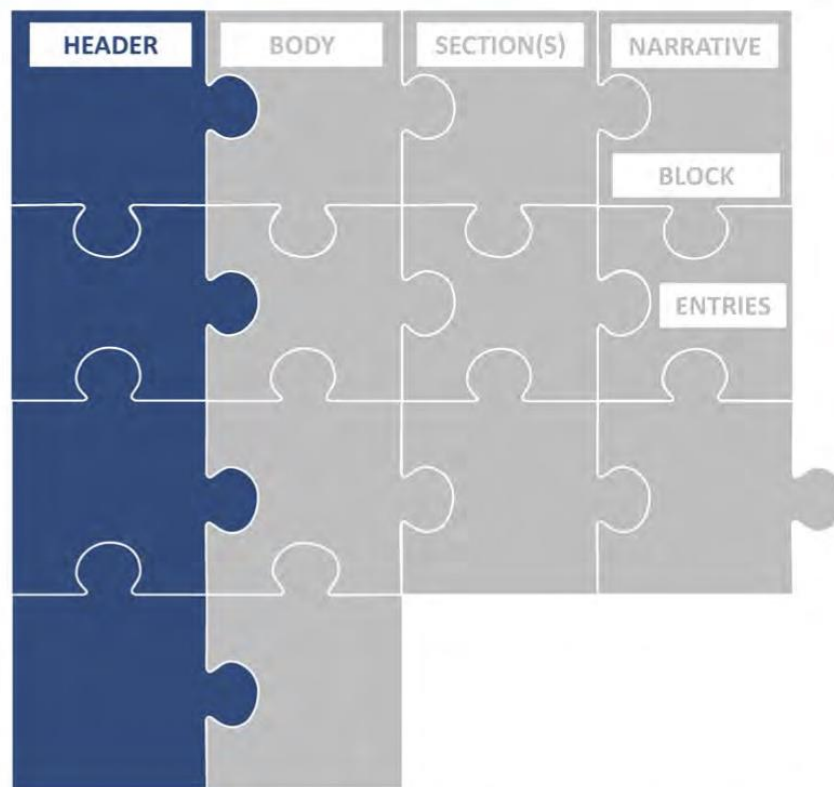
- » Header
- » Body
- » » Section(s)
- » » » Narrative Block
- » » » Entry(s)

T

CDA Header

CDA Structure: Header

Putting the I in HealthIT 
www.HealthIT.gov



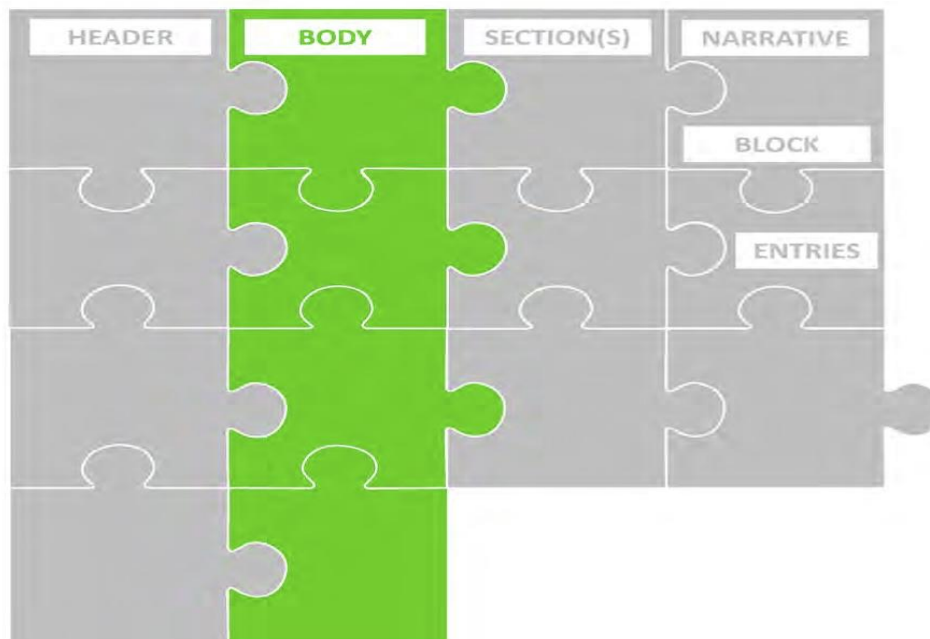
The **Header** sets the context for the clinical document as a whole and:

- enables clinical document exchange across and within institutions;
- facilitates clinical document management ; and
- facilitates compilation of an individual patient's clinical documents into a electronic patient record.

