Smart Open Services for European Patients

Open eHealth initiative for a European large scale pilot of

Patient Summary and Electronic Prescription

epSOS Architecture and Design

EED DESIGN – Specification

MRO

CDA R2 Implementation Guide

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1 Introduction

This document defines the implementation's rules to be satisfied for claiming the conformance with the MRO Semantic Signifier.

1.1 epSOS Service to be Bound

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1.2 The Standard used for Binding

HL7 CDA Release 2 [CDAR2]

1.3 Related EED Design Documents

No

1.4 Conventions

This section describes the conventions used in this specification.

The conventions used are derived from the US Realm Consolidated[1] CDA specifications [CCDA].

1.4.1 Keywords

The keywords **SHALL, SHOULD, MAY, NEED NOT, SHOULD NOT,** and **SHALL NOT** in this document are to be interpreted as follows

- **SHALL**: an absolute requirement
- **SHALL NOT**: an absolute prohibition against inclusion
- **SHOULD/SHOULD NOT**: best practice or recommendation. There may be valid reasons to ignore an item, but the full implications must be understood and carefully weighed before choosing a different course
- **MAY/NEED NOT**: truly optional; can be included or omitted as the author decides with no implications

The keyword "**SHALL**" allows the use of nullFlavor unless the requirement is on an attribute or the use of nullFlavor is explicitly precluded.

The subject of a conformance verb (keyword) in a top-level constraint is the template itself. In nested constraints, the subject is the element in the

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containing constraint. Top-level constraints are those that begin with a number and are not indented.

1.4.2 Cardinality

The cardinality indicator (0..1, 1..1, 1..*, etc.) specifies the allowable occurrences within a document instance. The cardinality indicators are interpreted with the following format "m…n" where m represents the least and n the most:

- 0..1 zero or one
- 1..1 exactly one
- 1..* at least one
- 0..* zero or more
- 1..n at least one and not more than n

When a constraint has subordinate clauses, the scope of the cardinality of the parent constraint must be clear. In the next figure, the constraint says exactly one participant is to be present. The subordinate constraint specifies some additional characteristics of that participant.

Figure 1: Constraints format – only one allowed

```
1. SHALL contain exactly one [1..1] participant
     a. This participant SHALL contain exactly one [1..1] @typeCode="LOC"
        (CodeSystem: 2.16.840.1.113883.5.90 HL7ParticipationType)
```

In the next figure, the constraint says only one participant "like this" is to be present. Other participant elements are not precluded by this constraint.

Figure 2: Constraints format – only one like this allowed

```
1. SHALL contain exactly one [1..1] participant such that it
     a. SHALL contain exactly one [1..1] @typeCode="LOC" (CodeSystem:
        2.16.840.1.113883.5.90 HL7ParticipationType)
```

1.4.3 Vocabulary Conformance

The templates in this document use terms from several code systems. These vocabularies are defined in various supporting specifications and may be maintained by other bodies, as is the case for the LOINC® and SNOMED CT® vocabularies.

Note that value-set identifiers (e.g., ValueSet `2.16.840.1.113883.1.11.78 Observation Interpretation (HL7)` **DYNAMIC** do not appear in CDA submissions; these identifiers tie the conformance requirements of an implementation guide to the appropriate code system for validation.

Value-set bindings adhere to HL7 Vocabulary Working Group best practices, and include both a conformance verb (**SHALL**, **SHOULD**, **MAY**, etc.) and an indication of **DYNAMIC** vs. **STATIC** binding. Value-set constraints can be **STATIC**, meaning that they are bound to a specified version of a value set, or **DYNAMIC**, meaning that they are bound to the most current version of the value set. A simplified

constraint, used when the binding is to a single code, includes the meaning of the code, as follows.

Figure 3: Binding to a single code

1. … code/@code="11450-4" Problem List (CodeSystem: 2.16.840.1.113883.6.1 LOINC).

The notation conveys the actual code (`11450-4`), the code's displayName (Problem List), the OID of the codeSystem from which the code is drawn (2.16.840.1.113883.6.1), and the codeSystemName (LOINC).

HL7 Data Types Release 1 requires the codeSystem attribute unless the underlying data type is "Coded Simple" or "CS", in which case it is prohibited.

The `displayName` and the `codeSystemName` attributes are

1. Mandatory, for the coded elements that are subject of the epSOS transformation process
2. recommended, for all the other coded elements

The above example would be properly expressed as follows.

