

Implementation Guide for CDA Release 2 HITSP Summary Documents using CCD and CDA Content Modules C32, C83, and C80



**C32 Version 2.5, C83 Version 2.0.1
DRAFT: FOR DEVELOPMENT USE ONLY**

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Revision History

| Rev | Date | By Whom | Changes |
|--|-------------------|--------------|--|
| First draft for posting | August 31, 2010 | Dave Carlson | Updated model content and publication format |
| First draft for IG consolidation project | December 29, 2010 | Dave Carlson | |

Notes on draft status

December 29, 2010: This is a first draft of HITSP/IHE/HL7 implementation guide consolidation for C32 and CCD. This draft includes all template sections defined in C83, some of which are not part of C32 summaries. The next draft will limit content to templates used in C32.

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 HITSP 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 document combines specifications from several HITSP documents, as summarized in the following sections. For the authoritative source, please refer to the approved specifications from HITSP.

C32 Patient Summary

The HITSP Summary Documents Using HL7 Continuity of Care Document (CCD) Component describes the document content summarizing a consumer's medical status for the purpose of information exchange. The content may include administrative (e.g., registration, demographics, insurance, etc.) and clinical (problem list, medication list, allergies, test results, etc) information. Any specific use of this Component by another HITSP specification may constrain the content further based upon the requirements and context of the document exchange. This specification defines content in order to promote interoperability between participating systems. Any given system creating or consuming the document may contain much more information than conveyed by this specification. Such systems may include Personal Health Record Systems (.1.s), Electronic Health Record Systems (EHRs), Practice Management Applications and other persons and systems as identified and permitted.

This Component is essentially a subset of the healthcare data that has been developed for specific business Use Cases. This subset contains the minimum critical or pertinent medical information sections as specified by the business case. Information conveyed according to the Component Construct is a representative extract of the information available on the creating system. The information in the HITSP Summary Documents Using HL7 Continuity of Care Document (CCD) Component and the creating systems must be consistent. Furthermore there should be no data elsewhere in the creating system that would contradict the meaning of any data in this construct. The expectation is that consuming systems will be able to use this specification as a source of information to input and/or update information in their instantiation of the healthcare record. This specification does not define the policies applicable to the import of this information.

It is anticipated and desirable that some implementers of the HITSP Summary Documents Using HL7 Continuity of Care Document (CCD) Component will want to add data and sections to permit greater communication between systems. The underlying standards (primarily HL7 CCD – Continuity of Care Document) have additional modules that may serve such purposes. This practice is beyond the scope of this HITSP Component. Implementers should be aware that they must assume that receivers of the document may only be able to view or process content modules as described in this specification, and may not be able to use the additional modules in the document. This means that the HITSP Summary Documents Using HL7 Continuity of Care Document (CCD) Component must be able to stand-alone. Applications may wish to display the document in two different user-selected views, one of which is restricted to the minimal dataset contents of this component. Adding optional sections and data elements should not generate errors. Optional data should be used if understood by the receiving system, but must not change the meaning of the document.

This Component refers to the HITSP 2008 work cycle. It expands upon the prior version of the specification for a consumer's registration/medication history information to include content to support the consumer's access to clinical information, medication management activities and supportive information for quality of care assessment.

C83 Content Modules

The purpose of the Healthcare Information Technology Standards Panel (HITSP) CDA Content Modules Component is to define the library of Components that may be used by CDA-based constructs developed by HITSP and others in standards based exchanges. The Components are organized into modules to simplify navigation. These modules are organized along the same principals as the HL7 Continuity of Care Document.

The data elements found in these modules are based on HL7 CDA Implementation Guides and the IHE PCC Technical Framework Volume II, Release 5 and its related supplements. These guides contain specifications for document sections that are consistent with all clinical documents currently selected for HITSP constructs.

C80 Clinical Document and Message Terminology

The purpose of the Health Information Technology Standards Panel (HITSP) Clinical Document and Message Terminology Component is to define the vocabulary for either document-based or message-based HITSP constructs such as Clinical Document Architecture (CDA) documents, HL7 V2 messages, etc. For more in-depth information about how this Component relates to other HITSP constructs, see HITSP/TN901 Clinical Documents.

Approach

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

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

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

Scope

TODO: scope of this implementation guide.

Audience

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

Organization of This Guide

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

Templates

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

Vocabulary and Value Sets

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

Use of Templates

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

Originator Responsibilities

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

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

Recipient Responsibilities

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

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

Conventions Used in This Guide

Conformance Requirements

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

Template name

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

Description of the template will be here

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

Figure 1: Template name and "conforms to" appearance

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

The following cardinality indicators may be interpreted as follows:

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

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

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

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

Figure 2: Template-based conformance statements example

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

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

Figure 3: CCD conformance statements example

Keywords

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

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

XML Examples

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

```
<ClinicalDocument xmlns='urn:hl7-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:

- [*Discharge Summary*](#)
- [*Patient Summary*](#)
- [*Referral Summary*](#)
- [*Unstructured Document*](#)
- [*Unstructured Or Scanned Document*](#)

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

Discharge Summary

[ClinicalDocument: templateId 2.16.840.1.113883.3.88.11.48.2]

1. **SHALL** conform to *IHE Medical Summary* template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.2) (C48-[CT3-1])
2. **SHALL** contain exactly one [1..1] **component** (C48-[CT2-1]), such that
 - a. Contains exactly one [1..1] *Problem List Section* (templateId: 2.16.840.1.113883.3.88.11.83.103)
3. **SHOULD** contain exactly one [1..1] **component** (C48-[CT2-2]), such that
 - a. Contains exactly one [1..1] *Admission Medication History Section* (templateId: 2.16.840.1.113883.3.88.11.83.113)
4. **SHALL** contain exactly one [1..1] **component** (C48-[CT2-3]), such that
 - a. Contains exactly one [1..1] *Hospital Admission Diagnosis Section* (templateId: 2.16.840.1.113883.3.88.11.83.110)
5. **MAY** contain zero or one [0..1] **component** (C48-[CT2-4]), such that
 - a. Contains exactly one [1..1] *Advance Directives Section* (templateId: 2.16.840.1.113883.3.88.11.83.116)
6. **SHALL** contain exactly one [1..1] **component** (C48-[CT2-5]), such that
 - a. Contains exactly one [1..1] *Allergies Reactions Section* (templateId: 2.16.840.1.113883.3.88.11.83.102)
7. **SHALL** contain exactly one [1..1] **component** (C48-[CT2-6]), such that
 - a. Contains exactly one [1..1] *Discharge Diagnosis Section* (templateId: 2.16.840.1.113883.3.88.11.83.111)
8. **MAY** contain zero or one [0..1] **component** (C48-[CT2-7]), such that
 - a. Contains exactly one [1..1] *IHE Discharge Diet* (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.33)
9. **SHALL** contain exactly one [1..1] **component** (C48-[CT2-8]), such that
 - a. Contains exactly one [1..1] *Hospital Discharge Medications Section* (templateId: 2.16.840.1.113883.3.88.11.83.114)
10. **MAY** contain zero or one [0..1] **component** (C48-[CT2-9]), such that
 - a. Contains exactly one [1..1] *Diagnostic Results Section* (templateId: 2.16.840.1.113883.3.88.11.83.122)
11. **MAY** contain zero or one [0..1] **component** (C48-[CT2-10]), such that
 - a. Contains exactly one [1..1] *Functional Status Section* (templateId: 2.16.840.1.113883.3.88.11.83.109)
12. **SHOULD** contain exactly one [1..1] **component** (C48-[CT2-11]), such that
 - a. Contains exactly one [1..1] *History Of Present Illness* (templateId: 2.16.840.1.113883.3.88.11.83.107)
13. **SHALL** contain exactly one [1..1] **component** (C48-[CT2-12]), such that
 - a. Contains exactly one [1..1] *Hospital Course Section* (templateId: 2.16.840.1.113883.3.88.11.83.121)
14. **SHOULD** contain exactly one [1..1] **component** (C48-[CT2-13]), such that
 - a. Contains exactly one [1..1] *Medical Equipment Section* (templateId: 2.16.840.1.113883.3.88.11.83.128)
15. **MAY** contain zero or one [0..1] **component** (C48-[CT2-15]), such that
 - a. Contains exactly one [1..1] *Physical Exam Section* (templateId: 2.16.840.1.113883.3.88.11.83.118)

16. **SHALL** contain exactly one [1..1] **component** (C48-[CT2-16]), such that
 - a. Contains exactly one [1..1] *Plan Of Care Section* (templateId: 2.16.840.1.113883.3.88.11.83.124)
17. **SHALL** contain exactly one [1..1] **component** (C48-[CT2-17]), such that
 - a. Contains exactly one [1..1] *History Of Past Illness Section* (templateId: 2.16.840.1.113883.3.88.11.83.104)
18. **MAY** contain zero or one [0..1] **component** (C48-[CT2-18]), such that
 - a. Contains exactly one [1..1] *Review Of Systems Section* (templateId: 2.16.840.1.113883.3.88.11.83.120)
19. **SHOULD** contain exactly one [1..1] **component** (C48-[CT2-19]), such that
 - a. Contains exactly one [1..1] *Medications Administered Section* (templateId: 2.16.840.1.113883.3.88.11.83.115)
20. **SHOULD** contain exactly one [1..1] **component** (C48-[CT2-20]), such that
 - a. Contains exactly one [1..1] *Vital Signs Section* (templateId: 2.16.840.1.113883.3.88.11.83.119)

Discharge Summary example

Patient Summary

[ClinicalDocument: templateId 2.16.840.1.113883.3.88.11.32.1]

This Component describes the document content that summarizes a consumer's medical status for the purpose of health information exchange. While an EHR or PHR system can contain much more information, this Component only deals with the summary information to be exchanged between such systems as established as requirements described in AHIC Use Cases.

1. **SHALL** conform to *IHE Medical Document* template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.1)
2. **SHALL** conform to *CCD Continuity Of Care Document* template (templateId: 2.16.840.1.113883.10.20.1)
3. **MAY** contain zero or one [0..1] **component** (C32-[CT1-1]), such that
 - a. Contains exactly one [1..1] *Advance Directives Section* (templateId: 2.16.840.1.113883.3.88.11.83.116)
4. **MAY** contain zero or one [0..1] **component** (C32-[CT1-2]), such that
 - a. Contains exactly one [1..1] *Allergies Reactions Section* (templateId: 2.16.840.1.113883.3.88.11.83.102)
5. **MAY** contain zero or more [0..*] **component** (C32-[CT1-3]), such that
 - a. Contains exactly one [1..1] *Comment* (templateId: 2.16.840.1.113883.3.88.11.83.11)
6. **MAY** contain zero or one [0..1] **component** (C32-[CT1-4]), such that
 - a. Contains exactly one [1..1] *Problem List Section* (templateId: 2.16.840.1.113883.3.88.11.83.103)
7. **MAY** contain zero or one [0..1] **component** (C32-[CT1-5]), such that
 - a. Contains exactly one [1..1] *Encounters Section* (templateId: 2.16.840.1.113883.3.88.11.83.127)
8. **MAY** contain zero or one [0..1] **component** (C32-[CT1-7]), such that
 - a. Contains exactly one [1..1] *Immunizations Section* (templateId: 2.16.840.1.113883.3.88.11.83.117)
9. **MAY** contain zero or one [0..1] **component** (C32-[CT1-9]), such that
 - a. Contains exactly one [1..1] *Payers Section* (templateId: 2.16.840.1.113883.3.88.11.83.101)
10. **MAY** contain zero or one [0..1] **component** (C32-[CT1-11]), such that
 - a. Contains exactly one [1..1] *Medications Section* (templateId: 2.16.840.1.113883.3.88.11.83.112)

11. **MAY** contain zero or one [0..1] **component** (C32-[CT1-13]), such that
 - a. Contains exactly one [1..1] *Plan Of Care Section* (templateId: 2.16.840.1.113883.3.88.11.83.124)
12. **MAY** contain zero or one [0..1] **component** (C32-[CT1-14]), such that
 - a. Contains exactly one [1..1] *IHE Pregnancy History Section* (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.5.3.4)
13. **MAY** contain zero or one [0..1] **component** (C32-[CT1-15]), such that
 - a. Contains exactly one [1..1] *Surgeries Section* (templateId: 2.16.840.1.113883.3.88.11.83.108)
14. **SHOULD** contain at least one [1..*] **supportHeaders** (C32-[CT1-16]), such that
15. **MAY** contain zero or one [0..1] **component** (C32-[CT1-17]), such that
 - a. Contains exactly one [1..1] *Vital Signs Section* (templateId: 2.16.840.1.113883.3.88.11.83.119)
16. **MAY** contain zero or one [0..1] **component** (C32-[CT1-18]), such that
 - a. Contains exactly one [1..1] *Diagnostic Results Section* (templateId: 2.16.840.1.113883.3.88.11.83.122)
17. **MAY** satisfy: Contains 0..* HealthcareProvider in cda:documentationOf/cda:serviceEvent/cda:performer (C32-[CT1-6])
 - [OCL]: `self.documentationOf.serviceEvent.performer->size() > 0`
18. **SHALL** satisfy: Contains 0..* InformationSource in ancestor-or-self::cda:author[1] (C32-[CT1-8])
19. **SHOULD** satisfy: Contains 0..* LanguageSpoken in cda:recordTarget/cda:patientRole/cda:patient/cda:languageCommunication (C32-[CT1-10])
20. **SHALL** satisfy: Contains 1..1 Person Information in cda:recordTarget/cda:patientRole (C32-[CT1-12])

Patient Summary example

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
  xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <realmCode code="US"/>
  <typeId root="2.16.840.1.113883.1.3"/>
  <templateId root="2.16.840.1.113883.10.20.1"/>
  <templateId root="2.16.840.1.113883.10.20.3"/>
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.1.1"/>
  <templateId root="2.16.840.1.113883.3.88.11.32.1"/>
  <id root="1510230328"/>
  <code code="34133-9" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Summarization of episode note"/>
  <title/>
  <effectiveTime/>
  <confidentialityCode code="Value"/>
  <languageCode/>
  <recordTarget/>
  <author/>
  <custodian/>
  <component>
    <structuredBody>
      <component>
        <section>
          <realmCode/>
          <typeId root="2.16.840.1.113883.1.3"/>
          <templateId root="2.16.840.1.113883.10.20.1.1"/>
          <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.34"/>
          <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.35"/>
          <templateId root="2.16.840.1.113883.3.88.11.83.116"/>
          <id root="742369455"/>
          <code code="42348-3" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Advance directives"/>
          <title/>
          <languageCode/>
```

```

    </section>
  </component>
</component>
  <section/>
</component>
<component>
  <section/>
</component>
<component>
  <section/>
</component>
<component>
  <section/>
</component>
<component>
  <section/>
</component>
<component>
  <section/>
</component>
<component>
  <section/>
</component>
</structuredBody>
</component>
</ClinicalDocument>

```

Referral Summary

[ClinicalDocument: templateId 2.16.840.1.113883.3.88.11.48.1]

1. **SHALL** conform to *IHE Medical Summary* template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.2)

Referral Summary example

Unstructured Document

[ClinicalDocument: templateId 2.16.840.1.113883.3.88.11.62.1]

IMPORTANT NOTE: The HITSP C62 specification does not include a templateId for this document type. The id 2.16.840.1.113883.3.88.11.62.1 is included in this model to support instance validation, but we are designing a solution to allow removal of this Id.

