# Implementation Guide for CDA Release 2 Health Story - Common Document Types (CDT) (U.S. Realm)



**DRAFT: FOR DEVELOPMENT USE ONLY** 

2   Implementation Guide for CDA Release 2   Introduction

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# **Revision History**

Rev	Date	By Whom	Changes
New	July 2010	Dave Carlson	
First draft for posting	August 31, 2010	Dave Carlson	Updated model content and publication format

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# 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 Health Story specifications have 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.

This guide is a combination of several Health Story specifications for History & Physical, Consultation Note, and others.

# **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, <a href="http://www.hl7.org/documentcenter/public/membership/HL7\_Governance\_and\_Operations\_Manual.pdf">http://www.hl7.org/documentcenter/public/membership/HL7\_Governance\_and\_Operations\_Manual.pdf</a>).

#### **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: <a href="http://wiki.hl7.org/index.php?title=CCD\_Suggested\_Enhancements">http://wiki.hl7.org/index.php?title=CCD\_Suggested\_Enhancements</a> 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:**

- Consultation Note
- General Header Constraints
- History And Physical
- Level One Conformance
- Level Three Conformance
- Level Two Conformance
- Progress Note

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

#### **Consultation Note**

[ClinicalDocument: templateId 2.16.840.1.113883.10.20.4]

- **1. SHALL** conform to *General Header Constraints* template (templateId: 2.16.840.1.113883.10.20.3) (CONF-CO-1)
- 2. SHALL contain exactly one [1..1] code, which SHALL be selected from ValueSet ConsultDocumentTypeCodes DYNAMIC (CONF-CO-2)
  - **a.** Implementations **MAY** use local codes in translation elements to specify a local code that is equivalent to the document type. An example of this is shown below. (CONF-CO-3)
- **3. SHALL** contain exactly one [1..1] **component** (CONF-CO-27), such that
  - **a.** Contains exactly one [1..1] *History Of Present Illness* (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.4)
- 4. SHALL contain exactly one [1..1] component (CONF-CO-28), such that
  - **a.** Contains exactly one [1..1] *Physical Examination Section* (templateId: 2.16.840.1.113883.10.20.2.10)
- **5.** MAY contain zero or one [0..1] component (CONF-CO-32), such that
  - a. Contains exactly one [1..1] CCD Problem Section (templateId: 2.16.840.1.113883.10.20.1.11)
- **6.** MAY contain zero or one [0..1] component (CONF-CO-33), such that
  - a. Contains exactly one [1..1] CCD Procedures Section (templateId: 2.16.840.1.113883.10.20.1.12)
- 7. MAY contain zero or one [0..1] component (CONF-CO-34), such that
  - **a.** Contains exactly one [1..1] *Past Medical History Section Consult* (templateId: 2.16.840.1.113883.10.20.4.9)
- **8.** MAY contain zero or one [0..1] component (CONF-CO-35), such that
  - a. Contains exactly one [1..1] CCD Immunizations Section (templateId: 2.16.840.1.113883.10.20.1.6)
- **9.** MAY contain zero or one [0..1] component (CONF-CO-36), such that
  - a. Contains exactly one [1..1] CCD Medications Section (templateId: 2.16.840.1.113883.10.20.1.8)
- 10. MAY contain zero or one [0..1] component (CONF-CO-37), such that
  - a. Contains exactly one [1..1] CCD Alerts Section (templateId: 2.16.840.1.113883.10.20.1.2)
- 11. MAY contain zero or one [0..1] component (CONF-CO-38), such that
  - **a.** Contains exactly one [1..1] *CCD Social History Section* (templateId: 2.16.840.1.113883.10.20.1.15)
- 12. MAY contain zero or one [0..1] component (CONF-CO-39), such that
  - **a.** Contains exactly one [1..1] *CCD Family History Section* (templateId: 2.16.840.1.113883.10.20.1.4)
- **13. MAY** contain zero or one [0..1] **component**, such that
  - a. Contains exactly one [1..1] Review Of Systems Section (templateId: 2.16.840.1.113883.10.20.4.10)
- **14. MAY** contain zero or one [0..1] **component** (CONF-CO-42), such that
  - a. Contains exactly one [1..1] CCD Vital Signs Section (templateId: 2.16.840.1.113883.10.20.1.16)
- **15. MAY** contain zero or one [0..1] **component** (CONF-CO-43), such that
  - **a.** Contains exactly one [1..1] *General Status Section* (templateId: 2.16.840.1.113883.10.20.2.5)
- **16. MAY** contain zero or one [0..1] **component** (CONF-CO-44), such that
  - a. Contains exactly one [1..1] Diagnostic Findings (templateId: 2.16.840.1.113883.10.20.1.14)
- 17. If pre-coordinated document type codes are used, values used in the assignedAuthor/code and assignedAuthor/author/functionCode elements SHALL NOT conflict with ClinicalDocument/code. (CONF-CO-4)

