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HL7 Implementation Guide for CDA Release 2: History and Physical (H&P) Notes

(U.S. Realm)

Draft Standard for Trial Use

Release 1

Levels 1, 2, and 3

A CDA Implementation guide for History and Physical Notes

July 16, 2008

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Revision History

Rev	Date	By Whom	Changes	Notes
2.0	4 June 2007	RM	Deleted the references to "Payers" throughout the document.	
2.0	15 July 2007	RM, LA	Review	Review of revisions, edit for consistency.
2.0	24 July 2007	RM, LA	Insert section on use of Templates; change DSTU template numbering.	Template within body of document changed from first ballot so we can use Levels 1, 2, and 3 to denote levels of compliance.
2.0	30 July 2007	LA	Review changes	
2.0	3 August 2007	LA	Discontinued use of italics for "explanatory text"; added template IDs for levels;	
2.0	6 August 2007	RG, LA	New template ID for ROS; final changes	Cardinality conflict w/PCC
2.0	January 2008	AALLC	Ballot changes and prep for publication. Insert sections on vocabulary conformance under DSTU conventions and exceptional values under Appendix A — Validation	
2.0	March 2008	GG, BM	QA for conformance numbering add of LOINC codes and prep for schema dvp., link questions answered,	
1.0	16 July 2008	SDWG	update for publication	

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1 INTRODUCTION

1.1 Purpose

The purpose of this document is to describe constraints on the CDA Header and Body for History and Physical (H&P) Notes. An H&P Note is a two-part medical report that documents the current and past conditions of the patient. It contains essential information that helps determine an individual's health status. The information forms the basis of most treatment plans.

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

The second half of the report contains information obtained by physically examining the patient and gathering diagnostic information in the form of laboratory tests, imaging, or other diagnostic procedures. The report ends with the clinician's assessment of the patient's situation and the intended plan to address those issues. A History and Physical Examination is required upon hospital admission as well as before operative procedures. An initial evaluation in an ambulatory setting is often documented in the form of an H&P Note.

1.2 Audience

The audience for this document includes software developers and consultants responsible for implementation of U.S. realm Electronic Health Record (EHR) systems, Electronic Medical Record (EMR) systems, Personal Health Record (PHR) systems, dictation/transcription systems, document management applications, and local, regional, and national health information exchange networks who wish to create and/or process CDA documents created according to this specification.

1.3 Approach

The approach taken in the development of this specification was to review existing draft and final specifications or Implementation Guides for similar artifacts in the U.S., specifically:

- ASTM's Standard Specifications for Healthcare Document Formats (E2184.02) (Headings and subheadings used in the health care industry and associated with specific report types)
- ASTM/HL7 Continuity of Care Document (CCD)
- Clinical LOINC® document and section codes
- HL7 ASIG CDA R2 Attachment for Clinical Notes
- HL7 Care Record Summary (CRS)
- IHE profiles, including the content profiles within Patient Care Coordination

- Sample CDA documents developed for local provider institutions (Mayo Clinic, University of Pittsburgh Medical Center, New York Presbyterian, and others)
- Non-CDA sample documents supplied by participating providers and vendors

A sample H&P Note was provided by the Military Health System (MHS) and used as a test against the design of this DSTU. It is provided as an example instance in a separate XML file.

In addition, M*Modal provided statistical analysis of approximately 15,000 sample reports and AHIMA, AHDI, and participating providers contributed extensive subject matter expertise. The design was matched against operational templates from transcription vendors and reviewed with the HL7 Structured Documents Technical Committee. While current divergent industry practices cannot be perfectly reflected in any consensus model, this design is optimized for widespread conformance and adoption with minimal disruption to current practice and workflow.

1.4 Use of Templates

Templates are collections of constraints that specify and validate agreed-to requirements for exchange. Collecting individual constraints and assigning a unique template identifier to the collection establishes a shorthand mechanism for the instance creator to assert conformance to those constraints. The template identifier itself carries no semantics. Validation errors against a template must not be construed as anything other than failure to meet the exact requirements of the template, and absence of a template identifier need not be construed as failure to meet the constraints required by the template.

1.4.1 Originator Responsibilities

An originator shall apply a templateId in order to assert conformance with a particular template (e.g., an originator must include the CCD templateId to assert that an instance is a CCD document).

An originator does not need to apply a templateId for every template that an object in an instance document conforms to (e.g., an originator does not have to include the Medications section templateId in a CDA R2 operative report, even though the medication representation may conform to the template).

1.4.2 Recipient Responsibilities

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

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

A recipient shall not report a conformance error about a failure to conform to a particular template on classes that do not claim conformance to that template and that are not required to be conformant by other templates (e.g., substanceAdministration acts within the CCD Medications section that do not have a templateId need not conform to the CCD template for medication clinical statements. However, within a CCD Payers section, the Act representing the patient coverage is only allowed, and is

further required, to have components that meet the requirements of the policy act template. Therefore, a recipient may indicate that those acts present inside the coverage act that do **NOT** meet the requirements of the policy act template are not allowed).

1.5 Conventions Used in This DSTU

This DSTU is a conformance profile, as described in the Refinement and Localization section of the HL7 Version 3 (CDA/V3) standards. The base standard for this DSTU is the HL7 Clinical Document Architecture, Release 2.0 (CDA R2). As defined in that document, this DSTU is both an annotation profile and a localization profile. Every aspect of the CDA R2, therefore, may not be described in this Guide.

1.5.1 Explanatory Statements

As an annotation profile, portions of this DSTU summarize or explain the base standard; therefore, not all requirements stated here are original to the DSTU. Some, like the requirement for typeId, originate in the base specification. Those requirements that do not add further constraints to the base standard and which can be validated through CDA.xsd do not have corresponding conformance statements. (See, for example, Section 2.1.10 ClinicalDocument/confidentialityCode.

1.5.2 Conformance Requirements

Conformance requirements for this DSTU are of two types: those that are collected within a published template of CDA/V3 conformance statements and those that are not associated with a published template.

- Where not associated with a published template, they are numbered sequentially and listed within the body of the DSTU as follows:

CONF-HP-1: This is an example conformance requirement original to this DSTU.

- Where conformance requirements from another DSTU or Implementation Guide are associated with a template, they are included through assertion of that template Identifier and listed in two ways:
  - In the body of the DSTU, they are listed as follows:

CONF-HP-66: All constraints from this section are from the CCD Medications section. See Appendix B — Externally Defined Constraints for CCD conformance requirements. This section **SHALL** include the CCD template identifier for the medications section (2.16.840.1.113883.10.20.1.8).

  - In Appendix B, they are listed using the original numbering sequence from the Source Guide:

    Medications (Template ID: 2.16.840.1.113883.10.20.1.8)

    CCD-CONF-299: CCD **SHOULD** contain exactly one and **SHALL NOT** contain…

Note: Every effort has been made to ensure consistency between this specification and the referenced specifications CDA and CCD. In case of a discrepancy, the original specification takes precedence.

1.5.3 Vocabulary Conformance

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 a value set. A simplified constraint is used when binding is to a single code.

- Syntax for vocabulary binding to DYNAMIC or STATIC value sets is as follows:

  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 2.16.840.1.113883.1.11.10870 DocumentType **DYNAMIC**.

CONF-ex6: The value for "**ClinicalDocument / code**" **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.10870 DocumentType **STATIC** 20061017.

- Syntax for vocabulary binding to a single code is as follows:

  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**.

1.5.4 XPath Notation

Instead of the traditional dotted notation used by HL7 to represent RIM classes, this DSTU uses XPath notation in conformance statements and elsewhere to identify the XML elements and attributes within the CDA document instance to which various constraints are applied. The implicit context of these expressions is the root of the document. The purpose of using this notation is to provide a mechanism that will be familiar to developers for identifying parts of an XML document.

1.5.5 Keywords

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

1.5.6 XML Samples

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

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

Within the narrative, XML element and attribute names in the text will appear in this font. Literal attribute values will appear in *this* font.

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

1.5.7 Content of the Publication Package

The publication package contains the following files:

Filename	Description
cda4cdt_HandP.pdf and cda4cdt_HandP.doc	This Guide
HandP.sample.xml	The sample CDA document
CDA.xsl	A stylesheet for displaying the content of the sample document in HTML

Table 1: Contents of the Publicaiton Package

A Schematron schema for this document will be created and posted on the HL7 wiki. The URL for the project wiki page is listed below:

http://wiki.hl7.org/index.php?title=Structured_Documents_TC

The user name is "wiki" and the password is "wikiwiki."

1.5.8 Sample XML

A sample document is provided that conforms to the Level 1, Level 2, and Level 3 constraints of this DSTU (see Section 1.6.1 Levels of Constraint). This sample document is an actual sample of a patient's H&P Note with identifying information changed for privacy. It was provided by a project participant and used as a test of the DSTU design. Because it is drawn from actual practice rather than composed to illustrate the DSTU, it covers all requirements and some of the options described here. It is the source of some, but not all, of the examples provided in this DSTU.

Throughout this Guide, the sample conforms to Level 1 and 2 requirements; the Medications and Social History sections contain CDA entries and conform to Level 3 (CCD-derived) requirements.

1.6 Scope

This specification defines additional constraints on the CDA Header and Body used in a History and Physical document in the U.S. realm, and provides examples of conforming fragments in the body of the document and an example of a conforming XML instance.

CDA provides a mechanism to reference a template, Implementation Guide, or DSTU that has been assigned a unique identifier. The following example shows how to formally assert the use of this DSTU. The templateID root has been assigned by the HL7 Structured Document Committee. The specification of workflows, messages, or procedures used to negotiate the transfer of care or referral is outside the scope of this specification.

```
<ClinicalDocument xmlns='urn:hl7-org:v3'>
  <typeId extension='POCD_HD000040' root='2.16.840.1.113883.1.3'/>
  <templateId root='2.16.840.1.113883.10.20.2'/> <!-- conforms to the DSTU -->
  <id extension='999021' root='2.16.840.1.113883.19'/>
    ...
</ClinicalDocument>
```

Figure 1: Use of the templateId element to indicate use of this DSTU

1.6.1 Levels of Constraint

Within this DSTU, the required and optional clinical content within the body is identified. While the clinical content requirements are invariant across all conforming instances, there may be extensive variation to the degree in which the content meets conformance requirements for machine interpretation.

This DSTU specifies three levels of conformance requirements:

- Level 1 requirements specify constraints upon the CDA header and the content of the document.
- Level 2 requirements specify constraints at the section level of the structuredBody of the ClinicalDocument element of the CDA document.
- Level 3 requirements specify constraints at the entry level within a section.

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

Conformance to the DSTU with no level specified makes no explicit assertion about the actual level of encoding of a given document instance. Conformance to the DSTU at Level 1 asserts header element compliance. Conformance to the DSTU with no level specified or at Level 1 allows use of a non-XML body or an XML body that may not conform to the coded section or entry templates defined herein. Likewise, conformance to the DSTU at Level 2 does not require conformance to entry-level templates, but does assert conformance to header- and section-level templates. *In all cases, required clinical content must be present.* For example, a CDA H&P Note carrying the templateId that asserts conformance with Level 1 may use a PDF or HTML format for the body of the document.

Note: Within a non-XML file or within an XML file of any level at any level of constraint, the clinical content required by this DSTU (History of Present Illness, et cetera) must be present.

If coded within CDA entries (Level 3), conformance can be tested against the conformance statements in the DSTU. Clinical information within the narrative block cannot be verified by software. At this time, all Level 3 requirements are drawn directly from the HL7 Implementation Guide: CDA Release 2 – Continuity of Care Document (CCD) (See Section 5 REFERENCES). Future work may add Level 3 constraints beyond those specified for CCD.

TemplateIds that indicate conformance to Levels 1, 2, or 3 are described in Section 2.1.2 Levels of Conformance.

1.6.2 Future Work

Future work includes the definition of increasingly refined (granular) machine-verifiable processing structures, including mapping all requirements for processing the components of the Evaluation and Management service level and harmonization with DEEDS (Data Elements for Emergency Department Systems).

This work will be performed in conjunction with other HL7 technical committees and in cooperation with professional societies and other Standards Development Organizations (SDO).There are many parallel efforts to create CDA Implementation Guides (IGs) and standards based on CDA. Future work will address libraries of templates, including those defined and reused here, and refinement of the document type hierarchy.

Future editions of this DSTU may constrain the History and Physical according to clinical setting and/or specialty. Additional work may harmonize this specification with History and Physical implementations outside the U.S.

Development of closely related specifications for the Consultation Note, Discharge Summary, and others may lead to consolidation of requirements into a single publication providing guidance across a range of document types.

2 CDA HEADER – GENERAL CONSTRAINTS

This section describes constraints that apply to the H&P Note and to other types of CDA documents defined for general exchange. The template defined here should be reused wherever these general header constraints are applied.

Note also that elements defined here may be further constrained within this or any other DSTU or Implementation Guide. For example, this section constrains the document type code to the LOINC® document type vocabulary. In Section 3 CDA Header.– H&P Note-specific Constraints, the document type code is further constrained, restricting the LOINC® codes that are valid for History and Physical documents.

2.1 Constraints on Header Elements

CONF-HP-1: A document conforming to the general header constraints in this DSTU **SHALL** indicate so by including the following template id in the header of the document or by including a template id in the header for a template that requires use of the general header constraint template: <templateId root="2.16.840.1.113883.10.20.3"/>

```
<ClinicalDocument xmlns='urn:hl7-org:v3'>
  <typeId extension='POCD_HD000040' root='2.16.840.1.113883.1.3'/>
    <templateId root='2.16.840.1.113883.10.20.2'/> <!-- indicates conformance with the DSTU -->
   <!-- templateId root='2.16.840.1.113883.10.20.3'/ -->
        <!-- indicates conformance with CDA4CDT general header constraints;
          not required here because the DSTU asserts usage of the general header constraints -->

  <id extension='999021' root='2.16.840.1.113883.19'/>
  <code  code='34117-2' codeSystem='2.16.840.1.113883.6.1'
      codeSystemName='LOINC' displayName=HISTORY AND PHYSICAL NOTE'/>
  <title>Good Health History &amp;amp; Physical</title>
  <effectiveTime value='20050329224411+0500'/>
  <confidentialityCode code='N' codeSystem='2.16.840.1.113883.5.25'/>
  <languageCode code='en-US'/>
  <setId extension='999021' root='2.16.840.1.113883.19'/>
  <versionNumber value='1'/>
    ...
</ClinicalDocument>
```

Figure 2: ClinicalDocument/general header constraints templateId example

2.1.1 ClinicalDocument

The namespace for CDA R2 is *urn:hl7-org:v3*. The appropriate namespace must be used in the XML instance of the Clinical Document. In the examples in this specification, all elements are shown unprefixed, assuming that the default namespace

is declared to be *urn:hl7-org:v3*. This DSTU does not require use of any specific namespace prefix. Instances should not include the xsi:schemaLocation[1] element.

