Continuity of Care Document (CCD)

Contents

Acknowledgments

TODO: Add acknowledgments specific to this project team.

We acknowledge the foundational work on HL7 Version 3 and the Reference Information Model (RIM), the HL7 domain committees, especially Patient Care, and the work done on Clinical Document Architecture (CDA) itself.

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 Draft Standard for Trial Use (DSTU), and the degree to which the DSTU reflects these efforts will foster interoperability across the spectrum of health care.

INTRODUCTION

Purpose

The purpose of this Implementation Guide (IG) is to specify a standard for ...

Approach

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

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

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

Scope

TODO: scope of this implementation guide.

Audience

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

Organization of This Guide

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

Templates

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

Vocabulary and Value Sets

Vocabularies recommended in this guide are from standard vocabularies. When SNOMED codes are used, rules defined in Using SNOMED CT in HL7 Version 3 are adhered to. In many cases, these vocabularies are further constrained into value sets for use within this guide. Value set names and OIDs are summarized in the table Summary

of Value Sets. Each named value set in this summary table is stored in a template database that will be maintained by CHCA.

Use of Templates

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

Originator Responsibilities

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

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

Recipient Responsibilities

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

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

DOCUMENT TEMPLATES

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

Continuity Of Care Document

[ClinicalDocument: templateId `2.16.840.1.113883.10.20.1`]

TODO: add class description

1. Conforms to *CDA Clinical Document*
2. **SHOULD** contain [0..1] `component` such that it
   a. **SHALL** contain [1..1] *Problem Section* (templateId: `2.16.840.1.113883.10.20.1.11`)
3. **SHOULD** contain [0..1] `component` such that it
   a. **SHALL** contain [1..1] *Family History Section* (templateId: `2.16.840.1.113883.10.20.1.4`)
4. **SHOULD** contain [0..1] `component` such that it
   a. **SHALL** contain [1..1] *Social History Section* (templateId: `2.16.840.1.113883.10.20.1.15`)
5. **SHOULD** contain [0..1] `component` such that it
   a. **SHALL** contain [1..1] *Alerts Section* (templateId: `2.16.840.1.113883.10.20.1.2`)
6. **SHOULD** contain [0..1] `component` such that it
   a. **SHALL** contain [1..1] *Medications Section* (templateId: `2.16.840.1.113883.10.20.1.8`)
7. **SHOULD** contain [0..1] `component` such that it
   a. **SHALL** contain [1..1] *Results Section* (templateId: `2.16.840.1.113883.10.20.1.14`)
8. **SHOULD** contain [0..1] `component` such that it
   a. **SHALL** contain [1..1] *Procedures Section* (templateId: `2.16.840.1.113883.10.20.1.12`)
9. **SHOULD** contain [0..1] `component` such that it
   a. **SHALL** contain [1..1] *Encounters Section* (templateId: `2.16.840.1.113883.10.20.1.3`)
10. **SHOULD** contain [0..1] `component` such that it
    a. **SHALL** contain [1..1] *Plan Of Care Section* (templateId: `2.16.840.1.113883.10.20.1.10`)
11. **SHOULD** contain [0..1] `component` such that it
    a. **SHALL** contain [1..1] *Immunizations Section* (templateId: `2.16.840.1.113883.10.20.1.6`)
12. **SHOULD** contain [0..1] `component` such that it
    a. **SHALL** contain [1..1] *Vital Signs Section* (templateId: `2.16.840.1.113883.10.20.1.16`)
13. **SHOULD** contain [0..1] `component` such that it
    a. **SHALL** contain [1..1] *Medical Equipment Section* (templateId: `2.16.840.1.113883.10.20.1.7`)
14. **SHOULD** contain [0..1] `component` such that it
    a. **SHALL** contain [1..1] *Functional Status Section* (templateId: `2.16.840.1.113883.10.20.1.5`)
15. **SHOULD** contain [0..1] `component` such that it
    a. **SHALL** contain [1..1] *Advance Directives Section* (templateId: `2.16.840.1.113883.10.20.1.1`)
16. **SHOULD** contain [0..1] `component` such that it
    a. **SHALL** contain [1..1] *Payers Section* (templateId: `2.16.840.1.113883.10.20.1.9`)
17. **SHALL** contain [1..1] `code/@code` = "34133-9" *Summarization of episode note* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC 2.26)

18. **SHALL** contain [1..1] `languageCode`
19. **MAY** contain [0..1] `component` such that it
    a. **SHALL** contain [1..1] *Purpose Section* (templateId: `2.16.840.1.113883.10.20.1.13`)
20. **SHALL** satisfy: Contains exactly one documentationOf / serviceEvent
21. **SHALL** satisfy: documentationOf / serviceEvent / @classCode SHALL be 'PCPR'
22. **SHALL** satisfy: documentationOf / serviceEvent contains exactly one serviceEvent / effectiveTime / low and exactly one serviveEvent / effectiveTime / high
23. **SHALL** satisfy: languageCode has the form nn, or nn-CC. The nn portion SHALL be an ISO-639-1 language code in lower case. The CC portion, if present, SHALL be an ISO-3166 country code in upper case
24. **SHALL** satisfy: SHALL NOT contain templateId / @extension
25. **SHALL** satisfy: effectiveTime is expressed with precision to include seconds
26. **SHALL** satisfy: effectiveTime includes an explicit time zone offset
27. **SHALL** satisfy: Contains one or two recordTarget
28. **SHOULD** satisfy: Contains one or more author / assignedAuthor / assignedPerson and/or author / assignedAuthor / representedOrganization
29. **SHALL** satisfy: If author has an associated representedOrganization with no assignedPerson or assignedAuthoringDevice, then the value for author / assignedAuthor / id / @NullFlavor SHALL be 'NA'
30. **MAY** satisfy: Contains one or more informationRecipient

```
TODO: XML document snippet
```

Figure 1: Continuity Of Care Document example

SECTION TEMPLATES

Advance Directives Section

[Section: templateId `2.16.840.1.113883.10.20.1.1`]

TODO: add class description

1. Conforms to *CDA Section*
2. **SHALL** contain [1..1] `code/@code` = "42348-3" *Advance directives* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC 2.26)
3. **SHALL** contain [1..1] `title`
4. **SHALL** contain [1..*] `entry` such that it
   a. **SHALL** contain [1..1] *Advance Directive Observation* (templateId: `2.16.840.1.113883.10.20.1.17`)

```
TODO: XML document snippet
```

Figure 2: Advance Directives Section example

Alerts Section

[Section: templateId `2.16.840.1.113883.10.20.1.2`]

This section is used to list and describe any allergies, adverse reactions, and alerts that are pertinent to the patient's current or past medical history. At a minimum, currently active and any relevant historical allergies and adverse reactions should be listed.

