ACC, HIMSS and RSNA

Integrating the Healthcare Enterprise

IHE Patient Care Coordination

Technical Framework
Volumes 1, 2 & 3

Revision 1.0
2005-2006

Final Text

August 11, 2006

Comments may be submitted to:

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

Select the "*Patient Care Coordination Supplements for Public Review*" sub-forum.

Table of Content

Volumes 1, 2 and 3

Foreword

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

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

This initiative has numerous sponsors and supporting organizations in different medical specialty domains and geographical regions. In North America the primary sponsors are the American College of Cardiology (ACC), 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 (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 MEDIS-DC; cooperating organizations include the Japan Industries Association of Radiological Systems (JIRA), the Japan Association of Healthcare Information Systems Industry (JAHIS), Japan Radiological Society (JRS), Japan Society of Radiological Technology (JSRT), and the Japan Association of Medical Informatics (JAMI). Other organizations representing healthcare professionals are actively involved and others are invited to join in the expansion of the IHE process across disciplinary and geographic boundaries.

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

The IHE Technical Framework identifies a subset of the functional components of the healthcare enterprise, called IHE Actors, and specifies their interactions in terms of a set of coordinated, standards-based transactions. It describes this body of transactions in progressively greater depth. 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.

1.1 Content of this Document

This profile defines the relevant standards and constraints on those standards in order to implement a specific use case for the transfer of information between systems. This document is organized into 3 volumes as follows:

1.1.1 Volume 1 – Overview

This volume is provided as a high level overview of the profile 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

1.1.2 Volume 2 – Transactions

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.

1.1.3 Volume 3 – Document Content

This volume describes additional constraints on documents content such as vocabularies, and metadata passed in the transaction. It is intended for technical implementers of the profile.

An Information Structure Appendix in Volume 3 contains the detailed information models and resulting information structured for medication, allergies and problems. It also contains supporting documentation and examples of document entry structures.

1.2 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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Volume 1- Overview

ACC, HIMSS and RSNA

Integrating the Healthcare Enterprise

IHE Patient Care Coordination Technical Framework

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1 Preface to Volume 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

1.2 Related Information for the Reader

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

- Volume 1 of the Cross-Enterprise Document Sharing (XDS) Integration Profile documented in the ITI Infrastructure Technical Framework (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:
    - Leveraging IHE to Build RHIO Interoperability
    - Cross-Enterprise Document Sharing (XDS)
    - Notification of Document Availability (NAV)
    - Patient Care Coordination
    - Use Cases for Medical Summaries
    - Patient Care Coordination - Overview of Profiles

1.3 How this Volume is Organized

Section 2 describes the general nature, structure, purpose and function of the Technical Framework.

Section 3 and the subsequent sections of this volume provide detailed documentation on each integration profile, including the Patient Care Coordination problem it is intended to address and the IHE actors and transactions it comprises.

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

1.4 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.

1.4.1 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.

1.4.2 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 Cross-Enterprise Document Sharing (XDS). These dependencies can be found by locating the desired profile in Table 2.6-1 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.

1.4.3 Process Flow Diagrams

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

These diagrams are intended to provide an overview so the transactions can be seen in the context of an institution's or cross-institutions' workflow. Certain transactions and activities not defined in detail by IHE are shown in these diagrams in *italics* to provide additional context on where the relevant IHE transactions fit into the broader scheme of healthcare information systems.

These diagrams are not intended to present the only possible scenario. Often other actor groupings are possible, and transactions from other profiles may be interspersed.

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

1.5 Copyright Permissions

1.6 How to Contact Us

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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/ , where the technical framework volumes specific to the various healthcare domains addressed by IHE may be found.

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

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

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

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

2.1 Relationship to Standards

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

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

In some cases, IHE recommends selection of specific options supported by these standards. However, IHE does not introduce technical choices that contradict conformance to these standards. If errors in or extensions to existing standards are identified, IHE's policy is to report

them to the appropriate standards bodies for resolution within their conformance and standards evolution strategy.

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

2.2 Relationship to Product Implementations

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

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

2.3 Framework Development and Maintenance

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

The first of these principles is that any extensions or clarifications to the Technical Framework must maintain backward compatibility with previous versions of the framework (except in rare cases for corrections) in order to maintain interoperability with systems that have implemented IHE Actors and Integration Profiles defined there.

The IHE Patient Care Coordination Technical Framework is developed and re-published annually following a three-step process:

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

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

2.4 Scope of Changes Introduced this Year

This document refers to 2005-2006 cycle of the IHE Patient Care Coordination initiative. It is the basis for the testing of implementations performed for example in January 2006 in North America and exhibition process associated with the HIMSS 2006 annual meeting.

This first version of IHE PCC Technical Framework introduces 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.

2.5 Patient Care Coordination Integration Profiles

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

Integration profiles are defined in terms of IHE Actors, transactions and their content. Actors (listed in PCC TF-1: Appendix A) are information systems or components of information

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

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

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

Figure 2.5-1 shows the relations between the Content Integration Profiles of the Patient Care Coordination Domain.

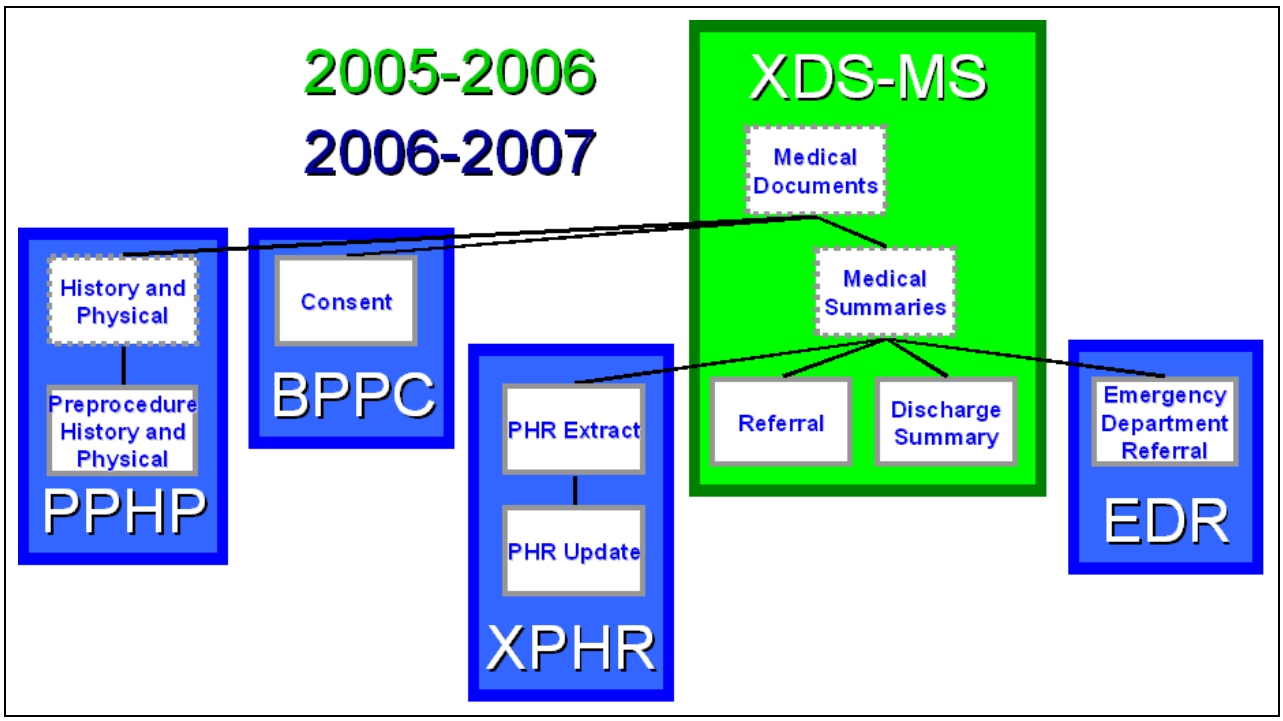


Figure 2.5-1 IHE Patient Care Coordination Content Integration Profiles

2.6 Dependencies among 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. Table 2-1 defines these dependencies in tabular form. 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 different participating actors support the Cross-Enterprise Document Sharing (XDS) Integration Profile as well as that its actors be grouped with a Secured Node Actor of the Audit Trail and Node Authentication (ATNA) Integration Profile. The dependency exists because XDS-MS and XDS actors must support a secured communication channel with proper auditing of the exchange of patient identified information in order to function properly in an environment where protection of patient privacy is critical.

Integration Profile	Depends on	Dependency Type	Purpose
All PCC Content Profiles	*Cross-Enterprise Document Sharing*	Implementers of a PCC Content Profile may implement the XDS Profile to enable sharing of the clinical documents within an XDS Affinity Domain. When the XDS profile is used to provide document interchange, each PCC Content Creators must be grouped with an XDS Document Source actor, and each PCC Content Consumer must be grouped with an XDS Document Consumer actor.	Ensure that the sharing of PCC Document Content Profiles within an XDS Affinity Domain can co-exist with the sharing of other types of documents (e.g. imaging, ECG, etc.)
All PCC Content Profiles	*Cross-Enterprise Document Media Interchange*	Implementers of a PCC Content Profile may implement the XDM Profile to enable sharing of the clinical documents using media. When the XDM profile is used to provide document interchange, each PCC Content Creator must be grouped with an XDM Portable Media Creator actors, and each PCC Content Consumer must be grouped with an XDM Portable Media Consumer.	Ensure that the sharing of PCC Document Content Profiles on media can co-exist with the sharing of other types of documents (e.g. imaging, ECG, etc.)
All PCC Content Profiles	*Cross-Enterprise Document Reliable Interchange*	Implementers of a PCC Content Profile may implement the XDR Profile to enable sharing of the clinical documents using reliable point-to-point network messages. When the XDR profile is used to provide document interchange, each PCC Content Creator must be grouped with an XDR Document actor, and each PCC Content Consumer must be grouped with an XDR Document Recipient.	Ensure that the sharing of PCC Document Content Profiles through reliable point-to-point messages can co-exist with the sharing of other types of documents (e.g. imaging, ECG, etc.)
All PCC Content Profiles	*Audit Trail and Node Authentication*	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.

Integration Profile	Depends on	Dependency Type	Purpose
All PCC Content Profiles	*Consistent Time*	Each Content Creator and Content Consumer actor shall be grouped with the Time Client Actor	Required to manage and resolve conflicts in multiple updates.

Table 2.6-1 XDS-MS Integration Profiles 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.

2.7 Integration Profiles Overview

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

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

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.

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.

2.7.1 Cross-Enterprise Sharing of Medical Summaries (XDS-MS)

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 by electronic medical record systems at points in time of transfers of care such as referrals or discharge.

Note that this Cross-Enterprise Sharing of Medical Summaries Integration Profile is specialized for regions or countries in term of detailed content of sections and information elements by a set of Document Content Profiles. This Integration profile has been structured to facilitate the

inclusion of national extensions in the form of country or "realm" specific Content Profiles. When developed by the national IHE Chapters these will be included in the PCC TF-3.

2.8 Product Implementations

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

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

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

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

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

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

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

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

3 Cross-Enterprise Sharing of Medical Summaries (XDS-MS) Integration Profile

3.1 Scope and Purpose

Patient, clinician, industry and governmental demands for improved healthcare quality have created increased focus to make patient healthcare information interoperability across disparate systems a reality.

A solution for interoperability is, however, not a simple undertaking. Unstructured textual data forms remains the predominate mechanism for information exchange among health care providers, and a good majority of data needed by physicians and other health care providers to make good clinical decisions is embedded in this free text. Efficient and effective interoperability therefore begins by identifying the most relevant documents and the most relevant sections within those documents.

By their nature, Medical Summaries form a class of clinical documents that contain the most relevant portions of this information. As the name would indicate they have the purpose of summarizing, both abstracting the most important pieces of information from the EMR and recording free-text summaries at the time of medical summary creation. Operationally, they are commonly created at points in time of transfers of care from one provider to another or from one setting to another.

Patient transfers and, therefore, the summary documents that accompany these transfers can be categorized into 3 primary types: Episodic, Collaborative, or Permanent. These categories are important because they represent a breadth of use case scenarios for Medical Summaries. For example, summaries for collaborative transfers of care such as referral notes have a focused objective for providing the most relevant information about the patient intended *for a specific provider*. Collaborative summaries have a general audience that is generated as an artifact since they also provide the most relevant spot to obtain information about specific classes of patient problems that the patient has.

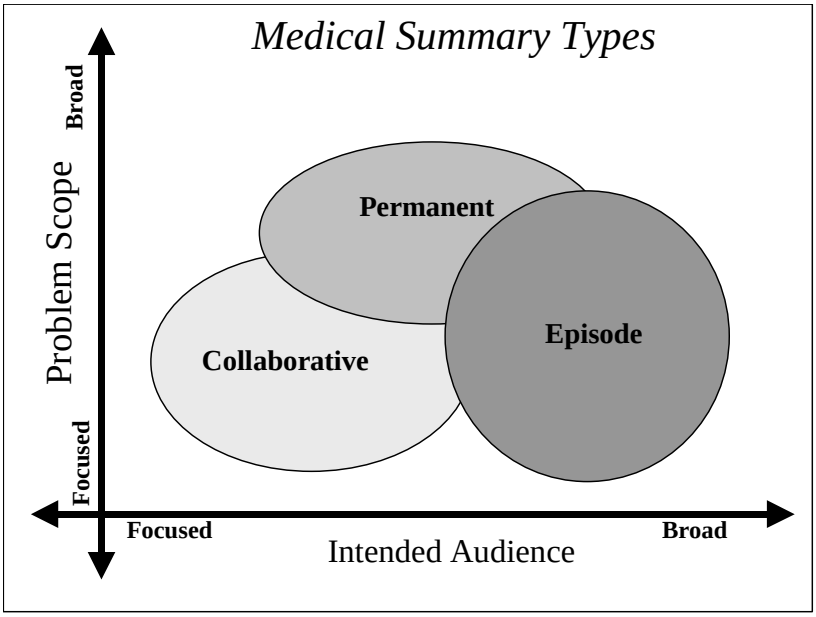


Figure 3.3-1

By contrast, episodic summaries have the primary purpose of highlighting the most relevant details of focused periods of time in a patient history. Examples include discharge summaries or history and physicals. Episodic summaries are written for a broad audience by intent.

Permanent transfers have yet a third purpose of summarizing the entirety of a patient's medical history and therefore covers a broader range of patient problems. The audience may be focused (as in a transfer to a new provider) or general (as in a discharge from the military).

The challenge is to identify the clinically relevant documents (and data elements those documents contain) that are used in typical "transfer of care" scenarios and then to provide interoperability standards to promote ease in transmission of those documents (and data elements). The Cross-Enterprise Sharing of Medical Summary (XDS-MS) Integration Profile facilitates this by defining the appropriate standards for document transmission and a minimum set of "record entries" that should be forwarded or made available to subsequent care provider(s) during specific transfer of care scenarios. In addition, this integration profile needs to define the utilization requirements/options for the receiving entity in order to ensure that the "care context" of the sending entity is appropriately maintained following the information transfer.

3.2 Process Flow

The basic process flow supported by XDS-MS mirrors current manual practices: someone gathers the appropriate documents from the patient medical record, copies them, packages them up with a cover letter explaining the reason the information is being sent, and then ships the package to the receiving provider. This is often accompanied by a telephone call from the sending provider to the receiving provider that indicates that such information is forthcoming.

Because the Collaborative care transfers and Episodic Care transfers differ significantly, these two use cases are defined. Users or implementers of this Integration Profile are offered options in the support of either of these two use cases. Permanent Care Summaries also differ significantly. However their use is less frequent; so this use case was deferred for future work.

3.2.1 Use Case 1: Ambulatory Specialist Referral

This use case involves a "collaborative" transfer of care for the referral of a patient from a primary care provider (PCP) to a specialist. This use case is a central component of an "e-referral" process, which typically requires an appropriate level of agreement/collaboration between the two parties prior to the actual transfer of clinical information being initiated.

The preconditions assume a PCP sees a patient in his office. The PCP has talked to the patient and performed an examination, and has decided to refer the patient to a specialist. An assumption is made that the PCP has an EMR system with capability to write notes and manage data elements. The specific data elements managed by the PCP's EMR are expected to be the source for the information used in creating the medical summary document related to this transfer of care. A variety of EMR implementations and usage by clinicians may result in some variability in the content of the medical summary.

The detailed content of the medical summary to support this use case will be detailed as part of the document content profile specification (See PCC TF-2: 5.4.1.3).

Steps to identify the specialist and obtain insurance preauthorization have been placed out of scope for this Integration Profile.

Post conditions include the specialist physician receiving the notification of referral, locating the documents (via the Document Registry), retrieving the Documents and viewing them and optionally importing data. Import assumes the specialist with an EMR system with the capability for managing those discrete data elements.

3.2.2 Use Case 2: Acute Care Discharge to Ambulatory Care Environment

This use case involves an episodic transfer of care in the form of a patient discharge from a hospital to home. The attending physician in the hospital generates a discharge summary document that is used by the hospital record keeping and billing abstraction. The attending physician in the hospital may or may not also be serving as the ambulatory PCP. If not, a copy of this record is sent to the PCP as well as other specialist providers that will have ambulatory follow-up care.

The events of the use case involve creation of the discharge summary, sharing it, and notifying other providers such as the PCP's office and the surgeon's office.

The post conditions include the receipt and viewing of the discharge summary with optional import into the ambulatory EMR system.

The detailed content of the medical summary to support this use case will be detailed as part of the document content profile specification (See PCC TF-2: 5.4.1.4).

Note that the two use cases above use the same set of transactions and differs only in the content of the Medical Summary. A process flow for these use cases using XDS and NAV is listed in Figure 3.2-1. Other process flows are possible using XDM and/or XDR.

