Implementation Guide for CDA Release 2
IHE Patient Care Coordination (PCC)

Revision 6.0

DRAFT: FOR DEVELOPMENT USE ONLY

Contents

Acknowledgments

Revision History

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

Chapter 1

INTRODUCTION

Topics:

Overview

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

Integrating the Healthcare Enterprise (IHE) is an initiative designed to stimulate the integration of the information systems that support modern healthcare institutions. Its fundamental objective is to ensure that in the care of patients all required information for medical decisions is both correct and available to healthcare professionals. The IHE initiative is both a process and a forum for encouraging integration efforts. It defines a technical framework for the implementation of established messaging standards to achieve specific clinical goals. It includes a rigorous testing process for the implementation of this framework. And it organizes educational sessions and exhibits at major meetings of medical professionals to demonstrate the benefits of this framework and encourage its adoption by industry and users.

The approach employed in the IHE initiative is not to define new integration standards, but rather to support the use of existing standards, HL7, DICOM, IETF, and others, as appropriate in their respective domains in an integrated manner, defining configuration choices when necessary. When clarifications or extensions to existing standards are necessary, IHE refers recommendations to the relevant standards bodies.

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 `templateId`s 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 `templateId`s).

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

Figure 4: ClinicalDocument example

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

Chapter 2

DOCUMENT TEMPLATES

Topics:

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

Discharge Summary

[ClinicalDocument: templateId `1.3.6.1.4.1.19376.1.5.3.1.1.4`]

1. **SHALL** conform to *Medical Summary* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.1.2`)
2. **SHALL** contain exactly one [1..1] **`code`** (CodeSystem: `2.16.840.1.113883.6.1 LOINC`)
3. **SHALL** contain exactly one [1..1] **`component`**, such that
   a. Contains exactly one [1..1] *Active Problems Section* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.3.6`)

Discharge 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="2.16.840.1.113883.10.20.3"/>
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.1.1"/>
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.1.2"/>
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.1.4"/>
  <id root="1361976085"/>
  <code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
  <title/>
  <effectiveTime/>
  <confidentialityCode code="Value"/>
  <languageCode/>
  <recordTarget>
    <realmCode/>
    <typeId root="2.16.840.1.113883.1.3"/>
    <patientRole/>
  </recordTarget>
  <author>
    <realmCode/>
    <typeId root="2.16.840.1.113883.1.3"/>
    <time/>
    <assignedAuthor/>
  </author>
  <custodian/>
  <component>
    <structuredBody>
      <component>
        <section>
          <realmCode/>
          <typeId root="2.16.840.1.113883.1.3"/>
          <templateId root="2.16.840.1.113883.10.20.1.11"/>
          <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.6"/>
          <id root="527395545"/>
          <code code="11450-4" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="Problem list"/>
          <title/>
          <languageCode/>
          <entry>
            <act/>
          </entry>
        </section>
      </component>
    </structuredBody>
  </component>
</ClinicalDocument>
```

Medical Document

[ClinicalDocument: templateId `1.3.6.1.4.1.19376.1.5.3.1.1.1`]

1. **SHALL** conform to *CDT General Header Constraints* template (templateId: `2.16.840.1.113883.10.20.3`)

Medical Document 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="2.16.840.1.113883.10.20.3"/>
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.1.1"/>
  <id root="444108228"/>
  <code code="Value"/>
  <title/>
  <effectiveTime/>
  <confidentialityCode code="Value"/>
  <languageCode/>
  <recordTarget>
    <realmCode/>
    <typeId root="2.16.840.1.113883.1.3"/>
    <patientRole/>
  </recordTarget>
  <author>
    <realmCode/>
    <typeId root="2.16.840.1.113883.1.3"/>
    <time/>
    <assignedAuthor/>
  </author>
  <custodian/>
  <component/>
</ClinicalDocument>
```

Medical Summary

[ClinicalDocument: templateId `1.3.6.1.4.1.19376.1.5.3.1.1.2`]

1. **SHALL** conform to *Medical Document* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.1.1`)
2. **SHALL** contain exactly one [1..1] **code** (CodeSystem: `2.16.840.1.113883.6.1 LOINC`)
3. **SHALL** satisfy: MedicalSummaryProblemConcernEntry
   - `[OCL]: self.getSections()->exists(sect : cda::Section | sect.getActs()->exists(act : cda::Act | act.oclIsKindOf(ihe::ProblemConcernEntry)))`
4. **SHALL** satisfy: MedicalSummaryAllergyConcernEntry
   - `[OCL]: self.getSections()->exists(sect : cda::Section | sect.getActs()->exists(act : cda::Act | act.oclIsKindOf(ihe::AllergyIntoleranceConcern)))`
5. **SHALL** satisfy: MedicalSummaryMedications
   - `[OCL]: self.getSections()->exists(sect : cda::Section | sect.getSubstanceAdministrations()->exists(sub : cda::SubstanceAdministration | sub.oclIsKindOf(ihe::Medication)))`

Medical 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="2.16.840.1.113883.10.20.3"/>
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.1.1"/>
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.1.2"/>
  <id root="51751251"/>
  <code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
  <title/>
  <effectiveTime/>
  <confidentialityCode code="Value"/>
  <languageCode/>
  <recordTarget>
    <realmCode/>
    <typeId root="2.16.840.1.113883.1.3"/>
    <patientRole/>
  </recordTarget>
  <author>
    <realmCode/>
    <typeId root="2.16.840.1.113883.1.3"/>
    <time/>
    <assignedAuthor/>
  </author>
  <custodian/>
  <component/>
</ClinicalDocument>
```

PHR Extract

[ClinicalDocument: templateId `1.3.6.1.4.1.19376.1.5.3.1.1.5`]

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

PHR Extract 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="2.16.840.1.113883.10.20.3"/>
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.1.1"/>
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.1.2"/>
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.1.5"/>
  <id root="376515751"/>
  <code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
  <title/>
  <effectiveTime/>
  <confidentialityCode code="Value"/>
  <languageCode/>
  <recordTarget>
    <realmCode/>
    <typeId root="2.16.840.1.113883.1.3"/>
    <patientRole/>
  </recordTarget>
  <author>
    <realmCode/>
    <typeId root="2.16.840.1.113883.1.3"/>
    <time/>
    <assignedAuthor/>
  </author>
  <custodian/>
  <component/>
</ClinicalDocument>
```

PHR Update

[ClinicalDocument: templateId `1.3.6.1.4.1.19376.1.5.3.1.1.6`]

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

PHR Update 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="2.16.840.1.113883.10.20.3"/>
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.1.1"/>
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.1.2"/>
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.1.6"/>
  <id root="1788691222"/>
  <code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
  <title/>
  <effectiveTime/>
  <confidentialityCode code="Value"/>
  <languageCode/>
  <recordTarget>
    <realmCode/>
    <typeId root="2.16.840.1.113883.1.3"/>
    <patientRole/>
  </recordTarget>
  <author>
    <realmCode/>
    <typeId root="2.16.840.1.113883.1.3"/>
    <time/>
    <assignedAuthor/>
  </author>
  <custodian/>
  <component/>
</ClinicalDocument>
```

Scanned Document

[ClinicalDocument: templateId `1.3.6.1.4.1.19376.1.2.20`]

A variety of legacy paper, film, electronic and scanner outputted formats are used to store and exchange clinical documents. These formats are not designed for healthcare documentation, and furthermore, do not have a uniform mechanism to store healthcare metadata associated with the documents, including patient identifiers, demographics, encounter, order or service information. The association of structured, healthcare metadata with this kind of document is important to maintain the integrity of the patient health record as managed by the source system. It is necessary to provide a mechanism that allows such source metadata to be stored with the document.

1. **SHALL** contain exactly one [1..1] **`code`**
   - Entered by operator or appropriately fixed for scanned content.
2. **SHALL** contain exactly one [1..1] **`confidentialityCode`**
   - Assigned by the operator in accordance with the scanning facility policy. The notion or level of confidentiality in the header may not be the same as that in the Affinity Domain, but in certain cases could be used to derive a confidentiality value among those specified by the Affinity Domain. Attributes @code and @codeSystem shall be present.
3. **SHALL** contain exactly one [1..1] **`effectiveTime`**

- Denotes the time at which the original content was scanned. At a minimum, the time shall be precise to the day and shall include the time zone offset from GMT.

4. **SHALL** contain exactly one [1..1] **`id`**
   - The root attribute shall contain the oid for the document, in which case the extension attribute shall be empty, or an oid that scopes the set of possible unique values for the extension attribute, in which case the extension shall be populated with a globally unique identifier within the scope of the root oid.
5. **SHALL** contain exactly one [1..1] **`languageCode`**
   - Denotes the language used in the character data of the wrapper CDA header. If the scanned content, when rendered, is in a language different than that of the header, the language context of the CDA will be overwritten at the body level (see ITI TF-3: 5.2.3.9 ClinicalDocument/component/nonXMLBody for an example). Attribute @code shall be present.
6. **SHOULD** contain exactly one [1..1] **`title`**
   - Entered by operator, or possibly can be taken from the scanned content.
7. **SHALL** contain exactly one [1..1] **`typeId`**
8. **SHOULD** contain at least one [1..*] **`scanOriginalAuthor`**, such that
   a. Contains exactly one [1..1] *Scan Original Author* (templateId: `1.3.6.1.4.1.19376.1.2.20.1`)
9. **SHALL** contain at least one [1..*] **`scanningDevice`**, such that
   a. Contains exactly one [1..1] *Scanning Device* (templateId: `1.3.6.1.4.1.19376.1.2.20.2`)
10. **SHALL** contain exactly one [1..1] **`scanDataEnterer`**, such that
    a. Contains exactly one [1..1] *Scan Data Enterer* (templateId: `1.3.6.1.4.1.19376.1.2.20.3`)
11. **MAY** contain zero or one [0..1] **`legalAuthenticator`**, such that
    - Context is left up to the scanning facility to refine in accordance with local policies.
12. **MAY** contain zero or one [0..1] **`documentationOf`**, such that
    - Used to encode the date/time range of the original content. If the original content is representative of a single point in time then the endpoints of the date/time range shall be the same. Information regarding this date/time range shall be included, if it is known. In many cases this will have to be supplied by the operator.
13. **SHALL** satisfy: The typeId root is 2.16.840.1.113883.1.3 and extension is POCD_HD000040.
    - ```
      [OCL]: self.typeId.root = '2.16.840.1.113883.1.3' and
       self.typeId.extension = 'POCD_HD000040'
      ```
14. **SHALL** satisfy: Contains exactly one recordTarget.
    - Contains identifying information about the patient concerned in the original content. In many cases this will have to be supplied by the operator.
    - ```
      [OCL]: self.recordTarget->size() = 1
      ```
15. **SHALL** satisfy: Contains one or more author / assignedAuthor / assignedPerson and/or author / assignedAuthor / representedOrganization
    - ```
      [OCL]: self.author->exists(author : cda::Author | not
       author.assignedAuthor.assignedPerson.oclIsUndefined()
         or not author.assignedAuthor.representedOrganization.oclIsUndefined())
      ```
16. **SHALL** satisfy: recordTarget/patientRole/id element includes both the root and the extension attributes.
    - ```
      [OCL]: self.recordTarget->forAll(target : cda::RecordTarget | not
       target.patientRole.oclIsUndefined()
         and target.patientRole.id->forAll(roleId : datatypes::II | not
       roleId.root.oclIsUndefined()
         and not roleId.extension.oclIsUndefined()))
      ```
17. **SHALL** satisfy: At least one recordTarget/patientRole/addr element includes at least the country subelement.

- The addr element has an unbounded upper limit on occurrences. It can, and should, be replicated to include additional addresses for a patient, each minimally specified by the country sub element.

