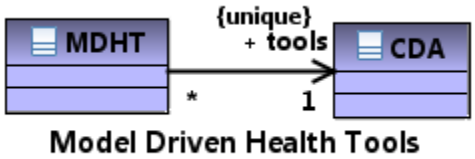
Implementation Guide for CDA Release 2
Public Health Case Report
US Realm
Informative Document



Model Driven Health Tools

PROTOTYPE: FOR DISCUSSION AND DEMONSTRATION USE ONLY
(Consolidated Developer Documentation)

Contents

Acknowledgments

In 2007, the Council of State and Territorial Epidemiologists (CSTE) compiled common data elements found in multiple states' reportable condition forms. These data elements form the basis for this implementation guide developed by the National Center for Public Health Informatics (NCPHI). This CDA implementation guide will allow healthcare facilities/providers to communicate these standardized data elements to state and local public health departments in CDA format—an interoperable, industry-standard format.

The editorial group that produced this guide was led by NCPHI and supported by Alschuler Associates, LLC, with representatives from CSTE whose guidance was critical in ensuring that the CSTE-identified data elements were appropriately captured and constrained into a useful CDA conformance profile implementation guide.

The editors wish to express their appreciation for the support and sponsorship of the Structured Documents Work Group, the Public Health and Emergency Response Work Group, Orders and Observations Work Group, and Patient Safety Work Group.

We also acknowledge the collaborative effort of the American Society for Standards and Materials (ASTM) and HL7, which produced the Continuity of Care Document (CCD). All these efforts were critical ingredients to the development of this implementation guide and the degree to which it reflects these efforts will foster interoperability across the spectrum of health care.

Chapter 1

INTRODUCTION

Topics:

Overview

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

Approach

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

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

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

Scope

The CDA for PHCR constrains CDA to meet the requirements of Public Health Case Reports for reportable conditions. Reportable conditions are those considered to be of great public health importance. Local and state agencies require that such conditions be reported when they are identified by providers or laboratories. Public Health Case Reports are reports of these conditions sent to local and state public health departments from providers. The scope of this project and this implementation guide is limited to the reporting flow from the provider to the local or state public health departments and NOT the verification process or the reporting of a confirmed condition to the national public health system (CDC). The common data elements were chosen by the CRSWg. These are modeled in a set of modular definitions (templates) reusable across forms and conformant with design patterns established for EHRs and interoperable data exchange. These reusable pieces are documented in the format required for HL7 ballot and in a database that will ensure consistency, optimize reuse, and lay the foundation for extensibility. The database is a catalogue of the templates designed for this project.

The CRSWg identified approximately 300 common data elements associated with public health reportable condition forms across the United States. These data elements were stratified as non-condition specific and condition specific. Each element was further identified as core (should be included) vs. extended data elements (may also be included). A handful of core data elements are required to be present in all reports: the date of report, the reporter's name, the telephone and address of the reporter, and the name of the condition. This is the minimum information necessary to route the report to the appropriate public health agency/program, and to allow an investigator to contact the reporter to begin an investigation.

From the perspective of this implementation guide, required core data elements and required CDA constructs (such as document id and document creation time) are to be present in all reports. The guide defines the templates (required and optional) and indicates how those templates are organized into documents, sections, and entries to construct valid PHCR instances. Each state and/or local health department will determine which of the core data elements they require versus simply request, if any.

NOTE: The exact method by which a CDA instance is packaged and exchanged is outside the scope of the CDA standard. Please refer to section 3 of the CDA base standard HL7 CDA, Release 2.0 “CDA Document Exchange in HL7 Messages”. Note that the public health reporting workflow requires that the time the document is sent be captured in the exchange message.

Audience

The audience for this document includes software developers and implementers with reporting capabilities within their EHR systems, and developers and analysts in public health departments who wish to create and/or process CDA PHCR documents created according to this specification. The intended audience also includes public health domain experts.

Organization of This Guide

The requirements as laid out in the body of this document are subject to change per the policy on implementation guides (see section 13.01" Informative Documents" within the HL7 Governance and Operations Manual, *http://www.hl7.org/documentcenter/public/membership/HL7_Governance_and_Operations_Manual.pdf*).

Templates

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

Vocabulary and Value Sets

Vocabularies recommended in this guide are primarily standard vocabularies recommended by the HITSP for use in the particular domains. In many cases these vocabularies are further constrained into value sets for use within this guide or were previously constrained into value sets by the CDC and maintained in PHIN VADS for use in the Public Health domain. PHIN VADS is the vocabulary server that this implementation guide is currently using, but PHIN VADS use is not a requirement for the CDA for PHCR. It is possible that the vocabulary hosting may shift to a different server later if so desired. In addition, while PHIN VADS is hosting the vocabulary, the contents of the dynamically bound value sets are subject to external (e.g., CSTE) governance.

PHIN VADS is based upon Whitehouse E-Gov Consolidated Health Informatics (CHI) domain recommendations and its main purpose is to distribute the vocabulary subsets that are needed for public health. PHIN VADS allows implementers to browse, search, and download the value sets associated with an implementation guide. PHIN VADS has the capability to host multiple versions of value sets and implementation guide vocabulary. PHIN VADS provides vocabulary metadata that are needed for HL7 messaging or CDA implementation. The latest version of any value set referenced in this implementation guide can be obtained from the CDC PHIN VADS [http://phinvads.cdc.gov].

Use of Templates

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

Originator Responsibilities

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

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

Recipient Responsibilities

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

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

If an object does not have a `templateId`, a recipient shall not report a conformance error about a failure to conform to a particular template on classes that do not claim conformance to that and that are not required to be conformant by other templates.

Conventions Used in This Guide

Conformance Requirements

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

Template name

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

Description of the template will be here .....

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

Figure 1: Template name and "conforms to" appearance

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

The following cardinality indicators may be interpreted as follows:

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

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

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

1. **SHALL** contain [1..1] component/structuredBody (CONF:4082).
    a. This component/structuredBody **SHOULD** contain [0..1] component (CONF:4130) such that it

   a. **SHALL** contain [1..1] Reporting Parameters section (templateId:2.16.840.1.113883.10.20.17.2.1) (CONF:4131).

b. This component/structuredBody **SHALL** contain [1..1] component (CONF:4132) such that it

   a. **SHALL** contain [1..1] Patient data section - NCR (templateId:2.16.840.1.113883.10.20.17.2.5) (CONF:4133).

Figure 2: Template-based conformance statements example

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

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

Figure 3: CCD conformance statements example

Keywords

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

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

XML Examples

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

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

Figure 4: ClinicalDocument example

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

Chapter 2

DOCUMENT TEMPLATES

Topics:

This section contains the document-level constraints for CDA PHCR documents. Here you will find the generic document-level template with constraints that apply across all PHCR case reports.

Public Health Case Report

[ClinicalDocument: templateId `2.16.840.1.113883.10.20.15`]

The CDA for PHCR constrains CDA to express the data elements identified by the CSTE CRSWg. This PHCR CDA R2 template root defines the data elements that belong in the header of a CDA document and prescribes the sections that belong in a generic PHCR. The person who completes a PHCR is referred to as the reporter. This reporter is represented with the CDA document author. This reporter is often the infection control professional at an institution but may be any individual at a healthcare organization who is designated to do so. The CDA legalAuthenticator is the verifier who officially confirms the accuracy of the document. In the public health workflow this legal authenticator may be the infection control professional who is also the author/reporter of the reportable condition or may be another individual designated to authenticate the report by the organization. It is required that the name and contact information of the reporter and the legal authenticator be provided. Most sections and data elements are optional. The clinical information section is required and contains data elements determined by the CRSWg to be required consistently when reporting a case to the state/local public health department. Note that state and/or local health departments may require additional data elements, beyond those identified by the CSTE CRSWg as required consistently across jurisdictions. Reporters must adhere to local and state rules applicable to their location. NOTE: A generic PHCR document may be sent where there is a case of a reportable condition for which no specific PHCR document template has been defined. In such a case, the report shall adhere to this template.