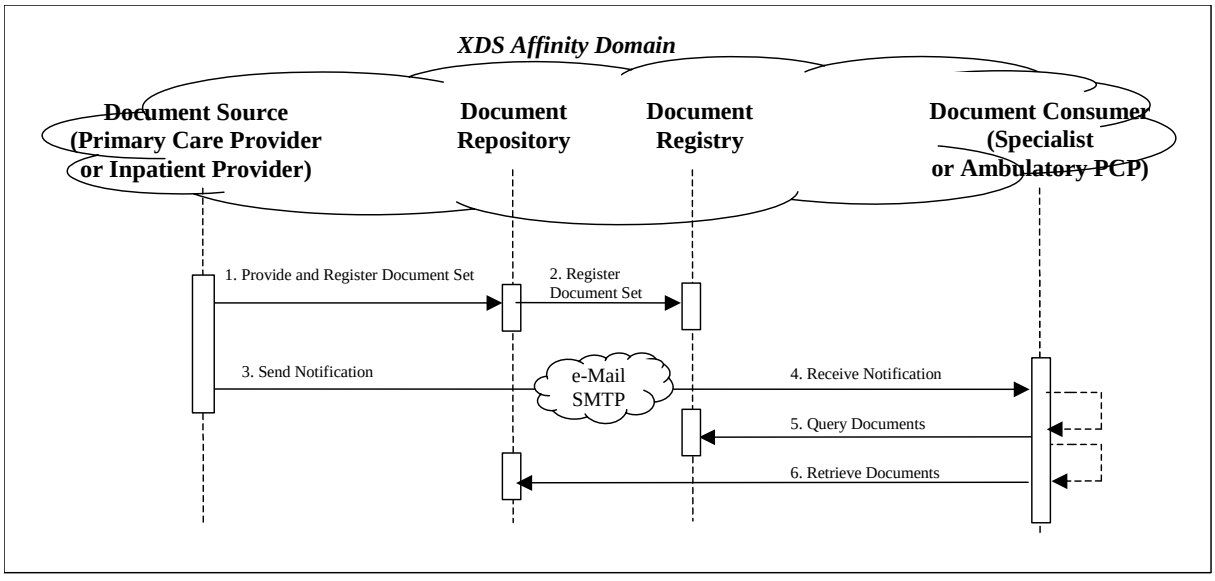


Figure 3.2-1 Use Case Process Flow Diagram

These steps are:

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

Finally, the receiving provider may choose to import relevant information from these records into their own EMR system.

3.2.3 Use Case for Unplanned Access to past Medical Summaries

In many cases, a provider may need to assess information from the patient care history, and patients may have Medical Summaries 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. Figure 3.2-2 shows the transactions required for this use case, again, using XDS. Other process flows are possible using XDM and/or XDR.

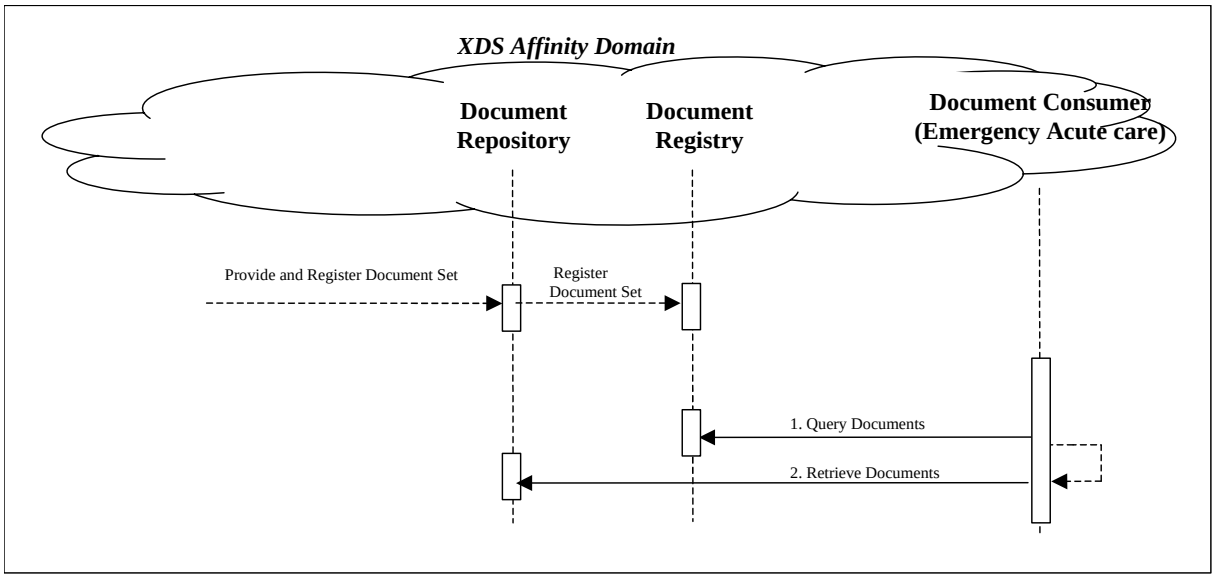


Figure 3.2-2 Process Flow Diagram for Unplanned Use

3.2.4 Content Interoperability Levels

The use cases described above imply different levels of interoperability. At the lowest level, a clinician simply needs to be able to access and view some content such as a medical summary. At this level, minimal structured data elements must be present – just enough metadata to verify that access to that document can be accessed appropriately associated with a visual representation of the document.

Beyond this simple metadata, nearly all medical summary documents have organizational elements that group the relevant parts of the medical summary. For humans this allows for more rapid review because it is easier to skip to portions of interest for care. Computers too can take advantage of this structuring. For example, it is relevant to see the list of discharge medications from a discharge summary in relation to current medications for comparison and reconciliation.

At a very high level of interoperability, the ability to pass fully structured and codified data is necessary for computer processing and mapping. For example, the ability to import medications identified in medical summaries from another institution could have tremendous potential for ensuring that medication orders are transferred correctly. Unfortunately, the cost for providing high levels of semantic interoperability is increased complexity of implementation, and therefore long implementation times.

The HL7 Clinical Document Architecture (CDA) standard and Care Record Summary (CRS) CDA implementation guides support progressive interoperability at multiple levels of complexity, from those needed to provide simple low level interoperability for supporting the most important use case of simple viewing to those providing a path to progressively higher levels of interoperability for vendors and providers wishing to implement it. CDA as constrained in the CRS implementation guides is therefore the base standard for the XDS-MS content profile.

The XDS-MS content profile builds on and further constrains the CDA-CRS implementation guide by defining the required and optional sections required for the Acute Care Discharge and Specialist Referral use cases. Additionally, it places constraints for the most important sections (Medication, Allergy and Problems) of Medical Summaries to ensure that structured field level data are provided.

Figure 3.2-3 shows how the XDS-MS Content profile defines these progressive levels of interoperability for sections of different importance. Header metadata must be present and coded. Most sections must define, at minimum, a section label to identify that section. For the Medication, Allergy, and Problems Sections, data must contain a more granular field level data as discrete text (for example dose or frequency). This is referred to as structured textual representation. Note that the textual strings in this structured text are not duplicates of the textual strings in the human readable text, but simply referenced extracts from the human readable text content, reducing the risk for inconsistencies

Granular field level data may then be optionally coded. If any coded terminology is used it shall be uniquely identified.

Note: The lack of mature and broadly accepted standards for coded terminology requires that this integration profile not specify specific coded vocabularies. However, when agreements can be reached, the capability to exchange coded level information is possible. IHE has on its roadmap to continue working with appropriate standards bodies so that coded terminology standards can be added to this profile in the future.

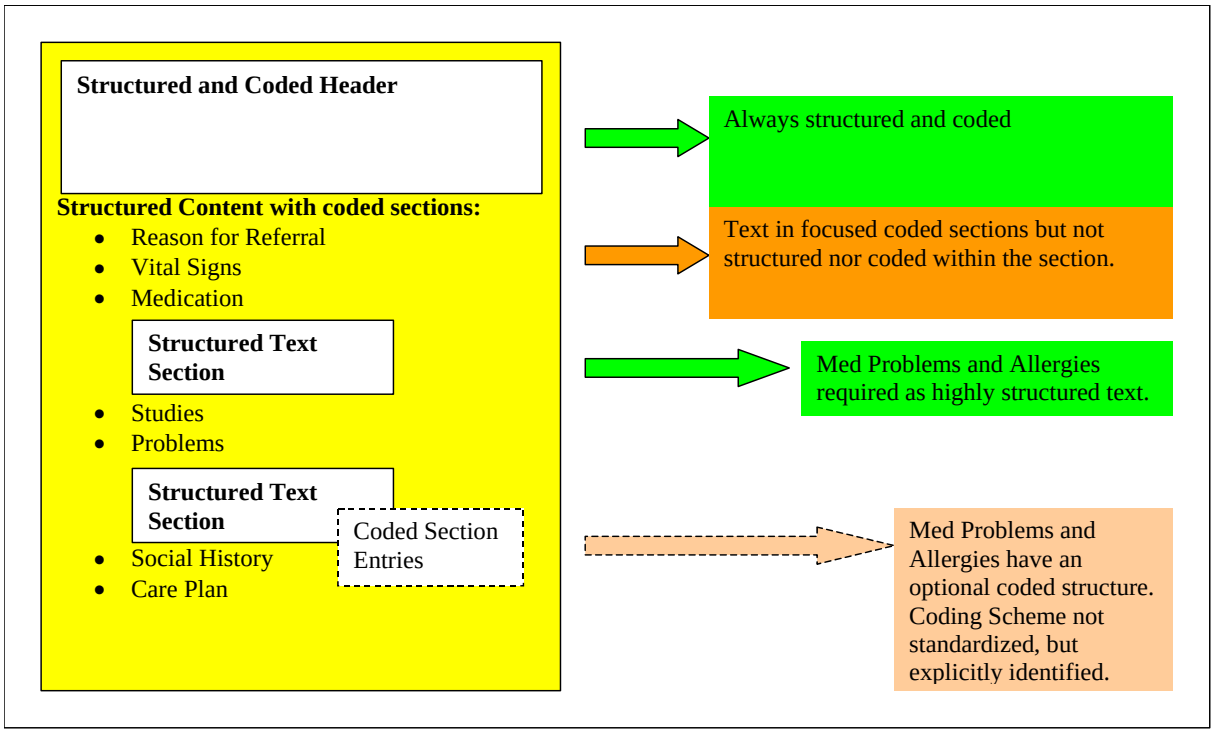


Figure 3.2-3 Tiered Interoperability Levels

3.2.5 Use Case Conclusion

The process flow of this profile exhibits a great deal more power and flexibility than the existing manual process. The physician workflow is improved by reusing an existing work product in the very first step (the summary report) to accomplish two purposes: recording care that has been provided, and communicating with another provider.

Secondly, each step utilizes the power of inter-connected EMR systems to make the entire process faster, easier, and less reliant on human labor to accomplish the same feats. This results in reduced time to transfer records between providers, safer transport of the information, and more reliable receipt.

Lastly, the process facilitates the import of relevant data from one set of patient records to the receiving physicians EMR system, resulting in more reliable transfer of information, reduced labor costs transferring information from one provider to another and less time required by the patient to provide information that is already in the physician's possession.

3.3 Actor/Transaction Relationships

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 PHR 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 below.

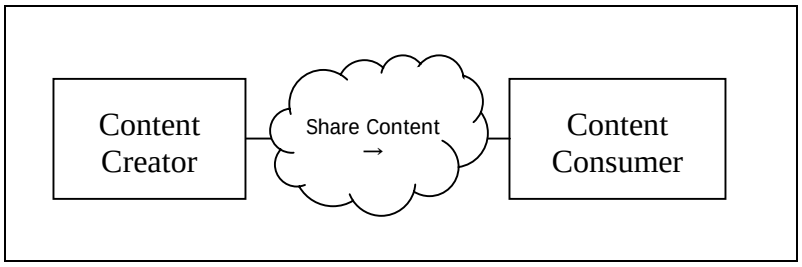


Figure 3.3-1 XDS-MS Actors

3.4 XDS-MS Integration Profile Options

Table 3.4-1 summarizes the options that actors may take for this Integration Profile. Dependencies between options when applicable are specified in notes.

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

Table 3.4-1 Actors and Options

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

3.5 Content Consumer Options

3.5.1 View Document Option

This option defines the processing requirements placed on Content Consumers for providing access, rendering and management of the Medical Summary. See PCC TF-2:3.1.1 for more details on this option.

3.5.1.1 Display Transform

A Content Creator Actor of Medical Summary should provide access to a style sheet that ensures consistent rendering of the medical summary content as was displayed by the Content Consumer Actor (See PCC TF-2: 5.4.1.1.2.1).

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

3.5.2 Document Import Option

This option defines the processing requirements placed on Content Consumers for providing access, and importing the entire Medical Summary document and managing it as part of the patient record. See PCC TF-2: 3.1.2 for more details on this option.

3.5.3 Section Import Option

This option defines the processing requirements placed on Content Consumers for providing access to, and importing the selected section of the Medical Summary document and managing them as part of the patient record. See PCC TF-2:3.1.3 for more details on this option.

3.5.4 Discrete Data Import Option

This option defines the processing requirements placed on Content Consumers for providing access, and importing discrete data from selected sections of the Medical Summary document

and managing them as part of the patient record. See PCC TF-2:3.1.4 for more details on this option.

3.6 Content Creator Options

3.6.1 Referral Option

Content Creators implementing this option shall create Referrals that comply with the Referral Content Module described in PCC TF-2: 5.4.1.3.

3.6.2 Discharge Summary Option

Content Creators implementing this option shall create Discharge Summaries that comply with the Discharge Summary Module described in PCC TF-2: 5.4.1.4.

3.6.3 Coded Terminologies

The Medical Summary Content Module (See PCC TF-2: 5.4.1.2) supports the optional capability to encode a number of coded record entries beyond the IHE required coding associated with structured text. The export and import of these specific coded record entries (See PCC TF-2: 3.1.4) is not an explicitly identified option in this XDS-MS Integration Profile, as the associated coded terminologies are not specified by this Profile. Content Creators and Content Consumers may choose to utilize coded data, but interoperability at this level requires an agreement between the communicating parties that is beyond the scope of this Profile. With further progress in the development of standard coded terminologies, future extensions to this Integration Profile are expected to address these higher levels of interoperability.

3.7 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 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 Medical Summaries.

A content binding describe how the payloads used in IHE transactions are related to and/or constrained by the data elements contained within the content sent or received in those transactions. This section is where any specific dependencies between the content and transaction are defined. The Patient Care Coordination Technical Framework defines one binding, which is used when grouping the Content Creator with the IHE ITI XDS, XDM or XDR Integration Profiles.

Table 3.7-1 describes the content that may be used with each transaction.

Content	Binding	Actor	Optionality
Discharge Summary *PCC TF-2: 5.4.1.3*	Medical Document Binding to XD* *PCC TF-2: 4.1*	Content Creator	O (Note 1)
		Content Consumer	R
Referral *PCC TF-2: 5.4.1.4*	Medical Document Binding to XD* *PCC TF-2: 4.1*	Content Creator	O (Note 1)
		Content Consumer	R

Table 3.7-1 Transactions and Content

Note 1: Content Creators must support generation of at least one type of content from this table with a transaction in order for the transaction to meet the requirements of the XDS-MS profile. Content Consumers must support both types of content to meet these requirements.

3.8 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. These dependencies are reflected in the Bindings listed above.

3.8.1 Discharge Summary

All discharge summaries shall be structured and coded as required by the Discharge Summary Content Module. The inclusion of the specific coded attributes explicitly defined as optional, may be supported by specific implementations of Document Sources using an IHE identified coded terminology (See PCC TF-2: 5.1.1) of their choice. The requirements and manner in which implementations support such capabilities is beyond the scope of this Integration Profile.

3.8.2 Referral

All referral summaries shall be structured and coded as required by the Medical Summary Content Module. The inclusion of the specific coded attributes explicitly defined as optional, may be supported by specific implementations of Document Sources using an IHE identified coded terminology (See PCC TF-2: 5.1.1) of their choice. The requirements and manner in which implementations support such capabilities is beyond the scope of this Integration Profile.

3.9 Grouping with other Profile Actors

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

3.9.1 Cross Enterprise Document Sharing, Media Interchange and Reliable Messages

Actors from the ITI XDS, XDM and XDR profiles embody the Content Creator and Content Consumer sharing function of this profile. A Content Creator or Content Consumer 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. These are described in 3.7 Content Bindings with XDS, XDM and XDR above.

3.9.2 Notification of Document Availability (NAV)

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

A Document Consumer should provide the capability to receive a Receive Notification Transaction per the NAV Integration Profile in order to be notified by Document Sources of the availability of one or more documents for retrieval. The Send Acknowledgement option may be used to issue a Send Acknowledgement to a Document Source that the notification was received and processed.

3.9.3 Document Digital Signature (DSG)

When a Content Creator Actor of the XDS-MS Integration Profile needs to digitally sign a medical summary or any other documents in a submission set, it may support the Digital Signature (DSG) Content Profile as a Document Source.

When a Content Consumer Actor of the XDS-MS Integration Profile needs to verify a Digital Signature, it may retrieve the digital signature document and may perform the verification against the signed document content.

3.10 Security Considerations

The XDS-MS Integration Profile assumes that a minimum security and privacy environment has been established across all participants. There must exist security policies regarding the use of training, agreements, risk management, business continuity and network security that need to be already in place prior to the implementation of XDS-MS.

The IHE ITI ATNA Integration Profile is required of the actors involved in the IHE transactions specified in this profile to protect node-to-node communication and to produce an audit trail of the PHI related actions when they exchange messages.

In addition, the IHE ITI DSG Integration Profiles can be applied to the actors involved in the transactions specified in this profile to securely identify individuals involved in transactions and verify document integrity and authorizations (DSG).

Interested parties should also read the detailed Security Considerations sections provided for each of the aforementioned profiles in the IHE ITI Technical Framework and its supplements.

The XDS-MS profile does have a few security considerations of its own.

EMR systems should be thoughtfully designed so that providers are able to review and verify information before it is imported into their EMR system, and that positive user acknowledgements are made before import, and audit trails are recorded when imports occur.

Imported information should be traceable both to the source [the sharing EMR], and the receiver that accepted it into the EMR system. XDS Affinity domain policies should support policies and procedures for tracing information flows between EMR systems.

