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HITSP Summary Documents Using HL7 Continuity of Care Document (CCD) Component

HITSP/C32

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Note: The title of HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD) Component, has been revised in this release to more accurately reflect the content of the document. It has been expanded to include additional types of information such as Medications, Immunizations, Advance Directives, etc.

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FIGURES AND TABLES

1.0 INTRODUCTION

As an introduction to the HITSP Summary Documents Using HL7 Continuity of Care Document (CCD) Component, this section provides a high level overview of the information sharing scenario enabled by following this specification, provides a document map of the construct relationships for this specification, acknowledges the copyright protections that pertain, and provides links to key reference documents and background material. If you are already familiar with this information, proceed to Section 2.0 Component Definition.

1.1 OVERVIEW

This section describes the contents of this specification and provides a high level definition of this Component and background information about the underlying standards that the Component is based on.

The HITSP Summary Document Using HL7 Continuity of Care Document (CCD) Component describes the document content summarizing a consumer's medical status for the purpose of information exchange. The content may include administrative (e.g., registration, demographics, insurance, etc.) and clinical (problem list, medication list, allergies, test results, etc) information. Any specific use of this Component specification may constrain the content further based upon the requirements and context of the document exchange. This specification defines content in order to promote interoperability between participating systems. Any given system creating or consuming the document may contain much more information than conveyed by this specification. Such systems may include Personal Health Records (PHRs), EHRs (Electronic Health Records), Practice Management Applications, and other persons and systems as identified and permitted.

The Summary Document is essentially a subset of the healthcare data that has been developed for specific business Use Cases. This subset contains the minimum critical or pertinent medical information of sections and data elements as specified by the business cases. A Summary Document must be a representative extract of the creating system. The information in the Summary Document and the creating system must be consistent. Furthermore there should be no data elsewhere in the creating system that would contradict the meaning of any data in the summary. The expectation is that consuming systems will be able use the Summary Document as a source of information to input and/or update information in their instantiation of the patient record. This specification does not define the policies applicable to the import of this information.

It is anticipated and desirable that some implementers of the Summary Document will want to add data and sections to permit greater communication between systems. The underlying standards (primarily CCD – Continuity of Care Document) have additional modules that may serve such purpose. This practice is beyond the scope of this HITSP Component. Implementers must be aware that they must assume that receivers of the document may only be able to view data as described in this specification, and may not be able to use the additional data in the document. This means that the Summary Document

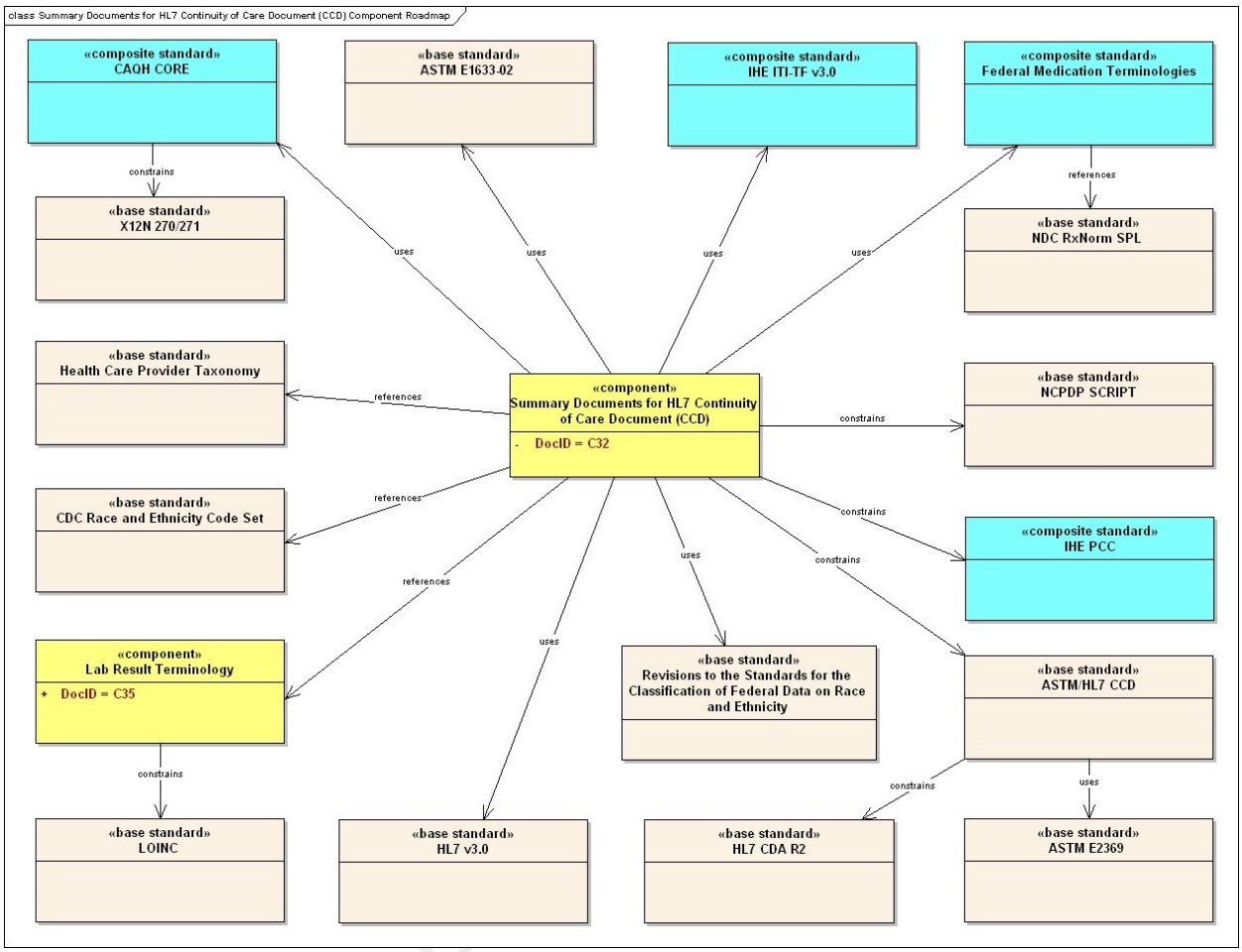
must be able to stand-alone. Applications may wish to display the document in two different user-selected views, one of which is restricted to the minimal dataset contents of a Summary Document. Adding additional optional sections and data elements should not generate errors. Optional data should be used if understood by the receiving system, but must not change the meaning of the document.

This document refers to the 2007 cycle of work for the HITSP Consumer Empowerment Technical Committee. It expands upon the prior version of the specification for a consumers' registration/medication history information to include data content to support the consumer's access to clinical information, medication management activities, and supportive information for quality of care assessment.

1.2 COMPONENT CONSTRUCT ROADMAP

Each HITSP Interoperability Specification (IS) is comprised of a suite of constructs that, taken as a whole, define how to integrate and constrain existing standards and specifications that will satisfy the requirements imposed by a given Use Case. The IS groups specific actions and actors to describe the relevant contexts using HITSP constructs that further identify and constrain standards where necessary. There are four types of HITSP constructs called Interoperability Specifications (IS), Transaction Packages (TP), Transactions (T), and Components (C). The current Summary Documents Using HL7 Continuity of Care Document (CCD) Component specification is used with other constructs to meet the requirements of one or more ISs. Review the Unified Modeling Language (UML) diagram from the relevant IS to better understand the context, dependencies, and relationships between the constructs that are used to meet the IS requirements. The roadmap in Figure 1.2-1 depicts primary standards that are selected, constrained, or referenced to define the atomic constructs used in an information exchange, or to meet an infrastructure requirement. Implementers should read the documents that describe the standards represented in the diagram for their details and specific uses.

Figure 1.2-1 Component Construct Roadmap



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1.4 REFERENCE DOCUMENTS

This section contains links to key reference documents and background material.

The HITSP Interoperability Specification Overview provides the background information about the HITSP and its role in the overall U.S. efforts to realize large scale interoperability of health information. The document also provides a description of the HITSP process for healthcare standards harmonization and explains how to use the Interoperability Specifications and other related documents to inform your health IT product development or product refinement.

The conventions that are used to convey the full descriptions and usage of standards in the HITSP specifications are contained in the HITSP Conventions List.

The acronyms used in this document are contained in the HITSP Acronyms List.

The HITSP Glossary provides definitions for relevant terms used by HITSP documents.

The HITSP Harmonization Framework describes the current framework within which the Interoperability Specifications are built.

2.0 COMPONENT DEFINITION

A Component defines atomic constructs used to support an information exchange or to meet an infrastructure requirement. This is accomplished by:

(a) Referencing one or more underlying standards
(b) Specifying constraints and other rules for using the standards

2.1 CONTEXT OVERVIEW

Summary Documents Using HL7 Continuity of Care Document (CCD) Component describes the document content that summarizes a consumer's registration/medication information. While an EHR or PHR system can contain much more information, this Component only deals with the summary information to be exchanged between such systems as established as requirements described in HITSP Use Cases.

Summary Documents Using HL7 Continuity of Care Document (CCD) Component is essentially a subset of the data in an EHR or PHR system that has been developed for interoperability purposes for specific business Use Cases. This subset contains the minimum critical or pertinent medical information of sections and data elements used in those business cases. The information in the subset of data to be exchanged and the EHR or PHR system must be consistent. Furthermore there should be no data elsewhere in the EHR or PHR system that would contradict the meaning of any data in the summary. The expectation is that consuming systems will be able to use the information received as appropriate information to input and/or update information in their instantiation of the patient record. This specification does not define the policies applicable to the import of this information.

2.1.1 COMPONENT CONSTRAINTS

This section describes the constraints that limit the context in which the Component may be used. A constraint describes a rule that limits the use of the actors, actions or data within the given context, or to which the interactions must conform to be used within the described context. It is a description of the limits and scope of the interactions and can describe actions or events that are not part of the initial definition for the context.

There are no constraints regarding use or reuse of this Component. It is intended for use and reuse whenever a consumer's patient registration and medical history information is needed. Individual Components of this specification may be reused where appropriate to convey similar information for other Use Cases. HITSP has assigned template identifiers to the reusable Components to facilitate this reuse.

However, there are specific constraints related to each of the modules defined in the data mapping section (2.2.1). Many constraints appearing in the data mapping section reference external vocabularies. Where vocabularies have been referenced, implementers are advised to obtain them from the

authoritative sources described in the list of standards in section 2.3 of this document. The authoritative source links are provided within these additional specifications for the Component. In the table below, each set of module constraints is listed in the first column, and the specific section that the constraint applies two is represented in the second column.

Table 2.1.1-1 Component Constraints

Constraint	Constraint Section
Person Information	2.2.1.1
Language Spoken	2.2.1.2
Support	2.2.1.3
Healthcare Provider	2.2.1.4
Insurance Provider	2.2.1.5
Allergies and Drug Sensitivity	2.2.1.6
Condition	2.2.1.7
Medications – Prescription and Non-Prescription	2.2.1.8
Pregnancy	2.2.1.9
Information Source	2.2.1.10
Comments	2.2.1.11
Advance Directives	2.2.1.12
Immunizations	2.2.1.13
Vital Signs	2.2.1.14
Results	2.2.1.15
Encounters	2.2.1.16

2.1.2 COMPONENT DEPENDENCIES

This section describes any specific mapping criteria for the standards underlying the Component. It elaborates on the relationships between different standards used by this Component, and how they map to each other. Additional required mapping criteria not currently enforced by the underlying standards, and any specific elements that are required for this mapping to succeed, are also provided.

Although no Component Dependencies exist, it is important to note the following dependencies that are specific to HITSP constructs:

When this Component is combined with HITSP/TP13 - Manage Sharing of Documents, the XDS Registry Entry Metadata to be used when registering any instance of a document specified by this HITSP/C32 construct, shall follow the specification defined in the IHE Patient Care Coordination Technical Framework Revision 1.0 (IHE PCC TF Rev 1.0) Section 4.1 of volume 2. This section titled "Medical Document Binding to XDS, XDM and XDR" defines a transformation that generates metadata for the XDSDocumentEntry element of appropriate transactions from the IHE XDS, XDM and XDR profiles given

a medical document and information from other sources. The medical document refers to the document being stored in a repository that will be referenced in the registry. The other sources of information include the configuration of the Document Source actor, the XDS Affinity Domain, the site or facility, local agreements and other documents in the registry/repository.

Table 2.1.2-1 Component Dependencies

Standard/HITSP Component	Depends On (Name of standard/HITSP Component that it depends on)	Dependency Type (Pre-condition, post-condition, general)	Purpose (Reason for this dependency)
No applicable Component dependencies			

2.2 RULES FOR IMPLEMENTING

The following section documents the content of the Component. It provides the basics elements and secondary standards that are supported by this Component and the constraints that are being placed on those standards. Specifically, it describes the subset or constraints that are required for this Component, and the minimum attributes of the Component as it relates to the base or composite standards on which it is based.

2.2.1 DATA MAPPING

This section describes the specific data elements used by this Component. Due to the potentially large number of data elements in a particular standard, only the fields that HITSP is constraining differently from the standard, will be described here.

This Component uses tables to provide the content of the Summary Documents Using HL7 Continuity of Care Document (CCD) summary. Requirement types are defined as follows:

Table 2.2.1-1 Data Mapping

Data Element ID	Data Element	Description	HITSP Opt / Repeat (OR)	CCD Name (Data Source)	HITSP Additional Specification for Component
A numeric identification of the data element, can be used for referencing this data element in this document only	The name of the data element being defined	Description of the data element being defined	Two fields can be displayed here, where the first defines the Requirement Type and the second a Repeating Definition	The CCD name is expressed as an XPath expression identifying the CCD data element that contains the content (see www.w3.org/TR/xpath.html for more information on XPath). These expressions assume that the namespace prefix "cda:" has been mapped to the CDA specified namespace "urn:hl7-org:v3", and the namespace prefix "sdtc:" has been mapped to the namespace "urn:hl7-org:sdtc"	Specifies HITSP requirements and restriction, if needed

Additional conventions are used for the HITSP Opt/Repeat column. These are as follows:

- **R = Required** - Required data elements must always be sent. Data elements that are required may under exceptional circumstances have an unknown value (e.g., the name of an unconscious patient). In these cases the sending application is required to indicate the reason that the data are not available
- **R2 = Required if known** - Data elements that are marked Required if Known (R2) must be sent when the sending application has that data available. The sending application must be able to demonstrate that it can send all required if known elements, unless it does not in fact gather that data. When the information is not available, the sending application may indicate the reason that the data are not available
- **O = Optional** - Data elements that are marked optional (O) may be sent at the choice of the sending application. An optional element need not be sent, but when it is sent, the content module defines the meaning of that data element, and a receiver can always be assured of what that data element represents when it is present. Senders should not send an optional data element with an unknown value. If the value is not known, simply do not send the data element

Other data elements not defined in this Component may be included in an instance of a content module. Receivers are not required to process these elements, and if they do not understand them, must ignore them. Thus, it is not an error to include more than is asked for, but it is an error to reject a content module because it contains more than is defined by the framework.

If a data element coded value may be derived from another data element coded value, the creator of this Component shall ensure the accuracy and consistency between the two data elements. If the receiver detects an inconsistency, it shall not correct the value without human intervention.

Whether a module or element may be repeated is defined for various entries in the tables. The convention for this is defined as Y = Yes, N = No.

Table 2.2.1-2 defines the Content Modules used by the Summary Documents Using HL7 Continuity of Care Document (CCD) Component.

Note: Content Modules in this document map to the CCD Entry elements.

Table 2.2.1-2 Component Modules

Content Module	HITSP Opt	HITSP Repeat	Specification Reference	Additional Specification for Component
Person Information	R	N	See CCD: 2.5	See section 2.2.1.2
Language Spoken	R2	Y	See HL7 RIM 3.2.2	See section 2.2.1.3
Support	R2	Y	See CCD: 3.3	See section 2.2.1.4

Content Module	HITSP Opt	HITSP Repeat	Specification Reference	Additional Specification for Component
Healthcare Provider	O	Y	See CCD: 3.17	See section 2.2.1.5
Insurance Provider	O	Y	See CCD: 3.1	See section 2.2.1.6
Allergy / Drug Sensitivity	O	Y	See CCD: 3.8	See section 2.2.1.7
Condition	O	Y	See CCD: 3.5	See section 2.2.1.8
Medication – Prescription and Non-Prescription	O	Y	See CCD: 3.9	See section 2.2.1.9
Pregnancy	O	N	See CCD: 3.5	See section 2.2.1.10
Information Source	R	N	See CCD: 5.2	See section 2.2.1.11
Comment	O	Y	See CCD: 4.3 HL7 CDAR2: 4.3.7.1 and 4.3.8.5	See section 2.2.1.12
Advance Directive	O	Y	See CCD 3.2	See section 2.2.1.13
Immunization	O	Y	See CCD 3.11	See section 2.2.1.14
Vital Sign	O	Y	See CCD 3.12	See section 2.2.1.15
Result	O	Y	See CCD 3.13	See section 2.2.1.16
Encounter	O	Y	See CCD 3.15	See section 2.2.1.17
Procedure	O	Y	See CCD 3.14	See section 2.2.1.18

Examples assume that the default namespace has been set to "urn:hl7-org:v3" to simplify reading, and the namespace prefix "sdtc:" has been mapped to the namespace "urn:hl7-org:sdtc". Some of the examples below have been elided for brevity using the symbol … to represent the elisions.

2.2.1.1 CDA Document

At the Clinical Document level, template identifiers are employed to assert which template(s) the document conforms to. The template identifier for the Registration and Medication History is 2.16.840.1.113883.3.88.11.32.1.

Note: Asserting conformance to this specification indicates that additional constraints from this specification are followed when applicable.

- Required modules from this specification shall be present and follow the associated constraints
- Excluded modules (none as of the current specifications) shall not be present
- Optional modules will be present and will follow the associated constraints if that module also asserts conformance to this document (i.e., includes the associated templateId)
- Additional CCD entry elements (the equivalent to modules in this specification) may be present. The consumer of the document may choose to accept or exclude the additional content, but shall not reject the document solely based upon the presence of the additional content

Table 2.2.1.1-1 CDA Document Constraints

Constraint ID	Constraint
C32-[1]	A CDA Document shall declare conformance to this specification by including a **<templateId>** element with the root attribute set to the value 2.16.840.1.113883.3.88.11.32.1

2.2.1.2 Person Information Module

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 Registration and Medication History document. See the HL7 Continuity of Care Document section 2.5 for constraints applicable to this module.

Table 2.2.1.2-1 Person Information Data Mapping Table - Definitions

Data Element ID	Data Element	Description
1.01	Document Timestamp	The date and time that this HITSP Summary Documents Using HL7 Continuity of Care Document (CCD) has been created.
Patient Information Event Entry		
1.02	Person ID	An identifier that uniquely identifies the individual to which the HITSP Summary Documents Using HL7 Continuity of Care Document (CCD) 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.
1.03	Person Address	The current address of the individual to which the HITSP Summary Documents Using HL7 Continuity of Care Document (CCD) refers. Multiple addresses are allowed and the work address may be a method of disclosing the employer.
1.04	Person Phone/Email/URL	A telephone number (voice or fax), E-mail address, or other locator for a resource mediated by telecommunication equipment. One object class is used to describe phone numbers, pagers, Email addresses, and URLs. 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.
Personal Information		
1.05	Person Name	The individual to whom the HITSP Summary Documents Using HL7 Continuity of Care Document (CCD) refers. Multiple names are allowed to retain birth name, maiden name, legal names, and aliases as required.
1.06	Gender	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 HITSP Summary Documents Using HL7 Continuity of Care Document (CCD) 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.
1.07	Person Date of Birth	The date and time of the birth of the individual to which this HITSP Summary Documents Using HL7 Continuity of Care Document (CCD) 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.
1.08	Marital Status	A value representing the domestic partnership status of a person. Marital status is

Data Element ID	Data Element	Description
		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 HITSP Summary Documents Using HL7 Continuity of Care Document (CCD) is produced. Former values might be part of the personal and social history.
1.09	Religious Affiliation	Religious affiliation is the religious preference of the person.
1.10	Race	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 Summary 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.
1.11	Ethnicity	Ethnicity is a term that extends the concept of race. The coding of ethnicity is aligned with public health and other Federal reporting standards of the CDC and the Census Bureau.

Table 2.2.1.2-2 Person Information Data Mapping Table - Requirements

Data Element ID	Data Element	O/R	Data Source	Additional Specification
1.01	Document Timestamp	R/N	/cda:ClinicalDocument/cda:effectiveTime	
	Patient Information Event Entry	R/N	/cda:ClinicalDocument/cda:recordTarget/ cda:patientRole	
1.02	Person ID	R/N	cda:id	
1.03	Person Address	R/Y	cda:addr	2.2.1.2.2
1.04	Person Phone/Email/URL	R/Y	cda:telecom	2.2.1.2.3
	Personal Information		cda:patient	
1.05	Person Name	R/Y	cda:name	2.2.1.2.1
1.06	Gender	R/N	cda:administrativeGenderCode	2.2.1.2.4
1.07	Person Date of Birth	R/N	cda:birthTime	
1.08	Marital Status	R2/ N	cda:maritalStatusCode	2.2.1.2.5
1.09	Religious Affiliation	O/N	cda:religiousAffiliationCode	2.2.1.2.8
1.10	Race	O/Y	cda:raceCode sdtc:raceCode	2.2.1.2.6
1.11	Ethnicity	O/N	cda:ethnicityCode	2.2.1.2.7

2.2.1.2.1 Person Name Constraints

The HL7 Clinical Document Architecture indicates how names are to be represented. A person's name appears in a **<name>** element, as a collection of name parts.

Figure 2.2.1.2.1-1 Person Name Example

```
<!-- These examples assume the default namespace is 'urn:hl7-org:v3' -->
<!-- example 1 -->
<name use="L">
     <prefix qualifier="AC">Dr.</prefix>
     <given>Margaret</given>
     <given>Ross</given>
     <family>Ellen</family>
</name>
<!-- example 2 -->
<name use="P">
     <given qualifier="CL">Meg</given>
     <family>Ellen</family>
</name>
<!-- example 3 -->
<name use="P">
     <given>Margaret</given>
     <given qualifier="BR">Josephine</given>
     <family qualifier ="BR">Ross</family>
</name>
<!-- example 4 -->
<name use="P">
     <prefix use="AC">Dr.</prefix>
     <given>Margaret</given>
     <given>Josephine</given>
     <family qualifier="BR">Ross</family>
</name>
```

Table 2.2.1.2.1-1 Person Name Constraints

Constraint ID	Constraint
C32-[2]	Each name part shall be identified using one of the tags **<given>**, **<family>**, **<prefix>** or **<suffix>**.
C32-[3]	The "first" name of the patient shall appear in the first **<given>** tag. In example 1 given below, "Margaret" is the patient's first name.
C32-[4]	The "middle" name of the patient, if it exists, shall appear in the second **<given>** tag. In example 1 given below, "Ross" is the patient's middle name.
C32-[5]	Name parts within a **<name>** tag shall be ordered in proper display order.
C32-[6]	At most one **<name>** tag shall have a **use** attribute containing the value "L", indicating that it is the legal name of the patient.
C32-[7]	More than one **<name>** tag may be present to retain birth name, maiden name and aliases.
C32-[8]	An alias or former name may be identified by the inclusion of a **use** attribute containing the value "P".
C32-[9]	Name parts may be identified as being a name given at birth or adoption by the inclusion of a **qualifier** attribute containing the value "BR" for birth or "AD" for adoption.
C32-[10]	A name part shall be identified as the patient's preferred name by the inclusion of a **qualifier** attribute containing the value "CL" on the name part.
C32-[11]	A prefix or suffix that is an academic title or credential shall be identified by the inclusion of a **qualifier** attribute containing the value "AC" on the name part.

2.2.1.2.2 Address Constraints

The HL7 Clinical Document Architecture indicates how addresses are to be represented. An address appears in a **<addr>** element, as a collection of address parts.

