

CDA Module, Unit 2:

## **CDA R2: Header, Body and Entries**

Reading Material

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## Unit Content and Learning Objectives

In this Unit, we will explore the CDA R2 architecture through a specific scenario. We devised this scenario to demonstrate the use of CDA R2 and its architecture (it may look similar to some scenarios previously used through this course). This is not intended to be usable (in a real clinical setting) or a complete example - it is only created for educational purposes.

This Unit is not a CDA R2 implementation guide. Our CDA R2 instance will only be compliant with the CDA R2 specification. We will cover the CDA R2 Implementation Guides in the next Unit.

## 1. Introduction

The CDA R2 architecture will now be explored through an "Ambulance Report" scenario that has been specifically created to demonstrate the use of CDA R2 and its architecture.



*Note: In the content of this Unit, we will use the terms CDA and CDA R2 as having the same meaning.*

*You should be aware that there was a previous CDA R1 (Release 1) specification. So whenever we refer to "CDA" we are specifically talking about CDA R2 (Release 2).*

The complete CDA R2 document described in this unit can be found in the file "CHH\_AMBULANCE\_REPORT\_CDA\_R2.XML". The file contains comments for all elements, so you will be able to understand the full document and the decisions that were made in creating the example scenario.

## 2. Scenario

*Community Healthcare and Hospitals, in Ann Arbor, Michigan, wants to send (directly from incoming ambulances) the Clinical Evaluation, Blood Gas and EKG results and Interpretation for their patients to the CHH-EHR document repository.*

*The repository can be accessed from each of their associated Hospitals and Satellite Clinics: Good Health Hospital, Lone Tree Island Clinic, Stone Mountain Clinic, Three Rivers Clinic and Bayview Clinic.*

*When transporting a patient to one of the CHH hospitals, at least one licensed emergency medical technician, registered nurse or physician is in attendance with the patient and is responsible for completing and transmitting the assessment. The document will be generated a few minutes before the ambulance arrives. All ambulances are connected to the same application running in two datacenters, through 3G modem connections.*

*If the author reviews and changes the document after it was sent to the repository, a new version of the document replacing the old one is generated.*

*Bayview Clinic patients are to be treated under very strict confidentiality policies because it only used by celebrities and Fortune 500 CEOs.*

*Patient identifiers will be provided by the CHH patient registry.*

*The Ambulance service is provided by two companies: Ambulances-are-Us, Inc and We-run Emergencies Corp*

*Please see CHH\_AMBULANCE\_REPORT.PDF for a sample of our current ambulance report document in PDF format.*

*Our goal is to transition to a CDA R2 document in order to leverage some of its features: we want to be able to get the context of the act exploring the document header, standardize sections and include coded entries for chief complaint, medication and vital signs. This will allow us to get this coded information into the Hospital's EHR quickly and efficiently.*

### 3. CDA Header Elements

ATTRIBUTES
<i>id</i>
<i>code</i>
<i>title</i>
<i>effectiveTime</i>
<i>confidentialityCode</i>
<i>languageCode</i>
<i>setId</i>
<i>versionNumber</i>

As we saw in the Introduction Unit, the required CDA R2 header contains the contextual information - below is the definition from the CDA R2 R-MIM, including data types, cardinalities and vocabularies:

```
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)
```

- classCode** and **moodCode** are fixed, mandatory and structural attributes (DOCCLIN, EVN respectively) meaning that this is a "document" Act in an "event" mood.
- The mandatory **id** element represents the unique instance identifier (UID) of the clinical document. The **id** element uniquely and universally distinguishes a document from all other documents. This allows documents to be stored/among systems without ID collision across those systems.

The id element contains a **root** and **extension** attribute

For our example scenario, we will generate clinical documents at the ambulance arrival. The document generator will be an application located in two separate data processing center, one located at the Good Health Hospital, and the other one at the Bayview Clinic - serving the other three hospitals.

We need to generate a root for each data processing center.

We will use the OID 2.16.840.1.113883.99.1 for processing center 1 and this OID for center 2: 2.16.840.1.113883.99.2

We use this OIDs beginning with 2.16.840.1.113883.99 because those are defined by HL7 as 'Example OID'. In real life, you need to have an OID assigned by HL7 or an Affiliate or any agency capable of assigning OIDs to an organization.

For more info on how to get or assign OIDs, please read [http://www.hl7.org/implement/standards/product\\_brief.cfm?product\\_id=210](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=210)

We will use the case number and a version sequencer for the extension, but if both data center assigns the same number, they will still be different documents (because of the root OIDs).

In this example, the case number is GHH-3029829 and version number is 1, so our extension is "GHH-3029829-1":

```
<id root="2.16.840.1.113883.99.1" extension="GHH-3029829-1"/>
```

- c. The optional **title** element will be shown in the web browser as the page caption. Note that the LOINC display name in the **code** element (see below) need not match the title of the document. The LOINC name might be "Outpatient Visit Note" and the actual title might be "Good Health Clinic Outpatient Note":

```
<title>GHH AMBULANCE EVALUATION NOTE</title>
```

- d. The mandatory **effectiveTime** element contains the document creation time - when the document first came into being. If the document is a transformation of another document, it should contain the original document's creation date.

Usually the precision of this TS element is given with minutes and seconds and a time zone offset:

```
<effectiveTime value="20180220102000+0300"/>
```

- e. The mandatory **code** element at the root level of the document specifies the particular kind of document that is being created.

The value set is drawn from LOINC, and has a "Coding, With Extensions" (CWE) datatype.

The required attributes are **code** and **codeSystem**, where **code** contains the string indicating the type of document, and the **codeSystem** is the OID of the organization that defined the string.

Remember that displayName and codeSystemName are included just for human readability and are not required.

We have chosen this code, but maybe there is a better choice. You can look up all the LOINC codes for document types at [www.LOINC.org](http://www.LOINC.org).

For our example scenario, we will generate clinical documents at the ambulance arrival:

```
<code code="34755-9" codeSystem="2.16.840.1.113883.6.1"
  codeSystemName="LOINC"
  displayName="TRANSFER SUMMARIZATION NOTE"/>
```

- f. **confidentialityCode** is a mandatory contextual component of CDA - where the value expressed in the header holds true for the entire document, unless overridden by a nested value. The datatype for this element is Coding With Extensions (CWE).

