Smart Open Services for European Patients

Open eHealth initiative for a European large scale pilot of

Patient Summary and Electronic Prescription

Work Package 3.5 - Semantic Services

Appendix C – Pivot Documents Specifications

D3.5.2

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WORK PACKAGE	**WP 3.5**
DOCUMENT VERSION	**0.0.7**
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Table of contents

For:

- Document Information
- Sub-Project Identification
- History of Alteration
- Referring Documents

Please refer to the main document:

"Semantic Services Definition D3.5.2" - D3.5.2_epSOS_WP3_5_v0.0.6_20100531.doc

Appendix C – Pivot Documents Specifications

DISCLAIMER: this document was produced based at the information at hand at the time. The reader is to be cautioned that if further, more updated information is needed, the work package 3.9 is to be consulted regarding the semantic implementation guide.

The following reference materials are of paramount importance:

- *Integrating the Healthcare Enterprise, Patient Care Coordination Technical Framework, Volume 1 and Volume 2- Revision 5, IHE International, August 10, 2009.*
- *Integrating the Healthcare Enterprise, Patient Care Coordination CDA Content Modules- Trial Implementation Supplement, August 10, 2009.*
- *HL7 Implementation Guide for CDA Release 2: History and Physical (H&P) Notes, HL7, July 16, 2008.*

1 Format Codes

The formatCode is a code globally uniquely specifying the format of the document (ITI TF-3) Cross-Transaction Specifications and Content Specifications, Revision 6.0 – Final Text, August 10, 2009

These following format codes used in epSOS to identify the <formatCode>.

Document	Format Code	Media Type	Template ID
epSOS ePrescription	urn:epSOS:ep:pre:2010	text/xml	1.3.6.1.4.1.12559.11.10.1.3.1.1.1
epSOS eDispensation	urn:epSOS:ep:dis:2010	text/xml	1.3.6.1.4.1.12559.11.10.1.3.1.1.2
epSOS Patient Summary	urn:epSOS:ps:ps:2010	text/xml	1.3.6.1.4.1.12559.11.10.1.3.1.1.3
epSOS pdf documents	urn:ihe:iti:xds-sd:pdf:2008	pdf/xml	1.3.6.1.4.1.19376.1.2.20
epSOS pdf documents	urn:ihe:iti:xds-sd:pdf:2008	text/xml	1.3.6.1.4.1.19376.1.2.20

***Table 1C** - Pivot Documents Format Codes*

2 LOINC codes

The LOINC codes proposed for the identification of the three documents are:

Document	LOINC
ePrescription	57829-4
eDispensation	DISPN-X
Patient Summary	34133-9 (this could be further changed according to the implementation group and the request made to LOINC). A note to the implementers: as you might see PCC is using the same LOINC code in several different contexts with a different, unique template ID. It is up to the implementers to discuss how to implement this).

***Table 2C** - LOINC Documents Codes*

3 Constraints

The constraints concerning the CDA Header (Level 1) can be found in the CDA for Common Document Types History and Physical Implementation Guide, in the section 2. CDA Header - General Constraints, published on July 16, 2008, as mentioned in the reference documents.

epSOS Pivot Documents **SHALL** follow all constraints found in the aforementioned section with the exception of the constraint on realm code found in **CONF-HP-15**, as follows:

Realm	Constraints	Template IDs Required
Universal	**CONF-HP-1** through **CONF-HP-14 CONF-HP-16** through **CONF-HP-67**	1.3.6.1.4.1.19376.1.5.3.1.1.1

Please do note that the specifications that this specification guide is referring to are **neither about the History and Physical document nor** about a **North American realm. These specifications deal with the universal realm. The implementers must discuss if/or what realm should be used for epSOS.** This document is taking into consideration only the header specifications for CDA documents in an attempt to make them easily implementable and conformant with the industry solutions.

The reader is considered to be familiar with these concepts. However, as a refresher, CDA provides a general architecture for clinical documents, the Continuity of Care Document (CCD) is providing constraints (additional rules pertaining to a general context of care), IHE Patient Care Coordination (IHE PCC) provides further constrains (rules) and the epSOS realm is adding its own demands on top of these constrains. This will lead to easier testing (all PCC profiles are implemented or implementable) and easily tested at events such as the Connectahon and Projectahon.

4 Style Sheets

Document sources **should** provide an XML style sheet to render the content of the Medical Summary document. The output of this style sheet **shall** be an XHTML Basic (see http://www.w3.org/TR/xhtml-basic/) document that renders the clinical content of a Medical Summary Document as closely as possible as the sending provider viewed the completed document.

When a style sheet is provided, at least one processing instruction **shall** be included in the document that including a link to the URL for the XML style sheet. In order to ensure that the style sheet is available to all receivers, more than one style sheet link may be included.

At this point no style sheet is yet defined by epSOS, this remaining a point to be discussed in the work package 3.9.

5 Standards

HL7V3 NE2006	HL7 V3 Normative Edition 2006
HL7V3 NE2008	HL7 V3 Normative Edition 2008
HL7V3 NE2009	HL7 V3 Normative Edition 2009
CDAR2	HL7 CDA Release 2.0

CDTHP	CDA for Common Document Types History and Physical Notes (DSTU)
CCD	ASTM/HL7 Continuity of Care Document
XMLXSL	Associating Style Sheets with XML documents

For more information, please refer to the references mentioned in this document's introduction as well as to the references mentioned in the main deliverable.