Figure 2.2.1.2.2-1 Address Example

```
<!-- These examples assume the default namespace is 'urn:hl7-org:v3' -->
<!-- example 1 -->
<addr use="HP">
     <streetAddressLine>17 Daws Road</streetAddressLine>
     <city>Blue Bell</city> <state>MA</state> <postalCode>00000</postalCode>
     <country>US</country>
</addr>
<!-- example 2 -->
<addr use="HV">
     <streetAddressLine>41 IDX Dr </streetAddressLine>
     <city>South Burlington </city> <state>VT</state> <postalCode>05403</postalCode>
     <country>US</country>
</addr>
<!-- example 3 -->
<addr use="WP">
     <streetAddressLine>116 Huntington Ave</streetAddressLine>
     <streetAddressLine>2nd Floor</streetAddressLine>
     <city>Boston</city> <state>MA</state> <postalCode>02116</postalCode>
     <country>US</country>
</addr>
```

Table 2.2.1.2.2-1 Address Constraints

Constraint ID	Constraint
C32-[12]	Each address part shall be identified using the **<streetAddressLine>**, **<city>**, **<state>**, **<postalCode>** and **<country>** tags.
C32-[13]	More than one **<streetAddressLine>** may be present.
C32-[14]	No more than four **<streetAddressLine>** elements may be present.[1]
C32-[15]	The **<country>** element shall be present for addresses outside of the United States.
C32-[16]	At most one address for a person shall have a **use** attribute with a value containing "HP"
C32-[17]	At least one address for a patient should have a **use** attribute with a value containing "HP".
C32-[18]	One or more vacation addresses may be present for a person.
C32-[19]	A vacation address shall be recorded with a **use** attribute containing the value "HV"
C32-[20]	One or more work addresses may be present.
C32-[21]	A work address shall be recorded with a **use** attribute containing the value "WP"
C32-[22]	The **<country>** shall be recorded using ISO-3166-1, using the two letter country codes.

2.2.1.2.3 Person Phone/Email/URL Constraints

The HL7 Clinical Document Architecture indicates how telecommunications addresses are to be represented. A telecommunications address appears in a **<telecom>** element.

[1] X12 and NCPDP standards only support two address lines. Implementations should not expect more than two address lines to be retained.

Figure 2.2.1.2.3-1 Telephone Numbers and E-mail Addresses Example

```
<!-- These examples assume the default namespace is 'urn:hl7-org:v3' -->
<!-- example 1 -->
<telecom use="HP" value='tel:+1-999-999-9999'/>
<!-- example 2 -->
<telecom use="WP" value='tel:+1-888-888-8888;ext=9999'/>
<!-- example 3 -->
<telecom use="MC" value='tel:+1-777-777-7777'/>
<!-- example 4 -->
<telecom value='mailto:user@hostname'/>
```

Table 2.2.1.2.3-1 Person/Phone/Email/URL Constraints

Constraint ID	Constraint
C32-[23]	A telephone number shall appear in a **<telecom>** element using the 'tel:' URL scheme (see IETF/RFC-3966)
C32-[24]	All telephone numbers shall be represented in international form. That means that U.S. telephone numbers appear with a leading +1, and are followed by the 10 digits used to dial the phone number.
C32-[25]	A telephone number may include hyphens or parenthesis characters for spacing, but these characters are not considered to be significant in comparisons.
C32-[26]	An extension shall be represented by adding the extension dialing digits after the phone number, preceded by ;ext= as represented in example 2 above.
C32-[27]	A home phone number shall be represented with a **use** attribute containing the value "HP"
C32-[28]	A vacation home phone number shall be represented with a **use** attribute containing the value "HV".
C32-[29]	A work phone number shall be represented with a **use** attribute containing the value "WP".
C32-[30]	A mobile phone number shall be represented with a **use** attribute containing the value "MC".
C32-[31]	An e-mail address shall appear in a **<telecom>** element using the 'mailto:' URL scheme (see IETF/RFC-2368), and shall encode only a single mailing address, without any headers.

2.2.1.2.4 Gender Constraints

Figure 2.2.1.2.4-1 Gender Code Examples

```
<!-- These examples assume the default namespace is 'urn:hl7-org:v3' -->
<!-- example 1 -->
<genderCode code="M" displayName="Male" codeSystem="2.16.840.1.113883.5.1"
    codeSystemName="AdministrativeGenderCode"/>
<!-- example 2 -->
<genderCode code="F" displayName="Female" codeSystem="2.16.840.1.113883.5.1"
    codeSystemName="AdministrativeGenderCode"/>
```

Table 2.2.1.2.4-1 Gender Constraints

Constraint ID	Constraint
C32-[32]	Gender shall be coded using the HL7 AdministrativeGenderCode terminology. The OID for this terminology is 2.16.840.1.113883.5.1.

2.2.1.2.5 Marital Status Constraints

Figure 2.2.1.2.5-1 Marital Status Example

```
<maritalStatusCode code='M' displayName='Married'
    codeSystem='2.16.840.1.113883.5.2'
    codeSystemName='MaritalStatusCode'/>
```

Table 2.2.1.2.5-1 Marital Status Constraints

Constraint ID	Constraint
C32-[33]	Marital Status shall be coded using the HL7 MaritalStatusCode terminology. The OID for this terminology is 2.16.840.1.113883.5.2

2.2.1.2.6 Race Constraints

Race is reported at the discretion of the patient, according to Federal Guidelines for race reporting.

Figure 2.2.1.2.6-1 Race Coding Example

```
<!-- These examples assume the default namespace is 'urn:hl7-org:v3' -->
<!-- example 1 -->
<raceCode code='1004-1' displayName='American Indian'
    codeSystem='2.16.840.1.113883.6.238' codeSystemName='CDC Race and Ethnicity'/>
<!-- example 2 -->
<sdtc:raceCode code='2058-6' displayName='African American'
    codeSystem='2.16.840.1.113883.6.238' codeSystemName='CDC Race and Ethnicity'/>
```

Table 2.2.1.2.6-1 Race Constraints

Conformance ID	Constraint
C32-[34]	Race shall be coded according to Federal Guidelines for reporting race, using the CDC Race and Ethnicity vocabulary for reporting race. The OID for this vocabulary is 2.16.840.1.113883.6.238.
C32-[35]	Second and subsequent raceCode elements may be recorded using the sdtc:raceCode extension

2.2.1.2.7 Ethnicity Constraints

Ethnicity is reported at the discretion of the patient, according to Federal Guidelines for ethnicity reporting.

Figure 2.2.1.2.7-1 Ethnicity Coding Example

```
<!-- This example assumes the default namespace is 'urn:hl7-org:v3' -->
<!-- example 1 -->
<ethnicityCode code='2178-2' displayName='Latin American'
    codeSystem='2.16.840.1.113883.6.238' codeSystemName='CDC Race and Ethnicity'/>
```

Table 2.2.1.2.7-1 Ethnicity Constraints

Constraint ID	Constraint
C32-[36]	Ethnicity shall be coded according to Federal Guidelines for reporting ethnicity, using the CDC Race and Ethnicity vocabulary for reporting ethnicity. The OID for this vocabulary is 2.16.840.1.113883.6.238.

2.2.1.2.8 Religious Affiliation Constraints

Religious affiliation is recorded at the discretion of the patient.

Figure 2.2.1.2.8-1 Religious Affiliation Example

```
<!-- This example assumes the default namespace is 'urn:hl7-org:v3' -->
<religiousAffilliationCode code='1022' displayName='Independent'
     codeSystem='2.16.840.1.113883.5.1076' codeSystemName='ReligiousAffiliation' />
```

Table 2.2.1.2.8-1 Religious Affiliation Constraints

Constraint ID	Constraint
C32-[27]	The primary religious affiliation may appear in the **<religiousAffilliationCode>** element.
C32-[38]	Religious affiliation shall be coded using the HL7 Religious Affiliation vocabulary. The OID for this vocabulary is 2.16.840.1.113883.5.1076.

2.2.1.3 Language Spoken Module

This module describes the primary and secondary languages of communication for the patient.

Table 2.2.1.3-1 Language Spoken Data Mapping Table - Definitions

Data Element ID	Data Element	Description
2.01	Language	Language will be identified as spoken, written, or understood; but no attempt will be made to assess proficiency. The default language is English, but English is to be entered explicitly similar to any other listed language. Languages spoken shall be recorded using the languageCommunication infrastructure class associated with the patient. The languageCommunication element describes the primary and secondary languages of communication for a person.

Table 2.2.1.3-2 Language Spoken Data Mapping Table - Requirements

Data Element ID	Data Element	O/R	Data Source	Additional Specification
2.01	Language	R/Y	cda:recordTarget/cda:patientRole/cda:patient/ cda:languageCommunication	2.2.1.3.1

2.2.1.3.1 Language Constraints

The template identifier for this construct is 2.16.840.1.113883.3.88.11.32.2.

Figure 2.2.1.3.1-1 Language Communication Examples

```
<!-- These examples assume the default namespace is 'urn:hl7-org:v3' -->
<!-- example 1 -->
<languageCommunication>
     <templateId root='2.16.840.1.113883.3.88.11.32.2'/>
     <languageCode code='fr-CN' displayName='Canadian French' />
     <preferenceInd value='true'/>
</languageCommunication>
<!-- example 2 -->
<languageCommunication>
     <templateId root='2.16.840.1.113883.3.88.11.32.2'/>
     <languageCode code='en-US' displayName='English' />
     <modeCode code='RWR' displayName='Recieve Written'
          codeSystem='2.16.840.1.113883.5.60' codeSystemName='LanguageAbilityMode'/>
     <preferenceInd value='false'/>
</languageCommunication>
<!-- example 3 -->
<languageCommunication>
     <templateId root='2.16.840.1.113883.3.88.11.32.2'/>
     <languageCode code='sgn-US' displayName='American Sign Language' />
     <preferenceInd value='true'/>
</languageCommunication>
```

Table 2.2.1.3.1-1 Language Constraints

Constraint ID	Constraint
C32-[39]	The language of communication shall appear in a <languageCommunication> element appearing beneath the <patient> element
C32-[40]	This element shall have a **<languageCode>** element that conveys the language of communication. Sign language shall be treated as a separate language for the purpose of this specification.
C32-[41]	The **<languageCommunication>** element should have a **<preferenceInd>** element to indicate the patient preference for use of that language for communication.
C32-[42]	More than one language preference may be recorded.
C32-[43]	To indicate only a specific mode of communication (expressing or receiving written, verbal, or signed communication), a **<modeCode>** element may be included.
C32-[44]	The codes for the **<modeCode>** element shall 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 (see example 2 below). On the other hand, American Sign Language would be represented using the code sgn-US (see example 3 below), and would only use mode codes for signed communication.
C32-[45]	While this HL7 CDA allows for the specification of proficiency using the **<proficiencyLevelCode>** element, this element should not be used[2].

2.2.1.4 Support Module

This module represents the patient's sources of support, such as immediate family, relatives, and guardian at the time as the summarization is generated. Support information also includes next of kin, caregivers, and support organizations. At a minimum, key support contacts relative to healthcare decisions, including next of kin, should be included. Support providers may include providers of healthcare related services, such as a personally controlled health record, or registry of emergency

[2] Judgments about language proficiency are subjective, and could have a negative impact on the desire of consumers to use this construct to exchange registration and medication information.

contacts. If no healthcare providers are supplied, the reason should be supplied as free text in the narrative block (e.g., Unknown, etc).

See the HL7 Continuity of Care Document section 3.3 for constraints applicable to this module.

The contact data object is used to store phone numbers, Email, and URL information for contacting the patient or others such as emergency contacts or healthcare providers.

The template identifier for this construct is 2.16.840.1.113883.3.88.11.32.3.

Table 2.2.1.4-1 Support Data Mapping Table - Definitions

Data Element ID	Data Element	Description
	Support	
3.01	Date	The period over which the support is provided.
	Contact	
3.02	Contact Type	This represents the type of support provided, such as immediate emergency contacts, next of kin, family relations, guardians, agents, et cetera.
3.03	Contact Relationship	Identifies the relationship of the contact person to the individual for which this HITSP Summary Documents Using HL7 Continuity of Care Document (CCD) Document refers.
3.04	Contact Address	The address of the contact individual or organization providing support to the individual for which this HITSP Summary Documents Using HL7 Continuity of Care Document (CCD)is produced.
3.05	Contact Phone/Email/URL	A telephone number (voice or fax), e-mail address, or other locator for the contact individual or organization providing support to the individual for which this the HITSP Summary Documents Using HL7 Continuity of Care Document (CCD) is produced. One object class is used to describe phone numbers, pagers, Email addresses, and URLs.
3.06	Contact Name	The name of the individual or organization providing support to the individual for which this HITSP Summary Documents Using HL7 Continuity of Care Document (CCD) is produced.

Table 2.2.1.4-2 Support Data Mapping Table - Requirements

Data Element ID	Data Element	O/R	Data Source	Additional Specification
	Support	R2/Y	/cda:ClinicalDocument/cda:participant	
3.01	Date	R/N	cda:time	
	Contact	R2/Y	cda:associatedEntity or cda:patientRole/cda:patient/cda:guardian	
3.02	Contact Type	R/N	@classCode	2.2.1.4.1
3.03	Contact Relationship	R2/N	cda:code	2.2.1.4.2

Data Element ID	Data Element	O/R	Data Source	Additional Specification
3.04	Contact Address	R2/Y	cda:addr	
3.05	Contact Phone/Email/URL	R2/Y	cda:telecom	
3.06	Contact Name	R/Y	cda:associatedPerson/cda:name or cda:guardianPerson/cda:name	

Figure 2.2.1.4-1 Support Examples

```
<!-- These examples assume the default namespace is 'urn:hl7-org:v3' -->
<!-- example 1 -->
<patient>
        …
    <guardian classCode='GUARD'>
        <templateId root='2.16.840.1.113883.3.88.11.32.3'/>
        <code code='GRMTH' displayName='Grandmother'
            codeSystem='2.16.840.1.113883.5.111' codeSystemName='RoleCode'/>
        <addr>…</addr>
        <telecom …/>
        <guardianPerson>
            <name>…</name>
        </guardianPerson>
    </guardian>
</patient>

<!-- example 2 -->
<participant typeCode='IND'>
    <templateId root='2.16.840.1.113883.3.88.11.32.3'/>
    <time value='20070213'/>
    <associatedEntity classCode='AGNT'>
        <code code='STPDAU' displayName='Step-Daughter'
            codeSystem='2.16.840.1.113883.5.111' codeSystemName='RoleCode'/>
        <addr>…</addr>
        <telecom …/>
        <assignedPerson>
            <name>…</name>
        </assignedPerson>
    </associatedEntity>
<participant>
```

2.2.1.4.1 Contact Type Constraints

The classCode attribute is filled in using HL7 RoleClass vocabulary. For this specification, the following values shall be used to express different types of contacts:

Table 2.2.1.4.1-1 Contact Type Additional Specifications

Term	HL7 Definition and Example	Clarification for use in the CE Context

AGNT	An entity that acts or is authorized to act on behalf of another entity (scoper).
	`<assignedEntity classCode='AGNT'>`
	`  …`
	`</assignedEntity>`
		Used to record persons that can act on behalf of the patient, e.g., someone holding a healthcare power of attorney, etc.

CAREGIVER	A person responsible for the primary care of a patient at home.	None

Term	HL7 Definition and Example	Clarification for use in the CE Context
	<assignedEntity classCode='CAREGIVER'> ... </assignedEntity>	
ECON	An entity to be contacted in the event of an emergency. <assignedEntity classCode='ECON'> ... </assignedEntity>	None
GUARD	Guardian of a ward <patient> ... <guardian classCode='GUARD'> ... </guardian> </patient>	The CCD specifies that the guardian relationship shall be encoded using the <cda:guardian> element that appears inside the <cda:patient> element.
NOK	An individual designated for notification as the next of kin for a given entity. <assignedEntity classCode='NOK'> ... </assignedEntity>	None
PRS	Links two people in a personal relationship. <assignedEntity classCode='PRS'> ... </assignedEntity>	Used to describe family members and other persons that have a personal relationship with the patient. When this value is used, the value used for Contact Relationship below is also constrained to the HL7 PersonalRelationshipRoleType vocabulary domain.

Table 2.2.1.4.1-2 Contact Type Constraints

Constraint ID	Constraint
C32-[46]	With the exception of guardians, supporting persons or organizations shall be represented in the HL7 CDA using the **<participant>** element in the header of the **<ClinicalDocument>**.
C32-[47]	Guardians shall be represented using the **<guardian>** element subordinate to the **<patient>** element.
C32-[48]	A patient may have more than one guardian.
C32-[49]	Contact type shall be expressed by the classCode attribute on the **<guardian>** or **<associatedEntity>**.

2.2.1.4.2 Contact Relationship Constraints

Table 2.2.1.4.2-1 Contact Relationship Constraints

Constraint ID	Constraint
C32-[50]	The contact relationship should be recorded in the **<code>** element beneath the **<assignedEntity>** or **<guardian>** element.
C32-[51]	The **<code>** element shall have a code value drawn from the HL7 PersonalRelationshipRoleType vocabulary. The OID for this vocabulary is 2.16.840.1.113883.5.111.

2.2.1.5 Healthcare Provider Module

This module represents the healthcare providers involved in the current or pertinent historical care of the patient. See the HL7 Continuity of Care Document section 3.17 for constraints applicable to this module. If no healthcare providers are supplied, the reason shall be supplied as free text in the narrative block (e.g., No Providers, Provider Unknown, etc.).

Providers listed in this module may be referred to by the Conditions Module defined in section 2.2.1.7 to link a condition to the treating provider or providers.

The template identifier for this construct is 2.16.840.1.113883.3.88.11.32.4.

Table 2.2.1.5-1 Healthcare Providers Data Mapping Table - Definitions

Data Element ID	Data Element	Description
Provider		
4.01	Date Range	The period over which this provider has provided healthcare services to the patient.
4.02	Provider Role Coded	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.
4.03	Provider Role Free Text	This unstructured text classifies providers according to the role they play in the healthcare of the patient.
Provider Entity		
4.04	Provider Type	Provider type classifies providers according to the type of license or accreditation they hold (e.g. physician, dentist, pharmacist, et cetera) or the service they provide.
4.05	Provider Address	The mailing address to which written correspondence to this provider should be directed.
4.06	Provider Phone/Email/URL	A telephone number (voice or fax), e-mail address, or other locator for a resource mediated by telecommunication equipment. One object class 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; temporary items can be entered for use on specific effective dates.
4.07	Provider Name	The name of the provider.
4.08	Provider's Organization Name	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.
4.09	Provider's Patient ID	The identifier used by this provider to identify the patient's medical record.

Table 2.2.1.5-2 Healthcare Providers Data Mapping Table - Requirements

Data Element ID	Data Element	O/R	Data Source	Additional Specification
	Provider	R2/Y	/cda:ClinicalDocument/cda:documentationOf/	2.2.1.5.1

Data Element ID	Data Element	O/R	Data Source	Additional Specification
			cda:serviceEvent/cda:performer	
4.01	Date Range	R/N	cda:time	
4.02	Provider Role Coded	R2/N	cda:functionCode	2.2.1.5.2
4.03	Provider Role Free Text	R2/N	cda:originalText	2.2.1.5.2
	Provider Entity	R/Y	cda:assignedEntity	
4.04	Provider Type	R2/N	cda:code	2.2.1.5.3
4.05	Provider Address	R2/Y	cda:addr	
4.06	Provider Phone/Email/URL	R2/Y	cda:telecom	
4.07	Provider Name	R2/N	cda:assignedPerson/cda:name	
4.08	Provider's Organization Name	R2/Y	cda:representedOrganization/cda:name	
4.09	Provider's Patient ID	R2/N	sdtc:patient/sdtc:id	

Figure 2.2.1.5-1 Healthcare Provider Example

```
<!-- These examples assume the default namespace is 'urn:hl7-org:v3' -->
<documentationOf>
    <serviceEvent classCode="PCPR">      <effectiveTime><low value="19650120"/><high
value="20070209"/></effectiveTime>
        <performer typeCode="PRF">
            <templateId root='2.16.840.1.113883.3.88.11.32.4'/>
            <functionCode code='CP' displayName='Consulting Provider'
                codeSystem='2.16.840.1.113883.12.443' codeSystemName='Provider Role'>
                <originalText>Consulting Provider</originalText>
            <time>
                <low value=''/>
                <high value=""/>
            </time>
            <assignedEntity>
                <id root='78A150ED-B890-49dc-B716-5EC0027B3982'
                    extension="ProviderID"/>
                <code code='200000000X '
                    displayName='Allopathic and Osteopathic Physicians'
                    codeSystem='2.16.840.1.113883.6.101'
                    codeSystemName='ProviderCodes'/>
                <assignedPerson>
                    <name>...</name>
                </assignedPerson>
                <sdtc:patient>
                    <sdtc:id root='78A150ED-B890-49dc-B716-5EC0027B3983'
                        extension='MedicalRecordNumber'/>
                </sdtc:patient>
            </assignedEntity>
        </performer>
    </serviceEvent>
</documentationOf>
```

2.2.1.5.1 Provider

Healthcare providers are encoded as shown below. The Registration and Medication History document provides documentation of the service event which is the provision of healthcare. This is reflected in the

<serviceEvent classCode='PCPR'> element in the example below. The value PCPR is required, and is a code meaning "provision of care".

2.2.1.5.2 Provider Role

Table 2.2.1.5.2-1 Provider Role Constraints

Constraint ID	Constraint
C32-[52]	Provider role shall be taken from a limited subset of the HL7 Version 2 Provider Role vocabulary. The OID for this terminology is 2.16.840.1.113883.12.443.

Table 2.2.1.5.2-2 Provider Role Terminology

Term	HL7 Definition
CP	Consulting Provider
PP	Primary Care Provider
RP	Referring Provider

2.2.1.5.3 Provider Type

Provider type shall be coded using a subset of the Healthcare Provider Taxonomy. This subset uses only the high-level provider codes, and eliminates a few codes not otherwise needed in the Consumer Empowerment Use Case. The OID for this terminology is 2.16.840.1.113883.6.101.

Table 2.2.1.5.3-1 Provider Type Additional Specifications

Term	Healthcare Provider Taxonomy
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

Term	Healthcare Provider Taxonomy
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

2.2.1.6 Insurance Provider Module

This 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.

See the HL7 Continuity of Care Document section 3.1.2.1.2 for constraints applicable to this module. Each unique instance of a payer or party with financial responsibility will include all the pertinent data needed to contact, bill to, and collect from that party. At a minimum, the patient's pertinent current payment sources should be listed. If no payment sources are supplied, the reason shall be supplied as free text in the narrative block (e.g., Not Insured, Payer Unknown, Medicare Pending, et cetera).

The template identifier for this construct is 2.16.840.1.113883.3.88.11.32.5.

Table 2.2.1.6-1 Insurance Providers Data Mapping Table - Definitions

Data Element ID	Data Element	Description
Payment Provider Event Entry		
5.01	Group Number	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.
5.02	Health Insurance Type	The type of health plan covering the individual, e.g., an HMO, PPO, POS, Medicare Part A/B, etc.
Payer		
5.03	Health Plan Insurance Information Source ID	The coded identifier of the payer corresponding to the Health Plan Information Source Name. It is important to note that Health Plan Information Source Name and ID are NOT synonymous with Health Plan Name or the health plan identifier (when/if health plans are enumerated under HIPAA).
5.04	Health Plan Insurance Information Source Address	The official mailing address to which written correspondence is to be directed.
5.05	Health Plan Insurance Information Source Phone/Email/URL	A telephone number (voice or fax), e-mail address, or other locator for a resource mediated by telecommunication equipment. One object class is used to describe phone numbers, pagers, Email addresses, and URLs. One or more of these contact

Data Element ID	Data Element	Description
		numbers can be designated as the preferred methods of contact; temporary items can be entered for use on specific effective dates.
5.06	Health Plan Insurance Information Source Name	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 Identifier (when/if health plans are enumerated under HIPAA). 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.
		Patient Information
5.07	Health Plan Coverage Dates	The begin 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 information in the registration / medication summary 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.
		Patient
5.08	Member ID	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.
5.09	Patient Relationship to Subscriber	Specifies only if patient is the subscriber or dependent within the context of the specified health plan.
5.10	Patient Address	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. See section 4.2.3.1.5.5
5.11	Patient Phone/Email/URL	A telephone number (voice or fax), e-mail address, or other locator for a resource mediated by telecommunication equipment. One object class 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; temporary items can be entered for use on specific effective dates.
5.12	Patient Name	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. See section 4.2.3.1.5.3
5.13	Patient Date of Birth	The date of birth of the patient as entered into the eligibility system of the health plan. See section 4.2.3.1.5.4
5.14	Financial Responsibility Party Type	The type of party that has responsibility for all or a portion of the patient's healthcare; includes health insurance, the patient directly, a guardian or other guarantor, or other third party that is not a health insurance plan.
		Subscriber Information
5.15	Subscriber ID	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.
5.16	Subscriber Address	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

Data Element ID	Data Element	Description
		written correspondence is to be directed.
5.17	Subscriber Phone/Email/URL	A telephone number (voice or fax), e-mail address, or other locator for a resource mediated by telecommunication equipment. One object class 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; temporary items can be entered for use on specific effective dates.
5.18	Subscriber Name	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. See section 4.2.3.1.5.1
5.19	Subscriber Date of Birth	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. See section 4.2.3.1.5.2
Guarantor Information		
5.20	Effective Date of Financial Responsibility	The time span over which the Financial Responsibility Party is responsible for the payment of the patient's healthcare.
5.21	Financial Responsibility Party Address	The official mailing address of the Financial Responsibility Party to which written correspondence is to be directed.
5.22	Financial Responsibility Party Phone/Email/URL	A telephone number (voice or fax), e-mail address, or other locator for a resource mediated by telecommunication equipment. One object class 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; temporary items can be entered for use on specific effective dates.
5.23	Financial Responsibility Party Name	The name of the financially responsible party.
Health Plan		
5.24	Health Plan Name	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.

