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Implementation Guide for CDA Release 2.0

Consolidated CDA Templates

(US Realm)

DRAFT

April 2011

Produced in collaboration with:



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The conformance requirements included here for review were generated from two model-driven tools: the Model-Driven Health Tools (MDHT)—developed as on open source tool under the auspices of the Veterans Administration, IBM, and the ONC—and the Template Database (Tdb)—developed initially for the Centers for Disease Control and Prevention (CDC) and released by Lantana under an open source license.

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# Introduction

## Audience

The audiences for this implementation guide are the architects and developers of healthcare information technology (HIT) systems in the US Realm that exchange patient clinical data including those exchanges that comply to the Health Information Technology for Economic and Clinical Health (HITECH) provisions of the [American Recovery And Reinvestment Act of 2009](http://www.gpo.gov/fdsys/pkg/PLAW-111publ5/content-detail.html) and the [Final Rules for Meaningful Use](http://edocket.access.gpo.gov/2010/pdf/2010-17207.pdf).

Business analysts and policy managers can also benefit from a basic understanding of the use of Clinical Document Architecture (CDA) templates across multiple implementation use cases.

## Purpose

This guide contains a library of CDA templates, incorporating and harmonizing previous efforts from Health Level Seven (HL7), Integrating the Healthcare Enterprise (IHE), and Health Information Technology Standards Panel (HITSP).

When complete, this guide will provide a single source for implementing the following CDA documents (see the [References](#_References) section for complete source listings):

* [Continuity of Care Document](#Doc_CCD) (CCD)
* [Consultation Notes](#Doc_ConsultationNote)
* [Discharge Summary](#Doc_DischargeSummary)
* Imaging Integration, and DICOM Diagnostic Imaging Reports (DIR)
* History and Physical (H&P)
* Operative Note
* Progress Note
* Procedure Note
* Unstructured Documents

HL7, IHE, and the Health Story Project collaborated to consolidate an initial set of requirements from the the HL7 Health Story guides, HITSP C32, related components of IHE Patient Care Coordination (IHE PCC), and CCD into this ballot.

This ballot package represents a partial harmonization of these works and includes all required CDA templates in [Final Rules for Meaningful Use](http://edocket.access.gpo.gov/2010/pdf/2010-17207.pdf).

## Scope

This document is scoped by the content of the eight Health Story Guides, CCD, and additional constraints from IHE and HITSP. New conformance rules were not introduced unless an ambiguity or conflict existed among the standards.

All CDA templates required for Final Rules for Meaningful Use[[1]](#footnote-1) are included in this guide. All CDA templates required for Health Story compliance to the section level are included, as well, of course, as the Health Story reuse of Meaningful Use templates.

When complete, this guide will fully specify a compliant CDA R2 document for each of document types. At present, the entry-level templates cover only those required for Meaningful Use. The next release of this guide will include the full set of entry-level templates used by CCD, Health Story, and the corresponding IHE profiles.

Additional optional CDA elements, not included here, can be included and the result will be compliant with the documents in this standard.

## Approach

In the development of this specification, the Consolidation Project team reviewed the eight existing HL7 Health Story guides, CCD, and the additional constraints from IHE, HITSP and Meaningful Use.

The Consolidation Project team members completed the analysis by creating a fully compliant CCD document, then layering in the additional HITSP, IHE and Meaningful Use constraints. When a new constraint introduced an issue, conflict or ambiguity, the item was flagged for review with the full consolidation team. The full analysis covered the CDA Header, section-level and entry-level requirements sufficient for Meaningful Use The Project also reviewed document and section-level requirements for the full set of document types. The full set of entries has not been reviewed. These unconsolidated entries are included here for reference, flagged as pre-review.

All major template changes are summarized in the [Change Appendix](#A_Changes). A full mapping of change is anticipated for after ballot.

All involved in the Consolidation Project recognize the critical need for an intrinsic tie between the human-readable conformance requirements, the computable expression of those requirements, the production of validation test suites and application interfaces to facilitate adoption. To that end, the analysis performed by the volunteers and staff of the Consolidation Project was the prelude to data entry into a set of model-based tools.

Most of the conformance requirements and value set tables published here were output from the Template Database (Tdb), an open source application first developed for the Centers for Disease and Prevention and in active use by the National Healthcare Safety Network[[2]](#footnote-2). Post-ballot, the Tdb will be the source for generation of platform-independent validation rules as Schematron[[3]](#footnote-3) (compiled XPath). Further demonstrating the emerging toolset for templated CDA, certain templates, those for the Problem Section and Entries, were output from the Model-Driven Health Tools (MDHT) developed under the auspices of the Veterans Administration and IBM with assistance from the ONC Standards & Interoperability Framework[[4]](#footnote-4). MDHT provides an Eclipse environment for model-driven validation and a set of APIs based on the underlying UML model.

The consolidation of templates developed across these organizations and their publication in catalog form driven from model-based tools is a strong step toward satisfying the full range of requirements for clincial information use and reuse through templated CDA.

## Organization of This Guide

This guide includes a set of CDA Templates, and prescribes their use for a set of specific document types. The main chapters are:

[Chapter 2. General Header Template](#_General_Header_Template). This chapter defines a template for the header constraints that apply across all of the consolidated document types.

[Chapter 3. Document-level Templates.](#_Document-Level_Templates) This chapter describes each of the nine document types. It defines header constraints specific to each and the section-level templates (required and optional) for each.

[Chapter 4. Section-level Templates.](#_Section-Level_Templates) This chapter describes the section-level constraints for sections referenced within the document types described here and which can be reused by future specifications.

[Chapter 5. Entry-level Templates.](#_Entry-level_Templates) This chapter specifies the atomic units of the report, the entry templates, or clinical statements. Machine-processable data is sent in the entry templates. The entry templates are referenced by section templates.

[Appendices](#A_Changes). The Appendices include non-normative content to support implementers. It includes a [Change Appendix](#A_Changes) summary of previous and updated templateId types.

## Use of Templates

Template identifiers (templateId) are assigned at the document, section, and entry level. When valued in an instance, the template identifier signals the imposition of a set of template-defined constraints. The value of this attribute provides a unique identifier for the template in question.

### Originator Responsibilities: General Case

An originator can apply a templateId if there is a desire 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. The implementation guide (IG) shall assert whenever templateIds are required for conformance.

### Recipient Responsibilities: General Case

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

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

## Conformance

### Levels of Constraint

CDA implementers think about conformance requirements in terms of three general levels corresponding to three different, incremental types of conformance statements:

* Level 1 requirements impose constraints upon the CDA Header. The body of a Level 1 document may be XML or an alternate allowed format. If XML, it must be CDA-conformant markup.
* Level 2 requirements specify constraints at the section level of a CDA XML document: most critically, the section code and the cardinality of the sections themselves, whether optional or required.
* Level 3 requirements specify constraints at the entry level within a section. A specification is considered “Level 3” if it requires any entry-level templates.

Note that these levels are rough indications of what a recipient can expect in terms of machine-processable coding and content reuse. They do not reflect the level or type of clinical content, and many additional levels of reusability could be defined.

In this consolidated guide, Unstructured Documents, by definition, are Level 1. Meaningful Use of CCD requires certain entries and is therefore a Level 3 requirement. The balance of the document types can be implemented at any level, although at this point, only the Meaningful Use entry-level templates have been consolidated.

In all cases, required clinical content must be present. For example, a CDA Procedure Note carrying the templateId that asserts conformance with Level 1 may use a PDF (portable document format) or HTML (hypertext markup language) format for the body of the document that contains the required clinical content. Conformance, in this case, to the clinical content requirements could not be validated without human review.

The section libraries for each document type list the required and optional sections.

### Conformance Statements

Most conformance statements within this implementation guide are presented as constraints from a Template Database (Tdb). An algorithm converts constraints recorded in a Templates Database to a printable presentation. Each constraint is uniquely identified by an identifier at or near the end of the constraint (e.g., CONF:7345). These identifiers are persistent but not sequential. Constraints from the Model-Driven Health Tools (MDHT) look similar, but do not contain the same unique identifiers; many reference conformance statements from the source document.

In open templates, all of the features of the CDA R2 base specification are allowed except as constrained by the templates. By contrast, a closed template specifies everything that is allowed and nothing further may be included.

Specific aspects of conformance statements—conformance verbs, cardinality, vocabulary conformance, and null flavors—are described in the next sections.

Figure 1: Constraints format example

**Severity Observation**

[observation: templateId 2.16.840.1.113883.10.20.21.4.8(open)]

This clinical statement represents the severity of the reaction to an agent. A person may manifest many symptoms …

1. **SHALL** contain exactly one [1..1] **@classCode**="OBS" Observation (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:7345).
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" Event (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:7346).
3. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.4.8" (CONF:7347).
4. **SHALL** contain exactly one [1..1] **code**="SEV" Severity Observation (CodeSystem: 2.16.840.1.113883.5.4 HL7ActCode) **STATIC** (CONF:7349).
5. **SHOULD** contain exactly one [1..1] **text** (CONF:7350).
   1. This text **SHOULD** contain exactly one [1..1] **reference** (CONF:7351).
      1. A reference/@value **SHOULD** point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1 ). (CONF:7378).
6. **SHALL** contain exactly one [1..1] **statusCode/@code**="completed" Completed (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:7352).
7. **SHALL** contain exactly one [1..1] **value with @xsi:type="CD"**, where the @code **SHALL** be selected from ValueSet 2.16.840.1.113883.3.88.12.3221.6.8 Problem Severity **DYNAMIC** (CONF:7356).

### Conformance Verbs (Keywords)

The keywords shall, should, may, need not, should not, and shall not in this document are to be interpreted as described in the [HL7 Version 3 Publishing Facilitator's Guide (http://www.hl7.org/v3ballot/html/help/pfg/pfg.htm)](http://www.hl7.org/v3ballot/html/help/pfg/pfg.htm):

* 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

The keyword "shall" implies a lower cardinality of 1, but allows NULL values. If NULL values are to be excluded, it will be via an additional explicit conformance statement.

The [Consolidated Conformance Verb Matrix](#T_ConsolidatedConformanceVerbMatrix) table represents a matrix of the conformance verbs used across the standards reviewed for the consolidation guide.

### Cardinality

The cardinality indicator (0..1, 1..1, 1..\*, etc.) specifies the allowable occurrences within a document instance. The cardinality indicators may be interpreted as follows:

* 0..1 zero or one
* 1..1 exactly one
* 1..\* at least one
* 0..\* zero or more
* 1..n at least one and not more than n

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.

When a constraint has subordinate clauses, the scope of the cardinality of the parent constraint must be clear. In the next figure, the constraint says exactly one participant is to be present. The subordinate constraint specifies some additional characteristics of that participant.

Figure 2: Constraints format – only one allowed

1. SHALL contain exactly one [1..1] **participant** (CONF:2777).

a. This participantSHALL contain exactly one [1..1] **@typeCode**="LOC"   
 (CodeSystem: 2.16.840.1.113883.5.90 HL7ParticipationType)   
 (CONF:2230).

In the next figure, the constraint says only one participant “like this” is to be present. Other participant elements are not precluded by this constraint

Figure 3: Constraints format – only one like this allowed

1. SHALL contain exactly one [1..1] **participant** (CONF:2777) such that it

a. SHALL contain exactly one [1..1] **@typeCode**="LOC" (CodeSystem:

2.16.840.1.113883.5.90 HL7ParticipationType) (CONF:2230).

### Vocabulary Conformance

The templates in this document use terms from several code systems. These controlled vocabularies are defined in various supporting specifications and may be maintained by other bodies, as is the case for the LOINC® and SNOMED CT® vocabularies.

Note that value-set identifiers do not appear in CDA submissions; they tie the conformance requirements of an implementation guide to the appropriate code system for validation.

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. Value-set constraints can be “static,” meaning that they are bound to a specified version of a value set, or “dynamic,” meaning that they are bound to the most current version of the value set. A simplified constraint, used when the binding is to a single code, includes the meaning of the code, for example “@moodCode="EVN" Event (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood)”.

There is a discrepancy in the implementation of translation code versus the original code between HL7 Data Types R1 and the convention agreed upon for this specification. The R1 data type requires the original code in the root. This implementation guide specifies the standard code in the root, whether it is original or a translation. This discrepancy is resolved in HL7 Data Types R2.

### Null Flavor

Information technology solutions store and manage data, but sometimes data are not available: an item may be unknown, not relevant, or not computable or measureable. In HL7, a *flavor* of null, or nullFlavor, describes the reason for missing data.

For example, if a patient arrives at an Emergency Department unconscious and with no identification, we would use a null flavor to represent the lack of information. The patient’s birth date would be represented with a null flavor of “NAV”, which is the code for “temporarily unavailable”. When the patient regains consciousness or a relative arrives, we expect to know the patient’s birth date.

Figure 4: nullFlavor example

<birthTime nullFlavor=”NAV”/> <!--coding an unknown birthdate-->

Use one of the following null flavors for unknown, required or optional attributes. Null flavors may not be used for mandatory attributes:

NI No information. This is the most general and default null flavor.

NA Not applicable. Known to have no proper value (e.g., last menstrual period for a male).

UNK Unknown. A proper value is applicable, but is not known.

ASKU Asked, but not known. Information was sought, but not found (e.g., the patient was asked but did not know).

NAV Temporarily unavailable. The information is not available, but is expected to be available later.

NASK Not asked. The patient was not asked.

MSK There is information on this item available but it has not been provided by the sender due to security, privacy, or other reasons. There may be an alternate mechanism for gaining access to this information.

This list contains those null value that are commonly used in clinical documents. For the full list and descriptions, see the nullFlavor vocabulary domain in the CDA Normative Edition.

Any SHALLconformance statement may use nullFlavor, unless the attribute is explicity required or the nullFlavor is explicitly disallowed.

Figure 5: Attribute explicity required

1. **SHALL** contain exactly one [1..1] **code/@code**="11450-4" Problem List (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:7878)

or

2**. SHALL** contain exactly one [1..1] **effectiveTime/@value** (CONF:5256).

Figure 6: nullFlavor explictly disallowed

1. **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:5256).

a. **SHALL NOT** contain [0..0] nullFlavor(CONF:52580).

## Conventions Used in This Guide

### XPath Notation

Instead of the traditional dotted notation used by HL7 to represent Reference Information Model (RIM) classes, this document uses XML Path Language (XPath) notation[[5]](#footnote-5) in conformance statements and elsewhere to identify the Extended Markup Language (XML) elements and attributes within the CDA document instance to which various constraints are applied. The implicit context of these expressions is the root of the document. This notation provides a mechanism that will be familiar to developers for identifying parts of an XML document.

Xpath statements appear in this document in a monospace font.

### XML Examples and Sample Documents

Extended Mark-up Language (XML) examples appear in figures in this document in this monospace font. Portions of the XML content may be omitted from the content for brevity, marked by an ellipsis (...) as shown in the example below.

Figure 7: ClinicalDocument example

<ClinicalDocument xmins="urn:h17-org:v3">

...

</ClinicalDocument>

Within the narrative, XML element and attribute names also appear in this monospace font.

This ballot package includes complete sample documents as listed in the [Content of the Package](#T_ContentOfDSTU) table below. These documents to the Level 1, Level 2, and Level 3 constraints of this guide (see the [Levels of Constraint](#_Levels_of_Constraint_1) section).

### Non-consolidated Entries

Where entries are referenced that have not yet gone through consolidation review, they are included here using the following convention:

**NOTE**: This conformance statement is for reference only. It has not yet been reviewed and consolidated according to the scope and intent of this guide.

* 1. CONF-XXXX: The Advance Directives section **SHOULD** contain clinical statements. Clinical statements **SHOULD** include one or more advance directive observations (templateId 2.16.840.1.113883.10.20.1.17). An advance directive observation **MAY** contain exactly one advance directive reference (templateId 2.16.840.1.113883.10.20.1.36) to an external advance directive document. (CONF:7958).

## Content of the Package

The following files comprise the package:

Table 1: Content of the Package

|  |  |
| --- | --- |
| Filename | Description |
| CDAR2\_IG\_CONSOL\_R1\_D1\_2011APR.doc | Implementation Guide |
| Consults.Sample.xml | Consultation Note |
| DIR.xml | Diagnostic Imaging Report |
| MU\_CCDSample.xml | Continuity of Care Document/C32 |
| DS\_Sample.xml | Discharge Summary Report |
| HandP.sample.xml | History and Physical Report |
| OpNote.xml | Operative Note |
| Procedure\_Note.xml | Procedure Note |
| Progress\_Note.xml | Progress Note |
| UD\_sample.xml | Unstructured Document |
| cda.xsl | CDA stylesheet |

# General Header Template

This section describes constraints that apply to the header for all documents within the scope of this implementation guide. Header constraints specific to each document type are described in the appropriate document-specific section below.

US Realm Clinical Document Header

[ClinicalDocument: templateId 2.16.840.1.113883.10.20.21.1.1(open)]

1. **SHALL** contain exactly one [1..1] **realmCode**="US" (CONF:5249).
2. **SHALL** contain exactly one [1..1] **typeId** (CONF:5361).
   1. This typeId **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.1.3" (CONF:5250).
   2. This typeId **SHALL** contain exactly one [1..1] **@extension**="POCD\_HD000040" (CONF:5251).
3. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.1.1" (CONF:5252).
4. **SHALL** contain exactly one [1..1] **id** (CONF:5363).
5. **SHALL** contain exactly one [1..1] **code** (CONF:5253).
6. **SHALL** contain exactly one [1..1] **title** (CONF:5254).
   1. can either be a locally defined name or the display name corresponding to clinicalDocument/code (CONF:5255).
7. **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:5256).
   1. The value of @value, if present, SHALL be precise to the day and SHOULD be precise to the minute. If precise to minute, SHOULD include time-zone offset (CONF:5257).
8. **SHALL** contain exactly one [1..1] **confidentialityCode**, which **SHOULD** be selected from ValueSet 2.16.840.1.113883.1.11.16926 BasicConfidentialityKind **STATIC** 2010-04-21 (CONF:5259).
9. **SHALL** contain exactly one [1..1] **languageCode/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.11526 LanguageValueSet **DYNAMIC** (CONF:5372).
10. **MAY** contain zero or one [0..1] **setId** (CONF:5261).
    1. setId and versionNumber SHALL both be present, or SHALL both be absent (CONF:6380).
11. **MAY** contain zero or one [0..1] **versionNumber** (CONF:5264).
    1. setId and versionNumber SHALL both be present, or SHALL both be absent (CONF:6387).

Table 2: Basic Confidentiality Kind Value Set

| Value Set: HL7 BasicConfidentialityKind 2.16.840.1.113883.1.11.16926 | | |
| --- | --- | --- |
| Code System(s): | HL7 Confidentiality Code 2.16.840.1.113883.5.25 | |
| Code | Code System | Print Name |
| N | HL7 Confidentiality Code | Normal |
| R | HL7 Confidentiality Code | Restricted |
| V | HL7 Confidentiality Code | Very Restricted |

Table 3: Language Value Set

| Value Set: Language 2.16.840.1.113883.1.11.11526 | | |
| --- | --- | --- |
| Code System(s): | Internet Society Language 2.16.840.1.113883.1.11.11526 | |
| Description: | A value set of codes defined by Internet RFC 4646 (replacing RFC 3066). Please see ISO 639 language code set maintained by Library of Congress for enumeration of language codes  <http://www.ietf.org/rfc/rfc4646.txt> | |
|  | Example codes for reference | |
| Code | Code System | Print Name |
| en | Internet Society Language | english |
| fr | Internet Society Language | french |
| ar | Internet Society Language | arabic |
| … |  |  |

### RecordTarget

The recordTarget records the patient whose health information is described by the clinical document; it must contain at least one patientRole element.

1. **SHALL** contain at least one [1..\*] **recordTarget** (CONF:5266).
   1. Such recordTargets **SHALL** contain at least one [1..\*] **patientRole** (CONF:5267).
      1. Such patientRoles **SHALL** contain at least one [1..\*] **id** (CONF:5268).
      2. Such patientRoles **SHALL** contain at least one [1..\*] [**US Realm Clinical Document Header Address**](#S_USRealmHeaderAddress) (templateId:2.16.840.1.113883.10.20.22.5.2) (CONF:5271).
      3. Such patientRoles **SHALL** contain at least one [1..\*] **telecom** (CONF:5280).
         1. Such telecoms **SHOULD** contain **@use**, which **SHOULD** be selected from ValueSet 2.16.840.1.113883.11.20.9.20 Telecom use (US Realm Clinical Document Header) **DYNAMIC** (CONF:5375).
      4. Such patientRoles **SHALL** contain exactly one [1..1] **patient** (CONF:5283).
         1. This patient **SHALL** contain exactly one [1..1] [**US Realm Clinical Document Header Name**](#S_USRealmHeaderName) (templateId:2.16.840.1.113883.10.20.22.5.1) (CONF:5284).
         2. This patient **SHALL** contain exactly one [1..1] **administrativeGenderCode/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.1 Administrative Gender (HL7 V3) **DYNAMIC** (CONF:6394).
         3. This patient **SHALL** contain exactly one [1..1] **birthTime** (CONF:5298).
            1. SHALL be precise to year (CONF:5299).
            2. SHOULD be precise to day (CONF:5300).
         4. This patient **SHOULD** contain zero or one [0..1] **maritalStatusCode/@code**, which **SHOULD** be selected from ValueSet 2.16.840.1.113883.1.11.12212 MaritalStatus **DYNAMIC** (CONF:5303).
         5. This patient **MAY** contain zero or one [0..1] **religiousAffiliationCode**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.19185 HL7 Religious Affiliation **DYNAMIC** (CONF:5317).
         6. This patient **MAY** contain zero or one [0..1] **raceCode**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.14914 Race **DYNAMIC** (CONF:5322).
         7. This patient **MAY** contain zero or more [0..\*] **sdwg:raceCode**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.14914 Race **DYNAMIC** (CONF:7263).
         8. This patient **MAY** contain zero or one [0..1] **ethnicGroupCode**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.15836 HITSP Ethnicity value set **DYNAMIC** (CONF:5323).
         9. This patient **SHOULD** contain zero or one [0..1] **guardian** (CONF:5325).
            1. This guardian, if present, **SHOULD** contain zero or one [0..1] **code/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.19563 Personal Relationship Role Type Value Set **DYNAMIC** (CONF:5326).
            2. This guardian, if present, **SHOULD** contain zero or more [0..\*] [**US Realm Clinical Document Header Address**](#S_USRealmHeaderAddress)(templateId:2.16.840.1.113883.10.20.22.5.2) (CONF:5359).
            3. This guardian, if present, **SHALL** contain exactly one [1..1] **telecom** (CONF:5382).

This telecom **SHOULD** contain **@use**, which **SHOULD** be selected from ValueSet 2.16.840.1.113883.11.20.9.20 Telecom use (US Realm Clinical Document Header) **DYNAMIC** (CONF:7993).

* + - * 1. This guardian, if present, **SHALL** contain exactly one [1..1] **guardianPerson** (CONF:5385).

This guardianPerson **SHALL** contain exactly one [1..1] [**US Realm Clinical Document Header Name**](#S_USRealmHeaderName) (templateId:2.16.840.1.113883.10.20.22.5.1) (CONF:5386).

* + - 1. This patient **MAY** contain zero or one [0..1] **birthplace** (CONF:5395).
         1. This birthplace, if present, **SHALL** contain exactly one [1..1] **place** (CONF:5396).

This place **SHALL** contain exactly one [1..1] **addr** (CONF:5397).

This addr **SHALL** contain exactly one [1..1] **state**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.3.88.12.80.1 StateValueSet **DYNAMIC** (CONF:5402).

This addr **MAY** contain zero or one [0..1] **postalCode**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.3.88.12.80.2 PostalCodeValueSet **DYNAMIC** (CONF:5403).

This addr **SHOULD** contain zero or one [0..1] **country**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.3.88.12.80.63 CountryValueSet **DYNAMIC** (CONF:5404).

* + - 1. This patient **SHOULD** contain zero or more [0..\*] **languageCommunication** (CONF:5406).
         1. Such languageCommunications, if present, **SHALL** contain exactly one [1..1] **languageCode**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.11526 LanguageValueSet **DYNAMIC** (CONF:5407).
         2. Such languageCommunications, if present, **MAY** contain zero or one [0..1] **modeCode**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.12249 LanguageAbilityMode **DYNAMIC** (CONF:5409).
         3. Such languageCommunications, if present, **MAY** contain zero or one [0..1] **preferenceInd** (CONF:5414).
    1. Such patientRoles **MAY** contain zero or one [0..1] **providerOrganization** (CONF:5416).
       1. This providerOrganization, if present, **SHALL** contain exactly one [1..1] **id** (CONF:5417).
       2. This providerOrganization, if present, **SHALL** contain at least one [1..\*] **name** (CONF:5419).
       3. This providerOrganization, if present, **SHALL** contain at least one [1..\*] **telecom** (CONF:5420).
          1. Such telecoms **SHOULD** contain **@use**, which **SHOULD** be selected from ValueSet 2.16.840.1.113883.11.20.9.20 Telecom use (US Realm Clinical Document Header) **DYNAMIC** (CONF:7994).
       4. This providerOrganization, if present, **SHALL** contain at least one [1..\*] [**US Realm Clinical Document Header Address**](#S_USRealmHeaderAddress)(templateId:2.16.840.1.113883.10.20.22.5.2) (CONF:5422).

Table 4: Telecom Use (US Realm Header) Value Set

| Value Set: Telecom Use (US Realm Header) 2.16.840.1.113883.11.20.9.20 | | |
| --- | --- | --- |
| Code System(s): | HL7 AddressUse 2.16.840.1.113883.5.1119 | |
| Code | Code System | Print Name |
| HP | HL7 AddressUse | primary home |
| WP | HL7 AddressUse | work place |
| MC | HL7 AddressUse | mobile contact |
| HV | HL7 AddressUse | vacation home |

Table 5: Administrative Gender (HL7) Value Set

|  |  |  |
| --- | --- | --- |
| Value Set: Administrative Gender (HL7 V3) 2.16.840.1.113883.1.11.1 | | |
| Code System(s): AdministrativeGender 2.16.840.1.113883.5.1 | | |
| Code | Code System | Print Name |
| F | AdministrativeGender | Female |
| M | AdministrativeGender | Male |
| UN | AdministrativeGender | Undifferentiated |

Table 6: Marital Status Value Set

| Value Set: HL7 Marital Status 2.16.840.1.113883.1.11.12212 | | |
| --- | --- | --- |
| Code System(s): | HL7 MaritalStatus 2.16.840.1.113883.5.2 | |
| Code | Code System | Print Name |
| A | MaritalStatus | Annulled |
| D | MaritalStatus | Divorced |
| I | MaritalStatus | Interlocutory |
| L | MaritalStatus | Legally Separated |
| M | MaritalStatus | Married |
| P | MaritalStatus | Polygamous |
| S | MaritalStatus | Never Married |
| T | MaritalStatus | Domestic partner |
| W | MaritalStatus | Widowed |

Table 7: Religious Affiliation Value Set

| Value Set: Religious Affiliation 2.16.840.1.113883.1.11.19185 | | |
| --- | --- | --- |
| Code System(s): | ReligiousAffiliation 2.16.840.1.113883.1.11.19185 | |
| Description: | A value set of codes that reflect spiritual faith affiliation  <http://www.hl7.org/memonly/downloads/v3edition.cfm#V32008> | |
|  | Example codes for reference | |
| Code | Code System | Print Name |
| 1026 | ReligiousAffiliation | Judaism |
| 1020 | ReligiousAffiliation | Hinduism |
| 1041 | ReligiousAffiliation | Roman Catholic Church |
| … |  |  |

Table 8: Race Value Set

| Value Set: Race 2.16.840.1.113883.1.11.14914 | | |
| --- | --- | --- |
| Code System(s): | Race and Ethnicity - CDC 2.16.840.1.113883.6.238 | |
| Description: | A Value Set of codes for Classifying data based upon race.  Race is always reported at the discretion of the person for whom this attribute is reported, and reporting must be completed according to Federal guidelines for race reporting. Any code descending from the Race concept (1000-9) in that terminology may be used in the exchange  <http://phinvads.cdc.gov/vads/ViewCodeSystemConcept.action?oid=2.16.840.1.113883.6.238&code=1000-9> | |
|  | Examples of codes for reference | |
| Code | Code System | Print Name |
| 2058-6 | Race and Ethnicity- CDC | African American |
| 1004-1 | Race and Ethnicity- CDC | American Indian |
| 2101-4 | Race and Ethnicity- CDC | Fijian |
| 2106-3 | Race and Ethnicity- CDC | White |
| … |  |  |

Table 9: Ethnicity Value Set

| Value Set: EthnicityGroup 2.16.840.1.113883.1.11.15836 | | |
| --- | --- | --- |
| Code System(s): | Race and Ethnicity Code Sets 2.16.840.1.113883.6.238 | |
| Code | Code System | Print Name |
| 2135-2 | Race and Ethnicity Code Sets | Hispanic or Latino |
| 2186-5 | Race and Ethnicity Code Sets | Not Hispanic or Latino |

Table 10: Personal Relationship Role Type Value Set

| Value Set: Personal Relationship Role Type 2.16.840.1.113883.1.11.19563 | | |
| --- | --- | --- |
| Code System(s): | Role Code 2.16.840.1.113883.5.111 | |
| Description: | A Personal Relationship records the role of a person in relation to another person. This value set is to be used when recording the relationships between different people who are not necessarily related by family ties, but also includes family relationships.  <http://www.hl7.org/memonly/downloads/v3edition.cfm#V32008> | |
|  | Example codes for reference | |
| Code | Code System | Print Name |
| HUSB | Role Code | husband |
| WIFE | Role Code | wife |
| FRND | Role Code | friend |
| SISINLAW | Role Code | sister-inlaw |
| … |  |  |

Table 11: State Value Set

| Value Set: State Value Set 2.16.840.1.113883.3.88.12.80.1 | | |
| --- | --- | --- |
| Code System(s): | FIPS 5-2 (State) 2.16.840.1.113883.6.92 | |
| Description: | Codes for the Identification of the States, the District of Columbia and the Outlying Areas of the United States, and Associated Areas Publication # 5-2, May, 1987  <http://www.itl.nist.gov/fipspubs/fip5-2.htm> | |
|  | Examples of codes for reference | |
| Code | Code System | Print Name |
|  | FIPS 5-2 (State) |  |
| 01 | FIPS 5-2 (State) | Alabama |
| 12 | FIPS 5-2 (State) | Florida |
| 64 | FIPS 5-2 (State) | Federated States of Micronesia |
| 15 | FIPS 5-2 (State) | Hawaii |
| … |  |  |

Table 12: Postal Code Value Set

| Value Set: Postal Code Value Set 2.16.840.1.113883.3.88.12.80.2 | | |
| --- | --- | --- |
| Code System(s): | US Postal Codes | |
| Description: | A value set of codes postal (ZIP) Code of an address in the United States.  <http://zip4.usps.com/zip4/welcome.jsp> | |
|  | Examples of codes for reference | |
| Code | Code System | Print Name |
| 19009 | US Postal Codes | Bryn Athyn, PA |
| 92869-1736 | US Postal Codes | Orange, CA |
| 32830-8413 | US Postal Codes | Lake Buena Vista Fl |
| … |  |  |

Table 13: Country Value Set

| Value Set: Country Value Set 2.16.840.1.113883.3.88.12.80.63 | | |
| --- | --- | --- |
| Code System(s): | ISO 3166-1 Country Codes: 1.0.3166.1 | |
| Description: | A value set of codes for the representation of names of countries, territories and areas of geographical interest.  Note: This table provides the ISO 3166-1 code elements available in the alpha-2 code of ISO's country code standard  <http://www.iso.org/iso/country_codes/iso_3166_code_lists.htm> | |
|  | Example codes for reference | |
| Code | Code System | Print Name |
| AW | ISO 3166-1 Country Codes | Aruba |
| IL | ISO 3166-1 Country Codes | Israel |
| KZ | ISO 3166-1 Country Codes | Kazakhstan |
| US | ISO 3166-1 Country Codes | United States |
| … |  |  |

Table 14: Language Ability Value Set

| Value Set: HL7 LanguageAbilityMode 2.16.840.1.113883.1.11.12249 | | |
| --- | --- | --- |
| Code System(s): | HL7 Language Ability Mode 2.16.840.1.113883.5.60 | |
| Description: | A value representing the method of expression of the language. | |
| Code | Code System | Print Name |
| ESGN | Language Ability Mode | Expressed signed |
| ESP | Language Ability Mode | Expressed spoken |
| EWR | Language Ability Mode | Expressed written |
| RSGN | Language Ability Mode | Received signed |
| RSP | Language Ability Mode | Received spoken |
| RWR | Language Ability Mode | Received written |

### Author

The author element represents the creator of the clinical document. The author may be a device, a person, or an organization.

1. **SHALL** contain at least one [1..\*] **author** (CONF:5444).
   1. Such authors **SHALL** contain exactly one [1..1] **time** (CONF:5445).
      1. SHALL be precise to the day and SHOULD be precise to the minute (CONF:5446).
   2. Such authors **SHALL** contain exactly one [1..1] **assignedAuthor** (CONF:5448).
      1. This assignedAuthor **SHALL** contain exactly one [1..1] **id** (CONF:5449).
      2. This assignedAuthor **SHALL** contain at least one [1..\*] [**US Realm Clinical Document Header Address**](#S_USRealmHeaderAddress)(templateId:2.16.840.1.113883.10.20.22.5.2) (CONF:5452).
      3. This assignedAuthor **SHALL** contain at least one [1..\*] **telecom** (CONF:5428).
         1. Such telecoms **SHOULD** contain **@use**, which **SHOULD** be selected from ValueSet 2.16.840.1.113883.11.20.9.20 Telecom use (US Realm Clinical Document Header) **DYNAMIC** (CONF:7995).
      4. This assignedAuthor **SHALL** contain exactly one [1..1] **assignedPerson** (CONF:5430).
         1. This assignedPerson **SHALL** contain exactly one [1..1] [**US Realm Clinical Document Header Name**](#S_USRealmHeaderName) (templateId:2.16.840.1.113883.10.20.22.5.1) (CONF:5431).

### DataEnterer

The dataEnterer element represents the person who transferred the content, written or dictated by someone else, into the clinical document. The guiding rule of thumb is that an author provides the content found within the header or body of the document, subject to their own interpretation, and the dataEnterer adds that information to the electronic system. In other words, a dataEnterer transfers information from one source to another (e.g., transcription from paper form to electronic system).

1. **MAY** contain zero or one [0..1] **dataEnterer** (CONF:5441).
   1. This dataEnterer, if present, **SHALL** contain exactly one [1..1] **assignedEntity** (CONF:5442).
      1. This assignedEntity **SHALL** contain exactly one [1..1] **id** (CONF:5443).
      2. This assignedEntity **SHALL** contain at least one [1..\*] [**US Realm Clinical Document Header Address**](#S_USRealmHeaderAddress) (templateId:2.16.840.1.113883.10.20.22.5.2) (CONF:5460).
      3. This assignedEntity **SHALL** contain at least one [1..\*] **telecom** (CONF:5466).
         1. Such telecoms **SHOULD** contain **@use**, which **SHOULD** be selected from ValueSet 2.16.840.1.113883.11.20.9.20 Telecom use (US Realm Clinical Document Header) **DYNAMIC** (CONF:7996).
      4. This assignedEntity **SHALL** contain exactly one [1..1] **assignedPerson** (CONF:5469).
         1. This assignedPerson **SHALL** contain exactly one [1..1] [**US Realm Clinical Document Header Name**](#S_USRealmHeaderName) (templateId:2.16.840.1.113883.10.20.22.5.1) (CONF:5470).

### Informant

The informant element describes the source of the information in a medical document.

Assigned health care providers may be a source of information when a document is created. (e.g., a nurse's aide who provides information about a recent significant health care event that occurred within an acute care facility.) In these cases, the assignedEntity element is used.

When the informant is a personal relation, that informant is represented in the relatedEntity element. The code element of the relatedEntity describes the relationship between the informant and the patient. The relationship between the informant and the patient needs to be described to help the receiver of the clinical document understand the information in the document.

1. **MAY** contain zero or more [0..\*] **informant** (CONF:8001).
   1. SHALL contain exactly one [1..1] assignedEntity OR exactly one [1..1] relatedEntity (CONF:8002).
      1. **SHOULD** contain at least one [1..\*] [**US Realm Clinical Document Header Address**](#S_USRealmHeaderAddress) (templateId:2.16.840.1.113883.10.20.22.5.2) (CONF:8220).
      2. SHALL contain exactly one [1..1] assignedPerson OR exactly one [1..1] relatedPerson (CONF:8221).
         1. **SHALL** contain at least one [1..\*] [**US Realm Clinical Document Header Name**](#S_USRealmHeaderName) (templateId:2.16.840.1.113883.10.20.22.5.1) (CONF:8222).

### Custodian

The custodian element represents the entity responsible for maintaining the availability of the clinical document. The custodian may be the document originator, a health information exchange, or other responsible party.

1. **SHALL** contain exactly one [1..1] **custodian** (CONF:5519).
   1. This custodian **SHALL** contain exactly one [1..1] **assignedCustodian** (CONF:5520).
      1. This assignedCustodian **SHALL** contain exactly one [1..1] **representedCustodianOrganization** (CONF:5521).
         1. This representedCustodianOrganization **SHALL** contain exactly one [1..1] **id** (CONF:5522).
         2. This representedCustodianOrganization **SHALL** contain exactly one [1..1] **name** (CONF:5524).
         3. This representedCustodianOrganization **SHALL** contain exactly one [1..1] **telecom** (CONF:5525).
            1. This telecom **SHOULD** contain **@use**, which **SHOULD** be selected from ValueSet 2.16.840.1.113883.11.20.9.20 Telecom use (US Realm Clinical Document Header) **DYNAMIC** (CONF:7998).
         4. This representedCustodianOrganization **SHALL** contain at least one [1..\*] [**US Realm Clinical Document Header Address**](#S_USRealmHeaderAddress) (templateId:2.16.840.1.113883.10.20.22.5.2) (CONF:5559).

### informationRecipient

The informationRecipient element records the intended recipient of the information at the time the document is created. The intended recipient may also be the health chart of the patient, in which case the receivedOrganization is the scoping organization of that chart.

1. **MAY** contain zero or more [0..\*] **informationRecipient** (CONF:5565).
   1. Such informationRecipients, if present, **SHALL** contain exactly one [1..1] **intendedRecipient** (CONF:5566).
      1. This intendedRecipient **MAY** contain zero or one [0..1] **informationRecipient** (CONF:5567).
         1. This informationRecipient, if present, **SHALL** contain exactly one [1..1] [**US Realm Clinical Document Header Name**](#S_USRealmHeaderName) (templateId:2.16.840.1.113883.10.20.22.5.1) (CONF:5568).
      2. This intendedRecipient **MAY** contain zero or one [0..1] **receivedOrganization** (CONF:5577).
         1. This receivedOrganization, if present, **SHALL** contain exactly one [1..1] **name** (CONF:5578).

### legalAuthenticator

The legalAuthenticator identifies the single person legally responsible for the document and must be present if the document has been legally authenticated. (Note that per the following section, there may also be one or more document authenticators.)

Based on local practice, clinical documents may be released before legal authentication. This implies that a clinical document that does not contain this element has not been legally authenticated.

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

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

1. **SHOULD** contain zero or one [0..1] **legalAuthenticator** (CONF:5579).
   1. This legalAuthenticator, if present, **SHALL** contain exactly one [1..1] **time** (CONF:5580).
      1. SHALL be precise to the day and SHOULD be precise to the minute. If precise to minute, SHOULD include time-zone offset (CONF:5581).
   2. This legalAuthenticator, if present, **SHALL** contain exactly one [1..1] **signatureCode** (CONF:5583).
      1. This signatureCode **SHALL** contain exactly one [1..1] **@code**="S" (CodeSystem: 2.16.840.1.113883.5.89 Participationsignature) (CONF:5584).
   3. This legalAuthenticator, if present, **SHALL** contain exactly one [1..1] **assignedEntity** (CONF:5585).
      1. This assignedEntity **SHALL** contain exactly one [1..1] **id** (CONF:5586).
      2. This assignedEntity **SHALL** contain at least one [1..\*] [**US Realm Clinical Document Header Address**](#S_USRealmHeaderAddress) (templateId:2.16.840.1.113883.10.20.22.5.2) (CONF:5589).
      3. This assignedEntity **SHALL** contain at least one [1..\*] **telecom** (CONF:5595).
         1. Such telecoms **SHOULD** contain **@use**, which **SHOULD** be selected from ValueSet 2.16.840.1.113883.11.20.9.20 Telecom use (US Realm Clinical Document Header) **DYNAMIC** (CONF:7999).
      4. This assignedEntity **SHALL** contain exactly one [1..1] **assignedPerson** (CONF:5597).
         1. This assignedPerson **SHALL** contain exactly one [1..1] [**US Realm Clinical Document Header Name**](#S_USRealmHeaderName) (templateId:2.16.840.1.113883.10.20.22.5.1) (CONF:5598).

### Authenticator

The authenticator identifies a participant or participants who attested to the accuracy of the information in the document.

1. **MAY** contain zero or more [0..\*] **authenticator** (CONF:5607).
   1. Such authenticators, if present, **SHALL** contain exactly one [1..1] **time** (CONF:5608).
      1. SHALL be precise to the day and SHOULD be precise to the minute. If precise to minute, SHOULD include time-zone offset (CONF:5634).
   2. Such authenticators, if present, **SHALL** contain exactly one [1..1] **signatureCode** (CONF:5610).
      1. This signatureCode **SHALL** contain exactly one [1..1] **@code**="S" (CodeSystem: 2.16.840.1.113883.5.89 Participationsignature) (CONF:5611).
   3. Such authenticators, if present, **SHALL** contain exactly one [1..1] **assignedEntity** (CONF:5612).
      1. This assignedEntity **SHALL** contain exactly one [1..1] **id** (CONF:5613).
      2. This assignedEntity **SHALL** contain at least one [1..\*] [**US Realm Clinical Document Header Address**](#S_USRealmHeaderAddress) (templateId:2.16.840.1.113883.10.20.22.5.2) (CONF:5616).
      3. This assignedEntity **SHALL** contain at least one [1..\*] **telecom** (CONF:5622).
         1. Such telecoms **SHOULD** contain **@use**, which **SHOULD** be selected from ValueSet 2.16.840.1.113883.11.20.9.20 Telecom use (US Realm Clinical Document Header) **DYNAMIC** (CONF:8000).
      4. This assignedEntity **SHALL** contain exactly one [1..1] **assignedPerson** (CONF:5624).
         1. This assignedPerson **SHALL** contain exactly one [1..1] [**US Realm Clinical Document Header Name**](#S_USRealmHeaderName) (templateId:2.16.840.1.113883.10.20.22.5.1) (CONF:5625).

US Realm Clinical Document Header Address

[addr: templateId 2.16.840.1.113883.10.20.21.5.2(open)]

The US Realm Clinical Document Header Address template is used by US Realm Clinical Document Header for the patient or any other person or organization mentioned within it.

1. SHALL NOT have mixed content (CONF:7296).
2. **SHOULD** contain **@use**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.10637 PostalAddressUse **STATIC** 2005-05-01 (CONF:7290).
3. **SHALL** contain at least one and not more than three [1..3] **streetAddressLine** (CONF:7291).
4. **SHALL** contain exactly one [1..1] **city** (CONF:7292).
5. **SHALL** contain exactly one [1..1] **state**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.3.88.12.80.1 StateValueSet **DYNAMIC** (CONF:7293).
6. **SHALL** contain exactly one [1..1] **postalCode**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.3.88.12.80.2 PostalCodeValueSet **DYNAMIC** (CONF:7294).
7. **SHOULD** contain zero or one [0..1] **country**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.3.88.12.80.63 CountryValueSet **DYNAMIC** (CONF:7295).

Table 15: PostalAddressUse Value Set

| Value Set: HL7 PostalAddressUse 2.16.840.1.113883.1.11.10637 | | |
| --- | --- | --- |
| Code System(s): | HL7AddressUse 2.16.840.1.113883.5.1119 | |
| Code | Code System | Print Name |
| BAD | HL7AddressUse | bad address |
| CONF | HL7AddressUse | confidential |
| DIR | HL7AddressUse | direct |
| H | HL7AddressUse | home address |
| HV | HL7AddressUse | vacation home |
| PHYS | HL7AddressUse | Physical visit address |
| PST | HL7AddressUse | postal address |
| PUB | HL7AddressUse | public |
| TMP | HL7AddressUse | temporary |
| WP | HL7AddressUse | work place |

US Realm Clinical Document Header Name

[name: templateId 2.16.840.1.113883.10.20.21.5.1(open)]

The US Realm Clinical Document Header Name template is used by US Realm Clinical Document Header for the patient or any other person or organization mentioned within it.

1. SHALL NOT have mixed content (CONF:7278).
2. **MAY** contain **@use**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.15913 EntityNameUse **STATIC** 2005-05-01 (CONF:7154).
3. **MAY** contain zero or more [0..\*] **prefix** (CONF:7155).
   1. Such prefixs, if present, **MAY** contain **@qualifier**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.15888 EntityNamePartQualifier **STATIC** 2005-05-01 (CONF:7156).
4. **SHALL** contain at least one [1..\*] **given** (CONF:7157).
   1. Second given is middle name (CONF:7163).
   2. Such givens **MAY** contain **@qualifier**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.15888 EntityNamePartQualifier **STATIC** 2005-05-01 (CONF:7158).
5. **SHALL** contain exactly one [1..1] **family** (CONF:7159).
   1. This family **MAY** contain **@qualifier**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.15888 EntityNamePartQualifier **STATIC** 2005-05-01 (CONF:7160).
6. **MAY** contain zero or one [0..1] **suffix** (CONF:7161).
   1. This suffix, if present, **MAY** contain **@qualifier**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.15888 EntityNamePartQualifier **STATIC** 2005-05-01 (CONF:7162).

Table 16: EntityNameUse Value Set

| Value Set: HL7 EntityNameUse 2.16.840.1.113883.1.11.15913 | | |
| --- | --- | --- |
| Code System(s): | HL7 EntityNameUse 2.16.840.1.113883.5.45 | |
| Code | Code System | Print Name |
| ABC | HL7 EntityNameUse | Alphabetic |
| IDE | HL7 EntityNameUse | Ideographic |
| SYL | HL7 EntityNameUse | Syllabic |
| ASGN | HL7 EntityNameUse | Assigned |
| C | HL7 EntityNameUse | License |
| I | HL7 EntityNameUse | Indigeneous/Tribal |
| L | HL7 EntityNameUse | Legal |
| OR | HL7 EntityNameUse | Original Registry |
| P | HL7 EntityNameUse | Pseudonym |
| A | HL7 EntityNameUse | Artist/Stage |
| R | HL7 EntityNameUse | Religious |
| SRCH | HL7 EntityNameUse | search |
| PHON | HL7 EntityNameUse | phonetic |
| SNDX | HL7 EntityNameUse | soundex |

Table 17: EntityNamePartQualifier Value Set

| Value Set:HL7 EntityNamePartQualifier 2.16.840.1.113883.1.11.15888 | | |
| --- | --- | --- |
| Code System(s): | HL7 EntityNamePartQualifier 2.16.840.1.113883.5.43 | |
| Code | Code System | Print Name |
| AC | HL7 EntityNamePartQualifier | academic |
| AD | HL7 EntityNamePartQualifier | adopted |
| BR | HL7 EntityNamePartQualifier | birth |
| CL | HL7 EntityNamePartQualifier | callme |
| IN | HL7 EntityNamePartQualifier | initial |
| LS | HL7 EntityNamePartQualifier | legal status |
| NB | HL7 EntityNamePartQualifier | nobility |
| PR | HL7 EntityNamePartQualifier | professional |
| SP | HL7 EntityNamePartQualifier | spouse |
| TITLE | HL7 EntityNamePartQualifier | title |
| VV | HL7 EntityNamePartQualifier | voorvoegsel |
| CON | HL7 EntityNamePartQualifier | container name |
| DEV | HL7 EntityNamePartQualifier | device name |
| FRM | HL7 EntityNamePartQualifier | from name |
| INV | HL7 EntityNamePartQualifier | invented name |
| SCI | HL7 EntityNamePartQualifier | scientific name |
| STR | HL7 EntityNamePartQualifier | strength name |
| TMK | HL7 EntityNamePartQualifier | trademark name |
| USE | HL7 EntityNamePartQualifier | intended use name |

serviceEvent in a CDA Header

[serviceEvent: templateId 2.16.840.1.113883.10.20.21.3.1(open)]

A serviceEvent further specializes the act inherent in the ClinicalDocument/code.

