Implementation Guide for CDA Release 2 Continuity of Care Document (CCD) (U.S. Realm)



DRAFT: FOR DEVELOPMENT USE ONLY

2 Implementation Guide for CDA Release 2 Introduction					

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10 Implementation Guide for CDA Release 2 Revision History	

Chapter

1

INTRODUCTION

Topics:

- Overview
- Approach
- Scope
- Audience
- Organization of This Guide
- Use of Templates
- Conventions Used in This Guide

Overview

This implementation guide is generated from UML models developed in the Open Health Tools (OHT) Model-Driven Health Tools (MDHT) project. The HL7 CCD specification has been formalized into computational models expressed in UML. These models are used by automated tooling to generate this publication, plus validation tools and Java libraries for implementers.

The purpose of this document is to describe constraints on the HL7 Clinical Document Architecture, Release 2 (CDA) specification in accordance with requirements set forward in ASTM E2369-05 Standard Specification for Continuity of Care Record (CCR).

The CCR 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. It provides a means for one healthcare practitioner, system, or setting to aggregate all of the pertinent data about a patient and forward it to another practitioner, system, or setting to support the continuity of care. The primary use case for the CCR is to provide a snapshot in time containing the pertinent clinical, demographic, and administrative data for a specific patient.

The HL7 Clinical Document Architecture (CDA) is a document markup standard that specifies the structure and semantics of clinical documents for the purpose of exchange. From its inception, CDA has supported the ability to represent professional society recommendations, national clinical practice guidelines, and standardized data sets. From the perspective of CDA, the CCR is a standardized data set that can be used to constrain CDA specifically for summary documents.

The resulting specification, known as the Continuity of Care Document (CCD), is developed as a collaborative effort between ASTM and HL7. It is intended as an alternate implementation to the one specified in ASTM ADJE2369 for those institutions or organizations committed to implementation of the HL7 Clinical Document Architecture.

Approach

Working with an initial portion of the data provides the opportunity to work with the data from the perspective of the underlying model and electronic format and to explore many design issues thoroughly. Taking this as an initial step ensures that the data set developers and standards community can reach consensus prior to the larger commitment of time that would be required to bring the full data set into standard format.

This project supports reusability and ease of data collection through a standard data representation harmonized with work developed through Health Information Technology Expert Panel (HITEP), balloted through Health Level Seven (HL7) and/or recognized by the Health Information Technology Standards Panel (HITSP).

This implementation guide (IG) specifies a standard for electronic submission of NCRs in a Clinical Document Architecture (CDA), Release 2 format.

Scope

TODO: scope of this implementation guide.

Audience

The audience for this document includes software developers and implementers who wish to develop...

Organization of This Guide

The requirements as laid out in the body of this document are subject to change per the policy on implementation guides (see section 13.02" Draft Standard for Trial Use Documents" within the HL7 Governance and Operations Manual, http://www.hl7.org/documentcenter/public/membership/HL7_Governance_and_Operations_Manual.pdf).

Templates

Templates are organized by document (see Document Templates), by section (see Section Templates), and by clinical statements (see Clinical Statement Templates). Within a section, templates are arranged hierarchically, where a more specific template is nested under the more generic template that it conforms to. See Templates by Containment for a listing of the higher level templates by containment; the appendix Templates Used in This Guide includes a table of all of the templates Organized Hierarchically.

Vocabulary and Value Sets

Vocabularies recommended in this guide are from standard vocabularies. When SNOMED codes are used, rules defined in Using SNOMED CT in HL7 Version 3 are adhered to. In many cases, these vocabularies are further constrained into value sets for use within this guide. Value set names and OIDs are summarized in the table Summary of Value Sets. Each named value set in this summary table is stored in a template database that will be maintained by CHCA.

Use of Templates

When valued in an instance, the template identifier (templateId) signals the imposition of a set of template-defined constraints. The value of this attribute provides a unique identifier for the templates in question.

Originator Responsibilities

An originator can apply a templateId to assert conformance with a particular template.

In the most general forms of CDA exchange, an originator need not apply a templateId for every template that an object in an instance document conforms to. This implementation guide asserts when templateIds are required for conformance.

Recipient Responsibilities

A recipient may reject an instance that does not contain a particular templateId (e.g., a recipient looking to receive only CCD documents can reject an instance without the appropriate templateId).

A recipient may process objects in an instance document that do not contain a templateId (e.g., a recipient can process entries that contain Observation acts within a Problems section, even if the entries do not have templateIds).

Conventions Used in This Guide

Conformance Requirements

Conformance statements are grouped and identified by the name of the template, along with the templateId and the context of the template (e.g., ClinicalDocument, section, observation), which specifies the element under constraint. If a template is a specialization of another template, its first constraint indicates the more general template. In all cases where a more specific template conforms to a more general template, asserting the more specific template also implies conformance to the more general template. An example is shown below.

Template name

```
[<type of template>: templateId <XXXX.XXX.XXX.XXX>]
```

Description of the template will be here

- 1. Conforms to <The template name> Template (templateId: XXXX<XX>XXX>YYY).
- **2. SHALL** contain [1..1] @classCode = <AAA> <code display name> (CodeSystem: 123.456.789 <XXX> Class) **STATIC** (CONF:<number>).
- **3.**

Figure 1: Template name and "conforms to" appearance

The conformance verb keyword at the start of a constraint (SHALL, SHOULD, MAY, etc.) indicates business conformance, whereas the cardinality indicator (0..1, 1..1, 1..*, etc.) specifies the allowable occurrences within an instance. Thus, "MAY contain 0..1" and "SHOULD contain 0..1" both allow for a document to omit the particular component, but the latter is a stronger recommendation that the component be included if it is known.

The following cardinality indicators may be interpreted as follows:

- 0..1 as zero to one present
- 1..1 as one and only one present
- 2..2 as two must be present
- 1..* as one or more present
- 0..* as zero to many present

Value set bindings adhere to HL7 Vocabulary Working Group best practices, and include both a conformance verb (SHALL, SHOULD, MAY, etc.) and an indication of DYNAMIC vs. STATIC binding. The use of SHALL requires that the component be valued with a member from the cited value set; however, in every case any HL7 "null" value such as other (OTH) or unknown (UNK) may be used.

Each constraint is uniquely identified (e.g., "CONF:605") by an identifier placed at or near the end of the constraint. These identifiers are not sequential as they are based on the order of creation of the constraint.

- 1. SHALL contain [1..1] component/structuredBody (CONF:4082).
 - a. This component/structuredBody SHOULD contain [0..1] component (CONF:4130) such that it
 - **a. SHALL** contain [1..1] Reporting Parameters section (templateId:2.16.840.1.113883.10.20.17.2.1) (CONF:4131).
 - b. This component/structuredBody SHALL contain [1..1] component (CONF:4132) such that it
 - **a. SHALL** contain [1..1] Patient data section NCR (templateId:2.16.840.1.113883.10.20.17.2.5) (CONF:4133).

Figure 2: Template-based conformance statements example

CCD templates are included within this implementation guide for ease of reference. CCD templates contained within this implementation guide are formatted WITHOUT typical **KEYWORD** and **XML** element styles. A WIKI site is available if you would like to make a comment to be considered for the next release of CCD: http://wiki.hl7.org/index.php?title=CCD_Suggested_Enhancements The user name and password are: wiki/wikiwiki. You will need to create an account to edit the page and add your suggestion.

- 1. The value for "Observation / @moodCode" in a problem observation SHALL be "EVN" 2.16.840.1.113883.5.1001 ActMood STATIC. (CONF: 814).
- 2. A problem observation SHALL include exactly one Observation / statusCode. (CONF: 815).
- **3.** The value for "Observation / statusCode" in a problem observation SHALL be "completed" 2.16.840.1.113883.5.14 ActStatus STATIC. (CONF: 816).
- **4.** A problem observation SHOULD contain exactly one Observation / effectiveTime, to indicate the biological timing of condition (e.g. the time the condition started, the onset of the illness or symptom, the duration of a condition). (CONF: 817).

Figure 3: CCD conformance statements example

Keywords

The keywords SHALL, SHALL NOT, SHOULD, SHOULD NOT, MAY, and NEED NOT in this document are to be interpreted as described in the *HL7 Version 3 Publishing Facilitator's Guide*:

- **SHALL**: an absolute requirement
- SHALL NOT: an absolute prohibition against inclusion
- SHOULD/SHOULD NOT: valid reasons to include or ignore a particular item, but must be understood and carefully weighed
- MAY/NEED NOT: truly optional; can be included or omitted as the author decides with no implications

XML Examples

XML samples appear in various figures in this document in a fixed-width font. Portions of the XML content may be omitted from the content for brevity, marked by an ellipsis (...) as shown in the example below.

```
<ClinicalDocument xmlns='urn:h17-org:v3'>
    ...
</ClinicalDocument>
```

Figure 4: ClinicalDocument example

XPath expressions are used in the narrative and conformance requirements to identify elements because they are familiar to many XML implementers.

Chapter

2

DOCUMENT TEMPLATES

Topics:

• Continuity Of Care Document

This section contains the document level constraints for CDA documents that are compliant with this implementation guide.

Continuity Of Care Document

```
[ClinicalDocument: templateId 2.16.840.1.113883.10.20.1]
1. SHALL conform to CDA Clinical Document
2. SHOULD contain [1..1] component, such that it
   a. contains Problem Section (templateId: 2.16.840.1.113883.10.20.1.11) (CONF-140)
3. SHOULD contain [1..1] component, such that it
   a. contains Family History Section (templateId: 2.16.840.1.113883.10.20.1.4)
4. SHOULD contain [1..1] component, such that it
   a. contains Social History Section (templateId: 2.16.840.1.113883.10.20.1.15)
5. SHOULD contain [1..1] component, such that it
   a. contains Alerts Section (templateId: 2.16.840.1.113883.10.20.1.2)
6. SHOULD contain [1..1] component, such that it
   a. contains Medications Section (templateId: 2.16.840.1.113883.10.20.1.8) (CONF-298)
7. SHOULD contain [1..1] component, such that it
   a. contains Results Section (templateId: 2.16.840.1.113883.10.20.1.14) (CONF-388)
8. SHOULD contain [1..1] component, such that it
   a. contains Procedures Section (templateId: 2.16.840.1.113883.10.20.1.12)
9. SHOULD contain [1..1] component, such that it
   a. contains Encounters Section (templateId: 2.16.840.1.113883.10.20.1.3)
10. SHOULD contain [1..1] component, such that it
   a. contains Plan Of Care Section (templateId: 2.16.840.1.113883.10.20.1.10)
11. SHOULD contain [1..1] component, such that it
   a. contains Immunizations Section (templateId: 2.16.840.1.113883.10.20.1.6)
12. SHOULD contain [1..1] component, such that it
   a. contains Vital Signs Section (templateId: 2.16.840.1.113883.10.20.1.16)
13. SHOULD contain [1..1] component, such that it
   a. contains Medical Equipment Section (templateId: 2.16.840.1.113883.10.20.1.7)
14. SHOULD contain [1..1] component, such that it
   a. contains Functional Status Section (templateId: 2.16.840.1.113883.10.20.1.5)
15. SHOULD contain [1..1] component, such that it
   a. contains Advance Directives Section (templateId: 2.16.840.1.113883.10.20.1.1)
16. SHOULD contain [1..1] component, such that it
   a. contains Payers Section (templateId: 2.16.840.1.113883.10.20.1.9)
17. SHALL contain [1..1] code/@code = "34133-9" Summarization of episode note (CodeSystem:
   2.16.840.1.113883.6.1 LOINC STATIC) (CONF-1)
18. SHALL contain [1..1] languageCode (CONF-5)
19. MAY contain [1..1] component, such that it
   a. contains Purpose Section (templateId: 2.16.840.1.113883.10.20.1.13) (CONF-15)
20. SHALL satisfy: Contains exactly one documentationOf / serviceEvent (CONF-2)
      [OCL]: self.documentationOf->one(doc : cda::DocumentationOf | not
       doc.serviceEvent.oclIsUndefined())
```

- 21. SHALL satisfy: documentationOf / serviceEvent / @classCode SHALL be 'PCPR' (CONF-3)
 - [OCL]: self.documentationOf->one(doc : cda::DocumentationOf | doc.serviceEvent.classCode = vocab::ActClassRoot::PCPR)
- **22. SHALL** satisfy: documentationOf / serviceEvent contains exactly one serviceEvent / effectiveTime / low and exactly one serviveEvent / effectiveTime / high (CONF-4)
 - [OCL]: self.documentationOf->one(doc : cda::DocumentationOf | not doc.serviceEvent.effectiveTime.low.oclIsUndefined() and not doc.serviceEvent.effectiveTime.high.oclIsUndefined())
- **23. SHALL** satisfy: languageCode has the form nn, or nn-CC. The nn portion SHALL be an ISO-639-1 language code in lower case. The CC portion, if present, SHALL be an ISO-3166 country code in upper case (CONF-6)
- **24. SHALL** satisfy: SHALL NOT contain templateId / @extension (CONF-8)
 - [OCL]: self.templateId->forAll(id : datatypes::II | id.root = '2.16.840.1.113883.10.20.1' implies id.extension.oclIsUndefined())
- **25. SHALL** satisfy: effective Time is expressed with precision to include seconds (CONF-9)
- **26. SHALL** satisfy: effectiveTime includes an explicit time zone offset (CONF-10)
- **27. SHALL** satisfy: Contains one or two recordTarget (CONF-11)
 - [OCL]: self.recordTarget->size() = 1 or self.recordTarget->size() = 2
- **28. SHOULD** satisfy: Contains one or more author / assignedAuthor / assignedPerson and/or author / assignedAuthor / representedOrganization (CONF-12)
 - [OCL]: self.author->exists(author : cda::Author | not author.assignedAuthor.assignedPerson.oclIsUndefined() or not author.assignedAuthor.representedOrganization.oclIsUndefined())
- **29. SHALL** satisfy: If author has an associated representedOrganization with no assignedPerson or assignedAuthoringDevice, then the value for author / assignedAuthor / id / @NullFlavor SHALL be 'NA' (CONF-13)
 - [OCL]: self.author->exists(author : cda::Author | (not author.assignedAuthor.representedOrganization.oclIsUndefined() and author.assignedAuthor.assignedPerson.oclIsUndefined() and author.assignedAuthoringDevice.oclIsUndefined()) implies author.assignedAuthor.id->one(id : datatypes::II | id.nullFlavor = vocab::NullFlavor::NA))
- **30. MAY** satisfy: Contains one or more informationRecipient (CONF-14)
 - [OCL]: self.informationRecipient->size() > 0
- **31. MAY** satisfy: The value for component / structuredBody / component / section / entry / @typeCode MAY be 'DRIV' "is derived from" 2.16.840.1.113883.5.1002 ActRelationshipType STATIC, to indicate that the CDA Narrative Block is fully derived from the structured entries. (CONF-28)
- **32. SHOULD** satisfy: A CCD entry SHOULD explicitly reference its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1 <content>). (CONF-29)

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"</pre>
xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <templateId root="2.16.840.1.113883.10.20.1" assigningAuthorityName="CCD</pre>
Continuity Of Care Document"/>
  <code code="34133-9" codeSystem="2.16.840.1.113883.6.1"</pre>
 codeSystemName="LOINC" displayName="Summarization of episode note"/>
  <languageCode/>
  <component>
    <structuredBody>
      <component>
        <section>
          <templateId root="2.16.840.1.113883.10.20.1.11"</pre>
 assigningAuthorityName="CCD Problem Section"/>
          <code code="11450-4" codeSystem="2.16.840.1.113883.6.1"</pre>
 codeSystemName="LOINC" displayName="Problem list"/>
          <title>Problem list</title>
        </section>
```

