Integrating the Healthcare Enterprise

IHE Patient Care Coordination (PCC) Technical Framework Supplement 2008-2009

Immunization Content (IC)

Draft for Trial Implementation

August 22, 2008

Forward

Integrating the Healthcare Enterprise (IHE) is an initiative designed to stimulate the integration of the information systems that support modern healthcare institutions. Its fundamental objective is to ensure that in the care of patients all required information for medical decisions is both correct and available to healthcare professionals. The IHE initiative is both a process and a forum for encouraging integration efforts. It defines a technical framework for the implementation of established messaging standards to achieve specific clinical goals. It includes a rigorous testing process for the implementation of this framework. And it organizes educational sessions and exhibits at major meetings of medical professionals to demonstrate the benefits of this framework and encourage its adoption by industry and users.

The approach employed in the IHE initiative is not to define new integration standards, but rather to support the use of existing standards, HL7, DICOM, IETF, and others, as appropriate in their respective domains in an integrated manner, defining configuration choices when necessary. When clarifications or extensions to existing standards are necessary, IHE refers recommendations to the relevant standards bodies.

This initiative has numerous sponsors and supporting organizations in different medical specialty domains and geographical regions. In North America the primary sponsors are the Healthcare Information and Management Systems Society (HIMSS) and the Radiological Society of North America (RSNA). IHE Canada has also been formed. IHE Europe (IHE-EUR) is supported by a large coalition of organizations including the European Association of Radiology (EAR) and European Congress of Radiologists (ECR), the Coordination Committee of the Radiological and Electromedical Industries (COCIR), Deutsche Röntgengesellschaft (DRG), the EuroPACS Association, Groupement pour la Modernisation du Système d'Information Hospitalier (GMSIH), Société Francaise de Radiologie ([www.sfr-radiologie.asso.fr SFR]), and Società Italiana di Radiologia Medica (SIRM). In Japan IHE-J is sponsored by the Ministry of Economy, Trade, and Industry (METI); the Ministry of Health, Labor, and Welfare; and [www.medis.or.jp MEDIS-DC]; cooperating organizations include the Japan Industries Association of Radiological Systems (JIRA), the Japan Association of Healthcare Information Systems Industry (JAHIS), Japan Radiological Society (JRS), Japan Society of Radiological Technology (JSRT), and the Japan Association of Medical Informatics (JAMI). Other organizations representing healthcare professionals are actively involved and others are invited to join in the expansion of the IHE process across disciplinary and geographic boundaries.

The IHE Technical Frameworks for the various domains (Patient Care Coordination, IT Infrastructure, Cardiology, Laboratory, Radiology, etc.) define specific implementations of established standards to achieve integration goals that promote appropriate sharing of medical information to support optimal patient care. These are expanded annually, after a period of public review, and maintained regularly through the identification and correction of errata. The current version for these Technical Frameworks may be found at www.ihe.net.

The IHE Technical Framework identifies a subset of the functional components of the healthcare enterprise, called IHE Actors, and specifies their interactions in terms of a set of coordinated, standards-based transactions. It describes this body of transactions in progressively greater depth. Volume I provides a high-level view of IHE functionality, showing the transactions organized into functional units called Integration Profiles that highlight their capacity to address specific clinical needs. Subsequent volumes provide detailed technical descriptions of each IHE transaction.

This IHE Patient Care Coordination (PCC) Technical Framework Supplement is issued for Trial Implementation through May 2009.

Comments and change proposals arising from Trial Implementation may be submitted to http://forums.rsna.org under the forum:

"Integrating the Healthcare Enterprise"

Select the sub-forum:

"IHE Patient Care Coordination 2008 Supplements for Trial Implementation"

The IHE IT Infrastructure Technical Committee will address these comments resulting from implementation, Connectathon testing, and demonstrations. Final text is expected to be published in June 2009, dependent upon results of IHE validation process.

Content of the Technical Framework

This technical framework defines relevant standards and constraints on those standards in order to implement a specific use cases for the transfer of information between systems. This document is organized into 2 volumes as follows:

Volume 1 - Overview

This volume is provided as a high level overview of the profiles including descriptions of the use case, the actors involved, the process flow, and dependencies on other standards and IHE profiles. It is of interest to care providers, vendors' management and technical architects and to all users of the profile

Volume 2 – Transactions and Content Profiles

This volume is intended as a technical reference for the implementation of specific transactions in the use case including references to the relevant standards, constraints, and interaction diagrams. It is intended for the technical implementers of the profile.

How to Contact Us

IHE Sponsors welcome comments on this document and the IHE initiative. They should be directed to the discussion server at http://forums.rsna.org or to:

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1.1 Preface to Volume 1 of the PCC Technical Framework

1.1.1 Intended Audience

The intended audience of this document is:

- Healthcare professionals involved in informatics
- IT departments of healthcare institutions
- Technical staff of vendors participating in the IHE initiative
- Experts involved in standards development
- Those interested in integrating healthcare information systems and workflows

1.1.2 Related Information for the Reader

The reader of volume 1 should read or be familiar with the following documents:

- Volume 1 of the Cross-Enterprise Document Sharing (XDS) Integration Profile documented in the ITI Infrastructure Technical Framework
- Volume 1 of the Notification of Document Availability (NAV) Integration Profile documented in the ITI Infrastructure Technical Framework
- Volume 1 of the Audit Trail and Node Authentication (ATNA) Integration Profile documented in the ITI Infrastructure Technical Framework http://www.ihe.net/Technical_Framework/index.cfm).
- HL7 Clinical Document Architecture Release 2: Section 1, CDA Overview.
- Care Record Summary – Implementation Guide for CDA Release 2 (US Realm): Section 1
- Presentations from IHE Workshop: Effective Integration of the Enterprise and the Health System - June 28–29, 2005: http://www.ihe.net/Participation/workshop_2005.cfm, June 2005:
- Leveraging IHE to Build RHIO Interoperability
- Cross-Enterprise Document Sharing (XDS)
- Notification of Document Availability (NAV)
- Patient Care Coordination
- Use Cases for Medical Summaries
- Patient Care Coordination - Overview of Profiles

1.1.3 How this Volume is Organized

Section 2 describes the general nature, structure, purpose and function of the Technical Framework. Section 3 and the subsequent sections of this volume provide detailed documentation on each integration profile, including the Patient Care Coordination problem it is intended to address and the IHE actors and transactions it comprises.

The appendices following the main body of the document provide a summary list of the actors and transactions, detailed discussion of specific issues related to the integration profiles and a glossary of terms and acronyms used.

1.1.4 Conventions Used in this Document

This document has adopted the following conventions for representing the framework concepts and specifying how the standards upon which the IHE Technical Framework is based should be applied.

1.1.4.1 Technical Framework Cross-references

When references are made to another section within a Technical Framework volume, a section number is used by itself. When references are made to other volumes or to a Technical Framework in another domain, the following format is used:

<domain designator> TF-<volume number>: <section number>

where:

<domain designator>

is a short designator for the IHE domain (PCC= Patient Care Coordination, ITI = IT Infrastructure, RAD = Radiology)

<volume number>

is the applicable volume within the given Domain Technical Framework (e.g., 1, 2, 3), and

<section number>

is the applicable section number.

For example: PCC TF-1: 3.1 refers to Section 3.1 in volume 1 of the IHE Patient Care Coordination Technical Framework, ITI TF-2: 4.33 refers to Section 4.33 in volume 2 of the IHE IT Infrastructure Technical Framework.

1.1.4.2 IHE Actor and Transaction Diagrams and Tables

Each integration profile is a representation of a real-world capability that is supported by a set of actors that interact through transactions. Actors are information systems or components of information systems that produce, manage, or act on categories of information required by operational activities in the enterprise. Transactions are interactions between actors that communicate the required information through standards-based messages.

The diagrams and tables of actors and transactions in subsequent sections indicate which transactions each actor in a given profile must support.

The transactions shown on the diagrams are identified both by their name and the transaction number as defined in PCC TF-2 (Volume 2 of the PCC Technical framework). The transaction numbers are shown on the diagrams as bracketed numbers prefixed with the specific Technical Framework domain.

In some cases, a profile is dependent on a prerequisite profile in order to function properly and be useful. For example, Cross-Enterprise Sharing of Medical Summaries depends on Audit Trail and Node Authentication (ATNA). These dependencies can be found by locating the desired profile in the dependencies section of this document to determine which profile(s) are listed as prerequisites. An actor must implement all required transactions in the prerequisite profiles in addition to those in the desired profile.

1.1.4.3 Process Flow Diagrams

The descriptions of integration profiles that follow include process flow diagrams that illustrate how the profile functions as a sequence of transactions between relevant actors.

These diagrams are intended to provide an overview so the transactions can be seen in the context of an institution's or cross-institutions' workflow. Certain transactions and activities not defined in detail by IHE are shown in these diagrams in italics to provide additional context on where the relevant IHE transactions fit into the broader scheme of healthcare information systems. These diagrams are not intended to present the only possible scenario. Often other actor groupings are possible, and transactions from other profiles may be interspersed.

In some cases the sequence of transactions may be flexible. Where this is the case there will generally be a note pointing out the possibility of variations. Transactions are shown as arrows oriented according to the flow of the primary information handled by the transaction and not necessarily the initiator.

1.1.5 Copyright Permissions

IHE has been very fortunate in having the American College of Obstetricians and Gynecologists (ACOG) help us in the definition of the data found in the Antepartum Summary Profile (APS).

The Antepartum Summary Profile (APS) describes the content structures and specifications the American College of Obstetricians and Gynecologists (ACOG) views are necessary in an antepartum record. ACOG encourages the use of the content structures contained in the Antepartum Summary Profile of the Patient Care Coordination Technical Framework. ACOG does not endorse any EMR products. Companies or individuals that use these content structures in EMR product or service are prohibited from using ACOG's name and/or its logo on any promotional material, packaging, advertisement, website or in any other context related to the EMR product or service.

permission to do so from the copyright holders. More information is available from
265 http://www.bradenscale.com/

2 Introduction

This document, the IHE Patient Care Coordination Technical Framework (PCC TF), defines specific implementations of established standards. These are intended to achieve integration goals that promote appropriate exchange of medical information to coordinate the optimal patient care among care providers in different care settings. It is expanded annually, after a period of public review, and maintained regularly through the identification and correction of errata. The latest version of the document is always available via the Internet at http://www.ihe.net/Technical_Framework/ , where the technical framework volumes specific to the various healthcare domains addressed by IHE may be found.

The IHE Patient Care Coordination Technical Framework identifies a subset of the functional components of the healthcare enterprises and health information networks, called IHE actors, and specifies their interactions in terms of a set of coordinated, standards-based transactions. The other domains within the IHE initiative also produce Technical Frameworks within their respective areas that together form the IHE Technical Framework. Currently, the following IHE Technical Framework(s) are available:

- IHE IT Infrastructure Technical Framework
- IHE Cardiology Technical Framework
- IHE Laboratory Technical framework
- IHE Radiology Technical Framework
- IHE Patient Care Coordination Technical Framework

Where applicable, references are made to other technical frameworks. For the conventions on referencing other frameworks, see the preface of this volume.

2.1 Relationship to Standards

The IHE Technical Framework identifies functional components of a distributed healthcare environment (referred to as IHE actors), solely from the point of view of their interactions in the healthcare enterprise. It further defines a coordinated set of transactions based on standards (such as HL7, IETF, ASTM, DICOM, ISO, OASIS, etc.) in order to accomplish a particular use case. As the scope of the IHE initiative expands, transactions based on other standards may be included as required.

At its current level of development, IHE has also created Content Integration Profiles to further specify the payloads of these transactions, again based on standards. This has become necessary as the healthcare industry moves towards the use of transaction standards that have been used in more traditional computing environments.

In some cases, IHE recommends selection of specific options supported by these standards. However, IHE does not introduce technical choices that contradict conformance to these standards. If errors in or extensions to existing standards are identified, IHE's policy is to report them to the appropriate standards bodies for resolution within their conformance and standards evolution strategy.

IHE is therefore an implementation framework, not a standard. Conformance claims for products must still be made in direct reference to specific standards. In addition, vendors who have implemented IHE integration capabilities in their products may publish IHE Integration Statements to communicate their products' capabilities. Vendors publishing IHE Integration Statements accept full responsibility for their content. By comparing the IHE Integration Statements from different products, a user familiar with the IHE concepts of actors and integration profiles can determine the level of integration between them. See PCC TF-1: Appendix C for the format of IHE Integration Statements.

2.2 Relationship to Product Implementations

The IHE actors and transactions described in the IHE Technical Framework are abstractions of the real-world healthcare information system environment. While some of the transactions are traditionally performed by specific product categories (e.g. HIS, Clinical Data Repository, Electronic Health record systems, Radiology Information Systems, Clinical Information Systems or Cardiology Information Systems), the IHE Technical Framework intentionally avoids associating functions or actors with such product categories. For each actor, the IHE Technical Framework defines only those functions associated with integrating information systems. The IHE definition of an actor should therefore not be taken as the complete definition of any product that might implement it, nor should the framework itself be taken to comprehensively describe the architecture of a healthcare information system.

The reason for defining actors and transactions is to provide a basis for defining the interactions among functional components of the healthcare information system environment. In situations where a single physical product implements multiple functions, only the interfaces between the product and external functions in the environment are considered to be significant by the IHE initiative. Therefore, the IHE initiative takes no position as to the relative merits of an integrated environment based on a single, all-encompassing information system versus one based on multiple systems that together achieve the same end.

2.3 Framework Development and Maintenance

The IHE Patient Care Coordination Technical Framework is continuously maintained and expanded on an annual basis by the IHE Patient Care Coordination Technical Committee. The development and maintenance process of the Framework follows a number of principles to ensure stability of the specification so that both vendors and users may use it reliably in specifying, developing and acquiring systems with IHE integration capabilities.

The first of these principles is that any extensions or clarifications to the Technical Framework must maintain backward compatibility with previous versions of the framework (except in rare cases for corrections) in order to maintain interoperability with systems that have implemented IHE Actors and Integration Profiles defined there. The IHE Patient Care Coordination Technical Framework is developed and re-published annually following a three-step process:

1. The Patient Care Coordination Technical Committee develops supplements to the current stable version of the Technical Framework to support new functionality identified by the IHE Strategic and PCC Planning Committees and issues them for public comment.
2. The Committee addresses all comments received during the public comment period and publishes an updated version of the Technical Framework for "Trial Implementation." This version contains both the stable body of the Technical Framework from the preceding cycle and the newly developed supplements. It is this version of the Technical Framework that is used by vendors in developing trial implementation software for the IHE Connectathons.
3. The Committee regularly considers change proposals to the Trial Implementation version of the Technical Framework, including those from implementers who participate in the Connectathon. After resolution of all change proposals received within 60 days of the Connectathon, the Technical Framework version is published as "Final Text".

As part of the Technical framework maintenance the Committee will consider change proposals received after the publication to the "Final Text".

2.4 About the Patient Care Coordination Integration Profiles

IHE Integration Profiles offer a common language that healthcare professionals and vendors can use to discuss integration needs of healthcare enterprises and the integration capabilities of information systems in precise terms. Integration Profiles specify implementations of standards that are designed to meet identified clinical needs. They enable users and vendors to state which IHE capabilities they require or provide, by reference to the detailed specifications of the IHE Patient Care Coordination Technical Framework.

Integration profiles are defined in terms of IHE Actors, transactions and their content. Actors (listed in PCC TF-1: Appendix A) are information systems or components of information systems that produce, manage, or act on information associated with clinical and operational activities. Transactions (listed in PCC TF-1: Appendix B) are interactions between actors that communicate the required information through standards-based messages. Content is what is exchanged in these transactions, and are defined by Content Profiles.

Vendor products support an Integration Profile by implementing the appropriate actor(s) and transactions. A given product may implement more than one actor and more than one integration profile.

Content Profiles define how the content used in a transaction is structured. Each transaction is viewed as having two components, a payload, which is the bulk of the information being carried, and metadata that describes that payload. The binding of the Content to an IHE transaction specifies how this payload influences the metadata of the transaction. Content modules within the Content Profile then define the payloads. Content modules are transaction neutral, in that what they describe is independent of the

transaction in which they are used, whereas content bindings explain how the payload influences the transaction metadata.

The figure below shows the relations between the Content Integration Profiles of the Patient Care Coordination Domain.

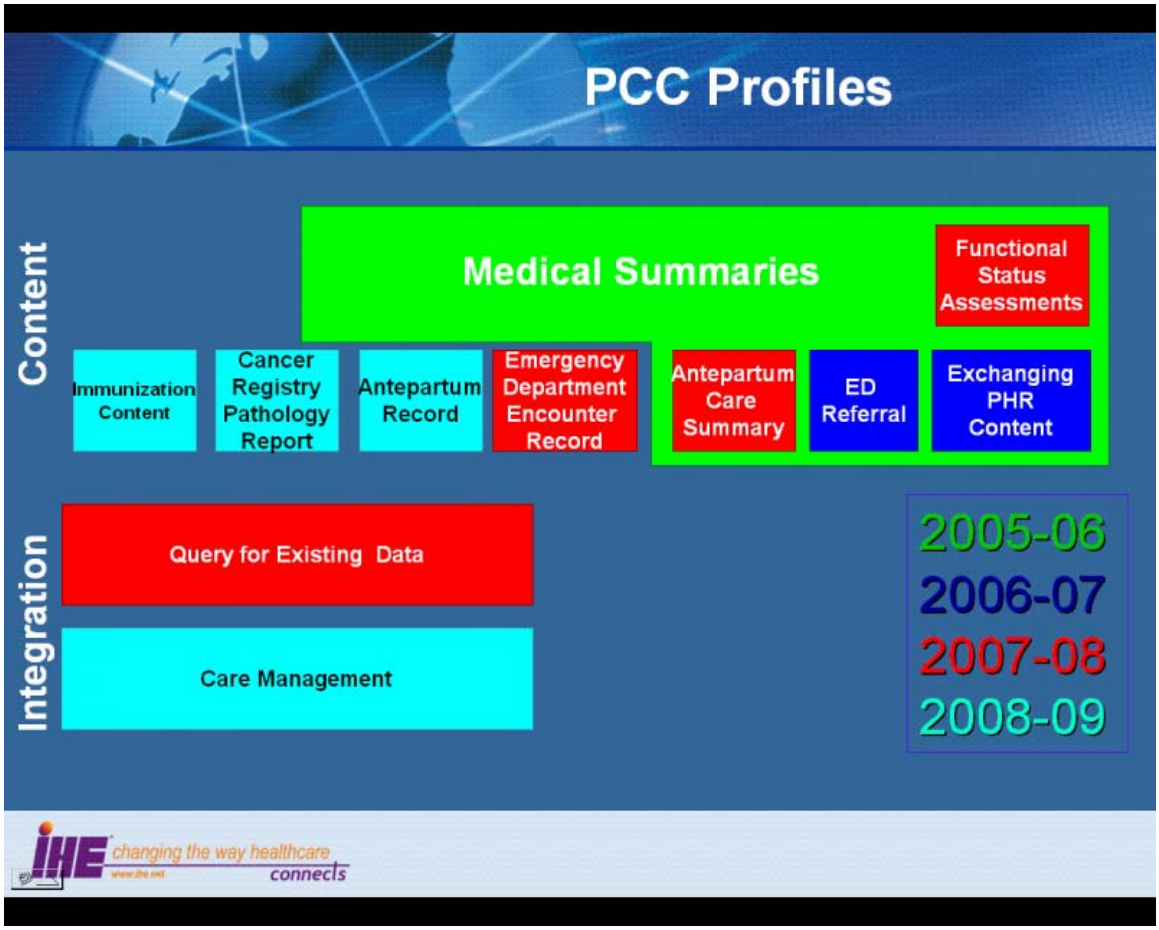

Figure 2.4-1 IHE Patient Care Coordination Content Integration Profiles

2.5 Dependencies of the PCC Integration Profiles

Dependencies among IHE Integration Profiles exist when implementation of one integration profile is a prerequisite for achieving the functionality defined in another integration profile. The table below defines these dependencies. Some dependencies require that an actor supporting one profile be grouped with one or more actors supporting other integration profiles. For example, Cross-Enterprise Sharing of Medical Summaries (XDS-MS) requires that its actors be grouped with a Secured Node Actor of the Audit Trail and Node Authentication (ATNA) Integration Profile. The dependency exists because XDS-MS and XDS actors must support a secured communication channel with proper auditing of the exchange of patient identified information in order to function properly in an environment where protection of patient privacy is critical.

Integration Profile	Depends on	Dependency Type	Purpose
All PCC Content Profiles	Audit Trail and Node Authentication (ATNA)	Each Content Creator and Content Consumer actor shall be grouped with the ATNA Secured Node Actor	Required to manage audit trail of exported PHI, node authentication, and transport encryption.
	Consistent Time (CT)	Each Content Creator and Content Consumer actor shall be grouped with the Time Client Actor	Required to manage and resolve conflicts in multiple updates.
Functional Status Assessments (FSA)	Cross Enterprise Document Exchange of Medical Summaries (XDS-MS) OR Exchange of Personal Health Record Content (XPHR) OR Emergency Department Referral (EDR)	Content Consumers implementing the Functional Status Assessments profile shall be grouped with either the XDS-MS, XPHR or EDR Content Consumer. Content Creators implementing the Functional Status Assessments profile shall be grouped with either the XDS-MS, XPHR or EDR Content Creator.	Ensures that the Functional Status Assessment is communicated as part of an exchange of medical summary information.
Functional Status Assessments (QED)	Audit Trail and Node Authentication (ATNA)	Each actor in this profile shall be grouped with the ATNA Secure Node or Secure Application actor.	Required to manage audit trail of exported PHI, node authentication, and transport encryption.
	Consistent Time (CT)	Each actor in this profile shall be grouped with the Time Client Actor	Required to manage and resolve conflicts in multiple updates.

Table 2.5-1 PCC Profile Dependencies

To support a dependent profile, an actor must implement all required transactions in the prerequisite profiles in addition to those in the dependent profile. In some cases, the prerequisite is that the actor selects any one of a given set of profiles.

2.6 PCC Integration Profiles Overview

In this document, each IHE Integration Profile is defined by:

- The IHE actors involved
- The specific set of IHE transactions exchanged by each IHE actor.
- The content of the IHE transactions

These requirements are presented in the form of a table of transactions required for each actor supporting the Integration Profile. Actors supporting multiple Integration Profiles are required to support all the required transactions of each Integration Profile supported.

When an Integration Profile depends upon another Integration Profile, the transactions required for the dependent Integration Profile have not been included in the table.

The content of the transactions are presented as Content Integration Profiles. These are specification of the content to be exchange, along with explanations (called bindings) of how the content affects the transactions in which it is exchanged. It is expected that Content Integration Profiles will be used environments where the physician offices and hospitals have a coordinated infrastructure that serves the information sharing needs of this community of care. Several mechanisms are supported by IHE profiles:

- A registry/repository-based infrastructure is defined by the IHE Cross-Enterprise Document Sharing (XDS) and other IHE Integration Profiles such as patient identification (PIX & PDQ), and notification of availability of documents (NAV).
- A media-based infrastructure is defined by the IHE Cross-Enterprise Document Media Interchange (XDM) profile.
- A reliable messaging-based infrastructure is defined by the IHE Cross-Enterprise Document Reliable Interchange (XDR) profile.
- All of these infrastructures support Security and privacy through the use of the Consistent Time (CT) and Audit Trail and Node Authentication (ATNA) profiles.

For more details on these profiles, see the IHE IT Infrastructure Technical Framework, found here: http://www.ihe.net/Technical_Framework/.

Such an infrastructure is assumed by the use cases that focus on the context for defining the specific clinical information content for this profile. These content integration profiles use similar transactions and differ only in the content exchanged. A process flow for these use cases using Cross Enterprise Document Sharing (XDS) and Notification of Document Availability (NAV) is shown in the figure below. Other process flows are possible using XDM and/or XDR.

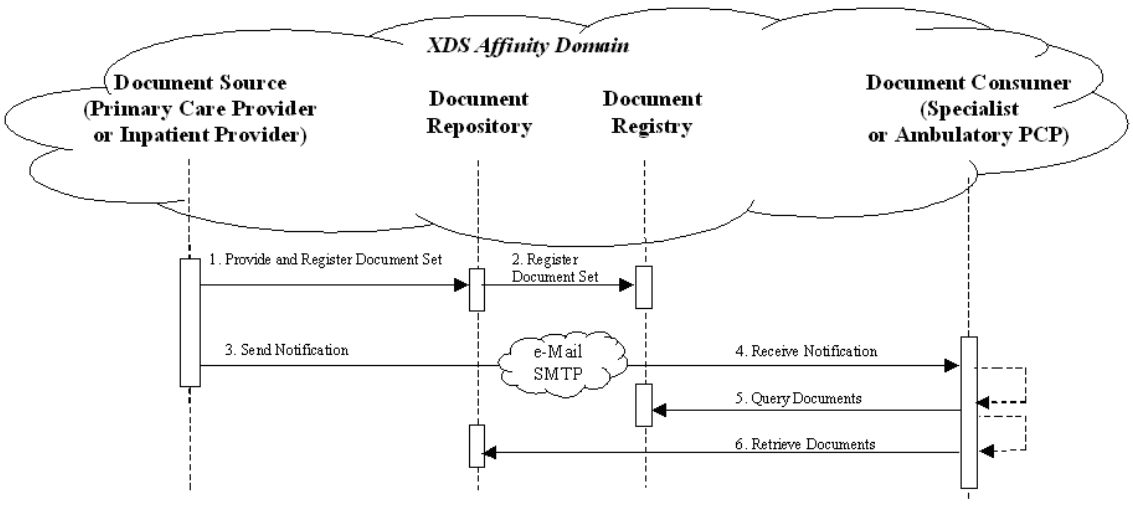

Figure 2.6-1 Use Case Process Flow Diagram

These steps are:

1. Extract/capture a collection of records into a set of documents packaged as an XDS Submission Set. This submission contains at least one clinical document, and may contain a number of other related clinical documents. For example, Medical Summaries are clinical documents (already known in the paper world), which often serve the dual purpose of documenting an encounter and providing the rationale for sending the information to another provider. This step utilizes the transactions provided by the ITI XDS profile to place the records in an XDS Repository (local or shared).
2. The Repository ensures that the documents of the submission set are registered with the XDS Registry of the Affinity Domain (set of cooperating care delivery institutions).
3. Notify the other provider that documents are now available for review. This step utilizes the transactions provided by the ITI NAV profile to perform the e-mail notification.
4. The e-mail notification that contains no patient identified information is received by the specialist EMR system.
5. The receiving provider can then utilize existing query transactions from the XDS profile to find the URL of the Documents.
6. Finally, the receiving provider may choose to display the document, or import relevant information from these records into their own EMR system.

2.6.1 Unplanned Access to past Content

In many cases, a provider may need to assess information from the patient care history, and patients may have content in the XDS repository from prior visits to other providers. For example, Medical Summaries, as well as other documents such as laboratory and radiology reports are critical for emergency physicians and nurses to provide the best care to patient in acute conditions. The figure below shows the transactions required for this use case, again, using XDS. Other process flows are possible using XDM and/or XDR.

