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MITRE TECHNICAL REPORT

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Lightweight C32 Implementation

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Abstract

The existing Healthcare Information Technology Standards (HITSP) standard for exchanging continuity of care data, the C32 Specification, is open to many interpretations. Differing interpretations can result in interoperability issues. The L32, or "Lightweight C32 Implementation," introduces the first Extensible Markup Language (XML) schema for the C32 Specification. The L32 is not a new standard, rather, it captures a machine-interpretable implementation of the C32 specification and adds additional constraints to make it easier to produce and consume C32 instances. The L32 can be used to create and validate fully-conformant C32 XML documents. This document is intended to guide developers using the L32 with a high level overview, as well as provide a detailed reference for each of the data elements. The L32 was developed to help accelerate health data interoperability by assisting those implementing the C32 standard.

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1 Introduction

1.1 Document Purpose

This document is intended to guide developers using the L32, or "Lightweight C32 Implementation," to implement the Healthcare Information Technology Standards Panel (HITSP) C32[1] Specification for exchanging continuity of care data. L32 is a World Wide Web Consortium (W3C) Extensible Markup Language (XML) schema implementation of the C32 Specification. This document provides a high level overview of the L32, as well as a detailed reference for each of the L32 data elements. Furthermore, it describes the benefits of using the L32 over the C32 Specification, documents the design decisions and assumptions made in developing the L32, and gives suggested workflows for using the L32 XML schema and related Extensible Stylesheet Language (XSL) style sheets.

1.2 Document Organization

This document serves as an overall reference for the L32. Section 2 provides much of the background information, including a description of the C32 and L32, and the benefits of L32. It also addresses the development process and design principles used. Section 3 includes an overview of the L32 with information such as the terminology used and information about the inclusion of xsi:type attributes. There is a detailed look at the L32 pre-processor and post-processor as well as sample workflows for producing or consuming an L32 instance. Finally, Section 4 is the L32 implementation reference which includes element-level descriptions, along with the path for each element, the data type, and any fixed values or enumerated lists.

[1] www.HITSP.org

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2 Background

2.1 What is the C32?

The HITSP C32 is a standard that addresses how to exchange continuity of care information in XML format and is based on the HL7[2] Clinical Document Architecture (CDA)[3]. The CDA provides the architecture for the HL7 Continuity of Care Document (CCD). The C32 specifies additional constraints on an HL7 CCD. This C32 ancestry is shown in Figure 2-1.

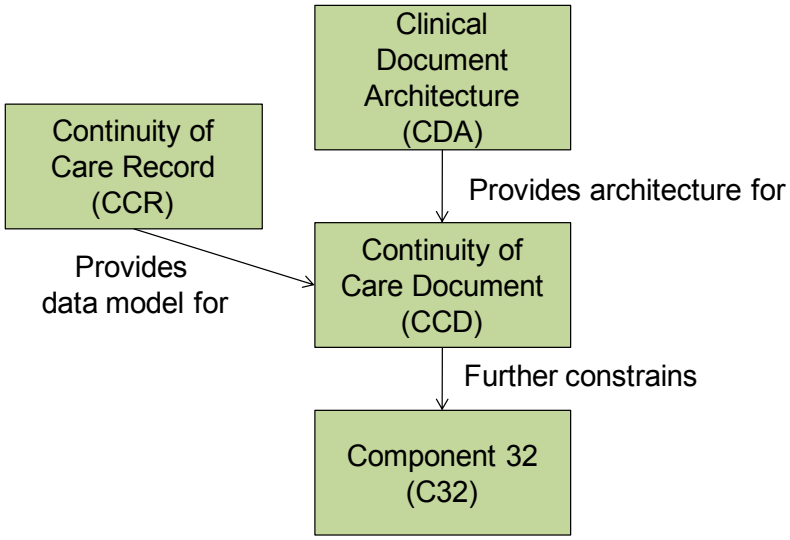

Figure 2-1 C32 Ancestry

2.2 What is the L32?

The L32, or "Lightweight C32 Implementation," is intended as one consistent, machine-interpretable implementation of the HITSP C32 specification. The L32 was developed to aid those implementing the C32 standard and accelerate health data interoperability. L32 creates a constrained C32 in that it greatly reduces the number of options available to someone generating a C32 document and constrains module contents to allow only relevant data elements. The L32 comes packaged as a set of XML schema files and two XML style sheets. The style sheets are used to add and remove some XML type declarations. The XML type declarations make the XML schema structure easier to understand and better able to capture the C32 constraints. This L32 package can be used to create and validate fully-conformant C32 XML documents (called C32 instances).

2.3 Why the L32?

The major goal of the L32 is to accelerate health data interoperability for The Department of Veterans Affairs (VA), The Department of Defense (DoD), and their external partners by making it easier for software developers to generate, validate, and consume C32 instances. To help achieve this goal, we created L32 as the first XML schema for the C32 standard. The L32 does

[2] www.hl7.org
[3] https://www.hl7.org/store/index.cfm

not introduce a new standard. Rather, it captures a machine-interpretable implementation of the C32 specification and adds additional constraints to make it easier to produce and consume C32 instances.

So, what are the differences in L32 that make it easier to use than the C32 specification? Below we describe several differences that make it easier for software developers to write code to produce and consume C32 instances using L32..

1. **XML Schema**- The development of an XML Schema means less hand-written code for implementers. Today, each developer interprets the specification and writes custom code, therefore, interpretations are likely to vary. The XML schema provides a single interpretation of the C32 specification.

2. **XML Tools**- With an XML schema, commercial off-the-shelf (COTS) and open source XML tools may be used to easily generate an application programming interface (API) and validate XML instances. The auto-generated API can be used to create and consume a C32 instance. This results in less custom code.

3. **Machine Interpretable**- The existing C32 standard is built upon the CDA and CCD specifications. Therefore, when trying to implement the C32, one must examine hundreds of pages across at least three different documents to grasp all that a C32 instance encompasses. The L32 provides a single source, the XML schema, where one is able to determine the structure of a C32 instance, which elements are optional versus required, and what data occurs once or is repeatable. The C32 is a human readable specification. The L32 is a machine interpretable XML schema. This is a key difference.

4. **C32 Document Structure**- The L32 XML Schema provides guidance for the overall structure of a C32 instance. This does not exist within the C32 specification. The C32 provides small snippets of sample XML, but it is not clear how and where each module fits to create a C32 instance.

5. **Strong Data Typing**- Strong data typing eases the process of validating data structure and content. The L32 XML Schema implements strong data typing wherever possible. Data types may be used to require that data adhere to a specified pattern or that codes be validated against an enumerated list of permitted values. For example, the L32 healthcare provider role code has an enumerated list data type that has only the three allowable code values specified in the C32 Specification (i.e., Consulting Provider, Primary Care Provider, or Referring Provider).

6. **Built-in Data Types**- The XML Schema for the L32 uses built-in XML data types, as opposed to user-defined data types, whenever possible. Built-in data types are supplied as part of the International W3C XML Schema standard. Using built-in data types should result in less custom code and code that is more likely to be interoperable.

7. **Remove Ambiguity**- The L32 removes ambiguity present in the C32 where possible. For example, the C32 specifies that a procedure can be recorded in an “act”, “observation”, or “procedure” element. The L32 requires that data in the Procedures Module be encoded in the “procedure” element.

Collectively, these differences lower the barrier to adoption of the C32 Specification. In other words, they make it easier for software developers to build and maintain code to produce and consume C32 documents. Less custom code and easier to understand specifications implies lower lifecycle costs. It also implies a larger pool of software development talent available, as the skills needed to implement the L32 are more generally available (i.e., knowledge of XML

schema and common XML tools rather than in depth knowledge of the contents of the C32, CCD and CDA documents).

2.4 L32 Development Process

The process of creating the L32 began with an in depth review of the existing standards on which the L32 is based, namely the C32, CCD, and CDA. The L32 is based mainly on C32 version 2.3[4], as this was the latest "Recognized" version at the time of development. However, we referenced C32 version 2.4, as well as the C80 and C83, when seeking further clarification on the specification. We used the <oXygen/> XML Editor[5] to develop both the XML Schemas and the XSL transforms.

Development of the L32 was executed in two phases, with a testing cycle at the conclusion of each phase. During Phase 1 we implemented the following C32 modules: Person Information, Information Source, Results, Conditions, and Medications, as well as the root "Clinical Document" element. The remaining modules, excluding Comments, were implemented in Phase 2. The implementation order was determined to correspond with both our testing use case and coverage of the 38 data types identified by the National Quality Foundation Health Information Technology Experts Panel (NQF HITEP)[6].We omitted the Comments module from the L32 implementation to avoid adding considerable complexity to the schema and because comments may already be included in the narrative portion of each module.

We tested the L32 Schema to verify its conformance to the existing C32 Specification, as well as to demonstrate the advantages of using the schema. Our team performed tests to show that instances created with the L32 XML schema could be validated with both the National Institute of Standards and Technology (NIST) validator[7] and the Laika Electronic Health Record (EHR) testing tool[8]. We used insights from the Phase 1 testing results to refactor the initial design of the schema and incorporated the resulting changes into the second phase of development. Our Phase 2 testing results helped us to identify and remove inconsistencies in the schema.

2.5 Design Principles

The goal of the L32 is to facilitate the creation, consumption and exchange of clinical documents adhering to the C32 specification. To this end, the L32 was developed based on the "80-20 rule"—cover 80 percent of the use cases with 20 percent of the effort. To the greatest extent possible, the L32 simplifies the C32 instance structure, and populates and defines many of the codes and much of the metadata required in a C32 document. We have collected information across multiple references including the C32 and CCD and embodied it in an XML Schema to allowing software developers to focus on implementation rather than multiple document investigation. The L32 errs on the side of ease of implementation and chooses simplicity over broad applicability. The L32 also requires the use of coded data in each of the C32 modules to promote machine interpretability. That is, each C32 Module included in the document body of an L32 has a <text> element that may contain unstructured data and an <entry> element that may contain coded information. The L32 requires that each C32 Module included in the document

[4] http://hitsp.org/ConstructSet_Details.aspx?&PrefixAlpha=4&PrefixNumeric=32
[5] http://www.oxygenxml.com/
[6] http://www.qualityforum.org/
[7] http://xreg2.nist.gov/cda-validation/index.html
[8] http://projectlaika.org

body of an L32 must populate at least one <entry> element. Free and/or structured text may also be included in the <text> element of each module, but this is not strictly enforced.

2.6 Conventions and Design Decisions

To maintain usability of the schema and resolve design trade-offs, the L32 adheres to certain conventions. This section captures key design decisions as well as some naming and capitalization conventions.

1. **Implement All Constraints from C32, Required Constraints from CCD**- The L32 implements all of the data elements described in the C32, except those in the Comments module and two elements from the Information Source module (*10.04 Reference Document ID* and *10.05 Reference Document URL*). The L32 implements all constraints from the C32 that an XML Schema is able to capture. The L32 also includes any required elements from the CCD ('SHALL' constraints). „SHOULD' and „MAY' constraints from the CCD were included when deemed essential upon consultation with clinical experts. Implementation specifics of each of the elements are given in Section 4: L32 Implementation Reference.
2. **CDA Subset**- The L32 Schema defines a subset of the CDA. In other words, all L32 documents are valid CDA documents and can be validated with the CDA schema.
3. **Namespace**- The L32 Schema is defined in the HL7 V3 namespace. This is required to ensure that L32 documents are valid CDA documents.
4. **Validation with existing tools**- The L32 was developed to pass both Laika and NIST validation.
5. **Naming**- Where possible, data element types in the schema are named for the specific elements they correspond to in the C32 instead of the generic names from the CDA. For example, the element that defines the C32 Allergies module is of type "Allergies" and not "Component4".
6. **Capitalization**- We implemented a capitalization convention for the naming of new data elements and data element types in the L32. Data element types in the schema begin with an uppercase letter while element names begin with a lowercase letter. Where we reused data types from the CDA schema, we retained their original syntax.
7. **XML Primitive Data Types**- Where possible, the L32 uses XML schema primitive data types such as string and integer instead of the CDA types or defining our own data type. Using commonly accepted types where possible increases the chance of interoperability and compatibility with COTS tools.
8. **Specific Data Types for Coded Values**- In the CDA, most coded values are implemented with the „CD' (concept descriptor) data type. The L32 defines specific types for most coded values, defines the accepted coding system, and enumerates allowable values (where available). For example, the „Gender' type is defined using the HL7 coding set and enumerates the three allowable values for that attribute.

3 L32 Overview

3.1 General L32 Description

As previously mentioned, L32 stands for "Lightweight C32 Implementation" and is intended to capture a single, consistent, machine-interpretable implementation of the C32 Specification. L32 implements all of the C32 modules except the Comments module. Thus, the L32 implementation includes the C32 modules listed in Table 3-1.

Table 3-1. C32 Modules Implemented in L32

C32 Module
Person Information
Language Spoken
Support
Healthcare Provider
Insurance Provider
Allergies and Drug Sensitivity
Conditions
Medications
Pregnancy
Information Source
Advance Directives
Immunizations
Vital Signs
Results
Encounters
Procedures

The only C32 module not included in the L32 Implementation is the Comments Module. The description of the Comments Module in the C32 specification had inconsistencies, therefore it was not implemented. The C32 states that the comments may be included in some sections that do not include a narrative section, or structurally do not allow a comments block. Also, integrating comments into those modules that do allow it would add considerable complexity to the schema and would diminish the schema's usability. Even without implementing the

Comments module, notes can be included in the narrative portion of each component module. The Comments module provides a link back to the corresponding narrative, which was deemed unnecessary.

3.2 L32 File Structure

The L32 XML Schema includes a number of XML Schema Document (XSD) files. L32_ClinicalDocument.xsd contains the DocumentRoot data type, which is the model for an L32 Clinical Document. All of the root level elements are included here, along with their data types.

If an element at the root level of the Clinical Document represents a C32 Module, then we stored the data type definition in a separate XSD file. For example, because the Person Information, Healthcare Provider, and Support C32 modules are located at the root level, we define these modules in corresponding files named L32_PersonInformation.xsd L32_HealthcareProvider.xsd, and L32_Support.xsd, respectively.

The root level of a Clinical Document also includes a <component> element. This <component> element contains other components, each of which represents a C32 module that is part of the document body. We defined an abstract data type, called L32Module for the C32 document body modules. We then extended the abstract L32Module data type with a derived data type specific to each module. We use the xsi:type attribute to specify one of the module data types derived from the L32Module abstract type. Each data type representing a C32 module is contained in its own file, named after the module. The C32 component module files follow the naming convention L32_ModuleName.xsd. For example, L32_Allergies.xsd, L32_Conditions.xsd, and L32_Medications.xsd are the XSD files that contain the corresponding complex data types "Allergies," "Medications," and "Conditions" for the component level modules.

The L32 XML Schema defines an L32_Datatypes.xsd file which contains declarations for the common data types that are used across many of the module files. There is a CDA_Datatypes.xsd that defines data types from the CDA that are required by the C32 Specification. Finally, L32_SDTC_Extension.xsd contains the element declarations that HITSP has used in extending the HL7 CDA.

3.3 L32 Terminology

The following is a description of the terminology used in this document when referring to the L32 and its parts.

L32- a "Lightweight C32 Implementation," or W3C XML Schema implementation of the C32 specification.

L32 Package- a C32 XML Schema (compliant with the international W3C XML Schema standard) and two XML style sheets used as a pre-processor and post-processor, respectively.

L32 Pre-Processor and L32 Post-Processor- two style sheets that are eXtensible Stylesheet Language (XSL) transformations. These style sheets are used to add and remove xsi:type attributes as described in sections 3.5 and 3.6.

L32 Instance- a C32 conformant instance, sometimes referred to as an "L32 Document." An L32 Instance does not contain xsi type attributes to identify each content module, and the instance can be validated with the CDA schema, NIST, and Laika. To validate an L32 Instance with the L32 XML Schema, the instance must be translated back to a "Native L32 Instance." If

the L32 Instance was created with the L32 XML Schema and associated XML style sheet, it can be easily translated back to a Native L32 Instance.

Native L32 Instance- an L32 Instance which includes the xsi:type declarations. The xsi:type declarations make the XML schema more straight-forward (easier to understand) and better able to capture the C32 constraints. A Native L32 Instance can be validated with the L32 XML schema. It is not, however, a valid CDA, CCD, or C32 document. Therefore, it will not validate with NIST Schematron or Laika until the appropriate XML style sheet is used to remove the xsi:type declarations.

3.4 Use of xsi:type attributes for each C32 Module

When designing the L32 XML Schema, one goal was to constrain the contents of each C32 module to make it easier for software developers to understand the C32, validate C32 instances, and implement software to produce and consume C32 instances. The existing CDA XML schema is highly recursive. For example, the <entryRelationship> element includes an <observation> element, which then includes another <entryRelationship>, and so on. Each CDA complex type includes the elements one may use in all of the C32 modules combined. This can be quite confusing, as it is difficult to understand which elements need to be included in which module. Rather than include many unnecessary elements, the L32 schema takes the approach of using xsi:type attributes to label each module. This allows the XML schema to specify which elements are allowed in each module. For example, the L32 enforces a constraint that the "substanceAdministration" element may appear only in the "Medications" module and not in any module as is allowed in the CDA schema. Therefore, by inserting the xsi:type attributes, the L32 XML schema is easier to understand and better captures intended C32 constraints.

Our initial design approach was to create a complex type for each C32 module. According to the C32 Specification, the content modules are each contained within a <component> element. Originally, the design idea was to define a complex type for each component, and that type would include only the data needed for the specified module. However, we discovered that it is not possible, using XML Schema, to define the same <component> element with different complex types.

Our solution for this problem was to include xsi:type attributes. By including this attribute in the <component> element, we are able to create a complex type for each C32 module. The L32 XML Schema defines the <component> element with an abstract type called L32Module. Each component module extends the abstract L32Module type with a complex type that includes the elements needed for that specific module. For example, there is a Conditions, Medications, Allergies, etc. type for each of the corresponding modules. A Native L32 Instance will define each component as <component xsi:type="ModuleName">. The xsi:type attribute identifies which derived type (C32 module) is intended. By including the xsi:type attribute, the instance can be validated using our L32 XML Schema.

We have developed very simple XSL style sheets that allow users to add and remove the xsi:type attributes. By using our pre-processor, the xsi:type attributes can be easily inserted into an L32 Instance and validated with our schema. The post-processor will remove xsi:type attributes (by commenting them out) to produce a C32 conformant instance. A detailed overview of the L32 pre-processor and post-processor XSL style sheets follow.

3.5 Pre-Processor

The pre-processor consists of an XSL style sheet that takes an L32 instance (C32 conformant) and inserts xsi:type attributes for each component. This is shown graphically in Figure 3-1 below. The C32 instance on the right has a template id that identifies each component. The XSL transform looks for the hardcoded template id to determine which module it is, then inserts an xsi:type attribute with a value that identifies each module. This is depicted in the Native L32 document on the left. This document is now ready to be validated with the L32 XML Schema. The XSL transform is straightforward and the style sheet code can be viewed in Figure 3-2 below.

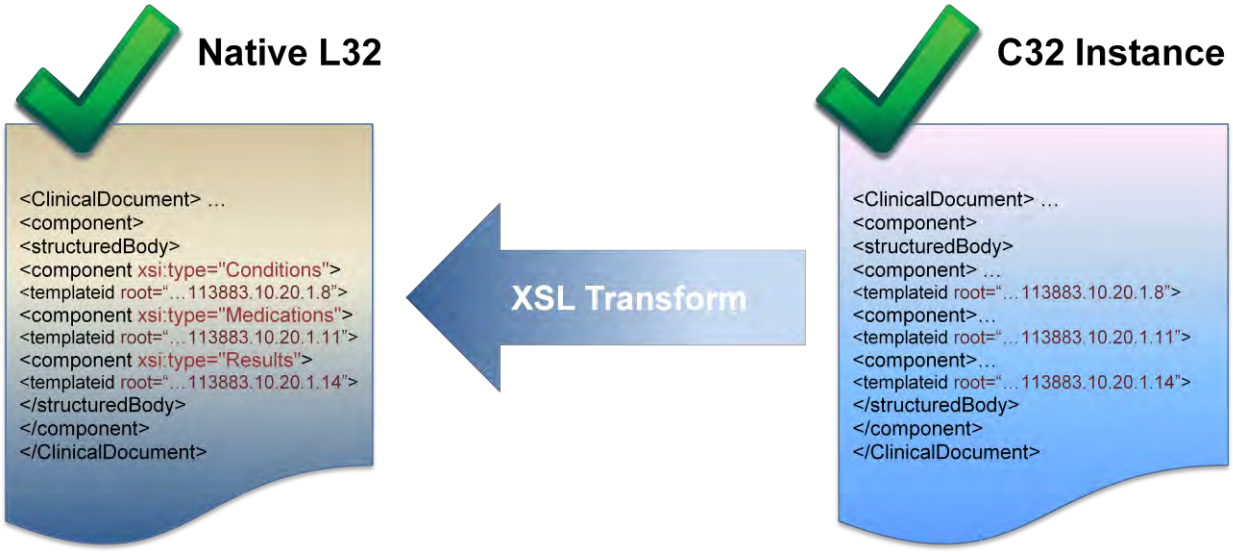

Figure 3-1. Graphical Representation of the L32 Pre-Processor

3.6 Post-Processor

The post-processor consists of an XSL style sheet that takes a native L32 instance (not C32 conformant) and removes the xsi:type attributes from each component by placing it in a comment. See Figure 3-3 for a graphical view of this process of transforming from a Native L32 instance to a L32 instance which is C32 conformant. The result is a C32 conformant L32 instance. The XSL transform is straightforward and the code can be viewed in Figure 3-4.

```
<xsl:stylesheet
   xmlns:C32="urn:hl7-org:v3"
   xmlns:xsl="http://www.w3.org/1999/XSL/Transform"
   xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
   version="2.0">

  <xsl:template match="@*|node()">
      <xsl:copy>
         <xsl:apply-templates select="@*|node()"/>
      </xsl:copy>
   </xsl:template>

   <xsl:template match="//C32:structuredBody/C32:component" >
      <xsl:copy>

         <xsl:if test="C32:section/C32:templateId/@root='2.16.840.1.113883.10.20.1.9'">
            <xsl:attribute name="xsi:type">InsuranceProviders</xsl:attribute>
         </xsl:if>

         <xsl:if test="C32:section/C32:templateId/@root='2.16.840.1.113883.10.20.1.2'">
            <xsl:attribute name="xsi:type">Allergies</xsl:attribute>
         </xsl:if>

         <xsl:if test="C32:section/C32:templateId/@root='2.16.840.1.113883.10.20.1.11'">
            <xsl:attribute name="xsi:type">Conditions</xsl:attribute>
         </xsl:if>

         <xsl:if test="C32:section/C32:templateId/@root='2.16.840.1.113883.10.20.1.8'">
            <xsl:attribute name="xsi:type">Medications</xsl:attribute>
         </xsl:if>

         <xsl:if test="C32:section/C32:templateId/@root='2.16.840.1.113883.10.20.1.1'">
            <xsl:attribute name="xsi:type">AdvanceDirectives</xsl:attribute>
         </xsl:if>

         <xsl:if test="C32:section/C32:templateId/@root='2.16.840.1.113883.10.20.1.6'">
            <xsl:attribute name="xsi:type">Immunizations</xsl:attribute>
         </xsl:if>

         <xsl:if test="C32:section/C32:templateId/@root='2.16.840.1.113883.10.20.1.16'">
            <xsl:attribute name="xsi:type">VitalSigns</xsl:attribute>
         </xsl:if>

         <xsl:if test="C32:section/C32:templateId/@root='2.16.840.1.113883.10.20.1.14'">
            <xsl:attribute name="xsi:type">Results</xsl:attribute>
         </xsl:if>
```

Figure 3-2. L32 Pre-Processor Style Sheet Code

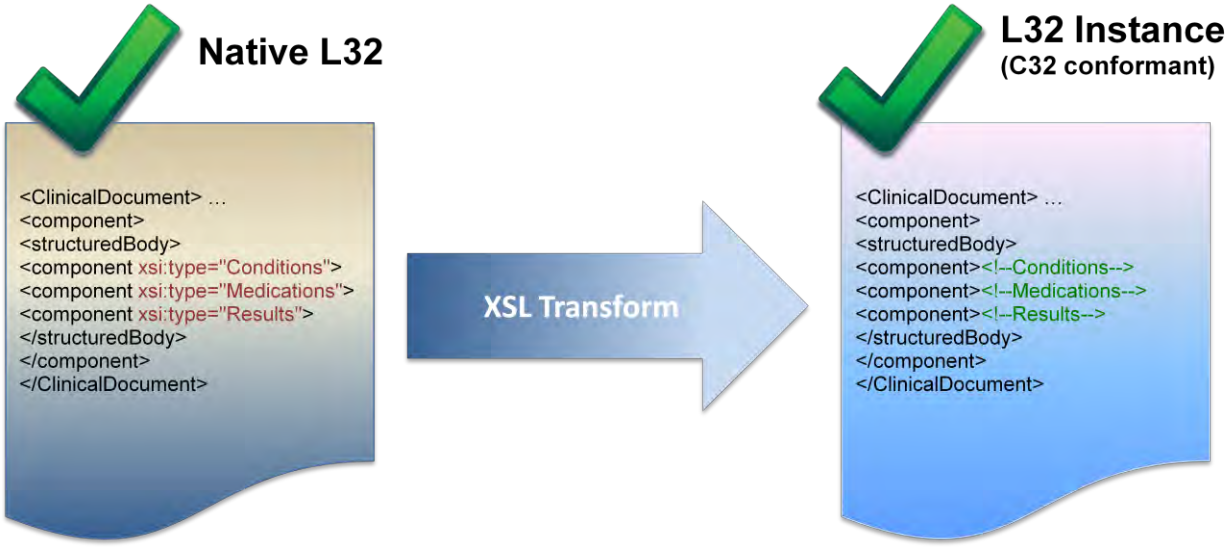

Figure 3-3. Graphical Representation of the L32 Post-Processor

```
<xsl:stylesheet
  xmlns:L32="urn:hl7-org:v3"
  xmlns:xsl="http://www.w3.org/1999/XSL/Transform"
  xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
  version="2.0">

  <xsl:template match="@*|node()">
    <xsl:copy>
      <xsl:apply-templates select="@*|node()"/>
    </xsl:copy>
  </xsl:template>

  <xsl:template match="//L32:component/@xsi:type">
    <xsl:comment>
      <xsl:value-of select="."/>
    </xsl:comment>
  </xsl:template>
</xsl:stylesheet>
```

Figure 3-4. L32 Post-Processor Style Sheet Code

3.7 Sample Workflow

This section provides sample workflows to aid software developers in producing an L32 instance, as well as consuming an L32 instance. Please see Figure 3-5 and Figure 3-6, along with more detailed descriptions below.

3.7.1 Produce

The workflow in Figure 3-5 shows the steps taken to produce an L32 instance. First, a Native L32 Instance is created from existing health data using software that maps this data into a format that complies with the L32 XML Schema. This instance includes the xsi:type attributes to identify each component module. Next, the Native L32 Instance is validated using the L32 XML Schema. Finally, our simple post-processor XSL style sheet removes the xsi:type attributes, resulting in a C32 conformant L32 instance that is ready for use or exchange.

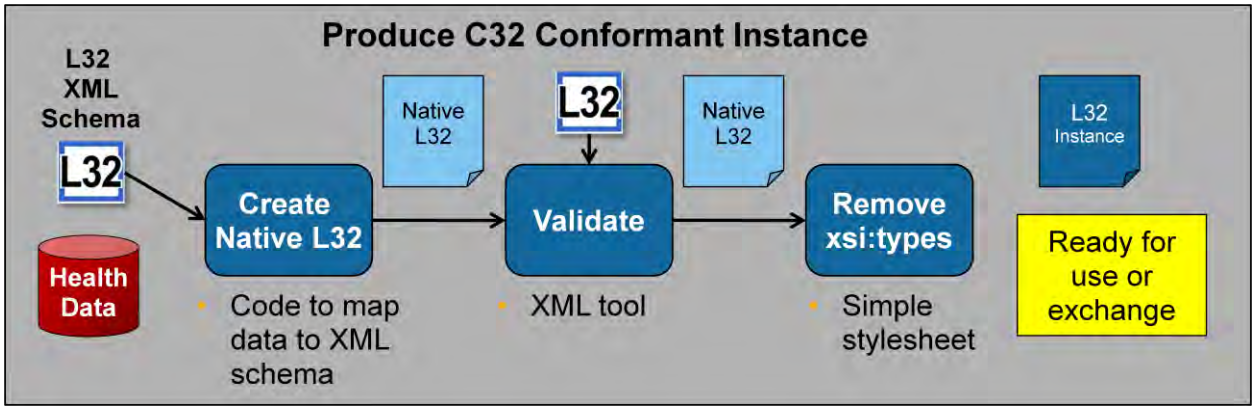

Figure 3-5. Workflow for Producing an L32 Instance

3.7.2 Consume

The workflow in Figure 3-6 shows the steps taken to consume an L32 instance. First, an existing L32 Instance (C32 conformant, no xsi:type attributes) is received. Our simple pre-processor XSL style sheet is used to insert xsi:type attributes to identify each component module, resulting in a Native L32 Instance. This Native L32 Instance can be validated using the L32 XML Schema. Once validated, a Native L32 Instance is ready to store or display.

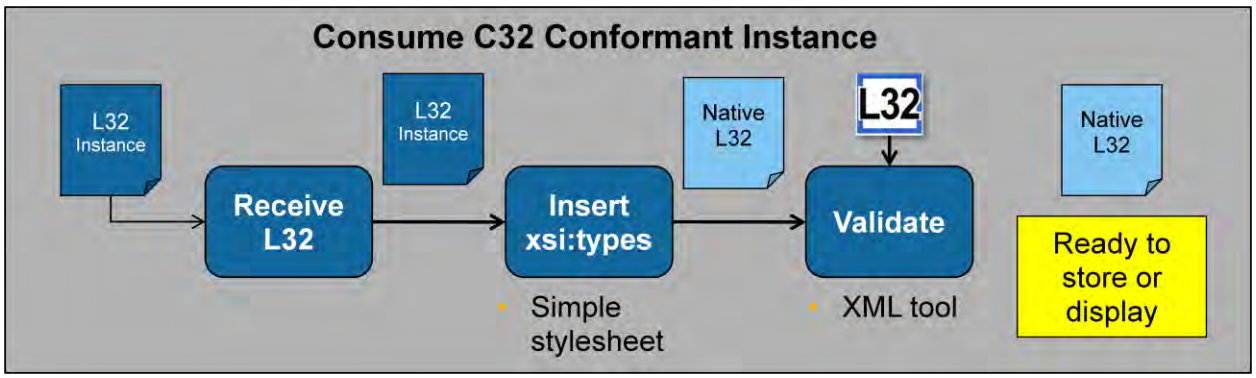

Figure 3-6. Workflow for Consuming an L32 Instance

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4 L32 Implementation Reference

This section provides an element-level reference for the L32 XML schema. The reference includes a section for each of the C32 modules. Within each module section, we have provided a subsection containing an overall description of the module, along with information about each element in the module.