We use the code system defined for HL7 for this element. Normal Confidentiality is usually used with the exception of patients arriving to the Bayview Clinic.

For patients arriving to the BayView Clinic, "Very Restricted Access" is declared by the Privacy Officer:

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

All other patients: Normal - only authorized individuals with medical or business need may access this item:

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

- g. **languageCode**: an optional element, specifies the human language of text information. The values of the attribute are identifiers as defined by the IETF (Internet Engineering Task Force) RFC 3066 (coded simple)

We use US English ("en-US"):

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

- h. **setId** and **versionNumber** are non-required contextual components of CDA, which allow us to differentiate between several versions of the same document. **versionNumber** is a sequential (integer) number.

In our case, the original document holds versionNumber = 1 and subsequent replacements of the document will hold versionNumber = 2, 3, etc.

It is used in combination with the **relatedDocument** element to signal each instance relationship to previous versions of the same document.

**setId** is an instance identifier.

Certain rules apply when creating new versions of previously existing documents.

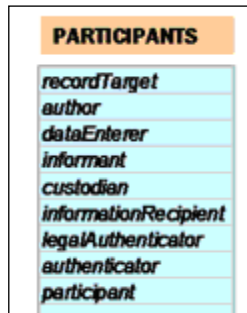
1. The **id** element will always be a new one, never repeated.
2. If we are **REPLACING** a document, we will use a new versionNumber (an incremental increase from the previous version number) and the same **setId** of the replaced document.
3. If we are **APPENDING** a document to a previous one, we will use the same **versionNumber** of the original document, but a new **setId**.



We used our case number identification for setId purposes (we don't use the APPEND use case). We use our case number as the extension:

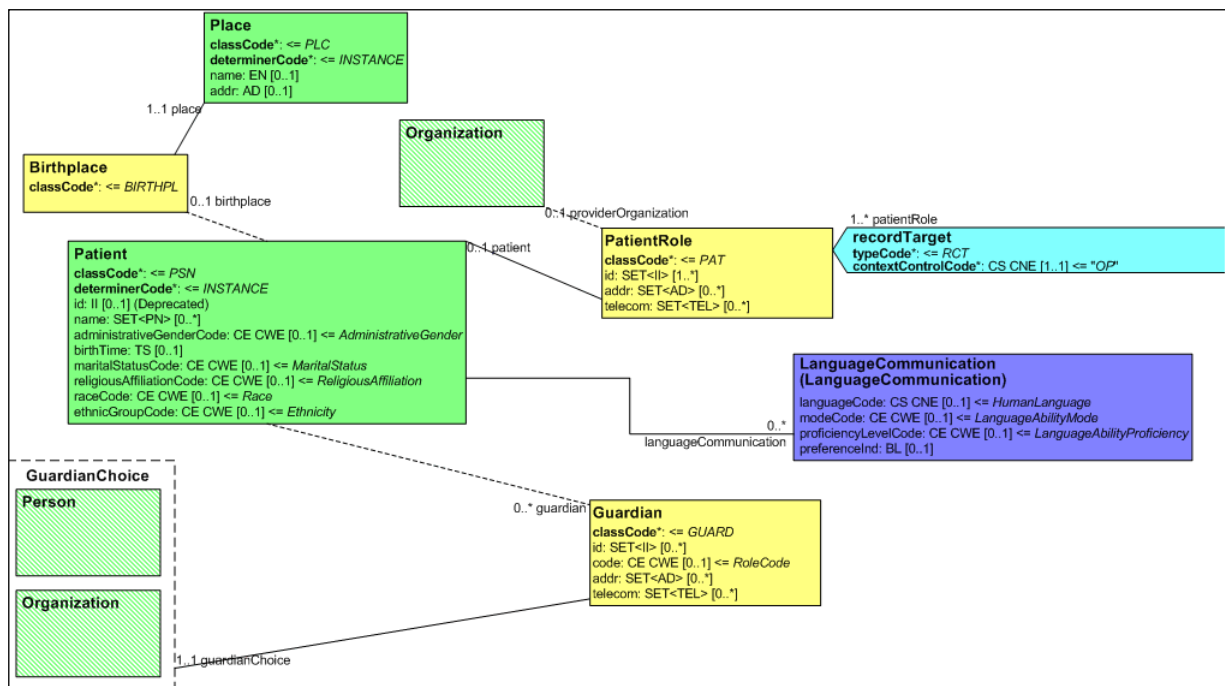
```
<setid root="2.16.840.1.113883.99.3"
  extension="GHH-3029829"/>
<versionNumber value="1">
```

## CDA Participants



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

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



For our scenario, we will use only an OID for patient identification, because we only have ONE patient registry with a unique identifier assigned to each patient for our whole domain.

In the following example, the **root** and **extension** of the **id** are supplied by the organization that is defining the patient. The **patient** and its child **name** element, while optional per the schema, are required in our scenario.

