Consolidated CDA R2

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Objectives of this Session

- What is the Clinical Document Architecture (CDA)?

  - The characteristics of a CDA document.
  - What is human readable vs. computable data?
  - What is the Consolidated CDA and what does it look like?

- The Structure of CDA / Templated CDA

- Examples

  - The Sending data
  - Generating data

- esMD Project

What is CDA R2?

- A specification for exchange of clinical documents, defining their structure and semantics

- ANSI standard developed by HL7's Structured Documents Work Group (SDWG)

- CDA Release 1 became an HL7 and ANSI standard in 2000.

- CDA Release 2 became an HL7 and ANSI standard in 2005, and later became an ISO standard in 2009.
  - Release 2 (R2) is the current version of the standard.

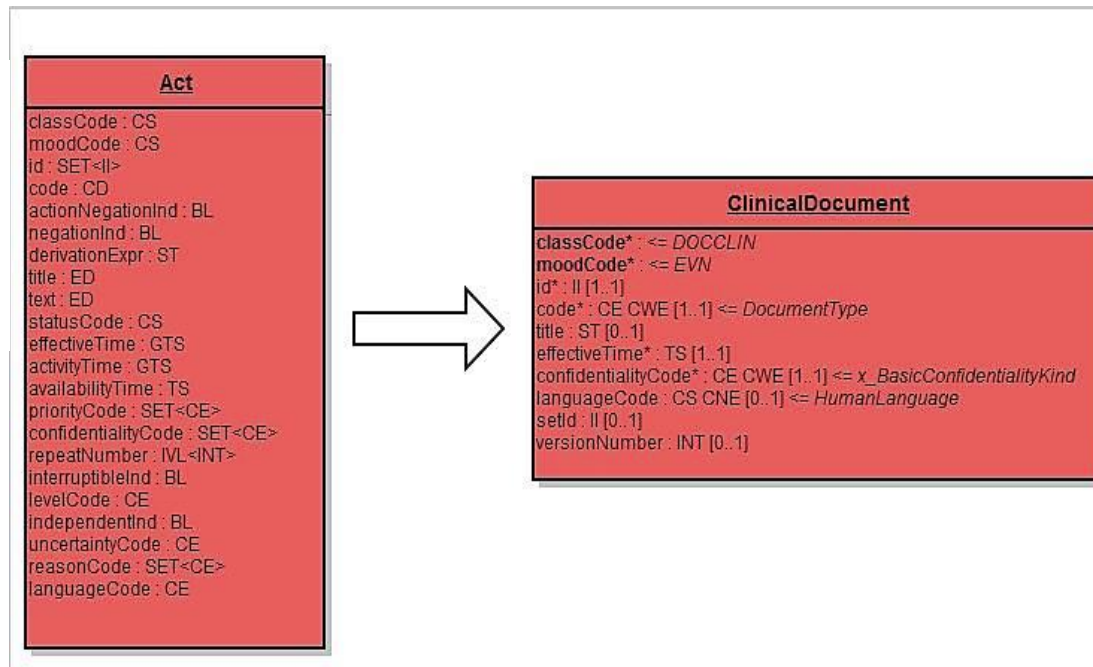# The CDA Refined Message Information Model (RMIM)

- As an HL7 V3 standard, CDA makes use of the HL7 Reference Information Model (RIM).

- The HL7 RIM is a generic information model expressed using Unified Modeling Language (UML) that covers healthcare as a whole.

- CDA restricts the HL7 RIM for clinical document exchange— this is known as the CDA RMIM.
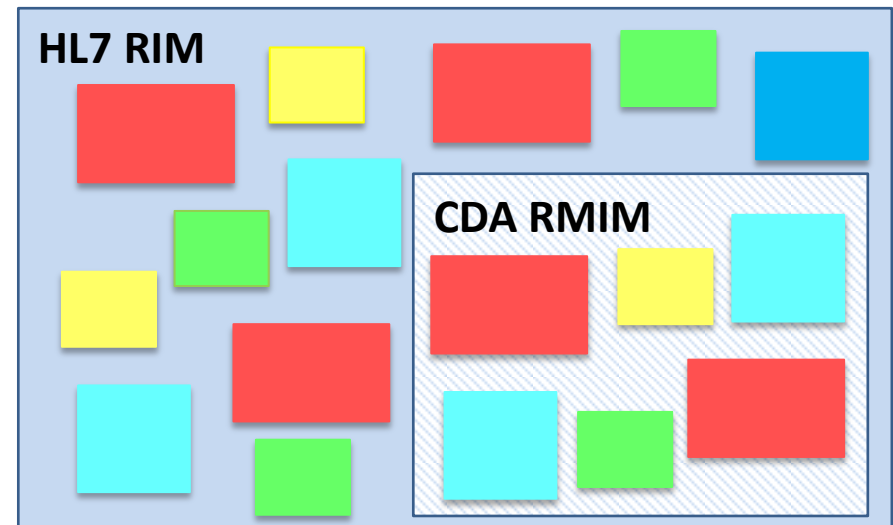
CDA RMIM Constraints on the HL7 RIM

- In the example below, we see how the CDA RMIM constrains the HL7 RIM to specify a *ClinicalDocument* as an Act

The generic Act is described in the HL7 RIM. It also specifies the attributes and their data types.

Act

classCode : CS
moodCode : CS
id : SET<II>
code : CD
actionNegationInd : BL
negationInd : BL
derivationExpr : ST
title : ED
text : ED
statusCode : CS
effectiveTime : GTS
activityTime : GTS
availabilityTime : TS
priorityCode : SET<CE>
confidentialityCode : SET<CE>
repeatNumber : IVL<INT>
interruptibleInd : BL
levelCode : CE
independentInd : BL
uncertaintyCode : CE
reasonCode : SET<CE>
languageCode : CE

ClinicalDocument

classCode* : <= DOCCLIN
moodCode* : <= EVN
id* : II [1..1]
code* : CE CWE [1..1] <= DocumentType
title : ST [0..1]
effectiveTime* : TS [1..1]
confidentialityCode* : CE CWE [1..1] <= x_BasicConfidentialityKind
languageCode : CS CNE [0..1] <= HumanLanguage
setId : II [0..1]
versionNumber : INT [0..1]

The CDA RMIM constrains the ACT to describe a ClinicalDocument. It also specifies the attributes, data types, and cardinality (number of instances).

The CDA

- A technical standard for authoring several types of clinical documents in a format that can easily be exchanged between organizations
- CDA defines the structure and semantics of clinical documents using:
  - Extensible Markup Language (XML)
  - HL7 Reference Information Model (RIM)
  - Controlled vocabularies (SNOMED, LOINC, CPT, HL7, etc.)
  - Designed to create documents that are both **Human Readable** and **Machine Interpretable**

```
- <section>
    <code code="11348-0" codeSystem="2.16.840.1.113883.6.1"
      codeSystemName="LOINC" displayName="HISTORY OF PAST
      ILLNESS" />
    <title>Antécédents médicaux</title>
  - <text>
    - <table border="1">
      - <tbody>
        - <tr>
            <th>Pathologie</th>
```

Human Readable / Machine Interpretable

Characteristics of a CDA Document

- A CDA document has the following characteristics:

  - **Persistence:** CDA documents continue to live in an unaltered state, for a time period defined by local and regulatory requirements.

  - **Stewardship:** CDA documents are maintained by an organization entrusted with its care.

  - **Potential for authentication:** CDA documents are able to record or attest to the signature of a responsible party.

  - **Context:** CDA documents detail the setting for event(s) described in the document so that it can be fully understood and assessed.

  - **Wholeness:** CDA documents, as a whole, tell a complete story.