In a Progress Note, a serviceEvent can represent the event of writing the Progress Note. The serviceEvent/effectiveTime is the time period the note documents.

When you know only the date for documenting the time, place the date in both the low and high elements. However, if you know the date and the duration of the documentation, use serviceEvent/effectiveTime/low with a width element.

1. **SHOULD** contain exactly one [1..1] **serviceEvent/@classCode**="PCPR" (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) (CONF:7601).
2. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.21.3.1" (CONF:7600).
3. **SHOULD** contain exactly one [1..1] **effectiveTime** (CONF:7612).
   1. The serviceEvent/effectiveTime element SHOULD be present with effectiveTime/low element and SHALL include effectiveTime/high element if a width element is not present. The serviceEvent/effectiveTime element SHALL be accurate to the day, and MAY be accurate to the second. (CONF:7602).

## Rendering Header Information for Human Presentation

Metadata carried in the header may already be available for rendering from electronic medical records (EMRs) or other sources external to the document; therefore, there is no strict requirement to render directly from the document. An example of this would be a doctor using an EMR that already contains the patient’s name, date of birth, current address, and phone number. When a CDA document is rendered within that EMR, those pieces of information may not need to be displayed since they are already known and displayed within the EMR’s user interface.

Good practice would recommend that the following be present whenever the document is viewed:

* Document title and document dates
* Service and encounter types, and date ranges as appropriate
* Names of all persons along with their roles, participations, participation date ranges, identifiers, address, and telecommunications information
* Names of selected organizations along with their roles, participations, participation date ranges, identifiers, address, and telecommunications information
* Date of birth for recordTarget(s)

In Operative and Procedure Notes, the following information is typically displayed in the electronic health record (EHR) and/or rendered directly in the document:

* The performers of the surgery or procedure, including any assistants
* The surgery or procedure performed (ServiceEvent)
* The date of the surgery or procedure

# Document-Level Templates

Document-level templates describe the purpose and rules for constructing a conforming CDA document. Document templates include constraints on the CDA header and refer to section-level templates. The [Document Types and Required/Optional Sections](#T_DocTypesAndReqOptSections) table lists the sections used by each document type.

Each document-level template contains the following information:

* Scope and intended use of the document type
* Description and explanatory narrative.
* Template metadata (e.g., templateID, etc.)
* Header constraints: this includes a reference to the US Realm Clinical Document Header template and additional constraints specific to each document type
* Required and optional section-level templates

Table 18: Document Types and Required/Optional Sections

| **Document Type**  **Preferred LOINC**  **templateID** | **Required Sections** | **Optional Sections** |
| --- | --- | --- |
| [CCD](#Doc_CCD)  34133-9  2.16.840.1.113883.10.20.22.1.2 | Allergies  Medications  Problem List  Procedures[[6]](#footnote-6)  Results | Advance Directives  Encounters  Family History  Functional Status  Immunizations  List of Surgeries (History of Procedures)  Medical Equipment  Payers  Plan of Care  Social History  Vital Signs |
| [Consultation Note](#Doc_ConsultationNote)  11488-4  2.16.840.1.113883.10.20.22.1.4 | Allergies  Assessment/Assessment and Plan  History of Present Illness  Medications  Physical Exam  Plan /Assessment and Plan  Reason for Referral | Advance Directives  Chief Complaint  Chief Complaint/Reason for Visit  Family History  Functional Status  General Status  History of Past Illness (Past Medical History)  Immunizations  List of Surgeries (History of Procedures)  Payers  Problem List  Procedures  Reason for Visit  Results  Review of Systems  Social History  Vital Signs |
| [Diagnostic Imaging Report](#Doc_DIR)  18748-4  2.16.840.1.113883.10.20.22.1.5 | DICOM Object Catalog  Findings (Radiology Comparison Study - Observation) | Addendum  Clinical presentation  Complications  Conclusions  Current imaging procedure descriptions  Document summary  History general  Key images  Prior imaging procedure descriptions  Radiology - impression  Radiology comparison study - observation  Radiology reason for study  Radiology study - recommendation  Radiology study observation  Requested imaging studies information |
| [Discharge Summary](#Doc_DischargeSummary)  18842-5  2.16.840.1.113883.10.20.22.1.8 | Allergies  Hospital Course  Hospital Discharge Diagnosis  Hospital Discharge Medications  Plan of Care | Chief Complaint  Chief Complaint/Reason for Visit  Discharge Diet  Family History  Functional Status  History of Present Illness  Hospital Discharge Physical  Hospital Discharge Studies Summary  Immunizations  List of Surgeries (History of Procedures)  Problem List  Procedures  Reason for Visit  Review of Systems  Social History  Vital Signs |
| [History & Physical Note](#Doc_HandPNote)  34117-2  2.16.840.1.113883.10.20.22.1.3 | Allergies  Assessment/Assessment and Plan  Chief Complaint  Chief Complaint/Reason for Visit  Family History  General Status  History of Past Illness (Past Medical History)  History of Present Illness  Medications  Physical Exam  Plan of Care/ Assessment and Plan  Reason for Visit  Results  Review of Systems  Social History  Vital Signs | Immunizations  Procedures  Problems  Vital Signs |
| [Operative Note](#Doc_OperativeNote)  11504-8  2.16.840.1.113883.10.20.22.1.7 | Anesthesia  Complications  Post Operative Diagnosis  Pre Operative Diagnosis  Procedure Estimated Blood Loss  Procedure Findings  Procedure Specimens Removed  Surgery Description | Disposition  Implants  Operative Note Fluids  Operative Note Surgical Procedure  Plan of Care  Planned Procedure  Procedure Disposition  Procedure Indications  Surgical Drains |
| [Procedure Note](#Doc_ProcedureNote)  28570-0  2.16.840.1.113883.10.20.22.1.6 | Anesthesia  Assessment/Assessment and Plan  Complications/Adverse Reactions  Plan of Care  Post Procedure Diagnosis  Procedure Description  Procedure Disposition  Procedure Indications | Allergies  Chief Complaint  Chief Complaint/Reason for Visit  Family History  History of Present Illness  List of Surgeries (History of Procedures)  Medical (General) History  Medications  Medications Administered  Physical Exam  Planned Procedure  Procedure Estimated Blood Loss  Procedure Findings  Procedure Implants  Procedure Specimens Removed  Procedures  Reason for Visit  Review of Systems  Social History |
| [Progress Note](#Doc_ProgressNote)  11506-3  2.16.840.1.113883.10.20.22.1.9 | Assessment and Plan | Allergies  Medications  Objective  Physical Exam  Problem List  Results  Review of Systems  Subjective  Vital Signs |
| [Unstructured Document](#Doc_UnstructuredDocument)  Non-preferred  2.16.840.1.113883.10.20.21.1.10 |  | any |

Continuity of Care Document (CCD)/C32

[ClinicalDocument: templateId 2.16.840.1.113883.10.20.22.1.2(open)]

The Continuity of Care Document (CCD) specification describes CDA constraints in accordance with Meaningful Use.

The CCD is a core data set of the most relevant administrative, demographic, and clinical information facts about a patient's healthcare, covering one or more healthcare encounters. It provides a means for one healthcare practitioner, system, or setting to aggregate all of the pertinent data about a patient and forward it to another practitioner, system, or setting to support the continuity of care. The primary use case for the CCD is to provide a snapshot in time containing the pertinent clinical, demographic, and administrative data for a specific patient[[7]](#footnote-7).

Developer Notes

This Developer Notes section is informational only and not part of the normative standard. Use the table below to navigate to the Sections of the CCD and their Entries. When navigating, press [Alt] + 🡸 to return to the previous location.

|  |  |  |
| --- | --- | --- |
| Template OID | Type | Template Title |
| 2.16.840.1.113883.10.20.17.1.1 | document | Continuity of Care Document |
| 2.16.840.1.113883.10.20.17.2.1 | Section | [Allergies](#_Allergies,_Adverse_Reactions,) |
| 2.16.840.1.113883.10.20.17.3.8 | entry | [Allergy Problem Act](#CS_AllergyProblemAct) |
| 2.16.840.1.113883.10.20.17.2.5 | section | [Medications](#S_MedicationsAdministeredSection) |
| 2.16.840.1.113883.10.20.17.3.4 | entry | [Medications Administrations Act](#CS_MedicationActivity) |
| 2.16.840.1.113883.10.20.17.2.2 | section | [Problem List](#_Problem_List_Section) |
| 2.16.840.1.113883.10.20.17.3.15 | entry | [Conditions](#CD_Condition) |
| 2.16.840.1.113883.10.20.17.2.2 | section | [Procedures](#_Procedures_Section_47519-4) |
| 2.16.840.1.113883.10.20.22.4.14 | entry | [Procedure Activity Procedure](#CS_ProcedureActivityProcedure) |
| 2.16.840.1.113883.10.20.22.4.13 | entry | [Procedure Activity Observation](#CS_ProcedureActivityObservation) |
| 2.16.840.1.113883.10.20.22.4.12 | entry | [Procedure Activity Act](#CS_ProcedureActivityAct) |
| 2.16.840.1.113883.10.20.17.2.2 | section | [Results](#_Results_Section_30954-2) |
| 2.16.840.1.113883.10.20.17.3.15 | entry | [Results Organizer](#CS_ResultOrganizer) |
| 2.16.840.1.113883.10.20.17.2.2 | section | [Advance Directives](#S_AdvanceDirectivesSection) |
| 2.16.840.1.113883.10.20.17.3.15 | entry |  |
| 2.16.840.1.113883.10.20.17.2.2 | section | [Encounters](#S_EncountersSection) |
| 2.16.840.1.113883.10.20.17.3.15 | entry |  |
| 2.16.840.1.113883.10.20.17.2.2 | section | [Family History](#S_FamilyHistorySection) |
| 2.16.840.1.113883.10.20.17.3.15 | entry |  |
| 2.16.840.1.113883.10.20.17.2.2 | section | [Functional Status](#S_FunctionalStatusSection) |
| 2.16.840.1.113883.10.20.17.3.15 | entry |  |
| 2.16.840.1.113883.10.20.17.2.2 | section | Immunizations |
| 2.16.840.1.113883.10.20.17.3.15 | entry |  |
| 2.16.840.1.113883.10.20.17.2.2 | section | [List of Surgeries](#S_SurgeryDescriptionSection) (History of Procedures) |
| 2.16.840.1.113883.10.20.17.3.15 | entry |  |
| 2.16.840.1.113883.10.20.17.2.2 | section | [Medical Equipment](#S_MedicalEQuipmentSection) |
| 2.16.840.1.113883.10.20.17.3.15 | entry |  |
| 2.16.840.1.113883.10.20.17.2.2 | section | Payers |
| 2.16.840.1.113883.10.20.17.3.15 | entry |  |
| 2.16.840.1.113883.10.20.17.2.2 | section | Plan of Care |
| 2.16.840.1.113883.10.20.17.3.15 | entry |  |
| 2.16.840.1.113883.10.20.17.2.2 | section | Social History |
| 2.16.840.1.113883.10.20.17.3.15 | entry |  |
| 2.16.840.1.113883.10.20.17.2.2 | section | Vital Signs |
| 2.16.840.1.113883.10.20.17.3.15 | entry |  |

### Header Constraints Specific to CCD

The Continuity of Care Document must conform to the US Realm Clinical Document Header. The following sections include additional header constraints for conformant CCD.

1. Conforms to US Realm Clinical Document Header Template (templateId: 2.16.840.1.113883.10.20.22.1.1).

#### ClinicalDocument/templateId

Conformant documents must carry the document-level templateId asserting conformance with specific constraints of CCD as well as the templateId for the US Realm Clinical Document Header template.

1. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.1.2" (CONF:8450).

Figure 8: CCD ClinicalDocument/templateId example

<!-- indicates conformance with US Realm Clinical Document Header template -->

<templateId root="2.16.840.1.113883.10.20.22.1.1"/>

<!-- conforms to CCD requirements -->

<templateId root='2.16.840.1.113883.10.20.22.1.2'/>

#### ClinicalDocument/code

In accordance with the CDA spcification, the ClinicalDocument/code element must be present and specifies the type of the clinical document.

1. **SHALL** contain exactly one [1..1] **code/@code**="34133-9" Summarization of Episode Note (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:8451).

#### documentationOf/serviceEvent

The main activity being described by a CCD is the provision of healthcare over a period of time. This is shown by setting the value of ClinicalDocument/documentationOf/serviceEvent/@classCode to “PCPR” (care provision) and indicating the duration over which care was provided in ClinicalDocument/documentationOf/serviceEvent/effectiveTime. Additional data from outside this duration may also be included if it is relevant to care provided during that time range (e.g., reviewed during the stated time range).

**NOTE:** Implementations originating a CCD should take care to discover what the episode of care being summarized is. For example, when a patient fills out a form providing relevant health history, the episode of care being documented might be from birth to the present.

1. **SHALL** contain exactly one [1..1] **documentationOf** (CONF:8452).
   1. This documentationOf **SHALL** contain exactly one [1..1] **serviceEvent** (CONF:8480).
      1. This serviceEvent **SHALL** contain exactly one [1..1] **@classCode**="PCPR" Care Provision (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) (CONF:8453).
      2. This serviceEvent **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:8481).
         1. This effectiveTime **SHALL** contain exactly one [1..1] **low** (CONF:8454).
         2. This effectiveTime **SHALL** contain exactly one [1..1] **high** (CONF:8455).

serviceEvent/performer represents the healthcare providers involved in the current or pertinent historical care of the patient. At a minimum, the patient’s key healthcare providers should be listed, particularly their primary physician and any active consulting physicians, therapists, and counselors.

* + 1. This serviceEvent **SHOULD** contain at least one [1..\*] **performer** (CONF:8482).
       1. Such performers **SHALL** contain at least one [1..\*] **@typeCode**="PRF" Participation physical performer (CodeSystem: 2.16.840.1.113883.5.90 HL7ParticipationType) (CONF:8458).
       2. Such performers **MAY** contain at least one [1..\*] **assignedEntity** (CONF:8459).
          1. Such assignedEntitys **SHALL** contain at least one [1..\*] **id** (CONF:8460).
          2. Such assignedEntitys **MAY** contain exactly one [1..1] **code** (CONF:8461).

The code MAY be the National Uniform Claims Committee Provider Taxonomy Code. (CONF:8462).

#### Author

1. CCD SHALL contain one or more ClinicalDocument / author / assignedAuthor / assignedPerson and/or ClinicalDocument / author / assignedAuthor / representedOrganization. (CONF:8456).
   1. If author has an associated representedOrganization with no assignedPerson or assignedAuthoringDevice, then the value for "ClinicalDocument / author / assignedAuthor / id / @NullFlavor" SHALL be "NA" "Not applicable" 2.16.840.1.113883.5.1008 NullFlavor STATIC. (CONF:8457).

### CCD Body Constraints

The Continuity of Care Document supports both narrative sections and sections requiring code clinical statements. The required and optional sections are listed in the [Document Types and Required/Optional Sections](#T_DocTypesAndReqOptSections) table.

Consultation Note

[ClinicalDocument: templateId 2.16.840.1.113883.10.20.22.1.4(open)]

For the purpose of this Implementation Guide, a consultation visit is defined by the evaluation and management guidelines for a consultation established by the Centers for Medicare and Medicaid Services (CMS). According to those guidelines, a Consultation Note must be generated as a result of a physician or nonphysician practitioner's (NPP) request for an opinion or advice from another physician or NPP. Consultations must involve face-to-face time with the patient or fall under guidelines for telemedicine visits.

A Consultation Note must be provided to the referring physician or NPP and must include the reason for the referral, history of present illness, physical examination, and decision-making component (Assessment and Plan).

An NPP is defined as any licensed medical professional as recognized by the state in which the professional practices, including, but not limited to, physician assistants, nurse practitioners, clinical nurse specialists, social workers, physical therapists, and speech therapists.

Reports on visits requested by a patient, family member, or other third party are not covered by this specification. Second opinions, sometimes called "confirmatory consultations," also are not covered here. Any question on use of the Consultation Note defined here should be resolved by reference to CMS or American Medical Association (AMA) guidelines.

### Consultation Note Header Constraints

The Consultation Note must conform to the US Realm Clinical Document Header. The following sections include additional header constraints for conformant Consultation Notes.

1. Conforms to US Realm Clinical Document Header Template (templateId: 2.16.840.1.113883.10.20.22.1.1).

#### ClinicalDocument/templateId

Conformant documents must carry the document-level templateId asserting conformance with specific constraints of a Consulation Note as well as the templateId for the US Realm Clinical Document Header template.

1. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.1.4" Consult Note (CONF:8375).

Figure 9: Consultation Note ClinicalDocument/templateId example

<!-- indicates conformance with US Realm Clinical Document Header template -->

<templateId root="2.16.840.1.113883.10.20.22.1.1"/>

<!-- conforms to a Consultation Note --><templateId root=2.16.840.1.113883.10.20.22.1.4'/>

#### ClinicalDocument/code

The Consultation Note limits document type codes to those codes listed in the [Consultation Note LOINC Document Codes](#T_ConsultLOINCDocDodes) table (invalid codes are included at the end of the table). Implementation may use translation elements to specify a local code that is equivalent to a document type (see the [Consultation Note translation of local code](#F_Consult_translationWithCode) figure).

Some LOINC codes (those listed under “Specialized by Specialty”) in the [Consultation Note LOINC Document Codes](#T_ConsultLOINCDocDodes) table are pre-coordinated with the practice setting or the training or professional level of the author. Use of these codes is not recommended, as this duplicates information potentially present in the header. When pre-coordinated codes are used, any coded values describing the author or performer of the service act or the practice setting must be consistent with the LOINC document type. For example, a Cardiology Consultation Note would not be authored by an Obstetrician. The last two figures in this section illustrate the use of [pre-coordinated](#F_Consult_PreCoordinatedCodes) and [uncoordinated](#F_Consult_NONPreCoordinatedCodes) document codes. The pre-coordinated document codes show consistancy between the document code and other codes found in the document; the uncoordinated codes eliminate the need to ensure consistency of the document type code. In either case, the title can be localized.

1. **SHALL** contain exactly one [1..1] **code/@code**, which **SHALL** be selected from ValueSet nnn ConsultDocumentType **DYNAMIC** (CONF:8376).

Table 19: Consultation Note LOINC Document Codes

| Value Set: TO\_BE\_ASSIGNED\_AFTER\_BALLOT  Code System: LOINC 2.16.840.1.113883.6.1 | | | |
| --- | --- | --- | --- |
| LOINC Code | Type of Service (“Component”) | Setting (“System”) | Specialty/ Training/ Professional Level (“Method”) |
| **Root Level Document Type Code** | | | |
| 11488-4 | Consultation Note |  | {Provider} |
| **Specialized by Setting** | | | |
| 34100-8 | Consultation Note | Critical care unit | {Provider} |
| 34104-0 | Consultation Note | Hospital | {Provider} |
| 51845-6 | Consultation Note | Outpatient | {Provider} |
| 51853-0 | Consultation Note | Inpatient | {Provider} |
| 51846-4 | Consultation Note | Emergency Dept. | {Provider} |
| **Specialized by Setting and Specialty** | | | |
| 34101-6 | Consultation Note | Outpatient | General medicine |
| 34749-2 | Consultation Note | Outpatient | Anesthesia |
| 34102-4 | Consultation Note | Hospital | Psychiatry |
| **Specialized by Specialty** | | | |
| 34099-2 | Consultation Note |  | Cardiology |
| 34756-7 | Consultation Note |  | Dentistry |
| 34758-3 | Consultation Note |  | Dermatology |
| 34760-9 | Consultation Note |  | Diabetology |
| 34879-7 | Consultation Note |  | Endocrinology |
| 34761-7 | Consultation Note |  | Gastroenterology |
| 34764-1 | Consultation Note |  | General medicine |
| 34771-6 | Consultation Note |  | General surgery |
| 34776-5 | Consultation Note |  | Gerontology |
| 34777-3 | Consultation Note |  | Gynecology |
| 34779-9 | Consultation Note |  | Hematology+Oncology |
| 34781-5 | Consultation Note |  | Infectious disease |
| 34783-1 | Consultation Note |  | Kinesiotherapy |
| 34785-6 | Consultation Note |  | Mental health |
| 34795-5 | Consultation Note |  | Nephrology |
| 34797-1 | Consultation Note |  | Neurology |
| 34798-9 | Consultation Note |  | Neurosurgery |
| 34800-3 | Consultation Note |  | Nutrition+Dietetics |
| 34803-7 | Consultation Note |  | Occupational health |
| 34855-7 | Consultation Note |  | Occupational therapy |
| 34805-2 | Consultation Note |  | Oncology |
| 34807-8 | Consultation Note |  | Ophthalmology |
| 34810-2 | Consultation Note |  | Optometry |
| 34812-8 | Consultation Note |  | Oromaxillofacial surgery |
| 34814-4 | Consultation Note |  | Orthopedics |
| 34816-9 | Consultation Note |  | Otorhinolaryngology |
| 34820-1 | Consultation Note |  | Pharmacy |
| 34822-7 | Consultation Note |  | Physical medicine and rehabilitation |
| 34824-3 | Consultation Note |  | Physical therapy |
| 34826-8 | Consultation Note |  | Plastic surgery |
| 34828-4 | Consultation Note |  | Podiatry |
| 34788-0 | Consultation Note |  | Psychiatry |
| 34791-4 | Consultation Note |  | Psychology |
| 34103-2 | Consultation Note |  | Pulmonary |
| 34831-8 | Consultation Note |  | Radiation oncology |
| 34833-4 | Consultation Note |  | Recreational therapy |
| 34835-9 | Consultation Note |  | Rehabilitation |
| 34837-5 | Consultation Note |  | Respiratory therapy |
| 34839-1 | Consultation Note |  | Rheumatology |
| 34841-7 | Consultation Note |  | Social work |
| 34845-8 | Consultation Note |  | Speech therapy+Audiology |
| 34847-4 | Consultation Note |  | Surgery |
| 34849-0 | Consultation Note |  | Thoracic surgery |
| 34851-6 | Consultation Note |  | Urology |
| 34853-2 | Consultation Note |  | Vascular surgery |
| Invalid Codes for Consultation Note[[8]](#footnote-8) | | | |
| 18841-7 | Hospital consultations |  |  |
| 8647-0 | Hospital consultations | (scale = nom) |  |
| 33720-4 | Blood bank consult |  |  |
| 24611-6 | Confirmatory consultation note | Outpatient | {Provider} |
| 47040-1 | Confirmatory consultation note |  | {Provider} |
| 47041-9 | Confirmatory consultation note | Inpatient | {Provider} |
| 28569-2 | Subsequent evaluation note |  | Consulting physician |
| 18763-3 | Initial evaluation note |  | Consulting physician |

Figure 10: Consultation Note ClinicalDocument/code example

<code codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'

code='11488-4' displayName='CONSULTATION **not**E'

/>

Figure 11: Consultation Note translation of local code example

<code code='34761-7' displayName='Gastroenterology CONSULTATION NOTE'  
 codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'>

<translation code='X-GICON' displayName='GI CONSULTATION NOTE'

codeSystem='2.16.840.1.113883.19'/>

</code>

Figure 12: Consulation Note pre-coordinated document type codes example

<ClinicalDocument xmlns='urn:hl7-org:v3'>

…

<code codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'

code='34099-2'

displayName='CARDIOLOGY CONSULTATION NOTE'/>

…

…

<title>Good Health Cardiology Consultation Note</title>

…

<author>

<functionCode codeSystem='2.16.840.1.113883.5.88'  
 codeSystemName='ParticipationFunction'

code='ATTPHYS' />

<assignedAuthor>

…

<code codeSystem='2.16.840.1.113883.6.96' codeSystemName='SNOMED CT'

code='17561000' displayName='Cardiologist' />

…

</assignedAuthor>

</author>

…

<componentOf>

<encompassingEncounter>

…

<healthCareFacility>

<code codeSystem='2.16.840.1.113883.5.111' codeSystemName='RoleCode'

code='HOSP' />

</healthCareFacility>

</encompassingEncounter>

</componentOf>

</ClinicalDocument>

Figure 13: Consulation Note uncoordinated document type codes example

<ClinicalDocument xmlns='urn:hl7-org:v3'>

…

<code codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'

code='11488-4' displayName='CONSULTATION **not**E'/>

<title>Good Health Cardiology Consultation Note</title>

…

<author>

<functionCode codeSystem='2.16.840.1.113883.5.88'  
 codeSystemName='ParticipationFunction'

code='ATTPHYS' />

<assignedAuthor>

…

<code codeSystem='2.16.840.1.113883.6.96' codeSystemName='SNOMED CT'

code='17561000' displayName='Cardiologist' />

…

</assignedAuthor>

</author>

…

<componentOf>

<encompassingEncounter>

…

<healthCareFacility>

<code codeSystem='2.16.840.1.113883.5.111' codeSystemName='RoleCode'

code='HOSP' />

</healthCareFacility>

</encompassingEncounter>

</componentOf>

</ClinicalDocument>

#### Participant

The participant element identifies other supporting participants, including parents, relatives, caregivers, insurance policyholders, guarantors, and other participants related in some way to the patient.

This guide does not specify any use for functionCode for participants. Local policies will determine how this element should be used in implementations.

A supporting person or organization is an individual or an organization that has a relationship to the patient. A supporting person who is also an emergency contact or next-of-kin should be recorded as a participant for each role played.

1. **MAY** contain zero or more [0..\*] **participant** (CONF:8377).
   1. A participant element, if present, SHALL contain an associatedEntity element which SHALL contain either an associatedPerson or scopingOrganization element. (CONF:8378).
   2. A special class of participant is the supporting person or organization: an individual or an organization that has a relationship to the patient, including including parents, relatives, caregivers, insurance policyholders, and guarantors. In the case of a supporting person who is also an emergency contact or next-of-kin, a participant element should be present for each role recorded. (CONF:8379).
   3. When participant/@typeCode is IND, associatedEntity/@classCode SHALL be PRS, NOK,CAREGIVER, AGNT,GUAR, or ECON. (CONF:8380).
   4. When associatedEntity/@classCode is PRS, NOK, or ECON, then associatedEntity/code SHALL be present having a value drawn from the PersonalRelationshipRoleType domain or from SNOMED, any subtype of "Person in the family" (303071001) DYNAMIC. (CONF:8381).

Figure 14: Consultation Note participant example for a supporting person

<participant typeCode='IND'>

<associatedEntity classCode='NOK'>

<code code='MTH' codeSystem='2.16.840.1.113883.5.111'/>

<addr>

<streetAddressLine>17 Daws Rd.</streetAddressLine>

<city>Blue Bell</city>

<state>MA</state>

<postalCode>02368</postalCode>

<country>USA</country>

</addr>

<telecom value='tel:(555)555-2006' use='WP'/>

<associatedPerson>

<name>

<prefix>Mrs.</prefix>

<given>Martha</given>

<family>Mum</family>

</name>

</associatedPerson>

</associatedEntity>

</participant>

#### inFulfillmentOf

The inFulfillmentOf element describes the prior orders that are fulfilled (in whole or part) by the service events described in the Consultation Note. For example, the prior order might be for the consultation being reported in the Note.

1. **SHALL** contain exactly one [1..1] **inFulfillmentOf** (CONF:8382).
   1. The inFulfillmentOf element records the prior orders that are fulfilled (in whole or part) by the service events described in this document. For example, the prior order might be an order for a Consult, and this Consultation Note would be in fulfillment of that order. (CONF:8383).
   2. This inFulfillmentOf **SHOULD** contain exactly one [1..1] **order/id/@root** (CONF:8385).

Figure 15: Consultation Note inFulfillmentOf example

<inFulfillmentOf typeCode="FLFS">

<order classCode="ACT" moodCode="RQO">

<id root="2.16.840.1.113883.19" extension="12345-67890"/>

</order>

</inFulfillmentOf>

#### authorization

The authorization elements may be present. The Consultation Note provides no guidance on the encoding of authorization elements.

#### componentOf

A Consultation Note is always associated with an encounter; the componentOf element must be present and the encounter must be identified.

CDA R2 requires encompasingEncounter and the id element of the encompassingEncounter is required to be present and represents the identifier for the encounter.

The encounterParticipant elements may be present. If present, they represent only those participants in the encounter, not necessarily the entire episode of care (see related information under [Participant](#_Participant_3) above).

The responsibleParty element may be present. If present, it represents only the party responsible for the encounter, not necessarily the entire episode of care.

1. **SHALL** contain exactly one [1..1] **componentOf** (CONF:8386).
   1. This componentOf **SHALL** contain exactly one [1..1] **encompassingEncounter** (CONF:8387).
      1. This encompassingEncounter **SHALL** contain exactly one [1..1] **id** (CONF:8388).
      2. This encompassingEncounter **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:8389).
      3. This encompassingEncounter **MAY** contain zero or one [0..1] **responsibleParty** (CONF:8391).
         1. The responsibleParty element records only the party responsible for the encounter, not necessarily the entire episode of care. (CONF:8393).
         2. The responsibleParty element, if present, SHALL contain an assignedEntity element which SHALL contain an assignedPerson element, a representedOrganization element, or both. (CONF:8394).
      4. This encompassingEncounter **MAY** contain zero or more [0..\*] **encounterParticipant** (CONF:8392).
         1. The encounterParticipant element, if present, records only participants in the encounter, not necessarily in the entire episode of care. (CONF:8395).
         2. An encounterParticipant element, if present, SHALL contain an assignedEntity element which SHALL contain an assignedPerson element, a representedOrganization element, or both. (CONF:8396).

Figure 16: Consultation Note componentOf example

<componentOf>

<encompassingEncounter>

<id extension='9937012' root='1.3.6.4.1.4.1.2835.12'/>

<code codeSystem='2.16.840.1.113883.6.12' codeSystemName='CPT-4'

code='99213' displayName='Evaluation and Management'/>

</encompassingEncounter>

</componentOf>

### Consultation Note Body Constraints

The Consultation Note supports both narrative sections and sections requiring code clinical statements. The required and optional sections are listed in the [Document Types and Required/Optional Sections](#T_DocTypesAndReqOptSections) table.

1. **SHALL** contain exactly one [1..1] **component** (CONF:8397).
   1. A Consult Note can have either a structuredBody or a nonXMLBody. (CONF:8398).
      1. A History and Physical document can conform to CDA Level 1 (nonXMLBody), CDA Level 2 (structuredBody with sections that contain a narrative block), or CDA Level 3 (structuredBody containing sections that contain a narrative block and coded entries). This Guide provides separate templateIds for documents in which coded entries are required and for documents in which coded entries are optional. In this template (templateId 2.16.840.1.113883.10.20.22.1.4), coded entries are optional. (CONF:8399).

## Diagnostic Imaging Report

[ClinicalDocument: templateId 2.16.840.1.113883.10.20.22.1.5(open)]

A Diagnostic Imaging Report (DIR) contains a consulting specialist’s interpretation of image data. It conveys the interpretation to the referring (ordering) physician and becomes part of the patient’s medical record. It is for use in Radiology, Endoscopy, Cardiology, and other imaging specialties.

### DIR Header Constraints

The DIR must conform to the US Realm Clinical Document Header. The following sections include additional header constraints for conformant DIR Notes.

1. Conforms to US Realm Clinical Document Header Template (templateId: 2.16.840.1.113883.10.20.22.1.1).

#### ClinicalDocument/templateId

Conformant documents must carry the document-level templateId asserting conformance with specific constraints of a DIR as well as the templateId for the U.S. Realm CDA Header Constraints template.

1. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.1.5" (CONF:8404).

Figure 17: DIR ClinicalDocument/templateId example

<!-- indicates conformance with US Realm Clinical Document Header template -->

<templateId root="2.16.840.1.113883.10.20.22.1.1"/>

<!-- conforms to DIR requirements -->

<templateId root='2.16.840.1.113883.10.20.22.1.5'/>

#### ClinicalDocument/id

1. The ClinicalDocument/id/@root attribute SHALL be a syntactically correct OID, and SHALL NOT be a UUID. (CONF:8405).
   1. OIDs SHALL be represented in dotted decimal notation, where each decimal number is either 0 or starts with a nonzero digit. More formally, an OID SHALL be in the form ([0-2])(.([1-9][0-9]\*|0))+ (CONF:8406).
   2. OIDs SHALL be no more than 64 characters in length. (CONF:8407).

#### ClinicalDocument/code

Given that DIR documents may be transformed from established collections of imaging reports already stored with their own type codes, there is no static set of Document Type codes. The set of LOINC codes listed in the [DIR LOINC Document Type Codes](#T_DIRLOINCDocCodes) table may be extended by additions to LOINC and supplemented by local codes as translations.

The [DIR LOINC Document Type Codes](#T_DIRLOINCDocCodes) table lists document type codes supported for DIR. Some of these codes are pre-coordinated with either the imaging modality, body part examined, or specific imaging method such as the view. Use of these codes is not recommended, as this duplicates information potentially present with the header. When pre-coordinated codes are used, any coded values describing the author or performer of the service act or the practice setting must be consistent with the LOINC document type. This table is drawn from LOINC Version 2.26, January 10, 2008, and consists of codes whose scale is DOC and that refer to reports for diagnostic imaging procedures.

1. **SHALL** contain exactly one [1..1] **code** (CONF:8408).
   1. This code **SHOULD** contain exactly one [1..1] **@code**="18748-4" Diagnostic Imaging Report (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:8409).

Table 20: DIR LOINC Document Type Codes

| Code System: LOINC 2.16.840.1.113883.6.1 | | |
| --- | --- | --- |
| LOINC Code | Display Name | Modality |
| **Preferred Code** | | |
| 18748-4 | Diagnostic Imaging Report | Any |
| **Additional Codes** | | |
| 18747-6 | CT Report | Computed Tomography |
| 18755-9 | MRI Report | Magnetic Resonance Imaging |
| 18760-9 | Ultrasound Report | Ultrasound |
| 18757-5 | Nuclear Medicine Report | Nuclear Medicine |
| 18758-3 | PET Scan Report | Positron Emission Tomography |
| 18745-0 | Cardiac Catheterization Report | Cardiac Radiography/Fluoroscopy |
| 11522-0 | Echocardiography Report | Cardiac Ultrasound |
| 18746-8 | Colonoscopy Report | Magnetic Resonance Imaging |
| 18751-8 | Endoscopy Report | Magnetic Resonance Imaging |
| 18750-0 | Electrophysiology Report | Cardiac Radiography/Fluoroscopy |
| 11525-3 | Obstetrical Ultrasound Report | Ultrasound |

Figure 18: DIR ClinicalDocument/code example

<code code="18748-4" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC" displayName="Diagnostic Imaging Report"/>

Figure 19: DIR use of the translation element to include local codes for document type

<code code="18748-4"

codeSystem="2.16.840.1.113883.6.1"

codeSystemName="LOINC"

displayName="Diagnostic Imaging Report”

<translation code='XRPEDS'

displayName='Pediatric Radiography Report'

codeSystem='2.16.840.1.123456.78.9'/>

</code>

#### Participant

1. **SHALL NOT** contain [0..0] **informant** (CONF:8410).
2. **MAY** contain zero or more [0..\*] **informationRecipient** (CONF:8411).
   1. The physician requesting the imaging procedure (ClincalDocument/participant[@typeCode=REF]/associatedEntity), if present, SHOULD also be recorded as an informationRecipient, unless in the local setting another physician (such as the attending physician for an inpatient) is known to be the appropriate recipient of the report. (CONF:8412).
   2. When no referring physician is present, as in the case of self-referred screening examinations allowed by law, the intendedRecipient MAY be absent. The intendedRecipient MAY also be the health chart of the patient, in which case the receivedOrganization SHALL be the scoping organization of that chart. (CONF:8413).
3. **MAY** contain zero or one [0..1] **participant** (CONF:8414) such that it
   1. If participant is present, the assignedEntity/assignedPerson element SHALL be present and SHALL represent the physician requesting the imaging procedure (the referring physician AssociatedEntity that is the target of ClincalDocument/participant@typeCode=REF). (CONF:8415).

Figure 20: DIR participant example

<participant typeCode="REF">

<associatedEntity classCode="PROV">

<id nullFlavor="NI"/>

<addr nullFlavor="NI"/>

<telecom nullFlavor="NI"/>

<associatedPerson>

<name>

<given>Amanda</given>

<family>Assigned</family>

<suffix>MD</suffix>

</name>

</associatedPerson>

</associatedEntity>

</participant>

#### inFullfillmentOf

An inFullfillmentOf element represents the Placer Order that is either a group of orders (modeled as PlacerGroup in the Placer Order RMIM of the Orders & Observations domain) or a single order item (modeled as ObservationRequest in the same RMIM). This optionality reflects two major approaches to the grouping of procedures as implemented in the installed base of imaging information systems. These approaches differ in their handling of grouped procedures and how they are mapped to identifiers in the Digital Imaging and Communications in Medicine (DICOM) image and structured reporting data. The example of a CT examination covering chest, abdomen, and pelvis will be used in the discussion below.

In the IHE Scheduled Workflow model, the Chest CT, Abdomen CT, and Pelvis CT each represent a Requested Procedure, and all three procedures are grouped under a single Filler Order. The Filler Order number maps directly to the DICOM Accession Number in the DICOM imaging and report data.

A widely deployed alternative approach maps the requested procedure identifiers directly to the DICOM Accession Number. The Requested Procedure ID in such implementations may or may not be different from the Accession Number, but is of little identifying importance because there is only one Requested Procedure per Accession Number. There is no identifier that formally connects the requested procedures ordered in this group.

In both cases, inFullfillmentOf/order/id is mapped to the DICOM Accession Number in the imaging data.

Figure 21: DIR inFulfillmentOf example

<inFulfillmentOf>

<order>

<id extension="10523475" root="2.16.840.1.113883.19.4.27"/>

<!-- {root}.27= accession number list \*-->

</order>

</inFulfillmentOf>

#### documentationOf

Each documentationOf/ServiceEvent indicates an imaging procedure that the provider describes and interprets in the content of the DIR. The main activity being described by this document is the interpretation of the imaging procedure. This is shown by setting the value of the @classCode attribute of the serviceEvent element to ACT, and indicating the duration over which care was provided in the effectiveTime element. Within each documentationOf element, there is one serviceEvent element. This event is the unit imaging procedure corresponding to a billable item. The type of imaging procedure may be further described in the serviceEvent/code element. This guide makes no specific recommendations about the vocabulary to use for describing this event.

Figure 22: DIR procedure context (CDA Header) illustration (non-normative)



In IHE Scheduled Workflow environments, one serviceEvent/id element contains the DICOM Study Instance UID from the Modality Worklist, and the second serviceEvent/id element contains the DICOM Requested Procedure ID from the Modality Worklist.

The effectiveTime for the serviceEvent covers the duration of the imaging procedure being reported. This event should have one or more performers, which may participate at the same or different periods of time.

Service events map to DICOM Requested Procedures. That is, documentationOf/ServiceEvent/id is the ID of the Requested Procedure.

1. **SHALL** contain exactly one [1..1] **documentationOf** (CONF:8416).
   1. This documentationOf **SHALL** contain exactly one [1..1] **serviceEvent** (CONF:8431).
      1. This serviceEvent **SHALL** contain exactly one [1..1] **@classCode**="ACT" (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) (CONF:8430).
      2. This serviceEvent **SHOULD** contain at least one [1..\*] **id** (CONF:8418).
      3. This serviceEvent **SHALL** contain exactly one [1..1] **code** (CONF:8419).
         1. The value of serviceEvent/code SHALL NOT conflict with the ClininicalDocument/code. When transforming from DICOM SR documents that do not contain a procedure code, an appropriate nullFlavor SHALL be used on serviceEvent/code. (CONF:8420).
      4. This serviceEvent **SHALL** contain exactly one [1..1] **effectiveTime/@value** (CONF:8421).
      5. This serviceEvent **SHOULD** contain at least one [1..\*] [**Physician Reading Study Performer**](#DIR_PhysicianReadingStudyPerformer) (templateId:2.16.840.1.113883.10.20.6.2.1) (CONF:8422).

Figure 23: DIR documentationOf example

<documentationOf>

<serviceEvent classCode="ACT">

<id root="1.2.840.113619.2.62.994044785528.114289542805"/>

<!-- study instance UID -->

<id extension="123453" root="1.2.840.113619.2.62.994044785528.26"/>

<!-- requested procedure ID , {root}.26 = procedure ID Namespace-->

<effectiveTime value="20060823222400"/>

<performer typeCode="PRF">

<templateId root="2.16.840.1.113883.10.20.6.2.1"/>

<assignedEntity>

<id extension="121008" root="2.16.840.1.113883.19.5"/>

<code code="2085R0202X" codeSystem="2.16.840.1.113883.11.19465" codeSystemName="NUCC" displayName="Diagnostic Radiology"/>

<addr nullFlavor="NI"/>

<telecom nullFlavor="NI"/>

<assignedPerson>

<name>

<given>Christine</given>

<family>Cure</family>

<suffix>MD</suffix>

</name>

</assignedPerson>

</assignedEntity>

</performer>

</serviceEvent>

</documentationOf>

#### authorization

The authorization elements may be present. This document provides no guidance on the encoding of authorization elements.

#### relatedDocument

A DIR may have three types of parent document:

* A superseded version that the present document wholly replaces (typeCode = RPLC). DIRs may go through stages of revision prior to being legally authenticated. Such early stages may be drafts from transcription, those created by residents, or other preliminary versions. Policies not covered by this specification may govern requirements for retention of such earlier versions. Except for forensic purposes, the latest version in a chain of revisions represents the complete and current report.
* An original version that the present document appends (typeCode = APND). When a DIR is legally authenticated, it can be amended by a separate addendum document that references the original.
* A source document from which the present document is transformed (typeCode = XFRM). A DIR may be created by transformation from a DICOM Structured Report (SR) document or from another DIR. An example of the latter case is the creation of a derived document for inclusion of imaging results in a clinical document.

1. **MAY** contain zero or one [0..1] **relatedDocument** (CONF:8432) such that it
   1. When a Diagnostic Imaging Report has been transformed from a DICOM SR document, relatedDocument/@typeCode SHALL be XFRM, and relatedDocument/parentDocument/id SHALL contain the SOP Instance UID of the original DICOM SR document. (CONF:8433).

Figure 24: DIR relatedDocument example

<!-- transformation of a DICOM SR -->

<relatedDocument typeCode="XFRM">

<parentDocument>

<id root="1.2.840.113619.2.62.994044785528.20060823.200608232232322.9"/>

<!-- SOP Instance UID (0008,0018) of SR sample document-->

</parentDocument>

</relatedDocument>

#### componentOf

The id element of the encompassingEncounter represents the identifier for the encounter. When the diagnostic imaging procedure is performed in the context of a hospital stay or an outpatient visit for which there is an Encounter Number, that number should be present as the ID of the encompassingEncounter.

The effectiveTime represents the time interval or point in time in which the encounter took place. The encompassing encounter might be that of the hospital or office visit in which the diagnostic imaging procedure was ordered. If the effective time is unknown, a nullFlavor attribute can be used.

1. **MAY** contain zero or one [0..1] **componentOf** (CONF:8434).
   1. This componentOf, if present, **SHALL** contain exactly one [1..1] **encompassingEncounter** (CONF:8449).
      1. This encompassingEncounter **SHALL** contain at least one [1..\*] **id** (CONF:8435).
         1. In the case of transformed DICOM SR documents, an appropriate null flavor MAY be used if the id is unavailable. (CONF:8436).
      2. This encompassingEncounter **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:8437).
      3. This encompassingEncounter **MAY** contain zero or more [0..\*] **responsibleParty** (CONF:8438).
         1. If present, responsibleParty/assignedEntity SHALL have at least one assignedPerson or representedOrganization element present. (CONF:8439).
      4. This encompassingEncounter **SHOULD** contain exactly one [1..1] [**Physician of Record Participant**](#DIR_PhysicianOFRecordParticipant) (templateId:2.16.840.1.113883.10.20.6.2.2) (CONF:8448).

Figure 25: DIR componentOf example

<componentOf>

<encompassingEncounter>

<id extension="9937012" root="1.3.6.4.1.4.1.2835.12"/>

<effectiveTime value="20060828170821"/>

<encounterParticipant typeCode="ATND">

<templateId root="2.16.840.1.113883.10.20.6.2.2"/>

<assignedEntity>

<id extension="4" root="2.16.840.1.113883.19"/>

<code code="208D00000X" codeSystem="2.16.840.1.113883.11.19465" codeSystemName="NUCC" displayName="General Practice"/>

<addr nullFlavor="NI"/>

<telecom nullFlavor="NI"/>

<assignedPerson>

<name>

<prefix>Dr.</prefix>

<given>Fay </given>

<family>Family</family>

</name>

</assignedPerson>

</assignedEntity>

</encounterParticipant>

</encompassingEncounter>

</componentOf>

Physician Reading Study Performer

[participant: templateId 2.16.840.1.113883.10.20.6.2.2(open)]

This participant is the attending physician and is usually different from the Physician Reading Study Performer defined in documentationOf/serviceEvent.

1. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.6.2.2" (CONF:8440).
2. **SHALL** contain exactly one [1..1] **encounterParticipant** (CONF:8441).
   1. This encounterParticipant **SHALL** contain exactly one [1..1] **@typeCode**="ATND" (CodeSystem: 2.16.840.1.113883.5.90 HL7ParticipationType) (CONF:8442).
   2. This encounterParticipant **SHALL** contain exactly one [1..1] **assignedEntity** (CONF:8443).
      1. This assignedEntity **SHALL** contain at least one [1..\*] **id** (CONF:8444).
      2. This assignedEntity **SHALL** contain exactly one [1..1] **code** (CONF:8445).
         1. SHALL contain a valid DICOM personal identification code sequence (@codeSystem is 1.2.840.10008.2.16.4) or an appropriate national health care provider coding system (e.g., NUCC in the U.S., where @codeSystem is 2.16.840.1.113883.11.19465). (CONF:8446).
   3. This encounterParticipant **SHOULD** contain exactly one [1..1] **assignedPerson/name** (CONF:8447).

#### Physician of Record Participant

[performer: templateId 2.16.840.1.113883.10.20.6.2.1(open)]

This participant is the attending physician and is usually different from the Physician Reading Study Performer defined in documentationOf/serviceEvent.

1. **SHALL** contain exactly one [1..1] **performer/@typeCode**="PRF" (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) (CONF:8424).
2. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.6.2.1" (CONF:8423).
3. **MAY** contain exactly one [1..1] **time** (CONF:8425).
4. **SHALL** contain exactly one [1..1] **assignedEntity** (CONF:8426).
   1. This assignedEntity **SHALL** contain exactly one [1..1] **code** (CONF:8427).
      1. SHALL contain a valid DICOM personal identification code sequence (@codeSystem is 1.2.840.10008.2.16.4) or an appropriate national health care provider coding system (e.g., NUCC in the U.S., where @code is 2.16.840.1.113883.11.19465). (CONF:8428).
   2. Every assignedEntity element SHALL have at least one assignedPerson or representedOrganization. (CONF:8429).

### DIR Body Constraints

The DIR supports both narrative sections and sections requiring code clinical statements. The required and optional sections are listed in the [Document Types and Required/Optional Sections](#T_DocTypesAndReqOptSections) table.

### Generic DIR Section Constraints: FUTURE CONSIDERATION

The Section Type codes used by DIR are described below in the [DIR Section Type Codes](#T_DIRSectionTypeCodes) table. All section codes shown in this table describe narrative document sections[[9]](#footnote-9).

