



**HL7 Implementation Guide for CDA, Release 2
Clinical Oncology Treatment Plan and Summary
May 2013**

HL7 Draft Standard for Trial Use (DSTU) Ballot

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1 INTRODUCTION

1.1 Purpose

This document describes constraints on the Clinical Document Architecture Release 2 (CDA R2) header and body elements for the Clinical Oncology Treatment Plan and Summary document which is derived from the American Society of Clinical Oncology (ASCO) Breast Cancer Adjuvant Treatment Plan and Summary. Templates in this release of the implementation guide are specific to a Breast Cancer Treatment Plan and Summary (BCTPS). Standardization of information used in this form will promote interoperability; create information suitable for reuse in quality measurement, public health, research, and for reimbursement.

This guide contains a library of CDA templates, and is compliant with the Consolidated CDA R2 cited in [Final Rules for Stage 2 Meaningful Use¹](#) and [45 CFR Part 170 – Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology; Final Rule²](#).

1.2 Audience

The audience for this document includes software developers and implementers with reporting capabilities within their electronic health record (EHR) systems; developers and analysts in receiving institutions; and local, regional, and national health information exchange networks who wish to create or process Clinical Oncology Treatment Plan and Summary documents according to this specification.

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.

1.3 Approach

Overall, the approach taken here is consistent with balloted implementation guides for CDA. These publications view the ultimate implementation specification as a series of layered constraints. CDA itself is a set of constraints on the Health Level Seven (HL7) Reference Information Model (RIM) defined in the CDA R2 Refined Message Information Model (RMIM). Implementation guides such as this add constraints to CDA through conformance statements that further define and restrict the sequence and cardinality of CDA objects and the vocabulary sets for coded elements.

This implementation guide is a conformance profile, as described in the “Refinement and Localization”³ section of the *HL7 Version 3 Interoperability Standards*. The base standard for this implementation guide is the *HL7 Clinical Document Architecture*,

¹ <http://www.gpo.gov/fdsys/pkg/FR-2012-09-04/pdf/2012-21050.pdf>

² <http://www.gpo.gov/fdsys/pkg/FR-2012-09-04/pdf/2012-20982.pdf>

³ <http://www.hl7.org/v3ballot/html/infrastructure/conformance/conformance.htm>

*Release 2.0*⁴. As defined in that document, this implementation guide is both an annotation profile and a localization profile. It does not describe every aspect of CDA.

The development of this guide includes a review and analysis of previously successfully balloted clinical exchange standards and published implementation guides for cancer treatment templates such as the [*Implementation Guide for Ambulatory Healthcare Provider Reporting to Central Cancer Registries*](#)⁵, the [*HL7 Implementation Guide for CDA R2: Quality Reporting Document Architecture, DSTU Release 2 \(QRDA\)*](#)⁶, and the [*HL7 Implementation Guide for CDA Release 2.0, Consolidated CDA Templates, \(US Realm\)*](#)⁷. Templates were re-used wherever possible.

1.4 CDA R2

CDA R2 is “... a document markup standard that specifies the structure and semantics of ‘clinical documents’ for the purpose of exchange” [CDA R2, Section 1.1]⁸. Clinical documents, according to CDA, have the following characteristics:

- Persistence
- Stewardship
- Potential for authentication
- Context
- Wholeness
- Human readability

CDA defines a header that for classification and management and a document body that carries the clinical record. While the header metadata are prescriptive and designed for consistency across all instances, the body is highly generic, leaving the designation of semantic requirements to implementation.

1.5 Templated CDA

CDA R2 can be constrained by mechanisms defined in the “Refinement and Localization”⁹ section of the *HL7 Version 3 Interoperability Standards*. The mechanism most commonly used to constrain CDA is referred to as “templated CDA”. In this approach, a library is created containing modular CDA templates such that the templates can be reused across any number of CDA document types, as shown in the following figure.

⁴ <http://www.hl7.org/implement/standards/cda.cfm>

⁵

http://www.cdc.gov/phn/library/guides/Implementation_Guide_for_Ambulatory_Healthcare_Provider_Reporting_to_Central_Cancer_Registries_August_2012.pdf

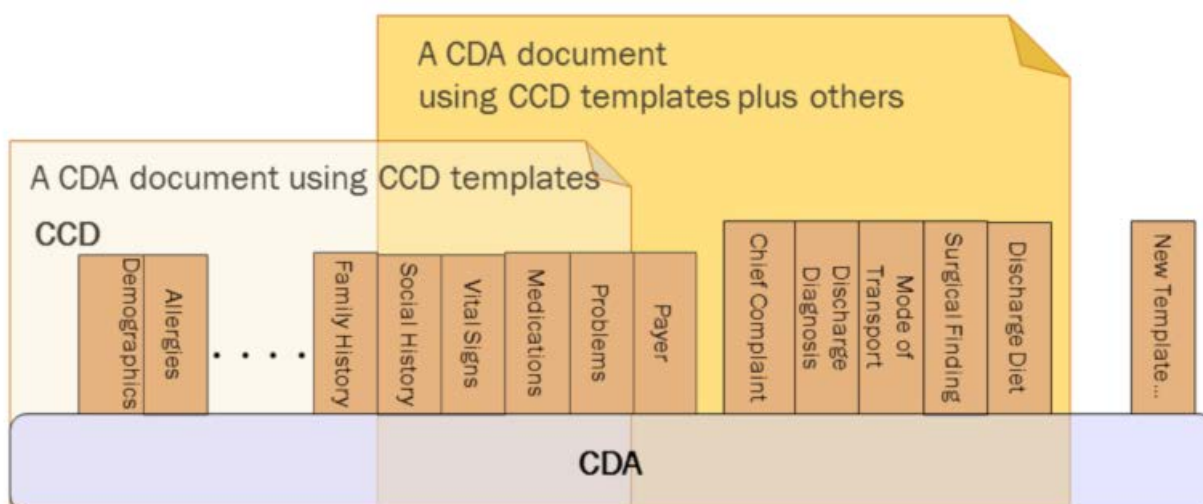
⁶ http://www.hl7.org/implement/standards/product_brief.cfm?product_id=35

⁷ http://www.hl7.org/implement/standards/product_brief.cfm?product_id=258

⁸ http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7

⁹ <http://www.hl7.org/v3ballot/html/infrastructure/conformance/conformance.htm>

Figure 1: Templated CDA



There are many different kinds of templates that might be created. Among them, the most common are:

- **Document-level templates:** These templates constrain fields in the CDA header, and define containment relationships to CDA sections. For example, a History-and-Physical document-level template might require that the patient's name be present, and that the document contain a Physical Exam section.
- **Section-level templates:** These templates constrain fields in the CDA section, and define containment relationships to CDA entries. For example, a Physical-exam section-level template might require that the section/code be fixed to a particular LOINC code, and that the section contain a Systolic Blood Pressure observation.
- **Entry-level templates:** These templates constrain the CDA clinical statement model in accordance with real world observations and acts. For example, a Systolic-blood-pressure entry-level template defines how the CDA Observation class is constrained (how to populate observation/code, how to populate observation/value, etc.) to represent the notion of a systolic blood pressure.

A CDA implementation guide (such as this one) includes reference to those templates that are applicable. On the implementation side, a CDA instance populates the template identifier (`templateId`) field where it wants to assert conformance to a given template. On the receiving side, the recipient can then not only test the instance for conformance against the CDA XML schema, but also test the instance for conformance against asserted templates.

1.6 Background

Electronic health records (EHRs) often contain data that are not shared between providers or not captured for research, quality, or public health reporting. Disease-specific templates are required for the continuity of care for cancer patients and current

templates lack the specificity needed for this population. ASCO's strategy is to promote interoperability and information exchange among cancer care providers and patients.

ASCO's strategy for 2012 is to promote and improve delivery of care to cancer patients through improved exchange and interoperability of the clinical information most critical for that care. Though multiple types of breast cancer treatment forms are used to record treatment and plans, the scope of the data elements was derived from the ASCO Breast Adjuvant Treatment Plan and Summary form, which is a paper form that records demographic, general medical, family, treatment, and plan history for a patient with moderately advanced stage breast cancer. This particular subgroup of cancer patients is an ideal use case as most of the diagnostic and treatment approaches used in cancer are represented.

1.7 Current Project

The intent of the project is to develop an initial, high-priority set of clinical oncology templates for CDA for HL7 ballot. This project will extend the initial, small set of data elements required for general meaningful use to cover elements crucial for cancer-care patients. This document describes constraints on the CDA R2 header and body elements for the Clinical Oncology Treatment Plan and Summary document in the US Realm.

The intent of the document is to communicate a basic set of patient oncology-related health status and treatment plan information between health care providers for an episode of care; it is a summary of plan and treatment received at the time the document was created. The document type may, therefore, not provide all the details to provide care; it is not intended to be used when a patient is discharged or transferred from one facility to another or to contain detailed specialty-specific information (e.g., exact radiation treatment dosages). Instead, the Clinical Oncology Treatment Plan and Summary document will provide a limited summary of a patient's care during and/or after treatment and continue to serve as a form of on-going communication to augment the coordination of care between health care providers while a patient is receiving care. Providers involved in the care of the patient may include the patient's primary care provider, medical oncologist, surgical oncologist, and radiation oncologist.

The project will reuse information available in electronic health record systems through development of cancer-specific data standards. The library of templates in this implementation guide will range from detailed data elements, such as tumor stage, to sections such as Plan of Care, which may contain full notes from a report from a medical oncologist to a primary care physician.

The CDA architecture and the use of a template library support and encourage greater capture and exchange of structured data. Standardization of information in this form will promote interoperability and create information suitable for reuse in quality measurement, public health, research, and for reimbursement

1.8 Organization of This Guide

This guide includes a set of CDA templates and prescribes their use within a Clinical Oncology Treatment Plan and Summary document. The main chapters are:

Chapter 2: [Document Level Templates](#) defines the document constraints that apply to Clinical Oncology Treatment Plan and Summary.

Chapter 3: [Section-Level Templates](#) defines the section templates in Clinical Oncology Treatment Plan and Summary.

Chapter 4: [Entry-Level Templates](#) Entry-Level Templates defines the entry template in Clinical Oncology Treatment Plan and Summary.

1.9 Conformance Conventions Used in This Guide

1.9.1 Templates Not Open for Comment

Many of the templates in this implementation guide were balloted and published in the July 2012 HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, Release 1.1 - US Realm and are, therefore, closed for comment in this ballot. These templates are indicated throughout this guide with the notation [Closed for comments; published July 2012] after the template name. An appendix on [Previously Published templates](#) lists these templates.

1.9.2 Templates and Conformance Statements

Conformance statements within this implementation guide are presented as constraints from Trifolia Workbench.¹⁰ An algorithm converts constraints recorded in Trifolia 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.

Bracketed information following each template title indicates the template type (section, observation, act, procedure, etc.), the `templateId`, and whether the template is [open or closed](#).

Section and entry templates in the guide also include context tables and constraint overview tables. In the context tables, the "Used By" column indicates which documents or sections use this template, and the "Contains Entries" column indicates any entries that the template uses. Constraint overview tables summarize the constraints following the table. Value set tables, where applicable, and brief XML example figures are included with most explanations.

A typical template, as presented in this guide, is shown in the [Constraints format example figure](#) below. The next sections describe specific aspects of conformance statements—open vs. closed statements, conformance verbs, cardinality, vocabulary conformance, containment relationships, and null flavors.

¹⁰ <http://trifolia.lantanagroup.com>

Figure 2: Constraints format example

Severity Observation

[observation: templateId 2.16.840.1.113883.10.20.22.4.8 (open)]

Table xxx: Severity Observation Contexts

Used By:	Contains Entries:
Reaction Observation (optional) Allergy - Intolerance Observation (optional) Substance or Device Allergy - Intolerance Observation (required)	

This clinical statement represents the the gravity of the problem, such as allergy or reaction, ...

Table yyy: Severity Observation Constraints Overview

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	observation[templateId/@root = '2.16.840.1.113883.10.20.22.4.8']					
	@classCode	1..1	SHALL		7345	2.16.840.1.113883.5.6 (HL7ActClass) = OBS
...						

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 ActMood) **STATIC** (CONF:7346).
3. **SHALL** contain exactly one [1..1] templateId (CONF:7347) such that it
 - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.8" (CONF:10525).
4. **SHALL** contain exactly one [1..1] code="SEV" Severity Observation (CodeSystem: 2.16.840.1.113883.5.4 ActCode) **STATIC** (CONF:7349).
5. **SHOULD** contain zero or one [0..1] text (CONF:7350).
 - a. This text, if present, **SHOULD** contain zero or one [0..1] reference/@value (CONF:7351).
 - i. This reference/@value **SHALL** begin with a '#' and **SHALL** point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:7378).
6. ...

1.9.3 Open and Closed Templates

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. Templates included in the Clinical Oncology Treatment Plan and Summary are open.

1.9.4 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*¹¹:

- **SHALL**: an absolute requirement
- **SHALL NOT**: an absolute prohibition against inclusion
- **SHOULD/SHOULD NOT**: best practice or recommendation. There may be valid reasons to ignore an item, but the full implications must be understood and carefully weighed before choosing a different course
- **MAY/NEED NOT**: truly optional; can be included or omitted as the author decides with no implications

1.9.5 Cardinality

The cardinality indicator (0..1, 1..1, 1..*, etc.) specifies the allowable occurrences within a document instance. The cardinality indicators are interpreted with the following format "m...n" where m represents the least and n the most:

- 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

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 3: Constraints format – only one allowed

<p>1. SHALL contain exactly one [1..1] participant (CONF:2777). a. This participant SHALL contain exactly one [1..1] @typeCode="LOC" (CodeSystem: 2.16.840.1.113883.5.90 HL7ParticipationType) (CONF:2230).</p>

¹¹ <http://www.hl7.org/v3ballot/html/help/pfg/pfg.htm>

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 4: Constraints format – only one like this allowed

- | |
|--|
| <ol style="list-style-type: none">1. SHALL contain exactly one [1..1] participant (CONF:2777) such that it<ol style="list-style-type: none">a. SHALL contain exactly one [1..1] @typeCode="LOC" (CodeSystem: 2.16.840.1.113883.5.90 HL7ParticipationType) (CONF:2230). |
|--|

1.9.6 Vocabulary Conformance

The templates in this document use terms from several code systems. These 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 (e.g., ValueSet 2.16.840.1.113883.1.11.78 Observation Interpretation (HL7) **DYNAMIC**) 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, as follows.

Figure 5: Binding to a single code

- | |
|--|
| <ol style="list-style-type: none">1. ... code/@code="11450-4" Problem List (CodeSystem: 2.16.840.1.113883.6.1 LOINC). |
|--|

The notation conveys the actual code (11450-4), the code’s `displayName` (Problem List), the OID of the `codeSystem` from which the code is drawn (2.16.840.1.113883.6.1), and the `codeSystemName` (LOINC).

HL7 Data Types Release 1 requires the `codeSystem` attribute unless the underlying data type is “Coded Simple” or “CS”, in which case it is prohibited. The `displayName` and the `codeSystemName` are optional, but recommended, in all cases.

The above example would be properly expressed as follows.

Figure 6: XML expression of a single-code binding

<pre><code code="11450-4" codeSystem="2.16.840.1.113883.6.1"/> <!-- or --> <code code="11450-4" codeSystem="2.16.840.1.113883.6.1" displayName="Problem List" codeSystemName="LOINC"/></pre>
--

A full discussion of the representation of vocabulary is outside the scope of this document; for more information, see the *HL7 Version 3 Interoperability Standards, Normative Edition 2010*¹² sections on Abstract Data Types and XML Data Types R1.

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.

Figure 7: Translation code example

```
<code code='206525008'
  displayName='neonatal necrotizing enterocolitis'
  codeSystem='2.16.840.1.113883.6.96'
  codeSystemName='SNOMED CT'>
  <translation code='NEC-1'
    displayName='necrotizing enterocolitis'
    codeSystem='2.16.840.1.113883.19' />
</code>
```

1.9.7 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 8: nullFlavor example

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

Use null flavors for unknown, required, or optional 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. |

¹² <http://www.hl7.org/memonly/downloads/v3edition.cfm#V32010> (must be a member to view)

- 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 above list contains those null flavors that are commonly used in clinical documents. For the full list and descriptions, see the `nullFlavor` vocabulary domain in the CDA normative edition¹³.

Any **SHALL** conformance statement may use `nullFlavor`, unless the attribute is required or the `nullFlavor` is explicitly disallowed. **SHOULD** and **MAY** conformance statement may also use `nullFlavor`.

Figure 9: Attribute required

1. **SHALL** contain exactly one [1..1] `code/@code="11450-4"` Problem List (CodeSystem: LOINC 2.16.840.1.113883.6.1) (CONF:7878)
or
2. **SHALL** contain exactly one [1..1] `effectiveTime/@value` (CONF:5256).

Figure 10: Allowed nullFlavors when element is required (with xml examples)

1. **SHALL** contain at least one [1..*] `id`
 2. **SHALL** contain exactly one [1..1] `code`
 3. **SHALL** contain exactly one [1..1] `effectiveTime`
- ```

<entry>
 <observation classCode="OBS" moodCode="EVN">
 <id nullFlavor="NI"/>
 <code nullFlavor="OTH">
 <originalText>New Grading system</originalText>
 </code>
 <statusCode code="completed"/>
 <effectiveTime nullFlavor="UNK"/>
 <value xsi:type="CD" nullFlavor="NAV">
 <originalText>Spiculated mass grade 5</originalText>
 </value>
 </observation>
</entry>

```

**Figure 11: nullFlavor explicitly disallowed**

1. **SHALL** contain exactly one [1..1] `effectiveTime` (CONF:5256).
  - a. **SHALL NOT** contain [0..0] `nullFlavor` (CONF:52580).

<sup>13</sup> HL7 Clinical Document Architecture (CDA Release 2) <http://www.hl7.org/implement/standards/cda.cfm>

## 1.9.8 Unknown Information

If a sender wants to state that a piece of information is unknown, the following principles apply:

1. If the sender doesn't know an attribute of an act, that attribute can be null.

**Figure 12: Unknown medication example**

```
<entry>
 <text>patient was given a medication but I do not know what it was</text>
 <substanceAdministration moodCode="EVN" classCode="SBADM">
 <consumable>
 <manufacturedProduct>
 <manufacturedLabeledDrug>
 <code nullFlavor="NI"/>
 </manufacturedLabeledDrug>
 </manufacturedProduct>
 </consumable>
 </substanceAdministration>
</entry>
```

2. If the sender doesn't know if an act occurred, the nullFlavor is on the act (detail could include specific allergy, drug, etc.).

**Figure 13: Unknown medication use of anticoagulant drug example**

```
<entry>
 <substanceAdministration moodCode="EVN" classCode="SBADM" nullFlavor="NI">
 <text>I do not know whether or not patient received an anticoagulant
 drug</text>
 <consumable>
 <manufacturedProduct>
 <manufacturedLabeledDrug>
 <code code="81839001" displayName="anticoagulant drug"
 codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMED CT"/>
 </manufacturedLabeledDrug>
 </manufacturedProduct>
 </consumable>
 </substanceAdministration>
</entry>
```



3. If the sender wants to state 'no known', a `negationInd` can be used on the corresponding act (substanceAdministration, Procedure, etc.)

**Figure 14: No known medications example**

```
<entry>
 <substanceAdministration moodCode="EVN" classCode="SBADM" negationInd="true">
 <text>No known medications</text>
 <consumable>
 <manufacturedProduct>
 <manufacturedLabeledDrug>
 <code code="410942007" displayName="drug or medication"
 codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMED CT"/>
 </manufacturedLabeledDrug>
 </manufacturedProduct>
 </consumable>
 </substanceAdministration>
</entry>
```

### 1.9.9 Asserting an Act Did Not Occur with a Reason

The `negationInd` attribute, if true, specifies that the act indicated was observed to not have occurred (which is subtly but importantly different from having not been observed). `NegationInd='true'` is an acceptable way to make a clinical assertion that something did not occur, for example, "no gestational diabetes".

A nested reason for the act not being done can be represented through the use of an `entryRelationship` clinical statement with an `actRelationship` type of "RSON".

**Figure 15: Asserting an act did not occur with reason**

```
<entry>
 <substanceAdministration classCode="SBADM" moodCode="EVN" negationInd="true">
 <templateId root="2.16.840.1.113883.10.20.22.4.52"/>
 <statusCode code="completed"/>
 <effectiveTime nullFlavor="NI"/>
 <doseQuantity nullFlavor="NI"/>
 <consumable>
 <manufacturedProduct>
 <templateId root="2.16.840.1.113883.10.20.22.4.54"/>
 <!-- ***** Immunization Medication Information ***** -->
 <manufacturedMaterial>
 <code code="88"
 codeSystem="2.16.840.1.113883.6.59"
 displayName="Influenza virus vaccine"
 codeSystemName="CVX"/>
 </code>
 </manufacturedMaterial>
 </manufacturedProduct>
 </consumable>
 <entryRelationship typeCode="RSON">
 <observation classCode="OBS" moodCode="EVN">
 <templateId root="2.16.840.1.113883.10.20.24.3.88"/>
 <code code="410666004"
 codeSystem="2.16.840.1.113883.6.96"
 displayName="reason"
 codeSystemName="SNOMED CT"/>
 <value xsi:type="CD"
 code="275984001"
 codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMED CT"
 displayName="Immunization refused"/>
 </observation>
 </entryRelationship>
</substanceAdministration>
</entry>
```

### 1.9.10 Data Types

All data types used in a CDA document are described in the CDA R2 normative edition<sup>14</sup>. All attributes of a data type are allowed unless explicitly prohibited by this specification.

<sup>14</sup> HL7 Clinical Document Architecture (CDA Release 2). <http://www.hl7.org/implement/standards/cda.cfm>

## 1.10 XML Conventions Used in This Guide

### 1.10.1 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<sup>15</sup> in conformance statements and elsewhere to identify the Extensible 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.

XPath syntax selects nodes from an XML document using a path containing the context of the node(s). The path is constructed from node names and attribute names (prefixed by a '@') and catenated with a '/' symbol.

**Figure 16: XML document example**

```
<author>
 <assignedAuthor>
 ...
 <code codeSystem='2.16.840.1.113883.6.96' codeSystemName='SNOMED CT'
 code='17561000' displayName='Cardiologist' />
 </assignedAuthor>
</author>
```

In the above example, the `code` attribute of the `code` could be selected with the XPath expression in the next figure.

**Figure 17: XPath expression example**

```
author/assignedAuthor/code/@code
```

---

<sup>15</sup> <http://www.w3.org/TR/xpath/>

## 1.10.2 XML Examples and Sample Documents

Extensible 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 18: ClinicalDocument example**

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

Within the narrative, XML element (code, assignedAuthor, etc.) and attribute (SNOMED CT, 17561000, etc.) names also appear in this monospace font.

This package includes complete sample documents as listed in the [Content of the Package](#) table below.

## 1.11 Content of the Package

The following files comprise this package.

**Table 1: Content of the Package**

Filename	Description	Applicability
CDAR2_IG_CLONDATA_R1_2013_MAY.docx	This guide	Normative
ASCO_BCTPS.xml	Sample Breast Cancer Treatment Plan and Summary file	Informative
CDA.xsl	A CDA stylesheet for display of BCTPS instances	Informative

## 2 DOCUMENT-LEVEL TEMPLATES

### 2.1 US Realm Header

**[Closed for comments; published July 2012]**

[ClinicalDocument: templateId 2.16.840.1.113883.10.20.22.1.1(open)]

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.NB

1. **SHALL** contain exactly one [1..1] **realmCode**="US" (CONF:16791).
2. **SHALL** contain exactly one [1..1] **typeId** (CONF:5361).
  - a. This typeId **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.1.3" (CONF:5250).
  - b. This typeId **SHALL** contain exactly one [1..1] **@extension**="POCD\_HD000040" (CONF:5251).
3. **SHALL** contain exactly one [1..1] **templateId** (CONF:5252) such that it
  - a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.1.1" (CONF:10036).
4. **SHALL** contain exactly one [1..1] **id** (CONF:5363).
  - a. This id **SHALL** be a globally unique identifier for the document (CONF:9991).
5. **SHALL** contain exactly one [1..1] **code** (CONF:5253).
  - a. This code **SHALL** specify the particular kind of document (e.g. History and Physical, Discharge Summary, Progress Note) (CONF:9992).
6. **SHALL** contain exactly one [1..1] **title** (CONF:5254).
  - a. 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).
  - a. The content **SHALL** be a conformant US Realm Date and Time (DTM.US.FIELDDED) (2.16.840.1.113883.10.20.22.5.4) (CONF:16865).
8. **SHALL** contain exactly one [1..1] **confidentialityCode**, which **SHOULD** be selected from ValueSet HL7 BasicConfidentialityKind 2.16.840.1.113883.1.11.16926 **STATIC** 2010-04-21 (CONF:5259).
9. **SHALL** contain exactly one [1..1] **languageCode**, which **SHALL** be selected from ValueSet Language 2.16.840.1.113883.1.11.11526 **DYNAMIC** (CONF:5372).
10. **MAY** contain zero or one [0..1] **setId** (CONF:5261).
  - a. If setId is present versionNumber **SHALL** be present (CONF:6380).
11. **MAY** contain zero or one [0..1] **versionNumber** (CONF:5264).
  - a. If versionNumber is present setId **SHALL** be present (CONF:6387).

**Table 2: Basic Confidentiality Kind Value Set**

Value Set: HL7 BasicConfidentialityKind 2.16.840.1.113883.1.11.16926 STATIC 2010-04-21		
Code System(s): Confidentiality Code 2.16.840.1.113883.5.25		
Code	Code System	Print Name
N	Confidentiality Code	Normal
R	Confidentiality Code	Restricted
V	Confidentiality Code	Very Restricted

**Table 3: Language Value Set (excerpt)**

Value Set: Language 2.16.840.1.113883.1.11.11526 DYNAMIC		
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 <a href="http://www.ietf.org/rfc/rfc4646.txt">http://www.ietf.org/rfc/rfc4646.txt</a>	
Code	Code System	Print Name
en	Internet Society Language	english
fr	Internet Society Language	french
ar	Internet Society Language	arabic
en-US	Internet Society Language	English, US
es-US	Internet Society Language	Spanish, US
...		

**Figure 19: US Realm Header example**

```
<realmCode
 code="US"/>
 <typeId
 root="2.16.840.1.113883.1.3"
 extension="POCD_HD000040"/>
 <!-- US General Header Template -->
 <templateId
 root="2.16.840.1.113883.10.20.22.1.1"/>
 <!-- *** Note: The next templateId, code and title will differ depending on
 what type of document is being sent. *** -->
 <!-- conforms to the document specific requirements -->
 <templateId
 root="2.16.840.1.113883.10.20.22.1.2"/>
 <id
 extension="TT988"
 root="2.16.840.1.113883.19.5.99999.1"/>
 <code
 codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC"
 code="34133-9"
 displayName="Summarization of Episode Note"/>
 <title>Community Health and Hospitals: Health Summary</title>
 <effectiveTime
 value="201209150000-0400"/>
 <confidentialityCode
 code="N"
 codeSystem="2.16.840.1.113883.5.25"/>
 <languageCode
 code="en-US"/>
 <setId
 extension="sTT988"
 root="2.16.840.1.113883.19.5.99999.19"/>
 <versionNumber
 value="1"/>
```

**Figure 20: effectiveTime with time zone example**

```
<!-- the syntax is "YYYYMMDDHHMMSS.UUUU[+|-ZZzz]" where digits can be omitted
 the right side to express less precision. -->
<effectiveTime value="201107061227-08"/>
<!-- July 6, 2011, 12:27, 8 hours before UTC -->
```

### 2.1.1 recordTarget

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

12. contain at least one [1..\*] **recordTarget** (CONF:5266).

- a. Such recordTargets **SHALL** contain exactly one [1..1] **patientRole** (CONF:5267).

- i. This patientRole **SHALL** contain at least one [1..\*] **id** (CONF:5268).
- ii. This patientRole **SHALL** contain at least one [1..\*] **addr** (CONF:5271).
  - 1. The content of addr **SHALL** be a conformant US Realm Address (AD.US.FIELDDED) (2.16.840.1.113883.10.20.22.5.2) (CONF:10412).
- iii. This patientRole **SHALL** contain at least one [1..\*] **telecom** (CONF:5280).
  - 1. Such telecoms **SHOULD** contain zero or one [0..1] **@use**, which **SHALL** be selected from ValueSet Telecom Use (US Realm Header) 2.16.840.1.113883.11.20.9.20 **DYNAMIC** (CONF:5375).

#### 2.1.1.1 patient

- iv. This patientRole **SHALL** contain exactly one [1..1] **patient** (CONF:5283).
  - 1. This patient **SHALL** contain exactly one [1..1] **name** (CONF:5284).
    - a. The content of name **SHALL** be a conformant US Realm Patient Name (PTN.US.FIELDDED) (2.16.840.1.113883.10.20.22.5.1) (CONF:10411).
  - 2. This patient **SHALL** contain exactly one [1..1] **administrativeGenderCode**, which **SHALL** be selected from ValueSet Administrative Gender (HL7 V3) 2.16.840.1.113883.1.11.1 **DYNAMIC** (CONF:6394).
  - 3. This patient **SHALL** contain exactly one [1..1] **birthTime** (CONF:5298).
    - a. **SHALL** be precise to year (CONF:5299).
    - b. **SHOULD** be precise to day (CONF:5300).
  - 4. This patient **SHOULD** contain zero or one [0..1] **maritalStatusCode**, which **SHALL** be selected from ValueSet Marital Status Value Set 2.16.840.1.113883.1.11.12212 **DYNAMIC** (CONF:5303).
  - 5. This patient **MAY** contain zero or one [0..1] **religiousAffiliationCode**, which **SHALL** be selected from ValueSet Religious Affiliation Value Set 2.16.840.1.113883.1.11.19185 **DYNAMIC** (CONF:5317).
  - 6. This patient **MAY** contain zero or one [0..1] **raceCode**, which **SHALL** be selected from ValueSet Race Value Set 2.16.840.1.113883.1.11.14914 **DYNAMIC** (CONF:5322).
  - 7. This patient **MAY** contain zero or one [0..1] **ethnicGroupCode**, which **SHALL** be selected from ValueSet EthnicityGroup 2.16.840.1.114222.4.11.837 **DYNAMIC** (CONF:5323).



### 2.1.1.2 guardian

8. This patient **MAY** contain zero or more [0..\*] **guardian** (CONF:5325).
  - a. The guardian, if present, **SHOULD** contain zero or one [0..1] **code**, which **SHALL** be selected from ValueSet PersonalRelationshipRoleType 2.16.840.1.113883.1.11.19563 **DYNAMIC** (CONF:5326).
  - b. The guardian, if present, **SHOULD** contain zero or more [0..\*] **addr** (CONF:5359).
    - i. The content of addr **SHALL** be a conformant US Realm Address (AD.US.FIELDDED) (2.16.840.1.113883.10.20.22.5.2) (CONF:10413).
  - c. The guardian, if present, **MAY** contain zero or more [0..\*] **telecom** (CONF:5382).
    - i. The telecom, if present, **SHOULD** contain zero or one [0..1] **@use**, which **SHALL** be selected from ValueSet Telecom Use (US Realm Header) 2.16.840.1.113883.11.20.9.20 **DYNAMIC** (CONF:7993).
  - d. The guardian, if present, **SHALL** contain exactly one [1..1] **guardianPerson** (CONF:5385).
    - i. This guardianPerson **SHALL** contain at least one [1..\*] **name** (CONF:5386).
    - ii. The content of name **SHALL** be a conformant US Realm Person Name (PN.US.FIELDDED) (2.16.840.1.113883.10.20.22.5.1.1) (CONF:10414).

### 2.1.1.3 birthplace

9. This patient **MAY** contain zero or one [0..1] **birthplace** (CONF:5395).
  - a. The birthplace, if present, **SHALL** contain exactly one [1..1] **place** (CONF:5396).
    - i. This place **SHALL** contain exactly one [1..1] **addr** (CONF:5397).
      1. This addr **SHOULD** contain zero or one [0..1] **country**, which **SHALL** be selected from ValueSet CountryValueSet 2.16.840.1.113883.3.88.12.80.63 **DYNAMIC** (CONF:5404).
      2. This addr **MAY** contain zero or one [0..1] **postalCode**, which **SHALL** be selected from ValueSet PostalCodeValueSet

2.16.840.1.113883.3.88.12.80.2  
**DYNAMIC** (CONF:5403).

3. If country is US, 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).

#### 2.1.1.4 languageCommunication

10. This patient **SHOULD** contain zero or more [0..\*] **languageCommunication** (CONF:5406).
  - a. The languageCommunication, if present, **SHALL** contain exactly one [1..1] **languageCode**, which **SHALL** be selected from ValueSet Language 2.16.840.1.113883.1.11.11526 **DYNAMIC** (CONF:5407).
  - b. The languageCommunication, if present, **MAY** contain zero or one [0..1] **modeCode**, which **SHALL** be selected from ValueSet LanguageAbilityMode Value Set 2.16.840.1.113883.1.11.12249 **DYNAMIC** (CONF:5409).
  - c. The languageCommunication, if present, **SHOULD** contain zero or one [0..1] **proficiencyLevelCode**, which **SHALL** be selected from ValueSet LanguageAbilityProficiency 2.16.840.1.113883.1.11.12199 **DYNAMIC** (CONF:9965).
  - d. The languageCommunication, if present, **MAY** contain zero or one [0..1] **preferenceInd** (CONF:5414).
11. This patient **MAY** contain zero or more [0..\*] **sdtc:raceCode**, where the @code **SHALL** be selected from ValueSet Race Value Set 2.16.840.1.113883.1.11.14914 **DYNAMIC** (CONF:7263).

#### 2.1.1.5 providerOrganization

- v. This patientRole **MAY** contain zero or one [0..1] **providerOrganization** (CONF:5416).
  1. The providerOrganization, if present, **SHALL** contain at least one [1..\*] **id** (CONF:5417).
    - a. Such ids **SHOULD** contain zero or one [0..1] @root="2.16.840.1.113883.4.6" National Provider Identifier (CONF:16820).
  2. The providerOrganization, if present, **SHALL** contain at least one [1..\*] **name** (CONF:5419).
  3. The providerOrganization, if present, **SHALL** contain at least one [1..\*] **telecom** (CONF:5420).

- a. Such telecoms **SHOULD** contain zero or one [0..1] @use, which **SHALL** be selected from ValueSet Telecom Use (US Realm Header) 2.16.840.1.113883.11.20.9.20 **DYNAMIC** (CONF:7994).
- 4. The providerOrganization, if present, **SHALL** contain at least one [1..\*] addr (CONF:5422).
  - a. The content of addr **SHALL** be a conformant US Realm Address (AD.US.FIELDDED) (2.16.840.1.113883.10.20.22.5.2) (CONF:10415).

#### 2.1.1.6 recordTarget Value Sets

**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 DYNAMIC		
Code System(s): AddressUse 2.16.840.1.113883.5.1119		
Code	Code System	Print Name
HP	AddressUse	primary home
WP	AddressUse	work place
MC	AddressUse	mobile contact
HV	AddressUse	vacation home

**Table 5: Administrative Gender (HL7) Value Set**

Value Set: Administrative Gender (HL7 V3) 2.16.840.1.113883.1.11.1 DYNAMIC		
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 DYNAMIC		
Code System(s): 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 (excerpt)**

Value Set: HL7 Religious Affiliation 2.16.840.1.113883.1.11.19185 DYNAMIC		
Code System(s): ReligiousAffiliation 2.16.840.1.113883.5.1076		
Description:	A value set of codes that reflect spiritual faith affiliation <a href="http://www.hl7.org/memonly/downloads/v3edition.cfm#V32008">http://www.hl7.org/memonly/downloads/v3edition.cfm#V32008</a>	
Code	Code System	Print Name
1026	ReligiousAffiliation	Judaism
1020	ReligiousAffiliation	Hinduism
1041	ReligiousAffiliation	Roman Catholic Church
...		

**Table 8: Race Value Set (excerpt)**

Value Set: Race 2.16.840.1.113883.1.11.14914 DYNAMIC		
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 <a href="http://phinvads.cdc.gov/vads/ViewCodeSystemConcept.action?oid=2.16.840.1.113883.6.238&amp;code=1000-9">http://phinvads.cdc.gov/vads/ViewCodeSystemConcept.action?oid=2.16.840.1.113883.6.238&amp;code=1000-9</a>		
Code	Code System	Print Name
1002-5	Race and Ethnicity- CDC	American Indian or Alaska Native
2028-9	Race and Ethnicity- CDC	Asian
2054-5	Race and Ethnicity- CDC	Black or African American
2076-8	Race and Ethnicity- CDC	Native Hawaiian or Other Pacific Islander
2106-3	Race and Ethnicity- CDC	White
...		

**Table 9: Ethnicity Value Set**

Value Set: Ethnicity Value Set 2.16.840.1.114222.4.11.837 DYNAMIC		
Code System(s): Race and Ethnicity - CDC 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 (excerpt)**

Value Set: Personal Relationship Role Type 2.16.840.1.113883.1.11.19563 DYNAMIC		
Code System(s): RoleCode 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. <a href="http://www.hl7.org/memonly/downloads/v3edition.cfm#V32008">http://www.hl7.org/memonly/downloads/v3edition.cfm#V32008</a>		
Code	Code System	Print Name
HUSB	RoleCode	husband
WIFE	RoleCode	wife
FRND	RoleCode	friend
SISINLAW	RoleCode	sister-in-law
...		

**Table 11: State Value Set (excerpt)**

Value Set: StateValueSet 2.16.840.1.113883.3.88.12.80.1 DYNAMIC		
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 <a href="http://www.itl.nist.gov/fipspubs/fip5-2.htm">http://www.itl.nist.gov/fipspubs/fip5-2.htm</a>		
Code	Code System	Print Name
AL	FIPS 5-2 (State Alpha Codes)	Alabama
AK	FIPS 5-2 (State Alpha Codes)	Alaska
AZ	FIPS 5-2 (State Alpha Codes)	Arizona
AR	FIPS 5-2 (State Alpha Codes)	Arkansas
...		

**Table 12: Postal Code Value Set (excerpt)**

Value Set: PostalCodeValueSet 2.16.840.1.113883.3.88.12.80.2 DYNAMIC		
Code System(s): US Postal Codes 2.16.840.1.113883.6.231		
Description: A value set of codes postal (ZIP) Code of an address in the United States. <a href="http://zip4.usps.com/zip4/welcome.jsp">http://zip4.usps.com/zip4/welcome.jsp</a>		
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 (excerpt)**

Value Set: CountryValueSet 2.16.840.1.113883.3.88.12.80.63 DYNAMIC		
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 <a href="http://www.iso.org/iso/country_codes/iso_3166_code_lists.htm">http://www.iso.org/iso/country_codes/iso_3166_code_lists.htm</a>		
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 DYNAMIC		
Code System(s): LanguageAbilityMode 2.16.840.1.113883.5.60		
Description: A value representing the method of expression of the language.		
Code	Code System	Print Name
ESGN	LanguageAbilityMode	Expressed signed
ESP	LanguageAbilityMode	Expressed spoken
EWR	LanguageAbilityMode	Expressed written
RSGN	LanguageAbilityMode	Received signed
RSP	LanguageAbilityMode	Received spoken
RWR	LanguageAbilityMode	Received written

**Table 15: Language Ability Proficiency Value Set**

Value Set: LanguageAbilityProficiency 2.16.840.1.113883.1.11.12199 DYNAMIC		
Code System(s): LanguageAbilityProficiency 2.16.840.1.113883.5.61		
Description: A value representing the level of proficiency in a language.		
Code	Code System	Print Name
E	LanguageAbilityProficiency	Excellent
F	LanguageAbilityProficiency	Fair
G	LanguageAbilityProficiency	Good
P	LanguageAbilityProficiency	Poor

## 2.1.1.7 recordTarget Example

**Figure 21: recordTarget example**

```
<recordTarget>
 <patientRole>
 <id
 extension="998991"
 root="2.16.840.1.113883.19.5.99999.2"/>
 <!-- Fake ID using HL7 example OID. -->
 <id
 extension="111-00-2330"
 root="2.16.840.1.113883.4.1"/>
 <!-- Fake Social Security Number using the actual SSN OID. -->
 <addr
 use="HP">
 <!-- HP is "primary home" from codeSystem 2.16.840.1.113883.5.1119 -->
 <streetAddressLine>1000 Home Drive</streetAddressLine>
 <city>Blue Bell</city>
 <state>MA</state>
 <postalCode>02368</postalCode>
 <country>US</country>
 <!-- US is "United States" from ISO 3166-1 Country Codes:
 1.0.3166.1 -->
 </addr>
 <telecom
 value="tel:(555)555-1212"
 use="HP"/>
 <!-- HP is "primary home" from HL7 AddressUse 2.16.840.1.113883.5.1119 -->
 <patient>
 <name
 use="L">
 <!-- L is "Legal" from HL7 EntityNameUse 2.16.840.1.113883.5.45 -->
 <given>Eve</given>
 <!-- CL is "Call me" from HL7 EntityNamePartQualifier
 2.16.840.1.113883.5.43 -->
 <family>Everywomen</family>
 </name>
 <administrativeGenderCode
 code="F"
 codeSystem="2.16.840.1.113883.5.1"
 displayName="Female"/>
 <birthTime
 value="20050501"/>
 <maritalStatusCode
 code="M"
 displayName="Married"
 codeSystem="2.16.840.1.113883.5.2"
 codeSystemName="MaritalStatusCode"/>
 <religiousAffiliationCode
 code="1013"
 displayName="Christian (non-Catholic, non-specific)"
 codeSystemName="HL7 Religious Affiliation"
 codeSystem="2.16.840.1.113883.5.1076"/>
```



```

<raceCode
 code="1966-1"
 displayName="Aleut"
 codeSystem="2.16.840.1.113883.6.238"
 codeSystemName="Race & Ethnicity - CDC"/>
<ethnicGroupCode
 code="2186-5"
 displayName="Not Hispanic or Latino"
 codeSystem="2.16.840.1.113883.6.238"
 codeSystemName="Race & Ethnicity - CDC"/>
<guardian>
 <code
 code="GRPRN"
 displayName="GrandParent"
 codeSystem="2.16.840.1.113883.5.111"
 codeSystemName="HL7 Role code"/>
 <addr
 use="HP">
 <!-- HP is "primary home" from codeSystem
 2.16.840.1.113883.5.1119 -->
 <streetAddressLine>1357 Amber Drive</streetAddressLine>
 <city>Beaverton</city>
 <state>OR</state>
 <postalCode>97867</postalCode>
 <country>US</country>
 <!-- US is "United States" from ISO 3166-1 Country Codes:
 1.0.3166.1 -->
 </addr>
 <telecom
 value="tel:(816)276-6909"
 use="HP"/>
 <guardianPerson>
 <name>
 <given>Ralph</given>
 <family>Jones</family>
 </name>
 </guardianPerson>
</guardian>
<birthplace>
 <place>
 <addr>
 <city>Beaverton</city>
 <state>OR</state>
 <postalCode>97867</postalCode>
 <country>US</country>
 </addr>
 </place>
</birthplace>

```

```

<languageCommunication>
 <languageCode
 code="en"/>
 <modeCode
 code="ESP"
 displayName="Expressed spoken"
 codeSystem="2.16.840.1.113883.5.60"
 codeSystemName="LanguageAbilityMode"/>
 <preferenceInd
 value="true"/>
</languageCommunication>
</patient>
<providerOrganization>
 <id
 root="2.16.840.1.113883.19.5.9999.1393"/>
 <name>Community Health and Hospitals</name>
 <telecom
 use="WP"
 value="tel: 555-555-5000"/>
 <addr>
 <streetAddressLine>1001 Village Avenue</streetAddressLine>
 <city>Portland</city>
 <state>OR</state>
 <postalCode>99123</postalCode>
 <country>US</country>
 </addr>
</providerOrganization>
</patientRole>
</recordTarget>

```

## 2.1.2 author

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

13. **SHALL** contain at least one [1..\*] **author** (CONF:5444).

- a. Such authors **SHALL** contain exactly one [1..1] **time** (CONF:5445).
  - i. The content **SHALL** be a conformant US Realm Date and Time (DTM.US.FIELDDED) (2.16.840.1.113883.10.20.22.5.4) (CONF:16866).
- b. Such authors **SHALL** contain exactly one [1..1] **assignedAuthor** (CONF:5448).
  - i. This **assignedAuthor** **SHALL** contain exactly one [1..1] **id** (CONF:5449) such that it
    1. **SHALL** contain exactly one [1..1] **@root** (CONF:16786).
      - a. If this **assignedAuthor** is an **assignedPerson** the **assignedAuthor id** **SHALL** contain exactly one [1..1] **@root="2.16.840.1.113883.4.6"** National Provider Identifier (CONF:19521).
  - ii. This **assignedAuthor** **SHOULD** contain zero or one [0..1] **code** (CONF:16787).

1. The code, if present, **SHALL** contain exactly one [1..1] **@code**, which **SHOULD** be selected from ValueSet [Healthcare Provider Taxonomy \(HIPAA\) 2.16.840.1.114222.4.11.1066](#) **DYNAMIC** (CONF:16788).
- iii. This assignedAuthor **SHALL** contain at least one [1..\*] **addr** (CONF:5452).
  1. The content **SHALL** be a conformant US Realm Address (AD.US.FIELDDED) (2.16.840.1.113883.10.20.22.5.2) (CONF:16871).
- iv. This assignedAuthor **SHALL** contain at least one [1..\*] **telecom** (CONF:5428).
  1. Such telecoms **SHOULD** contain zero or one [0..1] **@use**, which **SHALL** be selected from ValueSet Telecom Use (US Realm Header) 2.16.840.1.113883.11.20.9.20 **DYNAMIC** (CONF:7995).
- v. This assignedAuthor **SHOULD** contain zero or one [0..1] **assignedPerson** (CONF:5430).
  1. The assignedPerson, if present, **SHALL** contain at least one [1..\*] **name** (CONF:16789).
    - a. The content **SHALL** be a conformant US Realm Person Name (PN.US.FIELDDED) (2.16.840.1.113883.10.20.22.5.1.1) (CONF:16872).
- vi. This assignedAuthor **SHOULD** contain zero or one [0..1] **assignedAuthoringDevice** (CONF:16783).
  1. The assignedAuthoringDevice, if present, **SHALL** contain exactly one [1..1] **manufacturerModelName** (CONF:16784).
  2. The assignedAuthoringDevice, if present, **SHALL** contain exactly one [1..1] **softwareName** (CONF:16785).
- vii. There **SHALL** be exactly one assignedAuthor/assignedPerson or exactly one assignedAuthor/assignedAuthoringDevice (CONF:16790).

**Table 16: Healthcare Provider Taxonomy Value Set**

Value Set: Healthcare Provider Taxonomy (HIPAA) 2.16.840.1.114222.4.11.1066 DYNAMIC		
Code System(s): NUCC Health Care Provider Taxonomy 2.16.840.1.113883.6.101		
Code	Code System	Print Name
122300000X	NUCC Health Care Provider Taxonomy	Dentist
124Q00000X	NUCC Health Care Provider Taxonomy	Dental Hygienist
126800000X	NUCC Health Care Provider Taxonomy	Dental Assistant/Tech
133V00000X	NUCC Health Care Provider Taxonomy	Dietitian, Registered
146L00000X	NUCC Health Care Provider Taxonomy	EMT/Paramedic
163W00000X	NUCC Health Care Provider Taxonomy	Registered Nurse
163WI0500X	NUCC Health Care Provider Taxonomy	IVT Team Staff
163WI0600X	NUCC Health Care Provider Taxonomy	Infection Control Professional
163WX0106X	NUCC Health Care Provider Taxonomy	Occupational Health

Value Set: Healthcare Provider Taxonomy (HIPAA) 2.16.840.1.114222.4.11.1066 DYNAMIC		
Code System(s): NUCC Health Care Provider Taxonomy 2.16.840.1.113883.6.101		
Code	Code System	Print Name
		Professional
164W00000X	NUCC Health Care Provider Taxonomy	Licensed Practical Nurse
167G00000X	NUCC Health Care Provider Taxonomy	Psychiatric Technician
183500000X	NUCC Health Care Provider Taxonomy	Pharmacist
207PE0004X	NUCC Health Care Provider Taxonomy	Other First Responder
227800000X	NUCC Health Care Provider Taxonomy	Respiratory Therapist/Tech
227900000X	NUCC Health Care Provider Taxonomy	Other Student
246QM0706X	NUCC Health Care Provider Taxonomy	Medical Technologist
246RP1900X	NUCC Health Care Provider Taxonomy	Phlebotomist/IV Team
247100000X	NUCC Health Care Provider Taxonomy	Radiologic Technologist
261QD0000X	NUCC Health Care Provider Taxonomy	Other Dental Worker
261QP2000X	NUCC Health Care Provider Taxonomy	Physical Therapist
261QR1100X	NUCC Health Care Provider Taxonomy	Researcher
332B00000X	NUCC Health Care Provider Taxonomy	Central Supply
363A00000X	NUCC Health Care Provider Taxonomy	Physician Assistant
363L00000X	NUCC Health Care Provider Taxonomy	Nurse Practitioner
364SC1501X	NUCC Health Care Provider Taxonomy	Public Health Worker
367500000X	NUCC Health Care Provider Taxonomy	Nurse Anesthetist
367A00000X	NUCC Health Care Provider Taxonomy	Nurse Midwife
3747A0650X	NUCC Health Care Provider Taxonomy	Attendant/orderly
376K00000X	NUCC Health Care Provider Taxonomy	Nursing Assistant

**Figure 22: Person author example**

```
<author>
 <time
 value="20050329224411+0500"/>
 <assignedAuthor>
 <id
 extension="99999999"
 root="2.16.840.1.113883.4.6"/>
 <code
 code="200000000X"
 codeSystem="2.16.840.1.113883.6.101"
 displayName="Allopathic & Osteopathic Physicians"/>
 <addr>
 <streetAddressLine>1002 Healthcare Drive </streetAddressLine>
 <city>Portland</city>
 <state>OR</state>
 <postalCode>99123</postalCode>
 <country>US</country>
 </addr>
 <telecom
 use="WP"
 value="tel:555-555-1002"/>
 <assignedPerson>
 <name>
 <given>Henry</given>
 <family>Seven</family>
 </name>
 </assignedPerson>
 </assignedAuthor>
</author>
```

**Figure 23: Device author example**

```
<author>
 <time value="20050329224411+0500"/>
 <assignedAuthor>
 <id extension="KP00017dev" root="2.16.840.1.113883.19.5"/>
 <addr>
 <streetAddressLine>21 North Ave.</streetAddressLine>
 <city>Burlington</city>
 <state>MA</state>
 <postalCode>02368</postalCode>
 <country>US</country>
 </addr>
 <telecom use="WP" value="tel:(555)555-1003"/>
 <assignedAuthoringDevice>
 <manufacturerModelName>Good Health Medical
 Device</manufacturerModelName >
 <softwareName>Good Health Report Generator</softwareName >
 </ assignedAuthoringDevice >
 </assignedAuthor>
</author>
```

### 2.1.3 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).

14. **MAY** contain zero or one [0..1] `dataEnterer` (CONF:5441).

- a. The `dataEnterer`, if present, **SHALL** contain exactly one [1..1] `assignedEntity` (CONF:5442).
  - i. This `assignedEntity` **SHALL** contain at least one [1..\*] `id` (CONF:5443).
    1. Such `ids` **SHOULD** contain zero or one [0..1] `@root="2.16.840.1.113883.4.6"` National Provider Identifier (CONF:16821).
  - ii. This `assignedEntity` **SHALL** contain at least one [1..\*] `addr` (CONF:5460).
    1. The content of `addr` **SHALL** be a conformant US Realm Address (AD.US.FIELDDED) (2.16.840.1.113883.10.20.22.5.2) (CONF:10417).
  - iii. This `assignedEntity` **SHALL** contain at least one [1..\*] `telecom` (CONF:5466).
    1. Such `telecoms` **SHOULD** contain zero or one [0..1] `@use`, which **SHALL** be selected from ValueSet Telecom Use (US Realm Header) 2.16.840.1.113883.11.20.9.20 **DYNAMIC** (CONF:7996).
  - iv. This `assignedEntity` **SHALL** contain exactly one [1..1] `assignedPerson` (CONF:5469).
    1. This `assignedPerson` **SHALL** contain at least one [1..\*] `name` (CONF:5470).
      - a. The content of `name` **SHALL** be a conformant US Realm Person Name (PN.US.FIELDDED) (2.16.840.1.113883.10.20.22.5.1.1) (CONF:10418).
  - v. This `assignedEntity` **MAY** contain zero or one [0..1] `code` which **SHOULD** be selected from coding system NUCC Health Care Provider Taxonomy 2.16.840.1.113883.6.101 (CONF:9944).

**Figure 24: dataEnterer example**

```
<dataEnterer>
 <assignedEntity>
 <id
 root="2.16.840.1.113883.4.6"
 extension="999999943252"/>
 <addr>
 <streetAddressLine>1001 Village Avenue</streetAddressLine>
 <city>Portland</city>
 <state>OR</state>
 <postalCode>99123</postalCode>
 <country>US</country>
 </addr>
 <telecom
 use="WP"
 value="tel:555-555-1002"/>
 <assignedPerson>
 <name>
 <given>Henry</given>
 <family>Seven</family>
 </name>
 </assignedPerson>
 </assignedEntity>
</dataEnterer>
```

#### 2.1.4 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.

15. **MAY** contain zero or more [0..\*] **informant** (CONF:8001).

- a. The informant, if present, **SHALL** contain exactly one [1..1] **assignedEntity** (CONF:8002).
  - i. This **assignedEntity** **SHALL** contain at least one [1..\*] **id** (CONF:9945).
    1. If **assignedEntity/id** is a provider then this **id**, **SHOULD** include zero or one [0..1] **id** where `id/@root="2.16.840.1.113883.4.6"` National Provider Identifier (CONF:9946).
  - ii. This **assignedEntity** **SHALL** contain at least one [1..\*] **addr** (CONF:8220).

1. The content of `addr` **SHALL** be a conformant US Realm Address (AD.US.FIELDDED) (2.16.840.1.113883.10.20.22.5.2) (CONF:10419).
- iii. This `assignedEntity` **SHALL** contain exactly one [1..1] `assignedPerson` (CONF:8221).
  1. This `assignedPerson` **SHALL** contain at least one [1..\*] `name` (CONF:8222).
    - a. The content of `name` **SHALL** be a conformant US Realm Person Name (PN.US.FIELDDED) (2.16.840.1.113883.10.20.22.5.1.1) (CONF:10420).
- iv. This `assignedEntity` **MAY** contain zero or one [0..1] `code` which **SHOULD** be selected from coding system NUCC Health Care Provider Taxonomy 2.16.840.1.113883.6.101 (CONF:9947).

**Figure 25: informant with assignedEntity example**

```

<informant>
 <assignedEntity>
 <id
 extension="KP00017"
 root="2.16.840.1.113883.19.5"/>
 <addr>
 <streetAddressLine>1001 Village Avenue</streetAddressLine>
 <city>Portland</city>
 <state>OR</state>
 <postalCode>99123</postalCode>
 <country>US</country>
 </addr>
 <telecom
 use="WP"
 value="tel:555-555-1002"/>
 <assignedPerson>
 <name>
 <given>Henry</given>
 <family>Seven</family>
 </name>
 </assignedPerson>
 </assignedEntity>
</informant>

```

## 2.1.5 custodian

The `custodian` element represents the organization that is in charge of maintaining the document. The custodian is the steward that is entrusted with the care of the document. Every CDA document has exactly one custodian. The custodian participation satisfies the CDA definition of Stewardship. Because CDA is an exchange standard and may not represent the original form of the authenticated document (e.g., CDA could include scanned copy of original), the custodian represents the steward of the original source document. The custodian may be the document originator, a health information exchange, or other responsible party.



16. **SHALL** contain exactly one [1..1] **custodian** (CONF:5519).
- a. This custodian **SHALL** contain exactly one [1..1] **assignedCustodian** (CONF:5520).
    - i. This assignedCustodian **SHALL** contain exactly one [1..1] **representedCustodianOrganization** (CONF:5521).
      1. This representedCustodianOrganization **SHALL** contain at least one [1..\*] **id** (CONF:5522).
        - a. Such ids **SHOULD** contain zero or one [0..1] **@root**="2.16.840.1.113883.4.6" National Provider Identifier (CONF:16822).
      2. This representedCustodianOrganization **SHALL** contain exactly one [1..1] **name** (CONF:5524).
      3. This representedCustodianOrganization **SHALL** contain exactly one [1..1] **telecom** (CONF:5525).
        - a. This telecom **SHOULD** contain zero or one [0..1] **@use**, which **SHALL** be selected from ValueSet Telecom Use (US Realm Header) 2.16.840.1.113883.11.20.9.20 **DYNAMIC** (CONF:7998).
      4. This representedCustodianOrganization **SHALL** contain exactly one [1..1] **addr** (CONF:5559).
        - a. The content of addr **SHALL** be a conformant US Realm Address (AD.US.FIELDDED) (2.16.840.1.113883.10.20.22.5.2) (CONF:10421).

**Figure 26: custodian example**

```

<custodian>
 <assignedCustodian>
 <representedCustodianOrganization>
 <id
 extension="99999999"
 root="2.16.840.1.113883.4.6"/>
 <name>Community Health and Hospitals</name>
 <telecom
 value="tel: 555-555-1002"
 use="WP"/>
 <addr
 use="WP">
 <streetAddressLine>1002 Healthcare Drive </streetAddressLine>
 <city>Portland</city>
 <state>OR</state>
 <postalCode>99123</postalCode>
 <country>US</country>
 </addr>
 </representedCustodianOrganization>
 </assignedCustodian>
</custodian>

```

## 2.1.6 informationRecipient

The `informationRecipient` element records the intended recipient of the information at the time the document is created. For example, in cases where the intended recipient of the document is the patient's health chart, set the `receivedOrganization` to be the scoping organization for that chart.

17. **MAY** contain zero or more [0..\*] **informationRecipient** (CONF:5565).
  - a. The `informationRecipient`, if present, **SHALL** contain exactly one [1..1] **intendedRecipient** (CONF:5566).
    - i. This `intendedRecipient` **MAY** contain zero or one [0..1] **informationRecipient** (CONF:5567).
      1. The `informationRecipient`, if present, **SHALL** contain at least one [1..\*] **name** (CONF:5568).
        - a. The content of `name` **SHALL** be a conformant US Realm Person Name (PN.US.FIELDDED) (2.16.840.1.113883.10.20.22.5.1.1) (CONF:10427).
    - ii. This `intendedRecipient` **MAY** contain zero or one [0..1] **receivedOrganization** (CONF:5577).
      1. The `receivedOrganization`, if present, **SHALL** contain exactly one [1..1] **name** (CONF:5578).

**Figure 27: informationRecipient example**

```
<informationRecipient>
 <intendedRecipient>
 <informationRecipient>
 <name>
 <given>Henry</given>
 <family>Seven</family>
 </name>
 </informationRecipient>
 <receivedOrganization>
 <name>Community Health and Hospitals</name>
 </receivedOrganization>
 </intendedRecipient>
</informationRecipient>
```

## 2.1.7 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.

Note that the legal authenticator, if present, must be a person.

18. **SHOULD** contain zero or one [0..1] **legalAuthenticator** (CONF:5579).
- a. The legalAuthenticator, if present, **SHALL** contain exactly one [1..1] **time** (CONF:5580).
    - i. The content **SHALL** be a conformant US Realm Date and Time (DTM.US.FIELDDED) (2.16.840.1.113883.10.20.22.5.4) (CONF:16873).
  - b. The legalAuthenticator, if present, **SHALL** contain exactly one [1..1] **signatureCode** (CONF:5583).
    - i. This signatureCode **SHALL** contain exactly one [1..1] **@code="S"** (CodeSystem: Participationsignature 2.16.840.1.113883.5.89 **STATIC**) (CONF:5584).
  - c. The legalAuthenticator, if present, **SHALL** contain exactly one [1..1] **assignedEntity** (CONF:5585).
    - i. This assignedEntity **SHALL** contain at least one [1..\*] **id** (CONF:5586).
      1. Such ids **MAY** contain zero or one [0..1] **@root="2.16.840.1.113883.4.6"** National Provider Identifier (CONF:16823).
    - ii. This assignedEntity **MAY** contain zero or one [0..1] **code**, which **SHOULD** be selected from ValueSet [Healthcare Provider Taxonomy \(HIPAA\) 2.16.840.1.114222.4.11.1066](#) **STATIC** (CONF:17000).
    - iii. This assignedEntity **SHALL** contain at least one [1..\*] **addr** (CONF:5589).
      1. The content of addr **SHALL** be a conformant US Realm Address (AD.US.FIELDDED) (2.16.840.1.113883.10.20.22.5.2) (CONF:10429).
    - iv. This assignedEntity **SHALL** contain at least one [1..\*] **telecom** (CONF:5595).
      1. Such telecoms **SHOULD** contain zero or one [0..1] **@use**, which **SHALL** be selected from ValueSet Telecom Use (US Realm Header) 2.16.840.1.113883.11.20.9.20 **DYNAMIC** (CONF:7999).
    - v. This assignedEntity **SHALL** contain exactly one [1..1] **assignedPerson** (CONF:5597).
      1. This assignedPerson **SHALL** contain at least one [1..\*] **name** (CONF:5598).
        - a. The content of name **SHALL** be a conformant US Realm Person Name (PN.US.FIELDDED) (2.16.840.1.113883.10.20.22.5.1.1) (CONF:10430).

**Figure 28: legalAuthenticator example**

```
<legalAuthenticator>
 <time
 value="20090227130000+0500"/>
 <signatureCode
 code="S"/>
 <assignedEntity>
 <id
 extension="999999999"
 root="2.16.840.1.113883.4.6"/>
 <addr>
 <streetAddressLine>1001 Village Avenue</streetAddressLine>
 <city>Portland</city>
 <state>OR</state>
 <postalCode>99123</postalCode>
 <country>US</country>
 </addr>
 <telecom
 use="WP"
 value="tel:555-555-1002"/>
 <assignedPerson>
 <name>
 <given>Henry</given>
 <family>Seven</family>
 </name>
 </assignedPerson>
 </assignedEntity>
</legalAuthenticator>
```

## 2.1.8 authenticator

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

19. **MAY** contain zero or more [0..\*] **authenticator** (CONF:5607).
- a. The authenticator, if present, **SHALL** contain exactly one [1..1] **time** (CONF:5608).
    - i. The content **SHALL** be a conformant US Realm Date and Time (DTM.US.FIELDDED) (2.16.840.1.113883.10.20.22.5.4) (CONF:16874).
  - b. The authenticator, if present, **SHALL** contain exactly one [1..1] **signatureCode** (CONF:5610).
    - i. This signatureCode **SHALL** contain exactly one [1..1] **@code="S"** (CodeSystem: Participationsignature 2.16.840.1.113883.5.89 **STATIC**) (CONF:5611).
  - c. The authenticator, if present, **SHALL** contain exactly one [1..1] **assignedEntity** (CONF:5612).
    - i. This assignedEntity **SHALL** contain at least one [1..\*] **id** (CONF:5613).
      1. Such ids **SHOULD** contain zero or one [0..1] **@root="2.16.840.1.113883.4.6"** National Provider Identifier (CONF:16824).

- ii. This assignedEntity **MAY** contain zero or one [0..1] **code** (CONF:16825).
  - 1. The code, if present, **MAY** contain zero or one [0..1] **@code**, which **SHOULD** be selected from ValueSet [Healthcare Provider Taxonomy \(HIPAA\) 2.16.840.1.114222.4.11.1066](#) **STATIC** (CONF:16826).
- iii. This assignedEntity **SHALL** contain at least one [1..\*] **addr** (CONF:5616).
  - 1. The content of addr **SHALL** be a conformant US Realm Address (AD.US.FIELDDED) (2.16.840.1.113883.10.20.22.5.2) (CONF:10425).
- iv. This assignedEntity **SHALL** contain at least one [1..\*] **telecom** (CONF:5622).
  - 1. Such telecoms **SHOULD** contain zero or one [0..1] **@use**, which **SHALL** be selected from ValueSet Telecom Use (US Realm Header) 2.16.840.1.113883.11.20.9.20 **DYNAMIC** (CONF:8000).
- v. This assignedEntity **SHALL** contain exactly one [1..1] **assignedPerson** (CONF:5624).
  - 1. This assignedPerson **SHALL** contain at least one [1..\*] **name** (CONF:5625).
  - 2. The content of name **SHALL** be a conformant US Realm Person Name (PN.US.FIELDDED) (2.16.840.1.113883.10.20.22.5.1.1) (CONF:10424).

**Figure 29: authenticator example**

```
<authenticator>
 <time
 value="20090227130000+0500"/>
 <signatureCode
 code="S"/>
 <assignedEntity>
 <id
 extension="999999999"
 root="2.16.840.1.113883.4.6"/>
 <addr>
 <streetAddressLine>1001 Village Avenue</streetAddressLine>
 <city>Portland</city>
 <state>OR</state>
 <postalCode>99123</postalCode>
 <country>US</country>
 </addr>
 <telecom
 use="WP"
 value="tel:555-555-1002"/>
 <assignedPerson>
 <name>
 <given>Henry</given>
 <family>Seven</family>
 </name>
 </assignedPerson>
 </assignedEntity>
</authenticator>
```

### 2.1.9 participant (Support)

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

A supporting person or organization is an individual or an organization with a relationship to the patient. A supporting person who is playing multiple roles would be recorded in multiple participants (e.g., emergency contact and next-of-kin)

20. **MAY** contain zero or more [0..\*] **participant** (CONF:10003).

- a. The participant, if present, **MAY** contain zero or one [0..1] **time** (CONF:10004).
- b. Such participants, if present, **SHALL** have an associatedPerson or scopingOrganization element under participant/associatedEntity (CONF:10006).
- c. Unless otherwise specified by the document specific header constraints, when participant/@typeCode is IND, associatedEntity/@classCode **SHALL** be selected from ValueSet 2.16.840.1.113883.11.20.9.33 INDRoleclassCodes **STATIC** 2011-09-30 (CONF:10007).

**Table 17: IND Role classCode Value Set**

Value Set: INDRoleclassCodes 2.16.840.1.113883.11.20.9.33 STATIC 2011-09-30		
Code System(s): RoleClass 2.16.840.1.113883.5.110		
Code	Code System	Print Name
PRS	RoleClass	personal relationship
NOK	RoleClass	next of kin
CAREGIVER	RoleClass	caregiver
AGNT	RoleClass	agent
GUAR	RoleClass	guarantor
ECON	RoleClass	emergency contact

**Figure 30: participant example for a supporting person**

```

<participant
 typeCode="IND">
 <time
 xsi:type="IVL_TS">
 <low
 value="19590101"/>
 <high
 value="20111025"/>
 </time>
 <associatedEntity
 classCode="NOK">
 <code
 code="MTH"
 codeSystem="2.16.840.1.113883.5.111"/>
 <addr>
 <streetAddressLine>17 Daws Rd.</streetAddressLine>
 <city>Beaverton</city>
 <state>OR</state>
 <postalCode>97867</postalCode>
 <country>US</country>
 </addr>
 <telecom
 value="tel:(999)555-1212"
 use="WP"/>
 <associatedPerson>
 <name>
 <prefix>Mrs.</prefix>
 <given>Martha</given>
 <family>Jones</family>
 </name>
 </associatedPerson>
 </associatedEntity>
</participant>

```

## 2.1.10 inFulfillmentOf

The inFulfillmentOf element represents orders that are fulfilled by this document.

21. **MAY** contain zero or more [0..\*] inFulfillmentOf (CONF:9952).
  - a. The inFulfillmentOf, if present, **SHALL** contain exactly one [1..1] **order** (CONF:9953).
    - i. This order **SHALL** contain at least one [1..\*] **id** (CONF:9954).

## 2.1.11 documentationOf/serviceEvent

A serviceEvent represents the main act, such as a colonoscopy or a cardiac stress study, being documented. In a continuity of care document, CCD, the serviceEvent is a provision of healthcare over a period of time. In a provision of healthcare serviceEvent, the care providers, PCP or other longitudinal providers, are recorded within the serviceEvent. If the document is about a single encounter, the providers associated can be recorded in the componentOf/encompassingEncounter.

22. **MAY** contain zero or more [0..\*] documentationOf (CONF:14835).
  - a. The documentationOf, if present, **SHALL** contain exactly one [1..1] **serviceEvent** (CONF:14836).
    - i. This serviceEvent **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:14837).
      1. This effectiveTime **SHALL** contain exactly one [1..1] **low** (CONF:14838).
    - ii. This serviceEvent **SHOULD** contain zero or more [0..\*] **performer** (CONF:14839).
      1. The performer, if present, **SHALL** contain exactly one [1..1] **@typeCode** (CodeSystem: HL7ParticipationType 2.16.840.1.113883.5.90 **STATIC**) (CONF:14840).
        - a. The performer participant represents clinicians who actually and principally carry out the serviceEvent. In a transfer of care this represents the healthcare providers involved in the current or pertinent historical care of the patient. Preferably, the patient's key healthcare care team members would be listed, particularly their primary physician and any active consulting physicians, therapists, and counselors (CONF:16753).
      2. The performer, if present, **MAY** contain zero or one [0..1] **functionCode** (CONF:16818).
        - a. The functionCode, if present, **SHOULD** contain zero or one [0..1] **@codeSystem**, which **SHOULD** be selected from CodeSystem participationFunction (2.16.840.1.113883.5.88) **STATIC** (CONF:16819).
      3. The performer, if present, **SHALL** contain exactly one [1..1] **assignedEntity** (CONF:14841).



- a. This assignedEntity **SHALL** contain at least one [1..\*] **id** (CONF:14846).
  - i. Such ids **SHOULD** contain zero or one [0..1] **@root**="2.16.840.1.113883.4.6" National Provider Identifier (CONF:14847).
- b. This assignedEntity **SHOULD** contain zero or one [0..1] **code** (CONF:14842).
  - i. The code, if present, **SHALL** contain exactly one [1..1] **@code**, which **SHOULD** be selected from CodeSystem NUCCProviderTaxonomy (2.16.840.1.113883.6.101) **STATIC** (CONF:14843).

**Figure 31: documentationOf example**

```

<documentationOf
 typeCode="DOC">
 <serviceEvent
 classCode="PCPR">
 <code
 code="73761001"
 codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMED CT"
 displayName="Colonoscopy"/>
 <effectiveTime>
 <low
 value="201209080000-0400"/>
 <high
 value="201209150000-0400"/>
 </effectiveTime>
 <performer
 typeCode="PRF">
 <functionCode
 code="PP"
 displayName="Primary Care Provider"
 codeSystem="2.16.840.1.113883.12.443"
 codeSystemName="Provider Role">
 <originalText>Primary Care Provider</originalText>
 </functionCode>
 <time>
 <low
 value="201209080000-0400"/>
 <high
 value="201209150000-0400"/>
 </time>
 <assignedEntity>
 <id
 extension="PseudoMD-1"
 root="2.16.840.1.113883.4.6"/>
 <code
 code="200000000X"
 displayName="Allopathic and Osteopathic Physicians"
 codeSystemName="Provider Codes"
 codeSystem="2.16.840.1.113883.6.101"/>
 </assignedEntity>
 </serviceEvent>
</documentationOf>

```

```

 <addr>
 <streetAddressLine>1001 Village Avenue</streetAddressLine>
 <city>Portland</city>
 <state>OR</state>
 <postalCode>99123</postalCode>
 <country>US</country>
 </addr>
 <telecom
 value="tel:+1-555-555-5000"
 use="WP"/>
 <assignedPerson>
 <name>
 <prefix>Dr.</prefix>
 <given>Henry</given>
 <family>Seven</family>
 </name>
 </assignedPerson>
 <representedOrganization>
 <id
 root="2.16.840.1.113883.19.5.9999.1393"/>
 <name>Community Health and Hospitals</name>
 <telecom
 value="tel:+1-555-555-5000"
 use="WP"/>
 <addr>
 <streetAddressLine>1001 Village Avenue</streetAddressLine>
 <city>Portland</city>
 <state>OR</state>
 <postalCode>99123</postalCode>
 <country>US</country>
 </addr>
 </representedOrganization>
 </assignedEntity>
</performer>
</serviceEvent>
</documentationOf>

```

## 2.1.12 authorization/consent

The header can record information about the patient's consent.

The type of consent (e.g., a consent to perform the related `serviceEvent`) is conveyed in `consent/code`. Consents in the header have been finalized (`consent/statusCode` must equal `Completed`) and should be on file. This specification does not address how 'Privacy Consent' is represented, but does not preclude the inclusion of 'Privacy Consent'.

23. **MAY** contain zero or more [0..\*] **authorization** (CONF:16792) such that it

a. **SHALL** contain exactly one [1..1] **consent** (CONF:16793).

i. This consent **MAY** contain zero or more [0..\*] **id** (CONF:16794).

ii. This consent **MAY** contain zero or one [0..1] **code** (CONF:16795).

1. The type of consent (e.g., a consent to perform the related `serviceEvent`) is conveyed in `consent/code` (CONF:16796).

- iii. This consent **SHALL** contain exactly one [1..1] **statusCode** (CONF:16797).
  - 1. This **statusCode** **SHALL** contain exactly one [1..1] **@code="completed"** Completed (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:16798).

**Figure 32: 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="64293-4" displayName="Procedure consent"/>
 <statusCode code="completed"/>
 </consent>
</authorization>

```

### 2.1.13 componentOf

The `componentOf` element contains the encompassing encounter for this document. The encompassing encounter represents the setting of the clinical encounter during which the document act(s) or ServiceEvent occurred.

In order to represent providers associated with a specific encounter, they are recorded within the `encompassingEncounter` as participants.

In a CCD the `encompassingEncounter` may be used when documenting a specific encounter and its participants. All relevant encounters in a CCD may be listed in the encounters section.

- 24. **MAY** contain zero or one [0..1] **componentOf** (CONF:9955).
  - a. The `componentOf`, if present, **SHALL** contain exactly one [1..1] **encompassingEncounter** (CONF:9956).
    - i. This `encompassingEncounter` **SHALL** contain at least one [1..\*] **id** (CONF:9959).
    - ii. This `encompassingEncounter` **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:9958).

## 2.2 US Realm Address (AD.US.FIELDDED) [Closed for comments; published July 2012]

[AD: templateId 2.16.840.1.113883.10.20.22.5.2 (open)]

Reusable ""address"" template, designed for use in US Realm CDA Header.

- 1. **SHOULD** contain zero or one [0..1] **@use**, which **SHALL** be selected from ValueSet PostalAddressUse 2.16.840.1.113883.1.11.10637 **STATIC** 2005-05-01 (CONF:7290).
- 2. **SHOULD** contain zero or one [0..1] **country**, where the **@code** **SHALL** be selected from ValueSet CountryValueSet 2.16.840.1.113883.3.88.12.80.63 **DYNAMIC** (CONF:7295).

3. **SHOULD** contain zero or one [0..1] **state** (ValueSet: StateValueSet 2.16.840.1.113883.3.88.12.80.1 **DYNAMIC**) (CONF:7293).
  - a. State is required if the country is US. If country is not specified, its assumed to be US. If country is something other than US, the state **MAY** be present but **MAY** be bound to different vocabularies (CONF:10024).
4. **SHALL** contain exactly one [1..1] **city** (CONF:7292).
5. **SHOULD** contain zero or one [0..1] **postalCode** (ValueSet: PostalCodeValueSet 2.16.840.1.113883.3.88.12.80.2 **DYNAMIC**) (CONF:7294).
  - a. PostalCode is required if the country is US. If country is not specified, its assumed to be US. If country is something other than US, the postalCode **MAY** be present but **MAY** be bound to different vocabularies (CONF:10025).
6. **SHALL** contain at least one and not more than 4 **streetAddressLine** (CONF:7291).
7. **SHALL NOT** have mixed content except for white space (CONF:7296).

**Table 18: PostalAddressUse Value Set**

Value Set: PostalAddressUse 2.16.840.1.113883.1.11.10637 STATIC 2005-05-01		
Code System(s): AddressUse 2.16.840.1.113883.5.1119		
Code	Code System	Print Name
BAD	AddressUse	bad address
DIR	AddressUse	direct
H	AddressUse	home address
HP	AddressUse	primary home
HV	AddressUse	vacation home
PHYS	AddressUse	physical visit address
PST	AddressUse	postal address
PUB	AddressUse	public
TMP	AddressUse	temporary
WP	AddressUse	work place

## 2.3 US Realm Date and Time (DTM.US.FIELDDED) [Closed for comments; published July 2012]

[TS: templateId 2.16.840.1.113883.10.20.22.5.4 (open) ]

The US Realm Clinical Document Date and Time datatype flavor records date and time information. If no time zone offset is provided, you can make no assumption about time, unless you have made a local exchange agreement.

1. **SHALL** be precise to the day (CONF:10127).
2. **SHOULD** be precise to the minute (CONF:10128).
3. **MAY** be precise to the second (CONF:10129).
4. If more precise than day, **SHOULD** include time-zone offset (CONF:10130).

## 2.4 US Realm Patient Name (PTN.US.FIELDDED) [Closed for comments; published July 2012]

[PN: templateId 2.16.840.1.113883.10.20.22.5.1 (open)]

The US Realm Patient Name datatype flavor is a set of reusable constraints that can be used for the patient or any other person. It requires a first (given) and last (family) name. If a patient or person has only one name part (e.g., patient with first name only) place the name part in the field required by the organization. Use the appropriate nullFlavor, "Not Applicable" (NA), in the other field.

For information on mixed content see the Extensible Markup Language reference (<http://www.w3c.org/TR/2008/REC-xml-20081126/>).

1. **MAY** contain zero or one [0..1] @**use**, which **SHALL** be selected from ValueSet EntityNameUse 2.16.840.1.113883.1.11.15913 **STATIC** 2005-05-01 (CONF:7154).
2. **SHALL** contain exactly one [1..1] **family** (CONF:7159).
  - a. This family **MAY** contain zero or one [0..1] @**qualifier**, which **SHALL** be selected from ValueSet EntityPersonNamePartQualifier 2.16.840.1.113883.11.20.9.26 **STATIC** 2011-09-30 (CONF:7160).
3. **SHALL** contain at least one [1..\*] **given** (CONF:7157).
  - a. Such givens **MAY** contain zero or one [0..1] @**qualifier**, which **SHALL** be selected from ValueSet EntityPersonNamePartQualifier 2.16.840.1.113883.11.20.9.26 **STATIC** 2011-09-30 (CONF:7158).
  - b. The second occurrence of given (given[2]) if provided, **SHALL** include middle name or middle initial (CONF:7163).
4. **MAY** contain zero or more [0..\*] **prefix** (CONF:7155).
  - a. The prefix, if present, **MAY** contain zero or one [0..1] @**qualifier**, which **SHALL** be selected from ValueSet EntityPersonNamePartQualifier 2.16.840.1.113883.11.20.9.26 **STATIC** 2011-09-30 (CONF:7156).
5. **MAY** contain zero or one [0..1] **suffix** (CONF:7161).
  - a. The suffix, if present, **MAY** contain zero or one [0..1] @**qualifier**, which **SHALL** be selected from ValueSet EntityPersonNamePartQualifier 2.16.840.1.113883.11.20.9.26 **STATIC** 2011-09-30 (CONF:7162).
6. **SHALL NOT** have mixed content except for white space (CONF:7278).

**Table 19: EntityNameUse Value Set**

Value Set: EntityNameUse 2.16.840.1.113883.1.11.15913 STATIC 2005-05-01		
Code System(s): EntityNameUse 2.16.840.1.113883.5.45		
<b>Code</b>	<b>Code System</b>	<b>Print Name</b>
A	EntityNameUse	Artist/Stage
ABC	EntityNameUse	Alphabetic
ASGN	EntityNameUse	Assigned
C	EntityNameUse	License
I	EntityNameUse	Indigenous/Tribal
IDE	EntityNameUse	Ideographic
L	EntityNameUse	Legal
P	EntityNameUse	Pseudonym
PHON	EntityNameUse	Phonetic
R	EntityNameUse	Religious
SNDX	EntityNameUse	Soundex
SRCH	EntityNameUse	Search
SYL	EntityNameUse	Syllabic

**Table 20: EntityPersonNamePersonPartQualifier Value Set**

Value Set: EntityPersonNamePartQualifier 2.16.840.1.113883.1.1.20.9.26 STATIC 2011-09-30		
Code System(s): EntityNamePartQualifier 2.16.840.1.113883.5.43		
<b>Code</b>	<b>Code System</b>	<b>Print Name</b>
AC	EntityNamePartQualifier	academic
AD	EntityNamePartQualifier	adopted
BR	EntityNamePartQualifier	birth
CL	EntityNamePartQualifier	callme
IN	EntityNamePartQualifier	initial
NB	EntityNamePartQualifier	nobility
PR	EntityNamePartQualifier	professional
SP	EntityNamePartQualifier	spouse
TITLE	EntityNamePartQualifier	title
VV	EntityNamePartQualifier	voorvoegsel

## 2.5 US Realm Person Name (PN.US.FIELDDED) [Closed for comments; published July 2012]

[PN: templateId 2.16.840.1.113883.10.20.22.5.1.1 (open)]

The US Realm Clinical Document Person Name datatype flavor is a set of reusable constraints that can be used for Persons.

1. **SHALL** contain exactly one [1..1] **name** (CONF:9368).
  - a. The content of name **SHALL** be either a conformant Patient Name (PTN.US.FIELDDED), or a string (CONF:9371).

### 2.5.1 Clinical Oncology Treatment Plan and Summary

[ClinicalDocument: templateId 2.16.840.1.113883.10.20.30.1.1 (open)]

**Table 21: Clinical Oncology Treatment Plan and Summary Contexts**

Used By:	Contains Entries:
	<a href="#">Allergies Section (entries optional)</a> <a href="#">Encounters Section BCTPS</a> <a href="#">Family History Section BCTPS</a> <a href="#">Functional Status Section BCTPS</a> <a href="#">Medications Section BCTPS</a> <a href="#">Plan of Care Section BCTPS</a> <a href="#">Problem Section BCTPS</a> <a href="#">Procedures Section BCTPS</a> <a href="#">Results Section BCTPS</a> <a href="#">Vital Signs Section BCTPS</a>

This document template conforms to the US Realm Header and contains additional constraints for the Clinical Oncology Treatment Plan and Summary. The sections in this document contain constraints for a Breast Cancer Treatment Plan and Summary (BCTPS), which is based on the [Breast Cancer Adjuvant Treatment Plan and Summary](#) form.

**Table 22: Clinical Oncology Treatment Plan and Summary Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	ClinicalDocument[templateId/@root = '2.16.840.1.113883.10.20.30.1.1']					
	templateId	1..1	SHALL		<a href="#">19232</a>	
	@root	1..1	SHALL		<a href="#">19233</a>	2.16.840.1.113883.10.20.30.1.1
	code	1..1	SHALL		<a href="#">19234</a>	
	@code	1..1	SHALL		<a href="#">19235</a>	CLONC-X
	@codeSystem	1..1	SHALL		<a href="#">27086</a>	2.16.840.1.113883.6.1
	title	1..1	SHALL		<a href="#">19236</a>	
	recordTarget	1..1	SHALL		<a href="#">19237</a>	

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	patientRole	1..1	SHALL		<a href="#">19238</a>	
	id	1..*	SHALL		<a href="#">19240</a>	
	telecom	1..*	SHALL		<a href="#">19241</a>	
	provider Organization	1..1	SHALL		<a href="#">19692</a>	
	telecom	1..*	SHALL		<a href="#">19693</a>	
	addr	1..1	SHALL		<a href="#">19694</a>	
	legalAuthenticator	1..1	SHALL		<a href="#">19695</a>	
	participant	1..*	SHALL		<a href="#">19662</a>	
	associatedEntity	1..1	SHALL		<a href="#">19663</a>	
	telecom	1..*	SHALL		<a href="#">19664</a>	
	associatedPerson	1..1	SHALL		<a href="#">19665</a>	
	name	1..1	SHALL		<a href="#">19696</a>	
	family	1..1	SHALL		<a href="#">19697</a>	
	given	1..1	SHALL		<a href="#">19698</a>	
	documentationOf	1..1	SHALL		<a href="#">19242</a>	
	serviceEvent	1..1	SHALL		<a href="#">19243</a>	
	@classCode	1..1	SHALL		<a href="#">19322</a>	PCPR
	code	1..1	SHALL		<a href="#">19323</a>	2.16.840.1.113883.6.96 (SNOMED-CT) = 801460020
	performer	1..*	SHALL		<a href="#">19244</a>	
	assignedEntity	1..1	SHALL		<a href="#">19245</a>	
	code	1..1	SHALL		<a href="#">20955</a>	2.16.840.1.114222.4.11 .1066 (Healthcare Provider Taxonomy (HIPAA))
	addr	1..1	SHALL		<a href="#">19699</a>	
	telecom	0..*	SHOULD		<a href="#">19256</a>	
	assignedPerson	0..1	SHOULD		<a href="#">19326</a>	
	name	1..*	SHALL		<a href="#">19327</a>	
	family	1..1	SHALL		<a href="#">19700</a>	
	given	1..1	SHALL		<a href="#">19701</a>	
	component	1..1	SHALL		<a href="#">19501</a>	
	structuredBody	1..1	SHALL		<a href="#">19502</a>	
	component	1..1	SHALL		<a href="#">19503</a>	
	section	1..1	SHALL		<a href="#">23357</a>	
	component	1..1	SHALL		<a href="#">25978</a>	
	section	1..1	SHALL		<a href="#">25979</a>	
	component	1..1	SHALL		<a href="#">25980</a>	



Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	section	1..1	SHALL		<a href="#">25981</a>	
	component	1..1	SHALL		<a href="#">26317</a>	
	section	1..1	SHALL		<a href="#">26319</a>	
	component	1..1	SHALL		<a href="#">26320</a>	
	section	1..1	SHALL		<a href="#">26321</a>	
	component	1..1	SHALL		<a href="#">26322</a>	
	section	1..1	SHALL		<a href="#">26323</a>	
	component	1..1	SHALL		<a href="#">26324</a>	
	section	1..1	SHALL		<a href="#">26325</a>	
	component	1..1	SHALL		<a href="#">26326</a>	
	section	1..1	SHALL		<a href="#">26327</a>	
	component	1..1	SHALL		<a href="#">26444</a>	
	section	1..1	SHALL		<a href="#">26445</a>	
	component	0..1	MAY		<a href="#">26446</a>	
	section	1..1	SHALL		<a href="#">26447</a>	

1. Conforms to [US Realm Header](#) template (2.16.840.1.113883.10.20.22.1.1).
2. **SHALL** contain exactly one [1..1] **templateId** (CONF:19232) such that it
  - a. **SHALL** contain exactly one [1..1]
   
 @root="2.16.840.1.113883.10.20.30.1.1" (CONF:19233).
3. **SHALL** contain exactly one [1..1] **code** (CONF:19234).
  - a. This code **SHALL** contain exactly one [1..1] @code="BCTPS-X" Breast Cancer Treatment Plan and Summary (CONF:19235).
  - b. This code **SHALL** contain exactly one [1..1]
   
 @codeSystem="2.16.840.1.113883.6.1" (CONF:27086).

The clinical document title describes the type of Oncology Treatment Plan and Summary. For example: "Breast Cancer Adjuvant Treatment Plan and Summary". The document title should not conflict with the ClinicalDocument code or further document specification defined through the documentationOf/serviceEvent or an encompassingEncounter.

4. **SHALL** contain exactly one [1..1] **title** (CONF:19236).
5. **SHALL** contain exactly one [1..1] **recordTarget** (CONF:19237).
  - a. This recordTarget **SHALL** contain exactly one [1..1] **patientRole** (CONF:19238).

At least one patient ID would represent the patient medical record number (MRN).

- i. This patientRole **SHALL** contain at least one [1..\*] **id** (CONF:19240).
- ii. This patientRole **SHALL** contain at least one [1..\*] **telecom** (CONF:19241).

- iii. This patientRole **SHALL** contain exactly one [1..1] **providerOrganization** (CONF:19692).
  - 1. This providerOrganization **SHALL** contain at least one [1..\*] **telecom** (CONF:19693).
  - 2. This providerOrganization **SHALL** contain exactly one [1..1] **addr** (CONF:19694).
- 6. **SHALL** contain exactly one [1..1] **legalAuthenticator** (CONF:19695).

The participant element identifies supporting participants, including parents, relatives, caregivers, and other participants related in some way to the patient. The type of support person is identified with the "Not Applicable" (NA) as defined in the participant (Support) (link) in the US realm header. In BCTPS, it is also required to specify contact person's name and phone.

- 7. **SHALL** contain at least one [1..\*] **participant** (CONF:19662) such that it
  - a. **SHALL** contain exactly one [1..1] **associatedEntity** (CONF:19663).
    - i. This associatedEntity **SHALL** contain at least one [1..\*] **telecom** (CONF:19664).
    - ii. This associatedEntity **SHALL** contain exactly one [1..1] **associatedPerson** (CONF:19665).
      - 1. This associatedPerson **SHALL** contain exactly one [1..1] **name** (CONF:19696).
        - a. This name **SHALL** contain exactly one [1..1] **family** (CONF:19697).
        - b. This name **SHALL** contain exactly one [1..1] **given** (CONF:19698).

This documentationOf/serviceEvent represents the time period over which care was provided. It contains information about the providers involved in the cancer care of the patient during the period of care being summarized.

- 8. **SHALL** contain exactly one [1..1] **documentationOf** (CONF:19242).
  - a. This documentationOf **SHALL** contain exactly one [1..1] **serviceEvent** (CONF:19243).
    - i. This serviceEvent **SHALL** contain exactly one [1..1] **@classCode="PCPR"** Care Provision (CONF:19322).
    - ii. This serviceEvent **SHALL** contain at least one [1..\*] **performer** (CONF:19244).
      - 1. Such performers **SHALL** contain exactly one [1..1] **assignedEntity** (CONF:19245).
        - a. This assignedEntity **SHALL** contain exactly one [1..1] **code**, which **SHOULD** be selected from ValueSet [Healthcare Provider Taxonomy \(HIPAA\) 2.16.840.1.114222.4.11.1066 DYNAMIC](#) (CONF:20955).

This provider address represents the site where patient received treatment from this provider.

- b. This assignedEntity **SHALL** contain exactly one [1..1] **addr** (CONF:19699).
  - c. This assignedEntity **SHOULD** contain zero or more [0..\*] **telecom** (CONF:19256).
  - d. This assignedEntity **SHOULD** contain zero or one [0..1] **assignedPerson** (CONF:19326).
    - i. The assignedPerson, if present, **SHALL** contain at least one [1..\*] **name** (CONF:19327).
      - 1. Such names **SHALL** contain exactly one [1..1] **family** (CONF:19700).
      - 2. Such names **SHALL** contain exactly one [1..1] **given** (CONF:19701).
9. **SHALL** contain exactly one [1..1] **component** (CONF:19501).
- a. This component **SHALL** contain exactly one [1..1] **structuredBody** (CONF:19502).
    - i. This structuredBody **SHALL** contain exactly one [1..1] **component** (CONF:19503) such that it
      - 1. **SHALL** contain exactly one [1..1] Allergies Section (entries optional) (templateId:2.16.840.1.113883.10.20.22.2.6) (CONF:23357).
    - ii. This structuredBody **SHALL** contain exactly one [1..1] **component** (CONF:25978) such that it
      - 1. **SHALL** contain exactly one [1..1] Medications Section BCTPS (templateId:2.16.840.1.113883.10.20.30.2.7) (CONF:25979).
    - iii. This structuredBody **SHALL** contain exactly one [1..1] **component** (CONF:25980) such that it
      - 1. **SHALL** contain exactly one [1..1] Family History Section BCTPS (templateId:2.16.840.1.113883.10.20.30.2.3) (CONF:25981).
    - iv. This structuredBody **SHALL** contain exactly one [1..1] **component** (CONF:26317) such that it
      - 1. **SHALL** contain exactly one [1..1] Problem Section BCTPS (templateId:2.16.840.1.113883.10.20.30.2.1) (CONF:26319).
    - v. This structuredBody **SHALL** contain exactly one [1..1] **component** (CONF:26320) such that it
      - 1. **SHALL** contain exactly one [1..1] Procedures Section BCTPS (templateId:2.16.840.1.113883.10.20.30.2.4) (CONF:26321).
    - vi. This structuredBody **SHALL** contain exactly one [1..1] **component** (CONF:26322) such that it

1. **SHALL** contain exactly one [1..1] [Results Section BCTPS](#) (templateId:2.16.840.1.113883.10.20.30.2.2) (CONF:26323).
- vii. This structuredBody **SHALL** contain exactly one [1..1] **component** (CONF:26324) such that it
  1. **SHALL** contain exactly one [1..1] [Vital Signs Section BCTPS](#) (templateId:2.16.840.1.113883.10.20.30.2.5) (CONF:26325).
- viii. This structuredBody **SHALL** contain exactly one [1..1] **component** (CONF:26326) such that it
  1. **SHALL** contain exactly one [1..1] [Plan of Care Section BCTPS](#) (templateId:2.16.840.1.113883.10.20.30.2.6) (CONF:26327).
- ix. This structuredBody **SHALL** contain exactly one [1..1] **component** (CONF:26444) such that it
  1. **SHALL** contain exactly one [1..1] [Functional Status Section BCTPS](#) (templateId:2.16.840.1.113883.10.20.30.2.8) (CONF:26445).
- x. This structuredBody **MAY** contain zero or one [0..1] **component** (CONF:26446) such that it
  1. **SHALL** contain exactly one [1..1] [Encounters Section BCTPS](#) (templateId:2.16.840.1.113883.10.20.30.2.9 ) (CONF:26447).

**Figure 33: Clinical Oncology Treatment Plan and Summary example**

