Integrating the Healthcare Enterprise



IHE PCC Technical Framework Supplement 2008-2009

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Antepartum Record (APR)

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Public Comment Version 1.0 Comments due July 18 2008

1 Foreword

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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. IHE maintain formal relationships with several standards bodies including HL7, DICOM and refers recommendations to them when clarifications or extensions to existing standards are necessary.

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

[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. It is 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/Technical Framework.

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. The 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. The subsequent volumes provide detailed technical descriptions of each IHE transaction.

This supplement to the IHE PCC Technical Framework is submitted for Public Comment between June 16 2008 and July 18 2008, per the schedule announced in December 2007.

Comments shall be submitted before July 18 2008 to:

http://forums.rsna.org under the "IHE" forum

Select the "PCC Profiles for Public Review" sub-forum.

The IHE PCC Technical Committee will address these comments and publish the Trial Implementation version in August 2008.

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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

- 210 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

(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:
- 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

230 1.1.3 How this Volume is Organized

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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

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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

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Health Level Seven, Inc., has granted permission to the IHE to reproduce tables from the HL7 standard. The HL7 tables in this document are copyrighted by Health Level Seven, Inc. All rights reserved. Material drawn from these documents is credited where used.

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.

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Assessment Integration Profile to be provided to vendors for demonstration purposes only. Should a vendor chose to include the Braden Scale in their product, they must seek permission to do so from the copyright holders. More information is available from 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

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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.

360 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

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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 Connectation. After resolution of all change proposals received within 60 days of the Connectation, 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.

 420 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

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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.

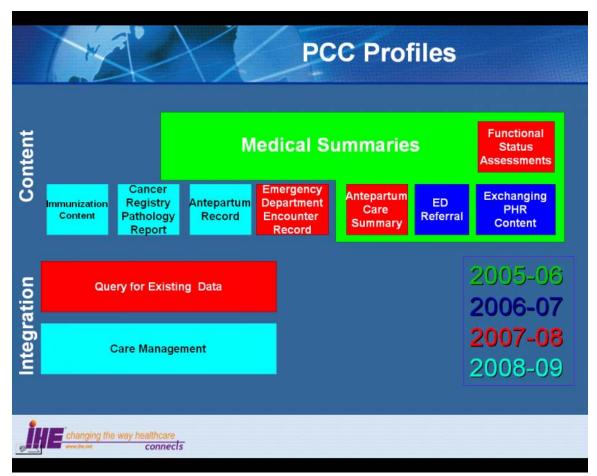


Figure 2.4-1 IHE Patient Care Coordination Content Integration Profiles

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

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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	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.
(QED)	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

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- 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.

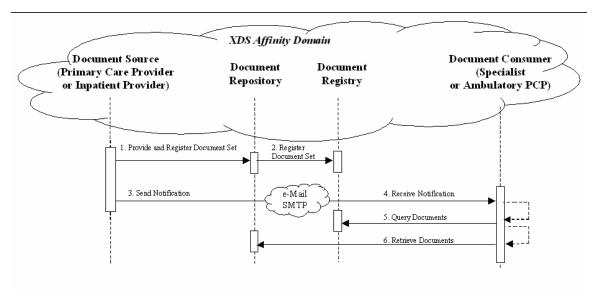


Figure 2.6-1 Use Case Process Flow Diagram

These steps are:

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- 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).

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• 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).

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• 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.

- The e-mail notification that contains no patient identified information is received by the specialist EMR system.
- The receiving provider can then utilize existing query transactions from the XDS profile to find the URL of the Documents.
- 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

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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.

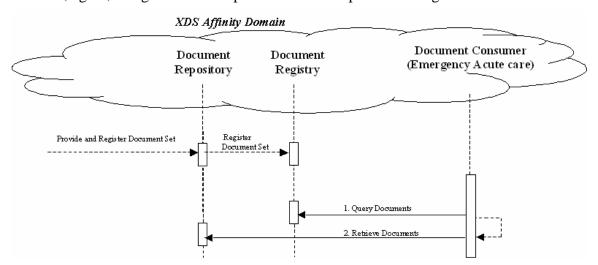


Figure 2.6-2 Unplanned Access Process Flow Diagram

- 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.

 Plagas Note: This profile was transferred to the ITI Domain in the Fall of

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

- <u>Pre-procedure History and Physical Content Profile (PPHP)</u> supports the exchange of information allowing for the assessment and amelioration of risks related to a procedure. *Please Note: This profile has been withdrawn*.
- <u>Emergency Department Referral Profile (EDR)</u> 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.
- <u>Emergency Department Encounter Summary (EDES)</u> describes the content and format of records created during an emergency department visit.
- <u>Functional Status Assessment Profile (FSA)</u> supports the handoff of assessment information between practitioners during transfers of care by

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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.
- <u>Public Health Laboratory Report(PHLAB)</u> 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.

- <u>Antepartum Record (APR)</u> describes the content and format of summary documents used during Antepartum care.
- <u>Care Management (CM)</u> describes the content and format of summary documents used during Antepartum care.
- <u>Immunization Content (IC)</u> describes the content and format of summary documents used during Antepartum care.
- <u>Cancer Registry Pathology Report (CPR)</u> 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-605 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

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IHE PCC Technical Framework Supplement – Antepartum Record (APR)

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 615 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).

- 620 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
- 625 physician practice might include a Document Source Actor, Document Consumer Actor, a Patient Demographics Client Actor, as well as a Secured Node Actor.

3 Antepartum Record (APR)

This is a draft of the Antepartum Record Profile (APR) supplement to the PCC Technical Framework. This draft is a work in progress, not the official supplement or profile.

3.1.1 Open Issues

- 1. How does the XDS Folder structure need to be handled?
- 2. Several LOINC and SNOMED codes are in the process of being created. These codes are denoted by a preceding "xx-" or "XX-" with an abbreviated description of the code following.

3.1.2 Closed Issues

1. For Antepartum Laboratory there is a LOINC code for Laboratory Studies (26436-6) - is this too general? Should a new code be requested specific to Antepartum labs? The concern is that this could cause mapping issues in an EMR that has other lab results that are considered to be specific to antepartum that would live under that same loinc section code. the IHE formatCode supplied in the XDS Metadata will identify this as an Antepartum Laboratory document so a LOINC code is not needed.

645 3.2 Profile Abstract

The Antepartum Record Profile (APR) extends the description of the content structures for the Antepartum Summary (APS), and is based on the data elements from prenatal records currently in common use. The Antepartum Record includes the following additional documents:

- 1. Antepartum History & Physical The initial assessment and physical
 - 2. Antepartum Laboratory Laboratory Evaluations
 - 3. Antepartum Education Education Record

Additional commonly used forms not included in this profile are:

- 1. A patient generated obstetric medical history
- 655 2. A postpartum form

A sample form showing the data elements may be found at: http://www.acog.org/acb-custom/aa128.pdf. This profile defines the implementation of HL7 CDA documents to represent these data elements along with the XDS, XDR and XDM bindings. This profile also defines mechanisms to group them into a single logical folder.

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Add the following bullet to the list of profiles

 Antepartum Record - A folder of content profiles that contains the record of Antepartum care including initial patient history and physical, recurring evaluations of mother and fetus(es), laboratory studies, patient education, and on-going plans of care.

3.3 Dependencies

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

Integration Profile	Dependency	Dependency Type	Purpose
Antepartum Record	Sharing of Laboratory Reports (XD-LAB)	child	share laboratory results

670 3.4 Overview

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The Antepartum Record Profile (APR) extends the description of the content structures for the Antepartum Summary (APS), and is based on the data elements from prenatal records currently in common use.

- Obstetric patients in labor and admitted to the hospital or birthing facility must have a complete summary of their antepartum ambulatory care available at the time of admission to evaluate and / or ameliorate risk. This same data is required at any visit to the birthing facility or hospital for any other problems or special care needs of the patient. The antepartum record must be available in its entirety for appropriate continuity of care and legal concerns.
- The aggregated record provides important information for all health care professionals who are part of the patient's obstetric care team. Patients may incorporate the data from this aggregated record into their personal health record. Administration staff may use data for billing and payment purposes.
- A typical pregnancy duration is approximately 40 weeks. Patient care during that time includes an initial history and physical examination, followed by repetitive office visits with multiple laboratory studies, imaging/ ultrasound studies, and serial physical examinations. As the patient is seen over a finite period for care, aggregation of data relevant to the evaluation of the obstetric patient upon presentation to the birthing facility or hospital is commonly collected on paper forms. This antepartum record contains the most critical information needed to provide care for the patient during pregnancy, delivery and the post-partum period. This data must all be presented and evaluated upon entry to the birthing facility or hospital to ensure optimal continuity of care for the patient and the fetus.
- Although the patient and her care provider may plan for a vaginal method of delivery, there is a substantive chance the delivery route may be surgical, requiring anesthesia and post-surgical care.

Current practice is to copy the patient's paper chart at various times during the pregnancy (as at 28 weeks and at 36 weeks of completed gestation), and transport the copies of the chart to the hospital the patient intends to use for delivery. Should the patient arrive at the birthing facility or hospital prior to the chart copy arriving, or if the chart (or information within the chart) is missing on presentation of the patient (a frequent occurrence), the care team must repeat laboratory or imaging studies. This results in unwarranted and duplicative tests, is wasteful of time and resources, and leads to dissatisfied patients. Further, missing or incomplete information about the patient's clinical status may create a situation where critical information is unavailable which may ultimately result in an injury, inadequate aftercare, or other undesirable outcomes.

A large portion of patients arrive at the birthing facility or hospital without complete documentation. In one recent U.S. study, approximately 70 % of patients (with paper charts) arrived at the birthing facility without their current medical record being available. While only one hospital was involved in this study, one can see the extent of the issue, with pregnant patients possibly going to a different hospital than planned (preterm labor, rapid labor and unable to make it to the planned delivery hospital, or visiting a distant city), moving mid-care, or with a covering physician (rather than the primary obstetrician) on call.

In a Swedish study done in the 1990's, critical data on paper records were incomplete from 45 to 87.5% of the time. Thus, availability of current medical records remains a significant problem for most hospital birthing facilities; availability of key information electronically will significantly enhance patient safety.

3.5 Use Cases

720 3.5.1 Use Case 1: Basic Antepartum Record Use Case

This use case reflects the course of care during an uncomplicated pregnancy.

Pre-condition

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The patient's obstetrician sees the patient for her initial and subsequent prenatal visits.

During the initial and/or subsequent prenatal visits information is collected and may be updated within the office Electronic Health Record (EHR), these include:

- Patient demographics
- Menstrual history
- Obstetric history
- Medical history including surgical history, psych-social history
- Genetic history and screening/Teratology counseling
- Infection history
- Family history
- Initial and subsequent physical examination
- 735 Medications

- Problems and risk factors for preterm birth
- Allergies
- Prenatal visit information
- Prenatal Laboratory results
- Documentation of patient education and counseling
- Plans for care

The information collected during the patient's prenatal visits make up the components which are included in the patient's Antepartum Record.

745 **Event(s)**

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Scenario 1 - At a specified time an initial and/or subsequent patient Antepartum Record is transmitted by the patient's obstetrician EHR to the intended facility for delivery.

The intended facility of delivery health information system receives the transmitted initial and/or subsequent patient Antepartum Record.

750 Scenario 2 - At a specified time the initial and/or subsequent patient Antepartum Record registry information is transmitted by the patient's obstetrician EHR to a registry.

The facility of delivery health information system queries the registry repository for the applicable patient's Antepartum Record(s). A request is made for the patient's Antepartum Record. The applicable system which contains the patient's Antepartum Record information to the

Record then makes available the patients Antepartum Record information to the requesting facility of delivery.

Post-condition

The received patient Antepartum Record can be viewed and/or imported into the facility for delivery health information system to facilitate patient care by healthcare professional at the time of delivery for the mother and newborn.

3.5.2 Use Case 2: Antepartum Consultative Care

This use case reflects an example of consultative prenatal care.

Pre-condition

The patient's obstetrician sees the patient for her pregnancy in the ambulatory (office) setting. During the pregnancy, the patient is noted to have a medical problem requiring consultation with a maternal-fetal medicine specialist (perinatologist). The office obtains pre-authorization from the insurance payer for the consult and for the intended or anticipated route of delivery. Preauthorization information is transmitted to both the consultant and to the hospital.

Events

The patient is seen in the obstetrician's office where a complete medical and relevant psycho-social history are obtained and recorded in the office EHR. Data from the

perinatologist's consultation report is incorporated as appropriate. Laboratory and imaging reports ordered by the perinatologist as well as the perinatologist's consultation report are displayed electronically to the obstetrician. The obstetrician reviews the consultation report from the perinatologist's office and imaging studies ordered by the perinatologist along with current recorded data. Physical exam reveals some abnormalities. The obstetrician orders additional laboratory studies, and sends the patient to the hospital or birthing facility.

When the laboratory results return, the physician completes the admission history and physical, allergies, medications, includes the data prepared or ordered by the perinatologist, and makes it available to the hospital or birthing facility. This data includes an assessment of the patient's health status, and the requisite data summarized from the antepartum care given. The care team assures the complete collection of documents needed is available and that there is a suitable environment with appropriate support for post-delivery after-care.

Post-condition

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The pre-delivery history and physical and Antepartum Summary with appropriate relationships to the Perinatologist consultation, and all the Antepartum laboratory and imaging studies are available to the obstetrician and the hospital or birthing center personnel for incorporation into their respective EHRs. The history and physical is also available to the patient for viewing and incorporation into the patient's PHR, and into the newborn baby's PHR.

795 3.5.3 Use Case 3: Antepartum Collaborative Care

This use case reflects two-way transmission of data in an example of collaborative care.

Pre-condition

A pregnant diabetic patient is seen by her obstetrician in the office for prenatal care. An ultrasound is performed to determine gestational age. The patient is sent for perinatology consult as a high-risk patient. Her obstetrician transmits preauthorization insurance information, labs and anticipated route of delivery to perinatologist and/or hospital birthing facility.

Events

The patient returns to her perinatologist biweekly for blood testing and ultrasounds (when necessary) in addition to regular ob visits. The perinatologist reports back to the obstetrician after each visit. Complete history and physical, imaging and additional labs are performed during patient's regular visit with her obstetrician.

The patient arrives at birthing facility. Obstetrician completes the admission history and physical, allergies, medications, and includes the data prepared or ordered by the perinatologist, and makes it available to the hospital birthing facility. This data includes an assessment of the patient's health status, and the requisite data summarized from the antepartum care given. The care team documents that the complete collection of documents required is available.

815 **Post-condition**

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The patient's obstetrician delivers by cesarean section after anesthesia. The post-partum discharge planning is notified and assures that there is a suitable environment with appropriate support for post-delivery after-care. Delivery information, i.e. birth weight, APGAR scores, type of delivery, etc is available for pediatrician. The patient's postpartum record is sent to the perinatologist for incorporation into the patient's record. The patient can incorporate the history and physical into her own personal health record and the newborn's records into the newborn's personal health record.

3.6 Actors/Transaction

There are two actors in this 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 by section 3.7 Content Bindings with XDS, XDM and XDR found in the Patient Care Coordination Technical Framework

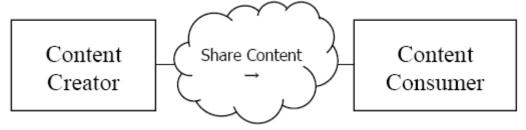


Figure 3.6-1 Antepartum Record Actor Diagram

3.7 Options

Actor	Option	Section
Content Consumer	View Option (1) Document Import Option (1) Section Import Option (1) Discrete Data Import Option (1)	PCC TF-1: 2.13.1 PCC TF-1: 2.13.2 PCC TF-1: 2.13.3 PCC TF-1: 2.13.4
Content Creator	Referral Option (1) Discharge Summary Option (1)	PCC TF-1: 2.13.5 PCC TF-1: 2.13.6

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

3.8 Grouping

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3.8.1 Content Bindings with XDS, XDM and XDR

It is expected that the transfers of care will occur in an environment 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 <u>Cross</u>
 <u>Enterprise Document Sharing</u> (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 <u>Cross Enterprise</u> Document Media Interchange (XDM) profile.
- A reliable messaging-based infrastructure is defined by the IHE <u>Cross Enterprise Document Reliable Interchange</u> (XDR) profile.
- All of these infrastructures support Security and privacy through the use of the <u>Consistent Time</u> (CT) and <u>Audit Trail and Node Authentication</u> (ATNA) profiles.

For more details on these profiles, see the IHE IT Infrastructure Technical Framework.

Content profiles may impose additional requirements on the transactions used when grouped with actors from other IHE Profiles.

3.8.2 Cross Enterprise Document Sharing, Media Interchange and Reliable Messages

Actors from the ITI XDS, XDM and XDR profiles embody the <u>Content Creator</u> and <u>Content Consumer</u> sharing function of this profile. A <u>Content Creator</u> or <u>Content Consumer</u> must be grouped with appropriate actors from the XDS, XDM or XDR profiles, and the metadata sent in the document sharing or interchange messages has specific relationships to the content of the clinical document described in the content profile.

865 3.8.3 Notification of Document Availability (NAV)

A Document Source should provide the capability to issue a <u>Send Notification</u> Transaction per the ITI <u>Notification of Document Availability</u> (NAV) Integration Profile in order to notify one or more <u>Document Consumer(s)</u> 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 <u>Receive Notification</u> 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 <u>Send Acknowledgement</u> option may be used to issue a Send

Acknowledgement to a <u>Document Source</u> that the notification was received and processed.

3.8.4 **Document Digital Signature** (DSG)

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

3.9 Content Modules

Content modules describe the content of a payload found in an IHE transaction. Content profiles are transaction neutral. They do not have dependencies upon the transaction that they appear in.

- 3.9.1 Antepartum History and Physical
- 3.9.2 Antepartum Summary
- 3.9.3 Antepartum Laboratory
- 890 3.9.4 Antepartum Education

3.10 Process Flow

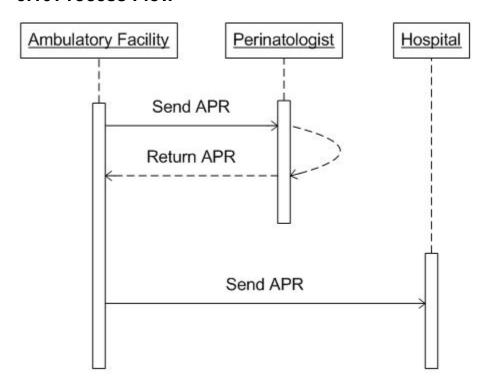


Figure 3.10-1 Antepartum Record Process Flow

This process flow diagram shows the movement of the antepartum record over the course of care for a pregnancy involving an ambulatory facility (obstetric provider), perinatologist (specialist) and hopsital (birthing facility). This diagram specifically excludes other infrastructure interactions for simplicity and readability. These infrastructure interactions may be found elsewhere in the framework.

Data from the patient's prenatal care aggregates into her electronic antepartum record by the obstetric provider. The antepartum record is then sent to a specialist for consultation (if any). The specialist provides the consultation, updates the antepartum record, and returns it to the obstetric provider. The electronic antepartum record is then sent to the birthing facility at the appropriate time(s).

905 4 Actor Descriptions

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

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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.

5 Transaction Descriptions

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

5.1 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.

945 A.1 Structure and Content of an IHE Integration Statement

An IHE Integration Statement for a product shall include:

1. The Vendor Name

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- 2. The Product Name (as used in the commercial context) to which the IHE Integration Statement applies.
- 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.

975 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
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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

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.

Glossary

The following elements are found in the Antepartum History & Physical document of the Antepartum Record:

985 Abortion, Induced (AB, Induced)

Number of induced abortions by patient. An induced abortion is a deliberate termination of pregnancy.

Abortion Spontaneous (AB, Spontaneous)

Number of spontaneous abortions by patient. A spontaneous abortion is a natural loss of the products of conception.

Ectopic pregnancy

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Number of ectopic pregnancies by patient. An ectopic pregnancy is the development of a fertilized ovum outside the uterus, as in a Fallopian tube.

Estimated Date of Delivery(EDD)/Estimated Date of Confinement(EDC)

Date of anticipated delivery (confinement).

Final/Corrected Estimated Date of Delivery (EDD)

Corrected EDD/EDC based upon parameters such as ultrasound, first auscultation of fetal heart tones, etc.

Full term

Number of babies the mother has delivered that were between 37 and 42 completed weeks of gestation.

Living Children

Number of living children of patient

Multiple births

Number of deliveries of more than one baby by patient

Premature

Delivery between 20 and 36 6/7 weeks gestation

Total Pregnancies

Number of total pregnancies

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Antepartum History & Physical - Menstrual History

Birth Control Pills (BCP)

Oral contraceptives

Frequency

Duration of the monthly menstrual cycle; from first day of menses to the first day of next menses.

hCG+

Human Chorionic Gonadotropin pregnancy test.

LMP (last menstrual period)

Date measured as the first day of the patient's most recent menstrual period.

- Approximate (month known) Patient is unsure of exact date but can offer an approximate date.
- Definite Patient can say with certainty the date of her last menstrual period.
- Final Finally agreed upon date of last menstrual period.
- Unknown Patient does not know the date of her last menstrual period.

Menarche

Age at onset of initial menstrual period.

Menses Monthly

Menses is the monthly flow of blood and cellular debris from the uterus that begins at puberty and ceases at menopause.

Normal Amount/duration

Last menstrual was typical in amount and duration.

Prior Menses

Date of most recent menstrual period.

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Antepartum History & Physical - Past Pregnancies

Anesthesia

The loss of the ability to feel pain caused by administration of a drug or other intervention.

1040 Artificial Reproductive Technology (ART) Treatment

Fertility procedures in which both eggs and sperm are handled in the laboratory (in vitro) to establish a pregnancy.

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Autoimmune disorder

An autoimmune disorder is a condition in which the body attacks its own tissues. (ACOG)

Birth weight

Weight of infant at birth.

Date

Month/Year of birth of patient's previous babies.

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Diethylstilbesterol

D (Rh) sensitized

Rh negative mother is sensitized to the Rh D antigen. A sensitized mother produces IgG anti-D (antibody) that crosses the placenta and coats D-positive fetal red cells which are then destroyed in the fetal spleen.

Gestational Age weeks

The number of weeks elapsed between the first day of the last normal menstrual period and the date of delivery.

Infertility

Infertility primarily refers to the biological inability of a man or a woman to contribute to conception. Infertility may also refer to the state of a woman who is unable to carry a pregnancy to full term.

Kidney disease

Kidney disease is either a declining or a sudden loss in renal function.

Length of labor

The interval between onset of contractions and childbirth.

Place of Delivery

Hospital name, city and state if known.

Preterm labor

Labor that begins before 37 weeks gestation.

Pulmonary (TB, Asthma)

Diseases or disorders of the lungs, i.e. asthma, tuberculosis or other pulmonary problems.

Sex Male/Female

1075 Sex of patient's previously delivered babies.

Type Delivery

Type of delivery in pregnancy: Vaginal (spontaneous, forceps, vacuum), Cesarean section (low-transverse, classical, low-vertical).

Urinary Tract Infection (UTI)

A urinary tract infection (UTI) is a bacterial infection that affects any part of the urinary tract.

Uterine Anomaly

- Any uterine structural abnormalities.

Varicosities/Phlebitis

1085 Swelling or inflammation of veins.

Antepartum History & Physical - Other elements:

Abdomen

Area of the body that lies between the chest and the pelvis and encloses the stomach, intestines, liver, spleen and pancreas

Adnexa

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Appendages of the uterus which include the fallopian tubes, the ovaries and the supporting ligaments of the uterus.

BMI - Body Mass Index.

Measurement of the relative percentages of fat and muscle mass in the human body.

BP - Blood Pressure

Pressure exerted by the blood against the walls of the arteries, maintained by the contraction of the left ventricle, the resistance of the arterioles and capillaries, the elasticity of the arterial walls, and by the viscosity and volume of the blood.

1100 Breasts

In humans, one of the paired regions in the anterior portion of the thorax. The breasts consists of mammary glands, the skin, the muscles, the adipose tissue and connective tissues.

Cervix

The lower, narrow end of the uterus, which protrudes into the vagina. (ACOG)

Diagonal Conjugate

The distance from the promontory of the sacrum to the lower margin of the pubic symphysis

IHE PCC Technical Framework Supplement – Antepartum Record (APR)

1110 Extremities

A bodily limb or appendage.

Fundi

Concave, interior of the eye, consisting of the retina, the choroid, the sclera, the optic disk, and blood vessels, seen by means of the opthalmoscope.

1115 Gynecoid pelvic type

The normal female pelvis.

Heart

The hollow, muscular organ that maintains the circulation of the blood.

HEENT

Head, Eyes, Ears, Nose and Throat

Height

Measurement of stature

Lungs

Either of the pair of organs occupying the cavity of the thorax that effect the aeration of the blood.

Lymph nodes

Any of the accumulations of lymphoid tissue organized as definite lymphoid organs varying from 1 to 25 mm in diameter situated along the course of lymphatic vessels and consisting of an outer cortical and inner medullary part.

1130 Rectum

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The distal segment of the large intestine, between the sigmoid colon and the anal canal.

Sacrum

Triangular bone below the lumbar vertebrae.

1135 Skin

Outer protective covering of the body

Spines

(Ischial Spines) Two parts of the maternal pelvis resulting from the bony processes projecting backward and medially from the posterior border of the ischium.

1140 Subpubic arch

Arch formed by the conjoined rami of the ischia and pubic bones of the two sides of the body.

Teeth

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one of the hard, calcified structures set in the alveloar processes of the jaws for the biting and mastication of food.

Thyroid

The thyroid gland. One of the largest endocrine glands in the body. This gland is found in the neck below the thyroid cartilage and at approximately the same level as the cricoid cartilage. The thyroid controls how quickly the body burns energy, makes proteins, and how sensitive the body should be to other hormones.

Uterus size

In pregnancy the uterine size is estimated in terms of weeks of gestation. e.g 12 weeks if the fundus reaches the top of the smphysis pubis or 20 weeks' gestation when the fundus reaches the umbilicus.

1155 Vagina

The genital canal in the female, leading from the opening of the vulva to the cervix of the uterus.

Vulva

The external genital organs of the female, including the labia majora, labia minora, clitoris, and vestibule of the vagina.