CONF-HP-2: The root of a History and Physical **SHALL** be a ClinicalDocument element from the *urn:hl7-org:v3* namespace.

2.1.2 Levels of Conformance

CONF-HP-3: To indicate conformance to Level 1 (which also asserts compliance with all general or non-level-specific constraints), ClinicalDocument/templateId elements **MAY** be present with the value shown below:

```
<templateId root='2.16.840.1.113883.10.20.10'/> <!-- conforms to Level 1 guidance -->
```

Figure 3: ClinicalDocument/templateId example conforming to Level 1

CONF-HP-4: To indicate conformance to Level 2 features (which also asserts compliance with Level 1 requirements and asserts the presence of section codes), ClinicalDocument/templateId elements **MAY** be present with the value shown below:

```
<templateId root='2.16.840.1.113883.10.20.20'/> <!-- conforms to Level 2 guidance -->
```

Figure 4: ClinicalDocument/templateId example conforming to Level 2

CONF-HP-5: To indicate conformance to Level 3 features (which also asserts compliance with Level 2 requirements and the use of CDA entries in some sections), ClinicalDocument/templateId elements **MAY** be present with the value shown below:

```
<templateId root='2.16.840.1.113883.10.20.30'/> <!-- conforms to Level 3 guidance -->
```

Figure 5: ClinicalDocument/templateId example conforming to Level 3

2.1.3 Name, Address, and Telephone Numbers

To support communication between the receiver of the document and the patient or any other person or organization mentioned within it, the elements representing them will be named.

CONF-HP-6: All patient, guardianPerson, assignedPerson, maintainingPerson, relatedPerson, intendedRecipient/informationRecipient, associatedPerson, and relatedSubject/subject elements **SHALL** have a name.

CONF-HP-7: All patientRole, assignedAuthor, assignedEntity[not(parent::dataEnterer)] and associatedEntity elements **SHALL** have an addr and telecom element.

CONF-HP-8: All guardian, dataEnterer/assignedEntity, relatedEntity, intendedRecipient, relatedSubject and participantRole elements **SHOULD** have an addr and telecom element.

---

[1] The xsi:schemaLocation element is not recommended by the XML ITS because of security risks. Receivers who choose to perform validation should use a locally cached schema.

CONF-HP-9: All guardianOrganization, providerOrganization, wholeOrganization, representedOrganization, representedCustodianOrganization, receivedOrganization, scopingOrganization and serviceProviderOrganization elements **SHALL** have name, addr and telecom elements.

When name, address, or telecom information is unknown and where these elements are required to be present, as with CDA conformance if the information is unknown, these elements will be represented using an appropriate value for the nullFlavor attribute on the element. Legal values according to this specification come from the HL7 NullFlavor vocabulary.

```
<assignedEntity>
  <id extension='3' root='2.16.840.1.113883.19'/>
  <addr nullFlavor='UNK'/>
  <telecom nullFlavor='ASKU' use='WP'/>
  <assignedPerson>
    <name nullFlavor='NAV'/>
  </assignedPerson>
</assignedEntity>
```

Figure 6: Various Uses of nullFlavor

Events occurring at a single point in time that are represented in the Clinical Document header will in general be precise to the day. These point-in-time events are the time of creation of the document; the starting time of a participation by an author, data enterer, authenticator, or legal authenticator; or the starting and ending time of an encounter.

CONF-HP-10: Times or time intervals found in the ClinicalDocument/effectiveTime, author/time, dataEnterer/time, legalAuthenticator/time, authenticator/time and encompassingEncounter/effectiveTime elements **SHALL** be precise to the day, **SHALL** include a time zone if more precise than to the day[2], and **SHOULD** be precise to the second.

CONF-HP-11: Times or time intervals found in the asOrganizationPartOf/effectiveTime, asMaintainedEntity/effectiveTime, relatedEntity/effectiveTime, serviceEvent/effectiveTime, ClinicalDocument/participant/time, serviceEvent/performer/time and encounterParticipant/time **SHALL** be precise at least to the year, **SHOULD** be precise to the day, and **MAY** omit time zone.

In CDA-conformant documents, all telephone numbers are to be encoded using a restricted form of the tel: URL [scheme as described below.

The telecom element is used to provide a contact telephone number for the various participants that requireit. The value attribute ofthis elements is a URL that specifies the telephone number, as indicated by the TEL data type

Within the specification, all telephone numbers are to be encoded using the grammar of Figure 7: Restricted URL grammar for telephone communications, which is a restriction

[2] The XML ITS precludes the use of time zone unless the precision of the timestamp is more than to the day.

on the TEL data type and RFC 2806[3]. It simplifies interchange between applications as it removes optional URL components found in RFC 2806 that applications typically do not know how to process, such as ISDN sub-address, phone context, or other dialing parameters.

A telephone number used for voice calls begins with the URL scheme *tel:*. If the number is a global phone number, it starts with a plus (+) sign. The remaining number is made up of the dialing digits and an optional extension and may also contain visual separators.

```
telephone-url  = telephone-scheme ':' telephone-subscriber
telephone-scheme  = 'tel'
telephone-subscriber = global-phone-number  [ extension ]
global-phone-number= '+' phone-number
phone-number   = digits
digits = phonedigit | digits phonedigit
phonedigit = DIGIT | visual-separator
extension = ';ext=' digits
visual-separator= '-' | '.' | '(' | ')'
```

Figure 7: Restricted URL grammar for telephone communications

CONF-HP-12: Telephone numbers **SHALL** match the regular expression pattern *tel:\+?[-0-9().]+*

CONF-HP-13: At least one dialing digit **SHALL** be present in the phone number after visual separators are removed.

There is no way to distinguish between an unknown phone number and an unknown e-mail or other telecommunications address. Therefore, the following convention will be used: Any telecom element that uses a flavor of null (has a nullFlavor attribute) is assumed to be a telephone number, which is the only required telecommunications address element within this DSTU.

CONF-HP-14: If the telephone number is unknown it **SHALL** be represented using the appropriate flavor of null.

```
<telecom nullFlavor='UNK'>
```

Figure 8: Unknown telephone number example

2.1.4 ClinicalDocument/realmCode

This value identifies the realm[4].

CONF-HP-15: The ClinicalDocument/realmCode element **SHALL** be present. It **SHALL** use the fixed value *US*.

---

[3] Note that RFC 3966 obsoletes RFC 2806, but is backwards-compatible. The restricted grammar is compatible with both RFC 3966 and RFC 2806 by virtue of Section 2.5.11 of RFC 2806, which provides for additional parameters, e.g., ';ext=', to be added as future extensions.

[4] This Implementation Guide is, by definition, for documents in the U.S. realm. A future guide may generalize this one, and define which constraints are imposed by virtue of the realm.

```
<realmCode code='US'/>
```

Figure 9: ClinicalDocument/realmCode example

2.1.5 ClinicalDocument/typeId

The clinical document type ID identifies the constraints imposed by CDA R2 on the content, essentially acting as a version identifier. The @root and @extension values of this element are specified as shown below.

```
<typeId extension='POCD_HD000040' root='2.16.840.1.113883.1.3'/>
```

Figure 10: ClinicalDocument/typeId example

CONF-HP-16: The extension attribute of the typeId element **SHALL** be *POCD_HD000040*.

2.1.6 ClinicalDocument/id

The ClinicalDocument/id element is an instance identifier data type (see HL7 Version 3 Abstract Data in Section 5 REFERENCES). The root attribute is a UUID or OID. The root uniquely identifies the scope of the extension. The root and extension attributes uniquely identify the document.

OIDs are limited by this specification to no more than 64 characters in length for compatibility with other standards and Implementation Guides.

CONF-HP-17: The ClinicalDocument/id element **SHALL** be present. The *ClinicalDocument/id/@root* attribute ***SHALL*** be a syntactically correct UUID or OID.

CONF-HP-18: UUIDs ***SHALL*** be represented in the form XXXXXXXX-XXXX-XXXX-XXXX-XXXXXXXXXXXX, where each X is a character from the set [A-Fa-f0-9].

CONF-HP-19: OIDs ***SHALL*** be represented in dotted decimal notation, where each decimal number is either 0, or starts with a nonzero digit. More formally, an OID ***SHALL*** be in the form ([0-2])(.([1-9][0-9]*|0))+.

CONF-HP-20: OIDs **SHALL** be no more than 64 characters in length.

```
<id extension='999021'  root='2.16.840.1.113883.19'/>
```

Figure 11: ClinicalDocument/id example

Organizations that wish to use OIDs should properly register their OID root and ensure uniqueness of the OID roots used in identifiers. A large number of mechanisms exist for obtaining OID roots for free or for a reasonable fee. HL7 maintains an OID registry page from which organizations may request an OID root under the HL7 OID root. This page can be accessed at: http://www.hl7.org/oid.

Another useful resource lists the many ways to obtain a registered OID Root for free or a small fee anywhere in the world and is located at:

http://www.dclunie.com/medical-image-faq/html/part8.html#UIDRegistration.

The manner in which the OID root is obtained is not constrained by this DSTU.

2.1.7 ClinicalDocument/code

CONF-HP-21: The ClinicalDocument/code element **SHALL** be present and specifies the type of the clinical document.

2.1.8 ClinicalDocument/title

CONF-HP-22: The title element **SHALL** be present and specifies the local name used for the document.

```
<title>Good Health History &amp;amp; Physical</title>
```

Figure 12: ClinicalDocument/title example

Note that the title does not need to be the same as the display name provided with the document type code. For example, the display name provided by LOINC® as an aid in debugging may be "HISTORY **AND** PHYSICAL." The title can be localized, as appropriate (see the figure above).

2.1.9 ClinicalDocument/effectiveTime

CONF-HP-23: The ClinicalDocument/effectiveTime element **SHALL** be present and specifies the creation time of the document All History and Physical documents authored by direct input to a computer system should record an effectiveTime that is precise to the second. When authored in other ways, for example, by filling out a paper form that is then transferred into an EHR system, the precision of effectiveTime may be less than to the second.

```
<effectiveTime value='20050303171504+0500'/>
```

Figure 13: CinicalDocument/effectiveTime example

2.1.10 ClinicalDocument/confidentialityCode

CDA R2 requires that the ClinicalDocument/confidentialityCode be present. It specifies the confidentiality assigned to the document. This DSTU provides no further guidance on documents with respect to the vocabulary used for confidentialityCode, nor treatment or implementation of confidentiality. A CDA R2-conforming example is shown below:

```
<confidentialityCode code='N' codeSystem='2.16.840.1.113883.5.25'/>
```

Figure 14: CinicalDocument/confidentialityCode example

2.1.11 ClinicalDocument/languageCode

The ClinicalDocument/languageCode specifies the language of the History and Physical. History and Physicals must be readable by medical practitioners, caregivers, and patients.

CONF-HP-24: ClinicalDocument / languageCode **SHALL** be present.

CONF-HP-25: ClinicalDocument / languageCode **SHALL** be in the form *nn*, or *nn-CC*.

CONF-HP-26: The *nn* portion of ClinicalDocument / languageCode **SHALL** be a legal ISO-639-1 language code in lowercase.

CONF-HP-27: The *CC* portion ClinicalDocument / languageCode, if present, **SHALL** be an ISO-3166 country code in uppercase.

```
<languageCode code='en'/>
```

Figure 15: ClinicalDocument/languageCode example with language only

```
<languageCode code='en-US'/>
```

Figure 16: ClinicalDocument/languageCode example with language and country

2.1.12 ClinicalDocument/setId and ClinicalDocument/versionNumber

The ClinicalDocument/setId element uses the instance identifier (II) data type. The root attribute is a UUID or OID that uniquely identifies the scope of the identifier, and the extension attribute is a value that is unique within the scope of the root for the set of versions of the document. See Document Identification, Revisions, and Addenda in Section 4.2.3.1 of the CDA Specification for some examples showing the use of the setId element.

CONF-HP-28: Both ClinicalDocument/setId and ClinicalDocument/versionNumber be present or both **SHALL** be absent.

CONF-HP-29: The @extension and/or @root of ClinicalDocument/setId and ClinicalDocument/id **SHALL** be different when both are present.

```
<setId extension='999021'  root='2.16.840.1.113883.19'/>
<versionNumber value='1'/>
```

Figure 17: ClinicalDocument/setId and ClinicalDocument/versionNumber example

2.1.13 ClinicalDocument/copyTime

The ClinicalDocument/copyTime element has been deprecated in CDA R2.

CONF-HP-30: A ClinicalDocument/copyTime element **SHALL NOT** be present.

2.1.14 Participants

This section describes the general constraints placed upon CDA participants.

The HL7 CDA Release 2.0 Specification, Section 4.2.2.13 describes various participant scenarios where a single person can participate in several roles. In these cases, the person needs to be listed for each role.

Note that Authentication requires that the participant be able to verify the accuracy of the document and Legal Authentication requires that the participant has the privilege to legally authenticate the document. Patients or other persons,such as a guardian or parent may not have these privileges, depending upon local policy.

The participants are listed below in the order in which they appear in CDA R2.

2.1.14.1 recordTarget

The recordTarget element must be present. The record target element records the patient or patients whose health information is described by the clinical document.

CONF-HP-31: At least one recordTarget/patientRole element **SHALL** be present.

CONF-HP-32: A patient/birthTime element **SHALL** be present. The patient/birthTime element SHALL be precise at least to the year, and **SHOULD** be precise at least to the day, and **MAY** omit time zone. If unknown, it **SHALL** be represented using a flavor of null.

CONF-HP-33: A patient/administrativeGenderCode element **SHALL** be present. If unknown, it **SHALL** be represented using a flavor of null. Values for administrativeGenderCode **SHOULD** be drawn from the HL7 AdministrativeGender vocabulary.

CONF-HP-34: The maritalStatusCode, religiousAffiliationCode, raceCode and ethnicGroupCode **MAY** be present. If maritalStatusCode, religiousAffiliationCode, raceCode and ethnicGroupCode elements are present, they **SHOULD** be encoded using the appropriate HL7 vocabularies.