- ```
  [OCL]: self.recordTarget->exists(target : cda::RecordTarget | not
   target.patientRole.oclIsUndefined()
     and target.patientRole.addr->exists(address : datatypes::AD |
   address.country->exists(c : datatypes::ADXP |
     not c.oclIsUndefined() and c.getText().size() > 0)))
  ```

18. **SHALL** satisfy: At least one recordTarget/patientRole/patient/name element has at least one given subelement and one family subelement.

    - ```
      [OCL]: self.recordTarget->exists(target : cda::RecordTarget | not
       target.patientRole.patient.oclIsUndefined()
         and target.patientRole.patient.name->exists(name: datatypes::PN |
            not name.given->isEmpty() and not name.family->isEmpty()))
      ```

19. **SHALL** satisfy: The recordTarget/patientRole/patient/ administrativeGenderCode element is present.

    - ```
      [OCL]: self.recordTarget->one(target : cda::RecordTarget |
         not
       target.patientRole.patient.administrativeGenderCode.oclIsUndefined())
      ```

20. **SHALL** satisfy: The recordTarget/patientRole/patient/ birthTime element is present with precision to the year.

    - ```
      [OCL]: self.recordTarget->one(target : cda::RecordTarget |
         not target.patientRole.patient.birthTime.oclIsUndefined())
      ```

21. **SHOULD** satisfy: Contains author of type ScanOriginalAuthor to represent original author of this scanned document.

    - ```
      [OCL]: self.author->exists(author : cda::Author | not
       author.oclIsUndefined() and author.oclIsKindOf(ihe::ScanOriginalAuthor))
      ```

22. **SHALL** satisfy: Contains author element of type ScanningDevice to represent the scanning device and software used to produce the scanned content.

    - ```
      [OCL]: self.author->exists(author : cda::Author | not
       author.oclIsUndefined() and author.oclIsKindOf(ihe::ScanningDevice))
      ```

23. **SHALL** satisfy: Contains ScanDataEnterer element to represent the scanner operator who produced the scanned content.

    - ```
      [OCL]: not self.dataEnterer.oclIsUndefined() and
       self.dataEnterer.oclIsKindOf(ihe::ScanDataEnterer)
      ```

24. **SHALL** satisfy: custodian/assignedCustodian/representedCustodianOrganization/name is present.

    - ```
      [OCL]: not
       self.custodian.assignedCustodian.representedCustodianOrganization.name.oclIsUndefir
      ```

25. **SHALL** satisfy: custodian/assignedCustodian/representedCustodianOrganization/addr is present and includes at least the country sub element.

    - ```
      [OCL]: not
       self.custodian.assignedCustodian.representedCustodianOrganization.addr.oclIsUndefir
         and
       self.custodian.assignedCustodian.representedCustodianOrganization.addr.country-
      >exists(c : datatypes::ADXP |
           not c.oclIsUndefined() and c.getText().size() > 0)
      ```

26. **SHALL** satisfy: The legalAuthenticator/assignedEntity/id element if known shall include both the root and the extension attributes.

    - ```
      [OCL]: self.legalAuthenticator.assignedEntity.id->size() > 0 implies (
         self.legalAuthenticator.assignedEntity.id->forAll(ident : datatypes::II
       |
           not ident.root.oclIsUndefined() and not
       ident.extension.oclIsUndefined()))
      ```

27. **SHALL** satisfy: The component/nonXMLBody is present.

- Used to wrap the scanned content. The nonXMLBody element is guaranteed to be unique; thus the x-path to recover the scanned content is essentially fixed.
- `[OCL]: not self.component.nonXMLBody.oclIsUndefined()`

28. **SHALL** satisfy: If the human-readable language of the scanned content is different than that of the wrapper (specified in ClinicalDocument/languageCode), then ClinicalDocument/component/nonXMLBody/languageCode shall be present. Attribute code@code shall be present. Attribute code@codeSystem shall be IETF (Internet Engineering Task Force) RFC 3066 in accordance with the HL7 CDA R2 documentation.
29. **SHALL** satisfy: The component/nonXMLBody/text element is present and encoded using xs:base64Binary encoding. Its #CDATA will contain the scanned content.
    - `[OCL]: not self.component.nonXMLBody.text.oclIsUndefined()`
30. **SHALL** satisfy: The component/nonXMLBody/text@mediaType is 'application/pdf' for PDF, or 'text/plain' for plaintext.
    - `[OCL]: self.component.nonXMLBody.text.mediaType = 'application/pdf' or self.component.nonXMLBody.text.mediaType = 'text/plain'`
31. **SHALL** satisfy: The component/nonXMLBody/text@representation is B64.
    - The @representation for both PDF and plaintext scanned content will be "B64", because this profile requires the base-64 encoding of both formats.
    - `[OCL]: self.component.nonXMLBody.text.representation = datatypes::BinaryDataEncoding::B64`

Scanned Document example

Chapter 3

SECTION TEMPLATES

Topics:

- *Pregnancy History Section*
- *Reason For Referral Section*
- *Review Of Systems Section*
- *Social History Section*
- *Surgeries Section*
- *Vital Signs Section*

Active Problems Section

[Section: templateId `1.3.6.1.4.1.19376.1.5.3.1.3.6`]

The active problem section shall contain a narrative description of the conditions currently being monitored for the patient. It shall include entries for patient conditions as described in the Entry Content Module.

1. **SHALL** conform to *CCD Problem Section* template (templateId: `2.16.840.1.113883.10.20.1.11`)
2. **SHALL** contain at least one [1..*] **`entry`**, such that
   a. Contains exactly one [1..1] *Problem Concern Entry* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.5.2`)

Active Problems 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"/>
  <id root="1226166837"/>
  <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"/>
      <id root="944620395"/>
      <code nullFlavor="NA"/>
      <text/>
      <effectiveTime>
        <low value="2011"/>
        <high value="2011"/>
      </effectiveTime>
      <entryRelationship>
        <observation/>
      </entryRelationship>
    </act>
  </entry>
</section>
```

Admission Medication History Section

[Section: templateId `1.3.6.1.4.1.19376.1.5.3.1.3.20`]

The admission medication history section shall contain a narrative description of the relevant medications administered to a patient prior to admission to a facility. It shall include entries for medication administration as described in the Entry Content Module.

1. **SHALL** contain exactly one [1..1] **`code/@code`**`="42346-7"` *MEDICATIONS ON ADMISSION* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`)

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"/>
  <id root="418230484"/>
```

```
  <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 `1.3.6.1.4.1.19376.1.5.3.1.3.34`]

The advance directive section shall contain a narrative description of the list of documents that define the patient's expectations and requests for care along with the locations of the documents.

1. **SHALL** conform to *CCD Advance Directives Section* template (templateId: `2.16.840.1.113883.10.20.1.1`)

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"/>
  <id root="684196388"/>
  <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 `1.3.6.1.4.1.19376.1.5.3.1.3.13`]

The adverse and other adverse reactions section shall contain a narrative description of the substance intolerances and the associated adverse reactions suffered by the patient.

1. **SHALL** conform to *CCD Alerts Section* template (templateId: `2.16.840.1.113883.10.20.1.2`)
2. **SHALL** contain at least one [1..*] **`entry`**, such that
   a. Contains exactly one [1..1] *Allergy Intolerance Concern* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.5.3`)

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"/>
  <id root="1178755871"/>
  <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 `1.3.6.1.4.1.19376.1.5.3.1.1.13.2.5`]

The assessment and plan section shall contain a narrative description of the assessment of the patient condition and expectations for care including proposals, goals, and order requests for monitoring, tracking, or improving the condition of the patient.

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

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"/>
  <id root="278653867"/>
  <code code="51847-2" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="ASSESSMENT AND PLAN"/>
  <title/>
</section>
```

Care Plan Section

[Section: templateId `1.3.6.1.4.1.19376.1.5.3.1.3.31`]

The care plan section shall contain a narrative description of the expectations for care including proposals, goals, and order requests for monitoring, tracking, or improving the condition of the patient.

1. **SHALL** conform to *CCD Plan Of Care Section* template (templateId: `2.16.840.1.113883.10.20.1.10`)

Care 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="2.16.840.1.113883.10.20.1.10"/>
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.31"/>
  <id root="1686505417"/>
  <code code="18776-5" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="Treatment plan"/>
  <title/>
  <text/>
</section>
```

Chief Complaint Section

[Section: templateId `1.3.6.1.4.1.19376.1.5.3.1.1.13.2.1`]

This contains a narrative description of the patient's chief complaint.

1. **SHALL** contain exactly one [1..1] **`code/@code`**`="10154-3"` *CHIEF COMPLAINT* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`)

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"/>
  <id root="1588629194"/>
```

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

Coded Advance Directives Section

[Section: templateId `1.3.6.1.4.1.19376.1.5.3.1.3.35`]

1. **SHALL** conform to *Advance Directives Section* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.3.34`)
2. **SHOULD** contain zero or more [0..*] **`entry`**, such that
   a. Contains exactly one [1..1] *Advance Directive Observation* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.13.7`)

Coded 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"/>
  <id root="1913866042"/>
  <code code="42348-3" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="Advance directives"/>
  <title/>
  <text/>
</section>
```

Coded Family Medical History Section

[Section: templateId `1.3.6.1.4.1.19376.1.5.3.1.3.15`]

1. **SHALL** conform to *Family Medical History Section* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.3.14`)
2. **SHALL** contain exactly one [1..1] **`entry`**, such that
   a. Contains exactly one [1..1] *Family History Organizer* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.15`)

Coded Family Medical History Section example

Coded Results Section

[Section: templateId `1.3.6.1.4.1.19376.1.5.3.1.3.28`]

The results section shall contain a narrative description of the relevant diagnostic procedures the patient received in the past. It shall include entries for procedures and references to procedure reports when known as described in the Entry Content Modules.

1. **SHALL** contain exactly one [1..1] **`code/@code`**`="30954-2"` *STUDIES SUMMARY* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`)
2. **SHALL** contain at least one [1..*] **`entry`**, such that
   a. Contains exactly one [1..1] *Procedure Entry* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.19`)
3. **SHOULD** contain at least one [1..*] **`entry`**, such that

   a. Contains exactly one [1..1] *External Reference* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.4`)
4. **MAY** contain zero or more [0..*] **`entry`**, such that
   a. Contains exactly one [1..1] *Simple Observation* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.13`)

Coded 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"/>
  <id root="1364840943"/>
  <code code="30954-2" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="STUDIES SUMMARY"/>
  <title/>
</section>
```

Coded Surgeries Section

[Section: templateId `1.3.6.1.4.1.19376.1.5.3.1.3.12`]

The list of surgeries section shall include entries for procedures and references to procedure reports when known as described in the Entry Content Modules.

1. **SHALL** conform to *Surgeries Section* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.3.11`)
2. **SHOULD** contain zero or one [0..1] **`entry`**, such that
   a. Contains exactly one [1..1] *External Reference* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.4`)
3. **SHALL** contain at least one [1..*] **`entry`**, such that
   a. Contains exactly one [1..1] *Procedure Entry Procedure Activity Procedure* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.19`)

Coded 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"/>
  <id root="1763885257"/>
  <code code="47519-4" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="History of procedures"/>
  <title/>
  <text/>
</section>
```

Coded Vital Signs Section

[Section: templateId `1.3.6.1.4.1.19376.1.5.3.1.1.5.3.2`]

The vital signs section contains coded measurement results of a patient's vital signs.

1. **SHALL** conform to *Vital Signs Section* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.3.25`) (6.3.3.4.5.1)
2. **SHALL** contain at least one [1..*] **`entry`** (6.3.3.4.5), such that
   a. Contains exactly one [1..1] *Vital Signs Organizer* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.13.1`)

Coded 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"/>
  <id root="1936026919"/>
  <code code="8716-3" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="Vital signs"/>
  <title/>
  <text/>
  <entry>
    <organizer moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.1.32"/>
      <templateId root="2.16.840.1.113883.10.20.1.35"/>
      <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.13.1"/>
      <id root="973558634"/>
      <code code="46680005" codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMEDCT" displayName="Vital signs"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2011"/>
        <high value="2011"/>
      </effectiveTime>
      <component>
        <observation/>
      </component>
    </organizer>
  </entry>
</section>
```

Discharge Diagnosis Section

[Section: templateId `1.3.6.1.4.1.19376.1.5.3.1.3.7`]

The discharge diagnosis section shall contain a narrative description of the conditions that need to be monitored after discharge from the hospital and those that were resolved during the hospital course. It shall include entries for patient conditions as described in the Entry Content Module.

1. **SHALL** contain exactly one [1..1] **`code/@code`**`="11535-2"` *HOSPITAL DISCHARGE DX* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`)
2. **SHALL** contain exactly one [1..1] **`entry`**, such that
    a. Contains exactly one [1..1] *Problem Concern Entry* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.5.2`)

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"/>
  <id root="1935369427"/>
  <code code="11535-2" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="HOSPITAL DISCHARGE DX"/>
  <title/>
</section>
```

Discharge Diet

[Section: templateId `1.3.6.1.4.1.19376.1.5.3.1.3.33`]

This section records a narrative description of the expectations for diet, including proposals, goals, and order requests for monitoring, tracking, or improving the dietary control of the patient, used in a discharge from a facility such as an emergency department, hospital, or nursing home.

1. **SHALL** contain exactly one [1..1] **`code/@code`**`="42344-2"` *Discharge Diet* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`)

Discharge Diet example

Encounter History Section

[Section: templateId `1.3.6.1.4.1.19376.1.5.3.1.1.5.3.3`]

The encounter history section contains coded entries describing the patient history of encounters.

1. **SHALL** conform to *CCD Encounters Section* template (templateId: `2.16.840.1.113883.10.20.1.3`)
2. **SHALL** contain at least one [1..*] **`entry`**, such that
   a. Contains exactly one [1..1] *Encounter Entry* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.14`)

Encounter 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="2.16.840.1.113883.10.20.1.3"/>
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.1.5.3.3"/>
  <id root="321607401"/>
  <code code="46240-8" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="History of encounters"/>
  <title/>
  <text/>
</section>
```

Family Medical History Section

[Section: templateId `1.3.6.1.4.1.19376.1.5.3.1.3.14`]

The family history section shall contain a narrative description of 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 *CCD Family History Section* template (templateId: `2.16.840.1.113883.10.20.1.4`)

Family Medical 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"/>
  <id root="854673304"/>
  <code code="10157-6" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="History of family member diseases"/>
  <title/>
  <text/>
</section>
```

History Of Past Illness Section

[Section: templateId `1.3.6.1.4.1.19376.1.5.3.1.3.8`]

The History of Past Illness section shall contain a narrative description of the conditions the patient suffered in the past. It shall include entries for problems as described in the Entry Content Modules.

