Smart Open Services for European Patients

Open eHealth initiative for a European large scale pilot of

Patient Summary and Electronic Prescription

Work Package 3.9 – Appendix B1/B2

epSOS Semantic

Implementation Guidelines

MVC/MTC

D3.9.1

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Change History					
Version	**Date**	**Status Changes**	**From**	**Details**	**Review**
V0.1	15/05/2010	Draft	ASIP DMP	Creating the document "epSOS_Implementation" based on earlier documents	
V0.2	01/07/2010	Draft	ASIP DMP	Updated document	
V0.3	12/07/2010	Draft	ASIP DMP	Updated document	
V0.4	29/07/2010	Draft	ASIP DMP	Updated document	
V0.5	09/08/2010	Draft	ASIP DMP	Updated document for Internal QA	
V0.6	31/08/2010	Draft	ASIP DMP / Lombardy	Updated document after Internal QA	
V0.7	03/09/2010	Draft	POSAM	Added Chapter 13: Translation	
V0.8	03/09/2010	Draft	Lombardy	Updated document for External QA Changed file name to align to other D3.9.1 appendixes	
V0.9	23/09/2010	Version for PEB approval	ASIP-DMP Lombardy	Accepted final changes following external review, integrated OIDs, editing	
V1.0	06/10/2010	Final	Lombardy	Last revisions after test development. Released.	
V1.1	11/11/2010	Review	Lombardy	Revision after test development.	
V1.2	21/12/2010	Review	Lombardy	Revision after the Project-a-thon in Bratislava	
V1.3	24/03/2011	Review	Lombardy	Typos fixed. Section code designations used in examples aligned with the current MVC (1.6). Added the section "Content Module Constraints" describing how section table should be interpreted. (derived by the IHE PCC documentation)	
V1.4	25/07/2011	Review	Lombardy	Typos fixed. Aligned with MVC 1.7 Appendix B1 and B2 have been merged in a single document (this one)	

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Appendix B1: epSOS Semantic Implementation Guidelines

1 DISCLAIMER

This document was produced based at the information at hand at the time of creation and/or update. Please do contact the persons responsible for this document for further updates as they are detected during the implementation and testing.

This document tries to represent in a syntactic and semantic format as best as possible the information conveyed by the functional work packages ePrescription (*WP3.1 - D3.1.1 Draft definition of functional service requirements – ePrescription, version 2.63*), and Patient Summary (*WP3.2 - D3.2.2 Final definition of functional service requirements- Patient Summary, version 0.4*).

This deliverable supersedes the *D3.5.2 Semantic Services Definition Specifications*.

These guidelines are subject to change according to the comments received during implementation. The implementers should verify that they have the latest version available.

The official concept code designations – used for valorizing the attribute displayName – are defined by the Master Valueset Catalogue.

These values may be subject to changes : implementers should always refer **to the latest published version of the MVC**. Designations are reported in this specification - if not otherwise specified - only for exemplification purposes.

2 Objective

This document describes the implementation specifications of the following documents within the epSOS project:

- ePrescription
- eDispensation
- Patient Summary

The implementers must be familiar with the context of the project, as it shall not be repeated in this document. The implementers must also be familiar with the content of the following documents:

- *CDA Release 2.0 Normative Web Edition, May, 2005*
- *HL7 Implementation Guide: CDA Release 2 – Continuity of Care Document (CCD), HL7, April 1, 2007.*

- *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.*

It must also be noted that although the guidelines are based on the above documents, they contain specific developments particular to the project epSOS. This document can be used as a standalone to develop the syntax of the epSOS documents; however in order to achieve the full functionality of the epSOS Semantic Services, they are to be used within the context of the deliverable 3.9.1.

3 Templates

Templates are collections of constraints that specify and validate agreed-to requirements for exchange. Collecting individual constraints and assigning a unique template identifier to the collection establishes a shorthand mechanism for the instance creator to assert conformance to those constraints. The template identifier itself carries no semantics.

These following ID are used in epSOS to identify the **Templates.**

Document	Template ID
epSOS ePrescription	1.3.6.1.4.1.12559.11.10.1.3.1.1.1
epSOS eDispensation	1.3.6.1.4.1.12559.11.10.1.3.1.1.2
epSOS Patient Summary	1.3.6.1.4.1.12559.11.10.1.3.1.1.3

Table 1C - Pivot Documents Templates

The patient consent specifications are not part of this document as they are based on the specification on IHE XDS-SD and ***out of scope of this document.***

4 LOINC codes

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

Document	LOINC code	LOINC description
ePrescription	57833-6	Prescription for medication (doc)
eDispensation	60593-1	Medication dispensed (doc)
Patient Summary	60591-5	Patient Summary (doc)

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

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5 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.

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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 and CONF-HP-16** through **CONF-HP-52**	1.3.6.1.4.1.19376.1.5.3.1.1.1

180 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.** 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 standards and industry solutions, while trying to respect as much as possible the specifications
185 indicated by the functional work packages WP3.1 and WP3.2.

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
190 (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.

5.1. Section Content Module Constraints

195 Section content modules will define the content of a section of a clinical document. Sections may contain various entries, and again, these may be required, required if known, or optional. A section

may not contain just entries; it must have at least some narrative text or subsections to be considered to be valid content[1].
Again, sections can inherit features from other section content modules. Once again, sections are classified using an external vocabulary (again typically this would be LOINC), and so the list of possible section codes is also specified. Sections that inherit from other sections will not specify a LOINC code unless it is to restrict the type of section to smaller set of LOINC codes specified by one of its ancestors.

Thus, a section content module **will contain as constraints**:

1. The template identifier of the parent content module when there is one.
2. The LOINC code or codes that shall be used to classify the section.
3. A possibly empty set of required, required if known, and optional section content modules, and their template identifiers for the subsections of this section.
4. A possibly empty set of required, required if known, and optional entry content modules, and their template identifiers.
5. Other constraints as necessary.

These constraints are presented in this document using a table for each section content module, as shown below.

Template ID	SampleSectionOID	
Parent Template	foo (SampleParentOID)	
General Description	Description of this section	
LOINC Code	**Opt**	**Description**
XXXXX-X	R	SAMPLE SECTION
Entries	**Opt**	**Description**
OID	R	Sample Entry

Please note that costrains apply to the LOINC code, entry content module template, template identifier, and NOT TO the descriptive field (General Description and description).
That is the name used in the Description field is not necessary that that shall be used as code designation (displayName): you should refer to the latest approved MVC for getting the valid displayName value.

[1] For this specification we don't make usage of subsections.

6 Narrative Block and CDA Conformance

The epSOS documents must be CDA conformant as per section 1.3 of the CDA Release 2.0 Normative Web Edition, May, 2005. The originator and the recipient must fulfill their responsibilities as indicated in the section 1.3.1 Recipient Responsibilities and section 1.3.2 Originator Responsibilities from the respective document. Additional recipient requirements are described in § 9.1 "Conformance".

7 Style Sheets

According to the IHE PC specifications 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. Moreover , 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.

For the scope of epSOS-I is not expected that the sender provides a rendering style sheet, since the original view of the data is guaranteed by the epSOS pdf document.

8 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.

9 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='1.3.6.1.4.1.12559.11.10.1.3.1.1.3'/>
  <id root=' ' extension=' '/>
  <code code='60591-5' displayName='Patient Summary'
    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-GB'/>
     :
  <component>
     <structuredBody>
        .
        .
     </structuredBody>
  </component>
</ClinicalDocument>
```

Figure 1C - Sample epSOS Document Identification

9.1. Recipient Responsibilities

Document recipient shall be able – beside the baseline requirements of the 1.3.1 paragraph of the CDA R2 standard - to parse, interpret and if applicable display - all the coded entries (including related <translation> elements) labeled as "required" by this specification documents.

For **safety reasons** Care Providers accessing the epSOS CDAs should be enabled to visualize:

- either the CDA level 3, either the CDA Level 1 format (i.e. the CDA with the PDF embedded), where applicable;
- for each coded element required by this specification, both the original country A representation, both the epSOS representation. (either with the country B designation , either with the epSOS (English) designation).

10 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.

OID for Object belonging to the epSOS semantics have the following root OID: 1.3.6.1.4.1.12559.11.10.1.3.1.

In cases where IHE PCC content modules were used, the original Template ID was used as to facilitate the implementation.

The optionality, as well as the cardinality information (column Cardinality/Optionality) refers to the Data Element in the table (corresponding to the deliverables from 3.1 and 3.2), and not to the corresponding XML representation (which is reflected in the XPath expression).

For example:

- the cardinality of the Primary Patient Identifier is [1..1] (see R 1.4.1), which means that we require the Primary Patient Identifier. The cardinality of the Secondary Patient Identifier is [0..*] (see R 1.4.2), which means that we can optionally have additional identifiers. In terms of the XML representation, this means that we expect to have at least one identifier, but more than one /ClinicalDocument/recordTarget/patientRole/id element may be present in the document;
- a patient summary may or may not include problems information, in fact all the problem related data elements are optional (see R 7.1, R7.2, R 7.3), however if a problem is reported, then in order to comply with the template used (1.3.6.1.4.1.19376.1.5.3.1.4.5) all the corresponding CDA XML elements are required.

Hereafter the description of the acronyms used for the "optionality" propriety:

- **R- means required, the mapped CDA element shall be present and shall not contain the nullFlavor attribute.**
- **RNFA (or R use NullFlavor) – means Required, Null Flavor Allowed, the mapped CDA element shall be present and it may be contain the nullFlavor attribute. In some cases, the recommended nullFlavor value is also indicated.**
- **O - means optional, the mapped CDA element may be omitted unless required by the CDA and/or by the template specifications.**
- **NA – means "not applicable" since the data element is not applicable in the respective document.**

These guidelines are subject to change according to the comments received during implementation. The implementers should verify that they have the latest version available.

Please remind that the HL7 Standard requires that the codeSystem attribute – when present - would be valorized with the Code System OID and NOT with the Value Set OID. See example below:

The Pharmaceutical Dose Form is recorded by means of the epSOSDoseForm (1.3.6.1.4.1.12559.11.10.1.3.1.42.2) Value Set [derived from the 'EDQM' code system (1.3.6.1.4.1.12559.11.10.1.3.1.44.1)] . Its representation is:

```
<epsos:formCode code="10604000" displayName="Eye drops, solution"
   codeSystem="1.3.6.1.4.1.12559.11.10.1.3.1.44.1"  codeSystemName="EDQM"/>
```

Note:
In order to allow the transcoding/translation of the coded concepts pointed out by the epSOS functional specifications (WP 3.1 and 3.2), all these elements SHALL have (if applicable[2]) the codeSystem attribute valorized.[3]

Moreover, it's strongly recommended for these coded elements to valorize also the related originalText.reference element, in order to make more clear the link between the coded entries and the Section narrative part. Even if recommended this is not mandatory for this version of the Implementation Guide.

[2] For example it cannot be specified for the CS type elements.

[3] According to § 14 "Addition of transcoding / translation data", also the displayName attribute shall be valorized, when applicable.

10.1. 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 Code System 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	If the attribute qualifier is used for this element it should be derived from epSOSEntityNamePartQualifier 2.16.840.1.113883.5.43
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	epSOSAdministrativeGender2.16.840.1.113883.5.1

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 Code System OID
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	
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. Optionalities and Cardinalities of the address sub-parts shall be interpreted according to this rule.			

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 Code System OID
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	O / O / O [0..*]	AD	
R1.5.2	**Patient's Number of Street (Number of Street)**	1.3.6.1.4.1.19376.1.5.3.1.1.1 /ClinicalDocument/recordTarget/patientRole/addr/streetAddressLine	O / O / O [0..*]	AD	
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	O / O / O [0..*]	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	O / O / O [0..*]	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	O / O / O [0..*]	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	O / O / O [0..*]	AD	epSOSCountry 1.0.3166.1

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 Code System OID
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 Optionalities and Cardinalities of the following two items shall be interpreted according to this rule: e.g. is not expected to have two nullFlavored telecom elements.			
R1.6.1	**Patient's telephone number** **(Telephone)**	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	epSOSURL 2.16.840.1.113883.5.143 epSOSTelecomAddress 2.16.840.1.113883.5.1119
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	epSOSURL 2.16.840.1.113883.5.143 epSOSTelecomAddress 2.16.840.1.113883.5.1119

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 Code System OID
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	O / O / O	CS	The language code **SHALL** be in the form *nn-CC*. The *nn* portion **SHALL** be an ISO-639-1 language code in lower case derived by the Value Set epSOSLanguage 1.0.639.1 The *CC* portion, if present, **SHALL** be an ISO-3166 country code in upper case derived by the value Set epSOSCountry 1.0.3166.1
R1.7.A	**Patient's Guardian**	**1.3.6.1.4.1.19376.1.5.3.1.2.4** /ClinicalDocument/recordTarget/patientRole/patient/guardian Only if the guardian participant is present the following rules for Optionalities and Cardinalities of the referred sub-elements shall be used.	O / O / O [1..*]		
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/guardianPerson/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 Code System OID
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/guardianPerson/name/given	R / R / R use nullFlavor [1..*]	PN	
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 If the guardian element is present, its 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. Optionalities and Cardinalities of the address sub-parts shall be interpreted according to this rule.			
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	O / O / O [0..*]	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	O / O / O [0..*]	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	O / O / O [0..*]	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 Code System OID
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	O / O / O [0..*]	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	O / O / O [0..*]	AD	
R1.7.A.3.6	**Guardian's Country** **(Country)**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/recordTarget/patientRole/patient/guardian/addr/country	O / O / O [0..*]	AD	epSOSCountry 1.0.3166.1
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 the guardian element is present. 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. Optionalities and Cardinalities of the following two items shall be interpreted according to this rule: e.g. is not expected to have two nullFlavored telecom elements			
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 AND /ClinicalDocument/recordTarget/patientRole/patient/guardian/telecom/@use	R / R / R use nullFlavor [1..*]	TEL	epSOSURL 2.16.840.1.113883.5.143 epSOSTelecomAddress 2.16.840.1.113883.5.1119

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 Code System OID
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 AND /ClinicalDocument/recordTarget/patientRole/patient/guardian/telecom/@use	R / R / R use nullFlavor [1..*]	TEL	epSOSURL 2.16.840.1.113883.5.143 epSOSTelecomAddress 2.16.840.1.113883.5.1119
R1.8	**Contact Person (Patient Contact Information)**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/participant/associatedEntity/associatedPerson When the participant element is used to describe the contact person all the following rules about optionality and cardinality of its sub-elements shall be applied. The Contact Person SHALL not be provided for eP and eD.			
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	NA / NA / R use nullFlavor [1..*]	PN	
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	NA / NA / 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 Code System OID
R1.8.3	**Patient Contact's Address (Address)**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/participant/associatedEntity/addr If the participant element is present, its 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. Optionalities and Cardinalities of the address sub-parts shall be interpreted according to this rule.			
R1.8.3.1	**Patient Contact's Street (Street)**	/ClinicalDocument/participant/associatedEntity/addr/streetAddressLine	NA / NA / O [0..*]	AD	
R1.8.3.2	**Patient Contact's Number of Street (Number of Street)**	/ClinicalDocument/participant/associatedEntity/addr/streetAddressLine	NA / NA / O [0..*]	AD	
R1.8.3.3	**Patient Contact's City (City)**	/ClinicalDocument/participant/associatedEntity/addr/city	NA / NA / O [0..*]	AD	
R1.8.3.4	**Patient Contact's Postal Code (Postal Code)**	/ClinicalDocument/participant/associatedEntity/addr/postalCode	NA / NA / O [0..*]	AD	
R1.8.3.5	**Patient Contact's State or Province (State or Province)**	/ClinicalDocument/participant/associatedEntity/addr/state	NA / NA / O [0..*]	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 Code System OID
R1.8.3.6	**Patient Contact's Country (Country)**	/ClinicalDocument/participant/associatedEntity/addr/country	NA / NA / O [0..*]	AD	epSOSCountry 1.0.3166.1
R1.8.4	**Patient Contact's Telecommunication**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/participant/associatedEntity/telecom If the participant element is present, 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 '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 Optionalities and Cardinalities of the following two items shall be interpreted according to this rule: e.g. is not expected to have two nullFlavored telecom elements.			
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/telecom/@value AND /ClinicalDocument/participant/associatedEntity/telecom/@use	NA / NA / R use nullFlavor [1..*]	TEL	epSOSURL 2.16.840.1.113883.5.143 epSOSTelecomAddress 2.16.840.1.113883.5.1119
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/telecom/@value AND /ClinicalDocument/participant/associatedEntity/telecom/@use	NA / NA / R use nullFlavor [1..*]	TEL	epSOSURL 2.16.840.1.113883.5.143 epSOSTelecomAddress 2.16.840.1.113883.5.1119

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 Code System OID
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'|...**	NA / NA / O [0..*]	CS	epSOSRoleClass 2.16.840.1.113883.5.110
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/associatedEntity/code	NA / NA / O [0..*]	CE	epSOSPersonalRelationship 2.16.840.1.113883.5.111

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 Code System OID
R1.9	**Prefered HCP/ Legal Organization[4]** **(Prefered HCP/ Legal Organization to contact)**	1.3.6.1.4.1.19376.1.5.3.1.2.4[5] /ClinicalDocument/participant[functionCode/@code="PCP" and functionCode/@codeSystem='2.16.840.1.113883.5.88']/associatedEntity[@classCode="PRS"]/scopingOrganization OR /ClinicalDocument/participant[functionCode/@code="PCP" and functionCode/@codeSystem='2.16.840.1.113883.5.88']/associatedEntity[@classCode="PRS"]/associatedPerson/ NOTE: further to the WP 3.1 and WP 3.2 deliverbales, only the Patient Summary document requires to always include the "Prefered HCP/ Legal Organization" . The Prefered HCP/ Legal Organization SHALL not be provided for the eP and eD. When the participant element is used to describe it the following rules about optionality and cardinality of its sub-elements shall be applied.			
R1.9.1	**Name of the prefered Legal Organization/HCP** **(Contact Organization Name)**	/ClinicalDocument/participant/associatedEntity/scopingOrganization/name OR /ClinicalDocument/participant/associatedEntity/associatedPerson/name	NA / NA / R use nullFlavor [1..1]	ON/PN	

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

[5] This template is applicable only for descrbing the "Prefered HCP"

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 Code System OID
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	NA / NA / R use nullFlavor [1..1]	PN	
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	NA / NA / R use nullFlavor [1..1]	PN	
R1.9.2	**Prefered HCP/ Legal Organization Address** **(Prefered HCP/ Legal Organization Address)**	/ClinicalDocument/participant/associatedEntity/addr OR /ClinicalDocument/participant/associatedEntity/scopingOrganization/addr This 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. Optionalities and Cardinalities of the address sub-parts shall be interpreted according to this rule.			
R1.9.2.1	**Prefered HCP/ Legal Organization Street** **(Street)**	/ClinicalDocument/participant/associatedEntity/addr/streetAddressLine OR /ClinicalDocument/participant/associatedEntity/scopingOrganization/addr/streetAddressLine	NA / NA / O [0..*]	AD	
R1.9.2.2	**Prefered HCP/ Legal Organization Number of Street** **(Number of Street)**	/ClinicalDocument/participant/associatedEntity/addr/streetAddressLine OR /ClinicalDocument/participant/associatedEntity/scopingOrganization/addr/streetAddressLine	NA / NA / O [0..*]	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 Code System OID
R1.9.2.3	**Prefered HCP/ Legal Organization City (City)**	/ClinicalDocument/participant/associatedEntity/addr/city OR /ClinicalDocument/participant/associatedEntity/scopingOrganization/addr/city	NA / NA / O [0..*]	AD	
R1.9.2.4	**Prefered HCP/ Legal Organization Postal Code (Postal Code)**	/ClinicalDocument/participant/associatedEntity/addr/postalCode OR /ClinicalDocument/participant/associatedEntity/scopingOrganization/addr/postalCode	NA / NA / O [0..*]	AD	
R1.9.2.5	**Prefered HCP/ Legal Organization State or Province (State or Province)**	/ClinicalDocument/participant/associatedEntity/addr/state OR /ClinicalDocument/participant/associatedEntity/scopingOrganization/addr/state	NA / NA / O [0..*]	AD	
R1.9.2.6	**Prefered HCP/ Legal Organization Country (Country)**	/ClinicalDocument/participant/associatedEntity/addr/country OR /ClinicalDocument/participant/associatedEntity/scopingOrganization/addr/country	NA / NA / O [0..*]	AD	epSOSCountry 1.0.3166.1
R1.9.3	**Prefered HCP/ Legal Organization Telecommunication**	/ClinicalDocument/participant/associatedEntity/scopingOrganization/telecom OR /ClinicalDocument/participant/associatedEntity/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 '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 Optionalities and Cardinalities of the following two items shall be interpreted according to this rule: e.g. is not expected to have two nullFlavored telecom 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 Code System OID
R1.9.3.1	**Preferred contact HCP/Legal Organization Telephone** **(Preferred Organization Telephone)**	/ClinicalDocument/participant/associatedEntity/scopingOrganization/telecom/@value /ClinicalDocument/participant/associatedEntity/scopingOrganization/telecom/@use OR /ClinicalDocument/participant/associatedEntity/telecom/@value /ClinicalDocument/participant/associatedEntity/telecom/@use	NA / NA / R use nullFlavor [1..*]	TEL	epSOSURL 2.16.840.1.113883.5.143 epSOSTelecomAddress 2.16.840.1.113883.5.1119
R1.9.3.2	**Preferred contact HCP/Legal Organization e-mail** **(Preferred Organization E-mail)**	/ClinicalDocument/participant/associatedEntity/scopingOrganization/telecom/@value /ClinicalDocument/participant/associatedEntity/scopingOrganization/telecom/@use OR /ClinicalDocument/participant/associatedEntity/telecom/@value /ClinicalDocument/participant/associatedEntity/telecom/@use	NA / NA / R use nullFlavor [1..*]	TEL	epSOSURL 2.16.840.1.113883.5.143 epSOSTelecomAddress 2.16.840.1.113883.5.1119

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 Code System OID
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 (without the PCC patient identifier extension) Depending on the effetive role played HCPs may appear as :one of the document authors: /ClinicalDocument/author/assignedAuthor performer of the Service the provided CDA is the documenation of : /ClinicalDocument/documentationOf/serviceEvent/performer. another type of participation (see for example R 1.9) The template ID referenced here refers to HCP information in the /ClinicalDocument/documentationOf/serviceEvent/performer structure. In this document, the same requirements apply to the person author of the document (if there is one), and to the prescriber and dispenser (see body). See also the § 11.1.7 "Authorship" for further details. Please note that for the PS document is not required to have a human author, neither to specify the service performer. However if it happens, the following requirements about the sub-elements optionality and cardinality shall be applied..			
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 OR /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 OR /ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/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 Code System OID
R1.10.3	**HCP Prefix**	1.3.6.1.4.1.19376.1.5.3.1.2.3 /ClinicalDocument/author/assignedAuthor/assignedPerson/name/prefix OR /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 OR /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 OR /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 OR /ClinicalDocument/documentationOf/serviceEvent/performer/functionCode	R / O / O [1..*]	CD	epSOSHealthcareProfessionalRoles 2.16.840.1.113883.2.9.6.2.7

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 Code System OID
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 OR /ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/code	O / O / O [0..*]	CE	
R1.10.8	**HCP Telecom**	1.3.6.1.4.1.19376.1.5.3.1.2.3 /ClinicalDocument/author/assignedAuthor/telecom OR /ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/telecom This 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 Optionalities and Cardinalities of the following two items shall be interpreted according to this rule: e.g. is not expected to have two nullFlavored telecom elements.			
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 OR /ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/telecom/@value /ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/telecom/@use	O / O / O [0..*]	TEL	epSOSURL 2.16.840.1.113883.5.143 epSOSTelecomAddress 2.16.840.1.113883.5.1119

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 Code System OID
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 OR /ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/telecom/@value /ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/telecom/@use	O / O / O [0..*]	TEL	epSOSURL 2.16.840.1.113883.5.143 epSOSTelecomAddress 2.16.840.1.113883.5.1119
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 OR /ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/representedOrganization			
R1.10.9.1	**Healthcare Facility's name** **(Health Care Facility's Name)**	1.3.6.1.4.1.19376.1.5.3.1.2.3 /ClinicalDocument/author/assignedAuthor/representedOrganization/name OR /ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/representedOrganization/name	R null flavor / R / R null flavor [1..1]	ON	
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 OR /ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/representedOrganization/id	R null flavor / R / R null flavor [1..1]	II	

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 Code System OID
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 OR /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 OR /ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/representedOrganization/addr/streetAddressLine	O/ RNFA / O [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 OR /ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/representedOrganization/addr/city	O / RNFA /O [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 OR /ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/representedOrganization/addr/state	O / RNFA / O [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 Code System 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 OR /ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/representedOrganization/addr/postalCode	O / RNFA / O [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 OR /ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/representedOrganization/addr/country	R / R / R [1..1]	AD	epSOSCountry 1.0.3166.1
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/ OR /ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/representedOrganization/telecom 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. Optionalities and Cardinalities of the following two items shall be interpreted according to this rule: e.g. is not expected to have two nullFlavored telecom 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 Code System OID
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 OR /ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/representedOrganization/telecom/@value /ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/representedOrganization/telecom/@use	O / RNFA / 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/telecom/@use OR /ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/representedOrganization/telecom/@value /ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/representedOrganization/telecom/@use	O / RNFA / O [0..*]	TEL	
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	

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 Code System OID
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 Please note that with this element we don't specify any document authoring time, but when the episode of care documented by this CDA ended. For a summary document, there is only one service event, describing the provision of care over a period of time. All information represented in the document must have occured within the time period specified in serviceEvent/effectiveTime. Therefore this elements represents also the last effetive date when the summary content has been updated (even if it may happen that this instance of the CDA has been authored later..). As for the eP and eD the last update of the document is better represented by authoring time. Please refers to the § 11.1.8 for further details	O / O / R [1..1]	TS	
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	
~~**R1.11.4**~~	~~**Document origin** **(Document Orgin)**~~	~~1.3.6.1.4.1.19376.1.5.3.1.2.1~~ ~~author/assignedAuthor/assignedPerson – if present, means person author~~ ~~author/assignedAuthor/assignedAuthoringDevice – if present, means automatic generation~~	~~O / O / R~~ ~~[1..1]~~	~~N/A at this level (entities)~~	This concept was modified and added in the author (HCP) and the legal authenticator field.
R1.11.5	**Author organization** **(Author organization)**	Same as R1.10.9			

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 Code System OID
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	epSOSDocumentCode 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	
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	epSOSConfidentiality 2.16.840.1.113883.5.25

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 Code System OID
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. In any case, as well described in the IG CDA R2 – Imaging Integration: *"Local policies may choose to delegate the function of legal authentication to a device or system that generates the clinical document. In these cases, the legal authenticator **is a person accepting responsibility for the document**, not the generating device or system."* For describing the person playing as legal authenticator, the same elements as in **R1.10.1 to R1.10.8.2 must be represented within the context of the legal Authenticator (except for functionCode which is not part of the legal CDA stucture for legal authenticator).** /ClinicalDocument/legalAuthenticator/assignedEntity/assignedPerson	R / R / R [1..*]		

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 Code System OID
R1.11.9	**Legal Authenticator**	1.3.6.1.4.1.19376.1.5.3.1.1.1 The regional authority or another organizations that are responsible for the legal authentication of the CDA document are represented using 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..*]		
R.11.10	**Document Language Code**	1.3.6.1.4.1.19376.1.5.3.1.1.1 /ClinicalDocument/languageCode	R / R / R [1..1]	CS	The language code **SHALL** be in the form *nn-CC*. The *nn* portion **SHALL** be an ISO-639-1 language code in lower case derived by the Value Set epSOSLanguage 1.0.639.1 The *CC* portion **SHALL** be an ISO-3166 country code in upper case derived by the value Set epSOSCountry 1.0.3166.1

11 Body Data Elements

These are the data elements that belong in the body of the documents. Please check again for the optionality/cardinality when implementing – this will indicate what elements are necessary for each document.

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 Code System 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**[6] **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 / **NA** / NA [1..1]	II	

[6] Prescription section, Dispensation section and Medication section instructions of coding contain elements which are 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 Code System OID
R.2.2	Prescriber (Prescriber)	**Prescription Section** **1.3.6.1.4.1.12559.11.10.1.3.1.2.1** /ClinicalDocument/author Optionally, also /ClinicalDocument/component/structuredBody/component/section[templateId/@root='1.3.6.1.4.1.12559.11.10.1.3.1.2.1']/author		R / **NA** / NA [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']/entryRelationship[typeCode="REFR"]/substanceAdministration/author	NA / O / NA [0..1]		
		Please see section R1.10 in the Header for the other Prescriber Attributes while follwing the /ClinicalDocument/component/structuredBody/component/section/author OR the /ClinicalDocument/component/structuredBody/component/section/entry/supply/entryRelationship/substanceAdministration/author XML element.				

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 Code System OID
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='LIC']/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='LIC']/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 Code System 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 / NA / NA [1..1]	II	See section 12.1.2.4.5.3
		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"]/substanceAdministration/id	NA/ R / NA [1..1]	II	See section 12.1.2.4.5.3
R3	Dispense	**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]		
		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.				

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 Code System OID
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="LIC"]/scopingEntity[@classCode="ORG"]/desc	NA / O / NA [0..1]	ST	
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="LIC"]/scopingEntity[@classCode="ORG"]/id	NA / O / 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 Code System OID
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/manufacturedProduct/manufacturedMaterial/id	NA / R / NA [1..*]	II	
R4	**Medication description (This section refers only to eP and eD. See the R19 for the PS requirements concerning the 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/manufacturedProduct/manufacturedMaterial/code	O / NA / NA	CE	
R4.2	**Brand name of the medicinal product prescribed in country A** **(Brand Name)**	**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/manufacturedProduct/manufacturedMaterial/name	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 Code System OID
R4.3	Active ingredient (Active Ingredient)	**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/manufacturedProduct/manufacturedMaterial/ingredient/[@classCode='ACTI']/ingredient/code[7]	R / NA/ NA [1..1]	CD	epSOSActiveIngredient 2.16.840.1.113883.6.73
		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/manufacturedProduct/manufacturedMaterial/ingredient/[@classCode='ACTI']/ingredient/code	NA / O / NA [0..1]	CD	epSOSActiveIngredient 2.16.840.1.113883.6.73

[7] In case of salts / compound ingredients the code describing the active ingredient is conveyed using the ingredient sub-element *subIngredient/ingredient/code*

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 Code System OID
R4.4	**Strength of the medicinal product** **(Strength of the medicinal product)**	**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/manufacturedProduct/manufacturedMaterial/ingredient/[@classCode='ACTI']/quantity[8]	R / NA / NA [1..1]	PQ, 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']/product/manufacturedProduct/manufacturedMaterial/ingredient/[@classCode='ACTI']/quantity[9]	NA / R / NA [1..1]	PQ, PQ	

[8] In case of salts / compound ingredients the strength of each active ingredient is conveyed using the ingredient sub-element *subIngredient/quantity*.

[9] In case of salts / compound ingredients the strength of each active ingredient is conveyed using the ingredient sub-element *subIngredient/quantity*.

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 Code System OID
R4.5	Medicinal product package (Medicinal product package)	**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/manufacturedProduct/manufacturedMaterial/asContent/containerPackageMedicine/formCode	RNFA / NA / NA [1..1]	CD	epSOSPackage 1.3.6.1.4.1.12559.11.10.1.3.1.44.1
		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/manufacturedProduct/manufacturedMaterial/asContent/containerPackageMedicine/formCode	NA / RNFA / NA [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 Code System OID
R4.6	Pharmaceutical dose form (Pharmaceutical dose form)	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/manufacturedProduct/manufacturedMaterial/formCode	R / NA / NA [1..1]	CD	epSOSDoseForm 1.3.6.1.4.1.12559.11.10.1.3.1.44.1
		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/manufacturedProduct/manufacturedMaterial/formCode	NA / R / NA [1..1]	CD	epSOSDoseForm 1.3.6.1.4.1.12559.11.10.1.3.1.44.1
R4.7	Route of Administration (Route of Administration)	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 / NA / NA	CD	epSOSRoutesofAdministration 1.3.6.1.4.1.12559.11.10.1.3.1.44.1

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 Code System OID
		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']/substanceAdministration/routeCode	NA / O / NA		
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']/entryRelationship[@typeCode='COMP']/supply[@moodCode= 'RQO' and independentInd/@value='false']/quantity	R / NA / NA	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	NA / R / NA		

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 Code System OID
R4.8.1	Package Size (Package Size)	**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/manufacturedProduct/manufacturedMaterial/asContent/containerPackagedMedicine/capacityQuantity /	R / NA / NA	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']/product/manufacturedProduct/manufacturedMaterial/asContent/containerPackagedMedicine/capacityQuantity	NA / R / NA		

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 Code System OID
R4.9	**Number of units per intake**[10] **(Number of units per intake)**	**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/low@value entry/substanceAdministration[templateId/[@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.4']/doseQuantity/high@value For split dosing the xPath is referred to the subordinate <substanceAdministration> entry	RNFA / NA / NA	INT	If this element is expressed using measureable units the value of the unit attribute comes from the epSOSUnits value set UCUM Code System: 2.16.840.1.113883.6.8 , otherwise (administration units) the value '1' should be used.

[10] 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 Code System OID
R4.10	**Frequency of intakes** **(Frequency of intakes)**	**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[2] For split dosing the xPath is referred to the subordinate <substanceAdministration> entry	RNFA[11] / NA / NA	TS IVL_TS PIVL_TS EIVL_TS SXPR_TS	If EIVL_TS mode is used, HL7 TimingEvent vocabulary (2.16.840.1.113883.5.139) SHALL be used.

[11] In order to avoid intersection with null set, this element should be omitted when not known.

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 Code System OID
R4.11	**Duration of treatment**[12] **(Duration of treament)**	**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/@value 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/@value For split dosing the xPath is referred to the subordinate <substanceAdministration> entry	RNFA / NA / NA	IVL_TS	

[12] 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 Code System OID
R4.12	Date of onset of treatment (Date of onset of treatment)	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/@value	RNFA / NA / NA	TS	
R4.13	Date of end of treatment (Date of end of treatment)	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/@value	RNFA /NA / NA	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 / 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 Code System OID
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 / NA / NA	TXT	
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']/[code/@code='SUBST' and code/@codeSystem='2.16.840.1.113883.5.6']value/@code	O / NA / NA	CE	epSOSSubstitutionCode 2.16.840.1.113883.5.1070

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 Code System OID
		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='COMP'] /act[@classCode ='ACT']/ [code/@code='SUBST' and code/@codeSystem='2.16.840.1.113883.5.6']	NA / O / NA		
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.					

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 Code System OID
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** When it represents the description of reactions (e.g. Eczema) it is reported in: entry/act[templateId/@root='2.16.840.1.113883.10.20.1.27']/entryRelationship[@typeCode='SUBJ']/observation[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.6']/entryRelationship[@typeCode='MFST']/observation[templateId/@root='2.16.840.1.113883.10.20.1.54']/value/@displayName if it refers instead to the description of the type of reaction (e.g. not allergic intollerance) this information is described by the element: entry/act[templateId/@root='2.16.840.1.113883.10.20.1.27']/entryRelationship[@typeCode='SUBJ']/observation[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.6']/code/@ displayName	NA / NA RNFA	ST	If referred to the description of reactions epSOSReactionAllergy 2.16.840.1.113883.6.96 If referred to the type (e.g. not allergic intollerance) epSOSAdverseEventType 2.16.840.1.113883.6.96

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 Code System OID
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= '2.16.840.1.113883.10.20.1.27']/entryRelationship[@typeCode='SUBJ']/observation[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.6']/code/@code	NA / NA / RNFA	CD	epSOSAdverseEventType 2.16.840.1.113883.6.96
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= '2.16.840.1.113883.10.20.1.27']/entryRelationship[@typeCode='SUBJ']/observation[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.6']/effectiveTime/low/@value	NA / NA / 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 Code System OID
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= '2.16.840.1.113883.10.20.1.27']/entryRelationship[@typeCode='SUBJ']/observation[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.6']/participant[@typeCode='CSM']/participantRole[@classCode='MANU']/playingEntity[@classCode='MMAT]/code/@displayName	NA / NA / RNFA	ST	If the allergenic agent is a medicament: WHO ATC 2.16.840.1.113883.6.73 If not: epSOSAllergenNoDrugs 2.16.840.1.113883.6.96
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= '2.16.840.1.113883.10.20.1.27']/entryRelationship[@typeCode='SUBJ']/observation[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.6']/participant[@typeCode='CSM']/participantRole[@classCode='MANU']/playingEntity[@classCode='MMAT]/code/@code	NA / NA / RNFA	CD	If the allergenic agent is a medicament: WHO ATC 2.16.840.1.113883.6.73 If not: epSOSAllergennoDrugs 2.16.840.1.113883.6.96
R6	This line is left purposely blank – see explanation for Allergy and Other Adverse Reactions 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 Code System OID
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**				

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 Code System OID
R7.1	**Problem Description** **(Problem Description)**		**Problem Concern Entry** **1.3.6.1.4.1.19376.1.5.3.1.4.5.2** A textual description of the Problem is provided either in the section narrative block and referenced in this element entry/act[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.5.2']/entryRelationship[@typeCode='SUBJ']/observation[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.5']/text/reference/@value either briefly via the displayName attribute of the coded concept: entry/act[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.5.2']/entryRelationship[@typeCode='SUBJ']/observation[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.5']/value/@displayName	NA / NA / O	ST	
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='1.3.6.1.4.1.19376.1.5.3.1.4.5.2']/entryRelationship[@typeCode='SUBJ']/observation[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.5']/value/@code	NA / NA / O	CD	epSOSIllnessesandDisorders 1.3.6.1.4.1.12559.11.10.1.3.1.44.2

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 Code System OID
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='1.3.6.1.4.1.19376.1.5.3.1.4.5.2']/ effectiveTime[@xsi:type='IVL_TS']/low	NA / NA / 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='1.3.6.1.4.1.19376.1.5.3.1.4.5.2']/ effectiveTime[@xsi:type='IVL_TS']/high	NA / NA / 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 Code System 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='1.3.6.1.4.1.19376.1.5.3.1.4.5.2']/entryRelationship[@typeCode='REFR']/observation[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.1.2']/text/reference/@value	NA / NA / O	URI[13]	
			Problem Concern Entry 1.3.6.1.4.1.19376.1.5.3.1.4.5.2 entry/act[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.5.2']/entryRelationship[@typeCode='REFR']/observation[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.1.2']/value/@code	NA / NA / O	CD	epSOSResolutionOutcome 2.16.840.1.113883.6.96

[13] 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[@typeCode='REFR']/observation[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.1.2']/entryRelationship[@typeCode='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.

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 Code System OID
R8	**Vaccinations**	**1.3.6.1.4.1.19376.1.5.3.1.3.23 Immunizations Section**				
R8.1	**Vaccinations Brand name**[14] **(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']/ consumable/manufacturedProduct/ manufacturedMaterial/code//translation/@displayName	NA / NA / O	TXT	
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	NA / NA / O	CD	epSOSVaccine 2.16.840.1.113883.6.96

[14] 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 Code System OID
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	NA / NA / 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	NA / NA / O	TS	
R9	**Surgical Procedures prior 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	NA / NA / O	TXT	
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	NA / NA / O	CD	epSOSProcedures 2.16.840.1.113883.6.96

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 Code System OID
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= '1.3.6.1.4.1.19376.1.5.3.1.4.19']/low/@effectiveTime	NA / NA / O	IVL_TS	
R10	**Major Surgical Procedures past 6 months**[15]	**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	NA / NA / RNFA	CD	epSOSProcedures 2.16.840.1.113883.6.96
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	NA / NA / RNFA	CD	

[15] 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 Code System 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= '1.3.6.1.4.1.19376.1.5.3.1.4.19']/effectiveTime	NA / NA / RNFA[16]	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		NA / NA / RNFA	TXT	

[16] The procedure date is required for this section; it can be of a null flavor if and only if the whole section is indicating that there were no procedures in the past 6 months.

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 Code System OID
		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='1.3.6.1.4.1.19376.1.5.3.1.4.5.2']/entryRelationship[@typeCode='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='1.3.6.1.4.1.19376.1.5.3.1.4.5.2']/entryRelationship[@typeCode='SUBJ']/observation[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.5']/value/@code	NA / NA / RNFA	CD	epSOSIllnessesandDisorders 2.16.840.1.113883.6.90
		1.3.6.1.4.1.19376.1.5.3.1.3.4 History of Present Illness Section	Same as above			
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='1.3.6.1.4.1.19376.1.5.3.1.4.5.2']/effectiveTime/low	NA / NA / RNFA	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 Code System OID
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	NA / NA / 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	NA / NA / RNFA	CE	epSOSMedicalDevices 2.16.840.1.113883.6.96

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 Code System OID
R12.3	**Device Implant Date** **(Device Implant Date)**	**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']/effectiveTime/@value	NA / NA / RNFA	TS or IVL_TS	
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		NA / NA / 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		NA / NA / 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 Code System OID
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, alcohol and diet. (Social History Observations)**	**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]/value/@code	NA / NA / 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 2.16.840.1.113883.6.96
			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	NA / NA / 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 2.16.840.1.113883.6.96

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 Code System OID
			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	NA / NA / 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 2.16.840.1.113883.6.96 Please note that the epSOSSocialHistory contains sub-value sets that are referenced in the epSOS Master Value Set Catalogue.
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[@xsi: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[@xsi:type='IVL_TS]/high/@value	NA / NA / 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 2.16.840.1.113883.6.96

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 Code System 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='160573003']/effectiveTime[@xsi: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='160573003']/effectiveTime[@xsi:type='IVL_TS]/high/@value	NA / NA / 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 2.16.840.1.113883.6.96
			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[@xsi: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='364393001']/effectiveTime[@xsi:type='IVL_TS]/high/@value	NA / NA / 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 2.16.840.1.113883.6.96
R16	**Pregnancy History**	**1.3.6.1.4.1.19376.1.5.3.1.1.5.3.4** **Pregnancy History 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 Code System OID
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	NA / NA / O	TS	
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				

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 Code System OID
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	NA / NA / 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 2.16.840.1.113883.6.1 Value unit SHALL use epSOSUnits 2.16.840.1.113883.6.8
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	NA / NA / 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 Code System 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	NA / NA / O	CE	epSOSBloodGroup 2.16.840.1.113883.6.96
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	NA / NA / 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/manufacturedProduct/manufacturedMaterial/ingredient/[@classCode='ACTI']/ingredient/code@displayName	NA / NA / RNFA [1..1]		epSOSActiveIngredient 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 Code System OID
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/manufacturedProduct/manufacturedMaterial/ingredient/[@classCode='ACTI']/ingredient/code@code	NA / NA / RNFA [1..1]	CD	epSOSActiveIngredient 2.16.840.1.113883.6.73
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/manufacturedProduct/manufacturedMaterial/ingredient/[@classCode='ACTI']/quantity	NA / NA / RNFA [1..1]	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/low@value entry/substanceAdministration[templateId/[@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.4']/doseQuantity/high@value	NA / NA / RNFA	INT	If this element is expressed using measureable units the value of the unit attribute comes from the epSOSUnits value set UCUM Code System: 2.16.840.1.113883.6.8 , otherwise (administration units) the value '1' should be used.

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 Code System OID
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] The data type for effectiveTime is SXCM_TS, which is direct extension of TS, and therefore TS is the straightforward use of effective time, e.g. <effectiveTime value='20100714215030'/> Even though the schema allows other types, the ones listed here are the only ones allowed. Section 12.1.1.2.4.5.3.1 has the full list for informational purposes. For split dosing the xPath is referred to the subordinate <substanceAdministration> entry	NA / NA / RNFA[17]	TS IVL_TS PIVL_TS EIVL_TS SXPR_TS	If EIVL_TS mode is used, HL7 TimingEvent vocabulary (2.16.840.1.113883.5.139) SHALL be used.

[17] In order to avoid intersection with null set, this element should be omitted when not known.

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 Code System OID
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']/ effectiveTime[1][@ xsi:type='IVL_TS']/high/@value For split dosing the xPath is referred to the subordinate <substanceAdministration> entry	NA / NA / RNFA	IVL_TS	
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	NA / NA / 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 Code System OID
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/manufacturedProduct/manufacturedMaterial/formCode	NA / NA / O [0..1]	CD	epSOSDoseForm 1.3.6.1.4.1.12559.11.10.1.3.1.44.1

11.1. 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 are explained below:

11.1.1. Document Instance Identifier

A CDA instance is uniquely idenfied by its ClinicalDocument.id.

A transformed document represent a new instance of this document: transforming and transformed CDA shall therefore have different ClinicalDocument.id values. The relationship between these two instances is kept via the relatedDocument association. (see next paragraph for details).

11.1.2. Links among documents

Depending on the document type, any instance of epSOS pivot CDA shall have a related CDA embedding the PDF representation of the original data from which the epSOS pivot has been derived (also known as "epSOS PDF"). The consumer of the epSOS services shall be able to access this epSOS PDF – if existing - any time it deems it is necessary for the document content comprehension. [*epSOS PDF – epSOS pivot link*]

Moreover countries shall be able: for a given epSOS pivot document, to identify the original national data/document (i.e. that in use in their national infrastructure) this CDA comes from [*Original document identification*]; to trace back from the eD what is the prescription dispensed, and for each dispensed item what is the prescription item supplied. [*eD to eP traceability*]

Hereafter how these requirements are fulfilled for the epSOS CDAs.

11.1.2.1. Original document identification

The relationship between the eP/eD/PS instance and the document (data) in use in the National Infrastructure ("original Country-A document") is kept via the XFRM relationship [XFRM (transform) = "The current document is a transformation of the ParentDocument"].
Where the "national" document is identified by its ID as the paretnDocuemnt relatedDocument association of the ("aa-bb-cc" in the example).