CONF-HP-35: The guardian element **SHOULD** be present when the patient is a minor child.

CONF-HP-36: The providerOrganization element **MAY** be present.

```
<recordTarget>
  <patientRole>
    <id extension='12345' root='2.16.840.1.113883.3.933'/>
    <addr>
      <streetAddressLine>17 Daws Rd.</streetAddressLine>
      <city>Blue Bell</city>
      <state>MA</state>
      <postalCode>02368</postalCode>
      <country>USA</country>
    </addr>
    <telecom value='tel:(781)555-1212'/>
    <patient>
      <name>
        <given>First</given>
        <family>Last</family>
      </name>
      <administrativeGenderCode code="M" codeSystem="2.16.840.1.113883.5.1"/>
      <birthTime value="19541125"/>
      <guardian>
        <id extension="23456" root="2.16.840.1.113883.19.5"/>
        <addr>
          <streetAddressLine>17 Daws Rd.</streetAddressLine>
          <city>Blue Bell</city>
          <state>MA</state>
          <postalCode>02368</postalCode>
          <country>USA</country>
        </addr>
        <telecom value="tel:(781)555-1212" use="HP"/>
        <guardianPerson>
          <name>
            <given>Father</given>
            <family>Last</family>
          </name>
        </guardianPerson>
      </guardian>
    </patient>
    <providerOrganization>
      <id extension='M345' root='2.16.840.1.113883.19.5'/>
      <name>Good Health Clinic</name>
      <telecom value='tel:(999)555-1212'/>
      <addr>
        <streetAddressLine>21 North Ave</streetAddressLine>
        <city>Burlington</city>
        <state>MA</state>
        <postalCode>01803</postalCode>
        <country>USA</country>
      </addr>
    </providerOrganization>
  </patientRole>
</recordTarget>
```

Figure 18: recordTarget example

2.1.14.2 author

The author element represents the creator of the clinical document. If the role of the actor is the entry of information from his or her own knowledge or application of skills, that actor is the author. If one actor provides information to another actor who filters,

reasons, or algorithmically creates new information, then that second actor is also an author, having created information from his or her own knowledge or skills. However, that determination is independent from the determination of the first actor's authorship.

CONF-HP-37: The author/time element represents the start time of the author's participation in the creation of the clinical document. The author/time element **SHALL** be present.

CONF-HP-38: The assignedAuthor/id element **SHALL** be present.

CONF-HP-39: An assignedAuthor element **SHALL** contain at least one assignedPerson or assignedAuthoringDevice elements.

```
<author>
  <time value='20050329224411+0500'/>
  <assignedAuthor>
    <id extension='1' root='2.16.840.1.113883.19'/>
    <addr>
      <streetAddressLine>21 North Ave</streetAddressLine>
      <city>Burlington</city>
      <state>MA</state>
      <postalCode>01803</postalCode>
      <country>USA</country>
    </addr>
    <telecom value='tel:(999)555-1212' use='WP'/>
    <assignedPerson>
      <name>
        <prefix>Dr.</prefix>
        <given>Bernard</given>
        <family>Wiseman</family>
        <suffix>Sr.</suffix>
      </name>
    </assignedPerson>
  </assignedAuthor>
</author>
```

Figure 19: author example

2.1.14.3 dataEnterer

The dataEnterer element represents the person who transferred the information from other sources into the clinical document, where the other sources wrote the content of the note. The guiding rule of thumb is that an author provides the content found within the header or body of the document, subject to their own interpretation. The dataEnterer adds information to the electronic system. A person can participate as both author and dataEnterer.

If the role of the actor is to transfer information from one source to another (e.g., transcription or transfer from paper form to electronic system), that actor is considered a dataEnterer.

CONF-HP-40: When dataEnterer is present, an assignedEntity/assignedPerson element **SHALL** be present.

CONF-HP-41: The time element **MAY** be present. If present, it represents the starting time of entry of the data.

```
<dataEnterer>
  <time value='20050329222451+0500'/>
  <assignedEntity>
    <id extension='2' root='2.16.840.1.113883.19'/>
    <assignedPerson>
      <name>
        <prefix>Mrs.</prefix>
        <given>Bernice</given>
        <family>Wiseman</family>
      </name>
    </assignedPerson>
  </assignedEntity>
</dataEnterer>
```

Figure 20: dataEnterer example

2.1.14.4 informant

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

CONF-HP-42: The informant element **MAY** be present.

CONF-HP-43: When informant is present, an assignedEntity/assignedPerson or relatedEntity/relatedPerson element **SHALL** be present.

2.1.14.4.1 Assigned Healthcare Providers

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

CONF-HP-44: When the informant is a healthcare provider with an assigned role, the informant **SHALL** be represented using the assignedEntity element

The code element is optional on the assignedEntity, since the person it identifies is already known to be in an assigned role.

```
<informant>
  <assignedEntity>
    <id extension='3' root='2.16.840.1.113883.19'/>
    <addr>
      <streetAddressLine>21 North Ave</streetAddressLine>
      <city>Burlington</city><state>MA</state><postalCode>01803</postalCode>
      <country>USA</country>
    </addr>
    <telecom value='tel:(999)555-1212' use='WP'/>
    <assignedPerson>
      <name>
        <prefix>Dr.</prefix>
        <given>Bernard</given>
        <family>Wiseman</family>
        <suffix>Jr.</suffix>
      </name>
    </assignedPerson>
  </assignedEntity>
</informant>
```

Figure 21: informant Example for health care providers in assigned roles

2.1.14.4.2 Personal Relations

When the informant is a personal relation, that informant is represented in the relatedEntity element. The code element of the relatedEntity describes the relationship between the informant and the patient.

The relationship between the informant and the patient needs to be described to help the receiver of the clinical document understand the information in the document.

CONF-HP-45: Allowable values for informant/relatedEntity/@classCode **SHALL** be *CON*, *PRS, CAREGIVER, AGNT* or *PROV* from the RoleClass vocabulary.

CONF-HP-46: When relatedEntity/@classCode is *PRS*, values in relatedEntity/code **SHALL** come from the HL7 PersonalRelationshipRoleType vocabulary or from SNOMED, any subtype of "Person in the family" (303071001).

```
<!-- To represent personal relation that provides information about a patient -->
<informant>
  <relatedEntity classCode='PRS'>
    <code code='MTH' codeSystem='2.16.840.1.113883.5.111'/>
    <relatedPerson>
      <name>
        <prefix>Mrs.</prefix>
        <given>Abigail</given>
        <family>Ruth</family>
      </name>
    </relatedPerson>
  </relatedEntity>
</informant>
```

Figure 22: informant example for a related person

2.1.14.4.3 Unrelated Person

Individuals with no prior personal relationship to the patient (e.g., a witness to a significant health care event) may provide information about the patient.

CONF-HP-47: When an informant is an unrelated person not otherwise specified, the value relatedEntity/@classCode **SHALL** be set to *CON* to indicate that this person is a contact.

```
<!-- To represent a witness to a significant health event -->
<informant>
  <relatedEntity classCode='CON'>
    <relatedPerson>
      <name>
        <prefix>Mr.</prefix>
        <given>Joseph</given>
        <given>T.</given>
        <family>Jones</family>
      </name>
    </relatedPerson>
  </relatedEntity>
</informant>
```

Figure 23: informant example for an unrelated person

2.1.14.4.4 Healthcare Providers

A health care provider who does not have an assigned role at the institution may provide information. To record an informant that does not have an assigned role that can be represented within the context of the document, the information will be represented using the relatedEntity element and the value of relatedEntity/@classCode will be set to *PROV*.

CONF-HP-48: When the informant is a healthcare provider without an assigned role, the informant **SHALL** be represented using the relatedEntity element and the value of relatedEntity/@classCode **SHALL** be set to *PROV*.

CONF-HP-49: The value of relatedEntity/code **SHOULD** be present and indicate the type of healthcare provider.

```
<!-- To represent a healthcare provider in a healthcare role without an assigned
   role known or representable to the author.  The example below represents a
   clinician who was the patient's primary care provider.
-->
<informant>
  <relatedEntity classCode='PROV'>
    <code code='208D00000X' codeSystem='2.16.840.1.113883.11.19465'  />
    <relatedPerson>
      <name>
        <given>Jane</given>
        <family>Queen</family>
        <suffix></suffix>
      </name>
    </relatedPerson>
  </relatedEntity>
</informant>
```

Figure 24: informant example for health care providers not in assigned roles

2.1.14.5 custodian

Based on the CDA R2 constraints (Section 4.2.2.3 of the CDA Normative Web Edition. See Section 5 REFERENCES), the custodian element is required and is the custodian of the clinical document.

```
<custodian>
  <assignedCustodian>
    <representedCustodianOrganization>
      <id extension='1' root='1.3.6.4.1.4.1.2835.3'/>
      <name>Good Health Clinic</name>
      <telecom value='tel:(999)555-1212' use='WP'/>
      <addr>
        <streetAddressLine>21 North Ave</streetAddressLine>
        <city>Burlington</city>
        <state>MA</state>
        <postalCode>01803</postalCode>
        <country>USA</country>
      </addr>
    </representedCustodianOrganization>
  </assignedCustodian>
</custodian>
```

Figure 25: custodian example

2.1.14.6 informationRecipient

informationRecipient, when used in the context of a referral or request for consultation, this records the intended recipient of the information at the time the document is created. The intended recipient may also be the health chart of the patient, in which case the receivedOrganization is the scoping organization of that chart.

CONF-HP-50: The ClinicalDocument/informationRecipient element **MAY** be present[5]. When informationRecipient is used, at least one informationRecipient/intendedRecipient/informationRecipient or informationRecipient/intendedRecipient/receivedOrganization **SHALL** be present.

```
<informationRecipient>
  <intendedRecipient>
    <id extension='4' root='2.16.840.1.113883.19'/>
    <addr>
      <streetAddressLine>21 North Ave</streetAddressLine>
      <city>Burlington</city>
      <state>MA</state>
      <postalCode>01803</postalCode>
      <country>USA</country>
    </addr>
    <telecom value='tel:(999)555-1212' use='WP'/>
    <informationRecipient>
      <name>
        <prefix>Dr.</prefix>
        <given>Phil</given>
        <family>Green</family>
      </name>
    </informationRecipient>
    <receivedOrganization>
      <name>Good Health Clinic</name>
    </receivedOrganization>
  </intendedRecipient>
</informationRecipient>
```

Figure 26: informationRecipient example

2.1.14.7 legalAuthenticator

The legalAuthenticator element identifies the legal authenticator of the document and must be present if the document has been legally authenticated. Based on local practice, clinical documents may be released before legal authentication. This implies that a clinical document that does not contain this element has not been legally authenticated.

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

---

[5] Note that there are two elements in the CDA Release 2.0 schema that are named informationRecipient. The outermost of these elements is what is being discussed here. The second element with the same name may appear as a descendent of this one.

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

CONF-HP-51: The assignedEntity/assignedPerson element **SHALL** be present in legalAuthenticator.

```
<legalAuthenticator>
  <time value='20050329224512+0500'/>
  <signatureCode code='S'/>
  <assignedEntity>
    <id extension='1' root='2.16.840.1.113883.19'/>
    <addr>
      <streetAddressLine>21 North Ave</streetAddressLine>
      <city>Burlington</city>
      <state>MA</state>
      <postalCode>01803</postalCode>
      <country>USA</country>
    </addr>
    <telecom value='tel:(999)555-1212' use='WP'/>
    <assignedPerson>
      <name>
        <prefix>Dr.</prefix>
        <given>Bernard</given>
        <family>Wiseman</family>
        <suffix>Sr.</suffix>
      </name>
    </assignedPerson>
  </assignedEntity>
</legalAuthenticator>
```

Figure 27: legalAuthenticator example

2.1.14.8 authenticator

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

CONF-HP-52: An authenticator **MAY** be present . The assignedEntity/assignedPerson element **SHALL** be present in an authenticator element.

```
<authenticator>
  <time value='20050329224512+0500'/>
  <signatureCode code='S'/>
  <assignedEntity>
    <id extension='3' root='2.16.840.1.113883.19'/>
    <addr>
      <streetAddressLine>21 North Ave</streetAddressLine>
      <city>Burlington</city>
      <state>MA</state>
      <postalCode>01803</postalCode>
      <country>USA</country>
    </addr>
    <telecom value='tel:(999)555-1212' use='WP'/>
    <assignedPerson>
      <name>
        <prefix>Dr.</prefix>
        <given>Bernard</given>
        <family>Wiseman</family>
        <suffix>Jr.</suffix>
      </name>
    </assignedPerson>
  </assignedEntity>
</authenticator>
```

Figure 28: authenticator example

Automated systems, such as a PHR, that allow a clinical document to be generated need to give special consideration to authentication permissions because the information contained in the document may come from sources or contain information that the author cannot validate[6].

2.2 Rendering Header Information for Human Presentation

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

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

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

3 CDA HEADER – H&P NOTE-SPECIFIC CONSTRAINTS

This section describes constraints specific to History and Physical documents.

3.1 ClinicalDocument/templateId

The ClinicalDocument/templateId element identifies the template that defines constraints on the content. The clinicalDocument/templateID with the content shown below indicates conformance to this DSTU.

CONF-HP-53: At least one ClinicalDocument/templateId element **SHALL** be present with the value 2.16.840.1.113883.10.20.2.

```
<templateId root=2.16.840.1.113883.10.20.2'/> <!-- conforms to the DSTU -->
```

Figure 29: ClinicalDocument/templateId example

3.2 ClinicalDocument/code

The ClinicalDocument/code element must be present and specifies the type of the clinical document. Valid codes are those whose scale is DOC and whose type of service is some variation of History and Physical. The valid codes as of issuance of this DSTU are shown below:

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

[6] This may in fact also be the case for practitioners at various degrees of skill.

Value set: 2.16.840.1.113883.1.11.20.22 HPDocumentType Code System: 2.16.840.1.113883.6.1 LOINC			
LOINC®	**Type of Service**	**Setting**	**Specialty/ Training/ Professional Level**
34138-8	Targeted History & Physical	------	------

Table 2: LOINC® Document Type Codes

CONF-HP-54: The value for "ClinicalDocument / code" **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.20.22 HPDocumentType DYNAMIC

```
<code codeSystem='2.16.840.1.113883.6.1'
        codeSystemName='LOINC'
        code='34117-2'
        displayName='HISTORY AND PHYSICAL'/>
```

Figure 30: ClinicalDocument/code example

CDA R2 states that LOINC® is the preferred vocabulary for document type specifications. This DSTU goes further, stating that only the codes described above **SHALL** be used for a History and Physical.