1. Conforms to *CDA Section*
2. **SHALL** contain [1..1] `code/@code` = "48765-2" *Allergies, adverse reactions, alerts* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC 2.26)
3. **SHALL** contain [1..1] `title`
4. **SHALL** contain [1..1] `text`
5. **SHOULD** contain [1..*] `entry` such that it
   a. **SHALL** contain [1..1] *Problem Act* (templateId: `2.16.840.1.113883.10.20.1.27`)
6. **SHOULD** satisfy: Contains a case-insensitive language-insensitive string containing "alert" and/or "allergies and adverse reactions".
7. **SHALL** satisfy: The absence of known allergies, adverse reactions or alerts SHALL be explicitly asserted.

```
TODO: XML document snippet
```

Figure 3: Alerts Section example

Encounters Section

[Section: templateId `2.16.840.1.113883.10.20.1.3`]

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

1. Conforms to *CDA Section*

2. **SHALL** contain [1..1] `code/@code` = "46240-8" *History of encounters* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC 2.26)
3. **SHALL** contain [1..1] `title`

```
TODO: XML document snippet
```

Figure 4: Encounters Section example

Family History Section

[Section: templateId `2.16.840.1.113883.10.20.1.4`]

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

1. Conforms to *CDA Section*
2. **SHALL** contain [1..1] `code/@code` = "10157-6" *History of family member diseases* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC 2.26)
3. **SHALL** contain [1..1] `title`

```
TODO: XML document snippet
```

Figure 5: Family History Section example

Functional Status Section

[Section: templateId `2.16.840.1.113883.10.20.1.5`]

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

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

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

1. Conforms to *CDA Section*
2. **SHALL** contain [1..1] `code/@code` = "47420-5" *Functional status assessment* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC 2.26)
3. **SHALL** contain [1..1] `title`
4. **SHOULD** contain [1..*] `entry` such that it
   a. **SHALL** contain [1..1] *Problem Act* (templateId: `2.16.840.1.113883.10.20.1.27`)
5. **SHOULD** contain [1..*] `entry` such that it
   a. **SHALL** contain [1..1] *Result Organizer* (templateId: `2.16.840.1.113883.10.20.1.32`)

```
TODO: XML document snippet
```

Figure 6: Functional Status Section example

Immunizations Section

[Section: templateId `2.16.840.1.113883.10.20.1.6`]

The Immunizations section defines a patient's current immunization status and pertinent immunization history. The primary use case for the Immunization section is to enable communication of a patient's immunization status. The section should include current immunization status, and may contain the entire immunization history that is relevant to the period of time being summarized. This section is optional, however it is strongly recommended that it be present in cases of pediatric care and in other cases when such information is available.

1. Conforms to *CDA Section*
2. **SHALL** contain [1..1] `code/@code` = "11369-6" *History of immunizations* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC 2.26)
3. **SHALL** contain [1..1] `title`
4. **SHALL** contain [1..1] `text`
5. **SHOULD** contain [1..*] `entry` such that it
   a. **SHALL** contain [1..1] *Medication Activity* (templateId: `2.16.840.1.113883.10.20.1.24`)
6. **SHOULD** contain [1..*] `entry` such that it
   a. **SHALL** contain [1..1] *Supply Activity* (templateId: `2.16.840.1.113883.10.20.1.34`)
7. **SHOULD** satisfy: Contains a case-insensitive language-insensitive string containing 'immunization'.

```
TODO: XML document snippet
```

Figure 7: Immunizations Section example

Medical Equipment Section

[Section: templateId `2.16.840.1.113883.10.20.1.7`]

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

1. Conforms to *CDA Section*
2. **SHALL** contain [1..1] `code/@code` = "46264-8" *History of medical device use* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC 2.26)
3. **SHALL** contain [1..1] `title`

```
TODO: XML document snippet
```

Figure 8: Medical Equipment Section example

Medications Section

[Section: templateId `2.16.840.1.113883.10.20.1.8`]

The Medications section defines a patient's current medications and pertinent medication history. At a minimum, the currently active medications should be listed, with an entire medication history as an option, particularly when the summary document is used for comprehensive data export. The section may also include a patient's prescription history, and enables the determination of the source of a medication list (e.g. from a pharmacy system vs. from the patient).

1. Conforms to *CDA Section*
2. **SHALL** contain [1..1] `code/@code` = "10160-0" *History of medication use* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC 2.26)

3. **SHALL** contain [1..1] `title`

```
TODO: XML document snippet
```

Figure 9: Medications Section example

Payers Section

[Section: templateId `2.16.840.1.113883.10.20.1.9`]

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

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

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

1. Conforms to *CDA Section*
2. **SHALL** contain [1..1] `code/@code` = "48768-6" *Payment sources* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC 2.26)
3. **SHALL** contain [1..1] `title`
4. **SHOULD** contain [1..*] `entry` such that it
   a. **SHALL** contain [1..1] *Coverage Activity* (templateId: `2.16.840.1.113883.10.20.1.20`)

```
TODO: XML document snippet
```

Figure 10: Payers Section example

Plan Of Care Section

[Section: templateId `2.16.840.1.113883.10.20.1.10`]

The plan of care section contains data defining pending orders, interventions, encounters, services, and procedures for the patient. It is limited to prospective, unfulfilled, or incomplete orders and requests only. All active, incomplete, or pending orders, appointments, referrals, procedures, services, or any other pending event of clinical significance to the current and ongoing care of the patient should be listed, unless constrained due to issues of privacy.

The plan of care section also contains information regarding goals and clinical reminders. Clinical reminders are placed here for purposes of providing prompts that may be used for disease prevention, disease management, patient safety, and healthcare quality improvements, including widely accepted performance measures.

1. Conforms to *CDA Section*
2. **SHALL** contain [1..1] `code/@code` = "18776-5" *Treatment plan* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC 2.26)
3. **SHALL** contain [1..1] `title`
4. **SHALL** contain [1..1] `text`
5. **MAY** contain [0..1] `entry` such that it
   a. **SHALL** contain [1..1] *Plan Of Care Activity Act* (templateId: `2.16.840.1.113883.10.20.1.25`)
6. **MAY** contain [0..1] `entry` such that it
   a. **SHALL** contain [1..1] *Plan Of Care Activity Encounter* (templateId: `2.16.840.1.113883.10.20.1.25`)
7. **MAY** contain [0..1] `entry` such that it

   a. **SHALL** contain [1..1] *Plan Of Care Activity Observation* (templateId: `2.16.840.1.113883.10.20.1.25`)
8. **MAY** contain [0..1] `entry` such that it
   a. **SHALL** contain [1..1] *Plan Of Care Activity Procedure* (templateId: `2.16.840.1.113883.10.20.1.25`)
9. **MAY** contain [0..1] `entry` such that it
   a. **SHALL** contain [1..1] *Plan Of Care Activity Substance Administration* (templateId: `2.16.840.1.113883.10.20.1.25`)
10. **MAY** contain [0..1] `entry` such that it
   a. **SHALL** contain [1..1] *Plan Of Care Activity Supply* (templateId: `2.16.840.1.113883.10.20.1.25`)
11. **SHALL** contain [1..1] `entry` such that it
   a. **SHALL** contain [1..1] *Plan Of Care Activity*
12. **SHALL** satisfy: Contains one or more plan of care activities, represented with Act, Encounter, Observation, Procedure, SubstanceAdministration, or Supply.

```
TODO: XML document snippet
```

Figure 11: Plan Of Care Section example

Problem Section

[Section: templateId `2.16.840.1.113883.10.20.1.11`]

This section lists and describes all relevant clinical problems at the time the summary is generated. At a minimum, all pertinent current and historical problems should be listed. CDA R2 represents problems as Observations.