```
<relatedDocument typeCode="XFRM" >
      <parentDocument>
            <id root="aa-bb-cc" />
      </parentDocument>
</relatedDocument>
```

N.B.: <u>This relationship is mandatory for this guide</u>

NOTE: Even for countries not dealing with real documents in their National Infrastructures (e.g. data collected from local databases), this mechanism could be useful to identify the collection of data used for generating the epSOS CDAs , facilitating the information backtracking. In that case the

ID might be that of the epSOS friendly document or of any other kind of intermediate document used for generating the NCP document input.

11.1.2.2. epSOS PDF – epSOS pivot link

The link between the epSOS pivot and the epSOS PDF may be derived at the document level in three ways:

(1) both have the same relatedDocument(XFRM).parentDocument

(2) if used, both have the same setId. This value should be equal to the "national document" setId, if existing.

(3) the pivot have a relatedDocument relationship with the epSOS PDF.

Even if no one of the allowable relationship defined by the CDA standard (XFRM, RPLC, APDN) fits perfectly with the relationship existing between the pivot and the PDF CDA; the APND relationship seems to be that better describing the epSOS scenario. In fact "An addendum is a separate document that references the parent document, and may extend or alter the observations in the prior document. The parent document remains a current component of the patient record, and the addendum and its parent are both read by report recipients."

This relationship would be therefore represented as follows

