The Office of the National Coordinator for Health Information Technology

Clinical Document Architecture (CDA), Consolidated-CDA (C-CDA) and their Role in Meaningful Use (MU)

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Learning Objectives

After completing this course, you will be able to:

- Describe how healthcare data was exchanged prior to Electronic Health Records (EHRs)
- Describe the purpose, functionality, usage and structure of the Clinical Document Architecture (CDA)
- Describe the usage of Implementation Guides (IGs) and Templates in CDA
- Describe the context, process, purpose and navigation of the Consolidated-CDA (C-CDA) IG
- Describe how C-CDA satisfies CDA-specific MU objectives
- Summarize the linkages between CDA, C-CDA and MU

Describe how healthcare data was exchanged prior to Electronic Health Records (EHRs)

Healthcare Data Exchange (Pre-EHR)

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Vast amounts of patient data collected through direct clinical interactions

Medical information such as vitals, orders, prescriptions, discharge summaries, etc. dictated or recorded by hand

All of this clinical data was stored as paper records (documents) at each point of care

If patient health records needed to be shared between providers, they usually required manual exchange (e.g. fax, "snail mail")

- **Coordination of care between providers slow, costly; patient outcomes inconsistent**
- **Duplicative healthcare services (e.g. labs imaging) frequent**

Describe the purpose, functionality, usage, and structure of HL7's Clinical Document Architecture (CDA)

Clinical Document Architecture (CDA) Overview

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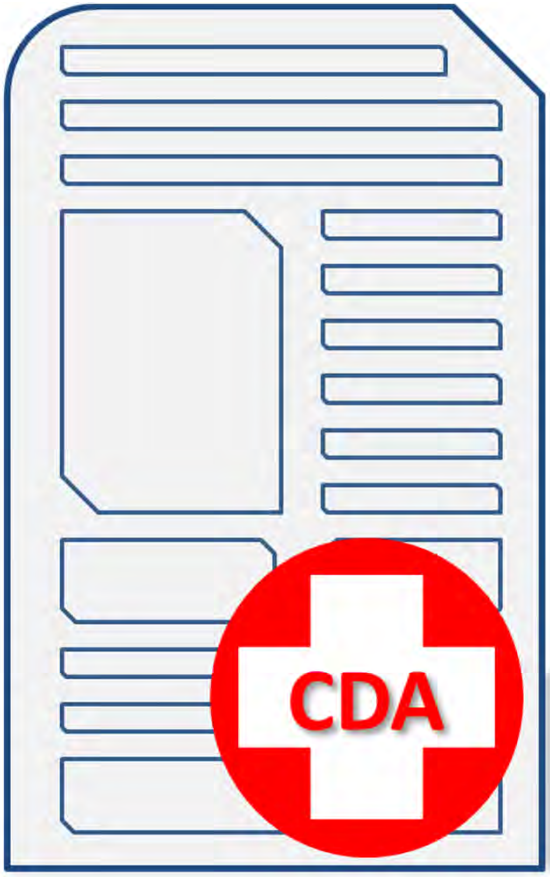

An international not-for-profit SDO with 2,300+ members across 500 corporations representing ~90% of IS vendors serving Healthcare.

Dedicated to providing a comprehensive framework for the exchange and management of health information

CDA is a base standard which provides a common architecture, coding, semantic framework, and markup language for the creation of electronic clinical documents

- CDA Docs are coded in Extensible Markup Language (XML)
  - HTML describes presentation, XML describes content
  - Human readable and machine interpretable
- **Templated:** standardized groupings of information organized according to clinical context
- **Object Oriented:** makes use of classes, associations, and inheritance; allows tremendous flexibility and re-use

CDA conformant Continuity of Care Document (CCD) example

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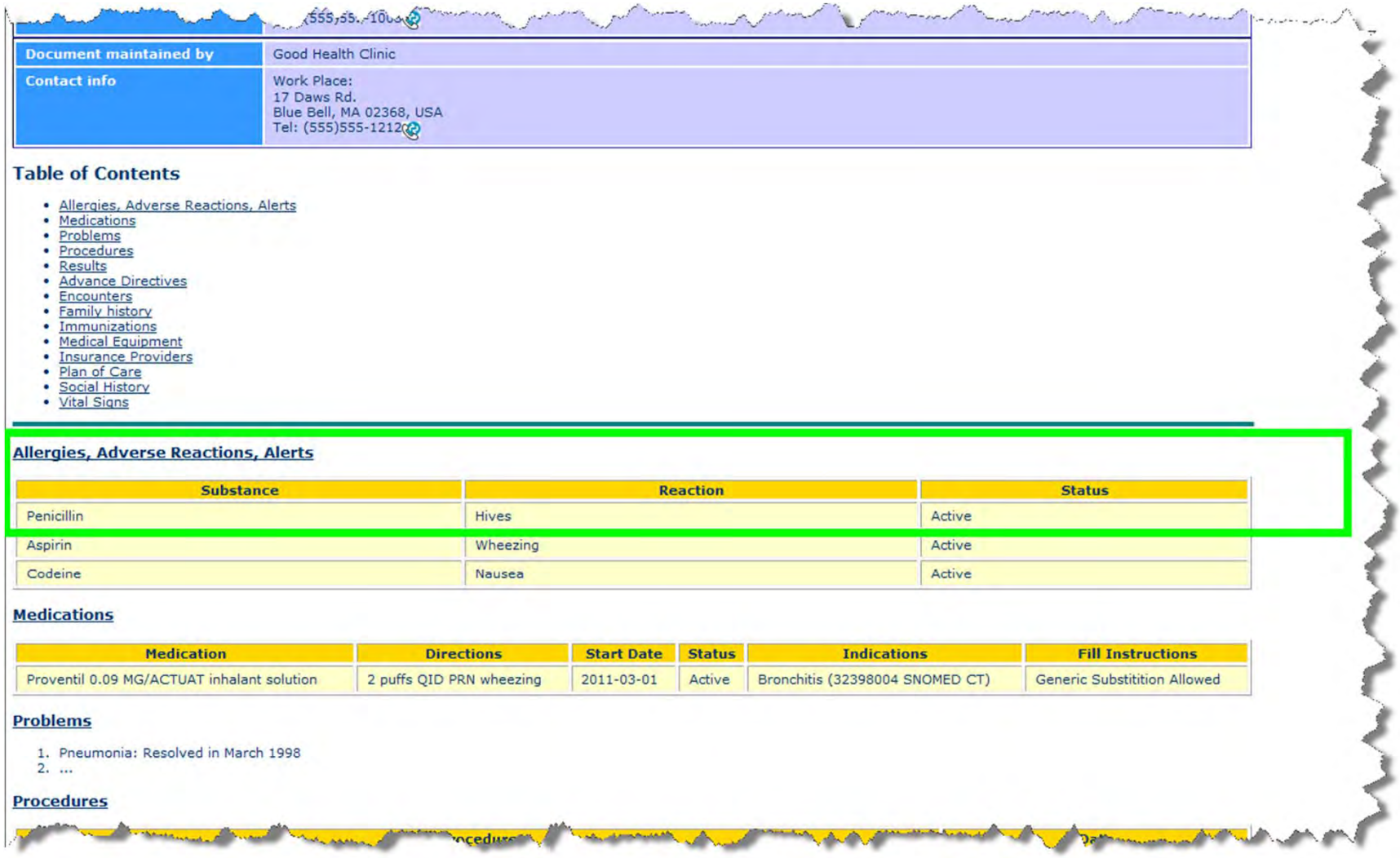

