

**Integrating the Healthcare Enterprise**

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

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**Query for Existing Data (QED)**

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**Draft for Trial Implementation  
August 22, 2008**

20 **Forward**

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

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

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

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

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

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

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

***“Integrating the Healthcare Enterprise”***

75 **Select the sub-forum:**

***“IHE Patient Care Coordination 2008 Supplements for Trial Implementation”***

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

## **Content of the Technical Framework**

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

### **Volume 1 - Overview**

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

### **Volume 2 – Transactions and Content Profiles**

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

### **How to Contact Us**

IHE Sponsors welcome comments on this document and the IHE initiative. They should be directed to the discussion server at <http://forums.rsna.org> or to:  
100 Didi Davis  
Senior Director of Integrating the Healthcare Enterprise  
HIMSS  
230 East Ohio St., Suite 500  
Chicago, IL 60611  
Email: [ihe@himss.org](mailto:ihe@himss.org)

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## 1.1 Preface to Volume 1 of the PCC Technical Framework

### 1.1.1 Intended Audience

The intended audience of this document is:

- 165
- Healthcare professionals involved in informatics
  - IT departments of healthcare institutions
  - Technical staff of vendors participating in the IHE initiative
  - Experts involved in standards development
  - Those interested in integrating healthcare information systems and workflows

### 1.1.2 Related Information for the Reader

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

- 175
- Volume 1 of the Cross-Enterprise Document Sharing (XDS) Integration Profile documented in the ITI Infrastructure Technical Framework
  - Volume 1 of the Notification of Document Availability (NAV) Integration Profile documented in the ITI Infrastructure Technical Framework
  - Volume 1 of the Audit Trail and Node Authentication (ATNA) Integration Profile documented in the ITI Infrastructure Technical Framework ([http://www.ihe.net/Technical\\_Framework/index.cfm](http://www.ihe.net/Technical_Framework/index.cfm)).
  - HL7 Clinical Document Architecture Release 2: Section 1, CDA Overview.
  - 180 • 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](http://www.ihe.net/Participation/workshop_2005.cfm), June 2005:
  - 185 • Leveraging IHE to Build RHIO Interoperability
  - Cross-Enterprise Document Sharing (XDS)
  - Notification of Document Availability (NAV)
  - Patient Care Coordination
  - Use Cases for Medical Summaries
  - 190 • Patient Care Coordination - Overview of Profiles

### 1.1.3 How this Volume is Organized

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

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

#### 1.1.4 Conventions Used in this Document

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

##### 1.1.4.1 Technical Framework Cross-references

205 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>

210 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

215 <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.

220

##### 1.1.4.2 IHE Actor and Transaction Diagrams and Tables

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

225

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

230 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.

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

#### 240 **1.1.4.3 Process Flow Diagrams**

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

245 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.

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

#### **1.1.5 Copyright Permissions**

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

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

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

270 Braden Scale For Predicting Pressure Sore Risk, Copyright © Barbara Braden and Nancy Bergstrom, 1988. Reprinted with permission. Barabara Braden and Nancy Bergstrom

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

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<http://www.bradenscale.com/>

## 2 Introduction

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

315 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  
320 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

325 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  
330 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.

335 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  
340 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

345 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.

350 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  
355 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.
- 360 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  
365 developing trial implementation software for the IHE Connectathons.
- 370 3. The Committee regularly considers change proposals to the Trial Implementation version of the Technical Framework, including those from implementers who participate in the Connectathon. After resolution of all change proposals received within 60 days of the Connectathon, the Technical Framework version is published as “Final Text”.

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

## 2.4 About the Patient Care Coordination Integration Profiles

375 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  
380 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  
385 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  
390 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  
395 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.

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

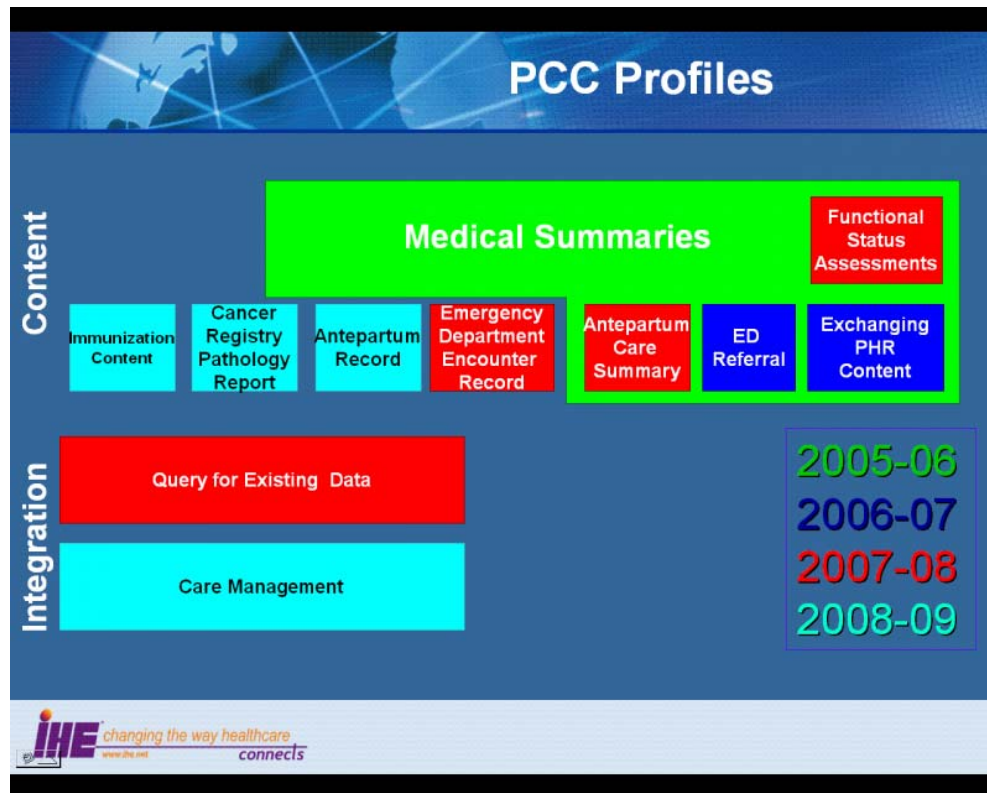


Figure 2.4-1 IHE Patient Care Coordination Content Integration Profiles

## 2.5 Dependencies of the PCC Integration Profiles

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

410

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

**Table 2.5-1 PCC Profile Dependencies**

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

## 420 2.6 PCC Integration Profiles Overview

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

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

425 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.

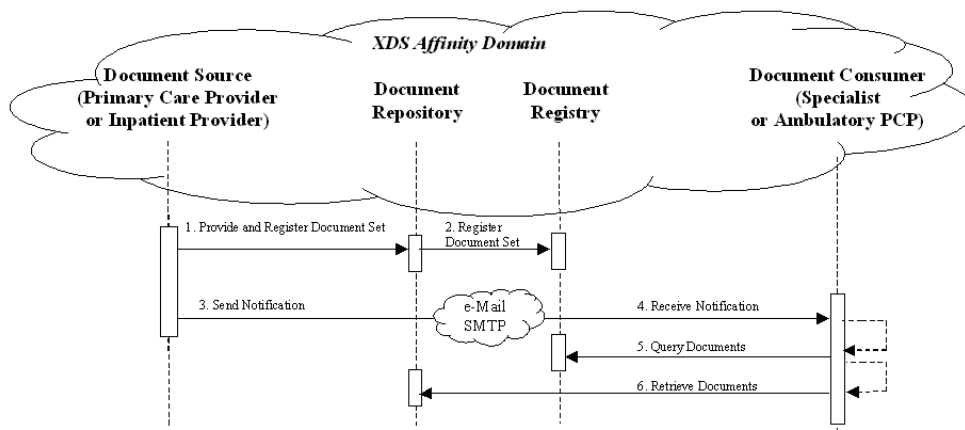
430 The content of the transactions are presented as Content Integration Profiles. These are specification of the content to be exchange, along with explanations (called bindings) of how the content affects the transactions in which it is exchanged. It is expected that Content Integration Profiles will be used environments where the physician offices and hospitals have a coordinated infrastructure that serves the information sharing needs of  
435 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).
- 440 • 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.
- 445 • 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/](http://www.ihe.net/Technical_Framework/).

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





455

**Figure 2.6-1 Use Case Process Flow Diagram**

These steps are:

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

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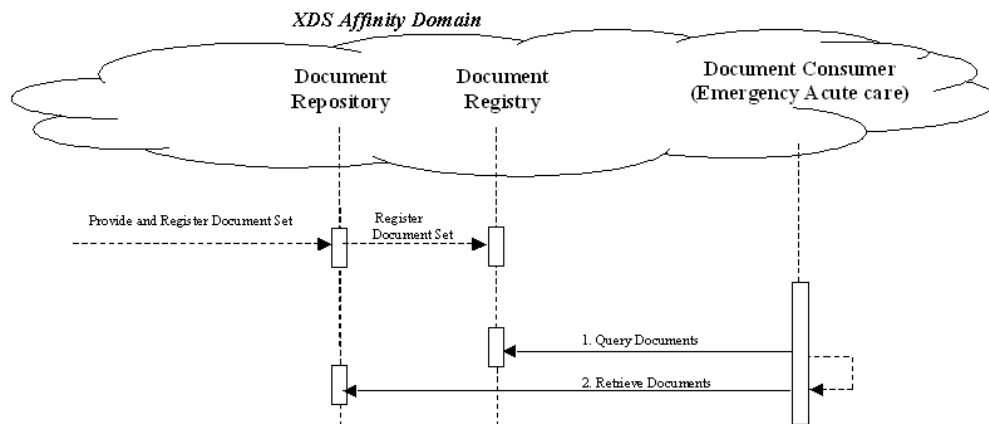
475

480

### 2.6.1 Unplanned Access to past Content

In many cases, a provider may need to assess information from the patient care history, and patients may have content in the XDS repository from prior visits to other providers.

For example, Medical Summaries, as well as other documents such as laboratory and radiology reports are critical for emergency physicians and nurses to provide the best care to patient in acute conditions. The figure below shows the transactions required for this use case, again, using XDS. Other process flows are possible using XDM and/or XDR.



485

**Figure 2.6-2 Unplanned Access Process Flow Diagram**

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

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

## 2.7 History of Annual Changes

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

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

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

- 510
- **Exchange of Personal Health Record Content (XPHR)** – provides a standards-based specification for managing the interchange of documents between a Personal Health Record used by a patient and systems used by other healthcare providers to enable better interoperability between these systems.
- 515
- **Basic Patient Privacy Consents (BPPC)** – enables XDS Affinity Domains to be more flexible in the privacy policies that they support, by providing mechanisms to record patient privacy consents, enforce these consents, and create Affinity Domain defined consent vocabularies that identify information sharing policies.  
*Please Note: This profile was transferred to the ITI Domain in the Fall of 2007, and can be found here*  
[http://www.ihe.net/Technical\\_Framework/index.cfm#ITI](http://www.ihe.net/Technical_Framework/index.cfm#ITI)
- 520
- **Pre-procedure History and Physical Content Profile (PPHP)** – supports the exchange of information allowing for the assessment and amelioration of risks related to a procedure. *Please Note: This profile has been withdrawn.*
- 525
- **Emergency Department Referral Profile (EDR)** – provides a means to communicate medical summary data from an EHR System to an EDIS System.