The Header: context of the document

- Identification of the document (ID, category/type, title, date, version)
- Confidentiality, language
- “Manager” of the document
- Patient
- Author
- Responsible Parties
- ...

CDA Body - Organizes the clinical content about the patient – either unstructured or structured



The **Body** contains the clinical report and can contain an unstructured “blob” or structured content organized in one or more **Sections**.

- Simple Body (Unstructured) - it may be a basic piece of information such as an X-ray image or a PDF document. Such basic pieces of information are called a non-XML body.
- Complex Body (Structured) – Divided into sections, each containing
 - Narrative block information, which is text that a human can read in a browser.
 - Entry block contains the same data described in the Narrative block, but in a format that a computer can consume.

CDA Body – Simple: Unstructured, e.g. containing a .pdf

Element/Attribute	DT	Card	Opt	Description
component	POCD_MT000040.Component2	[1..1]	M	
nonXMLBody	POCD_MT000040.NonXMLBody	[1..1]	M	

Element/Attribute	DT	Card	Opt	Description
nonXMLBody	POCD_MT000040.NonXMLBody	[1..1]	M	
text	ED	[1..1]	M	The actual narrative

(.PDF)

Element/Attribute	DT	Card	Opt	Description
text	ED	[1..1]	M	The actual narrative. The text value or the base 64 representation is to be written inside this tag.
@representation	BinaryDataEncoding	[0..1]	O	Values can be "B64" for base 64 encoding, or the default value "TXT".
@mediaType	cs	[0..1]	O	Values SHALL come from the Valueset eSanté_MimeTypes

Example: sending a PDF

```
<component>
  <nonXMLBody>
    <text mediaType='application/pdf'
representation='B64'>TWFuIGlzIGRpc3RpbmdlaXNoZWQsI= </text>
  </nonXMLBody>
</component>
```

CDA Body – Simple: Unstructured, e.g. containing a .pdf

- The CDA allows the capture of patient record in an unstructured format that is encapsulated within an image file or as unstructured text in an electronic file such as a word processing or Portable Document Format (PDF) documents
- The ‘component’ element is the first element of the CDA Body. It is common to both structured and unstructured narrative, and acts as a container for the actual data. Unstructured data is contained in the ‘nonXMLBody’ of the component element. The non-XML body is used when an external file contains all of the information to be transmitted as the attachment.
- The ‘nonXMLBody’ element carries the narrative through the ‘text’ element. Because the confidentiality and language code are already defined in the CDA Header, it would be a duplicate to specify them again here.
- The ‘text’ element is of type ED (Encapsulated Data). The text element contains the actual narrative, either as text, or base 64 content for PDF files. Accepted PDF documents are PDF/A compliant conforming to PDF/A-1b.
- The ‘@mediaType’ element should contain one of the following file type
 - Plain text .TXT text/plain
 - HTML .HTM, .HTML text/html
 - Joint Photographic Experts Group image ..JPG,..JPEG image/jpeg
 - Portable Document Format .PDF **application/pdf**
 - Portable Network Graphics image .PNG image/png
 - Graphics Interchange Format .GIF image/gif
 - Rich Text Format .RTF text/rtf
 - Tag Image File Format5 .TIF image/tiff
- In the case of a .PDF file the ‘@representation’ element should contain “64” for base 64 encoding.