```

<realmCode code="US"/>
<typeId root="2.16.840.1.113883.1.3" extension="POCD_HD000040"/>
<!-- US Realm Header, consolidated CDA header template -->
<templateId root="2.16.840.1.113883.10.20.22.1.1"
 assigningAuthorityName="HL7"/>
<!-- Clinical Oncology Treatment Plan and Summary -->
<templateId root="2.16.840.1.113883.10.20.30.1.1"
 assigningAuthorityName="HL7"/>
<id root="04fc2b90-10e0-11e2-892e-0800200c9a66"/>
<!--Temporary ClinicalDocument code -->
<code code="BCTPS-X"
 codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC"
 displayName="Breast Cancer Treatment Plan and Summary"/>
<title>Breast Cancer Treatment Plan and Summary</title>
<effectiveTime value="20130301"/>
<confidentialityCode code="N"/>
<languageCode code="en-US"/>

```

**Figure 34: Patient information example**

```
<recordTarget>
 <patientRole>
 <id root="1.2.1.173000" extension="2131823431"/>
 <addr use="HP">
 ...
 </addr>
 <!-- patient cell -->
 <telecom value="tel:(781)555-1212" use="MC"/>
 <!-- patient email -->
 <telecom value="mailto:my.email@address.com"/>
 <patient>
 <!-- patient name -->
 <name use="L">
 <given>Eve</given>
 <family>Everywomen</family>
 </name>
 <!-- patient gender -->
 <administrativeGenderCode code="F"
 codeSystem="2.16.840.1.113883.5.1"
 displayName="Female"/>
 <!-- patient date of birth -->
 <birthTime value="19670131"/>
 ...
 </patient>
 <providerOrganization>
 <id root="2.16.840.1.113883.19.5.9999.1393"/>
 <name>Cancer Clinic</name>
 <telecom use="WP" value="tel: 555-555-5000"/>
 <addr>
 ...
 </addr>
 </providerOrganization>
 </patientRole>
</recordTarget>
```

**Figure 35: author example**

```
<author>
 <time value="20130107224411+0500"/>
 <assignedAuthor>
 <id extension="99999999" root="2.16.840.1.113883.4.6"/>
 <code code="200000000X"
 codeSystem="2.16.840.1.113883.6.101"
 displayName="Cancer Associations PA"/>
 ...
 <telecom value="tel:(781)555-1200" use="WP"/>
 <assignedPerson>
 <name>
 <family>Nightengale</family>
 <given>Nancy</given>
 <suffix>AOCNP</suffix>
 </name>
 </assignedPerson>
 </assignedAuthor>
</author>
```

**Figure 36: Supporting person example**

```
<!-- SUPPORT CONTACT -->
<participant typeCode="IND">
 <associatedEntity classCode="NOK">
 <code code="MTH"
 codeSystem="2.16.840.1.113883.5.111"/>
 <!-- SUPPORT CONTACT phone -->
 <telecom value="tel:(555)555-2006" use="WP"/>
 <!-- SUPPORT CONTACT name -->
 <associatedPerson>
 <name>
 <prefix>Mrs.</prefix>
 <given>Martha</given>
 <family>Mum</family>
 </name>
 </associatedPerson>
 </associatedEntity>
</participant>
```

**Figure 37: Multi-disciplinary team of providers example**

```
<documentationOf>
 <!-- Healthcare provider Information -->
 <serviceEvent classCode="PCPR">
 <effectiveTime>
 <low value="20120320"/>
 <high value="20130102"/>
 </effectiveTime>
 <!--MEDICAL ONCOLOGIST -->
 <performer typeCode="PRF">
 <assignedEntity>
 <id extension="12345" root="2.16.840.1.113883.4.6"/>
 <code code="207RH0000X"
 codeSystem="2.16.840.1.113883.6.101"
 codeSystemName="NUCC" displayName="Hematologist"/>
 <addr>
 ...
 </addr>
 <telecom value="tel:+1-301-975-3251" use="WP"/>
 <assignedPerson>
 <name>
 <prefix>Dr.</prefix>
 <given>Trudy</given>
 <family>Tumor</family>
 </name>
 </assignedPerson>
 </assignedEntity>
 </performer>

 <performer typeCode="PRF">
 <!-- SURGICAL ONCOLOGIST-->
 <assignedEntity>
 <id extension="12345" root="2.16.840.1.113883.4.6"/>
 <code code="22086X0206X"
 codeSystem="2.16.840.1.113883.6.101"
 codeSystemName="NUCC" displayName="Surgical Oncology"/>
 <telecom value="tel:+1-301-975-3211" use="WP"/>
 <assignedPerson>
 <name>
 <prefix>Dr.</prefix>
 <given>Carl</given>
 <family>Cutter</family>
 </name>
 </assignedPerson>
 </assignedEntity>
 </performer>
 </serviceEvent>
</documentationOf>
```

```

<performer typeCode="PRF">
 <!-- RADIATION ONCOLOGIST-->
 <assignedEntity>
 <id extension="12345" root="2.16.840.1.113883.4.6"/>
 <code code="261QX0203X"
 codeSystem="2.16.840.1.113883.6.101"
 codeSystemName="NUCC"
 displayName="Radiation Oncology"/>
 <telecom value="tel:+1-301-975-3021" use="WP"/>
 <assignedPerson>
 <name>
 <prefix>Dr.</prefix>
 <given>Christine</given>
 <family>Curie</family>
 </name>
 </assignedPerson>
 </assignedEntity>
</performer>

<performer typeCode="PRF">
 <!-- Primary Care Provider-->
 <functionCode code="PCP" codeSystem="2.16.840.1.113883.5.88"/>
 <assignedEntity>
 <id extension="12345" root="2.16.840.1.113883.4.6"/>
 <code code="1223G0001X"
 codeSystem="2.16.840.1.113883.6.101"
 codeSystemName="NUCC"
 displayName="General Practice"/>
 <telecom value="tel:+1-301-975-3251" use="WP"/>
 <assignedPerson>
 <name>
 <prefix>Dr.</prefix>
 <given>General</given>
 <family>Practice</family>
 </name>
 </assignedPerson>
 </assignedEntity>
</performer>
</serviceEvent>
</documentationOf>

```



### 3 SECTION-LEVEL TEMPLATES

#### 3.1 Allergies Section (entries optional) [Closed for comments; published July 2012]

[section: templateId 2.16.840.1.113883.10.20.22.2.6 (open)]

**Table 23: Allergies Section (entries optional) Contexts**

Used By:	Contains Entries:
<a href="#">Clinical Oncology Treatment Plan and Summary</a> (required)	<a href="#">Allergy Problem Act</a>

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.

**Table 24: Allergies Section (entries optional) Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	section[templateId/@root = '2.16.840.1.113883.10.20.22.2.6']					
	templateId	1..1	SHALL		<a href="#">7800</a>	
	@root	1..1	SHALL		<a href="#">10378</a>	2.16.840.1.113883.10.20.22.2.6
	code	1..1	SHALL		<a href="#">15345</a>	
	@code	1..1	SHALL		<a href="#">15346</a>	2.16.840.1.113883.6.1 (LOINC) = 48765-2
	title	1..1	SHALL		<a href="#">7802</a>	
	text	1..1	SHALL		<a href="#">7803</a>	
	entry	0..*	SHOULD		<a href="#">7804</a>	
	act	1..1	SHALL		<a href="#">15444</a>	

1. **SHALL** contain exactly one [1..1] **templateId** (CONF:7800) such that it
  - a. **SHALL** contain exactly one [1..1] **@root="2.16.840.1.113883.10.20.22.2.6"** (CONF:10378).
2. **SHALL** contain exactly one [1..1] **code** (CONF:15345).
  - a. This code **SHALL** contain exactly one [1..1] **@code="48765-2"** Allergies, adverse reactions, alerts (CodeSystem: LOINC 2.16.840.1.113883.6.1 **STATIC**) (CONF:15346).
3. **SHALL** contain exactly one [1..1] **title** (CONF:7802).
4. **SHALL** contain exactly one [1..1] **text** (CONF:7803).
5. **SHOULD** contain zero or more [0..\*] **entry** (CONF:7804) such that it

- a. **SHALL** contain exactly one [1..1] [Allergy Problem Act](#) (templateId:2.16.840.1.113883.10.20.22.4.30) (CONF:15444).

**Figure 38: Allergies Section example**

```
<section>
 <templateId root="2.16.840.1.113883.10.20.22.2.6"/>
 <code code="48765-2"
 displayName="Allergies, adverse reactions, alerts"
 codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
 <title>Allergies</title>
 <text>
 ...
 </text>
 <entry typeCode="DRIV">
 <act classCode="ACT" moodCode="EVN">
 <templateId root="2.16.840.1.113883.10.20.22.4.30"/>
 <!-- Allergy Problem Act template -->
 ...
 </act>
 </entry>
</section>
```

### 3.2 Encounters Section (entries optional) [Closed for comments; published July 2012]

[section: templateId 2.16.840.1.113883.10.20.22.2.22 (open)]

**Table 25: Encounters Section (entries optional) Contexts**

Used By:	Contains Entries:
	<a href="#">Encounter Activities</a>

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.

**Table 26: Encounters Section (entries optional) Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	section[templateId/@root = '2.16.840.1.113883.10.20.22.2.22']					
	templateId	1..1	SHALL		<a href="#">7940</a>	
	@root	1..1	SHALL		<a href="#">10386</a>	2.16.840.1.113883.10.20.22.2.22
	code	1..1	SHALL		<a href="#">15461</a>	
	@code	1..1	SHALL		<a href="#">15462</a>	2.16.840.1.113883.6.1 (LOINC) = 46240-8
	title	1..1	SHALL		<a href="#">7942</a>	
	text	1..1	SHALL		<a href="#">7943</a>	
	entry	0..*	SHOULD		<a href="#">7951</a>	
	encounter	1..1	SHALL		<a href="#">15465</a>	

1. **SHALL** contain exactly one [1..1] **templateId** (CONF:7940) such that it
  - a. **SHALL** contain exactly one [1..1]
    - @root="2.16.840.1.113883.10.20.22.2.22" (CONF:10386).
2. **SHALL** contain exactly one [1..1] **code** (CONF:15461).
  - a. This code **SHALL** contain exactly one [1..1] @code="46240-8" Encounters (CodeSystem: LOINC 2.16.840.1.113883.6.1 **STATIC**) (CONF:15462).
3. **SHALL** contain exactly one [1..1] **title** (CONF:7942).
4. **SHALL** contain exactly one [1..1] **text** (CONF:7943).
5. **SHOULD** contain zero or more [0..\*] **entry** (CONF:7951) such that it
  - a. **SHALL** contain exactly one [1..1] [Encounter Activities](#) (templateId:2.16.840.1.113883.10.20.22.4.49) (CONF:15465).

### 3.2.1 Encounters Section BCTPS

[section: templateId 2.16.840.1.113883.10.20.30.2.9 (open)]

**Table 27: Encounters Section BCTPS Contexts**

Used By:	Contains Entries:
<a href="#">Clinical Oncology Treatment Plan and Summary</a> (optional)	<a href="#">Hospitalization for Toxicity</a>

This section contains encounters related to the patient's cancer treatment plan and summary. This section should describe inpatient encounters resulting from toxicity due to chemotherapy as well as other notable encounters.

**Table 28: Encounters Section BCTPS Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	section[templateId/@root = '2.16.840.1.113883.10.20.30.2.9 ']					
	templateId	1..1	SHALL		<a href="#">26309</a>	
	@root	1..1	SHALL		<a href="#">26310</a>	2.16.840.1.113883.10.20.30.2.9
	entry	1..*	SHALL		<a href="#">26315</a>	
	encounter	1..1	SHALL		<a href="#">26316</a>	

1. Conforms to [Encounters Section \(entries optional\) template](#) (2.16.840.1.113883.10.20.22.2.22).
2. **SHALL** contain exactly one [1..1] **templateId** (CONF:26309) such that it
  - a. **SHALL** contain exactly one [1..1]
   
@root="2.16.840.1.113883.10.20.30.2.9 " (CONF:26310).
3. **SHALL** contain at least one [1..\*] **entry** (CONF:26315) such that it
  - a. **SHALL** contain exactly one [1..1] [Hospitalization for Toxicity](#)
  
(templateId:2.16.840.1.113883.10.20.30.3.36) (CONF:26316).

**Figure 39: Encounters Section BCTPS example**

```

<section>
 <!-- C-CDA Encounters with entries optional section templateID -->
 <templateId root="2.16.840.1.113883.10.20.22.2.22"/>
 <!-- Encounters BCTPS section templateID -->
 <templateId root="2.16.840.1.113883.10.20.30.2.9"/>
 <code code="46240-8" codeSystem="2.16.840.1.113883.6.1"/>
 <title>ENCOUNTERS</title>
 <text>
 ...
 </text>
 <entry typeCode="DRIV">
 <encounter classCode="ENC" moodCode="EVN">
 <!-- C-CDA encounter activities TemplateID -->
 <templateId root="2.16.840.1.113883.10.20.22.4.49"/>
 <!-- Hospitalization for Toxicity templateID -->
 <templateId root="2.16.840.1.113883.10.20.30.3.36"/>
 ...
 </encounter>
 </entry>
</section>

```

### 3.3 Family History Section [Closed for comments; published July 2012]

[section: templateId 2.16.840.1.113883.10.20.22.2.15 (open)]

**Table 29: Family History Section Contexts**

Used By:	Contains Entries:
	<a href="#">Family History Organizer</a>

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.

**Table 30: Family History Section Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	section[templateId/@root = '2.16.840.1.113883.10.20.22.2.15']					
	templateId	1..1	SHALL		<a href="#">7932</a>	
	@root	1..1	SHALL		<a href="#">10388</a>	2.16.840.1.113883.10.20.22.2.15
	code	1..1	SHALL		<a href="#">15469</a>	
	@code	1..1	SHALL		<a href="#">15470</a>	2.16.840.1.113883.6.1 (LOINC) = 10157-6
	title	1..1	SHALL		<a href="#">7934</a>	
	text	1..1	SHALL		<a href="#">7935</a>	
	entry	0..*	MAY		<a href="#">7955</a>	
	organizer	1..1	SHALL		<a href="#">15471</a>	

1. **SHALL** contain exactly one [1..1] **templateId** (CONF:7932) such that it
  - a. **SHALL** contain exactly one [1..1]
   
@root="2.16.840.1.113883.10.20.22.2.15" (CONF:10388).
2. **SHALL** contain exactly one [1..1] **code** (CONF:15469).
  - a. This code **SHALL** contain exactly one [1..1] @code="10157-6" Family History (CodeSystem: LOINC 2.16.840.1.113883.6.1 **STATIC**) (CONF:15470).
3. **SHALL** contain exactly one [1..1] **title** (CONF:7934).
4. **SHALL** contain exactly one [1..1] **text** (CONF:7935).
5. **MAY** contain zero or more [0..\*] **entry** (CONF:7955) such that it
  - a. **SHALL** contain exactly one [1..1] [Family History Organizer](#) (templateId:2.16.840.1.113883.10.20.22.4.45) ( (CONF:15471).

### 3.3.1 Family History Section BCTPS

[Section: templateId 2.16.840.1.113883.10.20.30.2.3 (open)]

**Table 31: Family History Section BCTPS Contexts**

Used By:	Contains Entries:
<a href="#">Clinical Oncology Treatment Plan and Summary</a> (required)	<a href="#">Family History of Cancer None</a> <a href="#">Family History Organizer</a> <a href="#">Family History Pedigree</a>

This section contains the patient's family history (pedigree) information. It also allows assertion of no family history of cancer. The HL7 Family History (Pedigree) Model is required to be referenced as an external observation, and a nullFlavor can be sent if there is no pedigree available to point to. Non oncology family history may also be represented.

**Table 32: Family History Section BCTPS Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	Section[templateId/@root = '2.16.840.1.113883.10.20.30.2.3']					
	templateId	1..1	SHALL		<a href="#">25967</a>	
	@root	1..1	SHALL		<a href="#">25968</a>	2.16.840.1.113883.10.20.30.2.3
	entry	0..1	MAY		<a href="#">26011</a>	
	observation	1..1	SHALL		<a href="#">26027</a>	
	entry	1..1	SHALL		<a href="#">26759</a>	
	act	1..1	SHALL		<a href="#">26760</a>	
	entry	1..*	SHALL		<a href="#">26761</a>	
	organizer	1..1	SHALL		<a href="#">26762</a>	

1. Conforms to [Family History Section](#) template (2.16.840.1.113883.10.20.22.2.15).
2. **SHALL** contain exactly one [1..1] **templateId** (CONF:25967) such that it
  - a. **SHALL** contain exactly one [1..1] **@root="2.16.840.1.113883.10.20.30.2.3"** (CONF:25968).
3. **MAY** contain zero or one [0..1] **entry** (CONF:26011) such that it
  - a. **SHALL** contain exactly one [1..1] [Family History of Cancer None](#) (templateId:2.16.840.1.113883.10.20.30.3.11) (CONF:26027).
4. **SHALL** contain exactly one [1..1] **entry** (CONF:26759) such that it
  - a. **SHALL** contain exactly one [1..1] [Family History Pedigree](#) (templateId:2.16.840.1.113883.10.20.30.3.48) (CONF:26760).
5. **SHALL** contain at least one [1..\*] **entry** (CONF:26761) such that it
  - a. **SHALL** contain exactly one [1..1] [Family History Organizer](#) (templateId:2.16.840.1.113883.10.20.22.4.45) (CONF:26762).

**Figure 40: Family History Section BCTPS example**

```
<section>
 <!--C-CDA FAMILY HISTORY SECTION TemplateID-->
 <templateId root="2.16.840.1.113883.10.20.22.2.15"/>
 <!--FAMILY HISTORY BCTPS SECTION TemplateID-->
 <templateId root="2.16.840.1.113883.10.20.30.2.3"/>
 <code code="10157-6"
 displayName="History of family member diseases"
 codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC"/>
 <title>FAMILY HISTORY</title>
 <text> ... </text>

 <entry>
 <observation classCode="OBS" moodCode="EVN" negationInd="true">
 <!-- Family History of Cancer - None -->
 <templateId root="2.16.840.1.113883.10.20.30.3.11"/> ...
 </observation>
 </entry>

 <entry>
 <act classCode="ACT" moodCode="EVN">
 <!-- CDA FAMILY HISTORY PEDIGREE TemplateID -->
 <templateId root="2.16.840.1.113883.10.20.30.3.48"/> ...
 </act>
 </entry>

 <entry typeCode="DRIV">
 <!-- mother -->
 <organizer moodCode="EVN" classCode="CLUSTER">
 <!--C-CDA FAMILY HISTORY ORGANIZER TemplateID-->
 <templateId root="2.16.840.1.113883.10.20.22.4.45"/> ...
 </organizer>
 </entry>

 <entry typeCode="DRIV">
 <!-- father -->
 <organizer moodCode="EVN" classCode="CLUSTER">
 <!--C-CDA FAMILY HISTORY ORGANIZER TemplateID-->
 <templateId root="2.16.840.1.113883.10.20.22.4.45"/> ...
 </organizer>
 </entry>
</section>
```

### 3.4 Functional Status Section [Closed for comments; published July 2012]

[section: templateId 2.16.840.1.113883.10.20.22.2.14 (open)]

**Table 33: Functional Status Section Contexts**

Used By:	Contains Entries:
	<a href="#">Assessment Scale Observation</a> <a href="#">Caregiver Characteristics</a> <a href="#">Cognitive Status Problem Observation</a> <a href="#">Cognitive Status Result Observation</a> <a href="#">Cognitive Status Result Organizer</a> <a href="#">Functional Status Problem Observation</a> <a href="#">Functional Status Result Observation</a> <a href="#">Functional Status Result Organizer</a> <a href="#">Highest Pressure Ulcer Stage</a> <a href="#">Non-Medicinal Supply Activity</a> <a href="#">Number of Pressure Ulcers Observation</a> <a href="#">Pressure Ulcer Observation</a>

The Functional Status Section describes the patient’s physical state, status of functioning, and environmental status at the time the document was created.

A patient’s physical state may include information regarding the patient’s physical findings as they relate to problems, including but not limited to:

- Pressure Ulcers
- Amputations
- Heart murmur
- Ostomies

A patient’s functional status may include information regarding the patient relative to their general functional and cognitive ability, including:

- Ambulatory ability
- Mental status or competency
- Activities of Daily Living (ADLs), including bathing, dressing, feeding, grooming
- Home or 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

A patient’s environmental status may include information regarding the patient’s current exposures from their daily environment, including but not limited to:

- Airborne hazards such as second-hand smoke, volatile organic compounds, dust, or other allergens
- Radiation
- Safety hazards in home, such as throw rugs, poor lighting, lack of railings/grab bars, etc.
- Safety hazards at work, such as communicable diseases, excessive heat, excessive noise, etc.

The patient's functional status may be expressed as a problem or as a result observation. A functional or cognitive status problem observation describes a patient’s problem, symptoms or condition. A functional or cognitive status result observation may include observations resulting from an assessment scale, evaluation or question and answer assessment.

Any deviation from normal function displayed by the patient and recorded in the record should be included. Of particular interest are those limitations that would interfere with self-care or the medical therapeutic process in any way. In addition, a note of normal function, an improvement, or a change in functioning status may be included.

**Table 34: Functional Status Section Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	section[templateId/@root = '2.16.840.1.113883.10.20.22.2.14']					
	templateId	1..1	SHALL		<a href="#">7920</a>	
	@root	1..1	SHALL		<a href="#">10389</a>	2.16.840.1.113883.10.20.22.2.14
	code	1..1	SHALL		<a href="#">14578</a>	
	@code	1..1	SHALL		<a href="#">14579</a>	2.16.840.1.113883.6.1 (LOINC) = 47420-5
	title	1..1	SHALL		<a href="#">7922</a>	
	text	1..1	SHALL		<a href="#">7923</a>	
	entry	0..*	MAY		<a href="#">14414</a>	
	organizer	1..1	SHALL		<a href="#">14415</a>	
	entry	0..*	MAY		<a href="#">14416</a>	
	organizer	1..1	SHALL		<a href="#">14417</a>	
	entry	0..*	MAY		<a href="#">14418</a>	
	observation	1..1	SHALL		<a href="#">14419</a>	
	entry	0..*	MAY		<a href="#">14420</a>	

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	observation	1..1	SHALL		<a href="#">14421</a>	
	entry	0..*	MAY		<a href="#">14422</a>	
	observation	1..1	SHALL		<a href="#">14423</a>	
	entry	0..*	MAY		<a href="#">14424</a>	
	observation	1..1	SHALL		<a href="#">14425</a>	
	entry	0..*	MAY		<a href="#">14426</a>	
	observation	1..1	SHALL		<a href="#">14427</a>	
	entry	0..*	MAY		<a href="#">14580</a>	
	observation	1..1	SHALL		<a href="#">14581</a>	
	entry	0..*	MAY		<a href="#">14582</a>	
	observation	1..1	SHALL		<a href="#">14583</a>	
	entry	0..*	MAY		<a href="#">16777</a>	
	observation	1..1	SHALL		<a href="#">16778</a>	
	entry	0..*	MAY		<a href="#">16779</a>	
	observation	1..1	SHALL		<a href="#">16780</a>	
	entry	0..*	MAY		<a href="#">16781</a>	
	observation	1..1	SHALL		<a href="#">16782</a>	

1. **SHALL** contain exactly one [1..1] **templateId** (CONF:7920) such that it
  - a. **SHALL** contain exactly one [1..1]
    - @root="2.16.840.1.113883.10.20.22.2.14" (CONF:10389).
2. **SHALL** contain exactly one [1..1] **code** (CONF:14578).
  - a. This code **SHALL** contain exactly one [1..1] @code="47420-5" Functional Status (CodeSystem: LOINC 2.16.840.1.113883.6.1 **STATIC**) (CONF:14579).
3. **SHALL** contain exactly one [1..1] **title** (CONF:7922).
4. **SHALL** contain exactly one [1..1] **text** (CONF:7923).
5. **MAY** contain zero or more [0..\*] **entry** (CONF:14414) such that it
  - a. **SHALL** contain exactly one [1..1] [Functional Status Result Organizer](#) (templateId:2.16.840.1.113883.10.20.22.4.66) (CONF:14415).
6. **MAY** contain zero or more [0..\*] **entry** (CONF:14416) such that it
  - a. **SHALL** contain exactly one [1..1] [Cognitive Status Result Organizer](#) (templateId:2.16.840.1.113883.10.20.22.4.75) (CONF:14417).
7. **MAY** contain zero or more [0..\*] **entry** (CONF:14418) such that it
  - a. **SHALL** contain exactly one [1..1] [Functional Status Result Observation](#) (templateId:2.16.840.1.113883.10.20.22.4.67) (CONF:14419).
8. **MAY** contain zero or more [0..\*] **entry** (CONF:14420) such that it
  - a. **SHALL** contain exactly one [1..1] [Cognitive Status Result Observation](#) (templateId:2.16.840.1.113883.10.20.22.4.74) (CONF:14421).

9. **MAY** contain zero or more [0..\*] **entry** (CONF:14422) such that it
  - a. **SHALL** contain exactly one [1..1] [Functional Status Problem Observation](#) (templateId:2.16.840.1.113883.10.20.22.4.68) (CONF:14423).
10. **MAY** contain zero or more [0..\*] **entry** (CONF:14424) such that it
  - a. **SHALL** contain exactly one [1..1] [Cognitive Status Problem Observation](#) (templateId:2.16.840.1.113883.10.20.22.4.73) (CONF:14425).
11. **MAY** contain zero or more [0..\*] **entry** (CONF:14426) such that it
  - a. **SHALL** contain exactly one [1..1] [Caregiver Characteristics](#) (templateId:2.16.840.1.113883.10.20.22.4.72) (CONF:14427).
12. **MAY** contain zero or more [0..\*] **entry** (CONF:14580) such that it
  - a. **SHALL** contain exactly one [1..1] [Assessment Scale Observation](#) (templateId:2.16.840.1.113883.10.20.22.4.69) (CONF:14581).
13. **MAY** contain zero or more [0..\*] **entry** (CONF:14582) such that it
  - a. **SHALL** contain exactly one [1..1] [Non-Medicinal Supply Activity](#) (templateId:2.16.840.1.113883.10.20.22.4.50) (CONF:14583).
14. **MAY** contain zero or more [0..\*] **entry** (CONF:16777) such that it
  - a. **SHALL** contain exactly one [1..1] [Pressure Ulcer Observation](#) (templateId:2.16.840.1.113883.10.20.22.4.70) (CONF:16778).
15. **MAY** contain zero or more [0..\*] **entry** (CONF:16779) such that it
  - a. **SHALL** contain exactly one [1..1] [Number of Pressure Ulcers Observation](#) (templateId:2.16.840.1.113883.10.20.22.4.76) (CONF:16780).
16. **MAY** contain zero or more [0..\*] **entry** (CONF:16781) such that it
  - a. **SHALL** contain exactly one [1..1] [Highest Pressure Ulcer Stage](#) (templateId:2.16.840.1.113883.10.20.22.4.77) (CONF:16782).

### 3.4.1 Functional Status Section BCTPS

[section: templateId 2.16.840.1.113883.10.20.30.2.8 (open)]

**Table 35: Functional Status Section BCTPS Contexts**

Used By:	Contains Entries:
<a href="#">Clinical Oncology Treatment Plan and Summary</a> (required)	<a href="#">Neurotoxicity Impairment of ADLs</a>

This section describes the patient’s physical state, functioning status, and environmental status at the time the document was created. In particular, impairments to activities of daily living from neurotoxicity due to chemotherapy are noted within this section.

**Table 36: Functional Status Section BCTPS Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	section[templateId/@root = '2.16.840.1.113883.10.20.30.2.8']					
	templateId	1..1	SHALL		<a href="#">26375</a>	
	@root	1..1	SHALL		<a href="#">26376</a>	2.16.840.1.113883.10.20.30.2.8
	entry	0..*	MAY		<a href="#">26440</a>	
	observation	1..1	SHALL		<a href="#">26441</a>	

1. Conforms to [Functional Status Section](#) template (2.16.840.1.113883.10.20.22.2.14).
2. **SHALL** contain exactly one [1..1] **templateId** (CONF:26375) such that it
  - a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.30.2.8" (CONF:26376).
3. **MAY** contain zero or more [0..\*] **entry** (CONF:26440) such that it
  - a. **SHALL** contain exactly one [1..1] [Neurotoxicity Impairment of ADLs](#) (templateId:2.16.840.1.113883.10.20.30.3.37) (CONF:26441).

**Figure 41: Functional Status Section BCTPS example**

```

<section>
 <!-- C-CDA Functional Status section TemplateID -->
 <templateId root="2.16.840.1.113883.10.20.22.2.14"/>
 <!-- Functional Status BCTPS section TemplateID -->
 <templateId root="2.16.840.1.113883.10.20.30.2.8"/>
 <code code="47420-5" codeSystem="2.16.840.1.113883.6.1"/>
 <title>FUNCTIONAL STATUS</title>
 <text>

 </text>
 <entry typeCode="DRIV">
 <observation classCode="OBS" moodCode="EVN">
 <!-- C-CDA FUNCTIONAL STATUS PROBLEM OBSERVATION TemplateID -->
 <templateId root="2.16.840.1.113883.10.20.22.4.68"/>
 <!-- Neurotoxicity impairment of activities of daily living
 templateID -->
 <templateId root="2.16.840.1.113883.10.20.30.3.37"/>
 ...
 </observation>
 </entry>
</section>

```

### 3.5 Medications Section (entries optional) [Closed for comments; published July 2012]

[section: templateId 2.16.840.1.113883.10.20.22.2.1 (open)]

**Table 37: Medications Section (entries optional) Contexts**

<b>Used By:</b>	<b>Contains Entries:</b>
	<a href="#">Medication Activity</a>

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.

**Table 38: Medications Section (entries optional) Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
	section[templateId/@root = '2.16.840.1.113883.10.20.22.2.1']					
	templateId	1..1	SHALL		<a href="#">7791</a>	
	@root	1..1	SHALL		<a href="#">10432</a>	2.16.840.1.113883.10.20.22.2.1
	code	1..1	SHALL		<a href="#">15385</a>	
	@code	1..1	SHALL		<a href="#">15386</a>	2.16.840.1.113883.6.1 (LOINC) = 10160-0
	title	1..1	SHALL		<a href="#">7793</a>	
	text	1..1	SHALL		<a href="#">7794</a>	
	entry	0..*	SHOULD		<a href="#">7795</a>	
	substance Administration	1..1	SHALL		<a href="#">15984</a>	

1. **SHALL** contain exactly one [1..1] **templateId** (CONF:7791) such that it
  - a. **SHALL** contain exactly one [1..1] **@root="2.16.840.1.113883.10.20.22.2.1"** (CONF:10432).
2. **SHALL** contain exactly one [1..1] **code** (CONF:15385).
  - a. This code **SHALL** contain exactly one [1..1] **@code="10160-0"** History of medication use (CodeSystem: LOINC 2.16.840.1.113883.6.1 **STATIC**) (CONF:15386).
3. **SHALL** contain exactly one [1..1] **title** (CONF:7793).
4. **SHALL** contain exactly one [1..1] **text** (CONF:7794).
5. **SHOULD** contain zero or more [0..\*] **entry** (CONF:7795) such that it

- a. **SHALL** contain exactly one [1..1] [Medication Activity](#) (templateId:2.16.840.1.113883.10.20.22.4.16) (CONF:15984).
- b. If medication use is unknown, the appropriate nullFlavor **MAY** be present (see unknown information in Section 1) (CONF:10076).

### 3.5.1 Medications Section BCTPS

[Section: templateId 2.16.840.1.113883.10.20.30.2.7 (open)]

**Table 39: Medications Section BCTPS Contexts**

<b>Used By:</b>	<b>Contains Entries:</b>
<a href="#">Clinical Oncology Treatment Plan and Summary</a> (required)	<a href="#">Anthracyclines Lifetime Dose</a> <a href="#">Chemotherapy Medication Activity</a> <a href="#">Chemotherapeutic Drug Therapy Discontinued</a> <a href="#">Medication Activity</a>

This section contains therapies administered to the patient during cancer treatment. The specific chemotherapeutic agents are not specified, but attributes such as repeatNumber, to note the cycle, are constrained in the Chemotherapy Medication Activity Template. The total lifetime amount of drugs in the Anthracycline drug class that the patient has received up until the note was generated must be communicated. The common side effects that are possible from the combination of agents the patient has received must be sent. Actual toxicities related to an agent are communicated in this section rather than the Allergies and Adverse Events Section since the toxicities are not allergies or typically unexpected and may not result in termination of the drug, but may result in adjustments in dose. If a drug is discontinued due to toxicities it should be noted in this section along with the reason why.

**Table 40: Medications Section BCTPS Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
	Section[templateId/@root = '2.16.840.1.113883.10.20.30.2.7']					
	templateId	1..1	SHALL		<a href="#">23764</a>	
	@root	1..1	SHALL		<a href="#">23765</a>	2.16.840.1.113883.10.20.30.2.7
	entry	1..1	SHALL		<a href="#">25964</a>	
	substance Administration	1..1	SHALL		<a href="#">25966</a>	
	entry	0..*	SHOULD		<a href="#">27305</a>	
	substance Administration	1..1	SHALL		<a href="#">27306</a>	
	entry	0..*	MAY		<a href="#">27307</a>	
	observation	1..1	SHALL		<a href="#">27308</a>	
	entry	1..*	SHALL	Entry	<a href="#">27373</a>	
	substance Administration	1..1	SHALL		<a href="#">27374</a>	

1. Conforms to [Medications Section \(entries optional\)](#) template (2.16.840.1.113883.10.20.22.2.1).
2. **SHALL** contain exactly one [1..1] **templateId** (CONF:23764) such that it
  - a. **SHALL** contain exactly one [1..1] **@root="2.16.840.1.113883.10.20.30.2.7"** (CONF:23765).
3. **SHALL** contain exactly one [1..1] **entry** (CONF:25964) such that it
  - a. **SHALL** contain exactly one [1..1] [Anthracyclines Lifetime Dose](#) (templateId:2.16.840.1.113883.10.20.30.3.24) (CONF:25966).

Any pertinent medications the patient is on should be communicated with the C-CDA Medication Activity template. Of particular interest are pre-chemotherapy regimen medications such as dexamethasone and hormone therapy such as Tamoxifen and Aromatase inhibitors.

4. **SHOULD** contain zero or more [0..\*] **entry** (CONF:27305) such that it
  - a. **SHALL** contain exactly one [1..1] [Medication Activity](#) (templateId:2.16.840.1.113883.10.20.22.4.16) (CONF:27306).
5. **MAY** contain zero or more [0..\*] **entry** (CONF:27307) such that it
  - a. **SHALL** contain exactly one [1..1] [Chemotherapeutic Drug Therapy Discontinued](#) (templateId:2.16.840.1.113883.10.20.30.3.43) (CONF:27308).
6. **SHALL** contain at least one [1..\*] **entry** (CONF:27373) such that it
  - a. **SHALL** contain exactly one [1..1] [Chemotherapy Medication Activity](#) (templateId:2.16.840.1.113883.10.20.30.3.44) (CONF:27374).

**Figure 42: Medications Section BCTPS example**

```

<section>
 <templateId root="2.16.840.1.113883.10.20.22.2.1"/>
 <code code="10160-0"
 codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC"
 displayName="HISTORY OF MEDICATION USE"/>
 <title>MEDICATIONS</title>
 <text>
 ...
 </text>
 <entry>
 <substanceAdministration classCode="SBADM" moodCode="EVN">
 <templateId root="2.16.840.1.113883.10.20.22.4.16"/>
 <!-- Medication Activity template -->
 ...
 </substanceAdministration>
 </entry>
 <entry>
 <substanceAdministration classCode="SBADM" moodCode="EVN">
 <templateId root="2.16.840.1.113883.10.20.30.3.44"/>
 <!-- Chemotherapy Medication Activity template -->
 ...
 </substanceAdministration>
 </entry>
 <entry>
 <substanceAdministration classCode="SBADM" moodCode="EVN">
 <templateId root="2.16.840.1.113883.10.20.30.3.43"/>
 <!-- 2.16.840.1.113883.10.20.30.3.43 template -->
 ...
 </substanceAdministration>
 </entry>
</section>

```

### 3.6 Plan of Care Section [Closed for comments; published July 2012]

[section: templateId 2.16.840.1.113883.10.20.22.2.10 (open)]

**Table 41: Plan of Care Section Contexts**

Used By:	Contains Entries:
	<a href="#">Instructions</a> <a href="#">Plan of Care Activity Act</a> <a href="#">Plan of Care Activity Encounter</a> <a href="#">Plan of Care Activity Observation</a> <a href="#">Plan of Care Activity Procedure</a> <a href="#">Plan of Care Activity Substance Administration</a> <a href="#">Plan of Care Activity Supply</a>



The Plan of Care 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, which are indicated by the @moodCode of the entries within this section. 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 will be provided.

**Table 42: Plan of Care Section Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
	section[templateId/@root = '2.16.840.1.113883.10.20.22.2.10']					
	templateId	1..1	SHALL		<a href="#">7723</a>	
	@root	1..1	SHALL		<a href="#">10435</a>	2.16.840.1.113883.10.20.22.2.10
	code	1..1	SHALL		<a href="#">14749</a>	
	@code	1..1	SHALL		<a href="#">14750</a>	2.16.840.1.113883.6.1 (LOINC) = 18776-5
	title	1..1	SHALL		<a href="#">16986</a>	
	text	1..1	SHALL		<a href="#">7725</a>	
	entry	0..*	MAY		<a href="#">7726</a>	
	observation	1..1	SHALL		<a href="#">14751</a>	
	entry	0..*	MAY		<a href="#">8805</a>	
	observation	1..1	SHALL		<a href="#">14752</a>	
	entry	0..*	MAY		<a href="#">8807</a>	
	observation	1..1	SHALL		<a href="#">14753</a>	
	entry	0..*	MAY		<a href="#">8809</a>	
	observation	1..1	SHALL		<a href="#">14754</a>	
	entry	0..*	MAY		<a href="#">8811</a>	
	observation	1..1	SHALL		<a href="#">14755</a>	
	entry	0..*	MAY		<a href="#">8813</a>	
	observation	1..1	SHALL		<a href="#">14756</a>	
	entry	0..*	MAY		<a href="#">14695</a>	
	act	1..1	SHALL		<a href="#">16751</a>	

1. **SHALL** contain exactly one [1..1] **templateId** (CONF:7723) such that it
  - a. **SHALL** contain exactly one [1..1]
   
 @root="2.16.840.1.113883.10.20.22.2.10" (CONF:10435).
2. **SHALL** contain exactly one [1..1] **code** (CONF:14749).

- a. This code **SHALL** contain exactly one [1..1] @code="18776-5" Plan of Care (CodeSystem: LOINC 2.16.840.1.113883.6.1 **STATIC**) (CONF:14750).
- 3. **SHALL** contain exactly one [1..1] **title** (CONF:16986).
- 4. **SHALL** contain exactly one [1..1] **text** (CONF:7725).
- 5. **MAY** contain zero or more [0..\*] **entry** (CONF:7726) such that it
  - a. **SHALL** contain exactly one [1..1] [Plan of Care Activity Act](#) (templateId:2.16.840.1.113883.10.20.22.4.39) (CONF:14751).
- 6. **MAY** contain zero or more [0..\*] **entry** (CONF:8805) such that it
  - a. **SHALL** contain exactly one [1..1] [Plan of Care Activity Encounter](#) (templateId:2.16.840.1.113883.10.20.22.4.40) (CONF:14752).
- 7. **MAY** contain zero or more [0..\*] **entry** (CONF:8807) such that it
  - a. **SHALL** contain exactly one [1..1] [Plan of Care Activity Observation](#) (templateId:2.16.840.1.113883.10.20.22.4.44) (CONF:14753).
- 8. **MAY** contain zero or more [0..\*] **entry** (CONF:8809) such that it
  - a. **SHALL** contain exactly one [1..1] [Plan of Care Activity Procedure](#) (templateId:2.16.840.1.113883.10.20.22.4.41) (CONF:14754).
- 9. **MAY** contain zero or more [0..\*] **entry** (CONF:8811) such that it
  - a. **SHALL** contain exactly one [1..1] [Plan of Care Activity Substance Administration](#) (templateId:2.16.840.1.113883.10.20.22.4.42) (CONF:14755).
- 10. **MAY** contain zero or more [0..\*] **entry** (CONF:8813) such that it
  - a. **SHALL** contain exactly one [1..1] [Plan of Care Activity Supply](#) (templateId:2.16.840.1.113883.10.20.22.4.43) (CONF:14756).
- 11. **MAY** contain zero or more [0..\*] **entry** (CONF:14695) such that it
  - a. **SHALL** contain exactly one [1..1] [Instructions](#) (templateId:2.16.840.1.113883.10.20.22.4.20) (CONF:16751).

### 3.6.1 Plan of Care Section BCTPS

[section: templateId 2.16.840.1.113883.10.20.30.2.6 (open)]

**Table 43: Plan of Care Section BCTPS Contexts**

Used By:	Contains Entries:
<a href="#">Clinical Oncology Treatment Plan and Summary</a> (required)	<a href="#">Chemotherapy Regimen Plans</a> <a href="#">Plan of Care Activity Reconstruction Procedure</a> <a href="#">Plan of Care Radiation Activity</a>

This section contains information about planned radiation, chemotherapy, and reconstruction procedures for the patient. It is limited to prospective, unfulfilled or incomplete orders, and requests only, which are indicated by the @moodCode of the entries within this section.

**Table 44: Plan of Care Section BCTPS Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	section[templateId/@root = '2.16.840.1.113883.10.20.30.2.6']					
	templateId	1..1	SHALL		<a href="#">24087</a>	
	@root	1..1	SHALL		<a href="#">26271</a>	2.16.840.1.113883.10.20.30.2.6
	entry	0..1	SHOULD		<a href="#">24099</a>	
	procedure	1..1	SHALL		<a href="#">24130</a>	
	entry	0..1	SHOULD		<a href="#">24101</a>	
	procedure	1..1	SHALL		<a href="#">24131</a>	
	entry	0..1	SHOULD		<a href="#">24103</a>	
	act	1..1	SHALL		<a href="#">24132</a>	

1. Conforms to [Plan of Care Section](#) template (2.16.840.1.113883.10.20.22.2.10).
2. **SHALL** contain exactly one [1..1] **templateId** (CONF:24087) such that it
  - a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.30.2.6" (CONF:26271).
3. **SHOULD** contain zero or one [0..1] **entry** (CONF:24099) such that it
  - a. **SHALL** contain exactly one [1..1] [Chemotherapy Regimen Plans](#) (templateId:2.16.840.1.113883.10.20.30.3.30) (CONF:24130).
4. **SHOULD** contain zero or one [0..1] **entry** (CONF:24101) such that it
  - a. **SHALL** contain exactly one [1..1] [Plan of Care Activity Reconstruction Procedure](#) (templateId:2.16.840.1.113883.10.20.30.3.31) (CONF:24131).
5. **SHOULD** contain zero or one [0..1] **entry** (CONF:24103) such that it
  - a. **SHALL** contain exactly one [1..1] [Plan of Care Radiation Activity](#) (templateId:2.16.840.1.113883.10.20.30.3.32) (CONF:24132).

**Figure 43: Plan of Care Section BCTPS example**

```

<section>
 <templateId root="2.16.840.1.113883.10.20.22.2.10" />
 <!-- **** Plan of Care section template **** -->
 <code code="18776-5" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="Plan of Care"/>
 <title>Plan of Care</title>
 <text>
 ...
 </text>
 <entry>
 <observation classCode="OBS" moodCode="INT">
 <templateId root="22.16.840.1.113883.10.20.30.3.30"/>
 <!-- **** Chemotherapy Regimen Plans template **** -->
 ...
 </observation>
 </entry>
 <entry>
 <observation classCode="OBS" moodCode="INT">
 <templateId root="2.16.840.1.113883.10.20.30.3.31"/>
 <!-- **** Plan of Care Activity Reconstruction Procedure **** -->
 ...
 </act>
 </entry>
 <entry>
 <encounter moodCode="INT" classCode="ENC">
 <templateId root="2.16.840.1.113883.10.20.30.3.32"/>
 <!-- **** Plan of Care Radiation Activity **** -->
 ...
 </encounter>
 </entry>
</section>

```

### 3.7 Problem Section (entries optional) [Closed for comments; published July 2012]

[section: templateId 2.16.840.1.113883.10.20.22.2.5 (open)]

**Table 45: Problem Section (entries optional) Contexts**

Used By:	Contains Entries:
	<a href="#">Problem Concern Act (Condition)</a>

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.

**Table 46: Problem Section (entries optional) Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	section[templateId/@root = '2.16.840.1.113883.10.20.22.2.5']					
	templateId	1..1	SHALL		<a href="#">7877</a>	
	@root	1..1	SHALL		<a href="#">10440</a>	2.16.840.1.113883.10.20.22.2.5
	code	1..1	SHALL		<a href="#">15407</a>	
	@code	1..1	SHALL		<a href="#">15408</a>	2.16.840.1.113883.6.1 (LOINC) = 11450-4
	title	1..1	SHALL		<a href="#">7879</a>	
	text	1..1	SHALL		<a href="#">7880</a>	
	entry	0..*	SHOULD		<a href="#">7881</a>	
	act	1..1	SHALL		<a href="#">15505</a>	

1. **SHALL** contain exactly one [1..1] **templateId** (CONF:7877) such that it
  - a. **SHALL** contain exactly one [1..1]
    - @root="2.16.840.1.113883.10.20.22.2.5" (CONF:10440).
2. **SHALL** contain exactly one [1..1] **code** (CONF:15407).
  - a. This code **SHALL** contain exactly one [1..1] @code="11450-4" Problem List (CodeSystem: LOINC 2.16.840.1.113883.6.1 **STATIC**) (CONF:15408).
3. **SHALL** contain exactly one [1..1] **title** (CONF:7879).
4. **SHALL** contain exactly one [1..1] **text** (CONF:7880).
5. **SHOULD** contain zero or more [0..\*] **entry** (CONF:7881).
  - a. The entry, if present, **SHALL** contain exactly one [1..1] [Problem Concern Act \(Condition\)](#) (templateId:2.16.840.1.113883.10.20.22.4.3) (CONF:15505).

### 3.7.1 Problem Section BCTPS

[Section: templateId 2.16.840.1.113883.10.20.30.2.1 (open)]

**Table 47: Problem Section BCTPS Contexts**

Used By:	Contains Entries:
<a href="#">Clinical Oncology Treatment Plan and Summary</a> (required)	<a href="#">Breast Cancer Concern Act</a> <a href="#">Last Menstrual Period</a>

This section contains a Breast Cancer Concern Act, which contains information specific to a breast cancer diagnosis such as tumor type, staging, and location. This section may include additional problem concern acts that represent information about the patient's comorbid conditions and and contain details pertaining to the patient's last menstrual period.

**Table 48: Problem Section BCTPS Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	Section[templateId/@root = '2.16.840.1.113883.10.20.30.2.1']					
	templateId	1..1	SHALL		<a href="#">19335</a>	
	@root	1..1	SHALL		<a href="#">19336</a>	2.16.840.1.113883.10.20.30.2.1
	entry	1..1	SHALL		<a href="#">19456</a>	
	act	1..1	SHALL		<a href="#">21929</a>	
	entry	0..1	MAY		<a href="#">22074</a>	
	observation	1..1	SHALL		<a href="#">22075</a>	

1. Conforms to [Problem Section \(entries optional\)](#) template (2.16.840.1.113883.10.20.22.2.5).
2. **SHALL** contain exactly one [1..1] **templateId** (CONF:19335) such that it
  - a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.30.2.1" (CONF:19336).
3. **SHALL** contain at least one [1..\*] **entry** (CONF:19456) such that it
  - a. **SHALL** contain exactly one [1..1] [Breast Cancer Concern Act](#) (templateId:2.16.840.1.113883.10.20.30.3.6) (CONF:21929).
4. **MAY** contain zero or one [0..1] **entry** (CONF:22074) such that it
  - a. **SHALL** contain exactly one [1..1] [Last Menstrual Period](#) (templateId:2.16.840.1.113883.10.20.30.3.34) (CONF:22075).

**Figure 44: Problem Section BCTPS example**

```

<section>
 <!-- C-CDA PROBLEM SECTION TemplateID -->
 <templateId root="2.16.840.1.113883.10.20.22.2.5"/>
 <!-- Problem Section BCTPS TemplateID -->
 <templateId root="2.16.840.1.113883.10.20.30.2.1"/>
 <code code="11450-4" displayName="Problem Section"
 codeSystem="2.16.840.1.113883.6.1"/>
 <title>PROBLEMS</title>
 <text>
 ...>
 </text>

 <!-- BREAST CANCER CONCERN ACT -->
 <entry typeCode="DRIV">
 <act classCode="ACT" moodCode="EVN">
 <!-- C-CDA PROBLEM CONCERN ACT(Condition)TemplateID -->
 <templateId root="2.16.840.1.113883.10.20.22.4.3"/>
 <!-- Breast Cancer Concern Act TemplateID -->
 <templateId root="2.16.840.1.113883.10.20.30.3.6"/>
 <id root="ec8a6ff8-ed4b-4f7e-82c3-e98e58b45de7"/>
 ...
 </act>
 </entry>

```

```

<entry>
 <!-- LAST MENSTRUAL PERIOD -->
 <observation classCode="OBS" moodCode="EVN">
 <templateId root="2.16.840.1.113883.10.20.30.3.34"/>
 <id root="11f83a4d-344e-4c62-ac97-4ef857616562"/>
 ...
 </observation>
</entry>

<entry typeCode="DRIV">
 <!--CO MORBID CONDITIONS -->
 <act classCode="ACT" moodCode="EVN">
 <!-- C-CDA PROBLEM CONCERN ACT (Condition)TemplateID -->
 <templateId root="2.16.840.1.113883.10.20.22.4.3"/>
 <id root="ba27f335-8ef9-41b7-belc-2f9e81b41e5c"/>
 ...
 </act>
</entry>
</section>

```

### 3.8 Procedures Section (entries optional)

[section: templateId 2.16.840.1.113883.10.20.22.2.7 (open)]

**Table 49: Procedures Section (entries optional) Contexts**

Used By:	Contains Entries:
	<a href="#">Procedure Activity Act</a> <a href="#">Procedure Activity Observation</a> <a href="#">Procedure Activity Procedure</a>

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 is intended to include notable procedures, but can contain all procedures for the period of time being summarized. 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 that alter the 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).

The length of an encounter is documented in the documentationOf/encompassingEncounter/effectiveTime and length of service in documentationOf/ServiceEvent/effectiveTime.

**Table 50: Procedures Section (entries optional) Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	section[templateId/@root = '2.16.840.1.113883.10.20.22.2.7']					
	templateId	1..1	SHALL		<a href="#">6270</a>	
	@root	1..1	SHALL		<a href="#">6271</a>	2.16.840.1.113883.10.20.22.2.7
	code	1..1	SHALL		<a href="#">15423</a>	
	@code	1..1	SHALL		<a href="#">15424</a>	2.16.840.1.113883.6.1 (LOINC) = 47519-4
	title	1..1	SHALL		<a href="#">17184</a>	
	text	1..1	SHALL		<a href="#">6273</a>	
	entry	0..*	MAY		<a href="#">6274</a>	
	procedure	1..1	SHALL		<a href="#">15509</a>	
	entry	0..1	MAY		<a href="#">6278</a>	
	observation	1..1	SHALL		<a href="#">15510</a>	
	entry	0..1	MAY		<a href="#">8533</a>	
	act	1..1	SHALL		<a href="#">15511</a>	

1. **SHALL** contain exactly one [1..1] **templateId** (CONF:6270) such that it
  - a. **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** (CONF:15423).
  - a. This code **SHALL** contain exactly one [1..1] @code="47519-4" History of Procedures (CodeSystem: LOINC 2.16.840.1.113883.6.1 **STATIC**) (CONF:15424).
3. **SHALL** contain exactly one [1..1] **title** (CONF:17184).
4. **SHALL** contain exactly one [1..1] **text** (CONF:6273).
5. **MAY** contain zero or more [0..\*] **entry** (CONF:6274) such that it
  - a. **SHALL** contain exactly one [1..1] [Procedure Activity Procedure](#) (templateId:2.16.840.1.113883.10.20.22.4.14) (CONF:15509).
6. **MAY** contain zero or one [0..1] **entry** (CONF:6278) such that it
  - a. **SHALL** contain exactly one [1..1] [Procedure Activity Observation](#) (templateId:2.16.840.1.113883.10.20.22.4.13) (CONF:15510).
7. **MAY** contain zero or one [0..1] **entry** (CONF:8533) such that it
  - a. **SHALL** contain exactly one [1..1] [Procedure Activity Act](#) (templateId:2.16.840.1.113883.10.20.22.4.12) (CONF:15511).



### 3.8.1 Procedures Section BCTPS

[Section: templateId 2.16.840.1.113883.10.20.30.2.4 (open)]

**Table 51: Procedures Section BCTPS Contexts**

Used By:	Contains Entries:
<a href="#">Clinical Oncology Treatment Plan and Summary</a> (required)	<a href="#">Breast Cancer Procedures</a> <a href="#">Radiation Therapy Care Completed</a>

This section contains information about breast-cancer-related procedures and treatments such as radiation therapy care.

**Table 52: Procedures Section BCTPS Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	Section[templateId/@root = '2.16.840.1.113883.10.20.30.2.4']					
	templateId	1..1	SHALL		<a href="#">23138</a>	
	@root	1..1	SHALL		<a href="#">23139</a>	2.16.840.1.113883.10.20.30.2.4
	entry	1..*	SHALL		<a href="#">23135</a>	
	procedure	1..1	SHALL		<a href="#">23137</a>	
	entry	0..1	SHOULD		<a href="#">23189</a>	
	act	1..1	SHALL		<a href="#">23190</a>	

1. Conforms to [Procedures Section \(entries optional\)](#) template (2.16.840.1.113883.10.20.22.2.7).
2. **SHALL** contain exactly one [1..1] **templateId** (CONF:23138) such that it
  - a. **SHALL** contain exactly one [1..1] **@root="2.16.840.1.113883.10.20.30.2.4"** (CONF:23139).
3. **SHALL** contain at least one [1..\*] **entry** (CONF:23135) such that it
  - a. **SHALL** contain exactly one [1..1] [Breast Cancer Procedures](#) (templateId:2.16.840.1.113883.10.20.30.3.12) (CONF:23137).
4. **SHOULD** contain zero or one [0..1] **entry** (CONF:23189) such that it
  - a. **SHALL** contain exactly one [1..1] [Radiation Therapy Care Completed](#) (templateId:2.16.840.1.113883.10.20.30.3.16) (CONF:23190).

**Figure 45: Procedures Section BCTPS example**

```

<section>
 <!--C-CDA PROCEDURE SECTION Entries Optional)TemplateID-->
 <templateId root="2.16.840.1.113883.10.20.22.2.7"/>
 <!--Procedure Section BCTPS TemplateID-->
 <templateId root="2.16.840.1.113883.10.20.30.2.4"/>
 <code code="47519-4"
 codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC"
 displayName="HISTORY OF PROCEDURES"/>
 <title>PROCEDURES</title>
 <text>
 ...
 </text>

 <!-- BREAST CANCER PROCEDURES -->
 <entry typeCode="DRIV">
 <procedure classCode="PROC" moodCode="EVN">
 <!-- C-CDA PROCEDURE ACTIVITY PROCEDURE TemplateID -->
 <templateId root="2.16.840.1.113883.10.20.22.4.14"/>
 <!-- Breast Cancer Procedures templateID-->
 <templateId root="2.16.840.1.113883.10.20.30.3.12"/>
 ...
 </procedure>

 <!-- RADIATION THERAPY CARE COMPLETED -->
 <entry>
 <!-- NegationInd=false indicates the patient did have radiation
 therapy -->
 <act classCode="ACT" moodCode="EVN" negationInd="false">
 <!-- C-CDA PROCEDURE ACTIVITY ACT TemplateID -->
 <templateId root="2.16.840.1.113883.10.20.22.4.12"/>
 <!-- Radiation Therapy Care Completed TemplateID -->
 <templateId root="2.16.840.1.113883.10.20.30.3.16"/>
 ...
 </act>
 </entry>
 </section>

```

### 3.9 Results Section (entries optional) [Closed for comments; published July 2012]

[section: templateId 2.16.840.1.113883.10.20.22.2.3 (open)]

**Table 53: Results Section (entries optional) Contexts**

Used By:	Contains Entries:
	<a href="#">Result Organizer</a>

The Results Section contains the results of observations generated by laboratories, imaging procedures, and other procedures. The scope includes observations such as 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.

**Table 54: Results Section (entries optional) Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	section[templateId/@root = '2.16.840.1.113883.10.20.22.2.3']					
	templateId	1..1	SHALL		<a href="#">7116</a>	
	@root	1..1	SHALL		<a href="#">9136</a>	2.16.840.1.113883.10.20.22.2.3
	code	1..1	SHALL		<a href="#">15431</a>	
	@code	1..1	SHALL		<a href="#">15432</a>	2.16.840.1.113883.6.1 (LOINC) = 30954-2
	title	1..1	SHALL		<a href="#">8891</a>	
	text	1..1	SHALL		<a href="#">7118</a>	
	entry	0..*	SHOULD		<a href="#">7119</a>	
	organizer	1..1	SHALL		<a href="#">15515</a>	

1. **SHALL** contain exactly one [1..1] **templateId** (CONF:7116) such that it
  - a. **SHALL** contain exactly one [1..1]
   
@root="2.16.840.1.113883.10.20.22.2.3" (CONF:9136).
2. **SHALL** contain exactly one [1..1] **code** (CONF:15431).
  - a. This code **SHALL** contain exactly one [1..1] @code="30954-2" Relevant diagnostic tests and/or laboratory data (CodeSystem: LOINC 2.16.840.1.113883.6.1 **STATIC**) (CONF:15432).
3. **SHALL** contain exactly one [1..1] **title** (CONF:8891).
4. **SHALL** contain exactly one [1..1] **text** (CONF:7118).
5. **SHOULD** contain zero or more [0..\*] **entry** (CONF:7119) such that it
  - a. **SHALL** contain exactly one [1..1] [Result Organizer](#) (templateId:2.16.840.1.113883.10.20.22.4.1) (CONF:15515).

### 3.9.1 Results Section BCTPS

[Section: templateId 2.16.840.1.113883.10.20.30.2.2 (open)]

**Table 55: Results Section BCTPS Contexts**

Used By:	Contains Entries:
<a href="#">Clinical Oncology Treatment Plan and Summary</a> (required)	<a href="#">Cardiac Function Observation</a> <a href="#">Molecular Diagnostic Testing Organizer</a> <a href="#">Receptor Status Organizer</a>

This section contains the result of observations for laboratory or diagnostic studies performed on patients with breast cancer (e.g., pre- and post-chemotherapy cardiac diagnostic studies, and hormone receptor status results).

**Table 56: Results Section BCTPS Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	Section[templateId/@root = '2.16.840.1.113883.10.20.30.2.2']					
	templateId	1..1	SHALL		<a href="#">23515</a>	
	@root	1..1	SHALL		<a href="#">23516</a>	2.16.840.1.113883.10.20.30.2.2
	entry	1..*	SHALL		<a href="#">23517</a>	
	organizer	1..1	SHALL		<a href="#">23518</a>	
	entry	1..*	SHALL		<a href="#">23519</a>	
	observation	1..1	SHALL		<a href="#">23520</a>	
	entry	1..*	SHALL		<a href="#">26824</a>	
	organizer	1..1	SHALL		<a href="#">26826</a>	

1. Conforms to [Results Section \(entries optional\)](#) template (2.16.840.1.113883.10.20.22.2.3).
2. **SHALL** contain exactly one [1..1] **templateId** (CONF:23515) such that it
  - a. **SHALL** contain exactly one [1..1] **@root="2.16.840.1.113883.10.20.30.2.2"** (CONF:23516).
3. **SHALL** contain at least one [1..\*] **entry** (CONF:23517) such that it
  - a. **SHALL** contain exactly one [1..1] [Receptor Status Organizer](#) (templateId:2.16.840.1.113883.10.20.30.3.17) (CONF:23518).
4. **SHALL** contain at least one [1..\*] **entry** (CONF:23519) such that it
  - a. **SHALL** contain exactly one [1..1] [Cardiac Function Observation](#) (templateId:2.16.840.1.113883.10.20.30.3.21) (CONF:23520).
5. **SHALL** contain at least one [1..\*] **entry** (CONF:26824) such that it
  - a. **SHALL** contain exactly one [1..1] [Molecular Diagnostic Testing Organizer](#) (templateId:2.16.840.1.113883.10.20.30.3.49) (CONF:26826).

**Figure 46: Results Section BCTPS example**

```

<section>
 <!-- C-CDA RESULTS SECTION templateID-->
 <templateId root="2.16.840.1.113883.10.20.22.2.3.3"/>
 <!-- Result Section BCTPS -->
 <templateId root="2.16.840.1.113883.10.20.30.2.2"/>
 <code code="30954-2" codeSystem="2.16.840.1.113883.6.1"/>
 <title>RESULTS</title>
 <text> ... </text>

 <entry typeCode="DRIV">
 <organizer classCode="CLUSTER" moodCode="EVN">
 <!-- Result Organizer templateID from Consolidated CDA -->
 <templateId root="2.16.840.1.113883.10.20.22.4.1"/>
 <!-- MOLECULAR DIAGNOSTIC TESTING Organizer template -->
 <templateId root="2.16.840.1.113883.10.20.30.3.49"/>
 ...
 </organizer>
 </entry>
 <entry typeCode="DRIV">
 <organizer classCode="CLUSTER" moodCode="EVN">
 <!-- Result Organizer templateID from Consolidated CDA -->
 <templateId root="2.16.840.1.113883.10.20.22.4.1"/>
 <!-- Receptor status Organizer template ID -->
 <templateId root="2.16.840.1.113883.10.20.30.3.17"/>
 ...
 </organizer>
 </entry>
 <entry>
 <!-- consolidated CDA Result Observation templateID -->
 <templateId root="2.16.840.1.113883.10.20.22.4.2"/>
 <!-- Cardiac Function Observation templateID -->
 <templateId root="2.16.840.1.113883.10.20.30.3.21"/>
 ...
 </entry>
</section>

```

### 3.10 Vital Signs Section (entries optional) [Closed for comments; published July 2012]

[section: templateId 2.16.840.1.113883.10.20.22.2.4 (open)]

**Table 57: Vital Signs Section (entries optional) Contexts**

Used By:	Contains Entries:
	<a href="#">Vital Signs Organizer</a>

The Vital Signs Section contains 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.

**Table 58: Vital Signs Section (entries optional) Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	section[templateId/@root = '2.16.840.1.113883.10.20.22.2.4']					
	templateId	1..1	SHALL		<a href="#">7268</a>	
	@root	1..1	SHALL		<a href="#">10451</a>	2.16.840.1.113883.10.20.22.2.4
	code	1..1	SHALL		<a href="#">15242</a>	
	@code	1..1	SHALL		<a href="#">15243</a>	2.16.840.1.113883.6.1 (LOINC) = 8716-3
	title	1..1	SHALL		<a href="#">9966</a>	
	text	1..1	SHALL		<a href="#">7270</a>	
	entry	0..*	SHOULD		<a href="#">7271</a>	
	organizer	1..1	SHALL		<a href="#">15517</a>	

1. **SHALL** contain exactly one [1..1] **templateId** (CONF:7268) such that it
  - a. **SHALL** contain exactly one [1..1]
    - @root="2.16.840.1.113883.10.20.22.2.4" (CONF:10451).
2. **SHALL** contain exactly one [1..1] **code** (CONF:15242).
  - a. This code **SHALL** contain exactly one [1..1] @code="8716-3" Vital Signs (CodeSystem: LOINC 2.16.840.1.113883.6.1 **STATIC**) (CONF:15243).
3. **SHALL** contain exactly one [1..1] **title** (CONF:9966).
4. **SHALL** contain exactly one [1..1] **text** (CONF:7270).
5. **SHOULD** contain zero or more [0..\*] **entry** (CONF:7271) such that it
  - a. **SHALL** contain exactly one [1..1] **Vital Signs Organizer** (templateId:2.16.840.1.113883.10.20.22.4.26) (CONF:15517).

### 3.10.1 Vital Signs Section BCTPS

[section: templateId 2.16.840.1.113883.10.20.30.2.5 (open)]

**Table 59: Vital Signs Section BCTPS Contexts**

Used By:	Contains Entries:
<a href="#">Clinical Oncology Treatment Plan and Summary</a> (required)	<a href="#">Vital Signs Organizer BCTPS</a>

This section contains height, weight, and body surface area findings.

**Table 60: Vital Signs Section BCTPS Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	section[templateId/@root = '2.16.840.1.113883.10.20.30.2.5']					
	templateId	1..1	SHALL		<a href="#">24842</a>	
	@root	1..1	SHALL		<a href="#">24843</a>	2.16.840.1.113883.10.20.30.2.5
	entry	1..*	SHALL		<a href="#">24848</a>	
	organizer	1..1	SHALL		<a href="#">24906</a>	

1. Conforms to [Vital Signs Section \(entries optional\)](#) template (2.16.840.1.113883.10.20.22.2.4).
2. **SHALL** contain exactly one [1..1] **templateId** (CONF:24842) such that it
  - a. **SHALL** contain exactly one [1..1]
   
@root="2.16.840.1.113883.10.20.30.2.5" (CONF:24843).
3. **SHALL** contain at least one [1..\*] **entry** (CONF:24848) such that it
  - a. **SHALL** contain exactly one [1..1] [Vital Signs Organizer BCTPS](#) (templateId:2.16.840.1.113883.10.20.30.3.25) (CONF:24906).

**Figure 47: Vital Signs Section BCTPS example**

```

<section>
 <!--C-CDA Vital Signs Section with Coded Entries Optional templateID -->
 <templateId root="2.16.840.1.113883.10.20.22.2.4"/>
 <!-- BCTPS Vital Signs Section with Height weight and BSA Required -->
 <templateId root="2.16.840.1.113883.10.20.30.2.5"/>
 <code code="8716-3" displayName="Physical Findings - Vital signs"
 codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC">
 <originalText>Vital Signs</originalText>
 </code>
 <title>VITAL SIGNS</title>
 <text>
 ...
 </text>
 <entry typeCode="DRIV">
 <organizer classCode="CLUSTER" moodCode="EVN">
 <!-- C-CDA VITAL SIGNS ORGANIZER TemplateID -->
 <templateId root="2.16.840.1.113883.10.20.22.4.26"/>
 <!-- Vital Signs Organizer BCTPS templateID-->
 <templateId root="2.16.840.1.113883.10.20.30.3.25"/>
 ...
 </organizer>
 </entry>
</section>

```

## 4 ENTRY-LEVEL TEMPLATES

### 4.1 Age Observation

[Closed for comments; published July 2012]

[observation: templateId 2.16.840.1.113883.10.20.22.4.31 (open)]

**Table 61: Age Observation Contexts**

Used By:	Contains Entries:
<a href="#">Problem Observation</a> (optional) <a href="#">Family History Observation</a> (optional)	

This Age Observation represents the subject's age at onset of an event or observation. The age of a relative in a Family History Observation at the time of that observation could also be inferred by comparing `relatedSubject/subject/birthTime` with `observation/effectiveTime`. However, a common scenario is that a patient will know the age of a relative when the relative had a certain condition or when the relative died, but will not know the actual year (e.g., "grandpa died of a heart attack at the age of 50"). Often times, neither precise dates nor ages are known (e.g., "cousin died of congenital heart disease as an infant").

**Table 62: Age Observation Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	observation[templateId/@root = '2.16.840.1.113883.10.20.22.4.31']					
	@classCode	1..1	SHALL		<a href="#">7613</a>	2.16.840.1.113883.5.6 (HL7ActClass) = OBS
	@moodCode	1..1	SHALL		<a href="#">7614</a>	2.16.840.1.113883.5.1001 (ActMood) = EVN
	templateId	1..1	SHALL		<a href="#">7899</a>	
	@root	1..1	SHALL		<a href="#">10487</a>	2.16.840.1.113883.10.20.22.4.31
	code	1..1	SHALL		<a href="#">7615</a>	
	@code	1..1	SHALL		<a href="#">16776</a>	2.16.840.1.113883.6.96 (SNOMED-CT) = 445518008
	statusCode	1..1	SHALL		<a href="#">15965</a>	
	@code	1..1	SHALL		<a href="#">15966</a>	2.16.840.1.113883.5.14 (ActStatus) = completed
	value	1..1	SHALL	PQ	<a href="#">7617</a>	
	@unit	1..1	SHALL	CS	<a href="#">7618</a>	2.16.840.1.113883.11.20.9.21 (AgePQ_UCUM)

1. **SHALL** contain exactly one [1..1] @classCode="OBS" Observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:7613).



2. **SHALL** contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 **STATIC**) (CONF:7614).
3. **SHALL** contain exactly one [1..1] templateId (CONF:7899) such that it
  - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.31" (CONF:10487).
4. **SHALL** contain exactly one [1..1] code (CONF:7615).
  - a. This code **SHALL** contain exactly one [1..1] @code="445518008" Age At Onset (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96 **STATIC**) (CONF:16776).
5. **SHALL** contain exactly one [1..1] statusCode (CONF:15965).
  - a. This statusCode **SHALL** contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 **STATIC**) (CONF:15966).
6. **SHALL** contain exactly one [1..1] value with @xsi:type="PQ" (CONF:7617).
  - a. This value **SHALL** contain exactly one [1..1] @unit, which **SHALL** be selected from ValueSet AgePQ\_UCUM 2.16.840.1.113883.11.20.9.21 **DYNAMIC** (CONF:7618).

**Table 63: AgePQ\_UCUM Value Set**

Value Set: AgePQ_UCUM 2.16.840.1.113883.11.20.9.21 DYNAMIC		
Code System: Unified Code for Units of Measure (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

**Figure 48: Age Observation example**

```

<observation classCode="OBS" moodCode="EVN">
 <templateId root="2.16.840.1.113883.10.20.22.4.31"/>
 <!-- Age observation template -->
 <code code="445518008"
 codeSystem="2.16.840.1.113883.6.96"
 displayName="Age At Onset" />
 <statusCode code="completed" />
 <value xsi:type="PQ" value="57" unit="a" />
</observation>

```

## 4.2 Allergy Problem Act

**[Closed for comments; published July 2012]**

[act: templateId 2.16.840.1.113883.10.20.22.4.30 (open)]

**Table 64: Allergy Problem Act Contexts**

Used By:	Contains Entries:
<a href="#">Allergies Section (entries optional)</a> (optional)	<a href="#">Allergy - Intolerance Observation</a>

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 Allergy Problem Act, or "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.

**Table 65: Allergy Problem Act Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
	act[templateId/@root = '2.16.840.1.113883.10.20.22.4.30']					
	@classCode	1..1	SHALL		<a href="#">7469</a>	2.16.840.1.113883.5.6 (HL7ActClass) = ACT
	@moodCode	1..1	SHALL		<a href="#">7470</a>	2.16.840.1.113883.5.1001 (ActMood) = EVN
	templateId	1..1	SHALL		<a href="#">7471</a>	
	@root	1..1	SHALL		<a href="#">10489</a>	2.16.840.1.113883.10.20.22.4.30
	id	1..*	SHALL		<a href="#">7472</a>	
	code	1..1	SHALL		<a href="#">7477</a>	
	@code	1..1	SHALL		<a href="#">19158</a>	2.16.840.1.113883.6.1 (LOINC) = 48765-2
	statusCode	1..1	SHALL		<a href="#">7485</a>	
	@code	1..1	SHALL		<a href="#">19086</a>	2.16.840.1.113883.11.20.9.19 (ProblemAct statusCode)
	effectiveTime	1..1	SHALL		<a href="#">7498</a>	
	entryRelationship	1..*	SHALL		<a href="#">7509</a>	
	@typeCode	1..1	SHALL		<a href="#">7915</a>	2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = SUBJ
	observation	1..1	SHALL		<a href="#">14925</a>	

1. **SHALL** contain exactly one [1..1] @classCode="ACT" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:7469).

2. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 **STATIC**) (CONF:7470).
3. **SHALL** contain exactly one [1..1] **templateId** (CONF:7471) such that it
  - a. **SHALL** contain exactly one [1..1] **@root="2.16.840.1.113883.10.20.22.4.30"** (CONF:10489).
4. **SHALL** contain at least one [1..\*] **id** (CONF:7472).
5. **SHALL** contain exactly one [1..1] **code** (CONF:7477).
  - a. This code **SHALL** contain exactly one [1..1] **@code="48765-2"** Allergies, adverse reactions, alerts (CodeSystem: LOINC 2.16.840.1.113883.6.1 **STATIC**) (CONF:19158).
6. **SHALL** contain exactly one [1..1] **statusCode** (CONF:7485).
  - a. This statusCode **SHALL** contain exactly one [1..1] **@code**, which **SHALL** be selected from ValueSet ProblemAct statusCode 2.16.840.1.113883.11.20.9.19 **STATIC** 2011-09-09 (CONF:19086).
7. **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:7498).
  - a. If statusCode/@code="active" Active, then effectiveTime **SHALL** contain [1..1] low (CONF:7504).
  - b. If statusCode/@code="completed" Completed, then effectiveTime **SHALL** contain [1..1] high (CONF:10085).
8. **SHALL** contain at least one [1..\*] **entryRelationship** (CONF:7509) such that it
  - a. **SHALL** contain exactly one [1..1] **@typeCode="SUBJ"** Has subject (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**) (CONF:7915).
  - b. **SHALL** contain exactly one [1..1] **Allergy - Intolerance Observation** (templateId:2.16.840.1.113883.10.20.22.4.7) (CONF:14925).

**Table 66: ProblemAct statusCode Value Set**

Value Set: ProblemAct statusCode 2.16.840.1.113883.11.20.9.19 STATIC 2011-09-09 Code System: ActStatus 2.16.840.1.113883.5.14		
Code	Code System	Print Name
completed	ActStatus	Completed
aborted	ActStatus	Aborted
active	ActStatus	Active
suspended	ActStatus	Suspended

**Figure 49: Allergy Problem Act example**

```

<entry typeCode="DRIV">
 <act classCode="ACT" moodCode="EVN">
 <templateId root="2.16.840.1.113883.10.20.22.4.30"/>
 <id root="36e3e930-7b14-11db-9fe1-0800200c9a66"/>
 <code code="48765-2" codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC"
 displayName="Allergies, adverse reactions, alerts" />
 <statusCode code="active"/>
 <effectiveTime value="20060501">
 <low value="20060501"/>
 </effectiveTime>
 <entryRelationship typeCode="SUBJ">
 <observation classCode="OBS" moodCode="EVN">
 <templateId root="2.16.840.1.113883.10.20.22.4.7"/>
 . . .
 </observation>
 </entryRelationship>
 </act>
</entry>

```

### 4.3 Allergy Status Observation [Closed for comments; published July 2012]

[observation: templateId 2.16.840.1.113883.10.20.22.4.28 (open)]

**Table 67: Allergy Status Observation Contexts**

Used By:	Contains Entries:
<a href="#">Allergy - Intolerance Observation</a> (optional) <a href="#">Substance or Device Allergy - Intolerance Observation</a> (optional)	

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

**Table 68: Allergy Status Observation Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	observation[templateId/@root = '2.16.840.1.113883.10.20.22.4.28']					
	@classCode	1..1	SHALL		<a href="#">7318</a>	2.16.840.1.113883.5.6 (HL7ActClass) = OBS
	@moodCode	1..1	SHALL		<a href="#">7319</a>	2.16.840.1.113883.5.1001 (ActMood) = EVN
	templateId	1..1	SHALL		<a href="#">7317</a>	
	@root	1..1	SHALL		<a href="#">10490</a>	2.16.840.1.113883.10.20.22.4.28
	code	1..1	SHALL		<a href="#">7320</a>	
	@code	1..1	SHALL		<a href="#">19131</a>	2.16.840.1.113883.6.1 (LOINC) = 33999-4
	statusCode	1..1	SHALL		<a href="#">7321</a>	
	@code	1..1	SHALL		<a href="#">19087</a>	2.16.840.1.113883.5.14 (ActStatus) = completed
	value	1..1	SHALL	CE	<a href="#">7322</a>	2.16.840.1.113883.3.88.12.80.68 (Problem Status Value Set)

1. **SHALL** contain exactly one [1..1] @classCode="OBS" Observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:7318).
2. **SHALL** contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 **STATIC**) (CONF:7319).
3. **SHALL** contain exactly one [1..1] templateId (CONF:7317) such that it
  - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.28" (CONF:10490).
4. **SHALL** contain exactly one [1..1] code (CONF:7320).
  - a. This code **SHALL** contain exactly one [1..1] @code="33999-4" Status (CodeSystem: LOINC 2.16.840.1.113883.6.1 **STATIC**) (CONF:19131).
5. **SHALL** contain exactly one [1..1] statusCode (CONF:7321).
  - a. This statusCode **SHALL** contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 **STATIC**) (CONF:19087).
  - b. **SHALL** contain exactly one [1..1] value with @xsi:type="CE", where the @code **SHALL** be selected from ValueSet Problem Status Value Set 2.16.840.1.113883.3.88.12.80.68 **DYNAMIC** (CONF:7322).

**Table 69: Problem Status Value Set**

Value Set: Problem Status Value Set 2.16.840.1.113883.3.88.12.80.68		
Code System: SNOMED-CT 2.16.840.1.113883.6.96		
Code	Code System	Print Name
55561003	SNOMED-CT	Active
73425007	SNOMED-CT	Inactive
413322009	SNOMED-CT	Resolved

\* An inactive problems refers to one that is quiescent, and may appear again in future.

\*\* A resolved problem refers to one that used to affect a patient, but does not any more.

**Figure 50: Allergy Status Observation example**

```
<observation classCode="OBS" moodCode="EVN">
 <templateId root="2.16.840.1.113883.10.20.22.4.28" />
 <!-- Allergy status observation template -->
 <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"
 displayName="Active" />
</observation>
```

## 4.4 Anthracyclines Lifetime Dose

[SubstanceAdministration: templateId 2.16.840.1.113883.10.20.30.3.24  
(open) ]

**Table 70: Anthracyclines Lifetime Dose Contexts**

Used By:	Contains Entries:
<a href="#">Medications Section BCTPS</a> (required)	

This clinical statement represents the total amount of drugs in the Anthracycline drug class that a patient has received in his or her lifetime.

**Table 71: Anthracyclines Lifetime Dose Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	SubstanceAdministration[templateId/@root = '2.16.840.1.113883.10.20.30.3.24']					
	@classCode	1..1	SHALL		<a href="#">23637</a>	2.16.840.1.113883.5.6 (HL7ActClass) = SBADM
	@moodCode	1..1	SHALL		<a href="#">23638</a>	2.16.840.1.113883.5.1001 (ActMood) = EVN
	templateId	1..1	SHALL		<a href="#">23639</a>	
	@root	1..1	SHALL		<a href="#">23640</a>	2.16.840.1.113883.10.20.30.3.24
	statusCode	1..1	SHALL		<a href="#">23641</a>	
	@code	1..1	SHALL		<a href="#">23642</a>	2.16.840.1.113883.5.14 (ActStatus) = active
	effectiveTime	1..1	SHALL	IVL_TS	<a href="#">27315</a>	
	low	1..1	SHALL		<a href="#">27316</a>	
	@nullFlavor	1..1	SHALL		<a href="#">27317</a>	NINF
	high	1..1	SHALL		<a href="#">27318</a>	
	doseQuantity	1..1	SHALL		<a href="#">23645</a>	
	@unit	1..1	SHALL		<a href="#">23646</a>	
	consumable	1..1	SHALL		<a href="#">23647</a>	
	manufactured Product	1..1	SHALL		<a href="#">27310</a>	
	manufactured Material	1..1	SHALL		<a href="#">27311</a>	
	code	1..1	SHALL		<a href="#">27312</a>	
	@code	1..1	SHALL		<a href="#">27313</a>	N0000007530
	@codeSystem	1..1	SHALL		<a href="#">27314</a>	2.16.840.1.113883.3.26.1.5 (NDFRT) = 2.16.840.1.113883.3.26.1.5

1. **SHALL** contain exactly one [1..1] @classCode="SBADM" SubstanceAdministration (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:23637).
2. **SHALL** contain exactly one [1..1] @moodCode="EVN" event (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:23638).
3. **SHALL** contain exactly one [1..1] templateId (CONF:23639) such that it
  - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.3.24" (CONF:23640).
4. **SHALL** contain exactly one [1..1] statusCode (CONF:23641).
  - a. This statusCode **SHALL** contain exactly one [1..1] @code="active" Active (CodeSystem: ActStatus 2.16.840.1.113883.5.14) (CONF:23642).

In the absence of `doseCheckQuantity` as an attribute in CDA, this template uses the null value of "NINF" (negative infinity) to help to represent "From the beginning of time until this given date, this is the amount received".

5. **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:27315).
  - a. This **effectiveTime** **SHALL** contain exactly one [1..1] **low** (CONF:27316).
    - i. This **low** **SHALL** contain exactly one [1..1] **@nullFlavor="NINF"** negative infinity (CONF:27317).

The `effectiveTime/high` is equal to the date the note is generated.

- b. This **effectiveTime** **SHALL** contain exactly one [1..1] **high** (CONF:27318).

The `doseQuantity/unit` is not constrained. Anthracyclines are usually ordered in mg/m<sup>2</sup>, and the maximum lifetime dose is often noted in mg/m<sup>2</sup>. However, what is most likely to be found in EHR is what was recorded on a Medication Administration Record (MAR), which is typically the actual mg (both are allowed).

6. **SHALL** contain exactly one [1..1] **doseQuantity** (CONF:23645).
  - a. This **doseQuantity** **SHALL** contain exactly one [1..1] **@unit** (CONF:23646).
7. **SHALL** contain exactly one [1..1] **consumable** (CONF:23647).
  - a. This **consumable** **SHALL** contain exactly one [1..1] **manufacturedProduct** (CONF:27310).
    - i. This **manufacturedProduct** **SHALL** contain exactly one [1..1] **manufacturedMaterial** (CONF:27311).
      1. This **manufacturedMaterial** **SHALL** contain exactly one [1..1] **code** (CONF:27312).
        - a. This **code** **SHALL** contain exactly one [1..1] **@code="N0000007530"** Anthracyclines (Structural Class) (CONF:27313).
        - b. This **code** **SHALL** contain exactly one [1..1] **@codeSystem="2.16.840.1.113883.3.26.1.5"** NDF-RT (CodeSystem: NDFRT 2.16.840.1.113883.3.26.1.5) (CONF:27314).

**Figure 51: Anthracyclines Lifetime Dose example**