For each element, we provide the element name, xPath expression, element type, element description, and any fixed or enumerated values that pertain to the element. We also indicate if the element is optional, and whether it can be repeated. If not specified, the element is assumed to be mandatory and occurring only once. Here is the format we use:

Element Name (optional indicator, repeatable indicator)
Path: The xPath expression for the placement of the element within the document.
Type: If the element is a complex type, the name of the data type is indicated here. If it is not complex, it is noted as an "Anonymous Type."
Description: A description of the element. Where available, the descriptions are pulled directly from the C32 Specification. If the L32 diverges from the C32 standard or constrains the standard further, we provide additional notes in the description about the L32-specific implementation.
Enumerated values: If there is an enumerated set of values, we provide a table that includes all of the options.
Fixed value: If values for the element are hard-coded in the schema we list those here.

Finally, there is a section that includes descriptions of all of the L32 data types. These are the common data types that are used across all modules. Also, there is a CDA data types section that summarizes the data types that we needed to reuse from the CDA. For an overall schema diagram of each section or module, please see the associated figure in Appendix A.

4.1 Clinical Document (Root)

4.1.1 Description

This section includes information at the root level of the Clinical Document, including a number of root level C32 modules. The Person Information module is located within the <recordTarget> element. The Information Source module is contained within the <author> element. The Support module is found in the <participant> element, and the Healthcare Provider module is located in the <documentationOf> element. Other document level data is present, such as the document id, code, title, and timestamp. Please see section 4.1.2 for further details about each element included at the root level.

4.1.2 Root Elements

4.1.2.1 Document Type Id

Path: ClinicalDocument/typeId
Type: RootTypeId
Description: This is a technology-neutral explicit reference to a particular CDA release. L32 uses the POCD_MT000040 version of the CDA.

Fixed value: typeId/@root = “2.16.840.1.113883.1.3”
typeId/@extension = “POCD_HD000040”

4.1.2.2 Document Template Id

Path: ClinicalDocument/templateId

Type: RootTemplateId

Description: The value of the root attribute of this element provides a unique identifier for the template(s) applied to this clinical document. L32 is derived from the CCD and HITSP/C32 but only makes explicit reference to the C32 template identifier.

Fixed value: templateId/@root = “2.16.840.1.113883.3.88.11.32.1”
templateId/@assigningAuthorityName = “HITSP/C32”

4.1.2.3 Document Id

Path: ClinicalDocument/id

Type: InstanceIdentifier

Description: The unique instance identifier for a clinical document.

4.1.2.4 Document Code

Path: ClinicalDocument/code

Type: RootCode

Description: This code specifies the particular kind of this clinical document. The CCD specifies the value of this element.

Fixed value: code/@code = “34133-9”
code/@displayName = ”Summarization of episode note”
code/@codeSystemName = "LOINC"
code/@codeSystem = "2.16.840.1.113883.6.1"

4.1.2.5 Document Title (optional)

Path: ClinicalDocument/title

Type: xs:string

Description: Title of the document. Clinical documents commonly do not have a title and are referred to by the value in code/@displayName.

4.1.2.6 Document Timestamp

Path: ClinicalDocument/effectiveTime

Type: DateTime

Description: This represents the time the document was created and should be precise to the seconds. It should be represented in YYYYMMDDhhmmss format.

4.1.2.7 Confidentiality Code

Path: ClinicalDocument/confidentialityCode

Type: ConfidentialityCode

Description: The confidentiality setting for this document.

Enumerated values:

@code	@displayName
N	Normal
R	Restricted
V	Very Restricted

Fixed value: @codeSystem = “2.16.840.1.113883.5.25”

4.1.2.8 Language Code

Path: ClinicalDocument/languageCode

Type: LanguageCode

Description: This represents the language this document is written in.

Fixed value: languageCode/@code = “en-US”

4.1.2.9 Record Target/Person Information

Path: ClinicalDocument/recordTarget

Type: PersonInformation

Description: This element is a container for all the demographic/administrative information regarding the patient that this document refers to. See Section 4.2 Person Information for further specification.

4.1.2.10 Information Source (repeatable)

Path: ClinicalDocument/author

Type: InformationSource

Description: This element contains describes the author(s) of the document. See Section 4.11 Information Source for further specification.

4.1.2.11 Custodian

Path: ClinicalDocument/custodian

Type: Custodian

Description: An organization who is in charge of maintaining the information of this service object.

4.1.2.12 Support

Path: ClinicalDocument/participant

Type: Support

Description: Represents the patient's sources of support, such as immediate family, relatives and guardian, at the time the summarization is generated. See Section 3.3 for further specification.

4.1.2.13 Healthcare Provider (optional)

Path: ClinicalDocument/documentationOf

Type: Healthcare Provider

Description: This element is a container for information regarding the healthcare providers involved in the current of pertinent historical care of the patient. See Section 1.4 for further specification.

4.1.2.14 Document Body

Path: ClinicalDocument/component

Type: DocumentBody

Description: This element is a container for all of the L32 Modules (eg. Results, Conditions, etc.) See the section for each particular module for more information.

4.2 Person Information

Specification Reference: C32 Section 2.2.1.3
CCD 2.5 Patient

4.2.1 Person Information Module Description

This module provides the name, address, contact information, personal identification information, ethnic and racial affiliation and marital status of the person who is the subject of this document.

4.2.2 Person Information Elements

4.2.2.1 Person Id

Path: ClinicalDocument/recordTarget/patientRole/id

Type: InstanceIdentifier

Description: An identifier that uniquely identifies the individual to which the document refers and connects that document to the individual's personal health record. Potential security risks associated with use of SSN or driver's license for this element suggest that these should not be used routinely

4.2.2.2 Person Address

Path: ClinicalDocument/recordTarget/patientRole/addr

Type: PersonAddress

Description: The current address of the individual to which the document refers. Unlike C32, the L32 does not allow multiple addresses. The primary address shall be specified and shall include a use attribute to indicate if the address is a home, work, or vacation address.

4.2.2.3 Person Phone/Email/URL (repeatable)

Path: ClinicalDocument/recordTarget/patientRole/telecom

Type: PhoneEmail

Description: A telephone number, E-mail address or other locator for a resource mediated by telecommunication equipment. The patient may designate one of more of these contact numbers as the preferred methods of contact and temporary items can be entered for use on specific effective dates.

4.2.2.4 Person Name

Path: ClinicalDocument/recordTarget/patientRole/patient/name

Type: PersonName

Description: The individual to whom the HITSP Summary Documents Using HL7 Continuity of Care Document (CCD) Component refers. Multiple names are allowed to retain birth name, maiden name, legal names and aliases as required

4.2.2.5 Gender

Path: ../patientRole/patient/administrativeGenderCode

Type: Gender

Description: Gender is used to refer to administrative sex rather than biological sex and therefore should easily be classified into female and male. It is included in the document for purposes of linking to insurance information and other patient identification linkages and the value chosen by the patient should reflect the information under which any insurance or financial information will be filed, as well as the same information given to other healthcare providers, institutions or health data exchange networks.

Enumerated values:

@code	@displayName
M	Male
F	Female
UN	Undifferentiated

Fixed value: code/@codeSystemName = " HL7 AdministrativeGenderCode”

code/@codeSystem = 2.16.840.1.113883.5.1"

4.2.2.6 Person Date of Birth

Path: ../patientRole/patient/birthTime

Type: DateTime

Description: The date and time of the birth of the individual to which this document refers. The date of birth is typically a key patient identifier variable and used to enable computation of age at the effective date of any other data element. It is assumed to be unique and fixed throughout the patient's lifetime

4.2.2.7 Marital Status (optional)

Path: ../patientRole/patient/maritalStatusCode

Type: MaritalStatus

Description: A value representing the domestic partnership status of a person. Maritals status is important in determining insurance eligibility and other legal arrangements surrounding care. Marital status often changes during a patient's lifetime so the data should relate to the effective date of the patient data object and not entered with multiple values like an address or contact number. This element should only have one instance reflecting the current status of the individual at the time the document is produced. Former values might be part of the personal and social history.

Enumerated values:

@code	@displayName
A	Annulled
D	Divorced
I	Interlocutory
L	Legally Separated
M	Married
P	Polygamous
S	Never Married
T	Domestic Partner
W	Widowed

Fixed value: code/@codeSystemName = " HL7 MaritalStatusCode”
code/@codeSystem = " 2.16.840.1.113883.5.2"

4.2.2.8 Religious Affiliation (optional)

Path: ../patientRole/patient/religiousAffiliationCode

Type: ReligiousAffiliation

Description: Religious affiliation is the religious preference of the person and it recorded at the discretion of the patient. It is coded using the HL7 Religious Affiliation vocabulary.

Fixed value: code/@codeSystemName = “ReligiousAffiliation”
code/@codeSystem = " 2.16.840.1.113883.5.1076"

4.2.2.9 Race (optional)

Path: ../patientRole/patient/raceCode

Type: Race

Description: Race is usually a single valued term that may be constant over that patient's lifetime. The coding of race is aligned with public health and other Federal reporting standards of the CDC and the Census Bureau. Typically the patient is the source of the content of this element. However, the individual may opt to omit race. In this event, some healthcare organizations that receive the document may choose to enter an observed race as their current practice for manual registration. Such organization observed race data should be differentiated from patient sourced data in the patient's registration summary. The L32 limits race

options to the five minimum values determined by the Office of Management and Budget.

Enumerated values:

@code	@displayName
1004-1	American Indian or Alaska Native
2028-9	Asian
2058-6	Black or African American
2076-8	Native Hawaiian or Other Pacific Islander
2106-3	White
2131-1	Other Race

Fixed value: code/@codeSystemName = " CDC Race and Ethnicity”
code/@codeSystem = " 2.16.840.1.113883.6.238"

4.2.2.10 sdtc Race Extension (optional, repeatable)

Path: ../patientRole/patient/sdtc:raceCode

Type: Race

Description: The raceCode extension allows for multiple races to be reported for a patient. See Race element for enumerated values.

4.2.2.11 Ethnicity (optional)

Path: ../patientRole/patient/ethnicGroupCode

Type: Ethnicity

Description: Ethnicity extends the concept of race, and is reported at the discretion of the patient. The CDC Race and Ethnicity vocabulary is used. The L32 limits ethnicity options to two minimum values determined by the Office of Management and Budget.

Enumerated values:

@code	@displayName
2135-2	Hispanic or Latino
2186-5	Not Hispanic or Latino

Fixed value: code/@codeSystemName = "CDC Race and Ethnicity”
code/@codeSystem = "2.16.840.1.113883.6.238"

4.2.2.12 Guardian (optional, repeatable)

Path: ../patientRole/patient/guardian

Type: GuardianContact

Description: Please see the Support Module for constraints applicable to this module.

4.2.2.13 Language Spoken (repeatable)

Path: ../patientRole/patient/languageCommunication

Type: LanguageSpoken

Description: Please see the Language Spoken Module in section 1.3 of this document for constraints applicable to this module. Please see A.2 Person Information.

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4.3 Language Spoken

Specification Reference: C32 Section 2.2.1.4
CCD None

4.3.1 Module Description

This module describes the primary and secondary languages of communication for the patient. Language is identified as spoken, written, or understood, but proficiency is not recorded. The default language is English. Languages spoken are recorded using the <languageCommunication> element within the Person Information module. Please see A.2 Person Information.

4.3.2 Language Spoken Elements

4.3.2.1 Language (repeatable)

Path: ../recordTarget/patientRole/patient/languageCommunication

Type: LanguageSpoken

4.3.2.2 Language Spoken Template Identifier

Path: ../recordTarget/patientRole/patient/languageCommunication/templateId

Type: Anonymous Type

Description: Identifies this as the Language Spoken module.

Fixed Value: templateId/@root = "2.16.840.1.113883.3.88.11.32.2"

4.3.2.3 Language Code

Path: ..recordTarget/patientRole/patient/languageCommunication/languageCode

Type: LanguageOfCommunication

Description: A code that conveys the language of communication. Sign language is treated as a separate language for the purpose of this specification. This value set is defined by IETF RFC 3066. The code is composed of a combination of a 2 or 3 letter language code (defined by ISO 639-2), followed by a hyphen, followed by a 2 letter country code (defined by ISO 3166). There is no OID for the combined code.

4.3.2.4 Mode of Communication (optional)

Path: ../recordTarget/patientRole/patient/languageCommunication/modeCode

Type: ModeOfCommunication

Description: Indicates a specific mode of communication (expressing or receiving written, verbal, or signed communication). The codes for the <modeCode> element come from the HL7 LanguageAbilityMode vocabulary. Mode codes shall be appropriate to the type of language. Thus English, as spoken in the U.S. should use the code en-US and should

only use mode codes for written and verbal communications. On the other hand, American Sign Language would be represented using the code sgn-US, and would only use mode codes for signed communication.

Enumerated values:

@code	@displayName
ESGN	Expressed signed
ESP	Expressed spoken
EWR	Expressed written
RSGN	Received signed
RSP	Received spoken
RWR	Received written

Fixed value: code/@codeSystemName = "LanguageAbilityMode”
code/@codeSystem = "2.16.840.1.113883.5.60"

4.3.2.5 Patient Preference (optional)

Path: ../recordTarget/patientRole/patient/languageCommunication/preferenceInd

Type: Patient Preference

Description: Indicates the patient preference for use of that language for communication. The @value specifies a boolean value of true or false.

4.4 Support

Specification Reference: C32 Section 2.2.1.5
CCD 3.3 Support

4.4.1 Module Description

This module represents the patient's sources of support at the time that the summarization is generated. Support information includes immediate family, relatives, a guardian, next of kin, caregivers and support organizations. Key support contacts relative to healthcare decisions should be included.

4.4.2 Support Elements

4.4.2.1 Support (optional, repeatable)

Path: ClinicalDocument/participant

Type: Support

Description: With the exception of guardians, supporting persons or organizations are represented using the <participant> element in the header of the <ClinicalDocument>.

Fixed value: ClinicalDocument/participant/@typeCode = “IND”

4.4.2.2 Support Template Identifier

Path: ClinicalDocument/participant/templateId

Type: Anonymous Type

Description: Identifies this as the Support module.

Fixed value: templateId/@root = “2.16.840.1.113883.3.88.11.32.3”

4.4.2.3 Date

Path: ClinicalDocument/participant/time

Type: DateTime

Description: The period over which the support is provided.

4.4.2.4 Support Contact

Path: ClinicalDocument/participant/associatedEntity

Type: SupportContact

Description: This includes contact information such as the contact type, relationship, address, phone number, email, and name. The Contact Type represents the type of support provided. This can include immediate emergency contacts, next of kin, family relations, guardians, and agents and is filled in using the HL7 RoleClass vocabulary.

Enumerated values: Contact Type values for Support Contact Type

associatedEntity/@classCode	Description
AGNT	A person that can act on behalf of the patient
CAREGIVER	A person responsible for the primary care of a patient at home
ECON	An entity to be contacted in the event of an emergency
NOK	An individual designated for notification as the next of kin for a given entity
PRS	Links two people in a personal relationship

4.4.2.5 Support Contact Relationship

Path: ClinicalDocument/participant/associatedEntity/code

Type: ContactRelationship

Description: Identifies the relationship of the contact person to the individual for which this document component refers. All codes are enumerated in Contact Relationship tab of the SummaryRecordDataContentSpecification file.

Fixed value: code/@code = string

code/@displayName = string

code/@codeSystemName = "RoleCode”

code/@codeSystem = "2.16.840.1.113883.5.111"

4.4.2.6 Support Contact Address (repeatable)

Path: ClinicalDocument/participant/associatedEntity/addr

Type: Address

Description: The address of the contact individual or organization providing support to the individual for which this document is produced.

4.4.2.7 Support Contact Phone / Email / URL (repeatable)

Path: ClinicalDocument/participant/associatedEntity/telecom

Type: PhoneEmail

Description: A telephone number, e-mail address, or other locator for the contact individual or organization providing support to the individual for which this document is produced.

4.4.2.8 Support Contact Name

Path: ClinicalDocument/participant/associatedEntity/ associatedPerson/name

Type: PersonName

Description: The name of the individual or organization providing support to the individual for which this document is produced.

4.4.2.9 Guardian (optional, repeatable)

Path: ClinicalDocument/recordTarget/patientRole/patient/guardian

Type: GuardianContact

Description: The guardian relationship is encoded using a <guardian> element in the Person Information module.

Fixed value: guardian/@classCode = "GUARD" (Guardian of a ward)

4.4.2.10 Guardian Template Identifier

Path: ClinicalDocument/recordTarget/patientRole/patient/guardian/templateId

Type: Anonymous Type

Description: Identifies this as the Support module.

Fixed value: templateId/@root = "2.16.840.1.113883.3.88.11.32.3"

4.4.2.11 Guardian Contact Relationship

Path: ClinicalDocument/recordTarget/patientRole/patient/guardian/code

Type: ContactRelationship

Description: See description and fixed values above in the Support Contact Relationship element.

4.4.2.12 Guardian Contact Address (repeatable)

Path: ClinicalDocument/recordTarget/patientRole/patient/guardian/addr

Type: Address

Description: See details above in the Support Contact Address element.

4.4.2.13 Guardian Contact Phone / Email / URL (repeatable)

Path: ClinicalDocument/recordTarget/patientRole/patient/guardian/telecom

Type: PhoneEmail

Description: See details above in the Support Contact Phone / Email / URL element.

4.4.2.14 Guardian Contact Name

Path: ../recordTarget/patientRole/patient/guardian/guardianPerson/name

Type: PersonName

Description: See details above in the Support Contact Name element.

4.5 Healthcare Provider

Specification Reference: C32 Section 2.2.1.6
CCD 3.17 Healthcare Providers

4.5.1 Module Description

This module represents the healthcare providers involved in the current or pertinent historical care of the patient. At a minimum, the patient's key healthcare providers should be listed, particularly their primary physician and any active consulting physicians, therapists, and counselors. Relevant care providers during the summarization period are represented as ClinicalDocument /documentationOf /serviceEvent / performer. Providers listed in this module may be referred to by the Conditions Module to link a condition to the treating provider or providers.

4.5.2 Healthcare Provider Elements

4.5.2.1 Timestamp

Path: ClinicalDocument/ documentationOf/serviceEvent/effectiveTime

Type: DateRange

Description: This represents the time range being summarized. It contains <low> and <high> elements with a @value attribute represented in YYYYMMDDhhmmss format.

4.5.2.2 Provider (repeatable)

Path: ClinicalDocument/documentationOf/serviceEvent/performer

Type: Anonymous Type

Description: The relevant care providers during the summarization period. This element is a container for all of the healthcare provider information.

Fixed value: serviceEvent/@classCode = "PCPR"
performer/@typeCode = "PRF"

4.5.2.3 Healthcare Provider Module Template Id

Path: ../performer/templateId

Type: Anonymous Type

Description: The value of the root attribute of this element provides a unique identifier for the template(s) applied to this module of the clinical document.

Fixed value: templateId/@root = "2.16.840.1.113883.3.88.11.32.4"

4.5.2.4 Provider Role Coded (optional)

Path: ../performer/functionCode

Type: ProviderRoleCoded

Description: Provider role uses a coded value to classify providers according to the role they play in the healthcare of the patient and comes from a very limited set of values. The purpose of this data element is to express the information

often required during patient registration, identifying the patient's primary care provider, the referring physician or other consultant involved in the care of the patient.

Enumerated values:

@code	@displayName
CP	Consulting Provider
PP	Primary Care Provider
RP	Referring Provider

Fixed value: code/@codeSystemName = "Provider Role"

code/@codeSystem = "2.16.840.1.113883.12.443"

4.5.2.5 Provider Role Free Text (optional)

Path: ../performer/functionCode/originalText

Type: xs:string

Description: This unstructured text classifies providers according to the role they play in the healthcare of the patient.

4.5.2.6 Date Range

Path: ../performer/time

Type: DateRange

Description: This date range shows the specific time period over which this provider has provided healthcare services to the patient. It contains <low> and <high> elements with a @value attribute represented in YYYYMMDDhhmmss format.

4.5.2.7 Provider Entity

Path: ../performer/assignedEntity

Type: sdtc:ProviderEntity

Description: This element is a container for provider information including name, address, type, email, and phone.

4.5.2.8 Provider Id

Path: ../assignedEntity/id

Type: InstanceIdentifier

Description: The value may be a HIPAA National Provider Identifier.

4.5.2.9 Provider Type (optional)

Path: ../assignedEntity/code

Type: ProviderCode

Description: Provider type classifies providers according to the type of license or accreditation they hold, or the service they provide.

Enumerated values

@code	@displayName
100000000X	Behavioral Health and Social Service Providers
110000000X	Chiropractic Providers
120000000X	Dental Providers
130000000X	Dietary and Nutritional Service Providers
140000000X	Emergency Medical Service Providers
150000000X	Eye and Vision Service Providers
160000000X	Nursing Service Providers
180000000X	Pharmacy Service Providers (Individuals)
200000000X	Allopathic & Osteopathic Physicians
210000000X	Podiatric Medicine and Surgery Providers
220000000X	Respiratory, Rehabilitative and Restorative Service Providers
230000000X	Speech, Language and Hearing Providers
250000000X	Agencies
260000000X	Ambulatory Health Care Facilities
280000000X	Hospitals
290000000X	Laboratories
300000000X	Managed Care Organizations
310000000X	Nursing and Custodial Care Facilities
320000000X	Residential Treatment Facilities
330000000X	Suppliers (including Pharmacies and Durable Medical Equipment)
360000000X	Physician Assistants and Advanced Practice Nursing Providers
370000000X	Nursing Service Related Providers
380000000X	Respite Care Facility

Fixed value: code/@codeSystemName = “ProviderCodes”

code/@codeSystem = “2.16.840.1.113883.6.101”

4.5.2.10 Provider Address (optional)

Path: ../assignedEntity/addr

Type: Address

Description: The mailing address to which written correspondence to this provider should be directed. An address is a collection of parts including street, city, state, and postal code. Country codes shall be recorded using ISO-3166-1 and shall be present for addresses outside of the US.

4.5.2.11 Provider Phone/Email (optional, repeatable)

Path: ../assignedEntity/telecom

Type: PhoneEmail

Description: The use attribute shall contain a telecom use value, and the value attribute can contain a telephone number or email address. The format for a telephone number in international form is: tel:+1-999-999-9999. It uses the 'tel:' URL scheme. Please see IETF/RFC-3966. Represent an extension by appending ';ext=' at the end of the number. An email address uses the 'mailto:' URL scheme. Please see IETF/RFC-2368.

4.5.2.12 Provider Name (optional)

Path: ../assignedEntity/assignedPerson/name

Type: PersonName

Description: The name of the provider. A person name is represented as an optional prefix, given name, family name, and an optional suffix. The use attribute is fixed to L for legal name.

4.5.2.13 Provider's Organization Name (optional)

Path: ../assignedEntity/representedOranization/name

Type: xs:string

Description: The name of the organization with which the provider is affiliated. While providers may be affiliated with more than one organization, this should be the organization affiliated with this person's care.

4.5.2.14 Provider's Patient ID (optional)

Path: ../perfomer/assignedEntity/sdtc:patient/sdtc:id

Type: InstanceIdentifier

Description: The identifier used by this provider to identify the patient's medical record

4.6 Insurance Providers

Specification Reference: C32 Section 2.2.1.7
CCD 3.1 Payers

4.6.1 Module Description

The Insurance Providers Module contains data about the entities or other individuals who may pay for a patient's healthcare. Such entities or individuals may be health insurance plans, other payers, guarantors, parties with financial responsibility, some combination of payers or the patient directly. This module is used to define which entity or combination of entities has any financial responsibility for a patient's care. At a minimum, the patient's pertinent current payment sources should be listed. This data should be included in a L32_Module component tag with an xsi:type="InsuranceProviders" attribute.

4.6.2 Insurance Providers Elements

4.6.2.1 Insurance Providers Module

Path: ClinicalDocument/component/structuredBody/component

Type: InsuranceProviders < L32Module

4.6.2.2 Insurance Providers Template Identifier

Path: ../component/section/templateId

Type: Anonymous Type

Description: Identifies this as the Insurance Providers section.

Fixed Value: templateId/@root = “2.16.840.1.113883.10.20.1.9”

4.6.2.3 Insurance Providers Code

Path: ../section/code

Type: InsuranceProvidersCode

Description: The fixed values for an Insurance Providers section specified by the CCD to indicate section conformance.

Fixed value: code/@code = “48768-6”
code/@displayName = ”Payment Sources”
code/@codeSystemName = "LOINC"
code/@codeSystem = "2.16.840.1.113883.6.1"

4.6.2.4 Insurance Providers Title

Path: ../section/title

Type: xs:string

Description: The section title.

Fixed value: title = ”Insurance”

4.6.2.5 Insurance Providers Text

Path: ../section/text

Type: StrucDoc.Text

Description: The narrative text containing the insurance provider's information.

4.6.2.6 Insurance Provider Entry (optional, repeatable)

Path: ../section/entry/act

Type: PaymentProviderEventEntry

Description: A Payment Provider Event entry is a "Coverage Activity" in CCD which serves to order the payment sources. It includes one or more policy activities.

Fixed value: act/@classCode = "ACT"
act/@moodCode = "DEF"

4.6.2.7 Coverage Activity Template Identifier

Path: ../section/entry/act/templateId

Type: Anonymous Type

Description: Identifies a coverage activity.

Fixed value: templateId/@root = "2.16.840.1.113883.10.20.1.20"

4.6.2.8 Coverage Activity Id

Path: ../section/entry/act/id

Type: InstanceIdentifier

Description: Specifies an id for a coverage act.

4.6.2.9 Coverage Activity Code

Path: ../section/entry/act/code

Type: InsuranceProvidersCode

Description: The fixed values for an Insurance Providers coverage activity section specified by the CCD to indicate section conformance.

Fixed value: code/@code = "48768-6"
code/@displayName = "Payment Sources"
code/@codeSystemName = "LOINC"
code/@codeSystem = "2.16.840.1.113883.6.1"

4.6.2.10 Coverage Act Status Code

Path: ../section/entry/act/statusCode

Type: Anonymous Type

Description: The insurance provider's coverage act status code.

Fixed value: statusCode/@code = “completed”

4.6.2.11 Informant (repeatable)

Path: ../section/entry/act/informant

Type: InformantOrPerformer

Description: The source of information for the insurance provider’s coverage activity. Please see the L32 data types for a description of the contents of InformantOrPerformer.

4.6.2.12 Policy Activity (repeatable)

Path: ../section/entry/act/entryRelationship

Type: PolicyActivity

Description: A container for a "Policy Activity" represented with an act.

Fixed value: entryRelationship/@typeCode = “COMP”

4.6.2.13 Sequence Number (optional)

Path: ../section/entry/act/entryRelationship/sequenceNumber

Type: Anonymous Type

Description: The sequence number serves to prioritize the payment sources. The sequenceNumber element includes a value attribute that is an xs:integer.

4.6.2.14 Policy Activity Act

Path: ../section/entry/act/entryRelationship/act

Type: PolicyActivityAct

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

Fixed value: act/@classCode = “ACT”

act/@moodCode = “EVN”

4.6.2.15 Insurance Provider Template Id (minimum=2, maximum=2)

Path: ../section/entry/act/entryRelationship/act/templateId

Type: Anonymous Type

Description: Indicates conformance to the Insurance Providers Module. Two templateId elements are to be included. There is a CCD and a C32 template identifier.

Fixed value: templateId/@root = "2.16.840.1.113883.10.20.1.26"
templateId/@assigningAuthorityName = CCD

templateId/@root = "2.16.840.1.113883.3.88.11.32.5"
templateId/@assigningAuthorityName = HITSP/C32

4.6.2.16 Group Number

Path: ../section/entry/ act/entryRelationship/act/id

Type: InstanceIdentifier

Description: The policy or group contract number identifying the contract between a health plan sponsor and the health plan. This is not a number that uniquely identifies either the subscriber or person covered by the health insurance. The group or contract number shall be recorded in the extension attribute of the id. The root attribute should be the OID of the assigning authority for the identifier, or a GUID. Implementers should use the same GUID for each instance of the same group or contract number.

4.6.2.17 Health Insurance Type

Path: ../section/entry/act/entryRelationship/act/code

Type: HealthInsuranceTypeCode

Description: The type of health plan covering the individual (HMO, PPO, POS, Medicare Part A/B, etc). The X12N 270/271 Implementation Guide contains the values for this value set. This document is not freely available. Use code PP for self pay or pay by guarantor.

Fixed value: code/@codeSystemName = "X12N-1336"

code/@codeSystem = "2.16.840.1.113883.6.255.1336"

4.6.2.18 Policy Activity Status Code

Path: ../section/entry/act/entryRelationship/act/statusCode

Type: Anonymous Type

Description: The policy activity status code.

Fixed value: statusCode/@code = "completed

4.6.2.19 Payer

Path: ../section/entry/act/entryRelationship/act/performer

Type: Payer

Description: Payer Information OR Financial Responsibility Party Information including the Health Plan Insurance Information Source Id, Address, Phone, Email, and Name.

Fixed value: performer/@typeCode = "PRF"

4.6.2.20 Effective Date of Financial Responsibility (optional)

Path: ../section/entry/act/entryRelationship/act/performer/time

Type: DateRange

Description: The time span over which the Financial Responsibility Party is responsible for the payment of the patient's healthcare.

4.6.2.21 Payer or Guarantor Information

Path: ../section/entry/act/entryRelationship/act/performer/assignedEntity

Type: Anonymous Type

Description: Contains information about the Payer or Guarantor.