- **18.** If pre-coordinated document type codes are used, values used in encompassingEncounter/location/healthCareFacility/code **SHALL NOT** conflict with ClinicalDocument/code. (CONF-CO-5)
- 19. SHALL satisfy: A Consultation Note contains either ReasonForReferral or ReasonForVisit, but not both. (CONF-CO-26)

```
• [OCL]: self.getSections()->exists(section:
     cda::Section | not section.oclIsUndefined() and
     section.oclIsKindOf(cdt::ReasonForReferralSection))
       xor self.getSections()->exists(section :
     cda::Section | not section.oclIsUndefined() and
     section.oclIsKindOf(cdt::ReasonForVisitSectionConsult))
<?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">
  <realmCode code="US"/>
  <templateId root="2.16.840.1.113883.10.20.3"/>
  <templateId root="2.16.840.1.113883.10.20.4"/>
  <id root="cdbe7d17-4a06-47b9-875d-13bfd0c22290"/>
  <code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
  <title/>
  <effectiveTime/>
  <languageCode/>
  <component>
    <structuredBody>
      <component>
        <section>
          <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.4"/>
          <id root="ed7a33f6-5f3d-478f-a44e-b607f81e1b93"/>
          <code code="10164-2" codeSystem="2.16.840.1.113883.6.1"</pre>
 codeSystemName="LOINC" displayName="HISTORY OF PRESENT ILLNESS"/>
          <title>HISTORY OF PRESENT ILLNESS</title>
        </section>
      </component>
      <component>
        <section>
          <templateId root="2.16.840.1.113883.10.20.2.10"/>
          <id root="906b1650-ffd3-4b8c-b075-338edadb29c6"/>
          <code code="29545-1" codeSystem="2.16.840.1.113883.6.1"</pre>
 codeSystemName="LOINC" displayName="PHYSICAL FINDINGS"/>
          <title>PHYSICAL FINDINGS</title>
        </section>
      </component>
      <component>
        <section>
          <templateId root="2.16.840.1.113883.10.20.1.11"/>
          <id root="34f393fc-ee2e-4dd6-b0fd-6a7dc9ded12b"/>
          <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"/>
              <id root="74e1d272-2a54-47f8-99ff-a1037e979859"/>
              <code nullFlavor="NA"/>
              <effectiveTime>
                <low value="2011"/>
                <high value="2011"/>
              </effectiveTime>
              <entryRelationship>
                <observation classCode="OBS" moodCode="EVN">
                  <templateId root="2.16.840.1.113883.10.20.1.41"/>
                  <id root="17357602-bbef-4d65-b27b-a5bf29b31252"/>
```

```
<code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"</pre>
codeSystemName="ActCode"/>
                 <statusCode code="completed"/>
                 <effectiveTime>
                   <low value="2011"/>
                   <high value="2011"/>
                 </effectiveTime>
                 <value xsi:type="CD"/>
               </observation>
             </entryRelationship>
             <entryRelationship>
               <observation classCode="OBS" moodCode="EVN">
                 <templateId root="2.16.840.1.113883.10.20.1.28"/>
                 <id root="cc4cfe09-df55-4a5d-89ae-435d7c368cd9"/>
                 <code/>
                 <statusCode code="completed"/>
                 <effectiveTime>
                   <low value="2011"/>
                   <high value="2011"/>
                 </effectiveTime>
                 <entryRelationship>
                   <observation classCode="OBS" moodCode="EVN">
                     <templateId root="2.16.840.1.113883.10.20.1.57"/>
                     <templateId root="2.16.840.1.113883.10.20.1.50"/>
                     <id root="aab3a24d-8ff7-42cd-8487-c2a5c73ddb3e"/>
                     <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"</pre>
codeSystemName="LOINC" displayName="Status"/>
                     <statusCode code="completed"/>
                     <effectiveTime>
                       <low value="2011"/>
                        <high value="2011"/>
                     </effectiveTime>
                     <value xsi:type="CE"/>
                   </observation>
                 </entryRelationship>
                 <entryRelationship>
                   <observation classCode="OBS" moodCode="EVN">
                     <templateId root="2.16.840.1.113883.10.20.1.57"/>
                     <templateId root="2.16.840.1.113883.10.20.1.51"/>
                     <id root="bf7fd5b1-5edd-4df6-860e-f658dc7ae8c2"/>
                     <code code="11323-3" codeSystem="2.16.840.1.113883.6.1"</pre>
codeSystemName="LOINC" displayName="Health status"/>
                     <statusCode code="completed"/>
                     <effectiveTime>
                       <low value="2011"/>
                       <high value="2011"/>
                     </effectiveTime>
                     <value xsi:type="CE"/>
                   </observation>
                 </entryRelationship>
                 <entryRelationship>
                   <observation classCode="OBS" moodCode="EVN">
                     <templateId root="2.16.840.1.113883.10.20.1.38"/>
                     <id root="0e4dc89b-c129-4a1a-96f1-7c1c4a7aa1e1"/>
                     <code code="397659008"
codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMEDCT"
displayName="Age"/>
                     <statusCode code="completed"/>
                     <effectiveTime>
                       <low value="2011"/>
                       <high value="2011"/>
                     </effectiveTime>
                   </observation>
                 </entryRelationship>
```

```
</observation>
             </entryRelationship>
           </act>
         </entry>
       </section>
     </component>
     <component>
       <section>
         <templateId root="2.16.840.1.113883.10.20.1.12"/>
         <id root="1c21b1fc-c8d8-47c0-9093-e5eda9bee115"/>
         <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="2.16.840.1.113883.10.20.4.9"/>
         <id root="76b1fabb-88ea-4dd7-a215-68ae47df0faa"/>
         <code code="11348-0" codeSystem="2.16.840.1.113883.6.1"</pre>
codeSystemName="LOINC" displayName="HISTORY OF PAST ILLNESS"/>
         <title>HISTORY OF PAST ILLNESS</title>
       </section>
     </component>
     <component>
       <section>
         <templateId root="2.16.840.1.113883.10.20.1.6"/>
         <id root="6de9468c-e5d8-4ba3-bfe0-3572ed22d877"/>
         <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="2.16.840.1.113883.10.20.1.8"/>
         <id root="5260f994-ad7d-4bf5-8b9f-4c209bcdbbdc"/>
         <code code="10160-0" codeSystemName="" displayName="History of</pre>
medication use"/>
         <title>History of medication use</title>
         <entry>
           <substanceAdministration classCode="SBADM">
             <templateId root="2.16.840.1.113883.10.20.1.24"/>
             <id root="2a8d949f-ff58-4d71-9ed7-5a6552ca7440"/>
             <statusCode/>
             <effectiveTime value="20110616"/>
             <routeCode codeSystem="2.16.840.1.113883.5.112"</pre>
codeSystemName="HL7 RouteOfAdministration"/>
             <doseQuantity/>
             <rateQuantity/>
             <maxDoseQuantity/>
             <entryRelationship>
               <observation classCode="OBS" moodCode="EVN">
                 <templateId root="2.16.840.1.113883.10.20.1.46"/>
                 <id root="c09b2225-e609-4b57-9edc-800bc84c873d"/>
                 <code code="30973-2" codeSystemName="" displayName="Dose</pre>
number"/>
                 <statusCode/>
                 <effectiveTime>
                   <low value="2011"/>
                    <high value="2011"/>
                 </effectiveTime>
                 <value xsi:type="INT"/>
               </observation>
```

```
</entryRelationship>
             <entryRelationship>
               <observation classCode="OBS" moodCode="EVN">
                 <templateId root="2.16.840.1.113883.10.20.1.57"/>
                 <templateId root="2.16.840.1.113883.10.20.1.47"/>
                 <id root="4ae7eab1-265c-43a0-af56-b612ad9bc250"/>
                 <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"</pre>
codeSystemName="LOINC" displayName="Status"/>
                 <statusCode code="completed"/>
                 <effectiveTime>
                   <low value="2011"/>
                   <high value="2011"/>
                 </effectiveTime>
                 <value xsi:type="CE"/>
               </observation>
             </entryRelationship>
             <entryRelationship>
               <act moodCode="INT">
                 <templateId root="2.16.840.1.113883.10.20.1.49"/>
                 <id root="72d8b6ee-b04b-4e7b-ad23-ed1432808ee0"/>
                 <effectiveTime>
                   <low value="2011"/>
                   <high value="2011"/>
                 </effectiveTime>
               </act>
             </entryRelationship>
             <entryRelationship>
               <observation classCode="OBS" moodCode="EVN">
                 <templateId root="2.16.840.1.113883.10.20.1.54"/>
                 <id root="859d8a7d-30e7-4ef6-b9ba-e1757de96a85"/>
                 <statusCode code="completed"/>
                 <effectiveTime>
                   <low value="2011"/>
                   <high value="2011"/>
                 </effectiveTime>
                 <entryRelationship>
                   <observation classCode="OBS" moodCode="EVN">
                     <templateId root="2.16.840.1.113883.10.20.1.55"/>
                     <id root="54ef0153-d23a-49a4-bdea-e4334e1d632b"/>
                     <code code="SEV" codeSystem="2.16.840.1.113883.5.4"</pre>
codeSystemName="ActCode" displayName="Severity observation"/>
                     <statusCode code="completed"/>
                     <effectiveTime>
                       <low value="2011"/>
                       <high value="2011"/>
                     </effectiveTime>
                   </observation>
                 </entryRelationship>
               </observation>
             </entryRelationship>
           </substanceAdministration>
         </entry>
         <entry>
           <supply classCode="SPLY">
             <templateId root="2.16.840.1.113883.10.20.1.34"/>
             <id root="1c0e3f31-f7cc-4b76-a577-df21690b3b3e"/>
             <statusCode/>
             <effectiveTime value="20110616"/>
             <repeatNumber/>
             <quantity/>
             <entryRelationship>
               <observation classCode="OBS" moodCode="EVN">
                 <templateId root="2.16.840.1.113883.10.20.1.57"/>
                 <templateId root="2.16.840.1.113883.10.20.1.47"/>
```

```
<id root="3caa53cc-b414-4348-8a39-562e9e1af2af"/>
                 <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"</pre>
codeSystemName="LOINC" displayName="Status"/>
                 <statusCode code="completed"/>
                 <effectiveTime>
                   <low value="2011"/>
                   <high value="2011"/>
                 </effectiveTime>
                 <value xsi:type="CE"/>
               </observation>
             </entryRelationship>
             <entryRelationship>
               <act moodCode="INT">
                 <templateId root="2.16.840.1.113883.10.20.1.43"/>
                 <id root="903250ac-a5a4-4d53-8197-2f7eaeeb3777"/>
                 <effectiveTime>
                   <low value="2011"/>
                   <high value="2011"/>
                 </effectiveTime>
               </act>
             </entryRelationship>
           </supply>
         </entry>
       </section>
     </component>
     <component>
       <section>
         <templateId root="2.16.840.1.113883.10.20.1.2"/>
         <id root="813a7343-614a-48e6-824f-3ab7f6b495c1"/>
         <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>
         <entry>
           <act classCode="ACT" moodCode="EVN">
             <templateId root="2.16.840.1.113883.10.20.1.27"/>
             <id root="4425b0eb-373c-4c60-9db1-2bb480750b74"/>
             <code nullFlavor="NA"/>
             <effectiveTime>
               <low value="2011"/>
               <high value="2011"/>
             </effectiveTime>
             <entryRelationship>
               <observation classCode="OBS" moodCode="EVN">
                 <templateId root="2.16.840.1.113883.10.20.1.41"/>
                 <id root="3a39ed55-0266-428b-812d-b1d5c087aa9a"/>
                 <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"</pre>
codeSystemName="ActCode"/>
                 <statusCode code="completed"/>
                 <effectiveTime>
                   <low value="2011"/>
                   <high value="2011"/>
                 </effectiveTime>
                 <value xsi:type="CD"/>
               </observation>
             </entryRelationship>
             <entryRelationship>
               <observation classCode="OBS" moodCode="EVN">
                 <templateId root="2.16.840.1.113883.10.20.1.28"/>
                 <id root="6d2c6197-b5f5-4ae5-bb64-0d4310d25b2a"/>
                 <code/>
                 <statusCode code="completed"/>
                 <effectiveTime>
                   <low value="2011"/>
                   <high value="2011"/>
```

```
</effectiveTime>
                 <entryRelationship>
                   <observation classCode="OBS" moodCode="EVN">
                     <templateId root="2.16.840.1.113883.10.20.1.57"/>
                     <templateId root="2.16.840.1.113883.10.20.1.50"/>
                     <id root="a43611e5-3283-4d5b-b361-f58d554e3602"/>
                     <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"</pre>
codeSystemName="LOINC" displayName="Status"/>
                     <statusCode code="completed"/>
                     <effectiveTime>
                        <low value="2011"/>
                        <high value="2011"/>
                     </effectiveTime>
                     <value xsi:type="CE"/>
                   </observation>
                 </entryRelationship>
                 <entryRelationship>
                   <observation classCode="OBS" moodCode="EVN">
                     <templateId root="2.16.840.1.113883.10.20.1.57"/>
                     <templateId root="2.16.840.1.113883.10.20.1.51"/>
                     <id root="bc3dd3c7-ce99-432e-8665-7e9b5bcebc64"/>
                     <code code="11323-3" codeSystem="2.16.840.1.113883.6.1"</pre>
codeSystemName="LOINC" displayName="Health status"/>
                     <statusCode code="completed"/>
                     <effectiveTime>
                       <low value="2011"/>
                        <high value="2011"/>
                     </effectiveTime>
                      <value xsi:type="CE"/>
                   </observation>
                 </entryRelationship>
                 <entryRelationship>
                   <observation classCode="OBS" moodCode="EVN">
                     <templateId root="2.16.840.1.113883.10.20.1.38"/>
                     <id root="c86b88fa-3274-4b53-b74e-05c9c957f2e2"/>
                     <code code="397659008"</pre>
codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMEDCT"
displayName="Age"/>
                     <statusCode code="completed"/>
                     <effectiveTime>
                        <low value="2011"/>
                        <high value="2011"/>
                     </effectiveTime>
                   </observation>
                 </entryRelationship>
               </observation>
             </entryRelationship>
           </act>
         </entry>
       </section>
     </component>
     <component>
       <section>
         <templateId root="2.16.840.1.113883.10.20.1.15"/>
         <id root="5ea15bdf-06ff-408a-acbe-2554acabc567"/>
         <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="2.16.840.1.113883.10.20.1.4"/>
         <id root="a44abbff-a2e1-4cca-8eca-24bc03570a73"/>
```

```
<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="2.16.840.1.113883.10.20.4.10"/>
         <id root="2dbfdb68-801e-432e-94dd-3104c02c6104"/>
         <code code="10187-3" codeSystem="2.16.840.1.113883.6.1"</pre>
codeSystemName="LOINC" displayName="REVIEW OF SYSTEMS"/>
         <title>REVIEW OF SYSTEMS</title>
       </section>
     </component>
     <component>
       <section>
         <templateId root="2.16.840.1.113883.10.20.1.16"/>
         <id root="deae67ca-fc13-4c00-87fe-3eee7907ce8c"/>
         <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"/>
             <templateId root="2.16.840.1.113883.10.20.1.35"/>
             <id root="85e7a7c9-f0d5-4137-8298-e1b692dce878"/>
             <code/>
             <statusCode/>
             <effectiveTime>
               <low value="2011"/>
               <high value="2011"/>
             </effectiveTime>
             <component>
               <observation moodCode="EVN">
                 <templateId root="2.16.840.1.113883.10.20.1.31"/>
                 <id root="0b7ef119-723c-4c6f-a0cf-b350c84d53a5"/>
                 <code/>
                 <statusCode/>
                 <effectiveTime>
                   <low value="2011"/>
                   <high value="2011"/>
                 </effectiveTime>
                 <interpretationCode/>
                 <methodCode/>
               </observation>
             </component>
           </organizer>
         </entry>
       </section>
     </component>
     <component>
       <section>
         <templateId root="2.16.840.1.113883.10.20.2.5"/>
         <id root="7110dbab-579d-4ba9-ae99-64eb25b42f85"/>
         <code code="10210-3" codeSystem="2.16.840.1.113883.6.1"</pre>
codeSystemName="LOINC" displayName="GENERAL STATUS, PHYSICAL FINDINGS"/>
         <title>GENERAL STATUS, PHYSICAL FINDINGS</title>
       </section>
     </component>
     <component>
       <section>
         <templateId root="2.16.840.1.113883.10.20.1.14"/>
         <id root="b0a46973-78e1-46a7-91c3-b6623f5a6b8a"/>
```

```
<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"/>
              <id root="0af3fac9-5646-4a66-a70d-a940ea0d3c81"/>
              <code/>
              <statusCode/>
              <effectiveTime>
                <low value="2011"/>
                <high value="2011"/>
              </effectiveTime>
              <component>
                <observation moodCode="EVN">
                  <templateId root="2.16.840.1.113883.10.20.1.31"/>
                  <id root="0673827b-2c52-48be-804e-99154766422a"/>
                  <code/>
                  <statusCode/>
                  <effectiveTime>
                    <low value="2011"/>
                    <high value="2011"/>
                  </effectiveTime>
                  <interpretationCode/>
                  <methodCode/>
                </observation>
              </component>
            </organizer>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 5: Consultation Note example

#### **General Header Constraints**

[ClinicalDocument: templateId 2.16.840.1.113883.10.20.3]

This section describes constraints that apply to the H and P Note and to other types of CDA documents defined for general exchange. The template defined here should be reused wherever these general header constraints are applied.

To support communication between the receiver of the document and the patient or any other person or organization mentioned within it, the elements representing them will be named.

When name, address, or telecom information is unknown and where these elements are required to be present, as with CDA conformance if the information is unknown, these elements will be represented using an appropriate value for the nullFlavor attribute on the element.

Events occurring at a single point in time that are represented in the Clinical Document header will in general be precise to the day. These point-in-time events are the time of creation of the document; the starting time of a participation by an author, data enterer, authenticator, or legal authenticator; or the starting and ending time of an encounter.

Within the specification, all telephone numbers are to be encoded using a grammar which is a restriction on the TEL data type and RFC 2806. It simplifies interchange between applications as it removes optional URL components found in RFC 2806 that applications typically do not know how to process, such as ISDN sub-address, phone context, or other dialing parameters.

Organizations that wish to use OIDs should properly register their OID root and ensure uniqueness of the OID roots used in identifiers. A large number of mechanisms exist for obtaining OID roots for free or for a reasonable fee. HL7 maintains an OID registry page from which organizations may request an OID root under the HL7 OID root. This page can be accessed at: http://www.hl7.org/oid.

Another useful resource lists the many ways to obtain a registered OID Root for free or a small fee anywhere in the world and is located at:

http://www.dclunie.com/medical-image-faq/html/part8.html#UIDRegistration.

The manner in which the OID root is obtained is not constrained by this DSTU.

- 1. SHALL contain exactly one [1..1] code (CONF-HP-21)
  - Specifies the type of the clinical document.
- 2. Contains exactly one [1..1] confidentialityCode
  - Specifies the confidentiality assigned to the document. This specification provides no further guidance beyond CDA R2 on documents with respect to the vocabulary used for confidentialityCode, nor treatment or implementation of confidentiality.
- 3. SHALL contain exactly one [1..1] effectiveTime (CONF-HP-23)
  - Specifies the creation time of the document. All documents authored by direct input to a computer system should record an effective Time that is precise to the second. When authored in other ways, for example, by filling out a paper form that is then transferred into an EHR system, the precision of effective Time may be less than to the second.
- **4. SHALL** contain exactly one [1..1] **id** (CONF-HP-17)
  - The ClinicalDocument/id element is an instance identifier data type (see HL7 Version 3 Abstract Data in Section 5 REFERENCES). The root attribute is a UUID or OID. The root uniquely identifies the scope of the extension. The root and extension attributes uniquely identify the document.
- **5. SHALL** contain exactly one [1..1] **languageCode** (CONF-HP-24)
- 6. SHALL contain exactly one [1..1] realmCode/@code="US" (CONF-HP-15)
- 7. SHALL contain exactly one [1..1] title (CONF-HP-22)
  - Specifies the local name used for the document. Note that the title does not need to be the same as the display
    name provided with the document type code. For example, the display name provided by LOINC® as an aid in
    debugging may be "HISTORY AND PHYSICAL." The title can be localized, as appropriate.
- 8. SHALL contain exactly one [1..1] typeId (CONF-HP-16)
  - The clinical document type ID identifies the constraints imposed by CDA R2 on the content, essentially acting
    as a version identifier.
- **9.** Contains at least one [1..\*] **author**, such that
  - The author element represents the creator of the clinical document. If the role of the actor is the entry of information from his or her own knowledge or application of skills, that actor is the author. If one actor provides information to another actor who filters, reasons, or algorithmically creates new information, then that second actor is also an author, having created information from his or her own knowledge or skills. However, that determination is independent from the determination of the first actor's authorship.
- **10.** Contains zero or one [0..1] **dataEnterer**, such that
  - The dataEnterer element represents the person who transferred the information from other sources into the clinical document, where the other sources wrote the content of the note. The guiding rule of thumb is that an author provides the content found within the header or body of the document, subject to their own interpretation. The dataEnterer adds information to the electronic system. A person can participate as both author and dataEnterer.

If the role of the actor is to transfer information from one source to another (e.g., transcription or transfer from paper form to electronic system), that actor is considered a dataEnterer.

- 11. Contains exactly one [1..1] custodian, such that
  - Based on the CDA R2 constraints (Section 4.2.2.3 of the CDA Normative Web Edition. See Section 5 REFERENCES), the custodian element is required and is the custodian of the clinical document.

- 12. Contains zero or more [0..\*] informationRecipient, such that
  - informationRecipient, when used in the context of a referral or request for consultation, this records the intended recipient of the information at the time the document is created. The intended recipient may also be the health chart of the patient, in which case the receivedOrganization is the scoping organization of that chart.
- **13.** Contains zero or one [0..1] **legalAuthenticator**, such that
  - The legalAuthenticator element identifies the legal authenticator of the document and must be present if the
    document has been legally authenticated. Based on local practice, clinical documents may be released before
    legal authentication. This implies that a clinical document that does not contain this element has not been
    legally authenticated.

The act of legal authentication requires a certain privilege be granted to the legal authenticator depending upon local policy. All clinical documents have the potential for legal authentication, given the appropriate credentials.

Local policies may choose to delegate the function of legal authentication to a device or system that generates the clinical document. In these cases, the legal authenticator is a person accepting responsibility for the document, not the generating device or system.

- **14.** Contains zero or more [0..\*] **authenticator**, such that
  - The authenticator identifies the participant who attested to the accuracy of the information in the document.

Automated systems, such as a PHR, that allow a clinical document to be generated need to give special consideration to authentication permissions because the information contained in the document may come from sources or contain information that the author cannot validate.

- **15. SHALL** satisfy: All patient, guardianPerson, assignedPerson, maintainingPerson, relatedPerson, intendedRecipient/informationRecipient, associatedPerson, and relatedSubject/subject elements have a name. (CONF-HP-6)
  - [OCL]: -- implemented in Java using XPath selector

```
• [XPath]: *[self::cda:patient or self::cda:guardianPerson or self::cda:assignedPerson or self::cda:maintainingPerson or self::cda:relatedPerson or self::cda:associatedPerson or self::cda:intendedRecipient/cda:informationRecipient or self::cda:relatedSubject/cda:subject]
```

- **16. SHALL** satisfy: All patientRole, assignedAuthor, assignedEntity[not(parent::dataEnterer)] and associatedEntity elements have an addr and telecom element. (CONF-HP-7)
  - [OCL]: -- implemented in Java using XPath selector
  - [XPath]: \*[self::cda:patientRole or self::cda:assignedAuthor or self::cda:assignedEntity[not(parent::cda:dataEnterer)] or self::cda:associatedEntity]
- **17. SHOULD** satisfy: All guardian, dataEnterer/assignedEntity, relatedEntity, intendedRecipient, relatedSubject and participantRole elements have an addr and telecom element. (CONF-HP-8)
  - [OCL]: -- implemented in Java using XPath selector

```
• [XPath]: *[self::cda:guardian or
self::cda:assignedEntity[parent::cda:dataEnterer] or
self::cda:relatedEntity or self::cda:intendedRecipient or
self::cda:relatedSubject or self::cda:participantRole]
```

- **18. SHALL** satisfy: All guardianOrganization, providerOrganization, wholeOrganization, representedOrganization, representedCustodianOrganization, receivedOrganization, scopingOrganization and serviceProviderOrganization elements have name, addr and telecom elements. (CONF-HP-9)
  - When name, address, or telecom information is unknown and where these elements are required to be present, as with CDA conformance if the information is unknown, these elements will be represented using an

appropriate value for the nullFlavor attribute on the element. Legal values according to this specification come from the HL7 NullFlavor vocabulary.