Document maintained by	Good Health Clinic
Contact info	Work Place: 17 Daws Rd. Blue Bell, MA 02368, USA Tel: (555)555-1212

Table of Contents

- Allergies, Adverse Reactions, Alerts
- Medications
- Problems
- Procedures
- Results
- Advance Directives
- Encounters
- Family history
- Immunizations
- Medical Equipment
- Insurance Providers
- Plan of Care
- Social History
- Vital Signs

Allergies, Adverse Reactions, Alerts

Substance	Reaction	Status
Penicillin	Hives	Active
Aspirin	Wheezing	Active
Codeine	Nausea	Active

Medications

Medication	Directions	Start Date	Status	Indications	Fill Instructions
Proventil 0.09 MG/ACTUAT inhalant solution	2 puffs QID PRN wheezing	2011-03-01	Active	Bronchitis (32398004 SNOMED CT)	Generic Substitition Allowed

Problems

1. Pneumonia: Resolved in March 1998
2. ...

Procedures

CDA conformant CCD example (underlying XML)

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```
- <!
     ************************************************************

        CDA Body

        ************************************************************
  -->
- <component>
  - <structuredBody>
      <!--  **********************    -->
    - <!--

        ************************************************************

        Allergies, Adverse Reactions, Alerts

        ************************************************************

    -->
    - <component>
      - <section>
          <templateId root="2.16.840.1.113883.10.20.22.2.6.1" />
          <!--  Alerts section template   -->
          <code code="48765-2" codeSystem="2.16.840.1.113883.6.1" />
          <title>Allergies, Adverse Reactions, Alerts</title>
        - <text>
          - <table border="1" width="100%">
            + <thead>
            - <tbody>
              - <tr>
                  <td>Penicillin</td>
                - <td>
                    <content ID="reactionl">Hives</content>
                  </td>
                  <td>Active</td>
```

CDA Purpose & Functionality

