Consolidated CDA R2
Presenters

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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.

  - Release 2 (R2) is the current version of the standard.
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.
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.

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

```xml
<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>
        </tr>
      </tbody>
    </table>
  </text>
</section>
```
Human Readable / Machine Interpretable

Good Health Clinic Consultation Note

Patient: Henry Levin, the 7th
Birthdate: September 24, 1932
Consultant: Downey Gordon, MD

History of Present Illness

Henry Levin, the 7th, is a 67 year old male referred for asthma in his teens. He was hospitalized twice last year and has been able to be weaned off steroids for the past several months.

Past Medical History

- Asthma
- Hypertension (see HTN.cda for details)
- Osteoarthritis, right knee

Medications

- Theodur 200mg BID
- Proventil inhaler 2 puffs QID PRN
- Prednisone 20mg ad
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
<table>
<thead>
<tr>
<th>Section Entries</th>
</tr>
</thead>
<tbody>
<tr>
<td>Admission Medication</td>
</tr>
<tr>
<td>Advance Directive Observation</td>
</tr>
<tr>
<td>Age Observation</td>
</tr>
<tr>
<td>Allergy Observation</td>
</tr>
<tr>
<td>Allergy Problem Act</td>
</tr>
<tr>
<td>Allergy Status Observation</td>
</tr>
<tr>
<td>Boundary Observation</td>
</tr>
<tr>
<td>Code Observations</td>
</tr>
<tr>
<td>Comment Activity</td>
</tr>
<tr>
<td>Coverage Activity</td>
</tr>
<tr>
<td>Discharge Medication</td>
</tr>
<tr>
<td>Drug Vehicle</td>
</tr>
<tr>
<td>Encounter Activities</td>
</tr>
<tr>
<td>Estimated Date of Delivery</td>
</tr>
<tr>
<td>Family History Death Observation</td>
</tr>
<tr>
<td>Family History Observation</td>
</tr>
<tr>
<td>Family History Organizer</td>
</tr>
</tbody>
</table>
# 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
- Administrative 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
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, inconsistencies and ambiguities across cross-references have been resolved.

- Consolidated CDA requires more consistent and robust information
  - The C-CDA CCD requires inclusion of at least 4 clinical domains (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) incrementally easier.
  - Example: History & Physical template shares 9 of its 19 clinical domain templates with the CCD
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: Sections

CDA Body: Entries

External References
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.
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
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 setld 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)
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

- 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

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

- 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:

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

<table>
<thead>
<tr>
<th>structuredBody</th>
<th>nonXMLBody</th>
</tr>
</thead>
<tbody>
<tr>
<td>• A structuredBody follows markup rules for narrative text and CDA R2</td>
<td>• A nonXMLBody can be any supported format</td>
</tr>
<tr>
<td>– Allows more fine-grained expression of meaning</td>
<td>– The receiving application must be able to read:</td>
</tr>
<tr>
<td>– More rigid than nonXMLBody</td>
<td>• The associated MIME type</td>
</tr>
<tr>
<td>– More difficult to implement than nonXMLBody but allows for greater exchange of data</td>
<td>• The external file</td>
</tr>
<tr>
<td>– Machine-computable (coded values)</td>
<td>– Easier to implement than a structuredBody, but harder to exchange with other parties</td>
</tr>
<tr>
<td></td>
<td>– Not guaranteed to be machine-computable (e.g., image)</td>
</tr>
</tbody>
</table>
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.
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"/>
  </targetSiteCode>
 </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-processible to the extent that can be modeled in the RI
- All levels validate against the generic CDA schema.
<Section>
  <code code="11348-Q" codeSystem="2.16.840.1.113883.6.1"/>
  <title>Past Medical History</title>
  <text>
    <item><content>Asthma</content></item>
    <item><content>Hypertension</content></item>
    <item><content ID="a3">Osteoarthritis, right knee</content></item>
  </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"></reference></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"></reference></originalText>
      </targetSiteCode>
    </Observation>
  </component>
</Section>
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.
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!**