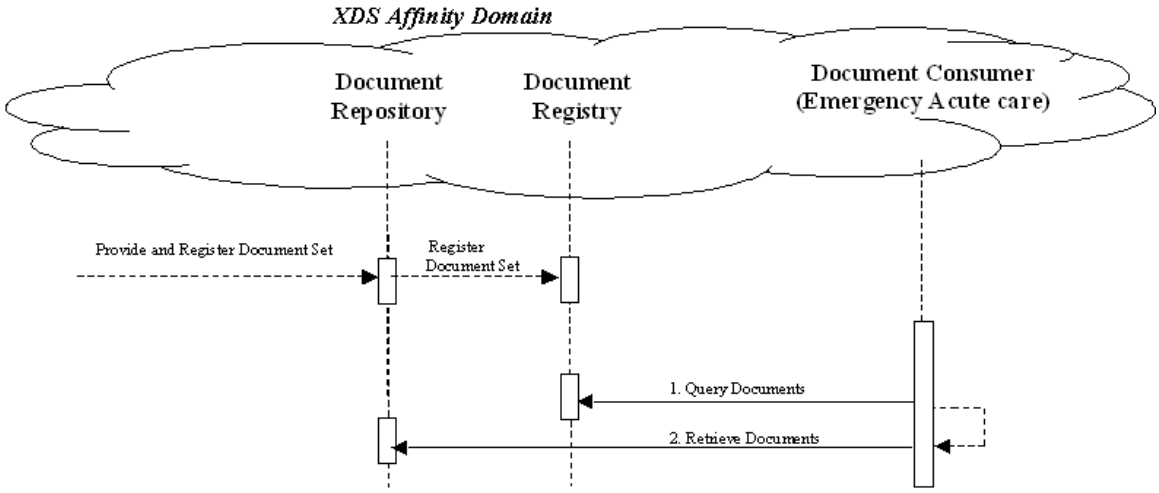

Figure 2.6-2 Unplanned Access Process Flow Diagram

Note that IHE Integration Profiles are not statements of conformance to standards, and IHE is not a certifying body. Users should continue to request that vendors provide statements of their conformance to standards issued by relevant standards bodies, such as HL7 and DICOM. Standards conformance is a prerequisite for vendors adopting IHE Integration Profiles.

Also note that there are critical requirements for any successful integration project that IHE cannot address. Successfully integrating systems still requires a project plan that minimizes disruptions and describes fail-safe strategies, specific and mutually understood performance expectations, well-defined user interface requirements, clearly identified systems limitations, detailed cost objectives, plans for maintenance and support, etc.

2.7 History of Annual Changes

In the 2005-2006 cycle of the IHE Patient Care Coordination initiative, the first release of the IHE PCC Technical Framework introduced the following integration profile:

- **Cross-Enterprise Sharing of Medical Summaries (XDS-MS) –** a mechanism to automate the sharing process between care providers of Medical Summaries, a class of clinical documents that contain the most relevant portions of information about the patient intended for a specific provider or a broad range of potential providers in different settings. Medical Summaries are commonly created and consumed at points in time of transfers of care such as referrals or discharge.

In the 2006-2007 cycle of the IHE Patient Care Coordination initiative, the following integration profiles were added to the technical framework.

- **Exchange of Personal Health Record Content (XPHR) –** provides a standards-based specification for managing the interchange of documents between a Personal Health Record used by a patient and systems used by other healthcare providers to enable better interoperability between these systems.

- **Basic Patient Privacy Consents (BPPC) –** enables XDS Affinity Domains to be more flexible in the privacy policies that they support, by providing mechanisms to record patient privacy consents, enforce these consents, and create Affinity Domain defined consent vocabularies that identify information sharing policies.
  Please Note: This profile was transferred to the ITI Domain in the Fall of 2007, and can be found here *http://www.ihe.net/Technical_Framework/index.cfm#IT*
- **Pre-procedure History and Physical Content Profile (PPHP) –** supports the exchange of information allowing for the assessment and amelioration of risks related to a procedure. *Please Note: This profile has been withdrawn.*
- **Emergency Department Referral Profile (EDR) –** provides a means to communicate medical summary data from an EHR System to an EDIS System.

In the 2007-2008 cycle of the IHE Patient Care Coordination initiative, the following integration profiles were added to the technical framework.

- **Antepartum Care Summary (APS)** - describes the content and format of summary documents used during Antepartum care.
- **Emergency Department Encounter Summary (EDES)** - describes the content and format of records created during an emergency department visit.
- **Functional Status Assessment Profile (FSA)** - supports the handoff of assessment information between practitioners during transfers of care by defining the Functional Status Assessment option on the XDS-MS and XPHR profiles.
- **Query for Existing Data (QED)** - allows information systems to query data repositories for clinical information on vital signs, problems, medications, immunizations, and diagnostic results.
- **Public Health Laboratory Report (PHLAB)** - extends the XD*-LAB profile to support reporting from public health laboratories for disease surveillance activities. *Please Note: This profile has been subsequently moved to the XD-LAB specification, and van be found here* *http://www.ihe.net/Technical_Framework/index.cfm#LAB*

In addition, all content within the technical framework was revised in the 2007-2008 cycle to encourage compatibility with the ASTM/HL7 Continuity of Care Document Implementation Guide.

In the 2008-2009 cycle of the IHE Patient Care Coordination initiative, the following integration profiles were added to the technical framework.

- **Antepartum Record (APR) -** describes the content and format of summary documents used during Antepartum care.
- **Care Management (CM) -** describes the content and format of summary documents used during Antepartum care.

- **Immunization Content (IC) -** describes the content and format of summary documents used during Antepartum care.
- **Cancer Registry Pathology Report (CPR) -** describes the content and format of summary documents used during Antepartum care.

2.8 Product Implementations

Developers have a number of options in implementing IHE actors and transactions in product implementations. The decisions cover three classes of optionality:

- For a system, select which actors it will incorporate (multiple actors per system are acceptable).
- For each actor, select the integration profiles in which it will participate.
- For each actor and profile, select which options will be implemented.

All required transactions must be implemented for the profile to be supported (for XDS-MS, refer to the transaction descriptions for XDS in ITI TF-2).

Implementers should provide a statement describing which IHE actors, IHE integration profiles and options are incorporated in a given product. The recommended form for such a statement is defined in PCC TF-1: Appendix C.

In general, a product implementation may incorporate any single actor or combination of actors. When two or more actors are grouped together, internal communication between actors is assumed to be sufficient to allow the necessary information flow to support their functionality; for example, the Document Source Actor of XDS-MS may use the Patient Identifier Cross-reference Consumer Actor to obtain the necessary patient identifier mapping information from its local patient id to that used in the document sharing domain. The exact mechanisms of such internal communication are outside the scope of the IHE Technical Framework.

When multiple actors are grouped in a single product implementation, all transactions originating or terminating with each of the supported actors shall be supported (i.e., the IHE transactions shall be offered on an external product interface).

The following examples describe which actors typical systems might be expected to support. This is not intended to be a requirement, but rather to provide illustrative examples.

An acute care EMR serving a hospital might include a Document Source Actor, Document Consumer Actor, a Document Repository Actor, a Patient Identification Consumer Actor, as well as a Secured Node Actor. An Ambulatory EMR serving a physician practice might include a Document Source Actor, Document Consumer Actor, a Patient Demographics Client Actor, as well as a Secured Node Actor.

3 The Immunization Content Profile (IC)

3.1 Profile Abstract

The Immunization Content Profile defines standard immunization data content for Immunization Information Systems (IISs), other public health systems, electronic medical records (EMR) systems, Health Information Exchanges, and others wishing to exchange immunization data electronically in a standard format.

3.2 Glossary

Immunization Information System (IIS)

Preferred term of the American Immunization Registry Association for "Immunization Registry"

3.3 Issue Log

3.3.1 Open Issues

Add the following bullet to the list of profiles

- Immunization Content - The Immunization Content Profile defines standard immunization data content for Immunization Information Systems, other public health systems, EMR systems, Health Information Exchanges, and others wishing to exchange immunization data electronically in a standard format.

3.4 Dependencies

Add the following row(s) to the list of dependencies

Integration Profile	Dependency	Dependency Type	Purpose
Immunization Content (IC)	ATNA	Actors the IC profile shall implement the Secure Node Actor of the ATNA profile	Ensures that transmissions and changes to patient health information are logged in an audit repository, and that communication is secured between nodes.
Immunization Content (IC)	CT	Actors the IC profile shall implement the Time Client Actor of the CT profile	Ensures that concistent time is used in all messages.

3.5 Overview

The Immunization Content Profile (IC) provides a standarddocument to exchange immunization data. It is intended to facilitate the exchange of immunization data among multiple systems belonging to a single or to multiple organizations. Data exchange with and among the installed base of U.S. Immunization Information System (IIS) base was a critical consideration in formulating this profile. However, its intention is to go beyond data exchange among IISs, and facilitate immunization data exchange on a healthcare information network that includes electronic medical record (EMR) systems, Health Information Exchanges, other public health systems, Personal Health Record (PHR) systems, and other stakeholder systems. Thus, the profile specifies common data formats for exchanging immunization data only, or for exchanging immunization data along with medical summary data needed for the overall care of a patient related to immunizations.

To accomplish this, IC includes history of administered vaccines with such details as lot number, who administered the shot, and so forth, and handles immunization as well as other information related to the patient's care. For example, it includes medical history, medications, allergies, vital signs, and so forth.

3.6 Use Cases

The following progression of use cases is illustrated in the drawing below

Use Case 1: Immunization Information System Participation

Various provider organizations - airport flu shot clinics, storefront vaccine clinics, and hospital vaccine clinics - wish to submit immunization histories for patients to a regional Immunization Information System (IIS) with appropriate patient consent. The provider IT departments configure HL7 Verion 2.3.1 connections with the IIS. Each time immunizations are recorded, records of the administered vaccines are automatically sent to the IIS using an HL7 version 2.3.1 standard format. This is representative of the present-state use case in the U.S.

3.6.1 Use Case 2: Immunization Yellow Card

A pediatrician's office produces official immunization records (sometimes called "Yellow Card") for patients. The provider electronic medical record (EMR) system retrieves demographic information and records of immunization its immunization repository. To supplement its records with immunizations that the patient may have received from other providers, it queries the regional Immunization Information System (IIS). It passes the immunization content to a software module or service that prints the information in the official Yellow Card format.

3.6.2 Use Case 3: Personal Health Record

The provider wishes to make the assembled immunization information available in the patient's Personal Health Record (PHR). The pediatrician's office EMR system includes the retrieved immunization information in its complete care provision information about the patient. The standard Care Provision information contains current conditions, allergies and past adverse events, medications, vital signs, past medical history such as disease history, and so forth, in addition to immunizations. Knowing that the patient also has visited providers in a neighboring state, the EMR system queries the neighboring state's Health Information Exchange (HIE) to retrieve additional care provision information in a standard format. Since the neighboring state IIS is also part of the HIE, the retrieved information also includes immunizations. The pediatrician's office EMR system combines the retrieved and local information and sends it to the provider's PHR system in a standard format.

3.6.3 Use Case 4: Vaccine Forecast

The pediatrician's office wishes to run an automated Vaccine Forecast Decision Support Service to calculate which vaccines due on the next visit, and to assist with reminder/recall. The service may be integrated within the EMR or may be accessed externally using a web service interface. The service accepts a standard XML-based payload in Immunization Content format. The pediatrician's EMR system submits the patients Care Provision data that it has previously assembled to the Vaccine Forecast Decision Support Service and receives a vaccine forecast care plan in return. It records the care plan and uses it in reminder/recall.

3.6.4 Actors/Transaction

There are two actors in the APS profile, the Content Creator and the Content Consumer. Content is created by a Content Creator and is to be consumed by a Content Consumer. The sharing or transmission of content from one actor to the other is addressed by the appropriate use of IHE profiles described below, and is out of scope of this profile. A Document Source or a Portable Media Creator may embody the Content Creator Actor. A Document Consumer, a Document Recipient or a Portable Media Importer may embody the Content Consumer Actor. The sharing or transmission of content or updates from one actor to the other is addressed by the use of appropriate IHE profiles described in the section on Content Bindings with XDS, XDM and XDR.

APS Actor Diagram

3.6.5 Options

Table 3.6-1 APS Options

Actor	Option
Content Consumer	View Option (1)
	Document Import Option (1)
	Section Import Option (1)
	Discrete Data Import Option (1)

Note 1: The Actor shall support at least one of these options.

3.6.6 Content Consumer Options

3.6.6.1 View Option

This option defines the processing requirements placed on Content Consumers for providing access, rendering and management of the medical document. See the View Option in PCC TF-2 for more details on this option.

A Content Creator Actor should provide access to a style sheet that ensures consistent rendering of the medical document content as was displayed by the Content Consumer Actor.

The Content Consumer Actor shall be able to present a view of the document using this style sheet if present.

3.6.6.2 Document Import Option

This option defines the processing requirements placed on Content Consumers for providing access, and importing the entire medical document and managing it as part of the patient record. See the Document Import Option in PCC TF-2 for more details on this option.

3.6.6.3 Section Import Option

This option defines the processing requirements placed on Content Consumers for providing access to, and importing the selected section of the medical document and managing them as part of the patient record. See the Section Import Option in PCC TF-2 for more details on this option.

3.6.6.4 Discrete Data Import Option

This option defines the processing requirements placed on Content Consumers for providing access, and importing discrete data from selected sections of the medical document and managing them as part of the patient record. See the Discrete Data Import Option in PCC TF-2 for more details on this option.

3.6.7 Coded Terminologies

This profile supports the capability to record entries beyond the IHE required coding associated with structured data. Actors from this profile may choose to utilize coded data, but interoperability at this level requires an agreement between the communicating parties that is beyond the scope of this Profile.

To facilitate this level of interoperability, the applications that implement actors within this profile shall provide a link to their HL7 conformance profile within their IHE Integration statement. The conformance profile describes the structure of the information which they are capable of creating or consuming. The conformance profile shall state which templates are supported by the application implementing the profile Actors, and which vocabularies and/or data types are used within those templates. It should also indicate the optional components of the entry that are supported.

An Example HL7 Conformance Profile is available to show how to construct such a statement. See the HL7 Refinement Constraint and Localization for more details on HL7 conformance profiles.

3.6.8 Antepartum Summary Content Module

An Antepartum Summary is a type of medical summary, and also incorporates the constraints defined for medical summaries found in a Medical Summary as described in PCC TF-2. In addition, the Antepartum Summary content profile includes additional information to support recording information specific to the ongoing care of a pregnant patient.

3.6.9 Grouping

3.6.9.1 Cross Enterprise Document Sharing, Media Interchange and Reliable Messages

Actors from the ITI XDS, XDM and XDR profiles embody the Content Creator and Content Consumer sharing function of this profile. A Content Creator or Content Consumer may be grouped with appropriate actors from the XDS, XDM or XDR profiles to exchange the content described therein. The metadata sent in the document sharing or interchange messages has specific relationships or dependencies (which we call bindings) to the content of the clinical document described in the content profile.

The Patient Care Coordination Technical Framework defines the bindings to use when grouping the Content Creator of this Profile with actors from the IHE ITI XDS, XDM or XDR Integration Profiles.

Content	Binding	Actor	Optionality
Immunization Content	Medical Document Binding to XDS, XDM and XDR	Content Creator	R
		Content Consumer	R

3.6.9.2 Notification of Document Availability (NAV)

A Document Source should provide the capability to issue a Send Notification Transaction per the ITI Notification of Document Availability (NAV) Integration Profile in order to notify one or more Document Consumer(s) of the availability of one or more documents for retrieval. One of the Acknowledgement Request options may be used to request from a Document Consumer that an acknowledgement should be returned when it has received and processed the notification. A Document Consumer should provide the capability to receive a Receive Notification Transaction per the NAV Integration Profile in order to be notified by Document Sources of the availability of one or more documents for retrieval. The Send Acknowledgement option may be used to issue a Send Acknowledgement to a Document Source that the notification was received and processed.

3.6.9.3 Document Digital Signature (DSG)

When a Content Creator Actor needs to digitally sign a document in a submission set, it may support the Digital Signature (DSG) Content Profile as a Document Source. When a Content Consumer Actor needs to verify a Digital Signature, it may retrieve the digital signature document and may perform the verification against the signed document content.

Actor Definitions

Actors are information systems or components of information systems that produce, manage, or act on information associated with operational activities in the enterprise.

Content Creator

The Content Creator Actor is responsible for the creation of content and transmission to a Content Consumer.

Content Consumer

A Content Consumer Actor is responsible for viewing, import, or other processing of content created by a Content Creator Actor.

Transaction Definitions

How to Prepare an IHE Integration Statement

IHE Integration Statements are documents prepared and published by vendors to describe the conformance of their products with the IHE Technical Framework. They identify the specific IHE capabilities a given product supports in terms of IHE actors and integration profiles described in the technical frameworks of each domain.

Users familiar with these concepts can use Integration Statements to determine what level of integration a vendor asserts a product supports with complementary systems and what clinical and operational benefits such integration might provide. Integration Statements are intended to be used in conjunction with statements of conformance to specific standards (e.g. HL7, IETF, DICOM, W3C, etc.).

IHE provides a process for vendors to test their implementations of IHE actors and integration profiles. The IHE testing process, culminating in a multi-party interactive testing event called the Connect-a-thon, provides vendors with valuable feedback and provides a baseline indication of the conformance of their implementations. The process is not intended to independently evaluate, or ensure, product compliance. In publishing the results of the Connect-a-thon and facilitating access to vendors' IHE Integration Statements, IHE and its sponsoring organizations are in no way attesting to the accuracy or validity of any vendor's IHE Integration Statements or any other claims by vendors regarding their products.

IMPORTANT -- PLEASE NOTE: Vendors have sole responsibility for the accuracy and validity of their IHE Integration Statements. Vendors' Integration Statements are made available through IHE simply for consideration by parties seeking information about the integration capabilities of particular products. IHE and its sponsoring organizations have not evaluated or approved any IHE Integration Statement or any related product, and IHE and its sponsoring organizations shall have no liability or responsibility to any party for any claims or damages, whether direct, indirect, incidental or consequential, including but not limited to business interruption and loss of revenue, arising from any use of, or reliance upon, any IHE Integration Statement.

A.1 Structure and Content of an IHE Integration Statement

An IHE Integration Statement for a product shall include:

1. The Vendor Name
2. The Product Name (as used in the commercial context) to which the IHE Integration Statement applies.
3. The Product Version to which the IHE Integration Statement applies.
4. A publication date and optionally a revision designation for the IHE Integration Statement.
5. The following statement: "This product implements all transactions required in the IHE Technical Framework to support the IHE Integration Profiles, Actors and Options listed below:"

6. A list of IHE Integration Profiles supported by the product and, for each Integration Profile, a list of IHE Actors supported. For each integration profile/actor combination, one or more of the options defined in the IHE Technical Framework may also be stated. Profiles, Actors and Options shall use the names defined by the IHE Technical Framework Volume I. (Note: The vendor may also elect to indicate the version number of the Technical Framework referenced for each Integration Profile.)

Note that implementation of the integration profile implies implementation of all required transactions for an actor as well as selected options.

The statement shall also include references and/or internet links to the following information:

1. Specific internet address (or universal resource locator [URL]) where the vendor's Integration Statements are posted
2. URL where the vendor's standards conformance statements (e.g., HL7, DICOM, etc.) relevant to the IHE transactions implemented by the product are posted.
3. URL of the IHE Initiative's web page for general IHE information www.himss.org/ihe

An IHE Integration Statement is not intended to promote or advertise aspects of a product not directly related to its implementation of IHE capabilities.

A.2 Format of an IHE Integration Statement

Each Integration Statement shall follow the format shown below. Vendors may add a cover page and any necessary additional information in accordance with their product documentation policies.

IHE Integration Statement	**Date**	**12 Oct 2005**
Vendor	**Product Name**	**Version**
Any Medical Systems Co.	IntegrateRecord	V2.3
This product implements all transactions required in the IHE Technical Framework to support the IHE Integration Profiles, Actors and Options listed below:		
Integration Profiles Implemented	**Actors Implemented**	**Options Implemented**
Cross-Enterprise Sharing of Medical Summaries	Document Consumer	View Option
Audit Trail and Node Authentication	Secure Node	none
Patient Identity Cross-referencing	Patient Identifier Cross-reference Consumer	PIX Update Notification
Internet address for vendor's IHE information: www.anymedicalsystemsco.com/ihe		
Links to Standards Conformance Statements for the Implementation		
HL7	www.anymedicalsystemsco.com/hl7	
Links to general information on IHE		
In North America: www.ihe.het	In Europe: www.ihe-europe.org	In Japan: www.jira-net.or.jp/ihe-j

855 The assumption of an integration statement is that all actors listed are functionally grouped and conform to any profile specifications for such groupings. In case of exceptions the vendor must explicitly describe the functional groupings.

Volume II

1 Preface to Volume 2

1.1 Intended Audience

The intended audience of this document is:

- Technical staff of vendors planning to participate in the IHE initiative
- IT departments of healthcare institutions
- Experts involved in standards development
- Anyone interested in the technical aspects of integrating healthcare information systems

1.2 Related Information for the Reader

The reader of volume 2 should read or be familiar with the following documents:

- Volume 1 of the Cross-Enterprise Document Sharing (XDS) Integration Profile documented in the ITI Infrastructure Technical Framework (See http://www.ihe.net/Technical_Framework/index.cfm).
- Volume 1 of the Notification of Document Availability (NAV) Integration Profile documented in the ITI Infrastructure Technical Framework (See http://www.ihe.net/Technical_Framework/index.cfm).
- Volume 1 of the Audit Trail and Node Authentication (ATNA) Integration Profile documented in the ITI Infrastructure Technical Framework (See http://www.ihe.net/Technical_Framework/index.cfm).
- HL7 Clinical Document Architecture Release 2: Section 1, CDA Overview.
- Care Record Summary – Implementation Guide for CDA Release 2 (US Realm): Section 1
- Presentations from IHE Workshop: Effective Integration of the Enterprise and the Health System - June 28–29, 2005: http://www.ihe.net/Participation/workshop_2005.cfm, June 2005:
- For a RHIO-3.ppt Leveraging IHE to Build RHIO Interoperability
- Cross-Enterprise Document Sharing (XDS)
- Notification of Document Availability (NAV)
- Educ.ppt Patient Care Coordination
- Use Cases for Medical Summaries
- Ovrw.ppt Patient Care Coordination - Overview of Profiles

1.2.1 How this Document is Organized

Section 1 is the preface, describing the intended audience, related resources, and organizations and conventions used within this document.

Section 2 provides an overview of the concepts of IHE actors and transactions used in IHE to define the functional components of a distributed healthcare environment.

Section 3 defines transactions in detail, specifying the roles for each actor, the standards employed, the information exchanged, and in some cases, implementation options for the transaction.

Section 4 defines a set of payload bindings with transactions.

Section 5 defines the content modules that may be used in transactions.

1.2.2 Conventions Used in this Volume

This document has adopted the following conventions for representing the framework concepts and specifying how the standards upon which the IHE Technical Framework is based should be applied.

1.2.2.1 The Generic IHE Transaction Model

Transaction descriptions are provided in section 4. In each transaction description, the actors, the roles they play, and the transactions between them are presented as use cases.

The generic IHE transaction description includes the following components:

- Scope: a brief description of the transaction.
- Use case roles: textual definitions of the actors and their roles, with a simple diagram relating them, e.g.:

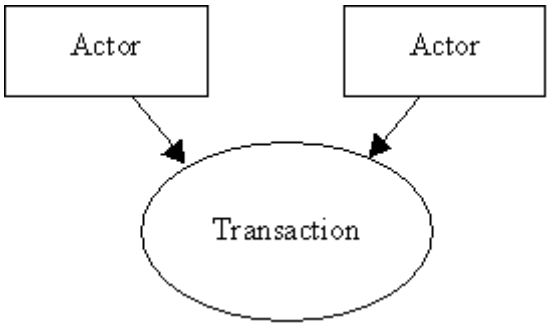

Figure 1.2-1 Use Case Role Diagram

- *Referenced Standards*: the standards (stating the specific parts, chapters or sections thereof) to be used for the transaction.
- *Interaction Diagram*: a graphical depiction of the actors and transactions, with related processing within an actor shown as a rectangle and time progressing downward, similar to:

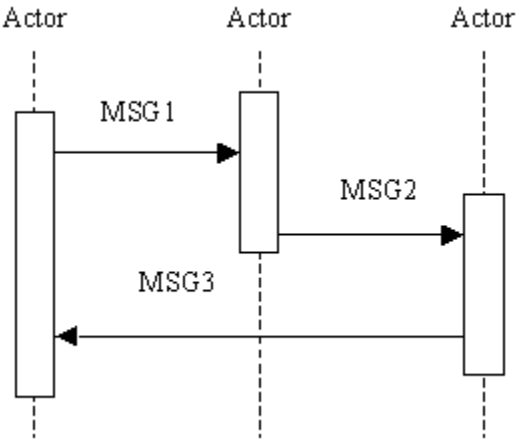

Figure 1.2-2 Interaction Diagram

The interaction diagrams used in the IHE Technical Framework are modeled after those described in Grady Booch, James Rumbaugh, and Ivar Jacobson, *The Unified Modeling Language User Guide*, ISBN 0-201-57168-4. Simple acknowledgment messages are omitted from the diagrams for brevity.

- *Message definitions*: descriptions of each message involved in the transaction, the events that trigger the message, its semantics, and the actions that the message triggers in the receiver.

1.3 Copyright Permissions

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1.4 How to Contact Us

IHE Sponsors welcome comments on this document and the IHE initiative. They should be directed to the discussion server at http://forums.rsna.org or to:

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2 Introduction

This document, the IHE Patient Care Coordination Technical Framework (PCC TF), defines specific implementations of established standards. These are intended to achieve integration goals that promote appropriate exchange of medical information to coordinate the optimal patient care among care providers in different care settings. It is expanded annually, after a period of public review, and maintained regularly through the identification and correction of errata. The latest version of the document is always available via the Internet at http://www.ihe.net/Technical_Framework/index.cfm , where the technical framework volumes specific to the various healthcare domains addressed by IHE may be found.

The IHE Patient Care Coordination Technical Framework identifies a subset of the functional components of the healthcare enterprises and health information networks, called IHE actors, and specifies their interactions in terms of a set of coordinated, standards-based transactions.

The other domains within the IHE initiative also produce Technical Frameworks within their respective areas that together form the IHE Technical Framework. Currently, the following IHE Technical Framework(s) are available:

- IHE IT Infrastructure Technical Framework
- IHE Cardiology Technical Framework
- IHE Laboratory Technical framework
- IHE Radiology Technical Framework
- IHE Patient Care Coordination Technical Framework

Where applicable, references are made to other technical frameworks. For the conventions on referencing other frameworks, see the preface of this volume.

2.1 Relationship to Standards

The IHE Technical Framework identifies functional components of a distributed healthcare environment (referred to as IHE actors), solely from the point of view of their interactions in the healthcare enterprise. At its current level of development, it defines a coordinated set of transactions based on standards (such as HL7, IETF, ASTM, DICOM, ISO, OASIS, etc.) in order to accomplish a particular use case. As the scope of the IHE initiative expands, transactions based on other standards may be included as required.

Each transaction may have as its payload one or more forms of content, as well as specific metadata describing that content within the transaction. The specification of the payload and metadata about it are the components of a Content Integration Profile. The payload is specified in a Content Module, and the impacts of any particular payload on a transaction are described within a content binding. The payloads of each transaction are also based on standards (such as HL7, IETF, ASTM, DICOM, ISO, OASIS, etc.), again, in order to meet the needs of a specific use case.

In some cases, IHE recommends selection of specific options supported by these standards. However, IHE does not introduce technical choices that contradict

conformance to these standards. If errors in or extensions to existing standards are identified, IHE's policy is to report them to the appropriate standards bodies for resolution within their conformance and standards evolution strategy.

IHE is therefore an implementation framework, not a standard. Conformance claims for products must still be made in direct reference to specific standards. In addition, vendors who have implemented IHE integration capabilities in their products may publish IHE Integration Statements to communicate their products' capabilities. Vendors publishing IHE Integration Statements accept full responsibility for their content. By comparing the IHE Integration Statements from different products, a user familiar with the IHE concepts of actors and integration profiles can determine the level of integration between them. See PCC TF-1: Appendix C for the format of IHE Integration Statements.

