HL7 Implementation Guide:
CDA Release 2 – Continuity of Care Document (CCD)

A CDA implementation of ASTM E2369-05
Standard Specification for Continuity of Care Record© (CCR)
which may be used in lieu of ASTM ADJE2369

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1 Introduction

1.1 Scope

The purpose of this document is to describe constraints on the HL7 Clinical Document Architecture, Release 2 (CDA) specification in accordance with requirements set forward in ASTM E2369-05 Standard Specification for Continuity of Care Record (CCR).

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

The HL7 Clinical Document Architecture (CDA) is a document markup standard that specifies the structure and semantics of clinical documents for the purpose of exchange. From its inception, CDA has supported the ability to represent professional society recommendations, national clinical practice guidelines, and standardized data sets. From the perspective of CDA, the CCR is a standardized data set that can be used to constrain CDA specifically for summary documents.

The resulting specification, known as the Continuity of Care Document (CCD), is developed as a collaborative effort between ASTM and HL7. It is intended as an alternate implementation to the one specified in ASTM ADJE2369 for those institutions or organizations committed to implementation of the HL7 Clinical Document Architecture.

> **NOTE:** The HL7 Implementation Guide for CDA Release 2 – Level 1 and 2 – Care Record Summary (US realm) (CRS) will be superseded by this CCD implementation guide where the scopes overlap.

1.2 How to read this document

This document is arranged analogously to the ASTM CCR specification. More specifically, the organization of this document follows the organization of ASTM CCR Table A1.1 “CCR Data Fields Spreadsheet”. It should be noted however that there are minor discrepancies between elements defined in the CCR Header/Body/Footer and the corresponding elements defined in the CDA Header/Body, such that, for instance, an element defined in the CCR Footer may map to an element defined in the CDA Header. As a result, constraints on, for example, the CDA Header, may be found in various sections of this document.

The document is organized into the following major sections:

- **Introduction** – provides an overview and scope of the CCD specification.
- **CCR Header Representation** – defines constraints on CDA R2 corresponding to CCR Header components.
- **CCR Body Representation** – defines constraints on CDA R2 corresponding to CCR Body components.
- **CCR Footer Representation** – defines constraints on CDA R2 corresponding to CCR Footer components.
- **General Constraints** – provides more detailed mappings and CDA R2 constraints for global CCR components, such as data types and identifiers.
- **Appendix** – provides detailed and conformant sample CCR and CCD instances.

Each major section or subsection of the document is organized to provide:

- **A narrative overview** – provides an overview and scope for the subsection.

- **CDA R2 constraints** – ASTM CCR requirements are expressed as constraints on the CDA R2 specification, making this document a "conformance profile", as described in the Refinement and Localization (http://www.hl7.org/v3ballot/html/infrastructure/conformance/conformance.htm) section of the HL7 Version 3 standards. As defined in that document, this guide is both an annotation profile and a localization profile. The base standard for this guide is the HL7 Clinical Document Architecture, Release 2.0.

  Where no constraints are stated in this guide, CCD instances are subject to and are to be created in accordance with the base CDA R2 specification. Where, for instance, the CDA R2 specification declares an attribute to be optional and the CCD specification contains no additional constraints, that attribute remains optional for use in a CCD instance.

  In the absence of an HL7-defined and fully parsable grammar for constraints, certain conventions are followed in this guide so as to minimize ambiguity.

  - The key words "**SHALL**", "**SHALL NOT**", "**SHOULD**", "**SHOULD NOT**", "**MAY**"[1], and "**NEED NOT**" in this document are to be interpreted as described in the HL7 Version 3 Publishing Facilitator's Guide (http://www.hl7.org/v3ballot/html/help/pfg/pfg.htm).

  - Cardinality constraints are stated from the perspective of the containing element. For instance, assume that SectionOne is optional, that if SectionOne is present then ObservationOne is required and one or more ObservationTwo's are optional, and that if ObservationTwo is present then ObservationTwo / effectiveTime is required. Corresponding constraints:

    CONF-ex1: **CCD MAY** contain exactly one **SectionOne**.
    CONF-ex2: **SectionOne SHALL** contain exactly one **ObservationOne**.
    CONF-ex3: **SectionOne MAY** contain one or more **ObservationTwo**.
    CONF-ex4: **ObservationTwo SHALL** contain exactly one **ObservationTwo / effectiveTime**.

  - Formalisms for value set constraints are based on the latest recommendations from the HL7 Vocabulary Committee. Value set constraints can be "**STATIC**", meaning that they are bound to a specified version of a value set, or "**DYNAMIC**", meaning that they are bound to the most current version of the value set. A simplified constraint is used when binding is to a single code.

    - Syntax for vocabulary binding to DYNAMIC or STATIC value sets: The value for ("pathName of coded element") (**SHALL** | **SHOULD** | **MAY**) be selected from ValueSet valueSetOID localValueSetName (**DYNAMIC** | **STATIC** (valueSetEffectiveDate)).

      CONF-ex5: The value for "**ClinicalDocument / code**" **SHALL** be selected from ValueSet 2.16.840.1.113883.19.3 LoincDocumentTypeCode **DYNAMIC**.

[1] "**MAY**" constraints are often used to call out vocabulary not mentioned in CDA R2, to call out attributes that are needed for CCR mapping, to minimize ambiguity by clarifying that a particular construct is allowed in a particular context, etc. "**MAY**" constraints are not used to simply replicate the underlying existing CDA constraints

CONF-ex6: The value for "**ClinicalDocument / code**" **SHALL** be selected from ValueSet 2.16.840.1.113883.19.3 LoincDocumentTypeCode **STATIC** 20061017.

- Syntax for vocabulary binding to a single code: The value for ("pathname of coded element") (**SHALL** | **SHOULD** | **MAY**) be ("code" ["displayName"] codeSystemOID [codeSystemName] **STATIC**.

  CONF-ex7: The value for "**ClinicalDocument / code**" **SHALL** be "34133-9" "Summarization of episode note" 2.16.840.1.113883.6.1 LOINC **STATIC**.

- Constraints assume context propagation. For example, if a CDA entry requires an author participant, and authorship is defined at the section level and propagates to the entry, then the constraint is satisfied.

- Constraints are expressed in a technology-neutral formalism. Section ***7.1.4 Sample CCD Validating Style Sheet*** provides a non-normative example of how one might implement the normative conformance statements, by expressing them as assertions within a Schematron schema.

- **CDA R2 model subset** – provides a graphical representation of those portions of the CDA R2 object model being constrained by conformance statements. Those parts of the CDA R2 object model not illustrated and not constrained are to be used in accordance with the base CDA R2 specification.

- **CDA R2 extensions** – where applicable, describes extensions to the CDA R2 specification.

- **ASTM CCR mapping** – provides a mapping from the CCR attributes and data objects defined in ASTM CCR Table A1.1 "CCR Data Fields Spreadsheet" to corresponding CDA R2 elements.

- **Additional examples** – Conformant CCR and CCD instances are provided in the appendix. Where applicable, additional examples may be provided.

1.3 Approach

The approach taken in the development of this specification is intended to reflect the ASTM CCR requirements in an HL7 CDA R2 framework, and to do so in such a way that CDA is constrained in accordance with models being developed by other HL7 committees.

The general steps taken include:

- Review a section of CCR, focusing on identifying the data requirements. For instance, review the CCR section describing the representation of lab results.

- Review overlapping HL7 domain models to see how similar data requirements have been represented. For instance, review the domain model from the Lab committee to see how it accommodates lab results.

- Review additional relevant references and standards for further cross-validation of requirements.

- Represent the CCR data requirements as a set of constraints against the HL7 Clinical Statement model, in a way that is isomorphic to existing HL7 domain models. This constrained Clinical Statement model

can then be used by any HL7 committee wanting to implement similar requirements in their own specifications.

- Reflect the Clinical Statement constraints as constraints against CDA R2, making minor adjustments as necessary to accommodate the differences between the models.

1.4 Asserting conformance to this Implementation Guide

This specification defines constraints on CDA Header and Body elements used in a Continuity of Care Document.

CDA provides a mechanism to reference a template or implementation guide that has been assigned a unique identifier. The following example shows how to formally assert the use of this implementation guide. Use of the templateId indicates that the CDA instance not only conforms to the CDA specification, but in addition, conforms to constraints specified in this implementation guide.

Figure 1. Use of the templateId element to assert use of this guide

```
<ClinicalDocument xmlns='urn:hl7-org:v3'>
        <typeId extension='POCD_HD000040' root='2.16.840.1.113883.1.3'/>
        <templateId root='2.16.840.1.113883.10.20.1'/>
        …
</ClinicalDocument>
```

In addition to assigning a template identifier to the overall implementation guide, this document assigns template identifiers to other patterns, such as document sections and specific clinical statements within document sections. Using the templateId to reference one of these patterns indicates that the CDA instance conforms to the constraints specified in that pattern.

Figure 2. Use of the templateId element to assert use of a pattern

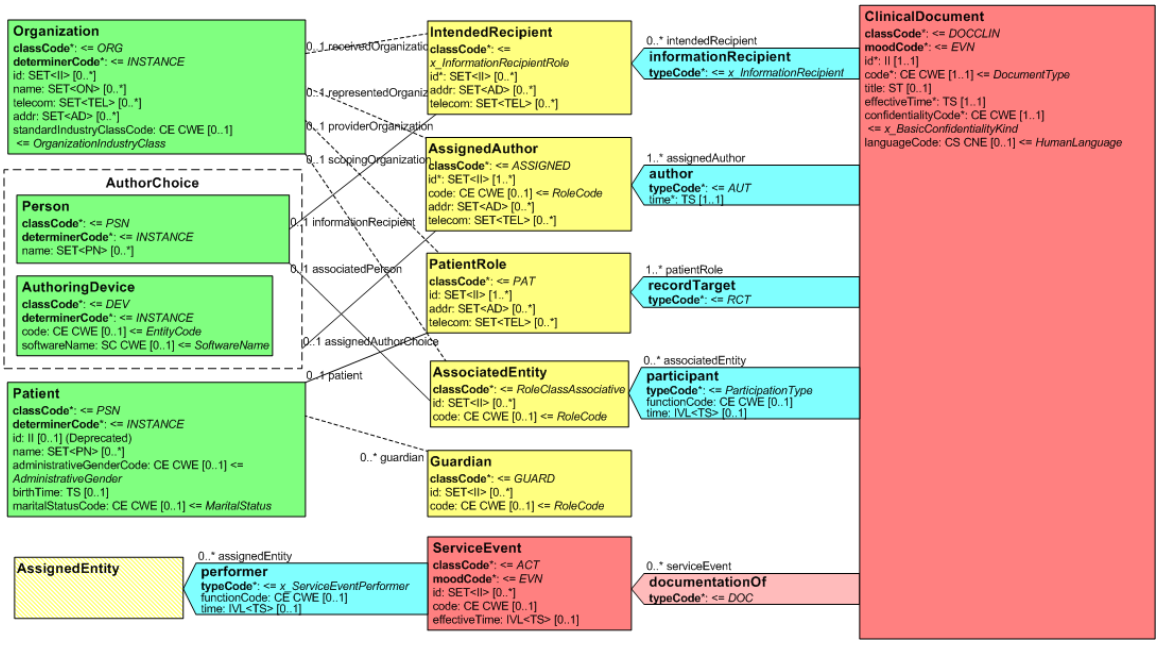
```
<section>
        <templateId root='2.16.840.1.113883.10.20.1.14'/>
        …
        <observation classCode=”OBS” moodCode=”EVN”>
                <templateId root='2.16.840.1.113883.10.20.1.32'/>
                …
        </observation>
</section>
```

2 CCR Header Representation

The CCR Header defines the document parameters, including its unique identifier, language, version, date/time, the patient whose data it contains, who or what has generated the CCR, to whom or what the CCR is directed, and the CCR's purpose.

The following figure shows a subset of the CDA R2 Header model containing those classes being constrained or referred to in the conformance statements that follow.

Figure 3. Subset of CDA R2 Header



2.1 CCR Unique Identifier

Represents a unique identifier for the current CCR instance. Corresponds to the **ClinicalDocument / id** in CDA R2. Required in both CCR and CDA. In addition, CDA R2 provides a **ClinicalDocument / code**, whose value is fixed by this specification.

CONF-1: The value for "**ClinicalDocument / code**" **SHALL** be "34133-9" "Summarization of episode note" 2.16.840.1.113883.6.1 LOINC **STATIC**.

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

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

CONF-2: A CCD **SHALL** contain exactly one **ClinicalDocument / documentationOf / serviceEvent**.

CONF-3: The value for "**ClinicalDocument / documentationOf / serviceEvent / @classCode**" **SHALL** be "PCPR" "Care provision" 2.16.840.1.113883.5.6 ActClass **STATIC**.

CONF-4: **ClinicalDocument / documentationOf / serviceEvent SHALL** contain exactly one **serviceEvent / effectiveTime / low** and exactly one **serviveEvent / effectiveTime / high**.

2.2 Language

No controlled vocabulary has been specified for Language in the CCR data set, whereas in CDA R2, the language is represented by a coded value using RFC-3066. Language is required in CCR, whereas it is optional in CDA R2.

CONF-5: CCD **SHALL** contain exactly one **ClinicalDocument / languageCode**.

CONF-6: **ClinicalDocument / languageCode SHALL** be in 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.

2.3 Version

Represents the version of the implementation guide used to create a given instance. In CDA, ClinicalDocument / templateId performs the same function, as described above in section ***1.4 Asserting conformance to this Implementation Guide***.

CONF-7: CCD **SHALL** contain one or more **ClinicalDocument / templateId**.

CONF-8: At least one **ClinicalDocument / templateId SHALL** value **ClinicalDocument / templateId / @root** with "2.16.840.1.113883.10.20.1", and **SHALL NOT** contain **ClinicalDocument / templateId / @extension**.

2.4 CCR Creation Date/Time

Represents the exact clock time that the summarization was created, corresponding to the CDA R2 ClinicalDocument / effectiveTime. CCR further requires that the time be precise to the second, and must express a time zone offset.

CONF-9: **ClinicalDocument / effectiveTime SHALL** be expressed with precision to include seconds.

CONF-10: **ClinicalDocument / effectiveTime SHALL** include an explicit time zone offset.

2.5 Patient

Represents the patient to which the summarization refers. Corresponds to CDA R2 ClinicalDocument / recordTarget. CCR can only be about one patient with the extreme exception of conjoined twins.

CONF-11: CCD **SHALL** contain one to two **ClinicalDocument / recordTarget**.

2.6 From

Identifies who or what has generated the summarization, corresponding to CDA's author paricipant. CDA R2 requires an author (which may be a person or a device), and stipulates that a completed document has been legally authenticated. CDA R2 also requires that a clinical document have a defined custodian. Where a CCD document is generated by a machine, legal authentication is represented as the organization responsible for generating the data.

CDA R2 author participant has a required participant time, which should be set to equal the ClinicalDocument / effectiveTime, and thus map back to CCR's creation date/time.

CONF-12: CCD **SHALL** contain one or more **ClinicalDocument / author / assignedAuthor / assignedPerson** and/or **ClinicalDocument / author / assignedAuthor / representedOrganization**.

CONF-13: If author has an associated representedOrganization with no **assignedPerson** or **assignedAuthoringDevice**, then the value for "**ClinicalDocument / author / assignedAuthor / id / @NullFlavor**" **SHALL** be "NA" "Not applicable" 2.16.840.1.113883.5.1008 NullFlavor **STATIC**.

2.7 To

Represents to whom or what the summarization is targeted. Corresponds to the CDA R2 ClinicalDocument / informationRecipient participant. This is optional in both CCR and CDA.

CONF-14: CCD **MAY** contain one or more **ClinicalDocument / informationRecipient**.

2.8 Purpose

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.

> **NOTE:** Purpose is represented as a document body section in CCD. The template identifier for the Purpose section is 2.16.840.1.113883.10.20.1.13.

CONF-15: **CCD MAY** contain exactly one and **SHALL NOT** contain more than one Purpose section (templateId 2.16.840.1.113883.10.20.1.13). The Purpose section **SHALL** contain a narrative block, and **SHOULD** contain clinical statements. Clinical statements **SHOULD** include one or more purpose activities (templateId 2.16.840.1.113883.10.20.1.30).

2.8.1 Section conformance

CONF-16: The purpose section **SHALL** contain **Section / code**.

CONF-17: The value for "**Section / code**" **SHALL** be "48764-5" "Summary purpose" 2.16.840.1.113883.6.1 LOINC **STATIC**.

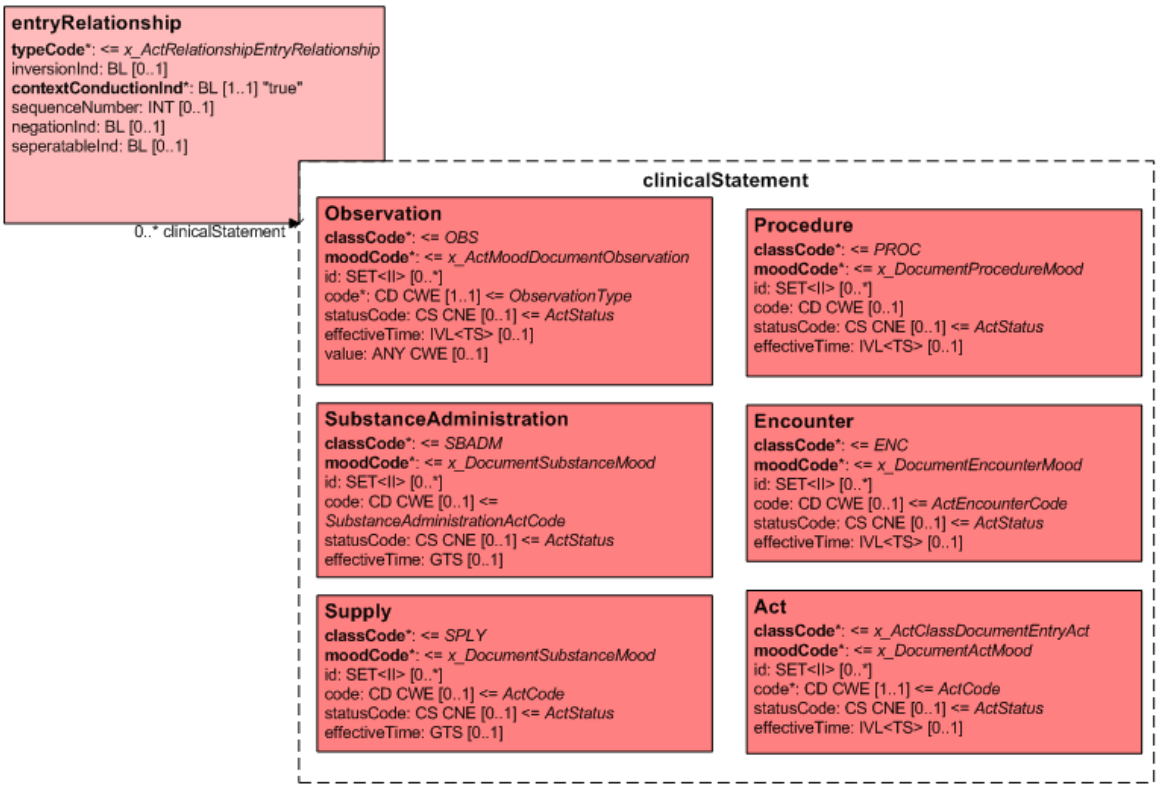
CONF-18: The purpose section **SHALL** contain **Section / title.**

CONF-19: **Section / title SHOULD** be valued with a case-insensitive language-insensitive text string containing "purpose".

2.8.2 Clinical statement conformance

The following figure shows a subset of the CDA Clinical Statement model containing those classes being constrained or referred to in the conformance statements that follow.

Figure 4. CDA R2 clinical statement model for purpose



2.8.2.1 Purpose activity

The template identifier for a purpose activity is 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.

CONF-20: A purpose activity (templateId 2.16.840.1.113883.10.20.1.30) **SHALL** be represented with **Act**.

CONF-21: The value for "**Act / @classCode**" in a purpose activity **SHALL** be "ACT" 2.16.840.1.113883.5.6 ActClass **STATIC**.

CONF-22: The value for "**Act / @moodCode**" in a purpose activity **SHALL** be "EVN" 2.16.840.1.113883.5.1001 ActMood **STATIC**.

CONF-23: A purpose activity **SHALL** contain exactly one **Act / statusCode**.

CONF-24: The value for "**Act / statusCode**" in a purpose activity **SHALL** be "completed" 2.16.840.1.113883.5.14 ActStatus **STATIC**.

CONF-25: A purpose activity **SHALL** contain exactly one **Act / code**, with a value of "23745001" "Documentation procedure" 2.16.840.1.113883.6.96 SNOMED CT **STATIC**.

CONF-26: A purpose activity **SHALL** contain exactly one **Act / 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.

CONF-27: The target of **Act / entryRelationship / @typeCode** in a purpose activity **SHALL** be an **Act**, **Encounter**, **Observation**, **Procedure**, **SubstanceAdministration**, or **Supply**.

2.9 ASTM CCR Header Mapping

The following table is the CCR Header subset of ASTM CCR Table A1.1 "CCR Data Fields Spreadsheet".

Table 1. CCR Header mapping to CDA R2

CCR Data Object	CCR XML Element	CCR Required or Optional	CDA R2 Correspondence	Mapping Comments
CCR Header Objects				
	/ccr:ContinuityOfCareRecord/		/ClniicalDocument/	
CCR Unique Identifier	ccr:CCRDocumentObjectID	Required	id	See section *5.4.5 Identifiers* for more details.
Language	ccr:Language	Required	languageCode	
Version	ccr:Version	Required	templateId	
CCR Creation Date/Time	ccr:DateTime	Required	effectiveTime	
Patient	ccr:Patient	Required	recordTarget	
From	ccr:From	Required	author	
To	ccr:To	Optional	informationRecipient	
Purpose	ccr:Purpose	Optional	Act / entryRelationship [@typeCode = "RSON"] /	Represented as a document body section in CCD
	ccr:DateTime	Optional	Act / effectiveTime	
	ccr:Description	Required	Act | Encounter | Observation | Procedure | SubstanceAdministration | Supply]	
	ccr:OrderRequest	Optional	[Act | Encounter | Observation | Procedure | SubstanceAdministration | Supply]	

CCR Data Object	CCR XML Element	CCR Required or Optional	CDA R2 Correspondence	Mapping Comments
	ccr:Indications	Optional	Act / entryRelationship [@typeCode = “RSON”] / [Act | Encounter | Observation | Procedure | SubstanceAdministration | Supply]	
	ccr:ReferenceID	Optional	See section ***4.2 References***.	
	ccr:CommentID	Optional	See section ***4.3 Comments***.	

3 CCR Body Representation

The CCR Body contains the core patient-specific data, such as current and past medications, problems, and procedures. Data are aggregated into sections based on common clinical conventions.

In a typical scenario, the body is dynamically created by pulling in existing data from a variety of sources, and no new content is specifically created for the summary. In some cases the source data will be narrative; in other cases there may be coded data supporting some aspects of the narrative; and in some cases the source data will be fully coded. Where the body is dynamically created by pulling in existing data, the originating application creating the Continuity of Care Document can create (narrative, partially coded, or fully coded) entries corresponding to the source data, and then algorithmically construct each CDA Narrative Block (**ClinicalDocument / component / structuredBody / component / section / text**). In such a situation, the entry relationship "DRIV" (is derived from) (**ClinicalDocument / component / structuredBody / component / section / entry / @typeCode="DRIV"**) can be used, to indicate that the CDA Narrative Block is fully derived from the (coded and/or non-coded) entries, and that the narrative contains no clinical content not derived from the entries.

CONF-28: The value for "**ClinicalDocument / component / structuredBody / component / section / entry / @typeCode**" **MAY** be "DRIV" "is derived from" 2.16.840.1.113883.5.1002 ActRelationshipType STATIC, to indicate that the CDA Narrative Block is fully derived from the structured entries.

CDA provides a mechanism to explicitly reference from an entry to the corresponding narrative, as illustrated in the following example (see CDA Release 2, section 4.3.5.1 <content> for details):

```
<section>
  <code/>
  <title/>
  <text>
    <content ID="Blob1">...procedure/code original text...</content>
    <content ID="Blob2">...act/text uncoded text blob...</content>
  </text>
  <entry>
    <procedure>
      <code code="12345" codeSystem="2.16.840.1.113883.19.1"/>
        <originalText><reference value="#Blob1"/></originalText>
      </code>
    </procedure>
  </entry>
  <entry>
    <act>
      <text><reference value="#Blob2"/></text>
    </act>
  </entry>
</section>
```

CCD recommends the use of these references to facilitate translation of CCD into ASTM's XML CCR format.

CONF-29: A CCD entry **SHOULD** explicitly reference its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1 <content>).

3.1 Payers

The template identifier for the Payers section is 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.

CONF-30: **CCD SHOULD** contain exactly one and **SHALL NOT** contain more than one Payers section (templateId 2.16.840.1.113883.10.20.1.9). The Payers section **SHALL** contain a narrative block, and **SHOULD** contain clinical statements. Clinical statements **SHOULD** include one or more coverage activities (templateId 2.16.840.1.113883.10.20.1.20).

3.1.1 Section conformance

CONF-31: The payer section **SHALL** contain **Section / code**.

CONF-32: The value for "**Section / code**" **SHALL** be "48768-6" "Payment sources" 2.16.840.1.113883.6.1 LOINC **STATIC**.

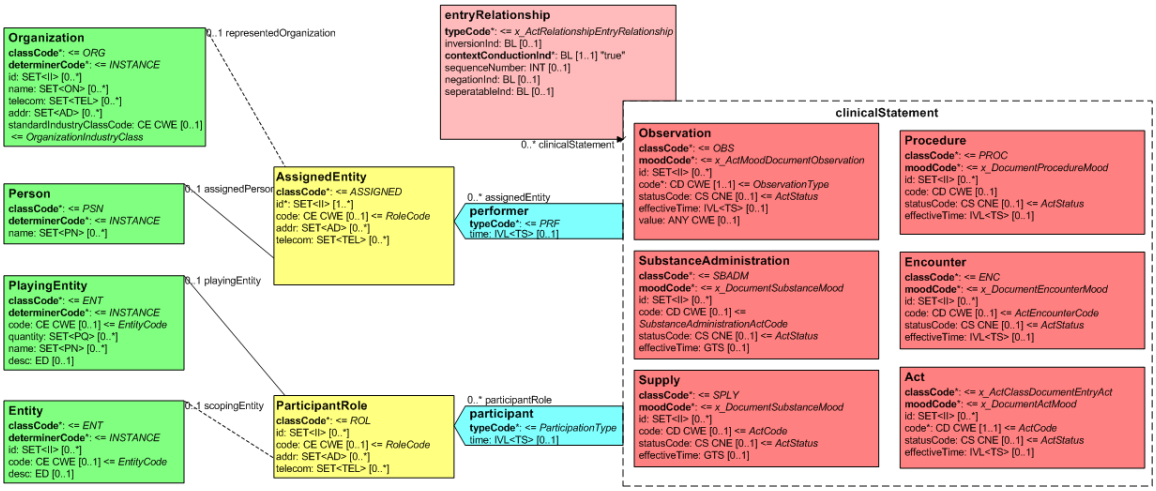
CONF-33: The payer section **SHALL** contain **Section / title.**

CONF-34: **Section / title SHOULD** be valued with a case-insensitive language-insensitive text string containing "insurance" or "payers".

3.1.2 Clinical statement conformance

The following figure shows a subset of the CDA R2 model containing those classes being constrained or referred to in the conformance statements that follow.

Figure 5. CDA R2 clinical statement model for payer information



3.1.2.1 Payer representation

The template identifier for a coverage activity is 2.16.840.1.113883.10.20.1.20.
The template identifier for a policy activity is 2.16.840.1.113883.10.20.1.26.
The template identifier for an authorization activity is 2.16.840.1.113883.10.20.1.19.

Insurance and authorization acts are represented as Acts within the section. These acts are grouped together under a single coverage activity, which serves to order the payment sources. A coverage activity contains one or more policy activities, each of which contains zero or more authorization activities.

> **NOTE:** To the extent possible, the conformance statements in this section are isomorphic and compatible with the HL7 Financial Management (FM) domain model. In some cases, CDA R2 lacks class codes or other RIM components used by FM, in which case the closest corresponding CDA R2 representation is used.

3.1.2.1.1 Coverage activity

CONF-35: A coverage activity (templateId 2.16.840.1.113883.10.20.1.20) **SHALL** be represented with **Act**.

CONF-36: The value for "**Act / @classCode**" in a coverage activity **SHALL** be "ACT" 2.16.840.1.113883.5.6 ActClass **STATIC**.

CONF-37: The value for "**Act / @moodCode**" in a coverage activity **SHALL** be "DEF" 2.16.840.1.113883.5.1001 ActMood **STATIC**.

CONF-38: A coverage activity **SHALL** contain at least one **Act / id**.

CONF-39: A coverage activity **SHALL** contain exactly one **Act / statusCode**.

CONF-40: The value for "**Act / statusCode**" in a coverage activity **SHALL** be "completed" 2.16.840.1.113883.5.14 ActStatus **STATIC**.

CONF-41: A coverage activity **SHALL** contain exactly one **Act / code**.

CONF-42: The value for "**Act / code**" in a coverage activity **SHALL** be "48768-6" "Payment sources" 2.16.840.1.113883.6.1 LOINC **STATIC**.

CONF-43: A coverage activity **SHALL** contain one or more **Act / entryRelationship**.