Table 2.2.1.6-2 Insurance Providers Data Mapping Table - Requirements

Data Element ID	Data Element	O/R	Data Source	Additional Specification
	Payment Provider Event Entry	R2/Y	cda:act[cda:templateId/@root= '2.16.840.1.113883.10.20.1.26']	2.2.1.6.1
5.01	Group Number	O/N	cda:id	2.2.1.6.2
5.02	Health Insurance Type	R2/N	cda:code	2.2.1.6.3
	Payer	R/N	cda:performer/cda:assignedEntity	
5.03	Health Plan Insurance Information Source ID	O/Y	cda:id	2.2.1.6.3
5.04	Health Plan Insurance Information Source Address	O/Y	cda:addr	

Data Element ID	Data Element	O/R	Data Source	Additional Specification
5.05	Health Plan Insurance Information Source Phone/Email/URL	O/Y	cda:telecom	
5.06	Health Plan Insurance Information Source Name	R2/N	cda:representedOrganization/cda:name	
	Member Information	R2/N	cda:participant[@typeCode='COV']	2.2.1.6.5
5.07	Health Plan Coverage Dates	R2/N	cda:time	2.2.1.6.6
	Patient	R/N	cda:participantRole[@classCode='PAT']	
5.08	Member ID	R2/N	cda:id	2.2.1.6.7
5.09	Patient Relationship to Subscriber	R/N	cda:code	2.2.1.6.8
5.10	Patient Address	R2/Y	cda:addr	
5.11	Patient Phone/Email/URL	R2/Y	cda:telecom	
5.12	Patient Name	R/N	cda:playingEntity/cda:name	2.2.1.6.9
5.13	Patient Date of Birth	R/N	cda:playingEntity/sdtc:birthTime	2.2.1.6.10
5.14	Financial Responsibility Party Type	R/N	cda:performer/cda:assignedEntity/cda:code	2.2.1.6.11
	Subscriber Information	R2/N	cda:participant[@typeCode='HLD']/ cda:participantRole	2.2.1.6.12
5.15	Subscriber ID	R/N	cda:id	2.2.1.6.13
5.16	Subscriber Address	R/N	cda:addr	
5.17	Subscriber Phone/Email/URL	R2/Y	cda:telecom	
5.18	Subscriber Name	R/N	cda:playingEntity/cda:name	
5.19	Subscriber Date of Birth	R/N	cda:playingEntity/sdtc:birthTime	2.2.1.6.14
	Guarantor Information	R2/Y	cda:performer[cda:assignedEntity/cda:code[@code='' and @codeSystem='']]	
5.20	Effective Date of Financial Responsibility	R2/N	cda:time	
5.21	Financial Responsibility Party Address	R2/Y	cda:assignedEntity/cda:addr	
5.22	Financial Responsibility Party Phone/Email/URL	R2/Y	cda:assignedEntity/cda:telecom	
5.23	Financial Responsibility Party Name	R2/N	cda:assignedEntity/cda:assignedPerson/ cda:name - AND/OR - cda:assignedEntity/ cda:representedOrganization/ cda:name	
	Health Plan	R2/N	cda:entryRelationship[@typeCode='REFR']/ cda:act[@classCode='ACT' and	2.2.1.6.15

Data Element ID	Data Element	O/R	Data Source	Additional Specification
			@moodCode='DEF']	
5.24	Health Plan Name	R2/N	cda:text	2.2.1.6.16

2.2.1.6.1 Payment Provider Constraints

Information for payment providers shall be recorded as a policy act inside the coverage act as described in section 3.1 of the Continuity of Care Document Implementation Guide.

Figure 2.2.1.6.1-1 Insurance Provider Examples

```
<!-- These examples assume the default namespace is 'urn:hl7-org:v3' -->
<!-- example 1 -->
<act classCode='ACT' moodCode='DEF'>
     <templateId root='2.16.840.1.113883.10.20.1.20'/>
     <id root=''/>
     <code code='48768-6' displayName='Payment Sources'
          codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
     <statusCode code='completed'/>

     <!-- Example 1, A health plan -->
     <entryRelationship typeCode='COMP'>
          <sequenceNumber value='1'/>
     <act classCode='ACT' moodCode='EVN'>
               <templateId root='2.16.840.1.113883.10.20.1.26'/>
               <templateId root='2.16.840.1.113883.3.88.11.32.5'/>
          <id root='2844AF96-37D5-42a8-9FE3-3995C110B4F8'
                    extension='GroupOrContract#'/>
          <code code='' displayName=''
                    codeSystem='2.16.840.1.113883.6.255.1336' codeSystemName='X12N-
1336'/>
          <statusCode code='completed'/>
          <performer typeCode='PRF'>…</performer>
               <participant typeCode='COV'>…</participant>
          <participant typeCode='HLD'>…</participant>
               <entryRelationship typeCode='REFR'>
               <act classCode='ACT' moodCode='DEF'>…</act>
               </entryRelationship>
     </act>
     </entryRelationship>

     <!-- Example 2, A guarantor -->
     <entryRelationship typeCode='COMP'>
          <sequenceNumber value='2'/>
     <act classCode='ACT' moodCode='EVN'>
               <templateId root='2.16.840.1.113883.10.20.1.26'/>
               <templateId root='2.16.840.1.113883.3.88.11.32.5'/>
          <id root='2844AF96-37D5-42a8-9FE3-3995C110B4F9'/>
               <code code='PP' displayName='Personal Payment'
                    codeSystem='2.16.840.1.113883.6.255.1336' codeSystemName='X12N-
1336'/>
          <statusCode code='completed'/>
          <performer typeCode='PRF'>
               <time value='…'/>
               <assignedEntity>
                    <id …/>
                    <code code='GUAR' displayName='Guarantor'
                              codeSystem='2.16.840.1.113883.5.110'
codeSystemName='RoleClass'/>
                    <assignedPerson><name>…</name></assignedPerson>
               </assignedEntity>
          </performer>
     </act>
     </entryRelationship>
</act>
```

2.2.1.6.2 Group Number Constraints

The group number identifies the sponsor to the health plan with respect to the sponsored contract or policy.

Figure 2.2.1.6.2-1 Group Number Example

```
...
<id root='2844AF96-37D5-42a8-9FE3-3995C110B4F8' extension='GroupOrContract#'/>
...
```

Table 2.2.1.6.2-1 Group Number Constraints

Constraint ID	Constraint
C32-[53]	The group or contract number shall be recorded in the **extension** attribute of the **<id>** element found in the **<act>**.
C32-[54]	The value of the **root** attribute of the **<id>** element shall be present.
C32-[55]	The **root** attribute should be the OID of the assigning authority for the identifier; however, determining the assigning authority is not feasible in all settings.
C32-[56]	A GUID may be used in place of the OID of the assigning authority.
C32-[57]	Implementers should use the same GUID for each instance of the same group or contract number.

2.2.1.6.3 Healthcare Insurance Type Constraints

Figure 2.2.1.6.3-1 Health Insurance Type Example

```
<!-- These examples assume the default namespace is 'urn:hl7-org:v3' -->
    <act classCode='ACT' moodCode='EVN'>
        <templateId root='2.16.840.1.113883.10.20.1.26'/>
            ...
        <code code='IP' displayName='Individual Policy'
            codeSystem='2.16.840.1.113883.6.255.1336' codeSystemName='X12N-1336'/>
            ...
    </act>
```

Table 2.2.1.6.3-1 Healthcare Insurance Type Constraints

Constraint ID	Constraint
C32-[58]	The health insurance type should be recorded in the **<code>** element beneath the act representing the policy.
C32-[59]	The **code** attribute value shall come from the X12 vocabulary for Insurance Type Code (X12 Data Element 1336), as restricted by the X12N 271 Transaction. The OID for this vocabulary is 2.16.840.1.113883.6.255.1336.
C32-[60]	The **code** attribute shall use the value PP to indicate self-pay or payment by a guarantor.

2.2.1.6.4 Health Plan Insurance Information Source ID Constraints

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 2.16.840.1.113883.3.88.3.1[3]
The OID for an RxPCN is 2.16.840.1.113883.3.88.3.1 plus the numeric identifier used in the RxBIN.

Figure 2.2.1.6.4-1 Payer Example

```
<!-- These examples assume the default namespace is 'urn:hl7-org:v3' -->
<!-- These examples assume an RxBIN of 699999 and an RxPCN of PZZZZ -->
<performer typeCode='PRF'>
    <assignedEntity classCode='ASSIGNED'>
        <id root='2.16.840.1.113883.3.88.3.1' extension='699999'/>
        <id root='2.16.840.1.113883.3.88.3.1.699999' extension='PZZZZ'/>
        <addr>…</addr>
        <telecom value='…'/>
        <representedOrganization classCode='ORG'>
            <name>…</name>
        </representedOrganization>
    </assignedEntity>
</performer>
```


[3] This OID has been provisionally assigned and may change before final publication.

2.2.1.6.5 Member Information Constraints

The data elements described below identify the member (patient) to the health plan for eligibility and/or claims processing. For various reasons, the health plan may not have the member's name, address or data of birth recorded in the same way as the provider has recorded the patient information. Using the member information as recorded by the health plan will improve the healthcare provider's ability to determine eligibility for benefits, and reduce rejections of claims.

Figure 2.2.1.6.5-1 Member Information Examples

```
<!-- These examples assume the default namespace is 'urn:hl7-org:v3' -->
<!-- Example 1, The patient is the subscriber -->
<participant typeCode='COV'>
    <time>
        <low value='20070101'/>
    </time>
    <participantRole classCode='PAT'>
        <id root='' extension=''/>
        <code code='SUBSCR' displayName='subscriber'
            codeSystem='2.16.840.1.113883.5.111'  codeSystemName='RoleCode'/>
        <playingEntity>
            <name>…</name>
            <sdtc:birthTime value='…'/>
        </playingEntity>
    </participant>
</participant>

<!-- Example 2, The patient is a dependent of the subscriber -->
<participant typeCode='COV'>
    <time>
        <low value='20070209'/>
    </time>
    <participantRole classCode='PAT'>
        <id root='' extension=''/>
        <code code='DEPEND' displayName='dependent'
            codeSystem='2.16.840.1.113883.5.111'  codeSystemName='RoleCode'/>
        <playingEntity>
            <name><given>Baby</given><family>Ross</family></name>
            <sdtc:birthTime value='20070209'/>
        </playingEntity>
    </participant>
</participant>
```

Table 2.2.1.6.5-1 Member Information Constraints

Constraint ID	Constraint
C32-[61]	Member information shall be recorded in a **<participant>** element with the typeCode attribute set to "COV".

2.2.1.6.6 Health Plan Coverage Dates Constraints

Table 2.2.1.6.6-1 Health Plan Coverage Dates Constraints

Constraint ID	Constraint
C32-[62]	The date when the plan began covering the member should be recorded in the **<low>** element of the **<time>** element beneath the **<participant>** element.
C32-[63]	The date when the plan stops covering the member should be recorded in the **<high>** element of the **<time>** element

Constraint ID	Constraint
	beneath the **<participant>** element.

2.2.1.6.7 Member ID Constraints

Table 2.2.1.6.7-1 Member ID Constraints

Constraint ID	Constraint
C32-[64]	The member identifier number shall be recorded in the **extension** attribute of the **<id>** element found in the **<participantRole>** element.
C32-[65]	The value of the **root** attribute of the **<id>** element shall be present.
C32-[66]	The **root** attribute should be the OID of the assigning authority for the identifier; however, determining the assigning authority is not feasible in all settings.
C32-[67]	A GUID may be used in place of the OID of the assigning authority.
C32-[68]	Implementers should use the same GUID for each instance of a member identifier from the same health plan.

2.2.1.6.8 Relationship to Subscriber Constraints

Table 2.2.1.6.8-1 Relationship to Subscriber Constraints

Constraint ID	Constraint
C32-[69]	The relationship to the subscriber shall be recorded in the **<code>** element underneath the **<participantRole>** element recording the member information.
C32-[70]	The **code** attribute shall be present, and shall contain a value from the HL7 CoverageRoleType vocabulary domain. The OID for this vocabulary is 2.16.841.1.113883.5.111.

2.2.1.6.9 Patient Name Constraints

Table 2.2.1.6.9-1 Patient Name Constraints

Constraint ID	Constraint
C32-[71]	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.
C32-[72]	Otherwise, the name shall be assumed to be the same as recorded for the patient, as described for data element 1.05 above.

2.2.1.6.10 Patient Date of Birth Constraints

Table 2.2.1.6.10-1 Patient Date of Birth Constraints

Constraint ID	Constraint
C32-[73]	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.

Constraint ID	Constraint
C32-[74]	Otherwise, the date of birth of the member shall be assumed to be the same as recorded for the patient, as described for data element 1.07 above. The **<sdtc:birthTime>** element represents an extension to the HL7 CDA Release 2.0

2.2.1.6.11 Financial Responsibility Party Type Constraints

This data element identifies the type of the financially responsible party.

Table 2.2.1.6.11-1 Financial Responsibility Party Constraints

Constraint ID	Constraint
C32-[75]	The type of financially responsible party shall be recorded in the **<code>** element beneath the **<assignedEntity>** element of the **<performer>**.
C32-[76]	The code attribute shall contain a value from the HL7 RoleClassRelationshipFormal vocabulary. The OID for this vocabulary is 2.16.840.1.113883.5.110.
C32-[77]	When the **code** of the encompassing act is PP, the **code** attribute value shall be set to GUAR or PAT to represent a guarantor or self-paying patient respectively.
C32-[78]	The **code** attribute shall be set to PAYOR when the **code** of the encompassing act is other than PP.

2.2.1.6.12 Subscriber Constraints

These data elements identify the subscriber to the health plan for eligibility and/or claims processing. For various reasons, the health plan's eligibility system may not have the subscriber's name, address or data of birth recorded in the same way as the provider records it. Using the subscriber information as recorded by the eligibility system will improve the healthcare provider's ability to determine eligibility for benefits, and reduce rejections of claims.

Figure 2.2.1.6.12-1 Subscriber Information Example

```
<!-- These examples assume the default namespace is 'urn:hl7-org:v3' -->
<participant typeCode='HLD'>
    <participantRole classCode='IND'>
        <id root='...' extension='...'/>
        <playingEntity>
            <name><given>Meg</given><family>Ellen</family></name>
            <sdtc:birthTime value='19600127'/>
        </playingEntity>
    </participant>
</participant>
```

Table 2.2.1.6.12-1 Subscriber Constraints

Constraint ID	Constraint
C32-[79]	When the Subscriber is other than the patient, subscriber information shall be recorded in a **<participant>** element with the typeCode attribute set to "HLD".
C32-[80]	When the Subscriber is the patient, no **<participant>** element describing the subscriber shall be present. This information will be recorded instead in the data elements used to record member information

2.2.1.6.13 Subscriber ID Constraints

Table 2.2.1.6.13-1 Subscriber ID Constraints

Constraint ID	Constraint
C32-[81]	The subscriber identifier number shall be recorded in the **extension** attribute of the **<id>** element found in the **<participantRole>** element.
C32-[82]	The value of the **root** attribute of the **<id>** element shall be present.
C32-[83]	The **root** attribute should be the OID of the assigning authority for the identifier; however, determining the assigning authority is not feasible in all settings.
C32-[84]	A GUID may be used in place of the OID of the assigning authority. Implementers should use the same GUID for each instance of a subscriber identifier from the same health plan.

2.2.1.6.14 Subscriber Date of Birth Constraints

Table 2.2.1.6.14-1 Subscriber Date of Birth Constraints

Constraint ID	Constraint
C32-[85]	The subscriber date of birth shall be recorded in the **<sdtc:birthTime>** element of the **<playingEntity>** element beneath the **<participantRole>** element. The **<sdtc:birthTime>** element represents an extension to the HL7 CDA Release 2.0.

2.2.1.6.15 Health Plan Constraints

The health plan description is recorded as specified by the Policy Activity Section of the HL7 Continuity of Care Document Implementation Guide.

Figure 2.2.1.6.15-1 Health Plan Example

```
<!-- These examples assume the default namespace is 'urn:hl7-org:v3' -->
    <entryRelationship typeCode='REFR'>
        <act classCode='ACT' moodCode='DEF'>
            <id root='2844AF96-37D5-42a8-9FE3-3995C110B4FA' extension='PlanCode'/>
            <code code='HMO' displayName='health maintenance organization policy'
                codeSystem='2.16.840.1.113883.5.4' codeSystemName='ActCode'/>
            <text>Health Plan Name</text>
        </act>
    </entryRelationship>
```

2.2.1.6.16 Health Plan Name Constraints

Table 2.2.1.6.16-1 Health Plan Name Constraints

Constraint ID	Constraint
C32-[86]	The name of the health plan shall be recorded in the **<text>** element of **<act>** element identifying the plan.
C32-[87]	The plan or group code[4] may be recorded in the **<id>** element of the **<act>** element identifying the plan.

[4] For pharmacy benefits, the group code is the RxGRP value.

2.2.1.7 Allergy / Drug Sensitivity Module

This module contains the allergy or intolerance conditions and the associated adverse reactions suffered by the patient. At a minimum, currently active and any relevant historical allergies and adverse reactions shall be listed. See the HL7 Continuity of Care Document section 3.8 for constraints applicable to this module.

The template identifier for this construct is 2.16.840.1.113883.3.88.11.32.6.

Table 2.2.1.7-1 Allergy / Drug Sensitivity Data Mapping Table - Definitions

Data Element ID	Data Element	Description
Adverse Event Entry		
6.01	Adverse Event Date	This is a date that expresses when this particular allergy or intolerance was known to be active for the patient.
6.02	Adverse Event Type	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.
Product		
6.03	Product Free-Text	This is the name or other description of the product or agent that causes the intolerance.
6.04	Product Coded	This value is a code describing the product.
Reaction		
6.05	Reaction Free-Text	This is the reaction that may be caused by the product or agent.
6.06	Reaction Coded	This value is a code describing the reaction.
Severity		
6.07	Severity Free-Text	This is a description of the level of severity of the allergy or intolerance.
6.08	Severity Coded	This value is a code describing the level severity of the allergy or intolerance.

Table 2.2.1.7-2 Allergy / Drug Sensitivity Data Mapping Table - Requirements

Data Element ID	Data Element	O/R	Data Source	Additional Specification
	Adverse Event Entry	R2/ Y	cda:act[cda:templateId/@root= '2.16.840.1.113883.10.20.1.27']/ cda:entryRelationship[@typeCode='SUBJ']/ cda:observation[cda:templateId/@root= '2.16.840.1.113883.10.20.1.18']	
6.01	Adverse Event Date	R2/ N	cda:effectiveTime	
6.02	Adverse Event Type	R/N	cda:code	2.2.1.7.1

Data Element ID	Data Element	O/R	Data Source	Additional Specification
	Product	R2/ Y	cda:participant[@typeCode='CSM']/ cda:participantRole[@classCode='MANU']/ cda:playingEntity[@classCode='MMAT']/	
6.03	Product Free-Text	R/N	cda:name	
6.04	Product Coded	R2/ N	cda:code	2.2.1.7.2
	Reaction	O/Y	cda:entryRelationship[@typeCode='MFST']/ cda:observation[templateId/@root= '2.16.840.1.113883.10.20.1.54']	
6.05	Reaction Free-Text	R2/ N	cda:text	
6.06	Reaction Coded	R2/ N	cda:value	2.2.1.7.3
	Severity	R2/ N	cda:entryRelationship[@typeCode='SUBJ']/ cda:observation[templateId/@root= '2.16.840.1.113883.10.20.1.55']	
6.07	Severity Free-Text	R2/ N	cda:text	
6.08	Severity Coded	R2/ N	cda:value	2.2.1.7.4

Figure 2.2.1.7-1 Allergies and Drug Sensitivities Example

```
<!-- These examples assume the default namespace is 'urn:hl7-org:v3' -->
<text>
    Penicillin Allergy on February 2, 2001
    <content ID='severity-1'>Severe</content> <content ID='reaction-1'>Hives</content>
</text>
<entry>
    <act classCode='ACT' moodCode='EVN'>
        <templateId root='2.16.840.1.113883.10.20.1.27'/>
        <templateId root='2.16.840.1.113883.3.88.11.32.6'/>
        <id root='2C748172-7CC2-4902-8AF0-23A105C4401B'/>
        <code nullFlavor='NA'/>
        <entryRelationship typeCode='SUBJ'>
        <observation classCode='OBS' moodCode='EVN'>
            <templateId root='2.16.840.1.113883.10.20.1.18'/>
                <code code='416098002' displayName='drug allergy'
                    codeSystem='2.16.840.1.113883.6.96' codeSystemName='SNOMED CT'/>
                <effectiveTime>
                    <low value='20010209'/>
                </effectiveTime>
                <participant typeCode='CSM'>
                    <participantRole classCode='MANU'>
                        <playingEntity classCode='MMAT'>
                            <code code='70618' displayName='Penicillin'
                                codeSystem='2.16.840.1.113883.6.88'
                                 codeSystemName='RxNorm'/>
                            <name>Penicillin</name>
                        </playingEntity>
                    </participantRole>
                </participant>
                <entryRelationship typeCode='MFST' inversionInd='true'>
                    <templateId root='2.16.840.1.113883.10.20.1.54'/>
                    <text><reference value='#reaction-1'/></text>
                <value xsi:type='CD' code='247472004' displayName='Weal'
                                codeSystem='2.16.840.1.113883.6.96'
                                codeSystemName='SNOMED CT' />
                    <entryRelationship  typeCode='SUBJ' inversionInd='true'>
                        <observation classCode='OBS' moodCode='EVN'>
                            <templateId root='2.16.840.1.113883.10.20.1.55'/>
                            <code code='SEV' displayName='Severity'
                                codeSystem='2.16.840.1.113883.5.4'
                                 codeSystemName='ActCode' />
                            <text><reference value='#severity-1'/></text>
                            <statusCode code='completed'/>
                            <value xsi:type='CD' code='24484000' displayName='Severe'
                                codeSystem='2.16.840.1.113883.6.96'
                                codeSystemName='SNOMED CT' />
                    </observation>
                    </entryRelationship>
                </entryRelationship>
        </observation>
        </entryRelationship>
    </act>
</entry>
```


2.2.1.7.1 Adverse Event Vocabulary Constraints

Table 2.2.1.7.1-1 Adverse Event Vocabulary Constraints

Constraint ID	Constraint
C32-[88]	The vocabulary used for adverse event types shall come from the limited set of values of SNOMED CT shown in Table

Constraint ID	Constraint
	2.2.1.6.1-2. The OID for this terminology is 2.16.840.1.113883.6.96

Table 2.2.1.7.1-2 Adverse Event Type Vocabulary

SNOMED CT Preferred Terms for Adverse Event Type	SNOMED CT Code	Usage
propensity to adverse reactions	420134006	Used to record an adverse reaction.
propensity to adverse reactions to substance	418038007	Used to record an adverse reaction to an environmental agent.
propensity to adverse reactions to drug	419511003	Used to record an adverse reaction to a drug.
propensity to adverse reactions to food	418471000	Used to record an adverse reaction to a food.
allergy to substance	419199007	Used to record an allergy to an environmental agent.
drug allergy	416098002	Used to record an allergy to a drug.
food allergy	414285001	Used to record an allergy to a food.
drug intolerance	59037007	Used to record intolerance to a drug.
food intolerance	235719002	Used to record intolerance to a food.

2.2.1.7.2 Product Coded Vocabulary Constraints

Table 2.2.1.7.2-1 Adverse Event Vocabulary Constraints

Constraint ID	Constraint
C32-[89]	The product causing the adverse event shall be coded to UNII for Food and substance allergies, or RxNorm when to medications, or NDF-RT when to classes of medications.