  - **Human readability:** CDA documents must be able to be read by a human

Primary Use Cases for CDA Documents

- Access / portability / exchange
  - Query / locate by patient, provider, practitioner, setting, encounter, date
  - Access distributed information through common metadata
  - Document management

- Integration
  - Transcription systems
  - Electronic health records

- Reuse / derivative data
  - Summaries, reports
  - Decision support

Document Sections

Advance Directives Section (entries optional)

Advance Directives Section (entries required)

Allergies Section (entries optional)

Allergies Section (entries required)

Anesthesia Section

Assessment and Plan Section

Assessment Section

Chief Complaint and Reason for Visit Section

Chief Complaint Section

Complications Section

DICOM Object Catalog Section - DCM 121181

Discharge Diet Section

Encounters Section (entries optional)

Encounters Section (entries required)

Family History Section

Fetus Subject Context

Findings Section (DIR)

Functional Status Section

General Status Section

History of Past Illness Section

History of Present Illness Section

Hospital Admission Diagnosis Section

Hospital Admission Medications Section (entries optional)

Hospital Consultations Section

Hospital Course Section

Hospital Discharge Diagnosis Section

Hospital Discharge Instructions Section

Hospital Discharge Medications Section (entries optional)

Hospital Discharge Medications Section (entries required)

Hospital Discharge Physical Section

Hospital Discharge Studies Summary Section

Immunizations Section (entries optional)

Immunizations Section (entries required)

Implants Section

Instructions Section

Interventions Section

Medical (General) History Section

Section Entries

Admission Medication

Advance Directive Observation

Age Observation

Allergy Observation

Allergy Problem Act

Allergy Status Observation

Boundary Observation

Code Observations

Comment Activity

Coverage Activity

Discharge Medication

Drug Vehicle

Encounter Activities

Estimated Date of Delivery

Family History Death Observation

Family History Observation

Family History Organizer

Health Status Observation

Hospital Admission Diagnosis

Hospital Discharge Diagnosis

Immunization Activity

Immunization Medication Information

Immunization Refusal Reason

Indication

Instructions

Medication Activity

Medication Dispense

Medication Information

Medication Supply Order

Medication Use - None Known (deprecated)

Non-Medicinal Supply Activity

Plan of Care Activity Act

Plan of Care Activity Encounter

Code Systems

Standard Code Systems

- LOINC
- SNOMED
- ICD-9/10
- RxNorm
- NUCC Health Care Provider Taxonomy
- ICD9 CM Procedures
- CPT-4
- Confidentiality Code
- National Cancer Institute (NCI) Thesaurus
- US Postal Codes

HL7 Value Sets

- Adminstrative Gender
- ActMood
- Religious Affiliation
- RoleClass
- RoleCode
- AddressUse
- ActStatus
- MaritalStatus

Investing in Information

- CDA can be simple or complex
- Simple encoding relatively inexpensive
- Complex encoding costs more
- You get what you pay for
  - The more detailed the encoding
  - The greater the potential for reuse

Consolidated CDA

A single source that defines the implementation of the following CDA documents:

- CCD
- Consultation Note
- Diagnostic Imaging Report
- Discharge Summary
- H&P
- Operative Note
- Procedure Note
- Progress Note
- Unstructured Document

- **Cited in Meaningful Use Stage 2**

CDAR2_IG_IHE_CONSOL_R1_U1_DSTU_2011JULY

HL7 INTERNATIONAL

Implementation Guide for CDA Release 2.0

Consolidated CDA Templates

(US Realm)

July 2012

Produced in collaboration with:

IHE   HEALTH STORY PROJECT   S&I FRAMEWORK

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Why the Consolidated CDA?

- Consolidated CDA is easier to implement
  - **Single reference** standard to work from, instead of many complex cross-references.
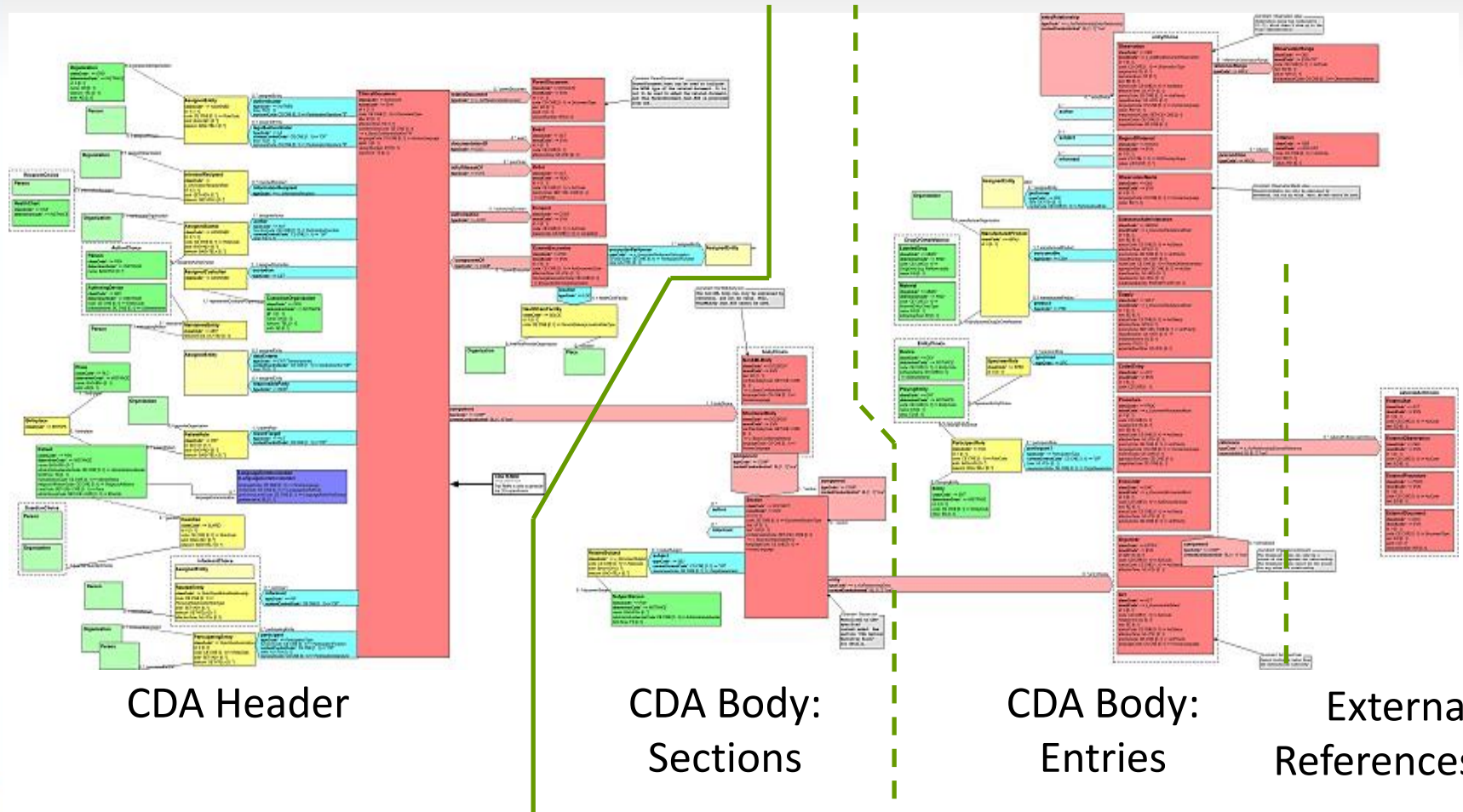 - In development of a single reference, <u>inconsistencies</u> and <u>ambiguities</u> across cross-references **have been resolved.**
- Consolidated CDA requires more consistent and robust information
  - The C-CDA CCD requires inclusion of at least <u>4 clinical domains</u> (allergies, medications, problems, results)
    - C32 only required document demographics
  - C-CDA **requires the use of vocabularies** for much of it's clinical data
- Consolidated CDA positions VLER to easily exchange other documents
  - **Modular template design** makes exchanging structured versions of additional clinical documents (e.g., high value notes) <u>incrementally easier</u>.
    - Example: History & Physical template shares 9 of its 19 clinical domain templates with the CCD

CDA Structure

Every CDA Document is composed of two parts:

- Header
  - Contains information about the document, establishes context for the details found in the Body:
    - Who: Participants such as patient, physician, author...
    - What: Document Title, encompassing encounter...
    - Where: Location
    - When: Creation date
    - And much more...
- Body
  - Contains clinically relevant information

CDA Model

CDA Header   CDA Body: CDA Body: External
                    Sections   Entries   References

Header Metadata

- The CDA document begins like any other introduction—by identifying itself
  - **id:** a globally unique identifier for the document
  - **code:** specifies the document type
  - **title:** descriptive heading or caption
  - **effectiveTime:** when the document was created
  - **confidentialityCode:** level of confidentiality for the document
  - **languageCode:** language for the document text
  - **setId** and **versionNumber:** used for document versioning
    - The setId refers to the same document and the versionNumber identifies the latest (newer) copy of the document.