6 Conformance

The CDA documents that conform to the requirements of this implementation guide shall indicate their conformance by the inclusion of the appropriate <templateId> elements in the header of the document. This is shown in the sample document below:

```
<ClinicalDocument xmlns='urn:hl7-org:v3'>
  <typeId extension="POCD_HD000040" root="2.16.840.1.113883.1.3"/>
  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.1'/>
  <id root=' ' extension=' '/>
  <code code='34133-9' displayName='SUMMARIZATION OF EPISODE NOTE'
    codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
  <title>epSOS Patient Summary</title>
  <effectiveTime value='20081004012005'/>
  <confidentialityCode code='N' displayName='Normal'
    codeSystem='2.16.840.1.113883.5.25' codeSystemName='Confidentiality' />
  <languageCode code='en'/>
     :
  <component>
     <structuredBody>
        .
        .
     </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 1C - Sample epSOS Document Identification

7 Mapping on the CDA templates - Header

The header specifications apply to all three documents. If special elements are needed for a particular type of document (such as ePrescription, eDispensation or Patient Summary), this shall be indicated.

The data elements specified by the functional work packages were mapped to different parts of the CDA document structure. The CDA header contains discrete information about the patient and the context of the document. Document sections and their entries contain the relevant clinical data represented in the document and are represented in section 7 of this appendix. This will take precedence over the specifications elsewhere mentioned as it is meant to be a project-specific implementation guide, namely epSOS.

The mapping and alignment between the data elements identified by the functional groups ePrescription (WP3.1) and Patient Summary (WP3.2) onto to the corresponding CDA templates is present in order to provide a more coherent approach in terms of the epSOS pivot documents and to reduce implementers' work.

The epSOS root OID **1.3.6.1.4.1.12559.11.10.1.3** for the WP3.5. Branch 1 was allocated to WP3.5; therefore the OID for object belonging to WP3.5 is 1.3.6.1.4.1.12559.11.10.1.3.1.

The optionality is explained right underneath the data elements. The definitions are given below:

- **R**- means required, with no null flavor
- **NS**- means not specified. Whenever not specified by a functional work-package WP3.5 made the decision to render it "**O**".
- **RNFA** - means Required, Null Flavor Allowed. This will be expressed as "**R**" with the recommended nullFlavor indicated.
- **O** - means optional
- **NA** – means "not applicable" since the data element is not applicable in the respective document.

The table in section seven (7) maps the data elements present in Appendix B onto the corresponding CDA/CCD/PCC content modules. Certain implementation details were added by the semantic group 3.5 in order to respect the requirements of the standard and in order to add clarity to the documents to be created, such as "Document ID" or "Document title" for example.

Appendix C provides further detail for the implementers of these specifications.

This guide is to be used as intended - namely it is a guide for implementers but it is expected that there will be a need for fine readjustment according to the technical abilities of the Member States, the exiting solutions, and the abilities of each Member State as well as the exiting Industry Solutions.

7.1. Common Header Data Elements

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Template CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
R1	**Patient Information**	1.3.6.1.4.1.19376.1.5.3.1.1.1 /ClinicalDocument/recordTarget/patientRole			
R1.1	**Patient Name**	1.3.6.1.4.1.19376.1.5.3.1.1.1 /ClinicalDocument/recordTarget/patientRole/patient/name			
R1.1.1	**Family Name/Surname** **(Family Name/Surname)**	1.3.6.1.4.1.19376.1.5.3.1.1.1 /ClinicalDocument/recordTarget/patientRole/patient/name/family	R / R / R [1..*]	PN	
R1.1.2	**Prefix**	/ClinicalDocument/recordTarget/patientRole/patient/name/prefix/	O / O / O [0..*]	PN	HL7:EntityNamePartQualifier 2.16.840.1.113883.5.1122
R1.1.3	**Given Name** **(Given Name)**	1.3.6.1.4.1.19376.1.5.3.1.1.1 /ClinicalDocument/recordTarget/patientRole/patient/name/given	R / R / R [1..*]	PN	
R1.2	**Gender** **(Gender)**	1.3.6.1.4.1.19376.1.5.3.1.1.1 /ClinicalDocument/recordTarget/patientRole/patient/ administrativeGenderCode	R/ R/R use nullFlavor = UNK [1..1]	CE	HL7:AdministrativeGender 2.16.840.1.113883.5.1
R1.3	**Date of Birth** **(Birth Date)**	1.3.6.1.4.1.19376.1.5.3.1.1.1 /ClinicalDocument/recordTarget/patientRole/patient/birthtime	R / R / R [1..1] The patient DOB may be a partial date such as only the year.	TS	

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Template CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
R1.4	**Patient Identifiers**	1.3.6.1.4.1.19376.1.5.3.1.1.1 /ClinicalDocument/recordTarget/patientRole/id			
R1.4.1	**Primary Patient Identifier** **(Regional/National Health Id)**	1.3.6.1.4.1.19376.1.5.3.1.1.1 /ClinicalDocument/recordTarget/patientRole/id	R / R / R [1..1]	II	
R1.4.2	**Secondary Patient Identifier** **(Social/Insurance Number)**	1.3.6.1.4.1.19376.1.5.3.1.1.1 /ClinicalDocument/recordTarget/patientRole//id	O / O / O [0..*]	II	
R1.5	**Patient Address** **(Address)**	1.3.6.1.4.1.19376.1.5.3.1.1.1 /ClinicalDocument/recordTarget/patientRole/addr The patient address <addr> element is required. If there is no information, the nullFlavor attribute shall have a value of 'NI' and no address parts shall be present, otherwise there shall be no nullFlavor attribute, and at least one of the address parts listed below shall be present			
R1.5.1	**Patient's Street** **(Street)**	1.3.6.1.4.1.19376.1.5.3.1.1.1 /ClinicalDocument/recordTarget/patientRole/addr/streetAddressLine	R / R / R[1] use nullFlavor [1..*]	AD	
R1.5.2	**Patient's Number of Street**	1.3.6.1.4.1.19376.1.5.3.1.1.1 /ClinicalDocument/recordTarget/patientRole/addr/streetAddressLine	R / R / R use	AD	

[1] This element although indicated as optional by the functional work packages, will be left as R with null flavour allowed in order following as closely as possible the most common Implementation Guides, The R null flavour allowed will be added by the Transformation Manager.

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Template CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
	(Number of Street)		nullFlavor [1..*]		
R1.5.3	**Patient's City** **(City)**	1.3.6.1.4.1.19376.1.5.3.1.1.1 /ClinicalDocument/recordTarget/patientRole/addr/city	R / R / R use nullFlavor [1..*]	AD	
R1.5.4	**Patient's Postal Code** **(Postal Code)**	1.3.6.1.4.1.19376.1.5.3.1.1.1 /ClinicalDocument/recordTarget/patientRole/addr/postalCode	R / R / R use nullFlavor [1..*]	AD	
R1.5.5	**Patient's State or Province** **(State or Province)**	1.3.6.1.4.1.19376.1.5.3.1.1.1 /ClinicalDocument/recordTarget/patientRole/addr/state	R / R / R use nullFlavor [1..*]	AD	
R1.5.6	**Patient's Country** **(Country)**	1.3.6.1.4.1.19376.1.5.3.1.1.1 /ClinicalDocument/recordTarget/patientRole/addr/country	R / R / R use nullFlavor [1..*]	AD	epSOSCountry 1.3.6.1.4.1.12559.11.10.1.3.1.42.4
R1.6	**Patient's Telecommunication**	1.3.6.1.4.1.19376.1.5.3.1.1.1 /ClinicalDocument/recordTarget/patientRole/telecom The patient telephone or e-mail <telecom> element is required. If there is no information, the nullFlavor attribute shall have a value of 'NI' and the "value" and "use" attributes shall be omitted, otherwise the nullFlavor attribute shall not be present, and the "value" and "use" attributes shall be present			
R1.6.1	**Patient's telephone number**	1.3.6.1.4.1.19376.1.5.3.1.1.1 /ClinicalDocument/recordTarget/patientRole/telecom/@value	R / R / R use	TEL	HL7: URLScheme 2.16.840.1.113883.5.143

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Template CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
	(Telephone)	/ClinicalDocument/recordTarget/patientRole/telecom/@use	nullFlavor [1..*]		HL7:TelecommunicationAddressUse 2.16.840.1.113883.11.201
R1.6.2	**Patient's e-mail address** **(E-mail)**	1.3.6.1.4.1.19376.1.5.3.1.1.1 /ClinicalDocument/recordTarget/patientRole/telecom/@value /ClinicalDocument/recordTarget/patientRole/telecom/@use	R / R / R use nullFlavor [1..*]	TEL	HL7: URLScheme 2.16.840.1.113883.5.143 HL7:TelecommunicationAddressUse 2.16.840.1.113883.11.201
R1.7	**Patient's preferred language** **(Preferred Language)**	1.3.6.1.4.1.19376.1.5.3.1.2.1 /ClinicalDocument/recordTarget/patientRole/patient/languageCommunication/languageCode	R / R / R use nullFlavor [1..*]	CS	epSOSCountry 1.3.6.1.4.1.12559.11.10.1.3.1.42.4 epSOSLanguage 1.3.6.1.4.1.12559.11.10.1.3.1.42.6
R1.7.A	**Patient's Guardian**	**1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/recordTarget/patientRole/patient/guardian**	**R / R / R use nullFlavor [1..*]**	**PN**	
R1.7.A.1	**Guardian's Family Name/Surname**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/recordTarget/patientRole/patient/guardian/name/family	R / R / R use nullFlavor [1..*]	PN	
R1.7.A.2	**Guardian's Given Name**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/recordTarget/patientRole/patient/guardian/name/given	R / R / R use nullFlavor [1..*]	PN	

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Template CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
R1.7.A.3	**Guardian's Address**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/recordTarget/patientRole/patient/guardian/addr The guardian's address <addr> element is required. If there is no information, the nullFlavor attribute shall have a value of 'UNK' and no address parts shall be present, otherwise there shall be no nullFlavor attribute, and at least one of the address parts listed below shall be present			
R1.7.A.3.1	**Guardian's Street (Street)**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/recordTarget/patientRole/patient/guardian/addr/streetAddressLine	R / R / R use nullFlavor [1..*]	AD	
R1.7.A.3.2	**Guradian's Number of Street (Number of Street)**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/recordTarget/patientRole/patient/guardian/addr/streetAddressLine	R / R / R use nullFlavor [1..*]	AD	
R1.7.A.3.3	**Guradian's City (City)**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/recordTarget/patientRole/patient/guardian/addr/city	R / R / R use nullFlavor [1..*]	AD	
R1.7.A.3.4	**Guardian's Postal Code (Postal Code)**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/recordTarget/patientRole/patient/guardian/addr/postalCode	R / R / R use nullFlavor [1..*]	AD	
R1.7.A.3.5	**Guardian's State or Province (State or Province)**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/recordTarget/patientRole/patient/guardian/addr/state	R / R / R use nullFlavor [1..*]	AD	
R1.7.A.3.6	**Guardian's Country**	1.3.6.1.4.1.19376.1.5.3.1.2.4	R / R / R	AD	epSOSCountry

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Template CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
	(Country)	/ClinicalDocument/recordTarget/patientRole/patient/guardian/addr/country	use nullFlavor [1..*]		1.3.6.1.4.1.12559.11.10.1.3.1.42.4
R1.7.A.4	**Guardian's Telecommunication**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/recordTarget/patientRole/patient/guardian/telecom The guardian's telecommunication <telecom> element is required. If there is no information, the nullFlavor attribute shall have a value of 'NI' and no address parts shall be present, otherwise there shall be no nullFlavor attribute, and at least one of the address parts listed below shall be present			
R1.7.A.4.1	**Guardian's Telephone**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/recordTarget/patientRole/patient/guardian/telecom/@value /ClinicalDocument/recordTarget/patientRole/patient/guardian/telecom/@use	R / R / R use nullFlavor [1..*]	TEL	HL7: URLScheme 2.16.840.1.113883.5.143 HL7:TelecommunicationAddressUse 2.16.840.1.113883.11.201
R1.7.A.4.2	**Guardian's e-mail addresss**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/recordTarget/patientRole/patient/guardian/telecom/@value /ClinicalDocument/recordTarget/patientRole/patient/guardian/telecom/@use	R / R / R use nullFlavor [1..*]	TEL	HL7: URLScheme 2.16.840.1.113883.5.143 HL7:TelecommunicationAddressUse 2.16.840.1.113883.11.201
R1.8	**Contact Person (Patient Contact Information)**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/participant/associatedEntity/associatedPerson			
R1.8.1	**Patient Contact's Family Name/ Surname** **(Family Name/Surname)**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/participant/associatedEntity/associatedPerson/name/family	R / R / R use nullFlavor [1..*]	PN	

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Template CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
R1.8.2	**Patient Contact's Given Name** **(Given Name)**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/participant/associatedEntity/associatedPerson/name /given	R / R / R use nullFlavor [1..*]	PN	
R1.8.3	**Patient Contact's Address** **(Address)**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/participant/associatedEntity/associatedPerson/addr			
R1.8.3.1	**Patient Contact's Street** **(Street)**	/ClinicalDocument/participant/associatedEntity/associatedPerson/addr /streetAddressLine	R / R / R use nullFlavor [1..*]	AD	
R1.8.3.2	**Patient Contact's Number of Street** **(Number of Street)**	/ClinicalDocument/participant/associatedEntity/associatedPerson/addr /streetAddressLine	R / R / R use nullFlavor [1..*]	AD	
R1.8.3.3	**Patient Contact's City** **(City)**	/ClinicalDocument/participant/associatedEntity/associatedPerson/addr city	R / R / R use nullFlavor [1..*]	AD	
R1.8.3.4	**Patient Contact's Postal Code** **(Postal Code)**	/ClinicalDocument/participant/associatedEntity/associatedPerson/addr /postalCode	R / R / R use nullFlavor [1..*]	AD	
R1.8.3.5	**Patient Contact's State or Province** **(State or Province)**	/ClinicalDocument/participant/associatedEntity/associatedPerson/addr /state	R / R / R use nullFlavor	AD	

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Template CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
			[1..*]		
R1.8.3.6	**Patient Contact's Country** **(Country)**	/ClinicalDocument/participant/associatedEntity/associatedPerson/addr /country	R / R / R use nullFlavor [1..*]	AD	
R1.8.4	**Patient Contact's Telecommunication**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/participant/associatedEntity/associatedPerson/telecom The patient contact's telephone or e-mail <telecom> element is required. If there is no information, the nullFlavor attribute shall have a value of 'UNK' and the "value" and "use" attributes shall be omitted, otherwise the nullFlavor attribute shall not be present, and the "value" and "use" attributes shall be present			
R1.8.4.1	**Patient Contact's Telephone** **(Telephone)**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/participant/associatedEntity/associatedPerson/telecom/@value /ClinicalDocument/participant/associatedEntity/associatedPerson/telecom/@use	R / R / R use nullFlavor [1..*]	TEL	HL7: URLScheme 2.16.840.1.113883.5.143 HL7:TelecommunicationAddressUse 2.16.840.1.113883.11.201
R1.8.4.2	**Patient Contact's Email** **(E-mail)**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/participant/associatedEntity/associatedPerson/telecom/@value /ClinicalDocument/participant/associatedEntity/associatedPerson/telecom/@use	R / R / R use nullFlavor [1..*]	TEL	HL7: URLScheme 2.16.840.1.113883.5.143 HL7:TelecommunicationAddressUse 2.16.840.1.113883.11.201
R1.8.5	**Participant typeCode = added by WP3.5** **(Type of contact)**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/participant/[@typeCode=**'IND']/associatedEntity@ classCode='NOK'|'ECON'|...**	O / O / O [0..*]	CS	HL7 : ParticipationType 2.16.840.1.113883.5.90 HL7: RoleClassAssociative 2.16.840.1.113883.1.11.19313

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Template CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
R1.8.6	**Contact Relationship Type** **= added by WP3.5** **(Contact Relationship)**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/participant/assignedEntity/code	O / O / O [0..*]	CE	HL7:PersonalRelationshipRoleType 2.16.840.1.113883.11.19563
R1.9	**Prefered HCP/ Legal Organization**[2] **(Prefered HCP/ Legal Organization to contact)**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/participant[functionCode/@code="PCP" and functionCode/@codeSystem='2.16.840.1.113883.5.88']/associatedEntity[@classCode="CAREGIVER"]/scopingOrganization /ClinicalDocument/participant[functionCode/@code="PCP" and functionCode/@codeSystem='2.16.840.1.113883.5.88']/associatedEntity[@classCode="CAREGIVER"]/associatedPerson/			
R1.9.1	**Name of the prefered Legal Organization/HCP** **(Contact Organization Name)**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/participant/associatedEntity/scopingOrganization/name /ClinicalDocument/participant/associatedEntity/associatedPerson//name	R / R / R use nullFlavor [1..1]	ON/PN	
R1.9.1.1	**Family Name/Surname of the prefered HCP** **(Family Name/Surname)**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/participant/associatedEntity/associatedPerson//name/family	R / R / R use nullFlavor [1..1]	PN	

[2] A foreign HCP may need a contact (HCP/legal organization) who knows the patient

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Template CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
R1.9.1.2	**Given Name of the prefered HCP (Given Name)**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/participant/associatedEntity/associatedPerson/name /given	R / R / R use nullFlavor [1..1]	PN	
R1.9.2	**Prefered HCP/ Legal Organization Address (Prefered HCP/ Legal Organization Address)**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/participant/associatedEntity/associatedPerson /addr /ClinicalDocument/participant/associatedEntity/scopingOrganization/addr			
R1.9.2.1	**Prefered HCP/ Legal Organization Street (Street)**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/participant/associatedEntityassociatedPerson / /addr /streetAddressLine /ClinicalDocument/participant/associatedEntity/scopingOrganization//addr /streetAddressLine	R / R / R use nullFlavor [1..*]	AD	
R1.9.2.2	**Prefered HCP/ Legal Organization Number of Street (Number of Street)**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/participant/associatedEntity/associatedPerson /addr /streetAddressLine /ClinicalDocument/participant/associatedEntity/scopingOrganization//addr /streetAddressLine	R / R / R use nullFlavor [1..*]	AD	
R1.9.2.3	**Prefered HCP/ Legal Organization City (City)**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/participant/associatedEntity/associatedPerson /addr city /ClinicalDocument/participant/associatedEntity/scopingOrganization//addr /city	R / R / R use nullFlavor [1..*]	AD	
R1.9.2.4	**Prefered HCP/ Legal Organization Postal Code (Postal Code)**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/participant/associatedEntity/associatedPerson /addr /postalCode /ClinicalDocument/participant/associatedEntity/scopingOrganization//a	R / R / R use nullFlavor [1..*]	AD	

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Template CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
		ddr /postalCode			
R1.9.2.5	**Prefered HCP/ Legal Organization State or Province** **(State or Province)**	/ClinicalDocument/participant/associatedEntity/associatedPerson / /addr /state /ClinicalDocument/participant/associatedEntity/scopingOrganization//addr /state	R / R / R use nullFlavor [1..*]	AD	
R1.9.2.6	**Prefered HCP/ Legal Organization Country** **(Country)**	/ClinicalDocument/participant/associatedEntity/associatedPerson / /addr /country /ClinicalDocument/participant/associatedEntity/scopingOrganization//addr /country	R / R / R use nullFlavor [1..*]	AD	epSOSCountry 1.3.6.1.4.1.12559.11.10.1.3.1.42.4
R1.9.3	**Prefered HCP/ Legal Organization Telecommunication**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/participant/associatedEntity/scopingOrganization/telecom /ClinicalDocument/participant/associatedEntity/associatedPerson/telecom The Prefered HCP/Legal Organization telephone or e-mail <telecom> element is required. If there is no information, the nullFlavor attribute shall have a value of 'UNK' and the "value" and "use" attributes shall be omitted, otherwise the nullFlavor attribute shall not be present, and the "value" and "use" attributes shall be present			
R1.9.3.1	**Preferred contact HCP/Legal Organization Telephone** **(Preferred Organization Telephone)**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/participant/associatedEntity/scopingOrganization/telecom/@value /ClinicalDocument/participant/associatedEntity/scopingOrganization/telecom/@use /ClinicalDocument/participant/associatedEntity/ associatedPerson /telecom@value /ClinicalDocument/participant/associatedEntity/associatedPerson /telecom@use	R / R / R use nullFlavor [1..*]	TEL	HL7: URLScheme 2.16.840.1.113883.5.143 HL7:TelecommunicationAddressUse 2.16.840.1.113883.11.201
R1.9.3.2	**Preferred contact HCP/Legal Organization**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/participant/associatedEntity/scopingOrganization/	R / R / R use	TEL	HL7: URLScheme

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Template CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
	e-mail **(Preferred Organization E-mail)**	telecom/@value /ClinicalDocument/participant/associatedEntity/scopingOrganization/telecom/@use /ClinicalDocument/participant/associatedEntity/associatedPerson/telecom@value /ClinicalDocument/participant/associatedEntity/associatedPerson/telecom@use	nullFlavor [1..*]		2.16.840.1.113883.5.143 HL7:TelecommunicationAddressUse 2.16.840.1.113883.11.201
R1.10	**HCP Identification** ***See also body for eP and eD*** **(Health Care Professional)**	1.3.6.1.4.1.19376.1.5.3.1.2.3 /ClinicalDocument/author/assignedAuthor /ClinicalDocument/documentationOf/serviceEvent/performer (this applies to the prescriber and the dispenser). The template ID referenced here refers to HCP information in the /ClinicalDocument/documentationOf/serviceEvent/performer structure. In this document, the same requriements apply to the person author of the document (if there is one), and to the prescrober and dispenser (see body). When there is no HCP but we have the method of assembly of data by a device, such as the "spider" method, we have the following expression; ClinicalDocument/author/assignedAuthor/assignedAuthoringDevice. When When the data is collected from different sources & pre-existing documents that are part of a bigger system. In that case the organization responsible of that collection "signed" the PS as responsible. ClinicalDocument/author/assignedAuthor/representedOrganization			
R1.10.1	**HCP Family Name/Surname** **(Family Name/Surname)**	1.3.6.1.4.1.19376.1.5.3.1.2.3 /ClinicalDocument/author/assignedAuthor/assignedPerson/name/family /ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/assignedPerson/name/family	R / R / R [1..*]	PN	
R1.10.2	**HCP Given Name** **(Given Name)**	1.3.6.1.4.1.19376.1.5.3.1.2.3 /ClinicalDocument/author/assignedAuthor/assignedPerson/name/given	R / R / R [1..*]	PN	

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Template CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
		/ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/assignedPerson/name/given			
R1.10.3	**HCP Prefix**	1.3.6.1.4.1.19376.1.5.3.1.2.3 /ClinicalDocument/author/assignedAuthor/assignedPerson/name/prefix /ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/assignedPerson/name/prefix	O / O / O [0..*]	PN	
R1.10.4	**HCP Suffix**	1.3.6.1.4.1.19376.1.5.3.1.2.3 /ClinicalDocument/author/assignedAuthor/assignedPerson/name/suffix /ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/assignedPerson/name/suffix	O / O / O [0..*]	PN	
R1.10.5	**HCP ID number** **(Identification)**	1.3.6.1.4.1.19376.1.5.3.1.2.3 /ClinicalDocument/author/assignedAuthor/id /ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/id	R / R / R [1..]	II	
R1.10.6	**Profession** **(Health Care Professional's Profession)**	1.3.6.1.4.1.19376.1.5.3.1.2.3 /ClinicalDocument/author/functionCode /ClinicalDocument/documentationOf/serviceEvent/performer/functionCode	R / O / O [1..*]	CWE	epSOS : HealthcareProfessionalRoles 1.3.6.1.4.1.12559.11.10.1.3.1.42.1
R1.10.7	**Specialty** **(Health Care Professional's Specialty)**	1.3.6.1.4.1.19376.1.5.3.1.2.3 /ClinicalDocument/author/assignedAuthor/code /ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/code	O / O / O [0..*]	CWE	
R1.10.8	**HCP Telecom**	1.3.6.1.4.1.19376.1.5.3.1.2.3 /ClinicalDocument/author/assignedAuthor/telecom			

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Template CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
		/ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/telecom			
R1.10.8.1	**HCP Telphone No** **(Health Care Professional's Telephone)**	1.3.6.1.4.1.19376.1.5.3.1.2.3 /ClinicalDocument/author/assignedAuthor/telecom/@value /ClinicalDocument/author/assignedAuthor/telecom/@use /ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/telecom/@value /ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/telecom@use	O / O / O [0..*]	TEL	HL7: URLScheme 2.16.840.1.113883.5.143 HL7:TelecommunicationAddressUse 2.16.840.1.113883.11.201
R1.10.8.2	**HCP E-mail** **(Health Care Professional's e-mail)**	1.3.6.1.4.1.19376.1.5.3.1.2.3 /ClinicalDocument/author/assignedAuthor/telecom/@value /ClinicalDocument/author/assignedAuthor/telecom/@use /ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/telecom/@value /ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/telecom@use	O / O / O [0..*]	TEL	HL7: URLScheme 2.16.840.1.113883.5.143 HL7:TelecommunicationAddressUse 2.16.840.1.113883.11.201
R1.10.9	**Healthcare Facility** ***(This is the Healthcare Facility that is responsible for the HCP)***	1.3.6.1.4.1.19376.1.5.3.1.2.3 /ClinicalDocument/author/assignedAuthor/representedOrganization /ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/representedOrganization			
R1.10.9.1	**Healthcare Facility's name** **(Health Care Facility's**	1.3.6.1.4.1.19376.1.5.3.1.2.3 /ClinicalDocument/author//assignedAuthor/representedOrganization/name	R null flavor / R / R null flavor [1..1]	ON	

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Template CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
	Name)	/ClinicalDocument/documentationOf/serviceEvent/performer/assigned Entity/representedOrganization/name			
R1.10.9.2	**Healthcare Facility's identifier** **(Health Care Facility's Identifier)**	1.3.6.1.4.1.19376.1.5.3.1.2.3 /ClinicalDocument/author//assignedAuthor/representedOrganization/id /ClinicalDocument/documentationOf/serviceEvent/performer/assigned Entity/representedOrganization/id	R null flavor / R / R null flavor [1..1]	II	
R1.10.9.3	**Healthcare Facility's Address**	1.3.6.1.4.1.19376.1.5.3.1.2.3 /ClinicalDocument/author//assignedAuthor/representedOrganization/addr /ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/representedOrganization/addr			
R1.10.9.3.1	**Healthcare Facility's Street** **(Street)**	1.3.6.1.4.1.19376.1.5.3.1.2.3 /ClinicalDocument/author//assignedAuthor/representedOrganization/addr/streetAddressLine /ClinicalDocument/documentationOf/serviceEvent/performer/assigned Entity/representedOrganization/addr/streetAddressLine	R null flavor / R / R null flavor [1..1]	AD	
R1.10.9.3.2	**Healthcare Facility's City** **(City)**	1.3.6.1.4.1.19376.1.5.3.1.2.3 /ClinicalDocument/author//assignedAuthor/representedOrganization/addr/city /ClinicalDocument/documentationOf/serviceEvent/performer/assigned Entity/representedOrganization/addr/city	R null flavor / R / R null flavor [1..1]	AD	
R1.10.9.3.3	**Healthcare Facility's State or Province** **(State or Province)**	1.3.6.1.4.1.19376.1.5.3.1.2.3 /ClinicalDocument/author//assignedAuthor/representedOrganization/addr/state /ClinicalDocument/documentationOf/serviceEvent/performer/assigned Entity/representedOrganization/addr/state	R null flavor / R / R null flavor [1..1]	AD	

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Template CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
R1.10.9.3.4	**Healthcare Facility's Zip or Postal Code** **(Postal Code)**	1.3.6.1.4.1.19376.1.5.3.1.2.3 /ClinicalDocument/author//assignedAuthor/representedOrganization/addr/postalCode /ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/representedOrganization/addr/postalCode	R null flavor / R / R null flavor [1..1]	AD	
R1.10.9.3.5	**Healthcare Facility's Country** **(Country)**	1.3.6.1.4.1.19376.1.5.3.1.2.3 /ClinicalDocument/author//assignedAuthor/representedOrganization/addr/country /ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/representedOrganization/addr/country	R / R / R [1..1]	AD	epSOSCountry 1.3.6.1.4.1.12559.11.10.1.3.1.42.4
R1.10.9.4	**Healthcare Facilities's Telecom**	1.3.6.1.4.1.19376.1.5.3.1.2.3 /ClinicalDocument/author//assignedAuthor/representedOrganization/telecom/ /ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/representedOrganization/telecom			
R1.10.9.4.1	**Healthcare Facility's telephone** **(Telephone)**	1.3.6.1.4.1.19376.1.5.3.1.2.3 /ClinicalDocument/author//assignedAuthor/representedOrganization/telecom/@value /ClinicalDocument/author//assignedAuthor/representedOrganization/telecom/@use /ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/representedOrganization/telecom/@value /ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/representedOrganization/telecom/@use	O / R / O [0..*]	TEL	
R1.10.9.4.2	**Healthcare Facility's e-mail address** **(E-mail)**	1.3.6.1.4.1.19376.1.5.3.1.2.3 /ClinicalDocument/author//assignedAuthor/representedOrganization/telecom/@value /ClinicalDocument/author//assignedAuthor/representedOrganization/tel	O / R / O [0..*]	TEL	

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Template CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
		ecom/@use /ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/representedOrganization/telecom/@value /ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/representedOrganization/telecom/@use			
R1.11	**Document identification**	/ClinicalDocument/			
R1.11.1	**Date of creation** **(Document Creation date)**	1.3.6.1.4.1.19376.1.5.3.1.1.1 /ClinicalDocument/effectiveTime	R / R / R [1..1]	TS	
R1.11.2	**Date of last update** **(Date of last update of document)**	1.3.6.1.4.1.19376.1.5.3.1.1.1 ClinicalDocument/documentationOf/serviceEvent/effectiveTime/high	O / O / R [1..1]	II	
R1.11.3	**Document ID** **(Document ID)**	1.3.6.1.4.1.19376.1.5.3.1.1.1 /ClinicalDocument/id	R / R / R [1..1]	II	
R1.11.5	**Author organization** **(Author organization)**	Same as R1.10.9			
R1.11.6	**Clinical document code** =added by WP3.5	1.3.6.1.4.1.19376.1.5.3.1.1.1 /ClinicalDocument/code	R / R / R [1..1]	CE	LOINC: Document Type 2.16.840.1.113883.6.1
R1.11.7	**Clinial document title** =added by WP3.5	1.3.6.1.4.1.19376.1.5.3.1.1.1 /ClinicalDocument/title	R / R / R [1..1]	ST	

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Template CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
R1.11.8	**Confidentiality code** =added by WP3.5	1.3.6.1.4.1.19376.1.5.3.1.1.1 /ClinicalDocument/confidentialityCode/@code	R null flavor / R null flavor / R null flavor [1..1]	CE	HL7: Confidentiality 2.16.840.1.113883.5.25
R1.11.9	**Legal Authenticator**	1.3.6.1.4.1.19376.1.5.3.1.1.1 The person taking responsibility for the medical content of the document. In Spain this is the regional authority in healthcare. This regional authority healthcare organization will send this to the NCP. The definition of the legal authenticator may vary accoriding to the rules set up in the framework agreement particular to each state. It may be a person or a regional authority, or an NCP. If the legal authetnicator is a person, the same elements as in **R1.10.1 to R1.10.8.2 must be represented within the context of the legal autehnticator.** /ClinicalDocument/legalAuthenticator/assignedEntity/assignedPerson	R / R / R [1..*]	PN	
R1.11.9	**Legal Authenticator**	1.3.6.1.4.1.19376.1.5.3.1.1.1 If the legal authenticator is a regional authority or another entitty, such as an NCP, the same elements as in **R1.10.9.1 to R1.10.9.4.2 must be represented within the context of the legal authenticator.** /ClinicalDocument/legalAuthenticator/assignedEntity/representedOrganization	R / R / R [1..*]	ON	

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Template CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
R.11.10	**Dcoument Language Code**	1.3.6.1.4.1.19376.1.5.3.1.1.1 /ClinicalDocument/Language	R / R / R [1..1]	CS	epSOSCountry 1.3.6.1.4.1.12559.11.10.1.3.1.42.4 epSOSLanguage 1.3.6.1.4.1.12559.11.10.1.3.1.42.6

7.2. Body Data Elements

The data elements present in the body concerning the prescriber and the dispenser DO belong in the body. The numbers are kept in the same order as they were listed in Appendix B. Please do note that following the work packages interactions, this will contain some requirements that are not present in Appendix B, but which have been later identified in the functional work packages or by the technical work packages.

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Section Template CDA XPath expression	PCC Entry content modules CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
R2	**Prescription**	**Prescription Document 1.3.6.1.4.1.12559.11.10.1.3.1.1.1**				
R2.1	**Prescription ID (Prescription ID)**	**Prescription Section**[3] **1.3.6.1.4.1.12559.11.10.1.3.1.2.1** /ClinicalDocument/component/structuredBody/component/section[templateId@root='1.3.6.1.4.1.12559.11.10.1.3.1.2.1']/id		R / R / NA [1..1]	II	
R.2.2	**Prescriber (Prescriber)**	**Prescription Section 1.3.6.1.4.1.12559.11.10.1.3.1.2.1** /ClinicalDocument/component/structuredBody/component/section[templateId@root='1.3.6.1.4.1.12559.11.10.1.3.1.2.1']/author		R / R / NA [1..1]	PN	

[3] Prescription section, Dispensation section and Medication section instructions of coding are used within the epSOS namespace. For sake of clarity, their Xpath expressions are not shown with this namespace.

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Section Template CDA XPath expression	PCC Entry content modules CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
		Please see section R1.10 in the Header for the other Prescriber Attributes while follwing the /ClinicalDocument/component/structuredBody/component/section/author XML element.				
R.2.3	**Prescriber Credentialing Organization (College) Identification** **(Prescriber Credentialing Organization)**	**Prescription Section** **1.3.6.1.4.1.12559.11.10.1.3.1.2.1**				
R2.3.1	**Prescriber Credentialing Organization (College) Name** **(Name)**		**Prescription item entry content module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.2** entry/substanceAdministration[templateId/@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/participant[@typeCode='AUT']/participantRole[@classCode='CRED']/scopingEntity[@classCode='ORG']/desc	O / NA / NA [0..1]	ST	
R2.3.2	**Prescribing Credentialing Organization's (College) Identifier** **(Identifier)**		**Prescription item entry content module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.2** entry/substanceAdministration[templateId/@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/participant[@typeCode='AUT']/participantRole[@classCode='CRED']/scopingEntity[@classCode='ORG']/id	O / NA / NA [0..1]	II	

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Section Template CDA XPath expression	PCC Entry content modules CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
R2.4	**Prescription Item ID** **(Prescription Item ID)**	**Prescription Section** **1.3.6.1.4.1.12559.11.10.1.3.1.2.1**	**Prescription Item Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.2** entry/substanceAdministration[templateId/@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/id	R / R / NA [1..*]	II	
R3	**Dispensation Document** **1.3.6.1.4.1.12559.11.10.1.3.1.2**					
R3.1	**Dispenser** **(Dispenser)**	**Dispensation Section** **1.3.6.1.4.1.12559.11.10.1.3.1.2.2**	**Dispensed Medicine Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.3** entry/supply[templateId/@root= '1.3.6.1.4.1.12559.11.10.1.3.1.3.3']/performer	NA / R / NA [1..1]	PN	
		Please see section R1.10 in the **Header** for the other **Dispenser Attributes** while follwing the /ClinicalDocument/component/structuredBody/component/section/ entry/supply/performer XML element.				
R3.2	**Dispenser Credentialing Organization** **(Dispenser Credentialing Organization)**	**Dispensation Section** **1.3.6.1.4.1.12559.11.10.1.3.1.2.2**				
R3.2.1	**Dispenser Credentialing Organization (College) Name** **Name**		**Dispensed Medicine Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.3** entry/supply[templateId/@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.3']/participant[@typeCode='PRF"]/participantRole[@classCode="CRED"]/scopingEntity	NA / O / NA [0..1]	ST	

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Section Template CDA XPath expression	PCC Entry content modules CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
			[@classCode="ORG"]/desc			
R3.2.2	**Dispenser Credentialing Organization's (College)** **Identifier**		**Dispensed Medicine Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.3** entry/supply[templateId/@root= '1.3.6.1.4.1.12559.11.10.1.3.1.3.3']/participant[@typeCode="PRF"]/participantRole[@classCode="CRED"]/scopingEntity[@classCode="ORG"]/id	NA / O / NA [0..1]	II	
R3.2.3	**Dispensed Medicine Id** **(Dispensed Medicine Id)**	**Dispensation Section** **1.3.6.1.4.1.12559.11.10.1.3.1.2.2**	**Dispensed Medicine Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.3** entry/supply[templateId/@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.3']/product/medication/administerableMedicine/id	NA / R / NA [1..*]	II	
R4	**Medication description**					
R4.1	**Country A Cross-border/regional/national medicinal product code** **(National medicinal product code)**	**Prescription Section** **1.3.6.1.4.1.12559.11.10.1.3.1.2.1**	**Prescription Item Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.2** entry/substanceAdministration[templateId/[@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/consumable/medication/admninisterableMedicine/code	O / NA / NA	TXT	
R4.2	**Brand name of the medicinal product prescribed in country A**	**Prescription Section** **1.3.6.1.4.1.12559.11.10.1.3.1.2.1**	**Prescription Item Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.2** entry/substanceAdministration[templateId/[@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/	R / NA / NA	TXT	

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Section Template CDA XPath expression	PCC Entry content modules CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
	(Brand Name)		consumable/medication/admninisterableMedicine/name			
R4.3	**Active ingredient (Active Ingredient)**	**Medication Summary Section 1.3.6.1.4.1.12559.11.10.1.3.1.2.3**	**Medication Item Entry Content Module 1.3.6.1.4.1.12559.11.10.1.3.1.3.4** entry/substanceAdministration[templateId/[@root= '1.3.6.1.4.1.12559.11.10.1.3.1.3.4']/consumable/medication/admninisterableMedicine/ingredient/[@classCode='ACTI']/ingredient/code	RNFA [1..1]	CD	WHO ATC 2.16.840.1.113883.6.73
		Prescription Section 1.3.6.1.4.1.12559.11.10.1.3.1.2.1	**Prescription Item Entry Content Module 1.3.6.1.4.1.12559.11.10.1.3.1.3.2** entry/substanceAdministration[templateId/[@root= '1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/consumable/medication/admninisterableMedicine/ingredient/[@classCode='ACTI']/ingredient/code	R [1..1]		
		Dispensation Section 1.3.6.1.4.1.12559.11.10.1.3.1.2.2	**Dispensed Medicine Entry Content Module 1.3.6.1.4.1.12559.11.10.1.3.1.3.3** entry/supply[templateId/@root= '1.3.6.1.4.1.12559.11.10.1.3.1.3.3']/product/medication/admninisterableMedicine/ingredient/[@classCode='ACTI']/ingredient/code	O [0..1]		
R4.4	**Strength of the medicinal product (Strength of the medicinal product)**	**Medication Summary Section 1.3.6.1.4.1.12559.11.10.1.3.1.2.3**	**Medication Item Entry Content Module 1.3.6.1.4.1.12559.11.10.1.3.1.3.4** entry/substanceAdministration[templateId/[@root= '1.3.6.1.4.1.12559.11.10.1.3.1.3.4']/consumable/medication/admninisterableMedicine/ingredient/[@classCode='ACTI']/qu	RNFA [1..1]	PQ, PQ	

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Section Template CDA XPath expression	PCC Entry content modules CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
			antity			
		Prescription Section 1.3.6.1.4.1.12559.11.10.1.3.1.2.1	**Prescription Item Entry Content Module 1.3.6.1.4.1.12559.11.10.1.3.1.3.2** entry/substanceAdministration[templateId/[@root= '1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/consumable/medication/admninisterableMedicine/ingredient/[@classCode='ACTI']/quantity	R [1..1]		
		Dispensation Section 1.3.6.1.4.1.12559.11.10.1.3.1.2.2	**Dispensed Medicine Entry Content Module 1.3.6.1.4.1.12559.11.10.1.3.1.3.3** entry/supply[templateId/@root= '1.3.6.1.4.1.12559.11.10.1.3.1.3.3']/product/medication/admninisterableMedicine/ingredient/[@classCode='ACTI']/quantity	R [1..1]		
R4.5	**Medicinal product package** (**Medicinal product package**)	**Medication Summary Section 1.3.6.1.4.1.12559.11.10.1.3.1.2.3**	**Medication Item Entry Content Module 1.3.6.1.4.1.12559.11.10.1.3.1.3.4** entry/substanceAdministration[templateId/[@root= '1.3.6.1.4.1.12559.11.10.1.3.1.3.4']/consumable//medication/admninisterableMedicine/ingredient/[@classCode='ACTI']/asContent/containerPackageMedicine/formCode	O [0..1]	CD	epSOS:Package 1.3.6.1.4.1.12559.11.10.1.3.1.42.3
		Prescription Section 1.3.6.1.4.1.12559.11.10.1.3.1.2.1	**Prescription Item Entry Content Module 1.3.6.1.4.1.12559.11.10.1.3.1.3.2** entry/substanceAdministration[templateId/[@root= '1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/consumable/medication/admninisterableMedicine/ingredient/[@classCode='ACTI']/as	R [1..1]		

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Section Template CDA XPath expression	PCC Entry content modules CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
			Content/containerPackageMedicine/formCode			
		Dispensation Section **1.3.6.1.4.1.12559.11.10.1.3.1.2.2**	**Dispensed Medicine Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.3** entry/supply[templateId/@root= '1.3.6.1.4.1.12559.11.10.1.3.1.3.3']/product/medication/admninisterableMedicine/ingredient/[@classCode='ACTI']/asContent/containerPackageMedicine/formCode	R [1..1]		
R4.6	**Pharmaceutical dose form** **(Pharmaceutical dose form)**	**Medication Summary Section** **1.3.6.1.4.1.12559.11.10.1.3.1.2.3**	**Medication Item Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.4** entry/substanceAdministration[templateId/[@root= '1.3.6.1.4.1.12559.11.10.1.3.1.3.4']/consumable/medication/admninisterableMedicine/formCode	O [0..1]	CD	epSOS:DoseForm 1.3.6.1.4.1.12559.11.10.1.3.1.42.2
		Prescription Section **1.3.6.1.4.1.12559.11.10.1.3.1.2.1**	**Prescription Item Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.2** entry/substanceAdministration[templateId/[@root= '1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/consumable/medication/admninisterableMedicine/formCode	R [1..1]		
		Dispensation Section **1.3.6.1.4.1.12559.11.10.1.3.1.2.2**	**Dispensed Medicine Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.3** entry/supply[templateId/@root= '1.3.6.1.4.1.12559.11.10.1.3.1.3.3']/product/medication/admninisterableMedicine/formCode	R [1..1]	CD	epSOS:DoseForm 1.3.6.1.4.1.12559.11.10.1.3.1.42.2

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Section Template CDA XPath expression	PCC Entry content modules CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
R4.7	**Route of Administration** **(Route of Administration)**	**Medication Summary Section** **1.3.6.1.4.1.12559.11.10.1.3.1.2.3**	**Medication Item Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.4** entry/substanceAdministration[templateId/ [@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.4']/routeCode	O	CD	epSOSRoutesofAdministration 1.3.6.1.4.1.12559.11.10.1.3.1.42.12
		Prescription Section **1.3.6.1.4.1.12559.11.10.1.3.1.2.1**	**Prescription Item Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.2** entry/substanceAdministration[templateId/ [@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/routeCode	O		
		Dispensation Section **1.3.6.1.4.1.12559.11.10.1.3.1.2.2**	**Dispensed Medicine Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.3** entry/supply[templateId/@root= '1.3.6.1.4. 1.12559.11.10.1.3.1.3.3']/entryRelationship [@typeCode='REFR']/substanceAdministra tion/routeCode	O		
R4.8	**Number of packages** **(Number of Packages)**	**Prescription Section** **1.3.6.1.4.1.12559.11.10.1.3.1.2.1**	**Prescription Item Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.2** entry/substanceAdministration[templateId/ [@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/ /consumable/medication/admninisterable Medicine/asContent/quantity/numerator	R	PQ	
		Dispensation Section **1.3.6.1.4.1.12559.11.10.1.3.1.2.2**	**Dispensed Medicine Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.3** entry/supply[templateId/@root= '1.3.6.1.4. 1.12559.11.10.1.3.1.3.3']/quantity	R		

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Section Template CDA XPath expression	PCC Entry content modules CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
R4.9	**Number of units per intake**[4] **(Number of units per intake)**	**Medication Summary Section 1.3.6.1.4.1.12559.11.10.1.3.1.2.3**	**Medication Item Entry Content Module 1.3.6.1.4.1.12559.11.10.1.3.1.3.4** entry/substanceAdministration[templateId/ [@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.4']/doseQuantity/@value	RNFA	INT	
		Prescription Section 1.3.6.1.4.1.12559.11.10.1.3.1.2.1	**Prescription Item Entry Content Module 1.3.6.1.4.1.12559.11.10.1.3.1.3.2** entry/substanceAdministration[templateId/ [@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/doseQuantity/@value	RNFA	INT	
R4.10	**Frequency of intakes**[21] **(Frequency of intakes)**	**Medication Summary Section 1.3.6.1.4.1.12559.11.10.1.3.1.2.3**	**Medication Item Entry Content Module 1.3.6.1.4.1.12559.11.10.1.3.1.3.4** entry/substanceAdministration[templateId/ [@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.4'] /effectiveTime[2]	RNFA	TS IVL_TS PIVL_TS EIVL_TS	If EIVL_TS mode is used, HL7 TimingEvent vocabulary (2.16.840.1.113883.5.139) SHALL be used.
		Prescription Section 1.3.6.1.4.1.12559.11.10.1.3.1.2.1	**Prescription Item Entry Content Module 1.3.6.1.4.1.12559.11.10.1.3.1.3.2** entry/substanceAdministration[templateId/ [@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2']	RNFA	TS IVL_TS PIVL_TS EIVL_TS	If EIVL_TS mode is used, HL7 TimingEvent vocabulary (2.16.840.1.113883.5.139) SHALL be used.

[4] Posology has been defined from the functional point of view as containing these three components: number of units per intake, frequency of intakes and duration of treatment:(example: 1 unit/intake every 24 hours for a duration of 14 days

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Section Template CDA XPath expression	PCC Entry content modules CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
			/effectiveTime[2]			
R4.11	**Duration of treatment**[5] **(Duration of treament)**	**Medication Summary Section 1.3.6.1.4.1.12559.11.10.1.3.1.2.3**	**Medication Item Entry Content Module 1.3.6.1.4.1.12559.11.10.1.3.1.3.4** entry/substanceAdministration[templateId/ @root='1.3.6.1.4.1.12559.11.10.1.3.1.3.4'] /effectiveTime[1][@ xsi:type='IVL_TS']/low/@value[6] entry/substanceAdministration[templateId/ @root='1.3.6.1.4.1.12559.11.10.1.3.1.3.4'] /effectiveTime[1][@ xsi:type='IVL_TS']/high/@value[7]	RNFA	IVL_TS	
		Prescription Section 1.3.6.1.4.1.12559.11.10.1.3.1.2.1	**Prescription Item Entry Content Module 1.3.6.1.4.1.12559.11.10.1.3.1.3.2** entry/substanceAdministration[templateId/[	RNFA	IVL_TS	

[5] The width of an interval may have to be calculated as the difference between the high and the low values for ePrescription in order to express posology. This does mean the validity of the prescription, this is a time indication about the onset and the end of the treatment. Variations are allowed according to the Member States.

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Section Template CDA XPath expression	PCC Entry content modules CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
			@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.4']/ effectiveTime[1][@ xsi:type='IVL_TS']/low/@value[8] entry/substanceAdministration[templateId/[@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.4']/ effectiveTime[1][@ xsi:type='IVL_TS']/high/@value[9]			
R4.12	**Date of onset of treatment** **(Date of onset of treatment)**	**Medication Summary Section** **1.3.6.1.4.1.12559.11.10.1.3.1.2.3**	**Medication Item Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.4** entry/substanceAdministration[templateId/ [@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.4']/effectiveTime[1][@ xsi:type='IVL_TS']/low	RNFA	TS	
		Prescription Section **1.3.6.1.4.1.12559.11.10.1.3.1.2.1**	**Prescription Item Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.2** entry/substanceAdministration[templateId/ [@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/effectiveTime[1][@ xsi:type='IVL_TS']/low	O	TS	

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Section Template CDA XPath expression	PCC Entry content modules CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
R4.13	**Date of end of treatment** **(Date of end of treatment)**	**Medication Summary Section** **1.3.6.1.4.1.12559.11.10.1.3.1.2.3**	**Medication Item Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.4** entry/substanceAdministration[templateId/[@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.4']/effectiveTime[1][@xsi:type='IVL_TS']/high	RNFA	TS	
		Prescription Section **1.3.6.1.4.1.12559.11.10.1.3.1.2.1**	**Prescription Item Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.2** entry/substanceAdministration[templateId/[@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/effectiveTime[1][@xsi:type='IVL_TS']/high	O	TS	
R4.14	**Instructions to patient** **(Instructions to patient)**	**Prescription Section** **1.3.6.1.4.1.12559.11.10.1.3.1.2.1**	**Prescription Item Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.2** entry/substanceAdministration[templateId/[@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/entryRelationship[@typeCode='SUBJ']/act[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.3']/text	O	TXT	
R4.15	**Advise to the dispenser** **(Advise to the dispenser)**	**Prescription Section** **1.3.6.1.4.1.12559.11.10.1.3.1.2.1**	**Prescription Item Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.2** /entry/substanceAdministration[templateId/[@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/entryRelationship[@typeCode='SUBJ']/act[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.3.1']/text	O	TXT	

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Section Template CDA XPath expression	PCC Entry content modules CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
R4.16	**Substitution** **(Substitution)**	**Prescription Section** **1.3.6.1.4.1.12559.11.10.1.3.1.2.1**	**Prescription Item Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.2** entry/substanceAdministration[templateId/[@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/entryRelationship[@typeCode='SUBJ'][@inversionInd='true']/observation[@classCode ='OBS']/value	O	BL	
		Dispensation Section **1.3.6.1.4.1.12559.11.10.1.3.1.2.2**	**Dispensed Medicine Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.3** entry/supply[templateId/[@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.3']/entryRelationship[@typeCode='SUBJ'][@inversionInd='true']/observation[@classCode ='OBS']/value	O	BL	
R5	**Allergy – the following data elements apply only the the Patient Summary.** The field "alerts" was originally defined to include all the important and objective medical information that should be highlighted (such as allergies, thrombosis risk, immune deficit …etc). When defining the content only allergies and intolerance to drugs appear to be the common understanding and the easiest to be transferred. A lot of surveys are being made in different countries (not only in Europe) to make a more evidence-based definition of what should represented and should not byt the concept "alerts", hence not enough information could be provided to take a further decision. As epSOS's intention is not to duplicate information, this shall not be repeated. Alerts are diffucult to represent since they are contextual. Alerts may be represented as severe or life-threatening allergies or other adverse reactions. Another area are certain selected procedures and implanted devivces. The section Allergies and Other Adverse Reactions contains the medical alerts as well, based on the serverity, and their representation becomes a Country B choice.					
R5.1	**Allergy Display Name** **(Allergy Description)**	**Allergies and Other Adverse Reactions Section** **1.3.6.1.4.1.19376.1.5.3.1.3.13**	**Allergy & Intolerance Concern Entry** **1.3.6.1.4.1.19376.1.5.3.1.4.5.3** entry/act[templateId/@root= '2.16.840.1.113883.10.20.27']/entryRelationship[@typeCode='SUBJ']/observation[templateId/@root='2.16.840.1.113883.10.20.1.18']/entryRel	RNFA	CD	epSOSReactionAllergy 1.3.6.1.4.1.12559.11.10.1.3.1.42.11

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Section Template CDA XPath expression	PCC Entry content modules CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
			ationship[@typeCode='MFST']/observation[templateId/@root='2.16.840.1.113883.10.20.1.54']/code@displayName			
R5.2	**Allergy id code** **(Allergy description id code)**	**Allergies and Other Adverse Reactions Section** **1.3.6.1.4.1.19376.1.5.3.1.3.13**	**Allergy & Intolerance Concern Entry** **1.3.6.1.4.1.19376.1.5.3.1.4.5.3** entry/act[templateId/@root= '2.16.840.1.113883.10.20.27']/entryRelationship[@typeCode='SUBJ']/observation[templateId/@root='2.16.840.1.113883.10.20.1.18']/code@code	RNFA	CD	
R5.3	**Allergy Onset Date** **(Allergy Onset Date)**	**Allergies and Other Adverse Reactions Section and Alerts** **1.3.6.1.4.1.19376.1.5.3.1.3.13**	**Allergy & Intolerance Concern Entry** **1.3.6.1.4.1.19376.1.5.3.1.4.5.3** entry/act[templateId/@root= '2.16.840.1.113883.10.20.27']/entryRelationship[@typeCode='SUBJ']/observation[templateId/@root='2.16.840.1.113883.10.20.1.18']/effectiveTime/low@value	O	IVL_TS	
R5.4	**Allergy Agent Description** **(Allergy Agent)**	**Allergies and Other Adverse Reactions Section** **1.3.6.1.4.1.19376.1.5.3.1.3.13**	**Allergy & Intolerance Concern Entry** **1.3.6.1.4.1.19376.1.5.3.1.4.5.3** entry/act[templateId/@root= '2.16.840.1.113883.10.20.27']/entryRelationship[@typeCode='SUBJ']/observation[templateId/@root='2.16.840.1.113883.10.20.1.18']/participant[@typeCode='CSM']/participantRole[@classCode='MANU']/playingEntity[@classCode='MMAT]/code@displayName	RNFA	CD	If the allergenic agent is a medicament: WHO ATC 2.16.840.1.113883.6.73 If not: epSOSAllergenNoDrugs 1.3.6.1.4.1.12559.11.10.1.3.1.42.19

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Section Template CDA XPath expression	PCC Entry content modules CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
R5.5	**Allergy Agent Code** **(Allergy Agent Code)**	**Allergies and Other Adverse Reactions Section** **1.3.6.1.4.1.19376.1.5.3.1.3.13**	**Allergy & Intolerance Concern Entry** **1.3.6.1.4.1.19376.1.5.3.1.4.5.3** entry/act[templateId/@root= '2.16.840.1.113883.10.20.27']/entryRelationship[@typeCode='SUBJ']/observation[templateId/@root='2.16.840.1.113883.10.20.1.18']/participant[@typeCode='CSM']/participantRole[@classCode='MANU']/playingEntity[@classCode='MMAT]/code@code	RNFA	II	If the allergenic agent is a medicament: WHO ATC 2.16.840.1.113883.6.73 If not: epSOSAllergennoDrugs 1.3.6.1.4.1.12559.11.10.1.3.1.42.19
R6	This line is left purposely blank – see explanation for Allergy and Other Adverse Reactions Section					
R7	**History of past illness and disorders** **(History of past illness)** (note *"disorders"* was added by WP3.5 due to medical concerns).	**1.3.6.1.4.1.19376.1.5.3.1.3.8** **History of Past Illness Section**				
R7.1	**Problem Description** **(Problem Description)**		**Problem Concern Entry** **1.3.6.1.4.1.19376.1.5.3.1.4.5.2** entry/act[templateId/@root='2.16.840.1.113883.10.20.1.27']/entryRelationship[@type='SUBJ']/observation[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.5']/text	O	TXT	

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Section Template CDA XPath expression	PCC Entry content modules CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
R7.2	**Problem Code** **(Problem Id code)**		**Problem Concern Entry** **1.3.6.1.4.1.19376.1.5.3.1.4.5.2** entry/act[templateId/@root='2.16.840.1.113883.10.20.1.27']/entryRelationship[@type='SUBJ']/observation[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.5']/value@code	O	CD	
R7.3	**Problem Onset time** **(Problem Onset Date)** Corrected from "*time*" to "*date*"		**Problem Concern Entry** **1.3.6.1.4.1.19376.1.5.3.1.4.5.2** entry/act[templateId/@root='2.16.840.1.113883.10.20.1.27']/ effectiveTime[@xsi:type='IVL_TS']/low	O	IVL_TS	
R7.4	**Problem End Date** **(Problem End Date)**		**Problem Concern Entry** **1.3.6.1.4.1.19376.1.5.3.1.4.5.2** entry/act[templateId/@root='2.16.840.1.113883.10.20.1.27']/ effectiveTime[@xsi:type='IVL_TS']/high	O	IVL_TS	

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Section Template CDA XPath expression	PCC Entry content modules CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
R7.5	**Resolution Circumstances** **(Resolution Cicumstances)**		**Problem Concern Entry** **1.3.6.1.4.1.19376.1.5.3.1.4.5.2** entry/act[templateId/@root='2.16.840.1.113883.10.20.1.27']/entryRelationship[@type='REFR']/observation[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.1.2']/text	O	TXT[10]	
			Problem Concern Entry **1.3.6.1.4.1.19376.1.5.3.1.4.5.2** entry/act[templateId/@root='2.16.840.1.113883.10.20.1.27']/entryRelationship[@type='REFR']/observation[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.1.2']/value@code	O	CD	epSOSResolutionOutcome 1.3.6.1.4.1.12559.11.10.1.3.1.42.24
R8	**Vaccinations**	**1.3.6.1.4.1.19376.1.5.3.1.3.23** **Immunizations Section**				
R8.1	**Vaccinations Brand name[11]** **(Vaccinations Brand Name)**		**Immunization Entry** **1.3.6.1.4.1.19376.1.5.3.1.4.12** entry/substanceAdministration[templateId/@root= '2.16.840.1.113883.10.20.1.24']/	O	TXT	

[10] This represents narrative form, which describes the resolution circumstances. At the same level of information, <value> is of type CD, will code the observed resolution circumstances using codes within the epSOSResolutionCircumstances value set. If this needs to be linked to another entry in the body, you could use template such as 1.3.6.1.4.1.19376.1.5.3.1.4.4., it would look like: entry/act[templateId/@root='2.16.840.1.113883.10.20.1.27']/entryRelationship[@type='REFR']/observation[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.1.2']/entryRelationship[@type='REFR']/act[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.4]/id, where the id is the same id as the procedure which was used to resolve the problem.

[11] The vaccination brand name SHALL appear in a <translation> element while the coded product name SHALL appear in the code attribute of the <code> element (R8.2)

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Section Template CDA XPath expression	PCC Entry content modules CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
			consumable/ manufacturedProduct/ manufacturedMaterial/code/translation@displayName			
R8.2	**Vaccination Description (Vaccinations)**		**Immunization Entry** **1.3.6.1.4.1.19376.1.5.3.1.4.12** entry/substanceAdministration[templateId/ @root= '2.16.840.1.113883.10.20.1.24']/ consumable/ manufacturedProduct/ manufacturedMaterial/code	O	CD	epSOSVaccine 1.3.6.1.4.1.12559.11.10.1.3.1.42.18
R8.2	**Vaccinations Code** **(Vaccination id code)**		**Immunization Entry** **1.3.6.1.4.1.19376.1.5.3.1.4.12** entry/substanceAdministration[templateId/ @root= '2.16.840.1.113883.10.20.1.24']/ consumable/ manufacturedProduct/ manufacturedMaterial/code@code	O	II	
R8.3	**Vaccinations Date** **(Vaccinations Date)**		**Immunization Entry** **1.3.6.1.4.1.19376.1.5.3.1.4.12** entry/substanceAdministration[templateId/ @root= '2.16.840.1.113883.10.20.1.24']/effectiveTime	O	TS	
R9	**Surgical Procedures <u>prior</u> past six months**	**1.3.6.1.4.1.19376.1.5.3.1.3.12** **Coded List of Surgeries Section**				
R9.1	**Procedure description** **(Procedure Description)**		**Procedure Entry** **1.3.6.1.4.1.19376.1.5.3.1.4.19** entry/procedure[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.4.19']/code/@displayName	O	TXT	

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Section Template CDA XPath expression	PCC Entry content modules CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
R9.2	**Procedure Code** **(Procedure Id Code)**		**Procedure Entry** **1.3.6.1.4.1.19376.1.5.3.1.4.19** entry/procedure[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.4.19']/code/@code	O	CD	epSOSProcedures 1.3.6.1.4.1.12559.11.10.1.3.1.42.10
R9.3	**Procedure date** **(Procedure Date)**		**Procedure Entry** **1.3.6.1.4.1.19376.1.5.3.1.4.19** entry/procedure[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.4.29']/effectiveTime	O	IVL_TS	
R10	**Major Surgical Procedures past 6 months**[12]	**1.3.6.1.4.1.19376.1.5.3.1.3.12** **Coded List of Surgeries Section**				
R10.1	**Procedure description** **(Procedure Description)**		**Procedure Entry** **1.3.6.1.4.1.19376.1.5.3.1.4.19** entry/procedure[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.4.19']/code/@displayName	RNFA	CD	
R10.2	**Procedure Code** **(Procedure Id Code)**		**Procedure Entry** **1.3.6.1.4.1.19376.1.5.3.1.4.19** entry/procedure[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.4.19']/code/@code	RNFA	II	epSOSProcedures 1.3.6.1.4.1.12559.11.10.1.3.1.42.10

[12] As there is subjectivity in the term 'relevant', the date of the procedure will be used as to delineate. As the date can be seen from the procedure, the two have the same expression. It is up to the implementers of the system to display it in a different way.

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Section Template CDA XPath expression	PCC Entry content modules CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
R10.3	**Procedure date** **(Procedure Date)**		**Procedure Entry** **1.3.6.1.4.1.19376.1.5.3.1.4.19** entry/procedure[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.4.29']/effectiveTime	RNFA	IVL_TS	
R11	**List of Current Problems/Diagnosis**					
R11.1	**Problem/diagnosis description** **(Problem/diagnosis description)**	**1.3.6.1.4.1.19376.1.5.3.1.3.4** **History of Present Illness Section** Narrative section section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.4']/text		RNFA	TXT	
		1.3.6.1.4.1.19376.1.5.3.1.3.6 **Active Problems Section**	**1.3.6.1.4.1.19376.1.5.3.1.4.5.2** **Problem Concern Entry** entry/act[templateId/@root='2.16.840.1.113883.10.20.1.27']/ entryRelationship[@type='SUBJ']/ observation[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.5']/value/@displayName		TXT	
R11.2	**Problem Code** **(Problem Id code)**	**1.3.6.1.4.1.19376.1.5.3.1.3.6** **Active Problems Section**	**1.3.6.1.4.1.19376.1.5.3.1.4.5.2** **Problem Concern Entry** entry/act[templateId/@root='2.16.840.1.113883.10.20.1.27']/ entryRelationship[@type='SUBJ']/ observation[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.5']/value/@code	RNFA	CD	ICD10 2.16.840.1.113883.6.3
		1.3.6.1.4.1.19376.1.5.3.1.3.4 **History of Present Illness Section**				

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Section Template CDA XPath expression	PCC Entry content modules CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
R11.3	**Problem onset time** **(Problem Onset Time)**	**1.3.6.1.4.1.19376.1.5.3.1.3.6** **Active Problems Section**	**1.3.6.1.4.1.19376.1.5.3.1.4.5.2** **Problem Concern Entry** entry/act[templateId/@root='2.16.840.1.113883.10.20.1.27']/effectiveTime/low	RNFA	IVL_TS	
R12	**Medical Devices and implants**	**1.3.6.1.4.1.12559.11.10.1.3.1.2.4** **Medical Devices Coded Section**				
R12.1	**Device and Implant Description** **(Device and Implant Description)**	**Medical Devices Coded Section** **1.3.6.1.4.1.12559.11.10.1.3.1.2.4**	**Medical Device Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.5** entry/supply[templateId/@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.5']/participant[@typeCode='DEV']/participantRole/playingDevice/code/@displayName	RNFA	TXT	
R12.2	**Device Code** **(Device Id Code)**	**Medical Devices Coded Section** **1.3.6.1.4.1.12559.11.10.1.3.1.2.4**	**Medical Device Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.5** entry/supply[templateId/@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.5']/participant[@typeCode='DEV']/participantRole/playingDevice/code/@code	RNFA	CE	epSOSMedicalDevices 1.3.6.1.4.1.12559.11.10.1.3.1.42.8
R12.3	**Device Implant Date**	**Medical Devices Coded Section**	**Medical Device Entry Content Module**	RNFA	TS	

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Section Template CDA XPath expression	PCC Entry content modules CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
	(Device Implant Date)	**1.3.6.1.4.1.12559.11.10.1.3.1.2.4**	**1.3.6.1.4.1.12559.11.10.1.3.1.3.5** entry/supply[templateId/@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.5']/effectiveTime/@value			
R13	**Treatment Recommendations**	**1.3.6.1.4.1.19376.1.5.3.1.1.9.50** **Health Maintenance Care Plan Section** **This is a narrative section as the codes that exists with regards to diet, exercise, and other therapeutic recommendations that do not include drugs.**				
R14	**Autonomy/Invalidity**	**1.3.6.1.4.1.19376.1.5.3.1.3.17** **Functional Status Section**				
R14.1	**Invalidity Description** **(Invalidity Description)**	Narrative section section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.17']/text		O	TXT	
R14.2	**Invalidity Id code** **(Invalidity Id code)**	section[templateId/[@root='1.3.6.1.4.1.19376.1.5.3.1.3.17']/text		O	TXT	
R15	**Social History**	**1.3.6.1.4.1.19376.1.5.3.1.3.16.1** **Coded Social History Section**				
R15.1	**Social History Observations related to: smoke,**	**1.3.6.1.4.1.19376.1.5.3.1.3.16.1** **Coded Social History Section**	**1.3.6.1.4.1.19376.1.5.3.1.4.13.4** **Smoke** Social History Observation	O	PQ	entry/observation[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.4.13.4']/code@code value is using epSOSSocialHistory value set

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Section Template CDA XPath expression	PCC Entry content modules CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
	alcohol and diet. **(Social History Observations)**		entry/observation[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.4.13.4'][code@code='229819007]/value/@code			1.3.6.1.4.1.12559.11.10.1.3.1.42.14
			1.3.6.1.4.1.19376.1.5.3.1.4.13.4 **Alcohol** Social History Observation entry/observation[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.4.13.4'][code@code='160573003]/value/@code	O	PQ	entry/observation[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.4.13.4']/code@code value is using epSOSSocialHistory value set 1.3.6.1.4.1.12559.11.10.1.3.1.42.14
			1.3.6.1.4.1.19376.1.5.3.1.4.13.4 **Diet** Social History Observation entry/observation[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.4.13.4'][code@code='364393001]/value/@code	O	CD	entry/observation[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.4.13.4']/code@code value is using epSOSSocialHistory value set 1.3.6.1.4.1.12559.11.10.1.3.1.42.14
R15.2	**Social History Reference date range** **(Social History Reference date range)**	**1.3.6.1.4.1.19376.1.5.3.1.3.16.1** **Coded Social History Section**	**1.3.6.1.4.1.19376.1.5.3.1.4.13.4** **Smoke** Social History Observation entry/observation[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.4.13.4'][code@code='229819007']/effectiveTime[@type='IVL_TS']/low/value entry/observation[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.4.13.4'][code@code='229819007']/effectiveTime[@type='IVL_TS']/high/value	O	IVL_TS	entry/observation[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.4.13.4']/code@code value is using epSOSSocialHistory value set 1.3.6.1.4.1.12559.11.10.1.3.1.42.14

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Section Template CDA XPath expression	PCC Entry content modules CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
			1.3.6.1.4.1.19376.1.5.3.1.4.13.4 **Alcohol** Social History Observation entry/observation[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.4.13.4'][code@code='229819007']/effectiveTime[@type='IVL_TS']/low/value entry/observation[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.4.13.4'][code@code='229819007']/effectiveTime[@type='IVL_TS']/high/value	O	IVL_TS	entry/observation[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.4.13.4']/code@code value is using epSOSSocialHistory value set 1.3.6.1.4.1.12559.11.10.1.3.1.42.14
			1.3.6.1.4.1.19376.1.5.3.1.4.13.4 **Diet** Social History Observation entry/observation[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.4.13.4'][code@code='364393001']/effectiveTime[@type='IVL_TS']/low/value entry/observation[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.4.13.4'][code@code='229819007']/effectiveTime[@type='IVL_TS']/high/value	O	IVL_TS	entry/observation[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.4.13.4']/code@code value is using epSOSSocialHistory value set 1.3.6.1.4.1.12559.11.10.1.3.1.42.14
R16	**Pregnancy History**	**1.3.6.1.4.1.19376.1.5.3.1.1.5.3.4** **Pregnancy History Section**				
R16.1	**Expected Date of Delivery**		**1.3.6.1.4.1.19376.1.5.3.1.4.13.5** **Pregnancy Observation** entry/observation[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.4.13.5'][code@code=' 11778-8']/value	O	TS	

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Section Template CDA XPath expression	PCC Entry content modules CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
R17	**Physical findings**					
R17.1	**Vital Signs Observations** **(Vital Signs Observations)**	**1.3.6.1.4.1.19376.1.5.3.1.1.5.3.2** **Coded Vital Signs Section**				
R17.1.1	**Blood pressure** **(Blood pressure)**		**1.3.6.1.4.1.19376.1.5.3.1.4.13.1** **Vital Sign Organizer** **Systolic** entry/organizer[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.4.13.1']/component/observation[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.13.2'][code@code='8480-6']/value **Diastolic** entry/organizer[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.4.13.1']/component/observation[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.13.2'][code@code='8462-4']/value	O	PQ	entry/organizer[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.4.13.1']/component/observation[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.13.2']/code@code SHALL use : epSOSBloodPressure 1.3.6.1.4.1.12559.11.10.1.3.1.42.21 Value unit SHALL use epSOSUnits 1.3.6.1.4.1.12559.11.10.1.3.1.42.16
R17.2	**Date** **(Date when blood pressure was measured)**		**1.3.6.1.4.1.19376.1.5.3.1.4.13.1** **Vital Sign Organizer** entry/organizer[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.4.13.1']/effectiveTime	O		

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Section Template CDA XPath expression	PCC Entry content modules CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
R18	**Diagnostic tests**					
R18.1	**Value of blood group observation** **(Result of blood group)**	**1.3.6.1.4.1.19376.1.5.3.1.3.28** **Coded Results Section**	**1.3.6.1.4.1.19376.1.5.3.1.4.13** **Simple observation Entry** entry/observation[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.4.13.6'][code/@code=' 34530-6 ']/value@code	O	CE	epSOSBloodGroup 1.3.6.1.4.1.12559.11.10.1.3.1.42.20
R18.2	**Date of observation** **(Date when blood group was determined)**		**1.3.6.1.4.1.19376.1.5.3.1.4.13** **Simple observation Entry** entry/observation[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.4.13.6'][code/@code =' 34530-6 ']/effectiveTime	O	TS	
R19	**Medication Summary** **(Medication Summary)**	**Medication Summary Section** **1.3.6.1.4.1.12559.11.10.1.3.1.2.3**				
R19.1	**Medication Summary Active ingredient description** **(Active ingredient)**		**Medication Item Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.4** entry/substanceAdministration[templateId/[@root= '1.3.6.1.4.1.12559.11.10.1.3.1.3.4']/consumable/medication/admninisterableMedicine/ingredient/[@classCode='ACTI']/ingredient	O		
R19.2	**Medication Summary Active ingredient code** **(Active ingredient id code)**		**Medication Item Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.4** entry/substanceAdministration[templateId/[@root= '1.3.6.1.4.1.12559.11.10.1.3.1.3.4']/consumable/medication/admninisterableMe	O	CD	WHO ATC 2.16.840.1.113883.6.73

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Section Template CDA XPath expression	PCC Entry content modules CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
			dicine/ingredient/[@classCode='ACTI']/ingredient@code			
R19.3	**Medication Summary Strenght**		**Medication Item Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.4** entry/substanceAdministration[templateId/[@root= '1.3.6.1.4.1.12559.11.10.1.3.1.3.4']/consumable/medication/admninisterableMedicine/ingredient/[@classCode='ACTI']/quantity	O	PQ ,PQ	
R19.4	**Medication Summary Number of units per intake**		**Medication Item Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.4** entry/substanceAdministration[templateId/[@root= '1.3.6.1.4.1.12559.11.10.1.3.1.3.4']/doseQuantity/@value	O	INT	
R19.5	**Medication Summary Frequency of intake**		**Medication Item Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.4** entry/substanceAdministration[templateId/[@root= '1.3.6.1.4.1.12559.11.10.1.3.1.3.4']/effectiveTime[2]	O	TS IVL_TS PIVL_TS EIVL_TS	If EIVL_TS mode is used, HL7 TimingEvent vocabulary (2.16.840.1.113883.5.139) SHALL be used.
R19.6	**Medication Summary Duration of treatment**		**Medication Item Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.4** entry/substanceAdministration[templateId/@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.4']/effectiveTime[1][@xsi:type='IVL_TS']/low/@value entry/substanceAdministration[templateId/@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.4']/	O	IVL_TS	

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Section Template CDA XPath expression	PCC Entry content modules CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
			effectiveTime[1][@ xsi:type='IVL_TS']/high/@value			
R19.7	**Medication Summary Date of onset of treatment**		**Medication Item Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.4** entry/substanceAdministration[templateId/[@root= '1.3.6.1.4.1.12559.11.10.1.3.1.3.4']/effectiveTime[1][@ xsi:type='IVL_TS']/low	O	TS	
R19.8	**Medication Summary Pharmaceutical Dose Form**		**Medication Item Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.4** entry/substanceAdministration[templateId/[@root= '1.3.6.1.4.1.12559.11.10.1.3.1.3.4']/consumable/medication/admninisterableMedicine/formCode	O	CD	epSOS:DoseForm 1.3.6.1.4.1.12559.11.10.1.3.1.42.2

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7.3. Additional Header Information

In addition to the XPath expression in the table containing the header data elements, there are certain constrains that must be respected. They have been noted in the table as "notes" and they are being explained in the sections below.

7.3.1. Guardian

Note 1
The guardians of a patient shall be recorded in the <guardian> element beneath the ***/ClinicalDocument/recordTarget/patientRole/patient*** XML - <patient> element. The <associatedEntity> element defines the type of contact. The classCode attribute shall be present, and contains a value from the set AGNT, CAREGIVER, ECON, NOK, or PRS to identify contacts that are agents of the patient, care givers, emergency contacts, next of kin, or other relations respectively.

The relationship between the patient and the guardian or other contact should be recorded in the <code> element. The code attribute is required and comes from the HL7 PersonalRelationshipRoleType vocabulary.

The address of the guardian or other contact should be present, and shall be represented as any other address would be in CDA.

The phone number of the guardian or other contact should be present, and shall be represented as any other phone number would be in CDA.

The name of the guardian or other contact shall be present, and shall be represented as any other name would be in CDA.

7.3.2. Healthcare Service Identification

Note 2
The Healthcare Service Identification information is represented in structures under the `/ClinicalDocument/author` XML element. The following table lists the relevant structures for the elements specified in the previous section.

Note: The Nature of Patient Summary is determined as follows: If there is a person author only, there was direct human intervention; if there is a device author only, the summary was automatically generated; if there are both a person and a device as authors, the summary was created via a mixed approach.

By definition, a Patient Summary document describes the Patient Summary at the time of creation of the document, represented by the `/ClinicalDocument/effectiveTime` XML Element. The latest summary update can be represented by the `/ClinicalDocument/documentationOf/serviceEvent/effectiveTime/high` XML Element (see section 2.1, CONF-2, CONF-3 and CONF-4 of the CCD specification).

7.4. Additional Body Specifications

The CDA body is organized in sections, which contain both the narrative text and the discrete data for that section. The discrete data is represented in structures under the `/ClinicalDocument/component/structuredBody/component/section/entry` XML element.

The reference materials are:

- IHE Patient Care Coordination (PCC), Technical Framework Volume 2, Revision 5.0, Final Text August 10, 2009
- IHE Patient Care Coordination, Technical Framework Supplement, CDA Content Modu Trial Implementation Supplement, August 10, 2009

  The functional requirements defined by the work packages WP3.1 and WP3.2 are mapped onto CDA content modules, with the appropriate template definitions.

7.4.1. Standards

HL7V3 NE2006	HL7 V3 Normative Edition 2006
HL7V3 NE2008	HL7 V3 Normative Edition 2008
HL7V3 NE2009	HL7 V3 Normative Edition 2009
CDAR2	HL7 CDA Release 2.0
CRS	HL7 Care Record Summary
CCD	ASTM/HL7 Continuity of Care Document
LOINC	Logical Observation Identifier Names and Codes

7.4.2. Mapping on the CDA templates - Body

The same approach was taken in this section as in the header section. The functional requirements were listed and the sections with their corresponding entries were listed. Wherever appropriate, binding vocabularies are indicated.

As the body contains clinical information and it is more complex than the header, individual descriptions are given for the elements needing more explanations.

For more information please read the main deliverable D3.5.2 for more information, namely Semantic Services Definition, D3.5.2_epSOS_WP3_5_v0.0.6_20100531.

7.4.3. Data Elements - CDA R2 Sections and Entries

This section will provide more information about the elements listed in the table of section 4.3.

The CDA body is organized in sections, which contain both the narrative text and the discrete data for that section. The discrete data is represented in structures under the `/ClinicalDocument/component/structuredBody/component/section/entry` XML element.

8 Prescription and Dispensed Medicine Data

The epSOS specification describes three distinct documents: ePrescription (eP), eDispensation (eD), and Patient Summary (PS).

The eD and eP documents are specific for the purposes of the epSOS project and as such contain sections and entries that are specific for each document's purpose. The PS document reuses a large number of sections and entry, which have been already defined by other standards.

8.1. General Information

The following table shows the overall structures of the eP and eD documents:

Structure	**ePrescription**	**eDispensation**	**Patient Summary**
Format Code	urn:epSOS:ep:pre:2010	urn:epSOS:ep:dis:2010	urn:epSOS:ps:ps:2010
Document Template ID	1.3.6.1.4.1.12559.11.10.1.3.1.1.1	1.3.6.1.4.1.12559.11.10.1.3.1.1.2	1.3.6.1.4.1.12559.11.10.1.3.1.1.3
Section name/template ID	Prescription 1.3.6.1.4.1.12559.11.10.1.3.1.2.1	Dispensation 1.3.6.1.4.1.12559.11.10.1.3.1.2.2	Medication Summary 1.3.6.1.4.1.12559.11.10.1.3.1.2.3
Entry name / template ID	Prescription Item 1.3.6.1.4.1.12559.11.10.1.3.1.3.2	Dispensed Medicine 1.3.6.1.4.1.12559.11.10.1.3.1.3.3	Medication Item 1.3.6.1.4.1.12559.11.10.1.3.1.3.4
Medicine Content Entry Module template ID	1.3.6.1.4.1.12559.11.10.1.3.1.3.1	1.3.6.1.4.1.12559.11.10.1.3.1.3.1	1.3.6.1.4.1.12559.11.10.1.3.1.3.1

Many of the prescription and dispensation data elements could be represented by the information contained in the **Medications section content module** (template ID 1.3.6.1.4.1.19376.1.5.3.1.3.19), described in the IHE PCC Technical Framework. The corresponding entry structure for discrete data is described in the **Medications Entry content module**, 1.3.6.1.4.1.19376.1.5.3.1.4.7. The following figure illustrates the basic structures of the eP and eD documents:

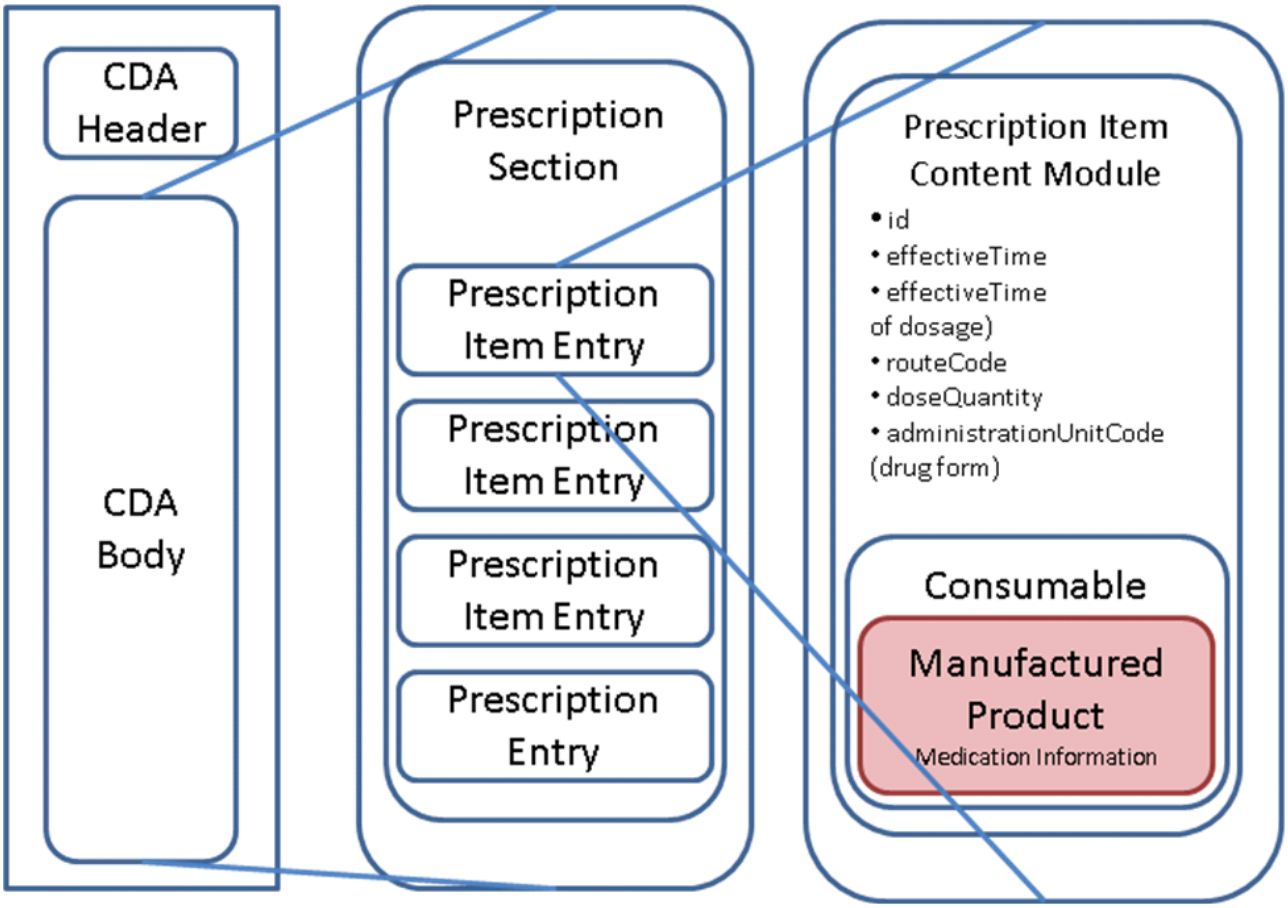

Figure 2C- *ePrescription Document Structure*

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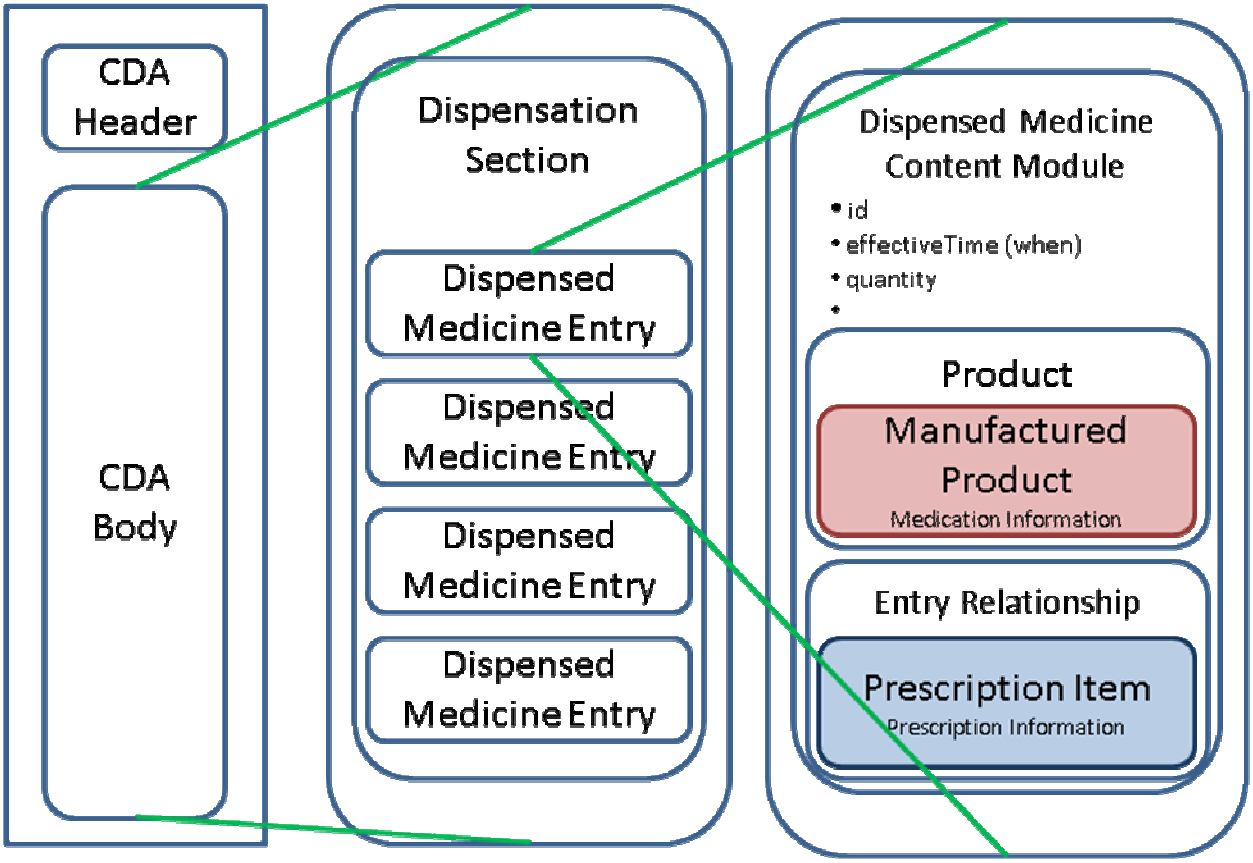
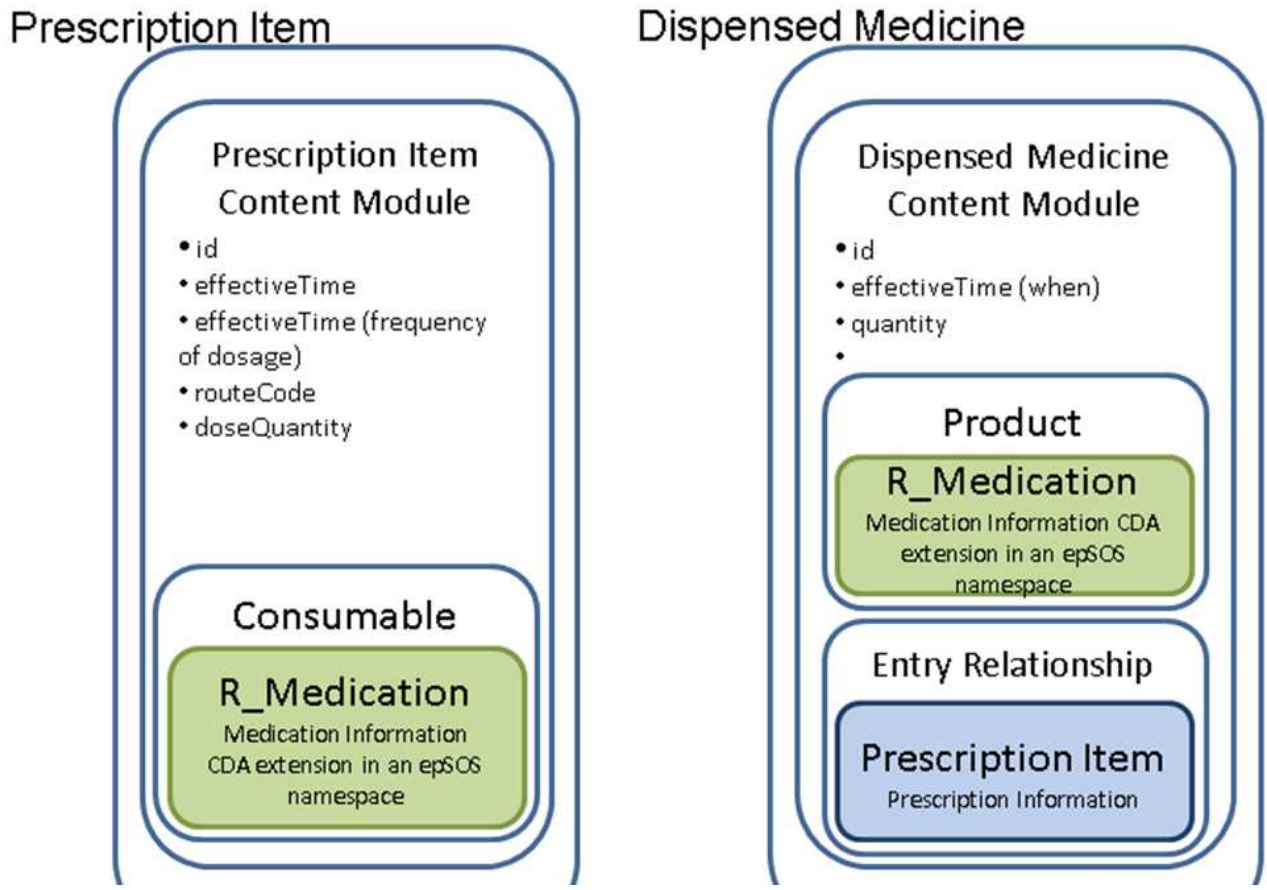


Figure 3C - *eDispensation Document Structure*

The data elements selected by Work Package 3.1, however, necessitate a more thorough representation of the actual medication. This is achieved by the use of a medication structure based on a standard HL7 V3 Common Message Element Type (CMET). The following figure shows how the use of the CMET fits within the overall entry by replacing the "Manufactured Product" structure with the Medication structure:



350 ***Figure 3C** - Using the R_Medication CMET*

8.1.1. Medication Summary Section 1.3.6.1.4.1.12559.11.10.1.3.1.2.3

Template ID	1.3.6.1.4.1.12559.11.10.1.3.1.2.3	
Parent Template	CCD 3.9 (2.16.840.1.113883.10.20.1.8) 1.3.6.1.4.1.19376.1.5.3.1.3.19	
General Description	The medication summary section shall contain a description of the patient's medications as part of the patient summary	
LOINC Code	**Opt**	**Description**
10160-0	R	HISTORY OF MEDICATION USE
Entries	**Opt**	**Description**
1.3.6.1.4.1.12559.11.10.1.3.1.3.4	R	Medication Item