1. **SHALL** conform to *IHE Scanned Document* template (templateId: 1.3.6.1.4.1.19376.1.2.20)
2. **SHALL** conform to *IHE Medical Document* template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.1)
3. **SHOULD** satisfy: This construct should not be used when the data are structured.

- [OCL]: self.component.structuredBody.ocIsUndefined()

4. **SHALL** satisfy: Each document pertains to one and only one patient.

- [OCL]: self.recordTarget->one(record : cda::RecordTarget
| not record.patientRole.ocIsUndefined() and not
record.patientRole.patient.ocIsUndefined())

Unstructured Document example

Unstructured Or Scanned Document

[ClinicalDocument: templateId 2.16.840.1.113883.10.20.19.1]

Used for documents that implement both HL7 Unstructured Documents and HITSP C62 based on IHE Scanned Documents.

1. **SHALL** conform to *CDT Unstructured Document* template (templateId: 2.16.840.1.113883.10.20.19.1)
2. **SHALL** conform to *Unstructured Document* template (templateId: 2.16.840.1.113883.3.88.11.62.1)

Unstructured Or Scanned Document example

Chapter

3

SECTION TEMPLATES

Topics:

- *Admission Medication History Section*
- *Advance Directives Section*
- *Allergies Reactions Section*
- *Assessment And Plan Section*
- *Chief Complaint Section*
- *Diagnostic Results Section*
- *Discharge Diagnosis Section*
- *Encounters Section*
- *Family History Section*
- *Functional Status Section*
- *History Of Past Illness Section*
- *History Of Present Illness*
- *Hospital Admission Diagnosis Section*
- *Hospital Course Section*
- *Hospital Discharge Medications Section*
- *Immunizations Section*
- *Medical Equipment Section*
- *Medications Administered Section*
- *Medications Section*
- *Payers Section*
- *Physical Exam Section*
- *Plan Of Care Section*
- *Problem List Section*
- *Reason For Referral Section*
- *Review Of Systems Section*
- *Social History Section*
- *Surgeries Section*
- *Vital Signs Section*

Admission Medication History Section

[Section: templateId 2.16.840.1.113883.3.88.11.83.113]

The Admission Medication Section contains information about the relevant medications of a patient prior to admission to a facility.

1. **SHALL** conform to *IHE Admission Medication History Section* template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.20)

Admission Medication History Section example

```
<?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="1.3.6.1.4.1.19376.1.5.3.1.3.20"/>
  <templateId root="2.16.840.1.113883.3.88.11.83.113"/>
  <id root="2137101550"/>
  <code code="42346-7" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="MEDICATIONS ON ADMISSION"/>
  <title/>
</section>
```

Advance Directives Section

[Section: templateId 2.16.840.1.113883.3.88.11.83.116]

The Advance Directives Section contains information that defines the patient's expectations and requests for care along with the locations of the documents.

1. **SHALL** conform to *IHE Coded Advance Directives Section* template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.35)
2. **SHALL** contain at least one [1..*] **entry**, such that
 - a. Contains exactly one [1..1] *Advance Directive* (templateId: 2.16.840.1.113883.3.88.11.83.12)

Advance Directives Section example

```
<?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="2.16.840.1.113883.10.20.1.1"/>
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.34"/>
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.35"/>
  <templateId root="2.16.840.1.113883.3.88.11.83.116"/>
  <id root="379762213"/>
  <code code="42348-3" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Advance directives"/>
  <title/>
  <text/>
</section>
```

Allergies Reactions Section

[Section: templateId 2.16.840.1.113883.3.88.11.83.102]

The Allergies and Other Adverse Reactions Section contains data on the substance intolerances and the associated adverse reactions suffered by the patient. At a minimum, currently active and any relevant historical allergies and adverse reactions shall be listed.

1. **SHALL** conform to *IHE Allergies Reactions Section* template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.13) (C83-[CT-102-2])

2. **SHALL** contain at least one [1..*] **entry**, such that

- a. Contains exactly one [1..1] [Allergy Drug Sensitivity](#) (templateId: 2.16.840.1.113883.3.88.11.83.6)

Allergies Reactions Section example

```
<?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="2.16.840.1.113883.10.20.1.2"/>
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.13"/>
  <templateId root="2.16.840.1.113883.3.88.11.83.102"/>
  <id root="20365049"/>
  <code code="48765-2" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Allergies, adverse reactions, alerts"/>
  <title/>
  <text/>
</section>
```

Assessment And Plan Section

[Section: templateId 2.16.840.1.113883.3.88.11.83.123]

The Assessment and Plan Section contains information about the assessment of the patient's condition and expectations for care including proposals, goals, and order requests for monitoring, tracking, or improving the condition of the patient.

An assessment and plan section varies from the plan of care section defined later in that it includes a physician assessment of the patient condition.

NOTE : The assessments described in this section are physician assessments of the patient's current condition, and do not include assessments of functional status, or other assessments typically used in nursing. In Implementation Guides currently selected, when both the assessment and plan are documented, they are included together in a single section documenting both. When the physician assessment is not present, only the plan of care section appears. There are no cases where a physician assessment is provided without a plan.

1. **SHALL** conform to [IHE Assessment And Plan Section](#) template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.13.2.5)

Assessment And Plan Section example

```
<?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="1.3.6.1.4.1.19376.1.5.3.1.1.13.2.5"/>
  <templateId root="2.16.840.1.113883.3.88.11.83.123"/>
  <id root="479927031"/>
  <code code="51847-2" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="ASSESSMENT AND PLAN"/>
  <title/>
</section>
```

Chief Complaint Section

[Section: templateId 2.16.840.1.113883.3.88.11.83.105]

The Chief Complaint Section contains information about the patient's chief complaint.

1. **SHALL** conform to [IHE Chief Complaint Section](#) template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.13.2.1)
2. **SHALL** conform to [CDT Chief Complaint Section](#) template (templateId: 2.16.840.1.113883.10.20.2.8)
3. **MAY** contain zero or one [0..1] **entry**, such that

- a. Contains exactly one [1..1] [Condition](#) (templateId: 2.16.840.1.113883.3.88.11.83.7)

Chief Complaint Section example

```
<?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="1.3.6.1.4.1.19376.1.5.3.1.1.13.2.1"/>
  <templateId root="2.16.840.1.113883.3.88.11.83.105"/>
  <id root="954843784"/>
  <code code="10154-3" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="CHIEF COMPLAINT"/>
  <title/>
</section>
```

Diagnostic Results Section

[Section: templateId 2.16.840.1.113883.3.88.11.83.122]

The Results 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.

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 to provide more granular information about component observations made during a procedure, such as where a gastroenterologist reports the size of a polyp observed during a colonoscopy.

1. **SHALL** conform to [IHE Coded Results Section](#) template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.28) (C83-[CT-122-1])
2. **SHALL** contain at least one [1..*] **entry** (C83-[CT-122-2]), such that
 - a. Contains exactly one [1..1] [Procedure](#) (templateId: 2.16.840.1.113883.3.88.11.83.17)
3. **MAY** contain zero or more [0..*] **entry**, such that
 - a. Contains exactly one [1..1] [Result](#) (templateId: 2.16.840.1.113883.3.88.11.83.15)
4. **MAY** contain zero or more [0..*] **entry**, such that
 - a. Contains exactly one [1..1] [Result Organizer](#) (templateId: 2.16.840.1.113883.10.20.1.32)
5. **SHALL** satisfy: Contains Result as entry within section, or within a ResultOrganizer. (C83-[CT-122-2])
 - [OCL]: self.entry->exists(entry : cda::Entry | entry.observation.ocIsKindOf(hitSp::Result)) or self.entry->exists(entry : cda::Entry | entry.organizer.ocIsKindOf(ccd::ResultOrganizer) and entry.organizer.component.observation->exists(obs : cda::Observation | obs.ocIsKindOf(hitSp::Result)))

Diagnostic Results Section example

```
<?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="1.3.6.1.4.1.19376.1.5.3.1.3.28"/>
  <templateId root="2.16.840.1.113883.3.88.11.83.122"/>
  <id root="653698079"/>
```



```
<code code="30954-2" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="STUDIES SUMMARY"/>
<title/>
</section>
```

Discharge Diagnosis Section

[Section: templateId 2.16.840.1.113883.3.88.11.83.111]

The Discharge Diagnosis Section contains information about the conditions identified during the hospital stay that either need to be monitored after discharge from the hospital and/or where resolved during the hospital course.

1. **SHALL** conform to [IHE Discharge Diagnosis Section](#) template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.7)
2. **SHALL** contain exactly one [1..1] **entry**, such that
 - a. Contains exactly one [1..1] [Condition](#) (templateId: 2.16.840.1.113883.3.88.11.83.7)

Discharge Diagnosis Section example

```
<?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="1.3.6.1.4.1.19376.1.5.3.1.3.7"/>
  <templateId root="2.16.840.1.113883.3.88.11.83.111"/>
  <id root="2086765011"/>
  <code code="11535-2" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="HOSPITAL DISCHARGE DX"/>
  <title/>
</section>
```

Encounters Section

[Section: templateId 2.16.840.1.113883.3.88.11.83.127]

The Encounter Section contains information describing the patient history of encounters. At a minimum, current and pertinent historical encounters should be included; a full encounter history may be included.

1. **SHALL** conform to [IHE Encounter History Section](#) template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.5.3.3)
2. **SHALL** contain at least one [1..*] **entry**, such that
 - a. Contains exactly one [1..1] [Encounter](#) (templateId: 2.16.840.1.113883.3.88.11.83.16)

Encounters Section example

```
<?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="2.16.840.1.113883.10.20.1.3"/>
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.1.5.3.3"/>
  <templateId root="2.16.840.1.113883.3.88.11.83.127"/>
  <id root="1379448278"/>
  <code code="46240-8" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="History of encounters"/>
  <title/>
  <text/>
  <entry>
    <encounter classCode="ENC" moodCode="EVN">
      <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.14"/>
      <templateId root="2.16.840.1.113883.10.20.1.21"/>
      <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.14"/>
      <templateId root="2.16.840.1.113883.3.88.11.83.16"/>
    </encounter>
  </entry>
</section>
```

```

    <id root="500404835"/>
    <code codeSystem="2.16.840.1.113883.6.12" codeSystemName="CPT-4"/>
    <text/>
    <effectiveTime>
      <low value="2011"/>
      <high value="2011"/>
    </effectiveTime>
  </encounter>
</entry>
</section>

```

Family History Section

[Section: templateId 2.16.840.1.113883.3.88.11.83.125]

The Family History Section contains information about the genetic family members, to the extent that they are known, the diseases they suffered from, their ages at death, and other relevant genetic information.

1. **SHALL** conform to [IHE Family Medical History Section](#) template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.14)
2. **SHALL** contain at least one [1..*] **entry**, such that
 - a. Contains exactly one [1..1] [Family History](#) (templateId: 2.16.840.1.113883.3.88.11.83.18)
3. **SHALL** conform to IHE Coded Family History Section and **SHALL** contain a templateId element whose root attribute is 1.3.6.1.4.1.19376.1.5.3.1.3.15 when this section is conveying structured family history.
4. When providing structured Family History Information **SHALL** include entries conforming to the Family History module

Family History Section example

```

<?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="2.16.840.1.113883.10.20.1.4"/>
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.14"/>
  <templateId root="2.16.840.1.113883.3.88.11.83.125"/>
  <id root="1123133172"/>
  <code code="10157-6" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="History of family member diseases"/>
  <title/>
  <text/>
</section>

```

Functional Status Section

[Section: templateId 2.16.840.1.113883.3.88.11.83.109]

The Functional Status Section provides information about the capability of the patient to perform acts of daily living.

1. **SHALL** conform to [CCD Functional Status Section](#) template (templateId: 2.16.840.1.113883.10.20.1.5)

Functional Status Section example

```

<?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="2.16.840.1.113883.10.20.1.5"/>
  <templateId root="2.16.840.1.113883.3.88.11.83.109"/>
  <id root="413914699"/>
  <code code="47420-5" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Functional status assessment"/>
  <title/>

```

```
<text/>
</section>
```

History Of Past Illness Section

[Section: templateId 2.16.840.1.113883.3.88.11.83.104]

The History of Past Illness Section contains data about problems the patient suffered in the past.