Because the information being transferred is in XML, it will be common that different EMR systems utilize different transformations to render the contents into human readable form. A Content Creator should make available the transforms used by the sending provider to review the documents, and a Content Consumer must support rendering the information as seen by the sending provider, allowing both providers to see what was sent in its original rendered form.

Appendix A 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 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.

Appendix B Transaction Descriptions

Transactions are interactions between actors that transfer the required information through standards-based messages. The PCC Technical Framework does not define any specific transactions, as these are assumed to be carried out through the use of transactions defined in other IHE Profiles.

Appendix C How to prepare a 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 ITI TF-1: 2).

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.

C.1 Structure and Content of an IHE Integration Statement

An IHE Integration Statement for a product shall include:

1. The Vendor Name
2. The Product Name (as used in the commercial context) to which the IHE Integration Statement applies.
3. The Product Version to which the IHE Integration Statement applies.
4. A publication date and optionally a revision designation for the IHE Integration Statement.
5. The following statement: "This product implements all transactions required in the IHE Technical Framework to support the IHE Integration Profiles, Actors and Options listed below:"
6. A list of IHE Integration Profiles supported by the product and, for each Integration Profile, a list of IHE Actors supported. For each integration profile/actor combination, one or more of the options defined in the IHE Technical Framework may also be stated. Profiles, Actors and Options shall use the names defined by the IHE Technical Framework Volume I. (Note: The vendor may also elect to indicate the version number of the Technical Framework referenced for each Integration Profile.)

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

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

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

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

C.2 Format of an IHE Integration Statement

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

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

GLOSSARY

Actor: An entity within a use case diagram that can perform an action within a use case diagram. Possible actions are creation or consumption of a message

ADT: Admit, Discharge & Transfer.

ASTM: Formerly the American Society of Testing and Materials, now ASTM International. An SDO that develops a number of standards across a wide variety of industries, including healthcare.

ATNA: Audit Trail and Node Authentication. An IHE ITI profile.

Care Context: The participations surrounding the care provision act, and the attributes of that act. Everything in the document header. Data history, links to clinical reasoning.

CDA: Clinical Document Architecture. An HL7 standard for the exchange for clinical documents.

Content Binding: A content binding describe how the payload used in an IHE transaction is related to and/or constrained by the data elements contained within the content sent or received in those transactions.

CRS: Care Record Summary. An implementation guide that constrains CDA Release 2 for Care Record Summary documents.

CT: Consistent Time Integration Profile.

DICOM:

DSG: Digital Signatures. An IHE ITI Profile.

eMPI: Enterprise Master Patient Index.

EMR: Electronic Medical Record, an Electronic Health Record system used within an enterprise to deliver care (also called EHR-CR by IHE-XDS).

EUA: Enterprise User Authentication Integration Profile.

Expected Actions: Actions which should occur as the result of a trigger event.

HIMSS: Healthcare Information and Management Systems Society.

HL7: Health Level Seven

HIS: Hospital Information System.

IHE: Integrating the Healthcare Enterprise.

Interaction Diagram: A diagram that depicts data flow and sequencing of events.

IT: Information Technology.

MPI: Master Patient Index.

MRN: Medicare Record Number.

NAV: Notification of Document Availability

OID: Object Identifier. (See also 'Globally Unique Identifier').

Patient Identifier Cross-reference Domain: Consists of a set of Patient Identifier Domains known and managed by a Patient Identifier Cross-reference Manager Actor. The Patient

Identifier Cross-reference Manager Actor is responsible for providing lists of "alias" identifiers from different Patient Identifier Domains.

Patient Identifier Domain: A single system or a set of interconnected systems that all share a common identification scheme for patients. Such a scheme includes: (1) a single identifier-issuing authority, (2) an assignment process of an identifier to a patient, (3) a permanent record of issued patient identifiers with associated traits, and (4) a maintenance process over time. The goal of Patient Identification is to reduce errors.

PDF: Portable Document Format.

PIX: Patient Identifier Cross Referencing. An IHE ITI Profile.

PDQ : Patient Demographics Query. An IHE ITI Profile.

Process Flow Diagram: A graphical illustration of the flow of processes and interactions among the actors involved in a particular example.

Role: The actions of an actor in a use case.

RSNA: Radiological Society of North America.

sig.: A Latin abbreviation for signetur used to represent the instruction following the medication name.

Scope: A brief description of the transaction.

Trigger Event: An event such as the reception of a message or completion of a process, which causes another action to occur.

UID: Unique Identifier (See also Globally Unique Identifier).

Universal ID: Unique identifier over time within the UID type. Each UID must belong to one of specifically enumerated species. Universal ID must follow syntactic rules of its scheme.

Use Case: A graphical depiction of the actors and operation of a system.

XUA: Cross Enterprise User Authentication

XDS: Cross Enterprise Document Sharing

Volume 2 - Transactions

ACC, HIMSS and RSNA

Integrating the Healthcare Enterprise

IHE Patient Care Coordination Technical Framework

2005-2006

Final Text

August 10, 2006

1 Preface to Volume 2

1.1 Intended Audience

The intended audience of this document is:

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

1.2 Related Information for the Reader

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

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

1.3 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.

1.4 Conventions Used in this Volume

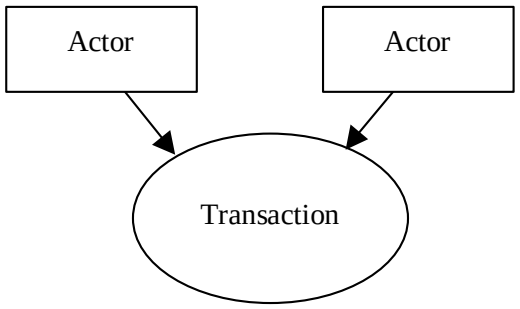
This document has adopted the following conventions for representing the framework concepts and specifying how the standards upon which the IHE Technical Framework is based should be applied.

1.4.1 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.

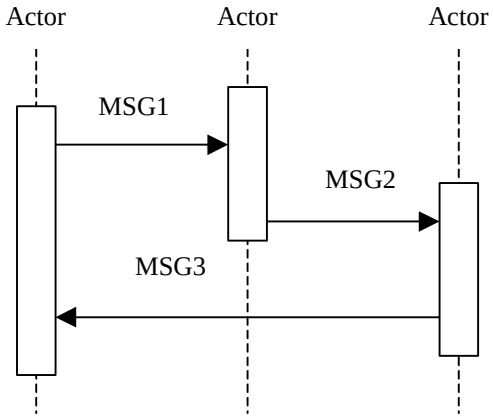
The generic IHE transaction description includes the following components:

- 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.:



- *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:



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.

1.5 Copyright Permissions

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Material drawn from these documents is credited where used.

1.6 How to Contact Us

The 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:

Joyce Sensmeier
Director of Professional Services
230 East Ohio St., Suite 500
Chicago, IL 60611
Email: ihe@himss.org

2 Introduction

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

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

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

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

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

2.1 Relationship to Standards

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

Each transaction may have as its payload one or more forms of content, as well as specific metadata describing that content within the transaction. The specification of the payload and metadata about it are the components of a Content Integration Profile. The payload is specified in a Content Module, and the impacts of any particular payload on a transaction are described within a content binding. The payloads of each transaction are

also based on standards (such as HL7, IETF, ASTM, DICOM, ISO, OASIS, etc.), again, in order to meet the needs of a specific use case.

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

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

2.2 Relationship to Product Implementations

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

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

2.3 Relation of this Volume to the Technical Framework

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

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

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

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

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

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

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

2.3.1 Content Modules

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

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

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

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

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

Required data elements must always be sent. Data elements that are required may under exceptional circumstances have an unknown value (e.g., the name of an unconscious patient). In these cases the sending application is required to indicate the reason that the data is not available.

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

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

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

contains more than is defined by the framework. This allows value to be added to the content modules delivered in this framework, through extensions to it that are not defined or profiled by IHE. It further allows content modules to be defined later by IHE that are refinements or improvements over previous content modules.

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

In order to retain this capability, there are a few rules about how the PCC Technical Committee creates constraints. Constraints that apply to any content module will always apply to any content modules that inherit from it. Thus, the "contracts" are always valid down the inheritance hierarchy. Secondly, data elements of a content module will rarely be deprecated. This will usually occur only in the cases where they have been deprecated by the base standard. While any specific content module has a limited scope and set of use cases, deprecating the data element prevents any future content module from taking advantage of what has already been defined when a particular data element has been deprecated simply because it was not necessary in the original use case.

2.3.1.1 Document Content Module Constraints

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

Thus, a document content module shall contain as constraints:

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

- A possibly empty set of required, required if known, and optional header content modules, and their template identifiers.
- Other constraints as necessary.

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

The remaining constraints are presented in two tables. The first table identifies the relevant data elements as determined during the technical analysis, and maps these data elements to one or more standards. A simplified example below shows a table that might have been used to develop a content profile for birthplace, if we ever wanted to go to such detail.

Data Elements	HL7 V3 ADDR Data Type
Address Line	<streetAddressLine>
City	<city>
State	<state>
Zip Code	<postalCode>
County	<county>
Country	<country>

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.

Data Elements	Opt	Reference	Template ID
Address Line	R	PCC TF-2:2.3.1.1	3
City	R	PCC TF-2:2.3.1.1	4
State	R	PCC TF-2:2.3.1.1	5
Zip Code	R	PCC TF-2:2.3.1.1	6
County	R2	PCC TF-2:2.3.1.1	7
Country	O	PCC TF-2:2.3.1.1	8

2.3.1.2 Section Content Module Constraints

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

Sections may contain various subsections, and these may be required, required if known or optional. Sections may also contain various entries, and again, these may be required,

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

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

Thus, a section content module will contain as constraints:

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

These constraints are presented in this document using a table for each section content module, as shown below in Figure 2.3-1.

TemplateID	1.3.6.1.4.1.19376.1.5.3.1.3.12	
Parent Template	1.3.6.1.4.1.19376.1.5.3.1.3.11	
General Description	The list of surgeries section shall include entries for procedures and references to procedure reports when known as described in the Entry Content Modules.	
Valid LOINC CODES	**Opt**	**Description**
10167-5	R	HISTORY OF SURGICAL PROCEDURES
Sub-sections		**Description**
None Specified		
Entries		**Description**
Procedure	R	IHE Procedure Structure
1.3.6.1.4.1.19376.1.5.3.1.4.4	R2	References

Figure 2.3-1 A Section RBR Diagram for the List of Surgeries Section

2.3.1.3 Entry and Header Content Modules

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

Entry and Header content modules will describe the required, required if known, and optional XML elements and attributes that are present in the CDA Release 2.0 instance. Header and Entry content modules may also be built up using other Header and Entry content modules.

An entry or header content module may also specify constraints on the vocabularies used for codes found in the entry, or data types for the values found in the entry.

Thus, an entry or header content module will contain as constraints:

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

3 IHE Transactions

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

At present, all transactions used by the PCC Profiles appear in ITI TF-2. Options defined by this profile for a Content Consumer are described below.

3.1 Content Consumer Options

3.1.1 View Option

A Content Consumer that supports the View Option shall be able to:

1) Use the appropriate XD* transactions to obtain the document along with associated necessary metadata.

2) Render the document for viewing. This rendering shall meet the requirements defined for CDA Release 2 content presentation semantics (See Section 1.2.4 of the CDA Specification: Human readability and rendering CDA Documents). CDA Header information providing context critical information shall also be rendered in a human readable manner. This includes at a minimum the ability to render the document with the stylesheet specifications provided by the document source, if the document source provides a stylesheet (see PCC TF-2: 5.3.4.1). Content Consumers may optionally view the document with their own stylesheet, but must provide a mechanism to view using the source stylesheet.

3) Support traversal of links for documents that contain links to other documents managed within the sharing framework.

4) Print the document to paper.

3.1.2 Document Import Option

This Option requires that the View Option be supported. In addition, the Content Consumer that supports the Document Import Option shall be able to support the storage of the entire document (as provided by the sharing framework, along with sufficient metadata to ensure its later viewing) both for discharge summary or referral documents. This Option requires the proper tracking of the document origin. Once a document has been imported, the Content Consumer shall offer a means to view the document without the need to retrieve it again from the sharing framework. When viewed after it was imported, a Content Consumer may chose to access the sharing framework to find out if the related Document viewed has been deprecated, replaced or addended.

Note: For example, when using XDS, a Content Consumer may choose to query the Document Registry about a document previously imported in order to find out if this previously imported document may have been replaced or has received an addendum. This capability is offered to Content Consumers by

this Integration Profile, but not required, as the events that may justify such a query are extremely implementation specific.

3.1.3 Section Level Copy Option

This Option requires that the View Option be supported. In addition, the Content Consumer that supports the Section Level Copy Option shall be able to support the import of one or more sections of the document (along with sufficient metadata to link the data to its source) both for discharge summary or referral. This Option requires the proper tracking of the document section origin. Once sections have been selected, a Content Consumer shall offer a means to copy the imported section(s) into local data structures as free text. This is to support the display of section level information for comparison or editing in workflows such as medication reconciliation while discrete data import is not possible. When viewed again after it is imported, a Content Consumer may chose to access the sharing framework to find out if the related information has been updated.

Note: For example, when using XDS, a Content Consumer may choose to query the Document Registry about a document whose sections were previously imported in order to find out if this previously imported document may have been replaced or has received an addendum. This capability is offered to Content Consumers by this Integration Profile, but not required, as the events that may justify such a query are extremely implementation specific.

This Option does not require, but does not exclude the Content Consumer from offering a means to select and import specific subsets of the narrative text of a section.

3.1.4 Discrete Data Import Option

This Option does not require that the View, Import Document or Section Import Options be supported. The Content Consumer that supports the Discrete Data Import Option shall be able to support the storage of the structured content of one or more sections of the document. This Option requires that the user be offered the possibility to select among the specific sections that include structured content a set of clinically relevant record entries (e.g. a problem or an allergy in a list) for import as part of the local patient record with the proper tracking of its origin.

Note: This note discusses an example of an implementation in an EMR supporting these options. The EMR implements a Content Consumer Actor for this XDS-MS Integration Profile that retrieves medical summary documents and allows the EMR user to use a number of import choices. One of them could be to save the retrieved document to the EMR system. This would be the support of the Document Import Option (See Section 3.4.2.2). If this implementation supports in addition the "Discrete Data Import" Option, the user may be offered the ability (implicitly or not) to have the document parsed for allergy, problem, and medication lists and all such structured entries found in the imported document are placed in quarantine for review by healthcare providers. A provider reviewing these quarantined items may decide to add some of them as discrete data items to the patient's local EMR record.

Note: This Discrete Data Import Option does not require the support of the View, Import Document or Import Sections Options so that it could be used alone to support implementations of Content Consumers other than EMRs, such as Public Health Data or Clinical Research systems that would want to aggregate and anonymize specific population healthcare information data as Document Consumer Actors, but one which no care provider actually views the medical summaries. It is expected that most EMR

supporting the Discrete Data Import Option would select also one of the View, Import Document or Import Sections Options.

When discrete data is accessed after it was imported, a Content Consumer may choose to check if the document related to the discrete data viewed has been deprecated, replaced or addended.

Note: For example, using XDS, a Content Consumer may choose to query the Document Registry about a document from which discrete data was previously imported in order to find out if this previously imported document may have been replaced or has received an addendum. This capability is offered to Content Consumers by this Integration Profile, but not required, as the events that may justify such a query are extremely implementation specific.

4 IHE Bindings

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.

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.

The source for all required and optional attributes have been defined in this section. 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.
- **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.
- **Constrained?** – Indicates where this Content Profile further constrains this attribute.
- **Extended Discussion?** – Indicates which section provides addition details of the handling of this attribute.
- **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.
O	**Other** – Extended Discussion must be 'yes' and details given in an Extended Discussion.

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

1480 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.

4.1.1 XDSDocumentEntry Metadata

XDSDocumentEntry Attribute	Optional?	Constrained?	Extended Discussion?	Source Type	Source/ Value
authorSpecialty	R2		4.1.2.1	CAD	
authorInstitution	R2			SA	`/ClinicalDocument/author /assignedAuthor /representedOrganization/name`
authorPerson	R2		4.1.2.2	SAT	`$person <= /ClinicalDocument/author`
classCode	R		4.1.2.3	CADT	`Must be consistent with /ClinicalDocument/code/@code`

classCodeDisplayName	R	4.1.2.4	CADT	Must be Consitent with /ClinicalDocument/code/@code
confidentialityCode	R	4.1.2.5	CADT	/ClinicalDocument/ confidentialityCode/@code
creationTime	R		SA	/ClinicalDocument/effectiveTime
eventCodeList	O	4.1.2.6	CADT	
eventCodeDisplay NameList	R (if event Code is valued)		CADT	
formatCode	R	4.1.2.7	FM	/ClinicalDocument/templateId
healthcareFacility TypeCode	R	4.1.2.8	O	Must be concistent with /clinicalDocument/code
healthcareFacility TypeCodeDisplay Name	R	4.1.2.8	O	Must be concistent with /clinicalDocument/code
intendedRecipient	R2	4.1.2.2	SAT	$person <= /ClinicalDocument/intendedRecipient
languageCode	R		SA	/ClinicalDocument/languageCode
legalAuthenticator	O	4.1.2.2	SAT	$person <= /ClinicalDocument/ legalAuthenticator
mimeType	R		FM	text/xml
parentDocument Relationship	R (when applicab le)		SA	/ClinicalDocument/relatedDocument/@ typeCode
parentDocumentId	R (when parent Docume nt Relations hip is present)	4.1.2.9	SAT	$docID <= /ClinicalDocument/ relatedDocument/parentDocument/ id
patientId	R	4.1.2.10	SAT	$patID <= /ClinicalDocument/recordTarget/ patientRole/id
practiceSettingCode	R	4.1.2.11	CAD	
practiceSettingCode DisplayName	R	4.1.2.10	CAD	

serviceStartTime	R2		SA	/ClinicalDocument/documentationOf/serviceEvent/effectiveTime/low/@value
serviceStopTime	R2		SA	/ClinicalDocument/documentationOf/serviceEvent/effectiveTime/high/@value
sourcePatientId	R		DS	
sourcePatientInfo	R		DS	
Title	O		SA	/ClinicalDocument/title
typeCode	R		SA	/ClinicalDocument/code/@code
typeCodeDisplayName	R		SA	/ClinicalDocument/code/@displayName
uniqueId	R	4.1.2.12	SAT	$docID <= /ClinicalDocument/id

4.1.2 Extended Discussion of XDSDocumentEntry Metadata

4.1.2.1 authorSpecialty

This metadata element should be based on a detailed defined classification system for healthcare providers such as those found in SNOMED-CT, or the HIPPA Healthcare Provider Taxonomy.