2.2 Relationship to Product Implementations

The IHE actors and transactions described in the IHE Technical Framework are abstractions of the real-world healthcare information system environment. While some of the transactions are traditionally performed by specific product categories (e.g. HIS, Clinical Data Repository, Electronic Health record systems, Radiology Information Systems, Clinical Information Systems or Cardiology Information Systems), the IHE Technical Framework intentionally avoids associating functions or actors with such product categories. For each actor, the IHE Technical Framework defines only those functions associated with integrating information systems. The IHE definition of an actor should therefore not be taken as the complete definition of any product that might implement it, nor should the framework itself be taken to comprehensively describe the architecture of a healthcare information system.

The reason for defining actors and transactions is to provide a basis for defining the interactions among functional components of the healthcare information system environment. In situations where a single physical product implements multiple functions, only the interfaces between the product and external functions in the environment are considered to be significant by the IHE initiative. Therefore, the IHE initiative takes no position as to the relative merits of an integrated environment based on a single, all-encompassing information system versus one based on multiple systems that together achieve the same end.

2.3 Relation of this Volume to the Technical Framework

The IHE Technical Framework is based on actors that interact through transactions using some form of content.

Actors are information systems or components of information systems that produce, manage, or act on information associated with operational activities in the enterprise.

Transactions are interactions between actors that transfer the required information through standards-based messages.

The implementation of the transactions described in this PCC TF-2 support the specification of Integration Profiles defined in PCC TF-1. The role and implementation of these transactions require the understanding of the Integration profile they support.

There is often a very clear distinction between the transactions in a messaging framework used to package and transmit information, and the information content actually transmitted in those messages. This is especially true when the messaging framework begins to move towards mainstream computing infrastructures being adopted by the healthcare industry.

In these cases, the same transactions may be used to support a wide variety of use cases in healthcare, and so more and more the content and use of the message also needs to be profiled, sometimes separately from the transaction itself. Towards this end IHE has developed the concept of a Content Integration Profile.

Content Integration Profiles specify how the payload of a transaction fits into a specific use of that transaction. A content integration profile has three main parts. The first part describes the use case. The second part is binding to a specific IHE transaction, which describes how the content affects the transaction. The third part is a Content Module, which describes the payload of the transaction. A content module is specified so as to be independent of the transaction in which it appears.

2.3.1 Content Modules

The Patient Care Coordination Technical Framework organizes content modules categorically by the base standard. At present, the PCC Technical Framework uses only one base standard, CDA Release 2.0, but this is expected to change over time. Underneath each standard, the content modules are organized using a very coarse hierarchy inherent to the standard. So for CDA Release 2.0 the modules are organized by document, section, entry, and header elements.

Each content module can be viewed as the definition of a "class" in software design terms, and has associated with it a name. Like "class" definitions in software design, a content module is a "contract", and the PCC Technical Framework defines that contract in terms of constraints that must be obeyed by instances of that content module. Each content module has a name, also known as its template identifier. The template identifiers are used to identify the contract agreed to by the content module. The PCC Technical Committee is responsible for assigning the template identifiers to each content module.

Like classes, content modules may inherit features of other content modules of the same type (Document, Section or Entry) by defining the parent content module that they inherit from. They may not inherit features from a different type. Although information in the CDA Header is in a different location that information in a CDA Entry, these two content modules are considered to be of the same type, and so may inherit from each other when necessary.

The PCC Technical Framework uses the convention that a content module cannot have more than one parent (although it may have several ancestors). This is similar to the constraint in the Java™ programming language, where classes can derive from only one parent. This convention is not due to any specific technical limitation of the technical framework, but does make it easier for software developers to implement content modules.

Each content module has a list of data elements that are required (R), required if known (R2), and optional (O). The presentation of this information varies with the type of content module, and is described in more detail below. Additional data elements may be provided by the sender that are not defined by a specific content module, but the receiver is not required to interpret them.

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 is not available.

Data elements that are marked required if known (R2) must be sent when the sending application has that data available. The sending application must be able to demonstrate that it can send all required if known elements, unless it does not in fact gather that data. When the information is not available, the sending application may indicate the reason that the data is not available.

Data elements that are marked optional (O) may be sent at the choice of the sending application. Since a content module may include data elements not specified by the profile, some might ask why these are specified in a content module. The reason for specifying the optional data elements is to ensure that both sender and receiver use the appropriate semantic interpretation of these elements. Thus, an optional element need not be sent, but when it is sent, the content module defines the meaning of that data element, and a receiver can always be assured of what that data element represents when it is present. Senders should not send an optional data element with an unknown value. If the value is not known, simply do not send the data element.

Other data elements may be included in an instance of a content module over what is defined by the PCC Technical Framework. Receivers are not required to process these elements, and if they do not understand them, must ignore them. Thus, it is not an error to include more than is asked for, but it is an error to reject a content module because it contains more than is defined by the framework. This allows value to be added to the content modules delivered in this framework, through extensions to it that are not defined or profiled by IHE. It further allows content modules to be defined later by IHE that are refinements or improvements over previous content modules.

For example, there is a Referral Summary content module defined in this framework. In later years an ED Referral content module can be created that inherits the constraints of the Referral Summary content module, with a few more use case specific constraints added. Systems that do not understand the ED Referral content module but do understand the Referral Summary content module will be able to interoperate with systems that send instances of documents that conform to the ED Referral content module. This interoperability, albeit at a reduced level of functionality, is by virtue of the fact that ED Referrals are simply a refinement of the Referral Summary.

In order to retain this capability, there are a few rules about how the PCC Technical Committee creates constraints. Constraints that apply to any content module will always apply to any content modules that inherit from it. Thus, the "contracts" are always valid down the inheritance hierarchy. Secondly, data elements of a content module will rarely be deprecated. This will usually occur only in the cases where they have been deprecated

by the base standard. While any specific content module has a limited scope and set of use cases, deprecating the data element prevents any future content module from taking advantage of what has already been defined when a particular data element has been deprecated simply because it was not necessary in the original use case.

2.3.1.1 Document Content Module Constraints

Each document content module will define the appropriate codes used to classify the document, and will also describe the specific data elements that are included. The code used to classify it is specified using an external vocabulary, typically LOINC in the case of CDA Release 2.0 documents. The set of data elements that make up the document are defined, including the whether these data elements must, should or may be included in the document. Each data element is typically a section within the document, but may also describe information that is contained elsewhere within of the document (e.g., in the header). Each data element is mapped into a content module via a template identifier, and the document content module will further indicate whether these are data elements are required, required if known or optional.

Thus, a document content module shall contain as constraints:

- The template identifier of the parent content module when there is one.
- The LOINC code or codes that shall be used to classify the document.
- A possibly empty set of required, required if known, and optional section content modules, and their template identifiers.
- A possibly empty set of required, required if known, and optional header content modules, and their template identifiers.
- Other constraints as necessary.

The template identifier for the document will be provided in the narrative, as will the legal LOINC document type codes and if present, any parent template identifier.

The remaining constraints are presented in two tables. The first table identifies the relevant data elements as determined during the technical analysis, and maps these data elements to one or more standards. The second table actually provides the constraints, wherein each data element identified in the first table is repeated, along with whether it is required, required if known, or optional. Following this column is a reference to the specification for the content module that encodes that data element, and the template identifier assigned to it. The simple example below completes the content specification described above. A simplified example is shown below.

Sample Document Specification SampleDocumentOID

Sample Document has one required section, and one entry that is required if known

2.3.1.1.1 Specification

Data Element Name	Opt	Template ID

Sample Section Comment on section	R	SampleSectionOID
Sample Entry Comment on entry	R2	SampleEntryOID

Table 2.3-1

2.3.1.1.2 Conformance

CDA Release 2.0 documents that conform to the requirements of this content module shall indicate their conformance by the inclusion of the appropriate <templateId> elements in the header of the document. This is shown in the sample document below.


```
<ClinicalDocument xmlns='urn:hl7-org:v3'>
  <typeId extension="POCD_HD000040" root="2.16.840.1.113883.1.3"/>
  <templateId root='SampleDocumentOID'/>
  <id root=' ' extension=' '/>
  <code code=' ' displayName=' '
    codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
  <title>Sample Document</title>
  <effectiveTime value='20080601012005'/>
  <confidentialityCode code='N' displayName='Normal'
    codeSystem='2.16.840.1.113883.5.25'
codeSystemName='Confidentiality' />
  <languageCode code='en-US'/>
     :
  <component><structuredBody>
    <component>
      <section>
        <templateId root='SampleSectionOID'/>
        <!-- Required Sample Section Section content -->
      </section>
    </component>

  </strucuredBody></component>
</ClinicalDocument>
```

2.3.1.1.3 Schematron

```
<pattern name='Template_SampleDocumentOID'>
 <rule context='*[cda:templateId/@root="SampleDocumentOID"]'>
   <!-- Verify that the template id is used on the appropriate
type of object -->
   <assert test='../cda:ClinicalDocument'>
     Error: The Sample Document can only be used on Clinical
Documents.
   </assert>
   <!-- Verify the document type code -->
   <assert test='cda:code[@code = "{{{LOINC}}}"]'>
     Error: The document type code of a Sample Document must be
{{{LOINC}}}
   </assert>
   <assert test='cda:code[@codeSystem = "2.16.840.1.113883.6.1"]'>
     Error: The document type code must come from the LOINC code
     system (2.16.840.1.113883.6.1).
   </assert>
   <assert test='.//cda:templateId[@root = "SampleSectionOID"]'>
     <!-- Verify that all required data elements are present -->
     Error: A(n) Sample Document must contain Sample Section.
     See http://wiki.ihe.net/index.php?title=SampleDocumentOID
   </assert>
   <assert test='.//cda:templateId[@root = "SampleEntryOID"]'>
     <!-- Alert on any missing required if known elements -->
     Warning: A(n) Sample Document should contain Sample Entry.
     See http://wiki.ihe.net/index.php?title=SampleDocumentOID
   </assert>
 </rule>
</pattern>
```

2.3.1.2 Section Content Module Constraints

Section content modules will define the content of a section of a clinical document. Sections will usually contain narrative text, and so this definition will often describe the information present in the narrative, although sections may be wholly comprised of subsections.

Sections may contain various subsections, and these may be required, required if known or optional. Sections may also contain various entries, and again, these may be required, required if known, or optional. A section may not contain just entries; it must have at least some narrative text or subsections to be considered to be valid content.

Again, sections can inherit features from other section content modules. Once again, sections are classified using an external vocabulary (again typically this would be LOINC), and so the list of possible section codes is also specified. Sections that inherit from other sections will not specify a LOINC code unless it is to restrict the type of section to smaller set of LOINC codes specified by one of its ancestors.

Thus, a section content module will contain as constraints:

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

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

Sample Section		
Template ID	SampleSectionOID	
Parent Template	foo (SampleParentOID)	
General Description	Desription of this section	
LOINC Codes	**Opt**	**Description**
XXXXX-X	R	SECTION NAME
Entries	**Opt**	**Description**
OID	R	Sample Entry
Subsections	**Opt**	**Description**
OID	R	Sample Subsection

2.3.1.2.1 Parent Template

The parent of this template is foo.


```
<component>
  <section>
    <templateId root='SampleParentOID'/>
    <templateId root='SampleSectionOID'/>
    <id root=' ' extension=' '/>
    <code code=' ' displayName=' '
      codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
    <text>
      Text as described above
    </text>
    <entry>
      Required and optional entries as described above
    </entry>

    <component>
      Required and optional subsections as described above
    </component>

  </section>
```

2.3.1.3 Entry and Header Content Modules Constraints

Entry and Header content modules are the lowest level of content for which content modules are defined. These content modules are associated with classes from the HL7 Reference Information Model (RIM). These "RIM" content modules will constrain a single RIM class. Entry content modules typically constrain an "Act" class or one of its subtypes, while header content modules will normally constrain "Participation", "Role" or "Entity" classes, but may also constrain an "Act" class.

Entry and Header content modules will describe the required, required if known, and optional XML elements and attributes that are present in the CDA Release 2.0 instance. Header and Entry content modules may also be built up using other Header and Entry content modules. An entry or header content module may also specify constraints on the vocabularies used for codes found in the entry, or data types for the values found in the entry. Thus, an entry or header content module will contain as constraints:

- The template identifier of the parent content module when there is one.
- A description of the XML elements and attributes used in the entry, along with explanations of their meaning.
- An indication of those XML elements or attributes that are required, required if known, or optional.
- Vocabulary domains to use when coding the entry.
- Data types used to specify the value of the entry.
- Other constraints as necessary.

An example is shown below:

Sample Entry

Some text describing the entry.


```
<observation classCode='OBS' moodCode='EVN'>
   <templateId root='foo'/>
</observation>
```

2.3.1.4 <observation classCode='OBS' moodCode='EVN'>

Some details about the observation element

2.3.1.5 <templateId root='foo'/>

Some details about the template id element

3 Namespaces and Vocabularies

This section lists the namespaces and identifiers defined or referenced by the IHE PCC Technical Framework, and the vocabularies defined or referenced herein. The following vocabularies are referenced in this document. An extensive list of registered vocabularies can be found at http://hl7.amg-hq.net/oid/frames.cfm.

codeSystem	codeSystemName	Description
1.3.6.1.4.1.19376.1.5.3.1	IHE PCC Template Identifiers	This is the root OID for all IHE PCC Templates. A list of PCC templates can be found below in CDA Release 2.0 Content Modules.
1.3.6.1.4.1.19376.1.5.3.2	IHEActCode	See IHEActCode Vocabulary below
1.3.6.1.4.1.19376.1.5.3.3	IHE PCC RoleCode	See IHERoleCode Vocabulary below
1.3.6.1.4.1.19376.1.5.3.4		Namespace OID used for IHE Extensions to CDA Release 2.0
2.16.840.1.113883.10.20.1	CCD Root OID	Root OID used for by ASTM/HL7 Continuity of Care Document
2.16.840.1.113883.5.112	RouteOfAdministration	See the HL7 RouteOfAdministration Vocabulary
2.16.840.1.113883.5.1063	SeverityObservation	See the HL7 SeverityObservation Vocabulary
2.16.840.1.113883.6.1	LOINC	Logical Observation Identifier Names and Codes
2.16.840.1.113883.6.96	SNOMED-CT	SNOMED Controlled Terminology
2.16.840.1.113883.6.103	ICD-9CM (diagnosis codes)	International Classification of Diseases, Clinical Modifiers, Version 9
2.16.840.1.113883.6.104	ICD-9CM (procedure codes)	International Classification of Diseases, Clinical Modifiers, Version 9
2.16.840.1.113883.6.26	MEDCIN	A classification system from MEDICOMP Systems.
2.16.840.1.113883.6.88	RxNorm	RxNorm
2.16.840.1.113883.6.63	FDDC	First DataBank Drug Codes
2.16.840.1.113883.6.12	C4	Current Procedure Terminology 4 (CPT-4) codes.
2.16.840.1.113883.6.257	Minimum Data Set for Long Term Care	The root OID for Minimum Data Set Answer Lists

3.1 IHE Format Codes

The table below lists the format codes, template identifiers and media types used by the IHE Profiles specified in the PCC Technical Framework, and also lists, for reference purposes the same values for other selected IHE Profiles from other committees.

Profile	Format Code	Media Type	Template ID
2006 Profiles			
Medical Summaries (XDS-MS)	urn:ihe:pcc:xds-ms:2007	text/xml	1.3.6.1.4.1.19376.1.5.3.1.1.3 (Referral) 1.3.6.1.4.1.19376.1.5.3.1.1.4 (Discharge Summary)
2007 Profiles			
Exchange of Personal Health Records (XPHR)	urn:ihe:pcc:xphr:2007	text/xml	1.3.6.1.4.1.19376.1.5.3.1.1.5 (Extract) 1.3.6.1.4.1.19376.1.5.3.1.1.6 (Update)
Emergency Department Referral (EDR)	urn:ihe:pcc:edr:2007	text/xml	1.3.6.1.4.1.19376.1.5.3.1.1.10
2008 Profiles			
Antepartum Summary (APS)	urn:ihe:pcc:aps:2007	text/xml	1.3.6.1.4.1.19376.1.5.3.1.1.11.2
Emergency Department Encounter Summary (EDES)	urn:ihe:pcc:edes:2007	text/xml	1.3.6.1.4.1.19376.1.5.3.1.1.13.1.1 (Triage Note) 1.3.6.1.4.1.19376.1.5.3.1.1.13.1.2 (Nursing Note) 1.3.6.1.4.1.19376.1.5.3.1.1.13.1.3 (Composite Triage and Nursing Note) 1.3.6.1.4.1.19376.1.5.3.1.1.13.1.4 (Physician Note)
2009 Profiles			
Antepartum Record (APR)	urn:ihe:pcc:apr:2008	text/xml	1.3.6.1.4.1.19376.1.5.3.1.1.16.1.1 (Antepartum History and Physical) 1.3.6.1.4.1.19376.1.5.3.1.1.16.1.2 (Antepartum Laboratory) 1.3.6.1.4.1.19376.1.5.3.1.1.16.1.3 (Antepartum Education)
Immunization Registry Content (IRC)	urn:ihe:pcc:irc:2008	text/xml	
Cancer Registry Content (CRC)	urn:ihe:pcc:crc:2008	text/xml	
Care Management (CM)	urn:ihe:pcc:cm:2008	text/xml	
ITI Profiles			
Scanned Documents	urn:ihe:iti:sd:2007	text/xml	
Basic Patient Privacy Consents	urn:ihe:iti:bppc:2007	text/xml	
Basic Patient Privacy Consents with Scanned	urn:ihe:iti:bppc-sd:2007	text/xml	

Document			
LAB Profiles			
CDA Laboratory Report	urn:ihe:lab:???:2007	text/xml	

3.2 IHEActCode Vocabulary

CCD	ASTM/HL7 Continuity of Care Document
CCR	ASTM CCR Implementation Guide

The IHEActCode vocabulary is a small vocabulary of clinical acts that are not presently supported by the HL7 ActCode vocabulary. The root namespace (OID) for this vocabulary is 1.3.5.1.4.1.19376.1.5.3.2. These vocabulary terms are based on the vocabulary and concepts used in the CCR and CCD standards listed above.

Code	Description
COMMENT	This is the act of commenting on another act.
PINSTRUCT	This is the act of providing instructions to a patient regarding the use of medication.
FINSTRUCT	This is the act of providing instructions to the supplier regarding the fulfillment of the medication order.
IMMUNIZ	The act of immunization of a patient using a particular substance or class of substances identified using a specified vocabulary. Use of this vocabulary term requires the use of either the SUBSTANCE or SUBSTCLASS qualifier described below, along with an identified substance or class of substances.
DRUG	The act of treating a patient with a particular substance or class of substances identified using a specified vocabulary. Use of this vocabulary term requires the use of either the SUBSTANCE or SUBSTCLASS qualifier described below, along with an identified substance or class of substances.
INTOL	An observation that a patient is somehow intollerant of (e.g., allergic to) a particular substance or class of substances using a specified vocabulary. Use of this vocabulary term requires the use of either the SUBSTANCE or SUBSTCLASS qualifier described below, along with an identified substance or class of substances.
SUBSTANCE	A qualifier that identifies the substance used to treat a patient in an immunization or drug treatment act. The substance is expected to be identified using a vocabulary such as RxNORM, SNOMED CT or other similar vocabulary and should be specific enough to identify the ingredients of the substance used.
SUBSTCLASS	A qualifier that identifies the class of substance used to treat a patient in an immunization or drug treatment act. The class of substances is expected to be identified using a vocabulary such as NDF-RT, SNOMED CT or other similar vocabulary, and should be broad enough to classify substances by mechanism of action (e.g., Beta Blocker), intended effect (Dieuretic, antibiotic) or ...

3.3 IHERoleCode Vocabulary

The IHERoleCode vocabulary is a small vocabulary of role codes that are not presently supported by the HL7 Role Code vocabulary. The root namespace (OID) for this vocabulary is 1.3.5.1.4.1.19376.1.5.3.3.

Code	Description
EMPLOYER	The employer of a person.
SCHOOL	The school in which a person is enrolled.
AFFILIATED	An organization with which a person is affiliated (e.g., a volunteer organization).
PHARMACY	The pharmacy a person uses.

4 PCC Content Modules

This chapter contains the various content modules and value sets that are used with IHE Patient Care Coordintation profiles and transactions.

4.1 Conventions

Various tables used in this section will further constrain the content. Within this volume, the follow conventions are used.

R

A "Required" data element is one that shall always be provided. If there is information available, the data element must be present. If there is no information available, or it cannot be transmitted, the data element must contain a value indicating the reason for omission of the data. (See PCC TF-2: 5.3.4.2 for a list of appropriate statements).

R2

A "Required if data present" data element is one that shall be provided when a value exists. If the information cannot be transmitted, the data element shall contain a value indicating the reason for omission of the data. If no such information is available to the creator or if such information is not available in a well identified manner (e.g. buried in a free form narrative that contains additional information relevant to other sections) or if the creator requires that information be absent, the R2 section shall be entirely absent. (See section PCC TF-2: 5.3.4.2 for a list of appropriate statements).

O

An optional data element is one that may be provided, irrespective of whether the information is available or not. If the implementation elects to support this optional section, then its support shall meet the requirement set forth for the "Required if data present" or R2.

C

A conditional data element is one that is required, required if known or optional depending upon other conditions. These will have further notes explaining when the data element is required, et cetera.

Note:	The definitions of R, R2, and O differ slightly from other IHE profiles. This is due in part to the fact that local regulations and policies may in fact prohibit the transmission of certain information, and that a human decision to transmit the information may be required in many cases.

4.2 Folder Content Modules

This section contains modules that describe the content requirements of Folders used with XDS, XDM or XDR. When workflows are completed normally, the folders will contain documents with the optionality specified in the tables shown below. Under certain circumstances, the folders will not meet the optionality requirements described below, for example, when the patient leaves before treatment is completed.

4.3 HL7 Version 3.0 Content Modules

This section contains content modules based upon the HL7 CDA Release 2.0 Standard, and related standards and/or implementation guides.

4.3.1 CDA Document Content Modules

4.3.1.1 Immunization Content Specification 1.3.6.1.4.1.19376.1.5.3.1.1.18.1.2

The Immunization Content Module is designed to document the record of a patient's immunizations. Furthermore, it can include information relevant to a clinical decision support system that would generate an immunization forecast. Within this document content module, the material necessary to generate an immunization record is required. This record can be used to electronically exchange the immunization record of a patient. Material needed for generating a vaccination forecast is required if known, as some of this information may not be provided to the generating application.

A content creator actor that implements this content profile shall be able to demonstrate that it can create a document that is sufficient for use in immunization forecasting. However, not all uses of this document content profile will be used for that purpose. There are cases where the data produced is limited to a smaller set due to security and privacy considerations. If for example, the purpose the document is for use as immunization record necessary to for enrollment in a school, the content creator actor needs to be able to conform to local law, regulation, and policy regarding the information that is permitted to be exchanged.

4.3.1.1.1 LOINC Code

The LOINC code for this document is **11369-6** HISTORY OF IMMUNIZATIONS

4.3.1.1.2 Standards

CDAR2	HL7 CDA Release 2.0
CCD	ASTM/HL7 Continuity of Care Document

4.3.1.1.3 Data Element Index

Data Element	Description
History of Immunizations	The information contained in this data element shall be able to record a list of immunizations for a patient. This list includes, for each immunization given, the date that it was given, the name of the immunization, a coded value for the immunization, the lot number of the vaccine, the manufacturer of the vaccine, the provider giving the immunization, any reactions or adverse events caused by the immunization, and the severity of those reactions, and if refused, the reason for the refusal.
Authors and Informants	The source of the information must be able to be recorded, including information obtained from a patient, parent or guardian, another provider, immunization registry, et cetera. Within the IHE PCC technical framework, all coded entries may include the author or informant that provided the information being recorded.
History of Past Illness	The history of past illnesses is where clinical diagnoses relevant to vaccine forecasting may be provided. This can include a list of any previous illnesses which might convey immunity or otherwise influence the immunization forecast.
Problem List	The problem list must be able to include problems that are relevant to immunization forecast, including current illnesses, conditions, or risks (e.g., immunosuppression), that might be contraindications for providing an immunization.
Allergies and Intolerances	This information includes a list of allergies or intolerances to substances commonly used in vaccinations, e.g. egg albumin, et cetera, as well as allergies or intolerances to other medications or immunizations
Medications	The list of medications should include the list of relevant medications for the patient.
Lab Results	The laboratory results section can include information about antibody tests or titers that show that immunization has or has not been already conferred to a patient. This section may also include information about the results of point of care tests, such as a TB test.
Coded Vital Signs	Vital signs such as height and weight should be able to be reported to enable dosing calculations to be performed. Other vital signs such as tempurature may be included to enable a clinical decision support to identify potential situations such as fever that may be a contraindication for immunization.
Pregnancy History	The pregnancy history section would include information relevant to the current pregnancy status for the patient, as this can also influence the type of vaccinations that may be proposed.
Advance Directives	Advance directives relevant to the provision of immunizations should be able to be included in the content when those directives would influence the immunizations proposed.
Comments	Additional text comments should be supported in the content to enable providers to comment

4.3.1.1.4 Specification

Data Element Name	Opt	Template ID
History of Immunizations	R	1.3.6.1.4.1.19376.1.5.3.1.3.23
Problem List	R2	1.3.6.1.4.1.19376.1.5.3.1.3.6
History of Past Illness	R2	1.3.6.1.4.1.19376.1.5.3.1.3.8
Allergies and Intolerances	R2	1.3.6.1.4.1.19376.1.5.3.1.3.13
Medications	R2	1.3.6.1.4.1.19376.1.5.3.1.3.19

Coded Results	R2	1.3.6.1.4.1.19376.1.5.3.1.3.28
Coded Vital Signs	R2	1.3.6.1.4.1.19376.1.5.3.1.1.5.3.2
Pregnancy History When present, the pregnancy history section shall contain a Pregnancy Observation using the 11449-6 PREGNANCY STATUS code from LOINC to indicate whether the patient is pregnant.	R2	1.3.6.1.4.1.19376.1.5.3.1.1.5.3.4
Coded Advance Directives	R2	1.3.6.1.4.1.19376.1.5.3.1.3.35

4.3.1.1.5 Conformance

CDA Release 2.0 documents that conform to the requirements of this content module shall indicate their conformance by the inclusion of the appropriate <templateId> elements in the header of the document. This is shown in the sample document below.


```
<ClinicalDocument xmlns='urn:hl7-org:v3'>
  <typeId extension="POCD_HD000040" root="2.16.840.1.113883.1.3"/>
  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.18.1.2'/>
  <id root=' ' extension=' '/>
  <code code='11369-6' displayName='HISTORY OF IMMUNIZATIONS'
    codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
  <title>Immunization Detail</title>
  <effectiveTime value='20080724012005'/>
  <confidentialityCode code='N' displayName='Normal'
    codeSystem='2.16.840.1.113883.5.25' codeSystemName='Confidentiality' />
  <languageCode code='en-US'/>
     :
  <component><structuredBody>
    <component>
      <section>
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.23'/>
        <!-- Required History of Immunizations Section content -->
      </section>
    </component>
    <component>
      <section>
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.6'/>
        <!-- Required if known Problem List Section content -->
      </section>
    </component>
    <component>
      <section>
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.8'/>
        <!-- Required if known History of Past Illness Section content -->
      </section>
    </component>
    <component>
      <section>
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.13'/>
        <!-- Required if known Allergies and Intolerances Section content -->
      </section>
    </component>
    <component>
      <section>
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.19'/>
        <!-- Required if known Medications Section content -->
      </section>
    </component>
    <component>
      <section>
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13'/>
        <!-- Required if known Lab Results Section content -->
      </section>
    </component>
    <component>
      <section>
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.5.3.2'/>
        <!-- Required if known Coded Vital Signs Section content -->
      </section>
    </component>
    <component>
      <section>
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.5.3.4'/>
        <!-- Required if known Pregnancy History Section content -->
      </section>
    </component>
    <component>
      <section>
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.35'/>
        <!-- Required if known Coded Advance Directives Section content -->
      </section>
    </component>
   </strucuredBody>
  </component>
</ClinicalDocument>
```


Figure 4.3-1 Sample Immunization Content Document

4.3.1.1.6 Schematron

```
<pattern name='Template_1.3.6.1.4.1.19376.1.5.3.1.1.18.1.2'>
 <rule context='*[cda:templateId/@root="1.3.6.1.4.1.19376.1.5.3.1.1.18.1.2"]'>
   <!-- Verify that the template id is used on the appropriate type of object -->
   <assert test='../cda:ClinicalDocument'>
     Error: The Immunization Detail can only be used on Clinical Documents.
   </assert>
   <!-- Verify the document type code -->
   <assert test='cda:code[@code = "11369-6"]'>
     Error: The document type code of a Immunization Detail must be 11369-6
   </assert>
   <assert test='cda:code[@codeSystem = "2.16.840.1.113883.6.1"]'>
     Error: The document type code must come from the LOINC code
     system (2.16.840.1.113883.6.1).
   </assert>
   <assert test='.//cda:templateId[@root = "1.3.6.1.4.1.19376.1.5.3.1.3.23"]'>
     <!-- Verify that all required data elements are present -->
     Error: A(n) Immunization Detail must contain History of Immunizations.
     See http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.1.18.1.2
   </assert>
   <assert test='.//cda:templateId[@root = "1.3.6.1.4.1.19376.1.5.3.1.3.6"]'>
     <!-- Alert on any missing required if known elements -->
     Warning: A(n) Immunization Detail should contain Problem List.
     See http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.1.18.1.2
   </assert>
   <assert test='.//cda:templateId[@root = "1.3.6.1.4.1.19376.1.5.3.1.3.8"]'>
     <!-- Alert on any missing required if known elements -->
     Warning: A(n) Immunization Detail should contain History of Past Illness.
     See http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.1.18.1.2
   </assert>
   <assert test='.//cda:templateId[@root = "1.3.6.1.4.1.19376.1.5.3.1.3.13"]'>
     <!-- Alert on any missing required if known elements -->
     Warning: A(n) Immunization Detail should contain Allergies and Intolerances.
     See http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.1.18.1.2
   </assert>
   <assert test='.//cda:templateId[@root = "1.3.6.1.4.1.19376.1.5.3.1.3.19"]'>
     <!-- Alert on any missing required if known elements -->
     Warning: A(n) Immunization Detail should contain Medications.
     See http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.1.18.1.2
   </assert>
   <assert test='.//cda:templateId[@root = "1.3.6.1.4.1.19376.1.5.3.1.4.13"]'>
     <!-- Alert on any missing required if known elements -->
     Warning: A(n) Immunization Detail should contain Lab Results.
     See http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.1.18.1.2
   </assert>
   <assert test='.//cda:templateId[@root = "1.3.6.1.4.1.19376.1.5.3.1.1.5.3.2"]'>
     <!-- Alert on any missing required if known elements -->
     Warning: A(n) Immunization Detail should contain Coded Vital Signs.
     See http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.1.18.1.2
   </assert>
   <assert test='.//cda:templateId[@root = "1.3.6.1.4.1.19376.1.5.3.1.1.5.3.4"]'>
     <!-- Alert on any missing required if known elements -->
     Warning: A(n) Immunization Detail should contain Pregnancy History.
     See http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.1.18.1.2
   </assert>
   <assert test='.//cda:templateId[@root = "1.3.6.1.4.1.19376.1.5.3.1.3.35"]'>
     <!-- Alert on any missing required if known elements -->
     Warning: A(n) Immunization Detail should contain Coded Advance Directives.
     See http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.1.18.1.2
   </assert>
 </rule>
</pattern>
```


4.3.2 CDA Section Content Modules

4.3.2.1 Other Condition Histories

The sections defined below provide historical information about the patient's conditions.