```
<entry>
 <substanceAdministration classCode="SBADM" moodCode="EVN">
 <!-- ANTHRACYCLINES LIFETIME DOSE templateID -->
 <templateId root="2.16.840.1.113883.10.20.30.3.24"/>
 <statusCode code="active"/>
 <!-- Lifetime till observation-->
 <effectiveTime xsi:type="IVL_TS">
 <!-- In the absence of doseCheckQuantity as an attribute in CDA
 this template uses the null value
 of negative infinity to help to represent
 "From the beginning of time until this given date, this is the
 amount received" -->
 <low nullFlavor="NINF"/>
 <!-- Date of observation or note generation -->
 <high value="20130301"/>
 </effectiveTime>
```



```

<!-- Dose expressed here in mg. Though ordered in mg/m2, amd the max
lifetime dose noted in mg/m2, what is
most likely to be found in EHR is what was recorded on an MAR,
which is typically the actual mg (both would be allowed)-->
<doseQuantity value="137" unit="mg"/>
<consumable>
 <manufacturedProduct classCode="MANU">
 <manufacturedMaterial>
 <code codeSystem="2.16.840.1.113883.3.26.1.5"
codeSystemName="NDF-RT"
code="N0000007530"
displayName="Anthracyclines (Structural Class)"/>
 </manufacturedMaterial>
 </manufacturedProduct>
</consumable>
</substanceAdministration>
</entry>

```

## 4.5 Assessment Scale Observation

**[Closed for comments; published July 2012]**

[observation: templateId 2.16.840.1.113883.10.20.22.4.69 (open)]

**Table 72: Assessment Scale Observation Contexts**

Used By:	Contains Entries:
<a href="#">Functional Status Section</a> (optional) <a href="#">Functional Status Result Observation</a> (optional) <a href="#">Cognitive Status Result Observation</a> (optional) <a href="#">Functional Status Problem Observation</a> (optional) <a href="#">Cognitive Status Problem Observation</a> (optional)	<a href="#">Assessment Scale Supporting Observation</a>

An assessment scale is a collection of observations that together yield a summary evaluation of a particular condition. Examples include the Braden Scale (assesses pressure ulcer risk), APACHE Score (estimates mortality in critically ill patients), Mini-Mental Status Exam (assesses cognitive function), APGAR Score (assesses the health of a newborn), and Glasgow Coma Scale (assesses coma and impaired consciousness.)

**Table 73: Assessment Scale Observation Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
	observation[templateId/@root = '2.16.840.1.113883.10.20.22.4.69']					
	@classCode	1..1	SHALL		<a href="#">14434</a>	2.16.840.1.113883.5.6 (HL7ActClass) = OBS
	@moodCode	1..1	SHALL		<a href="#">14435</a>	2.16.840.1.113883.5.1001 (ActMood) = EVN
	templateId	1..1	SHALL		<a href="#">14436</a>	
	@root	1..1	SHALL		<a href="#">14437</a>	2.16.840.1.113883.10.20.22.4.69
	id	1..*	SHALL		<a href="#">14438</a>	
	code	1..1	SHALL		<a href="#">14439</a>	
	derivationExpr	0..1	MAY		<a href="#">14637</a>	
	statusCode	1..1	SHALL		<a href="#">14444</a>	
	@code	1..1	SHALL		<a href="#">19088</a>	2.16.840.1.113883.5.14 (ActStatus) = completed
	effectiveTime	1..1	SHALL		<a href="#">14445</a>	
	value	1..1	SHALL		<a href="#">14450</a>	
	interpretationCode	0..*	MAY		<a href="#">14459</a>	
	translation	0..*	MAY		<a href="#">14888</a>	
	author	0..*	MAY		<a href="#">14460</a>	
	entryRelationship	0..*	SHOULD		<a href="#">14451</a>	
	@typeCode	1..1	SHALL		<a href="#">16741</a>	COMP
	observation	1..1	SHALL		<a href="#">16742</a>	
	referenceRange	0..*	MAY		<a href="#">16799</a>	
	observationRange	1..1	SHALL		<a href="#">16800</a>	
	text	0..1	SHOULD		<a href="#">16801</a>	
	reference	0..1	SHOULD		<a href="#">16802</a>	
	@value	0..1	MAY		<a href="#">16803</a>	

1. **SHALL** contain exactly one [1..1] @classCode="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:14434).
2. **SHALL** contain exactly one [1..1] @moodCode="EVN" (CodeSystem: ActMood 2.16.840.1.113883.5.1001 **STATIC**) (CONF:14435).
3. **SHALL** contain exactly one [1..1] templateId (CONF:14436) such that it
  - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.69" (CONF:14437).
4. **SHALL** contain at least one [1..\*] id (CONF:14438).
5. **SHALL** contain exactly one [1..1] code (CONF:14439).

- a. **SHOULD** be from LOINC (CodeSystem: 2.16.840.1.113883.6.1) or SNOMED CT (CodeSystem: 2.16.840.1.113883.6.96) identifying the assessment scale (CONF:14440).

Such derivation expression can contain a text calculation of how the components total up to the summed score

- 6. **MAY** contain zero or one [0..1] **derivationExpr** (CONF:14637).
- 7. **SHALL** contain exactly one [1..1] **statusCode** (CONF:14444).
  - a. This statusCode **SHALL** contain exactly one [1..1] **@code="completed"** Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 **STATIC**) (CONF:19088).

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)

- 8. **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:14445).
- 9. **SHALL** contain exactly one [1..1] **value** (CONF:14450).
- 10. **MAY** contain zero or more [0..\*] **interpretationCode** (CONF:14459).
  - a. The interpretationCode, if present, **MAY** contain zero or more [0..\*] **translation** (CONF:14888).
- 11. **MAY** contain zero or more [0..\*] **author** (CONF:14460).
- 12. **SHOULD** contain zero or more [0..\*] **entryRelationship** (CONF:14451) such that it
  - a. **SHALL** contain exactly one [1..1] **@typeCode="COMP"** has component (CONF:16741).
  - b. **SHALL** contain exactly one [1..1] **Assessment Scale Supporting Observation** (templateId:2.16.840.1.113883.10.20.22.4.86) (CONF:16742).

The referenceRange/observationRange/text, if present, **MAY** contain a description of the scale (e.g. for a Pain Scale 1 to 10: 1 to 3 = little pain, 4 to 7= moderate pain, 8 to 10 = severe pain)

- 13. **MAY** contain zero or more [0..\*] **referenceRange** (CONF:16799).
  - a. The referenceRange, if present, **SHALL** contain exactly one [1..1] **observationRange** (CONF:16800).
    - i. This observationRange **SHOULD** contain zero or one [0..1] **text** (CONF:16801).
      - 1. The text, if present, **SHOULD** contain zero or one [0..1] **reference** (CONF:16802).
        - a. The reference, if present, **MAY** contain zero or one [0..1] **@value** (CONF:16803).
          - i. This reference/@value **SHALL** begin with a '#' and **SHALL** point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:16804).

**Figure 52: Assessment Scale Observation example**

```

<observation classCode="OBS" moodCode="EVN">
 <!--Assessment Scale Observation -->
 <templateId root="2.16.840.1.113883.10.20.22.4.69"/>
 <id root="c6b5a04b-2bf4-49d1-8336-636a3813df0b"/>
 <code code="54614-3"
 displayName="Brief Interview for Mental Status"
 codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC"/>
 <derivationExpr>Text description of the calculation</derivationExpr>
 <statusCode code="completed"/>
 <effectiveTime value="20120214"/>
 <!-- Summed score of the component values -->
 <value xsi:type="INT" value="7"/>
 <entryRelationship typeCode="COMP">
 <observation classCode="OBS" moodCode="EVN">
 <!-- ** Assessment scale supporting observation ** -->
 <templateId root="2.16.840.1.113883.10.20.22.4.86"/>
 ...
 </observation>
 </entryRelationship>
 ...
</observation>

```

## 4.6 Assessment Scale Supporting Observation [Closed for comments; published July 2012]

[observation: templateId 2.16.840.1.113883.10.20.22.4.86 (open)]

**Table 74: Assessment Scale Supporting Observation Contexts**

Used By:	Contains Entries:
<a href="#">Assessment Scale Observation</a> (optional)	

An Assessment Scale Supporting observation represents the components of a scale used in an Assessment Scale Observation. The individual parts that make up the component may be a group of cognitive or functional status observations.

**Table 75: Assessment Scale Supporting Observation Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	observation[templateId/@root = '2.16.840.1.113883.10.20.22.4.86']					
	@classCode	1..1	SHALL		<a href="#">16715</a>	2.16.840.1.113883.5.6 (HL7ActClass) = OBS
	@moodCode	1..1	SHALL		<a href="#">16716</a>	2.16.840.1.113883.5.1001 (ActMood) = EVN
	templateId	1..1	SHALL		<a href="#">16722</a>	
	@root	1..1	SHALL		<a href="#">16723</a>	2.16.840.1.113883.10.20.22.4.86
	id	1..*	SHALL		<a href="#">16724</a>	
	code	1..1	SHALL		<a href="#">19178</a>	
	@code	1..1	SHALL		<a href="#">19179</a>	
	statusCode	1..1	SHALL		<a href="#">16720</a>	
	@code	1..1	SHALL		<a href="#">19089</a>	2.16.840.1.113883.5.14 (ActStatus) = completed
	value	1..*	SHALL		<a href="#">16754</a>	

1. **SHALL** contain exactly one [1..1] @classCode="OBS" Observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:16715).
2. **SHALL** contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 **STATIC**) (CONF:16716).
3. **SHALL** contain exactly one [1..1] templateId (CONF:16722) such that it
  - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.86" (CONF:16723).
4. **SHALL** contain at least one [1..\*] id (CONF:16724).
5. **SHALL** contain exactly one [1..1] code (CONF:19178).
  - a. This code **SHALL** contain exactly one [1..1] @code (CONF:19179).
    - i. Such that the @code **SHALL** be from LOINC (CodeSystem: 2.16.840.1.113883.6.1) or SNOMED CT (CodeSystem: 2.16.840.1.113883.6.96) and represents components of the scale (CONF:19180).
6. **SHALL** contain exactly one [1..1] statusCode (CONF:16720).
  - a. This statusCode **SHALL** contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 **STATIC**) (CONF:19089).
7. **SHALL** contain at least one [1..\*] value (CONF:16754).
  - a. If xsi:type="CD" , **MAY** have a translation code to further specify the source if the instrument has an applicable code system and valueSet for the integer (CONF:14639) (CONF:16755).

**Figure 53: Assessment Scale Supporting Observation example**

```

<entryRelationship typeCode="COMP">
 <observation classCode="OBS" moodCode="EVN">
 <templateId root="2.16.840.1.113883.10.20.22.4.86"/>
 <id root="f4dce790-8328-11db-9fe1-0800200c9a44"/>
 <code code="248240001" displayName="motor response"
 codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED"/>
 <statusCode code="completed"/>
 <value xsi:type="INT" value="3"/>
 </observation>
</entryRelationship>

```

## 4.7 Breast TNM Clinical Category

[Act: templateId 2.16.840.1.113883.10.20.30.3.3 (open)]

**Table 76: Breast TNM Clinical Category Contexts**

Used By:	Contains Entries:
<a href="#">Breast Cancer Diagnosis Observation</a> (required)	<a href="#">Breast TNM Metastasis Category</a> <a href="#">Breast TNM Node Category</a> <a href="#">Breast TNM Tumor Category</a>

This clinical statement represents the overall AJCC (American Joint Committee on Cancer) TNM clinical stage of the patient's breast cancer which may contain details on the Tumor, Node, and Metastasis (TNM) categories.

**Table 77: Breast TNM Clinical Category Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	Act[templateId/@root = '2.16.840.1.113883.10.20.30.3.3']					
	@classCode	1..1	SHALL		<a href="#">22056</a>	2.16.840.1.113883.5.6 (HL7ActClass) = ACT
	@moodCode	1..1	SHALL		<a href="#">22057</a>	2.16.840.1.113883.5.1001 (ActMood) = EVN
	templateId	1..1	SHALL		<a href="#">19292</a>	
	@root	1..1	SHALL		<a href="#">19293</a>	2.16.840.1.113883.10.20.30.3.3
	id	1..*	SHALL		<a href="#">24929</a>	
	code	1..1	SHALL		<a href="#">21897</a>	
	@code	1..1	SHALL		<a href="#">21898</a>	254326001
	@codeSystem	1..1	SHALL		<a href="#">23351</a>	2.16.840.1.113883.6.96 (SNOMED-CT) = 2.16.840.1.113883.6.96
	effectiveTime	1..1	SHALL		<a href="#">22077</a>	
	entryRelationship	1..1	SHALL		<a href="#">21899</a>	
	@typeCode	1..1	SHALL		<a href="#">21900</a>	COMP

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	observation	1..1	SHALL		<a href="#">24907</a>	
	@classCode	1..1	SHALL		<a href="#">24908</a>	2.16.840.1.113883.5.6 (HL7ActClass) = OBS
	@moodCode	1..1	SHALL		<a href="#">24909</a>	2.16.840.1.113883.5.1001 (ActMood) = EVN
	code	1..1	SHALL		<a href="#">24910</a>	
	@code	1..1	SHALL		<a href="#">24911</a>	399537006
	@code System	1..1	SHALL		<a href="#">24912</a>	2.16.840.1.113883.6.96 (SNOMED-CT) = 2.16.840.1.113883.6.96
	statusCode	1..1	SHALL		<a href="#">24913</a>	
	@code	1..1	SHALL		<a href="#">24914</a>	2.16.840.1.113883.5.14 (ActStatus) = completed
	value	1..1	SHALL	CD	<a href="#">24915</a>	2.16.840.1.113883.11.20.11.12 (Breast TNM Stage Group)
	methodCode	1..1	SHALL		<a href="#">24917</a>	2.16.840.1.113883.11.20.11.20 (Cancer Staging Method)
	entry Relationship	1..1	SHALL		<a href="#">26213</a>	
	@typeCode	1..1	SHALL		<a href="#">26214</a>	2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = COMP
	observation	1..1	SHALL		<a href="#">26215</a>	
	entry Relationship	1..1	SHALL		<a href="#">26216</a>	
	@typeCode	1..1	SHALL		<a href="#">26217</a>	2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = COMP
	observation	1..1	SHALL		<a href="#">26218</a>	
	entry Relationship	1..1	SHALL		<a href="#">26219</a>	
	@typeCode	1..1	SHALL		<a href="#">26220</a>	2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = COMP
	observation	1..1	SHALL		<a href="#">26221</a>	

1. **SHALL** contain exactly one [1..1] @classCode="ACT" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:22056).
2. **SHALL** contain exactly one [1..1] @moodCode="EVN" (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:22057).
3. **SHALL** contain exactly one [1..1] templateId (CONF:19292) such that it
  - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.3.3" (CONF:19293).
4. **SHALL** contain at least one [1..\*] id (CONF:24929).

5. **SHALL** contain exactly one [1..1] **code** (CONF:21897).
  - a. This code **SHALL** contain exactly one [1..1] **@code="254326001"** TNM Breast Cancer Staging (CONF:21898).
  - b. This code **SHALL** contain exactly one [1..1] **@codeSystem="2.16.840.1.113883.6.96"** (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96) (CONF:23351).
6. **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:22077).
7. **SHALL** contain exactly one [1..1] **entryRelationship** (CONF:21899) such that it
  - a. **SHALL** contain exactly one [1..1] **@typeCode="COMP"** Has Component (CONF:21900).
  - b. **SHALL** contain exactly one [1..1] **observation** (CONF:24907).
    - i. This observation **SHALL** contain exactly one [1..1] **@classCode="OBS"** (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:24908).
    - ii. This observation **SHALL** contain exactly one [1..1] **@moodCode="EVN"** (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:24909).
    - iii. This observation **SHALL** contain exactly one [1..1] **code** (CONF:24910).
      1. This code **SHALL** contain exactly one [1..1] **@code="399537006"** Clinical TNM stage grouping (CONF:24911).
      2. This code **SHALL** contain exactly one [1..1] **@codeSystem="2.16.840.1.113883.6.96"** (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96) (CONF:24912).
    - iv. This observation **SHALL** contain exactly one [1..1] **statusCode** (CONF:24913).
      1. This statusCode **SHALL** contain exactly one [1..1] **@code="completed"** Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14) (CONF:24914).
    - v. This observation **SHALL** contain exactly one [1..1] **value** with **@xsi:type="CD"**, where the **@code** **SHALL** be selected from ValueSet Breast TNM Stage Group 2.16.840.1.113883.11.20.11.12 **DYNAMIC** (CONF:24915).
    - vi. This observation **SHALL** contain exactly one [1..1] **methodCode**, which **SHOULD** be selected from ValueSet Cancer Staging Method 2.16.840.1.113883.11.20.11.20 **DYNAMIC** (CONF:24917).
    - vii. This observation **SHALL** contain exactly one [1..1] **entryRelationship** (CONF:26213) such that it
      1. **SHALL** contain exactly one [1..1] **@typeCode="COMP"** Has Component (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:26214).
      2. **SHALL** contain exactly one [1..1] **Breast TNM Tumor Category** (templateId:2.16.840.1.113883.10.20.30.3.5) (CONF:26215).



- viii. This observation **SHALL** contain exactly one [1..1] **entryRelationship** (CONF:26216) such that it
1. **SHALL** contain exactly one [1..1] **@typeCode="COMP"** Has Component (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:26217).
  2. **SHALL** contain exactly one [1..1] **Breast TNM Node Category** (templateId:2.16.840.1.113883.10.20.30.3.7) (CONF:26218).
- ix. This observation **SHALL** contain exactly one [1..1] **entryRelationship** (CONF:26219) such that it
1. **SHALL** contain exactly one [1..1] **@typeCode="COMP"** Has Component (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:26220).
  2. **SHALL** contain exactly one [1..1] **Breast TNM Metastasis Category** (templateId:2.16.840.1.113883.10.20.30.3.8) (CONF:26221).

**Table 78: Breast TNM Stage Group Value Set**

Value Set: Breast TNM Stage Group 2.16.840.1.113883.11.20.11.12 DYNAMIC		
Code System: SNOMED-CT 2.16.840.1.113883.6.96		
Description: TNM Stage Grouping which categorizes the progression of cancer using the Roman Numeral system		
Reference: <a href="http://www.cancerstaging.org/staging/posters/breast12x15.pdf">http://www.cancerstaging.org/staging/posters/breast12x15.pdf</a>		
Code	Code System	Print Name
13104003	SNOMED-CT	Clinical stage I (finding)
46333007	SNOMED-CT	Clinical Stage IA (finding)
786005	SNOMED-CT	Clinical Stage IB (finding)
60333009	SNOMED-CT	Clinical stage II (finding)
52774001	SNOMED-CT	Clinical Stage IIA (finding)
17816005	SNOMED-CT	Clinical Stage IIB (finding)
50283003	SNOMED-CT	Clinical stage III (finding)
73082003	SNOMED-CT	Clinical Stage IIIA (finding)
64062008	SNOMED-CT	Clinical Stage IIIB (finding)
48105005	SNOMED-CT	Clinical Stage IIIC (finding)
2640006	SNOMED-CT	Clinical StageIV (finding)

**Table 79: Cancer Staging Method Value Set**

Value Set: Cancer Staging Method 2.16.840.1.113883.11.20.11.20		
Code System: Code System: SNOMED-CT 2.16.840.1.113883.6.96		
Description: Resource, source, or guide for staging method.		
Code	Code System	Print Name
444256004	SNOMED-CT	American Joint Commission on Cancer, Cancer Staging Manual, 6th edition neoplasm staging system (tumor staging)
443830009	SNOMED-CT	American Joint Commission on Cancer, Cancer Staging Manual, 7th edition neoplasm staging system (tumor staging)

**Figure 54: Breast TNM Clinical Category example**

```

<entryRelationship typeCode="SPRT">
 <act classCode="ACT" moodCode="EVN">
 <!-- Breast TNM Clinical Category TemplateID -->
 <templateId root="2.16.840.1.113883.10.20.30.3.3"/>
 <code codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMED-CT" code="254326001"
 displayName="TNM Breast Cancer Staging"/>
 <effectiveTime value="20120112"/>
 <!-- This entryRelationship provides details as to the overall clinical
 stage-->
 <entryRelationship typeCode="COMP">
 <observation classCode="OBS" moodCode="EVN">
 <code codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMED-CT" code="399537006"
 displayName="Clinical TNM stage grouping "/>
 <statusCode code="completed"/>
 <value xsi:type="CD"
 codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMED-CT" code="13104003"
 displayName="clinical stage I"/>
 <methodCode code="443830009"
 displayName="American Joint Commission on Cancer, Cancer Staging
 Manual, 7th edition neoplasm staging system"
 codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMED-CT"/>

 <!-- Breast TNM Tumor Category-->
 <entryRelationship typeCode="COMP">
 <observation classCode="OBS" moodCode="EVN">
 <!-- Tumor (T) Staging TemplateID-->
 <templateId root="2.16.840.1.113883.10.20.30.3.5"/>
 ...
 </observation>
 </entryRelationship>
 </observation>
 </entryRelationship>
 </act>
</entryRelationship>

```

```

<!-- Breast TNM Node Category -->
<entryRelationship typeCode="COMP">
 <observation classCode="OBS" moodCode="EVN">
 <!--Node (N) STAGING TemplateID-->
 <templateId root="2.16.840.1.113883.10.20.30.3.7"/>
 ...
 </observation>
</entryRelationship>

<!-- Breast TNM Metastasis Category -->
<entryRelationship typeCode="COMP">
 <observation classCode="OBS" moodCode="EVN">
 <!-- Metastasis (M) STAGING TemplateID -->
 <templateId root="2.16.840.1.113883.10.20.30.3.8"/>
 ...
 </observation>
</entryRelationship>
</observation>
</entryRelationship>
</act>
</entryRelationship>

```

## 4.8 Breast TNM Metastasis Category

[Observation: templateId 2.16.840.1.113883.10.20.30.3.8 (open)]

**Table 80: Breast TNM Metastasis Category Contexts**

Used By:	Contains Entries:
<a href="#">Breast TNM Clinical Category</a> (required)	

This clinical statement represents the AJCC (American Joint Committee on Cancer) staging of metastasis (M) for breast cancer.

**Table 81: Breast TNM Metastasis Category Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	Observation[templateId/@root = '2.16.840.1.113883.10.20.30.3.8']					
	@classCode	1..1	SHALL		<a href="#">21872</a>	2.16.840.1.113883.5.6 (HL7ActClass) = OBS
	@moodCode	1..1	SHALL		<a href="#">21873</a>	2.16.840.1.113883.5.1001 (ActMood) = EVN
	templateId	1..1	SHALL		<a href="#">21874</a>	
	@root	1..1	SHALL		<a href="#">21875</a>	2.16.840.1.113883.10.20.30.3.8
	id	1..*	SHALL		<a href="#">22073</a>	
	code	1..1	SHALL		<a href="#">21877</a>	
	@code	1..1	SHALL	CD	<a href="#">21878</a>	277208005
	@code System	1..1	SHALL		<a href="#">23440</a>	2.16.840.1.113883.6.96 (SNOMED-CT) = 2.16.840.1.113883.6.96
	statusCode	1..1	SHALL		<a href="#">22047</a>	
	@code	1..1	SHALL		<a href="#">22048</a>	2.16.840.1.113883.5.14 (ActStatus) = completed
	effectiveTime	1..1	SHALL		<a href="#">22080</a>	
	value	1..1	SHALL	CD	<a href="#">22049</a>	2.16.840.1.113883.11.20.11.15 (Breast TNM Metastasis Category)
	methodCode	1..1	SHALL		<a href="#">24933</a>	2.16.840.1.113883.11.20.11.20 (Cancer Staging Method)

1. **SHALL** contain exactly one [1..1] @classCode="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:21872).
2. **SHALL** contain exactly one [1..1] @moodCode="EVN" (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:21873).
3. **SHALL** contain exactly one [1..1] templateId (CONF:21874) such that it
  - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.3.8" (CONF:21875).
4. **SHALL** contain at least one [1..\*] id (CONF:22073).
5. **SHALL** contain exactly one [1..1] code (CONF:21877).
  - a. This code **SHALL** contain exactly one [1..1] @code="277208005" M - Category (CONF:21878).
  - b. This code **SHALL** contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.96" (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96) (CONF:23440).
6. **SHALL** contain exactly one [1..1] statusCode (CONF:22047).
  - a. This statusCode **SHALL** contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 **STATIC**) (CONF:22048).
7. **SHALL** contain exactly one [1..1] effectiveTime (CONF:22080).

8. **SHALL** contain exactly one [1..1] **value** with `@xsi:type="CD"`, where the `@code` **SHALL** be selected from ValueSet `Breast TNM Metastasis Category 2.16.840.1.113883.11.20.11.15` **DYNAMIC** (CONF:22049).
- a. **SHALL** contain exactly one [1..1] **methodCode**, which **SHALL** be selected from ValueSet `Cancer Staging Method 2.16.840.1.113883.11.20.11.20` **DYNAMIC** (CONF:24933).

**Table 82: Breast TNM Metastasis Category Value Set**

Value Set: Breast TNM Metastasis Category 2.16.840.1.113883.11.20.11.15 DYNAMIC		
Code System: SNOMED-CT 2.16.840.1.113883.6.96		
Description: A subset of TNM metastasis codes from the TNM classification system. The "M" represents metastases.		
Reference: <a href="http://www.cancerstaging.org/staging/posters/breast12x15.pdf">http://www.cancerstaging.org/staging/posters/breast12x15.pdf</a>		
Code	Code System	Print Name
30893008	SNOMED-CT	M0 category (finding)
METS-X	SNOMED-CT	M0(i+)
55440008	SNOMED-CT	M1 category (finding)

**Figure 55: Breast TNM Metastasis Category example**

```

<entryRelationship typeCode="COMP">
 <observation classCode="OBS" moodCode="EVN">
 <!-- Breast TNM Metastasis Category TemplateID -->
 <templateId root="2.16.840.1.113883.10.20.30.3.8"/>
 <code codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMED-CT" code="277208005"
 displayName="M - Category"/>
 <statusCode code="completed"/>
 <value xsi:type="CD"
 codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMED-CT" code="55440008"
 displayName="M1 category (finding)"/>
 <methodCode code="443830009"
 displayName="American Joint Commission on Cancer, Cancer Staging
 Manual, 7th edition neoplasm staging system"
 codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMED-CT"/>
 </observation>
</entryRelationship>

```

## 4.9 Breast TNM Node Category

[Observation: templateId 2.16.840.1.113883.10.20.30.3.7 (open)]

**Table 83: Breast TNM Node Category Contexts**

Used By:	Contains Entries:
<a href="#">Breast TNM Clinical Category</a> (required)	

This clinical statement template represents the AJCC (American Joint Committee on Cancer) staging of lymph node (N) involvement for breast cancer.

**Table 84: Breast TNM Node Category Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	Observation[templateId/@root = '2.16.840.1.113883.10.20.30.3.7']					
	@classCode	1..1	SHALL		<a href="#">21846</a>	2.16.840.1.113883.5.6 (HL7ActClass) = OBS
	@moodCode	1..1	SHALL		<a href="#">21847</a>	2.16.840.1.113883.5.1001 (ActMood) = EVN
	templateId	1..1	SHALL		<a href="#">21848</a>	
	@root	1..1	SHALL		<a href="#">21849</a>	2.16.840.1.113883.10.20.30.3.7
	id	1..*	SHALL		<a href="#">22072</a>	
	code	1..1	SHALL		<a href="#">21851</a>	
	@code	1..1	SHALL		<a href="#">21852</a>	2.16.840.1.113883.6.96 (SNOMED-CT) = 385382003
	@code System	1..1	SHALL		<a href="#">23438</a>	2.16.840.1.113883.6.96 (SNOMED-CT) = 2.16.840.1.113883.6.96
	statusCode	1..1	SHALL		<a href="#">22043</a>	
	@code	1..1	SHALL		<a href="#">22044</a>	2.16.840.1.113883.5.14 (ActStatus) = completed
	effectiveTime	1..1	SHALL		<a href="#">22079</a>	
	value	1..1	SHALL	CD	<a href="#">22045</a>	2.16.840.1.113883.11.20.11.14 (Breast TNM Node Category)
	methodCode	1..1	SHALL		<a href="#">24936</a>	2.16.840.1.113883.11.20.11.20 (Cancer Staging Method)

1. **SHALL** contain exactly one [1..1] @classCode="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:21846).
2. **SHALL** contain exactly one [1..1] @moodCode="EVN" (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:21847).
3. **SHALL** contain exactly one [1..1] templateId (CONF:21848) such that it
  - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.3.7" (CONF:21849).
4. **SHALL** contain at least one [1..\*] id (CONF:22072).

5. **SHALL** contain exactly one [1..1] **code** (CONF:21851).
  - a. This code **SHALL** contain exactly one [1..1] **@code="385382003" Node Category Finding** (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96) (CONF:21852).
  - b. This code **SHALL** contain exactly one [1..1] **@codeSystem="2.16.840.1.113883.6.96" (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96) (CONF:23438)**.
6. **SHALL** contain exactly one [1..1] **statusCode** (CONF:22043).
  - a. This statusCode **SHALL** contain exactly one [1..1] **@code="completed" Completed** (CodeSystem: ActStatus 2.16.840.1.113883.5.14 **STATIC**) (CONF:22044).
7. **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:22079).
8. **SHALL** contain exactly one [1..1] **value** with **@xsi:type="CD"**, where the **@code** **SHALL** be selected from ValueSet Breast TNM Node Category 2.16.840.1.113883.11.20.11.14 **DYNAMIC** (CONF:22045).
  - a. **SHALL** contain exactly one [1..1] **methodCode**, which **SHALL** be selected from ValueSet Cancer Staging Method 2.16.840.1.113883.11.20.11.20 **DYNAMIC** (CONF:24936).

**Table 85: Breast TNM Node Category Value Set**

Value Set: Breast TNM Node Category 2.16.840.1.113883.11.20.11.14 DYNAMIC		
Code System: SNOMED-CT 2.16.840.1.113883.6.96		
Description: Part of the TNM classification system. The "N" represents node. The system categorizes number, size, and the extent of lymph node involvement.		
Reference: <a href="http://www.cancerstaging.org/staging/posters/breast12x15.pdf">http://www.cancerstaging.org/staging/posters/breast12x15.pdf</a>		
Code	Code System	Print Name
79420006	SNOMED-CT	NX category (finding)
62455006	SNOMED-CT	N0 category (finding)
53623008	SNOMED-CT	N1 category (finding)
46059003	SNOMED-CT	N2 category (finding)
261967001	SNOMED-CT	node stage N2a (finding)
261968006	SNOMED-CT	node stage n2b (finding)
5856006	SNOMED-CT	N3 category (finding)
NODE3A-X	SNOMED-CT	n3a
NODE3B-X	SNOMED-CT	n3b
NODE3C-X	SNOMED-CT	n3c

**Figure 56: Breast TNM Node Category example**

```

<entryRelationship typeCode="COMP">
 <observation classCode="OBS" moodCode="EVN">
 <!-- Breast TNM Node Category TemplateID-->
 <templateId root="2.16.840.1.113883.10.20.30.3.7"/>
 <code codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMED-CT" code="385382003"
 displayName="Node Category Finding"/>
 <statusCode code="completed"/>
 <value xsi:type="CD"
 codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMED-CT" code="53623008"
 displayName="N1 Category(finding)"/>
 <methodCode code="443830009"
 displayName="American Joint Commission on Cancer, Cancer Staging
 Manual, 7th edition neoplasm staging system"
 codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMED-CT"/>
 </observation>
</entryRelationship>

```

## 4.10 Breast TNM Tumor Category

[Observation: templateId 2.16.840.1.113883.10.20.30.3.5 (open)]

**Table 86: Breast TNM Tumor Category Contexts**

Used By:	Contains Entries:
<a href="#">Breast TNM Clinical Category</a> (required)	

This clinical statement template represents the AJCC (American Joint Committee on Cancer) staging of the tumor (T) for breast cancer.



**Table 87: Breast TNM Tumor Category Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	Observation[templateId/@root = '2.16.840.1.113883.10.20.30.3.5']					
	@classCode	1..1	SHALL		<a href="#">21822</a>	2.16.840.1.113883.5.6 (HL7ActClass) = OBS
	@moodCode	1..1	SHALL		<a href="#">21823</a>	2.16.840.1.113883.5.1001 (ActMood) = EVN
	templateId	1..1	SHALL		<a href="#">19350</a>	
	@root	1..1	SHALL		<a href="#">19351</a>	2.16.840.1.113883.10.20.30.3.5
	id	1..*	SHALL		<a href="#">22071</a>	
	code	1..1	SHALL		<a href="#">21825</a>	
	@code	1..1	SHALL		<a href="#">21826</a>	371508000
	@code System	1..1	SHALL		<a href="#">23436</a>	2.16.840.1.113883.6.96 (SNOMED-CT) = 2.16.840.1.113883.6.96
	statusCode	1..1	SHALL		<a href="#">22052</a>	
	@code	1..1	SHALL		<a href="#">22053</a>	2.16.840.1.113883.5.14 (ActStatus) = completed
	effectiveTime	1..1	SHALL		<a href="#">22078</a>	
	value	1..1	SHALL	CD	<a href="#">22054</a>	2.16.840.1.113883.11.20.11.13 (Breast TNM Tumor Category)
	methodCode	1..1	SHALL		<a href="#">27179</a>	2.16.840.1.113883.11.20.11.20 (Cancer Staging Method)

1. **SHALL** contain exactly one [1..1] **@classCode="OBS"** (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:21822).
2. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:21823).
3. **SHALL** contain exactly one [1..1] **templateId** (CONF:19350) such that it
  - a. **SHALL** contain exactly one [1..1] **@root="2.16.840.1.113883.10.20.30.3.5"** (CONF:19351).
4. **SHALL** contain at least one [1..\*] **id** (CONF:22071).
5. **SHALL** contain exactly one [1..1] **code** (CONF:21825).
  - a. This code **SHALL** contain exactly one [1..1] **@code="371508000"** Tumor Stage (CONF:21826).
  - b. This code **SHALL** contain exactly one [1..1] **@codeSystem="2.16.840.1.113883.6.96"** (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96) (CONF:23436).
6. **SHALL** contain exactly one [1..1] **statusCode** (CONF:22052).
  - a. This statusCode **SHALL** contain exactly one [1..1] **@code="completed"** Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 **STATIC**) (CONF:22053).
7. **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:22078).

8. **SHALL** contain exactly one [1..1] **value** with @xsi:type="CD", where the @code **SHALL** be selected from ValueSet Breast TNM Tumor Category 2.16.840.1.113883.11.20.11.13 **DYNAMIC** (CONF:22054).
- a. **SHALL** contain exactly one [1..1] **methodCode**, which **SHOULD** be selected from ValueSet Cancer Staging Method 2.16.840.1.113883.11.20.11.20 **DYNAMIC** (CONF:27179).

**Table 88: Breast TNM Tumor Category Value Set**

Value Set: Breast TNM Tumor Category 2.16.840.1.113883.11.20.11.13 DYNAMIC		
Code System: SNOMED-CT 2.16.840.1.113883.6.96		
Description: Part of the TNM classification system. The "T" represents tumor. The system categorizes the size of the primary tumor and its infiltration into nearby tissues.		
Reference: <a href="http://www.cancerstaging.org/staging/posters/breast12x15.pdf">http://www.cancerstaging.org/staging/posters/breast12x15.pdf</a>		
Code	Code System	Print Name
67101007	SNOMED-CT	TX category (finding)
58790005	SNOMED-CT	T0 category (finding)
23351008	SNOMED-CT	T1 category (finding)
433381000124109	SNOMED-CT	Tumor stage T1mi
261646003	SNOMED-CT	Tumor stage T1a (finding)
261649005	SNOMED-CT	Tumor stage T1b (finding)
261650005	SNOMED-CT	Tumor stage T1c (finding)
67673008	SNOMED-CT	T2 category (finding)
14410001	SNOMED-CT	T3 category (finding)
65565005	SNOMED-CT	T4 category (finding)
261659006	SNOMED-CT	Tumor stage T4a (finding)
261660001	SNOMED-CT	Tumor stage T4b (finding)
261661002	SNOMED-CT	Tumor stage T4c (finding)
261662009	SNOMED-CT	Tumor stage T4d (finding)

**Figure 57: Breast TNM Tumor Category example**

```

<entryRelationship typeCode="COMP">
 <observation classCode="OBS" moodCode="EVN">
 <!-- Breast TNM Tumor Category TemplateID-->
 <templateId root="2.16.840.1.113883.10.20.30.3.5"/>
 <code codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMED-CT" code="371508000"
 displayName="Tumor stage"/>
 <statusCode code="completed"/>
 <value xsi:type="CD"
 codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMED-CT" code=" 67673008"
 displayName=" T2 category(finding)"/>
 <methodCode code="443830009"
 displayName="American Joint Commission on Cancer, Cancer Staging
 Manual, 7th edition neoplasm staging system"
 codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMED-CT"/>
 </observation>
</entryRelationship>

```

## 4.11 Caregiver Characteristics

**[Closed for comments; published July 2012]**

[observation: templateId 2.16.840.1.113883.10.20.22.4.72 (open)]

**Table 89: Caregiver Characteristics Contexts**

Used By:	Contains Entries:
<a href="#">Functional Status Section</a> (optional) <a href="#">Functional Status Result Observation</a> (optional) <a href="#">Cognitive Status Result Observation</a> (optional) <a href="#">Functional Status Problem Observation</a> (optional) <a href="#">Cognitive Status Problem Observation</a> (optional)	

This clinical statement represents a caregiver’s willingness to provide care and the abilities of that caregiver to provide assistance to a patient in relation to a specific need.

**Table 90: Caregiver Characteristics Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	observation[templateId/@root = '2.16.840.1.113883.10.20.22.4.72']					
	@classCode	1..1	SHALL		<a href="#">14219</a>	2.16.840.1.113883.5.6 (HL7ActClass) = OBS
	@moodCode	1..1	SHALL		<a href="#">14220</a>	2.16.840.1.113883.5.1001 (ActMood) = EVN
	templateId	1..1	SHALL		<a href="#">14221</a>	
	@root	1..1	SHALL		<a href="#">14222</a>	2.16.840.1.113883.10.20.22.4.72
	id	1..*	SHALL		<a href="#">14223</a>	
	code	1..1	SHALL		<a href="#">14230</a>	
	statusCode	1..1	SHALL		<a href="#">14233</a>	
	@code	1..1	SHALL		<a href="#">19090</a>	2.16.840.1.113883.5.14 (ActStatus) = completed
	value	1..1	SHALL		<a href="#">14599</a>	
	participant	1..*	SHALL		<a href="#">14227</a>	
	time	0..1	MAY		<a href="#">14830</a>	
	low	1..1	SHALL		<a href="#">14831</a>	
	high	0..1	MAY		<a href="#">14832</a>	
	participantRole	1..1	SHALL		<a href="#">14228</a>	
	@classCode	1..1	SHALL		<a href="#">14229</a>	IND

1. **SHALL** contain exactly one [1..1] @classCode="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:14219).
2. **SHALL** contain exactly one [1..1] @moodCode="EVN" (CodeSystem: ActMood 2.16.840.1.113883.5.1001 **STATIC**) (CONF:14220).
3. **SHALL** contain exactly one [1..1] templateId (CONF:14221) such that it
  - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.72" (CONF:14222).
4. **SHALL** contain at least one [1..\*] id (CONF:14223).
5. **SHALL** contain exactly one [1..1] code (CONF:14230).
6. **SHALL** contain exactly one [1..1] statusCode (CONF:14233).
  - a. This statusCode **SHALL** contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 **STATIC**) (CONF:19090).
7. **SHALL** contain exactly one [1..1] value (CONF:14599).
  - a. Where the @code **SHALL** be selected from LOINC (codeSystem: 2.16.840.1.113883.6.1) or SNOMED CT (CodeSystem: 2.16.840.1.113883.6.96) (CONF:14600).
8. **SHALL** contain at least one [1..\*] participant (CONF:14227).
  - a. Such participants **MAY** contain zero or one [0..1] time (CONF:14830).

- i. The time, if present, **SHALL** contain exactly one [1..1] **low** (CONF:14831).
  - ii. The time, if present, **MAY** contain zero or one [0..1] **high** (CONF:14832).
- b. Such participants **SHALL** contain exactly one [1..1] **participantRole** (CONF:14228).
- i. This participantRole **SHALL** contain exactly one [1..1] **@classCode="IND"** (CONF:14229).

**Figure 58: Caregiver Characteristics example with assertion**

```

<observation classCode="OBS" moodCode="EVN">
 <!-- Caregiver Characteristics -->
 <templateId root="2.16.840.1.113883.10.20.22.4.72"/>
 <id root="c6b5a04b-2bf4-49d1-8336-636a3813df0c"/>
 <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"/>
 <statusCode code="completed"/>
 <value xsi:type="CD"
 code="422615001"
 codeSystem="2.16.840.1.113883.6.96"
 displayName="caregiver difficulty providing physical care"/>
 <participant typeCode="IND">
 <participantRole classCode="CAREGIVER">
 <code code="MTH"
 codeSystem="2.16.840.1.113883.5.111"
 displayName="Mother"/>
 </participantRole>
 </participant>
</observation>

```

**Figure 59: Caregiver Characteristics example without assertion**

```

<observation classCode="OBS" moodCode="EVN">
 <!-- Caregiver Characteristics -->
 <templateId root="2.16.840.1.113883.10.20.22.4.72"/>
 <id root="c6b5a04b-2bf4-49d1-8336-636a3813df0c"/>
 <code code=" 5267-7"
 codeSystem="2.16.840.1.113883.6.1"
 displayName=" ADL or IADL assistance from any caregiver"/>
 <statusCode code="completed"/>
 <value xsi:type="CD"
 code=" 422615001"
 codeSystem="2.16.840.1.113883.6.96"
 displayName="caregiver difficulty providing physical care"/>
 <participant typeCode="IND">
 <participantRole classCode="CAREGIVER">
 <code code="MTH"
 codeSystem="2.16.840.1.113883.5.111"
 displayName="Mother"/>
 </participantRole>
 </participant>
</observation>

```

## 4.12 Chemotherapeutic Drug Therapy Discontinued

[Observation: templateId 2.16.840.1.113883.10.20.30.3.43 (open)]

**Table 91: Chemotherapeutic Drug Therapy Discontinued Contexts**

Used By:	Contains Entries:
<a href="#">Medications Section BCTPS</a> (optional)	

This clinical statement represents chemotherapeutic drug therapy was stopped and the reason why it was discontinued.

**Table 92: Chemotherapeutic Drug Therapy Discontinued Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
	Observation[templateId/@root = '2.16.840.1.113883.10.20.30.3.43']					
	@classCode	1..1	SHALL		<a href="#">23906</a>	2.16.840.1.113883.5.6 (HL7ActClass) = OBS
	@moodCode	1..1	SHALL		<a href="#">23907</a>	2.16.840.1.113883.5.1001 (ActMood) = EVN
	templateId	1..1	SHALL		<a href="#">23908</a>	
	@root	1..1	SHALL		<a href="#">23909</a>	2.16.840.1.113883.10.20.30.3.43
	code	1..1	SHALL		<a href="#">23910</a>	
	@code	1..1	SHALL		<a href="#">23911</a>	2.16.840.1.113883.5.4 (ActCode) = ASSERTION
	@codeSystem	1..1	SHALL		<a href="#">27081</a>	2.16.840.1.113883.5.4 (ActCode) = 2.16.840.1.113883.5.4
	statusCode	1..1	SHALL		<a href="#">23912</a>	
	@code	1..1	SHALL		<a href="#">23913</a>	2.16.840.1.113883.5.14 (ActStatus) = Completed
	effectiveTime	1..1	SHOULD		<a href="#">23914</a>	
	high	1..1	SHALL		<a href="#">27405</a>	
	value	1..1	SHALL	CD	<a href="#">23916</a>	
	@code	1..1	SHALL		<a href="#">23917</a>	274512008
	@codeSystem	1..1	SHALL		<a href="#">27082</a>	2.16.840.1.113883.6.96
	entry Relationship	1..*	SHALL		<a href="#">23918</a>	
	@typeCode	1..1	SHALL		<a href="#">23919</a>	2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = RSON
	observation	1..1	SHALL		<a href="#">23920</a>	
	@classCode	1..1	SHALL		<a href="#">23921</a>	2.16.840.1.113883.5.6 (HL7ActClass) = OBS

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
	@moodCode	1..1	SHALL		<a href="#">23922</a>	2.16.840.1.113883.5.1001 (ActMood) = EVN
	code	1..1	SHALL		<a href="#">27375</a>	
	@code	1..1	SHALL		<a href="#">27376</a>	373832009
	@code System	1..1	SHALL		<a href="#">27377</a>	2.16.840.1.113883.6.96 (SNOMED-CT) = 2.16.840.1.113883.6.96
	statusCode	1..1	SHALL		<a href="#">23923</a>	
	@code	1..1	SHALL		<a href="#">23924</a>	2.16.840.1.113883.5.14 (ActStatus) = Completed
	value	1..1	SHALL	CD	<a href="#">23927</a>	2.16.840.1.113883.11.20.11.11 (Reason for Stopping Chemotherapy)
	@nullFlavor	0..1	MAY		<a href="#">27411</a>	2.16.840.1.113883.5.1008 (HL7NullFlavor) = OTH
	originalText	0..1	MAY		<a href="#">27412</a>	

1. **SHALL** contain exactly one [1..1] @classCode="OBS" observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:23906).
2. **SHALL** contain exactly one [1..1] @moodCode="EVN" event (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:23907).
3. **SHALL** contain exactly one [1..1] templateId (CONF:23908) such that it
  - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.3.43" (CONF:23909).
4. **SHALL** contain exactly one [1..1] code (CONF:23910).
  - a. This code **SHALL** contain exactly one [1..1] @code="ASSERTION" Assertion (CodeSystem: ActCode 2.16.840.1.113883.5.4) (CONF:23911).
  - b. This code **SHALL** contain exactly one [1..1] @codeSystem="2.16.840.1.113883.5.4" (CodeSystem: ActCode 2.16.840.1.113883.5.4) (CONF:27081).
5. **SHALL** contain exactly one [1..1] statusCode (CONF:23912).
  - a. This statusCode **SHALL** contain exactly one [1..1] @code="Completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14) (CONF:23913).
6. **SHALL** contain exactly one [1..1] effectiveTime (CONF:23914).
  - a. This effectiveTime **SHALL** contain exactly one [1..1] high (CONF:27405).
7. **SHALL** contain exactly one [1..1] value with @xsi:type="CD" (CONF:23916).
  - a. This value **SHALL** contain exactly one [1..1] @code="274512008" drug therapy discontinued (CONF:23917).
  - b. This value **SHALL** contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.96" (CONF:27082).
8. **SHALL** contain at least one [1..\*] entryRelationship (CONF:23918).

- a. Such entryRelationships **SHALL** contain exactly one [1..1] @typeCode="RSON" has reason (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:23919).
- b. Such entryRelationships **SHALL** contain exactly one [1..1] observation (CONF:23920).
  - i. This observation **SHALL** contain exactly one [1..1] @classCode="OBS" observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:23921).
  - ii. This observation **SHALL** contain exactly one [1..1] @moodCode="EVN" event (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:23922).
  - iii. This observation **SHALL** contain exactly one [1..1] code (CONF:27375).
    - 1. This code **SHALL** contain exactly one [1..1] @code="373832009" reason for change in planned chemotherapy treatment (CONF:27376).
    - 2. This code **SHALL** contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.96" (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96) (CONF:27377).
  - iv. This observation **SHALL** contain exactly one [1..1] statusCode (CONF:23923).
    - 1. This statusCode **SHALL** contain exactly one [1..1] @code="Completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14) (CONF:23924).
  - v. This observation **SHALL** contain exactly one [1..1] value with @xsi:type="CD", where the @code **SHALL** be selected from ValueSet Reason for Stopping Chemotherapy 2.16.840.1.113883.11.20.11.11 **DYNAMIC** (CONF:23927).
    - 1. This value **MAY** contain zero or one [0..1] @nullFlavor="OTH" other (CodeSystem: HL7NullFlavor 2.16.840.1.113883.5.1008) (CONF:27411).

If the reason for chemotherapeutic drug discontinuation is not adequate through a term available in the value set, additional explanatory text can be provided in value/originalText.

- 2. This value **MAY** contain zero or one [0..1] originalText (CONF:27412).



**Table 93: Reason for Stopping Chemotherapy Value Set**

Value Set: Reason for Stopping Chemotherapy 2.16.840.1.113883.11.20.11.11 DYNAMIC		
Code System: SNOMED-CT 2.16.840.1.113883.6.96		
Description: List of reason codes for stopping a chemotherapy treatment originating from ASCO's Quality Oncology Practice Initiative (QOPI)		
Reference: <a href="http://qopi.asco.org/">http://qopi.asco.org/</a>		
Code	Code System	Print Name
419099009	SNOMED-CT	dead (finding)
62014003	SNOMED-CT	adverse reaction to drug (disorder)
182868002	SNOMED-CT	treatment stopped - alternative therapy undertaken (situation)
399307001	SNOMED-CT	lost to follow-up (finding)
105480006	SNOMED-CT	refusal of treatment by patient (situation)
182992009	SNOMED-CT	treatment completed (situation)
399213007	SNOMED-CT	toxicity due to chemotherapy (disorder)
373833004	SNOMED-CT	chemotherapy changed - progressive disease during chemotherapy (finding)
365550006	SNOMED-CT	finding of financial circumstances (finding)
398192003	SNOMED-CT	co-morbid conditions (finding)

**Figure 60: Chemotherapeutic Drug Therapy Discontinued example**

```

<observation classCode="OBS" moodCode="EVN">
 <templateId root="2.16.840.1.113883.10.20.30.3.43"/>
 <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"/>
 <statusCode code="completed"/>
 <effectiveTime>
 <low nullFlavor="NI"/>
 </effectiveTime>
 <value xsi:type="CD"
 code="274512008"
 displayName="drug therapy discontinued"
 codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMED CT"/>
 <!-- SHOULD [0..*] reasons for stopping -->
 <entryRelationship typeCode="RSON">
 <observation classCode="OBS" moodCode="EVN">
 <code code="373832009"
 displayName="reason for change in planned chemotherapy
 treatment"
 codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMED CT"/></code>
 <statusCode code="completed"/>
 <effectiveTime>
 <low nullFlavor="NI"/>
 </effectiveTime>
 </observation>
 </entryRelationship>
</observation>

```

```

 <value xsi:type="CD"
 code="85898001"
 displayName="cardiomyopathy (disorder)"
 codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMED-CT" />
 </observation>
</entryRelationship>
</observation>

```

**Figure 61: Example of “OTH” for other values with Chemotherapeutic Drug Therapy Discontinued**

```

<entryRelationship typeCode="RSON">
 <observation classCode="OBS" moodCode="EVN">
 <code code="373832009"
 displayName="reason for change in planned chemotherapy treatment"
 codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMED CT"></code>
 <statusCode code="completed"/>
 <effectiveTime>
 <low nullFlavor="NI"/>
 </effectiveTime>
 <value xsi:type="CD" nullFlavor="OTH">
 <originalText>Severe shaking and cramping</originalText>
 </value>
 </observation>
</entryRelationship>

```

## 4.13 Chemotherapy Protocol Reference

[Act: templateId 2.16.840.1.113883.10.20.30.3.50 (open)]

**Table 94: Chemotherapy Protocol Reference Contexts**

Used By:	Contains Entries:
<a href="#">Chemotherapy Medication Activity</a> (optional)	
<a href="#">Chemotherapy Medication Activity Plan</a> (optional)	

This act references a cancer chemotherapy regimen protocol. The protocol referenced may contain information about other drugs in the regimen as well.

**Table 95: Chemotherapy Protocol Reference Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
	Act[templateId/@root = '2.16.840.1.113883.10.20.30.3.50']					
	@classCode	1..1	SHALL		<a href="#">27341</a>	2.16.840.1.113883.5.6 (HL7ActClass) = ACT
	@moodCode	1..1	SHALL		<a href="#">27342</a>	2.16.840.1.113883.5.1001 (ActMood) = EVN
	templateId	1..1	SHALL		<a href="#">27328</a>	
	@root	1..1	SHALL		<a href="#">27329</a>	2.16.840.1.113883.10.20.30.3.50
	code	1..1	SHALL		<a href="#">27330</a>	
	@code	1..1	SHALL		<a href="#">27331</a>	69960004
	@codeSystem	1..1	SHALL		<a href="#">27332</a>	2.16.840.1.113883.6.96 (SNOMED-CT) = 2.16.840.1.113883.6.96
	statusCode	1..1	SHALL		<a href="#">27333</a>	
	@code	1..1	SHALL		<a href="#">27334</a>	2.16.840.1.113883.5.14 (ActStatus) = completed
	reference	1..1	SHALL		<a href="#">27335</a>	
	@typeCode	1..1	SHALL		<a href="#">27336</a>	2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = REFR
	external Document	1..1	SHALL		<a href="#">27337</a>	
	@classCode	1..1	SHALL		<a href="#">27338</a>	2.16.840.1.113883.5.6 (HL7ActClass) = DOC
	id	1..1	SHALL		<a href="#">27339</a>	
	text	0..1	SHOULD		<a href="#">27340</a>	

1. **SHALL** contain exactly one [1..1] @classCode="ACT" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:27341).

2. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:27342).
3. **SHALL** contain exactly one [1..1] **templateId** (CONF:27328) such that it
  - a. **SHALL** contain exactly one [1..1] **@root="2.16.840.1.113883.10.20.30.3.50"** (CONF:27329).
4. **SHALL** contain exactly one [1..1] **code** (CONF:27330).
  - a. This code **SHALL** contain exactly one [1..1] **@code="69960004"** cancer chemotherapy regimen (CONF:27331).
  - b. This code **SHALL** contain exactly one [1..1] **@codeSystem="2.16.840.1.113883.6.96"** (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96) (CONF:27332).
5. **SHALL** contain exactly one [1..1] **statusCode** (CONF:27333).
  - a. This statusCode **SHALL** contain exactly one [1..1] **@code="completed"** Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14) (CONF:27334).
6. **SHALL** contain exactly one [1..1] **reference** (CONF:27335).
  - a. This reference **SHALL** contain exactly one [1..1] **@typeCode="REFR"** refers to (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:27336).
  - b. This reference **SHALL** contain exactly one [1..1] **externalDocument** (CONF:27337).
    - i. This externalDocument **SHALL** contain exactly one [1..1] **@classCode="DOC"** Document (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:27338).

This act/id represents the identifier of the regimen protocol.

- ii. This externalDocument **SHALL** contain exactly one [1..1] **id** (CONF:27339).

This act/text should contain text naming the regimen and a hyperlink to an internal institution or external protocol website.

- iii. This externalDocument **SHOULD** contain zero or one [0..1] **text** (CONF:27340).

**Figure 62: Chemotherapy Protocol Reference example**

```

<act classCode="ACT" moodCode="EVN">
 <!-- Chemotherapy Protocol Reference template ID -->
 <templateId root="2.16.840.1.113883.10.20.30.3.50"/>
 <code code="69960004" codeSystem="2.16.840.1.113883.6.96"
 displayName="cancer chemotherapy regimen"/>
 <statusCode code="completed"/>
 <reference typeCode="REFR">
 <externalDocument classCode="DOC" moodCode="EVN">
 <!--This would an identifier for the regimen protocol -->
 <id root="4e842410-8698-11e2-9e96-0800200c9a66"/>
 <!-- Could contain text naming the regimen and a link to an
 internal or external protocol website-->
 <text mediaType="text">TAC Regimen
 <reference
value="http://www.bccancer.bc.ca/HPI/ChemotherapyProtocols/default.htm"/>
 </text>
 </externalDocument>
 </reference>
 </act>

```

## 4.14 Clinical Drug Trial

[Act: templateId 2.16.840.1.113883.10.20.30.3.4 (open)]

**Table 96: Clinical Drug Trial Contexts**

Used By:	Contains Entries:
<a href="#">Chemotherapy Medication Activity</a> (optional) <a href="#">Chemotherapy Regimen Plans</a> (optional) <a href="#">Chemotherapy Medication Activity Plan</a> (optional)	

This clinical statement represents a treatment (e.g., chemotherapy administered) that is part of a clinical trial.

**Table 97: Clinical Drug Trial Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	Act[templateId/@root = '2.16.840.1.113883.10.20.30.3.4']					
	@classCode	1..1	SHALL		<a href="#">23859</a>	2.16.840.1.113883.5.6 (HL7ActClass) = ACT
	@moodCode	1..1	SHALL		<a href="#">23860</a>	2.16.840.1.113883.5.1001 (ActMood) = EVN
	templateId	1..1	SHALL		<a href="#">23861</a>	
	@root	1..1	SHALL		<a href="#">23862</a>	2.16.840.1.113883.10.20.30.3.4
	code	1..1	SHALL		<a href="#">23876</a>	
	@code	1..1	SHALL		<a href="#">23877</a>	185922005
	@code System	1..1	SHALL		<a href="#">26246</a>	2.16.840.1.113883.6.96 (SNOMED-CT) = 2.16.840.1.113883.6.96
	statusCode	1..1	SHALL		<a href="#">23863</a>	
	@code	1..1	SHALL		<a href="#">23864</a>	2.16.840.1.113883.5.14 (ActStatus) = completed

1. **SHALL** contain exactly one [1..1] @classCode="ACT" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:23859).
2. **SHALL** contain exactly one [1..1] @moodCode="EVN" event (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:23860).
3. **SHALL** contain exactly one [1..1] templateId (CONF:23861) such that it
  - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.3.4" (CONF:23862).
4. **SHALL** contain exactly one [1..1] code (CONF:23876).
  - a. This code **SHALL** contain exactly one [1..1] @code="185922005" clinical drug trials (CONF:23877).
  - b. This code **SHALL** contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.96" (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96) (CONF:26246).
5. **SHALL** contain exactly one [1..1] statusCode (CONF:23863).
  - a. This statusCode **SHALL** contain exactly one [1..1] @code="completed" (CodeSystem: ActStatus 2.16.840.1.113883.5.14) (CONF:23864).

**Figure 63: Clinical Drug Trial example**

```
<entryRelationship typeCode="REFR">
 <act classCode="ACT" moodCode="EVN">
 <templateId root="2.16.840.1.113883.10.20.30.3.4"/>
 <code code="185922005"
 displayName="clinical drug trials"
 codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMED-CT"/>
 <statusCode code="completed"/>
 </act>
</entryRelationship>
```

## 4.15 Drug Vehicle

**[Closed for comments; published July 2012]**

[participantRole: templateId 2.16.840.1.113883.10.20.22.4.24 (open)]

**Table 98: Drug Vehicle Contexts**

Used By:	Contains Entries:
<a href="#">Medication Activity</a> (optional)	

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

**Table 99: Drug Vehicle Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	participantRole[templateId/@root = '2.16.840.1.113883.10.20.22.4.24']					
	@classCode	1..1	SHALL		<a href="#">7490</a>	2.16.840.1.113883.5.110 (RoleClass) = MANU
	templateId	1..1	SHALL		<a href="#">7495</a>	
	@root	1..1	SHALL		<a href="#">10493</a>	2.16.840.1.113883.10.20.22.4.24
	code	1..1	SHALL		<a href="#">19137</a>	
	@code	1..1	SHALL		<a href="#">19138</a>	2.16.840.1.113883.6.96 (SNOMED-CT) = 412307009
	playingEntity	1..1	SHALL		<a href="#">7492</a>	
	code	1..1	SHALL		<a href="#">7493</a>	
	name	0..1	MAY		<a href="#">7494</a>	

1. **SHALL** contain exactly one [1..1] @classCode="MANU" (CodeSystem: RoleClass 2.16.840.1.113883.5.110 **STATIC**) (CONF:7490).
2. **SHALL** contain exactly one [1..1] templateId (CONF:7495) such that it
  - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.24" (CONF:10493).

3. **SHALL** contain exactly one [1..1] **code** (CONF:19137).
  - a. This code **SHALL** contain exactly one [1..1] **@code="412307009" Drug Vehicle** (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96 **STATIC**) (CONF:19138).
4. **SHALL** contain exactly one [1..1] **playingEntity** (CONF:7492).

This playingEntity/code is used to supply a coded term for the drug vehicle.

- a. This playingEntity **SHALL** contain exactly one [1..1] **code** (CONF:7493).
- b. This playingEntity **MAY** contain zero or one [0..1] **name** (CONF:7494).
  - i. This playingEntity/name **MAY** be used for the vehicle name in text, such as Normal Saline (CONF:10087).

**Figure 64: Drug Vehicle example**

```

<participantRole classCode="MANU">
 <templateId root="2.16.840.1.113883.10.20.22.4.24"/>
 <code code="412307009" displayName="drug vehicle"
 codeSystem="2.16.840.1.113883.6.96"/>
 <playingEntity classCode="MMAT">
 <code code="324049125464"
 displayName="Normal Saline"
 codeSystem="2.16.840.1.113883.6.88"
 codeSystemName="RxNorm"/>
 <name>Normal Saline</name>
 </playingEntity>
</participantRole>

```

## 4.16 Encounter Activities

**[Closed for comments; published July 2012]**

[encounter: templateId 2.16.840.1.113883.10.20.22.4.49 (open)]

**Table 100: Encounter Activities Contexts**

Used By:	Contains Entries:
<a href="#">Encounters Section (entries optional)</a> (optional)	<a href="#">Encounter Diagnosis</a> <a href="#">Indication</a> <a href="#">Service Delivery Location</a>

This clinical statement describes the interactions between the patient and clinicians. Interactions include in-person encounters, telephone conversations, and email exchanges.



**Table 101: Encounter Activities Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
Green Encounter Activities	encounter[templateId/@root = '2.16.840.1.113883.10.20.22.4.49']					
	@classCode	1..1	SHALL		<a href="#">8710</a>	2.16.840.1.113883.5.6 (HL7ActClass) = ENC
	@moodCode	1..1	SHALL		<a href="#">8711</a>	2.16.840.1.113883.5.1001 (ActMood) = EVN
	templateId	1..1	SHALL		<a href="#">8712</a>	
	@root	1..1	SHALL		<a href="#">26353</a>	2.16.840.1.113883.10.20.22.4.49
encounterID	id	1..*	SHALL		<a href="#">8713</a>	
encounter Type	code	0..1	SHOULD		<a href="#">8714</a>	2.16.840.1.113883.3.88.12.80.32 (EncounterTypeCode)
	originalText	0..1	SHOULD		<a href="#">8719</a>	
	reference	0..1	SHOULD		<a href="#">15970</a>	
	@value	0..1	SHOULD		<a href="#">15971</a>	
encounter FreeText Type	reference/ @value	0..1	SHOULD		<a href="#">8720</a>	
encounter DateTime	effectiveTime	1..1	SHALL		<a href="#">8715</a>	
	performer	0..*	MAY		<a href="#">8725</a>	
encounter Provider	assigned Entity	1..1	SHALL		<a href="#">8726</a>	
	code	0..1	MAY		<a href="#">8727</a>	
facility Location	participant	0..*	MAY		<a href="#">8738</a>	
	@typeCode	1..1	SHALL		<a href="#">8740</a>	2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = LOC
	participant Role	1..1	SHALL		<a href="#">14903</a>	
reasonFor Visit	entry Relationship	0..*	MAY		<a href="#">8722</a>	
	@typeCode	1..1	SHALL		<a href="#">8723</a>	2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = RSON
	observation	1..1	SHALL		<a href="#">14899</a>	
	entry Relationship	0..*	MAY		<a href="#">15492</a>	
	act	1..1	SHALL		<a href="#">15973</a>	

1. **SHALL** contain exactly one [1..1] `@classCode="ENC"` (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:8710).
2. **SHALL** contain exactly one [1..1] `@moodCode="EVN"` (CodeSystem: ActMood 2.16.840.1.113883.5.1001 **STATIC**) (CONF:8711).
3. **SHALL** contain exactly one [1..1] `templateId` (CONF:8712) such that it
  - a. **SHALL** contain exactly one [1..1] `@root="2.16.840.1.113883.10.20.22.4.49"` (CONF:26353).
4. **SHALL** contain at least one [1..\*] `id` (CONF:8713).
5. **SHOULD** contain zero or one [0..1] `code`, which **SHOULD** be selected from ValueSet EncounterTypeCode 2.16.840.1.113883.3.88.12.80.32 **DYNAMIC** (CONF:8714).
  - a. The code, if present, **SHOULD** contain zero or one [0..1] `originalText` (CONF:8719).
    - i. The `originalText`, if present, **SHOULD** contain zero or one [0..1] `reference` (CONF:15970).
      1. The reference, if present, **SHOULD** contain zero or one [0..1] `@value` (CONF:15971).
        - a. This reference/`@value` **SHALL** begin with a '#' and **SHALL** point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:15972).
      - ii. The `originalText`, if present, **SHOULD** contain zero or one [0..1] `reference/@value` (CONF:8720).
6. **SHALL** contain exactly one [1..1] `effectiveTime` (CONF:8715).
7. **MAY** contain zero or more [0..\*] `performer` (CONF:8725).
  - a. The performer, if present, **SHALL** contain exactly one [1..1] `assignedEntity` (CONF:8726).
    - i. This `assignedEntity` **MAY** contain zero or one [0..1] `code` (CONF:8727).
8. **MAY** contain zero or more [0..\*] `participant` (CONF:8738) such that it
  - a. **SHALL** contain exactly one [1..1] `@typeCode="LOC"` Location (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**) (CONF:8740).
  - b. **SHALL** contain exactly one [1..1] [Service Delivery Location](#) (`templateId:2.16.840.1.113883.10.20.22.4.32`) (CONF:14903).
9. **MAY** contain zero or more [0..\*] `entryRelationship` (CONF:8722) such that it
  - a. **SHALL** contain exactly one [1..1] `@typeCode="RSON"` Has Reason (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**) (CONF:8723).
  - b. **SHALL** contain exactly one [1..1] [Indication](#) (`templateId:2.16.840.1.113883.10.20.22.4.19`) (CONF:14899).
10. **MAY** contain zero or more [0..\*] `entryRelationship` (CONF:15492) such that it
  - a. **SHALL** contain exactly one [1..1] [Encounter Diagnosis](#) (`templateId:2.16.840.1.113883.10.20.22.4.80`) (CONF:15973).
11. **MAY** contain zero or one [0..1] `sdtc:dischargeDispositionCode`, which **SHALL** be selected from ValueSet 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 CodeSystem

2.16.840.1.113883.12.112 HL7 Discharge Disposition. The prefix sdtc: **SHALL** be bound to the namespace “urn:hl7-org:sdtc”. The use of the namespace provides a necessary extension to CDA R2 for the use of the dischargeDispositionCode element (CONF:9929).

#### 4.16.1 Hospitalization for Toxicity

[encounter: templateId 2.16.840.1.113883.10.20.30.3.36 (open)]

**Table 102: Hospitalization for Toxicity Contexts**

<b>Used By:</b>	<b>Contains Entries:</b>
<a href="#">Encounters Section BCTPS</a> (required)	<a href="#">Indication</a>

This clinical statement represents an inpatient hospitalization that occurred because of toxicity due to chemotherapy. The HL7 encounter code "IMP" (inpatient) identifies an inpatient encounter. The HL7 actRelationship typeCode "RSON" (reason) captures the reason for the inpatient hospitalization as toxicity due to chemotherapy. There can be additional entry relationships that describe what the clinical toxicities or problems were.

**Table 103: Hospitalization for Toxicity Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
	encounter[templateId/@root = '2.16.840.1.113883.10.20.30.3.36']					
	templateId	1..1	SHALL		<a href="#">26330</a>	
	@root	1..1	SHALL		<a href="#">26331</a>	2.16.840.1.113883.10.20.30.3.36
	code	1..1	SHALL		<a href="#">26333</a>	
	@code	1..1	SHALL		<a href="#">26442</a>	2.16.840.1.113883.5.4 (ActCode) = IMP
	@codeSystem	1..1	SHALL		<a href="#">26443</a>	2.16.840.1.113883.5.4
	entryRelationship	1..1	SHALL		<a href="#">26346</a>	
	@typeCode	1..1	SHALL		<a href="#">26347</a>	2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = RSON
	observation	1..1	SHALL		<a href="#">26374</a>	

1. Conforms to [Encounter Activities](#) template (2.16.840.1.113883.10.20.22.4.49).
2. **SHALL** contain exactly one [1..1] **templateId** (CONF:26330) such that it
  - a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.30.3.36" (CONF:26331).
3. **SHALL** contain exactly one [1..1] **code** (CONF:26333).
  - a. This code **SHALL** contain exactly one [1..1] **@code**="IMP" Inpatient encounter (CodeSystem: ActCode 2.16.840.1.113883.5.4) (CONF:26442).

- b. This code **SHALL** contain exactly one [1..1]
  - @codeSystem="2.16.840.1.113883.5.4" actCode (CONF:26443).
- 4. **SHALL** contain exactly one [1..1] **entryRelationship** (CONF:26346) such that it
  - a. **SHALL** contain exactly one [1..1] @typeCode="RSON" Has Reason (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**) (CONF:26347).
  - b. **SHALL** contain exactly one [1..1] **Indication** (templateId:2.16.840.1.113883.10.20.22.4.19) (CONF:26374).

**Figure 65: Hospitalization for Toxicity example**

```

<encounter classCode="ENC" moodCode="EVN">
 <!-- C-CDA encounter activities TemplateID -->
 <templateId root="2.16.840.1.113883.10.20.22.4.49"/>
 <!-- Hospitalization for Toxicity templateID -->
 <templateId root="2.16.840.1.113883.10.20.30.3.36"/>
 <id root="dd21f8ce-4cb4-43f7-b735-e64eb02b927c"/>
 <code codeSystem="2.16.840.1.113883.5.4" code="IMP"
 displayName="Inpatient encounter"/>
 <effectiveTime>
 <!-- Dates of admission and discharge -->
 <low value="20121109"/>
 <high value="20121130"/>
 </effectiveTime>
 <participant typeCode="LOC">
 <!-- Location participation TemplateID -->
 <templateId root="2.16.840.1.113883.10.20.1.45"/>
 <participantRole classCode="SDLOC">
 <id root="2.16.840.1.113883.19.5"/>
 <playingEntity classCode="PLC">
 <name>Good Health Hospital</name>
 </playingEntity>
 </participantRole>
 </participant>
 <!-- This states that the reason for admission was due to
 chemotherapy toxicity -->
 <entryRelationship typeCode="RSON">
 <observation classCode="OBS" moodCode="EVN">
 <!-- Consolidated CDA Indication template -->
 <templateId root="2.16.840.1.113883.10.20.22.4.19"/>
 <!-- Observation ID equals an ID on the problem list -->
 <id root="43faccd9-5b6e-45f3-b007-856e96b3d84d"/>
 <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4" />
 <statusCode code="completed" />
 <value xsi:type="CD" code="399213007"
 codeSystem="2.16.840.1.113883.6.96"
 displayName="toxicity due to chemotherapy"/>
 </observation>
 </entryRelationship>
</encounter>

```

## 4.17 Encounter Diagnosis

[Closed for comments; published July 2012]

[act: templateId 2.16.840.1.113883.10.20.22.4.80 (open)]

**Table 104: Encounter Diagnosis Contexts**

Used By:	Contains Entries:
<a href="#">Encounter Activities</a> (optional)	<a href="#">Problem Observation</a>

This template wraps relevant problems or diagnoses at the close of a visit or that need to be followed after the visit. If the encounter is associated with a Hospital Discharge, the Hospital Discharge Diagnosis must be used. This entry requires at least one Problem Observation entry.

**Table 105: Encounter Diagnosis Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
	act[templateId/@root = '2.16.840.1.113883.10.20.22.4.80']					
	@classCode	1..1	SHALL		<a href="#">14889</a>	2.16.840.1.113883.5.6 (HL7ActClass) = ACT
	@moodCode	1..1	SHALL		<a href="#">14890</a>	2.16.840.1.113883.5.1001 (ActMood) = EVN
	templateId	1..1	SHALL		<a href="#">14895</a>	
	@root	1..1	SHALL		<a href="#">14896</a>	2.16.840.1.113883.10.20.22.4.80
	code	1..1	SHALL		<a href="#">19182</a>	
	@code	1..1	SHALL		<a href="#">19183</a>	2.16.840.1.113883.6.1 (LOINC) = 29308-4
	entryRelationship	1..*	SHALL		<a href="#">14892</a>	
	@typeCode	1..1	SHALL		<a href="#">14893</a>	2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = SUBJ
	observation	1..1	SHALL		<a href="#">14898</a>	

1. **SHALL** contain exactly one [1..1] @classCode="ACT" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:14889).
2. **SHALL** contain exactly one [1..1] @moodCode="EVN" (CodeSystem: ActMood 2.16.840.1.113883.5.1001 **STATIC**) (CONF:14890).
3. **SHALL** contain exactly one [1..1] templateId (CONF:14895) such that it
  - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.80" (CONF:14896).
4. **SHALL** contain exactly one [1..1] code (CONF:19182).
  - a. This code **SHALL** contain exactly one [1..1] @code="29308-4" Diagnosis (CodeSystem: LOINC 2.16.840.1.113883.6.1 **STATIC**) (CONF:19183).
5. **SHALL** contain at least one [1..\*] entryRelationship (CONF:14892) such that it

- a. **SHALL** contain exactly one [1..1] @typeCode="SUBJ" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**) (CONF:14893).
- b. **SHALL** contain exactly one [1..1] [Problem Observation](#) (templateId:2.16.840.1.113883.10.20.22.4.4) (CONF:14898).

**Figure 66: Encounter Diagnosis example**

```

<act classCode="ACT" moodCode="EVN">
 <!--Encounter diagnosis act -->
 <templateId root="2.16.840.1.113883.10.20.22.4.80"/>
 <id root="5a784260-6856-4f38-9638-80c751aff2fb"/>
 <code code="29038-4"
 codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC"
 displayName=" DIAGNOSIS"/>
 <statusCode code="active"/>
 <effectiveTime>
 <low value="20903003"/>
 </effectiveTime>
 <entryRelationship typeCode="SUBJ" >
 <observation classCode="OBS" moodCode="EVN" >
 <templateId root="2.16.840.1.113883.10.20.22.4.4"/>
 <!-- Problem Observation -->
 ...
 </observation>
 </entryRelationship>
</act>

```

## 4.18 Family History Death Observation

**[Closed for comments; published July 2012]**

[observation: templateId 2.16.840.1.113883.10.20.22.4.47 (open)]

**Table 106: Family History Death Observation Contexts**

Used By:	Contains Entries:
<a href="#">Family History Observation</a> (optional)	

This clinical statement records whether the family member is deceased.

**Table 107: Family History Death Observation Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	observation[templateId/@root = '2.16.840.1.113883.10.20.22.4.47']					
	@classCode	1..1	SHALL		<a href="#">8621</a>	2.16.840.1.113883.5.6 (HL7ActClass) = OBS
	@moodCode	1..1	SHALL		<a href="#">8622</a>	2.16.840.1.113883.5.1001 (ActMood) = EVN
	templateId	1..1	SHALL		<a href="#">8623</a>	
	@root	1..1	SHALL		<a href="#">10495</a>	2.16.840.1.113883.10.20.22.4.47
	code	1..1	SHALL		<a href="#">19141</a>	
	@code	1..1	SHALL		<a href="#">19142</a>	2.16.840.1.113883.5.4 (ActCode) = ASSERTION
	statusCode	1..1	SHALL		<a href="#">8625</a>	
	@code	1..1	SHALL		<a href="#">19097</a>	2.16.840.1.113883.5.14 (ActStatus) = completed
	value	1..1	SHALL	CD	<a href="#">8626</a>	2.16.840.1.113883.6.96 (SNOMED-CT) = 419099009

1. **SHALL** contain exactly one [1..1] @classCode="OBS" Observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:8621).
2. **SHALL** contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 **STATIC**) (CONF:8622).
3. **SHALL** contain exactly one [1..1] templateId (CONF:8623) such that it
  - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.47" (CONF:10495).
4. **SHALL** contain exactly one [1..1] code (CONF:19141).
  - a. This code **SHALL** contain exactly one [1..1] @code="ASSERTION" Assertion (CodeSystem: ActCode 2.16.840.1.113883.5.4 **STATIC**) (CONF:19142).
5. **SHALL** contain exactly one [1..1] statusCode (CONF:8625).
  - a. This statusCode **SHALL** contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 **STATIC**) (CONF:19097).
6. **SHALL** contain exactly one [1..1] value="419099009" Dead with @xsi:type="CD" (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96 **STATIC**) (CONF:8626).

**Figure 67: Family History Death Observation example**

```
<observation classCode="OBS" moodCode="EVN">
 <templateId root="2.16.840.1.113883.10.20.22.4.47" />
 <!-- Family history death observation template -->
 <id root="6898fae0-5c8a-11db-b0de-0800200c9a66" />
 <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4" />
 <statusCode code="completed" />
 <value xsi:type="CD"
 code="419099009"
 codeSystem="2.16.840.1.113883.6.96"
 displayName="Dead"/>
</observation>
```

## 4.19 Family History Observation [Closed for comments; published July 2012]

[observation: templateId 2.16.840.1.113883.10.20.22.4.46 (open)]

**Table 108: Family History Observation Contexts**

Used By:	Contains Entries:
<a href="#">Family History Organizer</a> (required)	<a href="#">Age Observation</a> <a href="#">Family History Death Observation</a>

Family History Observations related to a particular family member are contained within a Family History Organizer. The `effectiveTime` in the Family History Observation is the biologically or clinically relevant time of the observation. The biologically or clinically relevant time is the time at which the observation holds (is effective) for the family member (the subject of the observation).

**Table 109: Family History Observation Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
Green Family History Observation	observation[templateId/@root = '2.16.840.1.113883.10.20.22.4.46']					
	@classCode	1..1	SHALL		<a href="#">8586</a>	2.16.840.1.113883.5.6 (HL7ActClass) = OBS
	@moodCode	1..1	SHALL		<a href="#">8587</a>	2.16.840.1.113883.5.1001 (ActMood) = EVN
	templateId	1..1	SHALL		<a href="#">8599</a>	
	@root	1..1	SHALL		<a href="#">10496</a>	2.16.840.1.113883.10.20.22.4.46
	id	1..*	SHALL		<a href="#">8592</a>	



Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
	code	1..1	SHALL		<a href="#">8589</a>	2.16.840.1.113883.3.88.12.3221.7.2 (Problem Type)
	statusCode	1..1	SHALL		<a href="#">8590</a>	
	@code	1..1	SHALL		<a href="#">19098</a>	2.16.840.1.113883.5.14 (ActStatus) = completed
	effectiveTime	0..1	SHOULD		<a href="#">8593</a>	
	value	1..1	SHALL	CD	<a href="#">8591</a>	2.16.840.1.113883.3.88.12.3221.7.4 (Problem Value Set)
	entry Relationship	0..1	MAY		<a href="#">8675</a>	
	@typeCode	1..1	SHALL		<a href="#">8676</a>	2.16.840.1.113883.5.90 (HL7ParticipationType) = SUBJ
	@inversion Ind	1..1	SHALL		<a href="#">8677</a>	true
	observation	1..1	SHALL		<a href="#">15526</a>	
	entry Relationship	0..1	MAY		<a href="#">8678</a>	
	@typeCode	1..1	SHALL		<a href="#">8679</a>	2.16.840.1.113883.5.90 (HL7ParticipationType) = CAUS
	observation	1..1	SHALL		<a href="#">15527</a>	

1. **SHALL** contain exactly one [1..1] @classCode="OBS" Observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:8586).
2. **SHALL** contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 **STATIC**) (CONF:8587).
3. **SHALL** contain exactly one [1..1] templateId (CONF:8599) such that it
  - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.46" (CONF:10496).
4. **SHALL** contain at least one [1..\*] id (CONF:8592).
5. **SHALL** contain exactly one [1..1] code, which **SHOULD** be selected from ValueSet Problem Type 2.16.840.1.113883.3.88.12.3221.7.2 **STATIC** 2012-06-01 (CONF:8589).
6. **SHALL** contain exactly one [1..1] statusCode (CONF:8590).
  - a. This statusCode **SHALL** contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 **STATIC**) (CONF:19098).
7. **SHOULD** contain zero or one [0..1] effectiveTime (CONF:8593).
8. **SHALL** contain exactly one [1..1] value with @xsi:type="CD", where the @code **SHALL** be selected from ValueSet Problem Value Set 2.16.840.1.113883.3.88.12.3221.7.4 **DYNAMIC** (CONF:8591).

9. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:8675) such that it
- SHALL** contain exactly one [1..1] **@typeCode="SUBJ"** Subject (CodeSystem: HL7ParticipationType 2.16.840.1.113883.5.90 **STATIC**) (CONF:8676).
  - SHALL** contain exactly one [1..1] **@inversionInd="true"** True (CONF:8677).
  - SHALL** contain exactly one [1..1] **Age Observation** (templateId:2.16.840.1.113883.10.20.22.4.31) (CONF:15526).
10. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:8678) such that it
- SHALL** contain exactly one [1..1] **@typeCode="CAUS"** Causal or Contributory (CodeSystem: HL7ParticipationType 2.16.840.1.113883.5.90 **STATIC**) (CONF:8679).
  - SHALL** contain exactly one [1..1] **Family History Death Observation** (templateId:2.16.840.1.113883.10.20.22.4.47) (CONF:15527).

**Table 110: Problem Type Value Set**

Value Set: Problem Type 2.16.840.1.113883.3.88.12.3221.7.2 STATIC Code System: SNOMED-CT 2.16.840.1.113883.6.96		
Code	Code System	Print Name
404684003	SNOMED-CT	Finding
409586006	SNOMED-CT	Complaint
282291009	SNOMED-CT	Diagnosis
64572001	SNOMED-CT	Condition
248536006	SNOMED-CT	Finding of functional performance and activity
418799008	SNOMED-CT	Symptom
55607006	SNOMED-CT	Problem
373930000	SNOMED-CT	Cognitive function finding

**Table 111: Problem Value Set (excerpt)**

Value Set: Problem 2.16.840.1.113883.3.88.12.3221.7.4 DYNAMIC Code System(s): SNOMED CT 2.16.840.1.113883.6.96		
Description: Problems and diagnoses. Limited to terms descending from the Clinical Findings (404684003) or Situation with Explicit Context (243796009) hierarchies. <a href="http://phinvads.cdc.gov/vads/ViewValueSet.action?id=70FDBFB5-A277-DE11-9B52-0015173D1785">http://phinvads.cdc.gov/vads/ViewValueSet.action?id=70FDBFB5-A277-DE11-9B52-0015173D1785</a>		
Code	Code System	Print Name
46635009	SNOMED CT	Diabetes mellitus type 1
234422006	SNOMED CT	Acute porphyria
31712002	SNOMED CT	Primary biliary cirrhosis
302002000	SNOMED CT	Difficulty moving
15188001	SNOMED CT	Hearing loss
48167000	SNOMED CT	Amnesia
...		

**Figure 68: Family History Observation example**

```

<observation classCode="OBS" moodCode="EVN">
 <templateId root="2.16.840.1.113883.10.20.22.4.46" />
 <!-- Family History Observation template -->
 <id root="d42ebf70-5c89-11db-b0de-0800200c9a66" />
 <code code="64572001"
 displayName="Condition"
 codeSystemName="SNOMED CT"
 codeSystem="2.16.840.1.113883.6.96" />
 <statusCode code="completed" />
 <effectiveTime value="1967" />
 <value xsi:type="CD" code="22298006"
 codeSystem="2.16.840.1.113883.6.96"
 displayName="Myocardial infarction" />

 <entryRelationship typeCode="CAUS">
 <observation classCode="OBS" moodCode="EVN">
 <templateId root="2.16.840.1.113883.10.20.22.4.47" />
 <!-- Family history death observation template -->
 ...
 </observation>
 </entryRelationship>

 <entryRelationship typeCode="SUBJ"
 <inversionInd="true">
 <observation classCode="OBS" moodCode="EVN">
 <templateId root="2.16.840.1.113883.10.20.22.4.31" />
 <!-- Age observation template -->
 ...
 </observation>
 </entryRelationship>
</observation>

```

## 4.20 Family History of Cancer None

[Observation: templateId 2.16.840.1.113883.10.20.30.3.11 (open)]

**Table 112: Family History of Cancer None Contexts**

Used By:	Contains Entries:
<a href="#">Family History Section BCTPS</a> (optional)	

This clinical statement asserts that the patient does not have a family history of cancer.

**Table 113: Family History of Cancer None Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
	Observation[templateId/@root = '2.16.840.1.113883.10.20.30.3.11']					
	@classCode	1..1	SHALL		<a href="#">26013</a>	2.16.840.1.113883.5.6 (HL7ActClass) = OBS
	@moodCode	1..1	SHALL		<a href="#">26014</a>	2.16.840.1.113883.5.1001 (ActMood) = EVN
	@negationInd	1..1	SHALL		<a href="#">26015</a>	true
	templateId	1..1	SHALL		<a href="#">26016</a>	
	@root	1..1	SHALL		<a href="#">26017</a>	2.16.840.1.113883.10.20.30.3.11
	code	1..1	SHALL		<a href="#">26018</a>	
	@code	1..1	SHALL		<a href="#">26019</a>	ASSERTION
	@codeSystem	1..1	SHALL		<a href="#">26020</a>	2.16.840.1.113883.5.4
	text	0..1	SHOULD		<a href="#">26021</a>	No family history of cancer
	statusCode	1..1	SHALL		<a href="#">26022</a>	
	@code	1..1	SHALL		<a href="#">26023</a>	2.16.840.1.113883.5.14 (ActStatus) = Completed
	value	1..1	SHALL	CD	<a href="#">26024</a>	
	@code	1..1	SHALL		<a href="#">26025</a>	275937001
	@codeSystem	1..1	SHALL		<a href="#">26026</a>	2.16.840.1.113883.6.96 (SNOMED-CT) = 2.16.840.1.113883.6.96

1. **SHALL** contain exactly one [1..1] @classCode="OBS" observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:26013).
2. **SHALL** contain exactly one [1..1] @moodCode="EVN" event (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:26014).
3. **SHALL** contain exactly one [1..1] @negationInd="true" (CONF:26015).
4. **SHALL** contain exactly one [1..1] templateId (CONF:26016) such that it
  - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.3.11" (CONF:26017).
5. **SHALL** contain exactly one [1..1] code (CONF:26018).
  - a. This code **SHALL** contain exactly one [1..1] @code="ASSERTION" Assertion (CONF:26019).
  - b. This code **SHALL** contain exactly one [1..1] @codeSystem="2.16.840.1.113883.5.4" (CONF:26020).
6. **SHOULD** contain zero or one [0..1] text="No family history of cancer" (CONF:26021).
7. **SHALL** contain exactly one [1..1] statusCode (CONF:26022).
  - a. This statusCode **SHALL** contain exactly one [1..1] @code="Completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14) (CONF:26023).

8. **SHALL** contain exactly one [1..1] **value** with @xsi:type="CD" (CONF:26024).
  - a. This value **SHALL** contain exactly one [1..1] @code="275937001" family history of cancer (CONF:26025).
  - b. This value **SHALL** contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.96" (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96) (CONF:26026).

**Figure 69: Family History of Cancer None example**