ClinicalDocument
classCode*: <= *DOCCLIN*
moodCode*: <= *EVN*
id*: II [1..1]
code*: CE CWE [1..1] <= *DocumentType*
title: ST [0..1]
effectiveTime*: TS [1..1]
confidentialityCode*: CE CWE [1..1]
 <= *x_BasicConfidentialityKind*
languageCode: CS CNE [0..1] <= *HumanLanguage*
setId: II [0..1]
versionNumber: INT [0..1]
copyTime: TS [0..1] (Deprecated)

Header Metadata

- The CDA Header includes a list of participants (who's who)

    - **recordTarget:** who the document is about (the patient)
    - **author:** who or what (device) created the document
    - **dataEnterer:** who entered the data into the document
    - **informant:** any person who provided information about the patient
    - **custodian:** organization charged with maintaining the document
    - **informationRecipient:** who is intended to receive the document
    - **authenticator:** person who attests to the accuracy of the document
    - **legalAuthenticator:** person who is legally responsible for the document content
    - **participant:** generic participant that can be used if not described elsewhere

Header Metadata: Encounters and Service Events

- The CDA Header describes the setting for the document as a service event, such as a procedure, and the encounter
  - **componentOf/encompassingEncounter:** encounter framing the document and/or service described within
    - Only one encounter can be expressed in a document—this gives the document a single purpose or reason for existence
    - Describes encounter participants, responsible party, location of healthcare facility
  - **documentationOf/serviceEvent:** the service being documented
    - Associates the document with an act (e.g., colonoscopy, ultrasound) and identifies the practitioners

Examples of How the CDA Header Is Used

- Indexing of records
  - The CDA Header can be used to quickly index CDA records.
  - Contains the document title, author, participants, location, and service event

- Longitudinal patient lookup
  - The CDA Header contains the demographic information for a patient and forms the foundation of longitudinal (repeated observations on the same subject) patient lookup.

- Version control systems
  - versionNumber and setId can be used by document management systems to track versions of a document.
  - Note that CDA documents are immutable, so any changes are published in a new version of the document.

CDA Body

- Contains clinical information
- Every CDA document contains exactly one Body
- The CDA Body can be structured (structuredBody) or unstructured (nonXMLBody)

CDA Header   CDA Body: CDA Body: External
                    Sections   Entries   References

The nonXMLBody

- A nonXMLBody can be any supported format:
  - Text- PDF, Microsoft Word, HTML, rich text, plain text
  - Images- GIF, JPEG, PNG, TIFF

- The nonXMLBody can point to an external file that should be used
  - The external file should be delivered with the CDA Document or placed in a location that is accessible to the receiver

- The nonXMLBody can link to and decode embedded base-64 encoded content

- The Header of the CDA document with a nonXMLBody can be displayed using an XSLT stylesheet and most browsers can display a number of the supported formats
  - Browsers may need to be configured to handle certain formats, such as PDF, Microsoft Word, rich text, and TIFF

nonXMLBody Example – External Reference

```xml
<component>
    <nonXMLBody>
        <text mediaType="application/pdf">
            <reference value="discharge-summary.pdf"/>
        </text>
    </nonXMLBody>
</component>
```

- Body starts with the component element
- Wrapped by nonXMLBody
- Text element specifies the MIME type
- Reference is a link to the document (PDF, JPG, etc.) being included

The structuredBody

- A structuredBody follows markup rules for narrative text and CDA (similar to HTML)

- structuredBody is a container for sections
  - The structuredBody class represents a CDA document Body that is composed of one or more document sections (Chief Complaint, Family History, Physical Exam, etc.)

- Document sections are used to organize and provide consistency to the contents of a document Body

- Sections contain narrative and can contain coded entries– this is the structure
  - Narrative is required- *this is what the clinician is **attesting** to*
  - Coded entries are optional

structuredBody Example – Chief Complaint

```xml
<component>
    <structuredBody>
        <component>
            <section>
                <code code="29299-5" codeSystemName="LOINC"
                      codeSystem="2.16.840.1.113883.6.1"
                      displayName="Chief Complaint"/>
                <title>CHIEF COMPLAINT</title>
                <text>Chest Pain</text>
            </section>
        </component>
    </structuredBody>
</component>
```
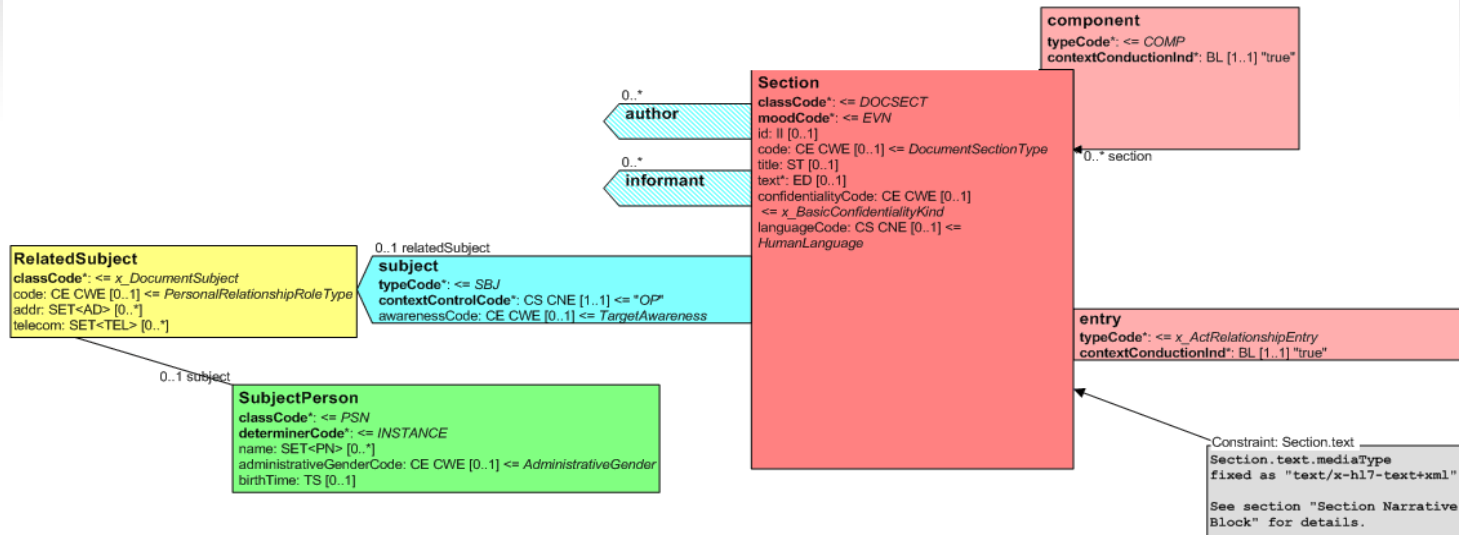
- Body starts with the component element
- Wrapped by structuredBody
- Section code specifies the section
- Text contains the 'narrative block'

The Narrative Block

- Section.text (the Narrative Block) is mandatory
  - Exception is when the section is being used as a container for other sections
- Contents of the Narrative Block are what the clinician is attesting to
- The Narrative Block schema is a registered MIME-type, which is the fixed media type for Section.text
  - Supported tags:

Tag	Description	Tag	Description
content	Wraps content and specifies style codes	footnoteRef	References existing footnote
linkHTML	Similar to HTML <a> (anchor)	renderMultimedia	References external multimedia
sub	Subscript	paragraph	Similar to HTML <p> (paragraph)
sup	Superscript	table	Similar to HTML <table>
br	Line break	list	List (can be ordered or unordered)
footnote	Footnote	caption	Label

CDA RMIM- Sections

- Minimum of three elements in every section:
  - **Section code** - specifies the particular kind of section (e.g. Chief Complaint, Review of Systems, Assessment), the value set is drawn from LOINC
  - **Title** - represents the label of a section-- if valued, it is to be rendered as part of the narrative content of the clinical document Body
  - **Text** - used to store narrative to be rendered, also referred to as the CDA Narrative Block

Comparing structuredBody and nonXMLBody

structuredBody

- A structuredBody follows markup rules for narrative text and CDA R2
  - Allows more fine-grained expression of meaning
  - More rigid than nonXMLBody
  - More difficult to implement than nonXMLBody but allows for greater exchange of data
  - Machine-computable (coded values)

nonXMLBody

- A nonXMLBody can be any supported format
  - The receiving application must be able to read:
    - The associated MIME type
    - The external file
  - Easier to implement than a structuredBody, but harder to exchange with other parties
  - Not guaranteed to be machine-computable (e.g., image)

Comparing structuredBody and nonXMLBody

- The CDA Body contains clinical information.