4.3.2.1.1 Active Problems Section

Template ID	1.3.6.1.4.1.19376.1.5.3.1.3.6	
Parent Template	CCD 3.5 (2.16.840.1.113883.10.20.1.11)	
General Description	The active problem section shall contain a narrative description of the conditions currently being monitored for the patient. It shall include entries for patient conditions as described in the Entry Content Module.	
LOINC Code	**Opt**	**Description**
11450-4	R	PROBLEM LIST
Entries	**Opt**	**Description**
1.3.6.1.4.1.19376.1.5.3.1.4.5.2	R	Problem Concern Entry

4.3.2.1.1.1 Parent Template

The parent of this template is CCD 3.5.

```
<component>
  <section>
    <templateId root='2.16.840.1.113883.10.20.1.11'/>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.6'/>
    <id root=' ' extension=' '/>
    <code code='11450-4' displayName='PROBLEM LIST'
      codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
    <text>
      Text as described above
    </text>
    <entry>
        :
      <!-- Required Problem Concern Entry element -->
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.2'/>
        :
    </entry>

  </section>
</component>
```

Figure 4.3-2 Sample Active Problems Section

4.3.2.1.1.2 Schematron

```
<pattern name='Template_1.3.6.1.4.1.19376.1.5.3.1.3.6'>
 <rule context='*[cda:templateId/@root="1.3.6.1.4.1.19376.1.5.3.1.3.6"]'>
     <!-- Verify that the template id is used on the appropriate type of object -->
   <assert test='../cda:section'>
      Error: The Active Problems can only be used on sections.
   </assert>
   <!-- Verify that the parent templateId is also present. -->
   <assert test='templateId[@root="2.16.840.1.113883.10.20.1.11"]'>
     Error: The parent template identifier for Active Problems is not present.
   </assert>
   <!-- Verify the section type code -->
   <assert test='cda:code[@code = "11450-4"]'>
     Error: The section type code of a Active Problems must be 11450-4
   </assert>
   <assert test='cda:code[@codeSystem = "2.16.840.1.113883.6.1"]'>
     Error: The section type code must come from the LOINC code
     system (2.16.840.1.113883.6.1).
   </assert>
   <assert test='.//cda:templateId[@root = "1.3.6.1.4.1.19376.1.5.3.1.4.5.2"]'>
     <!-- Verify that all required data elements are present -->
     Error: A(n) Active Problems must contain Problem Concern Entry.
     See http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.3.6
   </assert>
 </rule>
</pattern>
```

4.3.2.1.2 History of Past Illness Section

Template ID	1.3.6.1.4.1.19376.1.5.3.1.3.8	
General Description	The History of Past Illness section shall contain a narrative description of the conditions the patient suffered in the past. It shall include entries for problems as described in the Entry Content Modules.	
LOINC Code	**Opt**	**Description**
11348-0	R	HISTORY OF PAST ILLNESS
Entries	**Opt**	**Description**
1.3.6.1.4.1.19376.1.5.3.1.4.5.2	R	Problem Concern Entry

```
<component>
  <section>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.8'/>
    <id root=' ' extension=' '/>
    <code code='11348-0' displayName='HISTORY OF PAST ILLNESS'
      codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
    <text>
      Text as described above
    </text>
    <entry>
        :
      <!-- Required Problem Concern Entry element -->
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.2'/>
         :
    </entry>

  </section>
</component>
```

Figure 4.3-3 Sample History of Past Illness Section

4.3.2.1.2.1 Schematron

```
<pattern name='Template_1.3.6.1.4.1.19376.1.5.3.1.3.8'>
 <rule context='*[cda:templateId/@root="1.3.6.1.4.1.19376.1.5.3.1.3.8"]'>
     <!-- Verify that the template id is used on the appropriate type of object -->
   <assert test='../cda:section'>
      Error: The History of Past Illness can only be used on sections.
   </assert>
   <!-- Verify the section type code -->
   <assert test='cda:code[@code = "11348-0"]'>
     Error: The section type code of a History of Past Illness must be 11348-0
   </assert>
   <assert test='cda:code[@codeSystem = "2.16.840.1.113883.6.1"]'>
     Error: The section type code must come from the LOINC code
     system (2.16.840.1.113883.6.1).
   </assert>
   <assert test='.//cda:templateId[@root = "1.3.6.1.4.1.19376.1.5.3.1.4.5.2"]'>
     <!-- Verify that all required data elements are present -->
     Error: A(n) History of Past Illness must contain Problem Concern Entry.
     See http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.3.8
   </assert>
 </rule>
</pattern>
```

4.3.2.1.3 Allergies and Other Adverse Reactions Section

Template ID	1.3.6.1.4.1.19376.1.5.3.1.3.13	
Parent Template	CCD 3.8 (2.16.840.1.113883.10.20.1.2)	
General Description	The adverse and other adverse reactions section shall contain a narrative description of the substance intolerances and the associated adverse reactions suffered by the patient. It shall include entries for intolerances and adverse reactions as described in the Entry Content Modules.	
LOINC Code	**Opt**	**Description**
48765-2	R	Allergies, adverse reactions, alerts
Entries	**Opt**	**Description**
1.3.6.1.4.1.19376.1.5.3.1.4.5.3	R	Allergies and Intolerance Concern

4.3.2.1.3.1 Parent Template

The parent of this template is CCD 3.8. This template is compatible with the ASTM/HL7 Continuity of Care Document template: 2.16.840.1.113883.10.20.1.2


```
<component>
  <section>
    <templateId root='2.16.840.1.113883.10.20.1.2'/>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.13'/>
    <id root=' ' extension=' '/>
    <code code='48765-2' displayName='Allergies, adverse reactions, alerts'
      codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
    <text>
      Text as described above
    </text>
    <entry>
        :
      <!-- Required Allergies and Intolerances Concern element -->
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.3'/>
        :
    </entry>

  </section>
</component>
```

Figure 4.3-4 Sample Allergies and Other Adverse Reactions Section

4.3.2.1.3.2 Schematron

```
<pattern name='Template_1.3.6.1.4.1.19376.1.5.3.1.3.13'>
 <rule context='*[cda:templateId/@root="1.3.6.1.4.1.19376.1.5.3.1.3.13"]'>
     <!-- Verify that the template id is used on the appropriate type of object -->
   <assert test='../cda:section'>
      Error: The Allergies and Other Adverse Reactions can only be used on sections.
   </assert>
   <!-- Verify that the parent templateId is also present. -->
   <assert test='templateId[@root="2.16.840.1.113883.10.20.1.2"]'>
     Error: The parent template identifier for Allergies and Other Adverse Reactions is
not present.
   </assert>
   <!-- Verify the section type code -->
   <assert test='cda:code[@code = "48765-2"]'>
     Error: The section type code of a Allergies and Other Adverse Reactions must be
48765-2
   </assert>
   <assert test='cda:code[@codeSystem = "2.16.840.1.113883.6.1"]'>
     Error: The section type code must come from the LOINC code
     system (2.16.840.1.113883.6.1).
   </assert>
   <assert test='.//cda:templateId[@root = "1.3.6.1.4.1.19376.1.5.3.1.4.5.3"]'>
     <!-- Verify that all required data elements are present -->
     Error: A(n) Allergies and Other Adverse Reactions must contain Allergies and
Intolerances Concern.
     See http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.3.13
   </assert>
 </rule>
</pattern>
```

4.3.2.1.4 Pregnancy History Section

Template ID	1.3.6.1.4.1.19376.1.5.3.1.1.5.3.4	
General Description	The pregnancy history section contains coded entries describing the patient history of pregnancies.	
LOINC Code	**Opt**	**Description**
10162-6	R	HISTORY OF PREGNANCIES
Entries	**Opt**	**Description**
1.3.6.1.4.1.19376.1.5.3.1.4.13.5	R	Pregnancy Observation


```
<component>
  <section>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.5.3.4'/>
    <id root=' ' extension=' '/>
    <code code='10162-6' displayName='HISTORY OF PREGNANCIES'
      codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
    <text>
      Text as described above
    </text>
    <entry>
         :
      <!-- Required Pregnancy Observation  element -->
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13.5'/>
         :
    </entry>

  </section>
</component>
```

Figure 4.3-5 Sample Pregnancy History Section

4.3.2.1.4.1 Schematron

```
<pattern name='Template_1.3.6.1.4.1.19376.1.5.3.1.1.5.3.4'>
 <rule context='*[cda:templateId/@root="1.3.6.1.4.1.19376.1.5.3.1.1.5.3.4"]'>
     <!-- Verify that the template id is used on the appropriate type of object -->
   <assert test='../cda:section'>
      Error: The Pregnancy History can only be used on sections.
   </assert>
   <!-- Verify the section type code -->
   <assert test='cda:code[@code = "10162-6"]'>
     Error: The section type code of a Pregnancy History must be 10162-6
   </assert>
   <assert test='cda:code[@codeSystem = "2.16.840.1.113883.6.1"]'>
     Error: The section type code must come from the LOINC code
     system (2.16.840.1.113883.6.1).
   </assert>
   <assert test='.//cda:templateId[@root = "1.3.6.1.4.1.19376.1.5.3.1.4.13.5"]'>
     <!-- Verify that all required data elements are present -->
     Error: A(n) Pregnancy History must contain Pregnancy Observation .
     See http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.1.5.3.4
   </assert>
 </rule>
</pattern>
```

4.3.2.2 Medications

This section contains section content modules that describe activities surrounding the use of medication.

4.3.2.2.1 Medications Section

Template ID		1.3.6.1.4.1.19376.1.5.3.1.3.19
Parent Template		CCD 3.9 (2.16.840.1.113883.10.20.1.8)
General Description		The medications section shall contain a description of the relevant medications for the patient, e.g. an ambulatory prescription list. It shall include entries for medications as described in the Entry Content Module.
LOINC Code	**Opt**	**Description**
10160-0	R	HISTORY OF MEDICATION USE
Entries	**Opt**	**Description**
1.3.6.1.4.1.19376.1.5.3.1.4.7	R	Medications

4.3.2.2.1.1 Parent Template

The parent of this template is CCD 3.9.

```
<component>
  <section>
    <templateId root='2.16.840.1.113883.10.20.1.8'/>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.19'/>
    <id root=' ' extension=' '/>
    <code code='10160-0' displayName='HISTORY OF MEDICATION USE'
      codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
    <text>
      Text as described above
    </text>
    <entry>
        :
      <!-- Required Medications element -->
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7'/>
        :
    </entry>

  </section>
</component>
```

Figure 4.3-6 Sample Medications Section

4.3.2.2.1.2 Schematron

```
<pattern name='Template_1.3.6.1.4.1.19376.1.5.3.1.3.19'>
 <rule context='*[cda:templateId/@root="1.3.6.1.4.1.19376.1.5.3.1.3.19"]'>
     <!-- Verify that the template id is used on the appropriate type of object -->
   <assert test='../cda:section'>
      Error: The Medications can only be used on sections.
   </assert>
   <!-- Verify that the parent templateId is also present. -->
   <assert test='templateId[@root="2.16.840.1.113883.10.20.1.8"]'>
     Error: The parent template identifier for Medications is not present.
   </assert>
   <!-- Verify the section type code -->
   <assert test='cda:code[@code = "10160-0"]'>
     Error: The section type code of a Medications must be 10160-0
   </assert>
   <assert test='cda:code[@codeSystem = "2.16.840.1.113883.6.1"]'>
     Error: The section type code must come from the LOINC code
     system (2.16.840.1.113883.6.1).
   </assert>
   <assert test='.//cda:templateId[@root = "1.3.6.1.4.1.19376.1.5.3.1.4.7"]'>
     <!-- Verify that all required data elements are present -->
     Error: A(n) Medications must contain Medications.
     See http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.3.19
   </assert>
 </rule>
</pattern>
```

Note: This LOINC code is typically used to record the current medication list found in an EHR.

4.3.2.2.2 Immunizations Section

Template ID	1.3.6.1.4.1.19376.1.5.3.1.3.23	
Parent Template	CCD 3.11 (2.16.840.1.113883.10.20.1.6)	
General Description	The immunizations section shall contain a narrative description of the immunizations administered to the patient in the past. It shall include entries for medication administration as described in the Entry Content Modules.	
LOINC Code	**Opt**	**Description**
11369-6	R	HISTORY OF IMMUNIZATIONS
Entries	**Opt**	**Description**
1.3.6.1.4.1.19376.1.5.3.1.4.12	R	Immunization

4.3.2.2.2.1 Parent Template

The parent of this template is CCD 3.11.


```
<component>
  <section>
    <templateId root='2.16.840.1.113883.10.20.1.6'/>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.23'/>
    <id root=' ' extension=' '/>
    <code code='11369-6' displayName='HISTORY OF IMMUNIZATIONS'
      codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
    <text>
      Text as described above
    </text>
    <entry>
        :
      <!-- Required Immunization element -->
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.12'/>
        :
    </entry>

  </section>
</component>
```

Figure 4.3-7 Sample Immunizations Section

4.3.2.2.2.2 Schematron

```
<pattern name='Template_1.3.6.1.4.1.19376.1.5.3.1.3.23'>
 <rule context='*[cda:templateId/@root="1.3.6.1.4.1.19376.1.5.3.1.3.23"]'>
     <!-- Verify that the template id is used on the appropriate type of object -->
   <assert test='../cda:section'>
      Error: The Immunizations can only be used on sections.
   </assert>
   <!-- Verify that the parent templateId is also present. -->
   <assert test='templateId[@root="2.16.840.1.113883.10.20.1.6"]'>
     Error: The parent template identifier for Immunizations is not present.
   </assert>
   <!-- Verify the section type code -->
   <assert test='cda:code[@code = "11369-6"]'>
     Error: The section type code of a Immunizations must be 11369-6
   </assert>
   <assert test='cda:code[@codeSystem = "2.16.840.1.113883.6.1"]'>
     Error: The section type code must come from the LOINC code
     system (2.16.840.1.113883.6.1).
   </assert>
   <assert test='.//cda:templateId[@root = "1.3.6.1.4.1.19376.1.5.3.1.4.12"]'>
     <!-- Verify that all required data elements are present -->
     Error: A(n) Immunizations must contain Immunization.
     See http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.3.23
   </assert>
 </rule>
</pattern>
```

4.3.2.3 Physical Exams

4.3.2.3.1 Coded Vital Signs Section

Template ID	1.3.6.1.4.1.19376.1.5.3.1.1.5.3.2	
Parent Template	Vital Signs (1.3.6.1.4.1.19376.1.5.3.1.3.25)	
General Description	The vital signs section contains coded measurement results of a patient's vital signs.	
LOINC Code	**Opt**	**Description**
8716-3	R	VITAL SIGNS
Entries	**Opt**	**Description**

1.3.6.1.4.1.19376.1.5.3.1.4.13.1	R	Vital Signs Organizer

4.3.2.3.1.1 Parent Template

The parent of this template is Vital Signs.

```
<component>
  <section>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.25'/>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.5.3.2'/>
    <id root=' ' extension=' '/>
    <code code='8716-3' displayName='VITAL SIGNS'
      codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
    <text>
      Text as described above
    </text>
    <entry>
        :
      <!-- Required Vital Signs Organizer element -->
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13.1'/>
        :
    </entry>

  </section>
</component>
```

Figure 4.3-8 Sample Coded Vital Signs Section

4.3.2.3.1.2 Schematron

```
<pattern name='Template_1.3.6.1.4.1.19376.1.5.3.1.1.5.3.2'>
 <rule context='*[cda:templateId/@root="1.3.6.1.4.1.19376.1.5.3.1.1.5.3.2"]'>
     <!-- Verify that the template id is used on the appropriate type of object -->
   <assert test='../cda:section'>
      Error: The Coded Vital Signs can only be used on sections.
   </assert>
   <!-- Verify that the parent templateId is also present. -->
   <assert test='templateId[@root="1.3.6.1.4.1.19376.1.5.3.1.3.25"]'>
     Error: The parent template identifier for Coded Vital Signs is not present.
   </assert>
   <!-- Verify the section type code -->
   <assert test='cda:code[@code = "8716-3"]'>
     Error: The section type code of a Coded Vital Signs must be 8716-3
   </assert>
   <assert test='cda:code[@codeSystem = "2.16.840.1.113883.6.1"]'>
     Error: The section type code must come from the LOINC code
     system (2.16.840.1.113883.6.1).
   </assert>
   <assert test='.//cda:templateId[@root = "1.3.6.1.4.1.19376.1.5.3.1.4.13.1"]'>
     <!-- Verify that all required data elements are present -->
     Error: A(n) Coded Vital Signs must contain Vital Signs Organizer.
     See http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.1.5.3.2
   </assert>
 </rule>
</pattern>
```


4.3.2.4 Relevant Studies

4.3.2.4.1 Coded Results Section

Template ID		1.3.6.1.4.1.19376.1.5.3.1.3.28
General Description		The results section shall contain a narrative description of the relevant diagnostic procedures the patient received in the past. It shall include entries for procedures and references to procedure reports when known as described in the Entry Content Modules.
LOINC Code	**Opt**	**Description**
30954-2	R	STUDIES SUMMARY
Entries	**Opt**	**Description**
1.3.6.1.4.1.19376.1.5.3.1.4.19	R	Procedure Entry
1.3.6.1.4.1.19376.1.5.3.1.4.4	R2	References Entry
1.3.6.1.4.1.19376.1.5.3.1.4.13	O	Simple Observations

```
<component>
  <section>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.28'/>
    <id root=' ' extension=' '/>
    <code code='30954-2' displayName='STUDIES SUMMARY'
      codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
    <text>
      Text as described above
    </text>
    <entry>
         :
      <!-- Required Procedure Entry element -->
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.16'/>
         :
    </entry>
    <entry>
         :
      <!-- Required if known References Entry element -->
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.4'/>
         :
    </entry>
    <entry>
         :
      <!-- Optional Simple Observation element -->
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13'/>
         :
    </entry>

  </section>
</component>
```

Figure 4.3-9 Sample Coded Results Section

4.3.2.4.1.1 Schematron

```
<pattern name='Template_1.3.6.1.4.1.19376.1.5.3.1.3.28'>
 <rule context='*[cda:templateId/@root="1.3.6.1.4.1.19376.1.5.3.1.3.28"]'>
     <!-- Verify that the template id is used on the appropriate type of object -->
   <assert test='../cda:section'>
      Error: The Coded Results can only be used on sections.
   </assert>
   <!-- Verify the section type code -->
   <assert test='cda:code[@code = "30954-2"]'>
     Error: The section type code of a Coded Results must be 30954-2
   </assert>
   <assert test='cda:code[@codeSystem = "2.16.840.1.113883.6.1"]'>
     Error: The section type code must come from the LOINC code
     system (2.16.840.1.113883.6.1).
   </assert>
   <assert test='.//cda:templateId[@root = "1.3.6.1.4.1.19376.1.5.3.1.4.16"]'>
     <!-- Verify that all required data elements are present -->
     Error: A(n) Coded Results must contain Procedure Entry.
     See http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.3.28
   </assert>
   <assert test='.//cda:templateId[@root = "1.3.6.1.4.1.19376.1.5.3.1.4.4"]'>
     <!-- Alert on any missing required if known elements -->
     Warning: A(n) Coded Results should contain References Entry.
     See http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.3.28
   </assert>
   <assert test='.//cda:templateId[@root = "1.3.6.1.4.1.19376.1.5.3.1.4.13"]'>
     <!-- Note any missing optional elements -->
     Note: This Coded Results does not contain Simple Observation.
     See http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.3.28
   </assert>
 </rule>
</pattern>
```

4.3.2.5 Plans of Care

This section provides content modules for sections that describe the plan of care intended for the patient.

4.3.2.5.1 Advance Directives Section

Template ID	1.3.6.1.4.1.19376.1.5.3.1.3.34	
Parent Template	CCD 3.2 (2.16.840.1.113883.10.20.1.1)	
General Description	The advance directive section shall contain a narrative description of the list of documents that define the patient's expectations and requests for care along with the locations of the documents.	
LOINC Code	**Opt**	**Description**
42348-3	R	ADVANCE DIRECTIVES

4.3.2.5.1.1 Parent Template

The parent of this template is CCD 3.2. This template is compatible with the ASTM/HL7 Continuity of Care Document template: 2.16.840.1.113883.10.20.1.1


```
<component>
  <section>
    <templateId root='2.16.840.1.113883.10.20.1.1'/>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.34'/>
    <id root=' ' extension=' '/>
    <code code='42348-3' displayName='ADVANCE DIRECTIVES'
      codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
    <text>
      Text as described above
    </text>

  </section>
</component>
```

Figure 4.3-10 Sample Advance Directives Section

4.3.2.5.1.2 Schematron

```
<pattern name='Template_1.3.6.1.4.1.19376.1.5.3.1.3.34'>
 <rule context='*[cda:templateId/@root="1.3.6.1.4.1.19376.1.5.3.1.3.34"]'>
     <!-- Verify that the template id is used on the appropriate type of object -->
   <assert test='../cda:section'>
      Error: The Advance Directives can only be used on sections.
   </assert>
   <!-- Verify that the parent templateId is also present. -->
   <assert test='templateId[@root="2.16.840.1.113883.10.20.1.1"]'>
     Error: The parent template identifier for Advance Directives is not present.
   </assert>
   <!-- Verify the section type code -->
   <assert test='cda:code[@code = "42348-3"]'>
     Error: The section type code of a Advance Directives must be 42348-3
   </assert>
   <assert test='cda:code[@codeSystem = "2.16.840.1.113883.6.1"]'>
     Error: The section type code must come from the LOINC code
     system (2.16.840.1.113883.6.1).
   </assert>
 </rule>
</pattern>
```

4.3.2.5.2 Coded Advance Directives Section

Template ID	1.3.6.1.4.1.19376.1.5.3.1.3.35	
Parent Template	Advance Directives (1.3.6.1.4.1.19376.1.5.3.1.3.34)	
General Description	The advance directive section shall include entries for references to consent and advance directive documents when known as described in the Entry Content Modules.	
LOINC Code	**Opt**	**Description**
42348-3	R	ADVANCE DIRECTIVES
Entries	**Opt**	**Description**
1.3.6.1.4.1.19376.1.5.3.1.4.13.7	R2	Advance Directive Observation

4.3.2.5.2.1 Parent Template

The parent of this template is Advance Directives.


```
<component>
  <section>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.34'/>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.35'/>
    <id root=' ' extension=' '/>
    <code code='42348-3' displayName='ADVANCE DIRECTIVES'
      codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
    <text>
      Text as described above
    </text>
    <entry>
         :
      <!-- Required if known Advance Directive Observation element -->
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13.7'/>
         :
    </entry>

  </section>
</component>
```

Figure 4.3-11 Sample Coded Advance Directives Section

4.3.2.5.2.2 Schematron

```
<pattern name='Template_1.3.6.1.4.1.19376.1.5.3.1.3.35'>
 <rule context='*[cda:templateId/@root="1.3.6.1.4.1.19376.1.5.3.1.3.35"]'>
     <!-- Verify that the template id is used on the appropriate type of object -->
   <assert test='../cda:section'>
      Error: The Coded Advance Directives can only be used on sections.
   </assert>
   <!-- Verify that the parent templateId is also present. -->
   <assert test='templateId[@root="1.3.6.1.4.1.19376.1.5.3.1.3.34"]'>
     Error: The parent template identifier for Coded Advance Directives is not present.
   </assert>
   <!-- Verify the section type code -->
   <assert test='cda:code[@code = "42348-3"]'>
     Error: The section type code of a Coded Advance Directives must be 42348-3
   </assert>
   <assert test='cda:code[@codeSystem = "2.16.840.1.113883.6.1"]'>
     Error: The section type code must come from the LOINC code
     system (2.16.840.1.113883.6.1).
   </assert>
   <assert test='.//cda:templateId[@root = "1.3.6.1.4.1.19376.1.5.3.1.4.13.7"]'>
     <!-- Alert on any missing required if known elements -->
     Warning: A(n) Coded Advance Directives should contain Advance Directive Observation.
     See http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.3.35
   </assert>
 </rule>
</pattern>
```

4.3.3 CDA and HL7 Version 3 Entry Content Modules

4.3.3.1 Authors and Informants

Each clinical statement that can be made in a CDA Document or HL7 Version 3 message shall be attributable to one or more authors. These are found in <author> elements, either directly within the clinical statement, or in one of its ancestors in the XML document or message.