2.2.1.7.3 Reaction Coded Constraints

Table 2.2.1.7.3-1 Reaction Coded Constraints

Constraint ID	Constraint
C32-[90]	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 OID for this vocabulary is 2.16.840.1.113883.6.96. The problem list subset can be obtained from www.cancer.gov/cancertopics/terminologyresources/FDA.

2.2.1.7.4 Severity Coded Constraints

Table 2.2.1.7.4-1 Severity Coded Constraints

Constraint ID	Constraint
C32-[91]	The terminology used for severity of the adverse event shall be recorded using the subset of SNOMED CT shown in Table 2.2.1.6.4-2. These terms descend from the severities (272141005) concept. The OID for this vocabulary is 2.16.840.1.113883.6.96.

Table 2.2.1.7.4-2 SNOMED CT Preferred Terms for Severity

SNOMED CT Preferred Terms for Severity	SNOMED CT Code
mild	255604002
mild to moderate	371923003
moderate	6736007
moderate to severe	371924009
severe	24484000
fatal	399166001

2.2.1.8 Condition Module

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. See the HL7 Continuity of Care Document section 3.5 for constraints applicable to this module.

A Registration and Medication History is normally limited to a brief list of serious major medical conditions that should always be disclosed even in many ancillary service department settings. Because there is a difference between a full problem list and a brief checklist of major conditions, it should be apparent to the provider that this is a brief list.

The template identifier for this construct is 2.16.840.1.113883.3.88.11.32.7.

Table 2.2.1.8-1 Conditions Data Mapping Table - Definitions

Data Element ID	Data Element	Description
Problem Event Entry		
7.01	Problem Date	This is the range of time of which the problem was active for the patient.
7.02	Problem Type	This is a fixed value indicating the level of medical judgment used to determine the existence of a problem.
7.03	Problem Name	This is a text description of the problem suffered.
7.04	Problem Code	This value is a code describing the problem according to a specific vocabulary of problems.
7.05	Treating Provider	The provider or providers treating the patient for this condition.

Table 2.2.1.8-2 Conditions Data Mapping Table - Requirements

Data Element ID	Data Element	O/R	Data Source	Additional Specification
	Problem Entry	R2/ Y	cda:act[cda:templateId/@root= '2.16.840.1.113883.10.20.1.27']/ cda:entryRelationship[@typeCode='SUBJ']/ cda:observation[cda:templateId/@root= '2.16.840.1.113883.10.20.1.28']	
7.01	Problem Date	R2/ N	cda:effectiveTime	2.2.1.8.1
7.02	Problem Type	R2/ N	cda:code	2.2.1.8.2
7.03	Problem Name	R/N	cda:text	2.2.1.8.3
7.04	Problem Code	O/N	cda:value	2.2.1.8.4
7.05	Treating Provider	O/Y	cda:act[cda:templateId/@root= '2.16.840.1.113883.10.20.1.27']/ cda:performer	2.2.1.8.5

2.2.1.8.1 Problem Date Constraints

The problem date includes the onset and resolution dates for the problem. The onset date shall be recorded in the **<low>** element of the **<effectiveTime>** element when known (see example 1 below). The resolution data shall be recorded in the **<high>** element of the **<effectiveTime>** element when known.

If the problem is known to be resolved, but the date of resolution is not known, then the **<high>** element shall be present, and the nullFlavor attribute shall be set to 'UNK'. Therefore, the existence of an **<high>** element within a problem does indicate that the problem has been resolved.

> *NOTE: In the context of the PHR, the date of resolution is the date that the consumer is no longer concerned with the problem. This information may come from a provider, but the consumer should have control over whether they accept that judgment within their PHR.*

Figure 2.2.1.8.1-1 Problem Date Examples

```
<!-- These examples assume the default namespace is 'urn:hl7-org:v3' -->
<!-- example 1 -->
<effectiveTime>
     <low value='20070209'/>
     <high value='20070210'/>
</effectiveTime>
<!-- example 2 -->
<effectiveTime>
     <low value='20070209'/>
     <high nullFlavor='UNK'/>
</effectiveTime>
```

2.2.1.8.2 Problem Type Constraints

Figure 2.2.1.8.2-1 Problem Type Example

```
<!-- These examples assume the default namespace is 'urn:hl7-org:v3' -->
<observation classCode='OBS' moodCode='EVN'>
     <templateId root='2.16.840.1.113883.10.20.1.28'/>
          ...
     <code code='404684003' displayName='Finding'
               codeSystem='2.16.840.1.113883.96' codeSystemName='SNOMED CT'/>
          ...
```

Table 2.2.1.8.2-1 Problem Type Constraints

Constraint ID	Constraint
C32-[92]	The type of problem shall be recorded in the **<code>** element of the **<observation>**.
C32-[93]	The problem type shall be recorded using the subset of SNOMED CT shown in Table 2.2.1.8.2-2. The OID for this vocabulary is 2.16.840.1.113883.6.96.

Table 2.2.1.8.2-2 Problem Type Vocabulary

SNOMED CT Terms for Problem Type	SNOMED CT Code
Finding	404684003
Symptom	418799008
Problem	55607006
Complaint	409586006
Condition	64572001
Diagnosis	282291009
Functional limitation	248536006

2.2.1.8.3 Problem Name Constraints

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.

Figure 2.2.1.8.3-1 Problem Name Example

```
<!-- These examples assume the default namespace is 'urn:hl7-org:v3' -->
<text><p ID='problem-1'>migraine</p><text>
<entry>
    <act classCode='ACT' moodCode='EVN'>
        <templateId root='2.16.840.1.113883.10.20.1.27'/>
        <templateId root='2.16.840.1.113883.3.88.11.32.7'/>
        <id root='…'/>
        <code nullFlavor='NA'/>
        <entryRelationship typeCode='SUBJ'>
            <observation classCode='OBS' moodCode='EVN'>
                <templateId root='2.16.840.1.113883.10.20.1.28'/>
                    …
                <text><reference value='#problem-1'/></text>
            </observation>
        </entryRelationship>
    </act>
</entry>
```

2.2.1.8.4 Problem Code Constraints

Figure 2.2.1.8.4-1 Problem Code Example

```
<!-- These examples assume the default namespace is 'urn:hl7-org:v3' -->
<observation classCode='OBS' moodCode='EVN'>
    <templateId root='2.16.840.1.113883.10.20.1.28'/>
        …
    <value xsi:type='CD' code='37796009' displayName='Migraine'
        codeSystem='2.16.840.1.113883.96' codeSystemName='SNOMED CT'/>
</observation>
```

Table 2.2.1.8.4-1 Problem Code Constraints

Constraint ID	Constraint
C32-[94]	The problem 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 OID for this vocabulary is 2.16.840.1.113883.6.96. The problem list subset can be obtained from www.cancer.gov/cancertopics/terminologyresources/FDA.
C32-[95]	The problem shall be recorded in the **<value>** element using the CD data type.

NOTE: SNOMED CT provides crosswalks to ICD-9-CM covering more than 18,000 SNOMED CT concepts to over 10,000 ICD-9-CM codes. In addition, a large number of ICD-9-CM concepts are already incorporated into SNOMED CT.

2.2.1.8.5 Treating Provider Constraints

Figure 2.2.1.8.5-1 Treating Provider Example

```
<!-- These examples assume the default namespace is 'urn:hl7-org:v3' -->
<text><p ID='problem-1'>Migraine</p><text>
<entry>
    <act classCode='ACT' moodCode='EVN'>
        <templateId root='2.16.840.1.113883.10.20.1.27'/>
        <id root='...'/>
        <code nullFlavor='NA'/>
        <performer typeCode='PRF'>
            <time><low value='...'/><high value='...'/></time>
            <assignedEntity>
                <id root='...' extension='...'/>
            </assignedEntity>
        </performer>
            ...
    </act>
</entry>
```

Table 2.2.1.8.5-1 Treating Provider Constraints

Constraint ID	Constraint
C32-[96]	The time over which this provider treated the condition may be recorded in the **<time>** element beneath the **<performer>** element.
C32-[97]	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 providers module described in section 2.2.1.5.
C32-[98]	The treating provider or providers shall be recorded in a **<performer>** element under the **<act>** that describes the condition of concern.

2.2.1.9 Medication – Prescription and Non-Prescription Module

This module defines a patient's current medications and pertinent medication history. At a minimum, the currently active medications should be listed. See the HL7 Continuity of Care Document section 3.9 for constraints applicable to this module.

The template identifier for this construct is 2.16.840.1.113883.3.88.11.32.8.

Table 2.2.1.9-1 Medication – Prescription and Non-Prescription Data Mapping Table - Definitions

Data Element ID	Data Element	Description
Administration Information Event Entry		
8.01	Free Text Sig	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.
8.02	Indicate Medication Stopped	A Sig Component: Used to express a "hard stop", such as the last Sig 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.
8.03	Administration Timing	A Sig Component: defines a specific administration or use time. Can be a text string (Morning, Evening, Before Meals, 1 Hour After Meals, 3 Hours After Meals, Before Bed) or an exact time.

Data Element ID	Data Element	Description
8.04	Frequency	A Sig Component: 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).
8.05	Interval	A Sig Component: 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).
8.06	Duration	A Sig Component: for non-instantaneous administrations, indicates the length of time the administration should be continued. For example, (infuse) over 30 minutes.
8.07	Route	A Sig Component: indicates how the medication is received by the patient (e.g., by mouth, intravenously, topically, et cetera).
8.08	Dose	A Sig Component: 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 (see Dose Indicator).
8.09	Site	A Sig Component: The anatomic site where the medication is administered. Usually applicable to injected or topical products.
8.10	Dose Restriction	A Sig Component: defines a maximum or dose limit. This segment can repeat for more than one dose restriction.
8.11	Product Form	The physical form of the product as presented to the patient. For example: tablet, capsule, liquid, or ointment.
8.12	Delivery Method	A Sig Component: A description of how the product is administered/consumed.
	Medication Information	
8.13	Coded Product Name	A code describing the product from a controlled vocabulary.
8.14	Coded Brand Name	A code describing the product as a branded or trademarked entity from a controlled vocabulary.
8.15	Free Text Product Name	The name of the substance or product without reference to a specific vendor (e.g., generic or other non-proprietary name). If a Coded Product Name is present, this is the text associated with the coded concept. This should be sufficient for a provider to identify a medication, and may include additional information such as strength, dose form, etc. If the name of the product is unknown, the type, purpose or other description may be supplied.
8.16	Free Text Brand Name	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.
8.17	Drug Manufacturer	The manufacturer of the substance or product as ordered or supplied. The distributor may be supplied if the manufacturer is not known.
8.18	Product Concentration	The amount of active ingredient, or substance of interest, in a specified product dosage unit, mass or volume. For example 250 mg per 5 ml. Note: “product dosage unit” provides for describing the “concentration” of a physical form. For example, 800 mg per 1 tablet. In this manner, this data element may also be known as Product Strength.

Data Element ID	Data Element	Description
		This may be implicit in the product as named or as a codified product.
8.19	Type of Medication	A classification based on how the medication is marketed (e.g., prescription, over the counter drug).
8.20	Status of Medication	If the medication is Active, Discharged, Chronic, Acute, etc.
8.21	Indication	A Sig Component: The medical condition or problem intended to be addressed by the ordered product. For example: for chest pain, for pain, for high blood pressure.
8.22	Patient Instructions	Instructions to the patient that are not traditionally part of the Sig. For example, “keep in the refrigerator”. More extensive patient education materials can also be included.
8.23	Reaction	Any noted intended or unintended effects of the product. For example: full body rash, nausea, rash resolved.
8.24	Vehicle	A Sig Component: 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”.
8.25	Dose Indicator	A Sig Component: A criteria that specifies when an action is, or is not, to be taken. For example, “if blood sugar is above 250 mg/dl”.
		Order Information
8.26	Order Number	The order identifier from the perspective of the ordering clinician. Also know as the 'placer number' versus the pharmacies prescription number (or 'filler number').
8.27	Fills	The number of times that the ordering provider has authorized the pharmacy to dispense this medication.
8.28	Quantity Ordered	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.
8.29	Order Expiration Date/Time	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.
8.30	Order Date/Time	The date, including time if available, when the ordering provider wrote the order/prescription.
8.31	Ordering Provider	The person that wrote this order/prescription (may include both a name and an identifier).
8.32	Fulfillment Instructions	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”.
8.33	Fulfillment History	History of dispenses for this order. Comprised of Fulfillment History Components.
8.34	Prescription Number	Fulfillment History Component: The prescription identifier assigned by the pharmacy.
8.35	Provider	Fulfillment History Component: The pharmacy that performed this dispense (may include both a name and an identifier).
8.36	Location	Fulfillment History Component: The pharmacy's location.
8.37	Dispense Date	Fulfillment History Component: The date of this dispense.
8.38	Quantity Dispensed	Fulfillment History Component: The actual quantity of product supplied in this dispense. Note: this is comprised of both a numeric value and a unit of measure.
8.39	Fill number	Fulfillment History Component: The fill number for the history entry. Identifies this

Data Element ID	Data Element	Description
		dispense as a distinct event of the prescription.
8.40	Fill Status	Fulfillment History Component. 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”).

Table 2.2.1.9-2 Medication – Prescription and Non-Prescription Data Mapping Table - Requirements

Data Element ID	Data Element	O/R	Data Source	Additional Specification
	Administration Information Event Entry	R2/Y	cda:substanceAdministration[templateId/@root = '2.16.840.1.113883.10.20.1.24']	
8.01	Free Text Sig	O/N	cda:text	2.2.1.9.1
8.02	Indicate Medication Stopped	O/N	cda:effectiveTime[1]/cda:high	2.2.1.9.2
8.03	Administration Timing	O/Y	cda:effectiveTime[2]	2.2.1.9.3
8.04	Frequency	O/Y	cda:effectiveTime[2]	2.2.1.9.3
8.05	Interval	O/Y	cda:effectiveTime[2]	2.2.1.9.3
8.06	Duration	O/Y	cda:effectiveTime[2]	2.2.1.9.3
8.07	Route	O/Y	cda:routeCode	2.2.1.9.4
8.08	Dose	O/Y	cda:doseQuantity	2.2.1.9.5
8.09	Site	O/Y	cda:approachSiteCode	2.2.1.9.6
8.10	Dose Restriction	O/Y	cda:maxDoseQuantity	
8.11	Product Form	O/N	cda:administrationUnitCode	2.2.1.9.7
8.12	Delivery Method	O/Y	cda:code	2.2.1.9.8
	Medication Information	R/Y	cda:consumable/cda:manufacturedProduct	2.2.1.9.9
8.13	Coded Product Name	R2/Y	cda:manufacturedMaterial/cda:code	
8.14	Coded Brand Name	R2/Y	cda:translation	
8.15	Free Text Product Name	R/N	cda:orginalText	
8.16	Free Text Brand Name	R2/N	cda:manufacturedMaterial/cda:name	
8.17	Drug Manufacturer	O/N	cda:manufacturerOrganization	
8.18	Product Concentration	R2/N		
8.19	Type of Medication	R2/N	cda:entryRelationship[@typeCode='SUBJ']/ cda:observation[cda:templateId/@root= '2.16.840.1.113883.3.88.11.32.10']/ cda:value/@code	2.2.1.9.11
8.20	Status of Medication	R2/N	cda:entryRelationship[@typeCode='REFR']/ cda:observation[cda:templateId/@root= '2.16.840.1.113883.10.20.1.47']/ cda:value/@code	2.2.1.9.12
8.21	Indication	O/Y	cda:entryRelationship[@typeCode='RSON']/ cda:observation[cda:templateId/@root=	2.2.1.9.13

Data Element ID	Data Element	O/R	Data Source	Additional Specification
			'2.16.840.1.113883.10.20.1.28']	
8.22	Patient Instructions	O/N	cda:entryRelationship/cda:act[cda:templateId/@root= '2.16.840.1.113883.10.20.1.49']/ cda:text	2.2.1.9.14
8.23	Reaction	O/N	cda:entryRelationship[@typeCode='CAUS']/ cda:observation[cda:templateId/@root= '2.16.840.1.113883.10.20.1.54']	
8.24	Vehicle	O/Y	cda:participant/cda:participantRole[cda:code/@code = '412307009' and cda:code/@codeSystem= '2.16.840.1.113883.6.96']	2.2.1.9.15
8.25	Dose Indicator	O/Y	cda:precondition/cda:criteria	
	Order Information	R2/Y	cda:entryRelationship[@typeCode='REFR']/ cda:supply[moodCode='INT']	2.2.1.9.16
8.26	Order Number	R2/N	cda:id	
8.27	Fills	O/N	cda:repeatNumber	2.2.1.9.17
8.28	Quantity Ordered	R2/N	cda:quantity	2.2.1.9.18
8.29	Order Expiration Date/Time	R2/N	cda:effectivetime/cda:high	
8.30	Order Date/Time	O/N	cda:author/cda:time	
8.31	Ordering Provider	O/N	cda:author/cda:assignedEntity/ cda:assignedPerson/cda:name	
8.32	Fulfillment Instructions	O/N	cda:entryRelationship/ cda:act[cda:templateId/@root= '2.16.840.1.113883.10.20.1.43']/ cda:text	2.2.1.9.19
8.33	Fulfillment History	O/Y	cda:supply[@moodCode='EVN']	
8.34	Prescription Number	R2/N	cda:id	2.2.1.9.20
8.35	Provider	O/N	cda:performer/cda:assignedEntity	2.2.1.9.21
8.36	Location	O/N	cda:performer/cda:assignedEntity/ cda:addr	
8.37	Dispense Date	O/N	cda:effectiveTime	
8.38	Quantity Dispensed	R2/N	cda:quantity	2.2.1.9.22
8.39	Fill number	R2/N	cda:entryRelationship[@typeCode='COMP']/ cda:sequenceNum	2.2.1.9.23
8.40	Fill Status	O/N	cda:statusCode	2.2.1.9.24

2.2.1.9.1 Free Text Sig Constraints

Figure 2.2.1.9.1-1 Free Text Sig Example

```
<!-- These examples assume the default namespace is 'urn:hl7-org:v3' -->
<section>
        …
    <text>
            …
        <content ID='sig-1'> Acetaminophen 325 mg tablet tid po prn</content>
            …
    </text>
        …
    <entry>
        <substanceAdministration classCode='SBADM' moodCode='INT'>
            <templateId root='2.16.840.1.113883.10.20.1.24'/>
            <templateId root='2.16.840.1.113883.3.88.11.32.8'/>
                …
            <text><reference value='#sig-1'/></text>
                …
        </substanceAdministration>
    </entry>
</section>
```

Table 2.2.1.9.1-1 Free Text Sig Constraints

Constraint ID	Constraint
C32-[99]	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.

2.2.1.9.2 Indicate Medication Stopped Constraints

The time at which the medication was stopped is determined based on the first **`<effectiveTime>`** element.

Table 2.2.1.9.2-1 Indicate Medication Stopped Constraints

Constraint ID	Constraint
C32-[100]	The stop date of the medication shall be recorded in the **<high>** element of the first **<effectiveTime>** element in the **<substanceAdministration>** element.

2.2.1.9.3 Administrative Timing Constraints

The HL7 data type for PIVL_TS uses the institutionSpecified attribute to indicate whether it is the interval (time between dosing), or frequency (number of doses in a time period) that is important. If instititutionSpecified is not present, or is set to false, then the time between dosing is important (every 8 hours). If true, then the frequency of administration is important (e.g., 3 times per day).

Figure 2.2.1.9.3-1 Administration Timing Examples

```
<!-- These examples assume the default namespace is 'urn:hl7-org:v3' -->
<!-- twice a day for 10 days from 2/1/07 to 2/10/07 -->
<effectiveTime xsi:type='IVL_TS'>
     <low value='20070201'/>
     <high value='20070210'/>
</effeciveTime>
<effectiveTime xsi:type='PIVL_TS' institutionSpecified='true'  operator='A'>
     <period value='12' unit='h' />
</effectiveTime>

<!-- every 12 hours for 10 days from 2/1/07 to 2/10/07 -->
<effectiveTime xsi:type='IVL_TS'>
     <low value='20070201'/>
     <high value='20070210'/>
</effeciveTime>
<effectiveTime xsi:type='PIVL_TS' institutionSpecified='false' operator='A'>
     <period value='12' unit='h' />
</effectiveTime>

<!-- Once, on 2005-09-01 at 1:18am. -->
<effectiveTime xsi:type='TS' value='200509010118'/>

<!-- Three times a day, for 10 days from 2/1/07 to 2/10/07 -->
<effectiveTime xsi:type='IVL_TS'>
     <low value='20070201'/>
     <high value='20070210'/>
</effeciveTime>
<effectiveTime xsi:type='PIVL_TS' institutionSpecified='true' operator='A'>
     <period value='8' unit='h' />
</effectiveTime>

<!-- every 8 hours for 10 days from 2/1/07 to 2/10/07 -->
<effectiveTime xsi:type='IVL_TS'>
     <low value='20070201'/>
     <high value='20070210'/>
</effeciveTime>
<effectiveTime xsi:type='PIVL_TS' institutionSpecified='false' operator='A'>
     <period value='8' unit='h' />
</effectiveTime>

<!-- in the morning for 10 days from 2/1/07 to 2/10/07 -->
<effectiveTime xsi:type='IVL_TS'>
     <low value='20070201'/>
     <high value='20070210'/>
</effeciveTime>
<effectiveTime xsi:type='EIVL' operator='A'>
     <event code='ACM'/>
</effectiveTime>

<!-- Every day at 8 in the morning for 10 minutes for 10 days from 2/1/07 to 2/10/07 -->
<effectiveTime xsi:type='IVL_TS'>
     <low value='20070201'/>
     <high value='20070210'/>
</effeciveTime>
<effectiveTime xsi:type='PIVL_TS' operator='A'>
     <phase>
          <low  value="198701010800" inclusive="true"/>
          <width value="10" unit="min"/>
     </phase>
     <period value='1' unit='d'/>
</effectiveTime>
```

Table 2.2.1.9.3-1 Administrative Timing Constraints

Constraint ID	Constraint
C32-[101]	The timing of the medication administration shall be recorded in one or two **<effectiveTime>** elements beneath the **<substanceAdministration>** element.
C32-[102]	The first **<effectiveTime>** element shall record the range of time over which the medication is to be administered, i.e., the start and stop dates for administration of the medication, or for a single administration, the time of that administration.
C32-[103]	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.
C32-[104]	The second **<effectiveTime>** element shall record the details about frequency, interval and duration when more than one administration is to occur.
C32-[105]	The second **<effectiveTime>** element shall include the **operator** attribute, set to the value "A".
C32-[106]	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".
C32-[107]	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".
C32-[108]	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.

2.2.1.9.4 Route of Administration Constraints

Figure 2.2.1.9.4-1 Route of Administration Example

```
        ...
<routeCode code='C38288' displayName='ORAL'
        codeSystem='2.16.840.1.113883.3.26.1.1' codeSystemName='NCI Thesaurus'/>
        ...
```

Table 2.2.1.9.4-1 Route of Administration Constraints

Constraint ID	Constraint
C32-[109]	Shall have a value drawn from FDA route of administration. The OID for this vocabulary is 2.16.840.1.113883.3.26.1.1. See www.fda.gov/oc/datacouncil/splncicodes.html - route.

2.2.1.9.5 Dose Constraints

The units of presentation can be found www.fda.gov/oc/datacouncil/splncicodes.html#potency, and include only those terms which have not been mapped to Unified Code for Units of Measure (UCUM). Terms with mappings to UCUM are units of administration.

Figure 2.2.1.9.5-1 Dose Examples

```
<!-- These examples assume the default namespace is 'urn:hl7-org:v3' -->
<!-- example 1, dose is in units of tablets -->
<code code='' displayName='Acetaminophen 325 mg tablet'
    codeSystem='2.16.840.1.113883.6.88' codeSystemName='RxNorm'/>
    ...
<doseQuantity value='1' unit='{TABLET}'/>

<!-- example 2, dose is in measurable units -->
<code code='' displayName='Tylenol'
    codeSystem='2.16.840.1.113883.6.88' codeSystemName='RxNorm'/>
    ...
<doseQuantity value='325' unit='mg'/>
```

Table 2.2.1.9.5-1 Dose Constraints

Constraint ID	Constraint
C32-[110]	Dose shall be recorded in a **<doseQuantity>** element beneath the substance administration element, and have a **value** attribute.
C32-[111]	The **unit** attribute may be present when needed. If present it shall be coded using Unified Code for Units of Measure (UCUM).
C32-[112]	When the coded product or brand name describes the strength or concentration of the medication, and the dosing is in administration units (e.g., 1 tablet, 2 capsules), the **unit** attribute should contain the preferred name of the presentation units within braces { } using the units of presentation from the NCI Thesaurus.