```
<relatedDocument typeCode="APDN" >
      <parentDocument>
            <id root="aa1-bb1-cc1" />
      </parentDocument>
</relatedDocument>
```

Where aa1-bb1-cc1 is in this example the ID of the epSOS PDF.

11.1.2.3. eD to eP traceability

Each prescription shall have its own identifier recorded in the element section[templateId/@root='1.3.6.1.4.1.12559.11.10.1.3.1.2.1']/id (see R2.1 previous chapter).

Each prescription item shall have its own identifier recorder in entry/substanceAdministration[templateId/@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/id (see R2.4 previous chapter)

The prescription ID and prescription item ID must be globally unique. In countries where there can be only one item per prescription, the prescription item ID must be the same as the prescription ID

The main mechanism for handling the eD and eP linkage is through the prescription item ID that can be used by the prescribing system or provider to identify the prescription to which it belongs. (see section 12.1.3.4.8 Related prescription item).

Moreover the eD document SHALL refer the prescription ID using the InFulfillmentOf relationship. Please note that the target order.id attribute IS NOT the identifier of the document instance, but that of the prescription (as order).

11.1.3. Set ID

This attribute "represents an identifier that is common across all document revisions".

In the case of the NCP transcoding /translation this is the ID that remains unchanged among all the existing transformations.

Implementers are recommended to use this attribute.

11.1.4. Custodian

This elements represents the organization that is in charge of maintaining the document.

This information is required by the CDA R2 standard and shall be recorded in the ***ClinicalDocument/custodian/assignedCustodian/ representedCustodianOrganization*** element.

The representedCustodianOrganization **SHALL** have:

- the name, addr and telecom elements (nullFlavor allowed), due to constrains derived by the H&P specification (see § 5 Constraints)
- the id element from the CDA R2 model

11.1.5. Guardian and Other Patient Contact

The guardians of a patient shall be recorded in the <guardian> element beneath the ***/ClinicalDocument/recordTarget/patientRole/patient*** XML - <patient> element. Other patient contacts are described using the ***/ClinicalDocument/participant*** structure. 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 (epSOSPersonalRelationship value set).

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.

11.1.6. Healthcare Service Identification

The Healthcare Service Identification information is represented in structures under the `/ClinicalDocument/author` XML element.

11.1.7. Authorship

A CDA document shall have at least one author. Authors could be either human (ClinicalDocument/author/assignedAuthor/ assignedPerson) either devices (ClinicalDocument/author/assignedAuthor/assignedAuthoringDevice).

For definition "The `author` element represents the creator of the clinical document. If the role of the actor is the **entry of information from his or her own knowledge or application of skills**, that actor is the author. If one actor provides information to another actor **who filters, reasons, or algorithmically creates new information**, then that second actor **is also an author**, **having created information from his or her own knowledge or skills**." [From Implementation Guide for CDA Release 2: Imaging Integration – UV Relam, March 2009].

According to this definition, not any device that generates the electronic document has to be considered as an author:

- a spider collecting and filtering information from different repositories, according to defined rules and policies, for the scope of creating a Patient Summary is definitely a document author (and maybe the only one for this document);
- an application that transforms a prescription record into a epSOS eP CDA may not be an author instead;
- The NCP that modifies the concepts conveyed, should appear as one of the authors.
- The author of the parent document is often also an author of the document generated through a transformation process (in that case also the author time should be the same).

Further to this, is therefore possible to determine the Nature of Patient Summary as follows[18]:

[18] Excluding the NCPs as authors

- if there is a person author only, there the Patient Summary is the result of a practitioner clinical act;
- if there is a device author only, the summary was automatically generated according to well defined rules defined by the responsible organization;
- if there are both a person and a device as authors, the summary was created via a mixed approach.

The CDA provides a mechanism to better specify who authored what within the document, allowing the specification of authorship at the whole document level, at the section level and finally at the entry level. In any case is not required to repeat this information for each level, taking advantage of the context conduction propriety. Infact "context that is specified on an outer tag holds true for all nested tags, unless overridden on a nested tag. Context specified on a tag within the CDA body always overrides context propagated from an outer tag. For instance, the specification of authorship at a document section level overrides all authorship propagated from outer tags." (HL7 CDA R2 Standard).

11.1.8. Relevant times for the Patient Summary

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 time when this instance of the document has been authored may be instead recorded by the /ClinicalDocument/author/time element. (e.g. when a "spider" has collected information for generating this instance of the document; or a practitioner updated its local summary document).

Finally, the latest summary update, intended as the last date documented by this summary (e.g. the last update occurred to the PHR from which the PS data has been extracted) 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).

11.2. 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 Modules 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.**

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11.2.1. 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

11.2.2. Mapping on the CDA templates - Body

The same approach was taken in this section as in the header section. The functional requirements
560 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.

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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.

11.2.3. Data Elements - CDA R2 Sections and Entries

570 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.

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12 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
580 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 derived by already defined templates.

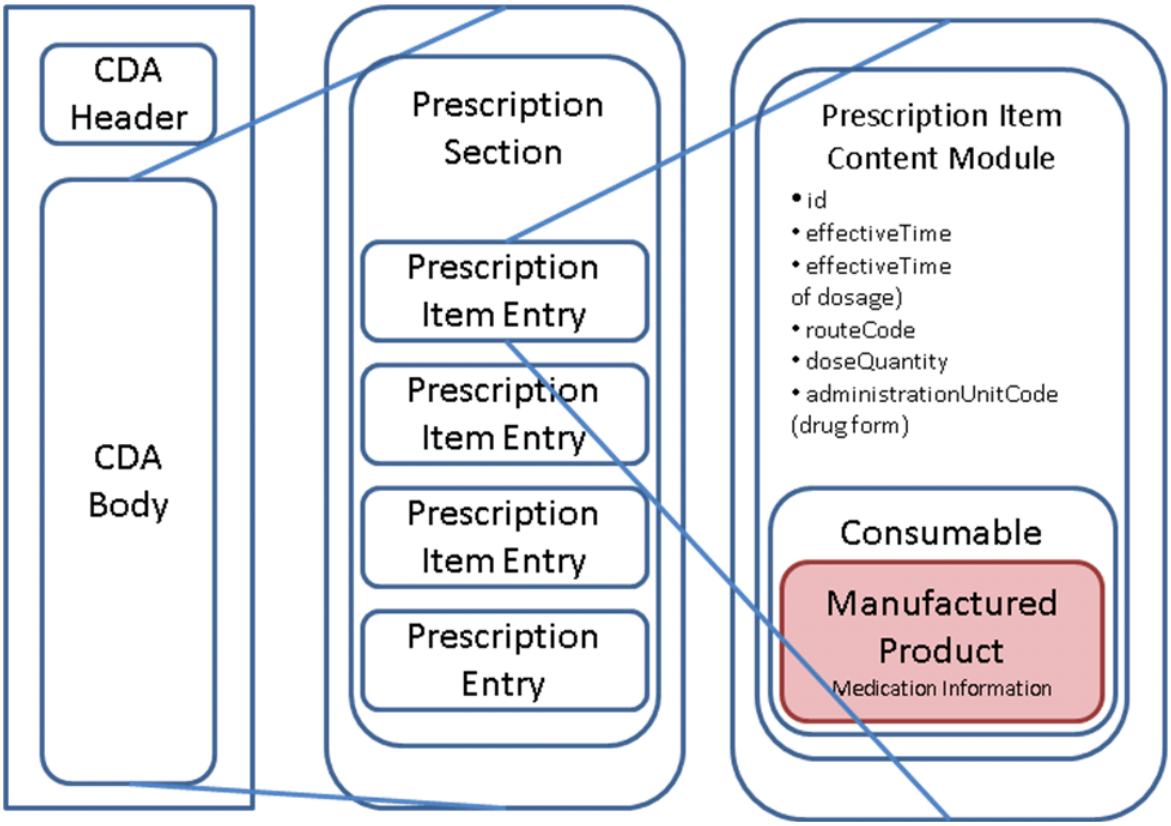
12.1. General Information

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[19]	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:

[19] Please note that this refers to the structured entry (e.g the "substanceAdministration" element for the Prescription Item) and not to the CDA "entry" element



595 **Figure 2C**- ePrescription Document Structure

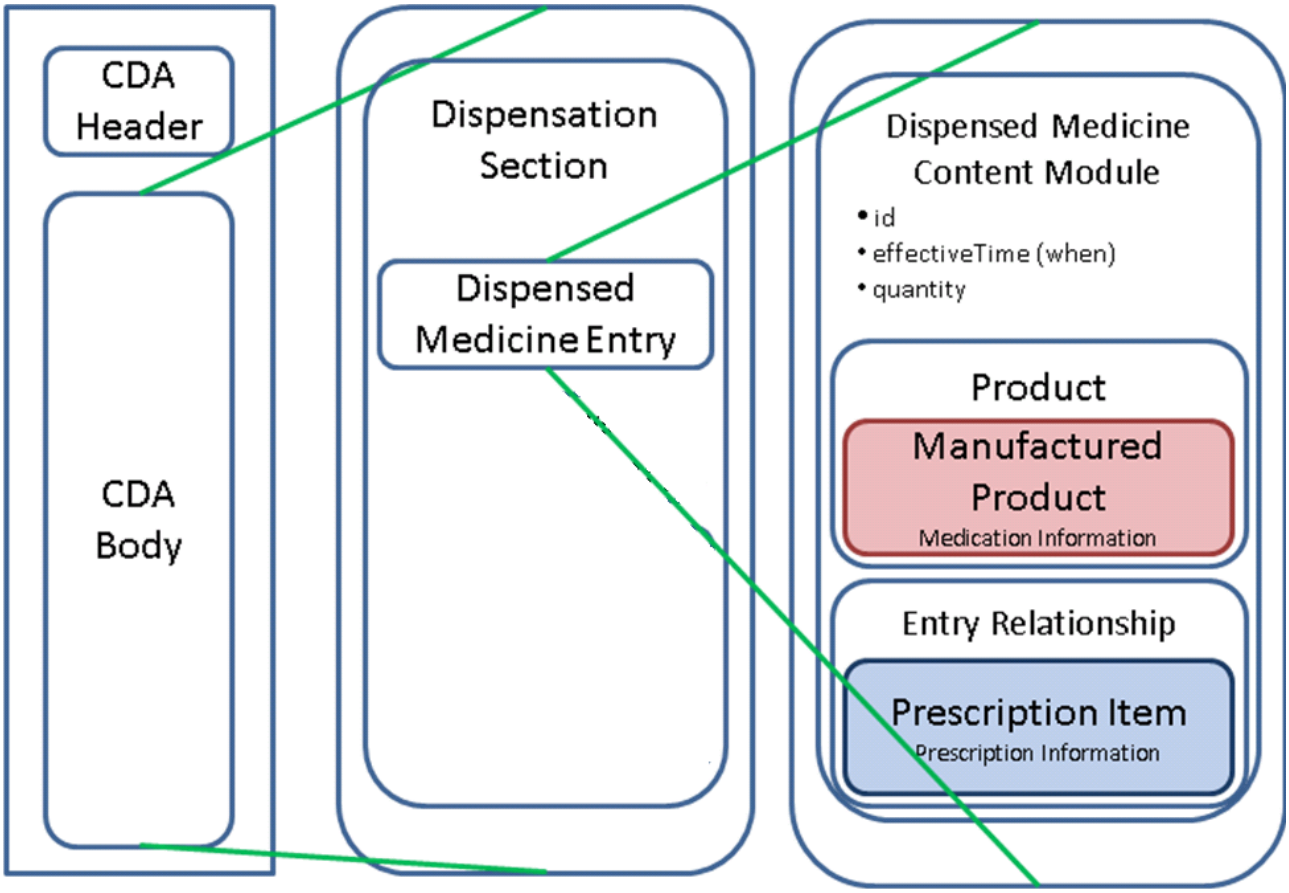


Figure 3C - eDispensation Document Structure

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 extending the "Manufactured Product" structure with the Medication structure:

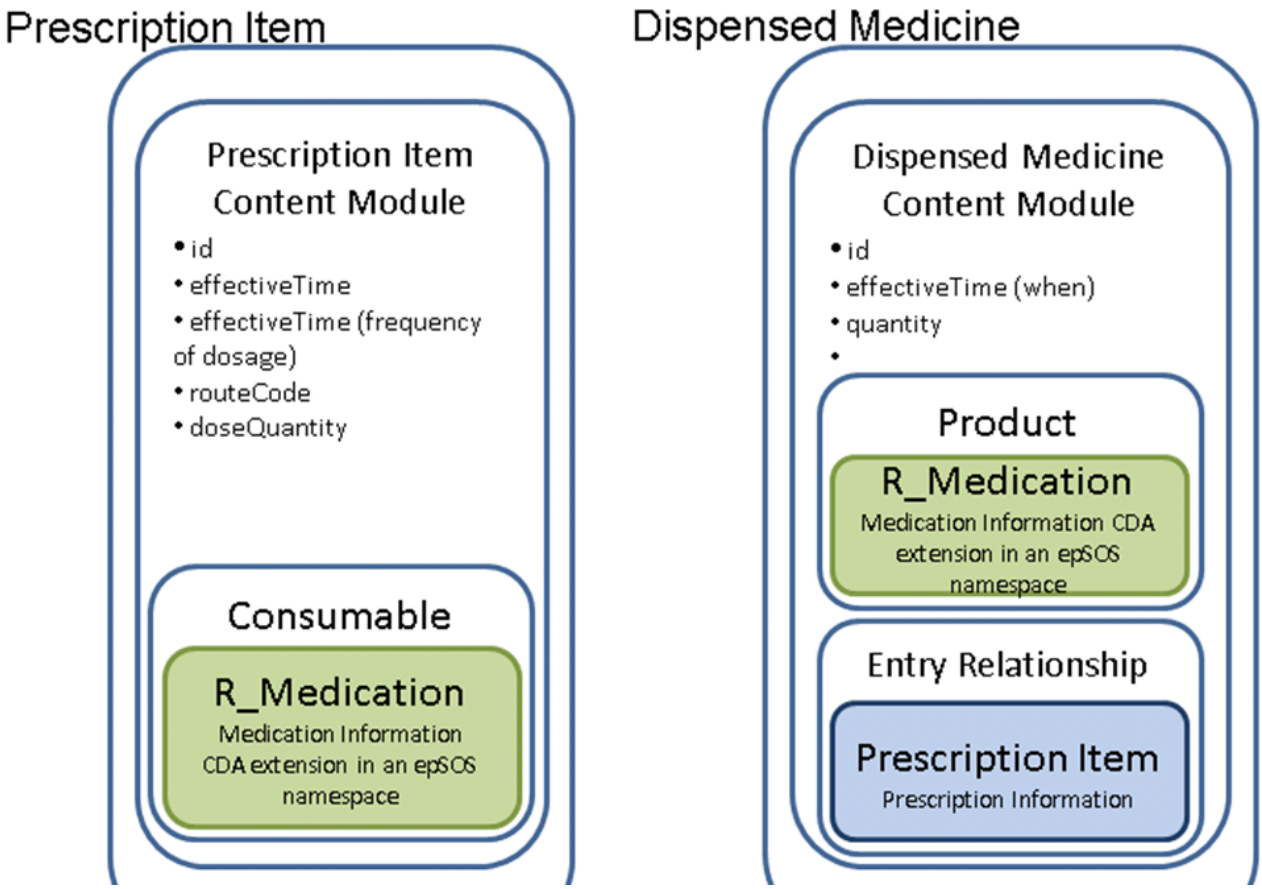


Figure 4C - Using the R_Medication CMET

The figures above show multiple Prescription Item entries within a Prescription section, and single Dispensed Medicine Entry within a Dispensation Section. This does not imply a requirement – it can be done either way and it is left to the implementer's discretion.

The eP document reflects the act of prescribing, it is not a collection of patient prescriptions. As a result of a clinical act, and independently the way it has been generated, will always have a well-defined human prescriber as document author.

The eD document reflects the act of dispensing medications belonging to a well-defined eP document.

Here is an example: The patient has prescription from his general practitioner (GP) for high blood pressure and asthma (prescribed at the same time), and a prescription for migraines from a neurologist - three medications altogether. Country A shall present these as two eP documents with one section each, one document for the medication prescribed by the GP, the other for the medication prescribed by the neurologist.

In Country B, the patient may need two of the three to be filled - the high blood pressure and the migraine medicine. Even if they are filled by the same pharmacist at the same time Country B shall create one eD document for each eP dispensed.

12.1.1. 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)	
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='1.3.6.1.4.1.12559.11.10.1.3.1.2.3'/>
    <!-- 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'/>
    <title>Medication Summary</title>
    <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 5C - Sample Patient Summary Section

This section requires that at least one entry compliant to the '1.3.6.1.4.1.12559.11.10.1.3.1.3.4' template shall be present. This entry could be used either for recording medication information either for asserting that a patient is either not on medications, or that medications are not known.

12.1.1.1. Parent Templates

The parents of this template are CCD 3.9.

12.1.1.2. Medication Item Entry Content Module (1.3.6.1.4.1.12559.11.10.1.3.1.3.4)

12.1.1.2.1. 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)

12.1.1.2.2. 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='1.3.6.1.4.1.12559.11.10.1.3.1.3.4'/>
  <id root='' extension=''/>
  <!—Optional NOT TO BE USED for medication being administered or prescribed -->
  <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| 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 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 6C - Sample Medication Entry Content Module

12.1.1.2.3. 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> <manufacturedProduct> <manufacturedMaterial> <name> </manufacturedMaterial> </manufacturedProduct> </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	<manufacturedMaterial> <ingredient> <quantity> </quantity> </ingredient> </manufacturedMaterial>	The strength of the medication is expressed as a the ratio of each active ingredient to a unit of medication. 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. Note: Due to restrictions of the CDA schema, there is no way to separately record the strength. The epSOS extension is used to provide this information. In order to be compliant with the IHE PCC template strength information should be also conveyed through the consumable/code/originalText element as reference to the narrative block.
Ingredient Code	<manufacturedMaterial> <ingredient> <ingredient> <code/> </ingredient> <ingredient> </manufacturedMaterial>	A code describing the active ingredient(s) of 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.

Field	CDA Tag	Description
Indication	<entryRelationship>	A link to supporting clinical information about the reason for providing the medication (e.g., a link to the relevant diagnosis).

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12.1.1.2.4. Medication Item Entry Content Module General Specifications

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

The general model is to record each prescribed medication in a <substanceAdministration> intent (moodCode='INT'). To record medications which were taken in the past, the moodCode shall be set to 'EVN'. 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, the split dosing 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.

- **Split Dosing 1.3.6.1.4.1.19376.1.5.3.1.4.9**

This template identifier is used to identify medication administration events that require special processing to handle split dosing. The parent template is 1.3.6.1.4.1.19376.1.5.3.1.4.7. A split dose is often used when different dosages are given at different times (e.g., at different times of day, or on different days). This may be to account for different metabolism rates at different times of day, or to simply address drug packaging deficiencies (e.g., and order for Coumadin 2mg on even days, 2.5mg on odd days is used because Coumadin does not come in a 2.25mg dose form).
In this case a subordinate <substanceAdministration> entry is required for each separate dosage.

12.1.1.2.4.1. 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)**

Note: The usage of statusCode values different from "completed" makes this specification not formally compliant with the current IHE PCC specification of the Medication Item Entry Content Module. All the requirements of conformance assertion with these IHE PCC templates cannot therefore be applied until the revision – if any - of the referenced IHE PCC templates.

12.1.1.2.4.2. 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[20] 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.
1.3.6.1.4.1.19376.1.5.3.1.4.9	A <substanceAdministration> act that records split dose information in 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.

[20] See note above

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. For the epSOS purposes, only the normal, the combination and the split dosing are described.

12.1.1.2.4.2.1. Substance Administration ID

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

12.1.1.2.4.2.2. 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.

Note: One of the 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.

12.1.1.2.4.3. 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.

12.1.1.2.4.4. Substance Administration Status Code

<statusCode code='active|completed'/>

The status of all <substanceAdministration> elements must be either "active" or "completed". Status of "active" indicates a currently valid prescription, status of completed indicates a previously taken medication.

12.1.1.2.4.5. 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.

12.1.1.2.4.5.1. 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.

12.1.1.2.4.5.2. Effective Time Expression

<effectiveTime operator='A' xsi:type='TS|PIVL_TS|EIVL_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.

12.1.1.2.4.5.3. 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'/>

Frequency	Description	XML Representation
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_TS" institutionSpecified="false" operator="A"> <period xsi:type="PPD_PQ" value="5" unit="h"> <standardDeviation value="1" unit="h"/> </period> </effectiveTime>

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.

12.1.1.2.4.5.3.1. 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)
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.

xsi:type	Description
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.
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).

12.1.1.2.4.6. Route of Administration