Figure 4: XML expression of a single-code binding

```
<code code="11450-4" codeSystem="2.16.840.1.113883.6.1"/>

<!-- or -->

<code code="11450-4" codeSystem="2.16.840.1.113883.6.1"
      displayName="Problem List"
      codeSystemName="LOINC"/>
```

A full discussion of the representation of vocabulary is outside the scope of this document; for more information, see the HL7 V3 Normative Edition 2010[2] sections on Abstract Data Types and XML Data Types R1.

There is a discrepancy in the implementation of translation code versus the original code between HL7 Data Types R1 and the convention agreed upon for this specification. The R1 data type requires the original code in the root. This implementation guide specifies the standard code in the root, whether it is original or a translation. This discrepancy is resolved in HL7 Data Types R2.

Figure 5: Translation code example

[2] HL7 Version 3 Interoperability Standards, Normative Edition 2010. http://www.hl7.org/memonly/downloads/v3edition.cfm - V32010

```
<code code='206525008'
      displayName='neonatal necrotizing enterocolitis'
      codeSystem='2.16.840.1.113883.6.96'
      codeSystemName='SNOMED CT'>
   <translation code='NEC-1'
      displayName='necrotizing enterocolitis'
      codeSystem='2.16.840.1.113883.19'/>
</code>
```

1.4.4 Containment Relationships

Containment constraints between a section and its entry are indirect in this guide, meaning that where a section asserts containment of an entry, that entry can either be a direct child or a further descendent of that section.

For example, in the following constraint:

1. **SHALL** contain at least one [1..*] **entry** (CONF:8647) such that it
    a. **SHALL** contain exactly one [1..1] **Advance Directive Observation** (templateId:2.16.840.1.113883.10.20.22.4.48)

the Advance Directive Observation can be a direct child of the section (i.e., section/entry/AdvanceDirectiveObservation) or a further descendent of that section (i.e., section/entry/…/AdvanceDirectiveObservation). Either of these are conformant.

All other containment relationships are direct, for example:

1. **SHALL** contain exactly one [1..1] **templateId/@root**="2.16.840.1.113883.10.20.22.2.21"

The templateId must be a direct child of the section (i.e., section/templateId).

1.4.5 Null Flavor

Information technology solutions store and manage data, but sometimes data are not available: an item may be unknown, not relevant, or not computable or measureable. In HL7, a *flavor* of null, or nullFlavor, describes the reason for missing data.

Any **SHALL** conformance statement may use nullFlavor, unless the attribute is required or the nullFlavor is explicitly disallowed. **SHOULD** and **MAY** conformance statement may also use nullFlavor.

Figure 6: Attribute required

1. **SHALL** contain exactly one [1..1] **code/@code**="11450-4" Problem List (CodeSystem: LOINC 2.16.840.1.113883.6.1)
   or
2. **SHALL** contain exactly one [1..1] **effectiveTime/@value**

Figure 7: Allowed nullFlavors when element is required (with xml examples)

1. **SHALL** contain at least one [1..*] id
2. **SHALL** contain exactly one [1..1] code
3. **SHALL** contain exactly one [1..1] effectiveTime

```
<entry>
  <observation classCode="OBS" moodCode="EVN">
    <id nullFlavor="NI"/>
    <code nullFlavor="OTH">
      <originalText>New Grading system</originalText>
    </code>
    <statusCode code="completed"/>
    <effectiveTime nullFlavor="UNK"/>
    <value xsi:type="CD" nullFlavor="NAV">
      <originalText>Spiculated mass grade 5</originalText>
    </value>
  </observation>
</entry>
```

Figure 8: nullFlavor explicitly disallowed

1. **SHALL** contain exactly one [1..1] **effectiveTime**.
   a. **SHALL NOT** contain [0..0] nullFlavor).

1.5 Terms and Definitions

MRO Medication Related Overview

1.6 Status of this Binding

The binding as defined in this document is a normative binding. All epSOS participating nations piloting the above mentioned epSOS services MUST conform this specification

2 The Binding

This section describes constraints that apply to the HCER document within the scope of this implementation guide.

This guide specifies only the constrains that are specific for this kind of document (e.g. the HCER).

Common implementation rules are described in the [epSOS_CM_IG] epSOS Common Modules Implementation Guide

Header constraints specific to this document are described in the section below

Body constraints specific to this document are described in the section 2.2 Body

2.1 Header

This section specifies ONLY the header's conformance rules specific of this document.

Common epSOS header implementation rules are described in the [epSOS_CM_IG] epSOS Common Modules Implementation Guide.

2.1.1.1templateId

Conformant documents must carry at least the document-level `templateId` asserting conformance with specific constraints of epSOS MRO.