CONF-44: An **entryRelationship** in a coverage activity **MAY** contain exactly one **entryRelationship / sequenceNumber**, which serves to prioritize the payment sources.

CONF-45: The value for "**Act / entryRelationship / @typeCode**" in a coverage activity **SHALL** be "COMP" 2.16.840.1.113883.5.1002 ActRelationshipType **STATIC**.

CONF-46: The target of a coverage activity **SHALL** be a policy activity (templateId 2.16.840.1.113883.10.20.1.26).

CONF-47: A coverage activity **SHALL** contain one or more sources of information, as defined in section ***5.2 Source***.

3.1.2.1.2 Policy Activity

A policy activity represents the policy or program providing the coverage. The person for whom payment is being provided (i.e. the patient) is the covered party. The subscriber of the policy or program is represented as a participant that is the holder the coverage. The payer is represented as the performer of the policy activity.

CONF-48: A policy activity (templateId 2.16.840.1.113883.10.20.1.26) **SHALL** be represented with **Act**.

CONF-49: The value for "**Act / @classCode**" in a policy activity **SHALL** be "ACT" 2.16.840.1.113883.5.6 ActClass **STATIC**.

CONF-50: The value for "**Act / @moodCode**" in a policy activity **SHALL** be "EVN" 2.16.840.1.113883.5.1001 ActMood **STATIC**.

CONF-51: A policy activity **SHALL** contain at least one **Act / id**, which represents the group or contract number related to the insurance policy or program.

CONF-52: A policy activity **SHALL** contain exactly one **Act / statusCode**.

CONF-53: The value for "**Act / statusCode**" in a policy activity **SHALL** be "completed" 2.16.840.1.113883.5.14 ActStatus **STATIC**.

CONF-54: A policy activity **SHOULD** contain zero to one **Act / code**., which represents the type of coverage.

CONF-55: The value for "**Act / code**" in a policy activity **SHOULD** be selected from ValueSet 2.16.840.1.113883.1.11.19832 ActCoverageType **DYNAMIC**.

CONF-56: A policy activity **SHALL** contain exactly one **Act / performer [@typeCode="PRF"]**, representing the payer.

CONF-57: A payer in a policy activity **SHALL** contain one or more **performer / assignedEntity / id**, to represent the payer identification number. For pharamacy benefit programs this can be valued using the RxBIN and RxPCN numbers assigned by ANSI and NCPDP respectively. When a nationally recognized payer identification number is available, it would be placed here.

CONF-58: A policy activity **SHALL** contain exactly one **Act / participant [@typeCode="COV"]**, representing the covered party.

CONF-59: A covered party in a policy activity **SHOULD** contain one or more **participant / participantRole / id**, to represent the patient's member or subscriber identifier with respect to the payer.

CONF-60: A covered party in a policy activity **SHOULD** contain exactly one **participant / participantRole / code**, to represent the reason for coverage (e.g. Self, Family dependent, student).

CONF-61: The value for "**participant / participantRole / code**" in a policy activity's covered party **MAY** be selected from ValueSet 2.16.840.1.113883.1.11.19809 PolicyOrProgramCoverageRoleType **DYNAMIC**.

CONF-62: A covered party in a policy activity **MAY** contain exactly one **participant / time**, to represent the time period over which the patient is covered.

CONF-63: A policy activity **MAY** contain exactly one **Act / participant [@typeCode="HLD"]**, representing the subscriber.

CONF-64: A subscriber in a policy activity **SHOULD** contain one or more **participant / participantRole / id**, to represent the subscriber's identifier with respect to the payer.

CONF-65: A subscriber in a policy activity **MAY** contain exactly one **participant / time**, to represent the time period for which the subscriber is enrolled.

CONF-66: The value for "**Act / entryRelationship / @typeCode**" in a policy activity **SHALL** be "REFR" 2.16.840.1.113883.5.1002 ActRelationshipType **STATIC**.

CONF-67: The target of a policy activity with **Act / entryRelationship / @typeCode="**REFR**" SHALL** be an authorization activity (templateId 2.16.840.1.113883.10.20.1.19) or an **Act**, with **Act [@classCode = "ACT"]** and **Act [@moodCode = "DEF"]**, representing a description of the coverage plan.

CONF-68: A description of the coverage plan **SHALL** contain one or more **Act / Id**, to represent the plan identifier.

3.1.2.1.3 Authorization Activity

An authorization activity represents authorizations or pre-authorizations currently active for the patient for the particular payer.

Authorizations are represented using an act subordinate to the policy or program that provided it. The policy or program is referred to by the authorization. Authorized treatments can be grouped into an Organizer class, where common properties, such as the reason for the authorization, can be expressed. Subordinate acts represent what was authorized.

CONF-69: An authorization activity (templateId 2.16.840.1.113883.10.20.1.19) **SHALL** be represented with **Act**.

CONF-70: The value for "**Act / @classCode**" in an authorization activity **SHALL** be "ACT" 2.16.840.1.113883.5.6 ActClass **STATIC**.

CONF-71: An authorization activity **SHALL** contain at least one **Act / id**.

CONF-72: The value for "**Act / @moodCode**" in an authorization activity **SHALL** be "EVN" 2.16.840.1.113883.5.1001 ActMood **STATIC**.

CONF-73: An authorization activity **SHALL** contain one or more **Act / entryRelationship**.

CONF-74: The value for "**Act / entryRelationship / @typeCode**" in an authorization activity **SHALL** be "SUBJ" 2.16.840.1.113883.5.1002 ActRelationshipType **STATIC**.

CONF-75: The target of an authorization activity with **Act / entryRelationship / @typeCode="**SUBJ**" SHALL** be a clinical statement with **moodCode = "PRMS" (Promise)**.

CONF-76: The target of an authorization activity **MAY** contain one or more **performer**, to indicate the providers that have been authorized to provide treatment.

3.2 Advance Directives

The template identifier for the Advance Directives section is 2.16.840.1.113883.10.20.1.1.

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

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

CONF-77: **CCD SHOULD** contain exactly one and **SHALL NOT** contain more than one Advance directives section (templateId 2.16.840.1.113883.10.20.1.1). The Advance directives section **SHALL** contain a narrative block, and **SHOULD** contain clinical statements. Clinical statements **SHOULD** include one or more advance directive observations (templateId 2.16.840.1.113883.10.20.1.17). An advance directive observation **MAY** contain exactly one advance directive reference (templateId 2.16.840.1.113883.10.20.1.36) to an external advance directive document.

3.2.1 Section conformance

CONF-78: The advance directive section **SHALL** contain **Section / code**.

CONF-79: The value for "**Section / code**" **SHALL** be "42348-3" "Advance directives" 2.16.840.1.113883.6.1 LOINC **STATIC**.

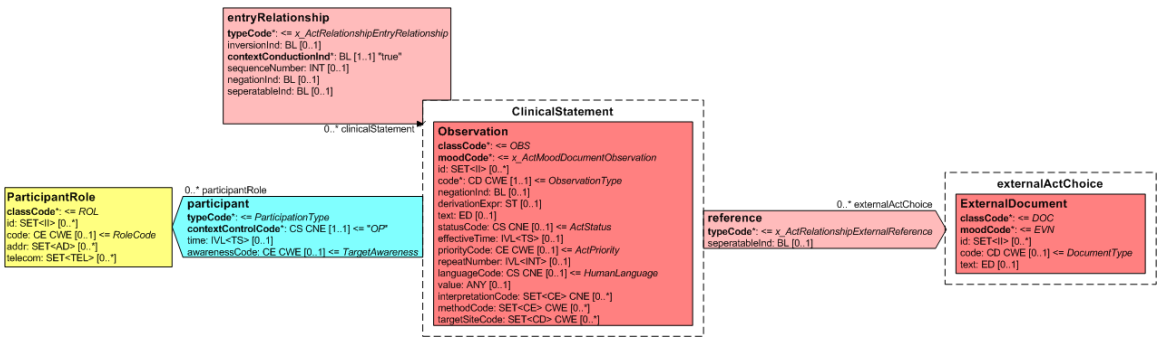
CONF-80: The advance directive section **SHALL** contain **Section / title.**

CONF-81: **Section / title SHOULD** be valued with a case-insensitive language-insensitive text string containing "advance directives".

3.2.2 Clinical statement conformance

The following figure shows a subset of the CDA Clinical Statement model containing those classes being constrained or referred to in the conformance statements that follow.

Figure 6. CDA R2 clinical statement model for advance directives



3.2.2.1 Advance directive observations

The template identifier for an advance directive observation is 2.16.840.1.113883.10.20.1.17.
The template identifier for verification of an advance directive observation is templateId 2.16.840.1.113883.10.20.1.58.

Advance directives in the ASTM CCR correspond to CDA R2 Observations in Event mood in that they assert findings (e.g. "resuscitation status is Full Code") rather than orders.

CONF-82: An advance directive observation (templateId 2.16.840.1.113883.10.20.1.17) **SHALL** be represented with **Observation**.

CONF-83: The value for "**Observation / @classCode**" in an advance directive observation **SHALL** be "OBS" 2.16.840.1.113883.5.6 ActClass **STATIC**.

CONF-84: The value for "**Observation / @moodCode**" in an advance directive observation **SHALL** be "EVN" 2.16.840.1.113883.5.1001 ActMood **STATIC**.

CONF-85: An advance directive observation **SHALL** contain at least one **Observation / id**.

CONF-86: An advance directive observation **SHALL** contain exactly one **Observation / statusCode**.

CONF-87: The value for "**Observation / statusCode**" in an advance directive observation **SHALL** be "completed" 2.16.840.1.113883.5.14 ActStatus **STATIC**.

CONF-88: An advance directive observation **SHOULD** contain exactly one **Observation / effectiveTime**, to indicate the effective time of the directive.

CONF-89: An advance directive observation **SHALL** contain exactly one **Observation / code**.

CONF-90: The value for "**Observation / code"** in an advance directive observation **MAY** be selected from ValueSet 2.16.840.1.113883.1.11.20.2 AdvanceDirectiveTypeCode **STATIC** 20061017.

CONF-91: There **SHOULD** be an advance directive observation whose value for "**Observation / code"** is "304251008" "Resuscitation status" 2.16.840.1.113883.6.96 SNOMED CT **STATIC**.

CONF-92: A verification of an advance directive observation (templateId 2.16.840.1.113883.10.20.1.58) **SHALL** be represented with **Observation / participant**.

CONF-93: An advance directive observation **MAY** include one or more verifications.

CONF-94: The value for "**Observation / participant / @typeCode**" in a verification **SHALL** be "VRF" "Verifier" 2.16.840.1.113883.5.90 ParticipationType **STATIC**.

CONF-95: A verification of an advance directive observation **SHOULD** contain **Observation / participant / time**.

CONF-96: The data type of **Observation / participant / time** in a verification **SHALL** be TS (time stamp).

CONF-97: An advance directive observation **SHALL** contain one or more sources of information, as defined in section ***5.2 Source***.

3.2.2.2 Representation of "status" values

The template identifier for an advance directive status observation is 2.16.840.1.113883.10.20.1.37.

CONF-98: An advance directive observation **SHALL** contain exactly one advance directive status observation.

CONF-99: An advance directive status observation (templateId 2.16.840.1.113883.10.20.1.37) **SHALL** be a conformant status observation (templateId 2.16.840.1.113883.10.20.1.57) (as defined in section *5.1 "Type" and "Status" values*).

CONF-100: The value for "**Observation / value**" in an advance directive status observation **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.20.1 AdvanceDirectiveStatusCode **STATIC** 20061017.

3.2.2.3 Advance directive references

The template identifier for an advance directive reference is 2.16.840.1.113883.10.20.1.36.

Referenced advance directive documents are represented with the **ExternalDocument** class.

CONF-101: An advance directive reference (templateId 2.16.840.1.113883.10.20.1.36) **SHALL** be represented with **Observation / reference / ExternalDocument**.

CONF-102: An advance directive observation **MAY** contain exactly one advance directive reference.

CONF-103: The value for "**Observation / reference / @typeCode**" in an advance directive reference **SHALL** be "REFR" 2.16.840.1.113883.5.1002 ActRelationshipType **STATIC**.

CONF-104: ExternalDocument **SHALL** contain at least one ExternalDocument / id.

CONF-105: The URL of a referenced advance directive document **MAY** be present, and **SHALL** be represented in **Observation / reference / ExternalDocument / text / reference**. A **<linkHTML>** element containing the same URL **SHOULD** be present in the associated CDA Narrative Block.

CONF-106: The MIME type of a referenced advance directive document **MAY** be present, and **SHALL** be represented in **Observation / reference / ExternalDocument / text / @mediaType**.

CONF-107: Where the value of **Observation / reference / seperatableInd** is "false", the referenced advance directive document **SHOULD** be included in the CCD exchange package. The exchange mechanism **SHOULD** be based on Internet standard RFC 2557 "MIME Encapsulation of Aggregate Documents, such as HTML (MHTML)" (http://www.ietf.org/rfc/rfc2557.txt). (See CDA Release 2, section 3 "CDA Document Exchange in HL7 Messages" for examples and additional details).

3.3 Support

Represents the patient's sources of support such as immediate family, relatives, and guardian at the time the summarization is generated. Support information also includes next of kin, caregivers, and support organizations. At a minimum, key support contacts relative to healthcare decisions, including next of kin, should be included.

CDA R2 represents a patient's guardian with the CDA Header **Guardian** class. Other Supporters are represented as **participant** participations in the CDA Header.

> **NOTE:** CCR Supporters are not represented as a CCD Body section, but rather, are represented as participants in the CCD Header.

CONF-108: **CCD MAY** contain one or more patient guardians.

CONF-109: A patient guardian **SHALL** be represented with **ClinicalDocument / recordTarget / patientRole / patient / guardian**.

CONF-110: **CCD MAY** contain one or more next of kin.

CONF-111: A next of kin **SHALL** be represented with **ClinicalDocument / participant / associatedEntity**.

CONF-112: The value for "**ClinicalDocument / participant / @typeCode**" in a next of kin participant **SHALL** be "IND" "Indirect participant" 2.16.840.1.113883.5.90 ParticipationType **STATIC**.

CONF-113: The value for "**ClinicalDocument / participant / associatedEntity / @classCode**" in a next of kin participant **SHALL** be "NOK" "Next of kin" 2.16.840.1.113883.5.41 EntityClass **STATIC**.

CONF-114: The value for "**ClinicalDocument / participant / associatedEntity / code**" in a next of kin participant **SHOULD** be selected from ValueSet 2.16.840.1.113883.1.11.19579 FamilyHistoryRelatedSubjectCode **DYNAMIC** or 2.16.840.1.113883.1.11.20.21 FamilyHistoryPersonCode **DYNAMIC**.

CONF-115: **CCD MAY** contain one or more emergency contact.

CONF-116: An emergency contact **SHALL** be represented with **ClinicalDocument / participant / associatedEntity**.

CONF-117: The value for "**ClinicalDocument / participant / @typeCode**" in an emergency contact participant **SHALL** be "IND" "Indirect participant" 2.16.840.1.113883.5.90 ParticipationType **STATIC**.

CONF-118: The value for "**ClinicalDocument / participant / associatedEntity / @classCode**" in an emergency contact participant **SHALL** be "ECON" "Emergency contact" 2.16.840.1.113883.5.41 EntityClass **STATIC**.

CONF-119: **CCD MAY** contain one or more patient caregivers.

CONF-120: A patient caregiver **SHALL** be represented with **ClinicalDocument / participant / associatedEntity**.

CONF-121: The value for "**ClinicalDocument / participant / @typeCode**" in a patient caregiver participant **SHALL** be "IND" "Indirect participant" 2.16.840.1.113883.5.90 ParticipationType **STATIC**.

CONF-122: The value for "**ClinicalDocument / participant / associatedEntity / @classCode**" in a patient caregiver participant **SHALL** be "CAREGIVER" "Caregiver" 2.16.840.1.113883.5.41 EntityClass **STATIC**.

3.4 Functional Status

The template identifier for the functional status section is 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.

CONF-123: **CCD SHOULD** contain exactly one and **SHALL NOT** contain more than one Functional status section (templateId 2.16.840.1.113883.10.20.1.5). The Functional status section **SHALL** contain a narrative block, and **SHOULD** contain clinical statements. Clinical statements **SHOULD** include one or more problem acts (templateId 2.16.840.1.113883.10.20.1.27) and/or result organizers (templateId 2.16.840.1.113883.10.20.1.32).

3.4.1 Section conformance

CONF-124: The functional status section **SHALL** contain **Section / code.**

CONF-125: The value for "**Section / code**" **SHALL** be "47420-5" "Functional status assessment" 2.16.840.1.113883.6.1 LOINC **STATIC**.

CONF-126: The functional status section **SHALL** contain **Section / title.**

CONF-127: **Section / title SHOULD** be valued with a case-insensitive language-insensitive text string containing "functional status".

3.4.2 Clinical statement conformance

The template identifier for a problem act is 2.16.840.1.113883.10.20.1.27.
The template identifier for a problem observation is 2.16.840.1.113883.10.20.1.28.
The template identifier for a result organizer is 2.16.840.1.113883.10.20.1.32.
The template identifier for a result observation is 2.16.840.1.113883.10.20.1.31.

Functional Statuses can be expressed in 3 different forms. They can occur as a Problem (see section ***3.5 Problems***), a Result (see section ***3.13 Results***) or as text. Text can be employed if and only if the Functional Status is neither a Problem nor a Result. Functional Statuses expressed as Problems include relevant clinical conditions, diagnoses, symptoms and findings. Results are the interpretation or conclusion derived from a clinical assessment or test battery, such as the Instrumental Activities of Daily Living (IADL) scale or the Functional Status Index (FSI).

CONF-128: A problem observation or result observation in the functional status section **SHALL** contain exactly one **observation / code**.

CONF-129: The value for "**Observation / code"** in a problem observation or result observation in the functional status section **MAY** be selected from ValueSet 2.16.840.1.113883.1.11.20.6 FunctionalStatusTypeCode **STATIC** 20061017.

CONF-130: If the functional status was collected using a standardized assessment instrument, then the instrument itself **SHOULD** be represented in the "**Organizer / code**" of a result organizer, with a value selected from LOINC (codeSystem 2.16.840.1.113883.6.1) or SNOMED CT (codeSystem 2.16.840.1.113883.6.96)[2].

CONF-131: If the functional status was collected using a standardized assessment instrument, then the question within that instrument **SHOULD** be represented in the "**Observation / code**" of a result observation, with a value selected from LOINC (codeSystem 2.16.840.1.113883.6.1) or SNOMED CT (codeSystem 2.16.840.1.113883.6.96).

CONF-132: If the functional status was collected using a standardized assessment instrument containing questions with enumerated values as answers, then the answer **SHOULD** be represented in the "**Observation / value**" of a result observation.

CONF-133: If **Observation / value** in a result observation in the functional status section is of data type CE or CD, then it **SHOULD** use the same code system used to code the question in **Observation / code**.

CONF-134: **Observation / value** in a result observation in the functional status section **MAY** be of datatype CE or CD and **MAY** contain one or more **Observation / value / translation**, to represent equivalent values from other code systems.

CONF-135: A problem observation or result observation in the functional status section **MAY** use codes from the International Classification of Functioning, Disability, and Health (ICF, http://www.who.int/classifications/icf/en/) (codeSystem 2.16.840.1.113883.6.254).

3.4.2.1 Representation of "status" values

The template identifier for a status of functional status observation is 2.16.840.1.113883.10.20.1.44.

CONF-136: A problem observation in the functional status section **SHALL** contain exactly one status of functional status observation.

CONF-137: A result observation in the functional status section **SHALL** contain exactly one status of functional status observation.

CONF-138: A status of functional status observation (templateId 2.16.840.1.113883.10.20.1.44) **SHALL** be a conformant status observation (templateId 2.16.840.1.113883.10.20.1.57) (as defined in section *5.1 "Type" and "Status" values*).

CONF-139: The value for "**Observation / value**" in a status of functional status observation **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.20.5 StatusOfFunctionalStatusCode **STATIC** 20061017.

3.5 Problems

The template identifier for the problem section is 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.

CONF-140: **CCD SHOULD** contain exactly one and **SHALL NOT** contain more than one Problem section (templateId 2.16.840.1.113883.10.20.1.11). The Problem section **SHALL** contain

[2] Clinical Care Classification (CCC) codes have been incorporated into SNOMED CT, so to use CCC, use the corresponding SNOMED CT codes.

a narrative block, and **SHOULD** contain clinical statements. Clinical statements **SHOULD** include one or more problem acts (templateId 2.16.840.1.113883.10.20.1.27). A problem act **SHOULD** include one or more problem observations (templateId 2.16.840.1.113883.10.20.1.28).

3.5.1 Section conformance

CONF-141: The problem section **SHALL** contain **Section / code.**

CONF-142: The value for "**Section / code**" **SHALL** be "11450-4" "Problem list" 2.16.840.1.113883.6.1 LOINC **STATIC**.

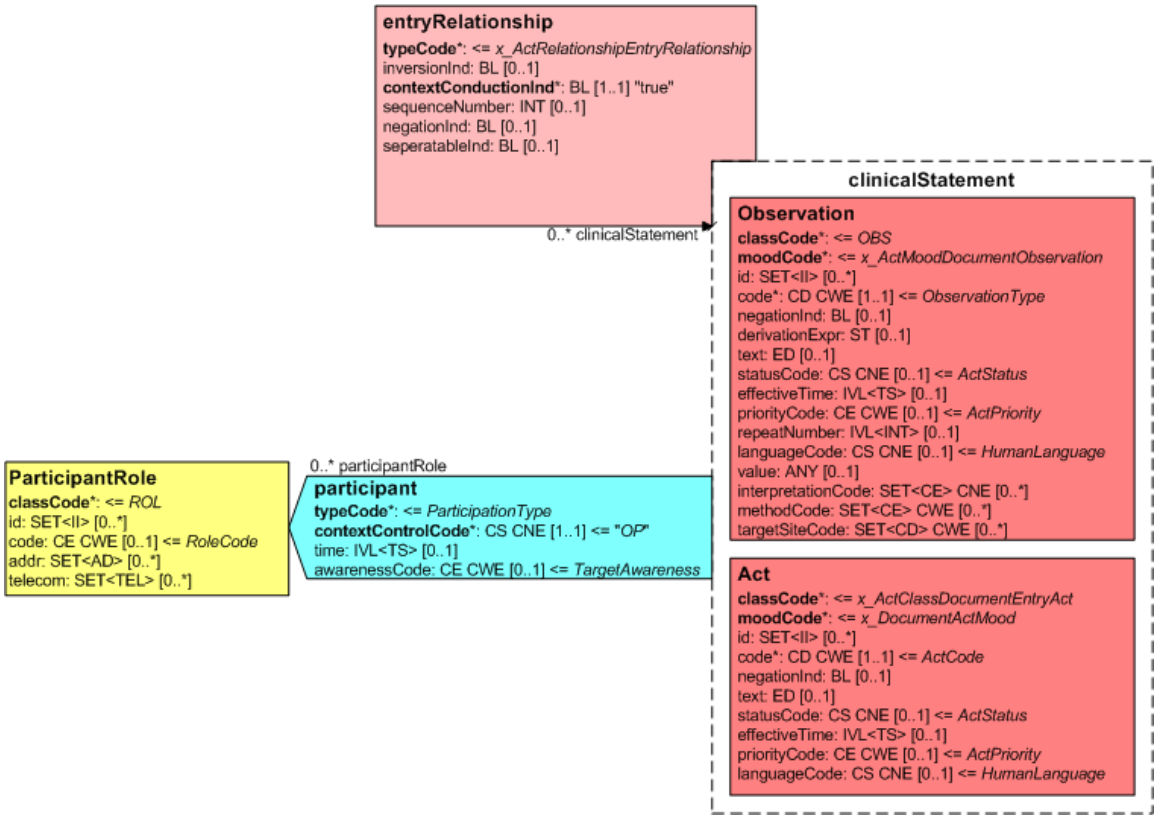
CONF-143: The problem section **SHALL** contain **Section / title.**

CONF-144: **Section / title SHOULD** be valued with a case-insensitive language-insensitive text string containing "problems".

3.5.2 Clinical statement conformance

The following figure shows a subset of the CDA Clinical Statement model containing those classes being constrained or referred to in the conformance statements that follow.

Figure 7. CDA R2 clinical statement model for problems



3.5.2.1 Representation of problems

The template identifier for a problem act is 2.16.840.1.113883.10.20.1.27.
The template identifier for a problem observation is 2.16.840.1.113883.10.20.1.28.

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).

> **NOTE:** The HL7 Patient Care Technical Committee is developing a formal model for condition tracking. In that model, observations of problems or other clinical statements captured at a point in time are wrapped in a "Concern" act which represents the ongoing process tracked over time. This allows for binding related observations of problems. For example, the observation of "Acute MI" in 2004, can be related to the observation of "History of MI" in 2006 because they are the same concern. The conformance statements in this section are compatable with the evolving Patient Care model and define an outer "problem act" (representing the "Concern") which can contain a nested "problem observation" or other nested clinical statements.

3.5.2.1.1 Problem act

CONF-145: A problem act (templateId 2.16.840.1.113883.10.20.1.27) **SHALL** be represented with **Act**.

CONF-146: The value for "**Act / @classCode**" in a problem act **SHALL** be "ACT" 2.16.840.1.113883.5.6 ActClass **STATIC**.

CONF-147: The value for "**Act / @moodCode**" in a problem act **SHALL** be "EVN" 2.16.840.1.113883.5.1001 ActMood **STATIC**.

CONF-148: A problem act **SHALL** contain at least one **Act / id**.

CONF-149: The value for "**Act / code / @NullFlavor**" in a problem act **SHALL** be "NA" "Not applicable" 2.16.840.1.113883.5.1008 NullFlavor **STATIC**.

CONF-150: A problem act **MAY** contain exactly one **Act / effectiveTime**, to indicate the timing of the concern (e.g. the interval of time for which the problem is a concern).

CONF-151: A problem act **SHALL** contain one or more **Act / entryRelationship**.

CONF-152: A problem act **MAY** reference a problem observation, alert observation (see section ***3.8 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.

CONF-153: 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, see section ***3.8 Alerts***), but **MAY** be some other clinical statement.

3.5.2.1.2 Problem observation

CONF-154: A problem observation (templateId 2.16.840.1.113883.10.20.1.28) **SHALL** be represented with **Observation**.

CONF-155: The value for "**Observation / @moodCode**" in a problem observation **SHALL** be "EVN" 2.16.840.1.113883.5.1001 ActMood **STATIC**.

CONF-156: A problem observation **SHALL** include exactly one **Observation / statusCode**.

CONF-157: The value for "**Observation / statusCode**" in a problem observation **SHALL** be "completed" 2.16.840.1.113883.5.14 ActStatus **STATIC**.

CONF-158: 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-159: The value for "**Observation / code"** in a problem observation **MAY** be selected from ValueSet 2.16.840.1.113883.1.11.20.14 ProblemTypeCode **STATIC** 20061017.

CONF-160: The value for "**Observation / entryRelationship / @typeCode**" in a problem observation **MAY** be "SUBJ" "Subject" 2.16.840.1.113883.5.1002 ActRelationshipType **STATIC** to reference an age observation (templateId 2.16.840.1.113883.10.20.1.38).[3]

CONF-161: A problem observation **SHALL** contain one or more sources of information, as defined in section ***5.2 Source***.

3.5.2.2 Representation of "status" values

The template identifier for a problem status observation is 2.16.840.1.113883.10.20.1.50.
The template identifier for a problem healthstatus observation is 2.16.840.1.113883.10.20.1.51.

ASTM CCR, in addition to the Status observations defined in many sections, defines a restricted set of optional **HealthStatus** values ("Alive And Well", "In Remission", "Symptom Free", "Chronically Ill", "Severely Ill", "Disabled", "Severely Disabled", "Deceased") that describe the status of the patient overall as a result of a particular problem, represented in CCD as an associated problem healthstatus observation.

CONF-162: A problem observation **MAY** contain exactly one problem status observation.

CONF-163: A problem status observation (templateId 2.16.840.1.113883.10.20.1.50) **SHALL** be a conformant status observation (templateId 2.16.840.1.113883.10.20.1.57) (as defined in section *5.1 "Type" and "Status" values*).

CONF-164: The value for "**Observation / value**" in a problem status observation **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.20.13 ProblemStatusCode **STATIC** 20061017.

CONF-165: A problem observation **MAY** contain exactly one problem healthstatus observation.

CONF-166: A problem healthstatus observation (templateId 2.16.840.1.113883.10.20.1.51) **SHALL** be a conformant status observation (templateId 2.16.840.1.113883.10.20.1.57) (as defined in section *5.1 "Type" and "Status" values*), except that the value for "**Observation / code**" in a problem healthstatus observation **SHALL** be "11323-3" "Health status" 2.16.840.1.113883.6.1 LOINC **STATIC**.

CONF-167: The value for "**Observation / value**" in a problem healthstatus observation **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.20.12 ProblemHealthStatusCode **STATIC** 20061017.

3.5.2.3 Episode observations

The template identifier for an episode observation is 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.

[3] Note that entryRelationship / inversionInd can be used to distinguish relationship source vs. target.

NOTE: The HL7 actRelationshipType "ELNK" (episodeLink) is used to indicate that linked observations are part of the SAME episode, whereas the ASTM CCR <Episodes> element is used to differentiate DIFFERENT episodes of the same condition.

CONF-168: A problem act **MAY** contain exactly one episode observation.