3.2.1 Use of Local Document Type Codes

CONF-HP-55: Implementations **MAY** use local codes in translation elements to specify a local code that is equivalent to the document type.

```
<code code='34117-2'
        displayName='HISTORY AND PHYSICAL'
        codeSystem='2.16.840.1.113883.6.1'
        codeSystemName='LOINC'>
  <translation code='X-GISOE'
                displayName='GI HISTORY AND PHYSICAL'
                codeSystem='2.16.840.1.113883.19'/>
</code>
```

Figure 31: Use of a translation to include local equivalents for document type

3.2.2 Precoordinated Document Type Codes

Some LOINC® document type codes, including those listed above, also indicate the practice setting or the training or the professional level of the author. These are precoordinated document type codes. When these codes are used, any coded values describing the author or performer of the service act, or the practice setting **SHALL** be consistent with the LOINC® document type.

The LOINC® document codes listed in **Error! Reference source not found.** is a list of document type codes supported under this specification. Some of these codes (those *not* indicated in boldface) are precoordinated with either the practice setting or the training or professional level of the author. Use of these codes is not recommended, as it duplicates information potentially present within the CDA document header.

CONF-HP-56: If precoordinated document type codes are used, values used in the *assignedAuthor/code* and *assignedAuthor/author/functionCode* elements ***SHALL NOT*** conflict with *ClinicalDocument/code*.

CONF-HP-57: If precoordinated document type codes are used, values used in *encompassingEncounter/location/healthCareFacility/code* ***SHALL NOT*** conflict with *ClinicalDocument/code*.

The various codes found in the header that need to be consistent when using precoordinated document type codes are illustrated below.

```
<ClinicalDocument xmlns='urn:hl7-org:v3'>
   …
  <code codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'
        code='34094-3'
        displayName='CARDIOLOGY HOSPITAL ADMISSION NOTE'/>
   …
  <title>Good Health Cardiology Admitting History &amp;amp; Physical</title>
   …
  <author>
    <functionCode codeSystem='2.16.840.1.113883.5.88'
                  codeSystemName='ParticipationFunction'
                   code='ATTPHYS' />
    <assignedAuthor>
    …
      <code codeSystem='2.16.840.1.113883.6.96' codeSystemName='SNOMED CT'
            code='17561000' displayName='Cardiologist' />
    …
    </assignedAuthor>
  </author>
   …
  <componentOf>
    <encompassingEncounter>
    …
      <healthCareFacility>
        <code codeSystem='2.16.840.1.113883.5.111'   codeSystemName='RoleCode'
              code='HOSP' />
      </healthCareFacility>
    </encompassingEncounter>
  </componentOf>
</ClinicalDocument>
```

Figure 32: Use of a precoordinated document type code in the CDA

Using document type codes that are not precoordinated eliminates having to ensure consistency between the document type and other codes found in the document. In the example shown above, changing the document type code to one that is not precoordinated, as shown below, eliminates the need to ensure consistency of the document type code with the codes assigned to an author or health care facility while conveying the same information. Note that in both cases, the title may be localized.

```
<ClinicalDocument xmlns='urn:hl7-org:v3'>
    …
    <code codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'
          code='47039-3' displayName='ADMISSION H&P NOTE'/>
    …
  <title>Good Health Cardiology Admitting History &amp;amp; Physical</title>

    …
  <author>
    <functionCode codeSystem='2.16.840.1.113883.5.88'
              codeSystemName='ParticipationFunction'
               code='ATTPHYS' />
    <assignedAuthor>
    …
      <code codeSystem='2.16.840.1.113883.6.96' codeSystemName='SNOMED CT'
            code='17561000' displayName='Cardiologist' />
    …
    </assignedAuthor>
  </author>
    …
  <componentOf>
    <encompassingEncounter>
    …
      <healthCareFacility>
        <code codeSystem='2.16.840.1.113883.5.111' codeSystemName='RoleCode'
              code='HOSP' />
      </healthCareFacility>
    </encompassingEncounter>
  </componentOf>
</ClinicalDocument>
```

Figure 33: Use of an unprecoordinated document type code

3.3 Participants

This section describes the History and Physical-specific constraints placed upon CDA Participants described in the CDA Header.

3.3.1 participant

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

CONF-HP-58: The participant element **MAY** be present . If present, the participant/associatedEntity element **SHALL** have an associatedPerson or scopingOrganization element.

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

3.3.2 Supporting Person or Organization

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

CONF-HP-59: When participant/@typeCode is *IND*, associatedEntity/@classCode **SHALL** be *PRS, NOK,CAREGIVER, AGNT,GUAR, or ECON.*

CONF-HP-60: When associatedEntity/@classCode is *PRS, NOK, or ECON*, then associatedEntity/code **SHALL** be present having a value drawn from the PersonalRelationshipRoleType domain or from SNOMED, any subtype of "Person in the family" (303071001).

```
<participant typeCode='IND'>
  <associatedEntity classCode='NOK'>
    <code code='MTH' codeSystem='2.16.840.1.113883.5.111'/>
    <addr>
      <streetAddressLine>17 Daws Rd.</streetAddressLine>
      <city>Blue Bell</city>
      <state>MA</state>
      <postalCode>02368</postalCode>
      <country>USA</country>
    </addr>
    <telecom value='tel:(999)555-1212' use='WP'/>
    <associatedPerson>
      <name>
        <prefix>Mrs.</prefix>
        <given>Abigail</given>
        <family>Ruth</family>
      </name>
    </associatedPerson>
  </associatedEntity>
</participant>
```

Figure 34: participant example for a supporting person

3.3.3 inFulfillmentOf

CONF-HP-61: The inFulfillmentOf elements **MAY** be present.

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

3.3.4 authorization

CONF-HP-62: The authorization elements **MAY** be present.

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

3.3.5 componentOf

The History and Physical is always associated with an encounter.

CONF-HP-63: The componentOf element **SHALL** be present.

CONF-HP-64: The encompassingEncounter element **SHALL** have an id element.

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

CONF-HP-65: The encompassingEncounter element **SHALL** have an effectiveTime element.

The encounterParticipant elements represent only those participants in the encounter, not necessarily the entire episode of care (see related information under the section for participant above).

CONF-HP-66: The encounterParticipant elements **MAY** be present. If present, the encounterParticipant/assignedEntity element **SHALL** have at least one assignedPerson or representedOrganization element present.

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

CONF-HP-67: The responsibleParty element **MAY** be present . If present, the responsibleParty/assignedEntity element **SHALL** have at least one assignedPerson or representedOrganization element present.

```
<componentOf>
  <encompassingEncounter>
    <id extension='9937012' root='2.16.840.1.113883.19'/>
    <code codeSystem='2.16.840.1.113883.6.12' codeSystemName='CPT-4'
        code='99213' displayName='Evaluation and Management'/>
    <effectiveTime>
      <low value='20050329'/>
      <high value='20050329'/>
    </effectiveTime>
  </encompassingEncounter>
</componentOf>
```

Figure 35: componentOf example

4 BODY

As with other CDA R2-conformant documents, a History and Physical document can have either a structuredBody or nonXMLBody element. The content of this element makes up the human-readable text of the document. This information is to be organized into sections and can also have subsections. A nonXMLBody element may contain the actual CDA content or may reference it by URL.

CONF-HP-68: A nonXMLBody/text **SHOULD NOT** contain both a reference element and character data.

The use of nonXMLBody does not eliminate the requirement that the required content be present in clearly identifiable sections according to the categories described in this section.

```
<component>
  <nonXMLBody mimeType='text/plain'>
    <text>This is where the text would go.</text>
  </nonXMLBody>
 </component>
```

Figure 36: nonXMLBody example with content

Figure 37 below illustrates a nonXMLBody with a reference to a URL. Note that there is no white space or new line characters between the opening or closing tags of the text and reference elements.

```
<component xmlns:xsi='http://www.w3.org/2001/XMLSchema-instance'>
  <nonXMLBody mimeType='text/plain'>
    <text><reference value='http://www.anyhospital.org/aDocument.txt'>
      </reference></text>
  </nonXMLBody>
</component>
```

Figure 37: nonXMLBody example with a reference

4.1 Section Descriptions

This DSTU defines required and optional sections.

The required LOINC® codes for these sections and whether a section is required or optional are described in Table 3: LOINC® Codes for Sections. All codes shown in that table describe narrative document sections for Level 2 and Level 3 conformance. Sections not appearing in this table may be added where necessary in the History and Physical according to local policy; such sections should be coded using the appropriate LOINC® codes.

All sections can occur in any order and can be nested under other sections according to local policy. For example, Procedure History may be a top-level section or may nest under Past Medical History.

A required section for which no content is available must indicate as such in the narrative block for that section. Local practice must ensure that the legal authenticator is aware that this statement will be part of the legally authenticated content. See Figure 45: Family history example below where the narrative states "None recorded."

Sections and subsections are required to have a title and the title cannot be empty. The titles used are to be based on the CCD, where CCD templates are cited. Note that section titles are shown in all caps per ASTM's Standard Specifications for Healthcare Document Formats (E2184.02).

Required sections for which multiple codes are given can satisfy the requirement using any of the indicated codes. For example, the requirement to include a Reason for Visit/Chief Complaint section can be met by inclusion of LOINC® codes 29299-5, 10154-3, or 46239-0.

Section Category	R/O	Code	Component Name
Reason for Visit/Chief Complaint	R	29299-5	REASON FOR VISIT
		10154-3	CHIEF COMPLAINT
		46239-0	REASON FOR VISIT+CHIEF COMPLAINT
History of Present Illness	R	10164-2	HISTORY OF PRESENT ILLNESS
Past Medical History	R	11348-0	HISTORY OF PAST ILLNESS
Medications	R	10160-0	HISTORY OF MEDICATION USE
Allergies	R	48765-2	ALLERGIES, ADVERSE REACTIONS, ALERTS
Social History	R	29762-2	SOCIAL HISTORY
Family History	R	10157-6	HISTORY OF FAMILY MEMBER DISEASES
Vital Signs	R	8716-3	VITAL SIGNS (may be a subsection of Physical Examination)
Review of Systems	R	10187-3	REVIEW OF SYSTEMS
Physical Examination	R	29545-1	PHYSICAL FINDINGS
		Optional Subsections	
		10210-3	GENERAL STATUS, PHYSICAL FINDINGS (optional, must be subsection)

Section Category	R/O	Code	Component Name
		See Appendix D — List of Additional Physical Examination Subsections.	Additional optional subsections. List include those in section 3.3.3 (Provider Unspecified H&P Note) of the "Additional Information Specification 0004: Clinical Reports Attachment" .
Diagnostic Findings	R	30954-2	RELEVANT DIAGNOSTIC TESTS **AND**/OR LABORATORY DATA
Assessment and Plan	R	51847-2	ASSESSMENT **AND** PLAN
		51848-0	ASSESSMENT
		18776-5	PLAN
Procedure History	O	10167-5	PROCEDURE HISTORY
Immunizations	O	11369-6	HISTORY OF IMMUNIZATIONS
Problems	O	11450-4	PROBLEM LIST

Table 3: LOINC® Codes for Sections

Section Category:	The section category column lists the general category of sections described in this DSTU
R/O:	This column indicates whether the section is Required (R) or Optional (O) in H&P Notes
Code:	The code of the section in LOINC®
Component Name:	The display name of the section in LOINC®

All section elements in the body of the document must have a code and some nonblank text or one or more subsections, even if the purpose of the text is only to indicate that the information is unknown.

CONF-HP-69: A section element **SHALL** have a code element.

CONF-HP-70: A section **SHALL** contain at least one text element or one or more component elements. A section **MAY** contain both text and component elements.

CONF-HP-71: All text or component elements **SHALL** contain content.

The section codes have been coordinated with the CDAR2AIS0004R030 (Additional Information Specification 0004, Clinical Reports Attachment) to support the reuse of information found in a History and Physical to respond to a query for a Claims Attachment. The requirements of this DSTU are consistent with the requirements of ASIG0004.

4.2 Required Sections

CONF-HP-72: A History and Physical **SHALL** contain the sections described hereunder.

4.2.1 Reason for Visit/Chief Complaint 29299-5/10154-3/46239-0

This section records the patient's chief complaint (the patient's own description) and/or the reason for the patient's visit (the provider's description of the reason for visit). Local

policy determines whether the information is divided into two sections or recorded in one section serving both purposes.

The constraints from this section were initially derived from CRS, but have been slightly modified.

CONF-HP-73: The Reason for Visit/Chief Complaint section **SHALL** include a template identifier with value 2.16.840.1.113883.10.20.2.8.

CONF-HP-74: When the Chief Complaint and the Reason for Visit are recorded separately there **SHALL** be a section whose value for "Section / code" **SHALL** be "10154-3" "Chief complaint" 2.16.840.1.113883.6.1 LOINC STATIC; **AND** there **SHALL** be a section whose value for "Section / code" **SHALL** be "29299-5" "Reason for visit" 2.16.840.1.113883.6.1 LOINC STATIC; **AND** there **SHALL NOT** be a section whose value for "Section / code" is "46239-0" "Reason for visit + Chief complaint."

CONF-HP-75: When the Chief Complaint and Reason for Visit are recorded together, the value for "Section / code" **SHALL** be "46239-0" "Reason for visit + Chief complaint" 2.16.840.1.113883.6.1 LOINC STATIC; **AND** there **SHALL NOT** be a section whose value for "Section / code" is "10154-3" "Chief complaint"; **AND** there **SHALL NOT** be a section whose value for "Section / code" is "29299-5" "Reason for visit."

```
<component>
 <section>
  <templateId root="2.16.840.1.113883.10.20.2.8"/>
  <code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
      code="29299-5" displayName="REASON FOR VISIT"/>
  <title>REASON FOR VISIT</title>
  <text>
   <paragraph>Twisted ankle.</paragraph>
  </text>
 </section>
</component>
```

Figure 38: Reason for visit example

4.2.2 History of Present Illness 10164-2

CONF-HP-76: All constraints in this section were derived from CRS. This section **SHALL** include the template identifier for the History of Present Illness section (1.3.6.1.4.1.19376.1.5.3.1.3.4, as defined in the IHE PCC Technical Framework – XDS-MS). A H&P Note **SHALL** contain exactly one and **SHALL NOT** contain more than one History of Present Illness section (templateId 1.3.6.1.4.1.19376.1.5.3.1.3.4). The History of Present Illness section **SHALL** contain a narrative block and **SHOULD** contain clinical statements.