```

<observation classCode="OBS" moodCode="EVN" negationInd="true">
 <!-- Family History of Cancer - None -->
 <templateId root="2.16.840.1.113883.10.20.30.3.11"/>
 <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"
 codeSystemName="ActCode"/>
 <text> No Family History of Cancer</text>
 <statusCode code="completed"/>
 <value xsi:type="CD"
 code="275937001"
 codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMED CT"
 displayName="family history of cancer"/>
</observation>

```

## 4.21 Family History Organizer

**[Closed for comments; published July 2012]**

[organizer: templateId 2.16.840.1.113883.10.20.22.4.45 (open)]

**Table 114: Family History Organizer Contexts**

Used By:	Contains Entries:
<a href="#">Family History Section</a> (optional)	<a href="#">Family History Observation</a>

The Family History Organizer associates a set of observations with a family member. For example, the Family History Organizer can group a set of observations about the patient's father.

**Table 115: Family History Organizer Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
Green Family History Organizer	organizer[templateId/@root = '2.16.840.1.113883.10.20.22.4.45']					
	@classCode	1..1	SHALL		<a href="#">8600</a>	2.16.840.1.113883.5.6 (HL7ActClass) = CLUSTER
	@moodCode	1..1	SHALL		<a href="#">8601</a>	2.16.840.1.113883.5.1001 (ActMood) = EVN
	templateId	1..1	SHALL		<a href="#">8604</a>	
	@root	1..1	SHALL		<a href="#">10497</a>	2.16.840.1.113883.10.20.22.4.45
	statusCode	1..1	SHALL		<a href="#">8602</a>	
	@code	1..1	SHALL		<a href="#">19099</a>	2.16.840.1.113883.5.14 (ActStatus) = completed
familyMember Demographics	subject	1..1	SHALL		<a href="#">8609</a>	
	relatedSubject	1..1	SHALL		<a href="#">15244</a>	
	@classCode	1..1	SHALL		<a href="#">15245</a>	2.16.840.1.113883.5.41 (EntityClass) = PRS
	code	1..1	SHALL		<a href="#">15246</a>	
	@code	1..1	SHALL		<a href="#">15247</a>	2.16.840.1.113883.1.11.19579 (Family Member Value Set)
	subject	0..1	SHOULD		<a href="#">15248</a>	
	administrative GenderCode	1..1	SHALL		<a href="#">15974</a>	
	@code	1..1	SHALL		<a href="#">15975</a>	2.16.840.1.113883.1.11.1 (Administrative Gender (HL7 V3))
	birthTime	0..1	SHOULD		<a href="#">15976</a>	
familyMember MedicalHistory	component	1..*	SHALL		<a href="#">8607</a>	
	observation	1..1	SHALL		<a href="#">16888</a>	

1. **SHALL** contain exactly one [1..1] @classCode="CLUSTER" Cluster (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:8600).
2. **SHALL** contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 **STATIC**) (CONF:8601).

3. **SHALL** contain exactly one [1..1] **templateId** (CONF:8604) such that it
  - a. **SHALL** contain exactly one [1..1]
    - @root**="2.16.840.1.113883.10.20.22.4.45" (CONF:10497).
4. **SHALL** contain exactly one [1..1] **statusCode** (CONF:8602).
  - a. This **statusCode** **SHALL** contain exactly one [1..1] **@code**="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 **STATIC**) (CONF:19099).
5. **SHALL** contain exactly one [1..1] **subject** (CONF:8609).
  - a. This **subject** **SHALL** contain exactly one [1..1] **relatedSubject** (CONF:15244).
    - i. This **relatedSubject** **SHALL** contain exactly one [1..1] **@classCode**="PRS" Person (CodeSystem: EntityClass 2.16.840.1.113883.5.41 **STATIC**) (CONF:15245).
    - ii. This **relatedSubject** **SHALL** contain exactly one [1..1] **code** (CONF:15246).
      1. This **code** **SHALL** contain exactly one [1..1] **@code**, which **SHOULD** be selected from ValueSet Family Member Value Set 2.16.840.1.113883.1.11.19579 **DYNAMIC** (CONF:15247).
    - iii. This **relatedSubject** **SHOULD** contain zero or one [0..1] **subject** (CONF:15248).
      1. The **subject**, if present, **SHALL** contain exactly one [1..1] **administrativeGenderCode** (CONF:15974).
        - a. This **administrativeGenderCode** **SHALL** contain exactly one [1..1] **@code**, which **SHALL** be selected from ValueSet [Administrative Gender \(HL7 V3\) 2.16.840.1.113883.1.11.1](#) **STATIC** (CONF:15975).
      2. The **subject**, if present, **SHOULD** contain zero or one [0..1] **birthTime** (CONF:15976).
      3. The **subject** **SHOULD** contain zero or more [0..\*] **sdctc:id**. The prefix **sdctc**: **SHALL** be bound to the namespace "urn:hl7-org:sdctc". The use of the namespace provides a necessary extension to CDA R2 for the use of the **id** element (CONF:15249).
      4. The **subject** **MAY** contain zero or one **sdctc:deceasedInd**. The prefix **sdctc**: **SHALL** be bound to the namespace "urn:hl7-org:sdctc". The use of the namespace provides a necessary extension to CDA R2 for the use of the **deceasedInd** element (CONF:15981).
      5. The **subject** **MAY** contain zero or one **sdctc:deceasedTime**. The prefix **sdctc**: **SHALL** be bound to the namespace "urn:hl7-org:sdctc". The use of the namespace provides a necessary extension to CDA R2 for the use of the **deceasedTime** element (CONF:15982).
      6. The age of a relative at the time of a family history observation **SHOULD** be inferred by comparing

RelatedSubject/subject/birthTime with  
Observation/effectiveTime (CONF:15983).

6. **SHALL** contain at least one [1..\*] **component** (CONF:8607).
- a. Such components **SHALL** contain exactly one [1..1] **Family History Observation** (templateId:2.16.840.1.113883.10.20.22.4.46) (CONF:16888).

**Table 116: Family Member Value Set**

Value Set: Family Member Value Set 2.16.840.1.113883.1.11.19579 DYNAMIC Code System: RoleCode 2.16.840.1.113883.5.111		
Code	Code System	Print Name
ADOPT	RoleCode	adopted child
AUNT	RoleCode	aunt
CHILD	RoleCode	Child
CHLDINLAW	RoleCode	child in-law
COUSN	RoleCode	cousin
DOMPART	RoleCode	domestic partner
FAMMEMB	RoleCode	Family Member
CHLDFOST	RoleCode	foster child
GRNDCHILD	RoleCode	grandchild
GRPRN	RoleCode	Grandparent
GPART	RoleCode	grandparent
GGRPRN	RoleCode	great grandparent
HSIB	RoleCode	half-sibling
MAUNT	RoleCode	MaternalAunt
MCOUSN	RoleCode	MaternalCousin
MGRPRN	RoleCode	MaternalGrandparent
MGGRPRN	RoleCode	MaternalGreatgrandparent
MUNCLE	RoleCode	MaternalUncle
NCHILD	RoleCode	natural child
NPRN	RoleCode	natural parent
NSIB	RoleCode	natural sibling
NIENEPH	RoleCode	niece/nephew
PRN	RoleCode	Parent
PRNINLAW	RoleCode	parent in-law
PAUNT	RoleCode	PaternalAunt
PCOUSN	RoleCode	PaternalCousin
PGRPRN	RoleCode	PaternalGrandparent
PGGRPRN	RoleCode	PaternalGreatgrandparent
PUNCLE	RoleCode	PaternalUncle
SIB	RoleCode	Sibling



Value Set: Family Member Value Set 2.16.840.1.113883.1.11.19579 DYNAMIC Code System: RoleCode 2.16.840.1.113883.5.111		
Code	Code System	Print Name
SIBINLAW	RoleCode	sibling in-law
SIGOTHR	RoleCode	significant other
SPS	RoleCode	spouse
STEP	RoleCode	step child
STPPRN	RoleCode	step parent
STPSIB	RoleCode	step sibling
UNCLE	RoleCode	uncle

**Figure 70: Family History Organizer – history of cancer example**

```

<entry typeCode="DRIV">
 <!-- mother -->
 <organizer moodCode="EVN" classCode="CLUSTER">
 <!--Consolidated CDA FAMILY HISTORY ORGANIZER TemplateID-->
 <templateId root="2.16.840.1.113883.10.20.22.4.45"/>
 <statusCode code="completed"/>
 <entry typeCode="DRIV">
 <!-- mother -->
 <organizer moodCode="EVN" classCode="CLUSTER">
 <!--Consolidated CDA FAMILY HISTORY ORGANIZER TemplateID-->
 <templateId root="2.16.840.1.113883.10.20.22.4.45"/>
 <statusCode code="completed"/>
 <!-- Example using HL7 Family Member Value Set. -->
 <subject>
 <relatedSubject classCode="PRS">
 <code code="MTH" displayName="Mother"
 codeSystemName="HL7 FamilyMember"
 codeSystem="2.16.840.1.113883.5.111">
 <translation code="9947008" displayName="Biological mother"
 codeSystemName="SNOMED"
 codeSystem="2.16.840.1.113883.6.96"/>
 </code>
 </subject>
 <sdctc:id root="2.16.840.1.113883.19.5.99999.2"
 extension="99999"/>
 <id xmlns="urn:hl7-org:sdctc"
 root="2.16.840.1.113883.19.5.99999.2"
 extension="1234"/>
 <administrativeGenderCode code="F"
 codeSystem="2.16.840.1.113883.5.1" displayName="Female"/>
 <birthTime value="1930"/>
 </subject>
 </relatedSubject>
 </entry>
 </organizer>
</entry>

```

```

<component>
 <observation classCode="OBS" moodCode="EVN">
 <!--C-CDA FAMILY HISTORY OBSERVATION TemplateID-->
 <templateId root="2.16.840.1.113883.10.20.22.4.46"/>
 ...
 </observation>
</component>
</organizer>
</entry>
...
</organizer>
</entry>

```

## 4.22 Family History Pedigree

[Act: templateId 2.16.840.1.113883.10.20.30.3.48 (open)]

**Table 117: Family History Pedigree Contexts**

Used By:	Contains Entries:
<a href="#">Family History Section BCTPS</a> (required)	

This clinical statement contains the pedigree of the patient by pointing to the HL7 Pedigree Model as an external observation. If there is no pedigree available, a nullFlavor can be sent.

**Table 118: Family History Pedigree Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
	Act[templateId/@root = '2.16.840.1.113883.10.20.30.3.48']					
	@classCode	1..1	SHALL		<a href="#">26743</a>	2.16.840.1.113883.5.6 (HL7ActClass) = ACT
	@moodCode	1..1	SHALL		<a href="#">26744</a>	2.16.840.1.113883.5.1001 (ActMood) = EVN
	templateId	1..1	SHALL		<a href="#">26745</a>	
	@root	1..1	SHALL		<a href="#">26746</a>	2.16.840.1.113883.10.20.30.3.48
	code	1..1	SHALL		<a href="#">26747</a>	
	@code	1..1	SHALL		<a href="#">26748</a>	10157-6
	@codeSystem	1..1	SHALL		<a href="#">26749</a>	2.16.840.1.113883.6.1 (LOINC) = 2.16.840.1.113883.6.1
	reference	1..1	SHALL		<a href="#">26750</a>	
	@typeCode	1..1	SHALL		<a href="#">26751</a>	2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = REFR

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
	external Observation	1..1	SHALL		<a href="#">26752</a>	
	@classCode	1..1	SHALL		<a href="#">26753</a>	2.16.840.1.113883.5.6 (HL7ActClass) = OBS
	@moodCode	1..1	SHALL		<a href="#">26754</a>	2.16.840.1.113883.5.1001 (ActMood) = EVN
	id	1..*	SHALL		<a href="#">26755</a>	
	text	0..1	SHOULD		<a href="#">26756</a>	
	reference	0..1	SHOULD		<a href="#">26757</a>	
	@value	1..1	SHALL		<a href="#">26758</a>	

1. **SHALL** contain exactly one [1..1] @classCode="ACT" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:26743).
2. **SHALL** contain exactly one [1..1] @moodCode="EVN" (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:26744).
3. **SHALL** contain exactly one [1..1] templateId (CONF:26745) such that it
  - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.3.48" (CONF:26746).
4. **SHALL** contain exactly one [1..1] code (CONF:26747).
  - a. This code **SHALL** contain exactly one [1..1] @code="10157-6" History of family member diseases (CONF:26748).
  - b. This code **SHALL** contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.1" (CodeSystem: LOINC 2.16.840.1.113883.6.1) (CONF:26749).
5. **SHALL** contain exactly one [1..1] reference (CONF:26750) such that it
  - a. **SHALL** contain exactly one [1..1] @typeCode="REFR" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:26751).
  - b. **SHALL** contain exactly one [1..1] externalObservation (CONF:26752).
    - i. This externalObservation **SHALL** contain exactly one [1..1] @classCode="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:26753).
    - ii. This externalObservation **SHALL** contain exactly one [1..1] @moodCode="EVN" (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:26754).

The id attribute shall hold the ID of a pedigree instance.

- iii. This externalObservation **SHALL** contain at least one [1..\*] id (CONF:26755).
- iv. This externalObservation **SHOULD** contain zero or one [0..1] text (CONF:26756).
  1. The text, if present, **SHOULD** contain zero or one [0..1] reference (CONF:26757).

2. The reference, if present, **SHALL** contain exactly one [1..1] @value (CONF:26758).

**Figure 71: Family History Pedigree example**

```

<entry>
 <act classCode="ACT" moodCode="EVN">
 <!-- CDA FAMILY HISTORY PEDIGREE TemplateID -->
 <templateId root="2.16.840.1.113883.10.20.30.3.48"/>
 <code code="10157-6" displayName="History of family member diseases"
codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
 <reference typeCode="REFR">
 <externalObservation classCode="OBS" moodCode="EVN">
 <!-- Example id -->
 <id root="2.16.840.1.113883.6.117" extension="299"
assigningAuthorityName="Avon Center Appointment Number"/>
 <text mediaType="text">FamilyPedigreeModel
 <reference
value="https://www.google.com/webhp?source=search_app"/>
 </text>
 </externalObservation>
 </reference>
 </act>
 </entry>

```

## 4.23 Health Status Observation [Closed for comments; published July 2012]

[observation: templateId 2.16.840.1.113883.10.20.22.4.5 (closed)]

**Table 119: Health Status Observation Contexts**

Used By:	Contains Entries:
<a href="#">Problem Observation</a> (optional)	

The Health Status Observation records information about the current health status of the patient.

**Table 120: Health Status Observation Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	observation[templateId/@root = '2.16.840.1.113883.10.20.22.4.5']					
	@classCode	1..1	SHALL		<a href="#">9057</a>	2.16.840.1.113883.5.6 (HL7ActClass) = OBS
	@moodCode	1..1	SHALL		<a href="#">9072</a>	2.16.840.1.113883.5.1001 (ActMood) = EVN
	templateId	1..1	SHALL		<a href="#">16756</a>	
	@root	1..1	SHALL		<a href="#">16757</a>	2.16.840.1.113883.10.20.22.4.5
	code	1..1	SHALL		<a href="#">19143</a>	

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	@code	1..1	SHALL		<a href="#">19144</a>	2.16.840.1.113883.6.1 (LOINC) = 11323-3
	text	0..1	SHOULD		<a href="#">9270</a>	
	reference	0..1	SHOULD		<a href="#">15529</a>	
	@value	0..1	SHOULD		<a href="#">15530</a>	
	statusCode	1..1	SHALL		<a href="#">9074</a>	
	@code	1..1	SHALL		<a href="#">19103</a>	2.16.840.1.113883.5.14 (ActStatus) = completed
	value	1..1	SHALL	CD	<a href="#">9075</a>	2.16.840.1.113883.1.11.20.12 (HealthStatus)

1. **SHALL** contain exactly one [1..1] @classCode="OBS" Observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:9057).
2. **SHALL** contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 **STATIC**) (CONF:9072).
3. **SHALL** contain exactly one [1..1] templateId (CONF:16756) such that it
  - a. **SHALL** contain exactly one [1..1]
    - @root="2.16.840.1.113883.10.20.22.4.5" (CONF:16757).
4. **SHALL** contain exactly one [1..1] code (CONF:19143).
  - a. This code **SHALL** contain exactly one [1..1] @code="11323-3" Health status (CodeSystem: LOINC 2.16.840.1.113883.6.1 **STATIC**) (CONF:19144).
5. **SHOULD** contain zero or one [0..1] text (CONF:9270).
  - a. The text, if present, **SHOULD** contain zero or one [0..1] reference (CONF:15529).
    - i. The reference, if present, **SHOULD** contain zero or one [0..1] @value (CONF:15530).
      1. **SHALL** begin with a '#' and **SHALL** point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:15531).
6. **SHALL** contain exactly one [1..1] statusCode (CONF:9074).
  - a. This statusCode **SHALL** contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 **STATIC**) (CONF:19103).
7. **SHALL** contain exactly one [1..1] value with @xsi:type="CD", where the @code **SHALL** be selected from ValueSet HealthStatus 2.16.840.1.113883.1.11.20.12 **DYNAMIC** (CONF:9075).

**Table 121: Health Status Value Set**

Value Set: HealthStatus 2.16.840.1.113883.1.11.20.12 DYNAMIC Code System: SNOMED-CT 2.16.840.1.113883.6.96		
Code	Code System	Print Name
81323004	SNOMED-CT	Alive and well
313386006	SNOMED-CT	In remission
162467007	SNOMED-CT	Symptom free
161901003	SNOMED-CT	Chronically ill
271593001	SNOMED-CT	Severely ill
21134002	SNOMED-CT	Disabled
161045001	SNOMED-CT	Severely disabled
419099009	SNOMED-CT	Deceased

**Figure 72: Health Status Observation example**

```

<observation classCode="OBS" moodCode="EVN">
 <templateId root="2.16.840.1.113883.10.20.22.4.5"/>
 <!-- Health status observation template -->
 <code code="11323-3"
 codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC"
 displayName="Health status"/>
 <text>
 <reference value="#problems"/>
 </text>
 <statusCode code="completed"/>
 <value xsi:type="CD" code="81323004"
 codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMED CT"
 displayName="Alive and well"/>
</observation>

```

#### 4.24 Highest Pressure Ulcer Stage [Closed for comments; published July 2012]

[observation: templateId 2.16.840.1.113883.10.20.22.4.77 (open)]

**Table 122: Highest Pressure Ulcer Stage Contexts**

Used By:	Contains Entries:
<a href="#">Functional Status Section</a> (optional)	

This observation contains a description of the wound tissue of the most severe or highest staged pressure ulcer observed on a patient.

**Table 123: Highest Pressure Ulcer Stage Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	observation[templateId/@root = '2.16.840.1.113883.10.20.22.4.77']					
	@classCode	1..1	SHALL		<a href="#">14726</a>	2.16.840.1.113883.5.6 (HL7ActClass) = OBS
	@moodCode	1..1	SHALL		<a href="#">14727</a>	2.16.840.1.113883.5.1001 (ActMood) = EVN
	templateId	1..1	SHALL		<a href="#">14728</a>	
	@root	1..1	SHALL		<a href="#">14729</a>	2.16.840.1.113883.10.20.22.4.77
	id	1..*	SHALL		<a href="#">14730</a>	
	code	1..1	SHALL		<a href="#">14731</a>	
	@code	1..1	SHALL		<a href="#">14732</a>	2.16.840.1.113883.6.96 (SNOMED-CT) = 420905001
	value	1..1	SHALL		<a href="#">14733</a>	

1. **SHALL** contain exactly one [1..1] @classCode="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:14726).
2. **SHALL** contain exactly one [1..1] @moodCode="EVN" (CodeSystem: ActMood 2.16.840.1.113883.5.1001 **STATIC**) (CONF:14727).
3. **SHALL** contain exactly one [1..1] templateId (CONF:14728) such that it
  - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.77" (CONF:14729).
4. **SHALL** contain at least one [1..\*] id (CONF:14730).
5. **SHALL** contain exactly one [1..1] code (CONF:14731).
  - a. This code **SHALL** contain exactly one [1..1] @code="420905001" Highest Pressure Ulcer Stage (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96 **STATIC**) (CONF:14732).
6. **SHALL** contain exactly one [1..1] value (CONF:14733).

**Figure 73: Highest Pressure Ulcer Stage example**

```

<entry typeCode="DRIV">
<observation classCode="OBS" moodCode="EVN">
 <templateId root="2.16.840.1.113883.10.20.22.4.77"/>
 <id root="08edb7c0-2111-43f2-a784-9a5fdfaa67f0"/>
 <code code="420905001" codeSystem="2.16.840.1.113883.6.96"
 displayName="Highest Pressure Ulcer Stage"/>
 <statusCode code="completed"/>
 <value xsi:type="CD" code="421306004"
 codeSystem="2.16.840.1.113883.6.96"
 displayName="necrotic eschar"/>
</observation>
</entry>

```

## 4.25 Immunization Medication Information [Closed for comments; published July 2012]

[manufacturedProduct: templateId 2.16.840.1.113883.10.20.22.4.54  
(open) ]

**Table 124: Immunization Medication Information Contexts**

Used By:	Contains Entries:
<a href="#">Medication Supply Order</a> (optional)	
<a href="#">Medication Dispense</a> (optional)	

The Immunization Medication Information represents product information about the immunization substance. The vaccine manufacturer and vaccine lot number are typically recorded in the medical record and should be included if known.

**Table 125: Immunization Medication Information Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
Green Immunization Medication Information	manufacturedProduct[templateId/@root = '2.16.840.1.113883.10.20.22.4.54']					
	@classCode	1..1	SHALL		<a href="#">9002</a>	2.16.840.1.113883.5.110 (RoleClass) = MANU
	templateId	1..1	SHALL		<a href="#">9004</a>	
	@root	1..1	SHALL		<a href="#">10499</a>	2.16.840.1.113883.10.20.22.4.54
	id	0..*	MAY		<a href="#">9005</a>	
	manufacturedMaterial	1..1	SHALL		<a href="#">9006</a>	
coded ProductName	code	1..1	SHALL		<a href="#">9007</a>	2.16.840.1.113883.3.88.12.80.22 (Vaccine Administered Value Set)
freeText ProductName	originalText	0..1	SHOULD		<a href="#">9008</a>	
	reference	0..1	SHOULD		<a href="#">15555</a>	
	@value	0..1	SHOULD		<a href="#">15556</a>	
	translation	0..*	MAY	SET <PQR>	<a href="#">9011</a>	
lotNumber	lotNumberText	0..1	SHOULD		<a href="#">9014</a>	
drug Manufacturer	manufacturer Organization	0..1	SHOULD		<a href="#">9012</a>	



1. **SHALL** contain exactly one [1..1] **@classCode="MANU"** (CodeSystem: RoleClass 2.16.840.1.113883.5.110 **STATIC**) (CONF:9002).
2. **SHALL** contain exactly one [1..1] **templateId** (CONF:9004) such that it
  - a. **SHALL** contain exactly one [1..1] **@root="2.16.840.1.113883.10.20.22.4.54"** (CONF:10499).
3. **MAY** contain zero or more [0..\*] **id** (CONF:9005).
4. **SHALL** contain exactly one [1..1] **manufacturedMaterial** (CONF:9006).
  - a. This **manufacturedMaterial SHALL** contain exactly one [1..1] **code**, which **SHALL** be selected from ValueSet Vaccine Administered Value Set 2.16.840.1.113883.3.88.12.80.22 **DYNAMIC** (CONF:9007).
    - i. This code **SHOULD** contain zero or one [0..1] **originalText** (CONF:9008).
      1. The **originalText**, if present, **SHOULD** contain zero or one [0..1] **reference** (CONF:15555).
        - a. The **reference**, if present, **SHOULD** contain zero or one [0..1] **evalue** (CONF:15556).
          - i. This **reference/@value SHALL** begin with a '#' and **SHALL** point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:15557).
        - ii. This code **MAY** contain zero or more [0..\*] **translation** (CONF:9011).
          1. **Translations** can be used to represent generic product name, packaged product code, etc (CONF:16887).
      - b. This **manufacturedMaterial SHOULD** contain zero or one [0..1] **lotNumberText** (CONF:9014).
  5. **SHOULD** contain zero or one [0..1] **manufacturerOrganization** (CONF:9012).

**Figure 74: Immunization Medication Information example**

```

<manufacturedProduct classCode="MANU">
 <templateId root="2.16.840.1.113883.10.20.22.4.54"/>
 <!-- ***** Immunization Medication Information ***** -->
 <manufacturedMaterial>
 <code code="88" codeSystem="2.16.840.1.113883.12.292 "
 displayName="Influenza virus vaccine" codeSystemName="CVX">
 <originalText>
 <reference value="#imm11"/>
 </originalText>
 <translation code="111"
 displayName="influenza, live, intranasal"
 codeSystemName="CVX"
 codeSystem=" 2.16.840.1.113883.12.292 " />
 </code>
 <lotNumberText>1</lotNumberText>
</manufacturedMaterial>
 <manufacturerOrganization>
 <name>Health LS - Immuno Inc.</name>
 </manufacturerOrganization>
</manufacturedProduct>

```

## 4.26 Indication

**[Closed for comments; published July 2012]**

[observation: templateId 2.16.840.1.113883.10.20.22.4.19 (open)]

**Table 126: Indication Contexts**

Used By:	Contains Entries:
<a href="#">Medication Activity</a> (optional) <a href="#">Procedure Activity Procedure</a> (optional) <a href="#">Procedure Activity Act</a> (optional) <a href="#">Procedure Activity Observation</a> (optional) <a href="#">Encounter Activities</a> (optional) <a href="#">Hospitalization for Toxicity</a> (required)	

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.

**Table 127: Indication Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	observation[templateId/@root = '2.16.840.1.113883.10.20.22.4.19']					
	@classCode	1..1	SHALL		<a href="#">7480</a>	2.16.840.1.113883.5.6 (HL7ActClass) = OBS
	@moodCode	1..1	SHALL		<a href="#">7481</a>	2.16.840.1.113883.5.1001 (ActMood) = EVN
	templateId	1..1	SHALL		<a href="#">7482</a>	
	@root	1..1	SHALL		<a href="#">10502</a>	2.16.840.1.113883.10.20.22.4.19
	id	1..1	SHALL		<a href="#">7483</a>	
	code	1..1	SHALL		<a href="#">16886</a>	2.16.840.1.113883.3.88.12.3221.7.2 (Problem Type)
	statusCode	1..1	SHALL		<a href="#">7487</a>	
	@code	1..1	SHALL		<a href="#">19105</a>	2.16.840.1.113883.5.14 (ActStatus) = completed
	effectiveTime	0..1	SHOULD		<a href="#">7488</a>	
	value	0..1	SHOULD	CD	<a href="#">7489</a>	
	@nullFlavor	0..1	MAY		<a href="#">15990</a>	
	@code	0..1	SHOULD		<a href="#">15985</a>	2.16.840.1.113883.3.88.12.3221.7.4 (Problem Value Set)

1. **SHALL** contain exactly one [1..1] @classCode="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:7480).
2. **SHALL** contain exactly one [1..1] @moodCode="EVN" (CodeSystem: ActMood 2.16.840.1.113883.5.1001 **STATIC**) (CONF:7481).
3. **SHALL** contain exactly one [1..1] templateId (CONF:7482) such that it
  - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.19" (CONF:10502).
4. **SHALL** contain exactly one [1..1] id (CONF:7483).
  - a. Set the observation/id equal to an ID on the problem list to signify that problem as an indication (CONF:16885).
5. **SHALL** contain exactly one [1..1] code, which **SHOULD** be selected from ValueSet [Problem Type 2.16.840.1.113883.3.88.12.3221.7.2](#) **STATIC** 2012-06-01 (CONF:16886).
6. **SHALL** contain exactly one [1..1] statusCode (CONF:7487).
  - a. This statusCode **SHALL** contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 **STATIC**) (CONF:19105).
7. **SHOULD** contain zero or one [0..1] effectiveTime (CONF:7488).
8. **SHOULD** contain zero or one [0..1] value with @xsi:type="CD" (CONF:7489).

- a. The value, if present, **MAY** contain zero or one [0..1] @nullFlavor (CONF:15990).
  - i. If the diagnosis is unknown or the SNOMED code is unknown, @nullFlavor **SHOULD** be “UNK”. If the code is something other than SNOMED, @nullFlavor **SHOULD** be “OTH” and the other code **SHOULD** be placed in the translation element (CONF:15991).
- b. The value, if present, **SHOULD** contain zero or one [0..1] @code, which **SHOULD** be selected from ValueSet [Problem Value Set 2.16.840.1.113883.3.88.12.3221.7.4 DYNAMIC](#) (CONF:15985).

**Figure 75: Indication example**

```

<observation classCode="OBS" moodCode="EVN">
 <templateId root="2.16.840.1.113883.10.20.22.4.19"/>
 <id root="db734647-fc99-424c-a864-7e3cda82e703" extension="45665"/>
 <code code="404684003"
 displayName="Finding"
 codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT"/>
 <statusCode code="completed"/>
 <effectiveTime>
 <low value="20070103"/>
 </effectiveTime>
 <value xsi:type="CD"
 code="233604007" displayName="Pneumonia"
 codeSystem="2.16.840.1.113883.6.96"/>
</observation>

```

## 4.27 Instructions

**[Closed for comments; published July 2012]**

[act: templateId 2.16.840.1.113883.10.20.22.4.20 (open)]

**Table 128: Instructions Contexts**

Used By:	Contains Entries:
<a href="#">Medication Activity</a> (optional) <a href="#">Medication Supply Order</a> (optional) <a href="#">Procedure Activity Procedure</a> (optional) <a href="#">Plan of Care Section</a> (optional) <a href="#">Procedure Activity Act</a> (optional) <a href="#">Procedure Activity Observation</a> (optional)	

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. Though not defined in this template, a Vaccine Information Statement (VIS) document could be referenced through act/reference/externalDocument, and patient awareness of the instructions can be represented with the generic participant and the participant/awarenessCode.

**Table 129: Instructions Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	act[templateId/@root = '2.16.840.1.113883.10.20.22.4.20']					
	@classCode	1..1	SHALL		<a href="#">7391</a>	2.16.840.1.113883.5.6 (HL7ActClass) = ACT
	@moodCode	1..1	SHALL		<a href="#">7392</a>	2.16.840.1.113883.5.1001 (ActMood) = INT
	templateId	1..1	SHALL		<a href="#">7393</a>	
	@root	1..1	SHALL		<a href="#">10503</a>	2.16.840.1.113883.10.20.22.4.20
	code	1..1	SHALL		<a href="#">16884</a>	2.16.840.1.113883.11.20.9.34 (Patient Education)
	text	0..1	SHOULD		<a href="#">7395</a>	
	reference	0..1	SHOULD		<a href="#">15577</a>	
	@value	0..1	SHOULD		<a href="#">15578</a>	
	statusCode	1..1	SHALL		<a href="#">7396</a>	
	@code	1..1	SHALL		<a href="#">19106</a>	2.16.840.1.113883.5.14 (ActStatus) = completed

1. **SHALL** contain exactly one [1..1] @classCode="ACT" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:7391).
2. **SHALL** contain exactly one [1..1] @moodCode="INT" (CodeSystem: ActMood 2.16.840.1.113883.5.1001 **STATIC**) (CONF:7392).
3. **SHALL** contain exactly one [1..1] templateId (CONF:7393) such that it
  - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.20" (CONF:10503).
4. **SHALL** contain exactly one [1..1] code, which **SHOULD** be selected from ValueSet Patient Education 2.16.840.1.113883.11.20.9.34 **DYNAMIC** (CONF:16884).
5. **SHOULD** contain zero or one [0..1] text (CONF:7395).
  - a. The text, if present, **SHOULD** contain zero or one [0..1] reference (CONF:15577).
    - i. The reference, if present, **SHOULD** contain zero or one [0..1] @value (CONF:15578).
      1. This @value **SHALL** begin with a '#' and **SHALL** point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:15579).
6. **SHALL** contain exactly one [1..1] statusCode (CONF:7396).
  - a. This statusCode **SHALL** contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 **STATIC**) (CONF:19106).

**Table 130: Patient Education Value Set**

Value Set: Patient Education 2.16.840.1.113883.11.20.9.34 DYNAMIC		
Code System: SNOMED-CG 2.16.840.1.113883.6.96		
Code	Code System	Print Name
311401005	SNOMED-CT	Patient Education
171044003	SNOMED-CT	Immunization Education
243072006	SNOMED-CT	Cancer Education

#### 4.27.1 Possible Side Effects

[Act: templateId 2.16.840.1.113883.10.20.30.3.35 (open) ]

**Table 131: Possible Side Effects Contexts**

Used By:	Contains Entries:
<a href="#">Chemotherapy Regimen Plans</a> (optional)	

This clinical statement represents the possible common side effects of breast cancer chemotherapy treatment. It does not seek to represent all possible side effects of any medication the patient may be on.

**Table 132: Possible Side Effects Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
	Act[templateId/@root = '2.16.840.1.113883.10.20.30.3.35']					
	@classCode	1..1	SHALL		<a href="#">24027</a>	2.16.840.1.113883.5.6 (HL7ActClass) = ACT
	@moodCode	1..1	SHALL		<a href="#">24028</a>	2.16.840.1.113883.5.1001 (ActMood) = INT
	templateId	1..1	SHALL		<a href="#">24029</a>	
	@root	1..1	SHALL		<a href="#">24030</a>	2.16.840.1.113883.10.20.30.3.35
	code	1..1	SHALL		<a href="#">24031</a>	
	@code	1..1	SHALL		<a href="#">24032</a>	396080005
	@codeSystem	1..1	SHALL		<a href="#">27083</a>	2.16.840.1.113883.6.96 (SNOMED-CT) = 2.16.840.1.113883.6.96
	entryRelationship	1..*	SHALL		<a href="#">24033</a>	
	@typeCode	1..1	SHALL		<a href="#">24034</a>	2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = SUBJ
	observation	1..1	SHALL		<a href="#">24035</a>	
	code	1..1	SHALL		<a href="#">24036</a>	
	@code	1..1	SHALL		<a href="#">24037</a>	ASSERTION

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
	@codeSystem	1..1	SHALL		<a href="#">27084</a>	2.16.840.1.113883.6.96 (SNOMED-CT) = 2.16.840.1.113883.6.96
	statusCode	1..1	SHALL		<a href="#">24038</a>	
	@code	1..1	SHALL		<a href="#">24039</a>	2.16.840.1.113883.5.14 (ActStatus) = Completed
	value	1..1	SHALL	CD	<a href="#">24040</a>	2.16.840.1.113883.11.20.11.9 (Chemotherapy Side Effects)

1. Conforms to [Instructions](#) template (2.16.840.1.113883.10.20.22.4.20).
2. **SHALL** contain exactly one [1..1] @classCode="ACT" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:24027).
3. **SHALL** contain exactly one [1..1] @moodCode="INT" intent (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:24028).
4. **SHALL** contain exactly one [1..1] templateId (CONF:24029) such that it
  - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.3.35" (CONF:24030).
5. **SHALL** contain exactly one [1..1] code (CONF:24031).
  - a. This code **SHALL** contain exactly one [1..1] @code="396080005" medication side effects education (CONF:24032).
  - b. This code **SHALL** contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.96" (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96) (CONF:27083).
6. **SHALL** contain at least one [1..\*] entryRelationship (CONF:24033) such that it
  - a. **SHALL** contain exactly one [1..1] @typeCode="SUBJ" has subject (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:24034).
  - b. **SHALL** contain exactly one [1..1] observation (CONF:24035).
    - i. This observation **SHALL** contain exactly one [1..1] code (CONF:24036).
      1. This code **SHALL** contain exactly one [1..1] @code="ASSERTION" Assertion (CONF:24037).
      2. This code **SHALL** contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.96" (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96) (CONF:27084).
    - ii. This observation **SHALL** contain exactly one [1..1] statusCode (CONF:24038).
      1. This statusCode **SHALL** contain exactly one [1..1] @code="Completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14) (CONF:24039).

A value observation code of "OTH" is used to communicate side effects not listed in ValueSet table. In these instances, the original text would be sent.

- iii. This observation **SHALL** contain exactly one [1..1] **value** with `@xsi:type="CD"`, where the `@code` **SHOULD** be selected from ValueSet Chemotherapy Side Effects 2.16.840.1.113883.11.20.11.9 **DYNAMIC** (CONF:24040).

**Table 133: Chemotherapy Side Effects Value Set**

Value Set: Chemotherapy Side Effects 2.16.840.1.113883.11.20.11.9 DYNAMIC		
Code System: SNOMED-CT 2.16.840.1.113883.6.96		
Description: Possible common side effects of chemotherapy		
Code	Code System	Print Name
278040002	SNOMED-CT	loss of hair
422587007	SNOMED-CT	nausea
386033004	SNOMED-CT	neuropathy
165423001	SNOMED-CT	red blood cell count low
84229001	SNOMED-CT	fatigue
170951000	SNOMED-CT	menopause symptoms present
415116008	SNOMED-CT	platelet count below reference range (finding)
30238006	SNOMED-CT	secondary female infertility (disorder)
236789001	SNOMED-CT	secondary male infertility (disorder)



**Figure 76: Possible Side Effects example**

```
<!-- Possible Side Effects 2.16.840.1.113883.10.20.30.3.35 -->
<entryRelationship typeCode="SUBJ">
 <!-- Instructions template requires intent mood -->
 <act classCode="ACT" moodCode="INT">
 <!-- C-CDA Instructions Template -->
 <templateId root="2.16.840.1.113883.10.20.22.4.20"/>
 <!-- Possible Side Effects Template -->
 <templateId root="2.16.840.1.113883.10.20.30.3.35"/>
 <code code="396080005"
 displayName="medication side effects education"
 codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMED-CT"/>
 <statusCode code="completed"/>
 <!-- SHALL 1..* entryRelationship (possible side effects) -->
 <entryRelationship typeCode="SUBJ">
 <!-- SHALL observation in definition mood -->
 <observation classCode="OBS" moodCode="DEF">
 <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"/>
 <statusCode code="completed"/>
 <!-- SHOULD bound to value set of common breast cancer regimen
 side effects: e.g., alopecia (hair loss) -->
 <!-- Chemotherapy Side Effects 2.16.840.1.113883.11.20.11.9 -->
 <value xsi:type="CD"
 code="56317004"
 codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMED CT"
 displayName="alopecia"/>
 </observation>
 </entryRelationship>
 </act>
</entryRelationship>
```

**Figure 77: Example of "OTH" for other values with Possible Side Effects**

```
<entryRelationship typeCode="SUBJ">
 <!-- SHALL observation in definition mood -->
 <observation classCode="OBS" moodCode="DEF">
 <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"/>
 <statusCode code="completed"/>
 <!-- SHOULD bound to value set of common breast cancer regimen side
 effects: e.g., alopecia (hair loss) -->
 <!-- Chemotherapy Side Effects 2.16.840.1.113883.11.20.11.9 -->
 <value xsi:type="CD" nullFlavor="OTH">
 <originalText>Intolerance to high pitched noises</originalText>
 </value>
 </observation>
</entryRelationship>
```

## 4.28 Last Menstrual Period

[Observation: templateId 2.16.840.1.113883.10.20.30.3.34 (open)]

**Table 134: Last Menstrual Period Contexts**

Used By:	Contains Entries:
<a href="#">Problem Section BCTPS</a> (required)	

This clinical statement represents the date of menstrual period of the patient. If known, the the first day of last menstrual period should be captured. An effective time is required to determine if the menstrual period occurred before or after treatment.

**Table 135: Last Menstrual Period Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	Observation[templateId/@root = '2.16.840.1.113883.10.20.30.3.34']					
	@classCode	1..1	SHALL		<a href="#">21960</a>	2.16.840.1.113883.5.6 (HL7ActClass) = OBS
	@moodCode	1..1	SHALL		<a href="#">21961</a>	2.16.840.1.113883.5.1001 (ActMood) = EVN
	templateId	1..1	SHALL		<a href="#">21962</a>	
	@root	1..1	SHALL		<a href="#">21963</a>	2.16.840.1.113883.10.20.30.3.34
	id	1..*	SHALL		<a href="#">22066</a>	
	code	1..1	SHALL		<a href="#">21964</a>	
	@code	1..1	SHALL		<a href="#">21965</a>	21840007
	@codeSystem	1..1	SHALL		<a href="#">23237</a>	2.16.840.1.113883.6.96 (SNOMED-CT) = 2.16.840.1.113883.6.96
	statusCode	1..1	SHALL		<a href="#">21966</a>	
	@code	1..1	SHALL		<a href="#">21967</a>	Completed
	effectiveTime	1..1	SHALL		<a href="#">22065</a>	
	value	1..1	SHALL	TS	<a href="#">21968</a>	

1. **SHALL** contain exactly one [1..1] @classCode="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:21960).
2. **SHALL** contain exactly one [1..1] @moodCode="EVN" (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:21961).
3. **SHALL** contain exactly one [1..1] templateId (CONF:21962) such that it
  - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.3.34" (CONF:21963).
4. **SHALL** contain at least one [1..\*] id (CONF:22066).
5. **SHALL** contain exactly one [1..1] code (CONF:21964).
  - a. This code **SHALL** contain exactly one [1..1] @code="21840007" Date of last menstrual period (CONF:21965).

- b. This code **SHALL** contain exactly one [1..1] `@codeSystem="2.16.840.1.113883.6.96"` (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96) (CONF:23237).
- 6. **SHALL** contain exactly one [1..1] `statusCode` (CONF:21966).
  - a. This `statusCode` **SHALL** contain exactly one [1..1] `@code="Completed"` Completed (CONF:21967).
- 7. **SHALL** contain exactly one [1..1] `effectiveTime` (CONF:22065).
- 8. **SHALL** contain exactly one [1..1] `value` with `@xsi:type="TS"` (CONF:21968).

**Figure 78: Last Menstrual Period example**

```
<observation classCode="OBS" moodCode="EVN">
 <templateId root="2.16.840.1.113883.10.20.30.3.34"/>
 <id root="11f83a4d-344e-4c62-ac97-4ef857616562"/>
 <code code="21840007" codeSystem="2.16.840.1.113883.6.1"
 displayName="Date of last menstrual period"/>
 <statusCode code="completed"/>
 <effectiveTime value="20121128"/>
 <value xsi:type="TS" value="20121104"/>
</observation>
```

## 4.29 Medication Activity

**[Closed for comments; published July 2012]**

[substanceAdministration: templateId 2.16.840.1.113883.10.20.22.4.16 (open) ]

**Table 136: Medication Activity Contexts**

Used By:	Contains Entries:
<a href="#">Reaction Observation</a> (optional) <a href="#">Procedure Activity Procedure</a> (optional) <a href="#">Medications Section (entries optional)</a> (optional) <a href="#">Procedure Activity Act</a> (optional) <a href="#">Procedure Activity Observation</a> (optional) <a href="#">Medications Section BCTPS</a> (optional)	<a href="#">Drug Vehicle</a> <a href="#">Indication</a> <a href="#">Instructions</a> <a href="#">Medication Dispense</a> <a href="#">Medication Information</a> <a href="#">Medication Supply Order</a> <a href="#">Precondition for Substance Administration</a> <a href="#">Reaction Observation</a>

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.

**Table 137: Medication Activity Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
Green Medication Activity	substanceAdministration[templateId/@root = '2.16.840.1.113883.10.20.22.4.16']					
	@classCode	1..1	SHALL		<a href="#">7496</a>	2.16.840.1.113883.5.6 (HL7ActClass) = SBADM
	@moodCode	1..1	SHALL		<a href="#">7497</a>	2.16.840.1.113883.11.20.9.18 (MoodCodeEvnInt)
	templateId	1..1	SHALL		<a href="#">7499</a>	
	@root	1..1	SHALL		<a href="#">10504</a>	2.16.840.1.113883.10.20.22.4.16
	id	1..*	SHALL		<a href="#">7500</a>	
delivery Method	code	0..1	MAY		<a href="#">7506</a>	
freeTextSig	text	0..1	SHOULD		<a href="#">7501</a>	
	reference	0..1	SHOULD		<a href="#">15977</a>	
	@value	0..1	SHOULD		<a href="#">15978</a>	
	statusCode	1..1	SHALL		<a href="#">7507</a>	
	effectiveTime	1..1	SHALL		<a href="#">7508</a>	
indicate Medication Started	low	1..1	SHALL		<a href="#">7511</a>	
indicate Medication Stopped	high	1..1	SHALL		<a href="#">7512</a>	
administration Timing	effectiveTime	0..1	SHOULD		<a href="#">7513</a>	
	@operator	1..1	SHALL		<a href="#">9106</a>	A
	repeatNumber	0..1	MAY		<a href="#">7555</a>	
route	routeCode	0..1	MAY		<a href="#">7514</a>	2.16.840.1.113883.3.88.12.3221.8.7 (Medication Route FDA Value Set)
site	approachSiteCode	0..1	MAY	SET< CD>	<a href="#">7515</a>	2.16.840.1.113883.3.88.12.3221.8.9 (Body Site Value Set)
dose	doseQuantity	0..1	SHOULD		<a href="#">7516</a>	
	@unit	0..1	SHOULD		<a href="#">7526</a>	2.16.840.1.113883.1.11.12839 (UnitsOfMeasure CaseSensitive)
	rateQuantity	0..1	MAY		<a href="#">7517</a>	

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
	@unit	1..1	SHALL		<a href="#">7525</a>	2.16.840.1.113883.1.11.12839 (UnitsOfMeasure CaseSensitive)
dose Restriction	maxDoseQuantity	0..1	MAY	RTO< PQ, PQ>	<a href="#">7518</a>	
productForm	administration UnitCode	0..1	MAY		<a href="#">7519</a>	2.16.840.1.113883.3.88.12.3221.8.11 (Medication Product Form Value Set)
medication Information	consumable	1..1	SHALL		<a href="#">7520</a>	
	manufactured Product	1..1	SHALL		<a href="#">16085</a>	
	performer	0..1	MAY		<a href="#">7522</a>	
vehicle	participant	0..*	MAY		<a href="#">7523</a>	
	@typeCode	1..1	SHALL		<a href="#">7524</a>	2.16.840.1.113883.5.90 (HL7Participation Type) = CSM
	participantRole	1..1	SHALL		<a href="#">16086</a>	
indication	entryRelationship	0..*	MAY		<a href="#">7536</a>	
	@typeCode	1..1	SHALL		<a href="#">7537</a>	2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = RSON
	observation	1..1	SHALL		<a href="#">16087</a>	
patient Instructions	entryRelationship	0..1	MAY		<a href="#">7539</a>	
	@typeCode	1..1	SHALL		<a href="#">7540</a>	2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = SUBJ
	@inversionInd	1..1	SHALL		<a href="#">7542</a>	true
	act	1..1	SHALL		<a href="#">16088</a>	
order Information	entryRelationship	0..1	MAY		<a href="#">7543</a>	
	@typeCode	1..1	SHALL		<a href="#">7547</a>	2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = REFR
	supply	1..1	SHALL		<a href="#">16089</a>	
fulfillment Instructions	entryRelationship	0..*	MAY		<a href="#">7549</a>	

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
	@typeCode	1..1	SHALL		<a href="#">7553</a>	2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = REFR
	supply	1..1	SHALL		<a href="#">16090</a>	
reaction	entryRelationship	0..1	MAY		<a href="#">7552</a>	
	@typeCode	1..1	SHALL		<a href="#">7544</a>	2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = CAUS
	observation	1..1	SHALL		<a href="#">16091</a>	
	precondition	0..*	MAY		<a href="#">7546</a>	
	@typeCode	1..1	SHALL		<a href="#">7550</a>	2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = PRCN
	criterion	1..1	SHALL		<a href="#">16092</a>	

1. **SHALL** contain exactly one [1..1] @classCode="SBADM" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:7496).
2. **SHALL** contain exactly one [1..1] @moodCode, which **SHALL** be selected from ValueSet [MoodCodeEvnInt 2.16.840.1.113883.11.20.9.18](#) **STATIC** 2011-04-03 (CONF:7497).
3. **SHALL** contain exactly one [1..1] templateId (CONF:7499) such that it
  - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.16" (CONF:10504).
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).
  - a. The text, if present, **SHOULD** contain zero or one [0..1] reference (CONF:15977).
    - i. The reference, if present, **SHOULD** contain zero or one [0..1] @value (CONF:15978).
      1. This reference/@value **SHALL** begin with a '#' and **SHALL** point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:15979).
7. **SHALL** contain exactly one [1..1] statusCode (CONF:7507).
8. **SHALL** contain exactly one [1..1] effectiveTime (CONF:7508) such that it
  - a. **SHALL** contain exactly one [1..1] low (CONF:7511).
  - b. **SHALL** contain exactly one [1..1] high (CONF:7512).
9. **SHOULD** contain zero or one [0..1] effectiveTime (CONF:7513) such that it
  - a. **SHALL** contain exactly one [1..1] @operator="A" (CONF:9106).

- b. **SHALL** contain exactly one [1..1] @xsi:type="PIVL\_TS" or "EIVL\_TS" (CONF:9105).
10. **MAY** contain zero or one [0..1] **repeatNumber** (CONF:7555).
    - a. 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 substance administration event means that the current administration is the 3rd in a series (CONF:16877).
  11. **MAY** contain zero or one [0..1] **routeCode**, which **SHALL** be selected from ValueSet [Medication Route FDA Value Set 2.16.840.1.113883.3.88.12.3221.8.7](#) **DYNAMIC** (CONF:7514).
  12. **MAY** contain zero or one [0..1] **approachSiteCode**, where the @code **SHALL** be selected from ValueSet [Body Site Value Set 2.16.840.1.113883.3.88.12.3221.8.9](#) **DYNAMIC** (CONF:7515).
  13. **SHOULD** contain zero or one [0..1] **doseQuantity** (CONF:7516).
    - a. The doseQuantity, if present, **SHOULD** contain zero or one [0..1] @unit, which **SHALL** be selected from ValueSet [UnitsOfMeasureCaseSensitive 2.16.840.1.113883.1.11.12839](#) **DYNAMIC** (CONF:7526).
    - b. Pre-coordinated consumable: If the consumable code is a pre-coordinated 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") (CONF:16878).
    - c. 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:16879).
  14. **MAY** contain zero or one [0..1] **rateQuantity** (CONF:7517).
    - a. The rateQuantity, if present, **SHALL** contain exactly one [1..1] @unit, which **SHALL** be selected from ValueSet [UnitsOfMeasureCaseSensitive 2.16.840.1.113883.1.11.12839](#) **DYNAMIC** (CONF:7525).
  15. **MAY** contain zero or one [0..1] **maxDoseQuantity** (CONF:7518).
  16. **MAY** contain zero or one [0..1] **administrationUnitCode**, which **SHALL** be selected from ValueSet [Medication Product Form Value Set 2.16.840.1.113883.3.88.12.3221.8.11](#) **DYNAMIC** (CONF:7519).
  17. **SHALL** contain exactly one [1..1] **consumable** (CONF:7520).
    - a. This consumable **SHALL** contain exactly one [1..1] [Medication Information \(templateId:2.16.840.1.113883.10.20.22.4.23\)](#) (CONF:16085).
  18. **MAY** contain zero or one [0..1] **performer** (CONF:7522).
  19. **MAY** contain zero or more [0..\*] **participant** (CONF:7523) such that it
    - a. **SHALL** contain exactly one [1..1] @typeCode="CSM" (CodeSystem: [HL7ParticipationType 2.16.840.1.113883.5.90](#) **STATIC**) (CONF:7524).
    - b. **SHALL** contain exactly one [1..1] [Drug Vehicle \(templateId:2.16.840.1.113883.10.20.22.4.24\)](#) (CONF:16086).
  20. **MAY** contain zero or more [0..\*] **entryRelationship** (CONF:7536) such that it

- a. **SHALL** contain exactly one [1..1] @typeCode="RSON" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**) (CONF:7537).
  - b. **SHALL** contain exactly one [1..1] Indication (templateId:2.16.840.1.113883.10.20.22.4.19) (CONF:16087).
21. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:7539) such that it
- a. **SHALL** contain exactly one [1..1] @typeCode="SUBJ" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**) (CONF:7540).
  - b. **SHALL** contain exactly one [1..1] @inversionInd="true" True (CONF:7542).
  - c. **SHALL** contain exactly one [1..1] Instructions (templateId:2.16.840.1.113883.10.20.22.4.20) (CONF:16088).
22. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:7543) such that it
- a. **SHALL** contain exactly one [1..1] @typeCode="REFR" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**) (CONF:7547).
  - b. **SHALL** contain exactly one [1..1] Medication Supply Order (templateId:2.16.840.1.113883.10.20.22.4.17) (CONF:16089).
23. **MAY** contain zero or more [0..\*] **entryRelationship** (CONF:7549) such that it
- a. **SHALL** contain exactly one [1..1] @typeCode="REFR" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**) (CONF:7553).
  - b. **SHALL** contain exactly one [1..1] Medication Dispense (templateId:2.16.840.1.113883.10.20.22.4.18) (CONF:16090).
24. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:7552) such that it
- a. **SHALL** contain exactly one [1..1] @typeCode="CAUS" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**) (CONF:7544).
  - b. **SHALL** contain exactly one [1..1] Reaction Observation (templateId:2.16.840.1.113883.10.20.22.4.9) (CONF:16091).
25. **MAY** contain zero or more [0..\*] **precondition** (CONF:7546) such that it
- a. **SHALL** contain exactly one [1..1] @typeCode="PRCN" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**) (CONF:7550).
  - b. **SHALL** contain exactly one [1..1] Precondition for Substance Administration (templateId:2.16.840.1.113883.10.20.22.4.25) (CONF:16092).
26. Medication Activity **SHOULD** include doseQuantity OR rateQuantity (CONF:7529).



**Table 138: MoodCodeEvnInt Value Set**

Value Set: MoodCodeEvnInt 2.16.840.1.113883.11.20.9.18 STATIC		
Code System(s): ActMood 2.16.840.1.113883.5.1001		
Code	Code System	Print Name
EVN	ActMood	Event
INT	ActMood	Intent

**Table 139: Medication Route FDA Value Set (excerpt)**

Value Set: Medication Route FDA Value Set 2.16.840.1.113883.3.88.12.3221.8.7 DYNAMIC		
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 <a href="http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162034.htm">http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162034.htm</a>	
Code	Code System	Print Name
C38229	NCI Thesaurus	INTRACAUDAL
C38276	NCI Thesaurus	INTRAVENOUS
C38288	NCI Thesaurus	ORAL
C38295	NCI Thesaurus	RECTAL
...		

**Table 140: Body Site Value Set (excerpt)**

Value Set: Body Site Value Set 2.16.840.1.113883.3.88.12.3221.8.9 DYNAMIC		
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.	
Reference:	<a href="http://www.nlm.nih.gov/research/umls/Snomed/snomed_main.html">http://www.nlm.nih.gov/research/umls/Snomed/snomed_main.html</a>	
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 141: Unit of Measure Value Set (excerpt)**

Value Set: UCUM Units of Measure (case sensitive) 2.16.840.1.113883.1.11.12839 DYNAMIC		
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.		
Reference: <a href="http://www.regenstrief.org/medinformatics/ucum">http://www.regenstrief.org/medinformatics/ucum</a>		
Code	Code System	Print Name
mmol/kg	UCUM	MilliMolesPerKiloGram
fL	UCUM	FemtoLiter
ug/mL	UCUM	MicroGramsPerMilliLiter
...		

**Table 142: Medication Product Form Value Set (excerpt)**

Value Set: Medication Product Form 2.16.840.1.113883.3.88.12.3221.8.11 DYNAMIC		
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.		
Reference: <a href="http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162038.htm">http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162038.htm</a>		
Code	Code System	Print Name
C42887	NCI Thesaurus	AEROSOL
C42909	NCI Thesaurus	GRANULE, EFFERVESCENT
C42998	NCI Thesaurus	TABLET
...		

#### 4.29.1 Chemotherapy Medication Activity

[SubstanceAdministration: templateId 2.16.840.1.113883.10.20.30.3.44 (open) ]

**Table 143: Chemotherapy Medication Activity Contexts**

Used By:	Contains Entries:
<a href="#">Medications Section BCTPS</a> (required)	<a href="#">Chemotherapy Protocol Reference</a> <a href="#">Clinical Drug Trial</a> <a href="#">Medication Information</a> <a href="#">Reaction Observation</a>

This clinical statement represents needed elements and attributes when communicating chemotherapeutic medications. The specific chemotherapeutic agents are not specified, but attributes such as `repeatNumber`, to note the cycle, dose, and route are required.

This template represents administered agents as the administration would be recorded in a Medication Administration Record (MAR); as such, the second recommended effectiveTime used to represent periodic intervals is not useful.

**Table 144: Chemotherapy Medication Activity Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
	SubstanceAdministration[templateId/@root = '2.16.840.1.113883.10.20.30.3.44']					
	@classCode	1..1	SHALL		<a href="#">23845</a>	2.16.840.1.113883.5.6 (HL7ActClass) = SBADM
	@moodCode	1..1	SHALL		<a href="#">23846</a>	2.16.840.1.113883.5.1001 (ActMood) = EVN
	templateId	1..1	SHALL		<a href="#">23847</a>	
	@root	1..1	SHALL		<a href="#">23848</a>	2.16.840.1.113883.10.20.30.3.44
	statusCode	1..1	SHALL		<a href="#">23849</a>	
	@code	1..1	SHALL		<a href="#">23850</a>	2.16.840.1.113883.5.14 (ActStatus) = Completed
	effectiveTime	1..1	SHALL	IVL_T S	<a href="#">26227</a>	
	low	1..1	SHALL		<a href="#">26228</a>	
	high	1..1	SHALL		<a href="#">26229</a>	
	repeatNumber	1..1	SHALL		<a href="#">27319</a>	
	routeCode	1..1	SHALL		<a href="#">23851</a>	
	@code	1..1	SHALL		<a href="#">23852</a>	2.16.840.1.113883.3.88.12.3221.8.7 (Medication Route FDA Value Set)
	doseQuantity	1..1	SHALL		<a href="#">23853</a>	
	@value	1..1	SHALL		<a href="#">27320</a>	
	@unit	1..1	SHALL		<a href="#">27321</a>	
	consumable	1..1	SHALL		<a href="#">23855</a>	
	entry Relationship	0..*	MAY		<a href="#">27322</a>	
	@typeCode	1..1	SHALL		<a href="#">27323</a>	2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = REFR
	act	1..1	SHALL		<a href="#">27324</a>	
	entry Relationship	0..*	MAY		<a href="#">27325</a>	
	@typeCode	1..1	SHALL		<a href="#">27326</a>	2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = REFR
	observation	1..1	SHALL		<a href="#">27327</a>	
	entry Relationship	0..*	MAY		<a href="#">27343</a>	

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
	@typeCode	1..1	SHALL		<a href="#">27345</a>	2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = REFR
	act	1..1	SHALL		<a href="#">27346</a>	

1. Conforms to [Medication Activity](#) template (2.16.840.1.113883.10.20.22.4.16).
2. **SHALL** contain exactly one [1..1] @classCode="SBADM" SubstanceAdministration (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:23845).
3. **SHALL** contain exactly one [1..1] @moodCode="EVN" event (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:23846).
4. **SHALL** contain exactly one [1..1] templateId (CONF:23847) such that it
  - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.3.44" (CONF:23848).
5. **SHALL** contain exactly one [1..1] statusCode (CONF:23849).
  - a. This statusCode **SHALL** contain exactly one [1..1] @code="Completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14) (CONF:23850).
6. **SHALL** contain exactly one [1..1] effectiveTime (CONF:26227) such that it
  - a. **SHALL** contain exactly one [1..1] low (CONF:26228).
  - b. **SHALL** contain exactly one [1..1] high (CONF:26229).
7. **SHALL** contain exactly one [1..1] repeatNumber (CONF:27319).
8. **SHALL** contain exactly one [1..1] routeCode (CONF:23851).
  - a. This routeCode **SHALL** contain exactly one [1..1] @code (ValueSet: [Medication Route FDA Value Set 2.16.840.1.113883.3.88.12.3221.8.7 DYNAMIC](#)) (CONF:23852).
9. **SHALL** contain exactly one [1..1] doseQuantity (CONF:23853).
  - a. This doseQuantity **SHALL** contain exactly one [1..1] @value (CONF:27320).
  - b. This doseQuantity **SHALL** contain exactly one [1..1] @unit (CONF:27321).
10. **SHALL** contain exactly one [1..1] [Medication Information](#) (templateId:2.16.840.1.113883.10.20.22.4.23) (CONF:23855).
11. **MAY** contain zero or more [0..\*] entryRelationship (CONF:27322) such that it
  - a. **SHALL** contain exactly one [1..1] @typeCode="REFR" Refers to (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:27323).
  - b. **SHALL** contain exactly one [1..1] [Clinical Drug Trial](#) (templateId:2.16.840.1.113883.10.20.30.3.4) (CONF:27324).

The Reaction Observation template represents reactions or toxicities to the chemotherapeutic drug. The reaction may or may not be expected and may or may not be a reason to discontinue or adjust the dose of an agent.

12. **MAY** contain zero or more [0..\*] entryRelationship (CONF:27325) such that it

- a. **SHALL** contain exactly one [1..1] @typeCode="REFR" Refers to (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:27326).
  - b. **SHALL** contain exactly one [1..1] [Reaction Observation](#) (templateId:2.16.840.1.113883.10.20.22.4.9) (CONF:27327).
13. **MAY** contain zero or more [0..\*] **entryRelationship** (CONF:27343) such that it
- a. **SHALL** contain exactly one [1..1] @typeCode="REFR" refers to (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:27345).
14. **SHALL** contain exactly one [1..1] [Chemotherapy Protocol Reference](#) (templateId:2.16.840.1.113883.10.20.30.3.50) (CONF:27346).

**Figure 79: Chemotherapy Medication Activity example**

```

<substanceAdministration classCode="SBADM" moodCode="EVN">
 <!-- Consolidated CDA Medication Activity templateID -->
 <templateId root="2.16.840.1.113883.10.20.22.4.16"/>
 <!-- Chemotherapy Medication Activity 2.16.840.1.113883.10.20.30.3.44-->
 <templateId root="2.16.840.1.113883.10.20.30.3.44"/>
 <id root="39c22143-e9f2-42b7-b117-d1f0d454b0d9"/>
 <statusCode code="completed"/>
 <!-- Administered Over 1 hour on January 6, 2013 from 1300 to 1400-->
 <effectiveTime xsi:type="IVL_TS">
 <low value="201301061300"/>
 <high value="201301061400"/>
 </effectiveTime>
 <!-- In "EVN" (event) mood, the repeatNumber is the number of occurrences.
 Repeat Number of 1 here means that this dose is the cycle of the chemo
 drug-->
 <!-- SHALL REPEAT NUMBER -->
 <repeatNumber value="1"/>
 <!-- 2nd (SHOULD) effectiveTime is intentionally absent - the med won't be
 given for another 21 days (if tolerated well). The first effectiveTime
 is used and is what would be available in from an MAR -->
 <!-- SHALL [1..1] route -->
 <routeCode code="C38276"
 displayName="intravenous"
 codeSystem="2.16.840.1.113883.3.26.1.1"
 codeSystemName="National Cancer Institute (NCI) Thesaurus"/>
 <!--Dose documented on an MAR would be actual mg given, not mg/m2 - though
 it is ordered in mg/m2-->
 <doseQuantity value="68.5" unit="mg"/>

```

```

<consumable>
 <manufacturedProduct classCode="MANU">
 <!-- SHALL Consolidated CDA Medication Information
 manufacturedMaterial) -->
 <templateId root="2.16.840.1.113883.10.20.22.4.23"/>
 <manufacturedMaterial>
 <code codeSystem="2.16.840.1.113883.6.88"
 codeSystemName="RxNorm" code="107037"
 displayName="Doxorubicin 1 MG/ML Irrigation Solution">
 <originalText>Doxorubicin 1 MG/ML Irrigation
 Solution</originalText>
 </code>
 <!-- Brand Name -->
 <name>Adriamycin</name>
 </manufacturedMaterial>
 </manufacturedProduct>
</consumable>
<!-- MAY contain information indicating the chemotherapy regimen protocol
reference -->
<entryRelationship typeCode="REFR">
 <act classCode="ACT" moodCode="EVN">
 <!-- Chemotherapy Protocol Reference template ID -->
 <templateId root="2.16.840.1.113883.10.20.30.3.50"/>
 ...
 </act>
</entryRelationship>
<!-- MAY contain information indicating the chemotherapy treatment is part
of a clinical trial -->
<entryRelationship typeCode="REFR">
 <act classCode="ACT" moodCode="EVN">
 <!-- Clinical drug trial -->
 <templateId root="2.16.840.1.113883.10.20.30.3.4"/>
 ...
 </act>
</entryRelationship>
<!-- MAY C-CDA Reaction Observation -->
<entryRelationship typeCode="MFST" inversionInd="true">
 <observation classCode="OBS" moodCode="EVN">
 <!-- C-CDA Reaction Observation 2.16.840.1.113883.10.20.22.4.9 -->
 <templateId root="2.16.840.1.113883.10.20.22.4.9"/>
 ...
 </observation>
</entryRelationship>
</substanceAdministration>

```

## 4.30 Medication Dispense

[Closed for comments; published July 2012]

[supply: templateId 2.16.840.1.113883.10.20.22.4.18 (open)]

**Table 145: Medication Dispense Contexts**

Used By:	Contains Entries:
<a href="#">Medication Activity</a> (optional)	<a href="#">Immunization Medication Information</a> <a href="#">Medication Information</a> <a href="#">Medication Supply Order</a>

This template records the act of supplying medications (i.e., dispensing).

**Table 146: Medication Dispense Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
Green Medication Dispense	supply[templateId/@root = '2.16.840.1.113883.10.20.22.4.18']					
	@classCode	1..1	SHALL		<a href="#">7451</a>	2.16.840.1.113883.5.6 (HL7ActClass) = SPLY
	@moodCode	1..1	SHALL		<a href="#">7452</a>	2.16.840.1.113883.5.1001 (ActMood) = EVN
	templateId	1..1	SHALL		<a href="#">7453</a>	
	@root	1..1	SHALL		<a href="#">10505</a>	2.16.840.1.113883.10.20.22.4.18
prescription Number	id	1..*	SHALL		<a href="#">7454</a>	
	statusCode	1..1	SHALL		<a href="#">7455</a>	2.16.840.1.113883.3.88.12.80.64 (Medication Fill Status)
dispense Date	effectiveTime	0..1	SHOULD		<a href="#">7456</a>	
fillNumber	repeatNumber	0..1	SHOULD		<a href="#">7457</a>	
quantity Dispensed	quantity	0..1	SHOULD		<a href="#">7458</a>	
	product	0..1	MAY		<a href="#">7459</a>	
	manufactured Product	1..1	SHALL		<a href="#">15607</a>	
	product	0..1	MAY		<a href="#">9331</a>	
	manufactured Product	1..1	SHALL		<a href="#">15608</a>	
	performer	0..1	MAY		<a href="#">7461</a>	
provider	assignedEntity	1..1	SHALL		<a href="#">7467</a>	
	addr	0..1	SHOULD		<a href="#">7468</a>	

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
order Information	entryRelationship	0..1	MAY		<a href="#">7473</a>	
	@typeCode	1..1	SHALL		<a href="#">7474</a>	2.16.840.1.113883.5.1002 (HL7ActRelationship Type) = REFR
	supply	1..1	SHALL		<a href="#">15606</a>	

1. **SHALL** contain exactly one [1..1] @classCode="SPLY" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:7451).
2. **SHALL** contain exactly one [1..1] @moodCode="EVN" (CodeSystem: ActMood 2.16.840.1.113883.5.1001 **STATIC**) (CONF:7452).
3. **SHALL** contain exactly one [1..1] templateId (CONF:7453) such that it
  - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.18" (CONF:10505).
4. **SHALL** contain at least one [1..\*] id (CONF:7454).
5. **SHALL** contain exactly one [1..1] statusCode, which **SHALL** be selected from ValueSet Medication Fill Status 2.16.840.1.113883.3.88.12.80.64 **DYNAMIC** (CONF:7455).
6. **SHOULD** contain zero or one [0..1] effectiveTime (CONF:7456).
7. **SHOULD** contain zero or one [0..1] repeatNumber (CONF:7457).
  - a. 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 (CONF:16876).
8. **SHOULD** contain zero or one [0..1] quantity (CONF:7458).
9. **MAY** contain zero or one [0..1] product (CONF:7459) such that it
  - a. **SHALL** contain exactly one [1..1] [Medication Information](#) (templateId:2.16.840.1.113883.10.20.22.4.23) (CONF:15607).
10. **MAY** contain zero or one [0..1] product (CONF:9331) such that it
  - a. **SHALL** contain exactly one [1..1] [Immunization Medication Information](#) (templateId:2.16.840.1.113883.10.20.22.4.54) (CONF:15608).
11. **MAY** contain zero or one [0..1] performer (CONF:7461).
  - a. The performer, if present, **SHALL** contain exactly one [1..1] assignedEntity (CONF:7467).
    - i. This assignedEntity **SHOULD** contain zero or one [0..1] addr (CONF:7468).
      1. The content of addr **SHALL** be a conformant US Realm Address (AD.US.FIELDDED) (2.16.840.1.113883.10.20.22.5.2) (CONF:10565).
12. **MAY** contain zero or one [0..1] entryRelationship (CONF:7473) such that it
  - a. **SHALL** contain exactly one [1..1] @typeCode="REFR" (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**) (CONF:7474).



- b. **SHALL** contain exactly one [1..1] [Medication Supply Order](#) (templateId:2.16.840.1.113883.10.20.22.4.17) (CONF:15606).

13. A supply act **SHALL** contain one product/Medication Information or one product/Immunization Medication Information template (CONF:9333).

**Table 147: Medication Fill Status Value Set**

Value Set: Medication Fill Status 2.16.840.1.113883.3.88.12.80.64 DYNAMIC		
Code System: ActStatus 2.16.840.1.113883.5.14		
Code	Code System	Print Name
aborted	ActStatus	Aborted
completed	ActStatus	Completed

**Figure 80: Medication Dispense example**

```

<supply classCode="SPLY" moodCode="EVN">
 <templateId root="2.16.840.1.113883.10.20.22.4.18"/>
 <id root="1.2.3.4.56789.1" extension="cb734647-fc99-424c-a864-7e3cda82e704"/>
 <statusCode code="completed"/>
 <effectiveTime value="20070103"/>
 <repeatNumber value="1"/>
 <quantity value="75"/>
 <product>
 <manufacturedProduct classCode="MANU">
 <templateId root="2.16.840.1.113883.10.20.22.4.23"/>
 <id root="2a620155-9d11-439e-92b3-5d9815ff4ee8"/>
 <manufacturedMaterial>
 <code code="573621" codeSystem="2.16.840.1.113883.6.88"
 displayName="Proventil 0.09 MG/ACTUAT inhalant solution">
 <originalText>
 <reference value="#MedSec_1" />
 </originalText>
 <translation code="573621"
 displayName="Proventil 0.09 MG/ACTUAT inhalant solution"
 codeSystem="2.16.840.1.113883.6.88" codeSystemName="RxNorm" />
 </code>
 </manufacturedMaterial>
 <manufacturerOrganization>
 <name>Medication Factory Inc.</name>
 </manufacturerOrganization>
 </manufacturedProduct>
 </product>

```

```

<performer>
 <time nullFlavor="UNK" />
 <assignedEntity>
 <id root="2.16.840.1.113883.19.5.9999.456" extension="2981823" />
 <addr>
 <streetAddressLine>1001 Village Avenue</streetAddressLine>
 <city>Portland</city>
 <state>OR</state>
 <postalCode>99123</postalCode>
 <country>US</country>
 </addr>
 <telecom nullFlavor="UNK" />
 <assignedPerson>
 <name>
 <prefix>Dr.</prefix>
 <given>Henry</given>
 <family>Seven</family>
 </name>
 </assignedPerson>
 <representedOrganization>
 <id root="2.16.840.1.113883.19.5.9999.1393" />
 <name>Community Health and Hospitals</name>
 <telecom nullFlavor="UNK" />
 <addr nullFlavor="UNK" />
 </representedOrganization>
 </assignedEntity>
</performer>
</supply>

```

### 4.31 Medication Information [Closed for comments; published July 2012]

[manufacturedProduct: templateId 2.16.840.1.113883.10.20.22.4.23  
(open)]

**Table 148: Medication Information Contexts**

Used By:	Contains Entries:
<a href="#">Medication Activity</a> (required) <a href="#">Medication Supply Order</a> (optional) <a href="#">Medication Dispense</a> (optional) <a href="#">Chemotherapy Medication Activity</a> (required) <a href="#">Chemotherapy Medication Activity Plan</a> (required)	

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

**Table 149: Medication Information Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
Green Medication Information	manufacturedProduct[templateId/@root = '2.16.840.1.113883.10.20.22.4.23']					
	@classCode	1..1	SHALL		<a href="#">7408</a>	2.16.840.1.113883.5.110 (RoleClass) = MANU
	templateId	1..1	SHALL		<a href="#">7409</a>	
	@root	1..1	SHALL		<a href="#">10506</a>	2.16.840.1.113883.10.20.22.4.23
	id	0..*	MAY		<a href="#">7410</a>	
	manufacturedMaterial	1..1	SHALL		<a href="#">7411</a>	
codedProduct Name	code	1..1	SHALL		<a href="#">7412</a>	2.16.840.1.113883.3.88.12.80.17 (Medication Clinical Drug Name Value Set)
freeText ProductName	originalText	0..1	SHOULD		<a href="#">7413</a>	
	reference	0..1	SHOULD		<a href="#">15986</a>	
	@value	0..1	SHOULD		<a href="#">15987</a>	
codedBrand Name	translation	0..*	MAY	SET<PQR>	<a href="#">7414</a>	
drug Manufacturer	manufacturer Organization	0..1	MAY		<a href="#">7416</a>	

1. **SHALL** contain exactly one [1..1] **@classCode**="MANU" (CodeSystem: RoleClass 2.16.840.1.113883.5.110 **STATIC**) (CONF:7408).
2. **SHALL** contain exactly one [1..1] **templateId** (CONF:7409) such that it
  - a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.4.23" (CONF:10506).
3. **MAY** contain zero or more [0..\*] **id** (CONF:7410).
4. **SHALL** contain exactly one [1..1] **manufacturedMaterial** (CONF:7411).
  - a. This **manufacturedMaterial** **SHALL** contain exactly one [1..1] **code**, which **SHALL** be selected from ValueSet Medication Clinical Drug Name Value Set 2.16.840.1.113883.3.88.12.80.17 **DYNAMIC** (CONF:7412).
    - i. This **code** **SHOULD** contain zero or one [0..1] **originalText** (CONF:7413).
      1. The **originalText**, if present, **SHOULD** contain zero or one [0..1] **reference** (CONF:15986).
        - a. The **reference**, if present, **SHOULD** contain zero or one [0..1] **@value** (CONF:15987).

- i. This reference/@value **SHALL** begin with a '#' and **SHALL** point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:15988).
    - ii. 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:16875).
- 5. **MAY** contain zero or one [0..1] **manufacturerOrganization** (CONF:7416).

**Figure 81: Medication Information example**

```

<manufacturedProduct classCode="MANU">
 <templateId root="2.16.840.1.113883.10.20.22.4.23"/>
 <id root="2a620155-9d11-439e-92b3-5d9815ff4ee8"/>
 <manufacturedMaterial>
 <code code="219483"
 codeSystem="2.16.840.1.113883.6.88"
 displayName="ProventilHFA">
 <originalText>
 <reference value="#MedSec_1" />
 </originalText>
 <translation code="219483"
 displayName="Proventil HFA"
 codeSystem="2.16.840.1.113883.6.88"
 codeSystemName="RxNorm" />
 </code>
 </manufacturedMaterial>
 <manufacturerOrganization>
 <name>Medication Factory Inc.</name>
 </manufacturerOrganization>
</manufacturedProduct>

```

### 4.32 Medication Supply Order [Closed for comments; published July 2012]

[supply: templateId 2.16.840.1.113883.10.20.22.4.17 (open)]

**Table 150: Medication Supply Order Contexts**

Used By:	Contains Entries:
<a href="#">Medication Activity</a> (optional) <a href="#">Medication Dispense</a> (optional)	<a href="#">Immunization Medication Information</a> <a href="#">Instructions</a> <a href="#">Medication Information</a>

This template records the intent to supply a patient with medications.

**Table 151: Medication Supply Order Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
	supply[templateId/@root = '2.16.840.1.113883.10.20.22.4.17']					
	@classCode	1..1	SHALL		<a href="#">7427</a>	2.16.840.1.113883.5.6 (HL7ActClass) = SPLY
	@moodCode	1..1	SHALL		<a href="#">7428</a>	2.16.840.1.113883.5.1001 (ActMood) = INT
	templateId	1..1	SHALL		<a href="#">7429</a>	
	@root	1..1	SHALL		<a href="#">10507</a>	2.16.840.1.113883.10.20.22.4.17
	id	1..*	SHALL		<a href="#">7430</a>	
	statusCode	1..1	SHALL		<a href="#">7432</a>	
	effectiveTime	0..1	SHOULD	IVL_TS	<a href="#">15143</a>	
	high	1..1	SHALL		<a href="#">15144</a>	
	repeatNumber	0..1	SHOULD		<a href="#">7434</a>	
	quantity	0..1	SHOULD		<a href="#">7436</a>	
	product	0..1	MAY		<a href="#">7439</a>	
	manufactured Product	1..1	SHALL		<a href="#">16093</a>	
	product	0..1	MAY		<a href="#">9334</a>	
	manufactured Product	1..1	SHALL		<a href="#">16094</a>	
	author	0..1	MAY		<a href="#">7438</a>	
	entryRelationship	0..1	MAY		<a href="#">7442</a>	
	@typeCode	1..1	SHALL		<a href="#">7444</a>	2.16.840.1.113883.5.1002 (HL7ActRelationship Type) = SUBJ
	@inversionInd	1..1	SHALL		<a href="#">7445</a>	true
	act	1..1	SHALL		<a href="#">16095</a>	

1. **SHALL** contain exactly one [1..1] @classCode="SPLY" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:7427).
2. **SHALL** contain exactly one [1..1] @moodCode="INT" (CodeSystem: ActMood 2.16.840.1.113883.5.1001 **STATIC**) (CONF:7428).
3. **SHALL** contain exactly one [1..1] templateId (CONF:7429) such that it
  - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.17" (CONF:10507).
4. **SHALL** contain at least one [1..\*] id (CONF:7430).
5. **SHALL** contain exactly one [1..1] statusCode (CONF:7432).
6. **SHOULD** contain zero or one [0..1] effectiveTime (CONF:15143) such that it
  - a. **SHALL** contain exactly one [1..1] high (CONF:15144).

7. **SHOULD** contain zero or one [0..1] **repeatNumber** (CONF:7434).
  - a. 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:16869).
8. **SHOULD** contain zero or one [0..1] **quantity** (CONF:7436).
9. **MAY** contain zero or one [0..1] **product** (CONF:7439) such that it
  - a. **SHALL** contain exactly one [1..1] **Medication Information** (templateId:2.16.840.1.113883.10.20.22.4.23) (CONF:16093).
10. **MAY** contain zero or one [0..1] **product** (CONF:9334) such that it
  - a. **SHALL** contain exactly one [1..1] **Immunization Medication Information** (templateId:2.16.840.1.113883.10.20.22.4.54) (CONF:16094).
    - i. A supply act **SHALL** contain one product/Medication Information or one product/Immunization Medication Information template (CONF:16870).
11. **MAY** contain zero or one [0..1] **author** (CONF:7438).
12. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:7442).
  - a. The entryRelationship, if present, **SHALL** contain exactly one [1..1] **@typeCode="SUBJ"** (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**) (CONF:7444).
  - b. The entryRelationship, if present, **SHALL** contain exactly one [1..1] **@inversionInd="true"** True (CONF:7445).
  - c. The entryRelationship, if present, **SHALL** contain exactly one [1..1] **Instructions** (templateId:2.16.840.1.113883.10.20.22.4.20) (CONF:16095).

**Figure 82: Medication Supply Order example**

```

<supply classCode="SPLY" moodCode="INT">
 <templateId root="2.16.840.1.113883.10.20.22.4.17" />
 <id nullFlavor="NI" />
 <statusCode code="completed" />
 <effectiveTime xsi:type="IVL_TS">
 <low value="20070103" />
 <high nullFlavor="UNK" />
 </effectiveTime>
 <repeatNumber value="1" />
 <quantity value="75" />
 <product>
 <manufacturedProduct classCode="MANU">
 <templateId root="2.16.840.1.113883.10.20.22.4.23" />
 ...
 </manufacturedProduct>
 </product>

```

```

<performer>
 <assignedEntity>
 <id extension="2981823" root="2.16.840.1.113883.19.5.9999.456" />
 <addr>
 <streetAddressLine>1001 Village Avenue</streetAddressLine>
 <city>Portland</city>
 <state>OR</state>
 <postalCode>99123</postalCode>
 <country>US</country>
 </addr>
 </assignedEntity>
</performer>
<author>
 <time nullFlavor="UNK" />
 <assignedAuthor>
 <id root="2a620155-9d11-439e-92b3-5d9815fe4de8" />
 <addr nullFlavor="UNK" />
 <telecom nullFlavor="UNK" />
 <assignedPerson>
 <name>
 <prefix>Dr.</prefix>
 <given>Henry</given>
 <family>Seven</family>
 </name>
 </assignedPerson>
 </assignedAuthor>
</author>
<entryRelationship typeCode="SUBJ"
 inversionInd="true">
 <act classCode="ACT" moodCode="INT">
 <templateId root="2.16.840.1.113883.10.20.22.4.20" />
 <!-- ** Instructions Template ** -->
 ...
 </act>
</entryRelationship>
</supply>

```

### 4.33 Non-Medicinal Supply Activity [Closed for comments; published July 2012]

[supply: templateId 2.16.840.1.113883.10.20.22.4.50 (open)]

**Table 152: Non-Medicinal Supply Activity Contexts**

Used By:	Contains Entries:
<a href="#">Functional Status Section</a> (optional) <a href="#">Functional Status Result Observation</a> (optional) <a href="#">Cognitive Status Result Observation</a> (optional) <a href="#">Functional Status Problem Observation</a> (optional) <a href="#">Cognitive Status Problem Observation</a> (optional)	<a href="#">Product Instance</a>

This template records non-medicinal supplies provided, such as medical equipment

**Table 153: Non-Medicinal Supply Activity Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
	supply[templateId/@root = '2.16.840.1.113883.10.20.22.4.50']					
	@classCode	1..1	SHALL		<a href="#">8745</a>	2.16.840.1.113883.5.6 (HL7ActClass) = SPLY
	@moodCode	1..1	SHALL		<a href="#">8746</a>	2.16.840.1.113883.11.20.9.18 (MoodCodeEvnInt)
	templateId	1..1	SHALL		<a href="#">8747</a>	
	@root	1..1	SHALL		<a href="#">10509</a>	2.16.840.1.113883.10.20.22.4.50
	id	1..*	SHALL		<a href="#">8748</a>	
	statusCode	1..1	SHALL		<a href="#">8749</a>	
	effectiveTime	0..1	SHOULD	IVL_TS	<a href="#">15498</a>	
	quantity	0..1	SHOULD		<a href="#">8751</a>	
	participant	0..1	MAY		<a href="#">8752</a>	
	@typeCode	1..1	SHALL		<a href="#">8754</a>	2.16.840.1.113883.5.90 (HL7ParticipationType) = PRD
	participantRole	1..1	SHALL		<a href="#">15900</a>	

1. **SHALL** contain exactly one [1..1] @classCode="SPLY" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:8745).
2. **SHALL** contain exactly one [1..1] @moodCode, which **SHALL** be selected from ValueSet [MoodCodeEvnInt 2.16.840.1.113883.11.20.9.18](#) **STATIC** 2011-04-03 (CONF:8746).
3. **SHALL** contain exactly one [1..1] templateId (CONF:8747) such that it
  - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.50" (CONF:10509).
4. **SHALL** contain at least one [1..\*] id (CONF:8748).
5. **SHALL** contain exactly one [1..1] statusCode (CONF:8749).
6. **SHOULD** contain zero or one [0..1] effectiveTime (CONF:15498).
  - a. The effectiveTime, if present, **SHOULD** contain zero or one [0..1] high (CONF:16867).
7. **SHOULD** contain zero or one [0..1] quantity (CONF:8751).
8. **MAY** contain zero or one [0..1] participant (CONF:8752) such that it
  - a. **SHALL** contain exactly one [1..1] @typeCode="PRD" Product (CodeSystem: HL7ParticipationType 2.16.840.1.113883.5.90 **STATIC**) (CONF:8754).
  - b. **SHALL** contain exactly one [1..1] [Product Instance](#) (templateId:2.16.840.1.113883.10.20.22.4.37) (CONF:15900).



**Figure 83: Non-Medicinal Supply Activity example**

```

<supply classCode="SPLY" moodCode="EVN">
 <templateId root="2.16.840.1.113883.10.20.22.4.50"/>
 <!-- Non-medicinal supply activity template ***** -->
 <id root="2413773c-2372-4299-bbe6-5b0f60664446"/>
 <statusCode code="completed"/>
 <effectiveTime xsi:type="IVL_TS">
 <high value="199911"/>
 </effectiveTime>
 <quantity value="2"/>
 <participant typeCode="PRD">
 <participantRole classCode="MANU">
 <templateId root="2.16.840.1.113883.10.20.22.4.37"/>
 <!-- ***** Product instance template ***** -->
 ...
 </participantRole>
 </participant>
</supply>

```

### 4.34 Number of Pressure Ulcers Observation [Closed for comments; published July 2012]

[observation: templateId 2.16.840.1.113883.10.20.22.4.76 (open)]

**Table 154: Number of Pressure Ulcers Observation Contexts**

Used By:	Contains Entries:
<a href="#">Functional Status Section</a> (optional)	

This clinical statement enumerates the number of pressure ulcers observed in a particular stage.

**Table 155: Number of Pressure Ulcers Observation Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	observation[templateId/@root = '2.16.840.1.113883.10.20.22.4.76']					
	@classCode	1..1	SHALL		<a href="#">14705</a>	2.16.840.1.113883.5.6 (HL7ActClass) = OBS
	@moodCode	1..1	SHALL		<a href="#">14706</a>	2.16.840.1.113883.5.1001 (ActMood) = EVN
	templateId	1..1	SHALL		<a href="#">14707</a>	
	@root	1..1	SHALL		<a href="#">14708</a>	2.16.840.1.113883.10.20.22.4.76
	id	1..*	SHALL		<a href="#">14709</a>	
	code	1..1	SHALL		<a href="#">14767</a>	
	@code	1..1	SHALL		<a href="#">14768</a>	2264892003
	statusCode	1..1	SHALL		<a href="#">14714</a>	
	@code	1..1	SHALL		<a href="#">19108</a>	2.16.840.1.113883.5.14 (ActStatus) = completed
	effectiveTime	1..1	SHALL		<a href="#">14715</a>	
	value	1..1	SHALL	INT	<a href="#">14771</a>	
	author	0..1	MAY		<a href="#">14717</a>	
	entry Relationship	1..1	SHALL		<a href="#">14718</a>	
	@typeCode	1..1	SHALL		<a href="#">14719</a>	2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = SUBJ
	observation	1..1	SHALL		<a href="#">14720</a>	
	@classCode	1..1	SHALL		<a href="#">14721</a>	2.16.840.1.113883.5.6 (HL7ActClass) = OBS
	@moodCode	1..1	SHALL		<a href="#">14722</a>	2.16.840.1.113883.5.1001 (ActMood) = EVN
	value	1..1	SHALL	CD	<a href="#">14725</a>	2.16.840.1.113883.11.20.9.35 (Pressure Ulcer Stage)

1. **SHALL** contain exactly one [1..1] @classCode="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:14705).
2. **SHALL** contain exactly one [1..1] @moodCode="EVN" (CodeSystem: ActMood 2.16.840.1.113883.5.1001 **STATIC**) (CONF:14706).
3. **SHALL** contain exactly one [1..1] templateId (CONF:14707) such that it
  - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.76" (CONF:14708).
4. **SHALL** contain at least one [1..\*] id (CONF:14709).
5. **SHALL** contain exactly one [1..1] code (CONF:14767).
  - a. This code **SHALL** contain exactly one [1..1] @code="2264892003" number of pressure ulcers (CONF:14768).
6. **SHALL** contain exactly one [1..1] statusCode (CONF:14714).

- a. This statusCode **SHALL** contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 **STATIC**) (CONF:19108).
- 7. **SHALL** contain exactly one [1..1] effectiveTime (CONF:14715).
- 8. **SHALL** contain exactly one [1..1] value with @xsi:type="INT" (CONF:14771).
- 9. **MAY** contain zero or one [0..1] author (CONF:14717).
- 10. **SHALL** contain exactly one [1..1] entryRelationship (CONF:14718).
  - a. This entryRelationship **SHALL** contain exactly one [1..1] @typeCode="SUBJ" Has subject (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**) (CONF:14719).
  - b. This entryRelationship **SHALL** contain exactly one [1..1] observation (CONF:14720).
    - i. This observation **SHALL** contain exactly one [1..1] @classCode="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:14721).
    - ii. This observation **SHALL** contain exactly one [1..1] @moodCode="EVN" (CodeSystem: ActMood 2.16.840.1.113883.5.1001 **STATIC**) (CONF:14722).
    - iii. This observation **SHALL** contain exactly one [1..1] value with @xsi:type="CD", where the @code **SHOULD** be selected from ValueSet Pressure Ulcer Stage 2.16.840.1.113883.11.20.9.35 **STATIC** (CONF:14725).

**Table 156: Pressure Ulcer Stage Value Set**

Value Set: Pressure Ulcer Stage 2.16.840.1.113883.11.20.9.35 STATIC Code System: SNOMED-CT 2.16.840.1.113883.6.96		
Code	Code System	Print Name
421076008	SNOMED-CT	Pressure Ulcer Stage 1
420324007	SNOMED-CT	Pressure Ulcer Stage 2
421927004	SNOMED-CT	Pressure Ulcer Stage 3
420597008	SNOMED-CT	Pressure Ulcer Stage 4
421594008	SNOMED-CT	Nonstageable pressure

**Figure 84: Number of Pressure Ulcers Observation example**