1. **SHALL** contain exactly one [1..1] **templateId** such that it
   a. **SHALL** contain exactly one [1..1] **@root**='1.3.6.1.4.1.12559.11.10.1.3.1.1.5'

Figure 9: epSOS MRO ClinicalDocument/templateId example

```
<!-- conforms to epSOS MRO requirements -->
<templateId root='1.3.6.1.4.1.12559.11.10.1.3.1.1.5'/>
```

2.1.1.2code

In accordance with the CDA spcification, the `ClinicalDocument/code` element must be present and specifies the type of the clinical document. epSOS MRO requires the document type code 56445-0 `" Medication Summary"`.

1. **SHALL** contain exactly one [1..1] **code**
   a. This code **SHALL** contain exactly one [1..1] **@code**="56445-0"

b. This code **SHALL** contain exactly one [1..1] **@root**=" 2.16.840.1.113883.6.1"
c. This code **SHALL** contain exactly one [1..1] **@displayName**

Figure 10: epSOS HCER ClinicalDocument/code example

```
<code codeSystem="2.16.840.1.113883.6.1"
      codeSystemName="LOINC" code="56445-0"
      displayName="Medication Summary"/>
```

2.1.1.3documentationOf/serviceEvent

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

1. **SHALL** contain exactly one [1..1] **documentationOf**
   a. This documentationOf **SHALL** contain exactly one [1..1] **serviceEvent**
      i. This serviceEvent **SHALL** contain exactly one [1..1] **@classCode**="PCPR" Care Provision (CodeSystem: `HL7ActClass 2.16.840.1.113883.5.6`)
      ii. This serviceEvent **SHALL** contain exactly one [1..1] **effectiveTime**
         1. This effectiveTime **SHALL** contain exactly one [1..1] **low**
         2. This effectiveTime **SHALL** contain exactly one [1..1] **high**
      iii. This serviceEvent **SHOULD** contain zero or more [0..*] **performer**
   1. `serviceEvent/performer` represents the healthcare providers involved in the current or pertinent historical care of the patient. Preferably, the patient's key healthcare providers would be listed, particularly their primary physician and any active consulting physicians, therapists, and counselors
      2. Such performers **SHALL** contain exactly one [1..1] **@typeCode**="PRF" Participation physical performer (CodeSystem: `HL7ParticipationType 2.16.840.1.113883.5.90`)
      3. Such performers **MAY** contain zero or one [0..1] **assignedEntity**.
         a. This assignedEntity **SHALL** contain at least one [1..*] **id**
   b. This assignedEntity **MAY** contain zero or one [0..1] **code**
   4. Such performers **SHALL** contain exactly one [1..1] **functionCode**

a. This functionCode **SHALL** be selected from the ValueSet epSOSHealthcareProfessionalRoles 1.3.6.1.4.1.12559.11.10.1.3.1.42.1 **DYNAMIC**

2.1.1.4participant

The `participant` element identifies other supporting participants, including parents, relatives, caregivers, insurance policy holders, guarantors, and other participants related in some way to the patient.

A supporting person or organization is an individual or an organization with a relationship to the patient. A supporting person who is playing multiple roles would be recorded in multiple particpants (e.g., emergency contact and next-of-kin)

This roles is used in this document for recording the Patient's contacts .

1. **MAY** contain zero or more [0..*] **participant**
   a. Such participants, if present, **SHALL** have an associatedPerson element under participant/associatedEntity.
   b. when participant/@typeCode is IND, associatedEntity/@classCode **SHALL** be selected from ValueSet epSOSRoleClass 1.3.6.1.4.1.12559.11.10.1.3.1.42.39 **DYNAMIC**.
   c. when participant/@typeCode is IND, associatedEntity/code **SHALL** be selected from ValueSet epSOSPersonalRelationship 1.3.6.1.4.1.12559.11.10.1.3.1.42.39 **DYNAMIC**

Figure 11: Participant example for a supporting person

```
<participant typeCode='IND'>
  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.2.4'/>
  <associatedEntity classCode='NOK'>
    <addr>
      <streetAddressLine>Promenade des Anglais 111</streetAddressLine>
      <city>Lyon</city>
      <postalCode>69001</postalCode>
      <country>FR</country>
    </addr>
    <telecom value='tel:(+33)555-20036' use='WP'/>
    <associatedPerson>
      <name>
        <given>Martha</given>
        <family>Mum</family>
      </name>
    </associatedPerson>
  </associatedEntity>
</participant>
```

2.1.1.4.1 Generic Participant: Preferred HP / HealthCare Provider to contact

The participant role is also used for identifying the primary care provider intended in this context as the preferred HP to be contacted. In fact a Health Professional in country B may need a contact that knows the patient.

