HITSP CDA Content Modules Component

HITSP/C83

Submitted to:
Healthcare Information Technology Standards Panel

Submitted by:
Care Management and Health Records Domain Technical Committee
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<td>July 8, 2009</td>
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1.0 INTRODUCTION

1.1 OVERVIEW

The purpose of the HITSP CDA Content Modules Component is to define the library of components that may be used by HITSP constructs in standards based exchanges. The components are organized into modules to simplify navigation. These modules are organized along the same principals as the HL7 Continuity of Care Document.

The data elements found in these modules are based on IHE PCC Technical Framework Volume II, Release 4. That Technical Framework contains specifications for document sections that are consistent with all Implementation Guides for clinical documents currently selected for HITSP constructs.

1.2 COPYRIGHT PERMISSIONS

COPYRIGHT NOTICE

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1.3 REFERENCE DOCUMENTS

This section provides a list of key reference documents and background material.

A list of key reference documents and background material is provided in the table below. These documents can be retrieved from www.hitsp.org.

<table>
<thead>
<tr>
<th>Reference Document</th>
<th>Document Description</th>
</tr>
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<tbody>
<tr>
<td>HITSP Acronyms List</td>
<td>Lists and defines the acronyms used in this document</td>
</tr>
<tr>
<td>HITSP Glossary</td>
<td>Provides definitions for relevant terms used by HITSP documents</td>
</tr>
<tr>
<td>TN901 - Clinical Documents</td>
<td>TN901 is a reference document that provides the overall context for use of the HITSP Care Management and Health Records constructs</td>
</tr>
<tr>
<td>TN903 – Data Architecture</td>
<td>TN903 is a reference document that provides the overall context for use of the HITSP Data Architecture constructs</td>
</tr>
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1.4 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.

1.4.1 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 implement all of the required interfaces 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 or Capability with which this construct is associated.

1.4.2 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 interface 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.

1.5 DOCUMENT CONVENTIONS

1.5.1 KEY WORDS

The key words **SHALL**, **SHALL NOT**, **SHOULD**, **SHOULD NOT** and **MAY** are to be interpreted as described in RFC 2119 and will appear when used in that fashion in this *TYPEFACE*.

The key words **REQUIRED** and **OPTIONAL** are also to be interpreted as described in RFC 2119 when they are used to indicate the optionality of components used in an exchange.

1.5.2 CONSTRAINTS

Constraints in this document will appear as shown below.

C83-[DE-7.04-1] The problem type **SHALL** be coded as specified in HITSP/C80 section 2.2.1.1.4.1.2 Problem Type. The first portion identifies the type of artifact being constrained. The second portion is the identifier for that artifact, and the final portion is the sequence number of the constraint on that artifact within this document. Constraints specific to CDA usage will contain the string CDA before the final number.
2.0 COMPONENT DEFINITION

2.1 CONTEXT OVERVIEW

This specification is a library of the HITSP defined data elements that will be used for mapping to data elements from the selected standards. It is used by other HITSP components to establish the set of harmonized constraints that HITSP applies across the selected standards.

This section provides an introduction to the concepts used in describing the data elements used in HITSP specifications. The HITSP Data Elements in this document are organized into modules described in Table 2-1 below. The module identifier is given in the first column, followed by the name and definition of what appears in that module. These modules are described in more detail below in section 2.1.2 HITSP Data Elements.

<table>
<thead>
<tr>
<th>#</th>
<th>Module Name</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Personal Information</td>
<td>The personal information includes name, address, contact information, personal identification information, ethnic and racial affiliation and marital status of a person</td>
</tr>
<tr>
<td>2</td>
<td>Language</td>
<td>The language spoken by the subject</td>
</tr>
<tr>
<td>3</td>
<td>Support</td>
<td>Support includes the patient's sources of support, such as immediate family, relatives and/or guardians. This includes next of kin, caregivers, support organizations, and key contacts relative to healthcare decisions. Support providers may include providers of healthcare related services, such as a personally controlled health record, or registry of emergency contacts</td>
</tr>
<tr>
<td>4</td>
<td>Healthcare Providers</td>
<td>This includes a list of the healthcare providers and organizations that provide or have provided care to the patient</td>
</tr>
<tr>
<td>5</td>
<td>Insurance Providers and Payers</td>
<td>Insurance providers include data about the organizations or individuals who may pay for a patient's healthcare, and the relationships, demographics and identifiers of those individuals with respect to the payer. Such organizations or individuals may be health insurance plans, other payers, guarantors, parties with financial responsibility, some combination of payers or the patient directly</td>
</tr>
<tr>
<td>6</td>
<td>Allergies and Drug Sensitivities</td>
<td>This includes the allergy or intolerance conditions, severity and associated adverse reactions suffered by the patient</td>
</tr>
<tr>
<td>7</td>
<td>Conditions</td>
<td>This includes relevant clinical problems and conditions for which the patient is receiving care, including information about onset, severity, and providers treating the condition. Conditions are broader than, but include diagnoses</td>
</tr>
<tr>
<td>8</td>
<td>Medications</td>
<td>This includes the patient's prescription or non-prescription medications and medication history, and may include prescriptions, fulfillments and medication administration activities</td>
</tr>
<tr>
<td>9</td>
<td>Pregnancy</td>
<td>This includes information about the patient's current and past pregnancy status</td>
</tr>
<tr>
<td>10</td>
<td>Information Source</td>
<td>This includes information about the author or creator of the information contained within the exchange</td>
</tr>
<tr>
<td>12</td>
<td>Advanced Directive</td>
<td>This includes data defining the patient’s advance directives and supporting documentation. It can include information about the existence of living wills, healthcare proxies, and CPR and resuscitation status</td>
</tr>
<tr>
<td>13</td>
<td>Immunizations</td>
<td>This includes data describing the patient's immunization history</td>
</tr>
<tr>
<td>14</td>
<td>Vital Signs</td>
<td>This includes data about the patient’s vital signs</td>
</tr>
<tr>
<td>15</td>
<td>Test Results</td>
<td>This includes data about current and historical test results from laboratory or other diagnostic testing performed on the patient</td>
</tr>
<tr>
<td>16</td>
<td>Encounter</td>
<td>This includes data describing the interactions between the patient and clinicians. Interaction includes both in-person and non-in-person encounters such as telephone and email</td>
</tr>
<tr>
<td>17</td>
<td>Procedures</td>
<td>This includes data describing procedures performed on a patient</td>
</tr>
<tr>
<td>18</td>
<td>Family History</td>
<td>Data defining the patient’s genetic relatives in terms of possible or relevant health risk factors</td>
</tr>
</tbody>
</table>
HITSP domain committees define HITSP Data Elements in response to the business requirements identified for an information exchange. The domain committees use existing data elements defined in this specification where feasible, and identify new data elements when existing data elements do not meet the established business requirements.

The data elements defined in this release of HITSP/C83 cover the HITSP specifications based upon the HL7 R2 CDA standard. HITSP plans to incorporate this harmonization approach for all standards selected in HITSP in future releases (i.e. data element constraints from HL7 V2 messages, ASC X12, NCPDP). For example HL7 V2 message data elements will be incorporated into the currently defined HITSP/C83 data elements or new data elements will be define when one does not exist. Implementers SHALL comply with data element constraints for HITSP data elements defined section 2.1.2 and SHALL comply with the data element constraints in HITSP components, transactions and transaction packages.

### 2.1.1 COMPONENT CONSTRAINTS

This section describes the data elements of each of the modules and the constraints that are placed upon the use of the components described in these modules.

#### Table 2-2 Data Element Definition

<table>
<thead>
<tr>
<th>Identifier</th>
<th>Name</th>
<th>Definition</th>
<th>Constraints</th>
</tr>
</thead>
<tbody>
<tr>
<td>A numeric identification of the data element used to reference it</td>
<td>The name of the data element being defined</td>
<td>A concise definition of the data element</td>
<td>Additional HITSP constraints for this data element</td>
</tr>
</tbody>
</table>

#### 2.1.1.1 DATA ELEMENT IDENTIFIER

Each data element has an identifier that uniquely identifies it. The first part of the identifier is assigned based upon the module where it is found. The second part of the identifier uniquely identifies the element within the module. As new data elements are created, they are added to the end of the data module. The data element identifiers are persistent and will not be changed or reused between versions of HITSP specifications.

#### 2.1.1.2 DATA ELEMENT NAME

Each data element has a name that briefly describes the content and purpose of the data element. Data element names may be changed between versions of HITSP specifications to better describe the content and purpose.

#### 2.1.1.3 DATA ELEMENT DEFINITION

Each HITSP data element has a definition that is intended to precisely describe the purpose and structure of the data element independent from the standards that it may be mapped to. This independence allows HITSP data elements to be mapped to data elements using a variety of standards. The concise definition and mapping to the standards data element also supports harmonization of data across exchanges using...
different standards. The definition should describe the data element with sufficient enough detail to clearly indicate the purpose and content of the data element.

2.1.1.4 DATA ELEMENT CONSTRAINTS

In some cases, the data element will have additional restrictions limiting the values that can be communicated within it. HITSP may apply restrictions to a data element when it is communicated. These restrictions could be with regard to its precision, the units, and the range of legal values that may be transmitted or other restrictions as necessary. These will be described in or referred to by this column.

This column defines universal constraints that apply to data elements regardless of the Base Standard (i.e. HL7 CDA, HL7 V2 messages, NCPDP, etc.) allowing for harmonized constraints across the various Base Standards. Additional data element constraints may also be defined in the CDA-specific sections of this document (2.2.x), or in HITSP Components, Transactions, Transaction Packages or Interoperability Specifications.

2.1.2 HITSP DATA ELEMENTS

2.1.2.1 PERSONAL INFORMATION

The personal information module contains the name, address, contact information, personal identification information, ethnic and racial affiliation and marital status of the person who is the subject of this Component. See the HL7 Continuity of Care Document Section 2.5 for constraints applicable to this module.

<table>
<thead>
<tr>
<th>Identifier</th>
<th>Name</th>
<th>Definition</th>
<th>Constraints</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.01</td>
<td>Timestamp</td>
<td>The date and time that this exchange has been created</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Identifier</th>
<th>Name</th>
<th>Definition</th>
<th>Constraints</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.02</td>
<td>Person ID</td>
<td>An identifier that uniquely identifies the individual to which the exchange 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</td>
<td></td>
</tr>
<tr>
<td>1.03</td>
<td>Person Address</td>
<td>The current address of the individual to which the exchange refers. Multiple addresses are allowed and the work address may be a method of disclosing the employer</td>
<td>C83-[DE-1.03-1] The state part of an address <strong>SHALL</strong> be recorded using HITSP/C80 Section 2.2.1.1.1 State C83-[DE-1.03-2] The postal code part of an address in the United States <strong>SHALL</strong> be recorded using HITSP/C80 Section 2.2.1.1.2 Postal Code C83-[DE-1.03-3] The country part of an address <strong>SHALL</strong> be recorded using HITSP/C80 Section 2.2.1.1.3 Country</td>
</tr>
<tr>
<td>Identifier</td>
<td>Name</td>
<td>Definition</td>
<td>Constraints</td>
</tr>
<tr>
<td>------------</td>
<td>-----------------------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>1.04</td>
<td>Person Phone/Email/URL</td>
<td>A telephone number (voice or fax), e-mail address or other locator for a resource mediated by telecommunication equipment. HITSP specifies just this one data element to describe phone numbers, pagers, e-mail addresses and URLs, but these may appear in different data elements in the selected standards. The patient may designate one of more of these contact numbers as the preferred method of contact and temporary items can be entered for use on specific effective dates</td>
<td></td>
</tr>
<tr>
<td>1.05</td>
<td>Person Name</td>
<td>The individual to whom the exchange refers. Multiple names are allowed to retain birth name, maiden name, legal names and aliases as required</td>
<td></td>
</tr>
<tr>
<td>1.06</td>
<td>Gender</td>
<td>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 exchange 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</td>
<td>C83-[DE-1.06-1] Gender SHALL be coded as specified in HITSP/C80 Section 2.2.1.2.1.2 V3 Administrative Gender</td>
</tr>
<tr>
<td>1.07</td>
<td>Person Date of Birth</td>
<td>The date and time of the birth of the individual to which this Exchange 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</td>
<td></td>
</tr>
<tr>
<td>1.08</td>
<td>Marital Status</td>
<td>A value representing the domestic partnership status of a person. Marital status is important in determining insurance eligibility and other legal arrangements surrounding care. Marital status often changes during a patient’s lifetime so the data should relate to the effective date of the patient data object and not entered with multiple values like an address or contact number. This element should only have one instance reflecting the current status of the individual at the time the Exchange is produced. Former values might be part of the personal and social history</td>
<td>C83-[DE-1.08-1] Marital Status SHALL be coded as specified in HITSP/C80 Section 2.2.1.2.3.2 Marital Status CDA and HLV3</td>
</tr>
<tr>
<td>1.09</td>
<td>Religious Affiliation</td>
<td>Religious affiliation is the religious preference of the person</td>
<td>C83-[DE-1.09–1] Religious affiliation SHALL be coded as specified in HITSP/C80 Section 2.2.1.2.8 Religious Affiliation</td>
</tr>
</tbody>
</table>
### 2.1.2.2 LANGUAGE SPOKEN

This module indicates the language spoken by the subject.

**Table 2-6 Language Spoken Data Mapping Table – Definitions**

<table>
<thead>
<tr>
<th>Identifier</th>
<th>Name</th>
<th>Definition</th>
<th>Constraints</th>
</tr>
</thead>
</table>
| 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. | C83-[DE-2.01-1] Language SHALL be coded as specified in HITSP/C80 Section 2.2.1.2.9 Language  
C83-[DE-2.01-2] Sign language SHALL be treated as a separate language |

### 2.1.2.3 SUPPORT

This module contains the patient's sources of support, such as immediate family, relatives and guardians. Support information also includes next of kin, caregivers and support organizations. Support providers may include providers of healthcare related services, such as a personally controlled health record, or registry of emergency contacts.

**Table 2-7 Support Data Mapping Table – Definitions: Support**

<table>
<thead>
<tr>
<th>Identifier</th>
<th>Name</th>
<th>Definition</th>
<th>Constraints</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.01</td>
<td>Date</td>
<td>The period over which the support is provided</td>
<td></td>
</tr>
</tbody>
</table>

**Table 2-8 Support Data Mapping Table – Definitions: Contact**

<table>
<thead>
<tr>
<th>Identifier</th>
<th>Name</th>
<th>Definition</th>
<th>Constraints</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.02</td>
<td>Contact Type</td>
<td>This represents the type of support provided, such as immediate emergency contacts, next of kin, family relations, guardians, agents, et cetera</td>
<td></td>
</tr>
<tr>
<td>3.03</td>
<td>Contact Relationship</td>
<td>Identifies the relationship of the contact person to the individual for which this exchange refers</td>
<td>C83-[DE-3.03-1] The contact relationship SHALL have be coded as specified in HITSP/C80 section 2.2.1.2.4 Personal Relationships</td>
</tr>
<tr>
<td>Identifier</td>
<td>Name</td>
<td>Definition</td>
<td>Constraints</td>
</tr>
<tr>
<td>------------</td>
<td>-----------------------</td>
<td>---------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>3.04</td>
<td>Contact Address</td>
<td>The address of the contact individual or organization providing support</td>
<td>C83-[DE-3.04-1] The state part of an address <strong>SHALL</strong> be recorded using HITSP/C80 Section 2.2.1.1.1 State</td>
</tr>
<tr>
<td></td>
<td></td>
<td>to the individual for which this exchange is produced</td>
<td>C83-[DE-3.04-2] The postal code part of an address in the United States <strong>SHALL</strong> be recorded using HITSP/C80 Section 2.2.1.1.2 Postal Code</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>C83-[DE-3.04-3] The country part of an address <strong>SHALL</strong> be recorded using HITSP/C80 Section 2.2.1.1.3 Country</td>
</tr>
<tr>
<td>3.05</td>
<td>Contact Phone/ Email/ URL</td>
<td>A telephone number (voice or fax), e-mail address, or other locator for</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>the contact individual or organization providing support to the individual</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>for which this exchange is produced. One data element is used to describe</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>phone numbers, pagers, e-mail addresses and URLs</td>
<td></td>
</tr>
<tr>
<td>3.06</td>
<td>Contact Name</td>
<td>The name of the individual or organization providing support to the</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>individual for which this exchange is produced</td>
<td></td>
</tr>
</tbody>
</table>

2.1.2.4 HEALTHCARE PROVIDER

This module contains the healthcare providers involved in the current or pertinent historical care of the patient.

**Table 2-9 Healthcare Providers Data Mapping Table – Definitions: Provider**

<table>
<thead>
<tr>
<th>Identifier</th>
<th>Name</th>
<th>Definition</th>
<th>Constraints</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.01</td>
<td>Date Range</td>
<td>The period over which this provider has provided healthcare services to</td>
<td>C83-[DE-4.02-1] Provider role <strong>SHALL</strong> be coded as specified in HITSP/C80 section 2.2.3.8.1 Provider Role</td>
</tr>
<tr>
<td></td>
<td></td>
<td>the patient</td>
<td></td>
</tr>
<tr>
<td>4.02</td>
<td>Provider Role Coded</td>
<td>Provider role uses a coded value to classify providers according to the</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>role they play in the healthcare of the patient and comes from a very</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>limited set of values. The purpose of this data element is to express the</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>information often required during patient registration, identifying the</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>patient's primary care provider, the referring physician or other</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>consultant involved in the care of the patient</td>
<td></td>
</tr>
<tr>
<td>4.03</td>
<td>Provider Role Free Text</td>
<td>This unstructured text classifies providers according to the role</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>they play in the healthcare of the patient</td>
<td></td>
</tr>
</tbody>
</table>

**Table 2-10 Healthcare Providers Data Mapping Table – Definitions: Provider Entity**

<table>
<thead>
<tr>
<th>Identifier</th>
<th>Name</th>
<th>Definition</th>
<th>Constraints</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.04</td>
<td>Provider Type</td>
<td>Provider type classifies providers according to the type of license or</td>
<td>C83-[DE-4.04-1] Provider type <strong>SHALL</strong> be coded as specified in HITSP/C80 section 2.2.3.8.2 Provider Type</td>
</tr>
<tr>
<td></td>
<td></td>
<td>accreditation they hold (e.g. physician, dentist, pharmacist, et cetera)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>or the service they provide</td>
<td></td>
</tr>
<tr>
<td>Identifier</td>
<td>Name</td>
<td>Definition</td>
<td>Constraints</td>
</tr>
<tr>
<td>------------</td>
<td>-----------------------</td>
<td>---------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------</td>
</tr>
</tbody>
</table>
| 4.05       | Provider Address      | The mailing address to which written correspondence to this provider should be directed | C83-[DE-4.05-1] The state part of an address SHALL be recorded using HITSP/C80 Section 2.2.1.1.1 State  
C83-[DE-4.05-2] The postal code part of an address in the United States SHALL be recorded using HITSP/C80 Section 2.2.1.1.2 Postal Code  
C83-[DE-4.05-3] The country part of an address SHALL be recorded using HITSP/C80 Section 2.2.1.1.3 Country |
| 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, e-mail 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 |                                                                 |

2.1.2.5 INSURANCE PROVIDER

This insurance provider 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, and 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.

Table 2-11 Insurance Provider Data Mapping Table – Definitions: Payment Provider Event Entry

<table>
<thead>
<tr>
<th>Identifier</th>
<th>Name</th>
<th>Definition</th>
<th>Constraints</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.01</td>
<td>Group Number</td>
<td>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</td>
<td></td>
</tr>
<tr>
<td>5.02</td>
<td>Health Insurance Type</td>
<td>The type of health plan covering the individual, e.g., an HMO, PPO, POS, Medicare Part A/B, etc</td>
<td>C83-[DE-5.02-1] The Health Insurance Type SHALL be coded as specified in HITSP/C80 Section 2.2.2.1 Health Insurance Type</td>
</tr>
</tbody>
</table>

Table 2-12 Insurance Provider Data Mapping Table – Definitions: Payer

<table>
<thead>
<tr>
<th>Identifier</th>
<th>Name</th>
<th>Definition</th>
<th>Constraints</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.03</td>
<td>Health Plan Insurance Source ID</td>
<td>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)</td>
<td></td>
</tr>
<tr>
<td>Identifier</td>
<td>Name</td>
<td>Definition</td>
<td>Constraints</td>
</tr>
<tr>
<td>------------</td>
<td>------</td>
<td>------------</td>
<td>-------------</td>
</tr>
</tbody>
</table>
| 5.04       | Health Plan Insurance Source Address | The official mailing address to which written correspondence is to be directed | C83-[DE-5.04-1] The state part of an address SHALL be recorded using HITSP/C80 Section 2.2.1.1.1 State 
C83-[DE-5.042] The postal code part of an address in the United States SHALL be recorded using HITSP/C80 Section 2.2.1.1.2 Postal Code 
C83-[DE-5.04-3] The country part of an address SHALL be recorded using HITSP/C80 Section 2.2.1.1.3 Country |
| 5.05       | Health Plan Insurance 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, e-mail 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 |
| 5.06       | Health Plan Insurance 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 |

Table 2-13 Insurance Provider Data Mapping Table – Definitions: Patient

<table>
<thead>
<tr>
<th>Identifier</th>
<th>Name</th>
<th>Definition</th>
<th>Constraints</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.08</td>
<td>Member ID</td>
<td>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</td>
<td>C83-[DE-5.09-1] The Patient Relationship to Subscriber SHALL be coded as specified in HITSP/C80 section 2.2.2.2 Subscriber Relationship</td>
</tr>
<tr>
<td>5.09</td>
<td>Patient Relationship to Subscriber</td>
<td>Specifies only if patient is the subscriber or dependent within the context of the specified health plan</td>
<td></td>
</tr>
</tbody>
</table>
| 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 2.2.2.5.7) | C83-[DE-5.10-1] The state part of an address SHALL be recorded using HITSP/C80 Section 2.2.1.1.1 State 
C83-[DE-5.10-2] The postal code part of an address in the United States SHALL be recorded using HITSP/C80 Section 2.2.1.1.2 Postal Code 
C83-[DE-5.10-3] The country part of an address SHALL be recorded using HITSP/C80 Section 2.2.1.1.3 Country |
<table>
<thead>
<tr>
<th>Identifier</th>
<th>Name</th>
<th>Definition</th>
<th>Constraints</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.11</td>
<td>Patient Phone/Email/URL</td>
<td>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, e-mail 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.</td>
<td></td>
</tr>
<tr>
<td>5.12</td>
<td>Patient Name</td>
<td>The name of the actual patient who is a member or enrollee of a 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 2.2.2.5.12)</td>
<td></td>
</tr>
<tr>
<td>5.13</td>
<td>Patient Date of Birth</td>
<td>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)</td>
<td></td>
</tr>
<tr>
<td>5.14</td>
<td>Financial Responsibility Party Type</td>
<td>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</td>
<td></td>
</tr>
</tbody>
</table>

**Table 2-14 Insurance Provider Data Mapping Table – Definitions: Patient Information**

<table>
<thead>
<tr>
<th>Identifier</th>
<th>Name</th>
<th>Definition</th>
<th>Constraints</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.07</td>
<td>Health Plan Coverage Dates</td>
<td>The beginning and end dates of the health plan coverage of the individual. These dates may not apply equally to all benefits included in the health plan coverage. Some benefits may have waiting periods for coverage to be effective which results in a different benefit begin date. The purpose of providing this 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.</td>
<td></td>
</tr>
</tbody>
</table>

**Table 2-15 Insurance Provider Data Mapping Table – Definitions: Patient**

<table>
<thead>
<tr>
<th>Identifier</th>
<th>Name</th>
<th>Definition</th>
<th>Constraints</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.08</td>
<td>Member ID</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>5.09</td>
<td>Patient Relationship to Subscriber</td>
<td>Specifies only if patient is the subscriber or dependent within the context of the specified health plan</td>
<td>C83-[DE-5.09-1] The Patient Relationship to Subscriber SHALL be coded as specified in HITSP/C80 section 2.2.2.2 Subscriber Relationship</td>
</tr>
</tbody>
</table>
### 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 2.2.2.5.7)

**Constraints**

- C83-[DE-5.10-1] The state part of an address **SHALL** be recorded using HITSP/C80 Section 2.2.1.1.1 State
- C83-[DE-5.10-2] The postal code part of an address in the United States **SHALL** be recorded using HITSP/C80 Section 2.2.1.1.2 Postal Code
- C83-[DE-5.10-3] The country part of an address **SHALL** be recorded using HITSP/C80 Section 2.2.1.1.3 Country

### 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, e-mail 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 a 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 2.2.2.5.12)

### 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.

### Table 2-16 Insurance Provider Data Mapping Table – Definitions: Subscriber Information

<table>
<thead>
<tr>
<th>Identifier</th>
<th>Name</th>
<th>Definition</th>
<th>Constraints</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.15</td>
<td>Subscriber ID</td>
<td>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</td>
<td>C83-[DE-5.16-1] The state part of an address <strong>SHALL</strong> be recorded using HITSP/C80 Section 2.2.1.1.1 State</td>
</tr>
<tr>
<td>5.16</td>
<td>Subscriber Address</td>
<td>The official mailing address of the actual member or health plan contract holder (the true subscriber) as entered into the eligibility system of the health plan to which written correspondence is to be directed</td>
<td>C83-[DE-5.16-2] The postal code part of an address in the United States <strong>SHALL</strong> be recorded using HITSP/C80 Section 2.2.1.1.2 Postal Code</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>C83-[DE-5.16-3] The country part of an address <strong>SHALL</strong> be recorded using HITSP/C80 Section 2.2.1.1.3 Country</td>
</tr>
</tbody>
</table>
### Identifier 5.17: Subscriber Phone/Email/URL
- **Definition:** 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, e-mail 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.

### Identifier 5.18: Subscriber Name
- **Definition:** 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)

### Identifier 5.19: Subscriber Date of Birth
- **Definition:** 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)

### Table 2-17 Insurance Provider Data Mapping Table – Definitions: Guarantor Information

<table>
<thead>
<tr>
<th>Identifier</th>
<th>Name</th>
<th>Definition</th>
<th>Constraints</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.20</td>
<td>Effective Date of Financial Responsibility</td>
<td>The time span over which the Financial Responsibility Party is responsible for the payment of the patient's healthcare</td>
<td></td>
</tr>
<tr>
<td>5.21</td>
<td>Financial Responsibility Party Address</td>
<td>The official mailing address of the Financial Responsibility Party to which written correspondence is to be directed</td>
<td>C83-[DE-5.21-1] The state part of an address SHALL be recorded using HITSP/C80 Section 2.2.1.1.1 State&lt;br&gt;C83-[DE-5.21-2] The postal code part of an address in the United States SHALL be recorded using HITSP/C80 Section 2.2.1.1.2 Postal Code&lt;br&gt;C83-[DE-5.21-3] The country part of an address SHALL be recorded using HITSP/C80 Section 2.2.1.1.3 Country</td>
</tr>
<tr>
<td>5.22</td>
<td>Financial Responsibility Party Phone/Email/URL</td>
<td>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, e-mail 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.</td>
<td></td>
</tr>
<tr>
<td>5.23</td>
<td>Financial Responsibility Party Name</td>
<td>The name of the Financially Responsible Party</td>
<td></td>
</tr>
</tbody>
</table>

### Table 2-18 Insurance Provider Data Mapping Table – Definitions: Health Plan

<table>
<thead>
<tr>
<th>Identifier</th>
<th>Name</th>
<th>Definition</th>
<th>Constraints</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.24</td>
<td>Health Plan Name</td>
<td>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</td>
<td></td>
</tr>
</tbody>
</table>
### 2.1.2.6 ALLERGY/DRUG SENSITIVITY

This module contains the allergy or intolerance conditions and the associated adverse reactions suffered by the patient.

#### Table 2-19 Allergy/Drug Sensitivity Data Mapping Table – Definitions: Adverse Event Entry

<table>
<thead>
<tr>
<th>Identifier</th>
<th>Name</th>
<th>Definition</th>
<th>Constraints</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.01</td>
<td>Adverse Event Date</td>
<td>This is a date that expresses when this particular allergy or intolerance was known to be active for the patient</td>
<td>C83-[DE-6.02-1] The vocabulary used for adverse event types <strong>SHALL</strong> be coded as specified in HITSP/C80 Section 2.2.3.4.2 Allergy/Adverse Event Type</td>
</tr>
<tr>
<td>6.02</td>
<td>Adverse Event Type</td>
<td>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</td>
<td>C83-[DE-6.02-1] The vocabulary used for adverse event types <strong>SHALL</strong> be coded as specified in HITSP/C80 Section 2.2.3.4.2 Allergy/Adverse Event Type</td>
</tr>
</tbody>
</table>

#### Table 2-20 Allergy/Drug Sensitivity Data Mapping Table – Definitions: Product

<table>
<thead>
<tr>
<th>Identifier</th>
<th>Name</th>
<th>Definition</th>
<th>Constraints</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.03</td>
<td>Product Free-Text</td>
<td>This is the name or other description of the product or agent that causes the intolerance</td>
<td>C83-[DE-6.04-1] Food and substance allergies <strong>SHALL</strong> be coded as specified in HITSP/C80 Section 2.2.3.3.11 Ingredient Name</td>
</tr>
<tr>
<td>6.04</td>
<td>Product Coded</td>
<td>This value is a code describing the product</td>
<td>C83-[DE-6.04-1] Allergies to a class of medication <strong>SHALL</strong> be coded as specified in HITSP/C80 Section 2.2.3.3.9 Medication Drug Class</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>C83-[DE-6.04-2] Allergies to a specific medication <strong>SHALL</strong> be coded as specified in HITSP/C80 Section 2.2.3.3.7 Medication Brand Name or HITSP/C80 Section 2.2.3.3.8 Medication Clinical Drug Names.</td>
</tr>
</tbody>
</table>

#### Table 2-21 Allergy/Drug Sensitivity Data Mapping Table – Definitions: Reaction

<table>
<thead>
<tr>
<th>Identifier</th>
<th>Name</th>
<th>Definition</th>
<th>Constraints</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.05</td>
<td>Reaction Free-Text</td>
<td>This is the reaction that may be caused by the product or agent</td>
<td>C83-[DE-6.06-1] The reaction <strong>SHALL</strong> be coded as specified in HITSP/C80 Section 2.2.3.4.1 Allergy/Adverse Event (Reaction)</td>
</tr>
<tr>
<td>6.06</td>
<td>Reaction Coded</td>
<td>This value is a code describing the reaction</td>
<td>C83-[DE-6.06-1] The reaction <strong>SHALL</strong> be coded as specified in HITSP/C80 Section 2.2.3.4.1 Allergy/Adverse Event (Reaction)</td>
</tr>
</tbody>
</table>

#### Table 2-22 Allergy/Drug Sensitivity Data Mapping Table – Definitions: Severity

<table>
<thead>
<tr>
<th>Identifier</th>
<th>Name</th>
<th>Definition</th>
<th>Constraints</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.07</td>
<td>Severity Free-Text</td>
<td>This is a description of the level of severity of the allergy or intolerance</td>
<td>C83-[DE-6.08-1] The terminology used for severity of the adverse event <strong>SHALL</strong> be coded as specified in HITSP/C80 Section 2.2.3.4.3 Allergy/Adverse Event Severity</td>
</tr>
<tr>
<td>6.08</td>
<td>Severity Coded</td>
<td>This value is a code describing the level severity of the allergy or intolerance</td>
<td>C83-[DE-6.08-1] The terminology used for severity of the adverse event <strong>SHALL</strong> be coded as specified in HITSP/C80 Section 2.2.3.4.3 Allergy/Adverse Event Severity</td>
</tr>
</tbody>
</table>
2.1.2.7 CONDITION

This module contains relevant clinical problems. See the HL7 Continuity of Care Document Section 3.5 for constraints applicable to this module.