```
    [OCL]: -- implemented in Java using XPath selector
    [XPath]: *[self::cda:guardianOrganization or self::cda:providerOrganization or self::cda:wholeOrganization or self::cda:representedOrganization or self::cda:representedCustodianOrganization or self::cda:receivedOrganization or self::cda:scopingOrganization or self::cda:serviceProviderOrganization]
```

- 19. Times or time intervals found in the ClinicalDocument/effectiveTime, author/time, dataEnterer/time, legalAuthenticator/time, authenticator/time and encompassingEncounter/effectiveTime elements SHALL be precise to the day, SHALL include a time zone if more precise than to the day, and SHOULD be precise to the second. (CONF-HP-10)
  - [OCL]: -- implemented in Java using XPath selector
     [XPath]: /cda:ClinicalDocument/cda:effectiveTime | //cda:author/cda:time | //cda:dataEnterer/cda:time | //cda:encompassingEncounter/cda:effectiveTime
- 20. Times or time intervals found in the asOrganizationPartOf/effectiveTime, asMaintainedEntity/effectiveTime, relatedEntity/effectiveTime, serviceEvent/effectiveTime, ClinicalDocument/participant/time, serviceEvent/ performer/time and encounterParticipant/time SHALL be precise at least to the year, SHOULD be precise to the day, and MAY omit time zone. (CONF-HP-11)

```
[OCL]: cda::OrganizationPartOf.allInstances()-
>select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject)-
> union( cda::MaintainedEntity.allInstances()-
>select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject) )-
>union( cda::RelatedEntity.allInstances()-
>select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject) )-
>union(cda::RelatedEntity.allInstances()-
>select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject) )-
>union(cda::RelatedEntity.allInstances()-
>select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject) )-
>union(cda::ServiceEvent.allInstances()-
>select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject) )-
>union(cda::EncounterParticipant.allInstances()-
>select( time.oclIsUndefined()).oclAsType( ecore::EObject))-
>union(self.participant-
>select( time.oclIsUndefined()).oclAsType( ecore::EObject))-
>union(cda::OrganizationPartOf.allInstances().effectiveTime-
>union(cda::MaintainedEntity.allInstances().effectiveTime)-
>union( cda::RelatedEntity.allInstances().effectiveTime)-
>union(cda::RelatedEntity.allInstances().effectiveTime)-
>union(cda::RelatedEntity.allInstances().effectiveTime)-
>union(cda::ServiceEvent.allInstances().effectiveTime)-
>union(cda::EncounterParticipant.allInstances().time)-
>union(self.participant.time)->select(current :
 datatypes::IVL_TS | ((not current.low.oclIsUndefined()) and
 (current.low.value.oclIsUndefined() or current.low.value.size()
 < 4)) or ((not current.center.oclIsUndefined()) and
 (current.center.value.oclIsUndefined() or current.center.value.size()
 < 4)) or ((not current.high.oclIsUndefined()) and
 (current.high.value.oclIsUndefined() or current.high.value.size() < 4))</pre>
 or (current.low.oclIsUndefined() and current.center.oclIsUndefined() and
 current.high.oclIsUndefined()) ).oclAsType( ecore::EObject))
```

- **21. SHALL** satisfy: Telephone numbers match the regular expression pattern tel:\+?[-0-9().]+ (CONF-HP-12)
  - The telecom element is used to provide a contact telephone number for the various participants that require it.
     The value attribute of this elements is a URL that specifies the telephone number, as indicated by the TEL data type.

- All telephone numbers are to be encoded using a restricted form of the tel: URL scheme. A telephone number used for voice calls begins with the URL scheme tel:. If the number is a global phone number, it starts with a plus (+) sign. The remaining number is made up of the dialing digits and an optional extension and may also contain visual separators.
- [OCL]: -- implemented in Java using XPath selector
- [XPath]: //\*[self::cda:telecom]
- **22. SHALL** satisfy: At least one dialing digit is present in the phone number after visual separators are removed. (CONF-HP-13)
  - [OCL]: -- implemented in Java using XPath selector
  - [XPath]: //\*[self::cda:telecom]
- **23. SHALL** satisfy: If the telephone number is unknown it is represented using the appropriate flavor of null. (CONF-HP-14)
  - There is no way to distinguish between an unknown phone number and an unknown e-mail or other telecommunications address. Therefore, the following convention will be used: Any telecom element that uses a flavor of null (has a nullFlavor attribute) is assumed to be a telephone number, which is the only required telecommunications address element within this DSTU.
  - [OCL]: -- implemented in Java using XPath selector
  - [XPath]: //\*[self::cda:telecom]
- 24. SHALL satisfy: The extension attribute of the typeId element is POCD\_HD000040. (CONF-HP-16)
  - [OCL]: self.typeId.extension = 'POCD\_HD000040'
- 25. SHALL satisfy: The id/@root attribute is a syntactically correct UUID or OID. (CONF-HP-17)
- **27.** OIDs are represented in dotted decimal notation, where each decimal number is either 0, or starts with a nonzero digit. More formally, an OID **SHALL** be in the form ([0-2])(.([1-9][0-9]\*|0))+. (CONF-HP-19)
  - Organizations that wish to use OIDs should properly register their OID root and ensure uniqueness of the
    OID roots used in identifiers. A large number of mechanisms exist for obtaining OID roots for free or for a
    reasonable fee. HL7 maintains an OID registry page from which organizations may request an OID root under
    the HL7 OID root. This page can be accessed at: http://www.hl7.org/oid.

Another useful resource lists the many ways to obtain a registered OID Root for free or a small fee anywhere in the world and is located at: http://www.dclunie.com/medical-image-faq/html/part8.html#UIDRegistration.

The manner in which the OID root is obtained is not constrained by this DSTU.

- **28. SHALL** satisfy: OIDs are no more than 64 characters in length. (CONF-HP-20)
  - OIDs are limited by this specification to no more than 64 characters in length for compatibility with other standards and Implementation Guides.
  - [OCL]: self.id->select((not id.root.oclIsUndefined()) and id.root.size() > 64 )
- **29. SHALL** satisfy: languageCode has the form nn, or nn-CC. (CONF-HP-25)
- **30. SHALL** satisfy: The nn portion of languageCode is a legal ISO-639-1 language code in lowercase. (CONF-HP-26)
- 31. The CC portion languageCode, if present, SHALL be an ISO-3166 country code in uppercase. (CONF-HP-27)
- 32. Both setId and versionNumber SHALL be present or both SHALL be absent. (CONF-HP-28)
  - The ClinicalDocument/setId element uses the instance identifier (II) data type. The root attribute is a UUID
    or OID that uniquely identifies the scope of the identifier, and the extension attribute is a value that is unique
    within the scope of the root for the set of versions of the document. See Document Identification, Revisions,
    and Addenda in Section 4.2.3.1 of the CDA Specification for some examples showing the use of the setId
    element.
  - [OCL]: (self.setId.oclIsUndefined() and self.versionNumber.oclIsUndefined())

```
xor (not self.setId.oclIsUndefined() and not
self.versionNumber.oclIsUndefined())
```

- 33. The @extension and/or @root of setId and id SHALL be different when both are present. (CONF-HP-29)
  - [OCL]: (not self.setId.oclIsUndefined() and not self.id.oclIsUndefined()) implies (self.setId.root <> self.id.root or self.setId.extension <> self.id.extension)
- **34.** A copyTime element **SHALL NOT** be present. (CONF-HP-30)
  - The ClinicalDocument/copyTime element has been deprecated in CDA R2.
  - [OCL]: self.copyTime.oclIsUndefined()
- **35. SHALL** satisfy: At least one recordTarget/patientRole element is present. (CONF-HP-31)
  - [OCL]: self.recordTarget->size() > 0 and self.recordTarget->exists(target : cda::RecordTarget | not target.patientRole.oclIsUndefined())
- **36.** A patient/birthTime element **SHALL** be present. The patient/birthTime element **SHALL** be precise at least to the year, and **SHOULD** be precise at least to the day, and **MAY** omit time zone. If unknown, it **SHALL** be represented using a flavor of null. (CONF-HP-32)
  - [OCL]: self.recordTarget->forAll(target : cda::RecordTarget | not target.patientRole.oclIsUndefined() implies (not target.patientRole.patient.birthTime.value.oclIsUndefined() or not target.patientRole.patient.birthTime.nullFlavor.oclIsUndefined()))
- **37.** A patient/administrativeGenderCode element **SHALL** be present. If unknown, it **SHALL** be represented using a flavor of null. Values for administrativeGenderCode **SHOULD** be drawn from the HL7 AdministrativeGender vocabulary. (CONF-HP-33)
  - TODO: add OCL test for terminology
  - [OCL]: self.recordTarget->forAll(target : cda::RecordTarget | not target.patientRole.oclIsUndefined() implies (not target.patientRole.patient.administrativeGenderCode.code.oclIsUndefined() or not target.patientRole.patient.administrativeGenderCode.nullFlavor.oclIsUndefined()))
- **38.** The maritalStatusCode, religiousAffiliationCode, raceCode and ethnicGroupCode **MAY** be present. If maritalStatusCode, religiousAffiliationCode, raceCode and ethnicGroupCode elements are present, they **SHOULD** be encoded using the appropriate HL7 vocabularies. (CONF-HP-34)
- **39. SHOULD** satisfy: The guardian element is present when the patient is a minor child. (CONF-HP-35)
- **40. MAY** satisfy: The providerOrganization element is present. (CONF-HP-36)
  - [OCL]: self.recordTarget->exists(target : cda::RecordTarget | not target.patientRole.providerOrganization.oclIsUndefined())
- **41. SHALL** satisfy: The author/time element is present. (CONF-HP-37)
  - The author/time element represents the start time of the author's participation in the creation of the clinical document.
  - [OCL]: self.author->forAll(author : cda::Author | not author.time.oclIsUndefined())
- **42. SHALL** satisfy: The assignedAuthor/id element is present. (CONF-HP-38)
  - [OCL]: self.author->forAll(author : cda::Author | author.assignedAuthor.id->size() > 0)
- **43. SHALL** satisfy: An assigned Author element contains at least one assigned Person or assigned Authoring Device elements. (CONF-HP-39)
  - [OCL]: self.author->forAll(author : cda::Author | not author.assignedAuthor.assignedPerson.oclIsUndefined() or not author.assignedAuthor.assignedAuthoringDevice.oclIsUndefined())

- **44. SHALL** satisfy: When dataEnterer is present, an assignedEntity/assignedPerson element is present. (CONF-HP-40)
  - [OCL]: not self.dataEnterer.oclIsUndefined() implies not self.dataEnterer.assignedEntity.assignedPerson.oclIsUndefined()
- **45.** The dataEnterer/time element **MAY** be present. If present, it represents the starting time of entry of the data. (CONF-HP-41)
  - [OCL]: not self.dataEnterer.oclIsUndefined() implies not self.dataEnterer.time.oclIsUndefined()
- **46. MAY** satisfy: The informant element is present. (CONF-HP-42)
  - [OCL]: self.informant->size() > 0
- **47.** When informant is present, an assignedEntity/assignedPerson or relatedEntity/relatedPerson element **SHALL** be present. (CONF-HP-43)

```
    [OCL]: self.informant->forAll(i : cda::Informant12 | not
i.assignedEntity.assignedPerson.oclIsUndefined()
or not i.relatedEntity.relatedPerson.oclIsUndefined())
```

- **48.** When the informant is a healthcare provider with an assigned role, the informant **SHALL** be represented using the assignedEntity element (CONF-HP-44)
  - Assigned health care providers may be a source of information when a document is created. (e.g., a nurse's
    aide who provides information about a recent significant health care event that occurred within an acute care
    facility.) In these cases, the assignedEntity element is used.
  - TODO: how to determin if informant is a healthcare provider? condition for implementing OCL
- **49.** Allowable values for informant/relatedEntity/@classCode **SHALL** be CON, PRS, CAREGIVER, AGNT or PROV from the RoleClass vocabulary. (CONF-HP-45)
  - When the informant is a personal relation, that informant is represented in the relatedEntity element. The code element of the relatedEntity describes the relationship between the informant and the patient.

The relationship between the informant and the patient needs to be described to help the receiver of the clinical document understand the information in the document.

- **50.** When relatedEntity/@classCode is PRS, values in relatedEntity/code **SHALL** come from the HL7 PersonalRelationshipRoleType vocabulary or from SNOMED, any subtype of "Person in the family" (303071001). (CONF-HP-46)
- **51.** When an informant is an unrelated person not otherwise specified, the value relatedEntity/@classCode **SHALL** be set to CON to indicate that this person is a contact. (CONF-HP-47)
  - Individuals with no prior personal relationship to the patient (e.g., a witness to a significant health care event) may provide information about the patient.
- **52.** When the informant is a healthcare provider without an assigned role, the informant **SHALL** be represented using the relatedEntity element and the value of relatedEntity/@classCode **SHALL** be set to PROV. (CONF-HP-48)
  - A health care provider who does not have an assigned role at the institution may provide information. To
    record an informant that does not have an assigned role that can be represented within the context of the
    document, the information will be represented using the relatedEntity element and the value of relatedEntity/
    @classCode will be set to PROV.
- **53.** When the informant is a healthcare provider, the value of relatedEntity/code **SHOULD** be present and indicate the type of healthcare provider. (CONF-HP-49)
- **54.** The ClinicalDocument/informationRecipient element **MAY** be present. When informationRecipient is used, at least one informationRecipient/intendedRecipient/informationRecipient or informationRecipient/intendedRecipient/receivedOrganization **SHALL** be present. (CONF-HP-50)
- **55.** The assignedEntity/assignedPerson element **SHALL** be present in legalAuthenticator. (CONF-HP-51)
  - [OCL]: not self.legalAuthenticator.oclIsUndefined() implies not self.legalAuthenticator.assignedEntity.assignedPerson.oclIsUndefined()
- 56. The assignedEntity/assignedPerson element SHALL be present in an authenticator element. (CONF-HP-52)
  - [OCL]: self.authenticator->forAll(auth : cda::Authenticator | auth.assignedEntity->forAll(entity : cda::AssignedEntity |

```
not entity.assignedPerson.oclIsUndefined()))
```

- **57.** Times or time intervals found in the ClinicalDocument/effectiveTime, author/time, dataEnterer/time, legalAuthenticator/time, authenticator/time and encompassingEncounter/effectiveTime elements **SHALL** be precise to the day, **SHALL** include a time zone if more precise than to the day, and **SHOULD** be precise to the second. (CONF-HP-10)
  - Should portion of CON-HP-10 constraitn
  - [OCL]: -- implemented in Java using XPath selector
  - [XPath]: /cda:ClinicalDocument/cda:effectiveTime | //cda:author/cda:time | //cda:dataEnterer/cda:time | //cda:encompassingEncounter/cda:effectiveTime
- **58.** Times or time intervals found in the asOrganizationPartOf/effectiveTime, asMaintainedEntity/effectiveTime, relatedEntity/effectiveTime, serviceEvent/effectiveTime, ClinicalDocument/participant/time, serviceEvent/ performer/time and encounterParticipant/time **SHALL** be precise at least to the year, **SHOULD** be precise to the day, and **MAY** omit time zone. (CONF-HP-11)
  - Should portion of CON-HP-11 constraint