1. Contains exactly one [1..1] **`typeId`**, where its data type is InfrastructureRootTypeId
2. Contains exactly one [1..1] **`id`**, where its data type is II
3. **SHALL** contain exactly one [1..1] **`code/@code="55751-2"`** *Public Health Case Report* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`) (CONF:546)
4. Contains exactly one [1..1] **`effectiveTime`**, where its data type is TS
5. Contains exactly one [1..1] **`confidentialityCode`**, where its data type is CE
6. Contains at least one [1..*] **`recordTarget`**, where its type is *Record Target*
7. Contains at least one [1..*] **`author`**, where its type is *Author*
8. Contains exactly one [1..1] **`custodian`**, where its type is *Custodian*
9. Contains exactly one [1..1] **`component`**, where its type is *Component2*
10. **SHOULD** contain zero or one [0..1] **`component`** (CONF:914, CONF:915), such that
    a. Contains exactly one [1..1] *Phcr Social History Section* (templateId: `2.16.840.1.113883.10.20.15.2.22`)
11. **SHALL** contain exactly one [1..1] **`component`** (CONF:606, CONF:607), such that
    a. Contains exactly one [1..1] *Phcr Clinical Information Section* (templateId: `2.16.840.1.113883.10.20.15.2.1`)
12. **SHOULD** contain zero or one [0..1] **`component`** (CONF:742, CONF:674), such that
    a. Contains exactly one [1..1] *Phcr Treatment Information Section* (templateId: `2.16.840.1.113883.10.20.15.2.4`)
13. **SHOULD** contain zero or one [0..1] **`component`** (CONF:643, CONF:609), such that
    a. Contains exactly one [1..1] *Phcr Encounters Section* (templateId: `2.16.840.1.113883.10.20.15.2.2`)
14. **SHOULD** contain zero or one [0..1] **`component`**, such that
    a. Contains exactly one [1..1] *Phcr Relevant Dx Tests Section* (templateId: `2.16.840.1.113883.10.20.15.2.3`)
15. **MAY** contain zero or one [0..1] **`component`**, such that
    a. Contains exactly one [1..1] *CCD Immunizations Section* (templateId: `2.16.840.1.113883.10.20.1.6`)
16. **SHALL** contain [1..1] recordTarget (CONF:547)

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

17. RecordTarget **SHALL** contain [1..1] patientRole (CONF:548)

- `[OCL]: self.recordTarget.patientRole->one(patientRole : cda::PatientRole | not patientRole.oclIsUndefined())`

18. RecordTarget / PatientRole **SHALL** contain [1..*] id (CONF:549)

- `[OCL]: self.recordTarget.patientRole.id->exists(id : datatypes::II | not id.root.oclIsUndefined() or not id.extension.oclIsUndefined() or not id.nullFlavor.oclIsUndefined())`

19. RecordTarget / PatientRole **SHOULD** contain [0..*] addr (CONF:550)

20. RecordTarget / PatientRole **SHOULD** contain [0..*] telecom (CONF:551)

21. RecordTarget / PatientRole **SHOULD** contain [0..1] patient (CONF:552)

22. RecordTarget / PatientRole / Patient **SHOULD** contain [0..*] name (CONF:553)

23. RecordTarget / PatientRole / Patient **SHOULD** contain [0..1] administrativeGenderCode/@code, which **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.1 Administrative Gender (HL7 V3) DYNAMIC (CONF:554)

24. RecordTarget / PatientRole / Patient **SHOULD** contain [0..1] birthTime (CONF:555)

25. RecordTarget / PatientRole / Patient **SHOULD** contain [0..1] ethnicGroupCode, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.837 Ethnicity group DYNAMIC (CONF:556)

26. RecordTarget / PatientRole / Patient **SHOULD** contain [0..1] birthplace/place, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.3200 Birth Country DYNAMIC (CONF:557)

27. **SHALL** contain [1..*] author (CONF:1853)

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

28. Author **SHALL** contain [1..1] time (CONF:560)

- `[OCL]: self.author.time->one(time : datatypes::TS | not time.value.oclIsUndefined() or not time.nullFlavor.oclIsUndefined())`

29. Author **SHALL** contain [1..1] assignedAuthor (CONF:561)

- `[OCL]: self.author.assignedAuthor->one(assignedAuthor : cda::AssignedAuthor | not assignedAuthor.oclIsUndefined())`

30. Author / AssignedAuthor **SHALL** contain [1..*] id (CONF:562)

- `[OCL]: self.author.assignedAuthor.id->exists(id : datatypes::II | not id.root.oclIsUndefined() or not id.extension.oclIsUndefined() or not id.nullFlavor.oclIsUndefined())`

31. Author / AssignedAuthor **SHALL** contain [1..1] addr (CONF:562)

- `[OCL]: self.author.assignedAuthor.addr->one(addr : datatypes::AD | not addr.oclIsUndefined())`

32. Author / AssignedAuthor **SHALL** contain [1..1] telecom (CONF:564)

- `[OCL]: self.author.assignedAuthor.telecom->one(tel : datatypes::TEL | not tel.oclIsUndefined())`

33. Author / AssignedAuthor **SHALL** contain [1..1] assignedPerson/name (CONF:565)

- `[OCL]: self.author.assignedAuthor.assignedPerson->one(assignedPerson : cda::Person | not assignedPerson.oclIsUndefined()) and self.author.assignedAuthor.assignedPerson.name->one(name : datatypes::PN | not name.oclIsUndefined())`

34. The custodian of a public health case report **SHALL** be the reporting organization. (CONF:1616)

35. **SHALL** contain [1..1] legalAuthenticator (CONF:1854)

- `[OCL]: self.legalAuthenticator->one(legalAuthenticator : cda::LegalAuthenticator | not legalAuthenticator.oclIsUndefined())`

36. LegalAuthenticator **SHALL** contain [1..1] time (CONF:1855)

- `[OCL]: self.legalAuthenticator.time->one(time : datatypes::TS | not time.value.oclIsUndefined() or not time.nullFlavor.oclIsUndefined())`

37. LegalAuthenticator **SHALL** contain [1..1] assignedEntity (CONF:1856)

- `[OCL]: self.legalAuthenticator.assignedEntity->one(assignedEntity : cda::AssignedEntity | not assignedEntity.oclIsUndefined())`

38. LegalAuthenticator / AssignedEntity **SHALL** contain [1..*] id (CONF:1857)

- ```
  [OCL]: self.legalAuthenticator.assignedEntity.id->exists(id :
   datatypes::II | not id.root.oclIsUndefined() or not
   id.extension.oclIsUndefined() or not id.nullFlavor.oclIsUndefined())
  ```

39. LegalAuthenticator / AssignedEntity **SHALL** contain [1..1] addr (CONF:1857)

- ```
  [OCL]: self.legalAuthenticator.assignedEntity.addr->one(addr :
   datatypes::AD | not addr.oclIsUndefined())
  ```

40. LegalAuthenticator / AssignedEntity **SHALL** contain [1..1] telecom (CONF:1859)

41. LegalAuthenticator / AssignedEntity **SHALL** contain [1..1] assignedPerson/name (CONF:1860)

- ```
  [OCL]: self.legalAuthenticator.assignedEntity.assignedPerson-
  >one(assignedPerson : cda::Person | not assignedPerson.oclIsUndefined())
   and self.legalAuthenticator.assignedEntity.assignedPerson.name-
  >one(name : datatypes::PN | not name.oclIsUndefined())
  ```

42. Where a Public Health Case Report CDA R2 document contains any of the section or clinical statement templates defined in this implementation guide, such section or clinical statement **SHALL** include a templateId/@root valued with the corresponding template's identifier. (CONF:2017)

Public Health Case Report example
  ```

Chapter 3

SECTION TEMPLATES

Topics:

This section contains the section level constraints for CDA PHCR sections. Here you will find the generic section level templates with constraints that apply across all Public Health Case Reports.

Phcr Clinical Information Section

[Section: templateId `2.16.840.1.113883.10.20.15.2.1`]

The PHCR clinical information section defines the code and title for all PHCR clinical information sections. This generic section also describes clinical statement templates that might be included in a generic PHCR report.

1. **SHALL** contain exactly one [1..1] **`code/@code="55752-0"`** *Clinical Information* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`) (CONF:540)
2. **SHALL** contain exactly one [1..1] **`title`** = "Clinical Information" (CONF:541)
3. **SHALL** contain exactly one [1..1] **`text`** (CONF:542)
4. **SHALL** contain exactly one [1..1] **`entry`** (CONF:1891, CONF:1892, CONF:1893), such that
   a. Contains **`@typeCode="DRIV"`** *DRIV (is derived from)*
   b. Contains exactly one [1..1] *Case Observation* (templateId: `2.16.840.1.113883.10.20.15.3.54`)
5. **SHOULD** contain zero or more [0..*] **`entry`**, such that
   a. Contains **`@typeCode="DRIV"`** *DRIV (is derived from)*
   b. Contains exactly one [1..1] *Phcr Relevant Medical Condition History Observation* (templateId: `2.16.840.1.113883.10.20.15.3.62`)
6. **MAY** contain zero or one [0..1] **`entry`** (CONF:1912, CONF:1913, CONF:1914), such that
   a. Contains **`@typeCode="DRIV"`** *DRIV (is derived from)*
   b. Contains exactly one [1..1] *Patient Condition Alive Observation* (templateId: `2.16.840.1.113883.10.20.15.3.42`)
7. **MAY** contain zero or one [0..1] **`entry`** (CONF:1915, CONF:1916, CONF:1917), such that
   a. Contains **`@typeCode="DRIV"`** *DRIV (is derived from)*
   b. Contains exactly one [1..1] *Patient Condition Deceased Observation* (templateId: `2.16.840.1.113883.10.20.15.3.17`)
8. TemplateId 2.16.840.1.113883.10.20.15.3.42 (Patient condition alive) and templateId 2.16.840.1.113883.10.20.15.3.17 (Patient condition deceased) **SHALL NOT** be present together in a CDA PHCR instance. (CONF:1918)