4.1.2.2 authorPerson, legalAuthenticator and intendedRecipient

The author, legal authenticator or intendedRecipient can be formatted using the following XPath expression, where **$person** in the expression below represents /ClinicalDocument/author, /ClinicalDocument/legalAuthenticator or /ClinicalDocument/intendedRecipient respectively.

```
concat(
$person/id/@extension,"^",
$person/assignedPerson/name/family,"^",
$person/assignedPerson/name/given,"^",
$person/assignedPerson/name/middle,"^",
$person/assignedPerson/name/suffix,"^",
$person/assignedPerson/name/prefix,"^",
$person/assignedPerson/name/degree,"^^&",
$person/id/@root,"&ISO"
)
```


4.1.2.3 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].

4.1.2.4 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.

4.1.2.5 ConfidentialityCode

Derived from a mapping of `/ClinicalDocument/confidentialityCode/@code` to an Affinity Domain specified coded value and coding system.

4.1.2.6 EventCodeList and eventCodeDisplayNameList

These values express a collection of keywords that may be relevant to the consumer of the documents in the registry. Public comment is sought on what value sets would be of use.

4.1.2.7 formatCode

The format code shall be the OID associated with the template identifier used to identify the content module that the document conforms to. See PCC TF-2:5.1.2 for a list of values that can be used as format codes.

4.1.2.8 healthcareFacilityTypeCode and healthcareFacilityTypeCodeDisplayName

A fixed value assigned to the Document Source and configured form a set of Affinity Domain defined values.

4.1.2.9 parentDocumentId and uniqueId

The parentDocumentId and/or uniqueId can be formatted using the following XPath expression, where **$docID** in the expression below represents the appropriate identifier.

```
concat($docID/@root,"^", $docID/@extension)
```

4.1.2.10 patientId

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")
```


4.1.2.11 practiceSettingCode and practiceSettingCodeDisplayName

These 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.

4.1.2.12 uniqueId

```
concat($docID/@root,"^", $docID/@extension)
```

4.1.3 XDSSubmissionSet Metadata

XDSSubmissionSet attribute	Optional?	Constrained?	Extended Discussion?	Source Type	Source/ Value
authorDepartment	R2		Yes	CAD	`See 1.4.1.2.1`
authorInstitution	R2			SA	`/ClinicalDocument/author/assignedAuthor /representedOrganization/name`
authorPerson	O	R2	Yes	SAT	`$person <= /ClinicalDocument/author` `See 1.4.1.2.2`
comments	R2		Yes		`string(//section[@code='42349-1']/text)` `This is the reason for referral if present.`
contentTypeCode	R			CAD	
contentTypeCode DisplayName	R			CAD	
patientId	R		Yes	SAT	`$patID <= /ClinicalDocument/recordTarget /patientRole/id` `See 1.4.1.2.6`
sourceId	R			DS	
submissionTime	R			DS	
uniqueId	R				

4.1.4 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.

4.1.5 Use of XDS Folders

No specific requirements identified.

4.1.6 Configuration

This Medical Summary Content Profile requires that Content Creators and Content Consumers using these documents be configured 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 medication summaries (See PCC TF-2: 5.4.1.1.2.1).

5 IHE Content Modules

This section provides a number of modules used to describe the content of a payload found in an IHE transaction. It specifies the standards used, and the constraints on those standards. Content modules are transaction neutral. They do not have dependencies upon the transaction that they appear in. Those dependencies are specified in the Bindings listed above.

The implementation of the document content modules specified in this section requires an understanding of the transactions and the integration profiles they support. These Content Modules provide the clinical information content for documents that are shared using ITI transactions specified by the XDS, XDM and XDR Integration Profiles. See ITI TF-1 and ITI TF-2 for more details on these profiles.

5.1 Namespaces and Vocabularies

This section lists the namespaces and identifiers defined or referenced by the IHE PCC Technical Framework, and the vocabularies defined or referenced herein.

5.1.1 Namespaces for Vocabularies used in this Document

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	See section 5.1.2 below.
1.3.6.1.4.1.19376.1.5.3.2	IHEActCode	See section 5.1.3 below.
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
2.16.840.1.113883.6.96	SNOMED-CT	SNOMED Controlled Terminology
2.16.840.1.113883.6.103	ICD-9CM (diagnosis codes)[1]	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[2]	Current Procedure Terminology 4 (CPT-4) codes.

1575 Table 5.1-1 Vocabularies Used

5.1.2 IHE PCC Template Identifiers

This document defines the template identifiers shown in the table below. The root namespace (OID) for these identifiers is 1.3.6.1.4.1.19376.1.5.3.1.

Template Identifier	Description	Reference
1.3.6.1.4.1.19376.1.5.3.1.1	CDA Document Template Identifiers	5.4
1.3.6.1.4.1.19376.1.5.3.1.1.1	Medical Document Template	5.4.1.1
1.3.6.1.4.1.19376.1.5.3.1.1.2	Medical Summary Template Identifier and XDS-MS formatCode	5.4.1.2
1.3.6.1.4.1.19376.1.5.3.1.1.3	Referral Summary Template	5.4.1.3
1.3.6.1.4.1.19376.1.5.3.1.1.4	Discharge Summary Template	5.4.1.4
1.3.6.1.4.1.19376.1.5.3.1.2	CDA Header Template Identifiers	5.4.2
1.3.6.1.4.1.19376.1.5.3.1.3	CDA Section Template Identifiers	5.4.3
1.3.6.1.4.1.19376.1.5.3.1.3.1	Reason for Referral	5.4.3.1.1
1.3.6.1.4.1.19376.1.5.3.1.3.2	Reason for Referral (Structured)	5.4.3.1.1
1.3.6.1.4.1.19376.1.5.3.1.3.3	Hospital Admission Diagnosis	5.4.3.1.2
1.3.6.1.4.1.19376.1.5.3.1.3.4	History of Present Illness	5.4.3.2.1

[1] The ICD-9CM codes were split into the diagnosis and procedure subsets by the HL7 Vocabulary TC in January of 2004

[2] This value is the requested symbolic name for CPT-4 as it was registered with HL7.

1.3.6.1.4.1.19376.1.5.3.1.3.5	Hospital Course	5.4.3.2.2
1.3.6.1.4.1.19376.1.5.3.1.3.6	Active Problems	5.4.3.2.3
1.3.6.1.4.1.19376.1.5.3.1.3.7	Discharge Problems	5.4.3.2.4
1.3.6.1.4.1.19376.1.5.3.1.3.8	Resolved Problems	5.4.3.2.5
1.3.6.1.4.1.19376.1.5.3.1.3.9	History of Outpatient Visits	5.4.3.2.6
1.3.6.1.4.1.19376.1.5.3.1.3.10	History of Inpatient Admissions	5.4.3.2.7
1.3.6.1.4.1.19376.1.5.3.1.3.11	List of Surgeries	5.4.3.2.8
1.3.6.1.4.1.19376.1.5.3.1.3.12	List of Surgeries (structured)	5.4.3.2.8
1.3.6.1.4.1.19376.1.5.3.1.3.13	Allergies and Other Adverse Reactions	5.4.3.2.9
1.3.6.1.4.1.19376.1.5.3.1.3.14	Family Medical History	5.4.3.2.10
1.3.6.1.4.1.19376.1.5.3.1.3.15	Family Medical History (structured)	5.4.3.2.10
1.3.6.1.4.1.19376.1.5.3.1.3.16	Social History	5.4.3.2.11
1.3.6.1.4.1.19376.1.5.3.1.3.17	Functional Status	5.4.3.2.12
1.3.6.1.4.1.19376.1.5.3.1.3.18	Review of Systems	5.4.3.2.13
1.3.6.1.4.1.19376.1.5.3.1.3.19	Medications	5.4.3.3.1
1.3.6.1.4.1.19376.1.5.3.1.3.20	Admission Medication History	5.4.3.3.2
1.3.6.1.4.1.19376.1.5.3.1.3.21	Hospital Medications	5.4.3.3.3
1.3.6.1.4.1.19376.1.5.3.1.3.22	Hospital Discharge Medications	5.4.3.3.4
1.3.6.1.4.1.19376.1.5.3.1.3.23	Immunizations	5.4.3.3.5
1.3.6.1.4.1.19376.1.5.3.1.3.24	Physical Exam	5.4.3.4.1

1.3.6.1.4.1.19376.1.5.3.1.3.25	Vital Signs	5.4.3.4.2
1.3.6.1.4.1.19376.1.5.3.1.3.26	Hospital Discharge Physical Exam	5.4.3.4.3
1.3.6.1.4.1.19376.1.5.3.1.3.27	Results	5.4.3.5.1
1.3.6.1.4.1.19376.1.5.3.1.3.28	Results (structured)	5.4.3.5.1
1.3.6.1.4.1.19376.1.5.3.1.3.29	Hospital Studies Summary	5.4.3.5.2
1.3.6.1.4.1.19376.1.5.3.1.3.30	Hospital Studies Summary (structured)	5.4.3.5.2
1.3.6.1.4.1.19376.1.5.3.1.3.31	Care Plan	5.4.3.6.1
1.3.6.1.4.1.19376.1.5.3.1.3.32	Discharge Disposition	5.4.3.6.2
1.3.6.1.4.1.19376.1.5.3.1.3.33	Discharge Diet	5.4.3.6.3
1.3.6.1.4.1.19376.1.5.3.1.3.34	Advance Directives	5.4.3.6.4
1.3.6.1.4.1.19376.1.5.3.1.3.35	Advance Directives (structured Reference)	5.4.3.6.4
1.3.6.1.4.1.19376.1.5.3.1.4	CDA Entry Template Identifiers	5.4.4
1.3.6.1.4.1.19376.1.5.3.1.4.1	The template identifier used to identify a severity observation.	5.4.4.2
1.3.6.1.4.1.19376.1.5.3.1.4.1.1	The template identifier used to identify a clinical status observation.	5.4.4.3
1.3.6.1.4.1.19376.1.5.3.1.4.1.2	The template identifier used to identify a health status observation.	5.4.4.4
1.3.6.1.4.1.19376.1.5.3.1.4.2	The template identifier used to identify a comment on an observation.	5.4.4.5
1.3.6.1.4.1.19376.1.5.3.1.4.3	The template identifier used to identify instructions in medication order.	5.4.4.6
1.3.6.1.4.1.19376.1.5.3.1.4.4	The template identifier used to identify references to external documents.	5.4.4.7
1.3.6.1.4.1.19376.1.5.3.1.4.5.1	The template identifier used to identify observation elements that indicate a concern.	5.4.4.8
1.3.6.1.4.1.19376.1.5.3.1.4.5.2	The template identifier used to identify observation elements that indicate a problem of concern.	5.4.4.9
1.3.6.1.4.1.19376.1.5.3.1.4.5.3	The template identifier used to identify observation elements that indicate an allergy or adverse reaction of concern.	5.4.4.10
1.3.6.1.4.1.19376.1.5.3.1.4.5	The template identifier used to identify observation elements that describe patient problem.	5.4.4.11
1.3.6.1.4.1.19376.1.5.3.1.4.6	The template identifier used to identify observation elements that describe patient allergy or adverse reaction.	5.4.4.12
1.3.6.1.4.1.19376.1.5.3.1.4.6.1	The template identifier used to identify observation elements that describe manifestations of an allergy; the symptom, sign, or diagnosis observation, e.g. rash, weal (hive), or urticaria.	5.4.4.12.4
1.3.6.1.4.1.19376.1.5.3.1.4.7	The template identifier for a <substanceAdministration> event that records medication administration events or requests. This is the root template for all medications.	5.4.4.13
1.3.6.1.4.1.19376.1.5.3.1.4.7.1	This template identifier identifies medications that do not require complex processing for dose (e.g., split, tapered, conditional dosing or combination medications).	5.4.4.13.2.1.1

1.3.6.1.4.1.19376.1.5.3.1.4.8	The template identifier for a <substanceAdministration> event that records tapered dose information in subordinate <substanceAdministration> events.	5.4.4.13.2.1.2
1.3.6.1.4.1.19376.1.5.3.1.4.9	The template identifier for a <substanceAdministration> event that records split dose information in subordinate <substanceAdministration> events.	5.4.4.13.2.1.3
1.3.6.1.4.1.19376.1.5.3.1.4.10	The template identifier for a <substanceAdministration> event that records conditional dose information in subordinate <substanceAdministration> events.	5.4.4.13.2.1.4
1.3.6.1.4.1.19376.1.5.3.1.4.11	The template identifier for a <substanceAdministration> event that records combination medication component information in subordinate <substanceAdministration> events.	5.4.4.13.2.1.5

Table 5.1-2 IHE PCC Template Identifiers

5.1.3 IHEActCode Vocabulary 1.3.6.1.4.1.19376.1.5.3.2

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.
INSTRUCT	This is the act of providing instructions regarding the use of medication.
PROBLEM	This is the undifferentiated process of establishing a symptom, finding, or diagnosis.
SX	This is the act of recording observations about the patient made by the patient or other persons.
COMPLAINT	This is the act of recording the concern of the patient.
FX	This is the act of examining the patient to find something out, "a finding".
CLINSTATUS	This is a specific finding about the clinical status of a problem, allergy or medication.
HLTHSTATUS	This is a specific finding of patient health status.
DX	This is the act of diagnosing an abnormality or illness, and is exactly equivalent to the HL7 ActCode vocabulary term of the same name.
FUNCLIMIT	This is the diagnosis of a functional limitation.

Table 5.1-3 IHEActCode Vocabulary

5.2 Conventions

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

R = Required Data Element

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

R2 = Required Section if data present.

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 = Optional section.

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.

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

5.3 Folder Modules

This section contains modules that describe the content requirements of XDS Folders. At present, the IHE PCC Technical Framework has not defined any Folder Modules.

5.4 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.

5.4.1 CDA Document Content Modules

5.4.1.1 Medical Documents 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.

5.4.1.1.1 Standards

CDAR2 Clinical Document Architecture, Release 2.0, 2005, HL7

CRS Implementation Guide for CDA Release 2 – Level 1 and 2 – Care Record Summary (US realm), 2006, HL7.

5.4.1.1.2 Document Specification

The constraints for encoding of the CDA Header (Level 1), and codes for sections within the section body follow all Level 1 constraints found in the HL7 Care Record Summary Implementation Guide, with the exception that the constraints on the type of document and its narrative content are not adopted by this content profile[3].

5.4.1.1.2.1 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 a processing instruction including a link to the URL for the XML style sheet must be included in the document, and the style sheet must be available to all receivers. Within an XDS Affinity domain this shall be via an HTTP or HTTPS GET. When using XDM or XDR to exchange documents, the stylesheet must also be exchanged. The style sheet should not rely on graphic or other media resources. If graphics other media resources are used, these shall be accessible in the same way. The content creator need not be the provider of the resources.

[3] Level 1 constraints on the CRS document type and content are specific to summary documents, and would not be applicable to other kinds of documents (such as an H&P or Operative Note).

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.

5.4.1.1.2.2 Distinctions of None

Information that is sent must clearly identify distinctions between

- None
  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.[4]
- 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.

5.4.1.2 Medical Summary Content 1.3.6.1.4.1.19376.1.5.3.1.1.2

5.4.1.2.1 Standards

CDAR2 Clinical Document Architecture, Release 2.0, 2005, HL7

CRS Implementation Guide for CDA Release 2 – Level 1 and 2 – Care Record Summary (US realm), 2006, HL7.

CCD ASTM/HL7 Continuity of Care Document (Draft)

[4] There may in fact be relevant information, but local regulation may prohibit disclosure.

5.4.1.2.2 Document Specification

A medical summary is a type of medical document, and incorporates the constraints defined for medical documents found in section 5.4.1.1 Medical Documents above.

The medical summary further constrains CDA Release 2.0 by adopting all Level 1 and Level 2 constraints of the HL7 Care Record Summary.

5.4.1.3 Referral Summary Content 1.3.6.1.4.1.19376.1.5.3.1.1.3

5.4.1.3.1 Standards

CDAR2 Clinical Document Architecture, Release 2.0, 2005, HL7

CRS Implementation Guide for CDA Release 2 – Level 1 and 2 – Care Record Summary (US realm), 2006, HL7.

CCD ASTM/HL7 Continuity of Care Document (Draft)

5.4.1.3.2 Data Element Index

The use case is described fully in PCC TF-1: 3.2.1. Briefly, it involves a "collaborative" transfer of care for the referral of a patient from a primary care provider (PCP) to a specialist. The important document data elements identified by physicians and nurses for this use case are listed in the table below under the column "Data Elements". These were then mapped to the categories given HL7 Care Record Summary Implementation Guide, and HL7 CDA Release 2.0. These mappings are provided in the next two columns.

Data Elements	HL7 Care Record Summary	CDA Release 2.0
Reason for Referral	Reason for Referral	REASON FOR REFERRAL
History Present Illness	History of Present Illness	HISTORY OF PRESENT ILLNESS
Active Problems	Conditions	PROBLEM LIST
Current Meds	Medications	HISTORY OF MEDICATION USE
Allergies	Allergies and Adverse Reactions	HISTORY OF ALLERGIES
Resolved Problems	Conditions	HISTORY OF PAST ILLNESS
List of Surgeries	Past Surgical History	HISTORY OF PRIOR SURGERIES
Immunizations	Immunizations	HISTORY OF IMMUNIZATIONS
Family History	Family History	HISTORY OF FAMILY ILLNESS
Social History	Social History	SOCIAL HISTORY
Pertinent Review of Systems	Review of Systems	REVIEW OF SYSTEMS
Vital Signs	Physical Exam	VITAL SIGNS
Physical Exam	Physical Exam	GENERAL STATUS, PHYSICAL FINDINGS
Relevant Diagnostic Surgical Procedures / Clinical Reports (including links)	Studies and Reports	RELEVANT DIAGNOSTIC TESTS AND/OR LABORATORY DATA
Relevant Diagnostic Test and Reports (Lab,	Studies and Reports	RELEVANT DIAGNOSTIC TESTS

Imaging, EKG's, etc.) including links.		AND/OR LABORATORY DATA
Plan of Care (new meds labs, or x-rays ordered)	Care Plan	TREATMENT PLAN
Advance Directives	Advance Directives	ADVANCE DIRECTIVES
Patient Administrative Identifiers	Header	patientRole/id
Pertinent Insurance Information	Participant	participant[@roleCode='HLD']
Data needed for state and local referral forms, if different than above	Optional Sections	section

Table 5.4-1 IHE Ambulatory Referral Data Elements

5.4.1.3.3 Document Specification

A referral summary is a type of medical summary, and incorporates the constraints defined for Medical Summaries found in section 5.4.1.2 above. This section defines additional constraints for Medical Summary Content used in a Referral summary. These tables present the Categories, as defined in Section 3 of CRS. In no case are these IHE requirements less strict than those defined by CRS.

Data Elements	Opt	Section	Template ID
Reason for Referral	R	5.4.3.1.1	1.3.6.1.4.1.19376.1.5.3.1.3.1
History Present Illness	R	5.4.3.2.1	1.3.6.1.4.1.19376.1.5.3.1.3.4
Active Problems	R	5.4.3.2.3	1.3.6.1.4.1.19376.1.5.3.1.3.6
Current Meds	R	5.4.3.3.1	1.3.6.1.4.1.19376.1.5.3.1.3.19
Allergies	R	5.4.3.2.9	1.3.6.1.4.1.19376.1.5.3.1.3.13
Resolved Problems	R2	5.4.3.2.5	1.3.6.1.4.1.19376.1.5.3.1.3.8
List of Surgeries	R2	5.4.3.2.8	1.3.6.1.4.1.19376.1.5.3.1.3.11
Immunizations	R2	5.4.3.3.5	1.3.6.1.4.1.19376.1.5.3.1.3.23
Family History	R2	5.4.3.2.10	1.3.6.1.4.1.19376.1.5.3.1.3.14
Social History	R2	5.4.3.2.11	1.3.6.1.4.1.19376.1.5.3.1.3.16
Pertinent Review of Systems	O	5.4.3.2.13	1.3.6.1.4.1.19376.1.5.3.1.3.18
Vital Signs	R2	5.4.3.4.2	1.3.6.1.4.1.19376.1.5.3.1.3.25
Physical Exam	R2	5.4.3.4.1	1.3.6.1.4.1.19376.1.5.3.1.3.24
Relevant Diagnostic Surgical Procedures / Clinical Reports and Relevant Diagnostic Test and Reports (Lab, Imaging, EKG's, etc.) including links.	R2	5.4.3.5.1	1.3.6.1.4.1.19376.1.5.3.1.3.27
Plan of Care (new meds, labs, or x-rays ordered)	R2	5.4.3.6.1	1.3.6.1.4.1.19376.1.5.3.1.3.31
Advance Directives	R2	5.4.3.6.4	1.3.6.1.4.1.19376.1.5.3.1.3.34
Patient Administrative Identifiers	R	5.4.1.1	These are handed by the Medical Documents Content Profile by reference to constraints in HL7 CRS.
Pertinent Insurance Information	R2	5.4.1.1	
Data needed for state and local referral forms, if different than above	R2	5.4.1.2	These are handed by including additional sections within the summary.

Table 5.4-2: IHE Ambulatory Referral Constraints

5.4.1.4 Discharge Summary Content 1.3.6.1.4.1.19376.1.5.3.1.1.4

5.4.1.4.1 Data Element Index

This use case is described fully in PCC TF-1: 3.2.2. Briefly, it involves an episodic transfer of care in the form of a patient discharge from a hospital to home. The important data elements identified by physicians and nurses for this use case are listed in the table below under the column “Data Elements”. These are mapped to the categories given HL7 Care Record Summary Implementation Guide, and HL7 CDA Release 2.0 in the next two columns.

Data Elements	HL7 Care Record Summary	HL7 CDA Release 2.0
Date of Admission	Header	encompassingEncounter/effectiveTime
Date of Discharge	Header	encompassingEncounter/effectiveTime
Participating Providers and Roles	Header	documentationOf/serviceEvent/performer
Discharge Disposition (who, how, where)	Care Plan	DISCHARGE DISPOSITION
Admitting Diagnosis	Conditions	HOSPITAL ADMISSION DX
History of Present Illness	History of Present Illness	HISTORY OF PRESENT ILLNESS
Hospital Course	Hospital Course	HOSPITAL COURSE
Discharge Diagnosis (including active and resolved problems)	Conditions	HOSPITAL DISCHARGE DX
Selected Medicine Administered during Hospitalization	Medications	HISTORY OF MEDICATION USE
Discharge Medications	Medications	HOSPITAL DISCHARGE MEDICATIONS
Allergies and adverse reactions	Allergies and Adverse Reactions	HISTORY OF ALLERGIES
Discharge Diet	Optionally found in Care Plan	DISCHARGE DIET
Review of Systems	Review of Systems	REVIEW OF SYSTEMS
Vital Signs (most recent, high/low/average)	Physical Exam	VITAL SIGNS
Functional Status	Functional Status	HISTORY OF FUNCTIONAL STATUS
Relevant Procedures and Reports (including links)	Studies and Reports	HOSPITAL DISCHARGE STUDIES
Relevant Diagnostic Tests and Reports (including links)	Studies and Reports	HOSPITAL DISCHARGE STUDIES
Plan of Care	Care Plan	TREATMENT PLAN
Administrative Identifiers	Header	patient/id
Pertinent Insurance Information	Header	participant[@roleCode='HLD']

Table 5.4-3 Acute Care Discharge Summary Data Elements

5.4.1.4.2 Standards

CDAR2 Clinical Document Architecture, Release 2.0, 2005, HL7

CRS Implementation Guide for CDA Release 2 – Level 1 and 2 – Care Record Summary (US realm), 2006, HL7

CCD ASTM/HL7 Continuity of Care Document (Draft)

5.4.1.4.3 Document Specification

A discharge summary is a type of medical summary, and incorporates the constraints defined for Medical Summaries found in section 5.4.1.2 above.

This section defines additional constraints for Medical Summary Content used in a Discharge Summary. These tables present the data elements described above, along with their optionality, and references to the section and template where these sections or header data elements are further defined.

In no case are these IHE requirements less strict than those defined by the HL7 Care Record Summary.

Data Elements	Opt	Reference	Template ID
Active Problems	R	5.4.3.2.3	1.3.6.1.4.1.19376.1.5.3.1.3.6
Resolved Problems	R	5.4.3.2.5	1.3.6.1.4.1.19376.1.5.3.1.3.8
Discharge Diagnosis	R	5.4.3.2.4	1.3.6.1.4.1.19376.1.5.3.1.3.7
Admitting Diagnosis	R	5.4.3.1.2	1.3.6.1.4.1.19376.1.5.3.1.3.3
Selected Meds Administered	R2	5.4.3.3.3	1.3.6.1.4.1.19376.1.5.3.1.3.21
Discharge Meds	R	5.4.3.3.4	1.3.6.1.4.1.19376.1.5.3.1.3.22
Admission Medications	R2	5.4.3.3.2	1.3.6.1.4.1.19376.1.5.3.1.3.20
Allergies	R	5.4.3.2.9	1.3.6.1.4.1.19376.1.5.3.1.3.13
Hospital Course	R	5.4.3.2.2	1.3.6.1.4.1.19376.1.5.3.1.3.5
Advance Directives	O	5.4.3.6.4	1.3.6.1.4.1.19376.1.5.3.1.3.34
History of Present Illness	R2	5.4.3.2.1	1.3.6.1.4.1.19376.1.5.3.1.3.4
Functional Status	O	5.4.3.2.12	1.3.6.1.4.1.19376.1.5.3.1.3.17
Review of Systems	O	5.4.3.2.13	1.3.6.1.4.1.19376.1.5.3.1.3.18
Physical Examination	O	5.4.3.4.1	1.3.6.1.4.1.19376.1.5.3.1.3.24
Vital Signs	O	5.4.3.4.2	1.3.6.1.4.1.19376.1.5.3.1.3.25
Discharge Procedures Tests, Reports	O	5.4.3.5.2	1.3.6.1.4.1.19376.1.5.3.1.3.29
Plan of Care	R	5.4.3.6.1	1.3.6.1.4.1.19376.1.5.3.1.3.31
Discharge Diet	O	5.4.3.6.3	1.3.6.1.4.1.19376.1.5.3.1.3.33

Table 5.4-4: IHE Acute Care Discharge Summary Constraints

5.4.2 Header Content Modules

This is a placeholder for header content modules to be defined in the future.

5.4.2.1 RIM Class Type A OID TBD

5.4.2.1.1 Standards

5.4.2.1.2 Constraints

Example XML is shown below:

```
This is the example.
```

5.4.2.1.2.1 This is the Example

Which then gets explained.

5.4.3 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.

5.4.3.1 Reasons for Care

The sections described below describe various reasons why healthcare is being provided to the patient.

5.4.3.1.1 Reason for Referral

TemplateID	1.3.6.1.4.1.19376.1.5.3.1.3.1	
General Description	The reason for referral section shall contain a narrative description of the reason that the patient is being referred.	
Valid LOINC CODES	**Opt**	**Description**
42349-1	R	REASON FOR REFERRAL

TemplateID	1.3.6.1.4.1.19376.1.5.3.1.3.2	
Parent Template	1.3.6.1.4.1.19376.1.5.3.1.3.1	
General Description	This section shall include at least one entry describing the reason for referral as described in the Entry Content Module.	
Entries		**Description**
1.3.6.1.4.1.19376.1.5.3.1.4.13	R[5]	Observation
1.3.6.1.4.1.19376.1.5.3.1.4.5		5.4.4.8 Conditions Entry

5.4.3.1.2 Hospital Admission Diagnosis

TemplateID	1.3.6.1.4.1.19376.1.5.3.1.3.3	
General Description	The hospital admitting diagnosis section shall contain a narrative description of the primary reason for admission to a hospital facility. It shall include entries for observations as described in the Entry Content Modules.	
Valid LOINC CODES	**Opt**	**Description**
46241-6	R	HOSPITAL ADMISSION DX
Entries		**Description**

[5] At least one Observation or Condition entry is required.

1.3.6.1.4.1.19376.1.5.3.1.4.5	R	5.4.4.8 Conditions Entry

5.4.3.2 Other Condition Histories

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

5.4.3.2.1 History of Present Illness

TemplateID	1.3.6.1.4.1.19376.1.5.3.1.3.4	
General Description	The history of present illness section shall contain a narrative description of the sequence of events preceding the patient's current complaints.	
Valid LOINC CODES	**Opt**	**Description**
10164-2	R	HISTORY OF PRESENT ILLNESS

5.4.3.2.2 Hospital Course

TemplateID	1.3.6.1.4.1.19376.1.5.3.1.3.5	
General Description	The hospital course section shall contain a narrative description of the sequence of events from admission to discharge in a hospital facility.	
Valid LOINC CODES	**Opt**	**Description**
8648-8	R	HOSPITAL COURSE

5.4.3.2.3 Active Problems

TemplateID	1.3.6.1.4.1.19376.1.5.3.1.3.6	
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.	
Valid LOINC CODES	**Opt**	**Description**
11450-4	R	PROBLEM LIST
Entries		**Description**
1.3.6.1.4.1.19376.1.5.3.1.4.5	R	5.4.4.8 Conditions Entry

5.4.3.2.4 Discharge Diagnosis

TemplateID	1.3.6.1.4.1.19376.1.5.3.1.3.7	
General Description	The discharge diagnosis section shall contain a narrative description of the conditions that need to be monitored after discharge from the hospital and those that were resolved during the hospital course. It shall include entries for patient conditions as described in the Entry Content Module.	
Valid LOINC CODES	**Opt**	**Description**
11535-2	R	HOSPITAL DISCHARGE DX
Entries		**Description**

1.3.6.1.4.1.19376.1.5.3.1.4.5	R	5.4.4.8 Conditions Entry

5.4.3.2.5 Resolved Problems

TemplateID	1.3.6.1.4.1.19376.1.5.3.1.3.8	
General Description	The resolved problems section shall contain a narrative description of the conditions the patient suffered in the past. It shall include entries for problems as described in the Entry Content Modules.	
Valid LOINC CODES	**Opt**	**Description**
11348-0	R	HISTORY OF PAST ILLNESS
Entries		**Description**
1.3.6.1.4.1.19376.1.5.3.1.4.5	R	5.4.4.8 Conditions Entry

5.4.3.2.6 History of Outpatient Visits

TemplateID	1.3.6.1.4.1.19376.1.5.3.1.3.9	
General Description	The outpatients visit section shall contain a narrative description of the completed visits to ambulatory facilities.	
Valid LOINC CODES	**Opt**	**Description**
11346-4	R	HISTORY OF OUTPATIENT VISITS

5.4.3.2.7 History of Inpatient Admissions

TemplateID	1.3.6.1.4.1.19376.1.5.3.1.3.10	
General Description	The inpatient admissions section shall contain a narrative description of the admissions and discharges to inpatient facilities.	
Valid LOINC CODES	**Opt**	**Description**
11336-5	R	HISTORY OF HOSPITALIZATIONS

5.4.3.2.8 List of Surgeries

TemplateID	1.3.6.1.4.1.19376.1.5.3.1.3.11	
General Description	The list of surgeries section shall contain a narrative description of the diagnostic and therapeutic operative procedures and associated anesthetic techniques the patient received in the past.	
Valid LOINC CODES	**Opt**	**Description**
10167-5	R	HISTORY OF SURGICAL PROCEDURES

TemplateID	1.3.6.1.4.1.19376.1.5.3.1.3.12	
Parent Template	1.3.6.1.4.1.19376.1.5.3.1.3.11	
General Description	The list of surgeries section shall include entries for procedures and references to procedure reports when known as described in the Entry Content Modules.	
Valid LOINC CODES	**Opt**	**Description**
10167-5	R	HISTORY OF SURGICAL PROCEDURES
Entries		**Description**
Procedure	R	IHE Procedure Structure
1.3.6.1.4.1.19376.1.5.3.1.4.4	R2	5.4.4.7 References Entry

5.4.3.2.9 Allergies and Other Adverse Reactions

TemplateID	1.3.6.1.4.1.19376.1.5.3.1.3.13	
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.	
Valid LOINC CODES	**Opt**	**Description**
10155-0	R	HISTORY OF ALLERGIES
Entries		**Description**
1.3.6.1.4.1.19376.1.5.3.1.4.6	R	5.4.4.12 Allergies and Intolerances Entry

5.4.3.2.10 Family Medical History

TemplateID	1.3.6.1.4.1.19376.1.5.3.1.3.14	
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.	
Valid LOINC CODES	**Opt**	**Description**
10157-6	R	HISTORY OF FAMILY MEMBER DISEASES

TemplateID	1.3.6.1.4.1.19376.1.5.3.1.3.15	
Parent Template	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.	
Entries		**Description**
GeneticFamily	R	IHE GeneticFamily Structure
1.3.6.1.4.1.19376.1.5.3.1.4.5	R	5.4.4.8 Conditions Entry

5.4.3.2.11 Social History

TemplateID	1.3.6.1.4.1.19376.1.5.3.1.3.16	
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.	
Valid LOINC CODES	**Opt**	**Description**
29762-2	R	SOCIAL HISTORY

5.4.3.2.12 Functional Status

TemplateID	1.3.6.1.4.1.19376.1.5.3.1.3.17	
General Description	The functional status section shall contain a narrative description of capability of the patient to perform acts of daily living.	
Valid LOINC CODES	**Opt**	**Description**
10158-4	R	HISTORY OF FUNCTIONAL STATUS

5.4.3.2.13 Review of Systems

TemplateID	1.3.6.1.4.1.19376.1.5.3.1.3.18	
General Description	The review of systems section shall contain a narrative description of the responses the patient gave to a set of routine questions on the functions of each anatomic body system.	
Valid LOINC CODES	**Opt**	**Description**
10187-3	R	REVIEW OF SYSTEMS

5.4.3.3 Medications

This section contains section content modules that describe activities surrounding the use
1765 of medication.

5.4.3.3.1 Medications

TemplateID	1.3.6.1.4.1.19376.1.5.3.1.3.19	
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.	
Valid LOINC CODES	**Opt**	**Description**
10160-0	R	HISTORY OF MEDICATION USE
Entries		**Description**
1.3.6.1.4.1.19376.1.5.3.1.4.7	R	5.4.4.13 Medications

5.4.3.3.2 Admission Medication History

TemplateID	1.3.6.1.4.1.19376.1.5.3.1.3.20	
General Description	The admission medication history section shall contain a narrative description of the relevant medications administered to a patient prior to admission to a facility. It shall include entries for medication administration as described in the Entry Content Module.	
Valid LOINC CODES	**Opt**	**Description**
42346-7	R	MEDICATIONS ON ADMISSION
Entries		**Description**
1.3.6.1.4.1.19376.1.5.3.1.4.7	R	5.4.4.13 Medications

5.4.3.3.3 Hospital Medications

TemplateID	1.3.6.1.4.1.19376.1.5.3.1.3.21	
General Description	The hospital medications section shall contain a narrative description of the relevant medications administered to a patient during the course of hospital admission. It shall include entries for medication administration as described in the Entry Content Module.	
Valid LOINC CODES	**Opt**	**Description**
10160-0	R	HISTORY OF MEDICATION USE
Entries		**Description**
1.3.6.1.4.1.19376.1.5.3.1.4.7	R	5.4.4.13 Medications

5.4.3.3.4 Hospital Discharge Medications

TemplateID	1.3.6.1.4.1.19376.1.5.3.1.3.22	
General Description	The hospital discharge medications section shall contain a narrative description of the medications requested (ordered) to be administered to the patient after discharge from the hospital. It shall include entries for medication requests as described in the Entry Content Module.	
Valid LOINC CODES	**Opt**	**Description**
10183-2	R	HOSPITAL DISCHARGE MEDICATIONS
Entries		**Description**
1.3.6.1.4.1.19376.1.5.3.1.4.7	R	5.4.4.13 Medications Note: All medications in this section must have sustanceAdministration/@moodCode = "RQO"

5.4.3.3.5 Immunizations

TemplateID	1.3.6.1.4.1.19376.1.5.3.1.3.23	
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.	
Valid LOINC CODES	**Opt**	**Description**
11369-6	R	HISTORY OF IMMUNIZATIONS
Entries		**Description**
1.3.6.1.4.1.19376.1.5.3.1.4.12	R	Immunization

5.4.3.4 Physical Exams

5.4.3.4.1 Physical Exam

TemplateID	1.3.6.1.4.1.19376.1.5.3.1.3.24	
General Description	The physical exam section shall contain a narrative description of the patient's physical findings.	
Valid LOINC CODES	**Opt**	**Description**
10210-3	R	GENERAL STATUS, PHYSICAL FINDINGS

5.4.3.4.2 Vital Signs

TemplateID	1.3.6.1.4.1.19376.1.5.3.1.3.25	
General Description	The vital signs section shall contain a narrative description of the measurement results of a patient's vital signs.	
Valid LOINC CODES	**Opt**	**Description**
8716-3	R	VITAL SIGNS

5.4.3.4.3 Hospital Discharge Physical Exam

TemplateID	1.3.6.1.4.1.19376.1.5.3.1.3.26	
General Description	The hospital discharge physical exam section shall contain a narrative description of the patient's physical findings at discharge from a hospital facility.	
Valid LOINC CODES	**Opt**	**Description**
10184-0	R	HOSPITAL DISCHARGE PHYSICAL

5.4.3.5 Relevant Studies

5.4.3.5.1 Results

TemplateID	1.3.6.1.4.1.19376.1.5.3.1.3.27	
General Description	The results section shall contain a narrative description of the patient's relevant studies.	
Valid LOINC CODES	**Opt**	**Description**
30954-2	R	STUDIES SUMMARY

TemplateID	1.3.6.1.4.1.19376.1.5.3.1.3.28	
Parent Template	1.3.6.1.4.1.19376.1.5.3.1.3.27	
General Description	The results section shall contain a narrative description of the relevant diagnostic procedures the patient received in the past. It shall include entries for procedures and references to procedure reports when known as described in the Entry Content Modules.	
Valid LOINC CODES	**Opt**	**Description**
30954-2	R	STUDIES SUMMARY
Entries		**Description**
Procedure	R	IHE Procedure Structure
1.3.6.1.4.1.19376.1.5.3.1.4.4	R2	5.4.4.7 References Entry

5.4.3.5.2 Hospital Studies Summary

TemplateID	1.3.6.1.4.1.19376.1.5.3.1.3.29	
General Description	The hospital studies summary section shall contain a narrative description of the relevant diagnostic procedures the patient received during the hospital admission.	
Valid LOINC CODES	**Opt**	**Description**
11493-4	R	HOSPITAL DISCHARGE STUDIES SUMMARY

TemplateID	1.3.6.1.4.1.19376.1.5.3.1.3.30	
Parent Template	1.3.6.1.4.1.19376.1.5.3.1.3.29	
General Description	The hospital studies summary section shall include entries for diagnostic procedures and references to procedure reports when known as described in the Entry Content Modules.	
Valid LOINC CODES	**Opt**	**Description**
11493-4	R	HOSPITAL DISCHARGE STUDIES SUMMARY
Entries		**Description**
Procedure	R	IHE Procedure Structure
1.3.6.1.4.1.19376.1.5.3.1.4.4	R2	5.4.4.7 References Entry

5.4.3.6 Plans of Care

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

5.4.3.6.1 Care Plan

Note: specific templates for entries within plans of care may be found in other categories such as the medications category.

TemplateID	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.	
Valid LOINC CODES	**Opt**	**Description**
18776-5	R	TREATMENT PLAN

5.4.3.6.2 Discharge Disposition

TemplateID	1.3.6.1.4.1.19376.1.5.3.1.3.32	
General Description	The plan of care 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, specifically used in a discharge from a facility such as an emergency department, hospital, or nursing home.	
Valid LOINC CODES	**Opt**	**Description**
18776-5	R	TREATMENT PLAN

5.4.3.6.3 Discharge Diet

TemplateID	1.3.6.1.4.1.19376.1.5.3.1.3.33	
General Description	The discharge diet section shall contain a narrative description of the expectations for diet including proposals, goals, and order requests for monitoring, tracking, or improving the dietary control of the patient, specifically used in a discharge from a facility such as an emergency department, hospital, or nursing home.	
Valid LOINC CODES	**Opt**	**Description**
42344-2	R	DISCHARGE DIET

5.4.3.6.4 Advance Directives

TemplateID	1.3.6.1.4.1.19376.1.5.3.1.3.34	
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.	
Valid LOINC CODES	**Opt**	**Description**
42348-3	R	ADVANCE DIRECTIVES

TemplateID	1.3.6.1.4.1.19376.1.5.3.1.3.35	
Parent Template	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.	
Entries		**Description**
1.3.6.1.4.1.19376.1.5.3.1.4.4	R2	5.4.4.7 References Entry

1790 ### 5.4.3.7 Procedures Performed

Holding Place for Procedures Performed Category for next year

5.4.3.8 Impressions

Holding Place for Impressions Category for next year

5.4.4 Entry Content Modules

This section describes the Level 3 entries in CDA documents that describe conditions, problems, medications, and references to external documents, as well as several common components that may be used by these entries.

- Severity observations allow practitioners to indicate the severity of a condition.
- Unstructured comments allow practitioners to specify additional information that they feel is relevant.
- Medication instructions allow practitioners to specify additional instructions for the use of a medication.

The common structures are included in the target act using the <entryRelationship> element defined in the CDA Schema. This element allows for arbitrary act relationships to be described. The normal containment structure includes the target of the related act inside an <entryRelationship> element that is contained in the source act. To invert the direction of the relationship the inversionInd attribute of <entryRelationship> element is set to true (inversionInd='true' in the samples below).

5.4.4.1 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.

5.4.4.1.1 Standards

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

5.4.4.1.2 Constraints

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[6].

Three different examples showing the use of the ID attribute, and references to it appear in Figure 7.3-2:

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

Figure 7.3-2 Example uses of ID

This allows the text to be located with a special type of URI reference, which simply contains a fragment identifier. This URI is local to the document and so just begins with a hash mark (#), and is followed by the value of the ID being referenced.

Given one of these URIs stored in a variable named `theURI`, the necessary text value can be found via the following XPath expression:

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

Table 7.3-1 below shows the result of this expression using the examples above in Figure 7.3-2:

$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"

[6] The production is actually a little more complex than that, but if those rules are followed, it will be a legal ID.

Table 7.3-1 URI Dereference Result

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

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

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

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

5.4.4.2 Severity 1.3.6.1.4.1.19376.1.5.3.1.4.1

5.4.4.2.1 Standards

PatCareStruct HL7 Care Provision Domain (DSTU)

5.4.4.2.2 Constraints

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.

Figure 5.3-3 is an example of recording the condition or allergy severity. This figure is used as the context for the following sections.

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

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

  </observation>
</entry>
```