```
</component>
     <component>
       <section>
         <templateId root="2.16.840.1.113883.10.20.1.4"</pre>
assigningAuthorityName="CCD Family History Section"/>
         <code code="10157-6" codeSystem="2.16.840.1.113883.6.1"</pre>
codeSystemName="LOINC" displayName="History of family member diseases"/>
         <title>History of family member diseases</title>
       </section>
     </component>
     <component>
       <section>
         <templateId root="2.16.840.1.113883.10.20.1.15"</pre>
assigningAuthorityName="CCD Social History Section"/>
         <code code="29762-2" codeSystem="2.16.840.1.113883.6.1"</pre>
codeSystemName="LOINC" displayName="Social history"/>
         <title>Social history</title>
       </section>
     </component>
     <component>
       <section>
         <templateId root="2.16.840.1.113883.10.20.1.2"</pre>
assigningAuthorityName="CCD Alerts Section"/>
         <code code="48765-2" codeSystem="2.16.840.1.113883.6.1"</pre>
codeSystemName="LOINC" displayName="Allergies, adverse reactions, alerts"/>
         <title>Allergies, adverse reactions, alerts</title>
       </section>
     </component>
     <component>
       <section>
         <templateId root="2.16.840.1.113883.10.20.1.8"</pre>
assigningAuthorityName="CCD Medications Section"/>
         <code code="10160-0" codeSystem="2.16.840.1.113883.6.1"</pre>
codeSystemName="LOINC" displayName="History of medication use"/>
         <title>History of medication use</title>
       </section>
     </component>
     <component>
       <section>
         <templateId root="2.16.840.1.113883.10.20.1.14"</pre>
assigningAuthorityName="CCD Results Section"/>
         <code code="30954-2" codeSystem="2.16.840.1.113883.6.1"</pre>
codeSystemName="LOINC" displayName="Relevant diagnostic tests and/or
laboratory data"/>
         <title>Relevant diagnostic tests and/or laboratory data</title>
       </section>
     </component>
     <component>
       <section>
         <templateId root="2.16.840.1.113883.10.20.1.12"</pre>
assigningAuthorityName="CCD Procedures Section"/>
         <code code="47519-4" codeSystem="2.16.840.1.113883.6.1"</pre>
codeSystemName="LOINC" displayName="History of procedures"/>
         <title>History of procedures</title>
       </section>
     </component>
     <component>
       <section>
         <templateId root="2.16.840.1.113883.10.20.1.3"</pre>
assigningAuthorityName="CCD Encounters Section"/>
         <code code="46240-8" codeSystem="2.16.840.1.113883.6.1"</pre>
codeSystemName="LOINC" displayName="History of encounters"/>
         <title>History of encounters</title>
       </section>
```

```
</component>
     <component>
       <section>
         <templateId root="2.16.840.1.113883.10.20.1.10"</pre>
assigningAuthorityName="CCD Plan Of Care Section"/>
         <code code="18776-5" codeSystem="2.16.840.1.113883.6.1"</pre>
codeSystemName="LOINC" displayName="Treatment plan"/>
         <title>Treatment plan</title>
       </section>
     </component>
     <component>
       <section>
         <templateId root="2.16.840.1.113883.10.20.1.6"</pre>
assigningAuthorityName="CCD Immunizations Section"/>
         <code code="11369-6" codeSystem="2.16.840.1.113883.6.1"</pre>
codeSystemName="LOINC" displayName="History of immunizations"/>
         <title>History of immunizations</title>
       </section>
     </component>
     <component>
       <section>
         <templateId root="2.16.840.1.113883.10.20.1.16"</pre>
assigningAuthorityName="CCD Vital Signs Section"/>
         <code code="8716-3" codeSystem="2.16.840.1.113883.6.1"</pre>
codeSystemName="LOINC" displayName="Vital signs"/>
         <title>Vital signs</title>
       </section>
     </component>
     <component>
       <section>
         <templateId root="2.16.840.1.113883.10.20.1.7"</pre>
assigningAuthorityName="CCD Medical Equipment Section"/>
         <code code="46264-8" codeSystem="2.16.840.1.113883.6.1"</pre>
codeSystemName="LOINC" displayName="History of medical device use"/>
         <title>History of medical device use</title>
       </section>
     </component>
     <component>
       <section>
         <templateId root="2.16.840.1.113883.10.20.1.5"</pre>
assigningAuthorityName="CCD Functional Status Section"/>
         <code code="47420-5" codeSystem="2.16.840.1.113883.6.1"</pre>
codeSystemName="LOINC" displayName="Functional status assessment"/>
         <title>Functional status assessment</title>
       </section>
     </component>
     <component>
       <section>
         <templateId root="2.16.840.1.113883.10.20.1.1"</pre>
assigningAuthorityName="CCD Advance Directives Section"/>
         <code code="42348-3" codeSystem="2.16.840.1.113883.6.1"</pre>
codeSystemName="LOINC" displayName="Advance directives"/>
         <title>Advance directives</title>
       </section>
     </component>
     <component>
       <section>
         <templateId root="2.16.840.1.113883.10.20.1.9"</pre>
assigningAuthorityName="CCD Payers Section"/>
         <code code="48768-6" codeSystem="2.16.840.1.113883.6.1"</pre>
codeSystemName="LOINC" displayName="Payment sources"/>
         <title>Payment sources</title>
       </section>
     </component>
```

Figure 5: Continuity Of Care Document example

Chapter

3

SECTION TEMPLATES

Topics:

- Advance Directives Section
- Alerts Section
- Encounters Section
- Family History Section
- Functional Status Section
- Immunizations Section
- Medical Equipment Section
- Medications Section
- Payers Section
- Plan Of Care Section
- Problem Section
- Procedures Section
- Purpose Section
- Results Section
- Social History Section
- Vital Signs Section

Advance Directives Section

```
[Section: templateId 2.16.840.1.113883.10.20.1.1]
1. SHALL conform to CDA Section
2. SHALL contain [1..1] code/@code = "42348-3" Advance directives (CodeSystem: 2.16.840.1.113883.6.1
  LOINC STATIC)
3. SHALL contain [1..1] title
4. SHALL contain [1..*] entry, such that it
  a. contains Advance Directive Observation (templateId: 2.16.840.1.113883.10.20.1.17)
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"</pre>
xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
         <section>
           <templateId root="2.16.840.1.113883.10.20.1.1"</pre>
 assigningAuthorityName="CCD Advance Directives Section"/>
           <code code="42348-3" codeSystem="2.16.840.1.113883.6.1"</pre>
 codeSystemName="LOINC" displayName="Advance directives"/>
           <title>Advance directives</title>
             <observation classCode="OBS" moodCode="EVN">
               <templateId root="2.16.840.1.113883.10.20.1.17"</pre>
 assigningAuthorityName="CCD Advance Directive Observation"/>
               <id root="bfc39c2e-7b3a-40e4-95c5-29fdeb00015f"/>
               <statusCode code="completed"/>
               <effectiveTime>
                 <low value="1972"/>
                 <high value="2008"/>
               </effectiveTime>
             </observation>
           </entry>
         </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 6: Advance Directives Section example

Alerts Section

```
[Section: templateId 2.16.840.1.113883.10.20.1.2]
```

This section is used to list and describe any allergies, adverse reactions, and alerts that are pertinent to the patient's current or past medical history. At a minimum, currently active and any relevant historical allergies and adverse reactions should be listed.

- 1. SHALL conform to CDA Section
- 2. SHALL contain [1..1] code/@code = "48765-2" Allergies, adverse reactions, alerts (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC)
- 3. SHALL contain [1..1] title
- 4. SHALL contain [1..1] text
- **5. SHOULD** contain [1..*] entry, such that it
 - **a.** contains *Problem Act* (templateId: 2.16.840.1.113883.10.20.1.27)

- 6. SHOULD satisfy: Contains a case-insensitive language-insensitive string containing "alert" and/or "allergies and adverse reactions".
- 7. SHALL satisfy: The absence of known allergies, adverse reactions or alerts SHALL be explicitly asserted.

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"</pre>
xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <templateId root="2.16.840.1.113883.10.20.1.2"</pre>
assigningAuthorityName="CCD Alerts Section"/>
          <code code="48765-2" codeSystem="2.16.840.1.113883.6.1"</pre>
 codeSystemName="LOINC" displayName="Allergies, adverse reactions, alerts"/>
          <title>Allergies, adverse reactions, alerts</title>
            <act classCode="ACT" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.27"</pre>
 assigningAuthorityName="CCD Problem Act"/>
              <id root="e8400700-23da-4550-b529-7af8a9a21987"/>
              <code nullFlavor="NA"/>
              <effectiveTime>
                <low value="1972"/>
                <high value="2008"/>
              </effectiveTime>
            </act>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 7: Alerts Section example

Encounters Section

[Section: templateId 2.16.840.1.113883.10.20.1.3]

This section is used to list and describe any healthcare encounters pertinent to the patient's current health status or historical health history. An Encounter is an interaction, regardless of the setting, between a patient and a practitioner who is vested with primary responsibility for diagnosing, evaluating, or treating the patient's condition. It may include visits, appointments, as well as non face-to-face interactions. It is also a contact between a patient and a practitioner who has primary responsibility for assessing and treating the patient at a given contact, exercising independent judgment. This section may contain all encounters for the time period being summarized, but should include notable encounters.

- 1. SHALL conform to *CDA Section*
- 2. SHALL contain [1..1] code/@code = "46240-8" *History of encounters* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC)
- 3. SHALL contain [1..1] title

Figure 8: Encounters Section example

Family History Section

```
[Section: templateId 2.16.840.1.113883.10.20.1.4]
```

This section contains data defining the patient's genetic relatives in terms of possible or relevant health risk factors that have a potential impact on the patient's healthcare risk profile.

- 1. SHALL conform to CDA Section
- **2. SHALL** contain [1..1] code/@code = "10157-6" *History of family member diseases* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC)
- 3. SHALL contain [1..1] title

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"</pre>
xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <templateId root="2.16.840.1.113883.10.20.1.4"</pre>
assigningAuthorityName="CCD Family History Section"/>
          <code code="10157-6" codeSystem="2.16.840.1.113883.6.1"</pre>
 codeSystemName="LOINC" displayName="History of family member diseases"/>
          <title>History of family member diseases</title>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 9: Family History Section example

Functional Status Section

```
[Section: templateId 2.16.840.1.113883.10.20.1.5]
```

Functional Status describes the patient's status of normal functioning at the time the Care Record was created. Functional statuses include information regarding the patient relative to:

- Ambulatory ability
- Mental status or competency
- Activities of Daily Living (ADLs), including bathing, dressing, feeding, grooming
- Home / living situation having an effect on the health status of the patient
- · Ability to care for self
- Social activity, including issues with social cognition, participation with friends and acquaintances other than family members
- Occupation activity, including activities partly or directly related to working, housework or volunteering, family
 and home responsibilities or activities related to home and family
- Communication ability, including issues with speech, writing or cognition required for communication
- Perception, including sight, hearing, taste, skin sensation, kinesthetic sense, proprioception, or balance

Any deviation from normal function that the patient displays and is recorded in the record should be included. Of particular interest are those limitations that would in any way interfere with self care or the medical therapeutic

process. In addition, an improvement, any change in or noting that the patient has normal functioning status is also valid for inclusion.

Functional Statuses can be expressed in 3 different forms. They can occur as a Problem, a Result or as text. Text can be employed if and only if the Functional Status is neither a Problem nor a Result. Functional Statuses expressed as Problems include relevant clinical conditions, diagnoses, symptoms and findings. Results are the interpretation or conclusion derived from a clinical assessment or test battery, such as the Instrumental Activities of Daily Living (IADL) scale or the Functional Status Index (FSI).

- 1. SHALL conform to CDA Section
- **2. SHALL** contain [1..1] code/@code = "47420-5" *Functional status assessment* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC)
- 3. SHALL contain [1..1] title
- 4. SHOULD satisfy: Contains one or more Problem Act and/or Result Organizer (CONF-123)

```
[OCL]: self.getEntryTargets(ccd::ProblemAct)->size() > 0
      or self.getEntryTargets(ccd::ResultOrganizer)->size() > 0
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"</pre>
xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <templateId root="2.16.840.1.113883.10.20.1.5"</pre>
 assigningAuthorityName="CCD Functional Status Section"/>
          <code code="47420-5" codeSystem="2.16.840.1.113883.6.1"</pre>
 codeSystemName="LOINC" displayName="Functional status assessment"/>
          <title>Functional status assessment</title>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 10: Functional Status Section example

Immunizations Section

[Section: templateId 2.16.840.1.113883.10.20.1.6]

The Immunizations section defines a patient's current immunization status and pertinent immunization history. The primary use case for the Immunization section is to enable communication of a patient's immunization status. The section should include current immunization status, and may contain the entire immunization history that is relevant to the period of time being summarized.

This section is optional, however it is strongly recommended that it be present in cases of pediatric care and in other cases when such information is available.

- 1. SHALL conform to CDA Section
- **2. SHALL** contain [1..1] code/@code = "11369-6" *History of immunizations* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC)
- 3. SHALL contain [1..1] title
- 4. SHALL contain [1..1] text
- 5. SHOULD satisfy: Contains a case-insensitive language-insensitive string containing 'immunization'.
- **6. SHOULD** satisfy: Contains one or more Medication Activity and/or Supply Activity (CONF-376)

```
• [OCL]: self.getEntryTargets(ccd::MedicationActivity)->size() > 0
    or self.getEntryTargets(ccd::SupplyActivity)->size() > 0
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
```

Figure 11: Immunizations Section example

Medical Equipment Section

[Section: templateId 2.16.840.1.113883.10.20.1.7]

The Medical Equipment section defines a patient's implanted and external medical devices and equipment that their health status depends on, as well as any pertinent equipment or device history. This section is also used to itemize any pertinent current or historical durable medical equipment (DME) used to help maintain the patient's health status. All pertinent equipment relevant to the diagnosis, care, and treatment of a patient should be included.

- 1. SHALL conform to CDA Section
- **2. SHALL** contain [1..1] code/@code = "46264-8" *History of medical device use* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC)
- 3. SHALL contain [1..1] title

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"</pre>
xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <templateId root="2.16.840.1.113883.10.20.1.7"</pre>
 assigningAuthorityName="CCD Medical Equipment Section"/>
          <code code="46264-8" codeSystem="2.16.840.1.113883.6.1"</pre>
 codeSystemName="LOINC" displayName="History of medical device use"/>
          <title>History of medical device use</title>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 12: Medical Equipment Section example

Medications Section

```
[Section: templateId 2.16.840.1.113883.10.20.1.8]
```

The Medications section defines a patient's current medications and pertinent medication history. At a minimum, the currently active medications should be listed, with an entire medication history as an option, particularly when the summary document is used for comprehensive data export. The section may also include a patient's prescription history, and enables the determination of the source of a medication list (e.g. from a pharmacy system vs. from the patient).

1. SHALL conform to CDA Section

- **2. SHALL** contain [1..1] code/@code = "10160-0" *History of medication use* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC) (CONF-300, CONF-301)
- **3. SHALL** contain [1..1] title (CONF-302)
- 4. SHALL contain [0..1] text
- 5. Contains [0..*] entry, such that it
 - **a.** contains *Medication Activity* (templateId: 2.16.840.1.113883.10.20.1.24)
- **6.** Contains [0..*] entry, such that it
 - **a.** contains *Supply Activity* (templateId: 2.16.840.1.113883.10.20.1.34)
- 7. SHALL satisfy: The absence of known medications is explicitly asserted. (CONF-299)
- **8. SHOULD** satisfy: Valued with a case-insensitive language-insensitive string containing 'medication'. (CONF-303)
- **9. SHOULD** satisfy: Clinical statements include one or more Medication Activity and/or one or more Supply Activity. (CONF-298)

```
• [OCL]: self.getSubstanceAdministrations()-
    >exists(activity : cda::SubstanceAdministration
     activity.oclIsKindOf(ccd::MedicationActivity))
       or self.getSupplies()->exists(activity : cda::Supply |
     activity.oclIsKindOf(ccd::SupplyActivity))
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"</pre>
xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
 <component>
   <structuredBody>
     <component>
        <section>
          <templateId root="2.16.840.1.113883.10.20.1.8"</pre>
 assigningAuthorityName="CCD Medications Section"/>
          <code code="10160-0" codeSystem="2.16.840.1.113883.6.1"</pre>
 codeSystemName="LOINC" displayName="History of medication use"/>
          <title>History of medication use</title>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 13: Medications Section example

Payers Section

[Section: templateId 2.16.840.1.113883.10.20.1.9]

Payers contains data on the patient's payers, whether a 'third party' insurance, self-pay, other payer or guarantor, or some combination of payers, and is used to define which entity is the responsible fiduciary for the financial aspects of a patient's care.