The template identifier for this module is 2.16.840.1.113883.3.88.11.83.7.

Table 2-23 Conditions Data Mapping Table – Problem Event Entry

<table>
<thead>
<tr>
<th>Identifier</th>
<th>Name</th>
<th>Definition</th>
<th>Constraints</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.01</td>
<td>Problem Date</td>
<td>This is the range of time of which the problem was active for the patient or subject</td>
<td></td>
</tr>
<tr>
<td>7.02</td>
<td>Problem Type</td>
<td>This is a fixed value indicating the level of medical judgment used to determine the existence of a problem</td>
<td>C83-[DE-7.02-1] The problem type SHALL be coded as specified in HITSP/C80 Section 2.2.3.1.2 Problem Type</td>
</tr>
<tr>
<td>7.03</td>
<td>Problem Name</td>
<td>This is a text description of the problem suffered</td>
<td></td>
</tr>
<tr>
<td>7.04</td>
<td>Problem Code</td>
<td>This value is a code describing the problem according to a specific vocabulary of problems</td>
<td>C83-[DE-7.04-1] The problem SHALL be coded as specified in HITSP/C80 Section 2.2.3.1.1 Problem</td>
</tr>
<tr>
<td>7.05</td>
<td>Treating Provider</td>
<td>The provider or providers treating the patient or subject for this condition</td>
<td></td>
</tr>
<tr>
<td>7.06</td>
<td>Age (at Onset)</td>
<td>The age of the patient or subject at onset of the condition.</td>
<td></td>
</tr>
<tr>
<td>7.07</td>
<td>Cause of Death</td>
<td>Indicates that this problem was one of the causes of death for the patient or subject of the condition</td>
<td></td>
</tr>
<tr>
<td>7.08</td>
<td>Age (at Death)</td>
<td>The age of the patient or subject at death</td>
<td></td>
</tr>
</tbody>
</table>

2.1.2.8 MEDICATION

This module contains a patient's prescription or non-prescription medications and pertinent medication history. See the HL7 Continuity of Care Document Section 3.9 for constraints applicable to this module.

The template identifier for this module is 2.16.840.1.113883.3.88.11.83.8.

Table 2-24 Prescription & Non-Prescription Data Mapping: Definitions - Administration Info Event Entry

<table>
<thead>
<tr>
<th>Identifier</th>
<th>Name</th>
<th>Definition</th>
<th>Constraints</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.01</td>
<td>Free Text Sig</td>
<td>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</td>
<td></td>
</tr>
<tr>
<td>8.02</td>
<td>Indicate Medication Stopped</td>
<td>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</td>
<td></td>
</tr>
<tr>
<td>8.03</td>
<td>Administration Timing</td>
<td>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</td>
<td></td>
</tr>
<tr>
<td>Identifier</td>
<td>Name</td>
<td>Definition</td>
<td>Constraints</td>
</tr>
<tr>
<td>------------</td>
<td>-----------------------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>8.04</td>
<td>Frequency</td>
<td>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)</td>
<td></td>
</tr>
<tr>
<td>8.05</td>
<td>Interval</td>
<td>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)</td>
<td></td>
</tr>
<tr>
<td>8.06</td>
<td>Duration</td>
<td>A Sig Component: for non-instantaneous administrations, indicates the length of time the administration should be continued. For example, (infuse) over 30 minutes</td>
<td></td>
</tr>
<tr>
<td>8.07</td>
<td>Route</td>
<td>A Sig Component: indicates how the medication is received by the patient (e.g., by mouth, intravenously, topically, et cetera)</td>
<td>C83-[DE-8.07-1] SHOULD be coded using value sets consistent with those specified in HITSP/C80 Section 2.2.3.4.1 Medication Route FDA¹.</td>
</tr>
<tr>
<td>8.08</td>
<td>Dose</td>
<td>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)</td>
<td>C83-[DE-8.08-1] Units MAY be present when needed. If present it SHALL be coded as specified in HITSP/C80 Section 2.2.3.6.6 Units of Measurement C83-[DE-8.08-2] 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), units SHOULD contain the preferred name of the presentation units within braces {} using the units of presentation from the NCI Thesaurus</td>
</tr>
<tr>
<td>8.09</td>
<td>Site</td>
<td>A Sig Component: The anatomic site where the medication is administered. Usually applicable to injected or topical products</td>
<td>C83-[DE-8.09-1] The Site SHALL be coded as specified in HITSP/C80 Section 2.2.3.2.1 Body Site</td>
</tr>
<tr>
<td>8.10</td>
<td>Dose Restriction</td>
<td>A Sig Component: defines a maximum or dose limit. This segment can repeat for more than one dose restriction</td>
<td></td>
</tr>
<tr>
<td>8.11</td>
<td>Product Form</td>
<td>The physical form of the product as presented to the patient. For example: tablet, capsule, liquid or ointment</td>
<td>C83-[DE-8.11-1] SHALL be coded as specified in HITSP/C80 Section 2.2.3.3.3 Medication Product Form</td>
</tr>
<tr>
<td>8.12</td>
<td>Delivery Method</td>
<td>A Sig Component: A description of how the product is administered/consumed</td>
<td></td>
</tr>
</tbody>
</table>

¹ Several HITSP selected standards use different code systems for this data element. The HITSP Foundations committee is working with the respective standards bodies to harmonize the standards. Until such time as harmonized standards are adopted, we recommend the use of a value set that is consistent with that specified by this constraint.
<table>
<thead>
<tr>
<th>Identifier</th>
<th>Name</th>
<th>Definition</th>
<th>Constraints</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.13</td>
<td>Coded Product Name</td>
<td>A code describing the product from a controlled vocabulary</td>
<td>C83-[DE-8.13-1] The coded product name <strong>SHALL</strong> be coded as specified in HITSP/C80 Section 2.2.3.3.8 Medication Clinical Drug Names.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>C83-[DE-8.13-2] When only the class of the drug is known (e.g., Beta Blocker or Sulfa Drug), it <strong>SHALL</strong> be coded as specified in HITSP/C80 Section 2.2.3.3.9 Medication Drug Class.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>C83-[DE-8.13-3] When only the medication ingredient name is known, the coded product name <strong>MAY</strong> be coded as specified in HITSP/C80 Section 2.2.3.3.11 Ingredient Name.</td>
</tr>
<tr>
<td>8.14</td>
<td>Coded Brand Name</td>
<td>A code describing the product as a branded or trademarked entity from a controlled vocabulary</td>
<td>C83-[DE-8.14-1] The brand name <strong>SHALL</strong> be coded as specified in HITSP/C80 Section 2.2.3.3.7 Medication Brand Name or 2.2.3.3.10 Medication Packaged Product.</td>
</tr>
<tr>
<td>8.15</td>
<td>Free Text Product Name</td>
<td>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.</td>
<td>C83-[DE-8.15-1] This <strong>SHOULD</strong> 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</td>
</tr>
<tr>
<td>8.16</td>
<td>Free Text Brand Name</td>
<td>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.</td>
<td>C83-[DE-8.16-1] This <strong>MAY</strong> include additional information such as strength, dose form, etc.</td>
</tr>
<tr>
<td>8.17</td>
<td>Drug Manufacturer</td>
<td>The manufacturer of the substance or product as ordered or supplied. The distributor may be supplied if the manufacturer is not known</td>
<td></td>
</tr>
<tr>
<td>8.18</td>
<td>Product Concentration</td>
<td>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</td>
<td>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. This may be implicit in the product as named or as a codified product.</td>
</tr>
<tr>
<td>8.19</td>
<td>Type of Medication</td>
<td>A classification based on how the medication is marketed (e.g., prescription, over the counter drug)</td>
<td>C83-[DE-8.19-1] The type of medication <strong>SHALL</strong> be coded as specified in HITSP/C80 Section 2.2.3.3.5 Medication Type.</td>
</tr>
<tr>
<td>8.20</td>
<td>Status of Medication</td>
<td>If the medication is Active, Discharged, Chronic, Acute, etc</td>
<td>C83-[DE-8.20-1] The medication status <strong>MAY</strong> be recorded using the CCD Medication Status observation using the value set defined in the CCD.</td>
</tr>
<tr>
<td>8.21</td>
<td>Indication</td>
<td>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</td>
<td>C83-[DE-8.21-1] The indication <strong>SHALL</strong> be coded as specified in HITSP/C80 Section 2.2.3.1.1 Problem.</td>
</tr>
<tr>
<td>8.22</td>
<td>Patient Instructions</td>
<td>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</td>
<td></td>
</tr>
<tr>
<td>Identifier</td>
<td>Name</td>
<td>Definition</td>
<td>Constraints</td>
</tr>
<tr>
<td>------------</td>
<td>--------------------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>8.23</td>
<td>Reaction</td>
<td>Any noted intended or unintended effects of the product. For example: full body rash, nausea, rash resolved</td>
<td></td>
</tr>
<tr>
<td>8.24</td>
<td>Vehicle</td>
<td>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 “Ampicillin 150mg in 50ml NS”; Aquaphor is the vehicle in “10% LCD in Aquaphor”</td>
<td>C83-[DE-8.24-1] The Vehicle shall be coded as specified in HITSP/C80 Section 2.2.3.3.12 Medication Vehicle</td>
</tr>
<tr>
<td>8.25</td>
<td>Dose Indicator</td>
<td>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”</td>
<td></td>
</tr>
</tbody>
</table>

Table 2-26 Prescription & Non-Prescription Data Mapping: Definitions - Order Information

<table>
<thead>
<tr>
<th>Identifier</th>
<th>Name</th>
<th>Definition</th>
<th>Constraints</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.26</td>
<td>Order Number</td>
<td>The order identifier from the perspective of the ordering clinician. Also known as the ‘placer number’ versus the pharmacies prescription number (or ‘filler number’)</td>
<td></td>
</tr>
<tr>
<td>8.27</td>
<td>Fills</td>
<td>The number of times that the ordering provider has authorized the pharmacy to dispense this medication</td>
<td></td>
</tr>
<tr>
<td>8.28</td>
<td>Quantity Ordered</td>
<td>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</td>
<td></td>
</tr>
<tr>
<td>8.29</td>
<td>Order Expiration Date/Time</td>
<td>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</td>
<td></td>
</tr>
<tr>
<td>8.30</td>
<td>Order Date/Time</td>
<td>The date, including time if available, when the ordering provider wrote the order/prescription</td>
<td></td>
</tr>
<tr>
<td>8.31</td>
<td>Ordering Provider</td>
<td>The person that wrote this order/prescription (may include both a name and an identifier)</td>
<td></td>
</tr>
<tr>
<td>8.32</td>
<td>Fulfillment Instructions</td>
<td>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”</td>
<td></td>
</tr>
<tr>
<td>8.33</td>
<td>Fulfillment History</td>
<td>History of dispenses for this order. Comprised of Fulfillment History Components</td>
<td></td>
</tr>
<tr>
<td>8.34</td>
<td>Prescription Number</td>
<td>Fulfillment History Component: The prescription identifier assigned by the pharmacy</td>
<td></td>
</tr>
<tr>
<td>8.35</td>
<td>Provider</td>
<td>Fulfillment History Component: The pharmacy that performed this dispense (may include both a name and an identifier)</td>
<td></td>
</tr>
<tr>
<td>8.36</td>
<td>Location</td>
<td>Fulfillment History Component: The pharmacy’s location</td>
<td></td>
</tr>
<tr>
<td>8.37</td>
<td>Dispense Date</td>
<td>Fulfillment History Component: The date of this dispense</td>
<td></td>
</tr>
<tr>
<td>8.38</td>
<td>Quantity Dispensed</td>
<td>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</td>
<td></td>
</tr>
</tbody>
</table>
### Table 2-27 Pregnancy Data Mapping Table – Definitions

<table>
<thead>
<tr>
<th>Identifier</th>
<th>Name</th>
<th>Definition</th>
<th>Constraints</th>
</tr>
</thead>
<tbody>
<tr>
<td>9.01</td>
<td>Pregnancy</td>
<td>This is a simple observation that records whether the patient is currently pregnant</td>
<td></td>
</tr>
</tbody>
</table>

### Table 2-28 Information Source Data Mapping Table – Definitions: Author

<table>
<thead>
<tr>
<th>Identifier</th>
<th>Name</th>
<th>Definition</th>
<th>Constraints</th>
</tr>
</thead>
<tbody>
<tr>
<td>10.01</td>
<td>Author Time</td>
<td>The time at which this information was created</td>
<td></td>
</tr>
<tr>
<td>10.02</td>
<td>Author Name</td>
<td>The name of the person who created the information content</td>
<td></td>
</tr>
<tr>
<td>10.03</td>
<td>Reference</td>
<td>A reference to the original document from which this information was obtained</td>
<td></td>
</tr>
<tr>
<td>10.04</td>
<td>Reference Document ID</td>
<td>Identifier of the external document that was referenced</td>
<td></td>
</tr>
<tr>
<td>10.05</td>
<td>Reference Document URL</td>
<td>A URL from which this document may be retrieved.</td>
<td>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</td>
</tr>
</tbody>
</table>

### Table 2-29 Information Source Data Mapping Table – Definitions: Information Source

<table>
<thead>
<tr>
<th>Identifier</th>
<th>Name</th>
<th>Definition</th>
<th>Constraints</th>
</tr>
</thead>
<tbody>
<tr>
<td>10.06</td>
<td>Information Source Name</td>
<td>The name of the person or organization that provided the information</td>
<td></td>
</tr>
</tbody>
</table>

### 2.1.2.11 ADVANCE DIRECTIVE

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.
### Table 2-30 Advance Directives Data Mapping Table – Definitions

<table>
<thead>
<tr>
<th>Identifier</th>
<th>Name</th>
<th>Definition</th>
<th>Constraints</th>
</tr>
</thead>
<tbody>
<tr>
<td>12.01</td>
<td>Advance Directive</td>
<td>This is a coded value describing the type of the Advance Directive</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Type</td>
<td></td>
<td>C83-[DE-12.02-1] The advance directive SHALL be coded as specified in HITSP/C80 Section 2.2.3.10.1 Advance Directive Type</td>
</tr>
<tr>
<td>12.02</td>
<td>Advance Directive</td>
<td>Free text comment to describe the Advance Directive</td>
<td>C83-[DE-12.02-1] The advance directive SHALL be coded as specified in HITSP/C80 Section 2.2.3.10.1 Advance Directive Type</td>
</tr>
<tr>
<td></td>
<td>Free Text Type</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12.03</td>
<td>Effective Date</td>
<td>The effective date for the Advance Directive</td>
<td></td>
</tr>
<tr>
<td>12.04</td>
<td>Custodian of the</td>
<td>Name, address or other contact information for the person or organization</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Document</td>
<td>that can provide a copy of the document</td>
<td></td>
</tr>
</tbody>
</table>

### 2.1.2.12 IMMUNIZATION

This module contains data describing the patient's immunization history.

### Table 2-31 Immunizations Data Mapping Table – Definitions: Immunization Event Entry

<table>
<thead>
<tr>
<th>Identifier</th>
<th>Name</th>
<th>Definition</th>
<th>Constraints</th>
</tr>
</thead>
<tbody>
<tr>
<td>13.01</td>
<td>Refusal</td>
<td>A flag that the immunization event did not occur. The nature of the refusal</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>(e.g., patient refused, adverse reaction)</td>
<td></td>
</tr>
<tr>
<td>13.02</td>
<td>Administered Date</td>
<td>The date and time of substance was administered or refused, i.e., when the</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>immunization was administered to the patient, or refused by the patient</td>
<td></td>
</tr>
<tr>
<td>13.03</td>
<td>Medication Series Number</td>
<td>Indicate which in a series of administrations a particular administration represents (e.g. “hepatitis B vaccine number 2”)</td>
<td></td>
</tr>
<tr>
<td>13.04</td>
<td>Reaction</td>
<td>Any noted intended or unintended effects of the product. For example: full body rash, nausea, rash resolved</td>
<td></td>
</tr>
<tr>
<td>13.05</td>
<td>Performer</td>
<td>The person that administered the immunization to the patient (may include both a name and an identifier)</td>
<td></td>
</tr>
</tbody>
</table>

### Table 2-32 Immunizations Data Mapping Table – Definitions: Medication Information

<table>
<thead>
<tr>
<th>Identifier</th>
<th>Name</th>
<th>Definition</th>
<th>Constraints</th>
</tr>
</thead>
<tbody>
<tr>
<td>13.06</td>
<td>Coded Product Name</td>
<td>A code describing the product from a controlled vocabulary</td>
<td>C83-[DE-13.06-1] Immunizations SHALL be coded as specified in HITSP/C80 Section 2.2.3.5.1 Vaccines Administered.</td>
</tr>
<tr>
<td>13.07</td>
<td>Free Text Product Name</td>
<td>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</td>
<td>C83-[DE-13.07-1] 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.</td>
</tr>
<tr>
<td>13.08</td>
<td>Drug Manufacturer</td>
<td>The manufacturer of the substance or product as ordered or supplied. The distributor may be supplied if the manufacturer is not known</td>
<td></td>
</tr>
<tr>
<td>13.09</td>
<td>Lot Number</td>
<td>The manufacturer's production lot number for the administered product</td>
<td></td>
</tr>
<tr>
<td>13.10</td>
<td>Refusal Reason</td>
<td>When an immunization is refused, this provides a coded representation of the reason for refusing the immunization</td>
<td>C83-[DE-13.10-1] The reason for refusal SHALL be coded as specified in HITSP/C80 Section 2.2.3.5.3 No Immunization Reason</td>
</tr>
</tbody>
</table>
2.1.2.13 VITAL SIGN

This module contains current and relevant historical vital signs for the patient. Vital Signs are a subset of Results (see section 2.1.2.14), but are reported in this section to follow clinical conventions. 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.

<table>
<thead>
<tr>
<th>Identifier</th>
<th>Name</th>
<th>Definition</th>
<th>Constraints</th>
</tr>
</thead>
<tbody>
<tr>
<td>14.01</td>
<td>Vital Sign Result ID</td>
<td>An identifier for this specific vital sign observation</td>
<td></td>
</tr>
<tr>
<td>14.02</td>
<td>Vital Sign Result Date/Time</td>
<td>The biologically relevant date/time for the vital sign observation</td>
<td></td>
</tr>
<tr>
<td>14.03</td>
<td>Vital Sign Result Type</td>
<td>A coded representation of the vital sign observation performed</td>
<td>C83-[DE-14.03-1] Vital signs SHOULD be coded as specified in HITSP/C80 Section 2.2.3.6.4 Vital Sign Result Type.</td>
</tr>
<tr>
<td>14.04</td>
<td>Vital Sign Result Status</td>
<td>Status for this vital sign observation, e.g., complete, preliminary</td>
<td></td>
</tr>
<tr>
<td>14.05</td>
<td>Vital Sign Result Value</td>
<td>The value of the result, including units of measure if applicable</td>
<td></td>
</tr>
<tr>
<td>14.06</td>
<td>Vital Sign Result Interpretation</td>
<td>An abbreviated interpretation of the vital sign observation, e.g., normal, abnormal, high, etc</td>
<td></td>
</tr>
<tr>
<td>14.07</td>
<td>Vital Sign Result Reference Range</td>
<td>Reference range(s) for the vital sign observation</td>
<td></td>
</tr>
</tbody>
</table>

2.1.2.14 RESULT

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 2.1.2.13 above).

<table>
<thead>
<tr>
<th>Identifier</th>
<th>Name</th>
<th>Definition</th>
<th>Constraints</th>
</tr>
</thead>
<tbody>
<tr>
<td>15.01</td>
<td>Result ID</td>
<td>An identifier for this specific observation</td>
<td></td>
</tr>
<tr>
<td>15.02</td>
<td>Result Date/Time</td>
<td>The biologically relevant date/time for the observation</td>
<td></td>
</tr>
<tr>
<td>15.03</td>
<td>Result Type</td>
<td>A coded representation of the observation performed</td>
<td>C83-[DE-15.03-1] 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) C83-[DE-15.03-2] Result Type for laboratory results SHOULD be coded as specified in HITSP/C80 Section 2.2.3.6.1 Laboratory Observations.</td>
</tr>
<tr>
<td>15.04</td>
<td>Result Status</td>
<td>Status for this observation, e.g., complete, preliminary</td>
<td></td>
</tr>
<tr>
<td>15.05</td>
<td>Result Value</td>
<td>The value of the result, including units of measure if applicable</td>
<td></td>
</tr>
<tr>
<td>15.06</td>
<td>Result Interpretation</td>
<td>An abbreviated interpretation of the observation, e.g., normal, abnormal, high, etc</td>
<td></td>
</tr>
<tr>
<td>15.07</td>
<td>Result Reference Range</td>
<td>Reference range(s) for the observation</td>
<td></td>
</tr>
</tbody>
</table>
2.1.2.15 ENCOUNTER

This module contains data describing the interactions between the patient and clinicians. Interaction includes both in-person and non-in-person encounters such as telephone and email communication. See the HL7 Continuity of Care Document Section 3.15 for constraints applicable to this module.

The template identifier for this module is 2.16.840.1.113883.3.88.11.83.16.

<table>
<thead>
<tr>
<th>Identifier</th>
<th>Name</th>
<th>Definition</th>
<th>Constraints</th>
</tr>
</thead>
<tbody>
<tr>
<td>16.01</td>
<td>Encounter ID</td>
<td>An identifier for this Encounter</td>
<td></td>
</tr>
<tr>
<td>16.02</td>
<td>Encounter Type</td>
<td>This is a coded value describing the type of the Encounter</td>
<td>C83-[DE-16.02-1] Encounter Type SHOULD be coded as specified in HITSP/C80 Section 2.2.3.9.3 Encounter Type.</td>
</tr>
<tr>
<td>16.03</td>
<td>Encounter Free Text</td>
<td>Free text describing the Encounter Type</td>
<td></td>
</tr>
<tr>
<td>16.04</td>
<td>Encounter Date/Time</td>
<td>The date and time of the Encounter, including duration if pertinent</td>
<td></td>
</tr>
<tr>
<td>16.05</td>
<td>Encounter Provider</td>
<td>Name and other information for the person or organization performed or hosted the Encounter</td>
<td></td>
</tr>
</tbody>
</table>

2.1.2.16 PROCEDURE

This module contains a coded entry indicating a procedure performed on a patient.

The template identifier for this module is 2.16.840.1.113883.3.88.11.83.17.

<table>
<thead>
<tr>
<th>Identifier</th>
<th>Name</th>
<th>Definition</th>
<th>Constraints</th>
</tr>
</thead>
<tbody>
<tr>
<td>17.01</td>
<td>Procedure ID</td>
<td>An identifier for this Procedure</td>
<td></td>
</tr>
<tr>
<td>17.02</td>
<td>Procedure Type</td>
<td>This is a coded value describing the type of the Procedure</td>
<td></td>
</tr>
<tr>
<td>17.03</td>
<td>Procedure Free Text</td>
<td>Free text describing the Procedure</td>
<td></td>
</tr>
<tr>
<td>17.04</td>
<td>Procedure Date / Time</td>
<td>The date and time of the Procedure, including duration if pertinent</td>
<td></td>
</tr>
<tr>
<td>17.05</td>
<td>Procedure Provider</td>
<td>Name and other information for the person or organization performed or hosted the Procedure</td>
<td></td>
</tr>
</tbody>
</table>

2.1.2.17 FAMILY HISTORY

This module contains data defining the patient’s genetic risk factors.
## Table 2-37 Family History Data Mapping Table – Definitions

<table>
<thead>
<tr>
<th>Identifier</th>
<th>Name</th>
<th>Definition</th>
<th>Constraints</th>
</tr>
</thead>
<tbody>
<tr>
<td>18.01</td>
<td>Pedigree</td>
<td>A pedigree is a graphic, visual presentation of a family's health history and genetic relationships for the purpose of health risk assessment. It can provide a mechanism to identify the distribution of a medical condition or a related condition in a group of close relatives. If the condition or related condition clusters among relatives or follows a clear pattern of inheritance, then the risk for the condition can be assessed for the unaffected family members. It is important that the structured data from which the pedigree is derived also be present, because identification of inherited conditions can be complex requiring clinical decision support algorithms.</td>
<td></td>
</tr>
<tr>
<td>18.02</td>
<td>Family Member Information</td>
<td>Family member information, including demographic data, health history, genetic test results, and relationships to other family members</td>
<td></td>
</tr>
<tr>
<td>18.03</td>
<td>Family Member Demographics</td>
<td>Demographic information for the family member</td>
<td></td>
</tr>
</tbody>
</table>
| 18.04      | Family Member Relationship    | Relationship of Family Member to Patient or other Family Member. Record information on relatives including 1<sup>st</sup> and 2<sup>nd</sup> degree, such as:  
- Mother  
- Siblings  
- Children  
- Aunts/uncles  
- Cousins  
- Grandchildren  
- Nieces/Nephews  
This data element also allows the recording of the natural father and mother, and the adoptive status. Consanguinity can be determined by including relationships between consanguineous individuals. Note: In order to record information for 3<sup>rd</sup> degree relatives and beyond, implementations can provide recursive entries. For example, the first entry could state a "grandmother", then the next entry could state the "grandmother’s mother" which would be a 3<sup>rd</sup> degree relative. This enables any degree on relatives.                                                                                           | C83-[DE-18.04-1] The Family Member Relationship (to Patient) **SHALL** be coded as specified in HITSP/C80 Section 2.2.1.2.5 Family Relationship Type |
<p>| 18.05      | Family Member Relationship Free Text | Free Text Data Entry for each relative used to note special cases. Examples include gamete donor and/or surrogate mother                                                                                       |                                                                                               |
| 18.06      | Family Member Identifier      | An identifier used to track the family member in communications between systems                                                                                                                       |                                                                                               |
| 18.07      | Family Member Name            | The name of the Family Member, used to distinguish family members textually, and need not be the actual legal name of the family members                                                                   |                                                                                               |
| 18.08      | Family Member Date of Birth   | Date of Birth of Family Member                                                                                                                                                                         |                                                                                               |
| 18.24      | Family Member Administrative Gender | The Administrative Gender is used to refer to administrative sex rather than biological sex and therefore should easily be classified into female and male. Biological sex is recorded separately when necessary.                                                                 | C83-[DE-18.24-1] Gender <strong>SHALL</strong> be coded as specified in HITSP/C80 Section 2.2.1.2.1.2 V3 Administrative Gender                                 |</p>
<table>
<thead>
<tr>
<th>Identifier</th>
<th>Name</th>
<th>Definition</th>
<th>Constraints</th>
</tr>
</thead>
<tbody>
<tr>
<td>18.09</td>
<td>Family Member Race</td>
<td>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</td>
<td>C83-[DE-18.09-1] Race SHALL be coded as specified in HITSP/C80 Section 2.2.1.2.7 Race</td>
</tr>
<tr>
<td>18.10</td>
<td>Family Member Ethnicity</td>
<td>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</td>
<td>C83-[DE-18.10-1] Ethnicity SHALL be coded as specified in HITSP/C80 Section 2.2.1.2 Ethnicity</td>
</tr>
<tr>
<td>18.11</td>
<td>Family Member Medical History</td>
<td>Information including current and past problems the family member, and genetic test results</td>
<td></td>
</tr>
<tr>
<td>18.12</td>
<td>Family Member Condition</td>
<td>Condition is the generic term used in the model to designate conditions, problems, diagnoses, etc.</td>
<td>C83-[DE-18.12-1] The problem type SHALL be coded as specified in HITSP/C80 Section 2.2.3.1.2 Problem Type. C83-[DE-18.12-2] The problem SHALL be coded as specified in HITSP/C80 Section 2.2.3.1.1 Problem</td>
</tr>
<tr>
<td>18.23</td>
<td>Family Member Age</td>
<td>The real or approximate age of the family member</td>
<td></td>
</tr>
<tr>
<td>18.13</td>
<td>Family Member Age (at Onset)</td>
<td>The age (real or approximate) of the family member at the onset of the illness</td>
<td></td>
</tr>
<tr>
<td>18.14</td>
<td>Family Member Cause of Death</td>
<td>An indicator that a particular problem was the cause of death of the family member</td>
<td></td>
</tr>
<tr>
<td>18.15</td>
<td>Family Member Age (at Death)</td>
<td>The age (real or approximate) of the family member at death</td>
<td></td>
</tr>
<tr>
<td>18.16</td>
<td>Family Member Biological Sex</td>
<td>The biological sex of the Family Member. To be used when Administrative Sex (male/female) is not adequate to describe the family member's sex</td>
<td></td>
</tr>
<tr>
<td>18.17</td>
<td>Family Member Multiple Birth Status</td>
<td>Specifies if the family member is a twin, triplet etc and whether identical or fraternal</td>
<td></td>
</tr>
<tr>
<td>18.18</td>
<td>Family Member Genetic Test Information</td>
<td>Information about genetic test results for family members</td>
<td>C83-[DE-18.18-1] Components of a Genetic Laboratory Test SHALL be coded as specified in HITSP/C80 Section 2.2.3.11 Genetic Testing</td>
</tr>
<tr>
<td>18.19</td>
<td>Family Member Genetic Test Code</td>
<td>The code for the genetic lab test</td>
<td></td>
</tr>
<tr>
<td>18.20</td>
<td>Family Member Genetic Test Name</td>
<td>The name of the genetic lab test</td>
<td></td>
</tr>
<tr>
<td>18.21</td>
<td>Family Member Genetic Test Result</td>
<td>The result produced by the genetic lab test</td>
<td></td>
</tr>
<tr>
<td>18.22</td>
<td>Family Member Genetic Test Date</td>
<td>The date of the genetic lab test</td>
<td></td>
</tr>
</tbody>
</table>

2.1.2.18 SOCIAL HISTORY

The text adapted from HL7 CDA Release 2 - Continuity of Care Document (CCD), Section 3.7 Social History, begins here:
This module contains data defining the patient’s occupational, personal (e.g. lifestyle), social, and environmental history and health risk factors, as well as administrative data such as marital status, race, ethnicity and religious affiliation.