2.2.1.9.6 Site Constraints

Table 2.2.1.9.6-1 Site Constraints

Constraint ID	Constraint
C32-[113]	The site of the medication administration shall be recorded in the **<administrationSiteCode>** element.
C32-[114]	The **code** attribute shall contain a value descending from the SNOMED CT Anatomical Structure (91723000) hierarchy.

2.2.1.9.7 Product Form Constraints

Figure 2.2.1.9.7-1 Product Form Example

```
    ...
<administrationUnitCode code="C42998" displayName="TABLET"
    codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" />
    ...
```

Table 2.2.1.9.7-1 Product Form Constraints

Constraint ID	Constraint
C32-[115]	Shall have a value drawn from dosage form - FDA dosage form – source NCI Thesaurus. The OID for this vocabulary is 2.16.840.1.113883.3.26.1.1 See www.fda.gov/oc/datacouncil/splncicodes.html - dosage.

2.2.1.9.8 Delivery Method Constraints

Figure 2.2.1.9.8-1 Delivery Method

```
<cda:code  code='…' displayName='…' codeSystem='…' codeSystemName='…' >
    <cda:originalText>Intraveinous Injection</cda:orginalText>
</cda:code>
```

NOTE: The HITSP Consumer Empowerment Technical Committee 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.

Table 2.2.1.9.8-1 Delivery Method Constraints

Constraint ID	Constraint
C32-[116]	The Delivery Method may be recorded in the **<cda:code>** element.
C32-[117]	The free text description of the delivery method may be included within a **<cda:orginalText>** element beneath the **<cda:code>** element.

2.2.1.9.9 Medication Information Constraints

The name and code for the medication are recorded in the **<consumable>** element, as shown below. The template identifier for this construct is 2.16.840.1.113883.3.88.11.32.9.

Figure 2.2.1.9.9-1 Medication Information Example

```
<!-- These examples assume the default namespace is 'urn:hl7-org:v3' -->
<substanceAdministration classCode='SBADM' moodCode='INT'>
        …
    <consumable>
        <manufacturedProduct classCode='MANU'>
            <templateId root='2.16.840.1.113883.10.20.1.53'/>
            <templateId root='2.16.840.1.113883.3.88.11.32.9'/>
            <manufacturedMaterial classCode='MMAT' determinerCode='KIND'>
                <code code='161' displayName='Acetaminophen'
                    codeSystem='2.16.840.1.113883.6.88' codeSystemName='RxNorm'>
                    <originalText>Acetaminophen</originalText>
                    <translation code='202433' displayName='Tylenol'
                        codeSystem='2.16.840.1.113883.6.88' codeSystemName='RxNorm'/>
                </code>
                <name>Tylenol</name>
            </manufacturedMaterial>
        </manufacturedProduct>
    </consumable>
        …
</substanceAdministration>
```

Table 2.2.1.9.9-1 Medication Information Constraints

Constraint ID	Constraint
C32-[118]	When a C32 Medication Information data element (2.16.840.1.113883.3.88.11.32.9) appears in a CCD Medications section (2.16.840.1.113883.10.20.1.8), then the product name or brand name shall be coded using RxNorm, or NDC. The code shall appear in the **code** attribute of the **<code>** or **<translation>** element.

Constraint ID	Constraint
C32-[119]	When only the class of the drug is known (e.g., Beta Blocker or Sulfa Drug), it shall be coded using NDF-RT.
C32-[120]	FDA Unique Ingredient Identifier codes (UNII) codes may be used when there are no suitable codes in the other vocabularies to identify the medication.
C32-[121]	The code for the product (generic) name shall appear in **code** attribute of the **<code>** element. If the code for the generic product is unknown, the **code** and **codeSystem** attributes may be omitted.
C32-[122]	The product (generic) name shall appear in the **<originalText>** element beneath the **<code>** element.
C32-[123]	The code for the specific brand of product shall appear in a **<translation>** element.
C32-[124]	The brand name shall appear in the **<name>** element of the **<manufacturedMaterial>**.

Table 2.2.1.9.9-2 Product / Brand Name Vocabulary

Vocabulary	OID	Used for	Example
RxNorm	2.16.840.1.113883.6.88	Brand Names	Tylenol
		Clinical Drugs	Acetaminophen 325 mg tablet
NDC	2.16.840.1.113883.6.69	Packaged Product	Tylenol 325 mg tablet bottle of 100
FDA Unique Ingredient Identifier (UNIII)	2.16.840.1.113883.4.9	Ingredient Name	Gentian violet
NDF-RT	2.16.840.1.113883.4.209	Drug Class	Cephalosporins

2.2.1.9.10 Product Concentration Constraints

The product concentration is determined from the coded product or brand name using knowledge base information in the vocabularies specified for these fields, and therefore this information is not explicitly included in the registration/medication summary.

2.2.1.9.11 Type of Medication Constraints

The template identifier for the type of medication construct is 2.16.840.1.113883.3.88.11.32.10.

Figure 2.2.1.9.11-1 Type of Medication

```
<!-- These examples assume the default namespace is 'urn:hl7-org:v3' -->
<substanceAdministration classCode='SBADM' moodCode='INT'>
        ...
    <entryRelationship typeCode='SUBJ'>
        <observation classCode='OBS' moodCode='EVN'>
            <templateId root='2.16.840.1.113883.3.88.1.11.32.10'/>
            <code code='73639000' displayName='Prescription Drug'
                codeSystem='2.16.840.1.113883.6.96' codeSystemName='SNOMED CT'/>
            <statusCode code='completed'/>
        </observation>
    </entryRelationship>
        ...
</substanceAdministration>
```

Table 2.2.1.9.11-1 Type of Medication Constraints

Constraint ID	Constraint
C32-[125]	Each **<supply>** or **<substanceAdministration>** act may reference an **<observation>** element that describes the type of

Constraint ID	Constraint
	medication, by including an **<entryRelationship typeCode=SUBJ/>** element.
C32-[126]	The type of a medication shall be represented with an **<observation>** element in the **<entryRelationship>**.
C32-[127]	The **<observation>** element shall have a **<templateId>** with a **root** attribute set to 2.16.840.1.113883.3.88.11.32.10
C32-[128]	The **<observation>** shall have a **<code>** element that represents the kind of medication actually or intended to be administered or supplied.
C32-[129]	The **code** attribute shall contain a code derived from a limited set of values SNOMED CT. The OID for this terminology is 2.16.840.1.113883.6.96.

Table 2.2.1.9.11-2 Type of Medication Vocabulary

SNOMED CT Preferred Terms for Type of Medication Vocabulary	SNOMED CT Code
Over the counter products	329505003
Prescription Drug	73639000

2.2.1.9.12 Status of Medication Constraints

See sections 3.9.2.3 and 5.1 of the HL7 Continuity of Care Document Implementation Guide for additional requirements for this data element.

Figure 2.2.1.9.12-1 Status of Medication Example

```
<!-- These examples assume the default namespace is 'urn:hl7-org:v3' -->
<substanceAdministration classCode='SBADM' moodCode='INT'>
        ...
    <entryRelationship typeCode='REFR'>
        <observation classCode='OBS' moodCode='EVN'>
            <code code='33999-4' displayName='Status'
                codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
            <statusCode code='completed'/>
            <value xsi:type='CE' code='55561003' displayName='Active'
                codeSystem='2.16.840.1.113883.6.96' codeSystemName='SNOMED CT'/>
        </observation>
    </entryRelationship>
        ...
</substanceAdministration>
```

Table 2.2.1.9.12-1 Status of Medication Constraints

Constraint ID	Constraint
C32-[130]	The medication status may be recorded using the CCD Medication Status observation. CCD defines the vocabulary.

2.2.1.9.13 Indication Constraints

Figure 2.2.1.9.13-1 Indication Example

```
<!-- These examples assume the default namespace is 'urn:hl7-org:v3' -->
<substanceAdministration classCode='SBADM' moodCode='INT'>
        …
    <entryRelationship typeCode="RSON">
        <observation classCode="OBS" moodCode="EVN">
            <templateId root="2.16.840.1.113883.10.20.1.28"/>
            <code code='' displayName=''
                codeSystem='2.16.840.1.113883.6.96' codeSystemName='SNOMED CT'/>
            <text><reference value="#indication-1"/></text>
            <statusCode code="completed"/>
            <effectiveTime value="…"/>
        </observation>
    </entryRelationship>
        …
</substanceAdministration>
```

Table 2.2.1.9.13-1 Indication Constraints

Constraint ID	Constraint
C32-[131]	The indication shall be recorded using the Indication **<observation>** described in section 3.9.2.2.1 of the HL7 Continuity of Care Document Implementation Guide.
C32-[132]	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.
C32-[133]	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 OID for this vocabulary is 2.16.840.1.113883.6.96. The problem list subset can be obtained at www.cancer.gov/cancertopics/terminologyresources/FDA.

2.2.1.9.14 Patient Instructions Constraints

External patient educational materials can be referenced with an appropriate URL entry in the **`text / reference / value`**.

Figure 2.2.1.9.14-1 Patient Instructions Example

```
<!-- These examples assume the default namespace is 'urn:hl7-org:v3' -->

<!-- an example of a patient instruction embedded in the document -->
<text>
        …
    <content ID='patient-instruction'>Take with food</content>
        …
</text>
<entry>
    <substanceAdministration>
            …
        <entryRelationship typeCode='SUBJ' inversionInd='true'>
            <act classCode='ACT' moodCode='INT'>
                <templateId root='2.16.840.1.113883.10.20.1.49'/>
                <text><reference value='#patient-instruction'/></text>
            </act>
        </entryRelationship>
    </substanceAdministration>
</entry>
    …

<!-- an example of a reference to an external document-->
<text>
    <reference value='http://www.fda.gov/cder/drug/infopage/COX2/NSAIDmedguide.pdf' />
</text>
```

Table 2.2.1.9.14-1 Patient Instructions Constraints

Constraint ID	Constraint
C32-[134]	Patient instructions shall be recorded as described in section 3.9.2.2.2 of the HL7 Continuity of Care Document.
C32-[135]	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.

2.2.1.9.15 Vehicle Constraints

Figure 2.2.1.9.15-1 Vehicle Example

```
<!-- These examples assume the default namespace is 'urn:hl7-org:v3' -->
<substanceAdministration classCode='SBADM' moodCode='…'>
        …
    <participant typeCode='CSM'>
        <participantRole classCode='MANU'>
            <code code='412307009' displayName='drug vehicle'
                codeSystem='2.16.840.1.113883.6.96' codeSystemName='SNOMED CT'/>
            <playingEntity classCode='MMAT'>
                <code …/>
                <name>…</name>
            </playingEntity>
        </participantRole>
    </participant>
</substanceAdministration>
```

Table 2.2.1.9.15-1 Vehicle Constraints

Constraint ID	Constraint
C32-[136]	The vehicle for administering a medication may be recorded in a **<participantRole>** element inside a **<participant>** element in the **<substanceAdministration>** element.
C32-[137]	The typeCode attribute of the **<participant>** element shall be CSM.
C32-[138]	The classCode of the **<participantRole>** shall be MANU.
C32-[139]	A **<code>** element for the **<participant>** shall be present, using the code 412307009 from SNOMED CT. The OID for SNOMED CT is 2.16.840.1.113883.6.96.
C32-[140]	The **<name>** element in the **<playingEntity>** element shall record the name of the drug vehicle.
C32-[141]	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 section above.

2.2.1.9.16 Order Information Constraints

Order information may be recorded as part of the fulfillment history, or as part of the administration information. The template identifier for this construct is 2.16.840.1.113883.3.88.1.11.32.11.

Figure 2.2.1.9.16-1 Order Information Examples

```
<!-- These examples assume the default namespace is 'urn:hl7-org:v3' -->
<!-- example 1, recording order information with substance administration event or intent -->
<substanceAdministration classCode='SBADM' moodCode='…'>
        …
    <entryRelationship typeCode='REFR'>
        <supply classCode='SPLY' moodCode='INT'>
            <templateId root='2.16.840.1.113883.3.88.1.11.32.11'/>
            <id root='14ED7742-2428-4e2c-9446-A9B0D0075272' extension='SCRIP#'/>
            <repeatNumber value='1'/>
            <quantity value='30'/>
            <author>
                <time value='20070210'/>
                <assignedAuthor>
                    <id …/>
                    <assignedPerson>
                        <name>…</name>
                    </assignedPerson>
                </assignedAuthor>
            </author>
        </supply>
    </entryRelationship>
</substanceAdministration>

<!-- example 2, recording order information with supply event -->
<supply classCode='SPLY' moodCode='EVN'>
        …
    <entryRelationship typeCode='REFR'>
        <supply classCode='SPLY' moodCode='INT'>
            <templateId root='2.16.840.1.113883.3.88.1.11.32.11'/>
            <id root='14ED7742-2428-4e2c-9446-A9B0D0075272' extension='SCRIP#'/>
            <repeatNumber value='3'/>
            <quantity value='30'/>
            <author>
                <time value='20070210'/>
                <assignedAuthor>
                    <id …/>
                    <assignedPerson><name>…</name></assignedPerson>
                </assignedAuthor>
            </author>
        </supply>
    </entryRelationship>
</supply>
```

Table 2.2.1.9.16-1 Order Information Constraints

Constraint ID	Constraint
C32-[142]	The order number, i.e., the identifier from the perspective of the ordering provider, should be recorded in the **<id>** element within the **<supply>** element used to record order information.

2.2.1.9.17 Fills Constraints

Figure 2.2.1.9.17-1 Fills Example

```
<!-- These examples assume the default namespace is 'urn:hl7-org:v3' -->
<!-- Example 1, 1 fill, no refills -->
<repeatNumber value='1'/>

<!-- Example 2, 3 fills = 1 initial fill + 2 refills -->
<repeatNumber value='3'/>

<!—Example 3, unbounded number of fills -->
<repeatNumber nullFlavor='PINF'/>
```

NOTE: 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.

Table 2.2.1.9.17-1 Fills Constraints

Constraint ID	Constraint
C32-[143]	The number of fills may be recorded in the **<repeatNumber>** element within the **<supply>** element used to record order information.

2.2.1.9.18 Quantity Ordered Constraints

The units of presentation can be found www.fda.gov/oc/datacouncil/splncicodes.html#potency, 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

Figure 2.2.1.9.18-1 Quantity Ordered Examples

```
<!-- These examples assume the default namespace is 'urn:hl7-org:v3' -->
<!-- Example 1, 100 tablets -->
<quantity value='100' unit='{TABLET}'/>

<!-- Example 2, 0.5 liters -->
<quantity value='0.5' unit='l'/>
```

Table 2.2.1.9.18-1 Quantity Ordered Constraints

Constraint ID	Constraint
C32-[144]	The quantity ordered shall be recorded in the **value** attribute of **<quantity>** element inside a **<supply>** element used to record order information.
C32-[145]	The **unit** attribute shall be present.
C32-[146]	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.
C32-[147]	Otherwise, the **unit** attribute should contain the preferred name of the presentation units within braces { } using the units of presentation from the NCI Thesaurus.

2.2.1.9.19 Fulfillment Instructions Constraints

Figure 2.2.1.9.19-1 Fulfillment Instructions Example

```
<!-- These examples assume the default namespace is 'urn:hl7-org:v3' -->

<!—This examples illustrates a specific preparation request -->
<text>
        …
    <content ID='fulfillment-instruction1'>Prepare with distilled water.</content>
        …
</text>
<entry>
    <substanceAdministration moodCode='INT'>
            …
        <entryRelationship typeCode='SUBJ' inversionInd='true'>
            <act classCode='ACT' moodCode='INT'>
                <templateId root='2.16.840.1.113883.10.20.1.43'/>
                <text><reference '#fulfillment-instruction1'/></text>
            </act>
        </entryRelationship>
    </substanceAdministration>
</entry>
    …

<!—This examples illustrates when the prescriber requires/required the medication to be
available by a specific time -->
<text>
        …
    <content ID='fulfillment-instruction2'> must be available by Friday noon.</content>
        …
</text>
<entry>
    <substanceAdministration moodCode='INT'>
            …
        <entryRelationship typeCode='SUBJ' inversionInd='true'>
            <act classCode='ACT' moodCode='INT'>
                <templateId root='2.16.840.1.113883.10.20.1.43'/>
                <text><reference '#fulfillment-instruction2'/></text>
            </act>
        </entryRelationship>
    </substanceAdministration>
</entry>
```

Table 2.2.1.9.19-1 Fulfillment Instructions Constraints

Constraint ID	Constraint
C32-[148]	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.

2.2.1.9.20 Prescription Number Constraints

Figure 2.2.1.9.20-1 Prescription Number Example

```
<supply moodCode='EVN'>
    <id root='14ED7742-2428-4e2c-9446-A9B0D0075272' extension='SCRIP#'/>
        …
</supply>
```

Table 2.2.1.9.20-1 Prescription Number Constraints

Constraint ID	Constraint
C32-[149]	The prescription number shall be recorded in the **extension** attribute of the **<id>** element within a **<supply>** element having a moodCode attribute of EVN.
C32-[150]	The **root** attribute of the **<id>** element should be the OID of the assigning authority for the identifier; however, determining the assigning authority is not feasible in all settings.
C32-[151]	A GUID may be used in place of the OID of the assigning authority.

2.2.1.9.21 Provider Constraints

Table 2.2.1.9.21-1 Provider Constraints

Constraint ID	Constraint
C32-[152]	The provider shall be recorded in the **<assignedEntity>** element.
C32-[153]	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.
C32-[154]	The name of the person shall appear in the **<name>** element of the **<assignedPerson>** element beneath the **<assignedEntity>** element.
C32-[155]	The name of the organization shall appear in the **<name>** element of the **<representedOrganization>** element beneath the **<assignedEntity>** element.

2.2.1.9.22 Quantity Dispensed Constraints

Table 2.2.1.9.22-1 Quantity Dispensed Constraints

Constraint ID	Constraint
C32-[156]	The quantity dispensed shall be recorded in the **value** attribute of **<quantity>** element inside a **<supply>** element with a **moodCode** attribute set to EVN.
C32-[157]	When the quantity dispensed 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.
C32-[158]	Otherwise, the **unit** attribute should contain the preferred name of the presentation units within braces { } using the units of presentation from the NCI Thesaurus.

The units of presentation can be found at www.fda.gov/oc/datacouncil/splncicodes.html#potency, 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.

2.2.1.9.23 Fill Number Constraints

The fill number identifies the supply (dispense) event as a distinct activities against the prescription.

Table 2.2.1.9.23-1 Fill Number Constraints

Constraint ID	Constraint
C32-[159]	The fill number may be recorded in the **sequenceNumber** attribute of a **<entryRelationship>** element with a **typeCode** attribute set to COMP.

2.2.1.9.24 Fill Status Constraints

Table 2.2.1.9.24-1 Fill Status Constraints

Constraint ID	Constraint
C32-[160]	The fill status may be recorded in the **statusCode** attribute.
C32-[161]	The **statusCode** attribute shall contain a code derived from a limited set of values HL7 ActStatusNormal. The OID for this terminology is 2.16.840.1.113883.11.15936.

Table 2.2.1.9.24-2 Fill Status Vocabulary

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

2.2.1.10 Pregnancy Module

This module contains a coded entry indicating whether the patient is currently pregnant.

Figure 2.2.1.10-1 Pregnancy Coding Example

```
<!-- These examples assume the default namespace is 'urn:hl7-org:v3' -->
<observation classCode='OBS' moodCode='EVN'>
    <value xsi:type='CD' code='77386006' displayName='patient currently pregnant'
        codeSystem='2.16.840.1.113883.6.96' codeSystemName='SNOMED CT'/>
</observation>
```

Table 2.2.1.10-1 Pregnancy Data Mapping Table - Definitions

Data Element ID	Data Element	Description
9.01	Pregnancy	This is a simple observation that records whether the patient is currently pregnant.

Table 2.2.1.10-2 Pregnancy Data Mapping Table - Requirements

Data Element ID	Data Element	O/R	Data Source	Additional Specification
9.01	Pregnancy	O/N	cda:observation[cda:code[@code='773860066' and @codeSystem='2.16.840.1.113883.6.96']]/cda:value	

2.2.1.11 Information Source Module

This module allows for information about the original author to be supplied and for a reference to the original document to be provided. This module may be applied to all other modules 2.2.1.1.1 through 2.2.1.1.18. See the HL7 Continuity of Care Document section 5.2 for constraints applicable to this module.

Table 2.2.1.11-1 Information Source Data Mapping Table - Definitions

Data Element ID	Data Element	Description
Author		
10.01	Author Time	The time at which this information was created
10.02	Author Name	The name of the person who created the information content.
10.03	Reference	A reference to the original document from which this information was obtained.
10.04	Reference Document ID	Identifier of the external document that was referenced.
10.05	Reference Document URL	A URL from which this document may be retrieved. Note: Depending on the architectural variant applied, only references to documents which have been registered, so as to ensure that the registry / repository / system access control mechanisms are used to access these documents.
Information Source		
10.06	Information Source Name	The name of the person or organization that provided the information.

Table 2.2.1.11-2 Information Source Data Mapping Table - Requirements

Data Element ID	Data Element	O/R	Data Source	Additional Specification
	Author	R/N	ancestor-or-self::./cda:author[1]	
10.01	Author Time	R/N	cda:time	
10.02	Author Name	R/N	cda:assignedAuthor/cda:assignedPerson/ cda:name	2.2.1.11.1
10.03	Reference	R2/ Y	cda:reference/cda:externalDocument	
10.04	Reference Document ID	R/N	cda:id	
10.05	Reference Document URL	O/N	cda:text/cda:reference/@value	
	Information Source	O/Y	ancestor-or-self::./cda:informant	
10.06	Information Source Name	R/N	cda:assignedPerson/cda:name	

Note: Each content module described above in subsection 2.2.1.5 through 2.2.2.9 above and in subsections 2.2.1.11 and 2.2.1.16 below may have one author. The author is the person who created the information content. The **<author>** element may be included in the **<observation>**,

<substanceAdministration> or **<supply>** element hosting the information described in the content modules defined above to indicate who created this information and when it was created.
Each content module described above in subsection 2.2.1.5 through 2.2.1.9 and in subsections 2.2.1.11 and 2.2.1.12 may have one **<reference>** element that describes the document that was the original source of the information. The **<reference>** element may be included in the **<observation>**, **<substanceAdministration>** or **<supply>** element hosting the information described in the content modules defined above to indicate what document the information came from.

2.2.1.11.1 Information Source Name Constraints

Table 2.2.1.11.1-1 Information Source Name Constraints

Constraint ID	Constraint
C32-[162]	The name of the information source shall be provided in the <name> element.
C32-[163]	The <name> element shall appear within an <assignedPerson> element within an <assignedEntity>, and within a <relatedPerson> element within a <relatedEntity> element beneath the <informant> element.

2.2.1.12 Comment Module

This module allows for a comment to be supplied for any other module listed in subsections 5 through 9 above and 12 below. Data elements defined elsewhere in the specification shall not be recorded using the Comments Module. See the HL7 Continuity of Care Document section 4.3 for constraints applicable to this module. The template identifier for this construct is 2.16.840.1.113883.3.88.11.32.12.

Note: Each content module described in subsection 5 through 9 above and in subsection 12 through 16 below may include one or more comments.

Figure 2.2.1.12-1 Comment Example

```
<!-- These examples assume the default namespace is 'urn:hl7-org:v3' -->
<entry>
    <act><!-- could also be observation, substanceAdministration, supply, et cetera -->
            …
        <entryRelationship typeCode='SUBJ' inversionInd='true'>
            <act classCode='ACT' moodCode='EVN'>
                <templateId root='2.16.840.1.113883.10.20.1.40'/>
                <templateId root='2.16.840.1.113883.3.88.11.32.12'/>
                <code code='' displayName='Annotation Comment'
                    codeSystem='2.16.840.1.113883.6.1'  codeSystemName='LOINC'/>
                <text><reference value='#comment-1'/></text>
                <author>
                    <assignedAuthor>
                        <assignedPerson>
                            <name>…</name>
                        </assignedPerson>
                    </assignedAuthor>
                </author>
            </act>
        </entryRelationship>
    </act>
</entry>
```

Table 2.2.1.12-1 Comments Data Mapping Table - Definitions

Data Element ID	Data Element	Description
Comment		
Author		
11.01	Free Text Comment	A free text comment.