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

- 530
- **Antepartum Care Summary (APS)** - describes the content and format of summary documents used during Antepartum care.
  - **Emergency Department Encounter Summary (EDES)** - describes the content and format of records created during an emergency department visit.
- 535
- **Functional Status Assessment Profile (FSA)** - supports the handoff of assessment information between practitioners during transfers of care by defining the Functional Status Assessment option on the XDS-MS and XPHR profiles.
  - **Query for Existing Data (QED)** - allows information systems to query data repositories for clinical information on vital signs, problems, medications, immunizations, and diagnostic results.
- 540
- **Public Health Laboratory Report (PHLAB)** - extends the XD\*-LAB profile to support reporting from public health laboratories for disease surveillance activities. *Please Note: This profile has been subsequently moved to the XD-LAB specification, and can be found here*  
[http://www.ihe.net/Technical\\_Framework/index.cfm#LAB](http://www.ihe.net/Technical_Framework/index.cfm#LAB)
- 545

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

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

- **Antepartum Record (APR)** - describes the content and format of summary documents used during Antepartum care.
- **Care Management (CM)** - describes the content and format of summary documents used during Antepartum care.
- 555 • **Immunization Content (IC)** - describes the content and format of summary documents used during Antepartum care.
- **Cancer Registry Pathology Report (CPR)** - describes the content and format of summary documents used during Antepartum care.

## 2.8 Product Implementations

560 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.
- 565 • 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.

570

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.

575

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.

580

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.

585

### 3 Query for Existing Data Integration Profile (QED)

590 The Query for Existing Data Profile (QED) supports dynamic queries for clinical data, ,  
including vital signs, problems, medications, immunizations, diagnostic results,  
procedures and visit history. A wide variety of systems often need access to dynamic  
clinical information stored and maintained in an EMR system or other clinical data  
595 repository. This profile makes the information widely available to other systems within  
and across enterprises to support provision of better clinical care. The information made  
available by this profile can be used to support clinical care, quality reporting, financial  
transactions, public health reporting, clinical trials, drug interaction checking, and patient  
qualification for various protocols.

#### 3.1 Technical Approach

600 The QED profile leverages the existing content modeling defined previously in other IHE  
document profiles and the HL7 CCD implementation guide to deliver information that is  
semantically equivalent as a web service using the IHE ITI web services and HL7 web  
services guidelines.

#### 3.2 Classification of Information

605 The QED profile classifies information into six different categories for the purpose of  
determining where it might be found.

##### Common Observations

610 These are a collection of simple measurements or reported values that can be  
determined using simple measuring devices (e.g., Height, Weight), or which can be  
reported by the patient (date of last menstrual period). These measurements do NOT  
include anything that might be recorded as a problem, allergy, risk, or which requires  
interpretation, clinical decision making, or diagnostic quality equipment or  
procedures for performing the measurement.

##### Diagnostic Results

615 These are a collection of observations made or performed using laboratory testing  
equipment, imaging procedures, vision examinations, et cetera.

##### Problems and Allergies

620 These are a collection of diagnoses, clinical findings, allergies, or other risk factors  
that are recorded for the patient. The information may be obtained from patient  
reports, or through clinical decision making. It includes such information as would be  
found in social and family history sections of clinical reports. This classification can  
be further subdivided into three groups.

##### Conditions

This is a collection of disease conditions for the patient.

625 Intolerances  
 This is a collection of the patient's allergies and other intolerances.

Risk Factors

630 This is a collection of the patients significant risk factors, as might be established based on a review of family history, social history, occupational exposures, et cetera. By themselves, they may not be indicative of a disease condition, but could contribute to one.

Medications

This is a collection of the medications that a patient is or has been taking for treatment of one or more conditions.

635 Immunizations

This is a collection of immunizations that have been given, or which are planned to be given to the patient.

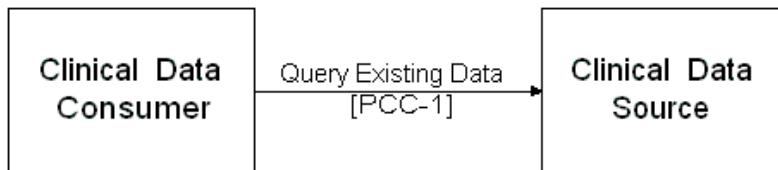
Professional Services

640 This is a collection of procedures and/or encounters which the patient has participated in, or is expected to participate in.

Each of these major classifications of information can often be found in distinct repositories of information. For example, patient vital signs, problems and allergies may be recorded in simple EHR system; diagnostic results in a laboratory or radiology information system; medications in a pharmacy information system, immunizations in an immunization registry, and professional services in a practice management system.  
 645

**3.3 Actors/Transaction**

There are two actors in this profile, the Clinical Data Consumer and the Clinical Data Source.



650 **Figure 3.3-1 Query for Existing Data Actor Diagram**

The table below lists the transactions for each actor directly involved in the Query for Existing Data Profile. In order to claim support of this Integration Profile, an implementation must perform the required transactions (labeled 'R'). Transactions labeled 'O' are optional. A complete list of options defined by this Integration Profile and that implementations may choose to support is listed below under [Options](#).  
 655

Actor	Name	Optionality	Transaction
Clinical Data Consumer	<a href="#">Query Existing Data</a>	R	PCC-1
Clinical Data Source	<a href="#">Query Existing Data</a>	R	PCC-1

Note <sup>1</sup>: The Actor shall support at least one of these transactions.

### 3.4 Options

Actor	Option
Clinical Data Source	<a href="#">Vital Signs Option</a> (1)
	<a href="#">Problems and Allergies Option</a> (1)
	<a href="#">Diagnostic Results Option</a> (1)
	<a href="#">Medications Option</a> (1)
	<a href="#">Immunizations Option</a> (1)
	<a href="#">Professional Services Option</a> (1)
Clinical Data Consumer	<a href="#">Vital Signs Option</a> (1)
	<a href="#">Problems and Allergies Option</a> (1)
	<a href="#">Diagnostic Results Option</a> (1)
	<a href="#">Medications Option</a> (1)
	<a href="#">Immunizations Option</a> (1)
	<a href="#">Professional Services Option</a> (1)

660 (1) At least one of these options shall be supported by the Actor

Requirements for the actors that implement these options are summarized below, and are given in more detail in the description of transaction [PCC-1](#) found in PCC TF-2:3.1.4.5.2.

#### 3.4.1 Vital Signs Option

665 A Clinical Data Consumer that implements the Vital Signs Option implements the Query Existing Data transaction using the specified vocabulary to query for vital signs. A Clinical Data Source that implements the Vital Signs Option responds to all vocabulary specified for vital signs in [PCC-1](#) in section 3.1.4.5.2.

#### 3.4.2 Problems and Allergies Option

670 A Clinical Data Consumer that implements the Problems and Allergies Option implements the Query Existing Data transaction using the specified vocabulary to query for problems or allergies or both. A Clinical Data Source that implements the Problems and Allergies Option responds to all vocabulary specified for problems and allergies in [PCC-1](#) in section 3.1.4.5.2.

675 **3.4.3 Diagnostic Results Option**

A Clinical Data Consumer that implements the Diagnostic Results Option implements the Query Existing Data transaction using the specified vocabulary to query for diagnostic results. A Clinical Data Source that implements the Diagnostic Results Option responds to all vocabulary specified for Diagnostic Results in [PCC-1](#) in section 3.1.4.5.2.

680 **3.4.4 Medications Option**

A Clinical Data Consumer that implements the Medications Option implements the Query Existing Data transaction using the specified vocabulary to query for medications. A Clinical Data Source that implements the Medications Option responds to all vocabulary specified for medications in [PCC-1](#) in section 3.1.4.5.2.

685 **3.4.5 Immunizations Option**

A Clinical Data Consumer that implements the Immunizations Option implements the Query Existing Data transaction using the specified vocabulary to query for immunizations. A Clinical Data Source that implements the Immunizations Option responds to all vocabulary specified for immunizations in [PCC-1](#) in section 3.1.4.5.2.

690 **3.4.6 Professional Services Option**

A Clinical Data Consumer that implements the Professional Services Option implements the Query Existing Data transaction using the specified vocabulary to query for professional services or both. A Clinical Data Source that implements the Professional Services Option responds to all vocabulary specified for professional services in [PCC-1](#) in section 3.1.4.5.2.

695

## **3.5 Grouping**

### **3.5.1 Audit Trail and Node Authentication and Consistent Time**

All actors of this profile shall be grouped with either the Secure Node or the Secure Application actor, to ensure the security of the information being exchanged. These actors shall also implement Time Client to ensure that consistent time is maintained across systems.

700

### **3.5.2 Retrieve Form for Data Capture**

When grouped with an Form Filler or Form Manager actor, a Clinical Data Consumer Actor shall appropriately populate forms with recently gathered clinical data.

### **3.5.3 Cross Enterprise Document Sharing**

A Clinical Data Source actor may be grouped with a Cross Enterprise Document Repository actor. Data gathered from clinical documents submitted to the Document Repository can be a source of information returned by the Clinical Data Source actor.



710 Information returned by the Clinical Data Source shall include references to all documents used in generating the results.

### 3.5.4 Content Integration Profiles

A Content Creator may be grouped with a Clinical Data Consumer to obtain some or all of the information necessary to create a Medical Summary based on information found in a Clinical Data Source.

715 A Content Creator may be grouped with a Clinical Data Source. When grouped with a Content Creator, the Clinical Data Source Actor shall respond to queries containing the relevant vocabulary codes used by the Content Creator.

Note: This may create additional vocabulary requirements on applications implementing the Clinical Data Source profile and another IHE content profile!

### 720 3.5.5 Patient Identity Cross Referencing and Patient Demographics Query

A clinical data consumer may be grouped with a Patient Identifier Cross-reference Consumer or a Patient Demographics Consumer actor to resolve patient identifiers prior to submitting queries to a Repository.

Within an enterprise, the need to cross-reference patient identifiers may not be necessary.

725 However, once enterprise boundaries are crossed, these identifiers will need to be resolved. In that case either PIX or PDQ shall be used.

## 3.6 Process Flow

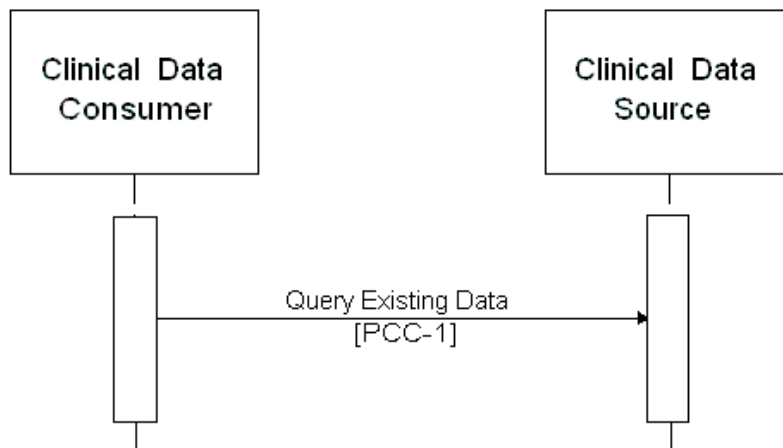


Figure 3.6-1 Query for Existing Data Process Flow

### 730 3.6.1 Clinical Trials

A patient participating in a clinical trial arrives for a trial-related visit to a physician office. The physician completes a report in his/her EMR gathering information relevant

to the trial. Upon completion of the visit, a research assistant gathers the data relevant to the trial and submits it to the clinical trial information system.

735 Among the data needed to gather are the patient's current medications. During the information gathering process, forms are populated with the list of the patient's current medications viaby a query of the EMR where the patient data is stored using [PCC-1]. Information gathered by these forms in then stored in the clinical trial information system.