```

<entry typeCode="DRIV">
 <observation classCode="OBS" moodCode="EVN">
 <templateId root="2.16.840.1.113883.10.20.22.4.76"/>
 <id root="08edb7c0-2111-43f2-a784-9a5fdfaa67f0"/>
 <code code="2264892003"
 codeSystem="2.16.840.1.113883.6.96"
 displayName="number of pressure ulcers"/>
 <statusCode code="completed"/>
 <value xsi:type="INT" value="3"/>
 <entryRelationship typeCode="SUBJ">
 <observation classCode="OBS" moodCode="EVN">
 <value xsi:type="CD" code="421927004"
 codeSystem="2.16.840.1.113883.6.96"
 displayName="Pressure ulcer stage 3"/>
 </observation>
 </entryRelationship>
 </observation>
</entry>

```

### 4.35 Plan of Care Activity Act [Closed for comments; published July 2012]

[act: templateId 2.16.840.1.113883.10.20.22.4.39 (open)]

**Table 157: Plan of Care Activity Act Contexts**

Used By:	Contains Entries:
<a href="#">Plan of Care Section</a> (optional)	

This is the generic template for the Plan of Care Activity.

**Table 158: Plan of Care Activity Act Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	act[templateId/@root = '2.16.840.1.113883.10.20.22.4.39']					
	@classCode	1..1	SHALL		<a href="#">8538</a>	2.16.840.1.113883.5.6 (HL7ActClass) = ACT
	@moodCode	1..1	SHALL		<a href="#">8539</a>	2.16.840.1.113883.11.20.9.23 (Plan of Care moodCode (Act/Encounter/Procedure))
	templateId	1..1	SHALL		<a href="#">8544</a>	
	@root	1..1	SHALL		<a href="#">10510</a>	2.16.840.1.113883.10.20.22.4.39
	id	1..*	SHALL		<a href="#">8546</a>	

1. **SHALL** contain exactly one [1..1] `@classCode="ACT"` (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:8538).
2. **SHALL** contain exactly one [1..1] `@moodCode`, which **SHALL** be selected from ValueSet [Plan of Care moodCode \(Act/Encounter/Procedure\)](#) 2.16.840.1.113883.11.20.9.23 **STATIC** 2011-09-30 (CONF:8539).
3. **SHALL** contain exactly one [1..1] `templateId` (CONF:8544) such that it
  - a. **SHALL** contain exactly one [1..1] `@root="2.16.840.1.113883.10.20.22.4.39"` (CONF:10510).
4. **SHALL** contain at least one [1..\*] `id` (CONF:8546).

#### 4.35.1 Plan of Care Radiation Activity

[act: templateId 2.16.840.1.113883.10.20.30.3.32 (open)]

**Table 159: Plan of Care Radiation Activity Contexts**

Used By:	Contains Entries:
<a href="#">Plan of Care Section BCTPS</a> (optional)	

This clinical statement represents a planned radiation therapy. It is a simple template to state that radiation care is planned. It does not provide details. More detail can be supplied with narrative in the `Plan of Care BCTPS section/text`.

**Table 160: Plan of Care Radiation Activity Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	act[templateId/@root = '2.16.840.1.113883.10.20.30.3.32']					
	<code>@classCode</code>	1..1	SHALL		<a href="#">23537</a>	2.16.840.1.113883.5.6 (HL7ActClass) = ACT
	<code>@moodCode</code>	1..1	SHALL		<a href="#">23538</a>	2.16.840.1.113883.11.20.9.23 (Plan of Care moodCode (Act/Encounter/Procedure))
	<code>templateId</code>	1..1	SHALL		<a href="#">23539</a>	
	<code>@root</code>	1..1	SHALL		<a href="#">23540</a>	2.16.840.1.113883.10.20.30.3.32
	<code>id</code>	1..*	SHALL		<a href="#">23541</a>	
	<code>code</code>	1..1	SHALL		<a href="#">23542</a>	
	<code>@code</code>	1..1	SHALL		<a href="#">23543</a>	385798007
	<code>@codeSystem</code>	1..1	SHALL		<a href="#">27087</a>	2.16.840.1.113883.6.96 (SNOMED-CT) = 2.16.840.1.113883.6.96
	<code>effectiveTime</code>	1..1	SHALL		<a href="#">23544</a>	

1. Conforms to [Plan of Care Activity Act](#) template (2.16.840.1.113883.10.20.22.4.39).
2. **SHALL** contain exactly one [1..1] `@classCode="ACT"` (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:23537).

3. **SHALL** contain exactly one [1..1] **@moodCode**, which **SHALL** be selected from ValueSet [Plan of Care moodCode \(Act/Encounter/Procedure\) 2.16.840.1.113883.11.20.9.23](#) **STATIC** 2011-09-30 (CONF:23538).
4. **SHALL** contain exactly one [1..1] **templateId** (CONF:23539) such that it
  - a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.30.3.32" (CONF:23540).
5. **SHALL** contain at least one [1..\*] **id** (CONF:23541).
6. **SHALL** contain exactly one [1..1] **code** (CONF:23542).
  - a. This code **SHALL** contain exactly one [1..1] **@code**="385798007" radiation therapy care (CONF:23543).
  - b. This code **SHALL** contain exactly one [1..1] **@codeSystem**="2.16.840.1.113883.6.96" (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96) (CONF:27087).
7. **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:23544).

**Table 161: Plan of Care moodCode (Act/Encounter/Procedure) Value Set**

Value Set: Plan of Care moodCode (Act/Encounter/Procedure) 2.16.840.1.113883.11.20.9.23 STATIC 2011-09-30 Code System: ActMood 2.16.840.1.113883.5.1001		
Code	Code System	Print Name
INT	ActMood	Intent
ARQ	ActMood	Appointment Request
PRMS	ActMood	Promise
PRP	ActMood	Proposal
RQO	ActMood	Request

**Figure 85: Plan of Care Radiation Activity example**

```

<act moodCode="RQO" classCode="ACT">
 <!-- Plan of Care Activity Act templateID -->
 <templateId root="2.16.840.1.113883.10.20.22.4.39"/>
 <!-- Plan of Care Radiation Activity templateID -->
 <templateId root="2.16.840.1.113883.10.20.30.3.32"/>
 <!-- **** Plan of Care Activity Act template **** -->
 <id root="ab3365e3-97b1-4461-8a60-290d9228ea26"/>
 <code code="385798007"
 codeSystem="2.16.840.1.113883.6.96"
 displayName="radiation therapy care"/>
 <statusCode code="new"/>
 <effectiveTime value="20130205"/>
</act>

```

## 4.36 Plan of Care Activity Encounter

[Closed for comments; published July 2012]

[encounter: templateId 2.16.840.1.113883.10.20.22.4.40 (open)]

**Table 162: Plan of Care Activity Encounter Contexts**

Used By:	Contains Entries:
<a href="#">Plan of Care Section</a> (optional)	

This is the template for the Plan of Care Activity Encounter.

**Table 163: Plan of Care Activity Encounter Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	encounter[templateId/@root = '2.16.840.1.113883.10.20.22.4.40']					
	@classCode	1..1	SHALL		<a href="#">8564</a>	2.16.840.1.113883.5.6 (HL7ActClass) = ENC
	@moodCode	1..1	SHALL		<a href="#">8565</a>	2.16.840.1.113883.11.20.9.23 (Plan of Care moodCode (Act/Encounter/Procedure))
	templateId	1..1	SHALL		<a href="#">8566</a>	
	@root	1..1	SHALL		<a href="#">10511</a>	2.16.840.1.113883.10.20.22.4.40
	id	1..*	SHALL		<a href="#">8567</a>	

1. **SHALL** contain exactly one [1..1] @classCode="ENC" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:8564).
2. **SHALL** contain exactly one [1..1] @moodCode, which **SHALL** be selected from ValueSet [Plan of Care moodCode \(Act/Encounter/Procedure\) 2.16.840.1.113883.11.20.9.23](#) **STATIC** 2011-09-30 (CONF:8565).
3. **SHALL** contain exactly one [1..1] templateId (CONF:8566) such that it
  - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.40" (CONF:10511).
4. **SHALL** contain at least one [1..\*] id (CONF:8567).

**Figure 86: Plan of Care Activity Encounter example**

```
<encounter moodCode="INT" classCode="ENC">
 <templateId root="2.16.840.1.113883.10.20.22.4.40"/>
 <!-- Plan of Care Activity Encounter template -->
 <id root="9a6d1bac-17d3-4195-89a4-1121bc809b4d"/>
 <!-- ... -->
</encounter>
```

### 4.37 Plan of Care Activity Observation [Closed for comments; published July 2012]

[observation: templateId 2.16.840.1.113883.10.20.22.4.44 (open)]

**Table 164: Plan of Care Activity Observation Contexts**

Used By:	Contains Entries:
<a href="#">Plan of Care Section</a> (optional)	

This is the template for the Plan of Care Activity Observation.

**Table 165: Plan of Care Activity Observation Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	observation[templateId/@root = '2.16.840.1.113883.10.20.22.4.44']					
	@classCode	1..1	SHALL		<a href="#">8581</a>	2.16.840.1.113883.5.6 (HL7ActClass) = OBS
	@moodCode	1..1	SHALL		<a href="#">8582</a>	2.16.840.1.113883.11.20.9.25 (Plan of Care moodCode (Observation))
	templateId	1..1	SHALL		<a href="#">8583</a>	
	@root	1..1	SHALL		<a href="#">10512</a>	2.16.840.1.113883.10.20.22.4.44
	id	1..*	SHALL		<a href="#">8584</a>	

1. **SHALL** contain exactly one [1..1] @classCode="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:8581).
2. **SHALL** contain exactly one [1..1] @moodCode, which **SHALL** be selected from ValueSet Plan of Care moodCode (Observation) 2.16.840.1.113883.11.20.9.25 **STATIC** 2011-09-30 (CONF:8582).
3. **SHALL** contain exactly one [1..1] templateId (CONF:8583) such that it
  - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.44" (CONF:10512).
4. **SHALL** contain at least one [1..\*] id (CONF:8584).



**Table 166: Plan of Care moodCode (Observation) Value Set**

Value Set: Plan of Care moodCode (Observation) 2.16.840.1.113883.11.20.9.25 STATIC 2011-09-30 Code System: ActMood 2.16.840.1.113883.5.1001		
Code	Code System	Print Name
INT	ActMood	Intent
GOL	ActMood	Goal
PRMS	ActMood	Promise
PRP	ActMood	Proposal
RQO	ActMood	Request

**Figure 87: Plan of Care Activity Observation example**

```
<observation classCode="OBS" moodCode="RQO">
 <templateId root="2.16.840.1.113883.10.20.22.4.44"/>
 <!-- Plan of Care Activity Observation template -->
 <id root="9a6d1bac-17d3-4195-89a4-1121bc809b4a" />
 <code code="73761001"
 codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMED CT"
 displayName="Colonoscopy"/>
 <statusCode code="new"/>
 <effectiveTime>
 <center value="20120512"/>
 </effectiveTime>
</observation>
```

### 4.38 Plan of Care Activity Procedure [Closed for comments; published July 2012]

[procedure: templateId 2.16.840.1.113883.10.20.22.4.41 (open)]

**Table 167: Plan of Care Activity Procedure Contexts**

Used By:	Contains Entries:
<a href="#">Plan of Care Section</a> (optional)	

This is the template for the Plan of Care Activity Procedure.

**Table 168: Plan of Care Activity Procedure Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	procedure[templateId/@root = '2.16.840.1.113883.10.20.22.4.41']					
	@classCode	1..1	SHALL		<a href="#">8568</a>	2.16.840.1.113883.5.6 (HL7ActClass) = PROC
	@moodCode	1..1	SHALL		<a href="#">8569</a>	2.16.840.1.113883.11.20.9.23 (Plan of Care moodCode (Act/Encounter/Procedure))
	templateId	1..1	SHALL		<a href="#">8570</a>	
	@root	1..1	SHALL		<a href="#">10513</a>	2.16.840.1.113883.10.20.22.4.41
	id	1..*	SHALL		<a href="#">8571</a>	

1. **SHALL** contain exactly one [1..1] @classCode="PROC" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:8568).
2. **SHALL** contain exactly one [1..1] @moodCode, which **SHALL** be selected from ValueSet [Plan of Care moodCode \(Act/Encounter/Procedure\) 2.16.840.1.113883.11.20.9.23](#) **STATIC** 2011-09-30 (CONF:8569).
3. **SHALL** contain exactly one [1..1] templateId (CONF:8570) such that it
  - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.41" (CONF:10513).
4. **SHALL** contain at least one [1..\*] id (CONF:8571).

#### 4.38.1 Chemotherapy Regimen Plans

[Procedure: templateId 2.16.840.1.113883.10.20.30.3.30 (open)]

**Table 169: Chemotherapy Regimen Plans Contexts**

Used By:	Contains Entries:
<a href="#">Plan of Care Section BCTPS</a> (optional)	<a href="#">Chemotherapy Medication Activity</a> <a href="#">Clinical Drug Trial</a> <a href="#">Possible Side Effects</a>

This clinical statement represents a Chemotherapy Regimen Plan that describes a patient's future course of chemotherapy. Complete coded modeling of the intricacies of chemo regimen plans/orders and timing are not intended to be reflected in the contained Medication activities. Chemotherapy regimen details and timing are very complex. Representation of the details is unlikely to be properly understood by a receiving EHR and could be dangerous and is beyond the scope of this template and plan summary. Section/text narrative in the Plan of Care BCTPS section should contain explicit and clear text describing the planned regimen.

**Table 170: Chemotherapy Regimen Plans Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
	Procedure[templateId/@root = '2.16.840.1.113883.10.20.30.3.30']					
	@classCode	1..1	SHALL		<a href="#">24047</a>	2.16.840.1.113883.5.6 (HL7ActClass) = PROC
	@moodCode	1..1	SHALL		<a href="#">24048</a>	2.16.840.1.113883.11.20.9.24 (Plan of Care moodCode (SubstanceAdministration /Supply))
	templateId	1..1	SHALL		<a href="#">24049</a>	
	@root	1..1	SHALL		<a href="#">24050</a>	2.16.840.1.113883.10.20.30.3.30
	id	1..*	SHALL		<a href="#">24051</a>	
	code	1..1	SHALL		<a href="#">24052</a>	
	@code	1..1	SHALL		<a href="#">24053</a>	69960004
	@codeSystem	1..1	SHALL		<a href="#">27088</a>	2.16.840.1.113883.6.96
	originalText	1..1	SHALL		<a href="#">24054</a>	
	statusCode	1..1	SHALL		<a href="#">24055</a>	
	effectiveTime	1..1	SHALL		<a href="#">24057</a>	
	low	1..1	SHALL		<a href="#">24058</a>	
	high	1..1	SHALL		<a href="#">24059</a>	
	entryRelationship	0..*	SHOULD		<a href="#">24060</a>	
	@typeCode	1..1	SHALL		<a href="#">24061</a>	2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = COMP
	substance Administration	1..1	SHALL		<a href="#">24062</a>	
	entryRelationship	0..1	MAY		<a href="#">24066</a>	
	@typeCode	1..1	SHALL		<a href="#">24067</a>	2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = COMP
	act	1..1	SHALL		<a href="#">24068</a>	
	entryRelationship	0..*	MAY		<a href="#">24076</a>	
	@typeCode	1..1	SHALL		<a href="#">24077</a>	2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = COMP
	act	1..1	SHALL		<a href="#">24078</a>	

1. Conforms to [Plan of Care Activity Procedure](#) template (2.16.840.1.113883.10.20.22.4.41).

2. **SHALL** contain exactly one [1..1] `@classCode="PROC"` procedure (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:24047).
3. **SHALL** contain exactly one [1..1] `@moodCode`, which **SHALL** be selected from ValueSet Plan of Care moodCode (SubstanceAdministration/Supply) 2.16.840.1.113883.11.20.9.24 **STATIC** (CONF:24048).
4. **SHALL** contain exactly one [1..1] `templateId` (CONF:24049) such that it
  - a. **SHALL** contain exactly one [1..1] `@root="2.16.840.1.113883.10.20.30.3.30"` (CONF:24050).
5. **SHALL** contain at least one [1..\*] `id` (CONF:24051).
6. **SHALL** contain exactly one [1..1] `code` (CONF:24052).
  - a. This code **SHALL** contain exactly one [1..1] `@code="69960004"` cancer chemotherapy regimen (CONF:24053).
  - b. This code **SHALL** contain exactly one [1..1] `@codeSystem="2.16.840.1.113883.6.96"` (CONF:27088).

The `originalText` element captures the name of the regimen plan. The regimen names are typically acronyms made up of the the first letters of the brand or clinical drug names that are part of the regimen. Regimens and their component drugs are variable and are not identified in standard code systems.

- c. This code **SHALL** contain exactly one [1..1] `originalText` (CONF:24054).

Typically, a regimen plan in a plan summary would either be "new" or "active". An `act/status` of "new" indicates that the regimen is in the preparatory stages and may not yet be acted upon. An `act/status` of "active" indicates the regimen can be performed or is being performed. However, other `actStatus` codes could possibly be applicable.

7. **SHALL** contain exactly one [1..1] `statusCode` (CONF:24055).

The `effectiveTime` is represents when the regimen plan is expected to begin and end.

8. **SHALL** contain exactly one [1..1] `effectiveTime` (CONF:24057).
  - a. This `effectiveTime` **SHALL** contain exactly one [1..1] `low` (CONF:24058).
  - b. This `effectiveTime` **SHALL** contain exactly one [1..1] `high` (CONF:24059).
9. **SHOULD** contain zero or more [0..\*] `entryRelationship` (CONF:24060) such that it
  - a. **SHALL** contain exactly one [1..1] `@typeCode="COMP"` has component (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:24061).
  - b. **SHALL** contain exactly one [1..1] [Chemotherapy Medication Activity Plan](#) (`templateId:2.16.840.1.113883.10.20.30.3.51`) (CONF:24062).
10. **MAY** contain zero or one [0..1] `entryRelationship` (CONF:24066) such that it
  - a. **SHALL** contain exactly one [1..1] `@typeCode="COMP"` has component (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:24067).
  - b. **SHALL** contain exactly one [1..1] [Clinical Drug Trial](#) (`templateId:2.16.840.1.113883.10.20.30.3.4`) (CONF:24068).
11. **MAY** contain zero or more [0..\*] `entryRelationship` (CONF:24076) such that it

- a. **SHALL** contain exactly one [1..1] @typeCode="COMP" has component (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:24077).
- b. **SHALL** contain exactly one [1..1] Possible Side Effects (templateId:2.16.840.1.113883.10.20.30.3.35) (CONF:24078).

**Table 171: Plan of Care moodCode (SubstanceAdministration/Supply) Value Set**

Value Set: Plan of Care moodCode (SubstanceAdministration/Supply) 2.16.840.1.113883.11.20.9.24 STATIC 2011-09-30 Code System: ActMood 2.16.840.1.113883.5.1001		
Code	Code System	Print Name
INT	ActMood	Intent
PRMS	ActMood	Promise
PRP	ActMood	Proposal
RQO	ActMood	Request

**Figure 88: Chemotherapy Regimen Plans example**

```

<procedure classCode="PROC" moodCode="INT">
 <!-- Plan of Care Activity Procedure-->
 <templateId root="2.16.840.1.113883.10.20.22.4.41"/>
 <!-- Chemotherapy regimen plans template-->
 <templateId root="2.16.840.1.113883.10.20.30.3.30"/>
 <id root="2baf9dc1-6d92-4ed0-8b4a-ad556adb90fe"/>
 <code code="69960004" codeSystem="2.16.840.1.113883.6.96"
 displayName="cancer chemotherapy regimen">
 <originalText>TAC chemotherapy regimen</originalText>
 </code>
 <!-- An act/status of "new" indicates that the regimen is in the
 preparatory stages and may not yet be acted upon.
 An act/status of "active" indicates the regimen can be performed or is
 being performed -->
 <statusCode code="active"/>
 <!-- Expected start and end dates of entire regimen planned dates (6 cycles
 of 21 days each - 126 days) -->
 <effectiveTime xsi:type="IVL_TS">
 <low value="201301010001"/>
 <high value="201304302359"/>
 </effectiveTime>
 <entryRelationship typeCode="COMP">
 <substanceAdministration classCode="SBADM" moodCode="INT">
 <!-- Consolidated CDA Plan of Care Activity Substance Admin -->
 <templateId root="2.16.840.1.113883.10.20.22.4.42"/>
 <!-- Chemotherapy Medication Activity Plans -->
 <templateId root="2.16.840.1.113883.10.20.30.3.51"/>
 ...
 </substanceAdministration>
 </entryRelationship>
 ...
</procedure>

```

## 4.38.2 Plan of Care Activity Reconstruction Procedure

[procedure: templateId 2.16.840.1.113883.10.20.30.3.31 (open)]

**Table 172: Plan of Care Activity Reconstruction Procedure Contexts**

Used By:	Contains Entries:
<a href="#">Plan of Care Section BCTPS</a> (optional)	

This clinical statement represents a planned breast reconstruction procedure. It is a simple template to state what breast procedure is planned. It does not provide extensive details. More detail can be supplied with narrative in the Plan of Care BCTPS section/text.

**Table 173: Plan of Care Activity Reconstruction Procedure Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	procedure[templateId/@root = '2.16.840.1.113883.10.20.30.3.31']					
	@classCode	1..1	SHALL		<a href="#">24079</a>	2.16.840.1.113883.5.6 (HL7ActClass) = PROC
	@moodCode	1..1	SHALL		<a href="#">24080</a>	2.16.840.1.113883.11.20.9.23 (Plan of Care moodCode (Act/Encounter/Procedure))
	templateId	1..1	SHALL		<a href="#">24081</a>	
	@root	1..1	SHALL		<a href="#">24082</a>	2.16.840.1.113883.10.20.30.3.31
	id	1..*	SHALL		<a href="#">24083</a>	
	code	1..1	SHALL		<a href="#">24084</a>	2.16.840.1.113883.11.20.11.16 (Breast Cancer Procedures)
	effectiveTime	1..1	SHALL		<a href="#">24086</a>	

1. Conforms to [Plan of Care Activity Procedure](#) template (2.16.840.1.113883.10.20.22.4.41).
2. **SHALL** contain exactly one [1..1] @classCode="PROC" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:24079).
3. **SHALL** contain exactly one [1..1] @moodCode, which **SHALL** be selected from ValueSet [Plan of Care moodCode \(Act/Encounter/Procedure\)](#) 2.16.840.1.113883.11.20.9.23 **STATIC** 2011-09-30 (CONF:24080).
4. **SHALL** contain exactly one [1..1] templateId (CONF:24081) such that it
  - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.3.31" (CONF:24082).
5. **SHALL** contain at least one [1..\*] id (CONF:24083).
6. **SHALL** contain exactly one [1..1] code, which **SHALL** be selected from ValueSet [Breast Cancer Procedures](#) 2.16.840.1.113883.11.20.11.16 **DYNAMIC** (CONF:24084).
7. **SHALL** contain exactly one [1..1] effectiveTime (CONF:24086).

**Table 174: Breast Cancer Procedures Value Set**

Value Set: Breast Cancer Procedures 2.16.840.1.113883.11.20.11.16 DYNAMIC		
Code System: SNOMED-CT 2.16.840.1.113883.6.96		
Description: List of common breast cancer procedures performed		
Code	Code System	Print Name
408469009	SNOMED-CT	breast surgery
79544006	SNOMED-CT	block dissection of axillary lymph nodes
396487001	SNOMED-CT	sentinel lymph node biopsy
33496007	SNOMED-CT	breast reconstruction
384723003	SNOMED-CT	radical mastectomy
172043006	SNOMED-CT	simple mastectomy
392022002	SNOMED-CT	lumpectomy
234262008	SNOMED-CT	excision of axillary lymph node

**Figure 89: Plan of Care Activity Reconstruction Procedure example**

```
<procedure classCode="PROC" moodCode="INT">
 <!-- Plan of Care Activity Procedure templateID -->
 <templateId root="2.16.840.1.113883.10.20.22.4.41"/>
 <!-- Plan of Care Activity Reconstruction Procedure templateID -->
 <templateId root="2.16.840.1.113883.10.20.30.3.31"/>
 <id root="2e606db3-66dc-4abe-8771-5cee29739935"/>
 <code code="33496007"
 codeSystem="2.16.840.1.113883.6.96"
 displayName="Reconstruction of breast"/>
 <statusCode code="new"/>
 <effectiveTime value="20130305"/>
</procedure>
```

### 4.39 Plan of Care Activity Substance Administration [Closed for comments; published July 2012]

[substanceAdministration: templateId 2.16.840.1.113883.10.20.22.4.42  
(open) ]

**Table 175: Plan of Care Activity Substance Administration Contexts**

Used By:	Contains Entries:
<a href="#">Plan of Care Section</a> (optional)	

This is the template for the Plan of Care Activity Substance Administration

**Table 176: Plan of Care Activity Substance Administration Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	substanceAdministration[templateId/@root = '2.16.840.1.113883.10.20.22.4.42']					
	@classCode	1..1	SHALL		<a href="#">8572</a>	2.16.840.1.113883.5.6 (HL7ActClass) = SBADM
	@moodCode	1..1	SHALL		<a href="#">8573</a>	2.16.840.1.113883.11.20.9.24 (Plan of Care moodCode (SubstanceAdministration/Supply))
	templateId	1..1	SHALL		<a href="#">8574</a>	
	@root	1..1	SHALL		<a href="#">10514</a>	2.16.840.1.113883.10.20.22.4.42
	id	1..*	SHALL		<a href="#">8575</a>	

1. **SHALL** contain exactly one [1..1] @classCode="SBADM" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:8572).
2. **SHALL** contain exactly one [1..1] @moodCode, which **SHALL** be selected from ValueSet [Plan of Care moodCode \(SubstanceAdministration/Supply\) 2.16.840.1.113883.11.20.9.24](#) **STATIC** 2011-09-30 (CONF:8573).
3. **SHALL** contain exactly one [1..1] templateId (CONF:8574) such that it
  - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.42" (CONF:10514).
4. **SHALL** contain at least one [1..\*] id (CONF:8575).

#### 4.39.1 Chemotherapy Medication Activity Plan

[SubstanceAdministration: templateId 2.16.840.1.113883.10.20.30.3.51 (open) ]

**Table 177: Chemotherapy Medication Activity Plan Contexts**

Used By:	Contains Entries:
<a href="#">Chemotherapy Regimen Plans</a> (optional)	<a href="#">Chemotherapy Protocol Reference</a> <a href="#">Clinical Drug Trial</a> <a href="#">Medication Information</a> <a href="#">Reaction Observation</a>

This clinical statement represents needed elements and attributes when communicating planned chemotherapeutic medications. The specific chemotherapeutic agents are not specified, but attributes such as repeatNumber, to note the cycle, dose, and route are required. Chemotherapy medication details and timing are very complex. Representation of the details is unlikely to be properly understood by a receiving EHR and could be dangerous and is beyond the scope of this template and plan summary. Section/text narrative in the Plan of Care BCTPS section should contain explicit and clear text describing the planned regimen.



**Table 178: Chemotherapy Medication Activity Plan Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
	SubstanceAdministration[templateId/@root = '2.16.840.1.113883.10.20.30.3.51']					
	@classCode	1..1	SHALL		<a href="#">27348</a>	2.16.840.1.113883.5.6 (HL7ActClass) = SBADM
	@moodCode	1..1	SHALL		<a href="#">27349</a>	2.16.840.1.113883.5.1001 (ActMood) = EVN
	templateId	1..1	SHALL		<a href="#">27350</a>	
	@root	1..1	SHALL		<a href="#">27351</a>	2.16.840.1.113883.10.20.30.3.44
	statusCode	1..1	SHALL		<a href="#">27352</a>	
	effectiveTime	1..1	SHALL	IVL_T S	<a href="#">27354</a>	
	low	1..1	SHALL		<a href="#">27355</a>	
	high	1..1	SHALL		<a href="#">27356</a>	
	repeatNumber	1..1	SHALL		<a href="#">27357</a>	
	routeCode	1..1	SHALL		<a href="#">27358</a>	
	@code	1..1	SHALL		<a href="#">27359</a>	2.16.840.1.113883.3.88.12.3221.8.7 (Medication Route FDA Value Set)
	doseQuantity	1..1	SHALL		<a href="#">27360</a>	
	@value	1..1	SHALL		<a href="#">27361</a>	
	@unit	1..1	SHALL		<a href="#">27362</a>	
	consumable	1..1	SHALL		<a href="#">27363</a>	
	entry Relationship	0..*	MAY		<a href="#">27364</a>	
	@typeCode	1..1	SHALL		<a href="#">27365</a>	2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = REFR
	act	1..1	SHALL		<a href="#">27366</a>	
	entry Relationship	0..*	MAY		<a href="#">27367</a>	
	@typeCode	1..1	SHALL		<a href="#">27368</a>	2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = REFR
	observation	1..1	SHALL		<a href="#">27369</a>	
	entry Relationship	0..*	MAY		<a href="#">27370</a>	
	@typeCode	1..1	SHALL		<a href="#">27371</a>	2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = REFR
	act	1..1	SHALL		<a href="#">27372</a>	

1. Conforms to [Plan of Care Activity Substance Administration](#) template (2.16.840.1.113883.10.20.22.4.42).
2. **SHALL** contain exactly one [1..1] **@classCode="SBADM"** SubstanceAdministration (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:27348).
3. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** event (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:27349).
4. **SHALL** contain exactly one [1..1] **templateId** (CONF:27350) such that it
  - a. **SHALL** contain exactly one [1..1] **@root="2.16.840.1.113883.10.20.30.3.44"** (CONF:27351).

Typically, a chemotherapeutic drug plan in a plan summary would either be "new" or "active". An act/status of "new" indicates that the regimen is in the preparatory stages and may not yet be acted upon. An act/status of "active" indicates the regimen can be performed or is being performed. However, other actStatus codes could possibly be applicable.

5. **SHALL** contain exactly one [1..1] **statusCode** (CONF:27352).
6. **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:27354) such that it
  - a. **SHALL** contain exactly one [1..1] **low** (CONF:27355).
  - b. **SHALL** contain exactly one [1..1] **high** (CONF:27356).

The repeatNumber represents the number of recommended chemotherapy drug cycles. In a substanceAdministration a substanceAdministration/moodCode in "INT" (intent) mood causes the repeatNumber to mean the number of intended administrations.

7. **SHALL** contain exactly one [1..1] **repeatNumber** (CONF:27357).
8. **SHALL** contain exactly one [1..1] **routeCode** (CONF:27358).
  - a. This routeCode **SHALL** contain exactly one [1..1] **@code** (ValueSet: [Medication Route FDA Value Set](#) 2.16.840.1.113883.3.88.12.3221.8.7 **DYNAMIC**) (CONF:27359).
9. **SHALL** contain exactly one [1..1] **doseQuantity** (CONF:27360).
  - a. This doseQuantity **SHALL** contain exactly one [1..1] **@value** (CONF:27361).
  - b. This doseQuantity **SHALL** contain exactly one [1..1] **@unit** (CONF:27362).
10. **SHALL** contain exactly one [1..1] [Medication Information](#) (templateId:2.16.840.1.113883.10.20.22.4.23) (CONF:27363).
11. **MAY** contain zero or more [0..\*] **entryRelationship** (CONF:27364) such that it
  - a. **SHALL** contain exactly one [1..1] **@typeCode="REFR"** Refers to (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:27365).
  - b. **SHALL** contain exactly one [1..1] [Clinical Drug Trial](#) (templateId:2.16.840.1.113883.10.20.30.3.4) (CONF:27366).

The Reaction Observation template is used to represent reactions or toxicities to the chemotherapeutic drug. The reaction may or may not be expected and may or may not be a reason to discontinue or adjust the dose of an agent.

12. **MAY** contain zero or more [0..\*] **entryRelationship** (CONF:27367) such that it
  - a. **SHALL** contain exactly one [1..1] **@typeCode="REFR"** Refers to (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:27368).

- b. **SHALL** contain exactly one [1..1] [Reaction Observation](#) (templateId:2.16.840.1.113883.10.20.22.4.9) (CONF:27369).
13. **MAY** contain zero or more [0..\*] **entryRelationship** (CONF:27370) such that it
- a. **SHALL** contain exactly one [1..1] **@typeCode="REFR"** refers to (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:27371).
  - b. **SHALL** contain exactly one [1..1] [Chemotherapy Protocol Reference](#) (templateId:2.16.840.1.113883.10.20.30.3.50) (CONF:27372).

**Figure 90: Chemotherapy Medication Activity Plan example**

```

<substanceAdministration classCode="SBADM" moodCode="INT">
 <!-- Consolidated CDA Plan of Care Activity Substance Administration -->
 <templateId root="2.16.840.1.113883.10.20.22.4.42"/>
 <!-- Chemotherapy Medication Activity Plans -->
 <templateId root="2.16.840.1.113883.10.20.30.3.51"/>
 <id root="393083d6-01d1-423c-b253-3e2658241287"/>
 <statusCode code="active"/>
 <effectiveTime xsi:type="IVL_TS">
 <!-- Starts 1 day after the dexamethasone dose and 1 hour after completion
 of Doxorubicin and Cyclophosphamide. Time is dependent on completion of
 the premedication (Dexamethasone) and the 2 other chemotherapeutics-->
 <low nullFlavor="NAV"/>
 <high nullFlavor="NAV"/>
 </effectiveTime>
 <!-- Over 1 hour -->
 <effectiveTime xsi:type="PIVL_TS" operator="A">
 <phase>
 <width value="1" unit="h"></width>
 </phase>
 </effectiveTime>
 <!-- every 21 days (3 weeks)-->
 <effectiveTime xsi:type="PIVL_TS" institutionSpecified="true" operator="A">
 <period value="21" unit="d"/>
 </effectiveTime>
 <!-- Number of recommended cycles (In "INT" (intent) mood, the repeatNumber
 defines the number of allowed administrations). -->
 <repeatNumber value="6" operator="A"/>
 <routeCode code="C38276"
 codeSystem="2.16.840.1.113883.3.26.1.1"
 displayName="Intravenous route"
 codeSystemName="FDA RouteOfAdministration"/>
 <doseQuantity value="75" unit="mg/m2"/>

```

```

<consumable>
 <manufacturedProduct classCode="MANU">
 <!-- Consolidated CDA Medication Information (manufacturedMaterial) -->
 <templateId root="2.16.840.1.113883.10.20.22.4.23"/>
 <manufacturedMaterial>
 <code code="72962"
 codeSystem="2.16.840.1.113883.6.88"
 codeSystemName="RXNorm" displayName="Docetaxel">
 <originalText>Docetaxel</originalText>
 </code>
 <!-- Brand Name -->
 <name>Taxotere</name>
 </manufacturedMaterial>
 </manufacturedProduct>
</consumable>
</substanceAdministration>

```

#### 4.40 Plan of Care Activity Supply [Closed for comments; published July 2012]

[supply: templateId 2.16.840.1.113883.10.20.22.4.43 (open)]

**Table 179: Plan of Care Activity Supply Contexts**

Used By:	Contains Entries:
<a href="#">Plan of Care Section</a> (optional)	

This is the template for the Plan of Care Activity Supply.

**Table 180: Plan of Care Activity Supply Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	supply[templateId/@root = '2.16.840.1.113883.10.20.22.4.43']					
	@classCode	1..1	SHALL		<a href="#">8577</a>	2.16.840.1.113883.5.6 (HL7ActClass) = SPLY
	@moodCode	1..1	SHALL		<a href="#">8578</a>	2.16.840.1.113883.11.20.9.24 (Plan of Care moodCode (SubstanceAdministration/Supply))
	templateId	1..1	SHALL		<a href="#">8579</a>	
	@root	1..1	SHALL		<a href="#">10515</a>	2.16.840.1.113883.10.20.22.4.43
	id	1..*	SHALL		<a href="#">8580</a>	

1. **SHALL** contain exactly one [1..1] @classCode="SPLY" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:8577).
2. **SHALL** contain exactly one [1..1] @moodCode, which **SHALL** be selected from ValueSet [Plan of Care moodCode \(SubstanceAdministration/Supply\) 2.16.840.1.113883.11.20.9.24](#) **STATIC** 2011-09-30 (CONF:8578).

3. **SHALL** contain exactly one [1..1] **templateId** (CONF:8579) such that it
  - a. **SHALL** contain exactly one [1..1]
   
     @root="2.16.840.1.113883.10.20.22.4.43" (CONF:10515).
4. **SHALL** contain at least one [1..\*] **id** (CONF:8580).

**Figure 91: Plan of Care Activity Supply example**

```

<supply moodCode="INT" classCode="SPLY">
 <templateId root="2.16.840.1.113883.10.20.22.4.43"/>
 <!-- ** Plan of Care Activity Supply ** -->
 <id root="9a6d1bac-17d3-4195-89c4-1121bc809b5d"/>
 <code .../>
</supply>

```

#### 4.41 Post Treatment Disease Status

[Observation: templateId 2.16.840.1.113883.10.20.30.3.29 (open)]

**Table 181: Post Treatment Disease Status Contexts**

Used By:	Contains Entries:
<a href="#">Breast Cancer Diagnosis Observation</a> (required)	

This clinical statement represents the disease status of the patient after treatment.

**Table 182: Post Treatment Disease Status Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	Observation[templateId/@root = '2.16.840.1.113883.10.20.30.3.29']					
	@classCode	1..1	SHALL		<a href="#">21934</a>	2.16.840.1.113883.5.6 (HL7ActClass)
	@moodCode	1..1	SHALL		<a href="#">21935</a>	2.16.840.1.113883.5.1001 (ActMood) = EVN
	templateId	1..1	SHALL		<a href="#">21932</a>	
	@root	1..1	SHALL		<a href="#">21933</a>	2.16.840.1.113883.10.20.30.3.29
	id	1..*	SHALL		<a href="#">21936</a>	
	code	1..1	SHALL		<a href="#">21937</a>	
	@code	1..1	SHALL		<a href="#">21938</a>	128926000
	@codeSystem	1..1	SHALL		<a href="#">23339</a>	2.16.840.1.113883.6.96 (SNOMED-CT) = 2.16.840.1.113883.6.96
	statusCode	1..1	SHALL		<a href="#">21939</a>	
	@code	1..1	SHALL		<a href="#">21940</a>	2.16.840.1.113883.5.14 (ActStatus) = Completed
	effectiveTime	1..1	SHALL		<a href="#">21941</a>	

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	value	1..1	SHALL	CD	<a href="#">21942</a>	2.16.840.1.113883.10.20.30.4.1 (Disease Status Post Treatment)

1. **SHALL** contain exactly one [1..1] **@classCode** (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:21934).
  2. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:21935).
  3. **SHALL** contain exactly one [1..1] **templateId** (CONF:21932) such that it
    - a. **SHALL** contain exactly one [1..1] **@root="2.16.840.1.113883.10.20.30.3.29"** (CONF:21933).
  4. **SHALL** contain at least one [1..\*] **id** (CONF:21936).
  5. **SHALL** contain exactly one [1..1] **code** (CONF:21937).
    - a. This code **SHALL** contain exactly one [1..1] **@code="405178006"** Postprocedural recovery status (CONF:21938).
    - b. This code **SHALL** contain exactly one [1..1] **@codeSystem="2.16.840.1.113883.6.96"** (CodeSystem:SNOMED-CT 2.16.840.1.113883.6.96) (CONF:23339).
  6. **SHALL** contain exactly one [1..1] **statusCode** (CONF:21939).
    - a. This statusCode **SHALL** contain exactly one [1..1] **@code="completed"** Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14) (CONF:21940).
  7. **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:21941).
- A value observation code of "OTH" communicates side effects not listed in ValueSet table. In these instances, the original text would be sent.
8. **SHALL** contain exactly one [1..1] **value** with **@xsi:type="CD"**, where the **@code** **SHOULD** be selected from ValueSet Disease Status Post Treatment 2.16.840.1.113883.10.20.30.4.1 **DYNAMIC** (CONF:21942).

**Table 183: Disease Status Post Treatment Value Set**

Value Set: Disease Status Post Treatment 2.16.840.1.113883.10.20.30.4.1 DYNAMIC Code System(s): SNOMED-CT 2.16.840.1.113883.6.96		
Code	Code System	Print Name
414861001	SNOMED-CT	no evidence of recurrence of cancer (situation)
58184002	SNOMED-CT	recurrent disease (disorder)
399056007	SNOMED-CT	complete therapeutic response (finding)

**Figure 92: Post Treatment Disease Status example**

```

<entryRelationship typeCode="COMP">
 <observation classCode="OBS" moodCode="EVN">
 <!-- Post Treatment Disease Status TemplateID-->
 <templateId root="2.16.840.1.113883.10.20.30.3.29"/>
 <id nullFlavor="NI"/>
 <code code="405178006"
 codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMED-CT"
 displayName="Postprocedural recovery status"/>
 <statusCode code="completed"/>
 <effectiveTime value="20120707"/>
 <value xsi:type="CD" code="58184002"
 codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMED CT"
 displayName="recurrent disease"/>
 </observation>
</entryRelationship>

```

#### 4.42 Precondition for Substance Administration [Closed for comments; published July 2012]

[criterion: templateId 2.16.840.1.113883.10.20.22.4.25 (open)]

**Table 184: Precondition for Substance Administration Contexts**

Used By:	Contains Entries:
<a href="#">Medication Activity</a> (optional)	

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

**Table 185: Precondition for Substance Administration Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	criterion[templateId/@root = '2.16.840.1.113883.10.20.22.4.25']					
	templateId	1..1	SHALL		<a href="#">7372</a>	
	@root	1..1	SHALL		<a href="#">10517</a>	2.16.840.1.113883.10.20.22.4.25
	code	0..1	SHOULD		<a href="#">16854</a>	
	text	0..1	MAY		<a href="#">7373</a>	
	value	0..1	SHOULD	CD	<a href="#">7369</a>	

1. **SHALL** contain exactly one [1..1] **templateId** (CONF:7372) such that it
  - a. **SHALL** contain exactly one [1..1]
    - @root**="2.16.840.1.113883.10.20.22.4.25" (CONF:10517).
2. **SHOULD** contain zero or one [0..1] **code** (CONF:16854).

3. **MAY** contain zero or one [0..1] **text** (CONF:7373).
4. **SHOULD** contain zero or one [0..1] **value** with @xsi:type="CD" (CONF:7369).

**Figure 93: Precondition for Substance Administration example**

```
<precondition typeCode="PRCN">
 <templateId root="2.16.840.1.113883.10.20.22.4.25" />
 <critierion>
 <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4" />
 <value xsi:type="CE"
 code="56018004"
 codeSystem="2.16.840.1.113883.6.96"
 displayName="Wheezing" />
 </critierion>
</precondition>
```

### 4.43 Pressure Ulcer Observation [Closed for comments; published July 2012]

[observation: templateId 2.16.840.1.113883.10.20.22.4.70 (open)]

**Table 186: Pressure Ulcer Observation Contexts**

Used By:	Contains Entries:
<a href="#">Functional Status Section</a> (optional)	

The pressure ulcer observation contains details about the pressure ulcer such as the stage of the ulcer, location, and dimensions. If the pressure ulcer is a diagnosis, you may find this on the problem list. An example of how this would appear is in the Problem Section.

**Table 187: Pressure Ulcer Observation Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
	observation[templateId/@root = '2.16.840.1.113883.10.20.22.4.70']					
	@classCode	1..1	SHALL		<a href="#">14383</a>	2.16.840.1.113883.5.6 (HL7ActClass) = OBS
	@moodCode	1..1	SHALL		<a href="#">14384</a>	2.16.840.1.113883.5.1001 (ActMood) = EVN
	@negationInd	0..1	MAY		<a href="#">14385</a>	
	templateId	1..1	SHALL		<a href="#">14387</a>	
	@root	1..1	SHALL		<a href="#">14388</a>	2.16.840.1.113883.10.20.22.4.70
	id	1..*	SHALL		<a href="#">14389</a>	
	code	1..1	SHALL		<a href="#">14759</a>	
	@code	1..1	SHALL		<a href="#">14760</a>	2.16.840.1.113883.5.4 (ActCode) = ASSERTION



Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
	text	0..1	SHOULD		<a href="#">14391</a>	
	reference	0..1	SHOULD		<a href="#">14392</a>	
	@value	1..1	SHALL		<a href="#">15585</a>	
	statusCode	1..1	SHALL		<a href="#">14394</a>	
	@code	1..1	SHALL		<a href="#">19111</a>	2.16.840.1.113883.5.14 (ActStatus) = completed
	effectiveTime	1..1	SHALL		<a href="#">14395</a>	
	value	1..1	SHALL	CD	<a href="#">14396</a>	2.16.840.1.113883.11.20.9.35 (Pressure Ulcer Stage)
	@nullFlavor	0..1	MAY		<a href="#">14397</a>	
	targetSiteCode	0..*	SHOULD		<a href="#">14797</a>	
	@code	1..1	SHALL		<a href="#">14798</a>	2.16.840.1.113883.11.20.9.36 (Pressure Point )
	qualifier	0..1	SHOULD		<a href="#">14799</a>	
	name	1..1	SHALL		<a href="#">14800</a>	
	@code	0..1	SHOULD		<a href="#">14801</a>	2.16.840.1.113883.6.96 (SNOMED-CT) = 272741003
	value	1..1	SHALL		<a href="#">14802</a>	
	@code	0..1	SHOULD		<a href="#">14803</a>	2.16.840.1.113883.11.20.9.37 (TargetSite Qualifiers )
	entry Relationship	0..1	SHOULD		<a href="#">14410</a>	
	@typeCode	1..1	SHALL		<a href="#">14411</a>	2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = COMP
	observation	1..1	SHALL		<a href="#">14619</a>	
	@classCode	1..1	SHALL		<a href="#">14685</a>	2.16.840.1.113883.5.6 (HL7ActClass) = OBS
	@moodCode	1..1	SHALL		<a href="#">14686</a>	2.16.840.1.113883.5.1001 (ActMood) = EVN
	code	1..1	SHALL		<a href="#">14620</a>	
	@code	1..1	SHALL		<a href="#">14621</a>	2.16.840.1.113883.6.96 (SNOMED-CT) = 401238003
	value	1..1	SHALL	PQ	<a href="#">14622</a>	
	entry Relationship	0..1	SHOULD		<a href="#">14601</a>	
	@typeCode	1..1	SHALL		<a href="#">14602</a>	COMP
	observation	1..1	SHALL		<a href="#">14623</a>	
	@classCode	1..1	SHALL		<a href="#">14687</a>	2.16.840.1.113883.5.6 (HL7ActClass) = OBS
	@moodCode	1..1	SHALL		<a href="#">14688</a>	2.16.840.1.113883.5.1001 (ActMood) = EVN
	code	1..1	SHALL		<a href="#">14624</a>	

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
	@code	1..1	SHALL		<a href="#">14625</a>	2.16.840.1.113883.6.96 (SNOMED-CT) = 401239006
	value	1..1	SHALL	PQ	<a href="#">14626</a>	
	entry Relationship	0..1	SHOULD		<a href="#">14605</a>	
	@typeCode	1..1	SHALL		<a href="#">14606</a>	COMP
	observation	1..1	SHALL		<a href="#">14627</a>	
	@classCode	1..1	SHALL		<a href="#">14689</a>	2.16.840.1.113883.5.6 (HL7ActClass) = OBS
	@moodCode	1..1	SHALL		<a href="#">14690</a>	2.16.840.1.113883.5.1001 (ActMood) = EVN
	code	1..1	SHALL		<a href="#">14628</a>	
	@code	1..1	SHALL		<a href="#">14629</a>	2.16.840.1.113883.6.96 (SNOMED-CT) = 425094009
	value	1..1	SHALL	PQ	<a href="#">14630</a>	

1. **SHALL** contain exactly one [1..1] @classCode="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:14383).
2. **SHALL** contain exactly one [1..1] @moodCode="EVN" (CodeSystem: ActMood 2.16.840.1.113883.5.1001 **STATIC**) (CONF:14384).

Use negationInd="true" to indicate that the problem was not observed.

3. **MAY** contain zero or one [0..1] @negationInd (CONF:14385).
4. **SHALL** contain exactly one [1..1] templateId (CONF:14387) such that it
  - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.70" (CONF:14388).
5. **SHALL** contain at least one [1..\*] id (CONF:14389).
6. **SHALL** contain exactly one [1..1] code (CONF:14759).
  - a. This code **SHALL** contain exactly one [1..1] @code="ASSERTION" Assertion (CodeSystem: ActCode 2.16.840.1.113883.5.4 **STATIC**) (CONF:14760).
7. **SHOULD** contain zero or one [0..1] text (CONF:14391).
  - a. The text, if present, **SHOULD** contain zero or one [0..1] reference (CONF:14392).
    - i. The reference, if present, **SHALL** contain exactly one [1..1] @value (CONF:15585).
      1. This reference/@value **SHALL** begin with a '#' and **SHALL** point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:15586).
8. **SHALL** contain exactly one [1..1] statusCode (CONF:14394).
  - a. This statusCode **SHALL** contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 **STATIC**) (CONF:19111).

9. **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:14395).
10. **SHALL** contain exactly one [1..1] **value** with **@xsi:type="CD"**, where the **@code** **SHOULD** be selected from ValueSet [Pressure Ulcer Stage 2.16.840.1.113883.11.20.9.35](#) **STATIC** (CONF:14396).
  - a. This value **MAY** contain zero or one [0..1] **@nullFlavor** (CONF:14397).
    - i. If the stage unknown or the SNOMED code is unknown, **@nullFlavor** **SHOULD** be "UNK". If the code is something other than SNOMED, **@nullFlavor** **SHOULD** be "OTH" and the other code **SHOULD** be placed in the translation element (CONF:14398).
11. **SHOULD** contain zero or more [0..\*] **targetSiteCode** (CONF:14797).
  - a. The targetSiteCode, if present, **SHALL** contain exactly one [1..1] **@code**, which **SHOULD** be selected from ValueSet [Pressure Point 2.16.840.1.113883.11.20.9.36](#) **STATIC** (CONF:14798).
  - b. The targetSiteCode, if present, **SHOULD** contain zero or one [0..1] **qualifier** (CONF:14799).
    - i. The qualifier, if present, **SHALL** contain exactly one [1..1] **name** (CONF:14800).
      1. This name **SHOULD** contain zero or one [0..1] **@code="272741003"** laterality (CodeSystem: SNOMED-CT [2.16.840.1.113883.6.96](#) **STATIC**) (CONF:14801).
    - ii. The qualifier, if present, **SHALL** contain exactly one [1..1] **value** (CONF:14802).
      1. This value **SHOULD** contain zero or one [0..1] **@code**, which **SHOULD** be selected from ValueSet [TargetSite Qualifiers 2.16.840.1.113883.11.20.9.37](#) **STATIC** (CONF:14803).
12. **SHOULD** contain zero or one [0..1] **entryRelationship** (CONF:14410) such that it
  - a. **SHALL** contain exactly one [1..1] **@typeCode="COMP"** (CodeSystem: [HL7ActRelationshipType 2.16.840.1.113883.5.1002](#) **STATIC**) (CONF:14411).
  - b. **SHALL** contain exactly one [1..1] **observation** (CONF:14619).
    - i. This observation **SHALL** contain exactly one [1..1] **@classCode="OBS"** (CodeSystem: [HL7ActClass 2.16.840.1.113883.5.6](#) **STATIC**) (CONF:14685).
    - ii. This observation **SHALL** contain exactly one [1..1] **@moodCode="EVN"** (CodeSystem: [ActMood 2.16.840.1.113883.5.1001](#) **STATIC**) (CONF:14686).
    - iii. This observation **SHALL** contain exactly one [1..1] **code** (CONF:14620).
      1. This code **SHALL** contain exactly one [1..1] **@code="401238003"** Length of Wound (CodeSystem: SNOMED-CT [2.16.840.1.113883.6.96](#) **STATIC**) (CONF:14621).
    - iv. This observation **SHALL** contain exactly one [1..1] **value** with **@xsi:type="PQ"** (CONF:14622).
13. **SHOULD** contain zero or one [0..1] **entryRelationship** (CONF:14601) such that it
  - a. **SHALL** contain exactly one [1..1] **@typeCode="COMP"** (CONF:14602).
  - b. **SHALL** contain exactly one [1..1] **observation** (CONF:14623).

- i. This observation **SHALL** contain exactly one [1..1] **@classCode="OBS"** (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:14687).
  - ii. This observation **SHALL** contain exactly one [1..1] **@moodCode="EVN"** (CodeSystem: ActMood 2.16.840.1.113883.5.1001 **STATIC**) (CONF:14688).
  - iii. This observation **SHALL** contain exactly one [1..1] **code** (CONF:14624).
    - 1. This code **SHALL** contain exactly one [1..1] **@code="401239006" Width of Wound** (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96 **STATIC**) (CONF:14625).
  - iv. This observation **SHALL** contain exactly one [1..1] **value** with **@xsi:type="PQ"** (CONF:14626).
14. **SHOULD** contain zero or one [0..1] **entryRelationship** (CONF:14605) such that it
- a. **SHALL** contain exactly one [1..1] **@typeCode="COMP"** (CONF:14606).
  - b. **SHALL** contain exactly one [1..1] **observation** (CONF:14627).
    - i. This observation **SHALL** contain exactly one [1..1] **@classCode="OBS"** (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:14689).
    - ii. This observation **SHALL** contain exactly one [1..1] **@moodCode="EVN"** (CodeSystem: ActMood 2.16.840.1.113883.5.1001 **STATIC**) (CONF:14690).
    - iii. This observation **SHALL** contain exactly one [1..1] **code** (CONF:14628).
      - 1. This code **SHALL** contain exactly one [1..1] **@code="425094009" Depth of Wound** (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96 **STATIC**) (CONF:14629).
    - iv. This observation **SHALL** contain exactly one [1..1] **value** with **@xsi:type="PQ"** (CONF:14630).

**Table 188: Pressure Point Value Set**

Value Set: Pressure Point 2.16.840.1.113883.11.20.9.36 STATIC		
Code System: SNOMED-CT 2.16.840.1.113883.6.96		
Code	Code System	Print Name
43631005	SNOMED-CT	occipital region structure
23747009	SNOMED-CT	skin structure of chin
91774008	SNOMED-CT	structure of right shoulder
7874003	SNOMED-CT	structure of scapular region of back; 272741003 = laterality; 24028007 = right (qualifier value)
368149001	SNOMED-CT	right elbow region structure
368148009	SNOMED-CT	left elbow region structure
87141009	SNOMED-CT	sacral vertebra structure
122495006	SNOMED-CT	thoracic spine structure
122496007	SNOMED-CT	lumbar spine structure
287579007	SNOMED-CT	right hip region structure
387679003	SNOMED-CT	left hip region structure
396993003	SNOMED-CT	right posterior iliac crest
396994009	SNOMED-CT	left posterior iliac crest
46862004	SNOMED-CT	buttock structure;272741003 = laterality;7771000 = left
6757004	SNOMED-CT	structure of right knee
82169009	SNOMED-CT	structure of left knee
76853006	SNOMED-CT	heel structure; 272741003 = laterality; 24028007 = right
182304008	SNOMED-CT	medial aspect of ankle; 272741003 = laterality; 24028007 = right
182305009	SNOMED-CT	lateral aspect of ankle; 272741003 = laterality; 24028007 = right
43631005	SNOMED-CT	occipital region structure
23747009	SNOMED-CT	skin structure of chin
91774008	SNOMED-CT	structure of right shoulder
7874003	SNOMED-CT	structure of scapular region of back; 272741003 = laterality; 24028007 = right (qualifier value)
368149001	SNOMED-CT	right elbow region structure
368148009	SNOMED-CT	left elbow region structure
87141009	SNOMED-CT	sacral vertebra structure
122495006	SNOMED-CT	thoracic spine structure
122496007	SNOMED-CT	lumbar spine structure
287579007	SNOMED-CT	right hip region structure
387679003	SNOMED-CT	left hip region structure
396993003	SNOMED-CT	right posterior iliac crest
396994009	SNOMED-CT	left posterior iliac crest
46862004	SNOMED-CT	buttock structure;272741003 = laterality;7771000 = left
6757004	SNOMED-CT	structure of right knee

Value Set: Pressure Point 2.16.840.1.113883.11.20.9.36 STATIC		
Code System: SNOMED-CT 2.16.840.1.113883.6.96		
Code	Code System	Print Name
82169009	SNOMED-CT	structure of left knee
76853006	SNOMED-CT	heel structure; 272741003 = laterality; 24028007 = right
182304008	SNOMED-CT	medial aspect of ankle; 272741003 = laterality; 7771000 = left
182305009	SNOMED-CT	lateral aspect of ankle; 272741003 = laterality; 7771000 = left
6685009	SNOMED-CT	structure of right ankle

**Table 189: TargetSite Qualifiers Value Set**

Value Set: TargetSite Qualifiers 2.16.840.1.113883.11.20.9.37 STATIC		
Code System: SNOMED-CT 2.16.840.1.113883.6.96		
Code	Code System	Print Name
255549009	SNOMED-CT	anterior
7771000	SNOMED-CT	left
255561001	SNOMED-CT	medial
255551008	SNOMED-CT	posterior
24028007	SNOMED-CT	right

**Figure 94: Pressure ulcer observation example**

```

<entry typeCode="DRIV">
 <observation classCode="OBS" moodCode="EVN">
 <templateId root="2.16.840.1.113883.10.20.22.4.70"/>
 <!-- Pressure Ulcer Observation in Plan of Care template -->
 <id root="e2292075-9183-4a25-b8c3-df8521130443"/>
 <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"/>
 <statusCode code="completed"/>
 <text>
 <reference value="#PULC1"/>
 </text>
 <effectiveTime value="20120328"/>
 <value xsi:type="CD" code="421927004" codeSystem="2.16.840.1.113883.6.96"
 displayName="Pressure ulcer stage 3"/>
 <targetSiteCode code="76552005" codeSystem="2.16.840.1.113883.6.96"
 displayName="skin structure of shoulder"/>
 <qualifier>
 <name code="272741003" displayName="Laterality"/>
 <value code="7771000" displayName="Left"/>
 </qualifier>
 </observation>
</entry>

```

```

<entryRelationship typeCode="COMP">
 <observation classCode="OBS" moodCode="EVN">
 <templateId root="2.16.840.1.113883.10.20.22.4.70"/>
 <id root="737b4094-ebb1-41ed-8fcd-f3c53f649e3b"/>
 <code code="401239006" codeSystem="2.16.840.1.113883.6.96"
 displayName="Width of Wound"/>
 <statusCode code="completed"/>
 <value xsi:type="PQ" value="1" unit="[in_i]"/>
 </observation>
</entryRelationship>

<entryRelationship typeCode="COMP">
 <observation classCode="OBS" moodCode="EVN">
 <templateId root="2.16.840.1.113883.10.20.22.4.70"/>
 <id root="737b4094-ebb1-41ed-8fcd-f3c53f649e3b"/>
 <code code="401238003" codeSystem="2.16.840.1.113883.6.96"
 displayName="Length of Wound"/>
 <statusCode code="completed"/>
 <value xsi:type="PQ" value="2" unit="[in_i]"/>
 </observation>
</entryRelationship>

<entryRelationship typeCode="COMP">
 <observation classCode="OBS" moodCode="EVN">
 <templateId root="2.16.840.1.113883.10.20.22.4.70"/>
 <id root="737b4094-ebb1-41ed-8fcd-f3c53f649e3b"/>
 <code code="425094009" codeSystem="2.16.840.1.113883.6.96"
 displayName="Depth of Wound"/>
 <statusCode code="completed"/>
 <value xsi:type="PQ" value="0.5" unit="[in_i]"/>
 </observation>
</entryRelationship>

```

#### 4.44 Problem Concern Act (Condition) [Closed for comments; published July 2012]

[act: templateId 2.16.840.1.113883.10.20.22.4.3 (open)]

**Table 190: Problem Concern Act (Condition) Contexts**

Used By:	Contains Entries:
<a href="#">Problem Section (entries optional)</a> (optional)	<a href="#">Problem Observation</a>

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 allows for binding related observations of problems. For example, the observation of "Acute MI" in 2004 can be related to the observation of "History of MI" in 2006 because they are the same concern. The conformance statements in this section define an outer "problem act" (representing the "Concern") that can contain a nested "problem observation" or other nested clinical statements.

**Table 191: Problem Concern Act (Condition) Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	act[templateId/@root = '2.16.840.1.113883.10.20.22.4.3']					
	@classCode	1..1	SHALL		<a href="#">9024</a>	2.16.840.1.113883.5.6 (HL7ActClass) = ACT
	@moodCode	1..1	SHALL		<a href="#">9025</a>	2.16.840.1.113883.5.1001 (ActMood) = EVN
	templateId	1..1	SHALL		<a href="#">16772</a>	
	@root	1..1	SHALL		<a href="#">16773</a>	2.16.840.1.113883.10.20.22.4.3
	id	1..*	SHALL		<a href="#">9026</a>	
	code	1..1	SHALL		<a href="#">9027</a>	
	@code	1..1	SHALL		<a href="#">19184</a>	2.16.840.1.113883.5.6 (HL7ActClass) = CONC
	statusCode	1..1	SHALL		<a href="#">9029</a>	2.16.840.1.113883.11.20.9.19 (ProblemAct statusCode)
	effectiveTime	1..1	SHALL		<a href="#">9030</a>	
	low	1..1	SHALL		<a href="#">9032</a>	
	high	0..1	SHOULD		<a href="#">9033</a>	
	entry Relationship	1..*	SHALL		<a href="#">9034</a>	
	@typeCode	1..1	SHALL		<a href="#">9035</a>	2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = SUBJ
	observation	1..1	SHALL		<a href="#">15980</a>	

1. **SHALL** contain exactly one [1..1] @classCode="ACT" Act (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:9024).
2. **SHALL** contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 **STATIC**) (CONF:9025).
3. **SHALL** contain exactly one [1..1] templateId (CONF:16772) such that it
  - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.3" (CONF:16773).
4. **SHALL** contain at least one [1..\*] id (CONF:9026).
5. **SHALL** contain exactly one [1..1] code (CONF:9027).
  - a. This code **SHALL** contain exactly one [1..1] @code="CONC" Concern (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:19184).
6. **SHALL** contain exactly one [1..1] statusCode, which **SHALL** be selected from ValueSet [ProblemAct statusCode 2.16.840.1.113883.11.20.9.19](#) **STATIC** 2011-09-09 (CONF:9029).

The effectiveTime element records the starting and ending times during which the concern was active on the Problem List.



7. **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:9030).
  - a. This effectiveTime **SHALL** contain exactly one [1..1] **low** (CONF:9032).
  - b. This effectiveTime **SHOULD** contain zero or one [0..1] **high** (CONF:9033).
8. **SHALL** contain at least one [1..\*] **entryRelationship** (CONF:9034) such that it
  - a. **SHALL** contain exactly one [1..1] **@typeCode="SUBJ"** Has subject (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**) (CONF:9035).
  - b. **SHALL** contain exactly one [1..1] **Problem Observation** (templateId:2.16.840.1.113883.10.20.22.4.4) (CONF:15980).

#### 4.44.1 Breast Cancer Concern Act

[Act: templateId 2.16.840.1.113883.10.20.30.3.6 (open)]

**Table 192: Breast Cancer Concern Act Contexts**

Used By:	Contains Entries:
<a href="#">Problem Section BCTPS</a> (required)	<a href="#">Breast Cancer Diagnosis Observation</a>

This clinical statement represents the breast cancer concern and contains the diagnosis of breast cancer which includes diagnosis detail and supporting observations such as breast cancer site, tumor type, and cancer staging.

**Table 193: Breast Cancer Concern Act Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	Act[templateId/@root = '2.16.840.1.113883.10.20.30.3.6']					
	templateId	1..1	SHALL		<a href="#">21814</a>	
	@root	1..1	SHALL		<a href="#">21815</a>	2.16.840.1.113883.10.20.30.3.6
	entryRelationship	1..1	SHALL		<a href="#">21817</a>	
	@typeCode	1..1	SHALL		<a href="#">21818</a>	2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = SUBJ
	observation	1..1	SHALL		<a href="#">21819</a>	
	entryRelationship	1..1	SHALL		<a href="#">21973</a>	

1. Conforms to [Problem Concern Act \(Condition\)](#) template (2.16.840.1.113883.10.20.22.4.3).
2. **SHALL** contain exactly one [1..1] **templateId** (CONF:21814) such that it
  - a. **SHALL** contain exactly one [1..1] **@root="2.16.840.1.113883.10.20.30.3.6"** (CONF:21815).
3. **SHALL** contain exactly one [1..1] **entryRelationship** (CONF:21817) such that it
  - a. **SHALL** contain exactly one [1..1] **@typeCode="SUBJ"** Has subject (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:21818).

- b. **SHALL** contain exactly one [1..1] [Breast Cancer Diagnosis Observation](#) (templateId:2.16.840.1.113883.10.20.30.3.2) (CONF:21819).
- 4. **SHALL** contain exactly one [1..1] **entryRelationship** (CONF:21973).

**Figure 95: Breast Cancer Concern Act example**

```

<entry typeCode="DRIV">
 <act classCode="ACT" moodCode="EVN">
 <!-- C-CDA PROBLEM CONCERN ACT(Condition)TemplateID -->
 <templateId root="2.16.840.1.113883.10.20.22.4.3"/>
 <!-- Breast Cancer Concern Act TemplateID -->
 <templateId root="2.16.840.1.113883.10.20.30.3.6"/>
 <id root="ec8a6ff8-ed4b-4f7e-82c3-e98e58b45de7"/>
 <code code="CONC" codeSystem="2.16.840.1.113883.5.6"
 displayName="Concern"/>
 <statusCode code="completed"/>
 <effectiveTime>
 <low value="20120104"/>
 <high value="20120104"/>
 </effectiveTime>

 <!-- BREAST CANCER DIAGNOSIS OBSERVATION -->
 <entryRelationship typeCode="SUBJ">
 <observation classCode="OBS" moodCode="EVN">
 <!-- C-CDA PROBLEM OBSERVATION TemplateID -->
 <templateId root="2.16.840.1.113883.10.20.22.4.4"/>
 <!-- Breast Cancer Diagnosis Observation TemplateID -->
 <templateId root="2.16.840.1.113883.10.20.30.3.2"/>
 ...
 </observation>
 </entryRelationship>
 </act>
</entry>

```

#### 4.45 Problem Observation

**[Closed for comments; published July 2012]**

[observation: templateId 2.16.840.1.113883.10.20.22.4.4 (open)]

**Table 194: Problem Observation Contexts**

Used By:	Contains Entries:
<a href="#">Problem Concern Act (Condition)</a> (required) <a href="#">Encounter Diagnosis</a> (required)	<a href="#">Age Observation</a> <a href="#">Health Status Observation</a> <a href="#">Problem Status</a>

A problem is a clinical statement that a clinician has noted. In health care it is a condition that requires monitoring or diagnostic, therapeutic, or educational action. It also refers to any unmet or partially met basic human need.

A Problem Observation is required to be wrapped in an act wrapper in locations such as the Problem Section, Allergies Section, and Hospital Discharge Diagnosis Section, where the type of problem needs to be identified or the condition tracked.

A Problem Observation can be a valid "standalone" template instance in cases where a simple problem observation is to be sent.

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). `NegationInd='true'` is an acceptable way to make a clinical assertion that something did not occur, for example, 'no diabetes'.

**Table 195: Problem Observation Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
Green Problem Observation	observation[templateId/@root = '2.16.840.1.113883.10.20.22.4.4']					
	@classCode	1..1	SHALL		<a href="#">9041</a>	2.16.840.1.113883.5.6 (HL7ActClass) = OBS
	@moodCode	1..1	SHALL		<a href="#">9042</a>	2.16.840.1.113883.5.1001 (ActMood) = EVN
	@negationInd	0..1	MAY		<a href="#">10139</a>	
	templateId	1..1	SHALL		<a href="#">14926</a>	
	@root	1..1	SHALL		<a href="#">14927</a>	2.16.840.1.113883.10.20.22.4.4
	id	1..*	SHALL		<a href="#">9043</a>	
problem Type	code	1..1	SHALL		<a href="#">9045</a>	2.16.840.1.113883.3.88.12.3221.7.2 (Problem Type)
problem Name	text	0..1	SHOULD		<a href="#">9185</a>	
	reference	0..1	SHOULD		<a href="#">15587</a>	
	@value	1..1	SHALL		<a href="#">15588</a>	
	statusCode	1..1	SHALL		<a href="#">9049</a>	
	@code	1..1	SHALL		<a href="#">19112</a>	2.16.840.1.113883.5.14 (ActStatus) = completed
problem Date	effectiveTime	0..1	SHOULD		<a href="#">9050</a>	
	low	1..1	SHALL		<a href="#">15603</a>	
	high	0..1	SHOULD		<a href="#">15604</a>	
problem Code	value	1..1	SHALL	CD	<a href="#">9058</a>	2.16.840.1.113883.3.88.12.3221.7.4 (Problem Value Set)
	translation	0..*	MAY		<a href="#">16749</a>	
	@code	0..1	MAY		<a href="#">16750</a>	2.16.840.1.113883.6.90 (ICD10CM)

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
	@nullFlavor	0..1	MAY		<a href="#">10141</a>	
ageAtOnset	entry Relationship	0..1	MAY		<a href="#">9059</a>	
	@typeCode	1..1	SHALL		<a href="#">9060</a>	2.16.840.1.113883.5.1002 (HL7ActRelationship Type) = SUBJ
	@inversionInd	1..1	SHALL		<a href="#">9069</a>	true
	observation	1..1	SHALL		<a href="#">15590</a>	
problem Status	entry Relationship	0..1	MAY		<a href="#">9063</a>	
	@typeCode	1..1	SHALL		<a href="#">9068</a>	2.16.840.1.113883.5.1002 (HL7ActRelationship Type) = REFR
	observation	1..1	SHALL		<a href="#">15591</a>	
	entry Relationship	0..1	MAY		<a href="#">9067</a>	
	@typeCode	1..1	SHALL		<a href="#">9064</a>	2.16.840.1.113883.5.1002 (HL7ActRelationship Type) = REFR
	observation	1..1	SHALL		<a href="#">15592</a>	

1. **SHALL** contain exactly one [1..1] @classCode="OBS" Observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:9041).
2. **SHALL** contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 **STATIC**) (CONF:9042).
3. **MAY** contain zero or one [0..1] @negationInd (CONF:10139).
  - a. Use negationInd="true" to indicate that the problem was not observed (CONF:16880).
4. **SHALL** contain exactly one [1..1] templateId (CONF:14926) such that it
  - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.4" (CONF:14927).
5. **SHALL** contain at least one [1..\*] id (CONF:9043).
6. **SHALL** contain exactly one [1..1] code, which **SHOULD** be selected from ValueSet [Problem Type 2.16.840.1.113883.3.88.12.3221.7.2 \*\*STATIC\*\* 2012-06-01](#) (CONF:9045).
7. **SHOULD** contain zero or one [0..1] text (CONF:9185).
  - a. The text, if present, **SHOULD** contain zero or one [0..1] reference (CONF:15587).
    - i. The reference, if present, **SHALL** contain exactly one [1..1] @value (CONF:15588).

1. This reference/@value **SHALL** begin with a '#' and **SHALL** point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:15589).
8. **SHALL** contain exactly one [1..1] **statusCode** (CONF:9049).
  - a. This statusCode **SHALL** contain exactly one [1..1] **@code="completed"** Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 **STATIC**) (CONF:19112).
9. **SHOULD** contain zero or one [0..1] **effectiveTime** (CONF:9050).
  - a. The effectiveTime, if present, **SHALL** contain exactly one [1..1] **low** (CONF:15603).
    - i. This field represents the onset date (CONF:16882).
  - b. The effectiveTime, if present, **SHOULD** contain zero or one [0..1] **high** (CONF:15604).
    - i. This field represents the resolution date (CONF:16883).
  - c. 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 (CONF:16881).
10. **SHALL** contain exactly one [1..1] **value** with **@xsi:type="CD"**, where the **@code** **SHOULD** be selected from ValueSet [Problem Value Set 2.16.840.1.113883.3.88.12.3221.7.4](#) **DYNAMIC** (CONF:9058).
  - a. This value **MAY** contain zero or more [0..\*] **translation** (CONF:16749).
    - i. The translation, if present, **MAY** contain zero or one [0..1] **@code** (CodeSystem: ICD10CM 2.16.840.1.113883.6.90 **STATIC**) (CONF:16750).
  - b. This value **MAY** contain zero or one [0..1] **@nullFlavor** (CONF:10141).
    - i. If the diagnosis is unknown or the SNOMED code is unknown, **@nullFlavor** **SHOULD** be "UNK". If the code is something other than SNOMED, **@nullFlavor** **SHOULD** be "OTH" and the other code **SHOULD** be placed in the translation element (CONF:10142).
11. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:9059) such that it
  - a. **SHALL** contain exactly one [1..1] **@typeCode="SUBJ"** Has subject (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**) (CONF:9060).
  - b. **SHALL** contain exactly one [1..1] **@inversionInd="true"** True (CONF:9069).
  - c. **SHALL** contain exactly one [1..1] [Age Observation](#) (templateId:2.16.840.1.113883.10.20.22.4.31) (CONF:15590).
12. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:9063) such that it
  - a. **SHALL** contain exactly one [1..1] **@typeCode="REFR"** Refers to (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**) (CONF:9068).
  - b. **SHALL** contain exactly one [1..1] [Problem Status](#) (templateId:2.16.840.1.113883.10.20.22.4.6) (CONF:15591).
13. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:9067) such that it

- a. **SHALL** contain exactly one [1..1] **@typeCode="REFR"** Refers to (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**) (CONF:9064).
- b. **SHALL** contain exactly one [1..1] **Health Status Observation** (templateId:2.16.840.1.113883.10.20.22.4.5) (CONF:15592).

#### 4.45.1 Breast Cancer Diagnosis Observation

[Observation: templateId 2.16.840.1.113883.10.20.30.3.2 (open)]

**Table 196: Breast Cancer Diagnosis Observation Contexts**

Used By:	Contains Entries:
<a href="#">Breast Cancer Concern Act</a> (required)	<a href="#">Breast TNM Clinical Category</a> <a href="#">Post Treatment Disease Status</a>

This clinical statement represents the diagnosis of breast cancer which includes diagnosis detail and supporting observations such as breast cancer site, tumor type, and cancer staging.

**Table 197: Breast Cancer Diagnosis Observation Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
	Observation[templateId/@root = '2.16.840.1.113883.10.20.30.3.2']					
	templateId	1..1	SHALL		<a href="#">19279</a>	
	@root	1..1	SHALL		<a href="#">19280</a>	2.16.840.1.113883.10.20.30.3.2
	id	1..*	SHALL		<a href="#">22067</a>	
	code	1..1	SHALL		<a href="#">21945</a>	
	@code	1..1	SHALL		<a href="#">21946</a>	282291009
	@codeSystem	1..1	SHALL		<a href="#">24942</a>	2.16.840.1.113883.6.96 (SNOMED-CT) = 2.16.840.1.113883.6.96
	statusCode	1..1	SHALL		<a href="#">26224</a>	
	@code	1..1	SHALL		<a href="#">26225</a>	2.16.840.1.113883.5.14 (ActStatus) = Completed
	effectiveTime	1..1	SHALL		<a href="#">22076</a>	
	value	1..1	SHALL	CD	<a href="#">27170</a>	2.16.840.1.113883.3.526.3.389 (Breast Cancer)
	targetSiteCode	1..*	SHALL		<a href="#">21925</a>	
	@code	1..1	SHALL		<a href="#">21947</a>	2.16.840.1.113883.3.88.12.3221.8.9 (Body Site Value Set)
	qualifier	0..*	MAY		<a href="#">22068</a>	
	name	1..1	SHALL		<a href="#">22069</a>	
	value	1..1	SHALL		<a href="#">22070</a>	

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
	entry Relationship	1..1	SHALL		<a href="#">21926</a>	
	@typeCode	1..1	SHALL		<a href="#">21927</a>	2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = SPRT
	act	1..1	SHALL		<a href="#">21928</a>	
	entry Relationship	0..1	MAY		<a href="#">24939</a>	
	@typeCode	1..1	SHALL		<a href="#">24940</a>	2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = COMP
	observation	1..1	SHALL		<a href="#">24941</a>	

1. Conforms to [Problem Observation](#) template (2.16.840.1.113883.10.20.22.4.4).
2. **SHALL** contain exactly one [1..1] **templateId** (CONF:19279) such that it
  - a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.30.3.2" (CONF:19280).
3. **SHALL** contain at least one [1..\*] **id** (CONF:22067).
4. **SHALL** contain exactly one [1..1] **code** (CONF:21945).
  - a. This code **SHALL** contain exactly one [1..1] **@code**="282291009" Diagnosis (CONF:21946).
  - b. This code **SHALL** contain exactly one [1..1] **@codeSystem**="2.16.840.1.113883.6.96" (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96) (CONF:24942).
5. **SHALL** contain exactly one [1..1] **statusCode** (CONF:26224).
  - a. This statusCode **SHALL** contain exactly one [1..1] **@code**="Completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14) (CONF:26225).

The presence of an effective time low indicates the problem onset date. The presence of an effective time high indicates the problem resolution date.

6. **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:22076).
7. **SHALL** contain exactly one [1..1] **value** with **@xsi:type**="CD", where the **@code** **SHALL** be selected from ValueSet Breast Cancer 2.16.840.1.113883.3.526.3.389 **DYNAMIC** (CONF:27170).
8. **SHALL** contain at least one [1..\*] **targetSiteCode** (CONF:21925).
  - a. Such targetSiteCodes **SHALL** contain exactly one [1..1] **@code** (ValueSet: [Body Site Value Set 2.16.840.1.113883.3.88.12.3221.8.9](#)) (CONF:21947).
  - b. Such targetSiteCodes **MAY** contain zero or more [0..\*] **qualifier** (CONF:22068).
    - i. The qualifier, if present, **SHALL** contain exactly one [1..1] **name** (CONF:22069).

- ii. The qualifier, if present, **SHALL** contain exactly one [1..1] **value** (CONF:22070).
9. **SHALL** contain exactly one [1..1] **entryRelationship** (CONF:21926) such that it
- a. **SHALL** contain exactly one [1..1] **@typeCode="SPRT"** Has support (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:21927).
  - b. **SHALL** contain exactly one [1..1] **Overall Stage** (templateId:2.16.840.1.113883.10.20.30.3.3) (CONF:21928).
10. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:24939) such that it
- a. **SHALL** contain exactly one [1..1] **@typeCode="COMP"** Has component (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:24940).
  - b. **SHALL** contain exactly one [1..1] **Post Treatment Disease Status** (templateId:2.16.840.1.113883.10.20.30.3.29) (CONF:24941).

**Table 198: Breast Cancer Value Set (excerpt)**

Value Set: Breast Cancer 2.16.840.1.113883.3.526.3.389 DYNAMIC		
Code System(s): SNOMED-CT 2.16.840.1.113883.6.96		
ICD9CM 2.16.840.1.113883.6.2		
ICD10CM 2.16.840.1.113883.6.90		
Description: List diagnoses related to breast cancer.		
Reference: <a href="https://vsac.nlm.nih.gov/">https://vsac.nlm.nih.gov/</a>		
Code	Code System	Print Name
109886000	SNOMED-CT	Overlapping malignant neoplasm of female breast (disorder)
174.0	ICD9CM	Malignant neoplasm of nipple and areola of female breast
174.1	ICD9CM	Malignant neoplasm of central portion of female breast
174.2	ICD9CM	Malignant neoplasm of upper-inner quadrant of female breast
188147009	SNOMED-CT	Malignant neoplasm of nipple and areola of female breast (disorder)
188151006	SNOMED-CT	Malignant neoplasm of central part of female breast (disorder)
188152004	SNOMED-CT	Malignant neoplasm of upper-inner quadrant of female breast (disorder)
C50.011	ICD10CM	Malignant neoplasm of nipple and areola, right female breast
C50.012	ICD10CM	Malignant neoplasm of nipple and areola, left female breast
C50.019	ICD10CM	Malignant neoplasm of nipple and areola, unspecified female breast
...		



**Figure 96: Breast Cancer Diagnosis Observation examples**

```
entryRelationship typeCode="SUBJ">
 <observation classCode="OBS" moodCode="EVN">
 <!-- C-CDA PROBLEM OBSERVATION TemplateID -->
 <templateId root="2.16.840.1.113883.10.20.22.4.4"/>
 <!-- Breast Cancer Diagnosis Observation TemplateID -->
 <templateId root="2.16.840.1.113883.10.20.30.3.2"/>
 <id root="4f5e6e60-e641-4e80-ac7b-cdea1029bcce"/>
 <code code="282291009"
 codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMED CT"
 displayName="diagnosis"/>
 <statusCode code="completed"/>
 <!-- Date of diagnosis -->
 <effectiveTime>
 <low value="20120104"/>
 </effectiveTime>
 <value xsi:type="CD" codeSystem="2.16.840.1.113883.6.2"
 codeSystemName="ICD-9"
 code="174.0"
 displayName="Malignant Neoplasm of Nipple and Areola of Female
 Breast"/>
 <targetSiteCode code="80248007"
 codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMED CT"
 displayName="left breast (body structure)"/>

 <!-- OVERALL STAGE-->
 <entryRelationship typeCode="SPRT">
 <act classCode="ACT" moodCode="EVN">
 <!-- Overall stage TemplateID -->
 <templateId root="2.16.840.1.113883.10.20.30.3.3"/>
 ...
 </act>
 </entryRelationship>

 <!-- POST TREATMENT DISEASE STATUS -->
 <entryRelationship typeCode="COMP">
 <observation classCode="OBS" moodCode="EVN">
 <!-- Post Treatment Disease Status TemplateID-->
 <templateId root="2.16.840.1.113883.10.20.30.3.29"/>
 ...
 </observation>
 </entryRelationship>
 </observation>
</entryRelationship>
```

#### 4.45.2 Cognitive Status Problem Observation [Closed for comments; published July 2012]

[observation: templateId 2.16.840.1.113883.10.20.22.4.73 (open)]

**Table 199: Cognitive Status Problem Observation Contexts**

Used By:	Contains Entries:
<a href="#">Functional Status Section</a> (optional)	<a href="#">Assessment Scale Observation</a> <a href="#">Caregiver Characteristics</a> <a href="#">Non-Medicinal Supply Activity</a>

A cognitive status problem observation is a clinical statement that describes a patient's cognitive condition, findings, or symptoms. Examples of cognitive problem observations are inability to recall, amnesia, dementia, and aggressive behavior.

A cognitive problem observation is a finding or medical condition. This is different from a cognitive result observation, which is a response to a question that provides insight into the patient's cognitive status, judgment, comprehension ability, or response speed.

**Table 200: Cognitive Status Problem Observation Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
	observation[templateId/@root = '2.16.840.1.113883.10.20.22.4.73']					
	@classCode	1..1	SHALL		<a href="#">14319</a>	2.16.840.1.113883.5.6 (HL7ActClass) = OBS
	@moodCode	1..1	SHALL		<a href="#">14320</a>	2.16.840.1.113883.5.1001 (ActMood) = EVN
	@negationInd	0..1	MAY		<a href="#">14344</a>	
	templateId	1..1	SHALL		<a href="#">14346</a>	
	@root	1..1	SHALL		<a href="#">14347</a>	2.16.840.1.113883.10.20.22.4.73
	id	1..*	SHALL		<a href="#">14321</a>	
	code	1..1	SHALL		<a href="#">14804</a>	
	@code	0..1	SHOULD		<a href="#">14805</a>	2.16.840.1.113883.6.96 (SNOMED-CT) = 373930000
	text	0..1	SHOULD		<a href="#">14341</a>	
	reference	0..1	SHOULD		<a href="#">15532</a>	
	@value	0..1	SHOULD		<a href="#">15533</a>	
	statusCode	1..1	SHALL		<a href="#">14323</a>	
	@code	1..1	SHALL		<a href="#">19091</a>	2.16.840.1.113883.5.14 (ActStatus) = completed
	effectiveTime	0..1	SHOULD		<a href="#">14324</a>	
	value	1..1	SHALL	CD	<a href="#">14349</a>	2.16.840.1.113883.3.88.12.322 1.7.4 (Problem Value Set)
	methodCode	0..*	MAY		<a href="#">14693</a>	

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
	entry Relationship	0..*	MAY		<a href="#">14331</a>	
	@typeCode	1..1	SHALL		<a href="#">14588</a>	2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = REFR
	supply	1..1	SHALL		<a href="#">14351</a>	
	entry Relationship	0..*	MAY		<a href="#">14335</a>	
	@typeCode	1..1	SHALL		<a href="#">14589</a>	2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = REFR
	observation	1..1	SHALL		<a href="#">14352</a>	
	entry Relationship	0..*	MAY		<a href="#">14467</a>	
	@typeCode	1..1	SHALL		<a href="#">14590</a>	2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = COMP
	observation	1..1	SHALL		<a href="#">14468</a>	

1. Conforms to [Problem Observation](#) template (2.16.840.1.113883.10.20.22.4.4).
2. **SHALL** contain exactly one [1..1] @classCode="OBS" Observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:14319).
3. **SHALL** contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 **STATIC**) (CONF:14320).

Use negationInd="true" to indicate that the problem was not observed.

4. **MAY** contain zero or one [0..1] @negationInd (CONF:14344).
5. **SHALL** contain exactly one [1..1] templateId (CONF:14346) such that it
  - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.73" (CONF:14347).
6. **SHALL** contain at least one [1..\*] id (CONF:14321).
7. **SHALL** contain exactly one [1..1] code (CONF:14804).
  - a. This code **SHOULD** contain zero or one [0..1] @code="373930000" Cognitive function finding (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96 **STATIC**) (CONF:14805).
8. **SHOULD** contain zero or one [0..1] text (CONF:14341).
  - a. The text, if present, **SHOULD** contain zero or one [0..1] reference (CONF:15532).
    - i. The reference, if present, **SHOULD** contain zero or one [0..1] @value (CONF:15533).
      1. **SHALL** begin with a '#' and **SHALL** point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:15534).

9. **SHALL** contain exactly one [1..1] **statusCode** (CONF:14323).
  - a. This statusCode **SHALL** contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 **STATIC**) (CONF:19091).
10. **SHOULD** contain zero or one [0..1] **effectiveTime** (CONF:14324).
  - a. The onset date **SHALL** be recorded in the low element of the effectiveTime element when known (CONF:14325).
  - b. The resolution date **SHALL** be recorded in the high element of the effectiveTime element when known (CONF:14326).
  - c. 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 a high element within a problem does indicate that the problem has been resolved (CONF:14327).
11. **SHALL** contain exactly one [1..1] **value** with @xsi:type="CD", where the @code **SHOULD** be selected from ValueSet [Problem Value Set 2.16.840.1.113883.3.88.12.3221.7.4](#) **DYNAMIC** (CONF:14349).
12. **MAY** contain zero or more [0..\*] **methodCode** (CONF:14693).
13. **MAY** contain zero or more [0..\*] **entryRelationship** (CONF:14331) such that it
  - a. **SHALL** contain exactly one [1..1] @typeCode="REFR" refers to (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**) (CONF:14588).
  - b. **SHALL** contain exactly one [1..1] [Non-Medicinal Supply Activity](#) (templateId:2.16.840.1.113883.10.20.22.4.50) (CONF:14351).
14. **MAY** contain zero or more [0..\*] **entryRelationship** (CONF:14335) such that it
  - a. **SHALL** contain exactly one [1..1] @typeCode="REFR" refers to (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**) (CONF:14589).
  - b. **SHALL** contain exactly one [1..1] [Caregiver Characteristics](#) (templateId:2.16.840.1.113883.10.20.22.4.72) (CONF:14352).
15. **MAY** contain zero or more [0..\*] **entryRelationship** (CONF:14467) such that it
  - a. **SHALL** contain exactly one [1..1] @typeCode="COMP" has component (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**) (CONF:14590).
  - b. **SHALL** contain exactly one [1..1] [Assessment Scale Observation](#) (templateId:2.16.840.1.113883.10.20.22.4.69) (CONF:14468).

**Figure 97: Cognitive Status Problem Observation example**