Figure 5.4-1 Severity

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.

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

The related statement is made about the severity of the condition (or allergy). 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'.

5.4.4.2.2.2 <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).

5.4.4.2.2.3 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.1'/>

The <templateId> element identifies this <observation> as a severity observation, allowing for validation of the content. As a side effect, readers[7] of the CDA can quickly locate and identify severity observations. The templateId must have root='1.3.6.1.4.1.19376.1.5.3.1.4.1.4.1'.

5.4.4.2.2.4 <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.

5.4.4.2.2.5 <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.

[7] Both machine and human.

5.4.4.2.2.6 <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.

5.4.4.2.2.7 <originalText><reference value='#severity-2'/></originalText>

The <value> element shall contain a <originalText> element. The <originalText> elements shall contain a <reference> element pointing to the narrative section (see PCC TF-3: A.3.2), rather than duplicate text. This is to avoid ambiguity.

5.4.4.3 Clinical Status 1.3.6.1.4.1.19376.1.5.3.1.4.1.1

5.4.4.3.1 Standards

PatCareStruct HL7 Care Provision Domain (DSTU)

5.4.4.3.2 Constraints

Any problem or allergy observation may be the subject of a clinical 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.

Figure 5.3-3 is an example of recording the condition or allergy clinical status. This figure is used as the context for the following sections.


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

    <entryRelationship typeCode='SUBJ' inversionInd='true'>
      <observation classCode='OBS' moodCode='EVN'>
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5'/>
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.1.1'/>
        <code code='CLINSTATUS' displayName='Clinical Status'
          codeSystem='1.3.6.1.4.1.19376.1.5.3.2' codeSystemName='IHEActCode' />
        <statusCode code='completed'/>
        <value xsi:type='CD' code='' codeSystem='' codeSystemName='' >
          <originalText><reference value='#cstatus-2'/></originalText>
        </value>
      </observation>
    </entryRelationship>

  </observation>
</entry>
```

Figure 5.4-2 Clinical Status

This specification models a clinical 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 clinical status in the coded condition observation, and a separate clinical status 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 clinical 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.

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

The related statement is made about the clinical status of the problem or allergy. This observation is recorded inside an <entryRelationship> element occurring in the problem or allergy. The containing <entry> is the subject (typeCode='SUBJ') of this new observation, which is the inverse of the normal containment structure, thus inversionInd='true'.

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

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

5.4.4.3.2.3 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.1.1'/>

The <templateId> element identifies this <observation> as a clinical status observation, allowing for validation of the content. As a side effect, readers[8] of the CDA can quickly locate and identify clinical status observations. The templateId must have root='1.3.6.1.4.1.19376.1.5.3.1.4.1.4.1.1'.

5.4.4.3.2.4 <code code='CLINSTATUS' codeSystem='1.3.6.1.4.1.19376.1.5.3.2' displayName='Clinical Status' codeSystemName='IHEActCode' />

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.

5.4.4.3.2.5 <statusCode code='completed'/>

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

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

The <value> element contains the clinical status. 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 may use any coding system that has appropriate values describing clinical status. Some suggested vocabularies are listed below.

codeSystem	codeSystemName	Description
2.16.840.1.113883.6.96	SNOMED-CT	SNOMED Controlled Terminology
2.16.840.1.113883.6.26	MEDCIN	A classification system from MEDICOMP Systems.

5.4.4.3.2.7 <originalText><reference value='#cstatus-2'/></originalText>

The <value> element shall contain a <originalText> element that points to the narrative text describing the clinical status. The <originalText> elements shall contain a <reference> element pointing to the narrative section (see PCC TF-2:5.4.4.1), rather than duplicate text to avoid ambiguity.

[8] Both machine and human.

5.4.4.4 Health Status 1.3.6.1.4.1.19376.1.5.3.1.4.1.2

5.4.4.4.1 Standards

PatCareStruct HL7 Care Provision Domain (DSTU)

5.4.4.4.2 Constraints

Any concern may have as its subject 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.

Figure 5.3-3 is an example of recording the health status. This figure is used as the context for the following sections.

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

    <entryRelationship typeCode='SUBJ'>
      <observation classCode='OBS' moodCode='EVN'>
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5'/>
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.1.2'/>
        <code code='HLTHSTATUS' displayName='Health Status'
          codeSystem='1.3.6.1.4.1.19376.1.5.3.2' codeSystemName='IHEActCode' />
        <statusCode code='completed'/>
        <value xsi:type='CD' code='' codeSystem='' codeSystemName='' >
          <originalText><reference value='#cstatus-2'/></originalText>
        </value>
      </observation>
    </entryRelationship>

  </observation>
</entry>
```

Figure 5.4-3 Clinical Status

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

5.4.4.4.2.1 <entryRelationship typeCode='SUBJ'>

The related statement is made about the health status of the patient. This observation is recorded inside an <entryRelationship> element occurring in the concern. The contained <entry> is a subject (typeCode='SUBJ') of the concern entry.

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

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

5.4.4.4.2.3 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.1.2'/>

The <templateId> element identifies this <observation> as a health status observation, allowing for validation of the content. As a side effect, readers of the CDA can quickly

locate and identify health status observations. The templateId must have root='1.3.6.1.4.1.19376.1.5.3.1.4.1.4.1.2'.

5.4.4.4.2.4 <code code='HLTHSTATUS' codeSystem='1.3.6.1.4.1.19376.1.5.3.2' displayName='Clinical Status' codeSystemName='IHEActCode' />

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

5.4.4.4.2.5 <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.

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

The <value> element contains the clinical status. 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 may use any coding system that has appropriate values describing clinical status. Some suggested vocabularies are listed below.

codeSystem	codeSystemName	Description
2.16.840.1.113883.6.96	SNOMED-CT	SNOMED Controlled Terminology
2.16.840.1.113883.6.26	MEDCIN	A classification system from MEDICOMP Systems.

5.4.4.4.2.7 <originalText><reference value='#cstatus-2'/></originalText>

The <value> element shall contain a <originalText> element that points to the narrative text describing the clinical status. The <originalText> elements shall contain a <reference> element pointing to the narrative section (see PCC TF-2:5.4.4.1), rather than duplicate text to avoid ambiguity.

5.4.4.5 Comments 1.3.6.1.4.1.19376.1.5.3.1.4.2

Any condition or allergy may be the subject of a comment.

5.4.4.5.1 Standards

PatCareStruct HL7 Care Provision Domain (DSTU)

5.4.4.5.2 Constraints

This profile allows for a comment to be supplied with each Act entry. This structure is included in the target act using the <entryRelationship> element defined in the CDA Schema.

While CDA and the HL7 V3 Patient Care Structures support more than one comment (called Annotations in the HL7 Patient Care Structures specification), this profile limits the cardinality to one. Figure 5.4-4 is an example of recording a comment for an <entry>. This figure is used as context for the following section.

```
<entry>
  <observation classCode='COND' moodCode='EVN'>
          ⋮
    <entryRelationship typeCode='SUBJ' inversionInd='true'>
      <observation classCode='OBS' moodCode='EVN'>
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.2'/>
        <code code='COMMENT' codeSystem='1.3.6.1.4.1.19376.1.5.3.2'
          codeSystemName='IHEActCode' />
        <text><reference value='#comment-2'/></text>
        <statusCode code='completed' />
      </observation>
    </entryRelationship>
          ⋮
  </observation>
</entry>
```

Figure 5.4-4 Comments

5.4.4.5.2.1 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.2'/>

The <templateId> element identifies this <observation> as a comment, allowing for validation of the content. As a side effect, readers of the CDA can quickly locate and identify comments. The templateId must have root='1.3.6.1.4.1.19376.1.5.3.1.4.1.4.2'.

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

Again, a related statement is made about the condition, allergy or medication. This observation is recorded inside an <entryRelationship> element occurring at the end of the condition or allergy 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'.

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

The related statement is an event (moodCode='EVN') making an arbitrary comment or providing instruction on the related entry. As this is simply an observation, so classCode='OBS'.

5.4.4.5.2.4 <code code='COMMENT' codeSystem='1.3.6.1.4.1.19376.1.5.3.2' codeSystemName='IHEActCode' />

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

Note: These values will be sent to HL7 for harmonization with the HL7 Act Vocabulary. It is expected that the final text of this profile will use the HL7 vocabulary system.

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

The <text> element provides a <reference> to the 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>.

5.4.4.5.2.6 <statusCode code='completed' />

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

5.4.4.6 Medication Instructions 1.3.6.1.4.1.19376.1.5.3.1.4.3

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

5.4.4.6.1 Standards

Pharmacy HL7 Pharmacy Domain (Normative)

5.4.4.6.2 Constraints

This structure is included in the target substance administration act using the <entryRelationship> element defined in the CDA Schema. Figure 5.4-4 is an example of recording an instruction for an <entry>. This figure is used as context for the following section.

```
<entry>
  <observation classCode='COND' moodCode='EVN'>
          ⋮
    <entryRelationship typeCode='SUBJ' inversionInd='true'>
      <observation classCode='OBS' moodCode='EVN'>
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.3'/>
        <code code='INSTRUCT' codeSystem='1.3.6.1.4.1.19376.1.5.3.2'
          codeSystemName='IHEActCode' />
        <text><reference value='#comment-2'/></text>
        <statusCode code='completed' />
      </observation>
    </entryRelationship>
          ⋮
  </observation>
</entry>
```

Figure 5.4-4 Medication Instructions

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

Again, a related statement is made about the condition, allergy or medication. This observation is recorded inside an <entryRelationship> element occurring at the end of the condition or allergy 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'.

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

The related statement is an event (moodCode='EVN') making an arbitrary comment or providing instruction on the related entry. As this is simply an observation, so classCode='OBS'.

5.4.4.6.2.3 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.3'/>

The <templateId> element identifies this <observation> 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. The templateId must have root='1.3.6.1.4.1.19376.1.5.3.1.4.1.4.3'.

5.4.4.6.2.4 <code code='INSTRUCT' codeSystem='1.3.6.1.4.1.19376.1.5.3.2' codeSystemName='IHEActCode' />

The <code> element indicates that this is a 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.

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

The <text> element provides a <reference> to the 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>.

5.4.4.6.2.6 <statusCode code='completed' />

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

5.4.4.7 References

5.4.4.7.1 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 in Figure 7.3-8.

```
<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 code='' codeSystem='2.16.840.1.113883.6.1'
        codeSystemName='LOINC' displayName=''/>
    <reference typeCode='REFR|SPRT'>
      <externalDocument classCode='DOC' moodCode='EVN'>
        <id extension='' root=''/>
        <code>
          <originalText><reference value='#study-1'/></originalText>
        </code>
      </externalDocument>
    </reference>
  </act>
</entry>
```

Figure 7.3-8 External Document Reference Example

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

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

5.4.4.7.1.2 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.4'/>

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

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

This <act> 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.