The column headings of this table are:

|  |  |
| --- | --- |
| DCM Code: | The code of the section in DICOM (Context Group CID 7001). |
| DCM Code Meaning: | The display name of the section in DICOM (Context Group CID 7001).. |
| LOINC Code: | The code of the section in LOINC®. |
| LOINC Component Name: | The display name of the section in LOINC®. |
| Use: | The use column indicates that a section in a Diagnostic Imaging Report is:  R – required  C – conditionally required  O – optional |

Table 21: DIR Section Type Codes

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| DICOM Code | DICOM Code meaning | LOINC® Code | LOINC® Code Meaning | Use |
| 121181 | DICOM Object Catalog | N/A | N/A | C |
| 121060 | History | 11329-0 | HISTORY GENERAL | O |
| 121062 | Request | 55115-0 | REQUESTED IMAGING STUDIES INFORMATION | O |
| 121064 | Current Procedure Descriptions | 55111-9 | CURRENT IMAGING PROCEDURE DESCRIPTIONS | O |
| 121066 | Prior Procedure Descriptions | 55114-3 | PRIOR IMAGING PROCEDURE DESCRIPTIONS | O |
| 121068 | Previous Findings | 18834-2 | RADIOLOGY COMPARISON STUDY - OBSERVATION | O |
| 121070 | Findings | 18782-3 | RADIOLOGY STUDY OBSERVATION | R |
| 121072 | Impressions | 19005-8 | RADIOLOGY - IMPRESSION | O |
| 121074 | Recommendations | 18783-1 | RADIOLOGY STUDY - RECOMMENDATION | O |
| 121076 | Conclusions | 55110-1 | CONCLUSIONS | O |
| 121078 | Addendum | 55107-7 | ADDENDUM | O |
| 121109 | Indications for Procedure | 18785-6 | RADIOLOGY REASON FOR STUDY | O |
| 121110 | Patient Presentation | 55108-5 | CLINICAL PRESENTATION | O |
| 121113 | Complications | 55109-3 | COMPLICATIONS | O |
| 121111 | Summary | 55112-7 | DOCUMENT SUMMARY | O |
| 121180 | Key Images | 55113-5 | KEY IMAGES | O |

**CONF:**  The DICOM Object Catalog section, if present, shall be the first section in the document Body.

**CONF:**  With the exception of the DICOM Object Catalog (templateId 2.16.840.1.113883.10.20.6.1.1), all sections within the Diagnostic Imaging Report content should contain a title element.

**CONF:**  sections not listed in the [DIR Section Type Codes](#T_DIRSectionTypeCodes) table, the section/code should be selected from LOINC® or DICOM.

The remainder of the examples in this section all show sample content that would appear in the structuredBody element.

For Level 2 conformance, all section elements that are present in the Body of the document must have a code and some nonblank text or one or more subsections, even if the purpose of the text is only to indicate that information is unknown.

All sections defined in the [DIR Section Type Codes](#T_DIRSectionTypeCodes) table shall be top-level sections.

**CONF-DIR:** A section element shall have a code element which shall contain a LOINC® code if available, or DCM code for sections which have no LOINC® equivalent. This only applies to sections described inthe [DIR Section Type Codes](#T_DIRSectionTypeCodes) table.

**CONF-DIR:** Apart from the DICOM Object Catalog, all other instances of section shall contain at least one text element or one or more component elements.

**CONF-DIR:** All text or component elements shall contain content. text elements shall contain PCDATA or child elements, and component elements shall contain child elements.

**CONF-DIR:** The text elements (and their children) may contain Web Access to DICOM Persistent Object (WADO) references to DICOM objects by including a linkHtml element where @href is a valid WADO URL and the text content of linkHtml is the visible text of the hyperlink.

Figure 26: WADO reference using linkHtml example

<text>

...

<paragraph>

<caption>Source of Measurement</caption>

<linkHtml href="http://www.example.org/wado?requestType=WADO&amp;studyUID=1.2.840.113619.2.62.994044785528.114289542805&amp;seriesUID=1.2.840.113619.2.62.994044785528.20060823223142485051&amp;objectUID=1.2.840.113619.2.62.994044785528.20060823.200608232232322.3&amp;contentType=application/dicom">Chest\_PA</linkHtml>

</paragraph>

...

</text>

There is no equivalent to section/title in DICOM SR, so for a CDA to SR transformation, the section/code will be transferred and the title element will be dropped.

**CONF-DIR:** If clinical statements are present, the section/text shall represent faithfully all such statements and may contain additional text.

**CONF-DIR:** If the service context of a section is different from the value specified in documentationOf/serviceEvent, then the section shall contain one or more entries containing Procedure Context (templateId 2.16.840.1.113883.10.20.6.2.5), which will reset the context for any clinical statements nested within those elements.

**CONF-DIR:** If the subject of a section is a fetus, the section shall contain a subject element containing a Fetus Subject Context (templateId 2.16.840.1.113883.10.20.6.2.3).

**CONF-DIR:** If the author of a section is different from the author(s) listed in the Header, an author element shall be present containing Observer Context (templateId 2.16.840.1.113883.10.20.6.2.4).

Discharge Summary

[ClinicalDocument: templateId 2.16.840.1.113883.10.20.22.1.8(open)]

The Discharge Summary is a synopsis of a patient's admission to a hospital; it provides pertinent information for the continuation of care following discharge.  The Joint Commission requires the following information to be included in the Discharge Summary[[10]](#footnote-10):

* The reason for hospitalization
* The procedures performed
* The care, treatment, and services provided
* The patient’s condition and disposition at discharge
* Information provided to the patient and family
* Provisions for follow-up care

### Discharge Summary Header Constraints

The Discharge Summary must conform to the US Realm Clinical Document Header. The following sections include additional header constraints for conformant Discharge Summaries.

1. Conforms to US Realm Clinical Document Header Template (templateId: 2.16.840.1.113883.10.20.22.1.1).

#### ClinicalDocument/templateId

Conformant documents must carry the document-level templateId asserting conformance with specific constraints of a Discharge Summary as well as the templateId for the US Realm Clinical Document Header template.

1. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.1.8" (CONF:8463).

Figure 27: Discharge Summary ClinicalDocument/templateId example

<!-- indicates conformance with Clinical Document Header Constraints -->

<templateId root="2.16.840.1.113883.10.20.3"/>

<!—indicates conformance to Discharge Summary -->

<templateId root="2.16.840.1.113883.10.20.22.1.8"/>

#### ClinicalDocument/code

CDA R2 states that LOINC is the preferred vocabulary for document type codes. The [Discharge Summary LOINC Document Codes](#T_DischargeSummLoincdocCodes) table shows the LOINC codes suitable for Discharge Summary, as of publication of this implementation guide.This is a dynamic value set meaning that these codes may be added to or deprecated by LOINC.

Discharge Summarization Note 18842-5 is the recommended value. This code can be post-coordinated with practice setting and other parameters in the CDA header. Some of the LOINC codes listed here pre-coordinate the practice setting or the training or professional level of the author. If used, the pre-coordinated codes must be consistent with the LOINC document type code.

1. **SHALL** contain exactly one [1..1] **code/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.11.20.4.1 DischargeSummaryDocumentTypeCode **DYNAMIC** (CONF:8466).

Table 22: Discharge Summary LOINC Document Codes

|  |  |  |  |
| --- | --- | --- | --- |
| Value Set: DischargeSummaryDocumentTypeCode 2.16.840.1.113883.11.20.4.1  Code System: LOINC 2.16.840.1.113883.6.1 | | | |
| LOINC Code | Type of Service ‘Component’ | Setting ‘System’ | Specialty/Training/Professional Level ‘Method\_Type’ |
| 18842-5 | Discharge summarization note | {Setting} | {Provider} |
| 11490-0 | Discharge summarization note | {Setting} | Physician |
| 28655-9 | Discharge summarization note | {Setting} | Attending physician |
| 29761-4 | Discharge summarization note | {Setting} | Dentistry |
| 34745-0 | Discharge summarization note | {Setting} | Nursing |
| 34105-7 | Discharge summarization note | Hospital | {Provider} |
| 34106-5 | Discharge summarization note | Hospital | Physician |

Figure 28: Discharge Summary ClinicalDocument/code example

<code codeSystem="2.16.840.1.113883.6.1"

codeSystemName="LOINC" code="18842-5"

displayName="DISCHARGE SUMMARIZATION NOTE"/>

#### Participant

The participant element identifies other supporting participants, including parents, relatives, caregivers, insurance policyholders, guarantors, and other participants related in some way to the patient. The time element of the participant may be present. When present, it indicates the time span over which the participation takes place. For example, in the case of health care providers or support persons or organizations, it indicates the time span over which care or support is provided.

Discharge Summary does not specify any use for functionCode for participants. Local policies will determine how this element should be used in implementations.

A supporting person or organization is an individual or an organization with a relationship to the patient. A supporting person who is also an emergency contact or next-of-kin should be recorded as a participant for each role played.

1. **MAY** contain at least one [1..\*] **participant** (CONF:8467).
   1. If present, the participant/associatedEntity element SHALL have an associatedPerson or scopingOrganization element. (CONF:8468).
   2. When participant/@typeCode is IND, associatedEntity/@classCode SHALL be PRS, NOK, CAREGIVER, AGNT, GUAR, or ECON. (CONF:8469).
   3. When associatedEntity/@classCode is PRS, NOK, or ECON, then associatedEntity/code SHALL be present having a value drawn from the PersonalRelationshipRoleType domain or from SNOMED using any subtype of "Person in the family" (303071001). (CONF:8470).

Figure 29: Discharge summary participant example for a supporting person

<participant typeCode="IND">

<associatedEntity classCode="NOK">

<code code="MTH" codeSystem="2.16.840.1.113883.5.111"

codeSystemName="HL7 RoleCode"/>

<addr>

<streetAddressLine>6666 Home Street</streetAddressLine>

<city>Blue Bell</city>

<state>MA</state>

<postalCode>02368</postalCode>

<country>USA</country>

</addr>

<telecom value="tel:(999)555-1212" use="WP"/>

<associatedPerson>

<name>

<prefix>Mrs.</prefix>

<given>Nelda</given>

<family>Nuclear</family>

</name>

</associatedPerson>

</associatedEntity>

</participant>

#### componentOf

The Discharge Summary is always associated with a Hospital Admission using the encompassingEncounter element in the header.

The dischargeDispositionCode records the disposition of the patient at time of discharge. Access to the National Uniform Billing Committee (NUBC) code system requires a membership. The following conformance statement aligns with HITSP C80 requirements.

The responsibleParty element represents only the party responsible for the encounter, not necessarily the entire episode of care.

The encounterParticipant elements represent only those participants in the encounter, not necessarily the entire episode of care.

1. **SHALL** contain exactly one [1..1] **componentOf** (CONF:8471).
   1. This componentOf **SHALL** contain exactly one [1..1] **encompassingEncounter** (CONF:8472).
      1. This encompassingEncounter **SHALL** contain exactly one [1..1] **effectiveTime/low** (CONF:8473).
      2. This encompassingEncounter **SHALL** contain exactly one [1..1] **effectiveTime/high** (CONF:8475).
      3. The dischargeDispositionCode SHALL be present where the value of @code is selected from 2.16.840.1.113883.3.88.12.80.33 NUBC UB-04 FL17-Patient Status DYNAMIC or, if access to NUBC is unavailable, from 2.16.840.1.113883.12.112 HL7 Discharge Disposition DYNAMIC. (CONF:8476).
         1. The dischargeDispositionCode SHALL be displayed when the document is rendered. (CONF:8477).
      4. The responsibleParty element MAY be present. If present, the responsibleParty/assignedEntity element SHALL have at least one assignedPerson or representedOrganization element present. (CONF:8479).
      5. The encounterParticipant elements MAY be present. If present, the encounterParticipant/assignedEntity element SHALL have at least one assignedPerson or representedOrganization element present. (CONF:8478).

Table 23: HL7 Discharge Disposition Codes

|  |  |
| --- | --- |
| Value Set: Discharge disposition 2.16.840.1.113883.3.88.12.80.33  Code System: HL7 Discharge Disposition 2.16.840.1.113883.12.112 | |
| Code | Print Name |
| 01 | Discharged to home or self care (routine discharge) |
| 02 | Discharged/transferred to another short-term general hospital for inpatient care |
| 03 | Discharged/transferred to skilled nursing facility (SNF) |
| 04 | Discharged/transferred to an intermediate-care facility (ICF) |
| 05 | Discharged/transferred to another type of institution for inpatient care or referred for outpatient services to another institution |
| 06 | Discharged/transferred to home under care of organized home health service organization |
| 07 | Left against medical advice or discontinued care |
| 08 | Discharged/transferred to home under care of Home IV provider |
| 09 | Admitted as an inpatient to this hospital |
| 10 …19 | Discharge to be defined at state level, if necessary |
| 20 | Expired (i.e., dead) |
| 21 ... 29 | Expired to be defined at state level, if necessary |
| 30 | Still patient or expected to return for outpatient services (i.e., still a patient) |
| 31 … 39 | Still patient to be defined at state level, if necessary (i.e., still a patient) |
| 40 | Expired (i.e., died) at home |
| 41 | Expired (i.e., died) in a medical facility; e.g., hospital, SNF, ICF, or free-standing hospice |
| 42 | Expired (i.e., died) - place unknown |

Figure 30: Discharge Summary componentOf example

<componentOf>

<encompassingEncounter>

<id extension="9937012" root="2.16.840.1.113883.19"/>

<effectiveTime>

<low value="20050329"/>

<high value="20050329"/>

</effectiveTime>

<dischargeDispositionCode code="01"

codeSystem="2.16.840.1.113883.12.112"

displayName="Routine Discharge"

codeSystemName="HL7 Discharge Disposition"/>

</encompassingEncounter>

</componentOf>

### Discharge Summary Body Constraints

The Discharge Summary supports both narrative sections and sections requiring code clinical statements. The required and optional sections are listed in the [Document Types and Required/Optional Sections](#T_DocTypesAndReqOptSections) table.

History and Physical (H&P) Note

[ClinicalDocument: templateId 2.16.840.1.113883.10.20.22.1.3(open)]

A History and Physical (H&P) Note is a medical report that documents the current and past conditions of the patient. It contains essential information that helps determine an individual's health status.

The first portion of the report is a current collection of organized information unique to an individual, typically supplied by the patient or their caregiver, about the current medical problem or the reason for the patient encounter. This information is followed by a description of any past or ongoing medical issues, including current medications and allergies. Information is also obtained about the patient's lifestyle, habits, and diseases among family members.

The next portion of the report contains information obtained by physically examining the patient and gathering diagnostic information in the form of laboratory tests, imaging, or other diagnostic procedures.

The report ends with the clinician's assessment of the patient's situation and the intended plan to address those issues.

A History and Physical Examination is required upon hospital admission as well as before operative procedures. An initial evaluation in an ambulatory setting is often documented in the form of an H&P Note.

### H&P Note Header Constraints

The H&P Note must conform to the US Realm Clinical Document Header. The following sections include additional header constraints for conformant H&P Notes.

1. Conforms to US Realm Clinical Document Header Template (templateId: 2.16.840.1.113883.10.20.22.1.1).

#### ClinicalDocument/templateId

Conformant documents must carry the document-level templateId asserting conformance with specific constraints of a H&P Note as well as the templateId for the US Realm Clinical Document Header template.

1. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.1.3" History and Physical Note (CONF:8283).

Figure 31: H&P ClinicalDocument/templateId example

<!-- indicates conformance with US Realm Clinical Document Header template -->

<templateId root="2.16.840.1.113883.10.20.22.1.1"/>

<!-- conforms to a H&P Note -->

<templateId root="2.16.840.1.113883.10.20.22.1.3"/>

#### ClinicalDocument/code

The ClinicalDocument/code element must be present and specifies the type of the clinical document. CDA R2 states that LOINC is the preferred vocabulary for document type specifications. At publication time for this guide, H&P Note limits those codes to those shown in the [H&P LOINC Document Type Codes](#T_HandPLoincdocCodes) table. Valid codes are those whose scale is DOC and whose type of service is some variation of History and Physical.

Some LOINC codes in the [H&P LOINC Document Type Codes](#T_HandPLoincdocCodes) table are pre-coordinated with the practice setting or the training or professional level of the author. Use of these codes is not recommended, as this duplicates information potentially present with the header. When pre-coordinated codes are used, any coded values describing the author or performer of the service act or the practice setting must be consistent with the LOINC document type.

The last two figures in this section illustrate the use of [pre-coordinated](#F_HandP_PreCoordinatedcodes) and [uncoordinated](#F_HandP_NONPreCoordinatedcodes) document codes. The pre-coordinated document codes show consistancy between the document code and other codes found in the document; the uncoordinated codes eliminate the need to ensure consistency of the document type code. In either case, the title can be localized.

1. **SHALL** contain exactly one [1..1] **code/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.20.22 HPDocumentType **DYNAMIC** (CONF:8335).

Table 24: H&P LOINC Document Type Codes

| Value Set: HPDocumentType 2.16.840.1.113883.1.11.20.22  Code System: LOINC 2.16.840.1.113883.6.1 | | | |
| --- | --- | --- | --- |
| LOINC Code | Type of Service | Setting | Specialty/ Training/ Professional Level |
| Preferred Code | | | |
| 34117-2 | History & Physical | ------ | ------ |
| Additional Codes | | | |
| 11492-6 | History & Physical | Hospital | ------ |
| 28626-0 | History & Physical | ------ | Physician |
| 34774-0 | History & Physical | ------ | General surgery |
| 34115-6 | History & Physical | Hospital | Medical Student |
| 34116-4 | History & Physical | Nursing home | Physician |
| 34095-0 | Comprehensive History & Physical | ------ | ------ |
| 34096-8 | Comprehensive History & Physical | Nursing home |  |
| 51849-8 | Admission History & Physical | ------ | ------ |
| 47039-3 | Admission History & Physical | Inpatient | ------ |
| 34763-3 | Admission History & Physical |  | General medicine |
| 34094-3 | Admission History & Physical | Hospital | Cardiology |
| 34138-8 | Targeted History & Physical | ------ | ------ |

Figure 32: H&P ClinicalDocument/code example

<code codeSystem='2.16.840.1.113883.6.1'

codeSystemName='LOINC'

code='34117-2'

displayName='HISTORY and PHYSICAL'/>

Figure 33: H&P use of translation to include local equivalents for document type

**<code code='34117-2'**

**displayName='HISTORY and PHYSICAL'  
 codeSystem='2.16.840.1.113883.6.1'**

**codeSystemName='LOINC'>**

**<translation code='X-GISOE'**

**displayName='GI HISTORY and PHYSICAL'**

**codeSystem='2.16.840.1.113883.19'/>**

**</code>**

Figure 34: H&P use of a pre-coordinated document type code

<ClinicalDocument xmlns='urn:hl7-org:v3'>

…

<code codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'

code='34094-3'

displayName='CARDIOLOGY HOSPITAL ADMISSION notE'/>

…

<title>Good Health Cardiology Admitting History &amp; Physical</title>

…

<author>

<functionCode codeSystem='2.16.840.1.113883.5.88'  
 codeSystemName='ParticipationFunction'

code='ATTPHYS' />

<assignedAuthor>

…

<code codeSystem='2.16.840.1.113883.6.96' codeSystemName='SNOMED CT'

code='17561000' displayName='Cardiologist' />

…

</assignedAuthor>

</author>

…

<componentOf>

<encompassingEncounter>

…

<healthCareFacility>

<code codeSystem='2.16.840.1.113883.5.111' codeSystemName='RoleCode'

code='HOSP' />

</healthCareFacility>

</encompassingEncounter>

</componentOf>

</ClinicalDocument>

Figure 35: H&P use of an uncoordinated document type code

<ClinicalDocument xmlns='urn:hl7-org:v3'>

…

<code codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'

code='47039-3' displayName='ADMISSION H&P notE'/>

…

<title>Good Health Cardiology Admitting History &amp; Physical</title>

…

<author>

<functionCode codeSystem='2.16.840.1.113883.5.88'  
 codeSystemName='ParticipationFunction'

code='ATTPHYS' />

<assignedAuthor>

…

<code codeSystem='2.16.840.1.113883.6.96' codeSystemName='SNOMED CT'

code='17561000' displayName='Cardiologist' />

…

</assignedAuthor>

</author>

…

<componentOf>

<encompassingEncounter>

…

<healthCareFacility>

<code codeSystem='2.16.840.1.113883.5.111' codeSystemName='RoleCode'

code='HOSP' />

</healthCareFacility>

</encompassingEncounter>

</componentOf>

</ClinicalDocument>

#### participant

The participant element identifies other supporting participants, including parents, relatives, caregivers, insurance policyholders, guarantors, and other participants related in some way to the patient. The time element of the participant may be present. When present, it indicates the time span over which the participation takes place. For example, in the case of an insurance policyholder, the time element indicates the effective time range for the insurance policy described. For health care providers or support persons or organizations, it indicates the time span over which care or support is provided.

H&P Note does not specify any use for functionCode for participants. Local policies will determine how this element should be used in implementations.

A supporting person or organization is an individual or an organization that has a relationship to the patient. A supporting person who is also an emergency contact or next-of-kin should be recorded as a participant for each role played.

1. **MAY** contain zero or more [0..\*] **participant** (CONF:8286).
   1. A participant element, if present, SHALL contain an associatedEntity element which SHALL contain either an associatedPerson or scopingOrganization element. (CONF:8287).
   2. A special class of participant is the supporting person or organization: an individual or an organization that has a relationship to the patient, including including parents, relatives, caregivers, insurance policyholders, and guarantors. In the case of a supporting person who is also an emergency contact or next-of-kin, a participant element should be present for each role recorded. (CONF:8288).
   3. When participant/@typeCode is IND, associatedEntity/@classCode SHALL be PRS, NOK,CAREGIVER, AGNT,GUAR, or ECON. (CONF:8333).
   4. When associatedEntity/@classCode is PRS, NOK, or ECON, then associatedEntity/code SHALL be present having a value drawn from the PersonalRelationshipRoleType domain or from SNOMED, any subtype of "Person in the family" (303071001). (CONF:8334).

Figure 36: H&P participant example for a supporting person

<participant typeCode='IND'>

<associatedEntity classCode='NOK'>

<code code='MTH' codeSystem='2.16.840.1.113883.5.111'/>

<addr>

<streetAddressLine>17 Daws Rd.</streetAddressLine>

<city>Blue Bell</city>

<state>MA</state>

<postalCode>02368</postalCode>

<country>USA</country>

</addr>

<telecom value='tel:(999)555-1212' use='WP'/>

<associatedPerson>

<name>

<prefix>Mrs.</prefix>

<given>Abigail</given>

<family>Ruth</family>

</name>

</associatedPerson>

</associatedEntity>

</participant>

#### inFulfillmentOf

inFulfillmentOf elements describe the prior orders that are fulfilled (in whole or part) by the service events described in this document. For example, the prior order might be a referral and the H&P Note may be in partial fulfillment of that referral.

1. **MAY** contain zero or more [0..\*] **inFulfillmentOf** (CONF:8336).
   1. An inFulfillmentOf element records the prior orders that are fulfilled (in whole or part) by the service events described in this document. For example, the prior order might be a referral and this H&P Note may be in partial fulfillment of that referral. (CONF:8337).

#### Authorization

This document provides no guidance on the encoding of authorization elements.

#### componentOf

The H&P Note is always associated with an encounter.

The effectiveTime represents the time interval or point in time in which the encounter took place.

The encounterParticipant elements represent only those participants in the encounter, not necessarily the entire episode of care.

The responsibleParty element represents only the party responsible for the encounter, not necessarily the entire episode of care.

1. **SHALL** contain exactly one [1..1] **componentOf** (CONF:8338).
   1. This componentOf **SHALL** contain exactly one [1..1] **encompassingEncounter** (CONF:8339).
      1. This encompassingEncounter **SHALL** contain exactly one [1..1] **id** (CONF:8340).
      2. This encompassingEncounter **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:8341).
      3. This encompassingEncounter **MAY** contain zero or one [0..1] **location** (CONF:8344).
      4. This encompassingEncounter **MAY** contain zero or one [0..1] **responsibleParty** (CONF:8345).
         1. The responsibleParty element records only the party responsible for the encounter, not necessarily the entire episode of care. (CONF:8347).
         2. The responsibleParty element, if present, SHALL contain an assignedEntity element which SHALL contain an assignedPerson element, a representedOrganization element, or both. (CONF:8348).
      5. This encompassingEncounter **MAY** contain zero or more [0..\*] **encounterParticipant** (CONF:8342).
         1. The encounterParticipant element, if present, records only participants in the encounter, not necessarily in the entire episode of care. (CONF:8346).
         2. An encounterParticipant element, if present, SHALL contain an assignedEntity element which SHALL contain an assignedPerson element, a representedOrganization element, or both. (CONF:8343).

Figure 37: H&P componentOf example

<componentOf>

<encompassingEncounter>

<id extension='9937012' root='2.16.840.1.113883.19'/>

<code codeSystem='2.16.840.1.113883.6.12' codeSystemName='CPT-4'

code='99213' displayName='Evaluation and Management'/>

<effectiveTime>

<low value='20050329'/>

<high value='20050329'/>

</effectiveTime>

</encompassingEncounter>

</componentOf>

### H&P Note Body Constraints

The H&P Note supports both narrative sections and sections requiring code clinical statements. The required and optional sections are listed in the [Document Types and Required/Optional Sections](#T_DocTypesAndReqOptSections) table.

1. **SHALL** contain exactly one [1..1] **component** (CONF:8349).
   1. A History and Physical document can have either a structuredBody or a nonXMLBody. (CONF:8350).
      1. A History and Physical document can conform to CDA Level 1 (nonXMLBody), CDA Level 2 (structuredBody with sections that contain a narrative block), or CDA Level 3 (structuredBody containing sections that contain a narrative block and coded entries). This guide provides separate templateIds for documents in which coded entries are required and for documents in which coded entries are optional. In this template (templateId 2.16.840.1.113883.10.20.22.1.3), coded entries are optional. (CONF:8352).

Operative Note

[ClinicalDocument: templateId 2.16.840.1.113883.10.20.22.1.7(open)]

The Operative Note is a frequently used type of procedure note with specific requirements set forth by regulatory agencies.

The Operative Note or Report is created immediately following a surgical or other high-risk procedure and records the pre- and post-surgical diagnosis, pertinent events of the procedure, as well as the condition of the patient following the procedure. The report should be sufficiently detailed to support the diagnoses, justify the treatment, document the course of the procedure, and provide continuity of care.[[11]](#footnote-11)

### Operative Note Header Constraints

The Operative Note must conform to the US Realm Clinical Document Header. The following sections include additional header constraints for conformant Operative Notes.

1. Conforms to US Realm Clinical Document Header Template (templateId: 2.16.840.1.113883.10.20.22.1.1).

#### ClinicalDocument/templateId

Conformant documents must carry the document-level templateId asserting conformance with specific constraints of an Operative Note as well as the templateId for the US Realm Clinical Document Header template.

The following asserts conformance to an Operative Note.

1. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.1.7" (CONF:8483).

Figure 38: Operative Note ClinicalDocument/templateId example

<!-- indicates conformance with US Realm Clinical Document Header template -->

<templateId root="2.16.840.1.113883.10.20.22.1.1"/>

<!-- conforms to the Operative Note requirements -->

<templateId root='2.16.840.1.113883.10.20.22.1.7'/>

#### ClinicalDocument/code

CDA R2 states that LOINC is the preferred vocabulary for document type specification. The [Surgical Operation Note LOINC Document Codes](#T_OpNoteLOINCDocCodes) table shows the LOINC codes suitable for Discharge Summary, as of publication of this implementation guide.This is a dynamic value set meaning that these codes may be added to or deprecated by LOINC.

Some of the LOINC codes in the [Surgical Operation Note LOINC Document Codes](#T_OpNoteLOINCDocCodes) table are pre-coordinated with the practice setting or the training or professional level of the author. Use of pre-coordinated codes is not recommended because of potential conflict with other information in the header. When these codes are used, any coded values describing the author or performer of the service act or the practice setting must be consistent with the LOINCdocument type.

1. **SHALL** contain exactly one [1..1] **code/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.11.20.1.1 SurgicalOperationNoteDocumentTypeCode **DYNAMIC** (CONF:8484).

Table 25: Surgical Operation Note LOINC Document Codes

|  |  |  |  |
| --- | --- | --- | --- |
| Value Set: 2.16.840.1.113883.11.20.1.1  Code System: LOINC 2.16.840.1.113883.6.1 | | | |
| LOINC Code | Type of Service ‘Component’ | Setting ‘System’ | Specialty/Training/Professional Level ‘Method\_Type’ |
| Preferred Code | | | |
| 11504-8 | Surgical operation note | {Setting} | {Provider} |
| Additional Codes | | | |
| 34137-0 | Surgical operation note | Outpatient | {Provider} |
| 28583-3 | Surgical operation note | {Setting} | Dentistry |
| 28624-5 | Surgical operation note | {Setting} | Podiatry |
| 28573-4 | Surgical operation note | {Setting} | Physician |
| 34877-1 | Surgical operation note | {Setting} | Urology |
| 34874-8 | Surgical operation note | {Setting} | Surgery |
| 34870-6 | Surgical operation note | {Setting} | Plastic surgery |
| 34868-0 | Surgical operation note | {Setting} | Orthopedics |
| 34818-5 | Surgical operation note | {Setting} | Otorhinolaryngology |
| The following code should not be used; it is a duplicate | | | |
| 34871-4 | Surgical operation note | {Setting} | Podiatry |

Figure 39: Operative Note ClinicalDocument/code example

<code codeSystem="2.16.840.1.113883.6.1"

codeSystemName="LOINC"code="11504-8"displayName="SURGICAL OPERATION NOTE"/>

#### Consent

Consents associated with a procedure can be recorded in the header or body of an Operative Note.

The Consent/code records the type of consent (e.g., a consent to perform the related ServiceEvent or a consent to release informaiton to a third party). Consents referenced in the header have been finalized (Consent/statusCode must equal "Completed") and should be on file.

1. A consent, if present, SHALL be represented as ClinicalDocument/authorization/consent. (CONF:8485).

Figure 40: Operative Note consent example

<authorization typeCode="AUTH">

<consent classCode="CONS" moodCode="EVN">

<id extension="99370125" root="2.16.840.1.113883.19"/>

<code codeSystem=" 2.16.840.1.113883.6.1" codeSystemName="LOINC" code="

CONSP-X" displayName="Consent for Surgical Procedure"/>

<statusCode code="completed"/>

</consent>

</authorization

#### documentationOf

A serviceEvent represents the main act, such as a colonoscopy or an appendectomy, being documented. A serviceEvent can further specialize the act inherent in the ClinicalDocument/code, such as where the ClinicalDocument/code is simply "Surgical Operation Note" and the procedure is "Appendectomy." ServiceEvent is required in the Operative Note and it must be equivalent to or further specialize the value inherent in the ClinicalDocument/code; it shall not conflict with the value inherent in the ClinicalDocument/code, as such a conflict would create ambiguity. ServiceEvent/effectiveTime can be used to indicate the time the actual event (as opposed to the encounter surrounding the event) took place.

If the date and the duration of the procedure is known, serviceEvent/effectiveTime/low is used with a width element; no high element is used. However, if only the date is known, the date is placed in both the low and high elements.

1. **SHALL** contain at least one [1..\*] **documentationOf** (CONF:8486).
   1. Such documentationOfs **SHALL** contain exactly one [1..1] **serviceEvent** (CONF:8493).
      1. The value of Clinical Document /documentationOf/serviceEvent/code SHALL be from ICD9 CM Procedures (codeSystem 2.16.840.1.113883.6.104), CPT-4 (codeSystem 2.16.840.1.113883.6.12), or values descending from 71388002 (Procedure) from the SNOMED-CT (codeSystem 2.16.840.1.113883.6.96) ValueSet 2.16.840.1.113883.3.88.12.80.28 DYNAMIC. (CONF:8487).
      2. This serviceEvent **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:8494).
         1. The ServiceEvent/effectiveTime **SHALL** be present with effectiveTime/low and **SHALL** include effectiveTime/high if a width is not present. The ServiceEvent/effectiveTime **SHALL** be accurate to the day, and MAY be accurate to the second. If only the date and the length of the procedure are known a width element **SHALL** be present and the ServiceEvent/effectiveTime/high **SHALL** not be present. (CONF:8488).

The performer represents clinicians who actually and principally carry out the serviceEvent. Typically, these are clinicians who have surgical privileges in their institutions such as Surgeons, Obstetrician/Gynecologists, and Family Practice Physicians. The performer may also be Nonphysician Providers (NPP) who have surgical privileges. There may be more than one primary performer in the case of complicated surgeries. There are occasionally co-surgeons. Usually they will be billing separately and will each dictate their own notes. An example may be spinal surgery , where a general surgeon and an orthopaedic surgeon both are present and billing off the same Current Procedural Terminology (CPT) codes. Typically two Operative Notes are generated; however, each will list the other as a co-surgeon.

* + 1. This serviceEvent **SHALL** contain exactly one [1..1] **performer** (CONF:8489) such that it
       1. **SHALL** contain exactly one [1..1] **@typeCode**="PPRF" Primary performer (CodeSystem: 2.16.840.1.113883.5.90 HL7ParticipationType) (CONF:8495).
       2. **SHALL** contain exactly one [1..1] **code** (CONF:8490).
          1. This code **SHOULD** contain **@code**, which **SHOULD** be selected from ValueSet 2.16.840.1.113883.3.88.12.3221.4 Provider Type Value Set **DYNAMIC** (CONF:8491).
  1. Any assistants **SHALL** be identified and **SHALL** be identified as secondary performers (SPRF). (CONF:8512).

Table 26: Provider Type Value Set

| Value Set: Provider Type 2.16.840.1.113883.3.88.12.3221.4 | | |
| --- | --- | --- |
| Code System(s): | Health Care Provider Taxonomy 2.16.840.1.113883.6.101 | |
| Description: | The Provider type vocabulary classifies providers according to the type of license or accreditation they hold or the service they provide.  <http://www.nucc.org/index.php?option=com_content&task=view&id=14&Itemid=40> | |
|  | Example of Codes for reference | |
| Code | Code System | Print Name |
| 207L00000X | Health Care Provider Taxonomy | Anesthesiology |
| 207X00000X | Health Care Provider Taxonomy | Orthopaedic Surgery |
| 207VG0400X | Health Care Provider Taxonomy | Gynecology |
| … |  |  |

Figure 41: Operative Note serviceEvent example

<serviceEvent classCode="PROC">

<code code="801460020" codeSystem="2.16.840.1.113883.6.96"

codeSystemName="SNOMED CT" displayName="Laparoscopic Appendectomy"/>

<effectiveTime value="20050329"/>

...

</serviceEvent>

Figure 42: Operative Note performer example

<performer typeCode="PPRF">

<assignedEntity>

<id extension="1" root="2.16.840.1.113883.19"/>

<code code=" 2086S0120X" codeSystem="2.16.840.1.113883.11.19465"

codeSystemName="NUCC" displayName="Pediatric Surgeon"/>

<addr>

<streetAddressLine>1013 Healthcare Drive</streetAddressLine>

<city>Ann Arbor</city>

<state>MI</state>

<postalCode>99999</postalCode>

<country>USA</country>

</addr>

<telecom value="tel:(555)555-1013"/>

<assignedPerson>

<name>

<prefix>Dr.</prefix>

<given>Carl</given>

<family>Cutter</family>

</name>

</assignedPerson>

</assignedEntity>

</performer>

### Operative Note Body Constraints

The Operative Note supports both narrative sections and sections requiring code clinical statements. The required and optional sections are listed in the [Document Types and Required/Optional Sections](#T_DocTypesAndReqOptSections) table.

Procedure Note

[ClinicalDocument: templateId 2.16.840.1.113883.10.20.22.1.6(open)]

Procedure Note is a broad term that encompasses many specific types of non-operative procedures including interventional cardiology, interventional radiology, gastrointestinal endoscopy, osteopathic manipulation, and many other specialty fields. Procedure Notes are differentiated from Operative Notes in that the procedures documented do not involve incision or excision as the primary act.

The Procedure Note is created immediately following a non-operative procedure and records the indications for the procedure and, when applicable, post-procedure diagnosis, pertinent events of the procedure, and the patient’s tolerance of the procedure. The document should be sufficiently detailed to justify the procedure, describe the course of the procedure, and provide continuity of care.

### Procedure Note Header Constraints

The Procedure Note must conform to the US Realm Clinical Document Header. The following sections include additional header constraints for conformant Procedure Notes

1. Conforms to Consolidated US Realm Header Template (templateId: 2.16.840.1.113883.10.20.22.1.1).

#### ClinicalDocument/templateId

Conformant documents must carry the document-level templateId asserting conformance with specific constraints of a Procedure Note as well as the templateId for the US Realm Clinical Document Header template.

1. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.1.6" (CONF:8496).

Figure 43: Procedure Note ClinicalDocument/templateId category I example

<!-- indicates conformance with US Realm Clinical Document Header template -->

<templateId root="2.16.840.1.113883.10.20.22.1.1"/>

<templateId root= "2.16.840.1.113883.10.20.22.1.6"/>

<!-- conforms to the Procedure Note constraints -->

#### ClinicalDocument/code

The [LOINC Codes for Procedure Note Documents](#T_PNLOINCDocCodes) table lists the preferred code and pre-coordinated LOINC codes that have the scale DOC (document) and a ‘component’ referring to a non-operative procedure, whether or not the text string "Procedure" is present. Although these pre-coordinated LOINC codes are available for use, we recommend the preferred code (28570-0 Procedure Note) with specialization further defined in ClinicalDocument/documentationOf/serviceEvent/code. When these pre-coordinated codes are used, any coded values describing the author or performer of the service act or the practice setting must be consistent with the LOINC document type.

CDA requires a code element that specifies the type of the clinical document.

1. **SHOULD** contain exactly one [1..1] **code/@code**="28570-0" Procedure Note (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:8497).
   1. This code/@code MAY contain exactly one [1..1] code/@code, which MAY be selected from ValueSet 2.16.840.1.113883.11.20.6.1 ProcedureNoteDocumentTypeCodes DYNAMIC (CONF:8498).

Table 27: Procedure Note LOINC Document Type Codes

|  |  |  |  |
| --- | --- | --- | --- |
| Value Set: ProcedureNoteDocumentTypeCodes 2.16.840.1.113883.11.20.6.1  Code System: LOINC 2.16.840.1.113883.6.1 | | | |
| LOINCCode | Type of Service ‘Component’ | Setting ‘System’ | Specialty/Training/Professional Level ‘Method\_Type’ |
| **Preferred Code** | | | |
| 28570-0 | Procedure note | {Setting} | {Provider} |
| Additional Codes | | | |
| 11505-5 | Procedure note | {Setting} | Physician |
| 18744-3 | Study report | Respiratory system | Bronchoscopy |
| 18745-0 | Study report | Heart | Cardiac catheterization |
| 18746-8 | Study report | Lower GI tract | Colonoscopy |
| 18751-8 | Study report | Upper GI tract | Endoscopy |
| 18753-4 | Study report | Lower GI tract | Flexible sigmoidoscopy |
| 18836-7 | Procedure | Cardiac stress study | \* |
| 28577-5 | Procedure note | {Setting} | Dentistry |
| 28625-2 | Procedure note | {Setting} | Podiatry |
| 29757-2 | Study report | Cvx/Vag | Colposcopy |
| 33721-2 | Bone marrow biopsy report | Bone mar |  |
| 34121-4 | Interventional procedure note | {Setting} |  |
| 34896-1 | Interventional procedure note | {Setting} | Cardiology |
| 34899-5 | Interventional procedure note | {Setting} | Gastroenterology |
| 47048-4 | Diagnostic interventional study report | {Setting} | Interventional radiology |
| 48807-2 | Bone marrow aspiration report | Bone mar |  |

Figure 44: Procedure Note ClinicalDocument/code example

<code codeSystem="2.16.840.1.113883.6.1"

codeSystemName="LOINC" code="28570-0" displayName="PROCEDURE NOTE"/>

#### componentOf

1. **SHOULD** contain exactly one [1..1] **componentOf/encompassingEncounter** (CONF:8499).
   1. This componentOf/encompassingEncounter **SHALL** contain exactly one [1..1] **code** (CONF:8501).
   2. This componentOf/encompassingEncounter **SHALL** contain at least one [1..\*] **location/healthCareFacility/id** (CONF:8500).
   3. This componentOf/encompassingEncounter **MAY** contain exactly one [1..1] **encounterParticipant** (CONF:8502) such that it
      1. **SHALL** contain exactly one [1..1] **@typeCode**="REF" Referrer (CodeSystem: 2.16.840.1.113883.5.90 HL7ParticipationType) (CONF:8503).

#### Participant

The [Participant Scenarios](#T_ParticipantScenarios) table shows a number of scenarios and the values for various participants.

1. **MAY** contain at least one [1..\*] **participant** (CONF:8504) such that it
   1. **SHALL** contain exactly one [1..1] **@typeCode**="IND" Individual (CodeSystem: 2.16.840.1.113883.5.90 HL7ParticipationType) (CONF:8505).
   2. **SHALL** contain exactly one [1..1] **functionCode/@code**="PCP" Primary Care Physician (CodeSystem: 2.16.840.1.113883.5.90 HL7ParticipationType) (CONF:8506).
   3. **SHALL** contain exactly one [1..1] **associatedEntity/@classCode**="PROV" Provider (CodeSystem: 2.16.840.1.113883.5.90 HL7ParticipationType) (CONF:8507).
      1. This associatedEntity/@classCode **SHALL** contain exactly one [1..1] **associatedPerson** (CONF:8508).

Table 28: Participant Scenario

| Scenario | Author | Custo-dian | Data Enterer | Encom-passing Encounter/ Encounter Participant | Legal Authen-ticator | Parti-cipant | Service Event/ Performer |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Colonoscopy Participant Scenario:** A surgeon refers a patient to an endoscopist. A colonoscopy is performed at an outpatient surgery center. The endoscopist inputs information into an EHR. The outpatient surgery center EHR generates a Procedure Note to send to the Hospital EHR. | | | | | | | |
| Endo-scopic CDA Procedure Note | Endo-scopist | Out-patient surgery center | None | Surgeon [REF (referrer)] | Endo-scopist | None | Endoscopist |
| **Office Removal of Wart Participation Scenario:** A wart is removed during an office visit. The PCP dictates the procedure into the local transcription system. The transcription system generates a CDA Procedure Note to the EHR. | | | | | | | |
| CDA Procedure Note | PCP | PCP office | Transcrip-tionist | None | PCP | None | PCP |
| **Dental Procedure Participation Scenario:** Dentist extracts a tooth after the patient has a cleaning by the hygenist. He enters the information into his Dental EHR. | | | | | | | |
| Procedure input to EHR | Dentist | Dentist office | Varies | None | Dentist | None | Dentist  Hygenist |
| **Transjugular Intrahepatic Portosystemic Shunt (TIPS) Procedure (Interventional Radiology) Participant Scenario:** At a university hospital, a TIPS procedure is performed by the interventional radiology fellow, with the help of an interventional radiology nurse, under the supervision of an attending interventional radiologist. The radiology technician enters the data into the EMR. The patient was referred to the university hospital by his oncologist. The patient is insured by Cigna. | | | | | | | |
| Procedure Note is input in EHR | Interven-tional radiology fellow | Good Health Hospital | Interven-tional radiology technician | REF (referrer) Oncologist | Attending interven-tional radiolo-gist | Cigna | Interven-tional radiology fellow  Nurse  Attending interven-tional radiologist |
| **Lumbar Puncture (spinal tap) Procedure Participant Scenario:** At a university hospital, a lumbar puncture is performed by a medical student, with the help of an intern, under the supervisory authority of an attending neurologist. The student performs the procedure and dictates the note. The note is signed by the intern and attending. The patient has a family doctor that is not participating in the procedure, did not refer the patient, and does not have privledges at the providing organization but is recorded in the note. | | | | | | | |
| Procedure Note is dictated by the medical student | Medical student | Good Health Hospital | Transcrip-tionist | None | Neurology attending  (Intern is authen-ticator) | Family doctor | Medical student  Intern |

#### Consent

Both the header and body may record information about the patient’s consent.

The type of consent (e.g., a consent to perform the related serviceEvent or a consent to release the information to a third party) is conveyed in consent/code. Consents referenced in the header have been finalized (consent/statusCode must equal Completed) and should be on file. The following conformance statement does not represent an additional constraint over base CDA; it calls out CDA’s construct for handling consent as consents are usually required prior to a procedure.

1. A consent, if present, **SHALL** be represented as ClinicalDocument/authorization/consent. (CONF:8509).

Figure 45: Procedure Note consent example

<authorization typeCode="AUTH">

<consent classCode="CONS" moodCode="EVN">

<id root="629deb70-5306-11df-9879-0800200c9a66" />

<code codeSystem=" 2.16.840.1.113883.6.1" codeSystemName="LOINC"

code="CONSP-X" displayName="Consent for Procedure"/>

<statusCode code="completed"/>

</consent>

</authorization

#### ServiceEvent

A serviceEvent is required in the Procedure Note to represent the main act, such as a colonoscopy or a cardiac stress study, being documented. It must be equivalent to or further specialize the value inherent in the ClinicalDocument/@code (such as where the ClinicalDocument/@code is simply "Procedure Note" and the procedure is "colonoscopy"), and it shall not conflict with the value inherent in the ClinicalDocument/@code, as such a conflict would create ambiguity. A serviceEvent/effectiveTime element indicates the time the actual event (as opposed to the encounter surrounding the event) took place.

ServiceEvent/effectiveTime may be represented two different ways in the Procedure Note. For accuracy to the second, the best method is effectiveTime/low together with effectiveTime/high. If a more general time, such as minutes or hours, is acceptable OR if the duration is unknown, an effectiveTime/low with a width element may be used. If the duration is unknown, the appropriate HL7 null value such as "NI" or "NA" must be used for the width element.

1. **SHALL** contain at least one [1..\*] **documentationOf/serviceEvent** (CONF:8510) such that it
   1. The value for serviceEvent/code SHOULD be selected from code system 2.16.840.1.113883.6.96 SNOMED CT and MAY be selected from a localized procedure coding system for a given country such as 2.16.840.1.113883.6.104 ICD9 CM Procedures or 2.16.840.1.113883.6.12 CPT-4 in the U.S. (CONF:8511).
   2. The serviceEvent/effectiveTime SHALL be present with effectiveTime/low and SHALL include effectiveTime/high if effectiveTime/width is not present. The serviceEvent/effectiveTime SHALL be accurate to the day, and MAY be accurate to the second. (CONF:8513).
      1. If the date and only the general length of the procedure are known, the serviceEvent/effectiveTime/low SHALL be present with an effectiveTime/width element. The serviceEvent/effectiveTime/low SHALL be accurate to the day, and MAY be accurate to the second. (CONF:8514).
      2. If only the date is known and the duration of the procedure is unknown, the serviceEvent/effectiveTime/width element SHALL contain the appropriate HL7 null value. (CONF:8515).

The performer participant represents clinicians who actually and principally carry out the serviceEvent. Typically, these are clinicians who have the appropriate privileges in their institutions such as gastroenterologists, interventional radiologists, and family practice physicians. Performers may also be non-physician providers (NPPs) who have other significant roles in the procedure such as a radiology technician, dental assistant, or nurse.

* 1. **SHALL** contain exactly one [1..1] **performer** (CONF:8520) such that it
     1. **SHALL** contain exactly one [1..1] **@typeCode**="PPRF" Primary Performer (CodeSystem: 2.16.840.1.113883.5.90 HL7ParticipationType) (CONF:8521).
     2. **SHOULD** contain exactly one [1..1] **code** (CONF:8522).
        1. This code **SHOULD** contain **@code**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.1066 Healthcare Provider Taxonomy (NUCC - HIPAA) **DYNAMIC** (CONF:8523).
  2. Any assistants SHALL be identified and SHALL be identified as secondary performers (SPRF). (CONF:8524).

Figure 46: Procedure Note serviceEvent example

<serviceEvent classCode="PROC">

<code code="118155006" codeSystem="2.16.840.1.113883.6.96"

codeSystemName="SNOMED CT"

displayName="Gastrointestinal tract endoscopy"/>

<effectiveTime>

<low value=" 201003292240" />

<width value="15" unit="m"/>

</effectiveTime>

...