The text adapted from HL7 CDA Release 2 - Continuity of Care Document (CCD), Section 3.7 Social History, ends here.

### Table 2-38 Social History Data Mapping Table – Definitions: Social History Event Entry

<table>
<thead>
<tr>
<th>Identifier</th>
<th>Name</th>
<th>Definition</th>
<th>Constraints</th>
</tr>
</thead>
<tbody>
<tr>
<td>19.01</td>
<td>Social History Date</td>
<td>This is the range of time of which the social history event was active for the patient or subject</td>
<td></td>
</tr>
<tr>
<td>19.02</td>
<td>Social History Type</td>
<td>This is a coded value indicating the type of social history observation</td>
<td>C83-[DE-19.02-1] The Social History type SHALL be coded as specified in HITSP/C80 Section 2.2.2.4 Social History Type</td>
</tr>
<tr>
<td>19.03</td>
<td>Social History Free Text</td>
<td>This is a text description of the social history</td>
<td></td>
</tr>
<tr>
<td>19.04</td>
<td>Social History Observed Value</td>
<td>A value describing the social history</td>
<td></td>
</tr>
</tbody>
</table>

#### 2.1.2.19 MEDICAL EQUIPMENT

Medical Equipment includes implanted and external medical devices and equipment that a patient’s health status depends on, as well as any pertinent equipment or device history.

The definition of this Module is for future development.

#### 2.1.2.20 FUNCTIONAL STATUS

The functional status module contains data defining the patient’s functional status with respect to Ambulatory ability, Mental status or competency, Activities of Daily Living, including bathing, dressing, feeding, grooming, Home / living situation having an effect on the health status of the patient or their Ability to care for themselves.

The definition of this Module is for future development.

#### 2.1.2.21 PLAN OF CARE

The plan of care contains data defining prospective or intended orders, interventions, encounters, services, and procedures for the patient.

The definition of this Module is for future development.

#### 2.1.3 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.
Table 2-39 Component Dependencies

<table>
<thead>
<tr>
<th>Standard/HITSP Component</th>
<th>Depends On (Name of standard/HITSP Component that it depends on)</th>
<th>Dependency Type (Pre-condition, Post-condition, General)</th>
<th>Purpose (Reason for this dependency)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HITSP/C83 - CDA Content Modules</td>
<td>HITSP/C80 - Clinical Document and Message Terminology</td>
<td>General</td>
<td>Identifies vocabulary constrained by this Component to be applied within the exchange</td>
</tr>
</tbody>
</table>

2.2 RULES FOR IMPLEMENTING COMPONENTS IN CDA

This section describes the rules for implementing the data elements described within this section when they are used in the context of the HL7 Clinical Document Architecture (CDA).

For CDA documents, this specification makes use of Templates as defined by the HL7 Version 3 Standard: Specification and Use of Reusable Constraint Templates Draft Standard for Trial Use. These templates declare a specific set of constraints on a document, section or clinical statement, and are assigned an OID to be uniquely identified over time. A clinical document created using this specification can then assert conformance to a template by the inclusion of the OID as the value for a templateID element in a document, section, or clinical statement. These may have multiple templateIDs provided there are no conflicting requirements as a result of aggregating the rules.

Template may be nested – a template may require the presence of child templates in order to satisfy an exchange requirement. A document level template can require the presence of section level templates, which in turn may require entry templates to ensure a minimum level of information to be exchanged in a given context.

All HITSP constructs that reference components from this specification shall follow the applicable constraints from this specification.

All clinical documents specified using these components must conform to the Medical Document Specifications defined in the IHE PCC Technical Framework Volume II, Release 4. Furthermore, these documents are also defined by HITSP for the US Realm. As such, they are required to include the information shown below.

Figure 2-1 Rules for Implementing Clinical Documents

```
<ClinicalDocument>
  <realmCode code='US'/>
  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.1'/>
  <templateId root='2.16.840.1.113883.10.20.3'/>
</ClinicalDocument>
```

C83-[CDA-1] A clinical document created using this specification SHALL contain a `<realmCode>` element with a value of US in the code attribute indicating that it conforms to US realm requirements.

C83-[CDA-2] A clinical document created using this specification SHALL contain the `<templateId>` element with a value of 1.3.6.1.4.1.19376.1.5.3.1.1.1 in the root attribute and no extension attribute indicating that it conforms to the IHE PCC Medical Documents specification.

C83-[CDA-3] A clinical document created using this specification SHALL contain the `<templateId>` element with a value of 2.16.840.1.113883.10.20.3 in the root attribute and no extension attribute, indicating that it conforms to the HL7 General
Header constraints defined in the HL7 Implementation Guide for History and Physical Notes\(^2\)

C83-[CDA-4] A clinical document created using this specification MAY include other data elements not defined in this specification in an instance of a Content Module. Receivers are not required to process these elements and if they do not understand them, they SHALL 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.

C83-[CDA-5] If a data element coded value may be derived from another data element coded value, the creator of a clinical document 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.

C83-[CDA-6] Required modules from this specification SHALL be present and follow the associated constraints.

C83-[CDA-7] Content Modules explicitly excluded from a clinical document specification SHALL NOT be present.

C83-[CDA-8] Optional modules, when present, SHALL follow the associated constraints if that module asserts conformance to this specification, i.e., includes the associated templates.

C83-[CDA-9] Additional CCD entry elements (the equivalent to Content Modules in this specification) MAY be present. The receiver 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.

The subsections below describe the specific document sections and entries defined 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 defines the section and entry Content Modules utilized by HITSP/C80 Clinical Documents and Message Terminology based upon HL7 CDA R2. Therefore the constraints are related to Content Modules and data mapping within the Content Modules.

The conventions for the mapping tables specified in this Component are shown below.

### Table 2-40 Mapping Tables Conventions

<table>
<thead>
<tr>
<th>CDA Data Location</th>
<th>HITSP Data Element Identifier and Name</th>
<th>O/R</th>
<th>Additional Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>The location of the data element in the CDA Document.</td>
<td>The numeric identifier and name of the data element from section 2.1.2 above.</td>
<td>This column indicates whether the data element is required or not, and whether it is repeatable.</td>
<td>References the sections providing additional explanation or constraints for use in the standard</td>
</tr>
</tbody>
</table>

**CDA Location**

This column identifies the location of the data element within CDA Document using W3C XPath Notation.

**HITSP Data Element ID and Name**

This column maps the CDA data element to the HITSP data element from Section 2.1.2 above. The existence of this mapping can be translated into the following conformance statement:

The (standard data element in the table) SHALL be communicated applying all constraints defined for (the HITSP Data Element in the table).

\(^2\) Given that this is a U.S. Realm specification, the template id 2.16.840.1.113883.10.20.3 is already required by the PCC template for medical documents. We include this information here for completeness.
Optionality/Repeatability

This column identifies the conditions under which the data element is sent, and whether it may be repeated in the exchange. The column contains two fields separate by a slash (/). The first field indicates when the data element is to be sent and the list of values used in that column is described below in Table 2-41.

<table>
<thead>
<tr>
<th>Value</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>R</td>
<td>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 where the standard permits. Some standards may not permit an unknown value at all.</td>
</tr>
<tr>
<td>R2</td>
<td>Required if known - If the sending application has data for the data element, it is REQUIRED to populate the data element. If the value is not known, the data element need not be sent.</td>
</tr>
<tr>
<td>O</td>
<td>OPTIONAL - Data elements that are marked optional may be sent at the choice of the sending application. An optional element need not be sent, but when it is sent, the data 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.</td>
</tr>
<tr>
<td>C</td>
<td>Conditional - Data elements that are marked conditional (C) are REQUIRED to be sent when the conditions specified in the HITSP additional specifications column are true. The conditions under which the data element is to be exchanged will be specified as a constraint on the data element in the last column.</td>
</tr>
</tbody>
</table>

The second field indicates whether the data element is repeatable and the list of values used is described below in Table 2-42.

<table>
<thead>
<tr>
<th>Value</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>No. The data element SHALL NOT be repeated.</td>
</tr>
<tr>
<td>Y</td>
<td>Yes. The data element MAY be repeated.</td>
</tr>
</tbody>
</table>

Further constraints on repeatability with respect to minimum or maximum number of occurrences will be defined as more specific constraints in the last column.

Data Element Constraints

This column references additional sections providing more explanation about the use of the data element, or the constraints that are placed upon it by this specification (e.g., regarding optionality, cardinality and value sets to be used).

2.2.1 CDA SECTIONS

Two types of content components are specified in this section, they are:

- CDA Entries – a collection of Data Elements pertaining to a single instance of the specified concept. For example, the Allergy/Drug Sensitivity Entry Module describes all the Data Elements for one allergy.
- CDA Sections – a collection Entries pertaining to a single specified concept. For example, the Allergies and Other Adverse Reactions Section can contain a list of allergies (multiple Entry Content Modules).

CDA Sections are typically selected from specifications created by SDOs, such as the HL7 CCD, other HL7 Implementation Guides, and IHE Integration Profiles. In order to synchronize the sections, certain
template IDs have changed from the previous IDs specified in HITSP/C32. Template ID changes also may have been needed in order to harmonize previously existing HITSP CDA based constructs.

Definitions for the document sections below are adapted from the IHE Patient Care Coordination Technical Framework, Volume II, Release 4.0, and are used with permission.

Note: We have added template identifiers to each of the sections that follow. These template identifiers are recommended be used in exchanges, but are not required due to restrictions on major change. It is possible that these identifiers could be required in future editions of this specification.

2.2.1.1 PAYERS SECTION

The Payers Section contains data on the patient’s payers, whether a ‘third party’ insurance, self-pay, other payer or guarantor, or some combination. 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 section is 2.16.840.1.113883.3.88.11.83.101
C83-[CT-101-1] This section SHALL conform to the IHE Payers Section template, and SHALL contain a templateId element whose root attribute is 1.3.6.1.4.1.19376.1.5.3.1.1.5.3.7
C83-[CT-101-2] This section SHALL include entries from the Insurance Provider module when this information is known.

2.2.1.2 ALLERGIES AND OTHER ADVERSE REACTIONS SECTION

The Allergies and Other Adverse Reactions Section contains data on the substance intolerances 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.

The template identifier for this section is 2.16.840.1.113883.3.88.11.83.102
C83-[CT-102-1] This section SHALL include entries from the Allergy/Drug Sensitivity module.
C83-[CT-102-2] This section SHALL conform to the IHE Allergies and Other Adverse Reactions Section template, and SHALL contain a templateId element whose root attribute is 1.3.6.1.4.1.19376.1.5.3.1.3.13.

2.2.1.3 PROBLEM LIST SECTION

The Problem List Section contains data on the problems currently being monitored for the patient.

The template identifier for this section is 2.16.840.1.113883.3.88.11.83.103
C83-[CT-103-1] This section SHALL include entries from the Condition module.
C83-[CT-103-2] This section SHALL conform to the IHE Active Problems Section template, and SHALL contain a templateId element whose root attribute is 1.3.6.1.4.1.19376.1.5.3.1.3.6.

2.2.1.4 HISTORY OF PAST ILLNESS SECTION

The History of Past Illness Section contains data about problems the patient suffered in the past.

The template identifier for this section is 2.16.840.1.113883.3.88.11.83.104
C83-[CT-104-1] This section SHALL include entries from the Condition module.
2.2.1.5 CHIEF COMPLAINT SECTION

The Chief Complaint Section contains information about the patient's chief complaint.

The template identifier for this section is 2.16.840.1.113883.3.88.11.83.105

2.2.1.6 REASON FOR REFERRAL SECTION

The Reason for Referral Section contains information about the reason that the patient is being referred.

The template identifier for this section is 2.16.840.1.113883.3.88.11.83.106

2.2.1.7 HISTORY OF PRESENT ILLNESS SECTION

The History of Present Illness Section contains information about the sequence of events preceding the patient's current complaints.

The template identifier for this section is 2.16.840.1.113883.3.88.11.83.107

2.2.1.8 LIST OF SURGERIES SECTION

The List of Surgeries Section provides a list of surgeries the patient has received.

The template identifier for this section is 2.16.840.1.113883.3.88.11.83.108
2.2.1.9 FUNCTIONAL STATUS SECTION

The template identifier for this section is 2.16.840.1.113883.3.88.11.83.109

The Functional Status Section provides information about the capability of the patient to perform acts of daily living.

C83-[CT-109-1] This section SHALL conform to the Continuity of Care Document Functional Status section described in section 3.4 of the CCD specification, and SHALL contain a templateId element whose root attribute is 2.16.840.1.113883.10.20.1.5

C83-[CT-109-2] This section SHALL include an entry from the Condition module to provide the admission diagnosis in coded form.

2.2.1.10 HOSPITAL ADMISSION DIAGNOSIS SECTION

The Hospital Admitting Diagnosis Section contains information about the primary reason for admission to a hospital facility.

The template identifier for this section is 2.16.840.1.113883.3.88.11.83.110

C83-[CT-110-1] This section SHALL conform to the IHE Hospital Admission Diagnosis section, and SHALL contain a templateId element whose root attribute is 1.3.6.1.4.1.19376.1.5.3.1.3.

C83-[CT-110-2] This section SHALL include entries from the Condition module to provide the admission diagnosis in coded form.

2.2.1.11 DISCHARGE DIAGNOSIS SECTION

The Discharge Diagnosis Section contains information about the conditions identified during the hospital stay that either need to be monitored after discharge from the hospital and/or where resolved during the hospital course.

The template identifier for this section is 2.16.840.1.113883.3.88.11.83.111

C83-[CT-111-1] This section SHALL conform to the IHE Hospital Discharge Diagnosis section, and SHALL contain a templateId element whose root attribute is 1.3.6.1.4.1.19376.1.5.3.1.7.

C83-[CT-111-2] This section SHALL include entries from the Condition module to provide the discharge diagnosis in coded form.

2.2.1.12 MEDICATIONS SECTION

The Medications Section contains information about the relevant medications for the patient. At a minimum, the currently active medications should be listed.

The template identifier for this section is 2.16.840.1.113883.3.88.11.83.112

C83-[CT-112-1] This section SHALL conform to the IHE Medications section, and SHALL contain a templateId element whose root attribute is 1.3.6.1.4.1.19376.1.5.3.1.19.

C83-[CT-112-2] This section SHALL include entries from the Medication module to provide the relevant medications in coded form.

2.2.1.13 ADMISSION MEDICATIONS HISTORY SECTION

The Admission Medication Section contains information about the relevant medications of a patient prior to admission to a facility.
The template identifier for this section is 2.16.840.1.113883.3.88.11.83.113

C83-[CT-113-1] This section **SHALL** conform to the IHE Admission Medications History section, and **SHALL** contain a `templateId` element whose root attribute is 1.3.6.1.4.1.19376.1.5.3.1.3.20.

C83-[CT-113-2] This section **SHALL** include entries from the Medication module to provide the relevant medications of a patient prior to admission in coded form.

### 2.2.1.14 HOSPITAL DISCHARGE MEDICATIONS SECTION

The Hospital Discharge Medications Section contains information about the relevant medications of the medications ordered for the patient for use after discharge from the hospital.

The template identifier for this section is 2.16.840.1.113883.3.88.11.83.114

C83-[CT-114-1] This section **SHALL** conform to the IHE Hospital Discharge Medications Section, and **SHALL** contain a `templateId` element whose root attribute is 1.3.6.1.4.1.19376.1.5.3.1.3.22.

C83-[CT-114-2] This section **SHALL** include entries from the Medication module to provide the relevant medications of the medications ordered for the patient for use after discharge in coded form.

### 2.2.1.15 MEDICATIONS ADMINISTERED SECTION

The Medications Administered Section contains information about the relevant medications administered to a patient during the course of an encounter.

The template identifier for this section is 2.16.840.1.113883.3.88.11.83.115

C83-[CT-115-1] This section **SHALL** conform to the IHE Medications Administered section, and **SHALL** contain a `templateId` element whose root attribute is 1.3.6.1.4.1.19376.1.5.3.1.3.21.

C83-[CT-115-2] This section **SHALL** include entries from the Medication module to provide the relevant medications administered to a patient in coded form.

### 2.2.1.16 ADVANCE DIRECTIVES SECTION

The template identifier for this section is 2.16.840.1.113883.3.88.11.83.116

The Advance Directives Section contains information that defines the patient's expectations and requests for care along with the locations of the documents.

C83-[CT-116-1] This section **SHALL** conform to the IHE Coded Advance Directives section, and **SHALL** contain a `templateId` element whose root attribute is 1.3.6.1.4.1.19376.1.5.3.1.3.35.

C83-[CT-116-2] This section **SHALL** include entries from the Advance Directive module.

### 2.2.1.17 IMMUNIZATIONS SECTION

The template identifier for this section is 2.16.840.1.113883.3.88.11.83.117

The Immunizations Section contains information describing the immunizations administered to the patient.

C83-[CT-117-1] This section **SHALL** conform to the IHE Immunizations section, and **SHALL** contain a `templateId` element whose root attribute is 1.3.6.1.4.1.19376.1.5.3.1.3.23.

C83-[CT-117-2] This section **SHALL** include entries from the Immunization module.
2.2.1.18 PHYSICAL EXAMINATION SECTION

The template identifier for this section is 2.16.840.1.113883.3.88.11.83.118

The Physical Examination Section contains information describing the physical findings.

C83-[CT-118-1] This section SHALL conform to the IHE Physical Examination section, and SHALL contain a templateId element whose root attribute is 1.3.6.1.4.1.19376.1.5.3.1.1.9.15.

C83-[CT-118-2] This section SHALL conform to the HL7 History and Physical Note and HL7 Consultation Note requirements for this section, and SHALL contain a templateId element whose root attribute is 2.16.840.1.113883.10.20.2.10

2.2.1.19 VITAL SIGNS SECTION

The Vital Signs Section contains information documenting the patient vital signs.

The template identifier for this section is 2.16.840.1.113883.3.88.11.83.119

C83-[CT-119-1] This section SHALL conform to the IHE Coded Vital Signs section, and SHALL contain a templateId element whose root attribute is 1.3.6.1.4.1.19376.1.5.3.1.1.5.3.2.

C83-[CT-119-2] This section SHALL contain entries conforming to the Vital Sign module.

2.2.1.20 REVIEW OF SYSTEMS SECTION

The Review of Systems Section contains information describing patient responses to questions about the function of various body systems.

The template identifier for this section is 2.16.840.1.113883.3.88.11.83.120

C83-[CT-120-1] This section SHALL conform to the IHE Review of Systems section, and SHALL contain a templateId element whose root attribute is 1.3.6.1.4.1.19376.1.5.3.1.3.18.

C83-[CT-120-2] This section SHALL conform to the HL7 Consultation Note requirements for this section, and SHALL contain a templateId element whose root attribute is 2.16.840.1.113883.10.20.4.10

2.2.1.21 HOSPITAL COURSE SECTION

The Hospital Course Section contains information about of the sequence of events from admission to discharge in a hospital facility.

The template identifier for this section is 2.16.840.1.113883.3.88.11.83.121

C83-[CT-121-1] This section SHALL conform to the IHE Hospital Course section, and SHALL contain a templateId element whose root attribute is 1.3.6.1.4.1.19376.1.5.3.1.3.5.

2.2.1.22 DIAGNOSTIC RESULTS SECTION

The Diagnostic Results Section contains information about the results from diagnostic procedures the patient received.

The template identifier for this section is 2.16.840.1.113883.3.88.11.83.122

C83-[CT-122-1] This section SHALL conform to the IHE Coded Results section, and SHALL contain a templateId element whose root attribute is 1.3.6.1.4.1.19376.1.5.3.1.3.28.

C83-[CT-122-2] This section SHALL include entries from the Procedure module to indicate the diagnostic procedure, and the Result module to provide the results of that procedure.
2.2.1.23 ASSESSMENT AND PLAN SECTION

The Assessment and Plan Section contains information about the assessment of the patient’s condition and expectations for care including proposals, goals, and order requests for monitoring, tracking, or improving the condition of the patient.

An assessment and plan section varies from the plan of care section defined later in that it includes a physician assessment of the patient condition.

The template identifier for this section is 2.16.840.1.113883.3.88.11.83.123

C83-[CT-123-1] This section **SHALL** conform to the IHE Assessment and Plans section, and **SHALL** contain a templateId element whose root attribute is 1.3.6.1.4.1.19376.1.5.3.1.13.2.5

C83-[CT-123-2] This section **SHALL** conform to the HL7 History and Physical Note and HL7 Consultation Note requirements for this section, and **SHALL** contain a templateId element whose root attribute is 2.16.840.1.113883.10.20.2.7

C83-[CT-123-3] This section **MAY** include entries conforming to the Medication, Immunization, Encounter, and Procedure modules to provide information about the intended care plan.

**NOTE:** The assessments described in this section are physician assessments of the patient's current condition, and do not include assessments of functional status, or other assessments typically used in nursing. In Implementation Guides currently selected, when both the assessment and plan are documented, they are included together in a single section documenting both. When the physician assessment is not present, only the plan of care section appears. There are no cases where a physician assessment is provided without a plan.

2.2.1.24 PLAN OF CARE SECTION

The Plan of Care Section contains information about the expectations for care to be provided including proposed interventions and goals for improving the condition of the patient.

A plan of care section varies from the assessment and plan section defined above in that it does not include a physician assessment of the patient condition.

The template identifier for this section is 2.16.840.1.113883.3.88.11.83.124

C83-[CT-124-1] This section **SHALL** conform to the IHE Care Plan section, and **SHALL** contain a templateId element whose root attribute is 1.3.6.1.4.1.19376.1.5.3.1.3.31.

C83-[CT-124-2] This section **SHALL** conform to the HL7 History and Physical Note and HL7 Consultation Note requirements for this section, and **SHALL** contain a templateId element whose root attribute is 2.16.840.1.113883.10.20.2.7

C83-[CT-124-3] This section **MAY** include entries conforming to the Medication, Immunization, Encounter, and Procedure modules to provide information about the intended care plan.

2.2.1.25 FAMILY HISTORY SECTION

The Family History Section contains information about the genetic family members, to the extent that they are known, the diseases they suffered from, their ages at death, and other relevant genetic information.

The template identifier for this section is 2.16.840.1.113883.3.88.11.83.125

C83-[CT-125-1] This section **SHALL** conform to the IHE Family Medical History section, and **SHALL** contain a templateId element whose root attribute is 1.3.6.1.4.1.19376.1.5.3.1.3.14.
When used to convey structured family histories, this section **SHALL** conform to the IHE Coded Family History section, and **SHALL** contain a `templateId` element whose root attribute is 1.3.6.1.4.1.19376.1.5.3.1.3.15.

When providing structured family history information this section **SHALL** include entries conforming to the Family History module.

### 2.2.1.26 SOCIAL HISTORY SECTION

The Social History Section contains information about the person’s beliefs, home life, community life, work life, hobbies, and risky habits.

The template identifier for this section is 2.16.840.1.113883.3.88.11.83.126

- **C83-[CT-126-1]** This section **SHALL** conform to the IHE Social History section, and **SHALL** contain a `templateId` element whose root attribute is 1.3.6.1.4.1.19376.1.5.3.1.3.15.
- **C83-[CT-126-2]** This section **May** contain entries conforming to the Social History module.

### 2.2.1.27 ENCOUNTERS SECTION

The Encounter Section contains information describing the patient history of encounters. At a minimum, current and pertinent historical encounters should be included; a full encounter history may be included.

The template identifier for this section is 2.16.840.1.113883.3.88.11.83.127

- **C83-[CT-127-1]** This section **SHALL** conform to the IHE Encounters History section, and **SHALL** contain a `templateId` element whose root attribute is 1.3.6.1.4.1.19376.1.5.3.1.3.16.
- **C83-[CT-127-2]** This section **SHALL** contain entries conforming to the Encounter module.

### 2.2.1.28 MEDICAL EQUIPMENT SECTION

The Medical Equipment section contains information describing a patient’s implanted and external medical devices and equipment that their health status depends on, as well as any pertinent equipment or device history.

The template identifier for this section is 2.16.840.1.113883.3.88.11.83.128

- **C83-[CT-128-1]** This section **SHALL** conform to the HL7 CCD section, and **SHALL** contain a `templateId` element whose root attribute is 2.16.840.1.113883.10.20.1.7.
- **C83-[CT-128-2]** This section **SHALL** conform to the IHE Medical Devices Section, and **SHALL** contain a `templateId` element whose root attribute is 1.3.6.1.4.1.19376.1.5.3.1.1.5.3.5

### 2.2.2 ENTRY CONTENT MODULES

#### 2.2.2.1 PERSONAL INFORMATION

Within a CDA document, the following information maps to HITSP Data Elements in the module defined in section 2.1.2.1 Personal Information of this document. Additional constraints applicable to this information can be found in the Continuity of Care Document Section 2.5.

---

**HITSP CDA Content Modules Component**
Released for Implementation
20090708 V1.1
Table 2-43 Person Information Data Mapping Table – Requirements

<table>
<thead>
<tr>
<th>CDA Data Location</th>
<th>HITSP Data Element Identifier and Name</th>
<th>O/R</th>
<th>Additional Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>/cda:ClinicalDocument/cda:effectiveTime</td>
<td>1.01 - Document Timestamp</td>
<td>R/N</td>
<td></td>
</tr>
<tr>
<td>/cda:ClinicalDocument/cda:recordTarget/cda:patientRole</td>
<td>Patient Information Entry</td>
<td>R/N</td>
<td></td>
</tr>
<tr>
<td>cda:id</td>
<td>1.02 - Person ID</td>
<td>R/N</td>
<td></td>
</tr>
<tr>
<td>cda:addr</td>
<td>1.03 - Person Address</td>
<td>R/Y</td>
<td>2.2.2.1.2</td>
</tr>
<tr>
<td>cda:telecom</td>
<td>1.04 - Person Phone /Email /URL</td>
<td>R/Y</td>
<td>2.2.2.1.3</td>
</tr>
<tr>
<td>cda:patient</td>
<td>Personal Information</td>
<td></td>
<td></td>
</tr>
<tr>
<td>cda:name</td>
<td>1.05 - Person Name</td>
<td>R/Y</td>
<td>2.2.2.1.1</td>
</tr>
<tr>
<td>cda:administrativeGenderCode</td>
<td>1.06 - Gender</td>
<td>R/N</td>
<td>2.2.2.1.4</td>
</tr>
<tr>
<td>cda:birthTime</td>
<td>1.07 - Person Date of Birth</td>
<td>R/N</td>
<td></td>
</tr>
<tr>
<td>cda:maritalStatusCode</td>
<td>1.08 - Marital Status</td>
<td>R2Y</td>
<td>2.2.2.1.5</td>
</tr>
<tr>
<td>cda:religiousAffiliationCode</td>
<td>1.09 - Religious Affiliation</td>
<td>O/N</td>
<td>2.2.2.1.8</td>
</tr>
<tr>
<td>cda:raceCode</td>
<td>1.10 - Race</td>
<td>O/Y</td>
<td>2.2.2.1.6</td>
</tr>
<tr>
<td>sdtc:raceCode</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>cda:ethnicityCode</td>
<td>1.11 - Ethnicity</td>
<td>O/N</td>
<td>2.2.2.1.7</td>
</tr>
</tbody>
</table>

2.2.2.1.1 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 Person Name Example

```xml
<!-- These examples assume the default namespace is 'urn:hl7-org:v3' -->
<name use="L">
    <prefix qualifier="AC">Dr.</prefix>
    <given>Margaret</given>
    <given>Ross</given>
    <family>Ellen</family>
</name>

<name use="P">
    <given qualifier="CL">Meg</given>
    <family>Ellen</family>
</name>

<name use="P">
    <given>Margaret</given>
    <given qualifier="BR">Josephine</given>
    <family qualifier="BR">Ross</family>
</name>

<name use="P">
    <prefix use="AC">Dr.</prefix>
    <given>Margaret</given>
    <given>Josephine</given>
    <family qualifier="BR">Ross</family>
</name>
```

3 NOTE: Optionality = “R” for Required, “R2” for Required if known, “O” for Optional and Repeat = “Y” for Yes or “N” for No
Each name part **SHALL** be identified using one of the tags `<given>`, `<family>`, `<prefix>` or `<suffix>`.

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.

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.

Name parts within a `<name>` tag **SHALL** be ordered in proper display order.

At most one `<name>` tag **SHALL** have a `use` attribute containing the value "L", indicating that it is the legal name of the patient.

More than one `<name>` tag **MAY** be present to retain birth name, maiden name and aliases.

An alias or former name **MAY** be identified by the inclusion of a `use` attribute containing the value "P".

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.

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.

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.