- A nonXMLBody can be any supported format while a structuredBody follows markup rules for narrative text and CDA.

- The Narrative Block is the section.text field that is used to store narrative to be rendered.

- Content of the Narrative Block are what the clinician is attesting to and can be displayed using a variety of HTML-like tags.

Entries

Combined with and complementary to structured Body

entry: for computational interoperability

- Uses LOINC/SNOMED CT or other controlled vocabulary

- Allows search, organization, and parsing by automated systems

- Standardized structure based on the Reference Information Model (RIM) and the HL7 pattern called a Clinical Statement

Entries

- Computable (coded) expression of a clinical information item:

    - Related to clinical care or public health

    - Recorded because it is relevant to patient care

  - Can be expressed with different levels of granularity, so detail and extension can vary

- Seven of the most common Entries are:
  - Clinical Measurements
  - Coded Findings
  - Laboratory Results
  - Encounters
  - Procedures
  - Medications
  - Product Supply

Entry Example

Procedures

```
<entry>
 <procedure classCode="PROC" moodCode="EVN">
  <code code="52734007"
       codeSystem="2.16.840.1.113883.6.96"
       displayName="Total Hip Replacement"/>
  <effectiveTime value="20120220"/>
  <targetSiteCode
       code="287679003"
       codeSystem="2.16.840.1.113883.6.96"
       displayName="left hip"/>
 </procedure>
</entry>
```

Total Left Hip Replacement on 02-20-2012

CDA Constraint Levels

- The CDA implementation guides define conformance requirements at three different levels. Distinguished by granularity of machine-processable markup.

  - **Level 1 -** Body is human-readable, no semantic codes

  - **Level 2** - Instances with machine-processible section-level semantics.

  - **Level 3 -** Instances that have at least some clinical statements, expressions that are machine-processable to the extent that can be modeled in the RI

- All levels validate against the generic CDA schema.

Release 2: Levels One, Two, Three

wedi

```
<Section>
  <code code="11348-0" codeSystem="2.16.840.1.113883.6.1"/>
   <title>Past Medical History</title>
   <text><list>
    <item><content>Asthma</content></item>
    <item><content>Hypertension</content></item>
    <item><content ID="a3">Osteoarthritis,           </item>
  </list></text>
  <component>
    <contextConductionInd value="TRUE"/>
    <Observation classCode="COND" moodCode="EVN">
      <code code="G-1001" codeSystem="2.16.840.1.113883.6.96"
        displayName="Prior dx"/>
      <value code="D1-201A8" codeSystem="2.16.840.1.113883.6.96"
        displayName="Osteoarthritis">
        <originalText><reference value="#a3"/></originalText>
      </value>
      <targetSiteCode code="T-15720" codeSystem="2.16.840.1.113883.6.96"
        displayName="Knee joint">
        <qualifier>
          <name code="G-C220" codeSystem="2.16.840.1.113883.6.96"
            displayName="with laterality"/>
          <value code="G-A100" codeSystem="2.16.840.1.113883.6.96"
            displayName="right"/>
        </qualifier>
        <originalText><reference value="#a4"/></originalText
      </targetSiteCode>
    </Observation>
  </component>
</Section>
```

Level 2

Level 1

human readable

machine processible

Level 3

What Constraint Levels Provide

- Information can be encoded at varying levels of specificity and understood at the highest, or most appropriate, **level of encoding**.

- Information encoded at varying levels can be analyzed at the **highest common level**

- *Incremental semantic interoperability*

  - It is not necessary to immediately implement all of CDA. An incremental approach can be taken, where first, the CDA Header can be implemented, and used as a wrapper for existing clinical documents as part of a CDA Level 1 implementation. Next, specific sections can be implemented as part of a structuredBody CDA Level 2 implantation. Lastly, a fully coded CDA Level 3 implementation can be developed using CDA Entries.

Incremental Approach

1. Get the data flowing, get the data flowing, get the data flowing.
2. Incrementally add structure, where cost effective to do so.

Quality Reporting

Decision Support

Clinical Applications

Meaningful Use!

Narrative Text

HL7 CDA Structured Documents

Coded Discrete Data Elements

SNOMED CT

Disease, DF-00000

Metabolic Disease, D6-00000

Disorder of carbohydrate metabolism, D6-50000

Disorder of glucose metabolism, D6-50100

Diabetes Mellitus, DB-61000

Type 1, DB-61010

Neonatal, DB75110

Carpenter Syndrome, DB-02324

Insulin dependant type IA, DB-61020

Implementation Guides (IGs)

- Developed by HL7 Structured Documents WG
  - With HL7 Domain Work Groups
  - By other standards organizations
  - By other agencies (CDC...)

- Balloted IGs to-date: US Realm-specific & Universal

- Define *templates* for CDA

Template Definition

- A template identifier (templateId) signals the imposition of a set of template-defined constraints.

- Document-level template

```
<ClinicalDocument>
   ...
<!-- Conformant to updated NHSN Generic Constraints -->
    <templateId root="2.16.840.1.113883.10.20.5.4"/>
    ...
  <section>
    <templateId root="2.16.840.1.113883.10.20.5.5.6"/>
    ...
  </section>
  …
</ClinicalDocument>
```

Template Definition

- Templates can be imposed at three levels within a CDA:

  (1) Document-level: applies to entire document

  (2) Section-level: applies to the document section

  (2) Entry-level: applies to entries within a document section

- Section-level template

```
<section>
  <!- CCD Vital signs section template -->
  <templateId root="2.16.840.1.113883.10.20.1.16"/>
  <code code="8716-3" codeSystem="2.16.840.1.113883.6.1"/>
  <title>Vital Signs</title>
...
</section>
```

Cooking with Templates

CDA Without Templates

- Like a kitchen full of raw ingredients, but no menu, recipes, cookbooks, or other guidance.
- Very flexible, but hard to work with if you are not an expert cook.
- Only the cook knows what's going on until the meal has been cooked and delivered to the table.

Templated CDA

- Same kitchen, but…
- Full menu and recipes are provided.
- Food is prepped and ready to be cooked to order according to the provided recipes.
- Less flexible, but much easier for the novice to work with.
- Both the cook and the diner know what to expect.

Cookbook Approach

The template (recipe) defines the basic structure, then an implementer (cook) fills in the blanks with live data (ingredients).

```xml
<observation classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.6.2.10" />
  <code code="[code]"
    codeSystem="[code_system]"
    codeSystemName="[code_system_name]"
    displayName="[display_name]"/>
  <statusCode code="completed"/>
  <effectiveTime value="[measurement_date]"/>
  <value xsi:type="PQ"
    value="[measure]" unit="[ucum_unit]"/>
</observation>
```

```xml
<observation classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.6.2.10" />
  <code code="50373000"
    codeSystem="2.16.840.1.113883.6.96"
    codeSystemName="SNOMED-CT"
    displayName="Body height"/>
  <statusCode code="completed"/>
  <effectiveTime value="20121114"/>
  <value xsi:type="PQ"
    value="177" unit="cm"/>
</observation>
```

Recipe: populate the [blue] fields with appropriate data.

Fully *cooked* data.

Examples

Example 1 – Sending Data

Use Case #1 Scenario Overview

Scenario: A patient is experiencing severe knee pain and is referred to a Orthopedist by their Primary Care Provider (PCP). The PCP needs to generate a summary document to provide to the Orthopedist.