```

<observation classCode="OBS" moodCode="EVN">
 <!-- ** conforms to Problem observation ** -->
 <templateId root="2.16.840.1.113883.10.20.22.4.4"/>
 <templateId root="2.16.840.1.113883.10.20.22.4.73"/>

 <id root="08edb7c0-2111-43f2-a784-9a5fdfaa67f0"/>
 <code code="373930000"
 codeSystem="2.16.840.1.113883.6.96"
 displayName="Cognitive Function Finding"/>
 <text>
 <reference value="#COG2"/>
 </text>
 <statusCode code="completed"/>
 <effectiveTime>
 <low value="200704"/>
 <high value="200706"/>
 </effectiveTime>
 <value xsi:type="CD" code=" 371632003"
 codeSystem="2.16.840.1.113883.6.96"
 displayName="Comatose"/>
</observation>

```

#### 4.45.3 Functional Status Problem Observation

**[Closed for comments; published July 2012]**

[observation: templateId 2.16.840.1.113883.10.20.22.4.68 (open)]

**Table 201: Functional Status Problem Observation Contexts**

Used By:	Contains Entries:
<a href="#">Functional Status Section</a> (optional)	<a href="#">Assessment Scale Observation</a> <a href="#">Caregiver Characteristics</a> <a href="#">Non-Medicinal Supply Activity</a>

A functional status problem observation is a clinical statement that represents a patient's functional performance and ability.

**Table 202: Functional Status Problem Observation Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
	observation[templateId/@root = '2.16.840.1.113883.10.20.22.4.68']					
	@classCode	1..1	SHALL		<a href="#">14282</a>	2.16.840.1.113883.5.6 (HL7ActClass) = OBS
	@moodCode	1..1	SHALL		<a href="#">14283</a>	2.16.840.1.113883.5.1001 (ActMood) = EVN
	@negationInd	0..1	MAY		<a href="#">14307</a>	
	templateId	1..1	SHALL		<a href="#">14312</a>	
	@root	1..1	SHALL		<a href="#">14313</a>	2.16.840.1.113883.10.20.22.4.68
	id	1..*	SHALL		<a href="#">14284</a>	
	code	1..1	SHALL		<a href="#">14314</a>	
	@code	0..1	SHOULD		<a href="#">14315</a>	2.16.840.1.113883.6.96 (SNOMED-CT) = 248536006
	text	0..1	SHOULD		<a href="#">14304</a>	
	reference	0..1	SHOULD		<a href="#">15552</a>	
	@value	0..1	SHOULD		<a href="#">15553</a>	
	statusCode	1..1	SHALL		<a href="#">14286</a>	
	@code	1..1	SHALL		<a href="#">19100</a>	2.16.840.1.113883.5.14 (ActStatus) = completed
	effectiveTime	0..1	SHOULD		<a href="#">14287</a>	
	value	1..1	SHALL	CD	<a href="#">14291</a>	2.16.840.1.113883.3.88.12.3221.7.4 (Problem Value Set)
	@nullFlavor	0..1	MAY		<a href="#">14292</a>	
	methodCode	0..1	MAY		<a href="#">14316</a>	
	entry Relationship	0..*	MAY		<a href="#">14294</a>	
	@typeCode	1..1	SHALL		<a href="#">14584</a>	2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = REFR
	supply	1..1	SHALL		<a href="#">14317</a>	
	entry Relationship	0..*	MAY		<a href="#">14298</a>	
	@typeCode	1..1	SHALL		<a href="#">14586</a>	2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = REFR
	observation	1..1	SHALL		<a href="#">14318</a>	
	entry Relationship	0..*	MAY		<a href="#">14463</a>	
	@typeCode	1..1	SHALL		<a href="#">14587</a>	2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = COMP
	observation	1..1	SHALL		<a href="#">14464</a>	

1. Conforms to [Problem Observation](#) template (2.16.840.1.113883.10.20.22.4.4).
2. **SHALL** contain exactly one [1..1] **@classCode**="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:14282).
3. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 **STATIC**) (CONF:14283).

Use negationInd="true" to indicate that the problem was not observed.

4. **MAY** contain zero or one [0..1] **@negationInd** (CONF:14307).
5. **SHALL** contain exactly one [1..1] **templateId** (CONF:14312) such that it
  - a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.22.4.68" (CONF:14313).
6. **SHALL** contain at least one [1..\*] **id** (CONF:14284).
7. **SHALL** contain exactly one [1..1] **code** (CONF:14314).
  - a. This code **SHOULD** contain zero or one [0..1] **@code**="248536006" finding of functional performance and activity (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96 **STATIC**) (CONF:14315).
8. **SHOULD** contain zero or one [0..1] **text** (CONF:14304).
  - a. The text, if present, **SHOULD** contain zero or one [0..1] **reference** (CONF:15552).
    - i. The reference, if present, **SHOULD** contain zero or one [0..1] **@value** (CONF:15553).
      1. This reference/**@value** **SHALL** begin with a '#' and **SHALL** point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:15554).
9. **SHALL** contain exactly one [1..1] **statusCode** (CONF:14286).
  - a. This statusCode **SHALL** contain exactly one [1..1] **@code**="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 **STATIC**) (CONF:19100).
10. **SHOULD** contain zero or one [0..1] **effectiveTime** (CONF:14287).
  - a. The onset date **SHALL** be recorded in the low element of the effectiveTime element when known (CONF:14288).
  - b. The resolution date **SHALL** be recorded in the high element of the effectiveTime element when known (CONF:14289).
  - c. 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 (CONF:14290).
11. **SHALL** contain exactly one [1..1] **value** with **@xsi:type**="CD", where the **@code** **SHOULD** be selected from ValueSet [Problem Value Set](#) 2.16.840.1.113883.3.88.12.3221.7.4 **DYNAMIC** (CONF:14291).
  - a. This value **MAY** contain zero or one [0..1] **@nullFlavor** (CONF:14292).
    - i. If the diagnosis is unknown or the SNOMED code is unknown, **@nullFlavor** **SHOULD** be "UNK". If the code is something other than

SNOMED, @nullFlavor **SHOULD** be “OTH” and the other code **SHOULD** be placed in the translation element (CONF:14293).

12. **MAY** contain zero or one [0..1] **methodCode** (CONF:14316).
13. **MAY** contain zero or more [0..\*] **entryRelationship** (CONF:14294) such that it
  - a. **SHALL** contain exactly one [1..1] **@typeCode="REFR"** refers to (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**) (CONF:14584).
  - b. **SHALL** contain exactly one [1..1] **Non-Medicinal Supply Activity** (templateId:2.16.840.1.113883.10.20.22.4.50) (CONF:14317).
14. **MAY** contain zero or more [0..\*] **entryRelationship** (CONF:14298) such that it
  - a. **SHALL** contain exactly one [1..1] **@typeCode="REFR"** refers to (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**) (CONF:14586).
  - b. **SHALL** contain exactly one [1..1] **Caregiver Characteristics** (templateId:2.16.840.1.113883.10.20.22.4.72) (CONF:14318).
15. **MAY** contain zero or more [0..\*] **entryRelationship** (CONF:14463) such that it
  - a. **SHALL** contain exactly one [1..1] **@typeCode="COMP"** has component (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**) (CONF:14587).
  - b. **SHALL** contain exactly one [1..1] **Assessment Scale Observation** (templateId:2.16.840.1.113883.10.20.22.4.69) (CONF:14464).

**Figure 98: Functional Status Problem Observation example**

```

<observation classCode="OBS" moodCode="EVN">
 <!-- conforms to Problem observation -->
 <templateId root="2.16.840.1.113883.10.20.22.4.4"/>
 <!-- Functional status problem observation -->
 <templateId root="2.16.840.1.113883.10.20.22.4.68"/>
 <id root="08edb7c0-2111-43f2-a784-9a5fdfaa67f0"/>
 <code code="248536006"
 codeSystem="2.16.840.1.113883.6.96"
 displayName="Finding of Functional Performance and activity"/>
 <text>
 <reference value="#FUNC2"/>
 </text>
 <statusCode code="completed"/>
 <effectiveTime>
 <low value="200702"/>
 <high value="200704"/>
 </effectiveTime>
 <value xsi:type="CD" code=" 162891007"
 codeSystem="2.16.840.1.113883.6.96"
 displayName="dyspnea"/>
 <entryRelationship typeCode=" REFR">
 <observation classCode="OBS" moodCode="EVN">
 <templateId root="2.16.840.1.113883.10.20.22.4.72"/>
 <!--Caregiver Characteristics -->
 ...
 </observation>
 </entryRelationship>

```



```

<entryRelationship typeCode="COMP">
 <observation classCode="OBS" moodCode="EVN">
 <templateId root="2.16.840.1.113883.10.20.22.4.69"/>
 <!-- Assessment Scale Observation -->
 ...
 </observation>
</entryRelationship>
</observation>

```

#### 4.45.4 Neurotoxicity Impairment of ADLs

[Observation: templateId 2.16.840.1.113883.10.20.30.3.37 (open)]

**Table 203: Neurotoxicity Impairment of ADLs Contexts**

Used By:	Contains Entries:
<a href="#">Functional Status Section BCTPS</a> (optional)	

This clinical statement associates neurotoxicity as the cause of a functional status observation.

**Table 204: Neurotoxicity Impairment of ADLs Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	Observation[templateId/@root = '2.16.840.1.113883.10.20.30.3.37']					
	@classCode	1..1	SHALL		<a href="#">26421</a>	2.16.840.1.113883.5.6 (HL7ActClass) = OBS
	@moodCode	1..1	SHALL		<a href="#">26422</a>	2.16.840.1.113883.5.1001 (ActMood) = EVN
	templateId	1..1	SHALL		<a href="#">26438</a>	
	@root	1..1	SHALL		<a href="#">26439</a>	2.16.840.1.113883.10.20.30.3.37
	entry Relationship	1..1	SHALL		<a href="#">26423</a>	
	@typeCode	1..1	SHALL		<a href="#">26424</a>	2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = CAUS
	@inversionInd	1..1	SHALL		<a href="#">26425</a>	true
	observation	1..1	SHALL		<a href="#">26426</a>	
	@classCode	1..1	SHALL		<a href="#">26427</a>	2.16.840.1.113883.5.6 (HL7ActClass) = OBS
	@moodCode	1..1	SHALL		<a href="#">26428</a>	2.16.840.1.113883.5.1001 (ActMood) = EVN
	id	1..*	SHALL		<a href="#">26429</a>	
	code	1..1	SHALL		<a href="#">26430</a>	
	@code	1..1	SHALL		<a href="#">26431</a>	ASSERTION

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	@codeSystem	1..1	SHALL		<a href="#">26432</a>	2.16.840.1.113883.5.4
	statusCode	1..1	SHALL		<a href="#">26433</a>	
	@code	1..1	SHALL		<a href="#">26437</a>	2.16.840.1.113883.5.14 (ActStatus) = completed
	value	1..1	SHALL	CD	<a href="#">26434</a>	
	@code	1..1	SHALL		<a href="#">26435</a>	1946603
	@codeSystem	1..1	SHALL		<a href="#">26436</a>	2.16.840.1.113883.6.96

1. Conforms to [Functional Status Problem Observation](#) template (2.16.840.1.113883.10.20.22.4.68).
  2. **SHALL** contain exactly one [1..1] @classCode="OBS" observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:26421).
  3. **SHALL** contain exactly one [1..1] @moodCode="EVN" event (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:26422).
  4. **SHALL** contain exactly one [1..1] templateId (CONF:26438) such that it
    - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.3.37" (CONF:26439).
  5. **SHALL** contain exactly one [1..1] entryRelationship (CONF:26423) such that it
    - a. **SHALL** contain exactly one [1..1] @typeCode="CAUS" has etiology for (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:26424).
    - b. **SHALL** contain exactly one [1..1] @inversionInd="true" True (CONF:26425).
    - c. **SHALL** contain exactly one [1..1] observation (CONF:26426).
      - i. This observation **SHALL** contain exactly one [1..1] @classCode="OBS" observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:26427).
      - ii. This observation **SHALL** contain exactly one [1..1] @moodCode="EVN" event (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:26428).
- This observation/id could reference the id of the detailed reaction observation in the chemo regimen or in Allergies/Adverse events section.
- iii. This observation **SHALL** contain at least one [1..\*] id (CONF:26429).
  - iv. This observation **SHALL** contain exactly one [1..1] code (CONF:26430).
    1. This code **SHALL** contain exactly one [1..1] @code="ASSERTION" Assertion (CONF:26431).
    2. This code **SHALL** contain exactly one [1..1] @codeSystem="2.16.840.1.113883.5.4" ActCode (CONF:26432).
  - v. This observation **SHALL** contain exactly one [1..1] statusCode (CONF:26433).

1. This statusCode **SHALL** contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 **STATIC**) (CONF:26437).
- vi. This observation **SHALL** contain exactly one [1..1] value with @xsi:type="CD" (CONF:26434).
  1. This value **SHALL** contain exactly one [1..1] @code="1946603" Neurotoxicity (CONF:26435).
  2. This value **SHALL** contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.96" SNOMED-CT (CONF:26436).

**Figure 99: Neurotoxicity Impairment of ADLs example**

```

<observation classCode="OBS" moodCode="EVN">
 <!-- C-CDA FUNCTIONAL STATUS PROBLEM OBSERVATION TemplateID -->
 <templateId root="2.16.840.1.113883.10.20.22.4.68"/>
 <!-- Neurotoxicity impairment of activities of daily living templateID -->
 <templateId root="2.16.840.1.113883.10.20.30.3.37"/>
 <id root="0a2405dd-7629-40e4-abb7-8eb12432e450"/>
 <code codeSystem="2.16.840.1.113883.6.96"
 code="248536006"
 displayName="finding of functional performance and activity"/>
 <statusCode code="completed"/>
 <effectiveTime>
 <low value="20121109"/>
 </effectiveTime>
 <value xsi:type="CD" code="282207002"
 codeSystem="2.16.840.1.113883.6.96"
 displayName="Difficulty initiating walking"/>
 <entryRelationship typeCode="CAUS" inversionInd="true">
 <observation classCode="OBS" moodCode="EVN">
 <!-- This could reference the id of the detailed reaction observation
 in the chemo regimen or in Allergies/Adverse events section -->
 <id root="ea3d6016-7d2c-450f-aa0c-e18f1bffbbe0"/>
 <code code="ASSERTION"
 codeSystem="2.16.840.1.113883.5.4"
 codeSystemName="ActCode"/>
 <statusCode code="completed"/>
 <value xsi:type="CD"
 code="1946603"
 codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMED CT"
 displayName="Neurotoxicity"/>
 </observation>
 </entryRelationship>
</observation>

```

## 4.46 Problem Status

[Closed for comments; published July 2012]

[observation: templateId 2.16.840.1.113883.10.20.22.4.6 (open)]

**Table 205: Problem Status Contexts**

Used By:	Contains Entries:
<a href="#">Problem Observation</a> (optional)	

The Problem Status records whether the indicated problem is active, inactive, or resolved.

**Table 206: Problem Status Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	observation[templateId/@root = '2.16.840.1.113883.10.20.22.4.6']					
	@classCode	1..1	SHALL		<a href="#">7357</a>	2.16.840.1.113883.5.6 (HL7ActClass) = OBS
	@moodCode	1..1	SHALL		<a href="#">7358</a>	2.16.840.1.113883.5.1001 (ActMood) = EVN
	templateId	1..1	SHALL		<a href="#">7359</a>	
	@root	1..1	SHALL		<a href="#">10518</a>	2.16.840.1.113883.10.20.22.4.6
	code	1..1	SHALL		<a href="#">19162</a>	
	@code	1..1	SHALL		<a href="#">19163</a>	2.16.840.1.113883.6.1 (LOINC) = 33999-4
	text	0..1	SHOULD		<a href="#">7362</a>	
	reference	0..1	SHOULD		<a href="#">15593</a>	
	@value	1..1	SHALL		<a href="#">15594</a>	
	statusCode	1..1	SHALL		<a href="#">7364</a>	
	@code	1..1	SHALL		<a href="#">19113</a>	2.16.840.1.113883.5.14 (ActStatus) = completed
	value	1..1	SHALL	CD	<a href="#">7365</a>	2.16.840.1.113883.3.88.12.80.68 (Problem Status Value Set)

1. **SHALL** contain exactly one [1..1] @classCode="OBS" Observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:7357).
2. **SHALL** contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 **STATIC**) (CONF:7358).
3. **SHALL** contain exactly one [1..1] templateId (CONF:7359) such that it
  - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.6" (CONF:10518).
4. **SHALL** contain exactly one [1..1] code (CONF:19162).
  - a. This code **SHALL** contain exactly one [1..1] @code="33999-4" Status (CodeSystem: LOINC 2.16.840.1.113883.6.1 **STATIC**) (CONF:19163).

5. **SHOULD** contain zero or one [0..1] **text** (CONF:7362).
  - a. The text, if present, **SHOULD** contain zero or one [0..1] **reference** (CONF:15593).
    - i. The reference, if present, **SHALL** contain exactly one [1..1] **@value** (CONF:15594).
      1. This reference/@value **SHALL** begin with a '#' and **SHALL** point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:15595).
6. **SHALL** contain exactly one [1..1] **statusCode** (CONF:7364).
  - a. This statusCode **SHALL** contain exactly one [1..1] **@code="completed"** Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 **STATIC**) (CONF:19113).
7. **SHALL** contain exactly one [1..1] **value** with **@xsi:type="CD"**, where the **@code** **SHALL** be selected from ValueSet [Problem Status Value Set 2.16.840.1.113883.3.88.12.80.68](#) **DYNAMIC** (CONF:7365).

**Figure 100: Problem Status example**

```

<observation classCode="OBS" moodCode="EVN">
 <!-- Status observation template -->
 <templateId root="2.16.840.1.113883.10.20.22.4.6"/>
 <code code="33999-4"
 codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC"
 displayName="Status"/>
 <text>
 <reference value="#STAT1"/>
 </text>
 <statusCode code="completed"/>
 <value xsi:type="CD"
 code="55561003"
 codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMED CT"
 displayName="Active"/>
</observation>

```

## 4.47 Procedure Activity Act

[Closed for comments; published July 2012]

[act: templateId 2.16.840.1.113883.10.20.22.4.12 (open)]

**Table 207: Procedure Activity Act Contexts**

Used By:	Contains Entries:
<a href="#">Procedures Section (entries optional)</a> (optional)	<a href="#">Indication</a> <a href="#">Instructions</a> <a href="#">Medication Activity</a> <a href="#">Service Delivery Location</a>

The common notion of "procedure" is broader than that specified by the HL7 Version 3 Reference Information Model (RIM). Therefore procedure templates can be represented with various RIM classes: act (e.g., dressing change), observation (e.g., EEG), procedure (e.g., splenectomy).

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.

**Table 208: Procedure Activity Act Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
	act[templateId/@root = '2.16.840.1.113883.10.20.22.4.12']					
	@classCode	1..1	SHALL		<a href="#">8289</a>	2.16.840.1.113883.5.6 (HL7ActClass) = ACT
	@moodCode	1..1	SHALL		<a href="#">8290</a>	2.16.840.1.113883.11.20.9.18 (MoodCodeEvnInt)
	templateId	1..1	SHALL		<a href="#">8291</a>	
	@root	1..1	SHALL		<a href="#">10519</a>	2.16.840.1.113883.10.20.22.4.12
	id	1..*	SHALL		<a href="#">8292</a>	
	code	1..1	SHALL		<a href="#">8293</a>	
	originalText	0..1	SHOULD		<a href="#">19186</a>	
	reference	0..1	MAY		<a href="#">19187</a>	
	@value	0..1	MAY		<a href="#">19188</a>	
	statusCode	1..1	SHALL		<a href="#">8298</a>	2.16.840.1.113883.11.20.9.22 (ProcedureAct statusCode)
	effectiveTime	0..1	SHOULD		<a href="#">8299</a>	
	priorityCode	0..1	MAY		<a href="#">8300</a>	2.16.840.1.113883.1.11.16866 (Act Priority Value Set)
	performer	0..*	SHOULD		<a href="#">8301</a>	

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
	assignedEntity	1..1	SHALL		<a href="#">8302</a>	
	id	1..*	SHALL		<a href="#">8303</a>	
	addr	1..1	SHALL		<a href="#">8304</a>	
	telecom	1..1	SHALL		<a href="#">8305</a>	
	represented Organization	0..1	SHOULD		<a href="#">8306</a>	
	id	0..*	SHOULD		<a href="#">8307</a>	
	name	0..*	MAY		<a href="#">8308</a>	
	telecom	1..1	SHALL		<a href="#">8310</a>	
	addr	1..1	SHALL		<a href="#">8309</a>	
	participant	0..*	MAY		<a href="#">8311</a>	
	@typeCode	1..1	SHALL		<a href="#">8312</a>	2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = LOC
	participantRole	1..1	SHALL		<a href="#">15599</a>	
	entryRelationship	0..*	MAY		<a href="#">8314</a>	
	@typeCode	1..1	SHALL		<a href="#">8315</a>	2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = COMP
	@inversionInd	1..1	SHALL		<a href="#">8316</a>	true
	encounter	1..1	SHALL		<a href="#">8317</a>	
	@classCode	1..1	SHALL		<a href="#">8318</a>	2.16.840.1.113883.5.6 (HL7ActClass) = ENC
	@moodCode	1..1	SHALL		<a href="#">8319</a>	2.16.840.1.113883.5.1001 (ActMood) = EVN
	id	1..1	SHALL		<a href="#">8320</a>	
	entryRelationship	0..1	MAY		<a href="#">8322</a>	
	@typeCode	1..1	SHALL		<a href="#">8323</a>	2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = SUBJ
	@inversionInd	1..1	SHALL		<a href="#">8324</a>	true
	act	1..1	SHALL		<a href="#">15600</a>	
	entryRelationship	0..*	MAY		<a href="#">8326</a>	
	@typeCode	1..1	SHALL		<a href="#">8327</a>	2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = RSON
	observation	1..1	SHALL		<a href="#">15601</a>	
	entryRelationship	0..*	MAY		<a href="#">8329</a>	

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
	@typeCode	1..1	SHALL		<a href="#">8330</a>	2.16.840.1.113883.5.1002 (HL7ActRelationship Type) = COMP
	substance Administration	1..1	SHALL		<a href="#">15602</a>	

1. **SHALL** contain exactly one [1..1] **@classCode="ACT"** Act (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:8289).
2. **SHALL** contain exactly one [1..1] **@moodCode**, which **SHALL** be selected from ValueSet [MoodCodeEvnInt 2.16.840.1.113883.11.20.9.18](#) **STATIC** 2011-04-03 (CONF:8290).
3. **SHALL** contain exactly one [1..1] **templateId** (CONF:8291) such that it
  - a. **SHALL** contain exactly one [1..1] **@root="2.16.840.1.113883.10.20.22.4.12"** (CONF:10519).
4. **SHALL** contain at least one [1..\*] **id** (CONF:8292).
5. **SHALL** contain exactly one [1..1] **code** (CONF:8293).
  - a. This code **SHOULD** contain zero or one [0..1] **originalText** (CONF:19186).
    - i. The originalText, if present, **MAY** contain zero or one [0..1] **reference** (CONF:19187).
      1. The reference, if present, **MAY** contain zero or one [0..1] **@value** (CONF:19188).
        - a. This reference/**@value** **SHALL** begin with a '#' and **SHALL** point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:19189).
      - b. This code in a procedure activity act **SHOULD** be selected from LOINC (CodeSystem: 2.16.840.1.113883.6.1) or SNOMED CT (CodeSystem: 2.16.840.1.113883.6.96) (CONF:19190).
6. **SHALL** contain exactly one [1..1] **statusCode**, which **SHALL** be selected from ValueSet ProcedureAct statusCode 2.16.840.1.113883.11.20.9.22 **DYNAMIC** (CONF:8298).
7. **SHOULD** contain zero or one [0..1] **effectiveTime** (CONF:8299).
8. **MAY** contain zero or one [0..1] **priorityCode**, which **SHALL** be selected from ValueSet Act Priority Value Set 2.16.840.1.113883.1.11.16866 **DYNAMIC** (CONF:8300).
9. **SHOULD** contain zero or more [0..\*] **performer** (CONF:8301).
  - a. The performer, if present, **SHALL** contain exactly one [1..1] **assignedEntity** (CONF:8302).
    - i. This assignedEntity **SHALL** contain at least one [1..\*] **id** (CONF:8303).
    - ii. This assignedEntity **SHALL** contain exactly one [1..1] **addr** (CONF:8304).



- iii. This assignedEntity **SHALL** contain exactly one [1..1] **telecom** (CONF:8305).
  - iv. This assignedEntity **SHOULD** contain zero or one [0..1] **representedOrganization** (CONF:8306).
    - 1. The representedOrganization, if present, **SHOULD** contain zero or more [0..\*] **id** (CONF:8307).
    - 2. The representedOrganization, if present, **MAY** contain zero or more [0..\*] **name** (CONF:8308).
    - 3. The representedOrganization, if present, **SHALL** contain exactly one [1..1] **telecom** (CONF:8310).
    - 4. The representedOrganization, if present, **SHALL** contain exactly one [1..1] **addr** (CONF:8309).
10. **MAY** contain zero or more [0..\*] **participant** (CONF:8311).
- a. The participant, if present, **SHALL** contain exactly one [1..1] **@typeCode="LOC" Location (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC)** (CONF:8312).
  - b. The participant, if present, **SHALL** contain exactly one [1..1] **Service Delivery Location** (templateId:2.16.840.1.113883.10.20.22.4.32) (CONF:15599).
11. **MAY** contain zero or more [0..\*] **entryRelationship** (CONF:8314).
- a. The entryRelationship, if present, **SHALL** contain exactly one [1..1] **@typeCode="COMP" Has Component (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC)** (CONF:8315).
  - b. The entryRelationship, if present, **SHALL** contain exactly one [1..1] **@inversionInd="true" true** (CONF:8316).
  - c. The entryRelationship, if present, **SHALL** contain exactly one [1..1] **encounter** (CONF:8317).
    - i. This encounter **SHALL** contain exactly one [1..1] **@classCode="ENC" Encounter (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 STATIC)** (CONF:8318).
    - ii. This encounter **SHALL** contain exactly one [1..1] **@moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 STATIC)** (CONF:8319).
    - iii. This encounter **SHALL** contain exactly one [1..1] **id** (CONF:8320).
      - 1. Set the encounter ID to the ID of an encounter in another section to signify they are the same encounter (CONF:16849).
12. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:8322).
- a. The entryRelationship, if present, **SHALL** contain exactly one [1..1] **@typeCode="SUBJ" Has Subject (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC)** (CONF:8323).
  - b. The entryRelationship, if present, **SHALL** contain exactly one [1..1] **@inversionInd="true" true** (CONF:8324).

- c. The entryRelationship, if present, **SHALL** contain exactly one [1..1] Instructions (templateId:2.16.840.1.113883.10.20.22.4.20) (CONF:15600).
13. **MAY** contain zero or more [0..\*] **entryRelationship** (CONF:8326).
- a. The entryRelationship, if present, **SHALL** contain exactly one [1..1] **@typeCode="RSON" Has Reason** (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**) (CONF:8327).
  - b. The entryRelationship, if present, **SHALL** contain exactly one [1..1] Indication (templateId:2.16.840.1.113883.10.20.22.4.19) (CONF:15601).
14. **MAY** contain zero or more [0..\*] **entryRelationship** (CONF:8329).
- a. The entryRelationship, if present, **SHALL** contain exactly one [1..1] **@typeCode="COMP" Has Component** (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**) (CONF:8330).
  - b. The entryRelationship, if present, **SHALL** contain exactly one [1..1] Medication Activity (templateId:2.16.840.1.113883.10.20.22.4.16) (CONF:15602).

**Table 209: ProcedureAct statusCode Value Set**

Value Set: ProcedureAct statusCode 2.16.840.1.113883.11.20.9.22 DYNAMIC Code System: ActStatus 2.16.840.1.113883.5.14		
Code	Code System	Print Name
completed	ActStatus	Completed
active	ActStatus	Active
aborted	ActStatus	Aborted
cancelled	ActStatus	Cancelled

**Table 210: Act Priority Value Set Value Set**

Value Set: Act Priority Value Set 2.16.840.1.113883.1.11.16866 DYNAMIC		
Code System: ActPriority		
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	Preoperative
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

#### 4.47.1 Radiation Therapy Care Completed

[Act: templateId 2.16.840.1.113883.10.20.30.3.16 (open)]

**Table 211: Radiation Therapy Care Completed Contexts**

Used By:	Contains Entries:
<a href="#">Procedures Section BCTPS</a> (optional)	

This clinical statement records whether or not patient received radiation therapy. The details of the radiation therapy are not represented. If the patient's radiation therapy was not completed, then the effective time high would have a nullFlavor="NI".

**Table 212: Radiation Therapy Care Completed Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
	Act[templateId/@root = '2.16.840.1.113883.10.20.30.3.16']					
	@negationInd	1..1	SHALL		<a href="#">24945</a>	
	templateId	1..1	SHALL		<a href="#">23179</a>	
	@root	1..1	SHALL		<a href="#">23180</a>	2.16.840.1.113883.10.20.30.3.16
	code	1..1	SHALL		<a href="#">23185</a>	
	@code	1..1	SHALL		<a href="#">23186</a>	385798007
	@codeSystem	1..1	SHALL		<a href="#">23445</a>	2.16.840.1.113883.6.96 (SNOMED-CT) = 2.16.840.1.113883.6.96
	statusCode	1..1	SHALL		<a href="#">23183</a>	
	@code	1..1	SHALL		<a href="#">23184</a>	2.16.840.1.113883.5.14 (ActStatus) = completed
	effectiveTime	1..1	SHALL		<a href="#">23181</a>	
	high	1..1	SHALL		<a href="#">23182</a>	

1. Conforms to [Procedure Activity Act](#) template (2.16.840.1.113883.10.20.22.4.12).

NegationInd=true indicates the patient did not complete radiation therapy and a NegationInd=false means the patient did complete radiation therapy.

2. **SHALL** contain exactly one [1..1] @negationInd (CONF:24945).
3. **SHALL** contain exactly one [1..1] templateId (CONF:23179) such that it
  - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.3.16" (CONF:23180).
4. **SHALL** contain exactly one [1..1] code (CONF:23185).
  - a. This code **SHALL** contain exactly one [1..1] @code="385798007" Radiation therapy care (CONF:23186).
  - b. This code **SHALL** contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.96" (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96) (CONF:23445).
5. **SHALL** contain exactly one [1..1] statusCode (CONF:23183).
  - a. This statusCode **SHALL** contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 **STATIC**) (CONF:23184).
6. **SHALL** contain exactly one [1..1] effectiveTime (CONF:23181).

The value for the effective time represents the date the radiation therapy is completed. If the the radiation therapy was not completed, use nullFlavor=NI for effective time high.

- a. This effectiveTime **SHALL** contain exactly one [1..1] high (CONF:23182)

**Figure 101: Radiation Therapy Care Completed example**

```

<entry>
 <!-- NegationInd=false indicates the patient did have radiation therapy -->
 <act classCode="ACT" moodCode="EVN" negationInd="false">
 <!-- C-CDA PROCEDURE ACTIVITY ACT TemplateID -->
 <templateId root="2.16.840.1.113883.10.20.22.4.12"/>
 <!-- Radiation Therapy Care Completed TemplateID -->
 <templateId root="2.16.840.1.113883.10.20.30.3.16"/>
 <id nullFlavor="NI"/>
 <code code="385798007"
 codeSystem="2.16.840.1.113883.6.96"
 displayName="radiation therapy care"/>
 <text>Radiation Therapy Care</text>
 <statusCode code="completed"/>
 <effectiveTime>
 <low value="20121201"/>
 <!-- If radiation therapy care was not completed, use nullFlavor=NI. -->
 <high value="20121221"/>
 </effectiveTime>
 </act>
</entry>

```

#### 4.48 Procedure Activity Observation [Closed for comments; published July 2012]

[observation: templateId 2.16.840.1.113883.10.20.22.4.13 (open)]

**Table 213: Procedure Activity Observation Contexts**

Used By:	Contains Entries:
<a href="#">Procedures Section (entries optional)</a> (optional)	<a href="#">Indication</a> <a href="#">Instructions</a> <a href="#">Medication Activity</a> <a href="#">Service Delivery Location</a>

The common notion of "procedure" is broader than that specified by the HL7 Version 3 Reference Information Model (RIM). Therefore procedure templates can be represented with various RIM classes: act (e.g., dressing change), observation (e.g., EEG), procedure (e.g. splenectomy).

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.

**Table 214: Procedure Activity Observation Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
	observation[templateId/@root = '2.16.840.1.113883.10.20.22.4.13']					
	@classCode	1..1	SHALL		<a href="#">8282</a>	2.16.840.1.113883.5.6 (HL7ActClass) = OBS
	@moodCode	1..1	SHALL		<a href="#">8237</a>	2.16.840.1.113883.11.20.9.18 (MoodCodeEvnInt)
	templateId	1..1	SHALL		<a href="#">8238</a>	
	@root	1..1	SHALL		<a href="#">10520</a>	2.16.840.1.113883.10.20.22.4.13
	id	1..*	SHALL		<a href="#">8239</a>	
	code	1..1	SHALL		<a href="#">19197</a>	
	originalText	0..1	SHOULD		<a href="#">19198</a>	
	reference	0..1	SHOULD		<a href="#">19199</a>	
	@value	0..1	SHOULD		<a href="#">19200</a>	
	statusCode	1..1	SHALL		<a href="#">8245</a>	2.16.840.1.113883.11.20.9.22 (ProcedureAct statusCode)
	effectiveTime	0..1	SHOULD		<a href="#">8246</a>	
	priorityCode	0..1	MAY		<a href="#">8247</a>	2.16.840.1.113883.1.11.16866 (Act Priority Value Set)
	value	1..1	SHALL		<a href="#">16846</a>	
	methodCode	0..1	MAY	SET< CE>	<a href="#">8248</a>	
	targetSiteCode	0..*	SHOULD		<a href="#">8250</a>	
	@code	1..1	SHALL		<a href="#">16071</a>	2.16.840.1.113883.3.88.12.3221.8.9 (Body Site Value Set)
	performer	0..*	SHOULD		<a href="#">8251</a>	
	assignedEntity	1..1	SHALL		<a href="#">8252</a>	
	id	1..*	SHALL		<a href="#">8253</a>	
	addr	1..1	SHALL		<a href="#">8254</a>	
	telecom	1..1	SHALL		<a href="#">8255</a>	
	represented Organization	0..1	SHOULD		<a href="#">8256</a>	
	id	0..*	SHOULD		<a href="#">8257</a>	
	name	0..*	MAY		<a href="#">8258</a>	
	telecom	1..1	SHALL		<a href="#">8260</a>	
	addr	1..1	SHALL		<a href="#">8259</a>	
	participant	0..*	MAY		<a href="#">8261</a>	

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
	@typeCode	1..1	SHALL		<a href="#">8262</a>	2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = LOC
	participantRole	1..1	SHALL		<a href="#">15904</a>	
	entryRelationship	0..*	MAY		<a href="#">8264</a>	
	@typeCode	1..1	SHALL		<a href="#">8265</a>	2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = COMP
	@inversionInd	1..1	SHALL		<a href="#">8266</a>	true
	encounter	1..1	SHALL		<a href="#">8267</a>	
	@classCode	1..1	SHALL		<a href="#">8268</a>	2.16.840.1.113883.5.6 (HL7ActClass) = ENC
	@moodCode	1..1	SHALL		<a href="#">8269</a>	2.16.840.1.113883.5.1001 (ActMood) = EVN
	id	1..1	SHALL		<a href="#">8270</a>	
	entryRelationship	0..1	MAY		<a href="#">8272</a>	
	@typeCode	1..1	SHALL		<a href="#">8273</a>	2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = SUBJ
	@inversionInd	1..1	SHALL		<a href="#">8274</a>	true
	act	1..1	SHALL		<a href="#">15905</a>	
	entryRelationship	0..*	MAY		<a href="#">8276</a>	
	@typeCode	1..1	SHALL		<a href="#">8277</a>	2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = RSON
	observation	1..1	SHALL		<a href="#">15906</a>	
	entryRelationship	0..*	MAY		<a href="#">8279</a>	
	@typeCode	1..1	SHALL		<a href="#">8280</a>	2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = COMP
	substance Administration	1..1	SHALL		<a href="#">15907</a>	

1. **SHALL** contain exactly one [1..1] @classCode="OBS" Observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:8282).
2. **SHALL** contain exactly one [1..1] @moodCode, which **SHALL** be selected from ValueSet [MoodCodeEvnInt 2.16.840.1.113883.11.20.9.18](#) **STATIC** 2011-04-03 (CONF:8237).
3. **SHALL** contain exactly one [1..1] templateId (CONF:8238) such that it
  - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.13" (CONF:10520).
4. **SHALL** contain at least one [1..\*] id (CONF:8239).
5. **SHALL** contain exactly one [1..1] code (CONF:19197).

- a. This code **SHOULD** contain zero or one [0..1] **originalText** (CONF:19198).
  - i. The originalText, if present, **SHOULD** contain zero or one [0..1] **reference** (CONF:19199).
    - 1. The reference, if present, **SHOULD** contain zero or one [0..1] **@value** (CONF:19200).
      - a. This reference/@value **SHALL** begin with a '#' and **SHALL** point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:19201).
  - b. This @code **SHOULD** be selected from LOINC (CodeSystem: 2.16.840.1.113883.6.1) or SNOMED CT (CodeSystem: 2.16.840.1.113883.6.96), and **MAY** be selected from CPT-4 (CodeSystem: 2.16.840.1.113883.6.12), ICD10 PCS (CodeSystem: 2.16.840.1.113883.6.4) (CONF:19202).
- 6. **SHALL** contain exactly one [1..1] **statusCode**, which **SHALL** be selected from ValueSet [ProcedureAct statusCode 2.16.840.1.113883.11.20.9.22 DYNAMIC](#) (CONF:8245).
- 7. **SHOULD** contain zero or one [0..1] **effectiveTime** (CONF:8246).
- 8. **MAY** contain zero or one [0..1] **priorityCode**, which **SHALL** be selected from ValueSet [Act Priority Value Set 2.16.840.1.113883.1.11.16866 DYNAMIC](#) (CONF:8247).
- 9. **SHALL** contain exactly one [1..1] **value** (CONF:16846).
- 10. **MAY** contain zero or one [0..1] **methodCode** (CONF:8248).
  - a. MethodCode **SHALL NOT** conflict with the method inherent in Observation / code (CONF:8249).
- 11. **SHOULD** contain zero or more [0..\*] **targetSiteCode** (CONF:8250).
  - a. The targetSiteCode, if present, **SHALL** contain exactly one [1..1] **@code**, which **SHALL** be selected from ValueSet [Body Site Value Set 2.16.840.1.113883.3.88.12.3221.8.9 DYNAMIC](#) (CONF:16071).
- 12. **SHOULD** contain zero or more [0..\*] **performer** (CONF:8251).
  - a. The performer, if present, **SHALL** contain exactly one [1..1] **assignedEntity** (CONF:8252).
    - i. This assignedEntity **SHALL** contain at least one [1..\*] **id** (CONF:8253).
    - ii. This assignedEntity **SHALL** contain exactly one [1..1] **addr** (CONF:8254).
    - iii. This assignedEntity **SHALL** contain exactly one [1..1] **telecom** (CONF:8255).
    - iv. This assignedEntity **SHOULD** contain zero or one [0..1] **representedOrganization** (CONF:8256).
      - 1. The representedOrganization, if present, **SHOULD** contain zero or more [0..\*] **id** (CONF:8257).
      - 2. The representedOrganization, if present, **MAY** contain zero or more [0..\*] **name** (CONF:8258).
      - 3. The representedOrganization, if present, **SHALL** contain exactly one [1..1] **telecom** (CONF:8260).



4. The representedOrganization, if present, **SHALL** contain exactly one [1..1] **addr** (CONF:8259).
13. **MAY** contain zero or more [0..\*] **participant** (CONF:8261).
    - a. The participant, if present, **SHALL** contain exactly one [1..1] **@typeCode="LOC"** Location (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**) (CONF:8262).
    - b. The participant, if present, **SHALL** contain exactly one [1..1] **Service Delivery Location** (templateId:2.16.840.1.113883.10.20.22.4.32) (CONF:15904).
  14. **MAY** contain zero or more [0..\*] **entryRelationship** (CONF:8264).
    - a. The entryRelationship, if present, **SHALL** contain exactly one [1..1] **@typeCode="COMP"** Component (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**) (CONF:8265).
    - b. The entryRelationship, if present, **SHALL** contain exactly one [1..1] **@inversionInd="true"** true (CONF:8266).
    - c. The entryRelationship, if present, **SHALL** contain exactly one [1..1] **encounter** (CONF:8267).
      - i. This encounter **SHALL** contain exactly one [1..1] **@classCode="ENC"** Encounter (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:8268).
      - ii. This encounter **SHALL** contain exactly one [1..1] **@moodCode="EVN"** Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 **STATIC**) (CONF:8269).
      - iii. This encounter **SHALL** contain exactly one [1..1] **id** (CONF:8270).
        1. Set encounter/id to the id of an encounter in another section to signify they are the same encounter (CONF:16847).
  15. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:8272) such that it
    - a. **SHALL** contain exactly one [1..1] **@typeCode="SUBJ"** Has Subject (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**) (CONF:8273).
    - b. **SHALL** contain exactly one [1..1] **@inversionInd="true"** true (CONF:8274).
    - c. **SHALL** contain exactly one [1..1] **Instructions** (templateId:2.16.840.1.113883.10.20.22.4.20) (CONF:15905).
  16. **MAY** contain zero or more [0..\*] **entryRelationship** (CONF:8276) such that it
    - a. **SHALL** contain exactly one [1..1] **@typeCode="RSON"** Has Reason (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**) (CONF:8277).
    - b. **SHALL** contain exactly one [1..1] **Indication** (templateId:2.16.840.1.113883.10.20.22.4.19) (CONF:15906).
  17. **MAY** contain zero or more [0..\*] **entryRelationship** (CONF:8279) such that it
    - a. **SHALL** contain exactly one [1..1] **@typeCode="COMP"** Has Component (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**) (CONF:8280).
    - b. **SHALL** contain exactly one [1..1] **Medication Activity** (templateId:2.16.840.1.113883.10.20.22.4.16) (CONF:15907).

**Figure 102: Procedure Activity Observation example**

```
<observation classCode="OBS" moodCode="EVN">
 <templateId root="2.16.840.1.113883.10.20.22.4.13" />
 <!-- Procedure Activity Observation -->
 <id extension="123456789" root="2.16.840.1.113883.19" />
 <code code="274025005"
 codeSystem="2.16.840.1.113883.6.96"
 displayName="Colonic polypectomy"
 codeSystemName="SNOMED-CT">
 <originalText>
 <reference value="#Proc1" />
 </originalText>
 </code>
 <statusCode code="aborted" />
 <effectiveTime value="20110203" />
 <priorityCode code="CR"
 codeSystem="2.16.840.1.113883.5.7"
 codeSystemName="ActPriority"
 displayName="Callback results" />
 <value xsi:type="CD" />
 <methodCode nullFlavor="UNK" />
 <targetSiteCode code="416949008"
 codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMED CT"
 displayName="Abdomen and pelvis" />

 <performer>
 <assignedEntity>
 <id root="2.16.840.1.113883.19.5" extension="1234" />
 <addr>
 <streetAddressLine>17 Daws Rd.</streetAddressLine>
 <city>Blue Bell</city>
 <state>MA</state>
 <postalCode>02368</postalCode>
 <country>US</country>
 </addr>
 <telecom use="WP" value="(555)555-555-1234" />
 <representedOrganization>
 <id root="2.16.840.1.113883.19.5" />
 <name>Community Health and Hospitals</name>
 <telecom nullFlavor="UNK" />
 <addr nullFlavor="UNK" />
 </representedOrganization>
 </assignedEntity>
 </performer>

 <participant typeCode="LOC">
 <participantRole classCode="SDLOC">
 <templateId root="2.16.840.1.113883.10.20.22.4.32" />
 <!-- Service Delivery Location template -->
 ...
 </participantRole>
 </participant>
</observation>
```

## 4.49 Procedure Activity Procedure [Closed for comments; published July 2012]

[procedure: templateId 2.16.840.1.113883.10.20.22.4.14 (open)]

**Table 215: Procedure Activity Procedure Contexts**

Used By:	Contains Entries:
<a href="#">Procedures Section (entries optional)</a> (optional) <a href="#">Reaction Observation</a> (optional)	<a href="#">Indication</a> <a href="#">Instructions</a> <a href="#">Medication Activity</a> <a href="#">Product Instance</a> <a href="#">Service Delivery Location</a>

The common notion of "procedure" is broader than that specified by the HL7 Version 3 Reference Information Model (RIM). Therefore procedure templates can be represented with various RIM classes: act (e.g., dressing change), observation (e.g., EEG), procedure (e.g., splenectomy).

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.

**Table 216: Procedure Activity Procedure Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
	procedure[templateId/@root = '2.16.840.1.113883.10.20.22.4.14']					
	@classCode	1..1	SHALL		<a href="#">7652</a>	2.16.840.1.113883.5.6 (HL7ActClass) = PROC
	@moodCode	1..1	SHALL		<a href="#">7653</a>	2.16.840.1.113883.11.20.9.18 (MoodCodeEvnInt)
	templateId	1..1	SHALL		<a href="#">7654</a>	
	@root	1..1	SHALL		<a href="#">10521</a>	2.16.840.1.113883.10.20.22.4.14
	id	1..*	SHALL		<a href="#">7655</a>	
	code	1..1	SHALL		<a href="#">7656</a>	
	originalText	0..1	SHOULD		<a href="#">19203</a>	
	reference	0..1	SHOULD		<a href="#">19204</a>	
	@value	0..1	SHOULD		<a href="#">19205</a>	
	statusCode	1..1	SHALL		<a href="#">7661</a>	2.16.840.1.113883.11.20.9.22 (ProcedureAct statusCode)
	effectiveTime	0..1	SHOULD		<a href="#">7662</a>	
	priorityCode	0..1	MAY		<a href="#">7668</a>	2.16.840.1.113883.1.11.16866 (Act Priority Value Set)

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
	methodCode	0..1	MAY	SET<CE>	<a href="#">7670</a>	
	targetSiteCode	0..*	SHOULD		<a href="#">7683</a>	
	@code	1..1	SHALL		<a href="#">16082</a>	2.16.840.1.113883.3.88.12.3221.8.9 (Body Site Value Set)
	specimen	0..*	MAY		<a href="#">7697</a>	
	specimenRole	1..1	SHALL		<a href="#">7704</a>	
	id	0..*	SHOULD		<a href="#">7716</a>	
	performer	0..*	SHOULD		<a href="#">7718</a>	
	assignedEntity	1..1	SHALL		<a href="#">7720</a>	
	id	1..*	SHALL		<a href="#">7722</a>	
	addr	1..1	SHALL		<a href="#">7731</a>	
	telecom	1..1	SHALL		<a href="#">7732</a>	
	represented Organization	0..1	SHOULD		<a href="#">7733</a>	
	id	0..*	SHOULD		<a href="#">7734</a>	
	name	0..*	MAY		<a href="#">7735</a>	
	telecom	1..1	SHALL		<a href="#">7737</a>	
	addr	1..1	SHALL		<a href="#">7736</a>	
	participant	0..*	MAY		<a href="#">7751</a>	
	@typeCode	1..1	SHALL		<a href="#">7752</a>	2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = DEV
	participantRole	1..1	SHALL		<a href="#">15911</a>	
	participant	0..*	MAY		<a href="#">7765</a>	
	@typeCode	1..1	SHALL		<a href="#">7766</a>	2.16.840.1.113883.5.90 (HL7ParticipationType) = LOC
	participantRole	1..1	SHALL		<a href="#">15912</a>	
	entryRelationship	0..*	MAY		<a href="#">7768</a>	
	@typeCode	1..1	SHALL		<a href="#">7769</a>	2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = COMP
	@inversionInd	1..1	SHALL		<a href="#">8009</a>	true
	encounter	1..1	SHALL		<a href="#">7770</a>	
	@classCode	1..1	SHALL		<a href="#">7771</a>	2.16.840.1.113883.5.6 (HL7ActClass) = ENC
	@moodCode	1..1	SHALL		<a href="#">7772</a>	2.16.840.1.113883.5.1001 (ActMood) = EVN
	id	1..1	SHALL		<a href="#">7773</a>	
	entryRelationship	0..1	MAY		<a href="#">7775</a>	

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
	@typeCode	1..1	SHALL		<a href="#">7776</a>	2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = SUBJ
	@inversionInd	1..1	SHALL		<a href="#">7777</a>	true
	act	1..1	SHALL		<a href="#">15913</a>	
	entryRelationship	0..*	MAY		<a href="#">7779</a>	
	@typeCode	1..1	SHALL		<a href="#">7780</a>	2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = RSON
	observation	1..1	SHALL		<a href="#">15914</a>	
	entryRelationship	0..*	MAY		<a href="#">7886</a>	
	@typeCode	1..1	SHALL		<a href="#">7887</a>	2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = COMP
	substance Administration	1..1	SHALL		<a href="#">15915</a>	

1. **SHALL** contain exactly one [1..1] @classCode="PROC" Procedure (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:7652).
2. **SHALL** contain exactly one [1..1] @moodCode, which **SHALL** be selected from ValueSet [MoodCodeEvnInt 2.16.840.1.113883.11.20.9.18](#) **STATIC** 2011-04-03 (CONF:7653).
3. **SHALL** contain exactly one [1..1] templateId (CONF:7654) such that it
  - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.14" (CONF:10521).
4. **SHALL** contain at least one [1..\*] id (CONF:7655).
5. **SHALL** contain exactly one [1..1] code (CONF:7656).
  - a. This code **SHOULD** contain zero or one [0..1] originalText (CONF:19203).
    - i. The originalText, if present, **SHOULD** contain zero or one [0..1] reference (CONF:19204).
      1. The reference, if present, **SHOULD** contain zero or one [0..1] @value (CONF:19205).
        - a. This reference/@value **SHALL** begin with a '#' and **SHALL** point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:19206).
    - b. This code in a procedure activity **SHOULD** be selected from LOINC (codeSystem 2.16.840.1.113883.6.1) or SNOMED CT (CodeSystem: 2.16.840.1.113883.6.96), and **MAY** be selected from CPT-4 (CodeSystem: 2.16.840.1.113883.6.12) or ICD10 PCS (CodeSystem: 2.16.840.1.113883.6.4) (CONF:19207).

6. **SHALL** contain exactly one [1..1] **statusCode**, which **SHALL** be selected from ValueSet [ProcedureAct statusCode 2.16.840.1.113883.11.20.9.22](#) **DYNAMIC** (CONF:7661).
7. **SHOULD** contain zero or one [0..1] **effectiveTime** (CONF:7662).
8. **MAY** contain zero or one [0..1] **priorityCode**, which **SHALL** be selected from ValueSet [Act Priority Value Set 2.16.840.1.113883.1.11.16866](#) **DYNAMIC** (CONF:7668).
9. **MAY** contain zero or one [0..1] **methodCode** (CONF:7670).
  - a. MethodCode **SHALL NOT** conflict with the method inherent in Procedure / code (CONF:7890).
10. **SHOULD** contain zero or more [0..\*] **targetSiteCode** (CONF:7683).
  - a. The targetSiteCode, if present, **SHALL** contain exactly one [1..1] **@code**, which **SHALL** be selected from ValueSet [Body Site Value Set 2.16.840.1.113883.3.88.12.3221.8.9](#) **DYNAMIC** (CONF:16082).
11. **MAY** contain zero or more [0..\*] **specimen** (CONF:7697).
  - a. The specimen, if present, **SHALL** contain exactly one [1..1] **specimenRole** (CONF:7704).
    - i. This specimenRole **SHOULD** contain zero or more [0..\*] **id** (CONF:7716).
      1. If you want to indicate that the Procedure and the Results are referring to the same specimen, the Procedure/specimen/specimenRole/id **SHOULD** be set to equal an Organizer/specimen/ specimenRole/id (CONF:7717).
    - b. This specimen is for representing specimens obtained from a procedure (CONF:16842).
12. **SHOULD** contain zero or more [0..\*] **performer** (CONF:7718) such that it
  - a. **SHALL** contain exactly one [1..1] **assignedEntity** (CONF:7720).
    - i. This assignedEntity **SHALL** contain at least one [1..\*] **id** (CONF:7722).
    - ii. This assignedEntity **SHALL** contain exactly one [1..1] **addr** (CONF:7731).
    - iii. This assignedEntity **SHALL** contain exactly one [1..1] **telecom** (CONF:7732).
    - iv. This assignedEntity **SHOULD** contain zero or one [0..1] **representedOrganization** (CONF:7733).
      1. The representedOrganization, if present, **SHOULD** contain zero or more [0..\*] **id** (CONF:7734).
      2. The representedOrganization, if present, **MAY** contain zero or more [0..\*] **name** (CONF:7735).
      3. The representedOrganization, if present, **SHALL** contain exactly one [1..1] **telecom** (CONF:7737).
      4. The representedOrganization, if present, **SHALL** contain exactly one [1..1] **addr** (CONF:7736).
13. **MAY** contain zero or more [0..\*] **participant** (CONF:7751) such that it

- a. **SHALL** contain exactly one [1..1] @typeCode="DEV" Device (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**) (CONF:7752).
  - b. **SHALL** contain exactly one [1..1] [Product Instance](#) (templateId:2.16.840.1.113883.10.20.22.4.37) (CONF:15911).
14. **MAY** contain zero or more [0..\*] **participant** (CONF:7765) such that it
- a. **SHALL** contain exactly one [1..1] @typeCode="LOC" Location (CodeSystem: HL7ParticipationType 2.16.840.1.113883.5.90 **STATIC**) (CONF:7766).
  - b. **SHALL** contain exactly one [1..1] [Service Delivery Location](#) (templateId:2.16.840.1.113883.10.20.22.4.32) (CONF:15912).
15. **MAY** contain zero or more [0..\*] **entryRelationship** (CONF:7768) such that it
- a. **SHALL** contain exactly one [1..1] @typeCode="COMP" Has Component (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**) (CONF:7769).
  - b. **SHALL** contain exactly one [1..1] @inversionInd="true" true (CONF:8009).
  - c. **SHALL** contain exactly one [1..1] **encounter** (CONF:7770).
    - i. This encounter **SHALL** contain exactly one [1..1] @classCode="ENC" Encounter (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:7771).
    - ii. This encounter **SHALL** contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 **STATIC**) (CONF:7772).
    - iii. 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:16843).
16. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:7775) such that it
- a. **SHALL** contain exactly one [1..1] @typeCode="SUBJ" Has Subject (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**) (CONF:7776).
  - b. **SHALL** contain exactly one [1..1] @inversionInd="true" true (CONF:7777).
  - c. **SHALL** contain exactly one [1..1] [Instructions](#) (templateId:2.16.840.1.113883.10.20.22.4.20) (CONF:15913).
17. **MAY** contain zero or more [0..\*] **entryRelationship** (CONF:7779) such that it
- a. **SHALL** contain exactly one [1..1] @typeCode="RSON" Has Reason (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**) (CONF:7780).
  - b. **SHALL** contain exactly one [1..1] [Indication](#) (templateId:2.16.840.1.113883.10.20.22.4.19) (CONF:15914).
18. **MAY** contain zero or more [0..\*] **entryRelationship** (CONF:7886) such that it
- a. **SHALL** contain exactly one [1..1] @typeCode="COMP" Has Component (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**) (CONF:7887).
  - b. **SHALL** contain exactly one [1..1] [Medication Activity](#) (templateId:2.16.840.1.113883.10.20.22.4.16) (CONF:15915).

#### 4.49.1 Breast Cancer Procedures

[Procedure: templateId 2.16.840.1.113883.10.20.30.3.12 (open)]

**Table 217: Breast Cancer Procedures Contexts**

Used By:	Contains Entries:
<a href="#">Procedures Section BCTPS</a> (required)	<a href="#">Lymph Node Sampling Result Organizer</a>

This clinical statement represents procedures that are performed on a patient with breast cancer.

**Table 218: Breast Cancer Procedures Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
	Procedure[templateId/@root = '2.16.840.1.113883.10.20.30.3.12']					
	templateId	1..1	SHALL		<a href="#">23112</a>	
	@root	1..1	SHALL		<a href="#">23113</a>	2.16.840.1.113883.10.20.30.3.12
	code	1..1	SHALL		<a href="#">26725</a>	2.16.840.1.113883.11.20.11.16 (Breast Cancer Procedures)
	statusCode	1..1	SHALL		<a href="#">23128</a>	
	@code	1..1	SHALL		<a href="#">23129</a>	2.16.840.1.113883.5.14 (ActStatus) = completed
	effectiveTime	1..1	SHALL		<a href="#">23130</a>	
	methodCode	0..1	MAY		<a href="#">24962</a>	
	entryRelationship	0..1	SHOULD		<a href="#">23131</a>	
	organizer	1..1	SHALL		<a href="#">23132</a>	

1. Conforms to [Procedure Activity Procedure](#) template (2.16.840.1.113883.10.20.22.4.14).
2. **SHALL** contain exactly one [1..1] **templateId** (CONF:23112) such that it
  - a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.30.3.12" (CONF:23113).
3. **SHALL** contain exactly one [1..1] **code**, which **SHALL** be selected from ValueSet [Breast Cancer Procedures 2.16.840.1.113883.11.20.11.16 DYNAMIC](#) (CONF:26725).
4. **SHALL** contain exactly one [1..1] **statusCode** (CONF:23128).
  - a. This statusCode **SHALL** contain exactly one [1..1] **@code**="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 **STATIC**) (CONF:23129).
5. **SHALL** contain exactly one [1..1] **effectiveTime** (CONF:23130).

A methodCode may be used to describe the surgical method used in performing the procedure. Many breast cancer procedure codes are pre-coordinated with the method



inherent in the code. If methodCode is used it should not conflict with the procedureCode.

6. **MAY** contain zero or one [0..1] **methodCode** (CONF:24962).
7. **SHOULD** contain zero or one [0..1] **entryRelationship** (CONF:23131).
  - a. The entryRelationship, if present, **SHALL** contain exactly one [1..1] [Lymph Node Sampling Result Organizer](#) (templateId:2.16.840.1.113883.10.20.30.3.13) (CONF:23132).

**Figure 103: Breast Cancer Procedures example**

```
<entry typeCode="DRIV">
 <procedure classCode="PROC" moodCode="EVN">
 <!-- C-CDA PROCEDURE ACTIVITY PROCEDURE TemplateID -->
 <templateId root="2.16.840.1.113883.10.20.22.4.14"/>
 <!-- Breast Cancer Procedures templateID-->
 <templateId root="2.16.840.1.113883.10.20.30.3.12"/>
 <id root="e401f340-7be2-11db-9fe1-0800200c9a66"/>
 <code code="301796003"
 codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMED CT"
 displayName="Axillary lymph node procedure"/>
 <text>Axillary lymph node procedure</text>
 <statusCode code="completed"/>
 <effectiveTime value="20120430"/>
 <methodCode code="62471006"
 codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMED CT"
 displayName="deep axillary lymphadenectomy"/>
 <targetSiteCode code="20437008"
 codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMED CT"
 displayName="left axillary region(body structure)"/>

 <!-- LYMPH NODE SAMPLING RESULT ORGANIZER -->
 <entryRelationship typeCode="COMP">
 <organizer classCode="CLUSTER" moodCode="EVN">
 <!-- C-CDA RESULT ORGANIZER TemplateID -->
 <templateId root="2.16.840.1.113883.10.20.22.4.1"/>
 <!-- Lymph Node Sampling Result organizer templateID -->
 <templateId root="2.16.840.1.113883.10.20.30.3.13"/>
 ...
 </organizer>
 </entryRelationship>
 </procedure>
</entry>
```

## 4.50 Product Instance

[Closed for comments; published July 2012]

[participantRole: templateId 2.16.840.1.113883.10.20.22.4.37 (open)]

**Table 219: Product Instance Contexts**

Used By:	Contains Entries:
<a href="#">Procedure Activity Procedure</a> (optional) <a href="#">Non-Medicinal Supply Activity</a> (optional)	

This clinical statement represents a particular device that was placed in or used as part of a procedure or other act. This provides 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 a patient but that it was a particular hip prostheses number with a unique identifier.

The FDA Amendments Act specifies the creation of a Unique Device Identification (UDI) System that requires the label of devices to bear a unique identifier that will standardize device identification and identify the device through distribution and use.

The UDI should be sent in the participantRole/id.

**Table 220: Product Instance Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	participantRole[templateId/@root = '2.16.840.1.113883.10.20.22.4.37']					
	@classCode	1..1	SHALL		<a href="#">7900</a>	2.16.840.1.113883.5.110 (RoleClass) = MANU
	templateId	1..1	SHALL		<a href="#">7901</a>	
	@root	1..1	SHALL		<a href="#">10522</a>	2.16.840.1.113883.10.20.22.4.37
	id	1..*	SHALL		<a href="#">7902</a>	
	playingDevice	1..1	SHALL		<a href="#">7903</a>	
	code	0..1	SHOULD		<a href="#">16837</a>	
	scopingEntity	1..1	SHALL		<a href="#">7905</a>	
	id	1..*	SHALL		<a href="#">7908</a>	

1. **SHALL** contain exactly one [1..1] @classCode="MANU" Manufactured Product (CodeSystem: RoleClass 2.16.840.1.113883.5.110 **STATIC**) (CONF:7900).
2. **SHALL** contain exactly one [1..1] templateId (CONF:7901) such that it
  - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.37" (CONF:10522).
3. **SHALL** contain at least one [1..\*] id (CONF:7902).
4. **SHALL** contain exactly one [1..1] playingDevice (CONF:7903).
  - a. This playingDevice **SHOULD** contain zero or one [0..1] code (CONF:16837).
5. **SHALL** contain exactly one [1..1] scopingEntity (CONF:7905).

- a. This scopingEntity **SHALL** contain at least one [1..\*] id (CONF:7908).

**Figure 104: Product Instance example**

```
<participantRole classCode="MANU">
 <templateId root="2.16.840.1.113883.10.20.22.4.37" />
 <!-- Product instance template -->
 <id root="742aee30-21c5-11e1-bfc2-0800200c9a66" />
 <playingDevice>
 <code code="90412006"
 codeSystem="2.16.840.1.113883.6.96"
 displayName="Colonoscope" />
 </playingDevice>
 <scopingEntity>
 <id root="eb936010-7b17-11db-9fe1-0800200c9b65" />
 </scopingEntity>
</participantRole>
```

## 4.51 Reaction Observation

**[Closed for comments; published July 2012]**

[observation: templateId 2.16.840.1.113883.10.20.22.4.9 (open)]

**Table 221: Reaction Observation Contexts**

Used By:	Contains Entries:
<a href="#">Medication Activity</a> (optional) <a href="#">Allergy - Intolerance Observation</a> (optional) <a href="#">Substance or Device Allergy - Intolerance Observation</a> (optional) <a href="#">Chemotherapy Medication Activity</a> (optional) <a href="#">Chemotherapy Medication Activity Plan</a> (optional)	<a href="#">Medication Activity</a> <a href="#">Procedure Activity Procedure</a> <a href="#">Severity Observation</a>

This clinical statement represents an undesired symptom, finding, etc., due to an administered or exposed substance. A reaction can be defined with respect to its severity, and can have been treated by one or more interventions.

**Table 222: Reaction Observation Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
Green Reaction Observation	observation[templateId/@root = '2.16.840.1.113883.10.20.22.4.9']					
	@classCode	1..1	SHALL		<a href="#">7325</a>	2.16.840.1.113883.5.6 (HL7ActClass) = OBS
	@moodCode	1..1	SHALL		<a href="#">7326</a>	2.16.840.1.113883.5.1001 (ActMood) = EVN
	templateId	1..1	SHALL		<a href="#">7323</a>	
	@root	1..1	SHALL		<a href="#">10523</a>	2.16.840.1.113883.10.20.22.4.9

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
	id	1..1	SHALL		<a href="#">7329</a>	
	code	1..1	SHALL		<a href="#">16851</a>	
reactionFree Text	text	0..1	SHOULD		<a href="#">7330</a>	
	reference	0..1	SHOULD		<a href="#">15917</a>	
	@value	0..1	SHOULD		<a href="#">15918</a>	
	statusCode	1..1	SHALL		<a href="#">7328</a>	
	@code	1..1	SHALL		<a href="#">19114</a>	2.16.840.1.113883.5.14 (ActStatus) = completed
	effectiveTime	0..1	SHOULD		<a href="#">7332</a>	
	low	0..1	SHOULD		<a href="#">7333</a>	
	high	0..1	SHOULD		<a href="#">7334</a>	
reaction Coded	value	1..1	SHALL	CD	<a href="#">7335</a>	2.16.840.1.113883.3.88.12.3221.7.4 (Problem Value Set)
	entry Relationship	0..*	MAY		<a href="#">7337</a>	
	@typeCode	1..1	SHALL		<a href="#">7338</a>	2.16.840.1.113883.5.1002 (HL7ActRelationship Type) = RSON
	@inversionInd	1..1	SHALL		<a href="#">7343</a>	true
	procedure	1..1	SHALL		<a href="#">15920</a>	
	entry Relationship	0..*	MAY		<a href="#">7340</a>	
	@typeCode	1..1	SHALL		<a href="#">7341</a>	2.16.840.1.113883.5.1002 (HL7ActRelationship Type) = RSON
	@inversionInd	1..1	SHALL		<a href="#">7344</a>	true
	substance Administration	1..1	SHALL		<a href="#">15921</a>	
severity	entry Relationship	0..1	SHOULD		<a href="#">7580</a>	
	@typeCode	1..1	SHALL		<a href="#">7581</a>	2.16.840.1.113883.5.1002 (HL7ActRelationship Type) = SUBJ
	@inversionInd	1..1	SHALL		<a href="#">10375</a>	true
	observation	1..1	SHALL		<a href="#">15922</a>	

1. **SHALL** contain exactly one [1..1] @classCode="OBS" Observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:7325).

2. **SHALL** contain exactly one [1..1] **@moodCode="EVN"** Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 **STATIC**) (CONF:7326).
3. **SHALL** contain exactly one [1..1] **templateId** (CONF:7323) such that it
  - a. **SHALL** contain exactly one [1..1] **@root="2.16.840.1.113883.10.20.22.4.9"** (CONF:10523).
4. **SHALL** contain exactly one [1..1] **id** (CONF:7329).
5. **SHALL** contain exactly one [1..1] **code** (CONF:16851).
  - a. The value set for this code element has not been specified. Implementers are allowed to use any code system, such as SNOMED CT, a locally determined code, or a nullFlavor (CONF:16852).
6. **SHOULD** contain zero or one [0..1] **text** (CONF:7330).
  - a. The text, if present, **SHOULD** contain zero or one [0..1] **reference** (CONF:15917).
    - i. The reference, if present, **SHOULD** contain zero or one [0..1] **@value** (CONF:15918).
      1. This reference/**@value** **SHALL** begin with a '#' and **SHALL** point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:15919).
7. **SHALL** contain exactly one [1..1] **statusCode** (CONF:7328).
  - a. This statusCode **SHALL** contain exactly one [1..1] **@code="completed"** Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 **STATIC**) (CONF:19114).
8. **SHOULD** contain zero or one [0..1] **effectiveTime** (CONF:7332).
  - a. The effectiveTime, if present, **SHOULD** contain zero or one [0..1] **low** (CONF:7333).
  - b. The effectiveTime, if present, **SHOULD** contain zero or one [0..1] **high** (CONF:7334).
9. **SHALL** contain exactly one [1..1] **value** with **@xsi:type="CD"**, where the **@code** **SHALL** be selected from ValueSet [Problem Value Set 2.16.840.1.113883.3.88.12.3221.7.4 DYNAMIC](#) (CONF:7335).
10. **MAY** contain zero or more [0..\*] **entryRelationship** (CONF:7337) such that it
  - a. **SHALL** contain exactly one [1..1] **@typeCode="RSON"** Has reason (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**) (CONF:7338).
  - b. **SHALL** contain exactly one [1..1] **@inversionInd="true"** True (CONF:7343).
  - c. **SHALL** contain exactly one [1..1] [Procedure Activity Procedure](#) (templateId:2.16.840.1.113883.10.20.22.4.14) (CONF:15920).
    - i. This procedure activity is intended to contain information about procedures that were performed in response to an allergy reaction (CONF:16853).
11. **MAY** contain zero or more [0..\*] **entryRelationship** (CONF:7340) such that it
  - a. **SHALL** contain exactly one [1..1] **@typeCode="RSON"** Has reason (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**) (CONF:7341).
  - b. **SHALL** contain exactly one [1..1] **@inversionInd="true"** True (CONF:7344).

- c. **SHALL** contain exactly one [1..1] [Medication Activity](#) (templateId:2.16.840.1.113883.10.20.22.4.16) (CONF:15921).
    - i. This medication activity is intended to contain information about medications that were administered in response to an allergy reaction (CONF:16840).
12. **SHOULD** contain zero or one [0..1] **entryRelationship** (CONF:7580) such that it
- a. **SHALL** contain exactly one [1..1] **@typeCode="SUBJ"** Has subject (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**) (CONF:7581).
  - b. **SHALL** contain exactly one [1..1] **@inversionInd="true"** TRUE (CONF:10375).
  - c. **SHALL** contain exactly one [1..1] [Severity Observation](#) (templateId:2.16.840.1.113883.10.20.22.4.8) (CONF:15922).

#### 4.51.1 Therapy Side Effects

[Observation: templateId 2.16.840.1.113883.10.20.30.3.42 (open)]

**Table 223: Therapy Side Effects Contexts**

Used By:	Contains Entries:
<a href="#">Chemotherapy Regimen</a> (optional)	

This clinical statement represents the side effects of a cancer treatment therapy that occurred during the patient's treatment.

**Table 224: Therapy Side Effects Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	Observation[templateId/@root = '2.16.840.1.113883.10.20.30.3.42']					
	@classCode	1..1	SHALL		<a href="#">23941</a>	2.16.840.1.113883.5.6 (HL7ActClass) = OBS
	@moodCode	1..1	SHALL		<a href="#">23942</a>	2.16.840.1.113883.5.1001 (ActMood) = EVN
	templateId	1..1	SHALL		<a href="#">23943</a>	
	@root	1..1	SHALL		<a href="#">23944</a>	2.16.840.1.113883.10.20.30.3.42
	value	0..1	SHOULD	CD	<a href="#">23945</a>	
	@code	1..1	SHALL		<a href="#">23946</a>	2.16.840.1.113883.11.20.11.9 (Chemotherapy Side Effects)

1. Conforms to [Reaction Observation](#) template (2.16.840.1.113883.10.20.22.4.9).
2. **SHALL** contain exactly one [1..1] **@classCode="OBS"** observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:23941).

3. **SHALL** contain exactly one [1..1] `@moodCode="EVN"` event (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:23942).
4. **SHALL** contain exactly one [1..1] `templateId` (CONF:23943) such that it
  - a. **SHALL** contain exactly one [1..1]
 `@root="2.16.840.1.113883.10.20.30.3.42"` (CONF:23944).
5. **SHOULD** contain zero or one [0..1] `value` with `@xsi:type="CD"` (CONF:23945).

A value observation code of "OTH" is used to communicate side effects not listed in ValueSet table. In these instances, the original text would be sent.

- a. The value, if present, **SHALL** contain exactly one [1..1] `@code` (ValueSet: [Chemotherapy Side Effects 2.16.840.1.113883.11.20.11.9 DYNAMIC](#)) (CONF:23946).

**Figure 105: Therapy Side Effects example**

```

<!-- Therapy Side Effects 2.16.840.1.113883.10.20.30.3.42 -->
<entryRelationship typeCode="MFST" inversionInd="true">
 <!-- SHALL [1..1] Reaction Observation 2.16.840.1.113883.10.20.22.4.9 -->
 <observation classCode="OBS" moodCode="EVN">
 <!-- C-CDA Reaction Observation 2.16.840.1.113883.10.20.22.4.9 -->
 <templateId root="2.16.840.1.113883.10.20.22.4.9"/>
 <!-- therapy side effects observation 2.16.840.1.113883.10.20.30.3.42 -->
 <!--
 <templateId root="2.16.840.1.113883.10.20.30.3.42"/>
 <id root="eac7fa14-c31e-4577-ba62-a021c4481bff"/>
 <code nullFlavor="NA"/>
 <statusCode code="completed"/>
 <effectiveTime>
 <low nullFlavor="NI"/>
 </effectiveTime>
 <value xsi:type="CD" code="56317004"
 codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT"
 displayName="alopecia"/>
 </observation>
</entryRelationship>

<!-- 2nd instance of actual reaction (toxicities) occurred during the
therapy -->
<entryRelationship typeCode="MFST" inversionInd="true">
 <!-- SHALL [1..1] Reaction Observation 2.16.840.1.113883.10.20.22.4.9 -->
 <observation classCode="OBS" moodCode="EVN">
 <!-- C-CDA Reaction Observation 2.16.840.1.113883.10.20.22.4.9 -->
 <templateId root="2.16.840.1.113883.10.20.22.4.9"/>
 <!-- therapy side effects observation 2.16.840.1.113883.10.20.30.3.42 -->
 <!--
 <templateId root="2.16.840.1.113883.10.20.30.3.42"/>
 <id root="7abbe099-ed3e-444b-8cd1-db7093aa94e4"/>
 <code nullFlavor="NA"/>
 <statusCode code="completed"/>
 <effectiveTime>
 <low nullFlavor="NI"/>
 </effectiveTime>
 </observation>
</entryRelationship>

```

```

 <value xsi:type="CD" code="16932000"
 codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT"
 displayName="nausea and vomiting"/>
 </observation>
</entryRelationship>

<!-- MAY [0..*] instructions (possible side effects of the therapy -->
<!-- Possible Side Effects 2.16.840.1.113883.10.20.30.3.35 -->
<entryRelationship typeCode="SUBJ">
 <!-- Instructions template requires intent mood -->
 <act classCode="ACT" moodCode="INT">
 <!-- C-CDA Instructions Template -->
 <templateId root="2.16.840.1.113883.10.20.22.4.20"/>
 <!-- Possible Side Effects Template -->
 <templateId root="2.16.840.1.113883.10.20.30.3.35"/>
 <code code="396080005"
 displayName="medication side effects education"
 codeSystem="2.16.840.1.113883.6.96"
 ...

```

**Figure 106: Example of “OTH” nullFlavors for other therapy side effects**

```

<entryRelationship typeCode="MFST" inversionInd="true">
 <!-- SHALL [1..1] Reaction Observation 2.16.840.1.113883.10.20.22.4.9 -->
 <observation classCode="OBS" moodCode="EVN">
 <!-- C-CDA Reaction Observation 2.16.840.1.113883.10.20.22.4.9 -->
 <templateId root="2.16.840.1.113883.10.20.22.4.9"/>
 <!-- therapy side effects observation 2.16.840.1.113883.10.20.30.3.42 -->
 <templateId root="2.16.840.1.113883.10.20.30.3.42"/>
 <id root="eac7fa14-c31e-4577-ba62-a021c4481bff"/>
 <code nullFlavor="NA"/>
 <statusCode code="completed"/>
 <effectiveTime>
 <low nullFlavor="NI"/>
 </effectiveTime>
 <value xsi:type="CD" nullFlavor="OTH">
 <originalText>Intolerance to cold food</originalText>
 </value>
 </observation>
</entryRelationship>

```



## 4.52 Result Observation

[Closed for comments; published July 2012]

[observation: templateId 2.16.840.1.113883.10.20.22.4.2 (open)]

**Table 225: Result Observation Contexts**

Used By:	Contains Entries:
<a href="#">Result Organizer</a> (required)	

This clinical statement represents details of a lab, radiology, or other study performed on a patient.

The result observation includes a `statusCode` to allow recording the status of an observation. If a Result Observation is not completed, the Result Organizer must include corresponding `statusCode`. “Pending” results (e.g., a test has been run but results have not been reported yet) should be represented as “active” `ActStatus`.

**Table 226: Result Observation Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
	observation[templateId/@root = '2.16.840.1.113883.10.20.22.4.2']					
	@classCode	1..1	SHALL		<a href="#">7130</a>	2.16.840.1.113883.5.6 (HL7ActClass) = OBS
	@moodCode	1..1	SHALL		<a href="#">7131</a>	2.16.840.1.113883.5.1001 (ActMood) = EVN
	templateId	1..1	SHALL		<a href="#">7136</a>	
	@root	1..1	SHALL		<a href="#">9138</a>	2.16.840.1.113883.10.20.22.4.2
	id	1..*	SHALL		<a href="#">7137</a>	
	code	1..1	SHALL		<a href="#">7133</a>	
	text	0..1	SHOULD		<a href="#">7138</a>	
	reference	0..1	SHOULD		<a href="#">15924</a>	
	@value	0..1	SHOULD		<a href="#">15925</a>	
	statusCode	1..1	SHALL		<a href="#">7134</a>	
	@code	1..1	SHALL		<a href="#">14849</a>	2.16.840.1.113883.11.20.9.39 (Result Status)
	effectiveTime	1..1	SHALL		<a href="#">7140</a>	
	value	1..1	SHALL		<a href="#">7143</a>	
	interpretation Code	0..*	SHOULD		<a href="#">7147</a>	
	methodCode	0..1	MAY	SET <CE>	<a href="#">7148</a>	
	targetSiteCode	0..1	MAY	SET <CD>	<a href="#">7153</a>	
	author	0..1	MAY		<a href="#">7149</a>	

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
	referenceRange	0..*	SHOULD		<a href="#">7150</a>	
	observation Range	1..1	SHALL		<a href="#">7151</a>	
	code	0..0	SHALL NOT		<a href="#">7152</a>	

1. **SHALL** contain exactly one [1..1] `@classCode="OBS"` Observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:7130).
2. **SHALL** contain exactly one [1..1] `@moodCode="EVN"` Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 **STATIC**) (CONF:7131).
3. **SHALL** contain exactly one [1..1] `templateId` (CONF:7136) such that it
  - a. **SHALL** contain exactly one [1..1] `@root="2.16.840.1.113883.10.20.22.4.2"` (CONF:9138).
4. **SHALL** contain at least one [1..\*] `id` (CONF:7137).
5. **SHALL** contain exactly one [1..1] `code` (CONF:7133).
  - a. **SHOULD** be from LOINC (CodeSystem: 2.16.840.1.113883.6.1) or SNOMED CT (CodeSystem: 2.16.840.1.113883.6.96) (CONF:19211).
  - b. Laboratory results **SHOULD** be from LOINC (CodeSystem: 2.16.840.1.113883.6.1) or other constrained terminology named by the US Department of Health and Human Services Office of National Coordinator or other federal agency. Local and/or regional codes for laboratory results are allowed. The Local and/or regional codes **SHOULD** be sent in the translation element. See the Local code example figure (CONF:19212).
6. **SHOULD** contain zero or one [0..1] `text` (CONF:7138).
  - a. The text, if present, **SHOULD** contain zero or one [0..1] `reference` (CONF:15924).
    - i. The reference, if present, **SHOULD** contain zero or one [0..1] `@value` (CONF:15925).
      1. This reference/`@value` **SHALL** begin with a '#' and **SHALL** point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:15926).
7. **SHALL** contain exactly one [1..1] `statusCode` (CONF:7134).
  - a. This `statusCode` **SHALL** contain exactly one [1..1] `@code`, which **SHALL** be selected from ValueSet [Result Status 2.16.840.1.113883.11.20.9.39](#) **STATIC** (CONF:14849).
8. **SHALL** contain exactly one [1..1] `effectiveTime` (CONF:7140).
  - a. 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:16838).
9. **SHALL** contain exactly one [1..1] `value` (CONF:7143).
10. **SHOULD** contain zero or more [0..\*] `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).
  - a. The referenceRange, if present, **SHALL** contain exactly one [1..1] **observationRange** (CONF:7151).
    - i. This observationRange **SHALL NOT** contain [0..0] **code** (CONF:7152).

**Table 227: Result Status Value Set**

Value Set: Result Status 2.16.840.1.113883.11.20.9.39 STATIC		
Code System: ActStatus 2.16.840.1.113883.5.14		
Code	Code System	Print Name
aborted	ActStatus	aborted
active	ActStatus	active
cancelled	ActStatus	cancelled
completed	ActStatus	completed
Held	ActStatus	held
suspended	ActStatus	suspended

#### 4.52.1 Cardiac Function Observation

Observation: `templateId 2.16.840.1.113883.10.20.30.3.21 (open]`

**Table 228: Cardiac Function Observation Contexts**

Used By:	Contains Entries:
<a href="#">Results Section BCTPS</a> (required)	

This clinical statement represents results from cardiac function tests. An `effectiveTime` is required and is used to infer whether a test was done prior to or after a treatment such as chemotherapy.

**Table 229: Cardiac Function Observation Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	Observation[templateId/@root = '2.16.840.1.113883.10.20.30.3.21']					
	templateId	1..1	SHALL		<a href="#">23497</a>	
	@root	1..1	SHALL		<a href="#">26226</a>	2.16.840.1.113883.10.20.30.3.21
	code	1..1	SHALL		<a href="#">27099</a>	2.16.840.1.113883.3.526.3.1134 (Ejection Fraction)
	statusCode	1..1	SHALL		<a href="#">23501</a>	
	@code	1..1	SHALL		<a href="#">23502</a>	2.16.840.1.113883.5.14 (ActStatus) = Completed
	value	1..1	SHALL	PQ	<a href="#">23504</a>	
	methodCode	1..1	SHALL		<a href="#">27098</a>	2.16.840.1.113883.11.20.11.2 (Cardiac Ejection Method)

1. Conforms to [Result Observation](#) template (2.16.840.1.113883.10.20.22.4.2).
2. **SHALL** contain exactly one [1..1] **templateId** (CONF:23497) such that it
  - a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.30.3.21" (CONF:26226).
3. **SHALL** contain exactly one [1..1] **code**, which **SHOULD** be selected from ValueSet Ejection Fraction 2.16.840.1.113883.3.526.3.1134 **DYNAMIC** (CONF:27099).
4. **SHALL** contain exactly one [1..1] **statusCode** (CONF:23501).
  - a. This statusCode **SHALL** contain exactly one [1..1] **@code**="Completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14) (CONF:23502).
5. **SHALL** contain exactly one [1..1] **value** with **@xsi:type**="PQ" (CONF:23504).
6. **SHALL** contain exactly one [1..1] **methodCode**, which **SHOULD** be selected from ValueSet Cardiac Ejection Method 2.16.840.1.113883.11.20.11.2 **DYNAMIC** (CONF:27098).

**Table 230: Ejection Fraction Value Set**

Value Set: Ejection Fraction 2.16.840.1.113883.3.526.3.1134 DYNAMIC		
Code System: LOINC 2.16.840.1.113883.6.1		
Description: Types of cardiac ejection observations		
Reference: <a href="https://vsac.nlm.nih.gov/">https://vsac.nlm.nih.gov/</a>		
Code	Code System	Print Name
18044-8	LOINC	Left ventricular Ejection fraction
18043-0	LOINC	Left ventricular Ejection fraction by US
18044-8	LOINC	Left ventricular Ejection fraction by US 2D single-plane ellipse
18045-5	LOINC	Left ventricular Ejection fraction by US 2D biplane ellipse
18046-3	LOINC	Left ventricular Ejection fraction by US 2D modified
18047-1	LOINC	Left ventricular Ejection fraction by US 2D modified biplane
18048-9	LOINC	Left ventricular Ejection fraction by US 2D modified single-plane
18049-7	LOINC	Left ventricular Ejection fraction by US.M-mode.Teichholz
8806-2	LOINC	Left ventricular Ejection fraction by 2D echo
8807-0	LOINC	Left ventricular Ejection fraction by 2D echo.visual estimate
8808-8	LOINC	Left ventricular Ejection fraction by Cardiac angiogram
8809-6	LOINC	Left ventricular Ejection fraction by Cardiac angiogram.visual estimate
8810-4	LOINC	Left ventricular Ejection fraction by Spiral CT
8811-2	LOINC	Left ventricular Ejection fraction by MRI
8812-0	LOINC	Left ventricular Ejection fraction by Nuclear blood pool

**Table 231: Cardiac Ejection Method Value Set**

Value Set: Cardiac Ejection Method 2.16.840.1.113883.11.20.11.2 DYNAMIC		
Code System: SNOMED-CT 2.16.840.1.113883.6.96		
Description: Methods used to measure cardiac ejection.		
Code	Code System	Print Name
40701008	SNOMED-CT	echocardiography
404221001	SNOMED-CT	multiple gated acquisition scanning

**Figure 107: Cardiac Function Observation example**