Fixed value: assignedEntity/@classCode = “ASSIGNED”

4.6.2.22 Health Plan Insurance Information Source ID (repeatable)

Path: ../section/entry/act/entryRelationship/act/performer/assignedEntity/id

Type: InstanceIdentifier

Description: The information source identifier corresponds to the RxBIN and RxPCN fields found on pharmacy benefit cards. When a national payer identifier is standardized, it would also go in this field.
The OID for RxBIN is 2.16.840.1.113883.3.88.3.14
The OID for an RxPCN is 2.16.840.1.113883.3.88.3.1 plus the numeric identifier used in the RxBIN.

4.6.2.23 Financial Responsibility Party Type

Path: ../section/entry/act/entryRelationship/act/performer/assignedEntity/code

Type: FinancialResponsibilityPartyType

Description: This data element identifies the type of the financially responsible party. The code attribute contains a value from the HL7 RoleClassRelationshipFormal vocabulary. When the code of the encompassing act is PP, the code attribute value is GUAR or PAT to represent a guarantor or self-paying patient. The code attribute is PAYOR when the code of the encompassing act is other than PP.

Fixed value: code/@codeSystemName = “RoleClass”

code/@codeSystem = “2. 2.16.840.1.113883.5.110”

4.6.2.24 Health Plan Insurance Information Source Address (optional) or Financial Responsibility Party Address

Path: ../section/entry/act/entryRelationship/act/performer/assignedEntity/addr

Type: Address

Description: The official mailing address of the Financial Responsibility Party or Insurance Information Source to which written correspondence is to be directed.

4.6.2.25 Health Plan Insurance Information Source Phone/Email/URL (optional, repeatable) or Financial Responsibility Party Phone/Email/URL

Path: ../entry/act/entryRelationship/act/performer/assignedEntity/telecom

Type: PhoneEmail

Description: A telephone number, e-mail address or other locator for a resource mediated by telecommunication equipment. One data type is used to describe phone numbers, pagers, Email addresses, and URLs. One or more of these contact numbers can be designated as the preferred methods of contact.

4.6.2.26 Financial Responsibility Party Name (optional, repeatable)

Path: ../entryRelationship/act/performer/assignedEntity/assignedPerson/name

Type: PersonName

Description: The name of the financially responsible party.

4.6.2.27 Health Plan Insurance Information Source Name or Financial Responsibility Party Name (optional)

Path: ../entryRelationship/act/performer/assignedEntity/representedOrganization

Type: Organization

Description: The name of the financially responsible party or the name of the entity that is the source of information about the health insurance. This name is not synonymous with a Health Plan Name or a Health Plan. In the context of the X12N 271 transaction, an information source could be the payer, a third party administrator (TPA), a health plan sponsor, or a gateway provider.

4.6.2.28 Member or Subscriber Information

Path: .. /act/entryRelationship/act/participant

Type: MemberOrSubscriberInformation

Description: The data elements described in the participant element identify the member(patient) or the subscriber to the health plan for eligibility and/or claims processing. The health plan may not have the member or subscriber's name, address or data of birth recorded in the same way as the provider. Using the member or subscriber information as recorded by the health plan will improve the provider's ability to determine eligibility for benefits and reduce rejections of claims. Only record information in participantRole(HLD) if the subscriber is not the patient, otherwise this information is recorded in Member Information.

Fixed value: participant/@typeCode = “COV” (Member Information Code)

participant/@typeCode = “HLD” (Subscriber Information Code)

4.6.2.29 Health Plan Coverage Dates (optional)

Path:	../section/entry/act/entryRelationship/act/participant/time
Type:	DateRange
Description:	The beginning and end dates of the health plan coverage of the individual. These dates may not apply equally to all benefits included in the health plan coverage. Some benefits may have waiting periods for coverage to be effective which results in a different benefit begin date. The purpose of providing this is to better inform patients about their health coverage. Providers should use the applicable standard transactions required under regulation to determine patient eligibility for benefits.

4.6.2.30 Patient or Subscriber Information

Path:	../section/entry/act/entryRelationship/act/participant/participantRole
Type:	PatientOrSubscriber
Description:	A container for patient or subscriber information including name, address, phone, and email.
Fixed value:	participantRole/@classCode = “PAT” (Patient Information Code) participantRole/@classCode = “IND” (Subscriber Information Code)

4.6.2.31 Member or Subscriber Id

Path:	../section/entry/act/entryRelationship/act/participant/participantRole/id
Type:	InstanceIdentifier
Description:	The identifier assigned by the health plan to the patient who is covered by the health plan. When the patient is the actual member or health plan contract holder (the true subscriber) and not a dependent of the subscriber, it is the same as the Subscriber ID. A related spouse, child, or dependent may not have a unique identification number of their own. Or, the identifier assigned by the health plan to the actual member or health plan contract holder (the true subscriber) entered into the eligibility system of the health plan.

4.6.2.32 Patient Relationship to Subscriber (optional)

Path:	../section/entry/act/entryRelationship/act/participant/participantRole/code
Type:	PatientRelationshipToSubscriber
Description:	Specifies only if the patient is the subscriber or dependent within the context of the specified health plan.

Enumerated values:

@code	@displayName
STUD	student
FSTUD	full-time student
PSTUD	part-time student
FAMDEP	family dependent
HANDIC	handicapped dependent
INJ	injured plaintiff
SELF	self
SPON	sponsored dependent

Fixed value: code/@codeSystemName = "RoleCode”
code/@codeSystem = " 2.16.840.1.113883.5.111"

4.6.2.33 Patient or Subscriber Address (optional)

Path: ../section/entry/act/entryRelationship/act/participant/participantRole/addr

Type: PersonAddress

Description: The mailing address of the patient who is a member or enrollee of health plan as recorded by the health plan. This address may be the same as or different from the true subscriber of the health plan. The mailing address used by the health plan may also differ from any other address otherwise used by the patient. Or, the official mailing address of the actual member or health plan contract holder (the true subscriber) as entered into the eligibility system of the health plan to which written correspondence is to be directed.

4.6.2.34 Patient or Subscriber Phone/Email (optional, repeatable)

Path: ../entry/act/entryRelationship/act/participant/participantRole/telecom

Type: PhoneEmail

Description: A telephone number, e-mail address or other locator for a resource mediated by telecommunication equipment. One data type is used to describe phone numbers, pagers, Email addresses and URLs. One or more of these contact numbers can be designated as the preferred methods of contact.

4.6.2.35 Playing Entity

Path: ../ act/entryRelationship/act/participant/participantRole/playingEntity

Type: MemberOfHealthPlan

Description: The playing entity includes the name and date of birth of the actual member or health plan contract holder (the true subscriber) as entered into the eligibility system of the health plan. This is not the name of a related spouse, child, or dependent.

4.6.2.36 Patient or Subscriber Name (optional)

Path:
../entry/act/entryRelationship/act/participant/participantRole/playingEntity/name

Type: PersonName

Description: The name of the actual patient who is a member or enrollee of health plan as entered into the eligibility system of the health plan. The patient may be the true subscriber or any related spouse, child, or dependent. Or, the name of the actual member or health plan contract holder (the true subscriber) as entered into the eligibility system of the health plan. This is not the name of a related spouse, child, or dependent.

If the member name as recorded by the health plan differs from the patient name as recorded in the registration/medication summary (e.g., due to marriage or for other reasons), then the member name shall be recorded in the <name> element of the <playingEntity> element beneath the <participantRole> element. Otherwise, the name shall be assumed to be the same as recorded for the patient.

4.6.2.37 Patient or Subscriber Date of Birth

Path:
../act/entryRelationship/act/participant/participantRole/playingEntity/sdtc:birthTime

Type: DateTime

Description: The date of birth of the patient as entered into the eligibility system of the health plan. Or, the date of birth of the actual member or health plan contract holder (the true subscriber) as entered into the eligibility system of the health plan.

If the member date of birth as recorded by the health plan differs from the patient date of birth as recorded in the registration/medication summary, then the member date of birth shall be recorded in the <sdtc:birthTime> element of the <playingEntity> element beneath the <participantRole> element. Otherwise, the date of birth of the member shall be assumed to be the same as recorded for the patient. The <sdtc:birthTime> element represents an extension to the HL7 CDA Release 2.0.

4.6.2.38 Health Plan (optional, repeatable)

Path: ../act/entryRelationship/act/entryRelationship

Type: HealthPlan

Description: A container for an act identifying the health plan name.

Fixed value: entryRelationship/@typeCode = “REFR”

4.6.2.39 Health Plan Act

Path: ../act/entryRelationship/act/entryRelationship/act

Type: Anonymous Type

Description: Container for health plan name information.

Fixed value: act/@classCode = “ACT”

act/@moodCode = “DEF”

4.6.2.40 Health Plan or Group Code

Path: ../act/entryRelationship/act/entryRelationship/act/id

Type: InstanceIdentifier

Description: The plan or group code.

4.6.2.41 Health Plan Name

Path: ../act/entryRelationship/act/entryRelationship/act/text

Type: xs:string

Description: The name of the specific health insurance product as specified by the insurance company offering the healthcare insurance. The HIPAA legislation requires the Secretary of HHS to establish unique health plan identifiers. To date, the Secretary of HHS has not promulgated plans for regulations specifying the enumeration and identification of health plans.

4.7 Allergies

Specification Reference: C32 Section 2.2.1.8
CCD 3.8 Alerts

4.7.1 Module Description

This represents the overall structure of the C32 Allergy/Drug Sensitivity Module. It contains the allergy or intolerance conditions and associated adverse reactions suffered by the patient. This data should be included in a L32_Module component tag with an xsi:type="Allergies" attribute.

4.7.2 Allergies Elements

4.7.2.1 Allergies Module

Path: ClinicalDocument/component/structuredBody/component

Type: Allergies < L32Module

4.7.2.2 Allergies Template Identifier

Path: ../component/section/templateId

Type: Anonymous Type

Description: Identifies this as the Allergies section.

Fixed Value: templateId/@root = “2.16.840.1.113883.3.88.11.32.6”

4.7.2.3 Allergies Code

Path: …/ component/section/code

Type: AllergiesCode

Description: The values for an Allergies (Alerts) section specified by the CCD to indicate section conformance.

Fixed value: code/@code = “48765-2”
code/@displayName = “Allergies, adverse reactions, alerts”
code/@codeSystemName = "LOINC”
code/@codeSystem = "2.16.840.1.113883.6.1"

4.7.2.4 Allergy Entry (optional, repeatable)

Path: …/component/section/entry/

Type: AllergyEntry

Description: A container for information about an allergy.

Fixed Value: entry/act/templateId/@root = "2.16.840.1.113883.10.20.1.27"
entry/act/templateId/@root = "2.16.840.1.113883.3.88.11.32.6"
entry/act/@classCode = “ACT”
entry/act/@moodCode = “EVN”

4.7.2.5 Adverse Event Entry

Path: …/entry/act/entryRelationship/observation

Type: AdverseEventEntry

Description: Information about an adverse event due to an allergy or intolerance suffered by the patient.

Fixed Value: entryRelationship/@typeCode = “SUBJ"

observation/templateId/@root = "2.16.840.1.113883.10.20.1.18"

observation/@classCode = “OBS”

observation/@moodCode = “EVN”

4.7.2.6 Adverse Event Date

Path: …/observation/effectiveTime

Type: DateRange

Description: This is a date that expresses when this particular allergy or intolerance was known to be active for the patient

4.7.2.7 Adverse Event Type

Path: …/observation/code

Type: AdverseEventType

Description: Describes the type of product and intolerance suffered by the patient. The type of product shall be classified with respect to whether the adverse event occurs in relationship with a medication, food, or environmental or other product. The adverse event should also be classified more specifically as an allergy, non-allergy intolerance, or just adverse reaction if that level of detail is not known.

The vocabulary used for adverse event types comes from a limited set of values of SNOMED CT.

Enumerated values:

@code	@displayName
420134006	propensity to adverse reactions
418038007	propensity to adverse reactions to substance
419511003	propensity to adverse reactions to drug
418471000	propensity to adverse reactions to food
419199007	allergy to substance
416098002	drug allergy
414285001	food allergy
59037007	drug intolerance
235719002	food intolerance

Fixed value: code/@codeSystemName = “SNOMED CT”
code/@codeSystem = “2.16.840.1.113883.6.96”

4.7.2.8 Product

Path: …/entry/act/entryRelationship/observation/participant
Type: AllergyProduct
Description: The product or agent that causes the intolerance.
Fixed Value: participant/@typeCode = “CSM”
participant/participantRole/@typeCode = “MANU”
participant/participantRole/playingEntity@typeCode = “MMAT”

4.7.2.9 Product Free Text

Path: …/participant/participantRole/playingEntity/name
Type: xs:string
Description: Free-text name of the product causing the allergy.

4.7.2.10 Product Coded

Path: …/participant/participantRole/playingEntity/code
Type: AllergyProductCode
Description: Coded value representing the product causing the allergy.

4.7.2.11 Reaction (optional, repeatable)

Path: …/entry/act/entryRelationship/
Type: AllergyEntryRelationship
Description: The reaction caused by the product or agent.
Fixed Value: entryRelationship/@typeCode = “MFST”
entryRelationship/observation/@classCode = “OBS”
entryRelationship/observation/@moodCode = “EVN”
observation/templateId/@root = “2.16.840.1.113883.10.20.1.54”
observation/statusCode/@code = “completed”

4.7.2.12 Reaction Free Text

Path: …/entry/act/entryRelationship/observation/text
Type: xs:string
Description: Free text description of reaction.

4.7.2.13 Reaction Coded

Path: …/entry/act/entryRelationship/observation/value

Type:	ANY (use xsi:type= CD; see type ReactionCode)
Description:	Coded value for reaction. The reaction SHALL be coded using the VA/KP Problem List Subset of SNOMED CT, and SHALL be terms that descend from the clinical finding (404684003) concept. The complete list of codes can be downloaded from http://www.fda.gov/oc/datacouncil/term.html, or a delimited text file containing the list can be found on the NHIN Cooperative Portal.

4.7.2.14 Severity (optional)

Path:	…/entry/act/entryRelationship/observation/entryRelationship
Type:	AllergySeverity
Description:	The level of severity of the allergy or intolerance.
Fixed Value:	entryRelationship/@typeCode = “SUBJ” entryRelationship/observation/@classCode = “OBS” entryRelationship/observation/@moodCode = “EVN” observation/templateId/@root = “2.16.840.1.113883.10.20.1.55” observation/code/@code = “SEV” observation/code/@displayName = “Severity” observation/code/@codeSystemName = “ActCode” observation/code/@codeSystem = “2.16.840.1.113883.5.4” observation/statusCode/@code = “completed”

4.7.2.15 Severity Free Text

Path:	…/ entryRelationship/observation/text
Type:	xs:string
Description:	Free text description of the level of severity of the allergy or intolerance

4.7.2.16 Severity Coded

Path:	…/ entryRelationship/observation/value
Type:	ANY (use xsi:type= CD; see type AllergySeverityCode)
Description:	Coded value for the severity. The terminology used for severity of the adverse event SHALL be recorded using the subset of SNOMED CT enumerated in this element. These terms descend from the severities (272141005) concept.

Enumerated values:

@code	@displayName
255604002	Mild
371923003	Mild to moderate
6736007	Moderate
371924009	Moderate to severe
24484000	Severe
399166001	Fatal

Fixed value: code/@codeSystemName = “SNOMED CT”
code/@codeSystem = “2.16.840.1.113883.6.96”

4.7.2.17 Alert Status

Path: …/entry/act/entryRelationship/observation/entryRelationship/observation
Type: AllergyEntryRelationship
Description: The status of the allergy/alert.
Fixed Value: entryRelationship/@typeCode = “REFR”
entryRelationship/observation/@classCode = “OBS”
entryRelationship/observation/@moodCode = “EVN”
observation/templateId/@root = “2.16.840.1.113883.10.20.1.39”

4.7.2.18 Alert Status Observation Code

Path: ../ act/entryRelationship/observation/entryRelationship/observation/code
Type: Anonymous Type
Description: The fixed values for an Alert Status Observation specified by the CCD to indicate section conformance. For a reaction, use the nullFlavor attribute.
Fixed value: code/@code = “33999-4”
code/@displayName = “Status”
code/@codeSystemName = " LOINC”
code/@codeSystem = " 2.16.840.1.113883.6.1"
code/@nullFlavor = “NA”

4.7.2.19 Alert Status Coded

Path: …/entry/act/entryRelationship/observation/value
Type: ANY (use xsi:type= CD; see type AlertStatusCode)

Description: Coded value for alert status.

Enumerated values:

@code	@displayName
55561003	Active
392521001	Prior History
73425007	No Longer Active

Fixed value: code/@codeSystemName = “SNOMED CT”
code/@codeSystem = “2.16.840.1.113883.6.96”

4.8 Conditions

Specification Reference: C32 Section 2.2.1.9
CCD 3.5 Problems

4.8.1 Module Description

This module lists and describes all relevant clinical problems at the time the summary is generated. At a minimum, all pertinent current and historical problems should be listed. A problem is a clinical statement that a clinician is particularly concerned about and wants to track. It has important patient management use cases (e.g. health records often present the problem list as a way of summarizing a patient's medical history). This data should be included in a L32_Module component tag with an xsi:type="Conditions" attribute.

4.8.2 Conditions Elements

4.8.2.1 Conditions Module

Path: ClinicalDocument/component/structuredBody/component

Type: Conditions < L32Module

4.8.2.2 Conditions Template Identifier

Path: ../component/section/templateId

Type: Anonymous Type

Description: Identifies this as the Conditions/Problems section.

Fixed Value: templateId/@root = “2.16.840.1.113883.10.20.1.11”

4.8.2.3 Problem Code

Path: ../section/code

Type: ConditionsCode

Description: The fixed values for a Condition section specified by the CCD to indicate section conformance.

Fixed value: code/@code = “11450-4”
code/@displayName = ”Problem list”
code/@codeSystemName = "LOINC”
code/@codeSystem = "2.16.840.1.113883.6.1"

4.8.2.4 Problem Title

Path: ../section/title

Type: xs:string

Description: The section title.

Fixed value: title = ”Problems”

4.8.2.5 Problem Text

Path: ../section/text

Type: StrucDoc.Text

Description: The narrative text containing the name of the problem.

4.8.2.6 Problem Entry (optional, repeatable)

Path: ../section/entry

Type: ProblemEventEntry

Description: A problem entry is a container for a problem act.

4.8.2.7 Problem Act

Path: ../section/entry/act

Type: Anonymous Type

Description: A problem act represents a problem observation or other clinical statement that is the subject of concern.

Fixed value: act/@classCode = “ACT”

act/@moodCode = “EVN”

4.8.2.8 Problem Act Template Id (minimum=2, maximum=2)

Path: ../section/entry/act/templateId

Type: Anonymous Type

Description: This is the template identifier for a problem act. The value of the root attribute of this element provides a unique identifier for the template(s) applied to this problem act. Two templateId elements are to be included. There is a CCD and a C32 template identifier for a problem act.

Fixed value: templateId/@root = “2.16.840.1.113883.10.20.1.27”

templateId/@assigningAuthorityName=CCD
templateId/@root = “2.16.840.1.113883.3.88.11.32.7”
templateId/@assigningAuthorityName=HITSP/C32

4.8.2.9 Problem Act Id

Path: ../section/entry/act/id

Type: InstanceIdentifier

Description: The CCD requires that a problem act shall contain an act id.

4.8.2.10 Problem Act Code

Path: ../section/entry/act/code

Type: Anonymous Type

Description: The CCD states that the value for a problem act code shall be “Not applicable.”

Fixed value: code/@nullFlavor = “NA”

4.8.2.11 Problem Date Range (optional)

Path: ../section/entry/act/effectiveTime

Type: DateRange

Description: This is the interval of time for which the problem is a concern. The <low> element will record onset date and the <high> element will record the resolution date with a @value attribute represented in YYYYMMDDhhmmss format.

4.8.2.12 Problem Entry

Path: ../section/entry/act/entryRelationship (repeatable)/observation

Type: ProblemEntry

Description: This element is a container for problem entry information.

Fixed value: entryRelationship/@typeCode = “SUBJ”

observation/@classCode = “OBS”

observation/@moodCode = “EVN”

4.8.2.13 Problem Entry Template Id

Path: ../section/entry/act/entryRelationship/observation/templateId

Type: Anonymous Type

Description: Identifies this as a Problem Observation.

Fixed value: templateId/@root = “"2.16.840.1.113883.10.20.1.28 ”

4.8.2.14 Problem Type

Path: ../section/entry/act/entryRelationship/observation/code

Type: ProblemType

Description: This is a fixed value indicating the level of medical judgment used to determine the existence of a problem.

Enumerated values:

@code	@displayName
404684003	Finding
418799008	Symptom
55607006	Problem
409586006	Complaint
64572001	Condition
282291009	Diagnosis
248536006	Functional limitation

Fixed value: code/@codeSystemName = " SNOMED CT"
code/@codeSystem = " 2.16.840.1.113883.6.96 "

4.8.2.15 Problem Name

Path: ../section/entry/act/entryRelationship/observation/text

Type: TextReference

Description: This is a text description of the problem suffered. The problem name shall be recorded in the entry by recording a <reference> where the value attribute points to the narrative text containing the name of the problem.

4.8.2.16 Problem Status Code

Path: ../section/entry/act/entryRelationship/observation/statusCode

Type: xs:string

Description: The problem observation status code.

Fixed value: statusCode/@code = "completed"

4.8.2.17 Problem Date (optional)

Path: ../section/entry/act/entryRelationship/observation/effectiveTime

Type: DateRange

Description: Indicates the biological timing of the condition (e.g. the time the condition started, the onset of the illness or symptom, the duration of a condition).

4.8.2.18 Problem Code (optional)

Path: ../section/entry/act/entryRelationship/observation/value

Type: ANY

Description: This value is a code describing the problem according to a specific vocabulary of problems. It shall be coded using the VA/KP Problem List

	Subset of SNOMED CT. The problem list subset can be obtained from www.cancer.gov/cancertopics/terminologyresources/FDA. The problem shall be recorded in the <value> element using the CD data type. This element can also be used to indicate whether the patient is currently pregnant. Please see the Pregnancy Module for more information.
Fixed value:	value/@xsi:type = "CD" value/@codeSystemName = "SNOMED CT" value/@codeSystem = "2.16.840.1.113883.96"

4.8.2.19 Source of Information (repeatable)

Path:	../section/entry/act/entryRelationship/observation/informant
Type:	InformantOrPerformer
Description:	The source or sources of information for the problem observation. Please see the InformantOrPerformer data type for more information.

4.8.2.20 Problem Status Observation (optional)

Path:	../entry/act/ entryRelationship/observation/entryRelationship/observation
Type:	HealthStatusObservation
Description:	The problem status or problem health status.
Fixed value:	entryRelationship/ @typeCode = "REFR" observation/@classCode = "OBS" observation/@moodCode = "EVN"

4.8.2.21 Problem Status Observation Template Id

Path:	../entry/act/ entryRelationship/observation/entryRelationship/observation
Type:	Anonymous Type
Description:	This is the template identifier for a problem status observation or a problem healthstatus observation. The value of the root attribute of this element provides a unique identifier for the template(s) applied to this problem observation. Choose the corresponding template id for the type of status observation being described.
Fixed value:	templateId/@root = "2.16.840.1.113883.10.20.1.50" (Problem Status Observation) templateId/@root = "2.16.840.1.113883.10.20.1.51" (Problem Healthstatus Observation)

4.8.2.22 Problem Observation Code

Path:	../ act/entryRelationship/observation/entryRelationship/observation/code
Type:	HealthStatusObservationCode
Description:	The fixed values for a Problem Status or HealthStatus Observation specified by the CCD to indicate section conformance.

Enumerated values:

@code	@displayName
33999-4	Status
11323-3	Health status

Fixed value: code/@codeSystemName = " LOINC”
code/@codeSystem = " 2.16.840.1.113883.6.1"

4.8.2.23 Problem Status Code

Path: ../entryRelationship/observation/entryRelationship/observation/statusCode
Type: xs:string
Description: The problem status observation status code.
Fixed value: statusCode/@code = “completed”

4.8.2.24 Problem Status Value

Path: ../act/ entryRelationship/observation/entryRelationship/observation/value
Type: ANY (use xsi:type = CE)
Description: The problem status or healthstatus observation value.
Fixed value: value/@codeSystem = “2.16.840.1.113883.1.11.20.13”
value/@codeSystemName = “ProblemStatusCode”
value/@codeSystem = “2.16.840.1.113883.1.11.20.12”
value/@codeSystemName = “ProblemHealthStatusCode”

4.8.2.25 Treating Provider (optional, repeatable)

Path: ../section/entry/act/performer
Type: TreatingProvider
Description: The provider or providers treating the patient for this condition.
Fixed value: performer /@typeCode = “PRF”

4.8.2.26 Time (optional)

Path: ../section/entry/act/performer/time
Type: DateRange
Description: The time over which this provider treated the condition.

4.8.2.27 Treating Provider Information

Path: ../section/entry/act/performer/assignedEntity
Type: Entity

Description: Information about the provider or providers treating the patient for this condition. The identifier of the treating provider shall be present in the <id> element beneath the <assignedEntity>. This identifier shall be the identifier of one of the providers listed in the healthcare provider's module.

4.9 Medications

Specification Reference: C32 Section 2.2.1.10
CCD 3.9 Medications

4.9.1 Module Description

This module defines a patient's current medications and pertinent medication history. At a minimum, the currently active medications should be listed. The section may also include a patient's prescription history, and enables the determination of the source of a medication list (e.g. from a pharmacy system vs. from the patient). This data should be included in a L32_Module component tag with an xsi:type="Medications" attribute.

4.9.2 Medications Elements

4.9.2.1 Medications Module

Path: ClinicalDocument/component/structuredBody/component

Type: Medications < L32Module

4.9.2.2 Medications Template Identifier

Path: ../component/section/templateId

Type: Anonymous Type

Description: Identifies this as the Medications section.

Fixed Value: templateId/@root = "2.16.840.1.113883.10.20.1.8"

4.9.2.3 Medications Code

Path: ../section/code

Type: MedicationsCode

Description: The fixed values for a Medication section specified by the CCD to indicate section conformance.

Fixed value: code/@code = "10160-0"
code/@displayName = "History of medication use"
code/@codeSystemName = "LOINC"
code/@codeSystem = "2.16.840.1.113883.6.1"

4.9.2.4 Medication Title

Path: ../section/title

Type: xs:string

Description: The section title.

Fixed value: title = "Medications"

4.9.2.5 Medication Text

Path: ../section/text

Type: StrucDoc.Text

Description: The narrative text containing medication information.

4.9.2.6 Medications Entry (optional, repeatable)

Path: ../section/entry

Type: MedicationsEntry

Description: A medication entry is a container for administration information.

4.9.2.7 Medication Activity

Path: ../section/entry/substanceAdministration

Type: AdministrationInformation

Description: A medication activity is used to describe what was administered. Substance administration includes information about what has been administered and what has been dispensed. A pharmacy system usually reports what was actually filled (supply event), along with intended use (substance administration intent). A physician often reports intended use (substance administration and supply intent). A patient or family member will usually report actual use (substance administration event). The substanceAdministration element is also used for an Immunization Event Entry. Please see the Immunization Module for more details.

Fixed value: substanceAdministration/@classCode = “SBADM”

substanceAdministration/@moodCode = “INT” (intent) or

substanceAdministration/@moodCode = “EVN” (event)

4.9.2.8 Medication Activity Template Id (minimum=2, maximum=2)

Path: ../section/entry/substanceAdministration/templateId

Type: Anonymous Type

Description: This is the template identifier for the medication module. The value of the root attribute of this element provides a unique identifier for the template(s) applied. Two templateId elements are to be included. There is a CCD and a C32 template identifier for a medications module.

Fixed value: templateId/@root = “2.16.840.1.113883.10.20.1.24”
templateId/@assigningAuthorityName= CCD

templateId/@root = “2.16.840.1.113883.3.88.11.32.8”
templateId/@assigningAuthorityName= HITSP/C32

4.9.2.9 Medication Activity Id

Path: ../section/entry/substanceAdministration/id

Type: InstanceIdentifier

Description: The CCD requires that a medication activity shall contain a substance administration id.

4.9.2.10 Delivery Method (optional)

Path: ../section/entry/substanceAdministration/code

Type: GenericCode

Description: A description of how the product is administered / consumed. HITSP has not specified a vocabulary for Delivery Method because ongoing harmonization work with the NCPDP Industry SIG Task Force and the e-Prescribing pilots has not yet published results.

4.9.2.11 Free Text (optional)

Path: ../section/entry/substanceAdministration/text

Type: TextReference

Description: The instructions, typically from the ordering provider, to the patient on the proper means and timing for the use of the product. This information is free-text but can also be represented as a series of Sig Components. The <text> element of the free text sig shall contain a <reference> element whose value attribute points to the text of the free text sig in the narrative portion of the CCD.

4.9.2.12 Medication Status Code (optional)

Path: ../section/entry/substanceAdministration/statusCode

Type: StatusCode

Description: A medication activity should contain a status code. Please see StatusCode data type for further details.

4.9.2.13 Indicate Medication Stopped (minimum=1, maximum=2)

Path: ../section/entry/substanceAdministration/effectiveTime

Type: TS (use xsi:type)

Description: Used to express a “hard stop,” such as the last sequence in a tapering dose, where the last sequence is 'then D/C' or where the therapy/drug is used to treat a condition and that treatment is for a fixed duration with a hard stop, such as antibiotic treatment, etc. The stop date of the medication shall be recorded in the <high> element of the first <effectiveTime> element in the <substanceAdministration> element. The first <effectiveTime> shall use the IVL_TS data type unless for a single administration, in which case, it shall use the TS data type.

4.9.2.14 Administration Timing (minimum=1, maximum=2)

Path: ../section/entry/substanceAdministration/effectiveTime

Type: TS (use xsi:type)

Description: Defines a specific administration or use time. It can be a text string (Morning, Evening, Before Meals, 1 Hour After Meals, 3 Hours After Meals, Before Bed) or an exact time. The first <effectiveTime> shall use

the IVL_TS data type unless for a single administration, in which case, it shall use the TS data type. Medications that are administered based on activities of daily living shall identify the events that trigger administration in the <event> element beneath the <effectiveTime> element. The <effectiveTime> element shall be of type EIVL.