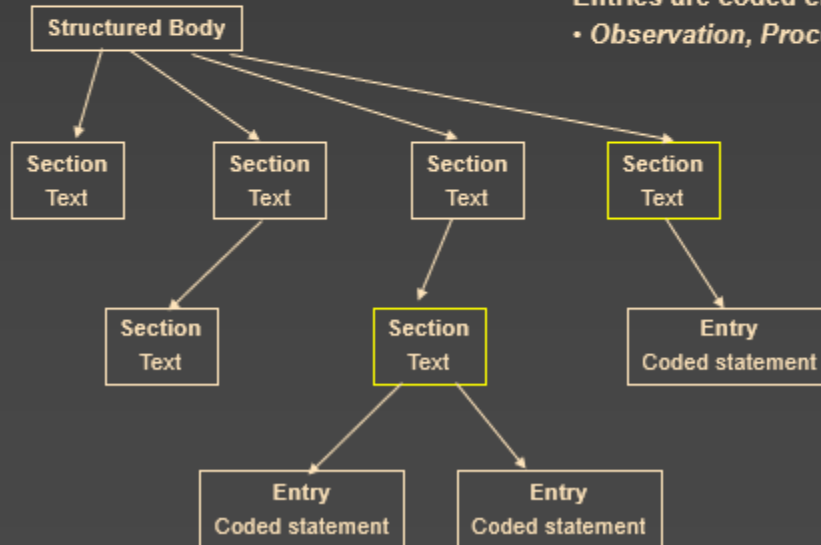
CDA Structured Body

Arrows are Act Relationships

• *Has component, Derived from, etc.*

Entries are coded clinical statements

• *Observation, Procedure, Substance administration, etc.*



Body Overview

- Header ✓

- Body

- Section

Human readable ✓

- Entry

Machine processable

- Entry

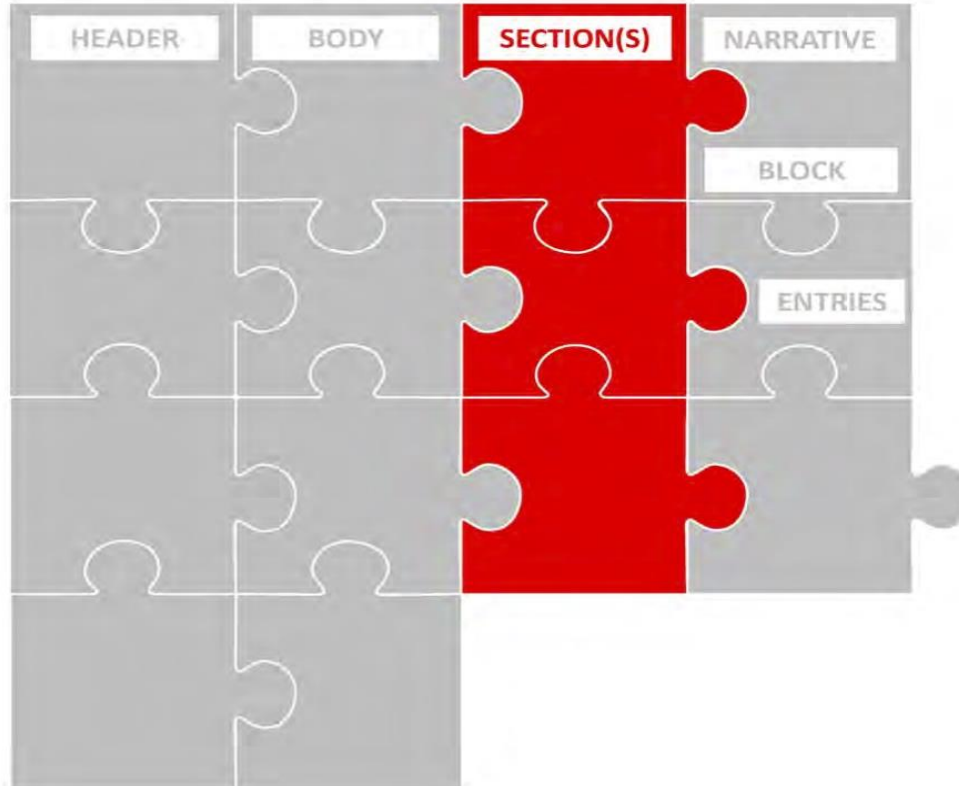
- Section

- Entry

- Section



IV. CDA Section (Structured Body)



Each **Section** contains one **Narrative Block** and zero to many coded **Entries**.