This section describes the history related to the chief complaint. It contains the historical details leading up to and pertaining to the patient's current complaint or reason for seeking medical care.

```
<component>
  <section>
    <templateId root= 1.3.6.1.4.1.19376.1.5.3.1.3.4"/>
    <code code='10164-2' codeSystem='2.16.840.1.113883.6.1'
        displayName='HISTORY OF PRESENT ILLNESS'/>
    <title>HISTORY OF PRESENT ILLNESS</title>
    <text>Patient slipped and fell on ice, twisting her ankle as she fell.</text>
  </section>
</component>
```

Figure 39: History of present illness example

4.2.3 Past Medical History 11348-0

This section describes the past medical history for the patient. It may contain information about past procedures or other illnesses that might have a bearing on the patient's current illness. Since past medical history can include past surgical history and other procedures, the Procedure History section may be included under the Past Medical History section or it may stand alone as its own section. By the same token, problems can be recorded in a standalone Problems section or in a nested Problems section. Wherever used, procedures and problems should conform to the CCD template for CDA entries cited in the Problems section.

CONF-HP-77: A History and Physical **SHALL** contain exactly one and **SHALL NOT** contain more than one Past Medical History section (templateId 2.16.840.1.113883.10.20.2.9). The Past Medical History section **SHALL** contain a narrative block, and **SHOULD** contain clinical statements.

CONF-HP-78: The section code for the section describing Past Medical History **SHALL** be *11348-0* (HISTORY OF PAST ILLNESS).

```
<component>
  <section>
    <templateId root= 2.16.840.1.113883.10.20.2.9 />
    <code code='11348-0' codeSystem="2.16.840.1.113883.6.1"
        displayName='HISTORY OF PAST ILLNESS'/>
    <title>PAST MEDICAL HISTORY</title>
    <text>No other recent fractures.</text>
  </section>
</component>
```

Figure 40: Past medical history example

4.2.4 Medications 10160-0

CONF-HP-79: All constraints in this section are from the CCD Medications section. See Appendix B — Externally Defined Constraints for CCD conformance requirements. This section **SHALL** include the CCD template identifier for the medications section (2.16.840.1.113883.10.20.1.8).

The Medications section defines a patient's current medications and pertinent medication history. In this case, the LOINC® displayName is not appropriate for the title of this section. The title should include the word "Medications." At a minimum, the currently active medications should be listed with an entire medication history as an option, particularly when the document is used for comprehensive data export. The

section may also include a patient's prescription history and enable the determination of the source of a medication list, e.g., from a pharmacy system versus from the patient.

A sample of a Medications section is shown below:

```
<!–Note: this simple coding of medications reflects what we might expect to see in a
dictated note. For a complete sample of medications encoding, see CCD  -->

<component>
  <section>
   <templateId root="2.16.840.1.113883.10.20.1.8"/>
   <code codeSystem="2.16.840.1.113883.6.1"
   codeSystemName="LOINC"
   code="10160-0"
   displayName="HISTORY OF MEDICATION USE"/>
   <title>CURRENT MEDICATIONS</title>
   <text>
   <list listType="ordered">
      <item><content ID="m1">Lisinopril 5 mg</content> 1 tablet once a day
        </item>
      <item><content ID="m2">Atenolol 25 mg</content> 1 tablet once a day
        </item>
      <item><content ID="m3">Furosemide 40 mg</content> 4 tablets daily in divided doses
        </item>
      <item><content ID="m4">Gabapentin 300 mg</content> 1 tablet twice a day
        </item>
      <item><content ID="m5">Simvastatin (Zocor) 10 mg</content> 1 tablet once a day at bedtime
        </item>
   </list>
   <paragraph>The patient has just completed a 4 week course of Vanco and Rifampin for a MRSA
UTI.</paragraph>
   <paragraph>I note that this patient has been on Prednisone for ? adrenal insufficiency in the past.</paragraph>
  </text>
     <entry>
       <substanceAdministration classCode="SBADM" moodCode="EVN">
         <consumable>
           <manufacturedProduct>
             <manufacturedLabeledDrug>
               <code codeSystem="2.16.840.1.113883.6.88"
               codeSystemName="RxNorm"
               code="203644"
               displayName="LISINOPRIL (PRINIVIL)--PO 5MG TAB">
                 <originalText>
                   <reference value="#m1"/>
                 </originalText>
               </code>
```

```
            </manufacturedLabeledDrug>
          </manufacturedProduct>
        </consumable>
      </substanceAdministration>
    </entry>
    <entry>
      <substanceAdministration classCode="SBADM" moodCode="EVN">
        <consumable>
          <manufacturedProduct>
            <manufacturedLabeledDrug>
              <code codeSystem="2.16.840.1.113883.6.88"
              codeSystemName="RxNorm"
              code="197380" displayName="ATENOLOL--PO 25MG TAB">
                <originalText>
                  <reference value="#m2"/>
                </originalText>
              </code>
            </manufacturedLabeledDrug>
          </manufacturedProduct>
        </consumable>
      </substanceAdministration>
    </entry>
    <entry>
      <substanceAdministration classCode="SBADM" moodCode="EVN">
        <consumable>
          <manufacturedProduct>
            <manufacturedLabeledDrug>
              <code codeSystem="2.16.840.1.113883.6.88"
              codeSystemName="RxNorm"
              code="313988" displayName="FUROSEMIDE--PO 40MG TAB">
                <originalText>
                  <reference value="#m3"/>
                </originalText>
              </code>
            </manufacturedLabeledDrug>
          </manufacturedProduct>
        </consumable>
      </substanceAdministration>
    </entry>
    <entry>
      <substanceAdministration classCode="SBADM" moodCode="EVN">
        <consumable>
          <manufacturedProduct>
            <manufacturedLabeledDrug>
              <code codeSystem="2.16.840.1.113883.6.88"
              codeSystemName="RxNorm"
              code="476677" displayName="GABAPENTIN--PO 300MG TAB">
                <originalText>
                  <reference value="#m4"/>
                </originalText>
              </code>
            </manufacturedLabeledDrug>
          </manufacturedProduct>
        </consumable>
      </substanceAdministration>
    </entry>
    <entry>
      <substanceAdministration classCode="SBADM" moodCode="EVN">
        <consumable>
```

```
          <manufacturedProduct>
            <manufacturedLabeledDrug>
              <code codeSystem="2.16.840.1.113883.6.88"
              codeSystemName="RxNorm"
              code="314231" displayName="SIMVASTATIN (ZOCOR)--PO 10MG TAB">
                <originalText>
                  <reference value="#m5"/>
                </originalText>
              </code>
            </manufacturedLabeledDrug>
          </manufacturedProduct>
        </consumable>
      </substanceAdministration>
    </entry>

  </section>
</component>
```

Figure 41: Medications example with Level 3 coding

4.2.5 Allergies 48765-2

CONF-HP-80: All constraints from this section are from the CCD Alerts section. See Appendix B — Externally Defined Constraints for CCD conformance requirements. This section **SHALL** include the CCD template identifier for the CCD Alerts section (2.16.840.1.113883.10.20.1.2).

This section is used to list and describe any medication allergies, adverse reactions, idiosyncratic reactions, anaphylaxis/anaphylactoid reactions to food items, and metabolic variations or adverse reactions/allergies to other substances (such as latex, iodine, tape adhesives) used to assure the safety of health care delivery. In general, environmental allergies, even if severe, should not be included in the Alerts section since they constitute a medical problem and should be listed in the problem list and past medical history, even if directly related to the presenting problem. A sample of an Allergies section is shown below:

```
<component>
  <section>
    <templateId root="2.16.840.1.113883.10.20.1.2"/>
    <code code='48765-2' codeSystem="2.16.840.1.113883.6.1"
        displayName='ALLERGIES, ADVERSE REACTIONS, ALERTS'/>
    <title>ALLERGIES AND ADVERSE REACTIONS</title>
    <text>
      <list listType="ordered">
        <item>Levaquin</item>
        <item>Lorazepam</item>
        <item>Peanuts</item>
      </list>
    </text>
  </section>
</component>
```

Figure 42: Allergies example

4.2.6 Social History 29762-2

CONF-HP-81: All constraints from this section are from the CCD Social History section. See Appendix B — Externally Defined Constraints for CCD conformance requirements. This section **SHALL** include the CCD template identifier for the Social History section (2.16.840.1.113883.10.20.1.15).

This section contains data defining the patient's occupational, personal (i.e., 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 a significant influence on a patient's physical, psychological, and emotional health and wellbeing, so should be considered in the development of a complete health record.

```
<component>
  <section>
    <templateId root= 2.16.840.1.113883.10.20.1.15"/>
    <code  code='29762-2' codeSystem="2.16.840.1.113883.6.1"
        displayName='SOCIAL HISTORY'/>
    <title>SOCIAL HISTORY</title>
    <text>
       <paragraph>Drug History: None.</paragraph>
       <paragraph>Smoking History: 1 pack per day 1972-2000, none 2001-present.</paragraph>
    </text>
  </section>
</component>
```

Figure 43: Social history example

A sample of a Social History section with Level 3 entries is shown below:

```
<component>
  <section>
    <templateId root= 2.16.840.1.113883.10.20.1.15"/>
    <code  code='29762-2' codeSystem="2.16.840.1.113883.6.1"
         displayName='SOCIAL HISTORY'/>
    <title>SOCIAL HISTORY</title>

    <text>
       <paragraph>Drug History: None.</paragraph>
       <paragraph>Smoking History: 1 pack per day 1972-2000, none 2001-present.</paragraph>
    </text>

<entry typeCode="DRIV">
  <observation classCode="OBS" moodCode="EVN">
    <!-- Social history observation template -->
    <templateId root="2.16.840.1.113883.10.20.1.33"/>
    <id extension="123456789" root="2.16.840.1.113883.19"/>
    <code codeSystem="2.16.840.1.113883.6.96"
         code="407586004" displayName="History of - recreational drug use"/>
    <statusCode code="completed"/>
    <value xsi:type="ST">None</value>
  </observation>
</entry>

<entry typeCode="DRIV">
  <observation classCode="OBS" moodCode="EVN">
    <!-- Social history observation template -->
    <templateId root="2.16.840.1.113883.10.20.1.33"/>
    <id extension="123456789" root="2.16.840.1.113883.19"/>
    <code codeSystem="2.16.840.1.113883.6.96"
         code="230056004" displayName="Cigarette smoking"/>
    <statusCode code="completed"/>
    <effectiveTime><low value="1972"/><high value="2000"/></effectiveTime>
    <value xsi:type="ST">1 pack per day</value>
  </observation>
</entry>

  </section>
</component>
```

Figure 44: Social history example with Level 3 entries

4.2.7 Family History 10157-6

CONF-HP-82: All constraints from this section are from the CCD Family History. See Appendix B — Externally Defined Constraints for CCD conformance requirements. This section **SHALL** include the CCD template identifier for the Family History section (2.16.840.1.113883.10.20.1.4).

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

```
<component>
  <section>
    <templateId root= 2.16.840.1.113883.10.20.1.4"/>
    <code code='10157-6' codeSystem="2.16.840.1.113883.6.1"
        displayName='HISTORY OF FAMILY MEMBER DISEASES'/>
    <title>FAMILY HISTORY</title>
    <text>None recorded.</text>
  </section>
</component>
```

Figure 45: Family history example

4.2.8 Review of Systems 10187-3

CONF-HP-83: All constraints from this section were derived from CRS. This section **SHALL** include the template identifier for the Review of Systems section (1.3.6.1.4.1.19376.1.5.3.1.3.18, as defined in the IHE PCC Technical Framework – XDS-MS). A History and Physical **SHALL** contain exactly one and **SHALL NOT** contain more than one Review of Systems section (templateId 3.6.1.4.1.19376.1.5.3.1.3.18). The Review of Systems section **SHALL** contain a narrative block and **SHOULD** contain clinical statements.

The review of systems is a relevant collection of symptoms and function systematically gathered by a clinician. It includes symptoms the patient is currently experiencing, some of which were not elicited during the history of present illness, as well as a potentially large number of pertinent negatives, e.g., symptoms that the patient was specifically asked if they had experienced or were currently experiencing, but had denied experiencing.

```
<component>
  <section>
    <templateId root= 1.3.6.1.4.1.19376.1.5.3.1.3.18"/>
    <code code='10187-3' codeSystem='2.16.840.1.113883.6.1'
        displayName='REVIEW OF SYSTEMS'/>
    <title>REVIEW OF SYSTEMS</title>
    <text>Review of systems otherwise negative.</text>
  </section>
</component>
```

Figure 46: Review of systems example

4.2.9 Physical Examination 29545-1

The Physical Examination section includes direct observations made by the clinician. The examination may include the use of simple instruments and may also describe simple maneuvers performed directly on the patient's body. This section only includes observations made by the examining clinician using inspection, palpation, auscultation, and percussion; it does not include laboratory or imaging findings. The exam may be limited to pertinent body systems based on the patient's chief complaint or it may include a comprehensive examination. The examination may be reported as a collection of random clinical statements or it may be reported categorically. Categorical report formats may be divided into multiple subsections, including Vital Signs, General Status, and any of the subsections listed in Appendix D — List of Additional Physical

Examination Subsections. Note that Vital Signs can be a top-level section or subsection of Physical Exam.

CONF-HP-84: A History and Physical **SHALL** contain exactly one Physical Examination section (templateId 2.16.840.1.113883.10.20.2.10).

CONF-HP-85: The section code for the section describing physical examination **SHALL** be *29545-1* (PHYSICAL FINDINGS).

The physical findings included in this section describe direct observations made by the clinician divided by organ or body system and may be included under appropriate subsections to Physical Exam. Systems are typically listed cephalic to caudal (i.e., starting with the head) and may include all body systems or only those pertinent to the chief complaint. The head, eyes, ears, nose, throat, mouth, and teeth may be described separately or combined into a single subsection labeled "HEENT." Other subsections may include Skin, Neck, Lymph Nodes, Thorax (Chest) and Lungs, Cardiovascular, Breasts, Abdomen, Pelvic, Genitourinary, Musculoskeletal, Extremities including Peripheral Vascular, and Neurologic. A detailed Mental Status Examination may be included when pertinent.