Table 2.2.1.12-2 Comments Data Mapping Table - Requirements

Data Element ID	Data Element	O/R	Data Source	Additional Specification
	Comment		cda:act[cda:templateId/@root = '2.16.840.1.113883.10.20.1.40']	
	Author		ancestor-or-self::./cda:author[1]	
11.01	Free Text Comment	R/N	cda:text/cda:reference/@value	2.2.1.12.1

2.2.1.12.1 Free Text Comment Constraints

Comments are free text data that cannot otherwise be recorded using data elements already defined by this specification. They are not to be used to record information that can be recorded elsewhere. For example, a free text description of the severity of an allergic reaction would not be recorded in a comment. Instead, it would be recorded using data element 6.07 defined above.

Table 2.2.1.12.1-1 Free Text Comment Constraints

Constraint ID	Constraint
C32-[164]	Comments shall be included in entries using an **<entryRelationship>** element.
C32-[165]	The typeCode attribute of the **<entryRelationship>** element shall be SUBJ.
C32-[166]	The inversionInd attribute of the **<entryRelationship>** element shall be true[5]
C32-[167]	The **<text>** element of a comment shall contain a **<reference>** element whose **value** attribute points to the text of the comment in the narrative portion of the CCD.
C32-[168]	The author of a comment shall be recorded as specified for authors in the Information Source module. See section 2.2.1.11 above

2.2.1.13 Advance Directive Module

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. See the HL7 Continuity of Care Document section 3.2 for constraints applicable to this module. The template identifier for this construct is 2.16.840.1.113883.3.88.11.32.13.

Table 2.2.1.13-1 Advance Directives Data Mapping Table - Definitions

Data Element ID	Data Element	Description
Advance Directive Event Entry		
12.01	Advance Directive Type	This is a coded value describing the type of the Advance Directive.
12.02	Advance Directive Free Text Type	Free text comment to describe the Advance Directive Type.
12.03	Effective Date	The effective date for the Advance Directive.
12.04	Custodian of the Document	Name, address or other contact information for the person or organization that can provide a copy of the document.

Table 2.2.1.13-2 Advance Directives Data Mapping Table - Requirements

Data Element ID	Data Element	O/R	Data Source	Additional Specification
	Advance Directive Event Entry		cda:observation[cda:templateId/@root= '2.16.840.1.113883.10.20.1.17']	
12.01	Advance Directive Type	R2/ N	cda:code	2.2.1.13.1
12.02	Advance Directive Free Text Type	R/N	cda:originalText/cda:reference/@value	2.2.1.13.2
12.03	Effective Date	R/N	cda:effectiveTime	2.2.1.13.3

[5] Setting inversionInd='true' tells us that the subject of the comment is the act (observation, substanceAdministration, supply, et cetera) that it is contained within, rather than the reverse.

Data Element ID	Data Element	O/R	Data Source	Additional Specification
12.04	Custodian of the Document	R/N	cda:participant[@typeCode='CST']/ cda:participantRole[@classCode='AGNT']	2.2.1.13.4

NOTE: The existence of an Advance Directive of a particular type (e.g., intubation) is a signal to the provider that such a directive exists. When determining how to care for a patient, the provider is advised to review the Advance Directive directly, rather than relying upon summary information contained within the Registration and Medication History

Figure 2.2.1.13-1 Advance Directive Example

```
<!-- These examples assume the default namespace is 'urn:hl7-org:v3' -->
<observation classCode='OBS' moodCode='EVN'>
    <templateId root='2.16.840.1.113883.10.20.1.17'/>
    <templateId root='2.16.840.1.113883.3.88.11.32.13'/>
    <code code='...' displayName='...'
        codeSystem='2.16.840.1.113883.6.96' codeSystemName='SNOMED CT'>
        <originalText><reference value='#directive-1'/></originalText>
    </code>
    <effectiveTime>
        <low value='...'/>
        <high value='...'/>
    </effectiveTime>
    <participant typeCode='CST'>
        <participantRole classCode='AGNT'>
            <addr>…</addr>
            <telecom>…</telecom>
            <playingEntity>
                <name>…</name>
            </playingEntity>
        </participantRole>
    </participant>
</observation>
```

2.2.1.13.1 Advance Directive Coded Type Constraints

Table 2.2.1.13.1-1 Advance Directive Coded Type Constraints

Constraint ID	Constraint
C32-[169]	The code shall appear in the **<code>** element, and shall use the AdvanceDirectiveTypeCode vocabulary defined by CCD. The OID for this vocabulary is 2.16.840.1.113883.6.96 (SNOMED CT).
C32-[170]	The type of Advance Directive should be coded.

2.2.1.13.2 Advance Directive Free Text Type Constraints

Table 2.2.1.13.2-1 Advance Directive Free Text Type Constraints

Constraint ID	Constraint
C32-[171]	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>**.

2.2.1.13.3 Effective Date

Table 2.2.1.13.3-1 Effective Date Constraints

Constraint ID	Constraint
C32-[172]	The starting time of the Advance Directive shall be recorded in the **<low>** element of the **<effectiveTime>** element in the Advance Directive **<observation>**.
C32-[173]	If the starting time is unknown, the **<low>** element shall have the nullFlavor attribute set to UNK.
C32-[174]	The ending time of the Advance Directive shall be recorded in the **<high>** element of the **<effectiveTime>** element in the Advance Directive **<observation>**.
C32-[175]	If the ending time is unknown, the **<high>** element shall have the nullFlavor attribute set to UNK.
C32-[176]	If the Advance Directive does not have a specified ending time, the **<high>** element shall have the nullFlavor attribute set to NA.

2.2.1.13.4 Custodian of the Document

Table 2.2.1.13.4-1 Custodian of the Document Constraints

Constraint ID	Constraint
C32-[177]	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>**.
C32-[178]	The typeCode attribute of the **<participant>** element shall be CST.
C32-[179]	The classCode of the **<participantRole>** element shall be AGNT.
C32-[180]	The address of the agent shall be recorded in an **<addr>** element when known.
C32-[181]	The telephone number or other electronic communications address for the agent shall be recorded in a **<telecom>** element when known.
C32-[182]	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.

2.2.1.14 Immunization Module

This module contains data describing the patient's immunization history. See the HL7 Continuity of Care Document section 3.11, and Medication module section, for constraints applicable to this module.

The template identifier for this construct is 2.16.840.1.113883.3.88.11.32.14.

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.

Table 2.2.1.14-1 Immunizations Data Mapping Table - Definitions

Data Element ID	Data Element	Description
	Immunization Event Entry	
13.01	Refusal	A flag that the immunization event did not occur. The nature of the refusal (e.g., patient refused, adverse reaction)
13.02	Administered Date	The date and time of substance was administered or refused, i.e., when the immunization was administered to the patient, or refused by the patient
13.03	Medication Series Number	Indicate which in a series of administrations a particular administration represents (e.g. “hepatitis B vaccine number 2”)
13.04	Reaction	Any noted intended or unintended effects of the product. For example: full body rash, nausea, rash resolved.
13.05	Performer	The person that administered the immunization to the patient (may include both a name and an identifier)
	Medication Information	
13.06	Coded Product Name	A code describing the product from a controlled vocabulary
13.07	Free Text Product Name	The name of the substance or product without reference to a specific vendor (e.g., generic or other non-proprietary name). If a Coded Product Name is present, this is the text associated with the coded concept. This should be sufficient for a provider to identify a medication, and may include additional information such as strength, dose form, etc. If the name of the product is unknown, the type, purpose or other description may be supplied.
13.08	Drug Manufacturer	The manufacturer of the substance or product as ordered or supplied. The distributor may be supplied if the manufacturer is not known.
13.09	Lot Number	The manufacturer's production lot number for the administered product.
13.10	Refusal Reason	When an immunization is refused, this provides a coded representation of the reason for refusing the immunization

Table 2.2.1.14-2 Immunizations Data Mapping Table - Requirements

Data Element ID	Data Element	O/R	Data Source	Additional Specification
	Immunization Event Entry		cda:substanceAdministration[cda:templateId/@root = '2.16.840.1.113883.10.20.1.24']	
13.01	Refusal	R/N	cda:negationInd	
13.02	Administered Date	O/N	cda:effectiveTime	
13.03	Medication Series Number	O/N	cda:entryRelationship [@typeCode='SUBJ']/ cda:observation/cda:value	
13.04	Reaction	O/Y	cda:entryRelationship[@typeCode='CAUS']/ cda:observation[cda:templateId/@root= ’2.16.840.1.113883.10.20.1.54’]	
13.05	Performer	O	cda:performer/cda:assignedEntity	
	Medication Information	R/Y	cda:consumable/cda:manufacturedProduct	

Data Element ID	Data Element	O/R	Data Source	Additional Specification
13.06	Coded Product Name	R2/ Y	cda:manufacturedMaterial/cda:code	
13.07	Free Text Product Name	R/N	cda:orginalText	
13.08	Drug Manufacturer	O/N	cda:manufacturerOrganization	
13.09	Lot Number	R2/ N	cda:manufacturedMaterial/ cda:lotNumberText	
13.10	Refusal Reason	R2/ N	cda:entryRelationship[@typeCode='RSON']/ cda:act[cda:templateId/@root= '2.16.840.1.113883.10.20.1.27']	

Figure 2.2.1.14-1 Immunization Example

```
<!-- These examples assume the default namespace is 'urn:hl7-org:v3' -->
<substanceAdministration classCode='SBADM' moodCode='EVN'>
    <templateId root='2.16.840.1.113883.10.20.1.24'/>
    <templateId root='2.16.840.1.113883.3.88.11.32.14'/>
    <code code='11369-6' displayName=' History of immunizations '
        codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'>
        </code>
  <entryRelationship>          <!-- medication series -->
    <typeCode value='SUBJ'/>
    <observation>
        <value xsi:type='INT' value='2'/>
    </observation>
  </entryRelationship>
  <entryRelationship>          <!-- reaction -->
    <typeCode value='CAUS'/>
    <observation>
        …
    </observation>
  </entryRelationship>
  <performer>
    <typeCode value='PRF'/>
    <assignedEntity>
        …
    </assignedEntity>
  </performer>
  <consumable>
    <manufacturedProduct classCode='MANU'>
        <templateId root='2.16.840.1.113883.10.20.1.53'/>
        <templateId root='2.16.840.1.113883.3.88.11.32.9'/>
        <organization>
            …
        </organization>
        <material>
            …
            <code code='…' displayName='…' codeSystem='…' codeSystemName='…'/>
            <lotNumberText>…</lotNumberText>
        </material>
    </manufacturedProduct>
  </consumable>
</substanceAdministration >
```

Table 2.2.1.14-3 Medication Information Constraints

Constraint ID	Constraint
C32-[198]	When a C32 Medication Information data element (2.16.840.1.113883.3.88.11.32.9) appears in a CCD Medications section (2.16.840.1.113883.10.20.1.8), then 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
C32-[199]	The reason for refusal shall be reported using HL7 ActNoImmunizationReason vocabulary. The OID for this vocabulary is 2.16.840.1.113883.11.19725

2.2.1.15 Vital Sign Module

This module contains current and relevant historical vital signs for the patient. Vital Signs are a subset of Results (see Section 2.2.2.16), but are reported in this section to follow clinical conventions. See the HL7 Continuity of Care Document section 3.12 for constraints applicable to this module.

The differentiation between Vital Signs and Results varies by clinical context. Common examples of vital signs include temperature, height, weight, blood pressure, etc. However, some clinical contexts may alter these common vitals, for example in neonatology “height” may be replaced by “crown-to-rump” measurement. The following LOINC codes are examples of measurement that would typically be considered “vital signs”. Note: LOINC concepts can include associated methodologies, sites, and specimen information in addition to that implied by the description.

Table 2.2.1.15-1 LOINC Concept Codes

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	CIRCUMFRENCE.OCCIPITAL-FRONTAL (TAPE MEASURE)
3141-9	BODY WEIGHT (MEASURED)

The template identifier for this construct is 2.16.840.1.113883.3.88.11.32.15.

Table 2.2.1.15-2 Vital Signs Data Mapping Table - Definitions

Data Element ID	Data Element	Description
	See Data Element Definitions for Results in section 2.2.1.15	

Table 2.2.1.15-3 Vital Signs Data Mapping Table - Requirements

Data Element ID	Data Element	O/R	Data Source	Additional Specification
	See Data Element Definitions for Results in section 2.2.1.15			Section 2.2.1.15

2.2.1.15.1 Vital Sign / Result Type Constraints

Table 2.2.1.15.1-1 Vital Sign / Result Type Constraints

Constraint ID	Constraint
C32-[200]	Result Type for Vital Sign entries SHOULD be selected from LOINC (codeSystem 2.16.840.1.113883.6.1)

2.2.1.16 Result Module

This module contains current and relevant historical result observations for the patient. The scope of "observations" is broad with the exception of "vital signs" which are contained in the Vital Signs sections (see section 2.2.1.15). See the HL7 Continuity of Care Document section 3.13 for constraints applicable to this module.

The template identifier for this construct is 2.16.840.1.113883.3.88.11.32.16.

As with the overall document created, the Results section is intended as a summary and not as an official, legal sanctioned report. For example, regulatory requirements for lab reports are not necessarily supported in the following Data Element Definitions. In the case of lab reports, the official report is supported in HITSP/C37 - Laboratory Report Document Using IHE XD* Lab.

This module is a subset of the content specified by HITSP/C37 Laboratory Report Document Using IHE XD* Lab. In addition, terminology constraints specified in HITSP/C35 - Laboratory Result Terminology apply to this module.

Table 2.2.1.16-1 Results Data Mapping Table - Definitions

Data Element ID	Data Element	Description
Result Event Entry		
15.01	Result ID	An identifier for this specific observation
15.02	Result Date/Time	The biologically relevant date/time for the observation
15.03	Result Type	A coded representation of the observation performed
15.04	Result Status	Status for this observation, e.g., complete, preliminary
15.05	Result Value	The value of the result, including units of measure if applicable
15.06	Result Interpretation	An abbreviated interpretation of the observation, e.g., normal, abnormal, high, etc.
15.07	Result Reference Range	Reference range(s) for the observation.

Table 2.2.1.16-2 Results Data Mapping Table - Requirements

Data Element ID	Data Element	O/R	Data Source	Additional Specification
	Result Event Entry		cda:observation[cda:templateId/@root = '2.16.840.1.113883.10.20.1.14']	
15.01	Result ID	R/Y	cda:id	
15.02	Result Date/Time	R/N	cda:effectiveTime	
15.03	Result Type	R/N	cda:code	2.2.1.16.2

Data Element ID	Data Element	O/R	Data Source	Additional Specification
15.04	Result Status	R2/ N	cda:statusCode	2.2.1.16.1
15.05	Result Value	R/N	cda:value	
15.06	Result Interpretation	O/N	cda:interpretationCode	
15.07	Result Reference Range	O/Y	cda:referenceRange	

Figure 2.2.1.16-1 Results Example

```
<!-- These examples assume the default namespace is 'urn:hl7-org:v3' -->
<observation classCode='OBS' moodCode='EVN'>
    <templateId root='2.16.840.1.113883.10.20.1.17'/>
    <templateId root='2.16.840.1.113883.3.88.11.32.16'/>
    <code code='...' displayName='...'  codeSystem='2.16.840.1.113883.6.1'
codeSystemName='LOINC'/>
    <effectiveTime low value='...'/>
    <statusCode value='N'/>
    <value xsi:type="PQ" value="100" unit="g/dl"/>
  <interpretationCode code="N" codeSystem="2.16.840.1.113883.5.83"/>
    <referenceRange>
        <observationRange>
            <text>M 13-18 g/dl; F 12-16 g/dl</text>
        </observationRange>
    </referenceRange>
</observation>
```

2.2.1.16.1 Result Status Constraints

Table 2.2.1.16.1-1 Result Status Constraints

Constraint ID	Constraint
C32-[201]	The **statusCode** attribute shall contain a code derived from a limited set of values HL7 ActStatusNormal. The OID for this terminology is 2.16.840.1.113883.11.15936.

2.2.1.16.2 Result Type Constraints

Table 2.2.1.16.2-1 Result Type Constraints

Constraint ID	Constraint
C32-[202]	Result Type SHOULD be selected from LOINC (codeSystem 2.16.840.1.113883.6.1) or SNOMED CT (codeSystem 2.16.840.1.113883.6.96)

2.2.1.17 Encounter Module

This module contains data describing the interactions between the patient and clinicians. As with the overall intent of the HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD), current and pertinent historical encounters should be included, a full encounter history may be included. Interaction includes both in-person and non-in-person encounters such as telephone and email

communication. See the HL7 Continuity of Care Document section 3.15 for constraints applicable to this module.

The template identifier for this construct is 2.16.840.1.113883.3.88.11.32.17.

As with the overall document created, the Encounters module is intend as a summary of pertinent information and not necessarily an exhaustive report.

> *Note to Public Commenters: We seek input on the breadth of Data Elements defined in this module. The intent of this document, and this section, is to summarize information. As such, every possible data element is not absolutely required. The following were considered essential for a summary. Comments on additional elements necessary for summary content is invited.*

Table 2.2.1.17-1 Encounters Data Mapping Table - Definitions

Data Element ID	Data Element	Description
Encounter Event Entry		
16.01	Encounter ID	An identifier for this encounter.
16.02	Encounter Type	This is a coded value describing the type of the Encounter.
16.03	Encounter Free Text Type	Free text comment to describe the Encounter Type.
16.04	Encounter Date/Time	The date and time of the Encounter, including duration if pertinent
16.05	Encounter Provider	Name and other information for the person or organization performed or hosted the encounter

Table 2.2.1.17-2 Encounters Data Mapping Table - Requirements

Data Element ID	Data Element	O/R	Data Source	Additional Specification
	Encounter Event Entry		cda:encounter[cda:templateId/@root = '2.16.840.1.113883.10.20.1.21']	
16.01	Encounter ID	R/Y	cda:id	
16.02	Encounter Type	R2/N	cda:code	2.2.1.17.1
16.03	Encounter Free Text Type	R/N	cda:originalText/cda:reference/@value	
16.04	Encounter Date/Time	R/N	cda:effectiveTime	
16.05	Encounter Provider	R2/Y	cda:participant/cda:assignedEntity	2.2.1.17.2

Figure 2.2.1.17-1 Encounters Example

```
<!-- These examples assume the default namespace is 'urn:hl7-org:v3' -->
<text><ID
<observation classCode='OBS' moodCode='EVN'>
    <templateId root='2.16.840.1.113883.10.20.1.21'/>
    <templateId root='2.16.840.1.113883.3.88.11.32.17'/>
    <code code='...' displayName='...' codeSystem='...' codeSystemName='...'>
        <originalText><reference value='#encounter-1'/></originalText>
    </code>
    <effectiveTime>
        <low value='20070610'/>
    </effectiveTime>
    <participant typeCode='PRF'>
        <participantRole classCode='PROV'>
            <addr>…</addr>
            <telecom>…</telecom>
            <playingEntity>
                <name>…</name>
            </playingEntity>
        </participantRole>
    </participant>
</observation>
```

2.2.1.17.1 Encounter Type Constraints

Table 2.2.1.17.1-1 Encounter Type Constraints

Constraint ID	Constraint
C32-[203]	Encounter Type SHOULD be selected from CPT-4 E&M codes. The OID for this terminology is 2.16.840.1.113883.6.12.

2.2.1.17.2 Encounter Provider Constraints

Table 2.2.1.17.2-1 Encounter Provider Constraints

Constraint ID	Constraint
C32-[183]	An Encounter should contain one **Encounter / performer** with **<typecode>** = PRF to identify the primary performer involved in the encounter.

2.2.1.18 Procedure Module

This module contains a coded entry indicating a procedure 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. Until this gap is addressed by the various stakeholder organizations, the coded procedure module (see CCD section 3.14.2) is optional and not further constrained by this specification. However, for the purposes of this specification, the Procedures section (see CCD section 3.14) shall employ the text element to describe the overall collection of procedures.

Table 2.2.1.18-1 Procedure Data Mapping Table - Definitions

Data Element ID	Data Element	Description
	Procedures	The CCD **section** where procedures the patient has undergone are described
17.01	Text	Structured textual representation of the procedures that patient has underdone
	Procedure Event Entry	Representation of a single procedure

Table 2.2.1.18-2 Procedure Data Mapping Table - Requirements

Data Element ID	Data Element	O/R	Data Source	Additional Specification
	Procedures	O/N	cda:section[cda:templateId[@root = '2.16.840.1.113883.10.20.1.12']]	
17.01	Text	O/N	cda:text	
	Procedure Event Entry	O/Y	cda:procedure[cda:templateId/@root= '2.16.840.1.113883.10.20.1.29']	

Table 2.2.1.18-3 Procedure Constraints

Constraint ID	Constraint
C32-[204]	The Procedures section shall contain a text element which describes the relevant procedures the patient has undergone.

2.2.2 ADDITIONAL GUIDELINES AND EXAMPLES

Individual examples have been included in the specific sections of 2.2.1 wherever appropriate. Additional guidelines and examples that support the underlying base or composite standards for the HITSP/C32 Summary Documents Using HL7 Continuity of Care Document (CCD) Component may be included in this section if appropriate in the future to help describe how these specifications differ from the underlying standards.

2.3 LIST OF STANDARDS

It is important to understand that the standards selected here are within the context of the specific Use Case requirements and do not necessarily reflect selection in other contexts. The standards identified in Table 3.2-1 are used to implement this Component specification.

2.3.1 BACKGROUND OF THE EVOLUTION TO THE HITSP/C32 - SUMMARY DOCUMENTS USING HL7 CONTINUITY OF CARE DOCUMENT (CCD) COMPONENT

From the Consumer Empowerment Use Case, the Consumer Empowerment Technical Committee was charged with introducing the consumer, and the PHR, as an integral partner of the healthcare information flow representing a new paradigm in healthcare interoperability. This paradigm establishes the consumer

as the active participant in health information exchange that touches all segments of the industry: providers/care facilities, health plans, pharmacies/prescription benefit managers (PBM), and others. This challenge is exacerbated by the current information technology situation wherein providers, health plans, pharmacies, and pharmacy benefit managers (PBMs) segments, each have created different standards based on differing business needs and timing, with shared and overlapping data elements via three different standards developers: Health Level Seven (HL7), Accredited Standards Committee (ASC) X12, and National Council for Prescription Drug Programs (NCPDP).

In addition to these aforementioned standards, a fourth standard initiative from American Society for Testing Materials Standards (ASTM), targeting the provider-provider and provider-consumer Interoperability space, entitled the Continuity of Care Record (CCR), passed favorable ballot in October 2005. In the latter phase of the successful CCR balloting process, ASTM and HL7 initiated a formal harmonization effort regarding their respective efforts addressing the same interoperability space. This harmonization initiative resulted in the joint development of the Continuity of Care Document (CCD) that was approved by HL7 ballot in January 2007.

The Consumer Empowerment Technical Committee determined that it is in the best interest of HITSP harmonization efforts to wholeheartedly support the HL7-ASTM harmonization initiative and leverage its deliverables to the highest degree possible. To this end, the approach taken by the Consumer Empowerment Technical Committee was to align its initial Interoperability Specification to the harmonized HL7-ASTM CCD with the creation of the HITSP/C32 Summary Documents Using HL7 Continuity of Care Document (CCD) Component designed to facilitate the transition from the current disparate standards environment to a harmonized state.

The Consumer Empowerment Technical Committee also recognized the need to ensure consistency of its specified data elements across all the standards deployed by the business actors that are potential sources of data in the PHR of the Use Case. For example, ASC X12 is used to describe health plan information that is relevant for updating a consumer's PHR. To this end, the HITSP/IS03 - Consumer Sharing of Health Information via Networks, and this HITSP/C32 Summary Documents Using HL7 Continuity of Care Document (CCD) Component, include appendices for informative data element cross-mapping tables between the CCD elements and the ASTM CCR, ASC X12, and NCPDP SCRIPT data elements, for all common content areas. It was therefore concluded to include informative element mapping tables as guidance to the SDOs and/or application system vendors using these base standards, for adapting these standards and their implementations to the HITSP Interoperability Specification work.

Following its initial publication, the HITSP/C32 construct has evolved into a principle source specification for deploying summary documents leveraging the HL7 CCD standard for a variety of interoperability requirements that are described in Use Cases across the HITSP spectrum of activity, e.g. Care Delivery, Population Health, etc.