Each unique instance of a payer and all the pertinent data needed to contact, bill to, and collect from that payer should be included. Authorization information that can be used to define pertinent referral, authorization tracking number, procedure, therapy, intervention, device, or similar authorizations for the patient or provider, or both should be included. At a minimum, the patient's pertinent current payment sources should be listed.

The CCD represents the sources of payment as a coverage act, which identifies all of the insurance policies or government or other programs that cover some or all of the patient's healthcare expenses. The policies or programs are sequenced by order of preference. Each policy or program identifies the covered party with respect to the payer, so that the identifiers can be recorded.

- 1. SHALL conform to CDA Section
- **2. SHALL** contain [1..1] code/@code = "48768-6" *Payment sources* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC) (CONF-31, CONF-32)

- SHALL contain [1..1] title (CONF-33)
 SHOULD contain [1..*] entry, such that it
 - **a.** contains *Coverage Activity* (templateId: 2.16.840.1.113883.10.20.1.20) (CONF-30)
- 5. SHALL contain [1..1] text (CONF-30)
- **6. SHOULD** satisfy: Contains a case-insensitive language-insensitive string containing 'insurance' or 'payers'. (CONF-34)

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"</pre>
xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <templateId root="2.16.840.1.113883.10.20.1.9"</pre>
assigningAuthorityName="CCD Payers Section"/>
          <code code="48768-6" codeSystem="2.16.840.1.113883.6.1"</pre>
 codeSystemName="LOINC" displayName="Payment sources"/>
          <title>Payment sources</title>
          <entry>
            <act classCode="ACT" moodCode="DEF">
              <templateId root="2.16.840.1.113883.10.20.1.20"</pre>
 assigningAuthorityName="CCD Coverage Activity"/>
              <id root="5f93cf95-40d8-42ea-a31b-f8233d0aaf23"/>
              <code code="48768-6" codeSystem="2.16.840.1.113883.6.1"</pre>
 codeSystemName="LOINC" displayName="Payment sources"/>
              <statusCode code="completed"/>
            </act>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 14: Payers Section example

Plan Of Care Section

```
[Section: templateId 2.16.840.1.113883.10.20.1.10]
```

The plan of care section contains data defining pending orders, interventions, encounters, services, and procedures for the patient. It is limited to prospective, unfulfilled, or incomplete orders and requests only. All active, incomplete, or pending orders, appointments, referrals, procedures, services, or any other pending event of clinical significance to the current and ongoing care of the patient should be listed, unless constrained due to issues of privacy.

The plan of care section also contains information regarding goals and clinical reminders. Clinical reminders are placed here for purposes of providing prompts that may be used for disease prevention, disease management, patient safety, and healthcare quality improvements, including widely accepted performance measures.

- 1. SHALL conform to CDA Section
- **2. SHALL** contain [1..1] code/@code = "18776-5" *Treatment plan* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC)
- 3. SHALL contain [1..1] title
- 4. SHALL contain [1..1] text
- 5. MAY contain [0..1] entry, such that it
 - a. contains *Plan Of Care Activity Act* (templateId: 2.16.840.1.113883.10.20.1.25)
- **6. MAY** contain [0..1] entry, such that it
 - a. contains *Plan Of Care Activity Encounter* (templateId: 2.16.840.1.113883.10.20.1.25)
- 7. MAY contain [0..1] entry, such that it

```
a. contains Plan Of Care Activity Observation (templateId: 2.16.840.1.113883.10.20.1.25)
8. MAY contain [0..1] entry, such that it
  a. contains Plan Of Care Activity Procedure (templateId: 2.16.840.1.113883.10.20.1.25)
9. MAY contain [0..1] entry, such that it
  a. contains Plan Of Care Activity Substance Administration (templateId:
     2.16.840.1.113883.10.20.1.25)
10. MAY contain [0..1] entry, such that it
  a. contains Plan Of Care Activity Supply (templateId: 2.16.840.1.113883.10.20.1.25)
11. SHALL contain [1..1] planOfCareActivity, such that it
  a. contains Plan Of Care Activity
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"</pre>
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
       <component>
         <section>
           <templateId root="2.16.840.1.113883.10.20.1.10"</pre>
 assigningAuthorityName="CCD Plan Of Care Section"/>
           <code code="18776-5" codeSystem="2.16.840.1.113883.6.1"</pre>
 codeSystemName="LOINC" displayName="Treatment plan"/>
           <title>Treatment plan</title>
           <entry>
             <act classCode="ACT" moodCode="EVN">
               <templateId root="2.16.840.1.113883.10.20.1.25"/>
               <id root="9ae535d4-2d42-4a67-a1e2-1d10070e9750"/>
             </act>
           </entry>
           <entry>
             <encounter>
               <templateId root="2.16.840.1.113883.10.20.1.25"/>
               <id root="f53fd4a3-2b0f-4926-be61-le6d56a5c01f"/>
             </encounter>
           </entry>
           <entry>
             <observation classCode="OBS" moodCode="EVN">
               <templateId root="2.16.840.1.113883.10.20.1.25"/>
               <id root="052018b7-036e-459d-af4a-e9aba132a0a5"/>
             </observation>
           </entry>
           <entry>
             cedure>
               <templateId root="2.16.840.1.113883.10.20.1.25"/>
               <id root="cf66ce04-e96c-493f-b159-ee2ac3c5faac"/>
             </procedure>
           </entry>
           <entry>
             <substanceAdministration classCode="SBADM">
               <templateId root="2.16.840.1.113883.10.20.1.25"/>
               <id root="2cca739c-b7a6-4913-a597-44e3b5efc31f"/>
             </substanceAdministration>
           </entry>
           <entry>
             <supply classCode="SPLY">
               <templateId root="2.16.840.1.113883.10.20.1.25"/>
               <id root="def966c2-cdba-41b8-9e41-cb659702c231"/>
             </supply>
           </entry>
         </section>
```

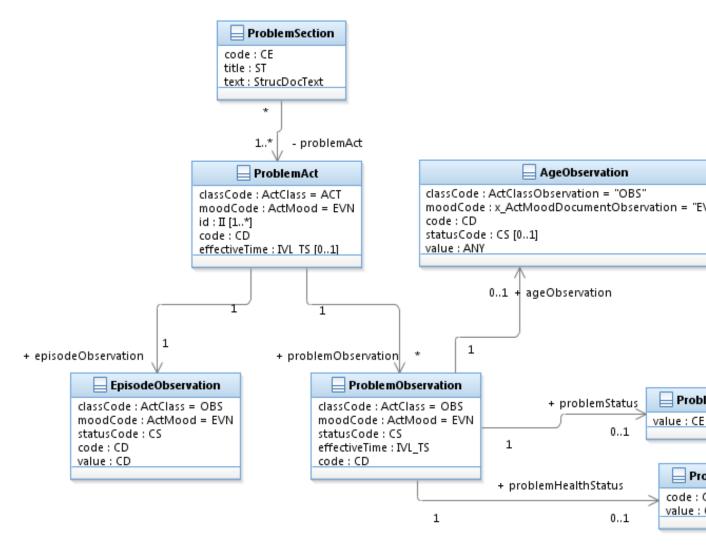
```
</component>
  </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 15: Plan Of Care Section example

Problem Section

[Section: templateId 2.16.840.1.113883.10.20.1.11]

This diagram will be updated to show all consolidated constraints from IHE and CCD. The image size will also be fixed to fit within the page width.



This section lists and describes all relevant clinical problems at the time the summary is generated. At a minimum, all pertinent current and historical problems should be listed. CDA R2 represents problems as Observations.

- 1. SHALL conform to CDA Section
- **2. SHALL** contain [1..1] code/@code = "11450-4" *Problem list* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC) (CONF-141, CONF-142)
- **3. SHALL** contain [1..1] title (CONF-143)
- 4. SHOULD contain [1..*] entry, such that it

```
a. contains Problem Act (templateId: 2.16.840.1.113883.10.20.1.27) (CONF-140)
5. SHALL contain [1..1] text (CONF-140)
6. SHOULD satisfy: Contains a case-insensitive language-insensitive string containing 'problems'. (CONF-144)
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"</pre>
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
           <templateId root="2.16.840.1.113883.10.20.1.11"</pre>
 assigningAuthorityName="CCD Problem Section"/>
           <code code="11450-4" codeSystem="2.16.840.1.113883.6.1"</pre>
 codeSystemName="LOINC" displayName="Problem list"/>
           <title>Problem list</title>
           <entry>
             <act classCode="ACT" moodCode="EVN">
               <templateId root="2.16.840.1.113883.10.20.1.27"</pre>
 assigningAuthorityName="CCD Problem Act"/>
               <id root="915913b7-7412-456e-9998-711c65a37933"/>
               <code nullFlavor="NA"/>
               <effectiveTime>
                 <low value="1972"/>
                 <high value="2008"/>
               </effectiveTime>
             </act>
           </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 16: Problem Section example

Procedures Section

```
[Section: templateId 2.16.840.1.113883.10.20.1.12]
```

This section defines all interventional, surgical, diagnostic, or therapeutic procedures or treatments pertinent to the patient historically at the time the document is generated. The section may contain all procedures for the period of time being summarized, but should include notable procedures.

- 1. SHALL conform to CDA Section
- **2. SHALL** contain [1..1] code/@code = "47519-4" *History of procedures* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC)
- **3. SHALL** contain [1..1] title
- **4. SHOULD** contain [1..*] procedureActivity, such that it
 - a. contains *Procedure Activity*

Figure 17: Procedures Section example

Purpose Section

```
[Section: templateId 2.16.840.1.113883.10.20.1.13]
```

Represents the specific reason for which the summarization was generated, such as in response to a request.

The general use case does not require a purpose. Purpose should be utilized when the CCD has a specific purpose such as a transfer, referral, or patient request.

- 1. SHALL conform to CDA Section
- **2. SHALL** contain [1..1] code/@code = "48764-5" *Summary purpose* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC) (CONF-16, CONF-17)
- **3. SHALL** contain [1..1] title (CONF-18)
- **4. SHOULD** contain [1..*] entry, such that it
 - **a.** contains *Purpose Activity* (templateId: 2.16.840.1.113883.10.20.1.30)
- 5. SHALL contain [1..1] text
- **6. SHOULD** satisfy: Contains a case-insensitive language-insensitive string containing 'purpose'. (CONF-19)

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"</pre>
xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <templateId root="2.16.840.1.113883.10.20.1.13"</pre>
 assigningAuthorityName="CCD Purpose Section"/>
          <code code="48764-5" codeSystem="2.16.840.1.113883.6.1"</pre>
 codeSystemName="LOINC" displayName="Summary purpose"/>
          <title>Summary purpose</title>
            <act classCode="ACT" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.30"</pre>
 assigningAuthorityName="CCD Purpose Activity"/>
              <code code="23745001" codeSystem="2.16.840.1.113883.6.96"</pre>
 codeSystemName="SNOMEDCT" displayName="Documentation procedure"/>
              <statusCode code="completed"/>
            </act>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 18: Purpose Section example

Results Section

```
[Section: templateId 2.16.840.1.113883.10.20.1.14]
```

This section contains the results of observations generated by laboratories, imaging procedures, and other procedures. The scope includes hematology, chemistry, serology, virology, toxicology, microbiology, plain x-ray, ultrasound, CT,

MRI, angiography, cardiac echo, nuclear medicine, pathology, and procedure observations. The section may contain all results for the period of time being summarized, but should include notable results such as abnormal values or relevant trends.

Lab results are typically generated by laboratories providing analytic services in areas such as chemistry, hematology, serology, histology, cytology, anatomic pathology, microbiology, and/or virology. These observations are based on analysis of specimens obtained from the patient, submitted to the lab.

Imaging results are typically generated by a clinician reviewing the output of an imaging procedure, such as where a cardiologist reports the left ventricular ejection fraction based on the review of a cardiac echo.

Procedure results are typically generated by a clinician wanting to provide more granular information about component observations made during the performance of a procedure, such as where a gastroenterologist reports the size of a polyp observed during a colonoscopy.

- 1. SHALL conform to CDA Section
- 2. SHALL contain [1..1] code/@code = "30954-2" Relevant diagnostic tests and/or laboratory data (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC) (CONF-389)
- **3. SHALL** contain [1..1] title (CONF-391)
- **4. SHOULD** contain [1..*] entry, such that it
 - a. contains *Result Organizer* (templateId: 2.16.840.1.113883.10.20.1.32) (CONF-388)
- **5. SHALL** contain [1..1] text (CONF-388)
- 6. SHOULD satisfy: Contains a case-insensitive language-insensitive string containing 'results'. (CONF-392)

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"</pre>
xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <templateId root="2.16.840.1.113883.10.20.1.14"</pre>
 assigningAuthorityName="CCD Results Section"/>
          <code code="30954-2" codeSystem="2.16.840.1.113883.6.1"</pre>
 codeSystemName="LOINC" displayName="Relevant diagnostic tests and/or
 laboratory data"/>
          <title>Relevant diagnostic tests and/or laboratory data</title>
          <entry>
            <organizer moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.32"</pre>
 assigningAuthorityName="CCD Result Organizer"/>
              <id root="f267faa9-089c-4e1b-b699-152f49c7697c"/>
              <code/>
              <statusCode/>
            </organizer>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 19: Results Section example

Social History Section

```
[Section: templateId 2.16.840.1.113883.10.20.1.15]
```

This section contains data defining the patient's occupational, personal (e.g. lifestyle), social, and environmental history and health risk factors, as well as administrative data such as marital status, race, ethnicity and religious affiliation. Social history can have significant influence on a patient's physical, psychological and emotional health and wellbeing so should be considered in the development of a complete record.