```
[OCL]: cda::OrganizationPartOf.allInstances()-
>select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject)-
> union( cda::MaintainedEntity.allInstances()-
>select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject) )-
>union( cda::RelatedEntity.allInstances()-
>select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject) )-
>union(cda::RelatedEntity.allInstances()-
>select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject) )-
>union(cda::RelatedEntity.allInstances()-
>select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject) )-
>union(cda::ServiceEvent.allInstances()-
>select( effectiveTime.oclIsUndefined()).oclAsType( ecore::EObject) )-
>union(cda::EncounterParticipant.allInstances()-
>select( time.oclIsUndefined()).oclAsType( ecore::EObject))-
>union(self.participant-
>select( time.oclIsUndefined()).oclAsType( ecore::EObject))-
>union(cda::OrganizationPartOf.allInstances().effectiveTime-
>union(cda::MaintainedEntity.allInstances().effectiveTime)-
>union( cda::RelatedEntity.allInstances().effectiveTime)-
>union(cda::RelatedEntity.allInstances().effectiveTime)-
>union(cda::RelatedEntity.allInstances().effectiveTime)-
>union(cda::ServiceEvent.allInstances().effectiveTime)-
>union(cda::EncounterParticipant.allInstances().time)-
>union(self.participant.time)->select(current :
 datatypes::IVL_TS | ((not current.low.oclIsUndefined()) and
 (current.low.value.oclIsUndefined() or current.low.value.size()
 < 8)) or ((not current.center.oclIsUndefined()) and</pre>
 (current.center.value.oclIsUndefined() or current.center.value.size()
 < 8)) or ((not current.high.oclIsUndefined()) and</pre>
 (current.high.value.oclIsUndefined() or current.high.value.size() < 8))</pre>
 or (current.low.oclIsUndefined() and current.center.oclIsUndefined() and
 current.high.oclIsUndefined()) ).oclAsType( ecore::EObject))
```

</ClinicalDocument>

Figure 6: General Header Constraints example

# **History And Physical**

[ClinicalDocument: templateId 2.16.840.1.113883.10.20.2]

- 1. SHALL conform to General Header Constraints template (templateId: 2.16.840.1.113883.10.20.3)
- 2. SHALL contain exactly one [1..1] code, which SHALL be selected from ValueSet 2.16.840.1.113883.1.11.20.22 HPDocumentType DYNAMIC (CONF-HP-54)
  - **a.** Implementations **MAY** use local codes in translation elements to specify a local code that is equivalent to the document type. (CONF-HP-55)
- 3. SHALL contain exactly one [1..1] component (CONF-HP-76), such that
  - This section describes the history related to the chief complaint. It contains the historical details leading up to and pertaining to the patient's current complaint or reason for seeking medical care.
  - **a.** Contains exactly one [1..1] *History Of Present Illness* (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.4)
- 4. SHALL contain exactly one [1..1] component (CONF-HP-77), such that
  - This section describes the past medical history for the patient. It may contain information about past procedures or other illnesses that might have a bearing on the patient's current illness. Since past medical history can include past surgical history and other procedures, the Procedure History section may be included under the Past Medical History section or it may stand alone as its own section. By the same token, problems can be recorded in a standalone Problems section or in a nested Problems section. Wherever used, procedures and problems should conform to the CCD template for CDA entries cited in the Problems section.
  - **a.** Contains exactly one [1..1] *Past Medical History Section* (templateId: 2.16.840.1.113883.10.20.2.9)
- 5. SHALL contain exactly one [1..1] component (CONF-HP-79), such that
  - The Medications section defines a patient's current medications and pertinent medication history. In this case, the LOINC displayName is not appropriate for the title of this section. The title should include the word "Medications." At a minimum, the currently active medications should be listed with an entire medication history as an option, particularly when the document is used for comprehensive data export. The section may also include a patient's prescription history and enable the determination of the source of a medication list, e.g., from a pharmacy system versus from the patient.
  - a. Contains exactly one [1..1] CCD Medications Section (templateId: 2.16.840.1.113883.10.20.1.8)
- 6. SHALL contain exactly one [1..1] component (CONF-HP-80), such that
  - This section is used to list and describe any medication allergies, adverse reactions, idiosyncratic reactions, anaphylaxis/anaphylactoid reactions to food items, and metabolic variations or adverse reactions/allergies to other substances (such as latex, iodine, tape adhesives) used to assure the safety of health care delivery. In general, environmental allergies, even if severe, should not be included in the Alerts section since they constitute a medical problem and should be listed in the problem list and past medical history, even if directly related to the presenting problem.
  - a. Contains exactly one [1..1] CCD Alerts Section (templateId: 2.16.840.1.113883.10.20.1.2)
- 7. SHALL contain exactly one [1..1] component (CONF-HP-81), such that
  - This section contains data defining the patient's occupational, personal (i.e., 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 a significant influence on a patient's physical,
    psychological, and emotional health and wellbeing, so should be considered in the development of a complete
    health record.

- **a.** Contains exactly one [1..1] *CCD Social History Section* (templateId: 2.16.840.1.113883.10.20.1.15)
- 8. SHALL contain exactly one [1..1] component (CONF-HP-82), such that
  - This section contains data defining the patient's genetic relatives in terms of relevant health-risk factors that
    have a potential impact on the patient's health care profile.
  - **a.** Contains exactly one [1..1] *CCD Family History Section* (templateId: 2.16.840.1.113883.10.20.1.4)
- 9. SHALL contain exactly one [1..1] component (CONF-HP-83), such that
  - The review of systems is a relevant collection of symptoms and function systematically gathered by a clinician. It includes symptoms the patient is currently experiencing, some of which were not elicited during the history of present illness, as well as a potentially large number of pertinent negatives, e.g., symptoms that the patient was specifically asked if they had experienced or were currently experiencing, but had denied experiencing.
  - **a.** Contains exactly one [1..1] *Review Of Systems Section IHE* (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.18)
- 10. SHALL contain exactly one [1..1] component (CONF-HP-84), such that
  - **a.** Contains exactly one [1..1] *Physical Examination Section* (templateId: 2.16.840.1.113883.10.20.2.10)
- 11. SHALL contain exactly one [1..1] component (CONF-HP-86), such that
  - **a.** Contains exactly one [1..1] *Vital Signs Section* (templateId: 2.16.840.1.113883.10.20.2.4)
- 12. SHALL contain exactly one [1..1] component (CONF-HP-88), such that
  - **a.** Contains exactly one [1..1] *General Status Section* (templateId: 2.16.840.1.113883.10.20.2.5)
- 13. SHALL contain exactly one [1..1] component (CONF-HP-90), such that
  - 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, echocardiography, nuclear medicine, pathology, and procedure observations. The section often includes notable results such as abnormal values or relevant trends, and could contain all results for the period of time being documented. In some situations, such as in the emergency department and pending surgery, diagnostic findings are not available when a History and Physical is released. As explained in Section 4.1 Section Descriptions above, a required section for which no content is available must contain some indication that no content is available. Laboratory 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 and submitted to the laboratory. 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 echocardiogram. 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.
- a. Contains exactly one [1..1] *Diagnostic Findings* (templateId: 2.16.840.1.113883.10.20.1.14)

  14. MAY contain zero or one [0..1] component (CONF-HP-93), such that
  - This section lists and describes all relevant clinical problems at the time the History and Physical is generated. At a minimum, all pertinent current and historical problems should be listed. This section is optional because the information contained in it may also appear in the Past Medical History section or the History of Present Illness section. When a problem list is inserted into either of these sections, it should use the CCD template.
- a. Contains exactly one [1..1] *CCD Problem Section* (templateId: 2.16.840.1.113883.10.20.1.11)

  15. MAY contain zero or one [0..1] component (CONF-HP-94), such that
  - a. Contains exactly one [1..1] CCD Procedures Section (templateId: 2.16.840.1.113883.10.20.1.12)

- **16. MAY** contain zero or one [0..1] **component** (CONF-HP-96), such that
  - The Immunizations section provides a patient's pertinent immunization history. The Immunizations section is optional, however it is recommended that it be present when such information is available.
  - **a.** Contains exactly one [1..1] *CCD Immunizations Section* (templateId: 2.16.840.1.113883.10.20.1.6)
- 17. If pre-coordinated document type codes are used, values used in the assignedAuthor/code and assignedAuthor/author/functionCode elements **SHALL NOT** conflict with ClinicalDocument/code. (CONF-HP-56)
- 18. If pre-coordinated document type codes are used, values used in encompassingEncounter/location/healthCareFacility/code SHALL NOT conflict with ClinicalDocument/code. (CONF-HP-57)
- **19. SHALL** satisfy: Either combined Assessment + Plan section is included, or separate Assessment section and Plan section included, but not both combined and separate sections. (CONF-HP-92)

```
[OCL]: self.getSections()->exists(section :
    cda::Section | not section.oclIsUndefined() and
    section.oclIsKindOf(cdt::AssessmentAndPlanSection))
    xor (self.getSections()->exists(section : cda::Section | not
    section.oclIsUndefined() and section.oclIsKindOf(cdt::AssessmentSection))
    and self.getSections()->exists(section : cda::Section | not
    section.oclIsUndefined() and section.oclIsKindOf(cdt::PlanSection)))
```

20. When Assessment section or Plan section is included, then both sections SHALL be included. (CONF-HP-91)

```
• [OCL]: let assessmentExists: Boolean = self.getSections()-
>exists(section: cda::Section | not section.oclIsUndefined() and
section.oclIsKindOf(cdt::AssessmentSection)) in
  let planExists: Boolean = self.getSections()->exists(section:
  cda::Section | not section.oclIsUndefined() and
  section.oclIsKindOf(cdt::PlanSection))
  in (assessmentExists or planExists) implies (assessmentExists and
  planExists)
```

**21. SHALL** satisfy: Either combined Reason for Visit and Chief Complaint section is included, or separate Reason for Visit section and Chief Complaint section included, but not both combined and separate sections. (CONF-HP-75)

```
• [OCL]: self.getSections()->exists(section :
    cda::Section | not section.oclIsUndefined() and
    section.oclIsKindOf(cdt::ReasonForVisitAndChiefComplaintSection))
        xor (self.getSections()->exists(section :
    cda::Section | not section.oclIsUndefined() and
    section.oclIsKindOf(cdt::ReasonForVisitSection))
        and self.getSections()->exists(section :
    cda::Section | not section.oclIsUndefined() and
    section.oclIsKindOf(cdt::ChiefComplaintSection)))
```

**22.** When Reason for Visit section or Chief Complaint section is included, then both sections **SHALL** be included. (CONF-HP-74)

```
• [OCL]: let reasonExists : Boolean = self.getSections()-
>exists(section : cda::Section | not section.oclIsUndefined() and
section.oclIsKindOf(cdt::ReasonForVisitSection)) in
  let complaintExists : Boolean = self.getSections()-
>exists(section : cda::Section | not section.oclIsUndefined() and
section.oclIsKindOf(cdt::ChiefComplaintSection))
  in (reasonExists or complaintExists) implies (reasonExists and
complaintExists)
```

```
<effectiveTime/>
 <languageCode/>
 <component>
   <structuredBody>
     <component>
       <section>
         <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.4"/>
         <id root="664ef3cf-90de-4ed1-8696-97fb74a3211f"/>
         <code code="10164-2" codeSystem="2.16.840.1.113883.6.1"</pre>
codeSystemName="LOINC" displayName="HISTORY OF PRESENT ILLNESS"/>
         <title>HISTORY OF PRESENT ILLNESS</title>
       </section>
     </component>
     <component>
       <section>
         <templateId root="2.16.840.1.113883.10.20.2.9"/>
         <id root="5790986e-ecf4-4fb6-bbe8-afab12c5e058"/>
         <code code="11348-0" codeSystem="2.16.840.1.113883.6.1"</pre>
codeSystemName="LOINC" displayName="HISTORY OF PAST ILLNESS"/>
         <title>HISTORY OF PAST ILLNESS</title>
       </section>
     </component>
     <component>
       <section>
         <templateId root="2.16.840.1.113883.10.20.1.8"/>
         <id root="f64faddd-95a3-4884-9d66-e7dc34be35a4"/>
         <code code="10160-0" codeSystemName="" displayName="History of
medication use"/>
         <title>History of medication use</title>
         <entry>
           <substanceAdministration classCode="SBADM">
             <templateId root="2.16.840.1.113883.10.20.1.24"/>
             <id root="c414686c-b5c0-49d7-ab8d-f988c3579d4b"/>
             <statusCode/>
             <effectiveTime value="20110616"/>
             <routeCode codeSystem="2.16.840.1.113883.5.112"</pre>
codeSystemName="HL7 RouteOfAdministration"/>
             <doseQuantity/>
             <rateQuantity/>
             <maxDoseQuantity/>
             <entryRelationship>
               <observation classCode="OBS" moodCode="EVN">
                 <templateId root="2.16.840.1.113883.10.20.1.46"/>
                 <id root="beac4e9c-93d5-4f60-9e19-77cfc3d7f849"/>
                 <code code="30973-2" codeSystemName="" displayName="Dose</pre>
number"/>
                 <statusCode/>
                 <effectiveTime>
                   <low value="2011"/>
                   <high value="2011"/>
                 </effectiveTime>
                 <value xsi:type="INT"/>
               </observation>
             </entryRelationship>
             <entryRelationship>
               <observation classCode="OBS" moodCode="EVN">
                 <templateId root="2.16.840.1.113883.10.20.1.57"/>
                 <templateId root="2.16.840.1.113883.10.20.1.47"/>
                 <id root="c327050b-b2c6-4488-ad64-104e2da68a84"/>
                 <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"</pre>
codeSystemName="LOINC" displayName="Status"/>
                 <statusCode code="completed"/>
                 <effectiveTime>
                   <low value="2011"/>
```

```
<high value="2011"/>
                 </effectiveTime>
                 <value xsi:type="CE"/>
               </observation>
             </entryRelationship>
             <entryRelationship>
               <act moodCode="INT">
                 <templateId root="2.16.840.1.113883.10.20.1.49"/>
                 <id root="6df89648-7f2b-4943-b1bb-56c69377cf65"/>
                 <effectiveTime>
                   <low value="2011"/>
                   <high value="2011"/>
                 </effectiveTime>
               </act>
             </entryRelationship>
             <entryRelationship>
               <observation classCode="OBS" moodCode="EVN">
                 <templateId root="2.16.840.1.113883.10.20.1.54"/>
                 <id root="1bd26117-858e-489d-82f8-12915d6bc639"/>
                 <statusCode code="completed"/>
                 <effectiveTime>
                   <low value="2011"/>
                   <high value="2011"/>
                 </effectiveTime>
                 <entryRelationship>
                   <observation classCode="OBS" moodCode="EVN">
                     <templateId root="2.16.840.1.113883.10.20.1.55"/>
                     <id root="c3bb0b91-f6cb-4272-bdd9-bc8181827135"/>
                     <code code="SEV" codeSystem="2.16.840.1.113883.5.4"</pre>
codeSystemName="ActCode" displayName="Severity observation"/>
                     <statusCode code="completed"/>
                     <effectiveTime>
                       <low value="2011"/>
                        <high value="2011"/>
                     </effectiveTime>
                   </observation>
                 </entryRelationship>
               </observation>
             </entryRelationship>
           </substanceAdministration>
         </entry>
         <entry>
           <supply classCode="SPLY">
             <templateId root="2.16.840.1.113883.10.20.1.34"/>
             <id root="fbf26051-7a04-4776-be84-e82bb3f887fa"/>
             <statusCode/>
             <effectiveTime value="20110616"/>
             <repeatNumber/>
             <quantity/>
             <entryRelationship>
               <observation classCode="OBS" moodCode="EVN">
                 <templateId root="2.16.840.1.113883.10.20.1.57"/>
                 <templateId root="2.16.840.1.113883.10.20.1.47"/>
                 <id root="05b38c57-d9e3-451a-815a-bc02ca16a1b6"/>
                 <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"</pre>
codeSystemName="LOINC" displayName="Status"/>
                 <statusCode code="completed"/>
                 <effectiveTime>
                   <low value="2011"/>
                   <high value="2011"/>
                 </effectiveTime>
                 <value xsi:type="CE"/>
               </observation>
             </entryRelationship>
```