Table 2.3-1 List of Standards

Standard	Description
Accredited Standards Committee (ASC) X12 Insurance Subcommittee (X12N) Implementation Guides Version 004010 plus Addenda 004010A1	Detailed Implementation Guides based on release 004010 of the X12 standards. These Implementation Guides provide details on the use of X12 standards to accomplish specific transaction functions. Some of the version 004010 Implementation Guides, but not all, have been adopted as Implementation Specifications under HIPAA. Many of the version 004010 Implementation Guides, including all of those adopted under HIPAA, have Addenda that contain updates -- only -- to the original Implementation Guides. These Addenda are identified as version 004010A1. Implementation Guides 004010X092 and 004010X092A1 describe transactions for Health Care Eligibility Benefit Inquiry and Response. Implementation Guides are published by Washington Publishing Company. Visit www.wpc-edi.com for more information.
Accredited Standards Committee (ASC) X12 Standards Release 004010	Release (version) 004010 of the Accredited Standards Committee (ASC) X12 standards including the X12.5 Interchange Control, X12.6 Application Control Structure, 270 Eligibility, Coverage or Benefit Inquiry, 271 Eligibility, Coverage or Benefit Information and other control standards for the uniform electronic interchange of business transactions. Published by the Data Interchange Standards Association (DISA). Visit www.x12.org for more information.
American Society for Testing and Materials (ASTM) Standard Specification for Coded Values Used in the Electronic Health Record: # E1633-02	Identifies the lexicons to be used for the data elements identified in ASTM's Standard Guide for Content and Structure of the Electronic Health Record (EHR): # E1384-02. E1633-02 "is intended to unify the representations for: (1) primary record of care data elements, (2) the data elements identified in other standard statistical data sets, (3) data elements used in other healthcare data message exchange format standards, or (4) in data gathering forms for this purpose, and (5) in data derived from these elements in order that data recorded in the course of patient care be exchangeable and be the source of accurate statistical and resource management data." {Source: ASTM E1633-02a, 2006} Visit www.astm.org for more information.
American Society for Testing and Materials (ASTM) Standard Specification for Continuity of Care Record (CCR): # E2369-05	A core data set of the most relevant and timely facts about a patient's healthcare. It is to be prepared by a practitioner at the conclusion of a healthcare encounter in order to enable the next practitioner to readily access such information. It includes a summary of the patient's health status (e.g., problems, medications, allergies) and basic information about insurance, Advance Directives, care documentation, and care plan recommendations. An XML version of the CCR, known as the Continuity of Care Document (CCD), prepared by Health Level Seven (HL7) in collaboration with ASTM, also exists and described under Health Level Seven standards. Visit www.astm.org for more information.
CDC Race and Ethnicity Code Sets	The U.S. Centers for Disease Control and Prevention (CDC) has prepared a code set for use in coding race and ethnicity data. This code set is based on current federal standards for classifying data on race and ethnicity, specifically the minimum race and ethnicity categories defined by the U.S. Office of Management and Budget (OMB) and a more detailed set of race and ethnicity categories maintained by the U.S. Bureau of the Census (BC). The main purpose of the code set is to facilitate use of federal standards for classifying data on race and ethnicity when these data are exchanged, stored, retrieved, or analyzed in electronic form. At the same time, the code set can be applied to paper-based record systems to the extent that these systems are used to collect, maintain, and report data on race and ethnicity in accordance with current federal standards. More information is available from www.cdc.gov/nedss/DataModels
Council for Affordable Quality Health Care (CAQH) Committee on Operating Rules for Information Exchange (CORE) Phase I Operating Rules	Provide agreed-upon business rules and guidelines for using and processing eligibility inquiry and response transactions between providers and health plans; in particular those that have been adopted under HIPAA. Visit www.caqh.org for more information.
Federal Medication Terminologies	A set of controlled terminologies and code sets developed and maintained as part

Standard	Description
	of a collaboration between the Food and Drug Administration, National Library of Medicine, Veterans Health Administration, National Cancer Institute and Agency for Healthcare Research and Quality related to medications, including medication proprietary and nonproprietary names, clinical drug code (RxNorm); ingredient names and Unique Ingredient Identifiers (UNII); routes of administration, dosage forms, and units of presentation from the NCI Thesaurus (NCIt); and certain pharmacological drug classes from the National Drug File Reference Terminology (NDF-RT) . The Federal Medication Terminology leverages medication models maintained by the Food and Drug Administration (ex. UNII, NDC Codes), National Library of Medicine (RxNorm), the Veterans Health Administration (NDF-RT), and the National Cancer Institute (NCIt). Information on the Federal Medication Terminologies may be found and downloaded from the NCI Web portal terminology resources page at www.cancer.gov/cancertopics/terminologyresources/FMT
Health Care Provider Taxonomy	The Health Care Provider Taxonomy code set is a collection of unique alphanumeric codes, ten characters in length. The Health Care Provider Taxonomy code set includes specialty categories for individuals, Groups of individuals, and non-individuals. The National Uniform Claims Committee maintains this code set. The complete code set is available from the Washington Publishing Company at www.wpc-edi.com/taxonomy/more_information
Health Level Seven (HL7) Version 3.0	The HL7 Version 3.0 Messaging Standard is an application protocol for electronic data exchange in healthcare. Version 3.0 is based on a Reference Information Model (RIM); which is used to instantiate various message formats. Value sets / code tables are contained in the standard. Visit www.hl7.org for more information.
Health Level Seven (HL7) Version 3.0 Clinical Document Architecture (CDA/CDA R2)	The HL7 Clinical Document Architecture is an XML-based document markup standard that specifies the structure and semantics of clinical documents for the purpose of exchange. CDA is one instantiation of HL7's Version 3.0 Reference Information Model (RIM) into a specific message format. Of particular focus for HITSP Interoperability Specifications are message formats for Laboratory Results and Continuity of Care (CCD) documents. Release 2 of the HL7 Clinical Document Architecture (CDA) is an extension to the original CDA document markup standard that specifies the structure and semantics of clinical documents for the purpose of exchange. CDA R2 includes a prose document in HTML, XML schemas, data dictionary, and sample CDA documents. CDA R2 further builds upon other HL7 standards beyond just the Version 3.0 Reference Information Model (RIM) and incorporates Version 3.0 Data Structures, Vocabulary, and the XML Implementation Technology Specifications for Data Types and Structures. Visit www.hl7.org for more information.
HL7 Implementation Guide: CDA Release 2 – Continuity of Care Document (CCD), Release 1.0, April 01, 2007	The Continuity of Care Document implementation guide describes constraints on the HL7 Clinical Document Architecture, Release 2 (CDA) specification in accordance with requirements set forward in ASTM E2369-05 Standard Specification for Continuity of Care Record (CCR). The resulting specification, known as the Continuity of Care Document (CCD), is developed as a collaborative effort between ASTM and HL7. It is intended as an alternate implementation to the one specified in ASTM ADJE2369 for those institutions or organizations committed to implementation of the HL7 Clinical Document Architecture. Visit www.hl7.org for more information.
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 3.0	The IHE IT Infrastructure Technical Framework defines specific implementations of established standards to achieve integration goals that promote appropriate sharing of health information to support optimal patient care. IHE Integration Profiles, offer a common language that healthcare professionals and vendors may use in

Standard	Description
	communicating requirements for the integration of products. The current version of the ITI-TF, rev. 3.0 for Final Text, specifies the IHE transactions defined and implemented as of December 9, 2006. The latest version of the IHE Technical Framework is available at www.ihe.net.
Integrating the Healthcare Enterprise (IHE) Patient Care Coordination (PCC) Technical Framework Revision 3.0	The IHE Patient Care Coordination Technical Framework (PCC TF) defines specific implementations (called Integration Profiles) of established standards to deal with integration issues that cross providers, patient problems or time. The Cross Enterprise Document Sharing of Medical Summaries (XDS-MS) Integration Profile enables sharing of health information between enterprises of a regional health network, and further describes how to map content in a CDA medical document into registry metadata. In the registry, healthcare providers publish pointers to documents stored in distributed repositories. Other healthcare providers may search and retrieve these and other documents. Visit www.ihe.net for more information.
Logical Observation Identifiers Names and Codes (LOINC®)	A database of universal identifiers for laboratory and other clinical observations. The laboratory portion of the LOINC database contains the usual categories of chemistry, hematology, serology, microbiology (including parasitology and virology), and toxicology; as well as categories for drugs and the cell counts typically reported on a complete blood count or a cerebrospinal fluid cell count. Antibiotic susceptibilities are a separate category. The clinical portion of the LOINC database includes entries for vital signs, hemodynamics, intake/output, EKG, obstetric ultrasound, cardiac echo, urologic imaging, gastroendoscopic procedures, pulmonary ventilator management, selected survey instruments, and other clinical observations. Visit www.loinc.org for more information.
National Council for Prescription Drug Programs (NCPDP) SCRIPT Standard Version 8.1	Provides for the real-time electronic transfer of prescription data between pharmacies and providers. Functions supported include communication of new prescriptions, prescription changes, refill requests, prescription fill status notifications, and prescription cancellations. Visit www.ncpdp.org for more information.
Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity	This classification provides a minimum standard for maintaining, collecting, and presenting data on race and ethnicity for all Federal-reporting purposes. The categories in this classification are social-political constructs and should not be interpreted as being scientific or anthropological in nature. The standards have been developed to provide a common language for uniformity and comparability in the collection and use of data on race and ethnicity by Federal agencies. Visit www.census.gov for more information.

3.0 TECHNICAL IMPLEMENTATION

3.1 CONFORMANCE

This section describes the conformance criteria, which are objective statements of requirements that can be used to determine if a specific behavior, function, interface, or code set has been implemented correctly.

3.1.1 CONFORMANCE CRITERIA

In order to claim conformance to this construct specification, an implementation must satisfy all the requirements and mandatory statements listed in this specification, the associated HITSP Interoperability Specification, its associated construct specifications, as well as conformance criteria from the selected base and composite standards. A conformant system must also be constrained as specified in table 2.1.1-1, and implement all of the required actors, where defined, within the scope, subset or implementation option that is selected from the associated Interoperability Specification.

Claims of conformance may only be made for the overall HITSP Interoperability Specification with which this construct is associated.

3.1.2 CONFORMANCE SCOPING, SUBSETTING AND OPTIONS

A HITSP Interoperability Specification must be implemented in its entirety for an implementation to claim conformance to the specification. HITSP may define the permissibility for actor scoping, subsetting or implementation options by which the specification may be implemented in a limited manner. Such scoping, subsetting and options may extend to associated constructs, such as this construct. This construct must implement all requirements within the selected scope, subset or options as defined in the associated Interoperability Specification to claim conformance.

4.0 APPENDIX

The following sections include relevant materials referenced throughout this document.

Three mappings of the HITSP/C32 Summary Documents Using HL7 Continuity of Care Document (CCD) Document Component elements are provided at this time, namely to NCPDP SCRIPT element names, X12N 271 Implementation Guide element names and ASTM E2369-5 CCR element names. A mapping of these same elements to HL7 v2.x segments and elements is not currently included, but may be provided in a future version of this Component document.

4.1 MAPPING OF NCPDP SCRIPT MEDICATION ATTRIBUTES INTO THE SUMMARY DOCUMENTS USING HL7 CONTINUITY OF CARE DOCUMENT (CCD) COMPONENT

This section illustrates a mapping of the NCPDP SCRIPT standard into the Person Information and Medications – Prescription and Non-Prescription Modules of the Summary Documents Using HL7 Continuity of Care Document (CCD) Component.[6] This is informative text only, and is not a normative part of this document.

The XML Companion Guide for NCPDP SCRIPT provides details and guidelines for developers to exchange electronic prescription messages, utilizing an XML implementation of NCPDP SCRIPT. The document describes the XML Message standard, the set of supported messages, and other variables related to the use of an XML implementation of SCRIPT. The XML Message standard supports the same featured message sets as EDIFACT implementations of NCPDP SCRIPT; a one-to-one correspondence for their respective data elements.

4.1.1 MEDICATIONS – PRESCRIPTION AND NON-PRESCRIPTION MODULE

Table 4.1.1-1 Medications – Prescription and Non-Prescription Data Element Mappings

Data Element ID	Data Element	NCPDP SCRIPT Name
8.01	Free Text Sig	DRU Ø3Ø-IØ14-Ø2, -Ø3 Dosage (Sig instructions. Dosage free text.)
8.02	Indicate Medication Stopped	Not Currently Mapped. Sig fields will be available in new Sig Segment in future version of SCRIPT after eprescribing pilots. Sig 13Ø Stop (Indicator, Text, Code, System, Version).
8.03	Administration Timing	Not Currently Mapped. Sig fields will be available in new Sig Segment in future version of SCRIPT after eprescribing pilots. Sig Ø8Ø Administration Timing (Text, Code, System, Version, Multiple Modifier).

[6] Other modules do not map to NCPDP.

Data Element ID	Data Element	NCPDP SCRIPT Name
8.04	Frequency	Not Currently Mapped. Sig fields will be available in new Sig Segment in future version of SCRIPT after eprescribing pilots. Sig Ø7Ø Frequency (Frequency, Units, Code, System, Version, Multiple Modifier).
8.05	Interval	Not Currently Mapped. Sig fields will be available in new Sig Segment in future version of SCRIPT after eprescribing pilots. Sig Ø9Ø Interval (Value, Text, Code, System, Version, Variable Interval Modifier).
8.06	Duration	Not Currently Mapped. Sig fields will be available in new Sig Segment in future version of SCRIPT after eprescribing pilots. Sig Ø9Ø Interval (Value, Text, Code, System, Version, Variable Interval Modifier).
8.07	Route	Not Currently Mapped. Sig fields will be available in new Sig Segment in future version of SCRIPT after eprescribing pilots. Sig Ø5Ø Route (Route, Code, System, Version, Multiple Modifier).
8.08	Dose	Not Currently Mapped. Sig fields will be available in new Sig Segment in future version of SCRIPT after eprescribing pilots. Sig Ø2Ø-1Ø Dose as text. Can also express Dose Units Text, Code, Code System, and Code System Version.
8.09	Site	Not Currently Mapped. Sig fields will be available in new Sig Segment in future version of SCRIPT after eprescribing pilots. Sig Ø6Ø Site (Site, Code, System, Version, Multiple Modifier).
8.10	Dose Restriction	Not Currently Mapped. Sig fields will be available in new Sig Segment in future version of SCRIPT after eprescribing pilots. Sig 11Ø Dose Restriction (Maximum Value, Units Text, Code, System, Version, Maximum Variable Value, Units Text, Code, System, Version, Maximum Calculation Equation Code, System, Version, Modifier).
8.11	Product Form	DRU Ø1Ø-IØ13-Ø5-1131 Code List Qualifier Drug form, in a code.
8.12	Delivery Method	Not Currently Mapped. Sig fields will be available in new Sig Segment in future version of SCRIPT after eprescribing pilots. Sig Ø2Ø-Ø2 Dose Delivery Method (Text, Code, Version, and System).
8.13	Coded Product Name	DRU Ø1Ø-IØ13-Ø3-714Ø Drug Number, Ø1Ø-IØ13-Ø4-3Ø55 Code List Responsibility Agency.
8.14	Coded Brand Name	Not Used.
8.15	Free Text Product Name	DRU Ø1Ø-IØ13-Ø2-7ØØ8, Ø1Ø-IØ13-1Ø-7ØØ8, Ø1Ø-IØ13-11-7ØØ8, Ø1Ø-IØ13-

Data Element ID	Data Element	NCPDP SCRIPT Name
		12-7ØØ8 Item Description.
8.16	Free Text Brand Name	Not Used.
8.17	Drug Manufacturer	Not Used.
8.18	Product Concentration	Not Used.
8.19	Type of Medication	Not Used.
8.20	Status of Medication	Not Used.
8.21	Indication	Not Currently Mapped. Sig fields will be available in new Sig Segment in future version of SCRIPT after eprescribing pilots. Sig 12Ø Indication (Timing Text, Code, System, Version, Text, Code, System, Version, Value, Value Units, Code, System, Version, Modifier).
8.22	Patient Instructions	DRU-Ø9Ø Free Text . Sig fields will be available in new Sig Segment in future version of SCRIPT after eprescribing pilots. Sig 14Ø Free Text.
8.23	Reaction	
8.24	Vehicle	Not Currently Mapped. Sig fields will be available in new Sig Segment in future version of SCRIPT after eprescribing pilots.Sig Ø4Ø Vehicle (Name, Name Code, Name Code System, Name Code System Version). Also Vehicle Volume, Multiple Vehicle Modifier.
8.25	Dose Indicator	Sig fields will be available in new Sig Segment in future version of SCRIPT after eprescribing pilots. Sig Ø2Ø-Ø1 Dose Indicator.
8.26	Order Number	DRU Ø8Ø-IØØ1-Ø1-1154 Reference Number. Where Ø8Ø-IØØ1-Ø2-1153 Reference Qualifier = 94 (Pharmacy or Prescriber File ID) and Ø1Ø-IØ13-Ø1-7ØØ9 Item Description Identification = P (Prescribed).
8.27	Fills	DRU - If number of Refills - Ø6Ø-IØØ9 Quantity Composite (Ø6Ø-IØØ9-Ø1-6Ø63 Quantity Qualifier (R = Number of Refills), Ø6Ø-IØØ9-Ø2-6Ø6Ø Quantity)
8.28	Quantity Ordered	DRU Ø2Ø-IØØ9 Quantity Composite (Ø2Ø-IØØ9-Ø1-6Ø63 Quantity Qualifier - Unit of Measure X-12 DE 355. Ø2Ø-IØØ9-Ø2-6Ø6Ø Quantity. Ø2Ø-IØØ9-Ø3-1131 Code List Qualifier (38 = Original Quantity)).
8.29	Order Expiration Date/Time	DRU Ø4Ø-IØØ6 Date Composite (Qualifier, Date, Format) SCRIPT value 36 = Expiration Date. CCYYMMDD.
8.30	Order Date/Time	DRU Ø4Ø-IØØ6 Date Composite (Qualifier, Date, Format) SCRIPT value 85 = Date Issued (Written Date) for original order date. CCYYMMDD.
8.31	Ordering Provider	NCPDP SCRIPT PVD Segment.
8.32	Fulfillment Instructions	DRU-Ø9Ø Free Text. Sig fields will be available in new Sig Segment in future version of SCRIPT after eprescribing pilots. Sig 14Ø Free Text.
8.33	Fulfillment History	Loops of PVD (Prescriber), PVD (Pharmacy) and DRU (Drug) Segments to relay up to 300 history occurrences, within Medication History Response.

Data Element ID	Data Element	NCPDP SCRIPT Name
8.34	Prescription Number	NCPDP SCRIPT DRU- Ø8Ø-Ø1.
8.35	Provider	Loops of PVD (Prescriber), PVD (Pharmacy) and DRU (Drug) Segments to relay up to 300 history occurrences, within Medication History Response.
8.36	Location	If provider location, contained in PVD Segment, within Medication History Response.
8.37	Dispense Date	DRU Ø4Ø-IØØ6 Date Composite (Qualifier, Date, Format) SCRIPT value LD = Last Demand (Last Fill) for original order date. CCYYMMDD. Within Medication History Response.
8.38	Quantity Dispensed	DRU Ø2Ø-IØØ9 Quantity Composite (Ø2Ø-IØØ9-Ø1-6Ø63 Quantity Qualifier - Unit of Measure X-12 DE 355. Ø2Ø-IØØ9-Ø2-6Ø6Ø Quantity. Ø2Ø-IØØ9-Ø3-1131 Code List Qualifier (38 = Original Quantity)) within Medication History Response.
8.39	Fill number	Not mapped.
8.40	Fill Status	Not mapped.

4.1.2 PERSON INFORMATION MODULE

Table 4.1.2-1 Person Information Data Element Mappings

Data Element ID	Data Element	NCPDP SCRIPT Name
1.01	Document Timestamp	Not mapped.
	Patient Information	
1.02	Person ID	PTT Ø5Ø-IØØ1-Ø1 Reference Number, qualified by PTT Ø5Ø-IØØ1-Ø2 Reference Qualifier.
1.03	Person Address	PTT Ø6Ø-IØØ4 Address.
1.04	Person Phone/Email/URL	PTT Ø7Ø-IØ16 -Ø1 Communication Number, qualified by PTT Ø7Ø IØ16 –Ø2 Code List Qualifier.
	Personal Information	
1.05	Person Name	PTT Ø3Ø-IØØ2 Name.
1.06	Gender	PTT Ø4Ø-97Ø3 Gender, coded.
1.07	Person Date of Birth	PTT Ø2Ø-27ØØ Century Date (CCYYMMDD).
1.08	Marital Status	Not mapped.
1.09	Religious Affiliation	Not mapped.
1.10	Race	Not mapped.
1.11	Ethnicity	Not mapped.

4.2 MAPPING OF X12 PATIENT REGISTRATION ATTRIBUTES INTO THE SUMMARY DOCUMENTS USING HL7 CONTINUITY OF CARE DOCUMENT (CCD) COMPONENT

This section illustrates a mapping of the X12N 271 Implementation Guide into the Insurance Providers Module of the HITSP Summary Documents Using HL7 Continuity of Care Document (CCD) Component. This X12N data content is expected to conform to both the HIPAA-Named implementation guide and the CORE Phase I Data Content Rules Version 1.0.0 Rule 154 Section 2 Subsection 2.2 – Health Plan Name and Rule 154 Section 2 Subsection 2.4 – Eligibility Dates. This is informative text only and is not a normative part of this document.

4.2.1 INSURANCE PROVIDERS MODULE

For the purposes of this mapping, the Patient in the X12 270/271 transaction can be located in either the Subscriber Loop (2000C) or Dependent Loop (2000D). The patient information is considered to be that of the Dependent if Loop 2000D is present, otherwise the patient information is considered to be that of the Subscriber in Loop 2000C.

Table 4.2.1-1 Insurance Providers Module

Data Elem. ID	Data Element	X12N 271 Name
5.01	Group Number	REF Segment/Loop 2100D if Loop 2000D present ELSE REF Segment/Loop 2100C REF01 = 6P (Group Number) or 1L (Group or Policy Number) REF02 Some plans still use code 1L in REF01 when they are unable to distinguish between the policy or group number.
5.02	Health Insurance Type	EB Segment/Loop 2110D if Loop 2000D present ELSE EB Segment/Loop 2110C EB04
5.03	Health Plan Insurance Information Source ID	NM1 Segment/Loop 2100A NM108 = id/@root NM109 = id/@extension
5.04	Health Plan Insurance Information Source Address	Not Used.
5.05	Health Plan Insurance Information Source Phone/Email/URL	PER Segment/Loop 2100A. PER04, PER06 or PER08, depending upon qualifiers present in PER03, PER05 and PER07. No URL.
5.06	Health Plan Insurance Information Source Name	NM1 Segment/Loop 2100A. NM103.
5.07	Health Plan Coverage Dates	DTP Segment/Loop 2100D if Loop 2000D present ELSE

Data Elem. ID	Data Element	X12N 271 Name
		DTP Segment/Loop 2100C Health plans which operate under CORE rules will provide this information using the eligibility date, which can be found in DTP03 when: DTP01 = 307 DTP03 = date value Other plans may also include this information in DTP03 using different values of DTP01, including 291 (Plan Dates), 346 and 347 (Plan Begin and End Dates), 356 and 357 (Eligibility Begin and End Dates) or 539 and 540 (Policy Effective and Expiration Dates).
5.08	Member ID	NM1 Segment/Loop 2100D if Loop 2000D present ELSE NM1 Segment/Loop 2100C NM108 = MI NM109
5.09	Relationship to Subscriber	INS Segment/Loop 2100D if Loop 2000D present Individual ELSE Self
5.10	Patient Address	N3/N4 Segments/Loop 2100D if Loop 2000D present ELSE N3/N4 Segments/Loop 2100C N301 = cda:addressLine[1] N302 = cda:addressLine[2] N401 = cda:city N402 = cda:state N403 = cda:postalCode N404 = cda:country (if null, US)
5.11	Patient Phone/Email/URL	PER Segment/Loop 2100D if Loop 2000D present ELSE PER Segment/Loop 2100C PER04, PER06 or PER08, depending upon qualifiers present in PER03, PER05 and PER07. No URL.
5.12	Patient Name	NM1 Segment/Loop 2100D if Loop 2000D present ELSE NM1 Segment/Loop 2100C NM103 = cda:family NM104 = cda:given[1] NM105 = cda:given[2] NM107 = cda:suffix
5.13	Patient Date of Birth	DMG Segment/Loop 2100D if Loop 2000D present ELSE DMG Segment/Loop 2100C DMG02
5.14	Financial Responsibility	Not Used.