### 2.2.2.1.2 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 2-3 Address Examples**

```xml
<!-- 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>
```

Each address part **SHALL** be identified using the `<streetAddressLine>`, `<city>`, `<state>`, `<postalCode>` and `<country>` tags.

More than one `<streetAddressLine>` **MAY** be present.

No more than four `<streetAddressLine>` elements **SHALL** be present.

The `<country>` element **SHALL** be present for addresses outside of the United States.
C83-[DE-1.03-CDA-5] At most one address for a person SHALL have a use attribute with a value containing "HP"
C83-[DE-1.03-CDA-6] At least one address for a patient SHOULD have a use attribute with a value containing "HP"
C83-[DE-1.03-CDA-7] One or more vacation addresses MAY be present for a person
C83-[DE-1.03-CDA-8] A vacation address SHALL be recorded with a use attribute containing the value "HV"
C83-[DE-1.03-CDA-9] One or more work addresses MAY be present
C83-[DE-1.03-CDA-10] A work address SHALL be recorded with a use attribute containing the value "WP"
C83-[DE-1.03-1] The <country> SHALL be recorded using HITSP/C80 Section 2.2.1.1.3 Country

2.2.2.1.3 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.

**Figure 2-4 Telephone Numbers and E-mail Addresses Example**

```xml
<!-- 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'/>
```

C83-[DE-1.04-CDA-1] A home phone number SHALL be represented with a use attribute containing the value "HP"
C83-[DE-1.04-CDA-2] A vacation home phone number SHALL be represented with a use attribute containing the value "HV"
C83-[DE-1.04-CDA-3] A work phone number SHALL be represented with a use attribute containing the value "WP"
C83-[DE-1.04-CDA-4] A mobile phone number SHALL be represented with a use attribute containing the value "MC"
C83-[DE-1.04-CDA-5] 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

2.2.2.1.4 Gender Constraints

**Figure 2-5 Gender Code Examples**

```xml
<!-- 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"/>
```

C83-[DE-1.06-1] Gender SHALL be coded as specified in HITSP/C80 Section 2.2.1.2.1.2 V3 Administrative Gender
2.2.2.1.5 Marital Status Constraints

**Figure 2-6 Marital Status Example**

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

C83-[DE-1.08-1] Marital Status **SHALL** be coded as specified in HITSP/C80 Section 2.2.1.2.3.2 Marital Status CDA and HL7V3

2.2.2.1.6 Race Constraints

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

**Figure 2-7 Race Coding Example**

```xml
<!-- 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'/>
```

C83-[DE-1.09-CDA-1] Second and subsequent raceCode elements **MAY** be recorded using the `sdtc:raceCode` extension

C83-[DE-1.09-1] Race **SHALL** be coded as specified in HITSP/C80 Section 2.2.1.2.7 Race

2.2.2.1.7 Ethnicity Constraints

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

**Figure 2-8 Ethnicity Coding Example**

```xml
<!-- 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'/>
```

C83-[DE-1.11-1] Ethnicity **SHALL** be coded as specified in HITSP/C80 Section 2.2.1.2.2 Ethnicity

2.2.2.1.8 Religious Affiliation Constraints

Religious affiliation is recorded at the discretion of the patient.

**Figure 2-9 Religious Affiliation Example**

```xml
<!-- This example assumes the default namespace is 'urn:hl7-org:v3' -->
<!-- example 1 -->
<br>igiousAffiliationCode code='1022' displayName='Independent' codeSystem='2.16.840.1.113883.5.1076' codeSystemName='ReligiousAffiliation'/>
```

C83-[DE-1.10-CDA-1] The primary religious affiliation **MAY** appear in the `<religiousAffiliationCode>` element

C83-[DE-1.10-1] Religious affiliation **SHALL** be coded as specified in HITSP/C80 Section 2.2.1.2.8 Religious Affiliation
2.2.2.2 LANGUAGE SPOKEN

Within a CDA document, the following information maps to HITSP Data Elements in the module defined in section 2.1.2.2 Language Spoken of this document.

This module contains the primary and secondary languages of communication for the patient. The template identifier for this module is 2.16.840.1.113883.3.88.11.83.2.

<table>
<thead>
<tr>
<th>CDA Data Location</th>
<th>HITSP Data Element Identifier and Name</th>
<th>O/R⁴</th>
<th>Additional Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>cda:recordTarget/cda:patientRole/cda:patient/</td>
<td>2.01 - Language</td>
<td>R/Y</td>
<td>2.2.2.2.1</td>
</tr>
<tr>
<td>cda:languageCommunication</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 2-44 Language Spoken Data Mapping Table - Requirements

2.2.2.2.1 Language Constraints

Figure 2-10 Language Communication Examples

```xml
<!-- These examples assume the default namespace is 'urn:hl7-org:v3' -->
<!-- example 1 -->
<languageCommunication>
  <templateId root='2.16.840.1.113883.3.88.11.83.2'/>
  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.2.1'/>
  <languageCode code='fr-CN' />
  <preferenceInd value='true'/>
</languageCommunication>

<!-- example 2 -->
<languageCommunication>
  <templateId root='2.16.840.1.113883.3.88.11.83.2'/>
  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.2.1'/>
  <languageCode code='en-US' />
  <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='2.16.840.1.113883.3.88.11.83.2'/>
  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.2.1'/>
  <languageCode code='sgn-US' />
  <preferenceInd value='true'/>
</languageCommunication>

<!-- example 4 – not known -->
<languageCommunication>
  <templateId root='2.16.840.1.113883.3.88.11.83.2'/>
  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.2.1'/>
  <languageCode nullFlavor="UNK"/>
</languageCommunication>
```

C83-[DE-2.01-CDA-1] 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.

⁴ NOTE: Optionality = “R” for Required, “R2” for Required if known, “O” for Optional and Repeat = “Y” for Yes or “N” for No
C83-[DE-2.01-CDA-2] A CDA Document SHALL declare conformance for the Language Spoken module by including a `<templateID>` element with the root attribute set to the value 2.16.840.1.113883.3.88.11.83.2.

C83-[DE-2.01-CDA-3] All Language Spoken entries SHALL declare conformance to the IHE Language Communication module by including a `<templateID>` element with the root attribute set to the value 1.3.6.1.4.1.19376.1.5.3.1.2.1.

C83-[DE-2.01-CDA-4] The codes for the `<modeCode>` element SHALL be coded as specified in HITSP/C80 section 2.2.1.2.10 Language Ability Mode. 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 in Figure 2-10 above). On the other hand, American Sign Language would be represented using the code sign-US (see example 3 in Figure 2-10 above), and would only use mode codes for signed communication.

C83-[DE-2.01-CDA-5] While this HL7 CDA allows for the specification of proficiency using the `<proficiencyLevelCode>` element, this element SHOULD NOT be used.

C83-[DE-2.01-1] Language SHALL be coded as specified in HITSP/C80 Section 2.2.1.2.9 Language

C83-[DE-2.01-2] Sign language SHALL be treated as a separate language.

2.2.2.3 SUPPORT

Within a CDA document, the following information maps to HITSP Data Elements in the module defined in section 2.1.2.3 Support of this document. At a minimum, key support contacts relative to healthcare decisions, including next of kin, should be included. 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 these data elements.

The template identifier for a CDA artifact conforming to this specification is 2.16.840.1.113883.3.88.11.83.3

<table>
<thead>
<tr>
<th>CDA Data Location</th>
<th>HITSP Data Element Identifier and Name</th>
<th>O/R⁶</th>
<th>Additional Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>/cda:ClinicalDocument/cda:participant</td>
<td>Support</td>
<td>R2/Y</td>
<td></td>
</tr>
<tr>
<td>cda:time</td>
<td>3.01 - Date</td>
<td>R/N</td>
<td></td>
</tr>
<tr>
<td>cda:associatedEntity or cda:patientRole/cda:patient/cda:guardian</td>
<td>Contact</td>
<td>R2/Y</td>
<td></td>
</tr>
<tr>
<td>@classCode</td>
<td>3.02 - Contact Type</td>
<td>R/N</td>
<td>2.2.2.3.2</td>
</tr>
<tr>
<td>cda:code</td>
<td>3.03 - Contact Relationship</td>
<td>R2/N</td>
<td>2.2.2.3.3</td>
</tr>
<tr>
<td>cda:addr</td>
<td>3.04 - Contact Address</td>
<td>R2/Y</td>
<td>2.2.2.3.4</td>
</tr>
<tr>
<td>cda:telecom</td>
<td>3.05 - Contact Phone / Email / URL</td>
<td>R2/Y</td>
<td></td>
</tr>
<tr>
<td>cda:associatedPerson/cda:name or cda:guardianPerson/cda:name</td>
<td>3.06 - Contact Name</td>
<td>R/Y</td>
<td></td>
</tr>
</tbody>
</table>

⁵ Judgments about language proficiency are subjective, and could have a negative impact on consumers.

⁶ NOTE: Optionality = “R” for Required, “R2” for Required if known, “O” for Optional and Repeat = “Y” for Yes or “N” for No.
Figure 2-11 Support Examples

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

<!-- example 1 -->

<patient>
  ...
  <guardian classCode='GUARD'>
    ...
    <templateId root='2.16.840.1.113883.3.88.11.83.3'/>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.2.4'/>
    <code code='GRMTH' displayName='Grandmother'
      codeSystem='2.16.840.1.113883.5.111'
      codeSystemName='RoleCode'/>
    <addr>...
    <telecom ...
    <guardianPerson>
      <name>...
    </guardianPerson>
  </guardian>
</patient>

<!-- example 2 -->

<participant typeCode='IND'>
  ...
  <templateId root='2.16.840.1.113883.3.88.11.83.3'/>
  <time value='20070213'/>
  <associatedEntity classCode='AGNT'>
    <code code='STPDAU' displayName='Step-Daughter'
      codeSystem='2.16.840.1.113883.5.111'
      codeSystemName='RoleCode'/>
    <addr>...
    <telecom ...
    <assignedPerson>
      <name>...
    </assignedPerson>
  </associatedEntity>
</participant>

2.2.2.3.1 Support Constraints

C83-[DE-3-CDA-1] A CDA Document SHALL declare conformance for the Support entry by including a <templateID> element with the root attribute set to the value 2.16.840.1.113883.3.88.11.83.3

C83-[DE-3-CDA-2] All support entries SHALL also declare conformance to the IHE Patient Contacts module by including a <templateID> element with the root attribute set to the value 1.3.6.1.4.1.19376.1.5.3.1.2.4

2.2.2.3.2 Contact Type Constraints

Figure 2-12 Contact Type Examples

<!-- example 1 -->

<assignedEntity classCode='AGNT'> ...
<assignedEntity classCode='CAREGIVER'> ...
<assignedEntity classCode='ECON'> ...
<guardian classCode='GUARD'> ...
<assignedEntity classCode='NOK'> ...
<assignedEntity classCode='PRS'> ...

C83-[DE-3.01-CDA-1] The classCode attribute SHALL be coded as specified in HITSP/C80 section 2.2.1.2.6 Contact Type
2.2.2.3.3 Contact Relationship Constraints

C83-[DE-3.03-1] The contact relationship SHALL have be coded as specified in HITSP/C80 section 2.2.1.2.4 Personal Relationships

2.2.2.3.4 Contact Address Constraints

C83-[DE-3.04-1] The state part of an address SHALL be recorded using HITSP/C80 Section 2.2.1.1.1 State

C83-[DE-3.04-2] The postal code part of an address in the United States SHALL be recorded using HITSP/C80 Section 2.2.1.1.2 Postal Code

C83-[DE-3.04-3] The country part of an address SHALL be recorded using HITSP/C80 Section 2.2.1.1.3 Country

2.2.2.4 HEALTHCARE PROVIDER

Within a CDA document, the following information maps to HITSP Data Elements in the module defined in section 2.1.2.4 Healthcare Provider of this document. These entries contain 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 these data elements. 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.).

The template identifier for this module is 2.16.840.1.113883.3.88.11.83.4.

Table 2-46 Healthcare Providers Data Mapping Table – Requirements

<table>
<thead>
<tr>
<th>CDA Data Location</th>
<th>HITSP Data Element Identifier and Name</th>
<th>O/R?</th>
<th>Additional Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>/cda:ClinicalDocument/cda:documentationOf/cda:serviceEvent/cda:performer</td>
<td>Provider</td>
<td>R2/Y</td>
<td>2.2.2.4.1</td>
</tr>
<tr>
<td>cda:time</td>
<td>4.01 - Date Range</td>
<td>R/N</td>
<td></td>
</tr>
<tr>
<td>cda:functionCode</td>
<td>4.02 - Provider Role Coded</td>
<td>R2/N</td>
<td>2.2.2.4.3</td>
</tr>
<tr>
<td>cda:originalText</td>
<td>4.03 - Provider Role Free Text</td>
<td>R2/N</td>
<td>2.2.2.4.3</td>
</tr>
<tr>
<td>cda:assignedEntity</td>
<td>Provider Entity</td>
<td>R/Y</td>
<td></td>
</tr>
<tr>
<td>cda:code</td>
<td>4.04 - Provider Type</td>
<td>R2/N</td>
<td>2.2.2.4.4</td>
</tr>
<tr>
<td>cda:addr</td>
<td>4.05 - Provider Address</td>
<td>R2/Y</td>
<td></td>
</tr>
<tr>
<td>cda:telecom</td>
<td>4.06 - Provider Phone / Email / URL</td>
<td>R2/Y</td>
<td></td>
</tr>
<tr>
<td>cda:assignedPerson/cda:name</td>
<td>4.07 - Provider Name</td>
<td>R2/N</td>
<td></td>
</tr>
<tr>
<td>cda:representedOrganization/cda:name</td>
<td>4.08 - Provider's Organization Name</td>
<td>R2/Y</td>
<td></td>
</tr>
<tr>
<td>sdtc:patient/sdtc:id</td>
<td>4.09 - Provider's Patient ID</td>
<td>R2/N</td>
<td></td>
</tr>
</tbody>
</table>

NOTE: Optionality = "R" for Required, "R2" for Required if known, "O" for Optional and Repeat = “Y” for Yes or “N” for No
2.2.2.4.1 Healthcare Provider Constraints

C83-[DE-4-CDA-1]  A CDA Document SHALL declare conformance for the Healthcare Provider entry by including a `<templateID>` element with the `root` attribute set to the value 2.16.840.1.113883.3.88.11.83.4

C83-[DE-4-CDA-2]  All healthcare providers entries SHALL declare conformance to the IHE Healthcare Providers and Pharmacies specification by including a `<templateID>` element with the `root` attribute set to the value 1.3.6.1.4.1.19376.1.5.3.1.2.3

2.2.2.4.2 Provider

Healthcare providers are encoded as shown above. 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”.

2.2.2.4.3 Provider Role

C83-[DE-4.02-1]  Provider role SHALL be coded as specified in HITSP/C80 section 2.2.3.8.1 Provider Role
2.2.2.4.4 Provider Type

C83-[DE-4.04-1] Provider type SHALL be coded as specified in HITSP/C80 section 2.2.3.8.2 Provider Type

2.2.2.4.5 Provider Address

C83-[DE-4.05-1] The state part of an address SHALL be recorded using HITSP/C80 Section 2.2.1.1.1 State

C83-[DE-4.05-2] The postal code part of an address in the United States SHALL be recorded using HITSP/C80 Section 2.2.1.1.2 Postal Code

C83-[DE-4.05-3] The country part of an address SHALL be recorded using HITSP/C80 Section 2.2.1.1.3 Country

2.2.2.5 INSURANCE PROVIDER

Within a CDA document, the following information maps to HITSP Data Elements in the module defined in Section 2.1.2.5 Insurance Provider of this document. See the HL7 Continuity of Care Document Section 3.1.2 for constraints applicable to these data elements. 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. The template identifier for these entries is 2.16.840.1.113883.3.88.11.83.5.

Table 2-47 Insurance Provider Data Mapping Table – Requirements

<table>
<thead>
<tr>
<th>CDA Data Location</th>
<th>HITSP Data Element Identifier and Name</th>
<th>O/R</th>
<th>Additional Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>cda:act[</td>
<td>Payment Provider Event Entry</td>
<td></td>
<td>2.2.2.5.2</td>
</tr>
<tr>
<td>cda:templateId/@root='2.16.840.1.113883.10.20.1.26']</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>cda:id</td>
<td>R/N</td>
<td>2.2.2.5.3</td>
<td></td>
</tr>
<tr>
<td>cda:code</td>
<td>5.02 - Health Insurance Type</td>
<td>R2/N</td>
<td>2.2.2.5.4</td>
</tr>
<tr>
<td>cda:performer/cda:assignedEntity</td>
<td>Payer</td>
<td>R/N</td>
<td></td>
</tr>
<tr>
<td>cda:id</td>
<td>5.03 - Health Plan Insurance Information Source ID</td>
<td>O/Y</td>
<td>2.2.2.5.5</td>
</tr>
<tr>
<td>cda:addr</td>
<td>5.04 - Health Plan Insurance Information Source Address</td>
<td>O/Y</td>
<td></td>
</tr>
<tr>
<td>cda:telecom</td>
<td>5.05 - Health Plan Insurance Information Source Phone / Email / URL</td>
<td>O/Y</td>
<td></td>
</tr>
<tr>
<td>cda:representedOrganization/cda:name</td>
<td>5.06 - Health Plan Insurance Information Source Name</td>
<td>R2/N</td>
<td></td>
</tr>
<tr>
<td>cda:participant[@typeCode='COV']</td>
<td>Member Information</td>
<td>R/N</td>
<td>2.2.2.5.7</td>
</tr>
<tr>
<td>cda:time</td>
<td>5.07 - Health Plan Coverage Dates</td>
<td>R2/N</td>
<td>2.2.2.5.8</td>
</tr>
<tr>
<td>cda:participantRole[@classCode='PAT']</td>
<td>Patient</td>
<td>R/N</td>
<td></td>
</tr>
<tr>
<td>cda:id</td>
<td>5.08 - Member ID</td>
<td>R2/N</td>
<td>2.2.2.5.9</td>
</tr>
<tr>
<td>cda:code</td>
<td>5.09 - Patient Relationship to Subscriber</td>
<td>R/N</td>
<td>2.2.2.5.10</td>
</tr>
<tr>
<td>cda:addr</td>
<td>5.10 - Patient Address</td>
<td>R2/Y</td>
<td>2.2.2.5.11</td>
</tr>
<tr>
<td>cda:telecom</td>
<td>5.11 - Patient Phone/Email/URL</td>
<td>R2/Y</td>
<td></td>
</tr>
</tbody>
</table>

8 NOTE: Optionality = “R” for Required, “R2” for Required if known, “O” for Optional and Repeat = “Y” for Yes or “N” for No
9 Requirements for Entries are defined at a higher level than the Entry Content Module (i.e. Section Content Modules, HITSP CDA based constructs and Interoperability Specifications).
<table>
<thead>
<tr>
<th>CDA Data Location</th>
<th>HITSP Data Element Identifier and Name</th>
<th>O/R#</th>
<th>Additional Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>cda:playingEntity/cda:name</td>
<td>5.12 - Patient Name</td>
<td>R/N</td>
<td>2.2.2.5.12</td>
</tr>
<tr>
<td>cda:playingEntity/sdtc:birthTime</td>
<td>5.13 - Patient Date of Birth</td>
<td>R/N</td>
<td>2.2.2.5.13</td>
</tr>
<tr>
<td>cda:performer/cda:assignedEntity/cda:code</td>
<td>5.14 - Financial Responsibility Party Type</td>
<td>R/N</td>
<td>2.2.2.5.14</td>
</tr>
<tr>
<td>cda:participant[@typeCode='HLD']/cda:participantRole</td>
<td>Subscriber Information</td>
<td>R2/N</td>
<td>2.2.2.5.15</td>
</tr>
<tr>
<td>cda:id</td>
<td>5.15 - Subscriber ID</td>
<td>R/N</td>
<td>2.2.2.5.16</td>
</tr>
<tr>
<td>cda:addr</td>
<td>5.16 - Subscriber Address</td>
<td>R/N</td>
<td>2.2.2.5.17</td>
</tr>
<tr>
<td>cda:telecom</td>
<td>5.17 - Subscriber Phone/Email/URL</td>
<td>R2/Y</td>
<td>2.2.2.5.18</td>
</tr>
<tr>
<td>cda:playingEntity/cda:name</td>
<td>5.18 - Subscriber Name</td>
<td>R/N</td>
<td>2.2.2.5.19</td>
</tr>
<tr>
<td>cda:playingEntity/sdtc:birthTime</td>
<td>5.19 - Subscriber Date of Birth</td>
<td>R/N</td>
<td>2.2.2.5.20</td>
</tr>
<tr>
<td>cda:performer[cda:assignedEntity/cda:code][@code='' and @codeSystem='']</td>
<td>Guarantor Information</td>
<td>R2/Y</td>
<td>2.2.2.5.21</td>
</tr>
<tr>
<td>cda:time</td>
<td>5.20 - Effective Date of Financial Responsibility</td>
<td>R2/N</td>
<td>2.2.2.5.22</td>
</tr>
<tr>
<td>cda:assignedEntity/cda:addr</td>
<td>5.21 - Financial Responsibility Party Address</td>
<td>R2/Y</td>
<td>2.2.2.5.23</td>
</tr>
<tr>
<td>cda:assignedEntity/cda:telecom</td>
<td>5.22 - Financial Responsibility Party Phone/Email/URL</td>
<td>R2/Y</td>
<td>2.2.2.5.24</td>
</tr>
<tr>
<td>cda:assignedEntity/cda:assignedPerson/cda:name - AND/OR - cda:assignedEntity/cda:representedOrganization/cda:name</td>
<td>5.23 - Financial Responsibility Party Name</td>
<td>R2/N</td>
<td>2.2.2.5.25</td>
</tr>
<tr>
<td>cda:entryRelationship[@typeCode='REFR']/cda:act[@classCode='ACT' and @moodCode='DEF']</td>
<td>Health Plan</td>
<td>R2/N</td>
<td>2.2.2.5.26</td>
</tr>
<tr>
<td>cda:text</td>
<td>5.24 - Health Plan Name</td>
<td>R2/N</td>
<td>2.2.2.5.27</td>
</tr>
</tbody>
</table>

2.2.2.5.1 Insurance Provider Constraints

C83-[DE-5-CDA-1] A CDA Document **SHALL** declare conformance for the Insurance Provider module by including a `<templateID>` element with the `root` attribute set to the value `2.16.840.1.113883.3.88.11.83.5`

C83-[DE-5-CDA-2] All Insurance Provider entries **SHALL** declare conformance to the IHE Coverage Entry by including a `<templateID>` element with the `root` attribute set to the value `1.3.6.1.4.1.19376.1.5.3.1.4.17`

2.2.2.5.2 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 2-14 Insurance Provider Examples

---

Information for payment providers **SHALL** be recorded as a policy act inside the coverage act.

---

C83-[DE-5-CDA-1]
2.2.2.5.3 Group Number Constraints

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

Figure 2-15 Group Number Example

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

C83-[DE-5.01-CDA-1] All Insurance Provider modules SHALL declare conformance to the IHE Payer Entry by including a `<templateID>` element with the `root` attribute set to the value 1.3.6.1.4.1.19376.1.5.3.1.4.18.

C83-[DE-5.01-CDA-2] 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.

C83-[DE-5.01-CDA-3] A GUID MAY be used in place of the OID of the assigning authority.

C83-[DE-5.01-CDA-4] Implementers SHOULD use the same GUID for each instance of the same group or contract number.

2.2.2.5.4 Healthcare Insurance Type Constraints

Figure 2-16 Health Insurance Type Example

```xml
<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>
```

C83-[DE-5.02-1] The Health Insurance Type SHALL be coded as specified in HITSP/C80 Section 2.2.2.1 Health Insurance Type.

2.2.2.5.5 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.

The OID for an RxPCN is 2.16.840.1.113883.3.88.3.1 plus the numeric identifier used in the RxBIN.
2.2.2.5.6 Health Plan Insurance Information Source Address Constraints

C83-[DE-5.04-1] The state part of an address SHALL be recorded using HITSP/C80 Section 2.2.1.1.1 State

C83-[DE-5.042] The postal code part of an address in the United States SHALL be recorded using HITSP/C80 Section 2.2.1.1.2 Postal Code

C83-[DE-5.04-3] The country part of an address SHALL be recorded using HITSP/C80 Section 2.2.1.1.3 Country

2.2.2.5.7 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 2-18 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>
  </participantRole>
</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>
  </participantRole>
</participant>

2.2.2.5.8 Health Plan Coverage Dates Constraints

  C83-[DE-5.07-CDA-1] The date when the plan began covering the member SHOULD be recorded in the
  <low> element of the <time> element beneath the <participant> element
  C83-[DE-5.07-CDA-2] The date when the plan stops covering the member SHOULD be recorded in the
  <high> element of the <time> element beneath the <participant> element

2.2.2.5.9 Member ID Constraints

  C83-[DE-5.08-CDA-1] The member identifier number SHALL be recorded in the extension attribute of the
  <id> element found in the <participantRole> element
  C83-[DE-5.08-CDA-2] 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
  C83-[DE-5.08-CDA-3] A GUID MAY be used in place of the OID of the assigning authority
  C83-[DE-5.08-CDA-4] Implementers SHOULD use the same GUID for each instance of a member identifier
      from the same health plan

2.2.2.5.10 Relationship to Subscriber Constraints

  C83-[DE-5.09-CDA-1] The relationship to the subscriber SHALL be resent and SHALL be recorded in the
  <code> element underneath the <participantRole> element recording the
  member information
C83-[DE-5.09-1] The Patient Relationship to Subscriber SHALL be coded as specified in HITSP/C80 section 2.2.2.2 Subscriber Relationship

2.2.2.5.11 Patient Address Constraints

C83-[DE-5.10-1] The state part of an address SHALL be recorded using HITSP/C80 Section 2.2.1.1.1 State
C83-[DE-5.10-2] The postal code part of an address in the United States SHALL be recorded using HITSP/C80 Section 2.2.1.1.2 Postal Code
C83-[DE-5.10-3] The country part of an address SHALL be recorded using HITSP/C80 Section 2.2.1.1.3 Country

2.2.2.5.12 Patient Name Constraints

C83-[DE-5.12-CDA-1] 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

2.2.2.5.13 Patient Date of Birth Constraints

C83-[DE-5.13-CDA-1] 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

2.2.2.5.14 Financial Responsibility Party Type Constraints

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

C83-[DE-5.14-CDA-1] The code attribute SHALL be coded as specified in HITSP/C80 Section 2.2.2.3 Financially Responsible Party Type
C83-[DE-5.14-CDA-2] 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
C83-[DE-5.14-CDA-3] The code attribute SHALL be set to PAYOR when the code of the encompassing act is other than PP

2.2.2.5.15 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 2-19 Subscriber Information Example

```xml
<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>
```
When the Subscriber is the patient, the `<participant>` element describing the subscriber **SHALL NOT** be present. This information will be recorded instead in the data elements used to record member information.

### 2.2.2.5.16 Subscriber ID Constraints

**C83-[DE-5.15-CDA-1]** 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.

**C83-[DE-5.15-CDA-2]** 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.

### 2.2.2.5.17 Subscriber Date of Birth Constraints

**C83-[DE-5.19-CDA-1]** 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.

### 2.2.2.5.18 Financial Responsibility Party Address Constraints

**C83-[DE-5.21-1]** The state part of an address **SHALL** be recorded using HITSP/C80 Section 2.2.1.1.1 State.

**C83-[DE-5.21-2]** The postal code part of an address in the United States **SHALL** be recorded using HITSP/C80 Section 2.2.1.1.2 Postal Code.

**C83-[DE-5.21-3]** The country part of an address **SHALL** be recorded using HITSP/C80 Section 2.2.1.1.3 Country.

### 2.2.2.5.19 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 2-20 Health Plan Example**

```xml
<!-- 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 name='ActCode'/>
    <codeSystemName='ActCode'/>
    <text>Health Plan Name</text>
  </act>
</entryRelationship>
```

### 2.2.2.6 ALLERGY/DRUG SENSITIVITY

Within a CDA document, the following information maps to HITSP Data Elements in the module defined in section 2.1.2.6 Allergy/Drug Sensitivity of this document. See the HL7 Continuity of Care Document Section 3.8 for constraints applicable to these data elements.