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

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"/>
  <id root="1454670315"/>
  <code code="11348-0" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="HISTORY OF PAST ILLNESS"/>
  <title/>
</section>
```

History Of Present Illness

[Section: templateId `1.3.6.1.4.1.19376.1.5.3.1.3.4`]

The history of present illness section shall contain a narrative description of the sequence of events preceding the patient's current complaints.

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

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"/>
  <id root="437668666"/>
  <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 `1.3.6.1.4.1.19376.1.5.3.1.3.3`]

The hospital admitting diagnosis section shall contain a narrative description of the primary reason for admission to a hospital facility. It shall include entries for observations as described in the Entry Content Modules.

1. **SHALL** contain exactly one [1..1] **`code/@code`**`="46241-6"` *HOSPITAL ADMISSION DX* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`)
2. **SHALL** contain exactly one [1..1] **`entry`**, such that
   a. Contains exactly one [1..1] *Problem Concern Entry* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.5.2`)

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"/>
  <id root="548750010"/>
  <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 `1.3.6.1.4.1.19376.1.5.3.1.3.5`]

The hospital course section shall contain a narrative description of the sequence of events from admission to discharge in a hospital facility.

1. **SHALL** contain exactly one [1..1] **`code/@code`**`="8648-8"` *HOSPITAL COURSE* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`)

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"/>
  <id root="606792773"/>
  <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 `1.3.6.1.4.1.19376.1.5.3.1.3.22`]

The hospital discharge medications section shall contain a narrative description of the medications requested (ordered) to be administered to the patient after discharge from the hospital. It shall include entries for medication requests as described in the Entry Content Module.

1. **SHALL** contain exactly one [1..1] **`code/@code`**`="10183-2"` *HOSPITAL DISCHARGE MEDICATIONS* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`)
2. **SHALL** contain exactly one [1..1] **`entry`**, such that
   a. Contains exactly one [1..1] *Medication* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.7`)

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"/>
  <id root="200170621"/>
  <code code="10183-2" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="HOSPITAL DISCHARGE MEDICATIONS"/>
  <title/>
</section>
```

Hospital Discharge Physical

[Section: templateId `1.3.6.1.4.1.19376.1.5.3.1.3.26`]

The Hospital Discharge Physical section records a narrative description of the patient's physical findings.

1. **SHALL** contain exactly one [1..1] **`code/@code`**`="10184-0"` *Hospital Discharge Physical* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`)

Hospital Discharge Physical example

Immunizations Section

[Section: templateId `1.3.6.1.4.1.19376.1.5.3.1.3.23`]

The immunizations section shall contain a narrative description of the immunizations administered to the patient in the past. It shall include entries for medication administration as described in the Entry Content Modules.

1. **SHALL** conform to *CCD Immunizations Section* template (templateId: `2.16.840.1.113883.10.20.1.6`)
2. **SHALL** contain at least one [1..*] **`entry`**, such that
   a. Contains exactly one [1..1] *Immunization* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.12`)

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"/>
  <id root="1674569173"/>
  <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"/>
      <id root="456401743"/>
      <code code="941141251"/>
      <text/>
      <effectiveTime value="20110830"/>
      <consumable/>
    </substanceAdministration>
  </entry>
</section>
```

Intake Output Section

[Section: templateId `1.3.6.1.4.1.19376.1.5.3.1.1.20.2.3`]

1.

Intake Output 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="1.3.6.1.4.1.19376.1.5.3.1.1.20.2.3"/>
  <id root="244657251"/>
  <title/>
</section>
```

Medical Devices Section

[Section: templateId `1.3.6.1.4.1.19376.1.5.3.1.1.5.3.5`]

The medical devices section contains narrative text describing the patient history of medical device use.

1. **SHALL** conform to *CCD Medical Equipment Section* template (templateId: `2.16.840.1.113883.10.20.1.7`)

Medical Devices 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"/>
  <id root="1079085279"/>
  <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 `1.3.6.1.4.1.19376.1.5.3.1.3.21`]

The medications administered section shall contain a narrative description of the relevant medications administered to a patient during the course of an encounter. It shall include entries for medication administration as described in the Entry Content Module.

1. **SHALL** contain exactly one [1..1] **`code/@code`**`="18610-6"` *MEDICATION ADMINISTERED* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`)

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"/>
  <id root="1423859324"/>
  <code code="18610-6" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="MEDICATION ADMINISTERED"/>
  <title/>
</section>
```

Medications Section

[Section: templateId `1.3.6.1.4.1.19376.1.5.3.1.3.19`]

The medications section shall contain a description of the relevant medications for the patient, e.g. an ambulatory prescription list. It shall include entries for medications as described in the Entry Content Module.

1. **SHALL** conform to *CCD Medications Section* template (templateId: `2.16.840.1.113883.10.20.1.8`)
2. **SHALL** contain at least one [1..*] **`entry`**, such that
   a. Contains exactly one [1..1] *Medication* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.7`)
3. **SHALL** satisfy: Contains one dosing template to identify this as a particular type of medication event. Possible dosing templates: 1.3.6.1.4.1.19376.1.5.3.1.4.7.1 Normal Dosing, 1.3.6.1.4.1.19376.1.5.3.1.4.8, Tapered Dosing, 1.3.6.1.4.1.19376.1.5.3.1.4.9 Split Dosing, 1.3.6.1.4.1.19376.1.5.3.1.4.10 Conditional Dosing, 1.3.6.1.4.1.19376.1.5.3.1.4.11 Combination Dosing.
   - There are a variety of special cases for dosing that need to be accounted for. Most of these special cases involve changing the dosage or frequency over time, or based on some measurement. When the dosage changes, then additional entries are required for each differing dosage.
4. **MAY** satisfy: contains one or more related components (<entryRelationship typeCode='COMP'>, either to handle split, tapered or conditional dosing, or to support combination medications.

- n the first three cases, the subordinate components shall specify only the changed <frequency> and/or <doseAmount> elements. For conditional dosing, each subordinate component shall have a <precondition> element that specifies the <observation> that must be obtained before administration of the dose. The value of the <sequenceNumber> shall be an ordinal number, starting at 1 for the first component, and increasing by 1 for each subsequent component. Components shall be sent in <sequenceNumber> order.

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"/>
  <id root="1999220307"/>
  <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 `1.3.6.1.4.1.19376.1.5.3.1.1.5.3.7`]

The Payers section contains data on the patient's payers, whether a 'third party' insurance, self-pay, other payer or guarantor, or some combination.

1. **SHALL** conform to *CCD Payers Section* template (templateId: `2.16.840.1.113883.10.20.1.9`)
2. **SHOULD** contain at least one [1..*] **`entry`**, such that
   a. Contains exactly one [1..1] *Coverage Entry* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.17`)

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"/>
  <id root="2010943714"/>
  <code code="48768-6" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="Payment sources"/>
  <title/>
  <text/>
  <entry>
    <act 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"/>
      <id root="1690787872"/>
      <code code="48768-6" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="Payment sources"/>
      <text/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2011"/>
        <high value="2011"/>
      </effectiveTime>
    </act>
  </entry>
</section>
```

Physical Exam Narrative Section

[Section: templateId `1.3.6.1.4.1.19376.1.5.3.1.3.24`]

The physical exam section shall contain a narrative description of the patient's physical findings.

1. **SHALL** contain exactly one [1..1] **`code/@code`**`="29545-1"` *PHYSICAL EXAMINATION* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`)

Physical Exam Narrative 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"/>
  <id root="645165265"/>
  <code code="29545-1" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="PHYSICAL EXAMINATION"/>
  <title/>
</section>
```

Physical Exam Section

[Section: templateId `1.3.6.1.4.1.19376.1.5.3.1.1.9.15`]

The physical exam section shall contain only the required and optional subsections performed.

1. **SHALL** conform to *Physical Exam Narrative Section* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.3.24`)

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"/>
  <id root="1125128936"/>
  <code code="29545-1" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="PHYSICAL EXAMINATION"/>
  <title/>
</section>
```

Pregnancy History Section

[Section: templateId `1.3.6.1.4.1.19376.1.5.3.1.1.5.3.4`]

The pregnancy history section contains coded entries describing the patient history of pregnancies.

1. **SHALL** contain zero or one [0..1] **`code/@code`**`="10162-6"` *HISTORY OF PREGNANCIES* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`)
2. **SHALL** contain at least one [1..*] **`entry`**, such that
   a. Contains exactly one [1..1] *Pregnancy Observation* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.13.5`)

Pregnancy History Section example

Reason For Referral Section

[Section: templateId `1.3.6.1.4.1.19376.1.5.3.1.3.1`]

The reason for referral section shall contain a narrative description of the reason that the patient is being referred.

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

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"/>
  <id root="1733648628"/>
  <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 `1.3.6.1.4.1.19376.1.5.3.1.3.18`]

The review of systems section shall contain a narrative description of the responses the patient gave to a set of routine questions on the functions of each anatomic body system.

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

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"/>
  <id root="1898967073"/>
  <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 `1.3.6.1.4.1.19376.1.5.3.1.3.16`]

The social history section shall contain a narrative description of the person's beliefs, home life, community life, work life, hobbies, and risky habits.

1. **SHALL** conform to *CCD Social History Section* template (templateId: `2.16.840.1.113883.10.20.1.15`)

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"/>
  <id root="1201705218"/>
```

```
  <code code="29762-2" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="Social history"/>
  <title/>
  <text/>
</section>
```

Surgeries Section

[Section: templateId `1.3.6.1.4.1.19376.1.5.3.1.3.11`]

The list of surgeries section shall contain a narrative description of the diagnostic and therapeutic operative procedures and associated anesthetic techniques the patient received in the past.

1. **SHALL** conform to *CCD Procedures Section* template (templateId: `2.16.840.1.113883.10.20.1.12`)

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"/>
  <id root="549435489"/>
  <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 `1.3.6.1.4.1.19376.1.5.3.1.3.25`]

The vital signs section shall contain a narrative description of the measurement results of a patient's vital signs.

1. **SHALL** conform to *CCD Vital Signs Section* template (templateId: `2.16.840.1.113883.10.20.1.16`) (6.3.3.4.4.1)

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"/>
  <id root="1130431681"/>
  <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:

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.

- *Simple Observation*
- *Social History Observation*
- *Split Dose*
- *Supply Entry*
- *Tapered Dose*
- *Vital Sign Observation*
- *Vital Signs Organizer*

Advance Directive Observation

Advance Directive Observation example

Allergy Intolerance

[Observation: templateId `1.3.6.1.4.1.19376.1.5.3.1.4.6`]

Allergies and intolerances are special kinds of problems, and so are also recorded in the CDA <observation> element, with classCode='OBS'. They follow the same pattern as the problem entry, with exceptions noted below.

1. **SHALL** conform to *Problem Entry* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.5`)
2. **SHALL** contain exactly one [1..1] **`code`** (CodeSystem: `2.16.840.1.113883.5.4 ObservationIntoleranceType`)
   - The <code> element represents the kind of allergy observation made, to a drug, food or environmental agent, and whether it is an allergy, non-allergy intolerance, or unknown class of intolerance (not known to be allergy or intolerance).
3. **SHALL** contain exactly one [1..1] **`value`**
   - The <value> is a description of the allergy or adverse reaction. While the value may be a coded or an uncoded string, the type is always a coded value (xsi: type='CD'). The codingSystem should reference a controlled vocabulary describing allergies and adverse reactions. The allergy or intolerance may not be known, in which case that fact shall be recorded appropriately. This might occur in the case where a patient experiences an allergic reaction to an unknown substance.
4. **MAY** contain zero or more [0..*] **`entryRelationship`**, such that
   a. Contains **`@typeCode="MFST"`** *MFST (is manifestation of)*
   b. Contains exactly one [1..1] *Problem Entry Reaction Observation Container* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.5`)
5. **MAY** contain zero or one [0..1] **`entryRelationship`**, such that
   a. Contains **`@typeCode="REFR"`** *REFR (refers to)*
   b. Contains exactly one [1..1] *Severity* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.1`)
6. **MAY** contain zero or one [0..1] **`entryRelationship`**, such that
   a. Contains **`@typeCode="REFR"`** *REFR (refers to)*
   b. Contains exactly one [1..1] *Problem Status Observation* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.1.1`)
7. **MAY** contain zero or more [0..*] **`entryRelationship`**, such that
   a. Contains **`@typeCode="SUBJ"`** *SUBJ (has subject)*
   b. Contains exactly one [1..1] *Comment* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.2`)
8. **MAY** satisfy: Other vocabularies may be used for code/@code, such as SNOMED-CT or MEDCIN.
9. **SHALL** satisfy: The code /@code and code/@codeSystem attribute shall be present.
10. **SHOULD** satisfy: The code/@displayName and code/@codeSystemName attributes should be present.
11. **SHALL** satisfy: If <value> is coded, the code and codeSystem attributes must be present. If uncoded, all attributes other than xsi:type='CD' must be absent.
12. **SHALL** satisfy: the <participant> element may be present
    - The substance that causes the allergy or intolerance may be specified in the <participant> element.
13. **SHALL** satisfy: the participant/@typecode attribute shall be 'CSM'
14. **MAY** satisfy: the participant/participantRole element may be present
15. **SHALL** satisfy: the participant/participantRole/@classcode attribute shall be 'MANU'
16. **MAY** satisfy: The participant/participantRole/PlayingEntity element may be present
17. **SHALL** satisfy: the participant/participantRole/playingEntity/@classcode attribute shall be 'MMAT'

18. **SHALL** satisfy: The participant/participantRole/playingEntity/code element shall be present. It may contain a code and codeSystem attribute to indicate the code for the substance causing the allergy or intolerance.
19. **SHALL** satisfy: participant/participantRole/playingEntity/code shall contain a originalText/reference element as reference to the original text in the narrative where the substance is named.
20. The entryRelationship/@inversionInd for Severity Entry template **SHALL** be 'true'
21. The entryRelationship/@inversionInd for Comment Entry template **SHALL** be 'true'

Allergy Intolerance 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"/>
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.6"/>
  <id root="1635817013"/>
  <code code="1331590950"/>
  <text/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
</observation>
```

Allergy Intolerance Concern

[Act: templateId `1.3.6.1.4.1.19376.1.5.3.1.4.5.3`]

This entry is a specialization of the Concern Entry, wherein the subject of the concern is focused on an allergy or intolerance.