```
[OCL]: self.getObservations()->exists(obs3 : cda::Observation
 | obs3.oclIsKindOf(phcr::PatientConditionAliveObservation) and
not self.getObservations()->exists(obs4 : cda::Observation |
obs4.oclIsKindOf(phcr::PatientConditionDeceasedObservation)))
or self.getObservations()->exists(obs1 : cda::Observation |
obs1.oclIsKindOf(phcr::PatientConditionDeceasedObservation)
and not self.getObservations()->exists(obs2 : cda::Observation
| obs2.oclIsKindOf(phcr::PatientConditionAliveObservation)))
or self.getObservations()->forAll(obs : cda::Observation | not
obs.oclIsKindOf(phcr::PatientConditionAliveObservation) and not
obs.oclIsKindOf(phcr::PatientConditionDeceasedObservation))
```

Phcr Clinical Information Section example

Phcr Encounters Section

[Section: templateId `2.16.840.1.113883.10.20.15.2.2`]

The PHCR encounters section defines the code and title for all PHCR encounters sections. This generic section also describes clinical statement templates that might be included in a generic PHCR report.

1. **SHALL** conform to *CCD Encounters Section* template (templateId: `2.16.840.1.113883.10.20.1.3`)

2. **SHALL** contain exactly one [1..1] **`code/@code`**`="46240-8"` *History of encounters* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`) (CONF-454, CONF-455)
3. **SHALL** contain exactly one [1..1] **`title`** = "Encounters" (CONF:598)
4. **SHALL** contain exactly one [1..1] **`text`** (CONF:599)
5. **SHOULD** contain at least one [1..*] **`entry`**, such that
   a. Contains exactly one [1..1] *Encounters Activity* (templateId: `2.16.840.1.113883.10.20.1.21`)
6. **SHALL** contain at least one [1..*] **`entry`** (CONF:602, CONF:603, CONF:604), such that
   a. Contains **`@typeCode="`**`DRIV"` *DRIV (is derived from)*
   b. Contains exactly one [1..1] *CCD Encounters Activity* (templateId: `2.16.840.1.113883.10.20.1.21`)
7. **SHOULD** be valued with a case-insensitive language-insensitive text string containing 'encounters'. (CONF-457)
   - UNIMPLEMENTABLE

Phcr Encounters Section example

Phcr Relevant Dx Tests Section

[Section: templateId `2.16.840.1.113883.10.20.15.2.3`]

1. **SHALL** conform to *CCD Results Section* template (templateId: `2.16.840.1.113883.10.20.1.14`)
2. **SHALL** contain exactly one [1..1] **`code/@code`**`="30954-2"` *Relevant diagnostic tests and/or laboratory data* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`) (CONF-389)
3. **SHALL** contain exactly one [1..1] **`title`** = "Relevant diagnostic tests and/or laboratory data" (CONF-391)
4. **SHALL** contain exactly one [1..1] **`text`** (CONF-388, CONF:737)
5. **MAY** contain zero or more [0..*] **`entry`** (CONF:854, CONF:855, CONF:856), such that
   a. Contains **`@typeCode="`**`DRIV"` *DRIV (is derived from)*
   b. Contains exactly one [1..1] *Result Organizer* (templateId: `2.16.840.1.113883.10.20.15.3.59`)
6. **MAY** contain zero or more [0..*] **`entry`** (CONF:2011, CONF:2012, CONF:2013), such that
   a. Contains **`@typeCode="`**`DRIV"` *DRIV (is derived from)*
   b. Contains exactly one [1..1] *Result Observation* (templateId: `2.16.840.1.113883.10.20.15.3.58`)
7. **MAY** contain zero or more [0..*] **`entry`** (CONF:2014, CONF:2015, CONF:2016), such that
   a. Contains **`@typeCode="`**`DRIV"` *DRIV (is derived from)*
   b. Contains exactly one [1..1] *Imaging Observation* (templateId: `2.16.840.1.113883.10.20.15.3.5`)
8. **SHOULD** satisfy: Contains a case-insensitive language-insensitive string containing 'results'. (CONF-392)
   - UNIMPLEMENTABLE

Phcr Relevant Dx Tests Section example

Phcr Social History Section

[Section: templateId `2.16.840.1.113883.10.20.15.2.22`]

The PHCR social history section template contains data defining the patients occupational, personal (e.g., lifestyle), social, and environmental history and health risk factors, as well as administrative data such as race. The section template is constrained beyond the CCD social history section to focus on data of importance to the case report.

1. **SHALL** conform to *CCD Social History Section* template (templateId: `2.16.840.1.113883.10.20.1.15`)
2. **SHALL** contain exactly one [1..1] **`code/@code`**`="29762-2"` *Social History* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`) (CONF:1894)

3. **SHALL** contain exactly one [1..1] **`title`** = "Social History" (CONF:1895)
4. **SHALL** contain exactly one [1..1] **`text`** (CONF:1896)
5. **SHOULD** contain zero or more [0..*] **`entry`**, such that
   a. Contains exactly one [1..1] *Social History Observation* (templateId: `2.16.840.1.113883.10.20.1.33`)
6. **SHOULD** contain zero or more [0..*] **`entry`** (CONF:1897, CONF:1898, CONF:1899), such that
   a. Contains **`@typeCode="DRIV"`** *DRIV (is derived from)*
   b. Contains exactly one [1..1] *Geotemporal History Observation* (templateId: `2.16.840.1.113883.10.20.15.3.3`)
7. **SHOULD** contain zero or one [0..1] **`entry`** (CONF:1900, CONF:1901, CONF:1902), such that
   a. Contains **`@typeCode="DRIV"`** *DRIV (is derived from)*
   b. Contains exactly one [1..1] *Most Recent Time Arrived In USA Observation* (templateId: `2.16.840.1.113883.10.20.15.3.6`)
8. **SHOULD** contain zero or more [0..*] **`entry`** (CONF:1903, CONF:1904, CONF:1905), such that
   a. Contains **`@typeCode="DRIV"`** *DRIV (is derived from)*
   b. Contains exactly one [1..1] *Race Observation* (templateId: `2.16.840.1.113883.10.20.15.3.9`)
9. **SHOULD** contain zero or more [0..*] **`entry`** (CONF:1906, CONF:1907, CONF:1908), such that
   a. Contains **`@typeCode="DRIV"`** *DRIV (is derived from)*
   b. Contains exactly one [1..1] *Occupation Observation* (templateId: `2.16.840.1.113883.10.20.15.3.7`)
10. **MAY** contain zero or more [0..*] **`entry`** (CONF:1909, CONF:1910, CONF:1911), such that
    a. Contains **`@typeCode="DRIV"`** *DRIV (is derived from)*
    b. Contains exactly one [1..1] *Pregnancy Observation* (templateId: `2.16.840.1.113883.10.20.15.3.8`)
11. **SHOULD** satisfy: Contains a case-insensitive language-insensitive string containing 'social history'. (CONF-236)
    - UNIMPLEMENTABLE
12. Marital status **SHOULD** be represented as ClinicalDocument / recordTarget / patientRole / patient / maritalStatusCode. Additional information **MAY** be represented as social history observations (CONF-250)
    - `[OCL]: self.getClinicalDocument().recordTarget->select(r | not r.patientRole.patient.maritalStatusCode.hasContent() )->isEmpty()`
13. Religious affiliation **SHOULD** be represented as ClinicalDocument / recordTarget / patientRole / patient / religiousAffiliationCode. Additional information **MAY** be represented as social history observations (CONF-251)
    - `[OCL]: self.getClinicalDocument().recordTarget->select(r | not r.patientRole.patient.religiousAffiliationCode.hasContent() )->isEmpty()`
14. A patients race **SHOULD** be represented as ClinicalDocument / recordTarget / patientRole / patient / raceCode. Additional information **MAY** be represented as social history observations (CONF-252)
    - `[OCL]: self.getClinicalDocument().recordTarget->select(r | not r.patientRole.patient.raceCode.hasContent() )->isEmpty()`
15. The value for ClinicalDocument / recordTarget / patientRole / patient / raceCode **MAY** be selected from codeSystem 2.16.840.1.113883.5.104 (Race) (CONF-253)
    - `[OCL]: self.getClinicalDocument().recordTarget->forAll(r | r.patientRole.patient.raceCode.codeSystem = '2.16.840.1.113883.5.104' )`
16. A patients ethnicity **SHOULD** be represented as ClinicalDocument / recordTarget / patientRole / patient / ethnicGroupCode. Additional information **MAY** be represented as social history observations. (CONF-254)
    - `[OCL]: self.getClinicalDocument().recordTarget->select(r | not r.patientRole.patient.ethnicGroupCode.hasContent() )->isEmpty()`
17. The value for ClinicalDocument / recordTarget / patientRole / patient / ethnicGroupCode **MAY** be selected from codeSystem 2.16.840.1.113883.5.50 (Ethnicity). (CONF-255)
    - `[OCL]: self.getClinicalDocument().recordTarget->forAll(r | r.patientRole.patient.ethnicGroupCode.codeSystem = '2.16.840.1.113883.5.50' )`

Phcr Social History Section example

Phcr Treatment Information Section

[Section: templateId `2.16.840.1.113883.10.20.15.2.4`]

The PHCR treatment information section defines the code and title for all PHCR treatment information sections. This generic section also describes clinical statement templates that might be included in a generic PHCR report.

1. **SHALL** contain exactly one [1..1] **`code/@code="55753-8"`** *Treatment Information* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`) (CONF:663)
2. **SHALL** contain exactly one [1..1] **`title`** = "Treatment Information" (CONF:664)
3. **SHALL** contain exactly one [1..1] **`text`** (CONF:665)
4. **SHALL** contain exactly one [1..1] **`entry`** (CONF:1959, CONF:1960, CONF:1961), such that
   a. Contains **`@typeCode="DRIV"`** *DRIV (is derived from)*
   b. Contains exactly one [1..1] *Therapeutic Regimen Act* (templateId: `2.16.840.1.113883.10.20.15.3.57`)

Phcr Treatment Information Section example

Chapter 4

CLINICAL STATEMENT TEMPLATES

Topics:

This section of the Implementation Guide details the clinical statement entries referenced in the document section templates. The clinical statement entry templates are arranged alphabetically.

Case Observation

[Observation: templateId `2.16.840.1.113883.10.20.15.3.54`]

This clinical statement represents the case observation and contains the name of the reportable condition, the date of the onset of symptoms, the date of diagnosis, the name of the subject of the case report, along with diagnosing clinician and other clinical details of the case. All known symptom observations should be sent. In some workflows, it should be asserted if it is known the patient did NOT have a typical symptom. This template contains 4 of the 5 data elements determined by the CRSWg to be required when reporting a case to the public health department: reporter name, telephone, and address, and the name of condition. Note that various state and/or local health departments may require additional data elements. Reporters must adhere to local and state rules applicable to their location.

1. **SHALL** conform to *CCD Problem Observation* template (templateId: `2.16.840.1.113883.10.20.1.28`)
2. **SHALL** contain exactly one [1..1] **`@classCode="OBS"`** *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF:1868)
3. **SHALL** contain exactly one [1..1] **`@moodCode="EVN"`** *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:1869)
4. **MAY** contain zero or more [0..*] **`id`** (CONF:1870)
5. **SHALL** contain exactly one [1..1] **`code/@code="ASSERTION"`** (CodeSystem: `2.16.840.1.113883.5.4 HL7ActCode`) (CONF:1871)
6. **SHALL** contain exactly one [1..1] **`statusCode/@code="completed"`** (CodeSystem: `2.16.840.1.113883.5.14 ActStatus`) (CONF:1872)
7. **SHOULD** contain zero or one [0..1] **`effectiveTime`** (CONF:1873)
8. **SHALL** contain exactly one [1..1] **`value`**, where its data type is CD (CONF:1874)
9. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF-162), such that
   a. Contains **`@typeCode="REFR"`** *REFR (refers to)*
   b. Contains exactly one [1..1] *Problem Status Observation* (templateId: `2.16.840.1.113883.10.20.1.50`)
10. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF-165), such that
    a. Contains **`@typeCode="REFR"`** *REFR (refers to)*
    b. Contains exactly one [1..1] *Problem Health Status Observation* (templateId: `2.16.840.1.113883.10.20.1.51`)
11. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF-160), such that
    a. Contains **`@typeCode="SUBJ"`** *SUBJ (has subject)*
    b. Contains exactly one [1..1] *Age Observation* (templateId: `2.16.840.1.113883.10.20.1.38`)
12. **SHOULD** contain zero or one [0..1] **`entryRelationship`** (CONF:1884, CONF:1885, CONF:1886), such that
    a. Contains **`@typeCode="REFR"`** *REFR (refers to)*
    b. Contains exactly one [1..1] *CCD Problem Status Observation* (templateId: `2.16.840.1.113883.10.20.1.50`)
13. **SHOULD** contain zero or more [0..*] **`entryRelationship`** (CONF:1887, CONF:1888, CONF:1890), such that
    a. Contains **`@typeCode="MFST"`** *MFST (is manifestation of)*
    b. Contains exactly one [1..1] *Signs And Symptoms Observation* (templateId: `2.16.840.1.113883.10.20.15.3.53`)
14. **SHALL** contain one or more sources of information. (CONF-161)