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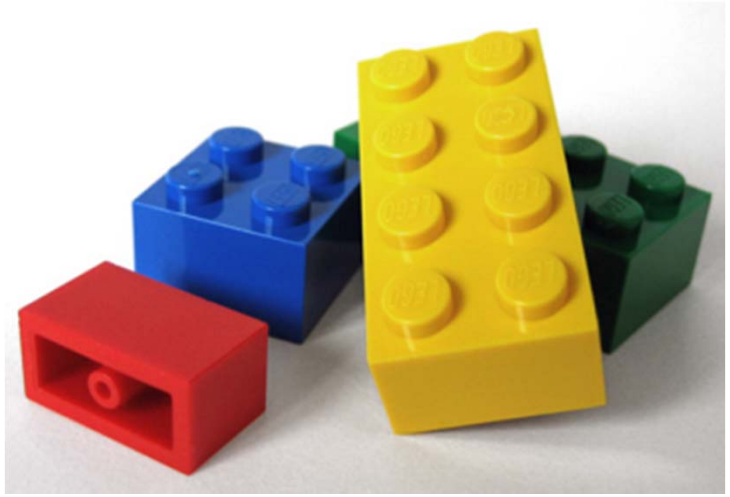
CDA defines the structure of building blocks which can be used to contain a multitude of healthcare data elements that can be captured, stored, accessed, displayed and transmitted electronically for use and reuse in many formats



CDA *DOES NOT* specify how documents are transported, simply how critical data elements should be encoded for exchange and interoperability

CDA can contain both structured and unstructured information

CDA Usage

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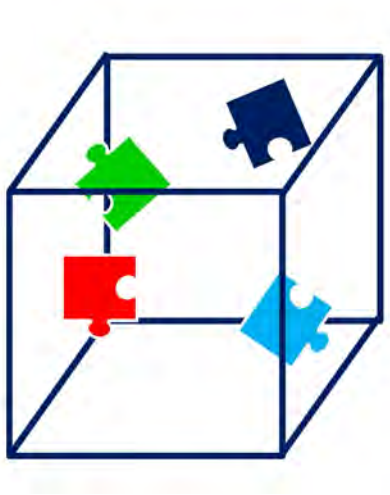
CDA defines building blocks which can be used to contain healthcare data elements that can be captured, stored, accessed, displayed and transmitted electronically for use and reuse in many formats



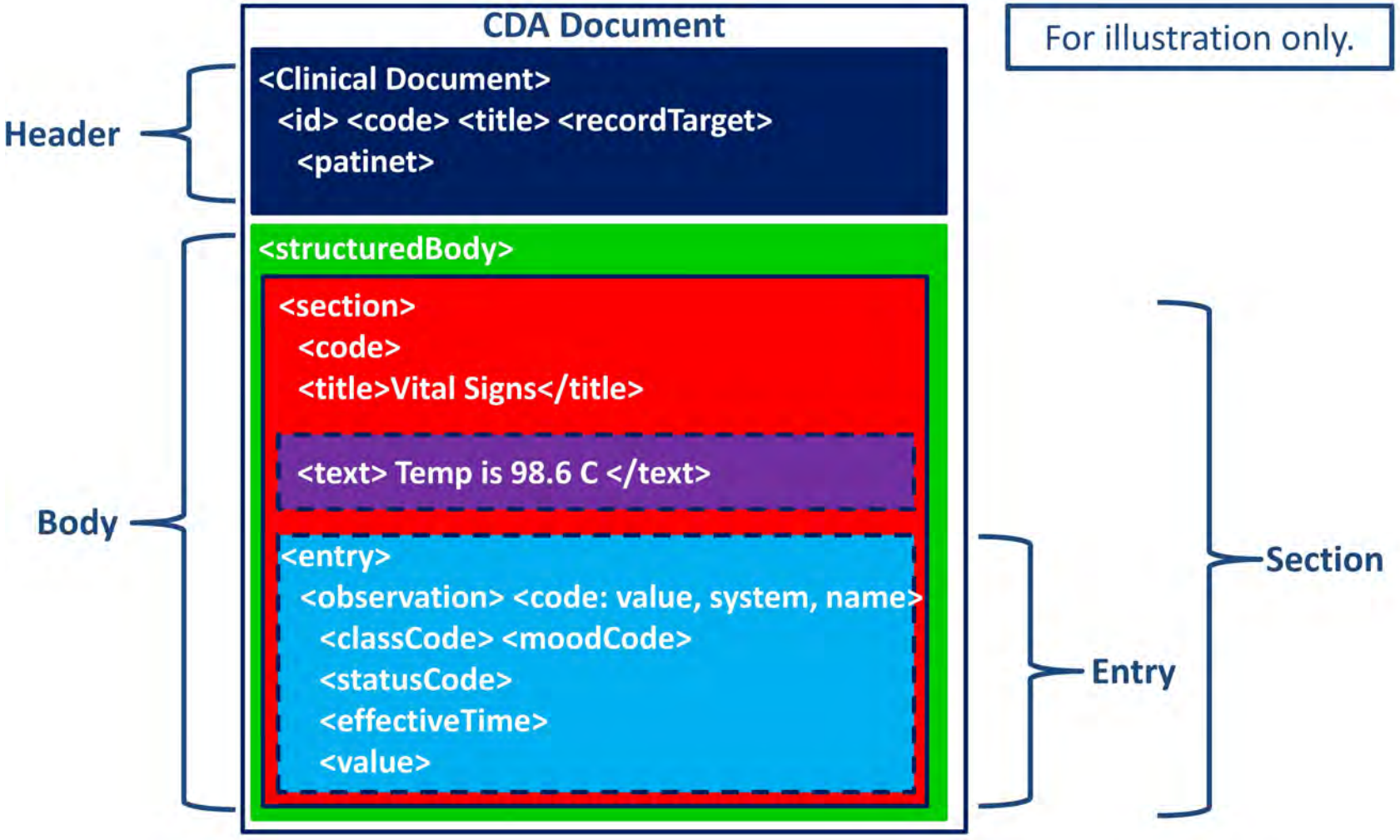
Sets of these CDA standardized building blocks can be arranged for whatever needs exist

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

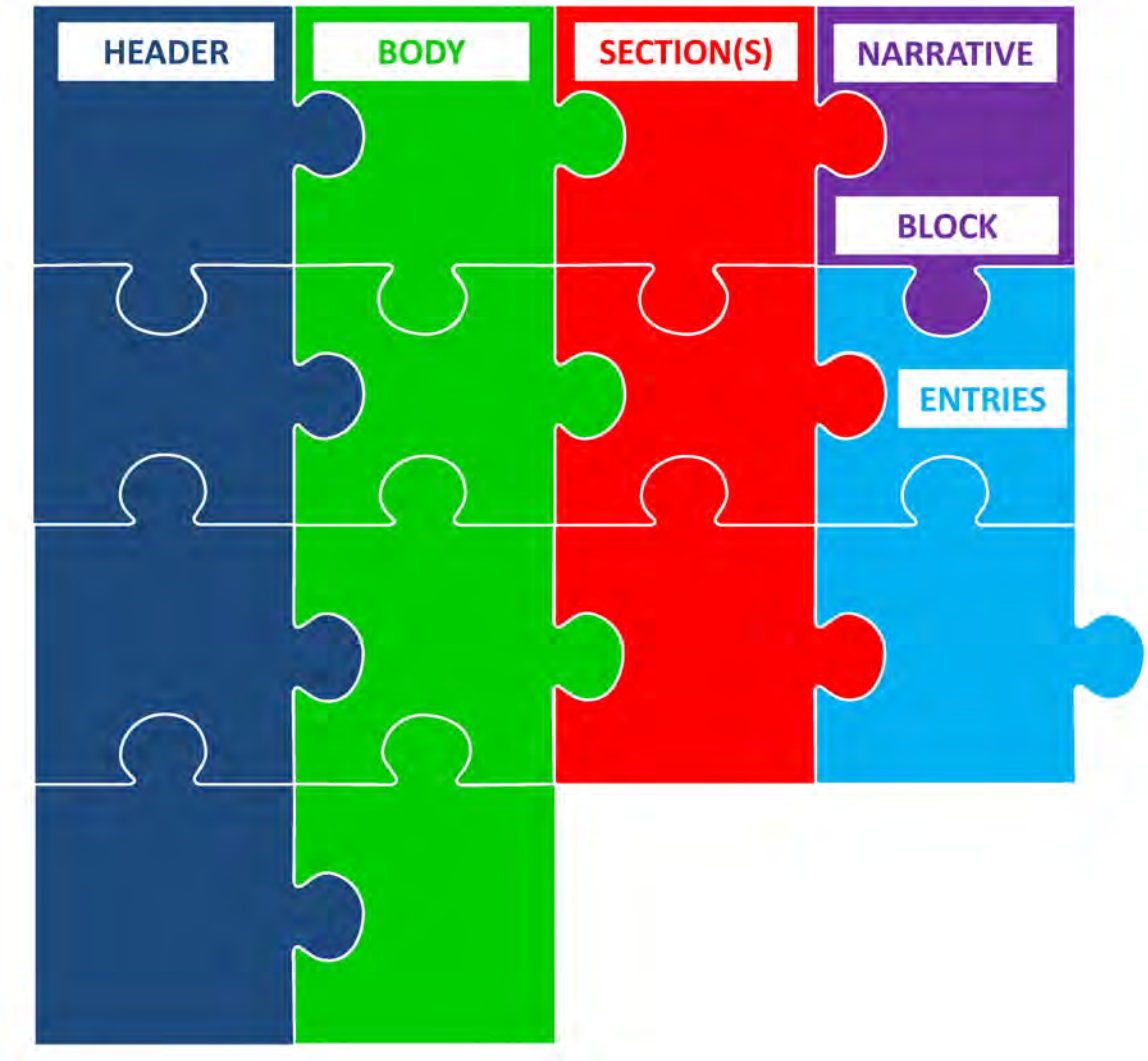
Arranging (or constraining) the CDA elements in defined ways using IGs and templates produces clinical documents

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

CDA Document Structure Example



CDA Structure: Overview



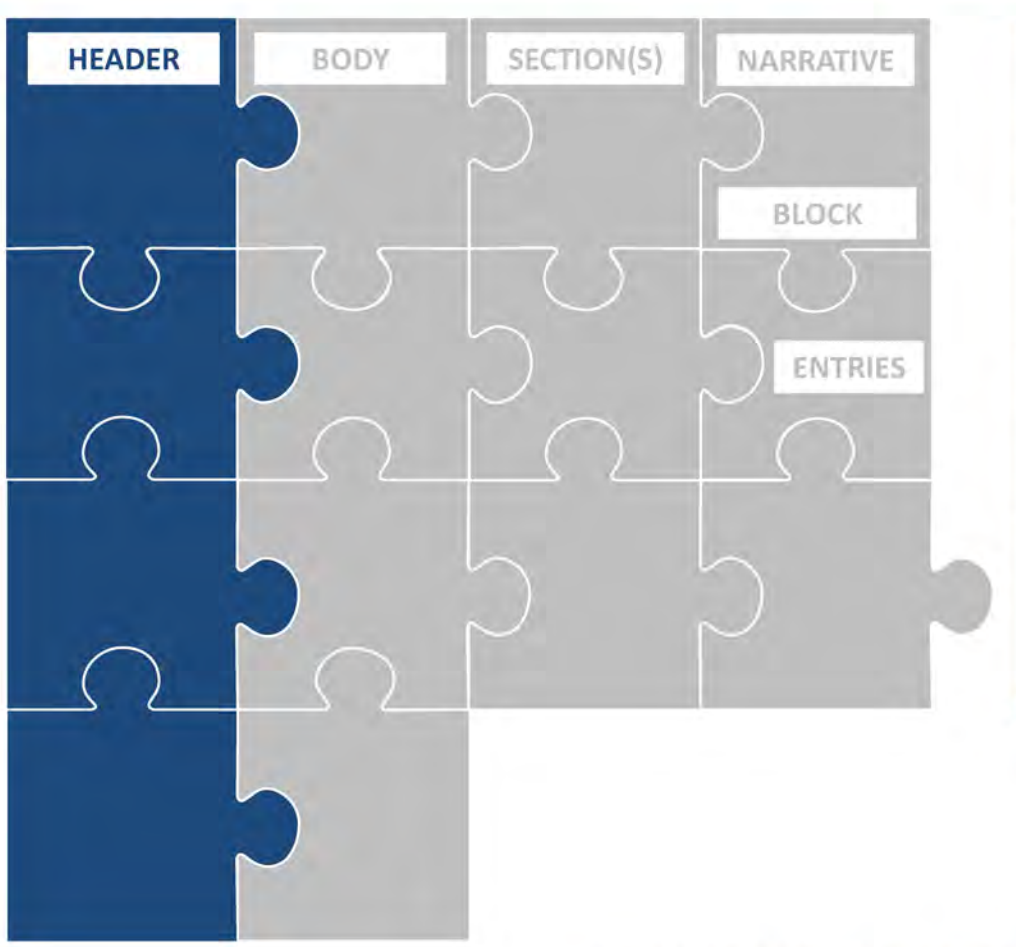
Every CDA document must have AT LEAST a **Header** AND a One **Section**.

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)

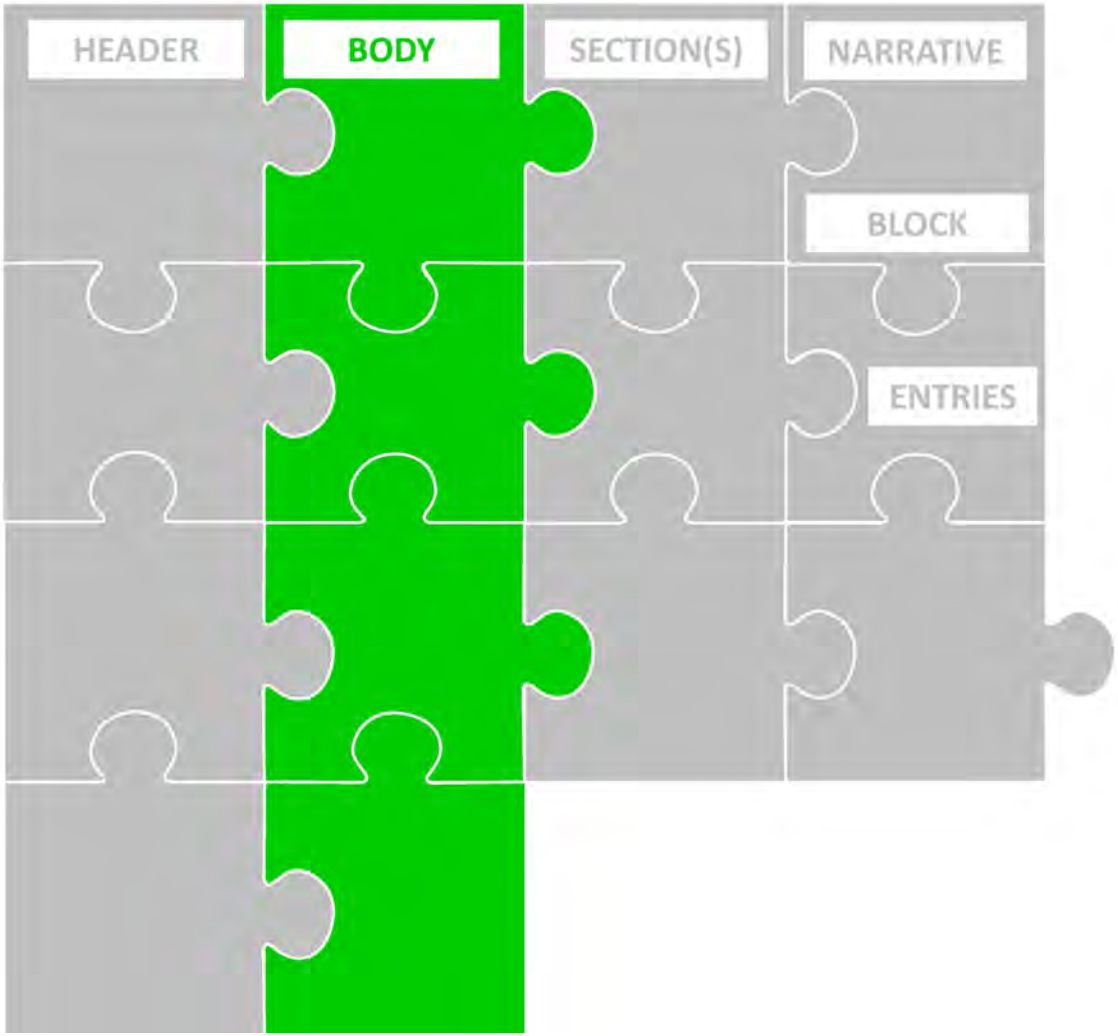
CDA Structure: Header



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

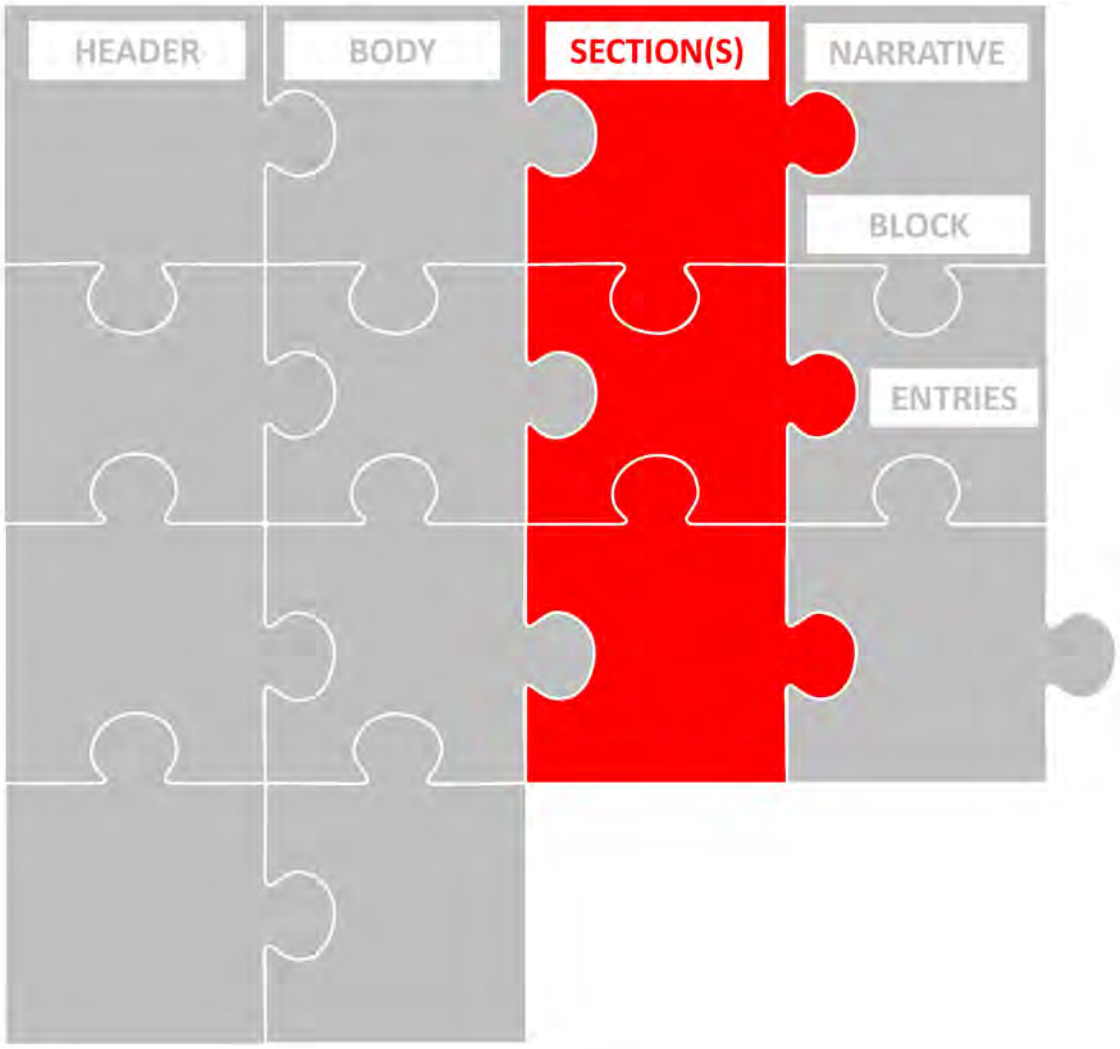
- enables clinical document exchange across and within institutions;
- facilitates clinical document management ; and
- facilitates compilation of an individual patient's clinical documents into a electronic patient record.

CDA Structure: Body



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

CDA XML Structure: Section(s)