No single C-CDA Document Template includes all of the elements needed to satisfy the data requirements.

NOTE: The Document Templates within C-CDA are considered "open" templates, which means that, in addition to the required and optional Sections defined in the template, an implementer can add to the Document whatever C-CDA Sections are necessary for his purposes.

How do I send the data?

Putting the **I** in Health**IT**
www.HealthIT.gov

Document Title	Description
Consultation Note	According to CMS evaluation and management guidelines, a Consultation Note must be generated as a result of a physician or non-physician practitioner's (NPP) request for an opinion or advice from another physician or NPP
Continuity of Care Document (CCD)	The CCD is a core data set of the most relevant administrative, demographic, and clinical information facts about a patient's healthcare, covering one or more healthcare encounters.
Discharge Summary	The Discharge Summary is a document that is a synopsis of a patient's admission to a hospital; it provides pertinent information for the continuation of care following discharge.

The C-CDA IG has 9 documents, but the three likely candidates for this situation are displayed above.

- Each C-CDA Document Template was designed to satisfy a specific information exchange scenario.
- Each document template defines the CDA structures to be used to document the applicable clinical information.

Best Fit Document to Scenario: CCD

Scenario: A patient is experiencing severe knee pain and is referred to a Orthopedist by their Primary Care Provider (PCP). The PCP needs to generate a summary document to provide to the Orthopedist.

In this scenario, treatment has been provided by a PCP:

- Given that this treatment is in an ambulatory setting, a **Discharge Summary** would not be appropriate.

- Since the PCP HAS NOT been providing care at the request of another provider, a **Consultation Note** would not be appropriate.

- Given the **clinical scenario** to be described, a **Continuity of Care Document (CCD)** is the most appropriate C-CDA Document Template to use.

CDA Document **Header**

CDA Document **Body**

Sections

48

Include C-CDA components defined by the Document Template (REQUIRED)

Start with the Sections required by the CCD Template in the C-CDA IG:

- US Realm Header → CDA Document **Header**

- Allergies
- Medications
- Problem
- Results

CDA Document **Body**

US Realm Header

Sections
Allergies
Medications
Problem
Results

NOTE: Sections are required for a Document Template when the information contained in those sections will *ALWAYS BE* clinically relevant to the clinical scenario the document template is intended to describe

Include C-CDA components defined by the Document Template (OPTIONAL)

Continue by adding the *clinically relevant* Sections that are optional in the CCD Template in the C-CDA IG:

NOTE: Sections are optional for a Document Template when the information contained in those sections will *SOMETIMES BE* clinically relevant to the clinical scenario the document template is intended to describe

CDA Document **Header**

CDA Document **Body**

- Encounters

- Plan of Care

- Vital Signs
  - Advance Directives
  - Family History
  - Functional Status
  - Immunizations
  - Medical Equipment
  - Payers
  - Procedures
  - Social History

US Realm Header

Sections
Allergies
Encounters
Medications
Plan of Care
Problem
Results
Vital Signs

Add Data from the source systems

Needed Data

- Care plan
- Care team member(s)
- Date of birth
- Ethnicity **
- Laboratory test(s) **
- Laboratory value(s)/result(s)
- Medications **
- Medication allergies **
- Patient name
- Preferred language
- Problem **
- Procedures **
- Race **
- Sex
- Smoking status **
- Vital signs

Specific Requirements

- Provider Name & Office Contact Information (Ambulatory Only)
- Reason for Referral (Ambulatory Only)
- Encounter Diagnoses **
- Cognitive Status
- Functional Status
- Discharge Instructions (Inpatient Only)
- Immunizations **

NOTE: Data requirements marked with a double asterisk (**) also have a defined vocabulary which must be used

Review the data to ensure its populated

Some of the data requirements have already been met through use of the C-CDA Document Template; some may also not apply to the care setting

- Care team member(s)
- Date of birth
- Ethnicity **
- Patient name
- Preferred language

- Provider Name & Office Contact Information (Ambulatory Only)
- Race **
- Sex

→ CDA Document **Header**

- Allergies ** →

- Medications ** →

- Care Plan
- Reason for Referral (Ambulatory Only)

→ CDA Document **Body**

- Problems **
- Encounter Diagnoses ** →

- Laboratory test(s) **
- Laboratory value(s)/result(s) ** →

- Vital Signs →

US Realm Header

Sections
Allergies
Encounters
Medications

Plan of Care

Problem

Results

Vital Signs

Add any remaining data

C-CDA Sections are added to the CCD to address the outstanding data requirements.

CDA Document **Header**

US Realm Header

- ~~Hospital Discharge Instructions (Inpatient Only)~~

- Cognitive Status   • Functional Status
- Immunizations **

CDA Document **Body**

- Procedures **

- Smoking Status **

Sections
Allergies
Encounters
Functional Status
Immunizations
Medications
Plan of Care
Problem
Procedures
Results
Social History
Vital Signs

Scenario Summary

Scenario: A patient is experiencing severe knee pain and is referred to a Orthopedist by their Primary Care Provider (PCP). The PCP needs to generate a summary document to provide to the Orthopedist.

- The Continuity of Care Document (CCD) Document Template was the **best fit for the clinical workflow** in this scenario

- Many of the data requirements were met using the C-CDA document template.

- Additional sections were added as necessary to meet outstanding data requirements.

CDA Document **Header**

CDA Document **Body**

C-CDA

MU

US Realm Header

Sections
Allergies
Encounters
Functional Status
Immunizations
Medications
Plan of Care
Problem
Procedures
Results
Social History
Vital Signs

54

Rendered CCD Example

Good Health Health Summary

Patient	Mr. Adam Everyman		
Date of birth	November 25, 1954	Sex	Male
Race	White	Ethnicity	Not Hispanic or Latino
Contact info	Pirmary Home: 17 Daws Rd. Blue Bell, MA 02368, US Tel: (781)555-1212	Patient IDs	12345 2.16.840.1.113883.19 111-00-1234 2.16.840.1.113883.4.1
Document Id	999021 2.16.840.1.113883.19		
Document Created:	March 29, 2005, 17:15:04 +0500		
Performer (primary care provider)	Dr. Pseudo Physician-1 of NIST HL7 Test Laboratory		
Performer (primary care provider)	Dr. Pseudo Physician-3 of HL7 Test Laboratory		
Author	Henry Seven		
Contact info	Work Place: 123 Main St Boston, MA 02368, USA Tel: (555)555-1003		
Entered by	Henry Seven		

"Good Health Health Summary" from the "U.S. Realm" Header (Document Title element)

"Document ID" from the "U.S. Realm" Header (Document ID element)

"Allergies", "Medications" & "Problems" sections implemented to meet "CCD" and Transition of Care Objective requirements

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

"Good Health Health Summary" – Sample CCD. "CCD.sample.xml" file. C-CDA R2 July 2012 via HL7.

- The CDT has VERY SPECIFIC optionality and requirements to follow
  - If a section or entry that is required cannot be included, a nullFlavor is used
  - This nullFlavor itself has a "meaning"
    - I can't provide data because I don't have it
    - I can't provide data because I don't know the answer

Specialist generating data

Scenario

Scenario: The Orthopedist, after consulting with the patient, schedules surgery to be performed and provides an ambulatory summary to the patient including the care plan to be followed leading up to the surgery.

No single C-CDA Document Template covers all of the data requirements to successfully meet this criterion using only the template's baseline required components.

NOTE: The Document Templates within C-CDA are considered "open" templates, which means that, in addition to the required and optional Sections defined in the template, an implementer can add to the Document whatever C-CDA Sections are necessary for his purposes.

How do I send the data?

Document Title	Description
Consultation Note	According to CMS evaluation and management guidelines, a Consultation Note must be generated as a result of a physician or non-physician practitioner's (NPP) request for an opinion or advice from another physician or NPP
Continuity of Care Document (CCD)	The CCD is a core data set of the most relevant administrative, demographic, and clinical information facts about a patient's healthcare, covering one or more healthcare encounters.
Discharge Summary	The Discharge Summary is a document that is a synopsis of a patient's admission to a hospital; it provides pertinent information for the continuation of care following discharge.

The C-CDA IG has 9 documents, but the three likely candidates for this situation are displayed above.