#### 740 **3.6.2 Claims**

A claims administrator begins a claim for treatment of a patient who is pregnant. They log into their practice management system to begin processing the claim. Since this claim is for services provided during pregnancy, a patient measurement is needed to complete the claim. The practice management / billing system queries the EMR for the date of last menstruation for the patient using [PCC-1], and completes the claim. It may also query the EMR for details of the procedures performed using [PCC-1].

#### **3.6.3 Drug Safety**

Medication to be administered for a radiology procedure may cause an allergic reaction in some patients. The RIS can query the EMR for current problems and allergies and medications using [PCC-1] to enable display of this information to the operator, or to send to a decision support system to determine if this medication is OK to administer.

750 A CPOE system needs to generate a medication order for a patient for a medication whose dosage is based on weight. Prior to generating the order, the system will query the EMR for the most recent weight measurements of the patient to determine the correct dose using [PCC-1]. The system also request information about the patient's current problems and allergies and medications to perform drug interaction checking before completing the order.

#### **3.6.4 Public Health, Biosurveillance, and Disease Registries**

760 During a routine pediatric visit, an EMR queries an immunization registry for the immunization history for the patient using [PCC-1]. Upon review of the information, it appears that on a recent visit, the patient was scheduled for immunization, but the immunization was not given due to a current fever. The fever ius not longer present, so the immunization is given to the patient.

765 Upon completion of the visit, a reporting application is notified. The reporting application queries the EMR visit data to see if any immunizations were given during the just completed visit using [PCC-1]. If an immunization was given during the visit, the reporting application collects the appropriate data and submits it to an immunization registry.

### 3.6.5 Identifying Qualifying Patients

770 Decision support systems can query the EMR to obtain specific data elements for a patient, and use that information to determine if the patient qualifies for a clinical trial, or if the visit is one that requires additional reporting.

775 Upon completion of a visit, the EMR activates a decision support system. The decision support system queries the EMR for patient diagnoses using [PCC-1]. Upon determining that the patient has been diagnosed with Diabetes, the decision support system notifies the EMR that it needs to activate protocols for diabetic care. This use case could be continued as described in the section below.

### 3.6.6 Quality Reports and Disease Management

780 Upon completion of a visit, certain quality measures need to be gathered in order to produce an aggregate measure. A quality system can query the EMR to determine for each patient the values that need to be measured.

785 A diabetic patient completes a routine visit. The EMR queries a Lab Result Repository using [PCC-1] to determine if a recent HgA1C result is available from the last six months. Upon failing to find one the EMR system notifies the physician that an updated HgA1C test is required.

### 3.6.7 Disease Management

790 A physician wants to monitor a patient's blood sugar levels and body mass index. She requests a graph of the patient's blood sugar lab results (lab) and BMI (vital signs) for the past 9 months from a desktop application. The desktop application queries the EMR for the selected vital signs for the indicated time period using [PCC-1], and graphs the data appropriately.

## Actor Definitions

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

795 Content Creator

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

Content Consumer

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

Clinical Data Consumer

A clinical data consumer makes use of clinical patient data.

Clinical Data Source

805 A Clinical Data Sources maintains patient information about vital signs, problem and allergies, results from diagnostic tests (e.g., Lab, Imaging, or other test results), medications, immunizations or historical or planned visits and procedures.

## Transaction Definitions

### Query Existing Data

810 Request information about recent patient information, used to obtain vital signs measurements, problems and allergies, diagnostic results, medications, immunizations, or procedures or visits relevant for a patient. The query may request information about some or all of the above topics, or may request information on a specific topic, or one entered for a specific encounter or date range.

## How to Prepare an IHE Integration Statement

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

820 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.).

825 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  
830 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  
835 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  
840 or consequential, including but not limited to business interruption and loss of revenue, arising from any use of, or reliance upon, any IHE Integration Statement.

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

An IHE Integration Statement for a product shall include:

1. The Vendor Name
- 845 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.
- 850 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:"
- 855 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.)
- 860 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:
  7. Specific internet address (or universal resource locator [URL]) where the vendor's Integration Statements are posted
  - 865 8. URL where the vendor's standards conformance statements (e.g., HL7, DICOM, etc.) relevant to the IHE transactions implemented by the product are posted.
  9. URL of the IHE Initiative's web page for general IHE information [www.himss.org/ihe](http://www.himss.org/ihe).

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

## A.2 Format of an IHE Integration Statement

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

<b>IHE Integration Statement</b>	<b>Date</b>	<b>12 Oct 2005</b>
<b>Vendor</b>	<b>Product Name</b>	<b>Version</b>
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:		
<b>Integration Profiles Implemented</b>	<b>Actors Implemented</b>	<b>Options Implemented</b>
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
<b>Internet address for vendor's IHE information:</b> <a href="http://www.anymedicalsystemsco.com/ihe">www.anymedicalsystemsco.com/ihe</a>		
<b>Links to Standards Conformance Statements for the Implementation</b>		
HL7	<a href="http://www.anymedicalsystemsco.com/hl7">www.anymedicalsystemsco.com/hl7</a>	
<b>Links to general information on IHE</b>		
In North America: <a href="http://www.ihe.net">www.ihe.net</a>	In Europe: <a href="http://www.ihe-europe.org">www.ihe-europe.org</a>	In Japan: <a href="http://www.jira-net.or.jp/ihe-j">www.jira-net.or.jp/ihe-j</a>

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

# Volume II

880 **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
- 885 • 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:

- 890 • 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](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
- 895 (See [http://www.ihe.net/Technical\\_Framework/index.cfm](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](http://www.ihe.net/Technical_Framework/index.cfm) ).
- HL7 Clinical Document Architecture Release 2: Section 1, CDA Overview.
- 900 • 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](http://www.ihe.net/Participation/workshop_2005.cfm), June 2005:
- 905 • [For a RHIO-3.ppt Leveraging IHE to Build RHIO Interoperability](#)
- [Cross-Enterprise Document Sharing \(XDS\)](#)
- [Notification of Document Availability \(NAV\)](#)
- [Educ.ppt Patient Care Coordination](#)
- [Use Cases for Medical Summaries](#)
- 910 • [Ovrw.ppt Patient Care Coordination - Overview of Profiles](#)

Comment [LAS1]: Keith: broken link

Comment [LAS2]: Broken link

Comment [LAS3]: Broken link



### 1.2.1 How this Document is Organized

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

915 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.

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

### 1.2.2 Conventions Used in this Volume

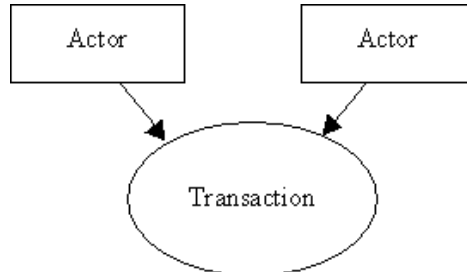
This document has adopted the following conventions for representing the framework concepts and specifying how the standards upon which the IHE Technical Framework is based should be applied.

#### 925 1.2.2.1 The Generic IHE Transaction Model

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

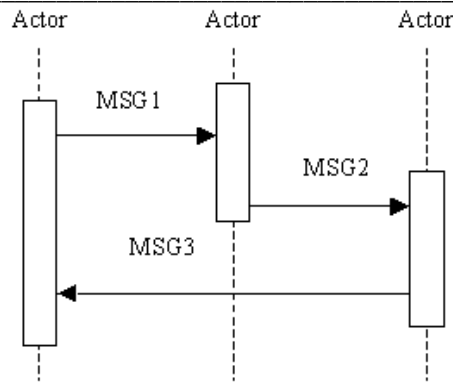
The generic IHE transaction description includes the following components:

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



**Figure 1.2-1 Use Case Role Diagram**

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



**Figure 1.2-2 Interaction Diagram**

940

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.

Comment [LAS4]: Link problem

945

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

### 1.3 Copyright Permissions

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

950

### 1.4 How to Contact Us

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

955

Didi Davis  
 Senior Director of Integrating the Healthcare Enterprise  
 230 East Ohio St., Suite 500  
 Chicago, IL 60611  
 Email: [ihe@himss.org](mailto:ihe@himss.org)

960

## 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](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.

1000 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.

1005 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  
1010 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

1015 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  
1020 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.

1025 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  
1030 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.

1035 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.

1040 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.

1045 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.

1050 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.

1055 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

1060 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.

1065 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  
1070 Committee is responsible for assigning the template identifiers to each content module.

1075 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 than 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

1080 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  
1085 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  
1090 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.  
1095 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  
1100 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  
1105 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  
1110 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  
1115 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  
1120 interoperability, albeit at a reduced level of functionality, is by virtue of the fact that ED Referrals are simply a refinement of the Referral Summary.

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

### 2.3.1.1 Document Content Module Constraints

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

Thus, a document content module shall contain as constraints:

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

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

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

Sample Document Specification SampleDocumentOID

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

**2.3.1.1.1 Specification**

Data Element Name	Opt	Template ID
<a href="#">Sample Section</a> Comment on section	R	SampleSectionOID
<a href="#">Sample Entry</a> Comment on entry	R2	SampleEntryOID

**Table 2.3-1**

**2.3.1.1.2 Conformance**

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



```

<ClinicalDocument xmlns='urn:h17-org:v3'>
  <typeId extension="POCD_HD000040" root="2.16.840.1.113883.1.3"/>
  <templateId root='SampleDocumentOID'/>
  <id root=' ' extension=' '/>
  <code code=' ' displayName=' '
    codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC' />
  <title>Sample Document</title>
  <effectiveTime value='20080601012005' />
  <confidentialityCode code='N' displayName='Normal'
    codeSystem='2.16.840.1.113883.5.25'
    codeSystemName='Confidentiality' />
  <languageCode code='en-US' />
  :
  <component><structuredBody>
    <component>
      <section>
        <templateId root='SampleSectionOID' />
        <!-- Required Sample Section Section content -->
      </section>
    </component>
  </structuredBody></component>
</ClinicalDocument>

```

### 2.3.1.1.3 Schematron

```

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

```

**2.3.1.2 Section Content Module Constraints**

1165 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.

1170 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.

1175 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.

1185 These constraints are presented in this document using a table for each section content module, as shown below.

Sample Section		
<b>Template ID</b>	SampleSectionOID	
<b>Parent Template</b>	<a href="#">foo</a> (SampleParentOID)	
<b>General Description</b>	Description of this section	
<b>LOINC Codes</b>	<b>Opt</b>	<b>Description</b>
XXXXX-X	R	SECTION NAME
<b>Entries</b>	<b>Opt</b>	<b>Description</b>
OID	R	<a href="#">Sample Entry</a>
<b>Subsections</b>	<b>Opt</b>	<b>Description</b>
OID	R	<a href="#">Sample Subsection</a>
<b>2.3.1.2.1 Parent Template</b>		
The parent of this template is <a href="#">foo</a> .		

```

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

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

```

### 2.3.1.3 Entry and Header Content Modules Constraints

1190 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.

1195 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:

- 1200
- 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.
- 1205
- Vocabulary domains to use when coding the entry.
  - Data types used to specify the value of the entry.
  - Other constraints as necessary.

An example is shown below:

Sample Entry

1210 Some text describing the entry.

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

1215 **2.3.1.4 <observation classCode='OBS' moodCode='EVN'>**

Some details about the observation element

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

Some details about the template id element

### 3 IHE Transactions

1220 This section defines each IHE transaction in detail, specifying the standards used, and the information transferred.

#### 3.1 Query Existing Data

1225 This section corresponds to Transaction PCC-1 of the IHE Patient Care Coordination Technical Framework. Transaction PCC-1 is used by the Clinical Data Consumer and Clinical Data Source Actors.

##### 3.1.1 Use Case Roles



Query Existing Data

Actor

Clinical Data Consumer

1230 Role

Requests clinical data matching a minimal set of selection criteria from the Clinical Data Source.