```
<component>
  <section>
    <templateId root='2.16.840.1.113883.10.20.1.8'/>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.19'/>
    <templateId root='1.3.6.1.4.1.12559.11.10.1.3.1.2.1'/>
    <!-- The section ID is the Prescription ID -->
    <id root=' ' extension=' '/>
    <code code='10160-0' displayName='HISTORY OF MEDICATION USE'
      codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
    <text>
      Text as described above
    </text>
    <!-- Each entry is a Medication -->
    <!-- Medication 1 -->
    <entry>
         :
      <!-- Required element indicating the medication item entry content module -->
        <templateId root='1.3.6.1.4.1.12559.11.10.1.3.1.3.4'/>
         :
    </entry>
    <!-- Medication 2 -->
    <entry>
         :
      <!-- Required element indicating the medication item entry content module -->
        <templateId root='1.3.6.1.4.1.12559.11.10.1.3.1.3.4'/>
         :
    </entry>
  </section>
</component>
```

***Figure 4C** - Sample Patient Summary Section*

8.1.1.1. Parent Templates

The parents of this template are CCD 3.9, and PCC 1.3.6.1.4.1.19376.1.5.3.1.3.19.

8.1.1.2. Medication Item Entry Content Module (1.3.6.1.4.1.12559.11.10.1.3.1.3.4)

8.1.1.2.1. Standards

This part describes the general structure for a medication. It is based on the following standards:

Medication CMET	HL7 V3 2009 Normative Edition
CCD	ASTM/HL7 Continuity of Care Document
IHE PCC	Medications Entry (1.3.6.1.4.1.19376.1.5.3.1.4.7)

8.1.1.2.2. Specification

This entry content module makes use of the medicine and instruction entry content modules. Medications and their prescriptions are perhaps the most difficult data elements to model due to variations in the ways that medications are prescribed.

This profile identifies the following relevant fields of a medication as being important to be able to generate in a medical summary. The table below identifies and describes these fields, and indicates the constraints on whether or not they are required to be sent. The fields are listed in the order that they appear in the CDA XML content.