- 1. SHALL conform to CDA Section
- 2. SHALL contain [1..1] code/@code = "29762-2" Social history (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC)
- 3. SHOULD contain [1..1] title

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"</pre>
xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <templateId root="2.16.840.1.113883.10.20.1.15"</pre>
assigningAuthorityName="CCD Social History Section"/>
          <code code="29762-2" codeSystem="2.16.840.1.113883.6.1"</pre>
 codeSystemName="LOINC" displayName="Social history"/>
          <title>Social history</title>
        </section>
      </component>
    </structuredBody>
 </component>
</ClinicalDocument>
```

Figure 20: Social History Section example

Vital Signs Section

```
[Section: templateId 2.16.840.1.113883.10.20.1.16]
```

This section contains current and historically relevant vital signs, such as blood pressure, heart rate, respiratory rate, height, weight, body mass index, head circumference, crown-to-rump length, and pulse oximetry. The section may contain all vital signs for the period of time being summarized, but at a minimum should include notable vital signs such as the most recent, maximum and/or minimum, or both, baseline, or relevant trends.

Vital signs are represented like other results (as defined in *Results Section*), but are aggregated into their own section in order to follow clinical conventions.

- **1. SHALL** conform to *CDA Section*
- **2. SHALL** contain [1..1] code/@code = "8716-3" *Vital signs* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC)
- 3. SHALL contain [1..1] title
- 4. SHOULD contain [1..*] entry, such that it
 - **a.** contains *Vital Signs Organizer* (templateId: 2.16.840.1.113883.10.20.1.35)
- 5. SHALL contain [1..1] text
- **6. SHOULD** satisfy: Contains a case-insensitive language-insensitive string containing 'vital signs'.

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"</pre>
xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <templateId root="2.16.840.1.113883.10.20.1.16"</pre>
assigningAuthorityName="CCD Vital Signs Section"/>
          <code code="8716-3" codeSystem="2.16.840.1.113883.6.1"</pre>
 codeSystemName="LOINC" displayName="Vital signs"/>
          <title>Vital signs</title>
          <entry>
            <organizer moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.32"</pre>
assigningAuthorityName="CCD Result Organizer"/>
```

Figure 21: Vital Signs Section example

Chapter



CLINICAL STATEMENT TEMPLATES

Topics:

- Advance Directive Observation
- Advance Directive Status Observation
- Age Observation
- Alert Observation
- Alert Status Observation
- Authorization Activity
- Cause Of Death Observation
- Comment
- Coverage Activity
- Coverage Plan Description
- Encounters Activity
- Episode Observation
- Family History Observation
- Family History Organizer
- Fulfillment Instruction
- Functional Status Observation
- Medication Activity
- Medication Series Number Observation
- Medication Status Observation
- Patient Instruction
- Plan Of Care Activity Act
- Plan Of Care Activity Encounter
- Plan Of Care Activity Observation
- Plan Of Care Activity Procedure
- Plan Of Care Activity Substance Administration
- Plan Of Care Activity Supply
- Policy Activity
- Problem Act
- Problem Health Status Observation
- Problem Observation
- Problem Status Observation
- Procedure Activity Act

This section of the Implementation Guide details the clinical statement entries referenced in the document section templates. The clinical statement entry templates are arranged alphabetically.

- Procedure Activity Observation
- Procedure Activity Procedure
- Purpose Activity
- Reaction Observation
- Result Observation
- Result Organizer
- Severity Observation
- Social History Observation
- Status Observation
- Supply Activity
- Vital Signs Organizer

Advance Directive Observation

```
[Observation: templateId 2.16.840.1.113883.10.20.1.17]
1. SHALL conform to CDA Observation
2. SHALL contain [1..1] @classCode = "OBS"
3. SHALL contain [1..1] @moodCode = "EVN"
4. SHALL contain [1..*] id
5. SHALL contain [1..1] statusCode/@code = "completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus
  STATIC V3NE08)
6. SHOULD contain [0..1] effectiveTime
7. MAY contain [1..1] code, which MAY be selected from ValueSet 2.16.840.1.113883.1.11.20.2
  AdvanceDirectiveTypeCode STATIC 20061017
8. MAY contain [1..*] advanceDirectiveVerification, such that it
  a. contains Advance Directive Verification (templateId: 2.16.840.1.113883.10.20.1.58)
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"</pre>
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
       <component>
         <section>
           <entry>
             <observation classCode="OBS" moodCode="EVN">
                <templateId root="2.16.840.1.113883.10.20.1.17"</pre>
 assigningAuthorityName="CCD Advance Directive Observation"/>
                <id root="5bda427f-bdfe-45f7-a08f-d2d1d8fe5486"/>
                <code/>
                <statusCode code="completed"/>
                <effectiveTime>
                  <low value="1972"/>
                  <high value="2008"/>
                </effectiveTime>
             </observation>
           </entry>
         </section>
       </component>
    </structuredBody>
  </component>
```

Figure 22: Advance Directive Observation example

Advance Directive Status Observation

</ClinicalDocument>

[Observation: templateId 2.16.840.1.113883.10.20.1.37]

- 1. SHALL conform to Status Observation template (templateId: 2.16.840.1.113883.10.20.1.57)
- 2. SHALL contain [1..1] value, which SHALL be selected from ValueSet 2.16.840.1.113883.1.11.20.1 AdvanceDirectiveStatusCode STATIC 20061017

```
<section>
          <entry>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.57"</pre>
 assigningAuthorityName="CCD Status Observation"/>
              <templateId root="2.16.840.1.113883.10.20.1.37"</pre>
 assigningAuthorityName="CCD Advance Directive Status Observation"/>
              <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"</pre>
 codeSystemName="LOINC" displayName="Status"/>
              <statusCode code="completed"/>
              <value xsi:type="CE"/>
            </observation>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 23: Advance Directive Status Observation example

Age Observation

```
[Observation: templateId 2.16.840.1.113883.10.20.1.38]
```

A common scenario is that a patient will know the age of a relative when they had a certain condition or when they died, but will not know the actual year (e.g. "grandpa died of a heart attack at the age of 50"). Often times, neither precise dates nor ages are known (e.g. "cousin died of congenital heart disease as an infant"). In all cases, dates and times and ages can be expressed in narrative.

- **1. SHALL** conform to *CDA Observation*
- 2. SHALL contain [1..1] @classCode = "OBS"
- SHALL contain [1..1] @moodCode = "EVN"
- **4. SHALL** contain [1..1] code/@code = "397659008" *Age* (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT STATIC)
- 5. SHALL contain [0..1] statusCode/@code = "completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus STATIC V3NE08)
- 6. SHALL contain [1..1] value

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"</pre>
xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.38"</pre>
 assigningAuthorityName="CCD Age Observation"/>
              <code code="397659008" codeSystem="2.16.840.1.113883.6.96"</pre>
 codeSystemName="SNOMEDCT" displayName="Age"/>
              <statusCode code="completed"/>
            </observation>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 24: Age Observation example

Alert Observation

[Observation: templateId 2.16.840.1.113883.10.20.1.18]

- 1. SHALL conform to CDA Observation
- 2. SHALL contain [1..1] @moodCode = "EVN"
- 3. SHALL contain [1..1] statusCode/@code = "completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus STATIC V3NE08)
- **4.** MAY contain [0..1] effectiveTime
- **5. MAY** contain [0..*] value, which **MAY** be selected from ValueSet 2.16.840.1.113883.1.11.20.4 AlertTypeCode STATIC 20061017, where its data type is CE
- **6. MAY** contain [0..1] entryRelationship, such that it
 - a. contains Alert Status Observation (templateId: 2.16.840.1.113883.10.20.1.39)
- 7. MAY contain [1..*] entryRelationship, such that it
 - **a.** has @typeCode="MFST" MFST (is manifestation of)
 - **b.** contains *Reaction Observation* (templateId: 2.16.840.1.113883.10.20.1.54)
- **8. SHOULD** satisfy: The absence of known allergies SHOULD be represented in an alert observation by valuing Observation / value with 160244002 "No known allergies" 2.16.840.1.113883.6.96 SNOMED CT STATIC.
- **9. SHALL** satisfy: An alert observation contains one or more sources of information.

```
• [OCL]: not self.informant->isEmpty()
or not self.getSection().informant->isEmpty()
or not self.getClinicalDocument().informant->isEmpty()
or self.reference->exists(ref : cda::Reference | ref.typeCode =
    vocab::x_ActRelationshipExternalReference::XCRPT)
or (self.entryRelationship->exists(rel : cda::EntryRelationship |
    rel.typeCode = vocab::x_ActRelationshipEntryRelationship::REFR
    and rel.observation.code.code = '48766-0'))
```

- **10. SHOULD** satisfy: An alert observation SHOULD contain at least one Observation / participant, representing the agent that is the cause of the allergy or adverse reaction. The value for participant / @typeCode in an agent participation SHALL be "CSM" "Consumable" 2.16.840.1.113883.5.90 ParticipationType STATIC.
 - [OCL]: self.participant->exists(participant : cda::Participant2 | participant.typeCode = vocab::ParticipationType::CSM)
- 11.SHALL satisfy: Contains exactly one participant / participantRole / playingEntity. The value for participant / participantRole / playingEntity / @classCode in an agent participation SHALL be "MMAT" "Manufactured material" 2.16.840.1.113883.5.41 EntityClass STATIC. Contains exactly one participant / participantRole / playingEntity / code.
 - [OCL]: self.participant.participantRole.playingEntity->one(entity: cda::PlayingEntity | entity.classCode = vocab::EntityClassRoot::MMAT and not entity.code.oclIsUndefined())
- **12. SHOULD** satisfy: The value for participant / participantRole / playingEntity / code in an agent participation SHOULD be selected from the RxNorm (2.16.840.1.113883.6.88) code system for medications, and from the CDC Vaccine Code (2.16.840.1.113883.6.59) code system for immunizations.

```
<statusCode code="completed"/>
              <effectiveTime>
                <low value="1972"/>
                <high value="2008"/>
              </effectiveTime>
              <value xsi:type="CE"/>
              <entryRelationship>
                <observation classCode="OBS" moodCode="EVN">
                   <templateId root="2.16.840.1.113883.10.20.1.57"</pre>
 assigningAuthorityName="CCD Status Observation"/>
                   <templateId root="2.16.840.1.113883.10.20.1.39"</pre>
 assigningAuthorityName="CCD Alert Status Observation"/>
                   <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"</pre>
 codeSystemName="LOINC" displayName="Status"/>
                  <statusCode code="completed"/>
                   <value xsi:type="CE"/>
                </observation>
              </entryRelationship>
              <entryRelationship>
                <observation classCode="OBS" moodCode="EVN">
                   <templateId root="2.16.840.1.113883.10.20.1.54"</pre>
 assigningAuthorityName="CCD Reaction Observation"/>
                   <statusCode code="completed"/>
                </observation>
              </entryRelationship>
            </observation>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 25: Alert Observation example

Alert Status Observation

[Observation: templateId 2.16.840.1.113883.10.20.1.39]

- 1. SHALL conform to Status Observation template (templateId: 2.16.840.1.113883.10.20.1.57)
- 2. SHALL contain [1..1] value, which SHALL be selected from ValueSet 2.16.840.1.113883.1.11.20.3 AlertStatusCode STATIC 20061017

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"</pre>
xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.57"</pre>
assigningAuthorityName="CCD Status Observation"/>
              <templateId root="2.16.840.1.113883.10.20.1.39"</pre>
 assigningAuthorityName="CCD Alert Status Observation"/>
              <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"</pre>
 codeSystemName="LOINC" displayName="Status"/>
              <statusCode code="completed"/>
              <value xsi:type="CE"/>
            </observation>
          </entry>
        </section>
```

```
</component>
  </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 26: Alert Status Observation example

Authorization Activity

```
[Act: templateId 2.16.840.1.113883.10.20.1.19]
```

An authorization activity represents authorizations or pre-authorizations currently active for the patient for the particular payer. Authorizations are represented using an act subordinate to the policy or program that provided it. The policy or program is referred to by the authorization. Authorized treatments can be grouped into an Organizer class, where common properties, such as the reason for the authorization, can be expressed. Subordinate acts represent what was authorized.

```
1. SHALL conform to CDA Act
2. SHALL contain [1..1] @classCode = "ACT"
3. SHALL contain [1..1] @moodCode = "EVN"
4. SHALL contain [1..*] id
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"</pre>
xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
             <act classCode="ACT" moodCode="EVN">
               <templateId root="2.16.840.1.113883.10.20.1.19"</pre>
 assigningAuthorityName="CCD Authorization Activity"/>
               <id root="19f573f8-2656-4727-861d-a4357b1538bb"/>
             </act>
           </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 27: Authorization Activity example

Cause Of Death Observation

[Observation: templateId 2.16.840.1.113883.10.20.1.42]

1. SHALL conform to Family History Observation template (templateId: 2.16.840.1.113883.10.20.1.22)

Figure 28: Cause Of Death Observation example

Comment

```
<structuredBody>
      <component>
        <section>
          <entry>
            <act classCode="ACT" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.40"</pre>
 assigningAuthorityName="CCD Comment"/>
              <code code="48767-8" codeSystem="2.16.840.1.113883.6.1"</pre>
 codeSystemName="LOINC" displayName="Annotation comment"/>
            </act>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 29: Comment example

Coverage Activity

SHALL conform to CDA Act
 SHALL contain [1..1] @classCode = "ACT" (CONF-36)
 SHALL contain [1..1] @moodCode = "DEF" (CONF-37)
 SHALL contain [1..*] id (CONF-38)
 SHALL contain [1..1] statusCode/@code = "completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus STATIC V3NE08) (CONF-39, CONF-40)
 SHALL contain [1..1] code/@code = "48768-6" Payment sources (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC) (CONF-41, CONF-42)

- 7. **SHALL** contain [1..*] entryRelationship, such that it
 - **a.** has @typeCode="COMP" COMP (has component)
 - **b.** contains *Policy Activity* (templateId: 2.16.840.1.113883.10.20.1.26) (CONF-43, CONF-45, CONF-46)
- **8. SHALL** satisfy: An alert observation contains one or more sources of information. (CONF-47)

```
• [OCL]: not self.informant->isEmpty()
    or not self.getSection().informant->isEmpty()
    or not self.getClinicalDocument().informant->isEmpty()
    or self.reference->exists(ref : cda::Reference | ref.typeCode =
    vocab::x_ActRelationshipExternalReference::XCRPT)
    or (self.entryRelationship->exists(rel : cda::EntryRelationship |
        rel.typeCode = vocab::x_ActRelationshipEntryRelationship::REFR
    and rel.observation.code.code = '48766-0'))
```

- **9. MAY** satisfy: entryRelationship contains sequenceNumber, which serves to prioritize the payment sources. (CONF-44)
 - [OCL]: self.entryRelationship->exists(rel : cda::EntryRelationship | not rel.sequenceNumber.oclIsUndefined())

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"</pre>
xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <act classCode="ACT" moodCode="DEF">
              <templateId root="2.16.840.1.113883.10.20.1.20"</pre>
 assigningAuthorityName="CCD Coverage Activity"/>
              <id root="572e7795-e666-44e9-a4ed-c6ada83d2156"/>
              <code code="48768-6" codeSystem="2.16.840.1.113883.6.1"</pre>
 codeSystemName="LOINC" displayName="Payment sources"/>
              <statusCode code="completed"/>
              <entryRelationship>
                <act classCode="ACT" moodCode="EVN">
                   <templateId root="2.16.840.1.113883.10.20.1.26"</pre>
 assigningAuthorityName="CCD Policy Activity"/>
                   <id root="a5e6a153-484f-4194-9398-5b0e070cfcb1"/>
                   <code/>
                   <statusCode code="completed"/>
                </act>
              </entryRelationship>
            </act>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 30: Coverage Activity example

Coverage Plan Description

[Act: templateId null]

```
    SHALL conform to CDA Act
    SHALL contain [1..1] @classCode = "ACT" (CONF-67)
```

4. SHALL contain [1..*] id (CONF-68)

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <act classCode="ACT" moodCode="DEF">
              <templateId assigningAuthorityName="CCD Coverage Plan</pre>
Description"/>
              <id root="f5395f03-46d2-4031-857d-4f3276da37bf"/>
            </act>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 31: Coverage Plan Description example

Encounters Activity

[Encounter: templateId 2.16.840.1.113883.10.20.1.21]

- **1. SHALL** conform to *CDA Encounter*
- 2. SHALL contain [1..1] @classCode = "ENC"
- **3. SHALL** contain [1..1] @moodCode = "EVN"
- 4. SHALL contain [1..*] id
- **5. SHOULD** contain [1..1] code, which **SHOULD** be selected from ValueSet 2.16.840.1.113883.1.11.13955 EncounterCode STATIC
- **6.** MAY contain [0..1] effectiveTime

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"</pre>
xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <encounter classCode="ENC" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.21"</pre>
 assigningAuthorityName="CCD Encounters Activity"/>
              <id root="93641c95-c5ca-40cb-8d96-a179bc52630b"/>
              <code/>
              <effectiveTime>
                <low value="1972"/>
                <high value="2008"/>
              </effectiveTime>
            </encounter>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 32: Encounters Activity example

Episode Observation

[Observation: templateId 2.16.840.1.113883.10.20.1.41]

Episode observations are used to distinguish among multiple occurrences of a problem or social history item. An episode observation is used to indicate that a problem act represents a new episode, distinct from other episodes of a similar concern.