1. **SHALL** conform to *Concern Entry* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.5.1`)
2. **SHALL** contain at least one [1..*] **`entryRelationship`**, such that
    a. Contains **`@typeCode="`**`SUBJ"` *SUBJ (has subject)*
    b. Contains exactly one [1..1] *Allergy Intolerance* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.6`)

Allergy Intolerance Concern 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"/>
  <id root="1252047379"/>
  <code nullFlavor="NA"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
</act>
```

Combination Medication

[SubstanceAdministration: templateId `1.3.6.1.4.1.19376.1.5.3.1.4.11`]

This template identifier is used to identify medication administration events that require special processing to handle combination medications. The parent template is 1.3.6.1.4.1.19376.1.5.3.1.4.7. A combination medication is made up of two or more other medications. These may be prepackaged, such as Percocet, which is a combination of Acetaminophen and oxycodone in predefined ratios, or prepared by a pharmacist, such as a GI cocktail.

In the case of the prepackaged combination, it is sufficient to supply the name of the combination drug product, and its strength designation in a single <substanceAdministation> entry. The dosing information should then be recorded as simply a count of administration units. In the latter case of a prepared mixture, the description of the mixture should be provided as the product name (e.g., "GI Cocktail") , in the <substanceAdministration> entry. That entry may, but is not required, to have subordinate <substanceAdministration> entries included beneath it to record the components of the mixture.

1. **SHALL** conform to *Medication* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.7`)
2. **SHALL** satisfy: Subordinate <substanceAdminstration> entries are included to record the components of the prepared mixture. If medication is a prepackaged mixture, a single <substanceAdministration> entry is sufficient.
   - `[OCL]: not self.entryRelationship.substanceAdministration->isEmpty()`

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"/>
  <id root="1001209190"/>
  <code code="2119138337"/>
  <statusCode code="completed"/>
  <effectiveTime value="20110830"/>
  <routeCode code="Value"/>
  <approachSiteCode code="325153680"/>
  <doseQuantity/>
  <rateQuantity/>
  <maxDoseQuantity/>
  <consumable/>
</substanceadministration>
```

Comment

[Act: templateId `1.3.6.1.4.1.19376.1.5.3.1.4.2`]

This entry allows for a comment to be supplied with each entry. For CDA this structure is usually included in the target act using the <entryRelationship> element defined in the CDA Schema, but can also be used in the <component> element when the comment appears within an <organizer>.

Any condition or allergy may be the subject of a comment.

1. **SHALL** conform to *CCD Comment* template (templateId: `2.16.840.1.113883.10.20.1.40`)
2. **SHALL** contain exactly one [1..1] **`statusCode/@code`**`="completed"` (CodeSystem: `2.16.840.1.113883.5.14 HL7ActStatus`) (CONF-6.3.4.6.8)
3. **SHALL** contain exactly one [1..1] **`text`**
4. **MAY** contain zero or one [0..1] **`author`**, such that
5. **SHALL** satisfy: A related statement is made about another section or entry. In CDA the former shall be recorded inside an <entryRelationship> element occurring at the end of the entry. The containing entry is the

subject (typeCode='SUBJ') of this comment, which is the inverse of the normal containment structure, thus inversionInd='true'. (CONF-6.3.4.6.3)

6. **SHALL** satisfy: The 'text' element contains a 'reference' element pointing to the narrative text section of the CDA, rather than duplicate text to avoid ambiguity. (CONF-6.3.4.6.7)
   - `[OCL]: not self.text.reference.oclIsUndefined()`
7. **SHALL** satisfy: The time of the comment creation is recorded in the 'time' element when the 'author' element is present. (CONF-6.3.4.6.10)
   - `[OCL]: not self.author->isEmpty() implies not self.effectiveTime.oclIsUndefined()`
8. **SHALL** satisfy: The identifier of the author, and their address and telephone number must be present inside the 'id', 'addr' and 'telecom' elements when the 'author' element is present. (CONF-6.3.4.6.11)
   - `[OCL]: not self.author->isEmpty() implies ( self.author.assignedAuthor.id ->size() > 0 and self.author.assignedAuthor.addr ->size() > 0 and self.author.assignedAuthor.telecom ->size() > 0)`
9. **SHALL** satisfy: The author's and/or the organization's name must be present when the 'author' element is present. (CONF-6.3.4.6.12)
   - `[OCL]: not self.author->isEmpty() implies ( self.author->exists( a : cda::Author | ( (not a.assignedAuthor.assignedPerson.oclIsUndefined()) and not a.assignedAuthor.assignedPerson.name->isEmpty()) or (not a.assignedAuthor.representedOrganization.name->isEmpty()) ) )`

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"/>
  <id root="1338223673"/>
  <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>
```

Concern Entry

[Act: templateId `1.3.6.1.4.1.19376.1.5.3.1.4.5.1`]

This event (moodCode='EVN') represents an act (act classCode='ACT') of being concerned about a problem, allergy or other issue. The <effectiveTime> element describes the period of concern. The subject of concern is one or more observations about related problems (see 1.3.6.1.4.1.19376.1.5.3.1.4.5.2) or allergies and intolerances (see 1.3.6.1.4.1.19376.1.5.3.1.4.5.3). Additional references can be provided having additional information related to the concern. The concern entry allows related acts to be grouped. This allows representing the history of a problem as a series of observation over time, for example.

All concerns reflect the act of recording (<act classCode='ACT'>) the event (moodCode='EVN') of being concerned about a problem, allergy or other issue about the patient condition.

1. **SHALL** conform to *CCD Problem Act* template (templateId: `2.16.840.1.113883.10.20.1.27`)
2. **SHALL** contain exactly one [1..1] **`effectiveTime`**
   - The effectiveTime element records the starting and ending times during which the concern was active.
3. **SHALL** contain exactly one [1..1] **`statusCode`**, which **SHALL** be selected from ValueSet *`ConcernEntryStatus`* **STATIC**

- The statusCode associated with any concern must be one of the following values:

  active: A concern that is still being tracked. **suspended**: A concern that is active, but which may be set aside. For example, this value might be used to suspend concern about a patient problem after some period of remission, but before assumption that the concern has been resolved. **aborted**: A concern that is no longer actively being tracked, but for reasons other than because the problem was resolved. This value might be used to mark a concern as being aborted after a patient leaves care against medical advice. **completed**: The problem, allergy or medical state has been resolved and the concern no longer needs to be tracked except for historical purposes.

4. The effectiveTime 'low' element **SHALL** be present. The 'high' element **SHALL** be present for concerns in the completed or aborted state, and **SHALL NOT** be present otherwise.

   - ```
     [OCL]: not self.effectiveTime.low.oclIsUndefined()
        and ((self.statusCode.code = 'completed' or self.statusCode.code =
      'aborted') implies not self.effectiveTime.high.oclIsUndefined())
        and ((self.statusCode.code <> 'completed' and self.statusCode.code <>
      'aborted') implies self.effectiveTime.high.oclIsUndefined())
     ```

5. This entry **SHALL** contain one or more problem or allergy entries that conform to the specification in section Problem Entry or Allergies and Intolerances.

   - Each concern is about one or more related problems or allergies. This is how a series of related observations can be grouped as a single concern.
   - ```
     [OCL]: self.entryRelationship.observation.templateId->exists(id :
      datatypes::II | id.root =  '1.3.6.1.4.1.19376.1.5.3.1.4.5') or
      self.entryRelationship.observation.templateId->exists(id : datatypes::II
      | id.root =  '1.3.6.1.4.1.19376.1.5.3.1.4.6')
     ```

6. This **SHALL** be represented using entryRelationship with typeCode = 'SUBJ'

   - ```
     [OCL]: self.entryRelationship->select(er|er.typeCode <>
      vocab::x_ActRelationshipEntryRelationship::SUBJ)->isEmpty()
     ```

7. Each concern **MAY** have 0 or more related references. This **MAY** be any valid CDA clinical statement, and **SHOULD** be an IHE entry template.

   - These may be used to represent related statements such related visits.

8. Related References **SHALL** be represented using entryRelationship with typeCode = 'REFR'.

Concern Entry 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"/>
  <id root="482153076"/>
  <code nullFlavor="NA"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
</act>
```

Conditional Dose

[SubstanceAdministration: templateId `1.3.6.1.4.1.19376.1.5.3.1.4.10`]

This template identifier is used to identify medication administration events that require special processing to handle conditional dosing. The parent template is 1.3.6.1.4.1.19376.1.5.3.1.4.7. A conditional dose is often used when the dose amount differs based on some measurement (e.g., an insulin sliding scale dose based on blood sugar level).
```

1. **SHALL** conform to *Medication* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.7`)
2. **SHALL** satisfy: A subordinate 'substanceAdministration' entry is required for each different dose, and the condition should be recorded
   - `[OCL]: not self.entryRelationship.substanceAdministration->isEmpty()`

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"/>
  <id root="176107050"/>
  <code code="1185888331"/>
  <statusCode code="completed"/>
  <effectiveTime value="20110830"/>
  <routeCode code="Value"/>
  <approachSiteCode code="737486681"/>
  <doseQuantity/>
  <rateQuantity/>
  <maxDoseQuantity/>
  <consumable/>
</substanceadministration>
```

Coverage Entry

[Act: templateId `1.3.6.1.4.1.19376.1.5.3.1.4.17`]

1. **SHALL** conform to *CCD Coverage Activity* template (templateId: `2.16.840.1.113883.10.20.1.20`)

Coverage Entry 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"/>
  <id root="1086918822"/>
  <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>
```

Encounter Activity

[Encounter: templateId `1.3.6.1.4.1.19376.1.5.3.1.4.14`]

1. **SHALL** conform to *CCD Encounters Activity* template (templateId: `2.16.840.1.113883.10.20.1.21`)
2. **SHALL** conform to *Encounter Entry* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.14`)

Encounter Activity 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"/>
  <id root="1350843614"/>
  <code codeSystem="2.16.840.1.113883.5.4" codeSystemName="ActEncounterCode"/>
  <text/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
</encounter>
```

Encounter Entry

[Encounter: templateId `1.3.6.1.4.1.19376.1.5.3.1.4.14`]

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="ENC"` (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
2. **SHOULD** contain zero or one [0..1] **`code`** (CodeSystem: `2.16.840.1.113883.5.4 ActEncounterCode`)
   - Developers should take care to check that rational combinations of encounter.code and encounter.moodCode are used , but this profile does not restrict any combination.
3. **SHALL** contain at least one [1..*] **`id`**
4. **SHALL** contain exactly one [1..1] **`text`**

Encounter Entry example

Encounter Plan Of Care

[Encounter: templateId `1.3.6.1.4.1.19376.1.5.3.1.4.14`]

1. **SHALL** conform to *CCD Plan Of Care Activity Encounter* template (templateId: `2.16.840.1.113883.10.20.1.25`)
2. **SHALL** conform to *Encounter Entry* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.14`)
3. **SHALL** satisfy: moodCodeValue
   - ```
     [OCL]: self.moodCode = vocab::x_DocumentEncounterMood::ARQ
       or self.moodCode = vocab::x_DocumentEncounterMood::PRMS
     ```

Encounter Plan Of Care 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">
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.14"/>
  <templateId root="2.16.840.1.113883.10.20.1.25"/>
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.14"/>
  <id root="717333801"/>
  <code codeSystem="2.16.840.1.113883.5.4" codeSystemName="ActEncounterCode"/>
  <text/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
```
```

```
</encounter>
```

External Reference

[Act: templateId `1.3.6.1.4.1.19376.1.5.3.1.4.4`]

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="ACT"` *Act* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)
3. **SHALL** contain zero or more [0..*] **`id`**
4. **SHALL** contain zero or one [0..1] **`text`**
5. **SHALL** satisfy: the code/@nullFlavor attribute value is 'NA'
   - `[OCL]: not self.code.oclIsUndefined() implies self.code.nullFlavor = vocab::NullFlavor::NA`
6. **SHALL** satisfy: reference/@typeCode attribute value is either 'SPRT' (supporting documentation) or 'REFR' (reference material)
   - External references are listed as either supporting documentation (typeCode='SPRT') or simply reference material (typeCode='REFR') for the reader. If this distinction is not supported by the source EMR system, the value of typeCode should be REFR.
   - `[OCL]: self.reference->select(r| r.typeCode <> vocab::x_ActRelationshipExternalReference::REFR and r.typeCode <> vocab::x_ActRelationshipExternalReference::SPRT)->size() = 0`
7. **SHALL** satisfy: the reference element contains an externalDocument element with @classCode = 'DOC' and @moodCode = 'EVN'.
   - `[OCL]: self.reference.externalDocument->select(ed | ed.classCode = vocab::ActClassDocument::DOC and ed.moodCode = vocab::ActMood::EVN )->size() = 1`
8. **SHALL** satisfy: the reference/externalDocument/id is present
   - A link to the original document may be provided here. This shall be a URL where the referenced document can be located. For CDA, the link should also be present in the narrative inside the CDA Narrative in a <linkHTML> element.
   - `[OCL]: self.reference->select( r | r.externalDocument.id->isEmpty() )->size() = 0`
9. **SHALL** satisfy: the reference/externalDocument/text is present to provide a link to the original document
   - `[OCL]: self.reference->select( r | r.externalDocument.text.reference.oclIsUndefined() )->size() = 0`