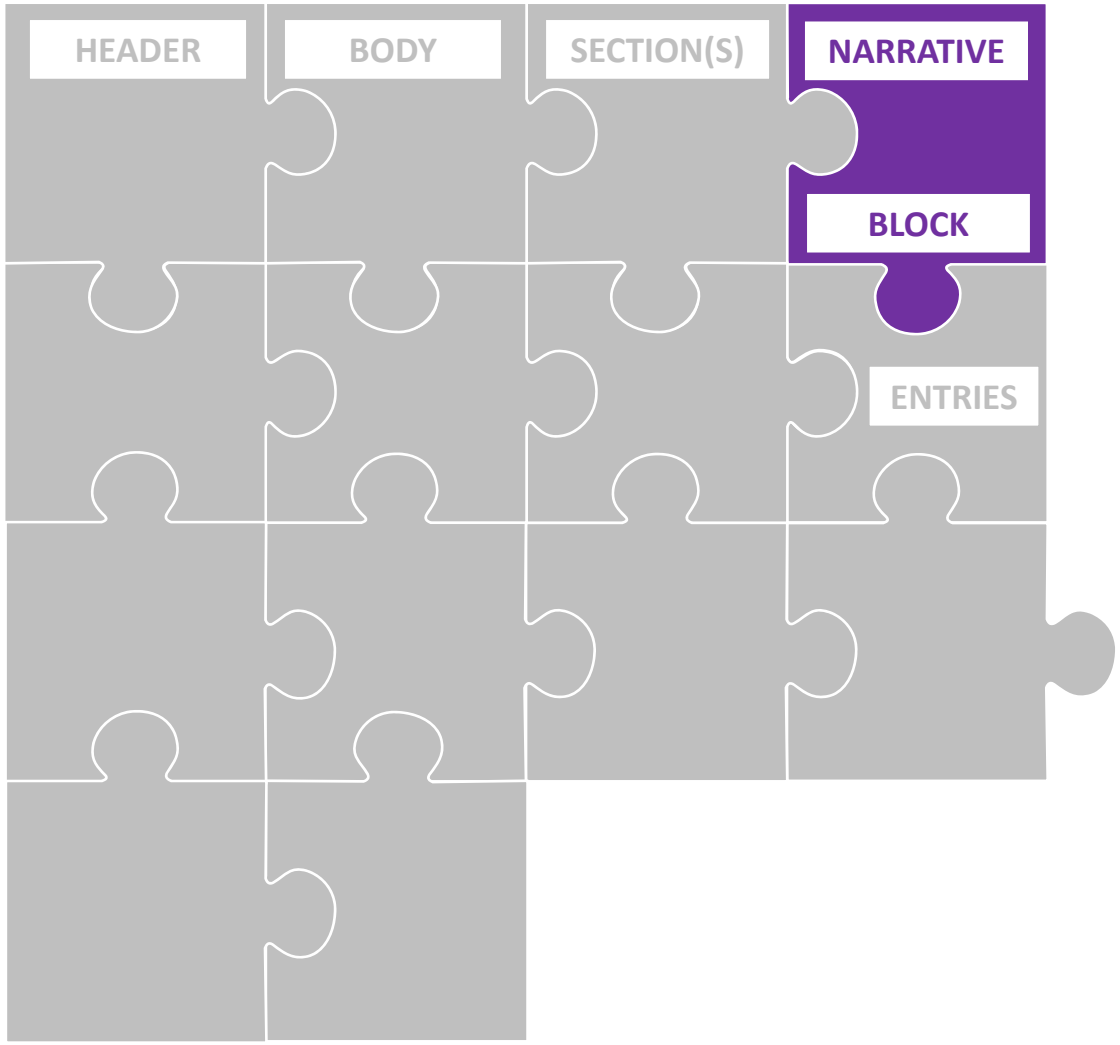


Each **Section** contains one **Narrative Block** and zero to many coded **Entries**.

Examples include:

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

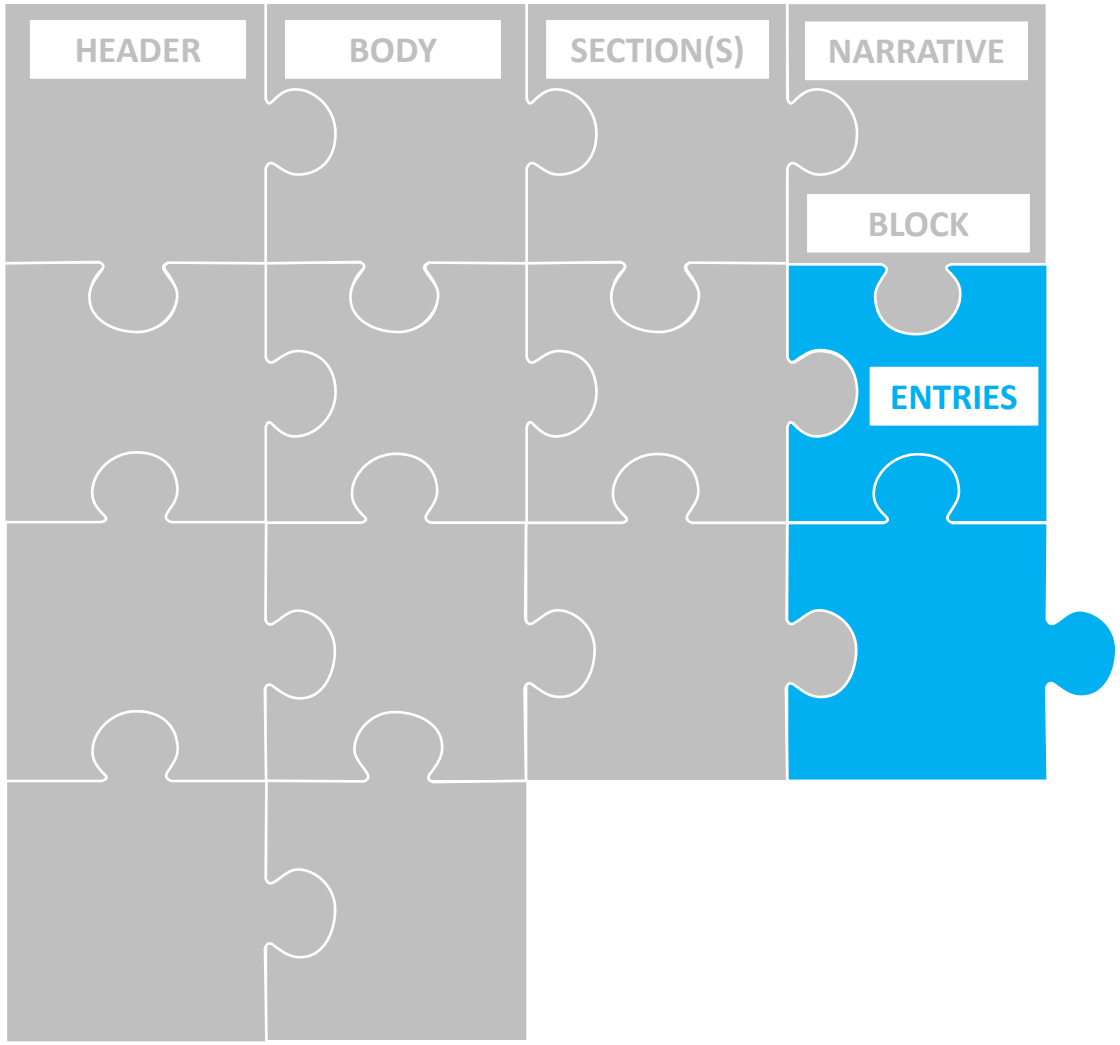
CDA XML Structure: Narrative Block(s)



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.

CDA XML Structure: Entries



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

Describe the usage of Implementation Guides (IGs) and Templates in CDA

CDA Templates and Implementation Guides (IGs)

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CDA Implementation Guides (IGs)

- serve as a how-to-guide for using CDA to satisfy a given use case
  - e.g. a CCD must contain an "Allergy, Adverse Reactions, Alerts" section
- includes subset of CDA templates which contain information relevant to a Use Case
- IGs generally define document Templates
  - e.g. CCD vs. Discharge Summary
- 8 critical CDA documents consolidated into single guide: *Consolidated-CDA (C-CDA) IG*

CDA Templates

- constrain elements in the CDA schema as needed to define function-specific information objects
  - e.g. defines what data is contained in an "Allergy, Adverse Reactions, Alerts" section used by multiple CDA documents
- provides a collection of business rules which apply to CDA components applied at multiple levels:
  - Header
  - Document
  - Section
  - Entry

Template Example

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Vital Signs Section with Coded Entries Optional

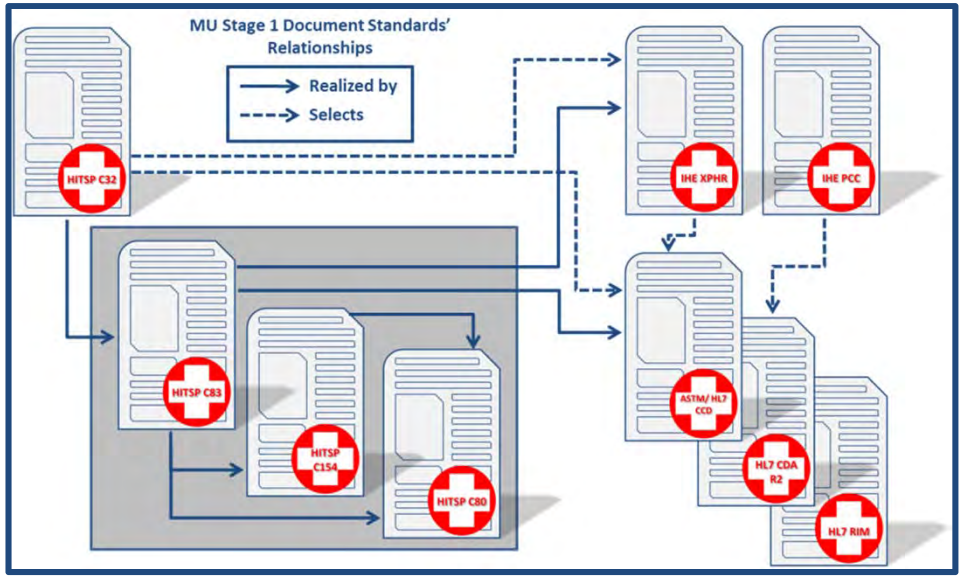
[section: templateId 2.16.840.1.113883.10.20.22.2.4 (open)]

The following constraints apply to a Vital Signs section in which entries are not required.

1. **SHALL** contain exactly one [1..1] **templateId** (CONF:7268) such that it
    a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.2.4" (CONF:10451).
2. **SHALL** contain exactly one [1..1] **code** (CONF:15242).