</serviceEvent>

Figure 47: Procedure Note serviceEvent example with null value in width element

<serviceEvent classCode="PROC">

<code code="118155006" codeSystem="2.16.840.1.113883.6.96"

codeSystemName="SNOMED CT"

displayName="Gastrointestinal tract endoscopy"/>

<effectiveTime>

<low value="201003292240" />

<width nullFlavor="NI"/>

</effectiveTime>

...

</serviceEvent>

Figure 48: Procedure Note performer example

<performer typeCode="PPRF">

<assignedEntity>

<id extension="IO00017" root="2.16.840.1.113883.19.5" />

<code code="207RG0100X"

codeSystem="2.16.840.1.113883.6.96"

codeSystemName="NUCC"

displayName="Gastroenterologist" />

<addr>

<streetAddressLine>1001 Hospital Lane</streetAddressLine>

<city>Ann Arbor</city>

<state>MI</state>

<postalCode>99999</postalCode>

<country>USA</country>

</addr>

<telecom value="tel:(999)555-1212" />

<assignedPerson>

<name>

<prefix>Dr.</prefix>

<given>Tony</given>

<family>Tum</family>

</name>

</assignedEntity>

</performer>

### Procedure Note Body Constraints

The Procedure Note supports both narrative sections and sections requiring code clinical statements. The required and optional sections are listed in the [Document Types and Required/Optional Sections](#T_DocTypesAndReqOptSections) table.

Progress Note

[ClinicalDocument: templateId 2.16.840.1.113883.10.20.22.1.9(open)]

A Progress Note documents a patient’s clinical status during a hospitalization or outpatient visit; thus, it is associated with an encounter.

Taber’s[[12]](#footnote-12) medical dictionary defines a Progress Note as “An ongoing record of a patient's illness and treatment. Physicians, nurses, consultants, and therapists record their notes concerning the progress or lack of progress made by the patient between the time of the previous note and the most recent note.”

Mosby’s[[13]](#footnote-13) medical dictionary defines a Progress Note as “Notes made by a nurse, physician, social worker, physical therapist, and other health care professionals that describe the patient's condition and the treatment given or planned.”

A Progress Note is not a revaluation note. A Progress Note is not intended to be a Progress Report for Medicare. Medicare B Section 1833(e) defines the requirements of a Medicare Progress Report.

### Progress Note Header Constraints

The Progress Note must conform to the US Realm Clinical Document Header. The following sections include additional header constraints for conformant Progress Notes.

1. Conforms to US Realm Clinical Document Header Template (templateId: 2.16.840.1.113883.10.20.22.1.1).

#### ClinicalDocument/templateId

Conformant documents must carry the document-level templateId asserting conformance with specific constraints of a Progress Note as well as the templateId for the US Realm Clinical Document Header template.

The following asserts conformance to a Progress Note.

1. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.1.9" (CONF:7588).

Figure 49: Progress Note ClinicalDocument/templateId example

<!-- indicates conformance with US Realm Clinical Document Header template -->

<templateId root="2.16.840.1.113883.10.20.22.1.1"/>

<!-- conforms to the Progress Note -->

<templateId root="2.16.840.1.113883.10.20.22.1.9"/>

#### ClinicalDocument/code

CDA R2 states that LOINC must be used for the document type code unless no appropriate code is available, in which case an alternative vocabulary can be used. (This is the coded with extensions, CWE, coding strength.) The Progress Note recommends use of a single document type code, 11506-3, “Subsequent evaluation note”, using post-coordination for author or performer, setting, or specialty .

The [Progress Note LOINC Document Codes](#T_DSLOINCDocCodes) table shows the preferred LOINC code and the full list of pre-coordinated codes available within LOINC for Progress Notes, as of publication of this implementation guide.This is a dynamic value set meaning that these codes may be added to or deprecated by LOINC.

The table lists all codes that have the scale DOC (document) and a ‘component’ referring to “subsequent evaluation notes”. When these pre-coordinated codes are used, any coded values describing the author or performer of the service act or the practice setting must be consistent with the LOINC document type. Note: The LOINC display name is “Subsequent evaluation note” and is equivalent to Progress Note.

1. **SHALL** contain exactly one [1..1] **code/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.11.20.8.1 ProgressNoteDocumentTypeCode **DYNAMIC** (CONF:7589).

Table 29: Progress Note LOINC Document Codes

|  |  |  |  |
| --- | --- | --- | --- |
| Value Set: ProgressNoteDocumentTypeCode 2.16.840.1.113883.11.20.8.1  Code System: LOINC 2.16.840.1.113883.6.1 | | | |
| LOINC Code | Type of Service ‘Component’ | Setting ‘System’ | Specialty/Training/ Professional Level ‘Method\_Type’ |
| **Preferred Code** | | | |
| 11506-3 | Subsequent evaluation note | {Setting} | {Provider} |
| **Additional Codes** | | | |
| 18733-6 | Subsequent evaluation note | {Setting} | Attending physician |
| 18762-5 | Subsequent evaluation note | {Setting} | Chiropractor |
| 28569-2 | Subsequent evaluation note | {Setting} | Consulting physician |
| 28617-9 | Subsequent evaluation note | {Setting} | Dentistry |
| 34900-1 | Subsequent evaluation note | {Setting} | General medicine |
| 34904-3 | Subsequent evaluation note | {Setting} | Mental health |
| 18764-1 | Subsequent evaluation note | {Setting} | Nurse practitioner |
| 28623-7 | Subsequent evaluation note | {Setting} | Nursing |
| 11507-1 | Subsequent evaluation note | {Setting} | Occupational therapy |
| 11508-9 | Subsequent evaluation note | {Setting} | Physical therapy |
| 11509-7 | Subsequent evaluation note | {Setting} | Podiatry |
| 28627-8 | Subsequent evaluation note | {Setting} | Psychiatry |
| 11510-5 | Subsequent evaluation note | {Setting} | Psychology |
| 28656-7 | Subsequent evaluation note | {Setting} | Social service |
| 11512-1 | Subsequent evaluation note | {Setting} | Speech therapy |
| 34126-3 | Subsequent evaluation note | Critical care unit | {Provider} |
| 15507-7 | Subsequent evaluation note | Emergency … | {Provider} |
| 34129-7 | Subsequent evaluation note | Home health | {Provider} |
| 34125-5 | Subsequent evaluation note | Home health care | Case manager |
| 34130-5 | Subsequent evaluation note | Hospital | {Provider} |
| 34131-3 | Subsequent evaluation note | Outpatient | {Provider} |
| 34124-8 | Subsequent evaluation note | Outpatient | Cardiology |
| 34127-1 | Subsequent evaluation note | Outpatient | Dental hygienist |
| 34128-9 | Subsequent evaluation note | Outpatient | Dentistry |
| 34901-9 | Subsequent evaluation note | Outpatient | General medicine |
| 34132-1 | Subsequent evaluation note | Outpatient | Pharmacy |

Figure 50: Progress Note ClinicalDocument/code example

<code codeSystem="2.16.840.1.113883.6.1"

codeSystemName="LOINC" code="11056-3"

displayName="Subsequent evaluation note"/>

<title>Progress Note</title>

#### documentationOf

A documentationOf can contain a serviceEvent to further specialize the act inherent in the ClinicalDocument/code.

In a Progress Note, a serviceEvent can represent the event of writing the Progress Note. The serviceEvent/effectiveTime is the time period the note documents.

1. **SHOULD** contain exactly one [1..1] **documentationOf** (CONF:7603).
   1. This documentationOf **SHALL** contain exactly one [1..1] [**serviceEvent in a CDA Header**](#S_serviceEventInCDAHeader) (templateId:2.16.840.1.113883.10.20.21.3.1) (CONF:7604).

Figure 51: Progress Note serviceEvent example

<documentationOf>

<serviceEvent classCode="PCPR">

<templateId root="2.16.840.1.113883.10.20.21.3.1"/>

<effectiveTime>

<low value="200503291200"/>

<high value="200503291400"/>

</effectiveTime>

...

</serviceEvent>

</documentationOf>

#### componentOf

The Progress Note is always associated with an encounter by the componentOf/encompassingEncounter element in the header.

The effectiveTime element for an encompassingEncounter represents the time or time interval in which the encounter took place. A single encounter may contain multiple Progress Notes; hence the effectiveTime elements for a Progress Note (recorded in serviceEvent) and for an encounter (recorded in encompassingEncounter) represent different time intervals.

All visits take place at a specific location. When available, the location ID is included in the encompassingEncounter/location/healthCareFacility/id element.

1. **SHALL** contain exactly one [1..1] **componentOf** (CONF:7595).
   1. This componentOf **SHALL** contain exactly one [1..1] **encompassingEncounter** (CONF:7596).
      1. This encompassingEncounter **SHALL** contain exactly one [1..1] **id** (CONF:7597).
      2. This encompassingEncounter **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:7598).
         1. This effectiveTime **SHALL** contain exactly one [1..1] **low** (CONF:7599).
      3. This encompassingEncounter **SHALL** contain exactly one [1..1] **location/healthCareFacility/id** (CONF:7611).

Figure 52: Progress Note componentOf example

<componentOf>

<encompassingEncounter>

<id extension="9937012" root="2.16.840.1.113883.19"/>

<effectiveTime>

<low value="20050329"/>

<high value="20050329"/>

</effectiveTime>

<location>

<healthCareFacility>

<id root="2.16.540.1.113883.19.2"/>

</healthCareFacility>

</location>

</encompassingEncounter>

</componentOf>

### Progress Note Body Constraints

The Progress Note supports both narrative sections and sections requiring code clinical statements. The required and optional sections are listed in the [Document Types and Required/Optional Sections](#T_DocTypesAndReqOptSections) table.

Unstructured Document

[ClinicalDocument: templateId 2.16.840.1.113883.10.20.21.1.10(open)]

In many environments much of the patient record is still captured in an unstructured format that is encapsulated within an image file or as unstructured text in an electronic file such as a word processing or Portable Document Format (PDF) document.

There is a need to raise the level of interoperability for these documents to provide full access to the longitudinal patient record across a continuum of care. Until this gap is addressed, image and multi-media files will continue to be a portion of the patient record that remains difficult to access and share with all participants in a patient’s care. The Unstructured Document type addresses this gap by providing consistent guidance on the use of CDA for such documents.

An Unstructured Document (UD) document type can (1) include unstructured content, such as a graphic, directly in a text element with a mediaType attribute, or (2) reference a single document file, such as a word-proccesing document, using a text/reference element.

For guidance on how to handle multiple files, on the selection of media types for this IG, and on the identification of external files, see the subsections which follow the constraints below.

IHE’s XDS-SD (Cross-Transaction Specifications and Content Specifications, Scanned Documents Module) profile addresses a similar, more restricted use case, specifically for scanned documents, and limits content to PDF-A or text. This Unstructured Documents implementation guide is applicable not only for scanned documents in non-PDF formats, but also for clinical documents produced through word processing applications, etc.

For conformance with both specifications, please review the appendix on [XDS-SD and US Realm Clinical Document Header Comparison](#App_XDS_SDandUSRealmHeader) and ensure that your documents at a minimum conform to all the SHALL constraints from either specification[[14]](#footnote-14).

### Unstructured Document Header Constraints

An Unstructured Document must conform to the US Realm Clinical Document Header. The following sections include additional header constraints for conformant Unstructured Documents.

1. Conforms to US Realm Clinical Document Header template (templateId: 2.16.840.1.113883.10.20.21.1.1).

#### ClinicalDocument/templateId

Conformant Unstructured Documents must carry the document-level templateId asserting conformance with this guide.

1. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.21.1.10" Unstructured Document (CONF:7710).

#### recordTarget

The recordTarget element records the patient or patients whose health information is recorded in the Unstructured Documents instance. The following constraint is an addition to those in the US Realm Clinical Document Header.

1. **SHALL** contain exactly one [1..1] **recordTarget/patientRole/id** (CONF:7643).

#### Author

The author represents the person who created the original document.

If the referenced document is a scan, the person who did the scan must be recorded in dataEnterer.

The following constraints are in addition to those in the US Realm Clinical Document Header.

1. **SHALL** contain exactly one [1..1] **author/assignedAuthor** (CONF:7640).
   1. This author/assignedAuthor **SHALL** contain exactly one [1..1] **addr** (CONF:7641).
   2. This author/assignedAuthor **SHALL** contain exactly one [1..1] **telecom** (CONF:7642).

#### Custodian

The following constraints are in addition to those in the US Ream Header.

1. **SHALL** contain exactly one [1..1] **custodian/assignedCustodian/representedCustodianOrganization** (CONF:7645).
   1. This custodian/assignedCustodian/representedCustodianOrganization **SHALL** contain exactly one [1..1] **id** (CONF:7648).
   2. This custodian/assignedCustodian/representedCustodianOrganization **SHALL** contain exactly one [1..1] **name** (CONF:7649).
   3. This custodian/assignedCustodian/representedCustodianOrganization **SHALL** contain exactly one [1..1] **telecom** (CONF:7650).
   4. This custodian/assignedCustodian/representedCustodianOrganization **SHALL** contain exactly one [1..1] **addr** (CONF:7651).

### Unstructured Document Body Constraints

An Unstructured Document must include a nonXMLBody component with a single text element. The text element can reference an external file using a reference element, or include unstructured content directly with a mediaType attribute.

1. **SHALL** contain exactly one [1..1] **component/nonXMLBody** (CONF:7620).
   1. This component/nonXMLBody **SHALL** contain exactly one [1..1] **text** (CONF:7622).
      1. The text element SHALL either contain a reference element with a value attribute, or have a representation attribute with the value of B64, a mediaType attribute, and contain the media content. (CONF:7623).
         1. The value of @mediaType, if present, SHALL be drawn from the value set 2.16.840.1.113883.11.20.7.1 SupportedFileFormats STATIC 20100512. (CONF:7624).

Table 30: Supported File Formats Value Set (Unstructured Documents)

|  |  |
| --- | --- |
| Value Set: SupportedFileFormats 2.16.840.1.113883.11.20.7.1 | |
| Word Processing/Narrative Formats | Code |
| MSWord | application/msword |
| PDF | application/pdf |
| Plain Text | text/plain |
| RTF Text | text/rtf |
| HTML | text/html |
| Graphic Formats | Code |
| GIF Image | image/gif |
| TIF Image | image/tiff |
| JPEG Image | image/jpeg |
| PNG Image | image/png |

Figure 53: nonXMLBody example with embedded content

<component>

<nonXMLBody>

<text mediaType="text/rtf" representation="B64">e1xydGY...</text>

</nonXMLBody>

</component>

Figure 54: nonXMLBody example with referenced content

<component>

<nonXMLBody>

<text>

<reference value="UD\_sample.pdf"/>

</text>

</nonXMLBody>

</component>

#### Multiple Files and File Packaging

If multiple files, such as several scanned files, constitute a single document, options include: use a CDA document type that has a structuredBody, use a multi-page/graphic file type such as PDF, or stitch the separate images into a single image.

For guidance on how to package a CDA Unstructured Document together with an unstructured document it references, see the [MIME Multipart/Related Messages](#App_MIMEMultipartRelatedMessages) appendix.

#### Media Types Supported

The Unstructured Document model does not support all possible file formats and it excludes structured formats such as generic XML. The media types supported are commonly used within a healthcare setting as part of the patient record.

The CDA Data Types specification[[15]](#footnote-15) provides an extensible value set of MIME (Multipurpose Internet Mail Extensions) media types that are supported by base CDA. Exclusions from and extensions to that list are discussed below.

**Media type exclusions.** This guide restricts usage of media types listed in the CDA Data Types specification. In the absence of a use case for a video format as part of the patient record, video formats are not included. However, an unstructured document can link to a video or other file format; for example, a Microsoft Word file can contain a link to a video.

**Media type extensions.** Although the CDA Data Types specification indicates that ‘application/msword’ should not be used, that format is very common in use cases that apply to Unstructured Documents, and this guide allows it. The usage applies only to documents in binary format; it is not appropriate for rich text format (RTF) which has a separate MIME type, or the .docx format, which is not currently recommended for use in an Unstructured Document.

**Local policy.** Some content formats—in particular, tagged-image file format (TIFF)—entail further complexity. While this guide allows TIFF because it is in common use, its variants introduce profound interoperability issues: local implementations would establish policy to ensure appropriate interoperability. Microsoft Word binary formats entail similar issues.

#### Identification of Referenced Files

The example code in this section and in the sample file use simple filenames with relative paths because they are easy to read as examples. However, simple filenames and relative paths can cause problems when files are moved among systems.

The hazard to be avoided can be illustrated as follows: Suppose an Unstructured Document that references a file "ekg.pdf" is transmitted to a receiver who places that Unstructured Document in a directory that already contains an Unstructured Document for another patient, which also references a file "ekg.pdf". Now the patient header information for the transmitted document is associated with the ekg.pdf of the previously-existing document. Thus, the use of relative paths and simple filenames can pose a danger to patient safety.

The alternative of providing an absolute URL (Uniform Resource Locator) will fail if the URL is inaccessible; even within a single organization, machine identifiers may be mapped differently at different locations.

Therefore this guide, while it cannot specify business practices, recommends the use of unique names for referenced files.

One approach to generating a unique name is to construct it from the globally-unique document id (root and extension) concatenated to a locally unique reference for the external file. The following figure illustrates this technique used with a CDA document that has an id root 2.16.840.1.113883.19 and extension 999021.

Figure 55: Unique file reference example

<reference value="ref-2.16.840.1.113883.19-999021-ekg-1.pdf"/>

# Section-Level Templates

This section contains the section-level templates referenced by one or more of the document types of this Consolidated Guide. These templates describe the purpose of each section and the section-level constraints.

Each section-level template contains the following:

* Template metadata (e.g., templateID, etc.)
* Description and explanatory narrative
* LOINC section code
* Section title
* Requirements for a text element
* Entry-level template names and Ids for referenced templates (required and optional)

The table on [Sections and Required/Optional Document Types](#T_SectionAndReqOptDoctypes) summarizes the use and reuse of section-level templates across the document types. Note that the constraints for the entry templates themselves are contained in the [entry-level templates](#_Entry-level_Templates_1) section of this guide.

Table 31: Sections and Required/Optional Document Types

| **Section Name** | **LOINC** | **templateId  Entries Required Entries Optional** | [**CCD**](#Doc_CCD) | **Consultation Note** | **Diagnostic Imaging Report** | **Discharge Summary** | **H&P Note** | **Operative Note** | **Procedure Note** | **Progress Note** | **Unstructured Document** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| [Advance Directives](#S_AdvanceDirectivesSection) | 42348-3 | --  2.16.840.1.113883.10.20.22.2.21 | [O](#S_AdvanceDirectivesSection) | O | – | – | – | – | – | – | \* |
| Addendum | 55107-7 |  | – | – | O | – | – | – | – | – | \* |
| Allergies and Other Adverse Reactions | 48765-2 | 2.16.840.1.113883.10.20.21.2.6.1 2.16.840.1.113883.10.20.21.2.6. | O | R | – | R | R | – | O | O | \* |
| Anesthesia | 59774-0 | — 2.16.840.1.113883.10.20.22.2.25 | – | – | – | – | – | R | O | – | \* |
| Assessment\*\* | 51848-0 | -- 2.16.840.1.113883.10.20.22.2.8 | – | R | – | – | R | – | R | – | \* |
| Assessment and Plan\*\* | 51487-2 | -- 2.16.840.1.113883.10.20.22.2.9 | – | R | – | – | R | – | R | R | \* |
| Chief Complaint\*\*\* | 10154-3 | 1.3.6.1.4.1.19376.1.5.3.1.1.13.2.1 |  | O |  | O | R |  | O |  |  |
| Chief Complaint/ Reason for Visit\*\*\* | 46239-0 | —  2.16.840.1.113883.10.20.22.2.13 | – | O | – | O | R | – | O | – | \* |
| Clinical Presentation | 55108-5 | xx  xx | – | – | O | – | – | – | – | – | \* |
| Complications | 10830-8 | — 2.16.840.1.113883.10.20.22.2.32 | – | – | – | – | – | R | – | – | \* |
| Complications / Adverse Events | 55109-3 | -- 2.16.840.1.113883.10.20.22.2.37 | – | – | O | – | – | – | R | – | \* |
| Conclusions | 55110-1 | xx  xx | – | – | O | – | – | – | – | – | \* |
| Current Imaging Procedure Descriptions | 55111-9 | xx  xx | – | – | O | – | – | – | – | – | \* |
| DICOM Object Catalog | 121181 (DCM) | 2.16.840.1.113883.10.20.6.1.1  -- | – | – | R | – | – | – | – | – | – |
| Discharge Diet | 42344-2 | --  1.3.6.1.4.1.19376.1.5.3.1.3.33 | – | – | – | O | – | – | – | – | \* |
| Disposition | 55102-8 | xx  xx | – | – | – | – | – | O | – | – | \* |
| Document Summary | 55112-7 | xx  xx | – | – | O | – | – | – | – | – | \* |
| Encounters | 46240-8 | --  2.16.840.1.113883.10.20.22.2.22 | O | – | – | – | – | – | – | – | \* |
| Family History | 10157-6 | --  2.16.840.1.113883.10.20.22.2.15 | O | O | – | O | R | – | O | – | \* |
| Findings (Radiology Comparison Study - Observation) | 18782-3 | --  2.16.840.1.113883.10.20.6.1.2 | – | – | R | – | – | – | – | – | \* |
| Functional Status | 47420-5 | --  2.16.840.1.113883.10.20.22.2.14 | O | O | – | O | – | – | – | – | \* |
| General Status | 10210-3 | --  2.16.840.1.113883.10.20.2.5 | – | O | – | – | R | – | – | – |  |
| History of Past Illness (Past Medical History) | 11348-0 | --  2.16.840.1.113883.10.20.22.2.20 | – | O | – | – | R | – | – | – | \* |
| History of Present Illness | 10164-2 | --  1.3.6.1.4.1.19376.1.5.3.1.3.4 | – | R | – | O | R | – | O | – | \* |
| Hospital Course | 8648-8 | --  1.3.6.1.4.1.19376.1.5.3.1.3.5 | – | – | – | R | – | – | – | – | \* |
| Hospital Discharge Diagnosis | 11535-2 | --  2.16.840.1.113883.10.20.22.2.24 | – | – | – | R | – | – | – | – | \* |
| Hospital Discharge Medications | 10183-2 | 2.16.840.1.113883.10.20.22.2.11.1  2.16.840.1.113883.10.20.22.2.11 | – | – | – | R | – | – | – | – | \* |
| Hospital Discharge Physical | 10184-0 | --  1.3.6.1.4.1.19376.1.5.3.1.3.26 | – | – | – | O | – | – | – | – | \* |
| Hospital Discharge Studies Summary | 11493-4 | --  2.16.840.1.113883.10.20.22.2.16 | – | – | – | O | – | – | – | – | \* |
| Immunizations | 11369-6 | 2.16.840.1.113883.10.20.22.2.2.1 2.16.840.1.113883.10.20.22.2.2 | O | O | – | O | O | – | – | – | \* |
| Implants | 55122-6 | — 2.16.840.1.113883.10.20.22.2.33 | – | – | – | – | – | O | – | – | \* |
| Key Images | 55113-5 |  | – | – | O | – | – | – | – | – | \* |
| Medical Equipment | 46264-8 | --  2.16.840.1.113883.10.20.22.2.23 | O | – | – | – | – | – | – | – | \* |
| Medical (General) History | 11329-0 | 2.16.840.1.113883.10.20.22.2.39 | – | – | O | – | – | – | O | – | \* |
| Medications | 10160-0 | 2.16.840.1.113883.10.20.22.2.1.1 2.16.840.1.113883.10.20.22.2.1 | O | R | – | – | R | – | O | O | \* |
| Medications Administered | 29549-3 | --  2.16.840.1.113883.10.20.22.2.38 | – | – | – | – | – | – | O | – | \* |
| Objective | 61149-1 | —  2.16.840.1.113883.10.20.21.2.1 | – | – | – | – | – | – | – | O | \* |
| Operative Note Fluids | 10216-0 | — 2.16.840.1.113883.10.20.7.12 | – | – | – | – | – | O | – | – | \* |
| Operative Note Surgical Procedure | 10223-6 | — 2.16.840.1.113883.10.20.7.14 | – | – | – | – | – | O | – | – | \* |
| Payers | 48768-6 | --  2.16.840.1.113883.10.20.22.2.18 | O | O | – | – | – | – | – | – | \* |
| Physical Exam | 29545-1 | —  2.16.840.1.113883.10.20.22.2.19 | – | R | – | – | R | – | O | O | \* |
| Plan of Care\*\* | 18776-5 | —  2.16.840.1.113883.10.20.22.2.10 | O | R | – | R | R | O | R | – | \* |
| Planned Procedure | 59772-4 | —  2.16.840.1.113883.10.20.22.2.30 | – | – | – | – | – | O | O | – | \* |
| Postoperative Diagnosis | 10218-6 | —  2.16.840.1.113883.10.20.22.2.35 | – | – | – | – | – | R | – | – | \* |
| Postprocedure Diagnosis | 59769-0 | — 2.16.840.1.113883.10.20.22.2.36 | – | – | – | – | – | – | R | – | \* |
| Preoperative Diagnosis | 10219-4 | — 2.16.840.1.113883.10.20.22.2.34 | – | – | – | – | – | R | – | – | \* |
| Prior Imaging Procedure Descriptions | 55114-3 | xx  xx | – | – | O | – | – | – | – | – | \* |
| Problem List | 11450-4 | 2.16.840.1.113883.10.20.22.2.5.1 2.16.840.1.113883.10.20.22.2.5 | O | O | – | O | O | – | – | O | \* |
| Procedure Description | 29554-3 | — 2.16.840.1.113883.10.20.22.2.27 | – | – | – | – | – | – | R | – | \* |
| Procedure Disposition | 59775-7 | -- 2.16.840.1.113883.10.20.18.2.12 | – | – | – | – | – | O | R | – | \* |
| Procedure Estimated Blood Loss | 59770-8 | -- 2.16.840.1.113883.10.20.18.2.9 | – | – | – | – | – | R | O | – | \* |
| Procedure Findings | 59776-5 | — 2.16.840.1.113883.10.20.22.2.28 | – | – | – | – | – | R | O | – | \* |
| Procedure Implants | 59771-6 | — 2.16.840.1.113883.10.20.22.2.40 | – | – | – | – | – | – | O |  | \* |
| Procedure Indications | 59768-2 | — 2.16.840.1.113883.10.20.22.2.29 | – | – | – | – | – | O | R | – | \* |
| Procedure Speciments Removed | 59773-2 | — 2.16.840.1.113883.10.20.22.2.31 | – | – | – | – | – | R | O | – | \* |
| Procedures  List of Surgeries (History of Procedures) | 47519-4 | 2.16.840.1.113883.10.20.22.2.7.1 2.16.840.1.113883.10.20.22.2.7 | O | O | – | O | O | – | O | – | \* |
| Radiology Comparison Study - Observation | 18834-2 | xx  xx | – | – | O | – | – | – | – | – | \* |
| Radiology - Impression | 19005-8 | xx  xx | – | – | O | – | – | – | – | – | \* |
| Radiology Study - Recommendations | 18783-1 | xx  xx | – | – | O | – | – | – | – | – | \* |
| Radiology Reason for Study | 18785-6 | xx  xx | – | – | O | – | – | – | – | – | \* |
| Reason for Referral | 42349-1 | --  1.3.6.1.4.1.19376.1.5.3.1.3.1 | – | R | – | – | – | – | – | – | \* |
| Reason for Visit\*\*\* | 29299-5 | 2.16.840.1.113883.10.20.22.2.12 |  | O |  | O | R |  | O |  |  |
| Requested Imaging Studies Information | 55115-0 | xx  xx | – | – | O | – | – | – | – | – | \* |
| Results | 30954-2 | 2.16.840.1.113883.10.20.22.2.3.1 2.16.840.1.113883.10.20.22.2.3 | O | O | – | – | R | – | – | O | \* |
| Review of Systems | 10187-3 | —  1.3.6.1.4.1.19376.1.5.3.1.3.18 | – | O | – | O | R | – | O | O | \* |
| Social History | 29762-2 | --  2.16.840.1.113883.10.20.22.2.17 | O | O | – | O | R | – | O | – | \* |
| Subjective | 61150-9 | --  2.16.840.1.113883.10.20.21.2.2 | – | – | – | – | – | – | – | O | \* |
| Surgery Description | 29554-3 | -- 2.16.840.1.113883.10.20.22.2.26 | – | – | – | – | – | R | – | – | \* |
| Surgical Drains | 11537-8 | -- 2.16.840.1.113883.10.20.7.13 | – | – | – | – | – | O | – | – | \* |
| Vital Signs | 8716-3 | 2.16.840.1.113883.10.20.22.2.4.1 2.16.840.1.113883.10.20.22.2.4 | O | O | – | O | R | – | – | O | \* |

\* content could be present and is unstructured

\*\* wherever referenced, intent is that either “Assessment and Plan” is present or both “Assessment” and “Plan”. Only these combinations should be used.

\*\*\* wherever referenced, intent is that either “Chief Complaint/Reason for Visit” is present or “Chief Complaint”, and/or “Reason for Visit”. Only these combinations should be used.

## Advance Directives Section 42348-3

[section: templateId 2.16.840.1.113883.10.20.22.2.21(open)]

This section contains data defining the patient’s advance directives and any reference to supporting documentation. The most recent and up-to-date directives are required, if known, and should be listed in as much detail as possible. This section contains data such as the existence of living wills, healthcare proxies, and CPR and resuscitation status. If referenced documents are available, they can be included in the CCD exchange package.

**NOTE:** The descriptions in this section differentiate between “advance directives” and “advance directive documents”. The former are the directions whereas the latter are legal documents containing those directions. Thus, an advance directive might be “no cardiopulmonary resuscitation”, and this directive might be stated in a legal advance directive document.

1. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.2.21" (CONF:7928).
2. **SHALL** contain exactly one [1..1] **code/@code**="42348-3" Advance Directives (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:7929).
3. **SHALL** contain exactly one [1..1] **title** (CONF:7930).
4. **SHALL** contain exactly one [1..1] **text** (CONF:7931).
5. **MAY** contain exactly one [1..1] **entry** (CONF:7957).
   1. **NOTE**: This conformance statement is for reference only. It has not yet been reviewed and consolidated according to the scope and intent of this guide.   
      CONF-XXXX: The Advance Directives section SHOULD contain clinical statements. Clinical statements SHOULD include one or more advance directive observations (templateId 2.16.840.1.113883.10.20.1.17). An advance directive observation MAY contain exactly one advance directive reference (templateId 2.16.840.1.113883.10.20.1.36) to an external advance directive document. (CONF:7958).

## Allergies, Adverse Reactions, Alerts Section 48765-2

This section lists and describes any medication allergies, adverse reactions, idiosyncratic reactions, anaphylaxis/anaphylactoid reactions to food items, and metabolic variations or adverse reactions/allergies to other substances (such as latex, iodine, tape adhesives) used to assure the safety of health care delivery. At a minimum, it should list currently active and any relevant historical allergies and adverse reactions. In general this section should not include environmental allergies, even if severe and directly related to the presenting problem, since they constitute a medical problem; environmental allergies should be listed in the problem list and past medical history.

Optional Entries

[section: templateId 2.16.840.1.113883.10.20.22.2.6(open)]

The following constraints apply to an Allergies, Adverse Reactions, Alerts section in which entries are not required.

1. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.2.6" (CONF:7800).
2. **SHALL** contain exactly one [1..1] **code/@code**="48765-2" Allergies, adverse reactions, alerts (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:7801).
3. **SHALL** contain exactly one [1..1] **title** (CONF:7802).
4. **SHALL** contain exactly one [1..1] **text** (CONF:7803).
5. **SHOULD** contain at least one [1..\*] **entry** (CONF:7804) such that it
   1. **SHALL** contain exactly one [1..1] [**Allergy Problem Act**](#CS_AllergyProblemAct) (templateId:2.16.840.1.113883.10.20.22.4.30) (CONF:7805).

Required Entries

[section: templateId 2.16.840.1.113883.10.20.21.2.6.1(open)]

The following constraints apply to an Allergies, Adverse Reactions, Alerts section in which entries are required.

1. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.2.6.1" (CONF:7527).
2. **SHALL** contain exactly one [1..1] **code/@code/@code**="48765-2" Allergies, adverse reactions, alerts (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:7528).
3. **SHALL** contain exactly one [1..1] **title**="Allergies, Adverse Reactions, Alerts" (CONF:7534).
4. **SHALL** contain exactly one [1..1] **text** (CONF:7530).
5. **SHALL** contain at least one [1..\*] **entry** (CONF:7531) such that it
   1. **SHALL** contain exactly one [1..1] [**Allergy Problem Act**](#CS_AllergyProblemAct) (templateId:2.16.840.1.113883.10.20.22.4.30) (CONF:7532).

Anesthesia Section 59774-0

section: templateId 2.16.840.1.113883.10.20.22.2.25(open)]

The Anesthesia section briefly records the type of anesthesia (e.g., general or local) and may state the actual agent used. This may or may not be a subsection of the Surgery Description section. The full details of anesthesia are usually found in a separate Anesthesia Note.

1. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.2.25" (CONF:8066).
2. **SHALL** contain exactly one [1..1] **code/@code**="59774-0" Anesthesia (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:8067).
3. **SHALL** contain exactly one [1..1] **title** (CONF:8068).
4. **SHALL** contain exactly one [1..1] **text** (CONF:8069).
5. **MAY** contain at least one [1..\*] **entry** (CONF:8092) such that it
   1. **SHALL** contain exactly one [1..1] [**Procedure Activity Procedure**](#CS_ProcedureActivityProcedure) (templateId:2.16.840.1.113883.10.20.22.4.14) (CONF:8093).
6. **MAY** contain at least one [1..\*] **entry** (CONF:8094) such that it
   1. **SHALL** contain exactly one [1..1] [**Medication Activity**](#CS_MedicationActivity) (templateId:2.16.840.1.113883.10.20.22.4.16) (CONF:8095).

Assessment Section 51848-0

[section: templateId 2.16.840.1.113883.10.20.21.2.8(open)]

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

1. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.21.2.8" (CONF:7711).
2. **SHALL** contain exactly one [1..1] **code/@code**="51848-0" Assessments (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:7712).
3. **SHALL** contain exactly one [1..1] **text** (CONF:7713).
4. **MAY** contain at least one [1..\*] **entry** (CONF:7714) such that it
   1. **NOTE:** This conformance statement is for reference only. It has not yet been reviewed and consolidated according to the scope and intent of this guide. CONF-XXXX: The Assessment, Plan, and Assessment and Plan section(s) MAY contain clinical statements. If present, the clinical statements SHALL conform to the CCD Plan of Care Activities template (2.16.840.1.113883.10.20.1.25) (CONF:7719).

Assessment and Plan Section 51487-2

[section: templateId 2.16.840.1.113883.10.20.21.2.9(open)]

The Assessment and Plan sections may be combined or separated to meet local policy requirements.

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

The Plan section contains data that defines pending orders, interventions, encounters, services, and procedures for the patient. It is limited to prospective, unfulfilled, or incomplete orders and requests only. All active, incomplete, or pending orders, appointments, referrals, procedures, services, or any other pending event of clinical significance to the current care of the patient should be listed unless constrained due to privacy issues. The plan may also contain information about ongoing care of the patient and information regarding goals and clinical reminders. Clinical reminders are placed here to provide prompts for disease prevention and management, patient safety, and health-care quality improvements, including widely accepted performance measures. The plan may also indicate that patient education was given or will be provided.

1. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.21.2.9" (CONF:7705).
2. **SHALL** contain exactly one [1..1] **code/@code**="51487-2" Assessment and Plan (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:7706).
3. **SHALL** contain exactly one [1..1] **text** (CONF:7707).
4. **MAY** contain at least one [1..\*] **entry** (CONF:7708) such that it
   1. **NOTE:** This conformance statement is for reference only. It has not yet been reviewed and consolidated according to the scope and intent of this guide. CONF-XXXX: The Assessment, Plan, and Assessment and Plan section(s) MAY contain clinical statements. If present, the clinical statements SHALL conform to the CCD Plan of Care Activities template (2.16.840.1.113883.10.20.1.25) (CONF:7721).

Chief Complaint Section 10154-3

[section: templateId 1.3.6.1.4.1.19376.1.5.3.1.1.13.2.1(open)]

This section records the patient's chief complaint (the patient’s own description).

1. **SHALL** contain exactly one [1..1] **templateId/@root**="1.3.6.1.4.1.19376.1.5.3.1.1.13.2.1" (CONF:7832).
2. **SHALL** contain exactly one [1..1] **code/@code**="10154-3" Chief Complaint (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:7833).
3. **SHALL** contain exactly one [1..1] **title** (CONF:7834).
4. **SHALL** contain exactly one [1..1] **text** (CONF:7835).

Chief Complaint and Reason for Visit Section 46239-0

[section: templateId 2.16.840.1.113883.10.20.22.2.13(open)]

This section records the patient's chief complaint (the patient’s own description) and/or the reason for the patient's visit (the provider’s description of the reason for visit). Local policy determines whether the information is divided into two sections or recorded in one section serving both purposes.

1. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.2.13" (CONF:7840).
2. **SHALL** contain exactly one [1..1] **code/@code**="46239-0" Chief Complaint and Reason for Visit (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:7841).
3. **SHALL** contain exactly one [1..1] **title** (CONF:7842).
4. **SHALL** contain exactly one [1..1] **text** (CONF:7843).

Complications Section 10830-8

[section: templateId 2.16.840.1.113883.10.20.22.2.32(open)]

The Complications section records problems that occurred during surgery. The complications may have been known risks or unanticipated problems. The Complications section may be a subsection of another section such as the Surgery Description section.

1. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.2.32" (CONF:8026).
2. **SHALL** contain exactly one [1..1] **code/@code**="10830-8" Complications (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:8027).
3. **SHALL** contain exactly one [1..1] **title** (CONF:8028).
4. **SHALL** contain exactly one [1..1] **text** (CONF:8029).
5. There SHALL be a statement providing details of the complication(s) or it SHALL explicitly state there were no complications. (CONF:8048).
6. **MAY** contain at least one [1..\*] **entry** (CONF:8049).
   1. Such entries **SHALL** contain exactly one [1..1] [**Condition Entry**](#CD_ConditionEntry) (templateId:2.16.840.1.113883.10.20.22.4.4) (CONF:8050).

Complications / Adverse Events Section 55109-3

[section: templateId 2.16.840.1.113883.10.20.22.2.37(open)]

The Complications section records problems that occurred during the procedure. The complications may have been known risks or unanticipated problems. The Complications section may be a subsection of another section such as the Procedure Description section.

1. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.2.37" (CONF:8174).
2. **SHALL** contain exactly one [1..1] **code/@code**="55109-3" Complications / Adverse Events (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:8175).
3. **SHALL** contain exactly one [1..1] **title** (CONF:8176).
4. **SHALL** contain exactly one [1..1] **text** (CONF:8177).

**NOTE**: This conformance statement is for reference only. It has not yet been reviewed and consolidated according to the scope and intent of this guide.

* 1. There shall be a statement providing details of the complication(s) or it shall explicitly state there were no complications.
  2. The Complications section may contain clinical statements. If present, the clinical statements MAY conform to the CCD Problem observation template (2.16.840.1.113883.10.20.1.28).
  3. The Complications section may contain clinical statements referring to imaging observations. If present, these clinical statements may conform to the PHCR Imaging observation template (2.16.840.1.113883.10.20.15.3.5), DIR Text Observation template (2.16.840.1.113883.10.20.6.2.12), DIR Code Observation template (2.16.840.1.113883.10.20.6.2.13), DIR Quantity Measurement Observation template (2.16.840.1.113883.10.20.6.2.14) or DIR SopInstance Observation template (2.16.840.1.113883.10.20.6.2.8).

DICOM Object Catalog - 121181

[section: templateId 2.16.840.1.113883.10.20.6.1.1(open)]

DICOM Object Catalog lists all referenced objects and their parent Series and Studies, plus other DICOM attributes required for retrieving the objects.

DICOM Object Catalog sections are not intended for viewing and contain empty section text.

1. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.6.1.1" (CONF:8525).
2. A DICOM Object Catalog SHALL be present if the document contains references to DICOM Images. If present, it SHALL be the first section in the document. (CONF:8527).
3. **SHALL** contain exactly one [1..1] **code/@code**="121181" *Dicom Object Catalog* (CodeSystem: 1.2.840.10008.2.16.4 DCM) (CONF:8526).
4. **SHALL NOT** contain [0..0] **title** (CONF:8528).
5. **SHALL NOT** contain [0..0] **text** (CONF:8529).

**NOTE**: This conformance statement is for reference only. It has not yet been reviewed and consolidated according to the scope and intent of this guide.

1. **SHALL** contain at least one [1..\*] Study Act (templateId:2.16.840.1.113883.10.20.6.2.6) (CONF:8530).

Discharge Diet Section 10154-3

[section: templateId 1.3.6.1.4.1.19376.1.5.3.1.3.33(open)]

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] **templateId/@root**="1.3.6.1.4.1.19376.1.5.3.1.1.13.2.1" (CONF:7832).
2. **SHALL** contain exactly one [1..1] **code/@code**="10154-3" Discharge Diet (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:7833).
3. **SHALL** contain exactly one [1..1] **title** (CONF:7834).
4. **SHALL** contain exactly one [1..1] **text** (CONF:7835).

Encounters Section 46240-8

[section: templateId 2.16.840.1.113883.10.20.22.2.22(open)]

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

1. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.2.22" (CONF:7940).
2. **SHALL** contain exactly one [1..1] **code/@code**="46240-8" Encounters (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:7941).
3. **SHALL** contain exactly one [1..1] **title** (CONF:7942).
4. **SHALL** contain exactly one [1..1] **text** (CONF:7943).
5. **SHOULD** contain exactly one [1..1] **entry** (CONF:7951).
   1. **NOTE**: This conformance statement is for reference only. It has not yet been reviewed and consolidated according to the scope and intent of this guide.  
      CONF-XXXX: The Encounters section SHOULD contain clinical statements. Clinical statements SHOULD include one or more encounter activities (templateId 2.16.840.1.113883.10.20.1.21). (CONF:7952).

Family History Section 10157-6

[section: templateId 2.16.840.1.113883.10.20.22.2.15(open)]

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

1. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.2.15" (CONF:7932).
2. **SHALL** contain exactly one [1..1] **code/@code**="10157-6" Family History (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:7933).
3. **SHALL** contain exactly one [1..1] **title** (CONF:7934).
4. **SHALL** contain exactly one [1..1] **text** (CONF:7935).
5. **MAY** contain exactly one [1..1] **entry** (CONF:7955).

**NOTE**: This conformance statement is for reference only. It has not yet been reviewed and consolidated according to the scope and intent of this guide.

* 1. CONF-XXXX: The Advance Directives section **SHOULD** contain clinical statements. Clinical statements **SHOULD** include one or more advance directive observations (templateId 2.16.840.1.113883.10.20.1.17). An advance directive observation **MAY** contain exactly one advance directive reference (templateId 2.16.840.1.113883.10.20.1.36) to an external advance directive document. (CONF:7958).

Findings Section 18782-3

[section: templateId 2.16.840.1.113883.10.20.6.1.2(open)]

The Findings section contains the main narrative body of the report. While not an absolute requirement for transformed DICOM SR reports, it is suggested that Diagnostic Imaging Reports authored in CDA follow Term Info guidelines for the codes in the various observations and procedures recorded in this section.

1. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.6.1.2" (CONF:8531).
2. This section SHOULD contain only the direct observations in the report, with topics such as Reason for Study, History, and Impression placed in separate sections. However, in cases where the source of report content provides a single block of text not separated into these sections, that text SHALL be placed in the Findings section. (CONF:8532).

Functional Status Section 47420-5

[section: templateId 2.16.840.1.113883.10.20.22.2.14(open)]

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

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

Any deviation from normal function that the patient displays and is recorded in the record should be included. Of particular interest are those limitations that would in any way interfere with self care or the medical therapeutic process. In addition, an improvement, any change in or noting that the patient has normal functioning status is also valid for inclusion.

1. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.2.14" (CONF:7920).
2. **SHALL** contain exactly one [1..1] **code/@code**="47420-5" Functional Status (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:7921).
3. **SHALL** contain exactly one [1..1] **title** (CONF:7922).
4. **SHALL** contain exactly one [1..1] **text** (CONF:7923).
5. **SHOULD** contain exactly one [1..1] **entry** (CONF:7961).
   1. **NOTE**: This conformance statement is for reference only. It has not yet been reviewed and consolidated according to the scope and intent of this guide.  
      CONF-XXXX: The Functional Status section **SHOULD** contain clinical statements. Clinical statements **SHOULD** include one or more problem acts (templateId 2.16.840.1.113883.10.20.22.4.3) and/or result organizers (templateId 2.16.840.1.113883.10.20.22.4.1). (CONF:7962).

General Status Section 10210-3

[section: templateId 2.16.840.1.113883.10.20.2.5(open)]

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

1. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.2.5" (CONF:7985).
2. **SHALL** contain exactly one [1..1] **code/@code/@code**="10210-3" General Status (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:7986).
3. **SHALL** contain exactly one [1..1] **title** (CONF:7987).
4. **SHALL** contain exactly one [1..1] **text** (CONF:7988).

History of Past Illness Section 11348-0

[section: templateId 2.16.840.1.113883.10.20.2.9(open)]

This section describes the history related to the patient’s current complaints, problems, or diagnoses. It records the historical details leading up to and pertaining to the patient’s current complaint or reason for seeking medical care.

1. **SHALL** contain exactly one [1..1] **code/@code**="11348-0" History of Past Illness (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:7829).
2. **SHALL** contain exactly one [1..1] **title** (CONF:7830).
3. **SHALL** contain exactly one [1..1] **text** (CONF:7831).
   1. **NOTE**: This conformance statement is for reference only. It has not yet been reviewed and consolidated according to the scope and intent of this guide. IHE requires the Problem Concern Entry.  
      CONF-XXXX: The History of Past Illness section MAY contain clinical statements. (CONF:7868).
4. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.2.9" (CONF:7828).

History of Present Illness Section 11348-0

[section: templateId 1.3.6.1.4.1.19376.1.5.3.1.3.4(open)]

The History of Present Illness section describes the history related to the reason for the procedure. It contains the historical details leading up to and pertaining to the patient’s current complaint or reason for seeking medical care. Because history of present illness can include past surgical history and other procedures, the Procedure History section may be included under the History of Present Illness section or it may stand alone as its own section.

1. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.2.9" (CONF:7828).
2. **SHALL** contain exactly one [1..1] **code/@code**="11348-0" History of Past Illness (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:7829).
3. **SHALL** contain exactly one [1..1] **title** (CONF:7830).
4. **SHALL** contain exactly one [1..1] **text** (CONF:7831).
   1. **NOTE**: This conformance statement is for reference only. It has not yet been reviewed and consolidated according to the scope and intent of this guide. IHE requires the Problem Concern Entry.  
      CONF-XXXX: The History of Past Illness section MAY contain clinical statements. (CONF:7868).

Hopsital Course Section 8648-8

[section: templateId 1.3.6.1.4.1.19376.1.5.3.1.3.5(open)]

The Hospital Course section describes the sequence of events from admission to discharge in a hospital facility.

1. **SHALL** contain exactly one [1..1] **templateId/@root**="1.3.6.1.4.1.19376.1.5.3.1.3.5" (CONF:7852).
2. **SHALL** contain exactly one [1..1] **code/@code**="8648-8" Hospital Course (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:7853).
3. **SHALL** contain exactly one [1..1] **title** (CONF:7854).
4. **SHALL** contain exactly one [1..1] **text** (CONF:7855).

Hospital Discharge Diagnosis Section 48765-2

[section: templateId 2.16.840.1.113883.10.20.22.2.24(open)]

The Discharge Diagnosis section describes the relevant problems or diagnoses that occurred during the hospitalization or that need to be followed after hospitalization. This section includes an optional entry to record patient conditions.

1. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.21.2.6.1" (CONF:7979).
2. **SHALL** contain exactly one [1..1] **code/@code**="48765-2" Allergies, adverse reactions, alerts (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:7980).
3. **SHALL** contain exactly one [1..1] **title** (CONF:7981).
4. **SHALL** contain exactly one [1..1] **text** (CONF:7982).
5. **SHOULD** contain exactly one [1..1] **entry** (CONF:7983).
   1. This entry **SHALL** contain exactly one [1..1] [**Discharge Diagnosis**](#CS_DischargeDiagnosis) (templateId:2.16.840.1.113883.10.20.22.4.33) (CONF:7984).

Hospital Discharge Medications Section (optional entries) 10183-2

[section: templateId 2.16.840.1.113883.10.20.22.2.11(open)]

The Hospital Discharge Medications section defines the medications that the patient is intended to take (or stop) after discharge. At a minimum, the currently active medications should be listed with an entire medication history as an option. The section may also include a patient’s prescription history and indicate the source of the medication list, for example, from a pharmacy system versus from the patient.

1. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.2.11" (CONF:7816).
2. **SHALL** contain exactly one [1..1] **code/@code**="10183-2" Hospital Discharge Medications (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:7817).
3. **SHALL** contain exactly one [1..1] **title** (CONF:7818).
4. **SHALL** contain exactly one [1..1] **text** (CONF:7819).
5. **SHOULD** contain at least one [1..\*] **entry** (CONF:7820) such that it
   1. **SHALL** contain exactly one [1..1] **Discharge medication** (templateId:2.16.840.1.113883.10.20.22.4.35) (CONF:7883).

Hospital Discharge Physical Section 10184-0

[section: templateId1.3.6.1.4.1.19376.1.5.3.1.3.26(open)]

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

1. **SHALL** contain exactly one [1..1] **templateId/@root**="1.3.6.1.4.1.19376.1.5.3.1.3.26" (CONF:7971).
2. **SHALL** contain exactly one [1..1] **code/@code**="10184-0" Hospital Discharge Physical (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:7972).
3. **SHALL** contain exactly one [1..1] **title** (CONF:7973).
4. **SHALL** contain exactly one [1..1] **text** (CONF:7974).

Hospital Discharge Studies Summary Section 11493-4

[section: templateId 2.16.840.1.113883.10.20.22.2.16(open)]

This section records the results of observations generated by laboratories, imaging procedures, and other procedures. The scope includes hematology, chemistry, serology, virology, toxicology, microbiology, plain x-ray, ultrasound, CT, MRI, angiography, echocardiography, nuclear medicine, pathology, and procedure observations. This section often includes notable results such as abnormal values or relevant trends, and could record all results for the period of time being documented.

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

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

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

Note that there are discrepancies between CCD and the lab domain model, such as the effectiveTime in specimen collection.

1. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.2.16" (CONF:7910).
2. **SHALL** contain exactly one [1..1] **code/@code**="11493-4" Hospital Discharge Studies Summary (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:7911).
3. **SHALL** contain exactly one [1..1] **title** (CONF:7912).
4. **SHALL** contain exactly one [1..1] **text** (CONF:7913).

Immunizations Section 11369-6

[section: templateId 2.16.840.1.113883.10.20.22.2.2(open)]

The Immunizations section defines a patient’s immunization status for the context and use case of the document type. The section should include current immunization status, and may contain the entire immunization history.

1. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.2.2" (CONF:7965).
2. **SHALL** contain exactly one [1..1] **code/@code**="11369-6" Immunizations (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:7966).
3. **SHALL** contain exactly one [1..1] **title** (CONF:7967).
4. **SHALL** contain exactly one [1..1] **text** (CONF:7968).
5. **SHOULD** contain exactly one [1..1] **entry** (CONF:7969).
   1. **NOTE**: This conformance statement is for reference only. It has not yet been reviewed and consolidated according to the scope and intent of this guide.  
      CONF-XXXX: The Immunizations section **SHOULD** contain clinical statements. Clinical statements **SHOULD** include one or more medication activities (templateId 2.16.840.1.113883.10.20.22.4.16) and/or supply activities (templateId 2.16.840.1.113883.10.20.22.4.17). (CONF:7970).

## Implants Section 55122-6

[section: templateId 2.16.840.1.113883.10.20.22.2.33(open)]

The Implants section may be used to record implants placed during a surgical procedure.

1. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.2.33" (CONF:8042).
2. **SHALL** contain exactly one [1..1] **code/@code**="55122-6" Implants (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:8043).
3. **SHALL** contain exactly one [1..1] **title** (CONF:8044).
4. **SHALL** contain exactly one [1..1] **text** (CONF:8045).

**NOTE**: This conformance statement is for reference only. It has not yet been reviewed and consolidated according to the scope and intent of this guide.

* 1. If the Implants section is present, there shall be a statement providing details of the implants placed or shall explicitly state there were no implants placed.
  2. The Implants section may contain clinical statements. If present, the clinical statements shall include one or more supply activities (CCD templateId 2.16.840.1.113883.10.20.1.34), may include product instance (CCD templateId 2.16.840.1.113883.10.20.1.52) and may include one or more medication activities (CCD templateId 2.16.840.1.113883.10.20.1.24).

Medical Equipment Section 46264-8

[section: templateId 2.16.840.1.113883.10.20.22.2.23(open)]

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

1. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.2.23" (CONF:7944).
2. **SHALL** contain exactly one [1..1] **code/@code**="46264-8" Medical Equipment (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:7945).
3. **SHALL** contain exactly one [1..1] **title** (CONF:7946).
4. **SHALL** contain exactly one [1..1] **text** (CONF:7947).
5. **SHOULD** contain exactly one [1..1] **entry** (CONF:7948).
   1. **NOTE**: This conformance statement is for reference only. It has not yet been reviewed and consolidated according to the scope and intent of this guide.   
      CONF-XXXX: The Medical Equipment section **SHOULD** contain clinical statements. Clinical statements **SHOULD** include one or more supply activities (templateId 2.16.840.1.113883.10.20.22.4.17) and MAY include one or more medication activities (templateId 2.16.840.1.113883.10.20.22.4.16). **NOTE**: This conformance statement is for reference only. It has not yet been reviewed and consolidated according to the scope and intent of this guide. (CONF:7950).

Medical (General) History Section 11329-0

[section: templateId 2.16.840.1.113883.10.20.22.2.39(open)]

The Medical History section describes all aspects of the medical history of the patient even if not pertinent to the current procedure, and may include chief complaint, past medical history, social history, family history, surgical or procedure history, medication history, and other history information. The history may be limited to information pertinent to the current procedure or may be more comprehensive. The history may be reported as a collection of random clinical statements or it may be reported categorically. Categorical report formats may be divided into multiple subsections including Past Medical History, Social History

1. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.2.39" (CONF:8160).
2. **SHALL** contain exactly one [1..1] **code/@code**="11329-0" Medical (General) History (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:8161).
3. **SHALL** contain exactly one [1..1] **title** (CONF:8162).
4. **SHALL** contain exactly one [1..1] **text** (CONF:8163).

**NOTE**: This conformance statement is for reference only. It has not yet been reviewed and consolidated according to the scope and intent of this guide.

* 1. If the Medication History section is NOT present, there may be a statement in the Medical History section providing details of historical medications taken by the patient before the procedure including medications in preparation for the procedure such as pre-procedure antibiotics, body system preps, and modifications to anticoagulant use for the procedure.
  2. The Medical History section may contain clinical statements. If present, the clinical statements may conform to the CCD Problem observation template (2.16.840.1.113883.10.20.1.28) and the CCD Problem status observation template (2.16.840.1.113883.10.20.1.50) and the CCD Problem healthstatus observation template (2.16.840.1.113883.10.20.1.51).
  3. The Medical History section may contain clinical statements referring to imaging observations. If present, these clinical statements may conform to the PHCR Imaging observation template (2.16.840.1.113883.10.20.15.3.5), DIR Text Observation template (2.16.840.1.113883.10.20.6.2.12), DIR Code Observation template (2.16.840.1.113883.10.20.6.2.13), DIR Quantity Measurement Observation template (2.16.840.1.113883.10.20.6.2.14) or DIR SopInstance Observation template (2.16.840.1.113883.10.20.6.2.8).

## Medications Section 10160-0

The Medications section defines a patient's current medications and pertinent medication history. At a minimum, the currently active medications are to be listed, with an entire medication history as an option. The section may also include a patient's prescription and dispense history.

This section requires that there be either an entry indicating the subject is not known to be on any medications, or that there be entries summarizing the subject's medications.

Optional Entries

[section: templateId 2.16.840.1.113883.10.20.21.2.1(open)]

The following constraints apply to a Medications section in which entries are not required.

1. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.2.1" (CONF:7791).
2. **SHALL** contain exactly one [1..1] **@code**="10160-0" History of medication use (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:7792).
3. **SHALL** contain exactly one [1..1] **title**="Medications" (CONF:7793).
4. **SHALL** contain exactly one [1..1] **text** (CONF:7794).
5. **SHOULD** contain at least one [1..\*] **entry** (CONF:7795) such that it
   1. **SHALL** contain exactly one [1..1] [**Medication Activity**](#CS_MedicationActivity) (templateId:2.16.840.1.113883.10.20.22.4.16) (CONF:7796).
6. **MAY** contain zero or one [0..1] **entry** (CONF:7797) such that it
   1. **SHALL** contain exactly one [1..1] [**Medication Use - None Known**](#CS_MedicationInUseNoneKnown) (templateId:2.16.840.1.113883.10.20.22.4.29) (CONF:7798).

Required Entries

[section: templateId 2.16.840.1.113883.10.20.21.2.1.1(open)]

The following constraints apply to a Medications section in which entries are required.

1. Conforms to Medications Section (optional entries) Template (templateId: 2.16.840.1.113883.10.20.22.2.1).
2. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.2.1.1" (CONF:7568).
3. **SHALL** contain exactly one [1..1] **@code**="10160-0" History of medication use (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:7569).
4. **SHALL** contain exactly one [1..1] **title**="Medications" (CONF:7570).
5. **SHALL** contain exactly one [1..1] **text** (CONF:7571).
6. **SHALL** contain at least one [1..\*] **entry** (CONF:7572) such that it
   1. **SHALL** contain exactly one [1..1] [**Medication Activity**](#CS_MedicationActivity) (templateId:2.16.840.1.113883.10.20.22.4.16) (CONF:7573).
7. **MAY** contain zero or one [0..1] **entry** (CONF:7574) such that it
   1. **SHALL** contain exactly one [1..1] [**Medication Use - None Known**](#CS_MedicationInUseNoneKnown) (templateId:2.16.840.1.113883.10.20.22.4.29) (CONF:7575).
8. Section SHALL contain exactly one [1..1] Medication use - none known (templateId:2.16.840.1.113883.10.20.21.4.29); OR at least one [1..\*] Medication Activity (templateId: 2.16.840.1.113883.10.20.21.4.16). (CONF:7576).

Medications Administered Section 29549-3

[section: templateId 2.16.840.1.113883.10.20.22.2.38(open)]

The Medications Administered section defines medications and fluids administered during the procedure excluding anesthetic medications. Medications administered for anesthesia should be documented as described in the section on [Anesthesia](#S_AnesthesiaSection).

1. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.2.38" (CONF:8152).
2. **SHALL** contain exactly one [1..1] **code/@code**="29549-3" Medications Administered (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:8153).
3. **SHALL** contain exactly one [1..1] **title** (CONF:8154).
4. **SHALL** contain exactly one [1..1] **text** (CONF:8155).
5. **MAY** contain at least one [1..\*] **entry** (CONF:8156).
   1. Such entries **SHALL** contain exactly one [1..1] [**Medication Activity**](#CS_MedicationActivity) (templateId:2.16.840.1.113883.10.20.22.4.16) (CONF:8157).

Objective Section 61149-1

[section: templateId 2.16.840.1.113883.10.20.21.2.1(open)]

The Objective section contains data about the patient gathered through tests, measures, or observations that produce a quantified or categorized result. It includes important and relevant positive and negative test results, physical findings, review of systems, and other measurements and observations.

1. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.21.2.1" (CONF:7869).
2. **SHALL** contain exactly one [1..1] **code/@code**="61149-1" Objective (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:7870).
3. **SHALL** contain exactly one [1..1] **title** (CONF:7871).
4. **SHALL** contain exactly one [1..1] **text** (CONF:7872).

Figure 56: Objective section example

<component>

<section>

<templateId root="2.16.840.1.113883.10.20.21.2.1"/>

<code code="61149-1 " codeSystem="2.16.840.1.113883.6.1"

codeSystemName="LOINC"

displayName="OBJECTIVE DATA "/>

<title>OBJECTIVE DATA</title>

<text>

<list listType="ordered">

<item>Chest: clear to ausc. No rales, normal breath sounds</item>

<item>Heart: RR, PMI in normal location and no heave or evidence of

cardiomegaly,normal heart sounds, no murm or gallop</item>

</list>

</text>

</section>

</component>

Operative Note Fluid Section 10216-0

[section: templateId 2.16.840.1.113883.10.20.7.12(open)]

The Operative Note Fluids section may be used to record fluids administered during the surgical procedure. Optionally, Operative Note fluids may be represented with a text element in the Surgery Description section.

1. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.7.12" (CONF:8030).
2. **SHALL** contain exactly one [1..1] **code/@code**="10216-0" Operative Note Fluids (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:8031).
3. **SHALL** contain exactly one [1..1] **title** (CONF:8032).
4. **SHALL** contain exactly one [1..1] **text** (CONF:8033).
5. If the Operative Note Fluids section is present, there SHALL be a statement providing details of the fluids administered or SHALL explicitly state there were no fluids administered. (CONF:8052).

Operative Note Surgical Procedure Section 10223-6

[section: templateId 2.16.840.1.113883.10.20.7.14(open)]

The Operative Note Surgical Procedure section may be used to restate the procedures performed if appropriate for an enterprise workflow. The procedure(s) performed associated with the Operative Note are formally modeled in the header using serviceEvent.

1. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.7.14" (CONF:8034).
2. **SHALL** contain exactly one [1..1] **code/@code**="10223-6" Operative Note Surgical Procedure (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:8035).
3. **SHALL** contain exactly one [1..1] **title** (CONF:8036).
4. **SHALL** contain exactly one [1..1] **text** (CONF:8037).
5. If the surgical procedure section is present there SHALL be text indicating the procedure performed. (CONF:8054).

Payers Section 48768-6

[section: templateId 2.16.840.1.113883.10.20.22.2.18(open)]

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

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

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

1. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.2.18" (CONF:7924).
2. **SHALL** contain exactly one [1..1] **code/@code**="48768-6" Payers (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:7925).
3. **SHALL** contain exactly one [1..1] **title** (CONF:7926).
4. **SHALL** contain exactly one [1..1] **text** (CONF:7927).
5. **SHOULD** contain exactly one [1..1] **entry** (CONF:7959).
   1. **NOTE**: This conformance statement is for reference only. It has not yet been reviewed and consolidated according to the scope and intent of this guide.   
      CONF-XXXX: The Payers section **SHOULD** include one or more coverage activities (templateId 2.16.840.1.113883.10.20.1.20). **NOTE**: This conformance statement is for reference only. It has not yet been reviewed and consolidated according to the scope and intent of this guide. (CONF:7960).

Physical Exam Section 29545-1

[section: templateId 2.16.840.1.113883.10.20.2.10(open)]

The Physical Examination section includes direct observations made by the clinician. The examination may include the use of simple instruments and may also describe simple maneuvers performed directly on the patient’s body. This section includes only observations made by the examining clinician using inspection, palpation, auscultation, and percussion; it does not include laboratory or imaging findings. The exam may be limited to pertinent body systems based on the patient’s chief complaint or it may include a comprehensive examination. The examination may be reported as a collection of random clinical statements or it may be reported categorically. Categorical report formats may be divided into multiple subsections, including [Vital Signs](#_Vital_Signs_Section) or Medical History Section. Note that Vital Signs can be a top-level section or a subsection of Physical Examination.

1. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.2.10" (CONF:7806).
2. **SHALL** contain exactly one [1..1] **code/@code**="29545-1" Physical Findings (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:7807).
3. **SHALL** contain exactly one [1..1] **title** (CONF:7808).
4. **SHALL** contain exactly one [1..1] **text** (CONF:7809).
   1. **NOTE**: This conformance statement is for reference only. CONF-XXXX: The Physical Exam section MAY contain clinical statements. It has not yet been reviewed and consolidated according to the scope and intent of this guide. IHE PCC includes 27 optional sections. (CONF:7867).

Figure 57: Physical exam section example

<component>

<section>

<templateId root="2.16.840.1.113883.10.20.2.10"/>

<code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"

code="29545-1" displayName="PHYSICAL FINDINGS"/>

<title>PHYSICAL EXAMINATION</title>

<text>

<paragraph>All normal to examination.</paragraph>

</text>

</section>

</component>

## Plan Section 18776-5

[section: templateId 2.16.840.1.113883.10.20.21.2.10(open)]

The Plan section contains data that defines pending orders, interventions, encounters, services, and procedures for the patient. It is limited to prospective, unfulfilled, or incomplete orders and requests only. All active, incomplete, or pending orders, appointments, referrals, procedures, services, or any other pending event of clinical significance to the current care of the patient should be listed unless constrained due to privacy issues. The plan may also contain information about ongoing care of the patient and information regarding goals and clinical reminders. Clinical reminders are placed here to provide prompts for disease prevention and management, patient safety, and health-care quality improvements, including widely accepted performance measures. The plan may also indicate that patient education was given or will be provided.

1. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.21.2.10" (CONF:7723).
2. **SHALL** contain exactly one [1..1] **code/@code**="18776-5" Plan of Care (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:7724).
3. **SHALL** contain exactly one [1..1] **text** (CONF:7725).
4. **MAY** contain at least one [1..\*] **entry** (CONF:7726) such that it
   1. **NOTE**: This conformance statement is for reference only. It has not yet been reviewed and consolidated. CONF-XXXX: The Assessment, Plan, and Assessment and Plan section(s) MAY contain clinical statements. If present, the clinical statements SHALL conform to the CCD Plan of Care activities template (2.16.840.1.113883.10.20.1.25) (CONF:7728).

Planned Procedure Section 59772-4

[section: templateId 2.16.840.1.113883.10.20.22.2.30(open)]

The Planned Procedure section records the procedure(s) that the surgeon thought would need to be done based on the preoperative assessment. The section will contain the procedure or procedures the patient specifically consented to. It may be important to record the procedure(s) that were originally planned for, consented to, and perhaps pre-approved by the payor, particularly if different from the actual procedure(s) and procedure details, to provide evidence to various stakeholders that the providers are aware of the discrepancy and the justification can be found in the procedure details.

1. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.2.30" (CONF:8082).
2. **SHALL** contain exactly one [1..1] **code/@code**="59772-4" Planned Procedure (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:8083).
3. **SHALL** contain exactly one [1..1] **title** (CONF:8084).
4. **SHALL** contain exactly one [1..1] **text** (CONF:8085).

**NOTE**: This conformance statement is for reference only. It has not yet been reviewed and consolidated according to the scope and intent of this guide.

* 1. The Planned procedure section MAY contain clinical statements. If present, the clinical statements may conform to the CCD Procedure activity template (2.16.840.1.113883.10.20.1.29), the CCD Product template (2.16.840.1.113883.10.20.1.53), and the CCD Product instance template (2.16.840.1.113883.10.20.1.52).
  2. The Indications section may contain clinical statements referring to imaging observations. If present, these clinical statements may conform to the PHCR Imaging observation template (2.16.840.1.113883.10.20.15.3.5), DIR Text Observation template (2.16.840.1.113883.10.20.6.2.12), DIR Code Observation template (2.16.840.1.113883.10.20.6.2.13), DIR Quantity Measurement Observation template (2.16.840.1.113883.10.20.6.2.14) or DIR SopInstance Observation template (2.16.840.1.113883.10.20.6.2.8).

Postoperative Diagnosis Section 10218-6

[section: templateId 2.16.840.1.113883.10.20.22.2.35(open)]

The Postoperative Diagnosis section records the diagnosis or diagnoses discovered or confirmed during the surgery. Often it is the same as the preoperative diagnosis.

1. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.2.35" (CONF:8101).
2. **SHALL** contain exactly one [1..1] **code/@code**="10218-6" Postoperative Diagnosis (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:8102).
3. **SHALL** contain exactly one [1..1] **title** (CONF:8103).
4. **SHALL** contain exactly one [1..1] **text** (CONF:8104).

Postprocedure Diagnosis Section 59769-0

[section: templateId 2.16.840.1.113883.10.20.22.2.36(open)]

The Postprocedure Diagnosis section records the diagnosis or diagnoses discovered or confirmed during the procedure. Often it is the same as the pre-procedure diagnosis or indication.

1. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.2.36" (CONF:8167).
2. **SHALL** contain exactly one [1..1] **code/@code**="59769-0" Postprocedure Diagnosis (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:8169).
3. **SHALL** contain exactly one [1..1] **title** (CONF:8170).
4. **SHALL** contain exactly one [1..1] **text** (CONF:8171).

**NOTE**: This conformance statement is for reference only. It has not yet been reviewed and consolidated according to the scope and intent of this guide.

* 1. The Postprocedure Diagnosis section may contain clinical statements. If present, the clinical statements may conform to the CCD Problem observation template (2.16.840.1.113883.10.20.1.28).
  2. The Postprocedure section may contain clinical statements referring to imaging observations. If present, these clinical statements MAY conform to the PHCR Imaging observation template (2.16.840.1.113883.10.20.15.3.5), DIR Text Observation template (2.16.840.1.113883.10.20.6.2.12), DIR Code Observation template (2.16.840.1.113883.10.20.6.2.13), DIR Quantity Measurement Observation template (2.16.840.1.113883.10.20.6.2.14) or DIR SopInstance Observation template (2.16.840.1.113883.10.20.6.2.8).

Preoperative Diagnosis Section 10219-4

[section: templateId 2.16.840.1.113883.10.20.22.2.34(open)]

The Preoperative Diagnosis section records the surgical diagnosis or diagnoses assigned to the patient before the surgical procedure and is the reason for the surgery. The preoperative diagnosis is, in the opinion of the surgeon, the diagnosis that will be confirmed during surgery.

1. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.2.34" (CONF:8097).
2. **SHALL** contain exactly one [1..1] **code/@code**="10219-4" Preoperative Diagnosis (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:8098).
3. **SHALL** contain exactly one [1..1] **title** (CONF:8099).
4. **SHALL** contain exactly one [1..1] **text** (CONF:8100).

## Problem List Section 11450-4

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

Optional Entries

[section: templateId 2.16.840.1.113883.10.20.22.2.5(open)]

The following constraints apply to a Problem List section in which entries are required.

1. **SHALL** contain exactly one [1..1] **code/@code**="11450-4" *Problem list* (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF-141, CONF-142)
2. **SHALL** contain exactly one [1..1] **title** (CONF-143)
3. **SHALL** contain exactly one [1..1] **text** (CONF-140)

Required Entries

[section: templateId 2.16.840.1.113883.10.20.22.2.5.1(open)]

The following constraints apply to a Problem List section in which entries are required.

1. **SHALL** conform to Problem List Section (optional entries) template (templateId: 2.16.840.1.113883.10.20.22.2.5)
2. **SHOULD** contain zero or more [0..\*] **entry** (CONF-CONSOL-549), such that
   1. Contains exactly one [1..1] [Condition](file://localhost/Users/seh/Alschuler%20Associates/Consolidation/xhtml%202/classes/Condition.html) (templateId: 2.16.840.1.113883.10.20.22.4.3)
3. **SHOULD** contain a case-insensitive language-insensitive string containing 'problems'. (CONF-144)

Figure 58: Problem list section example

<component>

<section>

<templateId root="2.16.840.1.113883.10.20.22.2.5"/>

<code code="11450-4" codeSystem="2.16.840.1.113883.6.1"

codeSystemName="LOINC"

displayName="PROBLEM LIST"/>

<title>PROBLEMS</title>

<text>

<list listType="ordered">

<item>Pneumonia: Resolved in March 1998 </item>

<item>...</item>

</list>

</text>

<entry typeCode="DRIV">  
 <act classCode="ACT" moodCode="EVN">

<!-- Problem act template -->

<templateId root="2.16.840.1.113883.10.20.1.27"/>

<id root="ec8a6ff8-ed4b-4f7e-82c3-e98e58b45de7"/>

<code nullFlavor="NA"/>

<entryRelationship typeCode="SUBJ">

<observation classCode="OBS" moodCode="EVN">

<!-- Problem observation template -->

<templateId root="2.16.840.1.113883.10.20.1.28"/>

<id root="ab1791b0-5c71-11db-b0de-0800200c9a66"/>

<code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"/>

<statusCode code="completed"/>

<effectiveTime>

<low value="199803"/>

</effectiveTime>

<value xsi:type="CD" code="233604007"

codeSystem="2.16.840.1.113883.6.96" displayName="Pneumonia"/>

<entryRelationship typeCode="REFR">

<observation classCode="OBS" moodCode="EVN">

<!-- Problem status observation template -->

<templateId root="2.16.840.1.113883.10.20.1.50"/>

<code code="33999-4" codeSystem="2.16.840.1.113883.6.1"

displayName="Status"/>

<statusCode code="completed"/>

<value xsi:type="CE" code="413322009"

codeSystem="2.16.840.1.113883.6.96" displayName="Resolved"/>

</observation>

</entryRelationship>

</observation>

</entryRelationship>

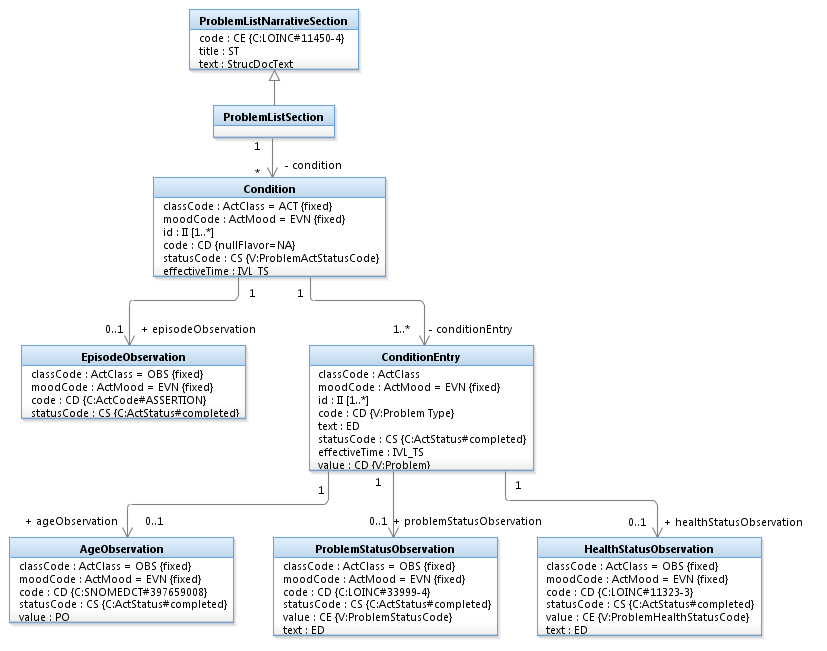
</act>

</entry>

</section>

</component>

Figure 59: Problem List UML Diagram



Procedure Description Section 29554-3

[section: templateId 2.16.840.1.113883.10.20.22.2.27(open)]

The Procedure Description section records the particulars of the procedure with an extensive narrative and may include procedure site preparation, pertinent details related to measurements and markings, procedure times, instrumentation, and vital signs and other monitoring data. [Complications](#S_ComplicationsAdverseEventsSection) and [Anesthesia](#S_AnesthesiaSection) may be recorded as subsections of this section. Local practice often identifies the level and type of detail required based on the procedure or specialty.

1. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.2.27" (CONF:8062).
2. **SHALL** contain exactly one [1..1] **code/@code**="29554-3" Procedure Description (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:8063).
3. **SHALL** contain exactly one [1..1] **title** (CONF:8064).
4. **SHALL** contain exactly one [1..1] **text** (CONF:8065).

Procedure Disposition Section 59775-7

[section: templateId 2.16.840.1.113883.10.20.18.2.12(open)]

The Procedure Disposition section records the status and condition of the patient at the completion of the procedure or surgery. It often also states where the patent was transferred to for the next level of care. The Disposition section may be a subsection of another section.

1. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.18.2.12" (CONF:8070).
2. **SHALL** contain exactly one [1..1] **code/@code**="59775-7" Procedure Disposition (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:8071).
3. **SHALL** contain exactly one [1..1] **title** (CONF:8072).
4. **SHALL** contain exactly one [1..1] **text** (CONF:8073).

**NOTE**: The following conformance statements are for reference only. It has not yet been reviewed and consolidated according to the scope and intent of this guide.

CONF-XXX. If the [Medications Administered](#_Medications_Administered__1) section is NOT present, there **may** be a statement in the Procedure Description section providing details of medications or fluids administered during the procedure or explicitly stating that there were no medications or fluids administered.

CONF-XXX. If the [Estimated Blood Loss](#_Estimated_Blood_Loss_1) section is NOT present, there **may** be a statement in the Procedure Description section providing details of the estimated blood lost during the procedure or explicitly stating there was no blood loss.

CONF-XXX. If the [Specimens Removed](#_Specimens_Removed_SPECRE-X_1) section is NOT present, there **may** be a statement in the Procedure Description section providing details of the specimens removed during the procedure or explicitly stating that there were no specimens removed.

CONF-XXX. If the [Implants](#_Implants__IMPL-X_1) section is NOT present, there **may** be a statement in the Procedure Description section providing details of implants such as stents, clips or drains left during the procedure or explicitly stating that there were no implants left.

CONF-XXX. The Procedure Description section **may** contain clinical statements about the procedure activity. If present, these clinical statements **may** conform to the [CCD Procedure activity](#CCD_ProcedureActivity) template (2.16.840.1.113883.10.20.1.29), the [CCD Product](#CCD_Product) template (2.16.840.1.113883.10.20.1.53), and the [CCD Product instance](#CCD_ProductInstance) template (2.16.840.1.113883.10.20.1.52).

CONF-XXX. The Procedure Description section **may** also contain clinical statements referring to the procedure related problems. If present, these clinical statements **may** conform to the [CCD Problem observation](#CCD_ProblemObservation) template (2.16.840.1.113883.10.20.1.28).

CONF-XXX. The Procedure Description section **may** contain clinical statements referring to imaging observations. If present, these clinical statements MAY conform to the [PHCR Imaging observation](#PHCR_ImagingObs) template (2.16.840.1.113883.10.20.15.3.5), [DIR Text Observation](#DIR_TextObservation) template (2.16.840.1.113883.10.20.6.2.12), [DIR Code Observation](#DIR_CodeObservation) template (2.16.840.1.113883.10.20.6.2.13), [DIR Quantity Measurement Observation](#DIR_QuantityMeasurementObservation) template (2.16.840.1.113883.10.20.6.2.14) or [DIR SopInstance Observation](#DIR_SopInstanceObservation) template (2.16.840.1.113883.10.20.6.2.8).

Procedure Estimated Blood Loss Section 59770-8

[section: templateId 2.16.840.1.113883.10.20.18.2.9(open)]

The Estimated Blood Loss section may be a subsection of another section such as the Procedure Description section. The Estimated Blood Loss section records the approximate amount of blood that the patient lost during the procedure or surgery. It may be an accurate quantitative amount, e.g., 250 milliliters, or it may be descriptive, e.g., “minimal” or “none”.

1. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.18.2.9" (CONF:8074).
2. **SHALL** contain exactly one [1..1] **code/@code**="59770-8" Procedure Estimated Blood Loss (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:8075).
3. **SHALL** contain exactly one [1..1] **title** (CONF:8076).
4. **SHALL** contain exactly one [1..1] **text** (CONF:8077).

**NOTE**: This conformance statement is for reference only. It has not yet been reviewed and consolidated according to the scope and intent of this guide.

* 1. The Estimated Blood Loss section shall include a statement providing an estimate of the amount of blood lost during the procedure, even if text such as minimal or none.

Procedure Findings Section 59776-5

[section: templateId 2.16.840.1.113883.10.20.22.2.28(open)]

The Procedure Findings section records clinically significant observations confirmed or discovered during the procedure or surgery. Often this section is a subsection of the Procedure Description section. This section is not for diagnostic findings that may be found in a History and Physical Note, as the results of observations generated by laboratories, imaging procedures, and other procedures would not yet be available.

1. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.2.28" (CONF:8078).
2. **SHALL** contain exactly one [1..1] **code/@code**="59776-5" Procedure Findings (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:8079).
3. **SHALL** contain exactly one [1..1] **title** (CONF:8080).
4. **SHALL** contain exactly one [1..1] **text** (CONF:8081).
5. **MAY** contain at least one [1..\*] **entry** (CONF:8090).
   1. Such entries **SHALL** contain exactly one [1..1] [**Condition Entry**](#CD_ConditionEntry) (templateId:2.16.840.1.113883.10.20.22.4.4) (CONF:8091).

Procedure Implants Section 59771-6

[section: templateId 2.16.840.1.113883.10.20.22.2.40(open)]

The Procedure Implants section records any materials placed during the procedure including stents, tubes, and drains.

1. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.2.40" (CONF:8178).
2. **SHALL** contain exactly one [1..1] **code/@code**="59771-6" Procedure Implants (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:8179).
3. **SHALL** contain exactly one [1..1] **title** (CONF:8180).
4. **SHALL** contain exactly one [1..1] **text** (CONF:8181).

**NOTE**: This conformance statement is for reference only. It has not yet been reviewed and consolidated according to the scope and intent of this guide.

* 1. The Implants section may contain clinical statements. If present, the clinical statements may include one or more CCD Supply activities (templateId 2.16.840.1.113883.10.20.1.34), may include CCD Product instance (templateId 2.16.840.1.113883.10.20.1.52), and may include one or more CCD Medication activities (templateId 2.16.840.1.113883.10.20.1.24).

Procedure Indications Section 59768-2

[section: templateId 2.16.840.1.113883.10.20.22.2.29(open)]

The Procedure Indications section records details about the reason for the procedure or surgery. This section may include the pre-procedure diagnosis or diagnoses as well as one or more symptoms that contribute to the reason the procedure is being performed.

1. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.2.29" (CONF:8058).
2. **SHALL** contain exactly one [1..1] **code/@code**="59768-2" Procedure Indications (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:8059).
3. **SHALL** contain exactly one [1..1] **title** (CONF:8060).
4. **SHALL** contain exactly one [1..1] **text** (CONF:8061).

**NOTE**: The following conformance statements are for reference only. It has not yet been reviewed and consolidated according to the scope and intent of this guide.

CONF-XXX. The Indications section may contain clinical statements referring to the reason for the procedure. If present, these clinical statements may conform to the CCD Problem observation template (2.16.840.1.113883.10.20.1.28).

CONF-XXX. If clinical statements conforming to the CCD Problem observation template and referring to the reason for the procedure are present, there shall be an entryRelationship with typeCode RSON. This entryRelationship shall adhere to CCD CONF 439.

CONF-XXX. The Indications section may contain clinical statements referring to imaging observations. If present, these clinical statements may conform to the PHCR Imaging observation template (2.16.840.1.113883.10.20.15.3.5), DIR Text Observation template (2.16.840.1.113883.10.20.6.2.12), DIR Code Observation template (2.16.840.1.113883.10.20.6.2.13), DIR Quantity Measurement Observation template (2.16.840.1.113883.10.20.6.2.14) or DIR SopInstance Observation template (2.16.840.1.113883.10.20.6.2.8).

CONF-XXX. The Indications section may contain clinical statements. If present, there shall be an entry relationship: RSON: This entry relationship shall adhere to CCD CONF 439: A procedure activity may contain one or more entryRelationship/@typeCode=”RSON”, the target of which represents the indication or reason for the procedure.

Procedure Specimens Taken Section 59773-2

[section: templateId 2.16.840.1.113883.10.20.22.2.31(open)]

The Procedure Specimens Taken section records the tissues, objects, or samples taken from the patient during the procedure including biopsies, aspiration fluid, or other samples sent for pathological analysis. The narrative may include a description of the specimens.

1. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.2.31" (CONF:8086).
2. **SHALL** contain exactly one [1..1] **code/@code**="59773-2" Procedure Specimens Taken (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:8087).
3. **SHALL** contain exactly one [1..1] **title** (CONF:8088).
4. **SHALL** contain exactly one [1..1] **text** (CONF:8089).

**NOTE**: This conformance statement is for reference only. It has not yet been reviewed and consolidated according to the scope and intent of this guide.

* 1. Specimens Removed section shall list all specimens removed or shall explicitly state that no specimens were removed.
  2. The Specimens Removed section may contain clinical statements. If present, the clinical statements may conform to the CCD Procedure activity template (2.16.840.1.113883.10.20.1.29).
  3. Specimens Removed section clinical statements may contain one or more specimen participant entries to reflect specimens that were obtained as part of the procedure. Each specimen should contain one specimen/specimenRole/id.

## Procedures Section 47519-4

This section defines all interventional, surgical, diagnostic, or therapeutic procedures or treatments pertinent to the patient historically at the time the document is generated. The section may contain all procedures for the period of time being summarized, but should include notable procedures. The common notion of "procedure" is broader than that specified by the HL7 Version 3 Reference Information Model (RIM). Therefore this section contains procedure templates represented with three RIM classes Act: Observation and Procedure. Procedure act is for procedures the alter that physical condition of a patient (Splenectomy). Observation act is for procedures that result in new information about a patient but do not cause physical alteration (EEG). Act is for all other types of procedures (dressing change).

Optional Entries

[section: templateId 2.16.840.1.113883.10.20.22.2.7(open)]

The following constraints apply to a Procedures section in which entries are not required.

1. **SHALL** contain exactly one [1..1] **templateId** (CONF:6270) such that it
   1. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.2.7" (CONF:6271).
2. **SHALL** contain exactly one [1..1] **code/@code**="47519-4" *History of procedures* (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:6272).
3. **SHALL** contain exactly one [1..1] **text** (CONF:6273).
4. **MAY** contain at least one [1..\*] **entry** (CONF:6274) such that it
   1. **SHALL** contain exactly one [1..1] [**Procedure Activity Procedure**](#CS_ProcedureActivityProcedure) (templateId:2.16.840.1.113883.10.20.22.4.14) (CONF:6277).
5. **MAY** contain zero or one [0..1] **entry** (CONF:6278) such that it
   1. **SHALL** contain exactly one [1..1] [**Procedure Activity Observation**](#CS_ProcedureActivityObservation) (templateId:2.16.840.1.113883.10.20.22.4.13) (CONF:6279).
6. **MAY** contain zero or one [0..1] **entry** (CONF:8533) such that it
   1. **SHALL** contain exactly one [1..1] [**Procedure Activity Act**](#CS_ProcedureActivityAct) (templateId:2.16.840.1.113883.10.20.22.4.12) (CONF:8534).

Required Entries

[section: templateId 2.16.840.1.113883.10.20.22.2.7.1(open)]

The following constraints apply to a Procedures section in which entries are required.

1. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.2.7.1" (CONF:7891).
2. **SHALL** contain exactly one [1..1] **@code**="47519-4" *History of Procedures* (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:7892).
3. **SHALL** contain exactly one [1..1] **title**="Procedures" (CONF:7893).
4. **SHALL** contain exactly one [1..1] **text** (CONF:7894).
5. **MAY** contain zero or more [0..\*] **entry** (CONF:7895) such that it
   1. **SHALL** contain exactly one [1..1] [**Procedure Activity Procedure**](#CS_ProcedureActivityProcedure) (templateId:2.16.840.1.113883.10.20.22.4.14) (CONF:7896).
6. **MAY** contain zero or more [0..\*] **entry** (CONF:8017) such that it
   1. **SHALL** contain exactly one [1..1] [**Procedure Activity Observation**](#CS_ProcedureActivityObservation) (templateId:2.16.840.1.113883.10.20.22.4.13) (CONF:8018).
7. **MAY** contain zero or more [0..\*] **entry** (CONF:8019) such that it
   1. **SHALL** contain exactly one [1..1] [**Procedure Activity Act**](#CS_ProcedureActivityAct) (templateId:2.16.840.1.113883.10.20.22.4.12) (CONF:8020).
8. There SHALL be at least one procedure, observation or act entry conformant to Procedure Activity Procedure template, Procedure Activity Observation template or Procedure Activity Act template in the Procedure Section. (CONF:8021).

Reason for Visit Section 29299-5

[component: templateId 2.16.840.1.113883.10.20.22.2.12(open)]

This section records the patient's the reason for the patient's visit (the provider’s description of the reason for visit). Local policy determines whether the information is divided into two sections or recorded in one section serving both purposes.

1. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.2.12" (CONF:7836).
2. **SHALL** contain exactly one [1..1] **code/@code**="" Reason for Visit (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:7837).
3. **SHALL** contain exactly one [1..1] **title** (CONF:7838).
4. **SHALL** contain exactly one [1..1] **text** (CONF:7839).

## Results Section 30954-2

The Results section contains the results of observations generated by laboratories, imaging procedures, and other procedures. The scope includes hematology, chemistry, serology, virology, toxicology, microbiology, plain x-ray, ultrasound, CT, MRI, angiography, echocardiography, nuclear medicine, pathology, and procedure observations. The section often includes notable results such as abnormal values or relevant trends, and could contain all results for the period of time being documented.

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

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

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

Optional Entries

[section: templateId 2.16.840.1.113883.10.20.21.2.3(open)]

The following constraints apply to a Results section in which entries are not required.

1. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.2.3" (CONF:7116).
2. **SHALL** contain exactly one [1..1] **code/@code**="30954-2" Relevant diagnostic tests and/or laboratory data (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:7117).
3. ***SHALL*** *contain exactly one [1..1]* ***text*** *(CONF:7118).*
4. ***SHOULD*** *contain at least one [1..\*]* ***entry*** *(CONF:7119) such that it* 
   1. ***SHALL*** *contain exactly one [1..1]* [***Result Organizer***](#CS_ResultOrganizer) *(templateId:2.16.840.1.113883.10.20.22.4.1) (CONF:7120).*

Required Entries

[component: templateId 2.16.840.1.113883.10.20.21.2.3.1(open)]

The following constraints apply to a Results section in which entries are required.

1. Conforms to Results Section (optional entries) Template (templateId: 2.16.840.1.113883.10.20.22.2.3).
2. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.2.3.1" (CONF:7108).
3. **SHALL** contain exactly one [1..1] **code/@code**="30954-2" Relevant diagnostic tests and/or laboratory data (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:7110).
4. ***SHALL*** *contain exactly one [1..1]* ***text*** *(CONF:7111).*
5. ***SHALL*** *contain at least one [1..\*]* ***entry*** *(CONF:7112) such that it* 
   1. ***SHALL*** *contain exactly one [1..1]* [***Result Organizer***](#CS_ResultOrganizer) *(templateId:2.16.840.1.113883.10.20.22.4.1) (CONF:7113).*

Developer Notes

The Developer Notes below are *informational only* and are not part of the normative standard.

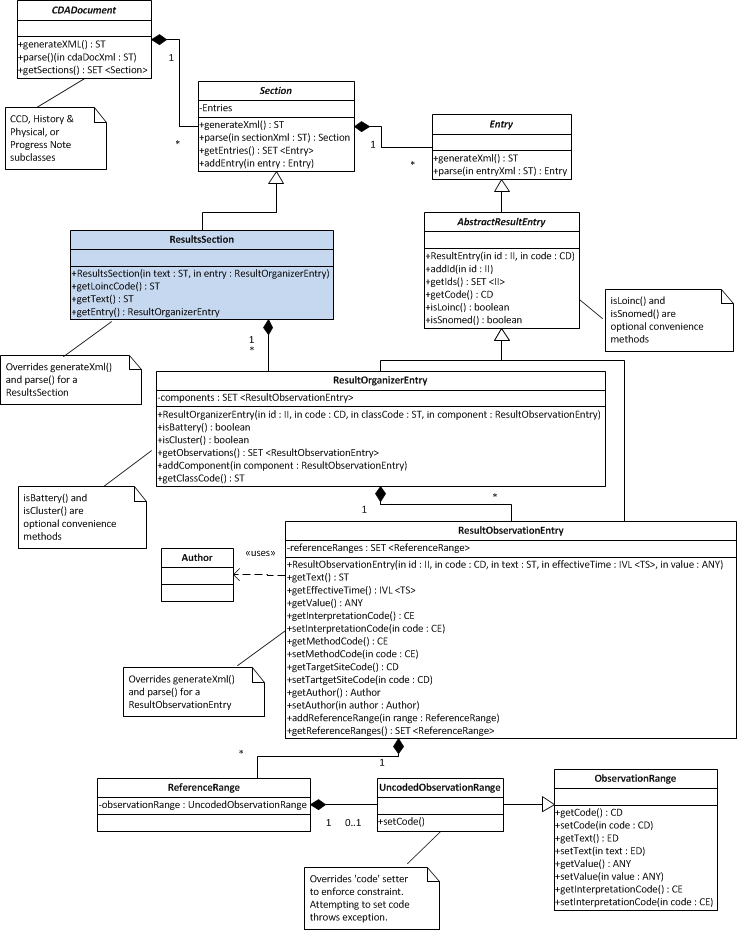
**Context**

The Results Section’s possible contexts are shown below.

|  |  |
| --- | --- |
| Contained by Documents | Contains Entries |
| [CCD](#Doc_CCD) (Required)  [History & Physical](#Doc_HandPNote) (Required)  [Progress Note](#Doc_ProgressNote) (Optional) | [Results Organizer](#CS_ResultOrganizer) |

**UML Class Diagram**

The UML Class diagram for the Results Section is shown below.



**Results Section UML Class Diagram**

**Application Programming Interface (API)**

|  |
| --- |
| Constructor Summary |
| [ResultsSection](#_Results_Section_30954-2_1) ([ST](datatypes.htm#dt-ST) ***text***, [ResultOrganizerEntry](#CS_ResultOrganizer) ***entry***) |

|  |  |
| --- | --- |
| Method Summary | |
| [ST](datatypes.htm#dt-ST) | generateXml ( ) |
| [ResultsSection](#_Results_Section_30954-2_1) | parse ([ST](datatypes.htm#dt-ST) resultsSectionXml) |
| [ST](datatypes.htm#dt-ST) | getLoincCode( ) |
| [ST](datatypes.htm#dt-ST) | getText() |
| [ResultOrganizerEntry](#CS_ResultOrganizer) | getEntry() |

Review of Systems Section 10187-3

[section: templateId 1.3.6.1.4.1.19376.1.5.3.1.3.18(open)]

The Review of Systems section contains a relevant collection of symptoms and functions systematically gathered by a clinician. It includes symptoms the patient is currently experiencing, some of which were not elicited during the history of present illness, as well as a potentially large number of pertinent negatives, for example, symptoms that the patient denied experiencing.

1. **SHALL** contain exactly one [1..1] **templateId/@root**="1.3.6.1.4.1.19376.1.5.3.1.3.18" (CONF:7812).
2. **SHALL** contain exactly one [1..1] **code/@code**="10187-3" Review of Systems (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:7813).
3. **SHALL** contain exactly one [1..1] **title** (CONF:7814).
4. **SHALL** contain exactly one [1..1] **text** (CONF:7815).

Figure 60: Review of systems section example

<component>

<section>

<templateId root="1.3.6.1.4.1.19376.1.5.3.1.3.18"/>

<code code="10187-3" codeSystem="2.16.840.1.113883.6.1"

codeSystemName="LOINC"

displayName="REVIEW OF SYSTEMS"/>

<title>REVIEW OF SYSTEMS</title>

<text>

<paragraph>

Patient denies recent history of fever or malaise. Positive

For weakness and shortness of breath. One episode of melena. No recent

headaches. Positive for osteoarthritis in hips, knees and hands.

</paragraph>

</text>

</section>

</component>

Social History Section 29762-2

[section: templateId 2.16.840.1.113883.10.20.22.2.17(open)]

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

1. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.2.17" (CONF:7936).
2. **SHALL** contain exactly one [1..1] **code/@code**="29762-2" Social History (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:7937).
3. **SHALL** contain exactly one [1..1] **title** (CONF:7938).
4. **SHALL** contain exactly one [1..1] **text** (CONF:7939).
5. **MAY** contain exactly one [1..1] **entry** (CONF:7953).
   1. **NOTE**: This conformance statement is for reference only. It has not yet been reviewed and consolidated according to the scope and intent of this guide.   
      CONF-XXXX: The Social History section **MAY** contain clinical statements. If present, the clinical statements **SHALL** conform to the social history observations (templateId 2.16.840.1.113883.10.20.1.33). (CONF:7954).