Corresponding HL7 Version 3 Application Roles

Care Record Query Placer ([QUPC\\_AR004030UV](#))

1235 Query by Parameter Placer ([QUQL\\_AR000001UV01](#))

Actor

Clinical Data Source

Role

1240 Returns clinical data matching the selection criteria supplied by the Clinical Data Consumer.

Corresponding HL7 Version 3 Application Roles

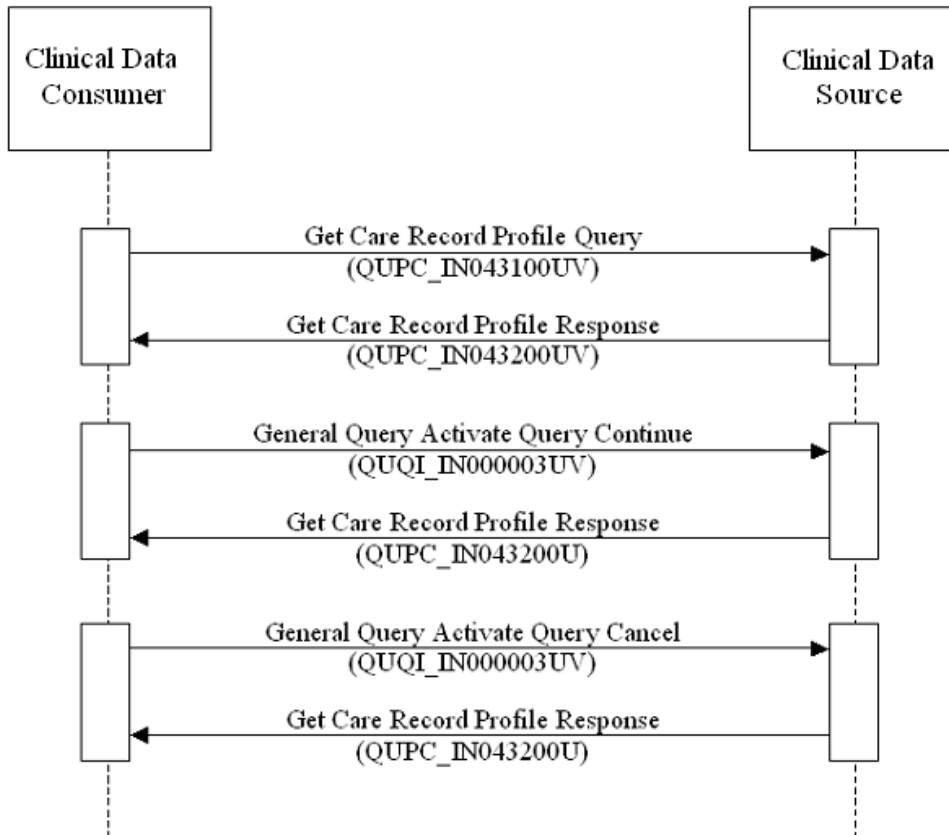
Care Record Query Fulfiller ([QUPC\\_AR004040UV](#))

Query by Parameter Fulfiller ([QUQL\\_AR000002UV01](#))

**3.1.2 Referenced Standards**

- CareRecord** [HL7 Care Provision Care Record \(DSTU\)](#)
- CareQuery** [HL7 Care Provision Care Record Query \(DSTU\)](#)
- HL7QI** [HL7 Version 3 Standard: Infrastructure Management – Query Infrastructure](#)
- HL7WS** [HL7 Version 3 Standard: Transport Specification - Web Services Profile, Release](#)
- SOAP** [Simple Object Access Protocol Version 1.1 \(SOAP 1.1\)](#)
- SOAP12** [Simple Object Access Protocol Version 1.2 \(SOAP 1.2\)](#)

**3.1.3 Interaction Diagrams**



### 3.1.4 Get Care Record Profile Query

#### 3.1.4.1 Trigger Events

1250 When the Clinical Data Consumer needs to obtain information about a patient it will trigger a Get Care Record Care Profile event. This corresponds to the HL7 trigger event: [QUPC\\_TE043100UV](#)

#### 3.1.4.2 Message Semantics

1255 The Query Care Record Event Profile Query corresponds to the HL7 Interaction [QUPC\\_IN043100UV](#).

A schema for this interaction can be found at:

[http://www.hl7.org/v3ballot2007may/html/processable/multicacheschemas/QUPC\\_IN043100UV.xsd](http://www.hl7.org/v3ballot2007may/html/processable/multicacheschemas/QUPC_IN043100UV.xsd). This schema includes:

- the transmission wrapper MCCI\_MT000100UV01,
- the control act wrapper QUQI\_MT020001UV01, and
- the message payload QUPC\_MT040100UV.

1260 These components of the interaction are specified in the HL7 standards described above.

#### 3.1.4.3 Transmission Wrapper

1265 The transmission wrapper MCCI\_MT000100UV01 provides information about the message transmission and routing. Transmission wrappers are further described in ITI TF-2: Appendix O. An example transmission wrapper is given below for this interaction. Items marked in dark gray are transmitted as specified in ITI TF-2: Appendix O. Items in bold black text are further constrained by this profile in this interaction.

```

1270 <QUPC_IN043100UV xmlns="urn:hl7-org:v3" ITSVersion="XML_1.0"
      xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">
      <id root=' ' extension=' '/>
      <creationTime value=' '/>
      <interactionId extension='QUPC_IN043100UV' root='2.16.840.1.113883.5' />
1275 <processingCode code='D|P|T' />
      <processingModeCode code='T' />
      <acceptAckCode code='AL' />
      <receiver typeCode="RCV">
        <device determinerCode="INSTANCE">
1280 <id />
          <name />
          <telecom value=' ' />
          <manufacturerModelName />
          <softwareName />
        </device>
1285 </receiver>
      <sender typeCode="SND">
        <device determinerCode="INSTANCE">
1290 <id />
          <name />
          <telecom value=' ' />
          <manufacturerModelName />
          <softwareName />
        </device>
1295 </sender>
      <controlActProcess>
        See Control Act Wrapper below
      </controlActProcess>
    </QUPC_IN043100UV>

```

1300 **3.1.4.3.1 <QUPC\_IN043100UV xmlns="urn:hl7-org:v3" ITSVersion="XML\_1.0" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">**

The HL7 Interaction being sent will control the name of the root element in the message. The namespace of this message shall be urn:hl7-org:v3, and the ITSVersion attribute shall be "XML\_1.0".

1305 **3.1.4.3.2 <interactionId extension='QUPC\_IN043100UV' root='2.16.840.1.113883.5' />**

The identifier for the interaction shall be sent as shown above.

**3.1.4.3.3 <processingModeCode code='T' />**

1310 The processingModeCode distinguishes the type of processing being performed. This element shall be present and have the value shown above to indicate that this message is for current processing.

**3.1.4.3.4 <acceptAckCode code='AL' />**

The acceptAckCode indicates whether the sender wants to receive an acknowledgement, and shall be sent as shown above.



1315 **3.1.4.4 Control Act Wrapper**

The control act wrapper QUQL\_MT020001UV01 provides information about the business actors related to the transaction, including the author or performer of the act. Control act wrappers are further described in ITI TF-2: Appendix O. An example transmission wrapper is given below for this interaction. Items marked in dark gray are transmitted as specified in ITI TF-2: Appendix O. Items in bold black text are further constrained by this profile in this interaction.

```

1325 <controlActProcess moodCode="RQO">
      <id root=' ' extension=' '/>
      <code code='QUPC_TE043100UV' />
      <effectiveTime value=' '/>
      <languageCode code=' '/>
      <authorOrPerformer typeCode=' '></authorOrPerformer>
1330 <queryByParameter>
      <id root=' ' extension=' '/>
      <statusCode code='new' />
      <responseModalityCode code='R' />
      <responsePriorityCode code='I' />
1335 <initialQuantity value=/>
      <initialQuantityCode code='REPC_RM000100UV' codeSystem='2.16.840.1.113883'>
      <parameterList>
        see Query Parameter List below
      </parameterList>
1340 </queryByParameter>
    </controlActProcess>

```

**3.1.4.4.1 <controlActProcess moodCode="RQO">**

The controlActProcess element is where information about the business act being performed is recorded. The moodCode is set to "RQO" by the sender to indicate a request to perform an action, in this case, a query.

1345 **3.1.4.4.2 <code code='QUPC\_TE043100UV' />**

The trigger event which caused the act to be transmitted is recorded in the code element is recorded as shown above.

**3.1.4.4.3 <queryByParameter>**

HL7 Version 3 messages that perform a query specify the details of it in the <queryByParameter> element.

1350 **3.1.4.4.4 <id root=' ' extension=' '/>**

The sending system shall specify the identifier of the query. This is the identifier that is used in subsequent continuation or cancel messages.

**3.1.4.4.5 <statusCode code='new' />**

1355 When passing the parameter list, the <statusCode> element shall be recorded as above to indicate that this is a new query.

**3.1.4.4.6 <responseModalityCode code='R'/>**

The query response shall always be in real-time.

**3.1.4.4.7 <responsePriorityCode code='I'/>**

1360 The query response shall always be immediate.

**3.1.4.4.8 <initialQuantityCode code='REPC\_RM000100UV' codeSystem='2.16.840.1.113883.5'/>**

The <initialQuantityCode> shall be sent when <initialQuantity> is sent. The code shall be the identifier of the HL7 artifact that is to be counted (e.g., R-MIM or C-MET identifier).

1365 In this profile what is being counted is clinical statements, so the code to use shall be REPC\_RM000100UV.

**3.1.4.5 Parameter List**

1370 The message supports specification of the data items listed in the table below as query parameters. The first column of this table provides the name of the parameter. The next column indicates the number of times it may occur in the query. The next column indicates the type of data expected for the query parameter. The next column indicates the vocabulary domain used for coded values. The last two columns indicate whether the Clinical Data Consumer must send this parameter and whether the Clinical Data Source must support this parameter.

1375 A Clinical Data Consumer may supply parameters other than those required by this profile, but must appropriately handle any detected issue alert raised by the Clinical Data Source in its response.

**Table 3.1-1 Query Parameters for PCC-1**

Parameter Name	Cardinality	Data Type	Vocabulary Domain	Clinical Data Consumer	Clinical Data Source
<a href="#">careProvisionCode</a>	0..1	CD		O	R
<a href="#">careProvisionReason</a>	0..*	CD		O	O
<a href="#">careRecordTimePeriod</a>	0..1	IVL<TS>		O	R
<a href="#">clinicalStatementTimePeriod</a>	0..1	IVL<TS>		O	R
<a href="#">includeCarePlanAttachment</a>	0..1	BL		R	R
<a href="#">maximumHistoryStatements</a>	0..1	INT		O	R
<a href="#">patientAdministrativeGender</a>	0..1	CE	AdministrativeGender	O	R
<a href="#">patientBirthTime</a>	0..1	TS		O	R
<a href="#">patientId</a>	1..1	II		R	R
<a href="#">patientName</a>	0..1	PN		O	R

An example of the query specification is described in the figure below.

1380

1385

1390

1395

1400

1405

```

<parameterList>
  <careProvisionCode>
    <value code='' displayName='' codeSystem='' codeSystemName=''/>
  </careProvisionCode>
  <careProvisionReason>
    <value code='' displayName='' codeSystem='' codeSystemName=''/>
  </careProvisionReason>
  <careRecordTimePeriod>
    <value><low value=''/><high value=''/></value>
  </careRecordTimePeriod>
  <clinicalStatementTimePeriod>
    <value><low value=''/><high value=''/></value>
  </clinicalStatementTimePeriod>
  <includeCarePlanAttachment><value
value='true|false'></includeCarePlanAttachment>
  <maximumHistoryStatements><value value=''/></maximumHistoryStatements>
  <patientAdministrativeGender>
    <value code='' displayName=''
codeSystem='2.16.840.1.113883.5.1'
codeSystemName='AdministrativeGender' />
  </patientAdministrativeGender>
  <patientBirthTime><value value=''/></patientBirthTime>
  <patientId><value root='' extension=''/></patientId>
  <patientName><value></value></patientName>
</parameterList>

```

#### 3.1.4.5.1 <parameterList>

The <parameterList> element shall be present, and contains the set of query parameters being used in this query.