1. Conforms to *CDA Section*
2. **SHALL** contain [1..1] `code/@code` = "11450-4" *Problem list* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC 2.26)
3. **SHALL** contain [1..1] `title`
4. **SHOULD** contain [1..*] `entry` such that it
   a. **SHALL** contain [1..1] *Problem Act* (templateId: `2.16.840.1.113883.10.20.1.27`)
5. **SHALL** contain [1..1] `text`
6. **SHOULD** satisfy: Contains a case-insensitive language-insensitive string containing 'problems'.

```
TODO: XML document snippet
```

Figure 12: Problem Section example

Procedures Section

[Section: templateId `2.16.840.1.113883.10.20.1.12`]

This section defines all interventional, surgical, diagnostic, or therapeutic procedures or treatments pertinent to the patient historically at the time the document is generated. The section may contain all procedures for the period of time being summarized, but should include notable procedures.

1. Conforms to *CDA Section*
2. **SHALL** contain [1..1] `code/@code` = "47519-4" *History of procedures* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC 2.26)
3. **SHALL** contain [1..1] `title`
4. **SHOULD** contain [1..*] `entry` such that it
   a. **SHALL** contain [1..1] *Procedure Activity*

```
TODO: XML document snippet
```

Figure 13: Procedures Section example

Purpose Section

[Section: templateId `2.16.840.1.113883.10.20.1.13`]

Represents the specific reason for which the summarization was generated, such as in response to a request.

The general use case does not require a purpose. Purpose should be utilized when the CCD has a specific purpose such as a transfer, referral, or patient request.

1. Conforms to *CDA Section*
2. **SHALL** contain [1..1] `code/@code` = "48764-5" *Summary purpose* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC 2.26)
3. **SHALL** contain [1..1] `title`
4. **SHOULD** contain [1..*] `entry` such that it
   a. **SHALL** contain [1..1] *Purpose Activity* (templateId: `2.16.840.1.113883.10.20.1.30`)
5. **SHALL** contain [1..1] `text`
6. **SHOULD** satisfy: Contains a case-insensitive language-insensitive string containing 'purpose'.

```
TODO: XML document snippet
```

Figure 14: Purpose Section example

Results Section

[Section: templateId `2.16.840.1.113883.10.20.1.14`]

This section contains the results of observations generated by laboratories, imaging procedures, and other procedures. The scope includes hematology, chemistry, serology, virology, toxicology, microbiology, plain x-ray, ultrasound, CT, MRI, angiography, cardiac echo, nuclear medicine, pathology, and procedure observations. The section may contain all results for the period of time being summarized, but should include notable results such as abnormal values or relevant trends.

Lab 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, submitted to the lab.

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 echo.

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

1. Conforms to *CDA Section*
2. **SHALL** contain [1..1] `code/@code` = "30954-2" *Relevant diagnostic tests and/or laboratory data* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC 2.26)
3. **SHALL** contain [1..1] `title`
4. **SHOULD** contain [1..*] `entry` such that it
   a. **SHALL** contain [1..1] *Result Organizer* (templateId: `2.16.840.1.113883.10.20.1.32`)
5. **SHALL** contain [1..1] `text`
6. **SHOULD** satisfy: Contains a case-insensitive language-insensitive string containing 'results'.

```
TODO: XML document snippet
```

Figure 15: Results Section example

Social History Section

[Section: templateId `2.16.840.1.113883.10.20.1.15`]

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

1. Conforms to *CDA Section*
2. **SHALL** contain [1..1] `code/@code` = "29762-2" *Social history* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC 2.26)
3. **SHOULD** contain [1..1] `title`

```
TODO: XML document snippet
```

Figure 16: Social History Section example

Vital Signs Section

[Section: templateId `2.16.840.1.113883.10.20.1.16`]

This section contains current and historically relevant vital signs, such as blood pressure, heart rate, respiratory rate, height, weight, body mass index, head circumference, crown-to-rump length, and pulse oximetry. The section may contain all vital signs for the period of time being summarized, but at a minimum should include notable vital signs such as the most recent, maximum and/or minimum, or both, baseline, or relevant trends.

Vital signs are represented like other results (as defined in ***Results Section***), but are aggregated into their own section in order to follow clinical conventions.

1. Conforms to *CDA Section*
2. **SHALL** contain [1..1] `code/@code` = "8716-3" *Vital signs* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC 2.26)
3. **SHALL** contain [1..1] `title`
4. **SHOULD** contain [1..*] `entry` such that it
   a. **SHALL** contain [1..1] *Vital Signs Organizer* (templateId: `2.16.840.1.113883.10.20.1.35`)
5. **SHALL** contain [1..1] `text`
6. **SHOULD** satisfy: Contains a case-insensitive language-insensitive string containing 'vital signs'.

```
TODO: XML document snippet
```

Figure 17: Vital Signs Section example

CLINICAL STATEMENT TEMPLATES

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

Advance Directive Observation

[Observation: templateId `2.16.840.1.113883.10.20.1.17`]

TODO: add class description

1. Conforms to *CDA Observation*
2. **SHALL** contain [1..1] `@classCode` = "OBS"
3. **SHALL** contain [1..1] `@moodCode` = "EVN"
4. **SHALL** contain [1..*] `id`
5. **SHALL** contain [1..1] `statusCode/@code` = "completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus STATIC V3NE08)
6. **SHOULD** contain [0..1] `effectiveTime`
7. **MAY** contain [1..1] `code`, which **MAY** be selected from ValueSet 2.16.840.1.113883.1.11.20.2 AdvanceDirectiveTypeCode STATIC 20061017
8. **MAY** contain [1..*] `entryRelationship` such that it
   a. **SHALL** contain [1..1] *Advance Directive Verification* (templateId: `2.16.840.1.113883.10.20.1.58`)

```
TODO: XML document snippet
```

Figure 18: Advance Directive Observation example

Advance Directive Status Observation

[Observation: templateId `2.16.840.1.113883.10.20.1.37`]