- ```
  [OCL]: not self.informant->isEmpty()
  or not self.getSection().informant->isEmpty()
  or not self.getClinicalDocument().informant->isEmpty()
  or self.reference->exists(ref : cda::Reference | ref.typeCode =
   vocab::x_ActRelationshipExternalReference::XCRPT)
  ```
  ```

```
or (self.entryRelationship->exists(rel : cda::EntryRelationship |
   rel.typeCode = vocab::x_ActRelationshipEntryRelationship::REFR
   and rel.observation.code.code = '48766-0'))
```

15. **MAY** contain exactly one Patient Awareness (CONF-180)
    - `[OCL]: self.participant->one(partic : cda::Participant2 | partic.oclIsKindOf(ccd::PatientAwareness))`
16. **SHOULD** contain [0..1] effectiveTime/low (CONF:1873)
    - `[OCL]: self.effectiveTime->exists(time : datatypes::IVL_TS | not time.low.oclIsUndefined())`
17. **SHOULD** contain [0..1] author (CONF:1875)
    - `[OCL]: self.author->exists(author : cda::Author | not author.oclIsUndefined())`
18. Author **SHALL** contain [1..1] time (CONF:1876)
19. Author **SHALL** contain [1..1] assignedAuthor (CONF:1877)
    - `[OCL]: self.author.assignedAuthor->exists(assignedAuthor : cda::AssignedAuthor | not assignedAuthor.oclIsUndefined())`
20. Author / AssignedAuthor **SHALL** contain [1..*] id (CONF:1878)
21. Author / AssignedAuthor **MAY** contain [0..*] addr (CONF:1879)
22. Author / AssignedAuthor **MAY** contain [0..*] telecom (CONF:1880)
23. Author / AssignedAuthor **MAY** contain [0..1] assignedPerson (CONF:1881)
24. Author / AssignedAuthor / Person **MAY** contain [0..1] name (CONF:1882)
25. Author / AssignedAuthor **MAY** contain [0..1] representedOrganization (CONF:1883)

Case Observation example

Estimated Date Of Delivery Observation

[Observation: templateId `2.16.840.1.113883.10.20.15.3.1`]

This clinical statement represents the anticipated date when a woman will give birth.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF:444)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:445)
3. **SHALL** contain exactly one [1..1] **`code/@code`**`="11778-8"` *Estimated Date of Delivery* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`) (CONF:446)
4. **SHALL** contain exactly one [1..1] **`statusCode/@code`**`="completed"` (CodeSystem: `2.16.840.1.113883.5.14 ActStatus`) (CONF:448)
5. **SHALL** contain exactly one [1..1] **`value`**, where its data type is TS (CONF:450)

Estimated Date Of Delivery Observation example

```
<entryRelationship typeCode="REFR">
  <!-- Estimated date of Delivery entry -->
  <observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.15.3.1" />
    <code code="11778-8" codeSystem="2.16.840.1.113883.6.1"
 displayName="Estimated delivery date" />
    <statusCode code="completed" />
    <value xsi:type="TS" value="20090215" />
  </observation>
</entryRelationship>
```

Geotemporal History Observation

[Observation: templateId `2.16.840.1.113883.10.20.15.3.3`]

This clinical statement represents locations within or out of the US that are potentially relevant to current condition. A text element is available for embellishing the observation.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF:420)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:421)
3. **SHALL** contain exactly one [1..1] **`code/@code`**`="55210-9"` *Geotemporal History* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`) (CONF:422)
4. **MAY** contain zero or one [0..1] **`text`** (CONF:1287)
5. **SHALL** contain exactly one [1..1] **`statusCode/@code`**`="completed"` (CodeSystem: `2.16.840.1.113883.5.14 ActStatus`) (CONF:423)
6. **SHOULD** contain zero or one [0..1] **`effectiveTime`** (CONF:424)
7. **SHALL** contain exactly one [1..1] **`value`**, which **SHALL** be selected from ValueSet `2.16.840.1.114222.4.11.3201 Geographical Location History` **STATIC**, where its data type is CD (CONF:425)

Geotemporal History Observation example

```
<entry typeCode="DRIV">
  <!-- Geotemporal History Observations-->
  <observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.15.3.3"/>
    <code code="55210-9" codeSystem="2.16.840.1.113883.6.1"
 displayName="Geotemporal History"/>
    <statusCode code="completed"/>
    <effectiveTime>
      <low value="1985"/>
      <high value="1993"/>
    </effectiveTime>
    <value xsi:type="CD" code="THA" codeSystem="1.0.3166.1"
 displayName="Thailand"/>
  </observation>
</entry>
```

Imaging Observation

[Observation: templateId `2.16.840.1.113883.10.20.15.3.5`]

This clinical statement represents radiologic image findings. It may be a simple coded value of an overall impression of a study, such as "radiologic infiltrates" and a statement of the procedure method that was used, such as "standard chest x-ray". Or, it could be an assertion of a finding with a narrative text explanation similar to the "Impression" section of a radiology report. It may also reference an external diagnostic image or the entire external document radiology report. The code/value can be coded (e.g., assertion: nodule) or it can be largely narrative (e.g., finding: A complete white out of left lung seen. The chest tube is dislodged.).