4.9.2.15 Frequency (minimum=1, maximum=2)

Path: ../section/entry/substanceAdministration/effectiveTime

Type: TS (use xsi:type)

Description: Defines how often the medication is to be administered as events per unit of time. Often expressed as the number of times per day (e.g., four times a day), but may also include event-related information (e.g., 1 hour before meals, in the morning, at bedtime). Complimentary to Interval, although equivalent expressions may have different implications (e.g., every 8 hours versus 3 times a day). The second <effectiveTime> element shall record the details about frequency, interval and duration when more than one administration is to occur. Medications that are administered at a specified frequency shall record the expected interval between doses in the <period> element beneath an <effectiveTime> of type PIVL_TS. The <effectiveTime> element shall have an institutionSpecified attribute value of "true".

4.9.2.16 Interval (minimum=1, maximum=2)

Path: ../section/entry/substanceAdministration/effectiveTime

Type: TS (use xsi:type)

Description: Defines how the product is to be administered as an interval of time, for example, every 8 hours. Complimentary to Frequency, although equivalent expressions may have different implications (e.g., every 8 hours versus 3 times a day). The second <effectiveTime> element shall record the details about frequency, interval and duration when more than one administration is to occur. Medications that are administered at a specified interval shall record interval between doses in the <period> element beneath an <effectiveTime> element of type PIVL_TS. The <effectiveTime> element shall have an institutionSpecified attribute value of "false".

4.9.2.17 Duration (minimum=1, maximum=2)

Path: ../section/entry/substanceAdministration/effectiveTime

Type: TS (use xsi:type)

Description: For non-instantaneous administrations, indicates the length of time the administration should be continued. For example, (infuse) over 30 minutes. The second <effectiveTime> element shall record the details about frequency, interval and duration when more than one administration is to occur.

4.9.2.18 Route (optional)

Path: ../section/entry/substanceAdministration/routeCode

Type: RouteOrProductForm

Description: Indicates how the medication is received by the patient (e.g., by mouth, intravenously, topically, et cetera). Route codes shall have a value drawn from FDA route of administration. See http://www.fda.gov/Drugs/DevelopmentApprovalProcess/UCM070829

Fixed value: routeCode/@codeSystemName = “NCI Thesaurus”

routeCode/@codeSystem = "2.16.840.1.113883.3.26.1.1"

4.9.2.19 Site (optional, repeatable)

Path: ../section/entry/substanceAdministration/approachSiteCode

Type: GenericCode

Description: The anatomic site where the medication is administered, usually applicable to injected or topical products. The code attribute shall contain a value descending from the SNOMED CT Anatomical Structure (91723000) hierarchy.

4.9.2.20 Dose (optional)

Path: ../section/entry/substanceAdministration/doseQuantity

Type: Dose

Description: The amount of the product to be given. This may be a known, measurable unit (e.g., milliliters), an administration unit (e.g., tablet), or an amount of active ingredient (e.g., 250 mg). May define a variable dose, dose range or dose options based upon identified criteria.

The units of presentation can be found at www.fda.gov, and include only those terms which have not been mapped to UCUM. Terms with mappings to UCUM are units of administration. The unit attribute is optional. If used, it contains the preferred name of the presentation units within braces { } using the units of presentation from the NCI Thesaurus.

4.9.2.21 Dose Restriction (optional)

Path: ../section/entry/substanceAdministration/maxDoseQuantity

Type: DoseRestriction

Description: Defines a maximum or dose limit. It consists of a numerator and denominator element, each of the Dose data type.

4.9.2.22 Product Form (optional)

Path: ../section/entry/substanceAdministration/administrationUnitCode

Type: RouteOrProductForm

Description: The physical form of the product as presented to the patient. For example: tablet, capsule, liquid or ointment. The administration unit code shall have a value drawn from the FDA dosage form, source NCI thesaurus. See http://www.fda.gov/Drugs/InformationOnDrugs/ucm142454.htm

Fixed value: administrationUnitCode/@codeSystemName = "NCI Thesaurus"

administrationUnitCode/@codeSystem = "2.16.840.1.113883.3.26.1.1"

4.9.2.23 Medication Information

Path: ../ entry/substanceAdministration/consumable/manufacturedProduct

Type: MedicationInformation

Description: The name and code for the medication are recorded in the consumable element.

Fixed value: manufacturedProduct/@classCode = "MANU"

4.9.2.24 Medication Information Template Identifier (minimum=2, maximum=2)

Path: ../ substanceAdministration/consumable/manufacturedProduct/templateId

Type: Anonymous Type

Description: This is the template identifier for medication information. The value of the root attribute of this element provides a unique identifier for the template(s) applied. Two templateId elements are to be included. There is a CCD and a C32 template identifier for medication information.

Fixed value: templateId/@root = "2.16.840.1.113883.10.20.1.53"
templateId/@assigningAuthorityName=CCD

templateId/@root = "2.16.840.1.113883.3.88.11.32.9"
templateId/@assigningAuthorityName=HITSP/C32

4.9.2.25 Manufactured Material

Path: ../consumable/manufacturedProduct/manufacturedMaterial

Type: Anonymous Type

Description: Contains information about the product including the product name, strength, form, concentration, and unit dose.

Fixed value: manufacturedMaterial/@classCode = "MMAT"

manufacturedMaterial/@determinerCode= "KIND"

4.9.2.26 Coded Product Name

Path: ../consumable/manufacturedProduct/manufacturedMaterial/code

Type: CodedProductName

Description: A code describing the product from a controlled vocabulary. The product name or brand name is coded using RxNorm, or NDC. When only the class of the drug is known use NDF-RT. FDA UNII codes can be used when there are no suitable codes in the other vocabularies to identify the medication. The product (generic) name shall appear in the <originalText> element beneath the <code> element. The code for the specific brand of product shall appear in a <translation> element. The brand name shall appear in the <name> element of the <manufacturedMaterial>.

Enumerated values:

@codeSystemName	@codeSystem	Used for
RxNorm	2.16.840.1.113883.6.88	Brand Names or Clinical Drugs
NDC	2.16.840.1.113883.6.69	Packaged Product
NDF-RT	2.16.840.1.113883.4.209	Ingredient Name
UNII	2.16.840.1.113883.4.9	Drug Class
CVX	2.16.840.1.113883.6.59	Used for Immunizations

4.9.2.27 Free Text Brand Name (optional)

Path: ../consumable/manufacturedProduct/manufacturedMaterial/name

Type: xs:string

Description: The branded or trademarked name of the substance or product. If a Coded Brand Name is present, this is the text associated with the coded concept. This may include additional information such as strength, dose form, etc.

4.9.2.28 Drug Manufacturer (optional)

Path: ../consumable/manufacturedProduct/manufacturedOrganization

Type: Organization

Description: The manufacturer of the substance or product as ordered or supplied. The distributor may be supplied if the manufacturer is not known.

4.9.2.29 Performer (optional, repeatable)

Path: ../section/entry/ substanceAdministration/performer

Type: InformantOrPerformer

Description: Indicates the person administering a substance. Please see the InformantOrPerformer data type for more details.

4.9.2.30 Informant (repeatable)

Path: ../section/entry/ substanceAdministration/informant

Type: InformantOrPerformer

Description: Source of information for a medication activity. Please see the InformantOrPerformer data type for more details.

4.9.2.31 Vehicle (optional, repeatable)

Path: ../section/entry/ substanceAdministration/participant/participantRole

Type: Vehicle

Description: The vehicle for administering medication. Non-active ingredient(s), or substances not of therapeutic interest, in which the active ingredients are dispersed. Most often applied to liquid products where the major fluid Component is considered the vehicle. For example: Normal Saline is the vehicle in "Ampicllin 150mg in 50ml NS"; Aquaphor is the vehicle in "10% LCD in Aquaphor".

Fixed value: participant/@typeCode = "CSM"

participantRole/@classCode = "MANU"

4.9.2.32 Vehicle Code

Path: ../section/entry/ substanceAdministration/participant/participantRole/code

Type: Anonymous Type

Description: A code for the participant.

Fixed value: code/@code = "412307009"

code/@displayName = "drug vehicle"

code/@codeSystemName = "SNOMED CT"

code/@codeSystem = "2.16.840.1.113883.6.96"

4.9.2.33 Drug Vehicle Name (optional)

Path: ../ participant/participantRole/playingEntity/name

Type: xs:string

Description: The <name> element in the <playingEntity> element shall record the name of the drug vehicle.

Fixed value: playingEntity /@classCode = "MMAT"

4.9.2.34 Drug Vehicle Coded Term (optional)

Path: ../ substanceAdministration/participant/participantRole/playingEntity/code

Type: Anonymous Type

Description: The <code> element in the <playingEntity> element may be used to supply a coded term for the drug vehicle. The codes for drug vehicles are the same as those used for the coded product or brand name found in Coded Product Name description.

Enumerated values:

@codeSystemName	@codeSystem	Used for
RxNorm	2.16.840.1.113883.6.88	Brand Names or Clinical Drugs
NDC	2.16.840.1.113883.6.69	Packaged Product
NDF-RT	2.16.840.1.113883.4.209	Ingredient Name
UNII	2.16.840.1.113883.4.9	Drug Class

4.9.2.35 Medication Information (optional, repeatable)

Path: ../entry/ substanceAdministration/entryRelationship

Type: MedicationInformationEntry

Description: A medication entry relationship can contain an act, observation, or supply.

Enumerated values:

@typeCode	Use
SUBJ	-Type of Medication, use with observation -Patient Instructions, use with act
REFR	-Status of Medication, use with observation -Order Information, use with supply
RSON	-Indication, use with observation -Immunization Refusal Reason, use with act
CAUS	-Medication Reaction, use with observation -Immunization Reaction, use with observation

4.9.2.36 Type of Medication

Path: ../entry/ substanceAdministration/entryRelationship/observation

Type: MedicationObservation

Description: A classification based on how the medication is marketed (e.g., prescription, over the counter drug).

Fixed value: entryRelationship /@typeCode = “SUBJ”

observation /@classCode = “OBS”

observation /@moodCode = “EVN”

4.9.2.37 Type of Medication Template Identifier

Path: ../ substanceAdministration/entryRelationship/observation/templateId

Type: Anonymous Type

Description: Identifies this as the Type of Medication section.

Fixed Value: templateId/@root = “2.16.840.1.113883.3.88.11.32.10”

4.9.2.38 Type of Medication Code

Path: ../entry/ substanceAdministration/entryRelationship/observation/code

Type: MedicationObservationCodes

Description: If a "Type of Medication" observation is being recorded, the code represents the medication actually or intended to be administered or supplied and is derived from a limited set of SNOMED CT values.

Enumerated values:

@code	@displayName
329505003	Over the counter products
73639000	Prescription Drug

Fixed value: code/@codeSystemName = “SNOMED CT”

code/@codeSystem = “2.16.840.1.113883.6.96”

4.9.2.39 Status Code (optional)

Path: ../ substanceAdministration/entryRelationship/observation/statusCode

Type: StatusCode

Description: Indicates the status of a Type of Medication observation, Status of Medication observation, or Indication observation. Please see StatusCode data type for enumerated values.

4.9.2.40 Status of Medication (optional)

Path:	../entry/ substanceAdministration/entryRelationship/observation
Type:	MedicationObservation
Description:	Specifies if the medication is Active, Discharged, Chronic, Acute, etc.
Fixed value:	entryRelationship /@typeCode = “REFR”
	observation /@classCode = “OBS”
	observation /@moodCode = “EVN”

4.9.2.41 Status of Medication Template Identifier

Path:	../ substanceAdministration/entryRelationship/observation/templateId
Type:	Anonymous Type
Description:	Identifies this as the Status of Medication section.
Fixed Value:	templateId/@root = “2.16.840.1.113883.10.20.1.47”

4.9.2.42 Status of Medication Code

Path:	../entry/ substanceAdministration/entryRelationship/observation/code
Type:	MedicationObservationCodes
Description:	If a "Medication Status" observation is being recorded, use the Status code 33999-4 from LOINC.
Fixed Value:	code/@code = “33999-4”
	code/@displayName = “Status”
	code/@codeSystemName = “LOINC”
	code/@codeSystem = “2.16.840.1.113883.6.1”

4.9.2.43 Status of Medication Value (optional)

Path:	../entry/ substanceAdministration/entryRelationship/observation/value
Type:	ANY (use xsi:type = CE)
Description:	The value for Observation/value in a medication status observation shall be selected from the MedicationStatusCode value set. The values below do not appear in the L32 XML Schema because the value element requires an xsi:type attribute.

Enumerated values:

@code	@displayName
55561003	Active
421139008	On Hold
392521001	Prior History
73425007	No Longer Active

Fixed value: code/@codeSystemName = “MedicationStatusCode”
code/@codeSystem = “2.16.840.1.113883.1.11.20.7”

4.9.2.44 Indication (optional)

Path: ../entry/ substanceAdministration/entryRelationship/observation

Type: MedicationObservation

Description: The medical condition or problem intended to be addressed by the ordered product. For example: for chest pain, for pain, for high blood pressure.

Fixed value: entryRelationship /@typeCode = “RSON” (Has Reason)
observation /@classCode = “OBS”
observation /@moodCode = “EVN”

4.9.2.45 Indication Template Identifier

Path: ../ substanceAdministration/entryRelationship/observation/templateId

Type: Anonymous Type

Description: Identifies this as the Indication section.

Fixed Value: templateId/@root = “2.16.840.1.113883.10.20.1.28”

4.9.2.46 Indication Code

Path: ../entry/ substanceAdministration/entryRelationship/observation/code

Type: MedicationObservationCodes

Description: The indication shall be coded using the VA/KP Problem List Subset of SNOMED CT, and shall be terms that descend from the clinical finding (404684003) concept. The problem list subset can be obtained at www.cancer.gov/cancertopics/terminologyresources/FDA

Fixed value: code/@codeSystemName = “SNOMED CT”
code/@codeSystem = “2.16.840.1.113883.6.96”

4.9.2.47 Text Indication for the Medication (optional)

Path: ../entry/ substanceAdministration/entryRelationship/observation/tex

Type: TextReference

Description: The indication <observation> shall contain a <text> element that includes a <reference> element whose value attribute points to the narrative text that is the indication for the medication.

4.9.2.48 Indication Time (optional)

Path: ../ substanceAdministration/entryRelationship/observation/effectiveTime

Type: DateTime

Description: Indication time.

4.9.2.49 Patient Instructions

Path: ../entry/ substanceAdministration/entryRelationship/act

Type: FulfillmentInstructions

Description: Patient instructions are additional information provided to a patient related to one of their medications (e.g. “take on an empty stomach”). More extensive patient education materials can also be included.

Fixed value: entryRelationship/@typeCode = “SUBJ”

act/@classCode = “ACT”

act/@moodCode = “INT”

4.9.2.50 Patient Instructions Template Identifier

Path: ../entry/ substanceAdministration/entryRelationship/act/templateId

Type: Anonymous Type

Description: Identifies this as the Patient Instructions section.

Fixed Value: templateId/@root = “2.16.840.1.113883.10.20.1.49”

4.9.2.51 Patient Instructions Text

Path: ../entry/ substanceAdministration/entryRelationship/act/text

Type: TextReference

Description: The <act> containing the instructions shall contain a <text> element that includes a <reference> element whose value attribute points to the narrative text or external reference that contains the instructions.

4.9.2.52 Reaction(optional)

Path: ../entry/ substanceAdministration/entryRelationship/observation

Type: MedicationObservation

Description: Any noted intended or unintended effects of the product. For example: full body rash, nausea, rash resolved.

Fixed value: entryRelationship/@typeCode = “CAUS”
observation /@classCode = “OBS”
observation /@moodCode = “EVN”

4.9.2.53 Reaction Template Identifier

Path: ../ substanceAdministration/entryRelationship/observation/templateId
Type: Anonymous Type
Description: Identifies this as the Reaction observation section.
Fixed Value: templateId/@root = “2.16.840.1.113883.10.20.1.54”

4.9.2.54 Reaction Status Code

Path: ../ substanceAdministration/entryRelationship/observation/statusCode
Type: StatusCode
Description: The status of the reaction observation.
Fixed Value: statusCode/@code = “completed”

4.9.2.55 Dose Indicator (optional, repeatable)

Path: ../entry/ substanceAdministration/precondition
Type: Dose Indicator
Description: A criteria that specifies when an action is, or is not, to be taken. For example, “if blood sugar is above 250 mg/dl”. A medication activity may contain one or more SubstanceAdministration/precondition/criterion, to indicate that the medication is administered only when the associated (coded or free text) criteria are met. The DoseIndicator data type includes an optional code and text element.

4.9.2.56 Order Information (optional)

Path: ../entry/ substanceAdministration/entryRelationship/supply
Type: OrderInformation
Description: A supply event is used to report medication that was actually filled. The L32 constrains the C32 in that order information can only be recorded with substance administration intent or event. Order information cannot be recorded with a supply event.
Fixed value: entryRelationship /@typeCode = “REFR”
supply /@classCode = “SPLY”
supply /@moodCode = “INT” (intent) or
supply/@moodCode = “EVN” (event)

4.9.2.57 Order Information Template Identifier (minimum=1, maximum=2)

Path: ../entry/substanceAdministration/entryRelationship/supply/templateId
Type: Anonymous Type

Description:	This is the template identifier for order information. The value of the root attribute of this element provides a unique identifier for the template(s) applied. Two templateId elements are to be included. There is a CCD and a C32 template identifier for order information.
Fixed value:	templateId/@root = "2.16.840.1.113883.10.20.1.34" templateId/@assigningAuthorityName=CCD templateId/@root = "2.16.840.1.113883.3.88.11.32.11" templateId/@assigningAuthorityName=HITSP/C32

4.9.2.58 Order Number

Path:	../entry/ substanceAdministration/entryRelationship/supply/id
Type:	InstanceIdentifier
Description:	The order identifier from the perspective of the ordering clinician. It is also known as the 'placer number' versus the pharmacies prescription number (or 'filler number').

4.9.2.59 Order Expiration Date/ Time (optional)

Path:	../entry/ substanceAdministration/entryRelationship/supply/effectiveTime
Type:	DateTime
Description:	The date, including time if applicable, when the order is no longer valid. Dispenses and administrations are not continued past this date for an order instance.

4.9.2.60 Fills (optional)

Path:	../entry/ substanceAdministration/entryRelationship/supply/repeatNumber
Type:	Anonymous Type
Description:	The number of times that the ordering provider has authorized the pharmacy to dispense this medication. The number of fills requested is what is recorded in the document, not the number of refills. The number of refills is simply one less than the number of fills. The repeatNumber element contains a value attribute to specify the number of fills, and a nullFlavor attribute with a fixed value of "PINF" if the number of fills is unbounded.

4.9.2.61 Quantity Ordered (optional)

Path:	../entry/ substanceAdministration/entryRelationship/supply/quantity
Type:	Dose
Description:	The amount of product indicated by the ordering provider to be dispensed. For example, number of dosage units or volume of a liquid substance. Note: this is comprised of both a numeric value and a unit of measure. The units of presentation can be found www.fda.gov, and include only those terms which have not been mapped to UCUM. Terms with

mappings to UCUM are units of administration, rather than units of presentation.

The quantity ordered shall be recorded in the value attribute of <quantity> element inside a <supply> element used to record order information. The unit attribute shall be present. When the quantity ordered is in other than administration units (e.g., when the quantity ordered is a volume of liquid or mass of substance) units shall be recorded using the Unified Code for Units of Measure. Otherwise, the unit attribute should contain the preferred name of the presentation units within braces { } using the units of presentation from the NCI Thesaurus.

4.9.2.62 Order Date/Time (optional)

Path:	../entry/ substanceAdministration/entryRelationship/supply/author/time
Type:	DateTime
Description:	The date, including time if available, when the ordering provider wrote the order/prescription.

4.9.2.63 Ordering Provider (optional)

Path:	../entryRelationship/supply/author/assignedAuthor/assignedPerson/name
Type:	PersonName
Description:	The person that wrote this order/prescription (may include both a name and an identifier).

4.9.2.64 Fulfillment Instructions (optional)

Path:	../entry/ substanceAdministration/entryRelationship/act
Type:	FulfillmentInstructions
Description:	Instructions to the dispensing pharmacist or nurse that are not traditionally part of the Sig. For example, “instruct patient on the use of occlusive dressing”.
Fixed value:	entryRelationship/@typeCode = “SUBJ” act/@classCode = “ACT” act/@moodCode = “INT”

4.9.2.65 Fulfillment Instructions Template Identifier

Path:	../entry/ substanceAdministration/entryRelationship/act/templateId
Type:	Anonymous Type
Description:	Identifies this as the Fullfillment Instructions section.
Fixed Value:	templateId/@root = “2.16.840.1.113883.10.20.1.43”

4.9.2.66 Fulfillment Instructions Text

Path: ../entry/ substanceAdministration/entryRelationship/act/text

Type: TextReference

Description: The <act> containing the instructions shall contain a <text> element that includes a <reference> element whose value attribute points to the narrative text that contains the instructions.

4.9.2.67 Fulfillment History (optional)

Path: ../entry/ substanceAdministration/entryRelationship/supply

Type: OrderInformation

Description: Used to record fulfillment history.

Fixed value: supply/@moodCode = “EVN”

4.9.2.68 Prescription Number

Path: ../entry/ substanceAdministration/entryRelationship/supply/id

Type: InstanceIdentifier

Description: Fulfillment History Component: The prescription identifier assigned by the pharmacy. The prescription number shall be recorded in the extension attribute of the <id> element within a <supply> element having a moodCode attribute of EVN.

The root attribute of the <id> element should be the OID of the assigning authority for the identifier. Determining the assigning authority is not feasible in all settings, so a GUID MAY be used in place of the OID of the assigning authority.

4.9.2.69 Provider (optional)

Path: ../ entryRelationship/supply/performer/assignedEntity

Type: InformantOrPerformer

Description: Fulfillment History Component: The pharmacy that performed this dispense (may include both a name and an identifier). At least one of <assignedPerson> or <representedOrganization> elements shall appear inside the <assignedEntity> to indicate the name of the person or the organization fulfilling the prescription. The name of the person shall appear in the <name> element of the <assignedPerson> element beneath the <assignedEntity> element. The name of the organization shall appear in the <name> element of the <representedOrganization> element beneath the <assignedEntity> element.

4.9.2.70 Location (optional)

Path: ../ entryRelationship/supply/performer/assignedEntity/addr

Type: Address

Description: The pharmacy's location.

4.9.2.71 Dispense Date (optional)

Path: ../substanceAdministration/entryRelationship/supply/effectiveTime

Type: DateTime

Description: The date of this dispense.

4.9.2.72 Quantity Dispensed (optional)

Path: ../substanceAdministration/entryRelationship/supply/quantity

Type: Dose

Description: This specifies the actual quantity of product supplied in this dispense. Note: this is comprised of both a numeric value and a unit of measure.

The quantity dispensed shall be recorded in the value attribute of <quantity> element inside a <supply> element with a moodCode attribute set to EVN. When the quantity dispensed is in other than administration units, units shall be recorded using UCUM. Otherwise, the unit attribute should contain the preferred name of the presentation units within braces { } using the units of presentation from the NCI Thesaurus.

4.9.2.73 Fill Number (optional)

Path: ../entryRelationship/supply/entryRelationship/sequenceNum

Type: xs:integer

Description: The fill number for the history entry. Identifies this dispense as a distinct event of the prescription.

Fixed value: supply/@moodCode = “EVN”

entryRelationship/@typeCode = “COMP”

4.9.2.74 Fill Status (optional)

Path: ../substanceAdministration/entryRelationship/supply/statusCode

Type: FillStatus

Description: The fill event status is typically 'complete' indicating the fill event has been, or is expected to be picked up. A status of 'aborted' indicates that the dispense was never picked up (e.g., “returned to stock”). Medication fill status shall contain a code derived from a limited set of HL7 ActStatusNormal values.

@code	HL7 ActStatusNormal Vocabulary
completed	An Act that has terminated normally after all of its constituents have been performed
aborted	The Act has been terminated prior to the originally intended completion

Enumerated values:

Fixed value: code/@codeSystemName = “HL7 ActStatusNormal”
code/@codeSystem = “2.16.840.1.113883.11.15936”

4.9.2.75 Source of Information (repeatable)

Path: ../ substanceAdministration /entryRelationship/supply/informant

Type: InformantOrPerformer

Description: The source of information for a supply activity. Please see the L32 data types for a description of the contents of InformantOrPerformer.

4.10 Pregnancy

Specification Reference: C32 Section 2.2.1.11
CCD 3.5 Conditions

4.10.1 Module Description

This module contains a coded entry indicating whether the patient is currently pregnant. Please see A.7 Conditions.

4.10.2 Pregnancy Elements

4.10.2.1 Pregnancy(optional)

Path: ../component/entry/act/entryRelationship/observation/value

Type: ANY

Description: This is a simple observation that records whether the patient is currently pregnant. It is recorded in the Conditions Module as an observation. The value element is an ANY type. It should be specified as xsi:type="CD" and the fixed values below should be used to indicate pregnancy.

Fixed value: code/@code = "77386006"
code/@displayName = "patient currently pregnant"
code/@codeSystemName = " SNOMED CT"
code/@codeSystem = " 2.16.840.1.113883.6.96"

4.11 Information Source

Specification Reference: C32 Section 2.2.1.12
CCD 5.2 Source

4.11.1 Module Description

This module allows for information about the original author to be supplied. This module may be applied to all other modules 2.2.1.1 through 2.2.1.18. See the HL7 Continuity of Care Document Section 5.2 for constraints applicable to this module. The Reference Document ID and Reference Document URL, which provide a reference to the original document from which this information was obtained, have not been implemented. Please see <author> element in A.1 Clinical Document <informant> element in modules A.4 - A.14.

4.11.2 Information Source Elements

4.11.2.1 Author

Type: InformationSource

Description: Please see the InformationSource data type for more details. This data type includes the Author Time and Author Name which represent the time at which this information was created and the name of the person who created the information content respectively.

4.11.2.2 Information Source

Type: InformantOrPerformer

Description: Please see the InformantOrPerformer data type for more details. This data type includes the information source name, or, the name of the person or organization that provided the information. This data type can be found throughout the other modules to indicate the source of information for each.

4.12 Advance Directives

Specification Reference: C32 Section 2.2.1.14
CCD 3.2 Advance Directives

4.12.1 Module Description

This module contains data describing the patient's Advance Directives and any reference to supporting documentation. This section contains data such as the existence of living wills, healthcare proxies and CPR and resuscitation status. The custodian of these documents may be described. This data should be included in a L32_Module component tag with an xsi:type="AdvanceDirectives" attribute.

4.12.2 Advance Directives Elements

4.12.2.1 Advance Directives Module

Path: ClinicalDocument/component/structuredBody/component

Type: AdvanceDirectives < L32Module

4.12.2.2 Advance Directives Template Identifier

Path: ../component/section/templateId

Type: Anonymous Type

Description: Identifies this as the Advance Directives section.

Fixed Value: templateId/@root = “2.16.840.1.113883.10.20.1.1”

4.12.2.3 Advance Directives Code

Path: ../section/code

Type: AdvanceDirectivesCode

Description: The fixed values for an Advance Directives section specified by the CCD to indicate section conformance.

Fixed value: code/@code = “42348-3”
code/@displayName = ”Advance directives”
code/@codeSystemName = "LOINC”
code/@codeSystem = "2.16.840.1.113883.6.1"

4.12.2.4 Advance Directives Title

Path: ../section/title

Type: xs:string

Description: The section title.

Fixed value: title = ”Advance Directives”

4.12.2.5 Advance Directive Text

Path: ../section/text

Type: StrucDoc.Text

Description: The narrative text containing the advance directive information.

4.12.2.6 Advance Directive Entry (optional, repeatable)

Path: ../section/entry

Type: AdvanceDirectiveEntry

Description: An advance directive entry is a container for an advance directive observation.

4.12.2.7 Advance Directive Observation

Path: ../section/entry/observation

Type: AdvanceDirectiveEventEntry

Description: An advance directive observation contains information including the advance directive type, effective date, custodian, and external documents.

Fixed value: observation/@classCode = “OBS”
observation /@moodCode = “EVN”

4.12.2.8 Advance Directive Template Id (minimum=2, maximum=2)

Path: ../section/entry/observation/templateId

Type: Anonymous Type

Description: This is the template identifier for an advance directive. The value of the root attribute of this element provides a unique identifier for the template(s) applied to this observation. Two templateId elements are to be included. There is a CCD and a C32 template identifier for an advance directive observation.

Fixed value: templateId/@root = “2.16.840.1.113883.10.20.1.17”
templateId/@assigningAuthorityName = CCD
templateId/@root = “2.16.840.1.113883.3.88.11.32.13”
templateId/@assigningAuthorityName = HITSP/C32

4.12.2.9 Advance Directive Observation Id

Path: ../section/entry/observation/id

Type: InstanceIdentifier

Description: The CCD requires that an advance directive observation shall contain an act id.

4.12.2.10 Advance Directive Type

Path: ../section/entry/observation/code

Type: AdvanceDirectiveType

Description: This is a coded value describing the type of the Advance Directive.

Enumerated values:

@code	@displayName
304251008	Resuscitation
52765003	Intubation
225204009	IV Fluid and Support
89666000	CPR
281789004	Antibiotics
78823007	Life Support
61420007	Tube Feeding
71388002	Other Directive

Fixed value: code/@codeSystemName = "SNOMED CT”
code/@codeSystem = "2.16.840.1.113883.6.96"

4.12.2.11 Advance Directive Free Text Type

Path: ../section/entry/observation/code/originalText

Type: TextReference

Description: Free text comment to describe the Advance Directive Type. The human readable description of the type of Advance Directive shall appear in the narrative text and shall be pointed to by the value attribute of the <reference> element inside the <originalText> element of the <code> .

4.12.2.12 Advance Directive Status Code

Path: ../section/entry/observation/statusCode

Type: xs:string

Description: The advance directive observation status code.

Fixed value: statusCode/@code = “completed”

4.12.2.13 Effective Date

Path: ../section/entry/observation/effectiveTime

Type: DateRange

Description: The effective date for the Advance Directive.

4.12.2.14 Source of Information (repeatable)

Path: ../section/entry/observation/informant

Type: InformantOrPerformer

Description: The source of information for the advance directive observation. Please see the L32 data types for a description of the contents of InformantOrPerformer.

4.12.2.15 Custodian of the Document

Path: ../section/entry/observation/participant

Type: CustodianOfTheDocument

Description: Name, address or other contact information for the person or organization that can provide a copy of the document.