```
<substanceAdministration classCode='SBADM' moodCode='INT|EVN'>
  <templateId root='2.16.840.1.113883.10.20.1.24'/>
  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7'/>
  <templateId root='1.3.6.1.4.1.12559.11.10.1.3.1.3.4'/>
  <id root='' extension=''/>
  <code code='' codeSystem='' displayName='' codeSystemName=''/>
  <text><reference value='#med-1'/></text>
  <statusCode code='completed'/>
  <effectiveTime xsi:type='IVL_TS'>
      <low value=''/>
      <high value=''/>
  </effectiveTime>
  <effectiveTime operator='A' xsi:type='TS|PIVL_TS|EIVL_TS|PIVL_PPD_TS|SXPR_TS'>
    :
  </effectiveTime>
  <routeCode code='' codeSystem='' displayName='' codeSystemName=''/>
  <doseQuantity value='' unit=''/>
  <approachSiteCode code='' codeSystem='' displayName='' codeSystemName=''/>
  <rateQuantity value='' unit=''/>
  <consumable>
    :
    .
  </consumable>
  <author>
      <time/>
      <assignedAuthor>
          <id/>
          <assignedPerson>
              <name></name>
          </assignedPerson>
      </assignedAuthor>
  </author>
  <!-- 0..* entries describing the components -->
  <entryRelationship typeCode='COMP' >
      <sequenceNumber value=''/>
  </entryRelationship>
  <!-- An optional entry relationship that indicates the the reason for use -->
  <entryRelationship typeCode='RSON'>
    <act classCode='ACT' moodCode='EVN'>
      <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.4.1'/>
      <id root='' extension=''/>
    </act>
  </entryRelationship>
  <!-- Optional instrctions for Phramacist -->
  <entryRelationship typeCode='SUBJ'>
     ...
  </entryRelationship>
  <precondition>
    <criterion>
      <text><reference value=''></text>
    </criterion>
  </precondition>
</substanceAdministation>
```

Figure 5C - *Sample Medication Entry Content Module*

460 **8.1.1.2.3. Medication Data Elements**

Field	CDA Tag	Description
Start and Stop Date	<effectiveTime>	The date (and time if available) when the medication regimen began and is expected to finish. The first component of the <effectiveTime> encodes the lower and upper bounds over which the <substanceAdministration> occurs, and the start time is determined from the lower bound. If the medication has been known to be stopped, the high value must be present, but expressed as a flavor of null (e.g., Unknown).
Frequency	<effectiveTime>	The frequency indicates how often the medication is to be administered. It is often expressed as the number of times per day, but which may also include information such as 1 hour before/after meals, or in the morning, or evening.The second <effectiveTime> element encodes the frequency. In cases where split or tapered doses are used, these may be found in subordinate <substanceAdministration> elements.
Route	<routeCode>	The route is a coded value, and indicates how the medication is received by the patient (by mouth, intravenously, topically, et cetera).
Dose	<doseQuantity>	The amount of the medication given. This should be in some known and measurable unit, such as grams, milligrams, et cetera. It may be measured in "administration" units (such as tablets or each), for medications where the strength is relevant. In this case, only the unit count is specified , no units are specified. It may be a range.
Product	<consumable> <name> </consumable>	The name of the substance or product. This should be sufficient for a provider to identify the kind of medication. It may be a trade name or a generic name. This information is required in all medication entries. If the name of the medication is unknown, the type, purpose or other description may be supplied. The name should not include packaging, strength or dosing information. Note: Due to restrictions of the CDA schema, there is no way to explicitly link the name to the narrative text.
Strength	<consumable> <code> <originalText/> </code> </consumable>	The name and strength of the medication. This information is only relevant for some medications, as the dose of the medication is often sufficient to indicate how much medication the patient receives. For example, the medication Percocet comes in a variety of strengths, which indicate specific amounts of two different medications being received in single tablet. Another example is eye-drops, where the medication is in a solution of a particular strength, and the dose quantity is some number of drops. The originalText referenced by the <code> element in the consumable should refer to the name and strength of the medication in the narrative text.Note: Due to restrictions of the CDA schema, there is no way to separately record the strength.
Code	<consumable> <code/> </consumable>	A code describing the product from a controlled vocabulary, such as ATC, for example.
Instructions	<entryRelationship>	A place to put free text comments to support additional relevant information, or to deal with specialized dosing instructions. For example, "take with food", or tapered dosing.
Indication	<entryRelationship>	A link to supporting clinical information about the reason for providing the medication (e.g., a link to the relevant diagnosis).

8.1.1.2.4. Medication Item Entry Content Module General Specifications

<substanceAdministration classCode='SBADM' moodCode='INT>

The general model is to record each prescribed medication in a <substanceAdministration> intent (moodCode='INT'). The <substanceAdministration> element may contain subordinate <substanceAdministration> elements in a related component entry to deal with special cases (see the following sections below on Special Cases).
These cases include split, tapered, or conditional dosing, or combination medications. The use of subordinate <substanceAdministration> elements to deal with these cases is optional. The comment field should always be used in these cases to provide the same information as free text in the top level <substanceAdministration> element. There are a variety of special cases for dosing that need to be accounted for. These are described below. Most of these special cases involve changing the dosage or frequency over time, or based on some measurement. When the dosage changes, then additional entries are required for each differing dosage. The last case deals with combination medications.

For the purposes of WP3.5 only the normal and the combination medications are addressed.

- **Normal Dosing 1.3.6.1.4.1.19376.1.5.3.1.4.7.1**
  This template identifier is used to identify medication administration events that do not require any special processing. The parent template is 1.3.6.1.4.1.19376.1.5.3.1.4.7. Medications that use this template identifier shall not use subordinate <substanceAdministation> acts.

- **Combination Medications 1.3.6.1.4.1.19376.1.5.3.1.4.11**
  This template identifier is used to identify medication administration events that require special processing to handle combination medications. The parent template is 1.3.6.1.4.1.19376.1.5.3.1.4.7. A combination medication is made up of two or more other medications. These may be prepackaged, such as Percocet, which is a combination of Acetaminophen and oxycodone in predefined ratios, or prepared by a pharmacist, such as a GI cocktail.

  In the case of the prepackaged combination, it is sufficient to supply the name of the combination drug product, and its strength designation in a single <substanceAdministation> entry. The dosing information should then be recorded as simply a count of administration units.

  In the latter case of a prepared mixture, the description of the mixture should be provided as the product name (e.g., "GI Cocktail") , in the <substanceAdministration> entry. That entry may, but is not required, to have subordinate <substanceAdministration> entries included beneath it to record the components of the mixture.

8.1.1.2.4.1. Medication Item Entry Content Module TemplateID

All prescription item entries use the <templateId> elements specified below to indicate that they are medication acts. This element is required. In addition, a medication entry shall further identify itself using one of the template identifiers detailed in the next section.

```
<templateId root='2.16.840.1.113883.10.20.1.24'/> (CCD)
<templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7' /> (PCC)
<templateId root='1.3.6.1.4.1.12559.11.10.1.3.1.3.4' /> (epSOS)
```

8.1.1.2.4.2. Medication Item Entry Content Module Additional TemplateID

<templateId root=' ' />

The <templateId> element identifies this <entry> as a particular type of medication event, allowing for validation of the content. As a side effect, readers of the CDA can quickly locate and identify medication events. The templateId must use one of the values in the table below for the root attribute.

Root	Description
1.3.6.1.4.1.19376.1.5.3.1.4.7.1	A "normal" <substanceAdministration> act that may not contain any subordinate <substanceAdministration> acts.
1.3.6.1.4.1.19376.1.5.3.1.4.11	A <substanceAdministration> act that records combination medication component information in subordinate <substanceAdministration> acts.

Other template IDs exist for the tapered doses, split dosing, conditional dosing, and combination medications. The reader is pointed to the PCC-TF:2 section 6.1.4.16.5.

8.1.1.2.4.2.1. Substance Administration ID

<id root=' ' extension=' '/>

A top level <substanceAdministration> element must be uniquely identified. This can be the prescription ID if appropriate. Although HL7 allows for multiple identifiers, one and only one shall be used.

8.1.1.2.4.2.2. Substance Administration Code

<code code=' ' displayName=' ' codeSystem=' ' codeSystemName=' '>

The <code> element is used to supply a code that describes the <substanceAdminstration> act, not the medication being administered or prescribed. This may be a procedure code, such as those found in ICD-10, or may describe the method of medication administration, such as by intravenous injection. The type of medication is coded in the consumable; do not supply the code for the medication in this element. This element is optional.

One of the following values from the Value Set **epSOSCodeNoMedication** shall be used in the <code> element to record that a patient is either not on medications, or that medications are not known.

8.1.1.2.4.3. Substance Administration Reference Value

<text><reference value=' '/></text>

The URI given in the value attribute of the <reference> element points to an element in the narrative content that contains the complete text describing the medication. In a CDA document, the URI given in the value attribute of the <reference> element points to an element in the narrative content that contains the complete text describing the medication.

8.1.1.2.4.4. Substance Administration Status Code

<statusCode code='completed'/>

The status of all <substanceAdministration> elements must be "completed". The act has either occurred, or the request or order has been placed.

8.1.1.2.4.5. Substance Administration Effective Time

<effectiveTime xsi:type='IVL_TS'>

The first <effectiveTime> element encodes the start and stop time of the medication regimen. This an interval of time (xsi:type='IVL_TS'), and must be specified as shown. This is an additional constraint placed upon CDA Release 2.0 by this profile, and simplifies the exchange of start/stop and frequency information between EMR systems.

8.1.1.2.4.5.1. Effective Time Low and High Values

<low value=' '/><high value=' '/>

The <low> and <high> values of the first <effectiveTime> element represent the start and stop times for the medication. The <low> value represents the start time, and the <high> value represents the stop time. If either the <low> or the <high> value is unknown, this shall be recorded by setting the nullFlavor attribute to UNK.

The <high> value records the end of the medication regime according to the information provided in the prescription or order. For example, if the prescription is for enough medication to last 30 days, then the high value should contain a date that is 30 days later then the <low> value. The rationale is that a provider, seeing an un-refilled prescription would normally assume that the medication is no longer being taken, even if the intent of the treatment plan is to continue the medication indefinitely.

8.1.1.2.4.5.2. Effective Time Expression

<effectiveTime operator='A' xsi:type='TS|PIVL_TS|EIVL_TS|PIVL_PPD_TS|SXPR_TS' />

The second <effectiveTime> element records the frequency of administration. This <effectiveTime> element must be intersected with the previous time specification (operator='A'), producing the bounded set containing only those time specifications that fall within the start and stop time of the medication regimen. Several common frequency expressions appear in the table below, along with their XML representations.

8.1.1.2.4.5.3. Medication Frequency Specifications

Frequency	Description	XML Representation
b.i.d.	Twice a day	<effectiveTime xsi:type='PIVL_TS' institutionSpecified='true' operator='A'> <period value='12' unit='h' /></effectiveTime>
q12h	Every 12 hours	<effectiveTime xsi:type='PIVL_TS' institutionSpecified='false' operator='A'> <period value='12' unit='h' /></effectiveTime>
Once	Once, on 2005-09-01 at 1:18am.	<effectiveTime xsi:type='TS' value='200509010118'/>
t.i.d.	Three times a day, at times determined by the person administering the medication .	<effectiveTime xsi:type='PIVL_TS' institutionSpecified='true' operator='A'> <period value='8' unit='h' /></effectiveTime>
q8h	Every 8 hours	<effectiveTime xsi:type='PIVL_TS' institutionSpecified='false' operator='A'> <period value='8' unit='h' /></effectiveTime>
qam	In the morning	<effectiveTime xsi:type='EIVL' operator='A'> <event code='ACM'/></effectiveTime>
	Every day at 8 in the morning for 10 minutes	<effectiveTime xsi:type='PIVL_TS' operator='A'> <phase> <low value="198701010800" inclusive="true"/> <width value="10" unit="min"/> </phase> <period value='1' unit='d'/></effectiveTime>
q4-6h	Every 4 to 6 hours.	<effectiveTime xsi:type='PIVL_PPD_TS' institutionSpecified='false' operator='A'> <period value='5' unit='h' /> <standardDeviation value='1' unit='h'></effectiveTime>

575 The mean (average) of the low and high values is specified for the period. The mean of 4 and 6 is 5. The standard deviation is recorded as one half the differences between the high and low values, with an unspecified distribution. The type attribute of the <effectiveTime> element describes the kind of frequency specification it contains. More detail is given for each type in the table below.

580 #### 8.1.1.2.4.5.3.1. Data types used in Frequency Specifications

xsi:type	Description
TS	An xsi:type of TS represents a single point in time, and is the simplest of all to represent. The value attribute of the <effectiveTime> element specifies the point in time in HL7 date-time format (CCYYMMDDHHMMSS)

xsi:type	Description
PIVL_TS	An xsi:type of PIVL_TS is the most commonly used, representing a periodic interval of time. The <low> element of <phase> may be present. If so it specifies the starting point, and only the lower order components of this value are relevant with respect to the <period>. The <width> element represents the duration of the dose administration (e.g., for IV administration). The <period> indicates how often the dose is given. Legal values for the unit attribute of <period> are s, min, h, d, wk and mo representing seconds, minutes, hours, days, weeks, and months respectively.
EIVL_TS	An xsi:type of EIVL_TS represents an event based time interval, where the event is not a precise time, but is often used for timing purposes (e.g. with meals, between meals, before breakfast, before sleep). Refer to the HL7 TimingEvent vocabulary for the codes to use for the <event> element. This interval may specify an <offset> which provides information about the time offset from the specified event (e.g., <offset><low value='-1' unit='h'/><width value='10' unit='min'/></offset> means 1 hour before the event. In that same example, the <width> element indicates the duration for the dose to be given.
PIVL_PPD_TS	An xsi:type of PIVL_PPD_TS represents an probabilistic time interval and is used to represent dosing frequencies like q4-6h. This profile requires that the distributionType of this interval be left unspecified. The <period> element specifies the average of the time interval, and the value of the <standardDeviation> shall be computed as half the width of the interval. The unit attributes of the <period> and <standardDeviation> elements shall be the same.
SXPR_TS	An xsi:type of SXPR_TS represents a parenthetical set of time expressions. This type is used when the frequency varies over time (e.g., for some cases of tapered dosing, or to handle split dosing). The <comp> elements of this <effectiveTime> element are themselves time expressions (using any of the types listed above). Each <comp> element may specify an operator (e.g. to intersect or form the union of two sets).

8.1.1.2.4.6. Route of Administration

```
<routeCode
  code=' '
  displayName=' '
  codeSystem=' 1.3.6.1.4.1.12559.11.10.1.3.1.42.12'
  codeSystemName='epSOSRoutesofAdministration'/>
```

The <routeCode> element specifies the route of administration using the EDQM route of administration vocabulary. A code must be specified if the route is known, and the displayName attribute should be specified. If the route is unknown, this element shall not be sent.

8.1.1.2.4.7. Dose Quantity

```
<doseQuantity>
  <low value=' ' unit=' '/>
  <high value=' ' unit=' '/>
</doseQuantity>
```

The dose is specified in the <doseQuantity> element. If a dose range is given (e.g., 1-2 tablets, or 325-750mg), then the <low> and <high> bounds are specified in their respective elements, otherwise both <low> and <high> have the same value. If the dose is in countable units (tablets, caplets, "eaches"), then the unit attribute is not sent. Otherwise the units are sent. The unit attribute shall be

derived from the **Value Sets epSOSUnits**, 1.3.6.1.4.1.12559.11.10.1.3.1.42.16 based on the UCUM code system. The countable units attribute shall be derived from the value set **epSOSDoseForm, OID 1.3.6.1.4.1.12559.11.10.1.3.1.42.2.**

8.1.1.2.4.7.1. Quantity values

```
<low|high value=' '>
  <translation>
    <originalText><reference value=' '/></originalText>
  </translation>
</low|high >
```

Any <low> and <high> elements used for <doseQuantity> or <rateQuantity> should contain a <translation> element that provides a <reference> to the <originalText> found in the narrative body of the document.

In a CDA document, any <low> and <high> elements used for <doseQuantity> or <rateQuantity> should contain a <translation> element that provides a <reference> to the <originalText> found in the narrative body of the document.

8.1.1.2.4.8. Rate Quantity

```
<rateQuantity>
  <low value=' ' unit=' '/>
  <high value=' ' unit=' '/>
</rateQuantity>
```

The rate is specified in the <rateQuantity> element. The rate is given in units that have measure over time. In this case, the units should be specified as a string made up of a unit of measure (see doseQuantity above), followed by a slash (/), followed by a time unit (s, min, h or d).

Again, if a range is given, then the <low> and <high> elements contain the lower and upper bound of the range, otherwise, they contain the same value.

8.1.1.2.4.9. Consumable

<consumable>...</consumable>

The <consumable> element shall be present, and shall contain a <medication> element, conforming to the Medicine Entry Content module template.

8.1.1.2.4.10. Author

<author>…</author>

In the case where there is a prescriber of a medication, the prescriber shall be represented by the <author> element of the entry. See the **Prescriber description** for the structure of the <author> element.

8.1.1.2.4.11. Fulfillment Instructions

<entryRelationship typeCode='SUBJ'>...</entryRelationship>

An entry relationship may be present to provide the fulfillment instructions. When present, this entry relationship shall contain a Medication Fulfillment Instructions entry content module.

8.1.1.2.4.12. Component

<entryRelationshiptypeCode='COMP'>
<sequenceNumbervalue=' '>
…
</entryRelationship>

A top level <substanceAdministration> element may contain one or more related components, either to handle split, tapered or conditional dosing, or to support combination medications.

In the first three cases, the subordinate components shall specify only the changed <frequency> and/or <doseAmount> elements. For conditional dosing, each subordinate component shall have a <precondition> element that specifies the <observation> that must be obtained before administration of the dose. The value of the <sequenceNumber> shall be an ordinal number, starting at 1 for the first component, and increasing by 1 for each subsequent component. Components shall be sent in <sequenceNumber> order.

This information is given for informative purposes as only normal or combination medications are administered in epSOS.

8.1.2. Prescription Section 1.3.6.1.4.1.12559.11.10.1.3.1.2.1

Template ID	1.3.6.1.4.1.12559.11.10.1.3.1.2.1	
Parent Template	CCD 3.9 (2.16.840.1.113883.10.20.1.8) 1.3.6.1.4.1.19376.1.5.3.1.3.19 1.3.6.1.4.1.12559.11.10.1.3.1.2.3	
General Description	The prescription section shall contain a description of the medications in a given prescription for the patient. It shall include entries for each prescription item as described in the Prescription Item Entry Content Module.	
LOINC Code	**Opt**	**Description**
10160-0	R	HISTORY OF MEDICATION USE
Entries	**Opt**	**Description**
1.3.6.1.4.1.12559.11.10.1.3.1.3.2	R	Prescription Item Entry Content Module

```
<component>
  <section>
    <templateId root='2.16.840.1.113883.10.20.1.8'/>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.19'/>
    <templateId root='1.3.6.1.4.1.12559.11.10.1.3.1.2.3'/>
    <templateId root='1.3.6.1.4.1.12559.11.10.1.3.1.2.1'/>
    <!-- The section ID is the Prescription ID -->
    <id root=' ' extension=' '/>
    <code code='10160-0' displayName='HISTORY OF MEDICATION USE'
      codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
    <text>
      Text as described above
    </text>
    <!-- Each entry is a prescription item -->
    <!-- Prescription item 1 -->
    <entry>
         :
      <!-- Required element indicating the prescription entry content module -->
        <templateId root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2'/>
         :
    </entry>
    <!-- Prescription item 2 -->
    <entry>
         :
      <!-- Required element indicating the prescription entry content module -->
        <templateId root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2'/>
         :
    </entry>
  </section>
</component>
```

Figure 6C - *Sample Prescription Section*

8.1.2.1. Parent Templates

The parents of this template are CCD 3.9, PCC 1.3.6.1.4.1.19376.1.5.3.1.3.19, and the Medication Summary Section 1.3.6.1.4.1.12559.11.10.1.3.1.2.3

8.1.2.2. Prescription ID

The Prescription identifier is represented in the section ID, as the `/ClinicalDocument/component/structuredBody/component/section/id` XML element. The data type of the ID is II

8.1.2.3. Prescriber

The prescriber is the author of a particular prescription, and is described within the specific entry structure of the prescription under the `/ClinicalDocument/component/structuredBody/component/section/author` XML element.

Data element	HL7 V3 Data Type	CDA Body position (relative XPath expression)
Prescriber Profession	CE	`author/functionCode`
Prescriber Specialty	CE	`author/functionCode`
Timestamp of prescribing	TS	`author/time`

Data element	HL7 V3 Data Type	CDA Body position (relative XPath expression)
Prescriber ID	II	*author/assignedAuthor/id*
Prescriber Name	PN	*author/assignedAuthor/assignedPerson/name*
Prescriber Organization Identifier	II	*author/assignedAuthor/representedOrganization/id*
Prescriber Organization Name	ON	*author/assignedAuthor/representedOrganization/name*
Prescriber Organization Address	AD	*author/assignedAuthor/representedOrganization/addr*

For more detail on the individual elements, please see section 3, within the header.

8.1.2.4. Prescription Item Entry Content Module (1.3.6.1.4.1.12559.11.10.1.3.1.3.2)

8.1.2.4.1. Standards

This part describes the general structure for a prescription item. It is based on the following standards:

Medication CMET	HL7 V3 2009 Normative Edition
CCD	ASTM/HL7 Continuity of Care Document
IHE PCC	Medications Entry (1.3.6.1.4.1.19376.1.5.3.1.4.7)

8.1.2.4.2. Parent Template

This entry content module inherits the structure of the Medication Entry Content Module, 1.3.6.1.4.1.12559.11.10.1.3.1.3.4.

8.1.2.4.3. Specification

This section makes use of the medicine and instruction entry content modules. Medications and their prescriptions are perhaps the most difficult data elements to model due to variations in the ways that medications are prescribed.

This specification identifies the following relevant fields of a medication as being important to be able to generate in a medical summary. The table below identifies and describes these fields, and indicates the constraints on whether or not they are required to be sent. The fields are listed in the order that they appear in the CDA XML content.