TODO: add class description

1. Conforms to *Status Observation* template (templateId: `2.16.840.1.113883.10.20.1.57`)
2. **SHALL** contain [1..1] `value`, which **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.20.1 AdvanceDirectiveStatusCode STATIC 20061017

```
TODO: XML document snippet
```

Figure 19: Advance Directive Status Observation example

Advance Directive Verification

[Participant2: templateId `2.16.840.1.113883.10.20.1.58`]

TODO: add class description

1. Conforms to *CDA Participant2*
2. **SHALL** contain [1..1] `@typeCode` = "VRF"
3. **SHOULD** contain [0..1] `time`, where its data type is TS

```
TODO: XML document snippet
```

Figure 20: Advance Directive Verification example

Age Observation

[Observation: templateId `2.16.840.1.113883.10.20.1.38`]

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

1. Conforms to *CDA Observation*
2. **SHALL** contain [1..1] `@classCode` = "OBS"
3. **SHALL** contain [1..1] `@moodCode` = "EVN"
4. **SHALL** contain [1..1] `code/@code` = "397659008" *Age* (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT STATIC 20080731)
5. **SHALL** contain [0..1] `statusCode/@code` = "completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus STATIC V3NE08)
6. **SHALL** contain [1..1] `value`

```
TODO: XML document snippet
```

Figure 21: Age Observation example

Alert Observation

[Observation: templateId `2.16.840.1.113883.10.20.1.18`]

TODO: add class description

1. Conforms to *CDA Observation*
2. **SHALL** contain [1..1] `@moodCode` = "EVN"
3. **SHALL** contain [1..1] `statusCode/@code` = "completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus STATIC V3NE08)
4. **SHALL** contain [0..1] `effectiveTime`
5. **MAY** contain [0..*] `value`, which **MAY** be selected from ValueSet 2.16.840.1.113883.1.11.20.4 AlertTypeCode STATIC 20061017, where its data type is CE
6. **MAY** contain [0..1] `entryRelationship` such that it
   a. **SHALL** contain [1..1] *Alert Status Observation* (templateId: `2.16.840.1.113883.10.20.1.39`)
7. **MAY** contain [1..*] `entryRelationship` such that it
   a. **SHALL** contain [1..1] @typeCode="MFST" *MFST (is manifestation of)*
   b. **SHALL** contain [1..1] *Reaction Observation* (templateId: `2.16.840.1.113883.10.20.1.54`)
8. **SHOULD** satisfy: The absence of known allergies SHOULD be represented in an alert observation by valuing Observation / value with 160244002 "No known allergies" 2.16.840.1.113883.6.96 SNOMED CT STATIC.
9. **SHALL** satisfy: An alert observation contains one or more sources of information.
10. **SHOULD** satisfy: An alert observation SHOULD contain at least one Observation / participant, representing the agent that is the cause of the allergy or adverse reaction. The value for participant / @typeCode in an agent participation SHALL be "CSM" "Consumable" 2.16.840.1.113883.5.90 ParticipationType STATIC.
11. **SHALL** satisfy: Contains exactly one participant / participantRole / playingEntity. The value for participant / participantRole / playingEntity / @classCode in an agent participation SHALL be "MMAT" "Manufactured material" 2.16.840.1.113883.5.41 EntityClass STATIC. Contains exactly one participant / participantRole / playingEntity / code.
12. **SHOULD** satisfy: The value for participant / participantRole / playingEntity / code in an agent participation SHOULD be selected from the RxNorm (2.16.840.1.113883.6.88) code system for medications, and from the CDC Vaccine Code (2.16.840.1.113883.6.59) code system for immunizations.

```
TODO: XML document snippet
```

Figure 22: Alert Observation example

Alert Status Observation

[Observation: templateId `2.16.840.1.113883.10.20.1.39`]

TODO: add class description

1. Conforms to *Status Observation* template (templateId: `2.16.840.1.113883.10.20.1.57`)
2. **SHALL** contain [1..1] `value`, which **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.20.3 AlertStatusCode STATIC 20061017

```
TODO: XML document snippet
```

Figure 23: Alert Status Observation example

Authorization Activity

[Act: templateId `2.16.840.1.113883.10.20.1.19`]

TODO: add class description

1. Conforms to *CDA Act*
2. **SHALL** contain [1..1] `@classCode` = "ACT"
3. **SHALL** contain [1..1] `@moodCode` = "EVN"
4. **SHALL** contain [1..*] `id`

```
TODO: XML document snippet
```

Figure 24: Authorization Activity example

Cause Of Death Observation

[Observation: templateId `2.16.840.1.113883.10.20.1.42`]

TODO: add class description

1. Conforms to *Family History Observation* template (templateId: `2.16.840.1.113883.10.20.1.22`)

```
TODO: XML document snippet
```

Figure 25: Cause Of Death Observation example

Coverage Activity

[Act: templateId `2.16.840.1.113883.10.20.1.20`]

TODO: add class description

1. Conforms to *CDA Act*
2. **SHALL** contain [1..1] `@classCode` = "ACT"
3. **SHALL** contain [1..1] `@moodCode` = "DEF"
4. **SHALL** contain [1..*] `id`
5. **SHALL** contain [1..1] `statusCode/@code` = "completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus STATIC V3NE08)
6. **SHALL** contain [1..1] `code/@code` = "48768-6" *Payment sources* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC 2.26)
7. **SHALL** contain [1..*] `entryRelationship` such that it
   a. **SHALL** contain [1..1] *Policy Activity* (templateId: `2.16.840.1.113883.10.20.1.26`)

```
TODO: XML document snippet
```

Figure 26: Coverage Activity example

Encounter Location

[Participant2: templateId `2.16.840.1.113883.10.20.1.45`]

TODO: add class description

1. Conforms to *CDA Participant2*
2. **SHALL** contain [1..1] `@typeCode` = "LOC"

```
TODO: XML document snippet
```

Figure 27: Encounter Location example

Encounters Activity

[Encounter: templateId `2.16.840.1.113883.10.20.1.21`]

TODO: add class description

1. Conforms to *CDA Encounter*
2. **SHALL** contain [1..1] `@classCode` = "ENC"
3. **SHALL** contain [1..1] `@moodCode` = "EVN"
4. **SHALL** contain [1..*] `id`
5. **SHOULD** contain [1..1] `code`, which **SHOULD** be selected from ValueSet 2.16.840.1.113883.1.11.13955 EncounterCode STATIC
6. **MAY** contain [0..1] `effectiveTime`

```
TODO: XML document snippet
```

Figure 28: Encounters Activity example

Episode Observation

[Observation: templateId `2.16.840.1.113883.10.20.1.41`]

Episode observations are used to distinguish among multiple occurrences of a problem or social history item. An episode observation is used to indicate that a problem act represents a new episode, distinct from other episodes of a similar concern.