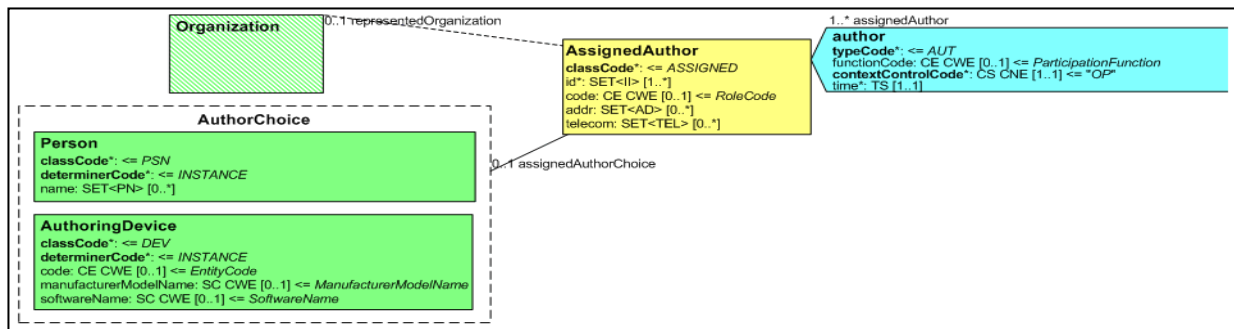
We have chosen to get our CDA R2 instances as complete as possible (to match the PDF note) so we include phone, addresses, birthdate and gender of the patient:

```
<recordTarget>
  <patientRole>
    <id extension="3029290"
      root="2.16.840.1.113883.2.99.1.4"/>
    <addr>
      <houseNumber>220</houseNumber>
      <streetName>Mayfair Drive</streetName>
      <city>Ann Arbor</city>
      <state>Michigan</state>
      <country>United States</country>
    </addr>
    <telecom use="HP" value="tel:5555555555"/>
    <patient>
      <name>
        <given>EVE</given>
        <given qualifier="IN">L.</given>
        <family>EVERYWOMAN</family>
      </name>
      <administrativeGenderCode code="F"
        codeSystem="2.16.840.1.113883.5.1"
        displayName="Female"/>
      <birthTime value="19550513"/>
    </patient>
    <providerOrganization>
      <id root="2.16.840.1.113883.2.99"/>
      <name>Community Health Hospitals</name>
    </providerOrganization>
  </patientRole>
</recordTarget>
```

- b. The mandatory **author** element represents the person or device that composed or created contents of the document.

The author could be any party: a nurse, a physician, a resident, an assistant or even the patient.

The role of the author can also be recorded in `functionCode` or (more commonly) the `AssignedAuthor.code` attribute.



For our scenario, we will identify the parties participating in the patient care in the ambulance by their staff number from each company, so we need an OID for each company staff registry.

Also due to regulatory needs, we need to include the Blood Gas Analyzer identification (model and serial number) along with the results, so we include also the device as an author of the laboratory section, but we do not include the device as document author.

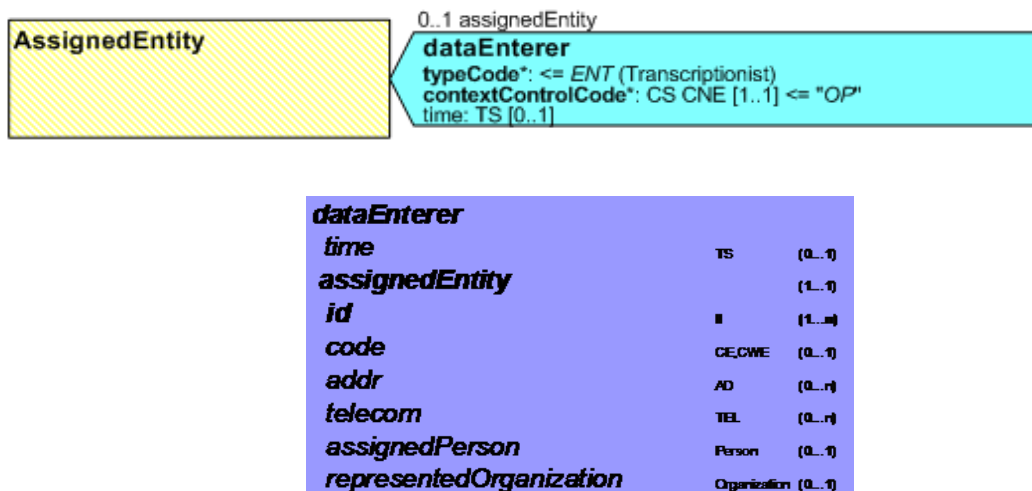
The **functionCode** vocabulary as defined by HL7 does not fit our needs. Since it is a CWE datatype, we have created our own vocabulary with ambulance care functions.

Author: Ambulance Responsible (physician or emt):

```

<author>
  <functionCode code="MD"
    codeSystem="2.16.840.1.113883.2.99.8"/>
  <time value="20180220102000+0300"/>
  <assignedAuthor>
    <id extension="1822"
      root="2.16.840.1.113883.2.99.6.1"/>
    <telecom use="EC" value="tel:5554444333"/>
    <assignedPerson>
      <name>
        <family>SAMPLE</family>
        <given>SANDY</given>
        <suffix>MD</suffix>
      </name>
    </assignedPerson>
    <representedOrganization>
      <id root="2.16.840.1.113883.2.99.6"/>
      <name>AMBULANCES-ARE-US, INC</name>
    </representedOrganization>
  </assignedAuthor>
</author>
  
```

- c. The optional **dataEnterer** element represents a person entering the data into the originating system. The data entry person is collected optionally for internal quality control purposes. This includes the transcriptionist for dictated text.



For our scenario, we will identify the dataEnterer separately from the primary author when the information is dictated by the author but input to the ambulance application by the assistant:

```
<dataEnterer>
  <time value="20180220101800+0300"></time>
  <assignedEntity>
    <id extension="4327" root="2.16.840.1.113883.2.99.6.1"/>
    <assignedPerson>
      <name>
        <family>TECHNICIAN</family>
        <given>TED</given>
        <suffix>EMT-I/99</suffix>
      </name>
    </assignedPerson>
    <representedOrganization>
      <id root="2.16.840.1.113883.2.99.6"/>
      <name>AMBULANCES-ARE-US, INC</name>
    </representedOrganization>
  </assignedEntity>
</dataEnterer>
```

- d. The mandatory **custodian** element represents the organization from which the document originates and who is in charge of maintaining the document. The custodian is entrusted with the care of the document. Every CDA document has exactly one custodian.

#### Example:

For our scenario, the custodian of our documents is the owner of the repository, which is the CHH organization itself, so we just identify our organization through its OID:

```
<custodian>
  <assignedCustodian>
    <representedCustodianOrganization>
      <id root="2.16.840.1.113883.2.99"/>
      <name>Community Health Hospitals</name>
    </representedCustodianOrganization>
  </assignedCustodian>
</custodian>
```

```

</assignedCustodian>
</custodian>

```

- e. The optional **informationRecipient** element represents a person and/or organization who shall receive a copy of the document.