```
<substanceAdministration classCode='SBADM' moodCode='INT'>
  <templateId root='2.16.840.1.113883.10.20.1.24'/>
  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7'/>
  <templateId root='1.3.6.1.4.1.12559.11.10.1.3.1.3.4'/>
  <templateId root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2'/>
  <templateId root=''/>
  <id root='' extension=''/>
  <code code='' codeSystem='' displayName='' codeSystemName=''/>
  <text><reference value='#med-1'/></text>
  <statusCode code='completed'/>
  <effectiveTime xsi:type='IVL_TS'>
      <low value=''/>
      <high value=''/>
  </effectiveTime>
  <effectiveTime operator='A' xsi:type='TS|PIVL_TS|EIVL_TS|PIVL_PPD_TS|SXPR_TS'>
    :
  </effectiveTime>
  <routeCode code='' codeSystem='' displayName='' codeSystemName=''/>
  <doseQuantity value='' unit=''/>
  <approachSiteCode code='' codeSystem='' displayName='' codeSystemName=''/>
  <rateQuantity value='' unit=''/>
  <consumable>
    :
    .
  </consumable>
  <author>
      <time/>
      <assignedAuthor>
          <id/>
          <assignedPerson>
              <name></name>
          </assignedPerson>
      </assignedAuthor>
  </author>
  <!-- 0..* entries describing the components -->
  <entryRelationship typeCode='COMP' >
      <sequenceNumber value=''/>
  </entryRelationship>
  <!-- An optional entry relationship that indicates the the reason for use -->
  <entryRelationship typeCode='RSON'>
    <act classCode='ACT' moodCode='EVN'>
      <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.4.1'/>
      <id root='' extension=''/>
    </act>
  </entryRelationship>
  <!-- Optional instrctions for Phramacist -->
  <entryRelationship typeCode='SUBJ'>
     ...
  </entryRelationship>
  <precondition>
    <criterion>
      <text><reference value=''></text>
    </criterion>
  </precondition>
</substanceAdministation>
```

Figure 7C - *Sample Medication Entry Content Module*

8.1.2.4.4. ePrescription Data Elements

See 2.4.2.2.3

8.1.2.4.5. Prescription Item Entry General Specifications

<substanceAdministration classCode='SBADM' moodCode='INT>
…
</substanceAdministration>

The general model is to record each prescribed medication in a <substanceAdministration> intent (moodCode='INT'). The <substanceAdministration> element may contain subordinate <substanceAdministration> elements in a related component entry to deal with special cases (see the following sections below on Special Cases). These cases include split, tapered, or conditional dosing, or combination medications.

The use of subordinate <substanceAdministration> elements to deal with these cases is optional. The comment field should always be used in these cases to provide the same information as free text in the top level <substanceAdministration> element. There are a variety of special cases for dosing that need to be accounted for. These are described below. Most of these special cases involve changing the dosage or frequency over time, or based on some measurement. When the dosage changes, then additional entries are required for each differing dosage. The last case deals with combination medications.

For the purposes of WP3.5 only the normal and the combination medications are addressed.

- **Normal Dosing 1.3.6.1.4.1.19376.1.5.3.1.4.7.1**
  This template identifier is used to identify medication administration events that do not require any special processing. The parent template is 1.3.6.1.4.1.19376.1.5.3.1.4.7. Medications that use this template identifier shall not use subordinate <substanceAdministation> acts.

- **Combination Medications 1.3.6.1.4.1.19376.1.5.3.1.4.11**
  This template identifier is used to identify medication administration events that require special processing to handle combination medications. The parent template is 1.3.6.1.4.1.19376.1.5.3.1.4.7. A combination medication is made up of two or more other medications. These may be prepackaged, such as Percocet, which is a combination of Acetaminophen and oxycodone in predefined ratios, or prepared by a pharmacist, such as a GI cocktail.

  In the case of the prepackaged combination, it is sufficient to supply the name of the combination drug product, and its strength designation in a single <substanceAdministation> entry. The dosing information should then be recorded as simply a count of administration units.

  In the latter case of a prepared mixture, the description of the mixture should be provided as the product name (e.g., "GI Cocktail") , in the <substanceAdministration> entry. That entry may, but is not required, to have

subordinate <substanceAdministration> entries included beneath it to record the components of the mixture.

8.1.2.4.5.1. Prescription Item Entry TemplateID

All prescription item entries use the <templateId> elements specified below to indicate that they are medication acts. This element is required. In addition, a medication entry shall further identify itself using one of the template identifiers detailed in the next section.

```
<templateId root='2.16.840.1.113883.10.20.1.24'/> (CCD)
<templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7' /> (PCC)
<templateId root='1.3.6.1.4.1.12559.11.10.1.3.1.3.4' /> (epSOS)
<templateId root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2' /> (epSOS)
```

8.1.2.4.5.2. Prescription Item Entry Additional TemplateID

<templateId root=' ' />
The <templateId> element identifies this <entry> as a particular type of medication event, allowing for validation of the content. As a side effect, readers of the CDA can quickly locate and identify medication events. The templateId must use one of the values in the table below for the root attribute.

Root	Description
1.3.6.1.4.1.19376.1.5.3.1.4.7.1	A "normal" <substanceAdministration> act that may not contain any subordinate <substanceAdministration> acts.
1.3.6.1.4.1.19376.1.5.3.1.4.11	A <substanceAdministration> act that records combination medication component information in subordinate <substanceAdministration> acts.

Other ~~root~~ template IDs exist for the tapered doses, split dosing, conditional dosing, and combination medications. The reader is pointed to the PCC-TF:2 section 6.1.4.16.5.

8.1.2.4.5.3. Substance Administration ID (Prescription Item ID)

<id root=' ' extension=' '/>
A top level <substanceAdministration> element must be uniquely identified. This is the prescription item ID. Although HL7 allows for multiple identifiers, one and only one shall be used.

8.1.2.4.5.4. Substance Administration Code

<code code=' ' displayName=' ' codeSystem=' ' codeSystemName=' '/>
Please see 2.4.2.2.4.4

8.1.2.4.5.5. Substance Administration Reference Value

<text><reference value=' '/></text>
Please see 2.4.2.2.4.5.

8.1.2.4.5.6. Substance Administration Status Code

<statusCode code='completed'/>
Please see 2.4.2.2.5.6.

8.1.2.4.5.7. Substance Administration Effective Time

<effectiveTime xsi:type='IVL_TS'>
Please see 2.4.2.2.4.7

8.1.2.4.5.8. Route of Administration

```
<routeCode
  code=' '
  displayName=' '
  codeSystem=' 1.3.6.1.4.1.12559.11.10.1.3.1.42.12'
  codeSystemName='epSOSRoutesofAdministration'/>
```

Please see 2.4.2.2.4.8.

8.1.2.4.5.9. Dose Quantity

```
<doseQuantity>
  <low value=' ' unit=' '/>
  <high value=' ' unit=' '/>
</doseQuantity>
```

Please see 2.4.2.2.4.9.

8.1.2.4.5.10. Rate Quantity

```
<rateQuantity>
  <low value=' ' unit=' '/>
  <high value=' ' unit=' '/>
```

8.1.2.4.5.11. </rateQuantity>

Please see 2.4.2.2.4.10.

8.1.2.4.5.12. Consumable

```
<consumable>
  <medication>…</medication>
</consumable>
```

The <consumable> element shall be present, and shall contain a <medication> entry, conforming to the Medicine Entry template (when describing prescriptions).

8.1.2.4.5.13. Author

<author>…</author>
In the unlikely case where the prescriber of a prescription item is different from the author of the prescription, the prescription item prescriber shall be represented by the <author> element of the entry. See the 2.4.3.3 Prescriber description for the structure of the <author> element.

8.1.2.4.5.14. Prescriber Credentialing Organization

```
<participant typeCode="AUT">
  <participantRole classCode="CRED">
    <id root=" " extension=" "/>
    <scopingEntity classCode="ORG">
      <id root=" " extension " "/>
      <desc>Name</desc>
    </scopingEntity>
  </participantRole>
</participant>
```

The organization which provided the credentialing for the prescriber needs to be expressed via a <participant> structure, which is in addition to the <author> element specified earlier. The type code of the <participant> element shall be "AUT", and the class code of the <participantRole> element shall be "CRED".

The ID of the participation role is optional, and when present it shall be the prescriber ID as specified in the <author> structure at the section or entry level.

The credentialing organization (College) is represented by the <scopingEntity> element with a class code of "ORG". The name is represented by the <desc> element, and the credentialing organization (College) ID is represented by the <id> element of the scoping entity

8.1.2.4.5.15. Fulfillment Instructions

<entryRelationship typeCode='SUBJ'>.. </entryRelationship>
An entry relationship may be present to provide the fulfillment instructions. When present, this entry relationship shall contain a Medication Fulfillment Instructions entry.

8.1.2.5. Medicine Entry Content Module (1.3.6.1.4.1.12559.11.10.1.3.1.3.1)

The medicine entry content module describes a medication used in a <substanceAdministratio> or <supply> act. This entry uses the the structure of the HL7 V3 R_Medication Universal Common Message Element (CMET), Release 2.

This structure is part of the HL7 V3 2009 Normative Edition (COCT_RM230100UV). The incorporation of this structure is done according to section ***1.4 CDA Extensibility*** of the HL7 CDA standard. Such an extension of the base CDA standard is an accepted practice in IHE (e.g. in the XD* Lab specification).

For the purposes of WP 3.5 this extension is necessary to satisfy the requirements for eP and eD data elements to represent a generic equivalent and ingredients.

The rules of section ***1.4 CDA Extensibility*** require the designation of a new XML namespace for the XML elements in this structure. For the purposes of documentation, the **namespace *urn:epsos-org:ep:medication*** shall be used.

The following specification and constraints are applied to the structures of the CMET.

8.1.2.5.1. Specification

```
<epsos:medication xmlns:epsos="urn:epsos-org:ep:medication"classCode="ADMM">
    <epsos:administerableMedicine classCode="MMAT" determinerCode="INSTANCE">
        <epsos:code code="10312003" codeSystem="2.16.840.1.113883.6.96"
             displayName="Prednisone preparation"/>
        <epsos:name>Prednisone</epsos:name>
        <epsos:formCode code="CAP" displayName="Capsule" codeSystem="2.2.43.34"
             codeSystemName="some system"/>
        <!-- Container information -->
        <epsos:asContent classCode="CONT">
            <epsos:containerPackagedMedicine classCode="CONT"
determinerCode="INSTANCE">
                <epsos:code code="bottle"/>
                <epsos:name>Package name</epsos:name>
                <epsos:formCode code="capsules"/>
                <epsos:lotNumberText>L33423</epsos:lotNumberText>
                <epsos:capacityQuantity value="30" unit="1"/>
                <epsos:capTypeCode code="ChildProof"/>
            </epsos:containerPackagedMedicine>
        </epsos:asContent>
        <!-- This is the generic equivalent -->
        <epsos:asSpecializedKind classCode="GRIC">
             <epsos:generalizedMedicineClass classCode="MMAT">
                  <epsos:code code="432" codeSystem="2.5.4.3"  displayName="Generic
Equivalent"/>
                  <epsos:name>Generic Equivalent</epsos:name>
             </epsos:generalizedMedicineClass>
        </epsos:asSpecializedKind>
        <!-- This is the list of active ingredients -->
        <epsos:ingredient classCode="ACTI">
             <epsos:ingredient classCode="MMAT" determinerCode="KIND">
                  <epsos:code code="45634" codeSystem="2.3.4.5" displayName="Active
Ingredient 1"/>
                  <epsos:name>Active Ingredient 1</epsos:name>
             </epsos:ingredient>
        </epsos:ingredient>
        <epsos:ingredient classCode="ACTI">
            <epsos:ingredient classCode="MMAT" determinerCode="KIND">
               <epsos:code code="45745" codeSystem="2.3.4.5" displayName="Active
Ingredient 2"/>
                  <epsos:name>Active Ingredient 2</epsos:name>
            </epsos:ingredient>
        </epsos:ingredient>
    </epsos:administerableMedicine>
</epsos:medication>
```

Figure 8C - *Sample Medicine Entry Content Module*

8.1.2.5.2. Template ID

```
<templateId root='1.3.6.1.4.1.12559.11.10.1.3.1.3.1'/>
```

In an epSOS ePrescription or eDispensation document, the name and coding of the medication are specified in the elements under the <epsos:medication> element. The templateId element is required and identifies this as a Medicine entry.

8.1.2.5.3. Medication Code

```
<epsos:code code=' '
  displayName=' '
  codeSystem=' '
  codeSystemName=' '>
   <epsos:originalText>
      <epsos:reference value=' '/>
   </epsos:originalText>
</epsos:code>
```

The <epsos:code> element of the <epsos:adminesterableMedicine> describes the medication. This may be coded using a controlled vocabulary.

In a CDA document, the <epsos:originalText> shall contain an <epsos:reference> whose URI value points to the generic name and strength of the medication in the narrative, or just the generic name alone if strength is not relevant.

Note: When the text is supplied from the narrative, the implication is that if the components of a combination medication are supplied in an entry, these must also be displayed in narrative text; the combination medication will not be able to be broken down into its component parts. This is entirely consistent with the CDA Release 2.0 requirements that the narrative supply the necessary and relevant human readable information content.

The <epsos:code> element is also used to support coding of the medication. If coded, it must provide a code and codeSystem attribute using a controlled vocabulary for medications. The displayName for the code and codeSystemName should be provided as well for diagnostic and human readability purposes, but are not required. ATC is the code systems used.

8.1.2.5.3.1. Medication Name

8.1.2.5.3.2. <epsos:name></epsos:name>

In an epSOS ePrescriprion or eDispensation document, the <epsos:name> element should contain the brand name of the medication.

8.1.2.5.3.3. Medication Form Code

<epsos:formCode code='' displayName='' codeSystem='' codeSystemName=''/>
This code represents the form of the medication (e.g. tablet, capsule, liquid). The value of this code affects the units used in the substance administration quantity element – if the form is a tablet, for example, the unit is 1; if the form is a liquid, the unit

will be part of UCUM. The value set is epSOSDoseForm, OID: 1.3.6.1.4.1.12559.11.10.1.3.1.42.2.

8.1.2.5.3.4. Medication Packaging

```
<epsos:asContent classCode='CONT'>
    <epsos:containerPackagedMedicine classCode='CONT' determinerCode='INSTANCE'>
        <epsos:code code=' '
           displayName=' '
           codeSystem=' '
           codeSystemName=' '/>
        <epsos:name></epsos:name>
        <epsos:formCode code=' '
           displayName=' '
           codeSystem=' '
           codeSystemName=' '/>
        <epsos:lotNumberText></epsos:lotNumberText>
        <epsos:capacityQuantity value=' ' unit=' '/>
        <epsos:capTypeCode code=' '
           displayName=' '
           codeSystem=' '
           codeSystemName=' '/>
    </epsos:containerPackagedMedicine>
</epsos:asContent>
```

Figure 9C *- Sample of the packaging of the medication*

This structure describes the packaging of the medication. The <epsos:code> element provides the code for the particular package. If the package has a brand name, it can be described in the <epsos:name> element. The <epsos:formCode> element must match the <epsos:formCode> element at the <epsos:administerableMedicine> layer. The <epsos:lotNumberText> element is a string representation of a possible lot number. The <epsos:capacityQuantity> element described the capacity of the packaging. For example, to represent 30 tablets, the <epsos:formCode> must indicate tablets as the form, value attribute of the <epsos:capacityQuantity> element must have the value of 30, and the unit attribute must be 1. In the cases where the unit attribute is not 1, UCUM units shall be used. The value set is epSOSUnits, OID 1.3.6.1.4.1.12559.11.10.1.3.1.42.16 and epSOSDoseForm, OID 1.3.6.1.4.1.12559.11.10.1.3.1.42.2.

8.1.2.5.3.5. Medication Generic Equivalent

```
<epsos:asSpecializedKind classCode='GRIC'>
   <epsos:generalizedMedicineClass classCode='MMAT'>
      <epsos:code code=' '
        codeSystem=' '
        displayName=' '
        codeSystemName=' '/>
      <epsos:name></epsos:name>
   </epsos:generalizedMedicineClass>
</epsos:asSpecializedKind>
```

The classCode of "GRIC" identifies this structure as the representation of a generic equivalent of the medication described in the current Medicine entry. The <epsos:code> element contains the coded representation of the generic medicine, and the <epsos:name> element may be used for the plain text representation.

8.1.2.5.3.6. Medication Active Ingredient List

```
<epsos:ingredient classCode='ACTI'>
  <epsos:ingredient classCode='MMAT' determinerCode='KIND'>
    <epsos:code code=' '
      codeSystem=' '
      displayName=' '
      codeSystemName=' '/>
    <epsos:name></epsos:name>
  </epsos:ingredient>
</epsos:ingredient>
```

One or more active ingredients may be represented with this structure. The classCode of "ACTI" indicates that this is an active ingredient. The <epsos:code> element contains the coded representation of the ingredient and the <epsos:name> element may be used for the plain text representation.

8.1.2.6. Medication Fulfillment Instructions Entry 1.3.6.1.4.1.19376.1.5.3.1.4.3.1

Any medication may be the subject of further instructions to the pharmacist, for example to indicate that it should be labeled in Spanish, et cetera. This structure is included in the target substance administration or supply act using the <entryRelationship> element defined in the CDA Schema. The figure below is an example of recording an instruction for an <entry>, and is used as context for the sections to follow.

8.1.2.6.1. Standards

Pharmacy	HL7 Pharmacy Domain (Normative)

8.1.2.6.2. Specification

```
<entry>
 <supply classCode='SPLY' moodCode='EVN'>
        :
   <entryRelationship typeCode='SUBJ' inversionInd='true'>
     <act classCode='ACT' moodCode='INT'>
       <templateId root='2.16.840.1.113883.10.20.1.43'/>
       <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.3.1'/>
       <code code='FINSTRUCT' codeSystem='1.3.6.1.4.1.19376.1.5.3.2'
         codeSystemName='IHEActCode' />
       <text><reference value='#comment-2'/></text>
       <statusCode code='completed' />
     </act>
   </entryRelationship>
        :
 </supply>
</entry>
```

***Figure 10C** - Sample Medication Fulfillment Instructions Entry*

8.1.2.6.2.1. Entry Relationship

```
<entryRelationship typeCode='SUBJ' inversionInd='true'>
```

Again, a related statement is made about the medication or immunization. In CDA, this observation is recorded inside an <entryRelationship> element occurring at the end of the substance administration or supply entry. The containing <act> is the subject (typeCode='SUBJ') of this new observation, which is the inverse of the normal containment structure, thus inversionInd='true'.

8.1.2.6.2.2. Act classCode

```
<act classCode='ACT' moodCode='INT'>
```

The related statement is the intent (moodCode='INT') on how the related entry is to be performed.

8.1.2.6.2.3. Template Id root

```
<templateId root='2.16.840.1.113883.10.20.1.43'/>
<templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.3.1'/>
```

These <templateId> elements identify this <act> as a medication fulfilment instruction, allowing for validation of the content.

8.1.2.6.2.4. Code

```
<code code='FINSTRUCT' codeSystem='1.3.6.1.4.1.19376.1.5.3.2' code-
SystemName='IHEActCode' />
```

The <code> element indicates that this is a medication fulfilment instruction. This element shall be recorded exactly as specified above.

8.1.2.6.2.5. Text-reference

```
<text><reference value='#comment'/></text>
```

The <text> element contains a free text representation of the instruction. For CDA this SHALL contain a provides a <reference>element to the link text of the comment in the narrative portion of the document. The comment itself is not the act being coded, so it appears in the <text> of the <observation>, not as part of the <code>.

8.1.2.6.2.6. Status Code

```
<statusCode code='completed' />
```

The code attribute of <statusCode> for all comments must be completed.

8.1.3. Dispensation Section 1.3.6.1.4.1.12559.11.10.1.3.1.2.2

Template ID	1.3.6.1.4.1.12559.11.10.1.3.1.2.2	
Parent Template	CCD 3.9 (2.16.840.1.113883.10.20.1.8)	
General Description	The dispensation section shall contain a description of the medications dipsensed for the patient at a given pharmacy. It shall include entries for each dispensed medication as described in the Entry Content Module.	
LOINC Code	**Opt**	**Description**
10160-0	R	HISTORY OF MEDICATION USE
Entries	**Opt**	**Description**
1.3.6.1.4.1.12559.11.10.1.3.1.3.3	R	Dispensed Medicine Entry Content Module

8.1.3.1. Specifications

```
<component>
  <section>
    <templateId root='2.16.840.1.113883.10.20.1.8'/>
    <templateId root='1.3.6.1.4.1.12559.11.10.1.3.1.2.2'/>
    <!-- The section ID is the Dispensation ID -->
    <id root=' ' extension=' '/>
    <code code='10160-0' displayName='HISTORY OF MEDICATION USE'
      codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
    <text>
      Text as described above
    </text>
    <!-- Each entry is a dispensed medication -->
    <!-- Dispensed Medication 1 -->
    <entry>
         :
      <!-- Required Supply element -->
        <templateId root='1.3.6.1.4.1.12559.11.10.1.3.1.3.3'/>
         :
    </entry>
    <!-- Dispensed Medication 2 -->
    <entry>
         :
      <!-- Required Supply element -->
        <templateId root='1.3.6.1.4.1.12559.11.10.1.3.1.3.3'/>
         :
    </entry>
  </section>
</component>
```

***Figure 11C** - Sample Dispensation Section*

8.1.3.2. Parent Templates

The parent of this template is CCD 3.9.

8.1.3.3. Dispensation ID

The Dispensation identifier is represented in the section ID, as the `/ClinicalDocument/component/structuredBody/component/section/id` XML element. The data type of the ID is II.

8.1.3.4. Dispensed Medicine Entry Content Module 1.3.6.1.4.1.12559.11.10.1.3.1.3.3

8.1.3.4.1. Specification

```
<supply classCode='SPLY' moodCode='EVN'>
  <templateId root='2.16.840.1.113883.10.20.1.34'/>
  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7.3'/>
  <templateId root='1.3.6.1.4.1.12559.11.10.1.3.1.3.3'/>
  <id root='' extension=''/>
  <quantity value='' unit=''/>
  <product>
      ...
  </product>
  <performer typeCode='PRF'>
    <time value=''/>
    <assignedEntity>
      <id root='' extension=''/>
      <addr></addr>
      <telecom use='' value=''/>
      <assignedPerson><name></name></assignedPerson>
      <representedOrganization><name></name></representedOrganization>
    </assignedEntity>
  </performer>
  <!—related prescription -->
  <entryRelationship typeCode="REFR">
      <substanceAdministration classCode="SBADM" moodCode="INT">
        ...
      </substanceAdministration>
  </entryRelationship>
  <!-- Optional Patient instrctions -->
  <entryRelationship typeCode='SUBJ'>
     ...
  </entryRelationship>
</supply>
```

***Figure 12C** - Sample Dispensed Medicine Entry Content Module*

8.1.3.4.2. Supply

```
<supply classCode='SPLY' moodCode='EVN'>
```

The <supply> element shall be present. The moodCode attribute shall be INT to reflect that a medication has been prescribed, or EVN to indicate that the prescription has been filled.

8.1.3.4.3. Template Id root

```
<templateId root='2.16.840.1.113883.10.20.1.34'/>
<templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7.3'/>
<templateId root='1.3.6.1.4.1.12559.11.10.1.3.1.3.3'/>
```

The <templateId> elements shown above shall be present, and identify this supply act as a Dispensed Medication Entry.

8.1.3.4.4. Id root

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

Each supply act shall have an identifier to uniquely identify the dispensation of this particular medication.

8.1.3.4.5. Quantity Value

```
<quantity value=' ' unit=' '/>
```

The supply entry should indicate the quantity supplied (such as tablets or containers). The value attribute shall be present and indicates the quantity of medication supplied. If the medication is supplied in dosing units (tablets or capsules), then the unit attribute need not be present (and should be set to 1 if present). Otherwise, the unit element shall be present to indicate the quantity (e.g., volume or mass) of medication supplied.

8.1.3.4.6. Product

```
<product><medication>…</medication></product>
```

The <product> element shall be present, and shall contain a <medication> entry, conforming to the Medicine Entry template. This is the actual medication dispensed, and may include packaging information.

8.1.3.4.7. Dispenser

<performer typeCode='PRF'> … </performer>
The <performer> element shall be present to indicate who actually filled (moodCode='EVN') the prescription. The dispenser is described within the specific entry structure of the prescription under the `/ClinicalDocument/component/structuredBody/component/section/entry/supply/performer` XML element.

Data element	HL7 V3 Data Type	CDA Header position (relative XPath expression)
Dispensation Time	TS	`performer/time`
Dispenser Name	PN	`performer/assignedEntity/assignedPerson/name`
Dispenser identifier	II	`performer/assignedEntity/id`

Data element	HL7 V3 Data Type	CDA Header position (relative XPath expression)
Pharmacy Organization Identifier	II	*performer/assignedEntity/representedOrganization/id*
Pharmacy Organization Name	ON	*performer/assignedEntity/representedOrganization/name*
Pharmacy Organization Address	AD	*performer/assignedEntity/representedOrganization/addr*

8.1.3.4.7.1. Dispenser Credentialing Organization

```
<participant typeCode="PRF">
  <participantRole classCode="CRED">
    <id root=" " extension=" "/>
    <scopingEntity classCode="ORG">
      <id root=" " extension " "/>
      <desc>Name</desc>
    </scopingEntity>
  </participantRole>
</participant>
```

The organization which provided the credentialing for the dispenser needs to be expressed via a <participant> structure, which is in addition to the <performer> element specified earlier. The type code of the <participant> element shall be "PRF", and the class code of the <participantRole> element shall be "CRED".

The ID of the participation role is optional, and when present it shall be the dispenser ID as specified in the <performer> structure.

The credentialing organization (College) is represented by the <scopingEntity> element with a class code of "ORG". The name is represented by the <desc> element, and the credentialing organization (College) ID is represented by the <id> element of the scoping entity

8.1.3.4.8. Related Prescription Item

```
<entryRelationship typeCode="REFR">
      <substanceAdministration classCode="SBADM" moodCode="INT">
          ...
      </substanceAdministration>
</entryRelationship>
```

The related prescription item is represented via an entry relationship of type code "REFR", and containing a prescription entry as described in section 2.4.3.4.

8.1.3.4.9. Patient Instructions

```
<entryRelationship typeCode="SUBJ" inversionInd='true'>
      <act classCode="ACT" moodCode="INT">
          ...
      </act>
</entryRelationship>
```

Any optional patient instructions can be specified as an entry relationship of type "SUBJ". This entry relationship contains an Act as described in the Patient Medication Instructions Entry Content Module.

8.1.3.4.10. Precondition Criterion

```
<precondition>
```

```
   <criterion>
      <text><reference value=' '></text>
   </criterion>
</precondition>
```

In a CDA document, the preconditions for use of the medication are recorded in the <precondition> element. The value attribute of the <reference> element is a URL that points to the CDA narrative describing those preconditions.

8.1.3.4.11. Patient Instructions Entry Content Module 1.3.6.1.4.1.19376.1.5.3.1.4.3

Any medication may be the subject of further instructions to the patient, for example to indicate that it should be taken with food, etc.
This structure is included in the target supply act using the <entryRelationship> element defined in the CDA Schema. The example below shows the recording of patient medication instruction for an <entry>, and is used as context for the following section.

8.1.3.4.11.1. Standards

Pharmacy	HL7 Pharmacy Domain (Normative)

8.1.3.4.11.2. Specification