1410

#### 3.1.4.5.2 <careProvisionCode><value code=' ' displayName=' ' codeSystem=' ' codeSystemName=' '/></careProvisionCode>

1415

This <careProvisionCode> may be present. This element describes the information that is being looked for in the <value> element. When the <careProvisionCode> element is not present, it indicates that all relevant results are to be reported up to the maximum number specified in [maximumHistoryStatements](#) for each result. To obtain results that have not been coded, the <value> element may be specified with a nullFlavor attribute. There are various *flavors* of NULL defined in the HL7 [NullFlavor](#) vocabulary. A query for results coded using a specific flavor of null shall return all flavors of null that are equal to, or subordinate to that flavor of null within the HL7 hierarchy of null flavors. A Clinical Data Consumer can restrict the results returned in the query by setting the value attribute of <value> element in the <careProvisionCode> element to a code identifying the clinical data to be returned. A Clinical Data Source can use the codes specified in the sections below to obtain different kinds of clinical data.

1420

1425

A Clinical Data Consumer implementing one of the options for that actor shall be able to issue a query using at least one of the codes listed for that option as specified in the table below. A Clinical Data Source implementing one of these options must support all codes listed in the table below for that option.

Actor Option	Code	Returns	Template Id
Vital Signs Option	COBSCAT	All Vital Signs	<a href="#">Vital Signs Observation</a>
	Any Code from the Vital Signs Table below	The vital sign identified by the code	<a href="#">Vital Signs Observation</a>
Problems and Allergies Option	MEDCCAT	All problem entries	<a href="#">Problem Entry</a>
	CONDLIST	All Concern Entries	<a href="#">Concern Entry</a>
	PROBLIST	All Problem Concerns	<a href="#">Problem Concern</a>
	INTOLIST	All Allergy Concerns	<a href="#">Allergy and Intolerance Concern</a>
	RISKLIST	All Risks <sup>1</sup>	<a href="#">Concern Entry</a>
Diagnostic Results Option	LABCAT	All Lab Results	<a href="#">Simple Observations</a>
	DICAT	All Imaging Results	<a href="#">Simple Observations</a>
Medications Option	RXCAT	All Medications	<a href="#">Medications</a>
	MEDLIST	All Medications	<a href="#">Medications</a>
	CURMEDLIST	All active medications	<a href="#">Medications</a>
	DISCHMEDLIST	Discharge Medications	<a href="#">Medications</a>
	HISTMEDLIST	All Historical Medications	<a href="#">Medications</a>
Immunizations Option	IMMUCAT	All Immunizations	<a href="#">Immunizations</a>
Professional Services Option	PSVCCAT	All professional service entries	<a href="#">Encounters</a> <a href="#">Procedures Entry</a>

1430 A Clinical Data Consumer Actor may make requests using other codes not specified above to obtain other clinical data, but these are not guaranteed to be supported by the Clinical Data Source actor.

Note: Clinical Data Sources that are grouped with Content Creators are required to support the vocabulary used within the templates defining the content being created!

#### Querying for Substances

1435 Often, a query needs to identify a particular substance, such as in the case for a query about the use of a specific medication, immunization, or allergy to a given substance. To support these queries, IHE requires that Clinical Data Sources that can respond to queries using appropriate vocabularies for substances use the following form:

1440

```
<value code='DRUG|IMMUNIZE|INTOL' displayName=' '
codeSystem='1.3.5.1.4.1.19376.1.5.3.2' codeSystemName='IHEActCode'>
  <qualifier>
    <name code='SUBSTANCE|SUBSTCLASS' />
    <value code=' ' displayName=' ' codeSystem=' ' codeSystemName=' ' />
  </qualifier>
</value>
```

1445

**3.1.4.5.3 <value code='DRUG|IMMUNIZE|INTOL' displayName=' ' codeSystem='1.3.5.1.4.1.19376.1.5.3.2' codeSystemName='IHEActCode'>**

1450

The <value> element expresses in the code attribute whether the act being queried for is:

Code	Definition
DRUG	Treatment with a specific drug
IMMUNIZ	Immunization of a patient
INTOL	A record of an allergy or intolerance to a substance

One of the values listed above shall be used in the code attribute. The codeSystem shall be recorded as listed above.

**3.1.4.5.4 <qualifier><name code='SUBSTANCE|SUBSTCLASS' />**

1455

The <qualifier> element further qualifies the concept being requested. The <name> element indicates whether the substance is being described, or the class of substances is being described.

Code	Definition
SUBSTANCE	The substance used
SUBSTCLASS	A class of substances used

**3.1.4.5.5 <value code=' ' displayName=' ' codeSystem=' ' codeSystemName=' ' />**

1460

The <value> element inside the <qualifier> describes the substance or class of substances of interest in the query.

**3.1.4.5.6 <careProvisionReason><value code=' ' displayName=' ' codeSystem=' ' codeSystemName=' ' /></careProvisionReason>**

1465

This element identifies the reason why the result was recorded. If specified, only those results which are recorded for the specified reason will be returned.

The <value> element of the <careProvisionReason> element may contain a value identifying a specific condition that was the reason for obtaining the result or prescribing

1470 the medication or immunization. A Clinical Data Source actor that chooses to honor this query parameter shall return only those results that were for the indicated reason. Should the Clinical Data Source Actor not support the use of the <careProvisionReason> element, it shall indicate this by raising the appropriate alert as described in the expected actions recorded in [PCC-1](#).

**For Public Comment** For immunizations, there is a desire to identify a specific immunization program that was the reason for the immunization, how might an immunization program be referenced? A code might identify the specific pathogen against which the patient is being immunized, but for public health use, a more discrete question is being asked: What program caused the patient to come in for immunization? This seems to require the ability to query for an identifier.

1475 **3.1.4.5.7 <careRecordTimePeriod><value><low value=' '/><high value=' '/></value></careRecordTimePeriod>**

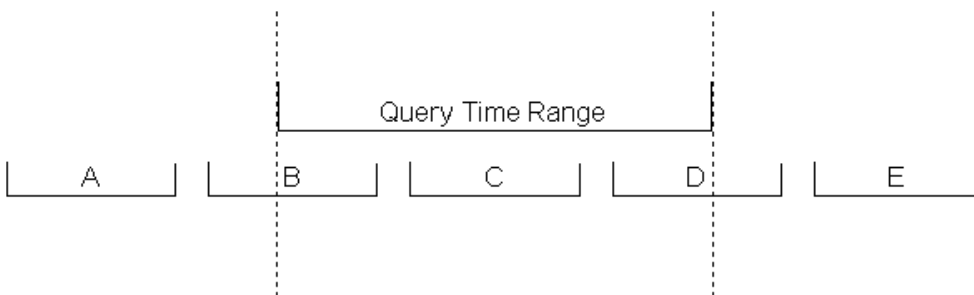
This element describes the time period over which the results were recorded. A query could for example, request new entries that have been processed for this patient since the last query request. If specified, only those results that were authored within the specified time period will be returned.

1480 **3.1.4.5.8 <clinicalStatementTimePeriod><value><low value=' '/><high value=' '/></value></clinicalStatementTimePeriod>**

This element describes the effective time for the clinical statement. If specified, only those results that were effective within the clinical statement effective time will be returned.

1485 The effectiveTime range of the returned clinical statements shall overlap or be wholly contained within the time range described by the <clinicalStatementTimePeriod> element. In the example below, the clinical statements with the effectiveTime values represented by time ranges B, C and D would be returned, while those with effectiveTime values represented by time ranges A and E would not, because they fall outside of the specified <clinicalStatementTimePeriod> value.

1490



**Figure 3.1-1 Effective Time and Clinical Statement Time Period**

1495 **3.1.4.5.9 <includeCarePlanAttachment><value  
value='true|false'/></includeCarePlanAttachment>**

1500 The <includeCarePlanAttachment> element shall be sent, and must be set to either true or false depending upon whether care plans should be returned or not. A Data Source may choose not to honor this request when the value is set to true, but must then raise a BUS detected issue alert to indicate that this capability is not supported. Note that many data repositories will not associate a care plan attachment with a specific result.

**3.1.4.5.10 <maximumHistoryStatements><value  
value=' '/></maximumHistoryStatements>**

1505 This value indicates the maximum number of each type of result that will be returned by the query. No more than the maximum number will be returned. This value is NOT the maximum number of clinical statements returned, rather it is the maximum number of clinical statements returned for individual type of clinical statement specified in the careProvisionCode. Thus, if all results are requested (e.g., all Vital Signs), and maximumHistoryStatements/value/@value = 1, you will receive the most current value for each kind of result requested (e.g., one each of the most recent value for height, weight, blood pressure, temperature, et cetera).

1510

**3.1.4.5.11 <patientAdministrativeGender>  
<value code=' ' displayName=' '  
codeSystem='2.16.840.1.113883.5.1'  
codeSystemName='AdministrativeGender'/>**

1515 The patient gender may be provided in the query. If provided, it serves as a verification of the patient identity. The value must match the patient gender of the patient specified in patientId. If the two values do not match, the Clinical Data Source will raise a detected issue alert.

**3.1.4.5.12 <patientBirthTime><value value=' '/></patientBirthTime>**

1520 The patient birth time may be provided in the query. If provided, it serves as a verification of the patient identity. The value must match the patient birth time of the patient specified in patientId. If the two values do not match, the Clinical Data Source will raise a detected issue alert.

**3.1.4.5.13 <patientId><value root=' ' extension=' '/></patientId>**

1525 The patient identifier shall be specified in this element. The root and extension attributes shall be present. When used in cross enterprise settings, the root attribute shall the affinity domain identity OID.

1530 Sending a query with a known invalid patientId element can be used to *ping* a Clinical Data Source. For example, setting the root attribute to "0" and omitting the extension attribute should result in a response that raises an ILLEGAL detected issue alert on the patientId field, since the value "0" will never be used as the OID of a patient identity

domain. This capability can be used by a Clinical Data Consumer to verify that it can connect to a Clinical Data Source when configuration parameters are modified.

#### 3.1.4.5.14 <patientName><value></value></patientName>

1535 The patient name may be provided in the query. If provided, it serves as a verification of the patient identity. The value must match the patient name of the patient specified in patientId. If the two values do not match, the Clinical Data Source will raise a detected issue alert.

#### 3.1.4.6 Expected Actions -- Clinical Data Consumer

1540 The clinical data consumer shall send a query as specified in the QUPC\_IN043100UV interaction. The message shall be sent using web services as specified in the ITI-TF: Appendix V. The name of the query response message shall be QUPC\_IN043100UV\_Message in the WSDL. The following WSDL snippet defines the type for this message:

1545

```
<types>
  <xsd:schema elementFormDefault="qualified"
    targetNamespace="urn:hl7-org:v3" xmlns:hl7="urn:hl7-org:v3">
    <!-- Include the message schema -->
    <xsd:import namespace="urn:hl7-org:v3"
      schemaLocation="QUPC_IN043100UV.xsd" />
    <xsd:element name="QUPC_IN043100UV" />
  </xsd:schema>
</types>
```

1550

1555 The message type is declared to be of the appropriate type by the following WSDL snippet:

1560

```
<message name='QUPC_IN043100UV_Message'>
  <part element='hl7:QUPC_IN043100UV' name="Body" />
</message>
```

Other WSDL declarations required for this transaction are defined under the Domain Content section.