    a. This code **SHALL** contain exactly one [1..1] @code="8716-3" Vital Signs (CodeSystem: LOINC 2.16.840.1.113883.6.1) (CONF:15243).
3. **SHALL** contain exactly one [1..1] **title** (CONF:9966).
4. **SHALL** contain exactly one [1..1] **text** (CONF:7270).
5. **SHOULD** contain zero or more [0..*] **entry** (CONF:7271) such that it
    a. **SHALL** contain exactly one [1..1] Vital Signs Organizer (2.16.840.1.113883.10.20.22.4.26) (CONF:7272).

Describe the context, process, purpose and navigation of the Consolidated-CDA (C-CDA) IG

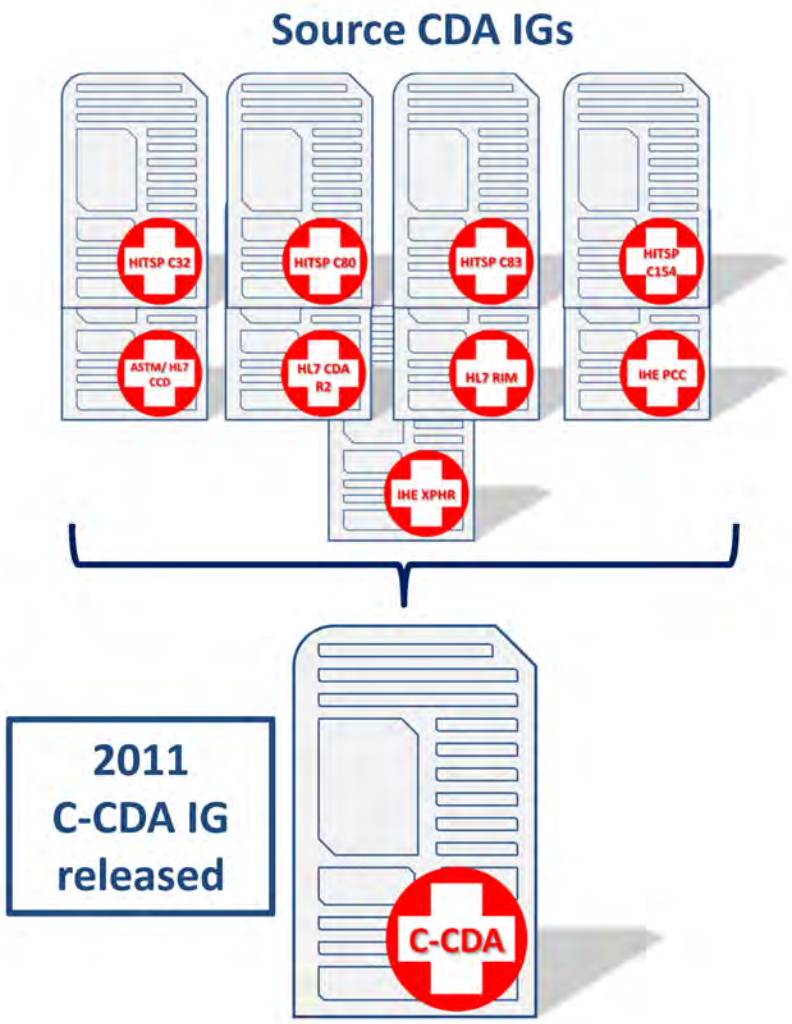
Pre-Consolidation Context



Before Consolidation, providers trying to implement a specific clinical document (e.g. *C32*) were faced with a "rabbit hole" of cross-referenced materials creating an ever growing, complex web of documentation – Consolidation was undertaken to address this issue.

- Duplicative and conflicting IGs published by different standards organizations (e.g. HITSP, HL7, IHE, Health Story); approved/balloted at different times
- Implementers faced with confusing collection of documents containing ambiguous and/or conflicting information
- C-CDA IG includes the following clinical documents (year released): Consultation Note (2008); Discharge Summary (2009); Imaging Integration and DICOM Diagnostic Imaging Reports (DIR) (2009); History and Physical (H&P) (2008); Operative Note (2009); Progress Note (2010); Procedure Note (2010); and Unstructured documents (2010)

Consolidation Process



As disparate SDOs (HL7, IHE, HITSP, etc.) developed CDA IGs, multiple approaches for documenting template requirements began to diverge threatening interoperability…

- S&I hosted a collaboration among the standards community in order to address CDA documentation issues which were hampering understanding and consistent implementation in order to:
  - examine and analyze CDA Templates across the existing documentation
  - identify and address errors, issues of ambiguity, and conflict