```
<routeCode
  code=' '
  displayName=' '
  codeSystem=' 1.3.6.1.4.1.12559.11.10.1.3.1.44.1'
  codeSystemName='EDQM'/>
```

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.

12.1.1.2.4.7. 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 should be valorized = ‘1’The unit attribute – when expresses measureable units - 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.

12.1.1.2.4.7.1. 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.

12.1.1.2.4.8. 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.

12.1.1.2.4.9. Consumable

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

12.1.1.2.4.10. Author

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

12.1.1.2.4.11. 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.

12.1.1.2.4.12. Component

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

A top level <substanceAdministration> element may contain one or more related components, either to handle split dosing, or to support combination medications.
In the first case, the subordinate components shall specify only the changed <effectiveTime> and/or <doseQuantity> elements. 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.

12.1.2. 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	None	
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**
57828-6	R	Prescriptions
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='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='57828-6' displayName='Prescriptions'
      codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
    <title>Prescriptions</title>
    <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 7C - Sample Prescription Section

12.1.2.1. Parent Templates

This template does not have a strict parent template. It is derived from the CCD 3.9 (2.16.840.1.113883.10.20.1.8), and fulfills all of their requirements except for CCD-CONF-301 (“The value for 'section/code' SHALL be “10160-0” “History of medication use”)

12.1.2.2. 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

12.1.2.3. Prescriber

The prescriber, as author of this particular prescription[21], is recorded as one of the eP document author (reasoneably the only human author) under the `/ClinicalDocument/author` XML element.
The prescriber is a required element.

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

[21] Note: an epSOS eP document includes one and ony one prescription.

12.1.2.4. Prescription Item Entry Content Module (1.3.6.1.4.1.12559.11.10.1.3.1.3.2)

12.1.2.4.1. 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)

12.1.2.4.2. Parent Template

This entry content module is based on the HL7 CCD template medication activity 2.16.840.1.113883.10.20.1.24 and inspired to the IHE PCC Medications Entry 1.3.6.1.4.1.19376.1.5.3.1.4.7.

12.1.2.4.3. 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='1.3.6.1.4.1.12559.11.10.1.3.1.3.2'/>
  <templateId root=''/>
  <!-- Prescription Item ID -->
  <id root='' extension=''/>
  <code code='' codeSystem='' displayName='' codeSystemName=''/>
  <!-- Reference to narrative text of prescription, e.g.
       Pyrimon, Chloramphenicol/ Dexamethasone 1% w/v/ 0.1% w/v 5 ml Eye Drops – three drops -->
  <text>
      <reference value='#med-1'/>
  </text>
  <statusCode code='active'/>
  <effectiveTime xsi:type='IVL_TS'>
      <low value=''/>
      <high value=''/>
  </effectiveTime>
  <effectiveTime operator='A' xsi:type='TS|PIVL_TS|EIVL_TS| SXPR_TS'>
    :
  </effectiveTime>
  <routeCode code='20051000' codeSystem='1.3.6.1.4.1.12559.11.10.1.3.1.44.1' displayName='Ocular
use' codeSystemName='EDQM'/>
  <doseQuantity value='3' />
  <!-- Optional -->
  <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>
  <!-- Optional instructions for Pharmacist -->
  <entryRelationship typeCode='SUBJ'>
     ...
  </entryRelationship>

..<!—Optional Substitution information -->
  <entryRelationship typeCode='SUBJ'>
     ...
  </entryRelationship>

</substanceAdministation>
```

Figure 8C - Sample Medication Entry Content Module

12.1.2.4.4. ePrescription Data Elements

See 12.1.1.2.3.

12.1.2.4.5. 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, the split dosing 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.

- **Split Dosing 1.3.6.1.4.1.19376.1.5.3.1.4.9**

This template identifier is used to identify medication administration events that require special processing to handle split dosing. The parent template is 1.3.6.1.4.1.19376.1.5.3.1.4.7. A split dose is often used when different dosages are given at different times (e.g., at different times of day, or on different days). This may be to account for different metabolism rates at different times of day, or to simply address drug packaging deficiencies (e.g., and order for Coumadin 2mg on even days, 2.5mg on odd days is used because Coumadin does not come in a 2.25mg dose form).
In this case a subordinate <substanceAdministration> entry is required for each separate dosage.

12.1.2.4.5.1. 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='1.3.6.1.4.1.12559.11.10.1.3.1.3.2' /> (epSOS)**

Note: The usage of statusCode values different from "completed" makes this specification not formally compliant with the current IHE PCC specification of the Medication Item Entry Content Module. All the requirements of conformance assertion with these IHE PCC templates cannot therefore be applied until the revision – if any - of the referenced IHE PCC templates.

12.1.2.4.5.2. 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[22] 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.
1.3.6.1.4.1.19376.1.5.3.1.4.9	A <substanceAdministration> act that records split dose information in subordinate <substanceAdministration> acts.

[22] See note above about template conformance assertion.

Root	Description
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. For the epSOS purposes, only the normal, the combination and the split dosing are described.

12.1.2.4.5.3. Substance Administration ID (Prescription Item ID)

The following must be true for the prescription item ID:

- The prescription item ID must be globally unique
- In countries where there can be only one item per prescription, the prescription item ID must be the same as the prescription ID
- The prescription item ID can be used by the prescribing system or provider to identify the prescription to which it belongs. This provides the link from the dispensed medicine to the prescription (see section 12.1.3.4.8 Related prescription item).

<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.

12.1.2.4.5.4. Substance Administration Code

<code code=' ' displayName=' ' codeSystem=' ' codeSystemName=' '/>
Please see 12.1.1.2.4.2.2

12.1.2.4.5.5. Substance Administration Reference Value

<text><reference value=' '/></text>
Please see 12.1.1.2.4.3.

12.1.2.4.5.6. Substance Administration Status Code

<statusCode code='active'/>

The status code of "active" indicates that the medication has not been yet administrated .

12.1.2.4.5.7. Substance Administration Effective Time

<effectiveTime xsi:type='IVL_TS'>
Please see 12.1.1.2.4.4

12.1.2.4.5.8. Route of Administration

```
<routeCode
  code=' '
  displayName=' '
  codeSystem='1.3.6.1.4.1.12559.11.10.1.3.1.44.1'
  codeSystemName='EDQM'/>
```

Please see 12.1.1.2.4.6

12.1.2.4.5.9. Dose Quantity

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

Please see 12.1.1.2.4.7.

12.1.2.4.5.10. Rate Quantity

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

Please see 12.1.1.2.4.8.

12.1.2.4.5.11. Consumable

```
<consumable>
  <manufacturedProduct>…</manufacturedProduct>
</consumable>
```

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

12.1.2.4.5.12. 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. When the Prescription Item Entry is part of a Dispensed Medicine Entry as a Related Prescription Item (see subsection 12.1.3.4.8), the author element shall be present, and shall contain the

prescription item author (or author of the prescription if the prescription item has no separate author). See the 2.4.3.3 Prescriber description for the structure of the <author> element.

12.1.2.4.5.13. Prescriber Credentialing Organization

```
<participant typeCode="AUT">
  <participantRole classCode="LIC">
    <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 "LIC".

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

12.1.2.4.5.14. 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.

12.1.2.4.5.15. Substitution Instructions

<entryRelationship typeCode='SUBJ'>.. </entryRelationship>
An entry relationship may be present to provide the substitution instructions. When present, this entry relationship SHALL contain one and only one observation.

This observation SHALL have :

1. the *code* element valorized with @code=’SUBST' and @codeSystem='2.16.840.1.113883.5.6';
2. the *value* element valorized with one of the value of the epSOSSubstitutionCode Value Set (Vaue Set OID 1.3.6.1.4.1.12559.11.10.1.3.1.42.7). Nullflavor is not allowed.

NOTE:
Within the epSOS-I scope the "N" code shall be interpreted as No substitution allowed excepting for the Package Size.

The presence of any other code that is not "N", or the absence of the substitution instructions, means that also the brand name (as well as the Package Size) can be changed.

12.1.2.5. 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 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.

12.1.2.5.1. Specification

```
<manufacturedProduct xmlns:epsos="urn:epsos-org:ep:medication"classCode="MANU">
    <templateId root="1.3.6.1.4.1.12559.11.10.1.3.1.3.1"/>
    <manufacturedMaterial classCode="MMAT" determinerCode="KIND">
        <!-- National medicinal product code -->
        <code code=" " displayName="Pyrimon" codeSystem=" "codeSystemName=" "/>
        <!-- Brand name -->
        <name>Pyrimon</name>
        <epsos:formCode code="10604000" displayName="Eye drops, solution"
codeSystem="1.3.6.1.4.1.12559.11.10.1.3.1.44.1"
             codeSystemName="EDQM"/>
        <!-- Container information -->
        <epsos:asContent classCode="CONT">
            <epsos:containerPackagedMedicine classCode="CONT" determinerCode="INSTANCE">


                <epsos:name>Pyrimon 5 ml Eye Drops</epsos:name>
                <epsos:formCode
code="30008000" displayName="Bottle" codeSystem="1.3.6.1.4.1.12559.11.10.1.3.1.44.1"
             codeSystemName="EDQM"/>

                <epsos:capacityQuantity value="5" unit="ml"/>
                <epsos:capTypeCode code="30022000" codeSystem=" 1.3.6.1.4.1.12559.11.10.1.3.1.44.1"
displayName="Dropper applicator" codeSystemName="EDQM"/>
            </epsos:containerPackagedMedicine>
        </epsos:asContent>
        <!-- This is the generic equivalent -->
        <epsos:asSpecializedKind classCode="GRIC">
             <epsos:generalizedMedicineClass classCode="MMAT">
                  <epsos:code nullFlavor="NA"/>
                  <epsos:name>Chloramphenicol/ Dexamethasone</epsos:name>
             </epsos:generalizedMedicineClass>
        </epsos:asSpecializedKind>
        <!-- This is the list of active ingredients -->
        <epsos:ingredient classCode="ACTI">
            <!-- Strength 1% w/v -->
            <epsos:quantity>
                <epsos:numerator xsi:type="epsos:PQ" value="10" unit="mg"/>
                <epsos:denominator xsi:type="epsos:PQ" value="1" unit="ml"/>
            </epsos:quantity>
            <epsos:ingredient classCode="MMAT" determinerCode="KIND">
                 <epsos:code code="S01AA01" codeSystem="1.3.6.1.4.1.12559.11.10.1.3.1.44.1"
displayName="chloramphenicol"/>
                  <epsos:name>Chloramphenicol</epsos:name>
             </epsos:ingredient>
        </epsos:ingredient>
        <epsos:ingredient classCode="ACTI">
            <!-- Strength 0.1% w/v -->
            <epsos:quantity>
                <epsos:numerator xsi:type="epsos:PQ" value="1" unit="mg"/>
                <epsos:denominator xsi:type="epsos:PQ" value="1" unit="ml"/>
            </epsos:quantity>
            <epsos:ingredient classCode="MMAT" determinerCode="KIND">
                <epsos:code code="D07CB04" codeSystem="1.3.6.1.4.1.12559.11.10.1.3.1.44.1"
displayName="dexamethasone and antibiotics"/>
                  <epsos:name>Dexamethasone</epsos:name>
            </epsos:ingredient>
        </epsos:ingredient>
    </manufacturedMaterial>
</manufacturedProduct>
```

Figure 9C - Sample Medicine Entry Content Module

The example above uses Pyrimon, Chloramphenicol/ Dexamethasone 1% w/v/ 0.1% w/v 5 ml Eye Drops as the medication. The structure is further explained in the following subsections.

12.1.2.5.2. 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 <manufacturedProduct> element. The templateId element is required and identifies this as a Medicine entry.

12.1.2.5.3. Medication Code

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

The <code> element of the <manufacturedMaterial> describes the medication.
For the scope of epSOS this is used to convey the "Country A Cross-border/regional/national medicinal product code.

In a CDA document, the <originalText> shall contain a <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.

12.1.2.5.3.1. Medication Name

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

12.1.2.5.3.2. 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.

12.1.2.5.3.3. Medication Packaging

```
<epsos:asContent classCode='CONT'>
    <epsos:containerPackagedMedicine classCode='CONT' determinerCode='INSTANCE'>

        <epsos:name></epsos:name>
        <epsos:formCode code=' '
           displayName=' '
           codeSystem=' '
           codeSystemName=' '/>
        <epsos:capacityQuantity value=' ' unit=' '/>

    </epsos:containerPackagedMedicine>
</epsos:asContent>
```

Figure 10C - Sample of the packaging of the medication

This structure describes the packaging of the medication. The <epsos:formCode> 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:capacityQuantity> element described the capacity of the packaging. For example, to represent 30 tablets, the <epsos:formCode> element at the <manufactured-Material> level 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.

12.1.2.5.3.4. 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.

12.1.2.5.3.5. 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.

12.1.2.5.3.6. Medication Strength

```
<epsos:ingredient classCode="ACTI">
    <epsos:quantity>
        <epsos:numerator xsi:type="epsos:PQ" value="24" unit="mg"/>
        <epsos:denominator xsi:type="epsos:PQ" value="1" unit="ml"/>
    </epsos:quantity>
    <epsos:ingredient classCode='MMAT' determinerCode='KIND'>
        …
    </epsos:ingredient>
</epsos:ingredient>
```

The medication strength is represented as the ratio of the active ingredient(s) to a unit of medication. The <epsos:quantity> element contains the numerator and denominator of the strength ratio.

12.1.2.6. 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.

12.1.2.6.1. Standards

Pharmacy	HL7 Pharmacy Domain (Normative)

12.1.2.6.2. 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 11C - Sample Medication Fulfillment Instructions Entry

12.1.2.6.2.1. 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'.

12.1.2.6.2.2. Act classCode

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

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

12.1.2.6.2.3. 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.

12.1.2.6.2.4. Code

<code code='FINSTRUCT' codeSystem='1.3.6.1.4.1.19376.1.5.3.2' codeSystemName='IHEActCode' />

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

12.1.2.6.2.5. Text-reference

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

The <text> element contains a free text representation of the instruction. For CDA this SHALL contain a <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>.

12.1.2.6.2.6. Status Code

<statusCode code='completed' />

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

12.1.3. 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 medication dispensed for the patient at a given pharmacy. It shall include only one entry for each dispensed medication as described in the Entry Content Module.	
LOINC Code	**Opt**	**Description**
60590-7	R	Medication dispensed
Entries	**Opt**	**Description**
1.3.6.1.4.1.12559.11.10.1.3.1.3.3	R	Dispensed Medicine Entry Content Module

12.1.3.1. 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='60590-7' displayName='Medication dispensed'      codeSystem='2.16.840.1.113883.6.1'
codeSystemName='LOINC'/>
    <title>Dispensation</title>
    <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 12C - Sample Dispensation Section

12.1.3.2. Parent Templates

The parent of this template is CCD 3.9.

12.1.3.3. 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.

12.1.3.4. Dispensed Medicine Entry Content Module 1.3.6.1.4.1.12559.11.10.1.3.1.3.3

12.1.3.4.1. 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 Substitution Act -->
  <entryRelationship typeCode="COMP">
      <act classCode="ACT" moodCode="EVN">
         ...
      </substanceAdministration>
  </entryRelationship>
  <entryRelationship typeCode="COMP">
      <substanceAdministration classCode="SBADM" moodCode="INT">
         <doseQuantity/>
      </substanceAdministration>
  </entryRelationship>
  <!-- Optional Patient instrctions -->
  <entryRelationship typeCode='SUBJ'>
     ...
  </entryRelationship>
</supply>
```

Figure 13C - Sample Dispensed Medicine Entry Content Module

12.1.3.4.2. 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.