CONF-169: An episode observation (templateId 2.16.840.1.113883.10.20.1.41) **SHALL** be represented with **Observation.**

CONF-170: The value for "**Observation / @classCode**" in an episode observation **SHALL** be "OBS" 2.16.840.1.113883.5.6 ActClass **STATIC**.

CONF-171: The value for "**Observation / @moodCode**" in an episode observation **SHALL** be "EVN" 2.16.840.1.113883.5.1001 ActMood **STATIC**.

CONF-172: An episode observation **SHALL** include exactly one **Observation / statusCode**.

CONF-173: The value for "**Observation / statusCode**" in an episode observation **SHALL** be "completed" 2.16.840.1.113883.5.14 ActStatus **STATIC**.

CONF-174: The value for "**Observation / Code**" in an episode observation **SHOULD** be "ASSERTION" 2.16.840.1.113883.5.4 ActCode **STATIC**.

CONF-175: "**Observation / 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>
```

CONF-176: An episode observation **SHALL** be the source of exactly one **entryRelationship** whose value for "**entryRelationship / @typeCode**" is "SUBJ" "Has subject" 2.16.840.1.113883.5.1002 ActRelationshipType **STATIC**[4]. This is used to link the episode observation to the target problem act or social history observation.

CONF-177: An episode observation **MAY** be the source of one or more **entryRelationship** whose value for "**entryRelationship / @typeCode**" is "SAS" "Starts after start" 2.16.840.1.113883.5.1002 ActRelationshipType **STATIC**. The target of the entryRelationship **SHALL** be a problem act or social history observation. This is used to represent the temporal sequence of episodes.

3.5.2.4 Patient awareness of a problem

The template identifier for patient awareness is templateId 2.16.840.1.113883.10.20.1.48.

CONF-178: Patient awareness (templateId 2.16.840.1.113883.10.20.1.48) of a problem, observation, or other clinical statement **SHALL** be represented with **participant**.

CONF-179: A problem act **MAY** contain exactly one patient awareness.

CONF-180: A problem observation **MAY** contain exactly one patient awareness.

CONF-181: The value for "**participant / @typeCode**" in a patient awareness **SHALL** be "SBJ" "Subject" 2.16.840.1.113883.5.90 ParticipationType **STATIC**.

CONF-182: Patient awareness **SHALL** contain exactly one **participant / awarenessCode**.

[4] Note that entryRelationship / inversionInd can be used to distinguish source vs. target.

CONF-183: 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**.

3.6 Family History

The template identifier for the family history section is 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.

CONF-184: **CCD SHOULD** contain exactly one and **SHALL NOT** contain more than one Family history section (templateId 2.16.840.1.113883.10.20.1.4). The Family history section **SHALL** contain a narrative block, and **SHOULD** contain clinical statements. Clinical statements **SHOULD** include one or more family history observations (templateId 2.16.840.1.113883.10.20.1.22), which **MAY** be contained within family history organizers (templateId 2.16.840.1.113883.10.20.1.23).

3.6.1 Section conformance

CONF-185: The family history section **SHALL** contain **Section / code**.

CONF-186: The value for "**Section / code**" **SHALL** be "10157-6" "History of family member diseases" 2.16.840.1.113883.6.1 LOINC **STATIC**.

CONF-187: The family history section **SHALL** contain **Section / title.**

CONF-188: **Section / title SHOULD** be valued with a case-insensitive language-insensitive text string containing "family history".

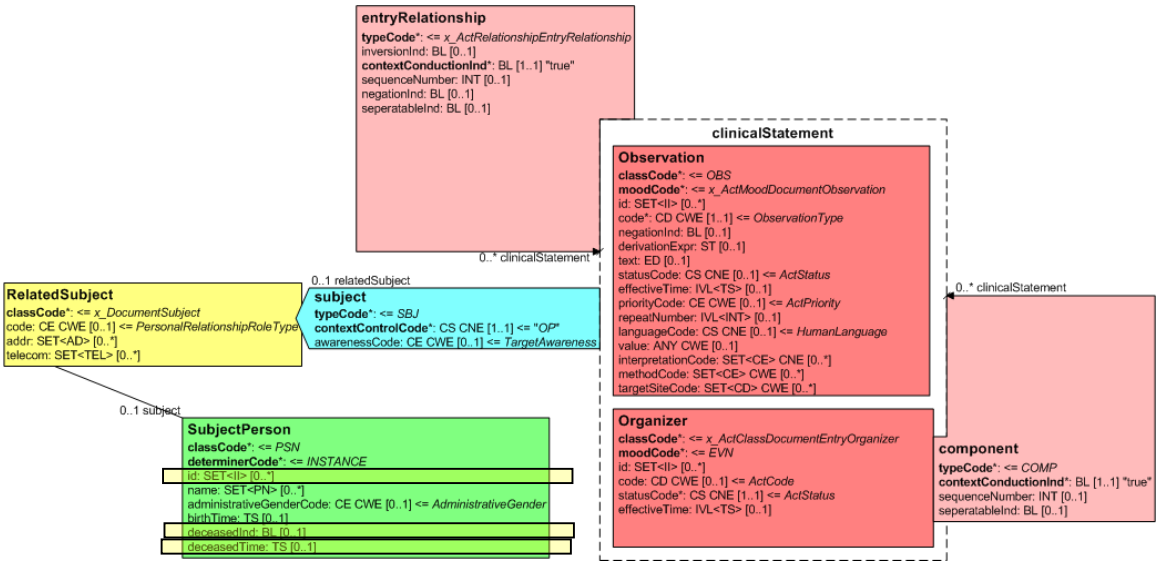
CONF-189: The family history section **SHALL NOT** contain **Section / subject**.

3.6.2 Clinical statement conformance

The following figure shows a subset of the CDA Clinical Statement model containing those classes being constrained or extended and are referred to in the conformance statements that follow.

Figure 8. CDA R2 clinical statement model for family history [5]

[5] CCD Extensions (see section ***3.6.3 Extensions***) are highlighted.



3.6.2.1 Family history representation

The template identifier for a family history observation is 2.16.840.1.113883.10.20.1.22.
The template identifier for a family history organizer is 2.16.840.1.113883.10.20.1.23.
The template identifier for a family history cause of death observation is 2.16.840.1.113883.10.20.1.42.

Family history observations may be contained within a family history organizer in order to group those observations related to a particular family member.

3.6.2.1.1 Family history observation

CONF-190: A family history observation (templateId 2.16.840.1.113883.10.20.1.22) **SHALL** be represented with **Observation.**

CONF-191: The value for "**Observation / @moodCode**" in a family history observation **SHALL** be "EVN" 2.16.840.1.113883.5.1001 ActMood **STATIC**.

CONF-192: A family history observation **SHALL** contain at least one **Observation / id**.

CONF-193: A family history observation **SHALL** include exactly one **Observation / statusCode**.

CONF-194: The value for "**Observation / statusCode**" in a family history observation **SHALL** be "completed" 2.16.840.1.113883.5.14 ActStatus **STATIC**.

CONF-195: A family history observation **SHOULD** include **Observation / effectiveTime**. (See also section ***3.6.2.4 Representation of age***).

CONF-196: A family history cause of death observation (templateId 2.16.840.1.113883.10.20.1.42) **SHALL** conform to the constraints and is a kind of family history observation (templateId 2.16.840.1.113883.10.20.1.22).

CONF-197: A family history cause of death observation **SHALL** contain one or more **entryRelationship / @typeCode**.

CONF-198: The value for at least one "**entryRelationship / @typeCode**" in a family history cause of death observation **SHALL** be "CAUS" "is etiology for" 2.16.840.1.113883.5.1002 ActRelationshipType **STATIC**, with a target family history observation of death.

CONF-199: A family history observation **SHALL** contain one or more sources of information, as defined in section ***5.2 Source***.

3.6.2.1.2 Family history organizer

CONF-200: A family history organizer (templateId 2.16.840.1.113883.10.20.1.23) **SHALL** be represented with **Organizer**.

CONF-201: The value for "**Organizer / @classCode**" in a family history organizer **SHALL** be "CLUSTER" 2.16.840.1.113883.5.6 ActClass **STATIC**.

CONF-202: The value for "**Organizer / @moodCode**" in a family history organizer **SHALL** be "EVN" 2.16.840.1.113883.5.1001 ActMood **STATIC**.

CONF-203: A family history organizer **SHALL** contain exactly one **Organizer / statusCode**.

CONF-204: The value for "**Organizer / statusCode**" in a family history organizer **SHALL** be "completed" 2.16.840.1.113883.5.14 ActStatus **STATIC**.

CONF-205: A family history organizer **SHALL** contain one or more **Organizer / component**.

CONF-206: The target of a family history organizer **Organizer / component** relationship **SHOULD** be a family history observation, but **MAY** be some other clinical statement.

3.6.2.2 Representation of "status" values

The template identifier for a problem status observation is 2.16.840.1.113883.10.20.1.50.

The representation of "status" values in the family history section is the same as the representation in the problems section.

CONF-207: A family history observation act **MAY** contain exactly one problem status observation (templateId 2.16.840.1.113883.10.20.1.50) (see section *3.5.2.2 Representation of "status" values*).

3.6.2.3 Family history participants

CONF-208: A family history organizer **SHALL** contain exactly one **subject** participant, representing the family member who is the subject of the family history observations.

CONF-209: A family history observation not contained within a family history organizer **SHALL** contain exactly one **subject** participant, representing the family member who is the subject of the observation[6].

CONF-210: Where the subject of an observation is explicit in a family history observation code (e.g. SNOMED CT concept 417001009 "Family history of tuberous sclerosis"), the **subject** participant **SHALL** be equivalent to or further specialize the code.

[6] Note that this constraint is satisfied if the subject participant is directly asserted for the family history observation and/or if the subject participant propagates to the family history observation from a containing element.

CONF-211: Where the subject of an observation is not explicit in a family history observation code (e.g. SNOMED CT concept 44054006 "Diabetes Mellitus type 2"), the **subject** participant **SHALL** be used to assert the affected relative.

CONF-212: A **subject** participant **SHALL** contain exactly one **RelatedSubject**, representing the relationship of the subject to the patient.

CONF-213: The value for "**RelatedSubject / @classCode**" **SHALL** be "PRS" "Personal relationship" 2.16.840.1.113883.5.110 RoleClass **STATIC**.

CONF-214: RelatedSubject **SHALL** contain exactly one RelatedSubject / code.

CONF-215: The value for "**RelatedSubject / code**" **SHOULD** be selected from ValueSet 2.16.840.1.113883.1.11.19579 FamilyHistoryRelatedSubjectCode **DYNAMIC** or 2.16.840.1.113883.1.11.20.21 FamilyHistoryPersonCode **DYNAMIC**.

CONF-216: Representation of a pedigree graph **SHALL** be done using **RelatedSubject / code** values (e.g. "great grandfather") to designate a hierarchical family tree.[7]

CONF-217: RelatedSubject **SHOULD** contain exactly one **RelatedSubject / subject**.

CONF-218: RelatedSubject / subject **SHOULD** contain exactly one **RelatedSubject / subject / administrativeGenderCode**.

3.6.2.4 Representation of age

The template identifier for an age observation is 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.

CONF-219: **RelatedSubject / subject SHOULD** contain exactly one **RelatedSubject / subject / birthTime**.

CONF-220: **RelatedSubject / subject MAY** contain exactly one **RelatedSubject / subject / sdtc:deceasedInd**. (See section ***7.4 Extensions to CDA R2*** for details on representation of CDA extensions).

CONF-221: **RelatedSubject / subject MAY** contain exactly one **RelatedSubject / subject / sdtc:deceasedTime**. (See section ***7.4 Extensions to CDA R2*** for details on representation of CDA extensions).

CONF-222: The age of a relative at the time of a family history observation **SHOULD** be inferred by comparing **RelatedSubject / subject / birthTime** with **Observation / effectiveTime**.

CONF-223: The age of a relative at the time of death **MAY** be inferred by comparing **RelatedSubject / subject / birthTime** with **RelatedSubject / subject / sdtc:deceasedTime**.

CONF-224: The value for "**Observation / entryRelationship / @typeCode**" in a family history observation **MAY** be "SUBJ" "Subject" 2.16.840.1.113883.5.1002 ActRelationshipType **STATIC** to reference an age observation.[8]

CONF-225: An age observation (templateId 2.16.840.1.113883.10.20.1.38) **SHALL** be represented with **Observation**.

---

[7] A more detailed pedigree graph, such as that used for genetic counseling, is being developed for CDA Release 3, in collaboration with the HL7 Clinical Genomics Committee.

[8] Note that entryRelationship / inversionInd can be used to distinguish relationship source vs. target.

CONF-226: The value for "**Observation / @classCode**" in an age observation **SHALL** be "OBS" 2.16.840.1.113883.5.6 ActClass **STATIC**.

CONF-227: The value for "**Observation / @moodCode**" in an age observation **SHALL** be "EVN" 2.16.840.1.113883.5.1001 ActMood **STATIC**.

CONF-228: The value for "**Observation / code**" in an age observation **SHALL** be "397659008" "Age" 2.16.840.1.113883.6.96 SNOMED CT **STATIC**.

CONF-229: An age observation **SHALL** include exactly one **Observation / statusCode**.

CONF-230: The value for "**Observation / statusCode**" in an age observation **SHALL** be "completed" 2.16.840.1.113883.5.14 ActStatus **STATIC**.

CONF-231: An age observation **SHALL** include exactly one **Observation / value**, valued using appropriate datatype.

3.6.3 Extensions

The family history section extends the CDA R2 model with the addition of Subject / id, SubjectPerson / deceasedInd, and SubjectPerson / deceasedTime. See section ***7.4 Extensions to CDA R2*** for more details.

3.7 Social History

The template identifier for the social history section is 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.

CONF-232: **CCD SHOULD** contain exactly one and **SHALL NOT** contain more than one Social history section (templateId 2.16.840.1.113883.10.20.1.15). The Social history section **SHALL** contain a narrative block, and **SHOULD** contain clinical statements. Clinical statements **SHOULD** include one or more social history observations (templateId 2.16.840.1.113883.10.20.1.33).

3.7.1 Section conformance

CONF-233: The social history section **SHALL** contain **Section / code**.

CONF-234: The value for "**Section / code**" **SHALL** be "29762-2" "Social history" 2.16.840.1.113883.6.1 LOINC **STATIC**.

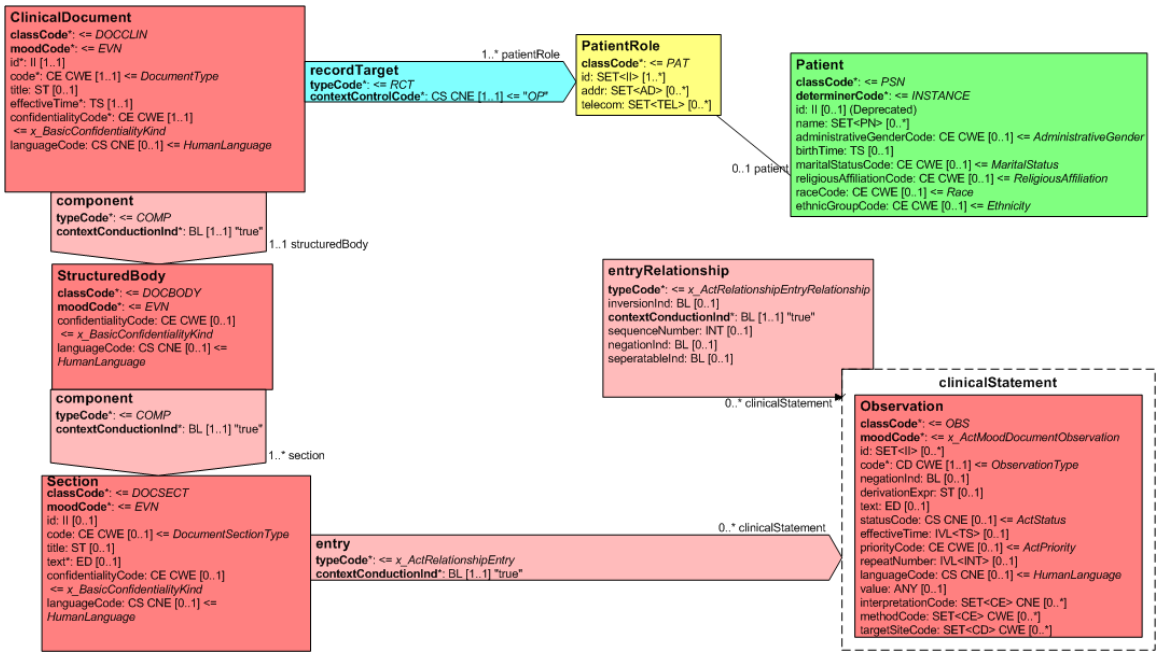
CONF-235: The social history section **SHALL** contain **Section / title.**

CONF-236: **Section / title SHOULD** be valued with a case-insensitive language-insensitive text string containing "social history".

3.7.2 Clinical statement conformance

The following figure shows a subset of the CDA Clinical Statement model containing those classes being constrained or referred to in the conformance statements that follow.

Figure 9. CDA R2 model for social history



3.7.2.1 Social history observation

The template identifier for a social history observation is 2.16.840.1.113883.10.20.1.33.

CONF-237: A social history observation (templateId 2.16.840.1.113883.10.20.1.33) **SHALL** be represented with **Observation.**

CONF-238: The value for "**Observation / @classCode**" in a social history observation **SHALL** be "OBS" 2.16.840.1.113883.5.6 ActClass **STATIC**.

CONF-239: The value for "**Observation / @moodCode**" in a social history observation **SHALL** be "EVN" 2.16.840.1.113883.5.1001 ActMood **STATIC**.

CONF-240: A social history observation **SHALL** contain at least one **Observation / id**.

CONF-241: A social history observation **SHALL** include exactly one **Observation / statusCode**.

CONF-242: The value for "**Observation / statusCode**" in a social history observation **SHALL** be "completed" 2.16.840.1.113883.5.14 ActStatus **STATIC**.

CONF-243: The value for "**Observation / code**" in a social history observation **SHOULD** be selected from LOINC (codeSystem 2.16.840.1.113883.6.1) or SNOMED CT (codeSystem 2.16.840.1.113883.6.96), or **MAY** be selected from ValueSet 2.16.840.1.113883.1.11.20.18 SocialHistoryTypeCode **STATIC** 20061017.

CONF-244: **Observation / value** can be any datatype. Where **Observation / value** is a physical quantity, the unit of measure **SHALL** be expressed using a valid Unified Code for Units of Measure (UCUM) expression.

CONF-245: A social history observation **SHALL** contain one or more sources of information, as defined in section ***5.2 Source***.

3.7.2.2 Representation of "status" values

The template identifier for a social history status observation is 2.16.840.1.113883.10.20.1.56.

CONF-246: A social history observation **MAY** contain exactly one social history status observation.

CONF-247: A social history status observation (templateId 2.16.840.1.113883.10.20.1.56) **SHALL** be a conformant status observation (templateId 2.16.840.1.113883.10.20.1.57) (as defined in section *5.1 "Type" and "Status" values*).

CONF-248: The value for "**Observation / value**" in a social history status observation **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.20.17 SocialHistoryStatusCode **STATIC** 20061017.

3.7.2.3 Episode observations

The template identifier for an episode observation is 2.16.840.1.113883.10.20.1.41.

The representation of episode in the social history section is the same as the representation in the problems section. See section ***3.5.2.3 Episode observations*** for details.

CONF-249: A social history observation **MAY** contain exactly one episode observation (templateId 2.16.840.1.113883.10.20.1.41) (see section ***3.5.2.3 Episode observations***).

3.7.2.4 Social history observations vs. CDA Header attributes

The ASTM CCR includes "administrative data (ADT) such as marital status, ethnicity, nationality, and religious preferences" in the Social History section. CDA R2 differentiates between administrative data and clinical observations, supporting the former in the CDA Header and the latter in the CDA Body. As a result, it is necessary at times to populate attributes in the CDA Header, and to provide richer clinical details in the CDA Body.

CONF-250: Marital status **SHOULD** be represented as **ClinicalDocument / recordTarget / patientRole / patient / maritalStatusCode**. Additional information **MAY** be represented as social history observations.

CONF-251: Religious affiliation **SHOULD** be represented as **ClinicalDocument / recordTarget / patientRole / patient / religiousAffiliationCode**. Additional information **MAY** be represented as social history observations.

CONF-252: A patient's race **SHOULD** be represented as **ClinicalDocument / recordTarget / patientRole / patient / raceCode**. Additional information **MAY** be represented as social history observations.

CONF-253: The value for "**ClinicalDocument / recordTarget / patientRole / patient / raceCode" MAY** be selected from codeSystem 2.16.840.1.113883.5.104 (Race).

CONF-254: A patient's ethnicity **SHOULD** be represented as **ClinicalDocument / recordTarget / patientRole / patient / ethnicGroupCode**. Additional information **MAY** be represented as social history observations.

CONF-255: The value for "**ClinicalDocument / recordTarget / patientRole / patient / ethnicGroupCode" MAY** be selected from codeSystem 2.16.840.1.113883.5.50 (Ethnicity).

3.8 Alerts

The template identifier for the alerts section is 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.

CONF-256: **CCD SHOULD** contain exactly one and **SHALL NOT** contain more than one Alerts section (templateId 2.16.840.1.113883.10.20.1.2). The Alerts section **SHALL** contain a narrative block, and **SHOULD** contain clinical statements. Clinical statements **SHOULD** include one or more problem acts (templateId 2.16.840.1.113883.10.20.1.27). A problem act **SHOULD** include one or more alert observations (templateId 2.16.840.1.113883.10.20.1.18).

CONF-257: The absence of known allergies, adverse reactions, or alerts **SHALL** be explicitly asserted.

3.8.1 Section conformance

CONF-258: The alert section **SHALL** contain **Section / code.**

CONF-259: The value for "**Section / code**" **SHALL** be "48765-2" "Allergies, adverse reactions, alerts" 2.16.840.1.113883.6.1 LOINC **STATIC**.

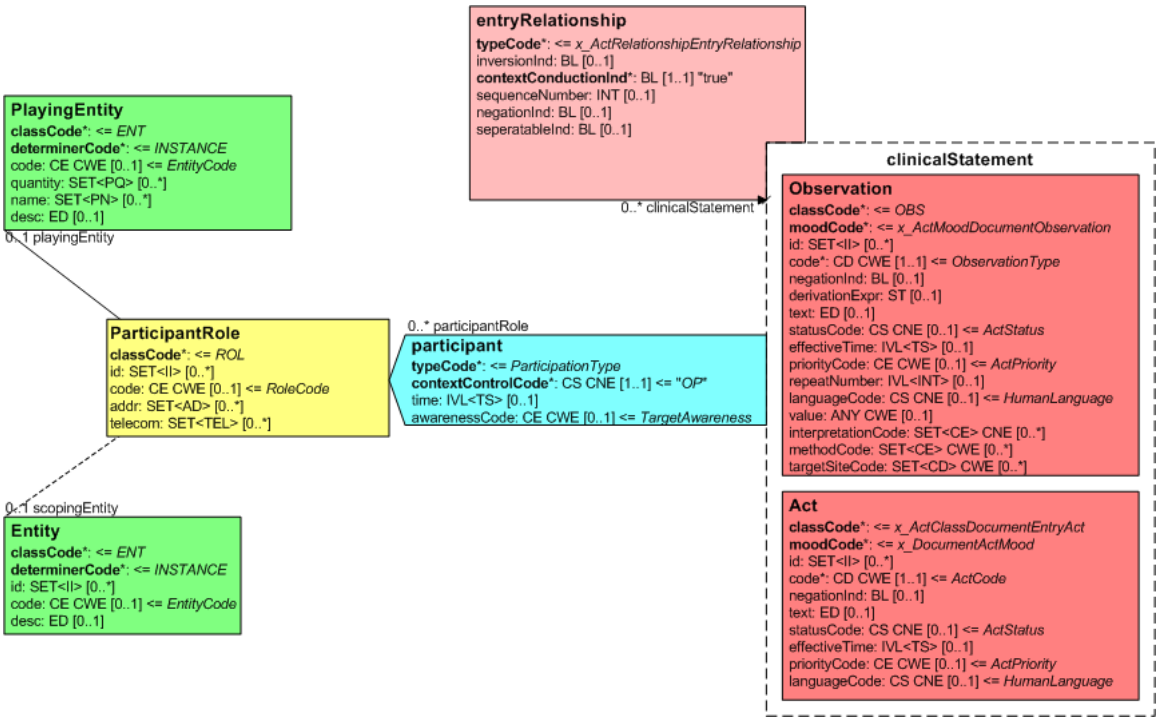
CONF-260: The alert section **SHALL** contain **Section / title.**

CONF-261: **Section / title SHOULD** be valued with a case-insensitive language-insensitive text string containing "alert" and/or "allergies and adverse reactions".

3.8.2 Clinical statement conformance

The following figure shows a subset of the CDA Clinical Statement model containing those classes being constrained or referred to in the conformance statements that follow.

Figure 10. CDA R2 clinical statement model for alerts



3.8.2.1 Representation of alerts

The template identifier for a problem act is 2.16.840.1.113883.10.20.1.27.
The template identifier for an alert observation is 2.16.840.1.113883.10.20.1.18.

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).

> **NOTE:** The HL7 Patient Care Technical Committee is developing a formal model for condition tracking. In that model, observations of problems or other clinical statements captured at a point in time are wrapped in a "Concern" act which represents the ongoing process tracked over time. This allows for binding related observations of problems. The conformance statements in this section are compatable with the evolving Patient Care model and define an outer "problem act" (representing the “Concern”) which can contain a nested "problem observation" or other nested clinical statements.

3.8.2.1.1 Problem act

The problem act (templateId 2.16.840.1.113883.10.20.1.27) is defined above in the Problem section (see section *3.5.2.1.1 Problem act*).

3.8.2.1.2 Alert observation

CONF-262: An alert observation (templateId 2.16.840.1.113883.10.20.1.18) **SHALL** be represented with **Observation**.

CONF-263: The value for "**Observation / @moodCode**" in an alert observation **SHALL** be "EVN" 2.16.840.1.113883.5.1001 ActMood **STATIC**.

CONF-264: An alert observation **SHALL** include exactly one **Observation / statusCode**.

CONF-265: The value for "**Observation / statusCode**" in an alert observation **SHALL** be "completed" 2.16.840.1.113883.5.14 ActStatus **STATIC**.

CONF-266: An alert observation **MAY** 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-267: The value for "**Observation / value"** in an alert observation **MAY** be selected from ValueSet 2.16.840.1.113883.1.11.20.4 AlertTypeCode **STATIC** 20061017.

CONF-268: 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**.

CONF-269: An alert observation **SHALL** contain one or more sources of information, as defined in section ***5.2 Source***.

3.8.2.2 Representation of "status" values

The template identifier for an alert status observation is 2.16.840.1.113883.10.20.1.39.

CONF-270: An alert observation **MAY** contain exactly one alert status observation.

CONF-271: An alert status observation (templateId 2.16.840.1.113883.10.20.1.39) **SHALL** be a conformant status observation (templateId 2.16.840.1.113883.10.20.1.57) (as defined in section *5.1 "Type" and "Status" values*).

CONF-272: The value for "**Observation / value**" in an alert status observation **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.20.3 AlertStatusCode **STATIC** 20061017.

3.8.2.3 Representation of agent

The agent indicates the entity that is the cause of the allergy or adverse reaction. While the agent is often implicit in the alert observation (e.g. "allergy to penicillin"), it should also be asserted explicitly as an entity.

> **NOTE:** The agent responsible for an allergy or adverse reaction is not always a manufactured material, nor is it necessarily consumed. The following constraints reflect limitations in the base CDA R2 specification, and should be used to represent any type of responsible agent.

CONF-273: An alert observation **SHOULD** contain at least one **Observation / participant**, representing the agent that is the cause of the allergy or adverse reaction.

CONF-274: An agent participation in an alert observation **SHALL** contain exactly one **participant / participantRole / playingEntity**.

CONF-275: The value for **Observation / participant / @typeCode** in an agent participation **SHALL** be "CSM" "Consumable" 2.16.840.1.113883.5.90 ParticipationType **STATIC**.

CONF-276: The value for **Observation / participant / participantRole / @classCode** in an agent participation **SHALL** be "MANU" "Manufactured" 2.16.840.1.113883.5.110 RoleClass **STATIC**.

CONF-277: The value for **Observation / participant / participantRole / playingEntity / @classCode** in an agent participation **SHALL** be "MMAT" "Manufactured material" 2.16.840.1.113883.5.41 EntityClass **STATIC**.

CONF-278: An agent participation in an alert observation **SHALL** contain exactly one **participant / participantRole / playingEntity / code**.

CONF-279: 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[9].

3.8.2.4 Reaction observations and interventions

The template identifier for a reaction observation is 2.16.840.1.113883.10.20.1.54.
The template identifier for a severity observation is 2.16.840.1.113883.10.20.1.55.

A reaction represents an adverse event due to an administered or exposed substance. A reaction can be defined with respect to its severity, and can have been treated by one or more interventions.

CONF-280: An alert observation **MAY** contain one or more reaction observations (templateId 2.16.840.1.113883.10.20.1.54), each of which **MAY** contain exactly one severity observation (templateId 2.16.840.1.113883.10.20.1.55) **AND/OR** one or more reaction interventions.

CONF-281: The value for "**entryRelationship / @typeCode**" in a relationship between an alert observation and reaction observation **SHALL** be "MFST" "Is manifestation of" 2.16.840.1.113883.5.1002 ActRelationshipType **STATIC**.

3.8.2.4.1.1 Reaction observation

CONF-282: A reaction observation (templateId 2.16.840.1.113883.10.20.1.54) **SHALL** be represented with **Observation**.

CONF-283: The value for "**Observation / @classCode**" in a reaction observation **SHALL** be "OBS" 2.16.840.1.113883.5.6 ActClass **STATIC**.

CONF-284: The value for "**Observation / @moodCode**" in a reaction observation **SHALL** be "EVN" 2.16.840.1.113883.5.1001 ActMood **STATIC**.

CONF-285: A reaction observation **SHALL** include exactly one **Observation / statusCode**.

CONF-286: The value for "**Observation / statusCode**" in a reaction observation **SHALL** be "completed" 2.16.840.1.113883.5.14 ActStatus **STATIC**.

3.8.2.4.1.2 Severity observation

CONF-287: A severity observation (templateId 2.16.840.1.113883.10.20.1.55) **SHALL** be represented with **Observation**.

[9]A table of CDC Vaccine Codes can be found at http://www.cdc.gov/nip/registry/st_terr/tech/stds/hl7-cvx.htm.

CONF-288: The value for "**entryRelationship / @typeCode**" in a relationship between a reaction observation and severity observation **SHALL** be "SUBJ" "Has subject" 2.16.840.1.113883.5.1002 ActRelationshipType **STATIC**.

CONF-289: The value for "**Observation / @classCode**" in a severity observation **SHALL** be "OBS" 2.16.840.1.113883.5.6 ActClass **STATIC**.

CONF-290: The value for "**Observation / @moodCode**" in a severity observation **SHALL** be "EVN" 2.16.840.1.113883.5.1001 ActMood **STATIC**.

CONF-291: A severity observation **SHALL** include exactly one **Observation / statusCode**.

CONF-292: The value for "**Observation / statusCode**" in a severity observation **SHALL** be "completed" 2.16.840.1.113883.5.14 ActStatus **STATIC**.

CONF-293: A severity observation **SHALL** contain exactly one **Observation / code**.

CONF-294: The value for "**Observation / code**" in a severity observation **SHALL** be "SEV" "Severity observation" 2.16.840.1.113883.5.4 ActCode **STATIC**.

CONF-295: A severity observation **SHALL** contain exactly one **Observation / value**.

3.8.2.4.1.3 Reaction intervention

CONF-296: 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**.

CONF-297: 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.

3.9 Medications

The template identifier for the medications section is 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).

CONF-298: **CCD SHOULD** contain exactly one and **SHALL NOT** contain more than one Medications section (templateId 2.16.840.1.113883.10.20.1.8). The Medications section **SHALL** contain a narrative block, and **SHOULD** contain clinical statements. Clinical statements **SHOULD** include one or more medication activities (templateId 2.16.840.1.113883.10.20.1.24) and/or supply activities (templateId 2.16.840.1.113883.10.20.1.34).

CONF-299: The absence of known medications **SHALL** be explicitly asserted.

3.9.1 Section conformance

CONF-300: The medications section **SHALL** contain **Section / code**.

CONF-301: The value for "**Section / code**" **SHALL** be "10160-0" "History of medication use" 2.16.840.1.113883.6.1 LOINC **STATIC**.

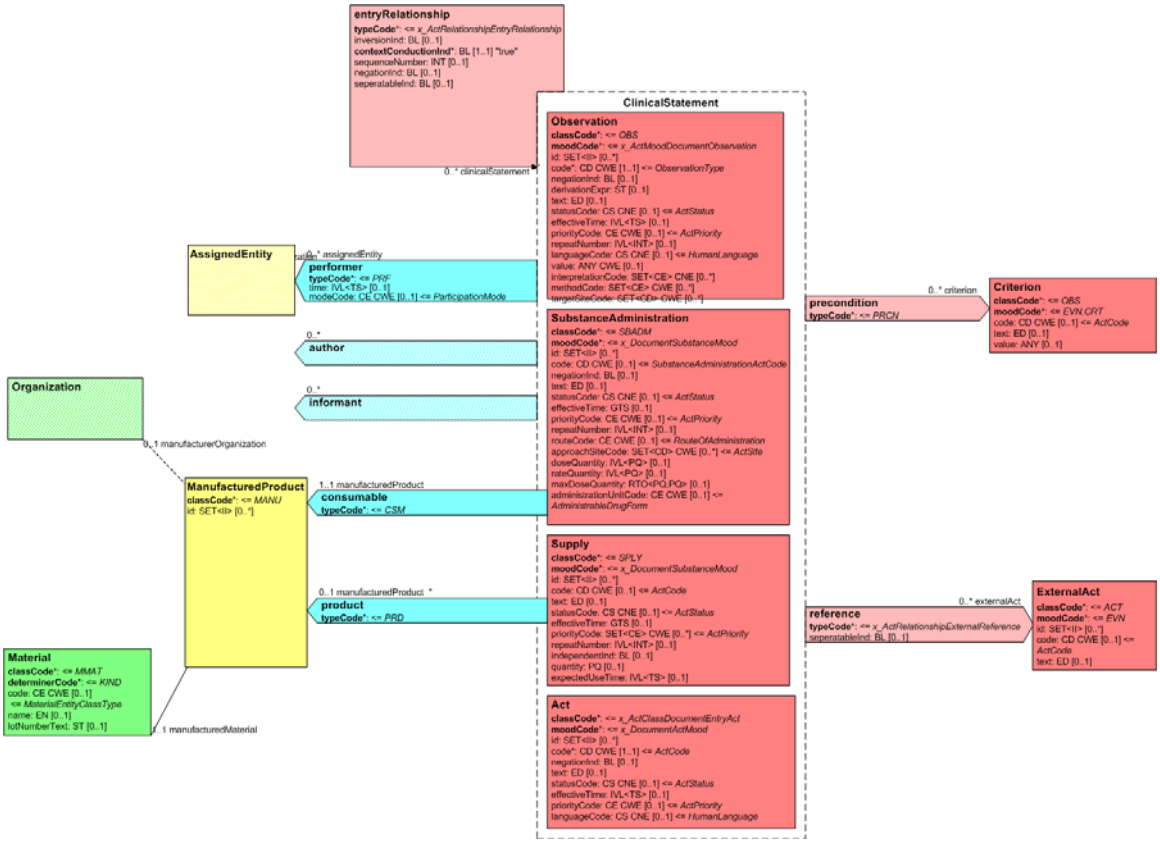
CONF-302: The medications section **SHALL** contain **Section / title.**

CONF-303: **Section / title SHOULD** be valued with a case-insensitive language-insensitive text string containing "medication".

3.9.2 Clinical statement conformance

The following figure shows a subset of the CDA Clinical Statement model containing those classes being constrained or referred to in the conformance statements that follow.

Figure 11. CDA R2 clinical statement model for medications



3.9.2.1 Medication and supply activities

The template identifier for a medication activity is 2.16.840.1.113883.10.20.1.24.
The template identifier for a supply activity is 2.16.840.1.113883.10.20.1.34.

A medication activity (templateId 2.16.840.1.113883.10.20.1.24) is used to describe what is administered whereas a supply activity (templateId 2.16.840.1.113883.10.20.1.34) is used to describe what has been dispensed.

Reconciliation of conflicting medication information from various sources is enabled both by indicating the source of information and by indicating whether the source is reporting intended or actual medication use. For instance, a physician may intend for a patient to be on a particular dose, but the patient may actually be taking a different dose; a pharmacy may fill a prescription for a particular dose only to then have the patient's physician lower the dose without notifying the pharmacy. Therefore, medication and supply activities can be expressed in CCD in either the "EVN" (event) mood or the "INT" (intent) mood. Medication activities in "INT" mood are not orders (which are represented in the Plan of Care section), but rather are reflections of what a clinician intends a patient to be taking. Medication activities in "EVN" mood reflect actual use. A pharmacy system will typically report what was actually filled (supply event), along with intended use (substance administration intent). A physician will often report intended use (substance administration and supply intent). A patient or family member will typically report actual use (substance administration event). (See section ***5.2 Source*** for additional details about the representation of source of information).

3.9.2.1.1 Medication activity

CONF-304: A medication activity (templateId 2.16.840.1.113883.10.20.1.24) **SHALL** be represented with **SubstanceAdministration**.

CONF-305: The value for "**SubstanceAdministration / @moodCode**" in a medication activity **SHALL** be "EVN" or "INT" 2.16.840.1.113883.5.1001 ActMood **STATIC**.

CONF-306: A medication activity **SHALL** contain at least one **SubstanceAdministration / id**.

CONF-307: A medication activity **SHOULD** contain exactly one **SubstanceAdministration / statusCode**.