1. Conforms to *CDA Observation*
2. **SHALL** contain [1..1] `@classCode` = "OBS"
3. **SHALL** contain [1..1] `@moodCode` = "EVN"
4. **SHALL** contain [1..1] `statusCode/@code` = "completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus STATIC V3NE08)
5. **SHOULD** contain [1..1] `code/@code` = "ASSERTION" (CodeSystem: 2.16.840.1.113883.5.4 ActCode STATIC V3NE08)
6. **SHOULD** contain [1..1] `value/@code` = "404684003" *Clinical finding* (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT STATIC 20080731), where its data type is CD
7. **SHOULD** satisfy: Value in an episode observation SHOULD be the following SNOMED CT expression: <value xsi:type="CD" code="404684003" codeSystem="2.16.840.1.113883.6.96" displayName="Clinical finding"> <qualifier> <name code="246456000" displayName="Episodicity"/> <value code="288527008" displayName="New episode"/> </qualifier> </value>
8. **SHALL** satisfy: Contains exactly one entryRelationship whose typeCode is 'SUBJ'. This is used to link the episode observation to the target problem act or social history observation.
9. **MAY** satisfy: Contain one or more entryRelationship whose typeCode is 'SAS'. The target of the entryRelationship SHALL be a problem act or social history observation. This is used to represent the temporal sequence of episodes.

```
TODO: XML document snippet
```

Figure 29: Episode Observation example

Family History Observation

[Observation: templateId `2.16.840.1.113883.10.20.1.22`]

TODO: add class description

1. Conforms to *CDA Observation*
2. **SHALL** contain [1..*] `id`
3. **SHALL** contain [1..1] `statusCode/@code` = "completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus STATIC V3NE08)

```
TODO: XML document snippet
```

Figure 30: Family History Observation example

Family History Organizer

[Organizer: templateId `2.16.840.1.113883.10.20.1.23`]

TODO: add class description

1. Conforms to *CDA Organizer*
2. **SHALL** contain [1..1] `statusCode/@code` = "completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus STATIC V3NE08)

```
TODO: XML document snippet
```

Figure 31: Family History Organizer example

Fulfillment Instruction

[Act: templateId `2.16.840.1.113883.10.20.1.43`]

Fulfillment instructions are additional information provided to the dispensing party (e.g. "label in spanish").

1. Conforms to *CDA Act*
2. **SHALL** contain [1..1] `@moodCode` = "INT"

```
TODO: XML document snippet
```

Figure 32: Fulfillment Instruction example

Functional Status Observation

[Observation: templateId `2.16.840.1.113883.10.20.1.44`]

TODO: add class description

1. Conforms to *Status Observation* template (templateId: `2.16.840.1.113883.10.20.1.57`)
2. **SHALL** contain [1..1] `value`, which **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.20.5 StatusOfFunctionalStatusCode STATIC 20061017

```
TODO: XML document snippet
```

Figure 33: Functional Status Observation example

Medication Activity

[SubstanceAdministration: templateId `2.16.840.1.113883.10.20.1.24`]

A medication activity is used to describe what is administered whereas a supply activity is used to describe what has been dispensed.

1. Conforms to *CDA Substance Administration*
2. **SHALL** contain [1..*] `id`
3. **SHOULD** contain [0..1] `statusCode`
4. **MAY** contain [0..1] `entryRelationship` such that it
   a. **SHALL** contain [1..1] *Medication Series Number Observation* (templateId: `2.16.840.1.113883.10.20.1.46`)
5. **MAY** contain [0..1] `entryRelationship` such that it
   a. **SHALL** contain [1..1] *Medication Status Observation* (templateId: `2.16.840.1.113883.10.20.1.47`)
6. **MAY** contain [0..*] `entryRelationship` such that it
   a. **SHALL** contain [1..1] @typeCode="SUBJ" *SUBJ (has subject)*
   b. **SHALL** contain [1..1] *Patient Instruction* (templateId: `2.16.840.1.113883.10.20.1.49`)
7. **SHALL** satisfy:

```
self.moodCode=vocab::x_DocumentSubstanceMood::EVN or
 self.moodCode=vocab::x_DocumentSubstanceMood::INT
```

```
TODO: XML document snippet
```

Figure 34: Medication Activity example

Medication Series Number Observation

[Observation: templateId `2.16.840.1.113883.10.20.1.46`]

The medication series number observation can be used to indicate which in a series of administrations a particular administration represents (e.g. "hepatitis B vaccine number 2 was administered on Feb 07, 2004).

1. Conforms to *CDA Observation*
2. **SHALL** contain [1..1] `@classCode` = "OBS"
3. **SHALL** contain [1..1] `@moodCode` = "EVN"
4. **SHALL** contain [1..1] `statusCode`
5. **SHALL** contain [1..1] `code/@code` = "30973-2" *Dose number* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC 2.26)
6. **SHALL** contain [1..1] `value`, where its data type is INT

```
TODO: XML document snippet
```

Figure 35: Medication Series Number Observation example

Medication Status Observation

[Observation: templateId `2.16.840.1.113883.10.20.1.47`]

TODO: add class description

1. Conforms to *Status Observation* template (templateId: `2.16.840.1.113883.10.20.1.57`)
2. **SHALL** contain [1..1] `value`, which **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.20.7 MedicationStatusCode STATIC 20061017

```
TODO: XML document snippet
```

Figure 36: Medication Status Observation example

Patient Awareness

[Participant2: templateId `2.16.840.1.113883.10.20.1.48`]

TODO: add class description

1. Conforms to *CDA Participant2*
2. **SHALL** contain [1..1] `@typeCode` = "SBJ"
3. **SHALL** contain [1..1] `awarenessCode`
4. **SHALL** satisfy: Patient awareness SHALL contain exactly one participant / participantRole / id, which SHALL have exactly one value, which SHALL also be present in ClinicalDocument / recordTarget / patientRole / id.

```
TODO: XML document snippet
```

Figure 37: Patient Awareness example

Patient Instruction

[Act: templateId `2.16.840.1.113883.10.20.1.49`]

Patient instructions are additional information provided to a patient related to one of their medications (e.g. "take on an empty stomach").