The template identifier for this module is 2.16.840.1.113883.3.88.11.83.6.
### Table 2-48 Allergy/Drug Sensitivity Data Mapping Table – Requirements

<table>
<thead>
<tr>
<th>CDA Data Location</th>
<th>HITSP Data Element Identifier and Name</th>
<th>O/R</th>
<th>Additional Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td><code>cda:act[cda:templateId/@root= '2.16.840.1.113883.10.20.1.27']/</code>...</td>
<td>Adverse Event Entry</td>
<td>See Note(^{11})</td>
<td></td>
</tr>
<tr>
<td><code>cda:effectiveTime</code></td>
<td>6.01 - Adverse Event Date</td>
<td>R2/N</td>
<td></td>
</tr>
<tr>
<td><code>cda:code</code></td>
<td>6.02 - Adverse Event Type</td>
<td>R/N</td>
<td>2.2.2.6.2</td>
</tr>
<tr>
<td><code>cda:participant[typeCode='CSM']/</code></td>
<td>Product</td>
<td>R2/Y</td>
<td></td>
</tr>
<tr>
<td><code>cda:participantRole[classCode='MANU']/</code></td>
<td>Product Detail</td>
<td>R/N</td>
<td></td>
</tr>
<tr>
<td><code>cda:playingEntity[classCode='MMAT']/</code></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><code>cda:name</code></td>
<td>6.03 - Product Free-Text</td>
<td>R/N</td>
<td></td>
</tr>
<tr>
<td><code>cda:code</code></td>
<td>6.04 - Product Coded</td>
<td>R2/N</td>
<td>2.2.2.6.3</td>
</tr>
<tr>
<td><code>cda:entryRelationship[typeCode='MFST']/</code></td>
<td>Reaction</td>
<td>O/Y</td>
<td></td>
</tr>
<tr>
<td><code>cda:observation[templateId/@root= '2.16.840.1.113883.10.20.1.54']</code></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><code>cda:text</code></td>
<td>6.05 - Reaction Free-Text</td>
<td>R2/N</td>
<td></td>
</tr>
<tr>
<td><code>cda:value</code></td>
<td>6.06 - Reaction Coded</td>
<td>R2/N</td>
<td>2.2.2.6.4</td>
</tr>
<tr>
<td><code>cda:entryRelationship[typeCode='SUBJ']/</code></td>
<td>Severity</td>
<td>R2/N</td>
<td></td>
</tr>
<tr>
<td><code>cda:observation[templateId/@root= '2.16.840.1.113883.10.20.1.55']</code></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><code>cda:text</code></td>
<td>6.07 - Severity Free-Text</td>
<td>R2/N</td>
<td></td>
</tr>
<tr>
<td><code>cda:value</code></td>
<td>6.08 - Severity Coded</td>
<td>R2/N</td>
<td>2.2.2.6.5</td>
</tr>
</tbody>
</table>

\(^{10}\) **NOTE:** Optionality = “R” for Required, “R2” for Required if known, “O” for Optional and Repeat = “Y” for Yes or “N” for No

\(^{11}\) Requirements for Entries are defined at a higher level than the Entry Content Module (i.e. Section Content Modules, HITSP CDA based constructs and Interoperability Specifications).
Figure 2-21 Allergies and Drug Sensitivities Example

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

<text>
  <content ID='reaction-1'>Anaphylaxis</content>
</text>

<entry>
  <act classCode='ACT' moodCode='EVN'>
    <templateId root='2.16.840.1.113883.10.20.1.27'/>
    <templateId root='2.16.840.1.113883.3.88.11.83.6'/>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.3'/>
    <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'/>
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.4'/>
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.6'/>
        <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'>
          <playingEntity classCode='MANU'>
            <code code='70618' displayName='Penicillin'
              codeSystem='2.16.840.1.113883.6.88'
              codeSystemName='RxNorm'/>
            <name>Penicillin</name>
          </playingEntity>
        </participant>
      </observation>
    </entryRelationship>
    <entryRelationship typeCode='MFST' inversionInd='true'>
      <text><reference value='#reaction-1'/></text>
      <value xsi:type='CD' code='39579001' displayName='Anaphylaxis'
        codeSystem='2.16.840.1.113883.6.96'
        codeSystemName='SNOMED CT'/>
    </entryRelationship>
  </act>
</entry>

<text>
  <content ID='severity-1'>Severe</content> Penicillin Allergy on February 2, 2001
</text>

<entry>
  <act classCode='ACT' moodCode='EVN'>
    <templateId root='2.16.840.1.113883.10.20.1.27'/>
    <templateId root='2.16.840.1.113883.3.88.11.83.6'/>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.3'/>
    <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'/>
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.4'/>
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.6'/>
        <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'>
          <playingEntity classCode='MANU'>
            <code code='70618' displayName='Penicillin'
              codeSystem='2.16.840.1.113883.6.88'
              codeSystemName='RxNorm'/>
            <name>Penicillin</name>
          </playingEntity>
        </participant>
      </observation>
    </entryRelationship>
    <entryRelationship typeCode='MFST' inversionInd='true'>
      <text><reference value='#reaction-1'/></text>
      <value xsi:type='CD' code='39579001' displayName='Anaphylaxis'
        codeSystem='2.16.840.1.113883.6.96'
        codeSystemName='SNOMED CT'/>
    </entryRelationship>
  </act>
</entry>
2.2.2.6.1 Allergy/Drug Sensitivity Module Constraints

C83-[DE-6-CDA-1] A CDA Document SHALL declare conformance for the Allergy/Drug Sensitivity Module by including a `<templateID>` element with the `root` attribute set to the value 2.16.840.1.113883.3.88.11.83.6

C83-[DE-6-CDA-2] All allergy entries SHALL conform to the IHE PCC Allergy and Intolerance Concern template by including a `<templateID>` element with the `root` attribute set to the value 1.3.6.1.4.1.19376.1.5.3.1.4.5.3

2.2.2.6.2 Adverse Event Vocabulary Constraints

C83-[DE-6.02-1] Adverse event types SHALL be coded as specified in HITSP/C80 Section 2.2.3.4.2 Allergy/Adverse Event Type

2.2.2.6.3 Product Coded Vocabulary Constraints

C83-[DE-6.04-1] Food and substance allergies SHALL be coded as specified in HITSP/C80 Section 2.2.3.3.11 Ingredient Name

C83-[DE-6.04-2] Allergies to a class of medication SHALL be coded as specified in HITSP/C80 Section 2.2.3.3.9 Medication Drug Class

C83-[DE-6.04-3] Allergies to a specific medication SHALL be coded as specified in HITSP/C80 Section 2.2.3.3.7 Medication Brand Name or HITSP/C80 Section 2.2.3.3.8 Medication Clinical Drug Names.

2.2.2.6.4 Reaction Coded Constraints

C83-[DE-6.06-1] The reaction SHALL be coded as specified in HITSP/C80 Section 2.2.3.4.1 Allergy/Adverse Event (Reaction)

2.2.2.6.5 Severity Coded Constraints

C83-[DE-6.08-1] The severity of the adverse event SHALL be coded as specified in HITSP/C80 Section 2.2.3.4.3 Allergy/Adverse Event Severity

2.2.2.7 CONDITION

Within a CDA document, the following information maps to HITSP Data Elements in the module defined in section 2.1.2.7 Condition of this document. See the HL7 Continuity of Care Document Section 3.5 for constraints applicable to these data elements.

The template identifier for this module is 2.16.840.1.113883.3.88.11.83.7.

<table>
<thead>
<tr>
<th>CDA Data Location</th>
<th>HITSP Data Element Identifier and Name</th>
<th>O/R</th>
<th>Additional Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>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']</td>
<td>Problem Entry</td>
<td>See Note 13</td>
<td></td>
</tr>
<tr>
<td>cda:effectiveTime</td>
<td>7.01 - Problem Date</td>
<td>R2/N</td>
<td>2.2.2.7.2</td>
</tr>
</tbody>
</table>

12 NOTE: Optionality = “R” for Required, “R2” for Required if known, “O” for Optional and Repeat = “Y” for Yes or “N” for No

13 Requirements for Entries are defined at a higher level than the Entry Content Module (i.e. Section Content Modules, HITSP CDA based constructs and Interoperability Specifications).
<table>
<thead>
<tr>
<th>CDA Data Location</th>
<th>HITSP Data Element Identifier and Name</th>
<th>O/R</th>
<th>Additional Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>cda:code</td>
<td>7.02 - Problem Type</td>
<td>R2/N</td>
<td>2.2.2.7.3</td>
</tr>
<tr>
<td>cda:text</td>
<td>7.03 - Problem Name</td>
<td>R/N</td>
<td>2.2.2.7.4</td>
</tr>
<tr>
<td>cda:value</td>
<td>7.04 - Problem Code</td>
<td>O/N</td>
<td>2.2.2.7.5</td>
</tr>
<tr>
<td>cda:act[cda:templateId/@root=&quot;2.16.840.1.113883.10.20.1.27&quot;]/cda:performer</td>
<td>7.05 - Treating Provider</td>
<td>O/Y</td>
<td>2.2.2.7.6</td>
</tr>
<tr>
<td>cda:entryRelationship/cda:observation[cda:templateId/@root=&quot;2.16.840.1.113883.10.20.1.38&quot;]</td>
<td>7.06 - Age (at Onset)</td>
<td>O/N</td>
<td>2.2.2.18.11</td>
</tr>
<tr>
<td>cda:entryRelationship[ @typeCode=&quot;CAUS&quot;]cda:observation</td>
<td>7.07 - Cause of Death</td>
<td>O/N</td>
<td>2.2.2.18.12</td>
</tr>
<tr>
<td>cda:entryRelationship/ cda:observation[cda:templateId/@root=&quot;2.16.840.1.113883.10.20.1.38&quot;]</td>
<td>7.08 - Age (at Death)</td>
<td>O/N</td>
<td>2.2.2.18.11</td>
</tr>
</tbody>
</table>

### 2.2.2.7.1 Condition Module Constraints

**C83-[DE-7-CDA-1]** A CDA Document SHALL declare conformance for the Condition Module by including a `<templateID>` element with the `root` attribute set to the value `2.16.840.1.113883.3.88.11.83.7`

**C83-[DE-7-CDA-2]** Problem Entries SHALL also declare conformance to the IHE Problem Concern by including a `<templateID>` element with the `root` attribute set to the value `1.3.6.1.4.1.19376.1.5.3.1.4.5.2`

### 2.2.2.7.2 Problem Date Constraints

The problem date constraints include 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. These dates represent the clinically effective time span over which the problem existed.

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.
2.2.2.7.3 Problem Type Constraints

The problem type **SHALL** be coded as specified in HITSP/C80 Section 2.2.3.1.2 Problem Type

2.2.2.7.4 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.

C83-[DE-7.02-1]
2.2.2.7.5 Problem Code Constraints

Figure 2-25 Problem Code Example

```xml
<!-- 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>
```

C83-[DE-7.04-1] The problem SHALL be coded as specified in HITSP/C80 Section 2.2.3.1.1 Problem

2.2.2.7.6 Treating Provider Constraints

Figure 2-26 Treating Provider Example

```xml
<!-- 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>
```

C83-[DE-7.05-CDA-1] The time over which this provider treated the condition MAY be recorded in the <time> element beneath the <performer> element

C83-[DE-7.05-CDA-2] 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 2.2.2.4

C83-[DE-7.05-CDA-3] The treating provider or providers SHALL be recorded in a <performer> element under the <act> that describes the condition of concern

2.2.2.8 MEDICATION

Within a CDA document, the following information maps to HITSP Data Elements in the module defined in section 2.1.2.8 Medication of this document. See the HL7 Continuity of Care Document Section 3.9 for constraints applicable to these data elements.

The template identifier for this module is 2.16.840.1.113883.3.88.11.83.8.
### Table 2-50 Medication – Prescription and Non-Prescription Data Mapping Table – Requirements

<table>
<thead>
<tr>
<th>CDA Data Location</th>
<th>HITSP Data Element Identifier and Name</th>
<th>O/R¹⁴</th>
<th>Additional Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>cda:substanceAdministration[@root = '2.16.840.1.113883.10.20.1.24']</td>
<td>Administration Information Event Entry</td>
<td></td>
<td>See Note¹⁵</td>
</tr>
<tr>
<td>cda.text</td>
<td>8.01 - Free Text Sig</td>
<td>O/N</td>
<td>2.2.2.8.2</td>
</tr>
<tr>
<td>cda.effectiveTime[1]/cda:high</td>
<td>8.02 - Indicate Medication Stopped</td>
<td>O/N</td>
<td>2.2.2.8.3</td>
</tr>
<tr>
<td>cda.effectiveTime[2]</td>
<td>8.03 - Administration Timing</td>
<td>O/Y</td>
<td>2.2.2.8.4</td>
</tr>
<tr>
<td>cda.effectiveTime[2]</td>
<td>8.04 - Frequency</td>
<td>O/Y</td>
<td>2.2.2.8.4</td>
</tr>
<tr>
<td>cda.effectiveTime[2]</td>
<td>8.05 - Interval</td>
<td>O/Y</td>
<td>2.2.2.8.4</td>
</tr>
<tr>
<td>cda.effectiveTime[2]</td>
<td>8.06 - Duration</td>
<td>O/Y</td>
<td>2.2.2.8.4</td>
</tr>
<tr>
<td>cda.routeCode</td>
<td>8.07 - Route</td>
<td>O/Y</td>
<td>2.2.2.8.5</td>
</tr>
<tr>
<td>cda.doseQuantity</td>
<td>8.08 - Dose</td>
<td>O/Y</td>
<td>2.2.2.8.6</td>
</tr>
<tr>
<td>cda.approachSiteCode</td>
<td>8.09 - Site</td>
<td>O/Y</td>
<td>2.2.2.8.7</td>
</tr>
<tr>
<td>cda.maxDoseQuantity</td>
<td>8.10 - Dose Restriction</td>
<td>O/Y</td>
<td>2.2.2.8.8</td>
</tr>
<tr>
<td>cda.administrationUnitCode</td>
<td>8.11 - Product Form</td>
<td>O/N</td>
<td>2.2.2.8.8</td>
</tr>
<tr>
<td>cda:code</td>
<td>8.12 - Delivery Method</td>
<td>O/Y</td>
<td>2.2.2.8.9</td>
</tr>
<tr>
<td>cda.consumable/cda:manufacturedProduct</td>
<td>Medication Information</td>
<td>R/Y</td>
<td>2.2.2.8.10</td>
</tr>
<tr>
<td>cda:manufacturedMaterial/cda:code</td>
<td>8.13 - Coded Product Name</td>
<td>R2/Y</td>
<td>2.2.2.8.11</td>
</tr>
<tr>
<td>cda:translation</td>
<td>8.14 - Coded Brand Name</td>
<td>R2/Y</td>
<td>2.2.2.8.12</td>
</tr>
<tr>
<td>cda:originalText</td>
<td>8.15 - Free Text Product Name</td>
<td>R/N</td>
<td>2.2.2.8.13</td>
</tr>
<tr>
<td>cda:manufacturedMaterial/cda:code</td>
<td>8.16 - Free Text Brand Name</td>
<td>R2/N</td>
<td>2.2.2.8.14</td>
</tr>
<tr>
<td>cda:manufacturerOrganization</td>
<td>8.17 - Drug Manufacturer</td>
<td>O/N</td>
<td></td>
</tr>
<tr>
<td>cda:entryRelationship[@typeCode='SUBJ']/cda:observation[@root=</td>
<td>8.18 - Product Concentration</td>
<td>R2/N</td>
<td></td>
</tr>
<tr>
<td>cda:entryRelationship[@typeCode='REFR']/cda:observation[@root=</td>
<td>8.19 - Type of Medication</td>
<td>R2/N</td>
<td>2.2.2.8.16</td>
</tr>
<tr>
<td>cda:entryRelationship[@typeCode='RSON']/cda:observation[@root=</td>
<td>8.20 - Status of Medication</td>
<td>R2/N</td>
<td>2.2.2.8.17</td>
</tr>
<tr>
<td>cda:entryRelationship[@typeCode='RSON']/cda:observation[@root=</td>
<td>8.21 - Indication</td>
<td>O/Y</td>
<td>2.2.2.8.18</td>
</tr>
</tbody>
</table>

¹⁴ **NOTE:** Optionality = “R” for Required, “R2” for Required if known, “O” for Optional and Repeat = “Y” for Yes or “N” for No

¹⁵ Requirements for Entries are defined at a higher level than the Entry Content Module (i.e. Section Content Modules, HITSP CDA based constructs and Interoperability Specifications).
<table>
<thead>
<tr>
<th>CDA Data Location</th>
<th>HITSP Data Element Identifier and Name</th>
<th>O/R</th>
<th>Additional Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>cda:entryRelationship/cda:act[ cda:templateId/@root= '2.16.840.1.113883.10.20.1.49' ]/cda:text</td>
<td>8.22 - Patient Instructions</td>
<td>O/N</td>
<td>2.2.2.8.19</td>
</tr>
<tr>
<td>cda:entryRelationship[@typeCode='CAUS']/cda:observation[cda:templateId/@root= '2.16.840.1.113883.10.20.1.54']</td>
<td>8.23 - Reaction</td>
<td>O/N</td>
<td></td>
</tr>
<tr>
<td>and cda:participant/cda:participantRole[ cda:code/@code = '412307009' cda:code/@codeSystem= '2.16.840.1.113883.6.96']</td>
<td>8.24 - Vehicle</td>
<td>O/Y</td>
<td>2.2.2.8.20</td>
</tr>
<tr>
<td>cda:condition</td>
<td>8.25 - Dose Indicator</td>
<td>O/Y</td>
<td></td>
</tr>
<tr>
<td>cda:entryRelationship[@typeCode='REFR']/cda:supply[moodCode='INT']</td>
<td>Order Information</td>
<td>R2/Y</td>
<td>2.2.2.8.21</td>
</tr>
<tr>
<td>cda:id</td>
<td>8.26 - Order Number</td>
<td>R2/N</td>
<td></td>
</tr>
<tr>
<td>cda:repeatNumber</td>
<td>8.27 - Fills</td>
<td>O/N</td>
<td>2.2.2.8.22</td>
</tr>
<tr>
<td>cda:quantity</td>
<td>8.28 - Quantity Ordered</td>
<td>R2/N</td>
<td>2.2.2.8.23</td>
</tr>
<tr>
<td>cda:effectiveTime/cda:high</td>
<td>8.29 - Order Expiration Date/Time</td>
<td>R2/N</td>
<td></td>
</tr>
<tr>
<td>cda:author/cda:time</td>
<td>8.30 - Order Date/Time</td>
<td>O/N</td>
<td></td>
</tr>
<tr>
<td>cda:author/cda:assignedAuthor/cda:assignedPerson/cda:name</td>
<td>8.31 - Ordering Provider</td>
<td>O/N</td>
<td></td>
</tr>
<tr>
<td>cda:entryRelationship/ cda:act[cda:templateId/@root= '2.16.840.1.113883.10.20.1.43']/cda:text</td>
<td>8.32 - Fulfillment Instructions</td>
<td>O/N</td>
<td>2.2.2.8.24</td>
</tr>
<tr>
<td>cda:supply[@moodCode='EVN']</td>
<td>8.33 - Fulfillment History</td>
<td>O/Y</td>
<td></td>
</tr>
<tr>
<td>cda:id</td>
<td>8.34 - Prescription Number</td>
<td>R2/N</td>
<td>2.2.2.8.25</td>
</tr>
<tr>
<td>cda:performer/cda:assignedEntity</td>
<td>8.35 - Provider</td>
<td>O/N</td>
<td>2.2.2.8.26</td>
</tr>
<tr>
<td>cda:performer/cda:assignedEntity/ cda:addr</td>
<td>8.36 - Location</td>
<td>O/N</td>
<td></td>
</tr>
<tr>
<td>cda:effectiveTime</td>
<td>8.37 - Dispense Date</td>
<td>O/N</td>
<td></td>
</tr>
<tr>
<td>cda:quantity</td>
<td>8.38 - Quantity Dispensed</td>
<td>R2/N</td>
<td>2.2.2.8.27</td>
</tr>
<tr>
<td>cda:entryRelationship[ @typeCode='COMP']/cda:sequenceNum</td>
<td>8.39 - Fill number</td>
<td>R2/N</td>
<td>2.2.2.8.28</td>
</tr>
<tr>
<td>cda:statusCode</td>
<td>8.40 - Fill Status</td>
<td>O/N</td>
<td>2.2.2.8.29</td>
</tr>
</tbody>
</table>
2.2.2.8.1 Medication – Prescription and Non-Prescription Module Constraints

C83-[DE-8-CDA-1] A CDA Document **SHALL** declare conformance for the Medication – Prescription and Non-Prescription module by including a `<templateID>` element with the `root` attribute set to the value 2.16.840.1.113883.3.88.11.83.8

C83-[DE-8-CDA-2] Substance Administration acts conforming to this module **SHALL** also declare conformance to the IHE Medications entity by including a `<templateID>` element with the `root` attribute set to the value 1.3.6.1.4.1.19376.1.5.3.1.4.7

2.2.2.8.2 Free Text Sig Constraints

**Figure 2-27 Free Text Sig Example**

```xml
<!-- 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='2.16.840.1.113883.3.88.11.83.8'/>
      <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7'/>
    ...
    <text><reference value='#sig-1'/></text>
  ...
  </substanceAdministration>
</section>
```

2.2.2.8.3 Indicate Medication Stopped Constraints

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

2.2.2.8.4 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 `institutionSpecified` 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>

Figure 2-28 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'/>  
</effectiveTime>
<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'/>  
</effectiveTime>
<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'/>  
</effectiveTime>
<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'/>  
</effectiveTime>
<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'/>  
</effectiveTime>
<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'/>  
</effectiveTime>
<effectiveTime xsi:type='PIVL_TS' operator='A'>
  <phase>
    <low value='198701010800' inclusive='true'/>  
    <width value='10' unit='min' />
  </phase>
</effectiveTime>
<period value='1' unit='d'/>
</effectiveTime>

</figure>
The first `<effectiveTime>` SHALL use the IVL_TS data type unless for a single administration, in which case, it SHALL use the TS data type.

Medications that are administered based on activities of daily living SHALL identify the events that trigger administration in the `<event>` element beneath the `<effectiveTime>` element. The `<effectiveTime>` element SHALL be of type EIVL_TS.

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".

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".

### 2.2.2.8.5 Route of Administration Constraints

**Figure 2-29 Route of Administration Example**

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

**C83-[DE-8.07-CDA-1]** SHALL be coded as specified in HITSP/C80 Section 2.2.3.3.4.1 Medication Route FDA.

### 2.2.2.8.6 Dose Constraints

The units of presentation can be found at [www.fda.gov](http://www.fda.gov), 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 2-30 Dose Examples**

```xml
<!-- 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'/>
```

**C83-[DE-8.08-1]** Units MAY be present when needed. If present it SHALL be coded as specified in HITSP/C80 Section 2.2.3.6.6 Units of Measurement.

**C83-[DE-8.08-2]** 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), units SHOULD contain the preferred name of the presentation units within braces {} using the units of presentation from the NCI Thesaurus.

### 2.2.2.8.7 Site Constraints

**C83-[DE-8.09-1]** The Site SHALL be coded as specified in HITSP/C80 Section 2.2.3.2.1 Body Site
2.2.2.8 Product Form Constraints

Figure 2-31 Product Form Example

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

C83-[DE-8.11-1] SHALL be coded as specified in HITSP/C80 Section 2.2.3.3.3 Medication Product Form

2.2.2.9 Delivery Method Constraints

Figure 2-32 Delivery Method

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

NOTE: HITSP has not specified a vocabulary for Delivery Method because ongoing harmonization work with the NCPDP Industry SIG Task Force and the e-Prescribing pilots has not yet published results.

C83-[DE-8.12-CDA-1] The Delivery Method MAY be recorded in the `<cda:code>` element

C83-[DE-8.12-CDA-2] The free text description of the delivery method MAY be included within a `<cda:originalText>` element beneath the `<cda:code>` element

2.2.2.10 Medication Information Constraints

The template identifier for this data element is 2.16.840.1.113883.3.88.11.83.8.2.

The name and code for the medication are recorded in the `<consumable>` element, as shown below.
Figure 2-33 Medication Information Example

```xml
<!-- 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='2.16.840.1.113883.3.88.11.83.8.2'/>
      <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7.2'/>
      <manufacturedMaterial classCode='MMAT' determinerCode='KIND'>
        <code code='161' displayName='Acetaminophen'
          codeSystem='2.16.840.1.113883.6.88'
          codeSystemName='RxNorm'>
          <originalText>Acetaminophen</originalText>
        </code>
        <translation code='202433' displayName='Tylenol'
          codeSystem='2.16.840.1.113883.6.88'>
          <originalText>Tylenol</originalText>
        </translation>
      </manufacturedMaterial>
    </manufacturedProduct>
  </consumable>

</substanceAdministration>
```


C83-[DE-8.13-CDA-1] If the code for the generic product is unknown, the `code` and `codeSystem` attributes **MAY** be omitted.

C83-[DE-8.13-1] The coded product name **SHALL** be coded as specified in HITSP/C80 Section 2.2.3.3.8 Medication Clinical Drug Names.

C83-[DE-8.13-2] When only the class of the drug is known (e.g., Beta Blocker or Sulfa Drug), it **SHALL** be coded as specified in HITSP/C80 Section 2.2.3.3.9 Medication Drug Class.

C83-[DE-8.13-3] When only the medication ingredient name is know, the coded product name **MAY** be coded as specified in HITSP/C80 Section 2.2.3.3.11 Ingredient Name

2.2.2.8.12 Coded Brand Name Constraints

C83-[DE-8.14-CDA-1] The code for the specific brand of product **SHALL** appear in a `translation` element

C83-[DE-8.14-1] The brand name **SHALL** be coded as specified in HITSP/C80 Section 2.2.3.3.7 Medication Brand Name or 2.2.3.3.10 Medication Packaged Product.

2.2.2.8.13 Free Text Product Name Constraints

C83-[DE-8.15-CDA-1] The product (generic) name **SHALL** appear in the `originalText` element beneath the `code` element
2.2.2.8.14 Free Text Brand Name Constraints


C83-[DE-8.14-CDA-2] The brand name SHALL appear in the <name> element of the <manufacturedMaterial>

2.2.2.8.15 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.

2.2.2.8.16 Type of Medication Constraints

The template identifier for this data element is 2.16.840.1.113883.3.88.11.83.8.1.

Figure 2-34 Type of Medication

```xml
<!-- 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='2.16.840.1.113883.3.88.11.83.8.1'/>
      <code code='73639000' displayName='Prescription Drug' codeSystem='2.16.840.1.113883.6.96' codeSystemName='SNOMED CT'/>
      <statusCode code='completed'/>
    </observation>
  </entryRelationship>
</substanceAdministration>
```

C83-[DE-8.19-CDA-1] A CDA Document SHALL declare conformance for the Type of Medication by including a <templateID> element with the root attribute set to the value 2.16.840.1.113883.3.88.11.83.8.1

C83-[DE-8.19-CDA-2] Each <supply> or <substanceAdministration> act MAY reference an <observation> element that describes the type of medication, by including an <entryRelationship typeCode='SUBJ'/> element

C83-[DE-8.19-CDA-3] The type of a medication SHALL be represented with an <observation> element in the <entryRelationship>

C83-[DE-8.19-CDA-4] The <observation> element SHALL have a <templateId> with a root attribute set to 2.16.840.1.113883.3.88.11.83.8.1

C83-[DE-8.19-CDA-5] The <observation> SHALL have a <code> element that represents the kind of medication actually or intended to be administered or supplied

C83-[DE-8.19-1] The type of medication SHALL be coded as specified in HITSP/C80 Section 2.2.3.3.5 Medication Type.

2.2.2.8.17 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 2-35 Status of Medication Example

```xml
<!-- 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>
```

C83-[DE-8.20-1] The medication status MAY be recorded using the CCD Medication Status observation using the value set defined in the CCD

2.2.2.8.18 Indication Constraints

Figure 2-36 Indication Example

```xml
<!-- 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>
```

C83-[DE-8.20-CDA-1] 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, and which conforms

C83-[DE-8.20-CDA-2] 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

C83-[DE-8.20-1] The indication SHALL be coded as specified in HITSP/C80 Section 2.2.3.1.1 Problem

2.2.2.8.19 Patient Instructions Constraints

External patient educational materials can be referenced with an appropriate URL entry in the text/reference/value.
**Figure 2-37 Patient Instructions Example**

```xml
<!-- 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'/>
      <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.3'/>
      <code code='PINSTRUCT' codeSystem='1.3.6.1.4.1.19376.1.5.3.2' 
        codeSystemName='IHEActCode' />
      <text><reference value='# patient-instruction'/></text>
    </act>
  </entryRelationship>
</substanceAdministration>
...

<!-- an example of a reference to an external document-->
<text>
</text>
```

C83-[DE-8.22-CDA-1] Medication Information data elements SHALL declare conformance to the IHE Patient Medication Instructions template by including a `<templateID>` element with the root attribute set to the value 1.3.6.1.4.1.19376.1.5.3.1.4.3

2.2.2.8.20 Vehicle Constraints

**Figure 2-38 Vehicle Example**

```xml
<!-- 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'/>
      <name>... </name>
    </participantRole>
  </participant>
</substanceAdministration>
```

C83-[DE-8.24-CDA-1] The vehicle for administering a medication MAY be recorded in a `<participantRole>` element inside a `<participant>` element in the `<substanceAdministration>` element

C83-[DE-8.24-CDA-2] The typeCode attribute of the `<participant>` element SHALL be CSM

C83-[DE-8.24-CDA-3] The classCode of the `<participantRole>` SHALL be MANU
A `<code>` element for the `<participantRole>` SHALL be present and SHALL contain the code 412307009 from the SNOMED CT code system as shown above.

The `<name>` element in the `<playingEntity>` element SHALL record the name of the drug vehicle

The `<code>` element in the `<playingEntity>` element MAY be used to supply a coded term for the drug vehicle

The Medication Vehicle shall be coded as specified in HITSP/C80 Section 2.2.3.3.12 Medication Vehicle

2.2.2.8.21 Order Information Constraints

Order information may be recorded as part of the fulfillment history or as part of the administration information.
Figure 2-39 Order Information Examples

A CDA Document **SHALL** declare conformance for the Order Information data element by including a `<templateID>` element with the `root` attribute set to the value 2.16.840.1.113883.3.88.11.83.8.3

Order Information data elements **SHALL** declare conformance to the IHE Supply Entry template by including a `<templateID>` element with the `root` attribute set to the value 1.3.6.1.4.1.19376.1.5.3.1.4.7.3

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
2.2.2.8.22 Fills Constraints

Figure 2-40 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.

2.2.2.8.23 Quantity Ordered Constraints

The units of presentation can be retrieved from www.fda.gov, and include only those terms which have not been mapped to UCUM. Terms with mappings to UCUM are units of administration, rather than units of presentation.