1. **SHALL** conform to [IHE History Of Past Illness Section](#) template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.8)
2. **SHALL** conform to [CDT Past Medical History Section](#) template (templateId: 2.16.840.1.113883.10.20.2.9)
3. **SHALL** contain exactly one [1..1] **entry**, such that
 - a. Contains exactly one [1..1] [Condition](#) (templateId: 2.16.840.1.113883.3.88.11.83.7)

History Of Past Illness Section example

```
<?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="1.3.6.1.4.1.19376.1.5.3.1.3.8"/>
  <templateId root="2.16.840.1.113883.3.88.11.83.104"/>
  <id root="252569199"/>
  <code code="11348-0" codeSystem="2.16.840.1.113883.6.1"
    codeSystemName="LOINC" displayName="HISTORY OF PAST ILLNESS"/>
  <title/>
  <text/>
</section>
```

History Of Present Illness

[Section: templateId 2.16.840.1.113883.3.88.11.83.107]

The History of Present Illness Section contains information about the sequence of events preceding the patient's current complaints.

1. **SHALL** conform to [IHE History Of Present Illness](#) template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.4)

History Of Present Illness example

```
<?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="1.3.6.1.4.1.19376.1.5.3.1.3.4"/>
  <templateId root="2.16.840.1.113883.3.88.11.83.107"/>
  <id root="1757178183"/>
  <code code="10164-2" codeSystem="2.16.840.1.113883.6.1"
    codeSystemName="LOINC" displayName="HISTORY OF PRESENT ILLNESS"/>
  <title/>
</section>
```

Hospital Admission Diagnosis Section

[Section: templateId 2.16.840.1.113883.3.88.11.83.110]

The Hospital Admitting Diagnosis Section contains information about the primary reason for admission to a hospital facility.

1. **SHALL** conform to [IHE Hospital Admission Diagnosis Section](#) template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.3)

2. **SHALL** contain exactly one [1..1] **entry**, such that
 - a. Contains exactly one [1..1] *Condition* (templateId: 2.16.840.1.113883.3.88.11.83.7)

Hospital Admission Diagnosis Section example

```
<?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="1.3.6.1.4.1.19376.1.5.3.1.3.3"/>
  <templateId root="2.16.840.1.113883.3.88.11.83.110"/>
  <id root="1257036181"/>
  <code code="46241-6" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="HOSPITAL ADMISSION DX"/>
  <title/>
</section>
```

Hospital Course Section

[Section: templateId 2.16.840.1.113883.3.88.11.83.121]

The Hospital Course Section contains information about the sequence of events from admission to discharge in a hospital facility.

1. **SHALL** conform to *IHE Hospital Course Section* template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.5)

Hospital Course Section example

```
<?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="1.3.6.1.4.1.19376.1.5.3.1.3.5"/>
  <templateId root="2.16.840.1.113883.3.88.11.83.121"/>
  <id root="1197592627"/>
  <code code="8648-8" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="HOSPITAL COURSE"/>
  <title/>
</section>
```

Hospital Discharge Medications Section

[Section: templateId 2.16.840.1.113883.3.88.11.83.114]

The Hospital Discharge Medications Section contains information about the relevant medications of the medications ordered for the patient for use after discharge from the hospital.

1. **SHALL** conform to *IHE Hospital Discharge Medications Section* template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.22)
2. **SHALL** contain exactly one [1..1] **entry**, such that
 - a. Contains exactly one [1..1] *Medication* (templateId: 2.16.840.1.113883.3.88.11.83.8)

Hospital Discharge Medications Section example

```
<?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="1.3.6.1.4.1.19376.1.5.3.1.3.22"/>
  <templateId root="2.16.840.1.113883.3.88.11.83.114"/>
  <id root="790656959"/>
  <code code="10183-2" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="HOSPITAL DISCHARGE MEDICATIONS"/>
  <title/>
</section>
```

```
<title/>
</section>
```

Immunizations Section

[Section: templateId 2.16.840.1.113883.3.88.11.83.117]

The Immunizations Section contains information describing the immunizations administered to the patient.

1. **SHALL** conform to *IHE Immunizations Section* template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.23)
2. **SHALL** contain at least one [1..*] **entry**, such that
 - a. Contains exactly one [1..1] *Immunization* (templateId: 2.16.840.1.113883.3.88.11.83.13)

Immunizations Section example

```
<?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="2.16.840.1.113883.10.20.1.6"/>
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.23"/>
  <templateId root="2.16.840.1.113883.3.88.11.83.117"/>
  <id root="1065880968"/>
  <code code="11369-6" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="History of immunizations"/>
  <title/>
  <text/>
  <entry>
    <substanceAdministration>
      <templateId root="2.16.840.1.113883.10.20.1.24"/>
      <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.12"/>
      <templateId root="2.16.840.1.113883.3.88.11.83.13"/>
      <id root="1668014118"/>
      <code code="535669514"/>
      <text/>
      <effectiveTime value="20110830"/>
      <consumable/>
    </substanceAdministration>
  </entry>
</section>
```

Medical Equipment Section

[Section: templateId 2.16.840.1.113883.3.88.11.83.128]

The Medical Equipment section contains information describing a patient's implanted and external medical devices and equipment that their health status depends on, as well as any pertinent equipment or device history.

1. **SHALL** conform to *IHE Medical Devices Section* template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.5.3.5)

Medical Equipment Section example

```
<?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="2.16.840.1.113883.10.20.1.7"/>
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.1.5.3.5"/>
  <templateId root="2.16.840.1.113883.3.88.11.83.128"/>
  <id root="39649793"/>
  <code code="46264-8" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="History of medical device use"/>
```

```
<title/>
<text/>
</section>
```

Medications Administered Section

[Section: templateId 2.16.840.1.113883.3.88.11.83.115]

The Medications Administered Section contains information about the relevant medications administered to a patient during the course of an encounter.

1. **SHALL** conform to *IHE Medications Administered Section* template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.21)

Medications Administered Section example

```
<?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="1.3.6.1.4.1.19376.1.5.3.1.3.21"/>
  <templateId root="2.16.840.1.113883.3.88.11.83.115"/>
  <id root="626583672"/>
  <code code="18610-6" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="MEDICATION ADMINISTERED"/>
  <title/>
</section>
```

Medications Section

[Section: templateId 2.16.840.1.113883.3.88.11.83.112]

The Medications Section contains information about the relevant medications for the patient. At a minimum, the currently active medications should be listed.

1. **SHALL** conform to *IHE Medications Section* template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.19) (C83-[CT-112-1])
2. **SHALL** contain at least one [1..*] **entry** (C83-[CT-112-2]), such that
 - a. Contains exactly one [1..1] *Medication* (templateId: 2.16.840.1.113883.3.88.11.83.8)

Medications Section example

```
<?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="2.16.840.1.113883.10.20.1.8"/>
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.19"/>
  <templateId root="2.16.840.1.113883.3.88.11.83.112"/>
  <id root="1900088090"/>
  <code code="10160-0" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="History of medication use"/>
  <title/>
  <text/>
</section>
```

Payers Section

[Section: templateId 2.16.840.1.113883.3.88.11.83.101]

The Payers Section contains data on the patient's payers, whether a 'third party' insurance, self-pay, other payer or guarantor, or some combination. At a minimum, the patient's pertinent current payment sources should be listed. If no

payment sources are supplied, the reason shall be supplied as free text in the narrative block (e.g., Not Insured, Payer Unknown, Medicare Pending, et cetera).

1. **SHALL** conform to [IHE Payers Section](#) template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.5.3.7)

Payers Section example

```
<?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="2.16.840.1.113883.10.20.1.9"/>
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.1.5.3.7"/>
  <templateId root="2.16.840.1.113883.3.88.11.83.101"/>
  <id root="2043042126"/>
  <code code="48768-6" codeSystem="2.16.840.1.113883.6.1"
  codeSystemName="LOINC" displayName="Payment sources"/>
  <title/>
  <text/>
</section>
```

Physical Exam Section

[Section: templateId 2.16.840.1.113883.3.88.11.83.118]

The Physical Examination Section contains information describing the physical findings.

1. **SHALL** conform to [IHE Physical Exam Section](#) template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.9.15)

Physical Exam Section example

```
<?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="1.3.6.1.4.1.19376.1.5.3.1.3.24"/>
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.1.9.15"/>
  <templateId root="2.16.840.1.113883.3.88.11.83.118"/>
  <id root="539668493"/>
  <code code="29545-1" codeSystem="2.16.840.1.113883.6.1"
  codeSystemName="LOINC" displayName="PHYSICAL EXAMINATION"/>
  <title/>
</section>
```

Plan Of Care Section

[Section: templateId 2.16.840.1.113883.3.88.11.83.124]

The Plan of Care Section contains information about the expectations for care to be provided including proposed interventions and goals for improving the condition of the patient.

A plan of care section varies from the assessment and plan section defined above in that it does not include a physician assessment of the patient condition.

1. **SHALL** conform to [IHE Care Plan Section](#) template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.31)
2. **SHALL** conform to [CDT Assessment And Plan Section](#) template (templateId: 2.16.840.1.113883.10.20.2.7)
3. **MAY** contain zero or one [0..1] **entry**, such that
 - a. Contains exactly one [1..1] [Medication](#) (templateId: 2.16.840.1.113883.3.88.11.83.8)
4. **MAY** contain zero or one [0..1] **entry**, such that
 - a. Contains exactly one [1..1] [Immunization](#) (templateId: 2.16.840.1.113883.3.88.11.83.13)
5. **MAY** contain zero or one [0..1] **entry**, such that

- a. Contains exactly one [1..1] [Encounter](#) (templateId: 2.16.840.1.113883.3.88.11.83.16)
- 6. **MAY** contain zero or one [0..1] **entry**, such that
 - a. Contains exactly one [1..1] [Procedure](#) (templateId: 2.16.840.1.113883.3.88.11.83.17)

Plan Of Care Section example

```
<?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="2.16.840.1.113883.10.20.1.10"/>
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.31"/>
  <templateId root="2.16.840.1.113883.3.88.11.83.124"/>
  <id root="72879230"/>
  <code code="18776-5" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Treatment plan"/>
  <title/>
  <text/>
</section>
```

Problem List Section

[Section: templateId 2.16.840.1.113883.3.88.11.83.103]

This section lists and describes all relevant clinical problems at the time the document is generated. At a minimum, all pertinent current and historical problems should be listed.

- 1. **SHALL** conform to [IHE Active Problems Section](#) template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.6) (C83-[CT-103-2])
- 2. **SHALL** contain at least one [1..*] **entry** (C83-[CT-103-1]), such that
 - a. Contains exactly one [1..1] [Condition](#) (templateId: 2.16.840.1.113883.3.88.11.83.7)

Problem List Section example

```
<?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="2.16.840.1.113883.10.20.1.11"/>
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.6"/>
  <templateId root="2.16.840.1.113883.3.88.11.83.103"/>
  <id root="897357884"/>
  <code code="11450-4" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Problem list"/>
  <title/>
  <text/>
  <entry>
    <act classCode="ACT" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.1.27"/>
      <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.5.1"/>
      <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.5.2"/>
      <templateId root="2.16.840.1.113883.3.88.11.83.7"/>
      <id root="1117672340"/>
      <code nullFlavor="NA"/>
      <text/>
      <effectiveTime>
        <low value="2011"/>
        <high value="2011"/>
      </effectiveTime>
      <entryRelationship>
        <observation/>
      </entryRelationship>
    </act>
  </entry>
</section>
```



```

    </act>
  </entry>
</section>

```

Reason For Referral Section

[Section: templateId 2.16.840.1.113883.3.88.11.83.106]

The Reason for Referral Section contains information about the reason that the patient is being referred.

1. **SHALL** conform to [IHE Reason For Referral Section](#) template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.1)

Reason For Referral Section example

```

<?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="1.3.6.1.4.1.19376.1.5.3.1.3.1"/>
  <templateId root="2.16.840.1.113883.3.88.11.83.106"/>
  <id root="328596174"/>
  <code code="42349-1" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="REASON FOR REFERRAL"/>
  <title/>
</section>

```

Review Of Systems Section

[Section: templateId 2.16.840.1.113883.3.88.11.83.120]

The Review of Systems Section contains information describing patient responses to questions about the function of various body systems.

1. **SHALL** conform to [IHE Review Of Systems Section](#) template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.18)
2. **SHALL** conform to [CDT Review Of Systems Section](#) template (templateId: 2.16.840.1.113883.10.20.4.10)

Review Of Systems Section example

```

<?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"/>
  <templateId root="2.16.840.1.113883.3.88.11.83.120"/>
  <id root="871559530"/>
  <code code="10187-3" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="REVIEW OF SYSTEMS"/>
  <title/>
</section>

```

Social History Section

[Section: templateId 2.16.840.1.113883.3.88.11.83.126]

The Social History Section contains information about the person's beliefs, home life, community life, work life, hobbies, and risky habits.

1. **SHALL** conform to [IHE Social History Section](#) template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.16)
2. **MAY** contain zero or more [0..*] **entry**, such that

- a. Contains exactly one [1..1] [Social History](#) (templateId: 2.16.840.1.113883.10.20.1.33)

Social History Section example

```
<?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="2.16.840.1.113883.10.20.1.15"/>
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.16"/>
  <templateId root="2.16.840.1.113883.3.88.11.83.126"/>
  <id root="2037233772"/>
  <code code="29762-2" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Social history"/>
  <title/>
  <text/>
</section>
```

Surgeries Section

[Section: templateId 2.16.840.1.113883.3.88.11.83.108]

1. **SHALL** conform to [IHE Coded Surgeries Section](#) template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.12) (C83-[CT-108-1])
2. **SHALL** contain at least one [1..*] **entry** (C83-[CT-108-2]), such that
 - a. Contains exactly one [1..1] [Procedure](#) (templateId: 2.16.840.1.113883.3.88.11.83.17)

Surgeries Section example

```
<?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="2.16.840.1.113883.10.20.1.12"/>
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.11"/>
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.12"/>
  <templateId root="2.16.840.1.113883.3.88.11.83.108"/>
  <id root="222110367"/>
  <code code="47519-4" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="History of procedures"/>
  <title/>
  <text/>
</section>
```

Vital Signs Section

[Section: templateId 2.16.840.1.113883.3.88.11.83.119]

The Vital Signs Section contains information documenting the patient vital signs.