The Physical Examination section may contain multiple nested subsections: Vital Signs, General Status, and those listed in Appendix D — List of Additional Physical Examination Subsections.

```
<component>
 <section>
  <templateId root="2.16.840.1.113883.10.20.2.10"/>
  <code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
      code="29545-1" displayName="PHYSICAL FINDINGS"/>
  <title>PHYSICAL EXAMINATION</title>

  <component>
   <section>
    <templateId root="2.16.840.1.113883.10.20.2.4"/>
    <code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
        code="8716-3" displayName="VITAL SIGNS"/>
   <title>VITAL SIGNS</title>
    <text>
     <paragraph>Heart Rate: 78, Respiratory Rate: 12, Temp (degF): 96.7, Oxygen Sat (%): 100.</paragraph>
     <paragraph>Non-invasive Blood Pressure: Systolic: 107, Diastolic: 51, Mean: 64.</paragraph>
    </text>
   </section>
  </component>

  <component>
   <section>
    <templateId root="2.16.840.1.113883.10.20.2.5"/>
    <code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
        code="10210-3" displayName="GENERAL STATUS "/>
     <title>GENERAL STATUS</title>
    <text>
     <paragraph>Alert and in good spirits, no acute distress. </paragraph>
    </text>
   </section>
  </component>

   <component>
    <section>
     <code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
       code="51850-6" displayName="HEENT"/>
     <title>HEENT</title>
      <text> <content>All normal to examination.</content>
      </text>
     </section>
   </component>
   <component>
    <section>
     <code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
        code="10200-4" displayName="HEART"/>
    <title>HEART</title>
     <text>
      <content> RRR, no murmur.</content>
     </text>
    </section>
   </component>
      ...
 </section>
</component>
```

Figure 47: Physical examination with subsections example

4.2.10 Vital Signs 8716-3

The Vital Signs section contains measured vital signs at the time of the examination. Measurements may include some or all of the following: blood pressure, heart rate, respiratory rate, body temperature, and pulse oximetry. Comments on relative trends may be appropriate, but not required. This section can be a first-level section or nested under Physical Exam.

CONF-HP-86: A History and Physical **SHALL** contain exactly one Vital Signs section (templateId 2.16.840.1.113883.10.20.2.4). The Vital Signs section **MAY** be contained within a History and Physical Examination section or **MAY** stand alone in a first level section.

CONF-HP-87: The section code for the section describing vital signs in a conforming History and Physical **SHALL** be *8716-3* (VITAL SIGNS).). The Vital Signs section **SHALL** contain a narrative block, and **SHOULD** contain clinical statements. Level 3 clinical statements **SHOULD** include one or more CCD vital signs organizers (templateId 2.16.840.1.113883.10.20.1.35), each of which **SHALL** contain one or more CCD result observations (templateId 2.16.840.1.113883.10.20.1.31).

4.2.11 General Status 10210-3

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

CONF-HP-88: A History and Physical Examination section **MAY** contain exactly one General Status section (templateId 2.16.840.1.113883.10.20.2.5).

CONF-HP-89: The section code for the section describing General Status **SHALL** be 10210-3 [GENERAL STATUS, PHYSICAL FINDINGS).

4.2.12 Diagnostic Findings 30954-2

CONF-HP-90: All constraints from this section are from the CCD Results section. See Appendix B — Externally Defined Constraints for CCD conformance requirements. This section **SHALL** include the CCD template identifier for the diagnostic findings section (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, echocardiography, nuclear medicine, pathology, and procedure observations. The section often includes notable results such as abnormal values or relevant trends, and could contain all results for the period of time being documented.

In some situations, such as in the emergency department and pending surgery, diagnostic findings are not available when a History and Physical is released. As explained in Section 4.1 Section Descriptions above, a required section for which no content is available must contain some indication that no content is available.

Laboratory results are typically generated by laboratories providing analytic services in areas such as chemistry, hematology, serology, histology, cytology, anatomic pathology,

microbiology, and/or virology. These observations are based on analysis of specimens obtained from the patient and submitted to the laboratory.

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

Procedure results are typically generated by a clinician 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.

```
<component>
<section>
  <templateId root="2.16.840.1.113883.10.20.1.14"/>
  <code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
      code="30954-2" displayName="RELEVANT DIAGNOSTIC TESTS AND/OR LABORATORY DATA"/>
  <title>DIAGNOSTIC FINDINGS</title>
  <text>
    <table>
      <tbody>
        <tr><td colspan="2">LABORATORY INFORMATION</td></tr>
        <tr><td colspan="2">Chemistries and drug levels</td></tr>
        <tr><td>Sodium</td><td>138</td></tr>
        ...
        <tr><td colspan="2">ELECTROCARDIOGRAM (EKG) INFORMATION</td></tr>
        <tr><td>EKG</td><td>Sinus rhythm without acute changes.</td></tr>
      </tbody>
    </table>
  </text>
</section>
</component>
```

Figure 48: Diagnostic findings example

4.2.13 Assessment and Plan 51847-2/51848-0/18776-5

A History and Physical contains either discrete sections for Assessment and for Plan or a single section combining the two (Assessment and Plan).

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

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

The assessment and plan may be interleaved or dictated as separate sections to meet local policy requirements

CONF-HP-91: When the Assessment and Plan are recorded separately, there **SHALL** be a section whose value for "Section / code" **SHALL** be "51848-0" "Assessment" 2.16.840.1.113883.6.1 LOINC STATIC The template identifier for the Assessment section shall be 2.1.6.840.1.113883.10.20.2.7; **AND** there **SHALL** be a section whose value for "Section / code" **SHALL** be "18776-5" "Plan" 2.16.840.1.113883.6.1 LOINC STATIC; The template identifier for the Plan section shall be 2.16.840.1.113883.10.20.2.7 **AND** there **SHALL NOT** be a section whose value for "Section / code" is "*51847-2*" "ASSESMENT **AND** PLAN."

CONF-HP-92: . When the Assessment and Plan and are recorded together, the value for "Section / code" **SHALL** be "*51847-2*" "Assessment + "Plan" 2.16.840.1.113883.6.1 LOINC STATIC; **AND** there **SHALL NOT** be a section whose value for "Section / code" is "51848-0" "Assessment"; **AND** there **SHALL NOT** be a section whose value for "Section / code" is "*18776-5*" "Plan." The template identifier for the assessment and plan section shall be 2.16.840.1.113883.10.20.2.7

```
<component>
  <section>
    <templateId root="2.16.840.1.113883.10.20.2.7"/>
    <code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
        code="51847-2" displayName="ASSESSMENT AND PLAN"/>
    <title>ASSESSMENT AND PLAN</title>
    <text>
      <list listType="ordered">
        <item>Recurrent GI bleed of unknown etiology; hypotension perhaps secondary to this but as likely
secondary to polypharmacy.</item>
        <item>Acute on chronic anemia secondary to #1.</item>
        <item>Azotemia, Acute renal failure with volume loss secondary to #1.</item>
        <item>Hyperkalemia secondary to #3 and on ACE and K+ supplement.</item>
        <item>Other chronic diagnoses as noted above, currently stable: ? hx adrenal insufficiency.</item>
        <item>I discussed the patient with Dr Olaf who will see him in the AM. There is no plan at this point for repeat
endoscopy .If the patient .... .... ....</item>
      </list>
    </text>
</section>
</component>
```

Figure 49: Assessment and plan example

4.3 Optional Sections

A History and Physical may contain optional sections that provide additional information, such as Mental Status Examination. As previously stated, when present, these sections need to be readily identifiable by their title.

Sections 4.3.1 through 4.3.4 provide guidance on commonly found optional sections: Problems, Procedure History, and Immunizations. Please keep in mind that these may either be top-level sections or nested subsections.

In addition, users may insert additional sections that conform to general CDA constraints to cover aspects of a report that are not described in one of the required or optional sections of this DSTU. These additional sections should use a LOINC® code to

identify section content and must at least have a code element as stated in CONF-HP-63.

4.3.1 Problems 11450-4

All constraints from this section are from CCD. See Appendix B — Externally Defined Constraints for CCD conformance requirements.

CONF-HP-93: The CCD template identifier for the Problems section is 2.16.840.1.113883.10.20.1.11. This is the template that **SHALL** be used for a problems section when present.

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

This section is optional because the information contained in it may also appear in the Past Medical History section or the History of Present Illness section. When a problem list is inserted into either of these sections, it should use the CCD template.

4.3.2 Procedure History 47519-4

All constraints from this section are from CCD. See Appendix B — Externally Defined Constraints for CCD conformance requirements.

This section is optional because the information contained in it may also appear in the Past Medical History section or the History of Present Illness section. When a problem list is inserted into either of these sections, it should use the CCD template.

CONF-HP-94: Procedure History **MAY** be in its own section or it **MAY** be contained as a subsection within the Past Medical History section.

CONF-HP-95: The CCD template identifier for the Procedure History section is 2.16.840.1.113883.10.20.1.12. This is the template that **SHALL** be used for a procedure history section when present.

The sample representation below is a table with the name of the procedure in the first column, the date of the procedure in the second column, and the location in the final column. The section may contain free-form text or lists to represent this information.

Procedure	Date	Location
Laparoscopic Cholecystectomy	9/28/2002	City Hospital
Cesarean Section	3/22/2002	Community Hospital

Figure 50: Procedure rendering

```
<component>
  <section>
    <templateId root='2.16.840.1.113883.10.20.1.12'/>
    <code codeSystem='2.16.840.1.113883.6.1'
        code='47519-4' displayName='HISTORY OF PROCEDURES'/>
    <title>PROCEDURES</title>
    <text>
      <table border='1'>
        <thead>
          <tr>
            <th>Procedure</th><th>Date</th><th>Location</th>2.16.840.1.113883.10.20.1.12
          </tr>
        </thead>
        <tbody>
          <tr><td>Laparoscopic Cholecystectomy</td><td>9/28/2002</td>
            <td>City Hospital</td>
          </tr>
          <tr><td>Cesarean Section</td><td>3/22/2002</td>
            <td>Community Hospital</td>
          </tr>
        </tbody>
      </table>
    </text>
  </section>
</component>
```

Figure 51: Procedure history section example

4.3.3 Immunizations 11369-6

The Immunizations section provides a patient's pertinent immunization history. The Immunizations section is optional, however it is recommended that it be present when such information is available.

All constraints from this section are from CCD. See Appendix B — Externally Defined Constraints for CCD conformance requirements.

CONF-HP-96: The CCD template identifier for the Immunizations section is 2.16.840.1.113883.10.20.1.6. This is the template that **SHALL** be used for an immunizations section when present.

```
<component>
  <section>
    <templateId root="2.16.840.1.113883.10.20.1.6"/>
    <code codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
        code="11369-6" displayName="HISTORY OF IMMUNIZATIONS"/>
    <title>IMMUNIZATIONS</title>
    <text>
      ...
    </text>
  </section>
</component>
```

Figure 52: History of immunizations example

5 REFERENCES

- ASTM E2184.02: ASTM Standard Specifications for Healthcare Document Formats. Headings and subheadings used in medical reports and associated with specific report types)
- CDA: Clinical Document Architecture Release 2: Clinical Document Architecture (CDA) Release 2, May 2005
- CCD: Continuity of Care Document (CCD) ASTM/HL7
- CDAR2AIS0000R021: HL7 Additional Information Specification Implementation Guide [HL7 Attachments Special Interest Group (ASIG)]
- CDAR2AIS0004R030: Additional Information Specification 0004, Clinical Reports Attachment
- HL7 Care Record Summary (CRS): Care Record Summary (HL7)
- IHE Profiles: Patient Care Coordination Profiles (Integrating the Healthcare Enterprise)
- IHE XDS-MS: IHE Patient Care Coordination, Technical Framework, Volumes 1, 2, and 3, 10 Revision 3.0, 2007-2008
- LOINC®: Logical Observation Identifiers Names and Codes, Regenstrief Institute
- Non-CDA sample documents supplied by participating providers and vendors
- Sample CDA documents developed for local provider institutions (Mayo Clinic, University of Pittsburgh Medical Center, New York Presbyterian, and others)
- SNOMED CT®: SNOMED Clinical Terms®, 2002, SNOMED International Organization

APPENDIX A — VALIDATION

Introduction

This appendix describes the vocabularies used or defined by this Guide and the Schematron schema that may be used to validate the content of the CDA header for History and Physical documents.

Vocabulary

A number of controlled vocabularies are referenced in this document. These controlled vocabularies are defined in various supporting specifications and may be maintained by other bodies, as is the case for the LOINC® and SNOMED CT®. The Schematron schema makes use of a supporting file (voc.xml) that contains these vocabularies or applicable subsets as of the release of this Guide.

Extending the Vocabulary Tables for Local Use

An implementation that uses an extended vocabulary file to validate instances may no longer validate against the voc.xml file provided with this DSTU.[7]

The structure of this file is shown below. New entries may be added to voc.xml to extend the controlled vocabularies contained within it.

```
<systems>
  <system codeSystemName='LOINC' root='2.16.840.1.113883.6.1'>
    <code value='34117-2' displayName='HISTORY AND PHYSICAL'/>
    ...
  </system>
    ...
</systems>
```

Figure 53: voc.xml structure

The file is a collection of coding systems, each with its own name (codeSystemName). The root of a system represents the registered OID for that coding system. Within each system are code elements that provide the code value and a displayName for the code.

Administrative Contact Role Type

Certain Administrative Contact Role Type codes are used to described emergency contacts and next-of-kin. These codes are drawn from the RoleCode vocabulary. The OID of this vocabulary domain is *2.16.840.1.113883.5.111*.

---

[7] An implementation may add new vocabularies to support restriction of other elements not specified by this Implementation Guide, or may restrict existing vocabularies by removing terms and still produce valid instances. Adding new terms to the listed vocabularies may result in nonvalidation to the voc.xml file included with this Implementation Guide.

Code	Display Name	Description
ECON	emergency contact	An individual designated for contact in emergent situations.
NOK	next-of-kin	Played by an individual who is designated as the next-of-kin for another individual which scopes the role.

Table 4: Administrative Contact Role Type

Administrative Gender

Administrative Gender codes used to describe the gender of the patient **SHOULD** come from the HL7 AdministrativeGender vocabulary. The OID for this vocabulary domain is *2.16.840.1.113883.5.1*.