Figure 2-41 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'/>
```

C83-[DE-8.26-CDA-1] The quantity ordered **SHALL** be recorded in the `value` attribute of `<quantity>` element inside a `<supply>` element used to record order information

C83-[DE-8.26-CDA-2] The `unit` attribute **SHALL** be present

C83-[DE-8.26-CDA-3] 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 coded as specified in HITSP/C80 Section 2.2.3.6.6 Units of Measure

C83-[DE-8.26-CDA-4] When the quantity ordered is in administration units, the `unit` attribute **SHOULD** contain the preferred name of the presentation units within braces `{ }` using the units of presentation as specified in HITSP/C80 Section 2.2.3.3.3 Medication Product Form
2.2.2.24 Fulfillment Instructions Constraints

Figure 2-42 Fulfillment Instructions Example

```xml
<!-- 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'/>
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.3.1'/>
        <code code='FINSTRUCT' codeSystem='1.3.6.1.4.1.19376.1.5.3.2'
              codeSystemName='IHEActCode'/>
        <text><reference value='#comment-2'/></text>
        <statusCode code='completed' />
      </act>
    </entryRelationship>
  </substanceAdministration>
</entry>
```

C83-[DE-8.32-CDA-1] Fulfillment instructions data elements SHALL declare conformance to the IHE Medication Fulfillment Instructions template by including a `<templateID>` element with the `root` attribute set to the value 1.3.6.1.4.1.19376.1.5.3.1.4.3.1

2.2.2.25 Prescription Number Constraints

Figure 2-43 Prescription Number Example

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

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C83-[DE-8.34-CDA-1] The prescription number SHALL be recorded in the extension attribute of the <id> element within a <supply> element having a moodCode attribute of EVN.

C83-[DE-8.34-CDA-2] 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.

C83-[DE-8.34-CDA-3] A GUID MAY be used in place of the OID of the assigning authority.

2.2.2.8.26 Provider Constraints

C83-[DE-8.35-CDA-1] The provider SHALL be recorded in the <assignedEntity> element.

C83-[DE-8.35-CDA-2] 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.

C83-[DE-8.35-CDA-3] The name of the person SHALL appear in the <name> element of the <assignedPerson> element beneath the <assignedEntity> element.

C83-[DE-8.35-CDA-4] The name of the organization SHALL appear in the <name> element of the <representedOrganization> element beneath the <assignedEntity> element.

2.2.2.8.27 Quantity Dispensed Constraints

C83-[DE-8.38-CDA-1] The quantity dispensed SHALL be recorded in the value attribute of <quantity> element inside a <supply> element with a moodCode attribute set to EVN.

C83-[DE-8.38-CDA-2] 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 as specified in HITSP/C80 Section 2.2.3.6.6 Units of Measure.

C83-[DE-8.38-CDA-3] When the quantity dispensed is in administration units the unit attribute SHOULD contain the preferred name of the presentation units within braces { } using the units of presentation as specified in HITSP/C80 Section 2.2.3.3.3 Medication Product Form.

The units of presentation can be found at www.fda.gov, and include only those terms which have not been mapped to UCUM. Terms with mappings to UCUM are units of administration, rather than units of presentation.

2.2.2.8.28 Fill Number Constraints

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

C83-[DE-8.39-CDA-1] The fill number MAY be recorded in the sequenceNumber attribute of a <entryRelationship> element with a typeCode attribute set to COMP.

2.2.2.8.29 Fill Status Constraints


C83-[DE-8.40-CDA-2] The statusCode attribute SHALL contain be coded as specified in HITSP/C80 Section 2.2.3.3.1 Medication Fill Status.

2.2.2.9 PREGNANCY

Within a CDA document, the following information maps to HITSP Data Elements in the module defined in section 2.1.2.9 Pregnancy of this document. This section describes a coded entry indicating whether the patient is currently pregnant.
Figure 2-44 Pregnancy Coding Example

```xml
<!-- These examples assume the default namespace is 'urn:hl7-org:v3' -->
<observation classCode='OBS' moodCode='EVN'>
  <value xsi:type='CD'
    code='773860066'
    display='patient currently pregnant'
    codeSystem='2.16.840.1.113883.6.96'
    codeSystemName='SNOMED CT'/>
</observation>
```

<table>
<thead>
<tr>
<th>CDA Data Location</th>
<th>HITSP Data Element Identifier and Name</th>
<th>O/R16</th>
<th>Additional Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>cda:observation/cda:value[@code='773860066' and @codeSystem='2.16.840.1.113883.6.96']</td>
<td>9.01 - Pregnancy</td>
<td>See Note17</td>
<td></td>
</tr>
</tbody>
</table>

2.2.2.10 INFORMATION SOURCE

This module contains 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 entry Content Modules. See the HL7 Continuity of Care Document Section 5.2 for constraints applicable to this module.

<table>
<thead>
<tr>
<th>CDA Data Location</th>
<th>HITSP Data Element Identifier and Name</th>
<th>O/R16</th>
<th>Additional Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>ancestor-or-self::cda:author[1]</td>
<td>Author</td>
<td>R/N</td>
<td></td>
</tr>
<tr>
<td>cda:time</td>
<td>10.01 - Author Time</td>
<td>R/N</td>
<td></td>
</tr>
<tr>
<td>cda:assignedAuthor/cda:assignedPerson/cda:name</td>
<td>10.02 - Author Name</td>
<td>R/N</td>
<td></td>
</tr>
<tr>
<td>cda:reference/cda:externalDocument</td>
<td>10.03 - Reference</td>
<td>R2/Y</td>
<td></td>
</tr>
<tr>
<td>cda:id</td>
<td>10.04 - Reference Document ID</td>
<td>R/N</td>
<td></td>
</tr>
<tr>
<td>cda:text/cda:reference/@value</td>
<td>10.05 - Reference Document URL</td>
<td>O/N</td>
<td></td>
</tr>
<tr>
<td>ancestor-or-self::cda:informant</td>
<td>Information Source</td>
<td>O/Y</td>
<td></td>
</tr>
<tr>
<td>cda:assignedPerson/cda:name</td>
<td></td>
<td>R/N</td>
<td>2.2.2.10.1</td>
</tr>
<tr>
<td>cda:assignedEntity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>cda:representedOrganization/cda:name</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>cda:relatedEntity/cda:relatedPerson/cda:name</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2.2.2.10.1 Information Source Name Constraints

C83-[DE-10.02-CDA-1] The name of the information source SHALL be provided in the <name> element
C83-[DE-10.02-CDA-2] The <name> element SHALL appear within an <assignedPerson> or <representedOrganization> element appearing in an <assignedEntity>, or within a <relatedPerson> element within a <relatedEntity> element beneath the <informant> element

16 NOTE: Optionality = “R” for Required, “R2” for Required if known, “O” for Optional and Repeat = “Y” for Yes or “N” for No
17 Requirements for Entries are defined at a higher level than the Entry Content Module (i.e. Section Content Modules, HITSP CDA based constructs and Interoperability Specifications).
18 NOTE: Optionality = “R” for Required, “R2” for Required if known, “O” for Optional and Repeat = “Y” for Yes or “N” for No
2.2.2.11 COMMENT

This module contains a comment to be supplied for any other entry Content Modules. See the HL7 Continuity of Care Document Section 4.3 for constraints applicable to this module.

The template identifier for this module is 2.16.840.1.113883.3.88.11.83.11.

Figure 2-45 Comment Example

```xml
<!-- 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='2.16.840.1.113883.3.88.11.83.11'/>
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.2'/>
        <code code='' displayName='Annotation Comment' codeSystem='2.16.840.1.113883.6.1'/>
        <text><reference value='#comment-1'/></text>
        <author>
          <assignedAuthor>
            <assignedPerson>
              <name>...
            </assignedPerson>
          </assignedAuthor>
          <assignedAuthor>
            <assignedPerson>
              <name>...
            </assignedPerson>
          </assignedAuthor>
        </author>
      </act>
    </entryRelationship>
  </act>
</entry>
```

Table 2-53 Comments Data Mapping Table – Definitions: Author

<table>
<thead>
<tr>
<th>Data Element ID</th>
<th>Data Element</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>11.01</td>
<td>Free Text Comment</td>
<td>A free text comment</td>
</tr>
</tbody>
</table>

Table 2-54 Comments Data Mapping Table – Requirements

<table>
<thead>
<tr>
<th>CDA Data Location</th>
<th>HITSP Data Element Identifier and Name</th>
<th>O/R&lt;sup&gt;19&lt;/sup&gt;</th>
<th>Additional Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>cda:act[cda:templateId/@root = '2.16.840.1.113883.10.20.1.40']</td>
<td>Comment</td>
<td>O/Y</td>
<td></td>
</tr>
<tr>
<td>ancestor-or-self:.cda:author[1]</td>
<td>Author</td>
<td>R/N</td>
<td></td>
</tr>
<tr>
<td>cda:text/cda:reference/@value</td>
<td>11.01 - Free Text Comment</td>
<td>R/N</td>
<td></td>
</tr>
</tbody>
</table>

2.2.2.11.1 Comments Module Constraints

C83-[DE-10-CDA-1] Data elements defined elsewhere in the specification SHALL NOT be recorded using the Comments Module.

C83-[DE-10-CDA-2] A CDA Document SHALL declare conformance for the Comments module by including a `<templateId>` element with the `root` attribute set to the value 2.16.840.1.113883.3.88.11.83.11

<sup>19</sup> NOTE: Optionality = “R” for Required, “R2” for Required if known, “O” for Optional and Repeat = “Y” for Yes or “N” for No
C83-[DE-10-CDA-3] Each comment module **SHALL** be conformant with the IHE Comment module and **SHALL** include a `<templateID>` element with the `root` attribute set to the value `1.3.6.1.4.1.19376.1.5.3.1.4.2`

2.2.2.11.2 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.

C83-[DE-10-CDA-4] The author of a comment **SHALL** be recorded as specified for authors in the Information Source module.

2.2.2.12 ADVANCE DIRECTIVE

Within a CDA document, the following information maps to HITSP Data Elements in the module defined in section `<fill in>` of this document. See the HL7 Continuity of Care Document Section `<fill in>` for constraints applicable to these data elements. 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 module is 2.16.840.1.113883.3.88.11.83.12.

### Table 2-55 Advance Directives Data Mapping Table – Requirements

<table>
<thead>
<tr>
<th>CDA Data Location</th>
<th>HITSP Data Element Identifier and Name</th>
<th>O/R</th>
<th>Additional Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td><code>cda:observation[cda:templateId/@root='2.16.840.1.113883.10.20.1.17']</code></td>
<td>Advance Directive Event Entry</td>
<td>See Below 21</td>
<td></td>
</tr>
<tr>
<td><code>cda:code</code></td>
<td>12.01 - Advance Directive Type</td>
<td>R2/N</td>
<td>2.2.2.12.2</td>
</tr>
<tr>
<td><code>cda:originalText/cda:reference/@value</code></td>
<td>12.02 - Advance Directive Free Text Type</td>
<td>R/N</td>
<td>2.2.2.12.3</td>
</tr>
<tr>
<td><code>cda:effectiveTime</code></td>
<td>12.03 - Effective Date</td>
<td>R/N</td>
<td>2.2.2.12.4</td>
</tr>
<tr>
<td><code>cda:participant[@typeCode='CST']/cda:participantRole[@classCode='AGNT']</code></td>
<td>12.04 - Custodian of the Document</td>
<td>R/N</td>
<td>2.2.2.12.5</td>
</tr>
</tbody>
</table>

**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.

---

20 **NOTE:** Optionality = “R” for Required, “R2” for Required if known, “O” for Optional and Repeat = “Y” for Yes or “N” for No

21 Requirements for Entries are defined at a higher level than the Entry Content Module (i.e. Section Content Modules, HITSP CDA based constructs and Interoperability Specifications).
2.2.2.12.1 Advance Directive Module Constraints

C83-[DE-12-CDA-1] A CDA Document SHALL declare conformance for the Advance Directive module by including a <templateID> element with the root attribute set to the value 2.16.840.1.113883.3.88.11.83.12

C83-[DE-12-CDA-2] An advance directive data element SHALL declare conformance to the IHE Advance Directive Observation by including a <templateID> element with the root attribute set to the value 1.3.6.1.4.1.19376.1.5.3.1.4.13.7

2.2.2.12.2 Advance Directive Coded Type Constraints

C83-[DE-12.01-1] The advance directive SHALL be coded as specified in HitSP/C80 Section 2.2.3.10.1 Advance Directive Type

2.2.2.12.3 Advance Directive Free Text Type Constraints

C83-[DE-12.02-1] 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>

2.2.2.12.4 Effective Date Constraints

C83-[DE-12.03-1] The starting time of the Advance Directive SHALL be recorded in the <low> element of the <effectiveTime> element in the Advance Directive <observation>

C83-[DE-12.03-2] If the starting time is unknown, the <low> element SHALL have the nullFlavor attribute set to UNK

C83-[DE-12.03-3] The ending time of the Advance Directive SHALL be recorded in the <high> element of the <effectiveTime> element in the Advance Directive <observation>

C83-[DE-12.03-4] If the ending time is unknown, the <high> element SHALL have the nullFlavor attribute set to UNK

C83-[DE-12.03-5] If the Advance Directive does not have a specified ending time, the <high> element SHALL have the nullFlavor attribute set to NA
2.2.2.12.5 Custodian of the Document Constraints

C83-[DE-12.04-1] 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>`

C83-[DE-12.04-2] The typeCode attribute of the `<participant>` element SHALL be CST

C83-[DE-12.04-3] The classCode of the `<participantRole>` element SHALL be AGNT

C83-[DE-12.04-4] The address of the agent SHALL be recorded in an `<addr>` element when known

C83-[DE-12.04-5] The telephone number or other electronic communications address for the agent SHALL be recorded in a `<telecom>` element when known

C83-[DE-12.04-6] 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

2.2.2.13 IMMUNIZATION

Within a CDA document, the following information maps to HITSP Data Elements in the module defined in section <fill in> of this document. See the HL7 Continuity of Care Document Section <fill in> for constraints applicable to these data elements. This module contains data describing the patient's immunization history. The HL7 Continuity of Care (CCD) Implementation Guide defines Immunizations using the same data objects and constraints as for Medications. See the HL7 Continuity of Care Document, Sections 3.9 Medications and 3.11 Immunizations; and also the Medication module Section 2.2.2.8 of this construct for constraints applicable to this module.

The template identifier for this module is 2.16.840.1.113883.3.88.11.83.13.

<table>
<thead>
<tr>
<th>CDA Data Location</th>
<th>HITSP Data Element Identifier and Name</th>
<th>O/R</th>
<th>Additional Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td><code>&lt;cda:substanceAdministration&gt;</code>[@root = '2.16.840.1.113883.10.20.1.24']</td>
<td>Immunization Event Entry</td>
<td>See Below&lt;sup&gt;23&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td>@negationInd</td>
<td>13.01 - Refusal</td>
<td>R/N</td>
<td></td>
</tr>
<tr>
<td><code>&lt;cda:effectiveTime&gt;</code></td>
<td>13.02 - Administered Date</td>
<td>O/N</td>
<td></td>
</tr>
<tr>
<td><code>&lt;cda:entryRelationship&gt;</code>[@typeCode='SUBJ']/<code>&lt;cda:observation&gt;</code>[@value]</td>
<td>13.03 - Medication Series Number</td>
<td>O/N</td>
<td></td>
</tr>
<tr>
<td><code>&lt;cda:entryRelationship&gt;</code>[@typeCode='CAUS']/<code>&lt;cda:observation&gt;</code>[@root= '2.16.840.1.113883.10.20.1.54']</td>
<td>13.04 - Reaction</td>
<td>O/Y</td>
<td></td>
</tr>
<tr>
<td><code>&lt;cda:performer&gt;</code>[@assignedEntity]</td>
<td>13.05 - Performer</td>
<td>O/N</td>
<td></td>
</tr>
<tr>
<td><code>&lt;cda:consumable&gt;</code>[@manufacturedProduct]</td>
<td>Medication Information</td>
<td>R/Y</td>
<td></td>
</tr>
<tr>
<td><code>&lt;cda:manufacturedMaterial&gt;</code>[@code]</td>
<td>13.06 - Coded Product Name</td>
<td>R2/Y</td>
<td>2.2.2.13.1</td>
</tr>
<tr>
<td><code>&lt;cda:originalText&gt;</code></td>
<td>13.07 - Free Text Product Name</td>
<td>R/N</td>
<td></td>
</tr>
<tr>
<td><code>&lt;cda:manufactureOrganization&gt;</code></td>
<td>13.08 - Drug Manufacturer</td>
<td>O/N</td>
<td></td>
</tr>
<tr>
<td><code>&lt;cda:manufacturedMaterial&gt;</code>[@lotNumberText]</td>
<td>13.09 - Lot Number</td>
<td>R2/N</td>
<td></td>
</tr>
</tbody>
</table>

<sup>22</sup> **NOTE:** Optionality = “R” for Required, “R2” for Required if known, “O” for Optional and Repeat = “Y” for Yes or “N” for No

<sup>23</sup> Requirements for Entries are defined at a higher level than the Entry Content Module (i.e. Section Content Modules, HITSP CDA based constructs and Interoperability Specifications).
<table>
<thead>
<tr>
<th>CDA Data Location</th>
<th>HITSP Data Element Identifier and Name</th>
<th>O/R</th>
<th>Additional Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>cda:entryRelationship[typeCode='RSON']/cda:act[cda:templateId/@root='2.16.840.1.113883.10.20.1.27']</td>
<td>13.10 - Refusal Reason</td>
<td>R2/N</td>
<td>2.2.2.13.2</td>
</tr>
</tbody>
</table>

**Figure 2-47 Immunization Example**

```xml
<!-- 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='2.16.840.1.113883.3.88.11.83.13'/>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.12'/>
    <code code='11369-6' display='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='2.16.840.1.113883.3.88.11.83.8.2'/>
        <organization>
            ...
        </organization>
        <material>
            ...
            <code code='...' display='...' codeSystem='...' codeSystemName='...'/>
        </material>
        <lotNumberText>...</lotNumberText>
    </manufacturedProduct>
</consumable>
</substanceAdministration>
```

C83-[DE-13-CDA-1] A CDA Document **SHALL** declare conformance for the Immunization module by including a `<templateID>` element with the `root` attribute set to the value `2.16.840.1.113883.3.88.11.83.13`

C83-[DE-13-CDA-2] Immunization data elements **SHALL** declare conformance to the IHE Immunization entry by including a `<templateID>` element with the `root` attribute set to the value `1.3.6.1.4.1.19376.1.5.3.1.4.12`
2.2.2.13.1 Coded Product Name Constraints

C83-[DE-13.06-CDA-1] The code **SHALL** appear in the **code** attribute of the `<code>` or `<translation>` element

C83-[DE-13.06-1] Immunizations **SHALL** be coded using CVX as specified in HITSP/C80 Section 2.2.3.5.1 Vaccines Administered.

2.2.2.13.2 Refusal Reason Constraints

C83-[DE-13.10-1] The reason for refusal **SHALL** be coded as specified in HITSP/C80 Section 2.2.3.5.3 No Immunization Reason

2.2.2.14 VITAL SIGN

Within a CDA document, the following information maps to HITSP Data Elements in the module defined in section 2.1.2.13 Vital Sign of this document. See the HL7 Continuity of Care Document Section 3.12 for constraints applicable to these data elements.

These entries are used to record current and relevant historical vital signs for the patient. Vital Signs are a subset of Results (see Section 2.2.2.15), but are reported in this section to follow clinical conventions.

The template identifier for this module is 2.16.840.1.113883.3.88.11.83.14.

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.

<table>
<thead>
<tr>
<th>CDA Data Location</th>
<th>HITSP Data Element Identifier and Name</th>
<th>O/R24</th>
<th>Additional Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>See Data Element Definitions for Results in Section 2.2.2.15</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2.2.2.14.1 Vital Signs Module Constraints

C83-[DE-14-CDA-1] A CDA Document **SHALL** declare conformance for the Vital Signs module by including a `<templateID>` element with the `root` attribute set to the value 2.16.840.1.113883.3.88.11.83.14

C83-[DE-14-CDA-2] Vital signs information elements **SHALL** be contained in a conforming IHE Vital Signs Organizer element that includes a `<templateID>` element with the `root` attribute set to the value 1.3.6.1.4.1.19376.1.5.3.1.4.13.1

2.2.2.14.2 Vital Sign/Result Type Constraints

C83-[DE-14.03-1] Vital signs **SHOULD** be coded as specified in HITSP/C80 Section 2.2.3.6.4 Vital Sign Result Type.

2.2.2.15 RESULT

Within a CDA document, the following information maps to HITSP Data Elements in the module defined in section 2.1.2.14 Result of this document. See the HL7 Continuity of Care Document Section 3.13 for constraints applicable to these data elements. This module contains current and relevant historical result

---

**NOTE:** Optionality = “R” for Required, “R2” for Required if known, “O” for Optional and Repeat = “Y” for Yes or “N” for No
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 2.2.2.14 above).

The template identifier for this module is 2.16.840.1.113883.3.88.11.83.15.

The Results section is intended as a summary and not as an official, legally 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.

### Table 2-58 Results Data Mapping Table – Requirements

<table>
<thead>
<tr>
<th>CDA Data Location</th>
<th>HITSP Data Element Identifier and Name</th>
<th>O/R(^{25})</th>
<th>Additional Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>cda:observation[cda:templateId/@root = '2.16.840.1.113883.10.20.1.31']</td>
<td>Result Event Entry</td>
<td>See Below(^{26})</td>
<td></td>
</tr>
<tr>
<td>cda:id</td>
<td>15.01 - Result ID</td>
<td>R/Y</td>
<td></td>
</tr>
<tr>
<td>cda:effectiveTime</td>
<td>15.02 - Result Date/Time</td>
<td>R/N</td>
<td></td>
</tr>
<tr>
<td>cda:code</td>
<td>15.03 - Result Type</td>
<td>R/N</td>
<td>2.2.2.15.2</td>
</tr>
<tr>
<td>cda:statusCode</td>
<td>15.04 - Result Status</td>
<td>R/N</td>
<td></td>
</tr>
<tr>
<td>cda:value</td>
<td>15.05 - Result Value</td>
<td>R/N</td>
<td></td>
</tr>
<tr>
<td>cda:interpretationCode</td>
<td>15.06 - Result Interpretation</td>
<td>O/N</td>
<td></td>
</tr>
<tr>
<td>cda:referenceRange</td>
<td>15.07 - Result Reference Range</td>
<td>O/Y</td>
<td></td>
</tr>
</tbody>
</table>

#### Figure 2-48 Results Example

```xml
<!-- These examples assume the default namespace is 'urn:hl7-org:v3' -->
<observation classCode='OBS' moodCode='EVN'>
  <templateId root='2.16.840.1.113883.10.20.1.31'/>
  <templateId root='2.16.840.1.113883.3.88.11.83.15'/>
  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13'/>
  <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>
```

2.2.2.15.1 Results Module Constraints

C83-[DE-15-CDA-1] A CDA Document **SHALL** declare conformance for the Results module by including a <templateId> element with the root attribute set to the value 2.16.840.1.113883.3.88.11.83.15

\(^{25}\) **NOTE:** Optionality = “R” for Required, “R2” for Required if known, “O” for Optional and Repeat = “Y” for Yes or “N” for No

\(^{26}\) Requirements for Entries are defined at a higher level than the Entry Content Module (i.e. Section Content Modules, HITSP CDA based constructs and Interoperability Specifications).
C83-[DE-15-CDA-2] Results data elements SHALL declare conformance to the IHE Simple Observation entry by including a `<templateID>` element with the `root` attribute set to the value 1.3.6.1.4.1.19376.1.5.3.1.4.13

[C83-[DE-15-CDA-3] Results data elements SHALL declare conformance to the CCD Result entry by including a `<templateID>` element with the `root` attribute set to the value 2.16.840.1.113883.10.20.1.31

2.2.2.15.2 Result Type Constraints

C83-[DE-15.03-1] 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)

C83-[DE-15.03-2] Result Type for laboratory results SHOULD be coded as specified in HITSP/C80 Section 2.2.3.6.1 Laboratory Observations.

2.2.2.16 ENCOUNTER

Within a CDA document, the following information maps to HITSP Data Elements in the module defined in section 2.1.2.15 Encounter of this document. See the HL7 Continuity of Care Document Section 3.15 for constraints applicable to these data elements. The encounter entry contains data describing the interactions between the patient and clinicians. Interaction includes both in-person and non-in-person encounters such as telephone and email communication.

The template identifier for this module is 2.16.840.1.113883.3.88.11.83.16.

<table>
<thead>
<tr>
<th>CDA Data Location</th>
<th>HITSP Data Element Identifier and Name</th>
<th>O/R²⁷</th>
<th>Additional Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>cda:encounter[cda:templateId/@root = '2.16.840.1.113883.10.20.1.21']</td>
<td>Encounter Event Entry</td>
<td></td>
<td>See Below²⁸</td>
</tr>
<tr>
<td>cda:id</td>
<td>16.01 - Encounter ID</td>
<td>R/Y</td>
<td></td>
</tr>
<tr>
<td>cda:code</td>
<td>16.02 - Encounter Type</td>
<td>R2/N</td>
<td>2.2.2.16.2</td>
</tr>
<tr>
<td>cda:originalText/cda:reference/@value</td>
<td>16.03 - Encounter Free Text Type</td>
<td>R/N</td>
<td></td>
</tr>
<tr>
<td>cda:effectiveTime</td>
<td>16.04 - Encounter Date / Time</td>
<td>R/N</td>
<td></td>
</tr>
<tr>
<td>cda:performer/cda:assignedEntity</td>
<td>16.05 - Encounter Provider</td>
<td>R2/Y</td>
<td></td>
</tr>
</tbody>
</table>

²⁷ NOTE: Optionality = “R” for Required, “R2” for Required if known, “O” for Optional and Repeat = “Y” for Yes or “N” for No

²⁸ Requirements for Entries are defined at a higher level than the Entry Content Module (i.e. Section Content Modules, HITSP CDA based constructs and Interoperability Specifications).
2.2.2.16.1 Encounters Module Constraints

C83-[DE-16-CDA-1] A CDA Document SHALL declare conformance for the Encounters module by including a `<templateID>` element with the `root` attribute set to the value 2.16.840.1.113883.3.88.11.83.16

C83-[DE-16-CDA-2] Encounter data elements SHALL declare conformance to the IHE Encounter entry by including a `<templateID>` element with the `root` attribute set to the value 1.3.6.1.4.1.19376.1.5.3.1.4.14

2.2.2.16.2 Encounter Type Constraints

Note: Encounter Type should be sent when available, and should be coded to the specified value set when possible. If the selected value set is not available but other coded values are, the desire is that these other coded values be sent. C83-[DE-16.02-1] Encounter Type SHOULD be coded as specified in HITSP/C80 Section 2.2.3.9.3 Encounter Type.

2.2.2.17 PROCEDURE

Within a CDA document, the following information maps to HITSP Data Elements in the module defined in section 2.1.2.16 Procedure of this document. See the HL7 Continuity of Care Document Section 3.14 for constraints applicable to these data elements.

This section defines a coded entry describing a procedure performed on a patient. The template identifier for this module is 2.16.840.1.113883.3.88.11.83.17.
Table 2-60 Procedure Data Mapping Table - Requirements

<table>
<thead>
<tr>
<th>CDA Data Location</th>
<th>HITSP Data Element Identifier and Name</th>
<th>O/R²⁹</th>
<th>Additional Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>cda:procedure[cda:templateId/@root=</td>
<td>Procedures</td>
<td></td>
<td>See Below³⁰</td>
</tr>
<tr>
<td>'2.16.840.1.113883.10.20.1.29']</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>cda:id</td>
<td>17.01 - Procedure ID</td>
<td>R/Y</td>
<td></td>
</tr>
<tr>
<td>cda:code</td>
<td>17.02 - Procedure Type</td>
<td>R2/N</td>
<td></td>
</tr>
<tr>
<td>cda:originalText[cda:reference/@value]</td>
<td>17.03 - Procedure Free Text Type</td>
<td>R/N</td>
<td></td>
</tr>
<tr>
<td>cda:effectiveTime</td>
<td>17.04 - Procedure Date / Time</td>
<td>R2/N</td>
<td></td>
</tr>
<tr>
<td>cda:performer/cda:assignedEntity</td>
<td>17.05 - Procedure Provider</td>
<td>R2/Y</td>
<td></td>
</tr>
</tbody>
</table>

2.2.2.18 FAMILY HISTORY

Within a CDA document, the following information maps to HITSP Data Elements in the module defined in section 2.1.2.17 Family History of this document. See the HL7 Continuity of Care Document Section 3.6 for constraints applicable to these data elements.

The text for the HL7 CDA Release 2 - Continuity of Care Document (CCD), Section 3.6 Family History, p.33 begins here:

This section contains data defining the patient’s genetic relatives in terms of possible or relevant health risk factors that have a potential impact on the patient’s healthcare risk profile.

The text for the HL7 CDA Release 2 - Continuity of Care Document (CCD), Section 3.6 Family History, p.33 ends here.

The template identifier for this module is 2.16.840.1.113883.3.88.11.83.18.

While blood relatives are the focus of family history, this specification recognize that it is necessary also to communication information about spouses, partners, and adopted or foster children, in order to clarify the consanguinity of relationships between family members. For family histories recorded in a clinical document the individual who is the focus of the family history is the patient, and represents the index case for the family history.

The current concept can be stated as follows:

Quoted Material from MedicineNet.com – MedTerms Dictionary starts here.

  Family: 1. A group of individuals related by blood or marriage or by a feeling of closeness.

  Family history: The family structure and relationships within the family, including information about diseases in family members.

Quoted Material from MedicineNet.com – MedTerms Dictionary ends here.

²⁹ NOTE: Optionality = “R” for Required, “R2” for Required if known, “O” for Optional and Repeat = “Y” for Yes or “N” for No

³⁰ Requirements for Entries are defined at a higher level than the Entry Content Module (i.e. Section Content Modules, HITSP CDA based constructs and Interoperability Specifications).
### Table 2-61 Family History Data Mapping Table – Requirements

<table>
<thead>
<tr>
<th>CDA Data Location</th>
<th>HITSP Data Element Identifier and Name</th>
<th>O/R</th>
<th>Additional Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>cda:section[cda:templateId/@root = '2.16.840.1.113883.10.20.1.23']</td>
<td>Family History Section</td>
<td></td>
<td>See Note 32</td>
</tr>
<tr>
<td>cda:entry/cda:observationMedia</td>
<td>18.01 - Pedigree</td>
<td>O/N</td>
<td>2.2.2.18.2</td>
</tr>
<tr>
<td>cda:entry/cda:organizer[</td>
<td>18.02 - Family Member Information</td>
<td>R/Y</td>
<td></td>
</tr>
<tr>
<td>cda:templateId/@root = '2.16.840.1.113883.1.38.11.83.18'</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>cda:subject/cda:relatedSubject</td>
<td>18.03 - Family Member Demographics</td>
<td>R/N</td>
<td></td>
</tr>
<tr>
<td>cda:code/@code</td>
<td>18.04 - Family Member Relationship (to Patient)</td>
<td>R/N</td>
<td>2.2.2.18.3</td>
</tr>
<tr>
<td>cda:code/cda:originalText</td>
<td>18.05 - Family Member Relationship Free Text</td>
<td>O/N</td>
<td></td>
</tr>
<tr>
<td>cda:subject</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>sdtc:id</td>
<td>18.06 - Family Member Identifier</td>
<td>R/Y</td>
<td>2.2.2.18.4</td>
</tr>
<tr>
<td>cda:name</td>
<td>18.07 - Family Member Name</td>
<td>R2/Y</td>
<td>2.2.2.18.5</td>
</tr>
<tr>
<td>cda:birthTime</td>
<td>18.08 - Family Member Date of Birth</td>
<td>R2/N</td>
<td></td>
</tr>
<tr>
<td>cda:administrativeGenderCode</td>
<td>18.24 Family Member Administrative Gender</td>
<td>O/N</td>
<td>2.2.2.18.6</td>
</tr>
<tr>
<td>sdtc:raceCode</td>
<td>18.09 - Family Member Race</td>
<td>R2/Y</td>
<td>2.2.2.18.7</td>
</tr>
<tr>
<td>sdtc:ethnicGroupCode</td>
<td>18.10 - Family Member Ethnicity</td>
<td>R2/N</td>
<td>2.2.2.18.8</td>
</tr>
<tr>
<td>cda:component</td>
<td>18.11 - Family Member Medical History</td>
<td>R2/Y</td>
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</tr>
<tr>
<td>cda:observation[cda:templateId/@root = '1.3.6.1.4.1.19376.1.5.3.1.4.13.3']</td>
<td>18.12 - Family Member Condition</td>
<td>R2/N</td>
<td>2.2.2.18.10</td>
</tr>
<tr>
<td>cda:entryRelationship/cda:observation</td>
<td>18.13 - Family Member Age (at Onset)</td>
<td>R2/N</td>
<td>2.2.2.18.11</td>
</tr>
<tr>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>cda:entryRelationship[</td>
<td>18.14 - Family Member Cause of Death</td>
<td>R2/N</td>
<td>2.2.2.18.12</td>
</tr>
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<td>@typeCode='CAUS'</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>cda:observation</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**NOTE:** Optionality = “R” for Required, “R2” for Required if known, “O” for Optional and Repeat = “Y” for Yes or “N” for No

32 Requirements for Entries are defined at a higher level than the Entry Content Module (i.e. Section Content Modules, HITSP CDA based constructs and Interoperability Specifications).
<table>
<thead>
<tr>
<th>CDA Data Location</th>
<th>HITSP Data Element Identifier and Name</th>
<th>O/R</th>
<th>Additional Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>cda:entryRelationship/</td>
<td>18.15 - Family Member Age (at Death)</td>
<td>R2/N</td>
<td>2.2.2.18.11</td>
</tr>
<tr>
<td>cda:observation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>[cda:templateId/@root =</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>'2.16.840.1.113883.10.20.1.38' ]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>cda:observation[cda:templateId/@root =</td>
<td>18.16 - Family Member Biological Sex</td>
<td>O/N</td>
<td>2.2.2.18.13</td>
</tr>
<tr>
<td>'1.3.6.1.4.1.19376.1.5.3.1.4.13.3' ]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>cda:observation[cda:templateId/@root =</td>
<td>18.17 - Family Member Multiple Birth Status</td>
<td>O/N</td>
<td>2.2.2.18.14</td>
</tr>
<tr>
<td>'1.3.6.1.4.1.19376.1.5.3.1.4.13.3' ]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>cda:observation</td>
<td>18.23 - Family Member Age</td>
<td>R2/N</td>
<td></td>
</tr>
<tr>
<td>[cda:templateId/@root =</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>'2.16.840.1.113883.10.20.1.38' ]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>cda:observation[cda:templateId/@root =</td>
<td>18.18 - Family Member Genetic Test Information</td>
<td>R2/Y</td>
<td>2.2.2.18.15</td>
</tr>
<tr>
<td>'1.3.6.1.4.1.19376.1.5.3.1.4.13.3' ]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>cda:code/@code</td>
<td>18.19 - Family Member Genetic Test Code</td>
<td>R2/N</td>
<td></td>
</tr>
<tr>
<td>cda:code/cda:originalText</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>cda:value</td>
<td>18.20 - Family Member Genetic Test Name</td>
<td>R/N</td>
<td></td>
</tr>
<tr>
<td>cda:effectiveTime</td>
<td>18.21 - Family Member Genetic Test Result</td>
<td>R2/N</td>
<td></td>
</tr>
<tr>
<td>cda:effectiveTime</td>
<td>18.22 - Family Member Genetic Test Date</td>
<td>R2/N</td>
<td></td>
</tr>
</tbody>
</table>

2.2.2.18.1 Family History Constraints

**C83-[DE-18-CDA-1]** A CDA Document **SHALL** declare conformance for the Family History module by including a `<templateID>` element with the `root` attribute set to the value `2.16.840.1.113883.3.88.11.83.18`

**C83-[DE-18-CDA-2]** Family History data elements **SHALL** declare conformance to the IHE Family History Organizer entry by including a `<templateID>` element with the `root` attribute set to the value `1.3.6.1.4.1.19376.1.5.3.1.4.15`
2.2.2.18.2 Pedigree

The pedigree graph may be included within the Family History section. This is a graphic image that would appear in the document to represent the pedigree of the patient, and can highlight key family history information. The example given below shows how a Family History section can include an pedigree graph.