CONF-308: A medication activity **SHOULD** contain one or more **SubstanceAdministration / effectiveTime** elements, used to indicate the actual or intended start and stop date of a medication, and the frequency of administration. (See section ***5.4.1 Dates and Times*** for additional details about time representation).

CONF-309: A medication activity **SHOULD** contain exactly one **SubstanceAdministration / routeCode**.

CONF-310: The value for "**SubstanceAdministration / routeCode**" in a medication activity **SHOULD** be selected from the HL7 RouteOfAdministration (2.16.840.1.113883.5.112) code system.

CONF-311: A medication activity **SHOULD** contain exactly one **SubstanceAdministration / doseQuantity** or **SubstanceAdministration / rateQuantity**.

CONF-312: A medication activity **MAY** contain exactly one **SubstanceAdministration / maxDoseQuantity**, which represents a maximum dose limit.

CONF-313: A medication activity **MAY** contain one or more **SubstanceAdministration / performer**, to indicate the person administering a substance.

CONF-314: A medication activity **MAY** have one or more associated consents, represented in the CCD Header as **ClinicalDocument / authorization / consent**.

CONF-315: A medication activity **SHALL** contain one or more sources of information, as defined in section ***5.2 Source***.

3.9.2.1.2 Supply activity

ASTM CCR defines a <FulfillmentHistory> element, used to indicate details about a dispensing activity. This corresponds to a supply event (a supply activity in "EVN" mood) in CCD, used to report what was actually filled.

CONF-316: A supply activity (templateId 2.16.840.1.113883.10.20.1.34) **SHALL** be represented with **Supply**.

CONF-317: The value for "**Supply / @moodCode**" in a supply activity **SHALL** be "EVN" or "INT" 2.16.840.1.113883.5.1001 ActMood **STATIC**.

CONF-318: A supply activity **SHALL** contain at least one **Supply / id**.

CONF-319: A supply activity **SHOULD** contain exactly one **Supply / statusCode**.

CONF-320: A supply activity **SHOULD** contain exactly one **Supply / effectiveTime**, to indicate the actual or intended time of dispensing.

CONF-321: A supply activity **MAY** contain exactly one **Supply / repeatNumber**, to indicate the number of fills. (Note that Supply / repeatNumber corresponds to the number of "fills", as opposed to the number of "refills").

CONF-322: A supply activity **MAY** contain exactly one **Supply / quantity**, to indicate the actual or intended supply quantity.

CONF-323: A supply activity **MAY** contain one or more **Supply / author**, to indicate the prescriber.

CONF-324: A supply activity **MAY** contain one or more **Supply / performer**, to indicate the person dispensing the product.

CONF-325: A supply activity **MAY** contain exactly one **Supply / participant / @typeCode = "LOC"**, to indicate the supply location.

CONF-326: A supply activity **SHALL** contain one or more sources of information, as defined in section ***5.2 Source***.

3.9.2.2 Medication related information

The template identifier for a patient instruction is 2.16.840.1.113883.10.20.1.49.
The template identifier for a fulfillment instruction is 2.16.840.1.113883.10.20.1.43.
The template identifier for a medication series number observation is 2.16.840.1.113883.10.20.1.46.
The template identifier for a reaction observation is 2.16.840.1.113883.10.20.1.54.
The template identifier for a severity observation is 2.16.840.1.113883.10.20.1.55.

ASTM CCR defines several additional pieces of information relevant to medications, such as indications, special instructions, and adverse reactions.

3.9.2.2.1 Indications

An indication describes the rationale for an activity. The indication can be an existing problem or can be a criterion that if met would warrant the activity. Criteria are typically associated with PRN (from the Latin "pro re nata", meaning "as needed") medications (e.g. "give Medication X as needed for nausea").

CONF-327: A medication activity **MAY** contain one or more **SubstanceAdministration / precondition / Criterion**, to indicate that the medication is administered only when the associated (coded or free text) criteria are met.

CONF-328: A medication activity **MAY** contain one or more **SubstanceAdministration / entryRelationship**, whose value for "**entryRelationship / @typeCode**" **SHALL** be

"RSON" "Has reason" 2.16.840.1.113883.5.1002 ActRelationshipType **STATIC**, where the target of the relationship represents the indication for the activity.

CONF-329: **SubstanceAdministration / entryRelationship / @typeCode="RSON"** in a medication activity **SHALL** have a target of problem act (templateId 2.16.840.1.113883.10.20.1.27), problem observation (templateId 2.16.840.1.113883.10.20.1.28), or some other clinical statement.

3.9.2.2.2 Patient instructions

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

CONF-330: A medication activity **MAY** contain one or more patient instructions.

CONF-331: A patient instruction (templateId 2.16.840.1.113883.10.20.1.49) **SHALL** be represented with **Act**.

CONF-332: The value for "**Act / @moodCode**" in a patient instruction **SHALL** be "INT" "Intent" 2.16.840.1.113883.5.1001 ActMood **STATIC**.

CONF-333: The value for "**entryRelationship / @typeCode**" in a relationship to a patient instruction **SHALL** be "SUBJ" "Subject" 2.16.840.1.113883.5.1002 ActRelationshipType **STATIC**.

3.9.2.2.3 Fulfillment instructions

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

CONF-334: A supply activity **MAY** contain one or more fulfillment instructions.

CONF-335: A fulfillment instruction (templateId 2.16.840.1.113883.10.20.1.43) **SHALL** be represented with **Act**.

CONF-336: The value for "**Act / @moodCode**" in a fulfillment instruction **SHALL** be "INT" "Intent" 2.16.840.1.113883.5.1001 ActMood **STATIC**.

CONF-337: The value for "**entryRelationship / @typeCode**" in a relationship between a supply activity and fulfillment instruction **SHALL** be "SUBJ" "Subject" 2.16.840.1.113883.5.1002 ActRelationshipType **STATIC**.

3.9.2.2.4 Medication series number observation

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).

CONF-338: A medication activity **MAY** contain exactly one medication series number observations.

CONF-339: The value for "**entryRelationship / @typeCode**" in a relationship between a medication activity and medication series number observation **SHALL** be "SUBJ" "Subject" 2.16.840.1.113883.5.1002 ActRelationshipType **STATIC**.

CONF-340: A medication series number observation (templateId 2.16.840.1.113883.10.20.1.46) **SHALL** be represented with **Observation**.

CONF-341: The value for "**Observation / @classCode**" in a medication series number observation **SHALL** be "OBS" 2.16.840.1.113883.5.6 ActClass **STATIC**.

CONF-342: The value for "**Observation / @moodCode**" in a medication series number observation **SHALL** be "EVN" 2.16.840.1.113883.5.1001 ActMood **STATIC**.

CONF-343: A medication series number observation **SHALL** include exactly one **Observation / statusCode**.

CONF-344: A medication series number observation **SHALL** contain exactly one **Observation / code**.

CONF-345: The value for "**Observation / code**" in a medication series number observation **SHALL** be "30973-2" "Dose number" 2.16.840.1.113883.6.1 LOINC **STATIC**.

CONF-346: A medication series number observation **SHALL** contain exactly one **Observation / value**.

CONF-347: The data type for "**Observation / value**" in a medication series number observation **SHALL** be INT (integer).

3.9.2.2.5 Reaction observations and interventions

A reaction represents an adverse event due to an administered substance. Significant reactions are to be listed in the Alerts section. Reactions in the Medications section can be used to track reactions associated with individual substance administrations or to track routine follow up to an administration (e.g. "no adverse reaction 30 minutes post administration").

The reaction observation (templateId 2.16.840.1.113883.10.20.1.54) and severity observation (templateId 2.16.840.1.113883.10.20.1.55) templates are defined above, in the Alerts section (see section ***3.8.2.4 Reaction observations and interventions***).

CONF-348: A medication activity **MAY** contain one or more reaction observations (templateId 2.16.840.1.113883.10.20.1.54), each of which **MAY** contain exactly one severity observation (templateId 2.16.840.1.113883.10.20.1.55) **AND/OR** one or more reaction interventions.

CONF-349: The value for "**entryRelationship / @typeCode**" in a relationship between a medication activity and reaction observation **SHALL** be "CAUS" "Is etiology for" 2.16.840.1.113883.5.1002 ActRelationshipType **STATIC**.

3.9.2.3 Representation of "status" values

The template identifier for a medication status observation is 2.16.840.1.113883.10.20.1.47.

CONF-350: A medication activity **MAY** contain exactly one medication status observation.

CONF-351: A supply activity **MAY** contain exactly one medication status observation.

CONF-352: A medication status observation (templateId 2.16.840.1.113883.10.20.1.47) **SHALL** be a conformant status observation (templateId 2.16.840.1.113883.10.20.1.57) (as defined in section *5.1 "Type" and "Status" values*).

CONF-353: The value for "**Observation / value**" in a medication status observation **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.20.7 MedicationStatusCode **STATIC** 20061017.

3.9.2.4 Representation of a product

The template identifier for a product is 2.16.840.1.113883.10.20.1.53.

The template identifier for a product instance is 2.16.840.1.113883.10.20.1.52.

CONF-354: A medication activity **SHALL** contain exactly one **SubstanceAdministration / consumable**, the target of which is a product template.

CONF-355: A supply activity **MAY** contain exactly one **Supply / product**, the target of which is a product template.

CONF-356: A product (templateId 2.16.840.1.113883.10.20.1.53) **SHALL** be represented with the **ManufacturedProduct** class.

CONF-357: A **ManufacturedProduct** in a product template **SHALL** contain exactly one **manufacturedProduct / manufacturedMaterial**.

CONF-358: A **manufacturedMaterial** in a product template **SHALL** contain exactly one **manufacturedMaterial / code**.

CONF-359: The value for "**manufacturedMaterial / code**" in a product template **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[10], or **MAY** be selected from ValueSet 2.16.840.1.113883.1.11.20.8 MedicationTypeCode **STATIC** 20061017.

CONF-360: The value for "**manufacturedMaterial / code**" in a product template **MAY** contain a precoordinated product strength, product form, or product concentration (e.g. "metoprolol 25mg tablet", "amoxicillin 400mg/5mL suspension").

CONF-361: If **manufacturedMaterial / code** contains a precoordinated unit dose (e.g. "metoprolol 25mg tablet"), then **SubstanceAdministration / doseQuantity SHALL** be a unitless number that indicates the number of products given per administration.

CONF-362: If **manufacturedMaterial / code** does not contain a precoordinated unit dose (e.g. "metoprolol product"), then **SubstanceAdministration / doseQuantity SHALL** be a physical quantity that indicates the amount of product given per administration.

CONF-363: A **manufacturedMaterial** in a product template **SHALL** contain exactly one **Material / code / originalText**, which represents the generic name of the product.

CONF-364: A **manufacturedMaterial** in a product template **MAY** contain exactly one **Material / name**, which represents the brand name of the product.

ASTM CCR defines an optional product size element which can be used to describe the physical characteristics of a product. CDA R2 has no corresponding field, but can uniquely identify a given manufacturer's product, thereby enabling a complete lookup of any detail related to the product.

CONF-365: A **ManufacturedProduct** in a product template **MAY** contain exactly one **manufacturedProduct / manufacturerOrganization**, which represents the manufacturer of the **Material**.

CONF-366: A **ManufacturedProduct** in a product template **MAY** contain one or more **manufacturedProduct / id**, which uniquely represent a particular kind of product.

CONF-367: If **ManufacturedProduct** in a product template contains **manufacturedProduct / id**, then **ManufacturedProduct SHOULD** also contain **manufacturedProduct / manufacturerOrganization**.

[10] A table of CDC Vaccine Codes can be found at http://www.cdc.gov/nip/registry/st_terr/tech/stds/hl7-cvx.htm.

CONF-368: A medication activity **MAY** contain one or more product instance templates (templateId 2.16.840.1.113883.10.20.1.52) (see section ***3.14.2.2 Procedure related products***), to identify a particular product instance.

CONF-369: A supply activity **MAY** contain one or more product instance templates (templateId 2.16.840.1.113883.10.20.1.52) (see section ***3.14.2.2 Procedure related products***), to identify a particular product instance.

CONF-370: **Supply / participant / participantRole / id SHOULD** be set to equal a **[Act | Observation | Procedure] / participant / participantRole / id** (see section ***3.14.2.2 Procedure related products***) to indicate that the Supply and the Procedure are referring to the same product instance.

3.10 Medical Equipment

The template identifier for the medical equipment section is 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.

The ASTM CCR defines medical equipment using the same data objects and constraints as for Medications.

CONF-371: **CCD SHOULD** contain exactly one and **SHALL NOT** contain more than one Medical Equipment section (templateId 2.16.840.1.113883.10.20.1.7). The Medical Equipment section **SHALL** contain a narrative block, and **SHOULD** contain clinical statements. Clinical statements **SHOULD** include one or more supply activities (templateId 2.16.840.1.113883.10.20.1.34) and **MAY** include one or more medication activities (templateId 2.16.840.1.113883.10.20.1.24).

3.10.1 Section conformance

CONF-372: The medical equipment section **SHALL** contain **Section / code**.

CONF-373: The value for "**Section / code**" **SHALL** be "46264-8" "History of medical device use" 2.16.840.1.113883.6.1 LOINC **STATIC**.

CONF-374: The medical equipment section **SHALL** contain **Section / title.**

CONF-375: **Section / title SHOULD** be valued with a case-insensitive language-insensitive text string containing "equipment".

3.10.2 Clinical statement conformance

The ASTM CCR defines medical equipment using the same data objects and constraints as for Medications. See section ***3.9 Medications*** for details.

3.11 Immunizations

The template identifier for the immunizations section is 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.

CONF-376: **CCD SHOULD** contain exactly one and **SHALL NOT** contain more than one Immunizations section (templateId 2.16.840.1.113883.10.20.1.6). The Immunizations section **SHALL** contain a narrative block, and **SHOULD** contain clinical statements. Clinical statements **SHOULD** include one or more medication activities (templateId 2.16.840.1.113883.10.20.1.24) and/or supply activities (templateId 2.16.840.1.113883.10.20.1.34).

3.11.1 Section conformance

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.

CONF-377: The immunizations section **SHALL** contain **Section / code**.

CONF-378: The value for "**Section / code**" **SHALL** be "11369-6" "History of immunizations" 2.16.840.1.113883.6.1 LOINC **STATIC**.

CONF-379: The immunizations section **SHALL** contain **Section / title.**

CONF-380: **Section / title SHOULD** be valued with a case-insensitive language-insensitive text string containing "immunization".

3.11.2 Clinical statement conformance

The ASTM CCR defines Immunizations using the same data objects and constraints as for Medications. See section ***3.9 Medications*** for details.

3.12 Vital Signs

The template identifier for the vital signs section is 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 section ***3.13 Results***), but are aggregated into their own section in order to follow clinical conventions.

CONF-381: **CCD SHOULD** contain exactly one and **SHALL NOT** contain more than one Vital signs section (templateId 2.16.840.1.113883.10.20.1.16). The Vital signs section **SHALL** contain a narrative block, and **SHOULD** contain clinical statements. Clinical statements **SHOULD** include one or more vital signs organizers (templateId 2.16.840.1.113883.10.20.1.35), each of which **SHALL** contain one or more result observations (templateId 2.16.840.1.113883.10.20.1.31).

3.12.1 Section conformance

CONF-382: The vital signs section **SHALL** contain **Section / code**.

CONF-383: The value for "**Section / code**" **SHALL** be "8716-3" "Vital signs" 2.16.840.1.113883.6.1 LOINC **STATIC**.

CONF-384: The vital signs section **SHALL** contain **Section / title.**

CONF-385: **Section / title SHOULD** be valued with a case-insensitive language-insensitive text string containing "vital signs".

3.12.2 Clinical statement conformance

The template identifier for a vital signs organizer is 2.16.840.1.113883.10.20.1.35.

Vital signs are represented like other results (as defined in section ***3.13 Results***), with additional vocabulary constraints.

CONF-386: A vital signs organizer (templateId 2.16.840.1.113883.10.20.1.35) **SHALL** be a conformant results organizer (templateId 2.16.840.1.113883.10.20.1.32).

CONF-387: A vital signs organizer **SHALL** contain one or more sources of information, as defined in section ***5.2 Source***.

3.13 Results

The template identifier for the results section is 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.

CONF-388: **CCD SHOULD** contain exactly one and **SHALL NOT** contain more than one Results section (templateId 2.16.840.1.113883.10.20.1.14). The Results section **SHALL** contain a narrative block, and **SHOULD** contain clinical statements. Clinical statements **SHOULD** include one or more result organizers (templateId 2.16.840.1.113883.10.20.1.32), each of which **SHALL** contain one or more result observations (templateId 2.16.840.1.113883.10.20.1.31).

3.13.1 Section conformance

CONF-389: The result section **SHALL** contain **Section / code**.

CONF-390: The value for "**Section / code**" **SHALL** be "30954-2" "Relevant diagnostic tests and/or laboratory data" 2.16.840.1.113883.6.1 LOINC **STATIC**.

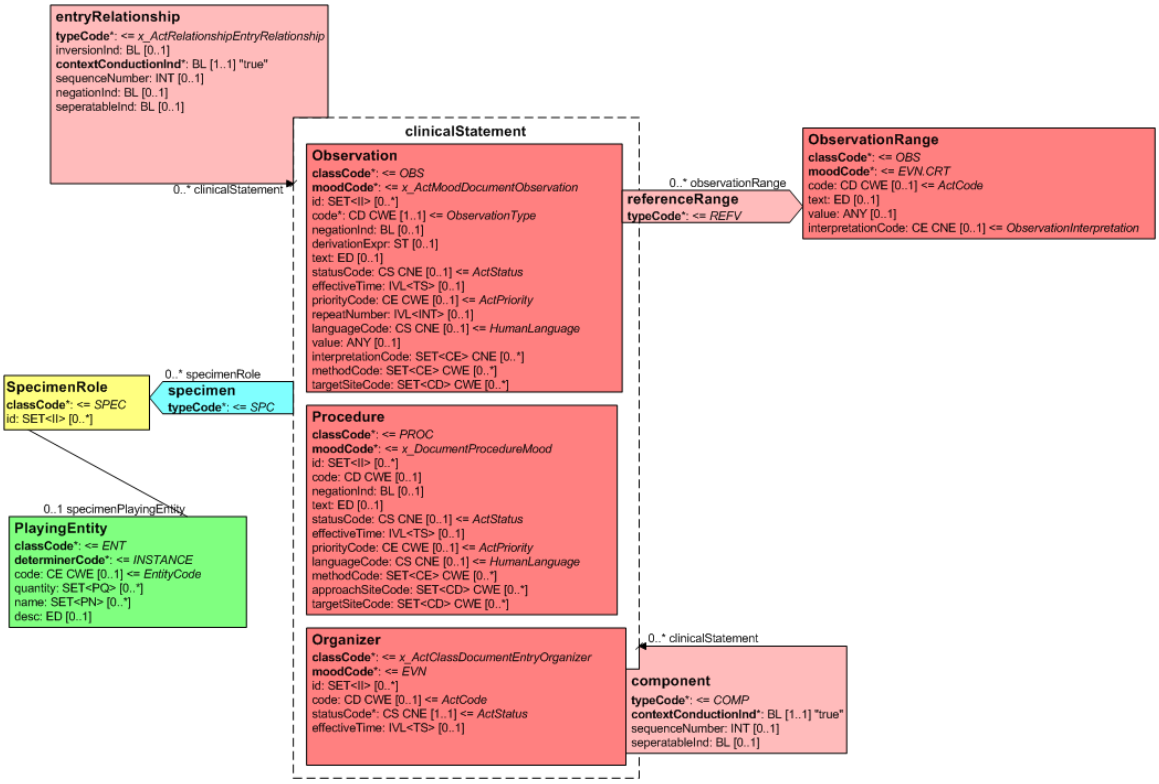
CONF-391: The results section **SHALL** contain **Section / title.**

CONF-392: **Section / title SHOULD** be valued with a case-insensitive language-insensitive text string containing "results".

3.13.2 Clinical statement conformance

The following figure shows a subset of the CDA Clinical Statement model containing those classes being constrained or referred to in the conformance statements that follow.

Figure 12. CDA R2 clinical statement model for results



3.13.2.1 Results representation

The template identifier for a result organizer is 2.16.840.1.113883.10.20.1.32.
The template identifier for a result observation is 2.16.840.1.113883.10.20.1.31.

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.

3.13.2.1.1 Result organizer

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.

CONF-393: A result organizer (templateId 2.16.840.1.113883.10.20.1.32) **SHALL** be represented with **Organizer**.

CONF-394: The value for "**Organizer / @moodCode**" in a result organizer **SHALL** be "EVN" 2.16.840.1.113883.5.1001 ActMood **STATIC**.

CONF-395: A result organizer **SHALL** contain at least one **Organizer / id**.

CONF-396: A result organizer **SHALL** contain exactly one **Organizer / statusCode**.

CONF-397: A result organizer **SHALL** contain exactly one **Organizer / code**.

ASTM CCR defines a restricted set of required result **Type** codes (see ResultTypeCode in section ***7.3 Summary of CCD value sets***), used to categorize a result into one of several commonly accepted values (e.g. "Hematology", "Chemistry", "Nuclear Medicine"). These values are often implicit in the Organizer / code (e.g. an Organizer / code of "complete blood count" implies a ResultTypeCode of "Hematology"). To better support translations between CCD and ASTM's XML CCR format, CCD requires Organizer / code to include a ResultTypeCode either directly or as a translation of a code from some other code system.

CONF-398: The value for "**Organizer / 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-399: A result organizer **SHOULD** include one or more **Organizer / specimen** if the specimen isn't inherent in **Organizer / code**.

CONF-400: **Organizer / specimen SHALL NOT** conflict with the specimen inherent in **Organizer / code**.

CONF-401: **Organizer / specimen / specimenRole / id SHOULD** be set to equal a **Procedure / specimen / specimenRole / id** (see section ***3.14 Procedures***) to indicate that the Results and the Procedure are referring to the same specimen.

CONF-402: A result organizer **SHALL** contain one or more **Organizer / component**.

CONF-403: The target of one or more result organizer **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 **Organizer / code** or if there is a need to further specialize the **Organizer / code** value.

CONF-404: A result organizer **Organizer / component / procedure MAY** be a reference to a procedure described in the Procedure section. (See section *5.3 InternalCCRLink* for more on referencing within CCD).

CONF-405: The target of one or more result organizer **Organizer / component** relationships **SHALL** be a result observation.

CONF-406: A result organizer **SHALL** contain one or more sources of information, as defined in section ***5.2 Source***.

3.13.2.1.2 Result observation

CONF-407: A result observation (templateId 2.16.840.1.113883.10.20.1.31) **SHALL** be represented with **Observation.**

CONF-408: The value for "**Observation / @moodCode**" in a result observation **SHALL** be "EVN" 2.16.840.1.113883.5.1001 ActMood **STATIC**.

CONF-409: A result observation **SHALL** contain at least one **Observation / id**.

CONF-410: A result observation **SHALL** contain exactly one **Observation / statusCode**.

CONF-411: A result observation **SHOULD** contain exactly one **Observation / effectiveTime**, which represents the biologically relevant time (e.g. time the specimen was obtained from the patient).

CONF-412: A result observation **SHALL** contain exactly one **Observation / code**.

CONF-413: The value for "**Observation / code**" in a result observation **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-414: A result observation **MAY** contain exactly one **Observation / methodCode** if the method isn't inherent in **Observation / code** or if there is a need to further specialize the method in **Observation / code**.

CONF-415: **Observation / methodCode SHALL NOT** conflict with the method inherent in **Observation / code**.

CONF-416: A result observation **SHALL** contain exactly one **Observation / value**.

CONF-417: Where **Observation / value** is a physical quantity, the unit of measure **SHALL** be expressed using a valid Unified Code for Units of Measure (UCUM) expression.

CONF-418: A result observation **SHOULD** contain exactly one **Observation / interpretationCode**, which 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.

CONF-419: A result observation **SHOULD** contain one or more **Observation / referenceRange** to show the normal range of values for the observation result.

CONF-420: A result observation **SHALL NOT** contain **Observation / referenceRange / observationRange / code**, as this attribute is not used by the HL7 Clinical Statement or Lab Committee models.

CONF-421: A result observation **SHALL** contain one or more sources of information, as defined in section ***5.2 Source***.

3.14 Procedures

The template identifier for the procedures section is 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.

> **NOTE:** ASTM CCR's notion of "procedure" is broader than that specified by the HL7 Version 3 Reference Information Model (RIM). Therefore this section uses several RIM classes (**Act**, **Observation**, **Procedure**) to represent CCR's procedure objects.

CONF-422: **CCD SHOULD** contain exactly one and **SHALL NOT** contain more than one Procedures section (templateId 2.16.840.1.113883.10.20.1.12). The Procedures section **SHALL** contain a narrative block, and **SHOULD** contain clinical statements. Clinical statements **SHOULD** include one or more procedure activities (templateId 2.16.840.1.113883.10.20.1.29).

3.14.1 Section conformance

CONF-423: The procedure section **SHALL** contain **Section / code**.

CONF-424: The value for "**Section / code**" **SHALL** be "47519-4" "History of procedures" 2.16.840.1.113883.6.1 LOINC **STATIC**.

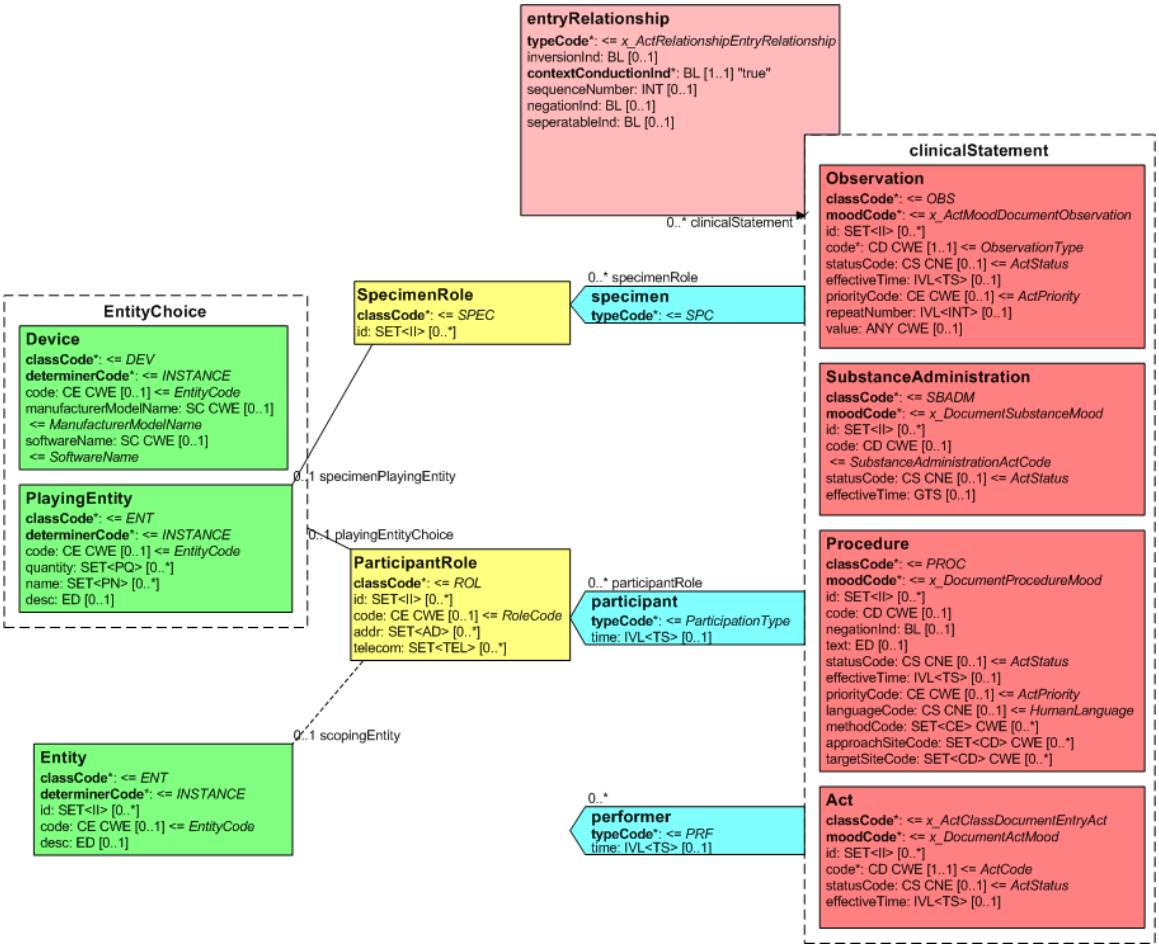
CONF-425: The procedure section **SHALL** contain **Section / title.**

CONF-426: **Section / title SHOULD** be valued with a case-insensitive language-insensitive text string containing "procedures".

3.14.2 Clinical statement conformance

The following figure shows a subset of the CDA Clinical Statement model containing those classes being constrained or referred to in the conformance statements that follow.

Figure 13. CDA R2 clinical statement model for procedures



3.14.2.1 Procedure activity

The template identifier for a procedure activity is 2.16.840.1.113883.10.20.1.29.

CONF-427: A procedure activity (templateId 2.16.840.1.113883.10.20.1.29) **SHALL** be represented with **Act**, **Observation**, or **Procedure**.

CONF-428: The value for "**[Act | Observation | Procedure] / @moodCode**" in a procedure activity **SHALL** be "EVN" 2.16.840.1.113883.5.1001 ActMood **STATIC**.

CONF-429: A procedure activity **SHALL** contain at least one **[Act | Observation | Procedure] / id**.

CONF-430: A procedure activity **SHALL** contain exactly one **[Act | Observation | Procedure] / statusCode**.

CONF-431: The value for "**[Act | Observation | Procedure] / statusCode**" in a procedure activity **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.20.15 ProcedureStatusCode **STATIC** 20061017.

CONF-432: A procedure activity **SHOULD** contain exactly one **[Act | Observation | Procedure] / effectiveTime**.

CONF-433: A procedure activity **SHALL** contain exactly one **[Act | Observation | Procedure] / code**.

CONF-434: The value for "**[Act | Observation | Procedure] / code**" in a procedure activity **SHOULD** be selected from LOINC (codeSystem 2.16.840.1.113883.6.1) or SNOMED

CT (codeSystem 2.16.840.1.113883.6.96), and **MAY** be selected from CPT-4 (codeSystem 2.16.840.1.113883.6.12), ICD9 Procedures (codeSystem 2.16.840.1.113883.6.104), ICD10 Procedure Coding System (codeSystem 2.16.840.1.113883.6.4).

CONF-435: A procedure activity **MAY** contain one or more **[Observation | Procedure] / methodCode** if the method isn't inherent in **[Observation | Procedure] / code** or if there is a need to further specialize the method in **[Observation | Procedure] / code**. **[Observation | Procedure] / methodCode SHALL NOT** conflict with the method inherent in **[Observation | Procedure] / code**.

CONF-436: A procedure activity **MAY** contain one or more **[Observation | Procedure] / targetSiteCode** to indicate the anatomical site or system that is the focus of the procedure, if the site isn't inherent in **[Observation | Procedure] / code** or if there is a need to further specialize the site in **[Observation | Procedure] / code**. **[Observation | Procedure] / targetSiteCode SHALL NOT** conflict with the site inherent in **[Observation | Procedure] / code**.

CONF-437: A procedure activity **MAY** contain one or more location participations (templateId 2.16.840.1.113883.10.20.1.45) (see section ***3.15.2.2 Encounter location***), to represent where the procedure was performed.

CONF-438: A procedure activity **MAY** contain one or more **[Act | Observation | Procedure] / performer**, to represent those practioners who performed the procedure.

CONF-439: A procedure activity **MAY** contain one or more **entryRelationship / @typeCode="RSON"**, the target of which represents the indication or reason for the procedure.

CONF-440: **[Act | Observation | Procedure] / entryRelationship / @typeCode="RSON"** in a procedure activity **SHALL** have a target of problem act (templateId 2.16.840.1.113883.10.20.1.27), problem observation (templateId 2.16.840.1.113883.10.20.1.28), or some other clinical statement.

CONF-441: A procedure activity **MAY** contain one or more patient instructions (templateId 2.16.840.1.113883.10.20.1.49) (see section ***3.9.2.2.2 Patient instructions***), to represent any additional information provided to a patient related to the procedure.

CONF-442: A procedure activity **MAY** have one or more associated consents, represented in the CCD Header as **ClinicalDocument / authorization / consent**.

CONF-443: A **Procedure** in a procedure activity **MAY** have one or more **Procedure / specimen**, reflecting specimens that were obtained as part of the procedure.

CONF-444: **Procedure / specimen / specimenRole / id SHOULD** be set to equal an **Organizer / specimen / specimenRole / id** (see section ***3.13 Results***) to indicate that the Procedure and the Results are referring to the same specimen.

CONF-445: The value for "**[Act | Observation | Procedure] / entryRelationship / @typeCode**" in a procedure activity **MAY** be "SUBJ" "Subject" 2.16.840.1.113883.5.1002 ActRelationshipType **STATIC** to reference an age observation (templateId 2.16.840.1.113883.10.20.1.38).[11]

CONF-446: A procedure activity **MAY** have one or more **[Act | Observation | Procedure] / entryRelationship [@typeCode="COMP"]**, the target of which is a medication activity (templateId 2.16.840.1.113883.10.20.1.24) (see section ***3.9.2.1.1 Medication activity***), to describe substances administered during the procedure.

CONF-447: A procedure activity **SHALL** contain one or more sources of information, as defined in section ***5.2 Source***.

[11] Note that entryRelationship / inversionInd can be used to distinguish relationship source vs. target.

3.14.2.2 Procedure related products

The template identifier for a product is 2.16.840.1.113883.10.20.1.53.
The template identifier for a product instance is 2.16.840.1.113883.10.20.1.52.

CONF-448: A procedure activity **MAY** have one or more **[Act | Observation | Procedure] / participant [@typeCode="DEV"]**, the target of which is a product instance template.