### 3.1.5 Get Care Record Profile Response

#### 3.1.5.1 Trigger Events

1565 This message is triggered upon receipt of a Query Care Record Event Profile Query, or General Query Activate Query Continue or General Query Query Cancel Message. This corresponds to HL7 trigger event: [QUPC\\_TE043200UV](#)

#### 3.1.5.2 Message Semantics

1570 The Get Care Record Profile Response corresponds to the HL7 Interaction [QUPC\\_IN043200UV](#). A schema for this interaction can be found at: [http://www.hl7.org/v3ballot2007may/html/processable/multicacheschemas/QUPC\\_IN043200UV.xsd](http://www.hl7.org/v3ballot2007may/html/processable/multicacheschemas/QUPC_IN043200UV.xsd). This schema includes:



- the transmission wrapper MCCI\_MT000300UV01,
- the control act wrapper MFMI\_MT700712UV01, and
- the message payload REPC\_MT004000UV.

1575

These components of the interaction are specified in the HL7 standards described above.

### 3.1.5.3 Transmission Wrapper

The transmission wrapper MCCI\_MT000300UV01 provides information about the message transmission and routing. Transmission wrappers are further described in ITI TF-2: Appendix O.

1580

An example transmission wrapper is given below for this interaction. Items marked in dark gray are transmitted as specified in ITI TF-2: Appendix O. Items in bold black text are further constrained by this profile in this interaction.

1585

```

<QUPC_IN043200UV xmlns="urn:hl7-org:v3" ITSVersion="XML_1.0"
  xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">
  <id root=' ' extension=' ' />
  <creationTime value=' ' />
  <interactionId extension='QUPC_IN043200UV' root='2.16.840.1.113883.5' />
  <processingCode code='D|P|T' />
  <processingModeCode code='T' />
  <acceptAckCode code='NE' />
  <receiver typeCode="RCV">
    <device determinerCode="INSTANCE">
      <id />
      <name />
      <telecom value=' ' />
      <manufacturerModelName />
      <softwareName />
    </device>
  </receiver>
  <sender typeCode="SND">
    <device determinerCode="INSTANCE">
      <id />
      <name />
      <telecom value=' ' />
      <manufacturerModelName />
      <softwareName />
    </device>
  </sender>
  <controlActProcess>
    See Control Act Wrapper below
  </controlActProcess>
</QUPC_IN043200UV>

```

1590

1595

1600

1605

1610

1615

**3.1.5.3.1 <QUPC\_IN043200UV xmlns="urn:hl7-org:v3"**  
**ITSVersion="XML\_1.0"**  
**xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">**

The HL7 Interaction being sent will control the name of the root element in the message. The namespace of this message shall be urn:hl7-org:v3, and the ITSVersion attribute shall be "XML\_1.0".

1620 **3.1.5.3.2 <interactionId extension='QUPC\_IN043200UV'  
root='2.16.840.1.113883.5'/>**

The identifier for the interaction shall be sent as shown above.

**3.1.5.3.3 <processingModeCode code='T'/>**

1625 The processingModeCode distinguishes the type of processing being performed. This element shall be present and have the value shown above to indicate that this message is for current processing.

**3.1.5.3.4 <acceptAckCode code='NE'/>**

1630 The acceptAckCode indicates whether the receiver wants to receive an acknowledgement, and shall be sent as shown above. Query responses shall not require acknowledgements.

**3.1.5.4 Control Act Wrapper**

1635 The control act wrapper MFMI\_MT700712UV01 provides information about the business actors related to the transaction, including the author or performer of the act. Control act wrappers are further described in ITI TF-2: Appendix O. An example transmission wrapper is given below for this interaction. Items marked in dark gray are transmitted as specified in ITI TF-2: Appendix O. Items in bold black text are further constrained by this profile in this interaction.

```

1640 <controlActProcess moodCode="EVN">=
  <id root=' ' extension=' '/>
  <code code='QUPC_TE043200UV' />
  <effectiveTime value=' '/>
  <languageCode code=' '/>
  <authorOrPerformer typeCode=' '></authorOrPerformer>
1645 <subject>
  See Query Response below
</subject>
  <queryAck>
1650   <queryId root=' ' extension=' '/>
   <statusCode code=' '/>
   <queryResponseCode code=' '/>
   <resultTotalQuantity value=' '/>
   <resultCurrentQuantity value=' '/>
1655   <resultRemainingQuantity value=' '/>
  </queryAck>
</controlActProcess>

```

**3.1.5.4.1 <controlActProcess moodCode="EVN">**

1660 The controlActProcess element is where information about the business act being performed is recorded. The moodCode is set to "EVN" by the sender to indicate a response to a query.

#### **3.1.5.4.2 <code code='QUPC\_TE043200UV'/>**

The trigger event which caused the act to be transmitted is recorded in the code element is recorded as shown above.

#### **3.1.5.4.3 <subject>**

1665 The <subject> element shall be present to record the responses in a query request or continuation response.

#### **3.1.5.4.4 <queryAck>**

The queryAck element is transmitted in any message that is a response to a query, query continuation or query cancellation message.

1670 **3.1.5.4.5 <queryId root=' ' extension=' '/>**

The <queryId> element shall be transmitted in a queryAck element. It shall contain an identifier that was used in the original query message.

#### **3.1.5.4.6 <statusCode code=' '/>**

1675 The statusCode element in the queryAck element indicates the status of the query. It may contain the value 'deliveredResponse' or 'aborted'. If the value is 'aborted', no additional messages should be sent to the Clinical Data Source for the specified query.

#### **3.1.5.4.7 <queryResponseCode code=' '/>**

1680 The queryResponseCode element indicates at a high level the results of performing the query. It may have the value 'OK' to indicate that the query was performed and has results. It may have the value 'NF' to indicate that the query was performed, but no results were located. It may have the value 'QE' to indicate that an error was detected in the incoming query message, or 'AE' to indicate some other application error occurred.

#### **3.1.5.4.8 <resultTotalQuantity value=' '/>**

1685 The resultTotalQuantity element should be present, and if so, enumerates the number of results found. It shall be present once the last result has been located by the Clinical Data Source. This element gives the count of the total number of results located by the query. When present, the resultRemainingQuantity element shall also be present.

#### **3.1.5.4.9 <resultCurrentQuantity value=' '/>**

1690 The resultCurrentQuantity element shall be present, and shall enumerate number of results returned in the current response.

#### **3.1.5.4.10 <resultRemainingQuantity value=' '/>**

This resultRemainingQuantity element may be present, and shall be present if resultTotalQuantity is present. It shall enumerate the number of results that follow the results currently returned.

1695 **3.1.5.5 Query Response**

The <subject> element of the <controlActProcess> element shall appear as shown in the example below.

```

1700 <subject>
      <registrationEvent>
        <statusCode code='active' />
        <custodian>
          <assignedEntity>
            <id root='' extension='' />
1705         <addr></addr>
            <telecom></telecom>
            <assignedOrganization>
              <name></name>
            </assignedOrganization>
          </assignedEntity>
        </custodian>
        <subject2>
          <careProvisionEvent>
            <recordTarget>
1715           <patient>
              <id root='' extension='' />
              <addr></addr>
              <telecom value='' use='' />
              <statusCode code='active' />
1720           <patientPerson>
              <name></name>
              <administrativeGenderCode code='' displayName=''
                codeSystem='2.16.840.1.113883.5.1'
1725             codeSystemName='AdministrativeGender' />
              <birthTime value='' />
            </patientPerson>
          </patient>
        </recordTarget>
        <pertinentInformation3>
1730         <!-- Domain Content -->
        </pertinentInformation3>
      </careProvisionEvent>
      <parameterList>
      </parameterList>
1735    </subject2>
  </registrationEvent>
</subject>

```

**3.1.5.5.1 <subject>**

The <subject> element shall be present, and is where the results are returned.

1740 **3.1.5.5.2 <registrationEvent>**

At least one <registrationEvent> element shall be present for each set of records returned from a different custodial source.

The <registrationEvent> is used to record the information about how the <careProvisionEvent> being returned was recorded or "registered" in the custodial system. The response to a Care Profile query is a CareProvisionEvent that is constructed

in response to the query. This <careProvisionEvent> is transitory in nature, and has limited "registration" information content.

1750 A Data Source that aggregates information from two or more other data repositories shall separate the information into multiple <registrationEvent> elements so as to record the different custodians of the information.

**3.1.5.5.3 <statusCode code='active'/>**

The <statusCode> element records the status of the data records. Queries shall only return active records, not replaced records, so the value of this element shall always be returned as 'active'.

1755 **3.1.5.5.4 <custodian>**

The <custodian> element records the Clinical Data Source that is the custodian, or "owner", of the data record. A Data Source actor may return records from multiple custodians, but shall separate the data records from each custodian into different <registrationEvent> elements.

1760 **3.1.5.5.5 <assignedEntity>**

The <assignedEntity> element shall be present, and provides contact and identification information about the <custodian>.

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

1765 The <id> element shall be present, and shall uniquely identify the custodian of the data records.

**3.1.5.5.7 <addr></addr>**

The <addr> element shall be present, and shall provide a postal address for the custodian of the data records.

**3.1.5.5.8 <telecom></telecom>**

1770 At least one <telecom> element shall be present that provides a telephone number to contact the custodian of the data records. A <telecom> element may be present that provides the web service end-point address of the custodian of the data records.

<b>For Public Comment</b>	How might the web service end-point address be used? Is it a good idea to include it, or should we omit this from the profile?
---------------------------	--

1775 **3.1.5.5.9 <assignedOrganization>  
<name></name>  
</assignedOrganization>**

The name of the organization that is the custodian of the data records shall be provided.

### **3.1.5.5.10 <subject2>**

The <subject2> element provides the data content requested from the query.

#### **1780 3.1.5.5.11 <careProvisionEvent>**

The <careProvisionEvent> elements returned by the Care Record Profile Query are compositions based upon the information requested in the query. It is transitory in nature, and does not necessarily correspond to a single care provision activity stored within the Clinical Data Source.

#### **1785 3.1.5.5.12 <recordTarget>**

The <recordTarget> element records information about the patient for whom the Clinical Data Source is returning results.

#### **3.1.5.5.13 <patient>**

1790 The <patient> element contains information identifying the patient and providing contact information.

#### **3.1.5.5.14 <id root=' ' extension=' '/>**

At least one <id> element shall be present that identifies the patient. This <id> element shall be the same as the value of the <patientId> passed in the query. Other <id> elements may be present.

#### **1795 3.1.5.5.15 <addr></addr>**

At least one <addr> element shall be present to provide a postal address for the patient. It may have the nullFlavor attribute set to UNK if unknown (e.g., for a repository that contains pseudonomized information), or set to MSK for repositories that may contain the information, but which do not choose to divulge the information (e.g., due to access permissions, et cetera).

1800

#### **3.1.5.5.16 <telecom value=' ' use=' '/>**

At least one <telecom> element shall be present to provide a telephone number to contact the patient. It may have the nullFlavor attribute set to UNK if unknown (e.g., for a repository that contains pseudonomized information), or set to MSK for repositories that may contain the information, but which do not choose to divulge the information (e.g., due to access permissions, et cetera). Other <telecom> elements may be present to contain other contact methods, e.g., e-mail. One cannot determine from a <telecom> element with the nullFlavor attribute whether it is supposed to contain a telephone number, e-mail address, URL, or other sort of telecommunciations address. Due to this limitation, the assumption will be made that a <telecom> element with a nullFlavor attribute represents a telephone number that is unavailable.