  - consolidate prior documentation to a new single IG and ballot (approve) through HL7
- Consolidation harmonized and balloted previous templates a single IG

C-CDA IG Purpose: Single Source for CDA Templates

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HL7 Implementation Guide for CDA R2: IHE Health Story Consolidation, DSTU Release 1.1 (US Realm) July 2012

Document Templates: 9

- *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

Section Templates: 60

Entry Templates: 82

Document Template	Section Template(s)		
CCD	Allergies Medications Problem List Procedures Results Advance Directives Encounters	Family History Functional Status Immunizations Medical Equipment Payers Plan of Care	Section templates highlighted in the two section template examples here demonstrate CDA's interoperability and reusability.
History and Physical	Allergies Medications Problem List Procedures Results Family History Immunizations Assessments	Assessment and Plan Plan of Care Social History Vital Signs History of Present Illness History of Present Illness	Chief Complaint Reason for Visit Review of Systems Physical Exam General Status

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 IG Navigation

Chapter 1: Introduction

Chapter 2: General Header Template – defines a template for the header constraints that apply across all of the consolidated document types

Chapter 3: Document-Level Templates – defines each of the nine document types; defines header constraints specific to each and the section-level templates (required and optional) for each

Chapter 4: Section-Level Templates – defines the section templates referenced within the document types described

Chapter 5: Entry-Level Templates – defines entry-level templates, called clinical statements (machine readable data)

Appendices – include non-normative content to support implementers; includes a *Change Appendix summary* of previous and updated templates

Click this link to access more information about the *HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, Release 1.1 - US Realm*