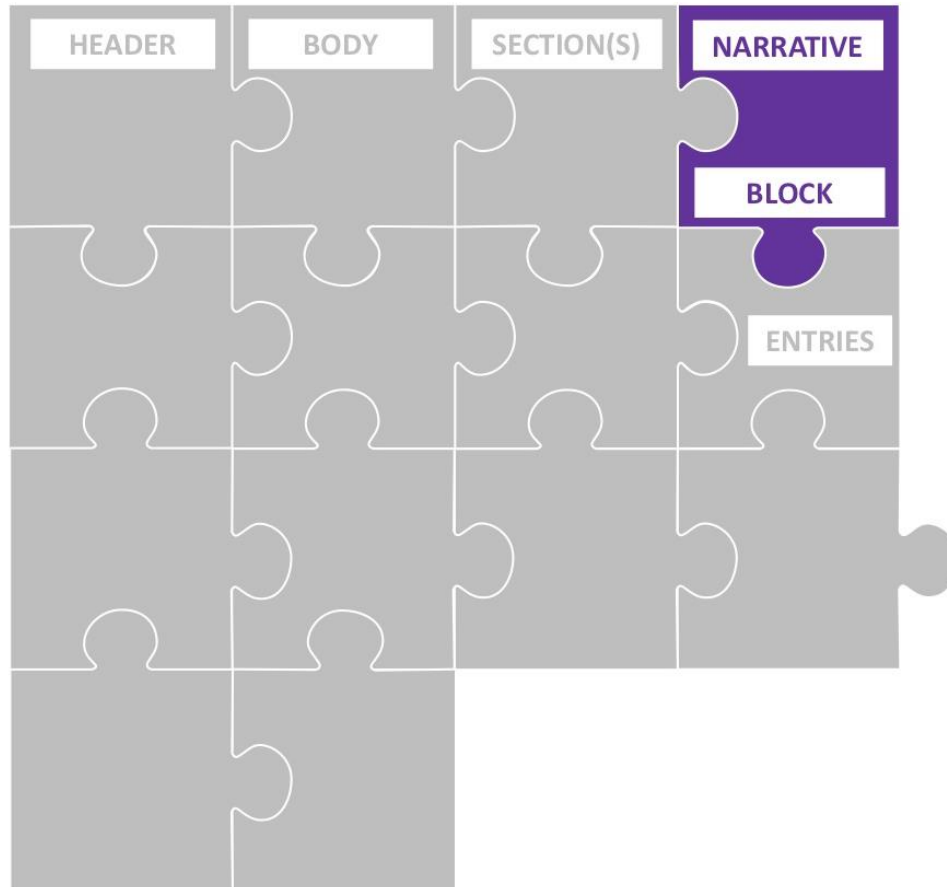
Examples include:

- **Allergies**
- **Meds**
- **Problems**
- **Immunizations**
- **Vital Signs**

The Narrative Block provides the human readable content.

CDA XML Structure: Narrative Block(s)