```

<entry>
 <!-- C-CDA Result Observation TemplateID -->
 <templateId root="2.16.840.1.113883.10.20.22.4.2"/>
 <!-- Cardiac Function Observation TemplateID -->
 <templateId root="2.16.840.1.113883.10.20.30.3.21"/>
 <observation classCode="OBS" moodCode="EVN">
 <code codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC"
 code="18044-8"
 displayName="Left ventricular Ejection fraction"/>
 <statusCode code="completed"/>
 <!-- C-CDA Result Observation requires effective time -->
 <effectiveTime value="20120430"/>
 <value xsi:type="PQ" value="76" unit="[%]"/>
 <methodCode code="404221001"
 codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMED CT"
 displayName="multiple gated acquisition scanning"/>
 </observation>
</entry>

```

#### 4.52.2 Cognitive Status Result Observation

**[Closed for comments; published July 2012]**

[observation: templateId 2.16.840.1.113883.10.20.22.4.74 (open)]

**Table 232: Cognitive Status Result Observation Contexts**

Used By:	Contains Entries:
<a href="#">Functional Status Section</a> (optional) <a href="#">Cognitive Status Result Organizer</a> (required)	<a href="#">Assessment Scale Observation</a> <a href="#">Caregiver Characteristics</a> <a href="#">Non-Medicinal Supply Activity</a>

This clinical statement contains details of an evaluation or assessment of a patient’s cognitive status. The evaluation may include assessment of a patient's mood, memory, and ability to make decisions. The statement, if present, will include supporting caregivers, non-medical devices, and the time period for which the evaluation and assessment were performed.

This is different from a cognitive status problem observation, which is a clinical statement that describes a patient's cognitive condition, findings, or symptoms. Examples of cognitive problem observations are inability to recall, amnesia, dementia, and aggressive behavior.

**Table 233: Cognitive Status Result Observation Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
	observation[templateId/@root = '2.16.840.1.113883.10.20.22.4.74']					
	@classCode	1..1	SHALL		<a href="#">14249</a>	2.16.840.1.113883.5.6 (HL7ActClass) = OBS
	@moodCode	1..1	SHALL		<a href="#">14250</a>	2.16.840.1.113883.5.1001 (ActMood) = EVN
	templateId	1..1	SHALL		<a href="#">14255</a>	
	@root	1..1	SHALL		<a href="#">14256</a>	2.16.840.1.113883.10.20.22.4.74
	id	1..*	SHALL		<a href="#">14257</a>	
	code	1..1	SHALL		<a href="#">14591</a>	
	@code	0..1	SHOULD		<a href="#">14592</a>	2.16.840.1.113883.6.96 (SNOMED-CT) = 373930000
	text	0..1	SHOULD		<a href="#">14258</a>	
	reference	0..1	SHOULD		<a href="#">15549</a>	
	@value	0..1	SHOULD		<a href="#">15550</a>	
	statusCode	1..1	SHALL		<a href="#">14254</a>	
	@code	1..1	SHALL		<a href="#">19092</a>	2.16.840.1.113883.5.14 (ActStatus) = completed
	effectiveTime	1..1	SHALL		<a href="#">14261</a>	
	value	1..1	SHALL		<a href="#">14263</a>	
	interpretation Code	0..*	SHOULD		<a href="#">14264</a>	
	methodCode	0..1	MAY	SET< CE>	<a href="#">14265</a>	
	targetSiteCode	0..1	MAY	SET< CD>	<a href="#">14270</a>	
	author	0..1	MAY		<a href="#">14266</a>	
	entry Relationship	0..*	MAY		<a href="#">14272</a>	
	@typeCode	1..1	SHALL		<a href="#">14593</a>	2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = REFR
	supply	1..1	SHALL		<a href="#">14273</a>	
	entry Relationship	0..*	MAY		<a href="#">14276</a>	
	@typeCode	1..1	SHALL		<a href="#">14594</a>	2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = REFR
	observation	1..1	SHALL		<a href="#">14277</a>	
	entry Relationship	0..*	MAY		<a href="#">14469</a>	

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
	@typeCode	1..1	SHALL		<a href="#">14595</a>	2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = COMP
	observation	1..1	SHALL		<a href="#">14470</a>	
	referenceRange	0..*	SHOULD		<a href="#">14267</a>	
	observation Range	1..1	SHALL		<a href="#">14268</a>	
	code	0..0	SHALL NOT		<a href="#">14269</a>	

1. Conforms to [Result Observation](#) template (2.16.840.1.113883.10.20.22.4.2).
2. **SHALL** contain exactly one [1..1] @classCode="OBS" Observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:14249).
3. **SHALL** contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 **STATIC**) (CONF:14250).
4. **SHALL** contain exactly one [1..1] templateId (CONF:14255) such that it
  - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.74" (CONF:14256).
5. **SHALL** contain at least one [1..\*] id (CONF:14257).
6. **SHALL** contain exactly one [1..1] code (CONF:14591).
  - a. This code **SHOULD** contain zero or one [0..1] @code="373930000" Cognitive function finding (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96 **STATIC**) (CONF:14592).
7. **SHOULD** contain zero or one [0..1] text (CONF:14258).
  - a. The text, if present, **SHOULD** contain zero or one [0..1] reference (CONF:15549).
    - i. The reference, if present, **SHOULD** contain zero or one [0..1] @value (CONF:15550).
      1. This reference/@value **SHALL** begin with a '#' and **SHALL** point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:15551).
8. **SHALL** contain exactly one [1..1] statusCode (CONF:14254).
  - a. This statusCode **SHALL** contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 **STATIC**) (CONF:19092).

Represents clinically effective time of the measurement, which may be the time the measurement was performed (e.g., a BP measurement), or may be the time the sample was taken (and measured some time afterwards).

9. **SHALL** contain exactly one [1..1] effectiveTime (CONF:14261).
10. **SHALL** contain exactly one [1..1] value (CONF:14263).



- a. If xsi:type="CD", **SHOULD** contain a code from SNOMED CT (CodeSystem: 2.16.840.1.113883.6.96) (CONF:14271).
- 11. **SHOULD** contain zero or more [0..\*] **interpretationCode** (CONF:14264).
- 12. **MAY** contain zero or one [0..1] **methodCode** (CONF:14265).
- 13. **MAY** contain zero or one [0..1] **targetSiteCode** (CONF:14270).
- 14. **MAY** contain zero or one [0..1] **author** (CONF:14266).
- 15. **MAY** contain zero or more [0..\*] **entryRelationship** (CONF:14272) such that it
  - a. **SHALL** contain exactly one [1..1] **@typeCode="REFR"** refers to (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**) (CONF:14593).
  - b. **SHALL** contain exactly one [1..1] **Non-Medicinal Supply Activity** (templateId:2.16.840.1.113883.10.20.22.4.50) (CONF:14273).
- 16. **MAY** contain zero or more [0..\*] **entryRelationship** (CONF:14276) such that it
  - a. **SHALL** contain exactly one [1..1] **@typeCode="REFR"** refers to (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**) (CONF:14594).
  - b. **SHALL** contain exactly one [1..1] **Caregiver Characteristics** (templateId:2.16.840.1.113883.10.20.22.4.72) (CONF:14277).
- 17. **MAY** contain zero or more [0..\*] **entryRelationship** (CONF:14469) such that it
  - a. **SHALL** contain exactly one [1..1] **@typeCode="COMP"** has component (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**) (CONF:14595).
  - b. **SHALL** contain exactly one [1..1] **Assessment Scale Observation** (templateId:2.16.840.1.113883.10.20.22.4.69) (CONF:14470).
- 18. **SHOULD** contain zero or more [0..\*] **referenceRange** (CONF:14267).
  - a. The referenceRange, if present, **SHALL** contain exactly one [1..1] **observationRange** (CONF:14268).
    - i. This observationRange **SHALL NOT** contain [0..0] **code** (CONF:14269).

**Figure 108: Cognitive Status Result Observation example**

```

<observation classCode="OBS" moodCode="EVN">
 <!-- ** conforms to Result observation ** -->
 <templateId root="2.16.840.1.113883.10.20.22.4.2"/>
 <!--Cognitive Status Result Observation template -->
 <templateId root="2.16.840.1.113883.10.20.22.4.74"/>
 <id root="c6b5a04b-2bf4-49d1-8336-636a3813df0a"/>
 <code code="373930000" displayName="Cognitive function finding"
 codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMED CT"/>
 <text>
 <reference value="#COG1"/>
 </text>
 <statusCode code="completed"/>
 <effectiveTime value="200903111230"/>
 <value xsi:type="CD"/>
 <code code="61372001" displayName="Aggressive behavior"
 codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMED CT"/>
 <interpretationCode code="HH" codeSystem="2.16.840.1.113883.5.83"/>
 <referenceRange>
 <observationRange>
 <text>Non Aggressive to Aggressive</text>
 </observationRange>
 </referenceRange>
</observation>

```

### 4.52.3 Estrogen Receptor Status

[Observation: templateId 2.16.840.1.113883.10.20.30.3.19 (open)]

**Table 234: Estrogen Receptor Status Contexts**

Used By:	Contains Entries:
<a href="#">Receptor Status Organizer</a> (required)	

This clinical statement represents the status of the estrogen receptors. If the estrogen status is positive, this indicates the presence of estrogen receptors, which increases the likelihood a patient will respond to hormonal therapy. Receptor status helps predict a patient's response to hormonal therapy and prognosis. The interpretationCode describes the value results as positive, negative, or indeterminate. The methodCode indicates the test performed to obtain the receptor status (e.g., immunohistochemistry).

**Table 235: Estrogen Receptor Status Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
	Observation[templateId/@root = '2.16.840.1.113883.10.20.30.3.19']					
	templateId	1..1	SHALL		<a href="#">23461</a>	
	@root	1..1	SHALL		<a href="#">23462</a>	2.16.840.1.113883.10.20.30.3.19
	code	1..1	SHALL		<a href="#">23463</a>	
	@code	1..1	SHALL		<a href="#">23464</a>	16112-5
	@codeSystem	1..1	SHALL		<a href="#">23465</a>	2.16.840.1.113883.6.1 (LOINC) = 2.16.840.1.113883.6.1
	statusCode	1..1	SHALL		<a href="#">23466</a>	
	@code	1..1	SHALL		<a href="#">23467</a>	2.16.840.1.113883.5.14 (ActStatus) = completed
	value	1..1	SHALL		<a href="#">27102</a>	
	interpretation Code	1..1	SHALL		<a href="#">27090</a>	2.16.840.1.113883.1.11.20328 (ObservationInterpretation Detected)
	methodCode	1..1	SHALL		<a href="#">27172</a>	
	@code	0..1	SHOULD		<a href="#">27173</a>	117617002
	@codeSystem	0..1	SHOULD		<a href="#">27174</a>	2.16.840.1.113883.6.96 (SNOMED-CT) = 2.16.840.1.113883.6.96

1. Conforms to [Result Observation](#) template (2.16.840.1.113883.10.20.22.4.2).
2. **SHALL** contain exactly one [1..1] **templateId** (CONF:23461) such that it
  - a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.30.3.19" (CONF:23462).
3. **SHALL** contain exactly one [1..1] **code** (CONF:23463).
  - a. This code **SHALL** contain exactly one [1..1] **@code**="16112-5" Estrogen Receptor [interpretation] in Tissue (CONF:23464).
  - b. This code **SHALL** contain exactly one [1..1] **@codeSystem**="2.16.840.1.113883.6.1" (CodeSystem: LOINC 2.16.840.1.113883.6.1) (CONF:23465).
4. **SHALL** contain exactly one [1..1] **statusCode** (CONF:23466).
  - a. This statusCode **SHALL** contain exactly one [1..1] **@code**="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 **STATIC**) (CONF:23467).

A value is required in this constraint in the parent template. A null value will sent if a numerical value is not available.

5. **SHALL** contain exactly one [1..1] **value** (CONF:27102).

6. **SHALL** contain exactly one [1..1] **interpretationCode**, which **SHALL** be selected from ValueSet ObservationInterpretationDetected 2.16.840.1.113883.1.11.20328 **DYNAMIC** (CONF:27090).
7. **SHALL** contain exactly one [1..1] **methodCode** (CONF:27172).
  - a. This methodCode **SHOULD** contain zero or one [0..1] **@code="117617002"** immunohistochemistry procedure (IHC) (CONF:27173).
8. This methodCode **SHOULD** contain zero or one [0..1] **@codeSystem="2.16.840.1.113883.6.96"** (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96) (CONF:27174).

**Table 236: Observation Interpretation Detected Value Set**

Value Set: ObservationInterpretationDetected 2.16.840.1.113883.1.11.20328 DYNAMIC Code System: ObservationInterpretation 2.16.840.1.113883.5.83		
Code	Code System	Print Name
IND	ObservationInterpretation	Indeterminate
NEG	ObservationInterpretation	Negative
POS	ObservationInterpretation	Positive

**Figure 109: Estrogen Receptor Status example**

```

<observation classCode="OBS" moodCode="EVN">
 <!-- C-CDA RESULT ORGANIZER TemplateID -->
 <templateId root="2.16.840.1.113883.10.20.22.4.2"/>
 <!-- Estrogen Receptor Status TemplateID -->
 <templateId root="2.16.840.1.113883.10.20.30.3.19"/>
 <id root="107c2dc0-67a5-11db-bd13-0800200c9a66"/>
 <code code="16112-5"
 displayName="Estrogen Receptor [interpretation] in Tissue"
 codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
 <text> ER status </text>
 <statusCode code="completed"/>
 <effectiveTime value="20120430"/>
 <value xsi:type="PQ" value="65" unit="%" />
 <interpretationCode code="POS"
 codeSystem="2.16.840.1.113883.5.83" displayName="positive"/>
 <methodCode code="117617002"
 codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMED CT"
 displayName="immunohistochemistry procedure"/>
</observation>

```

#### 4.52.4 Functional Status Result Observation [Closed for comments; published July 2012]

[observation: templateId 2.16.840.1.113883.10.20.22.4.67 (open)]

**Table 237: Functional Status Result Observation Contexts**

Used By:	Contains Entries:
<a href="#">Functional Status Section</a> (optional) <a href="#">Functional Status Result Organizer</a> (required)	<a href="#">Assessment Scale Observation</a> <a href="#">Caregiver Characteristics</a> <a href="#">Non-Medicinal Supply Activity</a>

This clinical statement represents details of an evaluation or assessment of a patient's functional status. The evaluation may include assessment of a patient's language, vision, hearing, activities of daily living, behavior, general function, mobility, and self-care status. The statement, if present, will include supporting caregivers, non-medical devices, and the time period for which the evaluation and assessment were performed.

**Table 238: Functional Status Result Observation Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
	observation[templateId/@root = '2.16.840.1.113883.10.20.22.4.67']					
	@classCode	1..1	SHALL		<a href="#">13905</a>	2.16.840.1.113883.5.6 (HL7ActClass) = OBS
	@moodCode	1..1	SHALL		<a href="#">13906</a>	2.16.840.1.113883.5.1001 (ActMood) = EVN
	templateId	1..1	SHALL		<a href="#">13889</a>	
	@root	1..1	SHALL		<a href="#">13890</a>	2.16.840.1.113883.10.20.22.4.67
	id	1..*	SHALL		<a href="#">13907</a>	
	code	1..1	SHALL		<a href="#">13908</a>	2.16.840.1.113883.6.1 (LOINC)
	@code	0..1	SHALL		<a href="#">26448</a>	2.16.840.1.113883.6.1 (LOINC)
	text	0..1	SHOULD		<a href="#">13926</a>	
	reference	0..1	SHOULD		<a href="#">13927</a>	
	statusCode	1..1	SHALL		<a href="#">13929</a>	
	@code	1..1	SHALL		<a href="#">19101</a>	2.16.840.1.113883.5.14 (ActStatus) = completed
	effectiveTime	1..1	SHALL		<a href="#">13930</a>	
	value	1..1	SHALL		<a href="#">13932</a>	
	interpretation Code	0..*	SHOULD		<a href="#">13933</a>	
	methodCode	0..1	MAY		<a href="#">13934</a>	
	targetSiteCode	0..1	MAY		<a href="#">13935</a>	
	author	0..1	MAY		<a href="#">13936</a>	

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
	entryRelationship	0..1	MAY		<a href="#">13892</a>	
	@typeCode	1..1	SHALL		<a href="#">14596</a>	REFR
	supply	1..1	SHALL		<a href="#">14218</a>	
	entryRelationship	0..1	MAY		<a href="#">13895</a>	
	@typeCode	1..1	SHALL		<a href="#">14597</a>	REFR
	observation	1..1	SHALL		<a href="#">13897</a>	
	entryRelationship	0..1	MAY		<a href="#">14465</a>	
	@typeCode	1..1	SHALL		<a href="#">14598</a>	COMP
	observation	1..1	SHALL		<a href="#">14466</a>	
	referenceRange	0..*	SHOULD		<a href="#">13937</a>	
	observationRange	1..1	SHALL		<a href="#">13938</a>	

1. Conforms to [Result Observation](#) template (2.16.840.1.113883.10.20.22.4.2).
2. **SHALL** contain exactly one [1..1] @classCode="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:13905).
3. **SHALL** contain exactly one [1..1] @moodCode="EVN" (CodeSystem: ActMood 2.16.840.1.113883.5.1001 **STATIC**) (CONF:13906).
4. **SHALL** contain exactly one [1..1] templateId (CONF:13889) such that it
  - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.67" (CONF:13890).
5. **SHALL** contain at least one [1..\*] id (CONF:13907).
6. **SHALL** contain exactly one [1..1] code (CodeSystem: LOINC 2.16.840.1.113883.6.1 **STATIC**) (CONF:13908).
  - a. This code **SHALL** contain zero or one [0..1] @code, which **SHOULD** be selected from CodeSystem LOINC (2.16.840.1.113883.6.1) **STATIC** (CONF:26448).
7. **SHOULD** contain zero or one [0..1] text (CONF:13926).
  - a. The text, if present, **SHOULD** contain zero or one [0..1] reference (CONF:13927).
    - i. This reference/@value **SHALL** begin with a '#' and **SHALL** point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:13928).
8. **SHALL** contain exactly one [1..1] statusCode (CONF:13929).
  - a. This statusCode **SHALL** contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 **STATIC**) (CONF:19101).

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)

9. **SHALL** contain exactly one [1..1] effectiveTime (CONF:13930).
10. **SHALL** contain exactly one [1..1] value (CONF:13932).

- a. If xsi:type="CD", **SHOULD** contain a code from SNOMED CT (CodeSystem: 2.16.840.1.113883.6.96) (CONF:14234).
- 11. **SHOULD** contain zero or more [0..\*] **interpretationCode** (CONF:13933).
- 12. **MAY** contain zero or one [0..1] **methodCode** (CONF:13934).
- 13. **MAY** contain zero or one [0..1] **targetSiteCode** (CONF:13935).
- 14. **MAY** contain zero or one [0..1] **author** (CONF:13936).
- 15. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:13892) such that it
  - a. **SHALL** contain exactly one [1..1] **@typeCode="REFR"** refers to (CONF:14596).
  - b. **SHALL** contain exactly one [1..1] **Non-Medicinal Supply Activity** (templateId:2.16.840.1.113883.10.20.22.4.50) (CONF:14218).
- 16. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:13895) such that it
  - a. **SHALL** contain exactly one [1..1] **@typeCode="REFR"** refers to (CONF:14597).
  - b. **SHALL** contain exactly one [1..1] **Caregiver Characteristics** (templateId:2.16.840.1.113883.10.20.22.4.72) (CONF:13897).
- 17. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:14465) such that it
  - a. **SHALL** contain exactly one [1..1] **@typeCode="COMP"** has component (CONF:14598).
  - b. **SHALL** contain exactly one [1..1] **Assessment Scale Observation** (templateId:2.16.840.1.113883.10.20.22.4.69) (CONF:14466).
- 18. **SHOULD** contain zero or more [0..\*] **referenceRange** (CONF:13937).
  - a. The referenceRange, if present, **SHALL** contain exactly one [1..1] **observationRange** (CONF:13938).
    - i. This observationRange **SHALL NOT** contain [0..0] code (CONF:13939).

**Figure 110: Functional status result observation example**

```

<observation classCode="OBS" moodCode="EVN">
 <!-- ** conforms to Result observation ** -->
 <templateId root="2.16.840.1.113883.10.20.22.4.2"/>
 <!-- Functional Status Result Observation template -->
 <templateId root="2.16.840.1.113883.10.20.22.4.67"/>
 <id root="c6b5a04b-2bf4-49d1-8336-636a3813df0a"/>
 <code code="57251-1"
 displayName="Ambulation"
 codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
 <text>
 <reference value="#FUNC1"/>
 </text>
 <statusCode code="completed"/>
 <effectiveTime value="200903111230"/>
 <value xsi:type="CD"
 code="371153006" displayName=" Independently able"
 codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMED CT"/>
 <interpretationCode code="B" codeSystem="2.16.840.1.113883.5.83"/>

```

```

<entryRelationship typeCode="COMP">
 <observation classCode="OBS" moodCode="EVN">
 <!--Assessment Scale Observation -->
 <templateId root="2.16.840.1.113883.10.20.22.4.69"/>
 ...
 </observation>
</entryRelationship>

<entryRelationship typeCode="REFR">
 <observation classCode="OBS" moodCode="EVN">
 <!-- Caregiver Characteristics -->
 <templateId root="2.16.840.1.113883.10.20.22.4.72"/>
 ...
 </observation>
</entryRelationship>
<referenceRange>
 <observationRange>
 <text>Dependent to Independent</text>
 </observationRange>
</referenceRange>
...
</observation>

```

#### 4.52.5 HER2 Receptor Status

[Observation: templateId 2.16.840.1.113883.10.20.30.3.38 (open)]

**Table 239: HER2 Receptor Status Contexts**

Used By:	Contains Entries:
<a href="#">Receptor Status Organizer</a> (required)	

This clinical statement represents the human epidermal growth factor (HER2) status. The HER2 result aids in predicting a patient's response to HER2-directed therapy and overall prognostic survival. The interpretationCode describes the value results as positive, negative, or indeterminate. The methodCode indicates the test performed to obtain the HER2 receptor status (e.g., immunohistochemistry).



**Table 240: HER2 Receptor Status Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
	Observation[templateId/@root = '2.16.840.1.113883.10.20.30.3.38']					
	templateId	1..1	SHALL		<a href="#">23525</a>	
	@root	1..1	SHALL		<a href="#">23526</a>	2.16.840.1.113883.10.20.30.3.38
	code	1..1	SHALL		<a href="#">23527</a>	
	@code	1..1	SHALL		<a href="#">23528</a>	48676-1
	@codeSystem	1..1	SHALL		<a href="#">23529</a>	2.16.840.1.113883.6.1 (LOINC) = 2.16.840.1.113883.6.1
	statusCode	1..1	SHALL		<a href="#">23530</a>	
	@code	1..1	SHALL		<a href="#">23531</a>	2.16.840.1.113883.5.14 (ActStatus) = completed
	value	1..1	SHALL		<a href="#">27100</a>	
	interpretation Code	1..1	SHALL		<a href="#">26828</a>	2.16.840.1.113883.1.11.20328 (ObservationInterpretation Detected)
	methodCode	1..1	SHALL		<a href="#">26831</a>	2.16.840.1.113883.11.20.11.4 (Receptor Status Measurement Methods)

1. Conforms to [Result Observation](#) template (2.16.840.1.113883.10.20.22.4.2).
2. **SHALL** contain exactly one [1..1] **templateId** (CONF:23525) such that it
  - a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.30.3.38" (CONF:23526).
3. **SHALL** contain exactly one [1..1] **code** (CONF:23527).
  - a. This code **SHALL** contain exactly one [1..1] **@code**="48676-1" HER2 [interpretation] in Tissue (CONF:23528).
  - b. This code **SHALL** contain exactly one [1..1] **@codeSystem**="2.16.840.1.113883.6.1" (CodeSystem: LOINC 2.16.840.1.113883.6.1) (CONF:23529).
4. **SHALL** contain exactly one [1..1] **statusCode** (CONF:23530).
  - a. This statusCode **SHALL** contain exactly one [1..1] **@code**="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14) (CONF:23531).
5. **SHALL** contain exactly one [1..1] **value** (CONF:27100).
6. **SHALL** contain exactly one [1..1] **interpretationCode**, which **SHALL** be selected from ValueSet [ObservationInterpretationDetected](#) 2.16.840.1.113883.1.11.20328 **DYNAMIC** (CONF:26828).
7. **SHALL** contain exactly one [1..1] **methodCode**, which **SHOULD** be selected from ValueSet Receptor Status Measurement Methods 2.16.840.1.113883.11.20.11.4 **DYNAMIC** (CONF:26831).

**Table 241: Receptor Status Measurement Methods Value Set**

Value Set: Receptor Status Measurement Methods 2.16.840.1.113883.11.20.11.4 DYNAMIC		
Code System: SNOMED-CT 2.16.840.1.113883.6.96		
Description: Methods used when evaluating tissue for HER2 receptor status		
Code	Code System	Print Name
426329006	SNOMED-CT	fluorescence in situ hybridisation (FISH)
117617002	SNOMED-CT	immunohistochemistry procedure (IHC)

**Figure 111: HER2 Receptor Status example with IHC result**

```

<!-- HER2 RECEPTOR STATUS - IHC -->
<component>
 <observation classCode="OBS" moodCode="EVN">
 <!-- C-CDA RESULT ORGANIZER TemplateID -->
 <templateId root="2.16.840.1.113883.10.20.22.4.2"/>
 <!-- HER2 Receptor Status TemplateID -->
 <templateId root="2.16.840.1.113883.10.20.30.3.38"/>
 <id root="107c2dc0-67a5-11db-bd13-0800200c9a66"/>
 <code code="48676-1"
 displayName="HER2 [interpretation] in tissue"
 codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
 <text> HER2 status </text>
 <statusCode code="completed"/>
 <effectiveTime value="20120430"/>
 <value xsi:type="PQ" value="3"/>
 <interpretationCode code="POS"
 codeSystem="2.16.840.1.113883.5.83"
 displayName="positive"/>
 <methodCode code="117617002"
 codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMED CT"
 displayName="immunohistochemistry procedure"/>
 </observation>
</component>

```

**Figure 112: HER2 Receptor Status example with FISH result**

```

<!-- HER2 RECEPTOR STATUS - FISH -->
<component>
 <observation classCode="OBS" moodCode="EVN">
 <!-- consolidated CDA Result Observation templateID -->
 <templateId root="2.16.840.1.113883.10.20.22.4.2"/>
 <!-- HER2 Receptor Status TemplateID -->
 <templateId root="2.16.840.1.113883.10.20.30.3.38"/>
 <id root="107c2dc0-67a5-11db-bd13-0800200c9a66"/>
 <code code="48676-1"
 displayName="HER2 [interpretation] in tissue"
 codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC"/>
 <text> HER2 status </text>
 <statusCode code="completed"/>
 <effectiveTime value="20120430"/>
 <value xsi:type="PQ" value="4.25"/>
 <interpretationCode code="POS"
 codeSystem="2.16.840.1.113883.5.83"
 displayName="positive"/>
 <methodCode code="426329006"
 codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMED CT"
 displayName=" fluorescence in situ hybridisation"/>
 </observation>
</component>

```

#### 4.52.6 Number of Lymph Nodes Positive

[Observation: templateId 2.16.840.1.113883.10.20.30.3.15 (open)]

**Table 242: Number of Lymph Nodes Positive Contexts**

Used By:	Contains Entries:
<a href="#">Lymph Node Sampling Result Organizer</a> (optional)	

This clinical statement represents of the number of lymph node that are positive for cancer.

**Table 243: Number of Lymph Nodes Positive Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	Observation[templateId/@root = '2.16.840.1.113883.10.20.30.3.15']					
	templateId	1..1	SHALL		<a href="#">22175</a>	
	@root	1..1	SHALL		<a href="#">22176</a>	2.16.840.1.113883.10.20.30.3.15
	code	1..1	SHALL		<a href="#">22177</a>	
	@code	1..1	SHALL		<a href="#">22178</a>	44622-9
	@codeSystem	1..1	SHALL		<a href="#">23442</a>	2.16.840.1.113883.6.1 (LOINC) = 2.16.840.1.113883.6.1
	value	1..1	SHALL	INT	<a href="#">22179</a>	

1. Conforms to [Result Observation](#) template (2.16.840.1.113883.10.20.22.4.2).
2. **SHALL** contain exactly one [1..1] **templateId** (CONF:22175) such that it
  - a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.30.3.15" (CONF:22176).
3. **SHALL** contain exactly one [1..1] **code** (CONF:22177).
  - a. This code **SHALL** contain exactly one [1..1] **@code**="44622-9" Regional lymph nodes containing metastases (CONF:22178).
  - b. This code **SHALL** contain exactly one [1..1] **@codeSystem**="2.16.840.1.113883.6.1" (CodeSystem: LOINC 2.16.840.1.113883.6.1) (CONF:23442).
4. **SHALL** contain exactly one [1..1] **value** with **@xsi:type**="INT" (CONF:22179).

**Figure 113: Number of Lymph Nodes Positive example**

```

<observation classCode="OBS" moodCode="EVN">
 <!-- C-CDA RESULT OBSERVATION TemplateId -->
 <templateId root="2.16.840.1.113883.10.20.22.4.2"
 assigningAuthorityName="HL7 C-CDA"/>
 <!-- Number of Lymph Nodes Positive emplateID -->
 <templateId root="2.16.840.1.113883.3.117.1.5.3.15"/>
 <id root="df9133b3-1adb-11e0-ac64-0800200c9a66"/>
 <code codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" code="44622-9"
 displayName="Regional lymph nodes containing metastases"/>
 <statusCode code="completed"/>
 <effectiveTime value="20120430"/>
 <value xsi:type="INT" value="3"/>
 <interpretationCode code="A"
 codeSystem="2.16.840.1.113883.5.83"/>
</observation>

```

#### 4.52.7 Number of Lymph Nodes Removed and Examined

[Observation: templateId 2.16.840.1.113883.10.20.30.3.14 (open)]

**Table 244: Number of Lymph Nodes Removed and Examined Contexts**

Used By:	Contains Entries:
<a href="#">Lymph Node Sampling Result Organizer</a> (optional)	

This clinical statement represents the number of lymph nodes examined.

**Table 245: Number of Lymph Nodes Removed and Examined Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	Observation[templateId/@root = '2.16.840.1.113883.10.20.30.3.14']					
	templateId	1..1	SHALL		<a href="#">22180</a>	
	@root	1..1	SHALL		<a href="#">22181</a>	2.16.840.1.113883.10.20.30.3.14
	code	1..1	SHALL		<a href="#">22182</a>	
	@code	1..1	SHALL		<a href="#">22183</a>	44621-1
	@codeSystem	1..1	SHALL		<a href="#">23443</a>	2.16.840.1.113883.6.1 (LOINC) = 2.16.840.1.113883.6.1
	value	1..1	SHALL	INT	<a href="#">22184</a>	

1. Conforms to [Result Observation](#) template (2.16.840.1.113883.10.20.22.4.2).
2. **SHALL** contain exactly one [1..1] **templateId** (CONF:22180) such that it
  - a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.30.3.14" (CONF:22181).
3. **SHALL** contain exactly one [1..1] **code** (CONF:22182).
  - a. This code **SHALL** contain exactly one [1..1] **@code**="44621-1" Regional lymph nodes identified (CONF:22183).
  - b. This code **SHALL** contain exactly one [1..1] **@codeSystem**="2.16.840.1.113883.6.1" (CodeSystem: LOINC 2.16.840.1.113883.6.1) (CONF:23443).
4. **SHALL** contain exactly one [1..1] **value** with **@xsi:type**="INT" (CONF:22184).

**Figure 114: Number of Lymph Nodes Removed and Examined example**

```
<observation classCode="OBS" moodCode="EVN">
 <!-- C-CDA RESULT OBSERVATION TemplateId -->
 <templateId root="2.16.840.1.113883.10.20.22.4.2" />
 <!-- Number of Lymph Nodes Removed and Examined TemplateId -->
 <templateId root="2.16.840.1.113883.10.20.30.3.14"/>
 <id root="df9133b2-1adb-11e0-ac64-0800200c9a66"/>
 <code codeSystem="2.16.840.1.113883.6.1"
 code="44621-1"
 codeSystemName="LOINC"
 displayName="Regional lymph nodes identified"/>
 <statusCode code="completed"/>
 <effectiveTime value="20120430"/>
 <value xsi:type="INT" value="6"/>
</observation>
```

#### 4.52.8 Oncotype DX Score

[Observation: templateId 2.16.840.1.113883.10.20.30.3.18 (open)]

**Table 246: Oncotype DX Score Contexts**

Used By:	Contains Entries:
<a href="#">Molecular Diagnostic Testing Organizer</a> (required)	

This clinical statement records the score of the oncotype diagnosis test which is a genomic test to determine the expression of the gene 21 panel. The test results assist providers in formulating a treatment plan and therapy for the patient. The score is recorded in the value as an integer.

**Table 247: Oncotype DX Score Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
	Observation[templateId/@root = '2.16.840.1.113883.10.20.30.3.18']					
	templateId	1..1	SHALL		<a href="#">23193</a>	
	@root	1..1	SHALL		<a href="#">23194</a>	2.16.840.1.113883.10.20.30.3.18
	code	1..1	SHALL		<a href="#">23196</a>	
	@code	1..1	SHALL		<a href="#">23197</a>	56780-0
	@codeSystem	1..1	SHALL		<a href="#">23494</a>	2.16.840.1.113883.6.1 (LOINC) = 2.16.840.1.113883.6.1
	statusCode	1..1	SHALL		<a href="#">23198</a>	
	@code	1..1	SHALL		<a href="#">23199</a>	2.16.840.1.113883.5.14 (ActStatus) = completed
	value	1..1	SHALL	INT	<a href="#">23201</a>	

1. Conforms to [Result Observation](#) template (2.16.840.1.113883.10.20.22.4.2).
2. **SHALL** contain exactly one [1..1] **templateId** (CONF:23193) such that it
  - a. **SHALL** contain exactly one [1..1]
   
@root="2.16.840.1.113883.10.20.30.3.18" (CONF:23194).
3. **SHALL** contain exactly one [1..1] **code** (CONF:23196).
  - a. This code **SHALL** contain exactly one [1..1] @code="56780-0" CYP21A2 gene mutations tested for in Blood or Tissue by Molecular genetics method Nominal (CONF:23197).
  - b. This code **SHALL** contain exactly one [1..1]
   
@codeSystem="2.16.840.1.113883.6.1" (CodeSystem: LOINC
   
2.16.840.1.113883.6.1) (CONF:23494).
4. **SHALL** contain exactly one [1..1] **statusCode** (CONF:23198).
  - a. This statusCode **SHALL** contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 **STATIC**) (CONF:23199).
5. **SHALL** contain exactly one [1..1] **value** with @xsi:type="INT" (CONF:23201).

**Figure 115: Oncotype DX Score example**

```

<observation classCode="OBS" moodCode="EVN">
 <!-- C-CDA RESULT OBSERVATION TemplateID -->
 <templateId root="2.16.840.1.113883.10.20.22.4.2"/>
 <!-- Oncotype DX Score TemplateID -->
 <templateId root="2.16.840.1.113883.10.20.30.3.18"/>
 <id root="107c2dc0-67a5-11db-bd13-0800200c9a66"/>
 <code code="56780-0"
 displayName="CYP21A2 gene mutations tested for in Blood or Tissue by
 Molecular genetics method Nominal"
 codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
 <text> ONCOTYPE DX </text>
 <statusCode code="completed"/>
 <effectiveTime value="20120430"/>
 <value xsi:type="INT" value="22"/>
</observation>

```

#### 4.52.9 Progesterone Receptor Status

[Observation: templateId 2.16.840.1.113883.10.20.30.3.20 (open)]

**Table 248: Progesterone Receptor Status Contexts**

Used By:	Contains Entries:
<a href="#">Receptor Status Organizer</a> (required)	

This clinical statement represents the status of the progesterone receptors. If the progesterone status is positive, this indicates the presence of progesterone receptors which increases the likelihood a patient will respond to hormonal therapy. Receptor status helps predict a patient's response to hormonal therapy and prognosis. The

interpretationCode describes the value results as positive, negative, or indeterminate. The methodCode indicates the test performed to obtain the receptor status (e.g., immunohistochemistry).

**Table 249: Progesterone Receptor Status Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
	Observation[templateId/@root = '2.16.840.1.113883.10.20.30.3.20']					
	templateId	1..1	SHALL		<a href="#">23470</a>	
	@root	1..1	SHALL		<a href="#">23471</a>	2.16.840.1.113883.10.20.30.3.20
	code	1..1	SHALL		<a href="#">23472</a>	
	@code	1..1	SHALL		<a href="#">23473</a>	16113-3
	@codeSystem	1..1	SHALL		<a href="#">23474</a>	2.16.840.1.113883.6.1 (LOINC) = 2.16.840.1.113883.6.1
	statusCode	1..1	SHALL		<a href="#">23475</a>	
	@code	1..1	SHALL		<a href="#">23476</a>	2.16.840.1.113883.5.14 (ActStatus) = completed
	value	1..1	SHALL		<a href="#">27101</a>	
	interpretation Code	1..1	SHALL		<a href="#">27095</a>	2.16.840.1.113883.1.11.20328 (ObservationInterpretation Detected)
	methodCode	1..1	SHALL		<a href="#">27175</a>	
	@code	0..1	SHOULD		<a href="#">27176</a>	117617002
	@codeSystem	0..1	SHOULD		<a href="#">27177</a>	2.16.840.1.113883.6.96 (SNOMED-CT) = 2.16.840.1.113883.6.96

1. Conforms to [Result Observation](#) template (2.16.840.1.113883.10.20.22.4.2).
2. **SHALL** contain exactly one [1..1] **templateId** (CONF:23470) such that it
  - a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.30.3.20" (CONF:23471).
3. **SHALL** contain exactly one [1..1] **code** (CONF:23472).
  - a. This code **SHALL** contain exactly one [1..1] **@code**="16113-3" Progesterone Receptor [interpretation] in Tissue (CONF:23473).
  - b. This code **SHALL** contain exactly one [1..1] **@codeSystem**="2.16.840.1.113883.6.1" (CodeSystem: LOINC 2.16.840.1.113883.6.1) (CONF:23474).
4. **SHALL** contain exactly one [1..1] **statusCode** (CONF:23475).
  - a. This statusCode **SHALL** contain exactly one [1..1] **@code**="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 **STATIC**) (CONF:23476).



A value is required in this constraint in the parent template. A null value is sent if a numerical value is not available.

5. **SHALL** contain exactly one [1..1] **value** (CONF:27101).
6. **SHALL** contain exactly one [1..1] **interpretationCode**, which **SHALL** be selected from ValueSet [ObservationInterpretationDetected 2.16.840.1.113883.1.11.20328 DYNAMIC](#) (CONF:27095).
7. **SHALL** contain exactly one [1..1] **methodCode** (CONF:27175).
  - a. This methodCode **SHOULD** contain zero or one [0..1] **@code**="117617002" immunohistochemistry procedure (IHC) (CONF:27176).
  - b. This methodCode **SHOULD** contain zero or one [0..1] **@codeSystem**="2.16.840.1.113883.6.96" (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96) (CONF:27177).

**Figure 116: Progesterone Receptor Status example**

```
<observation classCode="OBS" moodCode="EVN">
 <!-- C-CDA RESULT ORGANIZER TemplateID -->
 <templateId root="2.16.840.1.113883.10.20.22.4.2"/>
 <!-- Progesterone Receptor Status TemplateID -->
 <templateId root="2.16.840.1.113883.10.20.30.3.20"/>
 <id root="107c2dc0-67a5-11db-bd13-0800200c9a66"/>
 <code code="16113-3"
 displayName=" Progesterone Receptor [interpretation] in Tissue"
 codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC"/>
 <text> PR status </text>
 <statusCode code="completed"/>
 <effectiveTime value="20120430"/>
 <value xsi:type="PQ" value="70" unit="%"/>
 <interpretationCode code="POS"
 codeSystem="2.16.840.1.113883.5.83" displayName="positive"/>
 <methodCode code="117617002"
 codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMED CT"
 displayName="immunohistochemistry procedure"/>
</observation>
```

### 4.53 Result Organizer

**[Closed for comments; published July 2012]**

[organizer: templateId 2.16.840.1.113883.10.20.22.4.1 (open)]

**Table 250: Result Organizer Contexts**

Used By:	Contains Entries:
<a href="#">Results Section (entries optional)</a> (optional)	<a href="#">Result Observation</a>

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.

An appropriate nullFlavor can be used when the organizer/code or organizer/id is unknown.

If any Result Observation within the organizer has a statusCode of ‘active’, the Result Organizer must also have as statusCode of ‘active’.

**Table 251: Result Organizer Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
	organizer[templateId/@root = '2.16.840.1.113883.10.20.22.4.1']					
	@classCode	1..1	SHALL		<a href="#">7121</a>	2.16.840.1.113883.5.6 (HL7ActClass)
	@moodCode	1..1	SHALL		<a href="#">7122</a>	2.16.840.1.113883.5.1001 (ActMood) = EVN
	templateId	1..1	SHALL		<a href="#">7126</a>	
	@root	1..1	SHALL		<a href="#">9134</a>	2.16.840.1.113883.10.20.22.4.1
	id	1..*	SHALL		<a href="#">7127</a>	
	code	1..1	SHALL		<a href="#">7128</a>	
	statusCode	1..1	SHALL		<a href="#">7123</a>	
	@code	1..1	SHALL		<a href="#">14848</a>	2.16.840.1.113883.11.20.9.39 (Result Status)
	component	1..*	SHALL		<a href="#">7124</a>	
	observation	1..1	SHALL		<a href="#">14850</a>	

1. **SHALL** contain exactly one [1..1] @classCode (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:7121).
  - a. **SHOULD** contain zero or one [0..1] @classCode="CLUSTER" Cluster (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) OR **SHOULD** contain zero or one [0..1] @classCode="BATTERY" Battery (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) (CONF:7165).
2. **SHALL** contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 **STATIC**) (CONF:7122).
3. **SHALL** contain exactly one [1..1] templateId (CONF:7126) such that it
  - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.1" (CONF:9134).
4. **SHALL** contain at least one [1..\*] id (CONF:7127).
5. **SHALL** contain exactly one [1..1] code (CONF:7128).
  - a. **SHOULD** be selected from LOINC (codeSystem 2.16.840.1.113883.6.1) or SNOMED CT (codeSystem 2.16.840.1.113883.6.96), and **MAY** be selected from CPT-4 (codeSystem 2.16.840.1.113883.6.12) (CONF:19218).

- b. Laboratory results **SHOULD** be from LOINC (CodeSystem: 2.16.840.1.113883.6.1) or other constrained terminology named by the US Department of Health and Human Services Office of National Coordinator or other federal agency. Local and/or regional codes for laboratory results **SHOULD** also be allowed (CONF:19219).
- 6. **SHALL** contain exactly one [1..1] **statusCode** (CONF:7123).
  - a. This statusCode **SHALL** contain exactly one [1..1] **@code**, which **SHALL** be selected from ValueSet [Result Status 2.16.840.1.113883.11.20.9.39](#) **STATIC** (CONF:14848).
- 7. **SHALL** contain at least one [1..\*] **component** (CONF:7124) such that it
  - a. **SHALL** contain exactly one [1..1] [Result Observation](#) (templateId:2.16.840.1.113883.10.20.22.4.2) (CONF:14850).

4.53.1 Cognitive Status Result Organizer  
**[Closed for comments; published July 2012]**

[organizer: templateId 2.16.840.1.113883.10.20.22.4.75 (open)]

**Table 252: Cognitive Status Result Organizer Contexts**

Used By:	Contains Entries:
<a href="#">Functional Status Section</a> (optional)	<a href="#">Cognitive Status Result Observation</a>

This clinical statement identifies a set of cognitive status result observations. It contains information applicable to all of the contained cognitive status result observations. A result organizer may be used to group questions in a Patient Health Questionnaire (PHQ).

An appropriate nullFlavor can be used when the organizer/code or organizer/id is unknown.

**Table 253: Cognitive Status Result Organizer Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	organizer[templateId/@root = '2.16.840.1.113883.10.20.22.4.75']					
	@classCode	1..1	SHALL		<a href="#">14369</a>	2.16.840.1.113883.5.6 (HL7ActClass) = CLUSTER
	@moodCode	1..1	SHALL		<a href="#">14371</a>	2.16.840.1.113883.5.1001 (ActMood) = EVN
	templateId	1..1	SHALL		<a href="#">14375</a>	
	@root	1..1	SHALL		<a href="#">14376</a>	2.16.840.1.113883.10.20.22.4.75
	id	1..*	SHALL		<a href="#">14377</a>	
	code	1..1	SHALL		<a href="#">14378</a>	
	@code	0..1	SHOULD		<a href="#">14697</a>	
	statusCode	1..1	SHALL		<a href="#">14372</a>	
	@code	1..1	SHALL		<a href="#">19093</a>	2.16.840.1.113883.5.14 (ActStatus) = completed
	component	1..*	SHALL		<a href="#">14373</a>	
	observation	1..1	SHALL		<a href="#">14381</a>	

1. Conforms to [Result Organizer](#) template (2.16.840.1.113883.10.20.22.4.1).
2. **SHALL** contain exactly one [1..1] @classCode="CLUSTER", which **SHALL** be selected from CodeSystem HL7ActClass (2.16.840.1.113883.5.6) **STATIC** (CONF:14369).
3. **SHALL** contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 **STATIC**) (CONF:14371).
4. **SHALL** contain exactly one [1..1] templateId (CONF:14375) such that it
  - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.75" (CONF:14376).
5. **SHALL** contain at least one [1..\*] id (CONF:14377).
6. **SHALL** contain exactly one [1..1] code (CONF:14378).
  - a. This code **SHOULD** contain zero or one [0..1] @code (CONF:14697).
    - i. Should be selected from ICF (codeSystem 2.16.840.1.113883.6.254) or SNOMED CT (codeSystem 2.16.840.1.113883.6.96) (CONF:14698).
7. **SHALL** contain exactly one [1..1] statusCode (CONF:14372).
  - a. This statusCode **SHALL** contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 **STATIC**) (CONF:19093).
8. **SHALL** contain at least one [1..\*] component (CONF:14373) such that it
  - a. **SHALL** contain exactly one [1..1] [Cognitive Status Result Observation](#) (templateId:2.16.840.1.113883.10.20.22.4.74) (CONF:14381).

**Figure 117 Cognitive Status Result Organizer example**

```

<organizer classCode="CLUSTER" moodCode="EVN">
 <templateId root="2.16.840.1.113883.10.20.22.4.75"/>
 <id root="9295dba4-df05-46bb-b94e-f2c4e4b156f8"/>
 <code code="d3" displayName="Communication"
 codeSystem="2.16.840.1.113883.6.254" codeSystemName="ICF"/>
 <statusCode code="completed"/>

 <component>
 <observation classCode="OBS" moodCode="EVN">
 <templateId root="2.16.840.1.113883.10.20.22.4.2"/>
 <!-- Cognitive Status Result observation
 (Understanding Verbal Content) -->
 <templateId root="2.16.840.1.113883.10.20.22.4.74"/>
 ...
 </observation>
 </component>

 <component>
 <!-- ** conforms to Result observation ** -->
 <templateId root="2.16.840.1.113883.10.20.22.4.2"/>
 <observation classCode="OBS" moodCode="EVN">
 <!-- Cognitive Status Result observation(Expression of Ideas) -->
 <templateId root="2.16.840.1.113883.10.20.22.4.74"/>
 ...
 </observation>
 </component>
</organizer>

```

#### 4.53.2 Functional Status Result Organizer

**[Closed for comments; published July 2012]**

[organizer: templateId 2.16.840.1.113883.10.20.22.4.66 (open)]

**Table 254: Functional Status Result Organizer Contexts**

Used By:	Contains Entries:
<a href="#">Functional Status Section</a> (optional)	<a href="#">Functional Status Result Observation</a>

This clinical statement identifies a set of functional status result observations. It contains information applicable to all of the contained functional status result observations. A functional status organizer may group self-care observations related to a patient's ability to feed, bathe, and dress.

An appropriate nullFlavor can be used when the organizer/code or organizer/id is unknown.

**Table 255: Functional Status Result Organizer Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
	organizer[templateId/@root = '2.16.840.1.113883.10.20.22.4.66']					
	@classCode	1..1	SHALL		<a href="#">14355</a>	2.16.840.1.113883.5.6 (HL7ActClass) = CLUSTER
	@moodCode	1..1	SHALL		<a href="#">14357</a>	2.16.840.1.113883.5.1001 (ActMood) = EVN
	templateId	1..1	SHALL		<a href="#">14361</a>	
	@root	1..1	SHALL		<a href="#">14362</a>	2.16.840.1.113883.10.20.22.4.66
	id	1..*	SHALL		<a href="#">14363</a>	
	code	1..1	SHALL		<a href="#">14364</a>	
	@code	0..1	SHOULD		<a href="#">14747</a>	
	statusCode	1..1	SHALL		<a href="#">14358</a>	
	@code	1..1	SHALL		<a href="#">19102</a>	2.16.840.1.113883.5.14 (ActStatus) = completed
	component	1..*	SHALL		<a href="#">14359</a>	
	observation	1..1	SHALL		<a href="#">14368</a>	

1. Conforms to [Result Organizer](#) template (2.16.840.1.113883.10.20.22.4.1).
2. **SHALL** contain exactly one [1..1] @classCode="CLUSTER", which **SHALL** be selected from CodeSystem HL7ActClass (2.16.840.1.113883.5.6) **STATIC** (CONF:14355).
3. **SHALL** contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 **STATIC**) (CONF:14357).
4. **SHALL** contain exactly one [1..1] templateId (CONF:14361) such that it
  - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.66" (CONF:14362).
5. **SHALL** contain at least one [1..\*] id (CONF:14363).
6. **SHALL** contain exactly one [1..1] code (CONF:14364).
  - a. This code **SHOULD** contain zero or one [0..1] @code (CONF:14747).
    - i. **SHOULD** be selected from ICF (codeSystem 2.16.840.1.113883.6.254) or SNOMED CT (codeSystem 2.16.840.1.113883.6.96) (CONF:14748).
7. **SHALL** contain exactly one [1..1] statusCode (CONF:14358).
  - a. This statusCode **SHALL** contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 **STATIC**) (CONF:19102).
8. **SHALL** contain at least one [1..\*] component (CONF:14359) such that it
  - a. **SHALL** contain exactly one [1..1] [Functional Status Result Observation](#) (templateId:2.16.840.1.113883.10.20.22.4.67) (CONF:14368).

**Figure 118: Functional Status Result Organizer example**

```

<organizer classCode="CLUSTER" moodCode="EVN">
 <templateId root="2.16.840.1.113883.10.20.22.4.1"/>
 <!-- ** conforms to Result Organizer ** -->
 <templateId root="2.16.840.1.113883.10.20.22.4.66"/>
 <!-- Functional Status Result Organizer template -->
 <id root="9295dba4-df05-46bb-b94e-f2c4e4b156f8"/>
 <code code="d5" displayName="Self-Care"
 codeSystem="2.16.840.1.113883.6.254"
 codeSystemName="ICF"/>
 <statusCode code="completed"/>

 <component>
 <observation classCode="OBS" moodCode="EVN">
 <!-- ** conforms to Result observation ** -->
 <templateId root="2.16.840.1.113883.10.20.22.4.2"/>
 <!-- Functional Status Result observation(such as toileting) -->
 <templateId root="2.16.840.1.113883.10.20.22.4.67"/>
 ...
 </observation>
 </component>

 <component>
 <observation classCode="OBS" moodCode="EVN">
 <!-- ** conforms to Result observation ** -->
 <templateId root="2.16.840.1.113883.10.20.22.4.2"/>
 <!-- Functional Status Result observation(such as eating) -->
 <templateId root="2.16.840.1.113883.10.20.22.4.67"/>
 ...
 </observation>
 </component>
</organizer>

```

### 4.53.3 Lymph Node Sampling Result Organizer

[Organizer: templateId 2.16.840.1.113883.10.20.30.3.13 (open)]

**Table 256: Lymph Node Sampling Result Organizer Contexts**

Used By:	Contains Entries:
<a href="#">Breast Cancer Procedures</a> (optional)	<a href="#">Number of Lymph Nodes Positive</a> <a href="#">Number of Lymph Nodes Removed and Examined</a>

This clinical statement represents the lymph nodes that were removed and examined and the number of those that were positive for pathology. This representation may include a reference to the full pathology report or details about each pathology finding.

**Table 257: Lymph Node Sampling Result Organizer Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
	Organizer[templateId/@root = '2.16.840.1.113883.10.20.30.3.13']					
	@classCode	1..1	SHALL		<a href="#">23314</a>	2.16.840.1.113883.5.6 (HL7ActClass) = CLUSTER
	templateId	1..1	SHALL		<a href="#">23315</a>	
	@root	1..1	SHALL		<a href="#">23316</a>	2.16.840.1.113883.10.20.30.3.13
	code	1..1	SHALL		<a href="#">23324</a>	
	@code	1..1	SHALL		<a href="#">23325</a>	178292004
	@codeSystem	1..1	SHALL		<a href="#">23326</a>	2.16.840.1.113883.6.96 (SNOMED-CT) = 2.16.840.1.113883.6.96
	statusCode	1..1	SHALL		<a href="#">23327</a>	
	@code	1..1	SHALL		<a href="#">23328</a>	2.16.840.1.113883.5.14 (ActStatus) = completed
	effectiveTime	1..1	SHALL		<a href="#">23330</a>	
	specimen	1..*	SHALL		<a href="#">23331</a>	
	specimenRole	1..1	SHALL		<a href="#">23332</a>	
	id	1..1	SHALL		<a href="#">23333</a>	
	specimenPlaying Entity	0..1	SHOULD		<a href="#">23334</a>	
	code	1..1	SHALL		<a href="#">23335</a>	
	@codeSystem	1..1	SHALL		<a href="#">23336</a>	2.16.840.1.113883.6.96 (SNOMED-CT)
	reference	0..*	MAY		<a href="#">23337</a>	
	@typeCode	1..1	SHALL		<a href="#">24948</a>	2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = REFR
	externalDocument	1..1	SHALL		<a href="#">24949</a>	
	id	1..*	SHALL		<a href="#">24950</a>	
	code	0..1	MAY		<a href="#">24957</a>	
	@code	1..1	SHALL		<a href="#">24958</a>	34122-2
	@codeSystem	1..1	SHALL		<a href="#">24959</a>	2.16.840.1.113883.6.1 (LOINC) = 2.16.840.1.113883.6.1
	text	0..1	MAY		<a href="#">24951</a>	
	@mediaType	1..1	SHALL		<a href="#">24952</a>	
	reference	0..1	MAY		<a href="#">24953</a>	
	@value	1..1	SHALL		<a href="#">24968</a>	
	component	0..1	SHOULD		<a href="#">23318</a>	
	observation	1..1	SHALL		<a href="#">23320</a>	



Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
	component	0..1	SHOULD		<a href="#">23321</a>	
	observation	1..1	SHALL		<a href="#">23323</a>	

1. Conforms to [Result Organizer](#) template (2.16.840.1.113883.10.20.22.4.1).
  2. **SHALL** contain exactly one [1..1] `@classCode="CLUSTER"` (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:23314).
  3. **SHALL** contain exactly one [1..1] `templateId` (CONF:23315) such that it
    - a. **SHALL** contain exactly one [1..1] `@root="2.16.840.1.113883.10.20.30.3.13"` (CONF:23316).
  4. **SHALL** contain exactly one [1..1] `code` (CONF:23324).
    - a. This code **SHALL** contain exactly one [1..1] `@code="178292004"` Lymph node sampling (CONF:23325).
    - b. This code **SHALL** contain exactly one [1..1] `@codeSystem="2.16.840.1.113883.6.96"` (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96) (CONF:23326).
  5. **SHALL** contain exactly one [1..1] `statusCode` (CONF:23327).
    - a. This statusCode **SHALL** contain exactly one [1..1] `@code="completed"` Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 **STATIC**) (CONF:23328).
  6. **SHALL** contain exactly one [1..1] `effectiveTime` (CONF:23330).
  7. **SHALL** contain at least one [1..\*] `specimen` (CONF:23331).
    - a. Such specimens **SHALL** contain exactly one [1..1] `specimenRole` (CONF:23332).
      - i. This specimenRole **SHALL** contain exactly one [1..1] `id` (CONF:23333).
      - ii. This specimenRole **SHOULD** contain zero or one [0..1] `specimenPlayingEntity` (CONF:23334).
        1. The specimenPlayingEntity, if present, **SHALL** contain exactly one [1..1] `code` (CONF:23335).
          - a. This code **SHALL** contain exactly one [1..1] `@codeSystem` (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96) (CONF:23336).
- A reference may be made to additional information in a pathology report.
8. **MAY** contain zero or more [0..\*] `reference` (CONF:23337).
    - a. The reference, if present, **SHALL** contain exactly one [1..1] `@typeCode="REFR"` Refers to (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002) (CONF:24948).
    - b. The reference, if present, **SHALL** contain exactly one [1..1] `externalDocument` (CONF:24949).
      - i. This externalDocument **SHALL** contain at least one [1..\*] `id` (CONF:24950).

The code represents the type of document. Either a code and/or text description would be used to describe the external document.

- ii. This externalDocument **MAY** contain zero or one [0..1] **code** (CONF:24957).
  - 1. The code, if present, **SHALL** contain exactly one [1..1] **@code="34122-2" Pathology Note** (CONF:24958).
  - 2. The code, if present, **SHALL** contain exactly one [1..1] **@codeSystem="2.16.840.1.113883.6.1" LOINC** (CodeSystem: LOINC 2.16.840.1.113883.6.1) (CONF:24959).
- iii. This externalDocument **MAY** contain zero or one [0..1] **text** (CONF:24951).
  - 1. The text, if present, **SHALL** contain exactly one [1..1] **@mediaType** (CONF:24952).
  - 2. The text, if present, **MAY** contain zero or one [0..1] **reference** (CONF:24953).
    - a. The reference, if present, **SHALL** contain exactly one [1..1] **@value** (CONF:24968).
- 9. **SHOULD** contain zero or one [0..1] **component** (CONF:23318) such that it
  - a. **SHALL** contain exactly one [1..1] **Number of Lymph Nodes Removed and Examined** (templateId:2.16.840.1.113883.10.20.30.3.14) (CONF:23320).
- 10. **SHOULD** contain zero or one [0..1] **component** (CONF:23321) such that it
  - a. **SHALL** contain exactly one [1..1] **Number of Lymph Nodes Positive** (templateId:2.16.840.1.113883.10.20.30.3.15) (CONF:23323).

**Figure 119: Lymph Node Sampling Result Organizer example**

```
entryRelationship typeCode="COMP">
 <organizer classCode="CLUSTER" moodCode="EVN">
 <!-- C-CDA RESULT ORGANIZER TemplateID -->
 <templateId root="2.16.840.1.113883.10.20.22.4.1"/>
 <!-- Lymph Node Sampling Result organizer templateID -->
 <templateId root="2.16.840.1.113883.10.20.30.3.13"/>
 <id root="7d5a02b0-67a4-11db-bd13-0800200c9a66"/>
 <code codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMED-CT" code="178292004"
 displayName="Lymph node sampling"/>
 <statusCode code="completed"/>
 <effectiveTime value="20120430"/>
```

```

<specimen>
 <specimenRole>
 <id root="df9133b1-1adb-11e0-ac64-0800200c9a66"/>
 <specimenPlayingEntity>
 <!-- Specimen type -->
 <code codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMED-CT" code="397436009"
 displayName="(a)specimen obtained by lymphadenectomy"/>
 </specimenPlayingEntity>
 </specimenRole>
</specimen>
<reference typeCode="REFR">
 <externalDocument classCode="DOCCLIN" moodCode="EVN">
 <id root="10021d19-5b29-4771-bce4-236109943dd4"/>
 <code code="34122-2"
 codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="Pathology Note"/>
 <text mediaType="Pathology/pdf">
 <reference
 value="Pathology Note.10021d19-5b29-4771-bce4-236109943dd4.pdf" />
 </text>
 </externalDocument>
</reference>

<!-- NUMBER OF LYMPH NODES REMOVED AND EXAMINED -->
<component>
 <observation classCode="OBS" moodCode="EVN">
 <!-- C-CDA RESULT OBSERVATION TemplateId -->
 <templateId root="2.16.840.1.113883.10.20.22.4.2" />
 <!-- Number of Lymph Nodes Removed and Examined TemplateId -->
 <templateId root="2.16.840.1.113883.10.20.30.3.14"/>
 ...
 </observation>
</component>

<!-- NUMBER OF LYMPH NODES POSITIVE -->
<component>
 <observation classCode="OBS" moodCode="EVN">
 <!-- C-CDA RESULT OBSERVATION TemplateId -->
 <templateId root="2.16.840.1.113883.10.20.22.4.2"
 assigningAuthorityName="HL7 C-CDA"/>
 <!-- Number of Lymph Nodes Examined TemplateID -->
 <templateId root="2.16.840.1.113883.3.117.1.5.3.15"/>
 ...
 </observation>
</component>
</organizer>
</entryRelationship>

```

#### 4.53.4 Molecular Diagnostic Testing Organizer

[Organizer: templateId 2.16.840.1.113883.10.20.30.3.49 (open)]

**Table 258: Molecular Diagnostic Testing Organizer Contexts**

Used By:	Contains Entries:
<a href="#">Results Section BCTPS</a> (required)	<a href="#">Oncotype DX Score</a>

This clinical statement represents results from molecular diagnostic tests used in the evaluation of patients with breast cancer.

**Table 259: Molecular Diagnostic Testing Organizer Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	Organizer[templateId/@root = '2.16.840.1.113883.10.20.30.3.49']					
	templateId	1..1	SHALL		<a href="#">26815</a>	
	@root	1..1	SHALL		<a href="#">26816</a>	2.16.840.1.113883.10.20.30.3.49
	code	1..1	SHALL		<a href="#">26817</a>	
	@code	1..1	SHALL		<a href="#">26818</a>	396927009
	@codeSystem	1..1	SHALL		<a href="#">26819</a>	2.16.840.1.113883.6.96 (SNOMED-CT) = 2.16.840.1.113883.6.96
	statusCode	1..1	SHALL		<a href="#">26820</a>	
	@code	1..1	SHALL		<a href="#">26821</a>	2.16.840.1.113883.5.14 (ActStatus) = Completed
	component	1..*	SHALL		<a href="#">26822</a>	
	observation	1..1	SHALL		<a href="#">26823</a>	

1. Conforms to [Result Organizer](#) template (2.16.840.1.113883.10.20.22.4.1).
2. **SHALL** contain exactly one [1..1] **templateId** (CONF:26815) such that it
  - a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.30.3.49" (CONF:26816).
3. **SHALL** contain exactly one [1..1] **code** (CONF:26817).
  - a. This code **SHALL** contain exactly one [1..1] **@code**="396927009" molecular testing, diagnostic (CONF:26818).
  - b. This code **SHALL** contain exactly one [1..1] **@codeSystem**="2.16.840.1.113883.6.96" (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96) (CONF:26819).
4. **SHALL** contain exactly one [1..1] **statusCode** (CONF:26820).
  - a. This statusCode **SHALL** contain exactly one [1..1] **@code**="Completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14) (CONF:26821).
5. **SHALL** contain at least one [1..\*] **component** (CONF:26822) such that it

- a. **SHALL** contain exactly one [1..1] [Oncotype DX Score](#)  
(templateId:2.16.840.1.113883.10.20.30.3.18) (CONF:26823).

**Figure 120: Molecular Testing Organizer example**

```
<entry typeCode="DRIV">
 <organizer classCode="CLUSTER" moodCode="EVN">
 <!-- C-CDA RESULT ORGANIZER TemplateID -->
 <templateId root="2.16.840.1.113883.10.20.22.4.1"/>
 <!-- Molecular Diagnostic Testing Organizer Template ID-->
 <templateId root="2.16.840.1.113883.10.20.30.3.49"/>
 <id root="107c2dc0-67a5-11db-bd13-0800200c9a66"/>
 <code code="396927009"
 displayName="molecular testing, diagnostic"
 codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMED CT"/>
 <statusCode code="completed"/>

 <component>
 <observation classCode="OBS" moodCode="EVN">
 <!-- consolidated CDA Result Observation templateID -->
 <templateId root="2.16.840.1.113883.10.20.22.4.2"/>
 <!-- Oncotype DX Score templateID -->
 <templateId root="2.16.840.1.113883.10.20.30.3.18"/>
 ...
 </observation>
 </component>
 </organizer>
```

#### 4.53.5 Receptor Status Organizer

[Organizer: templateId 2.16.840.1.113883.10.20.30.3.17 (open)]

**Table 260: Receptor Status Organizer Contexts**

Used By:	Contains Entries:
<a href="#">Results Section BCTPS</a> (required)	<a href="#">Estrogen Receptor Status</a> <a href="#">HER2 Receptor Status</a> <a href="#">Progesterone Receptor Status</a>

This clinical statement represents a group of lab tests that are used to predict a patient's response to therapy.

**Table 261: Receptor Status Organizer Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
	Organizer[templateId/@root = '2.16.840.1.113883.10.20.30.3.17']					
	templateId	1..1	SHALL		<a href="#">23479</a>	
	@root	1..1	SHALL		<a href="#">23480</a>	2.16.840.1.113883.10.20.30.3.17
	code	1..1	SHALL		<a href="#">23481</a>	
	@code	1..1	SHALL		<a href="#">23482</a>	246113000
	@codeSystem	1..1	SHALL		<a href="#">23483</a>	2.16.840.1.113883.6.96 (SNOMED-CT)
	statusCode	1..1	SHALL		<a href="#">23484</a>	
	@code	1..1	SHALL		<a href="#">23485</a>	2.16.840.1.113883.5.14 (ActStatus) = Completed
	component	1..1	SHALL		<a href="#">23488</a>	
	observation	1..1	SHALL		<a href="#">23489</a>	
	component	1..1	SHALL		<a href="#">23490</a>	
	observation	1..1	SHALL		<a href="#">23491</a>	
	component	1..1	SHALL		<a href="#">23493</a>	
	observation	1..1	SHALL		<a href="#">23536</a>	

1. Conforms to [Result Organizer](#) template (2.16.840.1.113883.10.20.22.4.1).
2. **SHALL** contain exactly one [1..1] **templateId** (CONF:23479) such that it
  - a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.30.3.17" (CONF:23480).
3. **SHALL** contain exactly one [1..1] **code** (CONF:23481).
  - a. This code **SHALL** contain exactly one [1..1] **@code**="246113000" Receptor Status (CONF:23482).
  - b. This code **SHALL** contain exactly one [1..1] **@codeSystem** (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96) (CONF:23483).
4. **SHALL** contain exactly one [1..1] **statusCode** (CONF:23484).
  - a. This statusCode **SHALL** contain exactly one [1..1] **@code**="Completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 **STATIC**) (CONF:23485).
5. **SHALL** contain exactly one [1..1] **component** (CONF:23488) such that it
  - a. **SHALL** contain exactly one [1..1] [Estrogen Receptor Status](#) (templateId:2.16.840.1.113883.10.20.30.3.19) (CONF:23489).
6. **SHALL** contain exactly one [1..1] **component** (CONF:23490) such that it
  - a. **SHALL** contain exactly one [1..1] [Progesterone Receptor Status](#) (templateId:2.16.840.1.113883.10.20.30.3.20) (CONF:23491).
7. **SHALL** contain exactly one [1..1] **component** (CONF:23493) such that it
  - a. **SHALL** contain exactly one [1..1] [HER2 Receptor Status](#) (templateId:2.16.840.1.113883.10.20.30.3.38) (CONF:23536).

**Figure 121: Receptor Status Organizer example**

```
<organizer classCode="CLUSTER" moodCode="EVN">
 <!-- C-CDA RESULT ORGANIZER TemplateID -->
 <templateId root="2.16.840.1.113883.10.20.22.4.1"/>
 <!-- Receptor status Organizer Template ID -->
 <templateId root="2.16.840.1.113883.10.20.30.3.17"/>
 <id root="107c2dc0-67a5-11db-bd13-0800200c9a66"/>
 <code code="246113000"
 displayName="Receptor Status"
 codeSystem="2.16.840.1.113883.6.96"
 codeSystemName="SNOMED CT"/>
 <statusCode code="completed"/>

 <!-- ESTROGEN RECEPTOR STATUS -->
 <component>
 <observation classCode="OBS" moodCode="EVN">
 <!-- C-CDA RESULT ORGANIZER TemplateID -->
 <templateId root="2.16.840.1.113883.10.20.22.4.2"/>
 <!-- Estrogen Receptor Status TemplateID -->
 <templateId root="2.16.840.1.113883.10.20.30.3.19"/>
 ...
 </observation>
 </component>

 <!-- PROGESTERONE RECEPTOR STATUS -->
 <component>
 <observation classCode="OBS" moodCode="EVN">
 <!-- C-CDA RESULT ORGANIZER TemplateID -->
 <templateId root="2.16.840.1.113883.10.20.22.4.2"/>
 <!-- Progesterone Receptor Status TemplateID -->
 <templateId root="2.16.840.1.113883.10.20.30.3.20"/>
 ...
 </observation>
 </component>

 <!-- HER2 RECEPTOR STATUS -->
 <component>
 <observation classCode="OBS" moodCode="EVN">
 <!-- C-CDA RESULT ORGANIZER TemplateID -->
 <templateId root="2.16.840.1.113883.10.20.22.4.2"/>
 <!-- HER2 Receptor Status TemplateID -->
 <templateId root="2.16.840.1.113883.10.20.30.3.38"/>
 ...
 </observation>
 </component>
</organizer>
```

## 4.54 Service Delivery Location

[Closed for comments; published July 2012]

[participantRole: templateId 2.16.840.1.113883.10.20.22.4.32 (open)]

**Table 262: Service Delivery Location Contexts**

Used By:	Contains Entries:
<a href="#">Procedure Activity Procedure</a> (optional) <a href="#">Procedure Activity Act</a> (optional) <a href="#">Procedure Activity Observation</a> (optional) <a href="#">Encounter Activities</a> (optional)	

This clinical statement represents the location of a service event where an act, observation or procedure took place.

**Table 263: Service Delivery Location Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	participantRole[templateId/@root = '2.16.840.1.113883.10.20.22.4.32']					
	@classCode	1..1	SHALL		<a href="#">7758</a>	2.16.840.1.113883.5.111 (RoleCode) = SDLOC
	templateId	1..1	SHALL		<a href="#">7635</a>	
	@root	1..1	SHALL		<a href="#">10524</a>	2.16.840.1.113883.10.20.22.4.32
	code	1..1	SHALL		<a href="#">16850</a>	2.16.840.1.113883.1.11.20275 (HealthcareServiceLocation)
	addr	0..*	SHOULD		<a href="#">7760</a>	
	telecom	0..*	SHOULD		<a href="#">7761</a>	
	playingEntity	0..1	MAY		<a href="#">7762</a>	
	@classCode	1..1	SHALL		<a href="#">7763</a>	2.16.840.1.113883.5.41 (EntityClass) = PLC
	name	0..1	MAY		<a href="#">16037</a>	

1. **SHALL** contain exactly one [1..1] **@classCode="SDLOC"** (CodeSystem: RoleCode 2.16.840.1.113883.5.111 **STATIC**) (CONF:7758).
2. **SHALL** contain exactly one [1..1] **templateId** (CONF:7635) such that it
  - a. **SHALL** contain exactly one [1..1] **@root="2.16.840.1.113883.10.20.22.4.32"** (CONF:10524).
3. **SHALL** contain exactly one [1..1] **code**, which **SHALL** be selected from ValueSet HealthcareServiceLocation 2.16.840.1.113883.1.11.20275 **STATIC** (CONF:16850).
4. **SHOULD** contain zero or more [0..\*] **addr** (CONF:7760).
5. **SHOULD** contain zero or more [0..\*] **telecom** (CONF:7761).
6. **MAY** contain zero or one [0..1] **playingEntity** (CONF:7762).



- a. The playingEntity, if present, **SHALL** contain exactly one [1..1] @classCode="PLC" (CodeSystem: EntityClass 2.16.840.1.113883.5.41 **STATIC**) (CONF:7763).
- b. The playingEntity, if present, **MAY** contain zero or one [0..1] name (CONF:16037).

**Figure 122: Service Delivery Location example**

```

<participantRole classCode="SDLOC">
 <templateId root="2.16.840.1.113883.10.20.22.4.32" />
 <!-- Service Delivery Location template -->
 <code code="1160-1" codeSystem="2.16.840.1.113883.6.259"
 codeSystemName="HealthcareServiceLocation"
 displayName="Urgent Care Center" />
 <addr>
 <streetAddressLine>17 Daws Rd.</streetAddressLine>
 <city>Blue Bell</city>
 <state>MA</state>
 <postalCode>02368</postalCode>
 <country>US</country>
 </addr>
 <telecom nullFlavor="UNK" />
 <playingEntity classCode="PLC">
 <name>Community Health and Hospitals</name>
 </playingEntity>
</participantRole>

```

## 4.55 Severity Observation

**[Closed for comments; published July 2012]**

[observation: templateId 2.16.840.1.113883.10.20.22.4.8 (open)]

**Table 264: Severity Observation Contexts**

Used By:	Contains Entries:
<a href="#">Reaction Observation</a> (optional)	
<a href="#">Allergy - Intolerance Observation</a> (optional)	
<a href="#">Substance or Device Allergy - Intolerance Observation</a> (required)	

This clinical statement represents the gravity of the problem, such as allergy or reaction, in terms of its actual or potential impact on the patient. The Severity Observation can be associated with an Allergy Observation, Reaction Observation or both. When the Severity Observation is associated directly with an Allergy it characterizes the Allergy. When the Severity Observation is associated with a Reaction Observation it characterizes a Reaction. 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.

**Table 265: Severity Observation Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
Green Severity Observation	observation[templateId/@root = '2.16.840.1.113883.10.20.22.4.8']					
	@classCode	1..1	SHALL		<a href="#">7345</a>	2.16.840.1.113883.5.6 (HL7ActClass) = OBS
	@moodCode	1..1	SHALL		<a href="#">7346</a>	2.16.840.1.113883.5.1001 (ActMood) = EVN
	templateId	1..1	SHALL		<a href="#">7347</a>	
	@root	1..1	SHALL		<a href="#">10525</a>	2.16.840.1.113883.10.20.22.4.8
	code	1..1	SHALL		<a href="#">19168</a>	
	@code	1..1	SHALL		<a href="#">19169</a>	2.16.840.1.113883.5.4 (ActCode) = SEV
severityFree Text	text	0..1	SHOULD		<a href="#">7350</a>	
	reference	0..1	SHOULD		<a href="#">15928</a>	
	@value	0..1	SHOULD		<a href="#">15929</a>	
	statusCode	1..1	SHALL		<a href="#">7352</a>	
	@code	1..1	SHALL		<a href="#">19115</a>	2.16.840.1.113883.5.14 (ActStatus) = completed
severity Coded	value	1..1	SHALL	CD	<a href="#">7356</a>	2.16.840.1.113883.3.88.12.3221.6.8 (Problem Severity)
	interpretation Code	0..*	SHOULD		<a href="#">9117</a>	
	@code	0..1	SHOULD		<a href="#">16038</a>	2.16.840.1.113883.1.11.78 (Observation Interpretation (HL7))

1. **SHALL** contain exactly one [1..1] @classCode="OBS" Observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:7345).
2. **SHALL** contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 **STATIC**) (CONF:7346).
3. **SHALL** contain exactly one [1..1] templateId (CONF:7347) such that it
  - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.8" (CONF:10525).
4. **SHALL** contain exactly one [1..1] code (CONF:19168).
  - a. This code **SHALL** contain exactly one [1..1] @code="SEV" (CodeSystem: ActCode 2.16.840.1.113883.5.4 **STATIC**) (CONF:19169).
5. **SHOULD** contain zero or one [0..1] text (CONF:7350).
  - a. The text, if present, **SHOULD** contain zero or one [0..1] reference (CONF:15928).

- i. The reference, if present, **SHOULD** contain zero or one [0..1] @value (CONF:15929).
  - 1. This reference/@value **SHALL** begin with a '#' and **SHALL** point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:15930).
- 6. **SHALL** contain exactly one [1..1] statusCode (CONF:7352).
  - a. This statusCode **SHALL** contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 **STATIC**) (CONF:19115).
- 7. **SHALL** contain exactly one [1..1] value with @xsi:type="CD", where the @code **SHALL** be selected from ValueSet Problem Severity 2.16.840.1.113883.3.88.12.3221.6.8 **DYNAMIC** (CONF:7356).
- 8. **SHOULD** contain zero or more [0..\*] interpretationCode (CONF:9117).
  - a. The interpretationCode, if present, **SHOULD** contain zero or one [0..1] @code, which **SHOULD** be selected from ValueSet Observation Interpretation (HL7) 2.16.840.1.113883.1.11.78 **DYNAMIC** (CONF:16038).

**Table 266: Problem Severity Value Set**

Value Set: Problem Severity 2.16.840.1.113883.3.88.12.3221.6.8 DYNAMIC		
Code System: SNOMED-CT 2.16.840.1.113883.6.96		
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)

**Table 267: Observation Interpretation (HL7) Value Set**

Value Set: Observation Interpretation (HL7) 2.16.840.1.113883.1.11.78 DYNAMIC Code System: HITSP-CS-83		
Code	Code System	Print Name
A	HITSP-CS-83	Abnormal
B	HITSP-CS-83	better
Carrier	HITSP-CS-83	Carrier
D	HITSP-CS-83	decreased
HX	HITSP-CS-83	above high threshold
I	HITSP-CS-83	intermediate
IND	HITSP-CS-83	Indeterminate
LX	HITSP-CS-83	below low threshold
MS	HITSP-CS-83	moderately susceptible
N	HITSP-CS-83	Normal
NEG	HITSP-CS-83	Negative
POS	HITSP-CS-83	Positive
R	HITSP-CS-83	resistant
S	HITSP-CS-83	susceptible
U	HITSP-CS-83	increased
VS	HITSP-CS-83	Very susceptible
W	HITSP-CS-83	worse

**Figure 123: Severity Observation example**

```

<observation classCode="OBS" moodCode="EVN">
 <templateId root="2.16.840.1.113883.10.20.22.4.8" />
 <!-- ** Severity observation template ** -->
 <code code="SEV"
 displayName="Severity Observation"
 codeSystem="2.16.840.1.113883.5.4"
 codeSystemName="ActCode" />
 <text>
 <reference value="#severity1" />
 </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" />
 <interpretationCode code="S"
 displayName="Susceptible"
 codeSystem="2.16.840.1.113883.1.11.78"
 codeSystemName="Observation Interpretation"/>
</observation>

```

## 4.56 Substance or Device Allergy - Intolerance Observation [Closed for comments; published July 2012]

[observation: templateId 2.16.840.1.113883.10.20.24.3.90 (open)]

**Table 268: Substance or Device Allergy - Intolerance Observation Contexts**

Used By:	Contains Entries:
	<a href="#">Allergy Status Observation</a> <a href="#">Reaction Observation</a> <a href="#">Severity Observation</a>

This clinical statement represents that an allergy or adverse reaction to a substance or device exists or does not exist. The agent that is the cause of the allergy or adverse reaction is represented as a participant in the observation.

**Table 269: Substance or Device Allergy - Intolerance Observation Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
	observation[templateId/@root = '2.16.840.1.113883.10.20.24.3.90']					
	@classCode	1..1	SHALL		<a href="#">16303</a>	2.16.840.1.113883.5.6 (HL7ActClass) = OBS
	@moodCode	1..1	SHALL		<a href="#">16304</a>	2.16.840.1.113883.5.1001 (ActMood) = EVN
	templateId	1..1	SHALL		<a href="#">16305</a>	
	@root	1..1	SHALL		<a href="#">16306</a>	2.16.840.1.113883.10.20.24.3.90
	id	1..*	SHALL		<a href="#">16307</a>	
	code	1..1	SHALL		<a href="#">16345</a>	
	@code	1..1	SHALL		<a href="#">16346</a>	2.16.840.1.113883.5.4 (ActCode) = ASSERTION
	statusCode	1..1	SHALL		<a href="#">16308</a>	
	@code	1..1	SHALL		<a href="#">26354</a>	2.16.840.1.113883.5.14 (ActStatus) = completed
	effectiveTime	1..1	SHALL		<a href="#">16309</a>	
	value	1..1	SHALL	CD	<a href="#">16312</a>	
	@code	1..1	SHALL	CS	<a href="#">16317</a>	2.16.840.1.113883.3.88.12.3221.6.2 (Allergy/Adverse Event Type Value Set)
	participant	0..*	SHOULD		<a href="#">16318</a>	
	@typeCode	1..1	SHALL		<a href="#">16319</a>	2.16.840.1.113883.5.90 (HL7ParticipationType) = CSM
	participantRole	1..1	SHALL		<a href="#">16320</a>	
	@classCode	1..1	SHALL		<a href="#">16321</a>	2.16.840.1.113883.5.110 (RoleClass) = MANU

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
	playingEntity	1..1	SHALL		<a href="#">16322</a>	
	@classCode	1..1	SHALL		<a href="#">16323</a>	2.16.840.1.113883.5.41 (EntityClass) = MMAT
	code	1..1	SHALL		<a href="#">16324</a>	
	originalText	0..1	SHOULD		<a href="#">16326</a>	
	reference	0..1	SHOULD		<a href="#">16327</a>	
	@value	0..1	SHOULD		<a href="#">16328</a>	
	translation	0..*	MAY	SET<PQR>	<a href="#">16330</a>	
	entryRelationship	0..1	MAY		<a href="#">16333</a>	
	@typeCode	1..1	SHALL		<a href="#">16335</a>	2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = SUBJ
	@inversionInd	1..1	SHALL		<a href="#">16334</a>	true
	observation	1..1	SHALL		<a href="#">16336</a>	
	entryRelationship	0..*	SHOULD		<a href="#">16337</a>	
	@typeCode	1..1	SHALL		<a href="#">16339</a>	2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = MFST
	@inversionInd	1..1	SHALL		<a href="#">16338</a>	true
	observation	1..1	SHALL		<a href="#">16340</a>	
	entryRelationship	1..1	SHALL		<a href="#">16341</a>	
	@typeCode	1..1	SHALL		<a href="#">16342</a>	2.16.840.1.113883.5.1002 (HL7ActRelationshipType) = SUBJ
	@inversionInd	1..1	SHALL		<a href="#">16343</a>	true
	observation	1..1	SHALL		<a href="#">16344</a>	

1. **SHALL** contain exactly one [1..1] @classCode="OBS" Observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:16303).
2. **SHALL** contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 **STATIC**) (CONF:16304).
3. **SHALL** contain exactly one [1..1] templateId (CONF:16305) such that it
  - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.24.3.90" (CONF:16306).
4. **SHALL** contain at least one [1..\*] id (CONF:16307).
5. **SHALL** contain exactly one [1..1] code (CONF:16345).
  - a. This code **SHALL** contain exactly one [1..1] @code="ASSERTION" Assertion (CodeSystem: ActCode 2.16.840.1.113883.5.4 **STATIC**) (CONF:16346).
6. **SHALL** contain exactly one [1..1] statusCode (CONF:16308).

- a. This statusCode **SHALL** contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14) (CONF:26354).
- 7. **SHALL** contain exactly one [1..1] effectiveTime (CONF:16309).
- 8. **SHALL** contain exactly one [1..1] value with @xsi:type="CD" (CONF:16312).
  - a. This value **SHALL** contain exactly one [1..1] @code, which **SHALL** be selected from ValueSet Allergy/Adverse Event Type Value Set 2.16.840.1.113883.3.88.12.3221.6.2 **DYNAMIC** (CONF:16317).
- 9. **SHOULD** contain zero or more [0..\*] participant (CONF:16318).
  - a. The participant, if present, **SHALL** contain exactly one [1..1] @typeCode="CSM" Consumable (CodeSystem: HL7ParticipationType 2.16.840.1.113883.5.90 **STATIC**) (CONF:16319).
  - b. The participant, if present, **SHALL** contain exactly one [1..1] participantRole (CONF:16320).
    - i. This participantRole **SHALL** contain exactly one [1..1] @classCode="MANU" Manufactured Product (CodeSystem: RoleClass 2.16.840.1.113883.5.110 **STATIC**) (CONF:16321).
    - ii. This participantRole **SHALL** contain exactly one [1..1] playingEntity (CONF:16322).
      - 1. This playingEntity **SHALL** contain exactly one [1..1] @classCode="MMAT" Manufactured Material (CodeSystem: EntityClass 2.16.840.1.113883.5.41 **STATIC**) (CONF:16323).
      - 2. This playingEntity **SHALL** contain exactly one [1..1] code (CONF:16324).
        - a. This code **SHOULD** contain zero or one [0..1] originalText (CONF:16326).
          - i. The originalText, if present, **SHOULD** contain zero or one [0..1] reference (CONF:16327).
            - 1. The reference, if present, **SHOULD** contain zero or one [0..1] @value (CONF:16328).
              - 1. This reference/@value **SHALL** begin with a '#' and **SHALL** point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:16329).
  - b. This code **MAY** contain zero or more [0..\*] translation (CONF:16330).
  - c. In an allergy to a specific medication the code **SHALL** be selected from the ValueSet 2.16.840.1.113883.3.88.12.80.16 Medication Brand Name **DYNAMIC** or the ValueSet 2.16.840.1.113883.3.88.12.80.17 Medication Clinical Drug **DYNAMIC** (CONF:16325).
  - d. In an allergy to a class of medications the code **SHALL** be selected from the ValueSet

2.16.840.1.113883.3.88.12.80.18 Medication Drug Class **DYNAMIC** (CONF:16331).

- e. In an allergy to a food or other substance the code **SHALL** be selected from the ValueSet

2.16.840.1.113883.3.88.12.80.20 Ingredient Name **DYNAMIC** (CONF:16332).

10. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:16333) such that it

- a. **SHALL** contain exactly one [1..1] **@typeCode="SUBJ"** Has subject (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**) (CONF:16335).
- b. **SHALL** contain exactly one [1..1] **@inversionInd="true"** True (CONF:16334).
- c. **SHALL** contain exactly one [1..1] **Allergy Status Observation** (templateId:2.16.840.1.113883.10.20.22.4.28) (CONF:16336).

11. **SHOULD** contain zero or more [0..\*] **entryRelationship** (CONF:16337) such that it

- a. **SHALL** contain exactly one [1..1] **@typeCode="MFST"** Is Manifestation of (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**) (CONF:16339).
- b. **SHALL** contain exactly one [1..1] **@inversionInd="true"** True (CONF:16338).
- c. **SHALL** contain exactly one [1..1] **Reaction Observation** (templateId:2.16.840.1.113883.10.20.22.4.9) (CONF:16340).

12. **SHALL** contain exactly one [1..1] **entryRelationship** (CONF:16341) such that it

- a. **SHALL** contain exactly one [1..1] **@typeCode="SUBJ"** Has Subject (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**) (CONF:16342).
- b. **SHALL** contain exactly one [1..1] **@inversionInd="true"** True (CONF:16343).
- c. **SHALL** contain exactly one [1..1] **Severity Observation** (templateId:2.16.840.1.113883.10.20.22.4.8) (CONF:16344).



**Table 270: Allergy/Adverse Event Type Value Set**

Value Set: Allergy/Adverse Event Type Value Set 2.16.840.1.113883.3.88.12.3221.6.2 DYNAMIC		
Code System: SNOMED-CT 2.16.840.1.113883.6.96		
Code	Code System	Print Name
419199007	SNOMED-CT	Allergy to substance (disorder)
416098002	SNOMED-CT	Drug allergy (disorder)
59037007	SNOMED-CT	Drug intolerance (disorder)
414285001	SNOMED-CT	Food allergy (disorder)
235719002	SNOMED-CT	Food intolerance (disorder)
420134006	SNOMED-CT	Propensity to adverse reactions (disorder)
419511003	SNOMED-CT	Propensity to adverse reactions to drug (disorder)
418471000	SNOMED-CT	Propensity to adverse reactions to food (disorder)
418038007	SNOMED-CT	Propensity to adverse reactions to substance (disorder)

#### 4.56.1 Allergy - Intolerance Observation

**[Closed for comments; published July 2012]**

[observation: templateId 2.16.840.1.113883.10.20.22.4.7 (open)]

**Table 271: Allergy - Intolerance Observation Contexts**

Used By:	Contains Entries:
<a href="#">Allergy Problem Act</a> (required)	<a href="#">Allergy Status Observation</a> <a href="#">Reaction Observation</a> <a href="#">Severity Observation</a>

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. The manufactured material participant is used to represent natural and non-natural occurring substances.

NOTE: The agent responsible for an allergy or adverse reaction is not always a manufactured material (for example, food allergies), nor is it necessarily consumed. The following constraints reflect limitations in the base CDA R2 specification, and should be used to represent any type of responsible agent.

**Table 272: Allergy - Intolerance Observation Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
Green Allergy Observation	observation[templateId/@root = '2.16.840.1.113883.10.20.22.4.7']					
	@classCode	1..1	SHALL		<a href="#">7379</a>	2.16.840.1.113883.5.6 (HL7ActClass) = OBS
	@moodCode	1..1	SHALL		<a href="#">7380</a>	2.16.840.1.113883.5.1001 (ActMood) = EVN
	templateId	1..1	SHALL		<a href="#">7381</a>	
	@root	1..1	SHALL		<a href="#">10488</a>	2.16.840.1.113883.10.20.22.4.7
	id	1..*	SHALL		<a href="#">7382</a>	
	code	1..1	SHALL		<a href="#">15947</a>	
	@code	1..1	SHALL		<a href="#">15948</a>	2.16.840.1.113883.5.4 (ActCode) = ASSERTION
	statusCode	1..1	SHALL		<a href="#">19084</a>	
	@code	1..1	SHALL		<a href="#">19085</a>	2.16.840.1.113883.5.14 (ActStatus) = completed
adverseEvent Date	effectiveTime	1..1	SHALL		<a href="#">7387</a>	
	value	1..1	SHALL	CD	<a href="#">7390</a>	
	originalText	0..1	SHOULD		<a href="#">7422</a>	
	reference	0..1	MAY		<a href="#">15949</a>	
	@value	0..1	SHOULD		<a href="#">15950</a>	
adverseEvent Type	@code	1..1	SHALL		<a href="#">9139</a>	2.16.840.1.113883.3.88.12.3221.6.2 (Allergy/Adverse Event Type Value Set)
product	participant	0..1	SHOULD		<a href="#">7402</a>	
	@typeCode	1..1	SHALL		<a href="#">7403</a>	2.16.840.1.113883.5.90 (HL7Participation Type) = CSM
productDetail	participantRole	1..1	SHALL		<a href="#">7404</a>	
	@classCode	1..1	SHALL		<a href="#">7405</a>	2.16.840.1.113883.5.110 (RoleClass) = MANU
	playingEntity	1..1	SHALL		<a href="#">7406</a>	
	@classCode	1..1	SHALL		<a href="#">7407</a>	2.16.840.1.113883.5.41 (EntityClass) = MMAT

Name	XPath	Card.	Verb	Data Type	CONF #	Fixed Value
product Coded	code	1..1	SHALL		<a href="#">7419</a>	
productFree Text	originalText	0..1	SHOULD		<a href="#">7424</a>	
	reference	0..1	SHOULD		<a href="#">7425</a>	
	@value	0..1	SHOULD		<a href="#">15952</a>	
	translation	0..*	MAY	SET<PQR>	<a href="#">7431</a>	
	entryRelationship	0..1	MAY		<a href="#">7440</a>	
	@typeCode	1..1	SHALL		<a href="#">7906</a>	2.16.840.1.113883.5.1002 (HL7ActRelationship Type) = SUBJ
	@inversionInd	1..1	SHALL		<a href="#">7446</a>	true
	observation	1..1	SHALL		<a href="#">15954</a>	
reaction	entry Relationship	0..*	SHOULD		<a href="#">7447</a>	
	@typeCode	1..1	SHALL		<a href="#">7907</a>	2.16.840.1.113883.5.1002 (HL7ActRelationship Type) = MFST
	@inversionInd	1..1	SHALL		<a href="#">7449</a>	true
	observation	1..1	SHALL		<a href="#">15955</a>	
severity	entryRelationship	0..1	SHOULD		<a href="#">9961</a>	
	@typeCode	1..1	SHALL		<a href="#">9962</a>	2.16.840.1.113883.5.1002 (HL7ActRelationship Type) = SUBJ
	@inversionInd	1..1	SHALL		<a href="#">9964</a>	true
	observation	1..1	SHALL		<a href="#">15956</a>	

1. Conforms to [Substance or Device Allergy - Intolerance Observation](#) template (2.16.840.1.113883.10.20.24.3.90).
2. **SHALL** contain exactly one [1..1] @classCode="OBS" Observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:7379).
3. **SHALL** contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 **STATIC**) (CONF:7380).
4. **SHALL** contain exactly one [1..1] templateId (CONF:7381) such that it
  - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.7" (CONF:10488).
5. **SHALL** contain at least one [1..\*] id (CONF:7382).
6. **SHALL** contain exactly one [1..1] code (CONF:15947).

- a. This code **SHALL** contain exactly one [1..1] `@code="ASSERTION"` Assertion (CodeSystem: ActCode 2.16.840.1.113883.5.4 **STATIC**) (CONF:15948).
- 7. **SHALL** contain exactly one [1..1] `statusCode` (CONF:19084).
  - a. This `statusCode` **SHALL** contain exactly one [1..1] `@code="completed"` Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 **STATIC**) (CONF:19085).
- 8. **SHALL** contain exactly one [1..1] `effectiveTime` (CONF:7387).
  - a. If it is unknown when the allergy began, this `effectiveTime` **SHALL** contain `low/@nullFlavor="UNK"` (CONF:9103).
  - b. If the allergy is no longer a concern, this `effectiveTime` **MAY** contain zero or one [0..1] `high` (CONF:10082).
- 9. **SHALL** contain exactly one [1..1] `value` with `@xsi:type="CD"` (CONF:7390).
  - a. This `value` **SHOULD** contain zero or one [0..1] `originalText` (CONF:7422).
    - i. The `originalText`, if present, **MAY** contain zero or one [0..1] `reference` (CONF:15949).
      - 1. The `reference`, if present, **SHOULD** contain zero or one [0..1] `@value` (CONF:15950).
        - a. This `reference/@value` **SHALL** begin with a '#' and **SHALL** point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:15951).
    - b. This `value` **SHALL** contain exactly one [1..1] `@code`, which **SHALL** be selected from ValueSet [Allergy/Adverse Event Type Value Set 2.16.840.1.113883.3.88.12.3221.6.2](#) **DYNAMIC** (CONF:9139).
- 10. **SHOULD** contain zero or one [0..1] `participant` (CONF:7402) such that it
  - a. **SHALL** contain exactly one [1..1] `@typeCode="CSM"` Consumable (CodeSystem: HL7ParticipationType 2.16.840.1.113883.5.90 **STATIC**) (CONF:7403).
  - b. **SHALL** contain exactly one [1..1] `participantRole` (CONF:7404).
    - i. This `participantRole` **SHALL** contain exactly one [1..1] `@classCode="MANU"` Manufactured Product (CodeSystem: RoleClass 2.16.840.1.113883.5.110 **STATIC**) (CONF:7405).
    - ii. 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: EntityClass 2.16.840.1.113883.5.41 **STATIC**) (CONF:7407).
      - 2. This `playingEntity` **SHALL** contain exactly one [1..1] `code` (CONF:7419).
        - a. This `code` **SHOULD** contain zero or one [0..1] `originalText` (CONF:7424).
          - i. The `originalText`, if present, **SHOULD** contain zero or one [0..1] `reference` (CONF:7425).

1. The reference, if present, **SHOULD** contain zero or one [0..1] **@value** (CONF:15952).
  1. This reference/**@value** **SHALL** begin with a '#' and **SHALL** point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:15953).
  - b. This code **MAY** contain zero or more [0..\*] **translation** (CONF:7431).
  - c. In an allergy to a specific medication the code **SHALL** be selected from the ValueSet
    - 2.16.840.1.113883.3.88.12.80.16 Medication Brand Name **DYNAMIC** or the ValueSet
    - 2.16.840.1.113883.3.88.12.80.17 Medication Clinical Drug **DYNAMIC** (CONF:7421).
  - d. In an allergy to a class of medications the code **SHALL** be selected from the ValueSet
    - 2.16.840.1.113883.3.88.12.80.18 Medication Drug Class **DYNAMIC** (CONF:10083).
  - e. In an allergy to a food or other substance the code **SHALL** be selected from the ValueSet
    - 2.16.840.1.113883.3.88.12.80.20 Ingredient Name **DYNAMIC** (CONF:10084).
11. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:7440) such that it
  - a. **SHALL** contain exactly one [1..1] **@typeCode="SUBJ"** Has subject (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**) (CONF:7906).
  - b. **SHALL** contain exactly one [1..1] **@inversionInd="true"** True (CONF:7446).
  - c. **SHALL** contain exactly one [1..1] **Allergy Status Observation** (templateId:2.16.840.1.113883.10.20.22.4.28) (CONF:15954).
12. **SHOULD** contain zero or more [0..\*] **entryRelationship** (CONF:7447) such that it
  - a. **SHALL** contain exactly one [1..1] **@typeCode="MFST"** Is Manifestation of (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**) (CONF:7907).
  - b. **SHALL** contain exactly one [1..1] **@inversionInd="true"** True (CONF:7449).
  - c. **SHALL** contain exactly one [1..1] **Reaction Observation** (templateId:2.16.840.1.113883.10.20.22.4.9) (CONF:15955).
13. **SHOULD** contain zero or one [0..1] **entryRelationship** (CONF:9961) such that it
  - a. **SHALL** contain exactly one [1..1] **@typeCode="SUBJ"** Has Subject (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 **STATIC**) (CONF:9962).
  - b. **SHALL** contain exactly one [1..1] **@inversionInd="true"** True (CONF:9964).
  - c. **SHALL** contain exactly one [1..1] **Severity Observation** (templateId:2.16.840.1.113883.10.20.22.4.8) (CONF:15956).

**Figure 124: Allergy - Intolerance Observation example**