```
<entry>
 <supply classCode='SPLY' moodCode='EVN'>
         :
   <entryRelationship typeCode='SUBJ' inversionInd='true'>
     <act classCode='ACT' moodCode='INT'>
       <templateId root='2.16.840.1.113883.10.20.1.49'/>
       <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.3'/>
       <code code='PINSTRUCT' codeSystem='1.3.6.1.4.1.19376.1.5.3.2'
         codeSystemName='IHEActCode' />
       <text><reference value='#comment-2'/></text>
       <statusCode code='completed' />
     </act>
   </entryRelationship>
         :
 </supply>
</entry>
```

***Figure 10C** - Sample Patient Medication Instructions Entry*

8.1.3.4.11.3. Entry Relationship

```
<entryRelationship typeCode='SUBJ' inversionInd='true'>
```

Again, a related statement is made about the medication or immunization. In CDA, this observation is recorded inside an <entryRelationship> element occurring at the end of the supply entry. The containing <act> is the subject (typeCode='SUBJ') of this new observation, which is the inverse of the normal containment structure, thus inversionInd='true'.

8.1.3.4.11.4. Act classCode

```
<act classCode='ACT' moodCode='INT'>
```

The related statement is the intent (moodCode='INT') on how the related entry is to be performed.

8.1.3.4.11.5. Template Id root

```
<templateId root='2.16.840.1.113883.10.20.1.49'/>
<templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.3'/>
```

These <templateId> elements identify this <act> as a medication instruction, allowing for validation of the content.

8.1.3.4.11.6. Code

```
<code code='PINSTRUCT' codeSystem='1.3.6.1.4.1.19376.1.5.3.2' code-
SystemName='IHEActCode' />
```

The <code> element indicates that this is a patient medication instruction. This element shall be recorded exactly as specified above.

8.1.3.4.11.7. Text-reference

```
<text><reference value='#comment'/></text>
```

The <text> element contains a free text representation of the instruction. This element SHALL contain a <reference>element to the link text of the comment in the narrative portion of the document. The comment itself is not the act being coded, so it appears in the <text> of the <observation>, not as part of the <code>.

8.1.3.4.11.8. Status Code

```
<statusCode code='completed' />
```

The code attribute of <statusCode> for all comments must be completed.

8.1.4. Medication Summary 1.3.6.1.4.1.19376.1.5.3.1.3.19

The specifications in the Medication Summary are identical to those present in the Patient Care Coordination Technical Framework - (except for the optionality which is in line with WP3.1 and WP3.2, in the table in section 7). Please see the specifications in IHE PCC, Volume 2, Revision 5, section 6.3.3.3.

8.1.5. Allergies and Other Adverse Reactions Section 1.3.6.1.4.1.19376.1.5.3.1.3.13

Template ID	1.3.6.1.4.1.19376.1.5.3.1.3.13	
Parent Template	CCD 3.8 (2.16.840.1.113883.10.20.1.2)	
General Description	The adverse and other adverse reactions section shall contain a narrative description of the substance intolerances and the associated adverse reactions suffered by the patient. It shall include entries for intolerances and adverse reactions as described in the Entry Content Modules.	
LOINC Code	**Opt**	**Description**
48765-2	R	Allergies, adverse reactions, alerts
Entries	**Opt**	**Description**
1.3.6.1.4.1.19376.1.5.3.1.4.5.3	R	Allergies and Intolerances Concern

8.1.5.1. Parent Template

The parent of this template is CCD 3.8. This template is compatible with the ASTM/HL7 Continuity of Care Document template: 2.16.840.1.113883.10.20.1.2

```
<component>
  <section>
    <templateId root='2.16.840.1.113883.10.20.1.2'/>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.13'/>
    <id root=' ' extension=' '/>
    <code code='48765-2' displayName='Allergies, adverse reactions, alerts'
      codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
    <text>
      Text as described above
    </text>
    <entry>
          :
      <!-- Required Allergies and Intolerances Concern element -->
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.3'/>
          :
    </entry>

  </section>
</component>
```

***Figure 13C** - Sample Allergies and Other Adverse Reactions Section*

8.1.5.2. Allergy and Intolerance Concern Entry Content Module 1.3.6.1.4.1.19376.1.5.3.1.4.5.3

This entry is a specialization of the Concern Entry, wherein the subject of the concern is focused on an allergy or intolerance. Elements shown in the example below in gray are explained in that entry.

8.1.5.2.1. Standards

CCD	ASTM/HL7 Continuity of Care Document
CareStruct	HL7 Care Provision Care Structures (DSTU)

ClinStat	HL7 Clinical Statement Pattern (Draft)

8.1.5.2.2. Parent Template

The parent of this template is Concern Entry. This template is compatible with the ASTM/HL7 Continuity of Care Document template: 2.16.840.1.113883.10.20.1.27

8.1.5.2.3. Specification

```
<act classCode='ACT' moodCode='EVN'>
 <templateId root='2.16.840.1.113883.10.20.1.27'/>
 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.1'/>
 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.3'/>
 <id root=' ' extension=' '/>
 <code nullFlavor='NA'/>
 <statusCode code='active|suspended|aborted|completed'/>
 <effectiveTime>
   <low value=' '/>
   <high value=' '/>
 </effectiveTime>
 <!-- 1..* entry relationships identifying allergies of concern -->
 <entryRelationship typeCode='SUBJ'>
   <observation classCode='OBS' moodCode='EVN'/>
      <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.6'/>
        :
   </observation>
 </entryRelationship>
 <!-- optional entry relationship providing more information about the concern -->
 <entryRelationship type='REFR'>
 </entryRelationship>
</act>
```

Figure 14C *- Sample Allergy and Intolerance Concern Entry*

8.1.5.2.4. Template Id root

```
<templateId root='2.16.840.1.113883.10.20.1.27'/>
<templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.1'/>
<templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.3'/>
```

This entry has a template identifier of 1.3.6.1.4.1.19376.1.5.3.1.4.5.3, and is a subtype of the Concern entry, and so must also conform to the rules of the Concern Entry. These elements are required and shall be recorded exactly as shown above.

8.1.5.2.5. entryRelationships identifying allergies of concern

```
<entryRelationship typeCode='SUBJ'>
   <observation classCode='OBS' moodCode='EVN'/>
      <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.6'/>
        :
   </observation>
</entryRelationship>
```

This entry shall contain one or more allergy or intolerance entries that conform to the Allergy and Intolerance Entry Content Module. This shall be represented with the <entryRelationship> element. The typeCode shall be ‘SUBJ’ and inversionInd shall be ‘false’

8.1.6. Allergy and Intolerance Entry Content Module 1.3.6.1.4.1.19376.1.5.3.1.4.6

Allergies and intolerances are special kinds of problems, and so are also recorded in the CDA <observation> element, with classCode='OBS'. They follow the same pattern as the problem entry, with exceptions noted below.

8.1.6.1.1. Standards

CCD	ASTM/HL7 Continuity of Care Document
CareStruct	HL7 Care Provision Care Structures (DSTU)
ClinStat	HL7 Clinical Statement Pattern (Draft)

8.1.6.1.2.

8.1.6.1.3. Specification

```
<observation classCode='OBS' moodCode='EVN' negationInd='false'>
    <templateId root='2.16.840.1.113883.10.20.1.18'/>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.6'/>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5'/>
    <id root=' ' extension=' '/>
    <!-- This is the code that shows what kind of allergy or intolerance this is -->
    <code code='ALG|OINT|DALG|EALG|FALG|DINT|EINT|FINT|DNAINT|ENAINT|FNAINT'
codeSystem='2.16.840.1.113883.5.4'
codeSystemName='ObservationIntoleranceType'/>
    <text><reference value=' '/></text>
    <statusCode code='completed'/>
    <effectiveTime>
        <low value=' '/>
        <high value=' '/>
    </effectiveTime>
   <!-- no value element is present -->
   <!-- This is the allergen - the substance that caused the allergy -->
    <participant typeCode='CSM'>
        <participantRole classCode='MANU'>
            <playingEntity classCode='MMAT'>
                <code code=' ' codeSystem=' '>
                    <originalText><reference value='#substance'/></orginalText>
                </code>
                <name></name>
            </playingEntity>
        </participantRole>
    </participant
    <!-- This is how the allergy manifests itself -->
    <entryRelationship typeCode='MFST'>
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.6.1'/>
        <!-- a problem entry -->
        <observation classCode='OBS' moodCode='EVN'>
            <templateId root='2.16.840.1.113883.10.20.1.54'/>
            <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5'/>
            <!-- The code tells us that the observation is a symptom -->
            <code code="418799008" codeSystem="2.16.840.1.113883.6.96"
displayName="Symptom" codeSystemName-"SNOMED CT"/>
            <text><reference value='#manifest-1'/></text>
            <statusCode code='completed'/>
            <!-- The value tells us what the symptom (i.e. allergy manifestation) is -
->
            <!-- This is where anaphylaxy or angiooedema will be coded -->
            <value xsi:type='CD' code=' ' codeSystem=' ' displayName=' '
codeSystemName=' '/>
        </observation>
    </entryRelationship>
    <!-- This is how the severity of the allergy is described -->
    <entryRelationship typeCode='SUBJ' inversionInd='true'>
       <observation classCode='OBS' moodCode='EVN'>
           <templateId root='2.16.840.1.113883.10.20.1.55'/>
           <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.1'/>
           <!-- This code is from HL7 and indicates that the observation is about
severity -->
           <code code='SEV' displayName='Severity' codeSystem='2.16.840.1.113883.5.4'
codeSystemName='ActCode' />
         <text><reference value='#severity-1'/></text>
         <statusCode code='completed'/>
         <!-- This code is from SNOMED, according to the epSOS value set-->
         <value xsi:type='CD' code='' codeSystem='2.16.840.1.113883.6.96'
codeSystemName='SNOMED CT'/>
       </observation>
    </entryRelationship>
</observation>
```

8.1.6.1.4. <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5'/> <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.6'/>

This entry has a template identifier of 1.3.6.1.4.1.19376.1.5.3.1.4.6, and is a subtype of the Problem Entry, and so must also conform to the rules of the problem entry,

which has the template identifier of 1.3.6.1.4.1.19376.1.5.3.1.4.5.5. These elements are required and shall be recorded exactly as shown above.

8.1.6.1.5. <code code='ALG|OINT|DINT|EINT|FINT|DALG|EALG|FALG|DNAINT|ENAINT|FNAINT' displayName=' ' codeSystem='2.16.840.1.113883.5.4' codeSystemName='ObservationIntoleranceType'/>

The <code> element represents the kind of allergy observation made, to a drug, food or environmental agent, and whether it is an allergy, non-allergy intolerance, or unknown class of intolerance (not known to be allergy or intolerance). The <code> element of an allergy entry shall be provided, and a code and codeSystem attribute shall be present. The example above uses the HL7 ObservationIntoleranceType vocabulary domain, which does provide suitable observation codes.

8.1.6.1.6. <participant typeCode='CSM'> <participantRole classCode='MANU'> <playingEntity classCode='MMAT'>

The substance that causes the allergy or intolerance shall be specified in the <participant> structure.

8.1.6.1.6.1. <code code=' ' codeSystem=' '> <originalText> <reference value=' '/> </originalText> </code>

The <code> element shall be present. It may contain a code and codeSystem attribute to indicate the code for the substance causing the allergy or intolerance. It shall contain a <reference> to the <originalText> in the narrative where the substance is named.

8.1.6.1.7. <entryRelationship typeCode='MFST'> <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.6.1'

An allergy entry can record the reactions that are manifestations of the allergy or intolerance as shown below. It uses a related entry (<entryRelationship>) that indicates the manifestations (typeCode='MFST') the reported allergy or intolerance. These are events that may occur, or have occurred in the past as a reaction to the allergy or intolerance

```
<entryRelationship typeCode='MFST'>
   <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.6.1'/>
   <!-- a problem entry -->
   <observation classCode='OBS' moodCode='EVN'>
      <templateId root='2.16.840.1.113883.10.20.1.54'/>
      <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5'/>
      _
   </observation>
</entryRelationship>
```

8.1.6.1.7.1. <observation classCode='OBS' moodCode='EVN'> <templateId root='2.16.840.1.113883.10.20.1.54'/> <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5'/> _ </observation>

The entry contained with this entry relationship is some sort of problem that is a manifestation of the allergy. It is recorded using the Problem Entry structure, with the additional template identifier (2.16.840.1.113883.10.20.1.54) indicating that this problem is a reaction.

8.1.6.1.8. <entryRelationship typeCode='SUBJ' inversionInd='true'> - Severity

A required <entryRelationship> element shall be present indicating the severity of the problem. This <entryRelationship> element shall contain a severity observation conforming to the Severity entry template (1.3.6.1.4.1.19376.1.5.3.1.4.1).

8.1.6.2. Severity Entry Content Module 1.3.6.1.4.1.19376.1.5.3.1.4.1

Any condition or allergy may be the subject of a severity observation. This structure is included in the target act using the <entryRelationship> element defined in the CDA Schema.

Note: In order to highlight problems which require a specific attention to the user, the Severity Entry Content Module has been added as a required component to the following five sections:

- History of Past Illness Section,
- Coded List of Surgeries Section,
- Active Problems Section,
- Procedures and Interventions Section
- Allergies and other adverse reaction section

In these sections, the **procedure entries** (Coded List of Surgeries Section, Procedures and Interventions Section), **problem concern entries** (History of Past Illness Section and Active Problems Section) or **concern entry** (Allergies and Other Adverse Reaction Section) shall contain a Severity Entry Content Module.

An application providing a user display of the specific document shall visually display an alert for all entries with high severity.

8.1.6.2.1. Standards

CCD	ASTM/HL7 Continuity of Care Document
CareStruct	HL7 Care Provision Care Structures (DSTU)

8.1.6.2.2. Specification

The example below shows the recording the condition or allergy severity, and is used as the context for the following sub-sections.

```
<!-- The encompasing condition or allergy observation -->
<observation classCode='COND' moodCode='EVN'>
   ...
   <entryRelationship typeCode='SUBJ' inversionInd='true'>
      <observation classCode='OBS' moodCode='EVN'>
         <templateId root='2.16.840.1.113883.10.20.1.55'/>
         <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.1'/>
         <code code='SEV' displayName='Severity' codeSystem='2.16.840.1.113883.5.4'
codeSystemName='ActCode' />
         <text><reference value='#severity-2'/></text>
         <statusCode code='completed'/>
         <!-- This code is from SNOMED, according to the epSOS value set-->
         <value xsi:type='CD' code='' codeSystem='2.16.840.1.113883.6.96' codeSystemName='SNOMED
CT'/>
      </observation>
   </entryRelationship>
   ...
</observation>
```

8.1.6.2.3. <entryRelationship typeCode='SUBJ' inversionInd='true'>

The related statement is made about the severity of the condition, concern, or allergy). This observation is recorded inside an <entryRelationship> element occurring in the containing entry. The containing <entry> is the subject (typeCode='SUBJ') of this new observation, which is the inverse of the normal containment structure, thus inversionInd='true'.

8.1.6.2.4. <observation moodCode='EVN' classCode='OBS'>

The related statement is another event (moodCode='EVN') observing (<observation classCode='OBS'>) the severity of the (surrounding) related entry (e.g., a condition or allergy).

8.1.6.2.5. <templateId root='2.16.840.1.113883.10.20.1.55'/> <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.1'/>

The <templateId> elements identifies this <observation> as a severity observation, allowing for validation of the content. As a side effect, readers of the CDA can quickly locate and identify severity observations. The templateId elements shown above must be present.

8.1.6.2.6. <code code='SEV' codeSystem='2.16.840.1.113883.5.4' displayName='Severity' codeSystemName='ActCode' />

This observation is of severity, as indicated by the <code> element listed above. This element is required.

8.1.6.2.7. <text><reference value='#ref-1'/></text>

The <observation> element shall contain a <text> element. The <text> element shall contain a <reference> element pointing to the narrative where the severity is recorded,

8.1.6.2.8. <statusCode code='completed'/>

The code attribute of <statusCode> for all severity observations shall be completed. While the <statusCode> element is required in all acts to record the status of the act, the only sensible value of this element in this context is completed.

8.1.6.2.9. <value xsi:type='CD' code='' codeSystem=''2.16.840.1.113883.6.96' codeSystemName='SNOMED CT'/>

The <value> element contains the level of severity. It is always represented using the CD datatype (xsi:type='CD') and it shall use the SNOMED codes specified by the epSOS value sets.

8.1.7. Immunizations Section 1.3.6.1.4.1.19376.1.5.3.1.3.23

Template ID	1.3.6.1.4.1.19376.1.5.3.1.3.23	
Parent Template	CCD 3.11 (2.16.840.1.113883.10.20.1.6)	
General Description	The immunizations section shall contain a narrative description of the immunizations administered to the patient in the past. It shall include entries for medication administration as described in the Entry Content Modules.	
LOINC Code	**Opt**	**Description**
11369-6	R	HISTORY OF IMMUNIZATIONS
Entries	**Opt**	**Description**
1.3.6.1.4.1.19376.1.5.3.1.4.12	R	Immunization

8.1.7.1. Parent Template

The parent of this template is CCD 3.11.

```
<component>
  <section>
    <templateId root='2.16.840.1.113883.10.20.1.6'/>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.23'/>
    <id root=' ' extension=' '/>
    <code code='11369-6' displayName='HISTORY OF IMMUNIZATIONS'
      codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
    <text>
      Text as described above
    </text>
    <entry>
        :
      <!-- Required Immunization element -->
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.12'/>
        :
    </entry>

  </section>
</component>
```

Figure 15C *- Sample Immunizations Section*

8.1.7.2.

8.1.7.3. Immunization Entry 1.3.6.1.4.1.19376.1.5.3.1.4.12

An immunizations entry is used to record the patient's immunization history.

8.1.7.3.1. Specification

```
<substanceAdministration typeCode='SBADM' moodCode='EVN' negationInd='true{{!}}false'>
  <templateId root='2.16.840.1.113883.10.20.1.24'/>
  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.12'/>

  <id root='' extension=''/>
  <code code='IMMUNIZ' codeSystem='2.16.840.1.113883.5.4' codeSystemName='ActCode'/>
  <text><reference value='#xxx'/></text>
  <statusCode code='completed'/>
  <effectiveTime value=''/>
  <!-- The reasonCode would normally provide a reason why the immunization was
    not performed.  It isn't supported by CDA R2, and so comments will have to suffice.
    <reasonCode code='' codeSystem='' codeSystemName='ActNoImmunizationReasonIndicator'/>
  -->
  <routeCode code='' codeSystem='' codeSystemName='RouteOfAdministration'/>
  <approachSiteCode code='' codeSystem='' codeSystemName='HumanSubstanceAdministrationSite'/>
  <doseQuantity value='' units=''/>
  <consumable typeCode='CSM'>
    <manufacturedProduct classCode='MANU'>
      <manufacturedLabeledDrug classCode='MMAT' determinerCode='KIND'>
        <code code='' codeSystem='' codeSystemName=''>
          <originalText><reference value='#yyy'/></originalText>
        </code>
      </manufacturedLabeledDrug>
    </manufacturedProduct>
  </consumable>
  <!-- An optional entry relationship that provides prescription activity -->
  <entryRelationship typeCode='REFR'>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7.3'/>
      :
      .
  </entryRelationship>
  <!-- An optional entry relationship that identifies the immunization series number -->
  <entryRelationship typeCode='SUBJ'>
    <observation classCode='OBS' moodCode='EVN'>
      <templateId root='2.16.840.1.113883.10.20.1.46'/>
      <code code='30973-2' displayName='Dose Number'
        codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
      <statusCode code='completed'/>
      <value xsi:type='INT' value=''/>
    </observation>
  </entryRelationship>

  <entryRelationship inversionInd='false' typeCode='CAUS'>
    <observation classCode='OBS' moodCode='EVN'>
      <templateId root='2.16.840.1.113883.10.20.1.28'/>
      <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5'/>
      <templateId root='2.16.840.1.113883.10.20.1.54'/>
      <id root='' extension=''/>
    </observation>
  </entryRelationship>
  <!-- Optional <entryRelationship> element containing comments -->
</substanceAdministration>
```

Figure 16C *- Sample Immunizations Entry*

8.1.7.3.2.

substanceAdministration

<substanceAdministration
typeCode='SBADM'
moodCode='EVN'
negationInd='true|false'>

An immunization is a substance administration event. An immunization entry may be a record of why a specific immunization was not performed. In this case, negationInd shall be set to "true", otherwise, it shall be false.

8.1.7.3.3. Template Id root

<templateId root='2.16.840.1.113883.10.20.1.24'/>
<templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.12'/>

The <templateId> elements identifies this <substanceAdministration> as an immunization. Both elements shall be present as shown above.

8.1.7.3.4. Id root

<id root=' ' extension=' '/>
This shall be the identifier for the immunization event.

8.1.7.3.5. Type of substance administration act

<code code='IMMUNIZ'
codeSystem='2.16.840.1.113883.5.4'
codeSystemName='ActCode'/>

This required element records that the act was an immunization. The substance administration act must have a <code> element with code and codeSystem attributes present. If no coding system is used by the source, then simply record the code exactly as shown above. This <code> element shall not be used to record the type of vaccine used from a vocabulary of drug names.

codeSystem	codeSystemName	Description
2.16.840.1.113883.5.4	IMMUNIZ	The IMMUNIZ term from the HL7 ActCode vocabulary.

8.1.7.3.6. Text-reference

<text><reference value='#xxx'/></text>
The URI given in the value attribute of the <reference> element points to an element in the narrative content that contains the complete text describing the immunization activity.

8.1.7.3.7. Status Code

<statusCode code='completed'/>
The statusCode shall be set to "completed" for all immunizations.

8.1.7.3.7.1. Substance Administration Effective Time

<effectiveTime value=' '/>
The effectiveTime element shall be present and should contain a time value that indicates the date of the substance administration. If the date is unknown, this shall be recorded using the nullFlavor

attribute, with the reason that the information is unknown being specified. Otherwise, the date shall be recorded, and should have precision of at least the day.

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8.1.7.3.8. Route of administration

```
<routeCode code=' '
 codeSystem=' '
 codeSystemName='RouteOfAdministration'/>
```

See routeCode under the Medication Item Entry Content module.

8.1.7.3.9. Approach Site

```
<approachSiteCode
  code=' '
  codeSystem=' '
  codeSystemName='HumanSubstanceAdministrationSite'>
  <originalText><reference value=' '/></originalText>
</approachSiteCode>
```

The <approachSiteCode> element describes the site of immunization administration. It may be coded to a controlled vocabulary that lists such sites (e.g., SNOMED-CT). The <originalText> element contains a URI in the value attribute of the <reference> that points to the text in the narrative identifying the site.

8.1.7.3.10. Dose Quantity

```
<doseQuantity value=' ' units=' '/>
```

See doseQuantity under the Medication Item Entry Content module.

8.1.7.3.11. Consumable

```
<consumable typeCode='CSM'>
```

The <consumable> element shall be present, and shall contain a <manufacturedElement> element, conforming to the Product Entry Content Module template.

8.1.7.3.12. Optional entryRelationship: position of the vaccination

```
<entryRelationship typeCode='SUBJ'>
  <observation classCode='OBS' moodCode='EVN'>
    <templateId root='2.16.840.1.113883.10.20.1.46'/>
    <code
      code='30973-2'
      displayName='Dose Number'
      codeSystem='2.16.840.1.113883.6.1'
      codeSystemName='LOINC'/>
    <statusCode code='completed'/>
    <value xsi:type='INT' value=' '/>
  </observation>
</entryRelationship>
```

This optional entry relationship may be present to indicate that position of this immunization in a series of immunizations. The <code> element shall be present and must be recorded with the code and codeSystem attributes shown above. This element indicates that the observation describes the dose number for the immunization. The <statusCode> element shall be present, and must be recorded exactly as shown above. This element indicates that the observation has been completed. The <value> element shall be present, and shall indicate the immunization series number in the value attribute.

8.1.7.3.13. Optional entryRelationship: identifying adverse reactions caused by the immunization

```
<entryRelationship inversionInd='false' typeCode='CAUS'>
  <observation classCode='OBS' moodCode='EVN'>
    <templateId root='2.16.840.1.113883.10.20.1.28'/>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5'/>
    <templateId root='2.16.840.1.113883.10.20.1.54'/>
    <id root=' ' extension ' '/>
  </observation>
</entryRelationship>
```

This repeatable element should be used to identify adverse reactions caused by the immunization. The <observation> element provides a pointer to the adverse reaction caused by the immunization. The template IDs describe that it points to a conforming Problem Entry Content Module that also conform to the CCD Reaction template.

The <id> element is required, and gives the identifier of the adverse reaction. The adverse reaction pointed to by this element shall be described in more detail using the Allergies entry, elsewhere in the document where the Allergies and Intolerances section is found.

8.1.7.3.14. Optional <entryRelationship> element containing comments

An immunization entry can have negationInd set to true to indicate that an immunization did not occur. In this case, it shall have at least one comment that provides an explanation for why the immunization did not take place. Other comments may also be present.

8.1.7.4. Product Entry 1.3.6.1.4.1.19376.1.5.3.1.4.7.2

The product entry describes an immunization used in a <substanceAdministration> act. It adopts the constraints of the ASTM/HL7 Continuity of Care Document.

8.1.7.4.1. Specification

```
<!-- Within a CDA Document -->
<manufacturedProduct>
  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7.2'/>
  <templateId root='2.16.840.1.113883.10.20.1.53'/>
  <manufacturedMaterial>
    <code code='' displayName='' codeSystem='' codeSystemName=''>
      <originalText><reference value=''/></originalText>
    </code>
    <name></name>
  </manufacturedMaterial>
</manufacturedProduct>
```

Figure 17C *- Sample Product Entry*

8.1.7.4.2. Manufactured Product

```
<manufacturedProduct>
   <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7.2'/>
   <templateId root='2.16.840.1.113883.10.20.1.53'/>
   <manufacturedMaterial>
     :
   </manufacturedMaterial>
</manufacturedProduct>
```

Figure 18C *- Sample Manufactured Product*

In a CDA document, the name and strength of the immunization administered are specified in the elements under the <manufacturedMaterial> element. The templateId elements are required and identify this as a product entry.

8.1.7.4.2.1. Manufactured Product Code

```
<code code=' '
   displayName=' '
   codeSystem=' '
   codeSystemName=' '>
 <originalText><reference value=' '/></originalText>
</code>
```

Figure 18C *- Sample Manufactured Product Code*

The <code> element of the <manufacturedMaterial> describes the vaccine. This may be coded using a controlled vocabulary, for medication name and strength (e.g., acetaminophen and oxycodone -5/325), or just the generic medication name alone if strength is not relevant (Acetaminophen).

The <originalText> shall contain a <reference> whose URI value points to the generic name and strength of the medication, or just the generic name alone if strength is not relevant.

Note: When the text is supplied from the narrative, the implication is that if you supply the components of a combination vaccine in an entry, you must also display these in the narrative text, otherwise you would not be able to break the combination vaccine down into its component parts. This is entirely consistent with the CDA Release 2.0 requirements that the narrative supply the necessary and relevant human readable information content.

The <code> element is also used to support coding of the vaccine. If coded, it must provide a code and codeSystem attribute using a controlled vocabulary for medications. The displayName for the code and codeSystemName should be provided as well for diagnostic and human readability purposes, but are not required. The table below provides the codeSystem and codeSystemName for several controlled terminologies that may be used to encode immunizations. The value set is epSOSVaccine, OID: 1.3.6.1.4.1.12559.11.10.1.3.1.42.18.

8.1.7.4.2.2. Name

The <name> element should contain the brand name of the vaccine (or active ingredient in the case of subordinate <substanceAdministration> elements used to record components of a vaccine)

8.1.8. History of Past Illness Section 1.3.6.1.4.1.19376.1.5.3.1.3.8

Template ID	1.3.6.1.4.1.19376.1.5.3.1.3.8	
General Description	The History of Past Illness section shall contain a narrative description of the conditions the patient suffered in the past. It shall include entries for problems as described in the Entry Content Modules.	
LOINC Code	**Opt**	**Description**
11348-0	R	HISTORY OF PAST ILLNESS
Entries	**Opt**	**Description**
1.3.6.1.4.1.19376.1.5.3.1.4.5.2	R	Problem Concern Entry

8.1.8.1. Specification

```
<component>
  <section>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.8'/>
    <id root=' ' extension=' '/>
    <code code='11348-0' displayName='HISTORY OF PAST ILLNESS'
      codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
    <text>
      Text as described above
    </text>
    <entry>
         :
      <!-- Required Problem Concern Entry element -->
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.2'/>
         :
    </entry>

  </section>
</component>
```

***Figure 19C**- Sample History of Past Illness Section*

8.1.8.2. Problem Concern Entry 1.3.6.1.4.1.19376.1.5.3.1.4.5.2

This entry is a specialization of the Concern Entry, wherein the subject of the concern is focused on a problem. Elements shown in the example below in gray are explained in the Concern Entry.

8.1.8.2.1. Standards

CCD	ASTM/HL7 Continuity of Care Document
CareStruct	HL7 Care Provision Care Structures (DSTU)
ClinStat	HL7 Clinical Statement Pattern (Draft)

8.1.8.2.2. Parent Template

The parent of this template is Concern Entry. This template is compatible with the ASTM/HL7 Continuity of Care Document template: 2.16.840.1.113883.10.20.1.27

8.1.8.2.3. Specification