Putting the I in HealthIT 
www.HealthIT.gov



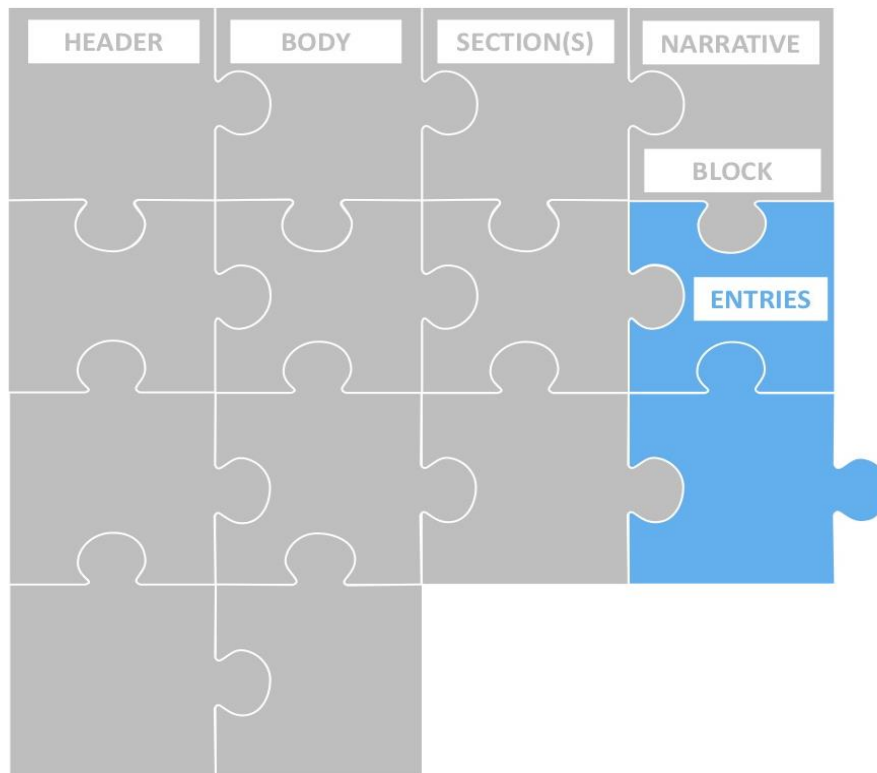
Narrative Blocks allows “human-readability” of a CDA document. Within a document section, the narrative block represents content to be rendered for viewing.

The **Narrative Block** has fixed markup, and must be populated by the document originator.

The Entries, if one is present, provides the machine readable version of the content.



CDA XML Structure: Entries

Putting the I in HealthIT
www.HealthIT.gov



Entries allows “machine-readability” (e.g. decision support applications). Within a document section, an entry represents structured content for further computer processing.

CDA Building Blocks / Templates



CDA Profiles Building Blocks

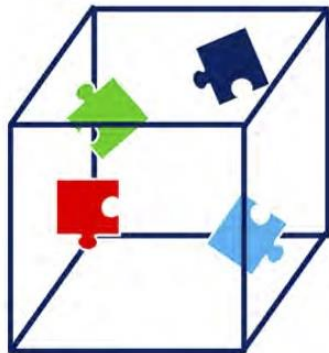
- Profiles are built from components
 - Patient
 - Medication List
 - Immunization Record
- Profiles specify which components *must* be included and which *may* be included

Toolkit for Planning an EHR-based Surveillance Program | www.phil.org/1HToolkit

CDA profiles (non-human readable) define the contents of the data package. They specify the requirements for each component and sub-component. For example, a patient is a person. A person has a name. The profile may specify that the name is required. The name is composed of subcomponents (last name, first name, middle name, etc.). The components will have documented requirements. For example, every person must have a name. Every name must have a last name and first name, but middle name may be optional.

CDA Usage

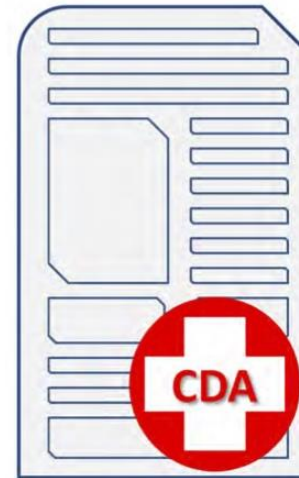
CDA defines building blocks which can be used to contain healthcare data elements that can be captured, stored, accessed, displayed and transmitted electronically for use and reuse in many formats



Sets of these CDA standardized building blocks can be arranged for whatever needs exist



Arranging (or constraining) the CDA elements in defined ways using IGs and templates produces clinical documents



This approach offers tremendous flexibility; it allows for the creation of a comprehensive variety of clinical documents which share common design patterns and use a single base standard

e.g. a *Discharge Summary* and an *Op Note* both draw from the same CDA schema but are scoped for different use cases