CONF-449: A product instance (templateId 2.16.840.1.113883.10.20.1.52) **SHALL** be represented with the **ParticipantRole** class.

CONF-450: The value for "**participantRole / @classCode**" in a product instance **SHALL** be "MANU" "Manufactured product" 2.16.840.1.113883.5.110 RoleClass **STATIC**.

CONF-451: If **participantRole** in a product instance contains **participantRole / id**, then **participantRole SHOULD** also contain **participantRole / scopingEntity**.

CONF-452: **[Act | Observation | Procedure] / participant / participantRole / id SHOULD** be set to equal a **Supply / participant / participantRole / id** (see section ***3.9.2.4 Representation of a product***) to indicate that the Procedure and the Supply are referring to the same product instance.

3.15 Encounters

The template identifier for the encounters section is 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.

CONF-453: **CCD SHOULD** contain exactly one and **SHALL NOT** contain more than one Encounters section (templateId 2.16.840.1.113883.10.20.1.3). The Encounters section **SHALL** contain a narrative block, and **SHOULD** contain clinical statements. Clinical statements **SHOULD** include one or more encounter activities (templateId 2.16.840.1.113883.10.20.1.21).

3.15.1 Section conformance

CONF-454: The encounters section **SHALL** contain **Section / code**.

CONF-455: The value for "**Section / code**" **SHALL** be "46240-8" "History of encounters" 2.16.840.1.113883.6.1 LOINC **STATIC**.

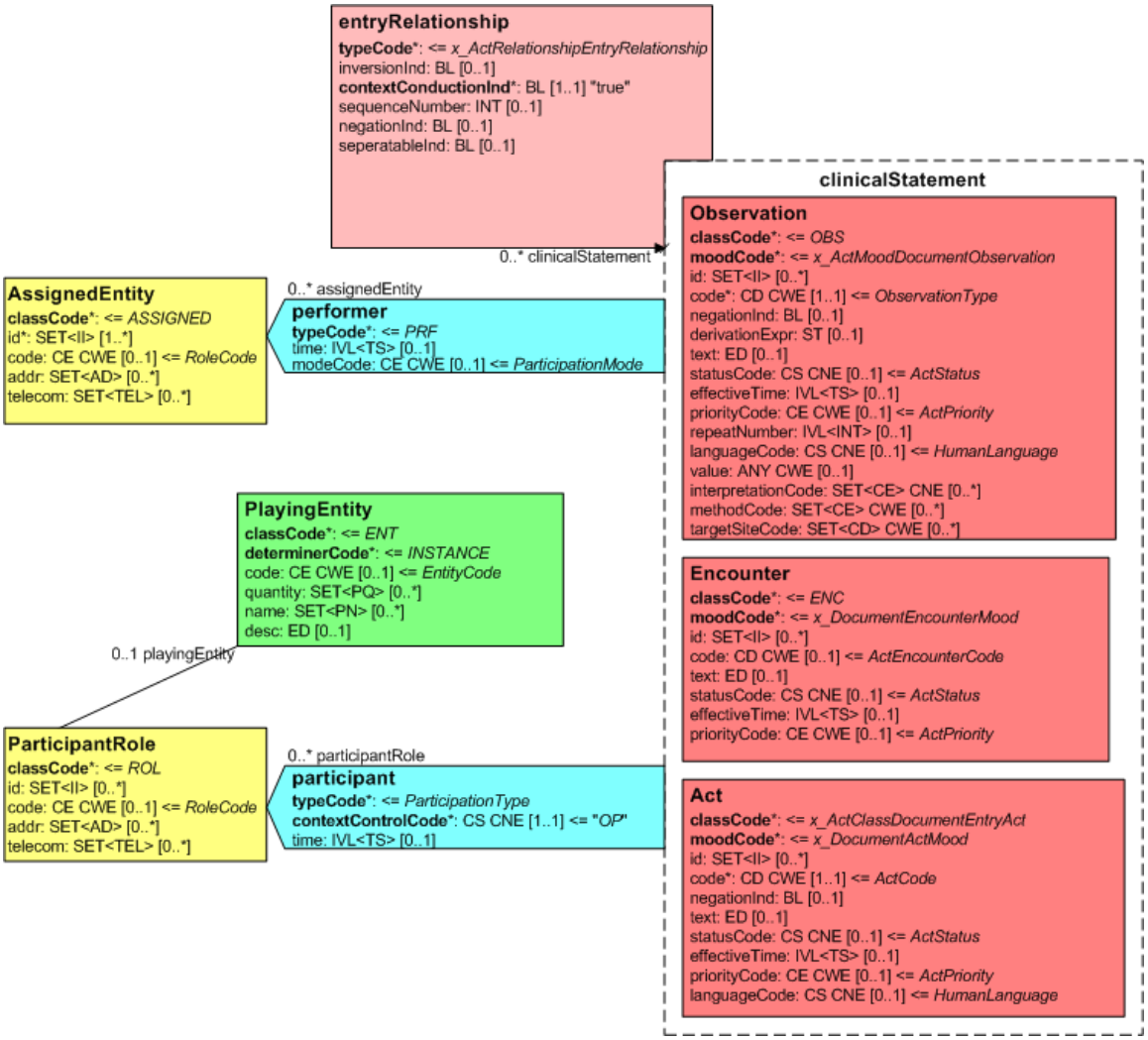
CONF-456: The encounters section **SHALL** contain **Section / title.**

CONF-457: **Section / title SHOULD** be valued with a case-insensitive language-insensitive text string containing "encounters".

3.15.2 Clinical statement conformance

The following figure shows a subset of the CDA Clinical Statement model containing those classes being constrained or referred to in the conformance statements that follow.

Figure 14. CDA R2 clinical statement model for encounters



3.15.2.1 Encounter activities

The template identifier for an encounter activity is 2.16.840.1.113883.10.20.1.21.

CONF-458: An encounter activity (templateId 2.16.840.1.113883.10.20.1.21) **SHALL** be represented with **Encounter**.

CONF-459: The value for "**Encounter / @classCode**" in an encounter activity **SHALL** be "ENC" 2.16.840.1.113883.5.6 ActClass **STATIC**.

CONF-460: The value for "**Encounter / @moodCode**" in an encounter activity **SHALL** be "EVN" 2.16.840.1.113883.5.1001 ActMood **STATIC**.

CONF-461: An encounter activity **SHALL** contain at least one **Encounter / id**.

CONF-462: An encounter activity **SHOULD** contain exactly one **Encounter / code**.

CONF-463: The value for "**Encounter / code**" in an encounter activity **SHOULD** be selected from ValueSet 2.16.840.1.113883.1.11.13955 EncounterCode 2.16.840.1.113883.5.4 ActCode **DYNAMIC**.

CONF-464: An encounter activity **MAY** contain exactly one **Encounter / effectiveTime**, to indicate date, time, and/or duration of an encounter.

CONF-465: An encounter activity **MAY** contain one or more **Encounter / entryRelationship**, whose value for "**entryRelationship / @typeCode**" **SHALL** be "RSON" "Has reason" 2.16.840.1.113883.5.1002 ActRelationshipType **STATIC**, where the target of the relationship represents the indication for the activity.

CONF-466: An encounter activity **MAY** contain one or more **Encounter / performer**, used to define the practioners involved in an encounter.

CONF-467: **Encounter / performer MAY** contain exactly one **Encounter / performer / assignedEntity / code**, to define the role of the practioner.

CONF-468: An encounter activity **MAY** contain one or more patient instructions (templateId 2.16.840.1.113883.10.20.1.49).

CONF-469: The value for "**Encounter / entryRelationship / @typeCode**" in an encounter activity **MAY** be "SUBJ" "Subject" 2.16.840.1.113883.5.1002 ActRelationshipType **STATIC** to reference an age observation (templateId 2.16.840.1.113883.10.20.1.38).[12]

CONF-470: An encounter activity **SHALL** contain one or more sources of information, as defined in section ***5.2 Source***.

3.15.2.2 Encounter location

The template identifier for a location participation is 2.16.840.1.113883.10.20.1.45.

CONF-471: An encounter activity **MAY** contain one or more location participations.

CONF-472: A location participation (templateId 2.16.840.1.113883.10.20.1.45) **SHALL** be represented with the **participant** participation.

CONF-473: The value for "**participant / @typeCode**" in a location participation **SHALL** be "LOC" 2.16.840.1.113883.5.90 ParticipationType **STATIC**.

CONF-474: A location participation **SHALL** contain exactly one **participant / participantRole**.

CONF-475: The value for "**participant / participantRole / @classCode**" in a location participation **SHALL** be "SDLOC" "Service delivery location" 2.16.840.1.113883.5.110 RoleClass **STATIC**.

CONF-476: **Participant / participantRole** in a location participation **MAY** contain exactly one **participant / participantRole / code**.

CONF-477: The value for "**participant / participantRole / code**" in a location participation **SHOULD** be selected from ValueSet 2.16.840.1.113883.1.11.17660 ServiceDeliveryLocationRoleType 2.16.840.1.113883.5.111 RoleCode **DYNAMIC**.

CONF-478: **Participant / participantRole** in a location participation **MAY** contain exactly one **participant / participantRole / playingEntity**.

CONF-479: The value for "**participant / participantRole / playingEntity / @classCode**" in a location participation **SHALL** be "PLC" "Place" 2.16.840.1.113883.5.41 EntityClass **STATIC**.

[12] Note that entryRelationship / inversionInd can be used to distinguish relationship source vs. target.

3.16 Plan of Care

The template identifier for the plan of care section is 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.

CONF-480: **CCD SHOULD** contain exactly one and **SHALL NOT** contain more than one Plan of Care section (templateId 2.16.840.1.113883.10.20.1.10). The Plan of Care section **SHALL** contain a narrative block, and **SHOULD** contain clinical statements. Clinical statements **SHALL** include one or more plan of care activities (templateId 2.16.840.1.113883.10.20.1.25).

3.16.1 Section conformance

CONF-481: The plan of care section **SHALL** contain **Section / code**.

CONF-482: The value for "**Section / code**" **SHALL** be "18776-5" "Treatment plan" 2.16.840.1.113883.6.1 LOINC **STATIC**.

CONF-483: The plan of care section **SHALL** contain **Section / title.**

CONF-484: **Section / title SHOULD** be valued with a case-insensitive language-insensitive text string containing "plan".

3.16.2 Clinical statement conformance

3.16.2.1 Plan of care activities

The template identifier for a plan of care activity is 2.16.840.1.113883.10.20.1.25.

CONF-485: A plan of care activity (templateId 2.16.840.1.113883.10.20.1.25) **SHALL** be represented with **Act, Encounter, Observation, Procedure, SubstanceAdministration,** or **Supply**.

CONF-486: A plan of care activity **SHALL** contain at least one **[Act | Encounter | Observation | Procedure | SubstanceAdministration | Supply] / id**.

CONF-487: A plan of care activity **SHALL** contain exactly one **[Act | Encounter | Observation | Procedure | SubstanceAdministration | Supply] / @moodCode**.

CONF-488: The value for "**[Act | Encounter | Procedure] / @moodCode**" in a plan of care activity **SHALL** be ["INT" (intent) | "ARQ" (appointment request) | "PRMS" (promise) | "PRP" (proposal) | "RQO" (request)] 2.16.840.1.113883.5.1001 ActMood **STATIC**.

CONF-489: The value for "**[SubstanceAdministration | Supply] / @moodCode**" in a plan of care activity **SHALL** be ["INT" (intent) | "PRMS" (promise) | "PRP" (proposal) | "RQO" (request)] 2.16.840.1.113883.5.1001 ActMood **STATIC**.

CONF-490: The value for "**Observation / @moodCode**" in a plan of care activity **SHALL** be ["INT" (intent) | "PRMS" (promise) | "PRP" (proposal) | "RQO" (request) | "GOL" (goal)] 2.16.840.1.113883.5.1001 ActMood **STATIC**.

CONF-491: A plan of care activity **SHALL** contain one or more sources of information, as defined in section ***5.2 Source***.

Table 2. Summary of allowable moodCode values in Plan of Care section

	Act	**Encounter**	**Procedure**	**Substance Admin**	**Supply**	**Observation**
INT (intent)	Allowed	Allowed	Allowed	Allowed	Allowed	Allowed
ARQ (appt request)	Allowed	Allowed	Allowed	Not Allowed	Not Allowed	Not Allowed
PRMS (promise)	Allowed	Allowed	Allowed	Allowed	Allowed	Allowed
PRP (proposal)	Allowed	Allowed	Allowed	Allowed	Allowed	Allowed
RQO (request)	Allowed	Allowed	Allowed	Allowed	Allowed	Allowed
GOL (goal)	Not Allowed	Not Allowed	Not Allowed	Not Allowed	Not Allowed	Allowed

3.17 Healthcare Providers

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

As noted above in section *2.1 CCR Unique Identifier*, and illustrated in *Figure 3 Subset of CDA R2 Header*, the CDA R2 Header contains a **ServiceEvent** class which is to be used to indicate the time range being summarized. The main activity being described by the CCD is the provision of healthcare over a period of time. Relevant care providers during the summarization period are represented as **ClinicalDocument / documentationOf / serviceEvent / performer**, where **performer / time** is used to show the specific time period that the particular provider was involved in the patient's care.

The CDA R2 Header contains additional participants, such as **ClinicalDocument / author** and **ClinicalDocument / informationRecipient**. Several CDA Header participations can be played by the same person. In such cases, the person should be identified as the player for each appropriate participation. For instance, if a person is both an author and a performer, the CDA Header should identify that person as both the author participant and as the serviceEvent / performer participant.

> **NOTE:** CCR Healthcare Providers are not represented as a CCD Body section, but rather, are represented as performer participants in the CCD Header.

CONF-492: The value for "**ClinicalDocument / documentationOf / serviceEvent / performer / @typeCode SHALL** be "PRF" "Participation physical performer" 2.16.840.1.113883.5.90 ParticipationType **STATIC**.

CONF-493: A value for "**ClinicalDocument / documentationOf / serviceEvent / performer / assignedEntity / id" MAY** be the HIPAA National Provider Identifier.

CONF-494: A value for "**ClinicalDocument / documentationOf / serviceEvent / performer / assignedEntity / code" MAY** be the National Uniform Claims Committee Provider Taxonomy Code.

3.18 ASTM CCR Body Mapping

The following table is the CCR Body subset of ASTM CCR Table A1.1 "CCR Data Fields Spreadsheet".

Table 3. CCR Body mapping to CDA R2

CCR Data Object	CCR XML Element	CCR Required or Optional	CDA R2 Correspondence	Mapping Comments
CCR Body Objects				
Payers	ccr:Payer	Required	Act	
	ccr:CCRDataObjectID	Required	Act / id	See section *5.4.5 Identifiers* for more details.
	ccr:DateTime	Optional	Act / effectiveTime	See section *5.4.1 Dates and Times* for more details.
	ccr:Type	Optional	Act / code	
	ccr:PaymentProvider	ccr:ActorID is Required; ccr:ActorRole is Optional	Act / performer [@typeCode="PRF"]	
	ccr:Subscriber	ccr:ActorID is Required; ccr:ActorRole is Optional	Act / participant [@typeCode="COV"]; Act / participant [@typeCode="HLD"]	
	ccr:Authorizations	Optional	Act	
	ccr:Source	Required	See section *5.2 Source*.	
	ccr:InternalCCRLink	Optional	See section ***5.3 InternalCCRLink***.	
	ccr:ReferenceID	Optional	See section ***4.2 References***.	
	ccr:CommentID	Optional	See section ***4.3 Comments***.	
Advance Directives	ccr:AdvanceDirective	Required if known	Observation	

CCR Data Object	CCR XML Element	CCR Required or Optional	CDA R2 Correspondence	Mapping Comments
	ccr:CCRDataObjectID	Required if known	Observation / id	See section *5.4.5 Identifiers* for more details.
	ccr:DateTime	Optional	Observation / effectiveTime	See section *5.4.1 Dates and Times* for more details.
	ccr:IDs	Optional	Observation / id; Role / id	
	ccr:Type	Required	Observation / code	
	ccr:Description	Required	Observation / value	
	ccr:Status	Required	Observation / value	See section *3.2.2.2 Representation of "status" values* for more details.
	ccr:Source	Required	See section *5.2 Source*.	
	ccr:InternalCCRLink	Optional	See section ***5.3 InternalCCRLink***.	
	ccr:ReferenceID	Optional	See section ***4.2 References***.	
	ccr:CommentID	Optional	See section ***4.3 Comments***.	
Support	ccr:SupportProvider	Optional	ClinicalDocument / recordTarget / patientRole / patient / guardian ; ClinicalDocument / participant	
Functional Status	ccr:Function	Optional	Observation; Act	
	ccr:CCRDataObjectID	Required	Observation / id; Act / id	See section *5.4.5 Identifiers* for more details.
	ccr:DateTime	Optional	Observation / effectiveTime; Act / effectiveTime	See section *5.4.1 Dates and Times* for more details.
	ccr:Type	Required	Observation / code	
	ccr:Description	Optional	Act	
	ccr:Status	Required	Observation / value	See section *3.4.2.1 Representation of "status" values* for more details.
	ccr:Problem	Optional	See section ***3.5 Problems***.	
	ccr:Test	Optional	See section ***3.13 Results***.	

CCR Data Object	CCR XML Element	CCR Required or Optional	CDA R2 Correspondence	Mapping Comments
	ccr:Source	Required	See section *5.2 Source*.	
	ccr:InternalCCRLink	Optional	See section ***5.3 InternalCCRLink***.	
	ccr:ReferenceID	Optional	See section ***4.2 References***.	
	ccr:CommentID	Optional	See section ***4.3 Comments***.	
Problems	ccr:Problem	Optional	Act	See section *3.5.2.1 Representation of problems* for more details.
	ccr:CCRDataObjectID	Required	Act / id	See section *5.4.5 Identifiers* for more details.
	ccr:DateTime	Optional	Act / effectiveTime; Observation / effectiveTime	See section *5.4.1 Dates and Times* for more details.
	ccr:IDs	Optional	ParticipantRole / id	
	ccr:Type	Optional	Observation / code	
	ccr:Description	Optional	Observation / value	
	ccr:Status	Optional	Observation / value	See section *3.5.2.2 Representation of "status" values* for more details.
	ccr:Episodes	Optional	Observation / reference / @typeCode="ELNK" / ExternalObservation; Act / reference / @typeCode="ELNK" / ExternalAct	
	ccr:HealthStatus	Optional	Observation / value	See section *3.5.2.2 Representation of "status" values* for more details.
	ccr:PatientKnowledge	Optional	Observation / participation / awarenessCode; Act / participation / awarenessCode	See section *3.5.2.4 Patient awareness of a problem* for more details.
	ccr:Source	Required	See section *5.2 Source*.	
	ccr:InternalCCRLink	Optional	See section ***5.3 InternalCCRLink***.	
	ccr:ReferenceID	Optional	See section ***4.2 References***.	
	ccr:CommentID	Optional	See section ***4.3 Comments***.	
Family History	ccr:FamilyProblemHistory	Optional	Observation	See section *3.6.2.1 Family history representation* for more details.

CCR Data Object	CCR XML Element	CCR Required or Optional	CDA R2 Correspondence	Mapping Comments
	ccr:CCRDataObjectID	Required	Observation / id	See section *5.4.5 Identifiers* for more details.
	ccr:DateTime	Optional	Observation / effectiveTime; RelatedSubject / subject / birthTime; RelatedSubject / subject / deceasedTime	See section *3.6.2.4 Representation of age* for more details. See section *5.4.1 Dates and Times* for more details.
	ccr:IDs	Optional	RelatedSubject / id	
	ccr:Type	Optional	Observation / code	
	ccr:Description	Optional	Observation / value	
	ccr:Status	Optional	Observation / value	See section *3.5.2.2 Representation of "status" values* for more details.
	ccr:Problem	Optional	See section ***3.5 Problems***.	
	ccr:FamilyMember	Optional	subject / RelatedSubject	See section 3.6.2.3 Family history participants for more details.
	ccr:Source	Required	See section *5.2 Source*.	
	ccr:InternalCCRLink	Optional	See section ***5.3 InternalCCRLink***.	
	ccr:ReferenceID	Optional	See section ***4.2 References***.	
	ccr:CommentID	Optional	See section ***4.3 Comments***.	
Social History	ccr:SocialHistoryElement	Optional	Observation	
	ccr:CCRDataObjectID	Required	Observation / id	See section *5.4.5 Identifiers* for more details.
	ccr:DateTime	Optional	Observation / effectiveTime	See section *5.4.1 Dates and Times* for more details.
	ccr:IDs	Optional	Observation / id; Role / id	
	ccr:Type	Optional	Observation / code	
	ccr:Description	Optional	Observation / value	
	ccr:Status	Optional	Observation / value	See section *3.5.2.2 Representation of "status" values* for more details.
	ccr:Episodes	Optional	Observation	See section *3.7.2.3 Episode observations* for more details.

CCR Data Object	CCR XML Element	CCR Required or Optional	CDA R2 Correspondence	Mapping Comments
	ccr:Source	Required	See section *5.2 Source*.	
	ccr:InternalCCRLink	Optional	See section ***5.3 InternalCCRLink***.	
	ccr:ReferenceID	Optional	See section ***4.2 References***.	
	ccr:CommentID	Optional	See section ***4.3 Comments***.	
Alerts	ccr:Alert	Optional	Act	
	ccr:CCRDataObjectID	Required	Act / id	See section *5.4.5 Identifiers* for more details.
	ccr:DateTime	Optional	Act / effectiveTime	See section *5.4.1 Dates and Times* for more details.
	ccr:IDs	Optional	Act / id; Role / id	
	ccr:Type	Optional	Observation / code	
	ccr:Description	Optional	Observation / code; Observation / value	
	ccr:Status	Optional	Observation / value	See section *3.8.2.2 Representation of "status" values* for more details.
	ccr:Agent	Optional. <Unknown> is required content.	Observation / participant [@typeCode="CSM"] / participantRole / playingEntity	
	ccr:Reaction	Optional	Observation / entryRelationship [@typeCode="MFST"] / Observation	
	ccr:Source	Required	See section *5.2 Source*.	
	ccr:InternalCCRLink	Optional	See section ***5.3 InternalCCRLink***.	
	ccr:ReferenceID	Optional	See section ***4.2 References***.	
	ccr:CommentID	Optional	See section ***4.3 Comments***.	
Medications	ccr:Medication	Optional	SubstanceAdministration	
	ccr:CCRDataObjectID	Required	SubstanceAdministration / id	See section *5.4.5 Identifiers* for more details.

CCR Data Object	CCR XML Element	CCR Required or Optional	CDA R2 Correspondence	Mapping Comments
	ccr:DateTime	Optional	SubstanceAdministration / effectiveTime	See section *5.4.1 Dates and Times* for more details.
	ccr:IDs	Optional	Act / id; Role / id	
	ccr:Type	Optional	Observation / code	
	ccr:Description	Optional	Section / text	
	ccr:Status	Optional	Observation / value	See section *3.9.2.3 Representation of "status" values* for more details.
	ccr:Product	Required	ManufacturedProduct / material	
	ccr:ProductName	Required	ManufacturedProduct / material / code / originalText	
	ccr:BrandName	Optional	ManufacturedProduct / material / name	
	ccr:Strength	Optional	ManufacturedProduct / material / code	
	ccr:Form	Optional	ManufacturedProduct / material / code	
	ccr:Concentration	Optional	ManufacturedProduct / material / code	
	ccr:Size	Optional	ManufacturedProduct / id	See section *3.9.2.4 Representation of a product* for more details.
	ccr:Manufacturer	Optional	ManufacturedProduct / manufacturerOrganization	
	ccr:IDs	Optional	ManufacturedProduct / id	
	ccr:Quantity	Optional	Supply / quantity	
	ccr:Directions	Optional	Section / text	
	ccr:DoseIndicator	Optional	Section / entry / @typeCode	The "DRIV" relationship indicates that narrative is derived from the component entries.
	ccr:DeliveryMethod	Optional	SubstanceAdministration / routeCode	
	ccr:Dose	Optional	SubstanceAdministration / doseQuantity	
	ccr:DoseCalculation	Optional	SubstanceAdministration / doseQuantity; SubstanceAdministration / rateQuantity	
	ccr:Vehicle	Optional	SubstanceAdministration / entryRelationship	For example, a 313 mg vial of lyophilized hematin can

CCR Data Object	CCR XML Element	CCR Required or Optional	CDA R2 Correspondence	Mapping Comments
			[@typeCode = "COMP"] / SubstanceAdministration	be reconstituted with 132 mL of 25% human serum albumin (which is the vehicle), resulting in a hemin concentration of 2.4 mg/mL.: o SubstanceAdministration (hematin in albumin) ▪ / component / SubstanceAdministration (hematin) ▪ / component / SubstanceAdministration (albumin)
	ccr:Route	Optional	SubstanceAdministration / routeCode	
	ccr:Site	Optional	SubstanceAdministration / approachSiteCode	
	ccr:AdministrationTiming	Optional	SubstanceAdministration / effectiveTime	
	ccr:Frequency	Optional	SubstanceAdministration / effectiveTime	
	ccr:Interval	Optional	SubstanceAdministration / effectiveTime	
	ccr:Duration	Optional	SubstanceAdministration / effectiveTime	
	ccr:DoseRestriction	Optional	SubstanceAdministration / maxDoseQuantity	
	ccr:Indication	Optional	SubstanceAdministration / precondition / criterion; Observation	See section *3.9.2.2 Medication related information* for more details.
	ccr:StopIndicator	Optional	SubstanceAdministration / effectiveTime	
	ccr:DirectionSequencePosition	Optional	SubstanceAdministration	Each direction in CCD is a distinct SubstanceAdministration.
	ccr:MultipleDirectionModifier	Optional	Section / text	Complex directions in CCD are expressed as free text.
	ccr:PatientInstructions	Optional	Observation	See section *3.9.2.2 Medication related information* for more details.

CCR Data Object	CCR XML Element	CCR Required or Optional	CDA R2 Correspondence	Mapping Comments
	ccr:FulfillmentInstructions	Optional	Observation	See section *3.9.2.2 Medication related information* for more details.
	ccr:Refill	Optional	Supply / repeatNumber	
	ccr:SeriesNumber	Optional	Observation	See section *3.9.2.2 Medication related information* for more details.
	ccr:Consent	Optional	ClinicalDocument / authorization / consent	
	ccr:Reaction	Optional	Observation	See section *3.9.2.2 Medication related information* for more details.
	ccr:FulfillmentHistory	Optional	Supply	
	ccr:Source	Required	See section *5.2 Source*.	
	ccr:InternalCCRLink	Optional	See section ***5.3 InternalCCRLink***.	
	ccr:ReferenceID	Optional	See section ***4.2 References***.	
	ccr:CommentID	Optional	See section ***4.3 Comments***.	
Medical Equipment	ccr:Equipment	Optional	Supply	
Immunizations	ccr:Immunization	Optional	SubstanceAdministration	
Vital Signs	ccr:Result	Optional	Organizer	
Results	ccr:Result	Optional	Organizer	
	ccr:CCRDataObjectID	Required	Organizer / id	See section *5.4.5 Identifiers* for more details.
	ccr:DateTime	Optional	Organizer / effectiveTime	See section *5.4.1 Dates and Times* for more details.
	ccr:IDs	Optional	Organizer / id; Role / id	
	ccr:Type	Required	Organizer / code	
	ccr:Description	Optional	Organizer / code	
	ccr:Procedure	Optional	Organizer / component / procedure	

CCR Data Object	CCR XML Element	CCR Required or Optional	CDA R2 Correspondence	Mapping Comments
	ccr:Substance	Optional	Organizer / specimen	
	ccr:Test	Optional	Observation	
	ccr:DateTime	Optional	Observation / effectiveTime	See section *5.4.1 Dates and Times* for more details.
	ccr:IDs	Optional	Observation / id; Role / id	
	ccr:Type	Required	Observation / code	
	ccr:Description	Optional	Observation / code	
	ccr:Status	Optional	Observation / statusCode	
	ccr:Method	Optional	Observation / methodCode	
	ccr:Agent	Optional	Observation / participant	
	ccr:TestResult	Required	Observation / value	
	ccr:NormalResult	Optional	Observation / referenceRange	
	ccr:Flag	Optional	Observation / interpretationCode	
	ccr:ConfidenceValue	Optional	Observation / value	HL7 Version 3 datatypes **UVP** (uncertain value, probabilistic), **NPPD** (non-parametric probability distribution), and **PPD** (parametric probability distribution) can be used to express confidence in an observation value.
	ccr:Source	Required	See section *5.2 Source*.	
	ccr:InternalCCRLink	Optional	See section ***5.3 InternalCCRLink***.	
	ccr:ReferenceID	Optional	See section ***4.2 References***.	
	ccr:CommentID	Optional	See section ***4.3 Comments***.	
Procedures	ccr:Procedure	Optional	Procedure	
	ccr:CCRDataObjectID	Required	Procedure / id	See section *5.4.5 Identifiers* for more details.

CCR Data Object	CCR XML Element	CCR Required or Optional	CDA R2 Correspondence	Mapping Comments
	ccr:DateTime	Optional	Procedure / effectiveTime	See section *5.4.1 Dates and Times* for more details.
	ccr:IDs	Optional	Procedure / id; role / id	
	ccr:Type	Optional	Procedure / code	
	ccr:Description	Optional	Procedure / code	
	ccr:Status	Optional	Procedure / statusCode	
	ccr:Location	Optional	Procedure / participant [@typeCode="LOC"]	
	ccr:Practitioner	Optional	Procedure / performer	
	ccr:Frequency	Optional	Observation	CDA R2 Procedure / effectiveTime is IVL_TS data type, so can't represent frequency. A nested frequency observation can be used.
	ccr:Duration	Optional	Procedure / effectiveTime	
	ccr:Indication	Optional	Procedure / entryRelationship [@typeCode="RSON"]	
	ccr:Product	Optional	Participant / participantRole [@typeCode="DEV"]	
	ccr:Substance	Optional	Procedure / entryRelationship / substanceAdministration	
	ccr:Method	Optional	Procedure / methodCode	
	ccr:Position	Optional	Procedure / methodCode	
	ccr:Site	Optional	Procedure / targetSiteCode	
	ccr:Source	Required	See section *5.2 Source*.	
	ccr:InternalCCRLink	Optional	See section ***5.3 InternalCCRLink***.	
	ccr:ReferenceID	Optional	See section ***4.2 References***.	
	ccr:CommentID	Optional	See section ***4.3 Comments***.	
Encounters	ccr:Encounter	Optional	Encounter	

CCR Data Object	CCR XML Element	CCR Required or Optional	CDA R2 Correspondence	Mapping Comments
	ccr:CCRDataObjectID	Required	Encounter / id	See section *5.4.5 Identifiers* for more details.
	ccr:DateTime	Optional	Encounter / effectiveTime	See section *5.4.1 Dates and Times* for more details.
	ccr:IDs	Optional	Encounter / id	
	ccr:Type	Optional	Encounter / code	
	ccr:Description	Required	Encounter / code	
	ccr:Location	Optional	Encounter / participant [@typeCode="LOC"]	
	ccr:Practitioner	Optional	Encounter / performer	
	ccr:Frequency	Optional	Observation	CDA R2 Encounter / effectiveTime is IVL_TS data type, so can't represent frequency. A nested frequency observation can be used.
	ccr:Duration	Optional	Encounter / effectiveTime	
	ccr:Indication	Optional	Observation	
	ccr:Instructions	Optional	Encounter / entryRelationship [@typeCode="SUBJ"] / Act [@classCode="ACT"]	
	ccr:Consent	Optional	ClinicalDocument / authorization / consent	
	ccr:Source	Required	See section *5.2 Source*.	
	ccr:InternalCCRLink	Optional	See section ***5.3 InternalCCRLink***.	
	ccr:ReferenceID	Optional	See section ***4.2 References***.	
	ccr:CommentID	Optional	See section ***4.3 Comments***.	
Plan of Care	ccr:Plan	Optional	Act; Encounter; Observation; Procedure; SubstanceAdministration; Supply	
	ccr:CCRDataObjectID	Required	[Act | Encounter | Observation | Procedure | SubstanceAdministration | Supply] / id	See section *5.4.5 Identifiers* for more details.
	ccr:DateTime	Optional	[Act | Encounter | Observation | Procedure |	See section *5.4.1 Dates and Times* for more details.

CCR Data Object	CCR XML Element	CCR Required or Optional	CDA R2 Correspondence	Mapping Comments
			SubstanceAdministration | Supply] / effectiveTime	
	ccr:IDs	Optional	[Act | Encounter | Observation | Procedure | SubstanceAdministration | Supply] / id; Role / id	
	ccr:Type	Optional	Observation / code	
	ccr:Description	Optional	[Act | Encounter | Observation | Procedure | SubstanceAdministration | Supply] / code	
	ccr:Status	Optional	Observation / statusCode	
	ccr:OrderRequest	Optional	[Act | Encounter | Observation | Procedure | SubstanceAdministration | Supply] / code	
	ccr:DateTime	Optional	[Act | Encounter | Observation | Procedure | SubstanceAdministration | Supply] / effectiveTime	See section *5.4.1 Dates and Times* for more details.
	ccr:IDs	Optional	[Act | Encounter | Observation | Procedure | SubstanceAdministration | Supply] / id; Role / id	
	ccr:Type	Optional	Observation / code	
	ccr:Description	Optional	[Act | Encounter | Observation | Procedure | SubstanceAdministration | Supply] / code	
	ccr:Status	Optional	Observation / statusCode	
	ccr:Procedure	Optional	Act; Observation; Procedure	
	ccr:Product	Optional	Supply	
	ccr:Medication	Optional	SubstanceAdministration	
	ccr:Immunization	Optional	SubstanceAdministration	
	ccr:Service	Optional	Act	
	ccr:Encounter	Optional	Encounter	

CCR Data Object	CCR XML Element	CCR Required or Optional	CDA R2 Correspondence	Mapping Comments
	ccr:Authorization	Optional	Act	
	ccr:Goals	Optional	Observation / @moodCode = GOL	
	ccr:Source	Required	See section *5.2 Source*.	
	ccr:InternalCCRLink	Optional	See section ***5.3 InternalCCRLink***.	
	ccr:ReferenceID	Optional	See section ***4.2 References***.	
	ccr:CommentID	Optional	See section ***4.3 Comments***.	
Healthcare Providers	ccr:Providers	Optional	ClinicalDocument / documentOf / serviceEvent / performer	

4 CCR Footer Representation

The CCR Footer contains data defining all of the actors, as well as information about external references, all text comments, and signatures associated with any data within the CCR.

4.1 Actors

Used as a container to define all of the individuals, organizations, locations, and systems associated with data in the summary document. Within the CCR data set, an Actor is a <Person>, <Organization> or <Device>. These correspond to the HL7 RIM Entity classes: LivingSubject, Person, Organization or Device, and are mapped accordingly to these classes as exposed in a CDA document. Whereas ASTM CCR enumerates all Actors in the CCR Footer and references those Actors from within the CCR Body with the <ActorLink> element, CCD defines many participants within the document header and body.

Actor roles are constructed in the CCR by relating an Actor to an element in the CCR via the <ActorLink> element. This element indicates the entity (person, organization or device) by reference in the <ActorID> element, and the role in the <ActorRole> element. Within CDA R2, the role typically includes the entity by value, not by reference. However, appropriate construction of a CDA document, and application of the Care Record Summary extensions, will allow use of entities by reference as follows:

CONF-495: Each actor **SHALL** appear in the appropriate section of the CDA at least once with all information fully specified, and **SHOULD** include an entity identifier.

CONF-496: Other references to the same entity (a person or organization) in the same or different role **NEED NOT** fully specify the actor information, provided they include the same entity identifier.

CONF-497: There **SHALL** be a one-to-one relationship between entity identifiers in a CDA and ActorID as represented in the CCR data set.