1. SHALL conform to *CDA Observation* (CONF-169)

</component>

- **2. SHALL** contain [1..1] @classCode = "OBS" (CONF-170)
- **3. SHALL** contain [1..1] @moodCode = "EVN" (CONF-171)
- **4. SHALL** contain [1..1] statusCode/@code = "completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus STATIC V3NE08) (CONF-172, CONF-173)
- **5. SHOULD** contain [1..1] code/@code = "ASSERTION" (CodeSystem: 2.16.840.1.113883.5.4 ActCode STATIC V3NE08) (CONF-174)
- **6. SHOULD** contain [1..1] value/@code = "404684003" *Clinical finding* (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT STATIC), where its data type is CD (CONF-175)
- 7. SHOULD satisfy: Value in an episode observation SHOULD be the following SNOMED CT expression: <codeblock><value xsi:type="CD" code="404684003" codeSystem="2.16.840.1.113883.6.96" displayName="Clinical finding"> <qualifier> <name code="246456000" displayName="Episodicity"/> <value code="288527008" displayName="New episode"/> </qualifier> </value></codeblock> (CONF-175)
- **8. SHALL** satisfy: Source of exactly one entryRelationship whose typeCode is 'SUBJ'. This is used to link the episode observation to the target problem act or social history observation. (CONF-176)

```
• [OCL]:
    self.getEntryRelationshipTargets(vocab::x_ActRelationshipEntryRelationship::SUBJ,
    ccd::ProblemAct)->size() = 1
    or
    self.getEntryRelationshipTargets(vocab::x_ActRelationshipEntryRelationship::SUBJ,
    ccd::SocialHistoryObservation)->size() = 1
```

9. MAY satisfy: Source of one or more entryRelationship whose typeCode is 'SAS'. The target of the entryRelationship SHALL be a problem act or social history observation. This is used to represent the temporal sequence of episodes. (CONF-177)

```
[OCL]:
     self.getEntryRelationshipTargets(vocab::x_ActRelationshipEntryRelationship::SAS,
     ccd::ProblemAct)->size() >0
      self.getEntryRelationshipTargets(vocab::x_ActRelationshipEntryRelationship::SAS,
     ccd::SocialHistoryObservation)->size() > 0
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"</pre>
xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.41"</pre>
assigningAuthorityName="CCD Episode Observation"/>
              <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"</pre>
 codeSystemName="ActCode"/>
              <statusCode code="completed"/>
              <value xsi:type="CD"/>
            </observation>
          </entry>
        </section>
```

```
</structuredBody>
  </component>
</ClinicalDocument>
```

Figure 33: Episode Observation example

Family History Observation

[Observation: templateId 2.16.840.1.113883.10.20.1.22]

- 1. SHALL conform to CDA Observation
- 2. SHALL contain [1..*] id
- 3. SHALL contain [1..1] statusCode/@code = "completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus STATIC V3NE08)

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"</pre>
xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.22"</pre>
assigningAuthorityName="CCD Family History Observation"/>
              <id root="9a0f9b24-5cea-46ce-8dee-da278769c0da"/>
              <statusCode code="completed"/>
            </observation>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 34: Family History Observation example

Family History Organizer

[Organizer: templateId 2.16.840.1.113883.10.20.1.23]

- **1. SHALL** conform to *CDA Organizer*
- 2. SHALL contain [1..1] statusCode/@code = "completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus STATIC V3NE08)

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"</pre>
xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <organizer>
              <templateId root="2.16.840.1.113883.10.20.1.23"</pre>
assigningAuthorityName="CCD Family History Organizer"/>
              <statusCode code="completed"/>
            </organizer>
          </entry>
        </section>
      </component>
```

```
</structuredBody>
</component>
</ClinicalDocument>
```

Figure 35: Family History Organizer example

Fulfillment Instruction

[Act: templateId 2.16.840.1.113883.10.20.1.43]

Fulfillment instructions are additional information provided to the dispensing party (e.g. "label in spanish").

- 1. SHALL conform to CDA Act
- SHALL contain [1..1] @moodCode = "INT"

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"</pre>
xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <act classCode="ACT" moodCode="INT">
              <templateId root="2.16.840.1.113883.10.20.1.43"</pre>
 assigningAuthorityName="CCD Fulfillment Instruction"/>
            </act>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 36: Fulfillment Instruction example

Functional Status Observation

[Observation: templateId 2.16.840.1.113883.10.20.1.44]

- 1. SHALL conform to Status Observation template (templateId: 2.16.840.1.113883.10.20.1.57)
- 2. SHALL contain [1..1] value, which SHALL be selected from ValueSet 2.16.840.1.113883.1.11.20.5 StatusOfFunctionalStatusCode STATIC 20061017

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"</pre>
xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.57"</pre>
 assigningAuthorityName="CCD Status Observation"/>
              <templateId root="2.16.840.1.113883.10.20.1.44"</pre>
 assigningAuthorityName="CCD Functional Status Observation"/>
              <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"</pre>
 codeSystemName="LOINC" displayName="Status"/>
              <statusCode code="completed"/>
              <value xsi:type="CE"/>
            </observation>
          </entry>
```

Figure 37: Functional Status Observation example

Medication Activity

[SubstanceAdministration: templateId 2.16.840.1.113883.10.20.1.24]

A medication activity is used to describe what is administered whereas a supply activity is used to describe what has been dispensed.

An indication describes the rationale for a medication activity. The indication can be an existing problem or can be a criterion that if met would warrant the activity. Criteria are typically associated with PRN (from the Latin "pro re nata", meaning "as needed") medications (e.g. "give Medication X as needed for nausea").

- 1. SHALL conform to *CDA Substance Administration* (CONF-304)
- 2. SHALL contain [1..*] id (CONF-306)
- **3. SHOULD** contain [1..1] statusCode (CONF-307)
- **4.** MAY contain [0..1] entryRelationship, such that it
 - a. contains Medication Series Number Observation (templateId: 2.16.840.1.113883.10.20.1.46)
- **5.** MAY contain [0..1] entryRelationship, such that it
 - a. contains Medication Status Observation (templateId: 2.16.840.1.113883.10.20.1.47)
- **6.** MAY contain [1..*] entryRelationship, such that it
 - **a.** has @typeCode="SUBJ" SUBJ (has subject)
 - b. contains Patient Instruction (templateId: 2.16.840.1.113883.10.20.1.49) (CONF-330, CONF-333)
- 7. **SHOULD** contain [1..*] effectiveTime (CONF-308)
 - Used to indicate the actual or intended start and stop date of a medication, and the frequency of administration.
- **8.** MAY contain [0..1] maxDoseQuantity (CONF-312)
- 9. SHOULD contain [1..1] routeCode (CodeSystem: 2.16.840.1.113883.5.112 HL7 RouteOfAdministration DYNAMIC) (CONF-309, CONF-310)
- **10. MAY** contain [0..1] performer, such that it
 - a. contains CDA Performer2 (CONF-313)
 - Indicates the person administering a substance.
- 11. SHALL satisfy: Value for moodCode is "EVN" or "INT" 2.16.840.1.113883.5.1001 ActMood STATIC (CONF-305)

```
• [OCL]: self.moodCode=vocab::x_DocumentSubstanceMood::EVN or self.moodCode=vocab::x_DocumentSubstanceMood::INT
```

- **12. SHOULD** satisfy: Contains exactly one doseQuantity or rateQuantity. (CONF-311)
 - [OCL]: not self.doseQuantity.oclIsUndefined() or not self.rateQuantity.oclIsUndefined()
- **13. MAY** satisfy: Has one or more associated consents, represented in the CCD Header as ClinicalDocument / authorization / consent. (CONF-314)

```
• [OCL]: self.getClinicalDocument().authorization->exists(auth: cda::Authorization | not auth.oclIsUndefined())
```

14. SHALL satisfy: Contains one or more sources of information. (CONF-315)

```
• [OCL]: not self.informant->isEmpty()
or not self.getSection().informant->isEmpty()
or not self.getClinicalDocument().informant->isEmpty()
```

```
or self.reference->exists(ref : cda::Reference | ref.typeCode =
  vocab::x_ActRelationshipExternalReference::XCRPT)
or (self.entryRelationship->exists(rel : cda::EntryRelationship |
  rel.typeCode = vocab::x_ActRelationshipEntryRelationship::REFR
  and rel.observation.code.code = '48766-0'))
```

- **15. MAY** satisfy: Contains one or more precondition / Criterion, to indicate that the medication is administered only when the associated (coded or free text) criteria are met. (CONF-327)
 - Indicates that the medication is administered only when the associated (coded or free text) criteria are met.
 - [OCL]: self.precondition->exists(precondition : cda::Precondition | not precondition.criterion.oclIsUndefined())
- **16.MAY** satisfy: Contains one or more entryRelationship, where the value for @typeCode is "RSON" "Has reason" 2.16.840.1.113883.5.1002 ActRelationshipType STATIC. (CONF-328)
 - The target of the relationship represents the indication for the activity.
 - [OCL]: self.entryRelationship->exists(entryRel : cda::EntryRelationship | entryRel.typeCode = vocab::x_ActRelationshipEntryRelationship::RSON)
- **17. SHALL** satisfy: entryRelationship / @typeCode="RSON" in a medication activity has a target of problem act, problem observation, or some other clinical statement. (CONF-329)

```
[OCL]:
     self.getEntryRelationshipTargets(vocab::x_ActRelationshipEntryRelationship::RSON,
     cda::ClinicalStatement)->forAll(target :
    cda::ClinicalStatement | not target.oclIsUndefined() and
      (target.oclIsKindOf(ccd::ProblemAct) or
     target.oclIsKindOf(ccd::ProblemObservation)))
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"</pre>
xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <substanceAdministration classCode="SBADM">
              <templateId root="2.16.840.1.113883.10.20.1.24"</pre>
 assigningAuthorityName="CCD Medication Activity"/>
              <id root="3365c342-3978-468a-b15a-2d1b568c7f3c"/>
              <statusCode/>
              <effectiveTime/>
              <routeCode codeSystem="2.16.840.1.113883.5.112"</pre>
 codeSystemName="HL7 RouteOfAdministration"/>
              <maxDoseQuantity/>
              <entryRelationship>
                <observation classCode="OBS" moodCode="EVN">
                  <templateId root="2.16.840.1.113883.10.20.1.46"</pre>
 assigningAuthorityName="CCD Medication Series Number Observation"/>
                  <code code="30973-2" codeSystem="2.16.840.1.113883.6.1"</pre>
 codeSystemName="LOINC" displayName="Dose number"/>
                  <statusCode/>
                  <value xsi:type="INT"/>
                </observation>
              </entryRelationship>
              <entryRelationship>
                <observation classCode="OBS" moodCode="EVN">
                  <templateId root="2.16.840.1.113883.10.20.1.57"</pre>
 assigningAuthorityName="CCD Status Observation"/>
                  <templateId root="2.16.840.1.113883.10.20.1.47"</pre>
 assigningAuthorityName="CCD Medication Status Observation"/>
                  <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"</pre>
 codeSystemName="LOINC" displayName="Status"/>
```

Figure 38: Medication Activity example

Medication Series Number Observation

```
[Observation: templateId 2.16.840.1.113883.10.20.1.46]
```

The medication series number observation can be used to indicate which in a series of administrations a particular administration represents (e.g. "hepatitis B vaccine number 2 was administered on Feb 07, 2004).