```xml
<section>
  <templateId root='2.16.840.1.113883.10.20.1.23'/>
  <entry>
    <organizer classCode='CLUSTER' moodCode='EVN'>
      <templateId root='2.16.840.1.113883.3.88.11.83.18'/>
      <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.15'/>
      <subject typeCode='SUBJ'>
        <relatedSubject classCode='PRS'>
          <code code='' displayName='
            codeSystem='2.16.840.1.113883.5.111' codeSystemName='RoleCode'/>
          <subject>
            <sdtc:id root='' extension=''/>
            <administrativeGenderCode code='' displayName='' codeSystem='' codeSystemName=''/>
          </subject>
        </relatedSubject>
      </subject>
    </organizer>
    <participant typeCode='PART'>
      <participantRole classCode='PRS'>
        <code code='' displayName='
          codeSystem='2.16.840.1.113883.5.111' codeSystemName='RoleCode'/>
        <playingEntity classCode='PSN'>
          <sdtc:id root='' extension=''/>
        </playingEntity>
      </participantRole>
    </participant>
    <!-- one or more entry relationships for family history observations -->
    <entryRelationship typeCode='COMP'>
      <observation classCode='OBS' moodCode='EVN'>
        <templateId root='2.16.840.1.113883.10.20.1.22'/>
      </observation>
    </entryRelationship>
  </entry>
</section>
```
A pedigree image MAY be included in an observationMedia element in an entry under the Family History section.

The mediaType of the observationMedia element SHALL be application/pdf, image/jpeg or image/png.

The representation of the observationMedia element SHALL be B64, and the data for the image SHALL be included within the value element.

NOTE: We are interested in feedback on whether the image should be included directly in the document, as shown in the example and conformance statements given above, or if this should be a reference to a separate image, and if so, how those references might be made (e.g., to a separate image within a document repository).

2.2.2.18.3 Family Member Relationship (to Patient)

The family member relationship to the patient is recorded by expressing that relationship in the code element.

The Family Member Relationship (to Patient) SHALL be coded as specified in HITSP/C80 Section 2.2.1.2.5 Family Relationship Type.

2.2.2.18.4 Family Member Identifier

Each family member in a family history must be identified to allow for reconciliation of updated family histories when exchanged between providers.

An sdtc:id element SHALL be present on family members.

2.2.2.18.5 Family Member Name

The family member name need not be the actual name of the family member. It may be a string (such as aunt1 or aunt2) to help the patient and providers distinguish between different family members with the same relationship to the patient.

2.2.2.18.6 Family Member Administrative Gender Constraints

Gender SHALL be coded as specified in HITSP/C80 Section 2.2.1.2.1.2 V3 Administrative Gender.
2.2.2.18.7 Family Member Race

The race of the family member should be included to help in the assessment of risk for genetic disease. This information is recorded using an extension to the HL7 CDA specification.

- C83-[DE-18.09-1] Race SHALL be coded as specified in HITSP/C80 Section 2.2.1.2.7 Race

2.2.2.18.8 Family Member Ethnicity

The ethnicity of the family member should be included to help in the assessment of risk for genetic disease. This information is recorded using an extension to the HL7 CDA specification.

- C83-[DE-18.10-1] Ethnicity SHALL be coded as specified in HITSP/C80 Section 2.2.1.2.2 Ethnicity

2.2.2.18.9 Family Member Relationship (to other Family Member)

2.2.2.18.10 Family Member Condition

Family member conditions are recorded using the IHE Family History Observation, and otherwise have the same constraints on the subfields as are found in the Condition Module described earlier with respect to vocabulary.

- C83-[DE-18.12-CDA-1] Family History Condition data elements SHALL declare conformance to the IHE Family History Observation entry by including a <templateID> element with the root attribute set to the value 1.3.6.1.4.1.19376.1.5.3.1.4.13.3
- C83-[DE-18.12-1] The problem type SHALL be coded as specified in HITSP/C80 Section 2.2.3.1.2 Problem Type.
- C83-[DE-18.12-2] The problem SHALL be coded as specified in HITSP/C80 Section 2.2.3.1.1 Problem

2.2.2.18.11 Family Member Age at Onset or at Death

The age of onset of disease or age at death of a family member should be computable from the family member date of birth and the effective time of the observation of the disease or the death. When that data are not available, the age of the patient at the time of the observation shall be recorded within a condition or test result observation using the Age Observation described in CCD 3.6.2.4.

**Figure 2-52 Age Example**

```xml
<entryRelationship typeCode='SUBJ' inversionInd='true'>
  <observation classCode='OBS' moodCode='EVN'>
    <templateId root='2.16.840.1.113883.10.20.1.38'/>
    <code code='397659008' displayName='age' codeSystem='2.16.840.1.113883.6.96' codeSystemName='SNOMED CT'/>
    <value value='55' unit='a' xsi:type='PQ'/>  
  </observation>
</entryRelationship>
```

- C83-[DE-18.13-CDA-1] Family History Condition data elements SHALL declare conformance to the IHE Family History Observation entry by including a <templateID> element with the root attribute set to the value 1.3.6.1.4.1.19376.1.5.3.1.4.13.3

2.2.2.18.12 Family Member Cause of Death

When a condition is one of the causes of death for the patient, that fact is related using the Cause of Death Observation described in CCD 3.6.2.1.1.
Figure 2-53 Cause of Death Example