Table 4. CCR <ActorLink> correspondence to CDA

CCR data element	CDA R2 correspondence	Comments
ccr:ActorLink		
ccr:ActorID	Role / Entity / id	There is a one to one relationship between ActorID and Entity / id, although the values need not be equivalent.
ccr:ActorRole	Role / code	
ccr:Text	Role / code / originalText	
ccr:Code	Role / code / @code ; Role / code / @codeSystem	

4.2 References

Used to list the details concerning references to external data sources. Corresponds to the CDA R2 <reference> element. Whereas ASTM CCR enumerates all references in the CCR Footer, CCD defines the reference within the section where it occurs.

CONF-498: A clinical statement in a CCD section **MAY** contain one or more **Observation / reference / externalDocument**, to represent externally an externally referenced document.

CONF-499: An externally referenced document **MAY** contain exactly one **Observation / reference / ExternalDocument / text / reference**, to indicate the URL of the referenced document. A **<linkHTML>** element containing the same URL **SHOULD** be present in the associated CDA Narrative Block.

CONF-500: An externally referenced document **MAY** contain exactly one **Observation / reference / ExternalDocument / text / @mediaType**, to indicate the MIME type of the referenced document.

CONF-501: Where the value of **Observation / reference / seperatableInd** is "false", the referenced document **SHOULD** be included in the CCD exchange package. The exchange mechanism **SHOULD** be based on Internet standard RFC 2557 "MIME Encapsulation of Aggregate Documents, such as HTML (MHTML)" (http://www.ietf.org/rfc/rfc2557.txt). (See CDA Release 2, section 3 "CDA Document Exchange in HL7 Messages" for examples and additional details).

4.3 Comments

The template identifier for a comment is 2.16.840.1.113883.10.20.1.40.

Used to contain comments associated with any of the data within the document. Whereas ASTM CCR enumerates all comments in the CCR Footer, CCD defines the comments within the section where they occur. CDA R2 represents comments as Acts.

CONF-502: A CCD section **MAY** contain one or more comments, either as a clinical statement or nested under another clinical statement.

CONF-503: A comment (templateId 2.16.840.1.113883.10.20.1.40) **SHALL** be represented with **Act**.

CONF-504: The value for "**Act / @classCode**" in a comment **SHALL** be "ACT" 2.16.840.1.113883.5.6 ActClass **STATIC**.

CONF-505: The value for "**Act / @moodCode**" in a comment **SHALL** be "EVN" 2.16.840.1.113883.5.1001 ActMood **STATIC**.

CONF-506: A comment **SHALL** contain exactly one **Act / code**.

CONF-507: The value for "**Act / code**" in a comment **SHALL** be 48767-8 "Annotation comment" 2.16.840.1.113883.6.1 LOINC **STATIC**.

4.4 Signatures

Used by ASTM CCR as a container for all signatures associated with any data in the summary document.

While electronic signatures are not captured in a CDA document, both authentication and legal authentication require that a document has been signed manually or electronically by the responsible individual. A **legalAuthenticator** has a required **legalAuthenticator / time** indicating the time of authentication, and a required **legalAuthenticator / signatureCode**, indicating that a signature has been obtained and is on file.

Application systems sending and receiving CDA documents are responsible for meeting all legal requirements for document authentication, confidentiality, and retention. For communications over public media, cryptographic techniques for source/recipient authentication and secure transport of encapsulated

documents may be required, and should be addressed with commercially available tools outside the scope of the CDA specification.

4.5 ASTM CCR Footer Mapping

The following table is the CCR Footer subset of ASTM CCR Table A1.1 "CCR Data Fields Spreadsheet".

Table 5. CCR Footer mapping to CDA R2

CCR Data Object	CCR XML Element	CCR Required or Optional	CDA R2 Correspondence	Mapping Comments
CCR Footer Objects				
Actors	ccr:Actor	Required	A participating entity (e.g. Person, Organization, Device)	
	ccr:ActorObjectID	Required	Entity / id	
	ccr:Person	Optional	Person	
	ccr:Name	Optional	See section ***5.4.2 Names***.	
	ccr:BirthName	Optional	See section ***5.4.2 Names***.	
	ccr:AdditionalName	Optional	See section ***5.4.2 Names***.	
	ccr:CurrentName	Optional	See section ***5.4.2 Names***.	
	ccr:DisplayName	Optional	See section ***5.4.2 Names***.	
	ccr:DateOfBirth	Optional	Patient / birthTime; subject / relatedSubject / subject / birthTime	**HL7:** Date of Birth is only present for the patient or subject. It is not used elsewhere in the CDA.
	ccr:Gender	Optional	Patient / administrativeGenderCode; subject / administrativeGenderCode	**ASTM:** Value set limited to Male, Female, Other and Unknown. **HL7:** Gender is only present for the patient or subject. It is not used elsewhere in the CDA. HL7 AdministrativeGender vocabulary covers Male, Female and Undifferentiated.
	ccr:Organization	Optional	assignedAuthor / representedOrganization; assignedEntity / representedOrganization; intendedRecipient / recievedOrganization; associatedEntity / scopingOrganization	
	ccr:InformationSystem	Optional	assignedAuthoringDevice; playingDevice	

CCR Data Object	CCR XML Element	CCR Required or Optional	CDA R2 Correspondence	Mapping Comments
	ccr:IDs	Optional	Entity / id; Role / id	**HL7:** Entities and Roles can have identifiers. Role identifiers are related to a specific role, but entities may participate in more than one role (and thus have more than one identifier). However, CDA Release 2.0 does not usually allow for Persons to have identifiers. CCD provides an extension that would allow recording of an arbitrary identifier for a person.
	ccr:Relation	Optional	sdtc:asPatientRelationship	See section *7.4 Extensions to CDA R2*.
	ccr:Specialty	Optional	Performer / functionCode	
	ccr:Address	Optional	Role / address	**HL7:** Both roles and entities can have addresses. Storing these on the Entity is most closely aligned with the CCR notion of an Actor, however CDA Release 2.0 often limits storage of this information to Roles.
	ccr:Telephone	Optional	Role / telecom	**HL7:** Both roles and entities can have telephjone numbers. Storing these on the Entity is most closely aligned with the CCR notion of an Actor, however CDA Release 2.0 often limits storage of this information to Roles
	ccr:Email	Optional	Role / telecom	**HL7:** Both roles and entities can have e-mail addresses. Storing these on the Entity is most closely aligned with the CCR notion of an Actor, however CDA Release 2.0 often limits storage of this information to Roles
	ccr:URL	Optional	Role / telecom	**HL7:** Both roles and entities can have web addresses. Storing these on the Entity is most closely aligned with the CCR notion of an Actor, however CDA Release 2.0 often limits storage of this information to Roles
	ccr:Status	Optional	-none-	**HL7:** Not needed in CCD
	ccr:Source	Required	See section *5.2 Source*.	
	ccr:InternalCCRLink	Optional	See section ***5.3 InternalCCRLink***.	
	ccr:ReferenceID	Optional	See section ***4.2 References***.	
	ccr:CommentID	Optional	See section ***4.3 Comments***.	
References	ccr:Reference	Optional	<reference>	
	ccr:ReferenceObjectID	Required	Not applicable	**HL7:** Because CCD states the reference within the section where it occurs, a referenceable object identifier is not required.
	ccr:DateTime	Optional	-none-	**HL7:** CDA R2 doesn't currently contain an effectiveTime

CCR Data Object	CCR XML Element	CCR Required or Optional	CDA R2 Correspondence	Mapping Comments
				attribute in the ExternalDocument class.
	ccr:Description	Optional	ExternalDocument / code	
	ccr:Source	Optional	See section *5.2 Source*.	
	ccr:Locations	Optional	ExternalDocument / text / reference	
Comments	ccr:Comment	Optional	Act	
	ccr:CommentObjectID	Required	Not applicable	**HL7:** Because CCD states the comment within the section where it occurs, a referenceable object identifier is not required.
	ccr:DateTime	Optional	Act / effectiveTime	See section *5.4.1 Dates and Times* for more details.
	ccr:Description	Required	Act / code; Act / text	
	ccr:Source	Optional	See section *5.2 Source*.	
	ccr:ReferenceID	Optional	See section ***4.2 References***.	
Signatures	ccr:CCRSignature	Optional	See section ***4.4 Signatures***.	
	ccr:SignatureObjectID	Required	See section ***4.4 Signatures***.	
	ccr:ExactDateTime	Optional	See section ***4.4 Signatures***.	
	ccr:Type	Optional	See section ***4.4 Signatures***.	
	ccr:IDs	Optional	See section ***4.4 Signatures***.	
	ccr:Source	Optional	See section ***4.4 Signatures***.	
	ccr:Signature	Optional	See section ***4.4 Signatures***.	

5 General Constraints

5.1 "Type" and "Status" values

The template identifier for a status observation is 2.16.840.1.113883.10.20.1.57.

ASTM CCR defines restricted **Type** and **Status** value sets to further define observations in many of the CCR sections. While the value sets differ between sections, the XML representation is constant. Those constraints that are constant across all the sections are defined here, and are then further specialized in the sections above.

A complete mapping between all ASTM CCR **Type** and **Status** values and their corresponding RIM (potentially coupled with SNOMED CT, LOINC, etc) representations is beyond the scope of this specification, and is a work item for a subsequent version. ASTM CCR **Type** values are represented as value sets, which can be conveyed in the code attribute of the various RIM classes (e.g. a value from the ProblemTypeCode value set can be conveyed in Observation.code). Where possible, ASTM CCR **Status** values have been mapped to HL7 ActStatus values, in which case they are conveyed in the statusCode attribute of the various RIM classes. Where the mapping is complex and incomplete, ASTM CCR **Status** values can be communicated as related status observations.

Often times, the **Type** or **Status** is implied by the codes used to characterize the observation (e.g. an observation of "Do Not Resuscitate" implies an Advance Directive Type "Resuscitation Status"), and/or by values asserted in other RIM attributes (e.g. an Observation.negationInd of "true" implies a Problem Status "Ruled out"). In no case should an ASTM CCR **Type** or **Status** value conflict with semantics carried in other RIM attributes.

CONF-508: A status observation (templateId 2.16.840.1.113883.10.20.1.57) **SHALL** be represented with **Observation**.

CONF-509: A status observation **SHALL** be the target of an **entryRelationship** whose value for "**entryRelationship / @typeCode**" **SHALL** be "REFR" 2.16.840.1.113883.5.1002 ActRelationshipType **STATIC**.

CONF-510: The value for "**Observation / @classCode**" in a status observation **SHALL** be "OBS" 2.16.840.1.113883.5.6 ActClass **STATIC**.

CONF-511: The value for "**Observation / @moodCode**" in a status observation **SHALL** be "EVN" 2.16.840.1.113883.5.1001 ActMood **STATIC**.

CONF-512: A status observation **SHALL** contain exactly one **Observation / code**.

CONF-513: The value for "**Observation / code**" in a status observation **SHALL** be "33999-4" "Status" 2.16.840.1.113883.6.1 LOINC **STATIC**.

CONF-514: A status observation **SHALL** contain exactly one **Observation / statusCode**.

CONF-515: The value for "**Observation / statusCode**" in a status observation **SHALL** be "completed" 2.16.840.1.113883.5.14 ActStatus **STATIC**.

CONF-516: A status observation **SHALL** contain exactly one **Observation / value**, which **SHALL** be of datatype "CE".

CONF-517: A status observation **SHALL NOT** contain any additional Observation attributes.

CONF-518: A status observation **SHALL NOT** contain any Observation participants.

CONF-519: A status observation **SHALL NOT** be the source of any Observation relationships.

5.2 Source

ASTM CCR requires that all data objects have a stated source (or state explicitly that the source is unknown) so that any data within the summary can be validated. The source of data may be a person, organization, reference to some other data object, etc.

CONF-520: A person source of information **SHALL** be represented with **informant**.

CONF-521: An organization source of information **SHALL** be represented with **informant**.

CONF-522: A reference source of information **SHALL** be represented with **reference [@typeCode = "XCRPT"]**.

CONF-523: Any other source of information **SHALL** be represented with a source of information observation.

CONF-524: A source of information observation **SHALL** be the target of an **entryRelationship** whose value for "**entryRelationship / @typeCode**" **SHALL** be "REFR" "Refers to" 2.16.840.1.113883.5.1002 ActRelationshipType **STATIC**.

CONF-525: A source of information observation **SHALL** be represented with **Observation**.

CONF-526: The value for "**Observation / @classCode**" in a source of information observation **SHALL** be "OBS" 2.16.840.1.113883.5.6 ActClass **STATIC**.

CONF-527: The value for "**Observation / @moodCode**" in a source of information observation **SHALL** be "EVN" 2.16.840.1.113883.5.1001 ActMood **STATIC**.

CONF-528: A source of information observation **SHALL** contain exactly one **Observation / statusCode**.

CONF-529: The value for "**Observation / statusCode**" in a source of information observation **SHALL** be "completed" 2.16.840.1.113883.5.14 ActStatus **STATIC**.

CONF-530: A source of information observation **SHALL** contain exactly one **Observation / code**.

CONF-531: The value for "**Observation / code**" in a source of information observation **SHALL** be "48766-0" "Information source" 2.16.840.1.113883.6.1 LOINC **STATIC**.

CONF-532: A source of information observation **SHALL** contain exactly one **Observation / value**.

CONF-533: The absence of a known source of information **SHALL** be explicity asserted by valuing **Observation / value** in a source of information observation with the text string "Unknown".

5.3 InternalCCRLink

Used by ASTM CCR to link one CCR data object to another CCR data object. Referencing between objects within CDA R2 or from an object within a CDA R2 document to an external object is via object identifiers. Where two objects have the same identifier, they are the same object.

Each InternalCCRLink has zero to many LinkRelationship elements used to express the link semantics. CDA R2 expresses the relationship between objects using **entryRelationship / @typeCode** and **reference / @typeCode**.

5.4 Data Types

Various CCR data types can be directly mapped onto HL7 RIM classes or data types. These mappings are described in the sections below.

5.4.1 Dates and Times

CCR <DateTime> elements are typically represented in CDA using the HL7 TS, IVL_TS or PPD_TS data types. Some elements may be represented as PQ or IVL_PQ (e.g., age is one such measurement). Values which give just a narrative or text representation will also need to be stored using PQ.

Table 6. CCR <DateTime> correspondence to CDA

CCR data element	CDA R2 correspondence	Comments
ccr:DateTime	effectiveTime time birthTime	**HL7:** Any element using GTS or derived data type (e.g. effectiveTime)
ccr:Type	Not Explicitly Modeled	**ASTM:** The list of values for <DateTime><Type> includes numerous values, but has not been formally constrained by the standard. **HL7:** The type of the date time is implicity determined its location within the XML structure.
ccr:ExactDateTime	@value	**HL7:** HL7 time stamps are recorded using ISO 8601 without any delimiters (hyphens, colons, the letter T between date and time). **ASTM:** ASTM time stamps are recored using ISO 8601 with delimiters (hyphens, colons, and the letter T between date and time).
ccr:Age	entryRelationship/observation/ value[xsi:type='PQ']	**ASTM:** Age less than 2 weeks is expressed in days, less than 2 months in weeks, and less than 2 years in months. All others expressed in years. **HL7:** Age is expressed as a physical quantity in a subordinate observation.
ccr:ApproximateDateTime	entryRelationship/observation/ value	**ASTM:** There is no specified mechanism or vocabulary to express a numerically approximated date time. These are represented in CCR using the Coded Description Type. **HL7:** Approximate date times may only be recorded in a CDA when they can be recorded in a related observation whose subject is the primary act. The code of this act should describe the purpose of the date time, and the value of this act should use an appropriate data

CCR data element	CDA R2 correspondence	Comments
		type, so that it can fully represent the Coded Descrition Type allowed by a CCR.
ccr:DateTimeRange	time[@xsi:type='IVL_TS']	
ccr:BeginRange	low	
ccr:ExactDateTime	@value	
ccr:Age		**HL7:** See notes on age above.
ccr:ApproximateDateTime		**HL7:** See notes on appriximate times above.
ccr:EndRange	high	
ccr:ExactDateTime	@value	
ccr:Age		**HL7:** See notes on age above.
ccr:ApproximateDateTime		**HL7:** See notes on appriximate times above.

Table 7. CCR <DateTime> correspondence to CDA mapping – Examples

CCR Data Representation	CDA R2 Data Representation

`<DateTime>`
`  <ExactDateTime>2004</ExactDateTime>`
`</DateTime>`
	`<time value='2004'/>`

`<DateTime>`
`  <ExactDateTime>2004-09</ExactDateTime>`
`</DateTime>`
	`<time value='200409'>`

`<DateTime>`
`  <ExactDateTime>2004-09-01</ExactDateTime>`
`</DateTime>`
	`<time value='20040901'/>`

`<DateTime>`
`  <ExactDateTime>`
`  2004-09-01T13-0500`
`  </ExactDateTime>`
`</DateTime>`
	`<time value='2004090113-0500'/>`

`<DateTime>`
`  <ExactDateTime>`
`  2004-09-01T13:25-0500`
`  </ExactDateTime>`
`</DateTime>`
	`<time value='200409011325-0500'/>`

`<DateTime>`
`  <ExactDateTime>`
`  2004-09-01T13:25:34-0500`
`  </ExactDateTime>`
`</DateTime>`
	`<time value='20040901132534-0500'/>`

`<DateTime>`
`  <DateTimeRange>`
`  <BeginRange>`
`  <ExactDateTime>`
`  1965-09-01`
`  </ExactDateTime >`
`  </BeginRange>`
`  </DateTimeRange>`
`</DateTime>`
	`<time>`
	`  <low value='19650901'/>`
	`</time>`

`<DateTime>`
`  <DateTimeRange>`
`  <EndRange>`
`  <ExactDateTime>`
`  2004-09-01`
`  </ExactDateTime >`
`  </EndRange>`
`  </DateTimeRange>`
	`<time>`
	`  <high value='20040901'/>`
	`</time>`

CCR Data Representation	CDA R2 Data Representation
</DateTime>	
<DateTime> <DateTimeRange> <BeginRange> <ExactDateTime> 1965-09-01 </ExactDateTime > </BeginRange> <EndRange> <ExactDateTime> 2004-09-01 </ExactDateTime > </EndRange> </DateTimeRange> </DateTime>	<time> <low value='19650901'/> <high value='20040901'/> </time>

5.4.2 Names

Table 8. CCR <CurrentName> correspondence to CDA

CCR data element	CDA R2 correspondence	Comments
ccr:CurrentName	name[use='L']	**ASTM:** The CCR current name is the current legal name.
ccr:Given	given[1]	
ccr:Middle	given[2]	**HL7:** HL7 Version 3 does not distinguish between "First" and "Middle" given names except by position.
ccr:Family	family	
ccr:Suffix	suffix	**ASTM:** The suffix is for "parts of the name", such as Jr., Sr., III, et cetera. **HL7:** A suffix appears after a name component. Jr., Sr., III, et cetera, would be suffixes in an HL7 name, but so would Ph.D. or M.D. (but see below for Title).
ccr:Title	suffix[@qualifier='TITLE'] - or - prefix[@qualifier='TITLE']	**ASTM:** Examples of titles in the CCR implementation guide show Ph.D., MD, which would be suffixes. It is not clear how Dr., Mr., Miss, Ms. Or Mrs. Would be handled in a CCR. **HL7:** The TITLE qualifier indicates that the prefix or suffix applies to the whole name, rather than just the preceeding or following component.

CCR data element	CDA R2 correspondence	Comments
ccr:NickName	given[@qualifier='CM']	**HL7:** The use of the "Call Me" coded value in qualifier indicates that this is what the person would like to be called.

Table 9. CCR <Name> correspondence to CDA – Examples

CCR encoded	CDA R2 encoded	Comments
<Name>		
<CurrentName> <Given></Given> <Middle></Middle> <Family></Family> <Suffix></Suffix> <Title></Title> <NickName></NickName> </CurrentName>	<name use='L'> <given></given> <given></given> <family></family> <suffix></suffix> <suffix qualifier='TITLE'> </suffix> </name> <name> <given qualifier='CM'> </given> </name>	Separate the nickname from the legal name in a separate <name> element.
<AdditionalName> <Given></Given> <Middle></Middle> <Family></Family> <Suffix></Suffix> <Title></Title> <NickName></NickName> </AdditionalName>	<name> <given></given> <given></given> <family></family> <suffix></suffix> <suffix qualifier='TITLE'> </suffix> </name> <name> <given qualifier='CM'> </given> </name>	
<CurrentName> <Given></Given> <Middle></Middle> <Family></Family> <Suffix></Suffix> <Title></Title> <NickName></NickName> </CurrentName>	<name use='L'> <given></given> <given></given> <family></family> <suffix></suffix> <suffix qualifier='TITLE'> </suffix> </name> <name> <given qualifier='CM'> </given> </name>	Separate the nickname from the legal name in a separate <name> element.
<BirthName> <Given></Given> <Middle></Middle> <Family></Family> <Suffix></Suffix> <BirthName>	<name> <given qualifier='BR'> </given> <given qualifier='BR'> </given> <family qualifier='BR'> </family>	Don't use Title or NickName with BirthName

CCR encoded	CDA R2 encoded	Comments
	<suffix></suffix> </name>	
<DisplayName></DisplayName>	<name></name>	Record the display name without delimiters.
</Name>		

5.4.3 Addresses

Table 10. CCR <Address> correspondence to CDA

CCR data element	CDA R2 correspondence	Comments
ccr:Address	addr	
ccr:Type	@use	**ASTM:** The ASTM recommended value set includes Home and Office. **HL7:** The use attribute indicates the type of address. Set addr.use='H' or addr.use='HP' for Home, addr.use='WP' for Office.
ccr:Line1	streetAddressLine[1]	**HL7:** Use one streetAddressLine for each line.
ccr:Line2	streetAddressLine[2]	
ccr:City	city	
ccr:County	.county	
ccr:State	state	
ccr:Country	country	
ccr:PostalCode	postalCode	
ccr:Priority		**ASTM:** The ASTM recommended value set includes Primary – Preferred and Secondary. **HL7:** There is no real way to distinguish between Primary and Secondary.
ccr:Status	@use	**ASTM:** The ASTM recommended value set includes Active and Temporary. **HL7:** Set addr.use='TMP' to indicate a temporary address.

Table 11. CCR <Address> correspondence to CDA – Examples

CCR encoded	CDA R2 encoded	Comments
<Address>	<addr	
<Type>Home</Type>	use='HP'>	
<Line1>**Address 1**</Line1>	<streetAddressLine> **Address 1** </streetAddressLine>	
<Line2>**Address 2**</Line2>	<streetAddressLine> **Address 2** </streetAddressLine>	
<City>**City**</City>	<city>**City**</city>	
<County>**County**</County>	<county>**County**</county>	

CCR encoded	CDA R2 encoded	Comments
<State>**State**</State>	<state>**State**</state>	
<Country>**Country**</Country>	<country></country>	
<PostalCode>**code**</PostalCode>	<postalCode>**code**</postalCode>	
<Priority></Priority>		
<Status>Temporary</Status>	use='TMP'	Add TMP to the use attribute.
</Address>		

NOTE: For addresses, ASTM defines elements for <Type>, <Priority> and <Status>, whereas HL7 only supplies a single attribute to indicate the type of use. All addresses can be assumed to be active unless otherwise specified. Addresses that are known to be inactive shall include the value 'BAD' in the use attribute to indicate that this address is no longer functioning. A temporary address shall include the value 'TMP' in the use attribute to indicate that this address is only temporary.

5.4.4 Telephone Numbers, E-Mail Addresses, and URLs

ASTM and HL7 Version 3 specifications have similar structures for telephone numbers, e-mail addresses, and web page addresses.

Table 12. CCR <Telephone> correspondence to CDA

CCR data element	CDA R2 correspondence	Comments
ccr:Telephone/	telecom/	**HL7:** The CDA uses URLs to represent all telecommunications. The value is represented as a tel: URL.
ccr:Value	@value	**ASTM**: The value is an unrestricted string. **HL7:** The value is a telephone URL conforming to RFC-2806.
ccr:Type	@use	**ASTM:** The ASTM recommended value set includes Home and Office, and also provides an example that uses Mobile. **HL7:** The use attribute indicates the type of address. Set telecom.use='H' or telecom.use='HP' for Home, telecom.use='WP' for Office, and telecom.use='MC' for Mobile.
ccr:Priority		**ASTM:** The ASTM recommended value set includes Primary – Preferred and Secondary. **HL7:** There is no real way to distinguish between Primary and Secondary.
ccr:Status	@use	**ASTM:** The ASTM recommended value set includes Active and Temporary (but does not directly included Inactive). **HL7:** Set addr.use='TMP' to indicate a temporary address.
Not Mappped	@useablePeriod	

Table 13. CCR <Telephone> correspondence to CDA – Examples

CCR encoded	CDA R2 encoded	Comments
<Telephone>	< telecom	
<Value>**phone number**</Value>	value='tel:**phone number**'	
<Type>Home</Type>	use='HP'>	
<Status>Temporary</Status>	use='HP TMP'>	Add TMP to the use attribute.
</Telephone>		
<Email>	<telecom	
<Value>**email address**</Value>	value='mailto:**email address**'	
<Type>Home</Type	use='HP'>	
<Status>Temporary</Status>	use='HP TMP'>	Add TMP to the use attribute.
</Email>		
<URL>	<telecom	
<Value>**URL**</Value>	value='http:**URL**'	
<Type>Home</Type	use='HP'>	
<Status>Temporary</Status>	use='HP TMP'>	Add TMP to the use attribute.
</URL>		

NOTE: For e-mail, telephone, and web page addresses, ASTM defines elements for <Type>, <Priority> and <Status>, whereas HL7 only supplies a single attribute to indicate the type of use of these addresses. All addresses should be assumed to be active unless otherwise specified. Addresses that are known to be inactive shall include the value 'BAD' in the use attribute to indicate that this address is no longer functioning. A temporary address shall include the value 'TMP' in the use attribute to indicate that this address is only temporary.

5.4.5 Identifiers

The CCR supports recording identifiers for Payers, Authorizations, Advance Directives, Problems, Social History, Family History, Alerts, Products, Results, Tests, Procedures, Encounters, Interventions, and Actors. Each identifier has a value, and may have a type, date time, and issuer. It may also include a Source, Link, Reference or Comment.

The purpose of the <DateTime> element in the identifier is unspecified, but is presumed to mean the effective time of the identifier. CDA does not support recording the effective times of identifiers.

Examples of <Type> given for <IDNumber>[13] in the CCR Implementation Guide (see Payor) include Subscriber Number, Member Number (if patient is not subscriber), Plan Number, Group Number and Plan Code.

Some common identifier issuers have already been assigned a root by HL7, as follows:

[13] Which does not appear in the schema.

Table 14. Common OIDs assigned by HL7

Issuer	OID Root
United States Social Security Number (SSN).	2.16.840.1.113883.4.1
United States Driver License Number (root). *See FIPS Pub 5-2 for individual numeric values underneath this root for each State. Note that leading 0 digits are not used in OIDs.*	2.16.840.1.113883.4.3
U.S. IRS Assigned Employer Identification Number EIN.	2.16.840.1.113883.4.4
National Provider Identifier	2.16.840.1.113883.4.6
Unique Physician Identification Number (UPIN)	2.16.840.1.113883.4.8

Table 15. CCR <IDs> correspondence to CDA

CCR data element	CDA R2 correspondence	Comments
ccr:IDs/	id	**ASTM:** Although named <IDs>, this element represents a single identifier. **HL7:** All identifiers are represented in the II datatype, and typically appear in an element named id.
ccr:DateTime	Not Mapped	**ASTM:** No guidance given.
ccr:Type	Role, Entity or Act identifier, e.g, participant/id assignedPerson/id act/id	**ASTM:** Identifers can be stored for Actors, procedures, products, fulfillments, payers, advanced directives, problems, alerts, medications, immunizations, family history, social history, equipment, result, encounter and plan. **HL7:** The type of an identifier is determined from its context.
ccr:ID	@extension	
ccr:IssuedBy	@assigningAuthority @root	**HL7:** The root uid will need to be mapped based on the assigning authority. This information might be assigned using information in the IssuedBy/ActorRole element of the CCR.

5.5 Terminology conformance

Users of CCD may have additional terminology constraints they wish to implement – such as those imposed by Consolidated Health Informatics (CHI, http://www.hhs.gov/healthit/chiinitiative.html) or Healthcare Information Technology Standards Panel (HITSP, http://www.ansi.org/standards_activities/standards_boards_panels/hisb/hitsp.aspx?menuid=3). Careful attention has been given to avoid introducing constraints in CCD that would impede one's ability to layer on these additional vocabulary constraints. CHI- and HITSP-endorsed vocabularies may be used in CCD where applicable.

5.5.1 Coded Information

The CCR <CodedDescriptionType> is represented using the HL7 CD data type, or any of its restrictions, depending upon usage. The table below shows the correspondence between CCR schema elements and CDA Release 2.0 schema elements.

Table 16. CCR <CodedDescriptionType> correspondence to CDA

CCR data element	CDA R2 correspondence	Comments
ccr:CodedDescriptionType	Any element using the CD or derived data type for example: code	
ccr:Text	originalText/reference	The original text should appear in the body of the section, and should be incorporated by reference, not by value (eliminating duplicated information).
ccr:Code	code	
ccr:Value	@code	
ccr:CodingSystem	@codeSystemName	
	@codeSystem	The OID appearing in code.codeSystem shall be appropriately mapped from the ASTM <CodingSystem> value. See section ***5.5.2 Coding System Usage*** for more details.
ccr:Version	@codeSystemVersion	
ccr:ObjectAttribute	qualifier	
ccr:Attribute	name	
ccr:AttributeValue	value	
ccr:Value	originalText/reference	
ccr:Code	code	
ccr:Value	@code	
ccr:CodingSystem	@codeSystemName	
ccr:Version	@codeSystemVersion	And so on…

Table 17. CCR <Description> correspondence to CDA – Examples

CCR-encoded	CDA-encoded
<Description> <Text> Acute Anteroseptal Myocardial Infarction </Text> <Code> <Value>410.1</Value> <CodingSystem>ICD-9 CM</CodingSystem> <Version>2004</Version>	<code code='410.1' codeSystemName='ICD9CM' codeSystem='2.16.840.1.113883.6.2' codeSystemVersion='2004'> <originalText> Acute Anteroseptal Myocardial Infarction </originalText> </code>

CCR-encoded	CDA-encoded
</Code> </Description>	