Code	Display Name	Description
F	Female	Female
M	Male	Male
UN	Undifferentiated	The gender of a person could not be uniquely defined as male or female, such as hermaphrodite.

Table 5: Administrative Gender

Ethnicity

Ethnicity codes used to describe the ethnicity of the patient **SHOULD** come from the HL7 Ethnicity vocabulary. The OID for this vocabulary domain is *2.16.840.1.113883.5.50*. This vocabulary is listed below.

In the United States, federal standards for classifying data on ethnicity determine the categories used by federal agencies and exert a strong influence on categorization by state and local agencies as well as private sector organizations. The federal standards do not conceptually define ethnicity and they recognize the absence of an anthropological or scientific basis for ethnicity classification. Instead, the federal standards acknowledge that ethnicity is a social-political construct in which an individual's own identification with a particular ethnicity is preferred over observer identification.

The standards specify two minimum ethnicity categories: “Hispanic or Latino” and “Not Hispanic or Latino.” The standards define a Hispanic or Latino as a person of "Mexican, Puerto Rican, Cuban, South or Central America, or other Spanish culture or origin, regardless of race." The standards stipulate that ethnicity data need not be limited to the two minimum categories, but any expansion must be collapsible to those categories. In addition, the standards stipulate that an individual can be Hispanic or Latino or can be Not Hispanic or Latino, but cannot be both.

Category	Code	Display Name or Mnemonic
EthnicityHispanic	2135-2	EthnicityHispanic
	2182-4	Cuban
	2184-0	Dominican
EthnicityHispanicCentralAmerican	2155-0	EthnicityHispanicCentralAmerican

Category	Code	Display Name or Mnemonic
	2163-4	Canal Zone
	2162-6	Central American Indian
	2156-8	Costa Rican
	2157-6	Guatemalan
	2158-4	Honduran
	2159-2	Nicaraguan
	2160-0	Panamanian
	2161-8	Salvadoran
EthnicityHispanicMexican	2148-5	EthnicityHispanicMexican
	2151-9	Chicano
	2152-7	La Raza
	2149-3	Mexican American
	2153-5	Mexican American Indian
	2150-1	Mexicano
EthnicityHispanicSouthAmerican	2165-9	EthnicityHispanicSouthAmerican
	2166-7	Argentinean
	2167-5	Bolivian
	2168-3	Chilean
	2169-1	Colombian
	2176-6	Criollo
	2170-9	Ecuadorian
	2171-7	Paraguayan
	2172-5	Peruvian
	2175-8	South American Indian
	2173-3	Uruguayan
	2174-1	Venezuelan
EthnicityHispanicSpaniard	2137-8	EthnicityHispanicSpaniard
	2138-6	Andalusian
	2139-4	Asturian
	2142-8	Belearic Islander
	2145-1	Canarian
	2140-2	Castillian
	2141-0	Catalonian
	2143-6	Gallego
	2146-9	Spanish Basque
	2144-4	Valencian
	2178-2	Latin American
	2180-8	Puerto Rican
	2186-5	Not Hispanic or Latino

Table 6: EthnicityMarital Status

Marital status codes used to describe the marital status of the patient should come from the HL7 MaritalStatus vocabulary. This vocabulary is listed below. The OID for this vocabulary domain is *2.16.840.1.113883.5.2*.

Code	Display Name	Description
A	Annulled	Marriage contract has been declared null and to not have existed
D	Divorced	Marriage contract has been declared dissolved and inactive
T	Domestic partner	Person declares that a domestic partner relationship exists.
I	Interlocutory	Subject to an Interlocutory Decree.
L	Legally Separated	
M	Married	A current marriage contract is active
S	Never Married	No marriage contract has ever been entered
P	Polygamous	More than 1 current spouse
W	Widowed	The spouse has died

Table 7: Marital Status

Exceptional Values

If a value is an exceptional value (NULL-value), this specifies in what way and why proper information is missing.

Code	Display Name	Description
NI	NoInformation	No information whatsoever can be inferred from this exceptional value. This is the most general exceptional value. It is also the default exceptional value.
OTH	other	The actual value is not an element in the value domain of a variable. (e.g., concept not provided by required code system).
NINF	negative infinity	Negative infinity of numbers.
PINF	positive infinity	Positive infinity of numbers.
UNK	unknown	A proper value is applicable, but not known.
ASKU	asked but unknown	Information was sought but not found (e.g., patient was asked but did not know)
NAV	temporarily unavailable	Information is not available at this time but it is expected that it will be available later.
NASK	not asked	This information has not been sought (e.g., patient was not asked)
TRC	trace	The content is greater than zero, but too small to be quantified.
MSK	masked	There is information on this item available but it has not been provided by the sender due to security, privacy or other reasons.

Code	Display Name	Description
		There may be an alternate mechanism for gaining access to this information. Note: using this null flavor does provide information that may be a breach of confidentiality, even though no detail data is provided. Its primary purpose is for those circumstances where it is necessary to inform the receiver that the information does exist without providing any detail.
NA	not applicable	No proper value is applicable in this context (e.g., last menstrual period for a male).
NP	not present	Value is not present in a message. This is only defined in messages, never in application data! All values not present in the message must be replaced by the applicable default, or no-information (NI) as the default of all defaults.

Table 8: Exceptional Values

Personal Relationship Role Type

The Personal Relationship Role Type provides more information about the link between two people in a personal relationship. These codes are drawn from the RoleCode vocabulary. The OID of this vocabulary domain is *2.16.840.1.113883.5.111*. As used within this DSTU, the scoping person is the patient.

Category	Code	Display Name	Description
FamilyMember			
Child	*CHILD*	Child	The player of the role is a child of the scoping entity.
AdoptedChild	*CHLDADOPT*	adopted child	The player of the role is a child taken into a family through legal means and raised by the scoping person (parent) as his or her own child.
	DAUADOPT	adopted daughter	The player of the role is a female child taken into a family through legal means and raised by the scoping person (parent) as his or her own child.
	SONADOPT	adopted son	The player of the role is a male child taken into a family through legal means and raised by the scoping person (parent) as his or her own child.
ChildInLaw	*CHLDINLAW*	child in-law	The player of the role is the spouse of scoping person's child.
	DAUINLAW	daughter in-law	The player of the role is the wife of scoping person's son.
	SONINLAW	son in-law	The player of the role is the husband of scoping person's daughter.
FosterChild	*CHLDFOST*	foster child	The player of the role is a child receiving parental care and nurture from the scoping person (parent) but not related to him or her through legal or blood ties.
	DAUFOST	foster daughter	The player of the role is a female child receiving parental care and nurture from the scoping person but not related to him or her through legal or blood ties.
	SONFOST	foster son	The player of the role is a male child receiving parental care and nurture from the scoping person (parent) but not related to him or her through legal or blood ties.
NaturalChild	*NCHILD*	natural child	The player of the role is an offspring of the scoping entity as determined by birth.
	DAU	natural daughter	The player of the role is a female offspring of the scoping entity (parent).
	SON	natural son	The player of the role is a male offspring of the scoping entity (parent).
StepChild	*STPCHLD*	step child	The player of the role is a child of the scoping person's spouse by a previous union.
	STPDAU	stepdaughter	The player of the role is a daughter of the scoping person's spouse by a previous union.

Category	Code	Display Name	Description
	STPSON	stepson	The player of the role is a son of the scoping person's spouse by a previous union.
GrandChild	*GRNDCHILD*	grandchild	The player of the role is a child of the scoping person's son or daughter.
	GRNDDAU	granddaughter	The player of the role is a daughter of the scoping person's son or daughter.
	GRNDSON	grandson	The player of the role is a son of the scoping person's son or daughter.
Grandparent	*GRPRN*	Grandparent	The player of the role is a parent of the scoping person's mother or father.
	GRFTH	Grandfather	The player of the role is the father of the scoping person's mother or father.
	GRMTH	Grandmother	The player of the role is the mother of the scoping person's mother or father.
GreatGrandparent	*GGRPRN*	great grandparent	The player of the role is a parent of the scoping person's grandparent.
	GGRFTH	great grandfather	The player of the role is the father of the scoping person's grandparent.
	GGRMTH	great grandmother	The player of the role is the mother of the scoping person's grandparent.
NieceNephew	*NIENEPH*	niece/nephew	The player of the role is a child of scoping person's brother or sister or of the brother or sister of the scoping person's spouse.
	NEPHEW	nephew	The player of the role is a son of the scoping person's brother or sister or of the brother or sister of the scoping person's spouse.
	NIECE	niece	The player of the role is a daughter of the scoping person's brother or sister or of the brother or sister of the scoping person's spouse.
Parent	*PRN*	Parent	The player of the role is one who begets, gives birth to, or nurtures and raises the scoping entity (child).
NaturalParent	*NPRN*	natural parent	
	NFTH	natural father	The player of the role is a male who begets the scoping entity (child).
	NMTH	natural mother	The player of the role is a female who conceives or gives birth to the scoping entity (child).
ParentInLaw	*PRNINLAW*	parent in-law	The player of the role is the parent of scoping person's husband or wife.
	FTHINLAW	father-in-law	The player of the role is the father of the scoping person's husband or wife.
	MTHINLOAW	mother-in-law	The player of the role is the mother of the scoping person's husband or wife.
StepParent	*STPPRN*	step parent	The player of the role is the spouse of the scoping person's parent and not the scoping person's natural parent.

Category	Code	Display Name	Description
	STPFTH	stepfather	The player of the role is the husband of scoping person's mother and not the scoping person's natural father.
	STPMTH	stepmother	The player of the role is the wife of scoping person's father and not the scoping person's natural mother.
	FTH	Father	The player of the role is a male who begets or raises or nurtures the scoping entity (child).
	MTH	Mother	The player of the role is a female who conceives, gives birth to, or raises and nurtures the scoping entity (child).
Sibling	*SIB*	Sibling	The player of the role shares one or both parents in common with the scoping entity.
HalfSibling	*HSIB*	half-sibling	The player of the role is related to the scoping entity by sharing only one biological parent.
	HBRO	half-brother	The player of the role is a male related to the scoping entity by sharing only one biological parent.
	HSIS	half-sister	The player of the role is a female related to the scoping entity by sharing only one biological parent.
NaturalSibling	*NSIB*	natural sibling	The player of the role has both biological parents in common with the scoping entity.
	NBRO	natural brother	The player of the role is a male having the same biological parents as the scoping entity.
	NSIS	natural sister	The player of the role is a female having the same biological parents as the scoping entity.
SiblingInLaw	*SIBINLAW*	sibling in-law	The player of the role is: (1) a sibling of the scoping person's spouse, or (2) the spouse of the scoping person's sibling, or (3) the spouse of a sibling of the scoping person's spouse.
	BROINLAW	brother-in-law	The player of the role is: (1) a brother of the scoping person's spouse, or (2) the husband of the scoping person's sister, or (3) the husband of a sister of the scoping person's spouse.
	SISLINLAW	sister-in-law	The player of the role is: (1) a sister of the scoping person's spouse, or (2) the wife of the scoping person's brother, or (3) the wife of a brother of the scoping person's spouse.
StepSibling	*STPSIB*	step sibling	The player of the role is a child of the scoping person's stepparent.
	STPBRO	stepbrother	The player of the role is a son of the scoping person's stepparent.
	STPSIS	stepsister	The player of the role is a daughter of the scoping person's stepparent.
	BRO	Brother	The player of the role is a male sharing one or both parents in common with the scoping entity.

Category	Code	Display Name	Description
	SIS	Sister	The player of the role is a female sharing one or both parents in common with the scoping entity.
SignificantOther RoleType	*SIGOTHR*	significant other	A person who is important to one's well being; especially a spouse or one in a similar relationship. (The player is the one who is important)
Spouse	*SPS*	spouse	The player of the role is a marriage partner of the scoping person.
	HUSB	husband	The player of the role is a man joined to a woman (scoping person) in marriage.
	WIFE	wife	The player of the role is a woman joined to a man (scoping person) in marriage.
	AUNT	aunt	The player of the role is a sister of the scoping person's mother or father.
	COUSN	cousin	The player of the role is a relative of the scoping person descended from a common ancestor, such as a grandparent, by two or more steps in a diverging line.
	DOMPART	domestic partner	The player of the role cohabits with the scoping person but is not the scoping person's spouse.
	ROOM	Roomate	One who shares living quarters with the subject.
	UNCLE	uncle	The player of the role is a brother of the scoping person's mother or father.
	FRND	unrelated friend	The player of the role is a person who is known, liked, and trusted by the scoping person.
	NBOR	neighbor	The player of the role lives near or next to the scoping person.

Table 9: Personal Relationship Role Type

Race

Race codes used to describe the race of the patient should come from the HL7 Race vocabulary. This vocabulary is too extensive to list in this document. The OID for this vocabulary domain is *2.16.840.1.113883.5.104*.

In the United States, federal standards for classifying data on race determine the categories used by federal agencies and exert a strong influence on categorization by state and local agencies and private sector organizations. The federal standards do not conceptually define race and they recognize the absence of an anthropological or scientific basis for racial classification. Instead, the federal standards acknowledge that race is a social-political construct in which an individual's own identification with one or more race categories is preferred over observer identification. The standards use a variety of features to define five minimum race categories. Among these features are descent from the “original peoples" of a specified region or nation. The minimum race categories are American Indian or Alaska Native, Asian, Black or African-American, Native Hawaiian or Other Pacific Islander, and White. The federal standards stipulate

that race data need not be limited to the five minimum categories, but any expansion must be collapsible to those categories.

SNOMED CT®

SNOMED Clinical Terms® (SNOMED CT®) is a comprehensive clinical terminology that provides clinical content and expressivity for clinical documentation and reporting. It is published by SNOMED International and is made available free of charge in the United States by the U.S. National Library of Medicine.

This DSTU uses SNOMED CT® to classify providers of health care. The OID for SNOMED CT® is *2.16.840.1.113883.6.96*.

APPENDIX B — EXTERNALLY DEFINED CONSTRAINTS

Introduction

This appendix lists all of the external conformance statements referenced from the body of this document. For a complete description of these constraints, please refer to the original specification they were derived from.

CCD Constraints

The following constraints are from the final publication of CCD dated April 1, 2007. Any discrepancy between this and the original is inadvertent and in all cases, the CCD source takes precedence.