Fixed value: participant /@typeCode = “'CST”

4.12.2.16 Participant Role

Path: ../section/entry/observation/participant/participantRole

Type: Anonymous Type

Description: Information required to obtain a copy of the Advance Directive shall be recorded in a <participantRole> element within a <participant> element of the Advance Directive <observation>

Fixed value: participantRole/@classCode = “AGNT”

4.12.2.17 Agent Address (optional, repeatable)

Path: ../section/entry/observation/participant/participantRole/addr

Type: Address

Description: The address of the agent shall be recorded when known.

4.12.2.18 Agent Telephone Number (optional, repeatable)

Path: ../section/entry/observation/participant/participantRole/telecom

Type: PhoneEmail

Description: The telephone number or other electronic communications address for the agent shall be recorded when known.

4.12.2.19 Agent Name

Path: ../ entry/observation/participant/participantRole/playingEntity/name

Type: PersonName

Description: The name of the agent who can provide a copy of the Advance Directive shall be recorded in the <name> element inside the <playingEntity> element.

4.12.2.20 Status Observation

Path: ../section/entry/observation/entryRelationship/observation

Type: StatusObservation

Description: An advance directive status observation.

Fixed value:	entryRelationship /@typeCode = “REFR”
	entryRelationship/observation/@classCode = “OBS”
	entryRelationship/observation/@moodCode = “EVN”

4.12.2.21 Status Observation Template Identifier

Path:	../section/entry/observation/entryRelationship/observation/templateId
Type:	Anonymous Type
Description:	Identifies this as an advance directive status observation.
Fixed value:	templateId /@root = “2.16.840.1.113883.10.20.1.37”

4.12.2.22 Status Observation Code

Path:	../section/entry/observation/entryRelationship/observation/code
Type:	StatusObservationCode
Description:	The values for a status observation section specified by the CCD to indicate section conformance.
Fixed value:	code/@code = “33999-4” code/@displayName = ”Status” code/@codeSystemName = "LOINC” code/@codeSystem = "2.16.840.1.113883.6.1"

4.12.2.23 Status Observation Status Code

Path:	../section/entry/observation/entryRelationship/observation/statusCode
Type:	Anonymous Type
Description:	An advance directive status observation status code.
Fixed value:	statusCode /@code = “completed”

4.12.2.24 Status Observation Value (optional, repeatable)

Path:	../section/entry/observation/entryRelationship/observation/value
Type:	ANY
Description:	An advance directive status observation value code shall be selected from the AdvanceDirectiveStatusCode value set. The data type should be specified as xsi:type= CE.

Enumerated values:

@code	@displayName
425392003	Current and Verified
425394002	Supported By Healthcare Will
425393008	Supported By Durable Power of Attorney for Healthcare
425396000	Verified With Family Only
310305009	Verified By Medical Record Only

Fixed value:

code/@codeSystemName = " AdvanceDirectiveStatusCode”

code/@codeSystem = " 2.16.840.1.113883.1.11.20.1”

4.13 Immunizations

Specification Reference: C32 Section 2.2.1.15
CCD 3.11 Immunizations

4.13.1 Module Description

This module contains data describing the patient's immunization history, and defines Immunizations using the same data objects and constraints as for Medications. As with the overall document created, the Immunization section is intended as a summary and not as an official, legal sanctioned report. The intent is not to replace or populate an Immunization Registry, but to provide pertinent summary immunization information.

The Immunizations section shall contain a narrative block, and should contain clinical statements. Clinical statements should include one or more medication activities and/or suppy activities.

This data should be included in a L32_Module component tag with an xsi:type="Immunizations" attribute.

4.13.2 Immunizations Elements

4.13.2.1 Immunizations Module

Path: ClinicalDocument/component/structuredBody/component

Type: Immunizations < L32Module

4.13.2.2 Immunizations Template Identifier

Path: ../component/section/templateId

Type: Anonymous Type

Description: Identifies this as the Immunizations section.

Fixed Value: templateId/@root = “2.16.840.1.113883.10.20.1.6”

4.13.2.3 Immunizations Code

Path: ../section/code

Type: ImmunizationsCode

Description: The fixed values for an Immunizations section specified by the CCD to indicate section conformance.

Fixed value: code/@code = “11369-6”
code/@displayName = ”History of immunizations”
code/@codeSystemName = "LOINC”
code/@codeSystem = "2.16.840.1.113883.6.1"

4.13.2.4 Immunizations Title

Path: ../section/title

Type: xs:string

Description: The section title.

Fixed value: title = ”Immunizations”

4.13.2.5 Immunization Text

Path: ../section/text

Type: StrucDoc.Text

Description: The narrative text containing immunization information.

4.13.2.6 Immunization Entry (optional, repeatable)

Path: ../section/entry

Type: ImmunizationEntry

Description: An immunization entry is a container for an immunization event.

4.13.2.7 Immunization Event Entry

Path: ../section/entry/substanceAdministration

Type: ImmunizationEventEntry

Description: This contains information about an immunization, and uses some data objects and constraints from the Medications module.

Fixed value: substanceAdministration/@classCode = “SBADM”

substanceAdministration /@moodCode = “EVN”

4.13.2.8 Immunization Event Entry Template Id (minimum=2, maximum=2)

Path: ../section/entry/ substanceAdministration /templateId

Type: Anonymous Type

Description: This is the template identifier for the immunization module. The value of the root attribute of this element provides a unique identifier for the template(s) applied. Two templateId elements are to be included. There is a CCD and a C32 template identifier for an immunizations module.

Fixed value: templateId/@root = “2.16.840.1.113883.10.20.1.24”
templateId/@assigningAuthorityName=CCD

templateId/@root = “ 2.16.840.1.113883.3.88.11.32.14”
templateId/@assigningAuthorityName=HITSP/C32

4.13.2.9 Refusal

Path: ../section/entry/substanceAdministration/@negationInd

Type: xs:boolean

Description: A flag that the immunization event did not occur. The nature of the refusal (e.g., patient refused, adverse reaction).

4.13.2.10 Immunization Id

Path: ../section/entry/substanceAdministration/id

Type: InstanceIdentifier

Description: The CCD requires that a medication activity shall contain a substance administration id.

4.13.2.11 Immunization Code(optional)

Path: ../section/entry/substanceAdministration/code

Type: ImmunizationsCode

Description: The fixed values for an Immunizations section specified by the CCD to indicate section conformance.

Fixed value: code/@code = “11369-6”
code/@displayName = ”History of immunizations”
code/@codeSystemName = "LOINC”
code/@codeSystem = "2.16.840.1.113883.6.1"

4.13.2.12 Free Text (optional)

Path: ../section/entry/substanceAdministration /text

Type: TextReference

Description: The instructions, typically from the ordering provider, to the patient on the proper means and timing for the use of the product. This information is free-text but can also be represented as a series of Sig Components. The <text> element of the free text sig shall contain a <reference> element whose value attribute points to the text of the free text sig in the narrative portion of the CCD.

4.13.2.13 Immunization Status Code (optional)

Path: ../section/entry/substanceAdministration /statusCode

Type: StatusCode

Description: A medication activity should contain a status code. Please see StatusCode data type for further details.

4.13.2.14 Administered Date (optional)

Path: ../section/entry/substanceAdministration/effectiveTime

Type: DateTime

Description: The date and time a substance was administered or refused, i.e., when the immunization was administered to the patient, or refused by the patient.

4.13.2.15 Route (optional)

Path: ../section/entry/substanceAdministration/routeCode

Type: RouteOrProductForm

Description: Indicates how the immunization is received by the patient (e.g., by mouth, intravenously, topically, et cetera). Route codes shall have a value drawn from FDA route of administration. See http://www.fda.gov/Drugs/DevelopmentApprovalProcess/UCM070829

Fixed value: routeCode/@codeSystemName = “NCI Thesaurus”

routeCode/@codeSystem = "2.16.840.1.113883.3.26.1.1"

4.13.2.16 Site (optional, repeatable)

Path: ../section/entry/substanceAdministration/approachSiteCode

Type: GenericCode

Description: The anatomic site where the medication is administered, usually applicable to injected or topical products. The code attribute shall contain a value descending from the SNOMED CT Anatomical Structure (91723000) hierarchy.

4.13.2.17 Dose (optional)

Path: ../section/entry/substanceAdministration/doseQuantity

Type: Dose

Description: The amount of the product to be given. This may be a known, measurable unit (e.g., milliliters), an administration unit (e.g., tablet), or an amount of active ingredient (e.g., 250 mg). May define a variable dose, dose range or dose options based upon identified criteria.

The units of presentation can be found at www.fda.gov, and include only those terms which have not been mapped to UCUM. Terms with mappings to UCUM are units of administration. The unit attribute is optional. If used, it contains the preferred name of the presentation units within braces { } using the units of presentation from the NCI Thesaurus.

4.13.2.18 Medication Information

Path: ../ entry/substanceAdministration/consumable/manufacturedProduct

Type: MedicationInformation

Description: The name and code for the medication are recorded in the consumable element. Please see the Medications Module for more details about the MedicationInformation data type.

Fixed value: manufacturedProduct/@classCode = “MANU”

4.13.2.19 Manufactured Material

Path: ../consumable/manufacturedProduct/manufacturedMaterial

Type: Anonymous Type

Description: Contains information about the product including the product name, strength, form, concentration, and unit dose.

Fixed value: manufacturedMaterial /@classCode = “MMAT”

manufacturedMaterial /@determinerCode= “KIND”

4.13.2.20 Coded Product Name

Path: ../consumable/manufacturedProduct/manufacturedMaterial/code

Type: CodedProductName

Description: A code describing the product from a controlled vocabulary. The product (generic) name shall appear in the <originalText> element beneath the <code> element. The code for the specific brand of product shall appear in a <translation> element. The brand name shall appear in the <name> element of the <manufacturedMaterial>. The code shall be coded using CVX. The code shall appear in the code attribute of the <code> or <translation> element. The OID for CVX is 2.16.840.1.113883.6.59.

4.13.2.21 Free Text Brand Name (optional)

Path: ../consumable/manufacturedProduct/manufacturedMaterial/name

Type: xs:string

Description: The branded or trademarked name of the substance or product. If a Coded Brand Name is present, this is the text associated with the coded concept. This may include additional information such as strength, dose form, etc.

4.13.2.22 Lot Number (optional)

Path: ../ manufacturedProduct/manufacturedMaterial/lotNumberText

Type: xs:string

Description: The manufacturer's production lot number for the administered product.

4.13.2.23 Drug Manufacturer (optional)

Path: ../consumable/manufacturedProduct/manufacturedOrganization

Type: Organization

Description: The manufacturer of the substance or product as ordered or supplied. The distributor may be supplied if the manufacturer is not known.

4.13.2.24 Performer (optional, repeatable)

Path: ../section/entry/substanceAdministration/performer

Type: InformantOrPerformer

Description: The person that administered the immunization to the patient (may include both a name and an identifier).

4.13.2.25 Informant (repeatable)

Path: ../section/entry/substanceAdministration/informant

Type: InformantOrPerformer

Description: Source of information for a medication activity. Please see the InformantOrPerformer data type for more details.

4.13.2.26 Medication Information Entry (optional, repeatable)

Path: ../entry/substanceAdministration/entryRelationship

Type: MedicationInformationEntry

Description: A medication entry relationship can contain an act, observation, or supply. Please see more details about this data type in the Medication Module. The elements specified in the Immunizations Module of the C32 are described in more detail below.

Enumerated values:

@typeCode	Use
SUBJ	Medication Series Number, use with observation
RSON	Refusal Reason, use with act
CAUS	Immunization Reaction, use with observation

4.13.2.27 Medication Series Number (optional)

Path: ../entry/substanceAdministration/entryRelationship/observation/value

Type: ANY (use xsi:type = INT)

Description: Indicate which in a series of administrations a particular administration represents (e.g. “hepatitis B vaccine number 2”).

Fixed value: entryRelationship /@typeCode = “SUBJ”

observation /@classCode = “OBS”

observation /@moodCode = “EVN”

4.13.2.28 Reaction (optional)

Path: ../entry/substanceAdministration/entryRelationship/observation

Type: MedicationObservation

Description: Any noted intended or unintended effects of the product. For example: full body rash, nausea, rash resolved. Please see the Medications Module for more information about the MedicationObservation data type.

Fixed value: entryRelationship/@typeCode = “CAUS”

4.13.2.29 Reaction Template Identifier

Path: ../entry/substanceAdministration/entryRelationship/observation/templateId

Type: Anonymous Type

Description: Indicates conformance to a reaction observation.

Fixed value: templateId/@root = “2.16.840.1.113883.10.20.1.54”

4.13.2.30 Refusal Reason (optional)

Path:	../entry/substanceAdministration/entryRelationship/act
Type:	FulfillmentInstructions
Description:	When an immunization is refused, this provides a coded representation of the reason for refusing the immunization. The reason for refusal shall be reported using HL7 ActNoImmunizationReason vocabulary. The OID for this vocabulary is 2.16.840.1.113883.11.19725. Please see more details about this data type in the Medications Module.
Fixed value:	entryRelationship /@typeCode = “RSON”

4.13.2.31 Refusal Reason Template Identifier

Path:	../entry/substanceAdministration/entryRelationship/act/templateId
Type:	Anonymous Type
Description:	Indicates conformance to an indication for a medication activity.
Fixed value:	templateId/@root = “2.16.840.1.113883.10.20.1.27”

4.14 Vital Signs

Specification Reference: C32 Section 2.2.1.16
CCD 3.12

4.14.1 Module Description

The Vital Signs Module contains current and relevant historical vital signs for the patient. Vital Signs are a subset of Results, but are reported in this section to follow clinical conventions. This data should be included in a L32_Module component tag with an xsi:type="VitalSigns" attribute. The table below summarizes the measurements typically considered “vital signs” and their LOINC concept codes (from the C32).

4.14.2 Vital Signs Elements

Element: Vital Signs Module
Path: ClinicalDocument/component/structuredBody/component
Type: VitalSigns < L32Module

LOINC Concept Code	Description
9279-1	RESPIRATION RATE
8867-4	HEART BEAT
2710-2	OXYGEN SATURATION
8480-6	INTRAVASCULAR SYSTOLIC
8462-4	INTRAVASCULAR DIASTOLIC
8310-5	BODY TEMPERATURE
8302-2	BODY HEIGHT (MEASURED)
8306-3	BODY HEIGHT^LYING
8287-5	CIRCUMFERENCE OCCIPITAL-FRONTAL (TAPE MEASURE)
3141-9	BODY WEIGHT (MEASURED)

4.14.2.1 Vital Signs Template Identifier

Path: ../component/section/templateId
Type: Anonymous Type
Description: Identifies this as the Vital Signs section.
Fixed Value: templateId/@root = “2.16.840.1.113883.3.88.11.32.15”

4.14.2.2 Vital Signs Code

Path:	…/ component/section/code
Type:	VitalSignsCode
Description:	The values for a Vital Signs section specified by the CCD to indicate section conformance.
Fixed value:	code/@code = “48765-2” code/@displayName = “Vital signs” code/@codeSystemName = "LOINC” code/@codeSystem = "2.16.840.1.113883.6.1"

4.14.2.3 Vital Signs Entry (optional, repeatable)

Path:	…/component/section/entry/
Type:	ResultEventEntry
Description:	A vital signs result observation. It has the same structure as any other result observation.

4.15 Results

Specification Reference: C32 Section 2.2.1.17
CCD 3.13 Results

4.15.1 Module Description

This module contains current and relevant historical result observations for the patient.

4.15.2 Results Elements

4.15.2.1 Results Module

Path: ClinicalDocument/component/structuredBody/component

Type: Results < L32Module

4.15.2.2 Results Template Identifier

Path: ../component/section/templateId

Type: Anonymous Type

Description: Identifies this as the Results section.

Fixed Value: templateId/@root = “2.16.840.1.113883.10.20.1.14”

4.15.2.3 Results Code

Path: …/ component/section/code

Type: ResultsCode

Description: The values for a Results section specified by the CCD to indicate section conformance.

Fixed value: code/@code = “30954-2”
code/@displayName = “Relevant diagnostic tests and/or laboratory data”
code/@codeSystemName = "LOINC”
code/@codeSystem = "2.16.840.1.113883.6.1"

4.15.2.4 Result Entry

Path: …/component/section/entry/

Type: ResultEventEntry

Description: This element represents a result entry. (It and its children are also used for vital signs.)

4.15.2.5 Result Event Entry

Path: …/component/section/entry/observation

Type: ResultEntry

Description: This element represents a result observation.

Fixed Value: templateId/@root = “2.16.840.1.113883.10.20.1.31”
templateId/@root = “2.16.840.1.113883.3.88.11.32.16”

4.15.2.6 Result ID

Path: …/component/section/entry/observation/id

Type: InstanceIdentifier

Description: Unique identifier for this specific observation.

4.15.2.7 Result Date/Time

Path: …/component/section/entry/observation/effectiveTime

Type: DateRange

Description: The biologically relevant date/time for the observation.

4.15.2.8 Result Type

Path: …/component/section/entry/observation/code

Type: ResultsType

Description: A coded representation of the observation performed.

The result type can be selected from LOINC or SNOMED CT codes. For vital signs, the result type SHOULD be selected from LOINC.

Enumerated values:

@codeSystemName	@codeSystem
LOINC	2.16.840.1.113883.6.1
SNOMED	2.16.840.1.113883.6.96

4.15.2.9 Result Status

Path: …/component/section/entry/observation/statusCode

Type: StatusCode

Description: The status for this observation.

4.15.2.10 Result Value

Path: …/component/section/entry/observation/value

Type: ANY

Description: The value of the result, including units of measure if applicable.

4.15.2.11 Result Interpretation (optional)

Path: …/component/section/entry/observation/interpretationCode

Type: GenericCode

Description:	An abbreviated interpretation of the observation, e.g., normal, abnormal, high, etc.

4.15.2.12 Result Reference Range (optional, repeatable)

Path:	…/component/section/entry/observation/referenceRange
Type:	ResultsReferenceRange
Description:	Reference range(s) for the observation.
Fixed Value:	@typeCode = “REFV"
	observationRange/@classCode = “OBS”
	observationRange/@moodCode = “EVN.CRT”

4.16 Encounters

Specification Reference: C32 Section 2.2.1.18
CCD 3.15 Encounters

4.16.1 Module Description

This represents the overall structure of the C32 Encounters Module. The Encounters Module contains data describing the interactions between the patient and clinicians. Interaction includes both in-person and non-in-person encounters such as telephone and email communication.

4.16.2 Encounters Elements

4.16.2.1 Encounters Module

Path: ClinicalDocument/component/structuredBody/component

Type: Encounters < L32Module

4.16.2.2 Encounters Template Identifier

Path: ../component/section/templateId

Type: Anonymous Type

Description: Identifies this as the Encounters section.

Fixed Value: templateId/@root = “2.16.840.1.113883.10.20.1.3”

4.16.2.3 Encounters Code

Path: …/ component/section/code

Type: EncountersCode

Description: The values for a Encounters section specified by the CCD to indicate section conformance.

Fixed value: code/@code = “46240-8”
code/@displayName = “History of encounters”
code/@codeSystemName = "LOINC”
code/@codeSystem = "2.16.840.1.113883.6.1"

4.16.2.4 Encounter Entry

Path: ../component/section/entry

Type: EncounterEntry

Description: The container for information about an encounter.

Fixed Value: encounter/@classCode = “ENC”
encounter/@moodCode = “EVN”
encounter/templateId/@root = “2.16.840.1.113883.10.20.1.21”
encounter/templateId/@root = “2.16.840.1.113883.3.88.11.32.17”

4.16.2.5 Encounter ID

Path: ../entry/encounter/id

Type: InstanceIdentifier

Description: A unique identifier for this encounter.

4.16.2.6 Encounter Type

Path: ../entry/encounter/code

Type: EncounterType

Description: This is a coded value describing the type of the Encounter and SHOULD be coded using CPT-4 E& M Codes.
CPT-4 codes are licensed by the AMA and are not freely available. HITSP C32 overrides the CCD Implementation Guide recommendation for this value set.

Fixed Value: code/@codeSystemName = " CPT-4 E&M”

code/@codeSystem = " 2.16.840.1.113883.6.12"

4.16.2.7 Encounter Free Text Type

Path: ../entry/encounter/code/originalText

Type: TextReference

Description: Free text comment to describe the Encounter Type. References text from the narrative section.

4.16.2.8 Encounter Date/Time

Path: ../entry/encounter/effectiveTime

Type: TS

Description: The date and time of the encounter, including duration if pertinent.

4.16.2.9 Encounter Provider (repeatable)

Path: ../entry/encounter/performer

Type: InformantOrPerformer

Description: Name and other information for the person or organization that performed or hosted the encounter.

4.17 Procedures

Specification Reference: C32 Section 2.2.1.19
CCD 3.14 Procedures

4.17.1 Module Description

This module contains coded entries indicating procedures performed on a patient. CCD allows for a number of vocabularies to be employed: SNOMED, LOINC, CPT4, ICD9 and ICD10. The wide variety of vocabularies, and the existence of additional procedures not currently addressed, complicates interoperability. This interoperability issue is recognized as a standards gap.

The L32 defines a limited procedure element that is optional, in addition to the required structured text. The CCD allows a procedure activity to be represented by either Act, Observation, or Procedure. This schema only implements/allows the Procedure element.

This data should be included in a component tag with an xsi:type="Procedures" attribute.

4.17.2 Procedures Elements

4.17.2.1 Procedures Module

Path: ClinicalDocument/component/structuredBody/component

Type: Procedures < L32Module

4.17.2.2 Procedures Template Identifier

Path: ../component/section/templateId

Type: Anonymous Type

Description: Identifies this as the Procedure section.

Fixed Value: templateId/@root = “2.16.840.1.113883.10.20.1.12”

4.17.2.3 Procedures Code

Path: …/ component/section/code

Type: ProceduresCode

Description: The values for a Procedures section specified by the CCD to indicate section conformance.

Fixed value: code/@code = “47519-4”
code/@displayName = “History of procedures”
code/@codeSystemName = "LOINC”
code/@codeSystem = "2.16.840.1.113883.6.1"

4.17.2.4 Procedures Text

Path: …/ component/section/text

Type: StrucDoc.Text

Description: Structured textual representation of the procedures that patient has undergone.

4.17.2.5 Procedure Entry (optional, repeatable)

Path: …/ component/section/entry

Type: ProcedureEntry

Description: A procedure entry.

4.17.2.6 Procedure

Path: …/ component/section/entry/procedure

Type: Procedure

Description: Information about a procedure performed on a patient.

Fixed Value: procedure/templateId/@root = “2.16.840.1.113883.10.20.1.29”

procedure/@classCode = “PROC”

procedure/@moodCode = “EVN”

4.17.2.7 Procedure Code

Path: …/ component/section/entry/procedure/code

Type: ProcedureCode

Description: The coded value describing the procedure. The CCD allows 5 different coding systems for encoding a procedure.

Enumerated values:

@codeSystemName	@codeSystem
LOINC	2.16.840.1.113883.6.1
SNOMED	2.16.840.1.113883.6.96
CPT-4	2.16.840.1.113883.6.12
ICD9 Procedures	2.16.840.1.113883.6.104
ICD10 Procedure Coding System	2.16.840.1.113883.6.4

4.17.2.8 Procedure Status

Path: …/ component/section/entry/procedure/statusCode

Type: ProcedureStatusCode

Description: Status of the procedure.

Enumerated values:

statusCode/@code
cancelled
held
active
aborted
completed

4.17.2.9 Procedure Time

Path: …/ component/section/entry/procedure/effectiveTime

Type: DateRange

Description: Date and time the procedure was performed.

4.18 L32 Datatypes

4.18.1 Address

Description: An address is a collection of parts including street, city, state, and postal code. Country codes shall be recorded using ISO-3166-1 and shall be present for addresses outside of the US.

Element: streetAddressLine (maximum=2)

Type: xs:string

Element: city

Type: xs:string

Element: postalCode

Type: xs:string

Pattern: [0-9]{5}(-[0-9]{4})?

Element: country (optional)

Type: xs:string (length = 2)

4.18.2 AddressUseValues

Description: Identifies an address as home, work, or vacation.

Enumerated values:

Use	Description
HP	Home Phone / Address
HV	Vacation Phone / Address
WP	Work Phone / Address

4.18.3 Author

Description: Identifies who or what has generated the summarization.

Element: id

Type: InstanceIdentifier

Element: addr (optional)

Type: Address

Element: telecom (optional, repeatable)

Type: PhoneEmail

Element: assignedPerson
Type: Anonymous Type

Element: assignedPerson/name
Type: PersonName

Element: representedOrganization (optional)
Type: Organization

4.18.4 DateRange

Description: An interval of time.
Element: low
Type: DateTime

Element: high (optional)
Type: DateTime

4.18.5 DateTime

Description: A quantity specifying a point in time between 1/1/1800 and 12/31/2099. The format is yyyymmddhhmmss.
Attribute: value
Type: xs:string with restrictions

4.18.6 Entity

Description: Identifies who or what has generated the summarization.
Element: id
Type: InstanceIdentifier

Element: code (optional)
Type: ProviderType

Element: addr (optional)
Type: Address

Element: telecom (optional, repeatable)
Type: PhoneEmail

Element: assignedPerson
Type: Anonymous Type:

Element: assignedPerson/name (optional)
Type: PersonName

Element: representedOrganization (optional)
Type: Organization

4.18.7 GenericCode

Description: Includes a code value, display name, the code system id, and the code system name.
Attribute: code
Type: xs:token with restrictions

Attribute: displayName (optional)
Type: xs:string

Attribute: codeSystemName (optional)
Type: xs:string

Attribute: codeSystem (optional)
Type: Id

4.18.8 Id

Description: A unique identifier that guarantees the global uniqueness of the instance identifier.

Type: xs:string with restrictions

4.18.9 InformationSource

Description: Information Source includes information about the Author, which can include an id, name, address, telephone, and email.
Element: time
Type: DateTime

Element: assignedAuthor

Type: Author

4.18.10 InformantOrPerformer

Description: A person or organization that is the source of information.

Element: assignedEntity

Type: Entity

4.18.11 InstanceIdentifier

Description: An identifier that uniquely identifies a thing or object. Examples are object identifier for HL7 RIM objects, medical record number, order id, service catalog item id, Vehicle Identification Number (VIN), etc. Instance identifiers are defined based on ISO object identifiers.

Attribute: root

Type: Id

Attribute: extension (optional)

Type: xs:string

4.18.12 L32Module (abstract type)

Description: The L32Module type is an abstract type that should be replaced by an xsi:type representing one of the C32 modules.

4.18.13 Organization

Description: Provides information about the author, entity, or manufacturer organization.

Element: id (optional)

Type: InstanceIdentifier

Element: name

Type: xs:string

Element: telecom (optional, maximum = 2)

Type: PhoneEmail

Element: addr (optional)

Type: Address

4.18.14 PersonName

Description: A person name is represented as an optional prefix, given name, family name, and an optional suffix. The use attribute is fixed to L for legal name.

Element: prefix (optional)

Type: xs:string

Element: given (maximum = 2)

Type: xs:string

Element: family

Type: xs:string

Element: suffix (optional)

Type: xs:string

Attribute: use (optional)

Type: xs:string

Fixed value: “L”

4.18.15 PhoneEmail

Description: The use attribute shall contain a telecom use value, and the value attribute can contain a telephone number or email address. The format for a telephone number in international form is: tel:+1-999-999-9999. It uses the 'tel:' URL scheme. Please see IETF/RFC-3966. Represent an extension by appending ';ext=' at the end of the number. An email address uses the 'mailto:' URL scheme. Please see IETF/RFC-2368.

Attribute: use (optional)

Type: TelecomUseValues

Attribute: value

Type: xs:string with restrictions to follow pattern described above

Name: StatusCode

Description: HL7 ActStatusNormal status code options.

Attribute: code

Enumerated values:

Code
Aborted
Completed
Active
Cancelled
Held
New
Suspended

4.18.16 TelecomUseValues

Description: Identifies a phone number or email address as home, vacation, work, or mobile.
Type: Enumerated Simple Type

Enumerated values:

Use	Description
HP	Home Phone / Address
HV	Vacation Phone / Address
WP	Work Phone / Address
MC	Mobile Phone

4.18.17 TextReference

Description: The value attribute refers to narrative text.
Element: reference
Type: Anonymous Type
Attribute: reference/@value
Type: xs:string

Attribute: mediaType (optional)

Type: xs:string

4.19 CDA Datatypes

4.19.1 ANY

Description: Defines the basic properties of every data value. This is an abstract type, meaning that no value can be just a data value without belonging to any concrete type. Every concrete type is a specialization of this general abstract DataValue type.

Attribute: nullFlavor (optional)

Type: xs:string

Fixed value: “UNK”

4.19.2 CD

Description: A concept descriptor represents any kind of concept usually by giving a code defined in a code system. A concept descriptor can contain the original text or phrase that served as the basis of the coding. A concept descriptor can also contain qualifiers to describe, e.g., the concept of a "left foot" as a postcoordinated term built from the primary code "FOOT" and the qualifier "LEFT". In exceptional cases, the concept descriptor need not contain a code but only the original text describing that concept. CD extends ANY type.

Element: originalText (optional)

Type: xs:string

Description: The text or phrase used as the basis for the coding.

Attribute: code (optional)

Type: xs:token

Description: The plain code symbol defined by the code system. For example, "784.0" is the code symbol of the ICD-9 code "784.0" for headache.

Attribute: codeSystem (optional)

Type: Id

Description: Specifies the code system that defines the code.

Attribute: codeSystemName (optional)

Type: xs:string

Description: A common name of the coding system.

Attribute:	displayName (optional)
Type:	xs:string
Description:	A name or title for the code, under which the sending system shows the code value to its users.

4.19.3 CE

Description:	Coded data, consists of a coded value (CV) and, optionally, coded value(s) from other coding systems that identify the same concept. Used when alternative codes may exist. CE restricts CD type.
Element:	originalText (optional)
Type:	xs:string
Description:	The text or phrase used as the basis for the coding.

Attribute:	code (optional)
Type:	xs:token
Description:	The plain code symbol defined by the code system. For example, "784.0" is the code symbol of the ICD-9 code "784.0" for headache.

Attribute:	codeSystem (optional)
Type:	Id
Description:	Specifies the code system that defines the code.

Attribute:	codeSystemName (optional)
Type:	xs:string
Description:	A common name of the coding system.