<Description> <Text> Acute Anteroseptal Myocardial Infarction </Text> <Code> <Value>410.1</Value> <CodingSystem>ICD-9 CM</CodingSystem> <Version>2004</Version> </Code> <Code> <Value>62295002</Value> <CodingSystem>SNOMED CT</CodingSystem> </Code> </Description>	<code code='410.1' codeSystemName='ICD9CM' codeSystem='2.16.840.1.113883.6.2' codeSystemVersion='2004'> <originalText> Acute Anteroseptal Myocardial Infarction </originalText> <translation code=62295002' codeSystemName='SNOMED-CT' codeSystem='2.16.840.1.113883.6.96'> <translation> </code>
<Description> <Text> Acute Anteroseptal Myocardial Infarction </Text> <Code> <Value>410.1</Value> <CodingSystem>ICD-9 CM</CodingSystem> <Version>2004</Version> </Code> <Code> <CodingSystem>SNOMED CT</CodingSystem> <Value>62695002</Value> </Code> <ObjectAttribute> <Attribute>Diagnosis</Attribute> <AttributeValue> <Value>Myocardial Infarction</Value> <Code> <Value>22298006</Value> <CodingSystem> SNOMED CT </CodingSystem> </Code> </AttributeValue> </ObjectAttribute> <ObjectAttribute> <Attribute>Acuity</Attribute> <AttributeValue> <Value>Acute</Value> <Code> <Value>53737009</Value> <CodingSystem> SNOMED CT </CodingSystem> </Code> </AttributeValue> </ObjectAttribute> <ObjectAttribute> <Attribute>Site</Attribute> <AttributeValue> <Value>Anteroseptal</Value> <Code> <Value>20706007</Value> <CodingSystem> SNOMED CT </CodingSystem> </Code> </AttributeValue> </ObjectAttribute> </Description>	<code code='410.1' codeSystemName='ICD9CM' codeSystem='2.16.840.1.113883.6.2' codeSystemVersion='2004'> <originalText> Acute Anteroseptal Myocardial Infarction </originalText> <translation code='62695002' codeSystemName='SNOMED-CT' codeSystem='2.16.840.1.113883.6.96 ' <translation code='22298006' codeSystemName='SNOMED-CT' codeSystem='2.16.840.1.113883.6.96' displayName='Myocardial Infarction'> <qualifier> <name code='260908002' displayName='Course'/> <value code='22298006' displayName='Acute'/> </qualifier> <qualifier> <name code='363698007' displayName='Finding Site'/> <value code='20706007' displayName='Anteroseptal'/> </qualifier> </translation> </translation> </code>

5.5.2 Coding System Usage

The CCR states that Problems should be coded using SNOMED CT, and ICD-9 CM codes, Procedures using SNOMED CT, LOINC and CPT codes, Products and Agents using RxNorm, and Results using CPT and LOINC. In order to utilize these coding systems, an agreement must be reached upon how to represent these systems within a CCR. The table below shows how to map `<CodingSystem>` values from a CCR into the `codeSystem` attribute of an HL7 Version 3 CD data type.

Table 18. CCR <CodingSystem> values and corresponding CDA CD.codeSystem values

CCR <CodingSystem>	CD.codeSystem	CD.codeSystemName
CPT-4	2.16.840.1.113883.6.12	CPT-4
ICD-9 CM	2.16.840.1.113883.6.1	ICD-9 CM
LOINC	2.16.840.1.113883.6.1	LOINC
NDC	2.16.840.1.113883.6.69	NDC
RxNorm	2.16.840.1.113883.6.88	RxNorm
SNOMED CT	2.16.840.1.113883.6.96	SNOMED CT

CONF-534: When representing the any of the coding systems listed above, the `codeSystem` attribute **SHALL** be present using the values listed in that table.

CONF-535: When the `codeSystemName` attribute is present, it **SHALL** be valued with the appropriate values from Table 18 above.

CONF-536: Where SNOMED CT is used, it **SHALL** be used per the "Using SNOMED CT in HL7 Version 3" Implementation Guide.

6 Acknowledgements

The CCD specification could never have been written without a close working relationship between HL7 and ASTM. CCD reflects an overlap of two complementary specifications (CCR, CDA) derived by different standards organizations, and shows what can be achieved when patient care is the driving priority. Special thanks to Rick Peters, Steven Waldren, and Alan Zuckerman for their active involvement in the creation of CCD.

7 Appendix

7.1 Sample

The following sample document depicts a fictional character's health summary. Any resemblance to a real person is coincidental. The sample is provided in three formats – rendered, CCD-encoded, CCR-encoded. The rendering shown below is neither recommended nor suggested by this specification, but is simply one of several possible ways to render CCD data. The CCD instance conforms to this specification. The CCR instance conforms to the ASTM CCR specification.

7.1.1 Sample Document

Good Health Clinic Continuity of Care Document
April 07, 2000

SUMMARY PURPOSE

Transfer of care

PAYERS

Payer name	Policy type / Coverage type	Covered party ID	Authorization(s)
Good Health Insurance	Extended healthcare / Self	14d4a520-7aae-11db-9fe1-0800200c9a66	Colonoscopy

ADVANCE DIRECTIVES

Directive	Description	Verification	Supporting Document(s)
Resuscitation status	Do not resuscitate	Dr. Robert Dolin, Nov 07, 1999	Advance directive

FUNCTIONAL STATUS

Functional Condition	Effective Dates	Condition Status
Dependence on cane	1998	Active
Memory impairment	1999	Active

PROBLEMS

Condition	Effective Dates	Condition Status
Asthma	1950	Active
Pneumonia	Jan 1997	Resolved
’’	Mar 1999	Resolved
Myocardial Infarction	Jan 1997	Resolved

FAMILY HISTORY

Father (deceased)

Diagnosis	Age At Onset
Myocardial Infarction (cause of death)	57
Hypertension	40

Mother (alive)

Diagnosis	Age At Onset
Asthma	30

SOCIAL HISTORY

Social History Element	Description	Effective Dates
Cigarette smoking	1 pack per day	1947 – 1972
’’	None	1973 -
Alcohol consumption	None	1973 -

ALLERGIES AND ADVERSE REACTIONS

Substance	Reaction	Status
Penicillin	Hives	Active
Aspirin	Wheezing	Active
Codeine	Nausea	Active

MEDICATIONS

Medication	Instructions	Start Date	Status
Albuterol inhalant	2 puffs QID PRN wheezing		Active
Clopidogrel (Plavix)	75mg PO daily		Active
Metoprolol	25mg PO BID		Active
Prednisone	20mg PO daily	Mar 28, 2000	Active

Cephalexin (Keflex)	500mg PO QID x 7 days (for bronchitis)	Mar 28, 2000	No longer active

MEDICAL EQUIPMENT

Supply/Device	Date Supplied
Automatic implantable cardioverter/defibrillator	Nov 1999
Total hip replacement prosthesis	1998
Wheelchair	1999

IMMUNIZATIONS

Vaccine	Date	Status
Influenza virus vaccine, IM	Nov 1999	Completed
Influenza virus vaccine, IM	Dec 1998	Completed
Pneumococcal polysaccharide vaccine, IM	Dec 1998	Completed
Tetanus and diphtheria toxoids, IM	1997	Completed

VITAL SIGNS

Date / Time	Nov 14, 1999	April 7, 2000
Height	177 cm	177 cm
Weight	86 kg	88 kg
Blood Pressure	132/86 mmHg	145/88 mmHg

RESULTS

	March 23, 2000	April 06, 2000
Hematology		
HGB (M 13-18 g/dl; F 12-16 g/dl)	13.2	
WBC (4.3-10.8 10+3/ul)	6.7	
PLT (150-350 10+3/ul)	123*	
Chemistry		
NA (135-145meq/l)		140
K (3.5-5.0 meq/l)		4.0
CL (98-106 meq/l)		102
HCO3 (18-23 meq/l)		35*

PROCEDURES

Procedure	Date
Total hip replacement, left	1998

ENCOUNTERS

Encounter	Location	Date
Checkup Examination	Good Health Clinic	Apr 07, 2000

PLAN OF CARE

Planned Activity	Planned Date
Pulmonary function test	Apr 21, 2000

7.1.2 CDA-encoded

This is an example instance encoded using CDA.
SampleCCDDocument.xml

7.1.3 CCR-encoded

This is an example instance encoded using CCR.
SampleCCRDocument.xml

7.1.4 Sample CCD Validating Style Sheet

The Schematron schema is a non-normative example of how one might implement the normative conformance statements so as to validate that a Continuity of Care Document conforms to this specification. This schema conforms to Schematron 1.5, and with a minor change to the namespace (replace "http://www.ascc.net/xml/schematron" with "http://purl.oclc.org/dsdl/schematron") it should then conform to ISO Schematron. [14]
CCD.sch

7.1.5 Sample CCD Rendering Style Sheet

This is a sample CCD XSLT style sheet that can be used to transform a CDA instance into HTML. It is provided as a convenient starting point for local style sheet development, and has several known limitations, including:

- Local implementations may have different requirements for rendering the CDA header.
- Does not support RegionOfInterest rendering.
- Does not support rendering of inline multimedia (e.g. multimedia that is Base 64 encoded within the CDA document).

[14] Updated rules and rules submitted by other authors can be found on the HL7 Wiki site [informatics.mayo.edu/wiki/index.php/Continuity_of_Care_Document_%28CCD%29 (userid: wiki; password: wikiwiki)]

- Does not support rendering of deleted text within the CDA Narrative Block.

CCD.xsl

7.2 Summary of CCD template identifiers

The following table summarizes the CCD template identifiers described above. The value in column "Template Identifier" is used to populate the templateId/@root attribute. The templateId/@extension attribute is not to be populated. The value in column "Reference" refers to the section of CCD where the template is described.

Table 19. Summary of CCD template identifiers

Template Identifier	Description	Reference
2.16.840.1.113883.10	HL7 Registered Templates Root	
2.16.840.1.113883.10.20	HL7 SDTC Registered Templates Root	
2.16.840.1.113883.10.20.1	CCD v1.0 Templates Root	***1.4 Asserting conformance to this Implementation Guide; 2.3 Version***
Section Templates		
2.16.840.1.113883.10.20.1.1	Advance directives section	***3.2 Advance Directives***
2.16.840.1.113883.10.20.1.2	Alerts section	***3.8 Alerts***
2.16.840.1.113883.10.20.1.3	Encounters section	***3.15 Encounters***
2.16.840.1.113883.10.20.1.4	Family history section	***3.6 Family History***
2.16.840.1.113883.10.20.1.5	Functional status section	***3.4 Functional Status***
2.16.840.1.113883.10.20.1.6	Immunizations section	***3.11 Immunizations***
2.16.840.1.113883.10.20.1.7	Medical equipment section	***3.10 Medical Equipment***
2.16.840.1.113883.10.20.1.8	Medications section	***3.9 Medications***
2.16.840.1.113883.10.20.1.9	Payers section	***3.1 Payers***
2.16.840.1.113883.10.20.1.10	Plan of care section	***3.16 Plan of Care***
2.16.840.1.113883.10.20.1.11	Problem section	***3.5 Problems***
2.16.840.1.113883.10.20.1.12	Procedures section	***3.14 Procedures***
2.16.840.1.113883.10.20.1.13	Purpose section	***2.8 Purpose***
2.16.840.1.113883.10.20.1.14	Results section	***3.13 Results***
2.16.840.1.113883.10.20.1.15	Social history section	***3.7 Social History***
2.16.840.1.113883.10.20.1.16	Vital signs section	***3.12 Vital Signs***
Clinical Statement Templates		
2.16.840.1.113883.10.20.1.17	Advance directive observation	***3.2 Advance Directives***
2.16.840.1.113883.10.20.1.18	Alert observation	***3.8 Alerts***
2.16.840.1.113883.10.20.1.19	Authorization activity	***3.1 Payers***
2.16.840.1.113883.10.20.1.20	Coverage activity	***3.1 Payers***
2.16.840.1.113883.10.20.1.21	Encounter activity	***3.15 Encounters***
2.16.840.1.113883.10.20.1.22	Family history observation	***3.6 Family History***
2.16.840.1.113883.10.20.1.23	Family history organizer	***3.6 Family History***
2.16.840.1.113883.10.20.1.24	Medication activity	***3.9 Medications***
2.16.840.1.113883.10.20.1.25	Plan of care activity	***3.16 Plan of Care***
2.16.840.1.113883.10.20.1.26	Policy activity	***3.1 Payers***
2.16.840.1.113883.10.20.1.27	Problem act	***3.5 Problems***
2.16.840.1.113883.10.20.1.28	Problem observation	***3.5 Problems***
2.16.840.1.113883.10.20.1.29	Procedure activity	***3.14 Procedures***
2.16.840.1.113883.10.20.1.30	Purpose activity	***2.8 Purpose***
2.16.840.1.113883.10.20.1.31	Result observation	***3.13 Results***
2.16.840.1.113883.10.20.1.32	Result organizer	***3.13 Results***
2.16.840.1.113883.10.20.1.33	Social history observation	***3.7 Social History***
2.16.840.1.113883.10.20.1.34	Supply activity	***3.9 Medications***
2.16.840.1.113883.10.20.1.35	Vital signs organizer	***3.12 Vital Signs***
Supporting Templates (used within a clinical statement)		
2.16.840.1.113883.10.20.1.36	Advance directive reference	***3.2 Advance Directives***
2.16.840.1.113883.10.20.1.37	Advance directive status observation	***3.2 Advance Directives***
2.16.840.1.113883.10.20.1.38	Age observation	***3.6.2.4 Representation of age***

Template Identifier	Description	Reference
2.16.840.1.113883.10.20.1.39	Alert status observation	***3.8 Alerts***
2.16.840.1.113883.10.20.1.40	Comment	***4.3 Comments***
2.16.840.1.113883.10.20.1.41	Episode observation	***3.5.2.3 Episode observations***
2.16.840.1.113883.10.20.1.42	Family history cause of death observation	***3.6 Family History***
2.16.840.1.113883.10.20.1.43	Fulfillment instruction	***3.9.2.2 Medication related information***
2.16.840.1.113883.10.20.1.45	Location participation	***3.15.2.2 Encounter location***
2.16.840.1.113883.10.20.1.46	Medication series number observation	***3.9.2.2 Medication related information***
2.16.840.1.113883.10.20.1.47	Medication status observation	***3.9 Medications***
2.16.840.1.113883.10.20.1.48	Patient awareness	***3.5.2.4 Patient awareness of a problem***
2.16.840.1.113883.10.20.1.49	Patient instruction	***3.9.2.2 Medication related information***
2.16.840.1.113883.10.20.1.51	Problem healthstatus observation	***3.5 Problems***
2.16.840.1.113883.10.20.1.50	Problem status observation	***3.5 Problems***
2.16.840.1.113883.10.20.1.53	Product	***3.9.2.4 Representation of a product***
2.16.840.1.113883.10.20.1.52	Product instance	***3.14.2.2 Procedure related products***
2.16.840.1.113883.10.20.1.54	Reaction observation	***3.9.2.2 Medication related information***
2.16.840.1.113883.10.20.1.55	Severity observation	***3.9.2.2 Medication related information***
2.16.840.1.113883.10.20.1.56	Social history status observation	***3.7 Social History***
2.16.840.1.113883.10.20.1.57	Status observation	***5.1 "Type" and "Status" values***
2.16.840.1.113883.10.20.1.44	Status of functional status observation	***3.4 Functional Status***
2.16.840.1.113883.10.20.1.58	Verification of an advance directive observation	***3.2 Advance Directives***

7.3 Summary of CCD value sets

The following table summarizes the CCD value sets described above. Single code bindings are not included.

Table 20. Value set enumerations

valueSetOID (localValueSetName)	**code**	**displayName**	**codeSystem**	**Code System Name**
2.16.840.1.113883.1.11.20 (HL7 SDTC Value Set OID Root)				
2.16.840.1.113883.1.11.19832 (ActCoverageType)	Any subtype of ActCoverageType		2.16.840.1.113883.5.4	ActCode
2.16.840.1.113883.1.11.20.1 (AdvanceDirectiveStatusCode)	425392003	Current and Verified	2.16.840.1.113883.6.96	SNOMED CT
	425394002	Supported By Healthcare Will	2.16.840.1.113883.6.96	SNOMED CT
	425393008	Supported By Durable Power of Attorney for Healthcare	2.16.840.1.113883.6.96	SNOMED CT
	425396000	Verified With Family Only	2.16.840.1.113883.6.96	SNOMED CT
	310305009	Verified By Medical Record Only	2.16.840.1.113883.6.96	SNOMED CT
2.16.840.1.113883.1.11.20.2 (AdvanceDirectiveTypeCode)	304251008	Resuscitation	2.16.840.1.113883.6.96	SNOMED CT
	52765003	Intubation	2.16.840.1.113883.6.96	SNOMED CT
	225204009	IV Fluid and Support	2.16.840.1.113883.6.96	SNOMED CT

valueSetOID (localValueSetName)	code	displayName	codeSystem	Code System Name
	89666000	CPR	2.16.840.1.113883.6.96	SNOMED CT
	281789004	Antibiotics	2.16.840.1.113883.6.96	SNOMED CT
	78823007	Life Support	2.16.840.1.113883.6.96	SNOMED CT
	61420007	Tube Feedings	2.16.840.1.113883.6.96	SNOMED CT
	71388002	Other Directive	2.16.840.1.113883.6.96	SNOMED CT
2.16.840.1.113883.1.11.20.3 (AlertStatusCode)	55561003	Active	2.16.840.1.113883.6.96	SNOMED CT
	392521001	Prior History	2.16.840.1.113883.6.96	SNOMED CT
	73425007	No Longer Active	2.16.840.1.113883.6.96	SNOMED CT
2.16.840.1.113883.1.11.20.4 (AlertTypeCode)	106190000	Allergy	2.16.840.1.113883.6.96	SNOMED CT
	281647001	Adverse Reaction	2.16.840.1.113883.6.96	SNOMED CT
2.16.840.1.113883.1.11.13955 (EncounterCode)	Any subtype of ActEncounterCode		2.16.840.1.113883.5.4	ActCode
2.16.840.1.113883.1.11.20.21 (FamilyHistoryPersonCode)	Any subtype of 303071001 “Person in the family”		2.16.840.1.113883.6.96	SNOMED CT
2.16.840.1.113883.1.11.19579 (FamilyHistoryRelated SubjectCode)	Any subtype of FAMMEMB		2.16.840.1.113883.5.111	RoleCode
2.16.840.1.113883.1.11.20.6 (FunctionalStatusTypeCode)	282097004	Ambulatory Status	2.16.840.1.113883.6.96	SNOMED CT
	363871006	Mental Status	2.16.840.1.113883.6.96	SNOMED CT
	129025006	Activities of Daily Living	2.16.840.1.113883.6.96	SNOMED CT
	4683004	Home/Living Situation	2.16.840.1.113883.6.96	SNOMED CT
	284773001	Ability to Care for Self	2.16.840.1.113883.6.96	SNOMED CT
2.16.840.1.113883.1.11.20.7 (MedicationStatusCode)	55561003	Active	2.16.840.1.113883.6.96	SNOMED CT
	421139008	On Hold	2.16.840.1.113883.6.96	SNOMED CT
	392521001	Prior History	2.16.840.1.113883.6.96	SNOMED CT
	73425007	No Longer Active	2.16.840.1.113883.6.96	SNOMED CT
2.16.840.1.113883.1.11.20.8 (MedicationTypeCode)	373873005	Medication	2.16.840.1.113883.6.96	SNOMED CT
	354078009	IV Fluid	2.16.840.1.113883.6.96	SNOMED CT
	327838005	Parenteral Nutrition	2.16.840.1.113883.6.96	SNOMED CT
	108961000	Supplemental Nutrition	2.16.840.1.113883.6.96	SNOMED CT
	350326008	Immunization	2.16.840.1.113883.6.96	SNOMED CT
	425398004	Supplies	2.16.840.1.113883.6.96	SNOMED CT
	49062001	Device	2.16.840.1.113883.6.96	SNOMED CT
	40388003	Implantable Device	2.16.840.1.113883.6.96	SNOMED CT
	425399007	Durable Medical Equipment	2.16.840.1.113883.6.96	SNOMED CT
2.16.840.1.113883.1.11.20.9 (OrderRequestTypeCode)	71388002	Order	2.16.840.1.113883.6.96	SNOMED CT
	308335008	Encounter	2.16.840.1.113883.6.96	SNOMED CT
	71388002	Procedure	2.16.840.1.113883.6.96	SNOMED CT
	127777001	Service	2.16.840.1.113883.6.96	SNOMED CT
	260787004	Product	2.16.840.1.113883.6.96	SNOMED CT
	127785005	Immunization	2.16.840.1.113883.6.96	SNOMED CT
	416118004	Medication	2.16.840.1.113883.6.96	SNOMED CT
	386336002	Authorization	2.16.840.1.113883.6.96	SNOMED CT
	3457005	Referral	2.16.840.1.113883.6.96	SNOMED CT
	11429006	Consultation	2.16.840.1.113883.6.96	SNOMED CT
2.16.840.1.113883.1.11.20.10 (PlanOfCareStatusCode)	new	Ordered	2.16.840.1.113883.5.14	ActStatus
	new	Requested	2.16.840.1.113883.5.14	ActStatus
	active	Pending	2.16.840.1.113883.5.14	ActStatus
	active	In Process	2.16.840.1.113883.5.14	ActStatus
	held	On Hold	2.16.840.1.113883.5.14	ActStatus
	cancelled	Cancelled	2.16.840.1.113883.5.14	ActStatus

valueSetOID (localValueSetName)	code	displayName	codeSystem	Code System Name
	-any-	Repeat	2.16.840.1.113883.5.14	ActStatus
	Aborted	No Show	2.16.840.1.113883.5.14	ActStatus
2.16.840.1.113883.1.11.20.11 (PlanOfCareTypeCode)	223452003	Reminder	2.16.840.1.113883.6.96	SNOMED CT
	71388002	Order	2.16.840.1.113883.6.96	SNOMED CT
	416118004	Prescription	2.16.840.1.113883.6.96	SNOMED CT
	386336002	Request For Authorization	2.16.840.1.113883.6.96	SNOMED CT
	386336002	Authorization	2.16.840.1.113883.6.96	SNOMED CT
	3457005	Referral	2.16.840.1.113883.6.96	SNOMED CT
	11429006	Request For Consultation	2.16.840.1.113883.6.96	SNOMED CT
	391157003	Treatment Recommendation	2.16.840.1.113883.6.96	SNOMED CT
2.16.840.1.113883.1.11.19809 (PolicyOrProgramCoverageRoleType)	Any subtype of PolicyOrProgramCoverage RoleType		2.16.840.1.113883.5.111	RoleCode
2.16.840.1.113883.1.11.20.12 (ProblemHealthStatusCode)	81323004	Alive and well	2.16.840.1.113883.6.96	SNOMED CT
	313386006	In remission	2.16.840.1.113883.6.96	SNOMED CT
	162467007	Symptom free	2.16.840.1.113883.6.96	SNOMED CT
	161901003	Chronically ill	2.16.840.1.113883.6.96	SNOMED CT
	271593001	Severely ill	2.16.840.1.113883.6.96	SNOMED CT
	21134002	Disabled	2.16.840.1.113883.6.96	SNOMED CT
	161045001	Severely disabled	2.16.840.1.113883.6.96	SNOMED CT
	419099009	Deceased	2.16.840.1.113883.6.96	SNOMED CT
2.16.840.1.113883.1.11.20.13 (ProblemStatusCode)	55561003	Active	2.16.840.1.113883.6.96	SNOMED CT
	73425007	Inactive	2.16.840.1.113883.6.96	SNOMED CT
	90734009	Chronic	2.16.840.1.113883.6.96	SNOMED CT
	7087005	Intermittent	2.16.840.1.113883.6.96	SNOMED CT
	255227004	Recurrent	2.16.840.1.113883.6.96	SNOMED CT
	415684004	Rule out	2.16.840.1.113883.6.96	SNOMED CT
	410516002	Ruled out	2.16.840.1.113883.6.96	SNOMED CT
	413322009	Resolved	2.16.840.1.113883.6.96	SNOMED CT
2.16.840.1.113883.1.11.20.14 (ProblemTypeCode)	64572001	Condition	2.16.840.1.113883.6.96	SNOMED CT
	418799008	Symptom	2.16.840.1.113883.6.96	SNOMED CT
	404684003	Finding	2.16.840.1.113883.6.96	SNOMED CT
	409586006	Complaint	2.16.840.1.113883.6.96	SNOMED CT
	248536006	Functional limitation	2.16.840.1.113883.6.96	SNOMED CT
	55607006	Problem	2.16.840.1.113883.6.96	SNOMED CT
	282291009	Diagnosis	2.16.840.1.113883.6.96	SNOMED CT
2.16.840.1.113883.1.11.20.15 (ProcedureStatusCode)	cancelled	Cancelled	2.16.840.1.113883.5.14	ActStatus
	Held	On Hold	2.16.840.1.113883.5.14	ActStatus
	Active	In Progress	2.16.840.1.113883.5.14	ActStatus
	Aborted	Not Completed	2.16.840.1.113883.5.14	ActStatus
	completed	Completed	2.16.840.1.113883.5.14	ActStatus
2.16.840.1.113883.1.11.20.16 (ResultTypeCode)	252275004	Hematology	2.16.840.1.113883.6.96	SNOMED CT
	275711006	Chemistry	2.16.840.1.113883.6.96	SNOMED CT
	68793005	Serology	2.16.840.1.113883.6.96	SNOMED CT
	395124008	Virology	2.16.840.1.113883.6.96	SNOMED CT
	69200006	Toxicology	2.16.840.1.113883.6.96	SNOMED CT
	19851009	Microbiology	2.16.840.1.113883.6.96	SNOMED CT
	363679005	Imaging	2.16.840.1.113883.6.96	SNOMED CT
	363680008	X-ray	2.16.840.1.113883.6.96	SNOMED CT
	16310003	Ultrasound	2.16.840.1.113883.6.96	SNOMED CT
	77477000	CT	2.16.840.1.113883.6.96	SNOMED CT
	113091000	MRI	2.16.840.1.113883.6.96	SNOMED CT
	77343006	Angiography	2.16.840.1.113883.6.96	SNOMED CT
	40701008	Cardiac Echo	2.16.840.1.113883.6.96	SNOMED CT
	371572003	Nuclear Medicine	2.16.840.1.113883.6.96	SNOMED CT
	108257001	Pathology	2.16.840.1.113883.6.96	SNOMED CT
	71388002	Procedure	2.16.840.1.113883.6.96	SNOMED CT

valueSetOID (localValueSetName)	code	displayName	codeSystem	Code System Name
	46680005	Vital Sign	2.16.840.1.113883.6.96	SNOMED CT
2.16.840.1.113883.1.11.14581 (RouteOfAdministration)	Any subtype of RouteOfAdministration		2.16.840.1.113883.5.112	RouteOf Administration
2.16.840.1.113883.1.11.17660 (ServiceDeliveryLocationRoleType)	Any subtype of ServiceDeliveryLocation RoleType		2.16.840.1.113883.5.111	RoleCode
2.16.840.1.113883.1.11.20.17 (SocialHistoryStatusCode)	55561003	Active	2.16.840.1.113883.6.96	SNOMED CT
	392521001	Prior History	2.16.840.1.113883.6.96	SNOMED CT
	73425007	No Longer Active	2.16.840.1.113883.6.96	SNOMED CT
	261665006	Unknown	2.16.840.1.113883.6.96	SNOMED CT
2.16.840.1.113883.1.11.20.18 (SocialHistoryTypeCode)	125680007	Marital Status	2.16.840.1.113883.6.96	SNOMED CT
	160538000	Religion	2.16.840.1.113883.6.96	SNOMED CT
	364699009	Ethnicity	2.16.840.1.113883.6.96	SNOMED CT
	103579009	Race	2.16.840.1.113883.6.96	SNOMED CT
	61909002	Language	2.16.840.1.113883.6.96	SNOMED CT
	229819007	Smoking	2.16.840.1.113883.6.96	SNOMED CT
	256235009	Exercise	2.16.840.1.113883.6.96	SNOMED CT
	364393001	Diet	2.16.840.1.113883.6.96	SNOMED CT
	364703007	Employment	2.16.840.1.113883.6.96	SNOMED CT
	425400000	Toxic Exposure	2.16.840.1.113883.6.96	SNOMED CT
	160573003	ETOH Use	2.16.840.1.113883.6.96	SNOMED CT
	363908000	Drug Use	2.16.840.1.113883.6.96	SNOMED CT
	228272008	Other Social History	2.16.840.1.113883.6.96	SNOMED CT
2.16.840.1.113883.1.11.20.5 (StatusOfFunctionalStatus Code)	55561003	Active	2.16.840.1.113883.6.96	SNOMED CT
	90734009	Chronic	2.16.840.1.113883.6.96	SNOMED CT
	14803004	Temporary	2.16.840.1.113883.6.96	SNOMED CT
	370996005	Resolved	2.16.840.1.113883.6.96	SNOMED CT
2.16.840.1.113883.1.11.20.19 (TestStatusCode)	active	Pending	2.16.840.1.113883.5.14	ActStatus
	active	In Process	2.16.840.1.113883.5.14	ActStatus
	active	Preliminary Results	2.16.840.1.113883.5.14	ActStatus
	completed	Final Results	2.16.840.1.113883.5.14	ActStatus
	completed	Corrected Results	2.16.840.1.113883.5.14	ActStatus
2.16.840.1.113883.1.11.20.20 (TestTypeCode)	71388002	Observation	2.16.840.1.113883.6.96	SNOMED CT
	404684003	Result	2.16.840.1.113883.6.96	SNOMED CT

7.4 Extensions to CDA R2

Where the ASTM CCR defines important components for which there is no suitable mapping in CDA R2, extensions to CDA R2 have been developed. These extensions are described above in the context of the section where they are used. This section serves to summarize the extensions and provide implementation guidance.

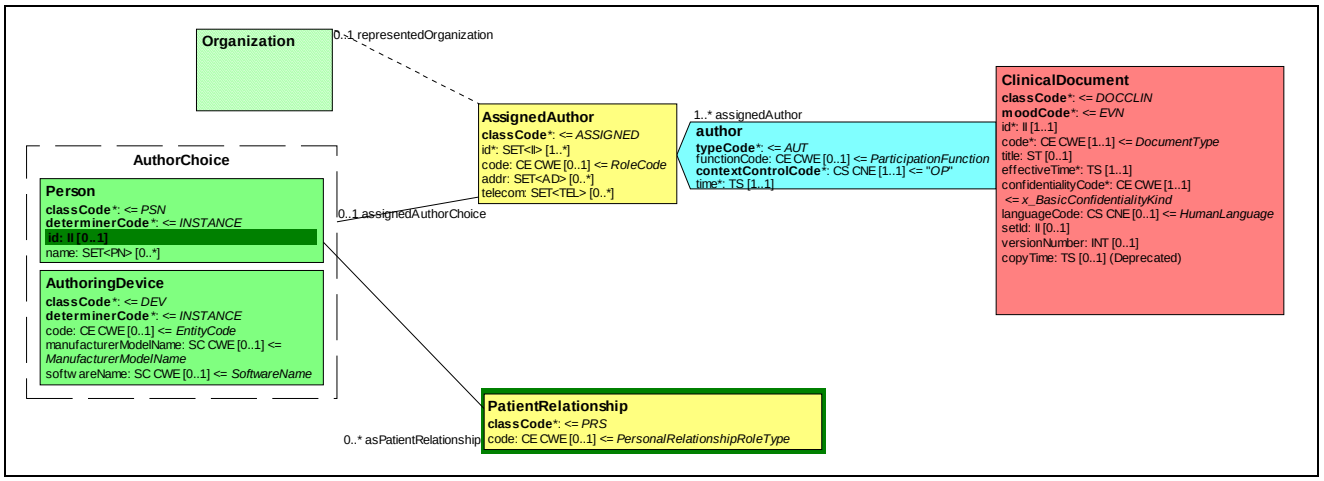
Extensions created for CCD include:

- AssignedPerson / id
- AssociatedPerson / id
- GuardianPerson / id
- InformationRecipient / id
- MaintainingPerson / id
- RelatedPerson / id
- Subject / id
- Subject / deceasedInd
- Subject / deceasedTime

- asPatientRelationship
- asPatientRelationship / @classCode
- asPatientRelationship / code

These extensions are illustrated in ***Figure 8 CDA R2 clinical statement model for family history*** and ***Figure 15 CDA R2 extensions***.

Figure 15. CDA R2 extensions



To resolve issues that need to be addressed by extension, the developers of this guide chose to approach extensions as follows:

- An extension is a collection of element or attribute declarations and rules for their application to the CDA Release 2.0.
- All extensions are optional. An extension may be used, but need not be under this guide.
- A single namespace for all extension elements or attributes that may be used by this guide will be defined.
- The namespace for extensions created by the HL7 Structured Documents Technical Committee shall be urn:hl7-org:sdtc.
- This namespace shall be used as the namespace for any extension elements or attributes that are defined by this implementation guide.
- Each extension element shall use the same HL7 vocabularies and data types used by CDA Release 2.0.
- Each extension element shall use the same conventions for order and naming as is used by the current HL7 tooling.
- An extension element shall appear in the XML where the expected RIM element of the same name would have appeared had that element not been otherwise constrained from appearing in the CDA XML schema.

7.4.1 Entity Identifiers

CDA Release 2.0 does not provide a mechanism to determine when two participants in different roles are in fact the same entity (i.e., an entity can be a person, organization or device). A CDA Document identifies each participant through the application of a role identifier. This identifier can be used to trace the participation of an entity in a given role, but cannot necessarily be used to determine that two entities are the same. While more role identities could be provided whose intended use is to unify the entities, this is better modeled through the use of an entity identifier. Therefore, to facilitate this capability, this guide

defines an extension to CDA Release 2.0 that allows the person or organization playing the role to be uniquely identified, by the inclusion of an identifier on the entity.

An entity identifier opaquely represents the entity referenced in a clinical document. It has no required relationship between the entity and the role that they play in that document. Use of an entity identifier therefore gives CDA producing and consuming applications a mechanism to unite the various entities represented in the CDA document, and thereby expose relationships that would otherwise be obscured when entities cannot be recognized as being identical. When two participants have the same entity identifier, they can be assumed to be the same entity.

In the CDA Release 2.0 schema, organizations and the patient already carry an identifier on the entity, and devices can have only one form of participation (as assignedAuthoringDevice). Therefore, only those elements describing participant persons that are not the patient need to support an element to identify the person. To state it simply, each person that is represented by the CDA document that does not already have an id element may now generate one if necessary using this extension. The identifier MAY be provided in an id element from the urn:hl7-org:sdtc namespace. This element SHALL be an instance identifier (II) and SHALL appear just before name element of any person described by any role in the CDA Release 2.0 schema.

A document that identifies one person in this fashion SHOULD identify all persons in this way, otherwise there will be unidentified persons described by the document, and the utility of this extension will be negated.

Because the patient already supports an identifier element according to the CDA schema, an additional id element is not necessary and SHOULD NOT be provided in the patient element. However, to represent the patient in any other role, the identifier used in the corresponding id element SHOULD be the same as the identifier used to represent the patient.

CONF-537: An **assignedPerson**, **informationRecipient**, **maintainingPerson**, **guardianPerson**, **relatedPerson**, **associatedPerson** or **subject MAY** include an **id** element from the **urn:hl7-org:sdtc** namespace to uniquely identify the person.

CONF-538: The **id** element **SHALL** use the instance identifier (II) data type.

CONF-539: The **id** element **SHALL** appear just before the **name** element of the entity.

7.4.2 Deceased Indicator and Time

Observations about members of the patient's family are recorded in the Family history section. The subject of the observation is the family member. In order to record information about whether this family member is deceased and when, the deceasedInd and deceacedTime extensions have been defined.

CONF-540: A **subject MAY** include a **deceasedInd** element from the **urn:hl7-org:sdtc** namespace to indicate whether the person is deceased.

CONF-541: The **deceasedInd** element **SHALL** be of the Boolean (BL) data type.

CONF-542: The **deceasedInd** element **SHALL** appear immediately following the **birthTime** element.

CONF-543: A **subject MAY** include a **deceasedTime** element from the **urn:hl7-org:sdtc** namespace to indicate when the person died.

CONF-544: The **deceasedTime** element **SHALL** be of the Time Stamp (TS) data type.

CONF-545: The **deceasedTime** element **SHALL** appear immediately following the **deceasedInd** element.

7.4.3 Patient Relationship

CDA Release 2.0 does not provide a mechanism to relate participants other than an informant to the patient. Often useful information, such as the relationship between the patient and the policy subscriber, or the patient and the author, cannot be easily determined by traversal of the CDA document. To facilitate this capability, this guide defines an extension to CDA Release 2.0 which allows the relationship to the patient to be expressed for any participant.

Each participant other than an informant may have zero or more relationship roles with the patient. Each of these roles can be expressed by an asPatientRelationship element which further describes the type of role in a code element. The informant participant already supports specification of the relationship between the informant and the patient via the RelatedEntity class, and therefore should not include this extension.

Figure 16. Example use of the sdtc:asPatientRelationship extension