1. **SHALL** conform to *CCD Problem Observation* template (templateId: `2.16.840.1.113883.10.20.1.28`)
2. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF:829)
3. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF-155, CONF:830)

4. **SHALL** contain at least one [1..*] **`id`** (CONF:821)
5. **MAY** contain exactly one [1..1] **`code`**, which **MAY** be selected from ValueSet `2.16.840.1.113883.1.11.20.14 ProblemTypeCode` **STATIC** 20061017 (CONF-159)
6. **SHALL** contain exactly one [1..1] **`statusCode/@code`**`="completed"` (CodeSystem: `2.16.840.1.113883.5.14 ActStatus`) (CONF-156, CONF-157)
7. **SHOULD** contain exactly one [1..1] **`effectiveTime`** (CONF-158, CONF:824)
8. **SHALL** contain exactly one [1..1] **`value`** (CONF:825)
9. **MAY** contain zero or one [0..1] **`methodCode`** (CONF:826)
10. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF-162), such that
    a. Contains **`@typeCode="`**`REFR"` *REFR (refers to)*
    b. Contains exactly one [1..1] *Problem Status Observation* (templateId: `2.16.840.1.113883.10.20.1.50`)
11. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF-165), such that
    a. Contains **`@typeCode="`**`REFR"` *REFR (refers to)*
    b. Contains exactly one [1..1] *Problem Health Status Observation* (templateId: `2.16.840.1.113883.10.20.1.51`)
12. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF-160), such that
    a. Contains **`@typeCode="`**`SUBJ"` *SUBJ (has subject)*
    b. Contains exactly one [1..1] *Age Observation* (templateId: `2.16.840.1.113883.10.20.1.38`)
13. **SHALL** contain one or more sources of information. (CONF-161)

```
[OCL]: not self.informant->isEmpty()
or not self.getSection().informant->isEmpty()
or not self.getClinicalDocument().informant->isEmpty()
or self.reference->exists(ref : cda::Reference | ref.typeCode =
 vocab::x_ActRelationshipExternalReference::XCRPT)
or (self.entryRelationship->exists(rel : cda::EntryRelationship |
   rel.typeCode = vocab::x_ActRelationshipEntryRelationship::REFR
   and rel.observation.code.code = '48766-0'))
```

14. **MAY** contain exactly one Patient Awareness (CONF-180)

```
[OCL]: self.participant->one(partic : cda::Participant2 |
 partic.oclIsKindOf(ccd::PatientAwareness))
```

15. **MAY** contain [1..1] externalObservation (CONF:827, CONF:828, CONF:831)
16. **MAY** contain [1..1] externalDocument (CONF:842, CONF:843, CONF:844)

Imaging Observation example

Most Recent Time Arrived In USA Observation

[Observation: templateId `2.16.840.1.113883.10.20.15.3.6`]

This clinical statement represents the date that the subject most recently arrived into the US.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF:426)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:427)
3. **SHALL** contain exactly one [1..1] **`code/@code`**`="55209-1"` *Most Recent Time Arrived in USA* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`) (CONF:428)
4. **SHALL** contain exactly one [1..1] **`statusCode/@code`**`="completed"` (CodeSystem: `2.16.840.1.113883.5.14 ActStatus`) (CONF:429)
5. **SHALL** contain exactly one [1..1] **`value`**, where its data type is TS (CONF:431)

Most Recent Time Arrived In USA Observation example

Occupation Observation

[Observation: templateId `2.16.840.1.113883.10.20.15.3.7`]

This clinical statement represents the occupation of the subject of the case report. The values are coded values from the Standard Occupational Classification (SOC) system used by federal statistical agencies to classify workers into occupational categories for the purpose of collecting, calculating, or disseminating data. A text element is available for embellishing the observation. The template allows for representation of the name and address of the employer. As much detail should be entered as possible. This information is used by public health departments in their investigation to determine the occupation of the subject of the case report. An observation of occupation may be negated (e.g., not a Healthcare Worker) if it is specifically known that the subject of the case report did or does NOT hold an occupation of interest/risk. In addition, this template allows for the representation of the related industry using codes from the Industry (NAICS).

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF:437)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:438)
3. **MAY** contain zero or one [0..1] **`@negationInd`** (CONF:1284)
4. **SHALL** contain exactly one [1..1] **`code/@code`**`="11341-5"` *History of Occupation* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`) (CONF:439)
5. **MAY** contain zero or one [0..1] **`text`**
6. **SHALL** contain exactly one [1..1] **`statusCode/@code`**`="completed"` (CodeSystem: `2.16.840.1.113883.5.14 ActStatus`) (CONF:440)
7. **SHOULD** contain zero or one [0..1] **`effectiveTime`** (CONF:443)
8. **SHALL** contain exactly one [1..1] **`value`**, which **SHALL** be selected from ValueSet `2.16.840.1.114222.4.11.887 Occupation` **STATIC**, where its data type is CD (CONF:441)
9. **MAY** contain [0..1] participant (CONF:2170)
10. **SHOULD** contain [0..*] Occupation Industry History Observations

Occupation Observation example

Patient Condition Alive Observation

[Observation: templateId `2.16.840.1.113883.10.20.15.3.42`]

This clinical statement represents the observation that the subject of the case report was alive at the time of the report.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF:1591)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:1592)
3. **SHALL** contain exactly one [1..1] **`code/@code`**`="ASSERTION"` (CodeSystem: `2.16.840.1.113883.5.4 HL7ActCode`) (CONF:1593)
4. **SHALL** contain exactly one [1..1] **`statusCode/@code`**`="completed"` (CodeSystem: `2.16.840.1.113883.5.14 ActStatus`) (CONF:1594)
5. **SHOULD** contain zero or one [0..1] **`effectiveTime`** (CONF:1595)
6. **SHALL** contain exactly one [1..1] **`value/@code`**`="438949009"` *Alive* (CodeSystem: `2.16.840.1.113883.6.96 SNOMEDCT`), where its data type is CD (CONF:1597)

Patient Condition Alive Observation example

Patient Condition Deceased Observation

[Observation: templateId `2.16.840.1.113883.10.20.15.3.17`]

This clinical statement represents the observation that the subject of the case report was deceased at the time of the report. It also represents if the death was caused by the condition being reported. The entryRelationship type of CAUS provides the link together with the observation/id and observation value as to whether or not the condition caused the death. A negationIndicator of false means the condition caused the death. A negationIndicator of true means the condition did not cause the death.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF:482)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:483)
3. **SHALL** contain exactly one [1..1] **`code/@code`**`="ASSERTION"` (CodeSystem: `2.16.840.1.113883.5.4 HL7ActCode`) (CONF:485)
4. **SHALL** contain exactly one [1..1] **`statusCode/@code`**`="completed"` (CodeSystem: `2.16.840.1.113883.5.14 ActStatus`) (CONF:486)
5. **SHOULD** contain zero or one [0..1] **`effectiveTime`** (CONF:487)
6. **SHALL** contain exactly one [1..1] **`value/@code`**`="419099009"` *Dead* (CodeSystem: `2.16.840.1.113883.6.96 SNOMEDCT`), where its data type is CD (CONF:488)
7. **SHALL** contain a Patient Condition Deceased Cause Observation (CONF:1581, CONF:1582, CONF:1584)

Patient Condition Deceased Observation example

Phcr Relevant Medical Condition History Observation

[Observation: templateId `2.16.840.1.113883.10.20.15.3.62`]

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`)
3. **MAY** contain zero or one [0..1] **`@negationInd`**
4. **SHALL** contain exactly one [1..1] **`code/@code`**`="ASSERTION"` (CodeSystem: `2.16.840.1.113883.5.4 HL7ActCode`)
5. **SHALL** contain exactly one [1..1] **`statusCode/@code`**`="completed"` (CodeSystem: `2.16.840.1.113883.5.14 ActStatus`)
6. **SHOULD** contain zero or one [0..1] **`effectiveTime`**
7. **SHALL** contain exactly one [1..1] **`value`**, which **SHALL** be selected from ValueSet *`Relevant Medical Condition Type`* **DYNAMIC**, where its data type is CD
8. **SHOULD** contain zero or more [0..*] **`entryRelationship`**, such that
   a. Contains **`@typeCode="`**`REFR"` *REFR (refers to)*
   b. Contains exactly one [1..1] *CCD Problem Observation* (templateId: `2.16.840.1.113883.10.20.1.28`)