1805

1810

**3.1.5.5.17 <statusCode code='normal'/>**

1815 The <statusCode> element shall be present, and shall be represented exactly as shown above. This indicates that the *role* of patient is in one of the normal states, e.g., has not been explicitly removed or "nullified".

**3.1.5.5.18 <patientPerson>**

The <patientPerson> element shall be present, and provides further identification information about the patient.

**3.1.5.5.19 <name></name>**

1820 The <name> element shall be present, and normally provides the patient's name. The <name> element may have the nullFlavor attribute set to UNK if unknown (e.g., for a repository that contains pseudonomized information), or set to MSK for repositories that may contain the information, but which do not choose to divulge the information (e.g., due to access permissions, et cetera).

1825 **3.1.5.5.20 <administrativeGenderCode code=' ' displayName=' ' codeSystem='2.16.840.1.113883.5.1' codeSystemName='AdministrativeGender'/>**

1830 The <administrativeGenderCode> element shall be present, and normally provides the patient's gender using the HL7 [AdministrativeGender](#) vocabulary. The <administrativeGender> element may have the nullFlavor attribute set to UNK if unknown (e.g., for a repository that contains pseudonomized information), or set to MSK for repositories that may contain the information, but which do not choose to divulge the information (e.g., due to access permissions, et cetera).

**3.1.5.5.21 <birthTime value=' '/>**

1835 The <birthTime> element shall be present, and normally provides the patient's birthTime. The <birthTime> element may have the nullFlavor attribute set to UNK if unknown (e.g., for a repository that contains pseudonomized information), or set to MSK for repositories that may contain the information, but which do not choose to divulge the information (e.g., due to access permissions, et cetera).

1840 **3.1.5.5.22 <pertinentInformation3>  
<!-- Domain Content>  
</pertinentInformation3>**

1845 This data element shall be present. It shall contain one of the data elements found in the Clinical Data Source that matches the specified query parameters. The content of this data element is a care statement that varies depending upon the specific transaction, and is further defined in the section on Domain Content. Each care statement shall have at least one <author> element that indicates to whom the care statement is attributed. Each care statement may have zero or more <informant> elements that indicates who provided

1850 information related to the care statement. See the section below on Authors and Informants for more information on how this information should be recorded.

### 3.1.5.5.23 <parameterList>

The <parameterList> shall be present, and shall contain content that is identical to the <parameterList> passed in the query.

### 3.1.5.6 Expected Actions -- Data Source

1855 The Clinical Data Source shall send a response as specified in the QUPC\_IN043200UV interaction. The message shall be sent using web services as specified in the ITI-TF: Appendix V. The name of the query response message shall be QUPC\_IN043200UV\_Message in the WSDL. The following WSDL snippet defines the type for this message:

1860

```
<types>
  <xsd:schema elementFormDefault="qualified"
    targetNamespace="urn:h17-org:v3" xmlns:h17="urn:h17-org:v3">
    <xsd:import namespace="urn:h17-org:v3"
      schemaLocation="QUPC_IN043200UV.xsd"/>
    <xsd:element name="QUPC_IN043200UV"/>
  </xsd:schema>
</types>
```

1865

1870 The message type is declared to be of the appropriate type by the following WSDL snippet:

```
<message name='QUPC_IN043200UV_Message'>
  <part element='h17:QUPC_IN043200UV' name="Body"/>
</message>
```

1875 Other WSDL declarations required for this transaction are defined under the Domain Content section.

#### 3.1.5.6.1 Response to a New Query

The Clinical Data Source, shall:

1. Receive and validate the query message.
- 1880 2. Create the response message.
- 1885 3. Add an ILLEGAL detected issue alert to the response message if the content is invalid (e.g., does not pass schema validation or is otherwise malformed), and immediately return a response indicating the error, and that the query was aborted. Set the text of the alert to the name of the first data element that is not valid. The Clinical Data Source may send more than one ILLEGAL detected issue alert if it is able to determine that multiple data elements in the query are not valid.
- 1890 4. Add a NAT detected issue alert to the response message if the requesting party is not authorized to perform the query, and immediately return a response indicating the error, and that the query was aborted.



- 1895 5. Add a VALIDAT detected issue alert to the response message for each of the patientName, patientGenderCode or patientBirthTime fields specified in the query that do not match the values known by the Clinical Data Source Actor. The text value on the alert shall be set to the name of the parameter that does not match (patientName, patientGenderCode or patientBirthTime).
- 1900 6. Add a BUS detected issue alert to the response message if includeCarePlanAttachment is true, but care plans are not associated with observation values. The text value on the alert shall be set to includeCarePlanAttachment.
- 1905 7. Add a BUS detected issue alert to the response message if a careProvisionReason value is specified, but the Clinical Data Source cannot query by this field. The text value on the alert shall be set to careProvisionReason.
- 1910 8. Add a KEY204 detected issue alert to the response message if any of the vocabulary domains are not recognized by the Clinical Data Source. The text value on the alert shall be set to the name of the query parameter that used the unrecognized vocabulary domain.
- 1915 9. Add a CODE\_INVALID detected issue alert to the response message if any of the codes specified are not recognized by the Clinical Data Source. The text value on the alert shall be set to the name of the query parameter that used the unrecognized vocabulary domain.
- 1920 10. Add a FORMAT detected issue alert to the response message if any date ranges are incorrectly formed (low > high). The text value on the alert shall be set to the name of the query parameter that has the error.
- 1925 11. Add a ILLEGAL detected issue alert to the response message if the the Clinical Data Source does not recognize the identity domain used to identify the patient. Set the text value on the alert to patientId.
- 1930 12. Add a KEY204 detected issue alert to the response message if the the Clinical Data Source does not know about the patient. Set the text value on the alert to patientId. This is distinct from having nothing to report. If the patient is recognized but there is no data to report, the result returned should simply have no data. However, if information is requested for a patient that isn't known, then the KEY204 alert shall be raised.
13. Add an appropriate detected issue alert if any parameters otherwise not specified by this profile have been provided, but are not supported by the Clinical Data Source.
14. If any issues were detected, Set queryAck/statusCode/@code to aborted, and queryAct/queryResponse/@code to QE, and return the response.
15. Add an ISSUE alert to the response message if at any time during response generation, an application error occurs that prevents further processing. Set the

text of the alert to the reason for the application error (e.g., a stack trace or exception message). Set queryAct/statusCode/@code to aborted, and queryAct/responseCode/@code to AE, and return the response.

16. Query for the data requested by the query.
- 1935 17. If results are found, set queryAct/queryResponse/@code to OK, otherwise set it to NF.
18. Set queryAck/statusCode/@code to deliveredResponse.
19. Add any results to the response up to the maximum number of history statements requested.
- 1940 20. If all results have been returned, release the query results.

A conforming Clinical Data Source shall support those parameters that have an R in the Source column from table Table 3.1-1, and need not support those query parameters that have an O in this column.

### 3.1.5.6.2 Response to a Query Continuation

1945 The Clinical Data Source, shall:

1. Receive and validate the query continuation message.
- 1950 2. Add an ILLEGAL detected issue alert to the response message if the content is invalid (e.g., does not pass schema validation or is otherwise malformed), and immediately return a response indicating the error, and that the query was aborted. Set the text of the alert to the name of the first data element that is not valid. The Clinical Data Source may send more than one ILLEGAL detected issue alert if it is able to determine that multiple data elements in the continuation are not valid.
3. Create the response message.
- 1955 4. Add a KEY204 detected issue alert to the response message if the the Clinical Data Source does not recognize the queryId.
5. Add a VALIDAT detected issue alert to the response message if the query was previously aborted or otherwise terminated.
- 1960 6. Add an appropriate detected issue alert if any parameters otherwise not specified by this profile have been provided, but are not supported by the Clinical Data Source.
7. If any issues were detected, Set queryAck/statusCode/@code to aborted, and queryAct/queryResponse/@code to QE, and return the response.
- 1965 8. Add an ISSUE alert to the response message if at any time during response generation, an application error occurs that prevents further processing. Set the text of the alert to the reason for the application error (e.g., a stack trace or

- exception message). Set queryAct/statusCode/@code to aborted, and queryAct/responseCode/@code to AE, and return the response.
- 1970 9. Scroll to the result requested in queryContinuation/startResultNumber, querying additional data if necessary.
10. If more results are found, set queryAct/queryResponse/@code to OK, otherwise set it to NF.
11. If no more results are found, ensure that the queryAck/resultTotalQuantity indicates the total number of results found.
- 1975 12. Set queryAck/statusCode/@code to deliveredResponse.
13. Add any results to the response up to the maximum number of history statements requested.
14. Return the response message.
- 1980 15. Release query results if no additional messages on the query are received within an application configurable timeout value.

### 3.1.5.6.3 Response to a Query Cancel

The Clinical Data Source, shall:

1. Receive and validate the query cancelation message.
2. Create the response message.
- 1985 3. Add an ILLEGAL detected issue alert to the response message if the content is invalid (e.g., does not pass schema validation or is otherwise malformed), and immediately return a response indicating the error, and that the query was aborted. Set the text of the alert to the name of the first data element that is not valid. The Clinical Data Source may send more than one ILLEGAL detected issue alert if it is able to determine that multiple data elements in the cancellation are not valid.
- 1990 4. Add a KEY204 detected issue alert to the response message if the the Clinical Data Source does not recognize the queryId.
- 1995 5. Add an appropriate detected issue alert if any parameters otherwise not specified by this profile have been provided, but are not supported by the Clinical Data Source.
- 2000 6. Add an ISSUE alert to the response message if at any time during response generation, an application error occurs that prevents further processing. Set the text of the alert to the reason for the application error (e.g., a stack trace or exception message).
7. Set queryAck/statusCode/@code to aborted,

8. If any application errors were detected, set the queryAct/queryResponse/@code to AE, otherwise, if any other issues were detected, set the value to QE, otherwise set it to NF.
- 2005 9. Return the response message.
10. Release query results.

#### 3.1.5.6.4 Raising Alerts

If the content of the request is not valid (e.g., according to the Schema or the rules of this profile), at least on ILLEGAL alert shall be raised indicating the data element that was invalid. A response will be sent indicating that the request was invalid, and no further processing shall be performed.

2010

If the requesting party is not authorized to perform the query, the minimum response shall be sent indicating only that the requester is not authorized to perform the query.

In other cases, all possible alerts shall be accumulated before returning a response to the caller. This enables Clinical Data Consumer actors to send a test query that will enable them to verify the vocabulary and other request parameters that are desired.

2015

An alert is raised by sending a response containing one or more <reasonOf> elements, coded as shown below.

```

2020 <reasonOf>
      <detectedIssueEvent>
        <code code='' displayName='' codeSystem='' codeSystemName='' />
        <text></text>
        <mitigatedBy>
2025     <detectedIssueManagement moodCode="RQO">
          <code code='' displayName='' codeSystem='' codeSystemName='' />
          <text></text>
        </detectedIssueManagement>
        </mitigatedBy>
2030 </detectedIssueEvent>>
    </reasonOf>
    
```

#### 3.1.5.6.5 <reasonOf>

The <reasonOf> element is required to indicate that an alert has occurred.

#### 3.1.5.6.6 <detectedIssueEvent>

2035 The details of the alert shall be present in the <detectedIssueEvent> element.

#### 3.1.5.6.7 <code code=' ' displayName=' ' codeSystem='2.16.840.1.113883.5.4' codeSystemName='ActCode' />

2040 The <code> element shall contain ISSUE or one of its descendants from the HL7 [ActCode](#) vocabulary.

### 3.1.5.6.8 <text></text>

If a validation or other business rule error occurred, the erroneous parameter shall be identified in <text> element using the element name, and nothing else should be present.