```
<entryRelationship>
               <act moodCode="INT">
                 <templateId root="2.16.840.1.113883.10.20.1.43"/>
                 <id root="ccf8932e-4bd5-49f8-b372-3a8cf7ef5a6b"/>
                 <effectiveTime>
                   <low value="2011"/>
                   <high value="2011"/>
                 </effectiveTime>
               </act>
             </entryRelationship>
           </supply>
         </entry>
       </section>
     </component>
     <component>
       <section>
         <templateId root="2.16.840.1.113883.10.20.1.2"/>
         <id root="5c4f2d24-1794-4c05-bb8f-9a7445c8c433"/>
         <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>
         <entry>
           <act classCode="ACT" moodCode="EVN">
             <templateId root="2.16.840.1.113883.10.20.1.27"/>
             <id root="3861007d-6932-4a3d-bb70-a39eb136dbf0"/>
             <code nullFlavor="NA"/>
             <effectiveTime>
               <low value="2011"/>
               <high value="2011"/>
             </effectiveTime>
             <entryRelationship>
               <observation classCode="OBS" moodCode="EVN">
                 <templateId root="2.16.840.1.113883.10.20.1.41"/>
                 <id root="06434658-e2f3-409b-bc7b-ddb13f154e28"/>
                 <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"</pre>
codeSystemName="ActCode"/>
                 <statusCode code="completed"/>
                 <effectiveTime>
                   <low value="2011"/>
                   <high value="2011"/>
                 </effectiveTime>
                 <value xsi:type="CD"/>
               </observation>
             </entryRelationship>
             <entryRelationship>
               <observation classCode="OBS" moodCode="EVN">
                 <templateId root="2.16.840.1.113883.10.20.1.28"/>
                 <id root="c2bad0d1-f22b-478d-9f63-d24b93f066c3"/>
                 <code/>
                 <statusCode code="completed"/>
                 <effectiveTime>
                   <low value="2011"/>
                   <high value="2011"/>
                 </effectiveTime>
                 <entryRelationship>
                   <observation classCode="OBS" moodCode="EVN">
                     <templateId root="2.16.840.1.113883.10.20.1.57"/>
                     <templateId root="2.16.840.1.113883.10.20.1.50"/>
                     <id root="09d31331-241d-4fd2-9674-96e6a4e3686f"/>
                     <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"</pre>
codeSystemName="LOINC" displayName="Status"/>
                     <statusCode code="completed"/>
                     <effectiveTime>
                       <low value="2011"/>
```

```
<high value="2011"/>
                     </effectiveTime>
                     <value xsi:type="CE"/>
                   </observation>
                 </entryRelationship>
                 <entryRelationship>
                   <observation classCode="OBS" moodCode="EVN">
                     <templateId root="2.16.840.1.113883.10.20.1.57"/>
                     <templateId root="2.16.840.1.113883.10.20.1.51"/>
                     <id root="f2099298-345b-4c53-a003-b8741b6ce3ac"/>
                     <code code="11323-3" codeSystem="2.16.840.1.113883.6.1"</pre>
codeSystemName="LOINC" displayName="Health status"/>
                     <statusCode code="completed"/>
                     <effectiveTime>
                        <low value="2011"/>
                        <high value="2011"/>
                     </effectiveTime>
                     <value xsi:type="CE"/>
                   </observation>
                 </entryRelationship>
                 <entryRelationship>
                   <observation classCode="OBS" moodCode="EVN">
                     <templateId root="2.16.840.1.113883.10.20.1.38"/>
                     <id root="4f0b1e5d-d9d8-4b2f-a8eb-e2b8608a3b83"/>
                     <code code="397659008"</pre>
codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMEDCT"
displayName="Age"/>
                     <statusCode code="completed"/>
                     <effectiveTime>
                       <low value="2011"/>
                        <high value="2011"/>
                     </effectiveTime>
                   </observation>
                 </entryRelationship>
               </observation>
             </entryRelationship>
           </act>
         </entry>
       </section>
     </component>
     <component>
       <section>
         <templateId root="2.16.840.1.113883.10.20.1.15"/>
         <id root="dc8ae0ef-7884-41ff-9a33-1323df9ed5a2"/>
         <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="2.16.840.1.113883.10.20.1.4"/>
         <id root="6769f18b-d537-4c6a-89a7-b976a7a5fbdf"/>
         <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="1.3.6.1.4.1.19376.1.5.3.1.3.18"/>
         <id root="686d790c-5a08-4bc1-b81e-01f76964e417"/>
         <code code="10187-3" codeSystem="2.16.840.1.113883.6.1"</pre>
codeSystemName="LOINC" displayName="REVIEW OF SYSTEMS"/>
```

```
<title>REVIEW OF SYSTEMS</title>
       </section>
     </component>
     <component>
       <section>
         <templateId root="2.16.840.1.113883.10.20.2.10"/>
         <id root="ea7799bd-8517-4223-86f5-91c0d4892d04"/>
         <code code="29545-1" codeSystem="2.16.840.1.113883.6.1"</pre>
codeSystemName="LOINC" displayName="PHYSICAL FINDINGS"/>
         <title>PHYSICAL FINDINGS</title>
       </section>
     </component>
     <component>
       <section>
         <templateId root="2.16.840.1.113883.10.20.2.4"/>
         <id root="4f9da7a9-2155-48c2-923c-2dabef91f275"/>
         <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"/>
             <templateId root="2.16.840.1.113883.10.20.1.35"/>
             <id root="74ac6d87-99a0-40d2-9fd0-392776fc0a44"/>
             <code/>
             <statusCode/>
             <effectiveTime>
               <low value="2011"/>
               <high value="2011"/>
             </effectiveTime>
             <component>
               <observation moodCode="EVN">
                 <templateId root="2.16.840.1.113883.10.20.1.31"/>
                 <id root="363ca04e-13b0-4d90-b3a8-68417a0f3cd6"/>
                 <code/>
                 <statusCode/>
                 <effectiveTime>
                   <low value="2011"/>
                   <high value="2011"/>
                 </effectiveTime>
                 <interpretationCode/>
                 <methodCode/>
               </observation>
             </component>
           </organizer>
         </entry>
       </section>
     </component>
     <component>
       <section>
         <templateId root="2.16.840.1.113883.10.20.2.5"/>
         <id root="50b65f26-e0eb-4ba9-b66f-119110f33bbe"/>
         <code code="10210-3" codeSystem="2.16.840.1.113883.6.1"</pre>
codeSystemName="LOINC" displayName="GENERAL STATUS, PHYSICAL FINDINGS"/>
         <title>GENERAL STATUS, PHYSICAL FINDINGS</title>
       </section>
     </component>
     <component>
       <section>
         <templateId root="2.16.840.1.113883.10.20.1.14"/>
         <id root="a75b2f6c-bd12-449b-a584-2046fda04ca3"/>
         <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"/>
             <id root="d2c4647c-90c5-41e5-acd0-a60d900a3d93"/>
             <code/>
             <statusCode/>
             <effectiveTime>
               <low value="2011"/>
               <high value="2011"/>
             </effectiveTime>
             <component>
               <observation moodCode="EVN">
                 <templateId root="2.16.840.1.113883.10.20.1.31"/>
                 <id root="220237c7-4764-4f65-a121-c4f61e5ec135"/>
                 <code/>
                 <statusCode/>
                 <effectiveTime>
                   <low value="2011"/>
                   <high value="2011"/>
                 </effectiveTime>
                 <interpretationCode/>
                 <methodCode/>
               </observation>
             </component>
           </organizer>
         </entry>
       </section>
     </component>
     <component>
       <section>
         <templateId root="2.16.840.1.113883.10.20.1.11"/>
         <id root="142db220-b2bf-42e2-ab1e-4eb688756fee"/>
         <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"/>
             <id root="3edbd0f2-5a7d-47b9-81c4-e64fd1c671c1"/>
             <code nullFlavor="NA"/>
             <effectiveTime>
               <low value="2011"/>
               <high value="2011"/>
             </effectiveTime>
             <entryRelationship>
               <observation classCode="OBS" moodCode="EVN">
                 <templateId root="2.16.840.1.113883.10.20.1.41"/>
                 <id root="ed4fc679-82a4-46c9-a526-12d6a8dcebae"/>
                 <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"</pre>
codeSystemName="ActCode"/>
                 <statusCode code="completed"/>
                 <effectiveTime>
                   <low value="2011"/>
                   <high value="2011"/>
                 </effectiveTime>
                 <value xsi:type="CD"/>
               </observation>
             </entryRelationship>
             <entryRelationship>
               <observation classCode="OBS" moodCode="EVN">
                 <templateId root="2.16.840.1.113883.10.20.1.28"/>
                 <id root="700f45dc-54e1-4392-87e2-e8ae48c53c3f"/>
                 <code/>
```

```
<statusCode code="completed"/>
                 <effectiveTime>
                   <low value="2011"/>
                   <high value="2011"/>
                 </effectiveTime>
                 <entryRelationship>
                   <observation classCode="OBS" moodCode="EVN">
                     <templateId root="2.16.840.1.113883.10.20.1.57"/>
                     <templateId root="2.16.840.1.113883.10.20.1.50"/>
                     <id root="88fd58c4-b468-42fa-82d1-6c8c480dbe26"/>
                     <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"</pre>
codeSystemName="LOINC" displayName="Status"/>
                     <statusCode code="completed"/>
                     <effectiveTime>
                        <low value="2011"/>
                        <high value="2011"/>
                     </effectiveTime>
                     <value xsi:type="CE"/>
                   </observation>
                 </entryRelationship>
                 <entryRelationship>
                   <observation classCode="OBS" moodCode="EVN">
                     <templateId root="2.16.840.1.113883.10.20.1.57"/>
                     <templateId root="2.16.840.1.113883.10.20.1.51"/>
                     <id root="71899490-a92e-4a08-9082-3a9b3b75e0f4"/>
                     <code code="11323-3" codeSystem="2.16.840.1.113883.6.1"</pre>
codeSystemName="LOINC" displayName="Health status"/>
                     <statusCode code="completed"/>
                     <effectiveTime>
                        <low value="2011"/>
                        <high value="2011"/>
                     </effectiveTime>
                      <value xsi:type="CE"/>
                   </observation>
                 </entryRelationship>
                 <entryRelationship>
                   <observation classCode="OBS" moodCode="EVN">
                     <templateId root="2.16.840.1.113883.10.20.1.38"/>
                     <id root="b3bead3d-f203-4ec6-9a91-2ef8f7a46663"/>
                     <code code="397659008"</pre>
codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMEDCT"
displayName="Age"/>
                     <statusCode code="completed"/>
                     <effectiveTime>
                        <low value="2011"/>
                        <high value="2011"/>
                     </effectiveTime>
                   </observation>
                 </entryRelationship>
               </observation>
             </entryRelationship>
           </act>
         </entry>
       </section>
     </component>
     <component>
       <section>
         <templateId root="2.16.840.1.113883.10.20.1.12"/>
         <id root="6a5ea6ff-7cc4-4947-b00d-7f1c3845923e"/>
         <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>
```

Figure 7: History And Physical example

#### **Level One Conformance**

```
[ClinicalDocument: templateId 2.16.840.1.113883.10.20.10]

1.

1.

<pr
```

Figure 8: Level One Conformance example

#### **Level Three Conformance**

[ClinicalDocument: templateId 2.16.840.1.113883.10.20.30]

1. SHALL conform to Level Two Conformance template (templateId: 2.16.840.1.113883.10.20.20)

Figure 9: Level Three Conformance example

#### Level Two Conformance

```
[ClinicalDocument: templateId 2.16.840.1.113883.10.20.20]
```

1. SHALL conform to Level One Conformance template (templateId: 2.16.840.1.113883.10.20.10)

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xmlns="urn:h17-org:v3" xsi:schemaLocation="urn:h17-org:v3 CDA.xsd">
        <templateId root="2.16.840.1.113883.10.20.10"/>
        <templateId root="2.16.840.1.113883.10.20.20"/>
```

```
<id root="f04ce9b2-2f6e-4025-8434-cfc7ea352350"/>
  <title/>
   <effectiveTime/>
</ClinicalDocument>
```

Figure 10: Level Two Conformance example

#### **Progress Note**

[ClinicalDocument: templateId 2.16.840.1.113883.10.20.21.1]

A Progress Note documents a patient's clinical status during a hospitalization or outpatient visit.

Taber's medical dictionary defines a Progress Note as "An ongoing record of a patient's illness and treatment. Physicians, nurses, consultants, and therapists record their notes concerning the progress or lack of progress made by the patient between the time of the previous note and the most recent note."

Mosby's medical dictionary defines a Progress Note as "Notes made by a nurse, physician, social worker, physical therapist, and other health care professionals that describe the patient's condition and the treatment given or planned."

- 1. SHALL conform to General Header Constraints template (templateId: 2.16.840.1.113883.10.20.3)
- SHALL contain exactly one [1..1] code, which SHALL be selected from ValueSet
   2.16.840.1.113883.11.20.8.1 ProgressNoteDocumentTypeCode DYNAMIC (CONF-PRGN-3)
- **3.** Contains zero or one [0..1] **component**, such that
  - **a.** Contains exactly one [1..1] *Assessment And Plan Section Proc Note* (templateId: 2.16.840.1.113883.10.20.18.2.14)
- **4.** Contains zero or one [0..1] **component**, such that
  - a. Contains exactly one [1..1] Assessment Section Proc Note (templateId: 2.16.840.1.113883.10.20.18.2.13)
- **5.** Contains zero or one [0..1] **component**, such that
  - a. Contains exactly one [1..1] CCD Plan Of Care Section (templateId: 2.16.840.1.113883.10.20.1.10)
- **6.** MAY contain zero or one [0..1] component (CONF-PRGN-21), such that
  - **a.** Contains exactly one [1..1] *CCD Alerts Section* (templateId: 2.16.840.1.113883.10.20.1.2)
- 7. MAY contain zero or one [0..1] component (CONF-PRGN-22), such that
  - **a.** Contains exactly one [1..1] *Chief Complaint Section Proc Note* (templateId: 2.16.840.1.113883.10.20.18.2.16)
- **8.** MAY contain zero or one [0..1] component (CONF-PRGN-23), such that
  - a. Contains exactly one [1..1] CCD Medications Section (templateId: 2.16.840.1.113883.10.20.1.8)
- **9.** MAY contain zero or one [0..1] **component** (CONF-PRGN-24), such that
  - a. Contains exactly one [1..1] Objective Section (templateId: 2.16.840.1.113883.10.20.21.2.1)
- **10. MAY** contain zero or one [0..1] **component** (CONF-PRGN-26), such that
  - **a.** Contains exactly one [1..1] *Physical Examination Section* (templateId: 2.16.840.1.113883.10.20.2.10)
- 11. MAY contain zero or one [0..1] component (CONF-PRGN-27), such that
  - a. Contains exactly one [1..1] CCD Problem Section (templateId: 2.16.840.1.113883.10.20.1.11)
- 12. MAY contain zero or one [0..1] component (CONF-PRGN-28), such that
  - **a.** Contains exactly one [1.1] *CCD Results Section* (templateId: 2.16.840.1.113883.10.20.1.14)
- 13. MAY contain zero or one [0..1] component (CONF-PRGN-29), such that
  - a. Contains exactly one [1..1] Vital Signs Section (templateId: 2.16.840.1.113883.10.20.2.4)
- **14. MAY** contain zero or one [0..1] **component** (CONF-PRGN-30), such that

- **a.** Contains exactly one [1..1] *Review Of Systems Section IHE* (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.18)
- **15. MAY** contain zero or one [0..1] **component** (CONF-PRGN-31), such that
  - a. Contains exactly one [1..1] Subjective Section (templateId: 2.16.840.1.113883.10.20.21.2.2)
- **16. SHALL** satisfy: Either combined Assessment + Plan section is included, or separate Assessment section and Plan section included, but not both combined and separate sections. (CONF-PN-45)

```
• [OCL]: self.getSections()->exists(section :
    cda::Section | not section.oclIsUndefined() and
    section.oclIsKindOf(cdt::AssessmentAndPlanSectionProcNote))
    xor (self.getSections()->exists(section :
    cda::Section | not section.oclIsUndefined() and
    section.oclIsKindOf(cdt::AssessmentSectionProcNote))
        and self.getSections()->exists(section :
    cda::Section | not section.oclIsUndefined() and
    section.oclIsKindOf(ccd::PlanOfCareSection)))
```