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

The document type code of the clinical document must be provided in the code attribute. If it is another CDA document, the codeSystem attribute should be the OID for LOINC as shown above[9]. The displayName attribute should also be provided for human readability and diagnostics, but is not strictly required.

[9] LOINC is the preferred coding system for CDA document types.

5.4.4.7.1.5 <reference typeCode='SPRT|REFR'>

The reference itself is 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.

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

The reference is to an <externalDocument> which documents (classCode='DOC') the event (moodCode='EVN').

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

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

5.4.4.7.1.8 <code> <originalText ><reference value='#*study-1*'/></originalText> </code>

In order to link the reference back to the original narrative text, the value of the <reference> is a URI to an element in the CDA narrative to which this entire external document reference is attached. As shown above, this <code> element does not use the code, codeSystem, codeSystemName or displayName attributes.

5.4.4.7.1.9 <setId root='' extension=''/>

The <setId> identifies a collection of revisions of the document. This element may be sent if desired, but is not required.

5.4.4.7.1.10 <versionNumber value=''/>

The value of the <versionNumber> is a positive integer representing which version of the document is being referenced. This value is required when the <setId> element is present, and may otherwise be omitted.

5.4.4.7.2 Internal References 1.3.6.1.4.1.19376.1.5.3.1.4.4.1

A CDA Entry may reference (point to) information contained in other entries within the same document as shown below in Figure 5.4-4.

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

Figure 5.4-4 Internal References

5.4.4.7.2.1 <entryRelationship typeCode='' inversionInd='*true*|false'>

The act being referenced appears inside a related entry. The type (typeCode) and direction (inversionInd) attributes will be specified in the entry content module that contains the reference.

5.4.4.7.2.2 <act classCode='' moodCode=''>

The act being referred to can be any CDA Clinical Statement element type (act, procedure, observation, et cetera). It shall have the same XML element type and attributes as the XML element in the CDA document that it references.

5.4.4.7.2.3 <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.

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

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

5.4.4.8 Concern Entry 1.3.6.1.4.1.19376.1.5.3.1.4.5.1

5.4.4.8.1 Standards

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

5.4.4.8.1.1 Constraints

```
<act classCode='ACT' moodCode='EVN'>
  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.1'/>
  <id root='' extension=''/>
  <statusCode code='active|suspended|aborted|completed'/>
  <effectiveTime>
    <low value=''/>
    <high value=''/>
  </effectiveTime>
  <!-- one or more entry relationships identifying problems of concern -->
  <entryRelationship type='SUBJ'>
  </entryRelationship>
  <!-- zero or one entry relationships identifying the health status of concern -->
  <entryRelationship type='SUBJ'>
  </entryRelationship>
  <!-- optional entry relationship providing more information about the concern -->
  <entryRelationship type='REFR'>
  </entryRelationship>
</act>
```

Figure 5.4-5 Concern Entry Example

This event (moodCode='EVN') represents an act (<act classCode='ACT') of being concerned about a problem (or allergy). The <effectiveTime> element describes the period of concern. The subject of concern is one or more observations about related problems (see section 5.4.4.11) or allergies and intolerances (see section 5.4.4.12). The subject of the concern may also include the current health status of the patient. Additional references can be provided having additional information related to the concern.

5.4.4.8.1.1.1 <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.

5.4.4.8.1.1.2 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.1'/>

The template identifier indicates this entry conforms to the concern content module.

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

This required element identifies the concern.

5.4.4.8.1.1.4 <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 that 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.

5.4.4.8.1.1.5 <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.

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

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 5.4.4.11 or 5.4.4.12. Note that the allergy concern entry in section 5.4.4.12 is a refinement of the problem concern entry defined in section 5.4.4.11.

5.4.4.8.1.1.7 <!-- zero or one entry relationships identifying the health status of concern --> <entryRelationship type='SUBJ'>

Also of concern may be the health status of the patient with respect to the problem and/or allergy described above.

5.4.4.8.1.1.8 <!-- optional entry relationship providing more information about the concern --> <entryRelationship type='REFR'>

5.4.4.9 Problem Concern Entry 1.3.6.1.4.1.19376.1.5.3.1.4.5.2

```
<act classCode='ACT' moodCode='EVN'>
  <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=''/>
  <statusCode code='active|suspended|aborted|completed'/>
  <effectiveTime>
    <low value=''/>
    <high value=''/>
  </effectiveTime>
  <!-- 1..* entry relationships identifying problems of concern -->
  <entryRelationship type='SUBJ'>
  </entryRelationship>
  <!-- zero or one entry relationships identifying the health status of concern -->
  <entryRelationship type='SUBJ'>
  </entryRelationship>
  <!-- optional entry relationship providing more information about the concern -->
  <entryRelationship type='REFR'>
  </entryRelationship>
</act>
```

Figure 5.4-6 Problem Concern Entry Example

This entry is a specialization of the Concern Entry, wherein the subject of the concern is focused on a problem. Elements shown in the diagram above in gray are explained above in section 5.4.4.8 Concern Entry.

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

This entry has a template identifier of 1.3.6.1.4.1.19376.1.5.3.1.4.5.2, and is a subtype of the Concern entry, and so must also conform to the rules of the concern entry, which has 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.

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

This entry shall contain one or more problem entries that conform to the specification in section 5.4.4.11.

5.4.4.10 Allergy and Intolerance Concern Entry 1.3.6.1.4.1.19376.1.5.3.1.4.5.3

```
<act classCode='ACT' moodCode='EVN'>
  <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=''/>
  <statusCode code='active|suspended|aborted|completed'/>
  <effectiveTime>
    <low value=''/>
    <high value=''/>
  </effectiveTime>
  <!-- 1..* entry relationships identifying allergies of concern -->
  <entryRelationship type='SUBJ'>
  </entryRelationship>
  <!-- zero or one entry relationships identifying the health status of concern -->
  <entryRelationship type='SUBJ'>
  </entryRelationship>
  <!-- optional entry relationship providing more information about the concern -->
  <entryRelationship type='REFR'>
  </entryRelationship>
</act>
```

Figure 5.4-7 Allergy and Intolerance Concern Entry Example

This entry is a specialization of the Concern Entry, wherein the subject of the concern is focused on an allergy or intolerance. Elements shown in the diagram above in gray are explained above in section 5.4.4.8 Concern Entry.

5.4.4.10.1 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.1'/> <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.3'/>

This entry has a template identifier of 1.3.6.1.4.1.19376.1.5.3.1.4.5.3, and is a subtype of the Concern entry, and so must also conform to the rules of the concern entry, which has 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.

5.4.4.10.2 <!-- 1..* entry relationships identifying allergies of concern --> <entryRelationship type='SUBJ'>

This entry shall contain one or more allergy or intolerance entries that conform to the specification in section 5.4.4.12.

5.4.4.11 Problem Entry 1.3.6.1.4.1.19376.1.5.3.1.4.5

5.4.4.11.1 Standards

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

5.4.4.11.2 Constraints

This section makes use of the linking, severity and clinical status and comment content specifications defined in sections 5.4.4.1, 5.4.4.2, 5.4.4.3 and 5.4.4.5 above.

In HL7 RIM parlance, observations about a problem, complaint, symptom, finding, diagnosis, or functional limitation of a patient is the event (moodCode='EVN') of observing (<observation classCode='OBS'>) that problem. The <value> of the observation comes from a controlled vocabulary representing such things. The <code> contained within the <observation> describes the method of determination from yet another controlled vocabulary.

An example appears below in Figure 7.4-5.

```
<observation classCode='OBS' moodCode='EVN' negationInd='false|true'>
  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5'/>
  <id root='' extension=''/>
  <code code='PROBLEM|SX|COMPLAINT|FX|DX|FUNCLIMIT' codeSystem='1.3.6.1.4.1.19376.1.5.3.2'
    displayName='' codeSystemName='IHEActCode'/>
  <statusCode code='completed'/>
  <effectiveTime><low value=''/><high value=''/></effectiveTime>
  <value xsi:type='CD' code=''
    codeSystem='' displayName='' codeSystemName=''>
    <originalText><reference value=''/></originalText>
  </value>
  <!-- <entryRelationship> element containing severity -->
  <!-- <entryRelationship> element containing clinical status -->
  <!-- <entryRelationship> element containing comments -->
</observation>
```

Figure 7.4-5 Problem Example

5.4.4.11.2.1 <observation classCode='OBS' moodCode='EVN' negationInd='false'>

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[10], or which do not allow the negation to be recorded with post-coordinated[11] coded terminology.

5.4.4.11.2.2 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5'/>

The <templateId> element identifies this <observation> as a problem, allowing for validation of the content. As a side effect, readers of the CDA can quickly locate and identify problems. The templateId must have root='1.3.6.1.4.1.19376.1.5.3.1.4.5'.

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

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

5.4.4.11.2.4 <code code='PROBLEM|SX|COMPLAINT|FX|DX|FUNCLIMIT' codeSystem='1.3.6.1.4.1.19376.1.5.3.2' displayName='' codeSystemName='IHEActCode'>

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 the IHEActCode vocabulary (see PCC TF-2:5.1.3), limited to the terms listed above. Subclasses of this content module may specify other vocabularies.

5.4.4.11.2.5 <statusCode code='completed'/>

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

[10] A pre-coordinated negation is a separately coded entry in the vocabulary. For example, a coded vocabulary could include "no prior history of chick pox" and "prior history of chicken pox", and so includes the pre-coordinated negative.

[11] Some vocabularies, such as SNOMED CT or MEDCIN, allow coded attributes to be added to the codes values so that more detailed coding can be performed.

5.4.4.11.2.6 <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 may not have a <low> element, in which case, the value is assumed to be unknown.

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).

5.4.4.11.2.7 <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 need to be negotiated within the affinity domain.

5.4.4.11.2.8 <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.

5.4.4.11.2.9 <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 codingSystem should reference a controlled vocabulary describing problems, complaints, symptoms, findings, diagnoses, or functional limitations, e.g., ICD-9, SNOMED-CT or MEDCIN, or others. Table 7-4.2 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.

Table 5.4-5 Example Problem Vocabularies

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.

5.4.4.11.2.10 <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.

5.4.4.11.2.11 <!-- <entryRelationship> element containing severity -->

An optional <entryRelationship> element may be present indicating the severity of the problem. When present, this <entryRelationship> element shall contain a severity observation conforming to the severity entry content module specified in section 5.4.4.2.

5.4.4.11.2.12 <!-- <entryRelationship> element 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 clinical status entry content module specified in section 5.4.4.3.

5.4.4.11.2.13 <!-- <entryRelationship> element containing comments -->

Following the severity, or the <value> if severity has not been specified, an optional <entryRelationship> may be present providing an additional comment (annotation) for

the condition. Although the Patient Care Structures allow for zero to many annotations, this profile restricts the upper bound to one. When present, this <entryRelationship> element shall contain a comment observation conforming to the comment entry content module specified in section 5.4.4.4.

5.4.4.12 Allergies and Intolerances 1.3.6.1.4.1.19376.1.5.3.1.4.6

```
<observation classCode='COND' moodCode='EVN' negationInd='false'>
  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5'/>
  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.6'/>
  <id root='' extension=''/>
  <code
    code='ALG|OINT|DALG|EALG|FALG|DINT|EINT|FINT|DNAINT|ENAINT|FNAINT'
    codeSystem='2.16.840.1.113883.5.4'
    codeSystemName='ObservationIntoleranceType'/>
  <statusCode code='completed'/>
  <effectiveTime>
    <low value=''/>
    <high value=''/>
  </effectiveTime>
  <value xsi:type='CD' code='' codeSystem='' displayName='' codeSystemName=''/>
  <participant typeCode='CSM'>
    <participantRole classCode='MANU'>
      <playingEntity classCode='MMAT'>
        <code code='' codeSystem=''>
          <originalText><reference value='#substance'/></orginalText>
        <name></name>
      </playingEntity>
    </participantRole>
  </participant>
  <!-- Optional <entryRelationship> element containing reactions -->
  <!-- Optional <entryRelationship> element containing clinical status -->
  <!-- Optional <entryRelationship> element containing severity -->
  <!-- Optional <entryRelationship> element containing comments -->
</observation>
```

Figure 7.5-6 Allergies Example

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.

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

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

5.4.4.12.2 <code code='ALG|OINT|DINT|EINT|FINT|DALG|EALG|FALG| DNAINT|ENAINT|FNAINT' displayName=''

codeSystem='2.16.840.1.113883.5.4'
codeSystemName='ObservationIntoleranceType'/>

The <code> element represents the kind of allergy observation made, to a drug, food or environmental agent, and whether it is an allergy, non-allergy intolerance, or unknown class of intolerance (not known to be allergy or intolerance).

The <code> element of an allergy entry shall be provided, and a code and codeSystem attribute shall be present. The example above uses the HL7 ObservationIntoleranceType vocabulary domain, which does provide suitable observation codes. Other vocabularies may be used, such as SNOMED-CT or MEDCIN. The displayName and codeSystemName attributes should be present.

See section 5.4.4.11.2.4 above for more detail.

5.4.4.12.3 <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 5.4-5 above[12].

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.

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

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

[12] A very limited set of codes for allergies is included in ICD-9-CM, including V14.0 – V14.9 and V15.0.

5.4.4.12.4.1 <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.

5.4.4.12.5 <!-- <entryRelationship> element containing reactions -->

An allergy entry can record the reactions that are manifestations of the allergy or intolerance as shown below in Figure 5.4-7.

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

Figure 5.4-7 Adverse Reaction Example

5.4.4.12.5.1 <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.

5.4.4.12.5.2 <observation classCode='OBS' moodCode='EVN'> <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5'/> ⋮ </observation>

The entry contained with this entry relationship is some sort of problem that is a manifestation of the allergy. It is recorded using the Problem Entry structure defined above in section 5.4.4.11.

5.4.4.13 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.

5.4.4.13.1 Standards

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

5.4.4.13.2 Constraints

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

Figure 5.4-8 Medications Entry Example

This section makes use of the linking, severity and instruction content specifications defined in sections 5.4.4.1, 5.4.4.2 and 5.4.4.6 above.

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. Table A.3-3 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.

Field	Opt.	CDA Tag	Description
Start and Stop Date	R2	<effectiveTime>	The date (and time if available) when the medication regimen began and is expected to finish. The first component of the <effectiveTime> encodes the lower and upper bounds over which the <substanceAdministration> occurs, and the start time is determined from the lower bound. If the medication has been known to be stopped, the high value must be present, but expressed as a flavor of null (e.g., Unknown).
Frequency	R2	<effectiveTime>	The frequency indicates how often the medication is to be administered. It is often expressed as the number of times per day, but which may also include information such as 1 hour before/after meals, or in the morning, or evening. The second <effectiveTime> element encodes the frequency. In cases where split or tapered doses are used, these may be found in subordinate <substanceAdministration> elements.
Route	R2	<routeCode>	The route is a coded value, and indicates how the medication is received by the patient (by mouth, intravenously, topically, et cetera).
Dose	R2	<doseQuantity>	The amount of the medication given. This should be in some known and measurable unit, such as grams, milligrams, et cetera. It may be measured in "administration" units (such as tablets or each), for medications where the strength is relevant. In this case, only the unit count is specified13, no units are specified. It may be a range.
Site	O	<approachSiteCode>	The site where the medication is administered, usually used with IV or topical drugs.
Rate	R2	<rateQuantity>	The rate is a measurement of how fast the dose is given to the patient over time (e.g., .5 liter / 1 hr), and is often used with IV drugs.

[13] The count need not be integral, e.g., 0.5 would represent 1 half of a tablet for a medication administered in tablet form.

Product	R	<consumable> <name> </consumable>	The name of the substance or product. This should be sufficient for a provider to identify the kind of medication. It may be a trade name or a generic name. This information is required in all medication entries. If the name of the medication is unknown, the type, purpose or other description may be supplied. The name should not include packaging, strength or dosing information. Note: Due to restrictions of the CDA schema, there is no way to explicitly link the name to the narrative text.
Strength	R2	<consumable> <code> <originalText/> </code> </consumable>	The name and strength of the medication. This information is only relevant for some medications, as the dose of the medication is often sufficient to indicate how much medication the patient receives. For example, the medication Percocet comes in a variety of strengths, which indicate specific amounts of two different medications being received in single tablet. Another example is eye-drops, where the medication is in a solution of a particular strength, and the dose quantity is some number of drops. The originalText referenced by the <code> element in the consumable should refer to the name and strength of the medication in the narrative text. Note: Due to restrictions of the CDA schema, there is no way to separately record the strength.
Code	R2	<consumable> <code/> </consumable>	A code describing the product from a controlled vocabulary, such as RxNorm, First DataBank, et cetera.
Instructions	R2	<entryRelationship>	A place to put free text comments to support additional relevant information, or to deal with specialized dosing instructions. For example, "take with food", or tapered dosing.
Indication	O	<entryRelationship>	A link to supporting clinical information about the reason for providing the medication (e.g., a link to the relevant diagnosis).

Table 7.6-3 Medication Fields

5.4.4.13.2.1 <substanceAdministration classCode='SBADM' moodCode='*RQO|EVN*'>

The general model is to record each reported or prescribed medication in an <substanceAdministration> request (moodCode='RQO'). Medications that have been administered (instead of prescribed or reported by the patient), are recorded in the same element, except that this is now an event (moodCode='EVN') instead of a request.

The <substanceAdministration> element may contain subordinate <substanceAdministration> elements in a related component entry to deal with special cases (see the section below on Special Cases). These cases include split, tapered, or conditional dosing, or combination medications. The use of subordinate <substanceAdministration> elements to deal with these cases is optional. The comment field should always be used in these cases to provide the same information as free text in the top level <substanceAdministration> element.

There are a variety of special cases for dosing that need to be accounted for. These are described below. Most of these special cases involve changing the dosage or frequency over time, or based on some measurement. When the dosage changes, then additional

entries are required for each differing dosage. The last case deals with combination medications.

5.4.4.13.2.1.1 Normal Dosing 1.3.6.1.4.1.19376.1.5.3.1.4.7.1

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

5.4.4.13.2.1.2 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.