Patient Weight

A measurement of mass.

The following terms are found in the Antepartum Laboratory document of the Antepartum Record:

1st Trimester Aneuploidy risk assessment (Free or Total)

Non-invasive screening for chromosomal abnormalities, such as Down syndrome, performed in the first trimester. Screening tests that uses a combination of fetal measurements (crown rump length and nuchal translucency) and maternal blood tests for beta-human chorionic gonadotropin (hCG) and pregnancy associated plasma protein (PAPP-A) to determine risk for trisomy 21, trisomy 13 and trisomy 18.

2nd Trimester serum screening

Non-invasive screening test for chromosomal abnormalities, such as Down yndrome, trisomy 18, or open neural defects. Blood test to measure alpha-fetoprotein (AFP), estriol, human chorionic gonadotropin (hCG) [free or total], and inhibin-A.

Amniocentesis (Amnio)

Percutaneous transabdominal puncture of the uterus during pregnancy to obtain amniotic fluid.

IHE PCC Technical Framework Supplement – Antepartum Record (APR)

Amniotic Fluid (AFP) Test

A test to detect the presence of Alpha-fetoprotein in amniotic fluid.

Antibody screen

A blood test to detect antibodies against red blood cell antigens.

Anti-D Immune Globulin (RHIG)

Anti-D antibodies given to prevent sensitization to the RhD antigen on red blood cells.

Blood type

1185

Test to determine blood group, i.e. A, B, AB or O

Chlamydia Test

Test done to detect the bacterium, Chlamydia trachomatis.

1190 Cystic Fibrosis Screening Test

Test to detect gene mutations that cause cystic fibrosis.

Chorionic Villi Sampling (CVS)

A method of sampling the cells of the placental chorionic villi, done either transabdominally or transcervically.

1195 D (Rh) Antibody screen

A blood screening test for presence of IgG antibodies to the Rh D antigen on red blood cells.

D (Rh) type

A blood test to detect the presence of the Rh D red blood surface antigen.

1200 Diabetes screen

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Laboratory test to screen for gestational diabetes.

Familial Dysautonomia

Autosomal disorder of the peripheral and autonomic nervous systems limited to individuals of Ashkenazic Jewish descent; clinical manifestations are present at birth and include diminished lacrimation, defective thermoregulation, orthostatic hypotension, fixed pupils, excessive sweating, loss of pain and temperature sensation, and absent reflexes; pathologic features include reduced numbers of small diameter peripheral nerve fibers and autonomic ganglion neurons.

Genetic Screening Test

Screening for genetic disorders, e.g. sickle cell, Thalassemia, Tay-Sachs, Canavan, cystic fibrosis, fragile X syndrome, or Duchenne's muscular dystrophy.

Gonorrhea Test

Test to detect Neisseria gonorrhea

Group B Streptococcus Rectovaginal Culture (Group B Strep)

A test to determine the presence of group B streptococcus (streptococcus agalactiae) in the lower genital tract in pregnant women.

GTT (if screen abnormal)

Glucose Tolerance Test. Used to determine how quickly the body metabolizes blood sugar. Test to diagnose gestational diabetes mellitus.

1220 HBsAg Test

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Test for the detection of the surface antigen of the Hepatitis-B virus.

HCT/HGB/MCV

- HCT- Hematocrit A blood test measuring the percentage of red blood cells found in a given volume of whole blood.
- HGB- Hemoglobin A blood test measuring the level of the protein carrying oxygen in red blood cells.
- MCV Mean corpuscular volume The average volume of red blood cells calculated from the hematocrit red blood cell count

Hemoglobin Electrophoresis

A blood test done to measure the different types of hemoglobin. The test can detect abnormal levels of hemoglobin such as that found in sickle cell anemia.

HIV Test

A test to detect for the presence of antibodies to the human immunodeficiency virus.

HIV Counseling

Discussion with pregnant patient regarding Human Immunodeficiency Virus/ HIV status, risks and prevention strategies.

Karotype

Test done on cells/tissue to identify and evaluate the number, shape, and size of chromosomes.

1240 MSAFP - Maternal Serum Alpha-Fetoprotein

A screening blood serum test on the mother for to determine the level of alphafetoprotein.

Multiple marker screening test

A maternal blood serum screening test for the detection of Down syndrome,
Trisomy 18, and neural tube defects in the fetus. The following analytes are
measured: alpha-fetoprotein, human chorionic gonadotriopin, estriol, and inhibin-

A. When the first three analytes are used, this is also called a maternal serum triple screen or a maternal serum quad screen when all four analytes are used.

Pap test

1250 Cervical cytology test to determine abnormal cells of the cervix.

PPD Skin Test

Mantoux test with purified protein derivative to screen for exposure to tuberculosis.

Rubella Test

A blood test to detect the presence of antibodies against the rubella virus (German measles).

Tay-Sachs Screening Test

A blood test done to measure the amount of beta-hexosaminidase A or B activity in serum or white blood cells, or for the most common DNA mutations causing Tay Sachs disease.

1260 Ultrasound

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A radiologic study using sound waves used in the assessment of gestational age, size, growth, anatomy, and blood flow of a fetus or in the assessment of maternal anatomy and blood flow.

Urine Culture

A Test that it used to detect the presenct of bacteria in the urine., sugar and/or protein in urine.

Urine Screen

A physical, chemical, and / or microscopic examination of the urine. It may be used to screen for / or to detect abnormal kidney function, kidney stones, urinary tract infections, or substance abuse.

Varicella

A blood test to detect the presence of anti-varicella antibodies.

VDRL (Venereal Disease Research Laboratories)

A blood test to screen for the presence of antibodies against Treponema pallidum, the bacteria that causes syphilis.

The following terms are found in the Antepartum Education document of the Antepartum Record:

1280 First Trimester

Alcohol

Discussion with patient about past and present use of alcohol and the perinatal implications of continued use during pregnancy; referral to treatment program if appropriate.

1285 Anticipated Course of prenatal care

Discussion with the patient on the scope of care that will be performed in the office, lab work that may be performed, signs and symptoms that should be reported, anticipated schedule of visits, physician coverage of labor and delivery.

Childbirth classes/hospital facilities

Discussion with the patient on educational programs available for childbirth and hospital choice.

Domestic violence

Screening/Discussion with patient regarding physical threats/abuse/safety concerns; referral to appropriate counseling, legal and/or social advocacy program if appropriate.

Environmental/Work hazards

Discussion with patient about potential exposures to environmental agents at work, home, or locations that may affect pregnancy.

Exercise

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Discussion with patient on appropriate level of exercise activities during the pregnancy.

Illicit/Recreational drugs

Discussion with patient about past and present use of illicit or recreational drugs and the perinatal implications of continued use during pregnancy; referral to treatment program if appropriate.

Indications for ultrasounds

Discussion with patient regarding reasons ultrasound test will be performed during pregnancy.

Influenza vaccine

Discussion with patient of risks/benefits of influenza and influenza vaccine.

Nutrition and weight gain counseling, special diet

Information about balanced nutrition, ideal caloric intake and weight gain.

1315 Risk factors identified by prenatal history

Seatbelt use

Discussion with patient on use of seatbelts.

Sexual activity

Discussion with the patient of sexual activity: concerns, restrictions, warning signs and/or safe sex practices.

Smoking counseling

Discussion with patient regarding smoking cessation and smoke exposure.

Tobacco (Ask,advise,assess,assist,and arrange)

status; Advise patient to stop smoking; Assess patient's willingness to attempt to quit smoking; Assist patients who are interested in quitting by providing pregnancy specific cessation materials; Arrange follow up visits to track progress.

Toxoplasmosis precautions

Discussion with patient of risk factors for toxoplasmosis and precautions for avoiding/preventing infection.

1330 Travel

Discussion with patient on travel precautions, if any.

Use of any medications (including supplements, vitamins, herbs or OTC drugs)

Discussion with patient of risks/benefits/safety of any medications currently used by patient.

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Second Trimester

Abnormal lab values

Discussion with patient of lab results that fall outside normal range and that may require further testing.

1340 Domestic violence

Screening/Discussion with patient regarding physical threats/abuse/safety concerns; referral to appropriate counseling, legal and/or social advocacy program if appropriate.

1345 Influenza vaccine

Discussion with patient of risks/benefits of influenza and influenza vaccine.

IHE PCC Technical Framework Supplement – Antepartum Record (APR)

Postpartum family planning/tubal sterilization

Discussion with patient of intended postpartum contraception options, including tubal sterilization.

1350 Selecting a newborn care provider

Discussion with patient to identify newborn care provider; referral to resources to help patient choose provider if none previously identified.

Signs and symptoms of preterm labor

Discussion with patient on risks, signs and symptoms of preterm labor.

1355 Smoking counseling

Discussion with patient regarding smoking cessation and smoke exposure.

Third Trimester

Anesthesia/Analgesia plans

Discussion with patient to determine intended method of pain management/discomfort during labor and delivery.

Breast or bottle feeding

Discussion with patient of nutritional advantages/disadvantages of human breast milk, bottled formula; advise on available lactation consultation services.

1365 Circumcision

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Discussion with patient on circumcision of male newborn.

Domestic violence

Screening/Discussion with patient regarding physical threats/abuse/safety concerns; referral to appropriate counseling, legal and/or social advocacy program if appropriate.

Family medical leave or disability forms

Discussion with patient about any forms the patient will need completed for employment or insurance purposes.

Fetal Movement monitoring

Discussion with patient regarding her perception and assessment of fetal movement.

Influenza vaccine

Discussion with patient of risks/benefits of influenza and influenza vaccine.

Labor signs

Discussion with patient on signs of labor, i.e. contractions, membrane rupture, bleeding, etc.

Newborn education (Newborn screening, jaundice, SIDS, car seat)

Prenatal discussion with patient of preventive public health screening procedures available to newborns; testing that will occur on baby after birth to screen for up to 30 disorders.

1385 Postpartum depression

Discussion with patient of signs of postpartum depression.

Postterm counseling

Discussion with patient of risks of pregnancy extending beyond 42 weeks.

Signs & Symptoms of Pregnancy-induced hypertension

Discussion with patient of signs and symptoms of hypertension.

Smoking counseling

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Discussion with patient regarding smoking cessation and smoke exposure.

VBAC (Vaginal Birth After Cesarean) counseling

Discussion with patient of risks/benefits of vaginal birth after previous cesarean surgery.

History and physical have been sent to hospital

Notation of date and initials of person transmitting history and physical to hospital prior to delivery.

Tubal sterilization consent signed

Notation of date the consent form for tubal sterilization signed and the initials of person witnessing.

Volume 2

1 Preface to Volume 2

1.1 Intended Audience

1405 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

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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

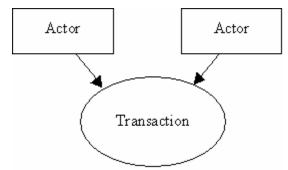
This document has adopted the following conventions for representing the framework concepts and specifying how the standards upon which the IHE Technical Framework is based should be applied.

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.:



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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:

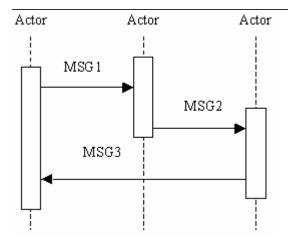


Figure 1.2-2 Interaction Diagram

- 1465 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

Health Level Seven, Inc., has granted permission to the IHE to reproduce tables from the HL7 standard. The HL7 tables in this document are copyrighted by Health Level Seven, Inc. All rights reserved.

Material drawn from these documents is credited where used.

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.

1510 **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.

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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.

1575 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

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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 JavaTM 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.

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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

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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		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'</pre>
  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

```
<!-- Verify the document type code -->
 <assert test='cda:code[@code = "{{{LOINC}}}"]'>
  Error: The document type code of a Sample Document must be {{{LOINC}}}}
 <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>
```

1685 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.

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• Other constraints as necessary.

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

module, as shown bere	, , ,				
Sample Section					
Template ID	SampleS	SampleSectionOID			
Parent Template	foo (San	npleParentOID)			
General Description	Desripti	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	R Sample Subsection			
		Parent Template			
The parent of this template is		·			
The parent of this template is foo. <component> <section> <templateid root="SampleParentOID"></templateid> <templateid root="SampleSectionOID"></templateid> <id extension=" " root=" "></id> <code code=" " codesystem="2.16.840.1.113883.6.1" codesystemname="LOINC" displayname=" "></code> <text> Text as described above </text> <text> Required and optional entries as described above </text></section></component>					
<component> Required and optional subsections as described above </component>					

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.

</section>

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.

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An example is shown below:

Sample Entry

Some text describing the entry.

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

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

Some details about the observation element

1740 **2.3.1.5 <templateId root='foo'/>**

Some details about the template id element

3 IHE Transactions

This section defines each IHE transaction in detail, specifying the standards used, and the information transferred.

1745 4 IHE Patient Care Coordination Bindings

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This section describes how the payload used in a transaction of an IHE profile is related to and/or constrains the data elements sent or received in those transactions. This section is where any specific dependencies between the content and transaction are defined. A content integration profile can define multiple bindings. Each binding should identify the transactions and content to which it applies.

The source for all required and optional attributes have been defined in in the bindings below. Three tables describe the three main XDS object types: XDSDocumentEntry, XDSSubmissionSet, and XDSFolder. XDSSubmissionSet and XDSDocumentEntry are required. Use of XDSFolder is optional. The columns of the following tables are:

- **<XXX>** attribute name of an XDS attribute, followed by any discussion of the binding detail.
- Optional? Indicates the required status of the XDS attribute, and is one of R, R2, or O (optional). This column is filled with the values specified in the XDS Profile as a convenience.

• **Source Type** – Will contain one of the following values:

Source Type	Description
SA	Source document Attribute – value is copied directly from source document. The Source/Value column identifies where in the source document this attribute comes from. Specify the location in XPath when possible.
SAT	Source document Attribute with Transformation – value is copied from source document and transformed. The Source/Value column identifies where in the source document this attribute comes from. Specify the location in XPath when possible. Extended Discussion column must not be empty and the transform must be defined in the extended discussion
FM	Fixed (constant) by Mapping - for all source documents. Source/Value column contains the value to be used in all documents.
FAD	Fixed by Affinity Domain – value configured into Affinity Domain, all documents will use this value.
CAD	Coded in Affinity Domain – a list of acceptable codes are to be configured into Affinity Domain. The value for this attribute shall be taken from this list.
CADT	Coded in Affinity Domain with Transform - a list of acceptable codes are to be configured into Affinity Domain. The value for this attribute shall be taken from this list.
n/a	Not Applicable – may be used with an optionality R2 or O attribute to indicate it is not to be used.
DS	Document Source – value comes from the Document Source actor. Use Source/Value column or Extended Discussion to give details.
О	Other – Extended Discussion must be 'yes' and details given in an Extended Discussion.

• **Source/Value** – This column indicates the source or the value used.

The following tables are intended to be summaries of the mapping and transforms. The accompanying sections labeled 'Extended Discussion' are to contain the details as necessary.

1765 CDA Document Binding to XDS, XDM and XDR

4.1 Medical Document Binding to XDS, XDM and XDR

This binding defines a transformation that generates metadata for the XDSDocumentEntry element of appropriate transactions from the XDS, XDM and XDR profiles given a medical document and information from other sources. The medical document refers to the document being stored in a repository that will be referenced in the registry. The other sources of information include the configuration of the Document Source actor, the Affinity Domain, the site or facility, local agreements, other documents in the registry/repository, and this Content Profile.

4.1.1 XDSDocumentEntry Metadata

XDSDocumentEntry Attribute	Optiona I?	Source Type	Source/ Value
availabilityStatus	R	DS	
authorInstitution The authorInstitution can be formated using the following XPath expression, where \$inst in the expression below represents the representedOrganization. concat(\$inst/id/@extension, "^", \$inst/name, "^^^^^\\", \$inst/id/@root, "&ISO")	R2	SAT	\$inst <= /ClinicalDocument/author /assignedAuthor /representedOrganization
authorPerson The author can be formatted using the following XPath expression, where \$person in the expression below represents the author. concat(\$person/id/@extension,"^", \$person/assignedPerson/name/family,"^", \$person/assignedPerson/name/given[1],"^", \$person/assignedPerson/name/given[2],"^", \$person/assignedPerson/name/suffix,"^", \$person/assignedPerson/name/prefix,"^", \$person/assignedPerson/name/degree,"^^&", \$person/assignedPerson/name/degree,"^^&", \$person/id/@root,"&ISO")	R2	SAT	\$person <= /ClinicalDocument/author
authorRole This metadata element should be based on a mapping of the participation function defined in the CDA document to the set of author roles configured for the affinity domain.	R2	SAT	/ClincicalDocument/author/ participationFunction

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authorSpecialty This metadata element should be based on a mapping of the code associated with the assignedAuthor to detailed defined classification system for healthcare providers such configured in the affinitity domain. Possible classifications include those found in SNOMED-CT, or the HIPAA Healthcare Provider Taxonomy.	R2	SAT	/ClinicalDocument/author/assignedAuthor/code
classCode Derived from a mapping of /ClinicalDocument/code/@code to an Affinity Domain specified coded value to use and coding system. Affinity Domains are encouraged to use the appropriate value for Type of Service, based on the LOINC Type of Service (see Page 53 of the LOINC User's Manual).	R	CADT	Must be consistent with /ClinicalDocument/code/@code
classCodeDisplayName DisplayName of the classCode derived. Derived from a mapping of /ClinicalDocument/code/@code to the appropriate Display Name based on the Type of Service.	R	CADT	Must be Consitent with /ClinicalDocument/code/@code
confidentialityCode Derived from a mapping of /ClinicalDocument/confidentialityCode/@cod e to an Affinity Domain specified coded value and coding system. When using the BPPC profile, the confidentialyCode may also be obtained from the <authorization> element.</authorization>	R	CADT	/ClinicalDocument/ confidentialityCode/@code -AND/OR- /ClinicalDocument/authorization/ consent[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.2.5']/code/@code
comments	0	DS	
creationTime Times specified in clinical documents may be specified with a precision in fractional sections, and may contain a time zone offset. In the XDS Metadata, it can be precise to the second, and is always given in UTC, so the timezone offset if present must be added to the current time to obtain the UTC time.	R	SAT	/ClinicalDocument/effectiveTime
entryUUID	R	DS	
eventCodeList These values express a collection of keywords that may be relevant to the consumer of the documents in the registry. They may be mapped from the service event code found in the clinical document.	O	CADT	/ClinicalDocument/documentationO f/ serviceEvent/code
eventCodeDisplayNameList	R	CADT	

$IHE\ PCC\ Technical\ Framework\ Supplement-Antepartum\ Record\ (APR)$

These are the display names for the collection of keywords described above.	(if event Code is valued)			
formatCode The format code for each PCC Document content profile is provided within the document specifications.	R	FM		
healthcareFacilityTypeCode A fixed value assigned to the Document Source and configured form a set of Affinity Domain defined values.	R	CAD	Must be concistent with /clinicalDocument/code	
healthcareFacility TypeCodeDisplay Name	R	CAD	Must be concistent with /clinicalDocument/code	
languageCode	R	SA	/ClinicalDocument/languageCode	
legalAuthenticator The legalAuthenticator can be formatted using the following XPath expression, where \$person in the expression below represents the legalAuthenticator. concat(\$person/id/@extension,"^", \$person/assignedPerson/name/family,"^", \$person/assignedPerson/name/given[1],"^", \$person/assignedPerson/name/given[2],"^", \$person/assignedPerson/name/suffix,"^", \$person/assignedPerson/name/prefix,"^", \$person/assignedPerson/name/degree,"^^&", \$person/assignedPerson/name/degree,"^^&", \$person/id/@root,"&ISO")	O	SAT	<pre>\$person <= /ClinicalDocument/ legalAuthenticator</pre>	
mimeType	R	FM	text/xml	
parentDocumentRelationship Local document versions need not always be published, and so no exact mapping can be determined from the content of the CDA document. The parentDocumentRelationship may be determined in some configurations from the relatedDocument element present in the CDA dsocument.	R (when applicable	DS	/ClinicalDocument/relatedDocument /@typeCode	
parentDocumentId Local document versions need not always be published, and so no exact mapping can be determined from the content of the CDA document. The parentDocumentId may be determined in some configurations from the	R (when parent Document Relationsh ip is present)	DS	\$docID <= /ClinicalDocument/ relatedDocument/parentDocument/ id	

$IHE\ PCC\ Technical\ Framework\ Supplement-Antepartum\ Record\ (APR)$

relatedDocument element present in the CDA dsocument. The parentDocumentId can be formatted using the following XPath expression, where \$docID in the expression below represents the identifier. concat(\$docID/@root,"^", \$docID/@extension)			
patientId The XDS Affinity Domain patient ID can be mapped from the patientRole/id element using transactions from the ITI PIX or PDQ profiles. See sourcePatientId below.	R	SAT	<pre>\$patID <= /ClinicalDocument/recordTarget/ patientRole/id</pre>
practiceSettingCode This elements should be based on a coarse classification system for the class of specialty practice. Recommend the use of the classification system for Practice Setting, such as that described by the Subject Matter Domain in LOINC.	R	CAD	
practiceSettingCodeDisplayName This element shall contain the display names associated with the codes described above.	R	CAD	
serviceStartTime Times specified in clinical documents may be specified with a precision in fractional sections, and may contain a time zone offset. In the XDS Metadata, it can be precise to the second, and is always given in UTC, so the timezone offset if present must be added to the current time to obtain the UTC time.	R2	SAT	/ClinicalDocument/documentationO f/ serviceEvent/effectiveTime/low/ @value
serviceStopTime Times specified in clinical documents may be specified with a precision in fractional sections, and may contain a time zone offset. In the XDS Metadata, it can be precise to the second, and is always given in UTC, so the timezone offset if present must be added to the current time to obtain the UTC time.	R2	SAT	/ClinicalDocument/documentationO f/ serviceEvent/effectiveTime/high/ @value
sourcePatientId The patientId can be formatted using the following XPath expression, where \$patID in the expression below represents the appropriate identifier. concat(\$patID/@extension,"^^^&", \$patID/@root, "&ISO")	R	SAT	<pre>\$patID <= /ClinicalDocument/recordTarget/ patientRole/id</pre>
sourcePatientInfo The sourcePatientInfo metadata element can be assembled from various components of the patientRole element in the clinical document.	R	SAT	/ClinicalDocument/recordTarget/ patientRole

title	О	SA	/ClinicalDocument/title
typeCode The typeCode should be mapped from the ClinicalDocument/code element to a set of document type codes configured in the affinity domain. One suggested coding system to use for typeCode is LOINC, in which case the mapping step can be omitted.	R	CADT	/ClinicalDocument/code/@code
typeCodeDisplay Name	R	CADT	/ClinicalDocument/code/@displayN ame
uniqueId The uniqueId can be formatted using the following XPath expression, where \$docID in the expression below represents the identifier. concat(\$docID/@root,"^", \$docID/@extension)	R	SAT	\$docID <= /ClinicalDocument/id

1775 4.1.1.1 XDSSubmissionSet Metadata

The submission set metadata is as defined for XDS, and is not necessarily affected by the content of the clinical document. Metadata values in an XDSSubmissionSet with names identical to those in the XDSDocumentEntry may be inherited from XDSDocumentEntry metadata, but this is left to affinity domain policy and/or application configuration.

1780 4.1.1.2 Use of XDS Submission Set

This content format uses the XDS Submission Set to create a package of information to send from one provider to another. All documents referenced by the Medical Summary in this Package must be in the submission set.

4.1.1.3 Use of XDS Folders

1785 No specific requirements identified.

4.1.1.4 Configuration

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IHE Content Profiles using this binding require that Content Creators and Content Consumers be configurable with institution and other specific attributes or parameters. Implementers should be aware of these requirements to make such attributes easily configurable. There shall be a mechanism for the publishing and distribution of style sheets used to view clinical documents.

- 4.1.2 Extensions from other Domains
- 4.1.2.1 Scanned Documents (XDS-SD)
- **4.1.2.2 Basic Patient Privacy Consents (BPPC)**
- 1795 **4.1.2.3 Laboratory Reports (XD-LAB)**

5 Namespaces and Vocabularies

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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 <u>CDA</u> <u>Release 2.0 Content Modules</u> .
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 <u>IHERoleCode Vocabulary</u> 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

5.1.1 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
Medical Summaries (XDS-MS)	urn:ihe:pcc:xds- ms:2007	text/xml	
Exchange of Personal Health Records (XPHR)	urn:ihe:pcc:xphr:2007	text/xml	
Emergency Department Referral (EDR)	urn:ihe:pcc:edr:2007	text/xml	
Antepartum Summary	urn:ihe:pcc:aps:2007	text/xml	
Exchange of Personal Health Records (XPHR)	urn:ihe:pcc:xphr:2007	text/xml	
Emergency Department Encounter Summary (EDES)	urn:ihe:pcc:edes:2007	text/xml	
2008 Profile Proposals			
Antepartum Record	urn:ihe:pcc:apr:2008	text/xml	
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 Content Profiles			
Scanned Documents	urn:ihe:iti:sd:200?	text/xml	
Basic Patient Privacy Consents	urn:ihe:iti:bppc:2007	text/xml	
Basic Patient Privacy Consents with Scanned Document	urn:ihe:iti:bppc-sd:2007	text/xml	
Laboratory Content Profiles			
CDA Laboratory Report			
Scanned Documents		text/xml	

1805 **5.1.2 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

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For Public	What else needs to appear above for SUBSTCLASS?
Comment	

mechanism of action (e.g., Beta Blocker), intended effect (Dieuretic, antibiotic) or ...

5.1.3 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.

1815 6 PCC Content Modules

6.1 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).

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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.

 \mathbf{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.

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.

6.2 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.

6.2.1 EDES Folder Specification

This is a content profile for the EDES folder. The EDES folder is a container for all documents created as a result of an ED encounter. These documents include, but are not limited to those described below. In the case of triage and nursing documentation, it is recognized that Triage Notes and ongoing ED Nursing Notes may or may not be documented the using the same form or EHR system. Therefore, these notes may either be sent separately, or in a Composite Triage and ED Nursing note.