For our scenario, we include the destination hospital as the information recipient. (We do not know the actual person.)

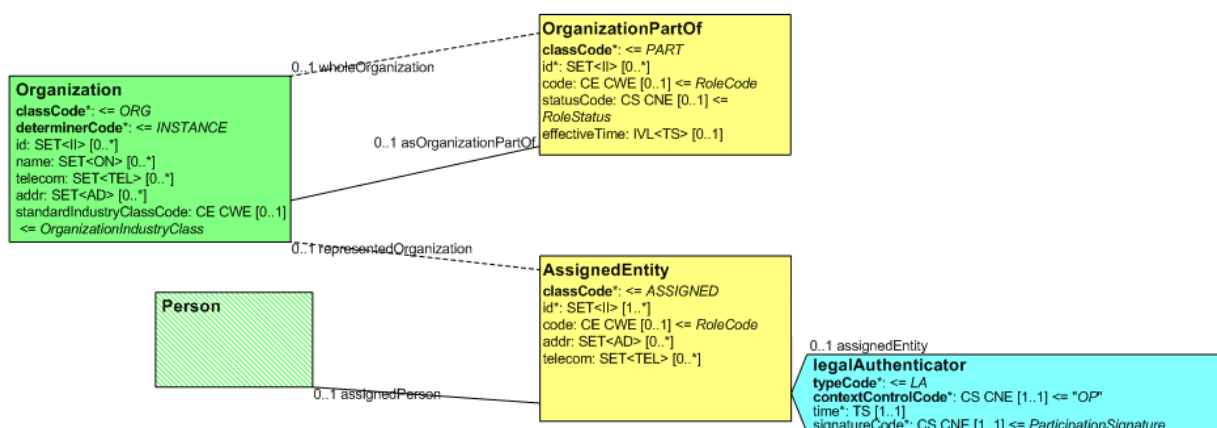
The hospital is identified by its OID and address and phone numbers are included:

```

<informationRecipient>
  <intendedRecipient>
    <telecom use="EC" value="tel:5554433221"/>
    <receivedOrganization>
      <id root="2.16.840.1.113883.2.99.9"/>
      <name>Good Health Hospital</name>
      <addr>
        <houseNumber>550</houseNumber>
        <streetName>Good Health Ave.</streetName>
        <city>Ann Arbor</city>
        <state>Michigan</state>
        <country>United States</country>
      </addr>
    </receivedOrganization>
  </intendedRecipient>
</informationRecipient>

```

- f. The optional **legalAuthenticator** element represents the person legally responsible for the document.



For our scenario, we will identify the persons participating in patient care in the ambulance by their staff number in each company, so we need an OID for each company staff registry.

Also due to regulatory needs, we need to include the Blood Gas Analyzer identification (model and serial number) along

Only one **legalAuthenticator** element can be included in a CDA R2 document.

For our scenario, the legal authenticator is the same person authoring the document:

```
<legalAuthenticator>
  <time value="20180220102000+0300"/>
  <signatureCode code="S"/>
  <assignedEntity>
    <id extension="1822" root="2.16.840.1.113883.2.99.6.1"/>
    <assignedPerson>
      <name>
        <family>SAMPLE</family>
        <given>SANDY</given>
        <suffix>MD</suffix>
      </name>
    </assignedPerson>
    <representedOrganization>
      <id root="2.16.840.1.113883.2.99.6"/>
      <name>AMBULANCES-ARE-US, INC </name>
    </representedOrganization>
  </assignedEntity>
</legalAuthenticator>
```

#### g. Authenticator

Represents a participant who has attested to the accuracy of the document, but who does not have privileges to legally authenticate the document. An example would be a resident physician who sees a patient and dictates a note, then later signs it. (See also legalAuthenticator)

A clinical document can have zero to many authenticators. While electronic signatures are not captured in a CDA document, both authentication and legal authentication require that a document has been signed manually or electronically by the responsible individual. An authenticator has a required authenticator.time indicating the time of authentication, and a required authenticator.signatureCode, indicating that a signature has been obtained and is on file.

- h. CDA R2 allows also the inclusion of a generic **participant** element that includes elements and attributes to define specific participations by combining the functionCode and the entity code, as well as the structural attributes participant.typeCode and role.classCode.

For our scenario, we include the ambulance as another participant (location for the healthcare service):

```
<participant>
  <functionCode code="EM"
  codeSystem="2.16.840.1.113883.2.99.14"
  displayName="Emergency Transportation"/>
  <associatedEntity classCode="SDLOC">
    <id root="2.16.840.1.113883.2.99.6.2"
      extension="AAU#3320"/>
    <code code="EM"
      codeSystem="2.16.840.1.113883.2.99.14"
```

```

        displayName="Emergency Ambulance"></code>
    <scopingOrganization>
        <id root="2.16.840.1.113883.2.99.6"/>
        <name>AMBULANCES-ARE-US, INC</name>
    </scopingOrganization>
</associatedEntity>
</participant>

```

## Other Elements in the Header (Related Acts)

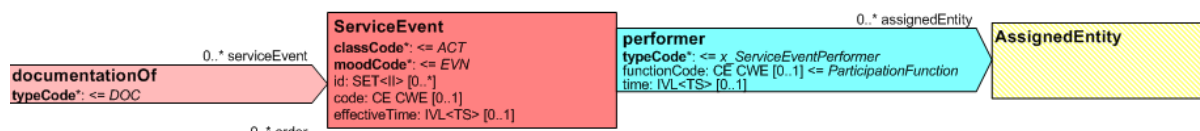
### RELATED ACTS

<i>inFulfillmentOf</i>
<i>documentationOf</i>
<i>relatedDocument</i>
<i>authorization</i>
<i>componentOf</i>

- a. The optional related act element **documentationOf** identifies the medical activity that is documented by the CDA instance. This element provides additional detail related to the medical activity when compared to the value of **ClinicalDocument.code**.