```

<observation classCode="OBS" moodCode="EVN">
 <!-- allergy observation template -->
 <templateId root="2.16.840.1.113883.10.20.22.4.7"/>
 <id root="4adc1020-7b14-11db-9fe1-0800200c9a66"/>
 <code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"/>
 <statusCode code="completed"/>
 <effectiveTime>
 <low value="20060501"/>
 </effectiveTime>
 <value xsi:type="CD"
 code="419511003"
 displayName="Propensity to adverse reactions to drug"
 codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT">
 <originalText>
 <reference value="#reaction2"/>
 </originalText>
 </value>
 <participant typeCode="CSM">
 <participantRole classCode="MANU">
 <playingEntity classCode="MMAT">
 <code code="763049"
 displayName="Codeine 30mg/ml"
 codeSystem="2.16.840.1.113883.6.88"
 codeSystemName="RxNorm">
 <originalText>
 <reference value="#reaction2"/>
 </originalText>
 </code>
 </playingEntity>
 </participantRole>
 </participant>
</observation>

```

## 4.57 Vital Sign Observation

**[Closed for comments; published July 2012]**

[observation: templateId 2.16.840.1.113883.10.20.22.4.27 (open)]

**Table 273: Vital Sign Observation Contexts**

Used By:	Contains Entries:
<a href="#">Vital Signs Organizer</a> (required)	

Vital signs are represented as are other results, with additional vocabulary constraints.

**Table 274: Vital Sign Observation Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	observation[templateId/@root = '2.16.840.1.113883.10.20.22.4.27']					
	@classCode	1..1	SHALL		<a href="#">7297</a>	2.16.840.1.113883.5.6 (HL7ActClass) = OBS
	@moodCode	1..1	SHALL		<a href="#">7298</a>	2.16.840.1.113883.5.1001 (ActMood) = EVN
	templateId	1..1	SHALL		<a href="#">7299</a>	
	@root	1..1	SHALL		<a href="#">10527</a>	2.16.840.1.113883.10.20.22.4.27
	id	1..*	SHALL		<a href="#">7300</a>	
	code	1..1	SHALL		<a href="#">7301</a>	2.16.840.1.113883.3.88.12.80.62 (Vital Sign Result Value Set)
	text	0..1	SHOULD		<a href="#">7302</a>	
	reference	0..1	SHOULD		<a href="#">15943</a>	
	@value	0..1	SHOULD		<a href="#">15944</a>	
	statusCode	1..1	SHALL		<a href="#">7303</a>	
	@code	1..1	SHALL		<a href="#">19119</a>	2.16.840.1.113883.5.14 (ActStatus) = completed
	effectiveTime	1..1	SHALL		<a href="#">7304</a>	
	value	1..1	SHALL	PQ	<a href="#">7305</a>	
	interpretation Code	0..1	MAY		<a href="#">7307</a>	
	methodCode	0..1	MAY	SET<CE>	<a href="#">7308</a>	
	targetSiteCode	0..1	MAY	SET<CD>	<a href="#">7309</a>	
	author	0..1	MAY		<a href="#">7310</a>	

1. **SHALL** contain exactly one [1..1] @classCode="OBS" Observation (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:7297).
2. **SHALL** contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 **STATIC**) (CONF:7298).
3. **SHALL** contain exactly one [1..1] templateId (CONF:7299) such that it
  - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.27" (CONF:10527).
4. **SHALL** contain at least one [1..\*] id (CONF:7300).
5. **SHALL** contain exactly one [1..1] code, which **SHOULD** be selected from ValueSet Vital Sign Result Value Set 2.16.840.1.113883.3.88.12.80.62 **DYNAMIC** (CONF:7301).
6. **SHOULD** contain zero or one [0..1] text (CONF:7302).
  - a. The text, if present, **SHOULD** contain zero or one [0..1] reference (CONF:15943).

- i. The reference, if present, **SHOULD** contain zero or one [0..1] @value (CONF:15944).
  - 1. This reference/@value **SHALL** begin with a '#' and **SHALL** point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:15945).
- 7. **SHALL** contain exactly one [1..1] **statusCode** (CONF:7303).
  - a. This statusCode **SHALL** contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 **STATIC**) (CONF:19119).
- 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 275: Vital Sign Result Value Set**

Value Set: Vital Sign Result Value Set 2.16.840.1.113883.3.88.12.80.62 DYNAMIC Code System: LOINC 2.16.840.1.113883.6.1		
Code	Code System	Print Name
8310-5	LOINC	Body Temperature
8462-4	LOINC	BP Diastolic
8480-6	LOINC	BP Systolic
8287-5	LOINC	Head Circumference
8867-4	LOINC	Heart Rate
8302-2	LOINC	Height
8306-3	LOINC	Height (Lying)
2710-2	LOINC	O2 % BldC Oximetry
9279-1	LOINC	Respiratory Rate
3141-9	LOINC	Weight Measured

#### 4.57.1 Body Height

[Observation: templateId 2.16.840.1.113883.10.20.30.3.26 (open)]

**Table 276: Body Height Contexts**

Used By:	Contains Entries:
<a href="#">Vital Signs Organizer BCTPS</a> (required)	

This clinical statement represents the the vertical height of an individual.



**Table 277: Body Height Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	Observation[templateId/@root = '2.16.840.1.113883.10.20.30.3.26']					
	@classCode	1..1	SHALL		<a href="#">24107</a>	2.16.840.1.113883.5.6 (HL7ActClass) = OBS
	@moodCode	1..1	SHALL		<a href="#">24108</a>	2.16.840.1.113883.5.1001 (ActMood) = EVN
	templateId	1..1	SHALL		<a href="#">24862</a>	
	@root	1..1	SHALL		<a href="#">24863</a>	2.16.840.1.113883.10.20.30.3.26
	code	1..1	SHALL		<a href="#">24113</a>	
	@code	1..1	SHALL		<a href="#">24114</a>	8302-2
	@codeSystem	1..1	SHALL		<a href="#">24129</a>	2.16.840.1.113883.6.1
	value	1..1	SHALL	PQ	<a href="#">24124</a>	
	@unit	1..1	SHALL		<a href="#">24126</a>	2.16.840.1.113883.11.20.11.18 (Unit Of Body Height)

1. Conforms to [Vital Sign Observation](#) template (2.16.840.1.113883.10.20.22.4.27).
2. **SHALL** contain exactly one [1..1] **@classCode**="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:24107).
3. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:24108).
4. **SHALL** contain exactly one [1..1] **templateId** (CONF:24862) such that it
  - a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.30.3.26" (CONF:24863).
5. **SHALL** contain exactly one [1..1] **code** (CONF:24113).
  - a. This code **SHALL** contain exactly one [1..1] **@code**="8302-2" Body height (CONF:24114).
  - b. This code **SHALL** contain exactly one [1..1] **@codeSystem**="2.16.840.1.113883.6.1" LOINC (CONF:24129).
6. **SHALL** contain exactly one [1..1] **value** with **@xsi:type**="PQ" (CONF:24124).
  - a. This value **SHALL** contain exactly one [1..1] **@unit**, which **SHALL** be selected from ValueSet Unit of Body Height 2.16.840.1.113883.11.20.11.18 **DYNAMIC** (CONF:24126).

**Table 278: Unit of Body Height Value Set**

Value Set: Unit of Body Height 2.16.840.1.113883.11.20.11.18 DYNAMIC		
Code System: UCUM 2.16.840.1.113883.6.8		
Description: Units of body height		
Code	Code System	Print Name
cm	UCUM	cm
[in_i]	UCUM	in

**Figure 125: Body Height example**

```

<observation classCode="OBS" moodCode="EVN">
 <!-- C-CDA VITAL SIGNS OBSERVATION TemplateID-->
 <templateId root="2.16.840.1.113883.10.20.22.4.27"/>
 <!-- Body Height template -->
 <templateId root="2.16.840.1.113883.10.20.30.3.26"/>
 <id root="c6f88321-67ad-11db-bd13-0800200c9a66"/>
 <code code="8302-2"
 codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC" displayName="Height"/>
 <text>
 <reference value="#height1"/>
 </text>
 <statusCode code="completed"/>
 <effectiveTime value="20120407"/>
 <value xsi:type="PQ" value="152.4" unit="cm"/>
 <interpretationCode code="N" codeSystem="2.16.840.1.113883.5.83"/>
</observation>

```

#### 4.57.2 Body Surface Area

[Observation: templateId 2.16.840.1.113883.10.20.30.3.28 (open)]

**Table 279: Body Surface Area Contexts**

Used By:	Contains Entries:
<a href="#">Vital Signs Organizer BCTPS</a> (required)	

This clinical statement represents the calculated numerical quantity that represents the two-dimensional extent of the body surface relating height to weight.

**Table 280: Body Surface Area Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	Observation[templateId/@root = '2.16.840.1.113883.10.20.30.3.28']					
	@classCode	1..1	SHALL		<a href="#">24864</a>	2.16.840.1.113883.5.6 (HL7ActClass) = OBS
	@moodCode	1..1	SHALL		<a href="#">24865</a>	2.16.840.1.113883.5.1001 (ActMood) = EVN
	templateId	1..1	SHALL		<a href="#">24868</a>	
	@root	1..1	SHALL		<a href="#">24869</a>	2.16.840.1.113883.10.20.30.3.28
	code	1..1	SHALL		<a href="#">24872</a>	
	@code	1..1	SHALL		<a href="#">24873</a>	3140-1
	@codeSystem	1..1	SHALL		<a href="#">25999</a>	2.16.840.1.113883.6.1
	value	1..1	SHALL	PQ	<a href="#">24883</a>	
	@unit	1..1	SHALL		<a href="#">24885</a>	2.16.840.1.113883.6.8 (UCUM) = m2

1. Conforms to [Vital Sign Observation](#) template (2.16.840.1.113883.10.20.22.4.27).
2. **SHALL** contain exactly one [1..1] **@classCode**="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:24864).
3. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:24865).
4. **SHALL** contain exactly one [1..1] **templateId** (CONF:24868) such that it
  - a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.30.3.28" (CONF:24869).
5. **SHALL** contain exactly one [1..1] **code** (CONF:24872).
  - a. This code **SHALL** contain exactly one [1..1] **@code**="3140-1" BSA (Body Surface Area) (CONF:24873).
  - b. This code **SHALL** contain exactly one [1..1] **@codeSystem**="2.16.840.1.113883.6.1" LOINC (CONF:25999).
6. **SHALL** contain exactly one [1..1] **value** with **@xsi:type**="PQ" (CONF:24883).
  - a. This value **SHALL** contain exactly one [1..1] **@unit**="m2" (CodeSystem: UCUM 2.16.840.1.113883.6.8 **STATIC**) (CONF:24885).

**Figure 126: Body Surface Area example**

```

<observation classCode="OBS" moodCode="EVN">
 <!-- C-CDA VITAL SIGNS OBSERVATION TemplateID-->
 <templateId root="2.16.840.1.113883.10.20.22.4.27"/>
 <!-- Body Surface Area TemplateID-->
 <templateId root="2.16.840.1.113883.10.20.30.3.28"/>
 <id root="c6f88321-67ad-11db-bd13-0800200c9a66"/>
 <code code="3140-1"
 codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC"
 displayName="BSA (Body Surface Area)"/>
 <text>
 <reference value="#BSA1"/>
 </text>
 <statusCode code="completed"/>
 <effectiveTime value="20120407"/>
 <value xsi:type="PQ" value="1.31" unit="m2"/>
 <interpretationCode code="N" codeSystem="2.16.840.1.113883.5.83"/>
</observation>

```

### 4.57.3 Body Weight

[Observation: templateId 2.16.840.1.113883.10.20.30.3.27 (open)]

**Table 281: Body Weight Contexts**

Used By:	Contains Entries:
<a href="#">Vital Signs Organizer BCTPS</a> (required)	

This clinical statement represents the vertical force exerted by the mass of an individual as a result of gravity.

**Table 282: Body Weight Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	Observation[templateId/@root = '2.16.840.1.113883.10.20.30.3.27']					
	@classCode	1..1	SHALL		<a href="#">23521</a>	2.16.840.1.113883.5.6 (HL7ActClass) = OBS
	@moodCode	1..1	SHALL		<a href="#">23522</a>	2.16.840.1.113883.5.1001 (ActMood) = EVN
	templateId	1..1	SHALL		<a href="#">24860</a>	
	@root	1..1	SHALL		<a href="#">24861</a>	2.16.840.1.113883.10.20.30.3.27
	code	1..1	SHALL		<a href="#">23547</a>	
	@code	1..1	SHALL		<a href="#">23548</a>	3141-9
	@codeSystem	1..1	SHALL		<a href="#">24947</a>	2.16.840.1.113883.6.1
	value	1..1	SHALL	PQ	<a href="#">23558</a>	
	@unit	1..1	SHALL		<a href="#">23560</a>	2.16.840.1.113883.11.20.11.17 (Unit Of Body Weight)

1. Conforms to [Vital Sign Observation](#) template (2.16.840.1.113883.10.20.22.4.27).
2. **SHALL** contain exactly one [1..1] **@classCode**="OBS" (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6) (CONF:23521).
3. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" (CodeSystem: ActMood 2.16.840.1.113883.5.1001) (CONF:23522).
4. **SHALL** contain exactly one [1..1] **templateId** (CONF:24860) such that it
  - a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.20.30.3.27" (CONF:24861).
5. **SHALL** contain exactly one [1..1] **code** (CONF:23547).
  - a. This code **SHALL** contain exactly one [1..1] **@code**="3141-9" Body weight Measured (CONF:23548).
  - b. This code **SHALL** contain exactly one [1..1] **@codeSystem**="2.16.840.1.113883.6.1" LOINC (CONF:24947).
6. **SHALL** contain exactly one [1..1] **value** with **@xsi:type**="PQ" (CONF:23558).
  - a. This value **SHALL** contain exactly one [1..1] **@unit**, which **SHALL** be selected from ValueSet Unit of Body Weight 2.16.840.1.113883.11.20.11.17 **DYNAMIC** (CONF:23560).

**Table 283: Unit Of Body Weight Value Set**

Value Set: Unit of Body Weight 2.16.840.1.113883.11.20.11.17 DYNAMIC		
Code System: UCUM 2.16.840.1.113883.6.8		
Description: Units of mass for body weight		
Code	Code System	Print Name
kg	UCUM	kg
[lb_av]	UCUM	lb

**Figure 127: Body Weight example**

```
<observation classCode="OBS" moodCode="EVN">
 <!-- C-CDA VITAL SIGNS OBSERVATION TemplateID-->
 <templateId root="2.16.840.1.113883.10.20.22.4.27"/>
 <!-- Body weight templateID-->
 <templateId root="2.16.840.1.113883.10.20.30.3.27"/>
 <id root="0dec5daa-7095-41d1-be80-75bd58dff2fb"/>
 <code code="3141-9"
 codeSystem="2.16.840.1.113883.6.1"
 codeSystemName="LOINC"
 displayName="Weight Measured"/>
 <text>
 <reference value="#weight1"/>
 </text>
 <statusCode code="completed"/>
 <effectiveTime value="20120407"/>
 <value xsi:type="PQ" value="45" unit="kg"/>
 <interpretationCode code="N" codeSystem="2.16.840.1.113883.5.83"/>
</observation>
```

## 4.58 Vital Signs Organizer

**[Closed for comments; published July 2012]**

[organizer: templateId 2.16.840.1.113883.10.20.22.4.26 (open)]

**Table 284: Vital Signs Organizer Contexts**

Used By:	Contains Entries:
<a href="#">Vital Signs Section (entries optional)</a> (optional)	<a href="#">Vital Sign Observation</a>

The Vital Signs Organizer groups vital signs, which is similar to the Result Organizer, but with further constraints.

An appropriate nullFlavor can be used when the organizer/code or organizer/id is unknown.

**Table 285: Vital Signs Organizer Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	organizer[templateId/@root = '2.16.840.1.113883.10.20.22.4.26']					
	@classCode	1..1	SHALL		<a href="#">7279</a>	2.16.840.1.113883.5.6 (HL7ActClass) = CLUSTER
	@moodCode	1..1	SHALL		<a href="#">7280</a>	2.16.840.1.113883.5.1001 (ActMood) = EVN
	templateId	1..1	SHALL		<a href="#">7281</a>	
	@root	1..1	SHALL		<a href="#">10528</a>	2.16.840.1.113883.10.20.22.4.26
	id	1..*	SHALL		<a href="#">7282</a>	
	code	1..1	SHALL		<a href="#">19176</a>	
	@code	1..1	SHALL		<a href="#">19177</a>	2.16.840.1.113883.6.96 (SNOMED-CT) = 46680005
	statusCode	1..1	SHALL		<a href="#">7284</a>	
	@code	1..1	SHALL		<a href="#">19120</a>	2.16.840.1.113883.5.14 (ActStatus) = completed
	effectiveTime	1..1	SHALL		<a href="#">7288</a>	
	component	1..*	SHALL		<a href="#">7285</a>	
	observation	1..1	SHALL		<a href="#">15946</a>	

1. **SHALL** contain exactly one [1..1] @classCode="CLUSTER" CLUSTER (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:7279).
2. **SHALL** contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 **STATIC**) (CONF:7280).
3. **SHALL** contain exactly one [1..1] templateId (CONF:7281) such that it
  - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.22.4.26" (CONF:10528).
4. **SHALL** contain at least one [1..\*] id (CONF:7282).
5. **SHALL** contain exactly one [1..1] code (CONF:19176).
  - a. This code **SHALL** contain exactly one [1..1] @code="46680005" Vital signs (CodeSystem: SNOMED-CT 2.16.840.1.113883.6.96 **STATIC**) (CONF:19177).
6. **SHALL** contain exactly one [1..1] statusCode (CONF:7284).
  - a. This statusCode **SHALL** contain exactly one [1..1] @code="completed" Completed (CodeSystem: ActStatus 2.16.840.1.113883.5.14 **STATIC**) (CONF:19120).

The effectiveTime represents clinically effective time of the measurement, which is most likely when the measurement was performed (e.g., a BP measurement).

7. **SHALL** contain exactly one [1..1] effectiveTime (CONF:7288).
8. **SHALL** contain at least one [1..\*] component (CONF:7285) such that it
  - a. **SHALL** contain exactly one [1..1] [Vital Sign Observation](#) (templateId:2.16.840.1.113883.10.20.22.4.27) (CONF:15946).

#### 4.58.1 Vital Signs Organizer BCTPS

[organizer: templateId 2.16.840.1.113883.10.20.30.3.25 (open)]

**Table 286: Vital Signs Organizer BCTPS Contexts**

Used By:	Contains Entries:
<a href="#">Vital Signs Section BCTPS</a> (required)	<a href="#">Body Height</a> <a href="#">Body Surface Area</a> <a href="#">Body Weight</a>

This clinical statement represents a vital signs organizer that conforms to the C-CDA Vital Signs Organizer; this is required with vital signs observation entries. This vital signs organizer contains height, weight, and body surface area entries.

**Table 287: Vital Signs Organizer BCTPS Constraints Overview**

Name	XPath	Card.	Verb	Data Type	CONF#	Fixed Value
	organizer[templateId/@root = '2.16.840.1.113883.10.20.30.3.25']					
	@classCode	1..1	SHALL		<a href="#">24889</a>	2.16.840.1.113883.5.6 (HL7ActClass) = CLUSTER
	@moodCode	1..1	SHALL		<a href="#">24890</a>	2.16.840.1.113883.5.1001 (ActMood) = EVN
	templateId	1..1	SHALL		<a href="#">24893</a>	
	@root	1..1	SHALL		<a href="#">24894</a>	2.16.840.1.113883.10.20.30.3.25
	code	1..1	SHALL		<a href="#">24896</a>	
	@code	1..1	SHALL		<a href="#">24897</a>	46680005
	@codeSystem	1..1	SHALL		<a href="#">26000</a>	2.16.840.1.113883.6.96
	component	1..1	SHALL		<a href="#">24901</a>	
	observation	1..1	SHALL		<a href="#">24902</a>	
	component	1..1	SHALL		<a href="#">24903</a>	
	observation	1..1	SHALL		<a href="#">24904</a>	
	component	1..1	SHALL		<a href="#">24905</a>	
	observation	1..1	SHALL		<a href="#">26001</a>	

1. Conforms to [Vital Signs Organizer](#) template (2.16.840.1.113883.10.20.22.4.26).
2. **SHALL** contain exactly one [1..1] @classCode="CLUSTER" CLUSTER (CodeSystem: HL7ActClass 2.16.840.1.113883.5.6 **STATIC**) (CONF:24889).
3. **SHALL** contain exactly one [1..1] @moodCode="EVN" Event (CodeSystem: ActMood 2.16.840.1.113883.5.1001 **STATIC**) (CONF:24890).
4. **SHALL** contain exactly one [1..1] templateId (CONF:24893) such that it
  - a. **SHALL** contain exactly one [1..1] @root="2.16.840.1.113883.10.20.30.3.25" (CONF:24894).



5. **SHALL** contain exactly one [1..1] **code** (CONF:24896).
  - a. This code **SHALL** contain exactly one [1..1] @code="46680005" vital signs (CONF:24897).
  - b. This code **SHALL** contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.96" SNOMED CT (CONF:26000).
6. **SHALL** contain exactly one [1..1] **component** (CONF:24901) such that it
  - a. **SHALL** contain exactly one [1..1] Body Height (templateId:2.16.840.1.113883.10.20.30.3.26) (CONF:24902).
7. **SHALL** contain exactly one [1..1] **component** (CONF:24903) such that it
  - a. **SHALL** contain exactly one [1..1] Body Weight (templateId:2.16.840.1.113883.10.20.30.3.27) (CONF:24904).
8. **SHALL** contain exactly one [1..1] **component** (CONF:24905) such that it
  - a. **SHALL** contain exactly one [1..1] Body Surface Area (templateId:2.16.840.1.113883.10.20.30.3.28) (CONF:26001).

**Figure 128: Vital Signs Organizer BCTPS example**

```

<entry typeCode="DRIV">
 <organizer classCode="CLUSTER" moodCode="EVN">
 <!-- C-CDA VITAL SIGNS ORGANIZER TemplateID -->
 <templateId root="2.16.840.1.113883.10.20.22.4.26"/>
 <!-- Vital Signs Organizer BCTPS templateID-->
 <templateId root="2.16.840.1.113883.10.20.30.3.25"/>
 <id root="16f81685-cb5b-470b-9823-fca324968479"/>
 <code code="46680005"
 codeSystem="2.16.840.1.113883.6.96"
 displayName="Vital Signs"
 codeSystemName="SNOMED CT">
 <originalText>Vital Signs</originalText>
 </code>
 <statusCode code="completed"/>
 <effectiveTime value="20120407"/>

 <component>
 <!-- BODY HEIGHT -->
 <observation classCode="OBS" moodCode="EVN">
 <!-- C-CDA VITAL SIGNS OBSERVATION TemplateID-->
 <templateId root="2.16.840.1.113883.10.20.22.4.27"/>
 <!-- Body Height template -->
 <templateId root="2.16.840.1.113883.10.20.30.3.26"/>
 ...
 </observation>
 </component>
 </organizer>
</entry>

```

```
<component>
 <!-- BODY WEIGHT -->
 <observation classCode="OBS" moodCode="EVN">
 <!-- C-CDA VITAL SIGNS OBSERVATION TemplateID-->
 <templateId root="2.16.840.1.113883.10.20.22.4.27"/>
 <!-- Body weight templateID-->
 <templateId root="2.16.840.1.113883.10.20.30.3.27"/>
 ...
 </observation>
</component>

<component>
 <!-- BODY SURFACE AREA -->
 <observation classCode="OBS" moodCode="EVN">
 <!-- C-CDA VITAL SIGNS OBSERVATION TemplateID-->
 <templateId root="2.16.840.1.113883.10.20.22.4.27"/>
 <!-- Body Surface Area TemplateID-->
 <templateId root="2.16.840.1.113883.10.20.30.3.28"/>
 ...
 </observation>
</component>
</organizer>
</entry>
```

## 5 REFERENCES

- *HL7 Clinical Document Architecture (CDA Release 2)*.  
<http://www.hl7.org/implement/standards/cda.cfm>
- *HL7 Clinical Document Architecture (CDA) Implementation Guide for Ambulatory Healthcare Provider Reporting to Central Cancer Registries*, Release 1, August 2012.  
[http://www.cdc.gov/phn/library/guides/Implementation\\_Guide\\_for\\_Ambulatory\\_Healthcare\\_Provider\\_Reporting\\_to\\_Central\\_Cancer\\_Registries\\_August\\_2012.pdf](http://www.cdc.gov/phn/library/guides/Implementation_Guide_for_Ambulatory_Healthcare_Provider_Reporting_to_Central_Cancer_Registries_August_2012.pdf)
- *HL7 Clinical Genomics Work Group The Family History Standard – Implementation Guide (US Realm)* December 2012.  
[http://www.hl7.org/implement/standards/product\\_brief.cfm?product\\_id=8](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=8)  
(must be an HL7 member)
- *HL7 Version 3 Interoperability Standards, Normative Edition 2010*.  
<http://www.hl7.org/memonly/downloads/v3edition.cfm> (must be an HL7 member)
- *HL7 Version 3 Publishing Facilitator's Guide*  
<http://www.hl7.org/v3ballot/html/help/pfg/pfg.htm>
- *HL7 Implementation Guide for CDA R2: Quality Reporting Document Architecture, DSTU Release 2 (QRDA)*.  
[http://www.hl7.org/implement/standards/product\\_brief.cfm?product\\_id=35](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=35)

## Appendix A — ACRONYMS AND ABBREVIATIONS

AJCC	American Joint Committee on Cancer
BCTPS	Breast Cancer Treatment Plan Summary
CCR	Continuity of Care Record
C-CDA	<i>HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, Release 1.1 - US Realm (Consolidated CDA)</i>
CDA	Clinical Document Architecture
CDC	Centers for Disease Control and Prevention
CRS	Care Record Summary
DSTU	Draft Standard for Trial Use
EHR	Electronic Health Record
EMR	Electronic Medical Record
HER2	Human Epidermal Growth Factor
HL7	Health Level Seven
IG	Implementation Guide
LOINC	Logical Observation Identifiers Names and Codes
MAR	Medication Administration Record
NHSN	National Healthcare Safety Network
OID	Object identifier
PHIN VADS	Public Health Information Network Vocabulary Access and Distribution System
PHQ	Patient Health Questionnaire
QOPI	Quality Oncology Practice Initiative
QRDA	Quality Reporting Document Architecture
R2	Release 2
RIM	Reference Information Model
RMIM	Refined Message Information Model
SDWG	Structured Documents Working Group
SNOMED CT	Systematized Nomenclature of Medicine, Clinical Terms
TNM	Tumor Nodal Metastasis
UDI	Unique Device Identification
VIS	Vaccine Information Statement
XML	Extensible Mark-up Language

## Appendix B — TEMPLATE IDS USED IN THIS GUIDE

This appendix lists all `templateIds` used in this guide in [alphabetical order](#) and in [containment order](#).

**Table 288: Template List in Alphabetical Order by Type**

Template Title	Template Type	templateId
<a href="#">Clinical Oncology Treatment Plan and Summary</a>	document	2.16.840.1.113883.10.20.30.1.1
<a href="#">US Realm Header</a>	document	2.16.840.1.113883.10.20.22.1.1
<a href="#">Allergies Section (entries optional)</a>	section	2.16.840.1.113883.10.20.22.2.6
<a href="#">Encounters Section (entries optional)</a>	section	2.16.840.1.113883.10.20.22.2.22
<a href="#">Encounters Section BCTPS</a>	section	2.16.840.1.113883.10.20.30.2.9
<a href="#">Family History Section</a>	section	2.16.840.1.113883.10.20.22.2.15
<a href="#">Family History Section BCTPS</a>	section	2.16.840.1.113883.10.20.30.2.3
<a href="#">Functional Status Section</a>	section	2.16.840.1.113883.10.20.22.2.14
<a href="#">Functional Status Section BCTPS</a>	section	2.16.840.1.113883.10.20.30.2.8
<a href="#">Medications Section (entries optional)</a>	section	2.16.840.1.113883.10.20.22.2.1
<a href="#">Medications Section BCTPS</a>	section	2.16.840.1.113883.10.20.30.2.7
<a href="#">Plan of Care Section</a>	section	2.16.840.1.113883.10.20.22.2.10
<a href="#">Plan of Care Section BCTPS</a>	section	2.16.840.1.113883.10.20.30.2.6
<a href="#">Problem Section (entries optional)</a>	section	2.16.840.1.113883.10.20.22.2.5
<a href="#">Problem Section BCTPS</a>	section	2.16.840.1.113883.10.20.30.2.1
<a href="#">Procedures Section (entries optional)</a>	section	2.16.840.1.113883.10.20.22.2.7
<a href="#">Procedures Section BCTPS</a>	section	2.16.840.1.113883.10.20.30.2.4
<a href="#">Results Section (entries optional)</a>	section	2.16.840.1.113883.10.20.22.2.3
<a href="#">Results Section BCTPS</a>	section	2.16.840.1.113883.10.20.30.2.2
<a href="#">Vital Signs Section (entries optional)</a>	section	2.16.840.1.113883.10.20.22.2.4
<a href="#">Vital Signs Section BCTPS</a>	section	2.16.840.1.113883.10.20.30.2.5
<a href="#">Age Observation</a>	entry	2.16.840.1.113883.10.20.22.4.31
<a href="#">Allergy - Intolerance Observation</a>	entry	2.16.840.1.113883.10.20.22.4.7
<a href="#">Allergy Problem Act</a>	entry	2.16.840.1.113883.10.20.22.4.30
<a href="#">Allergy Status Observation</a>	entry	2.16.840.1.113883.10.20.22.4.28
<a href="#">Anthracyclines Lifetime Dose</a>	entry	2.16.840.1.113883.10.20.30.3.24
<a href="#">Assessment Scale Observation</a>	entry	2.16.840.1.113883.10.20.22.4.69
<a href="#">Assessment Scale Supporting Observation</a>	entry	2.16.840.1.113883.10.20.22.4.86
<a href="#">Body Height</a>	entry	2.16.840.1.113883.10.20.30.3.26
<a href="#">Body Surface Area</a>	entry	2.16.840.1.113883.10.20.30.3.28
<a href="#">Body Weight</a>	entry	2.16.840.1.113883.10.20.30.3.27
<a href="#">Breast Cancer Concern Act</a>	entry	2.16.840.1.113883.10.20.30.3.6

<b>Template Title</b>	<b>Template Type</b>	<b>templateId</b>
<a href="#">Breast Cancer Diagnosis Observation</a>	entry	2.16.840.1.113883.10.20.30.3.2
<a href="#">Breast Cancer Procedures</a>	entry	2.16.840.1.113883.10.20.30.3.12
<a href="#">Breast TNM Clinical Category</a>	entry	2.16.840.1.113883.10.20.30.3.3
<a href="#">Breast TNM Metastasis Category</a>	entry	2.16.840.1.113883.10.20.30.3.8
<a href="#">Breast TNM Node Category</a>	entry	2.16.840.1.113883.10.20.30.3.7
<a href="#">Breast TNM Tumor Category</a>	entry	2.16.840.1.113883.10.20.30.3.5
<a href="#">Cardiac Function Observation</a>	entry	2.16.840.1.113883.10.20.30.3.21
<a href="#">Caregiver Characteristics</a>	entry	2.16.840.1.113883.10.20.22.4.72
<a href="#">Chemotherapeutic Drug Therapy Discontinued</a>	entry	2.16.840.1.113883.10.20.30.3.43
<a href="#">Chemotherapy Medication Activity</a>	entry	2.16.840.1.113883.10.20.30.3.44
<a href="#">Chemotherapy Medication Activity Plan</a>	entry	2.16.840.1.113883.10.20.30.3.51
<a href="#">Chemotherapy Protocol Reference</a>	entry	2.16.840.1.113883.10.20.30.3.50
<a href="#">Chemotherapy Regimen Plans</a>	entry	2.16.840.1.113883.10.20.30.3.30
<a href="#">Clinical Drug Trial</a>	entry	2.16.840.1.113883.10.20.30.3.4
<a href="#">Cognitive Status Problem Observation</a>	entry	2.16.840.1.113883.10.20.22.4.73
<a href="#">Cognitive Status Result Observation</a>	entry	2.16.840.1.113883.10.20.22.4.74
<a href="#">Cognitive Status Result Organizer</a>	entry	2.16.840.1.113883.10.20.22.4.75
<a href="#">Drug Vehicle</a>	entry	2.16.840.1.113883.10.20.22.4.24
<a href="#">Encounter Activities</a>	entry	2.16.840.1.113883.10.20.22.4.49
<a href="#">Encounter Diagnosis</a>	entry	2.16.840.1.113883.10.20.22.4.80
<a href="#">Estrogen Receptor Status</a>	entry	2.16.840.1.113883.10.20.30.3.19
<a href="#">Family History Death Observation</a>	entry	2.16.840.1.113883.10.20.22.4.47
<a href="#">Family History Observation</a>	entry	2.16.840.1.113883.10.20.22.4.46
<a href="#">Family History of Cancer None</a>	entry	2.16.840.1.113883.10.20.30.3.11
<a href="#">Family History Organizer</a>	entry	2.16.840.1.113883.10.20.22.4.45
<a href="#">Family History Pedigree</a>	entry	2.16.840.1.113883.10.20.30.3.48
<a href="#">Functional Status Problem Observation</a>	entry	2.16.840.1.113883.10.20.22.4.68
<a href="#">Functional Status Result Observation</a>	entry	2.16.840.1.113883.10.20.22.4.67
<a href="#">Functional Status Result Organizer</a>	entry	2.16.840.1.113883.10.20.22.4.66
<a href="#">Health Status Observation</a>	entry	2.16.840.1.113883.10.20.22.4.5
<a href="#">HER2 Receptor Status</a>	entry	2.16.840.1.113883.10.20.30.3.38
<a href="#">Highest Pressure Ulcer Stage</a>	entry	2.16.840.1.113883.10.20.22.4.77
<a href="#">Hospitalization for Toxicity</a>	entry	2.16.840.1.113883.10.20.30.3.36
<a href="#">Immunization Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.54
<a href="#">Indication</a>	entry	2.16.840.1.113883.10.20.22.4.19
<a href="#">Instructions</a>	entry	2.16.840.1.113883.10.20.22.4.20
<a href="#">Last Menstrual Period</a>	entry	2.16.840.1.113883.10.20.30.3.34
<a href="#">Lymph Node Sampling Result Organizer</a>	entry	2.16.840.1.113883.10.20.30.3.13

<b>Template Title</b>	<b>Template Type</b>	<b>templateId</b>
<a href="#">Medication Activity</a>	entry	2.16.840.1.113883.10.20.22.4.16
<a href="#">Medication Dispense</a>	entry	2.16.840.1.113883.10.20.22.4.18
<a href="#">Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.23
<a href="#">Medication Supply Order</a>	entry	2.16.840.1.113883.10.20.22.4.17
<a href="#">Molecular Diagnostic Testing Organizer</a>	entry	2.16.840.1.113883.10.20.30.3.49
<a href="#">Neurotoxicity Impairment of ADLs</a>	entry	2.16.840.1.113883.10.20.30.3.37
<a href="#">Non-Medicinal Supply Activity</a>	entry	2.16.840.1.113883.10.20.22.4.50
<a href="#">Number of Lymph Nodes Positive</a>	entry	2.16.840.1.113883.10.20.30.3.15
<a href="#">Number of Lymph Nodes Removed and Examined</a>	entry	2.16.840.1.113883.10.20.30.3.14
<a href="#">Number of Pressure Ulcers Observation</a>	entry	2.16.840.1.113883.10.20.22.4.76
<a href="#">Oncotype DX Score</a>	entry	2.16.840.1.113883.10.20.30.3.18
<a href="#">Plan of Care Activity Act</a>	entry	2.16.840.1.113883.10.20.22.4.39
<a href="#">Plan of Care Activity Encounter</a>	entry	2.16.840.1.113883.10.20.22.4.40
<a href="#">Plan of Care Activity Observation</a>	entry	2.16.840.1.113883.10.20.22.4.44
<a href="#">Plan of Care Activity Procedure</a>	entry	2.16.840.1.113883.10.20.22.4.41
<a href="#">Plan of Care Activity Reconstruction Procedure</a>	entry	2.16.840.1.113883.10.20.30.3.31
<a href="#">Plan of Care Activity Substance Administration</a>	entry	2.16.840.1.113883.10.20.22.4.42
<a href="#">Plan of Care Activity Supply</a>	entry	2.16.840.1.113883.10.20.22.4.43
<a href="#">Plan of Care Radiation Activity</a>	entry	2.16.840.1.113883.10.20.30.3.32
<a href="#">Possible Side Effects</a>	entry	2.16.840.1.113883.10.20.30.3.35
<a href="#">Post Treatment Disease Status</a>	entry	2.16.840.1.113883.10.20.30.3.29
<a href="#">Precondition for Substance Administration</a>	entry	2.16.840.1.113883.10.20.22.4.25
<a href="#">Pressure Ulcer Observation</a>	entry	2.16.840.1.113883.10.20.22.4.70
<a href="#">Problem Concern Act (Condition)</a>	entry	2.16.840.1.113883.10.20.22.4.3
<a href="#">Problem Observation</a>	entry	2.16.840.1.113883.10.20.22.4.4
<a href="#">Problem Status</a>	entry	2.16.840.1.113883.10.20.22.4.6
<a href="#">Procedure Activity Act</a>	entry	2.16.840.1.113883.10.20.22.4.12
<a href="#">Procedure Activity Observation</a>	entry	2.16.840.1.113883.10.20.22.4.13
<a href="#">Procedure Activity Procedure</a>	entry	2.16.840.1.113883.10.20.22.4.14
<a href="#">Product Instance</a>	entry	2.16.840.1.113883.10.20.22.4.37
<a href="#">Progesterone Receptor Status</a>	entry	2.16.840.1.113883.10.20.30.3.20
<a href="#">Radiation Therapy Care Completed</a>	entry	2.16.840.1.113883.10.20.30.3.16
<a href="#">Reaction Observation</a>	entry	2.16.840.1.113883.10.20.22.4.9
<a href="#">Receptor Status Organizer</a>	entry	2.16.840.1.113883.10.20.30.3.17
<a href="#">Result Observation</a>	entry	2.16.840.1.113883.10.20.22.4.2
<a href="#">Result Organizer</a>	entry	2.16.840.1.113883.10.20.22.4.1

Template Title	Template Type	templateId
<a href="#">Service Delivery Location</a>	entry	2.16.840.1.113883.10.20.22.4.32
<a href="#">Severity Observation</a>	entry	2.16.840.1.113883.10.20.22.4.8
<a href="#">Substance or Device Allergy - Intolerance Observation</a>	entry	2.16.840.1.113883.10.20.24.3.90
<a href="#">Therapy Side Effects</a>	entry	2.16.840.1.113883.10.20.30.3.42
<a href="#">Vital Sign Observation</a>	entry	2.16.840.1.113883.10.20.22.4.27
<a href="#">Vital Signs Organizer</a>	entry	2.16.840.1.113883.10.20.22.4.26
<a href="#">Vital Signs Organizer BCTPS</a>	entry	2.16.840.1.113883.10.20.30.3.25

**Table 289: Template List by Containments**

Template Title	Template Type	templateId
<a href="#">US Realm Header</a>	document	2.16.840.1.113883.10.20.22.1.1
<a href="#">Clinical Oncology Treatment Plan and Summary</a>	document	2.16.840.1.113883.10.20.30.1.1
<a href="#">Allergies Section (entries optional)</a>	section	2.16.840.1.113883.10.20.22.2.6
<a href="#">Allergy Problem Act</a>	entry	2.16.840.1.113883.10.20.22.4.30
<a href="#">Allergy - Intolerance Observation</a>	entry	2.16.840.1.113883.10.20.22.4.7
<a href="#">Allergy Status Observation</a>	entry	2.16.840.1.113883.10.20.22.4.28
<a href="#">Reaction Observation</a>	entry	2.16.840.1.113883.10.20.22.4.9
<a href="#">Medication Activity</a>	entry	2.16.840.1.113883.10.20.22.4.16
<a href="#">Drug Vehicle</a>	entry	2.16.840.1.113883.10.20.22.4.24
<a href="#">Indication</a>	entry	2.16.840.1.113883.10.20.22.4.19
<a href="#">Instructions</a>	entry	2.16.840.1.113883.10.20.22.4.20
<a href="#">Medication Dispense</a>	entry	2.16.840.1.113883.10.20.22.4.18
<a href="#">Immunization Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.54
<a href="#">Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.23
<a href="#">Medication Supply Order</a>	entry	2.16.840.1.113883.10.20.22.4.17
<a href="#">Immunization Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.54
<a href="#">Instructions</a>	entry	2.16.840.1.113883.10.20.22.4.20
<a href="#">Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.23
<a href="#">Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.23
<a href="#">Medication Supply Order</a>	entry	2.16.840.1.113883.10.20.22.4.17
<a href="#">Immunization Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.54
<a href="#">Instructions</a>	entry	2.16.840.1.113883.10.20.22.4.20
<a href="#">Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.23



<b>Template Title</b>	<b>Template Type</b>	<b>templateId</b>
<a href="#">Precondition for Substance Administration</a>	entry	2.16.840.1.113883.10.20.22.4.25
<a href="#">Procedure Activity Procedure</a>	entry	2.16.840.1.113883.10.20.22.4.14
<a href="#">Indication</a>	entry	2.16.840.1.113883.10.20.22.4.19
<a href="#">Instructions</a>	entry	2.16.840.1.113883.10.20.22.4.20
<a href="#">Medication Activity</a>	entry	2.16.840.1.113883.10.20.22.4.16
<a href="#">Drug Vehicle</a>	entry	2.16.840.1.113883.10.20.22.4.24
<a href="#">Indication</a>	entry	2.16.840.1.113883.10.20.22.4.19
<a href="#">Instructions</a>	entry	2.16.840.1.113883.10.20.22.4.20
<a href="#">Medication Dispense</a>	entry	2.16.840.1.113883.10.20.22.4.18
<a href="#">Immunization Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.54
<a href="#">Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.23
<a href="#">Medication Supply Order</a>	entry	2.16.840.1.113883.10.20.22.4.17
<a href="#">Immunization Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.54
<a href="#">Instructions</a>	entry	2.16.840.1.113883.10.20.22.4.20
<a href="#">Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.23
<a href="#">Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.23
<a href="#">Medication Supply Order</a>	entry	2.16.840.1.113883.10.20.22.4.17
<a href="#">Immunization Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.54
<a href="#">Instructions</a>	entry	2.16.840.1.113883.10.20.22.4.20
<a href="#">Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.23
<a href="#">Precondition for Substance Administration</a>	entry	2.16.840.1.113883.10.20.22.4.25
<a href="#">Product Instance</a>	entry	2.16.840.1.113883.10.20.22.4.37
<a href="#">Service Delivery Location</a>	entry	2.16.840.1.113883.10.20.22.4.32
<a href="#">Severity Observation</a>	entry	2.16.840.1.113883.10.20.22.4.8
<a href="#">Severity Observation</a>	entry	2.16.840.1.113883.10.20.22.4.8
<a href="#">Encounters Section BCTPS</a>	section	2.16.840.1.113883.10.20.30.2.9
<a href="#">Hospitalization for Toxicity</a>	entry	2.16.840.1.113883.10.20.30.3.36
<a href="#">Indication</a>	entry	2.16.840.1.113883.10.20.22.4.19
<a href="#">Family History Section BCTPS</a>	section	2.16.840.1.113883.10.20.30.2.3
<a href="#">Family History of Cancer None</a>	entry	2.16.840.1.113883.10.20.30.3.11
<a href="#">Family History Organizer</a>	entry	2.16.840.1.113883.10.20.22.4.45
<a href="#">Family History Observation</a>	entry	2.16.840.1.113883.10.20.22.4.46
<a href="#">Age Observation</a>	entry	2.16.840.1.113883.10.20.22.4.31
<a href="#">Family History Death Observation</a>	entry	2.16.840.1.113883.10.20.22.4.47
<a href="#">Family History Pedigree</a>	entry	2.16.840.1.113883.10.20.30.3.48

<b>Template Title</b>	<b>Template Type</b>	<b>templateId</b>
<a href="#">Functional Status Section BCTPS</a>	section	2.16.840.1.113883.10.20.30.2.8
<a href="#">Neurotoxicity Impairment of ADLs</a>	entry	2.16.840.1.113883.10.20.30.3.37
<a href="#">Medications Section BCTPS</a>	section	2.16.840.1.113883.10.20.30.2.7
<a href="#">Anthracyclines Lifetime Dose</a>	entry	2.16.840.1.113883.10.20.30.3.24
<a href="#">Chemotherapeutic Drug Therapy Discontinued</a>	entry	2.16.840.1.113883.10.20.30.3.43
<a href="#">Chemotherapy Medication Activity</a>	entry	2.16.840.1.113883.10.20.30.3.44
<a href="#">Chemotherapy Protocol Reference</a>	entry	2.16.840.1.113883.10.20.30.3.50
<a href="#">Clinical Drug Trial</a>	entry	2.16.840.1.113883.10.20.30.3.4
<a href="#">Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.23
<a href="#">Reaction Observation</a>	entry	2.16.840.1.113883.10.20.22.4.9
<a href="#">Medication Activity</a>	entry	2.16.840.1.113883.10.20.22.4.16
<a href="#">Drug Vehicle</a>	entry	2.16.840.1.113883.10.20.22.4.24
<a href="#">Indication</a>	entry	2.16.840.1.113883.10.20.22.4.19
<a href="#">Instructions</a>	entry	2.16.840.1.113883.10.20.22.4.20
<a href="#">Medication Dispense</a>	entry	2.16.840.1.113883.10.20.22.4.18
<a href="#">Immunization Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.54
<a href="#">Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.23
<a href="#">Medication Supply Order</a>	entry	2.16.840.1.113883.10.20.22.4.17
<a href="#">Immunization Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.54
<a href="#">Instructions</a>	entry	2.16.840.1.113883.10.20.22.4.20
<a href="#">Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.23
<a href="#">Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.23
<a href="#">Medication Supply Order</a>	entry	2.16.840.1.113883.10.20.22.4.17
<a href="#">Immunization Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.54
<a href="#">Instructions</a>	entry	2.16.840.1.113883.10.20.22.4.20
<a href="#">Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.23
<a href="#">Precondition for Substance Administration</a>	entry	2.16.840.1.113883.10.20.22.4.25
<a href="#">Procedure Activity Procedure</a>	entry	2.16.840.1.113883.10.20.22.4.14
<a href="#">Indication</a>	entry	2.16.840.1.113883.10.20.22.4.19
<a href="#">Instructions</a>	entry	2.16.840.1.113883.10.20.22.4.20
<a href="#">Medication Activity</a>	entry	2.16.840.1.113883.10.20.22.4.16
<a href="#">Drug Vehicle</a>	entry	2.16.840.1.113883.10.20.22.4.24
<a href="#">Indication</a>	entry	2.16.840.1.113883.10.20.22.4.19
<a href="#">Instructions</a>	entry	2.16.840.1.113883.10.20.22.4.20
<a href="#">Medication Dispense</a>	entry	2.16.840.1.113883.10.20.22.4.18

<b>Template Title</b>	<b>Template Type</b>	<b>templateId</b>
<a href="#">Immunization Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.54
<a href="#">Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.23
<a href="#">Medication Supply Order</a>	entry	2.16.840.1.113883.10.20.22.4.17
<a href="#">Immunization Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.54
<a href="#">Instructions</a>	entry	2.16.840.1.113883.10.20.22.4.20
<a href="#">Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.23
<a href="#">Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.23
<a href="#">Medication Supply Order</a>	entry	2.16.840.1.113883.10.20.22.4.17
<a href="#">Immunization Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.54
<a href="#">Instructions</a>	entry	2.16.840.1.113883.10.20.22.4.20
<a href="#">Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.23
<a href="#">Precondition for Substance Administration</a>	entry	2.16.840.1.113883.10.20.22.4.25
<a href="#">Product Instance</a>	entry	2.16.840.1.113883.10.20.22.4.37
<a href="#">Service Delivery Location</a>	entry	2.16.840.1.113883.10.20.22.4.32
<a href="#">Severity Observation</a>	entry	2.16.840.1.113883.10.20.22.4.8
<a href="#">Medication Activity</a>	entry	2.16.840.1.113883.10.20.22.4.16
<a href="#">Drug Vehicle</a>	entry	2.16.840.1.113883.10.20.22.4.24
<a href="#">Indication</a>	entry	2.16.840.1.113883.10.20.22.4.19
<a href="#">Instructions</a>	entry	2.16.840.1.113883.10.20.22.4.20
<a href="#">Medication Dispense</a>	entry	2.16.840.1.113883.10.20.22.4.18
<a href="#">Immunization Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.54
<a href="#">Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.23
<a href="#">Medication Supply Order</a>	entry	2.16.840.1.113883.10.20.22.4.17
<a href="#">Immunization Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.54
<a href="#">Instructions</a>	entry	2.16.840.1.113883.10.20.22.4.20
<a href="#">Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.23
<a href="#">Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.23
<a href="#">Medication Supply Order</a>	entry	2.16.840.1.113883.10.20.22.4.17
<a href="#">Immunization Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.54
<a href="#">Instructions</a>	entry	2.16.840.1.113883.10.20.22.4.20
<a href="#">Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.23
<a href="#">Precondition for Substance Administration</a>	entry	2.16.840.1.113883.10.20.22.4.25
<a href="#">Reaction Observation</a>	entry	2.16.840.1.113883.10.20.22.4.9

<b>Template Title</b>	<b>Template Type</b>	<b>templateId</b>
<a href="#">Procedure Activity Procedure</a>	entry	2.16.840.1.113883.10.20.22.4.14
<a href="#">Indication</a>	entry	2.16.840.1.113883.10.20.22.4.19
<a href="#">Instructions</a>	entry	2.16.840.1.113883.10.20.22.4.20
<a href="#">Product Instance</a>	entry	2.16.840.1.113883.10.20.22.4.37
<a href="#">Service Delivery Location</a>	entry	2.16.840.1.113883.10.20.22.4.32
<a href="#">Severity Observation</a>	entry	2.16.840.1.113883.10.20.22.4.8
<a href="#">Plan of Care Section BCTPS</a>	section	2.16.840.1.113883.10.20.30.2.6
<a href="#">Chemotherapy Regimen Plans</a>	entry	2.16.840.1.113883.10.20.30.3.30
<a href="#">Chemotherapy Medication Activity Plan</a>	entry	2.16.840.1.113883.10.20.30.3.51
<a href="#">Chemotherapy Protocol Reference</a>	entry	2.16.840.1.113883.10.20.30.3.50
<a href="#">Clinical Drug Trial</a>	entry	2.16.840.1.113883.10.20.30.3.4
<a href="#">Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.23
<a href="#">Reaction Observation</a>	entry	2.16.840.1.113883.10.20.22.4.9
<a href="#">Medication Activity</a>	entry	2.16.840.1.113883.10.20.22.4.16
<a href="#">Drug Vehicle</a>	entry	2.16.840.1.113883.10.20.22.4.24
<a href="#">Indication</a>	entry	2.16.840.1.113883.10.20.22.4.19
<a href="#">Instructions</a>	entry	2.16.840.1.113883.10.20.22.4.20
<a href="#">Medication Dispense</a>	entry	2.16.840.1.113883.10.20.22.4.18
<a href="#">Immunization Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.54
<a href="#">Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.23
<a href="#">Medication Supply Order</a>	entry	2.16.840.1.113883.10.20.22.4.17
<a href="#">Immunization Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.54
<a href="#">Instructions</a>	entry	2.16.840.1.113883.10.20.22.4.20
<a href="#">Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.23
<a href="#">Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.23
<a href="#">Medication Supply Order</a>	entry	2.16.840.1.113883.10.20.22.4.17
<a href="#">Immunization Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.54
<a href="#">Instructions</a>	entry	2.16.840.1.113883.10.20.22.4.20
<a href="#">Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.23
<a href="#">Precondition for Substance Administration</a>	entry	2.16.840.1.113883.10.20.22.4.25
<a href="#">Procedure Activity Procedure</a>	entry	2.16.840.1.113883.10.20.22.4.14
<a href="#">Indication</a>	entry	2.16.840.1.113883.10.20.22.4.19
<a href="#">Instructions</a>	entry	2.16.840.1.113883.10.20.22.4.20
<a href="#">Medication Activity</a>	entry	2.16.840.1.113883.10.20.22.4.16
<a href="#">Drug Vehicle</a>	entry	2.16.840.1.113883.10.20.22.4.24

<b>Template Title</b>	<b>Template Type</b>	<b>templateId</b>
<a href="#">Indication</a>	entry	2.16.840.1.113883.10.20.22.4.19
<a href="#">Instructions</a>	entry	2.16.840.1.113883.10.20.22.4.20
<a href="#">Medication Dispense</a>	entry	2.16.840.1.113883.10.20.22.4.18
<a href="#">Immunization Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.54
<a href="#">Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.23
<a href="#">Medication Supply Order</a>	entry	2.16.840.1.113883.10.20.22.4.17
<a href="#">Immunization Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.54
<a href="#">Instructions</a>	entry	2.16.840.1.113883.10.20.22.4.20
<a href="#">Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.23
<a href="#">Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.23
<a href="#">Medication Supply Order</a>	entry	2.16.840.1.113883.10.20.22.4.17
<a href="#">Immunization Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.54
<a href="#">Instructions</a>	entry	2.16.840.1.113883.10.20.22.4.20
<a href="#">Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.23
<a href="#">Precondition for Substance Administration</a>	entry	2.16.840.1.113883.10.20.22.4.25
<a href="#">Product Instance</a>	entry	2.16.840.1.113883.10.20.22.4.37
<a href="#">Service Delivery Location</a>	entry	2.16.840.1.113883.10.20.22.4.32
<a href="#">Severity Observation</a>	entry	2.16.840.1.113883.10.20.22.4.8
<a href="#">Clinical Drug Trial</a>	entry	2.16.840.1.113883.10.20.30.3.4
<a href="#">Possible Side Effects</a>	entry	2.16.840.1.113883.10.20.30.3.35
<a href="#">Plan of Care Activity Reconstruction Procedure</a>	entry	2.16.840.1.113883.10.20.30.3.31
<a href="#">Plan of Care Radiation Activity</a>	entry	2.16.840.1.113883.10.20.30.3.32
<a href="#">Problem Section BCTPS</a>	section	2.16.840.1.113883.10.20.30.2.1
<a href="#">Breast Cancer Concern Act</a>	entry	2.16.840.1.113883.10.20.30.3.6
<a href="#">Breast Cancer Diagnosis Observation</a>	entry	2.16.840.1.113883.10.20.30.3.2
<a href="#">Breast TNM Clinical Category</a>	entry	2.16.840.1.113883.10.20.30.3.3
<a href="#">Breast TNM Metastasis Category</a>	entry	2.16.840.1.113883.10.20.30.3.8
<a href="#">Breast TNM Node Category</a>	entry	2.16.840.1.113883.10.20.30.3.7
<a href="#">Breast TNM Tumor Category</a>	entry	2.16.840.1.113883.10.20.30.3.5
<a href="#">Post Treatment Disease Status</a>	entry	2.16.840.1.113883.10.20.30.3.29
<a href="#">Last Menstrual Period</a>	entry	2.16.840.1.113883.10.20.30.3.34
<a href="#">Procedures Section BCTPS</a>	section	2.16.840.1.113883.10.20.30.2.4
<a href="#">Breast Cancer Procedures</a>	entry	2.16.840.1.113883.10.20.30.3.12
<a href="#">Lymph Node Sampling Result Organizer</a>	entry	2.16.840.1.113883.10.20.30.3.13

<b>Template Title</b>	<b>Template Type</b>	<b>templateId</b>
<a href="#">Number of Lymph Nodes Positive</a>	entry	2.16.840.1.113883.10.20.30.3.15
<a href="#">Number of Lymph Nodes Removed and Examined</a>	entry	2.16.840.1.113883.10.20.30.3.14
<a href="#">Radiation Therapy Care Completed</a>	entry	2.16.840.1.113883.10.20.30.3.16
<a href="#">Results Section BCTPS</a>	section	2.16.840.1.113883.10.20.30.2.2
<a href="#">Cardiac Function Observation</a>	entry	2.16.840.1.113883.10.20.30.3.21
<a href="#">Molecular Diagnostic Testing Organizer</a>	entry	2.16.840.1.113883.10.20.30.3.49
<a href="#">Oncotype DX Score</a>	entry	2.16.840.1.113883.10.20.30.3.18
<a href="#">Receptor Status Organizer</a>	entry	2.16.840.1.113883.10.20.30.3.17
<a href="#">Estrogen Receptor Status</a>	entry	2.16.840.1.113883.10.20.30.3.19
<a href="#">HER2 Receptor Status</a>	entry	2.16.840.1.113883.10.20.30.3.38
<a href="#">Progesterone Receptor Status</a>	entry	2.16.840.1.113883.10.20.30.3.20
<a href="#">Vital Signs Section BCTPS</a>	section	2.16.840.1.113883.10.20.30.2.5
<a href="#">Vital Signs Organizer BCTPS</a>	entry	2.16.840.1.113883.10.20.30.3.25
<a href="#">Body Height</a>	entry	2.16.840.1.113883.10.20.30.3.26
<a href="#">Body Surface Area</a>	entry	2.16.840.1.113883.10.20.30.3.28
<a href="#">Body Weight</a>	entry	2.16.840.1.113883.10.20.30.3.27
<a href="#">Substance or Device Allergy - Intolerance Observation</a>	entry	2.16.840.1.113883.10.20.24.3.90
<a href="#">Allergy Status Observation</a>	entry	2.16.840.1.113883.10.20.22.4.28
<a href="#">Reaction Observation</a>	entry	2.16.840.1.113883.10.20.22.4.9
<a href="#">Medication Activity</a>	entry	2.16.840.1.113883.10.20.22.4.16
<a href="#">Drug Vehicle</a>	entry	2.16.840.1.113883.10.20.22.4.24
<a href="#">Indication</a>	entry	2.16.840.1.113883.10.20.22.4.19
<a href="#">Instructions</a>	entry	2.16.840.1.113883.10.20.22.4.20
<a href="#">Medication Dispense</a>	entry	2.16.840.1.113883.10.20.22.4.18
<a href="#">Immunization Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.54
<a href="#">Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.23
<a href="#">Medication Supply Order</a>	entry	2.16.840.1.113883.10.20.22.4.17
<a href="#">Immunization Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.54
<a href="#">Instructions</a>	entry	2.16.840.1.113883.10.20.22.4.20
<a href="#">Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.23
<a href="#">Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.23
<a href="#">Medication Supply Order</a>	entry	2.16.840.1.113883.10.20.22.4.17
<a href="#">Immunization Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.54
<a href="#">Instructions</a>	entry	2.16.840.1.113883.10.20.22.4.20
<a href="#">Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.23

<b>Template Title</b>	<b>Template Type</b>	<b>templateId</b>
<a href="#">Precondition for Substance Administration</a>	entry	2.16.840.1.113883.10.20.22.4.25
<a href="#">Procedure Activity Procedure</a>	entry	2.16.840.1.113883.10.20.22.4.14
<a href="#">Indication</a>	entry	2.16.840.1.113883.10.20.22.4.19
<a href="#">Instructions</a>	entry	2.16.840.1.113883.10.20.22.4.20
<a href="#">Medication Activity</a>	entry	2.16.840.1.113883.10.20.22.4.16
<a href="#">Drug Vehicle</a>	entry	2.16.840.1.113883.10.20.22.4.24
<a href="#">Indication</a>	entry	2.16.840.1.113883.10.20.22.4.19
<a href="#">Instructions</a>	entry	2.16.840.1.113883.10.20.22.4.20
<a href="#">Medication Dispense</a>	entry	2.16.840.1.113883.10.20.22.4.18
<a href="#">Immunization Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.54
<a href="#">Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.23
<a href="#">Medication Supply Order</a>	entry	2.16.840.1.113883.10.20.22.4.17
<a href="#">Immunization Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.54
<a href="#">Instructions</a>	entry	2.16.840.1.113883.10.20.22.4.20
<a href="#">Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.23
<a href="#">Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.23
<a href="#">Medication Supply Order</a>	entry	2.16.840.1.113883.10.20.22.4.17
<a href="#">Immunization Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.54
<a href="#">Instructions</a>	entry	2.16.840.1.113883.10.20.22.4.20
<a href="#">Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.23
<a href="#">Precondition for Substance Administration</a>	entry	2.16.840.1.113883.10.20.22.4.25
<a href="#">Product Instance</a>	entry	2.16.840.1.113883.10.20.22.4.37
<a href="#">Service Delivery Location</a>	entry	2.16.840.1.113883.10.20.22.4.32
<a href="#">Severity Observation</a>	entry	2.16.840.1.113883.10.20.22.4.8
<a href="#">Severity Observation</a>	entry	2.16.840.1.113883.10.20.22.4.8

## Appendix C — CODE SYSTEMS IN THIS GUIDE

For the user's convenience, this table summarizes the vocabularies (code systems) used in this guide.

**Table 290: List of Vocabularies**

<b>Root OIDs</b>	
<b>codeSystem</b>	<b>codeSystemName</b>
2.16.840.1.113883.5.4	ActCode
2.16.840.1.113883.5.1001	ActMood
2.16.840.1.113883.5.14	ActStatus
2.16.840.1.113883.5.1	AdministrativeGender
2.16.840.1.113883.6.59	CVX
2.16.840.1.113883.5.25	HL7 Confidentiality Code
2.16.840.1.113883.5.83	HL7 Observation Interpretation
2.16.840.1.113883.5.6	HL7ActClass
2.16.840.1.113883.5.1002	HL7ActRelationshipType
2.16.840.1.113883.6.90	ICD10CM
2.16.840.1.113883.6.2	ICD9CM
2.16.840.1.113883.6.1	LOINC
2.16.840.1.113883.3.26.1.1	National Cancer Institute (NCI) Thesaurus
2.16.840.1.113883.3.26.1.5	NDFRT
2.16.840.1.113883.6.101	NUCC Health Care Provider Taxonomy
2.16.840.1.113883.5.111	RoleCode
2.16.840.1.113883.6.88	RxNorm
2.16.840.1.113883.6.96	SNOMED CT
2.16.840.1.113883.6.8	UCUM



## Appendix D — BREAST CANCER ADJUVANT TREATMENT PLAN AND SUMMARY PAPER FORM

The form below is a copy of the American Society of Clinical Oncology's Breast Cancer Adjuvant Treatment Plan and Summary form. This CDA Implementation Guide's requirements were derived from this form with the design heuristic of what would ideally be available in an EHR.

<i>The Treatment Plan and Summary provide a brief record of major aspects of breast cancer adjuvant treatment. This is not a complete patient history or comprehensive record of intended therapies.</i>					
Patient name:			Patient DOB: ( ___/___/___ )		
Practice site:		Medical record number:			
Patient phone:		Patient cell:	Patient email:		
Hem-onc provider name:			Hem-onc phone:		
Support contact name:		Support contact phone:			
<b>BACKGROUND INFORMATION</b>					
Age at diagnosis:		Breast cancer site: <input type="checkbox"/> Left breast <input type="checkbox"/> Right breast <input type="checkbox"/> Bilateral			
Family history: <input type="checkbox"/> None <input type="checkbox"/> 2 <sup>nd</sup> degree relative <input type="checkbox"/> 1 <sup>st</sup> degree relative <input type="checkbox"/> Multiple relatives					
Definitive breast surgery: Date: ( ___/___/___ ) Type: <input type="checkbox"/> Lumpectomy <input type="checkbox"/> Mastectomy <input type="checkbox"/> Mastectomy/immediate recon					
# lymph nodes removed (total – sentinel node + dissection):			# lymph nodes positive:		
Axillary dissection: <input type="checkbox"/> Yes ( ___/___/___ ) <input type="checkbox"/> No		Sentinel node biopsy: <input type="checkbox"/> Yes ( ___/___/___ ) <input type="checkbox"/> No			
Notable surgical findings/comments:					
Tumor type: <input type="checkbox"/> Infiltrating ductal <input type="checkbox"/> Infiltrating lobular <input type="checkbox"/> Mixed lobular/ductal <input type="checkbox"/> Other: _____					
T stage: <input type="checkbox"/> T1 <input type="checkbox"/> T2 <input type="checkbox"/> T3 <input type="checkbox"/> T4a <input type="checkbox"/> T4b <input type="checkbox"/> T4c <input type="checkbox"/> T4d			N stage: <input type="checkbox"/> N0 <input type="checkbox"/> N1 <input type="checkbox"/> N2 <input type="checkbox"/> N3		
Stage: <input type="checkbox"/> 0 <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III		Oncotype DX recurrence score (if applicable):			
ER status: <input type="checkbox"/> Positive <input type="checkbox"/> Negative		PR status: <input type="checkbox"/> Positive <input type="checkbox"/> Negative		HER2 status: <input type="checkbox"/> Positive <input type="checkbox"/> Negative	
Major comorbid conditions:					
Echocardiogram or MUGA result prior to chemotherapy (if obtained): EF= _____ %					
<b>ADJUVANT TREATMENT PLAN</b>			<b>ADJUVANT TREATMENT SUMMARY</b>		
<i>White sections to be completed prior to chemotherapy administration, shaded sections following chemotherapy</i>					
Height: _____ in/cm		Pre-treatment weight: _____ lb/kg		Post-treatment weight: _____ lb/kg	
Pre-Treatment BSA:		Date last menstrual period: ( ___/___/___ )		Date last menstrual period: ( ___/___/___ )	
Name of regimen:					
Treatment on clinical trial: <input type="checkbox"/> Yes <input type="checkbox"/> No			Pre-operative chemo administered: <input type="checkbox"/> Yes <input type="checkbox"/> No		
Start Date: ( ___/___/___ )				End Date: ( ___/___/___ )	
Chemotherapy drug name	Route	Dose	Schedule	Dose reduction needed	Number of cycles administered
				<input type="checkbox"/> No <input type="checkbox"/> Yes Reasons/comments	
				<input type="checkbox"/> No <input type="checkbox"/> Yes Reasons/comments	
				<input type="checkbox"/> No <input type="checkbox"/> Yes Reasons/comments	
				<input type="checkbox"/> No <input type="checkbox"/> Yes Reasons/comments	

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*diagnostic information, or educational materials that describe strategies for coping with breast cancer and adjuvant chemotherapy in detail. Both medical science and an individual's health care needs change, and therefore this document is current only as of the date of preparation. This summary document does not prescribe or recommend any particular medical treatment or care for breast cancer or any other disease and does not substitute for the independent medical judgment of the treating professional.*

## Appendix E — EXTENSIONS TO CDA R2

Where there is a need to communicate information for which there is no suitable representation in CDA R2, extensions to CDA R2 have been developed. These extensions are described above in the context of the section where they are used. This section serves to summarize the extensions and provide implementation guidance.

Extensions created for this guide include:

- **sdct:raceCode** - The **raceCode** extension allows for multiple races to be reported for a patient.
- **sdct:id** - The **id** extension in the family history organizer on the related subject allows for unique identification of the family member(s).
- **sdct:deceasedInd** - The **deceasedInd** extension (= “true” or “false”) in the family history organizer on the related subject is used inside to indicate if a family member is deceased.
- **sdct:deceasedTime** - The **deceasedTime** extension in the family history organizer on the related subject allows for reporting the date and time a family member died.
- **sdct:birthTime** - The **birthTime** extension allows for the birth date of any person to be recorded. The purpose of this extension is to allow the recording of the subscriber or member of a health plan in cases where the health plan eligibility system has different information on file than the provider does for the patient.
- **sdct:dischargeDispositionCode** - The **dischargeDispositionCode** extension allows the provider to record a discharge disposition in an encounter activity.
- **sdct:valueSet** - the **valueSet** extension allows the implementer to reference a particular value set from which a code was drawn.
- **sdct:valueSetVersion** - the **valueSetVersion** extension allows the implementer to reference a specific version of a value set.

To resolve issues that need to be addressed by extension, the developers of this guide chose to approach extensions as follows:

- An extension is a collection of element or attribute declarations and rules for their application to the CDA Release 2.0.
- A single namespace for all extension elements or attributes that may be used by this guide will be defined.
- The namespace for extensions created by the HL7 Structured Documents Working Group (formerly Structured Documents Technical Committee) shall be urn:hl7-org:sdct.
- This namespace shall be used as the namespace for any extension elements or attributes that are defined by this implementation guide.

- Each extension element shall use the same HL7 vocabularies and data types used by CDA Release 2.0.
- Each extension element shall use the same conventions for order and naming as is used by the current HL7 tooling.
- An extension element shall appear in the XML where the expected RIM element of the same name would have appeared had that element not been otherwise constrained from appearing in the CDA XML schema.

## Appendix F — PREVIOUSLY PUBLISHED TEMPLATES

The following templates were first published in other implementation guides and are re-used and republished in this guide. Enhancements or errata requested in these templates may be noted on the HL7 DSTU comments page

<http://www.hl7.org/dstucomments/>. Specifically, these CDA templates are from *HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, Release 1.1 - US Realm*<sup>16</sup> (C-CDA) or *HL7 Implementation Guide for CDA R2: Quality Reporting Document Architecture, DSTU Release 2*<sup>17</sup> (QRDA). For more information on the reuse of templates, see the [Templated CDA](#) section in this document.

**Table 291: Templates Previously Published in C-CDA or QRDA Implementation Guides**

Template Title	Template Type	templateId	Published In
<a href="#">US Realm Header</a>	document	2.16.840.1.113883.10.20.22.1.1	C-CDA
<a href="#">Allergies Section (entries optional)</a>	section	2.16.840.1.113883.10.20.22.2.6	C-CDA
<a href="#">Encounters Section (entries optional)</a>	section	2.16.840.1.113883.10.20.22.2.22	C-CDA
<a href="#">Family History Section</a>	section	2.16.840.1.113883.10.20.22.2.15	C-CDA
<a href="#">Functional Status Section</a>	section	2.16.840.1.113883.10.20.22.2.14	C-CDA
<a href="#">Medications Section (entries optional)</a>	section	2.16.840.1.113883.10.20.22.2.1	C-CDA
<a href="#">Plan of Care Section</a>	section	2.16.840.1.113883.10.20.22.2.10	C-CDA
<a href="#">Problem Section (entries optional)</a>	section	2.16.840.1.113883.10.20.22.2.5	C-CDA
<a href="#">Procedures Section (entries optional)</a>	section	2.16.840.1.113883.10.20.22.2.7	C-CDA
<a href="#">Results Section (entries optional)</a>	section	2.16.840.1.113883.10.20.22.2.3	C-CDA
<a href="#">Vital Signs Section (entries optional)</a>	section	2.16.840.1.113883.10.20.22.2.4	C-CDA
<a href="#">Age Observation</a>	entry	2.16.840.1.113883.10.20.22.4.31	C-CDA
<a href="#">Allergy - Intolerance Observation</a>	entry	2.16.840.1.113883.10.20.22.4.7	C-CDA
<a href="#">Allergy Problem Act</a>	entry	2.16.840.1.113883.10.20.22.4.30	C-CDA
<a href="#">Allergy Status Observation</a>	entry	2.16.840.1.113883.10.20.22.4.28	C-CDA
<a href="#">Assessment Scale Observation</a>	entry	2.16.840.1.113883.10.20.22.4.69	C-CDA

<sup>16</sup> [http://www.hl7.org/implement/standards/product\\_brief.cfm?product\\_id=258](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=258)

The direct link to comments on C-CDA IG is:

<http://www.hl7.org/dstucomments/showdetail.cfm?dstuid=82>

<sup>17</sup> [http://www.hl7.org/implement/standards/product\\_brief.cfm?product\\_id=35](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=35)

The direct link to comments on the QRDA IG is:

<http://www.hl7.org/dstucomments/showdetail.cfm?dstuid=80>

<b>Template Title</b>	<b>Template Type</b>	<b>templateId</b>	<b>Published In</b>
<a href="#">Assessment Scale Supporting Observation</a>	entry	2.16.840.1.113883.10.20.22.4.86	C-CDA
<a href="#">Caregiver Characteristics</a>	entry	2.16.840.1.113883.10.20.22.4.72	C-CDA
<a href="#">Cognitive Status Problem Observation</a>	entry	2.16.840.1.113883.10.20.22.4.73	C-CDA
<a href="#">Cognitive Status Result Observation</a>	entry	2.16.840.1.113883.10.20.22.4.74	C-CDA
<a href="#">Cognitive Status Result Organizer</a>	entry	2.16.840.1.113883.10.20.22.4.75	C-CDA
<a href="#">Drug Vehicle</a>	entry	2.16.840.1.113883.10.20.22.4.24	C-CDA
<a href="#">Encounter Activities</a>	entry	2.16.840.1.113883.10.20.22.4.49	C-CDA
<a href="#">Encounter Diagnosis</a>	entry	2.16.840.1.113883.10.20.22.4.80	C-CDA
<a href="#">Family History Death Observation</a>	entry	2.16.840.1.113883.10.20.22.4.47	C-CDA
<a href="#">Family History Observation</a>	entry	2.16.840.1.113883.10.20.22.4.46	C-CDA
<a href="#">Family History Organizer</a>	entry	2.16.840.1.113883.10.20.22.4.45	C-CDA
<a href="#">Functional Status Problem Observation</a>	entry	2.16.840.1.113883.10.20.22.4.68	C-CDA
<a href="#">Functional Status Result Observation</a>	entry	2.16.840.1.113883.10.20.22.4.67	C-CDA
<a href="#">Functional Status Result Organizer</a>	entry	2.16.840.1.113883.10.20.22.4.66	C-CDA
<a href="#">Health Status Observation</a>	entry	2.16.840.1.113883.10.20.22.4.5	C-CDA
<a href="#">Highest Pressure Ulcer Stage</a>	entry	2.16.840.1.113883.10.20.22.4.77	C-CDA
<a href="#">Immunization Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.54	C-CDA
<a href="#">Indication</a>	entry	2.16.840.1.113883.10.20.22.4.19	C-CDA
<a href="#">Instructions</a>	entry	2.16.840.1.113883.10.20.22.4.20	C-CDA
<a href="#">Medication Activity</a>	entry	2.16.840.1.113883.10.20.22.4.16	C-CDA
<a href="#">Medication Dispense</a>	entry	2.16.840.1.113883.10.20.22.4.18	C-CDA
<a href="#">Medication Information</a>	entry	2.16.840.1.113883.10.20.22.4.23	C-CDA
<a href="#">Medication Supply Order</a>	entry	2.16.840.1.113883.10.20.22.4.17	C-CDA
<a href="#">Non-Medicinal Supply Activity</a>	entry	2.16.840.1.113883.10.20.22.4.50	C-CDA
<a href="#">Number of Pressure Ulcers Observation</a>	entry	2.16.840.1.113883.10.20.22.4.76	C-CDA
<a href="#">Plan of Care Activity Act</a>	entry	2.16.840.1.113883.10.20.22.4.39	C-CDA
<a href="#">Plan of Care Activity Encounter</a>	entry	2.16.840.1.113883.10.20.22.4.40	C-CDA
<a href="#">Plan of Care Activity Observation</a>	entry	2.16.840.1.113883.10.20.22.4.44	C-CDA
<a href="#">Plan of Care Activity Procedure</a>	entry	2.16.840.1.113883.10.20.22.4.41	C-CDA
<a href="#">Plan of Care Activity Substance Administration</a>	entry	2.16.840.1.113883.10.20.22.4.42	C-CDA

<b>Template Title</b>	<b>Template Type</b>	<b>templateId</b>	<b>Published In</b>
<a href="#">Plan of Care Activity Supply</a>	entry	2.16.840.1.113883.10.20.22.4.43	C-CDA
<a href="#">Precondition for Substance Administration</a>	entry	2.16.840.1.113883.10.20.22.4.25	C-CDA
<a href="#">Pressure Ulcer Observation</a>	entry	2.16.840.1.113883.10.20.22.4.70	C-CDA
<a href="#">Problem Concern Act (Condition)</a>	entry	2.16.840.1.113883.10.20.22.4.3	C-CDA
<a href="#">Problem Observation</a>	entry	2.16.840.1.113883.10.20.22.4.4	C-CDA
<a href="#">Problem Status</a>	entry	2.16.840.1.113883.10.20.22.4.6	C-CDA
<a href="#">Procedure Activity Act</a>	entry	2.16.840.1.113883.10.20.22.4.12	C-CDA
<a href="#">Procedure Activity Observation</a>	entry	2.16.840.1.113883.10.20.22.4.13	C-CDA
<a href="#">Procedure Activity Procedure</a>	entry	2.16.840.1.113883.10.20.22.4.14	C-CDA
<a href="#">Product Instance</a>	entry	2.16.840.1.113883.10.20.22.4.37	C-CDA
<a href="#">Reaction Observation</a>	entry	2.16.840.1.113883.10.20.22.4.9	C-CDA
<a href="#">Result Observation</a>	entry	2.16.840.1.113883.10.20.22.4.2	C-CDA
<a href="#">Result Organizer</a>	entry	2.16.840.1.113883.10.20.22.4.1	C-CDA
<a href="#">Service Delivery Location</a>	entry	2.16.840.1.113883.10.20.22.4.32	C-CDA
<a href="#">Severity Observation</a>	entry	2.16.840.1.113883.10.20.22.4.8	C-CDA
<a href="#">Substance or Device Allergy - Intolerance Observation</a>	entry	2.16.840.1.113883.10.20.24.3.90	QRDA
<a href="#">Vital Sign Observation</a>	entry	2.16.840.1.113883.10.20.22.4.27	C-CDA
<a href="#">Vital Signs Organizer</a>	entry	2.16.840.1.113883.10.20.22.4.26	C-CDA



## Appendix G — MIME MULTIPART/RELATED MESSAGES

The contents of this appendix were added in the event that implementers may want additional guidance when referencing external observations or documents.

The following text is taken from the Claims Attachments Implementation Guide (AIS00000) in Section 2.4  
[http://www.hl7.org/documentcenter/public/wg/ca/CDAR2AIS0000R030\\_ImplementationGuideDraft.pdf](http://www.hl7.org/documentcenter/public/wg/ca/CDAR2AIS0000R030_ImplementationGuideDraft.pdf). 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 to 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 Multipart 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.