1. **SHALL** conform to [IHE Coded Vital Signs Section](#) template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.5.3.2) (C83-[CT-119-1])
2. **SHALL** satisfy: Contains entries conforming to the Vital Sign module. (C83-[CT-119-2])

- [OCL]: self.entry->exists(entry : cda::Entry | entry.organizer.oclIsKindOf(ihe::VitalSignsOrganizer) and entry.organizer.component.observation->exists(obs : cda::Observation | obs.oclIsKindOf(hitsp::VitalSign)))

Vital Signs Section example

```
<?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="2.16.840.1.113883.10.20.1.16"/>
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.25"/>
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.1.5.3.2"/>
  <templateId root="2.16.840.1.113883.3.88.11.83.119"/>
  <id root="1008978172"/>
  <code code="8716-3" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Vital signs"/>
  <title/>
  <text/>
</section>

```

Chapter

4

CLINICAL STATEMENT TEMPLATES

Topics:

- [*Advance Directive*](#)
- [*Allergy Drug Sensitivity*](#)
- [*Comment*](#)
- [*Condition*](#)
- [*Condition Entry*](#)
- [*Encounter*](#)
- [*Family History*](#)
- [*Immunization*](#)
- [*Insurance Provider*](#)
- [*Medication*](#)
- [*Medication Combination Medication*](#)
- [*Medication Conditional Dose*](#)
- [*Medication Normal Dose*](#)
- [*Medication Order Information*](#)
- [*Medication Split Dose*](#)
- [*Medication Tapered Dose*](#)
- [*Medication Type*](#)
- [*Procedure*](#)
- [*Result*](#)
- [*Result Organizer*](#)
- [*Social History*](#)
- [*Vital Sign*](#)

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.

Advance Directive

Advance Directive example

Allergy Drug Sensitivity

[Act: templateId 2.16.840.1.113883.3.88.11.83.6]

This module contains the allergy or intolerance conditions and the associated adverse reactions suffered by the patient. See the HL7 Continuity of Care Document Section 3.8 for constraints applicable to this module.

1. **SHALL** conform to *IHE Allergy Intolerance Concern* template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.5.3) (C83-[DE-6-CDA-2])
2. **SHOULD** satisfy: the observation/effectiveTime element is present to record event date
 - This is a date that expresses when this particular allergy or intolerance was known to be active for the patient
 - [OCL]: `self.getObservations()->exists(obs : cda::Observation | obs.ocIsKindOf(ccd::AlertObservation) and not obs.effectiveTime.ocIsUndefined())`
3. **SHALL** satisfy: the observation/code element shall be present to record the adverse event type
 - Describes the type of product and intolerance suffered by the patient. The type of product shall be classified with respect to whether the adverse event occurs in relationship with a medication, food, or environmental or other product. The adverse event should also be classified more specifically as an allergy, non-allergy intolerance, or just adverse reaction if that level of detail is not known
 - [OCL]: `self.getObservations()->exists(obs : cda::Observation | obs.ocIsKindOf(ccd::AlertObservation) and not obs.code.ocIsUndefined())`
4. **SHALL** satisfy: the code/@code attribute value is from Allergy/Adverse Event Type Value Set, 2.16.840.1.113883.3.88.12.3221.6.2, version: 20081218, Static (C154-[DE-6.02-1])
 - [OCL]: `self.getObservations()->exists(obs : cda::Observation | obs.ocIsKindOf(ccd::AlertObservation) and not obs.code.ocIsUndefined() and obs.code.codeSystem = '2.16.840.1.113883.3.88.12.3221.6.2')`
5. the observation/participant element **SHOULD** be present
 - [OCL]: `self.getObservations()->exists(obs : cda::Observation | obs.ocIsKindOf(ccd::AlertObservation) and obs.participant->exists(par : cda::Participant2 | not par.ocIsUndefined()))`
6. **SHALL** satisfy: the participant/@typecode attribute shall be 'CSM'
 - [OCL]: `self.getObservations()->exists(obs : cda::Observation | obs.ocIsKindOf(ccd::AlertObservation) and obs.participant->exists(par : cda::Participant2 | not par.ocIsUndefined() implies par.typeCode = vocab::ParticipationType::CSM))`
7. **SHALL** satisfy: the participant/participantRole element may be present
 - [OCL]: `self.getObservations()->exists(obs : cda::Observation | obs.ocIsKindOf(ccd::AlertObservation) and obs.participant->exists(par : cda::Participant2 | not par.ocIsUndefined() implies (par.typeCode = vocab::ParticipationType::CSM and par.participantRole->exists(prole : cda::ParticipantRole | not prole.ocIsUndefined()))))`
8. **SHALL** satisfy: the participant/participantRole/@classcode attribute shall be 'MANU'
 - [OCL]: `self.getObservations()->exists(obs : cda::Observation | obs.ocIsKindOf(ccd::AlertObservation) and`

```
obs.participant->exists( par : cda::Participant2 |
  not par.ocIsUndefined() implies (par.typeCode =
    vocab::ParticipationType::CSM and par.participantRole->exists(prole :
      cda::ParticipantRole | not prole.ocIsUndefined() and
      prole.classCode=vocab::RoleClassRoot::MANU))))
```

9. **SHALL** satisfy: The participant/participantRole/PlayingEntity element may be present

- [OCL]: self.getObservations()->exists(obs : cda::Observation |
 obs.ocIsKindOf(ccd::AlertObservation) and
 obs.participant->exists(par : cda::Participant2 | not
 par.ocIsUndefined() implies (par.typeCode =vocab::ParticipationType::CSM
 and par.participantRole->exists(prole : cda::ParticipantRole | not
 prole.ocIsUndefined() and
 prole.classCode=vocab::RoleClassRoot::MANU and prole.playingEntity-
 >exists(playe : cda::PlayingEntity | not playe.ocIsUndefined())))))

10. **SHALL** satisfy: the participant/participantRole/playingEntity/@classcode attribute shall be 'MMAT'

- [OCL]: self.getObservations()->exists(obs : cda::Observation |
 obs.ocIsKindOf(ccd::AlertObservation) and
 obs.participant->exists(par : cda::Participant2 | not
 par.ocIsUndefined() implies (par.typeCode =vocab::ParticipationType::CSM
 and par.participantRole->exists(prole : cda::ParticipantRole | not
 prole.ocIsUndefined() and
 prole.classCode=vocab::RoleClassRoot::MANU and prole.playingEntity-
 >exists(playe : cda::PlayingEntity | not playe.ocIsUndefined() and
 playe.classCode =vocab::EntityClassRoot::MMAT)))))

11. **SHALL** satisfy: the participant/participantRole/playingEntity/name element is present

- This is the name or other description of the product or agent that causes the intolerance
- [OCL]: self.getObservations()->exists(obs : cda::Observation |
 obs.ocIsKindOf(ccd::AlertObservation) and
 obs.participant->exists(par : cda::Participant2 |
 not par.ocIsUndefined() implies (par.typeCode =
 vocab::ParticipationType::CSM and par.participantRole->exists(prole :
 cda::ParticipantRole | not prole.ocIsUndefined() and
 prole.classCode=vocab::RoleClassRoot::MANU and prole.playingEntity-
 >exists(playe : cda::PlayingEntity | not playe.ocIsUndefined() and
 playe.classCode = vocab::EntityClassRoot::MMAT and playe.name->size() =
 1))))))

12. **SHOULD** satisfy: participant/participantRole/playingEntity/code element is present

- This value is a code describing the product
- [OCL]: self.getObservations()->exists(obs : cda::Observation |
 obs.ocIsKindOf(ccd::AlertObservation) and
 obs.participant->exists(par : cda::Participant2 |
 not par.ocIsUndefined() implies (par.typeCode =
 vocab::ParticipationType::CSM and par.participantRole->exists(prole :
 cda::ParticipantRole | not prole.ocIsUndefined() and
 prole.classCode=vocab::RoleClassRoot::MANU and prole.playingEntity-
 >exists(playe : cda::PlayingEntity | not playe.ocIsUndefined() and
 playe.classCode = vocab::EntityClassRoot::MMAT and playe.code->size() =
 1))))))

13. For participant/participantRole/playingEntity/code element, Food and substance allergies **SHALL** be coded as Ingredient Name Value Set, 2.16.840.1.113883.3.88.12.80.20, Dynamic (C154-[DE-6.04-1])

- [OCL]: self.getObservations()->exists(obs : cda::Observation |
 obs.ocIsKindOf(ccd::AlertObservation) and
 obs.participant->exists(par : cda::Participant2 |
 not par.ocIsUndefined() implies (par.typeCode =
 vocab::ParticipationType::CSM and par.participantRole->exists(prole :
 cda::ParticipantRole | not prole.ocIsUndefined() and
 prole.classCode= vocab::RoleClassRoot::MANU and prole.playingEntity-
 >exists(playe : cda::PlayingEntity | not playe.ocIsUndefined() and

```

playe.classCode = vocab::EntityClassRoot::MMAT and playe.code->size()
= 1 and (playe.code.codeSystem = '2.16.840.1.113883.3.88.12.80.20'
or playe.code.codeSystem = '2.16.840.1.113883.3.88.12.80.17' or
playe.code.codeSystem = '2.16.840.1.113883.3.88.12.80.16')))))))

```

14. For participant/participantRole/playingEntity/code element, Allergies to a class of medication **SHALL** be coded as Medication Drug Class Value Set, 2.16.840.1.113883.3.88.12.80.17, version: 20081218, Dynamic (C154-[DE-6.04-2])

```

• [OCL]: self.getObservations()->exists(obs : cda::Observation |
obs.ocIsKindOf(ccd::AlertObservation) and
obs.participant->exists( par : cda::Participant2 |
not par.ocIsUndefined() implies (par.typeCode =
vocab::ParticipationType::CSM and par.participantRole->exists(prole :
cda::ParticipantRole | not prole.ocIsUndefined() and
prole.classCode= vocab::RoleClassRoot::MANU and prole.playingEntity-
>exists( playe : cda::PlayingEntity | not playe.ocIsUndefined() and
playe.classCode = vocab::EntityClassRoot::MMAT and playe.code->size()
= 1 and (playe.code.codeSystem = '2.16.840.1.113883.3.88.12.80.20'
or playe.code.codeSystem = '2.16.840.1.113883.3.88.12.80.17' or
playe.code.codeSystem = '2.16.840.1.113883.3.88.12.80.16')))))))

```

15. For participant/participantRole/playingEntity/code element, Allergies to a specific medication **SHALL** be coded with Medication Brand Name Value Set, 2.16.840.1.113883.3.88.12.80.16, version: 20081218, Dynamic (C154-[DE-6.04-3])

```

• [OCL]: self.getObservations()->exists(obs : cda::Observation |
obs.ocIsKindOf(ccd::AlertObservation) and
obs.participant->exists( par : cda::Participant2 |
not par.ocIsUndefined() implies (par.typeCode =
vocab::ParticipationType::CSM and par.participantRole->exists(prole :
cda::ParticipantRole | not prole.ocIsUndefined() and
prole.classCode= vocab::RoleClassRoot::MANU and prole.playingEntity-
>exists( playe : cda::PlayingEntity | not playe.ocIsUndefined() and
playe.classCode = vocab::EntityClassRoot::MMAT and playe.code->size()
= 1 and (playe.code.codeSystem = '2.16.840.1.113883.3.88.12.80.20'
or playe.code.codeSystem = '2.16.840.1.113883.3.88.12.80.17' or
playe.code.codeSystem = '2.16.840.1.113883.3.88.12.80.16')))))))

```

16. **SHOULD** satisfy: the text element is present in the Reaction Observation entry

```

• This is the reaction that may be caused by the product or agent
• [OCL]: self.getObservations()->exists(obs : cda::Observation |
obs.ocIsKindOf(ccd::AlertObservation) and obs.getObservations()-
>exists(o : cda::Observation | o.ocIsKindOf(ccd::ReactionObservation) and
not o.text.ocIsUndefined()))

```

17. **SHOULD** satisfy: the code element is present in the Reaction Observation entry

```

• This value is a code describing the reaction
• [OCL]: self.getObservations()->exists(obs : cda::Observation |
obs.ocIsKindOf(ccd::AlertObservation) and obs.getObservations()-
>exists(o : cda::Observation | o.ocIsKindOf(ccd::ReactionObservation) and
not o.code.ocIsUndefined()))

```

18. **SHALL** satisfy: the code element is coded as Problem Value Set, 2.16.840.1.113883.3.88.12.3221.7.4, version: 20100125, Dynamic (C154-[DE-6.06-1])

```

• [OCL]: self.getObservations()->exists(obs : cda::Observation |
obs.ocIsKindOf(ccd::AlertObservation) and obs.getObservations()-
>exists(o : cda::Observation | o.ocIsKindOf(ccd::ReactionObservation)
and not o.code.ocIsUndefined() and o.code.codeSystem =
'2.16.840.1.113883.3.88.12.3221.7.4'))

```

19. **SHOULD** satisfy: The text element is present in the Severity Observation template

- This is a description of the level of severity of the allergy or intolerance
- [OCL]: self.getObservations()->exists(obs : cda::Observation | obs.ocIsKindOf(ccd::AlertObservation) and obs.getObservations()->exists(o : cda::Observation | o.ocIsKindOf(ccd::SeverityObservation) and not o.text.ocIsUndefined()))

20. SHOULD satisfy: the code element is present in the Severity Observation entry

- This value is a code describing the level severity of the allergy or intolerance
- [OCL]: self.getObservations()->exists(obs : cda::Observation | obs.ocIsKindOf(ccd::AlertObservation) and obs.getObservations()->exists(o : cda::Observation | o.ocIsKindOf(ccd::SeverityObservation) and not o.code.ocIsUndefined()))

21. SHALL satisfy: the code element is coded as Problem Severity Value Set, 2.16.840.1.113883.3.88.12.3221.6.8, version: 20081218, Static (C154-[DE-6.08-1])

- [OCL]: self.getObservations()->exists(obs : cda::Observation | obs.ocIsKindOf(ccd::AlertObservation) and obs.getObservations()->exists(o : cda::Observation | o.ocIsKindOf(ccd::SeverityObservation) and not o.code.ocIsUndefined() and o.code.codeSystem = '2.16.840.1.113883.3.88.12.3221.6.8'))

Allergy Drug Sensitivity example

```
<?xml version="1.0" encoding="UTF-8"?>
<act xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd" classCode="ACT" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.1.27"/>
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.5.1"/>
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.5.3"/>
  <templateId root="2.16.840.1.113883.3.88.11.83.6"/>
  <id root="1247369622"/>
  <code nullFlavor="NA"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
</act>
```

Comment

[Act: templateId 2.16.840.1.113883.3.88.11.83.11]

This module contains a comment to be supplied for any other entry Content Modules.