```
<act classCode='ACT' moodCode='EVN'>
 <templateId root='2.16.840.1.113883.10.20.1.27'/>
 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.1'/>
 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.2'/>
 <id root=' ' extension=' '/>
 <code nullFlavor='NA'/>
 <statusCode code='active|suspended|aborted|completed'/>
 <effectiveTime>
   <low value=' '/>
   <high value=' '/>
 </effectiveTime>
 <!-- 1..* entry relationships identifying problems of concern -->
 <entryRelationship type='SUBJ'>
   <observation classCode='OBS' moodCode='EVN'/>
      <templateID root='1.3.6.1.4.1.19376.1.5.3.1.4.5'>
        :
   </observation>
 </entryRelationship>
 <!-- optional entry relationship providing more information about the concern -->
 <entryRelationship type='REFR'>
 </entryRelationship>
</act>
```

***Figure 19C**- Sample History of Concern Entry*

8.1.8.2.4. Template Id root

<templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.1'/>
<templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.2'/>

This entry has a template identifier of 1.3.6.1.4.1.19376.1.5.3.1.4.5.2, and is a subtype of the Concern Entry, and so must also conform to that specification, with the template identifier of 1.3.6.1.4.1.19376.1.5.3.1.4.5.1. These elements are required and shall be recorded exactly as shown above.

8.1.8.2.5. entry relationships identifying problems of concern

<observation classCode='OBS' moodCode='EVN'>
<templateID root=' 1.3.6.1.4.1.19376.1.5.3.1.4.5'/>
…
</observation>
<entryRelationship type='SUBJ'>

This entry shall contain one or more problem entries that conform to the Problem Entry template 1.3.6.1.4.1.19376.1.5.3.1.4.5. For CDA this SHALL be represented with the <entryRelationship> element. For HL7 Version 3 Messages, this SHALL be represented as a <subjectOf> element. The typeCode SHALL be 'SUBJ' and inversionInd SHALL be 'false'

Note: every Problem Entry used in this section to identify problem of concern SHALL have an <entryRelationship> that will indicate the severity of the problem, conforming to the severity entry template (1.3.6.1.4.1.19376.1.5.3.1.4.1). The severity codes to be used are epSOSSeverity, OID 1.3.6.1.4.1.12559.11.10.1.3.1.42.13.

8.1.9. Coded List of Surgeries Section 1.3.6.1.4.1.19376.1.5.3.1.3.12

Template ID	1.3.6.1.4.1.19376.1.5.3.1.3.12	
Parent Template	List of Surgeries (1.3.6.1.4.1.19376.1.5.3.1.3.11)	
General Description	The list of surgeries section shall include entries for procedures and references to procedure reports when known as described in the Entry Content Modules.	
LOINC Code	**Opt**	**Description**
47519-4	R	HISTORY OF PROCEDURES
Entries	**Opt**	**Description**
1.3.6.1.4.1.19376.1.5.3.1.4.19	R	Procedure Entry

8.1.9.1. Parent Template

The parent of this template is List of Surgeries.

8.1.9.2. Specification

```
<component>
  <section>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.11'/>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.12'/>
    <id root=' ' extension=' '/>
    <code code='47519-4' displayName='HISTORY OF PROCEDURES'
      codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
    <text>
      Text as described above
    </text>
    <entry>
          :
      <!-- Required Procedure Entry  element -->
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.19'/>
          :
    </entry>
    <entry>
          :
      <!-- Required if known References Entry element -->
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.4'/>
          :
    </entry>

  </section>
</component>
```

***Figure 20C**- Sample Coded List of Surgeries Section*

8.1.9.3. Procedure Entry 1.3.6.1.4.1.19376.1.5.3.1.4.19

The procedure entry is used to record procedures that have occurred, or which are planned for in the future.

8.1.9.3.1. Specification

```
<procedure classCode='PROC' moodCode='EVN|INT'>
  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.19'/>
  <templateId root='2.16.840.1.113883.10.20.1.29'/><!-- see text of section 0 -->
  <templateId root='2.16.840.1.113883.10.20.1.25'/><!-- see text of section 0 -->
  <id root='' extension=''/>
  <code code='' codeSystem='2.16.840.1.113883.5.4' codeSystemName='ActCode' />
  <text><reference value='#xxx'/></text>
  <statusCode code='completed|active|aborted|cancelled'/>
  <effectiveTime>
    <low value=''/>
    <high value=''/>
  </effectiveTime>
  <priorityCode code=''/>
  <approachSiteCode code='' displayName='' codeSystem='' codeSystemName=''/>
  <targetSiteCode code='' displayName='' codeSystem='' codeSystemName=''/>
  <author />
  <informant />
  <entryRelationship typeCode='COMP' inversionInd='true'>
    <act classCode='ACT' moodCode=''>
      <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.4.1'/>
      <id root='' extension=''/>
    </act>
  </entryRelationship>
  <entryRelationship typeCode='RSON'>
    <act classCode='ACT' moodCode='EVN'>
      <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.4.1'/>
      <id root='' extension=''/>
    </act>
  </entryRelationship>
</procedure>
```

***Figure 21C**- Sample Procedure Entry*

8.1.9.3.2. Standards

CCD	ASTM/HL7 Continuity of Care Document

8.1.9.3.3. Procedure

<procedure classCode='PROC' moodCode='EVN|INT'>

This element is a procedure. The classCode shall be 'PROC'. The moodCode may be INT to indicate a planned procedure, or EVN, to describe a procedure that has already occurred.

8.1.9.3.4. Template Id root

<templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.19'/>

The templateId indicates that this <procedure> entry conforms to the constraints of this content module. NOTE: When the procedure is in event mood (moodCode='EVN'), this entry conforms to the CCD template 2.16.840.1.113883.10.20.1.29, and when in intent mood, this entry conforms to the CCD template 2.16.840.1.113883.10.20.1.25.

8.1.9.3.5. Id root

<id root='' extension=''/>

This required element shall contain an identifier for the procedure. More than one procedure identifier may be present.

8.1.9.3.6. Type of procedure

<code code='' displayName='' codeSystem='' codeSystemName='' />
This element shall be present, and should contain a code describing the type of procedure.

8.1.9.3.7. Text-reference

<text><reference value='#xxx'/></text>
The <text> element shall contain a reference to the narrative text describing the procedure.

8.1.9.3.8. Status Code

<statusCode code='completed|active|aborted|cancelled'/>
The <statusCode> element shall be present when used to describe a procedure event. It shall have the value 'completed' for procedures that have been completed and 'active' for procedures that are still in progress. Procedures that were stopped prior to completion shall use the value 'aborted', and procedures that were cancelled before being started shall use the value 'cancelled'.

8.1.9.3.9. Procedure effective time

```
<effectiveTime>
  <low value=''/>
  <high value=''/>
</effectiveTime>
```

This element should be present, and records the time at which the procedure occurred (in EVN mood), or the desired time of the procedure in INT mood.

8.1.9.3.10. Priority Code

8.1.9.4. <priorityCode code=''/>

This element shall be present in INT mood when effectiveTime is not provided, it may be present in other moods. It indicates the priority of the procedure.

8.1.9.4.1. Approach Site

```
<approachSiteCode code=''
  displayName=''
  codeSystem=''
  codeSystemName=''/>
```

This element may be present to indicate the procedure approach.

8.1.9.4.2. Target Site

<targetSiteCode
code=''
displayName=''
codeSystem=''
codeSystemName=''/>

This element may be present to indicate the target site of the procedure.

8.1.9.4.3. Optional entryRelationship: linking the procedure to an encounter

<entryRelationship typeCode='COMP' inversionInd='true'>
This element may be present to point the encounter in which the procedure was performed, and shall contain an internal reference to the encounter. See Internal References entry content model for more details.

8.1.9.4.4. Required entryRelationship: indicate the reason for the procedure

<entryRelationship typeCode='RSON'>
A <procedure> act SHALL indicate one or more reasons for the procedure. These reasons identify the concern that was the reason for the procedure via an Internal Reference entry content model to the concern. The extension and root of each observation present must match the identifier of a concern entry contained elsewhere within the CDA document.

The concern to which the procedure will then be linked to is a Problem Entry element that SHALL have an <entryRelationship> that will indicate the severity of the problem, conforming to the severity entry template (1.3.6.1.4.1.19376.1.5.3.1.4.1). The severity codes to be used are epSOSSeverity, OID 1.3.6.1.4.1.12559.11.10.1.3.1.42.13.

8.1.10. Optional entryRelationship: linking to Internal References Entry Content Model 1.3.6.1.4.1.19376.1.5.3.1.4.4.1

CDA and HL7 Version 3 Entries may reference (point to) information contained in other entries within the same document or message as shown below.

8.1.10.1. Specification

```
<entryRelationship typeCode='' inversionInd='true|false'>
    <act classCode='' moodCode=''>
      <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.4.1'/>
      <id root='' extension=''/>
      <code code='' displayName='' codeSystem='' codeSystemName=''/>
    </act>
</entryRelationship>
```

Figure 22C*- Sample Optional entryRelatiobship*

8.1.10.2. entryRelationship definition

<entryRelationship typeCode=' ' inversionInd='true|false'>
For CDA the act being referenced appears inside a related entryRelationship. The type (typeCode) and direction (inversionInd) attributes will be specified in the entry content module that contains the

reference. For HL7 Version 3 Messages, the relationship is indicated with a <sourceOf> element, however typeCodes and semantics remain unchanged.

8.1.10.3. Reference act

<act classCode=' ' moodCode=' '>

The act being referred to can be any CDA Clinical Statement element type (act, procedure, observation, substanceAdministration, supply, et cetera). For compatibility with the Clinical Statement model the internal reference shall always use the <act> class, regardless of the XML element type of the act it refers to.

8.1.10.4. Template Id root

<templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.4.1'/>

The <templateId> element identifies this as an internal reference that conforms to all rules specified in this section.

8.1.10.5. Id root

<id root=' ' extension=' '/>

This element shall be present. The root and extension attributes shall identify an element defined elsewhere in the same document.

8.1.10.6. Internal reference code

<code code=' ' displayName=' ' codeSystem=' ' codeSystemName=' '/>

This element shall be present. It shall be valued when the internal reference is to element that has a <code> element, and shall have the same attributes as the <code> element in the act it references. If the element it references does not have a <code> element, then the nullFlavor attribute should be set to "NA".

8.1.11. Active Problems Section 1.3.6.1.4.1.19376.1.5.3.1.3.6

Template ID	1.3.6.1.4.1.19376.1.5.3.1.3.6	
Parent Template	CCD 3.5 (2.16.840.1.113883.10.20.1.11)	
General Description	The active problem section shall contain a narrative description of the conditions currently being monitored for the patient. It shall include entries for patient conditions as described in the Entry Content Module.	
LOINC Code	**Opt**	**Description**
11450-4	R	PROBLEM LIST
Entries	**Opt**	**Description**
1.3.6.1.4.1.19376.1.5.3.1.4.5.2	R	Problem Concern Entry

8.1.11.1. Active Problems Section Parent Template

The parent of this template is CCD 3.5.

8.1.11.2. Specification

```
<component>
  <section>
    <templateId root='2.16.840.1.113883.10.20.1.11'/>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.6'/>
    <id root=' ' extension=' '/>
    <code code='11450-4' displayName='PROBLEM LIST'
      codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
    <text>
      Text as described above
    </text>
    <entry>
        :
      <!-- Required Problem Concern Entry element -->
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.2'/>
        :
    </entry>

  </section>
</component>
```

***Figure 23C**- Sample Active Problems Section*

8.1.11.3. Problem Concern Entry 1.3.6.1.4.1.19376.1.5.3.1.4.5.2

This entry is a specialization of the Concern Entry, wherein the subject of the concern is focused on a problem. Elements shown in the example below in gray are explained in the Concern Entry.

8.1.11.3.1. Standards

CCD	ASTM/HL7 Continuity of Care Document
CareStruct	HL7 Care Provision Care Structures (DSTU)
ClinStat	HL7 Clinical Statement Pattern (Draft)

8.1.11.3.2. Parent Template

The parent of this template is Concern Entry. This template is compatible with the ASTM/HL7 Continuity of Care Document template: 2.16.840.1.113883.10.20.1.27

8.1.11.3.3. Specification

```
<act classCode='ACT' moodCode='EVN'>
 <templateId root='2.16.840.1.113883.10.20.1.27'/>
 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.1'/>
 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.2'/>
 <id root=' ' extension=' '/>
 <code nullFlavor='NA'/>
 <statusCode code='active|suspended|aborted|completed'/>
 <effectiveTime>
   <low value=' '/>
   <high value=' '/>
 </effectiveTime>
 <!-- 1..* entry relationships identifying problems of concern -->
 <entryRelationship type='SUBJ'>
   <observation classCode='OBS' moodCode='EVN'/>
      <templateID root='1.3.6.1.4.1.19376.1.5.3.1.4.5'>
        :
   </observation>
 </entryRelationship>
 <!-- optional entry relationship providing more information about the concern -->
 <entryRelationship type='REFR'>
 </entryRelationship>
</act>
```

***Figure 24C**- Sample Active Problems Section*

8.1.11.3.4. Template Id root

<templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.1'/>
<templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.2'/>
This entry has a template identifier of 1.3.6.1.4.1.19376.1.5.3.1.4.5.2, and is a subtype of the Concern Entry, and so must also conform to that specification, with the template identifier of 1.3.6.1.4.1.19376.1.5.3.1.4.5.1. These elements are required and shall be recorded exactly as shown above.

8.1.11.3.5. EntryRelationships identifying problems of concern

```
<entryRelationship type='SUBJ'>
  <observation classCode='OBS' moodCode='EVN'>
    <templateID root=' 1.3.6.1.4.1.19376.1.5.3.1.4.5'/>
    …
  </observation>
</entryRelationship>
```

This entry shall contain one or more problem entries that conform to the Problem Entry template 1.3.6.1.4.1.19376.1.5.3.1.4.5. For CDA this SHALL be represented with the <entryRelationship> element. For HL7 Version 3 Messages, this SHALL be represented as a <subjectOf> element. The typeCode SHALL be 'SUBJ' and inversionInd SHALL be 'false'.

Note: every Problem Entry used in this section to identify problem of concern SHALL have an <entryRelationship> that will indicate the severity of the problem, conforming to the severity entry template (1.3.6.1.4.1.19376.1.5.3.1.4.1). The severity codes to be used are epSOSSeverity, OID 1.3.6.1.4.1.12559.11.10.1.3.1.42.13.

8.1.12. Concern Entry 1.3.6.1.4.1.19376.1.5.3.1.4.5.1

This event (moodCode='EVN') represents an act (<act classCode='ACT') of being concerned about a problem, allergy or other issue. The <effectiveTime> element describes the period of concern. The subject of concern is one or more observations about related problems (see 1.3.6.1.4.1.19376.1.5.3.1.4.5.2) or allergies and intolerances (see 1.3.6.1.4.1.19376.1.5.3.1.4.5.3). Additional references can be provided having additional information related to the concern. The concern entry allows related acts to be grouped. This allows representing the history of a problem as a series of observation over time, for example.

8.1.12.1. Standards

CCD	ASTM/HL7 Continuity of Care Document
CareStruct	HL7 Care Provision Care Structures (DSTU)
ClinStat	HL7 Clinical Statement Pattern (Draft)

8.1.12.2. Parent Template

The parent of this template is the ASTM/HL7 Continuity of Care Document template: 2.16.840.1.113883.10.20.1.27.

8.1.12.3. Specification

```
<act classCode='ACT' moodCode='EVN'>
  <templateId root='2.16.840.1.113883.10.20.1.27'/>
  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.1'/>
  <id root='' extension=''/>
  <code nullFlavor='NA'/>
  <statusCode code='active|suspended|aborted|completed'/>
  <effectiveTime>
    <low value=''/>
    <high value=''/>
  </effectiveTime>
  <!-- one or more entry relationships identifying problems of concern -->
  <entryRelationship typeCode='SUBJ' inversionInd='false'>
     :
  </entryRelationship>
  <!-- optional entry relationship providing more information about the concern -->
  <entryRelationship typeCode='REFR'>
     :
  </entryRelationship>
</act>
```

***Figure 25C**- Sample Concern Entry*

8.1.12.4. Act code

<act classCode='ACT' moodCode='EVN'>
All concerns reflect the act of recording (<act classCode='ACT'>) the event (moodCode='EVN') of being concerned about a problem, allergy or other issue about the patient condition.

8.1.12.5. Template Id root

<templateId root='2.16.840.1.113883.10.20.1.27'/>
<templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.1'/>
These template identifiers indicate this entry conforms to the concern content module. This content module inherits constraints from the HL7 CCD Template for problem acts, and so also includes that template identifier.

8.1.12.6. Id root

<id root=' ' extension=' '/>
This required element identifies the concern.

8.1.12.7. nullFlavor

<code nullFlavor='NA'/>
The code is not applicable to a concern act, and so shall be recorded as shown above.

8.1.12.8. Status Code

<statusCode code='active|suspended|aborted|completed'/>
The statusCode associated with any concern must be one part of the epSOSstatusCode, OID 1.3.6.1.4.1.12559.11.10.1.3.1.42.15.

Note: A concern in the "active" state represents one for which some ongoing clinical activity is expected, and that no activity is expected in other states. Specific uses of the suspended and aborted states are left to the implementation.

8.1.12.9. Concern effective time

<effectiveTime>
<low value=' '/>
<high value=' '/>
</effectiveTime>

The <effectiveTime> element records the starting and ending times during which the concern was active. The <low> element shall be present. The <high> element shall be present for concerns in the completed or aborted state, and shall not be present otherwise.

8.1.12.10. entryRelationships identifying problems of concern

<entryRelationship type='SUBJ' inversionInd='false'>
Each concern is about one or more related problems or allergies. This entry shall contain one or more problem or allergy entries that conform to the specification in section Problem Entry or Allergies and Intolerances. This is how a series of related observations can be grouped as a single concern.

This shall be represented with the <entryRelationship> element. The typeCode shall be 'SUBJ'.

Note: every Problem Entry (or Allergy Entry) used in the section to identify problem of concern SHALL have an <entryRelationship> that will indicate the severity of the problem, conforming to the severity entry template (1.3.6.1.4.1.19376.1.5.3.1.4.1). The severity codes to be used are epSOSSeverity, OID 1.3.6.1.4.1.12559.11.10.1.3.1.42.13.

Note: The Allergy and Intolerances entry is a refinement of the Problem entry.

8.1.12.11. Optional entry relationship providing more information about the concern

<entryRelationship type='REFR' inversionInd='false'>
Each concern may have 0 or more related references. These may be used to represent related statements such related visits. This may be any valid CDA clinical statement, and SHOULD be an IHE entry template. For CDA this SHALL be represented with the <entryRelationship> element. For HL7 Version 3 Messages, this SHALL be represented as a <subjectOf> element. The typeCode SHALL be 'SUBJ' and inversionInd SHALL be 'false'

8.1.13. Problem Entry 1.3.6.1.4.1.19376.1.5.3.1.4.5

This section makes use of the linking, severity, clinical status and comment content specifications defined elsewhere in the technical framework. In HL7 RIM parlance, observations about a problem, complaint, symptom, finding, diagnosis, or functional limitation of a patient is the event (moodCode='EVN') of observing (<observation classCode='OBS'>) that problem. The <value> of the ob-

790 servation comes from a controlled vocabulary representing such things. The <code> contained within the <observation> describes the method of determination from yet another controlled vocabulary. An example appears below in the figure below.

8.1.13.1. Standards

CCD	ASTM/HL7 Continuity of Care Document
CareStruct	HL7 Care Provision Care Structures (DSTU)
ClinStat	HL7 Clinical Statement Pattern (Draft)

795 #### 8.1.13.2. Parent Template

This template is compatible with the ASTM/HL7 Continuity of Care Document template: 2.16.840.1.113883.10.20.1.28

8.1.13.3. Specification

```
<observation classCode='OBS' moodCode='EVN' negationInd=' false|true '>
 <templateId root='2.16.840.1.113883.10.20.1.28'/>
 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5'/>
 <id root=' ' extension=' '/>
 <code code=' ' displayName=' '
   codeSystem='2.16.840.1.113883.6.96' codeSystemName='SNOMED CT'/>
 <text><reference value=' '/></text>
 <statusCode code='completed'/>
 <effectiveTime><low value=' '/><high value=' '/></effectiveTime>
 <value xsi:type='CD' code=' '
   codeSystem=' ' displayName=' ' codeSystemName=' '>
   <originalText><reference value=' '/></originalText>
 </value>
 <
 <!-- zero or one <entryRelationship typeCode='REFR' inversionInd='false'> elements
      identifying the health status of concern -->
 <!-- zero or one <entryRelationship typeCode='REFR' inversionInd='false'> elements
      containing clinical status -->
 <!-- zero to many <entryRelationship typeCode='REFR' inversionInd='true'> elements
      containing comments -->
</observation>
```

820 ***Figure 26C*** *- Sample Problem Entry*

8.1.13.4. Observation code

8.1.13.5. <observation classCode='OBS' moodCode='EVN' negationInd='false|true'>

The basic pattern for reporting a problem uses the CDA <observation> element, setting the classCode='OBS' to represent that this is an observation of a problem, and the moodCode='EVN', to represent that this is an observation that has in fact taken place. The negationInd attribute, if true, specifies that the problem indicated was observed to not have occurred (which is subtly but importantly different from having not been observed).

The value of negationInd should not normally be set to true. Instead, to record that there is "no prior history of chicken pox", one would use a coded value indicated exactly that. However, it is not always possible to record problems in this manner, especially if using a controlled vocabulary that does not supply pre-coordinated negations , or which do not allow the negation to be recorded with post-coordinated coded terminology.

8.1.13.6. Template Id

<templateId root='2.16.840.1.113883.10.20.1.28'/>
<templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5'/>

These <templateId> elements identify this <observation> as a problem, under both IHE and CCD specifications. This SHALL be included as shown above.

8.1.13.7. Id root

<id root=' ' extension=' '/>
The specific observation being recorded must have an identifier (<id>) that shall be provided for tracking purposes. If the source EMR does not or cannot supply an intrinsic identifier, then a GUID shall be provided as the root, with no extension (e.g., <id root='CE1215CD-69EC-4C7B-805F-569233C5E159'/>). While CDA allows for more than one identifier element to be provided, this profile requires that only one be used.

8.1.13.8. Description of the problem

<code code=' '
displayName=' '
codeSystem=' 1.3.6.1.4.1.12559.11.10.1.3.1.42.23'
codeSystemName=' epSOSCodeProb'>

The <code> describes the process of establishing a problem. The code element should be used, as the process of determining the value is important to clinicians (e.g., a diagnosis is a more advanced statement than a symptom). The recommended vocabulary for describing problems is Value set epSOSCodeProb, OID 1.3.6.1.4.1.12559.11.10.1.3.1.42.23.

8.1.13.9. Reference text

<text><reference value=' '/></text>
The <text> element is required and points to the text describing the problem being recorded; including any dates, comments, et cetera. The <reference> contains a URI in value attribute. This URI points to the free text description of the problem in the document that is being described.

8.1.13.10. Problem Status

<statusCode code='completed'/>
A clinical document normally records only those condition observation events that have been completed, not observations that are in any other state. Therefore, the <statusCode> shall always have code='completed'.

8.1.13.11. Problem effective time

<effectiveTime>
<low value=' '/>
<high value=' '/>
</effectiveTime>

The <effectiveTime> of this <observation> is the time interval over which the <observation> is known to be true. The <low> and <high> values should be no more precise than known, but as precise as possible.

While CDA allows for multiple mechanisms to record this time interval (e.g. by low and high values, low and width, high and width, or centre point and width), we are constraining Medical summaries to use only the low/high form.

The <low> value is the earliest point for which the condition is known to have existed.

The <high> value, when present, indicates the time at which the observation was no longer known to be true. Thus, the implication is made that if the <high> value is specified, that the observation was no longer seen after this time, and it thus represents the date of resolution of the problem.

Similarly, the <low> value may seem to represent onset of the problem. Neither of these statements is necessarily precise, as the <low> and <high> values may represent only an approximation of the true onset and resolution (respectively) times. For example, it may be the case that onset occurred prior to the <low> value, but no observation may have been possible before that time to discern whether the condition existed prior to that time.

The <low> value should normally be present. There are exceptions, such as for the case where the patient may be able to report that they had chicken pox, but are unsure when. In this case, the <effectiveTime> element shall have a <low> element with a nullFlavor attribute set to 'UNK'. The <high> value need not be present when the observation is about a state of the patient that is unlikely to change (e.g., the diagnosis of an incurable disease).

8.1.13.12. Condition found

<value xsi:type='CD'
code=' '
codeSystem=' '
codeSystemName=' '
displayName=' '>

The <value> is the condition that was found. This element is required. While the value may be a coded or an un-coded string, the type is always a coded value (xsi:type='CD'). If coded, the code and codeSystem attributes shall be present. The codeSystem used is epSOSIllnessesandDisorders, with the OID 1.3.6.1.4.1.12559.11.10.1.3.1.42.5.

In cases where information about a problem or allergy is unknown or where there are no problems or allergies, an entry shall use codes from epSOSUnknownInformation, OID 1.3.6.1.4.1.12559.11.10.1.3.1.42.17.

8.1.13.13. Reference Text

<originalText><reference value=' '/></originalText>
The <originalText> element within the <code> element described above is used as follows: the <value> contains a <reference> to the <originalText> in order to link the coded value to the problem narrative text (minus any dates, comments, et cetera). The <reference> contains a URI in value

attribute. This URI points to the free text description of the problem in the document that is being described.

8.1.13.14. Required entryRelationship: severity

< entryRelationship typeCode='SUBJ' inversionInd='true'>
A required <entryRelationship> element SHALL be present indicating the severity of the problem. This <entryRelationship> element SHALL contain a severity observation conforming to the Severity entry template (1.3.6.1.4.1.19376.1.5.3.1.4.1). The severity codes to be used are epSOSSeverity, OID 1.3.6.1.4.1.12559.11.10.1.3.1.42.13.

This shall be represented with the <entryRelationship> element. The typeCode shall be 'SUBJ' and inversionInd shall be 'true'.

8.1.13.15. Optional entryRelationship: clinical status

<entryRelationship typeCode='REFR' inversionInd='false'>
An optional <entryRelationship> may be present indicating the clinical status of the problem, e.g., resolved, in remission, active. When present, this <entryRelationship> element shall contain a clinical status observation conforming to the Problem Status Observation template (1.3.6.1.4.1.19376.1.5.3.1.4.1.1). The code system to be used is epSOSstatusCode, OID 1.3.6.1.4.1.12559.11.10.1.3.1.42.15.

This shall be represented with the <entryRelationship> element. The typeCode shall be 'REFR' and inversionInd shall be 'false'.

8.1.13.16. Optional entreyRelationship: health status of concern

<entryRelationship typeCode='REFR' inversionInd='false'>
An optional <entryRelationship> may be present referencing the health status of the patient, e.g., resolved, in remission, active. When present, this <entryRelationship> element shall contain a clinical status observation conforming to the Health Status Observation template (1.3.6.1.4.1.19376.1.5.3.1.4.1.1). The typeCode shall be 'REFR' and inversionInd shall be 'false'.

This shall be represented with the <entryRelationship> element.

8.1.13.17. Optional entryRelationship: comments

<entryRelationship typeCode='SUBJ' inversionInd='true'>
One or more optional <entryRelationship> elements may be present providing an additional comments (annotations) for the condition. When present, this <entryRelationship> element shall contain a comment observation conforming to the Comment entry template (1.3.6.1.4.1.19376.1.5.3.1.4.2). The typeCode shall be 'SUBJ' and inversionInd shall be 'true'.

This shall be represented with the <entryRelationship> element.

8.1.14. History of Present Illness Section 1.3.6.1.4.1.19376.1.5.3.1.3.4

Template ID	1.3.6.1.4.1.19376.1.5.3.1.3.4	
General Description	The history of present illness section shall contain a narrative description of the sequence of events preceding the patient's current complaints.	
LOINC Code	**Opt**	**Description**
10164-2	R	HISTORY OF PRESENT ILLNESS

8.1.14.1. Specification

```
<component>
  <section>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.4'/>
    <id root=' ' extension=' '/>
    <code code='10164-2' displayName='HISTORY OF PRESENT ILLNESS'
      codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
    <text>
      Text as described above
    </text>

  </section>
</component>
```

***Figure 27C**-Sample History of Present Illness Section*

8.1.15. Medical Devices Coded Section 1.3.6.1.4.1.12559.11.10.1.3.1.2.4

Template ID	1.3.6.1.4.1.12559.11.10.1.3.1.2.4	
Parent Template	2.16.840.1.11383.10.20.1.7 (2.16.840.1.11383.10.20.1.7) 1.3.6.1.4.1.19376.1.5.3.1.1.5.3.5	
General Description	The medical devices section contains narrative text describing the patient history of medical device use.	
LOINC Code	**Opt**	**Description**
46264-8	R	HISTORY OF MEDICAL DEVICE USE
Entries	**Opt**	**Description**
1.3.6.1.4.1.12559.11.10.1.3.1.3.5	R	Medical Device Entry Content Module

8.1.15.1. Parent Template

The parents of this template are 2.16.840.1.11383.10.20.1.7 and 1.3.6.1.4.1.19376.1.5.3.1.1.5.3.5

8.1.15.2. Specification

```
<component>
  <section>
    <templateId root='2.16.840.1.11383.10.20.1.7'/>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.5.3.5'/>
    <id root=' ' extension=' '/>
    <code code='46264-8' displayName='HISTORY OF MEDICAL DEVICE USE'
      codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
    <text>
      Text as described above
    </text>
    <entry>

    </entry>
  </section>
</component>
```

Figure 28C- *Sample Medical Devices Section*

8.1.15.3. Medical Devices Entry Content Module 1.3.6.1.4.1.12559.11.10.1.3.1.3.5

The medical devices entry content module describes the kind of device that is, or has been used by the patient

8.1.15.3.1. Specification