**HL7 CDA Structured Documents**

**Coded Discrete Data Elements**

**SNOMED CT**

- Disease, DT-00000
- Metabolic Disease, D6-00000
- Disorder of carbohydrate metabolism, D6-50000
- Disorder of glucose metabolism, D6-50010
- Diabetes Mellitus, DB-61000
  - Type 1, DB-61010
  - Neonatal, DB75110
  - Carpenter Syndrome, DB-02324
- Insulin dependant type IA, DB-61020

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

Document-level template

```xml
<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>
```
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
3. Entry-level: applies to entries within a document section

Section-level template

```xml
<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>
```
<table>
<thead>
<tr>
<th>CDA Without Templates</th>
<th>Templated CDA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Like a kitchen full of raw ingredients, but no menu,</td>
<td>Same kitchen, but…</td>
</tr>
<tr>
<td>recipes, cookbooks, or other guidance.</td>
<td>Full menu and recipes are provided.</td>
</tr>
<tr>
<td>Very flexible, but hard to work with if you are not an</td>
<td>Food is prepped and ready to be cooked to order according to the provided recipes.</td>
</tr>
<tr>
<td>expert cook.</td>
<td></td>
</tr>
<tr>
<td>Only the cook knows what’s going on until the meal has</td>
<td>Less flexible, but much easier for the novice to work with.</td>
</tr>
<tr>
<td>been cooked and delivered to the table.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Both the cook and the diner know what to expect.</td>
</tr>
</tbody>
</table>
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>
```

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