External Reference example

Family History Observation

[Observation: templateId `1.3.6.1.4.1.19376.1.5.3.1.4.13.3`]

1. **SHALL** conform to *Simple Observation* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.13`)
2. **SHALL** conform to *CCD Family History Observation* template (templateId: `2.16.840.1.113883.10.20.1.22`)
3. **SHALL** contain exactly one [1..1] **`code`**, which **SHALL** be selected from ValueSet `2.16.840.1.113883.3.88.12.3221.7.2 Problem Type` **STATIC** 1
4. **SHALL** contain at least one [1..*] **`value`**, where its data type is CD

Family History Observation example

Family History Organizer

[Organizer: templateId `1.3.6.1.4.1.19376.1.5.3.1.4.15`]

1. **SHALL** conform to *CCD Family History Organizer* template (templateId: `2.16.840.1.113883.10.20.1.23`)
2. **SHALL** contain at least one [1..*] **`component`**, such that
   a. Contains exactly one [1..1] *Family History Observation* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.13.3`)
3. **SHALL** contain exactly one [1..1] **`code`** (CodeSystem: `2.16.840.1.113883.5.111 RoleCode`)
4. One RelatedSubject/subject/sdtc:id element **SHOULD** be present. It is used to identify the patient relation to create a pedigree graph.
5. The participant element **MAY** be present to record the relationship of the subject to other family members to create a pedigree graph.
6. **SHALL** satisfy: Participant shall contain a participantRole/@classCode = "PRS" element showing the relationship of the subject to other family members
7. **SHALL** satisfy: The Participant/ParticipantRole/code element shall be present, and gives the relationship of the participant to the subject. The code attribute shall be present, and shall contain a value from the HL7 FamilyMember vocabulary
8. **SHALL** satisfy: The Participant/ParticipantRole/PlayingEntity element shall be present with @classCode = 'PSN'
9. **SHALL** satisfy: The Participant/ParticipantRole/PlayingEntity/sdtc:id shall be present. It must have the same root and extension attributes of the subject element of a separate family history organizer.

Family History Organizer example

Health Status Observation

[Observation: templateId `1.3.6.1.4.1.19376.1.5.3.1.4.1.2`]

The health status observation records information about the current health status of the patient.

1. **SHALL** conform to *CCD Problem Health Status Observation* template (templateId: `2.16.840.1.113883.10.20.1.51`)
2. **SHALL** contain exactly one [1..1] **`text`**
3. **SHALL** contain exactly one [1..1] **`value`**, which **SHALL** be selected from ValueSet `HealthStatusValue` **STATIC**
4. The 'text' elements **SHALL** contain a 'reference' element pointing to the narrative where the severity is recorded, rather than duplicate text to avoid ambiguity.
   - `[OCL]: not self.text.reference.oclIsUndefined()`

Health Status Observation example

Immunization

[SubstanceAdministration: templateId `1.3.6.1.4.1.19376.1.5.3.1.4.12`]

1. **SHALL** conform to *CCD Medication Activity* template (templateId: `2.16.840.1.113883.10.20.1.24`)

2. **SHALL** contain exactly one [1..1] **`@moodCode="EVN"`** *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (6.3.4.17.2)
3. **SHALL** contain zero or one [0..1] **`code/@code="IMMUNIZ"`** (CodeSystem: `2.16.840.1.113883.5.4 HL7ActCode`) (6.3.4.17.5)
4. **SHALL** contain exactly one [1..1] **`statusCode`** (6.3.4.17.7)
5. Contains zero or more [0..*] **`approachSiteCode`**
   - The site where the medication is administered, usually used with IV or topical drugs. The <approachSiteCode> element describes the site of medication administrion. It may be coded to a controlled vocabulary that lists such sites (e.g., SNOMED-CT). In CDA documents, this 4805 element contains a URI in the value attribute of the <reference> that points to the text in the narrative identifying the site. In a message, the <originalText> element shall contain the text identifying the site.
6. Contains zero or one [0..1] **`doseQuantity`**
   - The amount of the medication given. This should be in some known and measurable unit, such as grams, milligrams, et cetera. It may be measured in "administration" units (such as tablets or each), for medications where the strength is relevant. In this case, only the unit count is specified , no units are specified. It may be a range.
7. Contains zero or one [0..1] **`rateQuantity`**
   - The rate is a measurement of how fast the dose is given to the patient over time (e.g., .5 liter / 1 hr), and is often used with IV drugs.
8. **SHALL** contain exactly one [1..1] **`effectiveTime`** (CONF-308)
9. **SHALL** satisfy: In a CDA document, the URI given in the value attribute of the <reference> element points to an element in the narrative content that contains the complete text describing the immunization activity.
   - In a CDA document, the URI given in the value attribute of the 'reference' element points to an element in the narrative content that contains the complete text describing the immunization activity. In an HL7 message, the content of the text element shall contain the complete text describing the immunization activity.
10. **SHALL** satisfy: CPT-4 codes may be used for immunization procedures
11. **SHALL** satisfy: If negationInd is set to TRUE atleast one comment shall exist that provides an explanation for why the immunization did not take place. Other comments may also be present
    - `[OCL]: self.negationInd=true implies not self.entryRelationship.act->select( act | act.oclIsKindOf(ccd::Comment) )->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"/>
  <id root="1229836082"/>
  <code code="1964325380"/>
  <statusCode code="completed"/>
  <effectiveTime value="20110830"/>
  <routeCode code="Value"/>
  <doseQuantity/>
  <rateQuantity/>
  <maxDoseQuantity/>
  <consumable/>
</substanceadministration>
```

Internal Reference

[Act: templateId `1.3.6.1.4.1.19376.1.5.3.1.4.4.1`]

CDA and HL7 Version 3 Entries may reference (point to) information contained in other entries within the same document or message

The act being referred to can be any CDA Clinical Statement element type (act, procedure, observation, substanceAdministration, supply, et cetera). For compatibility with the Clinical Statement model the internal reference shall always use the <act> class, regardless of the XML element type of the act it refers to.

1. **SHALL** contain exactly one [1..1] **`code`**
   - This element shall be present. It shall be valued when the internal reference is to element that has a <code> element, and shall have the same attributes as the <code> element in the act it references. If the element it references does not have a <code> element, then the nullFlavor attribute should be set to "NA".
2. **SHALL** contain zero or more [0..*] **`id`**
   - This element shall be present. The root and extension attributes shall identify an element defined elsewhere in the same document.

Internal Reference example

Medication

[SubstanceAdministration: templateId `1.3.6.1.4.1.19376.1.5.3.1.4.7`]

This content module describes the general structure for a medication. All medication administration acts will be derived from this content module.

The <substanceAdministration> element may contain subordinate <substanceAdministration> elements in a related component entry to deal with special cases (see the section below on Special Cases). These cases include split, tapered, or conditional dosing, or combination medications. The use of subordinate <substanceAdministration> elements to deal with these cases is optional. The comment field should always be used in these cases to provide the same information as free text in the top level <substanceAdministration> element.

1. **SHALL** conform to *CCD Medication Activity* template (templateId: `2.16.840.1.113883.10.20.1.24`)
2. **MAY** contain zero or more [0..*] **`approachSiteCode`**
   - The site where the medication is administered, usually used with IV or topical drugs. The <approachSiteCode> element describes the site of medication administrion. It may be coded to a controlled vocabulary that lists such sites (e.g., SNOMED-CT). In CDA documents, this 4805 element contains a URI in the value attribute of the <reference> that points to the text in the narrative identifying the site. In a message, the <originalText> element shall contain the text identifying the site.
3. **SHOULD** contain zero or one [0..1] **`doseQuantity`**
   - The amount of the medication given. This should be in some known and measurable unit, such as grams, milligrams, et cetera. It may be measured in 'administration' units (such as tablets or each), for medications where the strength is relevant. In this case, only the unit count is specified , no units are specified. It may be a range.
4. **SHOULD** contain zero or one [0..1] **`rateQuantity`**
   - The rate is a measurement of how fast the dose is given to the patient over time (e.g., .5 liter / 1 hr), and is often used with IV drugs.
5. **SHALL** contain exactly one [1..1] **`code`** (CodeSystem: `2.16.840.1.113883.6.96 SNOMEDCT`)
   - The <code> element is used to supply a code that describes the <substanceAdminstration> act, not the medication being administered or prescribed. This may be a procedure code, such as those found in CPT-4 (and often used for billing), or may describe the method of medication administration, such as by intravenous injection. The type of medication is coded in the consumable, do not supply the code for the medication in this element. This element is optional.
6. **SHALL** contain exactly one [1..1] **`statusCode`** (CONF-307)
   - The status of all 'substanceAdministration' elements must be "completed". The act has either occurred, or the request or order has been placed.
7. Contains at least one [1..*] **`entryRelationship`**, such that

- Entry may indicate one or more reasons for the use of the medication. The extension and root of each observation present must match the identifier of a concern entry contained elsewhere within the CDA document. A consumer of the Medical Summary is encouraged, but not required to maintain these links on import.

a. Contains exactly one [1..1] *Internal Reference* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.4.1`)

8. Contains at least one [1..*] **`entryRelationship`**, such that
   - At most one instruction may be provided for each <substanceAdministration> entry. The instructions shall contain any special case dosing instructions (e.g., split, tapered, or conditional dosing), and may contain other information (take with food, et cetera).

   a. Contains exactly one [1..1] *Patient Medical Instructions* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.3`)
9. Contains exactly one [1..1] **`entryRelationship`**, such that

   a. Contains exactly one [1..1] *Supply Entry* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.7.3`)
10. **SHALL** contain [0..2] **`effectiveTime`** (CONF-308)
11. **SHALL** satisfy: Contains one dosing template to identify this entry as a particular type of medication event. Possible dosing templates: 1.3.6.1.4.1.19376.1.5.3.1.4.7.1 Normal Dosing, 1.3.6.1.4.1.19376.1.5.3.1.4.8, Tapered Dosing, 1.3.6.1.4.1.19376.1.5.3.1.4.9 Split Dosing, 1.3.6.1.4.1.19376.1.5.3.1.4.10 Conditional Dosing, 1.3.6.1.4.1.19376.1.5.3.1.4.11 Combination Dosing.
    - There are a variety of special cases for dosing that need to be accounted for. Most of these special cases involve changing the dosage or frequency over time, or based on some measurement. When the dosage changes, then additional entries are required for each differing dosage.
    - ```
      [OCL]: self.templateId->exists(id : datatypes::II | id.root =
       '1.3.6.1.4.1.19376.1.5.3.1.4.7.1') xor self.templateId->exists(id :
       datatypes::II | id.root = '1.3.6.1.4.1.19376.1.5.3.1.4.8')
       xor self.templateId->exists(id : datatypes::II | id.root =
       '1.3.6.1.4.1.19376.1.5.3.1.4.9') xor self.templateId->exists(id :
       datatypes::II | id.root = '1.3.6.1.4.1.19376.1.5.3.1.4.10')
       xor self.templateId->exists(id : datatypes::II | id.root =
       '1.3.6.1.4.1.19376.1.5.3.1.4.11')
      ```
12. **SHALL** satisfy: contains one or more related components (<entryRelationship typeCode='COMP'>, either to handle split, tapered or conditional dosing, or to support combination medications.
    - n the first three cases, the subordinate components shall specify only the changed <frequency> and/or <doseAmount> elements. For conditional dosing, each subordinate component shall have a <precondition> element that specifies the <observation> that must be obtained before administration of the dose. The value of the <sequenceNumber> shall be an ordinal number, starting at 1 for the first component, and increasing by 1 for each subsequent component. Components shall be sent in <sequenceNumber> order.
    - ```
      [OCL]: self.templateId->exists(id : datatypes::II | id.root =
       '1.3.6.1.4.1.19376.1.5.3.1.4.8') xor
      self.templateId->exists(id : datatypes::II | id.root =
       '1.3.6.1.4.1.19376.1.5.3.1.4.9') xor
      self.templateId->exists(id : datatypes::II | id.root =
       '1.3.6.1.4.1.19376.1.5.3.1.4.10') xor
      self.templateId->exists(id : datatypes::II | id.root =
       '1.3.6.1.4.1.19376.1.5.3.1.4.11') implies self.entryRelationship-
      >exists(er | er.typeCode=vocab::x_ActRelationshipEntryRelationship::COMP)
      ```
13. **SHALL** satisfy: Values from SNOMED CT shall be used in the <code> element to record that a patient is either not on medications, or that medications are not known.
    - 182904002 "Drug Treatment Unknown" (To indicate lack of knowledge about drug therapy)

      182849000 "No Drug Therapy Prescribed" (To indicate the absense of any prescribed medications)

      408350003 "Patient Not On Self-Medications" (To indicate no treatment)
    - ```
      [OCL]: true
      ```
      ```

14. **SHALL** satisfy: The act/@classCode='ACT' and act/@moodCode='EVN' when recording reason for medication in InternalReference Template. (6.3.4.16.22)
    - self.internalReference->exists(ir : ihe::InternalReference | ar.classCode <> 'ACT' or ar.moodCode <> 'EVN')
    - OCL Issue - What is the internalReference relationship? unable to get OCL to reference
    - `[OCL]: true`
15. **SHALL** satisfy: The <consumable> element shall be present, and shall contain a Product Entry template
    - `[OCL]: self.consumable.manufacturedProduct.templateId->exists(id : datatypes::II | id.root = '1.3.6.1.4.1.19376.1.5.3.1.4.7.2')`
16. **SHALL** satisfy: The entryRelationship/@inversionInd attribute is 'true' for Patient Medical Instructions relationship
    - OCL Issue - What is the patientInstructions relationship? unable to get OCL to reference
    - `[OCL]: not self.entryRelationship->exists( er : cda::EntryRelationship | er.inversionInd <> true and er.act.templateId->exists(id : datatypes::II | id.root = '1.3.6.1.4.1.19376.1.5.3.1.4.3') )`
17. **SHOULD** satisfy: The name and strength of the medication is recorded in consumable/manufacturedProduct/manufacturedMaterial/code/originalText
    - `[OCL]: not self.consumable.manufacturedProduct.manufacturedMaterial.code.oclIsUndefined() implies not self.consumable.manufacturedProduct.manufacturedMaterial.code.originalText.oclIsUnd`
18. **SHALL** satisfy: Name of the substance or product is recorded in consumable/manufacturedProduct/manufacturedMaterial/name
    - `[OCL]: not self.consumable.manufacturedProduct.manufacturedMaterial.name.oclIsUndefined()`
19. **MAY** satisfy: the preconditions for use of the medication are recorded in the <precondition> element. element. The value attribute of the <reference> element is a URL that points to the CDA narrative describing those preconditions.
    - `[OCL]: not self.precondition.criterion.text->exists (t | t.reference.oclIsUndefined())`
20. **SHALL** satisfy: The entryRelationship/@inversionInd attribute is 'false' for Supply Entry relationship
    - `[OCL]: not self.entryRelationship->exists(er : cda::EntryRelationship | (not er.supply->isEmpty()) and er.inversionInd<>false )`
21. **SHOULD** satisfy: entryRelationship/sequenceNumber element should be present when the embedded 'supply' element has a moodCode attribute of EVN.
    - The prescription activity may have a <sequenceNumber> element to indicate the fill number. A value of 1, 2 or N indicates that it is the first, second, or Nth fill respectively of a specific prescription.
    - `[OCL]: not self.entryRelationship->exists(er| (not er.supply->isEmpty()) and er.sequenceNumber.value.oclIsUndefined() )`

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"/>
  <id root="243384677"/>
  <code code="1111999968"/>
  <statusCode code="completed"/>
  <effectiveTime value="20110830"/>
  <routeCode code="Value"/>
  <approachSiteCode code="267251964"/>
  <doseQuantity/>
  <rateQuantity/>
```

```
  <maxDoseQuantity/>
  <consumable/>
</substanceadministration>
```