17. When Assessment section or Plan section is included, then both sections SHALL be included. (CONF-PN-44)

```
[OCL]: let assessmentExists : Boolean = self.getSections()-
>exists(section : cda::Section | not section.oclIsUndefined() and
section.oclIsKindOf(cdt::AssessmentSectionProcNote)) in
  let planExists : Boolean = self.getSections()->exists(section :
  cda::Section | not section.oclIsUndefined() and
  section.oclIsKindOf(ccd::PlanOfCareSection))
  in (assessmentExists or planExists) implies (assessmentExists and
  planExists)
```

- **18. SHOULD** satisfy: Contains a serviceEvent element. (CONF-PRGN-4)
  - The serviceEvent represents the event of writing the Progress Note.
  - [OCL]: self.documentationOf->exists(doc : cda::DocumentationOf | not doc.oclIsUndefined() and not doc.serviceEvent.oclIsUndefined())
- **19.** The documentationOf/serviceEvent/code **SHALL** be 371532007 Progress Report 2.16.840.1.113883.6.96 SNOMED CT STATIC. (CONF-PRGN-5)
  - [OCL]: self.documentationOf->exists(doc : cda::DocumentationOf | not doc.oclIsUndefined() and not doc.serviceEvent.oclIsUndefined() and doc.serviceEvent.code.code = '371532007' and doc.serviceEvent.code.codeSystem = '2.16.840.1.113883.6.96')
- 20. The serviceEvent/effectiveTime element SHOULD be present with effectiveTime/low element and SHALL include effectiveTime/high element if a width element is not present. The serviceEvent/effectiveTime element SHALLL be accurate to the day, and MAY be accurate to the second. (CONF-PRGN-6)
  - When you know only the date for documenting the time, place the date in both the low and high elements. However, if you know the date and the duration of the documentation, use serviceEvent/effectiveTime/low with a width element.
  - [OCL]: self.documentationOf->exists(doc : cda::DocumentationOf | not doc.oclIsUndefined() and not doc.serviceEvent.oclIsUndefined() and not doc.serviceEvent.effectiveTime.oclIsUndefined() and not doc.serviceEvent.effectiveTime.low.oclIsUndefined())
- **21. SHALL** satisfy: Contains componentOf element. (CONF-PRGN-7)
  - [OCL]: not self.componentOf.oclIsUndefined()
- **22. SHALL** satisfy: The encompassing Encounter has an 'id' element. (CONF-PRGN-8)
  - The Progress Note is always associated with an encounter by the componentOf/encompassingEncounter element in the header.
  - [OCL]: self.componentOf.encompassingEncounter.id->notEmpty()
- 23. SHALL satisfy: The encompassing Encounter has an effective Time element. (CONF-PRGN-9)

- The effectiveTime element for an encompassingEncounter represents the time or time interval in which the encounter took place. A single encounter may contain multiple Progress Notes; hence the effectiveTime elements for a Progress Note (recorded in serviceEvent) and for an encounter (recorded in encompassingEncounter) represent different time intervals.
- [OCL]: not self.componentOf.encompassingEncounter.effectiveTime.oclIsUndefined()
- 24. SHALL satisfy: The encompassing Encounter has an effective Time/low element. (CONF-PRGN-10)
  - [OCL]: not self.componentOf.encompassingEncounter.effectiveTime.low.oclIsUndefined()
- 25. SHOULD satisfy: The encompassingEncounter element has an encompassingEncounter/location/healthCareFacility/id element. (CONF-PRGN-11)
  - All visits take place at a specific location. When available, the location ID is included in the encompassingEncounter/location/healthCareFacility/id element.
  - [OCL]:
     self.componentOf.encompassingEncounter.location.healthCareFacility.id>notEmpty()

```
<?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">
  <realmCode code="US"/>
  <templateId root="2.16.840.1.113883.10.20.3"/>
  <templateId root="2.16.840.1.113883.10.20.21.1"/>
  <id root="18eb49e4-cc24-476a-9391-076cabfe5414"/>
  <code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
  <title/>
  <effectiveTime/>
  <languageCode/>
  <component>
    <structuredBody>
      <component>
        <section>
          <templateId root="2.16.840.1.113883.10.20.18.2.14"/>
          <id root="473ddf7b-43be-4480-99be-eda8c537de2d"/>
          <code code="51847-2" codeSystem="2.16.840.1.113883.6.1"</pre>
 codeSystemName="LOINC" displayName="ASSESSMENT AND PLAN"/>
          <title>ASSESSMENT AND PLAN</title>
        </section>
      </component>
      <component>
        <section>
          <templateId root="2.16.840.1.113883.10.20.18.2.13"/>
          <id root="ce2d6276-72fb-4ff6-be3c-a42c789bf1c5"/>
          <code code="51848-0" codeSystem="2.16.840.1.113883.6.1"</pre>
 codeSystemName="LOINC" displayName="ASSESSMENT"/>
          <title>ASSESSMENT</title>
        </section>
      </component>
      <component>
        <section>
          <templateId root="2.16.840.1.113883.10.20.1.10"/>
          <id root="70233feb-04f4-40f7-a0af-16368baeb1a6"/>
          <code code="18776-5" codeSystem="2.16.840.1.113883.6.1"</pre>
 codeSystemName="LOINC" displayName="Treatment plan"/>
          <title>Treatment plan</title>
          <entry>
            <act>
              <templateId root="2.16.840.1.113883.10.20.1.25"/>
              <id root="583ca1c7-a144-4a4e-8fae-0a8c840f1869"/>
              <effectiveTime>
```

```
<low value="2011"/>
               <high value="2011"/>
             </effectiveTime>
           </act>
         </entry>
         <entry>
           <encounter>
             <templateId root="2.16.840.1.113883.10.20.1.25"/>
             <id root="d22a1cae-262a-4289-ae58-58498af34d54"/>
             <effectiveTime>
               <low value="2011"/>
               <high value="2011"/>
             </effectiveTime>
           </encounter>
         </entry>
         <entry>
           <observation>
             <templateId root="2.16.840.1.113883.10.20.1.25"/>
             <id root="9eb620b6-d519-4bb4-aa7b-0995aefedb1f"/>
             <effectiveTime>
               <low value="2011"/>
               <high value="2011"/>
             </effectiveTime>
           </observation>
         </entry>
         <entry>
           <templateId root="2.16.840.1.113883.10.20.1.25"/>
             <id root="2ee04e3d-b8bf-4c57-8e75-be53f7915cb0"/>
             <effectiveTime>
               <low value="2011"/>
               <high value="2011"/>
             </effectiveTime>
           </procedure>
         </entry>
         <entry>
           <substanceAdministration classCode="SBADM">
             <templateId root="2.16.840.1.113883.10.20.1.25"/>
             <id root="754a4c9f-02ce-44d9-8070-6095a0ccb38e"/>
             <effectiveTime value="20110616"/>
           </substanceAdministration>
         </entry>
         <entry>
           <supply classCode="SPLY">
             <templateId root="2.16.840.1.113883.10.20.1.25"/>
             <id root="443283b1-1202-4cae-8a24-b456ce24a025"/>
             <effectiveTime value="20110616"/>
           </supply>
         </entry>
       </section>
     </component>
     <component>
       <section>
         <templateId root="2.16.840.1.113883.10.20.1.2"/>
         <id root="0ab67622-3a7e-4794-8770-c9fcda9a5b4a"/>
         <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>
         <entry>
           <act classCode="ACT" moodCode="EVN">
             <templateId root="2.16.840.1.113883.10.20.1.27"/>
             <id root="9eec3b96-eca6-4836-af7b-abd79daae930"/>
             <code nullFlavor="NA"/>
             <effectiveTime>
```

```
<low value="2011"/>
               <high value="2011"/>
             </effectiveTime>
             <entryRelationship>
               <observation classCode="OBS" moodCode="EVN">
                 <templateId root="2.16.840.1.113883.10.20.1.41"/>
                 <id root="e0db824f-1dcf-44bc-8956-63715ab4a208"/>
                 <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"</pre>
codeSystemName="ActCode"/>
                 <statusCode code="completed"/>
                 <effectiveTime>
                   <low value="2011"/>
                   <high value="2011"/>
                 </effectiveTime>
                 <value xsi:type="CD"/>
               </observation>
             </entryRelationship>
             <entryRelationship>
               <observation classCode="OBS" moodCode="EVN">
                 <templateId root="2.16.840.1.113883.10.20.1.28"/>
                 <id root="0fb4260f-516e-4314-bbda-813936b2414c"/>
                 <code/>
                 <statusCode code="completed"/>
                 <effectiveTime>
                   <low value="2011"/>
                   <high value="2011"/>
                 </effectiveTime>
                 <entryRelationship>
                   <observation classCode="OBS" moodCode="EVN">
                      <templateId root="2.16.840.1.113883.10.20.1.57"/>
                      <templateId root="2.16.840.1.113883.10.20.1.50"/>
                      <id root="5796796b-4669-4fb8-8831-d1a31be585b6"/>
                      <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"</pre>
codeSystemName="LOINC" displayName="Status"/>
                     <statusCode code="completed"/>
                      <effectiveTime>
                        <low value="2011"/>
                        <high value="2011"/>
                      </effectiveTime>
                      <value xsi:type="CE"/>
                   </observation>
                 </entryRelationship>
                 <entryRelationship>
                   <observation classCode="OBS" moodCode="EVN">
                      <templateId root="2.16.840.1.113883.10.20.1.57"/>
                      <templateId root="2.16.840.1.113883.10.20.1.51"/>
                      <id root="6bf1f12a-6248-43a2-aa8c-c26ff1120c2d"/>
                      <code code="11323-3" codeSystem="2.16.840.1.113883.6.1"</pre>
codeSystemName="LOINC" displayName="Health status"/>
                     <statusCode code="completed"/>
                      <effectiveTime>
                        <low value="2011"/>
                        <high value="2011"/>
                      </effectiveTime>
                      <value xsi:type="CE"/>
                   </observation>
                 </entryRelationship>
                 <entryRelationship>
                   <observation classCode="OBS" moodCode="EVN">
                      <templateId root="2.16.840.1.113883.10.20.1.38"/>
                      <id root="5002ab8b-6d05-4239-92ff-dc4c21a71554"/>
                      <code code="397659008"</pre>
codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMEDCT"
displayName="Age"/>
```

```
<statusCode code="completed"/>
                      <effectiveTime>
                        <low value="2011"/>
                        <high value="2011"/>
                      </effectiveTime>
                   </observation>
                 </entryRelationship>
               </observation>
             </entryRelationship>
           </act>
         </entry>
       </section>
     </component>
     <component>
       <section>
         <templateId root="2.16.840.1.113883.10.20.18.2.16"/>
         <id root="2a035555-ed25-4da2-9e85-24b9fe694668"/>
         <code code="10154-3" codeSystem="2.16.840.1.113883.6.1"</pre>
codeSystemName="LOINC" displayName="CHIEF COMPLAINT"/>
         <title>CHIEF COMPLAINT</title>
       </section>
     </component>
     <component>
       <section>
         <templateId root="2.16.840.1.113883.10.20.1.8"/>
         <id root="19bc0eee-56f1-4fe3-b609-4c1f7bbb4f80"/>
         <code code="10160-0" codeSystemName="" displayName="History of
medication use"/>
         <title>History of medication use</title>
         <entry>
           <substanceAdministration classCode="SBADM">
             <templateId root="2.16.840.1.113883.10.20.1.24"/>
             <id root="82b7b42a-c5b3-4dee-8a31-649a19975a1a"/>
             <statusCode/>
             <effectiveTime value="20110616"/>
             <routeCode codeSystem="2.16.840.1.113883.5.112"</pre>
codeSystemName="HL7 RouteOfAdministration"/>
             <doseQuantity/>
             <rateQuantity/>
             <maxDoseQuantity/>
             <entryRelationship>
               <observation classCode="OBS" moodCode="EVN">
                 <templateId root="2.16.840.1.113883.10.20.1.46"/>
                 <id root="347efc1d-0df8-4a21-8539-e098faffb201"/>
                 <code code="30973-2" codeSystemName="" displayName="Dose</pre>
number"/>
                 <statusCode/>
                 <effectiveTime>
                   <low value="2011"/>
                   <high value="2011"/>
                 </effectiveTime>
                 <value xsi:type="INT"/>
               </observation>
             </entryRelationship>
             <entryRelationship>
               <observation classCode="OBS" moodCode="EVN">
                 <templateId root="2.16.840.1.113883.10.20.1.57"/>
                 <templateId root="2.16.840.1.113883.10.20.1.47"/>
                 <id root="ala2b594-215b-4868-8fa0-4762befa92b4"/>
                 <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"</pre>
codeSystemName="LOINC" displayName="Status"/>
                 <statusCode code="completed"/>
                 <effectiveTime>
                   <low value="2011"/>
```

```
<high value="2011"/>
                 </effectiveTime>
                 <value xsi:type="CE"/>
               </observation>
             </entryRelationship>
             <entryRelationship>
               <act moodCode="INT">
                 <templateId root="2.16.840.1.113883.10.20.1.49"/>
                 <id root="92d17bf9-ab0d-4e41-b92e-e142e9e6911c"/>
                 <effectiveTime>
                   <low value="2011"/>
                   <high value="2011"/>
                 </effectiveTime>
               </act>
             </entryRelationship>
             <entryRelationship>
               <observation classCode="OBS" moodCode="EVN">
                 <templateId root="2.16.840.1.113883.10.20.1.54"/>
                 <id root="22aabf87-5271-47bd-a5c3-lec7ac071f1b"/>
                 <statusCode code="completed"/>
                 <effectiveTime>
                   <low value="2011"/>
                   <high value="2011"/>
                 </effectiveTime>
                 <entryRelationship>
                   <observation classCode="OBS" moodCode="EVN">
                     <templateId root="2.16.840.1.113883.10.20.1.55"/>
                     <id root="68e768e5-058b-4812-8a5b-6691a8587eb5"/>
                     <code code="SEV" codeSystem="2.16.840.1.113883.5.4"</pre>
codeSystemName="ActCode" displayName="Severity observation"/>
                     <statusCode code="completed"/>
                     <effectiveTime>
                       <low value="2011"/>
                        <high value="2011"/>
                     </effectiveTime>
                   </observation>
                 </entryRelationship>
               </observation>
             </entryRelationship>
           </substanceAdministration>
         </entry>
         <entry>
           <supply classCode="SPLY">
             <templateId root="2.16.840.1.113883.10.20.1.34"/>
             <id root="b350ffd6-7321-4631-99cc-2dc3889a9d34"/>
             <statusCode/>
             <effectiveTime value="20110616"/>
             <repeatNumber/>
             <quantity/>
             <entryRelationship>
               <observation classCode="OBS" moodCode="EVN">
                 <templateId root="2.16.840.1.113883.10.20.1.57"/>
                 <templateId root="2.16.840.1.113883.10.20.1.47"/>
                 <id root="6fd5bce4-2fa8-49c5-a1e5-2a3a28b5bf78"/>
                 <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"</pre>
codeSystemName="LOINC" displayName="Status"/>
                 <statusCode code="completed"/>
                 <effectiveTime>
                   <low value="2011"/>
                   <high value="2011"/>
                 </effectiveTime>
                 <value xsi:type="CE"/>
               </observation>
             </entryRelationship>
```

```
<entryRelationship>
               <act moodCode="INT">
                 <templateId root="2.16.840.1.113883.10.20.1.43"/>
                 <id root="f05c6201-5791-4a35-8174-3c91edf6b88f"/>
                 <effectiveTime>
                   <low value="2011"/>
                   <high value="2011"/>
                 </effectiveTime>
               </act>
             </entryRelationship>
           </supply>
         </entry>
       </section>
     </component>
     <component>
       <section>
         <templateId root="2.16.840.1.113883.10.20.21.2.1"/>
         <id root="450f50db-cdd2-4665-bccd-5e514bef2eca"/>
         <code code="OBJEC-X" codeSystem="2.16.840.1.113883.6.1"</pre>
codeSystemName="LOINC" displayName="OBJECTIVE DATA"/>
         <title>OBJECTIVE DATA</title>
       </section>
     </component>
     <component>
       <section>
         <templateId root="2.16.840.1.113883.10.20.2.10"/>
         <id root="fc0cfc44-9c64-4564-9aff-9dfeb5611810"/>
         <code code="29545-1" codeSystem="2.16.840.1.113883.6.1"</pre>
codeSystemName="LOINC" displayName="PHYSICAL FINDINGS"/>
         <title>PHYSICAL FINDINGS</title>
       </section>
     </component>
     <component>
       <section>
         <templateId root="2.16.840.1.113883.10.20.1.11"/>
         <id root="2afeffbf-3c29-4245-b92e-2056787f37b8"/>
         <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"/>
             <id root="c9e8f1c6-b77c-4982-a85e-bf9003308684"/>
             <code nullFlavor="NA"/>
             <effectiveTime>
               <low value="2011"/>
               <high value="2011"/>
             </effectiveTime>
             <entryRelationship>
               <observation classCode="OBS" moodCode="EVN">
                 <templateId root="2.16.840.1.113883.10.20.1.41"/>
                 <id root="613ff975-d240-4102-987d-3ce077c291a9"/>
                 <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"</pre>
codeSystemName="ActCode"/>
                 <statusCode code="completed"/>
                 <effectiveTime>
                   <low value="2011"/>
                   <high value="2011"/>
                 </effectiveTime>
                 <value xsi:type="CD"/>
               </observation>
             </entryRelationship>
             <entryRelationship>
               <observation classCode="OBS" moodCode="EVN">
```

```
<templateId root="2.16.840.1.113883.10.20.1.28"/>
                 <id root="8ebde8ea-a049-4342-8a50-33b70d1f597e"/>
                 <code/>
                 <statusCode code="completed"/>
                 <effectiveTime>
                   <low value="2011"/>
                   <high value="2011"/>
                 </effectiveTime>
                 <entryRelationship>
                   <observation classCode="OBS" moodCode="EVN">
                     <templateId root="2.16.840.1.113883.10.20.1.57"/>
                     <templateId root="2.16.840.1.113883.10.20.1.50"/>
                     <id root="7884376c-b86e-411f-aed3-227e7bcc76dc"/>
                     <code code="33999-4" codeSystem="2.16.840.1.113883.6.1"</pre>
codeSystemName="LOINC" displayName="Status"/>
                     <statusCode code="completed"/>
                     <effectiveTime>
                       <low value="2011"/>
                       <high value="2011"/>
                     </effectiveTime>
                     <value xsi:type="CE"/>
                   </observation>
                 </entryRelationship>
                 <entryRelationship>
                   <observation classCode="OBS" moodCode="EVN">
                     <templateId root="2.16.840.1.113883.10.20.1.57"/>
                     <templateId root="2.16.840.1.113883.10.20.1.51"/>
                     <id root="12955206-8f40-4dae-9cc0-2c945e196c35"/>
                     <code code="11323-3" codeSystem="2.16.840.1.113883.6.1"</pre>
codeSystemName="LOINC" displayName="Health status"/>
                     <statusCode code="completed"/>
                     <effectiveTime>
                       <low value="2011"/>
                        <high value="2011"/>
                     </effectiveTime>
                     <value xsi:type="CE"/>
                   </observation>
                 </entryRelationship>
                 <entryRelationship>
                   <observation classCode="OBS" moodCode="EVN">
                     <templateId root="2.16.840.1.113883.10.20.1.38"/>
                     <id root="62ef6282-4488-4554-b86b-dfb0c4ef5407"/>
                     <code code="397659008"
codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMEDCT"
displayName="Age"/>
                     <statusCode code="completed"/>
                     <effectiveTime>
                       <low value="2011"/>
                       <high value="2011"/>
                     </effectiveTime>
                   </observation>
                 </entryRelationship>
               </observation>
             </entryRelationship>
           </act>
         </entry>
       </section>
     </component>
     <component>
       <section>
         <templateId root="2.16.840.1.113883.10.20.1.14"/>
         <id root="81a57997-076c-40a4-a278-fb6c6a91171f"/>
```

```
<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"/>
             <id root="0d1f3b8b-b202-4036-94e0-7cbf4236e189"/>
             <code/>
             <statusCode/>
             <effectiveTime>
               <low value="2011"/>
               <high value="2011"/>
             </effectiveTime>
             <component>
               <observation moodCode="EVN">
                 <templateId root="2.16.840.1.113883.10.20.1.31"/>
                 <id root="c4612272-27cd-4721-9e34-38271b83a6ae"/>
                 <code/>
                 <statusCode/>
                 <effectiveTime>
                   <low value="2011"/>
                   <high value="2011"/>
                 </effectiveTime>
                 <interpretationCode/>
                 <methodCode/>
               </observation>
             </component>
           </organizer>
         </entry>
       </section>
     </component>
     <component>
       <section>
         <templateId root="2.16.840.1.113883.10.20.2.4"/>
         <id root="c047743e-ad1b-4c03-a613-f0cf2e9dae19"/>
         <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"/>
             <templateId root="2.16.840.1.113883.10.20.1.35"/>
             <id root="0477043f-9d21-4c6f-aac5-e2097a264072"/>
             <code/>
             <statusCode/>
             <effectiveTime>
               <low value="2011"/>
               <high value="2011"/>
             </effectiveTime>
             <component>
               <observation moodCode="EVN">
                 <templateId root="2.16.840.1.113883.10.20.1.31"/>
                 <id root="356d9734-8920-44e9-8f3f-a1e11560c23a"/>
                 <code/>
                 <statusCode/>
                 <effectiveTime>
                   <low value="2011"/>
                   <high value="2011"/>
                 </effectiveTime>
                 <interpretationCode/>
                 <methodCode/>
               </observation>
             </component>
```

```
</organizer>
          </entry>
        </section>
      </component>
      <component>
        <section>
          <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.18"/>
          <id root="762fffcf-3855-4e78-b9d9-36b99708315c"/>
          <code code="10187-3" codeSystem="2.16.840.1.113883.6.1"</pre>
codeSystemName="LOINC" displayName="REVIEW OF SYSTEMS"/>
          <title>REVIEW OF SYSTEMS</title>
        </section>
      </component>
      <component>
        <section>
          <templateId root="2.16.840.1.113883.10.20.21.2.2"/>
          <id root="f243b795-ca42-493c-bd15-d5d3560a28b1"/>
          <code code="SUBJ-X" codeSystem="2.16.840.1.113883.6.1"</pre>
codeSystemName="LOINC" displayName="SUBJECTIVE DATA"/>
          <title>SUBJECTIVE DATA</title>
        </section>
      </component>
    </structuredBody>
 </component>
</ClinicalDocument>
```