<http://www.hl7.org/implement/standards/product_brief.cfm?product_id=258>

Describe how C-CDA satisfies CDA-specific MU objectives

Meaningful Use (MU) Overview

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CMS
Medicare and Medicaid Programs: Electronic Health Record Incentive Program: Final Rule
28 JUL 2010

Meaningful Use objectives are the measurable benchmarks that eligible health care professionals and hospitals must meet in adopting and using EHR technology to qualify for Medicare and Medicaid incentive payments.

Eligible Professionals (EP):

- EPs (doctors and other medical professionals) must choose to participate in either the Medicare and Medicaid Incentive Program upon registration.
- Generally, EPs must have a minimum 30% Medicaid patient volume to qualify for Medicaid payments.
- Before 2016, an EP may switch programs after the first payment.

Eligible Hospitals (EH):

- The Medicare Program recognizes "subsection (d) hospitals, Critical Access Hospitals, and Medicare Advantage Hospitals. The Medicaid Program recognizes Acute care hospitals with a minimum 10% Medicaid patient volume and Children's Hospitals.
- Hospitals may be eligible and receive payments under both programs.

MU Standards & Certification Criteria (S&CC) (proposed 2014)

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Meaningful Use	meaningful use objectives are the measurable benchmarks that eligible health care professionals and hospitals must meet in adopting and using EHR technology to qualify for Medicare and Medicaid incentive payments
Cert. Criteria	**Objective**	**Description**

MU S&CC Final Rule establishes HL7's CDA as the standard per C-CDA IG – 2 objectives above conceptualized together as "Summary of Care" record

Care Coordination	**Transition of Care**	**when transitioning a patient to another care setting, the provider should provide a summary care record**