12.1.3.4.3. 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.

12.1.3.4.4. Id root

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

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

12.1.3.4.5. 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.

12.1.3.4.6. Product

<product><manufacturedProduct>…</manufacturedProduct></product>

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

12.1.3.4.7. 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*
Pharmacy Organization Identifier	II	*performer/assignedEntity/representedOrganization/id*

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

12.1.3.4.7.1. Dispenser Credentialing Organization

```
<participant typeCode="PRF">
   <participantRole classCode="LIC">
      <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 "LIC".

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

12.1.3.4.8. 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 12.1.2.4. The prescription item ID is required within the Dispensed Medication Entry.

12.1.3.4.8.1. Substitution

An entry relationship may be present to inform that a substitution occured. When present, this entry relationship SHALL contain one and only one act.

This act SHALL have the *code* element valorized with @code=’SUBST' and @codeSystem='2.16.840.1.113883.5.6';

12.1.3.4.9. Change of Dosage Information

```
<entryRelationship typeCode="COMP">
      <substanceAdministration classCode="SBADM" moodCode="INT">
<!- Only changed dosage/administration information should be recorded -->        <effectiveTime
xsi:type='IVL_TS'>
            <low value=' '/>
            <high value=' '/>
        </effectiveTime>
        <effectiveTime operator='A' xsi:type='TS|PIVL_TS|EIVL_TS|SXPR_TS'>
              :
        </effectiveTime>
        <routeCode code=' ' codeSystem=' ' displayName=' ' codeSystemName=' '/>
        <doseQuantity value=' ' unit=' '/>
        <approachSiteCode code=' ' codeSystem=' ' displayName=' ' codeSystemName=' '/>
        <rateQuantity value=' ' unit=' '/>
      </substanceAdministration>
</entryRelationship>
```

If for some reason the dispense included a change in the dosing of the dispensed medication, the new dosing informationis represented via an entry relationship of type code "COMP", and containing a substance administration entry, which in turn contains the different dosing information.

12.1.3.4.10. 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.

12.1.3.4.11. 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.

12.1.3.4.12. Patient Medication 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.

12.1.3.4.12.1. Standards

Pharmacy	HL7 Pharmacy Domain (Normative)

12.1.3.4.12.2. 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 14C - Sample Patient Medication Instructions Entry

12.1.3.4.12.3. 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'.

12.1.3.4.12.4. Act classCode

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

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

12.1.3.4.12.5. 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.

12.1.3.4.12.6. Code

<code code='PINSTRUCT' codeSystem='1.3.6.1.4.1.19376.1.5.3.2' codeSystemName='IHEActCode' />

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

12.1.3.4.12.7. 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>.

12.1.3.4.12.8. Status Code

<statusCode code='completed' />

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

13 Patient Summary Data

As described in the previous chapter the epSOS specification makes use of 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 derived by already defined templates.

13.1. General Information

Prescribed and dispensed medications, including a specification of the Medication Summary section used in the Patient Summary document, have described in the previous chapter. The following subparagraphs specify how other sections that may be present in a Patient Summary are implemented.

According to requirements described in the § 11- Body Data Elements, the following sections - at least - shall be present in a Patient Summary document:

- The Medication Summary Section 1.3.6.1.4.1.12559.11.10.1.3.1.2.3 (§ 12.1.1)
- The Allergies and Other Adverse Reactions Section 1.3.6.1.4.1.19376.1.5.3.1.3.13 (§ 13.1.1)
- The Coded List of Surgeries Section 1.3.6.1.4.1.19376.1.5.3.1.3.12 (§ 13.1.5)
- The Active Problems Section 1.3.6.1.4.1.19376.1.5.3.1.3.6 (§ 13.1.6)
- The Medical Devices Coded Section 1.3.6.1.4.1.12559.11.10.1.3.1.2.4 (§ 13.1.8)

Appropriated codes and/or nullFlavor values will be used in these sections to express for example that coded information is not available, either that an entry is not applicable or that information is not known, ….. See the related paragraph for further details.

13.1.1. 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

13.1.1.1. 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'/>
    <title>Allergies and Other Adverse Reactions</title>
    <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 15C - Sample Allergies and Other Adverse Reactions Section

13.1.1.2. 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.

13.1.1.2.1. Standards

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

13.1.1.2.2. 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

13.1.1.2.3. 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 16C - Sample Allergy and Intolerance Concern Entry

13.1.1.2.4. 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.

13.1.1.2.5. 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'

13.1.2. 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.

13.1.2.1.1. Standards

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

13.1.2.1.2. Parent Template

This is a specialization of the IHE PCC Problem Entry 1.3.6.1.4.1.19376.1.5.3.1.4.5 and of the CCD alert observation template 2.16.840.1.113883.10.20.1.18

13.1.2.1.3. Specification

```
<observation classCode='OBS' moodCode='EVN' negationInd='false'>
    <templateId root='2.16.840.1.113883.10.20.1.18'/>
    <templateId root='2.16.840.1.113883.10.20.1.28'/>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.6'/>
    <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 derived from the
epSOSAdverseEventType Value Set-->
    <code code='' codeSystem='2.16.840.1.113883.6.96'
/>
    <text><reference value=' '/></text>
    <statusCode code='completed'/>
    <effectiveTime>
        <low value=' '/>
        <high value=' '/>
    </effectiveTime>
   <!-- value element is present only to indicate no known allergies, in all other cases is used for
referenicng text in the narrative -->
   <value xsi:type='CD'/>
   <!-- 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="Finding reported
by subject or history provider" 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 (Optional)-->
    <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>
```

13.1.2.1.4. <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. These elements are required and shall be recorded exactly as shown above.
Note: the 1.3.6.1.4.1.19376.1.5.3.1.4.5 requires that also the template ID '2.16.840.1.113883.10.20.1.28' is included.

13.1.2.1.5. <code code='' displayName=' ' codeSystem='2.16.840.1.113883.6.96' ' />

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.

13.1.2.1.6. <value xsi:type='CD'> <originalText> <reference value=' '/> </originalText> </value>

The value element shall be present in a coded or uncoded form. In both cases the type shall be set to `xsi:type='CD'`. The coded form shall be used to indicate "No known Allergies" (`code='160244002' codeSystem='2.16.840.1.113883.6.96' codeSystemName='SNOMED CD'`). In all other cases it shall be in its uncoded form and may contain a <reference> to the <originalText> in the narrative where the allergy is described.

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

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

13.1.2.1.7.1. <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.

13.1.2.1.8. <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='2.16.840.1.113883.10.20.1.28'/>
      <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>
```

13.1.2.1.8.1. <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.
Note: the 1.3.6.1.4.1.19376.1.5.3.1.4.5 requires that also the template ID '2.16.840.1.113883.10.20.1.28' is included.

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

An optional <entryRelationship> element may be present indicating the severity of the problem. If present, 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).

13.1.2.2. 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.

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

13.1.2.2.1. Standards

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

13.1.2.2.2. 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>
```

13.1.2.2.3. <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'.

13.1.2.2.4. <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).

13.1.2.2.5. <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.

13.1.2.2.6. <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.

13.1.2.2.7. <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,

13.1.2.2.8. <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.

13.1.2.2.9. <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 epSOSSeverity 1.3.6.1.4.1.12559.11.10.1.3.1.42.13..

13.1.3. 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 immunization
Entries	**Opt**	**Description**
1.3.6.1.4.1.19376.1.5.3.1.4.12	R	Immunization

13.1.3.1. Parent Template

The parent of this template is CCD 3.11.

13.1.3.2. Specification

```
<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 immunization'
      codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
    <title>Immunizations</title>
    <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 17C - Sample Immunizations Section

13.1.3.3. 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.

13.1.3.3.1. 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='1.3.5.1.4.1.19376.1.5.3.2' codeSystemName='IHEActCode'/>
  <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'>
      <manufacturedMaterialclassCode='MMAT' determinerCode='KIND'>
        <code code='' codeSystem='' codeSystemName=''>
          <originalText><reference value='#yyy'/></originalText>
        </code>
      </manufacturedMaterial>
    </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 18C - Sample Immunizations Entry

13.1.3.3.2. 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.

13.1.3.3.3. 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.

13.1.3.3.4. Id root

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

13.1.3.3.5. Type of substance administration act

<code code='IMMUNIZ'
codeSystem='1.3.5.1.4.1.19376.1.5.3.2'
codeSystemName='IHEActCode'/>

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
1.3.5.1.4.1.19376.1.5.3.2	ActCode	The IMMUNIZ term from the IHE ActCode vocabulary.

13.1.3.3.6. 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.

13.1.3.3.7. Status Code

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

13.1.3.3.7.1. 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.

13.1.3.3.8. Route of administration

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

See routeCode under the Medication Item Entry Content module.

13.1.3.3.9. 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.

13.1.3.3.10. Dose Quantity

<doseQuantity value=' ' units=' '/>
See doseQuantity under the Medication Item Entry Content module.

13.1.3.3.11. Consumable

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

13.1.3.3.12. 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.

13.1.3.3.13. 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.

13.1.3.3.14. 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.

13.1.3.4. 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.

13.1.3.4.1. 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 19C - Sample Product Entry

13.1.3.4.2. 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 20C - 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.

13.1.3.4.2.1. Manufactured Product Code

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

Figure 21C - Sample Manufactured Product Code

The <code> element of the <manufacturedMaterial> describes the vaccine. The values for the code attribute come from the epSOSVaccine value set (OID 1.3.6.1.4.1.12559.11.10.1.3.1.42.28). The code system is SNOMED CT (codeSystem OID 2.16.840.1.113883.6.96).

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.

13.1.3.4.2.2. Name

The <name> element should contain the name of the vaccine (or active ingredient in the case of subordinate <substanceAdministration> elements used to record components of a vaccine). Note that the brand name should be represented as a translation of the code element.

13.1.4. 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

13.1.4.1. 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'/>
    <title>History of Past Illness</title>
    <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 22C- Sample History of Past Illness Section

13.1.4.2. 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.

13.1.4.2.1. Standards

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

13.1.4.2.2. 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

13.1.4.2.3. 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 23C- Sample History of Concern Entry

13.1.4.2.4. 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.

13.1.4.2.5. entry relationships identifying problems of concern

```
  <entryRelationship typeCode='SUBJ' inversionInd='false'>
<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'/>
</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 MAY 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.

13.1.5. 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

13.1.5.1. Parent Template

The parent of this template is List of Surgeries.

13.1.5.2. Specification

```
<component>
  <section>
    <templateId root=’2.16.840.1.113883.10.20.1.12'/>
    <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'/>
    <title>Coded List of Surgeries</title>
    <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 24C- Sample Coded List of Surgeries Section

This section should be used to describe the Surgical Procedures prior past six months (optional) and shall be used to record the Major Surgical Procedures past 6 months[23] (required).
Each surgical procedure shall be described using the “Procedure Entry” template (1.3.6.1.4.1.19376.1.5.3.1.4.19).
In case no procedures are expected to be recorded, a single “NA” nullFlavored procedure entry shall be included in this section.

13.1.5.3. 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.

[23] 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.

13.1.5.3.1. 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 />
  <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 25C- Sample Procedure Entry

13.1.5.3.2. Standards

CCD	ASTM/HL7 Continuity of Care Document

13.1.5.3.3. 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.

13.1.5.3.4. 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.

13.1.5.3.5. Id root

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

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

13.1.5.3.6. Type of procedure

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

This element shall be present, and should contain a code describing the type of procedure.

13.1.5.3.7. Text-reference

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

The <text> element shall contain a reference to the narrative text describing the procedure.

13.1.5.3.8. 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'.

13.1.5.3.9. 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.

13.1.5.3.10. Priority Code

13.1.5.4. <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.

13.1.5.4.1. Approach Site

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

This element may be present to indicate the procedure approach.

13.1.5.4.2. Target Site

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

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

13.1.5.4.3. 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.

13.1.5.4.4. Optional entryRelationship: indicate the reason for the procedure

<entryRelationship typeCode='RSON'>
A <procedure> act MAY 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.

13.1.5.4.5. 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.

13.1.5.4.5.1. 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 26C- Sample Optional entryRelatiobship

13.1.5.4.6. 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.

13.1.5.5. Reference act

<act classCode=' ' moodCode=' '>
The act being referred to can be any CDA Clinical Statement element type (act, procedure, observation, substanceAdministration, supply, etcetera). 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.

13.1.5.6. 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.

13.1.5.7. 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.

13.1.5.8. 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".

13.1.6. 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

13.1.6.1. Active Problems Section Parent Template

The parent of this template is CCD 3.5.

13.1.6.2. 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'/>
    <title>Active Problems</title>
    <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 27C- Sample Active Problems Section

13.1.6.3. 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.

13.1.6.3.1. Standards

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

13.1.6.3.2. 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

13.1.6.3.3. 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 28C- Sample Active Problems Section

13.1.6.3.4. 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.

13.1.6.3.5. 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 1.3.6.1.4.1.19376.1.5.3.1.4.5This SHALL be represented with the <entryRelationship> element. The typeCode SHALL be 'SUBJ' and inversionInd SHALL be 'false'.

Note: every Problem Entry used in this section to identify problem of concern MAY 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.

13.1.6.3.6. 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.

13.1.6.3.7. Standards

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

13.1.6.4. 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.

13.1.6.5. 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 29C- Sample Concern Entry

13.1.6.6. 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.

13.1.6.7. 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.

13.1.6.8. Id root

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

13.1.6.9. nullFlavor

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

13.1.6.10. Status Code

<statusCode code='active|suspended|aborted|completed'/>
The statusCode associated with any concern must be one part of the above mentioned values.

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.

13.1.6.11. 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.

13.1.6.12. 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 MAY 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 epSOS-Severity, 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.

13.1.6.13. 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'

13.1.6.14. 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 observation 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.

13.1.6.14.1. Standards

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

13.1.6.14.2. Parent Template

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

13.1.6.14.3. 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>
```

Figure 30C - Sample Problem Entry

13.1.6.14.4. Observation code

<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.

13.1.6.14.5. 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.

13.1.6.14.6. 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.

13.1.6.14.7. Description of the problem

<code code=' '
displayName=' '
codeSystem=' 2.16.840.1.113883.6.96
codeSystemName='SNOMED-CT>

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 required (only recommended for the IHE template) vocabulary for describing problems is Value set epSOSCodeProb, OID 1.3.6.1.4.1.12559.11.10.1.3.1.42.23.

13.1.6.14.8. 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.

13.1.6.14.9. 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'.

13.1.6.14.10. 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).

13.1.6.14.11. 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 Value Set 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.

13.1.6.14.12. 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.

13.1.6.14.13. Optional entryRelationship: severity

< entryRelationship typeCode='SUBJ' inversionInd='true'>
An optional <entryRelationship> element MAY be present indicating the severity of the problem. If present, 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 epSOS-Severity, 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'.

13.1.6.14.14. 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 value set 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'.

13.1.6.14.15. 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 (1.3.6.1.4.1.19376.1.5.3.1.4.1.2).). The value set to be used is epSOSResolutionOutcome, OID 1.3.6.1.4.1.12559.11.10.1.3.1.42.30. The typeCode shall be 'REFR' and inversionInd shall be 'false'.
This shall be represented with the <entryRelationship> element.

13.1.6.14.16. 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.

13.1.7. 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

13.1.7.1. 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'/>
    <title>History of Present Illness</title>
    <text>
      Text as described above
    </text>

  </section>
</component>
```

Figure 31C-Sample History of Present Illness Section

13.1.8. 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	2.16.840.1.113883.10.20.1.7 (2.16.840.1.113883.10.20.1.7) 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

13.1.8.1. Parent Template

The parents of this template are 2.16.840.1.113883.10.20.1.7 and 1.3.6.1.4.1.19376.1.5.3.1.1.5.3.5