Document Name	Opt	Template ID
Triage Note If this document is sent, then an ED Nursing note is also required and a Composite Triage and ED Nursing Note may not be sent.	С	1.3.6.1.4.1.19376.1.5.3.1.1.13.1.1
ED Nursing Note If this document is sent, then a Triage Note is also required and a Composite Triage and ED Nursing Note may not be sent.	С	1.3.6.1.4.1.19376.1.5.3.1.1.13.1.2
Composite Triage and ED Nursing Note If this note is sent, then neither the Triage Note, nor the ED Nursing note may be sent.	С	1.3.6.1.4.1.19376.1.5.3.1.1.13.1.3
ED Physician Note	R	1.3.6.1.4.1.19376.1.5.3.1.1.13.1.4
Prehospital Care Report	R2	
Diagnostic Imaging Reports	R2	
Lab Reports	R2	
Consultations	R2	
Transfer Summary	R2	
Summary of Death	R2	

6.2.2 APR Folder Specification

This is a content profile for the APR folder. The APR folder is a container for all documents created as a result of antepartum care. These documents include, but are not limited to those described below.

Document Name	Opt	Template ID
Antepartum History and Physical	С	1.3.6.1.4.1.19376.1.5.3.1.1.16.1.1
Antepartum Summary	С	1.3.6.1.4.1.19376.1.5.3.1.1.11.2
Antepartum Laboratory Report	С	1.3.6.1.4.1.19376.1.5.3.1.1.16.1.2
Antepartum Education	С	1.3.6.1.4.1.19376.1.5.3.1.1.16.1.3
Diagnostic Imaging Reports	R2	
Other Lab Reports	R2	
Consultations	R2	

6.3 CDA Release 2.0 Content Modules

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

1865 6.3.1 CDA Document Content Modules

6.3.1.1 Medical Documents Specification 1.3.6.1.4.1.19376.1.5.3.1.1.1

This section defines the base set of constraints used by almost all medical document profiles described the PCC Technical Framework.

6.3.1.1.1 Standards

```
CDAR2 HL7 CDA Release 2.0

CDTHP CDA for Common Document Types History and Physical Notes (DSTU)

XMLXSL Associating Style Sheets with XML documents
```

1870 **6.3.1.1.2 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:h17-org:v3'>
1875
          <typeId extension="POCD HD000040" root="2.16.840.1.113883.1.3"/>
          <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.1'/>
         <id root=' ' extension=' '/>
          <code code=' ' displayName='</pre>
            codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
1880
          <title>Medical Documents</title>
          <effectiveTime value='20080601012005'/>
          <confidentialityCode code='N' displayName='Normal'</pre>
            codeSystem='2.16.840.1.113883.5.25' codeSystemName='Confidentiality' />
          <languageCode code='en-US'/>
1885
          <component><structuredBody>
          </strucuredBody></component>
        </ClinicalDocument>
```

Figure 6.3-1 Sample Medical Documents Document

1900 **6.3.1.1.3 Specification**

The constraints for encoding of the CDA Header (Level 1) can be found in the CDA for Common Document Types History and Physical Implementation Guide, in the section 2. CDA Header -- General Constraints.

- IHE Medical Documents **SHALL** follow all constraints found in that section with the exception of the constraint on realmoode found in **CONF-HP-10**:
- IHE Medical Documents which are implemented for the US Realm SHALL follow ALL constraints found in that section, and SHALL use both the IHE Medical Document templateId (1.3.6.1.4.1.19376.1.5.3.1.1.1) and the HL7 General Header Constraints templateId (2.16.840.1.113883.10.20.3).}}

Realm	Constraints	Template IDs Required
Universal	CONF-HP-1 through CONF-HP-9 CONF-HP-11 through CONF-HP-40	1.3.6.1.4.1.19376.1.5.3.1.1.1
US	CONF-HP-1 through CONF-HP-40	1.3.6.1.4.1.19376.1.5.3.1.1.1 2.16.840.1.113883.10.20.3

1910 **6.3.1.1.4 Style Sheets**

Document sources SHOULD provide an XML style sheet to render the content of the Medical Summary document. The output of this style sheet SHALL be an XHTML Basic (see http://www.w3.org/TR/xhtml-basic/) document that renders the clinical content of a Medical Summary Document as closely as possible as the sending provider viewed the completed document. When a style sheet is provided, at least one processing instruction SHALL be included in the document that including a link to the URL for the XML style sheet. To ensure that the style sheet is available to all receivers, more than one stylesheet link MAY be included. When a stylesheet is used within an XDS Affinity domain, the link to it SHALL be provided using an HTTPS or HTTP URL.

```
<?xml-stylesheet href='https://foobar:8080/mystylesheet.xsl' type='text/xsl'?>
```

When using XDM or XDR to exchange documents, the stylesheet SHALL also be exchanged on the media. The link to the stylesheet SHALL be recorded as a relative URL. <?xml-stylesheet href='../../stylesheets/mystylesheet.xsl' type='text/xsl'?>

1925

1915

1920

Style sheets **SHOULD NOT** rely on graphic or other media resources. If graphics other media resources are used, these **SHALL** be accessible in the same way as the stylesheet. The Content Creator **NEED NOT** be the provider of the resources (stylesheet or graphcs).

When a Content Creator provides a style sheet, Content Consumers MUST provide a mechanism to render the document with that style sheet. Content Consumers MAY view the document with their own style sheet.

To record the stylesheet within a CDA Document that might be used in both an XDS and XDM environment, more than one stylesheet processing instruction is required. In this case, all style sheet processing instructions included MUST include the alternate='yes' attribute

```
<?xml-stylesheet href='https://foobar:8080/mystylesheet.xsl' type='text/xsl'
alternate='yes'?>
<?xml-stylesheet href='../../stylesheets/mystylesheet.xsl' type='text/xsl'
alternate='yes'?>
```

A Content Consumer that is attempting to render a document using the document supplied stylesheet MAY use the first style sheet processing instruction for which it is able to obtain the style sheet content, and SHALL NOT report any errors if it is able to find at least one stylesheet to render with.

1945 **6.3.1.1.5 Distinctions of None**

Information that is sent MUST clearly identify distinctions between

None

1935

1940

It is known with complete confidence that there are none. Used in the context of problem and medication lists, this indicates that the sender knows that there is no relevant information that can be sent.

None Known

None are known at this time, but it is not known with complete confidence than none exist. Used in the context of allergy lists, where essentially, it is impossible to prove the negative that no allergies exist, it is only possible to assert that none have been found to date.

None Known Did Ask (NKDA)

None are known at this time, and it is not known with complete confidence than none exist, but the information was requested. Also used in the context of allergy lists, where essentially, it is impossible to prove the negative that no allergies exist, it is only possible to assert that none have been found to date.

Unknown

The information is not known, or is otherwise unavailable. In the context of CDA, sections that are required to be present but have no information should use one of the above phrases where appropriate.

1960

1955

1950

1965 **6.3.1.2 Medical Summary Specification 1.3.6.1.4.1.19376.1.5.3.1.1.2**

A medical summary contains a snapshot of the patient's medical information, including at the very least, a list of the patients problems, medications and allergies.

6.3.1.2.1 Standards

CDAR2 HL7 CDA Release 2.0
CRS HL7 Care Record Summary

1970

6.3.1.2.2 Specification

Data Element Name	Opt	Template ID
Problem Concern Entry	R	1.3.6.1.4.1.19376.1.5.3.1.4.5.2
Allergy Concern Entry	R	1.3.6.1.4.1.19376.1.5.3.1.4.5.3
Medications	R	1.3.6.1.4.1.19376.1.5.3.1.4.7

6.3.1.2.3 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. A CDA Document may conform to more than one template. This content module inherits from the Medical Document content module, and so must conform to the requirements of that template as well, thus all <templateId> elements shown in the example below shall be included.

```
1980
       <ClinicalDocument xmlns='urn:h17-org:v3'>
          <typeId extension="POCD HD000040" root="2.16.840.1.113883.1.3"/>
          <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.1'/>
         <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.2'/>
         <id root=' ' extension=' '/>
1985
          <code code=' ' displayName='</pre>
           codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
          <title>Medical Summary</title>
          <effectiveTime value='20080601012005'/>
          <confidentialityCode code='N' displayName='Normal'</pre>
1990
            codeSystem='2.16.840.1.113883.5.25' codeSystemName='Confidentiality' />
          <languageCode code='en-US'/>
          <component><structuredBody>
1995
          </strucuredBody></component>
        </ClinicalDocument>
```

Figure 6.3-2 Sample Medical Summary Document

6.3.1.2.4 Schematron

```
<pattern name='Template 1.3.6.1.4.1.19376.1.5.3.1.1.2'>
2000
         <rule context='*[cda:templateId/@root="1.3.6.1.4.1.19376.1.5.3.1.1.2"]'>
           <!-- Verify that the template id is used on the appropriate type of object -
           <assert test='../cda:ClinicalDocument'>
             Error: The Medical Summary can only be used on Clinical Documents.
2005
           <!-- Verify that the parent templateId is also present. -->
           <assert test='cda:templateId[@root="1.3.6.1.4.1.19376.1.5.3.1.1.1"]'>
             Error: The parent template identifier for Medical Summary is not present.
2010
           <!-- Verify the document type code -->
           <assert test='cda:code[@code = "{{{LOINC}}}"]'>
             Error: The document type code of a Medical Summary must be {{{LOINC}}}
           <assert test='cda:code[@codeSystem = "2.16.840.1.113883.6.1"]'>
2015
             Error: The document type code must come from the LOINC code
             system (2.16.840.1.113883.6.1).
           <assert test='.//cda:templateId[@root =</pre>
        "1.3.6.1.4.1.19376.1.5.3.1.4.5.2"] '>
2020
             <!-- Verify that all required data elements are present -->
             Error: A(n) Medical Summary must contain Problem Concern Entry.
             See http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.1.2
           </assert>
           <assert test='.//cda:templateId[@root =</pre>
2025
        "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) Medical Summary must contain Allergy Concern Entry.
             See http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.1.2
           </assert>
2030
           <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) Medical Summary must contain Medications.
             See http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.1.2
           </assert>
2035
         </rule>
        </pattern>
```

6.3.1.2.5 Document Specification

A medical summary is a type of medical document, and incorporates the constraints defined for Medical Documents(1.3.6.1.4.1.19376.1.5.3.1.1.1).

2040 6.3.1.3 History and Physical Specification 1.3.6.1.4.1.19376.1.5.3.1.1.16.1.4

The intention of this work is to provide a parent template for the Antepartum History and Physical specifications. Future work in IHE may create an integration profile for a history and physical.

6.3.1.3.1 Format Code

The XDSDocumentEntry format code for this content is **TBD**

6.3.1.3.2 LOINC Code

The LOINC code for this document is 34117-2 HISTORY AND PHYSICAL

6.3.1.3.3 Standards

CDAR2 HL7 CDA Release 2.0

CDTHP CDA for Common Document Types History and Physical Notes (DSTU)

2050 **6.3.1.3.4 Specification**

Data Element Name	Opt	Template ID
Chief Complaint	R	1.3.6.1.4.1.19376.1.5.3.1.1.13.2.1
History of Present Illness	R	1.3.6.1.4.1.19376.1.5.3.1.3.4
Past Medical History	R	1.3.6.1.4.1.19376.1.5.3.1.3.8
Medications	R	1.3.6.1.4.1.19376.1.5.3.1.3.19
Allergies and Other Adverse Reactions Section	R	1.3.6.1.4.1.19376.1.5.3.1.3.13
Social History	R	1.3.6.1.4.1.19376.1.5.3.1.3.16
Family History	R	1.3.6.1.4.1.19376.1.5.3.1.3.14
Review of Systems	R	1.3.6.1.4.1.19376.1.5.3.1.3.18
Physical Examination	R	1.3.6.1.4.1.19376.1.5.3.1.1.9.15
<u>Vital Signs</u>	R	1.3.6.1.4.1.19376.1.5.3.1.3.25
Results Diagnostic Findings; use this OR Coded Results	R	1.3.6.1.4.1.19376.1.5.3.1.3.27
Coded Results Diagnostic Findings; use this OR Results	R	1.3.6.1.4.1.19376.1.5.3.1.3.28
Assessment and Plan	R	1.3.6.1.4.1.19376.1.5.3.1.1.13.2.5

Table 6.3-1

6.3.1.3.5 Conformance

2055

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. A CDA Document may conform to more than one template. This content module inherits from the Medical Summaries content module, and so must conform to the requirements of that template as well, thus all <templateId> elements shown in the example below shall be included.

```
2060
        <ClinicalDocument xmlns='urn:h17-org:v3'>
          <typeId extension="POCD HD000040" root="2.16.840.1.113883.1.3"/>
          <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.2'/>
          <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.16.1.4'/>
          <id root=' ' extension=' '/>
2065
          <code code='34117-2' displayName='HISTORY AND PHYSICAL'</pre>
            codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
          <title>History and Physical</title>
          <effectiveTime value='20080601012005'/>
          <confidentialityCode code='N' displayName='Normal'</pre>
2070
            codeSystem='2.16.840.1.113883.5.25' codeSystemName='Confidentiality' />
          <languageCode code='en-US'/>
          <component><structuredBody>
            <component>
2075
              <section>
                <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.13.2.1'/>
                <!-- Required Chief Complaint Section content -->
              </section>
            </component>
2080
            <component>
              <section>
                <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.4'/>
                <!-- Required History of Present Illness Section content -->
2085
              </section>
            </component>
            <component>
              <section>
2090
                <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.8'/>
                <!-- Required Past Medical History Section content -->
              </section>
            </component>
2095
            <component>
              <section>
                <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.19'/>
                <!-- Required Medications Section content -->
              </section>
2100
            </component>
            <component>
              <section>
                <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.13'/>
2105
                <!-- Required Allergies and Other Adverse Reactions Section Section
        content -->
              </section>
            </component>
2110
            <component>
                <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.16'/>
                <!-- Required Social History Section content -->
              </section>
2115
            </component>
            <component>
              <section>
                <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.14'/>
```

```
2120
                <!-- Required Family History Section content -->
              </section>
            </component>
            <component>
2125
              <section>
                <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.18'/>
               <!-- Required Review of Systems Section content -->
              </section>
            </component>
2130
            <component>
              <section>
                <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.9.15'/>
                <!-- Required Physical Examination Section content -->
2135
              </section>
            </component>
            <component>
              <section>
2140
                <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.25'/>
                <!-- Required Vital Signs Section content -->
              </section>
            </component>
2145
            <component>
              <section>
                <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.27'/>
                <!-- Required Results Section content -->
              </section>
2150
            </component>
            <component>
              <section>
                <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.28'/>
2155
                <!-- Required Coded Results Section content -->
              </section>
            </component>
            <component>
2160
              <section>
                <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.13.2.5'/>
                <!-- Required Assessment and Plan Section content -->
              </section>
            </component>
2165
          </strucuredBody></component>
        </ClinicalDocument>
```

Figure 6.3-3 Sample History and Physical Document

```
2170
        6.3.1.3.6 Schematron
        <pattern name='Template 1.3.6.1.4.1.19376.1.5.3.1.1.16.1.4'>
         <rule context='*[cda:templateId/@root="1.3.6.1.4.1.19376.1.5.3.1.1.16.1.4"]'>
           <!-- Verify that the template id is used on the appropriate type of object -
2175
           <assert test='../cda:ClinicalDocument'>
            Error: The History and Physical can only be used on Clinical Documents.
           <!-- Verify that the parent templateId is also present. -->
           <assert test='cda:templateId[@root="1.3.6.1.4.1.19376.1.5.3.1.1.2"]'>
2180
            Error: The parent template identifier for History and Physical is not
        present.
           </assert>
           <!-- Verify the document type code -->
           <assert test='cda:code[@code = "34117-2"]'>
2185
             Error: The document type code of a History and Physical must be 34117-2
           </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).
2190
           </assert>
           <assert test='.//cda:templateId[@root =</pre>
        "1.3.6.1.4.1.19376.1.5.3.1.1.13.2.1"]'>
             <!-- Verify that all required data elements are present -->
             Error: A(n) History and Physical must contain Chief Complaint.
2195
             See http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.1.16.1.4
           </assert>
           <assert test='.//cda:templateId[@root = "1.3.6.1.4.1.19376.1.5.3.1.3.4"]'>
            <!-- Verify that all required data elements are present -->
             Error: A(n) History and Physical must contain History of Present Illness.
2200
            See http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.1.16.1.4
           </assert>
           <assert test='.//cda:templateId[@root = "1.3.6.1.4.1.19376.1.5.3.1.3.8"]'>
             <!-- Verify that all required data elements are present -->
             Error: A(n) History and Physical must contain Past Medical History.
2205
             See http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.1.16.1.4
           <assert test='.//cda:templateId[@root = "1.3.6.1.4.1.19376.1.5.3.1.3.19"]'>
             <!-- Verify that all required data elements are present -->
             Error: A(n) History and Physical must contain Medications.
2210
             See http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.1.16.1.4
           </assert>
           <assert test='.//cda:templateId[@root = "1.3.6.1.4.1.19376.1.5.3.1.3.13"]'>
             <!-- Verify that all required data elements are present -->
             Error: A(n) History and Physical must contain Allergies and Other Adverse
2215
        Reactions Section.
             See http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.1.16.1.4
           </assert>
           <assert test='.//cda:templateId[@root = "1.3.6.1.4.1.19376.1.5.3.1.3.16"]'>
             <!-- Verify that all required data elements are present -->
2220
             Error: A(n) History and Physical must contain Social History.
            See http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.1.16.1.4
           </assert>
           <assert test='.//cda:templateId[@root = "1.3.6.1.4.1.19376.1.5.3.1.3.14"]'>
            <!-- Verify that all required data elements are present -->
2225
             Error: A(n) History and Physical must contain Family History.
             See http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.1.16.1.4
           </assert>
           <assert test='.//cda:templateId[@root = "1.3.6.1.4.1.19376.1.5.3.1.3.18"]'>
```

```
<!-- Verify that all required data elements are present -->
2230
             Error: A(n) History and Physical must contain Review of Systems.
             See http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.1.16.1.4
           <assert test='.//cda:templateId[@root =</pre>
        "1.3.6.1.4.1.19376.1.5.3.1.1.9.15"]'>
2235
             <!-- Verify that all required data elements are present -->
             Error: A(n) History and Physical must contain Physical Examination.
             See http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.1.16.1.4
           </assert>
           <assert test='.//cda:templateId[@root = "1.3.6.1.4.1.19376.1.5.3.1.3.25"]'>
2240
            <!-- Verify that all required data elements are present -->
             Error: A(n) History and Physical must contain Vital Signs.
             See http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.1.16.1.4
           </assert>
           <assert test='.//cda:templateId[@root = "1.3.6.1.4.1.19376.1.5.3.1.3.27"]'>
2245
             <!-- Verify that all required data elements are present -->
             Error: A(n) History and Physical must contain Results.
       http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.1.16.1.4
           </assert>
2250
           <assert test='.//cda:templateId[@root = "1.3.6.1.4.1.19376.1.5.3.1.3.28"]'>
             <!-- Verify that all required data elements are present -->
             Error: A(n) History and Physical must contain Coded Results.
       http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.1.16.1.4
2255
           </assert>
           <assert test='.//cda:templateId[@root =</pre>
        "1.3.6.1.4.1.19376.1.5.3.1.1.13.2.5"] '>
             <!-- Verify that all required data elements are present -->
             Error: A(n) History and Physical must contain Assessment and Plan.
2260
             See http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.1.16.1.4
           </assert>
         </rule>
        </pattern>
```

6.3.1.4 Antepartum Summary Specification 1.3.6.1.4.1.19376.1.5.3.1.1.11.2

The Antepartum Summary represents a summary of the most critical information to Obstetrician regarding the status of a patients pregnancy. The APS document is a medical summary and inherits all header constraints from Medical Summaries. The use case for this document is described fully in the APS Profile in PCC TF-1.

6.3.1.4.1 Format Code

2270 The XDSDocumentEntry format code for this content is **urn:ihe:pcc:aps:2007**

6.3.1.4.2 Standards

CCD ASTM/HL7 Continuity of Care Document

CDAR2 HL7 CDA Release 2.0

ACOGAR American College of Obstretricians and Gynecologists (ACOG), Antepartum Record

LOINC Logical Observation Identifiers, Names and Codes

SNOMED Systemized Nomenclature for Medicine

6.3.1.4.3 Data Element Index	

IHE PCC Technical Framework Supplement – Antepartum Record (APR)

This section maps the ACOG Antepartum Record to corresponding CDA sections as constrained by IHE.

ACOG Antepartum Record Datum	CDA Section	Trial
Drug Allergy/Latex Allergy	Allergies	
Is Blood Transfusion Acceptable	Advance Directives	
Antepartum Anesthesia Consult Planned	Plan of Care	
Problems/Plans	Problems	Related plans should be listed in Plan of Care
Medication List	Active Medications	
EDD Confirmation/18-20 Week EDD Update	Estimated Delivery Dates	
Prepregnancy Weight	Visit Summary Flowsheet	
Visit Flowsheet	Visit Summary Flowsheet	

2275 **6.3.1.4.4 Specification**

Data Element Name	Opt	Template ID
Allergies This section is the same as for Medical Summary, however it SHALL include one observation of Latex Allergy which may be negated through the negationInd attribute. Latex Allergy is particularly relevant for Obstetrics because of the frequency of vaginal exams that might involve the use of latex gloves. The observation value code for Latex Allergy is '300916003'. The codeSystem is '2.16.840.1.113883.6.96'. The codeSystemName is 'SNOMED CT'	R	1.3.6.1.4.1.19376.1.5.3.1.3.13
Advance Directives APS includes an explicit check of patients preference for blood transfusion because the risk of massive hemorrhage during delivery is much higher. This observation SHALL be recorded in the Advance Directives section. APS Form C documents SHALL include a simple observation of "blood transfusion acceptable?" The observation value for this observation is '(xx-bld-transf-ok)'. The codeSystem is '2.16.840.1.113883.6.1'. The codeSystemName is 'LOINC'	R	1.3.6.1.4.1.19376.1.5.3.1.3.34
Plan of Care APS forms SHOULD include an observation stating if an anesthesia consult is planned. When present, the observation value for this observation is '(xx-anest-cons-pland)'. The codeSystem is '2.16.840.1.113883.6.1'. The codeSystemName is 'LOINC'. If the type of anesthesia planned is known, systems SHOULD	R	1.3.6.1.4.1.19376.1.5.3.1.3.31

include an observation to represent that data using the LOINC code '(xx-type-of-anesth-pland)' with a CD value including one of the following values: (General Epidural Spinal) or a Null flavor to represent unknown or not listed.		
Medications Medications should include start and stop date if known.	R	1.3.6.1.4.1.19376.1.5.3.1.3.19
Problems Related Plans should be included in the Plan of Care section.	R	1.3.6.1.4.1.19376.1.5.3.1.3.6
Estimated Delivery Dates	R	1.3.6.1.4.1.19376.1.5.3.1.1.11.2.2.1
Antepartum Visit Summary Flowsheet	R	1.3.6.1.4.1.19376.1.5.3.1.1.11.2.2.2

Table 6.3-2

6.3.1.4.5 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. A CDA Document may conform to more than one template. This content module inherits from the Medical Summary content module, and so must conform to the requirements of that template as well, thus all <templateId> elements shown in the example below shall be included.