```
<supply moodCode="EVN" classCode="SPLY">
   <templateId root="1.3.6.1.4.1.12559.11.10.1.3.1.3.5"/>
   <id root="2.16.840.1.113883.19.811.3"/>
   <text><reference value="#DevDescr"/></text>
   <effectiveTime value="20070728"/>
   <participant typeCode="DEV">
      <participantRole classCode="MANU">
         <id root=""/>
         <playingDevice classCode="DEV" determinerCode="INSTANCE">
            <code code="" codeSystem=""/>
         </playingDevice>
      </participantRole>
   </participant>
   .
   .
   .
</supply>
```

Figure 28C- *Sample Medical Devices Entry*

8.1.15.3.2. Supply

<supply moodCode="EVN" classCode="SPLY"> … </supply>
The <supply> element shall be present. The moodCode attribute shall be EVN to reflect that a medical device has been provided.

8.1.15.3.3. Template ID

<templateId root="1.3.6.1.4.1.12559.11.10.1.3.1.3.5"/>
The tamplate ID indicates that this content module describes a medical device.

8.1.15.3.4. Supply ID

<id root="" extension=""/>
This optional element identifies the provision of the device.

8.1.15.3.5. Device Description

<text><reference value=""/><text>
The <text> element references the part of the section narrative, which contains the description of the device.

8.1.15.3.6. Time of provision

<effectiveTime value=""/>
- or -
<effectiveTime xs:type="IVL_TS">
<low value=""/>
<high value=""/>
</effectiveTime>
The <effectiveTime> element denotes the date and time the device was provided to the patient. For an implanted device, that is the date and time of implantation. If this entry indicate a past use if a device, the time interval form of shall be used, with the low and high values describing when the device was used.

8.1.15.3.7. Device Structure

```
<participant typeCode="DEV">
  <participantRole classCode="MANU">
    <id root=""/>
    <playingDevice classCode="DEV" determinerCode="INSTANCE">
      <code code="" codeSystem=""/>
      ...
    </playingDevice>
  </participantRole>
</participant>
```

The device is represented as a participant in the supply structure. The following descriptions apply to the device structure.

8.1.15.3.8. Participant

<participant typeCode="DEV"> … </participant>
The type code of the <participant> element shall contain the value of "DEV".

8.1.15.3.9. Participant Role

<participantRole classCode="MANU"> … </participantRole>
The participant role shall contain the class code of "MANU", indicating a manufactured entity (device).

8.1.15.3.10. Device ID

<id root="" extension=""/>

The device ID is represented by the <id> element of the participant role. This element is optional, as not all device identifiers (serial numbers) may be known to the provider or patient.

8.1.15.3.11. Device

<playingDevice classCode="" determinerCode=""> … </playingDevice>

The <playingDevice> element describes the device instance. The class code shall contain the value of "DEV", and the determiner code shall contain "INSTANCE".

8.1.15.3.12. Device Code

<code code="" codeSystem="2.16.840.1.113883.6.96"/>

The device code describes the type of device (e.g. arm prosthesis, arterial stent). It shall contain codes from the epSOSMedicalDevices value set OID 1.3.6.1.4.1.12559.11.10.1.3.1.42.8.

8.1.16. Procedures and Interventions Section 1.3.6.1.4.1.19376.1.5.3.1.1.13.2.11

Template ID	1.3.6.1.4.1.19376.1.5.3.1.1.13.2.11	
General Description	The Procedures and Interventionssection shall contain a narrative description of the actions performed by a clinician.	
LOINC Code	**Opt**	**Description**
29544-3	R	PROCEDURES
Entries	**Opt**	**Description**
1.3.6.1.4.1.19376.1.5.3.1.4.19	R	Procedures This entry provides coded values for procedures performed during the encounter.

Please follow the link and reference against the **Procedure Entry 1.3.6.1.4.1.19376.1.5.3.1.4.19** described above in the document, section 2.4.8.3.

8.1.16.1. Specification

```
<component>
  <section>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.13.2.11'/>
    <id root=' ' extension=' '/>
    <code code='X-PROC' displayName='PROCEDURES PERFORMED'
      codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
    <text>
      Text as described above
    </text>
    <entry>
        :
      <!-- Required Procedures element -->
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.19'/>
        :
    </entry>

  </section>
</component>
```

***Figure 29C** - Specification for Procedures and Interventions Section*

8.1.17. Health Maintenance Care Plan Section 1.3.6.1.4.1.19376.1.5.3.1.1.9.50

Template ID	1.3.6.1.4.1.19376.1.5.3.1.1.9.50	
Parent Template	1.3.6.1.4.1.19376.1.5.3.1.3.31	
General Description	The health maintenance care plan section shall contain a description of the expectations for wellness care including proposals, goals, and order requests for monitoring, tracking, or improving the lifetime condition of the patient with goals of educating the patient on how to reduce the modifiable risks of the patient's genetic, behavioral, and environmental pre-conditions and otherwise optimizing lifetime outcomes.	
LOINC Code	**Opt**	**Description**
18776-5	R	TREATMENT PLAN

8.1.17.1. Parent Template

The parent of this template is 1.3.6.1.4.1.19376.1.5.3.1.3.31.

8.1.17.2. Specification

```
<component>

  <section>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.31'/>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.9.50'/>
    <id root=' ' extension=' '/>
    <code code='18776-5' displayName='TREATMENT PLAN'
      codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
    <text>
      Text as described above
    </text>

  </section>

</component>
```

***Figure 30C**- Sample Health Maintenance Care Plan Section*

8.1.18. Functional Status Section 1.3.6.1.4.1.19376.1.5.3.1.3.17

Template ID	1.3.6.1.4.1.19376.1.5.3.1.3.17	
Parent Template	CCD 3.4 (2.16.840.1.113883.10.20.1.5)	
General Description	The functional status section shall contain a narrative description of capability of the patient to perform acts of daily living.	
LOINC Code	**Opt**	**Description**
47420-5	R	FUNCTIONAL STATUS ASSESSMENT

8.1.18.1. Parent Template

The parent of this template is CCD 3.4.

8.1.18.2. Specification

```
<component>

  <section>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.31'/>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.9.50'/>
    <id root=' ' extension=' '/>
    <code code='18776-5' displayName='TREATMENT PLAN'
      codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
    <text>
      Text as described above
    </text>

  </section>

</component>
```

***Figure 31C**- Sample Functional Status Section*

8.1.19. Coded Social History Section 1.3.6.1.4.1.19376.1.5.3.1.3.16.1

Template ID	1.3.6.1.4.1.19376.1.5.3.1.3.16.1	
Parent Template	Social History (1.3.6.1.4.1.19376.1.5.3.1.3.16)	
General Description	The social history section shall contain a narrative description of the person's beliefs, home life, community life, work life, hobbies, and risky habits. It shall include Social History Observations.	
LOINC Code	**Opt**	**Description**
29762-2	R	SOCIAL HISTORY
Entries	**Opt**	**Description**
1.3.6.1.4.1.19376.1.5.3.1.4.13.4	R	Social History Observation

8.1.19.1. Parent Template

The parent of this template is 1.3.6.1.4.1.19376.1.5.3.1.3.16.

8.1.19.2. Specification

```
<component>
  <section>
    <templateId root='11.3.6.1.4.1.19376.1.5.3.1.3.16'/>
    <templateId root='11.3.6.1.4.1.19376.1.5.3.1.3.16.1'/>
    <id root=' ' extension=' '/>
    <code code='29762-2' displayName='SOCIAL HISTORY'
      codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
    <text>
      Text as described above
    </text>
  </section>
</component>
```

***Figure 32C**- Sample Social History Section*

8.1.19.3. Social History Observation Entry Content Module 1.3.6.1.4.1.19376.1.5.3.1.4.13.4

A social history observation is a simple observation that uses a specific vocabulary, and inherits constraints from CCD.

8.1.19.4. Standards

CCD	ASTM/HL7 Continuity of Care Document

8.1.19.5. Parent Template

The parent of this template is Simple Observation. This template is compatible with the ASTM/HL7 Continuity of Care Document template: 2.16.840.1.113883.10.20.1.33.

8.1.19.6. Specification

```
<observation typeCode='OBS' moodCode='EVN'>
 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13'/>
 <templateId root='2.16.840.1.113883.10.20.1.33'/>
 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13.4'/>
 <id root=' ' extension=' '/>
 <code code=' ' displayName=' ' codeSystem=' ' codeSystemName=' '/>
 <text><reference value='#xxx'/></text>
 <statusCode code='completed'/>
 <effectiveTime value=' '/>
 <repeatNumber value=' '/>
 <value xsi:type=' ' />
 <interpretationCode code=' ' codeSystem=' ' codeSystemName=' '/>
 <methodCode code=' ' codeSystem=' ' codeSystemName=' '/>
 <targetSiteCode code=' ' codeSystem=' ' codeSystemName=' '/>
</observation>
```

***Figure 33C** - Sample Social History Observation Entry Content Module*

8.1.19.7. Template Id

<templateId root='2.16.840.1.113883.10.20.1.33/>
<templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13.4'/>

These <templateId> elements identify this as a Social History observation.

425400000	Toxic exposure status	PQ	{pack}/d or {pack}/wk or {pack}/a
256235009	Exercise		{times}/wk
160573003	ETOH (Alcohol) Use		{drink}/d or {drink}/wk
364393001	Nutritional observable	CD	N/A
364703007	Employment detail		
425400000	Toxic exposure status		
363908000	Details of drug misuse behavior		
228272008	Health-related behavior	ANY	

8.1.19.8. Type of social history observation

<code code=' ' displayName=' ' codeSystem=' ' codeSystemName=' '/>
The <code> element identifies the type social history observation.

8.1.19.9. ~~<repeatNumber value=' '/>~~

The <repeatNumber> element should not be used in a social history observation.

8.1.19.10. Representation

<value xsi:type=' ' ... />text

The <value> element reports the value associated with the social history observation. The data type to use for each observation should be drawn from the table above.

Observations in the table above using the PQ data type have a unit in the form {xxx}/d, {xxx}/wk or {xxx}/a represent the number of items per day, week or year respectively. The value attribute indicates the number of times of the act performed, and the units represent the frequency. The example below shows how to represent 1 drink per day.

```
  :
<code code='160573003' displayName='ETOH Use'
      codeSystem='2.16.840.1.113883.6.96'
      codeSystemName='SNOMED CT'/>
  :
<value xsi:type='PQ' value='1' unit='{drink}/d'/>
  :
```

Observations in the table using the CD data type should include coded values from an appropriate vocabulary to represent the social history item. The example below shows the encoding to indicate drug use of cannabis.

```
  :
<code code='363908000' displayName='Drug Use'
      codeSystem='2.16.840.1.113883.6.96'
      codeSystemName='SNOMED CT'/>
  :
<value xsi:type='CD' code='398705004' displayName='cannabis'
       codeSystem='2.16.840.1.113883.6.96'
       codeSystemName='SNOMED CT'/>
  :
```

Other social history observations may use any appropriate data type.

The <interpretationCode>, <methodCode>, and <targetSiteCode> elements should not be used in a social history observation.

8.1.20. Pregnancy History Section 1.3.6.1.4.1.19376.1.5.3.1.1.5.3.4

Template ID	1.3.6.1.4.1.19376.1.5.3.1.1.5.3.4	
General Description	The pregnancy history section contains coded entries describing the patient history of pregnancies.	
LOINC Code	**Opt**	**Description**
10162-6	R	HISTORY OF PREGNANCIES
Entries	**Opt**	**Description**
1.3.6.1.4.1.19376.1.5.3.1.4.13.5	R	Pregnancy Observation

8.1.20.1. Specification

```
<component>
  <section>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.5.3.4'/>
    <id root=' ' extension=' '/>
    <code code='10162-6' displayName='HISTORY OF PREGNANCIES'
      codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
    <text>
      Text as described above
    </text>
    <entry>
         :
      <!-- Required Pregnancy Observation  element -->
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13.5'/>
         :
    </entry>

  </section>
</component>
```

***Figure 34C**- Sample Pregnancy History Section*

8.1.20.2. Pregnancy Observation Entry Content Module 1.3.6.1.4.19376.1.5.3.1.4.13.5

A pregnancy observation is a Simple Observation that uses a specific vocabulary to record observations about a patient's pregnancy history.

8.1.20.3. Parent Template

The parent of this template is Simple Observation.

8.1.20.4. Specification

```
observation typeCode='OBS' moodCode='EVN'>
 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13'/>
 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13.5'/>
 <id root=' ' extension=' '/>
 <code code=' ' displayName=' ' codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
 <text><reference value='#xxx'/></text>
 <statusCode code='completed'/>
 <effectiveTime value=' '/>
 <repeatNumber value=' '/>
 <value xsi:type=' ' .../>
 <interpretationCode code=' ' codeSystem=' ' codeSystemName=' '/>
 <methodCode code=' ' codeSystem=' ' codeSystemName=/>
 <targetSiteCode code=' ' codeSystem=' ' codeSystemName=' '/>
</observation>
```

***Figure 35C**- Sample Pregnancy Observation Entry Content Module*

8.1.20.4.1. Template ID

<templateId root=''1.3.6.1.4.1.19376.1.5.3.1.4.13'/>
<templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13.5'/>

These <templateId> elements identify this <observation> as a pregnancy observation, allowing for validation of the content. The <templateId> elements shall be recorded as shown above.

8.1.20.5. Description of the pregnancy

<code code=' '
displayName=' '
codeSystem=' 1.3.6.1.4.1.12559.11.10.1.3.1.42.9'
codeSystemName=' epSOSPregnancyInformation'>

A pregnancy observation shall have a code describing what facet of patient's pregnancy history is being recorded. These codes should come from the value set listed above, namely epSOSPregnancyInformation, OID 1.3.6.1.4.1.12559.11.10.1.3.1.42.9.

11778-8	Delivery date estimated (clinical)	TS	No code system applicable
11779-6	Delivery date estimated from last menstrual period		
11780-4	Delivery date estimated from ovulation		

8.1.20.6. ~~<repeatNumber value=' '/>~~

The <repeatNumber> element should not be present in a pregnancy observation.

8.1.20.7. Representation

<value xsi:type=' ' ... />text
The value of the observation shall be recording using a data type appropriate to the coded observation according to the table above.

The <interpretationCode>, <methodCode>, and <targetSiteCode> should not be present in a pregnancy observation.

8.1.21. Coded Vital Signs Section 1.3.6.1.4.1.19376.1.5.3.1.1.5.3.2

Template ID	1.3.6.1.4.1.19376.1.5.3.1.3.16.1	
Parent Template	Vital Signs (1.3.6.1.4.1.19376.1.5.3.1.3.25)	
General Description	The vital signs section contains coded measurement results of a patient's vital signs.	
LOINC Code	**Opt**	**Description**
8716-3	R	VITAL SIGNS
Entries	**Opt**	**Description**
1.3.6.1.4.1.19376.1.5.3.1.4.13.1	R	Vital Signs Organizer

8.1.21.1. Parent Template

The parent of this template is Vital Signs.

8.1.21.2. Specification

```
<component>
  <section>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.25'/>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.5.3.2'/>
    <id root=' ' extension=' '/>
    <code code='8716-3' displayName='VITAL SIGNS'
      codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
    <text>
      Text as described above
    </text>
    <entry>
        :
      <!-- Required Vital Signs Organizer element -->
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13.1'/>
        :
    </entry>

  </section>
</component>
```

Figure 35C*- Sample Coded Vital Signs Section*

8.1.21.3. Vital Signs Organizer 1.3.6.1.4.1.19376.1.5.3.1.4.13.1

A vital signs organizer collects vital signs observations.

8.1.21.3.1. Specification

```
<organizer classCode='CLUSTER' moodCode='EVN'>
  <templateId root='2.16.840.1.113883.10.20.1.32'/>
  <templateId root='2.16.840.1.113883.10.20.1.35'/>
  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13.1'/>
  <id root='' extension=''/>
  <code code='46680005' displayName='Vital signs'
    codeSystem='2.16.840.1.113883.6.96' codeSystemName='SNOMED CT'/>
  <statusCode code='completed'/>
  <effectiveTime value=''/>
  <!-- For HL7 Version 3 Messages
  <author classCode='AUT'>
     <assignedEntity1 typeCode='ASSIGNED'>
        :
     <assignedEntity1>
  </author>
  -->
  <!-- one or more vital signs observations -->
  <component typeCode='COMP'>
    <observation classCode='OBS' moodCode='EVN'>
      <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13.2'/>
        :
    </observation>
  </component>
</organizer>
```

Figure 36C*- Sample Vital Signs Organizer*

8.1.21.3.2. Vital Signs Organizer Definition

<organizer classCode='CLUSTER' moodCode='EVN'>

The vital signs organizer is a cluster of vital signs observations.

8.1.21.3.3. Template ID

<templateId root=''2.16.840.1.113883.10.20.1.32'/>
<templateId root=''2.16.840.1.113883.10.20.1.35'/>
<templateId root=''1.3.6.1.4.1.19376.1.5.3.1.4.13.1''/>

The vital signs organizer shall have the <templateId> elements shown above to indicate that it inherits constraints from the ASTM/HL7 CCD Specification for Vital signs, and the constraints of this specification.

8.1.21.3.4. Id root

<id root=' ' extension=' '/>
The organizer shall have an <id> element.

8.1.21.3.5. Description of the vital signs organizer

<code code='46680005 '
displayName='Vital signs'
codeSystem='2.16.840.1.113883.6.96'
codeSystemName=' SNOMED CT'/>

The <code> element shall be recorded as shown above to indicate that this organizer captures information about patient vital signs.

8.1.21.3.6. Vital Signs Measurement Status Code

<statusCode code='completed'/>

The observations have all been completed.

8.1.21.3.7. Vital Signs Measurement Time

<effectiveTime value=' '/>

The effective time element shall be present to indicate when the measurement was taken.

8.1.21.3.8. Vital Signs Measurement Author

<author typeCode='AUT'><assignedEntity1 typeCode='ASSIGNED'>...</assignedEntity1></author>

For use with HL7 Version 3, Vital Sign organizers SHALL contain an <author> element to represent the person or device.

8.1.21.3.9. Vital Signs Organizer Component

<!-- one or more vital signs observations --> <component typeCode='COMP'>

The organizer shall have one or more <component> elements that are <observation> elements using the Vital Signs Observation template.

8.1.21.4. Vital Signs Observation 1.3.6.1.4.1.19376.1.5.3.1.4.13.2

A vital signs observation is a simple observation that uses a specific vocabulary, and inherits constraints from CCD.

8.1.21.4.1. Specification

```
<observation classCode='OBS' moodCode='EVN'>
 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13'/>
 <templateId root='2.16.840.1.113883.10.20.1.31'/>
 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13.2'/>
 <id root=' ' extension=' '/>
 <code code=' ' codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
 <text><reference value='#xxx'/></text>
 <statusCode code='completed'/>
 <effectiveTime value=' '/>
 <repeatNumber value=' '/>
 <value xsi:type='PQ' value=' ' unit=' '/>
 <interpretationCode code=' ' codeSystem=' ' codeSystemName=' '/>
 <methodCode code=' ' codeSystem=' ' codeSystemName=' '/>
 <targetSiteCode code=' ' codeSystem=' ' codeSystemName=' '/>
</observation>
```

Figure 37C*- Sample Vital Signs Organizer*

8.1.21.4.2. Template ID

<templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13'/>
<templateId root='2.16.840.1.113883.10.20.1.31'/>
<templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13.2'/>

A vital signs observation shall have the <templateId> elements shown above to indicate that it inherits constraints from the ASTM/HL7 CCD Specification for Vital signs, and the constraints of this specification.

8.1.21.4.3. Description of the vital signs organizer

<code code=' '
displayName=' '
codeSystem=' 1.3.6.1.4.1.12559.11.10.1.3.1.42.21'
codeSystemName=' epSOSBloodPressure'/>

A vital signs observation entry shall use one of the following LOINC codes, with the specified data types and units.

8480-6	INTRAVASCULAR SYSTOLIC	mm[Hg]	PQ
8462-4	INTRAVASCULAR DIASTOLIC		

8.1.21.4.4. Vital Signs Observation Units

<value xsi:type='PQ' value=' ' unit=' '/>

The <value> element shall be present, and shall be of the appropriate data type specified for measure in the table above.

8.1.21.4.5. Vital Signs Observation Interpretation

<interpretationCode code=' ' codeSystem=' ' codeSystemName=' '/>
The interpretation code may be present to provide an interpretation of the vital signs measure (e.g. high, normal, low).

8.1.21.4.6. Vital Signs Observation method of measurement

<methodCode code=' ' codeSystem=' ' codeSystemName=' '/>

The <methodCode> element may be present to indicate the method used to obtain the measure. Note that method used is distinct from, but possibly related to the target site.

8.1.21.4.7. Vital Signs Observation site of measurement

<targetSiteCode code=' ' codeSystem=' ' codeSystemName=' '/>
The target site of the measure may be identified in the <targetSiteCode> element (e.g. Left arm)

8.1.22. Coded Results Section 1.3.6.1.4.1.19376.1.5.3.1.3.28

Template ID	1.3.6.1.4.1.19376.1.5.3.1.3.28	
General Description	The results section shall contain a narrative description of the relevant diagnostic procedures the patient received in the past. It shall include entries for procedures and references to procedure reports when known as described in the Entry Content Modules.	
LOINC Code	**Opt**	**Description**
30954-2	R	STUDIES SUMMARY
Entries	**Opt**	**Description**
1.3.6.1.4.1.19376.1.5.3.1.4.19	O	Procedure Entry
1.3.6.1.4.1.19376.1.5.3.1.4.4	O	References Entry
1.3.6.1.4.1.19376.1.5.3.1.4.13	O	Simple Observation

8.1.22.1. Specification

```
component>
  <section>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.28'/>
    <id root=' ' extension=' '/>
    <code code='30954-2' displayName='STUDIES SUMMARY'
      codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
    <text>
      Text as described above
    </text>
    <entry>
         :
      <!-- Required Procedure Entry element -->
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.19'/>
         :
    </entry>
    <entry>
         :
      <!-- Required if known References Entry element -->
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.4'/>
         :
    </entry>
    <entry>
         :
      <!-- Optional Simple Observation element -->
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13'/>
         :
    </entry>

  </section>
</component>
```

***Figure 38C**- Sample Coded Results Section*

The measurements required were the results for the blood group. This is determined in the simple observation entry; hence only this entry will be described. Nevertheless, the IHE PCC Coded Results Section is used in order to accommodate possible future requirements and in order to be as compliant as possible with the already-existing solutions on the market, thereby reducing costs and time for the implemeters.

8.1.22.1.1. Simple Observation Entry 1.3.6.1.4.1.19376.1.5.3.1.4.13

The simple observation entry is meant to be an abstract representation of many of the observations used in this specification. It can be made concrete by the specification of a few additional constraints, namely the vocabulary used for codes, and the value representation. A simple observation may also inherit constraints from other specifications (e.g., ASTM/HL7 Continuity of Care Document).

8.1.22.1.1.1. Specification

```
observation classCode='OBS' moodCode='EVN'>
  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13'/>
  <id root='' extension=''/>
  <code code='' displayName='' codeSystem='' codeSystemName=''/>
  <!-- for CDA -->
  <text><reference value='#xxx'/></text>
  <!-- For HL7 Version 3 Messages
  <text>text</text>
  -->
  <statusCode code='completed'/>
  <effectiveTime value=''/>
  <repeatNumber value=''/>
  <value xsi:type='' …/>
  <interpretationCode code='' codeSystem='' codeSystemName=''/>
  <methodCode code='' codeSystem='' codeSystemName=''/>
  <targetSiteCode code='' codeSystem='' codeSystemName=''/>
  <author typeCode='AUT'>
    <assignedAuthor typeCode='ASSIGNED'><id ... /></assignedAuthor> <!-- for CDA -->
    <!-- For HL7 Version 3 Messages
    <assignedEntity typeCode='ASSIGNED'>
       <Person classCode='PSN'>
          <determinerCode root=''>
          <name>…</name>
       </Person>
    <assignedEntity>
     -->
  </author>
</observation>
```

Figure 39C*- Sample Simple Observation Entry*

8.1.22.1.1.2. Observation Mood Code

<observation classCode='OBS' moodCode='EVN'>

These acts are simply observations that have occurred, and so are recorded using the <observation> element as shown above.

8.1.22.1.1.3. Template ID

<templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13'/>

The <templateId> element identifies this <observation> as a simple observation, allowing for validation of the content. The templateId must appear as shown above.

8.1.22.1.1.4. Id root

<id root=' ' extension=' '/>

The organizer shall have an <id> element.

8.1.22.1.1.5. Description of the problem

<code code=' '
  displayName=' '
  codeSystem=' '
  codeSystemName=' '/>

Observations shall have a code describing what was measured. The code system used is determined by the vocabulary constraints on the types of measurements that might be recorded in a section. Content modules that are derived from the Simple Observation content module may restrict the code system and code values used for the observation.

8.1.22.1.1.6. Simple Observation Reference Text

<text><reference value='#xxx'/></text> -OR- <text>text</text>
Each observation measurement entry may contain a <text> element providing the free text that provides the same information as the observation within the narrative portion of the document with a <text> element. For CDA based uses of Simple Observations, this element SHALL be present, and SHALL contain a <reference> element that points to the related string in the narrative portion of the document. For HL7 Version 3 based uses, the <text> element MAY be included.

8.1.22.1.1.7. Simple Observation Status Code

<statusCode code='completed'/>
The status code of all observations shall be completed.

8.1.22.1.1.8. Simple Observation Time

<effectiveTime value=' '/>
The <effectiveTime> element shall be present in standalone observations , and shall record the date and time when the measurement was taken. This element should be precise to the day. If the date and time is unknown, this element should record that using the nullFlavor attribute.

8.1.22.1.1.9. Simple Observation Representation

<value xsi:type=' ' ... />text
The value of the observation shall be recording using a data type appropriate to the observation. Content modules derived from the Simple Observation content module may restrict the allowable data types used for the observation.

8.1.22.1.1.10. Simple Observation Interpretation

<interpretationCode code=' ' codeSystem=' ' codeSystemName=' '/>

If there is an interpretation that can be performed using an observation result (e.g., high, borderline, normal, low), these may be recorded within the interpretationCode element.

8.1.22.1.1.11. Simple Observation method of measurement

<methodCode code=' ' codeSystem=' ' codeSystemName=' '/>
The methodCode element may be used to record the specific method used to make an observation when this information is not already pre-coordinated with the observation code.

8.1.22.1.1.12. Simple Observation site of measurement

<targetSiteCode code=' ' codeSystem=' ' codeSystemName=' '/>
The targetSiteCode may be used to record the target site where an observation is made when this information is not already pre-coordinated with the observation code.

8.1.22.1.1.13. Simple Observation author

<author><assignedAuthor classCode='ASSIGNED'>...<assignedAuthor></author>
In CDA uses, SimpleObservations are assumed to be authored by the same author as the document through context conduction. However specific authorship of observation may be represented by listing the author in the header and referencing the author in a <author> relationship. If authors are explicitly listed in documents, an <id> element SHOULD reference the ID of the author in the header through an assignedAuthor Role. If the author of the observation is not an author of the document the <person> object including a name and ID SHALL be included.

For HL7 Version 3 purposes, the <author> element SHOULD be present unless it can be determined by conduction from organizers or higher level structures. When used for HL7 Version 3 the role element name is <assignedEntity> and the author is represented a <assignedPerson> element.

9 Translation Code

This element is necessary so that the original code in which the document was coded is preserved (Country A). This will enable the receiver to see the document in its own language (Country B), even if at a higher granular level. At the same time, the original code is kept, enabling the receiver to look it up if needed. The higher level of granularity is kept since it is nearly impossible to translate 12,000 terms (ICD-10) in the epSOS existing languages and also to transcode it if ICD-9 is involved. This will be an issue to be further explored in epSOS II.

	Country A (France)	*NCP A-> NCPB*	*Country B (Austria)*
Document	*Document A*	*Document E*	*Document B*
Code System	*ICD-10*	*epSOSIllnessesandDisorders*	*epSOSIllnessesandDisorders*
Code	*S80.1*	*S80*	*S80*
Language	*French*	*English*	*German*
DisplayName	Contusion de parties autres et non précisées de la jambe	Superficial injury of lower leg	Oberflächliche Verletzung des Unterschenkels
CDA schema	<value xsi:type="CE" code="S80.1" codeSystem="2.16.840.1.113883.6.3" codeSystemName="ICD10" displayName="Contusion de parties autres et non précisées de la jambe "> </value>	<value xsi:type="CE" code="S80" codeSystem="1.3.6.1.4.1.12559.11.10.1.3.1.42.5" codeSystemName="epSOSIllnessesandDisorders" displayName="Superficial injury of lower leg "> <translation code="S80.1" codeSystem="2.16.840.1.113883.6.3" codeSystemName="ICD10 " displayName="Contusion de parties autres et non précisées de la jambe"> </translation> </value>	<value xsi:type="CE" code="S80" codeSystem="1.3.6.1.4.1.12559.11.10.1.3.1.42.5" codeSystemName="epSOSIllnessesandDisorders" displayName="Oberflächliche Verletzung des Unterschenkels "> <translation code="S80.1" codeSystem="1.3.6.1.4.1.12559.11.10.1.3.1.42.5" codeSystemName="ICD10 " displayName="Contusion de parties autres et non précisées de la jambe "> </translation> </value>

10 Transaction Bindings

Please see the recommendations in work package 3.4, Common Components for the transaction binding. These will be taken up further within the implementation work package 3.9.