Subjective Section 61150-9

[section: templateId 2.16.840.1.113883.10.20.21.2.2(open)]

The Subjective section describes in a narrative format the patient’s current condition and/or interval changes as reported by the patient or by the patient’s guardian or another informant.

1. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.21.2.2" (CONF:7873).
2. **SHALL** contain exactly one [1..1] **code/@code**="61150-9" Subjective (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:7874).
3. **SHALL** contain exactly one [1..1] **title** (CONF:7875).
4. **SHALL** contain exactly one [1..1] **text** (CONF:7876).

Figure 61: Subjective section example

<component>

<section>

<templateId root="2.16.840.1.113883.10.20.21.2.2"/>

<code code="61150-9" codeSystem="2.16.840.1.113883.6.1"

codeSystemName="LOINC"

displayName="SUBJECTIVE"/>

<title>SUBJECTIVE DATA</title>

<text>

<paragraph>

I have used the peripheral nerve stimulator in my back for five days.

While using it I found that I was able to do physical activity

without pain. However, afterwards for one day, I would feel pain but

then it would go away. I also noticed that I didn’t have to take the

Vicodin as much. I took 2 less Vicodin per day and 2 less tramadol

everyday. I have not lain in my bed in a year and a half. I sleep in

a recliner.

</paragraph>

</text>

</section>

</component>

Surgery Description Section 29554-3

[section: templateId 2.16.840.1.113883.10.20.22.2.26(open)]

The Surgery Description section records the particulars of the surgery with an extensive narrative and may include surgical site preparation, pertinent details related to sedation/anesthesia, measurements and markings, waiting times, incisions, surgical approach, instrumentation, sponge counts, tissue manipulation, wound closure, sutures used, and vital signs and other monitoring data. Complications may be recorded in this section. Local practice often identifies the level and type of detail required based on the procedure or specialty.

1. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.2.26" (CONF:8022).
2. **SHALL** contain exactly one [1..1] **code/@code**="29554-3" Surgery Description (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:8023).
3. **SHALL** contain exactly one [1..1] **title** (CONF:8024).
4. **SHALL** contain exactly one [1..1] **text** (CONF:8025).

**NOTE**: This conformance statement is for reference only. It has not yet been reviewed and consolidated according to the scope and intent of this guide.

* 1. The Surgery Description section shall include a statement regarding whether or not a sponge and needle count was completed.
  2. The Surgery Description section should include a statement regarding whether or not an instrument count was completed.
  3. If the Operative Note Fluids section is NOT present, there may be a statement in the Surgery Description section providing details of the fluids administered or explicitly stating there were no fluids administered.
  4. If the Surgical Drains section is NOT present, there may be a statement in the Surgery Description section providing details of the drains placed or explicitly stating there were no drains placed.

Surgical Drains Section 11537-8

[section: templateId 2.16.840.1.113883.10.20.7.13(open)]

The Surgical Drains section may be used to record drains placed during the surgical procedure. Optionally, surgical drain placement may be represented with a text element in the Surgery Description Section.

1. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.7.13" (CONF:8038).
2. **SHALL** contain exactly one [1..1] **code/@code**="11537-8" Surgical Drains (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:8039).
3. **SHALL** contain exactly one [1..1] **title** (CONF:8040).
4. **SHALL** contain exactly one [1..1] **text** (CONF:8041).
5. If the Surgical Drains section is present, there SHALL be a statement providing details of the drains placed or SHALL explicitly state there were no drains placed. (CONF:8056).

## Vital Signs Section 8716-3

The Vital Signs section contains current and historically relevant vital signs for the context and use case of the document type, such as blood pressure, heart rate, respiratory rate, height, weight, body mass index, head circumference, and pulse oximetry. The section should include notable vital signs such as the most recent, maximum and/or minimum, baseline, or relevant trends.

Vital signs are represented in the same way as other results, but are aggregated into their own section to follow clinical conventions.

Optional Entries

[section: templateId 2.16.840.1.113883.10.20.21.2.4(open)]

The following constraints apply to a Vital Signs section in which entries are not required.

1. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.2.4" (CONF:7268).
2. **SHALL** contain exactly one [1..1] **code/@code**="8716-3" Vital Signs (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:7269).
3. **SHALL** contain exactly one [1..1] **text** (CONF:7270).
4. **SHOULD** contain at least one [1..\*] **entry** (CONF:7271) such that it
   1. **SHALL** contain exactly one [1..1] [**Vital Signs Organizer**](#CS_VitalSignsOrganizer) (templateId:2.16.840.1.113883.10.20.22.4.26) (CONF:7272).

Required Entries

[section: templateId 2.16.840.1.113883.10.20.21.2.4.1(open)]

The following constraints apply to a Vital Signs section in which entries are required.

1. Conforms to Vital Signs Section (optional entries) Template (templateId: 2.16.840.1.113883.10.20.22.2.4).
2. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.2.4.1" (CONF:7273).
3. **SHALL** contain exactly one [1..1] **code/@code**="8716-3" Vital Signs (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:7274).
4. **SHALL** contain exactly one [1..1] **text** (CONF:7275).
5. **SHALL** contain at least one [1..\*] **entry** (CONF:7276) such that it
   1. **SHALL** contain exactly one [1..1] [**Vital Signs Organizer**](#CS_VitalSignsOrganizer) (templateId:2.16.840.1.113883.10.20.22.4.26) (CONF:7277).

# Entry-level Templates

This part of the guide describes the clinical statement entry templates used within the sections of the consolidated documents. Entry templates contain constraints that are required for conformance. Note that the clinical statement templates are presented in alphabetical order; templates are not grouped by possible containing templates.

Each entry-level template description contains the following information:

* Key template metadata (e.g., templateID, etc.)
* Description and explanatory narrative.
* Required CDA acts, participants and vocabularies.
* Optional CDA acts, participants and vocabularies.

Age Observation

[Observation: templateId 2.16.840.1.113883.10.20.22.4.31(open)]

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

1. **SHALL** contain exactly one [1..1] **@classCode**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) (CONF-226)
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) (CONF-227)
3. **SHALL** contain exactly one [1..1] **code/@code**="397659008" *Age* (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT) (CONF-228)
4. **SHALL** contain exactly one [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus) (CONF-229, CONF-230)
5. **SHALL** contain exactly one [1..1] **value**, where its data type is PQ (CONF-231)
   1. **SHALL** contain @unit, which **SHALL** be selected from ValueSet 2.16.840.1.113883.11.20.9.21 AgePQ\_UCUM DYNAMIC

Table 32: AgePQ\_UCUM Value Set

| Value Set: AgePQ\_UCUM 2.16.840.1.113883.11.20.9.21 | | |
| --- | --- | --- |
| Code System(s): | UCUM 2.16.840.1.113883.6.8 | |
| Description: | A valueSet of UCUM codes for representing age value units | |
| Code | Code System | Print Name |
| min | UCUM | Minute |
| h | UCUM | Hour |
| d | UCUM | Day |
| wk | UCUM | Week |
| mo | UCUM | Month |
| a | UCUM | Year |

Alert Status Observation

[observation: templateId 2.16.840.1.113883.10.20.21.4.28(open)]

This template represents the status of the allergy or alert indicating whether it is active, no longer active, or is an historic allergy or alert. There can be only one alert status observation per alert/allergy observation.

1. **SHALL** contain exactly one [1..1] **@classCode**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:7318).
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:7319).
3. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.21.4.28" (CONF:7317).
4. **SHALL** contain exactly one [1..1] **code/@code**="33999-4" *Status* (CodeSystem: 2.16.840.1.113883.6.1 LOINC) **STATIC** (CONF:7320).
5. **SHALL** contain exactly one [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:7321).
6. **SHALL** contain exactly one [1..1] **value with @xsi:type="CE"**, where the @code **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.20.3 AlertStatusCode **DYNAMIC** (CONF:7322).

Table 33: Alert Status Code Value Set

| Value Set: Alert Status Code 2.16.840.1.113883.1.11.20.3 | | |
| --- | --- | --- |
| Code System(s): | SNOMED CT 2.16.840.1.113883.6.96 | |
| Description: | A valueSet of codes for the status of an allergy or alert | |
| Code | Code System | Print Name |
| 55561003 | SNOMED CT | Active |
| 392521001 | SNOMED CT | Prior History |
| 73425007 | SNOMED CT | No Longer Active |

Allergy Problem Act

[act: templateId 2.16.840.1.113883.10.20.21.4.30(open)]

This clinical statement act represents a concern relating to a patient's allergies or adverse events. A concern is a term used when referring to patient's problems that are related to one another. Observations of problems or other clinical statements captured at a point in time are wrapped in a "Concern" act which represents the ongoing process tracked over time. This outer allergy problem act (representing the "Concern") can contain nested problem observations or other nested clinical statements relevant to the allergy concern.

1. **SHALL** contain exactly one [1..1] **@classCode**="ACT" (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:7469).
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" Event (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:7470).
3. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.4.30" (CONF:7471).
4. **SHALL** contain at least one [1..\*] **id** (CONF:7472).
5. **SHALL** contain exactly one [1..1] **code**="48765-2" Allergies, adverse reactions, alerts (CodeSystem: 2.16.840.1.113883.6.1 LOINC) **STATIC** (CONF:7477).
6. **SHALL** contain exactly one [1..1] **statusCode**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.11.20.9.19 ProblemAct statusCode **DYNAMIC** (CONF:7485).
7. **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:7498).
   1. If statusCode/@code = "active|supended", then effectiveTime SHALL contain [1..1] low. If statusCode/@code="aborted|completed", then effectiveTime SHALL contain [1..1] high (CONF:7504).
8. **SHALL** contain at least one [1..\*] **entryRelationship** (CONF:7509) such that it
   1. **SHALL** contain exactly one [1..1] **@typeCode**="SUBJ" Has subject (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:7915).
   2. **SHALL** contain exactly one [1..1] [**Allergy/Alert Observation**](#629) (templateId:2.16.840.1.113883.10.20.22.4.7) (CONF:7510).

Table 34: Problem Act Status Code Value Set

| Value Set: Problem Act Status Code 2.16.840.1.113883.11.20.9.19 | | |
| --- | --- | --- |
| Code System(s): | HL7ActStatus 2.16.840.1.113883.5.14 | |
| Description: | A ValueSet of HL7 actStatus codes for use on the concern act. | |
| Code | Code System | Print Name |
| completed | HL7ActStatus | Completed |
| aborted | HL7ActStatus | Aborted |
| active | HL7ActStatus | Active |
| suspended | HL7ActStatus | Suspended |

Allergy/Alert Observation

[observation: templateId 2.16.840.1.113883.10.20.21.4.7(open)]

This clinical statement represents that an allergy or adverse reaction exists or does not exist. The agent that is the cause of the allergy or adverse reaction is represented as a manufactured material participant playing entity in the allergy observation. While the agent is often implicit in the alert observation (e.g. "allergy to penicillin"), it should also be asserted explicitly as an entity.

1. **SHALL** contain exactly one [1..1] **@classCode**="OBS" Observation (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:7379).
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" Event (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:7380).
3. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.4.7" (CONF:7381).
4. **SHALL** contain at least one [1..\*] **id** (CONF:7382).
5. **SHALL** contain exactly one [1..1] **code**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.3.88.12.3221.6.2 Allergy/Adverse Event Type **DYNAMIC** (CONF:7383).
6. **SHALL** contain exactly one [1..1] **statusCode/@code**="completed" Completed (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:7386).
7. **SHOULD** contain exactly one [1..1] **effectiveTime** (CONF:7387).
8. **SHALL** contain exactly one [1..1] **value with @xsi:type="CD"** (CONF:7390).
   1. This value **SHOULD** contain exactly one [1..1] **originalText** (CONF:7422).
      1. This originalText **SHOULD** contain exactly one [1..1] **reference** (CONF:7400).
         1. A reference/@value SHOULD point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1 ). (CONF:7401).
9. **SHOULD** contain exactly one [1..1] **participant** (CONF:7402) such that it
   1. **SHALL** contain exactly one [1..1] **@typeCode**="CSM" Product (CodeSystem: 2.16.840.1.113883.5.90 HL7ParticipationType) **STATIC** (CONF:7403).
   2. **SHALL** contain exactly one [1..1] **participantRole** (CONF:7404).
      1. This participantRole **SHALL** contain exactly one [1..1] **@classCode**="MANU" Manufactured Product (CodeSystem: 2.16.840.1.113883.5.110 HL7RoleClass) **STATIC** (CONF:7405).
      2. This participantRole **SHALL** contain exactly one [1..1] **playingEntity** (CONF:7406).
         1. This playingEntity **SHALL** contain exactly one [1..1] **@classCode**="MMAT" Manufactured Material (CodeSystem: 2.16.840.1.113883.5.41 HL7EntityClass) **STATIC** (CONF:7407).
         2. This playingEntity **SHALL** contain exactly one [1..1] **code** (CONF:7419).
            1. This code @code in an allergy to a specific medication SHALL be selected from the ValueSet 2.16.840.1.113883.3.88.12.80.16 Medication Brand Name or the ValueSet 2.16.840.1.113883.3.88.12.80.17 Medication Clinical Drug. In an allergy to a class of medications the code@code SHALL be selected from the ValueSet 2.16.840.1.113883.3.88.12.80.18 Medication Drug Class. In an allergy to a food or other substance the code@code SHALL be selected from the ValueSet 2.16.840.1.113883.3.88.12.80.20 Ingredient Name. (CONF:7421).
            2. This code **SHOULD** contain exactly one [1..1] **originalText** (CONF:7424).

This originalText **SHOULD** contain exactly one [1..1] **reference** (CONF:7425).

A reference/@value SHOULD point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1 ). (CONF:7426).

* + - * 1. This code **MAY** contain zero or more [0..\*] **translation** (CONF:7431).

1. **SHALL** contain exactly one [1..1] **entryRelationship** (CONF:7440) such that it
   1. **SHALL** contain exactly one [1..1] **@typeCode**="SUBJ" Has subject (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:7906).
   2. **SHALL** contain exactly one [1..1] **@inversionInd**="true" (CONF:7446).
   3. **SHALL** contain exactly one [1..1] [**Problem Status**](#CS_ProblemStatus) (templateId:2.16.840.1.113883.10.20.22.4.6) (CONF:7441).
2. **SHOULD** contain zero or more [0..\*] **entryRelationship** (CONF:7447) such that it
   1. **SHALL** contain exactly one [1..1] **@typeCode**="MFST" Is Manifestation of (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:7907).
   2. **SHALL** contain exactly one [1..1] **@inversionInd**="true" (CONF:7449).
   3. **SHALL** contain exactly one [1..1] [**Reaction Observation**](#CS_ReactionObservation) (templateId:2.16.840.1.113883.10.20.22.4.9) (CONF:7450).

Table 35: Allergy/Adverse Event Type Value Set

| Value Set: Allergy/Adverse Event Type 2.16.840.1.113883.3.88.12.3221.6.2 | | |
| --- | --- | --- |
| Code System(s): | SNOMED CT 2.16.840.1.113883.6.96 | |
| Description: | This describes the type of product and intolerance suffered by the patient | |
| Code | Code System | Print Name |
| 420134006 | SNOMED CT | Propensity to adverse reactions (disorder) |
| 418038007 | SNOMED CT | Propensity to adverse reactions to substance (disorder) |
| 419511003 | SNOMED CT | Propensity to adverse reactions to drug (disorder) |
| 418471000 | SNOMED CT | Propensity to adverse reactions to food (disorder) |
| 419199007 | SNOMED CT | Allergy to substance (disorder) |
| 416098002 | SNOMED CT | Drug allergy (disorder) |
| 414285001 | SNOMED CT | Food allergy (disorder) |
| 59037007 | SNOMED CT | Drug intolerance (disorder) |
| 235719002 | SNOMED CT | Food intolerance (disorder) |

Table 36: Medication Brand Name Value Set

| Value Set: Medication Brand Name 2.16.840.1.113883.3.88.12.80.16 | | |
| --- | --- | --- |
| Code System(s): | RxNorm 2.16.840.1.113883.6.88 | |
| Description: | Brand names | |
|  | Example of Codes for reference | |
| Code | Code System | Print Name |
| 205734 | RxNorm | Amoxicillin 25 MG/ML Oral Suspension [Amoxil] |
| 856537 | RxNorm | 24 HR Propranolol Hydrochloride 60 MG Extended Release Capsule [Inderal] |
| 104700 | RxNorm | Diazepam 5 MG Oral Tablet [Valium] |
| … |  |  |

Table 37: Medication Drug Class Value Set

| Value Set: Medication Drug Class 2.16.840.1.113883.3.88.12.80.18 | | |
| --- | --- | --- |
| Code System(s): | NDF-RT 2.16.840.1.113883.3.26.1.5 | |
| Description: | This identifies the pharmacological drug class, such as Cephalosporins. Shall contain a value descending from the NDF-RT concept types of “Mechanism of Action - N0000000223”, “Physiologic Effect - N0000009802” or “Chemical Structure - N0000000002”`. NUI will be used as the concept code.  <http://www.cancer.gov/cancertopics/terminologyresources/page5> | |
|  | Example of Codes for reference | |
| Code | Code System | Print Name |
| N0000011161 | NDF-RT | Cephalosporins |
| N0000005909 | NDF-RT | 2-Propanol |
| N0000006629 | NDF-RT | Filgrastim |
| … |  |  |

Table 38: Medication Clinical Drug Value Set

| Value Set: Medication Clinical Drug 2.16.840.1.113883.3.88.12.80.17 | | |
| --- | --- | --- |
| Code System(s): | RxNorm 2.16.840.1.113883.6.88 | |
| Description: | Clinical drug names | |
|  | Example of Codes for reference | |
| Code | Code System | Print Name |
| 313850 | RxNorm | Amoxicillin 40 MG/ML Oral Suspension |
| 856448 | RxNorm | Propranolol Hydrochloride 10 MG Oral Tablet |
| 197589 | RxNorm | Diazepam 10 MG Oral Tablet |
| … |  |  |

Table 39: Ingredient Name Value Set

| Value Set: Ingredient Name 2.16.840.1.113883.3.88.12.80.20 | | |
| --- | --- | --- |
| Code System(s): | Unique Ingredient Identifier (UNII) 2.16.840.1.113883.4.9 | |
| Description: | Unique identifiers for active drug ingredients.  <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162523.htm> | |
|  | Example of Codes for reference | |
| Code | Code System | Print Name |
| OLT4M28U3Z | UNII | ((3-TRIFLUOROMETHYL)PHENYL)METHYL-PHOSPHONIC ACID |
| L0VRY82PKO | UNII | CYCLOHEXENE, 4-[(1Z)-1,5-DIMETHYL-1,4-HEXADIEN-1-YL]-1-METHYL- |
| 62H4W26906 | UNII | BISNAFIDE |
| … |  |  |

Figure 62: Allergy/alert observation example

<observation classCode="OBS" moodCode="EVN">

<!-- allergy observation template -->

<templateId root="2.16.840.1.113883.10.20.21.4.7"/>

<id root="4adc1020-7b14-11db-9fe1-0800200c9a66"/>

<code code="416098002" displayName="drug allergy"

codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT"/>

<statusCode code="completed"/>

<effectiveTime>

<low value="20110215"/>

</effectiveTime>

<value xsi:type="CD" code="282100009" displayName="Adverse reaction to

substance" codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT"

xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">

<originalText>

<reference value=""/>

</originalText>

</value>

<participant typeCode="CSM">

<participantRole classCode="MANU">

<playingEntity classCode="MMAT">

<code code="314422" displayName="ALLERGENIC EXTRACT, PENICILLIN"

codeSystem="2.16.840.1.113883.6.88" codeSystemName="RxNorm">

<originalText>

<reference value=""/>

</originalText>

</code>

<name>Penicillin</name>

</playingEntity>

</participantRole>

</participant>

</entryRelationship typeCode="REFR">

</observation classCode="OBS" moodCode="EVN">

Condition

[Act: templateId 2.16.840.1.113883.10.20.22.4.3(open)]

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

1. **SHALL** contain exactly one [1..1] **@classCode**="ACT" *Act* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) (CONF-146)
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) (CONF-147)
3. **SHALL** contain at least one [1..\*] **id** (CONF-148)
4. **SHALL** contain exactly one [1..1] **code**/@nullFlavor = "NA" *NA (not applicable)* (CONF-149)
5. **SHALL** contain exactly one [1..1] **statusCode**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.11.20.9.19 ProblemAct statusCode  **STATIC** (CONF-CONSOL-525)
6. **SHALL** contain exactly one [1..1] **effectiveTime** (CONF-CONSOL-526)
   1. The effectiveTime element records the starting and ending times during which the concern was active.
   2. **SHALL** contain exactly one [1..1] effectiveTime/low element (CONF-CONSOL-520)
   3. **SHALL** contain exactly one [1..1] effectiveTime/high element if statusCode@code=completed or aborted (CONF-CONSOL-521)
   4. **SHALL NOT** contain effectiveTime/high element if statusCode@code=active or suspended (CONF-CONSOL-522)
7. **SHALL** contain at least one [1..\*] **entryRelationship**, such that
   1. Contains **@typeCode="**SUBJ" *SUBJ (has subject)*
   2. Contains exactly one [1..1] [Condition Entry](file://localhost/Users/seh/Alschuler%20Associates/Consolidation/xhtml%202/classes/ConditionEntry.html) (templateId: 2.16.840.1.113883.10.20.22.4.4)
8. **MAY** contain zero or one [0..1] **entryRelationship**, such that
   1. Contains **@typeCode="**SUBJ" *SUBJ (has subject)*
   2. **SHALL** contain exactly one [1..1] @inversionInd = "true"
   3. Contains exactly one [1..1] [Episode Observation](file://localhost/Users/seh/Alschuler%20Associates/Consolidation/xhtml%202/classes/EpisodeObservation.html) (templateId: 2.16.840.1.113883.10.20.1.41)

Condition Entry

[Observation: templateId 2.16.840.1.113883.10.20.22.4.4(open)]

This section uses 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** contain exactly one [1..1] **@classCode**
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) (CONF-155)
3. **SHALL** contain at least one [1..\*] **id** (CONF-CONSOL-529)
   1. 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.
4. **SHALL** 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 (CONF-CONSOL-530)
5. **SHOULD** contain exactly one [1..1] **text** (CONF-CONSOL-531)
   1. The <text> element 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.
   2. The problem name **SHOULD** be recorded in the entry by recording a <reference> where the value attribute points to the narrative text containing the name of the problem. (CONF-CONSOL-527)
6. **SHALL** contain exactly one [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus) (CONF-156, CONF-157)
7. **SHOULD** contain exactly one [1..1] **effectiveTime** (CONF-CONSOL-532)
   1. 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).
   2. The onset date **SHALL** be recorded in the <low> element of the <effectiveTime> element when known. (C83-[DE-7.01-1])
   3. The resolution data **SHALL** be recorded in the <high> element of the <effectiveTime> element when known. (C83-[DE-7.01-2])
   4. If the problem is known to be resolved, but the date of resolution is not known, then the <high> element **SHALL** be present, and the nullFlavor attribute **SHALL** be set to 'UNK'. Therefore, the existence of an <high> element within a problem does indicate that the problem has been resolved. (C83-[DE-7.01-3])
8. **SHALL** contain exactly one [1..1] **value**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.3.88.12.3221.7.4 Problem **DYNAMIC** (CONF-CONSOL-533)
9. **MAY** contain zero or one [0..1] **entryRelationship** (CONF-160), such that
   1. Contains **@typeCode="**SUBJ" *SUBJ (has subject)*
   2. **SHALL** contain exactly one [1..1] @inversionInd = "true"
   3. Contains exactly one [1..1] [Age Observation](#CS_AgeObservation) (templateId: 2.16.840.1.113883.10.20.22.4.31)
10. **MAY** contain zero or one [0..1] **entryRelationship** (CONF-CONSOL-535), such that
    1. Contains **@typeCode="**REFR" *REFR (refers to)*
    2. Contains exactly one [1..1] [Problem Status Observation](#CS_ProblemStatus) (templateId: 2.16.840.1.113883.10.20.22.4.6)
11. **MAY** contain zero or one [0..1] **entryRelationship** (CONF-CONSOL-536), such that
    1. Contains **@typeCode="**REFR" *REFR (refers to)*
    2. Contains exactly one [1..1] [Health Status Observation](#CS_HealthStatusObservation) (templateId: 2.16.840.1.113883.10.20.22.4.5)

Table 40: Problem Type Value Set

| Value Set: Problem Type 2.16.840.1.113883.3.88.12.3221.7.2 | | |
| --- | --- | --- |
| Code System(s): | SNOMEDCT 2.16.840.1.113883.6.96 | |
| Description: | This value set indicates the level of medical judgment used to determine the existence of a problem. | |
| Code | Code System | Print Name |
| 404684003 | SNOMED CT | Finding |
| 409586006 | SNOMED CT | Complaint |
| 282291009 | SNOMED CT | Diagnosis |
| 64572001 | SNOMED CT | Condition |
| 248536006 | SNOMED CT | Functional limitation |
| 418799008 | SNOMED CT | Symptom |
| 55607006 | SNOMED CT | Problem |

Table 41: Problem Value Set

| Value Set: Problem 2.16.840.1.113883.3.88.12.3221.7.4 | | |
| --- | --- | --- |
| Code System(s): | SNOMED CT 2.16.840.1.113883.6.96 | |
| Description: | Problems and diagnoses. Limited to terms decending from the Clinical Findings (404684003) or Situation with Explicit Context (243796009) hierarchies. | |
|  | Example of Codes for reference | |
| Code | Code System | Print Name |
| 46635009 | SNOMED CT | Diabetes mellitus type 1 |
| 234422006 | SNOMED CT | Acute porphyria |
| 31712002 | SNOMED CT | Primary biliary chrrhosis |
| … |  |  |

Discharge Diagnosis

[act: templateId 2.16.840.1.113883.10.20.22.4.33(open)

The Discharge Diagnosis entry encodes the patients relevant problems or diagnoses that occurred during the hospitalization or that need to be followed after hospitalization.

1. **SHALL** contain exactly one [1..1] **@classCode**="ACT" (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) (CONF:7663).
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) (CONF:7664).
3. **SHALL** contain exactly one [1..1] **code/@code**="11535-2" Discharge diagnosis (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:7665).
4. **SHALL** contain exactly one [1..1] **entryRelationship** (CONF:7666) such that it
   1. **SHALL** contain exactly one [1..1] **@typeCode**="SUBJ" (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) (CONF:7667).
   2. **SHALL** contain exactly one [1..1] [**Condition Entry**](#CD_ConditionEntry) (templateId:2.16.840.1.113883.10.20.22.4.4) (CONF:7669).

Discharge Medication

[act: templateId 2.16.840.1.113883.10.20.22.4.35(open)]

The Discharge Medications entry codes medications that the patient is intended to take (or stop) after discharge. At a minimum, the currently active medications should be coded.

1. **SHALL** contain exactly one [1..1] **@classCode**="ACT" (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) (CONF:7689).
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) (CONF:7690).
3. **SHALL** contain exactly one [1..1] **code/@code**="10183-2" Discharge medication (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:7691).
4. **SHALL** contain exactly one [1..1] **entryRelationship** (CONF:7692) such that it
   1. **SHALL** contain exactly one [1..1] **@typeCode**="SUBJ" (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) (CONF:7693).
   2. **SHALL** contain exactly one [1..1] [**Medication Activity**](#CS_MedicationActivity) (templateId:2.16.840.1.113883.10.20.22.4.16) (CONF:7694).

Drug Vehicle

[participantRole: templateId 2.16.840.1.113883.10.20.21.4.24(open)]

This template represents the vehicle (e.g. saline, dextrose) for administering a medication.

1. **SHALL** contain exactly one [1..1] **@classCode**="MANU" (CodeSystem: 2.16.840.1.113883.5.110 HL7RoleClass) (CONF:7490).
2. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.4.24" (CONF:7495).
3. **SHALL** contain exactly one [1..1] **code/@code**="412307009" Drug vehicle (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT) (CONF:7491).
4. **SHALL** contain exactly one [1..1] **playingEntity** (CONF:7492).
   1. This playingEntity **SHALL** contain exactly one [1..1] **code** (CONF:7493).
   2. This playingEntity **MAY** contain zero or one [0..1] **name** (CONF:7494).

## Episode Observation

[Observation: templateId 2.16.840.1.113883.10.20.1.41(open)]

This clinical statement represents instances of a problem. Episode observations distinguish among multiple occurrences of a problem or social history item. An episode observation indicates that a problem act represents a new episode, distinct from other episodes of a similar concern.

1. **SHALL** contain exactly one [1..1] **@classCode**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) (CONF-170)
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) (CONF-171)
3. **SHOULD** contain exactly one [1..1] **code/@code**="ASSERTION" (CodeSystem: 2.16.840.1.113883.5.4 ActCode) (CONF-174)
4. **SHALL** contain exactly one [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus) (CONF-172, CONF-173)
5. value element in an episode observation **SHOULD** be the following SNOMED CT expression: <value xsi:type="CD" code="404684003" codeSystem="2.16.840.1.113883.6.96" displayName="Clinical finding"> <qualifier> <name code="246456000" displayName="Episodicity"/> <value code="288527008" displayName="New episode"/> </qualifier> </value> (CONF-175)

Figure 63: Episode observation example

<observation>

</observation>

Health Status Observation

[Observation: templateId 2.16.840.1.113883.10.20.22.4.5(open)]

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

1. **SHALL** contain exactly one [1..1] **@classCode**="OBS" *Observation* (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 exactly one [1..1] **code/@code**="11323-3" *Health status* (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF-166)
4. **SHALL** contain exactly one [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus)
5. **SHALL** contain exactly one [1..1] **value**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.20.12 ProblemHealthStatusCode **STATIC** (CONF-CONSOL-545)
6. **SHOULD** contain exactly one [1..1] **text** (CONF-CONSOL-546)
   1. The 'text' elements **SHOULD** contain a 'reference' element pointing to the narrative where the severity is recorded, rather than duplicate text to avoid ambiguity. (CONF-CONSOL-544)
7. **SHALL NOT** contain any additional Observation attributes.
8. **SHALL NOT** contain any Observation participants.
9. **SHALL NOT** be the source of any Observation relationships.

Table 42: Problem Health Status Code Value Set

|  |  |  |
| --- | --- | --- |
| Value Set: ProblemHealthStatusCode 2.16.840.1.113883.1.11.20.12  Code System: SNOMED CT 2.16.840.1.113883.6.96 | | |
| Concept Code | Concept Name | Code System |
| 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 |

Indication

[observation: templateId 2.16.840.1.113883.10.20.21.4.19(open)]

The Indication Observation documents the rationale for an activity. It can do this with the id element to reference a problem recorded elsewhere in the document or with a code and value to record the problem type and problem within the Indication. For example, the indication for a prescription of a painkiller might be a headache that is documented in the Problems Section.

1. **SHALL** contain exactly one [1..1] **@classCode**="OBS" (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) (CONF:7480).
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) (CONF:7481).
3. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.4.19" (CONF:7482).
4. **SHALL** contain exactly one [1..1] **id** (CONF:7483).
5. Set the observation/id equal to an ID on the problem list to signify that problem as an indication. (In such a case, it may not be necessary to also populate the indication's observation/code and observation/value, particularly if the referenced problem is within the same CDA document). (CONF:7484).
6. **SHALL** contain exactly one [1..1] **statusCode/@code/@code**="completed" Completed (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) (CONF:7487).
7. **SHOULD** contain exactly one [1..1] **effectiveTime** (CONF:7488).
8. **SHOULD** contain exactly one [1..1] **value with @xsi:type="CD"** (CONF:7489).
   1. This value **SHOULD** contain **@code**, which **SHOULD** be selected from ValueSet 2.16.840.1.113883.3.88.12.3221.7.4 Problem **DYNAMIC** (CONF:7991).

Instructions

[act: templateId 2.16.840.1.113883.10.20.21.4.20(open)]

The Instructions template can be used in several ways, such as to record patient instructions within a Medication Activity or to record fill instructions within a supply order. The Act/code defines the type of instruction (e.g. code="311401005" codeSystem="2.16.840.1.113883.6.96" displayName="patient instruction").

1. **SHALL** contain exactly one [1..1] **@classCode**="ACT" (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) (CONF:7391).
2. **SHALL** contain exactly one [1..1] **@moodCode**="INT" (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) (CONF:7392).
3. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.4.20" (CONF:7393).
4. **SHALL** contain exactly one [1..1] **code/@code** (CONF:7394).
5. **SHALL** contain exactly one [1..1] **text** (CONF:7395).
   1. This text **SHOULD** contain zero or one [0..1] **reference** (CONF:7397).
      1. A reference/@value can point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1 ). (CONF:7398).
6. **SHALL** contain exactly one [1..1] **statusCode/@code/@code**="completed" Completed (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) (CONF:7396).

Medication Activity

[substanceAdministration: templateId 2.16.840.1.113883.10.20.21.4.16(open)]

A medication activity describes substance administrations that have actually occurred (e.g. pills ingested or injections given) or are intended to occur (e.g. "take 2 tablets twice a day for the next 10 days"). Medication activities in "INT" mood are reflections of what a clinician intends a patient to be taking. Medication activities in "EVN" mood reflect actual use.

Medication timing is complex. This template requires that there be a substanceAdministration/effectiveTime valued with a time interval, representing the start and stop dates. Additional effectiveTime elements are optional, and can be used to represent frequency and other aspects of more detailed dosing regimens.

1. **SHALL** contain exactly one [1..1] **@classCode**="SBADM" (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) (CONF:7496).
2. **SHALL** contain **@moodCode**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.11.20.9.18 MoodCodeEvnInt **STATIC** 2011-04-03 (CONF:7497).
3. **SHALL** contain exactly one [1..1] **templateId/@root** (CONF:7499).
4. **SHALL** contain at least one [1..\*] **id** (CONF:7500).
5. **MAY** contain zero or one [0..1] **code** (CONF:7506).
6. **SHOULD** contain zero or one [0..1] **text** (CONF:7501).
   1. This text, if present, **SHOULD** contain exactly one [1..1] **reference** (CONF:7502).
      1. A reference/@value SHOULD point to its corresponding narrative. (CONF:7503).
7. **SHALL** contain exactly one [1..1] **statusCode** (CONF:7507).
8. **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:7508) such that it
   1. **SHALL** contain exactly one [1..1] **low** (CONF:7511).
   2. **SHALL** contain exactly one [1..1] **high** (CONF:7512).
9. **SHOULD** contain at least one [1..\*] **effectiveTime** (CONF:7513).
10. **MAY** contain zero or one [0..1] **repeatNumber** (CONF:7555).
    1. In "INT" (intent) mood, the repeatNumber defines the number of allowed administrations. For example, a repeatNumber of "3" means that the substance can be administered up to 3 times. In "EVN" (event) mood, the repeatNumber is the number of occurrences. For example, a repeatNumber of "3" in a dispense act means that the current dispensation is the 3rd. A repeatNumber of "3" in a substance administration event means that the current administration is the 3rd in a series. (CONF:7556).
11. **MAY** contain zero or one [0..1] **routeCode/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.3.88.12.3221.8.7 Medication Route FDA **DYNAMIC** (CONF:7514).
12. **MAY** contain zero or one [0..1] **approachSiteCode/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.3.88.12.3221.8.9 Body site **DYNAMIC** (CONF:7515).
13. **SHOULD** contain exactly one [1..1] **doseQuantity** (CONF:7516).
    1. Pre-coordinated consumable: If the consumable code is a precoordinated unit dose (e.g. "metoprolol 25mg tablet") then doseQuantity is a unitless number that indicates the number of products given per administration (e.g. "2", meaning 2 x "metoprolol 25mg tablet"). Not pre-coordinated consumable: If the consumable code is not pre-coordinated (e.g. is simply "metoprolol"), then doseQuantity must represent a physical quantity with @unit, e.g. "25" and "mg", specifying the amount of product given per administration. (CONF:7533).
    2. This doseQuantity **SHOULD** contain **@unit**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.12839 UCUM Units of Measure (case sensitive) **DYNAMIC** (CONF:7526).
14. **MAY** contain zero or one [0..1] **rateQuantity** (CONF:7517).
    1. This rateQuantity, if present, **SHALL** contain **@unit**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.12839 UCUM Units of Measure (case sensitive) **DYNAMIC** (CONF:7525).
15. Medication Activity SHOULD include doseQuantity OR rateQuantity (CONF:7529).
16. **MAY** contain zero or one [0..1] **maxDoseQuantity** (CONF:7518).
17. **MAY** contain zero or one [0..1] **administrationUnitCode/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.3.88.12.3221.8.11 Medication Product Form **DYNAMIC** (CONF:7519).
18. **SHALL** contain exactly one [1..1] **consumable** (CONF:7520).
    1. This consumable **SHALL** contain exactly one [1..1] [**Medication Information**](#CS_MedicationInformation) (templateId:2.16.840.1.113883.10.20.22.4.23) (CONF:7521).
19. **MAY** contain zero or one [0..1] **performer** (CONF:7522).
20. **MAY** contain zero or more [0..\*] **participant** (CONF:7523) such that it
    1. **SHALL** contain exactly one [1..1] **@typeCode**="CSM" (CodeSystem: 2.16.840.1.113883.5.90 HL7ParticipationType) (CONF:7524).
    2. **SHALL** contain exactly one [1..1] [**Drug vehicle**](#CS_DrugVehicle) (templateId:2.16.840.1.113883.10.20.22.4.24) (CONF:7535).
21. **MAY** contain zero or more [0..\*] **entryRelationship** (CONF:7536) such that it
    1. **SHALL** contain exactly one [1..1] **@typeCode**="RSON" (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) (CONF:7537).
    2. **SHALL** contain exactly one [1..1] [**Indication**](#CS_Indication) (templateId:2.16.840.1.113883.10.20.22.4.19) (CONF:7538).
22. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:7539) such that it
    1. **SHALL** contain exactly one [1..1] **@typeCode**="SUBJ" (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) (CONF:7540).
    2. **SHALL** contain exactly one [1..1] **@inversionInd**="true" (CONF:7542).
    3. **SHALL** contain exactly one [1..1] [**Instructions**](#CS_Instruction) (templateId:2.16.840.1.113883.10.20.22.4.20) (CONF:7541).
23. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:7543) such that it
    1. **SHALL** contain exactly one [1..1] **@typeCode**="REFR" (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) (CONF:7547).
    2. **SHALL** contain exactly one [1..1] [**Medication Supply Order**](#CS_MedicationInSupplyOrder) (templateId:2.16.840.1.113883.10.20.22.4.17) (CONF:7545).
24. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:7549) such that it
    1. **SHALL** contain exactly one [1..1] **@typeCode**="REFR" (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) (CONF:7553).
    2. **SHALL** contain exactly one [1..1] [**Medication Dispense**](#CS_MedicationDispense) (templateId:2.16.840.1.113883.10.20.22.4.18) (CONF:7554).
25. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:7552) such that it
    1. **SHALL** contain exactly one [1..1] **@typeCode**="CAUS" (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) (CONF:7544).
    2. **SHALL** contain exactly one [1..1] [**Reaction Observation**](#CS_ReactionObservation) (templateId:2.16.840.1.113883.10.20.22.4.9) (CONF:7548).
26. **MAY** contain zero or more [0..\*] **precondition** (CONF:7546) such that it
    1. **SHALL** contain exactly one [1..1] **@typeCode**="PRCN" (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) (CONF:7550).
    2. **SHALL** contain exactly one [1..1] [**Precondition for Substance Administration**](#CS_PreconditionForSubstanceAdmin) (templateId:2.16.840.1.113883.10.20.22.4.25) (CONF:7551).

Table 43: MoodCodeEvnInt Value Set

| Value Set: MoodCodeEvnInt 2.16.840.1.113883.11.20.9.18 | | |
| --- | --- | --- |
| Code System(s): | HL7ActMood 2.16.840.1.113883.5.1001 | |
| Description: | Subset of HL7 ActMood codes, constrained to represent event (EVN) and intent (INT) moodes | |
| Code | Code System | Print Name |
| EVN | HL7ActMood | Event |
| INT | HL7ActMood | Intent |

Table 44: Medication Route FDA Value Set

| Value Set: Medication Route FDA Value Set 2.16.840.1.113883.3.88.12.3221.8.7 | | |
| --- | --- | --- |
| Code System(s): | National Cancer Institute (NCI) Thesaurus 2.16.840.1.113883.3.26.1.1 | |
| Description: | This indicates the method for the medication received by the individual (e.g., by mouth, intravenously, topically, etc). NCI concept code for route of administration: C38114  <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162034.htm> | |
|  | Examples of codes for reference | |
| Code | Code System | Print Name |
| C38229 | NCI Thesaurus | INTRACAUDAL |
| C38276 | NCI Thesaurus | INTRAVENOUS |
| C38288 | NCI Thesaurus | ORAL |
| C38295 | NCI Thesaurus | RECTAL |
| … |  |  |

Table 45: Body Site Value Set

| Value Set: Body Site Value Set 2.16.840.1.113883.3.88.12.3221.8.9 | | |
| --- | --- | --- |
| Code System(s): | SNOMED CT 2.16.840.1.113883.6.96 | |
| Description: | Contains values descending from the SNOMED CT® Anatomical Structure (91723000) hierarchy or Acquired body structure (body structure) (280115004) or Anatomical site notations for tumor staging (body structure) (258331007) or Body structure, altered from its original anatomical structure (morphologic abnormality) (118956008) or Physical anatomical entity (body structure) (91722005) This indicates the anatomical site.  <http://www.nlm.nih.gov/research/umls/Snomed/snomed_main.html> | |
|  | Examples of codes for reference | |
| Code | Code System | Print Name |
| 361316009 | SNOMED CT | entire embryonic artery |
| 38033009 | SNOMED CT | amputation stump |
| 9550003 | SNOMED CT | bronchogenic cyst |
| 302509004 | SNOMED CT | heart |
| … |  |  |

Table 46: Medication Product Form Value Set

| Value Set: Medication Product Form 2.16.840.1.113883.3.88.12.3221.8.11 | | |
| --- | --- | --- |
| Code System(s): | National Cancer Institute (NCI) Thesaurus 2.16.840.1.113883.3.26.1.1 | |
| Description: | This is the physical form of the product as presented to the individual. For example: tablet, capsule, liquid or ointment.  <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162038.htm> | |
|  | Example of Codes for reference | |
| Code | Code System | Print Name |
| C42887 | NCI Thesaurus | AEROSOL |
| C42909 | NCI Thesaurus | GRANULE, EFFERVESCENT |
| C42998 | NCI Thesaurus | TABLET |
| … |  |  |

Table 47: Unit of Measure Value Set

| Value Set: Unit of Measure 2.16.840.1.113883.3.88.12.80.29 (or 2.16.840.1.113883.1.11.12839) | | |
| --- | --- | --- |
| Code System(s): | Unified Code for Units of Measure (UCUM) 2.16.840.1.113883.6.8 | |
| Description: | UCUM codes include all units of measures being contemporarily used in international science, engineering, and business. The purpose is to facilitate unambiguous electronic communication of quantities together with their units. The focus is on electronic communication, as opposed to communication between humans.  <http://www.regenstrief.org/medinformatics/ucum> | |
|  | Example of Codes for reference | |
| Code | Code System | Print Name |
| mmol/kg | UCUM | MilliMolesPerKiloGram |
| fL | UCUM | FemtoLiter |
| ug/mL | UCUM | MicroGramsPerMilliLiter |
| … |  |  |

Medication Dispense

[supply: templateId 2.16.840.1.113883.10.20.21.4.18(open)]

1. **SHALL** contain exactly one [1..1] **@classCode**="SPLY" (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) (CONF:7451).
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) (CONF:7452).
3. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.4.18" (CONF:7453).
4. **SHALL** contain at least one [1..\*] **id** (CONF:7454).
5. **SHALL** contain exactly one [1..1] **statusCode/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.3.88.12.80.64 Medication Fill Status **DYNAMIC** (CONF:7455).
6. **SHOULD** contain exactly one [1..1] **effectiveTime** (CONF:7456).
7. **SHOULD** contain exactly one [1..1] **repeatNumber** (CONF:7457).
   1. In "EVN" (event) mood, the repeatNumber is the number of occurrences. For example, a repeatNumber of "3" in a dispense act means that the current dispensation is the 3rd. A repeatNumber of "3" in a substance administration event means that the current administration is the 3rd in a series. (CONF:7466).
8. **SHOULD** contain exactly one [1..1] **quantity** (CONF:7458).
9. **MAY** contain zero or one [0..1] **product** (CONF:7459) such that it
   1. **SHALL** contain exactly one [1..1] [**Medication Information**](#CS_MedicationInformation) (templateId:2.16.840.1.113883.10.20.22.4.23) (CONF:7460).
10. **MAY** contain zero or one [0..1] **performer** (CONF:7461).
11. **SHALL** contain exactly one [1..1] **assignedEntity** (CONF:7467).
    1. This assignedEntity **SHOULD** contain exactly one [1..1] [**US Realm Clinical Document Header Address**](#S_USRealmHeaderAddress) (templateId:2.16.840.1.113883.10.20.22.5.2) (CONF:7468).
12. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:7473) such that it
    1. **SHALL** contain exactly one [1..1] **@typeCode**="REFR" (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) (CONF:7474).
    2. **SHALL** contain exactly one [1..1] [**Medication Supply Order**](#CS_MedicationInSupplyOrder) (templateId:2.16.840.1.113883.10.20.22.4.17) (CONF:7476).

Table 48: Medication Fill Status

|  |  |  |
| --- | --- | --- |
| Value Set: Medication Fill Status 2.16.840.1.113883.3.88.12.80.64  Code System: ActStatus 2.16.840.1.113883.5.14 | | |
| Concept Code | Concept Name | Code System | |
| aborted | Aborted | ActStatus | |
| completed | Completed | ActStatus | |

Medication Information

[manufacturedProduct: templateId 2.16.840.1.113883.10.20.21.4.23(open)]

The medication can be recorded as a precoordinated product strength, product form, or product concentration (e.g. "metoprolol 25mg tablet", "amoxicillin 400mg/5mL suspension"); or not pre-coordinated (e.g. "metoprolol product").

1. **SHALL** contain exactly one [1..1] **@classCode**="MANU" (CodeSystem: 2.16.840.1.113883.5.110 HL7RoleClass) (CONF:7408).
2. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.4.23" (CONF:7409).
3. **MAY** contain zero or more [0..\*] **id** (CONF:7410).
4. **SHALL** contain exactly one [1..1] **manufacturedMaterial** (CONF:7411).
   1. This manufacturedMaterial **SHALL** contain exactly one [1..1] **code**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.3.88.12.80.17 Medication Clinical Drug **DYNAMIC** (CONF:7412).
      1. This code **SHOULD** contain exactly one [1..1] **originalText** (CONF:7413).
         1. This originalText **SHOULD** contain exactly one [1..1] **reference** (CONF:7417).
            1. A reference/@value SHOULD point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1 ). (CONF:7418).
      2. This code **MAY** contain zero or more [0..\*] **translation** (CONF:7414).
         1. Translations can be used to represent generic product name, packaged product code, etc. (CONF:7420).
5. **MAY** contain zero or one [0..1] **manufacturerOrganization** (CONF:7416).