Phcr Relevant Medical Condition History Observation example

Pregnancy Observation

[Observation: templateId `2.16.840.1.113883.10.20.15.3.8`]

This clinical statement represents current and/or prior pregnancy dates enabling investigators to determine if the subject of the case report was pregnant during the course of a condition.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF:451)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:452)
3. **SHALL** contain exactly one [1..1] **`code/@code`**`="ASSERTION"` (CodeSystem: `2.16.840.1.113883.5.4 HL7ActCode`) (CONF:454)
4. **SHALL** contain exactly one [1..1] **`statusCode/@code`**`="completed"` (CodeSystem: `2.16.840.1.113883.5.14 ActStatus`) (CONF:455)
5. **SHOULD** contain zero or one [0..1] **`effectiveTime`** (CONF:2018)
6. **SHALL** contain exactly one [1..1] **`value/@code`**`="77386006"` *Pregnant* (CodeSystem: `2.16.840.1.113883.6.96 SNOMEDCT`), where its data type is CD (CONF:457)
7. **MAY** contain zero or one [0..1] **`entryRelationship`** (CONF:458, CONF:459, CONF:460), such that
   a. Contains **`@typeCode="`**`REFR"` *REFR (refers to)*
   b. Contains exactly one [1..1] *Estimated Date Of Delivery Observation* (templateId: `2.16.840.1.113883.10.20.15.3.1`)

Pregnancy Observation example

Race Observation

[Observation: templateId `2.16.840.1.113883.10.20.15.3.9`]

This clinical statement represents the race of the subject of the case report.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF:432)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:433)
3. **SHALL** contain exactly one [1..1] **`code/@code`**`="32624-9"` *Race* (CodeSystem: `2.16.840.1.113883.6.1 LOINC`) (CONF:434)
4. **SHALL** contain exactly one [1..1] **`statusCode/@code`**`="completed"` (CodeSystem: `2.16.840.1.113883.5.14 ActStatus`) (CONF:435)
5. **SHALL** contain exactly one [1..1] **`value`**, which **SHALL** be selected from ValueSet `2.16.840.1.113883.1.11.14914 Race` **STATIC**, where its data type is CD (CONF:436)

Race Observation example

```
<entry typeCode="DRIV">
  <!-- Race observations -->
  <observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.15.3.9" />
    <code code="32624-9" codeSystem="2.16.840.1.113883.6.1"
 displayName="Race" />
    <statusCode code="completed" />
    <value xsi:type="CD" code="1002-5" codeSystem="2.16.840.1.113883.6.238"
           displayName="AMERICAN INDIAN OR ALASKA NATIVE" />
  </observation>
```

```
</entry>
```

Result Observation

[Observation: templateId `2.16.840.1.113883.10.20.15.3.58`]

1. **SHALL** conform to *CCD Result Observation* template (templateId: `2.16.840.1.113883.10.20.1.31`)
2. **SHALL** contain exactly one [1..1] **`@classCode="OBS"`** *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF:1967)
3. **SHALL** contain exactly one [1..1] **`@moodCode="EVN"`** *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF-408)
4. **SHALL** contain at least one [1..*] **`id`** (CONF-409)
5. **SHALL** contain exactly one [1..1] **`code`** (CONF-412)
6. **SHALL** contain exactly one [1..1] **`statusCode/@code="completed"`** (CodeSystem: `2.16.840.1.113883.5.14 ActStatus`) (CONF:1971)
7. **SHOULD** contain exactly one [1..1] **`effectiveTime`** (CONF-411)
   - Represents the biologically relevant time (e.g. time the specimen was obtained from the patient).
8. **SHALL** contain exactly one [1..1] **`value`** (CONF-416)
9. **SHOULD** contain zero or more [0..*] **`interpretationCode`** (CONF-418)
   - Can be used to provide a rough qualitative interpretation of the observation, such as 'N' (normal), 'L' (low), 'S' (susceptible), etc. Interpretation is generally provided for numeric results where an interpretation range has been defined, or for antimicrobial susceptibility test interpretation.
10. **MAY** contain zero or one [0..1] **`methodCode`** (CONF-414)
    - Included if the method isn't inherent in code or if there is a need to further specialize the method in code.
11. **MAY** contain zero or more [0..*] **`entryRelationship`** (CONF:1990), such that
    a. Contains **`@typeCode="REFR"`** *REFR (refers to)*
    b. Contains exactly one [1..1] *Specimen Collection Procedure* (templateId: `2.16.840.1.113883.10.20.15.3.2`)
12. **MAY** contain zero or more [0..*] **`entryRelationship`** (CONF:1993), such that
    a. Contains **`@typeCode="COMP"`** *COMP (has component)*
    b. Contains exactly one [1..1] *Susceptibility Result* (templateId: `2.16.840.1.113883.10.20.15.3.10`)
13. The value for '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). (CONF-413)
    - ```
      [OCL]: self.code.codeSystem = '2.16.840.1.113883.6.1' xor
       self.code.codeSystem = '2.16.840.1.113883.6.96' xor self.code.codeSystem
       = '2.16.840.1.113883.6.12'
      ```
14. The methodCode **SHALL NOT** conflict with the method inherent in code (CONF-415)
    - UNIMPLEMENTABLE
15. Where value is a physical quantity, the unit of measure **SHALL** be expressed using a valid Unified Code for Units of Measure (UCUM) expression. (CONF-417)
    - UNIMPLEMENTABLE
16. **SHOULD** satisfy: Contain one or more referenceRange to show the normal range of values for the observation result (CONF-419)
    - ```
      [OCL]: not self.referenceRange->isEmpty()
      ```
17. **SHALL NOT** contain referenceRange / observationRange / code, as this attribute is not used by the HL7 Clinical Statement or Lab Committee models. (CONF-420)
    - ```
      [OCL]: self.referenceRange->forAll(range : cda::ReferenceRange |
       range.observationRange.code.code.oclIsUndefined())
      ```
      ```

18. **SHALL** satisfy: Contains one or more sources of information. (CONF-421)

- ```
  [OCL]: not self.informant->isEmpty()
  or not self.getSection().informant->isEmpty()
  or not self.getClinicalDocument().informant->isEmpty()
  or self.reference->exists(ref : cda::Reference | ref.typeCode =
   vocab::x_ActRelationshipExternalReference::XCRPT)
  or (self.entryRelationship->exists(rel : cda::EntryRelationship |
     rel.typeCode = vocab::x_ActRelationshipEntryRelationship::REFR
     and rel.observation.code.code = '48766-0'))
  ```

Result Observation example

Result Organizer

[Organizer: templateId `2.16.840.1.113883.10.20.15.3.59`]

The PHCR result organizer identifies an observation set, contained within the result organizer as a set of result observations. It contains information applicable to all of the contained result observations. It is particularly useful to group a number of tests, such as culture results, that are performed on a common specimen. Note: Where there is a specimen, one can set the specimenRole/id to equal the specimen collection procedure's participantRole[@classCode="SPEC"]/id in order to assert that this observation is being made on the specimen collected in the corresponding specimen collection procedure.

1. **SHALL** conform to *CCD Result Organizer* template (templateId: `2.16.840.1.113883.10.20.1.32`)
2. **SHALL** contain exactly one [1..1] **`@classCode`**`="BATTERY"` (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF:1996)
3. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF-394, CONF:1997)
4. **SHALL** contain at least one [1..*] **`id`** (CONF-395, CONF:1998)
5. **SHALL** contain exactly one [1..1] **`code`** (CONF-397, CONF:1999)
6. **SHALL** contain exactly one [1..1] **`statusCode/@code`**`="completed"` (CodeSystem: `2.16.840.1.113883.5.14 ActStatus`) (CONF:2000)
7. **SHALL** contain exactly one [1..1] **`effectiveTime`** (CONF:2001)
8. **SHOULD** contain at least one [1..*] **`specimen`** (CONF-399), such that
   - Should be included if the specimen isn't inherent in code value.
9. **SHALL** contain at least one [1..*] **`component`** (CONF:2008), such that
   a. Contains exactly one [1..1] *Result Observation* (templateId: `2.16.840.1.113883.10.20.15.3.58`)
10. **MAY** contain zero or one [0..1] **`component`** (CONF:2009, CONF:2010), such that
    a. Contains exactly one [1..1] *Specimen Collection Procedure* (templateId: `2.16.840.1.113883.10.20.15.3.2`)
11. The value for 'code' in a result organizer **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 ValueSet 2.16.840.1.113883.1.11.20.16 ResultTypeCode STATIC. (CONF-398)
    - ```
      [OCL]: self.code.codeSystem = '2.16.840.1.113883.6.1' xor
       self.code.codeSystem = '2.16.840.1.113883.6.96' xor self.code.codeSystem
       = '2.16.840.1.113883.6.12' xor self.code.codeSystem =
       '2.16.840.1.113883.1.11.20.16'
      ```
12. The specimen element **SHALL NOT** conflict with the specimen inherent in code (CONF-400)
    - UNIMPLEMENTABLE
13. specimen / specimenRole / id **SHOULD** be set to equal a Procedure / specimen / specimenRole / id to indicate that the Results and the Procedure are referring to the same specimen. (CONF-401)

- UNIMPLEMENTABLE

14. **SHALL** satisfy: Contains one or more component (CONF-402)
    - `[OCL]: not self.component->isEmpty()`
15. The target of one or more result organizer component relationships **MAY** be a procedure, to indicate the means or technique by which a result is obtained, particularly if the means or technique isn't inherent in code or if there is a need to further specialize the code value. (CONF-403)
    - UNIMPLEMENTABLE
16. A result organizer component / procedure **MAY** be a reference to a procedure described in the Procedure section. (CONF-404)
    - UNIMPLEMENTABLE
17. **SHALL** satisfy: Contains one or more sources of information. (CONF-406)
    -
    ```
    [OCL]: not self.informant->isEmpty()
    or not self.getSection().informant->isEmpty()
    or not self.getClinicalDocument().informant->isEmpty()
    or self.reference->exists(ref : cda::Reference | ref.typeCode =
     vocab::x_ActRelationshipExternalReference::XCRPT)
    ```

Result Organizer example

Signs And Symptoms Observation

[Observation: templateId `2.16.840.1.113883.10.20.15.3.53`]

This clinical statement is available to represent the signs and symptoms that are associated with the condition. In some workflows, information will also be sent if explicitly known that a common symptom was NOT observed.