5.4.4.13.2.1.3 Split Dosing 1.3.6.1.4.1.19376.1.5.3.1.4.9

This template identifier is used to identify medication administration events that require special processing to handle split dosing. The parent template is 1.3.6.1.4.1.19376.1.5.3.1.4.7.

A split dose is often used when different dosages are given at different times (e.g., at different times of day, or on different days). This may be to account for different metabolism rates at different times of day, or to simply address drug packaging deficiencies (e.g., and order for Coumadin 2mg on even days, 2.5mg on odd days is used because Coumadin does not come in a 2.25mg dose form).

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

5.4.4.13.2.1.4 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.

5.4.4.13.2.1.5 Combination Medications 1.3.6.1.4.1.19376.1.5.3.1.4.11

This template identifier is used to identify medication administration events that require special processing to handle combination medications. The parent template is 1.3.6.1.4.1.19376.1.5.3.1.4.7.

A combination medication is made up of two or more other medications. These may be prepackaged, such as Percocet, which is a combination of Acetaminophen and oxycodone in predefined ratios, or prepared by a pharmacist, such as a GI cocktail.

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

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

5.4.4.13.2.1.6 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7' />

All medications entries use the <templateId> element 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.

5.4.4.13.2.1.7 <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 Table 5.4-4 below for the root attribute.

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

Table 5.4-4 Extension values for <templateId> in <substanceAdministration>

5.4.4.13.2.2 <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.

5.4.4.13.2.3 <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). This element is optional.

5.4.4.13.2.4 <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.

5.4.4.13.2.5 <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. Unlike the condition observation, this attribute does not indicate whether or not the patient is still under the medication regime.

5.4.4.13.2.6 <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.

5.4.4.13.2.7 <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. Either the <low> or the <high> value may be omitted if unknown.

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.

If both the <low> and <high> values are unknown, then no <effectiveTime> elements shall be sent.[14]

5.4.4.13.2.8 <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 Table A.3-5 below, along with their XML representations.

[14] This might seem to be problematic because then the frequency information would be lost. While technically accurate, the relative likelihood that frequency would be known, but even an imprecise start and stop time is not known seems rare enough to ignore the problem this would introduce.

Freq	Description	XML Representation
b.i.d.	Twice a day	`<effectiveTime xsi:type='PIVL_TS' institutionSpecified='true' operator='A'> <period value='12' unit='h' /> </effectiveTime>`
q12h	Every 12 hours	`<effectiveTime xsi:type='PIVL_TS' institutionSpecified='false' operator='A'> <period value='12' unit='h' /> </effectiveTime>`
Once	Once, on 2005-09-01 at 1:18am.	`<effectiveTime xsi:type='TS' value='200509010118' operator='A'/>`
t.i.d.	Three times a day, at times determined by the person administering the medication[15].	`<effectiveTime xsi:type='PIVL_TS' institutionSpecified='true' operator='A'> <period value='8' unit='h' /> </effectiveTime>`
q8h	Every 8 hours	`<effectiveTime xsi:type='PIVL_TS' institutionSpecified='false' operator='A'> <period value='8' unit='h' /> </effectiveTime>`
qam	In the morning[16]	`<effectiveTime xsi:type='EIVL' operator='A'> <event code='ACM'/> </effectiveTime>`
	Every day at 8 in the morning for 10 minutes[17]	`<effectiveTime xsi:type='PIVL_TS' operator='A'> <phase> <low value="198701010800" inclusive="true"/> <width value="10" unit="min"/> </phase> <period value='1' unit='d'/> </effectiveTime>`
q4-6h	Every 4 to 6 hours.	`<effectiveTime xsi:type='PIVL_PPD_TS' institutionSpecified='false' operator='A'> <period value='5' unit='h' /> <standardDeviation value='1' unit='h'> </effectiveTime>`

Table 7.6-5 Sample Frequency Specifications

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

[15] The institutionSpecified='true' attribute indicates that the frequency of administration is determined by the person or institution that administers the medication. It is unfortunately named, because while this time is "institution specified" in an inpatient setting, it really just means that the frequency is the average rather than a precise specification.

[16] Technically, this representation is encoded as "before breakfast", which is not quite the same as qam.

[17] Treat this example as a pulse wave, with a specified width, starting point, and period. The <low> value of phase specifies any point in time in the past or future that the repeating wave would be at the start of its cycle. The width specifies the width of the pulse, and the <period> is how often the wave repeats itself. Thus, in this example, the date several years in the past is totally irrelevant, only the time, 0800 hours, is relevant. Note that the lack of timezone specification indicates local time.

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 Table 5.4-6 below.

xsi:type	Description
TS	An xsi:type of TS represents a single point in time, and is the simplest of all to represent. The value attribute of the <effectiveTime> element specifies the point in time in HL7 date-time format (CCYYMMDDHHMMSS)
PIVL_TS	An xsi:type of PIVL_TS is the most commonly used, representing a periodic interval of time. The <low> element of <phase> may be present. If so it specifies the starting point, and only the lower order components of this value are relevant with respect to the <period>. The <width> element represents the duration of the dose administration (e.g., for IV administration). The <period> indicates how often the dose is given. Legal values for the unit attribute of <period> are s, min, h, d, wk and mo representing seconds, minutes, hours, days, weeks, and months respectively.
EIVL_TS	An xsi:type of EIVL_TS represents an event based time interval, where the event is not a precise time, but is often used for timing purposes (e.g. with meals, between meals, before breakfast, before sleep). Refer to the HL7 TimingEvent vocabulary for the codes to use for the <event> element. This interval may specify an <offset> which provides information about the time offset from the specified event (e.g., <offset><low value='-1' unit='h'/><width value='10' unit='min'/></offset> means 1 hour before the event. In that same example, the <width> element indicates the duration for the dose to be given.
PIVL_PPD_TS	An xsi:type of PIVL_PPD_TS represents an probabilistic time interval and is used to represent dosing frequencies like q4-6h. This profile requires that the distributionType of this interval be left unspecified. The <period> element specifies the average of the time interval, and the value of the <standardDeviation> shall be computed as half the width of the interval. The unit attributes of the <period> and <standardDeviation> elements shall be the same.
SXPR_TS	An xsi:type of SXPR_TS represents a parenthetical set of time expressions. This type is used when the frequency varies over time (e.g., for some cases of tapered dosing, or to handle split dosing). The <comp> elements of this <effectiveTime> element are themselves time expressions (using any of the types listed above). Each <comp> element may specify an operator (e.g. to intersect or form the union of two sets).

Table 5.4-6 <effectiveTime> types used in Frequency Specifications

5.4.4.13.2.9 <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.

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

The <approachSiteCode> element contains a URI in the value attribute of the <reference> that points to the text in the narrative identifying the site. It may be coded to a controlled vocabulary that lists such sites (e.g., SNOMED-CT).

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

The dose is specified if the <doseQuantity> element. If a dose range is given (e.g., 1-2 tablets, or 325-750mg), then the <low> and <high> bounds are specified in their respective elements, otherwise both <low> and <high> have the same value. If the dose is in countable units (tablets, caplets, "eaches"), then the unit attribute is not sent. Otherwise the units are sent. The unit attribute should be derived from the HL7 UnitsOfMeasureCaseSensitive vocabulary[18].

5.4.4.13.2.12 <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[19].

5.4.4.13.2.13 <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).

[18] This vocabulary has atomic units and prefixes. A prefix (e.g. m for milli) may be combined with an atomic unit (e.g., g for gram) to produce mg for milligram, or zwk for zepto-week which is about 19 quadrillion years.

[19] Ideally, this would also be true for dates or times that are represented in an <entry>, unfortunately, this is not supported by the HL7 Version 3 datatypes.

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.

5.4.4.13.2.14 <consumable> <manufacturedProduct><manufacturedLabeledDrug>

The name and strength of the medication are specified in the elements under the <manufacturedLabeledDrug> element. These elements are required in a top level <substanceAdministration> event. In the case of subordinate <substanceAdministration> events for tapered, split or conditional dosing, this element shall be nil (xsi:nil='true'), as this information is already present in the top level <substanceAdministration> event. When the subordinate <substanceAdministation> events exist to describe the components of combination medications, these elements must be present.

5.4.4.13.2.15 <code code=" displayName=" codeSystem=" codeSystemName="> <originalText><reference value="/></originalText> </code>

The <code> element of the <manufacturedLabeledDrug> shall contain a <reference> whose URI value points to the name and strength of the medication, or just the name alone if strength is not relevant. 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 medication name and strength (e.g., Percocet-5/325), or just the medication name alone if strength is not relevant (Acetaminophen). Names may be either trademark or generic names.

Note: Since 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 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. Table A.3-7 below provides the codeSystem and codeSystemName for several controlled terminologies that may be used to encode medications.

codeSystem	codeSystemName	Description
2.16.840.1.113883.6.88	RxNorm	RxNorm
2.16.840.1.113883.6.63	FDDC	First DataBank Drug Codes
2.16.840.1.113883.6.96	SNOMED-CT	SNOMED Controlled Terminology

Table 7.6-7 Example Medication Vocabularies

5.4.4.13.2.16 <name>

The <name> element should contain the name of the medication (or active ingredient in the case of subordinate <substanceAdministration> elements used to record components of a medication) without any strength designation.

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

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

In the first three cases, the subordinate components shall specify only the changed <frequency> and/or <doseAmount> elements. For conditional dosing, each subordinate component shall have a <precondition> element that specifies the <observation> that must be obtained before administration of the dose.

The value of the <sequenceNumber> shall be an ordinal number, starting at 1 for the first component, and increasing by 1 for each subsequent component. Components shall be sent in <sequenceNumber> order.

5.4.4.13.2.18 <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).

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

A <substanceAdministration> event may indicate one or more reasons for the use of the medication. These reasons identify the concern that was the reason for use via the Internal Reference entry content module specified in section 5.4.4.7.2.

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.

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

A top level <substanceAdministration> event may contain a <precondition> that specifies the human readable text from the narrative that indicates the condition upon which the dosage should be administered.

A subordinate <substanceAdministration> event must contain a <precondition> in the case where the top level <substanceAdministration> event is for conditional dosing.

Appendix A Reserved for Future Use

Appendix B Validating CDA Documents using the Framework

Many of the constraints specified by the content modules defined in the PCC Technical Framework can be validated automatically by software. Automated validation is a very desirable capability, as it makes it easier for implementers to test the correctness of their implementations. With regard to validation of the content module, the PCC Technical Framework narrative is the authoritative specification, not any automated software tool. Having said that, it is still very easy to create a validation framework for the IHE PCC Technical Framework using a XML validation tool such as Schematron.

Since each content module has a name (the template identifier), any XML instance that reports itself to be of that "class" can be validated by creating assertions that must be true for each constraint indicated for the content module. In the XML representation, the `<templateId>` element is a child of the element that is claiming conformance to the template named. Thus the general pattern of a Schematron that validates a specific template is shown below:

```
<schema xmlns="http://www.ascc.net/xml/schematron" xmlns:cda="urn:hl7-org:v3">
  <ns prefix="cda" uri="urn:hl7-org:v3" />
  <pattern name='ReferralSummary'>
    <rule context='*[cda:templateId/@root="1.3.6.1.4.1.19376.1.5.3.1.1.3]"'>
      <!-- one or more assertions made by the content module -->
    </rule>
  </pattern>
</schema>
```


B.1 Validating Documents

For document content modules, the pattern can be extended to support common document content module constraints as shown below:

```
<schema xmlns="http://www.ascc.net/xml/schematron" xmlns:cda="urn:hl7-org:v3">
  <ns prefix="cda" uri="urn:hl7-org:v3" />
  <pattern name='ReferralSummary'>
    <rule context='*[templateId/@root="1.3.6.1.4.1.19376.1.5.3.1.1.3]"'>
      <!-- Verify that the template id is used on the appropriate type of object -->
      <assert test='../ClinicalDocument'>
        Error: The referral content module can only be used on Clinical Documents.
      </assert>
      <!-- Verify that the parent templateId is also present. -->
      <assert test='templateId[@root="1.3.6.1.4.1.19376.1.5.3.1.1.2"]'>
        Error: The parent template identifier for medical summary is not present.
      </assert>
      <!-- Verify the document type code -->
      <assert test='code[@code = "34133-9"]'>
        Error: The document type code of a referral summary must be
        34133-9 SUMMARIZATION OF EPISODE NOTE.
      </assert>
      <assert test='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>
      <!-- Verify that all required data elements are present -->
      <assert test='.//templateId[@root = "1.3.6.1.4.1.19376.1.5.3.1.3.1"]'>
        Error: A referral summary must contain a reason for referral.
      </assert>
      <!-- Alert on any missing required if known elements -->
      <assert test='.//templateId[@root = "1.3.6.1.4.1.19376.1.5.3.1.3.8"]'>
        Warning: A referral summary should contain a list of resolved problems.
      </assert>
      <!-- Note any missing optional elements -->
      <assert test='.//templateId[@root = "1.3.6.1.4.1.19376.1.5.3.1.3.18"]'>
        Note: This referral summary does not contain the pertinent review of systems.
      </assert>
    </rule>
  </pattern>
</schema>
```


B.2 Validating Sections

The same pattern can be also applied to sections with just a few minor alterations.

```
<schema xmlns="http://www.ascc.net/xml/schematron" xmlns:cda="urn:hl7-org:v3">
  <ns prefix="cda" uri="urn:hl7-org:v3" />
  <pattern name='ReasonForReferralUncoded'>
    <rule context='*[templateId/@root="1.3.6.1.4.1.19376.1.5.3.1.3.1"]'>
      <!-- Verify that the template id is used on the appropriate type of object -->
      <assert test='section'>
        Error: The coded reason for referral module can only be used on a section.
      </assert>
      <assert test='false'>
        Manual: Manually verify that this section contains narrative providing the
        reason for referral.
      </assert>
      <!-- Verify that the parent templateId is also present. -->
      <assert test='templateId[@root="1.3.6.1.4.1.19376.1.5.3.1.3.1"]'>
        Error: The parent template identifier for the reason for referral
        module is not present.
      </assert>
      <!-- Verify the section type code -->
      <assert test='code[@code = "42349-1"]'>
        Error: The section type code of the reason for referral section must be 42349-1
        REASON FOR REFERRAL.
      </assert>
      <assert test='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>
  </pattern>
  <pattern name='ReasonForReferralCoded'>
    <rule context='*[templateId/@root="1.3.6.1.4.1.19376.1.5.3.1.3.2"]'>
      <!-- The parent template will have already verified the type of object -->
      <!-- Verify that the parent templateId is also present. -->
      <assert test='templateId[@root="1.3.6.1.4.1.19376.1.5.3.1.3.1"]'>
        Error: The parent template identifier for the reason for referral
        module is not present.
      </assert>
      <!-- Don't bother with the section type code, as the parent template caught it -->
      <!-- Verify that all required data elements are present -->
      <assert test='.//templateId[@root = "1.3.6.1.4.1.19376.1.5.3.1.4.13"]'>
        Error: A coded reason for referral section must contain an simple observation.
      </assert>
      <!-- Alert on any missing required if known elements -->
      <!-- Note any missing optional elements -->
    </rule>
  </pattern>
</schema>
```

A similar pattern can also be followed for Entry and Header content modules, and these are left as an exercise for the reader.

B.3 Phases of Validation and Types of Errors

Note that each message in the Schematrons shown above start with a simple text string that indicates whether the message indicates one of the following conditions:

An error, e.g., the failure to transmit a required element,

A warning, e.g., the failure to transmit a required if known element,

A note, e.g., the failure to transmit an optional element.

A manual test, e.g., a reminder to manually verify some piece of content.

Schematron supports the capability to group sets of rules into phases by the pattern name, and to specify which phases of validation should be run during processing.

To take advantage of this capability, one simply breaks each <pattern> element above up into separate patterns depending upon whether the assertion indicates an error, warning, note or manual test, and then associate each pattern with a different phase. This is shown in the figure below.

```
<schema xmlns="http://www.ascc.net/xml/schematron" xmlns:cda="urn:hl7-org:v3">
  <ns prefix="cda" uri="urn:hl7-org:v3" />
  <phase id="errors">
    <active pattern="ReasonForReferralUncoded_Errors"/>
    <active pattern="ReasonForReferralCoded_Errors"/>
  </phase>
  <phase id="manual">
    <active pattern="ReasonForReferralUncoded_Manual"/>
  </phase>
  <pattern name='ReasonForReferralUncoded_Errors'>
    <rule context='*[templateId/@root="1.3.6.1.4.1.19376.1.5.3.1.3.1"]'>
      <assert test='section'>
        Error: The coded reason for referral module can only be used on a section.
      </assert>
      <assert test='code[@code = "42349-1"]'>
        Error: The section type code of the reason for referral section must be 42349-1
        REASON FOR REFERRAL.
      </assert>
      <assert test='code[@codeSystem = "2.16.840.1.113883.6.1"]'>
        Error: The section type code must come from the LOINC code
        system (2.16.840.1.113883.6.1).
      </assert>
    </rule>
  </pattern>
  <pattern name='ReasonForReferralUncoded_Manual'>
    <rule context='*[templateId/@root="1.3.6.1.4.1.19376.1.5.3.1.3.1"]'>
      <assert test='false'>
        Manual: Manually verify that this section contains narrative providing the
        reason for referral.
      </assert>
  </pattern>
  <pattern name='ReasonForReferralCoded_Errors'>
    <rule context='*[templateId/@root="1.3.6.1.4.1.19376.1.5.3.1.3.2"]'>
      <assert test='templateId[@root="1.3.6.1.4.1.19376.1.5.3.1.3.1"]'>
        Error: The parent template identifier for the reason for referral not present.
      </assert>
      <assert test='.//templateId[@root = "1.3.6.1.4.1.19376.1.5.3.1.4.13"]'>
        Error: A coded reason for referral section must contain an simple observation.
      </assert>
    </rule>
  </pattern>
</schema>
```

Using these simple "templates" for template validation one can simply create a collection of Schematron patterns that can be used to validate the content modules in the PCC Technical Framework. Such Schematrons are expected to be made available as part of

the MESA test tools that are provided to IHE Connectathon participants, and which will also be made available to the general public after connectathon.