Data Elem. ID	Data Element	X12N 271 Name
	Party Type	
5.15	Subscriber ID	NM1 Segment/Loop 2100C NM108 = MI NM109
5.16	Subscriber Address	N3/N4 Segments/Loop 2100C N301 = cda:addressLine[1] N302 = cda:addressLine[2] N401 = cda:city N402 = cda:state N403 = cda:postalCode N404 = cda:country (if null, US)
5.17	Subscriber Phone/Email/URL	PER Segment/Loop 2100CPER04, PER06 or PER08, depending upon qualifiers present in PER03, PER05 and PER07. No URL.
5.18	Subscriber Name	NM1 Segment/Loop 2100C NM103 = cda:family NM104 = cda:given[1] NM105 = cda:given[2] NM107 = cda:suffix
5.19	Subscriber Date of Birth	DMG Segment/Loop 2100C DMG02
5.20	Effective Date of Financial Responsibility	Not Used.
5.21	Financial Responsibility Party Address	Not Used.
5.22	Financial Responsibility Party Phone/Email/URL	Not Used.
5.23	Financial Responsibility Party Name	Not Used.
5.24	Health Plan Name	EB Segment/Loop 2110D if Loop 2000D present ELSE EB Segment/Loop 2110C EB05

4.3 MAPPING OF ASTM E2369 CCR ATTRIBUTES INTO THE SUMMARY DOCUMENTS USING HL7 CONTINUITY OF CARE DOCUMENT (CCD) COMPONENT

This section illustrates a mapping of the ASTM E2369 CCR standard[7] into the HITSP/C32 Summary Documents Using HL7 Continuity of Care Document (CCD) Component. This is informative text only and is not a normative part of this document.

4.3.1 PERSON INFORMATION MODULE

Table 4.3.1-1 Person Information Data Element Mappings

Data Elem. ID	Data Element	ASTM E2369-05 CCR Name
1.01	Document Timestamp	/ContinuityOfCareRecord/DateTime
	Person Information	/ContinuityOfCareRecord/Actors/Actor[ActorObjectID = /ContinuityOfCareRecord/Patient/ActorID]
1.02	Person ID	IDs
1.03	Person Address	Address
1.04	Person Phone/Email/URL	Telephone | Email | URL
1.05	Person Name	Person/Name
1.06	Gender	Person/Gender
1.07	Person Date of Birth	Person/DateOfBirth
1.08	Marital Status	/ContinuityOfCareRecord/Body/SocialHistory/SocialHistoryElement/Type[Text = 'Marital Status']/../Description
1.08	Religious Affiliation	/ContinuityOfCareRecord/Body/SocialHistory/SocialHistoryElement/Type[Text = 'Religion']/../Description
1.10	Race	/ContinuityOfCareRecord/Body/SocialHistory/SocialHistoryElement/Type[Text = 'Race']/../Description
1.11	Ethnicity	/ContinuityOfCareRecord/Body/SocialHistory/SocialHistoryElement/Type[Text = 'Ethnicity']/../Description

4.3.2 LANGUAGE MODULE

Table 4.3.2-1 Language Data Element Mappings

Data Elem. ID	Data Element	ASTM E2369-05 CCR Name
2.01	Language	/ContinuityOfCareRecord/Body/SocialHistory/SocialHistoryElement/Type[Text = 'Language']/../Description

[7] ASTM International materials used in this document have been extracted, with permission from E-2369-05 Standard Specification for Continuity of Care Record (CCR), copyright ASTM International, 100 Barr Harbor Drive, West Conshohocken, PA 19428. Copies of these standards may be retrieved through the ASTM Web Site at www.astm.org.

4.3.3 SUPPORT MODULE

Table 4.3.3-1 Support Data Element Mappings

Data Elem. ID	Data Element	ASTM E2369-05 CCR Name
3.01	Date	
3.02	Contact Type	/ContinuityOfCareRecord/Body/Support/SupportProvider/ActorRole
	Contact Information	/ContinuityOfCareRecord/Actors/Actor[ActorObjectID = /ContinuityOfCareRecord/Body/Support/SupportProvider/ActorID]
3.03	Contact Relationship	Relation
3.04	Contact Address	Address
3.05	Contact Phone/Email/URL	Telephone | Email | URL
3.06	Contact Name	Person/Name

4.3.4 HEALTHCARE PROVIDERS MODULE

Table 4.3.4-1 Healthcare Providers Data Element Mappings

Data Elem. ID	Data Element	ASTM E2369-05 CCR Name
4.01	Date	
4.02	Provider Role Coded	/ContinuityOfCareRecord/Body/HealthCareProviders/Provider/ActorRole/Code
4.03	Provider Role Free Text	/ContinuityOfCareRecord/Body/HealthCareProviders/Provider/ActorRole/Text
	Provider Information	/ContinuityOfCareRecord/Actors/Actor[ActorObjectID = /ContinuityOfCareRecord/Body/HealthCareProviders/Provider/ActorID]
4.04	Provider Type	Specialty
4.05	Provider Address	Address
4.06	Provider Phone/Email/URL	Telephone | Email | URL
4.07	Provider Name	Person/Name
4.08	Provider's Organization Name	See 6.3.4.1.
4.09	Provider's Patient ID	/ContinuityOfCareRecord/Actors/Actor/IDs[../ActorObjectID = /ContinuityOfCareRecord/Body/HealthCareProviders/Provider /ActorID]/IDs

4.3.4.1 Provider's Organization Name

The ASTM CCR is patient-centric and not provider-centric. Those clinics or organizations where the patient has been seen would be represented as an Actor. For this reason there is no explicit tagging of a provider's organization. This can be encoded in the CCR though, using the InternalCCRLink.

/ContinuityOfCareRecord/Actors/Actor [ActorObjectID = /ContinuityOfCareRecord/Actors/Actor[ActorObjectID = /ContinuityOfCareRecord/Body/HealthCareProviders/Provider/ActorID]/InternalCCRLink[LinkRelationship = 'Organization']/LinkID]/Organization/Name

4.3.5 INSURANCE PROVIDERS MODULE

Table 4.3.5-1 Insurance Providers Data Element Mappings

Data Elem. ID	Data Element	ASTM E2369-05 CCR Name
5.01	Group Number	/ContinuityOfCareRecord/Body/Payers/Payer/IDs[Type/Text = 'GroupID']/ID
5.02	Health Insurance Type	/ContinuityOfCareRecord/Body/Payers/Payer/Type
	Health Plan Information Source Information	/ContinuityOfCareRecord/Actors/Actor[ActorObjectID = /ContinuityOfCareRecord/Body/Payers/Payer/PaymentProvider/ActorID]/
5.03	Health Plan Information Source ID	IDs

Data Elem. ID	Data Element	ASTM E2369-05 CCR Name
5.04	Health Plan Insurance Information Source Address	Address
5.05	Health Plan Insurance Information Source Phone/Email/URL	Telephone | Email | URL
5.06	Health Plan Insurance Information Source Name	Organization/Name
5.07	Health Plan Coverage Dates	/ContinuityOfCareRecord/Body/Payers/Payer/DateTime
5.08	Member ID	/ContinuityOfCareRecord/Body/Payers/Payer/IDs[Type/Text = 'MemberID']/ID
5.09	Patient Relationship to Subscriber	See 6.3.5.1.
	Patient Information	/ContinuityOfCareRecord/Actors/Actor[ActorObjectID = /ContinuityOfCareRecord/Patient/ActorID]/
5.10	Patient Address	Address
5.11	Patient Phone/Email/URL	Telephone Email URL
5.12	Patient Name	Person/Name
5.13	Patient Date of Birth	Person/DateOfBirth
5.14	Financial Responsibility Party Type	/ContinuityOfCareRecord/Body/Payers/Payer/Type
5.15	Subscriber ID	/ContinuityOfCareRecord/Body/Payers/Payer/IDs[Type/Text = 'SubscriberID']/ID
	Subscriber Information	/ContinuityOfCareRecord/Actors/Actor[ActorObjectID = /ContinuityOfCareRecord/Body/Payers/Payer/Subscriber/ActorID]
5.16	Subscriber Address	Address
5.17	Subscriber Phone/Email/URL	Telephone | Email | URL
5.18	Subscriber Name	Person/Name
5.19	Subscriber Date of Birth	Person/DateOfBirth
5.20	Effective Date of Financial Responsibility	/ContinuityOfCareRecord/Body/Payers/Payer/DateTime[Type = 'Effective Date']
5.21	Financial Responsibility Party Address	Same as 5.04.
5.22	Financial Responsibility Party Phone/Email/URL	Same as 5.05.
5.23	Financial Responsibility Party Name	Same as 5.06.
5.24	Health Plan Name	/ContinuityOfCareRecord/Body/Payers/Payer/Description

4.3.5.1 Relationship to Subscriber

The ASTM CCR is patient-centric not insurance-centric, so the relationship to the subscriber is carried in the CCR as the subscriber's relationship to the patient. The mapping to this relationship is:

/ContinuityOfCareRecord/Actors/Actor[ActorObjectID =
/ContinuityOfCareRecord/Body/Payers/Payer/Subscriber/ActorID]/Relation

A logical inversion of the relationship would be required.

4.3.6 ALLERGIES AND DRUG SENSITIVITIES MODULE

Table 4.3.6-1 Allergies and Drug Sensitivities Data Element Mappings

Data Elem. ID	Data Element	ASTM E2369-05 CCR Name
	Alert Information	/ContinuityOfCareRecord/Body/Alerts/Alert/
6.01	Allergy Date	DateTime
6.02	Allergy Type	Type
6.03	Product Free-Text	Agent/Products/Product/Description/Text | Agent/Products/Product/Product/ProductName/Text
6.04	Product Coded	Agent/Products/Product/Description/Code | Agent/Products/Product/Product/ProductName/Code
6.05	Reaction Free-Text	Reaction/Description/Text
6.06	Reaction Coded	Reaction/Description/Code
6.07	Severity Free-Text	Reaction/Severity/Text
6.08	Severity Coded	Reaction/Severity/Code

4.3.7 CONDITIONS MODULE

Table 4.3.7-1 Conditions Data Element Mappings

Data Elem. ID	Data Element	ASTM E2369-05 CCR Name
	Problem	/ContinuityOfCareRecord/Body/Problems/Problem/
7.01	Problem Date	DateTime
7.02	Problem Type	Type
7.03	Problem Name	Description/Text
7.04	Problem Code	Description/Code
7.05	Treating Provider	Source/Actor/ActorID[ActorRole='Treating Provider']

4.3.8 MEDICATIONS – PRESCRIPTION AND NON-PRESCRIPTION MODULE

Table 4.3.8-1 Medications – Prescription and Non-Prescription Data Element Mappings

Data Elem. ID	Data Element	ASTM E2369-05 CCR Name
	Medication Information	/ContinuityOfCareRecord/Body/Medications/Medication/
	Directions	Directions
8.01	Free Text Sig	Description/Text
8.02	Indicate Medication Stopped	StopIndicator
8.03	Administration Timing	AdministrationTiming
8.04	Frequency	Frequency
8.05	Interval	Interval
8.06	Duration	Duration
8.07	Route	Route
8.08	Dose	Dose
8.09	Site	Site
8.10	Dose Restriction	DoseRestriction
8.12	Delivery Method	DeliveryMethod
8.21	Indication	Indication
8.24	Vehicle	Vehicle
8.25	Dose Indicator	DoseIndicator
	Product Information	Product
8.11	Product Form	Form
8.13	Coded Product Name	ProductName/Code
8.14	Coded Brand Name	BrandName/Code
8.15	Free Text Product Name	ProductName/Text
8.16	Free Text Brand Name	BrandName/Text
8.18	Product Concentration	Strength | Concentration
8.17	Drug Manufacturer	Manufacturer/ActorID
8.19	Type of Medication	Type
8.20	Status of Medication	Status
8.22	Patient Instructions	PatientInstructions
8.23	Reaction	Reaction
8.27	Fills	Refills
8.28	Quantity Ordered	Quantity
8.31	Ordering Provider	Source/Actor[ActorRole = 'Prescriber']
8.30	Order Date/Time	DateTime[Type = 'Order Date']

Data Elem. ID	Data Element	ASTM E2369-05 CCR Name
8.26	Order Number	SeriesNumber
8.29	Order Expiration Date/time	DateTime[Type = 'Order Expiration Date']
8.32	Fullfillment Instructions	FulfillmentInstructions
8.33	Fulfillment History	FulfillmentHistory
8.34	Prescription Number	Fulfillment/IDs
8.35	Provider	Fulfillment/Provider
8.36	Location	Fulfillment/Location
8.37	Dispense Date	Fulfillment/DateTime[Type = 'Dispense Date']
8.38	Quantity Dispensed	Fulfillment/Quantity
8.39	Fill Number	Fulfillment/SeriesNumber
8.40	Fill Status	Fulfillment/Status

4.3.9 PREGNANCY MODULE

Table 4.3.9-1 Pregnancy Data Element Mappings

Data Elem. ID	Data Element	ASTM E2369-05 CCR Name
9.01	Pregnancy	/ContinuityOfCareRecord/Body/Problems/Problem[Description/Code[Value = 'V22.1' & /CodingSystem = 'ICD9-CM']

4.3.10 INFORMATION SOURCE MODULE

Table 4.3.10-1 Information Source Data Element Mappings

Data Elem. ID	Data Element	ASTM E2369-05 CCR Name
10.01	Author Time	/ContinuityOfCareRecord/DateTime
10.02	Author Name	/ContinuityOfCareRecord/Actors/Actor[ActorObjectID = /ContinuityOfCareRecord/From/ActorLink/ActorID]/Person/Name | /ContinuityOfCareRecord/Actors/Actor[ActorObjectID = /ContinuityOfCareRecord/From/ActorLink/ActorID]/Organization/Name
10.03	Reference	/ContinuityOfCareRecord/References/Reference
10.04	Reference Document ID	/ContinuityOfCareRecord/References/Reference/Description/ObjectAttribute[Attribute = 'DocumentID']/AttributeValue
10.05	Reference Document URL	/ContinuityOfCareRecord/Actors/Actor[ActorObjectID = /ContinuityOfCareRecord/References/Reference/Locations/Location/ActorID]/URL /ContinuityOfCareRecord/References/Reference/Locations/Location/Description/ObjectAttribute[Attribute = 'DocumentURL']/AttributeValue

Data Elem. ID	Data Element	ASTM E2369-05 CCR Name
10.06	Information Source Name	/ContinuityOfCareRecord/Actors/Actor[ActorObjectID = ancestor-or-self /Source/Actor/ActorID[ActorRole='Informant']]/Person/Name | /ContinuityOfCareRecord/Actors/Actor[ActorObjectID = ancestor-or-self /Source/Actor/ActorID[ActorRole='Informant']]/Organization/Name

4.3.11 COMMENTS MODULE

Table 4.3.11-1 Comments Data Element Mappings

Data Elem. ID	Data Element	ASTM E2369-05 CCR Name
	Author Name	/ContinuityOfCareRecord/Actors/Actor[ActorObjectID = /ContinuityOfCareRecord/Comments/Comment/Source/ActorID]/Person/Name
	Date	/ContinuityOfCareRecord/Comments/Comment/DateTime
11.01	Free Text Comment	/ContinuityOfCareRecord/Comments/Comment/Description/Text

4.3.12 ADVANCE DIRECTIVES

Table 4.3.12-1 Advance Directives Data Element Mappings

Data Elem. ID	Data Element	ASTM E2369-05 CCR Name
	Advance Directive Information	/ContinuityOfCareRecord/Body/AdvanceDirectives/AdvanceDirective
12.01	Advance Directive Type	Type/Code
12.02	Advance Directive Free Text Type	Type/Text
12.03	Effective Date	DateTime
12.04	Custodian of the Document	InternalCCRLink/LinkID[../LinkRelationship = 'Document Custodian']

4.3.13 PROCEDURE MODULE

Table 4.3.13-1 Procedure Data Element Mappings

Data Elem. ID	Data Element	ASTM E2369-05 CCR Name
	Procedures	/ContinuityOfCareRecord/Body/Procedures
17.01	Textual report	text
	Procedure	Procedure

4.4 EXTENSIONS

During the development of the HITSP/C32 construct, it became necessary to extend the HL7 Clinical Document Architecture standard in a few places. The Consumer Empowerment Technical Committee has used the following guidelines in creating extensions:

- An extension is a collection of element or attribute declarations and rules for their application to the applicable HL7 Version 3 standard, in this case HL7 CDA Release 2.0
- A single namespace for all extension elements or attributes defined by HITSP will be defined
- The namespace for these extensions shall be urn:hl7-org:sdtc
- This namespace shall be used as the namespace for any extension elements or attributes that are defined by this implementation guide
- Each extension element shall use the same HL7 vocabularies and data types used by the relevant HL7 Version 3 standard
- Each extension element shall use the same conventions for order and naming as is used by the current HL7 tooling
- An extension element shall appear in XML where the expected RIM element of the same name would have appeared had that element not been otherwise constrained from appearing in the CDA XML schema

These guidelines are very similar to the guidelines used by the HL7 Structured Documents Technical Committee in the development of the Continuity of Care Document Implementation Guide. The HL7 Structured Documents Technical Committee has agreed to publish these extensions on the CDA Release 3.0 open issues list, and to be responsible for maintaining them.

4.4.1 EXTENSIONS TO CDA

4.4.1.1 SDTC:RACECODE

The raceCode extension allows for multiple races to be reported for a patient. Example use of this extension appears below in Figure 4.4-1.

Table 4.4.1.1-1 sdtc:raceCode Constraints

Constraint ID	Constraint
C32-[197]	Multiple <sdtc:raceCode> extension elements may appear after a CDA <raceCode> to report multiple races

Figure 4.4.1.1-1 sdtc:raceCode Extension Example

```
<raceCode code='' displayName='' codeSystem='' codeSystemName=''/>
<sdtc:raceCode code='' displayName='' codeSystem='' codeSystemName=''/>
```

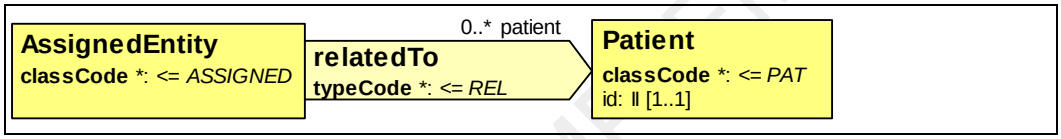
4.4.1.2 SDTC:PATIENT

The **<sdtc:patient>** extension element allows for the patient identifier used by a given provider to be reported. The provider in their role as an assigned entity is related to the patient.

Figure 4.4.1.2-1 sdtc:patient Extension Example

```
<assignedEntity>
    <id root='78A150ED-B890-49dc-B716-5EC0027B3982' extension="ProviderID"/>
    <code code='200000000X '
        displayName='Allopathic and Osteopathic Physicians'
        codeSystem='2.16.840.1.113883.6.101'
        codeSystemName='ProviderCodes'/>
    <assignedPerson>
        <name>...</name>
    </assignedPerson>
    <sdtc:patient>
        <sdtc:id root='78A150ED-B890-49dc-B716-5EC0027B3983' extension='MRN'/>
    </sdtc:patient>
</assignedEntity>
```

Figure 4.4.1.2-1 sdtc:patient Extension



4.4.1.3 SDTC:BIRTHTIME

The **<sdtc:birthTime>** element allows for the birth date of any person to be recorded. The purpose of this extension is to allow the recording of the subscriber or member of a health plan in cases where the health plan eligibility system has different information on file than the provider does for the patient. This element appears after the **<name>** of the person.

Figure 4.4.1.3-1 sdtc:birthTime Extension Example

```
<playingEntity>
    <name><given>Baby</given><family>Ross</family></name>
    <sdtc:birthTime value='20070209'/>
</playingEntity>
```

5.0 CHANGE HISTORY

The following sections provide the history of all changes made to this document since the last publication.

5.1 MAY 11, 2007

This document is now “Released for Implementation”.

5.2 SEPTEMBER 18, 2007

Section 4.2.3.1.1.5 – Marital Status. Changed assigned vocabulary from ASTM E1633 to HL7 MaritalStatus. This had been noted as a “technical error” after C32 v2.0 published.

Enhancement to supported CCD content to support additional Use Cases: Consumer Access to Clinical Information (CACI) Use Case; Medication Management Use Case; Quality Use Case. Changes in this regard included:

- Immunization module added (2.2.1.13) [from CACI Use Case definition of PHR]
- Vital Signs module added (2.2.1.14) [from CACI Use Case]
- Results module added – primarily to support summary of lab results (2.2.1.15) [from CACI Use Case]
- Encounters module added (2.2.1.16) [from CACI Use Case definition of PHR]
- Consents module/support added (2.2.1.17) [from HITSP Medication Management Work Group]
- Data element additions to Medications module (2.2.1.8). In order to maintain logical groupings, these additions resulted in changes to Data Element IDs and section numbering in the Medications module
    - Fill number (2.2.1.8.23)
    - Fill status (2.2.1.8.24), provides for indicating that the patient did not pick up the dispense
    - Order number (2.2.1.8.16)
    - Patient Education Material support added to Patient Instructions (2.2.1.8.14)

The following open issues were requested for addition to this Component at the September 2007 HITSP Technical Committee meetings. They are noted here with comments related to their future development. This will serve as a means to track these issues for ongoing development

- Content module to support reporting patient functional requirements, such as nature of functional limitations (e.g. standards exist perhaps in SSA and elsewhere), mobility (e.g. in wheelchair cannot get up on an exam table, requires high-low exam table), assistive technology, and communication (e.g. reads lips, needs translator). The CCD Functional Status module will support this and related content. Inclusion of the Functional Status module is deferred to future work for determination of the minimum necessary data content, any limitations to the range of reportable items to include, and consideration and review of terminologies that are not currently within the “library” of HITSP resources
- Medication Module (2.2.1.8) deferred to future work

- First Administration Time / Last Administration Time. At present this Component does not support direct administration events [from HITSP Quality TC]
- Differentiation between inpatient and outpatient medication orders [from HITSP Medication Management Work Group]
- "Pricing information for dispenses (amount paid, copay, benefit amount, etc)" – no apparent means available to tie pricing activities to a dispense event in CCD [from HITSP Medication Management Work Group]
- "Facility (e.g., long-term care facility)" [from HITSP Medication Management Work Group]
- "Medication needed no later than" [from HITSP Quality TC]

5.3 DECEMBER 5, 2007

The results of TC dispositions of public comments received against this Component construct have been appropriately reflected in the text and tables of the Component. Specifically, comment dispositions for the following comment topic categories have been effectively included:

- Data Element OIDs and Attributes: comments #2364, 2370, 2381, 2382, 2383, 2386, 2387, 2388, 2390 to 2400, 2473, 2475
- Document Layout (Component Template) issues: comments# 2367,2368,2372, 2373, 2376, 2377, 2379, 2380, 2385, 2476
- Consents Sharing: comments #2369, 2401
- XPath Expressions: comments #2371, 2378, 2389, 2402
- Missed content: comment 2403

The specific changes made to the specification were:

- Removed Consent module. Consensus is that if Consents are needed, the actual Consent should be accessed. This 'brief listing of available consents' may infer information that is not actually present
- Moved example 'snippets' back to the data mapping section. It was felt to be more user-friendly to have the example fragment present in the context of the narrative
- Recovered and reformatted constraint ID. Constraint IDs will be static over versions of the document, i.e., new constraints will be assigned new numbers
- Added Procedure Module
- Converted Data Mapping tables back to the two table format, and recovered the references
- Revised multiple points in 2.2.1 to make the relationship between the HITSP/C32 modules and CCD entries (Modules relate to CCE event element, rather than CCD section element)
- Numerous corrections to XPath statements to align with CCD structures. Corrected indentation of XPath statements in Data Mapping tables where noted or observed
- Introduction revised to reflect possible uses/reuses of this construct: this is not exclusively a PHR specification. Options include PHR-PHR, EHR-EHR, PHR-EHR, and even Other-Other
- Added Person module mapping to NCPDP
- Added Procedure module mapping to CCR. Mapping of additional Medication fields to CCR
- Changed vocabulary selections to constraint statements

- Recovered constraint statement for overall templateID, and corrected issues on templateID placement in examples
- Revised example for external and internal references
- Updated several points in Immunization section. Changed base class to substanceAdministration, revised data element optionality and repetition for some data elements, clarified vocabulary constraint, added data element for "reason for refusal"
- Updated LOINC codes related to Vital Signs
- Corrected URN references
- Added reference to IHE PCC TF

5.4 DECEMBER 13, 2007

Upon approval by the HITSP Panel on December 13, 2007, this document is now Released for Implementation.