13.1.8.2. Specification

```
<component>
  <section>
    <templateId root='2.16.840.1.113883.10.20.1.7'/>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.5.3.5'/>
    <templateId root='1.3.6.1.4.1.12559.11.10.1.3.1.2.4'/>
    <id root=' ' extension=' '/>
    <code code='46264-8' displayName='History of medical device use'
      codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
    <title>Coded Medical Devices</title>
    <text>
      Text as described above
    </text>
    <entry>

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

Figure 32C- Sample Medical Devices Section

This mandatory section shall be used to record the Medical Devices and Implants.
Each devices shall be described using the "Medical Devices Entry Content Module" template (1.3.6.1.4.1.12559.11.10.1.3.1.3.5).
In **case no devices or implants are expected to be recorded**, a single "NA" nullFlavored supply entry shall be included in this section.

13.1.8.3. 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

13.1.8.3.1. 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 33C- Sample Medical Devices Entry

13.1.8.3.2. 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.

13.1.8.3.3. 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.

13.1.8.3.4. Supply ID

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

13.1.8.3.5. Device Description

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

13.1.8.3.6. 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.

13.1.8.3.7. 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.

13.1.8.3.8. Participant

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

13.1.8.3.9. Participant Role

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

13.1.8.3.10. 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.

13.1.8.3.11. 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".

13.1.8.3.12. 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.

13.1.9. 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 13.1.5.3.

13.1.9.1. 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='29544-3' displayName='Procedures'
      codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
    <title>Procedures and Interventions</title>
    <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 34C - Specification for Procedures and Interventions Section

13.1.10. 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 preconditions and otherwise optimizing lifetime outcomes.	
LOINC Code	**Opt**	**Description**
18776-5	R	Plan of treatment

13.1.10.1. Parent Template

The parent of this template is 1.3.6.1.4.1.19376.1.5.3.1.3.31.

13.1.10.2. Specification

```
<component>

  <section>
    <templateId root='2.16.840.1.113883.10.20.1.10'/>
    <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='Plan of treatment'
      codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
    <title>Health Maintenance Care Plan</title>
    <text>
      Text as described above
    </text>

  </section>

</component>
```

Figure 35C- Sample Health Maintenance Care Plan Section

13.1.11. 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

13.1.11.1. Parent Template

The parent of this template is CCD 3.4.

13.1.11.2. Specification

```
<component>
  <section>
    <templateId root='2.16.840.1.113883.10.20.1.5'/>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.17'/>
    <id root=' ' extension=' '/>
    <code code='47420-5' displayName='Functional status assessment'
        codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
    <title>Functional Status</title>
    <text>
        Text as described above
    </text>
   </section>
</component>
```

Figure 36C- Sample Functional Status Section

13.1.12. 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

13.1.12.1. Parent Template

The parent of this template is 1.3.6.1.4.1.19376.1.5.3.1.3.16.

13.1.12.2. Specification

```
<component>
  <section>
    <templateId root='2.16.840.1.113883.10.20.1.15'/>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.16'/>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.16.1'/>
    <id root=' ' extension=' '/>
    <code code='29762-2' displayName='Social history'
      codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
    <title>Coded Social History</title>
    <text>
      Text as described above
    </text>
  </section>
</component>
```

Figure 37C- Sample Social History Section

13.1.12.3. 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.

13.1.12.4. Standards

CCD	ASTM/HL7 Continuity of Care Document

13.1.12.5. 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.

13.1.12.6. 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 38C - Sample Social History Observation Entry Content Module

13.1.12.7. 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.

13.1.12.8. Type of social history observation

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

The first two columns of following table describe the value set to be used for this attribute, derived from the code systeme SNOMED CT (2.16.840.1.113883.6.96). For each used concept the data type of the "value" attribute, and the related unit, is reported.

CODE		VALUE	
Code	displayName	xsi:type	unit
229819007	Smoking	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	

13.1.12.9.<repeatNumber value=' '/>

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

13.1.12.10. 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.

13.1.13. 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

13.1.13.1. 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'/>
    <title>Pregnancy History</title>
    <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 39C- Sample Pregnancy History Section

13.1.13.2. 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.

13.1.13.3. Parent Template

The parent of this template is Simple Observation.

13.1.13.4. 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 40C- Sample Pregnancy Observation Entry Content Module

13.1.13.4.1. 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.

13.1.13.5. Description of the pregnancy

<code code=' '
displayName=' '
codeSystem='2.16.840.1.113883.6.1''
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.

Code	Description	Data Type
11778-8	Delivery date estimated (clinical)	TS
11779-6	Delivery date estimated from last menstrual period	
11780-4	Delivery date estimated from ovulation	

13.1.13.6. <repeatNumber value=' '/>

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

13.1.13.7. 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 prenancy observation.

13.1.14. 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	Physical findings
Entries	**Opt**	**Description**
1.3.6.1.4.1.19376.1.5.3.1.4.13.1	R	Vital Signs Organizer

13.1.14.1. Parent Template

The parent of this template is Vital Signs.

13.1.14.2. Specification

```
<component>
  <section>
    <templateId root='2.16.840.1.113883.10.20.1.16'/>
    <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='Physical findings'
      codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
    <title>Coded Vital Signs</title>
    <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 41C- Sample Coded Vital Signs Section

13.1.14.3. 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.

13.1.14.3.1. 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 42C- Sample Vital Signs Organizer

13.1.14.3.2. Vital Signs Organizer Definition

<organizer classCode='CLUSTER' moodCode='EVN'>
The vital signs organizer is a cluster of vital signs observations.

13.1.14.3.3. 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.

13.1.14.3.4. Id root

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

13.1.14.3.5. 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.

13.1.14.3.6. Vital Signs Measurement Status Code

<statusCode code='completed'/>
The observations have all been completed.

13.1.14.3.7. Vital Signs Measurement Time

<effectiveTime value=' '/>

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

13.1.14.3.8. 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.

13.1.14.4. 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.

Warning: Some of these elements were not included in the functional specification of WP3.2, however they have been introduced as optional elements for compliance with IHE PCC. Since they were not validated at a functional level yet, the following elements:

- • 13.1.14.4.5 Vital Signs Observation Interpretation
- 13.1.14.4.6 Vital Signs Observation method of measurement
- 13.1.14.4.7 Vital Signs Observation site of measurement

are not activated in current release of epSOS Pivot CDA.

13.1.14.4.1. 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 43C- Sample Vital Signs Observation

13.1.14.4.2. 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.

13.1.14.4.3. Description of the vital signs observation

<code code=' '
displayName=' '
codeSystem=' 2.16.840.1.113883.6.1'
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		

13.1.14.4.4. 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.

13.1.14.4.5. 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).

13.1.14.4.6. 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.

13.1.14.4.7. 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)

13.1.15. 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	Relevant diagnostic tests/laboratory data
Entries	**Opt**	**Description**
1.3.6.1.4.1.19376.1.5.3.1.4.19	O [Not to be used in epSOS-I]	Procedure Entry
1.3.6.1.4.1.19376.1.5.3.1.4.4	O [Not to be used in epSOS-I]	References Entry
1.3.6.1.4.1.19376.1.5.3.1.4.13	O [R in epSOS-I]	Simple Observation

This section is used within epSOS only for the purpose of providing the results for the blood group. This is determined in the simple observation entry; hence only this entry will be described.
If this section is present at least one simple observation element SHALL be present.

13.1.15.1. 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='Relevant diagnostic tests/laboratory data'
      codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
    <title>Coded Results</title>
    <text>
      Text as described above
    </text>
      <!-- Required Simple Observation element -->
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13'/>
         :
    </entry>

  </section>
</component>
```

Figure 44C- Sample Coded Results Section

13.1.15.1.1. 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).

13.1.15.1.1.1. 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 45C- Sample Simple Observation Entry

13.1.15.1.1.2. 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.

13.1.15.1.1.3. 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.

13.1.15.1.1.4. Id root

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

13.1.15.1.1.5. 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.

13.1.15.1.1.6. 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.

13.1.15.1.1.7. Simple Observation Status Code

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

13.1.15.1.1.8. 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.

13.1.15.1.1.9. 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.

13.1.15.1.1.10. 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.

13.1.15.1.1.11. 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.

13.1.15.1.1.12. 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.

13.1.15.1.1.13. 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 as a <assignedPerson> element.

14 Addition of transcoding / translation data

The process of translation/transcoding of particular coded element is presented in following example:

	Country A (Slovakia)	*NCP A-> NCPB*	*Country B (Austria)*
Document	*Document A*	*Document E*	*Document B*
Code System	*SNOMED CT*	*ICD10*	*ICD10*
Code	*230291001*	*G20*	*G20*
Language	*Slovak*	*English*	*German*
DisplayName	*Juvenile Parkinson's disease*	*Parkinson's disease*	*Primäres Parkinson-Syndrom*
CDA schema	<value xsi:type="CE" code="230291001" codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT" displayName="juvenilná Parkinsonova choroba"> </value>	<value xsi:type="CE" code="G20" codeSystem="1.3.6.1.4.1.12559.11.10.1.3.1.44.2" codeSystemName=" ICD10" displayName="Parkinson's disease"> <translation code="230291001" codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT" displayName=" juvenilná Parkinsonova choroba"/> </value>	<value xsi:type="CE" code="G20" codeSystem="1.3.6.1.4.1.12559.11.10.1.3.1.44.2" codeSystemName=" ICD10" displayName="Primäres Parkinson-Syndrom"> <translation displayName="Parkinson's disease"> <translation code="230291001" codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT" displayName=" juvenilná Parkinsonova choroba"/> </translation> </value>

14.1. Element <translation>

As a result of transformation, for each coded element, nested translation elements will be created. These elements are necessary so that the original code in which the document was coded is preserved (Country A). It keeps also English translation of epSOS coded concept.

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 and English version of epSOS code are kept, enabling the receiver to look it up if needed.

Translation element contains the same set of information as the original coded element, i.e. code, codeSystem (OID), codeSystemName, displayName.

```
<translation
      code="230291001"
      codeSystem="2.16.840.1.113883.6.96"
      codeSystemName="SNOMED CT"
            displayName="Juvenile Parkinson's disease"/>
```

As a result of transcoding in country A, translation element will be nested into original coded element (first nested level inside original coded element).

```
<value xsi:type="CE"
      code="G20"
      codeSystem="1.3.6.1.4.1.12559.11.10.1.3.1.44.2"
      codeSystemName="ICD10"
      displayName="Parkinson's disease">
      <translation
            code="230291001"
            codeSystem="2.16.840.1.113883.6.96"
            codeSystemName="SNOMED CT"
            displayName="juvenilná Parkinsonova choroba"/>
</value>
```

As a result of translation in country B, another translation element will be created and nested below original coded element (first nested level inside original coded element). Already existing translation element created by transcoding in country A, will be shifted one level below and nested to the new translation element (second nested level inside original coded element).

```
<value xsi:type="CE"
      code="G20"
      codeSystem="1.3.6.1.4.1.12559.11.10.1.3.1.44.2"
       codeSystemName="ICD10"
      displayName="Primäres Parkinson-Syndrom">
      <translation
            displayName="Parkinson's disease">
             <translation
                        code="230291001"
                        codeSystem="2.16.840.1.113883.6.96"
                        codeSystemName="SNOMED CT"
                        displayName=" juvenilná Parkinsonova choroba"/>
            </translation>
</value>
```

If some of the data is the same as in the element having nested translation element, these should not be repeated again.

```
<value xsi:type="CE"
      code="230291001"
      codeSystem="2.16.840.1.113883.6.96"
      codeSystemName="SNOMED CT"
      displayName="Juvenile Parkinson's disease">
      <translation
            displayName="juvenilná Parkinsonova choroba"/>
</value>
```

If original coded element contains other nested elements, these will be kept without any change in transformed document.

14.2. Example of transformation process

This section shows on example of one coded element, how transformation in Country A change its structure and content.

Country A provides epSOS compliant CDA document with original data containing coded element:

```
<value xsi:type='CE'
   code="230291001"
   codeSystem="2.16.840.1.113883.6.96"
   codeSystemName="SNOMED CT"
   codeSystemVersion="July2009"
   displayName="juvenilná Parkinsonova choroba">
      <originalText>
            <reference value="#a1"/>
      </originalText>
</value>
```

14.2.1. Transformation in Country A

As a result of transformation in country A, new <translation> element will be added to coded element.

Data obtained from terminology repository as transcoding of coded concept replace original data of the element and the original data are stored in <translation> element. All other elements related to transformed coded element remains unchanged.

```
<value xsi:type='CE'
   code="G20"
   codeSystem="1.3.6.1.4.1.12559.11.10.1.3.1.44.2"
   codeSystemName="ICD10"
   codeSystemVersion="2007"
   displayName="Parkinson's disease">
<originalText>
      <reference value="#a1"/>
</originalText>
      <translation
            code="230291001"
            codeSystem="2.16.840.1.113883.6.96"
            codeSystemName="SNOMED CT"
            codeSystemVersion="July2009"
            displayName="juvenilná Parkinsonova choroba"/>
</value>
```

14.2.2. Transformation in Country B

As a result of transformation in country B, new <translation> element will be added to coded element.

Data obtained from terminology repository as transcoding of coded concept replace original data of the element and the original data are stored in another <translation> element. Already existing <translation> will be nested into the new one.

```
<value xsi:type='CE'
   code="G20"
   codeSystem="1.3.6.1.4.1.12559.11.10.1.3.1.44.2"
   codeSystemName="ICD10"
   codeSystemVersion=”2007”
   displayName="Primäres Parkinson-Syndrom">
<originalText>
      <reference value="#a1"/>
</originalText>
      <translation
            code="G20"
            codeSystem="1.3.6.1.4.1.12559.11.10.1.3.1.44.2"
            codeSystemName="ICD10"
            codeSystemVersion=”2007”
            displayName="Parkinson’s disease">
            <translation
                  code="230291001"
                  codeSystem="2.16.840.1.113883.6.96"
                  codeSystemName="SNOMED CT"
                  codeSystemVersion=”July2009”
                  displayName="juvenilná Parkinsonova choroba"/>
      </translation>
</value>
```

Information about code, code system and its version does not have to be repeated in added <translation> element, because it is the same as in original data.

```
<value xsi:type='CE'
   code="G20"
   codeSystem="1.3.6.1.4.1.12559.11.10.1.3.1.44.2"
   codeSystemName="ICD10"
   codeSystemVersion=”2007”
   displayName="Primäres Parkinson-Syndrom">
<originalText>
      <reference value="#a1"/>
</originalText>
      <translation
            displayName="Parkinson’s disease">
            <translation
                  code="230291001"
                  codeSystem="2.16.840.1.113883.6.96"
                  codeSystemName="SNOMED CT"
                  codeSystemVersion=”July2009”
                  displayName="juvenilná Parkinsonova choroba"/>
      </translation>
</value>
```

14.2.3. Reference coded system used in Country A

There is a special case, when Country A uses the same code system as epSOS chosen for reference system. In that case, there is no need for transcoding to another code system in country A. Transformation will just add English display name in such case.
Then, format of resulting CDA element could look like:

As a result of transformation in country B, new <translation> element will be added to coded element.
Data obtained from terminology repository as transcoding of coded concept replace original data of the element and the original data are stored in another <translation> element. Already existing <translation> will be nested into the new one.