Medication Supply Order

[supply: templateId 2.16.840.1.113883.10.20.21.4.17(open)]

1. **SHALL** contain exactly one [1..1] **@classCode**="SPLY" (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) (CONF:7427).
2. **SHALL** contain exactly one [1..1] **@moodCode**="INT" (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) (CONF:7428).
3. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.4.17" (CONF:7429).
4. **SHALL** contain at least one [1..\*] **id** (CONF:7430).
5. **SHALL** contain exactly one [1..1] **statusCode** (CONF:7432).
6. **SHOULD** contain exactly one [1..1] **effectiveTime/high** (CONF:7433).
7. **SHOULD** contain exactly one [1..1] **repeatNumber** (CONF:7434).
   1. In "INT" (intent) mood, the repeatNumber defines the number of allowed fills. For example, a repeatNumber of "3" means that the substance can be supplied up to 3 times (or, can be dispensed, with 2 refills). (CONF:7435).
8. **SHOULD** contain exactly one [1..1] **quantity** (CONF:7436).
9. **MAY** contain zero or one [0..1] **product** (CONF:7439) such that it
   1. **SHALL** contain exactly one [1..1] [**Medication Information**](#CS_MedicationInformation) (templateId:2.16.840.1.113883.10.20.22.4.23) (CONF:7437).
10. **MAY** contain zero or one [0..1] **author** (CONF:7438).
11. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:7442) such that it
    1. **SHALL** contain exactly one [1..1] **@typeCode**="SUBJ" (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) (CONF:7444).
    2. **SHALL** contain exactly one [1..1] **@inversionInd**="true" (CONF:7445).
    3. **SHALL** contain exactly one [1..1] [**Instructions**](#CS_Instruction) (templateId:2.16.840.1.113883.10.20.22.4.20) (CONF:7443).

Medication Use – None Known

observation: templateId 2.16.840.1.113883.10.20.21.4.29(open)]

This template indicates that the subject is not known to be on any medications.

1. **SHALL** contain exactly one [1..1] **@classCode**="OBS" (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) (CONF:7557).
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) (CONF:7558).
3. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.4.29" (CONF:7559).
4. **SHALL** contain at least one [1..\*] **id** (CONF:7560).
5. **SHALL** contain exactly one [1..1] **code/@code**="ASSERTION" (CodeSystem: 2.16.840.1.113883.5.4 HL7ActCode) (CONF:7561).
6. **MAY** contain zero or one [0..1] **text** (CONF:7565).
   1. This text, if present, **SHOULD** contain exactly one [1..1] **reference** (CONF:7566).
      1. A reference/@value SHOULD point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1 ). (CONF:7567).
7. **SHALL** contain exactly one [1..1] **statusCode/@code/@code**="completed" Completed (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) (CONF:7562).
8. **SHOULD** contain exactly one [1..1] **effectiveTime** (CONF:7563).
9. **SHALL** contain exactly one [1..1] **value/@code**="182904002" Drug treatment unknown (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT) (CONF:7564).

Precondition for Substance Administration

[precondition: templateId 2.16.840.1.113883.10.20.21.4.25(open)]

A criterion for administration can be used to record that the medication is to be administered only when the associated criteria are met.

1. **SHALL** contain exactly one [1..1] **@classCode**="OBS" (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) (CONF:7370).
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN.CRT" (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) (CONF:7371).
3. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.4.25" (CONF:7372).
4. **SHALL** contain exactly one [1..1] **criterion** (CONF:7366).
   1. This criterion **SHOULD** contain exactly one [1..1] **code/@code** (CONF:7367).
   2. This criterion **MAY** contain zero or one [0..1] **text** (CONF:7373).
   3. This criterion **SHOULD** contain exactly one [1..1] **value with @xsi:type="CD"** (CONF:7369).

Problem Status

[observation: templateId 2.16.840.1.113883.10.20.22.4.6(open)]

This clinical statement represents the status of a patient problem. Typical values are "Active", "Inactive", and "Resolved". A resolved problem no longer exists as a problem for the patient as of the time of recording (it may reoccur, but that would be a new instance). An inactive problem is one that still exists for the patient but is not currently a cause for concern (e.g., diabetes that is under control). An active problem exists and is a current cause for concern. A problem status observation will always refer to and be contained in a single problem observation.

1. **SHALL** contain exactly one [1..1] **@classCode**="OBS" Observation (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:7357).
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" Event (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:7358).
3. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.4.6" (CONF:7359).
4. **SHALL** contain exactly one [1..1] **code**="33999-4" Status (CodeSystem: 2.16.840.1.113883.6.1 LOINC) **STATIC** (CONF:7361).
5. **SHOULD** contain exactly one [1..1] **text** (CONF:7362).
   1. This text **SHOULD** contain exactly one [1..1] **reference** (CONF:7363).
      1. A reference/@value SHOULD point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1 ). (CONF:7375).
6. **SHALL** contain exactly one [1..1] **statusCode/@code**="completed" Completed (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:7364).
7. **SHALL** contain exactly one [1..1] **value with @xsi:type="CD"**, where the @code **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.20.13 Problem Status **DYNAMIC** (CONF:7365).

Table 49: Problem Status Value Set

|  |  |  |
| --- | --- | --- |
| Value Set: ProblemStatusCode 2.16.840.1.113883.1.11.20.13  Code System: SNOMED CT 2.16.840.1.113883.6.96 | | |
| Concept Code | Concept Name | Code System | |
| 55561003 | Active | SNOMED CT | |
| 73425007 | Inactive | SNOMED CT | |
| 90734009 | Chronic | SNOMED CT | |
| 7087005 | Intermittent | SNOMED CT | |
| 255227004 | Recurrent | SNOMED CT | |
| 415684004 | Rule out | SNOMED CT | |
| 410516002 | Ruled out | SNOMED CT | |
| 413322009 | Resolved | SNOMED CT | |

Figure 64: Problem status example

<observation classCode="OBS" moodCode="EVN">

<!-- Status observation template -->

<templateId root="2.16.840.1.113883.10.20.21.4.6"/>

<code code="33999-4" codeSystem="2.16.840.1.113883.6.1"

codeSystemName="LOINC" displayName="Status"/>

<statusCode code="completed"/>

<value xsi:type="CE" code="55561003"

codeSystem="2.16.840.1.113883.6.96"

codeSystemName="SNOMED" displayName="Active"/>

</observation>

Procedure Activity Act

[act: templateId 2.16.840.1.113883.10.20.22.4.12(open)]

This clinical statement represents any procedure that cannot be classified as an observation or a procedure according to the HL7 RIM. Examples of these procedures are a dressing change, teaching or feeding a patient or providing comfort measures.

1. **SHALL** contain exactly one [1..1] **@classCode**="ACT" *Act* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:8289).
2. **SHALL** contain **@moodCode**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.11.20.9.18 MoodCodeEvnInt **STATIC** 2011-04-03 (CONF:8290).
3. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.4.12" (CONF:8291).
4. **SHALL** contain at least one [1..\*] **id** (CONF:8292).
5. **SHALL** contain exactly one [1..1] **code** (CONF:8293).
   1. This code @code in a procedure activity observation SHOULD be selected from LOINC (codeSystem 2.16.840.1.113883.6.1) or SNOMED-CT CT (codeSystem 2.16.840.1.113883.6.96). (CONF:8294).
   2. This code **SHOULD** contain exactly one [1..1] **originalText** (CONF:8295).
      1. This originalText **SHOULD** contain exactly one [1..1] **reference** (CONF:8296).
         1. A reference/@value SHOULD point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1 ). (CONF:8297).
6. **SHALL** contain exactly one [1..1] **statusCode/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.11.20.9.22 ProcedureAct statusCode **DYNAMIC** (CONF:8298).
7. **SHOULD** contain zero or one [0..1] **effectiveTime** (CONF:8299).
8. **MAY** contain zero or one [0..1] **priorityCode/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.16866 ActPriority **DYNAMIC** (CONF:8300).
9. **SHOULD** contain zero or more [0..\*] **performer** (CONF:8301).
   1. Such performers, if present, **SHALL** contain exactly one [1..1] **assignedEntity** (CONF:8302).
      1. This assignedEntity **SHALL** contain at least one [1..\*] **id** (CONF:8303).
      2. This assignedEntity **SHALL** contain exactly one [1..1] **addr** (CONF:8304).
      3. This assignedEntity **SHALL** contain exactly one [1..1] **telecom** (CONF:8305).
      4. This assignedEntity **SHOULD** contain zero or one [0..1] **representedOrganization** (CONF:8306).
         1. This representedOrganization, if present, **SHOULD** contain zero or more [0..\*] **id** (CONF:8307).
         2. This representedOrganization, if present, **MAY** contain zero or more [0..\*] **name** (CONF:8308).
         3. This representedOrganization, if present, **SHALL** contain exactly one [1..1] **addr** (CONF:8309).
         4. This representedOrganization, if present, **SHALL** contain exactly one [1..1] **telecom** (CONF:8310).
10. **MAY** contain zero or more [0..\*] **participant** (CONF:8311).
    1. Such participants, if present, **SHALL** contain exactly one [1..1] **@typeCode**="LOC" *Location* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:8312).
    2. Such participants, if present, **SHALL** contain exactly one [1..1] [**Service Delivery Location**](#CS_ServiceDellivery) (templateId:2.16.840.1.113883.10.20.22.4.32) (CONF:8313).
11. **MAY** contain zero or more [0..\*] **entryRelationship** (CONF:8314).
    1. Such entryRelationships, if present, **SHALL** contain exactly one [1..1] **@typeCode**="COMP" *Component* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:8315).
    2. Such entryRelationships, if present, **SHALL** contain exactly one [1..1] **@inversionInd**="true" *true* (CONF:8316).
    3. Such entryRelationships, if present, **SHALL** contain exactly one [1..1] **encounter** (CONF:8317).
       1. This encounter **SHALL** contain exactly one [1..1] **@classCode**="ENC" *Encounter* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:8318).
       2. This encounter **SHALL** contain exactly one [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:8319).
          1. Set the encounter ID to the ID of an encounter in another section to signify they are the same encounter. (CONF:8321).
       3. This encounter **SHALL** contain exactly one [1..1] **id** (CONF:8320).
12. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:8322).
    1. This entryRelationship, if present, **SHALL** contain exactly one [1..1] **@typeCode**="SUBJ" *Has Subject* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:8323).
    2. This entryRelationship, if present, **SHALL** contain exactly one [1..1] **@inversionInd**="true" *true* (CONF:8324).
    3. This entryRelationship, if present, **SHALL** contain exactly one [1..1] [**Instructions**](#CS_Instruction) (templateId:2.16.840.1.113883.10.20.22.4.20) (CONF:8325).
13. **MAY** contain zero or more [0..\*] **entryRelationship** (CONF:8326).
    1. Such entryRelationships, if present, **SHALL** contain exactly one [1..1] **@typeCode**="RSON" *Has Reason* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:8327).
    2. Such entryRelationships, if present, **SHALL** contain exactly one [1..1] [**Indication**](#CS_Indication) (templateId:2.16.840.1.113883.10.20.22.4.19) (CONF:8328).
14. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:8329).
    1. This entryRelationship, if present, **SHALL** contain exactly one [1..1] **@typeCode**="COMP" *Has Compenent* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:8330).
    2. This entryRelationship, if present, **SHALL** contain exactly one [1..1] [**Medication Activity**](#CS_MedicationActivity) (templateId:2.16.840.1.113883.10.20.22.4.16) (CONF:8331).

Table 50: Procedure Act Status Code Value Set

| Value Set: ProcedureAct statusCode 2.16.840.1.113883.11.20.9.22 | | |
| --- | --- | --- |
| Code System(s): | HL7ActStatus 2.16.840.1.113883.5.14 | |
| Description: | A ValueSet of HL7 actStatus codes for use with a procedure activity | |
| Code | Code System | Print Name |
| Completed | HL7ActStatus | Completed |
| active | HL7ActStatus | Active |
| aborted | HL7ActStatus | Aborted |
| cancelled | HL7ActStatus | Cancelled |

Table 51: Act Priority Value Set

| Value Set: ActPriority 2.16.840.1.113883.1.11.16866 | | |
| --- | --- | --- |
| Code System(s): | ActPriority 2.16.840.1.113883.5.7 | |
| Description: | A code or set of codes (e.g., for routine, emergency,) specifying the urgency under which the Act happened, can happen, is happening, is intended to happen, or is requested/demanded to happen. | |
| Code | Code System | Print Name |
| A | ActPriority | ASAP |
| CR | ActPriority | Callback results |
| CS | ActPriority | Callback for scheduling |
| CSP | ActPriority | Callback placer for scheduling |
| CSR | ActPriority | Contact recipient for scheduling |
| EL | ActPriority | Elective |
| EM | ActPriority | Emergency |
| P | ActPriority | Preop |
| PRN | ActPriority | As needed |
| R | ActPriority | Routine |
| RR | ActPriority | Rush reporting |
| S | ActPriority | Stat |
| T | ActPriority | Timing critical |
| UD | ActPriority | Use as directed |
| UR | ActPriority | Urgent |

Procedure Activity Observation

[observation: templateId 2.16.840.1.113883.10.20.22.4.13(open)]

This clinical statement represents procedures that result in new information about the patient that cannot be classified as a procedure according to the HL7 RIM. Examples of these procedures are diagnostic imaging procedures, EEGs and EKGs.

1. **SHALL** contain exactly one [1..1] **@classCode**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:8282).
2. **SHALL** contain **@moodCode**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.11.20.9.18 MoodCodeEvnInt **STATIC** 2011-04-03 (CONF:8237).
3. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.4.13" (CONF:8238).
4. **SHALL** contain at least one [1..\*] **id** (CONF:8239).
5. **SHALL** contain exactly one [1..1] **code** (CONF:8240).
   1. This code @code in a procedure activity SHOULD be selected from LOINC (codeSystem 2.16.840.1.113883.6.1) or SNOMED-CT CT (codeSystem 2.16.840.1.113883.6.96), and MAY be selected from CPT-4 (codeSystem 2.16.840.1.113883.6.12), ICD9 Procedures (codeSystem 2.16.840.1.113883.6.4). (CONF:8241).
   2. This code **SHOULD** contain exactly one [1..1] **originalText** (CONF:8242).
      1. This originalText **SHOULD** contain exactly one [1..1] **reference** (CONF:8243).
         1. A reference/@value SHOULD point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1 ). (CONF:8244).
6. **SHALL** contain exactly one [1..1] **statusCode/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.11.20.9.22 ProcedureAct statusCode **DYNAMIC** (CONF:8245).
7. **SHALL** contain exactly one [1..1] **value** (CONF:8368).
8. **SHOULD** contain zero or one [0..1] **effectiveTime** (CONF:8246).
9. **MAY** contain zero or one [0..1] **priorityCode/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.16866 ActPriority **DYNAMIC** (CONF:8247).
10. **MAY** contain zero or one [0..1] **methodCode** (CONF:8248).
11. **SHOULD** contain zero or more [0..\*] **targetSiteCode/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.3.88.12.3221.8.9 Body site **DYNAMIC** (CONF:8250).
12. **SHOULD** contain zero or more [0..\*] **performer** (CONF:8251).
    1. Such performers, if present, **SHALL** contain exactly one [1..1] **assignedEntity** (CONF:8252).
       1. This assignedEntity **SHALL** contain at least one [1..\*] **id** (CONF:8253).
       2. This assignedEntity **SHALL** contain exactly one [1..1] **addr** (CONF:8254).
       3. This assignedEntity **SHALL** contain exactly one [1..1] **telecom** (CONF:8255).
       4. This assignedEntity **SHOULD** contain zero or one [0..1] **representedOrganization** (CONF:8256).
          1. This representedOrganization, if present, **SHOULD** contain zero or more [0..\*] **id** (CONF:8257).
          2. This representedOrganization, if present, **MAY** contain zero or more [0..\*] **name** (CONF:8258).
             1. methodCode SHALL NOT conflict with the method inherent in Observation / code. (CONF:8249).
          3. This representedOrganization, if present, **SHALL** contain exactly one [1..1] **addr** (CONF:8259).
          4. This representedOrganization, if present, **SHALL** contain exactly one [1..1] **telecom** (CONF:8260).
13. **MAY** contain zero or more [0..\*] **participant** (CONF:8261).
    1. Such participants, if present, **SHALL** contain exactly one [1..1] **@typeCode**="LOC" *Location* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:8262).
    2. Such participants, if present, **SHALL** contain exactly one [1..1] [**Service Delivery Location**](#CS_ServiceDellivery) (templateId:2.16.840.1.113883.10.20.22.4.32) (CONF:8263).
14. **MAY** contain zero or more [0..\*] **entryRelationship** (CONF:8264).
    1. Such entryRelationships, if present, **SHALL** contain exactly one [1..1] **@typeCode**="COMP" *Component* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:8265).
    2. Such entryRelationships, if present, **SHALL** contain exactly one [1..1] **@inversionInd**="true" *true* (CONF:8266).
    3. Such entryRelationships, if present, **SHALL** contain exactly one [1..1] **encounter** (CONF:8267).
       1. This encounter **SHALL** contain exactly one [1..1] **@classCode**="ENC" *Encounter* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:8268).
       2. This encounter **SHALL** contain exactly one [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:8269).
       3. This encounter **SHALL** contain exactly one [1..1] **id** (CONF:8270).
          1. Set the encounter ID to the ID of an encounter in another section to signify they are the same encounter. (CONF:8271).
15. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:8272).
    1. This entryRelationship, if present, **SHALL** contain exactly one [1..1] **@typeCode**="SUBJ" *Has Subject* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:8273).
    2. This entryRelationship, if present, **SHALL** contain exactly one [1..1] **@inversionInd**="true" *true* (CONF:8274).
    3. This entryRelationship, if present, **SHALL** contain exactly one [1..1] [**Instructions**](#CS_Instruction) (templateId:2.16.840.1.113883.10.20.22.4.20) (CONF:8275).
16. **MAY** contain zero or more [0..\*] **entryRelationship** (CONF:8276).
    1. Such entryRelationships, if present, **SHALL** contain exactly one [1..1] **@typeCode**="RSON" *Has Reason* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:8277).
    2. Such entryRelationships, if present, **SHALL** contain exactly one [1..1] [**Indication**](#CS_Indication) (templateId:2.16.840.1.113883.10.20.22.4.19) (CONF:8278).
17. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:8279).
    1. This entryRelationship, if present, **SHALL** contain exactly one [1..1] **@typeCode**="COMP" *Has Compenent* (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:8280).
    2. This entryRelationship, if present, **SHALL** contain exactly one [1..1] [**Medication Activity**](#CS_MedicationActivity) (templateId:2.16.840.1.113883.10.20.22.4.16) (CONF:8281).

## Procedure Activity Procedure

[procedure: templateId 2.16.840.1.113883.10.20.22.4.14(open)]

This clinical statement represents procedures whose immediate and primary outcome (post-condition) is the alteration of the physical condition of the patient. Examples of these procedures are an appendectomy, hip replacement and a creation of a gastrostomy.

1. **SHALL** contain exactly one [1..1] **@classCode**="PROC" Procedure (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:7652).
2. **SHALL** contain **@moodCode**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.11.20.9.18 MoodCodeEvnInt **STATIC** 2011-04-03 (CONF:7653).
3. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.4.14" (CONF:7654).
4. **SHALL** contain at least one [1..\*] **id** (CONF:7655).
5. **SHALL** contain exactly one [1..1] **code** (CONF:7656).
   1. This code @code in a procedure activity SHOULD be selected from LOINC (codeSystem 2.16.840.1.113883.6.1) or SNOMED-CT CT (codeSystem 2.16.840.1.113883.6.96), and MAY be selected from CPT-4 (codeSystem 2.16.840.1.113883.6.12), ICD9 Procedures (codeSystem 2.16.840.1.113883.6.104), ICD10 Procedure Coding System (codeSystem 2.16.840.1.113883.6.4). (CONF:7657).
   2. This code **SHOULD** contain exactly one [1..1] **originalText** (CONF:7658).
      1. This originalText **SHOULD** contain exactly one [1..1] **reference** (CONF:7659).
         1. A reference/@value SHOULD point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1 ). (CONF:7660).
6. **SHALL** contain exactly one [1..1] **statusCode/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.11.20.9.22 ProcedureAct statusCode **DYNAMIC** (CONF:7661).
7. **SHOULD** contain zero or one [0..1] **effectiveTime** (CONF:7662).
8. **MAY** contain zero or one [0..1] **priorityCode/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.16866 ActPriority **DYNAMIC** (CONF:7668).
9. **MAY** contain zero or one [0..1] **methodCode** (CONF:7670).
   1. methodCode SHALL NOT conflict with the method inherent in Procedure / code. (CONF:7890).
10. **SHOULD** contain zero or more [0..\*] **targetSiteCode/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.3.88.12.3221.8.9 Body site **DYNAMIC** (CONF:7683).
11. **MAY** contain zero or more [0..\*] **specimen** (CONF:7697).
    1. This specimen is for representing specimens obtained from a procedure. (CONF:8008).
    2. Such specimens, if present, **SHALL** contain exactly one [1..1] **specimenRole** (CONF:7704).
       1. This specimenRole **SHOULD** contain zero or more [0..\*] **id** (CONF:7716).
          1. Procedure / specimen / specimenRole / id SHOULD be set to equal an Organizer / specimen / specimenRole / id to indicate that the Procedure and the Results are referring to the same specimen. (CONF:7717).
12. **SHOULD** contain zero or more [0..\*] **performer** (CONF:7718) such that it
    1. **SHALL** contain exactly one [1..1] **assignedEntity** (CONF:7720).
       1. This assignedEntity **SHALL** contain at least one [1..\*] **id** (CONF:7722).
       2. This assignedEntity **SHALL** contain exactly one [1..1] **addr** (CONF:7731).
       3. This assignedEntity **SHALL** contain exactly one [1..1] **telecom** (CONF:7732).
       4. This assignedEntity **SHOULD** contain zero or one [0..1] **representedOrganization** (CONF:7733).
          1. This representedOrganization, if present, **SHOULD** contain zero or more [0..\*] **id** (CONF:7734).
          2. This representedOrganization, if present, **MAY** contain zero or more [0..\*] **name** (CONF:7735).
          3. This representedOrganization, if present, **SHALL** contain exactly one [1..1] **addr** (CONF:7736).
          4. This representedOrganization, if present, **SHALL** contain exactly one [1..1] **telecom** (CONF:7737).
13. **MAY** contain zero or more [0..\*] **participant** (CONF:7751) such that it
    1. **SHALL** contain exactly one [1..1] **@typeCode**="DEV" Device (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:7752).
    2. **SHALL** contain exactly one [1..1] [**Product Instance**](#CS_ProductInstance) (templateId:2.16.840.1.113883.10.20.22.4.37) (CONF:7754).
14. **MAY** contain zero or more [0..\*] **participant** (CONF:7765) such that it
    1. **SHALL** contain exactly one [1..1] **@typeCode**="LOC" Location (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:7766).
    2. **SHALL** contain exactly one [1..1] [**Service Delivery Location**](#CS_ServiceDellivery) (templateId:2.16.840.1.113883.10.20.22.4.32) (CONF:7767).
15. **MAY** contain zero or more [0..\*] **entryRelationship** (CONF:7768) such that it
    1. **SHALL** contain exactly one [1..1] **@typeCode**="COMP" Component (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:7769).
    2. **SHALL** contain exactly one [1..1] **@inversionInd**="true" true (CONF:8009).
    3. **SHALL** contain exactly one [1..1] **encounter** (CONF:7770).
       1. This encounter **SHALL** contain exactly one [1..1] **@classCode**="ENC" Encounter (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:7771).
       2. This encounter **SHALL** contain exactly one [1..1] **@moodCode**="EVN" Event (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:7772).
       3. This encounter **SHALL** contain exactly one [1..1] **id** (CONF:7773).
          1. Set the encounter ID to the ID of an encounter in another section to signify they are the same encounter. (CONF:7774).
16. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:7775) such that it
    1. **SHALL** contain exactly one [1..1] **@typeCode**="SUBJ" Has Subject (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:7776).
    2. **SHALL** contain exactly one [1..1] **@inversionInd**="true" true (CONF:7777).
    3. **SHALL** contain exactly one [1..1] [**Instructions**](#CS_Instruction) (templateId:2.16.840.1.113883.10.20.22.4.20) (CONF:7778).
17. **MAY** contain zero or more [0..\*] **entryRelationship** (CONF:7779) such that it
    1. **SHALL** contain exactly one [1..1] **@typeCode**="RSON" Has Reason (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:7780).
    2. **SHALL** contain exactly one [1..1] [**Indication**](#CS_Indication) (templateId:2.16.840.1.113883.10.20.22.4.19) (CONF:7781).
18. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:7886) such that it
    1. **SHALL** contain exactly one [1..1] **@typeCode**="COMP" Has Compenent (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:7887).
    2. **SHALL** contain exactly one [1..1] [**Medication Activity**](#CS_MedicationActivity) (templateId:2.16.840.1.113883.10.20.22.4.16) (CONF:7888).

Figure 65: Procedure activity procedure example

<procedure classCode="PROC" moodCode="EVN">

<!-- Procedure activity procedure template -->

<templateId root="2.16.840.1.113883.10.20.22.4.14"/>

<id root="e401f340-7be2-11db-9fe1-0800200c9a66"/>

<code code="397394009" codeSystem="2.16.840.1.113883.6.96"

displayName="Bronchoalveolar lavage">

<originalText>Bronchoalveolar<reference value="procedure1"/></originalText>

</code>

<text>

<reference value="procedure1"/>

</text>

<statusCode code="completed"/>

<effectiveTime value="1998"/>

<methodCode code="168731009" codeSystem="2.16.840.1.113883.6.96"

displayName="Standard chest X-ray"/>

<targetSiteCode code="82094008" codeSystem="2.16.840.1.113883.6.96"

displayName="Lower respiratory tract structure"/>

<specimen>

<specimenRole>

<id extension="234234"/>

</specimenRole>

</specimen>

<participant typeCode="DEV">

<participantRole classCode="MANU">

<!-- Product instance template -->

<templateId root="2.16.840.1.113883.10.20.22.4.37"/>

<id root="03ca01b0-7be1-11db-9fe1-0800200c9a66"/>

<addr nullFlavor="NA"/>

<telecom nullFlavor="NA"/>

<scopingEntity nullFlavor="NA"/>

</participantRole>

</participant>

<entryRelationship typeCode="SUBJ">

<act classCode="ACT" moodCode="INT">

<code code="29630014" codeSystem="2.16.840.1.113883.6.96"

codeSystemName="SNOMED CT" displayName="Bed rest"/>

<text>Bed-rest for next 7 days.</text>

</act>

</entryRelationship>

<entryRelationship typeCode="RSON">

<observation classCode="OBS" moodCode="EVN">

<code code="1778239014" codeSystem="2.16.840.1.113883.6.96"

displayName="Rheumatoid lung disease"

codeSystemName="SNOMED CT"/>

<statusCode code="completed"/>

</observation>

</entryRelationship>

<entryRelationship typeCode="SUBJ">

<observation classCode="OBS" moodCode="EVN">

<!-- Age observation template -->

<templateId root=" 2.16.840.1.113883.10.20.22.4.31"/>

<code code="397659008" codeSystem="2.16.840.1.113883.6.96"

codeSystemName="SNOMEDCT" displayName="Age"/>

<statusCode code="completed"/>

<value xsi:type="INT" value="54"/>

</observation>

</entryRelationship>

<entryRelationship typeCode="COMP" inversionInd="true">

<substanceAdministration classCode="SBADM" moodCode="INT">

<!-- Medication activity template -->

<templateId root=" 2.16.840.1.113883.10.20.22.4.16"/>

...

</substanceAdministration>

</entryRelationship>

<entryRelationship typeCode="REFR">

<act classCode="ACT" moodCode="EVN">

<!-- Reference entry template -->

...

</act>

</entryRelationship>

</procedure>

Product Instance

[participantRole: templateId 2.16.840.1.113883.10.20.22.4.37(open)]

This clinical statement represents a particular device that was placed in or used as part of a procedure or other act. This is used to have a record of the identifier and other details about the given product that was used. For example, it is important to have a record that indicates not just that a hip prostheses was placed in patient but that it was a particular hip prostheses number with a unique identifier.

1. **SHALL** contain exactly one [1..1] **@typeCode**="MANU" Manufactured Product (CodeSystem: 2.16.840.1.113883.5.110 HL7RoleClass) (CONF:7900).
2. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.4.37" (CONF:7901).
3. **SHALL** contain at least one [1..\*] **id** (CONF:7902).
4. **SHALL** contain exactly one [1..1] **playingDevice** (CONF:7903).
   1. This playingDevice **SHOULD** contain zero or one [0..1] **code** (CONF:7904).
5. **SHALL** contain exactly one [1..1] **scopingEntity** (CONF:7905).
   1. This scopingEntity **SHALL** contain at least one [1..\*] **id** (CONF:7908).

Reaction Observation

[observation: templateId 2.16.840.1.113883.10.20.21.4.9(open)]

This template represents the symptom the patient presents with when exposed to the substance.

1. **SHALL** contain exactly one [1..1] **@classCode**="OBS" Observation (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:7325).
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" Event (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:7326).
3. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.4.9" (CONF:7323).
4. **SHALL** contain exactly one [1..1] **id** (CONF:7329).
5. **SHALL** contain exactly one [1..1] **code** (CONF:7327).
6. **SHOULD** contain exactly one [1..1] **text** (CONF:7330).
   1. This text **SHOULD** contain exactly one [1..1] **reference** (CONF:7331).
      1. A reference/@value SHOULD point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1 ). (CONF:7377).
7. **SHALL** contain exactly one [1..1] **statusCode/@code**="completed" Completed (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:7328).
8. **SHOULD** contain exactly one [1..1] **effectiveTime** (CONF:7332).
   1. This effectiveTime **SHOULD** contain exactly one [1..1] **low** (CONF:7333).
   2. This effectiveTime **SHOULD** contain exactly one [1..1] **high** (CONF:7334).
9. **SHALL** contain exactly one [1..1] **value with @xsi:type="CD"**, where the @code **SHALL** be selected from ValueSet 2.16.840.1.113883.3.88.12.3221.7.4 Problem **DYNAMIC** (CONF:7335).
10. **SHOULD** contain exactly one [1..1] **entryRelationship** (CONF:7580) such that it
    1. **SHALL** contain exactly one [1..1] **@typeCode**="SUBJ" Has subject (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) (CONF:7581).
    2. **SHALL** contain exactly one [1..1] [**Severity Observation**](#CS_SeverityObservation) (templateId:2.16.840.1.113883.10.20.22.4.8) (CONF:7582).
11. **MAY** contain zero or more [0..\*] **entryRelationship** (CONF:7337) such that it
    1. **SHALL** contain exactly one [1..1] **@typeCode**="RSON" Has reason (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:7338).
    2. **SHALL** contain exactly one [1..1] **@inversionInd**="true" (CONF:7343).
    3. **SHALL** contain exactly one [1..1] [**Procedure Activity Procedure**](#CS_ProcedureActivityProcedure) (templateId:2.16.840.1.113883.10.20.22.4.14) (CONF:7339).
       1. This procedure activity is intended to contain information about procedures that were performed in response to an allergy reaction (CONF:7583).
12. **MAY** contain zero or more [0..\*] **entryRelationship** (CONF:7340) such that it
    1. **SHALL** contain exactly one [1..1] **@typeCode**="RSON" Has reason (CodeSystem: 2.16.840.1.113883.5.1002 HL7ActRelationshipType) **STATIC** (CONF:7341).
    2. **SHALL** contain exactly one [1..1] **@inversionInd**="true" (CONF:7344).
    3. **SHALL** contain exactly one [1..1] [**Medication Activity**](#CS_MedicationActivity) (templateId:2.16.840.1.113883.10.20.22.4.16) (CONF:7342).
       1. This medication activity is intended to contain information about medications that were administered in response to an allergy reaction. (CONF:7584).

Figure 66: Reaction observation example

<observation classCode="OBS" moodCode="EVN">

<templateId root="2.16.840.1.113883.10.20.21.4.9"/>

<!-- Reaction observation template -->

<code code="ASSERTION"

codeSystem="2.16.840.1.113883.5.4"/>

<statusCode code="completed"/>

<value xsi:type="CD" code="56018004"

codeSystem="2.16.840.1.113883.6.96"

displayName="Wheezing"

xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"/>

</observation>

Result Organizer

[organizer: templateId 2.16.840.1.113883.10.20.21.4.1(open)]

This clinical statement identifies set of result observations. It contains information applicable to all of the contained result observations. Result type codes categorize a result into one of several commonly accepted values (e.g., “Hematology”, “Chemistry”, “Nuclear Medicine”). These values are often implicit in the Organizer/code (e.g., an Organizer/code of “complete blood count” implies a ResultTypeCode of “Hematology”). This template requires Organizer/code to include a ResultTypeCode either directly or as a translation of a code from some other code system.

1. ***SHALL*** *contain* ***@classCode*** *(CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) (CONF:7121).* 
   1. *SHOULD be "BATTERY" or "CLUSTER" (CONF:7165).*
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" Event (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) (CONF:7122).
3. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.4.1" (CONF:7126).
4. ***SHALL*** *contain at least one [1..\*]* ***id*** *(CONF:7127).*
5. ***SHALL*** *contain exactly one [1..1]* ***code*** *(CONF:7128).* 
   1. SHOULD be from LOINC (CodeSystem: 2.16.840.1.113883.6.1) or SNOMED CT (CodeSystem: 2.16.840.1.113883.6.96), and MAY be selected from CPT-4 (CodeSystem: 2.16.840.1.113883.6.12) (CONF:7164).
6. **SHALL** contain exactly one [1..1] **statusCode/@code**="completed" Completed (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) (CONF:7123).
7. ***SHALL*** *contain at least one [1..\*]* ***component*** *(CONF:7124) such that it* 
   1. ***SHALL*** *contain exactly one [1..1]* [***Result Observation***](#CS_ResultObservation) *(templateId:2.16.840.1.113883.10.20.22.4.2) (CONF:7125).*

Figure 67: Result organizer example

<organizer classCode="BATTERY" moodCode="EVN">

<!-- Result organizer template -->

<templateId root="2.16.840.1.113883.10.20.21.4.1"/>

<id root="7d5a02b0-67a4-11db-bd13-0800200c9a66"/>

<code code="43789009" displayName="CBC WO DIFFERENTIAL"

codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT"/>

<statusCode code="completed"/>

<component>

<observation classCode="OBS" moodCode="EVN">

<!-- Result observation template -->

<templateId root="2.16.840.1.113883.10.20.21.4.2"/>

...

</observation>

</component>

<component>

<observation classCode="OBS" moodCode="EVN">

<!-- Result observation template -->

<templateId root="2.16.840.1.113883.10.20.21.4.2"/>

...

</observation>

</component>

<component>

<observation classCode="OBS" moodCode="EVN">

<!-- Result observation template -->

<templateId root="2.16.840.1.113883.10.20.21.4.2"/>

...

</observation>

</component>

</organizer>

Developer Notes

The Developer Notes below are *informational only* and are not part of the normative standard.

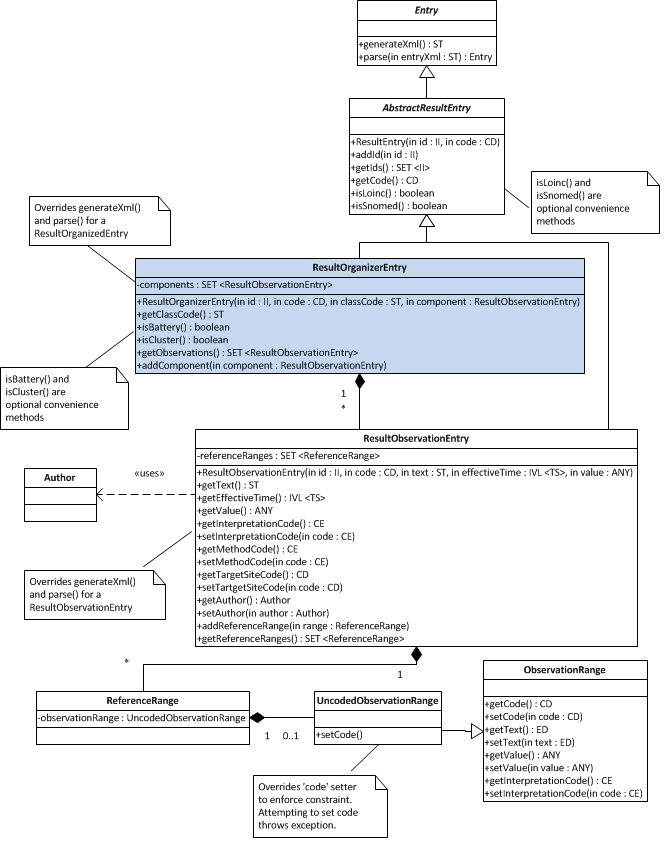
**Context**

The Result Organizer Entry’s possible contexts are shown below.

|  |  |
| --- | --- |
| Contained by Sections | Contains Entries |
| [Results](#_Results_Section_30954-2_2) | [Result Observation](#CS_ResultObservation) |

**UML Class Diagram**

The UML Class diagram for the Results Section is shown below.

**Result Organizer UML Class Diagram**

**Application Programming Interface (API)**

|  |
| --- |
| Constructor Summary |
| [ResultOrganizer](#CS_ResultOrganizer) ([II](datatypes.htm#dt-II) ***id***, [CD](datatypes.htm#dt-CD) *code*, [ST](datatypes.htm#dt-ST) *classCode*, [ResultObservationEntry](#CS_ResultObservation) ***component***) |

|  |  |
| --- | --- |
| Method Summary | |
| [ST](datatypes.htm#dt-ST) | generateXml ( ) |
| [ResultObservationEntry](#CS_ResultObservation) | parse ([ST](datatypes.htm#dt-ST) resultObservationXml) |
| [BL](datatypes.htm#dt-BL) | isBattery( ) |
| [BL](datatypes.htm#dt-BL) | isCluster( ) |
| [ST](datatypes.htm#dt-ST) | getClassCode( ) |
| [SET](datatypes.htm#dt-SET) <[ResultObservationEntry](#CS_ResultObservation)> | getObservations() |
| void | addComponent([ResultObservationEntry](#CS_ResultObservation) ***component*)** |

Result Observation

[observation: templateId 2.16.840.1.113883.10.20.21.4.2(open)]

This clinical statement represents details of a lab, radiology, or other study performed on a patient.

1. **SHALL** contain exactly one [1..1] **@classCode**="OBS" Observation (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) (CONF:7130).
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" Event (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) (CONF:7131).
3. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.4.2" (CONF:7136).
4. ***SHALL*** *contain at least one [1..\*]* ***id*** *(CONF:7137).*
5. ***SHALL*** *contain exactly one [1..1]* ***code*** *(CONF:7133).* 
   1. *SHOULD be from LOINC (CodeSystem: 2.16.840.1.113883.6.1) or SNOMED CT (CodeSystem: 2.16.840.1.113883.6.96) (CONF:7166).*
6. ***SHOULD*** *contain exactly one [1..1]* ***text*** *(CONF:7138).* 
   1. *element SHOULD include a reference element which SHOULD reference the narrative. The reference/@value SHALL begin with a hash '#' mark. (CONF:7139).*
7. **SHALL** contain exactly one [1..1] **statusCode/@code**="completed" Completed (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) (CONF:7134).
8. ***SHALL*** *contain exactly one [1..1]* ***effectiveTime*** *(CONF:7140).* 
   1. *represents clinically effective time of the measurement, which may be when the measurement was performed (e.g., a BP measurement), or may be when sample was taken (and measured some time afterwards). (CONF:7141).*
9. ***SHALL*** *contain exactly one [1..1]* ***value*** *(CONF:7143).*
10. ***SHOULD*** *contain zero or one [0..1]* ***interpretationCode*** *(CONF:7147).*
11. ***MAY*** *contain zero or one [0..1]* ***methodCode*** *(CONF:7148).*
12. ***MAY*** *contain zero or one [0..1]* ***targetSiteCode*** *(CONF:7153).*
13. ***MAY*** *contain zero or one [0..1]* ***author*** *(CONF:7149).*
14. ***SHOULD*** *contain zero or more [0..\*]* ***referenceRange*** *(CONF:7150).* 
    1. *Such referenceRanges, if present,* ***SHALL*** *contain zero or one [0..1]* ***observationRange*** *(CONF:7151).* 
       1. *This observationRange, if present,* ***SHALL NOT*** *contain [0..0]* ***code*** *(CONF:7152).*

Figure 68: Result observation example

<observation classCode="OBS" moodCode="EVN">

<!-- Result observation template -->

<templateId root="2.16.840.1.113883.10.20.21.4.2"/>

<id root="107c2dc0-67a5-11db-bd13-0800200c9a66"/>

<code code="30313-1" displayName="HGB" codeSystem="2.16.840.1.113883.6.1"

codeSystemName="LOINC"/>

<text></text>

<statusCode code="completed"/>

<effectiveTime value="200003231430"/>

<value xsi:type="PQ" value="13.2" unit="g/dl"/>

<interpretationCode code="N" codeSystem="2.16.840.1.113883.5.83"/>

<methodCode/>

<targetSiteCode/>

<author>

<time/>

<assignedAuthor>

<id/>

</assignedAuthor>

</author>

<referenceRange>

<observationRange>

<text>M 13-18 g/dl; F 12-16 g/dl</text>

</observationRange>

</referenceRange>

</observation>

Developer Notes

The Developer Notes below are *informational only* and are not part of the normative standard.

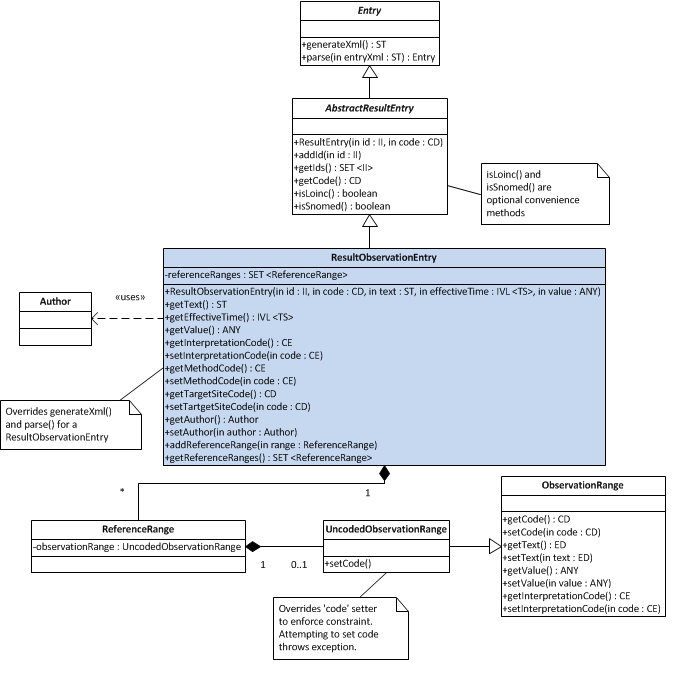
**Context**

The Result Observation Entry’s possible contexts are shown below.

|  |  |  |
| --- | --- | --- |
| Contained by Sections | Contained by Entries | Contains Entries |
| -- | [ResultOrganizer](#CS_ResultOrganizer) | -- |

**UML Class Diagram**

The UML Class diagram for the Result Observation Entry is shown below.

**Result Observation UML Class Diagram**

**Application Programming Interface (API)**

|  |
| --- |
| Constructor Summary |
| [ResultObservationEntry](#CS_ResultObservation) ([II](datatypes.htm#dt-II) ***id***, [CD](datatypes.htm#dt-CD) *code*, [ST](datatypes.htm#dt-ST) *text*, [IVL <TS>](datatypes.htm#dt-IVL_TS) *effectiveTime*, [ANY](datatypes.htm#dt-ANY) *value*) |

|  |  |
| --- | --- |
| Method Summary | |
| [ST](datatypes.htm#dt-ST) | generateXml ( ) |
| [ResultObservationEntry](#CS_ResultObservation) | parse ([ST](datatypes.htm#dt-ST) resultObservationXml) |
| [ST](datatypes.htm#dt-ST) | getText() |
| [IVL <TS>](datatypes.htm#dt-IVL_TS) | getEffectiveTime() |
| [CE](datatypes.htm#dt-CE) | getInterpretationCode() |
| void | setInterpretationCode([CE](datatypes.htm#dt-CE) code) |
| [CE](datatypes.htm#dt-CE) | getMethodCode() |
| void | setMethodCode([CE](datatypes.htm#dt-CE) code) |
| [CD](datatypes.htm#dt-CD) | getTargetSiteCode() |
| void | setTargetSiteCode([CD](datatypes.htm#dt-CD) code) |
| Author | getAuthor() |
| void | setAuthor(Author author) |
| [SET](datatypes.htm#dt-SET) <ReferenceRange> | getReferenceRanges() |
| void | addReferenceRange(ReferenceRange referenceRange**)** |

Service Delivery Location

[participantRole: templateId 2.16.840.1.113883.10.20.22.4.32(open)]

This clinical statement represents the location of a service event where an act, observation or procedure took place.

1. **SHALL** contain exactly one [1..1] **@classCode**="SDLOC" (CodeSystem: 2.16.840.1.113883.5.111 HL7RoleCode) **STATIC** (CONF:7758).
2. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.4.32" (CONF:7635).
3. **SHALL** contain exactly one [1..1] **code/@code**, which **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.17660 ServiceDeliveryLocationRoleType **DYNAMIC** (CONF:7759).
4. **SHOULD** contain at least one [1..\*] **addr** (CONF:7760).
5. **SHOULD** contain at least one [1..\*] **telecom** (CONF:7761).
6. **MAY** contain zero or one [0..1] **playingEntity** (CONF:7762).
   1. This playingEntity, if present, **SHALL** contain exactly one [1..1] **@classCode**="PLC" (CodeSystem: 2.16.840.1.113883.5.41 HL7EntityClass) **STATIC** (CONF:7763).
      1. This @classCode **MAY** contain exactly one [1..1] **name** (CONF:7764).

Table 52: Service Delivery Location Role Type Value Set

| Value Set: HL7 ServiceDeliveryLocationRoleType 2.16.840.1.113883.1.11.17660 | | |
| --- | --- | --- |
| Code System(s): | HL7 RoleCode (2.16.840.1.113883.5.111 | |
| Description: | A role of a place that further classifies the setting (e.g., hospital, accident site, road side, work site, community location) in which services are delivered.  <http://www.hl7.org/memonly/downloads/v3edition.cfm#V32008> | |
|  | Example codes for reference | |
| Code | Code System | Print Name |
| GACH | HL7 RoleCode | General Acute Care Hospital |
| RH | HL7 RoleCode | Rehabilitation Hospital |
| PEDU | HL7 RoleCode | Pediatric Unit |
| COMM | HL7 RoleCode | Community |
| WORK | HL7 RoleCode | Work site |
| … |  |  |

Severity Observation

[observation: templateId 2.16.840.1.113883.10.20.21.4.8(open)]

This clinical statement represents the severity of the reaction to an agent. A person may manifest many symptoms in a reaction to a single substance, and each reaction to the substance can be represented. However, each reaction observation can have only one severity observation associated with it. For example, someone may have a rash reaction observation as well as an itching reaction observation, but each can have only one level of severity.

1. **SHALL** contain exactly one [1..1] **@classCode**="OBS" Observation (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) **STATIC** (CONF:7345).
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" Event (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) **STATIC** (CONF:7346).
3. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.4.8" (CONF:7347).
4. **SHALL** contain exactly one [1..1] **code**="SEV" Severity Observation (CodeSystem: 2.16.840.1.113883.5.4 HL7ActCode) **STATIC** (CONF:7349).
5. **SHOULD** contain exactly one [1..1] **text** (CONF:7350).
   1. This text **SHOULD** contain exactly one [1..1] **reference** (CONF:7351).
      1. A reference/@value SHOULD point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1 ). (CONF:7378).
6. **SHALL** contain exactly one [1..1] **statusCode/@code**="completed" Completed (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) **STATIC** (CONF:7352).
7. **SHALL** contain exactly one [1..1] **value with @xsi:type="CD"**, where the @code **SHALL** be selected from ValueSet 2.16.840.1.113883.3.88.12.3221.6.8 Problem Severity **DYNAMIC** (CONF:7356).