Medications (Template ID: 2.16.840.1.113883.10.20.1.8)

CCD-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).

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

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

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

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

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

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

CCD-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**.

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

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

CCD-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).

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

CCD-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.

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

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

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

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

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

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

CCD-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**.

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

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

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

CCD-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").

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

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

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

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

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

CCD-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.

CCD-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.

CCD-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.

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

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

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

CCD-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**.

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

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

CCD-CONF-337: The value for "**Act** / **@moodCode**" in a fulfillment instruction **SHALL** be "INT" "Intent" 2.16.840.1.113883.5.1001 ActMood **STATIC**.

CCD-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**.

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

CCD-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**.

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

CCD-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**.

CCD-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**.

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

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

CCD-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**.

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

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

CCD-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.

CCD-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**.

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

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

CCD-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*).

CCD-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.

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

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

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

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

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

CCD-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, or **MAY** be selected from ValueSet 2.16.840.1.113883.1.11.20.8 MedicationTypeCode **STATIC** 20061017.

CCD-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").

CCD-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.

CCD-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.

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

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

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

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

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

CCD-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 ***3.15.2.2 Procedure related products***), to identify a particular product instance.

CCD-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 **3.15.2.2 Procedure related products**), to identify a particular product instance.

CCD-CONF-370: Supply / participant / participantRole / id **SHOULD** be set to equal a [Act | Observation | Procedure] / participant / participantRole / id (see section *3.15.2.2 Procedure related products*) to indicate that the Supply and the Procedure are referring to the same product instance.

Allergies (Template ID 2.16.840.1.113883.10.20.1.2)

Note: This Section is titled "Alerts" in CCD

CCD-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).

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

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

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

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

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

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

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

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

CCD-CONF-266: The value for "**Observation** / **statusCode**" in an alert observation **SHALL** be "completed" 2.16.840.1.113883.5.14 ActStatus **STATIC**.

CCD-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).

CCD-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.

CCD-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**.

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

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

CCD-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*).

CCD-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.

CCD-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.

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

CCD-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**.

CCD-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**.

CCD-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**.

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

CCD-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 .

CCD-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.

CCD-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**.

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

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

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

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

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

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

CCD-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**.

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

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

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

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

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

CCD-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**.

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

CCD-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**.

CCD-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.

Social History (Template ID: 2.16.840.1.113883.10.20.1.15)

CCD-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).

CCD-CONF-233: The Social History section **SHALL** contain **Section** / **code**.

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

CCD-CONF-235: The Social History section **SHALL** contain **Section** / **title**.

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

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

CCD-CONF-237: The value for "**Observation** / **@classCode**" in a social history observation **SHALL** be "OBS" 2.16.840.1.113883.5.6 ActClass **STATIC**.

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

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

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

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

CCD-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.

CCD-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.

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

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

CCD-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*).

CCD-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.

CCD-CONF-249: A social history observation **MAY** contain exactly one episode observation (templateId 2.16.840.1.113883.10.20.1.41) (see section ***3.6.2.3 Episode observations***).

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

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

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

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

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

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

Family History (Template ID: 2.16.840.1.113883.10.20.1.4)

CCD-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).

CCD-CONF-185: The Family History section **SHALL** contain **Section** / **code**.

CCD-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**.

CCD-CONF-187: The Family History section **SHALL** contain **Section** / **title**.

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

CCD-CONF-189: The Family History section **SHALL NOT** contain **Section** / **subject**.

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

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

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

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

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

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

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

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

CCD-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.

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

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

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

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

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

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

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

CCD-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.

CCD-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 *3.6.2.2 Representation of "status" values*).

CCD-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.

CCD-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 .

CCD-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.

CCD-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.

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

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

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

CCD-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**.

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

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

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

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

CCD-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).

CCD-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).

CCD-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**.

CCD-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**.

CCD-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.

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

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

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

CCD-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**.

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

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

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

Diagnostic Findings (Template ID: 2.16.840.1.113883.10.20.1.14)

Note: This section is titled "Results" in CCD.

CCD-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).

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

CCD-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**.

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

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

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

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

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

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

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

CCD-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**.

CCD-CONF-399: A result organizer **SHOULD** include one or more **Organizer** / **specimen** if the specimen is not inherent in **Organizer** / **code**.

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

CCD-CONF-402: **Organizer** / **specimen** / **specimenRole** / **id** **SHOULD** be set to equal a **Procedure** / **specimen** / **specimenRole** / **id** (see section ***3.15 Procedures***) to indicate that the Results and the Procedure are referring to the same specimen.

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

CCD-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 is not inherent in **Organizer** / **code** or if there is a need to further specialize the **Organizer** / **code** value.

CCD-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).

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

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

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

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

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

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

CCD-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).

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

CCD-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).

CCD-CONF-414: A result observation **MAY** contain exactly one **Observation** / **methodCode** if the method is not inherent in **Observation** / **code** or if there is a need to further specialize the method in **Observation** / **code**.

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

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

CCD-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.

CCD-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 "normal", "abnormal", resistant", "susceptible", etc. Interpretation is generally provided for numeric results where an interpretation range has been defined, or for antimicrobial susceptibility test interpretation.

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

CCD-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.

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

Problems (Template ID: 2.16.840.1.113883.10.20.1.11)

CCD-CONF-140: CCD **SHOULD** contain exactly one and **SHALL NOT** contain more than one Problems section (templateId 2.16.840.1.113883.10.20.1.11). The Problems 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 problem observations (templateId 2.16.840.1.113883.10.20.1.28).

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

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

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

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

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

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

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

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

CCD-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**.

CCD-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).

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

CCD-CONF-152: A problem act **MAY** reference a problem observation, alert observation (see section ***3.9 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**.

CCD-CONF-153: The target of a problem act with A**ct** / **entryRelationship** / **@typeCode="SUBJ"** **SHOULD** be a problem observation (in the Problems section) or alert observation (in the Alerts section, see section ***3.9 Alerts***), but **MAY** be some other clinical statement.

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

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

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

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

CCD-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).

CCD-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.

CCD-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).

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

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

CCD-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*).

CCD-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.

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

CCD-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**.

CCD-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.

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

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

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

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

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

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

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

CCD-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>

CCD-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** . This is used to link the episode observation to the target problem act or social history observation.

CCD-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.

CCD-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.

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

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

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

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

CCD-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**.

Immunizations (Template ID: 2.16.840.1.113883.10.20.1.6)

CCD-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).

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

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

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

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

Procedures (Template ID: 2.16.840.1.113883.10.20.1.12)

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

CCD-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).

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

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

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

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

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

CCD-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**.

CCD-CONF-420: A procedure activity **SHALL** contain at least one **[Act | Observation | Procedure] / id**.

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

CCD-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.

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

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

CCD-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).

CCD-CONF-435: A procedure activity **MAY** contain one or more **[Observation | Procedure] / methodCode** if the method is not 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.**

CCD-CONF-436A: 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 is not 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**.

CCD-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* within CCD for more on referencing within CCD) to represent where the procedure was performed.

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

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

CCD-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.

CCD-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* within CCD), to represent any additional information provided to a patient related to the procedure.

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

CCD-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.

CCD-CONF-444: **Procedure / specimen / specimenRole / id SHOULD** be set to equal an **Organizer / specimen / specimenRole / id** (see section *3.14 Results*) to indicate that the Procedure and the Results are referring to the same specimen.

CCD-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).8

CCD-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* within CCD), to describe substances administered during the procedure.

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

CCD-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.

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

CCD-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**.

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

CCD-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* within CCD) to indicate that the Procedure and the Supply are referring to the same product instance.

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

CRS Constraints

History of Present Illness (Template ID: 1.3.6.1.4.1.19376.1.5.3.1.3.4)

CRS-L2-14: The LOINC section type code for the section describing the History of Present Illness in a Level 2-conforming Care Record Summary **SHALL** be 10164-2 (HISTORY OF PRESENT ILLNESS).

Review of Systems (Template ID: 1.3.6.1.4.1.19376.1.5.3.1.3.18)

CRS-L2-22: The LOINC section code used for the section describing the Review of Systems in a Level 2-conforming Care Record Summary **SHALL** be 10187-3 (REVIEW OF SYSTEMS).

APPENDIX C — TEMPLATE IDS DEFINED IN THIS DSTU

Template ID	Description
2.16.840.1.113883.10.20.3	CDA for common document types, general header constraints
2.16.840.1.113883.10.20.10	Conforms to Level 1
2.16.840.1.113883.10.20.20	Conforms to Level 2
2.16.840.1.113883.10.20.30	Conforms to Level 3
2.16.840.1.113883.10.20.2	H&P v1.0 Templates Root
2.16.840.1.113883.10.20.2.4	Vital Signs
2.16.840.1.113883.10.20.2.5	General Status Physical Findings
2.16.840.1.113883.10.20.2.7	Assessment and Plan
2.16.840.1.113883.10.20.2.8	Reason for Visit / Chief Complaint
2.16.840.1.113883.10.20.2.9	Past Medical History
2.16.840.1.113883.10.20.2.10	Physical Examination

APPENDIX D — LIST OF ADDITIONAL PHYSICAL EXAMINATION SUBSECTIONS

Below is the list of additional optional subsections that **MAY** be used under the Physical Examination section. Most of the codes for these subsections are included in the HL7 document entitled "CDAR2AIS0004R030, Additional Information Specification 0004: Clinical Reports Attachment," which also lists General Status (10210-3) and Vital Signs (8716-3), defined in the body of this Guide.

10190-7	MENTAL STATUS
11451-2	PSYCHIATRIC FINDINGS
10199-8	HEAD, PHYSICAL FINDINGS
10197-2	EYE, PHYSICAL FINDINGS
10195-6	EAR, PHYSICAL FINDINGS
10203-8	NOSE, PHYSICAL FINDINGS
11393-6	EARS & NOSE & MOUTH & THROAT, PHYSICAL FINDINGS
10201-2	MOUTH & THROAT & TEETH, PHYSICAL FINDINGS
51850-6	HEAD & EARS & EYES & NOSE & THROAT, PHYSICAL FINDINGS
11411-6	NECK, PHYSICAL FINDINGS
10207-9	THORAX & LUNGS, PHYSICAL FINDINGS
11391-0	CHEST, PHYSICAL FINDINGS
11392-8	CHEST WALL, PHYSICAL FINDINGS
10200-4	HEART, PHYSICAL FINDINGS
10193-1	BREASTS, PHYSICAL FINDINGS
10192-3	BACK, PHYSICAL FINDINGS
10191-5	ABDOMEN, PHYSICAL FINDINGS
10204-6	PELVIS, PHYSICAL FINDINGS
11403-3	GROIN, PHYSICAL FINDINGS
10198-0	GENITOURINARY TRACT, PHYSICAL FINDINGS
11400-9	GENITALIA, PHYSICAL FINDINGS
11401-7	GENITALIA FEMALE, PHYSICAL FINDINGS
11402-5	GENITALIA MALE, PHYSICAL FINDINGS
11388-6	BUTTOCKS, PHYSICAL FINDINGS
10205-3	RECTUM, PHYSICAL FINDINGS
10196-4	EXTREMITIES, PHYSICAL FINDINGS
11413-2	SHOULDER, PHYSICAL FINDINGS
11387-8	AXILLA, PHYSICAL FINDINGS
11386-0	UPPER ARM, PHYSICAL FINDINGS
11394-4	ELBOW, PHYSICAL FINDINGS
11398-5	FOREARM, PHYSICAL FINDINGS
11415-7	WRIST, PHYSICAL FINDINGS
11404-1	HAND, PHYSICAL FINDINGS
11406-6	HIP, PHYSICAL FINDINGS

11414-0 THIGH, PHYSICAL FINDINGS
11407-4 KNEE, PHYSICAL FINDINGS
11389-4 CALF, PHYSICAL FINDINGS
11385-2 ANKLE, PHYSICAL FINDINGS
11397-7 FOOT, PHYSICAL FINDINGS
10209-5 BALANCE+COORDINATION, PHYSICAL FINDINGS
10212-9 STRENGTH PHYSICAL FINDINGS
10211-1 SENSATION, PHYSICAL FINDINGS
10206-1 SKIN, PHYSICAL FINDINGS
10194-9 DEEP TENDON REFLEXES, PHYSICAL FINDINGS
10208-7 VESSELS, PHYSICAL FINDINGS
11384-5 PHYSICAL EXAMINATION BY ORGAN SYSTEMS
11447-0 HEMATOLOGIC+LYMPHATIC+IMMUNOLOGIC PHYSICAL FINDINGS
11390-2 CARDIOVASCULAR SYSTEM, PHYSICAL FINDINGS
11399-3 GASTROINTESTINAL SYSTEM, PHYSICAL FINDINGS
10202-0 NEUROLOGIC SYSTEM, PHYSICAL FINDINGS
11410-8 MUSCULOSKELETAL SYSTEM, PHYSICAL FINDINGS

APPENDIX E — SECTION CARDINALITY

The following table summarizes the use of sections within the CCD, this DSTU, and the draft Consult Note DSTU.

Section	CCD	H&P	Consultation	Defined In
Reason for Visit/Chief Complaint *	N/A	R	N/A	H&P
Reason for Referral **	N/A	N/A	R	Consultation
History of Present Illness	N/A	R	R	CRS
Past Medical History	N/A	R	O	H&P
Allergies/Alerts	O	R	O	CCD
Physical Examination	N/A	R	R	H&P
Physical Examination—General Status	N/A	O	O	H&P
Review of Systems	N/A	R	O	CRS
Vital Signs	O	R	O	H&P/CRS
Results/Diagnostic Findings	O	R	O	CCD
Family History	O	R	O	CCD
Social History	O	R	O	CCD
Medications	O	R	O	CCD
Assessment***	N/A	R	R	H&P
Plan/Plan of Care ***	O	R	R	CCD
Problems	O	O	O	CCD
Procedures/Procedure History ****	O	O	O	CCD
Immunizations	O	O	O	CCD
Functional Status	O	N/A	N/A	CCD
Medical Equipment	O	N/A	N/A	CCD
Encounters	O	N/A	N/A	CCD
Payers	O	N/A	N/A	CCD
Advanced Directives	O	N/A	N/A	CCD

O	Optional
R	Required
N/A	Not addressed or not applicable
*	Reason for Visit/Chief Complaint may be combined or in two separate sections
**	May substitute Reason for Visit
***	Assessment and Plan must be present and may be combined under a single section where required
****	Data may also be included within Past Medical History