1. **SHALL** contain exactly one [1..1] **`@classCode`**`="OBS"` *Observation* (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF:1861)
2. **SHALL** contain exactly one [1..1] **`@moodCode`**`="EVN"` *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:1862)
3. **SHALL** contain exactly one [1..1] **`@negationInd`** (CONF:1863)
4. **SHALL** contain exactly one [1..1] **`code/@code`**`="ASSERTION"` (CodeSystem: `2.16.840.1.113883.5.4 HL7ActCode`) (CONF:1864)
5. **SHALL** contain exactly one [1..1] **`statusCode/@code`**`="completed"` (CodeSystem: `2.16.840.1.113883.5.14 ActStatus`) (CONF:1865)
6. **SHOULD** contain zero or one [0..1] **`effectiveTime`** (CONF:1866)
7. **SHALL** contain exactly one [1..1] **`value`**, where its data type is CD (CONF:1867)
8. PHCR Case Observation **SHOULD** contain zero or more [0..*] entryRelationship (CONF:1887, CONF:1888, CONF:1890), such that Contains @typeCode="MFST" MFST (is manifestation of), such that Contains @inversionInd="true", and Contains exactly one [1..1] Signs And Symptoms Observation (templateId: 2.16.840.1.113883.10.20.15.3.53) (CONF:1889)

Signs And Symptoms Observation example

Specimen Collection Procedure

[Procedure: templateId `2.16.840.1.113883.10.20.15.3.2`]

This clinical statement represents clinical information about the specimen and administrative data such as where (e.g., the name of the lab) the specimen was collected.

1. **SHALL** contain exactly one [1..1] **@classCode**="PROC" (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) (CONF:691)
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) (CONF:692)
3. **SHALL** contain exactly one [1..1] **code**, which **SHALL** be selected from ValueSet 2.16.840.1.114222.4.11.3204 Non-Laboratory Intervention and Procedure **STATIC** (CONF:693)
4. **SHOULD** contain zero or one [0..1] **effectiveTime** (CONF:694)
5. **SHOULD** contain zero or one [0..1] **targetSiteCode**, which **SHOULD** be selected from ValueSet 2.16.840.1.113883.3.88.12.3221.8.9 Body Site **DYNAMIC** (CONF:695)

Specimen Collection Procedure example

Susceptibility Result

[Observation: templateId 2.16.840.1.113883.10.20.15.3.10]

This clinical statement represents the susceptibility of an organism to an antibiotic. Note that participantRole/id shall be set to equal the result observation templateId observation/participant/participantRole/id to show that these susceptibilities are performed on the referenced organism.

1. **SHALL** contain exactly one [1..1] **@classCode**="OBS" *Observation* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) (CONF:771)
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) (CONF:772)
3. **SHALL** contain exactly one [1..1] **code/@code**="18769-0" *Microbial susceptibility tests* (CodeSystem: 2.16.840.1.113883.6.1 LOINC) (CONF:773)
4. **SHALL** contain exactly one [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus) (CONF:774)
5. **SHALL** contain [1..1] participant (CONF:775)
6. **SHALL** contain [1..*] observation (CONF:782, CONF:926, CONF:783)

Susceptibility Result example

Therapeutic Regimen Act

[Act: templateId 2.16.840.1.113883.10.20.15.3.57]

This clinical statement represents if treatment was administered for the reported condition. A negationInd "false" means treatment was given. A negationInd "true" means treatment was not given. If treatment(s) were given, they should be reflected in corresponding "PHCR treatment given" template(s). "PHCR treatment not given" templates may also be present.

1. **SHALL** contain exactly one [1..1] **@classCode**="ACT" *Act* (CodeSystem: 2.16.840.1.113883.5.6 HL7ActClass) (CONF:1940)
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" *Event* (CodeSystem: 2.16.840.1.113883.5.1001 HL7ActMood) (CONF:1941)
3. **SHALL** contain exactly one [1..1] **@negationInd** (CONF:1942)
4. **SHALL** contain exactly one [1..1] **code/@code**="133877004" *Therapeutic regimen* (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT) (CONF:1943)
5. **SHALL** contain exactly one [1..1] **statusCode/@code**="completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus) (CONF:1944)

6. **SHOULD** contain zero or more [0..*] **`entryRelationship`** (COMP:1953, COMP:1954, COMP:1955), such that
   a. Contains **`@typeCode="COMP"`** *COMP (has component)*
   b. Contains exactly one [1..1] *Treatment Given Substance Administration* (templateId: `2.16.840.1.113883.10.20.15.3.55`)
7. **MAY** contain zero or more [0..*] **`entryRelationship`** (COMP:1956, COMP:1957, COMP:1958), such that
   a. Contains **`@typeCode="COMP"`** *COMP (has component)*
   b. Contains exactly one [1..1] *Treatment Not Given Substance Administration* (templateId: `2.16.840.1.113883.10.20.15.3.56`)
8. **SHALL**

Therapeutic Regimen Act example

Treatment Given Substance Administration

[SubstanceAdministration: templateId `2.16.840.1.113883.10.20.15.3.55`]

This clinical statement represents treatments administered to the subject of the case report, for treatment of reported condition.

1. **SHALL** contain exactly one [1..1] **`@classCode="SBADM"`** (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF:1919)
2. **SHALL** contain exactly one [1..1] **`@moodCode="EVN"`** *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:1920)
3. **SHALL** contain exactly one [1..1] **`@negationInd`** (CONF:1921)
4. **SHALL** contain exactly one [1..1] **`statusCode`** (CodeSystem: `2.16.840.1.113883.5.14 ActStatus`) (CONF:1922)
5. **SHOULD** contain zero or one [0..1] **`effectiveTime`** (CONF:1923)
6. **SHALL** contain zero or one [0..1] **`routeCode`**, which **SHALL** be selected from ValueSet `2.16.840.1.113883.3.88.12.3221.8.7` *`Medication Route FDA`* **DYNAMIC** (CONF:1925)
7. Contains exactly one [1..1] **`consumable`**, where its type is *Consumable*
8. **SHOULD** satisfy: Should contain [0..1] low (CONF:1924)
9. **SHALL** satisfy: Shall contain consumable (CONF:1926)
10. **SHALL** contain exactly one [1..1] @negationInd="false" (CONF:1921)
    - `[OCL]: self.negationInd=false`

Treatment Given Substance Administration example

Treatment Not Given Substance Administration

[SubstanceAdministration: templateId `2.16.840.1.113883.10.20.15.3.56`]

This clinical statement represents treatments not administered to the subject of the case report for the treatment of the reported condition. Some workflows may require reporting of typical treatments that were NOT administered.

1. **SHALL** contain exactly one [1..1] **`@classCode="SBADM"`** (CodeSystem: `2.16.840.1.113883.5.6 HL7ActClass`) (CONF:1931)
2. **SHALL** contain exactly one [1..1] **`@moodCode="EVN"`** *Event* (CodeSystem: `2.16.840.1.113883.5.1001 HL7ActMood`) (CONF:1932)

3. **SHALL** contain exactly one [1..1] **`@negationInd`** (CONF:1933)
4. **SHALL** contain exactly one [1..1] **`statusCode/@code`**`="completed"` (CodeSystem: `2.16.840.1.113883.5.14 ActStatus`) (CONF:1934)
5. Contains exactly one [1..1] **`consumable`**, where its type is *Consumable*
6. **SHALL** satisfy: Shall contain consumable (CONF:1935)
7. **SHALL** contain exactly one [1..1] @negationInd="true" (CONF:1933)
   - `[OCL]: self.negationInd=true`

Treatment Not Given Substance Administration example

Chapter 5

OTHER CLASSES

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

Chapter 6

VALUE SETS

Topics:

All CDA PHCR Value Sets may be accessed in PHIN VADS via Public Health Case Reporting (CDA) Value Sets. In addition each PHIN VADS valueSetCode in this table links to the corresponding value set in PHIN VADS. For PHIN VADS questions or problems, please contact PHIN VADS via: phinvs@cdc.gov.