```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>
```

Fully cooked data.
Examples
Example 1 – Sending Data
**Scenario:** A patient is experiencing severe knee pain and is referred to an 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?

<table>
<thead>
<tr>
<th>Document Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consultation Note</td>
<td>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.</td>
</tr>
<tr>
<td>Continuity of Care Document (CCD)</td>
<td>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.</td>
</tr>
<tr>
<td>Discharge Summary</td>
<td>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.</td>
</tr>
</tbody>
</table>

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.
**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.
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
- 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.

- Encounters
- Plan of Care
- Vital Signs
  - Advance Directives
  - Family History
  - Functional Status
  - Immunizations
  - Medical Equipment
  - Payers
  - Procedures
  - Social History

CDA Document Header

US Realm Header
- Sections
  - Allergies
  - Encounters
  - Medications
  - Plan of Care
  - Problem
  - Results
  - Vital Signs
Add Data from the source systems

<table>
<thead>
<tr>
<th><strong>Needed Data</strong></th>
<th><strong>Specific Requirements</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Care plan</td>
<td>• Provider Name &amp; Office Contact Information (Ambulatory Only)</td>
</tr>
<tr>
<td>• Care team member(s)</td>
<td>• Reason for Referral (Ambulatory Only)</td>
</tr>
<tr>
<td>• Date of birth</td>
<td>• Encounter Diagnoses **</td>
</tr>
<tr>
<td>• Ethnicity **</td>
<td>• Cognitive Status</td>
</tr>
<tr>
<td>• Laboratory test(s) **</td>
<td>• Functional Status</td>
</tr>
<tr>
<td>• Laboratory value(s)/result(s)</td>
<td>• Discharge Instructions (Inpatient Only)</td>
</tr>
<tr>
<td>• Medications **</td>
<td>• Immunizations **</td>
</tr>
<tr>
<td>• Medication allergies **</td>
<td></td>
</tr>
<tr>
<td>• Patient name</td>
<td></td>
</tr>
<tr>
<td>• Preferred language</td>
<td></td>
</tr>
<tr>
<td>• Problem **</td>
<td></td>
</tr>
<tr>
<td>• Procedures **</td>
<td></td>
</tr>
<tr>
<td>• Race **</td>
<td></td>
</tr>
<tr>
<td>• Sex</td>
<td></td>
</tr>
<tr>
<td>• Smoking status **</td>
<td></td>
</tr>
<tr>
<td>• Vital signs</td>
<td></td>
</tr>
</tbody>
</table>

**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

<table>
<thead>
<tr>
<th>Section</th>
<th>Required Fields</th>
</tr>
</thead>
<tbody>
<tr>
<td>Care team member(s)</td>
<td></td>
</tr>
<tr>
<td>Date of birth</td>
<td></td>
</tr>
<tr>
<td>Ethnicity **</td>
<td></td>
</tr>
<tr>
<td>Patient name</td>
<td></td>
</tr>
<tr>
<td>Preferred language</td>
<td></td>
</tr>
<tr>
<td>Provider Name &amp; Office Contact Information (Ambulatory Only)</td>
<td></td>
</tr>
<tr>
<td>Race **</td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td></td>
</tr>
<tr>
<td>Allergies **</td>
<td></td>
</tr>
<tr>
<td>Medications **</td>
<td></td>
</tr>
<tr>
<td>Care Plan</td>
<td></td>
</tr>
<tr>
<td>Reason for Referral (Ambulatory Only)</td>
<td></td>
</tr>
<tr>
<td>Problems **</td>
<td></td>
</tr>
<tr>
<td>Encounter Diagnoses **</td>
<td></td>
</tr>
<tr>
<td>Laboratory test(s) **</td>
<td>Laboratory value(s)/result(s) **</td>
</tr>
<tr>
<td>Vital Signs</td>
<td></td>
</tr>
</tbody>
</table>

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.

- Hospital Discharge Instructions (Inpatient Only)

<table>
<thead>
<tr>
<th>CDA Document Header</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sections</td>
</tr>
<tr>
<td>Allergies</td>
</tr>
<tr>
<td>Encounters</td>
</tr>
<tr>
<td>Functional Status</td>
</tr>
<tr>
<td>Immunizations</td>
</tr>
<tr>
<td>Medications</td>
</tr>
<tr>
<td>Plan of Care</td>
</tr>
<tr>
<td>Problem</td>
</tr>
<tr>
<td>Procedures</td>
</tr>
<tr>
<td>Results</td>
</tr>
<tr>
<td>Social History</td>
</tr>
<tr>
<td>Vital Signs</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CDA Document Body</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cognitive Status</td>
</tr>
<tr>
<td>Functional Status</td>
</tr>
<tr>
<td>Immunizations **</td>
</tr>
<tr>
<td>Procedures **</td>
</tr>
<tr>
<td>Smoking Status **</td>
</tr>
</tbody>
</table>
**Scenario:** A patient is experiencing severe knee pain and is referred to an 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.
**Rendered CCD Example**

### “Good Health Health Summary” from the “U.S. Realm” Header (Document Title element)

<table>
<thead>
<tr>
<th>Patient</th>
<th>Mr. Adam Evryman</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of birth</td>
<td>November 25, 1954</td>
</tr>
<tr>
<td>Race</td>
<td>White</td>
</tr>
<tr>
<td>Contact info</td>
<td>Primary Home: 17 Dawes Rd.</td>
</tr>
<tr>
<td></td>
<td>Blue Bell, MA 02368, US</td>
</tr>
<tr>
<td></td>
<td>Tel: (731)985-1212</td>
</tr>
<tr>
<td>Patient IDs</td>
<td></td>
</tr>
<tr>
<td></td>
<td>12345 2.16.840.1.113883.19</td>
</tr>
<tr>
<td></td>
<td>111-00-1234 2.16.840.1.113883.4.1</td>