Each clinical statement may also contain information from zero or more informants. These are found in <informant> elements, again, either directly within the clinical statement, or in one of its ancestors in the XML document or message.

4.3.3.1.1 <author>

Authors shall be described in an <author> element that is either directly on the clinical statement, or which can be reached by one of its ancestors.

4.3.3.1.2 <time value=' '/>

The time of authorship shall be recorded in the <time> element.

4.3.3.1.3 <assignedAuthor> -OR- <assignedEntity1> <id root=' ' extension=' '> <addr></addr> <telecom value=' ' use=' '>

In a CDA document details about the author are provided in the <assignedAuthor> element. In Version 3 messages, they are provided in the <assignedEntity1> element. The semantics are identical even though the element names differ. The identifier of the author, and their address and telephone number shall be present inside the <id>, <addr> and <telecom> elements.

4.3.3.1.4 <assignedPerson><name></name></assignedPerson> <representedOrganization><name></name></representedOrganization>

The author's and/or the organization's name shall be present when the <author> element is present.

4.3.3.2 Linking Narrative and Coded Entries

This section defines a linking mechanism that allows entries or portions thereof to be connected to the text of the clinical document.

4.3.3.2.1 Standards

RIM	HL7 Version 3 Reference Information Model
CDAR2	HL7 Clinical Document Architecture Release 2.0

4.3.3.2.2 Constraints for CDA

Elements within the narrative <text> will use the ID attribute to provide a destination for links. Elements within an <entry> will be linked to the text via a URI reference using this attribute as the fragment identifier. This links the coded entry to the specific narrative text it is related to within the CDA instance, and can be traversed in either direction. This serves three purposes:

1. It supports diagnostics during software development and testing.
2. It provides a mechanism to enrich the markup that can be supported in the viewing application.
3. It eliminates the need to duplicate content in two places, which prevents a common source of error, and eliminates steps needed to validate that content that should be identical in fact is.

Each narrative content element within CDA may have an ID attribute. This attribute is of type xs:ID. This means that each ID in the document must be unique within that document. Within an XML document, an attribute of type xs:ID must start with a letter, and may be followed one or more letters, digits, hyphens or underscores . Three different examples showing the use of the ID attribute, and references to it appear below:

Use of ID	References to ID
<tr ID='foo'> <td ID='bar'>Table Cell 1</td> <td>Table Cell 2</td> </tr>	<code> <originalText><reference value='#foo'></originalText> </code> <code> <originalText><reference value='#bar'></originalText> </code>
<list> <item ID='baz'>List item 1</item> </list>	<code> <originalText><reference value='#baz'></originalText> </code>
<paragraph ID='p-1'>A paragraph <content ID='c-1'>with content</content> </paragraph>	<code> <originalText><reference value='#p-1'></originalText> </code> <code> <originalText><reference value='#c-1'></originalText> </code>

Table 4.3-1. Example Uses of ID

This allows the text to be located with a special type of URI reference, which simply contains a fragment identifier. This URI is local to the document and so just begins with a

hash mark (#), and is followed by the value of the ID being referenced. Given one of these URIs stored in a variable named theURI, the necessary text value can be found via the following XPath expression:

```
string(//*[@ID=substring-after('#',$theURI)])
```

The table below shows the result of this expression using the examples above:

$theURI	Returned Value
"#bar"	"Table Cell 1"
"#foo"	"Table Cell 1Table Cell 2" (note the spacing issue between 1 and T)
"#p-1"	"A paragraph with content"
"#c-1"	"with content"

If your XSLT processor is schema aware, even more efficient mechanisms exist to locate the element than the above expression.

Having identified the critical text in the narrative, any elements using the HL7 CD datatype (e.g., <code>) can then contain a <reference> to the <originalText> found in the narrative. That is why, although CDA allows <value> to be of any type in <entry> elements, this profile restricts them to always be of xsi:type='CD'.

Now, given an item with an ID stored in a variable named theID all <reference> elements referring to it can be found via the following XPath expression:

```
//cda:reference[@URI=concat('#',$theID)]
```

4.3.3.2.3 Constraints for HL7 Version 3 Messages

Unlike CDA entries, structured statements in HL7 Version 3 Messages do not have a related narrative text section. Therefore full text representations should be included in the <text> element care statement acts.

4.3.3.3 Severity 1.3.6.1.4.1.19376.1.5.3.1.4.1

Any condition or allergy may be the subject of a severity observation. This structure is included in the target act using the <entryRelationship> element defined in the CDA Schema.

The example below shows the recording the condition or allergy severity, and is used as the context for the following sections.

4.3.3.3.1 Standards

PatCareStruct	HL7 Care Provision Domain (DSTU)
CCD	ASTM/HL7 Continuity of Care Document

4.3.3.3.2 Specification

```
<observation classCode='COND' moodCode='EVN'>

  <entryRelationship typeCode='SUBJ' inversionInd='true'>
    <observation classCode='OBS' moodCode='EVN'>
      <templateId root='2.16.840.1.113883.10.20.1.55'/>
      <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.1'/>
      <code code='SEV' displayName='Severity'
        codeSystem='2.16.840.1.113883.5.4' codeSystemName='ActCode' />
      <text><reference value='#severity-2'/></text>
      <statusCode code='completed'/>
      <value xsi:type='CD' code='H|M|L'
        codeSystem='2.16.840.1.113883.5.1063'
        codeSystemName='ObservationValue' />
    </observation>
  </entryRelationship>

</observation>
```

This specification models a severity observation as a separate observation from the condition. While this model is different from work presently underway by various organizations (i.e., SNOMED, HL7, TermInfo), it is not wholly incompatible with that work. In that work, qualifiers may be used to identify severity in the coded condition observation, and a separate severity observation is no longer necessary. The use of qualifiers is not precluded by this specification. However, to support semantic interoperability between EMR systems using different vocabularies, this specification does require that severity information also be provided in a separate observation. This ensures that all EMR systems have equal access to the information, regardless of the vocabularies they support.

4.3.3.3.2.1 <entryRelationship typeCode='SUBJ' inversionInd='true'>

The related statement is made about the severity of the condition (or allergy). For CDA, this observation is recorded inside an <entryRelationship> element occurring in the condition, allergy or medication entry. The containing <entry> is the subject (typeCode='SUBJ') of this new observation, which is the inverse of the normal containment structure, thus inversionInd='true'. For HL7 Version 3 Messages this relationship is represented with a <sourceOf> element, however the semantics, typeCode, and inversionInd is unchanged.

4.3.3.3.2.2 <observation moodCode='EVN' classCode='OBS'>

The related statement is another event (moodCode='EVN') observing (<observation classCode='OBS'>) the severity of the (surrounding) related entry (e.g., a condition or allergy).

4.3.3.3.2.3 <templateId root='2.16.840.1.113883.10.20.1.55'/> <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.1'/>

The <templateId> elements identifies this <observation> as a severity observation, allowing for validation of the content. As a side effect, readers of the CDA can quickly locate and identify severity observations. The templateId elements shown above must be present.

4.3.3.3.2.4 <code code='SEV' codeSystem='2.16.840.1.113883.5.4' displayName='Severity' codeSystemName='ActCode' />

This observation is of severity, as indicated by the <code> element listed above. This element is required. The code and codeSystem attributes shall be recorded exactly as shown above.

4.3.3.3.2.5 <text><reference value='#severity-2'/></text>

The <observation> element shall contain a <text> element. For CDA, the <text> elements shall contain a <reference> element pointing to the narrative where the severity is recorded, rather than duplicate text to avoid ambiguity. For HL7 Version 3 Messages, the <text> element should contain the full narrative text.

4.3.3.3.2.6 <statusCode code='completed'/>

The code attribute of <statusCode> for all severity observations shall be completed. While the <statusCode> element is required in all acts to record the status of the act, the only sensible value of this element in this context is completed.

4.3.3.3.2.7 <value xsi:type='CD' code='H|M|L' codeSystem='2.16.840.1.113883.5.1063' codeSystemName='SeverityObservation'>

The <value> element contains the level of severity. It is always represented using the CD datatype (xsi:type='CD'), even though the value may be a coded or uncoded string. If coded, it should use the HL7 SeverityObservation vocabulary (codeSystem='2.16.840.1.113883.5.1063') containing three values (H, M, and L), representing high, moderate and low severity depending upon whether the severity is life threatening, presents noticeable adverse consequences, or is unlikely substantially effect the situation of the subject.

4.3.3.4 Problem Status Observation 1.3.6.1.4.1.19376.1.5.3.1.4.1.1

Any problem or allergy observation may reference a problem status observation. This structure is included in the target observation using the <entryRelationship> element defined in the CDA Schema. The clinical status observation records information about the current status of the problem or allergy, for example, whether it is active, in remission, resolved, et cetera. The example below shows the recording of clinical status of a condition or allergy, and is used as the context for the following sections.

4.3.3.4.1 Standards

CCD	ASTM/HL7 Continuity of Care Document

4.3.3.4.2 Specification

```
  <entry>
   <observation classCode='OBS' moodCode='EVN'>

     <entryRelationship typeCode='REFR' inversionInd='false'>
       <observation classCode='OBS' moodCode='EVN'>
         <templateId root='2.16.840.1.113883.10.20.1.57'/>
         <templateId root='2.16.840.1.113883.10.20.1.50'/>
         <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.1.1'/>
         <code code='33999-4' displayName='Status'
           codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC' />
         <text><reference value='#cstatus-2'/></text>
         <statusCode code='completed'/>
         <value xsi:type='CE' code=' ' codeSystem='2.16.840.1.113883.6.96'
codeSystemName='SNOMED CT'/>
       </observation>
     </entryRelationship>

   </observation>
 </entry>
```

This CCD models a problem status observation as a separate observation from the problem, allergy or medication observation. While this model is different from work presently underway by various organizations (i.e., SNOMED, HL7, TermInfo), it is not wholly incompatible with that work. In that work, qualifiers may be used to identify problem status in the coded condition observation, and a separate clinical status observation is no longer necessary. The use of qualifiers in the problem observation is not precluded by this specification or by CCD. However, to support semantic interoperability between EMR systems using different vocabularies, this specification does require that problem status information also be provided in a separate observation. This ensures that all EMR systems have equal access to the information, regardless of the vocabularies they support.

4.3.3.4.3 <entryRelationship typeCode='REFR' inversionInd='false'>

The related statement is made about the clinical status of the problem or allergy. For CDA, this observation is recorded inside an <entryRelationship> element occurring in the problem or allergy. For HL7 Version 3 Messages, the <entryRelationship> tag name is <sourceOf>, though the typeCode and inversionInd attributes and other semantics remain the same. The containing observation refers to (typeCode='REFR') this new observation.

4.3.3.4.4 <observation moodCode='EVN' classCode='OBS'>

The related statement is another event (moodCode='EVN') observing (<observation classCode='OBS'>) the clinical status of the (surrounding) related observation (e.g., a problem or allergy).

4.3.3.4.5 <templateId root='2.16.840.1.113883.10.20.1.57'/> <templateId root='2.16.840.1.113883.10.20.1.50'/> <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.1.1'/>

These <templateId> elements identify this <observation> as a problem status observation, allowing for validation of the content.

4.3.3.4.6 <code code='33999-4' codeSystem='2.16.840.1.113883.6.1' displayName='Status' codeSystemName='LOINC' />

This observation is of clinical status, as indicated by the <code> element. This element must be present. The code and codeSystem shall be recorded exactly as shown above.

4.3.3.4.7 <text><reference value='#cstatus-2'/></text>

The <observation> element shall contain a <text> element that points to the narrative text describing the clinical status. For CDA, the <text> elements shall contain a <reference> element pointing to the narrative section (see Linking Narrative and Coded Entries), rather than duplicate text to avoid ambiguity. For HL7 Version 3 Messages, the <text> element SHALL contain the full narrative text.

4.3.3.4.8 <statusCode code='completed'/>

The code attribute of <statusCode> for all clinical status observations shall be completed. While the <statusCode> element is required in all acts to record the status of the act, the only sensible value of this element in this context is completed.

4.3.3.4.9 <value xsi:type='CE' code=' ' displayName=' ' codeSystem='2.16.840.1.113883.6.96' codeSystemName='SNOMED CT'>

The <value> element contains the clinical status. It is always represented using the CE datatype (xsi:type='CE'). It shall contain a code from the following set of values from SNOMED CT.

Code	Description
55561003	Active
73425007	Inactive
90734009	Chronic
7087005	Intermittent
255227004	Recurrent
415684004	Rule out
410516002	Ruled out
413322009	Resolved

4.3.3.5 Health Status 1.3.6.1.4.1.19376.1.5.3.1.4.1.2

A problem observation may reference a health status observation. This structure is included in the target observation using the <entryRelationship> element defined in the CDA Schema. The health status observation records information about the current health status of the patient. The example below shows the recording the health status, and is used as the context for the following sections.

4.3.3.5.1 Specification

```
<entry>
 <observation classCode='OBS' moodCode='EVN'>

   <entryRelationship typeCode='REFR' inversionInd='false'>
     <observation classCode='OBS' moodCode='EVN'>
       <templateId root='2.16.840.1.113883.10.20.1.57'/>
       <templateId root='2.16.840.1.113883.10.20.1.51'/>
       <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.1.2'/>
       <code code='11323-3' displayName='Health Status'
         codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC' />
       <text><reference value='#hstatus-2'/></text>
       <statusCode code='completed'/>
       </value>
       <value xsi:type='CE' code=' ' codeSystem='2.16.840.1.113883.6.96'
codeSystemName='SNOMED CT'/>
     </observation>
   </entryRelationship>

 </observation>
</entry>
```

This specification models a health status observation as a separate observation about the patient.

4.3.3.5.2 <entryRelationship typeCode='REFR'>

The related statement is made about the health status of the patient. For CDA, this observation is recorded inside an <entryRelationship> element occurring in the observation. The contained observersation is referenced (typeCode='REFR') by the observation entry. For HL7 Version 3 Messages, the entryRelationship tagName is sourceOf, though the typeCode and inversionInd attributes and other semantics remain the same.

4.3.3.5.3 <observation moodCode='EVN' classCode='OBS'>

The related statement is another event (moodCode='EVN') observing (<observation classCode='OBS'>) the health status of the patient.

4.3.3.5.4 <templateId root='2.16.840.1.113883.10.20.1.57'/> <templateId root='2.16.840.1.113883.10.20.1.51'/> <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.1.2'/>

The <templateId> element identifies this <observation> as a health status observation, allowing for validation of the content.

4.3.3.5.5 <code code='11323-3' displayName='Health Status'

codeSystem='2.16.840.1.113883.6.1'
codeSystemName='LOINC' />

This observation is of health status, as indicated by the <code> element. This element must be present. The code and codeSystem attributes shall be recorded exactly as shown above.

4.3.3.5.6 <text><reference value='#hstatus-2'/></text>

The <observation> element shall contain a <text> element that contains the narrative text describing the clinical status. For CDA, the <text> elements shall contain a <reference> element pointing to the narrative section (see Linking Narrative and Coded Entries, rather than duplicate text to avoid ambiguity. For HL7 Version 3 Messages, the <text> element shall contain the full narrative text.

4.3.3.5.7 <statusCode code='completed'/>

The code attribute of <statusCode> for all health status observations shall be completed. While the <statusCode> element is required in all acts to record the status of the act, the only sensible value of this element in this context is completed.

4.3.3.5.8 <value xsi:type='CE' code=' ' displayName=' ' codeSystem='2.16.840.1.113883.6.96' codeSystemName='SNOMED CT'>

The <value> element contains the clinical status. It is always represented using the CE datatype (xsi:type='CE').

Code	Description
81323004	Alive and well
313386006	In remission
162467007	Symptom free
161901003	Chronically ill
271593001	Severely ill
21134002	Disabled
161045001	Severely disabled
419099009	Deceased

4.3.3.6 Comments 1.3.6.1.4.1.19376.1.5.3.1.4.2

This entry allows for a comment to be supplied with each entry. For CDA this structure is included in the target act using the <entryRelationship> element defined in the CDA Schema. The example below shows recording a comment for an <entry>, and is used as context for the following sections. For HL7 Version 3 Messages, this relationship is represented with the element <sourceOf>, although the remainder of the typecodes and semantics are unchanged. Any condition or allergy may be the subject of a comment.

4.3.3.6.1 Standards

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

4.3.3.6.2 Specification

```
<entry>
  <observation classCode='OBS' moodCode='EVN'>

    <entryRelationship typeCode='SUBJ' inversionInd='true'>
      <act classCode='ACT' moodCode='EVN'>
        <templateId root='2.16.840.1.113883.10.20.1.40'/>
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.2'/>
        <code code='48767-8' displayName='Annotation Comment'
          codeSystem='2.16.840.1.113883.6.1'
          codeSystemName='LOINC' />
        <text><reference value='#comment-2'/></text>
        <statusCode code='completed' />
        <author>
          <time value=''/>
          <assignedAuthor>
            <id root='' extension=''>
            <addr></addr>
            <telecom value='' use=''>
            <assignedPerson><name></name></assignedPerson>
            <representedOrganization><name></name></representedOrganization>
          </assignedAuthor>
        </author>
      </act>
    </entryRelationship>

  </observation>
</entry>
```

4.3.3.6.3 <entryRelationship typeCode='SUBJ' inversionInd='true'>

Again, a related statement is made about the condition, allergy or medication. In CDA this observation is recorded inside an <entryRelationship> element occurring at the end of the condition or allergy entry. The containing <observation> is the subject (typeCode='SUBJ') of this new observation, which is the inverse of the normal containment structure, thus inversionInd='true'. For HL7 Version 3 Messages, the relationship element is <sourceOf>, however the typeCode and inversionInd remain the same.

4.3.3.6.4 <act classCode='ACT' moodCode='EVN'>

The related statement is an event (moodCode='EVN') describing the act (classCode='ACT') of making an arbitrary comment or providing instruction on the related entry.

4.3.3.6.5 <templateId root='2.16.840.1.113883.10.20.1.40'/> <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.2'/>

These <templateId> elements identify this <act> as a comment, allowing for validation of the content.

4.3.3.6.6 <code code='48767-8' displayName='Annotation Comment' codeSystem='1.3.6.1.4.1.19376.1.5.3.2' codeSystemName='LOINC' />

The <code> element indicates that this is a comment and shall be recorded as shown above. The codeSystem and code attributes shall use the values specified above.

4.3.3.6.7 <text><reference value='#comment-2'/></text>

The <text> element provides a way to represent the <reference> to the text of the comment in the narrative portion of the document. For CDA, this SHALL be represented as a <reference> element that points to the narrative text section of the CDA. The comment itself is not the act being coded, so it appears in the <text> of the <observation>, not as part of the <code>. For HL7 Version 3 Messages, the <text> element SHALL contain the full narrative text.

4.3.3.6.8 <statusCode code='completed' />

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

4.3.3.6.9 <author>

The comment may have an author.

4.3.3.6.10 <time value=' '/>

The time of the comment creation shall be recorded in the <time> element when the <author> element is present.

4.3.3.6.11 <assignedAuthor> <id root=' ' extension=' '> <addr></addr> <telecom value=' ' use=' '>

The identifier of the author, and their address and telephone number must be present inside the <id>, <addr> and <telecom> elements when the <author> element is present.

4.3.3.6.12 <assignedPerson><name></name></assignedPerson> <representedOrganization><name></name></representedOrganization>

The author's and/or the organization's name must be present when the <author> element is present.

4.3.3.7 Patient Medication Instructions 1.3.6.1.4.1.19376.1.5.3.1.4.3

Any medication may be the subject of further instructions to the patient, for example to indicate that it should be taken with food, et cetera.

This structure is included in the target substance administration or supply act using the <entryRelationship> element defined in the CDA Schema. The example below shows the

recording of patient medication instruction for an <entry>, and is used as context for the following section.

4.3.3.7.1 Standards

Pharmacy HL7 Pharmacy Domain (Normative)

4.3.3.7.2 Specification

```
<entry>
 <substanceAdministration classCode='SBADM' moodCode='EVN'>

   <entryRelationship typeCode='SUBJ' inversionInd='true'>
     <act classCode='ACT' moodCode='INT'>
       <templateId root='2.16.840.1.113883.10.20.1.49'/>
       <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.3'/>
       <code code='PINSTRUCT' codeSystem='1.3.6.1.4.1.19376.1.5.3.2'
         codeSystemName='IHEActCode' />
       <text><reference value='#comment-2'/></text>
       <statusCode code='completed' />
     </act>
   </entryRelationship>

 </substanceAdministration>
</entry>
```

4.3.3.7.3 <entryRelationship typeCode='SUBJ' inversionInd='true'>

Again, a related statement is made about the medication or immunization. This observation is recorded inside an <entryRelationship> element occurring at the end of the substance administration or supply entry. The containing <entry> is the subject (typeCode='SUBJ') of this new observation, which is the inverse of the normal containment structure, thus inversionInd='true'.

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

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

4.3.3.7.5 <templateId root='2.16.840.1.113883.10.20.1.49'/> <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.3'/>

These <templateId> elements identify this <act> as a medication instruction, allowing for validation of the content. As a side effect, readers of the CDA can quickly locate and identify medication instructions.

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

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

Note: These values will be sent to HL7 for harmonization with the HL7 Act Vocabulary.

4.3.3.7.7 <text><reference value='#comment-2'/></text>

The <text> element indicates the text of the comment. For CDA, this SHALL be represented as a <reference> element that points at the narrative portion of the document. The comment itself is not the act being coded, so it appears in the <text> of the <observation>, not as part of the <code>. For HL7 Version 3 Messages, the full text SHALL be represented here.

4.3.3.7.8 <statusCode code='completed' />

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

4.3.3.8 Medication Fulfillment Instructions 1.3.6.1.4.1.19376.1.5.3.1.4.3.1

Any medication may be the subject of further instructions to the pharmacist, for example to indicate that it should be labeled in Spanish, et cetera.

This structure is included in the target substance administration or supply act using the <entryRelationship> element defined in the CDA Schema. The figure below is an example of recording an instruction for an <entry>, and is used as context for the following sections.

4.3.3.8.1 Standards

Pharmacy	HL7 Pharmacy Domain (Normative)

4.3.3.8.1.1 Specification

```
<entry>
 <supply classCode='SPLY' moodCode='EVN'>
   <entryRelationship typeCode='SUBJ' inversionInd='true'>
     <act classCode='ACT' moodCode='INT'>
       <templateId root='2.16.840.1.113883.10.20.1.43'/>
       <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.3.1'/>
       <code code='FINSTRUCT' codeSystem='1.3.6.1.4.1.19376.1.5.3.2'
         codeSystemName='IHEActCode' />
       <text><reference value='#comment-2'/></text>
       <statusCode code='completed' />
     </act>
   </entryRelationship>
 </supply>
</entry>
```

4.3.3.8.2 <entryRelationship typeCode='SUBJ' inversionInd='true'>

Again, a related statement is made about the medication or immunization. In CDA, this observation is recorded inside an <entryRelationship> element occurring at the end of the substance administration or supply entry. The containing <act> is the subject (typeCode='SUBJ') of this new observation, which is the inverse of the normal containment structure, thus inversionInd='true'. For HL7 Version 3 Messages, this relationship is represented with the <sourceOf> element however the semantics, typeCode, and inversionInd remain the same.

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

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

4.3.3.8.4 <templateId root='2.16.840.1.113883.10.20.1.43'/> <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.3.1'/>

These <templateId> elements identify this <act> as a medication fulfillment instruction, allowing for validation of the content.

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

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

Note: These values will be sent to HL7 for harmonization with the HL7 Act Vocabulary.

4.3.3.8.6 <text><reference value='#comment-2'/></text>

The <text> element contains a free text representation of the instruction. For CDA this SHALL contain a provides a <reference>element to thelink text of the comment in the narrative portion of the document. The comment itself is not the act being coded, so it appears in the <text> of the <observation>, not as part of the <code>. For HL7 Version 3 Messages, the full text SHALL be represented here.

4.3.3.8.7 <statusCode code='completed' />

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

4.3.3.9 External References 1.3.6.1.4.1.19376.1.5.3.1.4.4

CDA Documents may reference information contained in other documents. While CDA Release 2.0 supports references in content via the <linkHtml> element, this is insufficient for many EMR systems as the link is assumed to be accessible via a URL, which is often not the case. In order to link an external reference, one needs the document identifier, and access to the clinical system wherein the document resides. For a variety of reasons, it is desirable to refer to the document by its identity, rather than by linking through a URL.

1. The identity of a document does not change, but the URLs used to access it may vary depending upon location, implementation, or other factors.
2. Referencing clinical documents by identity does not impose any implementation specific constraints on the mechanism used to resolve these references, allowing the content to be implementation neutral. For example, in the context of an XDS Affinity domain the clinical system used to access documents would be an XDS Registry and one or more XDS Repositories where documents are stored. In other contexts, access might be through a Clinical Data Repository (CDR), or Document Content Management System (DCMS). Each of these may have different mechanisms to resolve a document identifier to the document resource.

3. The identity of a document is known before the document is published (e.g., in an XDS Repository, Clinical Data Repository, or Document Content Management System), but its URL is often not known. Using the document identity allows references to existing documents to be created before those documents have been published to a URL. This is important to document creators, as it does not impose workflow restrictions on how links are created during the authoring process.

Fortunately, CDA Release 2.0 also provides a mechanism to refer to external documents in an entry, as shown below.

4.3.3.9.1 Specification

```
<entry>
  <act classCode='ACT' moodCode='EVN'>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.4'/>
    <id root='' extension=''/>
    <code nullFlavor='NA' />
    <text><reference value='#study-1'/></text>
    <!-- For CDA -->
    <reference typeCode='REFR|SPRT'>
      <externalDocument classCode='DOC' moodCode='EVN'>
        <id extension='' root=''/>
        <text><reference value='http://foo..'/></text>
      </externalDocument>
    </reference>
    <!-- For HL7 Version 3 Messages
    <sourceOf typeCode='REFR|SPRT'>
       <act classCode='DOC' moodCode='EVN'>
          <id extension='' root=''/>
          <text><reference value='http://foo…'</text>
       </act>
    </sourceOf>
     -->
  </act>
</entry>
```

4.3.3.9.2 <act classCode='ACT' moodCode='EVN'>

The external reference is an act that refers to documentation of an <act> (classCode='ACT'), that previously occurred (moodCode='EVN').

4.3.3.9.3 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.4'/>

The <templateId> element identifies this <act> as a reference act, allowing for validation of the content. As a side effect, readers of the CDA can quickly locate and identify reference acts. The templateId must have root='1.3.6.1.4.1.19376.1.5.3.1.4.1.4.4'.

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

The reference is an act of itself, and must be uniquely identified. If there is no explicit identifier for this act in the source EMR system, a GUID may be used for the root attribute, and the extension may be omitted. Although HL7 allows for multiple identifiers, this profile requires that one and only one be used.

4.3.3.9.5 <code nullFlavor='NA'/>

The reference act has no code associated with it.

4.3.3.9.6 <text><reference value='#study-1'/></text>

In order to connect this external reference to the narrative text which it refers, the value of the <reference> element in the <text> element is a URI to an element in the CDA narrative of this document.

4.3.3.9.7 <reference typeCode='SPRT|REFR'> <externalDocument classCode='DOC' moodCode='EVN'>

External references are listed as either supporting documentation (typeCode='SPRT') or simply reference material (typeCode='REFR') for the reader. If this distinction is not supported by the source EMR system, the value of typeCode should be REFR. For CDA, the reference is indicated by a <reference> element containing an <externalDocument> element which documents (classCode='DOC') the event (moodCode='EVN'). For HL7 Version 3 Messages, the reference is represented with the element <sourceOf> and the external document is representated with a <act> element, however semantics, and attributes remain otherwise without change.

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

The identifier of the document is supplied in the <id> element.

4.3.3.9.9 <text><reference value=' '/></text>

A link to the original document may be provided here. This shall be a URL where the referenced document can be located. For CDA, the link should also be present in the narrative inside the CDA Narrative in a <linkHTML> element.