Attribute:	displayName (optional)
Type:	xs:string
Description:	A name or title for the code, under which the sending system shows the code value to its users.

4.19.4 INT

Description:	Integer numbers (-1,0,1,2, 100, 3398129, etc.) are precise numbers that are results of counting and enumerating. Integer numbers are discrete, the set of integers is infinite but countable. No arbitrary limit is imposed on the range of integer numbers. Two NULL flavors are defined for the positive and negative infinity. INT extends ANY type.
Attribute:	value (optional)

Type: xs:integer

4.19.5 PIVL_TS

Description: An extension of the TS data type.

Element: phase (optional)

Type: IVL_TS

Description: A prototype of the repeating interval specifying the duration of each occurrence and anchors the periodic interval sequence at a certain point in time.

Element: period (optional)

Type: PQ

Description: A time duration specifying a reciprocal measure of the frequency at which the periodic interval repeats.

Attribute: institutionSpecified (optional)

Type: xs:boolean

Default: false

Description: Indicates whether the exact timing is up to the party executing the schedule (e.g., to distinguish "every 8 hours" from "3 times a day".)

4.19.6 EIVL_TS

Description: An extension of the TS data type.

Element: event (optional)

Type: EIVL.event

Description: A code for a common (periodical) activity of daily living based on which the event related periodic interval is specified.

4.19.7 TS

Description: A quantity specifying a point on the axis of natural time. A point in time is most often represented as a calendar expression. TS extends ANY data type.

Attribute: value

Type: restricts xs:string

Pattern: "((18|19|20)\d\d(0[1-9]|1[012])(0[1-9]|[12][0-9]|3[01]))((([0-1][0-9])|([2][0-3]))([0-5][0-9])(([0-5][0-9])))?(-\d{4})?"

4.19.8 IVL_TS

Description: An extension of the TS data type, an interval of time.

Element:	low
Type:	DateTime
Description:	The low limit of the interval.

Element:	high (optional)
Type:	DateTime
Description:	The high limit of the interval.

4.19.9 PQ

Description:	A dimensioned quantity expressing the result of a measurement act, extends the ANY data type.
Attribute:	value (optional)
Type:	xs:double
Description:	The magnitude of the quantity measured in terms of the unit.

Attribute:	unit (optional)
Type:	xs:token
Default:	1
Description:	The unit of measure specified in the Unified Code for Units of Measure (UCUM) [http://aurora.rg.iupui.edu/UCUM].

4.19.10 EIVL.event

Description:	A code for a common (periodical) activity of daily living based on which the event related periodic interval is specified. EIVL.event restricts the CE data type.
Attribute:	code (optional)
Type:	xs:token
Description:	The plain code symbol defined by the code system. For example, "784.0" is the code symbol of the ICD-9 code "784.0" for headache.
Attribute:	codeSystem (optional)
Type:	Id
Fixed:	2.16.840.1.113883.5.139
Description:	Specifies the code system that defines the code.

Attribute:	codeSystemName
Type:	xs:string
Fixed:	TimingEvent
Description:	A common name of the coding system.

5 References

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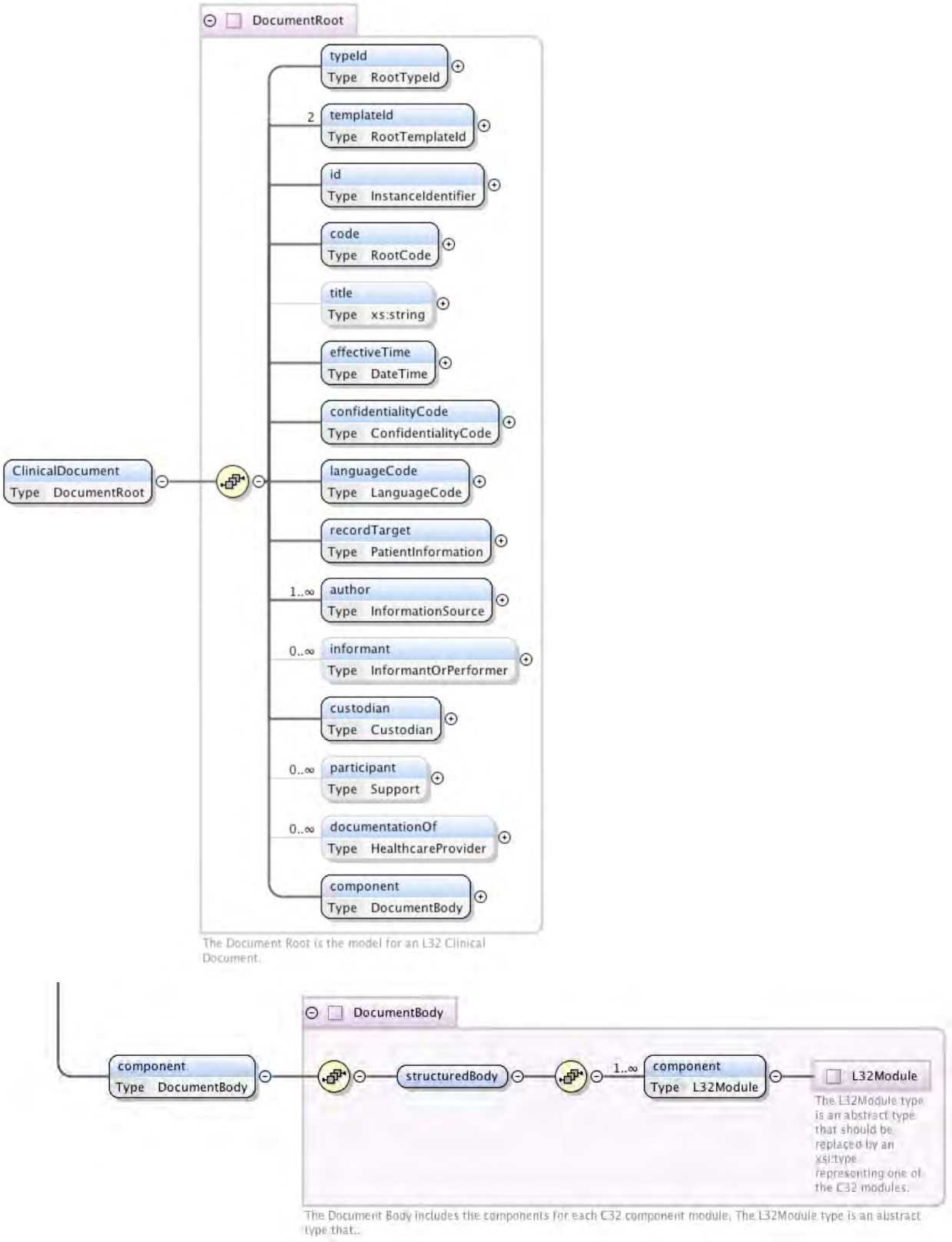
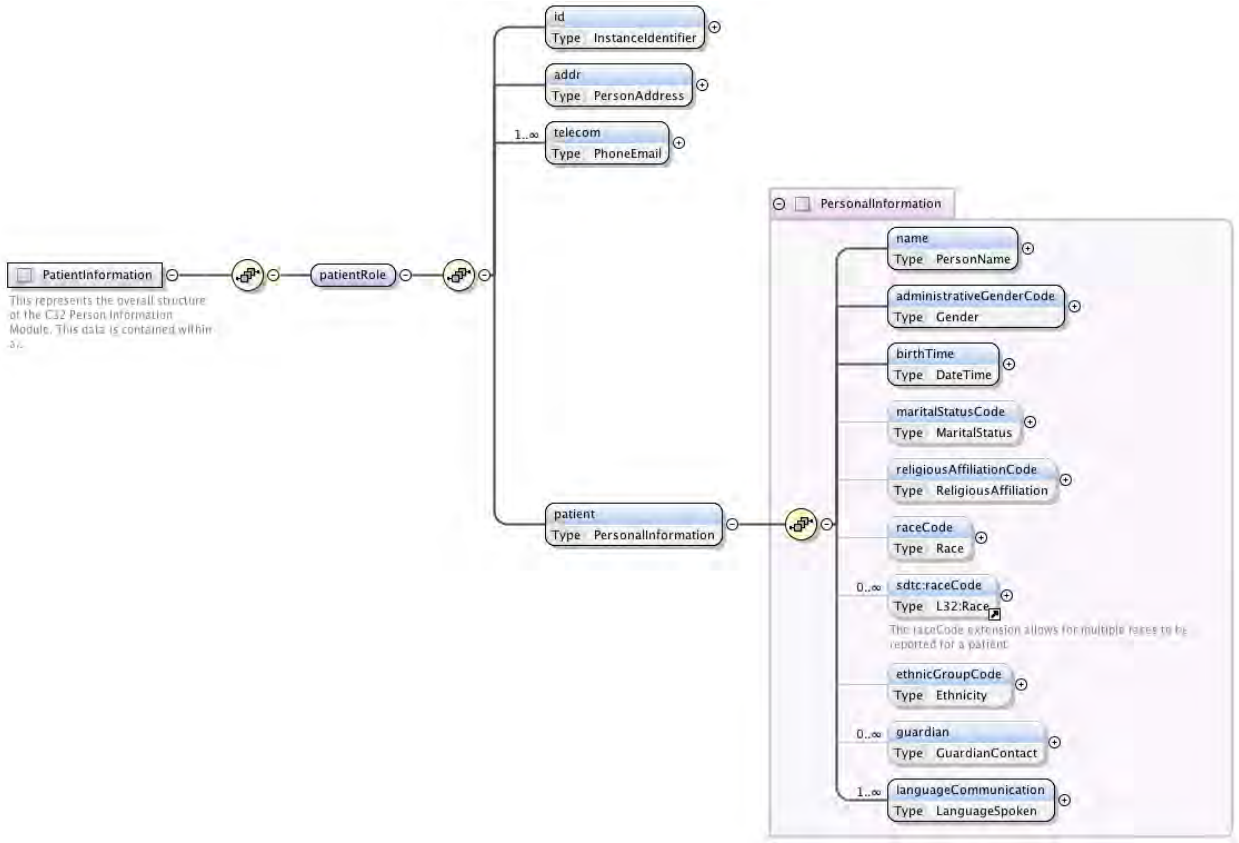
Appendix A L32 Schema Diagrams

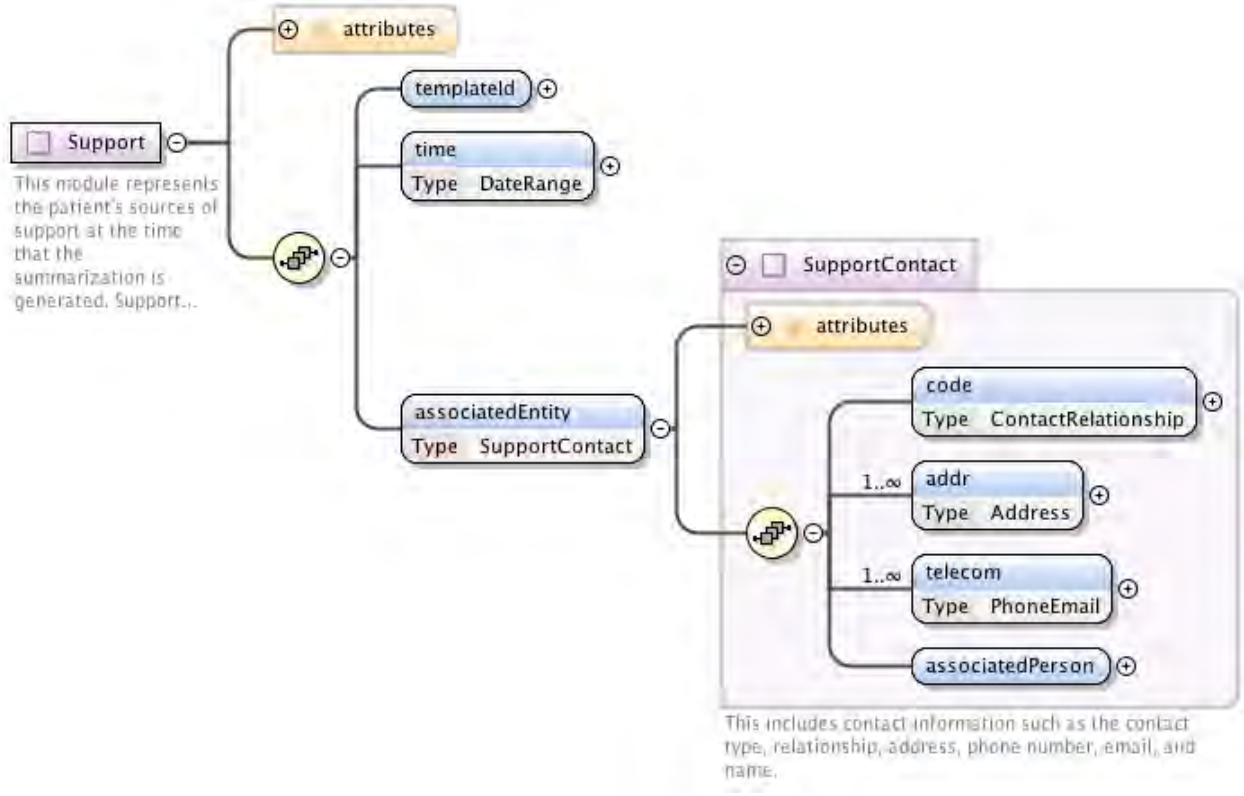
A.1 Clinical Document (Root)