```
2285
        <ClinicalDocument xmlns='urn:h17-org:v3'>
          <typeId extension="POCD HD000040" root="2.16.840.1.113883.1.3"/>
          <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.2'/>
          <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.11.2'/>
          <id root=' ' extension=' '/>
2290
          <code code=' ' displayName=' '</pre>
            codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
          <title>Antepartum Summary</title>
          <effectiveTime value='20080601012005'/>
          <confidentialityCode code='N' displayName='Normal'</pre>
2295
            codeSystem='2.16.840.1.113883.5.25' codeSystemName='Confidentiality' />
          <languageCode code='en-US'/>
          <component><structuredBody>
            <component>
2300
              <section>
                <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.13'/>
                <!-- Required Allergies Section content -->
              </section>
            </component>
2305
            <component>
              <section>
                <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.34'/>
                <!-- Required Advance Directives Section content -->
2310
              </section>
            </component>
            <component>
              <section>
2315
                <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.31'/>
                <!-- Required Plan of Care Section content -->
              </section>
            </component>
2320
            <component>
              <section>
                <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.19'/>
                <!-- Required Medications Section content -->
              </section>
2325
            </component>
            <component>
              <section>
                <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.6'/>
2330
                <!-- Required Problems Section content -->
              </section>
            </component>
            <component>
2335
              <section>
                <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.11.2.2.1'/>
                <!-- Required Estimated Delivery Dates Section content -->
              </section>
            </component>
2340
            <component>
              <section>
                <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.11.2.2.2'/>
                <!-- Required Antepartum Visit Summary Flowsheet Section content -->
```

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Figure 6.3-4 Sample Antepartum Summary Document

6.3.1.4.6 Schematron

```
<pattern name='Template 1.3.6.1.4.1.19376.1.5.3.1.1.11.2'>
         <rule context='*[cda:templateId/@root="1.3.6.1.4.1.19376.1.5.3.1.1.11.2"]'>
2355
           <!-- Verify that the template id is used on the appropriate type of object -
           <assert test='../cda:ClinicalDocument'>
             Error: The Antepartum Summary can only be used on Clinical Documents.
           </assert>
2360
           <!-- Verify that the parent templateId is also present. -->
           <assert test='cda:templateId[@root="1.3.6.1.4.1.19376.1.5.3.1.1.2"]'>
             Error: The parent template identifier for Antepartum Summary is not
       present.
           </assert>
2365
           <!-- Verify the document type code -->
           <assert test='cda:code[@code = "{{{LOINC}}}"]'>
             Error: The document type code of a Antepartum Summary must be {{{LOINC}}}
           </assert>
           <assert test='cda:code[@codeSystem = "2.16.840.1.113883.6.1"]'>
2370
             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 = "1.3.6.1.4.1.19376.1.5.3.1.3.13"]'>
             <!-- Verify that all required data elements are present -->
2375
             Error: A(n) Antepartum Summary must contain Allergies.
             See http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.1.11.2
           </assert>
           <assert test='.//cda:templateId[@root = "1.3.6.1.4.1.19376.1.5.3.1.3.34"]'>
             <!-- Verify that all required data elements are present -->
2380
             Error: A(n) Antepartum Summary must contain Advance Directives.
             See http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.1.11.2
           </assert>
           <assert test='.//cda:templateId[@root = "1.3.6.1.4.1.19376.1.5.3.1.3.31"]'>
             <!-- Verify that all required data elements are present -->
2385
             Error: A(n) Antepartum Summary must contain Plan of Care.
             See http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.1.11.2
           </assert>
           <assert test='.//cda:templateId[@root = "1.3.6.1.4.1.19376.1.5.3.1.3.19"]'>
             <!-- Verify that all required data elements are present -->
2390
             Error: A(n) Antepartum Summary must contain Medications.
             See http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.1.11.2
           </assert>
           <assert test='.//cda:templateId[@root = "1.3.6.1.4.1.19376.1.5.3.1.3.6"]'>
             <!-- Verify that all required data elements are present -->
2395
             Error: A(n) Antepartum Summary must contain Problems.
             See http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.1.11.2
           </assert>
           <assert test='.//cda:templateId[@root =</pre>
        "1.3.6.1.4.1.19376.1.5.3.1.1.11.2.2.1"] '>
2400
             <!-- Verify that all required data elements are present -->
             Error: A(n) Antepartum Summary must contain Estimated Delivery Dates.
             See http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.1.11.2
           </assert>
           <assert test='.//cda:templateId[@root =</pre>
2405
        "1.3.6.1.4.1.19376.1.5.3.1.1.11.2.2.2"] '>
             <!-- Verify that all required data elements are present -->
             Error: A(n) Antepartum Summary must contain Antepartum Visit Summary
        Flowsheet.
             See http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.1.11.2
2410
           </assert>
```

```
<assert test="cda:entry/cda:observation/cda:value[@code='300916003']">
             Antepartum Summary Requires an observation of Latex Allergy to be
             asserted. This may be negated via the negationInd attribute.
2415
           <assert test="cda:entry/cda:observation/cda:value[@code='(xx-bld-transf-</pre>
        ok) ']">
             Antepartum Summary Requires an observation of blood transfusion
             acceptability to be asserted. This may be negated via the negationInd
        attribute.
2420
           </assert>
           <assert test="cda:entry/cda:observation/cda:value[@code='(xx-anest-cons-</pre>
       pland) ']">
            Antepartum Summary Requires an observation of anesthesia consult
             planned to be asserted. This may be negated via the negationInd
2425
       attribute.
           </assert>
         </rule>
        </pattern>
```

6.3.1.5 Antepartum History and Physical Specification 1.3.6.1.4.1.19376.1.5.3.1.1.16.1.1

The Antepartum History and Physical contains a record of the initial History and Physical performed during the initial visit.

6.3.1.5.1 Format Code

The XDSDocumentEntry format code for this content is urn:ihe:pcc:apr:2008

2435 **6.3.1.5.2 LOINC Code**

2430

The LOINC code for this document is **34117-2** HISTORY AND PHYSICAL

6.3.1.5.3 Standards

CDAR2 HL7 CDA Release 2.0

CCD <u>ASTM/HL7 Continuity of Care Document</u>

CDTHP CDA for Common Document Types History and Physical Notes (DSTU)

6.3.1.5.4 Data Element Index

Data Element	CDA Section	Comments
Header	Need to include Language, Ethnicity, Husband/Domestic Partner, Father of Baby; needs further analysis	
Chief Complaint	Chief Complaint	
Pregnancy History	Pregnancy History	Summary (Gravida Para Abortus) and detailed history of pregnancies
Medical History	Past Medical History	Exclude social and family history (included

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		in other sections)
Medical History - Tobacco, Alcohol, Drugs	Social History	
Medical History - Relevant Family History	Family History	
Medications	Medications	
Allergies	Allergies and Other Adverse Reactions Section	
Menstrual History/Symptoms Since LMP	Review of Systems	
Genetic Screening/Teratology Counseling	Family History	
Infection History	History of Infection	
Initial Physical Examination	Physical Examination	
Vital Signs	Vital Signs	subsection of Physical Examination
Diagnostic Findings	This section is required by CDA4CDT H&P - The intent in the APR specification is to have the antepartum specific laboratory results in the APR Laboratory document. However, this type of data may also be included here.	

6.3.1.5.5 Specification

Data Element Name	Opt	Template ID
Spouse	R	1.3.6.1.4.1.19376.1.5.3.1.2.4.1
Natural Father of Fetus	R	1.3.6.1.4.1.19376.1.5.3.1.2.4.2
Enthnicity The enthnicity of the patient should be recorded	R2	
Chief Complaint	R	1.3.6.1.4.1.19376.1.5.3.1.1.13.2.1
History of Present Illness	R	1.3.6.1.4.1.19376.1.5.3.1.3.4
Past Medical History This section is the same as it is for History and Physical, and it SHALL contain entries and SHOULD use the codes specified in the appropriate Antepartum Past Medical History Value Set. There is currently a CP to change this section name from Resolved Problems to Past Medical History.	R	1.3.6.1.4.1.19376.1.5.3.1.3.8
History of Infection This section SHALL contain coded entries for infection history and SHOULD use the codes as specified in the Antepartum Infection History	R	1.3.6.1.4.1.19376.1.5.3.1.1.16.2.1.1

Value Set.		
Pregnancy History This section will consist of two entries, both of which will live under the existing Pregnancy History section. Fields that don't exist in the current Pregnancy Observation list:' Summary - ectopics, multiple births Details - length of labor, birth weight, sex, type of delivery, anesthestics, place of delivery, preterm labor	R	1.3.6.1.4.1.19376.1.5.3.1.1.5.3.4
Pregnancy Summary History SHALL use the existing observation Pregnancy Observation and MAY use LOINC or SNOMED CT coded value sets	R	1.3.6.1.4.1.19376.1.5.3.1.1.16.4.1
Pregnancy Detail History Will contain the details of each pregnancy as specified in the Antepartum Pregnancy History Value Set.	0	1.3.6.1.4.1.19376.1.5.3.1.1.16.4.2
Social History This section is the same as it is for History & Physical, however it SHALL contain coded entries and SHOULD use the codes specified in the Antepartum Social History Value Set.	R	1.3.6.1.4.1.19376.1.5.3.1.3.16
Coded Family Medical History This section is the same as it is for History & Physical, however it SHALL contain Genetic Screening and Teratology Counseling information as specified in the Antepartum Family History and Genetic Screening Value Set. This section SHOULD also contain any additional relevant family history.	R	1.3.6.1.4.1.19376.1.5.3.1.3.15
Review of Systems This section is the same as it is for History & Physical, however it SHALL include organizers for Menstrual History and MAY include CDA entries for general review of systems data. The 'Menstrual History observations SHOULD use the codes specified in the Antepartum Menstrual History Value Set. The section code for the Menstrual History organizer SHALL be 49033-4 and the code system name is LOINC.		1.3.6.1.4.1.19376.1.5.3.1.3.18
Physical Examination This section is the same as it is for History & Physical, and if Vital Signs data are present it SHALL include a Vital Signs subsection.	R	1.3.6.1.4.1.19376.1.5.3.1.1.9.15
Vital Signs If Vital Signs data are present they SHALL be included as a subsection of Physical Examination.	С	1.3.6.1.4.1.19376.1.5.3.1.3.25

2440 Table 6.3-3

6.3.1.5.6 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. A CDA Document may conform to more than one template. This content module inherits from the History and Physical content module, and so must conform to the requirements of that template as well, thus all <templateId> elements shown in the example below shall be included.

93

```
<ClinicalDocument xmlns='urn:h17-org:v3'>
2450
          <typeId extension="POCD HD000040" root="2.16.840.1.113883.1.3"/>
          <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.16.1.4'/>
          <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.16.1.1'/>
          <id root=' ' extension=' '/>
          <code code='34117-2' displayName='HISTORY AND PHYSICAL'</pre>
2455
            codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
          <title>Antepartum History and Physical</title>
          <effectiveTime value='20080601012005'/>
          <confidentialityCode code='N' displayName='Normal'</pre>
            codeSystem='2.16.840.1.113883.5.25' codeSystemName='Confidentiality' />
2460
          <languageCode code='en-US'/>
          <component><structuredBody>
            <component>
              <section>
2465
                <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.13.2.1'/>
                <!-- Required Chief Complaint Section content -->
              </section>
            </component>
2470
            <component>
              <section>
                <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.4'/>
                <!-- Required History of Present Illness Section content -->
              </section>
2475
            </component>
            <component>
              <section>
                <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.8'/>
2480
                <!-- Required Past Medical History Section content -->
              </section>
            </component>
            <component>
2485
              <section>
                <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.16.2.1.1'/>
                <!-- Required History of Infection Section content -->
              </section>
            </component>
2490
            <component>
              <section>
                <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.5.3.4'/>
                <!-- Required Pregnancy History Section content -->
2495
              </section>
            </component>
            <component>
              <section>
2500
                <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.16.4.1'/>
                <!-- Required Pregnancy Summary History Section content -->
              </section>
            </component>
2505
            <component>
              <section>
                <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.16.4.2'/>
                <!-- Optional Pregnancy Detail History Section content -->
```

```
</section>
2510
            </component>
            <component>
              <section>
                <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.16'/>
2515
               <!-- Required Social History Section content -->
              </section>
            </component>
            <component>
2520
              <section>
                <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.15'/>
                <!-- Required Coded Family Medical History Section content -->
              </section>
            </component>
2525
            <component>
              <section>
                <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.18'/>
                <!-- Required Review of Systems Section content -->
2530
              </section>
            </component>
            <component>
              <section>
2535
                <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.9.15'/>
                <!-- Required Physical Examination Section content -->
              </section>
            </component>
2540
            <component>
              <section>
                <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.25'/>
                <!-- Conditional Vital Signs Section content -->
              </section>
2545
            </component>
          </strucuredBody></component>
        </ClinicalDocument>
```

Figure 6.3-5 Sample Antepartum History and Physical Document

6.3.1.5.7 Schematron

```
<pattern name='Template 1.3.6.1.4.1.19376.1.5.3.1.1.16.1.1'>
         <rule context='*[cda:templateId/@root="1.3.6.1.4.1.19376.1.5.3.1.1.16.1.1"]'>
           <!-- Verify that the template id is used on the appropriate type of object -
2555
           <assert test='../cda:ClinicalDocument'>
             Error: The Antepartum History and Physical can only be used on Clinical
        Documents.
           </assert>
2560
           <!-- Verify that the parent templateId is also present. -->
           <assert test='cda:templateId[@root="1.3.6.1.4.1.19376.1.5.3.1.1.16.1.4"]'>
             Error: The parent template identifier for Antepartum History and Physical
        is not present.
           </assert>
2565
           <!-- Verify the document type code -->
           <assert test='cda:code[@code = "34117-2"]'>
             Error: The document type code of a Antepartum History and Physical must be
        34117-2
           </assert>
2570
           <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 =</pre>
2575
        "1.3.6.1.4.1.19376.1.5.3.1.2.4.1"]'>
             <!-- Verify that all required data elements are present -->
             Error: A(n) Antepartum History and Physical must contain Spouse.
             See http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.1.16.1.1
           </assert>
2580
           <assert test='.//cda:templateId[@root =</pre>
        "1.3.6.1.4.1.19376.1.5.3.1.2.4.2"]'>
             <!-- Verify that all required data elements are present -->
             Error: A(n) Antepartum History and Physical must contain Natural Father of
       Fetus.
2585
             See http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.1.16.1.1
           </assert>
           <assert test='.//cda:templateId[@root = ""]'>
             <!-- Alert on any missing required if known elements -->
             Warning: A(n) Antepartum History and Physical should contain Enthnicity.
2590
             See
        http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.1.16.1.1
           </assert>
           <assert test='.//cda:templateId[@root =</pre>
        "1.3.6.1.4.1.19376.1.5.3.1.1.13.2.1"] '>
2595
             <!-- Verify that all required data elements are present -->
             Error: A(n) Antepartum History and Physical must contain Chief Complaint.
             See http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.1.16.1.1
           </assert>
           <assert test='.//cda:templateId[@root = "1.3.6.1.4.1.19376.1.5.3.1.3.4"]'>
2600
             <!-- Verify that all required data elements are present -->
             Error: A(n) Antepartum History and Physical must contain History of
        Present Illness.
             See http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.1.16.1.1
           </assert>
2605
           <assert test='.//cda:templateId[@root = "1.3.6.1.4.1.19376.1.5.3.1.3.8"]'>
             <!-- Verify that all required data elements are present -->
             Error: A(n) Antepartum History and Physical must contain Past Medical
        History.
```

```
2610
       http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.1.16.1.1
           </assert>
           <assert test='.//cda:templateId[@root =</pre>
        "1.3.6.1.4.1.19376.1.5.3.1.1.16.2.1.1"] '>
             <!-- Verify that all required data elements are present -->
2615
             Error: A(n) Antepartum History and Physical must contain History of
        Infection.
             See
       http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.1.16.1.1
           </assert>
2620
           <assert test='.//cda:templateId[@root =</pre>
        "1.3.6.1.4.1.19376.1.5.3.1.1.5.3.4"]'>
             <!-- Verify that all required data elements are present -->
             Error: A(n) Antepartum History and Physical must contain Pregnancy
       History.
2625
             See
       http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.1.16.1.1
           </assert>
           <assert test='.//cda:templateId[@root =</pre>
        "1.3.6.1.4.1.19376.1.5.3.1.1.16.4.1"] '>
2630
             <!-- Verify that all required data elements are present -->
             Error: A(n) Antepartum History and Physical must contain Pregnancy Summary
        History.
        http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.1.16.1.1
2635
           </assert>
           <assert test='.//cda:templateId[@root =</pre>
        "1.3.6.1.4.1.19376.1.5.3.1.1.16.4.2"]'>
            <!-- Note any missing optional elements -->
             Note: This Antepartum History and Physical does not contain Pregnancy
2640
        Detail History.
             See
        http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.1.16.1.1
           </assert>
           <assert test='.//cda:templateId[@root = "1.3.6.1.4.1.19376.1.5.3.1.3.16"]'>
2645
             <!-- Verify that all required data elements are present -->
             Error: A(n) Antepartum History and Physical must contain Social History.
       http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.1.16.1.1
           </assert>
2650
           <assert test='.//cda:templateId[@root = "1.3.6.1.4.1.19376.1.5.3.1.3.15"]'>
             <!-- Verify that all required data elements are present -->
             Error: A(n) Antepartum History and Physical must contain Coded Family
       Medical History.
             See
2655
       http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.1.16.1.1
           <assert test='.//cda:templateId[@root = "1.3.6.1.4.1.19376.1.5.3.1.3.18"]'>
             <!-- Verify that all required data elements are present -->
             Error: A(n) Antepartum History and Physical must contain Review of
2660
        Systems.
             See
       http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.1.16.1.1
           </assert>
           <assert test='.//cda:templateId[@root =</pre>
2665
        "1.3.6.1.4.1.19376.1.5.3.1.1.9.15"]'>
             <!-- Verify that all required data elements are present -->
             Error: A(n) Antepartum History and Physical must contain Physical
        Examination.
```

2680 **6.3.1.6 Antepartum Laboratory Specification 1.3.6.1.4.1.19376.1.5.3.1.1.16.1.2**

The Antepartum Laboratory document SHALL follow all constraints as defined in the XD-LAB Harmonization profile, as described in LAB TF-3:4.

6.3.1.6.1 Format Code

2685 The XDSDocumentEntry format code for this content is **formatCode**

6.3.1.6.2 LOINC Code

The LOINC code for this document is **26436-6** Laboratory Studies

6.3.1.6.3 Standards

CDAR2 HL7 CDA Release 2.0

6.3.1.6.4 Conformance

be included.

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. A CDA Document may conform to more than one template. This content module inherits from the XD Lab Report content module, and so must conform to the requirements of that template as well, thus all <templateId> elements shown in the example below shall

```
<ClinicalDocument xmlns='urn:h17-org:v3'>
          <typeId extension="POCD HD000040" root="2.16.840.1.113883.1.3"/>
          <templateId root='1.3.6.1.4.1.19376.1.3.3.2.1'/>
2700
          <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.16.1.2'/>
          <id root=' ' extension=' '/>
          <code code='26436-6' displayName='Laboratory Studies'</pre>
            codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
          <title>Antepartum Laboratory</title>
2705
          <effectiveTime value='20080601012005'/>
          <confidentialityCode code='N' displayName='Normal'</pre>
            codeSystem='2.16.840.1.113883.5.25' codeSystemName='Confidentiality' />
          <languageCode code='en-US'/>
2710
          <component><structuredBody>
          </strucuredBody></component>
        </ClinicalDocument>
```

Figure 6.3-6 Sample Antepartum Laboratory Document

2715 **6.3.1.6.5 Schematron**

```
<pattern name='Template 1.3.6.1.4.1.19376.1.5.3.1.1.16.1.2'>
         <rule context='*[cda:templateId/@root="1.3.6.1.4.1.19376.1.5.3.1.1.16.1.2"]'>
           <!-- Verify that the template id is used on the appropriate type of object -
2720
           <assert test='../cda:ClinicalDocument'>
            Error: The Antepartum Laboratory can only be used on Clinical Documents.
           </assert>
           <!-- Verify that the parent templateId is also present. -->
           <assert test='cda:templateId[@root="1.3.6.1.4.1.19376.1.3.3.2.1"]'>
2725
            Error: The parent template identifier for Antepartum Laboratory is not
        present.
          </assert>
           <!-- Verify the document type code -->
           <assert test='cda:code[@code = "26436-6"]'>
2730
            Error: The document type code of a Antepartum Laboratory must be 26436-6
           <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).
2735
           </assert>
         </rule>
        </pattern>
```

6.3.1.7 APR Laboratory Value Sets

2740

6.3.2 Antepartum Record Laboratory LOINC Codes 1.3.6.1.4.1.19376.1.5.3.1.1.16.5.7

Lab	LOINC Code	Comments	
Antibody Screen (AB)	890-4 Ab Screen		
Blood Type	XX-AR ABO RH (profile test)	XX-AR: A LOINC profile code will be requested	
Hepatitis B virus (HBV) surface Antigen (Ag)	5196-1 HBV surface Ag (EIA)		
	5195-3 HBV surface Ag		
	5197-9 HBV surface Ag (RIA)		
	7905-3 HBV surface Ag (Neut)		
	718-7 Hgb		
Hemoglobin (Hgb)/Hematocrit (Hct)	4544-3 Hct (Automated count)		
(11ge), 11emateure (11ee)	30350-3 Hgb		
	21440-3 HPV I/H Risk DNA Cervix (Probe)		
	21441-1 HPV Low Risk DNA Cervix (Probe)		
Pap Test/Human papilloma	10524-7 Cytology Cervix		
virus (HPV)	18500-9 Thin Prep Cervix		
	19765-7 Cytology Cervix/Vaginal (Nominal)		
	19766-5 Cytology Cervix/Vaginal (Narrative)		
	5334-8 RUBV Ab IgG (EIA)		
Rubella Virus (RUBV)	25514-1 RUBV Ab IgG		
Antibody (Ab)	40667-8 RUBV Ab IgG (EIA)		
	8014-3 RUBV Ab IgG		
Urine Culture Screen	630-4 Bacteria Urine Culture		
Hemoglobin (Hgb) Electrophoresis	XX- Hemoglobinopathy/Thalassemia Panel HTPR (Reflexive) (Profile)	XX-HTPR: A LOINC profile code will be requested	
Purified protein derivative (PPD)	1647-7 Purified protein derivative skin test		
	6347-9 Chlamydia Ag		
Chlamydia	XX-CTD Chlamydia Trachomatis (DFA) (Profile)	XX-CTD, XX-CTA and XX-CTNGA: A LOINC profile code will be requested	
	XX-CTA Chlamydia Trachomatis (Aptima) (Profile)		

 $IHE\ PCC\ Technical\ Framework\ Supplement-Antepartum\ Record\ (APR)$

	6349-5 Neisseria Gonorrhoeae		
	XX- Chlamydia Trachomatis Neisseria CTNGA Gonorrhoeae (Aptima) (Profile)		
Gonorrhea	XX- Chlamydia Trachomatis Neisseria CTNGA Gonorrhoeae (Aptima) (Profile)		
	691-6 Neisseria Gonorrhoeaea	XX-CTNGA and XX-CNGA: A LOINC profile code will be	
	9568-7 Neisseria Gonorrhoeaea Ab	requested	
	XX- Chlamydia Neisseria Gonorrhoeae CNGA (Aptima) (Profile)		
Ultrasound	35096-7 OB Ultrasound Panel		
	XX- Alpha-Feto Protein (Maternal) AFPM (Profile)		
MSAFP Multiple Markers	1834-1 Alpha-1 Fetoprotein	XX-AFPM and XX-AFP: A LOINC profile code will be	
-	8270-1 Prenatal Risk Quad Screen	requested	
	XX-AFP Alpha-Feto Protein (Profile)		
Amnio Chorionic Villus Sampling (CVS)	XX-CVS CVS	XX-CVS: A LOINC profile code will be requested	
Karotype	33373-2 Karyotype (Amino Fluid)		
	33774-0 Karyotype (CVS)		
Amniotic Fluid (AFP)	XX- Alpha-Feto Protein, Amniotic AFPAFR Fluid (Reflexive) (Profile)	XX-AFPAFR: A LOINC profile code will be requested	
Diabetes Screen	12646-6 Glucose Challenge, Pregnant (1hr)		
	12646-6 Glucose Challenge, Pregnant (1hr)	XX-GTP2 and XX-GTP3: A	
Glucose Tolerance Test (GTT)	XX-GTP2 Glucose Tolerance, Pregnant (2hr)	LOINC profile code will be requested	
(-1)	XX-GTP3 Glucose Tolerance, Pregnant (3hr)		
Anti-D Immune Globulin (RhIG)	XX-RHIG Anti-D Immune Globulin (RhIG)	XX-RHIG: A LOINC profile code will be requested	
Venereal Disease Research Laboratory (VDRL)	20507-0 Rapid Plasma Reagin (RPR)		
	XX- RPR with Reflex to Titer	XX-RWRTT and XX-RR: A LOINC profile code will be requested	
	RWRTT (Reflexive) (Profile) XX-RR Rubella and RPR (Profile)		
Group B Strep	XX-BSGB Beta Strep Group B (PCR)		
	11267-2 Strep Group B	XX-BSGB: A LOINC profile code will be requested	
Beta Human Chorionic Gonadotropin (HCG)	21198-7 Beta HCG		

	XX-UM	Urinalysis with Microscopic (Profile)	XX-UMON: A LOINC profile code will be requested
	XX- UMA	Urinalysis with Microscopic Analysis (Profile)	
	XX-UD	Urinalysis Dipstick (Profile)	
	XX-UDO	Urinalysis Dipstick Only (Profile)	
	XX- UMO	Urinalysis Microscopic Only (Profile)	
	XX- UMON	Urinalysis Microscopic Only (New)(Profile)	
Aneuploidy Screening (Ultrasound)	XX-ASU Aneuploidy Screening (Ultrasound)		XX-ASU: A LOINC profile code will be requested
First Trimester Screening with Nuchal Translucency and maternal serum	XX-NTMS Nuchal Translucency and Maternal Serum		XX-NTMS: A LOINC profile code will be requested
Maternal Serum Triple Screen	XX-MSTS Maternal Serum Triple Screen (Profile		XX-MSTS: A LOINC profile code will be requested
Thyroid Stimulating Hormone (TSH)	3016-3	Thyrotropin (3rd generation) TSH Thyrotropin Receptor Ab	
Triiodothyronine (T3)	3051-0 3052-8 3054-4 3050-2 XX-T3FT	T3 Free T3 Reverse T3 True T3 Resin Uptake T3 Free and Total (Profile)	XX-T3FT: A LOINC profile code will be requested
Varicella Zoster Virus (VZV) Ab	22600-1 XX- VZVP 10860-5 6584-7	Varicella Zoster Virus Ab Varicella Zoster Virus (PCR) (Profile) Varicella Zoster Virus Virus Identified	XX-VZVP: A LOINC profile code will be requested

6.3.2.1 Antepartum Education Specification 1.3.6.1.4.1.19376.1.5.3.1.1.16.1.3

The Antepartum Education document contains a list of patient education activities that have occured, or have been planned to review with the patient.

2745 **6.3.2.1.1** Format Code

The XDSDocumentEntry format code for this content is urn:ihe:pcc:apr:2008

6.3.2.1.2 LOINC Code

The LOINC code for this document is 34895-3 EDUCATION NOTE

6.3.2.1.3 Standards

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2750

6.3.2.1.4 Specification

Data Element Name	Opt	Template ID
Coded Patient Education and Consents This section SHALL be the same as it is for History & Physical, and SHOULD use the codes available in the Antepartum Education Code table.	R	1.3.6.1.4.1.19376.1.5.3.1.1.9.39

Table 6.3-4

6.3.2.1.5 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. A CDA Document may conform to more than one template. This content module inherits from the Medical Documents content module, and so must conform to the requirements of that template as well, thus all <templateId> elements shown in the example below shall be included.