- Each C-CDA Document Template was designed to satisfy a specific information exchange scenario.
- Each document template defines the CDA structures to be used to document the applicable clinical information.

Best Fit Document to Scenario: Consultation Note

Scenario: The Orthopedist, after the consultation with the patient, schedules surgery to be performed and provides an ambulatory summary to the patient including the care plan to be followed leading up to the surgery.

In this scenario, treatment has been provided by a PCP:

- Given that this treatment is in an ambulatory setting, a **Discharge Summary** would not be appropriate.

- The **Continuity of Care Document (CCD)** is intended to summarize a full episode of care, and as such may be too cumbersome for this scenario.

- Since the Orthopedist is providing care at the request of the PCP, a **Consultation Note** is the best fit for the clinical workflow

CDA Document **Header**

CDA Document **Body**

Sections

Include C-CDA components defined by the Document Template (REQUIRED)

Putting the I in Health IT
www.HealthIT.gov

Start with the Sections required by the CCD Template in the C-CDA IG:

- US Realm Header

CDA Document **Header**

- Assessment and Plan
- Reason for Visit
- Chief Complaint
- History of Present Illness

CDA Document **Body**

NOTE: Sections are required for a Document Template when the information contained in those sections will *ALWAYS BE* clinically relevant to the clinical scenario the document template is intended to describe

US Realm Header

Sections
Assessment and Plan
Reason for Visit
Chief Complaint
History of Present Illness

Include C-CDA components defined by the Document Template (OPTIONAL)

Putting the **I** in Health**IT**
www.HealthIT.gov

Continue by adding the *clinically relevant* Sections that are optional in the Consultation Note Template in the C-CDA IG:

CDA Document **Header**

- ~~Allergies~~
- ~~Family History~~
- ~~General Status~~
- ~~History of Past Illnesses~~
- ~~Immunizations~~

- ~~Medications~~
- ~~Review of Systems~~
- ~~Social History~~
- ~~Physical Exam~~

CDA Document **Body**

- Problem
- Procedures
- Results
- Vital Signs

US Realm Header

Sections
Assessment and Plan
Reason for Visit
Chief Complaint
History of Present Illness
Problem
Procedures
Results
Vital Signs

NOTE: Sections are optional for a Document Template when the information contained in those sections will *SOMETIMES BE* clinically relevant to the clinical scenario the document template is intended to describe

Add Data from the source systems

Putting the **I** in Health**IT**
www.HealthIT.gov

Needed Data

- Care plan
- Care team member(s)
- Date of birth
- Ethnicity **
- Laboratory test(s) **
- Laboratory value(s)/result(s)
- Medications **
- Medication Allergies **
- Patient name
- Preferred language
- Problems **
- Procedures **
- Race **
- Sex
- Smoking status **
- Vital signs

Scenario Specific Data

- Admission & Discharge Dates (Inpatient Only)
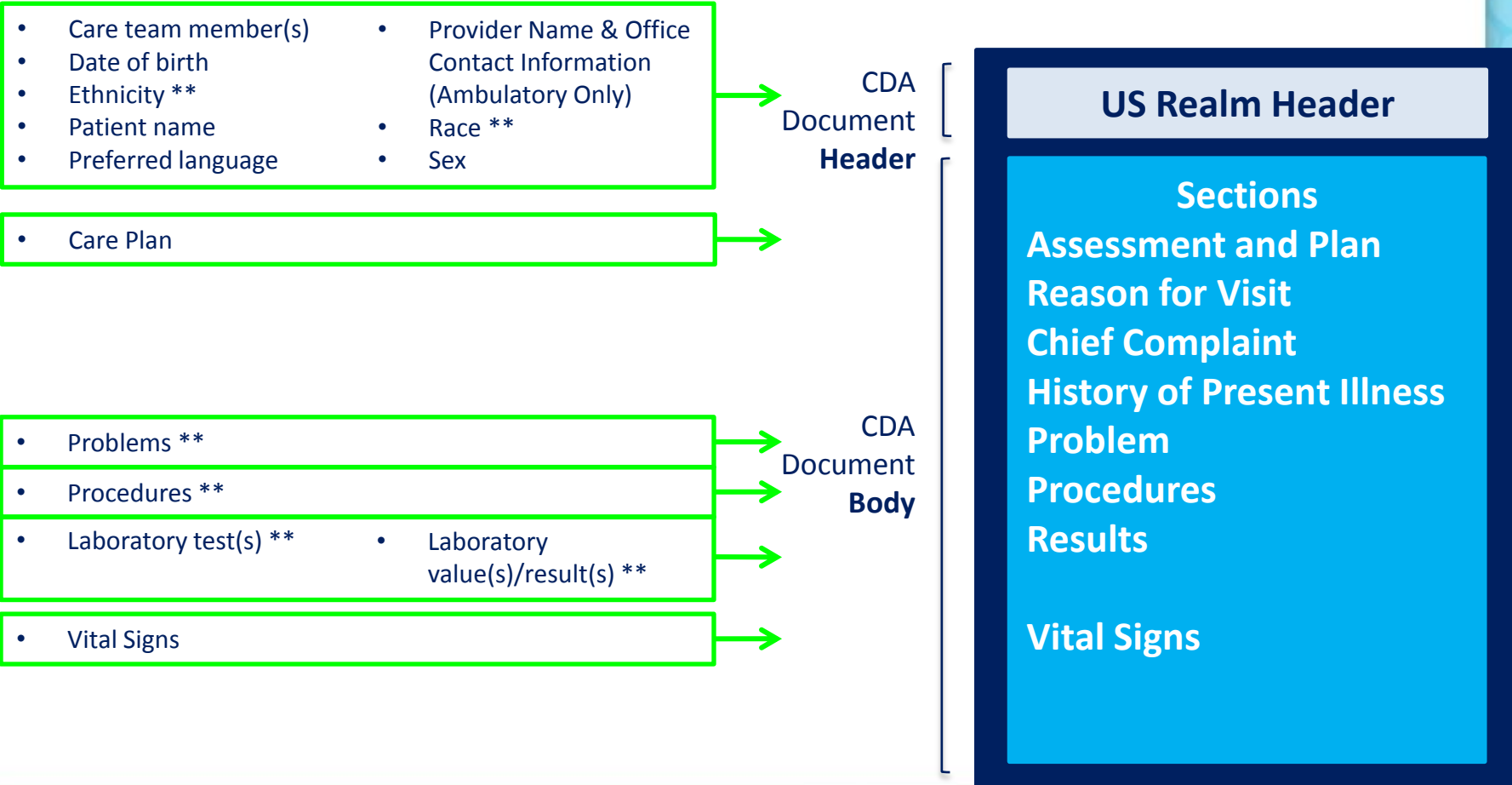- Admission & Discharge Locations (Inpatient Only)
- Discharge Instructions (Inpatient Only)
- Provider Name & Office Contact Information (Ambulatory Only)
- Reason(s) for Hospitalization (Inpatient Only)

NOTE: Data requirements marked with a double asterisk (**) also have a defined vocabulary which must be used

Review data requirements that have already been met

Some of the data requirements have already been met through use of the C-CDA Document Template; some may also not apply to the care setting

- Care team member(s)
- Date of birth
- Ethnicity **
- Patient name
- Preferred language
- Provider Name & Office Contact Information (Ambulatory Only)
- Race **
- Sex

→ CDA Document **Header**

- Care Plan

→

- Problems **

→ CDA Document **Body**

- Procedures **

→

- Laboratory test(s) **
- Laboratory value(s)/result(s) **

→

- Vital Signs

→

US Realm Header

Sections
Assessment and Plan
Reason for Visit
Chief Complaint
History of Present Illness
Problem
Procedures
Results

Vital Signs

Add C-CDA components

C-CDA Sections are added to the Consultation Note to address the outstanding data requirements.

- ~~Admission & Discharge Dates (Inpatient Only)~~
- ~~Admission & Discharge Locations (Inpatient Only)~~
- ~~Discharge Instructions (Inpatient Only)~~
- ~~Reason(s) for Hospitalization (Inpatient Only)~~

- Allergies ** →

- Medications ** →

- Smoking Status ** →

CDA Document **Header**

CDA Document **Body**

US Realm Header

Sections
Allergies
Assessment and Plan
Reason for Visit
Chief Complaint
History of Present Illness
Medications
Problem
Procedures
Results
Vital Signs
Social History

Summary of Scenario

Scenario: The Orthopedist, after the consultation with the patient, schedules surgery to be performed and provides an ambulatory summary to the patient including the care plan to be followed leading up to the surgery.