- **1. SHALL** conform to *CDA Observation*
- 2. Contains [1..1] @classCode = "OBS"
- **3.** Contains [1..1] @moodCode = "EVN"
- **4. SHALL** contain [1..1] statusCode
- **5. SHALL** contain [1..1] code/@code = "30973-2" *Dose number* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC)
- **6. SHALL** contain [1..1] value, where its data type is INT

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"</pre>
xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.46"</pre>
 assigningAuthorityName="CCD Medication Series Number Observation"/>
              <code code="30973-2" codeSystem="2.16.840.1.113883.6.1"</pre>
 codeSystemName="LOINC" displayName="Dose number"/>
              <statusCode/>
              <value xsi:type="INT"/>
            </observation>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 39: Medication Series Number Observation example

Medication Status Observation

[Observation: templateId 2.16.840.1.113883.10.20.1.47]

- 1. SHALL conform to Status Observation template (templateId: 2.16.840.1.113883.10.20.1.57)
- SHALL contain [1..1] value, which SHALL be selected from ValueSet 2.16.840.1.113883.1.11.20.7 MedicationStatusCode STATIC 20061017

```
<?xml version="1.0" encoding="UTF-8"?>
```

```
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"</pre>
xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.57"</pre>
 assigningAuthorityName="CCD Status Observation"/>
              <templateId root="2.16.840.1.113883.10.20.1.47"</pre>
 assigningAuthorityName="CCD Medication Status Observation"/>
              <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"</pre>
 codeSystemName="LOINC" displayName="Status"/>
              <statusCode code="completed"/>
              <value xsi:type="CE"/>
            </observation>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 40: Medication Status Observation example

Patient Instruction

```
[Act: templateId 2.16.840.1.113883.10.20.1.49]
```

Patient instructions are additional information provided to a patient related to one of their medications (e.g. "take on an empty stomach").

- **1. SHALL** conform to *CDA Act* (CONF-331)
- **2.** SHALL contain [1..1] @moodCode = "INT" (CONF-332)

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"</pre>
xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
            <act classCode="ACT" moodCode="INT">
              <templateId root="2.16.840.1.113883.10.20.1.49"</pre>
 assigningAuthorityName="CCD Patient Instruction"/>
            </act>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 41: Patient Instruction example

Plan Of Care Activity Act

[Act: templateId 2.16.840.1.113883.10.20.1.25]

1. SHALL conform to CDA Act

- 2. SHALL conform to Plan Of Care Activity
- 3. SHALL contain [1..1] @moodCode
- 4. SHALL contain [1..*] id
- **5. SHALL** satisfy: moodCodeValue

```
• [OCL]: self.moodCode = vocab::x_DocumentActMood::INT or self.moodCode =
     vocab::x DocumentActMood::ARQ
      or self.moodCode = vocab::x_DocumentActMood::PRMS or self.moodCode =
     vocab::x DocumentActMood::PRP
      or self.moodCode = vocab::x_DocumentActMood::RQO
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"</pre>
xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <act classCode="ACT" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.25"/>
              <id root="c3778ca7-f379-4f0a-85c7-5b5ab9c92938"/>
            </act>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 42: Plan Of Care Activity Act example

Plan Of Care Activity Encounter

```
[Encounter: templateId 2.16.840.1.113883.10.20.1.25]
```

- **1. SHALL** conform to *CDA Encounter*
- 2. SHALL conform to Plan Of Care Activity
- 3. SHALL contain [1..1] @moodCode
- 4. SHALL contain [1..*] id
- **5. SHALL** satisfy: moodCodeValue

```
self.moodCode = vocab::x DocumentEncounterMood::ARO
      or self.moodCode = vocab::x DocumentEncounterMood::PRMS or self.moodCode
     = vocab::x_DocumentEncounterMood::PRP
      or self.moodCode = vocab::x_DocumentEncounterMood::RQO
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"</pre>
xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <encounter>
              <templateId root="2.16.840.1.113883.10.20.1.25"/>
              <id root="face0a03-8bef-4ff5-8d6a-f0cf9d8a12aa"/>
            </encounter>
          </entry>
        </section>
```

[OCL]: self.moodCode = vocab::x DocumentEncounterMood::INT or

```
</component>
  </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 43: Plan Of Care Activity Encounter example

Plan Of Care Activity Observation

```
[Observation: templateId 2.16.840.1.113883.10.20.1.25]
1. SHALL conform to CDA Observation
2. SHALL conform to Plan Of Care Activity
3. SHALL contain [1..1] @moodCode
4. SHALL contain [1..*] id
5. SHALL satisfy: moodCodeValue

    [OCL]: self.moodCode = vocab::x ActMoodDocumentObservation::INT or

      self.moodCode = vocab::x ActMoodDocumentObservation::GOL
       or self.moodCode = vocab::x ActMoodDocumentObservation::PRMS or
      self.moodCode = vocab::x_ActMoodDocumentObservation::PRP
       or self.moodCode = vocab::x_ActMoodDocumentObservation::RQO
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"</pre>
xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
             <observation classCode="OBS" moodCode="EVN">
               <templateId root="2.16.840.1.113883.10.20.1.25"/>
               <id root="95e5ed89-6762-4cd8-a827-7fab8afe6218"/>
             </observation>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
```

Figure 44: Plan Of Care Activity Observation example

Plan Of Care Activity Procedure

</ClinicalDocument>

```
[Procedure: templateId 2.16.840.1.113883.10.20.1.25]

1. SHALL conform to CDA Procedure
2. SHALL conform to Plan Of Care Activity
3. SHALL contain [1..1] @moodCode
4. SHALL contain [1..*] id
5. SHALL satisfy: moodCodeValue

• [OCL]: self.moodCode = vocab::x_DocumentProcedureMood::INT or self.moodCode = vocab::x_DocumentProcedureMood::ARQ or self.moodCode = vocab::x_DocumentProcedureMood::PRMS or self.moodCode = vocab::x_DocumentProcedureMood::RQO

<?xml version="1.0" encoding="UTF-8"?>
```

```
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"</pre>
xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            cedure>
              <templateId root="2.16.840.1.113883.10.20.1.25"/>
              <id root="e7b1de42-8a6a-4985-b9fb-93ae51f7dd67"/>
            </procedure>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 45: Plan Of Care Activity Procedure example

Plan Of Care Activity Substance Administration

```
[SubstanceAdministration: templateId 2.16.840.1.113883.10.20.1.25]
```

```
1. SHALL conform to CDA Substance Administration
```

- 2. SHALL conform to Plan Of Care Activity
- 3. SHALL contain [1..1] @moodCode
- 4. SHALL contain [1..*] id
- **5. SHALL** satisfy: moodCodeValue

```
[OCL]: self.moodCode = vocab::x DocumentSubstanceMood::INT or
     self.moodCode = vocab::x_DocumentSubstanceMood::RQO
      or self.moodCode = vocab::x DocumentSubstanceMood::PRMS or self.moodCode
     = vocab::x DocumentSubstanceMood::PRP
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"</pre>
xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <substanceAdministration classCode="SBADM">
              <templateId root="2.16.840.1.113883.10.20.1.25"/>
              <id root="ec70a535-b52d-493b-97d9-50f168856c49"/>
            </substanceAdministration>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 46: Plan Of Care Activity Substance Administration example

Plan Of Care Activity Supply

```
[Supply: templateId 2.16.840.1.113883.10.20.1.25]
```

1. SHALL conform to CDA Supply

- 2. SHALL conform to Plan Of Care Activity
- 3. SHALL contain [1..1] @moodCode
- 4. SHALL contain [1..*] id
- **5. SHALL** satisfy: moodCodeValue

```
• [OCL]: self.moodCode = vocab::x_DocumentSubstanceMood::INT or
     self.moodCode = vocab::x_DocumentSubstanceMood::RQO
      or self.moodCode = vocab::x_DocumentSubstanceMood::PRMS or self.moodCode
     = vocab::x_DocumentSubstanceMood::PRP
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"</pre>
xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <supply classCode="SPLY">
              <templateId root="2.16.840.1.113883.10.20.1.25"/>
              <id root="725f9db3-d267-45d3-92e2-cf4657c432a9"/>
            </supply>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 47: Plan Of Care Activity Supply example

Policy Activity

```
[Act: templateId 2.16.840.1.113883.10.20.1.26]
```

A policy activity represents the policy or program providing the coverage. The person for whom payment is being provided (i.e. the patient) is the covered party. The subscriber of the policy or program is represented as a participant that is the holder the coverage. The payer is represented as the performer of the policy activity.

- 1. SHALL conform to CDA Act
- 2. SHALL contain [1..1] @classCode = "ACT" (CONF-49)
- **3. SHALL** contain [1..1] @moodCode = "EVN" (CONF-50)
- **4. SHALL** contain [1..*] id (CONF-51)
- 5. SHALL contain [1..1] statusCode/@code = "completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus STATIC V3NE08) (CONF-52, CONF-53)
- **6. SHOULD** contain [1..1] code, which **SHOULD** be selected from ValueSet 2.16.840.1.113883.1.11.19832 ActCoverageType DYNAMIC (CONF-54, CONF-55)
- 7. SHALL contain [1..1] performer, such that it
 - a. contains Payer Entity (CONF-56)
- 8. SHALL contain [1..1] participant, such that it
 - **a.** contains *Covered Party* (CONF-58)
- 9. MAY contain [1..1] participant, such that it
 - **a.** contains *Policy Subscriber* (CONF-63)
- **10. SHALL** satisfy: A policy activity contains exactly one performer [@typeCode='PRF'], representing the payer. (CONF-56)
 - [OCL]: self.performer->one(perf : cda::Performer2 | perf.typeCode = vocab::ParticipationPhysicalPerformer::PRF)

- **11. SHALL** satisfy: A policy activity contains exactly one participant [@typeCode='COV'], representing the covered party. (CONF-58)
 - [OCL]: self.participant->one(part : cda::Participant2 | part.typeCode = vocab::ParticipationType::COV)
- **12. MAY** satisfy: The value for participant / participantRole / code in a policy activity's covered party MAY be selected from ValueSet 2.16.840.1.113883.1.11.19809 PolicyOrProgramCoverageRoleType DYNAMIC. (CONF-61)
- **13.MAY** satisfy: A covered party in a policy activity MAY contain exactly one participant / time, to represent the time period over which the patient is covered. (CONF-62)
 - [OCL]: self.participant->one(part : cda::Participant2 | part.typeCode = vocab::ParticipationType::COV implies not part.time.oclIsUndefined())
- **14. MAY** satisfy: A policy activity MAY contain exactly one participant [@typeCode='HLD'], representing the subscriber. (CONF-63)
 - [OCL]: self.participant->one(part : cda::Participant2 | part.typeCode = vocab::ParticipationType::HLD)
- **15. MAY** satisfy: A subscriber in a policy activity MAY contain exactly one participant / time, to represent the time period for which the subscriber is enrolled. (CONF-65)
 - [OCL]: self.participant->one(part : cda::Participant2 | part.typeCode = vocab::ParticipationType::HLD implies not part.time.oclIsUndefined())
- **16. SHALL** satisfy: The value for entryRelationship / @typeCode in a policy activity SHALL be 'REFR' 2.16.840.1.113883.5.1002 ActRelationshipType STATIC. (CONF-66)
 - [OCL]: self.entryRelationship->forAll(rel : cda::EntryRelationship | rel.typeCode = vocab::x_ActRelationshipEntryRelationship::REFR)
- 17. SHALL satisfy: The target of a policy activity with entryRelationship / @typeCode='REFR' SHALL be an Authorization Activity or an Act, with Act [@classCode = 'ACT'] and Act [@moodCode = 'DEF'], representing a description of the coverage plan. (CONF-67)
 - [OCL]: self.entryRelationship->forAll(rel : cda::EntryRelationship | rel.act.oclIsKindOf(ccd::AuthorizationActivity) or rel.act.oclIsKindOf(ccd::CoveragePlanDescription))

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"</pre>
xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <act classCode="ACT" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.26"</pre>
 assigningAuthorityName="CCD Policy Activity"/>
              <id root="93986702-c2a3-41bc-a29d-b7d0665333b0"/>
              <code/>
              <statusCode code="completed"/>
              <performer>
                <assignedEntity>
                  <templateId assigningAuthorityName="CCD Payer Entity"/>
                  <id root="8e2ce89b-cbeb-4df1-9cf4-dd95f9a3a2dc"/>
                </assignedEntity>
              </performer>
              <participant>
                <participantRole>
                  <templateId assigningAuthorityName="CCD Covered Party"/>
                  <id root="95ebe59b-f0e0-4324-a932-32f043b1e4a8"/>
                  <code/>
                </participantRole>
```

Figure 48: Policy Activity example

Problem Act

```
[Act: templateId 2.16.840.1.113883.10.20.1.27]
```

A problem is a clinical statement that a clinician is particularly concerned about and wants to track. It has important patient management use cases (e.g. health records often present the problem list as a way of summarizing a patient's medical history).

- **1. SHALL** conform to *CDA Act* (CONF-145)
- 2. SHALL contain [1..1] @classCode = "ACT" (CONF-146)
- **3. SHALL** contain [1..1] @moodCode = "EVN" (CONF-147)
- **4. SHALL** contain [1..*] id (CONF-148)
- **5. SHALL** contain [1..1] code/@nullFlavor = "NA" *NA* (not applicable) (CONF-149)
- **6.** MAY contain [0..1] effectiveTime (CONF-150)
 - Indicates the timing of the concern (e.g. the interval of time for which the problem is a concern).
- 7. MAY contain [1..1] entryRelationship, such that it
 - a. contains Episode Observation (templateId: 2.16.840.1.113883.10.20.1.41) (CONF-168)
- **8.** Contains [0..*] entryRelationship, such that it
 - a. contains Problem Observation (templateId: 2.16.840.1.113883.10.20.1.28)
- **9. SHALL** satisfy: Contains one or more entryRelationship (CONF-151)
 - [OCL]: not self.entryRelationship->isEmpty()
- **10. MAY** satisfy: A problem act MAY reference a problem observation, alert observation (see section Alerts) or other clinical statement that is the subject of concern, by setting the value for "Act / entryRelationship / @typeCode" to be "SUBJ" 2.16.840.1.113883.5.1002 ActRelationshipType STATIC. (CONF-152)
- **11. SHOULD** satisfy: The target of a problem act with Act / entryRelationship / @typeCode="SUBJ" SHOULD be a problem observation (in the Problem section) or alert observation (in the Alert section), but MAY be some other clinical statement. (CONF-153)

```
• [OCL]:
    self.getEntryRelationshipTargets(vocab::x_ActRelationshipEntryRelationship::SUBJ,
    cda::ClinicalStatement)->forAll(target : cda::ClinicalStatement | not
    target.oclIsUndefined() and
    (target.oclIsKindOf(ccd::ProblemObservation) or
    target.oclIsKindOf(ccd::AlertObservation)))
```

12. SHOULD satisfy: In Problem Section, a Problem Act SHOULD contain one or more Problem Observations. (CONF-140)

```
[OCL]: self.getSection().oclIsKindOf(ccd::ProblemSection) implies
self.getObservations()
   ->exists(obs : cda::Observation |
   obs.oclIsKindOf(ccd::ProblemObservation))
```

13. SHOULD satisfy: In Alert Section, a ProblemAct SHOULD contain one or more Alert Observations. (CONF-256)

```
• [OCL]: self.getSection().oclIsKindOf(ccd::AlertsSection) implies
      self.getObservations()
        ->exists(obs : cda::Observation
     obs.oclIsKindOf(ccd::AlertObservation))
14. MAY satisfy: Contains exactly one Patient Awareness (CONF-179)
    [OCL]: self.participant->one(partic : cda::Participant2 |
     partic.oclIsKindOf(ccd::PatientAwareness))
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"</pre>
xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <act classCode="ACT" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.27"</pre>
 assigningAuthorityName="CCD Problem Act"/>
              <id root="02e62b5a-bb1b-4a2b-af9c-ab39d0855c0b"/>
              <code nullFlavor="NA"/>
              <effectiveTime>
                <low value="1972"/>
                <high value="2008"/>
              </effectiveTime>
              <entryRelationship>
                <observation classCode="OBS" moodCode="EVN">
                   <templateId root="2.16.840.1.113883.10.20.1.41"</pre>
 assigningAuthorityName="CCD Episode Observation"/>
                  <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"</pre>
 codeSystemName="ActCode"/>
                  <statusCode code="completed"/>
                  <value xsi:type="CD"/>
                </observation>
              </entryRelationship>
            </act>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 49: Problem Act example

Problem Health Status Observation

[Observation: templateId 2.16.840.1.113883.10.20.1.51]

- 1. SHALL conform to *Status Observation* template (templateId: 2.16.840.1.113883.10.20.1.57) (CONF-166)
- **2. SHALL** contain [1..1] code/@code = "11323-3" *Health status* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC) (CONF-166)
- 3. SHALL contain [1..1] value, which SHALL be selected from ValueSet 2.16.840.1.113883.1.11.20.12 ProblemHealthStatusCode STATIC 20061017 (CONF-167)