```
<ClinicalDocument xmlns='urn:h17-org:v3'>
          <typeId extension="POCD HD000040" root="2.16.840.1.113883.1.3"/>
          <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.1'/>
          <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.16.1.3'/>
2765
          <id root=' ' extension=' '/>
          <code code='34895-3' displayName='EDUCATION NOTE'</pre>
            codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
          <title>Antepartum Education</title>
          <effectiveTime value='20080601012005'/>
2770
          <confidentialityCode code='N' displayName='Normal'</pre>
            codeSystem='2.16.840.1.113883.5.25' codeSystemName='Confidentiality' />
          <languageCode code='en-US'/>
          <component><structuredBody>
2775
            <component>
              <section>
                <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.9.39'/>
                <!-- Required Coded Patient Education and Consents Section content -->
              </section>
2780
            </component>
          </strucuredBody></component>
        </ClinicalDocument>
```

Figure 6.3-7 Sample Antepartum Education Document

6.3.2.1.6 Schematron

```
<pattern name='Template 1.3.6.1.4.1.19376.1.5.3.1.1.16.1.3'>
         <rule context='*[cda:templateId/@root="1.3.6.1.4.1.19376.1.5.3.1.1.16.1.3"]'>
           <!-- Verify that the template id is used on the appropriate type of object -
2790
           <assert test='../cda:ClinicalDocument'>
             Error: The Antepartum Education can only be used on Clinical Documents.
           <!-- Verify that the parent templateId is also present. -->
2795
           <assert test='cda:templateId[@root="1.3.6.1.4.1.19376.1.5.3.1.1.1"]'>
             Error: The parent template identifier for Antepartum Education is not
       present.
           </assert>
           <!-- Verify the document type code -->
2800
           <assert test='cda:code[@code = "34895-3"]'>
             Error: The document type code of a Antepartum Education must be 34895-3
           </assert>
           <assert test='cda:code[@codeSystem = "2.16.840.1.113883.6.1"]'>
            Error: The document type code must come from the LOINC code
2805
             system (2.16.840.1.113883.6.1).
           </assert>
           <assert test='.//cda:templateId[@root =</pre>
        "1.3.6.1.4.1.19376.1.5.3.1.1.9.39"]'>
             <!-- Verify that all required data elements are present -->
2810
             Error: A(n) Antepartum Education must contain Coded Patient Education and
        Consents.
             See
       http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.1.16.1.3
           </assert>
2815
         </rule>
        </pattern>
```

6.3.3 CDA Header Content Modules

6.3.3.1 Patient Contacts 1.3.6.1.4.1.19376.1.5.3.1.2.4

Patient contacts are recorded as described in HL7 CCD: 3.3

6.3.3.1.1 Specification

Guardians

6.3.3.1.2 <guardian classCode='GUARD'>

The guardians of a patient shall be recorded in the <guardian> element beneath the <patient> element.

6.3.3.1.3 <participant typeCode='IND'>

Other contacts are recorded as <participant> elements appearing in the document header. The classCode attribute shall be set to 'IND'.

6.3.3.1.4 <templateld root='1.3.6.1.4.1.19376.1.5.3.1.2.4'/>

The <templateId> element identifies this person as a patient contact and must be recorded exactly as shown above.

2855 **6.3.3.1.5 <time value=' '>**

The <time> element may be present and indicates the time of the participation.

6.3.3.1.6 <associatedEntity classCode='AGNT|CAREGIVER|ECON|NOK|PRS'>

The <associatedEntity> element identifies the type of contact. The classCode attribute shall be present, and contains a value from the set AGNT, CAREGIVER, ECON, NOK, or PRS to identify contacts that are agents of the patient, care givers, emergency contacts, next of kin, or other relations respectively.

6.3.3.1.7 <code code=' ' displayName=' ' codeSystem='2.16.840.1.113883.5.111' codeSystemName='RoleCode'/>

2865

The relationship between the patient and the guardian or other contact should be recorded in the <code> element. The code attribute is required and comes from the HL7 PersonalRelationshipRoleType vocabulary. The codeSystem attribute is required and shall be represented exactly as shown above.

2870 6.3.3.1.8 <addr>

The address of the guardian or other contact should be present, and shall be represented as any other address would be in CDA.

6.3.3.1.9 <telecom>

The phone number of the guardian or other contact should be present, and shall be 2875 represented as any other phone number would be in CDA.

6.3.3.1.10<guardianPerson><name/> or <assignedPerson><name/>

The name of the guardian or other contact shall be present, and shall be represented as any other name would be in CDA.

6.3.3.2 Spouse 1.3.6.1.4.1.19376.1.5.3.1.2.4.1

2880 The spouse header element records the spouse of a patient, and inherits other constraints from the Patient Contacts entry. Items in bold in the example below show the additional constraints on this element.

This element SHALL be included as a participant in the header of the CDA document in the event of the pregnancy. If this does not apply to the patient this element SHALL use a null flavor.

6.3.3.2.1 Parent Template

The parent of this template is **Patient Contacts**.

6.3.3.2.2 Specification

6.3.3.2.3 <templateld root='1.3.6.1.4.1.19376.1.5.3.1.2.4'/><templateld root='1.3.6.1.4.1.19376.1.5.3.1.2.4.1'/>

The <templateId> element identifies this person as a spouse and must be recorded exactly as shown above.

6.3.3.2.4 <associatedEntity classCode='PRS'>

The classCode attribute of the <associatedEntity> element shall be PRS.

2920 6.3.3.2.5 <code code='xx-spouse|184142008' displayName=' ' codeSystem='2.16.840.1.113883.6.96' codeSystemName='SNOMED CT'/>

This element SHALL use xx-spouse (requested) to represent the patient's spouse or 184142008 to represent the patient's next of kin. The code system name is SNOMED CT.

6.3.3.2.6 Completed Example

2925

2955

```
<!-- Husband/Domestic Partner -->
          <participant typeCode="IND">
            <associatedEntity classCode="NOK">
2930
              <code code="184142008" displayName="patient's next of kin"</pre>
                codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT"/>
                <streetAddressLine>45 Chunn Dr.</streetAddressLine>
                <city>Spring Hill</city>
2935
                <state>TN</state>
                <postalCode>37174</postalCode>
                <country>USA</country>
              <telecom value="tel:(999)555-1212" use="WP"/>
2940
              <associatedPerson>
                <name>
                  <prefix>Mr.</prefix>
                  <given>John</given>
                  <family>Youngston</family>
2945
                </name>
              </associatedPerson>
            </associatedEntity>
          </participant>
```

6.3.3.3 Natural Father of Fetus 1.3.6.1.4.1.19376.1.5.3.1.2.4.2

This header element records the natural father of the fetus, and inherits other constraints from the <u>Patient Contacts</u> entry. Items in bold in the example below show the additional constraints on this element.

This element SHALL be included as a participant in the header of the CDA document in the event of the pregnancy. If the father of the baby is unknown this element SHALL use a null flavor.

6.3.3.3.1 Parent Template

The parent of this template is Patient Contacts.

6.3.3.3.2 Specification

2975

2980

2985

2990

6.3.3.3.3 <templateld root='1.3.6.1.4.1.19376.1.5.3.1.2.4'/><templateld root='1.3.6.1.4.1.19376.1.5.3.1.2.4.2'/>

The <templateId> element identifies this person as the natural father and must be recorded exactly as shown above.

6.3.3.3.4 <associatedEntity classCode='PRS'>

The classCode attribute of the <associatedEntity> element shall be PRS.

```
<rule context='hl7:templateId/@root="1.3.6.1.4.1.19376.1.5.3.1.2.4.2"]'>
    <assert test='../hl7:associatedEntity/@classCode = "PRS"'>
        The classCode attribute of the associated entity shall be PRS.
      </assert>
    </rule>
```

6.3.3.3.5 <code code='xx-fatherofbaby' displayName=' ' codeSystem='2.16.840.1.113883.6.96' codeSystemName='SNOMED CT'/>

For father of baby the code SHALL be xx-fatherofbaby (requested). The code system name is SNOMED CT

6.3.3.3.6 Completed Example

```
2995
          <!-- Father of baby -->
          <participant typeCode="IND">
            <associatedEntity classCode="NOK">
              <code code="xx-fatherofbaby" displayName="Father of Baby"</pre>
3000
                codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT"/>
                <streetAddressLine>18 Oak Valley Dr.</streetAddressLine>
                <city>Monteagle</city>
                <state>TN</state>
3005
                <postalCode>37205</postalCode>
                <country>USA</country>
              <telecom value="tel:(999)555-1212" use="WP"/>
              <associatedPerson>
3010
                <name>
                  <prefix>Mr.</prefix>
                  <given>Thomas</given>
                  <family>Caster</family>
                </name>
3015
              </associatedPerson>
            </associatedEntity>
          </participant>
```

6.3.3.4 Authorization 1.3.6.1.4.1.19376.1.5.3.1.2.5

Each <authorization> element in the CDA Header represents an informed consent. When the document being shared represents the informed consent to a policy expressed by the XDS Affinity Domain within the document, it shall do so in an <authorization> element. More than one <authorization> element may be present. The consent to share information shall have a unique identifier contained in the <id> element, representing the patient consent to that policy. The policy being consented to shall be represented in the <code> element. Note that other <authorization> elements may be present representing other sorts of consents associated with the document.

6.3.3.4.1 Specification

Policies are identified using an Affinity Domain specified coding system. Each coded value in that vocabulary represents one affinity domain specific policy.

3040 6.3.3.4.2 <authorization typeCode='AUTH'>

At least one <authorization> element must be present in a consent medical document in documents shared by Document Source actors that implement the privacy option. The typeCode attribute shall be present and be valued with AUTH, indicating that this is an authorization act related to the document.

3045 6.3.3.4.3 <consent classCode='CONS' moodCode='EVN'>

Each authorization element shall have one <consent> element. The classCode shall be present and be valued with CONS, indicating that the related act is an informed consent. The moodCode shall be EVN, indicating that this element represents and act that has occurred.

3050 6.3.3.4.4 <templateld root='1.3.6.1.4.1.19376.1.5.3.1.2.5'/>

The <templateId> element shall be recorded as shown above and identifies this consent as an authorization entry.

6.3.3.4.5 <id root=' '/>

The <consent> element shall have one identifier that is used to uniquely identify the consent act. This identifier shall contain a root attribute, and shall not contain an extension attribute.

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

The <consent> element shall have one <code> element that is used to identify the consent policy that was agreed to by the patient.

6.3.4 CDA Section Content Modules

This list defines the sections that may appear in a medical document. It is intended to be a comprehensive list of all document sections that are used by any content profile defined in the Patient Care Coordination Technical Framework. All sections shall have a narrative component that may be freely formatted into normal text, lists, tables, or other appropriate human-readable presentations. Additional subsections or entry content modules may be required.

6.3.4.1 Other Condition Histories

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

3070 Active Problems Section

Template ID	1.3.6.1.4.1	1.3.6.1.4.1.19376.1.5.3.1.3.6	
Parent Template	CCD 3.5 (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	

6.3.4.1.1.1 Parent Template

The parent of this template is CCD 3.5.

```
<component>
          <section>
3075
            <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'</pre>
              codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
3080
            <text>
              Text as described above
            </text>
            <entry>
3085
              <!-- Required Problem Concern Entry element -->
                <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.2'/>
            </entry>
3090
          </section>
        </component>
```

Figure 6.3-8 Sample Active Problems Section

6.3.4.1.1.2Schematron

```
<pattern name='Template 1.3.6.1.4.1.19376.1.5.3.1.3.6'>
3095
         <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.
3100
           <!-- 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.
3105
           <!-- 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 test='cda:code[@codeSystem = "2.16.840.1.113883.6.1"]'>
3110
             Error: The section type code must come from the LOINC code
             system (2.16.840.1.113883.6.1).
           <assert test='.//cda:templateId[@root =</pre>
        "1.3.6.1.4.1.19376.1.5.3.1.4.5.2"] '>
3115
             <!-- 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>
3120
        </pattern>
```

6.3.4.1.2 Allergies and Other Adverse Reactions Section

Template ID	1.3.6.1.4.1	1.3.6.1.4.1.19376.1.5.3.1.3.13		
Parent Template	CCD 3.8 (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 Intolerances Concern		

6.3.4.1.2.1 Parent Template

The parent of this template is <u>CCD 3.8</u>. 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'/>
3130
            <id root=' ' extension=' '/>
            <code code='48765-2' displayName='Allergies, adverse reactions, alerts'</pre>
              codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
            <text>
              Text as described above
3135
            </text>
            <entry>
              <!-- Required Allergies and Intolerances Concern element -->
                <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.3'/>
3140
            </entry>
          </section>
        </component>
```

Figure 6.3-9 Sample Allergies and Other Adverse Reactions Section

6.3.4.1.2.2 Schematron

3145

```
<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
3150
           <assert test='../cda:section'>
             Error: The Allergies and Other Adverse Reactions can only be used on
       sections.
           </assert>
3155
           <!-- 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>
3160
           <!-- 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>
3165
           <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 =</pre>
3170
        "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
3175
           </assert>
        </rule>
        </pattern>
```

6.3.4.1.3 Family Medical History Section

Template ID	1.3.6.1.4.1.19376.1.5.3.1.3.14
-------------	--------------------------------

$IHE\ PCC\ Technical\ Framework\ Supplement-Antepartum\ Record\ (APR)$

Parent Template	<u>2.16.840.1.113883.10.20.1.4</u> (2.16.840.1.113883.10.20.1.4)	
General Description	The family history section shall contain a narrative description of the genetic family members, to the extent that they are known, the diseases they suffered from, their ages at death, and other relevant genetic information.	
LOINC Code	Opt	Description
10157-6	R	HISTORY OF FAMILY MEMBER DISEASES

Parent Template

The parent of this template is 2.16.840.1.113883.10.20.1.4.

Figure 6.3-10 Sample Family Medical History Section

6.3.4.1.3.1 Schematron

```
<pattern name='Template 1.3.6.1.4.1.19376.1.5.3.1.3.14'>
        <rule context='*[cda:templateId/@root="1.3.6.1.4.1.19376.1.5.3.1.3.14"]'>
3200
            <!-- Verify that the template id is used on the appropriate type of object
          <assert test='../cda:section'>
             Error: The Family Medical History can only be used on sections.
          </assert>
3205
          <!-- Verify that the parent templateId is also present. -->
          <assert test='templateId[@root="2.16.840.1.113883.10.20.1.4"]'>
            Error: The parent template identifier for Family Medical History is not
       present.
          </assert>
3210
          <!-- Verify the section type code -->
          <assert test='cda:code[@code = "10157-6"]'>
            Error: The section type code of a Family Medical History must be 10157-6
          </assert>
          <assert test='cda:code[@codeSystem = "2.16.840.1.113883.6.1"]'>
3215
            Error: The section type code must come from the LOINC code
            system (2.16.840.1.113883.6.1).
          </assert>
        </rule>
        </pattern>
```

3220 Coded Family Medical History Section

Template ID	1.3.6.1.4.1	1.3.6.1.4.1.19376.1.5.3.1.3.15	
Parent Template	Family Me	Family Medical History (1.3.6.1.4.1.19376.1.5.3.1.3.14)	
General Description	The family history section shall include entries for family history as described in the Entry Content Modules.		
LOINC Code	Opt	Description	
10157-6	R	HISTORY OF FAMILY MEMBER DISEASES	
Entries	Opt	Description	
1.3.6.1.4.1.19376.1.5.3.1.4.15	R	Family History Organizer	

6.3.4.1.3.2 Parent Template

The parent of this template is Family Medical History.

```
<component>
3225
          <section>
            <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.14'/>
            <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.15'/>
            <id root=' ' extension=' '/>
            <code code='10157-6' displayName='HISTORY OF FAMILY MEMBER DISEASES'</pre>
3230
              codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
            <text>
              Text as described above
            </text>
            <entry>
3235
              <!-- Required Family History Organizer element -->
                <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.15'/>
            </entry>
3240
          </section>
        </component>
```

Figure 6.3-11 Sample Coded Family Medical History Section

6.3.4.1.3.3 Schematron

```
3245
        <pattern name='Template 1.3.6.1.4.1.19376.1.5.3.1.3.15'>
         <rule context='*[cda:templateId/@root="1.3.6.1.4.1.19376.1.5.3.1.3.15"]'>
             <!-- Verify that the template id is used on the appropriate type of object
           <assert test='../cda:section'>
3250
             Error: The Coded Family Medical History can only be used on sections.
           <!-- Verify that the parent templateId is also present. -->
           <assert test='templateId[@root="1.3.6.1.4.1.19376.1.5.3.1.3.14"]'>
            Error: The parent template identifier for Coded Family Medical History is
3255
       not present.
           </assert>
           <!-- Verify the section type code -->
           <assert test='cda:code[@code = "10157-6"]'>
            Error: The section type code of a Coded Family Medical History must be
3260
       10157-6
           </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).
3265
           <assert test='.//cda:templateId[@root = "1.3.6.1.4.1.19376.1.5.3.1.4.15"]'>
            <!-- Verify that all required data elements are present -->
            Error: A(n) Coded Family Medical History must contain Family History
        Organizer.
3270
            See http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.3.15
           </assert>
         </rule>
        </pattern>
```

6.3.4.1.4 Social History Section

Template ID	1.3.6.1.4.1.19376.1.5.3.1.3.16	
Parent Template	CCD 3.7 (2.16.840.1.113883.10.20.1.15)	
General Description	The social history section shall contain a narrative description of the person's beliefs, home life, community life, work life, hobbies, and risky habits.	
LOINC Code	Opt	Description
29762-2	R	SOCIAL HISTORY

Parent Template

The parent of this template is CCD 3.7.

Figure 6.3-12 Sample Social History Section

6.3.4.1.4.1 Schematron

```
<pattern name='Template 1.3.6.1.4.1.19376.1.5.3.1.3.16'>
        <rule context='*[cda:templateId/@root="1.3.6.1.4.1.19376.1.5.3.1.3.16"]'>
3295
            <!-- Verify that the template id is used on the appropriate type of object
          <assert test='../cda:section'>
             Error: The Social History can only be used on sections.
3300
          <!-- Verify that the parent templateId is also present. -->
          <assert test='templateId[@root="2.16.840.1.113883.10.20.1.15"]'>
            Error: The parent template identifier for Social History is not present.
          <!-- Verify the section type code -->
3305
          <assert test='cda:code[@code = "29762-2"]'>
            Error: The section type code of a Social History must be 29762-2
          <assert test='cda:code[@codeSystem = "2.16.840.1.113883.6.1"]'>
            Error: The section type code must come from the LOINC code
3310
            system (2.16.840.1.113883.6.1).
          </assert>
        </rule>
        </pattern>
```

6.3.4.1.5 Estimated Due Dates Section Section

Template ID	1.3.6.1.4.	1.19376.1.5.3.1.1.11.2.2.1
General Description	This section houses the physicians best estimate of the patients due date. This is generally done both on an initial evaluation, and later confirmed at 18-20 weeks. The date is supported by evidence such as the patients history of last menstral period, a physical examination, or ultrasound measurements. If an gestational age based on ultrasound is present, it is generally considered the most accurate measurement and so that date would be chosen.	
LOINC Code	Opt	Description
(xx-edd-section)	R	ESTIMATED DELIVERY DATE-^PATIENT-FIND-PT-NAR-
Entries	Opt	Description

```
3315
```

```
<component>
          <section>
            <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.11.2.2.1'/>
3320
            <id root=' ' extension=' '/>
            <code code='(xx-edd-section)' displayName='ESTIMATED DELIVERY DATE-</pre>
        ^PATIENT-FIND-PT-NAR-'
              codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
            <text>
3325
              Text as described above
            </text>
            <entry>
              <!-- Required Estimated Due Date Observation element -->
3330
                <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.11.2.3.1'/>
            </entry>
          </section>
3335
        </component>
```

Figure 6.3-13 Sample Estimated Due Dates Section Section

6.3.4.1.5.1 Schematron

```
<pattern name='Template_1.3.6.1.4.1.19376.1.5.3.1.1.11.2.2.1'>
         <rule
3340
        context='*[cda:templateId/@root="1.3.6.1.4.1.19376.1.5.3.1.1.11.2.2.1"]'>
             <!-- Verify that the template id is used on the appropriate type of object
           <assert test='../cda:section'>
              Error: The Estimated Due Dates Section can only be used on sections.
3345
           </assert>
           <!-- Verify the section type code -->
           <assert test='cda:code[@code = "(xx-edd-section)"]'>
             Error: The section type code of a Estimated Due Dates Section must be (xx-
        edd-section)
3350
           </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>
3355
           <assert test='.//cda:templateId[@root =</pre>
        "1.3.6.1.4.1.19376.1.5.3.1.1.11.2.3.1"1'>
             <!-- Verify that all required data elements are present -->
             Error: A(n) Estimated Due Dates Section must contain Estimated Due Date
        Observation.
3360
             See
        http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.1.11.2.2.1
           </assert>
         </rule>
        </pattern>
```

3365 **6.3.4.2 Medications**

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

6.3.4.2.1 Medications Section

Template ID	1.3.6.1.4.1	1.3.6.1.4.1.19376.1.5.3.1.3.19		
Parent Template	CCD 3.9 (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		

6.3.4.2.2 Parent Template

The parent of this template is $\underline{\text{CCD 3.9}}$.

```
<component>
          <section>
3375
            <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'</pre>
              codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
3380
              Text as described above
            </text>
            <entry>
3385
              <!-- Required Medications element -->
                <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7'/>
            </entry>
3390
          </section>
        </component>
```

Figure 6.3-14 Sample Medications Section

6.3.4.2.2.1 Schematron

```
<pattern name='Template 1.3.6.1.4.1.19376.1.5.3.1.3.19'>
3395
        <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.
3400
          <!-- 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>
3405
          <!-- 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"]'>
3410
            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 -->
3415
            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>
```

6.3.4.2.3 Immunizations Section

3420

Template ID	1.3.6.1.4.1	1.3.6.1.4.1.19376.1.5.3.1.3.23	
Parent Template	CCD 3.11	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	
LOINC Code 11369-6	Opt	Description HISTORY OF IMMUNIZATIONS	
	-	•	

6.3.4.2.3.1 Parent Template

The parent of this template is CCD 3.11.

```
<component>
3425
          <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'</pre>
3430
              codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
            <text>
              Text as described above
            </text>
            <entry>
3435
              <!-- Required Immunization element -->
                <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.12'/>
            </entry>
3440
          </section>
        </component>
```

Figure 6.3-15 Sample Immunizations Section

6.3.4.2.3.2Schematron

```
3445
        <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'>
3450
             Error: The Immunizations can only be used on sections.
           <!-- 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.
3455
           </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
3460
           <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 test='.//cda:templateId[@root = "1.3.6.1.4.1.19376.1.5.3.1.4.12"]'>
3465
             <!-- 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>
3470
        </pattern>
```

6.3.4.3 Physical Exams

6.3.4.3.1 Vital Signs Section

Template ID	1.3.6.1.4.1.19376.1.5.3.1.3.25	
Parent Template	CCD 3.12 (2.16.840.1.113883.10.20.1.16)	
General Description	The vital signs section shall contain a narrative description of the measurement results of a patient's vital signs.	
LOINC Code	Opt	Description
8716-3	R	VITAL SIGNS

Parent Template

3475 The parent of this template is <u>CCD 3.12</u>.

Figure 6.3-16 Sample Vital Signs Section

3490 **6.3.4.3.1.1 Schematron**

```
<pattern name='Template 1.3.6.1.4.1.19376.1.5.3.1.3.25'>
        <rule context='*[cda:templateId/@root="1.3.6.1.4.1.19376.1.5.3.1.3.25"]'>
            <!-- Verify that the template id is used on the appropriate type of object
3495
          <assert test='../cda:section'>
             Error: The Vital Signs can only be used on sections.
          <!-- Verify that the parent templateId is also present. -->
          <assert test='templateId[@root="2.16.840.1.113883.10.20.1.16"]'>
3500
            Error: The parent template identifier for 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 Vital Signs must be 8716-3
3505
          </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>
3510
         </rule>
        </pattern>
```

6.3.4.3.2 Coded Vital Signs Section

Template ID	1.3.6.1.4.1	1.3.6.1.4.1.19376.1.5.3.1.1.5.3.2	
Parent Template	Vital Signs	<u>Vital Signs</u> (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	
LOING GOOD	Opt	Description	
8716-3	R	VITAL SIGNS	
	•	·	

6.3.4.3.2.1 Parent Template

The parent of this template is <u>Vital Signs</u>.

```
<component>
          <section>
            <templateId root='1.3.6.1.4.1.19376.1.5.3.1.3.25'/>
3520
            <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'</pre>
              codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
3525
              Text as described above
            </text>
            <entry>
              <!-- Required Vital Signs Organizer element -->
3530
                <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13.1'/>
            </entry>
          </section>
3535
        </component>
```

Figure 6.3-17 Sample Coded Vital Signs Section

6.3.4.3.2.2Schematron

```
<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"]'>
3540
             <!-- 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.
3545
           <!-- 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>
3550
           <!-- 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"]'>
3555
            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 =</pre>
        "1.3.6.1.4.1.19376.1.5.3.1.4.13.1"]'>
3560
             <!-- 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>
3565
        </pattern>
```

6.3.4.4 Plans of Care

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

6.3.4.4.1 Care Plan Section

Template ID	1.3.6.1.4.1.19376.1.5.3.1.3.31	
General Description	The care plan section shall contain a narrative description of the expectations for care including proposals, goals, and order requests for monitoring, tracking, or improving the condition of the patient.	
LOINC Code	Opt Description	
18776-5	R	TREATMENT PLAN

Figure 6.3-18 Sample Care Plan Section

6.3.4.4.1.1 Schematron

```
<pattern name='Template 1.3.6.1.4.1.19376.1.5.3.1.3.31'>
        <rule context='*[cda:templateId/@root="1.3.6.1.4.1.19376.1.5.3.1.3.31"]'>
            <!-- Verify that the template id is used on the appropriate type of object
3590
           <assert test='../cda:section'>
             Error: The Care Plan can only be used on sections.
           </assert>
           <!-- Verify the section type code -->
           <assert test='cda:code[@code = "18776-5"]'>
3595
            Error: The section type code of a Care Plan must be 18776-5
           </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).
3600
           </assert>
        </rule>
        </pattern>
```

6.3.4.4.2 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

3605

Parent Template

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

Figure 6.3-19 Sample Advance Directives Section

6.3.4.4.2.1 Schematron

```
<pattern name='Template 1.3.6.1.4.1.19376.1.5.3.1.3.34'>
3625
        <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.
3630
          </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.
3635
          </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
3640
          <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>
3645
        </pattern>
```

Coded Advance Directives Section

Template ID	1.3.6.1.4.1	1.3.6.1.4.1.19376.1.5.3.1.3.35	
Parent Template	Advance I	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	
LOINC Code	Opt	Description ADVANCE DIRECTIVES	
	•	·	

6.3.4.4.2.2 Parent Template

The parent of this template is Advance Directives.

```
3650
        <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=' '/>
3655
            <code code='42348-3' displayName='ADVANCE DIRECTIVES'</pre>
              codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
            <text>
              Text as described above
            </text>
3660
            <entry>
              <!-- Required if known Advance Directive Observation element -->
                <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13.7'/>
3665
            </entry>
          </section>
        </component>
```