- 1. SHALL** conform to [IHE Comment](#) template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.2) (C83-[DE-10-CDA-3])
- 2. SHALL** contain exactly one [1..1] **author** (C83-[DE-10-CDA-4]), such that
 - The author of a comment is recorded as specified for authors in the Information Source module.
- 3. Data elements** defined elsewhere in the specification **SHALL NOT** be recorded using the Comments Module. (C83-[DE-10-CDA-1])
 - Comments are free text data that cannot otherwise be recorded using data elements already defined by this specification. They are not to be used to record information that can be recorded elsewhere. For example, a free text description of the severity of an allergic reaction would not be recorded in a comment. Instead, it would be recorded using the data element defined in Allergy/Drug Sensitivity.

Comment example

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

```
<act xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd" classCode="ACT" moodCode="EVN">
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.2"/>
  <templateId root="2.16.840.1.113883.3.88.11.83.11"/>
  <id root="757210204"/>
  <code code="48767-8" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC" displayName="Annotation Comment"/>
  <text/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
</act>
```

Condition

[Act: templateId 2.16.840.1.113883.3.88.11.83.7]

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

1. **SHALL** conform to [IHE Problem Concern Entry](#) template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.5.2) (C83-[DE-7-CDA-2])
2. **SHALL** contain at least one [1..*] **entryRelationship**, such that
 - a. Contains **@typeCode="SUBJ"** *SUBJ (has subject)*
 - b. Contains exactly one [1..1] [Condition Entry](#) (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.5)
3. The treating provider or providers **SHALL** be recorded in a <performer> element under the <act> that describes the condition of concern (C83-[DE-7.05-CDA-3])
 - [OCL]: not self.performer->isEmpty()
4. The identifier of the treating provider **SHALL** be present in the <id> element beneath the <assignedEntity>. This identifier **SHALL** be the identifier of one of the providers listed in the healthcare providers module. (C83-[DE-7.05-CDA-2])
 - [OCL]: self.performer->exists(p : cda::Performer2 | p.assignedEntity.id-size() > 0)
5. The time over which this provider treated the condition **MAY** be recorded in the <time> element beneath the <performer> element (C83-[DE-7.05-CDA-1])
 - [OCL]: self.performer->exists(p : cda::Performer2 | p.time.oclIsUndefined())

Condition example

```
<?xml version="1.0" encoding="UTF-8"?>
<act xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd" classCode="ACT" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.1.27"/>
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.5.1"/>
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.5.2"/>
  <templateId root="2.16.840.1.113883.3.88.11.83.7"/>
  <id root="407972766"/>
  <code nullFlavor="NA"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
  <entryRelationship>
```

```

<observation classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.1.28"/>
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.5"/>
  <id root="830293690"/>
  <code code="765781764"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
</observation>
</entryRelationship>
</act>

```

Condition Entry

[Observation: templateId 1.3.6.1.4.1.19376.1.5.3.1.4.5]

This section makes use of the linking, severity, clinical status and comment content specifications defined elsewhere in the technical framework. In HL7 RIM parlance, observations about a problem, complaint, symptom, finding, diagnosis, or functional limitation of a patient is the event (moodCode='EVN') of observing (<observation classCode='OBS'>) that problem. The <value> of the observation comes from a controlled vocabulary representing such things. The <code> contained within the <observation> describes the method of determination from yet another controlled vocabulary.

The basic pattern for reporting a problem uses the CDA <observation> element, setting the classCode='OBS' to represent that this is an observation of a problem, and the moodCode='EVN', to represent that this is an observation that has in fact taken place. The negationInd attribute, if true, specifies that the problem indicated was observed to not have occurred (which is subtly but importantly different from having not been observed). The value of negationInd should not normally be set to true. Instead, to record that there is "no prior history of chicken pox", one would use a coded value indicated exactly that. However, it is not always possible to record problems in this manner, especially if using a controlled vocabulary that does not supply pre-coordinated negations, or which do not allow the negation to be recorded with post-coordinated coded terminology.

1. **SHALL** conform to *IHE Problem Entry* template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.5)
2. **SHOULD** contain exactly one [1..1] **code**, which **SHOULD** be selected from ValueSet
2.16.840.1.113883.3.88.12.3221.7.2 Problem Type **STATIC** 1
3. **SHALL** contain exactly one [1..1] **text**
 - The <text> element is required and points to the text describing the problem being recorded; including any dates, comments, et cetera. The <reference> contains a URI in value attribute. This URI points to the free text description of the problem in the document that is being described.
4. **SHALL** contain exactly one [1..1] **value**, which **SHALL** be selected from ValueSet
2.16.840.1.113883.3.88.12.3221.7.4 Problem **STATIC** 1
 - The <value> is the condition that was found. This element is required. While the value may be a coded or an un-coded string, the type is always a coded value (xsi:type='CD'). If coded, the code and codeSystem attributes shall be present. The codeSystem should reference a controlled vocabulary describing problems, complaints, symptoms, findings, diagnoses, or functional limitations, e.g., ICD-9, SNOMED-CT or MEDCIN, or others.

It is recommended that the codeSystemName associated with the codeSystem, and the displayName for the code also be provided for diagnostic and human readability purposes, but this is not required by this profile.

If uncoded, all attributes other than xsi:type='CD' must be absent.

The <value> contains a <reference> to the <originalText> in order to link the coded value to the problem narrative text (minus any dates, comments, et cetera). The <reference> contains a URI in value attribute. This URI points to the free text description of the problem in the document that is being described.

5. **MAY** contain zero or one [0..1] **entryRelationship** (CONF-160), such that
 - a. Contains @typeCode="SUBJ" SUBJ (has subject)

- b. Contains exactly one [1..1] [CCD Age Observation](#) (templateId: 2.16.840.1.113883.10.20.1.38)
- 6. **MAY** contain zero or one [0..1] **entryRelationship**, such that
 - a. Contains **@typeCode="CAUS"** *CAUS (is etiology for)*
 - b. Contains exactly one [1..1] [CCD Cause Of Death Observation](#) (templateId: 2.16.840.1.113883.10.20.1.42)
- 7. **MAY** contain zero or one [0..1] **entryRelationship**, such that
 - a. Contains **@typeCode="REFR"** *REFR (refers to)*
 - b. Contains exactly one [1..1] [IHE Problem Status Observation](#) (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.1.1)
- 8. The onset date **SHALL** be recorded in the <low> element of the <effectiveTime> element when known. (C83-[DE-7.01-1])
 - [OCL]: `not self.effectiveTime.low.ocIsUndefined()`
- 9. The resolution data **SHALL** be recorded in the <high> element of the <effectiveTime> element when known. (C83-[DE-7.01-2])
 - [OCL]: `not self.effectiveTime.high.ocIsUndefined()`
- 10. If the problem is known to be resolved, but the date of resolution is not known, then the <high> element **SHALL** be present, and the nullFlavor attribute **SHALL** be set to 'UNK'. Therefore, the existence of an <high> element within a problem does indicate that the problem has been resolved. (C83-[DE-7.01-3])
 - [OCL]: `not self.effectiveTime.high.ocIsUndefined()`

Condition Entry example

```
<?xml version="1.0" encoding="UTF-8"?>
<observation xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
  xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
  classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.1.28"/>
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.5"/>
  <id root="1919803384"/>
  <code code="851390642"/>
  <text/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
</observation>
```

Encounter

[Encounter: templateId 2.16.840.1.113883.3.88.11.83.16]

The encounter entry contains data describing the interactions between the patient and clinicians. Interaction includes both in-person and non-in-person encounters such as telephone and e-mail communication.

1. **SHALL** conform to [IHE Encounter Entry](#) template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.14)
2. **SHOULD** contain exactly one [1..1] **code**, which **SHOULD** be selected from ValueSet 2.16.840.1.113883.3.88.12.80.32 EncounterType **DYNAMIC** (C83-[DE-16.02-1])
3. **MAY** contain zero or one [0..1] **priorityCode**, which **MAY** be selected from ValueSet 2.16.840.1.113883.3.88.12.80.33 Admission Type (NUBC) **STATIC** (C154-[DE-16.07-1])
4. participant/@typeCode='ORG'/code **SHALL** be coded with ValueSet 2.16.840.1.113883.3.88.12.80.33, Admission Source Value Set, **STATIC**
5. ClinicalDocument/componentOf/encompassingEncounter/code/@code **SHALL** be coded with ValueSet 2.16.840.1.113883.3.88.12.80.66, Patient Class Value Set, 20090630, **STATIC**
6. The state part of ClinicalDocument/componentOf/encompassingEncounter/location/addr **SHALL** be coded with ValueSet 2.16.840.1.113883.3.88.12.80.1, State Value Set, 20081218, **Dynamic**

7. The country part of ClinicalDocument/componentOf/encompassingEncounter/location/addr **SHALL** be coded with ValueSet 2.16.840.1.113883.3.88.12.80.63, Country Value Set, 20081218, Dynamic
8. The postal code part of ClinicalDocument/componentOf/encompassingEncounter/location/addr **SHALL** be coded with ValueSet 2.16.840.1.113883.3.88.12.80.2, Postal Code Value Set, 20081218, Dynamic
9. **MAY** satisfy: The order to admit time reflects the time of participation of the provider referring the patient to an inpatient setting. The encounter type should reflect that this is an inpatient encounter.

Encounter example

```
<?xml version="1.0" encoding="UTF-8"?>
<encounter xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
  xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
  classCode="ENC" moodCode="EVN">
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.14" />
  <templateId root="2.16.840.1.113883.10.20.1.21" />
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.14" />
  <templateId root="2.16.840.1.113883.3.88.11.83.16" />
  <id root="1779936356" />
  <code codeSystem="2.16.840.1.113883.6.12" codeSystemName="CPT-4" />
  <text/>
  <effectiveTime>
    <low value="2011" />
    <high value="2011" />
  </effectiveTime>
  <priorityCode code="Value" />
</encounter>
```

Family History

[Organizer: templateId 2.16.840.1.113883.3.88.11.83.18]

1. **SHALL** conform to *IHE Family History Organizer* template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.15)
2. **SHOULD** contain zero or more [0..*] **component**, such that
 - a. Contains exactly one [1..1] *IHE Problem Status Observation* (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.1.1)
3. A pedigree image **MAY** be included in an observationMedia element in an entry under the Family History section
4. value/@mediaType element of the observationMedia element **SHALL** be application/pdf, image/jpeg or image/png
5. value/@representation element of the observationMedia element **SHALL** be B64, and the data for the image **SHALL** be included within the value element
6. RelatedSubject/Code (Family Member Relationship to Patient) **SHALL** be coded as 2.16.840.1.113883.1.11.19579, Family Member Value Set, STATIC, V3NE08
7. One RelatedSubject/subject/sdtc:id element **SHALL** be present.
 - Each family member in a family history must be identified to allow for reconciliation of updated family histories when exchanged between providers
8. RelatedSubject/subject/name **SHOULD** be present.
 - The family member name need not be the actual name of the family member. It may be a string (such as aunt1 or aunt2) to help the patient and providers distinguish between different family members with the same relationship to the patient
9. RelatedSubject/subject/administrationGenderCode **SHALL** be code as 2.16.840.1.113883.1.11.1, Administrative Gender Value Set, STATIC, 20081218
10. The race of the family member, when recorded, **SHALL** appear in an RelatedSubject/subject/sdtc:raceCode element.
11. raceCode **SHALL** be coded as 2.16.840.1.113883.1.11.14914, Race Value Set, Dynamic