Medication Fullfillment Instructions

[Act: templateId `1.3.6.1.4.1.19376.1.5.3.1.4.3.1`]

1. **SHALL** conform to *CCD Fulfillment Instruction* template (templateId: `2.16.840.1.113883.10.20.1.43`)
2. **SHALL** contain exactly one [1..1] **`code/@code`**`="FINSTRUCT"` (CodeSystem: `1.3.6.1.4.1.19376.1.5.3.2 IHEActCode`)
   - The <code> element indicates that this is a medication fulfillment instruction.
3. **SHALL** contain zero or one [0..1] **`statusCode`**
4. **SHALL** contain zero or one [0..1] **`text`**
   - The <text> element contains a free text representation of the instruction. For CDA this SHALL contain a provides a <reference>element to thelink text of the comment in the narrative portion of the document. The comment itself is not the act being coded, so it appears in the <text> of the <observation>, not as part of the <code>.

Medication Fullfillment Instructions example

Normal Dose

[SubstanceAdministration: templateId `1.3.6.1.4.1.19376.1.5.3.1.4.7.1`]

This template identifier is used to identify medication administration events that do not require any special processing.

1. **SHALL** conform to *Medication* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.7`)
2. **SHALL** satisfy: Medications that use this template identifier shall not use subordinate 'substanceAdministation' acts.
   - `[OCL]: self.entryRelationship.substanceAdministration->isEmpty()`

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="1.3.6.1.4.1.19376.1.5.3.1.4.7.1"/>
  <id root="1056208127"/>
  <code code="931982622"/>
  <statusCode code="completed"/>
  <effectiveTime value="20110830"/>
  <routeCode code="Value"/>
  <approachSiteCode code="1978855735"/>
  <doseQuantity/>
  <rateQuantity/>
  <maxDoseQuantity/>
  <consumable/>
</substanceadministration>
```

Observation Request Entry

[Observation: templateId `1.3.6.1.4.1.19376.1.5.3.1.1.20.3.1`]

1. **SHALL** conform to *CCD Plan Of Care Activity Observation* template (templateId: `2.16.840.1.113883.10.20.1.25`)

Observation Request 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">
  <templateId root="2.16.840.1.113883.10.20.1.25"/>
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.1.20.3.1"/>
  <id root="553693513"/>
  <code code="523356042"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
</observation>
```

Patient Medical Instructions

[Act: templateId `1.3.6.1.4.1.19376.1.5.3.1.4.3`]

Any medication may be the subject of further instructions to the patient, for example to indicate that it should be taken with food, et cetera. This structure is included in the target substance administration or supply act using the <entryRelationship> element defined in the CDA Schema.

1. **SHALL** conform to *CCD Patient Instruction* template (templateId: `2.16.840.1.113883.10.20.1.49`)
2. **SHALL** contain exactly one [1..1] **`@classCode`**`="ACT"` *Act* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
3. **SHALL** contain exactly one [1..1] **`code/@code`**`="PINSTRUCT"` (CodeSystem: `1.3.6.1.4.1.19376.1.5.3.2 IHEActCode`)
4. **SHALL** contain zero or one [0..1] **`statusCode`**
   - The code attribute of <statusCode> for all comments must be completed
5. **SHALL** contain zero or one [0..1] **`text`**
   - The <text> element indicates the text of the comment. For CDA, this SHALL be represented as a <reference> element that points at the narrative portion of the document. The comment itself is not the act being coded, so it appears in the <text> of the <observation>, not as part of the <code>.

Patient Medical Instructions example

Payer Entry

[Act: templateId `1.3.6.1.4.1.19376.1.5.3.1.4.18`]

1. **SHALL** conform to *CCD Policy Activity* template (templateId: `2.16.840.1.113883.10.20.1.26`)

Payer Entry 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="2.16.840.1.113883.10.20.1.26"/>
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.18"/>
  <id root="1022991518"/>
  <code code="384462973"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2011"/>
```

```
    <high value="2011"/>
  </effectiveTime>
</act>
```

Pregnancy Observation

[Observation: templateId `1.3.6.1.4.1.19376.1.5.3.1.4.13.5`]

A pregnancy observation is a Simple Observation that uses a specific vocabulary to record observations about a patient's current or historical pregnancies.

1. **SHALL** conform to *Simple Observation* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.13`)
2. **SHALL** contain exactly one [1..1] **`code`**
3. **SHALL** contain [0..0] **`interpretationCode`**
4. **SHALL** contain [0..0] **`methodCode`**
5. **SHALL** contain [0..0] **`repeatNumber`**
6. **SHALL** contain [0..0] **`targetSiteCode`**
7. **SHALL** contain at least one [1..*] **`value`**
   - The value of the observation shall be recording using a data type appropriate to the coded observation according to the table provided by IHE PCC specification.

Pregnancy Observation example

Problem Concern Entry

[Act: templateId `1.3.6.1.4.1.19376.1.5.3.1.4.5.2`]

This entry is a specialization of the Concern Entry, wherein the subject of the concern is focused on a problem.

1. **SHALL** conform to *Concern Entry* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.5.1`)
2. **SHALL** contain at least one [1..*] **`entryRelationship`**, such that
   a. Contains **`@typeCode="SUBJ"`** *SUBJ (has subject)*
   b. Contains exactly one [1..1] *Problem Entry* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.5`)

Problem Concern Entry 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"/>
  <id root="102271185"/>
  <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="2079356744"/>
      <code code="1619287599"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2011"/>
        <high value="2011"/>
```

```
      </effectiveTime>
    </observation>
  </entryRelationship>
</act>
```

Problem 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 *CCD Problem Observation* template (templateId: `2.16.840.1.113883.10.20.1.28`)
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
   - The <code> describes the process of establishing a problem. The code element should be used, as the process of determining the value is important to clinicians (e.g., a diagnosis is a more advanced statement than a symptom). When a physical exam observation is being recorded the code used should be "Finding." When a review of systems observation is being recorded the code used should be "Symptom." The recommended vocabulary for describing problems is specified as a value set. Subclasses of this content module may specify other vocabularies.
3. **SHOULD** contain exactly one [1..1] **`effectiveTime`**
   - The <effectiveTime> of this <observation> is the time interval over which the <observation> is known to be true. The <low> and <high> values should be no more precise than known, but as precise as possible. While CDA allows for multiple mechanisms to record this time interval (e.g., by low and high values, low and width, high and width, or center point and width), we are constraining Medical summaries to use only the low/high form. The <low> value is the earliest point for which the condition is known to have existed. The <high> value, when present, indicates the time at which the observation was no longer known to be true. Thus, the implication is made that if the <high> value is specified, that the observation was no longer seen after this time, and it thus represents the date of resolution of the problem. Similarly, the <low> value may seem to represent onset of the problem. Neither of these statements is necessarily precise, as the <low> and <high> values may represent only an approximation of the true onset and resolution (respectively) times. For example, it may be the case that onset occurred prior to the <low> value, but no observation may have been possible before that time to discern whether the condition existed prior to that time. The <low> value should normally be present. There are exceptions, such as for the case where the patient may be able to report that they had chicken pox, but are unsure when. In this case, the <effectiveTime> element shall have a <low> element with a nullFlavor attribute set to 'UNK'. The <high> value need not be present when the observation is about a state of the patient that is unlikely to change (e.g., the diagnosis of an incurable disease).
4. **SHALL** contain at least one [1..*] **`id`**
   - The specific observation being recorded must have an identifier (<id>) that shall be provided for tracking purposes. If the source EMR does not or cannot supply an intrinsic identifier, then a GUID shall be provided as the root, with no extension (e.g., <id root='CE1215CD-69EC-4C7B-805F-569233C5E159'/>). At least one identifier must be present, more than one may appear.

5. **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.
6. **SHALL** contain exactly one [1..1] **`value`**, where its data type is CD
   - 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.
7. **MAY** contain zero or one [0..1] **`entryRelationship`**, such that
   a. Contains exactly one [1..1] *Severity* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.1`)
8. **MAY** contain zero or one [0..1] **`entryRelationship`**, such that
   a. Contains **`@typeCode="`**`REFR"` *REFR (refers to)*
   b. Contains exactly one [1..1] *Problem Status Observation* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.1.1`)
9. **MAY** contain zero or one [0..1] **`entryRelationship`**, such that
   a. Contains **`@typeCode="`**`REFR"` *REFR (refers to)*
   b. Contains exactly one [1..1] *Health Status Observation* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.1.2`)
10. **MAY** contain zero or more [0..*] **`entryRelationship`**, such that
    a. Contains **`@typeCode="`**`SUBJ"` *SUBJ (has subject)*
    b. Contains exactly one [1..1] *Comment* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.2`)
11. The problem name **SHALL** be recorded in the entry by recording a <reference> where the value attribute points to the narrative text containing the name of the problem.
    - `[OCL]: not self.text.reference.oclIsUndefined()`
12. If entryRelationship / Comment is present, then entryRelationship **SHALL** include inversionInd = 'true'.
    - ```
      [OCL]: self.entryRelationship->forAll(rel : cda::EntryRelationship | (not
       rel.act.oclIsUndefined() and rel.act.oclIsKindOf(ihe::Comment)) implies
       rel.inversionInd=true)
      ```

Problem 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="723162898"/>
  <code code="636862358"/>
  <text/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
```
```

```
</observation>
```

Problem Entry Reaction Observation Container

[Observation: templateId `1.3.6.1.4.1.19376.1.5.3.1.4.5`]

1. **SHALL** conform to *Problem Entry* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.5`)
2. **SHALL** conform to *CCD Reaction Observation* template (templateId: `2.16.840.1.113883.10.20.1.54`)

Problem Entry Reaction Observation Container example

Problem Status Observation

[Observation: templateId `1.3.6.1.4.1.19376.1.5.3.1.4.1.1`]

Any problem or allergy observation may reference a problem status observation. The clinical status observation records information about the current status of the problem or allergy, for example, whether it is active, in remission, resolved, et cetera.

1. **SHALL** conform to *CCD Problem Status Observation* template (templateId: `2.16.840.1.113883.10.20.1.50`)
2. **SHALL** contain exactly one [1..1] **`text`**
3. **SHALL** contain exactly one [1..1] **`value`**, which **SHALL** be selected from ValueSet `ProblemStatusValue` **STATIC**
4. The 'text' elements **SHALL** contain a 'reference' element pointing to the narrative where the severity is recorded, rather than duplicate text to avoid ambiguity.
   - `[OCL]: not self.text.reference.oclIsUndefined()`

Problem Status Observation example

Procedure Entry

[Procedure: templateId `1.3.6.1.4.1.19376.1.5.3.1.4.19`]

1.