4.3.3.10 Internal References 1.3.6.1.4.1.19376.1.5.3.1.4.4.1

CDA and HL7 Version 3 Entries may reference (point to) information contained in other entries within the same document or message as shown below.

4.3.3.10.1 Specification

```
<entryRelationship typeCode='' inversionInd='true|false'>
    <act classCode='' moodCode=''>
      <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.4.1'/>
      <id root='' extension=''/>
      <code code='' displayName='' codeSystem='' codeSystemName=''/>
    </act>
</entryRelationship>
```

4.3.3.10.2 <entryRelationship typeCode=' ' inversionInd='true|false'>

For CDA the act being referenced appears inside a related entryRelationship. The type (typeCode) and direction (inversionInd) attributes will be specified in the entry content module that contains the reference. For HL7 Version 3 Messages, the relationship is indicated with a <sourceOf> element, however typeCodes and semantics remain unchanged.

4.3.3.10.3 <act classCode=' ' moodCode=' '>

The act being referred to can be any CDA Clinical Statement element type (act, procedure, observation, substanceAdministration, supply, et cetera). For compatibility with the Clinical Statement model the internal reference shall always use the <act> class, regardless of the XML element type of the act it refers to.

4.3.3.10.4 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.4.1'/>

The <templateId> element identifies this as an internal reference that conforms to all rules specified in this section.

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

This element shall be present. The root and extension attributes shall identify an element defined elsewhere in the same document.

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

This element shall be present. It shall be valued when the internal reference is to element that has a <code> element, and shall have the same attributes as the <code> element in the act it references. If the element it references does not have a <code> element, then the nullFlavor attribute should be set to "NA".

4.3.3.11 Concern Entry 1.3.6.1.4.1.19376.1.5.3.1.4.5.1

This event (moodCode='EVN') represents an act (<act classCode='ACT') of being concerned about a problem, allergy or other issue. The <effectiveTime> element describes the period of concern. The subject of concern is one or more observations about related problems (see 1.3.6.1.4.1.19376.1.5.3.1.4.5.2) or allergies and intolerances (see 1.3.6.1.4.1.19376.1.5.3.1.4.5.3). Additional references can be provided having additional information related to the concern. The concern entry allows related acts to be grouped. This allows representing the history of a problem as a series of observation over time, for example.

4.3.3.11.1 Standards

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

4.3.3.11.2 Specification

```
<act classCode='ACT' moodCode='EVN'>
  <templateId root='2.16.840.1.113883.10.20.1.27'/>
  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.1'/>
  <id root='' extension=''/>
  <code nullFlavor='NA'/>
  <statusCode code='active|suspended|aborted|completed'/>
  <effectiveTime>
    <low value=''/>
    <high value=''/>
  </effectiveTime>
  <!-- one or more entry relationships identifying problems of concern -->
  <entryRelationship typeCode='SUBJ' inversionInd='false'>
     :
  </entryRelationship>
  <!-- For HL7 Version 3 Messages
  <sourceOf typeCode='SUBJ' inversionInd='false'>
     :
  </sourceOf>
  -->
  <!-- optional entry relationship providing more information about the concern -->
  <entryRelationship typeCode='REFR'>
     :
  </entryRelationship>
  <!-- For HL7 Version 3 Messages
  <sourceOf typeCode='REFR' inversionInd='false'>
     :
  </sourceOf>
  -->
</act>
```

4.3.3.11.3 <act classCode='ACT' moodCode='EVN'>

All concerns reflect the act of recording (<act classCode='ACT'>) the event (moodCode='EVN') of being concerned about a problem, allergy or other issue about the patient condition.

4.3.3.11.4 <templateId root='2.16.840.1.113883.10.20.1.27'/> <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.1'/>

These template identifiers indicates this entry conforms to the concern content module. This content module inherits constraints from the HL7 CCD Template for problem acts, and so also includes that template identifier.

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

This required element identifies the concern.

4.3.3.11.6 <code nullFlavor='NA'/>

The code is not applicable to a concern act, and so shall be recorded as shown above.

4.3.3.11.7 <statusCode code='active|suspended|aborted|completed'/>

The statusCode associated with any concern must be one of the following values:

Value	Description
active	A concern that is still being tracked.

suspended	A concern that is active, but which may be set aside. For example, this value might be used to suspend concern about a patient problem after some period of remission, but before assumption that the concern has been resolved.
aborted	A concern that is no longer actively being tracked, but for reasons other than because the problem was resolved. This value might be used to mark a concern as being aborted after a patient leaves care against medical advice.
completed	The problem, allergy or medical state has been resolved and the concern no longer needs to be tracked except for historical purposes.

Note	A concern in the "active" state represents one for which some ongoing clinical activity is expected, and that no activity is expected in other states. Specific uses of the suspended and aborted states are left to the implementation.

4.3.3.11.8 <effectiveTime><low value=' '/><high value=' '/></effectiveTime>

The <effectiveTime> element records the starting and ending times during which the concern was active. The <low> element shall be present. The <high> element shall be present for concerns in the completed or aborted state, and shall not be present otherwise.

4.3.3.11.9 <!-- 1..* entry relationships identifying problems of concern --> <entryRelationship type='SUBJ' inversionInd='false'>

Each concern is about one or more related problems or allergies. This entry shall contain one or more problem or allergy entries that conform to the specification in section Problem Entry or Allergies and Intolerances. This is how a series of related observations can be grouped as a single concern.

For CDA this SHALL be represented with the <entryRelationship> element. For HL7 Version 3 Messages, this SHALL be represented as a <sourceOf> element. The typeCode SHALL be 'SUBJ' for both HL7 Version 3 and CDA. HL7 Version 3 additionally requires that inversionInd SHALL be 'false'.

Note: The Allergy and Intolerances entry is a refinement of the Problem entry.

4.3.3.11.10 <!-- 0..n optional entry relationship providing more information about the concern --> <entryRelationship type='REFR' inversionInd='false'>

Each concern may have 0 or more related references. These may be used to represent related statements such related visits. This may be any valid CDA clinical statement, and SHOULD be an IHE entry template. For CDA this SHALL be represented with the <entryRelationship> element. For HL7 Version 3 Messages, this SHALL be represented as a <subjectOf> element. The typeCode SHALL be 'SUBJ' and inversionInd SHALL be 'false'

4.3.3.12 Problem Concern Entry 1.3.6.1.4.1.19376.1.5.3.1.4.5.2

This entry is a specialization of the Concern Entry, wherein the subject of the concern is focused on a problem. Elements shown in the example below in gray are explained in the Concern Entry.

4.3.3.12.1 Standards

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

4.3.3.12.2 Parent Template

The parent of this template is Concern Entry. This template is compatible with the ASTM/HL7 Continuity of Care Document template: 2.16.840.1.113883.10.20.1.27

4.3.3.12.3 Specification

```
<act classCode='ACT' moodCode='EVN'>
 <templateId root='2.16.840.1.113883.10.20.1.27'/>
 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.1'/>
 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.2'/>
 <id root=' ' extension=' '/>
 <code nullFlavor='NA'/>
 <statusCode code='active|suspended|aborted|completed'/>
 <effectiveTime>
   <low value=' '/>
   <high value=' '/>
 </effectiveTime>
 <!-- 1..* entry relationships identifying problems of concern -->
 <entryRelationship type='SUBJ'>
   <observation classCode='OBS' moodCode='EVN'/>
      <templateID root='1.3.6.1.4.1.19376.1.5.3.1.4.5'>
        :
   </observation>
 </entryRelationship>
 <!-- optional entry relationship providing more information about the concern -->
 <entryRelationship type='REFR'>
 </entryRelationship>
</act>
```

4.3.3.12.4 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.1'/> <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.2'/>

This entry has a template identifier of 1.3.6.1.4.1.19376.1.5.3.1.4.5.2, and is a subtype of the Concern Entry, and so must also conform to that specification, with the template identifier of 1.3.6.1.4.1.19376.1.5.3.1.4.5.1. These elements are required and shall be recorded exactly as shown above.

4.3.3.12.5 <!-- 1..* entry relationships identifying problems of concern --> <observation classCode='OBS' moodCode='EVN'> <templateID root=' 1.3.6.1.4.1.19376.1.5.3.1.4.5'/> … </observation> <entryRelationship type='SUBJ'>

This entry shall contain one or more problem entries that conform to the Problem Entry template 1.3.6.1.4.1.19376.1.5.3.1.4.5. For CDA this SHALL be represented with the <entryRelationship> element. For HL7 Version 3 Messages, this SHALL be represented as a <subjectOf> element. The typeCode SHALL be ‘SUBJ’ and inversionInd SHALL be ‘false’

4.3.3.13 Allergy and Intolerance Concern 1.3.6.1.4.1.19376.1.5.3.1.4.5.3

This entry is a specialization of the Concern Entry, wherein the subject of the concern is focused on an allergy or intolerance. Elements shown in the example below in gray are explained in that entry.

4.3.3.13.1 Standards

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

4.3.3.13.2 Parent Template

The parent of this template is Concern Entry. This template is compatible with the ASTM/HL7 Continuity of Care Document template: 2.16.840.1.113883.10.20.1.27

4.3.3.13.3 Specification

```
<act classCode='ACT' moodCode='EVN'>
 <templateId root='2.16.840.1.113883.10.20.1.27'/>
 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.1'/>
 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.3'/>
 <id root=' ' extension=' '/>
 <code nullFlavor='NA'/>
 <statusCode code='active|suspended|aborted|completed'/>
 <effectiveTime>
   <low value=' '/>
   <high value=' '/>
 </effectiveTime>
 <!-- 1..* entry relationships identifying allergies of concern -->
 <entryRelationship type='SUBJ'>
   <observation classCode='OBS' moodCode='EVN'/>
      <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.6'/>
        :
   </observation>
 </entryRelationship>
 <!-- optional entry relationship providing more information about the concern -->
 <entryRelationship type='REFR'>
 </entryRelationship>
</act>
```

4.3.3.13.4 <templateId root='2.16.840.1.113883.10.20.1.27'/> <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.1'/> <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.3'/>

This entry has a template identifier of 1.3.6.1.4.1.19376.1.5.3.1.4.5.3, and is a subtype of the Concern entry, and so must also conform to the rules of the Concern Entry. These elements are required and shall be recorded exactly as shown above.

4.3.3.13.4.1 <!-- 1..* entry relationships identifying allergies of concern --> <observation classCode='OBS' moodCode='EVN'/> <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.6'/> :

</observation>
<entryRelationship type='SUBJ'>

This entry shall contain one or more allergy or intolerance entries that conform to the Allergy and Intolerance Entry. For CDA this SHALL be represented with the <entryRelationship> element. For HL7 Version 3 Messages, this SHALL be represented as a <sourceOf> element. The typeCode SHALL be 'SUBJ' and inversionInd SHALL be 'false'

4.3.3.14 Problem Entry 1.3.6.1.4.1.19376.1.5.3.1.4.5

This section makes use of the linking, severity, clinical status and comment content specifications defined elsewhere in the technical framework. In HL7 RIM parlance, observations about a problem, complaint, symptom, finding, diagnosis, or functional limitation of a patient is the event (moodCode='EVN') of observing (<observation classCode='OBS'>) that problem. The <value> of the observation comes from a controlled vocabulary representing such things. The <code> contained within the <observation> describes the method of determination from yet another controlled vocabulary. An example appears below in the figure below.

4.3.3.14.1 Standards

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

4.3.3.14.2 Parent Template

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

4.3.3.14.3 Specification

```
<observation classCode='OBS' moodCode='EVN' negationInd=' false|true '>
 <templateId root='2.16.840.1.113883.10.20.1.28'/>
 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5'/>
 <id root=' ' extension=' '/>
 <code code=' ' displayName=' '
   codeSystem='2.16.840.1.113883.6.96' codeSystemName='SNOMED CT'/>
 <statusCode code='completed'/>
 <effectiveTime><low value=' '/><high value=' '/></effectiveTime>
 <value xsi:type='CD' code=' '
   codeSystem=' ' displayName=' ' codeSystemName=' '>
   <originalText><reference value=' '/></originalText>
 </value>
 <
 <!-- zero or one <entryRelationship typeCode='REFR' inversionInd='false'> elements
      identifying the health status of concern -->
 <!-- zero or one <entryRelationship typeCode='REFR' inversionInd='false'> elements
      containing clinical status -->
 <!-- zero to many <entryRelationship typeCode='REFR' inversionInd='true'> elements
      containing comments -->
</observation>
```

4.3.3.14.4<observation classCode='OBS' moodCode='EVN' negationInd='false|true'>

The basic pattern for reporting a problem uses the CDA <observation> element, setting the classCode='OBS' to represent that this is an observation of a problem, and the moodCode='EVN', to represent that this is an observation that has in fact taken place. The negationInd attribute, if true, specifies that the problem indicated was observed to not have occurred (which is subtly but importantly different from having not been observed). The value of negationInd should not normally be set to true. Instead, to record that there is "no prior history of chicken pox", one would use a coded value indicated exactly that. However, it is not always possible to record problems in this manner, especially if using a controlled vocabulary that does not supply pre-coordinated negations , or which do not allow the negation to be recorded with post-coordinated coded terminology.

4.3.3.14.5 <templateId root='2.16.840.1.113883.10.20.1.28'/> <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5'/>

These <templateId> elements identify this <observation> as a problem, under both IHE and CCD specifications. This SHALL be included as shown above.

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

The specific observation being recorded must have an identifier (<id>) that shall be provided for tracking purposes. If the source EMR does not or cannot supply an intrinsic identifier, then a GUID shall be provided as the root, with no extension (e.g., <id root='CE1215CD-69EC-4C7B-805F-569233C5E159'/>). While CDA allows for more than one identifier element to be provided, this profile requires that only one be used.

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

The <code> describes the process of establishing a problem. The code element should be used, as the process of determining the value is important to clinicians (e.g., a diagnosis is a more advanced statement than a symptom). The recommended vocabulary for describing problems is shown in the table below. Subclasses of this content module may specify other vocabularies. When the list below is used, the codeSystem is '2.16.840.1.113883.6.96' and codeSystemName is SNOMED CT.

Code	Description
64572001	Condition
418799008	Symptom
404684003	Finding
409586006	Complaint
248536006	Functional limitation
55607006	Problem
282291009	Diagnosis

4.3.3.14.8 <statusCode code='completed'/>

A clinical document normally records only those condition observation events that have been completed, not observations that are in any other state. Therefore, the <statusCode> shall always have code='completed'.

4.3.3.14.9 <effectiveTime><low value=' '/><high value=' '/></effectiveTime>

The <effectiveTime> of this <observation> is the time interval over which the <observation> is known to be true. The <low> and <high> values should be no more precise than known, but as precise as possible. While CDA allows for multiple mechanisms to record this time interval (e.g. by low and high values, low and width, high and width, or center point and width), we are constraining Medical summaries to use only the low/high form. The <low> value is the earliest point for which the condition is known to have existed. The <high> value, when present, indicates the time at which the observation was no longer known to be true. Thus, the implication is made that if the <high> value is specified, that the observation was no longer seen after this time, and it thus represents the date of resolution of the problem. Similarly, the <low> value may seem to represent onset of the problem. Neither of these statements is necessarily precise, as the <low> and <high> values may represent only an approximation of the true onset and resolution (respectively) times. For example, it may be the case that onset occurred prior to the <low> value, but no observation may have been possible before that time to discern whether the condition existed prior to that time. The <low> value should normally be present. There are exceptions, such as for the case where the patient may be

able to report that they had chicken pox, but are unsure when. In this case, the <effectiveTime> element shall have a <low> element with a nullFlavor attribute set to 'UNK'. The <high> value need not be present when the observation is about a state of the patient that is unlikely to change (e.g., the diagnosis of an incurable disease).

4.3.3.14.10 <confidentialityCode code=' '/>

While CDA allows for a condition to specify a <confidentialtyCode> for an observation, in practice there is no way to enforce consistent use of this information across institutions to secure confidential patient information. Therefore, it is recommended that this element not be sent. If there are confidentiality issues that need to be addressed other mechanisms should be negotiated within the affinity domain.

4.3.3.14.11 <uncertaintyCode code=' '/>

CDA allows a condition to be specified with an <uncertaintyCode>. Such conditions can also be recorded as a possible condition (e.g. possible ear infection). There is no present consensus on the best use of this element; therefore, it is recommended that this element not be sent.

4.3.3.14.12 <value xsi:type='CD' code=' ' codeSystem=' ' codeSystemName=' ' displayName=' '>

The <value> is the condition that was found. This element is required. While the value may be a coded or an un-coded string, the type is always a coded value (xsi:type='CD'). If coded, the code and codeSystem attributes shall be present. The codeSystem should reference a controlled vocabulary describing problems, complaints, symptoms, findings, diagnoses, or functional limitations, e.g., ICD-9, SNOMED-CT or MEDCIN, or others. The table below is an incomplete listing of acceptable values for the codeSystem attribute, along with the codeSystemName.

CodeSystem	codeSystemName	Description
2.16.840.1.113883.6.96	SNOMED-CT	SNOMED Controlled Terminology
2.16.840.1.113883.6.103	ICD-9CM (diagnoses)	International Classification of Diseases, Clinical Modifiers, Version 9
2.16.840.1.113883.6.26	MEDCIN	A classification system from MEDICOMP Systems.

It is recommended that the codeSystemName associated with the codeSystem, and the displayName for the code also be provided for diagnostic and human readability purposes, but this is not required by this profile. If uncoded, all attributes other than xsi:type='CD' must be absent.

4.3.3.14.13 <originalText><reference value=' '/></originalText>

The <value> contains a <reference> to the <originalText> in order to link the coded value to the narrative text. The <reference> contains a URI in value attribute. This URI points to the free text description of the problem in the document that is being described.

4.3.3.14.14 <!-- zero or one <entryRelationship typeCode='SUBJ' inversionInd='true'> elements containing severity -->

An optional <entryRelationship> element may be present indicating the severity of the problem. When present, this <entryRelationship> element shall contain a severity observation conforming to the Severity entry template (1.3.6.1.4.1.19376.1.5.3.1.4.1).

For CDA this SHALL be represented with the <entryRelationship> element. For HL7 Version 3 Messages, this SHALL be represented as a <subjectOf> element. The typeCode SHALL be 'SUBJ' and inversionInd SHALL be 'true'.

4.3.3.14.15 <!-- zero or one <entryRelationship typeCode='REFR' inversionInd='false'> elements containing clinical status -->

An optional <entryRelationship> may be present indicating the clinical status of the problem, e.g., resolved, in remission, active. When present, this <entryRelationship> element shall contain a clinical status observation conforming to the Problem Status Observation template (1.3.6.1.4.1.19376.1.5.3.1.4.1.1).

For CDA this SHALL be represented with the <entryRelationship> element. For HL7 Version 3 Messages, this SHALL be represented as a <sourceOf> element. The typeCode SHALL be 'REFR' and inversionInd SHALL be 'false'.

4.3.3.14.16 <!-- zero or one <entryRelationship typeCode='REFR' inversionInd='false'> elements identifying the health status of concern -->

An optional <entryRelationship> may be present referencing the health status of the patient, e.g., resolved, in remission, active. When present, this <entryRelationship> element shall contain a clinical status observation conforming to the Health Status Observation template (1.3.6.1.4.1.19376.1.5.3.1.4.1.1). The typeCode SHALL be 'REFR' and inversionInd SHALL be 'false'.

For CDA this SHALL be represented with the <entryRelationship> element. For HL7 Version 3 Messages, this SHALL be represented as a <sourceOf> element.

4.3.3.14.17 <!-- zero to many <entryRelationship typeCode='SUBJ' inversionInd='true'> element containing comments -->

One or more optional <entryRelationship> elements may be present providing an additional comments (annotations) for the condition. When present, this <entryRelationship> element shall contain a comment observation conforming to the Comment entry template (1.3.6.1.4.1.19376.1.5.3.1.4.2). The typeCode SHALL be 'SUBJ' and inversionInd SHALL be 'true'.

For CDA this SHALL be represented with the <entryRelationship> element. For HL7 Version 3 Messages, this SHALL be represented as a <sourceOf> element.

4.3.3.15 Allergies and Intolerances 1.3.6.1.4.1.19376.1.5.3.1.4.6

Allergies and intolerances are special kinds of problems, and so are also recorded in the CDA <observation> element, with classCode='OBS'. They follow the same pattern as the problem entry, with exceptions noted below.

4.3.3.15.1 Standards

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

4.3.3.15.2 Specification

```
<observation classCode='OBS' moodCode='EVN' negationInd='false'>
 <templateId root='2.16.840.1.113883.10.20.1.18'/>
 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.6'/>
 <id root=' ' extension=' '/>
 <code
   code='ALG|OINT|DALG|EALG|FALG|DINT|EINT|FINT|DNAINT|ENAINT|FNAINT'
   codeSystem='2.16.840.1.113883.5.4'
   codeSystemName='ObservationIntoleranceType'/>
 <statusCode code='completed'/>
 <effectiveTime>
   <low value=' '/>
   <high value=' '/>
 </effectiveTime>
 <value xsi:type='CD' code=' ' codeSystem=' ' displayName=' ' codeSystemName=' '/>
 <participant typeCode='CSM'>
   <participantRole classCode='MANU'>
     <playingEntity classCode='MMAT'>
       <code  code=' ' codeSystem=' '>
         <originalText><reference value='#substance'/></orginalText>
       </code>
       <name></name>
     </playingEntity>
   </participantRole>
 </participant>
 <!-- zero to many <entryRelationship> elements containing reactions -->
 <!-- zero or one <entryRelationship> elements containing severity -->
 <!-- zero or one <entryRelationship> elements containing clinical status -->
 <!-- zero to many <entryRelationship> elements containing comments -->
</observation>
```

4.3.3.15.3 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5'/> <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.6'/>

This entry has a template identifier of 1.3.6.1.4.1.19376.1.5.3.1.4.5.6, and is a subtype of the Problem entry, and so must also conform to the rules of the problem entry, which has the template identifier of 1.3.6.1.4.1.19376.1.5.3.1.4.5.5. These elements are required and shall be recorded exactly as shown above.

4.3.3.15.4 <code code='ALG|OINT|DINT|EINT|FINT|DALG|EALG|FALG|DNAINT|ENAINT|FNAINT' displayName=' ' codeSystem='2.16.840.1.113883.5.4' codeSystemName='ObservationIntoleranceType'/>

The <code> element represents the kind of allergy observation made, to a drug, food or environmental agent, and whether it is an allergy, non-allergy intolerance, or unknown class of intolerance (not known to be allergy or intolerance). The <code> element of an allergy entry shall be provided, and a code and codeSystem attribute shall be present. The example above uses the HL7 ObservationIntoleranceType vocabulary domain, which does provide suitable observation codes. Other vocabularies may be used, such as SNOMED-CT or MEDCIN. The displayName and codeSystemName attributes should be present.

4.3.3.15.5 <value xsi:type='CD' code=' ' codeSystem=' ' codeSystemName=' ' displayName=' '>

The <value> is a description of the allergy or adverse reaction. While the value may be a coded or an uncoded string, the type is always a coded value (xsi:type='CD'). If coded, the code and codeSystem attributes must be present. The codingSystem should reference a controlled vocabulary describing allergies and adverse reactions, see Table 5.4 12Table 5.4 12 above . If uncoded, all attributes other than xsi:type='CD' must be absent. The allergy or intolerance may not be known, in which case that fact shall be recorded appropriately. This might occur in the case where a patient experiences an allergic reaction to an unknown substance.

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

The substance that causes the allergy or intolerance may be specified in the <participant> element.

4.3.3.15.7 <code code=' ' codeSystem=' '> <originalText><reference value=' '/></originalText> </code>

The <code> element shall be present. It may contain a code and codeSystem attribute to indicate the code for the substance causing the allergy or intolerance. It shall contain a <reference> to the <originalText> in the narrative where the substance is named.

4.3.3.15.8 <!-- zero to many <entryRelationship> elements containing reactions -->

An allergy entry can record the reactions that are manifestations of the allergy or intolerance as shown below.


```
<entryRelationship typeCode='MFST'>
  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.6.1'/>
  <!-- a problem entry  -->
  <observation classCode='OBS' moodCode='EVN'>
    <templateId root='2.16.840.1.113883.10.20.1.54'/>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5'/>

  </observation>
</entryRelationship>
```

4.3.3.15.9 <entryRelationship typeCode='MFST'>

This is a related entry (<entryRelationship>) that indicates the manifestations (typeCode='MFST') the reported allergy or intolerance. These are events that may occur, or have occurred in the past as a reaction to the allergy or intolerance.

4.3.3.15.10 <observation classCode='OBS' moodCode='EVN'> <templateId root='2.16.840.1.113883.10.20.1.54'/> <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5'/> </observation>

The entry contained with this entry relationship is some sort of problem that is a manifestation of the allergy. It is recorded using the Problem Entry structure, with the additional template identifier (2.16.840.1.113883.10.20.1.54) indicating that this problem is a reaction.

4.3.3.15.11 <!-- zero or one <entryRelationship typeCode='SUBJ' inversionInd='true'> elements containing severity -->

An optional <entryRelationship> element may be present indicating the severity of the problem. When present, this <entryRelationship> element shall contain a severity observation conforming to the Severity entry template (1.3.6.1.4.1.19376.1.5.3.1.4.1). For CDA this SHALL be represented with the <entryRelationship> element. For HL7 Version 3 Messages, this SHALL be represented as a <sourceOf> element. The typeCode SHALL be 'SUBJ' and inversionInd SHALL be 'true'.

4.3.3.15.12 <!-- zero or one <entryRelationship typeCode='REFR' inversionInd='false'> elements containing clinical status -->

An optional <entryRelationship> may be present indicating the clinical status of the allergy, e.g., resolved, in remission, active. When present, this <entryRelationship> element shall contain a clinical status observation conforming to the Problem Status Observation template (1.3.6.1.4.1.19376.1.5.3.1.4.1.1). The typeCode SHALL be 'REFR' and inversionInd SHALL be 'false'. For CDA this SHALL be represented with the <entryRelationship> element. For HL7 Version 3 Messages, this SHALL be represented as a <sourceOf> element.

4.3.3.15.13 <!-- zero to many <entryRelationship typeCode='SUBJ' inversionInd='true'> element containing comments -->

One or more optional <entryRelationship> elements may be present providing an additional comments (annotations) for the allergy. When present, this <entryRelationship> element shall contain an entry conforming to the Comment entry

template (1.3.6.1.4.1.19376.1.5.3.1.4.2). The typeCode SHALL be 'SUBJ' and inversionInd SHALL be 'true'.

For CDA this SHALL be represented with the <entryRelationship> element. For HL7 Version 3 Messages, this SHALL be represented as a <sourceOf> element.

4.3.3.16 Medications 1.3.6.1.4.1.19376.1.5.3.1.4.7

This content module describes the general structure for a medication. All medication administration acts will be derived from this content module.

4.3.3.16.1 Standards

Pharmacy	HL7 Pharmacy Domain (Normative)
CCD	ASTM/HL7 Continuity of Care Document

4.3.3.16.2 Specification

```
<substanceAdministration classCode='SBADM' moodCode='INT|EVN'>
  <templateId root='2.16.840.1.113883.10.20.1.24'/>
  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7'/>
  <templateId root=''/>
  <id root='' extension=''/>
  <code code='' codeSystem='' displayName='' codeSystemName=''/>
  <text><reference value='#med-1'/></text>
  <statusCode code='completed'/>
  <effectiveTime xsi:type='IVL_TS'>
      <low value=''/>
      <high value=''/>
  </effectiveTime>
  <effectiveTime operator='A' xsi:type='TS|PIVL_TS|EIVL_TS|PIVL_PPD_TS|SXPR_TS'>
    :
  </effectiveTime>
  <routeCode code='' codeSystem='' displayName='' codeSystemName=''>
  <doseQuantity value='' unit=''/>
  <approachSiteCode code='' codeSystem='' displayName='' codeSystemName=''>
  <rateQuantity value='' unit=''/>
  <consumable>
    :
    .
  </consumable>
  <!-- 0..* entries describing the components -->
  <entryRelationship typeCode='COMP' >
      <sequenceNumber value=''/>
  </entryRelationship>
  <!-- An optional entry relationship that indicates the the reason for use -->
  <entryRelationship typeCode='RSON'>
    <act classCode='ACT' moodCode='EVN'>
      <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.4.1'/>
      <id root='' extension=''/>
    </act>
  </entryRelationship>
  <!-- An optional entry relationship that provides prescription activity -->
  <entryRelationship typeCode='REFR'>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7.3'/>
      :
      .
  </entryRelationship>
  <precondition>
    <criterion>
      <text><reference value=''></text>
    </criterion>
  </precondition>
</substanceAdministation>
```

This section makes use of the linking, severity and instruction entries.