12. The ethnicity of the family member, when recorded, **SHALL** appear in an RelatedSubject/subject/sdtc:ethnicGroupCode element
13. Ethnicity **SHALL** be coded as 2.16.840.1.113883.1.11.15836, Ethnicity Value Set, Dynamic
14. Family History Condition data elements **SHALL** declare conformance to the IHE Family History Observation entry by including a <templateID> element with the root attribute set to the value 1.3.6.1.4.1.19376.1.5.3.1.4.13.3
15. **SHOULD** satisfy: The age of onset of disease or age at death of a family member should be computable from the family member date of birth and the effective time of the observation of the disease or the death. When that data are not available, the age of the patient at the time of the observation shall be recorded within a condition or test result observation using the CCD Age Observation
16. **SHOULD** satisfy: When a condition is one of the causes of death for the patient, that fact is related using the CCD Cause of Death Observation
17. **MAY** satisfy: The biological sex may be recorded as a IHE Family History Observation to identify the biological sex of the subject where it differs from the administrative gender
18. **MAY** satisfy: Multiple birth status is may be recorded as a IHE Family History observation on the subject when it is relevant for a family member (18.17 Family Member Multiple Birth Status) or the patient (1.13 Multiple Birth Indicator).
19. **MAY** satisfy: Multiple birth order is may be recorded as a IHE Family History observation on the subject when it is relevant for a family member (18.26 - Family Member Multiple Birth Order) or the patient (1.14 - Birth Order). Family Member Age
20. **MAY** satisfy: The age may be recorded as a CCD Age Observation on the subject when it is relevant for a family member (18.23 - Family Member Age) or the patient (1.14 - Age)
21. **MAY** satisfy: Genetic test results may be recorded as Family History observations on the subject
22. Components of a Genetic Laboratory Test **SHALL** be coded as specified in HITSP/C80 Section 2.2.3.11 Genetic Testing

Family History example

Immunization

[SubstanceAdministration: templateId 2.16.840.1.113883.3.88.11.83.13]

1. **SHALL** conform to *IHE Immunization* template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.12)
2. **SHALL** contain zero or one [0..1] **code**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.934 Vaccines administered (CVX) **STATIC 3**
3. The reason for refusal **SHALL** be coded as specified in HITSP/C80 Section 2.2.3.5.3 No Immunization Reason
 - [OCL]: self.entryRelationship->select(er | er.typeCode = vocab::x_ActRelationshipEntryRelationship::RSON and er.act.code.codeSystem <> '2.16.840.1.113883.1.11.19717')->isEmpty()

Immunization example

```
<?xml version="1.0" encoding="UTF-8"?>
<substanceadministration xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
  xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <templateId root="2.16.840.1.113883.10.20.1.24"/>
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.12"/>
  <templateId root="2.16.840.1.113883.3.88.11.83.13"/>
  <id root="1533475457"/>
  <code code="708131749"/>
  <statusCode code="completed"/>
  <effectiveTime value="20110830"/>
  <routeCode code="Value"/>
  <doseQuantity/>
  <rateQuantity/>
  <maxDoseQuantity/>
  <consumable/>
</substanceadministration>
```

Insurance Provider

[Act: templateId 2.16.840.1.113883.3.88.11.83.5]

1. **SHALL** conform to *IHE Coverage Entry* template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.17)

Insurance Provider example

```
<?xml version="1.0" encoding="UTF-8"?>
<act xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-
org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd" classCode="ACT"
moodCode="DEF">
  <templateId root="2.16.840.1.113883.10.20.1.20"/>
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.17"/>
  <templateId root="2.16.840.1.113883.3.88.11.83.5"/>
  <id root="301971587"/>
  <code code="48768-6" codeSystem="2.16.840.1.113883.6.1"
codeSystemName="LOINC" displayName="Payment sources"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
</act>
```

Medication

[SubstanceAdministration: templateId 2.16.840.1.113883.3.88.11.83.8]

1. **SHALL** conform to *IHE Medication* template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.7) (C83- [DE-8-CDA-2])
2. **MAY** contain at least one [1..*] **effectiveTime**, where its data type is IVL_TS (CONF-308)
 - Indicate Medication Stopped: Used to express a "hard stop," such as the last Sig sequence in a tapering dose, where the last sequence is 'then D/C' or where the therapy/drug is used to treat a condition and that treatment is for a fixed duration with a hard stop, such as antibiotic treatment, etc.
 - Administration Timing: defines a specific administration or use time. Can be a text string (Morning, Evening, Before Meals, 1 Hour After Meals, 3 Hours After Meals, Before Bed) or an exact time.
 - Frequency: defines how often the medication is to be administered as events per unit of time. Often expressed as the number of times per day (e.g., four times a day), but may also include event-related information (e.g., 1 hour before meals, in the morning, at bedtime). Complimentary to Interval, although equivalent expressions may have different implications (e.g., every 8 hours versus 3 times a day).
 - Interval: defines how the product is to be administered as an interval of time. For example, every 8 hours. Complimentary to Frequency, although equivalent expressions may have different implications (e.g., every 8 hours versus 3 times a day).
 - Duration: for non-instantaneous administrations, indicates the length of time the administration should be continued. For example, (infuse) over 30 minutes.
3. **MAY** contain at least one [1..*] **routeCode**, which **MAY** be selected from ValueSet 2.16.840.1.113883.3.88.12.3221.8.7 Medication Route FDA **STATIC** 1 (CONF-309, CONF-310)
 - The route is a coded value, and indicates how the medication is received by the patient (by mouth, intravenously, topically, et cetera).
4. **MAY** contain at least one [1..*] **doseQuantity**
 - the amount of the product to be given. This may be a known, measurable unit (e.g., milliliters), an administration unit (e.g., tablet), or an amount of active ingredient (e.g., 250 mg). May define a variable dose, dose range or dose options based upon identified criteria (see Dose Indicator)

5. **MAY** contain exactly one [1..1] **administrationUnitCode**, which **MAY** be selected from ValueSet 2.16.840.1.113883.3.88.12.3221.8.11 Medication Product Form **STATIC** 1 (C154-[DE-8.11-1])
 - The physical form of the product as presented to the patient. For example: tablet, capsule, liquid or ointment
6. **MAY** contain at least one [1..*] **maxDoseQuantity** (CONF-312)
 - defines a maximum or dose limit. This segment can repeat for more than one dose restriction
7. **MAY** contain zero or more [0..*] **approachSiteCode**, which **MAY** be selected from ValueSet 2.16.840.1.113883.3.88.12.3221.8.9 Body Site **STATIC** 2 (C154-[DE-8.09-1])
 - The anatomic site where the medication is administered. Usually applicable to injected or topical products
8. **MAY** contain zero or more [0..*] **code** (C83-[DE-8.12-CDA-1])
 - Delivery Method: A description of how the product is administered/consumed
9. Contains zero or one [0..1] **entryRelationship**, such that
 - a. Contains exactly one [1..1] *Medication Type* (templateId: 2.16.840.1.113883.3.88.11.83.8.1)
10. Contains at least one [1..*] **entryRelationship**, such that
 - a. Contains exactly one [1..1] *Medication Order Information* (templateId: 2.16.840.1.113883.3.88.11.83.8.3)
11. Contains zero or one [0..1] **entryRelationship**, such that
 - Any noted intended or unintended effects of the product. For example: full body rash, nausea, rash resolved
 - a. Contains exactly one [1..1] *CCD Reaction Observation* (templateId: 2.16.840.1.113883.10.20.1.54)
12. **SHALL** satisfy: The time at which the medication was stopped is determined based on the content of the <high> element of the first <effectiveTime> element. (2.2.2.8.3)
13. **SHALL** satisfy: The HL7 data type for PIVL_TS uses the institutionSpecified attribute to indicate whether it is the interval (time between dosing), or frequency (number of doses in a time period) that is important. If institutionSpecified is not present or is set to false, then the time between dosing is important (every 8 hours). If true, then the frequency of administration is important (e.g., 3 times per day). (2.2.2.8.4)
 - defines a specific administration or use time. Can be a text string (Morning, Evening, Before Meals, 1 Hour After Meals, 3 Hours After Meals, Before Bed) or an exact time
14. The first <effectiveTime> **SHALL** use the IVL_TS data type unless for a single administration, in which case, it **SHALL** use the TS data type. (C83-[DE-8-CDA-3])
 - ```
[OCL]: self.effectiveTime->exists (ef : datatypes::SXCM_TS | not ef.ocIsUndefined())
```
15. Medications that are administered based on activities of daily living **SHALL** identify the events that trigger administration in the <event> element beneath the <effectiveTime> element. The <effectiveTime> element **SHALL** be of type EIVL\_TS. (C83-[DE-8.03-CDA-1])
16. Medications that are administered at a specified frequency **SHALL** record the expected interval between doses in the <period> element beneath an <effectiveTime> of type PIVL\_TS. The <effectiveTime> element **SHALL** have an institutionSpecified attribute value of "true". (C83-[DE-8.04-CDA-1])
  - defines how often the medication is to be administered as events per unit of time. Often expressed as the number of times per day (e.g., four times a day), but may also include event-related information (e.g., 1 hour before meals, in the morning, at bedtime). Complimentary to Interval, although equivalent expressions may have different implications (e.g., every 8 hours versus 3 times a day)
17. Medications that are administered at a specified interval **SHALL** record interval between doses in the <period> element beneath an <effectiveTime> element of type PIVL\_TS. The <effectiveTime> element **SHALL** have an institutionSpecified attribute value of "false". (C83-[DE-8.05-CDA-1])
  - defines how the product is to be administered as an interval of time. For example, every 8 hours. Complimentary to Frequency, although equivalent expressions may have different implications (e.g., every 8 hours versus 3 times a day)



18. doseQuantity/@unit, Dose Units **MAY** be present when needed. If present it **SHALL** be coded as 2.16.840.1.113883.3.88.12.80.29 Unit of Measure (C154-[DE-8.08-1])
- `[OCL]: self.doseQuantity->exists(dq : datatypes::IVL_PQ | dq.unit='2.16.840.1.113883.3.88.12.80.29')`
19. When the coded product or brand name describes the strength or concentration of the medication, and the dosing is in administration units (e.g., 1 tablet, 2 capsules), units **SHOULD** contain the preferred name of the presentation units within braces { } using the units of presentation from the NCI Thesaurus (C154-[DE-8.08-2])
20. The free text description of the delivery method **MAY** be included within a <originalText> element beneath the <code> element (C83-[DE-8.12-CDA-2])
- `[OCL]: not self.code.originalText.oclIsUndefined()`
21. **SHALL** satisfy: Contains one consumable element which contains the Medication Information template. The name and code for the medication are recorded in the <consumable> element.
- `[OCL]: self.consumable.manufacturedProduct->exists(mp : cda::ManufacturedProduct | mp.oclIsKindOf(hitsp::MedicationInformation))`
22. The medication status **MAY** be recorded using the CCD Medication Status observation using the value set defined in the CCD (C154-[DE-8.20-1])
- If the medication is Active, Discharged, Chronic, Acute, etc
  - `[OCL]: self.getObservations()->exists(po : cda::Observation | po.oclIsKindOf(ccd::MedicationStatusObservation))`
23. [0..\*] indications **SHALL** be recorded using the Indication problem observation (templateID 2.16.840.1.113883.10.20.1.28) described in the CCD Implementation Guide. (C83-[DE-8.20-CDA-1])
- The medical condition or problem intended to be addressed by the ordered product. For example: for chest pain, for pain, for high blood pressure
  - `[OCL]: self.getObservations()->exists(po : cda::Observation | po.oclIsKindOf(ccd::ProblemObservation))`
24. The indication problem observation **SHALL** contain a <text> element that includes a <reference> element whose value attribute points to the narrative text that is the indication for the medication (C83-[DE-8.20-CDA-2])
- `[OCL]: self.getObservations()->exists(po : cda::Observation | po.oclIsKindOf(ccd::ProblemObservation) and not po.text.reference.oclIsUndefined())`
25. The indication **SHALL** be coded as 2.16.840.1.113883.3.88.12.3221.7.4, Problem Value Set, version: 20100125, Dynamic (C154-[DE-8.20-1])
- `[OCL]: self.getObservations()->exists(po : cda::Observation | po.oclIsKindOf(ccd::ProblemObservation) and po.code.codeSystem = '2.16.840.1.113883.3.88.12.3221.7.4')`
26. Patient Instructions **SHALL** be recorded using the Patient Medication Instructions template (templateID 1.3.6.1.4.1.19376.1.5.3.1.4.3) (C83-[DE-8.22-CDA-1])
- Instructions to the patient that are not traditionally part of the Sig. For example, "keep in the refrigerator." More extensive patient education materials can also be included
  - External patient educational materials can be referenced with an appropriate URL entry in the text/ reference/ value.
  - `[OCL]: self.getActs()->exists(po : cda::Act | po.oclIsKindOf(ihe::PatientMedicalInstructions))`
27. The vehicle for administering a medication **MAY** be recorded in a <participantRole> element inside a <participant> element in the <substanceAdministration> element (C83-[DE-8.24-CDA-1])
- Non-active ingredient(s), or substances not of therapeutic interest, in which the active ingredients are dispersed. Most often applied to liquid products where the major fluid component is considered the vehicle.