The serviceEvent activity contains:

- **id** - an identification of the act - the id of the act should be different from the identification of the document
- **code** - to identify the type of serviceEvent
- **effectiveTime** - time of the serviceEvent
- **performer** - the person engaged in executing the serviceEvent



For our scenario, we include the case number as the service event id, and the performers' information, as well as the service begin/time:

```

<documentationOf>
<serviceEvent>
  <id root="2.16.840.1.113883.2.99.3"
    extension="GHH-3029829"/>
  <effectiveTime>
    <low value="20180220102000+0300"/>
    <high value="20180220103000+0300"/>
  </effectiveTime>
  <performer typeCode="PPRF">
    <assignedEntity>
      <id extension="1822"

```

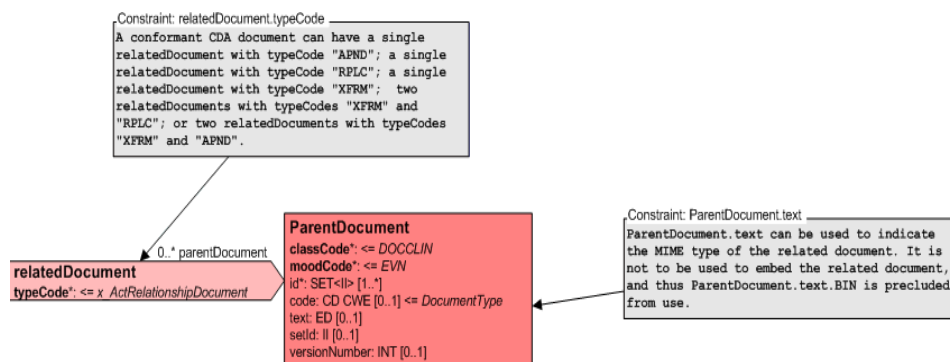
```

    root="2.16.840.1.113883.2.99.6.1"/>
  <assignedPerson>
    <name>
      <family>SAMPLE</family>
      <given>SANDY</given>
      <suffix>MD</suffix>
    </name>
  </assignedPerson>
  <representedOrganization>
    <id root="2.16.840.1.113883.2.99.6"/>
    <name>AMBULANCES-ARE-US, INC </name>
  </representedOrganization>
</assignedEntity>
</performer>
</serviceEvent>
</documentationOf>

```

- b. The optional related act element **relatedDocument** allows the expression of the relationship between this document and its parent (if any exists).

This is achieved by populating its **parentDocument** element:



**typeCode** attribute of **relatedDocument** defines the kind of relationship:

- APND: Current document is an addendum to the parent
- RPLC: Current document is a replacement of the parent
- XFRM: Current document is a transform of the parent

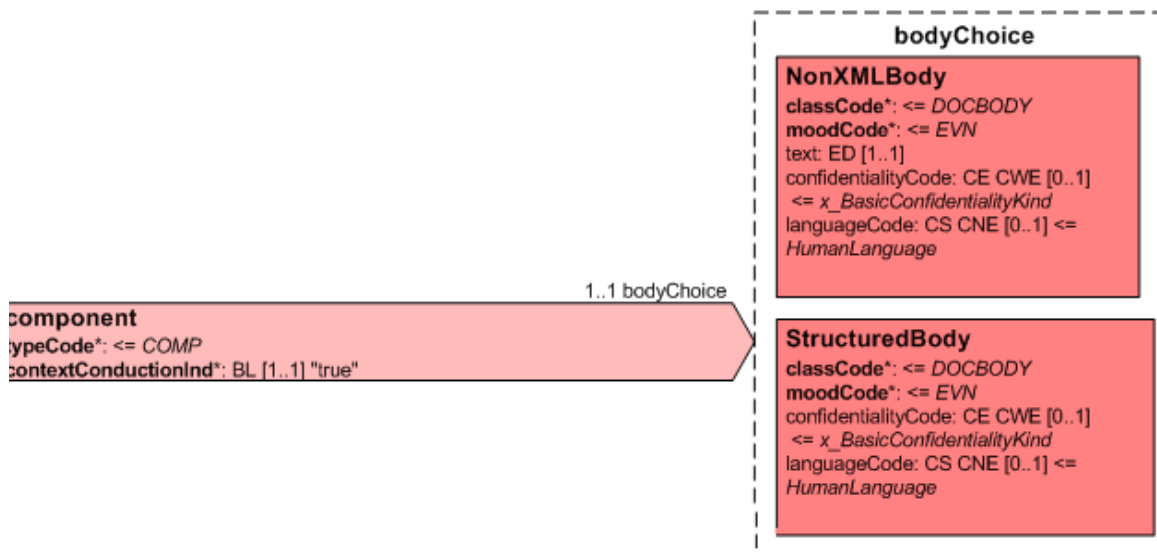


For our scenario, we only include this element in case of document replacement. In this case, we are replacing the original document for version 2 of the document for the same case:

```
<ClinicalDocument>
...
  <id root="2.16.840.1.113883.99.1"
    extension="GHH-3029829-2"/>
...
  <setId root="2.16.840.1.113883.2.99.3"
    extension="GHH-3029829"/>
  <versionNumber value="2"/>
...

  <relatedDocument typeCode="RPLC">
    <parentDocument>
      <id root="2.16.840.1.113883.99.1"
        extension="GHH-3029829-1"/>
      <setId extension="GHH-3029829"
        root="2.16.840.1.113883.99.3"/>
      <versionNumber value="1"/>
    </parentDocument>
  </relatedDocument>
...
</ClinicalDocument>
```

## 4. CDA Body Elements



A CDA body can take one of two forms:

- It can be unstructured. An *unstructured body* could contain anything and everything. As far as the CDA specification is concerned, the contents of the body are unstructured.
- It can be structured. The CDA specification contains a description of the allowable XML structures. A *structured body* has two kinds of content: a human readable and a software processable part.

### Unstructured Body

If a document has an unstructured body, it will have a **NonXMLBody** element. An unstructured body contains any content, for example, a base64 encoded document (PDF, HTML, Word, etc.).

We do not use this kind of construct for our scenario, so we will use a **StructuredBody**, made up of XML components and sections.