</tr>
</tbody>
</table>

### “Document ID” from the “U.S. Realm” Header (Document ID element)

**Document ID**: 999021:2.16.840.1.113883.19

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

#### Allergies, Adverse Reactions, Alerts

<table>
<thead>
<tr>
<th>Substance</th>
<th>Reaction</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Penicillin</td>
<td>Hives</td>
<td>Active</td>
</tr>
<tr>
<td>Aspirin</td>
<td>Wheezing</td>
<td>Active</td>
</tr>
<tr>
<td>Codeine</td>
<td>Nausea</td>
<td>Active</td>
</tr>
</tbody>
</table>

#### Medications

<table>
<thead>
<tr>
<th>Medication</th>
<th>Directions</th>
<th>Start Date</th>
<th>Status</th>
<th>Indications</th>
<th>Fill Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proventil 0.09 MG/ACTUAT inhalant solution</td>
<td>2 puffs QID PRN wheezing</td>
<td>2011-03-01</td>
<td>Active</td>
<td>Bronchitis (32398004 SNOMED CT)</td>
<td>Generic Substitution Allowed</td>
</tr>
</tbody>
</table>

#### Problems

1. Pneumonia: Resolved in March 1996
2. ...

---

• 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?

<table>
<thead>
<tr>
<th>Document Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consultation Note</td>
<td>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.</td>
</tr>
<tr>
<td>Continuity of Care Document (CCD)</td>
<td>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.</td>
</tr>
<tr>
<td>Discharge Summary</td>
<td>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.</td>
</tr>
</tbody>
</table>

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

**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 Consultation Note Template in the C-CDA IG:

- Allergies
- Family History
- General Status
- History of Past Illnesses
- Immunizations
- Medications
- Review of Systems
- Social History
- Physical Exam

- 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

<table>
<thead>
<tr>
<th>Needed Data</th>
<th>Scenario Specific Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Care plan</td>
<td>• Admission &amp; Discharge Dates (Inpatient Only)</td>
</tr>
<tr>
<td>• Care team member(s)</td>
<td>• Admission &amp; Discharge Locations (Inpatient Only)</td>
</tr>
<tr>
<td>• Date of birth</td>
<td>• Discharge Instructions (Inpatient Only)</td>
</tr>
<tr>
<td>• Ethnicity **</td>
<td>• Provider Name &amp; Office Contact Information (Ambulatory Only)</td>
</tr>
<tr>
<td>• Laboratory test(s) **</td>
<td>• Reason(s) for Hospitalization (Inpatient Only)</td>
</tr>
<tr>
<td>• Laboratory value(s)/result(s)</td>
<td></td>
</tr>
<tr>
<td>• Medications **</td>
<td></td>
</tr>
<tr>
<td>• Medication Allergies **</td>
<td></td>
</tr>
<tr>
<td>• Patient name</td>
<td></td>
</tr>
<tr>
<td>• Preferred language</td>
<td></td>
</tr>
<tr>
<td>• Problems **</td>
<td></td>
</tr>
<tr>
<td>• Procedures **</td>
<td></td>
</tr>
<tr>
<td>• Race **</td>
<td></td>
</tr>
<tr>
<td>• Sex</td>
<td></td>
</tr>
<tr>
<td>• Smoking status **</td>
<td></td>
</tr>
<tr>
<td>• Vital signs</td>
<td></td>
</tr>
</tbody>
</table>

**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
- Care Plan
- Problems **
- Procedures **
- Laboratory test(s) **
- Laboratory value(s)/result(s) **
- 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)
- Admissions & Discharge Locations (Inpatient Only)
- Discharge Instructions (Inpatient Only)
- Reason(s) for Hospitalization (Inpatient Only)

- Allergies **
- Medications **
- Smoking Status **
**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.
"Allergies" section template required by ALL MU2-compliant clinical document

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

Lessons for CDT and Attachments

• It's important to pick the right document
  – CDT has multiple document types that might represent a claims attachment, each with its own data requirements

• It's 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?

• It's 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 images 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
**Compare C-CDA and CDT**

<table>
<thead>
<tr>
<th>Consolidated-CDA R1</th>
<th>Complete Document Template</th>
</tr>
</thead>
<tbody>
<tr>
<td>IHE Health Story</td>
<td></td>
</tr>
<tr>
<td>Continuity of Care Document, Consultation Note, Diagnostic Imaging Report, Discharge Summary, History &amp; Physical, Operative Note, Procedure Note, Progress Note, Unstructured</td>
<td>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.</td>
</tr>
<tr>
<td>C-CDA R2 Clinical Notes adds 4 more: Care Plan, Referral Note, Transfer Summary, Patient Generated Document</td>
<td>Consists of 5 more document types: Complete Encounter, Complete Hospitalization, Complete Operative Note, Complete Procedure Note, Time Boxed</td>
</tr>
</tbody>
</table>
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 fulfillment 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 nullFlavor 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?

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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