1. Conforms to *CDA Act*
2. **SHALL** contain [1..1] `@moodCode` = "INT"

```
TODO: XML document snippet
```

Figure 38: Patient Instruction example

Plan Of Care Activity Act

[Act: templateId `2.16.840.1.113883.10.20.1.25`]

TODO: add class description

1. Conforms to *CDA Act*
2. Conforms to *Plan Of Care Activity*
3. **SHALL** contain [1..*] `id`
4. **SHALL** contain [1..1] `@moodCode`
5. **SHALL** satisfy:

```
self.moodCode = vocab::x_DocumentActMood::INT or self.moodCode =
 vocab::x_DocumentActMood::ARQ
  or self.moodCode = vocab::x_DocumentActMood::PRMS or self.moodCode =
 vocab::x_DocumentActMood::PRP
  or self.moodCode = vocab::x_DocumentActMood::RQO
```

```
TODO: XML document snippet
```

Figure 39: Plan Of Care Activity Act example

Plan Of Care Activity Encounter

[Encounter: templateId `2.16.840.1.113883.10.20.1.25`]

TODO: add class description

1. Conforms to *CDA Encounter*
2. Conforms to *Plan Of Care Activity*
3. **SHALL** contain [1..*] `id`
4. **SHALL** contain [1..1] `@moodCode`
5. **SHALL** satisfy:

```
self.moodCode = vocab::x_DocumentEncounterMood::INT or self.moodCode =
 vocab::x_DocumentEncounterMood::ARQ
```

```
 or self.moodCode = vocab::x_DocumentEncounterMood::PRMS or self.moodCode =
vocab::x_DocumentEncounterMood::PRP
 or self.moodCode = vocab::x_DocumentEncounterMood::RQO
```

```
TODO: XML document snippet
```

Figure 40: Plan Of Care Activity Encounter example

Plan Of Care Activity Observation

[Observation: templateId `2.16.840.1.113883.10.20.1.25`]

TODO: add class description

1. Conforms to *CDA Observation*
2. Conforms to *Plan Of Care Activity*
3. **SHALL** contain [1..*] `id`
4. **SHALL** contain [1..1] `@moodCode`
5. **SHALL** satisfy:

```
self.moodCode = vocab::x_ActMoodDocumentObservation::INT or self.moodCode =
vocab::x_ActMoodDocumentObservation::GOL
 or self.moodCode = vocab::x_ActMoodDocumentObservation::PRMS or
self.moodCode = vocab::x_ActMoodDocumentObservation::PRP
 or self.moodCode = vocab::x_ActMoodDocumentObservation::RQO
```

```
TODO: XML document snippet
```

Figure 41: Plan Of Care Activity Observation example

Plan Of Care Activity Procedure

[Procedure: templateId `2.16.840.1.113883.10.20.1.25`]

TODO: add class description

1. Conforms to *CDA Procedure*
2. Conforms to *Plan Of Care Activity*
3. **SHALL** contain [1..*] `id`
4. **SHALL** contain [1..1] `@moodCode`
5. **SHALL** satisfy:

```
self.moodCode = vocab::x_DocumentProcedureMood::INT or self.moodCode =
vocab::x_DocumentProcedureMood::ARQ
 or self.moodCode = vocab::x_DocumentProcedureMood::PRMS or self.moodCode =
vocab::x_DocumentProcedureMood::PRP
 or self.moodCode = vocab::x_DocumentProcedureMood::RQO
```

```
TODO: XML document snippet
```

Figure 42: Plan Of Care Activity Procedure example

Plan Of Care Activity Substance Administration

[SubstanceAdministration: templateId `2.16.840.1.113883.10.20.1.25`]

TODO: add class description

1. Conforms to *CDA Substance Administration*
2. Conforms to *Plan Of Care Activity*
3. **SHALL** contain [1..*] `id`
4. **SHALL** contain [1..1] `@moodCode`

5. **SHALL** satisfy:

```
self.moodCode = vocab::x_DocumentSubstanceMood::INT or self.moodCode =
 vocab::x_DocumentSubstanceMood::RQO
  or self.moodCode = vocab::x_DocumentSubstanceMood::PRMS or self.moodCode =
 vocab::x_DocumentSubstanceMood::PRP
```

```
TODO: XML document snippet
```

Figure 43: Plan Of Care Activity Substance Administration example

Plan Of Care Activity Supply

[Supply: templateId `2.16.840.1.113883.10.20.1.25`]

TODO: add class description

1. Conforms to *CDA Supply*
2. Conforms to *Plan Of Care Activity*
3. **SHALL** contain [1..*] `id`
4. **SHALL** contain [1..1] `@moodCode`
5. **SHALL** satisfy:

```
self.moodCode = vocab::x_DocumentSubstanceMood::INT or self.moodCode =
 vocab::x_DocumentSubstanceMood::RQO
  or self.moodCode = vocab::x_DocumentSubstanceMood::PRMS or self.moodCode =
 vocab::x_DocumentSubstanceMood::PRP
```

```
TODO: XML document snippet
```

Figure 44: Plan Of Care Activity Supply example

Policy Activity

[Act: templateId `2.16.840.1.113883.10.20.1.26`]

TODO: add class description

1. Conforms to *CDA Act*
2. **SHALL** contain [1..1] `@classCode` = "ACT"
3. **SHALL** contain [1..1] `@moodCode` = "EVN"
4. **SHALL** contain [1..*] `id`
5. **SHALL** contain [1..1] `statusCode/@code` = "completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus STATIC V3NE08)
6. **SHALL** contain [1..1] `code`, which **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.19832 ActCoverageType DYNAMIC
7. **SHALL** contain [1..1] `entryRelationship` such that it
   a. **SHALL** contain [1..1] @typeCode="REFR" *REFR (refers to)*
   b. **SHALL** contain [1..1] *Authorization Activity* (templateId: `2.16.840.1.113883.10.20.1.19`)

```
TODO: XML document snippet
```

Figure 45: Policy Activity example

Problem Act

[Act: templateId `2.16.840.1.113883.10.20.1.27`]

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

1. Conforms to *CDA Act*
2. **SHALL** contain [1..1] `@classCode` = "ACT"
3. **SHALL** contain [1..1] `@moodCode` = "EVN"
4. **SHALL** contain [1..*] `id`
5. **SHALL** contain [1..1] `code/@nullFlavor` = "NA" *NA (not applicable)*
6. **MAY** contain [0..1] `effectiveTime`
7. **MAY** contain [0..1] `entryRelationship` such that it
   a. **SHALL** contain [1..1] *Episode Observation* (templateId: `2.16.840.1.113883.10.20.1.41`)
8. **SHALL** satisfy: Contains one or more entryRelationship
9. **MAY** satisfy: A problem act MAY reference a problem observation, alert observation (see section Alerts) or other clinical statement that is the subject of concern, by setting the value for "Act / entryRelationship / @typeCode" to be "SUBJ" 2.16.840.1.113883.5.1002 ActRelationshipType STATIC.
10. **SHOULD** satisfy: The target of a problem act with Act / entryRelationship / @typeCode="SUBJ" SHOULD be a problem observation (in the Problem section) or alert observation (in the Alert section), but MAY be some other clinical statement.
11. **SHOULD** satisfy: In Problems Section, a Problem Act SHOULD contain a Problem Observation.
12. **SHOULD** satisfy: In Alert Section, a ProblemAct SHOULD contain an Alert Observation.
13. **MAY** satisfy: Contains exactly one Patient Awareness

```
TODO: XML document snippet
```