Procedure Entry example

```
Unable to create XML Snippet
```

Procedure Entry Plan Of Care Activity Procedure

[Procedure: templateId `1.3.6.1.4.1.19376.1.5.3.1.4.19`]

1. **SHALL** conform to *CCD Plan Of Care Activity Procedure* template (templateId: `2.16.840.1.113883.10.20.1.25`)
2. **SHALL** conform to *Procedure Entry* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.19`)

Procedure Entry Plan Of Care Activity Procedure example

```
<?xml version="1.0" encoding="UTF-8"?>
<procedure xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <templateId root="2.16.840.1.113883.10.20.1.25"/>
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.19"/>
  <id root="880062333"/>
```

```
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
</procedure>
```

Procedure Entry Procedure Activity Procedure

[Procedure: templateId `1.3.6.1.4.1.19376.1.5.3.1.4.19`]

1. **SHALL** conform to *CCD Procedure Activity Procedure* template (templateId: `2.16.840.1.113883.10.20.1.29`)
2. **SHALL** conform to *Procedure Entry* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.19`)
3. **SHALL** contain exactly one [1..1] **`@classCode="PROC"`** (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
4. **SHALL** contain exactly one [1..1] **`text`**
5. **MAY** contain zero or one [0..1] **`entryRelationship`**, such that
   - This element may be present to point the encounter in which the procedure was performed, and shall contain an internal reference to the encounter.
   a. Contains **`@typeCode="COMP"`** *COMP (has component)*
   b. Contains exactly one [1..1] *Internal Reference* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.4.1`)
6. **MAY** contain at least one [1..*] **`entryRelationship`**, such that
   - A <procedure> act may indicate one or more reasons for the procedure. These reasons identify the concern that was the reason for use via the Internal Reference entry content module. The extension and root of each observation present must match the identifier of a concern entry contained elsewhere within the CDA document.
   a. Contains **`@typeCode="RSON"`** *RSON (has reason)*
   b. Contains exactly one [1..1] *Internal Reference* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.4.1`)
7. **SHALL** contain exactly one [1..1] **`statusCode`**, which **SHALL** be selected from ValueSet `2.16.840.1.113883.1.11.20.15 ProcedureStatusCode` **STATIC** 20061017 (CONF-430, CONF-431)
   - The <statusCode> element shall be present when used to describe a procedure event. It shall have the value 'completed' for procedures that have been completed, and 'active' for procedures that are still in progress. Procedures that were stopped prior to completion shall use the value 'aborted', and procedures that were cancelled before being started shall use the value 'cancelled'.
8. **MAY** contain zero or more [0..*] **`approachSiteCode`**
   - This element may be present to indicate the procedure approach.
9. **SHALL** satisfy: Value for moodCode is 'INT' to indicate a planned procedure or 'EVN' to describe a procedure that has already occured.
   - `[OCL]: self.moodCode = vocab::x_DocumentProcedureMood::EVN or self.moodCode = vocab::x_DocumentProcedureMood::INT`
10. **SHALL** satisfy: The <text> element shall contain a reference to the narrative text describing the procedure.
    - `[OCL]: not self.text.reference.oclIsUndefined()`
11. **SHALL** satisfy: When the procedure is in event mood (moodCode='EVN'), this entry conforms to the CCD template 2.16.840.1.113883.10.20.1.29, and when in intent mood, this entry conforms to the CCD template 2.16.840.1.113883.10.20.1.25
12. <priorityCode> **SHALL** be present in INT mood when effectiveTime is not provided, it **MAY** be present in other moods
    - `[OCL]: self.moodCode = vocab::x_DocumentProcedureMood::INT and self.effectiveTime.oclIsUndefined() implies not self.priorityCode.oclIsUndefined()`

13. **SHALL** satisfy: The entryRelationship/@inversionInd attribute is 'true' for the reference to encounter (typecode=COMP)
    - `[OCL]: self.entryRelationship->select(er | er.typeCode = vocab::x_ActRelationshipEntryRelationship::COMP and er.inversionInd <> true)->isEmpty()`

Procedure Entry Procedure Activity Procedure example

```
<?xml version="1.0" encoding="UTF-8"?>
<procedure xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <templateId root="2.16.840.1.113883.10.20.1.29"/>
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.19"/>
  <id root="270284483"/>
  <code code="1548596338"/>
  <text/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
  <approachSiteCode code="1635002020"/>
</procedure>
```

Severity

[Observation: templateId `1.3.6.1.4.1.19376.1.5.3.1.4.1`]

This specification models a severity observation as a separate observation from the condition. While this model is different from work presently underway by various organizations (i.e., SNOMED, HL7, TermInfo), it is not wholly incompatible with that work. In that work, qualifiers may be used to identify severity in the coded condition observation, and a separate severity observation is no longer necessary. The use of qualifiers is not precluded by this specification. However, to support semantic interoperability between EMR systems using different vocabularies, this specification does require that severity information also be provided in a separate observation. This ensures that all EMR systems have equal access to the information, regardless of the vocabularies they support.

1. **SHALL** conform to *CCD Severity Observation* template (templateId: `2.16.840.1.113883.10.20.1.55`)
2. **SHALL** contain exactly one [1..1] **`text`**
3. **SHALL** contain exactly one [1..1] **`value`**, which **SHALL** be selected from ValueSet `SeverityObservation` **STATIC**, where its data type is CD
    - Value code representing high, moderate and low severity depending upon whether the severity is life threatening, presents noticeable adverse consequences, or is unlikely substantially effect the situation of the subject.
4. The 'text' elements **SHALL** contain a 'reference' element pointing to the narrative where the severity is recorded, rather than duplicate text to avoid ambiguity.
    - `[OCL]: not self.text.reference.oclIsUndefined()`

Severity example

Simple Observation

[Observation: templateId `1.3.6.1.4.1.19376.1.5.3.1.4.13`]

The simple observation entry is meant to be an abstract representation of many of the observations used in this specification. It can be made concrete by the specification of a few additional constraints, namely the vocabulary used for codes, and the value representation. A simple observation may also inherit constraints from other specifications (e.g., ASTM/HL7 Continuity of Care Document).

1. **SHALL** contain at least one [1..*] **`id`**

2. **SHALL** contain exactly one [1..1] **`statusCode/@code`**`="completed"` (CodeSystem: `2.16.840.1.113883.5.14 HL7ActStatus`)

Simple Observation example

Social History Observation

[Observation: templateId `1.3.6.1.4.1.19376.1.5.3.1.4.13.4`]

1. **SHALL** conform to *Simple Observation* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.13`)
2. **SHALL** conform to *CCD Social History Observation* template (templateId: `2.16.840.1.113883.10.20.1.33`)
3. **MAY** contain zero or more [0..*] **`value`**
   - The data type to use for each observation should be drawn from the table below. Observations in the table above using the PQ data type have a unit in the form {xxx}/d, {xxx}/wk or {xxx}/a represent the number of items per day, week or year respectively. The value attribute indicates the number of times of the act performed, and the units represent the frequency.

     229819007 Smoking PQ {pack}/d or {pack}/wk or {pack}/a 256235009 Exercise PQ {times}/wk 160573003 ETOH (Alcohol) Use PQ {drink}/d or {drink}/wk 364393001 Diet CD N/A 364703007 Employment CD N/A 425400000 Toxic Exposure CD N/A 363908000 Drug Use CD N/A 228272008 Other Social History ANY N/A
4. **SHOULD** satisfy: The <repeatNumber> element should not be used in a social history observation
5. **SHOULD** satisfy: The <interpretationCode> element should not be used in a social history observation
6. **SHOULD** satisfy: The <methodCode> element should not be used in a social history observation
7. **SHOULD** satisfy: The <targetSiteCode> element should not be used in a social history observation

Social History Observation example

Split Dose

[SubstanceAdministration: templateId `1.3.6.1.4.1.19376.1.5.3.1.4.9`]

This template identifier is used to identify medication administration events that require special processing to handle split dosing. The parent template is 1.3.6.1.4.1.19376.1.5.3.1.4.7. A split dose is often used when different dosages are given at different times (e.g., at different times of day, or on different days). This may be to account for different metabolism rates at different times of day, or to simply address drug packaging deficiencies (e.g., and order for Coumadin 2mg on even days, 2.5mg on odd days is used because Coumadin does not come in a 2.25mg dose form).

1. **SHALL** conform to *Medication* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.7`)
2. **SHALL** satisfy: A subordinate <substanceAdministration> entry is required for each separate dosage.
   - `[OCL]: not self.entryRelationship.substanceAdministration->isEmpty()`

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="1.3.6.1.4.1.19376.1.5.3.1.4.9"/>
  <id root="1657441095"/>
  <code code="1146950203"/>
  <statusCode code="completed"/>
  <effectiveTime value="20110830"/>
  <routeCode code="Value"/>
  <approachSiteCode code="1309956355"/>
```

```
  <doseQuantity/>
  <rateQuantity/>
  <maxDoseQuantity/>
  <consumable/>
</substanceadministration>
```

Supply Entry

[Supply: templateId `1.3.6.1.4.1.19376.1.5.3.1.4.7.3`]

The supply entry describes a prescription activity. The moodCode attribute shall be INT to reflect that a medication has been prescribed, or EVN to indicate that the prescription has been filled.

1. **SHALL** conform to *CCD Supply Activity* template (templateId: `2.16.840.1.113883.10.20.1.34`)
2. **SHOULD** contain exactly one [1..1] **`quantity`** (CONF-322)
   - The supply entry should indicate the quantity supplied. The value attribute shall be present and indicates the quantity of medication supplied. If the medication is supplied in dosing units (tablets or capsules), then the unit attribute need not be present (and should be set to 1 if present). Otherwise, the unit element shall be present to indicate the quantity (e.g., volume or mass) of medication supplied.
3. **SHOULD** contain exactly one [1..1] **`repeatNumber`** (CONF-321)
   - Each supply entry should have a <repeatNumber> element that indicates the number of times the prescription can be filled.
4. Contains zero or one [0..1] **`entryRelationship`**, such that
   a. Contains exactly one [1..1] *Medication Fullfillment Instructions* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.3.1`)
5. **MAY** satisfy: A supply entry that describes an intent (<supply classCode='SPLY' moodCode='INT'>) may include an <author> element to identify the prescribing provider.
6. **SHALL** satisfy: The <time> element must be present to indicate when the author created the prescription. If this information is unknown, it shall be recorded by setting the nullFlavor attribute to UNK.
7. **SHALL** satisfy: The <assignedAuthor> element shall be present in author, and identifies the author.
8. **SHOULD** satisfy: One or more <id> elements should be present in assignedAuthor
   - These identifiers identify the author of the act. When the author is the prescribing physician they may include local identifiers or regional identifiers necessary for prescribing.
9. **SHALL** satisfy: An <assignedPerson> and/or <representedOriganization> element shall be present in assignedAuthor. This element shall contain a <name> element to identify the prescriber or their organization.
10. **SHALL** satisfy: The <time> element shall be present in performer to indicate when the prescription was filled (moodCode='EVN'). If this information is unknown, it shall be recorded by setting the nullFlavor attribute to UNK.
11. **SHOULD** satisfy: The <time> element should be present to indicate when the prescription is intended to be filled (moodCode='INT').
12. **SHALL** satisfy: The performer/assignedEntity element shall be present, and identifies the filler of the prescription.
13. **SHOULD** satisfy: One or more <id> elements should be present. These identify the performer.
14. **SHALL** satisfy: An <assignedPerson> and/or <representedOriganization> element shall be present. This element shall contain a <name> element to identify the filler or their organization.

Supply Entry example

Tapered Dose

[SubstanceAdministration: templateId `1.3.6.1.4.1.19376.1.5.3.1.4.8`]

This template identifier is used to identify medication administration events that require special processing to handle tapered dosing. The parent template is 1.3.6.1.4.1.19376.1.5.3.1.4.7. A tapered dose is often used for certain

medications where abrupt termination of the medication can have negative consequences. Tapered dosages may be done by adjusting the dose frequency, the dose amount, or both.

When merely the dose frequency is adjusted, (e.g., Prednisone 5mg b.i.d. for three days, then 5mg. daily for three days, and then 5mg every other day), then only one medication entry is needed, multiple frequency specifications recorded in <effectiveTime> elements. When the dose varies (eg. Prednisone 15mg daily for three days, then 10 mg daily for three days, the 5 mg daily for three days), subordinate medication entries should be created for each distinct dosage.

1. **SHALL** conform to *Medication* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.7`)
2. **SHALL** satisfy: Subordinate Medication entries should be created for each distinct dosage.
   - `[OCL]: self.entryRelationship.substanceAdministration->exists( substanceAdministration | substanceAdministration.oclIsKindOf( ihe::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="1.3.6.1.4.1.19376.1.5.3.1.4.8"/>
  <id root="1065412211"/>
  <code code="2045459477"/>
  <statusCode code="completed"/>
  <effectiveTime value="20110830"/>
  <routeCode code="Value"/>
  <approachSiteCode code="26710906"/>
  <doseQuantity/>
  <rateQuantity/>
  <maxDoseQuantity/>
  <consumable/>
</substanceadministration>
```

Vital Sign Observation

[Observation: templateId `1.3.6.1.4.1.19376.1.5.3.1.4.13.2`]

A vital signs observation is a simple observation that uses a specific vocabulary, and inherits constraints from CCD.