For example: Normal Saline is the vehicle in "Ampicillin 150mg in 50ml NS"; Aquaphor is the vehicle in "10% LCD in Aquaphor"

- [OCL]: self.getSubstanceAdministrations()->exists(sa : cda::SubstanceAdministration | sa.participant.participantRole->size() > 0)

28. The typeCode attribute of the <participant> element **SHALL** be CSM (C83-[DE-8.24-CDA-2])

- [OCL]: self.getSubstanceAdministrations()->exists(sa : cda::SubstanceAdministration | sa.participant->exists(par : cda::Participant2 | par.typeCode = vocab::ParticipationType::CSM))

29. The classCode of the <participantRole> **SHALL** be MANU (C83-[DE-8.24-CDA-3])

- [OCL]: self.getSubstanceAdministrations()->exists(sa : cda::SubstanceAdministration | sa.participant->exists(par : cda::Participant2 | par.typeCode = vocab::ParticipationType::CSM and par.participantRole->exists(pr : cda::ParticipantRole | pr.classCode = vocab::RoleClassRoot::MANU)))

30. A <code> element for the <participantRole> **SHALL** be present and **SHALL** contain the code 412307009 from the SNOMED CT code system (C83-[DE-8.24-CDA-4])

- [OCL]: self.getSubstanceAdministrations()->exists(sa : cda::SubstanceAdministration | sa.participant->exists(par : cda::Participant2 | par.typeCode = vocab::ParticipationType::CSM and par.participantRole->exists(pr : cda::ParticipantRole | pr.classCode = vocab::RoleClassRoot::MANU and pr.code.code = '412307009' and pr.code.codeSystem = '2.16.840.1.113883.6.96')))

31. The <name> element in the <playingEntity> element **SHALL** record the name of the drug vehicle (C83-[DE-8.24-CDA-5])

- [OCL]: self.getSubstanceAdministrations()->exists(sa : cda::SubstanceAdministration | sa.participant->exists(par : cda::Participant2 | par.typeCode = vocab::ParticipationType::CSM and par.participantRole->exists(pr : cda::ParticipantRole | pr.classCode = vocab::RoleClassRoot::MANU and pr.code.code = '412307009' and pr.code.codeSystem = '2.16.840.1.113883.6.96' and pr.playingEntity.name->size() > 0)))

32. The <code> element in the <playingEntity> element **MAY** be used to supply a coded term for the drug vehicle (C83-[DE-8.24-CDA-6])

- [OCL]: self.getSubstanceAdministrations()->exists(sa : cda::SubstanceAdministration | sa.participant->exists(par : cda::Participant2 | par.typeCode = vocab::ParticipationType::CSM and par.participantRole->exists(pr : cda::ParticipantRole | pr.classCode = vocab::RoleClassRoot::MANU and pr.code.code = '412307009' and pr.code.codeSystem = '2.16.840.1.113883.6.96' and pr.playingEntity.code->size() > 0)))

33. **SHALL** satisfy: The Medication Vehicle shall be coded as 2.16.840.1.113883.3.88.12.80.21, Medication Vehicle Value Set, version: 20081218, Dynamic (C154-[DE-8.24-1])

- [OCL]: self.getSubstanceAdministrations()->exists(sa : cda::SubstanceAdministration | sa.participant->exists(par : cda::Participant2 | par.typeCode = vocab::ParticipationType::CSM and par.participantRole->exists(pr : cda::ParticipantRole | pr.classCode = vocab::RoleClassRoot::MANU and pr.code.code = '412307009' and pr.code.codeSystem = '2.16.840.1.113883.6.96' and pr.playingEntity.code->size() > 0 and pr.playingEntity.code.codeSystem = '2.16.840.1.113883.3.88.12.80.21')))

### Medication example

```
<?xml version="1.0" encoding="UTF-8"?>
<substanceadministration xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
 <templateId root="2.16.840.1.113883.10.20.1.24"/>
```

```

<templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.7"/>
<templateId root="2.16.840.1.113883.3.88.11.83.8"/>
<id root="918582166"/>
<code code="1618250392"/>
<statusCode code="completed"/>
<effectiveTime value="20110830"/>
<routeCode code="Value"/>
<approachSiteCode code="654775090"/>
<doseQuantity/>
<rateQuantity/>
<maxDoseQuantity/>
<administrationUnitCode code="Value"/>
<consumable/>
</substanceadministration>

```

## Medication Combination Medication

---

[SubstanceAdministration: templateId 2.16.840.1.113883.3.88.11.83.8]

1. **SHALL** conform to [Medication](#) template (templateId: 2.16.840.1.113883.3.88.11.83.8)
2. **SHALL** conform to [IHE Combination Medication](#) template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.11)

### Medication Combination Medication example

```

<?xml version="1.0" encoding="UTF-8"?>
<substanceadministration xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
 <templateId root="2.16.840.1.113883.10.20.1.24"/>
 <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.7"/>
 <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.11"/>
 <templateId root="2.16.840.1.113883.3.88.11.83.8"/>
 <id root="1627073366"/>
 <code code="444888176"/>
 <statusCode code="completed"/>
 <effectiveTime value="20110830"/>
 <routeCode code="Value"/>
 <approachSiteCode code="1680447802"/>
 <doseQuantity/>
 <rateQuantity/>
 <maxDoseQuantity/>
 <administrationUnitCode code="Value"/>
 <consumable/>
</substanceadministration>

```

## Medication Conditional Dose

---

[SubstanceAdministration: templateId 2.16.840.1.113883.3.88.11.83.8]

1. **SHALL** conform to [Medication](#) template (templateId: 2.16.840.1.113883.3.88.11.83.8)
2. **SHALL** conform to [IHE Conditional Dose](#) template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.10)

### Medication Conditional Dose example

```

<?xml version="1.0" encoding="UTF-8"?>
<substanceadministration xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
 <templateId root="2.16.840.1.113883.10.20.1.24"/>
 <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.7"/>
 <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.10"/>
 <templateId root="2.16.840.1.113883.3.88.11.83.8"/>
 <id root="892073322"/>

```

```

<code code="284646573"/>
<statusCode code="completed"/>
<effectiveTime value="20110830"/>
<routeCode code="Value"/>
<approachSiteCode code="779552760"/>
<doseQuantity/>
<rateQuantity/>
<maxDoseQuantity/>
<administrationUnitCode code="Value"/>
<consumable/>
</substanceadministration>

```

## Medication Normal Dose

[SubstanceAdministration: templateId 2.16.840.1.113883.3.88.11.83.8]

1. **SHALL** conform to [Medication](#) template (templateId: 2.16.840.1.113883.3.88.11.83.8)
2. **SHALL** conform to [IHE Normal Dose](#) template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.7.1)

### Medication Normal Dose example

```

<?xml version="1.0" encoding="UTF-8"?>
<substanceadministration xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
 <templateId root="2.16.840.1.113883.10.20.1.24"/>
 <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.7"/>
 <templateId root="2.16.840.1.113883.3.88.11.83.8"/>
 <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.7.1"/>
 <id root="1002257676"/>
 <code code="356969973"/>
 <statusCode code="completed"/>
 <effectiveTime value="20110830"/>
 <routeCode code="Value"/>
 <approachSiteCode code="1430001311"/>
 <doseQuantity/>
 <rateQuantity/>
 <maxDoseQuantity/>
 <administrationUnitCode code="Value"/>
 <consumable/>
</substanceadministration>

```

## Medication Order Information

[Supply: templateId 2.16.840.1.113883.3.88.11.83.8.3]

Order information may be recorded as part of the fulfillment history (moodcode = EVN) or as part of the administration information (moodcode = INT)

1. **SHALL** conform to [IHE Supply Entry](#) template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.7.3) (C83-[DE-8-CDA-7])
2. **MAY** contain exactly one [1..1] **repeatNumber** (CONF-321)
  - The number of times that the ordering provider has authorized the pharmacy to dispense this medication

Please note that the number of fills requested is what is recorded in the document, not the number of refills. The number of refills is simply one less than the number of fills.
3. **MAY** contain exactly one [1..1] **statusCode**, which **MAY** be selected from ValueSet 2.16.840.1.113883.3.88.12.80.64 Medication Fill Status **STATIC** 1 (CONF-319)
  - When supply element has a moodCode attribute set to EVN
4. The order number, i.e., the identifier from the perspective of the ordering provider, **SHOULD** be recorded in the id element within the supply element with moodcode = 'INT' (C83-[DE-8.26-CDA-1])

- The order identifier from the perspective of the ordering clinician. Also known as the 'placer number' versus the pharmacies prescription number (or 'filler number')
  - [OCL]: `self.moodCode = vocab::x_DocumentSubstanceMood::INT implies self.id->size() > 0`
5. **SHOULD** satisfy: The effectiveTime/high element is present to record the order expiration date and time when supply/@moodcode = INT
    - The date, including time if applicable, when the order is no longer valid. Dispenses and administrations are not continued past this date for an order instance
    - [OCL]: `self.moodCode = vocab::x_DocumentSubstanceMood::INT implies not self.effectiveTime->select(et | et.value.oclIsUndefined())->isEmpty()`
  6. The quantity ordered **SHALL** be recorded in the value attribute of quantity element inside a supply element used to record order information (C83-[DE-8.26-CDA-1])
    - The amount of product indicated by the ordering provider to be dispensed. For example, number of dosage units or volume of a liquid substance. Note: this is comprised of both a numeric value and a unit of measure
    - [OCL]: `not self.quantity.value.oclIsUndefined()`
  7. **SHALL** satisfy: the @unit attribute of quantity element is present (C83-[DE-8.26-CDA-2])
    - [OCL]: `not self.quantity.unit.oclIsUndefined()`
  8. When the quantity ordered or dispensed is in other than administration units (e.g., when the quantity ordered is a volume of liquid or mass of substance) units **SHALL** be coded as 2.16.840.1.113883.3.88.12.80.29, Unit of Measure, Dynamic (C83-[DE-8.26-CDA-3], C83-[DE-8.38-CDA-2])
  9. When the quantity ordered or dispensed is in administration units, the unit attribute **SHOULD** contain the preferred name of the presentation units within braces { } using the units of presentation as 2.16.840.1.113883.3.88.12.3221.8.11, Medication Product Form Value Set, Dynamic (C83-[DE-8.26-CDA-4], C83-[DE-8.38-CDA-3])
  10. The prescription number **SHALL** be recorded in the extension attribute of the <id> element within a supply element having a moodCode attribute of EVN (C83-[DE-8.34-CDA-1])
    - The prescription identifier assigned by the pharmacy
    - [OCL]: `self.moodCode = vocab::x_DocumentSubstanceMood::EVN implies not self.id->isEmpty()`
  11. The root attribute of the id element **SHOULD** be the OID of the assigning authority for the identifier. (C83-[DE-8.34-CDA-2])
    - determining the assigning authority is not feasible in all settings.
    - [OCL]: `self.id.root->size() > 0`
  12. A GUID **MAY** be used in place of the OID of the assigning authority (C83-[DE-8.34-CDA-3])
  13. **SHALL** satisfy: The dispense date is recorded in effectiveTime element within a supply element with a moodCode attribute set to EVN
    - The date of this dispense
    - [OCL]: `self.moodCode = vocab::x_DocumentSubstanceMood::EVN implies self.effectiveTime->size() > 0`
  14. **MAY** satisfy: The dispensing pharmacy's location is present in the addr element in performer/assignEntity element inside a supply element with a moodCode attribute set to EVN
    - [OCL]: `self.moodCode = vocab::x_DocumentSubstanceMood::EVN implies self.performer->select(p | p.assignedEntity.addr->isEmpty())->isEmpty()`
  15. The state element of the performer/assignedEntity/addr element in the United States **SHALL** be recorded using 2.16.840.1.113883.3.88.12.80.1, State Value Set, version: 20081218, Dynamic (C154-[DE-8.36-1])
  16. The postalCode element of the performer/assignedEntity/addr element in the United States **SHALL** be recorded using 2.16.840.1.113883.3.88.12.80.2, Postal Code Value Set, version: 20081218, Dynamic (C154-[DE-8.36-2])
  17. The country element of the performer/assignedEntity/addr element in the United States **SHALL** be recorded using 2.16.840.1.113883.3.88.12.80.3, Country Value Set, version: 20081218, Dynamic (C154-[DE-8.36-3])

18. The quantity dispensed **SHALL** be recorded in the value attribute of quantity element inside a supply element with a moodCode attribute set to EVN

- The actual quantity of product supplied in this dispense. Note: This is comprised of both a numeric value and a unit of measure
- [OCL]: self.moodCode = vocab::x\_DocumentSubstanceMood::EVN implies not self.quantity.value.ocIsUndefined()

19. The fill number **SHOULD** be recorded in the sequenceNumber attribute of a entryRelationship element with a typeCode attribute set to COMP (C83-[DE-8.39-CDA-1])

- The fill number for the history entry. The fill number identifies the supply (dispense) event as a distinct activities against the prescription.
- [OCL]: self.entryRelationship->select(er | er.typeCode = vocab::x\_ActRelationshipEntryRelationship::COMP and er.sequenceNumber.ocIsUndefined())->isEmpty()

#### Medication Order Information example

## Medication Split Dose

[SubstanceAdministration: templateId 2.16.840.1.113883.3.88.11.83.8]

1. **SHALL** conform to [Medication](#) template (templateId: 2.16.840.1.113883.3.88.11.83.8)
2. **SHALL** conform to [IHE Split Dose](#) template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.9)

#### Medication Split Dose example

```
<?xml version="1.0" encoding="UTF-8"?>
<substanceadministration xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
 <templateId root="2.16.840.1.113883.10.20.1.24"/>
 <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.7"/>
 <templateId root="2.16.840.1.113883.3.88.11.83.8"/>
 <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.9"/>
 <id root="2091176612"/>
 <code code="1029670314"/>
 <statusCode code="completed"/>
 <effectiveTime value="20110830"/>
 <routeCode code="Value"/>
 <approachSiteCode code="480218151"/>
 <doseQuantity/>
 <rateQuantity/>
 <maxDoseQuantity/>
 <administrationUnitCode code="Value"/>
 <consumable/>
</substanceadministration>
```

## Medication Tapered Dose

[SubstanceAdministration: templateId null]

1. **SHALL** conform to [Medication](#) template (templateId: 2.16.840.1.113883.3.88.11.83.8)
2. **SHALL** conform to [IHE Tapered Dose](#) template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.8)

#### Medication Tapered Dose example

```
<?xml version="1.0" encoding="UTF-8"?>
<substanceadministration xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
 <templateId root="2.16.840.1.113883.10.20.1.24"/>
```

```

<templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.7"/>
<templateId root="2.16.840.1.113883.3.88.11.83.8"/>
<templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.8"/>
<templateId root="null"/>
<id root="603234973"/>
<code code="1635865673"/>
<statusCode code="completed"/>
<effectiveTime value="20110830"/>
<routeCode code="Value"/>
<approachSiteCode code="496887056"/>
<doseQuantity/>
<rateQuantity/>
<maxDoseQuantity/>
<administrationUnitCode code="Value"/>
<consumable/>
</substanceadministration>

```

## Medication Type

[Observation: templateId 2.16.840.1.113883.3.88.11.83.8.1]

A classification based on how the medication is marketed (e.g., prescription, over the counter drug)

1. **SHALL** contain exactly one [1..1] **code**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.3.88.12.3221.8.19 Medication Type **STATIC** 1 (C83-[DE-8.19-CDA-5], C154-[DE-8.19-1])

### Medication Type example

## Procedure

[Procedure: templateId 2.16.840.1.113883.3.88.11.83.17]

Defines a coded entry describing a procedure performed on a patient.