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
        <component>
```

```
<structuredBody>
      <component>
        <section>
          <entry>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.57"</pre>
 assigningAuthorityName="CCD Status Observation"/>
              <templateId root="2.16.840.1.113883.10.20.1.51"</pre>
 assigningAuthorityName="CCD Problem Health Status Observation"/>
              <code code="11323-3" codeSystem="2.16.840.1.113883.6.1"</pre>
 codeSystemName="LOINC" displayName="Health status"/>
              <statusCode code="completed"/>
              <value xsi:type="CE"/>
            </observation>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 50: Problem Health Status Observation example

Problem Observation

```
[Observation: templateId 2.16.840.1.113883.10.20.1.28]
```

- **1. SHALL** conform to *CDA Observation* (CONF-154)
- 2. Contains [1..1] @classCode = "OBS"
- **3. SHALL** contain [1..1] @moodCode = "EVN" (CONF-155)
- **4.** SHALL contain [1..1] statusCode/@code = "completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus STATIC V3NE08) (CONF-156, CONF-157)
- **5. SHOULD** contain [1..1] effectiveTime (CONF-158)
 - Indicates the biological timing of condition (e.g. the time the condition started, the onset of the illness or symptom, the duration of a condition).
- **6. MAY** contain [1..1] code, which **MAY** be selected from ValueSet 2.16.840.1.113883.1.11.20.14 ProblemTypeCode STATIC 20061017 (CONF-159)
 - code SHALL be present (per CDA schema), by MAY use specified value set.
- 7. MAY contain [0..1] entryRelationship, such that it
 - **a.** has @typeCode="REFR" REFR (refers to)
 - b. contains Problem Status Observation (templateId: 2.16.840.1.113883.10.20.1.50) (CONF-162)
- 8. MAY contain [0..1] entryRelationship, such that it
 - **a.** has @typeCode="REFR" REFR (refers to)
 - **b.** contains *Problem Health Status Observation* (templateId: 2.16.840.1.113883.10.20.1.51) (CONF-165)
- **9.** MAY contain [0..1] entryRelationship, such that it
 - **a.** has @typeCode="SUBJ" SUBJ (has subject)
 - **b.** contains *Age Observation* (templateId: 2.16.840.1.113883.10.20.1.38) (CONF-160)
- 10. SHALL satisfy: Contains one or more sources of information. (CONF-161)

```
• [OCL]: not self.informant->isEmpty()
or not self.getSection().informant->isEmpty()
or not self.getClinicalDocument().informant->isEmpty()
or self.reference->exists(ref : cda::Reference | ref.typeCode =
   vocab::x_ActRelationshipExternalReference::XCRPT)
or (self.entryRelationship->exists(rel : cda::EntryRelationship |
```

```
rel.typeCode = vocab::x_ActRelationshipEntryRelationship::REFR and rel.observation.code.code = '48766-0'))
```

11. MAY satisfy: Contains exactly one Patient Awareness (CONF-180)

• [OCL]: self.participant->one(partic : cda::Participant2 | partic.oclIsKindOf(ccd::PatientAwareness))

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"</pre>
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.28"</pre>
 assigningAuthorityName="CCD Problem Observation"/>
              <code/>
              <statusCode code="completed"/>
              <effectiveTime>
                <low value="1972"/>
                <high value="2008"/>
              </effectiveTime>
              <entryRelationship>
                <observation classCode="OBS" moodCode="EVN">
                   <templateId root="2.16.840.1.113883.10.20.1.57"</pre>
 assigningAuthorityName="CCD Status Observation"/>
                   <templateId root="2.16.840.1.113883.10.20.1.50"</pre>
 assigningAuthorityName="CCD Problem Status Observation"/>
                   <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"</pre>
 codeSystemName="LOINC" displayName="Status"/>
                   <statusCode code="completed"/>
                   <value xsi:type="CE"/>
                </observation>
              </entryRelationship>
              <entryRelationship>
                <observation classCode="OBS" moodCode="EVN">
                   <templateId root="2.16.840.1.113883.10.20.1.57"</pre>
 assigningAuthorityName="CCD Status Observation"/>
                   <templateId root="2.16.840.1.113883.10.20.1.51"</pre>
 assigningAuthorityName="CCD Problem Health Status Observation"/>
                   <code code="11323-3" codeSystem="2.16.840.1.113883.6.1"</pre>
 codeSystemName="LOINC" displayName="Health status"/>
                   <statusCode code="completed"/>
                   <value xsi:type="CE"/>
                </observation>
              </entryRelationship>
              <entryRelationship>
                <observation classCode="OBS" moodCode="EVN">
                   <templateId root="2.16.840.1.113883.10.20.1.38"</pre>
 assigningAuthorityName="CCD Age Observation"/>
                   <code code="397659008" codeSystem="2.16.840.1.113883.6.96"</pre>
 codeSystemName="SNOMEDCT" displayName="Age"/>
                   <statusCode code="completed"/>
                </observation>
              </entryRelationship>
            </observation>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
```

</ClinicalDocument>

Figure 51: Problem Observation example

Problem Status Observation

[Observation: templateId 2.16.840.1.113883.10.20.1.50]

- 1. SHALL conform to *Status Observation* template (templateId: 2.16.840.1.113883.10.20.1.57) (CONF-163)
- 2. SHALL contain [1..1] value, which SHALL be selected from ValueSet 2.16.840.1.113883.1.11.20.13 ProblemStatusCode STATIC 20061017 (CONF-164)

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"</pre>
xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.57"</pre>
assigningAuthorityName="CCD Status Observation"/>
              <templateId root="2.16.840.1.113883.10.20.1.50"</pre>
 assigningAuthorityName="CCD Problem Status Observation"/>
              <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"</pre>
 codeSystemName="LOINC" displayName="Status"/>
              <statusCode code="completed"/>
              <value xsi:type="CE"/>
            </observation>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 52: Problem Status Observation example

Procedure Activity Act

[Act: templateId 2.16.840.1.113883.10.20.1.29]

- 1. SHALL conform to CDA Act
- 2. SHALL conform to *Procedure Activity*

```
</component>
  </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 53: Procedure Activity Act example

Procedure Activity Observation

[Observation: templateId 2.16.840.1.113883.10.20.1.29]

- 1. SHALL conform to CDA Observation
- 2. SHALL conform to *Procedure Activity*

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"</pre>
xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.29"/>
              <statusCode code="completed"/>
            </observation>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 54: Procedure Activity Observation example

Procedure Activity Procedure

[Procedure: templateId 2.16.840.1.113883.10.20.1.29]

- 1. SHALL conform to CDA Procedure
- 2. SHALL conform to *Procedure Activity*

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"</pre>
xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
 <component>
   <structuredBody>
     <component>
        <section>
          <entry>
            cedure>
              <templateId root="2.16.840.1.113883.10.20.1.29"/>
              <statusCode code="completed"/>
            </procedure>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 55: Procedure Activity Procedure example

Purpose Activity

```
[Act: templateId 2.16.840.1.113883.10.20.1.30]
```

CCD represents the ASTM CCR <Purpose> object as a relationship between two classes -- the source represents the act of creating a summary document, the target is the reason for creating the document, and the relationship type is "RSON" (has reason). The target act may be an Observation, Procedure, or some other kind of act, and it may represent an order, an event, etc.

- 1. SHALL conform to CDA Act
- 2. SHALL contain [1..1] @classCode = "ACT" (CONF-21)
- **3. SHALL** contain [1..1] @moodCode = "EVN" (CONF-22)
- **4. SHALL** contain [1..1] code/@code = "23745001" *Documentation procedure* (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT STATIC) (CONF-25)
- 5. SHALL contain [1..1] statusCode/@code = "completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus STATIC V3NE08) (CONF-23, CONF-24)
- **6. SHALL** satisfy: Contains exactly one entryRelationship / @typeCode, with a value of 'RSON' 'Has reason' 2.16.840.1.113883.5.1002 ActRelationshipType STATIC, to indicate the reason or purpose for creating the CCD. (CONF-26)

```
• [OCL]: self.entryRelationship->one(entryRelationship:
   cda::EntryRelationship |
   entryRelationship.typeCode =
   vocab::x_ActRelationshipEntryRelationship::RSON)
```

7. SHALL satisfy: The target of entryRelationship SHALL be an Act, Encounter, Observation, Procedure, SubstanceAdministration, or Supply. (CONF-27)

```
• [OCL]: self.entryRelationship->forAll(entryRelationship :
    cda::EntryRelationship |
    entryRelationship.typeCode =
    vocab::x_ActRelationshipEntryRelationship::RSON implies(
    not (entryRelationship.act.oclIsUndefined() and
    entryRelationship.encounter.oclIsUndefined()
        and entryRelationship.observation.oclIsUndefined() and
    entryRelationship.procedure.oclIsUndefined()
        and entryRelationship.substanceAdministration.oclIsUndefined() and
    entryRelationship.supply.oclIsUndefined())))
```

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"</pre>
xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <act classCode="ACT" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.30"</pre>
 assigningAuthorityName="CCD Purpose Activity"/>
              <code code="23745001" codeSystem="2.16.840.1.113883.6.96"</pre>
 codeSystemName="SNOMEDCT" displayName="Documentation procedure"/>
              <statusCode code="completed"/>
            </act>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 56: Purpose Activity example

Reaction Observation

[Observation: templateId 2.16.840.1.113883.10.20.1.54]

- 1. SHALL conform to CDA Observation
- 2. SHALL contain [1..1] @classCode = "OBS"
- **3. SHALL** contain [1..1] @moodCode = "EVN"
- **4.** MAY contain [0..1] entryRelationship, such that it
 - a. contains Severity Observation (templateId: 2.16.840.1.113883.10.20.1.55)
- 5. SHALL contain [1..1] statusCode/@code = "completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus STATIC V3NE08)
- 6. SHALL satisfy: The value for entryRelationship / @typeCode in a relationship between a reaction observation and reaction intervention SHALL be "RSON" "Has reason" 2.16.840.1.113883.5.1002 ActRelationshipType STATIC
- **7. SHALL** satisfy: A reaction observation MAY contain one or more reation interventions. A reaction intervention SHALL be represented as a procedure activity (templateId 2.16.840.1.113883.10.20.1.29), a medication activity (templateId 2.16.840.1.113883.10.20.1.24), or some other clinical statement.

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"</pre>
xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.54"</pre>
 assigningAuthorityName="CCD Reaction Observation"/>
              <statusCode code="completed"/>
              <entryRelationship>
                <observation classCode="OBS" moodCode="EVN">
                   <templateId root="2.16.840.1.113883.10.20.1.55"</pre>
 assigningAuthorityName="CCD Severity Observation"/>
                  <code code="SEV" codeSystem="2.16.840.1.113883.5.4"</pre>
 codeSystemName="ActCode" displayName="Severity observation"/>
                  <statusCode code="completed"/>
                </observation>
              </entryRelationship>
            </observation>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 57: Reaction Observation example

Result Observation

[Observation: templateId 2.16.840.1.113883.10.20.1.31]

- **1. SHALL** conform to *CDA Observation* (CONF-407)
- 2. SHALL contain [1..1] @moodCode = "EVN" (CONF-408)
- **3. SHALL** contain [1..*] id (CONF-409)
- **4. SHOULD** contain [1..1] effectiveTime (CONF-411)

- Represents the biologically relevant time (e.g. time the specimen was obtained from the patient).
- **5. SHALL** contain [1..1] statusCode (CONF-410)
- **6. SHALL** contain [1..1] code (CONF-412)
- 7. MAY contain [0..1] methodCode (CONF-414)
 - Included if the method isn't inherent in code or if there is a need to further specialize the method in code.
- **8. SHOULD** contain [0..*] interpretationCode (CONF-418)
 - Can be used to provide a rough qualitative interpretation of the observation, such as 'N' (normal), 'L' (low), 'S' (susceptible), etc. Interpretation is generally provided for numeric results where an interpretation range has been defined, or for antimicrobial susceptibility test interpretation.
- **9. SHALL** contain [1..1] value (CONF-416)
- 10. SHOULD satisfy: The value for 'code' SHOULD be selected from LOINC (codeSystem 2.16.840.1.113883.6.1) or SNOMED CT (codeSystem 2.16.840.1.113883.6.96), and MAY be selected from CPT-4 (codeSystem 2.16.840.1.113883.6.12). (CONF-413)
- 11. SHALL satisfy: The methodCode SHALL NOT conflict with the method inherent in code (CONF-415)
- **12. SHALL** satisfy: Where value is a physical quantity, the unit of measure SHALL be expressed using a valid Unified Code for Units of Measure (UCUM) expression. (CONF-417)
- **13. SHOULD** satisfy: Contain one or more referenceRange to show the normal range of values for the observation result (CONF-419)
 - [OCL]: not self.referenceRange->isEmpty()
- **14. SHALL** satisfy: SHALL NOT contain referenceRange / observationRange / code, as this attribute is not used by the HL7 Clinical Statement or Lab Committee models. (CONF-420)
 - [OCL]: self.referenceRange->forAll(range : cda::ReferenceRange | range.observationRange.code.code.oclIsUndefined())
- **15. SHALL** satisfy: Contains one or more sources of information. (CONF-421)

```
• [OCL]: not self.informant->isEmpty()
or not self.getSection().informant->isEmpty()
or not self.getClinicalDocument().informant->isEmpty()
or self.reference->exists(ref : cda::Reference | ref.typeCode =
    vocab::x_ActRelationshipExternalReference::XCRPT)
or (self.entryRelationship->exists(rel : cda::EntryRelationship |
    rel.typeCode = vocab::x_ActRelationshipEntryRelationship::REFR
    and rel.observation.code.code = '48766-0'))
```

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"</pre>
xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.31"</pre>
 assigningAuthorityName="CCD Result Observation"/>
              <id root="b3a7eb89-a547-4d2c-a302-ae2585cabeb1"/>
              <code/>
              <statusCode/>
              <effectiveTime>
                <low value="1972"/>
                <high value="2008"/>
              </effectiveTime>
              <interpretationCode/>
              <methodCode/>
            </observation>
          </entry>
        </section>
      </component>
```

```
</structuredBody>
  </component>
</ClinicalDocument>
```

Figure 58: Result Observation example

Result Organizer

```
[Organizer: templateId 2.16.840.1.113883.10.20.1.32]
```

The result organizer identifies an observation set, contained with the result organizer as a set of result observations. It contains information applicable to all of the contained result observations.

Results in ASTM CCR and CCD are structured similarly to the HL7 Version 2 ORU Observation message, where there is an outer result organizer (templateId 2.16.840.1.113883.10.20.1.32), analogous to the HL7 Version 2 OBR Observation Result Segment, which contains one or more result observations (templateId 2.16.840.1.113883.10.20.1.31), analogous to the HL7 Version 2 OBX Observation/Result Segment.

- 1. SHALL conform to *CDA Organizer* (CONF-393)
- 2. SHALL contain [1..1] @moodCode = "EVN" (CONF-394)
- 3. SHALL contain [1..*] component, such that it
 - a. contains *Result Observation* (templateId: 2.16.840.1.113883.10.20.1.31) (CONF-405)
- 4. SHOULD contain [1..*] specimen, such that it
 - **a.** contains *CDA Specimen* (CONF-399)
 - Should be included if the specimen isn't inherent in code value.
- **5. SHALL** contain [1..*] id (CONF-395)
- **6. SHALL** contain [1..1] code (CONF-397)
- 7. SHALL contain [1..1] statusCode (CONF-396)
- 8. SHOULD satisfy: The value for 'code' in a result organizer SHOULD be selected from LOINC (codeSystem 2.16.840.1.113883.6.1) or SNOMED CT (codeSystem 2.16.840.1.113883.6.96), and MAY be selected from CPT-4 (codeSystem 2.16.840.1.113883.6.12) or ValueSet 2.16.840.1.113883.1.11.20.16 ResultTypeCode STATIC. (CONF-398)
- **9. SHALL** satisfy: The specimen element SHALL NOT conflict with the specimen inherent in code (CONF-400)
- **10. SHOULD** satisfy: specimen / specimenRole / id SHOULD be set to equal a Procedure / specimen / specimenRole / id to indicate that the Results and the Procedure are referring to the same specimen. (CONF-401)
- **11. SHALL** satisfy: Contains one or more component (CONF-402)
 - [OCL]: not self.component->isEmpty()
- **12. MAY** satisfy: The target of one or more result organizer component relationships MAY be a procedure, to indicate the means or technique by which a result is obtained, particularly if the means or technique isn't inherent in code or if there is a need to further specialize the code value. (CONF-403)
- **13. MAY** satisfy: A result organizer component / procedure MAY be a reference to a procedure described in the Procedure section. (CONF-404)
- **14. SHALL** satisfy: Contains one or more sources of information. (CONF-406)