Templates

Table 1: Template Containments

Template Title	Template Type	templateId
Trauma Registry Submission Document	document	2.16.840.1.113883.3.2898.10.1
Hospital Care Episode Section	section	2.16.840.1.113883.3.2898.10.8
Hospital Care Episode Encounter	entry	2.16.840.1.113883.3.2898.10.81
Emergency Hospital Encounter	subentry	2.16.840.1.113883.3.2898.10.811
Emergency Hospital Observation Organizer	subentry	2.16.840.1.113883.3.2898.10.8111
Emergency Hospital Social History Observation Organizer	subentry	2.16.840.1.113883.3.2898.10.8112
Hospital Care Observation Organizer	subentry	2.16.840.1.113883.3.2898.10.813
Hospital Care Episode Observation Organizer	subentry	2.16.840.1.113883.3.2898.10.8131
Transportation Method Observation	subentry	2.16.840.1.113.883.3.2898.10.6111
Hospital Care Physiological Observation	subentry	2.16.840.1.113883.3.2898.10.8133
Nervous System Observation Organizer	subentry	2.16.840.1.113883.3.2898.10.8132
Nervous System Observation Organizer Entry	subentry	2.16.840.1.113.883.3.2898.10.511
Respiratory System Organizer	subentry	2.16.840.1.113883.3.2898.10.8134
Respiratory System Observation Organizer Entry	subentry	2.16.840.1.113.883.3.2898.10.411
Inpatient Hospital Encounter	subentry	2.16.840.1.113883.3.2898.10.812
Inpatient Hospital Encounter Detail Observation Organizer	subentry	2.16.840.1.113883.3.2898.10.8121

Document Template

3.1 Trauma Registry Submission Document

[ClinicalDocument: templateId 2.16.840.1.113883.3.2898.10.1 (closed)]

The Trauma Registry Submission Document (TRSD) is a collection of injury event, episode of care encounter, and clinical observations submitted to the National Trauma Data Bank by participating Hospitals or their agents for inclusion in the trauma registry.

CIM: TraumaRegistrySubmissionDocument

1. **SHALL** contain exactly one [1..1] @classCode="DOCCLIN" (CONF:28347).
2. **SHALL** contain exactly one [1..1] @moodCode="EVN" (CONF:28348).
3. **MAY** contain zero or more [0..*] realmCode (CONF:27764).

Note: This document specification is limited to the US realm only. It may be used outside the US realm, however, the user should be aware that data requirements outside the US realm were not considered when defining this specification.

4. **SHALL** contain exactly one [1..1] templateId="2.16.840.1.113883.3.2898.10.1" (CONF:27766).
 - a. This templateId **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.3.2898.10.1" (CONF:27786).
 - b. This templateId **MAY** contain zero or one [0..1] @extension

References

- https://www.healthit.gov/sites/default/files/resources/cda_c-cda_theirrole_in_mu.pdf
- [https://www.hl7.org/documentcenter/public_temp_C21C3892-1C23-BA17-0C3BF165F3DC65CD/calendarofevents/himss/2016/Introduction%20to%20Clinical%20Document%20Architecture%20\(CDA\)%20and%20Consolidated%20CDA%20\(C-CDA\).pdf](https://www.hl7.org/documentcenter/public_temp_C21C3892-1C23-BA17-0C3BF165F3DC65CD/calendarofevents/himss/2016/Introduction%20to%20Clinical%20Document%20Architecture%20(CDA)%20and%20Consolidated%20CDA%20(C-CDA).pdf)
- <https://www.slideshare.net/AShakil/introduction-to-cda-may-2019-montreal>
- <https://www.naaccr.org/wp-content/uploads/2016/11/CDA-Understanding-Templates-Presentation-Slides.pdf>
- <https://videos.intersystems.com/detail/video/2665364961001/an-introduction-to-cda>
- <https://phii.org/sites/default/files/resource/files/HL7%20CDA%20Introduction.pdf>
- <https://art-decor.org/mediawiki/images/1/17/Ihic-cda-kheitmann-web.pdf>
- http://dicom.nema.org/dicom/rsna2006/Reporting_RSNA06_01.ppt