### CDA R2 Structured Body

A structured body may include an arbitrary number of **sections** as **components** (a repeat of the **component/Section** element of the document header). Sections may have a **title**, a **code** (to classify its content), and **text** elements. Complex document structures may use sections as components of other sections.

The human readable part of a section consists of the **title** and **text**. These are the parts that have to be presented to a human reader (using a style-sheet or comparable technologies) and the parts that a legal authenticator will be held responsible for.

For our example, we will use the following sections:

- Emergency transportation information
- Clinical evaluation
- Laboratory
- ECG

Sections can contain a **code** element. It is recommended to use LOINC to define this element's codeSystem.

Some of our sections also contain sections (i.e. section nesting).

### Clinical Evaluation

Sub-Section	LOINC Code
Chief Complaint	10154-3
Brief history of present illness	10164-2
Major Past illnesses	10153-2
Medication	10160-0
Mental Status	10190-7
Baseline Vital Signs	8716-3
Pertinent findings of physical examination	29545-1
Emergency medical care given	29544-3

### Text Element (Narrative Text)

The Narrative text is mandatory in CDA R2 and it uses a related subset of X/HTML to allow narrative text expressions.

These are the allowed elements:

Element	Intended Use
paragraph	Divides the section into paragraphs
list	Includes a list of sorted/unsorted items
table	Includes a table
caption	Includes a caption for a table
linkHTML	Includes an external hyperlink
content	Divides the text into separate blocks to allow special formatting instructions (bold, italics, etc.) or for the referencing of software processable parts related to a part of the text (see <i>entries</i> below)
revise (delete/insert)	Expresses that some content was deleted or inserted in a new version of a document
sub, sup	Indicates superscript or subscript
Br	Includes blank paragraphs or line breaks
renderMultiMedia	Includes an image or other multimedia object that is part of the narrative block

For our example, we only use the following constructs:

a. **table** element

Similar to an HTML table:

**thead**: allows to declare column headers - these headers have no meaning - they are NOT field names, they are only here for presentation purposes.

**tbody**: body of the table

**tr**: one for each table row

**td**: one for each table cell inside a row

**th**: one for each column heading

```
<table>
<thead>
  <tr>
    <th>DESCRIPTION</th>
    <th>RESULT</th>
    <th>FLAG</th>
    <th>NORMAL RANGE</th>
    <th>UNITS</th>
  </tr>
</thead>
<tbody>
  <tr>
    <td>pH</td>
    <td>7.19</td>
    <td/>
    <td>7.35-7.45</td>
    <td/>
  </tr>
  ...
</tbody>
</table>
```

... is displayed as:

**ARTERIAL BLOOD GAS**

DESCRIPTION	RESULT	FLAG	NORMAL RANGE	UNITS
pH	7.19		7.35-7.45	
PaCO <sub>2</sub>	65	[H]	35-45	mm Hg
PaO <sub>2</sub>	45	[L]	70-100	mm Hg
SaO <sub>2</sub>	90	[L]	93-98	%
HCO <sub>3</sub>	24		22-26	mEq/L
%COHb	1.1		<3	%
CaO <sub>2</sub>	18.3		16-22	MI O <sub>2</sub> /dL

b. **list** element

Similar to a HTML list, with an optional caption:

```
<text>
  <list>
    <item>EKG</item>
    <item>Blood Gas </item>
    <item>Oxygen Administration </item>
    <item>Bronchodilator</item>
  </list>
</text>
```

... is displayed as:

**Emergency medical care given**

- EKG
- Blood Gas
- Oxygen Administration
- Bronchodilator

c. **renderMultimedia** element

Allows presentation of an image (e.g. gif/jpeg). The element requires reference to an ObservationMedia entry (see entries below):

```
<text>
<renderMultiMedia referencedObject="MM1"/>
  ...
</text>
```

... is displayed as:

**EKG**



d. **paragraph** element: allows paragraph separation:

```
<paragraph>
  <caption>EKG By</caption>
  <content> AutoEKG AutoBGASoft v.3.0, 02-20-2018 10:18</content>
</paragraph>
<paragraph>
  <content>Assessment by: Sandy Sample, MD</content>
</paragraph>
```

... is displayed as:

EKG By: AutoEKG AutoBGASoft v.3.0, 02-20-2018 10:15 Assessment by: Sandy Sample, MD
--

The author can be overridden for any given section - in our case, we included the device as author of the Laboratory section.