Figure 11: Progress Note example

3

## **SECTION TEMPLATES**

#### **Topics:**

- Assessment And Plan Section
- Assessment And Plan Section Proc Note
- Assessment Section
- Assessment Section Proc Note
- Chief Complaint Section
- Chief Complaint Section Proc Note
- Diagnostic Findings
- General Status Section
- History Of Present Illness
- Objective Section
- Past Medical History Section
- Past Medical History Section Consult
- Physical Examination Section
- Plan Section
- Reason For Referral Section
- Reason For Visit And Chief Complaint Section
- Reason For Visit Section
- Reason For Visit Section Consult
- Review Of Systems Section
- Review Of Systems Section IHE
- Subjective Section
- Vital Signs Section

#### **Assessment And Plan Section**

```
[Section: templateId 2.16.840.1.113883.10.20.2.7]
```

The Assessment section (also called impression or diagnoses) represents the clinician's conclusions and working assumptions that will guide treatment of the patient. The assessment formulates a specific plan or set of recommendations. The assessment may be a list of specific disease entities or a narrative block.

The Plan section contains data that defines 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 care of the patient should be listed unless constrained due to privacy issues. The plan may also contain information about ongoing care of the patient and information regarding goals and clinical reminders. Clinical reminders are placed here to provide prompts for disease prevention and management, patient safety, and health-care quality improvements, including widely accepted performance measures. The plan may also indicate that patient education was given or will be provided.

1. SHALL contain exactly one [1..1] code/@code="51847-2" Assessment + Plan (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF-HP-92)

Figure 12: Assessment And Plan Section example

#### Assessment And Plan Section Proc Note

```
[Section: templateId 2.16.840.1.113883.10.20.18.2.14]
```

The Assessment section (also called impression or diagnoses) represents the clinician's conclusions and working assumptions that will guide treatment of the patient. The assessment formulates a specific plan or set of recommendations. The assessment may be a list of specific disease entities or a narrative block.

The Plan section contains data that defines 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 care of the patient should be listed unless constrained due to privacy issues. The plan may also contain information about ongoing care of the patient and information regarding goals and clinical reminders. Clinical reminders are placed here to provide prompts for disease prevention and management, patient safety, and health-care quality improvements, including widely accepted performance measures. The plan may also indicate that patient education was given or will be provided.

1. SHALL contain exactly one [1..1] code/@code="51847-2" ASSESSMENT AND PLAN (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF-PN-46)

```
<?xml version="1.0" encoding="UTF-8"?>
<section xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:h17-
org:v3" xsi:schemaLocation="urn:h17-org:v3 CDA.xsd">
        <templateId root="2.16.840.1.113883.10.20.18.2.14"/>
        <id root="34aa950d-f30b-45c8-9ba6-0da95df282f7"/>
        <code code="51847-2" codeSystem="2.16.840.1.113883.6.1"
        codeSystemName="LOINC" displayName="ASSESSMENT AND PLAN"/>
        <title>ASSESSMENT AND PLAN</title>
```

</section>

Figure 13: Assessment And Plan Section Proc Note example

#### Assessment Section

[Section: templateId 2.16.840.1.113883.10.20.2.7]

The Assessment section (also called impression or diagnoses) represents the clinician's conclusions and working assumptions that will guide treatment of the patient. The assessment formulates a specific plan or set of recommendations. The assessment may be a list of specific disease entities or a narrative block.

**1. SHALL** contain exactly one [1..1] **code/@code=** "51848-0" *Assessment* (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF-HP-91)

Figure 14: Assessment Section example

#### Assessment Section Proc Note

[Section: templateId 2.16.840.1.113883.10.20.18.2.13]

The Assessment section (also called impression or diagnoses) represents the clinician's conclusions and working assumptions that will guide treatment of the patient. The assessment formulates a specific plan or set of recommendations. The assessment may be a list of specific disease entities or a narrative block.

1. SHALL contain exactly one [1..1] code/@code="51848-0" ASSESSMENT (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF-PN-45)

Figure 15: Assessment Section Proc Note example

## **Chief Complaint Section**

[Section: templateId 2.16.840.1.113883.10.20.2.8]

**1. SHALL** contain exactly one [1..1] **code/@code**="10154-3" *Chief complaint* (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF-HP-74)

```
<?xml version="1.0" encoding="UTF-8"?>
<section xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-
org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
        <templateId root="2.16.840.1.113883.10.20.2.8"/>
        <id root="3e13009d-3cb3-4a9b-a968-f67c81144122"/>
```

```
<code code="10154-3" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Chief complaint"/>
   <title>Chief complaint</title>
</section>
```

Figure 16: Chief Complaint Section example

### **Chief Complaint Section Proc Note**

[Section: templateId 2.16.840.1.113883.10.20.18.2.16]

The Chief Complaint section records the patient's chief complaint (the patient's own description). The Chief Complaint section may be a subsection of the Medical History section.

- **1. SHALL** contain exactly one [1..1] **code/@code**="10154-3" *CHIEF COMPLAINT* (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF-PN-108)
- 2. If the Chief Complaint section is NOT present, there **MAY** be a statement in the Medical History section providing the patient's chief compliant. (CONF-PN-109)

```
<?xml version="1.0" encoding="UTF-8"?>
<section xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-
org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
        <templateId root="2.16.840.1.113883.10.20.18.2.16"/>
        <id root="19dcb161-aaae-443b-8521-7d077e9bdc67"/>
        <code code="10154-3" codeSystem="2.16.840.1.113883.6.1"
        codeSystemName="LOINC" displayName="CHIEF COMPLAINT"/>
        <title>CHIEF COMPLAINT</title>
</section>
```

Figure 17: Chief Complaint Section Proc Note example

## **Diagnostic Findings**

```
[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 usually includes notable results such as abnormal values or relevant trends, and may contain all results for the period of time being documented.

In some situations, such in an emergency department diagnostic findings may not be available when a Consultation Note is released. As explained in 4.1 Section Descriptions above, a required section for which no content is available must contain some indication of such.

Laboratory 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 and submitted to the laboratory.

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 CCD Results Section template (templateId: 2.16.840.1.113883.10.20.1.14)
- 2. SHALL contain exactly one [1..1] title

```
<?xml version="1.0" encoding="UTF-8"?>
<section xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:h17-
org:v3" xsi:schemaLocation="urn:h17-org:v3 CDA.xsd">
        <templateId root="2.16.840.1.113883.10.20.1.14"/>
        <id root="bf071924-7e7e-4560-8659-b0d9c15c5a2a"/>
```

```
<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"/>
      <id root="579c9346-e539-4700-bf2f-8815cd4ea37d"/>
      <code/>
      <statusCode/>
      <effectiveTime>
        <low value="2011"/>
        <high value="2011"/>
      </effectiveTime>
      <component>
        <observation moodCode="EVN">
          <templateId root="2.16.840.1.113883.10.20.1.31"/>
          <id root="5116dfdc-1711-4566-ab5e-857758ec81cf"/>
          <code/>
          <statusCode/>
          <effectiveTime>
            <low value="2011"/>
            <high value="2011"/>
          </effectiveTime>
          <interpretationCode/>
          <methodCode/>
        </observation>
      </component>
    </organizer>
  </entry>
</section>
```

Figure 18: Diagnostic Findings example

#### **General Status Section**

[Section: templateId 2.16.840.1.113883.10.20.2.5]

The General Status section describes general observations and readily observable attributes of the patient, including affect and demeanor, apparent age compared to actual age, gender, ethnicity, nutritional status based on appearance, body build and habitus (e.g., muscular, cachectic, obese), developmental or other deformities, gait and mobility, personal hygiene, evidence of distress, and voice quality and speech. These observations may be nested under this heading or directly under the Physical Exam heading.

1. SHALL contain exactly one [1..1] code/@code="10210-3" GENERAL STATUS, PHYSICAL FINDINGS (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF-HP-89)

```
<?xml version="1.0" encoding="UTF-8"?>
<section xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:h17-
org:v3" xsi:schemaLocation="urn:h17-org:v3 CDA.xsd">
        <templateId root="2.16.840.1.113883.10.20.2.5"/>
        <id root="baf35398-a033-4ef6-af85-2408a78bb8bf"/>
            <code code="10210-3" codeSystem="2.16.840.1.113883.6.1"
        codeSystemName="LOINC" displayName="GENERAL STATUS, PHYSICAL FINDINGS"/>
            <title>GENERAL STATUS, PHYSICAL FINDINGS</title>
</section>
```

Figure 19: General Status Section example

### **History Of Present Illness**

[Section: templateId 1.3.6.1.4.1.19376.1.5.3.1.3.4]

Conforms to IHE PCC template.

1. SHALL contain exactly one [1..1] code/@code="10164-2" HISTORY OF PRESENT ILLNESS (CodeSystem: 2.16.840.1.113883.6.1 LOINC)

Figure 20: History Of Present Illness example

## **Objective Section**

[Section: templateId 2.16.840.1.113883.10.20.21.2.1]

The Objective section contains directly observed and/or quantifiable data about the patient. It includes important and relevant positive and negative test results, and physical findings.

- 1. SHALL contain exactly one [1..1] code/@code="OBJEC-X" OBJECTIVE DATA (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF-PRGN-25)
- 2. SHALL contain exactly one [1..1] text (CONF-PRGN-15)
- **3. SHALL** contain exactly one [1..1] **title** (CONF-PRGN-14)
- **4. SHOULD** satisfy: Contains clinical statements. (CONF-PRGN-15)

```
• [OCL]: not self.entry->isEmpty()

<?xml version="1.0" encoding="UTF-8"?>
<section xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:h17-org:v3" xsi:schemaLocation="urn:h17-org:v3 CDA.xsd">
    <templateId root="2.16.840.1.113883.10.20.21.2.1"/>
        <id root="abd06c31-e259-45f2-8842-340ac0ddb5a9"/>
        <code code="OBJEC-X" codeSystem="2.16.840.1.113883.6.1"

codeSystemName="LOINC" displayName="OBJECTIVE DATA"/>
        <title>OBJECTIVE DATA</title>
</section>
```

Figure 21: Objective Section example

## Past Medical History Section

[Section: templateId 2.16.840.1.113883.10.20.2.9]

This section describes the past medical history for the patient. It may contain information about past procedures or other illnesses that might have a bearing on the patient's current illness. Since past medical history can include past surgical history and other procedures, the Procedure History section may be included under the Past Medical History section or it may stand alone as its own section. By the same token, problems can be recorded in a standalone Problems section or in a nested Problems section. Wherever used, procedures and problems should conform to the CCD template for CDA entries cited in the respective sections.

1. SHALL contain exactly one [1..1] code/@code="11348-0" HISTORY OF PAST ILLNESS (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF-HP-78)

- 2. SHALL contain exactly one [1..1] text
- 3. SHOULD satisfy: Contains clinical statements.