- The Consultation Note Document Template was the **best fit for the clinical workflow** in this scenario

- Many of the View/Download/Transmit data requirements were met using the C-CDA document template.

- Additional sections were added as necessary to meet outstanding data requirements.

CDA Document **Header**

CDA Document **Body**

C-CDA ✔   MU ✔

US Realm Header

Sections
Allergies
Assessment and Plan
Reason for Visit
Chief Complaint
History of Present Illness
Medications
Problem
Procedures
Results
Vital Signs
Social History

Rendered Consultation Note Example

Consultation Note

Patient	Mr. Adam Everyman		
Date of birth	November 25, 1954	Sex	Male
Race	White	Ethnicity	Not Hispanic or Latino
Contact info	Pirmary Home: 17 Daws Rd. Blue Bell, MA 02368, US Tel: (781)555-1212	Patient IDs	12345 2.16.840.1.113883.19 111-00-1234 2.16.840.1.113883.4.1

Document Id	999021 2.16.840.1.113883.19		
Document Created:	March 29, 2005, 17:15:04 +0500		
Author	Henry Seven		
Contact info	Work Place: 123 Main St Boston, MA 02368, USA Tel: (555)555-1003		

	9937012 2.16.840.1.113883.19	Encounter Type	Evaluation and Management
	From March 29, 2005 to March 29, 2005		
	Mrs. Abigail Ruth		
	Work Place: 123 Main St		

"Patient Information" from the "Consultation Note" template required Header data elements

Allergies, Adverse Reactions, Alerts

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

"Allergies" section template required by ALL MU2-compliant clinical document

ASSESSMENT

1. Recurrent GI bleed of unknown etiology; hypotension perhaps secondary to this but as likely secondary to polypharmacy.
2. Acute on chronic anemia secondary to #1.
3. Azotemia, acute renal failure with volume loss secondary to #1.
4. Hyperkalemia secondary to #3 and on ACE and K+ supplement.
5. Other chronic diagnoses as noted above, currently stable.

REASON FOR VISIT/CHIEF COMPLAINT

Dark stools.

Family history

"Reason for Visit/Chief Complaint" section template required to meet Consultation Note document template requirements

"Consultation Note" – Sample Consultation Note. "Consults.sample.xml" file. C-CDA R2 July 2012 via HL7.

67

- Its important to pick the right document
  - CDT has multiple document types that might represent a claims attachment, each with its own data requirements
- Its important to have a strategy to populate each document type
  - What data do I need for each document type and what system(s) will it come from?
- Its important to have providers understand what they are attesting to

Summing it up

- While its structured and its documented, it still requires a learning curve
- Collaboration between payers and providers needs to happen early and often:
  - Interface development needs to occur with input from all partners that will need to build to them.
  - Payers can start with the CDA standard, but it may need to be tailored to meet payer requirements
- Centralized resources are critical to success:
  - A common use of CDA that can be delivered to new partners fosters a scalable and repeatable process.
  - A centralized validation capability provides a method to ensure all CDA documents efforts are accountable to the standard

Summing it up

- While its structured and its documented, it still requires a learning curve
- Collaboration between payers and providers needs to happen early and often:
  - Interface development needs to occur with input from all partners that will need to build to them.
  - Payers can start with the CDA standard, but it may need to be tailored to meet payer requirements
- Centralized resources are critical to success:
  - A common use of CDA that can be delivered to new partners fosters a scalable and repeatable process.
  - A centralized validation capability provides a method to ensure all CDA documents efforts are accountable to the standard

esMD Project

esMD Project

Business Case

1) Reduce administrative burden

2) Reduce improper payment (~$30B in Medicare, ~$20B Medicaid)

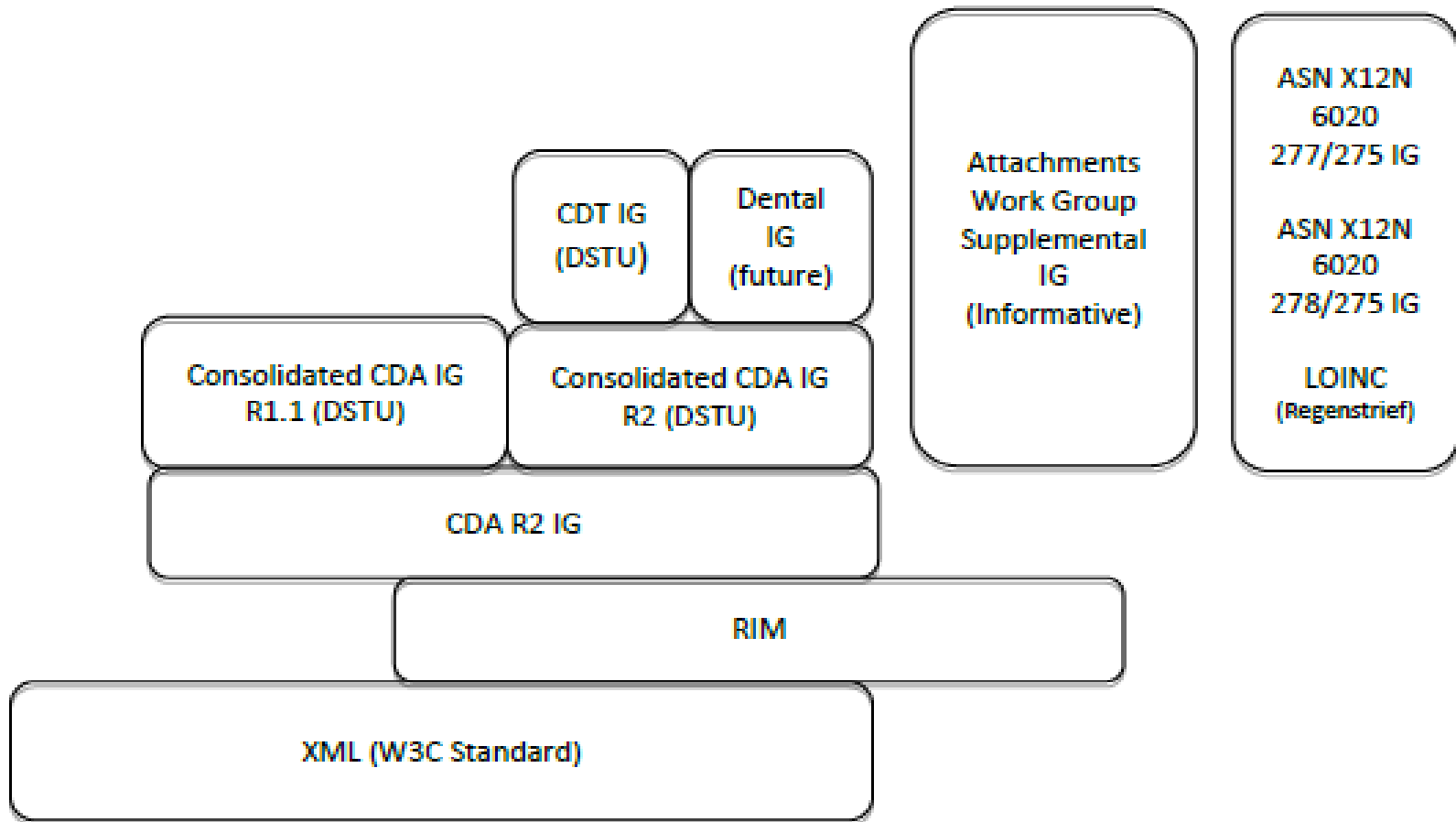3) Move from "post payment audit" to prior-authorization or pre-payment review (e-Determination of Coverage)