Figure 6.3-20 Sample Coded Advance Directives Section

3670 **6.3.4.4.2.3Schematron**

```
<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
3675
           <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"]'>
3680
            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"]'>
3685
            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).
3690
           </assert>
           <assert test='.//cda:templateId[@root =</pre>
        "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
3695
       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>
```

3700 **6.3.4.5 Procedures Performed**

6.3.4.5.1 Patient Education and Consents Section

Template ID	1.3.6.1.4.1.19376.1.5.3.1.1.9.38	
General Description	The patient education and consents section shall contain a description of the patient education the patient received, the results of the education, and the consents the patient signed.	
LOINC Code	Opt	Description
34895-3	R	EDUCATION NOTE

Figure 6.3-21 Sample Patient Education and Consents Section

6.3.4.5.1.1 Schematron

```
<pattern name='Template 1.3.6.1.4.1.19376.1.5.3.1.1.9.38'>
         <rule context='*[cda:templateId/@root="1.3.6.1.4.1.19376.1.5.3.1.1.9.38"]'>
3720
             <!-- Verify that the template id is used on the appropriate type of object
           <assert test='../cda:section'>
             Error: The Patient Education and Consents can only be used on sections.
           </assert>
3725
           <!-- Verify the section type code -->
           <assert test='cda:code[@code = "34895-3"]'>
            Error: The section type code of a Patient Education and Consents must be
        34895-3
           </assert>
3730
           <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>
3735
        </pattern>
```

6.3.4.5.2 Patient Education and Consents Section

Template ID	1.3.6.1.4.1.19376.1.5.3.1.1.9.39	
Parent Template	1.3.6.1.4.1	.19376.1.5.3.1.1.9.38 (1.3.6.1.4.1.19376.1.5.3.1.1.9.38)
General Description	The patient education and consents section shall contain a description of the patient education the patient received, the results of the education, and references to the consents the patient signed. It shall include entries for procedures and references to consent documents as described in the Entry Content Modules.	
LOINC Code	Opt Description	
34895-3	R	EDUCATION NOTE
Entries	Opt Description	
1.3.6.1.4.1.19376.1.5.3.1.4.19	R	Procedure Entry The procedures shall be in INT mood
1.3.6.1.4.1.19376.1.5.3.1.4.13	R2	Simple Observations
1.3.6.1.4.1.19376.1.5.3.1.4.4	R2	External References

6.3.4.5.2.1 Parent Template

3740 The parent of this template is 1.3.6.1.4.1.19376.1.5.3.1.1.9.38.

```
<component>
          <section>
            <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.9.38'/>
            <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.9.39'/>
3745
            <id root=' ' extension=' '/>
            <code code='34895-3' displayName='EDUCATION NOTE'</pre>
              codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
            <text>
              Text as described above
3750
            </text>
            <entry>
              <!-- Required Procedure Entry element -->
                <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.19'/>
3755
            </entry>
            <entry>
              <!-- Required if known Simple Observations element -->
3760
                <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13'/>
            </entry>
            <entry>
3765
              <!-- Required if known External References element -->
                <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.4'/>
            </entry>
3770
          </section>
        </component>
```

Figure 6.3-22 Sample Patient Education and Consents Section

6.3.4.5.2.2 Schematron

```
<pattern name='Template 1.3.6.1.4.1.19376.1.5.3.1.1.9.39'>
3775
         <rule context='*[cda:templateId/@root="1.3.6.1.4.1.19376.1.5.3.1.1.9.39"]'>
             <!-- Verify that the template id is used on the appropriate type of object
           <assert test='../cda:section'>
             Error: The Patient Education and Consents can only be used on sections.
3780
          <!-- Verify that the parent templateId is also present. -->
          <assert test='templateId[@root="1.3.6.1.4.1.19376.1.5.3.1.1.9.38"]'>
            Error: The parent template identifier for Patient Education and Consents
       is not present.
3785
          </assert>
          <!-- Verify the section type code -->
           <assert test='cda:code[@code = "34895-3"]'>
            Error: The section type code of a Patient Education and Consents must be
       34895-3
3790
          </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).
3795
          <assert test='.//cda:templateId[@root = "1.3.6.1.4.1.19376.1.5.3.1.4.19"]'>
            <!-- Verify that all required data elements are present -->
            Error: A(n) Patient Education and Consents must contain Procedure Entry.
            See http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.1.9.39
          </assert>
3800
          <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) Patient Education and Consents should contain Simple
        Observations.
            See http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.1.9.39
3805
          </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) Patient Education and Consents should contain External
3810
            See http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.1.9.39
          </assert>
        </rule>
        </pattern>
```

6.3.4.6 Impressions

3815 **6.3.4.6.1 Visit Summary Section**

Template ID	1.3.6.1.4.	1.3.6.1.4.1.19376.1.5.3.1.1.11.2.2.2	
General Description		This section is a running history of the most important elements noted for a pregnant woman.	
LOINC Code	Opt	Description	
(xx-acog-visit-sum-section)	R	PREGNANCY VISIT SUMMARY-^PATIENT-FIND-PT-NAR	
Entries	Opt	Description	
1.3.6.1.4.1.19376.1.5.3.1.4.13	R	Simple Observation The flowsheet contains one simple observation to represent the Prepregancy Weight. This observation SHALL be valued with the	

		LOINC code 8348-5, BODY WEIGHT^PRE PREGNANCY-MASS-PT-QN-MEASURED. The value SHALL be of type PQ. The units may be either "lb_av" or "kg".
1.3.6.1.4.1.19376.1.5.3.1.1.11.2.3.2	R	Antepartum Flowsheet Panel Other entries on the flowsheet are "batteries" which represent a single visit.

```
<component>
          <section>
3820
            <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.11.2.2.2'/>
            <id root=' ' extension=' '/>
            <code code='(xx-acog-visit-sum-section)' displayName='PREGNANCY VISIT</pre>
        SUMMARY-^PATIENT-FIND-PT-NAR'
              codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
3825
            <text>
              Text as described above
            </text>
            <entry>
3830
              <!-- Required Simple Observation element -->
                <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13'/>
            </entry>
            <entry>
3835
              <!-- Required Antepartum Flowsheet Panel element -->
                <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.11.2.3.2'/>
            </entry>
3840
          </section>
        </component>
```

Figure 6.3-23 Sample Visit Summary Section

6.3.4.6.1.1 Schematron

```
3845
        <pattern name='Template 1.3.6.1.4.1.19376.1.5.3.1.1.11.2.2.2'>
        <rule
        context='*[cda:templateId/@root="1.3.6.1.4.1.19376.1.5.3.1.1.11.2.2.2"]'>
            <!-- Verify that the template id is used on the appropriate type of object
3850
           <assert test='../cda:section'>
             Error: The Visit Summary can only be used on sections.
           </assert>
           <!-- Verify the section type code -->
           <assert test='cda:code[@code = "(xx-acog-visit-sum-section)"]'>
3855
            Error: The section type code of a Visit Summary must be (xx-acog-visit-
        sum-section)
           </assert>
           <assert test='cda:code[@codeSystem = "2.16.840.1.113883.6.1"]'>
             Error: The section type code must come from the LOINC code
3860
            system (2.16.840.1.113883.6.1).
           <assert test='.//cda:templateId[@root = "1.3.6.1.4.1.19376.1.5.3.1.4.13"]'>
             <!-- Verify that all required data elements are present -->
            Error: A(n) Visit Summary must contain Simple Observation.
3865
        http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.1.11.2.2.2
           </assert>
           <assert test='.//cda:templateId[@root =</pre>
        "1.3.6.1.4.1.19376.1.5.3.1.1.11.2.3.2"] '>
3870
            <!-- Verify that all required data elements are present -->
             Error: A(n) Visit Summary must contain Antepartum Flowsheet Panel.
       http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.1.11.2.2.2
           </assert>
3875
           <assert test='.//cda:observation/cda:code[@code="8348-5"]'>
            Error: The Visit Summary must have at least one simple observation with
        the LOINC
            code 8348-5 to represent the prepregnancy weight.
3880
       http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.1.11.2.2.2
           </assert>
           <assert test='.//cda:observation[cda:code/@code='8348-</pre>
        5']/cda:value[@unit='kg' or @unit='lb_av']">
             Error: The prepregnancy weight shall record the units in kg or lbs
3885
       http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.1.11.2.2.2
           </assert>
        </rule>
       </pattern>
```

6.3.5 CDA and HL7 Version 3 Entry Content Modules

6.3.5.1 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.

3890

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.

6.3.5.1.1 <author>

3905

3910

3915

3920

3925

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.

6.3.5.1.2 <time value=' '/>

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

6.3.5.1.3 <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.

6.3.5.1.4 <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.

6.3.5.2 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.

6.3.5.2.1 Standards

RIM HL7 Version 3 Reference Information Model

CDAR2 HL7 Clinical Document Architecture Release 2.0

6.3.5.2.2 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
Table Cell 1 1 Table Cell 2	<pre><code> <originaltext><reference value="#foo"></reference></originaltext> </code> <code> <originaltext><reference value="#bar"></reference></originaltext> </code></pre>
<item id="baz">List item 1</item>	<pre><code> <originaltext><reference value="#baz"></reference></originaltext> </code></pre>
<pre><paragraph id="p-1">A paragraph <content id="c-1">with content</content> </paragraph></pre>	<pre><code> <originaltext><reference value="#p-1"></reference></originaltext> </code> <code> <originaltext><reference value="#c-1"></reference></originaltext> </code></pre>

Table 6.3-5 Example Uses of ID

3940

3945

3930

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 the URI, 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:

3950

\$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:

3960

3965

3955

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

6.3.5.2.3 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.

6.3.5.3 Oseverity 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.

3970 The example below shows the recording the condition or allergy severity, and is used as the context for the following sections.

6.3.5.3.1 Standards

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

6.3.5.3.2 Specification

```
<observation classCode='COND' moodCode='EVN'>
            <entryRelationship typeCode='SUBJ' inversionInd='true'>
3980
              <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'</pre>
                  codeSystem='2.16.840.1.113883.5.4' codeSystemName='ActCode' />
3985
                <text><reference value='#severity-2'/></text>
                <statusCode code='completed'/>
                <value xsi:type='CD' code='H|M|L'</pre>
                  codeSystem='2.16.840.1.113883.5.1063'
                  codeSystemName='ObservationValue' />
3990
              </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.

6.3.5.3.2.1 < 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.

6.3.5.3.2.2<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).

3995

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.

6.3.5.3.2.4 <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.

6.3.5.3.2.5 <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.

6.3.5.3.2.6 <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.

6.3.5.3.2.7 <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.

6.3.5.4 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.

4025

4040

4055

6.3.5.4.1 Standards

CCD ASTM/HL7 Continuity of Care Document

6.3.5.4.2 Specification

```
<entry>
           <observation classCode='OBS' moodCode='EVN'>
4060
             <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'/>
4065
                 <code code='33999-4' displayName='Status'</pre>
                   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'</pre>
4070
        codeSystemName='SNOMED CT'/>
               </observation>
             </entryRelationship>
           </observation>
4075
         </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 4080 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 4085 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.

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

The related statement is made about the clinical status of the problem or allergy. For 4090 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.

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

4095 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).

6.3.5.4.5 <templateld root='2.16.840.1.113883.10.20.1.57'/> <templateld root='2.16.840.1.113883.10.20.1.50'/> <templateld 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.

6.3.5.4.6 <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.

6.3.5.4.7 <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 <u>Linking Narrative and Coded Entries</u>), rather than duplicate text to avoid ambiguity. For HL7 Version 3 Messages, the <text> element SHALL contain the full narrative text.

6.3.5.4.8 <statusCode code='completed'/>

4100

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.

6.3.5.4.9 <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

6.3.5.5 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.

6.3.5.5.1 Specification

```
4130
         <entry>
          <observation classCode='OBS' moodCode='EVN'>
            <entryRelationship typeCode='REFR' inversionInd='false'>
              <observation classCode='OBS' moodCode='EVN'>
4135
                <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'</pre>
                  codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC' />
4140
                <text><reference value='#hstatus-2'/></text>
                <statusCode code='completed'/>
                </value>
                <value xsi:type='CE' code=' ' codeSystem='2.16.840.1.113883.6.96'</pre>
         codeSystemName='SNOMED CT'/>
4145
              </observation>
            </entryRelationship>
          </observation>
         </entry>
4150
```

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

6.3.5.5.2 <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.

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

```
6.3.5.5.4 <templateld root='2.16.840.1.113883.10.20.1.57'/> <templateld root='2.16.840.1.113883.10.20.1.51'/> <templateld 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.

144

6.3.5.5.5 < code code='11323-3'

4170

4180

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.

4175 **6.3.5.5.6 <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 <u>Linking Narrative and Coded Entries</u>, rather than duplicate text to avoid ambiguity. For HL7 Version 3 Messages, the <text> element shall contain the full narrative text.

6.3.5.5.7 <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.

4185 6.3.5.5.8 <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

4190 **6.3.5.6 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.

6.3.5.6.1 Standards

4195

CCD ASTM/HL7 Continuity of Care Document

6.3.5.6.2 Specification

```
4200
        <entry>
          <observation classCode='OBS' moodCode='EVN'>
            <entryRelationship typeCode='SUBJ' inversionInd='true'>
4205
              <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'</pre>
                  codeSystem='2.16.840.1.113883.6.1'
4210
                  codeSystemName='LOINC' />
                <text><reference value='#comment-2'/></text>
                <statusCode code='completed' />
                <author>
                  <time value=''/>
4215
                  <assignedAuthor>
                    <id root='' extension=''>
                    <addr></addr>
                    <telecom value='' use=''>
                    <assignedPerson><name></name></assignedPerson>
4220
                    <representedOrganization><name></representedOrganization>
                  </assignedAuthor>
                </author>
              </act>
            </entryRelationship>
4225
          </observation>
        </entry>
```

6.3.5.6.3 <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.

6.3.5.6.4 <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.

6.3.5.6.5 <templateld root='2.16.840.1.113883.10.20.1.40'/> <templateld 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.

4245 6.3.5.6.6 <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.

4250 **6.3.5.6.7 <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.

6.3.5.6.8 <statusCode code='completed' />

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

6.3.5.6.9 <author>

4240

4255

4265

4260 The comment may have an author.

6.3.5.6.10 <time value=' '/>

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

6.3.5.6.11 <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.

4270 6.3.5.6.12 <assignedPerson><name></name></assignedPerson> <representedOrganization><name></representedOrganization>

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

4275 **6.3.5.7 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.

6.3.5.7.1 Standards

4280

4300

4305

Pharmacy HL7 Pharmacy Domain (Normative)

6.3.5.7.2 Specification

```
<entry>
4285
         <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'/>
4290
               <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'</pre>
                 codeSystemName='IHEActCode' />
               <text><reference value='#comment-2'/></text>
               <statusCode code='completed' />
4295
             </act>
           </entryRelationship>
         </substanceAdministration>
        </entry>
```

6.3.5.7.3 <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'.

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

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

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.

4315 **6.3.5.7.6 <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.

6.3.5.7.7 <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.

4325 6.3.5.7.8 <statusCode code='completed' />

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

6.3.5.8 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.

6.3.5.8.1 Standards

Pharmacy HL7 Pharmacy Domain (Normative)

4335 **6.3.5.8.2 Specification**

```
<entry>
         <supply classCode='SPLY' moodCode='EVN'>
4340
           <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'/>
4345
               <code code='FINSTRUCT' codeSystem='1.3.6.1.4.1.19376.1.5.3.2'</pre>
                 codeSystemName='IHEActCode' />
               <text><reference value='#comment-2'/></text>
               <statusCode code='completed' />
             </act>
4350
           </entryRelationship>
         </supply>
        </entry>
```

6.3.5.8.3 <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.

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

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

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

6.3.5.8.6 <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.

6.3.5.8.7 <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 the link 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.

6.3.5.8.8 <statusCode code='completed' />

4385

4400

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

6.3.5.9 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 Clincial 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, Clincial 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.

6.3.5.9.1 Specification

```
4410
        <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' />
4415
            <text><reference value='#study-1'/></text>
            <!-- For CDA -->
            <reference typeCode='REFR|SPRT'>
              <externalDocument classCode='DOC' moodCode='EVN'>
                <id extension='' root=''/>
4420
                <text><reference value='http://foo..'/></text>
              </externalDocument>
            </reference>
            <!-- For HL7 Version 3 Messages
            <sourceOf typeCode='REFR|SPRT'>
4425
               <act classCode='DOC' moodCode='EVN'>
                  <id extension='' root=''/>
                  <text><reference value='http://foo...'</text>
               </act>
            </sourceOf>
4430
             -->
          </act>
        </entry>
```

6.3.5.9.2 <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').

6.3.5.9.3 <templateld 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'.

6.3.5.9.4 <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.

6.3.5.9.5 <code nullFlavor='NA'/>

The reference act has no code associated with it.

6.3.5.9.6 <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.

·-----

4440

6.3.5.9.7 <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.

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

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

6.3.5.9.9 <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.

6.3.5.10 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.

6.3.5.10.1 Specification

6.3.5.10.2<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.

6.3.5.10.3<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.

6.3.5.10.4<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.

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

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

4500 6.3.5.10.6<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".

6.3.5.11 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.

4515 **6.3.5.11.1Standards**

4505

CCD ASTM/HL7 Continuity of Care Document

CareStruct HL7 Care Provision Care Structures (DSTU)

ClinStat HL7 Clinical Statement (DRAFT)

6.3.5.11.2Specification

```
<act classCode='ACT' moodCode='EVN'>
          <templateId root='2.16.840.1.113883.10.20.1.27'/>
4520
          <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>
4525
            <low value=''/>
            <high value=''/>
          </effectiveTime>
          <!-- one or more entry relationships identifying problems of concern -->
          <entryRelationship typeCode='SUBJ' inversionInd='false'>
4530
          </entryRelationship>
          <!-- For HL7 Version 3 Messages
          <sourceOf typeCode='SUBJ' inversionInd='false'>
4535
          </sourceOf>
          -->
          <!-- optional entry relationship providing more information about the concern
          <entryRelationship typeCode='REFR'>
4540
          </entryRelationship>
          <!-- For HL7 Version 3 Messages
          <sourceOf typeCode='REFR' inversionInd='false'>
4545
          </sourceOf>
          -->
        </act>
```

4550 6.3.5.11.3 <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.

6.3.5.11.4 <templateld root='2.16.840.1.113883.10.20.1.27'/> <templateld 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.

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

4560 This required element identifies the concern.

6.3.5.11.6 <code nullFlavor='NA'/>

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

6.3.5.11.7 <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.		

4565 **Table 6.3-6**

6.3.5.11.8 <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.

4570 **6.3.5.11.9 <!-- 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'.

 $\begin{tabular}{ll} \textbf{Note:} \\ \begin{tabular}{ll} \textbf{Note:}$

6.3.5.11.10 <!-- 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

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<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'

4590 **6.3.5.12 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.

6.3.5.12.1 Standards

CCD ASTM/HL7 Continuity of Care Document

CareStruct HL7 Care Provision Care Structures (DSTU)

ClinStat HL7 Clinical Statement Pattern (Draft)

4595 **6.3.5.12.2 Parent Template**

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

6.3.5.12.3 Specification

```
4600
        <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=' '/>
4605
         <code nullFlavor='NA'/>
         <statusCode code='active|suspended|aborted|completed'/>
         <effectiveTime>
           <low value=' '/>
           <high value=' '/>
4610
        </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'>
4615
           </observation>
         </entryRelationship>
         <!-- optional entry relationship providing more information about the concern
4620
         <entryRelationship type='REFR'>
         </entryRelationship>
        </act>
```

6.3.5.12.4 <templateld root='1.3.6.1.4.1.19376.1.5.3.1.4.5.1'/> <templateld 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.

4630 6.3.5.12.5 <!-- 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'/>

...

4625

4635

4640

</observation>

<entryRelationship type='SUBJ'>

This entry shall contain one or more problem entries that conform to the <u>Problem Entry</u> 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'

6.3.5.13 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 <u>Concern Entry</u>, 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.

4645 **6.3.5.13.1Standards**

CCD ASTM/HL7 Continuity of Care Document

CareStruct HL7 Care Provision Care Structures (DSTU)

ClinStat HL7 Clinical Statement Pattern (Draft)

6.3.5.13.2 Parent Template

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

6.3.5.13.3 Specification

```
4650
        <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=' '/>
4655
         <code nullFlavor='NA'/>
         <statusCode code='active|suspended|aborted|completed'/>
         <effectiveTime>
           <low value=' '/>
           <high value=' '/>
4660
         </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'/>
4665
           </observation>
         </entryRelationship>
         <!-- optional entry relationship providing more information about the concern
4670
         <entryRelationship type='REFR'>
         </entryRelationship>
        </act>
```


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 <u>Concern Entry</u>. These elements are required and shall be recorded exactly as shown above.

This entry shall contain one or more allergy or intolerance entries that conform to the <u>Allergy and Intolerance Entry</u>. 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'

4690 6.3.5.14 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

4695 classCode='OBS'>) that problem. The <value> of the observation comes from a

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.

6.3.5.14.1 Standards

CCD ASTM/HL7 Continuity of Care Document

CareStruct HL7 Care Provision Care Structures (DSTU)

ClinStat HL7 Clinical Statement Pattern (Draft)

4700 **6.3.5.14.2** Parent Template

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

6.3.5.14.3 Specification

```
4705
        <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=' '/>
4710
         <code code=' ' displayName='</pre>
          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=' '</pre>
4715
           codeSystem=' ' displayName=' ' codeSystemName=' '>
           <originalText><reference value=' '/></originalText>
         </value>
         <!-- zero or one <entryRelationship typeCode='REFR' inversionInd='false'>
4720
              identifying the health status of concern -->
        <!-- zero or one <entryRelationship typeCode='REFR' inversionInd='false'>
        elements
              containing clinical status -->
4725
        <!-- zero to many <entryRelationship typeCode='REFR' inversionInd='true'>
              containing comments -->
        </observation>
```

4730 6.3.5.14.4 <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.

6.3.5.14.5 <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.

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

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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.

6.3.5.14.7<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

6.3.5.14.8 <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'.

4765 6.3.5.14.9 <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).

6.3.5.14.10 <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.

6.3.5.14.11 <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.

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6.3.5.14.12 <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.

6.3.5.14.13 <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.

4815 **6.3.5.14.14** <!-- 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 <u>Severity</u> 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'.

6.3.5.14.15 <!-- 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'.

6.3.5.14.16 <!-- 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.

6.3.5.14.17 <!-- 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.

6.3.5.15 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.

4855 **6.3.5.15.1Standards**

ASTM/HL7 Continuity of Care Document

CareStruct HL7 Care Provision Care Structures (DSTU)

ClinStat HL7 Clinical Statement Pattern (Draft)

6.3.5.15.2Specification

```
<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'/>
4860
         <id root=' ' extension=' '/>
           code='ALG|OINT|DALG|EALG|FALG|DINT|EINT|FINT|DNAINT|ENAINT|FNAINT'
           codeSystem='2.16.840.1.113883.5.4'
           codeSystemName='ObservationIntoleranceType'/>
4865
         <statusCode code='completed'/>
         <effectiveTime>
           <low value=' '/>
           <high value=' '/>
         </effectiveTime>
4870
         <value xsi:type='CD' code=' ' codeSystem=' ' displayName=' ' codeSystemName='</pre>
         <participant typeCode='CSM'>
           <participantRole classCode='MANU'>
             <playingEntity classCode='MMAT'>
4875
               <code code=' ' codeSystem=' '>
                 <originalText><reference value='#substance'/></orginalText>
               <name></name>
             </playingEntity>
4880
           </participantRole>
         </participant>
         <!-- zero to many <entryRelationship> elements containing reactions -->
         <!-- zero or one <entryRelationship> elements containing severity -->
         <!-- zero or one <entryRelationship> elements containing clinical status -->
4885
         <!-- zero to many <entryRelationship> elements containing comments -->
        </observation>
```

6.3.5.15.3 <templateld root='1.3.6.1.4.1.19376.1.5.3.1.4.5'/> <templateld 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 <u>Problem</u> 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.

6.3.5.15.4 < code

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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.

6.3.5.15.5 <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.

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

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The substance that causes the allergy or intolerance may be specified in the <participant> 4920 element.

6.3.5.15.6 <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.

6.3.5.15.7 <!-- 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.

6.3.5.15.8 <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.

4945 6.3.5.15.9
 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>

4955

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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.

6.3.5.15.10 <!-- 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 <u>Severity</u> 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'.

6.3.5.15.11 <!-- 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.

6.3.5.15.12 <!-- 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.

4980 **6.3.5.16 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.

6.3.5.16.1 Standards

Pharmacy HL7 Pharmacy Domain (Normative)

CCD ASTM/HL7 Continuity of Care Document

6.3.5.16.2 Specification

```
4985
        <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=''/>
4990
          <id root='' extension=''/>
          <code code='' codeSystem='' displayName='' codeSystemName=''/>
          <text><reference value='#med-1'/></text>
          <statusCode code='completed'/>
          <effectiveTime xsi:type='IVL TS'>
4995
              <low value=''/>
              <high value=''/>
          </effectiveTime>
          <effectiveTime operator='A'</pre>
       xsi:type='TS|PIVL TS|EIVL TS|PIVL PPD TS|SXPR TS'>
5000
          </effectiveTime>
          <routeCode code='' codeSystem='' displayName='' codeSystemName=''>
          <doseQuantity value='' unit=''/>
          <approachSiteCode code='' codeSystem='' displayName='' codeSystemName=''>
5005
          <rateQuantity value='' unit=''/>
          <consumable>
          </consumable>
5010
          <!-- 0..* entries describing the components -->
          <entryRelationship typeCode='COMP' >
              <sequenceNumber value=''/>
          </entryRelationship>
          <!-- An optional entry relationship that indicates the the reason for use -->
5015
          <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>
5020
          </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'/>
5025
          </entryRelationship>
          condition>
            <criterion>
              <text><reference value=''></text>
5030
            </criterion>
          condition>
        </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.