```
<ClinicalDocument xmlns='urn:hl7-org:v3' xmlns:sdtc='urn:hl7-org:sdtc'>
  ...
  <author>
    <time value='20050329224411+0500'/>
    <assignedAuthor>
      ...
      <assignedPerson>
        <sdtc:id extension='12345' root='2.16.840.1.113883.3.933'/>
        <name>
          <prefix>Mrs.</prefix>
          <given>Abigail</given>
          <family>Ruth</family>
        </name>
        <sdtc:asPatientRelationship classCode='PRS'>
          <code code='65656005' codeSystem='2.16.840.1.113883.6.96'
            displayName='Biological mother'/>
        </sdtc:asPatientRelationship>
      </assignedPerson>
    </assignedAuthor>
  </author>
  ...
</ClinicalDocument>
```

CONF-546: **sdtc:asPatientRelationship SHALL** contain exactly one **sdtc:asPatientRelationship / @classCode**, valued with "PRS".

CONF-547: **sdtc:asPatientRelationship SHALL** contain exactly one **sdtc:asPatientRelationship / code**, of datatype CE.

CONF-548: The value for "**sdtc:asPatientRelationship / code**" **SHOULD** be selected from ValueSet 2.16.840.1.113883.1.11.19579 FamilyHistoryRelatedSubjectCode **DYNAMIC** or 2.16.840.1.113883.1.11.20.21 FamilyHistoryPersonCode **DYNAMIC**.

CONF-549: An informant **SHALL NOT** contain any **relatedPerson / sdtc:asPatientRelationship** elements.

<endOfDocument/>