Goals

1) Move from paper to electronic communication

2) Replace "wet signatures" with digital signatures

3) Migrate to structured data from unstructured data

esMD Project

1. esMD Phase 1 – provider sends document <u>images</u> electronically to Medicare through Health Information Handler
   A. Unstructured images
   B. Using NwHIN - CONNECT
2. S&I esMD Phase 2 – e-Determination of Coverage work group
   A. Medicare sending a secure eMDR (Request for information) to a 'registered' provider
      I. Provider Profile Authentication IG   (IHE HDR or X12 274)
      II. eMDR and Structured Content IG   (IHE XD* or X12 277 and CORE 270)
   B. Digital signature for Author of Record
      I. Author of Record IG
      II. HL7 Digital Signature DSTU
   C. Define and support structured documentation

      I. Complete Document Template (Balloted HL7 CDA based on C-CDA)
      II. Companion Guides for X12 275 and X12 278

Relationship of CDT to C-CDA

Compare C-CDA and CDT

Consolidated-CDA R1
IHE Health Story

Continuity of Care Document,

Consultation Note,

Diagnostic Imaging Report,

Discharge Summary,

History & Physical,

Operative Note,

Procedure Note,

Progress Note,

Unstructured

C-CDA R2 Clinical Notes adds 4 more:

Care Plan

Referral Note

Transfer Summary

Patient Generated Document

Complete Document Template

Includes all sections from C-CDA Document, with New Conformance Statements requiring all Sections, Permitting Null values,

Requires Digital Signature for Affirmative Attestation to all data being reported.

Consists of 5 more document types:

Complete Encounter,

Complete Hospitalization,

Complete Operative Note,

Complete Procedure Note,

Time Boxed

New CDT Documents

1) Complete Encounter Document includes all:

    a. C-CDA R2 Progress Note Document sections

    b. C-CDA R2 Consult Document sections

    c. C-CDA R2 History and Physical Document sections

    + New Sections: Additional Document, External Defined CDE, Orders Placed, Transportation

2) Complete Hospitalization Document includes all:

    a. C-CDA R2 Discharge Summary Document sections

    b. C-CDA R2 History and Physical Document sections

    + New Sections: Additional Document, External Defined CDE, Orders Placed, Transportation

3) Complete Procedure Document includes all:

    a.　C-CDA R2 Procedure Document sections

    + New Sections: Additional Document, External Defined CDE, Orders Placed

4) Complete Operative Note Document includes all:

    a.　C-CDA R2 Operative Note Document sections

    + New Sections: Additional Document, External Defined CDE, Orders Placed

5) Time Boxed Document has no equivalent templates.

Descriptions of CDT Documents

- **Complete Encounter** - support the entire contents of the medical record related to a specific encounter with a patient for the administrative or clinical exchange with a third party

- **Complete Hospitalization** - to support a complete synopsis of the admission and discharge portion of the medical record related to a specific admission of a patient for the administrative or clinical exchange with a third party

- **Complete Op Note** - to support the entire contents of the medical record related to a specific operative procedure performed on a patient for the administrative or clinical exchange with a third party

- **Complete Proc. Note** -to support the entire contents of the medical record related to a specific procedure performed on a patient for the administrative or clinical exchange with a third party

- **Time Boxed** - to capture the complete activity for the period covered. It may exclude anything that is covered in one of the other Complete Document Templates (e.g. Complete Procedure Document).

New CDT Sections

Additional Documentation Section,

Externally Defined Clinical Data Elements,

Placed Orders,

Transportation

Any section for which data is not available (not collected, not relevant, not supported by the EHR technology, etc.) SHALL have the appropriate nullFlavor specified as affirmative attestation that the information was not available

Descriptions of CDT Sections

- **Additional Documentation** - This section contains additional documentation captured by the provider related to care provided or planned for the patient that is not supported in any other section of the document. (example – physicians rationale for decision)

- **External Defined CDE**- This section contains additional documentation captured by the provider related to care provided or planned for the patient that is not supported in any other section of the document. (example – physicians rationale for decision)

- **Placed Orders** - This section contains data that defines orders for observations, interventions, encounters, services, and procedures for the patient. It includes orders that have been entered into an EHR. These are indicated by the @moodCode RQO and statusCode completed or active for the entries within this section. The entries in this section represent the details of the orders and not the acts involved in the processing and fulfilment of the order. The process of and fulfillment of the order is represented by other entries.

- **Transportation** - The Transportation Section describes in a narrative format the transportation method (such as emergency transport), other than the patient's or caregiver's personal transportation, that was used to bring the patient to the location for the current encounter. This information is normally provided as a summary by the entity that provides the transportation service.

- If information for an entry level template does not exist, the appropriate nullFalvor may be supplied as an attestation that the information does not exist or cannot be shared .

Current Recommendation

- Consolidated-CDA R1

  Harmonized CCD, C32, and IHE Health Story

  9 Document Templates

  Continuity of Care Document, Consultation Note, Diagnostic Imaging Report, Discharge Summary, History & Physical, Operative Note, Procedure Note, Progress Note, Unstructured

  LOINC codes assigned at Document Level

  Request for document type, not at the element level

  HIPAA Panel Lists the Structured and Unstructured document types

- X12 277 Request, 275 Response v6020
- X12 278 Referral / Prior Authorization v5010

Current Recommendation

- HL7 Attachments Supplemental Guide to C-CDA

  How to use Consolidated-CDA for exchange with health plans
  Meta-data defined (sender, receiver, type of document)
  Matching Attachments with the Claim
  Requests defined – Solicited, Unsolicited
  Responses defined – Structured, Unstructured
  How to find, obtain new, and use LOINC codes
  Transport Agnostic
  Examples

Current Implementations

- Implementations related to claim support:

  NGS/Mayo,

  Unsolicited, Unstructured (image,text)

  HCSC/Availity,

  Unsolicited, Unstructured

  AZ Medicaid

  Unsolicited, Unstructured

  esMD paper

  request, unstructured response

Work In Progress – Future adoption?

To support any clinical exchange including Attachments:

- HL7 Consolidated-CDA R2 Templates for Clinical Notes

    Adding document templates (balloted):

    - Care Plan
    - Referral Note
    - Transfer Summary
    - Patient Generated Document

- HL7 Complete Document Templates (esMD-balloted)

    Report Null values for any data not collected or reported

    Adds new document and section templates

- CORE Operating Rules (TBD)
- WEDI – How to Guide (being developed)

Work In Progress – Future adoption?

- **HL7 C-CDA R2 – Templates for Clinical Notes**

  Includes 9 R1.1 Document Templates

  > Continuity of Care Document, Consultation Note, Diagnostic Imaging Report, Discharge Summary, History & Physical, Operative Note, Procedure Note, Progress Note, Unstructured

  Adds 4 New Document Templates:

  > Care Plan, Referral Note, Transfer Summary,
  >
  > Patient Generated Document

  Adds Digital Signature

  Allows Null values at Section Levels

Work In Progress – Future adoption?

- **HL7 C-CDA Complete Document Templates (balloted)**

  Defines 5 new Document Templates

  > Complete Encounter, Complete Hospitalization,
  > Complete Operative Note, Complete Procedure Note, Time Boxed

  Defines 4 new Section Templates

  > Additional Documentation Section, Externally Defined Clinical Data
  > Elements,Placed Orders, Transportation

  Additional Constraints on 4 existing Section Templates

  > Plan of Treatment, Social History, Functional Status, Mental Status

  Requires Affirmative Attestation, via the use of Null Flavors, for any data not reported (may be defaulted by system or template)

  > NI - no information, NA – not applicable

  Supports exchange of the entire contents of the medical record related to a specific encounter

Future Needs

- Better Harmonize Clinical Care and Administrative Needs
- Move to more Structured Data
- Support for variety of transport options
- Adopt other Document Types

Open Questions

- Can we harmonize the use of CDA Templates for Administrative and Clinical purposes?
  - Can we get to the same set of Templates for different use cases?

- How might multiple document templates impact the providers workflow?

- Others?

Summary

- Clinical Document Architecture (CDA R2) defines an XML based standard for representing Clinical Documents.

- CDA documents must have a canonical human readable form.

- The CDA Header can be used in conjunction with the nonXML body to transfer existing clinical documents.

- CDA allows for an incremental approach to development.

- CDA Implementation Guides are intended to define different kinds of documents, specifying the expected sections and any clinical statement entries or machine processable content.

Thank you!

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