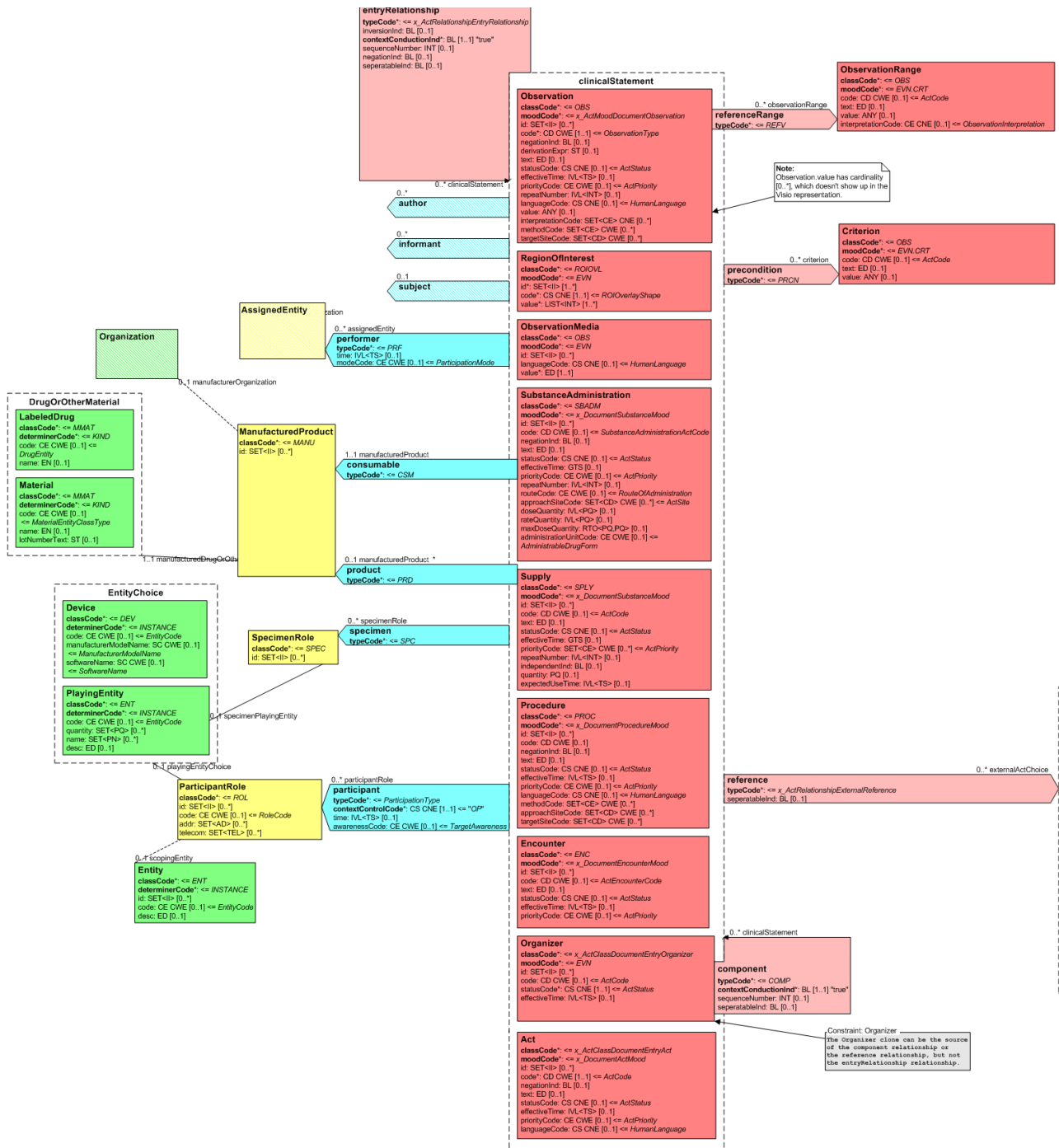
Author: Lab Device for Blood Gas:

```
<author>
  <time value="20180220101500+0300"/>
  <assignedAuthor>
    <id root="2.16.840.1.113883.2.99.6.3"
      extension="202091"/>
    <assignedAuthoringDevice>
      <manufacturerModelName>
AutoBloodGas Analyzer
      </manufacturerModelName>
      <softwareName>
AutoBGASoft v3.0
      </softwareName>
    </assignedAuthoringDevice>
  </assignedAuthor>
</author>
```

## 5. Entries

Entries are RIM-based structures used to convey machine-processable information in CDA documents with a structured body.

Entries are based on the concept of "Clinical Statements".<sup>1</sup> The use of entries is optional.



<sup>1</sup> For more information about the "Clinical Statement", see the foregoing "HL7 Clinical Statements" Unit.

Entry Type	Intended Use
encounter	Identifies a patient encounter related to a particular item/of clinical data
observation	Contains information related to the (order related to) an observation (e.g. a laboratory, radiology observation) or diagnoses
observationMedia	Contains a multi-media observation (e.g. image)
organizer	Used to organize sets of clinical data into collections, sets or lists
procedure	Contains information related to the (order related to) a procedure (e.g. surgery)
RegionOfInterest	Identifies what part(s) of a multi-media observation are of clinical relevance in a specific context (e.g. region of an X-Ray image showing a lymphoma)
SubstanceAdministration	Contains information related to the (order related to) a substance administration activity. (e.g. prescription and administration data related to pharmaceutical products)
Supply	Contains information about the (logistical) supply activity (e.g. a packet of medication, a set of crutches)
Act	Contains information about generic/other clinical activities (not modeled by one of the more specialized activities shown above)

## observation

```

Observation
classCode*: <= OBS
moodCode*: <= x_ActMoodDocumentObservation
id: SET<II> [0..*]
code*: CD CWE [1..1] <= ObservationType
negationInd: BL [0..1]
derivationExpr: ST [0..1]
text: ED [0..1]
statusCode: CS CNE [0..1] <= ActStatus
effectiveTime: IVL<TS> [0..1]
priorityCode: CE CWE [0..1] <= ActPriority
repeatNumber: IVL<INT> [0..1]
languageCode: CS CNE [0..1] <= HumanLanguage
value: ANY [0..1]
interpretationCode: SET<CE> CNE [0..*]
methodCode: SET<CE> CWE [0..*]
targetSiteCode: SET<CD> CWE [0..*]

```

Derived from the RIM Observation class, the observation element is used to represent coded and other observations, such as diagnoses, findings, lab results, etc.

The observation negation indicator, when set to the "true" value, is a positive assertion that the descriptive attributes of the Observation as a whole are negated.

Elements:

**code**: classification of the observation

**value**: observation - can be any datatype (set using xsi:type)

**effectiveTime**: the observation date/time

**moodCode**: the observation was requested (RQO) or produced (EVN)



For our scenario, we created some entries for vital signs:

```
<entry>
<observation classCode="OBS" moodCode="EVN">
  <code code="364075005" codeSystem="2.16.840.1.113883.6.96"
    codeSystemName="SNOMED CT" displayName="Heart rate">
    <originalText>
      <reference value="#ID01"/>
    </originalText>
  </code>
  <statusCode code="completed"/>
  <effectiveTime value="20180220102600+0300"/>
  <value xsi:type="RTO_PQ_PQ">
    <numerator value="35"/>
    <denominator value="1" unit="min"/>
  </value>
</observation>
</entry>
```

We also created an Observation entry to encode the chief complaint:

```
<entry>
<observation classCode="OBS" moodCode="EVN">
  <code code="11292-0" codeSystem="2.16.840.1.113883.6.1"
    displayName="Chief Complaint" codeSystemName="LOINC"/>
  <statusCode code="completed"
    codeSystem="2.16.840.1.113883.5.14"/>
  <effectiveTime value="20180220"/>
  <value xsi:type="CD" code="267036007"
    codeSystem="2.16.840.1.113883.6.96"
    codeSystemName="SNOMED"
    displayName="Dyspnea">
    <originalText>
      <reference value="#CC01"/>
    </originalText>
  </value>
</observation>
</entry>
```