```
<entry>
            <organizer moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.32"</pre>
assigningAuthorityName="CCD Result Organizer"/>
              <id root="cdefc18c-de20-41f8-840c-7c1ac6a9d5fa"/>
              <code/>
              <statusCode/>
              <component>
                <observation classCode="OBS" moodCode="EVN">
                   <templateId root="2.16.840.1.113883.10.20.1.31"</pre>
 assigningAuthorityName="CCD Result Observation"/>
                   <id root="3d5d24b8-544a-4842-95f5-2dfc09a38bf7"/>
                   <code/>
                   <statusCode/>
                   <effectiveTime>
                     <low value="1972"/>
                     <high value="2008"/>
                   </effectiveTime>
                   <interpretationCode/>
                   <methodCode/>
                </observation>
              </component>
            </organizer>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 59: Result Organizer example

Severity Observation

[Observation: templateId 2.16.840.1.113883.10.20.1.55]

- 1. SHALL conform to CDA Observation
- SHALL contain [1..1] @classCode = "OBS"
- 3. SHALL contain [1..1] @moodCode = "EVN"
- **4.** SHALL contain [1..1] code/@code = "SEV" Severity observation (CodeSystem: 2.16.840.1.113883.5.4 ActCode STATIC V3NE08)
- 5. SHALL contain [1..1] statusCode/@code = "completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus STATIC V3NE08)
- 6. SHALL contain [1..1] value

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"</pre>
xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.55"</pre>
assigningAuthorityName="CCD Severity Observation"/>
              <code code="SEV" codeSystem="2.16.840.1.113883.5.4"</pre>
 codeSystemName="ActCode" displayName="Severity observation"/>
              <statusCode code="completed"/>
            </observation>
          </entry>
```

Figure 60: Severity Observation example

Social History Observation

[Observation: templateId 2.16.840.1.113883.10.20.1.33]

1. SHALL conform to CDA Observation

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"</pre>
xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.33"</pre>
assigningAuthorityName="CCD Social History Observation"/>
            </observation>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 61: Social History Observation example

Status Observation

[Observation: templateId 2.16.840.1.113883.10.20.1.57]

- 1. SHALL conform to *CDA Observation* (CONF-508)
- **2. SHALL** contain [1..1] @classCode = "OBS" (CONF-510)
- **3. SHALL** contain [1..1] @moodCode = "EVN" (CONF-511)
- **4. SHALL** contain [1..1] code/@code = "33999-4" *Status* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC) (CONF-512, CONF-513)
- 5. SHALL contain [1..1] statusCode/@code = "completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus STATIC V3NE08) (CONF-514, CONF-515)
- **6. SHALL** contain [1..1] value, where its data type is CE (CONF-516)
- 7. SHALL satisfy: Target of an entryRelationship whose value for "entryRelationship / @typeCode" SHALL be "REFR" 2.16.840.1.113883.5.1002 ActRelationshipType STATIC. (CONF-509)
- 8. SHALL satisfy: SHALL NOT contain any additional Observation attributes. (CONF-517)
- **9. SHALL** satisfy: SHALL NOT contain any Observation participants. (CONF-518)
 - [OCL]: self.participant->isEmpty()

10. SHALL satisfy: SHALL NOT be the source of any Observation relationships. (CONF-519)

```
<component>
        <section>
          <entry>
            <observation classCode="OBS" moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.57"</pre>
 assigningAuthorityName="CCD Status Observation"/>
              <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"</pre>
 codeSystemName="LOINC" displayName="Status"/>
              <statusCode code="completed"/>
              <value xsi:type="CE"/>
            </observation>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 62: Status Observation example

Supply Activity

```
[Supply: templateId 2.16.840.1.113883.10.20.1.34]
```

A medication activity is used to describe what is administered whereas a supply activity is used to describe what has been dispensed.

- **1. SHALL** conform to *CDA Supply* (CONF-316)
- 2. SHALL contain [1..*] id (CONF-318)
- 3. SHOULD contain [1..1] statusCode (CONF-319)
- **4.** MAY contain [0..1] entryRelationship, such that it
 - a. contains Medication Status Observation (templateId: 2.16.840.1.113883.10.20.1.47)
- **5. MAY** contain [0..*] entryRelationship, such that it
 - **a.** has @typeCode="SUBJ" SUBJ (has subject)
 - **b.** contains *Fulfillment Instruction* (templateId: 2.16.840.1.113883.10.20.1.43)
- 6. SHOULD contain [1..1] effectiveTime (CONF-320)
 - · Indicates the actual or intended time of dispensing.
- **7. MAY** contain [0..1] quantity (CONF-322)
 - Indicates the actual or intended supply quantity.
- 8. MAY contain [0..1] repeatNumber (CONF-321)
 - Indicates the number of fills. (Note that repeatNumber corresponds to the number of "fills", as opposed to the number of "refills").
- SHALL satisfy: Value for moodCode is 'EVN' or 'INT' 2.16.840.1.113883.5.1001 ActMood STATIC (CONF-317)
 - [OCL]: self.moodCode=vocab::x_DocumentSubstanceMood::EVN or self.moodCode=vocab::x_DocumentSubstanceMood::INT
- 10. MAY satisfy: Contains one or more author. (CONF-323)
 - Indicates the prescriber.
 - [OCL]: not self.author->isEmpty()
- 11. MAY satisfy: Contains one or more performer. (CONF-324)
 - Indicates the person dispensing the product.
 - [OCL]: not self.performer->isEmpty()

12. MAY satisfy: Contains exactly one participant / @typeCode = "LOC". (CONF-325)

Iindicates the supply location.

```
• [OCL]: self.participant->one(part : cda::Participant2 | part.typeCode = vocab::ParticipationType::LOC)
```

13. SHALL satisfy: Contains one or more sources of information. (CONF-326)

```
• [OCL]: not self.informant->isEmpty()
    or not self.getSection().informant->isEmpty()
    or not self.getClinicalDocument().informant->isEmpty()
    or self.reference->exists(ref : cda::Reference | ref.typeCode =
     vocab::x_ActRelationshipExternalReference::XCRPT)
    or (self.entryRelationship->exists(rel : cda::EntryRelationship
       rel.typeCode = vocab::x_ActRelationshipEntryRelationship::REFR
       and rel.observation.code.code = '48766-0'))
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"</pre>
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <component>
    <structuredBody>
      <component>
        <section>
          <entry>
            <supply classCode="SPLY">
              <templateId root="2.16.840.1.113883.10.20.1.34"</pre>
 assigningAuthorityName="CCD Supply Activity"/>
              <id root="37c88f0d-9927-4ba5-bb11-a6a92d4ab6d9"/>
              <statusCode/>
              <effectiveTime/>
              <repeatNumber/>
              <quantity/>
            </supply>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 63: Supply Activity example

Vital Signs Organizer

[Organizer: templateId 2.16.840.1.113883.10.20.1.35]

- 1. SHALL conform to Result Organizer template (templateId: 2.16.840.1.113883.10.20.1.32)
- **2. SHALL** satisfy: Contains one or more sources of information.

```
<organizer moodCode="EVN">
              <templateId root="2.16.840.1.113883.10.20.1.32"</pre>
assigningAuthorityName="CCD Result Organizer"/>
              <templateId root="2.16.840.1.113883.10.20.1.35"</pre>
assigningAuthorityName="CCD Vital Signs Organizer"/>
              <id root="1de190a0-7a35-4826-aa3c-9ef79899adc7"/>
              <code/>
              <statusCode/>
              <component>
                <observation classCode="OBS" moodCode="EVN">
                  <templateId root="2.16.840.1.113883.10.20.1.31"</pre>
assigningAuthorityName="CCD Result Observation"/>
                  <id root="2f0889b3-b381-4d5b-80bb-9467e334608f"/>
                  <code/>
                  <statusCode/>
                  <effectiveTime>
                    <low value="1972"/>
                    <high value="2008"/>
                  </effectiveTime>
                  <interpretationCode/>
                  <methodCode/>
                </observation>
              </component>
            </organizer>
          </entry>
        </section>
      </component>
    </structuredBody>
 </component>
</ClinicalDocument>
```

Figure 64: Vital Signs Organizer example

Chapter

5

OTHER CLASSES

Topics:

- Advance Directive Verification
- Covered Party
- Encounter Location
- Patient Awareness
- Payer Entity
- Plan Of Care Activity
- Policy Subscriber
- Procedure Activity
- Product
- Product Instance
- Support
- Support Guardian
- Support Participant

This section of the Implementation Guide describes other classes that are not CDA Clinical Documents, Sections, or Clinical Statements.

Advance Directive Verification

[Participant2: templateId 2.16.840.1.113883.10.20.1.58]

- 1. SHALL conform to CDA Participant2
- **2. SHALL** contain [1..1] @typeCode = "VRF"
- **3. SHOULD** contain [0..1] time, where its data type is TS

Figure 65: Advance Directive Verification example

Covered Party

[ParticipantRole: templateId null]

- 1. SHALL conform to CDA Participant Role
- **2. SHOULD** contain [1..*] id (CONF-59)
- 3. SHOULD contain [1..1] code (CONF-60)

Figure 66: Covered Party example

Encounter Location

[Participant2: templateId 2.16.840.1.113883.10.20.1.45]

- 1. SHALL conform to CDA Participant2
- 2. SHALL contain [1..1] @typeCode = "LOC"

Figure 67: Encounter Location example

Patient Awareness

[Participant2: templateId 2.16.840.1.113883.10.20.1.48]

- 1. SHALL conform to *CDA Participant2* (CONF-178)
- 2. SHALL contain [1..1] @typeCode = "SBJ" (CONF-181)
- 3. SHALL contain [1..1] awarenessCode (CONF-182)
- **4. SHALL** satisfy: Patient awareness SHALL contain exactly one participant / participantRole / id, which SHALL have exactly one value, which SHALL also be present in ClinicalDocument / recordTarget / patientRole / id. (CONF-183)

```
    [OCL]: self.participantRole.id->one(id : datatypes::II | not id.root.oclIsUndefined())
    TODO compare with ClinicalDocument/recordTarget/patientRole/id
```

Figure 68: Patient Awareness example

Payer Entity

[AssignedEntity: templateId null]

1. SHALL conform to CDA Assigned Entity

2. SHALL contain [1..*] id (CONF-57)

Figure 69: Payer Entity example

Plan Of Care Activity

1.

Figure 70: Plan Of Care Activity example

Policy Subscriber

[ParticipantRole: templateId null]

- 1. SHALL conform to CDA Participant Role
- 2. **SHOULD** contain [0..*] id (CONF-64)

Figure 71: Policy Subscriber example

Procedure Activity

- 1. SHALL contain [1..1] moodCode, where its data type is ActMood
- 2. SHALL contain [1..*] id, where its data type is II
- **3.** SHALL contain [1..1] statusCode/@code = "completed" (CodeSystem: 2.16.840.1.113883.1.11.20.15 ProcedureStatusCode STATIC 20061017), where its data type is CS
- **4. SHOULD** contain [0..1] effectiveTime, where its data type is IVL_TS
- 5. SHALL contain [1..1] code, where its data type is CD

Figure 72: Procedure Activity example

Product

[ManufacturedProduct: templateId 2.16.840.1.113883.10.20.1.53]

1. SHALL conform to CDA Manufactured Product

Figure 73: Product example

Product Instance

[ParticipantRole: templateId 2.16.840.1.113883.10.20.1.52]

- 1. SHALL conform to CDA Participant Role
- 2. SHALL contain [1..1] @classCode = "MANU"

Figure 74: Product Instance example

Support

Represents the patient's sources of support such as immediate family, relatives, and guardian at the time the summarization is generated. Support information also includes next of kin, caregivers, and support organizations. At a minimum, key support contacts relative to healthcare decisions, including next of kin, should be included.

CDA R2 represents a patient's guardian with the CDA Header Guardian class. Other Supporters are represented as participant participations in the CDA Header.

1.

Figure 75: Support example

Support Guardian

[Guardian: templateId null]

- 1. SHALL conform to CDA Guardian
- 2. SHALL conform to Support

Figure 76: Support Guardian example

Support Participant

[Participant1: templateId null]

- 1. SHALL conform to CDA Participant1
- 2. SHALL conform to Support

Figure 77: Support Participant example

Chapter



VALUE SETS

The following tables summarize the value sets used in this Implementation Guide.

REFERENCES

- HL7 Implementation Guide: CDA Release 2 Continuity of Care Document (CCD) A CDA implementation of ASTM E2369-05 Standard Specification for Continuity of Care Record[©] (CCR) April 01, 2007 available through HL7.
- HL7 Implementation Guide for CDA Release 2 Quality Reporting Document Architecture (QRDA) Draft Standard for Trial Use March 2009. Available at: Quality Reporting Document Architecture (QRDA)
- HL7 Implementation Guide for CDA Release 2 CDA for Public Health Case Reports (PHCR) Informative Standard October 2009. Available through *HL7*.
- HL7 Implementation Guide for CDA Release 2: NHSN Healthcare Associated Infection (HAI) Reports, Release 2 Draft Standard for Trial Use January 2009 Available at: NHSN Healthcare Associated Infection (HAI) Reports
- Dolin RH, Alschuler L, Boyer S, Beebe C, Behlen FM, Biron PV, Shabo A, (Editors). HL7 Clinical Document Architecture, Release 2.0. ANSI-approved HL7 Standard; May 2005. Ann Arbor, Mich.: Health Level Seven, Inc. Available through *HL7* or if an HL7 member with the following link: *CDA Release 2 Normative Web Edition*.
- LOINC®: Logical Observation Identifiers Names and Codes, Regenstrief Institute.
- SNOMED CT®: SNOMED Clinical Terms SNOMED International Organization.
- Extensible Markup Language, www.w3.org/XML.
- Dolin RH, Alschuler L, Boyer S, Beebe C, Behlen FM, Biron PV, Shabo A., HL7 Clinical Document Architecture, Release 2. J Am Med Inform Assoc. 2006;13:30-39. Available at: http://www.jamia.org/cgi/reprint/13/1/30.
- Using SNOMED CT in HL7 Version 3; Implementation Guide, Release 1.5. Available through *HL7* or if an HL7 member with the following link: *Using SNOMED CT in HL7 Version 3*