1. **SHALL** conform to *IHE Procedure Entry* template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.19)
2. **SHOULD** contain exactly one [1..1] **targetSiteCode**, which **SHOULD** be selected from ValueSet 2.16.840.1.113883.3.88.12.3221.8.9 Body Site **STATIC** 2 (C83-[DE-17-CDA-3])
  - The anatomical site where a procedure is performed
3. **SHOULD** contain exactly one [1..1] **code** (CONF-433)
4. **SHALL** satisfy: The code/originalText/reference/@value is present.
  - Free text describing the Procedure
  - [OCL]: `not self.code.originalText.reference.value.ocIsUndefined()`
5. **SHOULD** satisfy: Contains the procedure provider in performer / assignedEntity.
  - Name and other information for the person or organization performed or hosted the Procedure
  - [OCL]: `self.performer->forall(perf : cda::Performer2 | not perf.ocIsUndefined() and perf.assignedEntity->size() > 0)`

### Procedure example

Unable to create XML Snippet

## Result

[Observation: templateId 2.16.840.1.113883.3.88.11.83.15]

This clinical statement represents details of a lab, radiology, or other study performed on a patient. The scope of result observations is broad with the exception of "vital signs" which are contained in the Vital Signs section.

1. **SHALL** conform to *CCD Result Observation* template (templateId: 2.16.840.1.113883.10.20.1.31) (C83-[DE-15-CDA-3])
2. **SHALL** conform to *IHE Simple Observation* template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.13) (C83-[DE-15-CDA-2])
3. **SHALL** contain exactly one [1..1] **code**
  - a. Result Type **SHOULD** be selected from LOINC (codeSystem 2.16.840.1.113883.6.1) or SNOMED CT (codeSystem 2.16.840.1.113883.6.96) (C154-[DE-15.03-1])
    - [OCL]: self.code.codeSystem = '2.16.840.1.113883.6.1' or self.code.codeSystem = '2.16.840.1.113883.6.96'
  - b. Result Type for laboratory results **SHOULD** be coded as specified in HITSP/C80 Section 2.2.3.6.1 Laboratory Observations. (C154-[DE-15.03-2])
    - [OCL]: self.code.codeSystem = '2.16.840.1.113883.6.1'
4. **SHALL** contain exactly one [1..1] **effectiveTime**
  - Represents clinically effective time of the measurement, which may be when the measurement was performed (e.g., a BP measurement), or may be when sample was taken (and measured some time afterwards).
5. **SHALL** contain exactly one [1..1] **value**
  - The Result value records the desired result in a goal or recorded event, and will not be present when recording an intent, request or proposal to measure a result.
  - a. Result Value **SHALL** be present when the observation/@moodCode is EVN or GOL, and **SHALL NOT** be present when observation/@moodCode is INT or PRP. (C83-[DE-15.05-CDA-1])
    - [OCL]: (self.moodCode = vocab::x\_ActMoodDocumentObservation::EVN or self.moodCode = vocab::x\_ActMoodDocumentObservation::EVN) implies (not self.value->isEmpty()) and (self.moodCode = vocab::x\_ActMoodDocumentObservation::INT or self.moodCode = vocab::x\_ActMoodDocumentObservation::PRP) implies (self.value->isEmpty())

### Result example

```
<?xml version="1.0" encoding="UTF-8"?>
<observation xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 moodCode="EVN">
 <templateId root="2.16.840.1.113883.10.20.1.31"/>
 <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.13"/>
 <templateId root="2.16.840.1.113883.3.88.11.83.15"/>
 <id root="31244074"/>
 <code code="717302251"/>
 <statusCode code="completed"/>
 <effectiveTime>
 <low value="2011"/>
 <high value="2011"/>
 </effectiveTime>
 <interpretationCode code="Value"/>
 <methodCode code="Value"/>
</observation>
```



## Result Organizer

---

[Organizer: templateId 2.16.840.1.113883.10.20.1.32]

Non-template subclass of CCD ResultOrganizer that requires entire to be HITSP Result.

1. **SHALL** conform to *CCD Result Organizer* template (templateId: 2.16.840.1.113883.10.20.1.32)
2. **SHALL** contain at least one [1..\*] **component**, such that
  - a. Contains exactly one [1..1] *Result* (templateId: 2.16.840.1.113883.3.88.11.83.15)

### Result Organizer example

## Social History

---

[Observation: templateId 2.16.840.1.113883.10.20.1.33]

1. **SHALL** conform to *IHE Social History Observation* template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.13.4)
2. **SHOULD** contain zero or more [0..\*] **code**, which **SHOULD** be selected from ValueSet 2.16.840.1.113883.3.88.12.80.60 Social History Type **STATIC 1**
3. **SHOULD** contain zero or one [0..1] **effectiveTime**
4. **SHALL** contain exactly one [1..1] **text**

### Social History example

## Vital Sign

---

[Observation: templateId 2.16.840.1.113883.3.88.11.83.14]

These entries are used to record current and relevant historical vital signs for the patient. Vital Signs are a subset of **Results Section**, but are reported in this section to follow clinical conventions.

The differentiation between Vital Signs and Results varies by clinical context. Common examples of vital signs include temperature, height, weight, blood pressure, etc. However, some clinical contexts may alter these common vitals, for example in neonatology "height" may be replaced by "crown-to-rump" measurement.

1. **SHALL** conform to *IHE Vital Sign Observation* template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.13.2) (C83-[DE-14-CDA-2])
2. **SHALL** contain exactly one [1..1] **code**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.3.88.12.80.62 Vital Sign Result **STATIC 1** (C154-[DE-14.03-1])
3. **SHALL** satisfy: Data Element Definitions for Results [Placeholder]
  - Vital Signs are a subset of Results Section, but are reported in this section to follow clinical conventions.

### Vital Sign example

```
<?xml version="1.0" encoding="UTF-8"?>
<observation xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd"
 moodCode="EVN">
 <templateId root="2.16.840.1.113883.10.20.1.31"/>
 <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.13"/>
 <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.13.2"/>
```

```
<templateId root="2.16.840.1.113883.3.88.11.83.14"/>
<id root="521796036"/>
<code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
<statusCode code="completed"/>
<effectiveTime>
 <low value="2011"/>
 <high value="2011"/>
</effectiveTime>
<interpretationCode code="Value"/>
<methodCode code="Value"/>
<targetSiteCode code="568878188"/>
</observation>
```

---

# Chapter

# 5

---

## OTHER CLASSES

---

### Topics:

- *Healthcare Provider*
- *Language Spoken*
- *Medication Information*
- *Support*
- *Support Guardian*
- *Support Participant*

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

## Healthcare Provider

---

[Performer1: templateId 2.16.840.1.113883.3.88.11.83.4]

1. **SHALL** conform to *IHE Healthcare Providers Pharmacies* template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.2.3)

### Healthcare Provider example

```
<?xml version="1.0" encoding="UTF-8"?>
<performer1 xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
 <templateId root="1.3.6.1.4.1.19376.1.5.3.1.2.3"/>
 <templateId root="2.16.840.1.113883.3.88.11.83.4"/>
 <time>
 <low value="2011"/>
 <high value="2011"/>
 </time>
 <assignedEntity/>
</performer1>
```

## Language Spoken

---

[LanguageCommunication: templateId 2.16.840.1.113883.3.88.11.83.2]

1. **SHALL** conform to *IHE Language Communication* template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.2.1) (C83-[DE-2.01-CDA-3])
2. **SHALL** contain exactly one [1..1] **languageCode**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.11526 Language **DYNAMIC** (C154-[DE-2.01-1])
3. **SHALL** contain zero or one [0..1] **modeCode**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.12249 LanguageAbilityMode **STATIC** 1 (C83-[DE-2.01-CDA-4])
  - Mode codes **SHALL** be appropriate to the type of language. Thus English, as spoken in the U.S. **SHOULD** use the code en-US and **SHOULD** only use mode codes for written and verbal communications. On the other hand, American Sign Language would be represented using the code sign-US, and would only use mode codes for signed communication.
4. **SHALL** satisfy: Languages spoken shall be recorded using the <languageCommunication> infrastructure class associated with the patient. The <languageCommunication> element describes the primary and secondary languages of communication for a person. (C83-[DE-2.01-CDA-1])
5. **SHALL** satisfy: Sign language is treated as a separate language. (C154-[DE-2.01-2])
6. CDA allows for use of proficiencyLevelCode element, but this element **SHOULD NOT** be used. (C83-[DE-2.01-CDA-5])
  - Judgments about language proficiency are subjective, and could have a negative impact on consumers.
  - [OCL]: `self.proficiencyLevelCode.ocIsUndefined()`

### Language Spoken example

Unable to create XML Snippet

## Medication Information

---

[ManufacturedProduct: templateId 2.16.840.1.113883.3.88.11.83.8.2]

The product concentration is determined from the coded product or brand name using knowledge base information in the vocabularies specified for these fields, and therefore this information is not explicitly included.

1. **SHALL** conform to *IHE Product Entry* template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.4.7.2) (C83-[DE-8-CDA-4])
2. The coded product name **SHALL** appear in the @code attribute of the manufacturedMaterial/code element. (C83-[DE-8.13-CDA-1])
  - A code describing the product from a controlled vocabulary
  - [OCL]: `not self.manufacturedMaterial.code.code.ocIsUndefined()`
3. If the code for the generic product is unknown, the code and codeSystem attributes **MAY** be omitted (C83-[DE-8.13-CDA-2])
4. The coded product name **SHALL** be coded as 2.16.840.1.113883.3.88.12.80.17, Medication Clinical Drug Name Value Set, version: 20081218, Dynamic (C154-[DE-8.13-1])
  - [OCL]: `self.manufacturedMaterial.code.codeSystem = '2.16.840.1.113883.3.88.12.80.17'`
5. When only the class of the drug is known (e.g., Beta Blocker or Sulfa Drug), it **SHALL** be coded as 2.16.840.1.113883.3.88.12.80.18, Medication Drug Class Value Set, version: 20081218, Dynamic (C154-[DE-8.13-2])
  - [OCL]: `self.manufacturedMaterial.code.codeSystem = '2.16.840.1.113883.3.88.12.80.18'`
6. When only the medication ingredient name is know, the coded product name **MAY** be coded as 2.16.840.1.113883.3.88.12.80.20, Ingredient Name Value Set, Dynamic (C154-[DE-8.13-3])
  - [OCL]: `self.manufacturedMaterial.code.codeSystem = '2.16.840.1.113883.3.88.12.80.20'`
7. The code for the specific brand of product **SHALL** appear in a manufacturedMaterial/translation element (C83-[DE-8.14-CDA-1])
  - A code describing the product as a branded or trademarked entity from a controlled vocabulary
  - [OCL]: `self.manufacturedMaterial.code.translation->size() > 0`
8. The brand name **SHALL** be coded as 2.16.840.1.113883.3.88.12.80.16, Medication Brand Name Value Set, version: 20081218, Dynamic, **OR SHALL** be coded as 2.16.840.1.113883.3.88.12.80.19, Medication Packaged Product Value Set, Dynamic (C154-[DE-8.14-1])
  - [OCL]: `self.manufacturedMaterial.code.codeSystem = '2.16.840.1.113883.3.88.12.80.16'`
9. The product (generic) name **SHALL** appear in the originalText element beneath the manufacturedMaterial/code element (C83-[DE-8.15-CDA-1])
  - The name of the substance or product without reference to a specific vendor (e.g., generic or other non-proprietary name). If a Coded Product Name is present, this is the text associated with the coded concept
  - [OCL]: `not self.manufacturedMaterial.code.originalText.ocIsUndefined()`
10. The brand name **SHALL** appear in the <name> element of the <manufacturedMaterial> element (C83-[DE-8.14-CDA-2])
  - The branded or trademarked name of the substance or product. If a Coded Brand Name is present, this is the text associated with the coded concept
  - [OCL]: `not self.manufacturedMaterial.name.ocIsUndefined()`

### Medication Information example

## Support

At a minimum, key support contacts relative to healthcare decisions, including next of kin, should be included. If no healthcare providers are supplied, the reason should be supplied as free text in the narrative block (e.g., Unknown, etc).

1. **SHALL** conform to *IHE Patient Contact*

**Support example**

## Support Guardian

---

[Guardian: templateId 2.16.840.1.113883.3.88.11.83.3]

At a minimum, key support contacts relative to healthcare decisions, including next of kin, should be included. If no healthcare providers are supplied, the reason should be supplied as free text in the narrative block (e.g., Unknown, etc).

1. **SHALL** conform to *IHE Patient Contact Guardian* template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.2.4)
2. **SHALL** conform to *Support*

**Support Guardian example**

## Support Participant

---

[Participant1: templateId 2.16.840.1.113883.3.88.11.83.3]

At a minimum, key support contacts relative to healthcare decisions, including next of kin, should be included. If no healthcare providers are supplied, the reason should be supplied as free text in the narrative block (e.g., Unknown, etc).

1. **SHALL** conform to *IHE Patient Contact Participant* template (templateId: 1.3.6.1.4.1.19376.1.5.3.1.2.4)
2. **SHALL** conform to *Support*

**Support Participant example**

---

# Chapter

# 6

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## VALUE SETS

---

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





## REFERENCES

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