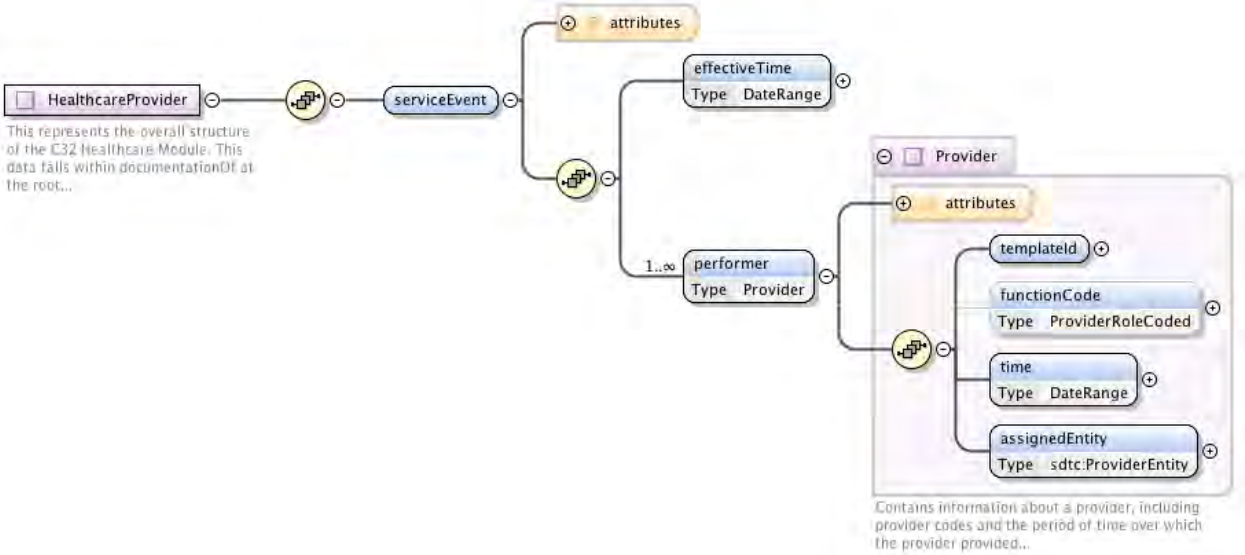
A.2 Person Information



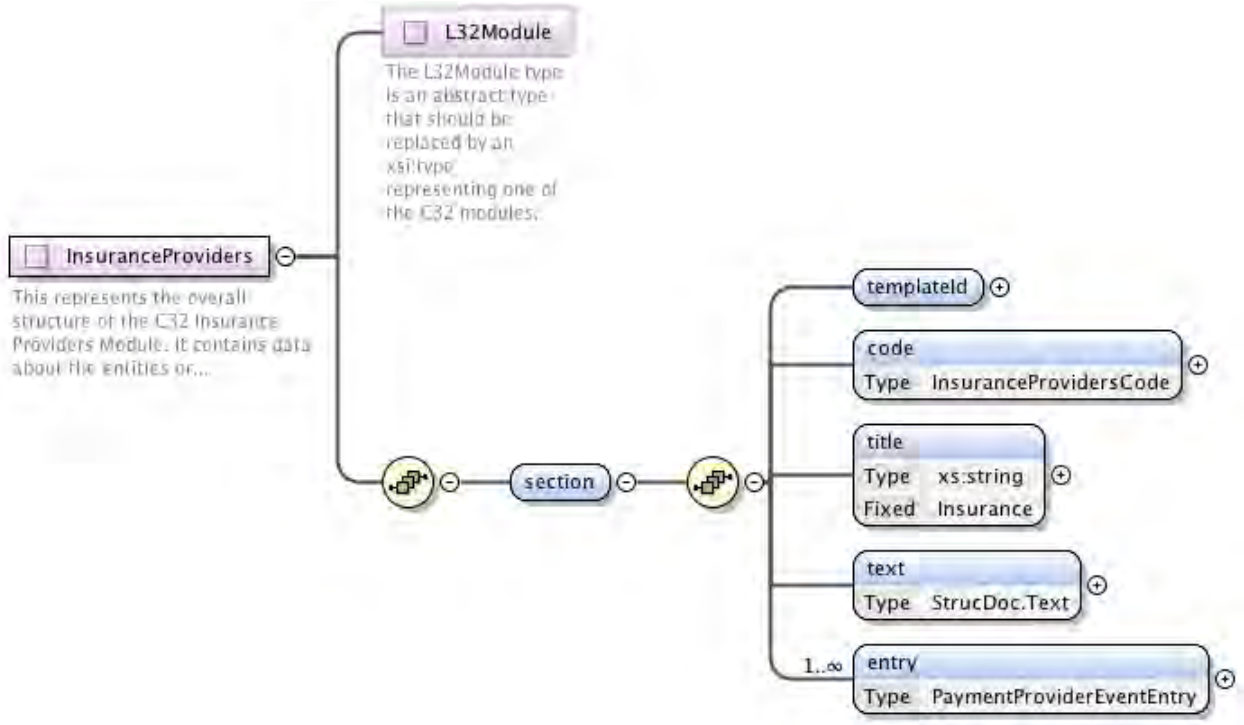
A.3 Support

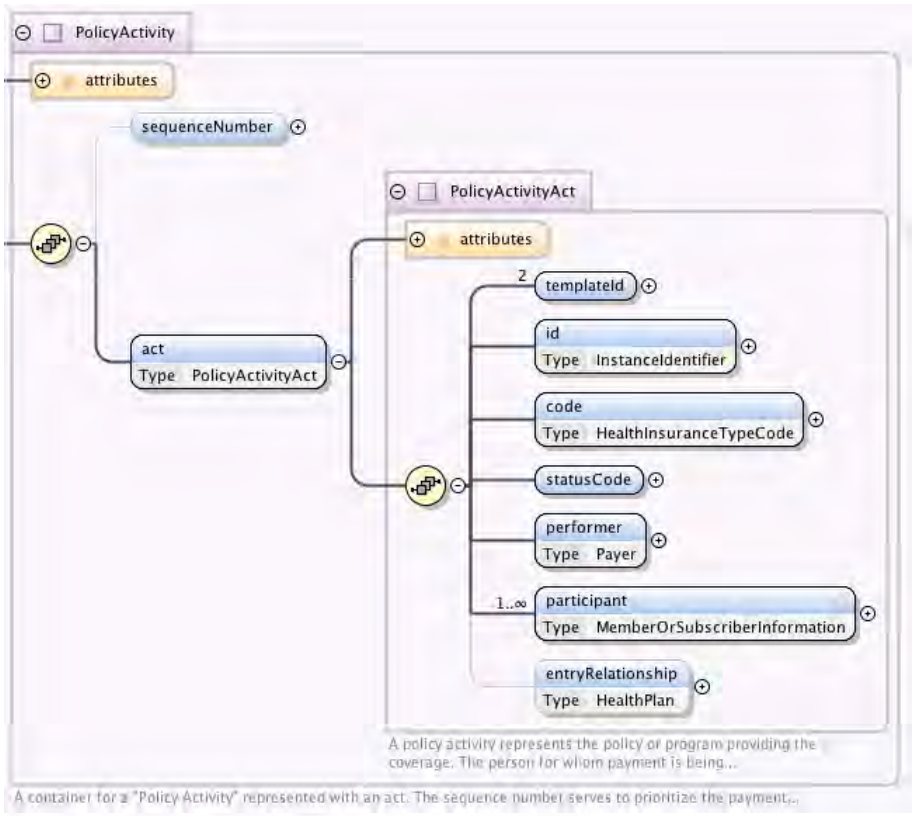


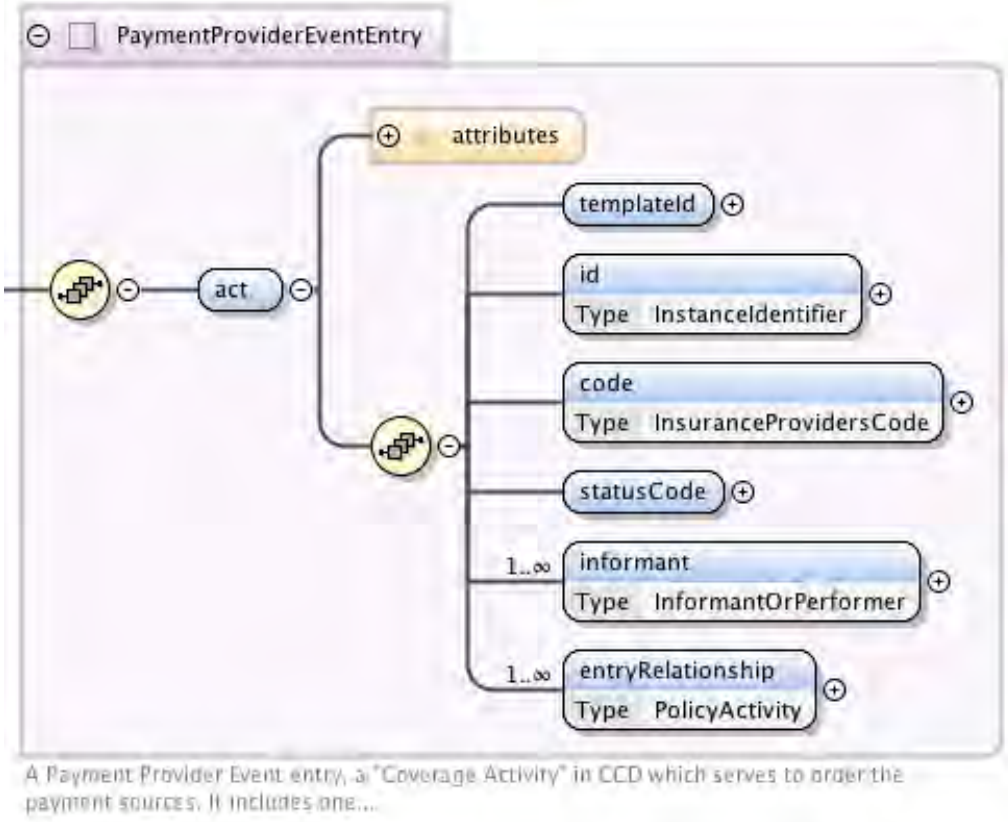
A.4 Healthcare Provider



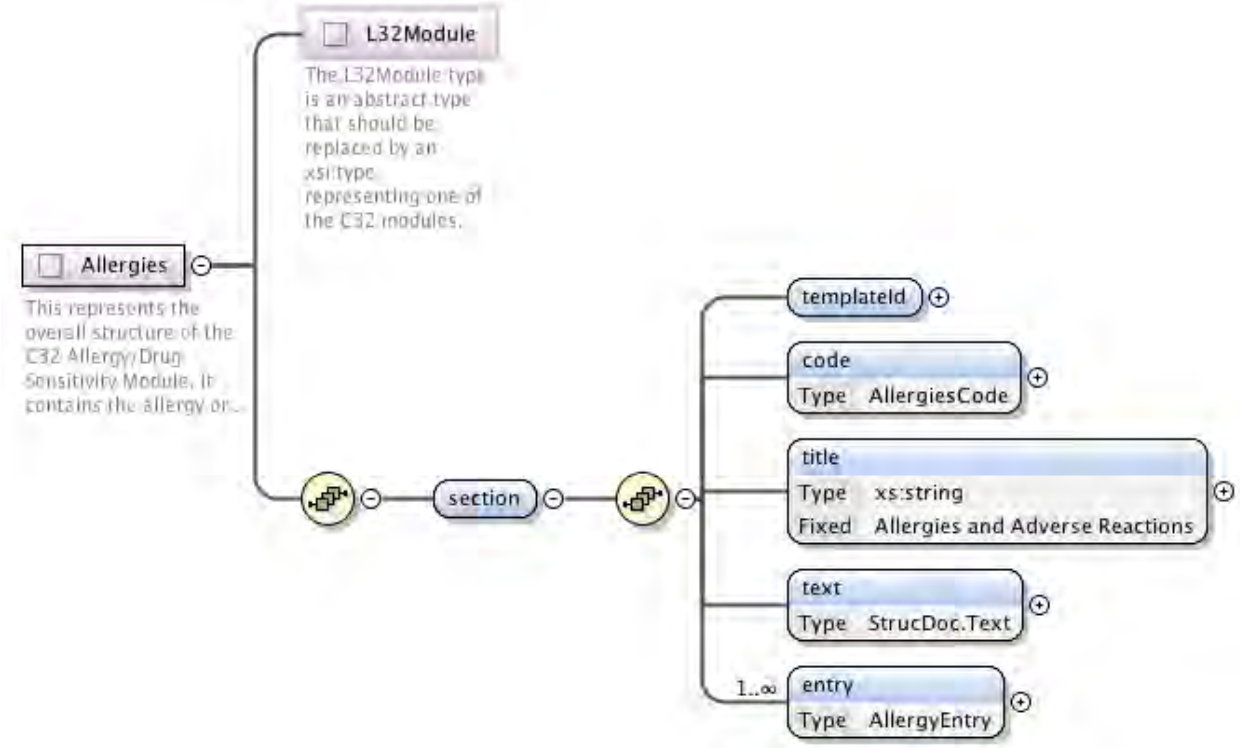
A.5 Insurance Providers

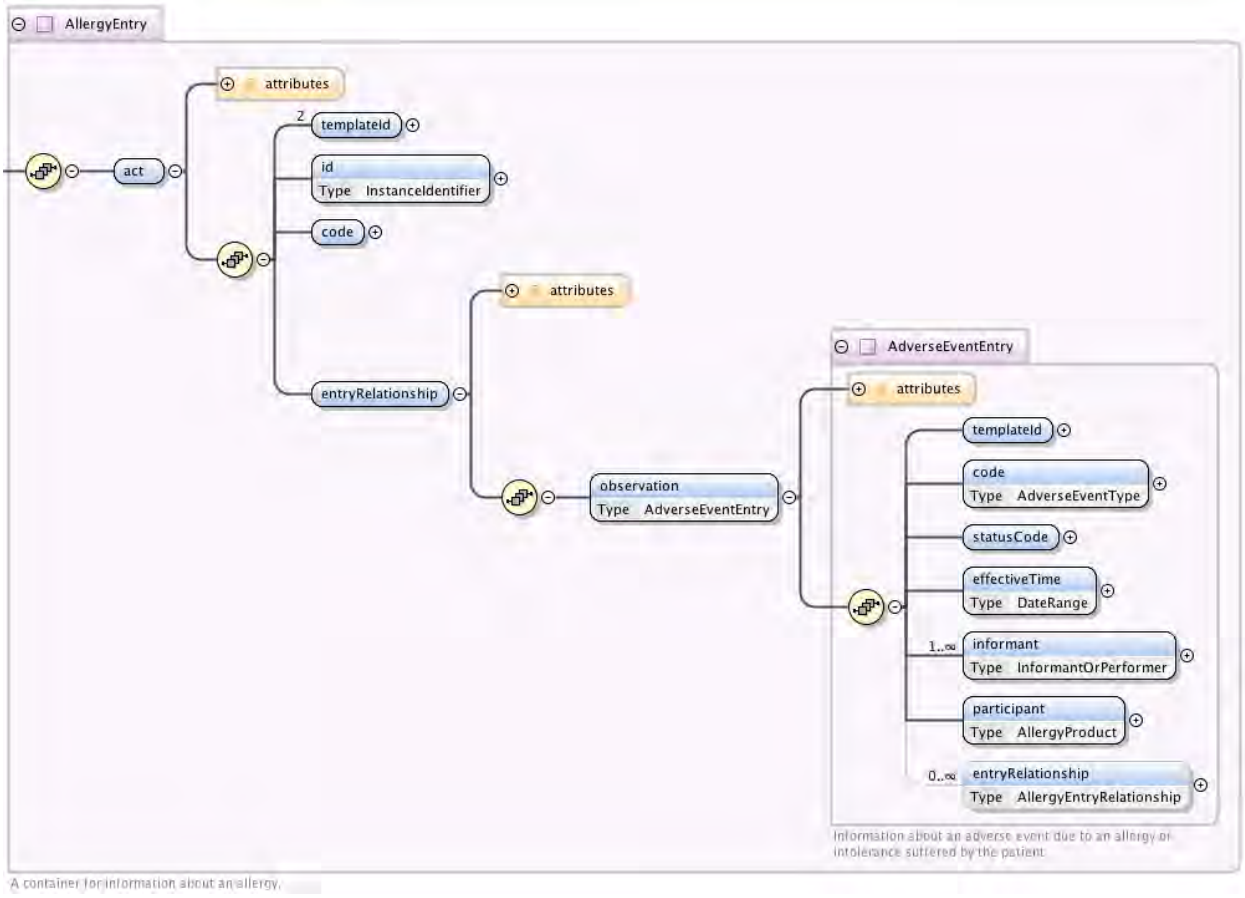


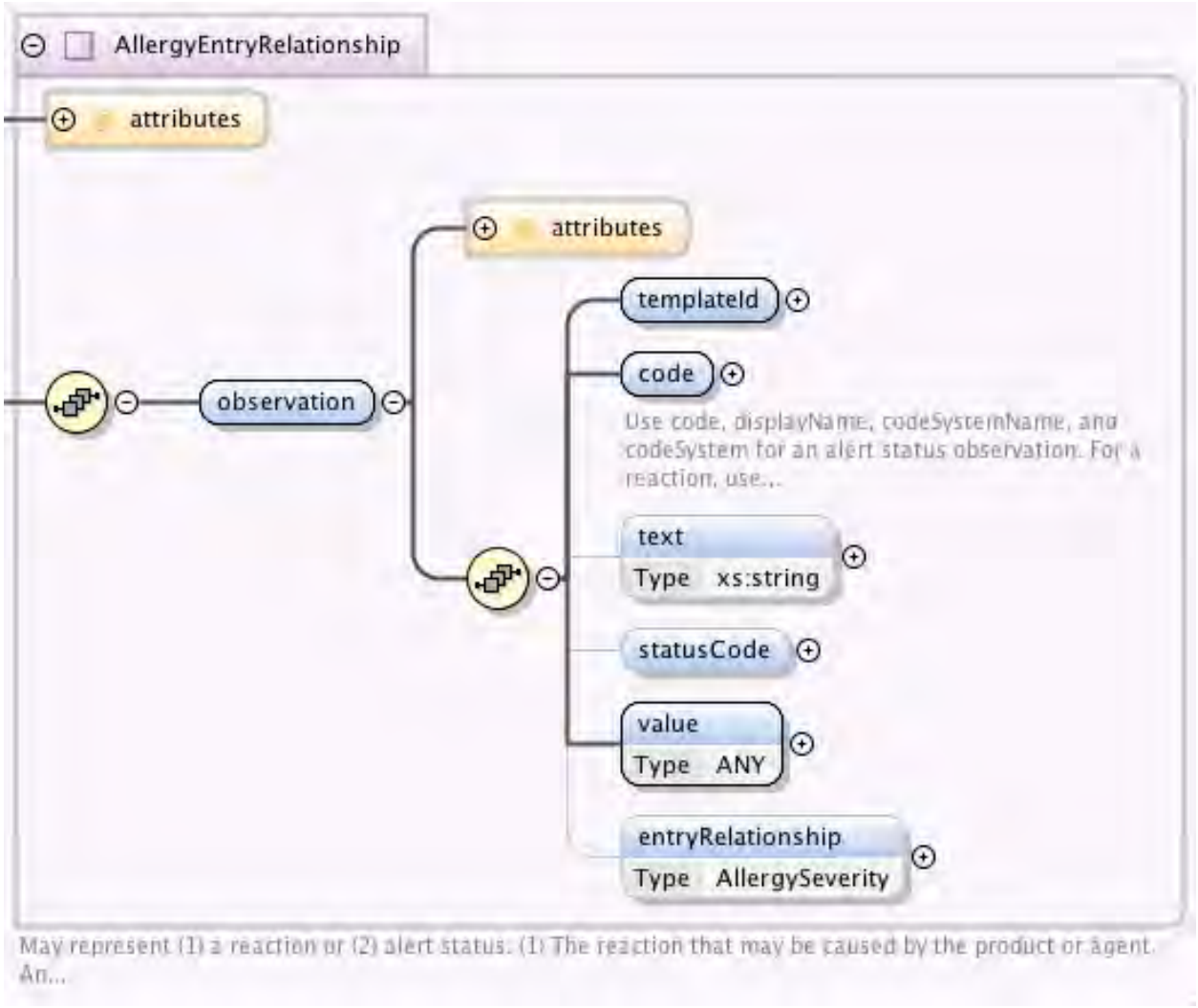




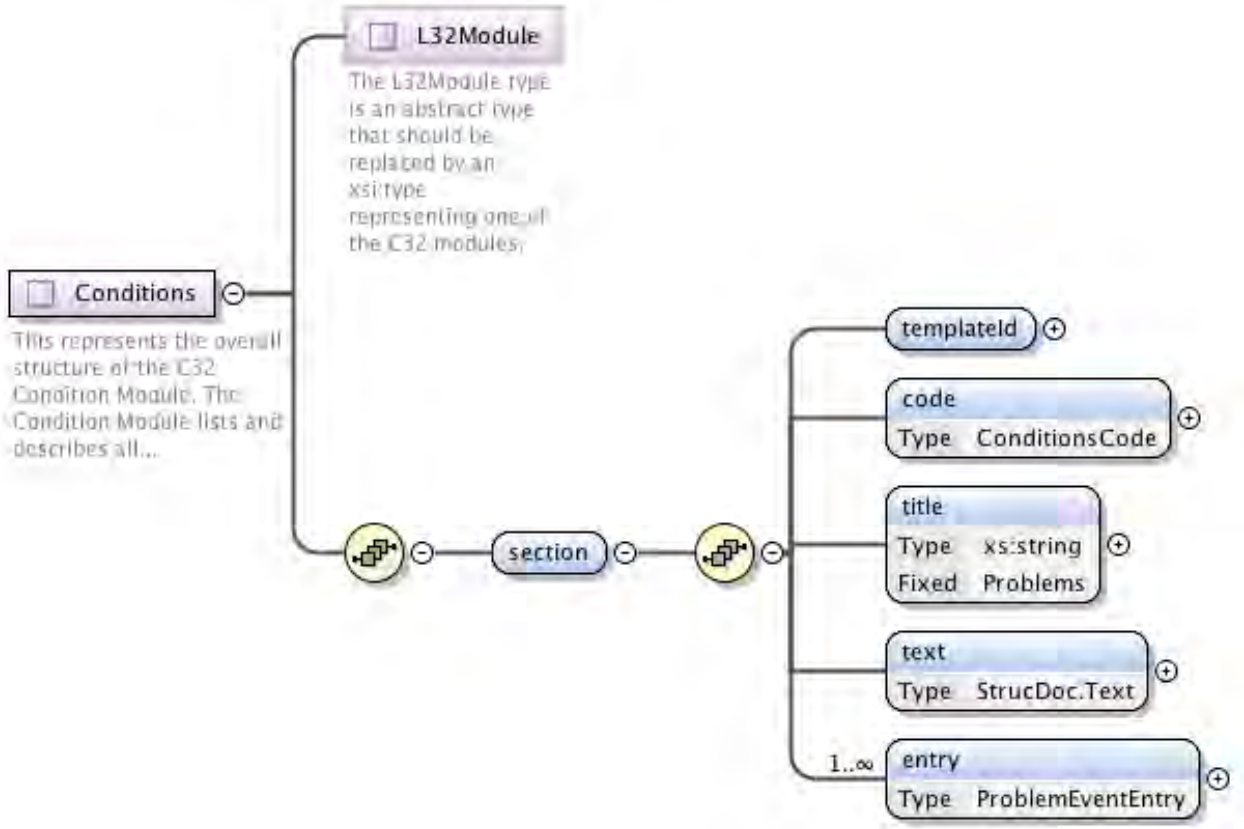
A.6 Allergies

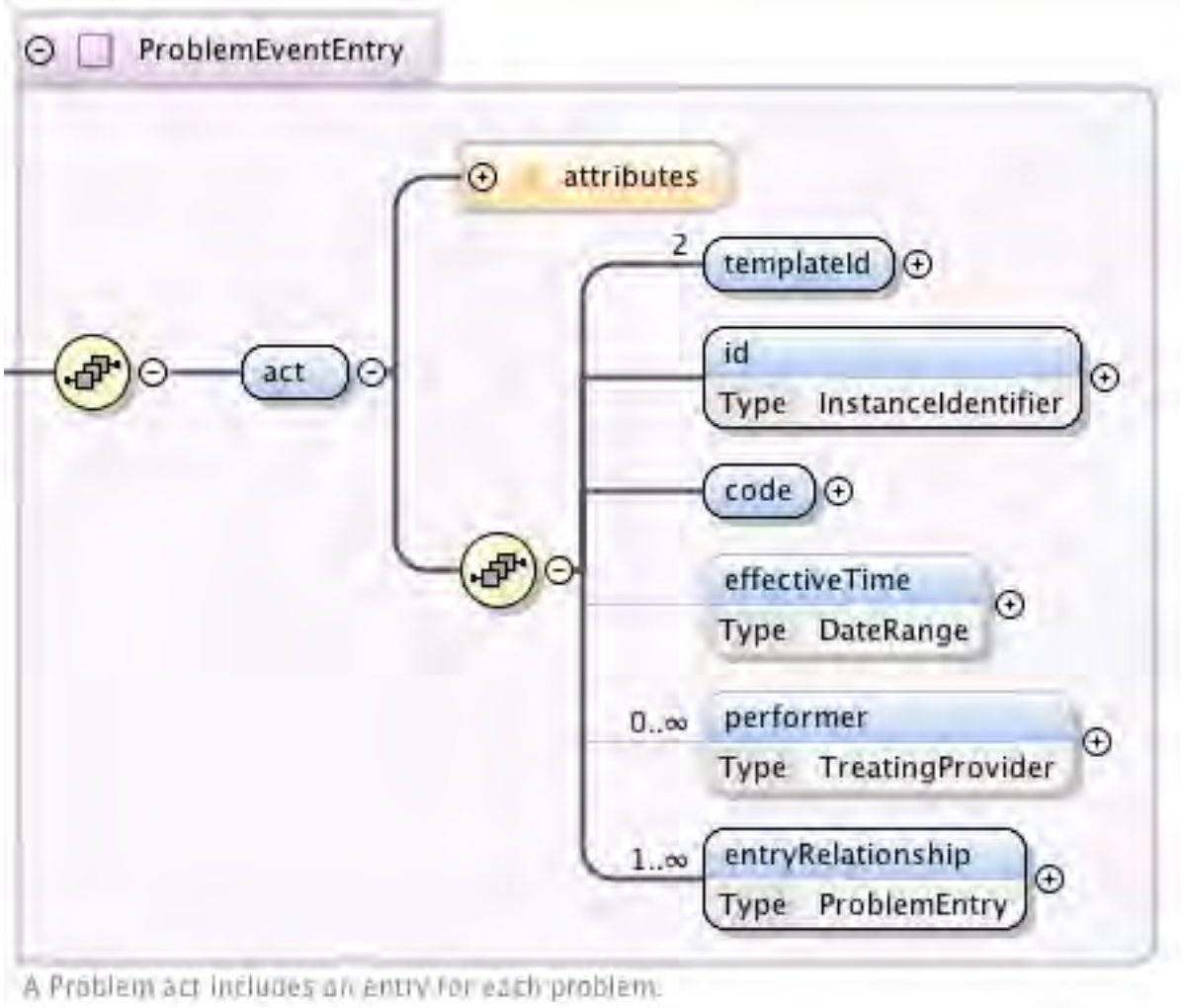


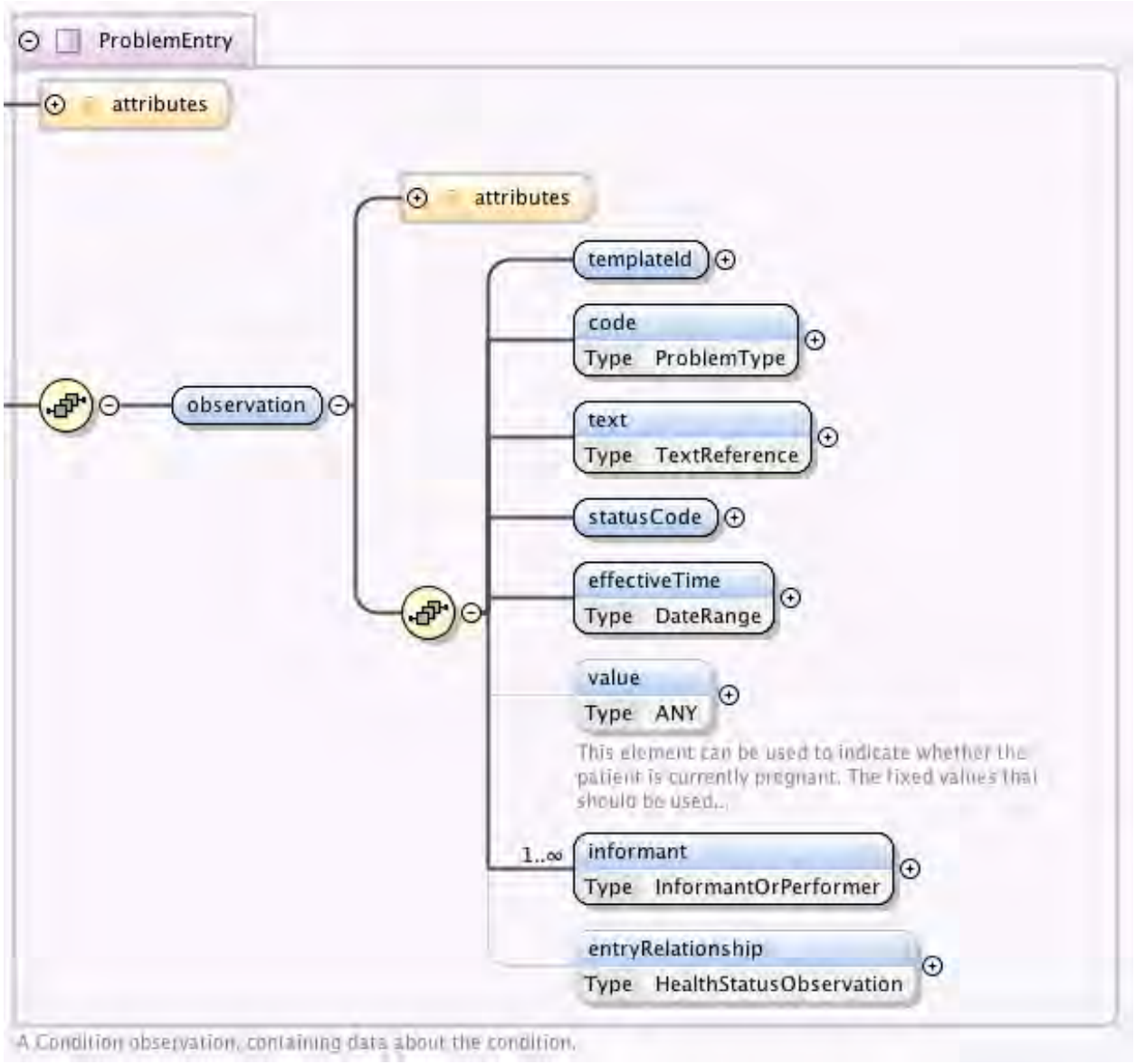




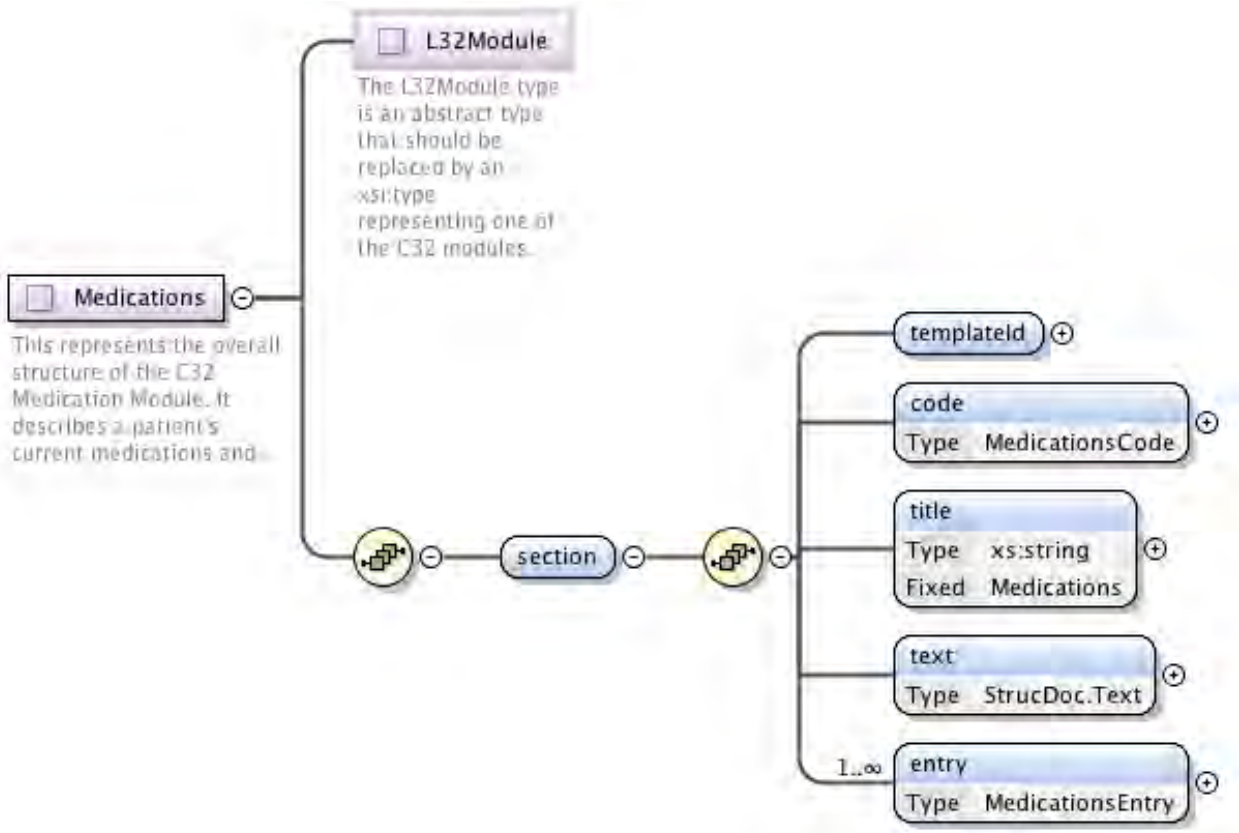
A.7 Conditions

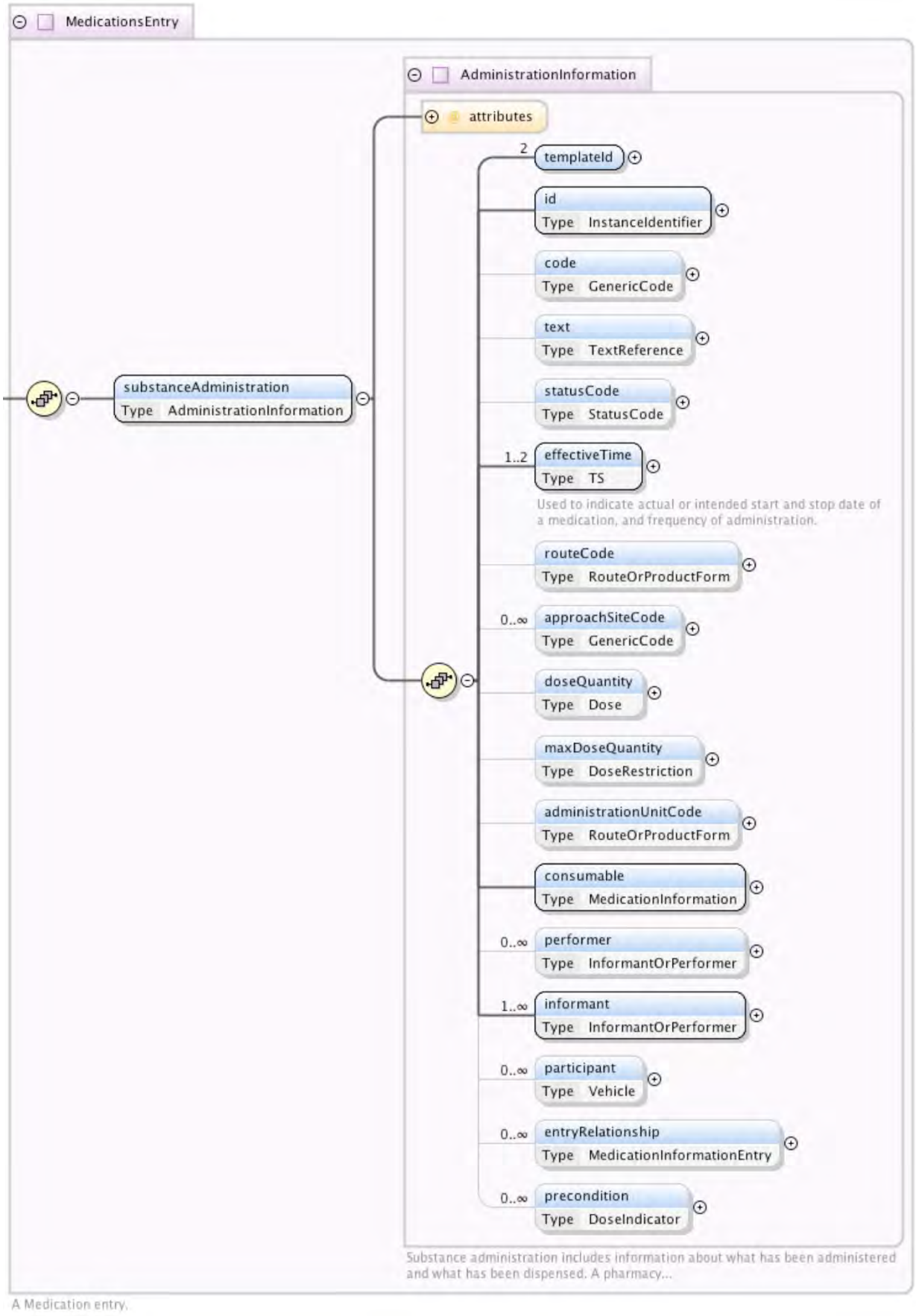




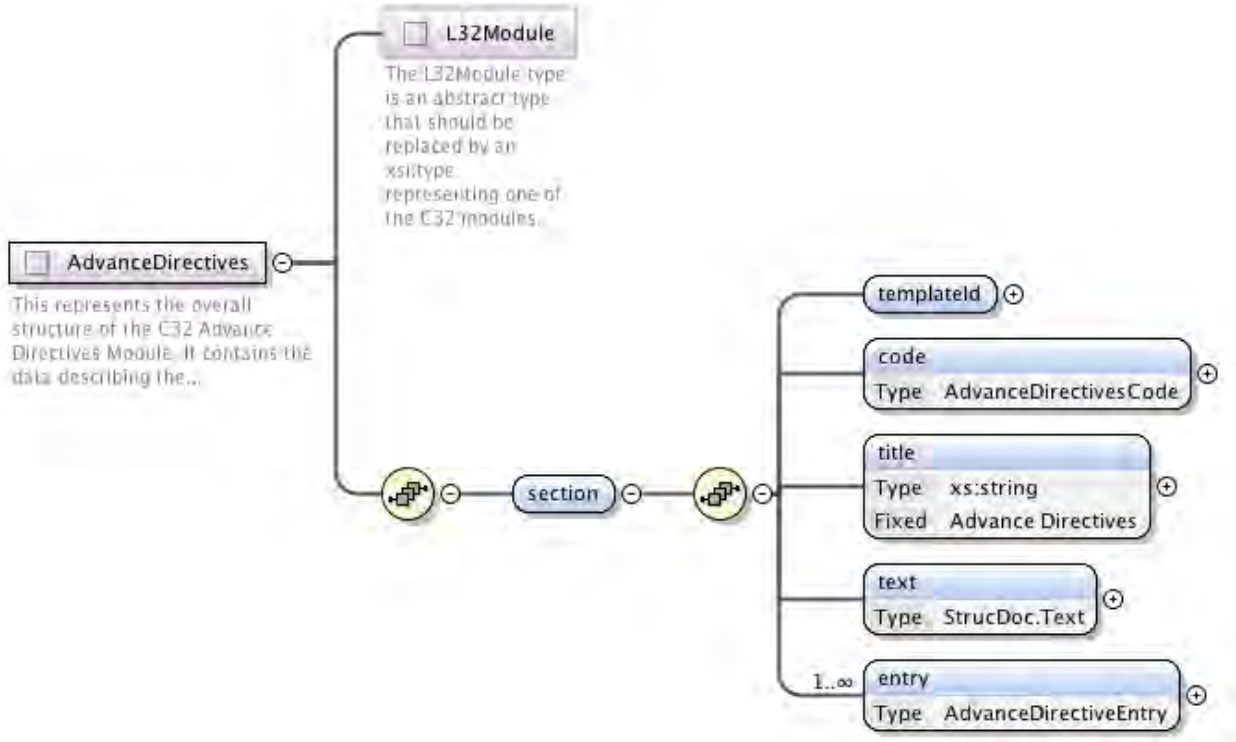


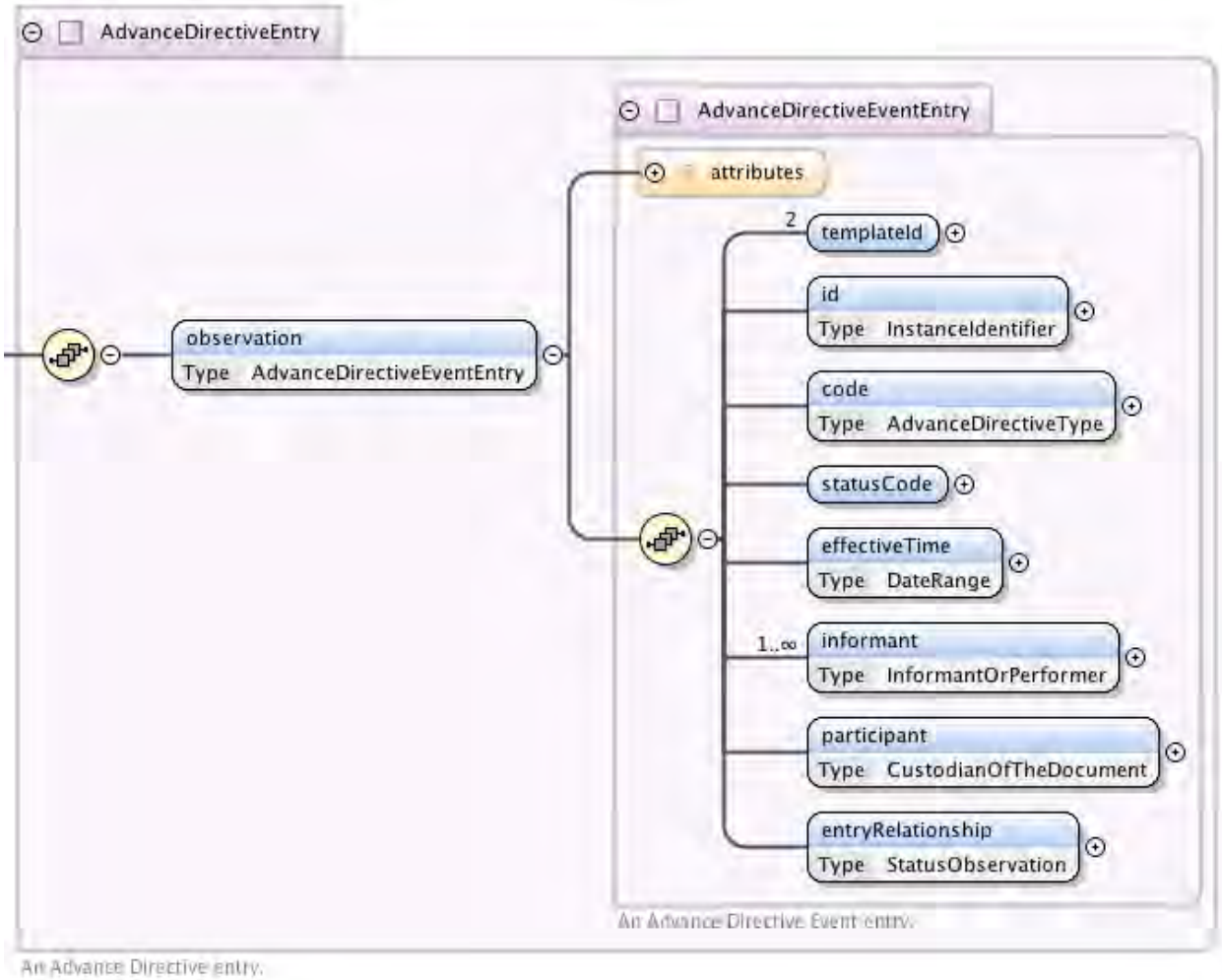
A.8 Medications



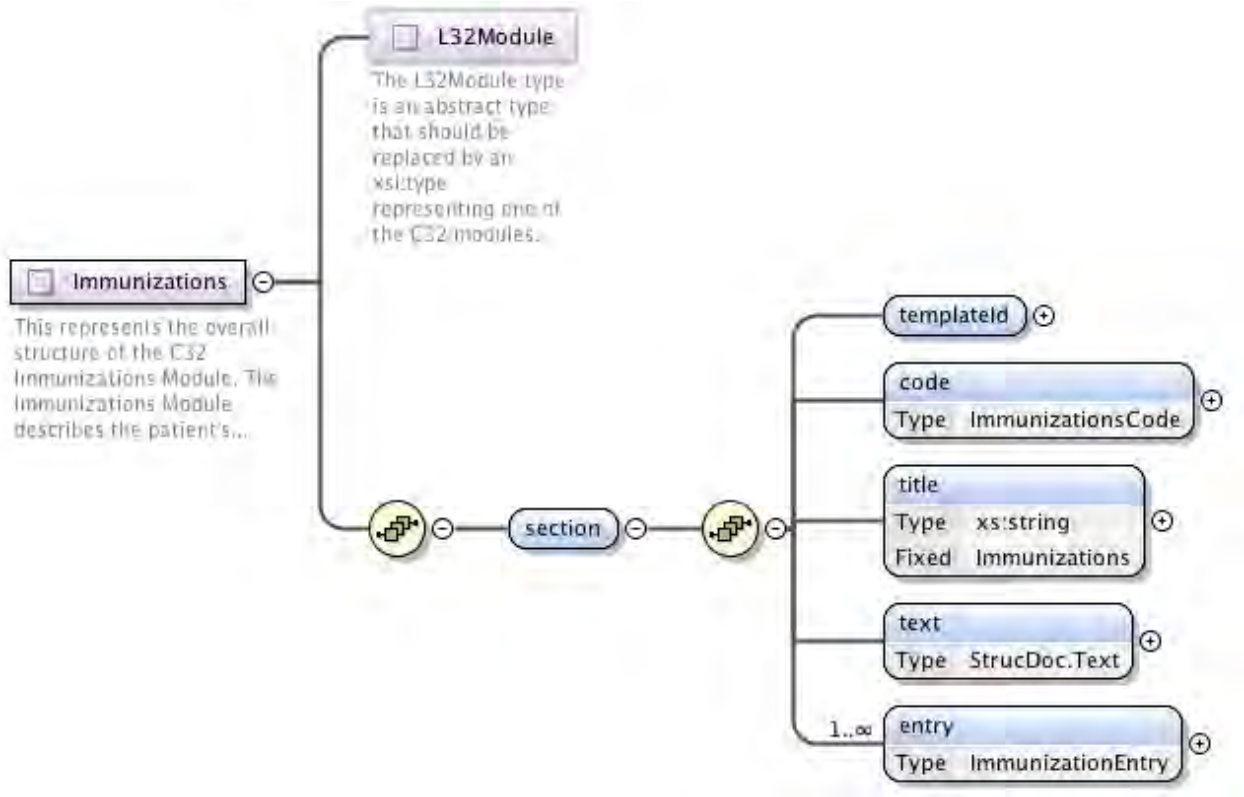


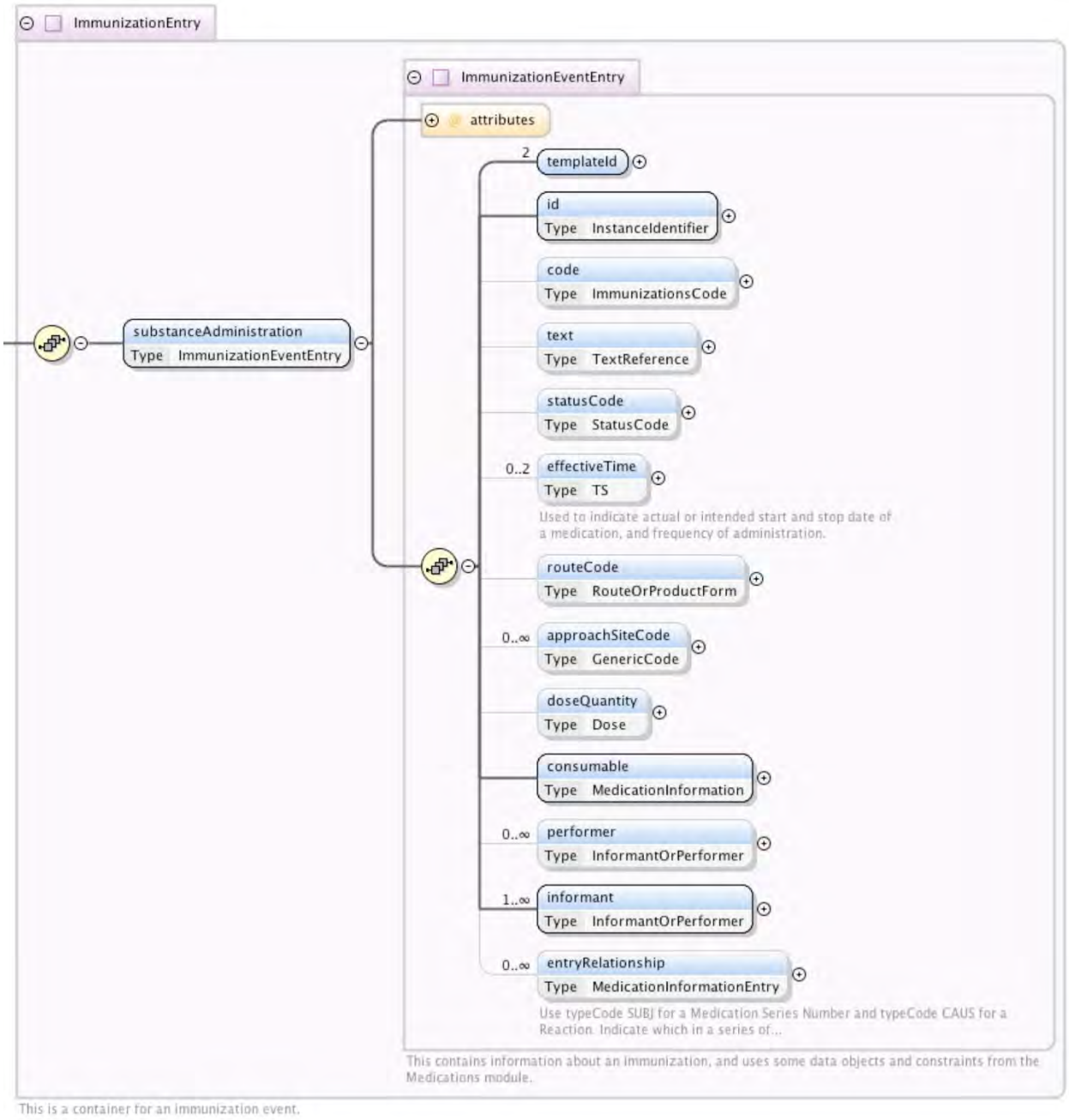
A.9 Advance Directive



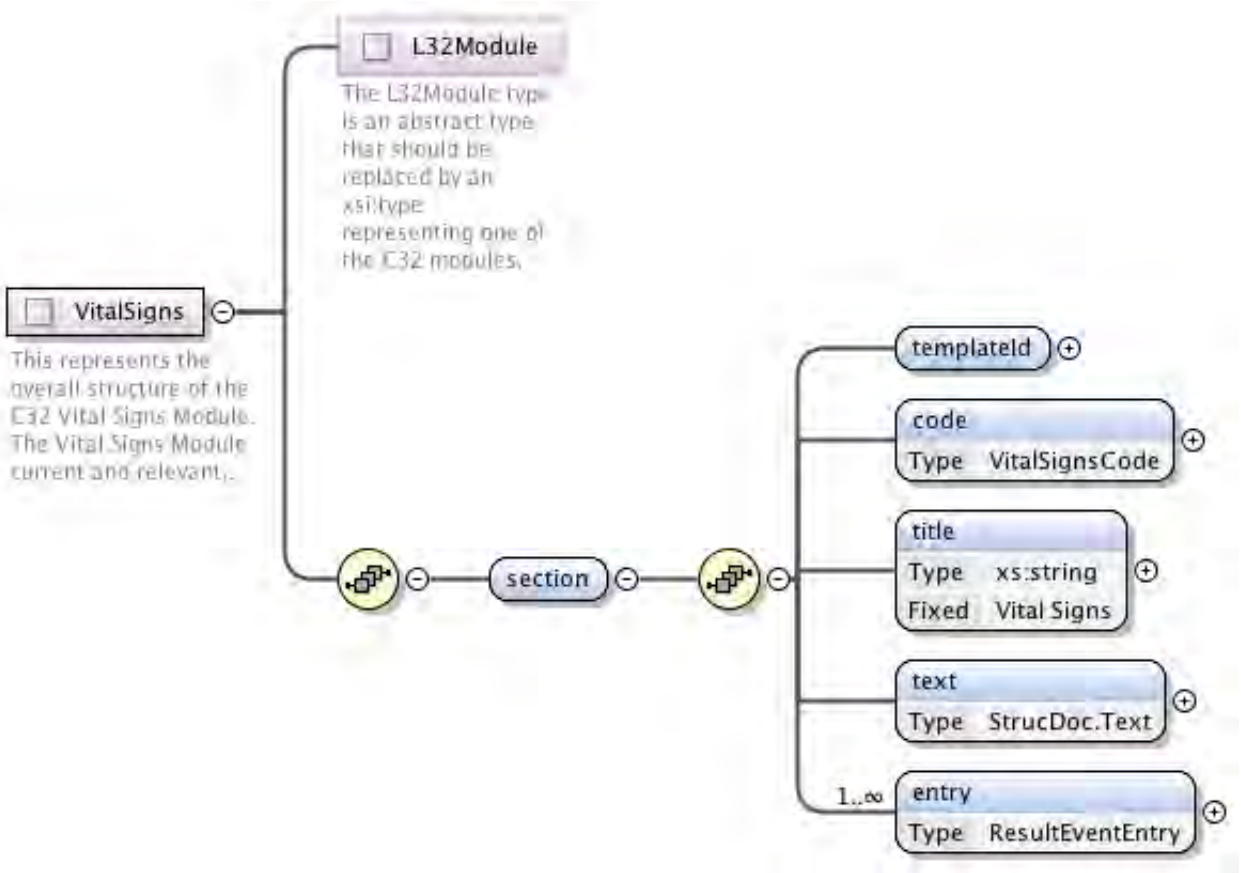


A.10 Immunizations

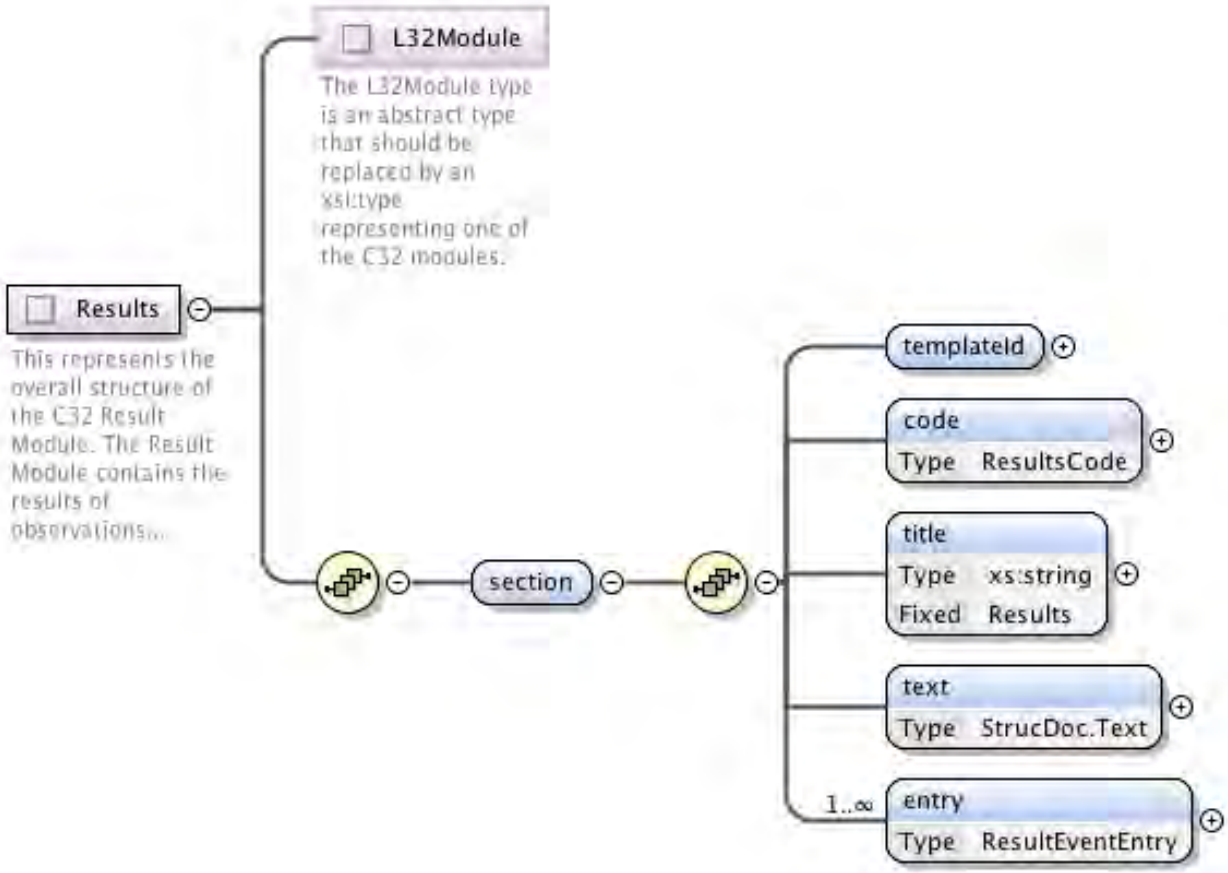