6.3.5.16.2.1 Medication Fields

Field	Opt.	CDA Tag	Description
Start and Stop Date	R2	<effectivetime></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).</substanceadministration></effectivetime>
Frequency	R2	<effectivetime></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.</substanceadministration></effectivetime>
Route	R2	<routecode></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></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	О	<approachsitecode></approachsitecode>	The site where the medication is administered, usually used with IV or topical drugs.
Rate	R2	<ratequantity></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> </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	<code> <code> <originaltext></originaltext> </code></code>	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>
Code	R2	<consumable> <code></code> </consumable>	A code describing the product from a controlled vocabulary, such as RxNorm, First DataBank, et cetera.
Instructions	R2	<entryrelationship></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	О	<entryrelationship></entryrelationship>	A link to supporting clinical information about the reason for providing the medication (e.g., a link to the relevant diagnosis).

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

The general model is to record each prescribed medication in a 5045 <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 5050 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. 5055 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.

6.3.5.16.3.1 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 <u>1.3.6.1.4.1.19376.1.5.3.1.4.7</u>. Medications that use this template identifier shall not use subordinate <substanceAdministration> acts.

6.3.5.16.3.2 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.

6.3.5.16.3.3 Split Dosing 1.3.6.1.4.1.19376.1.5.3.1.4.9

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).

This template identifier is used to identify medication administration events that require

In this case a subordinate <substanceAdministration> entry is required for each separate dosage.

6.3.5.16.3.4 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.

6.3.5.16.3.5 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

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entry may, but is not required, to have subordinate <substanceAdministration> entries included beneath it to record the components of the mixture.

6.3.5.16.4<templateld root='2.16.840.1.113883.10.20.1.24'/> <templateld 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.

6.3.5.16.5<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.</substanceadministration></substanceadministration>	
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.</substanceadministration></substanceadministration>	
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.</substanceadministration></substanceadministration>	
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.</substanceadministration></substanceadministration>	
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.</substanceadministration></substanceadministration>	

6.3.5.16.6 <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.

6.3.5.16.7 <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.

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6.3.5.16.8 <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.

6.3.5.16.9 <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.

6.3.5.16.10 <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.

6.3.5.16.11 <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.

6.3.5.16.12 <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.

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5165 **6.3.5.16.12.1 Specifying Medication Frequency**

Freq	Description	XML Representation
b.i.d.	Twice a day	<pre><effectivetime institutionspecified="true" operator="A" xsi:type="PIVL_TS"> <period unit="h" value="12"></period> </effectivetime></pre>
q12h	Every 12 hours	<pre><effectivetime institutionspecified="false" operator="A" xsi:type="PIVL_TS"> <period unit="h" value="12"></period> </effectivetime></pre>
Once	Once, on 2005-09-01 at 1:18am. <effectivetime value="200509010118" xsi:type="TS"></effectivetime>	
t.i.d.	Three times a day, at times determined by the person administering the medication .	
q8h	Every 8 hours	<pre><effectivetime institutionspecified="false" operator="A" xsi:type="PIVL_TS"> <period unit="h" value="8"></period></effectivetime></pre>
qam	In the morning	<effectivetime operator="A" xsi:type="EIVL"> <event code="ACM"></event></effectivetime>
	Every day at 8 in the morning for 10 minutes	<pre><effectivetime operator="A" xsi:type="PIVL_TS"> <phase> <low inclusive="true" value="198701010800"></low> <width unit="min" value="10"></width> </phase> <period unit="d" value="1"></period> </effectivetime></pre>
q4-6h	Every 4 to 6 hours.	<pre><effectivetime institutionspecified="false" operator="A" xsi:type="PIVL_PPD_TS"> <period unit="h" value="5"></period> <standarddeviation unit="h" value="1"></standarddeviation></effectivetime></pre>

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.

6.3.5.16.12.2 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 for (CCYYMMDDHHMMSS)</effectivetime>		
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.</period></period></width></period></phase></low>		
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 unit="h" value="-1"></low><width unit="min" value="10"></width></offset> means 1 hour before the event. In that same example, the <width> element indicates the duration for the dose to be given.</width></offset></event>
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.</standarddeviation></period></standarddeviation></period>
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).</comp></effectivetime></comp>

6.3.5.16.13 <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.

5180 6.3.5.16.14 <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.

6.3.5.16.15 <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
- 5195 UnitsOfMeasureCaseSensitive vocabulary .

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6.3.5.16.16 <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.

5205 6.3.5.16.17 <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.

6.3.5.16.18 <consumable>

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

6.3.5.16.19 <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.

5220 6.3.5.16.20 <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.

6.3.5.16.21 <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).

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.

6.3.5.16.23 criterion> <text><reference value=' '></text> </criterion>

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

5255 **6.3.5.16.24 <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>.

6.3.5.17 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.

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6.3.5.17.1Specification

```
5270
        <substanceAdministration typeCode='SBADM' moodCode='EVN'</pre>
        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'/>
5275
          <id root='' extension=''/>
          <code code='IMMUNIZ' codeSystem='2.16.840.1.113883.5.4'</pre>
        codeSystemName='ActCode'/>
          <text><reference value='#xxx'/><text>
5280
          <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
5285
            <reasonCode code='' codeSystem=''</pre>
        codeSystemName='ActNoImmunizationReasonIndicator'/>
          -->
          <routeCode code='' codeSystem='' codeSystemName='RouteOfAdministration'/>
          <approachSiteCode code='' codeSystem=''</pre>
5290
        codeSystemName='HumanSubstanceAdministrationSite'/>
          <doseQuantity value='' units=''/>
          <consumable typeCode='CSM'>
            <manufacturedProduct classCode='MANU'>
              <manufacturedLabeledDrug classCode='MMAT' determinerCode='KIND'>
5295
                <code code='' codeSystem='' codeSystemName=''>
                  <originalText><reference value='#yyy'/></originalText>
                </code>
              </manufacturedLabeledDrug>
            </manufacturedProduct>
5300
          </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'/>
5305
          </entryRelationship>
          <!-- An optional entry relationship that identifies the immunization series
        number -->
          <entryRelationship typeCode='SUBJ'>
5310
            <observation typeCode='OBS' moodCode='EVN'>
              <templateId root='2.16.840.1.113883.10.20.1.46'/>
              <code code='30973-2' displayName='Dose Number'</pre>
                codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
              <statusCode code='completed'/>
5315
              <value xsi:type='INT' value=''/>
            </observation>
          </entryRelationship>
          <entryRelationship inversionInd='true' typeCode='CAUS'>
5320
            <observation typeCode='OBS' moodCode='EVN'>
              <id root='' extension=''/>
            </observation>
          </entryRelationship>
          <!-- Optional <entryRelationship> element containing comments -->
5325
        </substanceAdministration>
```

6.3.5.17.2 <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.

6.3.5.17.3 <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'.

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

5335

This shall be the identifier for the immunization event.

6.3.5.17.5 <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.

6.3.5.17.6 <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.

6.3.5.17.7 <statusCode code='completed'/>

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

6.3.5.17.8 <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 unknown, 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.

5360 6.3.5.17.9 <routeCode code=' ' codeSystem=' ' codeSystemName='RouteOfAdministration'/>

See routeCode under Medications.

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

5365 See approachSiteCode under Medications.

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

See doseQuantity under Medications.

6.3.5.17.12 <consumable typeCode='CSM'>

See consumable under Medications.

5375

5380

5370 **6.3.5.17.13** <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

6.3.5.17.14 <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.

6.3.5.17.15 <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.

6.3.5.17.16 <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.

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

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

5390 6.3.5.17.18 <entryRelationship inversionInd='true' typeCode='CAUS'>

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

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

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

6.3.5.17.20 <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.

5400 6.3.5.17.21 <!-- 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.

6.3.5.18 Supply Entry 1.3.6.1.4.1.19376.1.5.3.1.4.7.3

The supply entry describes a prescription activity.

6.3.5.18.1 Specification

```
5410
        <substanceAdministration classCode='SBADM' moodCode='INT|EVN'>
          <entryRelationship type='REFR' inversionInd='false'>
5415
            <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=''/>
5420
              <repeatNumber value=''/>
              <quantity value='' unit=''/>
              <author>
                <time value=''/>
                <assignedAuthor>
5425
                 <id root='' extension=''/>
                 <addr></addr>
                 <telecom use='' value=''/>
                  <assignedPerson><name></name></assignedPerson>
                  <representedOrganization></name></representedOrganization>
5430
                </assignedAuthor>
              </author>
              <performer typeCode='PRF'>
               <time value=''/>
                <assignedEntity>
5435
                 <id root='' extension=''/>
                  <addr></addr>
                  <telecom use='' value=''/>
                  <assignedPerson><name></name></assignedPerson>
                  <representedOrganization><name></representedOrganization>
5440
               </assignedEntity>
              </performer>
              <!-- Optional Fulfillment instrctions -->
              <entryRelationship typeCode='SUBJ'>
              </entryRelationship>
5445
            </supply>
          <entryRelationship>
        </substanceAdministration>
```

6.3.5.18.2 <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.

6.3.5.18.3 <templateld 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.

6.3.5.18.4 <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.

6.3.5.18.5 <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.

6.3.5.18.6 <templateld root='2.16.840.1.113883.10.20.1.34'/> <templateld 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.

5470 **6.3.5.18.7** <id root=' ' extension=' '/>

5465

5480

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

6.3.5.18.8 <repeatNumber value=' '/>

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

5475 **6.3.5.18.9 <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.

6.3.5.18.10 <author>

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

6.3.5.18.11 <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.

6.3.5.18.12 <assignedAuthor>

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

5490 **6.3.5.18.13** <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.

6.3.5.18.14 <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.

6.3.5.18.15 <performer typeCode='PRF'>

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

6.3.5.18.16 <time value=' '/>

5495

5500

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').

6.3.5.18.17 <assignedEntity>

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

5510 **6.3.5.18.18** <id root=' ' extension=' '/>

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

6.3.5.18.19 <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.

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

6.3.5.19 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.

5525 **6.3.5.19.1 Specification**

5550

5555

5560

```
<!-- Within a CDA Document -->
        <manufacturedProduct>
          <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7.2'/>
5530
          <templateId root='2.16.840.1.113883.10.20.1.53'/>
          <manufacturedMaterial>
            <code code='' displayName='' codeSystem='' codeSystemName=''>
              <originalText><reference value=''/></originalText>
            </code>
5535
            <name></name>
          </manufacturedMaterial>
        </manufacturedProduct>
        <!-- Within a message -->
        <administerableMaterial>
5540
          <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>
5545
         </administerableMaterial>
        </administerableMaterial>
```

6.3.5.19.2 <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> element¹. The templateId elements are required and identify this as a product entry.

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

```
6.3.5.19.3 <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.

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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.

6.3.5.19.4 <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.

6.3.5.20 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).

5595 **6.3.5.20.1 Specification**

```
<observation typeCode='OBS' moodCode='EVN'>
          <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13'/>
          <id root='' extension=''/>
5600
          <code code='' displayName='' codeSystem='' codeSystemName=''/>
          <!-- for CDA -->
          <text><reference value='#xxx'/></text>
          <!-- For HL7 Version 3 Messages
          <text>text</text>
5605
          <statusCode code='completed'/>
          <effectiveTime value=''/>
          <repeatNumber value=''/>
          <value xsi:type='' .../>
5610
          <interpretationCode code='' codeSystem='' codeSystemName=''/>
          <methodCode code='' codeSystem='' codeSystemName=''/>
          <targetSiteCode code='' codeSystem='' codeSystemName=''/>
         <author typeCode='AUT'>
            <assignedAuthor typeCode='ASSIGNED'><id></assignedAuthor> <!-- for CDA -->
5615
            <!-- For HL7 Version 3 Messages
            <assignedEntity typeCode='ASSIGNED'>
               <Person classCode='PSN'>
                  <determinerCode root=''>
                  <name>...</name>
5620
               </Person>
            <assignedEntity>
             -->
          </author>
        </observation>
5625
```

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

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

5630 **6.3.5.20.3** <p

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

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

Each observation shall have an identifier.

5635 6.3.5.20.5 <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.

6.3.5.20.6 <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.

6.3.5.20.7 <statusCode code='completed'/>

The status code of all observations shall be completed.

5650 **6.3.5.20.8 <effectiveTime value=' '/>**

5640

5645

5660

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.

5655 **6.3.5.20.9** <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.

6.3.5.20.10 <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.

6.3.5.20.11 <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 .

6 2 5 20 12 <targetSiteCode code=' ' codeSystem=' '

6.3.5.20.12 <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.

6.3.5.20.13 <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 eperson 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.

6.3.5.21 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.

6.3.5.21.1 Specification

```
<organizer classCode='CLUSTER' moodCode='EVN'>
5690
          <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'</pre>
5695
            codeSystem='2.16.840.1.113883.6.96' codeSystemName='SNOMED CT'/>
          <statusCode code='completed'/>
          <effectiveTime value=''/>
          <!-- For HL7 Version 3 Messages
          <author classCode='AUT'>
5700
             <assignedEntity1 typeCode='ASSIGNED'>
             <assignedEntity1>
          </author>
          -->
5705
          <!-- 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'/>
5710
            </observation>
          </component>
        </organizer>
```

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

5715 The vital signs organizer is a cluster of vital signs observations.

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.

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

The organizer shall have an <id> element.

6.3.5.21.5 <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.

6.3.5.21.6 <statusCode code='completed'/>

5730 The observations have all been completed.

6.3.5.21.7 <effectiveTime value=' '/>

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

6.3.5.21.8 <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.

6.3.5.21.9 <!-- 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.

6.3.5.22 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.

6.3.5.22.1 Specification

```
5745
        <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'/>
5750
        <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=' '/>
5755
        <repeatNumber value=' '/>
         <value xsi:type='PQ' value=' ' unit=' '/>
        <interpretationCode code=' ' codeSystem=' ' codeSystemName=' '/>
        <methodCode code=' ' codeSystem=' ' codeSystemName=' '/>
         <targetSiteCode code=' ' codeSystem=' ' codeSystemName=' '/>
5760
        </observation>
```

6.3.5.22.2 <templateld root='1.3.6.1.4.1.19376.1.5.3.1.4.13'/> <templateld root='2.16.840.1.113883.10.20.1.31'/> <templateld 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.

6.3.5.22.3 <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	Туре
9279-1	RESPIRATION RATE	/min	
8867 4	HEART BEAT	711111	
2710-2	OXYGEN SATURATION	%	
8480-6	INTRAVASCULAR SYSTOLIC	mm[Hg]	PQ
8462-4	INTRAVASCULAR DIASTOLIC	mm[11g]	
8310-5	BODY TEMPERATURE	Cel or [degF]	1Q
8302-2	BODY HEIGHT (MEASURED)		
8306-3	BODY HEIGHT^LYING	m, cm,[in_us] or [in_uk]	
8287-5	CIRCUMFRENCE.OCCIPITAL-FRONTAL (TAPE MEASURE)		
3141-9	BODY WEIGHT (MEASURED)	kg, g, [lb_av] or [oz_av]	

6.3.5.22.4 <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.

5775 6.3.5.22.5 <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).

6.3.5.22.6 <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.

6.3.5.22.7 <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).

5785 **6.3.5.23 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.

6.3.5.23.1 Parent Template

5790 The parent of this template is Simple Observation.

6.3.5.23.2 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'/>
5795
         <id root=' ' extension=' '/>
         <code code=' ' displayName=' ' codeSystem='2.16.840.1.113883.6.1'</pre>
        codeSystemName='LOINC'/>
         <text><reference value='#xxx'/></text>
         <statusCode code='completed'/>
5800
         <effectiveTime value=' '/>
         <repeatNumber value=' '/>
         <value xsi:type=' ' .../>
         <interpretationCode code=' ' codeSystem=' ' codeSystemName='</pre>
        <methodCode code=' ' codeSystem=' ' codeSystemName=/>
5805
        <targetSiteCode code=' ' codeSystem=' ' codeSystemName=' '/>
        </observation>
```

6.3.5.23.3 <templateld root='1.3.6.1.4.1.19376.1.5.3.1.4.13'/> <templateld 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.

6.3.5.23.4 <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.

LOINC CODE	Ligerintian		Units or Vocabulary	
	Summary over All Pregnancies	s		
11636-8	BIRTHS LIVE (REPORTED)			
11637-6	BIRTHS PRETERM (REPORTED)			
11638-4	BIRTHS STILL LIVING (REPORTED)			
11639-2	BIRTHS TERM (REPORTED)	QTY	N/A	
11640-0	BIRTHS TOTAL (REPORTED)	QII	IV/A	
11612-9	ABORTIONS (REPORTED)			
11613-7	ABORTIONS INDUCED (REPORTED)			
11614-5	ABORTIONS SPONTANEOUS (REPORTED)			
33065-4	ECTOPIC PREGNANCY (REPORTED)			
Detailed Preg	nancy Data			
11449-6	PREGNANCY STATUS		SNOMED CT, ICD-9- CM (V22)	
8678-5	MENSTRUAL STATUS		SNOMED CT	
8665-2	DATE LAST MENSTRUAL PERIOD	TS		
11778-8	DELIVERY DATE (CLINICAL ESTIMATE)		N/A	
11779-6	DELIVERY DATE (ESTIMATED FROM LAST MENSTRUAL PERIOD)	TS		
11780-4	DELIVERY DATE (ESTIMATED FROM OVULATION DATE)			
11884-4	FETUS, GESTATIONAL AGE (CLINICAL ESTIMATE)			
11885-1	FETUS, GESTATIONAL AGE (ESTIMATED FROM LAST MENSTRUAL PERIOD)		d, wk or mo	
11886-9	FETUS, GESTATIONAL AGE (ESTIMATED FROM OVULATION DATE)	PQ		
11887-7	FETUS, GESTATIONAL AGE (ESTIMATED FROM SELECTED DELIVERY DATE)			
45371-2	MULTIPLE PREGNANCY			

6.3.5.23.5 <repeatNumber value=' '/>

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

6.3.5.23.6 <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.

6.3.5.23.7 <- 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.

6.3.5.24 EDD Observation 1.3.6.1.4.1.19376.1.5.3.1.1.11.2.3.1

The EDD observation reflects the clinicians best judgement about the estimated delivery date of the patient. It can be supported by patient history (eg last menses or quickening), physical examination findings (uterine size), or Ultrasound. If present, ultrasound findings generally are the most accurate supporting evidence. The observation is a Simple Observation with a supporting entryRelation of another Observation. The supporting observation may in turn have a entryRelation that gives the original observation as a gestational age or date from which the estimated due date is calculated.

6.3.5.24.1 Specification

```
5845
        <observation classCode='OBS' moodCode='EVN'>
         <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13'/>
         <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.11.2.3.1'>
         <statusCode code='completed'/>
         <effectiveTime value=' '/>
5850
         <author typeCode='AUT'>
           <time value=' '/>
           <assignedAuthor>
             <id root=' ' extension=' '/>
           </assignedAuthor>
5855
         </author>
         <id root=' ' extension=' '/>
         <code code='11778-8'
               displayName='DELIVERY DATE-TMSTP-PT-^PATIENT-QN-CLINICAL.ESTIMATED'
               codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
5860
         <text><reference value='id-foo'/></text>
         <value xsi:type='TS' value=' '/>
         <entryRelationship typeCode='SPRT'>
           <observation classCode='OBS' moodCode='EVN'>
             <id root=' ' extension=' '/>
5865
             <statusCode code='completed'/>
             <effectiveTime value=' '/>
             <author typeCode='AUT'>
                <time value=' '/>
                <assignedAuthor classCode=' '>
5870
                  <id root=' ' extension=' '/>
                </assignedAuthor>
             </author>
             <code code='[11779-6|(xx-EDD-by-PE)|11781-2|(xx-EDD-by-Qck)|(xx-EDD-by-</pre>
        Fund) ] '
5875
                   codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
             <value type='TS' value=' '>
             <entryRelationship typeCode='DRIV'>
               <observation classCode='OBS' moodCode='EVN'>
                 <id root=' ' extension=' '/>
5880
                 <statusCode code='completed'/>
                 <effectiveTime value=' '/>
                 <author typeCode='AUT'>
                   <time value=' '/>
                   <assignedAuthor>
5885
                     <id root=' ' extension=' '/>
                   </assignedAuthor>
                 </author>
                 <informant typeCode='INF'>
                   <relatedEntity classCode=' '>
5890
                     <id root=' ' extension=' '/>
                   </relatedEntity>
                 </informant>
                 <code code='[8655-2|(xx-ga-by-pe)|11888-5|(xx-date-of-qck)|(xx-date-</pre>
        of-fund-umb) ]'
5895
                       codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
                 <value type='[PQ|TS]' value=' ' units='week'/>
               </observation>
             </entryRelationship>
           </observation>
5900
         </entryRelationship>
        </observation>
```

6.3.5.24.2 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.11.2.3.1'/>

The <templateId> identifies the observation as a type of Estimated Delivery Date Observation. The root attribute SHALL be valued with '1.3.6.1.4.1.19376.1.5.3.1.1.11.2.3.1'.

6.3.5.24.3 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13'/>

EDD observation SHALL comply with the restrictions of the <u>Simple Observation</u> entry. The observation SHALL NOT include repeatNumber, interpretationCode, methodCode, or targetSiteCode as listed below.

6.3.5.24.4 <code code='11778-8' codeSystem='2.16.840.1.113883.6.1'/>

The <code> element indicates that this is a "clinically estimated" estimated delivery date (for example, this code is used to represent the field on the last line of the EDD section of the ACOG form). This code SHALL be the LOINC code 11778-8. It is good style to include the displayName and codeSystemName to help debugging.

6.3.5.24.5 <value xsi:type='TS' value=' '>

5910

5915

The value of the EDD SHALL be represented as a point in time.

6.3.5.24.6 <author typeCode='AUT'><assignedAuthor><id root=' 'extension=' '/></assignedAuthor></author>

There may be multiple clinicians following the patient and authoring the overall document, however the EDD observation has an individual author. For CDA based content, this author SHALL be listed in the CDA header and referenced from the entry by including the id element of the assignedAuthor. For HL7 Version 3 Messages based content, the author SHALL be included in full through this element.

5925 6.3.5.24.7 <author typeCode='AUT'><time value=' '/></author>

The author time is used to record the time that the author recorded the observation. It SHALL be included.

6.3.5.24.8 <entryRelationship typeCode='SPRT'>

The <entryRelationship> element binds the clinicians estimated EDD to supporting observations by different methods. Supporting observations SHOULD be included. If included, the typeCode SHALL be 'SPRT'. For HL7 Version 3 Messages based content, the element name is <sourceOf> rather than <entryRelationship>, however the semantics, typeCode, and nested elements remain unchanged.

6.3.5.24.9 < observation >

5935

<templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13'/>

:

</observation> [1st nesting]

Observations that support the clinical observation SHALL be included if known. These observations are the supporting calculated dates from various methods such as ultrasound dates or dates calculated from LMP (i.e., the left column of fields on the ACOG form). Supporting observations SHALL also conform to the simple observation template. Supporting observations MAY include a different effectiveTime, author, or informant. Supporting observations SHALL NOT include repeatNumber, interpretationCode, methodCode, or targetSiteCode. (Method is implied by the LOINC code). The templateId SHALL be valued as '1.3.6.1.4.1.19376.1.5.3.1.4.13'

6.3.5.24.10 <code code=' ' codeSystem='2.16.840.1.113883.6.1'/> [1st nesting]

Supporting observations SHALL include one of following LOINC values to indicate the method used to calculate the EDD.

Code	Description	
11779-6	DELIVERY DATE-TMSTP-PT-^PATIENT-QN-ESTIMATED FROM LAST MENSTRUAL PERIOD	
(xx-EDD-by- PE)	DELIVERY DATE-TMSTP-PT-^PATIENT-QN-ESTIMATED FROM CLINICIANS PHYSICAL EXAM	
11781-2	DELIVERY DATE-TMSTP-PT-^PATIENT-QN-US.COMPOSITE.ESTIMATED	
(xx-EDD-by- Qck)	DELIVERY DATE-TMSTP-PT-^PATIENT-QN-ESTIMATED FROM DATE OF QUICKENING	
(xx-EDD-by- Fund)	DELIVERY DATE-TMSTP-PT-^PATIENT-QN-ESTIMATED FROM DATE FUNDAL HEIGHT REACHES UMBILICUS	

6.3.5.24.11 <entryRelationship typeCode='DRIV'>

Observations of supporting EDD should provide observations from which they were derived such as the patients last menses, or gestational age value at a point in time.

For HL7 Version 3 Messages based content, the element name is <sourceOf> rather than <entryRelationship>, however the semantics, typeCode, and nested elements remain unchanged. ===== <observation>

<templateId root=' '/>

:

5960

</observation> [2st nesting] Observations that support the calculation of supporting observation SHALL be included if known. These observations are the supporting dates or

ages from various methods such as ultrasound gestational age or the date of last Menses (for example, the right column of fields on the ACOG form). Supporting observations SHALL also conform to the simple observation template. Supporting observations MAY include a different effectiveTime, author, or informant. Supporting observations SHALL NOT include repeatNumber, interpretationCode, methodCode, or targetSiteCode. (Method is implied by the LOINC code)

6.3.5.24.12 <code code=' ' codeSystem='2.16.840.1.113883.6.1'/> [2nd nesting]

This code is used to represent the either the relevant date, or the gestational age
observation from which the EDD is derived. The following table lists the relevant LOINC
codes for methods used. For observations that record the gestational age the value is
recorded as a physical quantity (PQ) with the units of weeks and the activity time should
be recorded to indicate the date at which the gestational age was observed. For
observations that simply record a date (eg LMP) the observation value is recorded as a
point in time (TS).

Code	Description	Туре
8655-2	DATE LAST MENSTRUAL PERIOD-TMSTP-PT-^PATIENT-QN-REPORTED	TS
(xx-ga-by-PE)	GESTATIONAL AGE-TIME-PT-^FETUS-QN-ESTIMATED FROM CLINICIANS PHYSICAL EXAM	PQ
11888-5	GESTATIONAL AGE-TIME-PT-^FETUS-QN-US.COMPOSITE.ESTIMATED	PQ
(xx-date-of-Qck)	DATE OF QUICKENING-TMSTP-PT-^PATIENT-QN-REPORTED	TS
(xx-date-of- Fund-Umb)	DATE FUNDAL HEIGHT REACHES UMBILICUS-TMSTP-PT-^PATIENT-QN-CLINICIANS PHYSICAL EXAM	TS

The <repeatNumber> <interpretationCode>, and <targetSiteCode> elements should not be present in a EDD observation.