Medications are perhaps the most difficult data elements to model due to variations in the ways that medications are prescribed. This profile identifies the following relevant fields of a medication as being important to be able to generate in a medical summary. The table below identifies and describes these fields, and indicates the constraints on whether or not they are required to be sent. The fields are listed in the order that they appear in the CDA XML content.

4.3.3.16.2.1 Medication Fields

Field	Opt	CDA Tag	Description
Start and Stop Date	R2	<effectiveTime>	The date (and time if available) when the medication regimen began and is expected to finish. The first component of the <effectiveTime> encodes the lower and upper bounds over which the <substanceAdministration> occurs, and the start time is determined from the lower bound. If the medication has been known to be stopped, the high value must be present, but expressed as a flavor of null (e.g., Unknown).
Frequency	R2	<effectiveTime>	The frequency indicates how often the medication is to be administered. It is often expressed as the number of times per day, but which may also include information such as 1 hour before/after meals, or in the morning, or evening.The second <effectiveTime> element encodes the frequency. In cases where split or tapered doses are used, these may be found in subordinate <substanceAdministration> elements.
Route	R2	<routeCode>	The route is a coded value, and indicates how the medication is received by the patient (by mouth, intravenously, topically, et cetera).
Dose	R2	<doseQuantity>	The amount of the medication given. This should be in some known and measurable unit, such as grams, milligrams, et cetera. It may be measured in "administration" units (such as tablets or each), for medications where the strength is relevant. In this case, only the unit count is specified , no units are specified. It may be a range.
Site	O	<approachSiteCode>	The site where the medication is administered, usually used with IV or topical drugs.
Rate	R2	<rateQuantity>	The rate is a measurement of how fast the dose is given to the patient over time (e.g., .5 liter / 1 hr), and is often used with IV drugs.
Product	R	<consumable> <name> </consumable>	The name of the substance or product. This should be sufficient for a provider to identify the kind of medication. It may be a trade name or a generic name. This information is required in all medication entries. If the name of the medication is unknown, the type, purpose or other description may be supplied. The name should not include packaging, strength or dosing information.Note: Due to restrictions of the CDA schema, there is no way to explicitly link the name to the narrative text.
Strength	R2	<consumable> <code> <originalText/> </code> </consumable>	The name and strength of the medication. This information is only relevant for some medications, as the dose of the medication is often sufficient to indicate how much medication the patient receives. For example, the medication Percocet comes in a variety of strengths, which indicate specific amounts of two different medications being received in single tablet. Another example is eye-drops, where the medication is in a solution of a particular strength, and the dose quantity is some number of drops. The originalText referenced by the <code> element in the consumable should refer to the name and strength of the medication in the narrative text.Note: Due to restrictions of the CDA schema, there is no way to separately record the strength.
Code	R2	<consumable> <code/> </consumable>	A code describing the product from a controlled vocabulary, such as RxNorm, First DataBank, et cetera.
Instructions	R2	<entryRelationship>	A place to put free text comments to support additional relevant information, or to deal with specialized dosing instructions. For example, "take with food", or tapered dosing.
Indication	O	<entryRelationship>	A link to supporting clinical information about the reason for providing the medication (e.g., a link to the relevant diagnosis).

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

The general model is to record each prescribed medication in a <substanceAdministration> intent (moodCode='INT'). Medications that have been reported by the patient or administered (instead of prescribed), are recorded in the same element, except that this is now an event (moodCode='EVN'). The <substanceAdministration> element may contain subordinate <substanceAdministration> elements in a related component entry to deal with special cases (see the section below on Special Cases). These cases include split, tapered, or conditional dosing, or combination medications. The use of subordinate <substanceAdministration> elements to deal with these cases is optional. The comment field should always be used in these cases to provide the same information as free text in the top level <substanceAdministration> element. There are a variety of special cases for dosing that need to be accounted for. These are described below. Most of these special cases involve changing the dosage or frequency over time, or based on some measurement. When the dosage changes, then additional entries are required for each differing dosage. The last case deals with combination medications.

4.3.3.16.3.1 Normal Dosing 1.3.6.1.4.1.19376.1.5.3.1.4.7.1

This template identifier is used to identify medication administration events that do not require any special processing. The parent template is 1.3.6.1.4.1.19376.1.5.3.1.4.7. Medications that use this template identifier shall not use subordinate <substanceAdministation> acts.

4.3.3.16.3.2 Tapered Doses 1.3.6.1.4.1.19376.1.5.3.1.4.8

This template identifier is used to identify medication administration events that require special processing to handle tapered dosing. The parent template is 1.3.6.1.4.1.19376.1.5.3.1.4.7. A tapered dose is often used for certain medications where abrupt termination of the medication can have negative consequences. Tapered dosages may be done by adjusting the dose frequency, the dose amount, or both.

When merely the dose frequency is adjusted, (e.g., Prednisone 5mg b.i.d. for three days, then 5mg. daily for three days, and then 5mg every other day), then only one medication entry is needed, multiple frequency specifications recorded in <effectiveTime> elements. When the dose varies (eg. Prednisone 15mg daily for three days, then 10 mg daily for three days, the 5 mg daily for three days), subordinate medication entries should be created for each distinct dosage.

4.3.3.16.3.3 Split Dosing 1.3.6.1.4.1.19376.1.5.3.1.4.9

This template identifier is used to identify medication administration events that require special processing to handle split dosing. The parent template is 1.3.6.1.4.1.19376.1.5.3.1.4.7. A split dose is often used when different dosages are given at different times (e.g., at different times of day, or on different days). This may be to account for different metabolism rates at different times of day, or to simply address drug packaging deficiencies (e.g., and order for Coumadin 2mg on even days, 2.5mg on odd

days is used because Coumadin does not come in a 2.25mg dose form). In this case a subordinate <substanceAdministration> entry is required for each separate dosage.

4.3.3.16.3.4 Conditional Dosing 1.3.6.1.4.1.19376.1.5.3.1.4.10

This template identifier is used to identify medication administration events that require special processing to handle conditional dosing. The parent template is 1.3.6.1.4.1.19376.1.5.3.1.4.7. A conditional dose is often used when the dose amount differs based on some measurement (e.g., an insulin sliding scale dose based on blood sugar level). In this case a subordinate <substanceAdministration> entry is required for each different dose, and the condition should be recorded.

4.3.3.16.3.5 Combination Medications 1.3.6.1.4.1.19376.1.5.3.1.4.11

This template identifier is used to identify medication administration events that require special processing to handle combination medications. The parent template is 1.3.6.1.4.1.19376.1.5.3.1.4.7. A combination medication is made up of two or more other medications. These may be prepackaged, such as Percocet, which is a combination of Acetaminophen and oxycodone in predefined ratios, or prepared by a pharmacist, such as a GI cocktail.

In the case of the prepackaged combination, it is sufficient to supply the name of the combination drug product, and its strength designation in a single <substanceAdministation> entry. The dosing information should then be recorded as simply a count of administration units.

In the latter case of a prepared mixture, the description of the mixture should be provided as the product name (e.g., "GI Cocktail") , in the <substanceAdministration> entry. That entry may, but is not required, to have subordinate <substanceAdministration> entries included beneath it to record the components of the mixture.

4.3.3.16.4 <templateId root='2.16.840.1.113883.10.20.1.24'/> <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7' />

All medications entries use the <templateId> elements specified above to indicate that they are medication acts. This element is required. In addition, a medication entry shall further identify itself using one of the template identifiers detailed in the next section.

4.3.3.16.5 <templateId root=' ' />

The <templateId> element identifies this <entry> as a particular type of medication event, allowing for validation of the content. As a side effect, readers of the CDA can quickly locate and identify medication events. The templateId must use one of the values in the table below for the root attribute.

Root	Description
1.3.6.1.4.1.19376.1.5.3.1.4.7.1	A "normal" <substanceAdministration> act that may not contain any subordinate <substanceAdministration> acts.
1.3.6.1.4.1.19376.1.5.3.1.4.8	A <substanceAdministration> act that records tapered dose information in subordinate <substanceAdministration> act.
1.3.6.1.4.1.19376.1.5.3.1.4.9	A <substanceAdministration> act that records split dose information in subordinate <substanceAdministration> acts.
1.3.6.1.4.1.19376.1.5.3.1.4.10	A <substanceAdministration> act that records conditional dose information in subordinate <substanceAdministration> acts.
1.3.6.1.4.1.19376.1.5.3.1.4.11	A <substanceAdministration> act that records combination medication component information in subordinate <substanceAdministration> acts.

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

A top level <substanceAdministration> element must be uniquely identified. If there is no explicit identifier for this observation in the source EMR system, a GUID may be used for the root attribute, and the extension may be omitted. Although HL7 allows for multiple identifiers, this profile requires that one and only one be used. Subordinate <substanceAdministration> elements may, but need not be uniquely identified.

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

Do NOT code the medication here. This <code> element is used to supply a code that describes the <substanceAdminstration> act, not the medication being administered or prescribed. This may be a procedure code, such as those found in CPT-4 (and often used for billing), or may describe the method of medication administration, such as by intravenous injection. This element is optional.

4.3.3.16.8 <text><reference value=' '/></text>

The URI given in the value attribute of the <reference> element points to an element in the narrative content that contains the complete text describing the medication. In a CDA document, the URI given in the value attribute of the <reference> element points to an element in the narrative content that contains the complete text describing the medication. In an HL7 message, the content of the text element shall contain the complete text describing the medication.

4.3.3.16.9 <statusCode code='completed'/>

The status of all <substanceAdministration> elements must be "completed". The act has either occurred, or the request or order has been placed.

4.3.3.16.10 <effectiveTime xsi:type='IVL_TS'>

The first <effectiveTime> element encodes the start and stop time of the medication regimen. This an interval of time (xsi:type='IVL_TS'), and must be specified as shown.

This is an additional constraint placed upon CDA Release 2.0 by this profile, and simplifies the exchange of start/stop and frequency information between EMR systems.

4.3.3.16.11 <low value=' '/><high value=' '/>

The <low> and <high> values of the first <effectiveTime> element represent the start and stop times for the medication. The <low> value represents the start time, and the <high> value represents the stop time. If either the <low> or the <high> value is unknown, this shall be recorded by setting the nullFlavor attribute to UNK. The <high> value records the end of the medication regime according to the information provided in the prescription or order. For example, if the prescription is for enough medication to last 30 days, then the high value should contain a date that is 30 days later then the <low> value. The rationale is that a provider, seeing an un-refilled prescription would normally assume that the medication is no longer being taken, even if the intent of the treatment plan is to continue the medication indefinitely.

4.3.3.16.12 <effectiveTime operator='A' xsi:type='TS|PIVL_TS|EIVL_TS|PIVL_PPD_TS|SXPR_TS' />

The second <effectiveTime> element records the frequency of administration. This <effectiveTime> element must be intersected with the previous time specification (operator='A'), producing the bounded set containing only those time specifications that fall within the start and stop time of the medication regimen. Several common frequency expressions appear in the table below, along with their XML representations.

4.3.3.16.12.1 Specifying Medication Frequency

Freq	Description	XML Representation
b.i.d.	Twice a day	<effectiveTime xsi:type='PIVL_TS' institutionSpecified='true' operator='A'> <period value='12' unit='h' /></effectiveTime>
q12h	Every 12 hours	<effectiveTime xsi:type='PIVL_TS' institutionSpecified='false' operator='A'> <period value='12' unit='h' /></effectiveTime>
Once	Once, on 2005-09-01 at 1:18am.	<effectiveTime xsi:type='TS' value='200509010118'/>
t.i.d.	Three times a day, at times determined by the person administering the medication .	<effectiveTime xsi:type='PIVL_TS' institutionSpecified='true' operator='A'> <period value='8' unit='h' /></effectiveTime>
q8h	Every 8 hours	<effectiveTime xsi:type='PIVL_TS' institutionSpecified='false' operator='A'> <period value='8' unit='h' /></effectiveTime>
qam	In the morning	<effectiveTime xsi:type='EIVL' operator='A'> <event code='ACM'/></effectiveTime>
	Every day at 8 in the morning for 10 minutes	<effectiveTime xsi:type='PIVL_TS' operator='A'> <phase> <low value="198701010800" inclusive="true"/> <width value="10" unit="min"/> </phase> <period value='1' unit='d'/></effectiveTime>
q4-6h	Every 4 to 6 hours.	<effectiveTime xsi:type='PIVL_PPD_TS' institutionSpecified='false' operator='A'> <period value='5' unit='h' /> <standardDeviation value='1' unit='h'></effectiveTime>

The last frequency specification is about as bad as it gets, but can still be represented accurately within the HL7 V3 datatypes. The mean (average) of the low and high values is specified for the period. The mean of 4 and 6 is 5. The standard deviation is recorded as one half the difference between the high and low values, with an unspecified distribution. The type attribute of the <effectiveTime> element describes the kind of frequency specification it contains. More detail is given for each type in the table below.

4.3.3.16.12.2 Data types used in Frequency Specifications

xsi:type	Description
TS	An xsi:type of TS represents a single point in time, and is the simplest of all to represent. The value attribute of the <effectiveTime> element specifies the point in time in HL7 date-time format (CCYYMMDDHHMMSS)
PIVL_TS	An xsi:type of PIVL_TS is the most commonly used, representing a periodic interval of time. The <low> element of <phase> may be present. If so it specifies the starting point, and only the lower order components of this value are relevant with respect to the <period>. The <width> element represents the duration of the dose administration (e.g., for IV administration). The <period> indicates how often the dose is given. Legal values for the unit attribute of <period> are s, min, h, d, wk and mo representing seconds, minutes, hours, days, weeks, and months respectively.
EIVL_TS	An xsi:type of EIVL_TS represents an event based time interval, where the event is not a precise time, but is often used for timing purposes (e.g. with meals, between meals, before breakfast, before sleep). Refer to the HL7 TimingEvent vocabulary for the codes to use for the <event> element. This interval may specify an <offset> which provides information about the time offset from the specified event (e.g., <offset><low value='-1' unit='h'/><width value='10' unit='min'/></offset> means 1 hour before the event. In that same example, the <width> element

	indicates the duration for the dose to be given.
PIVL_PPD_TS	An xsi:type of PIVL_PPD_TS represents an probabilistic time interval and is used to represent dosing frequencies like q4-6h. This profile requires that the distributionType of this interval be left unspecified. The <period> element specifies the average of the time interval, and the value of the <standardDeviation> shall be computed as half the width of the interval. The unit attributes of the <period> and <standardDeviation> elements shall be the same.
SXPR_TS	An xsi:type of SXPR_TS represents a parenthetical set of time expressions. This type is used when the frequency varies over time (e.g., for some cases of tapered dosing, or to handle split dosing). The <comp> elements of this <effectiveTime> element are themselves time expressions (using any of the types listed above). Each <comp> element may specify an operator (e.g. to intersect or form the union of two sets).

4.3.3.16.13 <routeCode code=' ' displayName=' ' codeSystem='2.16.840.1.113883.5.112' codeSystemName='RouteOfAdministration'>

The <routeCode> element specifies the route of administration using the HL7 RouteOfAdministration vocabulary. A code must be specified if the route is known, and the displayName attribute should be specified. If the route is unknown, this element shall not be sent.

4.3.3.16.14 <approachSiteCode code=' ' codeSystem=' '> originalText><reference value=' '/></originalText> </approachSiteCode>

The <approachSiteCode> element describes the site of medication administrion. It may be coded to a controlled vocabulary that lists such sites (e.g., SNOMED-CT). In CDA documents, this element contains a URI in the value attribute of the <reference> that points to the text in the narrative identifying the site. In a message, the <originalText> element shall contain the text identifying the site.

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

The dose is specified if the <doseQuantity> element. If a dose range is given (e.g., 1-2 tablets, or 325-750mg), then the <low> and <high> bounds are specified in their respective elements, otherwise both <low> and <high> have the same value. If the dose is in countable units (tablets, caplets, "eaches"), then the unit attribute is not sent. Otherwise the units are sent. The unit attribute should be derived from the HL7 UnitsOfMeasureCaseSensitive vocabulary .

4.3.3.16.16 <low|high value=' '> <translation> <originalText><reference value=' '/></originalText> </translation></low|high >

Any <low> and <high> elements used for <doseQuantity> or <rateQuantity> should contain a <translation> element that provides a <reference> to the <originalText> found in the narrative body of the document. In a CDA document, any <low> and <high> elements used for <doseQuantity> or <rateQuantity> should contain a <translation> element that provides a <reference> to the <originalText> found in the narrative body of

the document. In a message, the <originalText> may contain the original text used to describe dose quantity.

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

The rate is specified in the <rateQuantity> element. The rate is given in units that have measure over time. In this case, the units should be specified as a string made up of a unit of measure (see doseQuantity above), followed by a slash (/), followed by a time unit (s, min, h or d).

Again, if a range is given, then the <low> and <high> elements contain the lower and upper bound of the range, otherwise, they contain the same value.

4.3.3.16.18 <consumable>

The <consumable> element shall be present, and shall contain a <manufacturedProduct> entry conforming to the Product Entry template

4.3.3.16.19 <entryRelationship typeCode='REFR'> &nsbp;<templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7.3'/>

The top level <substanceAdministration> element may contain a reference (typeCode='REFR') to related prescription activity as described in section 5.4.4.16.

4.3.3.16.20 <entryRelationship typeCode='COMP'> <sequenceNumber value=' '>

A top level <substanceAdministration> element may contain one or more related components, either to handle split, tapered or conditional dosing, or to support combination medications.

In the first three cases, the subordinate components shall specify only the changed <frequency> and/or <doseAmount> elements. For conditional dosing, each subordinate component shall have a <precondition> element that specifies the <observation> that must be obtained before administration of the dose. The value of the <sequenceNumber> shall be an ordinal number, starting at 1 for the first component, and increasing by 1 for each subsequent component. Components shall be sent in <sequenceNumber> order.

4.3.3.16.21 <entryRelationship typeCode='SUBJ' inversionInd='true'/>

At most one instruction may be provided for each <substanceAdministration> entry. If provided, it shall conform to the requirements listed above under section 5.4.4.6 on medication instructions. The instructions shall contain any special case dosing instructions (e.g., split, tapered, or conditional dosing), and may contain other information (take with food, et cetera).

4.3.3.16.22 <entryRelationship typeCode='RSON'> <act classCode='ACT' moodCode='EVN'> <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.4.1'/> <id root=' ' extension=' '/>


```
 </act>
</entryRelationship>
```

A <substanceAdministration> event may indicate one or more reasons for the use of the medication. These reasons identify the concern that was the reason for use via the Internal Reference entry content module specified in section 5.4.4.8.2.

The extension and root of each observation present must match the identifier of a concern entry contained elsewhere within the CDA document.

A consumer of the Medical Summary is encouraged, but not required to maintain these links on import.

4.3.3.16.23 <precondition><criterion>

```
 <text><reference value=' '></text>
</criterion></precondition>
```

In a CDA document, the preconditions for use of the medication are recorded in the <precondition> element. The value attribute of the <reference> element is a URL that points to the CDA narrative describing those preconditions.

4.3.3.16.24 <condition typeCode='PRCN'>

```
 <criterion>
  <text></text>
  <value nullFlavor='UNK'/>
  <interpretationCode nullFlavor='UNK'/>
 </criterion>
</condition>
```

In a message, the preconditions for use of the medication are recorded in the <condition> element. The typeCode shall be PRCN. The <text> element of the criterion shall contain a text description of the precondition. The <value> element is required, and may be recorded in a structured data type if known, and if not, may be recorded using a nullFlavor as shown above. The same is true for <interpretationCode>.

4.3.3.17 Immunizations 1.3.6.1.4.1.19376.1.5.3.1.4.12

An immunizations entry is used to record the patient's immunization history.

4.3.3.17.1 Specification

```
<substanceAdministration typeCode='SBADM' moodCode='EVN' negationInd='true{{!}}false'>
  <templateId root='2.16.840.1.113883.10.20.1.24'/>
  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.12'/>

  <id root='' extension=''/>
  <code code='IMMUNIZ' codeSystem='2.16.840.1.113883.5.4' codeSystemName='ActCode'/>
  <text><reference value='#xxx'/><text>
  <statusCode code='completed'/>
  <effectiveTime value=''/>
  <!-- The reasonCode would normally provide a reason why the immunization was
    not performed.  It isn't supported by CDA R2, and so comments will have to suffice.
    <reasonCode code='' codeSystem='' codeSystemName='ActNoImmunizationReasonIndicator'/>
  -->
  <routeCode code='' codeSystem='' codeSystemName='RouteOfAdministration'/>
  <approachSiteCode code='' codeSystem=''
codeSystemName='HumanSubstanceAdministrationSite'/>
  <doseQuantity value='' units=''/>
  <consumable typeCode='CSM'>
    <manufacturedProduct classCode='MANU'>
      <manufacturedLabeledDrug classCode='MMAT' determinerCode='KIND'>
        <code code='' codeSystem='' codeSystemName=''>
          <originalText><reference value='#yyy'/></originalText>
        </code>
      </manufacturedLabeledDrug>
    </manufacturedProduct>
  </consumable>
  <!-- An optional entry relationship that provides prescription activity -->
  <entryRelationship typeCode='REFR'>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7.3'/>
      :
      .
  </entryRelationship>
  <!-- An optional entry relationship that identifies the immunization series number -->
  <entryRelationship typeCode='SUBJ'>
    <observation typeCode='OBS' moodCode='EVN'>
      <templateId root='2.16.840.1.113883.10.20.1.46'/>
      <code code='30973-2' displayName='Dose Number'
        codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
      <statusCode code='completed'/>
      <value xsi:type='INT' value=''/>
    </observation>
  </entryRelationship>

  <entryRelationship inversionInd='true' typeCode='CAUS'>
    <observation typeCode='OBS' moodCode='EVN'>
      <id root='' extension=''/>
    </observation>
  </entryRelationship>
  <!-- Optional <entryRelationship> element containing comments -->
</substanceAdministration>
```

4.3.3.17.2 <substanceAdministration typeCode='SBADM' moodCode='EVN' negationInd='true|false'>

An immunization is a substance administration event. An immunization entry may be a record of why a specific immunization was not performed. In this case, negationInd shall be set to "true", otherwise, it shall be false.

4.3.3.17.3 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.12'/>

The <templateId> element identifies this <substanceAdministration> as an immunization, allowing for validation of the content. The templateId must have root='1.3.6.1.4.1.19376.1.5.3.1.4.12'.

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

This shall be the identifier for the immunization event.

4.3.3.17.5 <code code='IMMUNIZ' codeSystem='2.16.840.1.113883.5.4' codeSystemName='ActCode'/>

This required element records that the act was an immunization. The substance administration act must have a <code> element with code and codeSystem attributes present. If no coding system is used by the source, then simply record the code exactly as shown above. Another coding system that may be used for codes for immunizations are the CPT-4 codes for immunization procedures. This <code> element shall not be used to record the type of vaccine used from a vocabulary of drug names.

codeSystem	codeSystemName	Description
2.16.840.1.113883.5.4	IMMUNIZ	The IMMUNIZ term from the HL7 ActCode vocabulary.
2.16.840.1.113883.6.12	C4	Current Procedure Terminology 4 (CPT-4) codes.

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

In a CDA document, the URI given in the value attribute of the <reference> element points to an element in the narrative content that contains the complete text describing the immunization activity. In an HL7 message, the content of the text element shall contain the complete text describing the immunization activity.

4.3.3.17.7 <statusCode code='completed'/>

The statusCode shall be set to "completed" for all immunizations.

4.3.3.17.8 <effectiveTime value=' '/>

The effectiveTime element shall be present and should contain a time value that indicates the date of the substance administration. If the date is unkown, this shall be recorded using the nullFlavor attribute, with the reason that the information is unknown being specified. Otherwise, the date shall be recorded, and should have precision of at least the day.

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

See routeCode under Medications.

4.3.3.17.10 <approachSiteCode code=' ' codeSystem=' ' codeSystemName='HumanSubstanceAdministrationSite'/>

See approachSiteCode under Medications.

4.3.3.17.11 <doseQuantity value=' ' units=' '/>

See doseQuantity under Medications.

4.3.3.17.12 <consumable typeCode='CSM'>

See consumable under Medications.

4.3.3.17.13 <entryRelationship typeCode='REFR'> <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7.3'/>

The top level <substanceAdministration> element may contain a reference (typeCode='REFR') to related Supply entry

4.3.3.17.14 <entryRelationship typeCode='SUBJ'> <observation classCode='OBS' moodCode='EVN'> <templateId root='2.16.840.1.113883.10.20.1.46'/>

This optional entry relationship may be present to indicate that position of this immunization in a series of immunizations.

4.3.3.17.15 <code code='30973-2' displayName='Dose Number' codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>

The <code> element shall be present and must be recorded with the code and codeSystem attributes shown above. This element indicates that the observation describes the dose number for the immunization.

4.3.3.17.16 <statusCode code='completed'/>

The <statusCode> element shall be present, and must be recorded exactly as shown above. This element indicates that the observation has been completed.

4.3.3.17.17 <value xsi:type='INT' value=' '/>

The <value> element shall be present, and shall indicate the immunization series number in the value attribute.

4.3.3.17.18 <entryRelationship inversionInd='true' typeCode='CAUS'>

This repeatable element should be used to identify adverse reactions caused by the immunization.

4.3.3.17.19 <observation typeCode='OBS' moodCode='EVN'>

This element is required, and provides a pointer to the the adverse reaction caused by the immunization.

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

This element is required, and gives the identifier of the adverse reaction. The adverse reaction pointed to by this element shall be described in more detail using the Allergies entry, elsewhere in the document where this element was found.

4.3.3.17.21 <!-- Optional <entryRelationship> element containing comments -->

An immunization entry can have negationInd set to true to indicate that an immunization did not occur. In this case, it shall have at least one comment that provides an explaination for why the immunization did not take place . Other comments may also be present.

4.3.3.18 Supply Entry 1.3.6.1.4.1.19376.1.5.3.1.4.7.3

The supply entry describes a prescription activity.

4.3.3.18.1 Specification

```
<substanceAdministration classCode='SBADM' moodCode='INT|EVN'>
    :
    .
  <entryRelationship type='REFR' inversionInd='false'>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7.3'/>
    <sequenceNumber value=''/>
    <supply classCode='SPLY' moodCode='INT|EVN'>
      <templateId root='2.16.840.1.113883.10.20.1.34'/>
      <id root='' extension=''/>
      <repeatNumber value=''/>
      <quantity value='' unit=''/>
      <author>
        <time value=''/>
        <assignedAuthor>
          <id root='' extension=''/>
          <addr></addr>
          <telecom use='' value=''/>
          <assignedPerson><name></name></assignedPerson>
          <representedOrganization><name></name></representedOrganization>
        </assignedAuthor>
      </author>
      <performer typeCode='PRF'>
        <time value=''/>
        <assignedEntity>
          <id root='' extension=''/>
          <addr></addr>
          <telecom use='' value=''/>
          <assignedPerson><name></name></assignedPerson>
          <representedOrganization><name></name></representedOrganization>
        </assignedEntity>
      </performer>
      <!-- Optional Fulfillment instrctions -->
      <entryRelationship typeCode='SUBJ'>
      </entryRelationship>
    </supply>
  <entryRelationship>
</substanceAdministration>
```

4.3.3.18.2 <entryRelationship typeCode='REFR' inversionInd='false'>

A <substanceAdministration> act may reference (typeCode='REFR') a prescription activity in an <entryRelationship> element in a CDA document. In a message, the relationship is recorded using a <sourceOf> element instead of the <entryRelationship> element. The typeCode and inversionInd attributes, and the semantics remain identical.