```xml
<entryRelationship typeCode='CAUS'>
  <observation classCode='OBS' moodCode='EVN'>
    <templateId root='2.16.840.1.113883.10.20.1.42'/>
    <code code='419620001' displayName='death'
      codeSystem='2.16.840.1.113883.6.96' codeSystemName='SNOMED CT'/>
  </observation>
</entryRelationship>
```

2.2.2.18.13 Family Member Biological Sex

The biological sex may be recorded as a Family History observation to identify the biological sex of the subject where it differs from the administrative gender.

2.2.2.18.14 Family Member Multiple Birth Status

Multiple birth status is may be recorded as a Family History observation on the subject when it is relevant for a family member.

2.2.2.18.15 Family Member Genetic Test Information

Genetic test results may be recorded as Family History observations on the subject.

C83-[DE-18.18-1] Components of a Genetic Laboratory Test SHALL be coded as specified in HITSP/C80 Section 2.2.3.11 Genetic Testing

2.2.2.19 SOCIAL HISTORY

Within a CDA document, the following information maps to HITSP Data Elements in the module defined in section <fill in> of this document. See the HL7 Continuity of Care Document Section <fill in> for constraints applicable to these data elements.

*The text for the HL7 CDA Release 2 - Continuity of Care Document (CCD), Section 3.7 Social History, p.37.begins here:*

This section contains data defining the patient’s occupational, personal (e.g. lifestyle), social, and environmental history and health risk factors, as well as administrative data such as marital status, race, ethnicity and religious affiliation.

*The text for the HL7 CDA Release 2 - Continuity of Care Document (CCD), Section 3.7 Social History, p.37 ends here.*

The template identifier for this module is 2.16.840.1.113883.3.88.11.83.19.
Table 2-62 Social History Mapping Table - Requirements

<table>
<thead>
<tr>
<th>CDA Data Location</th>
<th>HITSP Data Element Identifier and Name</th>
<th>O/R</th>
<th>Additional Specification</th>
</tr>
</thead>
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<td>cda:observation[</td>
<td>Social History Event Entry</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>'2.16.840.1.113883.10.20.1.33']</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>cda:effectiveTime</td>
<td>19.01 - Social History Dates</td>
<td>R2/N</td>
<td></td>
</tr>
<tr>
<td>cda:code</td>
<td>19.02 - Social History Type</td>
<td>R2/N</td>
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<tr>
<td>cda:text</td>
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</tr>
<tr>
<td>cda:value</td>
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<td></td>
</tr>
</tbody>
</table>

C83-[DE-19-CDA-1] A CDA Document **SHALL** declare conformance for the Social History module by including a `<templateID>` element with the `root` attribute set to the value 2.16.840.1.113883.10.20.1.33

C83-[DE-19-CDA-2] Social History data elements **SHALL** declare conformance to the IHE Social History Observation entry by including a `<templateID>` element with the `root` attribute set to the value 1.3.6.1.4.1.19376.1.5.3.1.4.13.4

2.2.2.19.1 Social History Type Constraints

C83-[DE-19.02-1] The Social History type **SHALL** be coded as specified in HITSP/C80 Section 2.2.2.4 Social History Type

### 2.3 STANDARDS

#### 2.3.1 REGULATORY GUIDANCE

Table 2-63 Regulatory Guidance

<table>
<thead>
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<th>Description</th>
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<tbody>
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</tr>
</tbody>
</table>

#### 2.3.2 SELECTED STANDARDS

Table 2-64 Selected Standards

<table>
<thead>
<tr>
<th>Standard</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health Level Seven (HL7) HL7 Version 3 Standard: Clinical Document Architecture (CDA), Release 2</td>
<td>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. For more information visit <a href="http://www.hl7.org">www.hl7.org</a></td>
</tr>
</tbody>
</table>

**NOTE:** Optionality = "R" for Required, "R2" for Required if known, "O" for Optional and Repeat = "Y" for Yes or "N" for No

**Requirements for Entries are defined at a higher level than the Entry Content Module (i.e. Section Content Modules, HITSP CDA based constructs and Interoperability Specifications).**
### Standard Name | Description
--- | ---
Health Level Seven (HL7) Implementation Guide: CDA Release 2 – Continuity of Care Document (CCD), 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. For more information visit [www.hl7.org](http://www.hl7.org).

Health Level Seven (HL7) Implementation Guide for CDA Release 2: History and Physical (H&P) Notes | The HL7 Implementation Guide for CDA Release 2: History and Physical (H&P) Notes defines additional constraints on the CDA Header and Body used in a History and Physical document in the U.S. realm, and provides examples of conforming fragments in the body of the document and an example of a conforming XML instance.

Health Level Seven (HL7) Implementation Guide for CDA Release 2: Consultation Note | The HL7 Implementation Guide for CDA Release 2: Consultation Note defines additional constraints on the CDA Header and Body used in a Consultation document in the U.S. realm, and provides examples of conforming fragments in the body of the document and an example of a conforming XML instance.

Integrating the Healthcare Enterprise (IHE) Patient Care Coordination (PCC), Revision 4.0 | 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. For more information visit [www.ihe.net](http://www.ihe.net).

### 2.3.3 INFORMATIVE REFERENCE STANDARDS

#### Table 2-65 Informative Reference Standards

<table>
<thead>
<tr>
<th>Standard Name</th>
<th>Reason for Use</th>
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</tr>
</tbody>
</table>

HITSP CDA Content Modules Component
Released for Implementation
20090708 V1.1
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3.0 APPENDIX

The following sections include relevant materials referenced throughout this document.

- A listing of all HITSP Constraints defined within this document.
- A listing of all HITSP Template identifiers defined within this document.

3.1 HITSP CONSTRAINTS DEFINED IN THIS DOCUMENT

C83-[DE-7.04-1] The problem type SHALL be coded as specified in HITSP/C80 section 2.2.1.1.4.1.2 Problem Type. The first portion identifies the type of artifact being constrained. The second portion is the identifier for that artifact, and the final portion is the sequence number of the constraint on that artifact within this document. Constraints specific to CDA usage will contain the string CDA before the final number.

C83-[CDA-1] A clinical document created using this specification SHALL contain a `<realmCode>` element with a value of US in the code attribute indicating that it conforms to US realm requirements.

C83-[CDA-2] A clinical document created using this specification SHALL contain the `<templateId>` element with a value of 1.3.6.1.4.1.19376.1.5.3.1.1.1 in the root attribute and no `extension` attribute indicating that it conforms to the IHE PCC Medical Documents specification.

C83-[CDA-3] A clinical document created using this specification SHALL contain the `<templateId>` element with a value of 2.16.840.1.113883.10.20.3 in the root attribute and no `extension` attribute, indicating that it conforms to the HL7 General Header constraints defined in the HL7 Implementation Guide for History and Physical Notes.

C83-[CDA-4] A clinical document created using this specification MAY include other data elements not defined in this specification in an instance of a Content Module. Receivers are not required to process these elements and if they do not understand them, they SHALL 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.

C83-[CDA-5] If a data element coded value may be derived from another data element coded value, the creator of a clinical document 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.

C83-[CDA-6] Required modules from this specification SHALL be present and follow the associated constraints.

C83-[CDA-7] Content Modules explicitly excluded from a clinical document specification SHALL NOT be present.

C83-[CDA-8] Optional modules, when present, SHALL follow the associated constraints if that module asserts conformance to this specification, i.e., includes the associated templates.

C83-[CDA-9] Additional CCD entry elements (the equivalent to Content Modules in this specification) MAY be present. The receiver 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.

The (standard data element in the table) SHALL be communicated applying all constraints defined for (the HITSP Data Element in the table).

C83-[CT-101-1] This section SHALL conform to the IHE Payers Section template, and SHALL contain a `<templateId>` element whose root attribute is 1.3.6.1.4.1.19376.1.5.3.1.1.5.3.7.

C83-[CT-101-2] This section SHALL include entries from the Insurance Provider module when this information is known.

C83-[CT-102-1] This section SHALL include entries from the Allergy/Drug Sensitivity module.
This section SHALL conform to the IHE Allergies and Other Adverse Reactions Section template, and SHALL contain a templateId element whose root attribute is 1.3.6.1.4.1.19376.1.5.3.1.3.13.

This section SHALL include entries from the Condition module.

This section SHALL conform to the IHE Active Problems Section template, and SHALL contain a templateId element whose root attribute is 1.3.6.1.4.1.19376.1.5.3.1.3.6.

This section SHALL include entries from the Condition module.

This section SHALL conform to the IHE History of Past Illness Section template, and SHALL contain a templateId element whose root attribute is 1.3.6.1.4.1.19376.1.5.3.1.3.8.

This section SHALL conform to the HL7 History and Physical Note and HL7 Consultation Note implementation guide requirements for this section, and SHALL contain a templateId element whose root attribute is 2.16.840.1.113883.10.20.2.9

This section SHALL conform to the IHE Chief Complaint Section template, and SHALL contain a templateId element whose root attribute is 1.3.6.1.4.1.19376.1.5.3.1.1.13.2.1

This section MAY include an entry from the Condition module to provide the chief complaint in coded form.

This section SHALL conform to the IHE Reason for Referral Section template, and SHALL contain a templateId element whose root attribute is 1.3.6.1.4.1.19376.1.5.3.1.3.1.

This section SHALL conform to the HL7 Consultation Note requirements for this section, and SHALL contain a templateId element whose root attribute is 2.16.840.1.113883.10.20.4.8

This section MAY conform to the IHE Coded Reason for Referral Section template, in which case it SHALL contain a templateId element whose root attribute is 1.3.6.1.4.1.19376.1.5.3.1.3.2 to indicate conformance.

This section MAY include entries from the Condition module or the Result module to provide the reason for referral in coded form.

This section SHALL conform to the IHE Coded List of Surgeries template, and SHALL contain a templateId element whose root attribute is 1.3.6.1.4.1.19376.1.5.3.1.3.12

This section SHALL include entries from the Procedure module.

This section SHALL conform to the Continuity of Care Document Functional Status section described in section 3.4 of the CCD specification, and SHALL contain a templateId element whose root attribute is 2.16.840.1.113883.10.20.1.5

This section SHALL conform to the IHE Hospital Admission Diagnosis section, and SHALL contain a templateId element whose root attribute is 1.3.6.1.4.1.19376.1.5.3.1.3.3.

This section SHALL include an entry from the Condition module to provide the admission diagnosis in coded form.

This section SHALL conform to the IHE Hospital Discharge Diagnosis section, and SHALL contain a templateId element whose root attribute is 1.3.6.1.4.1.19376.1.5.3.1.3.7.

This section SHALL include entries from the Condition module to provide the discharge diagnosis in coded form.
This section SHALL conform to the IHE Medications section, and SHALL contain a templateId element whose root attribute is 1.3.6.1.4.1.19376.1.5.3.1.3.19.

This section SHALL include entries from the Medication module to provide the relevant medications in coded form.

This section SHALL conform to the IHE Admission Medications History section, and SHALL contain a templateId element whose root attribute is 1.3.6.1.4.1.19376.1.5.3.1.3.20.

This section SHALL include entries from the Medication module to provide the relevant medications of a patient prior to admission in coded form.

This section SHALL conform to the IHE Hospital Discharge Medications Section, and SHALL contain a templateId element whose root attribute is 1.3.6.1.4.1.19376.1.5.3.1.3.22.

This section SHALL include entries from the Medication module to provide the relevant medications ordered for the patient for use after discharge in coded form.

This section SHALL conform to the IHE Medications Administered section, and SHALL contain a templateId element whose root attribute is 1.3.6.1.4.1.19376.1.5.3.1.3.21.

This section SHALL include entries from the Medication module to provide the relevant medications administered to a patient in coded form.

This section SHALL conform to the IHE Coded Advance Directives section, and SHALL contain a templateId element whose root attribute is 1.3.6.1.4.1.19376.1.5.3.1.3.35.

This section SHALL include entries from the Advance Directive module.

This section SHALL conform to the IHE Immunizations section, and SHALL contain a templateId element whose root attribute is 1.3.6.1.4.1.19376.1.5.3.1.3.23.

This section SHALL include entries from the Immunization module.

This section SHALL conform to the IHE Physical Examination section, and SHALL contain a templateId element whose root attribute is 1.3.6.1.4.1.19376.1.5.3.1.1.9.15.

This section SHALL conform to the HL7 History and Physical Note and HL7 Consultation Note requirements for this section, and SHALL contain a templateId element whose root attribute is 2.16.840.1.113883.10.20.2.10

This section SHALL conform to the IHE Coded Vital Signs section, and SHALL contain a templateId element whose root attribute is 1.3.6.1.4.1.19376.1.5.3.1.1.5.3.2.

This section SHALL contain entries conforming to the Vital Sign module.

This section SHALL conform to the IHE Review of Systems section, and SHALL contain a templateId element whose root attribute is 1.3.6.1.4.1.19376.1.5.3.1.3.18.

This section SHALL conform to the HL7 Consultation Note requirements for this section, and SHALL contain a templateId element whose root attribute is 2.16.840.1.113883.10.20.4.10

This section SHALL conform to the IHE Hospital Course section, and SHALL contain a templateId element whose root attribute is 1.3.6.1.4.1.19376.1.5.3.1.3.35.

This section SHALL conform to the IHE Coded Results section, and SHALL contain a templateId element whose root attribute is 1.3.6.1.4.1.19376.1.5.3.1.3.28.

This section SHALL include entries from the Procedure module to indicate the diagnostic procedure, and the Result module to provide the results of that procedure.

This section SHALL conform to the IHE Assessment and Plans section, and SHALL contain a templateId element whose root attribute is 1.3.6.1.4.1.19376.1.5.3.1.13.2.5
This section SHALL conform to the HL7 History and Physical Note and HL7 Consultation Note requirements for this section, and SHALL contain a `templateId` element whose root attribute is `2.16.840.1.113883.10.20.2.7`.

This section MAY include entries conforming to the Medication, Immunization, Encounter, and Procedure modules to provide information about the intended care plan.

This section SHALL conform to the IHE Care Plan section, and SHALL contain a `templateId` element whose root attribute is `1.3.6.1.4.1.19376.1.5.3.1.3.31`.

This section SHALL conform to the HL7 History and Physical Note and HL7 Consultation Note requirements for this section, and SHALL contain a `templateId` element whose root attribute is `2.16.840.1.113883.10.20.2.7`.

This section MAY include entries conforming to the Medication, Immunization, Encounter, and Procedure modules to provide information about the intended care plan.

This section SHALL conform to the IHE Family Medical History section, and SHALL contain a `templateId` element whose root attribute is `1.3.6.1.4.1.19376.1.5.3.1.14`.

When used to convey structured family histories, this section SHALL conform to the IHE Coded Family History section, and SHALL contain a `templateId` element whose root attribute is `1.3.6.1.4.1.19376.1.5.3.1.3.15`.

When providing structured family history information this section SHALL include entries conforming to the Family History module.

This section SHALL conform to the IHE Social History section, and SHALL contain a `templateId` element whose root attribute is `1.3.6.1.4.1.19376.1.5.3.1.16`.

This section MAY contain entries conforming to the Social History module.

This section SHALL conform to the IHE Encounters History section, and SHALL contain a `templateId` element whose root attribute is `1.3.6.1.4.1.19376.1.5.3.1.1.5.3.3`.

This section SHALL contain entries conforming to the Encounter module.

This section SHALL conform to the HL7 CCD section, and SHALL contain a `templateId` element whose root attribute is `2.16.840.1.113883.10.20.1.7`.

This section SHALL conform to the IHE Medical Devices Section, and SHALL contain a `templateId` element whose root attribute is `1.3.6.1.4.1.19376.1.5.3.1.1.5.3.5`.

Each name part SHALL be identified using one of the tags `<given>` or `<family>` or `<prefix>` or `<suffix>`.

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.

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.

Name parts within a `<name>` tag SHALL be ordered in proper display order.

At most one `<name>` tag SHALL have a `use` attribute containing the value "L", indicating that it is the legal name of the patient.

More than one `<name>` tag MAY be present to retain birth name, maiden name and aliases.

An alias or former name MAY be identified by the inclusion of a `use` attribute containing the value "P".

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.

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.
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.

Each address part SHALL be identified using the <streetAddressLine>, <city>, <state>, <postalCode> and <country> tags.

More than one <streetAddressLine> MAY be present.

No more than four <streetAddressLine> elements SHALL be present.

The <country> element SHALL be present for addresses outside of the United States.

At most one address for a person SHALL have a use attribute with a value containing "HP".

At least one address for a patient SHOULD have a use attribute with a value containing "HP".

One or more vacation addresses MAY be present for a person.

A vacation address SHALL be recorded with a use attribute containing the value "HV".

One or more work addresses MAY be present.

A work address SHALL be recorded with a use attribute containing the value "WP".

The <country> SHALL be recorded using HITSP/C80 Section 2.2.1.1.3 Country.

A home phone number SHALL be represented with a use attribute containing the value "HP".

A vacation home phone number SHALL be represented with a use attribute containing the value "HV".

A work phone number SHALL be represented with a use attribute containing the value "WP".

A mobile phone number SHALL be represented with a use attribute containing the value "MC".

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.

Gender SHALL be coded as specified in HITSP/C80 Section 2.2.1.2.1.2 V3 Administrative Gender.

Marital Status SHALL be coded as specified in HITSP/C80 Section 2.2.1.2.3.2 Marital Status CDA and HL7V3.

Second and subsequent raceCode elements MAY be recorded using the sdtc:raceCode extension.

Race SHALL be coded as specified in HITSP/C80 Section 2.2.1.2.7 Race.

Ethnicity SHALL be coded as specified in HITSP/C80 Section 2.2.1.2.2 Ethnicity.

The primary religious affiliation MAY appear in the <religiousAffiliationCode> element.

Religious affiliation SHALL be coded as specified in HITSP/C80 Section 2.2.1.2.8 Religious Affiliation.

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.

A CDA Document SHALL declare conformance for the Language Spoken module by including a <templateID> element with the root attribute set to the value 2.16.840.1.113883.3.88.1.113883.3.88.11.83.2.

All Language Spoken entries SHALL declare conformance to the IHE Language Communication module by including a <templateID> element with the root attribute set to the value 1.3.6.1.4.1.19376.1.5.3.1.2.1.
The codes for the `<modeCode>` element SHALL be coded as specified in HITSP/C80 section 2.2.1.2.10 Language Ability Mode. 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 in Figure 2-10 above). On the other hand, American Sign Language would be represented using the code sign-US (see example 3 in Figure 2-10 above), and would only use mode codes for signed communication.

While this HL7 CDA allows for the specification of proficiency using the `<proficiencyLevelCode>` element, this element SHOULD NOT be used.

A CDA Document SHALL declare conformance for the Support entry by including a `<templateID>` element with the root attribute set to the value 2.16.840.1.113883.3.88.11.83.3.

All support entries SHALL also declare conformance to the IHE Patient Contacts module by including a `<templateID>` element with the root attribute set to the value 1.3.6.1.4.1.19376.1.5.3.1.2.4.

The `classCode` attribute SHALL be coded as specified in HITSP/C80 section 2.2.1.2.6 Contact Type.

The contact relationship SHALL have be coded as specified in HITSP/C80 section 2.2.1.2.4 Personal Relationships.

The state part of an address SHALL be recorded using HITSP/C80 Section 2.2.1.1.1 State.

The postal code part of an address in the United States SHALL be recorded using HITSP/C80 Section 2.2.1.1.2 Postal Code.

The country part of an address SHALL be recorded using HITSP/C80 Section 2.2.1.1.3 Country.

A CDA Document SHALL declare conformance for the Healthcare Provider entry by including a `<templateID>` element with the root attribute set to the value 2.16.840.1.113883.3.88.11.83.4.

All healthcare providers entries SHALL declare conformance to the IHE Healthcare Providers and Pharmacies specification by including a `<templateID>` element with the root attribute set to the value 1.3.6.1.4.1.19376.1.5.3.1.2.3.

Provider role SHALL be coded as specified in HITSP/C80 section 2.2.3.8.1 Provider Role.

Provider type SHALL be coded as specified in HITSP/C80 section 2.2.3.8.2 Provider Type.

The state part of an address SHALL be recorded using HITSP/C80 Section 2.2.1.1.1 State.

The postal code part of an address in the United States SHALL be recorded using HITSP/C80 Section 2.2.1.1.2 Postal Code.

The country part of an address SHALL be recorded using HITSP/C80 Section 2.2.1.1.3 Country.

A CDA Document SHALL declare conformance for the Insurance Provider module by including a `<templateID>` element with the root attribute set to the value 2.16.840.1.113883.3.88.11.83.5.

All Insurance Provider entries SHALL declare conformance to the IHE Coverage Entry by including a `<templateID>` element with the root attribute set to the value 1.3.6.1.4.1.19376.1.5.3.1.4.17.

Information for payment providers SHALL be recorded as a policy act inside the coverage act.
C83-[DE-5.01-CDA-1] All Insurance Provider modules **SHALL** declare conformance to the IHE Payer Entry by including a `<templateID>` element with the `root` attribute set to the value `1.3.6.1.4.1.19376.1.5.3.1.4.18`.

C83-[DE-5.01-CDA-2] 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.

C83-[DE-5.01-CDA-3] A GUID **MAY** be used in place of the OID of the assigning authority.

C83-[DE-5.01-CDA-4] Implementers **SHOULD** use the same GUID for each instance of the same group or contract number.

C83-[DE-5.02-1] The Health Insurance Type **SHALL** be coded as specified in HITSP/C80 Section 2.2.2.1 Health Insurance Type.

C83-[DE-5.04-1] The state part of an address **SHALL** be recorded using HITSP/C80 Section 2.2.1.1.1 State.

C83-[DE-5.042] The postal code part of an address in the United States **SHALL** be recorded using HITSP/C80 Section 2.2.1.1.2 Postal Code.

C83-[DE-5.04-3] The country part of an address **SHALL** be recorded using HITSP/C80 Section 2.2.1.1.3 Country.

C83-[DE-5.07-CDA-1] The date when the plan began covering the member **SHOULD** be recorded in the `<low>` element of the `<time>` element beneath the `<participant>` element.

C83-[DE-5.07-CDA-2] The date when the plan stops covering the member **SHOULD** be recorded in the `<high>` element of the `<time>` element beneath the `<participant>` element.

C83-[DE-5.08-CDA-1] The member identifier number **SHALL** be recorded in the `extension` attribute of the `<id>` element found in the `<participantRole>` element.

C83-[DE-5.08-CDA-2] 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.

C83-[DE-5.08-CDA-3] A GUID **MAY** be used in place of the OID of the assigning authority.

C83-[DE-5.08-CDA-4] Implementers **SHOULD** use the same GUID for each instance of a member identifier from the same health plan.

C83-[DE-5.09-CDA-1] The relationship to the subscriber **SHALL** be resent and **SHALL** be recorded in the `<code>` element underneath the `<participantRole>` element recording the member information.

C83-[DE-5.09-1] The Patient Relationship to Subscriber **SHALL** be coded as specified in HITSP/C80 section 2.2.2.2 Subscriber Relationship.

C83-[DE-5.10-1] The state part of an address **SHALL** be recorded using HITSP/C80 Section 2.2.1.1.1 State.

C83-[DE-5.10-2] The postal code part of an address in the United States **SHALL** be recorded using HITSP/C80 Section 2.2.1.1.2 Postal Code.

C83-[DE-5.10-3] The country part of an address **SHALL** be recorded using HITSP/C80 Section 2.2.1.1.3 Country.

C83-[DE-5.12-CDA-1] 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.

C83-[DE-5.13-CDA-1] 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.

C83-[DE-5.14-CDA-1] The code attribute **SHALL** be coded as specified in HITSP/C80 Section 2.2.2.3 Financially Responsible Party Type.

C83-[DE-5.14-CDA-2] 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.

C83-[DE-5.14-CDA-3] The `code` attribute **SHALL** be set to PAYOR when the `code` of the encompassing act is other than PP.
When the Subscriber is the patient, the `<participant>` element describing the subscriber **SHALL NOT** be present. This information will be recorded instead in the data elements used to record member information.

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.

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.

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

The state part of an address **SHALL** be recorded using HITSP/C80 Section 2.2.1.1.1 State

The postal code part of an address in the United States **SHALL** be recorded using HITSP/C80 Section 2.2.1.1.2 Postal Code

The country part of an address **SHALL** be recorded using HITSP/C80 Section 2.2.1.1.3 Country

A CDA Document **SHALL** declare conformance for the Allergy/Drug Sensitivity Module by including a `<templateID>` element with the `root` attribute set to the value 2.16.840.1.113883.3.88.11.83.6

All allergy entries **SHALL** conform to the IHE PCC Allergy and Intolerance Concern template by including a `<templateID>` element with the `root` attribute set to the value 1.3.6.1.4.1.19376.1.5.3.1.4.5.3

Adverse event types **SHALL** be coded as specified in HITSP/C80 Section 2.2.3.4.2 Allergy/Adverse Event Type

Food and substance allergies **SHALL** be coded as specified in HITSP/C80 Section 2.2.3.3.11 Ingredient Name

Allergies to a class of medication **SHALL** be coded as specified in HITSP/C80 Section 2.2.3.3.9 Medication Drug Class

Allergies to a specific medication **SHALL** be coded as specified in HITSP/C80 Section 2.2.3.3.7 Medication Brand Name or HITSP/C80 Section 2.2.3.3.8 Medication Clinical Drug Names.

The reaction **SHALL** be coded as specified in HITSP/C80 Section 2.2.3.4.1 Allergy/Adverse Event (Reaction)

The severity of the adverse event **SHALL** be coded as specified in HITSP/C80 Section 2.2.3.4.3 Allergy/Adverse Event Severity

A CDA Document **SHALL** declare conformance for the Condition Module by including a `<templateID>` element with the `root` attribute set to the value 2.16.840.1.113883.3.88.11.83.7

Problem Entries **SHALL** also declare conformance to the IHE Problem Concern by including a `<templateID>` element with the `root` attribute set to the value 1.3.6.1.4.1.19376.1.5.3.1.4.5.2

The problem type **SHALL** be coded as specified in HITSP/C80 Section 2.2.3.1.2 Problem Type

The problem **SHALL** be coded as specified in HITSP/C80 Section 2.2.3.1.1 Problem

The time over which this provider treated the condition **MAY** be recorded in the `<time>` element beneath the `<performer>` element

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 2.2.2.4

The treating provider or providers **SHALL** be recorded in a `<performer>` element under the `<act>` that describes the condition of concern
A CDA Document **SHALL** declare conformance for the Medication – Prescription and Non-Prescription module by including a `<templateID>` element with the `root` attribute set to the value 2.16.840.1.113883.3.88.11.83.8.

Substance Administration acts conforming to this module **SHALL** also declare conformance to the IHE Medications entity by including a `<templateID>` element with the `root` attribute set to the value 1.3.6.1.4.1.19376.1.5.3.1.4.7.

The first `<effectiveTime>` **SHALL** use the IVL_TS data type unless for a single administration, in which case, it **SHALL** use the TS data type.

Medications that are administered based on activities of daily living **SHALL** identify the events that trigger administration in the `<event>` element beneath the `<effectiveTime>` element. The `<effectiveTime>` element **SHALL** be of type EIVL_TS.

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".

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".

**SHALL** be coded as specified in HITSP/C80 Section 2.2.3.3.4.1 Medication Route FDA.

Units **MAY** be present when needed. If present it **SHALL** be coded as specified in HITSP/C80 Section 2.2.3.6.6 Units of Measurement.

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), units **SHOULD** contain the preferred name of the presentation units within braces {} using the units of presentation from the NCI Thesaurus.

The Site **SHALL** be coded as specified in HITSP/C80 Section 2.2.3.2.1 Body Site.

**SHALL** be coded as specified in HITSP/C80 Section 2.2.3.3.3 Medication Product Form.

The Delivery Method **MAY** be recorded in the `<cda:code>` element.

The free text description of the delivery method **MAY** be included within a `<cda:originalText>` element beneath the `<cda:code>` element.

Medication Information data elements **SHALL** declare conformance to the IHE Product Entry template by including a `<templateID>` element with the `root` attribute set to the value 1.3.6.1.4.1.19376.1.5.3.1.4.7.2.

A CDA Document **SHALL** declare conformance for the Medication Information data element by including a `<templateID>` element with the `root` attribute set to the value 2.16.840.1.113883.3.88.11.83.8.2.

The coded product name **SHALL** appear in the `code` attribute of the `<code>` element.

If the code for the generic product is unknown, the `code` and `codeSystem` attributes **MAY** be omitted.

The coded product name **SHALL** be coded as specified in HITSP/C80 Section 2.2.3.3.8 Medication Clinical Drug Names.

When only the class of the drug is known (e.g., Beta Blocker or Sulfa Drug), it **SHALL** be coded as specified in HITSP/C80 Section 2.2.3.3.9 Medication Drug Class.

When only the medication ingredient name is known, the coded product name **MAY** be coded as specified in HITSP/C80 Section 2.2.3.3.11 Ingredient Name.

The code for the specific brand of product **SHALL** appear in a `<translation>` element.
The brand name SHALL be coded as specified in HITSP/C80 Section 2.2.3.3.7 Medication Brand Name or 2.2.3.3.10 Medication Packaged Product.

The product (generic) name SHALL appear in the <originalText> element beneath the <code> element

The coded product name SHALL appear in the code attribute of the <translation> element

The brand name SHALL appear in the <name> element of the <manufacturedMaterial>

A CDA Document SHALL declare conformance for the Type of Medication by including a <templateID> element with the root attribute set to the value 2.16.840.1.113883.3.88.11.83.8.1

Each <supply> or <substanceAdministration> act MAY reference an <observation> element that describes the type of medication, by including an <entryRelationship typeCode=SUBJ/> element

The type of a medication SHALL be represented with an <observation> element in the <entryRelationship>

The <observation> element SHALL have a <templateId> with a root attribute set to 2.16.840.1.113883.3.88.11.83.8.1

The observation SHALL have a <code> element that represents the kind of medication actually or intended to be administered or supplied

The type of medication SHALL be coded as specified in HITSP/C80 Section 2.2.3.3.5 Medication Type.

The medication status MAY be recorded using the CCD Medication Status observation using the value set defined in the CCD

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, and which conforms

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

The indication SHALL be coded as specified in HITSP/C80 Section 2.2.3.1.1 Problem

Medication Information data elements SHALL declare conformance to the IHE Patient Medication Instructions template by including a <templateID> element with the root attribute set to the value 1.3.6.1.4.1.19376.1.5.3.1.4.3

The vehicle for administering a medication MAY be recorded in a <participantRole> element inside a <participant> element in the <substanceAdministration> element

The typeCode attribute of the <participant> element SHALL be CSM

The classCode of the <participantRole> SHALL be MANU

A <code> element for the <participantRole> SHALL be present and SHALL contain the code 412307009 from the SNOMED CT code system as shown above.

The <name> element in the <playingEntity> element SHALL record the name of the drug vehicle

The <code> element in the <playingEntity> element MAY be used to supply a coded term for the drug vehicle

The Medication Vehicle shall be coded as specified in HITSP/C80 Section 2.2.3.3.12 Medication Vehicle

A CDA Document SHALL declare conformance for the Order Information data element by including a <templateID> element with the root attribute set to the value 2.16.840.1.113883.3.88.11.83.8.3
Order Information data elements **SHALL** declare conformance to the IHE Supply Entry template by including a `<templateID>` element with the `root` attribute set to the value 1.3.6.1.4.1.19376.1.5.3.1.4.7.3.

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.

The quantity ordered **SHALL** be recorded in the `value` attribute of `<quantity>` element inside a `<supply>` element used to record order information.

The `unit` attribute **SHALL** be present.

When the quantity ordered is in other than administration units (e.g., when the quantity ordered is a volume of liquid or mass of substance) **SHALL** be coded as specified in HITSP/C80 Section 2.2.3.6.6 Units of Measure.

When the quantity ordered is in administration units, the `unit` attribute **SHOULD** contain the preferred name of the presentation units within braces {} using the units of presentation as specified in HITSP/C80 Section 2.2.3.3.3 Medication Product Form.

Fulfillment instructions data elements **SHALL** declare conformance to the IHE Medication Fulfillment Instructions template by including a `<templateID>` element with the `root` attribute set to the value 1.3.6.1.4.1.19376.1.5.3.1.4.3.1.

The prescription number **SHALL** be recorded in the `extension` attribute of the `<id>` element within a `<supply>` element having a moodCode attribute of EVN.

The `root` attribute of the `<id>` element **SHOULD** be the OID of the assigning authority for the identifier; however, determining the assigning authority is not feasible in all settings.

A GUID **MAY** be used in place of the OID of the assigning authority.

The provider **SHALL** be recorded in the `<assignedEntity>` element.

At least one of `<assignedPerson>` or `<representedOrganization>` elements **SHALL** appear inside the `<assignedEntity>` to indicate the name of the person or the organization fulfilling the prescription.

The name of the person **SHALL** appear in the `<name>` element of the `<assignedPerson>` element beneath the `<assignedEntity>` element.

The name of the organization **SHALL** appear in the `<name>` element of the `<representedOrganization>` element beneath the `<assignedEntity>` element.

The quantity dispensed **SHALL** be recorded in the `value` attribute of `<quantity>` element inside a `<supply>` element with a moodCode attribute set to EVN.

When the quantity dispensed is in other than administration units (e.g., when the quantity ordered is a volume of liquid or mass of substance) **SHALL** be recorded as specified in HITSP/C80 Section 2.2.3.6.6 Units of Measure.

When the quantity dispensed is in administration units the `unit` attribute **SHOULD** contain the preferred name of the presentation units within braces {} using the units of presentation as specified in HITSP/C80 Section 2.2.3.3.3 Medication Product Form.

The fill number **MAY** be recorded in the `sequenceNumber` attribute of a `<entryRelationship>` element with a `typeCode` attribute set to COMP.

The fill status **MAY** be recorded in the `statusCode` attribute.

The `statusCode` attribute **SHALL** contain be coded as specified in HITSP/C80 Section 2.2.3.3.1 Medication Fill Status.

The name of the information source **SHALL** be provided in the `<name>` element.

The `<name>` element **SHALL** appear within an `<assignedPerson>` or `<representedOrganization>` element appearing in an `<assignedEntity>`, or within a `<relatedPerson>` element within a `<relatedEntity>` element beneath the `<informant>` element.
C83-[DE-10-CDA-1] Data elements defined elsewhere in the specification **SHALL NOT** be recorded using the Comments Module.

C83-[DE-10-CDA-2] A CDA Document **SHALL** declare conformance for the Comments module by including a `<templateID>` element with the `root` attribute set to the value 2.16.840.1.113883.3.88.11.83.11

C83-[DE-10-CDA-3] Each comment module **SHALL** be conformant with the IHE Comment module and **SHALL** include a `<templateID>` element with the `root` attribute set to the value 1.3.6.1.4.1.19376.1.5.3.1.4.2

C83-[DE-10-CDA-4] The author of a comment **SHALL** be recorded as specified for authors in the Information Source module.

C83-[DE-12-CDA-1] A CDA Document **SHALL** declare conformance for the Advance Directive module by including a `<templateID>` element with the `root` attribute set to the value 2.16.840.1.113883.3.88.11.83.12

C83-[DE-12-CDA-2] An advance directive data element **SHALL** declare conformance to the IHE Advance Directive Observation by including a `<templateID>` element with the `root` attribute set to the value 1.3.6.1.4.1.19376.1.5.3.1.4.13.7

C83-[DE-12.01-1] The advance directive **SHALL** be coded as specified in HITSP/C80 Section 2.2.3.10.1 Advance Directive Type

C83-[DE-12.02-1] 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>`

C83-[DE-12.03-1] The starting time of the Advance Directive **SHALL** be recorded in the `<low>` element of the `<effectiveTime>` element in the Advance Directive `<observation>`

C83-[DE-12.03-2] If the starting time is unknown, the `<low>` element **SHALL** have the nullFlavor attribute set to UNK

C83-[DE-12.03-3] The ending time of the Advance Directive **SHALL** be recorded in the `<high>` element of the `<effectiveTime>` element in the Advance Directive `<observation>`

C83-[DE-12.03-4] If the ending time is unknown, the `<high>` element **SHALL** have the nullFlavor attribute set to UNK

C83-[DE-12.03-5] If the Advance Directive does not have a specified ending time, the `<high>` element **SHALL** have the nullFlavor attribute set to NA

C83-[DE-12.04-1] 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>`

C83-[DE-12.04-2] The typeCode attribute of the `<participant>` element **SHALL** be CST

C83-[DE-12.04-3] The classCode of the `<participantRole>` element **SHALL** be AGNT

C83-[DE-12.04-4] The address of the agent **SHALL** be recorded in an `<addr>` element when known

C83-[DE-12.04-5] The telephone number or other electronic communications address for the agent **SHALL** be recorded in a `<telecom>` element when known

C83-[DE-12.04-6] 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

C83-[DE-13-CDA-1] A CDA Document **SHALL** declare conformance for the Immunization module by including a `<templateID>` element with the `root` attribute set to the value 2.16.840.1.113883.3.88.11.83.13

C83-[DE-13-CDA-2] Immunization data elements **SHALL** declare conformance to the IHE Immunization entry by including a `<templateID>` element with the `root` attribute set to the value 1.3.6.1.4.1.19376.1.5.3.1.4.12

C83-[DE-13.06-CDA-1] The code **SHALL** appear in the `code` attribute of the `<code>` or `<translation>` element

C83-[DE-13.06-1] Immunizations **SHALL** be coded using CVX as specified in HITSP/C80 Section 2.2.3.5.1 Vaccines Administered.
The reason for refusal **SHALL** be coded as specified in HITSP/C80 Section 2.2.3.5.3 No Immunization Reason

A CDA Document **SHALL** declare conformance for the Vital Signs module by including a `<templateID>` element with the root attribute set to the value 2.16.840.1.113883.88.11.83.14

Vital signs information elements **SHALL** be contained in a conforming IHE Vital Signs Organizer element that includes a `<templateID>` element with the root attribute set to the value 1.3.6.1.4.1.19376.1.5.3.1.4.13

Vital signs **SHOULD** be coded as specified in HITSP/C80 Section 2.2.3.6.4 Vital Sign Result Type.

A CDA Document **SHALL** declare conformance for the Vital Signs module by including a `<templateID>` element with the root attribute set to the value 2.16.840.1.113883.88.11.83.15

Vital signs information elements **SHALL** declare conformance to the Vital Signs module by including a `<templateID>` element with the root attribute set to the value 1.3.6.1.4.1.19376.1.5.3.1.4.14

Results data elements **SHALL** declare conformance to the IHE Simple Observation entry by including a `<templateID>` element with the root attribute set to the value 1.3.6.1.4.1.19376.1.5.3.1.4.13

Results data elements **SHALL** declare conformance to the CCD Result entry by including a `<templateID>` element with the root attribute set to the value 2.16.840.1.113883.10.20.1.31

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)

Result Type for laboratory results **SHOULD** be coded as specified in HITSP/C80 Section 2.2.3.6.1 Laboratory Observations.

A CDA Document **SHALL** declare conformance for the Results module by including a `<templateID>` element with the root attribute set to the value 2.16.840.1.113883.88.11.83.15

Encounter data elements **SHALL** declare conformance to the IHE Encounter entry by including a `<templateID>` element with the root attribute set to the value 1.3.6.1.4.1.19376.1.5.3.1.4.14

Note: Encounter Type should be sent when available, and should be coded to the specified value set when possible. If the selected value set is not available but other coded values are, the desire is that these other coded values be sent.

Gender **SHALL** be coded as specified in HITSP/C80 Section 2.2.1.2.1.2 V3 Administrative Gender

The family member relationship (to Patient) **SHALL** be coded as specified in HITSP/C80 Section 2.2.1.2.5 Family Relationship Type

A pedigree image **MAY** be included in an `observationMedia` element in an entry under the Family History section

The `mediaType` of the `observationMedia` element **SHALL** be application/pdf, image/jpeg or image/png

The representation of the `observationMedia` element **SHALL** be B64, and the data for the image **SHALL** be included within the value element

The Family Member Relationship (to Patient) **SHALL** be coded as specified in HITSP/C80 Section 2.2.1.2.5 Family Relationship Type

An `sdtc:id` element **SHALL** be present on family members

Gender **SHALL** be coded as specified in HITSP/C80 Section 2.2.1.2.1.2 V3 Administrative Gender

The race of the family member, when recorded, **SHALL** appear in an `sdtc:race` element
C83-[DE-18.09-1] Race **SHALL** be coded as specified in HITSP/C80 Section 2.2.1.2.7 Race
C83-[DE-18.10-CDA-1] The ethnicity of the family member, when recorded, **SHALL** appear in an sdtc:ethnicGroupCode element.
C83-[DE-18.10-1] Ethnicity **SHALL** be coded as specified in HITSP/C80 Section 2.2.1.2.2 Ethnicity
C83-[DE-18.12-CDA-1] Family History Condition data elements **SHALL** declare conformance to the IHE Family History Observation entry by including a <templateID> element with the root attribute set to the value 1.3.6.1.4.1.19376.1.5.3.1.4.13.3
C83-[DE-18.12-1] The problem type **SHALL** be coded as specified in HITSP/C80 Section 2.2.3.1.2 Problem Type.
C83-[DE-18.12-2] The problem **SHALL** be coded as specified in HITSP/C80 Section 2.2.3.1.1 Problem
C83-[DE-18.13-CDA-1] Family History Condition data elements **SHALL** declare conformance to the IHE Family History Observation entry by including a <templateID> element with the root attribute set to the value 1.3.6.1.4.1.19376.1.5.3.1.4.13.3
C83-[DE-18.18-1] Components of a Genetic Laboratory Test **SHALL** be coded as specified in HITSP/C80 Section 2.2.3.11 Genetic Testing
C83-[DE-19-CDA-1] A CDA Document **SHALL** declare conformance for the Social History module by including a <templateID> element with the root attribute set to the value 2.16.840.1.113883.10.20.1.33
C83-[DE-19-CDA-2] Social History data elements **SHALL** declare conformance to the IHE Social History Observation entry by including a <templateID> element with the root attribute set to the value 1.3.6.1.4.1.19376.1.5.3.1.4.13.4
C83-[DE-19.02-1] The Social History type **SHALL** be coded as specified in HITSP/C80 Section 2.2.2.4 Social History Type

### 3.2 TEMPLATE IDENTIFIERS

See the relevant HL7 Implementation Guides and IHE Profiles for a complete listing of all other template identifiers that are required for declaring conformance to HITSP defined templates.

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<thead>
<tr>
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4.0 DOCUMENT UPDATES

The following sections provide the details of updates made to this document.

4.1 DECEMBER 10, 2008

The changes in this construct address the following comments received during the Public Comment and Inspection Testing period (September 29 – October 24, 2008).

- 5081, 5082, 5109, 5192, 5468, 5473, 5485, 5489, 5621, 5623, 5631, 5643, 5028, 5626, 5624

The full text of the comments along with the Technical Committee’s disposition can be reviewed on the HITSP Public Web Site.

4.1.1 GLOBAL

The following changes were applies through-out the document for consistency with the HITSP suite of Interoperability Specifications

- Changed the name of the document to HITSP/C83 – CDA Content Modules
- Fixed various table numbering errors
- Many Entry Content Modules contained descriptions pertaining to related Section Content Modules. This text has been moved to the appropriate Section Content Module and re-worded when needed. The sections modified are:
  - 2.2.2.3, 2.2.2.5, 2.2.1.1, 2.2.2.6, 2.2.1.2, 2.2.2.7, 2.2.2.8, 2.2.1.12, 2.2.2.16, 2.2.1.27, 2.2.2.19
- Added the following footnote under all Entry Content Module tables
  - NOTE: Optionality = “R” for Required, "R2" for Required if known, “O” for Optional and Repeat = “Y” for Yes or ‘N’ for No
- Fixed incorrect references to “Discharge Diagnosis” in sections:
  - 2.2.1.12, 2.2.1.13, 2.2.1.14, 2.2.1.15
- Fixed incorrect template IDs for the following sections:
  - 2.2.1.7 - IHE History of Present Illness
  - 2.2.1.12 - IHE Medications
  - 2.2.1.23 - IHE Assessment and Plans
- Added text and removed requirements in Entry data elements in the Entry Content Modules
  - Requirements for Entries are defined at a higher level than the Entry Content Module (i.e. Section Content Modules, HITSP CDA based constructs and Interoperability Specifications), for:
    - 2.2.2.5, 2.2.2.6, 2.2.2.7, 2.2.2.8, 2.2.2.9, 2.2.2.12, 2.2.2.13, 2.2.2.14, 2.2.2.15, 2.2.2.16, 2.2.2.17, 2.2.2.18, 2.2.2.19
- Fixed various IHE Template Ids defined in Entry Content Module Constraints
  - IHE Patient Contacts

4.1.2 SECTION 2.1 CONTEXT OVERVIEW

- Updated the overview text to improve the explanation of HITSP/C83
- Added text to describe why Template IDs may have changed from HITSP/C32 to HITSP/C83
- Introduced Entry and Section Content Module descriptions.
4.1.3 SECTION 2.2 RULES FOR IMPLEMENTING
Added constraints that were previously specified in HITSP/C32 but now apply to all HITSP CDA based documents. Added C[83] 4 – 11.

4.1.4 SECTION 2.2.1.X SECTION CONTENT MODULES
Editorial update to names of various IHE Section Content Modules:
- 2.2.1.22, 2.2.1.24, 2.2.1.25, 2.2.1.27

4.1.5 SECTION 2.2.1.23 ASSESSMENTS AND PLAN SECTION
Clarified and moved note related to Assessments and Plan.

4.1.6 SECTION 2.2.1.28 MEDICAL EQUIPMENT SECTION
Added new Section Content Module.

4.1.7 SECTION 2.2.2.5 INSURANCE PROVIDER
This section is based upon HL7 CCD and HITSP cannot lower a field requirement if required by the CCD, thus two requirements have been modified.
- Data Element 5.01 Group Number was changed from O to R
- Member Information was changed from R2 to R

4.1.8 SECTION 2.2.2.7 CONDITION
Removed text related to Registration and Medication History. This information is part of IS03.

4.1.9 SECTION 2.2.2.11 COMMENT
Added requirements for Comment and Author

4.1.10 SECTION 2.2.2.15.2 RESULTS TYPE
Deleted Results Type reference for imaging procedures

4.1.11 SECTION 2.2.2.17 PROCEDURE
Deleted and moved text to TN901 that described standard’s overlap for procedure terminologies.

4.1.12 SECTION 2.2.2.18 FAMILY HISTORY
- Update text description for Pedigree (18.01)
- Clarified that Family Member Relationships (18.04) can reference beyond 2nd degree
- Added requirements to data elements that were missing specification
- Fixed Temp Id for Family History Section to '2.16.840.1.113883.10.20.1.23'
- Updated Family History Example

4.1.13 SECTION 2.2.2.19 SOCIAL HISTORY
- Modified text description of Social History
- Corrected Temp ID for Social History Event to 2.16.840.1.113883.10.20.1.33'
4.1.14 SECTION 2.3.2 SELECTED STANDARDS

- Corrected the reference to the Integrating the Healthcare Enterprise (IHE) Patient Care Coordination (PCC) from version 3 to version 4
- Minor editorial changes were made to this document.

4.2 DECEMBER 18, 2008

Upon approval by the HITSP Panel on December 18, 2008, this document is now Released for Implementation.

4.3 JUNE 30, 2009

Changes based upon Public Comments:

- 7071, 7078, 7079, 7080, 7081, 7086, 7089, 7090, 7091, 7094, 7096, 7097, 7098, 7112, 7116, 7117, 7118, 7126, 7122

The full text of the comments along with the Technical Committee’s disposition can be reviewed on the HITSP Public Web Site.

Minor editorial changes were made to this construct. Removed boilerplate text for simplification. The term “actor” was replaced with “interface”.

Revised the document based on HITSP/TN903 Data Architecture:

- Section 1.4 Document Conventions
  - Added this section to indicate conventions for Constraints
- Section 2.1 Context Overview
  - Updated to include descriptions of Data Modules.
- Section 2.1.1 Component Constraints
  - Updated to describe the tables used to describe HITSP Data Elements
- Section 2.1.2 HITSP Data Elements
  - Added this section, which now contains the Data Element Definitions previously found in the Entry Content Modules Section.
  - Moved common value set constraints from the Entry Content Modules Section to this section where these constraints should be applied across exchanges using different selected standards.
  - Added common constraints on addresses across all addresses in this section.
- Section 2.2 Rules for Implementing Components in CDA
  - Change the name of the Rules for Implementing Components to Rules for Implementing Components in CDA to reflect the purpose of this section.
- Section 2.2.2 Entry Content Modules
  - Removed Data Element Definitions from the Entry Content Modules
  - Change the Constraint Numbers to reflect the numbering scheme agreed upon by the Data Architecture Tiger Team.
  - Reordered and re-titled the Mapping Tables to conform to material provided in TN903.
  - Moved common value set constraints to the Data Element table in Section 2.1.2
- Section 2.2.2.8.10 Medication Information
  - Moved constraints to appropriate subsections.
- Section 2.2.2.8.11 – 2.2.2.8.14
  - Added these sections to re-factor constraints assigned to Section 2.2.2.8.10
- Section 2.2.2.8.20 Vehicle Constraints
- Fixed errors in this section with respect to constraints.
- **Section 2.2.2 Section Content Modules**
  - Changed constraints to conform to identification scheme.
  - Added Section Template Identifiers
  - Renumbered Tables and Figures to conform to new template

### 4.4 JULY 8, 2009

Upon approval by the HITSP Panel on July 8, 2009, this document is now Released for Implementation.