## ObservationMedia

The Observation media element is used to represent multimedia that is logically part of the current document. It is used only for sending multimedia by reference, and only for multimedia that is logically part of the attested content of the document. Since inline transmission of multimedia is not allowed, the use of observation media value "BIN" is precluded from use. Rendering a referenced observation media requires a software tool that recognizes the particular MIME media type:

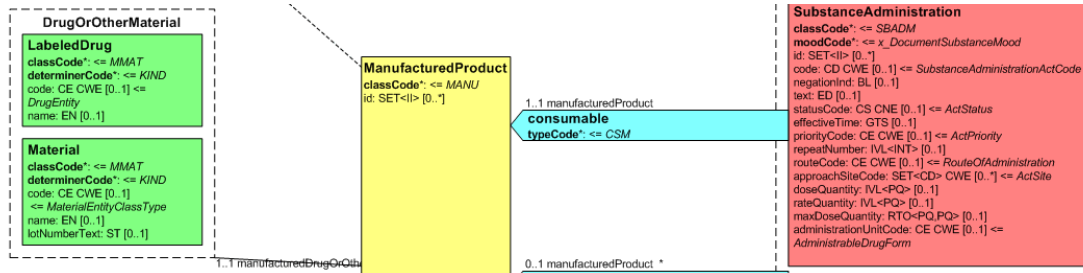
```
<entry>
<observationMedia classCode="OBS"
  moodCode="EVN" ID="MM1">
```

```

<value mediaType="image/jpeg">
  <reference value="ekg.jpg" />
</value>
</observationMedia>
</entry>

```

## substanceAdministration



The Substance Administration entry is used to represent medication-related events (active medication, history of medication or planned medication orders). The doseQuantity indicates how much medication is given per dose. The rateQuantity can be used to indicate the rate at which the dose is to be administered (flow rate). The effectiveTime is used to describe the timing (can use the TS, EIVL-TS and PIVL-TS data types combined).

For our scenario, we created entries to represent medications:

```

<substanceAdministration classCode="SBADM" moodCode="EVN">
  <text>Ambien (Zolpidem) 10 mg daily after dinner</text>
  <statusCode code="active"
    codeSystem="2.16.840.1.113883.5.14"/>
  <effectiveTime xsi:type="EIVL_TS">
    <event code="PCV"
      codeSystem="2.16.840.1.113883.5.139"/>
  </effectiveTime>
  <routeCode code="PO" codeSystem="2.16.840.1.113883.5.112"
    codeSystemName="RouteOfAdministration"/>
  <doseQuantity value="10" unit="mg"/>
  <consumable>
    <manufacturedProduct>
      <manufacturedLabeledDrug>
        <code code="0024-5421-31"
          codeSystem="2.16.840.1.113883.12.549"
          codeSystemName="NDC" displayName="Ambien"/>
      </manufacturedLabeledDrug>
    </manufacturedProduct>
  </consumable>
</substanceAdministration>

```

## Appendix: Use of OIDs

For this example, we have defined an OID tree and a local vocabulary:

OID	DESCRIPTION
2.16.840.1.113883.2.99	Community Health Hospitals
2.16.840.1.113883.2.99.1	Identifier for CDA Documents generated in Datacenter #1
2.16.840.1.113883.2.99.2	Identifier for CDA Documents generated in Datacenter #2
2.16.840.1.113883.2.99.3	Identifier for Cases generated in Datacenter #1, also functions as SETID
2.16.840.1.113883.2.99.4	Identifier for Cases generated in Datacenter #1, also functions as SETID
2.16.840.1.113883.2.99.5	Identifier for Patients in CHH Master Patient Index
2.16.840.1.113883.2.99.6	Ambulances-are-Us, Inc
2.16.840.1.113883.2.99.6.1	Ambulances-are-Us, Inc - Personnel Registry
2.16.840.1.113883.2.99.6.2	Ambulances-are-Us, Inc - Vehicle Registry
2.16.840.1.113883.2.99.6.3	Ambulances-are-Us, Inc - Device Registry
2.16.840.1.113883.2.99.7	We-run Emergencies, Inc
2.16.840.1.113883.2.99.7.1	We-run Emergencies, Inc - Personnel Registry
2.16.840.1.113883.2.99.7.2	We-run Emergencies, Inc - Vehicle Registry
2.16.840.1.113883.2.99.7.3	We-run Emergencies, Inc - Device Registry
2.16.840.1.113883.2.99.9	Goodhealth Hospital
2.16.840.1.113883.2.99.10	Lone Tree Island Clinic
2.16.840.1.113883.2.99.11	Stone Mountain Clinic
2.16.840.1.113883.2.99.12	Three Rivers Clinic
2.16.840.1.113883.2.99.13	Bayview Clinic

CodeSystem	Description	Used in
2.16.840.1.113883.2.99.8	Participation Function for Staff	author/functionCode
2.16.840.1.113883.2.99.14	Participation Function for Ambular participant/functionCode	
2.16.840.1.113883.2.99.15	Entity Classification for Ambulance participant/associatedEntity/code	
Code System		
2.16.840.1.113883.2.99.8	code	value
FR	First Responder	
AD	Ambulance Driver	
ACA	Ambulance Care Assistant	
EMT	Emergency Medical Technician	
EMT-P	Paramedic	
CCEMTP	Critical Care Paramedic	
PP	Paramedic Practitioner	
RN	Registered nurse	
MD	Physician	
2.16.840.1.113883.2.99.14	code	value
EM	Emergency Transportation	
R	Routine Transportation	
2.16.840.1.113883.2.99.15	code	value
EM	Emergency Ambulance	
PTA	Patient Transport Ambulance	
RU	Response Unit/Fly car	
CHA	Charity Ambulance	

## Unit Summary and Conclusion

In this Unit, we explored the use of CDA R2 and its architecture through a specific scenario.

In the next Unit, we will explore further validation of CDA R2 using templates and implementation guides, and more detail about entries and the clinical statement.