```
• [OCL]: not self.entry->isEmpty()

<?xml version="1.0" encoding="UTF-8"?>
<section xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:h17-
org:v3" xsi:schemaLocation="urn:h17-org:v3 CDA.xsd">
        <templateId root="2.16.840.1.113883.10.20.2.9"/>
        <id root="3fb21428-7b6f-4c20-8736-ebc5409103a5"/>
        <code code="11348-0" codeSystem="2.16.840.1.113883.6.1"
        codeSystemName="LOINC" displayName="HISTORY OF PAST ILLNESS"/>
        <title>HISTORY OF PAST ILLNESS</title>
</section>
```

Figure 22: Past Medical History Section example

### **Past Medical History Section Consult**

```
[Section: templateId 2.16.840.1.113883.10.20.4.9]
```

This section describes the past medical history for the patient. It may contain information about past procedures or other illnesses that might have a bearing on the patient's current illness. Since past medical history can include past surgical history and other procedures, the Procedure History section may be included under the Past Medical History section or it may stand alone as its own section. By the same token, problems can be recorded in a standalone Problems section or in a nested Problems section. Wherever used, procedures and problems should conform to the CCD template for CDA entries cited in the respective sections.

- **1. SHALL** contain exactly one [1..1] **code/@code**="11348-0" *HISTORY OF PAST ILLNESS* (CodeSystem: 2.16.840.1.113883.6.1 LOINC)
- 2. SHALL contain exactly one [1..1] text

Figure 23: Past Medical History Section Consult example

## **Physical Examination Section**

```
[Section: templateId 2.16.840.1.113883.10.20.2.10]
```

The Physical Examination section includes direct observations made by the clinician. The examination may include the use of simple instruments and may also describe simple maneuvers performed directly on the patient's body. This section only includes observations made by the examining clinician using inspection, palpation, auscultation, and percussion; it does not include laboratory or imaging findings. The exam may be limited to pertinent body systems based on the patient's chief complaint or it may include a comprehensive examination. The examination may be reported as a collection of random clinical statements or it may be reported categorically. Categorical report formats may be divided into multiple subsections, including Vital Signs, General Status, and any of the subsections listed in Appendix D: List of Additional Physical Examination Subsections. Note that Vital Signs can be a top-level section or subsection of Physical Exam.

The physical findings included in this section describe direct observations made by the clinician divided by organ or body system and may be included under appropriate subsections to Physical Exam. Systems are typically listed cephalic to caudal (i.e., starting with the head) and may include all body systems or only those pertinent to the chief

complaint. The head, eyes, ears, nose, throat, mouth, and teeth may be described separately or combined into a single subsection labeled "HEENT." Other subsections may include Skin, Neck, Lymph Nodes, Thorax (Chest) and Lungs, Cardiovascular, Breasts, Abdomen, Pelvic, Genitourinary, Musculoskeletal, Extremities including Peripheral Vascular, and Neurologic. A detailed Mental Status Examination may be included when pertinent.

The Physical Examination section may contain multiple nested subsections: Vital Signs, General Status, and those listed in Appendix D: List of Additional Physical Examination Subsections.

1. SHALL contain exactly one [1..1] code/@code="29545-1" *PHYSICAL FINDINGS* (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF-HP-85)

Figure 24: Physical Examination Section example

#### Plan Section

[Section: templateId 2.16.840.1.113883.10.20.2.7]

The Plan section contains data that defines 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 care of the patient should be listed unless constrained due to privacy issues. The plan may also contain information about ongoing care of the patient and information regarding goals and clinical reminders. Clinical reminders are placed here to provide prompts for disease prevention and management, patient safety, and health-care quality improvements, including widely accepted performance measures. The plan may also indicate that patient education was given or will be provided.

**1. SHALL** contain exactly one [1..1] **code/@code**="18776-5" *Plan* (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF-HP-91)

```
<?xml version="1.0" encoding="UTF-8"?>
<section xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:h17-
org:v3" xsi:schemaLocation="urn:h17-org:v3 CDA.xsd">
        <templateId root="2.16.840.1.113883.10.20.2.7"/>
        <id root="90ff8bd0-efde-4d12-9875-82768194d6ff"/>
        <code code="18776-5" codeSystem="2.16.840.1.113883.6.1"
        codeSystemName="LOINC" displayName="Plan"/>
        <title>Plan</title>
</section>
```

Figure 25: Plan Section example

#### Reason For Referral Section

[Section: templateId 2.16.840.1.113883.10.20.4.8]

**1. SHALL** contain exactly one [1..1] **code/@code**="42349-1" *REASON FOR REFERRAL* (CodeSystem: 2.16.840.1.113883.6.1 LOINC)

```
<?xml version="1.0" encoding="UTF-8"?>
<section xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-
org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
        <templateId root="2.16.840.1.113883.10.20.4.8"/>
```

```
<id root="0df87c29-4b45-4d21-83fb-75b7ac344c3f"/>
  <code code="42349-1" codeSystem="2.16.840.1.113883.6.1"
  codeSystemName="LOINC" displayName="REASON FOR REFERRAL"/>
    <title>REASON FOR REFERRAL</title>
</section>
```

Figure 26: Reason For Referral Section example

### Reason For Visit And Chief Complaint Section

[Section: templateId 2.16.840.1.113883.10.20.2.8]

1. SHALL contain exactly one [1..1] code/@code="46239-0" Reason for visit + Chief complaint (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF-HP-75)

Figure 27: Reason For Visit And Chief Complaint Section example

#### **Reason For Visit Section**

[Section: templateId 2.16.840.1.113883.10.20.2.8]

**1. SHALL** contain exactly one [1..1] **code/@code**="29299-5" *Reason for visit* (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF-HP-74)

Figure 28: Reason For Visit Section example

#### **Reason For Visit Section Consult**

[Section: templateId 2.16.840.1.113883.10.20.4.8]

1. SHALL contain exactly one [1..1] code/@code="29299-5" *REASON FOR VISIT* (CodeSystem: 2.16.840.1.113883.6.1 LOINC)

```
<title>REASON FOR VISIT</title>
</section>
```

Figure 29: Reason For Visit Section Consult example

### **Review Of Systems Section**

```
[Section: templateId 2.16.840.1.113883.10.20.4.10]
```

The review of systems is a relevant collection of symptoms and functions systematically gathered by a clinician. It includes symptoms the patient is currently experiencing, some of which were not elicited during the history of present illness, as well as a potentially large number of pertinent negatives, e.g., symptoms that the patient was specifically asked if they had experienced or were currently experiencing, but had denied experiencing.

**1. SHALL** contain exactly one [1..1] **code/@code=**"10187-3" *REVIEW OF SYSTEMS* (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF-CO-41)

```
<?xml version="1.0" encoding="UTF-8"?>
<section xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:h17-
org:v3" xsi:schemaLocation="urn:h17-org:v3 CDA.xsd">
    <templateId root="2.16.840.1.113883.10.20.4.10"/>
        <id root="67e99eb4-b138-4399-b981-fca62dd925c3"/>
            <code code="10187-3" codeSystem="2.16.840.1.113883.6.1"
            codeSystemName="LOINC" displayName="REVIEW OF SYSTEMS"/>
            <title>REVIEW OF SYSTEMS</title>
</section>
```

Figure 30: Review Of Systems Section example

### **Review Of Systems Section IHE**

```
[Section: templateId 1.3.6.1.4.1.19376.1.5.3.1.3.18]
```

The review of systems is a relevant collection of symptoms and function systematically gathered by a clinician. It includes symptoms the patient is currently experiencing, some of which were not elicited during the history of present illness, as well as a potentially large number of pertinent negatives, e.g., symptoms that the patient was specifically asked if they had experienced or were currently experiencing, but had denied experiencing.

1. SHALL contain exactly one [1..1] code/@code="10187-3" *REVIEW OF SYSTEMS* (CodeSystem: 2.16.840.1.113883.6.1 LOINC)

```
<?xml version="1.0" encoding="UTF-8"?>
<section xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-
org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
        <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.18"/>
        <id root="3a0762c7-783b-492b-a196-bfedfd9e37b1"/>
        <code code="10187-3" codeSystem="2.16.840.1.113883.6.1"
        codeSystemName="LOINC" displayName="REVIEW OF SYSTEMS"/>
        <title>REVIEW OF SYSTEMS</title>
</section>
```

Figure 31: Review Of Systems Section IHE example

## **Subjective Section**

```
[Section: templateId 2.16.840.1.113883.10.20.21.2.2]
```

This section describes in a narrative format the patient's current condition and/or interval changes as reported by the patient or by the patient's guardian or caregiver.

1. SHALL contain exactly one [1..1] code/@code="SUBJ-X" SUBJECTIVE DATA (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF-PRGN-32)

- 2. SHALL contain exactly one [1..1] text (CONF-PRGN-15)
- **3. SHALL** contain exactly one [1..1] **title** (CONF-PRGN-14)
- **4. SHOULD** satisfy: Contains clinical statements. (CONF-PRGN-15)

```
• [OCL]: not self.entry->isEmpty()

<?xml version="1.0" encoding="UTF-8"?>
<section xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
    <templateId root="2.16.840.1.113883.10.20.21.2.2"/>
    <id root="101bfaad-582e-401e-a9f5-85d7432cda36"/>
    <code code="SUBJ-X" codeSystem="2.16.840.1.113883.6.1"
    codeSystemName="LOINC" displayName="SUBJECTIVE DATA"/>
    <title>SUBJECTIVE DATA</title>
</section>
```

Figure 32: Subjective Section example

### Vital Signs Section

```
[Section: templateId 2.16.840.1.113883.10.20.2.4]
```

The Vital Signs section contains measured vital signs at the time of the examination. Measurements may include some or all of the following: blood pressure, heart rate, respiratory rate, body temperature, and pulse oximetry. Comments on relative trends may be appropriate, but not required. This section can be a first-level section or nested under Physical Exam.

- 1. SHALL contain exactly one [1..1] code/@code="8716-3" VITAL SIGNS (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF-HP-87)
- 2. SHALL contain exactly one [1..1] text
- **3. SHOULD** contain zero or one [0..1] **entry** (CONF-HP-87), such that
  - **a.** Contains exactly one [1..1] *CCD Vital Signs Organizer* (templateId: 2.16.840.1.113883.10.20.1.35)
- **4. SHOULD** satisfy: Contains clinical statements. (CONF-HP-87)
- [OCL]: not self.entry->isEmpty() <?xml version="1.0" encoding="UTF-8"?> <section xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:h17-</pre> org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"> <templateId root="2.16.840.1.113883.10.20.2.4"/> <id root="2f82d6e2-fa20-49b0-a084-a1472a6deb98"/> <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"/> <templateId root="2.16.840.1.113883.10.20.1.35"/> <id root="6ad254e4-ca73-42f6-9731-6ce9ed944d40"/> <code/> <statusCode/> <effectiveTime> <low value="2011"/> <high value="2011"/> </effectiveTime> <component> <observation moodCode="EVN"> <templateId root="2.16.840.1.113883.10.20.1.31"/> <id root="7f908962-a640-42b3-933e-8b2f86c91665"/> <code/> <statusCode/>

Figure 33: Vital Signs Section example

4

## **CLINICAL STATEMENT TEMPLATES**

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.

66   Implementation Guide for CDA Release 2   CLINICAL STATEMENT TEMPLATES

5

## **OTHER CLASSES**

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



## **VALUE SETS**

### Topics:

- Consult Document Type Codes
- HP Document Type
- Personal Relationship Role Type
- Progress Note Document Type Code

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

### **Consult Document Type Codes**

Value Set ConsultDocumentTypeCodes - (OID not specified)

Code System LOINC - 2.16.840.1.113883.6.1

Source Health Level Seven (HL7)

Definition LOINC codes whose scale is DOC, and whose type of service (component)

is Consultation Note. Document type codes for "Blood Bank Consultation," "Confirmatory Consultation Note," or those codes giving "Hospital Consultation" as type of service (18841-7 and 8647-0) are not allowed as document type codes. In their place, the code 34104-0 with types of service = Consultation Note and setting =

hospital should be used.

### **HP Document Type**

Value Set HPDocumentType - 2.16.840.1.113883.1.11.20.22

Code System LOINC - 2.16.840.1.113883.6.1

Source Health Level Seven (HL7)

Definition Valid codes are those whose scale is DOC and whose type of service is some variation

of History and Physical.

### Personal Relationship Role Type

Value Set PersonalRelationshipRoleType - (OID not specified)

Code System RoleCode - 2.16.840.1.113883.5.111

Source Health Level Seven (HL7)

Description Provides more information about the link between two people in a personal

relationship.

## **Progress Note Document Type Code**

Value Set ProgressNoteDocumentTypeCode - 2.16.840.1.113883.11.20.8.1

Code System LOINC - 2.16.840.1.113883.6.1

Source HL7

Definition This value set includes the preferred code and pre-coordinated LOINC codes that

have the scale DOC (document) and a 'component' referring to "subsequent evaluation notes". Although these pre-coordinated LOINC codes are available for use, we recommend the preferred code (11506-3 Progress Note). When these pre-coordinated codes are used, any coded values describing the author or performer of the service act or the practice setting must be consistent with the LOINC document type. Note:

"Subsequent evaluation note" is equivalent to Progress Note.

### 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<sup>©</sup> (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: <a href="http://www.jamia.org/cgi/reprint/13/1/30">http://www.jamia.org/cgi/reprint/13/1/30</a>.
- 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*