1. **SHALL** conform to *CCD Result Observation* template (templateId: `2.16.840.1.113883.10.20.1.31`) (6.3.4.22.2)
2. **SHALL** conform to *Simple Observation* template (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.13`) (6.3.4.22.2)
3. **SHALL** contain exactly one [1..1] **`code`** (CodeSystem: `2.16.840.1.113883.6.1 LOINC`) (6.3.4.22.3)
4. **MAY** contain zero or more [0..*] **`interpretationCode`** (6.3.4.22.5)
   - The interpretation code may be present to provide an interpretation of the vital signs measure (e.g., High, Normal, Low, et cetera).
5. **MAY** contain zero or one [0..1] **`methodCode`** (6.3.4.22.6)
   - The method code element may be present to indicate the method used to obtain the measure. Note that method used is distinct from, but possibly related to the target site.
6. **MAY** contain zero or more [0..*] **`targetSiteCode`** (6.3.4.22.7)
   - The target site of the measure may be identified in the targetSiteCode element (e.g., Left arm [blood pressure], oral [temperature], et cetera).
7. **SHALL** contain exactly one [1..1] **`value`**, where its data type is PQ (6.3.4.22.4)

Vital Sign Observation 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"/>
  <id root="3565782"/>
  <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="237001224"/>
</observation>
```

Vital Signs Organizer

[Organizer: templateId `1.3.6.1.4.1.19376.1.5.3.1.4.13.1`]

A vital signs organizer collects vital signs observations.

1. **SHALL** conform to *CCD Vital Signs Organizer* template (templateId: `2.16.840.1.113883.10.20.1.35`) (6.3.4.21.3)
2. **SHALL** contain exactly one [1..1] **`@classCode`**`="CLUSTER"` (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (6.3.4.21.2)
   - The vital signs organizer is a cluster of vital signs observations.
3. **SHALL** contain exactly one [1..1] **`code/@code`**`="46680005"` *Vital signs* (CodeSystem: `2.16.840.1.113883.6.96 SNOMEDCT`) (6.3.4.21.5)
4. **SHALL** contain exactly one [1..1] **`effectiveTime`** (6.3.4.21.7)
   - The effective time element shall be present to indicate when the measurement was taken.
5. **SHALL** contain exactly one [1..1] **`statusCode/@code`**`="completed"` (CodeSystem: `2.16.840.1.113883.5.14 HL7ActStatus`) (6.3.4.21.6)
   - The observations have all been completed.
6. **SHALL** contain at least one [1..*] **`component`** (6.3.4.21.9), such that
   a. Contains exactly one [1..1] *Vital Sign Observation* (templateId: `1.3.6.1.4.1.19376.1.5.3.1.4.13.2`)
7. **SHALL** contain exactly one [1..1] **`author`** (6.3.4.21.8), such that
8. **SHALL** contain exactly one [1..1] **`id`** (6.3.4.21.4)
   - The organizer shall have an <id> element.
9. **SHALL** satisfy: ccd::ResultOrganizer template ID (2.16.840.1.113883.10.20.1.32) is included (6.3.4.21.3)
   -
```
[OCL]: self.templateId->exists(id : datatypes::II | id.root
 ='2.16.840.1.113883.10.20.1.32')
```

Vital Signs Organizer example

```
<?xml version="1.0" encoding="UTF-8"?>
<organizer 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="2.16.840.1.113883.10.20.1.32"/>
  <templateId root="2.16.840.1.113883.10.20.1.35"/>
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.13.1"/>
  <id root="1952640469"/>
```

```
  <code code="46680005" codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMEDCT" displayName="Vital signs"/>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="2011"/>
    <high value="2011"/>
  </effectiveTime>
  <component>
    <observation 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"/>
      <id root="708546724"/>
      <code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
      <statusCode code="completed"/>
      <effectiveTime>
        <low value="2011"/>
        <high value="2011"/>
      </effectiveTime>
    </observation>
  </component>
</organizer>
```

Chapter 5

OTHER CLASSES

Topics:

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

Healthcare Providers Pharmacies

[Performer1: templateId `1.3.6.1.4.1.19376.1.5.3.1.2.3`]

1.

Healthcare Providers Pharmacies 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"/>
  <time>
    <low value="2011"/>
    <high value="2011"/>
  </time>
  <assignedEntity/>
</performer1>
```

Language Communication

[LanguageCommunication: templateId `1.3.6.1.4.1.19376.1.5.3.1.2.1`]

1.

Language Communication example

```
Unable to create XML Snippet
```

Patient Contact

1. **SHALL** conform to *CCD Support*

Patient Contact example

Patient Contact Guardian

[Guardian: templateId `1.3.6.1.4.1.19376.1.5.3.1.2.4`]

1. **SHALL** conform to *CCD Support Guardian*
2. **SHALL** conform to *Patient Contact*
3. **SHALL** contain exactly one [1..1] **`@classCode`**`="GUAR"`
4. **SHOULD** contain zero or more [0..*] **`addr`**
5. **SHALL** contain zero or one [0..1] **`code`** (CodeSystem: `2.16.840.1.113883.5.111 RoleCode`)
6. **SHOULD** contain zero or more [0..*] **`telecom`**

Patient Contact Guardian example

Patient Contact Participant

[Participant1: templateId `1.3.6.1.4.1.19376.1.5.3.1.2.4`]

1. **SHALL** conform to *CCD Support Participant*
2. **SHALL** conform to *Patient Contact*
3. **SHALL** contain exactly one [1..1] **`@typeCode`**`="IND"`
4. **MAY** contain zero or one [0..1] **`time`**

- Indicates the time of the participation.

Patient Contact Participant example

Product Entry

[ManufacturedProduct: templateId `1.3.6.1.4.1.19376.1.5.3.1.4.7.2`]

The product entry describes a medication or immunization used in a 'substanceAdministration' or 'supply' act

In a CDA document, the name and strength of the medication are specified in the elements under the 'manufacturedMaterial' element.

The 'code' element of the 'manufacturedMaterial' describes the medication. This may be coded using a controlled vocabulary, such as RxNorm, First Databank, or other vocabulary system for medications, and should be the code that represents the generic medication name and strength (e.g., acetaminophen and oxycodone -5/325), or just the generic medication name alone if strength is not relevant (Acetaminophen). In a CDA document, the <originalText> shall contain a 'reference' whose URI value points to the generic name and strength of the medication, or just the generic name alone if strength is not relevant.

1. **SHALL** conform to *CCD Product* template (templateId: `2.16.840.1.113883.10.20.1.53`)

Product Entry example

```
<?xml version="1.0" encoding="UTF-8"?>
<manufacturedproduct xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
 xmlns="urn:hl7-org:v3" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <templateId root="2.16.840.1.113883.10.20.1.53"/>
  <templateId root="1.3.6.1.4.1.19376.1.5.3.1.4.7.2"/>
  <id root="40193670"/>
</manufacturedproduct>
```

Scan Data Enterer

[DataEnterer: templateId `1.3.6.1.4.1.19376.1.2.20.3`]

Represents the scanner operator who produced the scanned content.

1. **SHALL** contain exactly one [1..1] **`time`**
   - Denotes the time at which the original content was scanned.
2. **SHALL** satisfy: The time shall be equal to that of ClinicalDocument/effectiveTime. At a minimum, the time shall be precise to the day and shall include the time zone offset from GMT.
   - `[OCL]: self.time.value = self.getClinicalDocument().effectiveTime.value`
3. **SHALL** satisfy: The assignedEntity/id element has both the root and the extension attributes. The root shall be the oid of the scanning facility and the extension shall be an appropriately assigned, facility unique id of the operator.
   - `[OCL]: self.assignedEntity.id->forAll(ident : datatypes::II | not ident.root.oclIsUndefined() and not ident.extension.oclIsUndefined())`

Scan Data Enterer example

Scan Original Author

[Author: templateId `1.3.6.1.4.1.19376.1.2.20.1`]

Represents the author of the original content. It additionally can encode the original author?s institution in the subelement representedOrganization. Information regarding the original author and his/her institution shall be included, if it is known. In many cases this will have to be supplied by the operator.

1. Contains exactly one [1..1] **`time`**

- Represents the day and time of the authoring of the original content. This value is not restricted beyond statements made in the HL7 CDA R2 documentation.

2. **SHOULD** satisfy: The assignedAuthor/id element if known shall include both the root and the extension attributes. Refer to PCC TF-2: 4.1.1 for more details.

   - `[OCL]: self.assignedAuthor.id->forAll(ident : datatypes::II | not ident.root.oclIsUndefined() and not ident.extension.oclIsUndefined())`

3. **SHOULD** satisfy: The assignedAuthor/representedOrganization/id element if known shall include both the root and the extension attributes. Refer to PCC TF-2: 4.1.1 for more details.

   - `[OCL]: self.assignedAuthor.representedOrganization.id->forAll(ident : datatypes::II | not ident.root.oclIsUndefined() and not ident.extension.oclIsUndefined())`

Scan Original Author example

Scanning Device

[Author: templateId `1.3.6.1.4.1.19376.1.2.20.2`]

Represents the scanning device and software used to produce the scanned content.

1. Contains exactly one [1..1] **`time`**

   - Denotes the time at which the original content was scanned.

2. **SHALL** satisfy: The time shall be equal to that of ClinicalDocument/effectiveTime. At a minimum, the time shall be precise to the day and shall include the time zone offset from GMT.

   - `[OCL]: self.time.value = self.getClinicalDocument().effectiveTime.value`

3. **SHALL** satisfy: The assignedAuthor/id element shall be at least the root oid of the scanning device.

   - `[OCL]: self.assignedAuthor.id->forAll(ident : datatypes::II | not ident.root.oclIsUndefined())`

4. **SHALL** satisfy: The assignedAuthor/assignedAuthoringDevice/code element is present. The values set here are taken from appropriate DICOM vocabulary. The value of code@codeSystem shall be set to "1.2.840.10008.2.16.4". The value of code@code shall be set to "CAPTURE" for PDF scanned content and "WSD" for plaintext. The value of code@displayName shall be set to "Image Capture" for PDF scanned content and "Workstation" for plaintext.

   - `[OCL]: self.assignedAuthor.assignedAuthoringDevice.code.codeSystem = '1.2.840.10008.2.16.4' and not self.assignedAuthor.assignedAuthoringDevice.code.code.oclIsUndefined() and not self.assignedAuthor.assignedAuthoringDevice.code.displayName.oclIsUndefined()`

5. **SHALL** satisfy: The assignedAuthor/assignedAuthoringDevice/manufacturerModelName element is present.

   - The mixed content shall contain string information that specifies the scanner product name and model number. From this information, features like bit depth and resolution can be inferred. In the case of virtually scanned documents (for example, print to PDF), the manufactureModelName referenced here refers to the makers of the technology that was used to produce the embedded content.

   - `[OCL]: not self.assignedAuthor.assignedAuthoringDevice.manufacturerModelName.oclIsUndefined()`

6. **SHALL** satisfy: The assignedAuthor/assignedAuthoringDevice/softwareName element is present.

- The mixed content shall contain string information that specifies the scanning software name and version. In the case of virtually scanned documents, the softwareName referenced here refers to the technology that was used to produce the embedded content.
- `[OCL]: not self.assignedAuthor.assignedAuthoringDevice.softwareName.oclIsUndefined()`

7. **SHALL** satisfy: The assignedAuthor/representedOrganization/id element is present. The root attribute shall be set to the oid of the scanning facility.
   - `[OCL]: self.assignedAuthor.representedOrganization.id->forAll(ident : datatypes::II | not ident.root.oclIsUndefined())`

Scanning Device example

Chapter 6

VALUE SETS

Topics:

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

Concern Entry Status

Value Set	ConcernEntryStatus - (OID not specified)
Description	A concern in the "active" state represents one for which some ongoing clinical activity is expected, and that no activity is expected in other states. Specific uses of the suspended and aborted states are left to the implementation.

Concept Code	Concept Name	Code System	Description
active			
suspended			
aborted			
completed			

Health Status Value

Value Set	HealthStatusValue - (OID not specified)
Code System	SNOMEDCT - 2.16.840.1.113883.6.96

Concept Code	Concept Name	Code System	Description
81323004	Alive and well	SNOMEDCT	
313386006	In remission	SNOMEDCT	
162467007	Symptom free	SNOMEDCT	
161901003	Chronically ill	SNOMEDCT	
271593001	Severely ill	SNOMEDCT	
21134002	Disabled	SNOMEDCT	
161045001	Severely disabled	SNOMEDCT	
419099009	Deceased	SNOMEDCT	

Problem Status Value

Value Set	ProblemStatusValue - (OID not specified)
Code System	SNOMEDCT - 2.16.840.1.113883.6.96

Concept Code	Concept Name	Code System	Description
55561003	Active	SNOMEDCT	
73425007	Inactive	SNOMEDCT	
90734009	Chronic	SNOMEDCT	
7087005	Intermittent	SNOMEDCT	

Concept Code	Concept Name	Code System	Description
255227004	Recurrent	SNOMEDCT	
415684004	Rule out	SNOMEDCT	
410516002	Ruled out	SNOMEDCT	
413322009	Resolved	SNOMEDCT	

Severity Observation

Value Set	SeverityObservation - (OID not specified)
Code System	SeverityObservation - 2.16.840.1.113883.5.1063

Concept Code	Concept Name	Code System	Description
H	High	SeverityObservation	
M	Moderate	SeverityObservation	
L	Low	SeverityObservation	

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- HL7 Implementation Guide for CDA Release 2 CDA for Public Health Case Reports (PHCR) Informative Standard October 2009. Available through *HL7* .
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- *SNOMED CT®* : SNOMED Clinical Terms SNOMED International Organization.
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- 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*