Administrative Gender (HL7 V3)

Value Set	Administrative Gender (HL7 V3) - 2.16.840.1.113883.1.11.1
Source	PHIN VADS
Source URL	https://phinvads.cdc.gov/vads/ViewValueSet.action?oid=2.16.840.1.113883.1.11.1
Definition	Administrative Gender based upon HL7 V3 vocabulary. This value set contains only male, female and undifferentiated concepts.

Concept Code	Concept Name	Code System	Description
M	Male	AdministrativeGenderCode	
F	Female	AdministrativeGenderCode	
UN	Undifferentiated	AdministrativeGenderCode	

Birth Country

Value Set	Birth Country - 2.16.840.1.114222.4.11.3200
Code System	Country (ISO 3166-1) - 1.0.3166.1
Source	PHIN VADS
Source URL	https://phinvads.cdc.gov/vads/ViewValueSet.action?oid=2.16.840.1.114222.4.11.3200
Definition	Country of Birth value set includes current countries as well as historical countries (eg. USSR). This value set is based upon ISO 3166-1, Alpha-3 codes (current countries), ISO 3166-3 (retired countries) and FIPS 10-4 (US Territories, Countries that are not found in ISO 3166)

Body Site

Value Set	Body Site - 2.16.840.1.113883.3.88.12.3221.8.9
Source	PHIN VADS
Source URL	https://phinvads.cdc.gov/vads/ViewValueSet.action?oid=2.16.840.1.113883.3.88.12.3221.8.9
Definition	Body site value set is based upon the concepts descending from the SNOMED CT Anatomical Structure (91723000) hierarchy.

Drug Susceptibility Test Result Name

Value Set	Drug Susceptibility Test Result Name - 2.16.840.1.114222.4.11.1071
Code System	LOINC - 2.16.840.1.113883.6.1
Source	PHIN VADS
Source URL	https://phinvads.cdc.gov/vads/ViewValueSet.action?oid=2.16.840.1.114222.4.11.1071
Definition	Drug / Antimicrobial Test Result Name

Ethnicity Group

Value Set	Ethnicity Group - 2.16.840.1.114222.4.11.837
Source	PHIN VADS
Source URL	https://phinvads.cdc.gov/vads/ViewValueSet.action?oid=2.16.840.1.114222.4.11.837
Definition	Whether the patient is hispanic or not

Concept Code	Concept Name	Code System	Description
2135-2	Hispanic or Latino	Race and Ethnicity - CDC	
2186-5	Not Hispanic or Latino	Race and Ethnicity - CDC	

Exposure Location

Value Set	Exposure Location - 2.16.840.1.114222.4.11.3209
Source	PHIN VADS
Source URL	https://phinvads.cdc.gov/vads/ViewValueSet.action?oid=2.16.840.1.114222.4.11.3209
Definition	Locations that have been identified by public health departments as locations that have been associated with higher risk of coming into contact with infectious diseases such as tuberculosis and Hepatitis B

Concept Code	Concept Name	Code System	Description
224864007	College	SNOMEDCT	
285202004	Community environment	SNOMEDCT	
1348009	Day care center	SNOMEDCT	
PHC46	Federal Prison	PHIN VS (CDC Local Coding System)	
264362003	Home	SNOMEDCT	
22232009	Hospital	SNOMEDCT	
PHC221	Hospital-Based Facility	PHIN VS (CDC Local	

Concept Code	Concept Name	Code System	Description
		Coding System)	
8434001	Jail	SNOMEDCT	
46274009	Jet airplane	SNOMEDCT	
C0680668	Juvenile Correctional Facility	UMLS	
PHC62	Local Jail	PHIN VS (CDC Local Coding System)	
32074000	Long term care hospital	SNOMEDCT	
282E00000X	Long-Term Care Facility Healthcare	Healthcare Provider Taxonomy (HIPAA)	
C0028688	Nursing Home	UMLS	
283Q00000X	Psychiatric Hospital	Healthcare Provider Taxonomy (HIPAA)	
C0035187	Residential Facility	UMLS	
257698009	School	SNOMEDCT	
324500000X	Substance Abuse Disorder Rehabilitation	Healthcare Provider Taxonomy (HIPAA)	
285141008	Work environment	SNOMEDCT	

Geographical location history

Value Set	Geographical location history - 2.16.840.1.114222.4.11.3201
Source	PHIN VADS
Source URL	https://phinvads.cdc.gov/vads/ViewValueSet.action?oid=2.16.840.1.114222.4.11.3201
Definition	Locations out of US (Birth Country) and jurisdictions within US (states) that are potentially relevent to current condition. This value set is based upon ISO 3166 (Countries) as well as FIPS 5-2 (States).

Industry (NAICS)

Value Set	Industry (NAICS) - 2.16.840.1.114222.4.11.1100

Code System	Industry (NAICS) - 2.16.840.1.113883.6.85
Source	PHIN VADS
Source URL	https://phinvads.cdc.gov/vads/ViewValueSet.action?oid=2.16.840.1.114222.4.11.1100
Definition	The North American Industry Classification System (NAICS) consists of a set of six digit codes that classify and categorize industries. It also organizes the categories on a production/process-oriented basis. This new, uniform, industry-wide classification system has been designed as the index for statistical reporting of all economic activities of the U.S., Canada, and Mexico.

Medication Route FDA

Value Set	Medication Route FDA - 2.16.840.1.113883.3.88.12.3221.8.7
Code System	NCI Thesaurus - 2.16.840.1.113883.3.26.1.1
Source	PHIN VADS
Source URL	https://phinvads.cdc.gov/vads/ViewValueSet.action?oid=2.16.840.1.113883.3.88.12.3221.8.7
Definition	Route of Administration value set is based upon FDA Drug Registration and Listing Database (FDA Orange Book) which are used in FDA structured product and labelling (SPL).

Microorganism

Value Set	Microorganism - 2.16.840.1.114222.4.11.1009
Code System	SNOMEDCT - 2.16.840.1.113883.6.96
Source	PHIN VADS
Source URL	https://phinvads.cdc.gov/vads/ViewValueSet.action?iod=2.16.840.1.114222.4.11.1009
Definition	Microorganisms/infectious agents

Non-Laboratory Intervention and Procedure

Value Set	Non-Laboratory Intervention and Procedure - 2.16.840.1.114222.4.11.3204
Code System	SNOMEDCT - 2.16.840.1.113883.6.96
Source	PHIN VADS
Source URL	https://phinvads.cdc.gov/vads/ViewValueSet.action?oid=2.16.840.1.114222.4.11.3204
Definition	This value set includes medical and surgical procedures performed on human body. This is based upon the concepts descending from the SNOMED CT Procedures (71388002) hierarchy. This value set does not include administrative billing procedure or laboratory procedure.

Observation Interpretation (HL7)

Value Set	Observation Interpretation (HL7) - 2.16.840.1.113883.1.11.78

Code System	ObservationInterpretation - 2.16.840.1.113883.5.83
Source	PHIN VADS
Source URL	https://phinvads.cdc.gov/vads/ViewValueSet.action?oid=2.16.840.1.113883.1.11.78
Definition	Observation interpretation concepts that are based upon HL7 V3 vocabulary.

Occupation

Value Set	Occupation - 2.16.840.1.114222.4.11.887
Code System	Occupation (SOC 2000) - 2.16.840.1.113883.6.243
Source	PHIN VADS
Source URL	https://phinvads.cdc.gov/vads/ViewValueSet.action?oid=2.16.840.1.114222.4.11.887
Definition	Occupations or job codes

Race

Value Set	Race - 2.16.840.1.113883.1.11.14914
Code System	Race and Ethnicity - CDC - 2.16.840.1.113883.6.238
Source	PHIN VADS
Source URL	https://phinvads.cdc.gov/vads/ViewValueSet.action?oid=2.16.840.1.113883.1.11.14914
Definition	Concepts in the race value set include the OMB minimum categories, 5 races, along with a sixth race category, Other race, and a more detailed set of race categories used by the Bureau of Census.

Relevant Medical Condition Type

Value Set	Relevant Medical Condition Type - (OID not specified)

Concept Code	Concept Name	Code System	Description
398192003	Co-morbid conditions	SNOMEDCT	
370391006	Patient immunosuppressed	SNOMEDCT	

Specimen

Value Set	Specimen - 2.16.840.1.114222.4.11.946
Code System	SNOMEDCT - 2.16.840.1.113883.6.96
Source	PHIN VADS
Source URL	https://phinvads.cdc.gov/vads/ViewValueSet.action?oid=2.16.840.1.114222.4.11.946

Definition	Specimen based on SNOMED hierarchy (123038009) Keyword: Specimen Source, Specimen Type

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