Figure 46: Problem Act example

Problem Health Status Observation

[Observation: templateId `2.16.840.1.113883.10.20.1.51`]

TODO: add class description

1. Conforms to *Status Observation* template (templateId: `2.16.840.1.113883.10.20.1.57`)
2. **SHALL** contain [1..1] `code/@code` = "11323-3" *Health status* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC 2.26)
3. **SHALL** contain [1..1] `value`, which **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.20.12 ProblemHealthStatusCode STATIC 20061017

```
TODO: XML document snippet
```

Figure 47: Problem Health Status Observation example

Problem Observation

[Observation: templateId `2.16.840.1.113883.10.20.1.28`]

TODO: add class description

1. Conforms to *CDA Observation*
2. **SHALL** contain [1..1] `@classCode` = "OBS"
3. **SHALL** contain [1..1] `@moodCode` = "EVN"
4. **SHALL** contain [1..1] `statusCode/@code` = "completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus STATIC V3NE08)
5. **SHOULD** contain [0..1] `effectiveTime`
6. **MAY** contain [1..1] `code`, which **MAY** be selected from ValueSet 2.16.840.1.113883.1.11.20.14 ProblemTypeCode STATIC 20061017
7. **MAY** contain [0..1] `entryRelationship` such that it
   a. **SHALL** contain [1..1] @typeCode="REFR" *REFR (refers to)*
   b. **SHALL** contain [1..1] *Problem Status Observation* (templateId: `2.16.840.1.113883.10.20.1.50`)
8. **MAY** contain [0..1] `entryRelationship` such that it

   a. **SHALL** contain [1..1] @typeCode="REFR" *REFR (refers to)*
   b. **SHALL** contain [1..1] *Problem Health Status Observation* (templateId: `2.16.840.1.113883.10.20.1.51`)
9. **MAY** contain [0..1] `entryRelationship` such that it
   a. **SHALL** contain [1..1] @typeCode="SUBJ" *SUBJ (has subject)*
   b. **SHALL** contain [1..1] *Age Observation* (templateId: `2.16.840.1.113883.10.20.1.38`)
10. **SHALL** satisfy: Contains one or more sources of information.
11. **MAY** satisfy: Contains exactly one Patient Awareness

```
TODO: XML document snippet
```

Figure 48: Problem Observation example

Problem Status Observation

[Observation: templateId `2.16.840.1.113883.10.20.1.50`]

TODO: add class description

1. Conforms to *Status Observation* template (templateId: `2.16.840.1.113883.10.20.1.57`)
2. **SHALL** contain [1..1] `value`, which **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.20.13 ProblemStatusCode STATIC 20061017

```
TODO: XML document snippet
```

Figure 49: Problem Status Observation example

Procedure Activity Act

[Act: templateId `2.16.840.1.113883.10.20.1.29`]

TODO: add class description

1. Conforms to *CDA Act*
2. Conforms to *Procedure Activity*

```
TODO: XML document snippet
```

Figure 50: Procedure Activity Act example

Procedure Activity Observation

[Observation: templateId `2.16.840.1.113883.10.20.1.29`]

TODO: add class description

1. Conforms to *CDA Observation*
2. Conforms to *Procedure Activity*

```
TODO: XML document snippet
```

Figure 51: Procedure Activity Observation example

Procedure Activity Procedure

[Procedure: templateId `2.16.840.1.113883.10.20.1.29`]

TODO: add class description

1. Conforms to *CDA Procedure*

2. Conforms to *Procedure Activity*

```
TODO: XML document snippet
```

Figure 52: Procedure Activity Procedure example

Product

[ManufacturedProduct: templateId `2.16.840.1.113883.10.20.1.53`]

TODO: add class description

1. Conforms to *CDA Manufactured Product*

```
TODO: XML document snippet
```

Figure 53: Product example

Product Instance

[ParticipantRole: templateId `2.16.840.1.113883.10.20.1.52`]

TODO: add class description

1. Conforms to *CDA Participant Role*
2. **SHALL** contain [1..1] `@classCode` = "MANU"

```
TODO: XML document snippet
```

Figure 54: Product Instance example

Purpose Activity

[Act: templateId `2.16.840.1.113883.10.20.1.30`]

CCD represents the ASTM CCR <Purpose> object as a relationship between two classes -- the source represents the act of creating a summary document, the target is the reason for creating the document, and the relationship type is "RSON" (has reason). The target act may be an Observation, Procedure, or some other kind of act, and it may represent an order, an event, etc.

1. Conforms to *CDA Act*
2. **SHALL** contain [1..1] `@classCode` = "ACT"
3. **SHALL** contain [1..1] `@moodCode` = "EVN"
4. **SHALL** contain [1..1] `code/@code` = "23745001" *Documentation procedure* (CodeSystem: 2.16.840.1.113883.6.96 SNOMEDCT STATIC 20080731)
5. **SHALL** contain [1..1] `statusCode/@code` = "completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus STATIC V3NE08)
6. **SHALL** satisfy: Contains exactly one entryRelationship / @typeCode, with a value of 'RSON' 'Has reason' 2.16.840.1.113883.5.1002 ActRelationshipType STATIC, to indicate the reason or purpose for creating the CCD.
7. **SHALL** satisfy: The target of entryRelationship SHALL be an Act, Encounter, Observation, Procedure, SubstanceAdministration, or Supply.

```
TODO: XML document snippet
```

Figure 55: Purpose Activity example

Reaction Observation

[Observation: templateId `2.16.840.1.113883.10.20.1.54`]

TODO: add class description

1. Conforms to *CDA Observation*
2. **MAY** contain [0..1] `entryRelationship` such that it
   a. **SHALL** contain [1..1] *Severity Observation* (templateId: `2.16.840.1.113883.10.20.1.55`)
3. **SHALL** contain [1..1] `@classCode` = "OBS"
4. **SHALL** contain [1..1] `@moodCode` = "EVN"
5. **SHALL** contain [1..1] `statusCode/@code` = "completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus STATIC V3NE08)
6. **SHALL** satisfy: The value for entryRelationship / @typeCode in a relationship between a reaction observation and reaction intervention SHALL be "RSON" "Has reason" 2.16.840.1.113883.5.1002 ActRelationshipType STATIC.
7. **SHALL** satisfy: A reaction observation MAY contain one or more reation interventions. A reaction intervention SHALL be represented as a procedure activity (templateId 2.16.840.1.113883.10.20.1.29), a medication activity (templateId 2.16.840.1.113883.10.20.1.24), or some other clinical statement.

```
TODO: XML document snippet
```

Figure 56: Reaction Observation example

Result Observation

[Observation: templateId `2.16.840.1.113883.10.20.1.31`]