1. **SHALL** contain exactly one [1..1] **participant** such that it
   a. **SHALL** contain exactly one [1..1] **@typeCode**="IND" Individual (CodeSystem: HL7ParticipationType 2.16.840.1.113883.5.90)
   b. **SHALL** contain exactly one [1..1] **functionCode**="PCP" Primary Care Physician (CodeSystem: HL7ParticipationType 2.16.840.1.113883.5.90)
   c. **SHALL** contain exactly one [1..1] **associatedEntity/@classCode**="PRS" Provider (CodeSystem: HL7ParticipationType 2.16.840.1.113883.5.90).
      i. This associatedEntity **SHALL** contain exactly one [1..1] **associatedPerson OR scopingOrganization**

Figure 12: Participant example for the preferred HP to contact

```
<participant typeCode='IND'>
  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.2.4'/>
  <functionCode code="PCP" codeSystem="2.16.840.1.113883.5.88"/>
  <associatedEntity classCode='PRS'>
    <addr>
      <streetAddressLine>Karl Strasse</streetAddressLine>
      <city>Freiberg</city>
      <postalCode>09599</postalCode>
      <country>DE</country>
    </addr>
    <telecom value='tel:(+49)761-11110000' use='WP'/>
    <associatedPerson>
      <name>
        <given>Arzt</given>
        <family>Guter</family>
      </name>
    </associatedPerson>
  </associatedEntity>
</participant>
```

Figure 13: Participant example for the Provider Organization to contact

```
<participant typeCode='IND'>
  <functionCode code="PCP" codeSystem="2.16.840.1.113883.5.88"/>
  <associatedEntity classCode='PRS'>
        <addr>
         <country>TR</country>
         <city>Ankara</city>
         <postalCode>06100</postalCode>
         <streetAddressLine>Mithatpaşa Cad. No:3 Sıhhiye</streetAddressLine>
        </addr>
        <telecom use="WP" value="tel:+903125851900"/>
    <scopingOrganization>
        <name>T.C. Sağlık Bakanlığı</name>
        <telecom use="WP" value="tel:+903125851900"/>
        <addr>
         <country>TR</country>
         <city>Ankara</city>
         <postalCode>06100</postalCode>
         <streetAddressLine>Mithatpaşa Cad. No:3 Sıhhiye</streetAddressLine>
        </addr>
    </scopingOrganization >
  </associatedEntity>
</participant>
```

2.2 Body

The epSOS MRO supports sections requiring coded clinical statements.

The implementation rules to be applied for the below mentioned section templates – even when IHE PCC templates are referred - are those defined in the epSOS Common Modules Implementation Guide[3] [epSOS_CM_IG].

1. **SHALL** contain exactly one [1..1] **component**
    a. **SHALL NOT** include the **component/nonXMLBody**
    b. **SHALL** contain exactly one [1..1] **component/structuredBody**
    c. the **component/structuredBody SHALL** conform to the section constraints below
        i. **SHALL** contain exactly one [1..1] Medication Summary Section (templateId: 1.3.6.1.4.1.12559.11.10.1.3.1.2.3).
        ii. **SHALL** contain exactly one [1..1] Allergies and Other Adverse Reactions Section (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.13).
        iii. **MAY** contain zero or one [0..1] Active Problems Section (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.6).
        iv. **MAY** contain zero or one [0..1] Immunizations Section (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.23).
        v. **MAY** contain zero or one [0..1] Coded Social History Section (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.16.1).
        vi. **MAY** contain zero or one [0..1] Pregnancy History Section (templateId: 1.3.6.1.4.1.19376.1.5.3.1.1.5.3.4).
        vii. **MAY** contain zero or one [0..1] Coded Vital Signs Section (templateId: 1.3.6.1.4.1.19376.1.5.3.1.3.16.1).

[3] Even for those cases where IHE PCC templates are indicated, epSOS imposes additional constrains usually related to vocabulary bindings. This should be formally expressed in the conformance rules by means of epSOS section template IDs (specialization of the IHE PCC templates), instead of referring the generic templates (i.e. the IHE PCC ones).
This more formal approach will be applied in future version of this specification. (please note that this does not imply necessarily any change on the document implementation)

3 References

3.1 Normative References

[epSOS_CM_IG] epSOS Common Modules Implementation Guide

[CDAR2] CDA® Release 2 (http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7)

3.2 Non-Normative References

[CCDA] US Realm Consolidated[4] CDA specifications
(http://www.hl7.org/implement/standards/product_brief.cfm?product_id=258)

3.3 Open Source Solutions (non-normative)

Not applicable

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