Table 53: Problem Severity Value Set

| Value Set: Problem Severity 2.16.840.1.113883.3.88.12.3221.6.8 | | |
| --- | --- | --- |
| Code System(s): | SNOMED CT 2.16.840.1.113883.6.96 | |
| Description: | This is a description of the level of the severity of the problem. | |
| Code | Code System | Print Name |
| 255604002 | SNOMED CT | Mild (qualifier value) |
| 371923003 | SNOMED CT | Mild to moderate (qualifier value) |
| 6736007 | SNOMED CT | Moderate (severity modifier) (qualifier value) |
| 371924009 | SNOMED CT | Moderate to severe (qualifier value) |
| 24484000 | SNOMED CT | Severe (severity modifier) (qualifier value) |
| 399166001 | SNOMED CT | Fatal (qualifier value) |

Figure 69: Severity observation example

<observation classCode="OBS" moodCode="EVN">

<!-- Severity observation template -->

<templateId root=" 2.16.840.1.113883.10.20.22.4.8"/>

<code code="SEV"

displayName="Severity Observation"

codeSystem="2.16.840.1.113883.5.4"

codeSystemName="ActCode"/>

<text>

<reference value="#severity"/>

</text>

<statusCode code="completed"/>

<value xsi:type="CD" code="371924009" displayName="Moderate to severe"

codeSystem="2.16.840.1.113883.6.96"

codeSystemName="SNOMED CT"

xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"/>

</observation>

Vital Signs Organizer

[organizer: templateId 2.16.840.1.113883.10.20.21.4.26(open)]

The Vital Signs Organizer is similar to the [Result Organizer](#CS_ResultOrganizer) but with further constraints.

1. **SHALL** contain exactly one [1..1] **@classCode**="CLUSTER" CLUSTER (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) (CONF:7279).
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" Event (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) (CONF:7280).
3. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.4.26" (CONF:7281).
4. **SHALL** contain at least one [1..\*] **id** (CONF:7282).
5. **SHALL** contain exactly one [1..1] **code/@code**="46680005" Vital Signs (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT) (CONF:7283).
6. **SHALL** contain exactly one [1..1] **statusCode/@code**="completed" Completed (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) (CONF:7284).
7. **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:7288).
   1. represents clinically effective time of the measurement, which is most likely when the measurement was performed (e.g., a BP measurement). (CONF:7289).
8. **SHALL** contain at least one [1..\*] **component** (CONF:7285) such that it
   1. **SHALL** contain exactly one [1..1] [**Vital Sign Observation**](#CS_VitalSignObservation) (templateId:2.16.840.1.113883.10.20.22.4.27) (CONF:7286).

Vital Sign Observation

[observation: templateId 2.16.840.1.113883.10.20.21.4.27(open)]

Vital signs are represented as are other [results](#CS_ResultObservation), with additional vocabulary constraints.

1. **SHALL** contain exactly one [1..1] **@classCode**="OBS" Observation (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) (CONF:7297).
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" Event (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) (CONF:7298).
3. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.4.27" (CONF:7299).
4. **SHALL** contain at least one [1..\*] **id** (CONF:7300).
5. **SHALL** contain exactly one [1..1] **code/@code**, which **SHOULD** be selected from ValueSet 2.16.840.1.113883.3.88.12.80.62 HITSP Vital Sign Result Type **DYNAMIC** (CONF:7301).
6. **SHOULD** contain exactly one [1..1] **text** (CONF:7302).
   1. element SHOULD include a reference element which SHOULD reference the narrative. The reference/@value SHALL begin with a hash '#' mark (CONF:7314).
7. **SHALL** contain exactly one [1..1] **statusCode/@code**="completed" Completed (CodeSystem: 2.16.840.1.113883.5.14 HL7ActStatus) (CONF:7303).
8. **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:7304).
9. **SHALL** contain exactly one [1..1] **value with @xsi:type="PQ"** (CONF:7305).
10. **MAY** contain zero or one [0..1] **interpretationCode** (CONF:7307).
11. **MAY** contain zero or one [0..1] **methodCode** (CONF:7308).
12. **MAY** contain zero or one [0..1] **targetSiteCode** (CONF:7309).
13. **MAY** contain zero or one [0..1] **author** (CONF:7310).

Table 54: Vital Sign Result Value Set

| Value Set: Vital Sign Result 2.16.840.1.113883.3.88.12.80.62 | | |
| --- | --- | --- |
| Code System(s): | LOINC 2.16.840.1.113883.6.1 | |
| Description: | This identifies the vital sign result type | |
| Code | Code System | Print Name |
| 9279-1 | LOINC | Respiratory Rate |
| 8867-4 | LOINC | Heart Rate |
| 2710-2 | LOINC | O2 % BldC Oximetry |
| 8480-6 | LOINC | BP Systolic |
| 8462-4 | LOINC | BP Diastolic |
| 8310-5 | LOINC | Body Temperature |
| 8302-2 | LOINC | Height |
| 8306-3 | LOINC | Height (Lying) |
| 8287-5 | LOINC | Head Circumference |
| 3141-9 | LOINC | Weight Measured |

# References

* *Cross Transaction Specifications and Content Specifications.* IHE ITI Technical Framework, Volume 3 (ITI TF-3)(see 5.2 Scanned Documents Content Model)*.* <http://www.ihe.net/Technical_Framework/upload/IHE_ITI_TF_6-0_Vol3_FT_2009-08-10.pdf>
* *HL7 Clinical Document Architecture, Release 2.0*. <http://www.hl7.org/v3ballot/html/infrastructure/cda/cda.htm>
* *HL7 Implementation Guide for CDA Release 2: Consultation Notes*, (U.S. Realm), Draft Standard for Trial Use, Release 1, Levels 1, 2, and 3, DSTU Updated: January 2010
* *HL7 Implementation Guide for CDA Release 2: History and Physical (H&P) Notes* (U.S. Realm) Draft Standard for Trial Use, Release 1, Levels 1, 2, and 3 A CDA Implementation guide for History and Physical Notes, DSTU Updated: January 2010
* *HL7 Implementation Guide for CDA Release 2: Procedure Note* (Universal Realm), Draft Standard for Trial Use, Release 1, Levels 1, 2, and 3, July 2010
* *HL7 Implementation Guide for CDA Release 2: Unstructured Documents*, Release 1, Level 1 (Universal Realm), Draft Standard for Trial Use, September 2010
* *HL7 Implementation Guide: CDA Release 2 – Continuity of Care Document (CCD)* A CDA implementation of ASTM E2369-05 Standard Specification for Continuity of Care Record© (CCR), April 01, 2007
* *Implementation Guide for CDA Release 2: Imaging Integration, Levels 1, 2, and 3, Basic Imaging Reports in CDA and DICOM Diagnostic Imaging Reports (DIR)* – Universal Realm, Based on HL7 CDA Release 2.0, Release 1.0, Informative Document, First Release, March 2009
* *Implementation Guide for CDA Release 2.0 Operative Note*, (U.S. Realm), Draft Standard for Trial Use, Release 1, Levels 1, 2 and 3, Published, March 2009
* *Implementation Guide for CDA Release 2.0, Care Record Summary Release 2  
  Discharge Summary*, (U.S. Realm) Draft Standard for Trial Use, Levels 1, 2 and 3, December 2009
* *Implementation Guide for CDA Release 2.0, Progress Note* (U.S. Realm), Draft Standard for Trial Use, Levels 1, 2, and 3, January 2011
* Joint Commission Requirements for Discharge Summary (JCAHO IM.6.10 EP7). See [http://www.jointcommission.org/NR/rdonlyres/C9298DD0-6726-4105-A007-FE2C65F77075/0/CMS\_New\_Revised\_HAP\_FINAL\_withScoring.pdf (page 26](http://www.jointcommission.org/NR/rdonlyres/C9298DD0-6726-4105-A007-FE2C65F77075/0/CMS_New_Revised_HAP_FINAL_withScoring.pdf)).
* *Mosby's Medical Dictionary*, 8th edition. © 2009, Elsevier.
* Taber's Cyclopedic Medical Dictionary, 21st Edition, F.A. Davis Company. <http://www.tabers.com>
* XML Path Language (XPath), Version 1.0. <http://www.w3.org/TR/xpath/>

1. Acronyms and Abbreviations

ADL Activities of Daily Living

AMA American Medical Association

CCD Continuity of Care Document

CDA Clinical Document Architecture

CRS Care Record Summary

DICOM Digital Imaging and Communications in Medicine

DIR Diagnostic Imaging Report

EHR electronic health record

DSTU Draft Standard for Trial Use

H&P History and Physical

HIMSS Healthcare Information and Management Systems Society

HIT healthcare information technology

HITECH Health Information Technology for Economic and Clinical Health

HITSP Health Information Technology Standards Panel

HL7 Health Level Seven

HSS U.S. Department of Health and Human Services

HTML Hypertext Markup Language

IG implementation guide

IHE Integrating the Healthcare Enterprise

IHTSDO International Health Terminology Standard Development Organisation

LOINC Logical Observation Identifiers Names and Codes

MDHT Model-Driven Health Tools

MIME Multipurpose Internet Mail Extensions

NPP non-physician providers

NUCC Healthcare Provider Taxonomy Code

ONC Office of National Coordinator

PCP primary care provider

PDF portable document format

PHCR Public Health case reports

PHR personal health record

PPRF primary performers

RIM Reference Information Model

RTF rich text format

S&I Standards and Interoperability

SDWG Structured Documents Working Group

SDO Standards Development Organization

SNOMED CT Systemized Nomenclature for Medicine – Clinical Terms

SR Structured Report

Tdb Template Database

TIFF tagged-image file format

UD Unstructured Document

URL Uniform Resource Locator

WADO Web Access to Persistent DICOM Objects

XPath XML Path Language

1. Changes From Previous Guides

The following table documents changes to section codes used in the current Operative Note templates to conform to those in use for general procedures.

Table 55: Surgical Operative Codes Mapping to Generic Procedure Codes

|  |  |  |  |
| --- | --- | --- | --- |
| Sections Names | Section Codes | Sections Names | Section Codes |
| Previous Operative Section Codes | | Now Using | |
| Surgical Operation Note Anesthesia | 10213-7 | Procedure Anesthesia | 59774-0 |
| Surgical Operation Note Description | 8724-7 | Procedure Description | 29554-3 |
| Surgical Operation Note Disposition | 55102-8 | Procedure Disposition | 59775-7 |
| Surgical Operation Note Estimated Blood Loss | 55103-6 | Procedure Estimated Blood Loss | 59770-8 |
| Surgical Operation Note Findings | 10215-2 | Procedure Findings | 59776-5 |
| Surgical Operation Note Indications | 10217-8 | Procedure Indications | 59768-2 |
| Surgical Operation Note Planned Procedure | 55104-4 | Planned Procedure | 59772-4 |
| Surgical Operation Note Specimens Taken | 10221-0 | Procedure Specimens taken | 59773-2 |

Table 56: H&P Cardinality Updates

|  |  |  |  |
| --- | --- | --- | --- |
| Sections Names | HITSP  (C84) | HL7  (H&P) | Current Cardinality |
| Problems | R | O | O |
| Resolved Problems | R | - |  |
| Vital Signs | - | R | R |
| Past Medical History | - | R | R |

Table 57: Consultation Cardinality Updates

|  |  |  |  |
| --- | --- | --- | --- |
| Sections Names | HITSP  (C84) | HL7  (H&P) | Current Cardinality |
| Active Problems | R | O | O – Problems |
| Resolved Problems | R2 | - |
| Allergies | R | O | R |
| Current Meds | R | O | R |
| Past Medical History | - | O | O |
| Chief Complaint | - | O | O |
| Functional Status | R2 | - | O |
| Advance Directives | R | - | O |
| Pertinent Insurance Information (Payers) | R2 | - | O |

Table 58: Discharge Summary Cardinality Updates

|  |  |  |  |
| --- | --- | --- | --- |
| Sections Names | HITSP  (C48) | HL7  (H&P) | Current Cardinality |
| Problems | R | O | O |
| Hospital Admission Diagnosis Section | R | - | O |

The next table represents a matrix of the conformance verbs used across the standards reviewed for the consolidation guide. Cells with a dash (-) did not have an equivalent conformance convention.

Table 59: Consolidated Conformance Verb  Matrix

| RFC 2119 | HL7 | IHE | HITSP | Workgroup Consensus |
| --- | --- | --- | --- | --- |
| SHALL  Absolute requirement of the specification | SHALL  Required/Mandatory | R (Required)  Element must be present but can be NULL | R (Required)  Data elements must always be sent. A NULL can be sent. | SHALL  Element must be present but can be NULL  Where necessary to explicitly preclude nullFlavor (e.g. where you want to preclude nullFlavor on observation/value), can include something like "SHALL NOT include nullFlavor".  Where SHALL is applied to an attribute, it must be present and cannot be a NULL |
| SHALL NOT  Absolute prohibition of the specification | SHALL NOT  Not Required/Mandatory | - | - | SHALL NOT  Absolute prohibition against inclusion |
| SHOULD  Recommended  There may exist valid reasons in particular circumstances to ignore a particular item, but the full implications must be understood and carefully weighed before choosing a different course. | SHOULD  Best Practice or Recommendation | R2 (Required if known)  The sending application must be able to demonstrate that it can send all required if known elements, unless it does not in fact gather that data. If the information cannot be transmitted, the data element shall contain a value indicating the reason for omission of the data. | R2 (Required if known)  If the sending application has data for the data element, it is REQUIRED to populate the data element. If the value is not known, the data element need not be sent | SHOULD  Best Practice or Recommendation  There may exist valid reasons in particular circumstances to ignore a particular item, but the full implications must be understood and carefully weighed before choosing a different course |
| SHOULD NOT  Not Recommended | SHOULD NOT  Not Recommended | - | - | SHOULD NOT  Not Recommended |
| MAY  Optional | MAY  Accepted/Permitted | O (Optional) | O (Optional) | MAY  Optional |
| - | - | C (Conditional)  A conditional data element is one that is required, required if known or optional depending upon other conditions. | C (Conditional)  Required to be sent when the conditions specified in the HITSP additional specifications column are true | - |

The following table tracks changes in template IDs, for the most part representing a consolidation of separate templates into a single template. In some cases, two new template IDs are assigned to distinguish sections where computable data entries are required and those where entries are optional and only the human-readable narrative is required.

Table 60: Section Template Change Tracking

| Section | LOINC Code(s) | Consolidated Entry Optional TemplateId | Consolidated Entry Required TemplateId | Previous TemplateIds | Was |
| --- | --- | --- | --- | --- | --- |
| ***Medications Category*** | | | | | |
| Medications Section | 10160-0 | 2.16.840.1.113883.10.20.22.2.1 | 2.16.840.1.113883.10.20.22.2.1.1 | 2.16.840.1.113883.10.20.1.8 (CCD) | HL7 |
| 2.16.840.1.113883.3.88.11.83.112 | HITSP |
| 1.3.6.1.4.1.19376.1.5.3.1.3.19 | IHE |
| Hospital Discharge Medications Section | 10183-2 | 2.16.840.1.113883.10.20.22.2.11 | 2.16.840.1.113883.10.20.22.2.11.1 | 2.16.840.1.113883.10.20.16.2.2 (DS) | HL7 |
| 2.16.840.1.113883.3.88.11.83.114 | HITSP |
| 1.3.6.1.4.1.19376.1.5.3.1.3.22 | IHE |
| Medications Administered Section[[16]](#footnote-16) | 29549-3  18610-6 | 2.16.840.1.113883.10.20.22.2.38 | Future assignment | 2.16.840.1.113883.10.20.18.2.8 (Proc Note) | HL7 |
| 2.16.840.1.113883.3.88.11.83.115 | HITSP |
| 1.3.6.1.4.1.19376.1.5.3.1.3.21 | IHE |
| Immunizations Section | 11369-6 | 2.16.840.1.113883.10.20.22.2.2 | Future assignment | 2.16.840.1.113883.10.20.1.6 (CCD) | HL7 |
| 2.16.840.1.113883.3.88.11.83.117 | HITSP |
| 1.3.6.1.4.1.19376.1.5.3.1.3.23 | IHE |
| ***Conditions/Concern Category*** | | | | | |
| Allergies and Other Adverse Reactions Section (2.2.1.2) | 48765-2 | 2.16.840.1.113883.10.20.22.2.6 | 2.16.840.1.113883.10.20.22.2.6.1 | 2.16.840.1.113883.10.20.1.2 (CCD) | HL7 |
| 2.16.840.1.113883.3.88.11.83.102 | HITSP |
| 1.3.6.1.4.1.19376.1.5.3.1.3.13 | IHE |
| Problem List Section | 11450-4 | 2.16.840.1.113883.10.20.22.2.5 | 2.16.840.1.113883.10.20.22.2.5.1 | 2.16.840.1.113883.10.20.1.11 | HL7 |
| 2.16.840.1.113883.3.88.11.83.103 | HITSP |
| 1.3.6.1.4.1.19376.1.5.3.1.3.6 | IHE |
| History of Past Illness Section (2.2.1.4) | 11348-0 | 2.16.840.1.113883.10.20.2.9 |  | 2.16.840.1.113883.10.20.2.9 (H&P) | HL7 |
| 2.16.840.1.113883.3.88.11.83.104 | HITSP |
| 1.3.6.1.4.1.19376.1.5.3.1.3.8 | IHE |
| Hospital Discharge Diagnosis Section | 11535-2 | 2.16.840.1.113883.10.20.22.2.24 |  | 2.16.840.1.113883.10.20.16.2.1 (DS) | HL7 |
| 2.16.840.1.113883.3.88.11.83.111 | HITSP |
| 1.3.6.1.4.1.19376.1.5.3.1.3.7 | IHE |
| Preoperative Diagnosis Section | 10219-4 | 2.16.840.1.113883.10.20.22.2.34 |  | 2.16.840.1.113883.10.20.7.1 (OpNote) | HL7 |
| 2.16.840.1.113883.3.88.11.83.129 | HITSP |
| Postoperative Diagnosis Section | 10218-6 | 2.16.840.1.113883.10.20.22.2.35 |  | 2.16.840.1.113883.10.20.7.2 (OpNote) | HL7 |
| 2.16.840.1.113883.3.88.11.83.130 | HITSP |
| Chief Complaint Section / Reason for Visit | 10154-3 29299-5 46239-0 | Chief complaint (1.3.6.1.4.1.19376.1.5.3.1.1.13.2.1) Reason for Visit (2.16.840.1.113883.10.20.22.2.12) Chief Complaint + Reason for Visit (2.16.840.1.113883.10.20.22.2.13) | N/A (narrative-only) | 2.16.840.1.113883.10.20.2.8 (H&P) 2.16.840.1.113883.10.20.18.2.16 (Proc Note) | HL7 |
| 2.16.840.1.113883.3.88.11.83.105 | HITSP |
| 1.3.6.1.4.1.19376.1.5.3.1.1.13.2.1 | IHE |
| Reason for Referral Section | 42349-1 | 1.3.6.1.4.1.19376.1.5.3.1.3.1 | N/A (narrative-only) | 2.16.840.1.113883.10.20.4.8 (Consult Note) | HL7 |
| 2.16.840.1.113883.3.88.11.83.106 | HITSP |
| 1.3.6.1.4.1.19376.1.5.3.1.3.1 (narrative-only) 1.3.6.1.4.1.19376.1.5.3.1.3.2 (coded) | IHE |
| History of Present Illness Section | 10164-2 | N/A (use IHE 1.3.6.1.4.1.19376.1.5.3.1.3.4) | N/A (narrative-only) | 1.3.6.1.4.1.19376.1.5.3.1.3.4 | HL7 |
| 2.16.840.1.113883.3.88.11.83.107 | HITSP |
| 1.3.6.1.4.1.19376.1.5.3.1.3.4 | IHE |
| Medical (General) History Section | 11329-0 | 2.16.840.1.113883.10.20.22.2.39 |  | 2.16.840.1.113883.10.20.18.2.5 (Proc Note) | HL7 |
| ***Procedure and Surgery Category*** | | | | | |
| List of Surgeries (History of Procedures) Section | 47519-4 | 2.16.840.1.113883.10.20.22.2.7 | N/A (narrative-only) | 2.16.840.1.113883.10.20.1.12 (CCD) HL7:2.16.840.1.113883.10.20.18.2.18 (Proc Note) | HL7 |
| 2.16.840.1.113883.3.88.11.83.108 | HITSP |
| 1.3.6.1.4.1.19376.1.5.3.1.3.12 | IHE |
| Surgery Description Section | 29554-3 | 2.16.840.1.113883.10.20.22.2.26 |  | 2.16.840.1.113883.10.20.7.3 (OpNote) | HL7 |
| Complications Section | 10830-8 | 2.16.840.1.113883.10.20.22.2.32 |  | 2.16.840.1.113883.10.20.7.10 (OpNote) | HL7 |
| Operative Note Fluids Section | 10216-0 | 2.16.840.1.113883.10.20.7.12 |  | 2.16.840.1.113883.10.20.7.12 (OpNote) | HL7 |
| Operative Note Surgical Procedure Section | 10223-6 | 2.16.840.1.113883.10.20.7.14 |  | 2.16.840.1.113883.10.20.7.14 (OpNote) | HL7 |
| Surgical Drains Section | 11537-8 | 2.16.840.1.113883.10.20.7.13 |  | 2.16.840.1.113883.10.20.7.13 (OpNote) | HL7 |
| Implants Section | 55122-6 | 2.16.840.1.113883.10.20.22.2.33 |  | 2.16.840.1.113883.10.20.7.15 (OpNote) | HL7 |
| Procedure Indications Section | 59768-2 | 2.16.840.1.113883.10.20.22.2.29 |  | 2.16.840.1.113883.10.20.18.2.1 (Proc Note) | HL7 |
| Procedure Description Section | 29554-3 | 2.16.840.1.113883.10.20.22.2.27 |  | 2.16.840.1.113883.10.20.18.2.2 (Proc Note) | HL7 |
| Postprocedure Diagnosis Section | 59769-0 | 2.16.840.1.113883.10.20.22.2.36 |  | 2.16.840.1.113883.10.20.18.2.3 (Proc Note) | HL7 |
| Complications / Adverse Events Section | 55109-3 | 2.16.840.1.113883.10.20.22.2.37 |  | 2.16.840.1.113883.10.20.18.2.4 (Proc Note) | HL7 |
| Anesthesia Section | 59774-0 | 2.16.840.1.113883.10.20.22.2.25 |  | 2.16.840.1.113883.10.20.18.2.7 (Proc Note) 2.16.840.1.113883.10.20.7.5 (OpNote) | HL7 |
| Procedure Disposition Section | 59775-7 | 2.16.840.1.113883.10.20.18.2.12 |  | 2.16.840.1.113883.10.20.18.2.12 (Proc Note) | HL7 |
| Procedure Estimated Blood Loss Section | 59770-8 | 2.16.840.1.113883.10.20.18.2.9 |  | 2.16.840.1.113883.10.20.18.2.9 (Proc Note) | HL7 |
| Procedure Findings Section | 59776-5 | 2.16.840.1.113883.10.20.22.2.28 |  | 2.16.840.1.113883.10.20.18.2.15 (Proc Note) | HL7 |
| Procedure Implants Section | 59771-6 | 2.16.840.1.113883.10.20.22.2.40 |  | 2.16.840.1.113883.10.20.18.2.11 (Proc Note) | HL7 |
| Planned Procedure Section | 59772-4 | 2.16.840.1.113883.10.20.22.2.30 |  | 2.16.840.1.113883.10.20.18.2.6 (Proc Note) | HL7 |
| Procedure Specimens Taken Section | 59773-2 | 2.16.840.1.113883.10.20.22.2.31 |  | 2.16.840.1.113883.10.20.18.2.10 (Proc Note) | HL7 |
| ***Care Planning/Assessment Category*** | | | | | |
| Assessments Section | 51848-0 | 2.16.840.1.113883.10.20.22.2.8 | Need to assign | 2.16.840.1.113883.10.20.2.7 (H&P) 2.16.840.1.113883.10.20.18.2.13 (Proc Note) | HL7 |
| 1.3.6.1.4.1.19376.1.5.3.1.1.13.2.4 | HITSP |
| 1.3.6.1.4.1.19376.1.5.3.1.1.13.2.4 | IHE |
| Assessment and Plan Section | 51487-2 | 2.16.840.1.113883.10.20.22.2.9 | Need to assign | 2.16.840.1.113883.10.20.2.7 (H&P) 2.16.840.1.113883.10.20.18.2.14 (Proc Note) | HL7 |
| 1.3.6.1.4.1.19376.1.5.3.1.1.13.2.5 | IHE |
| Plan of Care Section *(may be used for Discharge Instructions)* | 18776-5 | 2.16.840.1.113883.10.20.22.2.10 | Need to assign | 2.16.840.1.113883.10.20.2.7 (H&P) 2.16.840.1.113883.10.20.1.10 (CCD) | HL7 |
| 2.16.840.1.113883.3.88.11.83.124 | HITSP |
| 1.3.6.1.4.1.19376.1.5.3.1.3.31 | IHE |
| Functional Status Section | 47420-5 | 2.16.840.1.113883.10.20.22.2.14 | Need to assign | 2.16.840.1.113883.10.20.1.5 (CCD) | HL7 |
| 2.16.840.1.113883.3.88.11.83.109 | HITSP |
| 1.3.6.1.4.1.19376.1.5.3.1.3.17 | IHE |
| ***Results Category*** | | | | | |
| Results Section (Diagnostic Results in HITSP) | 30954-2 | 2.16.840.1.113883.10.20.22.2.3 | 2.16.840.1.113883.10.20.22.2.3.1 | 2.16.840.1.113883.10.20.1.14 (CCD) | HL7 |
| 2.16.840.1.113883.3.88.11.83.122 | HITSP |
| 1.3.6.1.4.1.19376.1.5.3.1.3.28 | IHE |
| Vital Signs Section | 8716-3 | 2.16.840.1.113883.10.20.22.2.4 | 2.16.840.1.113883.10.20.22.2.4.1 | 2.16.840.1.113883.10.20.1.16 (CCD) 2.16.840.1.113883.10.20.2.4 (H&P) | HL7 |
| 2.16.840.1.113883.3.88.11.83.119 | HITSP |
| 1.3.6.1.4.1.19376.1.5.3.1.3.25 | IHE |
| DICOM Object Catalog Section | 121181 | N/A | 2.16.840.1.113883.10.20.6.1.1 | 2.16.840.1.113883.10.20.6.1.1 | HL7 |
| Findings (Radiology Comparison Study - Observation) Section | 18782-3 | 2.16.840.1.113883.10.20.6.1.2 |  | 2.16.840.1.113883.10.20.6.1.2 | HL7 |
| ***Other Templates*** | | | | | |
| Payers Section | 48768-6 | 2.16.840.1.113883.10.20.22.2.18 | Need to assign | 2.16.840.1.113883.10.20.1.9 (CCD) | HL7 |
| 2.16.840.1.113883.3.88.11.83.101.1 | HITSP |
| 1.3.6.1.4.1.19376.1.5.3.1.1.5.3.7 | IHE |
| Advance Directives Section | 42348-3 | 2.16.840.1.113883.10.20.22.2.21 | Need to assign | 2.16.840.1.113883.10.20.1.1 (CCD) | HL7 |
| 2.16.840.1.113883.3.88.11.83.116 | HITSP |
| 1.3.6.1.4.1.19376.1.5.3.1.3.34 (narrative-only) 1.3.6.1.4.1.19376.1.5.3.1.3.35 (coded) | IHE |
| Physical Exam Section | 29545-1 | 2.16.840.1.113883.10.20.2.10 | Need to assign | 2.16.840.1.113883.10.20.2.10 (H&P) | HL7 |
| 2.16.840.1.113883.3.88.11.83.118 | HITSP |
| 1.3.6.1.4.1.19376.1.5.3.1.3.24 (narrative-only) 1.3.6.1.4.1.19376.1.5.3.1.1.9.15 (coded) | IHE |
| Review of Systems Section | 10187-3 | 1.3.6.1.4.1.19376.1.5.3.1.3.18 | N/A (narrative-only) | 2.16.840.1.113883.10.20.4.10 (Consult) | HL7 |
| 2.16.840.1.113883.3.88.11.83.120 | HITSP |
| 1.3.6.1.4.1.19376.1.5.3.1.3.18 | IHE |
| Hospital Course Section *(may be used as part of Discharge Summary)* | 8648-8 | 1.3.6.1.4.1.19376.1.5.3.1.3.5 | N/A (narrative-only) | 1.3.6.1.4.1.19376.1.5.3.1.3.5 | HL7 |
| 2.16.840.1.113883.3.88.11.83.121 | HITSP |
| 1.3.6.1.4.1.19376.1.5.3.1.3.5 | IHE |
| Family History Section | 10157-6 | 2.16.840.1.113883.10.20.22.2.15 | Need to assign | 2.16.840.1.113883.10.20.1.4 (CCD) 2.16.840.1.113883.10.20.18.2.17 (Proc Note) | HL7 |
| 2.16.840.1.113883.3.88.11.83.125 | HITSP |
| 1.3.6.1.4.1.19376.1.5.3.1.3.14 (narrative-only) 1.3.6.1.4.1.19376.1.5.3.1.3.15 (coded) | IHE |
| Social History Section(incl. smoking) | 29762-2 | 2.16.840.1.113883.10.20.22.2.17 | N/A (no stds require entry) | 2.16.840.1.113883.10.20.1.15 (CCD) | HL7 |
| 2.16.840.1.113883.3.88.11.83.126 | HITSP |
| 1.3.6.1.4.1.19376.1.5.3.1.3.16 | IHE |
| Encounters Section | 46240-8 | 2.16.840.1.113883.10.20.22.2.22 | Need to assign | 2.16.840.1.113883.10.20.1.3 (CCD) | HL7 |
| 2.16.840.1.113883.3.88.11.83.127 | HITSP |
| 1.3.6.1.4.1.19376.1.5.3.1.1.5.3.3 | IHE |
| Medical Equipment Section | 46264-8 | 2.16.840.1.113883.10.20.22.2.23 | Need to assign | 2.16.840.1.113883.10.20.1.7 (CCD) | HL7 |
| 2.16.840.1.113883.3.88.11.83.128 | HITSP |
| 1.3.6.1.4.1.19376.1.5.3.1.1.5.3.5 | IHE |
| Hospital Discharge Physical Section | 10184-0 | N/A (1.3.6.1.4.1.19376.1.5.3.1.3.26) | N/A (narrative-only) | N/A – Used IHE | HL7 |
| 1.3.6.1.4.1.19376.1.5.3.1.3.26 | IHE |
| General Status Section | 10210-3 | N/A (2.16.840.1.113883.10.20.2.5) | N/A (narrative-only) | 2.16.840.1.113883.10.20.2.5 (H&P) | HL7 |
| Objective Section | 61149-1 | N/A (2.16.840.1.113883.10.20.21.2.1) | N/A (narrative-only) | 2.16.840.1.113883.10.20.22.2.1 (Prog Note) | HL7 |
| Subjective Section | 61150-9 | N/A (2.16.840.1.113883.10.20.21.2.2) | N/A (narrative-only) | 2.16.840.1.113883.10.20.22.2.2 (Prog Note) | HL7 |
| Discharge Diet | 42344-2 | N/A (1.3.6.1.4.1.19376.1.5.3.1.3.33) | N/A (narrative-only) | N/A – Used IHE | HL7 |
| 1.3.6.1.4.1.19376.1.5.3.1.3.33 | IHE |
| Hospital Discharge Studies Summary Section | 11493-4 | 2.16.840.1.113883.10.20.22.2.16 | N/A (no stds require entry) | 2.16.840.1.113883.10.20.16.2.3 (DS) | HL7 |

The following table tracks changes made to consolidate templates originating in HL7, IHE and HITSP.

Table 61: Entry Change Tracking Table

| Entry | New TemplateId | Previous Title | Previous TemplateId | Previous template organization |
| --- | --- | --- | --- | --- |
| Result Organizer | 2.16.840.1.113883.10.20.22.4.1 | Result Organizer | 2.16.840.1.113883.10.20.1.32 | CCD |
| Result Observation | 2.16.840.1.113883.10.20.22.4.2 | Result Observation  Result Entry Content Module | 2.16.840.1.113883.10.20.1.31  2.16.840.1.113883.3.88.11.83.15.1 | CCD  HITSP C83 |
| Problem Act | 2.16.840.1.113883.10.20.22.4.3 | Problem Act  Concern  Condition Entry Module | 2.16.840.1.113883.10.20.1.27  1.3.6.1.4.1.19376.1.5.3.1.4.5.1  2.16.840.1.113883.3.88.11.83.7 | CCD  IHE PCC R6-0 V2  HITSP C83 |
| Problem Observation | 2.16.840.1.113883.10.20.22.4.4 | Problem Observation  Problem  Concern  Problem Concern | 2.16.840.1.113883.10.20.1.28  1.3.6.1.4.1.19376.1.5.3.1.4.5  1.3.6.1.4.1.19376.1.5.3.1.4.5.1  1.3.6.1.4.1.19376.1.5.3.1.4.5.2 | CCD  IHE PCC R6-0 V2  IHE PCC R6-0 V2  IHE PCC R6-0 V2 |
| Health Status Observation | 2.16.840.1.113883.10.20.22.4.5 | Problem Healthstatus observation  Health Status | 2.16.840.1.113883.10.20.1.51  1.3.6.1.4.1.19376.1.5.3.1.4.1.2 | CCD  IHE PCC R6-0 V2 |
| Problem Status Observation | 2.16.840.1.113883.10.20.22.4.6 | Problem status observation  Problem Status Observation | 2.16.840.1.113883.10.20.1.50  1.3.6.1.4.1.19376.1.5.3.1.4.1.1 | CCD  IHE PCC R6-0 V2 |
| Allergy Observation | 2.16.840.1.113883.10.20.22.4.7 | Alert observation  Allergy and Intolerance Concern  Allergy/Drug Sensitivity Module | 2.16.840.1.113883.10.20.1.18  1.3.6.1.4.1.19376.1.5.3.1.4.5.3  2.16.840.1.113883.3.88.11.83.6 | CCD  IHE PCC R6-0 V2  HITSP C83 |
| Severity Observation | 2.16.840.1.113883.10.20.22.4.8 | Severity observation  Severity | 2.16.840.1.113883.10.20.1.55  1.3.6.1.4.1.19376.1.5.3.1.4.1 | CCD  IHE PCC R6-0 V2 |
| Reaction Observation | 2.16.840.1.113883.10.20.22.4.9 | Reaction Observation | 2.16.840.1.113883.10.20.1.54 | CCD |
| Procedure Activity | 2.16.840.1.113883.10.20.22.4.11 | Procedure activity  Procedure Entry  Procedure | 2.16.840.1.113883.10.20.1.29  1.3.6.1.4.1.19376.1.5.3.1.4.19 2.16.840.1.113883.3.88.11.83.17 | CCD  IHE PCC R6-0 V2  HITSP C83 |
| Procedure Activity Act | 2.16.840.1.113883.10.20.22.4.12 |  |  |  |
| Procedure Activity Observation | 2.16.840.1.113883.10.20.22.4.13 |  |  |  |
| Procedure Activity Procedure | 2.16.840.1.113883.10.20.22.4.14 |  |  |  |
| Immunization SubstanceAdministration | 2.16.840.1.113883.10.20.22.4.15 | Medication Activity (for immunization)  Immunization  Immunization | 2.16.840.1.113883.10.20.1.24  1.3.6.1.4.1.19376.1.5.3.1.4.12  2.16.840.1.113883.3.88.11.83.13 | CCD  IHE PCC R6-0 V2  HITSP C83 |
| Medication Activity | 2.16.840.1.113883.10.20.22.4.16 | Medication Activity  Medication  Medication | 2.16.840.1.113883.10.20.1.24  1.3.6.1.4.1.19376.1.5.3.1.4.7  2.16.840.1.113883.3.88.11.83.8 | CCD  IHE PCC R6-0 V2  HITSP C83 |
| Medication Supply Order | 2.16.840.1.113883.10.20.22.4.17 | Supply Activity  Supply entry  Order Information Constraint | 2.16.840.1.113883.10.20.1.34  1.3.6.1.4.1.19376.1.5.3.1.4.7.3  2.16.840.1.113883.3.88.11.83.8.3 | CCD  IHE PCC R6-0 V2  HITSP C83 |
| Medication Dispense | 2.16.840.1.113883.10.20.22.4.18 | Supply Activity  Supply entry | 2.16.840.1.113883.10.20.1.34  1.3.6.1.4.1.19376.1.5.3.1.4.7.3 | CCD  IHE PCC R6-0 V2 |
| Indication | 2.16.840.1.113883.10.20.22.4.19 | Indications | 2.16.840.1.113883.3.88.11.83.138 | HITSP C83 |
| Instructions | 2.16.840.1.113883.10.20.22.4.20 | Patient instruction  Patient Medication Instructions | 2.16.840.1.113883.10.20.1.49  1.3.6.1.4.1.19376.1.5.3.1.4.3 | CCD  IHE PCC R6-0 V2 |
| Sequence Number | 2.16.840.1.113883.10.20.22.4.22 |  |  |  |
| Medication Information (manufacturedMaterial) |  | Product  Product Entry  Medication Information Constraints | 2.16.840.1.113883.10.20.1.53  1.3.6.1.4.1.19376.1.5.3.1.4.7.2  2.16.840.1.113883.3.88.11.83.8.2 | CCD  IHE PCC R6-0 V2  HITSP C83 |
| Drug Vehicle (participant) | 2.16.840.1.113883.10.20.22.4.24 |  |  |  |
| Precondition (criterion) | 2.16.840.1.113883.10.20.22.4.25 |  |  |  |
| On no medications | 2.16.840.1.113883.10.20.22.4.29 |  |  |  |
| Vital Signs Organizer | 2.16.840.1.113883.10.20.22.4.26 | Vital signs organizer  Vital Signs Organizer | 2.16.840.1.113883.10.20.1.35  1.3.6.1.4.1.19376.1.5.3.1.4.13.1 | CCD  IHE PCC R6-0 V2 |
| Vital Signs Observation | 2.16.840.1.113883.10.20.22.4.27 | Vital Signs Observation | 1.3.6.1.4.1.19376.1.5.3.1.4.13.2 | IHE PCC R6-0 V2 |
| Alert Status Observation | 2.16.840.1.113883.10.20.22.4.28 | Alert Status | 2.16.840.1.113883.10.20.1.39 | CCD |
| Allergy Problem Act | 2.16.840.1.113883.10.20.22.4.30 |  |  |  |
| Age Observation | 2.16.840.1.113883.10.20.22.4.31 |  |  |  |
| Encounter Location | 2.16.840.1.113883.10.20.22.4.32 | Encounter Location | 2.16.840.1.113883.10.20.1.45 | CCD |
| Discharge diagnosis | 2.16.840.1.113883.10.20.22.4.33 |  |  |  |
| Admission diagnosis | 2.16.840.1.113883.10.20.22.4.34 |  |  |  |
| Discharge medication | 2.16.840.1.113883.10.20.22.4.35 |  |  |  |
| Admission medication | 2.16.840.1.113883.10.20.22.4.36 |  |  |  |
| Product Instance | 2.16.840.1.113883.10.20.22.4.37 |  |  |  |

1. Template IDs in This Guide

TO BE UPDATED AFTER BALLOT

1. Value Sets in This Guide

TO BE UPDATED AFTER BALLOT

1. XDS-SD and US Realm Clinical Document Header Comparison

The following table can help the implementer familiar with XDS-SD decide whether to assert conformance to Unstructured Documents and the US Realm Clinical Document Header constraints specified in this guide. [See [References](#_References) for a link to XDS-SD (Cross-Transaction Specifications and Content Specifications, Scanned Documents Module).]

Areas where this Unstructured Document specification and the Clinical Document Header constraints are more restrictive than XDS-SD have been highlighted in yellow.

Table 62: Comparison of XDS-SD and Clinical Document Header

| CDA | XDS-SD | Clinical Document Header |
| --- | --- | --- |
| ClinicalDocument | SHALL | SHALL |
| ClinicalDocument/ realmcode | SHALL | SHALL |
| ClinicalDocument/ typeId | SHALL | SHALL |
| ClinicalDocument/ templateID | SHALL | SHALL |
| ClinicalDocument/ id | SHALL | SHALL |
| ClinicalDocument/ code | SHALL | SHALL |
| ClinicalDocument/ title | SHOULD | SHALL |
| ClinicalDocument/ effectiveTime | SHALL | SHALL |
| ClinicalDocument/ confidentialityCode | SHALL | SHALL |
| ClinicalDocument/ languageCode | SHALL | SHALL |
| ClinicalDocument/ documentationOf/ serviceEvent/ effectiveTime | SHALL | Not required |
| ClinicalDocument/ recordTarget | SHALL | SHALL |
| ClinicalDocument/ recordTarget/ patientRole | SHALL | SHALL |
| ClinicalDocument/ recordTarget/ patientRole/ addr | SHALL | SHALL |
| ClinicalDocument/ recordTarget/ patientRole/ telecom | Not required | SHALL |
| ClinicalDocument/ recordTarget/ patientRole/ patient/ name | SHALL | SHALL |
| ClinicalDocument/ recordTarget/ patientRole/ patient/ administrativeGenderCode | SHALL | SHALL |
| ClinicalDocument/ recordTarget/ patientRole/ patient/ birthTime | SHALL | SHALL |
| ClinicalDocument/ author/ time | Not required | SHALL |
| ClinicalDocument/ author/ assignedAuthor | SHALL | SHALL |
| ClinicalDocument/ author/ assignedAuthor/ id | assignedPerson:  SHOULD  assignedAuthoringDevice: SHALL | SHALL |
| ClinicalDocument/ author/ assignedAuthor/ addr | Not required | SHALL |
| ClinicalDocument/ author/ assignedAuthor/ telecom | Not required | SHALL |
| ClinicalDocument/ custodian | SHALL | SHALL |
| ClinicalDocument/ custodian/ assignedCustodian/ representedCustodianOrganization/ name | SHALL | SHALL |
| ClinicalDocument/ custodian/ assignedCustodian/ representedCustodianOrganization/ addr | SHALL | SHALL |
| ClinicalDocument/ custodian/ assignedCustodian/ representedCustodianOrganization/ telecom | Not required | SHALL |
| ClinicalDocument/ author (scanner) | SHALL |  |
| ClinicalDocument/ author/ assignedAuthor/ authoringDevice (scanner) | SHALL |  |
| ClinicalDocument/ dataEnterer | SHALL |  |
| ClinicalDocument/ legalAuthenticator | SHOULD |  |
| ClinicalDocument/ component/ nonXMLBody | SHALL |  |

1. MIME Multipart/Related Messages

The following text is taken from the Claims Attachments Implementation Guide (AIS00000) in Section 2.4. For up-to-date guidance, refer to the latest edition of that specification.

MIME Multipart/Related Messages

An attachment is comprised of the CDA document, including any supporting files necessary to render the attested content of the document. Two Internet request for comments (RFCs) are needed to properly construct the mime multipart message. When supporting files are needed, the collection of information shall be organized using a MIME multipart/related package constructed according to RFC 2557. Within the MIME package, supporting files must be encoded using Base-64. RFC-4648 should be used when encoding the contents of the MIME package using Base-64. Finally, RFC-2392 may be used to reference other content that appears in the same X12 transaction to use the same content to answer multiple questions for a single claim. Internet RFCs can be downloaded from the RFC editor page at <http://www.rfc-editor.org>.

RFC-2557 MIME Encapsulation of Aggregate Documents, Such as HTML (MHTML)

This RFC describes how to construct a MIME multipart/related package, and how URLs are resolved within content items of that package. RFC-2557 can be obtained at: <http://www.rfc-editor.org/rfc/rfc2557.txt>

A MIME multipart/related package is made up of individual content items. Each content item has a MIME header identifying the item. Each content item is delimited from other content items using a string of application specified text. In addition, there must be an ending boundary. The actual content is recorded between these delimiter strings using a BASE-64 encoding of the content item. There is also a MIME header for the entire package.

The first content item of a multipart/related message supporting attachments is the CDA document, containing the header and structured or non-structured body. Subsequent content items included in this package will contain additional content that appears within the body of the document. The CDA document will reference these additional content items by their URLs.

Referencing Supporting Files in Multipart/Related Messages

Because the CDA document and its supporting files may have already existed in a clinical information system, references may already exist within the CDA document to URLs that are not accessible outside of the clinical information system that created the document. When the CDA document is sent via attachments, these URLs may no longer be accessible by the receiving information system. Therefore, each content item that is referenced by a URL within the CDA document must be included as a content item in the MIME package. Each content item may specify the URL by which it is known using the Content-Location header. The receiver of this MIME package shall translate URL references according the RFC-2557. This will ensure resolution of the original URL to the correct content item within the MIME package. Thus, URL references contained within an original document need not be rewritten when the CDA package is transmitted. Instead, these URLs are simply supplied as the value of the Content-Location header in the MIME package.

This capability allows for the same content item to be referred to more than once in a MIME multipart/related package without requiring the content item to be supplied twice. However, it does not allow a separate MIME multipart/related package to contain references to information sent in a previously recorded package.

Referencing Documents from Other Multiparts within the Same X12 Transactions

RFC-2392 is used when referencing content across MIME package boundaries, but still contained within the same X12 transaction (ST to SE). This can occur when the same document answers multiple questions for a single claim. Each component of a MIME package may be assigned a content identifier using the Content-ID header for the content item. For example, this header would appear as:

Content-ID: <07EE4DAC-76C4-4a98-967E-F6EF9667DED1>

This content identifier is a unique identifier for the content item, which means it must never be used to refer to any other content item. RFC-2392 defines the cid: URL scheme (http: and ftp: are two other URL schemes). This URL scheme allows for references by the Content-ID header to be resolved. The URL for the content item identified above would be:

cid:07EE4DAC-76C4-4a98-967E-F6EF9667DED1

Receivers of the MIME multipart message must be able to resolve a cid: URL to the content item that it identifies. Senders must ensure that they only refer to items that have already been transmitted to the receiver by their cid: URL. Thus, this implementation guide prohibits forward URL references using the cid: URL scheme.

Content items shall not be referenced across X12 transactions using the cid: URL scheme. For example, if the payer previously requested information using a 277, and the provider returned that information in a MIME multipart/related package in a 275, and then the payer requested additional information in another 277, the provider may not refer to the content item previously returned in the prior 275 transaction.

1. <http://edocket.access.gpo.gov/2010/pdf/2010-17207.pdf> [↑](#footnote-ref-1)
2. <http://www.lantanagroup.com/resources/tools/> [↑](#footnote-ref-2)
3. <http://www.schematron.com/> [↑](#footnote-ref-3)
4. <http://www.openhealthtools.org/charter/Charter-ModelingToolsForHealthcare.pdf> [↑](#footnote-ref-4)
5. <http://www.w3.org/TR/xpath/> [↑](#footnote-ref-5)
6. Required only for inpatient settings [↑](#footnote-ref-6)
7. CCD was initially scoped to reflect the ASTM E2369-05 Standard Specification for Continuity of Care Record (CCR). The requirements specified here, comply with Meaningful Use. [↑](#footnote-ref-7)
8. The Invalid Codes for Consultation Note are from the original Consultation Note DSTU. [↑](#footnote-ref-8)
9. SCALE\_TYP = 'NAR' in the LOINC tables. [↑](#footnote-ref-9)
10. Joint Commission Requirements for Discharge Summary (JCAHO IM.6.10 EP7). See <http://www.jointcommission.org/NR/rdonlyres/C9298DD0-6726-4105-A007-FE2C65F77075/0/CMS_New_Revised_HAP_FINAL_withScoring.pdf> (page 26). [↑](#footnote-ref-10)
11. <http://www.jointcommission.org/AccreditationPrograms/Office-BasedSurgery/Standards/FAQs/Management+of+Info/Patient+Specific+Info/Operative_Reports.htm>

    <http://www.jointcommission.org/NR/rdonlyres/A032623D-02AF-4955-AF7C-08F3D5802E64/0/06_obs_im.pdf>. [↑](#footnote-ref-11)
12. Taber's Cyclopedic Medical Dictionary, 21st Edition, F.A. Davis Company. <http://www.tabers.com> [↑](#footnote-ref-12)
13. Mosby's Medical Dictionary, 8th edition. © 2009, Elsevier. [↑](#footnote-ref-13)
14. Note that the Consolidation Project is providing a number of change requests to IHE. One of those recommendations should be the elimination of these discrepancies so that the IHE profile is a proper subset of this guide. [↑](#footnote-ref-14)
15. <http://www.hl7.org/v3ballot/html/infrastructure/datatypes/datatypes.htm> [↑](#footnote-ref-15)
16. Requires further discussion and resolution. [↑](#footnote-ref-16)