TODO: add class description

1. Conforms to *CDA Observation*
2. **SHALL** contain [1..1] `@moodCode` = "EVN"
3. **SHALL** contain [1..*] `id`
4. **SHOULD** contain [1..1] `effectiveTime`
5. **SHALL** contain [1..1] `statusCode`
6. **SHALL** contain [1..1] `code`
7. **MAY** contain [0..1] `methodCode`
8. **SHOULD** contain [0..*] `interpretationCode`
9. **SHALL** contain [1..1] `value`
10. **SHOULD** satisfy: 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).
11. **SHALL** satisfy: The methodCode SHALL NOT conflict with the method inherent in code
12. **SHALL** satisfy: Where value is a physical quantity, the unit of measure SHALL be expressed using a valid Unified Code for Units of Measure (UCUM) expression.
13. **SHOULD** satisfy: Contain one or more referenceRange to show the normal range of values for the observation result
14. **SHALL** satisfy: SHALL NOT contain referenceRange / observationRange / code, as this attribute is not used by the HL7 Clinical Statement or Lab Committee models.
15. **SHALL** satisfy: Contains one or more sources of information.

```
TODO: XML document snippet
```

Figure 57: Result Observation example

Result Organizer

[Organizer: templateId `2.16.840.1.113883.10.20.1.32`]

The result organizer identifies an observation set, contained with the result organizer as a set of result observations. It contains information applicable to all of the contained result observations.

Results in ASTM CCR and CCD are structured similarly to the HL7 Version 2 ORU Observation message, where there is an outer result organizer (templateId 2.16.840.1.113883.10.20.1.32), analogous to the HL7 Version 2 OBR Observation Result Segment, which contains one or more result observations (templateId 2.16.840.1.113883.10.20.1.31), analogous to the HL7 Version 2 OBX Observation/Result Segment.

1. Conforms to *CDA Organizer*
2. **SHALL** contain [1..*] `component` such that it
   a. **SHALL** contain [1..1] *Result Observation* (templateId: `2.16.840.1.113883.10.20.1.31`)
3. **SHOULD** contain [1..*] `component` such that it
   a. **SHALL** contain [1..1] *CDA Specimen*
4. **SHALL** contain [1..1] `@moodCode` = "EVN"
5. **SHALL** contain [1..*] `id`
6. **SHALL** contain [1..1] `code`
7. **SHALL** contain [1..1] `statusCode`
8. **SHOULD** satisfy: 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.
9. **SHOULD** satisfy: Contains one or more Specimen if the specimen isn't inherent in code value.
10. **SHALL** satisfy: The specimen element SHALL NOT conflict with the specimen inherent in code
11. **SHALL** satisfy: Contains one or more component
12. **MAY** satisfy: 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.
13. **MAY** satisfy: A result organizer component / procedure MAY be a reference to a procedure described in the Procedure section.
14. **SHALL** satisfy: Contains one or more sources of information.

```
TODO: XML document snippet
```

Figure 58: Result Organizer example

Severity Observation

[Observation: templateId `2.16.840.1.113883.10.20.1.55`]

TODO: add class description

1. Conforms to *CDA Observation*
2. **SHALL** contain [1..1] `@classCode` = "OBS"
3. **SHALL** contain [1..1] `@moodCode` = "EVN"
4. **SHALL** contain [1..1] `code/@code` = "SEV" *Severity observation* (CodeSystem: 2.16.840.1.113883.5.4 ActCode STATIC V3NE08)
5. **SHALL** contain [1..1] `statusCode/@code` = "completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus STATIC V3NE08)
6. **SHALL** contain [1..1] `value`

```
TODO: XML document snippet
```

Figure 59: Severity Observation example

Social History Observation

[Observation: templateId `2.16.840.1.113883.10.20.1.33`]

TODO: add class description

1. Conforms to *CDA Observation*

```
TODO: XML document snippet
```

Figure 60: Social History Observation example

Status Observation

[Observation: templateId `2.16.840.1.113883.10.20.1.57`]

TODO: add class description

1. Conforms to *CDA Observation*
2. **SHALL** contain [1..1] `@classCode` = "OBS"
3. **SHALL** contain [1..1] `@moodCode` = "EVN"
4. **SHALL** contain [1..1] `code/@code` = "33999-4" *Status* (CodeSystem: 2.16.840.1.113883.6.1 LOINC STATIC 2.26)
5. **SHALL** contain [1..1] `statusCode/@code` = "completed" (CodeSystem: 2.16.840.1.113883.5.14 ActStatus STATIC V3NE08)
6. **SHALL** contain [1..1] `value`, where its data type is CE
7. **SHALL** satisfy: SHALL NOT contain any additional Observation attributes.
8. **SHALL** satisfy: SHALL NOT contain any Observation participants.
9. **SHALL** satisfy: SHALL NOT be the source of any Observation relationships.

```
TODO: XML document snippet
```

Figure 61: Status Observation example

Supply Activity

[Supply: templateId `2.16.840.1.113883.10.20.1.34`]

TODO: add class description

1. Conforms to *CDA Supply*
2. **SHALL** contain [1..*] `id`
3. **SHALL** contain [1..1] `statusCode`
4. **MAY** contain [0..1] `entryRelationship` such that it
   a. **SHALL** contain [1..1] *Medication Status Observation* (templateId: `2.16.840.1.113883.10.20.1.47`)
5. **MAY** contain [0..*] `entryRelationship` such that it
   a. **SHALL** contain [1..1] @typeCode="SUBJ" *SUBJ (has subject)*
   b. **SHALL** contain [1..1] *Fulfillment Instruction* (templateId: `2.16.840.1.113883.10.20.1.43`)

```
TODO: XML document snippet
```

Figure 62: Supply Activity example

Vital Signs Organizer

[Organizer: templateId `2.16.840.1.113883.10.20.1.35`]

TODO: add class description

1. Conforms to *Result Organizer* template (templateId: `2.16.840.1.113883.10.20.1.32`)
2. **SHALL** satisfy: Contains one or more sources of information.

```
TODO: XML document snippet
```

Figure 63: Vital Signs Organizer example

CLASSES

This section of the Implementation Guide details the non-template classes, i.e. those that do not have a templateId.

Plan Of Care Activity

TODO: add class description

1.

Procedure Activity

TODO: add class description

1. **SHALL** contain [1..1] `moodCode`, where its data type is ActMood
2. **SHALL** contain [1..*] `id`, where its data type is II
3. **SHALL** contain [1..1] `statusCode/@code` = "completed" (CodeSystem: 2.16.840.1.113883.1.11.20.15 ProcedureStatusCode STATIC 20061017), where its data type is CS
4. **SHOULD** contain [0..1] `effectiveTime`, where its data type is IVL_TS
5. **SHALL** contain [1..1] `code`, where its data type is CD

REFERENCES

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