4.3.3.18.3 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7.3'/>

The <entryRelationship> element shall contain a <templateId> element that appears exactly as shown above. This element identifies this entry as a prescription activity.

4.3.3.18.4 <sequenceNumber value=' '/>

The prescription activity may have a <sequenceNumber> element to indicate the fill number. A value of 1, 2 or N indicates that it is the first, second, or Nth fill respectively of a specific prescription. This element should be present when the embedded <supply> element has a moodCode attribute of EVN.

4.3.3.18.5 <supply classCode='SPLY' moodCode='INT|EVN'>

The <supply> element shall be present. The moodCode attribute shall be INT to reflect that a medication has been prescribed, or EVN to indicate that the prescription has been filled.

4.3.3.18.6 <templateId root='2.16.840.1.113883.10.20.1.34'/> <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7.3'/>

The <templateId> elements shown above shall be present, and identify this supply act as a Supply Entry.

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

Each supply act shall have an identifier to uniquely identify the supply entry.

4.3.3.18.8 <repeatNumber value=' '/>

Each supply entry should have a <repeatNumber> element that indicates the number of times the prescription can be filled.

4.3.3.18.9 <quantity value=' ' unit=' '/>

The supply entry should indicate the quantity supplied. The value attribute shall be present and indicates the quantity of medication supplied. If the medication is supplied in dosing units (tablets or capsules), then the unit attribute need not be present (and should be set to 1 if present). Otherwise, the unit element shall be present to indicate the quantity (e.g., volume or mass) of medication supplied.

4.3.3.18.10 <author>

A supply entry that describes an intent (<supply classCode='SPLY' moodCode='INT'>) may include an <author> element to identify the prescribing provider.

4.3.3.18.11 <time value=' '/>

The <time> element must be present to indicate when the author created the prescription. If this information is unknown, it shall be recorded by setting the nullFlavor attribute to UNK.

4.3.3.18.12 <assignedAuthor>

The <assignedAuthor> element shall be present, and identifies the author.

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

One or more <id> elements should be present. These identifiers identify the author of the act. When the author is the prescribing physician they may include local identifiers or regional identifiers necessary for prescribing.

4.3.3.18.14 <assignedPerson><name/></assignedPerson> <representedOrganization><name/></ representedOrganization>

An <assignedPerson> and/or <representedOriganization> element shall be present. This element shall contain a <name> element to identify the prescriber or their organization.

4.3.3.18.15 <performer typeCode='PRF'>

The <performer> element may be present to indicate who is intended (moodCode='INT'), or actually filled (moodCode='EVN') the prescription.

4.3.3.18.16 <time value=' '/>

The <time> element shall be present to indicate when the prescription was filled (moodCode='EVN'). If this information is unknown, it shall be recorded by setting the nullFlavor attribute to UNK.

The <time> element should be present to indicate when the prescription is intended to be filled (moodCode='INT').

4.3.3.18.17 <assignedEntity>

The < assignedEntity> element shall be present, and identifies the filler of the prescription.

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

One or more <id> elements should be present. These identify the performer.

4.3.3.18.19 <assignedPerson><name/></assignedPerson> <representedOrganization><name/></ representedOrganization>

An <assignedPerson> and/or <representedOriganization> element shall be present. This element shall contain a <name> element to identify the filler or their organization.

4.3.3.18.20 <!-- Optional Fulfillment instrctions --> <entryRelationship typeCode='SUBJ'> </entryRelationship>

An entry relationship may be present to provide the fulfillment instructions. When present, this entry relationship shall contain a Medication Fulfillment Instructions entry.

4.3.3.19 Product Entry 1.3.6.1.4.1.19376.1.5.3.1.4.7.2

The product entry describes a medication or immunization used in a <substanceAdministration> or <supply> act. It adopts the constraints of the ASTM/HL7 Continuity of Care Document.

4.3.3.19.1 Specification

```
<!-- Within a CDA Document -->
<manufacturedProduct>
  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7.2'/>
  <templateId root='2.16.840.1.113883.10.20.1.53'/>
  <manufacturedMaterial>
    <code code='' displayName='' codeSystem='' codeSystemName=''>
      <originalText><reference value=''/></originalText>
    </code>
    <name></name>
  </manufacturedMaterial>
</manufacturedProduct>
<!-- Within a message -->
<administerableMaterial>
  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7.2'/>
  <templateId root='2.16.840.1.113883.10.20.1.53'/>
    <administerableMaterial>
        <code></code>
    <desc></desc>
  </administerableMaterial>
</administerableMaterial>
```

4.3.3.19.2<manufacturedProduct> -OR- <administerableMaterial> <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7.2'/> <templateId root='2.16.840.1.113883.10.20.1.53'/> <manufacturedMaterial> -OR- <administerableMaterial>

In a CDA document, the name and strength of the medication are specified in the elements under the <manufacturedMaterial> element. In a message, the are contained within the <administeredMaterial> element, inside another <administerableMaterial> element[1]. The templateId elements are required and identify this as a product entry.

[1] This duplication of element names is an artifact of the standard.

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

The <code> element of the <manufacturedMaterial> describes the medication. This may be coded using a controlled vocabulary, such as RxNorm, First Databank, or other vocabulary system for medications, and should be the code that represents the generic medication name and strength (e.g., acetaminophen and oxycodone -5/325), or just the generic medication name alone if strength is not relevant (Acetaminophen).

In a CDA document, the <originalText> shall contain a <reference> whose URI value points to the generic name and strength of the medication, or just the generic name alone if strength is not relevant. Inside a message, the <originalText> may contain the actual text that describes the medication in similar fashion.

Note: When the text is supplied from the narrative, the implication is that if you supply the components of a combination medication in an entry, you must also display these in the narrative text; otherwise you would not be able to break the combination medication down into its component parts. This is entirely consistent with the CDA Release 2.0 requirements that the narrative supply the necessary and relevant human readable information content.

The <code> element is also used to support coding of the medication. If coded, it must provide a code and codeSystem attribute using a controlled vocabulary for medications. The displayName for the code and codeSystemName should be provided as well for diagnostic and human readability purposes, but are not required. The table below provides the codeSystem and codeSystemName for several controlled terminologies that may be used to encode medications and/or immunizations.

codeSystem	codeSystemName	Description
2.16.840.1.113883.6.88	RxNorm	RxNorm
2.16.840.1.113883.6.69	NDC	National Drug Codes
2.16.840.1.113883.6.63	FDDC	First DataBank Drug Codes
2.16.840.1.113883.6.96	SNOMED-CT	SNOMED Controlled Terminology
2.16.840.1.113883.6.59	CVX	CDC Vaccine Codes

The code used for an immunization may use code systems other than what might be used for other medications, such as the CDC maintained CVX codes. Code systems that describe vaccination *procedures* (such as CPT-4) shall not be used to describe the vaccine entry.

4.3.3.19.4 <name> -OR- <desc>

In a CDA document, the <name> element should contain the brand name of the medication (or active ingredient in the case of subordinate <substanceAdministration> elements used to record components of a medication). Within a message, this information shall be provided in the <desc> element.

4.3.3.20 Simple Observations 1.3.6.1.4.1.19376.1.5.3.1.4.13

The simple observation entry is meant to be an abstract representation of many of the observations used in this specification. It can be made concrete by the specification of a few additional constraints, namely the vocabulary used for codes, and the value representation. A simple observation may also inherit constraints from other specifications (e.g., ASTM/HL7 Continuity of Care Document).

4.3.3.20.1 Specification

```
<observation typeCode='OBS' moodCode='EVN'>
  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13'/>
  <id root='' extension=''/>
  <code code='' displayName='' codeSystem='' codeSystemName=''/>
  <!-- for CDA -->
  <text><reference value='#xxx'/></text>
  <!-- For HL7 Version 3 Messages
  <text>text</text>
  -->
  <statusCode code='completed'/>
  <effectiveTime value=''/>
  <repeatNumber value=''/>
  <value xsi:type='' …/>
  <interpretationCode code='' codeSystem='' codeSystemName=''/>
  <methodCode code='' codeSystem='' codeSystemName=''/>
  <targetSiteCode code='' codeSystem='' codeSystemName=''/>
  <author typeCode='AUT'>
    <assignedAuthor typeCode='ASSIGNED'><id></assignedAuthor> <!-- for CDA -->
    <!-- For HL7 Version 3 Messages
    <assignedEntity typeCode='ASSIGNED'>
       <Person classCode='PSN'>
          <determinerCode root=''>
          <name>…</name>
       </Person>
    <assignedEntity>
     -->
  </author>
</observation>
```

4.3.3.20.2 <observation typeCode='OBS' moodCode='EVN'>

These acts are simply observations that have occurred, and so are recored using the <observation> element as shown above.

4.3.3.20.3 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13'/>

The <templateId> element identifies this <observation> as a simple observation, allowing for validation of the content. The templateId must appear as shown above.

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

Each observation shall have an identifier.

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

Observations shall have a code describing what was measured. The code system used is determined by the vocabulary constraints on the types of measurements that might be recorded in a section. Content modules that are derived from the Simple Observation content module may restrict the code system and code values used for the observation.

4.3.3.20.6 <text><reference value='#xxx'/></text> -OR- <text>text</text>

Each observation measurement entry may contain a <text> element providing the free text that provides the same information as the observation within the narrative portion of the document with a <text> element. For CDA based uses of Simple Observations, this element SHALL be present, and SHALL contain a <reference> element that points to the

related string in the narrative portion of the document. For HL7 Version 3 based uses, the <text> element MAY be included.

4.3.3.20.7 <statusCode code='completed'/>

The status code of all observations shall be completed.

4.3.3.20.8 <effectiveTime value=' '/>

The <effectiveTime> element shall be present in standalone observations , and shall record the date and time when the measurement was taken. This element should be precise to the day. If the date and time is unknown, this element should record that using the nullFlavor attribute.

4.3.3.20.9 <value xsi:type=' ' …/>

The value of the observation shall be recording using a data type appropriate to the observation. Content modules derived from the Simple Observation content module may restrict the allowable data types used for the observation.

4.3.3.20.10 <interpretationCode code=' ' codeSystem=' ' codeSystemName=' '/>

If there is an interpretation that can be performed using an observation result (e.g., high, borderline, normal, low), these may be recorded within the interpretationCode element.

4.3.3.20.11 <methodCode code=' ' codeSystem=' ' codeSystemName=' '/>

The methodCode element may be used to record the specific method used to make an observation when this information is not already pre-coordinated with the observation code .

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

The targetSiteCode may be used to record the target site where an observation is made when this information is not already pre-coordinated with the observation code.

4.3.3.20.13 <author><assignedAuthor classCode='ASSIGNED'>...<assignedAuthor></author>

In CDA uses, SimpleObservaions are assumed to be authored by the same author as the document through context conduction. However specific authorship of observation may be represented by listing the author in the header and referencing the author in a <author> relationship. If authors are explicitly listed in documents, an <id> element SHOULD reference the ID of the author in the header through an assignedAuthor Role. If the author of the observation is not an author of the document the <person> object including a name and ID SHALL be included.

For HL7 Version 3 purposes, the <author> element SHOULD be present unless it can be determined by conduction from organizers or higher level structures. When used for HL7

Version 3 the role element name is <assignedEntity> and the author is represented a <assignedPerson> element.

4.3.3.21 Vital Signs Organizer 1.3.6.1.4.1.19376.1.5.3.1.4.13.1

A vital signs organizer collects vital signs observations.

4.3.3.21.1 Specification

```
<organizer classCode='CLUSTER' moodCode='EVN'>
  <templateId root='2.16.840.1.113883.10.20.1.32'/>
  <templateId root='2.16.840.1.113883.10.20.1.35'/>
  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13.1'/>
  <id root='' extension=''/>
  <code code='46680005' displayName='Vital signs'
    codeSystem='2.16.840.1.113883.6.96' codeSystemName='SNOMED CT'/>
  <statusCode code='completed'/>
  <effectiveTime value=''/>
  <!-- For HL7 Version 3 Messages
  <author classCode='AUT'>
     <assignedEntity1 typeCode='ASSIGNED'>
        :
     <assignedEntity1>
  </author>
  -->
  <!-- one or more vital signs observations -->
  <component typeCode='COMP'>
    <observation classCode='OBS' moodCode='EVN'>
      <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13.2'/>
        :
    </observation>
  </component>
</organizer>
```

4.3.3.21.2 <organizer classCode='CLUSTER' moodCode='EVN'>

The vital signs organizer is a cluster of vital signs observations.

4.3.3.21.3 <templateId root='2.16.840.1.113883.10.20.1.32'/> <templateId root='2.16.840.1.113883.10.20.1.35'/> <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13.1'/>

The vital signs organizer shall have the <templateId> elements shown above to indicate that it inherits constraints from the ASTM/HL7 CCD Specification for Vital signs, and the constraints of this specification.

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

The organizer shall have an <id> element.

4.3.3.21.5 <code code='46680005' displayName='Vital signs' codeSystem='2.16.840.1.113883.6.96' codeSystemName='SNOMED CT'/>

The <code> element shall be recorded as shown above to indicate that this organizer captures information about patient vital signs.

4.3.3.21.6 <statusCode code='completed'/>

The observations have all been completed.

4.3.3.21.7 <effectiveTime value=' '/>

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

4.3.3.21.8 <author typeCode='AUT'><assignedEntity1 typeCode='ASSIGNED'>...</assignedEntity1></author>

For use with HL7 Version 3, Vital Sign organizers SHALL contain an <author> element to represent the person or device.

4.3.3.21.9 <!-- one or more vital signs observations --> <component typeCode='COMP'>

The organizer shall have one or more <component> elements that are <observation> elements using the Vital Signs Observation template.

4.3.3.22 Vital Signs Observation 1.3.6.1.4.1.19376.1.5.3.1.4.13.2

A vital signs observation is a simple observation that uses a specific vocabulary, and inherits constraints from CCD.

4.3.3.22.1 Specification

```
<observation classCode='OBS' moodCode='EVN'>
 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13'/>
 <templateId root='2.16.840.1.113883.10.20.1.31'/>
 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13.2'/>
 <id root=' ' extension=' '/>
 <code code=' ' codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
 <text><reference value='#xxx'/></text>
 <statusCode code='completed'/>
 <effectiveTime value=' '/>
 <repeatNumber value=' '/>
 <value xsi:type='PQ' value=' ' unit=' '/>
 <interpretationCode code=' ' codeSystem=' ' codeSystemName=' '/>
 <methodCode code=' ' codeSystem=' ' codeSystemName=' '/>
 <targetSiteCode code=' ' codeSystem=' ' codeSystemName=' '/>
</observation>
```

4.3.3.22.2 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13'/> <templateId root='2.16.840.1.113883.10.20.1.31'/> <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13.2'/>

A vital signs observation shall have the <templateId> elements shown above to indicate that it inherits constraints from the ASTM/HL7 CCD Specification for Vital signs, and the constraints of this specification.

4.3.3.22.3 <code code=' ' codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>

A vital signs observation entry shall use one of the following LOINC codes, with the specified data types and units.

LOINC	Description	Units	Type
9279-1	RESPIRATION RATE	/min	PQ
8867 4	HEART BEAT		
2710-2	OXYGEN SATURATION	%	
8480-6	INTRAVASCULAR SYSTOLIC	mm[Hg]	
8462-4	INTRAVASCULAR DIASTOLIC		
8310-5	BODY TEMPERATURE	Cel or [degF]	
8302-2	BODY HEIGHT (MEASURED)	m, cm,[in_us] or [in_uk]	
8306-3	BODY HEIGHT^LYING		
8287-5	CIRCUMFRENCE.OCCIPITAL-FRONTAL (TAPE MEASURE)		
3141-9	BODY WEIGHT (MEASURED)	kg, g, [lb_av] or [oz_av]	

4.3.3.22.4 <value xsi:type='PQ' value=' ' unit=' '/>

The <value> element shall be present, and shall be of the appropriate data type specified for measure in the table above.

4.3.3.22.5 <interpretationCode code=' ' codeSystem=' ' codeSystemName=' '/>

The interpretation code may be present to provide an interpretation of the vital signs measure (e.g., High, Normal, Low, et cetera).

4.3.3.22.6 <methodCode code=' ' codeSystem=' ' codeSystemName=' '/>

The <methodCode> element may be present to indicate the method used to obtain the measure. Note that method used is distinct from, but possibly related to the target site.

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

The target site of the measure may be identified in the <targetSiteCode> element (e.g., Left arm [blood pressure], oral [temperature], et cetera).

4.3.3.23 Pregnancy Observation 1.3.6.1.4.1.19376.1.5.3.1.4.13.5

A pregnancy observation is a Simple Observation that uses a specific vocabulary to record observations about a patient's pregnancy history.

4.3.3.23.1 Parent Template

The parent of this template is Simple Observation.

4.3.3.23.2 Specification

```
<observation typeCode='OBS' moodCode='EVN'>
 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13'/>
 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13.5'/>
 <id root=' ' extension=' '/>
 <code code=' ' displayName=' ' codeSystem='2.16.840.1.113883.6.1'
codeSystemName='LOINC'/>
 <text><reference value='#xxx'/></text>
 <statusCode code='completed'/>
 <effectiveTime value=' '/>
 <repeatNumber value=' '/>
 <value xsi:type=' ' .../>
 <interpretationCode code=' ' codeSystem=' ' codeSystemName=' '/>
 <methodCode code=' ' codeSystem=' ' codeSystemName=/>
 <targetSiteCode code=' ' codeSystem=' ' codeSystemName=' '/>
</observation>
```

Figure 4.3-12 Pregnancy Observation Example

4.3.3.23.3 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13'/> <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13.5'/>

These <templateId> elements identify this <observation> as a pregnancy observation, allowing for validation of the content. The <templateId> elements shall be recorded as shown above.

4.3.3.23.4 <code code=' ' displayName=' ' codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>

A pregnancy observations shall have a LOINC code describing what facet of patient's pregnancy history is being recorded. These codes should come from the list of codes shown below. Additional codes may be used to reflect additional information about the pregnancy history.

Table 4.3-2 Pregnancy Observation Codes

LOINC CODE	Description	Type	Units or Vocabulary
Summary over All Pregnancies			
11636-8	BIRTHS LIVE (REPORTED)	QTY	N/A
11637-6	BIRTHS PRETERM (REPORTED)		
11638-4	BIRTHS STILL LIVING (REPORTED)		
11639-2	BIRTHS TERM (REPORTED)		
11640-0	BIRTHS TOTAL (REPORTED)		
11612-9	ABORTIONS (REPORTED)		
11613-7	ABORTIONS INDUCED (REPORTED)		
11614-5	ABORTIONS SPONTANEOUS (REPORTED)		
33065-4	ECTOPIC PREGNANCY (REPORTED)		
Detailed Pregnancy Data			
11449-6	PREGNANCY STATUS	CE	SNOMED CT, ICD-9-CM (V22)

8678-5	MENSTRUAL STATUS		SNOMED CT
8665-2	DATE LAST MENSTRUAL PERIOD	TS	N/A
11778-8	DELIVERY DATE (CLINICAL ESTIMATE)	TS	
11779-6	DELIVERY DATE (ESTIMATED FROM LAST MENSTRUAL PERIOD)		
11780-4	DELIVERY DATE (ESTIMATED FROM OVULATION DATE)		
11884-4	FETUS, GESTATIONAL AGE (CLINICAL ESTIMATE)	PQ	d, wk or mo
11885-1	FETUS, GESTATIONAL AGE (ESTIMATED FROM LAST MENSTRUAL PERIOD)		
11886-9	FETUS, GESTATIONAL AGE (ESTIMATED FROM OVULATION DATE)		
11887-7	FETUS, GESTATIONAL AGE (ESTIMATED FROM SELECTED DELIVERY DATE)		
45371-2	MULTIPLE PREGNANCY		

4.3.3.23.5 ~~<repeatNumber value=' '/>~~

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

4.3.3.23.6 <value xsi:type=' ' .../>

The value of the observation shall be recording using a data type appropriate to the coded observation according to the table above.

4.3.3.23.7 ~~<interpretationCode code=' ' codeSystem=' ' codeSystemName=' '/>~~ ~~<methodCode code=' ' codeSystem=' ' codeSystemName=' '/>~~ ~~<targetSiteCode code=' ' codeSystem=' ' codeSystemName=' '/>~~

The <interpretationCode>, <methodCode>, and <targetSiteCode> should not be present in a pregnancy observation.

4.3.3.24 Advance Directive Observation 1.3.6.1.4.1.19376.1.5.3.1.4.13.7

An advance directive observation is a simple observation that uses a specific vocabulary, and inherits constraints from CCD.

4.3.3.24.1 Standards

CCD ASTM/HL7 Continuity of Care Document

4.3.3.24.2 Specification

```
<observation typeCode='OBS' moodCode='EVN'>
 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13'/>
 <templateId root='2.16.840.1.113883.10.20.1.17'/>
 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13.7'/>
 <id root=' ' extension=' '/>
 <code code=' ' codeSystem='2.16.840.1.113883.6.96' codeSystemName='SNOMED CT'/>
 <text><reference value='#xxx'/></text>
 <statusCode code='completed'/>
 <effectiveTime value=' '/>
 <repeatNumber value=' '/>
 <value xsi:type='BL' value='true|false'/>
 <interpretationCode code=' ' codeSystem=' ' codeSystemName=' '/>
 <methodCode code=' ' codeSystem=' ' codeSystemName=' '/>
 <targetSiteCode code=' ' codeSystem=' ' codeSystemName=' '/>
 <reference typeCode='REFR'>
   <templateId root='2.16.840.1.113883.10.20.1.36'/>
   <externalDocument classCode='DOC' moodCode='EVN'>
     <id root=' ' extension=' '/>
     <text><reference value=' '/></text>
   </externalDocument>
 </reference>
</observation>
```

Figure 4.3-13 Advance Directive Observation Example

An advanced directive <observation> shall be represented as shown above. They shall not contain any <repeatNumber>, <interpretationCode>, <methodCode> or <targetSiteCode> elements.

4.3.3.24.3 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13'/> <templateId root='2.16.840.1.113883.10.20.1.17'/> <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13.7'/>

The <templateId> elements shown above shall be present, and indicated that this is an Advance Directive entry.

4.3.3.24.4 <code code=' ' codeSystem='2.16.840.1.113883.6.96' codeSystemName='SNOMED CT'/>

The <code> element records the type of advance directive. It should use one of the following SNOMED codes in the table below.

Table 4.3-3 Advance Directive Type Codes

Code	Description	Data Type
304251008	Resuscitation	BL
52765003	Intubation	
225204009	IV Fluid and Support	
89666000	CPR	
281789004	Antibiotics	
78823007	Life Support	
61420007	Tube Feedings	
116859006	Transfusion of blood product	
71388002	Other Directive	<value> not permitted

4.3.3.24.5 <value xsi:type='BL' value='true|false'/>

The advance directive observation may include a <value> element using the Boolean (xsi:type='BL') data type to indicate simply whether the procedure described is permitted. Absence of the <value> element indicates that an advance directive of the specified type has been recorded, and must be examined to determine what type of treatment should be performed. The value element is not permitted when the <code> element describes an *Other directive*.

4.3.3.24.6 <reference typeCode='REFR'>

```
<templateId root='2.16.840.1.113883.10.20.1.36'/>
<externalDocument classCode='DOC' moodCode='EVN'>
 <id root=' ' extension=' '/>
 <text><reference value=' '/></text>
```

The advanced directive observation may contain a single reference to an external document. That reference shall be recorded as shown above. The <id> element shall contain the appropriate root and extension attributes to identify the document. The <text> element may be present to provide a URL link to the document in the value attribute of the <reference> element. If the <reference> element is present, the Advance Directive in the narrative shall contain a <linkHTML> element to the same URL found in the value attribute.

4.3.3.25 Procedure Entry 1.3.6.1.4.1.19376.1.5.3.1.4.19

The procedure entry is used to record procedures that have occured, or which are planned for in the future.

4.3.3.25.1 Standards

CCD ASTM/HL7 Continuity of Care Document

4.3.3.25.2 Specification

```
<procedure classCode='PROC' moodCode='EVN|INT'>
  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.19'/>
  <templateId root='2.16.840.1.113883.10.20.1.29'/><!-- see text of section 0 -->
  <templateId root='2.16.840.1.113883.10.20.1.25'/><!-- see text of section 0 -->
  <id root='' extension=''/>
  <code code='' codeSystem='2.16.840.1.113883.5.4' codeSystemName='ActCode' />
  <text><reference value='#xxx'/></text>
  <statusCode code='completed|active|aborted|cancelled'/>
  <effectiveTime>
    <low value=''/>
    <high value=''/>
  </effectiveTime>
  <priorityCode code=''/>
  <approachSiteCode code='' displayName='' codeSystem='' codeSystemName=''/>
  <targetSiteCode code='' displayName='' codeSystem='' codeSystemName=''/>
  <author />
  <informant />
  <entryRelationship typeCode='REFR'>
    <encounter classCode='ENC' moodCode=''>
      <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.4.1'/>
      <id root='' extension=''/>
    </encounter>
  </entryRelationship>
  <entryRelationship typeCode='RSON'>
    <act classCode='ACT' moodCode='EVN'>
      <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.4.1'/>
      <id root='' extension=''/>
    </act>
  </entryRelationship>
</procedure>
```

Figure 4.3-14 Procedure Entry Example

4.3.3.25.3 <procedure classCode='PROC' moodCode='EVN|INT'>

This element is a procedure. The classCode shall be 'PROC'. The moodCode may be INT to indicated a planned procedure or EVN, to describe a procedure that has already occurred.

4.3.3.25.4 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.19'/>

The templateId indicates that this <procedure> entry conforms to the constraints of this content module. NOTE: When the procedure is in event mood (moodCode='EVN'), this entry conforms to the CCD template 2.16.840.1.113883.10.20.1.29, and when in intent mood, this entry conforms to the CCD template 2.16.840.1.113883.10.20.1.25.

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

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

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

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

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

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

4.3.3.25.8<statusCode code='completed|active|aborted|cancelled'/>

The <statusCode> element shall be present when used to describe a procedure event. It shall have the value 'completed' for procedures that have been completed, and 'active' for procedures that are still in progress. Procedures that were stopped prior to completion shall use the value 'aborted', and procedures that were cancelled before being started shall use the value 'cancelled'.

4.3.3.25.9<effectiveTime><low value=' '/><high value=' '/></effectiveTime>

This element should be present, and records the time at which the procedure occurred (in EVN mood), or the desired time of the procedure in INT mood.

4.3.3.25.10 <priorityCode code=' '/>

This element shall be present in INT mood when effectiveTime is not provided, it may be present in other moods. It indicates the priority of the procedure.

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

This element may be present to indicate the procedure approach.

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

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

4.3.3.25.13 <entryRelationship typeCode='COMP' inversionInd='true'>

This element may be present to point the encounter in which the procedure was performed, and shall contain an internal reference to the encounter. See section 1.3.6.1.4.1.19376.1.5.3.1.4.4.1 for more details.

4.3.3.25.14 <entryRelationship typeCode='RSON'>

A <procedure> act may indicate one or more reasons for the procedure. These reasons identify the concern that was the reason for use via the Internal Reference entry content module specified in section 1.3.6.1.4.1.19376.1.5.3.1.4.4.1. The extension and root of each observation present must match the identifier of a concern entry contained elsewhere within the CDA document.