6.3.5.24.14 Schematron

```
-->>TODO:<<---
       must include templateID and simple obs templateID
5985
       must include loinc 11778-8
       must include author.assignedAuthor with Id valued
       must include author.time
       must have value xsi:type=ts
       must include text.reference.value
5990
       may include effectiveTime
       warn should include sprt relation to simple obs
       assert must not include entryRelationship other than SPRT.
       must not include repeatNumber, interpretationCode, methodCode, or
       targetSiteCode
5995
       if sprt relation included then
         must include obs.id
         must include includes obs.code=(one of loincs)
         may include obs.author
         may include obs.effectiveTime
```

6000 6.3.5.25 Antepartum Visit Summary Battery 1.3.6.1.4.1.19376.1.5.3.1.1.11.2.3.2

This entry describes a single row in the Visit Summary flowsheet. The single observation date and provider is applied to all other observations.

6005 **6.3.5.25.1 Specification**

```
<entry>
          <organizer classCode='BATTERY' moodCode='EVN'>
6010
            <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.11.2.3.2'/>
            <id root=' ' extension=' '/>
            <code code='(xx-acoq-battery)' displayName='ACOG Summary Visit Battery---</pre>
        PT--'
                  codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
6015
            <statusCode code='completed'/>
            <author>
               <time value=' '/>
               <assignedAuthor>
                  <id root=' ' extension=' '/>
6020
               </assignedAuthor>
            </author>
            <component>
               <observation classCode='OBS' moodCode='EVN'>
                  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13'/>
6025
               </observation>
            </component>
            <component>
               <observation classCode='OBS' moodCode='EVN'>
6030
                  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13'/>
               </observation>
            </component>
6035
          </organizer>
        </entry>
```

6.3.5.25.2 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.11.2.3.2'/>

The <templateId> element specifies that this organizer entry conforms to the APS profile Visit Summary Flowsheet battery. The root attribute SHALL contain the value "1.3.6.1.4.1.19376.1.5.3.1.1.11.2.3.2"

6.3.5.25.3 <organizer classCode='BATTERY' moodCode='EVN'>

Each row in the visit Summary flowsheet of the Antepartum Summary form C SHALL be represented by an organizer with the classCode of 'BATTERY' and the moodCode of 'EVN'

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

Each battery SHALL have a globally unique identifier.

6.3.5.25.5 <code code='(xx-acog-battery)' codeSystem='2.16.840.1.113883.6.1'/>

The <code> element specifies the loinc code that represents the content of the battery. The codeSystem attribute SHALL contain the value '2.16.840.1.113883.6.1'. The code attribute SHALL contain the value='(xx-acog-battery)'. It is good practice to include

displayName and codeSystemName for clarity and debugging. The corresponding values are 'ACOG VISIT SUMMARY BATTERY--PT--' and 'LOINC' respectively.

6055 6.3.5.25.6<author/><time/><assignedAuthor><id/></assignedAuthor></author>

The <author> relation element points at the author that records the visit battery. This assigned Author may be different than the author of the document. The time element is used to record when the assigned author recorded the battery.

6060 6.3.5.25.7 <statusCode code='completed'/>

The status code for all batteries SHALL be 'completed'

6.3.5.25.8 <component>

6065

The battery is made of several component <u>simple observations</u>. The following table lists the allowable LOINC codes, displayNames, and observation types, and unit of measures for these observations.

code	displayName	xsi:type	units	value set
11884-4	GESTATIONAL AGE-TIME-PT- ^FETUS-QN- CLINICAL.ESTIMATED	PQ	week	
11881-0	FUNDAL HEIGHT-LEN-PT- UTERUS-QN-TAPE MEASURE	PQ	cm	
11876-0 (by PE) or 11877-8 (by US)	FETAL PRESENTATION-TYPE-PT-PELVIS-NOM-PALPATION or FETAL PRESENTATION-TYPE-PT-PELVIS-NOM-US	CD		SNOMED CT Vertex (70028003) Breech (6096002) Transverse (73161006) Oblique (63750008) Compound (124736009) Brow (8014007) Face (21882006)
11948-7 or (xx-fetal-hr- ausc)	HEART RATE-NRAT-PT-^FETUS- QN-US.MEASURED or HEART RATE-NRAT-PT-^FETUS- QN-AUSCULTATION	PQ	/min	
(xx-fetal- movement)	MOVEMENT-FIND-PT-^FETUS- ORD-PATIENT REPORTED	СО		SNOMED CT Yes (373066001) No (373067005) Reduced (260400001)
(xx-SS- Preterm- Labor)	PRETERM LABOR SYMPTOMS- FIND-PT-^PATIENT-QL-CLINICAL JUDGEMENT	BL		
(xx-cerv-dil- palp) or (xx-cerv-dil-	DILATION-LEN-PT-CERVIX-QN-PALPATION or DILATION-LEN-PT-CERVIX-QN-	PQ	cm	

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us)	US			
11867-9	EFFACEMENT-PRCTL-PT-CERVIX-ORD-PALPATION	СО		0 10 20 30 40 50 60 70 80 90 100
11961-0	LONG AXIS-LEN-PT-CERVIX-QN- US.MEASURED	PQ	cm	
8480-6	INTRAVASCULAR SYSTOLIC- PRES-PT-ARTERIAL SYSTEM-QN-	PQ	mmHg	
8462-4	INTRAVASCULAR DIASTOLIC- PRES-PT-ARTERIAL SYSTEM-QN-	PQ	mmHg	
3141-9	BODY WEIGHT-MASS-PT- ^PATIENT-QN-MEASURED	PQ	g, kg, lb_av, or oz_av	
1753-3	ALBUMIN-ACNC-PT-UR-ORD-	СО		SNOMED CT None (260413007) Trace (260405006) 1+ (260347006) 2+ (260348001) 3+ (260349009) 4+ (260350009)
2349-9 or 25428-4(test strip)	GLUCOSE-ACNC-PT-UR-ORD- or GLUCOSE-ACNC-PT-UR-ORD- TEST STRIP	СО		SNOMED CT None (260413007) Trace (260405006) 1+ (260347006) 2+ (260348001) 3+ (260349009) 4+ (260350009)
44966-0	EDEMA-FIND-PT-^PATIENT-ORD-	СО		SNOMED CT None (260413007) Trace (260405006) 1+ (260347006) 2+ (260348001) 3+ (260349009) 4+ (260350009)
38208-5	PAIN SEVERITY-FIND-PT- ^PATIENT-ORD-REPORTED	СО		0 (no pain) : 10 (worst possible pain) Note: This observation should correspond to the functional status pain score observation
(xx-time-to- next-appt)	TIME TO NEXT VISIT- or	PQ	day,week,mo	

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or ?39165	?Date next screen visit-TmStp-PT- ^PATIENT-QN-CPHS		
48767-8	ANNOTATION COMMENT-FIND- PT-^PATIENT-NAR-	ED	

6.3.5.25.9 Schematron

```
-->>TODO:<<--
```

6.3.5.26 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.

6.3.5.26.1 Standards

6070

CCD ASTM/HL7 Continuity of Care Document

6.3.5.26.2 Specification

```
<observation typeCode='OBS' moodCode='EVN'>
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13'/>
6075
        <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</pre>
        CT'/>
6080
        <text><reference value='#xxx'/></text>
        <statusCode code='completed'/>
        <effectiveTime value=' '/>
        <repeatNumber value=' '/>
        <value xsi:type='BL' value='true|false'/>
6085
        <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'/>
6090
           <externalDocument classCode='DOC' moodCode='EVN'>
             <id root=' ' extension=' '/>
             <text><reference value=' '/></text>
           </externalDocument>
        </reference>
6095
       </observation>
```

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

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

6105 6.3.5.26.4 <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.

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

6.3.5.26.5 <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 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*.

6.3.5.26.6 <reference typeCode='REFR'> <templateId root='2.16.840.1.113883.10.20.1.36'/>

<externalDocument classCode='DOC' moodCode='EVN'>

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

6120 <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.

6.3.5.27 Pain Score Observation 1.3.6.1.4.1.19376.1.5.3.1.1.12.3.1

The pain score observation is a <u>Simple Observation</u> that records the patient's assessment of their pain on a scale from 0 to 10.

6.3.5.27.1 Parent Template

The parent of this template is <u>Simple Observation</u>.

6.3.5.27.2 Specification

```
<observation typeCode='OBS' moodCode='EVN'>
6135
         <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'/>
         <id root=' ' extension=' '/>
         <code code='38208-5|38221-8|38214-3' codeSystem='2.16.840.1.113883.6.1'</pre>
        codeSystemName='LOINC'>
6140
           <translation code='406127006' displayName='Pain intensity'</pre>
             codeSystem='2.16.840.1.113883.6.96' codeSystemName='SNOMED CT'/>
         <text><reference value='#xxx'/></text>
         <statusCode code='completed'/>
6145
         <effectiveTime value=' '/>
         <repeatNumber value=' '/>
         <value xsi:type='CO|REAL' />
         <interpretationCode code= codeSystem='2.16.840.1.113883.6.96'</pre>
        codeSystemName='SNOMED CT'/>
6150
        <methodCode code=' ' codeSystem=' ' codeSystemName='</pre>
         <tarqetSiteCode code=' ' codeSystem=' ' codeSystemName=' '/>
        </observation>
```

6.3.5.27.3 <templateld root='1.3.6.1.4.1.19376.1.5.3.1.4.13'/>

The <templateId> identifies this as a Pain Score Observation, and shall be present as shown above.

6.3.5.27.4 <code code='38208-5' codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'>

<translation code='406127006' displayName='Pain intensity' codeSystem='2.16.840.1.113883.6.96' codeSystemName='SNOMED CT'/>

The <code> element indicates what kind of pain observation was made. It shall contain the code and codeSystem attribute values shown above. The <translation> element may be present, and provides a mapping to SNOMED CT of the observation. If present, is shall have the code and codeSystem attribute values shown above.

Code	Data Type	Description
------	--------------	-------------

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38208-5		A Pain Score made using the Numerical Rating Scale (NRS), where pain is assessed on a scale from 0 to 10>>The code system to use for this observation<<
---------	--	---

6.3.5.27.5 <value xsi:type='CO' value=' ' />

The <value> element records the assessed pain score. If using the NRS the pain is assessed using coded ordinal values that range from 0 to 10. The use of the coded ordinal type is required because while pain assessments are ordered values, and can be compared, the differences between two pain assessment values cannot be compared, and so these values are not really numbers.

6.3.5.27.6 <interpretationCode code='301379001|40196000|76948002|67849003' codeSystem='2.16.840.1.113883.6.96' codeSystemName='SNOMED CT'/>

The <interpretationCode> element should be present to provide an interpretation of the pain scale assessment using SNOMED CT. When the <interpretationCode> element is present, the <translation> element described above shall be present. These interpretations are provided to assist decision support systems that are making secondary use of the assessment information, and are not intended to replace the score values.

Pain Score Range	Code	Description
0	301379001	No Present Pain
1-3	40196000	Mild Pain
4-6	50415004	Moderate Pain
7-9	76948002	Severe Pain
10	67849003	Excruciating Pain

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

The <methodCode> should not be present in a Pain Score Observation, as the method is implied by the <code> element.

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

The <targetSiteCode> element should be present, and shall indicate the location of the pain being assessed.

6.4 HL7 Version 2 Content Modules

This section contains content modules based upon the HL7 Version 2 Standard, and related standards and/or implementation guides.

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6.5 PCC Value Sets

This section contains value sets used by Content Modules.

6.5.1 APR H&P Past Medical History Observation Codes - Medical History Value Set 1.3.6.1.4.1.19376.1.5.3.1.1.16.5.1

Name	Opt	Туре	Units	SNOMED CT	LOINC
Diabetes	R	CD		73211009	
Hypertension	R	CD		38341003	
Heart Disease	R	CD		56265001	
Autoimmune Disorder	R	CD		85828009	
Kidney Disease	R	CD		90708001	
UTI	R	CD		68566005	
Neurologic	R	CD		118940003	
Epilepsy	R	CD		84757009	
Psychiatric	R	CD		74732009	
Depression	R	CD		41006004	
Postpartum Depression	R	CD		58703003	
Hepatitis	R	CD		128241005	
Liver Disease	R	CD		235856003	
Varicosities	R	CD		276504003	
Phlebitis	R	CD		61599003	
Thyroid Dysfunction	R	CD		14304000	
Trauma	R	CD		417746004	
Violence	R	CD		225818009	
History of Blood Transfusion	R	CD		116859006	
D(Rh) Sensitized	R	CD		3885002	
Pulmonary	R	CD		19829001	

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Seasonal Allergies	R	CD	367498001
Drug Allergy	R	CD	416098002
Latex Allergy	R	CD	300916003
Food Allergy	R	CD	414285001
Breast	R	CD	79604008
Gyn Surgery	R	CD	12658000
Operations	R	CD	387713003
Hospitalizations	R	CD	32485007
Anesthetic Complications	R	CD	33211000
History of Abnormal Pap	R	CD	274688009
Uterine Anomaly/DES	R	CD	37849005
DES Exposure	R	CD	xx- desexposure
Infertility	R	CD	8619003
Art Treatment	R	CD	63487001

6195 **6.5.2** APR H&P Pregnancy History Observation Codes Value Set 1.3.6.1.4.1.19376.1.5.3.1.1.16.5.2

Name	Opt	Туре	Units	SNOMED CT	LOINC
Total Pregnancies (Gravida)	R	PQ		161732006	
Full Term Deliveries	R	PQ		xx-fullterm	
Premature Deliveries	R	PQ		xx-premature	
Abortion, Induced	R	PQ		252114001	
Abortion, Spontaneous (Miscarriages)	R	PQ		248989003	
Ectopic Pregnancies	R	PQ		xx-ectopics	
Multiple Births	R	PQ		364323006	
Live Births	R	PQ		248991006	

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Detailed Pregnancy Data			
Date Month/Year	R	TS	184099003
Weeks Gestation at Delivery	R	PQ	268477000
Length of Labor	R	PQ	271562002
Birth Weight	R	PQ	364589006
Sex	R	ST	365873007
Type of Delivery (Past Pregnancy Outcome)	R	ST	267013003
Type of Anesthetic	R	ST	399084002
Place of Delivery	R	ST	169812000
Preterm Labor	R	BL	6383007

6.5.3 APR H&P Social History Observation Codes Value Set 1.3.6.1.4.1.19376.1.5.3.1.1.16.5.3

Name	Opt	Туре	Units	SNOMED CT	LOINC
Tobacco Use	R	ED		266918002	
Alcohol Use	R	ED		160573003	
Illicit/Recreational Drugs	R	ED		xx-illicitdrugs	

6.5.4 APR H&P Family History and Genetic Screening Observation Codes Value Set 1.3.6.1.4.1.19376.1.5.3.1.1.16.5.4

Name	Opt	Туре	Units	SNOMED CT	LOINC
Thalassemia	R	CD		40108008	
Neural Tube Defect	R	CD		253098009	
Congenital Heart Defect	R	CD		13213009	
Down Syndrome	R	CD		41040004	
Tay-Sachs	R	CD		111385000	
Canavan Disease	R	CD		80544005	

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Familial Dysautonomia	R	CD	29159009
Sick Cell Disease	R	CD	417357006
Sick Cell Trait	R	CD	16402000
Hemophilia	R	CD	90935002
Blood Disorders	R	CD	414022008
Muscular Dystrophy	R	CD	73297009
Cystic Fibrosis	R	CD	190905008
Huntington's Chorea	R	CD	58756001
Mental Retardation	R	CD	91138005
Autism	R	CD	408856003
Chrosomosal Disorder Includes any inherited genetic or chromosomal disorders	R	CD	409709004
Maternal Metabolic Disorder	R	CD	75934005
Dysmorphism (Birth Defect) Patient or baby's father has a child with birth defects	R	CD	276720006
Recurrent pregnancy loss/stillbirth	R	CD	102878001

6.5.5 APR H&P Review of Systems - Menstrual History Observation Codes Value Set 1.3.6.1.4.1.19376.1.5.3.1.1.16.5.5

Name	Opt	Туре	Units	SNOMED CT	LOINC
Date of Last Menstrual Period	R	TS		21840007	
Menses Monthly	R	BL		364307006	
Prior Menses Date	R	TS		21840007	
Duration of Menstrual Flow Frequency	R	PQ	days	364306002	
on Birth Control Pills at conception	R	BL		xx-onbcp	
Menarche	R	PQ		398700009	
hCG+	R	TS		xx-dateofhcg	

6.5.6 APR H&P History of Infection Observation Codes Value Set 1.3.6.1.4.1.19376.1.5.3.1.1.16.5.6

Name	Opt	Туре	Units	SNOMED CT	LOINC
Live with someone with TB or exposed to TB	R	CD		170464005	
History of Genital Herpes	R	CD		402888002	
Exposed to Genital Herpes	R	CD		240480009	
Rash since LMP	R	CD		49882001	
Viral illness since LMP	R	CD		34014006	
Rash or viral illness since LMP	R	CD		49882001	
Hepatitis B	R	CD		235871004	
Hepatitis C	R	CD		235872006	
History of STD	R	CD		8098009	
History of Gonorrhea	R	CD		15628003	
History of Chlamydia	R	CD		312099009	
History of HPV	R	CD		302812006	
History of HIV	R	CD		165816005	
History of Syphilis	R	CD		76272004	

6205 **6.5.7 Antepartum Record Laboratory LOINC Codes** 1.3.6.1.4.1.19376.1.5.3.1.1.16.5.7

Lab	LOINC Code	Comments
Antibody Screen (AB)	890-4 Ab Screen	
Blood Type	XX-AR ABO RH (profile test)	XX-AR: A LOINC profile code will be requested
	5196-1 HBV surface Ag (EIA)	
Hepatitis B virus (HBV)	5195-3 HBV surface Ag	
surface Antigen (Ag)	5197-9 HBV surface Ag (RIA)	
	7905-3 HBV surface Ag (Neut)	
Hemoglobin (Hgb)/Hematocrit (Hct)	718-7 Hgb	

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	4544.2 H . (A		
	4544-3 Hct (Automated count)		
	30350-3 Hgb		
	21440-3 HPV I/H Risk DNA Cervix (Probe)		
	21441-1 HPV Low Risk DNA Cervix (Probe)		
Pap Test/Human papilloma	10524-7 Cytology Cervix		
virus (HPV)	18500-9 Thin Prep Cervix		
	19765-7 Cytology Cervix/Vaginal (Nominal)		
	19766-5 Cytology Cervix/Vaginal (Narrative)		
	5334-8 RUBV Ab IgG (EIA)		
Rubella Virus (RUBV)	25514-1 RUBV Ab IgG		
Antibody (Ab)	40667-8 RUBV Ab IgG (EIA)		
	8014-3 RUBV Ab IgG		
Urine Culture Screen	630-4 Bacteria Urine Culture		
Hemoglobin (Hgb) Electrophoresis	XX- Hemoglobinopathy/Thalassemia Panel HTPR (Reflexive) (Profile)	XX-HTPR: A LOINC profile code will be requested	
Purified protein derivative (PPD)	1647-7 Purified protein derivative skin test		
	6347-9 Chlamydia Ag		
	XX-CTD Chlamydia Trachomatis (DFA) (Profile)		
Chlamydia	XX-CTA Chlamydia Trachomatis (Aptima) (Profile)	XX-CTD, XX-CTA and XX- CTNGA: A LOINC profile code will be requested	
	6349-5 Neisseria Gonorrhoeae	-	
	XX- Chlamydia Trachomatis Neisseria CTNGA Gonorrhoeae (Aptima) (Profile)		
	XX- Chlamydia Trachomatis Neisseria CTNGA Gonorrhoeae (Aptima) (Profile)		
	691-6 Neisseria Gonorrhoeaea	XX-CTNGA and XX-CNGA: A	
Gonorrhea	9568-7 Neisseria Gonorrhoeaea Ab	LOINC profile code will be requested	
	XX- Chlamydia Neisseria Gonorrhoeae CNGA (Aptima) (Profile)		
Ultrasound	35096-7 OB Ultrasound Panel		
	XX- Alpha-Feto Protein (Maternal) AFPM (Profile)	XX-AFPM and XX-AFP: A	
MSAFP Multiple Markers	1834-1 Alpha-1 Fetoprotein	LOINC profile code will be requested	
	8270-1 Prenatal Risk Quad Screen		

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	XX-AFP Alpha-Feto Protein (Profile)	
Amnio Chorionic Villus Sampling (CVS)	XX-CVS CVS	XX-CVS: A LOINC profile code will be requested
Varatura	33373-2 Karyotype (Amino Fluid)	
Karotype	33774-0 Karyotype (CVS)	
Amniotic Fluid (AFP)	XX- Alpha-Feto Protein, Amniotic AFPAFR Fluid (Reflexive) (Profile)	XX-AFPAFR: A LOINC profile code will be requested
Diabetes Screen	12646-6 Glucose Challenge, Pregnant (1hr)	
Glucose Tolerance Test (GTT)	12646-6 Glucose Challenge, Pregnant (1hr) XX-GTP2 Glucose Tolerance, Pregnant (2hr) XX-GTP3 Glucose Tolerance, Pregnant (3hr)	XX-GTP2 and XX-GTP3: A LOINC profile code will be requested
Anti-D Immune Globulin (RhIG)	XX-RHIG Anti-D Immune Globulin (RhIG)	XX-RHIG: A LOINC profile code will be requested
Venereal Disease Research Laboratory (VDRL)	20507-0 Rapid Plasma Reagin (RPR) XX- RPR with Reflex to Titer RWRTT (Reflexive) (Profile) XX-RR Rubella and RPR (Profile)	XX-RWRTT and XX-RR: A LOINC profile code will be requested
Group B Strep	XX-BSGB Beta Strep Group B (PCR) 11267-2 Strep Group B	XX-BSGB: A LOINC profile code will be requested
Beta Human Chorionic Gonadotropin (HCG)	21198-7 Beta HCG	
Urinalysis (Urine Screen)	XX-U Urinalysis (Profile) XX-UM Urinalysis with Microscopic (Profile) XX- Urinalysis with Microscopic UMA Analysis (Profile) XX-UD Urinalysis Dipstick (Profile) XX-UDO Urinalysis Dipstick Only (Profile) XX- Urinalysis Microscopic Only UMO (Profile)	XX-U, XX-UM, XX-UMA, XX-UD, XX-UDO, XX-UMO and XX-UMON: A LOINC profile code will be requested
Aneuploidy Screening	XX- Urinalysis Microscopic Only UMON (New)(Profile)	XX-ASU: A LOINC profile code
(Ultrasound)	XX-ASU Aneuploidy Screening (Ultrasound)	will be requested
First Trimester Screening with Nuchal Translucency and maternal serum	XX-NTMS Nuchal Translucency and Maternal Serum	XX-NTMS: A LOINC profile code will be requested
Maternal Serum Triple	XX-MSTS Maternal Serum Triple Screen	XX-MSTS: A LOINC profile

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Screen	(Profile	code will be requested
Thyroid Stimulating Hormone (TSH)	11580-8 Thyrotropin (3rd generation)	
	3016-3 TSH	
	5385-0 Thyrotropin Receptor Ab	
Triiodothyronine (T3)	3051-0 T3 Free	
	3052-8 T3 Reverse	
	3054-4 T3 True	XX-T3FT: A LOINC profile code will be requested
	3050-2 T3 Resin Uptake	
	XX-T3FT T3 Free and Total (Profile)	
Varicella Zoster Virus (VZV) Ab	22600-1 Varicella Zoster Virus Ab	
	XX- Varicella Zoster Virus (PCR) VZVP (Profile)	XX-VZVP: A LOINC profile
	10860-5 Varicella Zoster Virus	code will be requested
	6584-7 Virus Identified	

6.5.8 APR Education Codes Value Set 1.3.6.1.4.1.19376.1.5.3.1.1.16.5.8

Name	Opt	Туре	units	SNOMED CT	LOINC		
First Trimester							
Risk factors identified by prenatal history	R	CD		xx-edu-prenatalriskfactors			
Anticipated course of prenatal care	R	CD		17629007			
Special Diet	R	CD		171054004			
Nutrition and weight gain counseling	R	CD		429095004			
Toxoplasmosis precautions (cats/raw meat)	R	CD		xx-edu-toxoplasmosis			
Sexual activity	R	CD		162169002			
Exercise	R	CD		171056002			
Influenza vaccine	R	CD		xx-edu-influenza			
Smoking/tobacco counseling	R	CD		171055003			
Environmental/work hazards	R	CD		370995009			
Travel	R	CD		xx-edu-travel			
Alcohol	R	CD		171057006			

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Illicit/recreational drugs	R	CD	171058001		
Use of any medications	R	CD	xx-edu-useofmeds		
Indications for ultrasound	R	CD	xx-edu- indicationsforultrasound		
Domestic violence	R	CD	413457006		
Seatbelt use	R	CD	xx-edu-seatbeltuse		
Childbirth classes/hospital facilities	R	CD	61324002		
Second Trimester					
Childbirth classes/hospital facilities	R	CD	61324002		
Signs and symptoms of preterm labor	R	CD	xx-edu- pretermlaborsignssympto ms		
Abnormal Lab Values	R	CD	410299006		
Influenza vaccine	R	CD	xx-edu-fluvaccine		
Selecting a newborn care provider	R	CD	xx-edu- newborncareprovider		
Postpartum family planning	R	CD	54070000		
Tubal sterilization	R	CD	243064009		
Third Trimester					
Anesthesia/analgesia plans	R	CD	243062008		
Fetal movement monitoring	R	CD	xx-edu-fetalmovement		
Labor signs	R	CD	xx-edu-sslabor		
VBAC counseling	R	CD	xx-edu-vbac		
Signs & Symptoms of Pregnancy-induced hypertension	R	CD	xx-edu-sspreclampsia		
Postterm counseling	R	CD	xx-edu-postterm		
Circumcision	R	CD	184002001		
Bottle feeding	R	CD	169644004		
Breast feeding	R	CD	169643005		

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Postpartum depression	R	CD	xx-edu-ssppd	
Newborn education (Newborn screening, jaundice, SIDS, car seat)	R	CD	75461000	
Family medical leave or disability forms	R	CD	40791000	
Tubal sterilazation consent signed	R	CD	408835000	