Patient Engagement	**View/Download/Transmit**	**patients must be able to view and download their own medical info and also be able to transmit that info to a 3rd party**
	Clinical Summary	**providers must make office visit summaries available to patients subsequent to a visit**

Non-CDA-related MU S&CC not shown here because they are outside the scope of this training

- Clinical
- CQMs
- Privacy & Security
- Public Health
- Utilization

MU S&CC Final Rule establishes HL7's CDA as the standard per C-CDA IG – 2 objectives above conceptualized together as "Summary of Care" record

Non-CDA-related MU S&CC not shown here because they are outside the scope of this training

Summarize the linkages between CDA, C-CDA and MU

CDA, C-CDA & MU Linkages

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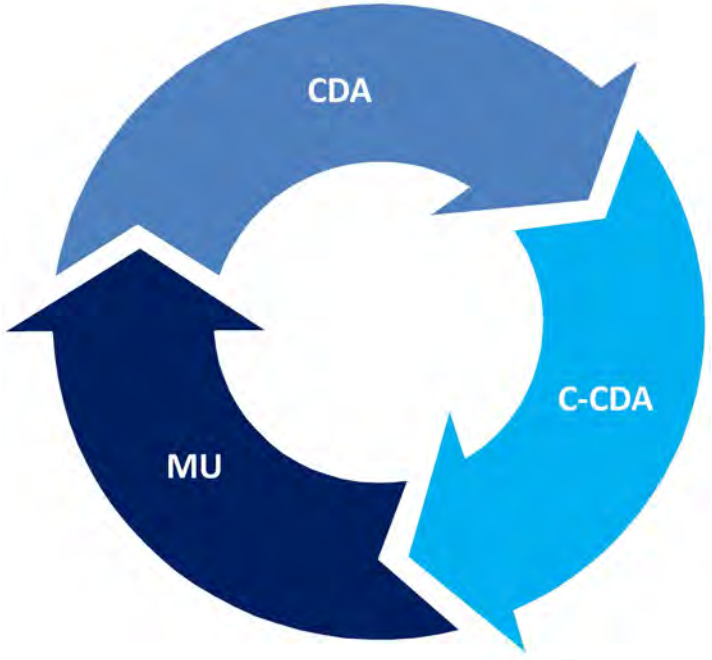
Clinical Document Architecture (CDA)

CDA provides single standardized, interoperable schema for the creation of clinical documents

- CDA is XML-based clinical document standard using common, reusable data elements
- Supports human- AND machine-readability
- CDA + unique CDA implementation guides (IGs) » CDA-conformant clinical document



Meaningful Use (MU)

MU "…rewards the 'meaningful use' of health IT *not* the purchase of health IT."

- Currently in Stage I; moving towards Stage II
- Early adopters rewarded; non-compliance eventually penalized
- MU-2 focuses on 7 key criteria (2 achieved using C-CDA)

Consolidated-CDA (C-CDA) IG

C-CDA IG critical to fulfilling MU S&CC objectives for standardization, interoperability of EHRs

- C-CDA IG harmonizes numerous CDA standards
- IGs for 8 key clinical documents + unstructured documents consolidated into C-CDA

Thank you for your participation

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This concludes today's training concerning "CDA, C-CDA and Their Role in Meaningful Use".

For more information of these and other related topics, visit the ONC website

http://www.healthit.gov