```
<value xsi:type='CE'
   code="43116000"
   codeSystem="2.16.840.1.113883.6.96"
   codeSystemName="SNOMED CT"
   codeSystemVersion=”July2009”
   displayName="Ekzem">
      <translation
            displayName="Eczema">
            <translation
                  displayName="vyrážka"/>
      </translation>
</value>
```

15 epSOS pdf

The epSOS pdf is an unstructured CDA that embedds the pdf file, “printable” human readeable representation of the original content.

1. The encoding rules of the pdf, including the allowed pdf formats, SHALL be the same defined by the IHE XDS-SD profile

2. The epSOS PDF document code SHALL be one of those defined in the § 4 “LOINC codes” and SHALL be the same used for the related epSOS pivot

3. The epSOS PDF and the epSOS pivot SHALL use the same patient ID

4. The epSOS PDF SHALL refer the same “Original document” of the epSOS pivot as defined in § 11.1.2.1 “Original document identification”

5. The epSOS PDF SHOULD applies the same optionality and cardinality rules of the header elements defined in § 10.1 Header Data Elements for the epSOS pivot.

16 Open Issues

Topics to be analyzed for future epSOS enhancements:

3870 1. Optionality of the linkage between the coded entry and the section narrative block by means of the originalText.reference element (currently recommended not mandatory) (Issue risen by ELGA).
2. Due to the well known ambiguity of the supply / substance administration quantity attribute, a revision of the usage of the quantity related attributes may be done according to possible
3875 wider agreed interpretations (issue risen by Spain for eP piloting).
3. Distinction between coding of medicine on a brand-level and coding on package-level (issue risen by ELGA).
4. Actual meaning of the LegalAuthentication element of a transformed document.

In general the CDA specifications have been built starting from HCP and CDA experts opinion
3880 gathered both in epSOS internal activities (WP3.1, WP3.2, WP3.5, WG-Semantic) and external experts (CALLepSO). At present epSOS MSs are applying the specifications to extract the data from their own eHealth systems data base and generate documents in epSOS defined CDA format. Many MSs are encountering difficulties because not all the expected coded data aree available. A statistical analysis of which optional elements are really transferred has to be performed during the pre-
3885 production testing, to get objective inputs for CDA implementation guide and MVC review.

Appendix B2: MVC/MTC

1 Preface

The **MVC** (Master Value set Catalogue) is a data structure containing all the value sets selected by WP 3.5. The value sets should represent the codes needed for a MS to being able to send the information needed in the tree pivot documents: ePrescription, eDispensation and Patient Summary.

Every value set has a name, a universally unique identifier OID and a reference to the parent Code System identifier. Please note that **the value set OID is used for management purposes only and not in the syntax of the pivot documents.**

Most of the OIDs for the code systems are the official ones from the respective SDOs. In cases where an SDO does not have an OID for a Code System, an OID was assigned in the epSOS context.

Some of the value sets are technical and therefore not to find in the MTC file since they are value sets which should not be translated.

The **MTC** (Master Translation/Transcoding Catalogue) is the set of :

- (a subset of the) MVC value sets translated by the PN Terminology Responsibles
- If any, the mapping tables between PN Value Sets and the epSOS ones needed for managing the local codes transcoding/mappings

The **eCRTS** (epSOS Central Reference Terminology Server) runs the CareCom system HealthTerm on which MVC are loaded and by which PNs can generate their MTC.

Descriptions and guidelines are provided in D3.9.1 – Appendix B3: epSOS Cental Reference Terminology Server.

This appendix B2 provides a synthetic view of the MVC ValueSets, indicating, for every ValueSets, the Value Set OID, the Code System Name, its OID and version, a short description, if it needed to be translated - per document type (PS/eP/eD) and role (Country A, CountryB) - and the skill (medical / technical) needed to translate it.

The currently valid MVC is stored on epSOS Central Services: http://ecrts.nczisk.sk/

								PS		eP/eD	
No,	Value Set OID	Value Set Name	Code system	Code System OID used in epSOS	Code system Version in eCRTS	Description	Skills to translate	Country A	Country B	Country A	Country B
1	1.3.6.1.4.1.12559.11.10.1.3.1.42.27	epSOSCodedElements	epSOS:CodedElements	1.3.6.1.4.1.12559.11.10.1.3.1.44.3	July 2010	The Value Set is used to denominate all the coded fields present in the three specification documents	Medical	NO	NO	NO	NO
2	1.3.6.1.4.1.12559.11.10.1.3.1.42.29	epSOSActCode	ActCode	2.16.840.1.113883.5.4	913-20091020	General category of medical service provided to the patient during their encounter.	Technical	Mapping if needed	YES	NO	NO
3	1.3.6.1.4.1.12559.11.10.1.3.1.42.24	epSOSActiveIngredient	Anatomical Therapeutic Chemical	2.16.840.1.113883.6.73	913-20091020	The Value Set is used as a mandatory code for the Active Ingredient of medications in the Medications Summary as well as the prescription Sections. Also used to code allergy agents in the Allergies and Other Adverse Reactions Section of the patient Summary.	Medical	Mapping if needed	YES	Mapping if needed	YES
4	1.3.6.1.4.1.12559.11.10.1.3.1.42.18	epSOSAdverseEventType	Snomed CT	2.16.840.1.113883.6.96	913-20091020	The value set is used to code the patient's kind of adverse reactions against substance, food or drugs.	Medical	Mapping if needed	YES	NO	NO
5	1.3.6.1.4.1.12559.11.10.1.3.1.42.19	epSOSAllergenNoDrugs	Snomed CT	2.16.840.1.113883.6.96	913-20091020	The Value Set is used to code the allergenic agents (apart from drugs) against which the patient has developed an adverse reaction.	Medical	Mapping if needed	YES	NO	NO
6	1.3.6.1.4.1.12559.11.10.1.3.1.42.20	epSOSBloodGroup	Snomed CT	2.16.840.1.113883.6.96	913-20091020	The Value Set is used to code the value of patient's blood group + Rh	Medical	Mapping if needed	YES	NO	NO
7	1.3.6.1.4.1.12559.11.10.1.3.1.42.21	epSOSBloodPressure	LOINC	2.16.840.1.113883.6.1	913-20091020	The Value Set is used for the observations of Blood Pressure recorded in the section for Vital Signs Observations in the Patient Summary. It codes what type of pressure (diastolic, systolic) is measured.	Medical	Mapping if needed	YES	NO	NO
8	1.3.6.1.4.1.12559.11.10.1.3.1.42.22	epSOSCodeNoMedication	Snomed CT	2.16.840.1.113883.6.96	July 2009	The Value Set is used to indicate, when a patient has no medication, if it is because the treatment is unknown, or if no medication was prescribed, or if the patient doesn't take medication on his own (self-medication)	Medical	Mapping if needed	YES	NO	NO
9	1.3.6.1.4.1.12559.11.10.1.3.1.42.23	epSOSCodeProb	Snomed CT	2.16.840.1.113883.6.96	July 2009	The Value Set is used as an optional description of a problem in the patient Summary. It gives an information on the circumstances under which the problem was defined/discovered.	Medical	Mapping if needed	YES	NO	NO
10	1.3.6.1.4.1.12559.11.10.1.3.1.42.31	epSOSConfidentiality	Confidentiality	2.16.840.1.113883.5.25	913-20091020	The Value Set is used for encoding the confidentiality level of the entire CDA. This Value Set encodes the level of access with regards to the content of the Value Set – for example N concerns all the medical team, R is restricted for specialist that take care of the patient in certain circumstances, and VIP would be for the persons that need the Privacy Officer present or other special consideration (for example a celebrity hospitalized who needs their records protected)	Technical	Mapping if needed	YES	Mapping if needed	YES
11	1.3.6.1.4.1.12559.11.10.1.3.1.42.4	epSOSCountry	ISO 3166-1	1.0.3166.1	2001	The Value Set is used to identify the nationality of all persons and organizations.	Technical	Mapping if needed	YES	Mapping if needed	YES
12	1.3.6.1.4.1.12559.11.10.1.3.1.42.32	epSOSDocumentCode	LOINC	2.16.840.1.113883.6.1	June 2010	Defines to which category the document belongs to : summary, prescription, or dispensation.	Technical	Mapping if needed	YES	Mapping if needed	YES
13	1.3.6.1.4.1.12559.11.10.1.3.1.42.2	epSOSDoseForm	EDQM	1.3.6.1.4.1.12559.11.10.1.3.1.44.1	2010	The Value Set is used for the pharmaceutical dose form. Required for ePrescriptions and optional for medication summaries	Medical	Mapping if needed	YES	Mapping if needed	YES
14	1.3.6.1.4.1.12559.11.10.1.3.1.42.33	epSOSEntityNamePartQualifier	EntityNamePartQualifier	2.16.840.1.113883.5.43	913-20091020	The Value Set is used to define the type of prefixes or suffixes to be added (if any) to the patient's name.	Technical	Mapping if needed	YES	Mapping if needed	YES
15	1.3.6.1.4.1.12559.11.10.1.3.1.42.7	epSOSSubstitutionCode	SubstanceAdminSubstitution	2.16.840.1.113883.5.1070	913-20091020	The Value Set is used to indicate if the replacement of a prescribed medication is allowed if it is not available in country where the dispensation is proceeded. It also is used to indicate if the patient needs care in a specific healthcare facility	Medical	NO	NO	Mapping if needed	YES

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								PS		eP/eD	
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17	1.3.6.1.4.1.12559.11.10.1.3.1.42.34	epSOSAdministrativeGender	AdministrativeGender	2.16.840.1.113883.5.1	913-20091020	The gender of a person used for adminstrative purposes (as opposed to clinical gender)	Technical	Mapping if needed	YES	Mapping if needed	YES
18	1.3.6.1.4.1.12559.11.10.1.3.1.42.1	epSOSHealthcareProfessionalRole	ISCO	2.16.840.1.113883.2.9.6.2.7	2008	The Value Set is used to code the HCP's profession (functional code). It is mandatory for each Prescriber (author) in the prescription message and optional for all other Health Care Professionals	Medical	Mapping if needed	YES	Mapping if needed	YES
19	1.3.6.1.4.1.12559.11.10.1.3.1.42.35	IHEActCode	IHEActCode	1.3.5.1.4.1.19376.1.5.3.2	August 2009 (R5)	Thisi is a technical value set which describes what kind of information (immunization, intolerance, instructions) are related to the entry. Describes what the entry is all about. For example describes the purpose of acts, e.g. a comment on another act, to distinguish the act of immunization from the act of treating a patient with a medication	Medical / Technical	Mapping if needed	NO	Mapping if needed	NO
20	1.3.6.1.4.1.12559.11.10.1.3.1.42.36	IHERoleCode	IHERoleCode	1.3.5.1.4.1.19376.1.5.3.3	August 2009 (R5)	It is a set of technical codes defined by IHE to represent certain roles that entities play or are scoped by.	Technical	Mapping if needed	NO	Mapping if needed	NO
21	1.3.6.1.4.1.12559.11.10.1.3.1.42.5	epSOSIllnessesandDisorders	ICD-10	1.3.6.1.4.1.12559.11.10.1.3.1.44.2	2008	The Value Set is used to code illnesess, allergies, syndromes or symptoms the patient suffered in the past or is currently suffering.	Medical	Mapping if needed	YES	NO	NO
22	1.3.6.1.4.1.12559.11.10.1.3.1.42.6	epSOSLanguage	ISO 639-1	1.0.639.1	2001	The Value Set is used to identify the language the document will be written with, as well as the patient's preferred language.	Technical	Mapping if needed	YES	Mapping if needed	YES
23	1.3.6.1.4.1.12559.11.10.1.3.1.42.8	epSOSMedicalDevices	Snomed CT	2.16.840.1.113883.6.96	July 2009	The Value Set is used for describing the patients Medical Devices and implants in the Patient Summary	Medical	Mapping if needed	YES	NO	NO
24	1.3.6.1.4.1.12559.11.10.1.3.1.42.37	epSOSNullFavor	NullFavor	2.16.840.1.113883.5.1008	913-20091020	The Value Set is used for describing why non mandatory elements throughout the entire document are not specified.	Technical	NO	YES	NO	YES
25	1.3.6.1.4.1.12559.11.10.1.3.1.42.3	epSOSPackage	EDQM	1.3.6.1.4.1.12559.11.10.1.3.1.44.1	2010	The Value Set is used to encode the Medicinal product package. Required for prescriptions and optional for medication summaries	Medical	NO	NO	Mapping if needed	YES
26	1.3.6.1.4.1.12559.11.10.1.3.1.42.38	epSOSPersonalRelationship	RoleCode	2.16.840.1.113883.5.111	913-20091020	The Value Set is used (optionally) to code the type of contact relationship between a person and the patient.	Technical	Mapping if needed	YES	NO	NO
27	1.3.6.1.4.1.12559.11.10.1.3.1.42.9	epSOSPregnancyInformation	LOINC	2.16.840.1.113883.6.1	June 2010	The Value Set is used to determine the patient's delivery date estimation	Medical	Mapping if needed	YES	NO	NO
28	1.3.6.1.4.1.12559.11.10.1.3.1.42.10	epSOSProcedures	Snomed CT	2.16.840.1.113883.6.96	July 2009	The Value Set is used to encode procedures in the section "Surgical Procedures prior past six months" in the patient Summary	Medical	Mapping if needed	YES	NO	NO
29	1.3.6.1.4.1.12559.11.10.1.3.1.42.11	epSOSReactionAllergy	Snomed CT	2.16.840.1.113883.6.96	July 2009	The Value Set is used to code the clinical manifestations of allergy developed by patient in the "Allergies and Other Adverse Reactions" section of the patient Summary (along with epSOSActiveIngredient)	Medical	Mapping if needed	YES	NO	NO

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30	1.3.6.1.4.1.12559.11.10.1.3.1.42.30	epSOSResolutionOutcome	Snomed CT	2.16.840.1.113883.6.96	July 2009	The Value Set is used to describe the clinical status of a problem outcome.	Medical	Mapping if needed	YES	NO	NO
31	1.3.6.1.4.1.12559.11.10.1.3.1.42.39	epSOSRoleClass	RoleClass	2.16.840.1.113883.5.110	913-20091020	The Value Set is used to make the distinction between an emergency contact and the next of kin for a patient.	Technical	Mapping if needed	YES	NO	NO
32	1.3.6.1.4.1.12559.11.10.1.3.1.42.12	epSOSRouteofAdministration	EDQM	1.3.6.1.4.1.12559.11.10.1.3.1.44.1	2010	The Value Set is used to encode the (optional) "Route of Administration" for a given medication in the Prescription section and the Medication Summary.	Medical	NO	NO	Mapping if needed	YES
33	1.3.6.1.4.1.12559.11.10.1.3.1.42.26	epSOSSections	LOINC	2.16.840.1.113883.6.1	June 2010	The Value Set is used for naming the sections used by the three CDA-documents.	Technical	Mapping if needed	YES	Mapping if needed	YES
34	1.3.6.1.4.1.12559.11.10.1.3.1.42.13	epSOSSeverity	Snomed CT	2.16.840.1.113883.6.96	July 2009	The Value Set is used for all Problems and Allergies in the Patient Summary to indicate the severity of the problem (or Allergy)	Medical	Mapping if needed	YES	NO	NO
35	1.3.6.1.4.1.12559.11.10.1.3.1.42.14	epSOSSocialHistory	Snomed CT	2.16.840.1.113883.6.96	July 2009	The Value Set is used to code the different elements of the patient's social history	Technical	Mapping if needed	YES	NO	NO
36	1.3.6.1.4.1.12559.11.10.1.3.1.42.15	epSOSstatusCode	Snomed CT	2.16.840.1.113883.6.96	July 2009	The Value Set is used to encode the clinical status of both problems and concerns within the Patient Summary document	Technical	Mapping if needed	YES	NO	NO
37	1.3.6.1.4.1.12559.11.10.1.3.1.42.40	epSOSTelecommAddress	AddressUse	2.16.840.1.113883.5.1119	913-20091020	The Value Set is used (optionally) to code the usage of a phone number, email and all telecommunications. Can be used for all phone numbers mentioned in the three CDA-documents.	Technical	NO	YES	NO	YES
38	1.3.6.1.4.1.12559.11.10.1.3.1.42.41	epSOSTimingEvent	TimingEvent	2.16.840.1.113883.5.139	20050824	The Value Set is used (optionally) to encode the frequency of intake of medications in the Medication Summary as well as the Prescription.	Technical	Mapping if needed	YES	Mapping if needed	YES
39	1.3.6.1.4.1.12559.11.10.1.3.1.42.16	epSOSUnits	UCUM Unified Code for Units of Measure	2.16.840.1.113883.6.8	July 2009	The Value Set is used to provide values with an international unit codification to quantify it.	Technical	NO	NO	NO	NO
40	1.3.6.1.4.1.12559.11.10.1.3.1.42.17	epSOSUnknownInformation	Snomed CT	2.16.840.1.113883.6.96	July 2009	The Value Set is used when information about a problem or allergy is unknown or where there are no problems or allergies. This element is actually used to confirm explicitely the absence of information.	Medical	Mapping if needed	YES	NO	NO
41	1.3.6.1.4.1.12559.11.10.1.3.1.42.42	epSOSURL	URLScheme	2.16.840.1.113883.5.143	913-20091020	The Value Set is used (in this very case) to make the distinction between telephone numbers and e-mails in contact information for all roles involved. Also for coding any other forms of communication.	Technical	NO	NO	NO	NO

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42	1.3.6.1.4.1.12559.11.10.1.3.1.42.28	epSOSVaccine	Snomed CT	2.16.840.1.113883.6.96	July 2009	The Value Set is used to identify the patient's vaccinations in the Patient Summary	Medical	Mapping if needed	YES	NO	NO
43	1.3.6.1.4.1.12559.11.10.1.3.1.42.43	epSOSObservationInterpretation	ObservationInterpretation	2.16.840.1.113883.5.83	913-20091020	The Value Set is used to classify the result of an observation or a measurement	Technical	NO	NO	NO	NO
44	1.3.6.1.4.1.12559.11.10.1.3.1.42.44	epSOSActSite	ActSite	2.16.840.1.113883.5.1052	913-20091020	The Value Set is used to indicate the body location of a measurement.	Technical	NO	NO	NO	NO
44	1.3.6.1.4.1.12559.11.10.1.3.1.42.45	epSOSMedicalEquipment	Snomed CT	2.16.840.1.113883.6.96	July 2009	The Value Set is used to identify the medical equipment used in various observations or procedures	Medical	NO	NO	NO	NO
44	1.3.6.1.4.1.12559.11.10.1.3.1.42.46	epSOSDisplayLabel	epSOS Display Labels	1.3.6.1.4.1.12559.11.10.1.3.1.44.4	July 2009	The value set is used for identifying the labels and messages used for the epSOS CDA display.	Medical	NO	YES	NO	YES

NOTE: The Value set epSOSObservationInterpretation, epSOSActSite and epSOSMedicalEquipment are not expected to be used within epSOS-I.