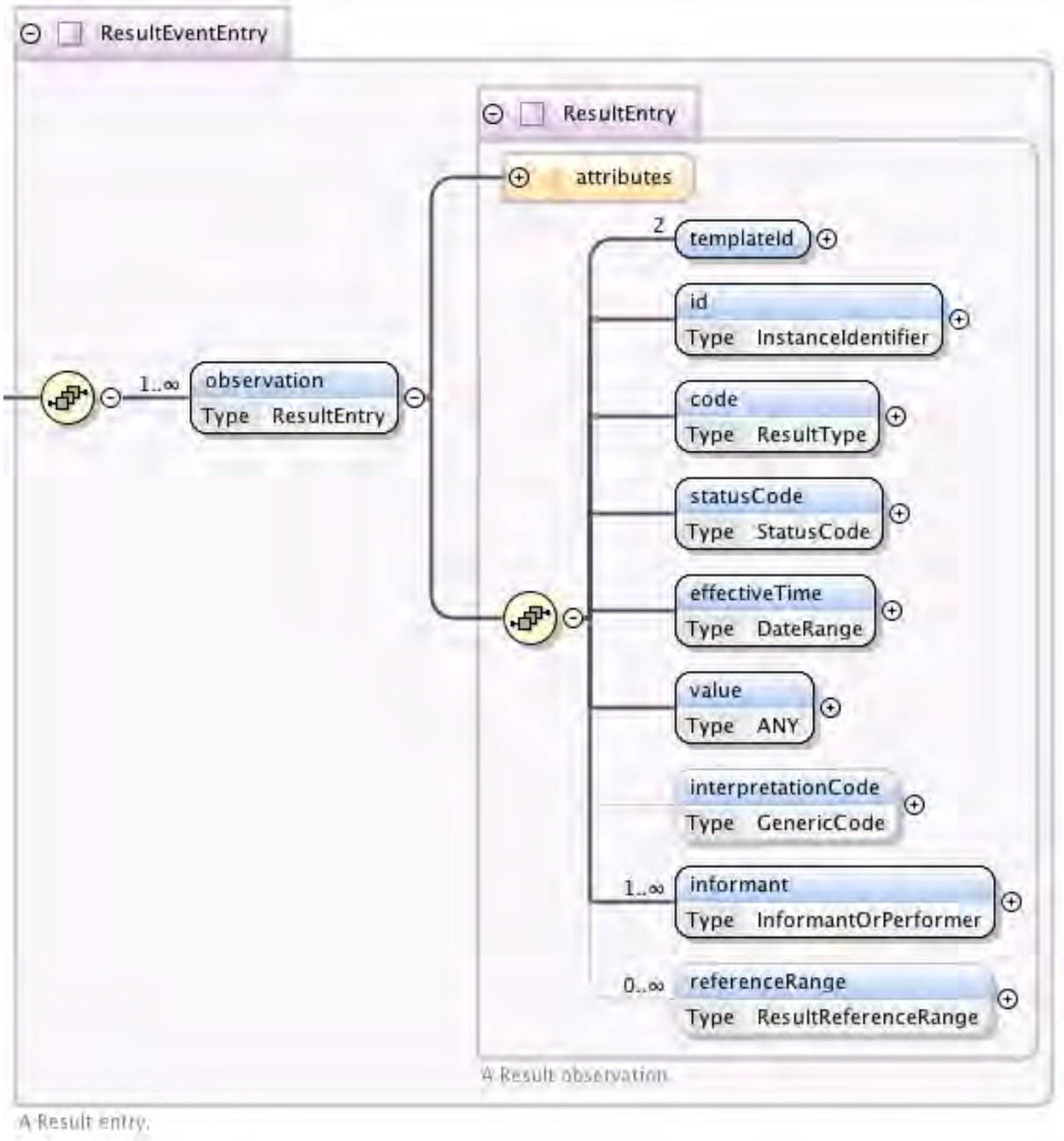


A.11 Vital Signs

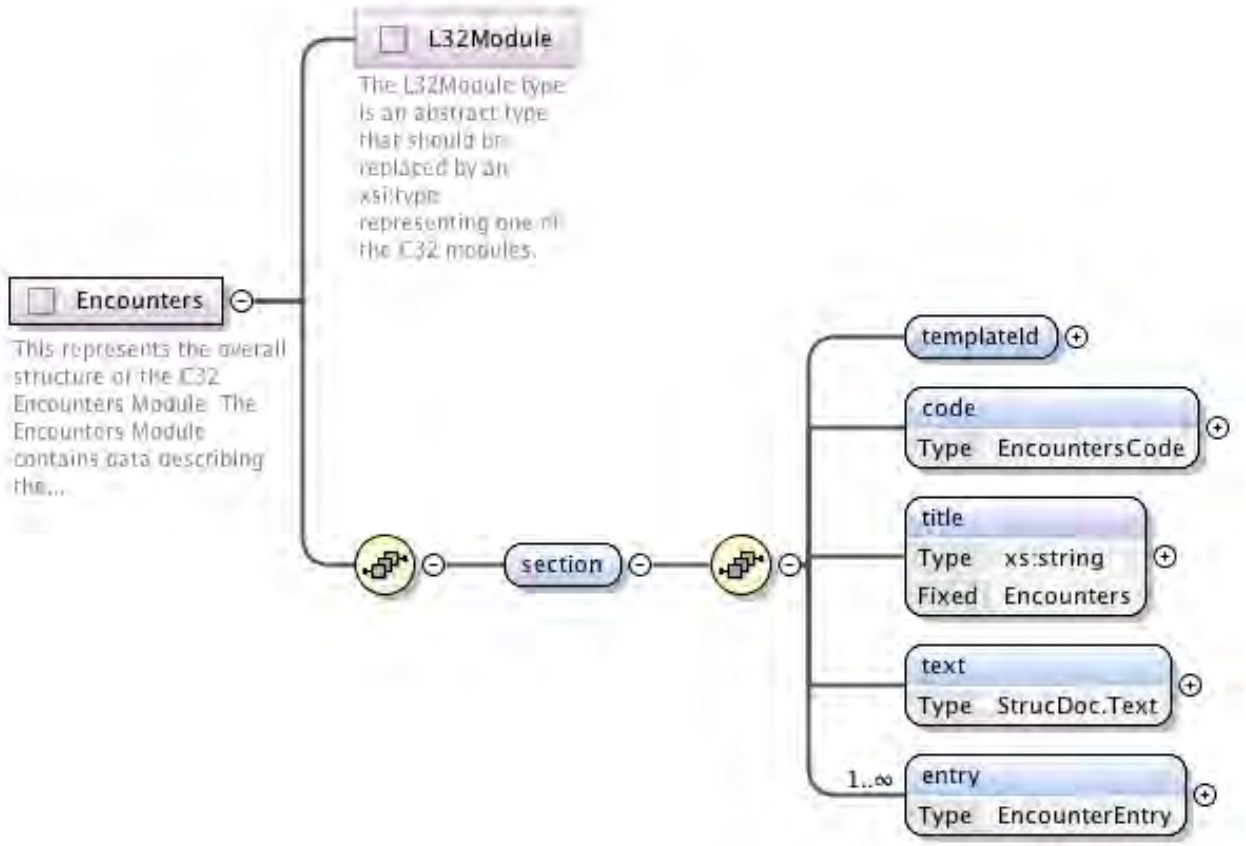


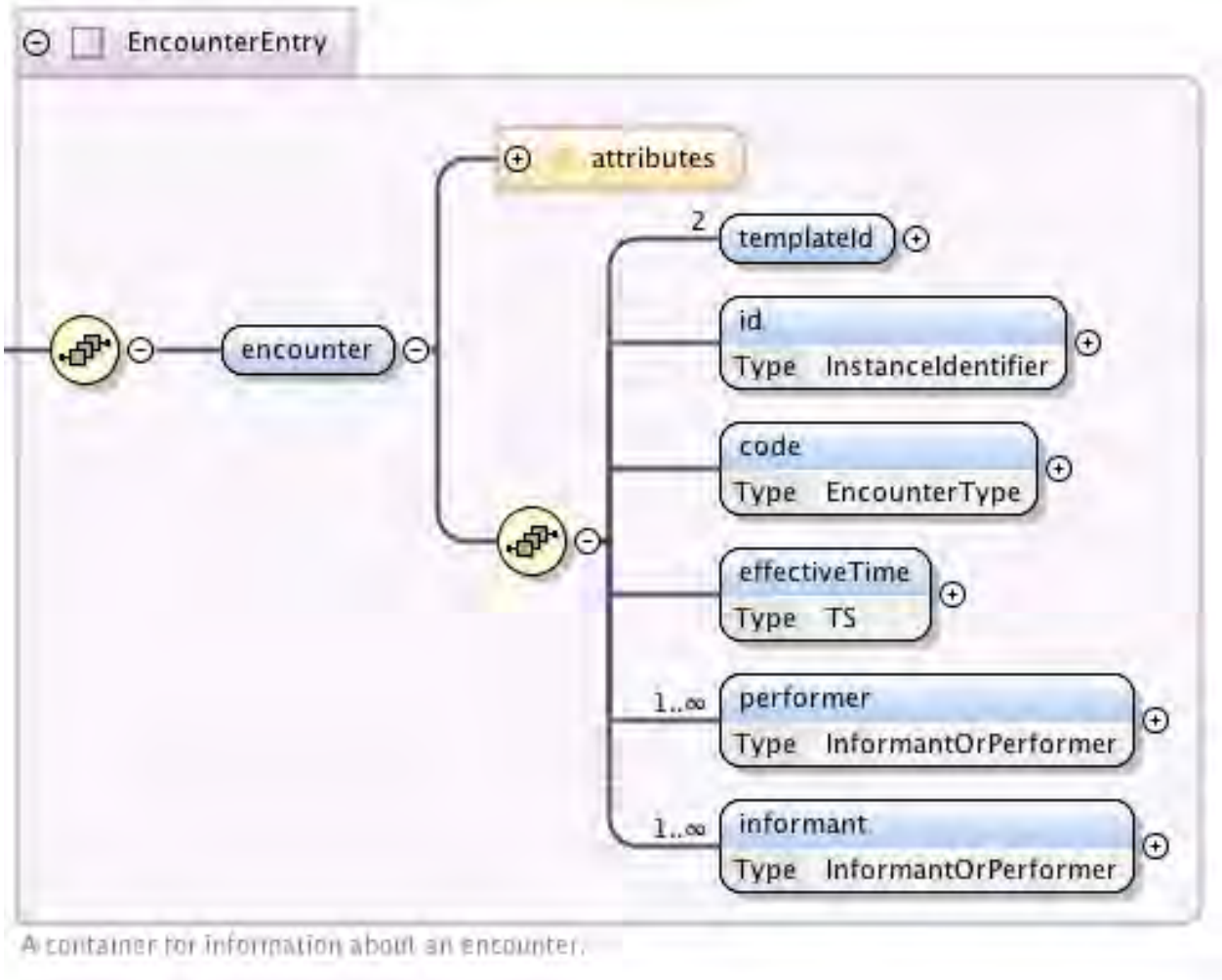
A.12 Results



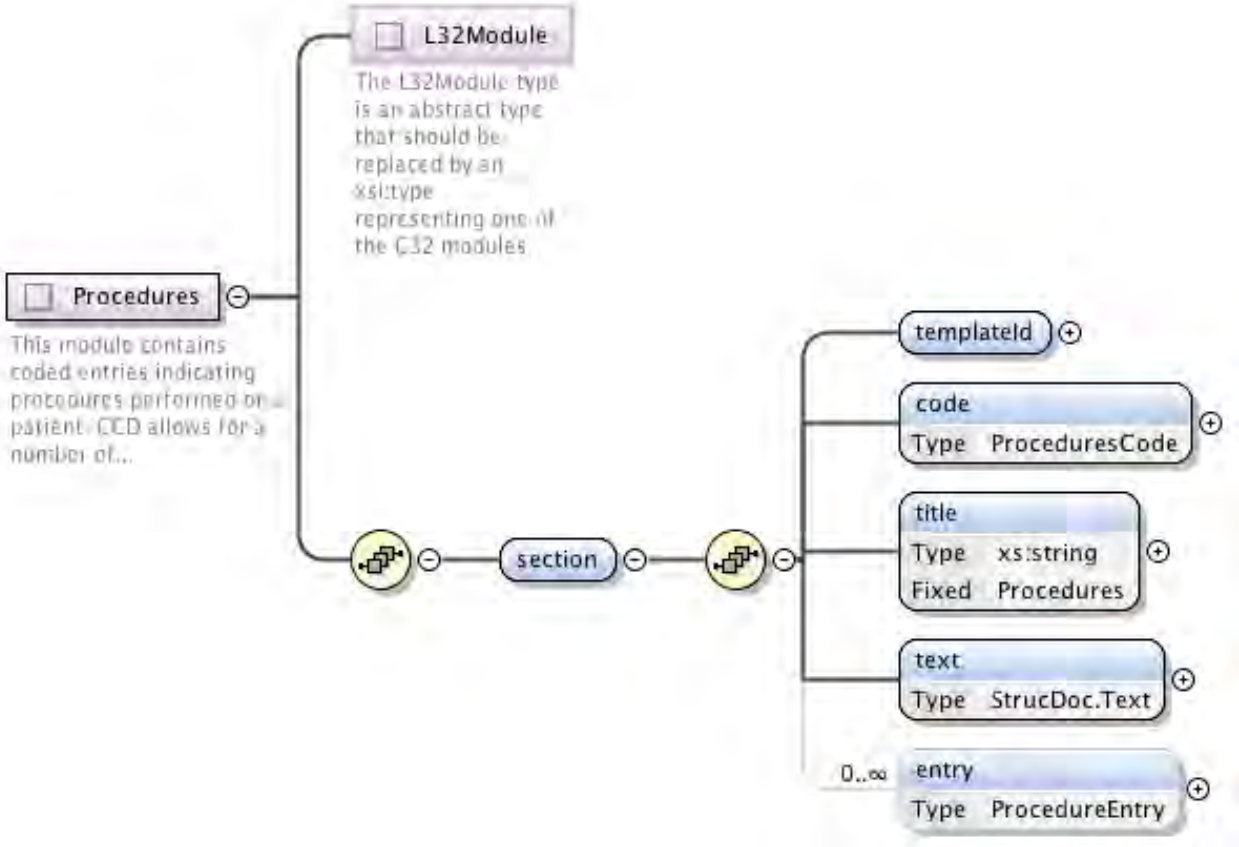


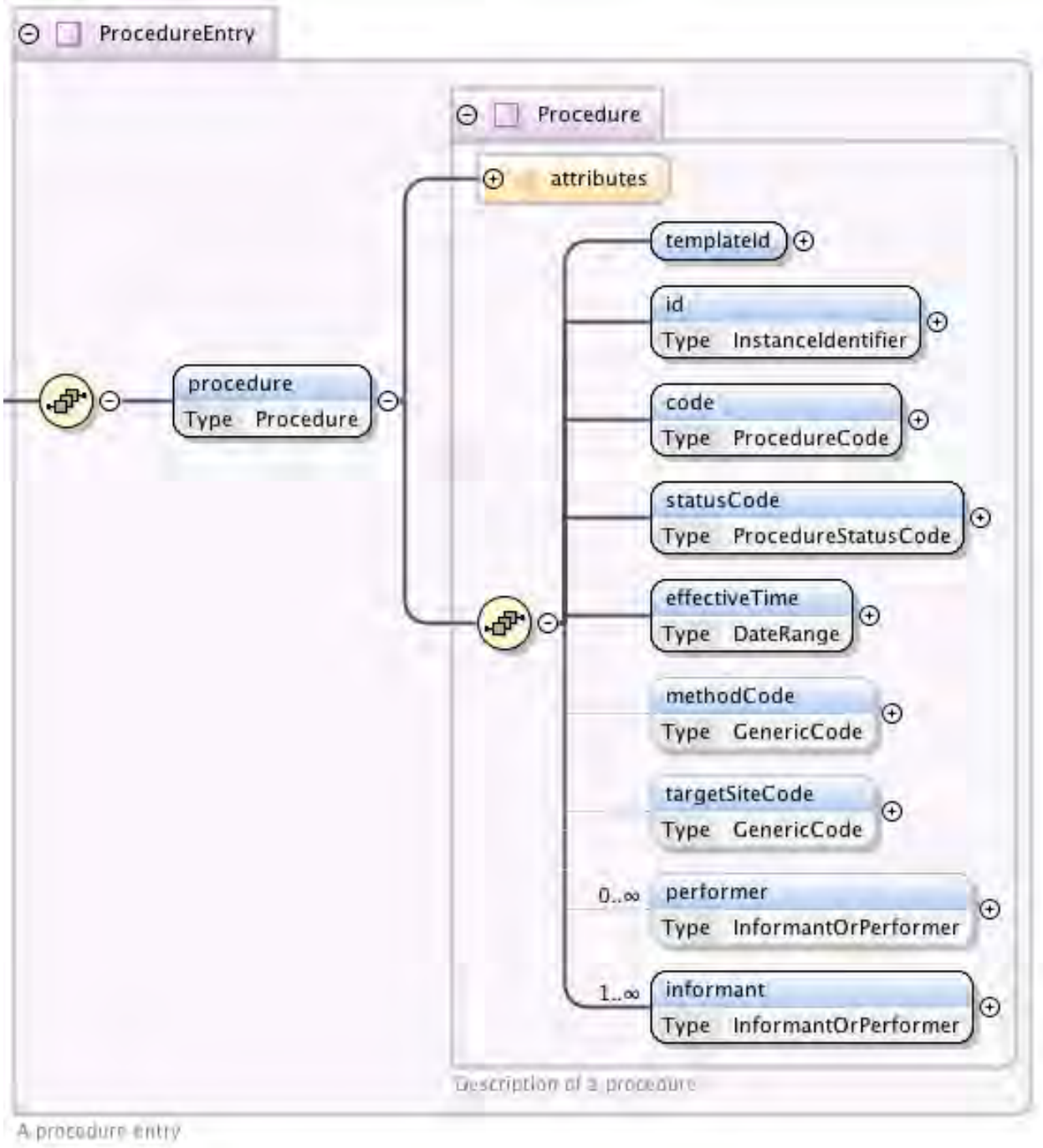
A.13 Encounters





A.14 Procedures





Appendix B Glossary

API	Application Programming Interface
CCD	Cotinuity of Care Document
CDA	Clinical Document Architecture
COTS	Commerical Off-the-Shelf
CV	Coded Value
DoD	Department of Defense
	Experts Panel
HER	Electronic Health Record
HITSP	Healthcare Information Technology Standards Panel
L32	Lightweight C32 Implementation
NIST	National Institute of Standards and Technology
NQF HTIEP	National Quality Foundation Health Information Technology
TPA	Third Party Administrator
UCUM	Unified Code for Units of Measure
VA	Veteran's Affairs
VIN	Vehicle Identification Number
W3C	World Wide Web Consortium
XML	Extensible Markup Language
XSL	Extensible Stylesheet Language