2045 If an application error occurred, the <text> element shall contain diagnostic information (e.g., stack trace or exception message).

If the reason for the alert was an unrecognized code (CODE\_INVALID), the text element shall contain the name of the erroneous parameter, and may contain a space separated list of OIDs identifying value sets which would be valid.

2050 If the reason for the alert was an unrecognized identifier (KEY204) for the vocabulary used in the careProvisionCode or careProvisionReason element, the text element shall contain the name of the erroneous parameter, and may contain a space separated list of the OIDs for code systems which would be valid.

### 3.1.5.7 Expected Actions -- Clinical Data Consumer

2055 The clinical data consumer processes the query response data. If the response indicates that more data is available, the clinical data consumer can request additional data using the General Query Activate Query Continue message, indicating which data is being requested.

## 3.1.6 General Query Activate Query Continue

### 3.1.6.1 Trigger Events

2060 When a Clinical Data Consumer needs to obtain more results from a query, it will trigger the continuation of the query. This corresponds to the HL7 trigger event: [QUQI\\_TE000003UV01](#)

### 3.1.6.2 Message Semantics

2065 The Query Care Record Event Profile Query corresponds to the HL7 Interaction QUQI\_IN000003UV01. A schema for this interaction can be found at: [http://www.hl7.org/v3ballot2007may/html/processable/multicacheschemas/QUQI\\_IN000003UV01.xsd](http://www.hl7.org/v3ballot2007may/html/processable/multicacheschemas/QUQI_IN000003UV01.xsd). This schema includes:

- the transmission wrapper MCCI\_MT000300UV01, and
- the control act wrapper QUQI\_MT000001UV01.

2070 These components of the interaction are specified in the HL7 standards described above.

### 3.1.6.3 Transmission Wrapper

2075 The transmission wrapper MCCI\_MT000300UV01 provides information about the message transmission and routing. Transmission wrappers are further described in ITI TF-2: Appendix O. An example transmission wrapper is given below for this interaction. Items marked in dark gray are transmitted as specified in ITI TF-2: Appendix O. Items in bold black text are further constrained by this profile in this interaction.

```

2080 <QUQI_IN000003UV01 xmlns="urn:hl7-org:v3" ITSVersion="XML_1.0"
      xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">
      <id root=' ' extension=' '/>
      <creationTime value=' '/>
      <interactionId extension='QUQI_IN000003UV01' root='2.16.840.1.113883.5' />
2085 <processingCode code='D|P|T' />
      <processingModeCode code='T' />
      <acceptAckCode code='AL' />
      <receiver typeCode="RCV">
        <device determinerCode="INSTANCE">
2090          <id />
          <name />
          <telecom value=' ' />
          <manufacturerModelName />
          <softwareName />
        </device>
2095 </receiver>
      <sender typeCode="SND">
        <device determinerCode="INSTANCE">
2100          <id />
          <name />
          <telecom value=' ' />
          <manufacturerModelName />
          <softwareName />
        </device>
2105 </sender>
      <controlActProcess>
        See Control Act Wrapper below
      </controlActProcess>
    </QUQI_IN000003UV01>

```

2110 **3.1.6.3.1 <QUQI\_IN000003UV01 xmlns="urn:hl7-org:v3" ITSVersion="XML\_1.0" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">**

The HL7 Interaction being sent will control the name of the root element in the message. The namespace of this message shall be urn:hl7-org:v3, and the ITSVersion attribute shall be "XML\_1.0".

2115 **3.1.6.3.2 <interactionId extension='QUQI\_IN000003UV01' root='2.16.840.1.113883.5' />**

The identifier for the interaction shall be sent as shown above.

**3.1.6.3.3 <processingModeCode code='T' />**

2120 The processingModeCode distinguishes the type of processing being performed. This element shall be present and have the value shown above to indicate that this message is for current processing.

**3.1.6.3.4 <acceptAckCode code='AL'/>**

The acceptAckCode indicates whether the sender wants to receive an acknowledgement, and shall be sent as shown above.

2125 **3.1.6.4 Control Act Wrapper**

The control act wrapper QUQI\_MT020001UV01 provides information about the business actors related to the transaction, including the author or performer of the act. Control act wrappers are further described in ITI TF-2: Appendix O. An example transmission wrapper is given below for this interaction. Items marked in gray are transmitted as specified in ITI TF-2: Appendix O. Items in bold black text are further constrained by this profile in this interaction.

```

2135 <controlActProcess moodCode="RQO">
      <id root=' ' extension=' '/>
      <code code='QUQI_TE000003UV01'/>
      <effectiveTime value=' '/>
      <languageCode code=' '/>
      <authorOrPerformer typeCode=' '></authorOrPerformer>
2140 <queryContinuation>
      <queryId root=' ' extension=' '/>
      <statusCode code='waitContinuedQueryResponse'/>
      <startResultNumber value=' '/>
      <continuationQuantity value=' '/>
2145 </queryContinuation>
    </controlActProcess>

```

**3.1.6.4.1 <controlActProcess moodCode="RQO">**

The controlActProcess element is where information about the business act being performed is recorded. The moodCode is set to "RQO" by the sender to indicate a request to perform an action, in this case, a continuation of a query.

**3.1.6.4.2 <code code='QUQI\_TE000003UV01'/>**

The trigger event which caused the act to be transmitted is recorded in the code element as shown above.

**3.1.6.5 Continuation Request**2155 **3.1.6.5.1 <queryContinuation>**

The queryContinuation element shall be sent in messages that are used to obtain more query results or cancel a current query.

**3.1.6.5.2 <queryId root=' ' extension=' '/>**

The identifier of the query to continue or cancel shall be reported in the queryId element.

2160 **3.1.6.5.3 <statusCode code='waitContinuedQueryResponse'/>**

The statusCode element shall be sent, and indicates that this is a continuation of the query.

**3.1.6.5.4 <startResultNumber value=' '/>**

2165 The startResultNumber element may be sent to indicate the query result to start returning from. If this element is sent, it shall be honored by the Clinical Data Source. If this element is omitted, results will be sent that follow the last set of results sent. Results are numbered from 1, so setting this value to 1 will start with the first result returned. Setting this value to a number less than 1 will result in undefined application behavior.

**3.1.6.5.5 <continuationQuantity value=' '/>**

2170 The continuationQuantity element may be sent on continuation requests to indicate the number of addition records to return. If sent it shall have a value greater than 0. The Clinical Data Source may send fewer results than requested, but shall send no more than this value.

**3.1.6.5.6 Expected Actions -- Clinical Data Consumer**

2175 Upon completion of all result processing, the clinical data consumer shall send a General Query Query Activate Continue message to obtain additional results.

The Clinical Data Source shall send a response as specified in the [QUQI\\_IN000003UV01](#) interaction. The message shall be sent using web services as specified in the ITI-TF: Appendix V. The name of the query response message shall be

2180 QUQI\_IN000003UV01\_Message in the WSDL. The following WSDL snippet defines the type for this message:

```
2185 <types>
  <xsd:schema elementFormDefault="qualified"
    targetNamespace="urn:h17-org:v3" xmlns:h17="urn:h17-org:v3">
    <xsd:import namespace="urn:h17-org:v3"
      schemaLocation="QUQI_IN000003UV01.xsd"/>
    <xsd:element name="QUQI_IN000003UV01"/>
  </xsd:schema>
2190 </types>
```

The message type is declared to be of the appropriate type by the following WSDL snippet:

```
2195 <message name='QUQI_IN000003UV01_Message'>
  <part element='h17:QUQI_IN000003UV01' name="Body"/>
</message>
```

Other WSDL declarations required for this transaction are defined under the Domain Content section.



### 3.1.7 General Query Query Cancel

#### 2200 3.1.7.1 Trigger Events

When the Clinical Data Consumer is finished with the query, it shall cancel the query. This corresponds to the HL7 trigger event: [QUOI TE000003UV01](#) -- General Query Activate Query Continue

#### 3.1.7.2 Message Semantics

2205 The Query Care Record Event Profile Query Cancel corresponds to the HL7 Interaction QUOI\_IN000003UV01. A schema for this interaction can be found at: [http://www.hl7.org/v3ballot2007may/html/processable/multicacheschemas/QUOI\\_IN000003UV01.xsd](http://www.hl7.org/v3ballot2007may/html/processable/multicacheschemas/QUOI_IN000003UV01.xsd). This schema includes:

- the transmission wrapper MCCI\_MT000300UV01, and
- the control act wrapper QUOI\_MT000001UV01.

2210 These components of the interaction are specified in the HL7 standards described above.

#### 3.1.7.3 Transmission Wrapper

2215 The transmission wrapper MCCI\_MT000300UV01 provides information about the message transmission and routing. Transmission wrappers are further described in ITI TF-2: Appendix O. The transmission wrapper used in the Query Cancel message is the same as the transmission wrapper used in the Query Continuation message described in the previous section.

#### 3.1.7.4 Control Act Wrapper

2220 The control act wrapper QUOI\_MT020001UV01 provides information about the business actors related to the transaction, including the author or performer of the act. Control act wrappers are further described in ITI TF-2: Appendix O. An example transmission wrapper is given below for this interaction. Items marked in gray are transmitted as specified in ITI TF-2: Appendix O. Items in bold black text are further constrained by this profile in this interaction.

2225

```

2230 <controlActProcess moodCode="RQO">
      <id root=' ' extension=' '/>
      <code code='QUQI_TE000003UV01'/>
      <effectiveTime value=' '/>
      <languageCode code=' '/>
      <authorOrPerformer typeCode=' '></authorOrPerformer>
      <queryContinuation>
2235   <queryId root=' ' extension=' '/>
         <statusCode code='aborted'/>
         <startResultNumber value=' '/>
         <continuationQuantity value='0'/>
      </queryContinuation>
    </controlActProcess>

```

#### 2240 3.1.7.4.1 <controlActProcess moodCode="RQO">

The controlActProcess element is where information about the business act being performed is recorded. The moodCode is set to "RQO" by the sender to indicate a request to perform an action, in this case, a continuation of a query.

#### 3.1.7.4.2 <code code='QUQI\_TE000003UV01'/>

2245 The trigger event which caused the act to be transmitted is recorded in the code element as shown above.

### 3.1.7.5 Cancellation Request

#### 3.1.7.5.1 <queryContinuation>

2250 The queryContinuation element shall be sent in messages that are used to obtain more query results or cancel a current query.

#### 3.1.7.5.2 <queryId root=' ' extension=' '/>

The identifier of the query to continue or cancel shall be reported in the <queryId> element.

#### 3.1.7.5.3 <statusCode code='aborted'/>

2255 The statusCode element shall be sent as shown above, and indicates that this is a continuation of the query.

#### 3.1.7.5.4 <startResultNumber value=' '/>

The startResultNumber element shall not be sent in a cancellation request.

#### 3.1.7.5.5 <continuationQuantity value=' 0'/>

2260 The continuationQuantity element shall be sent and shall have a value 0 to indicate a cancellation.

### 3.1.7.6 Expected Actions -- Clinical Data Consumer

2265 When finished with all query results, the clinical data consumer shall send a General Query Query Cancel message to cancel the query. The name of the query response message shall be QUQI\_IN000003UV01\_Message in the WSDL, and this is declared as shown above for the Query Continue message. Other WSDL declarations required for this transaction are defined under the Domain Content section.

### 3.1.8 Get Care Record Profile Response

2270 A Clinical Data Source Actor shall respond to a query request by returning matching clinical statements within <pertinentInformation3> elements. All information returned shall specify the author or authors of the returned information in a subordinate <author> element, and may indicate the informants in <informant> elements.

#### 3.1.8.1 Common Observations and Vital Signs

2275 The following rules applied to a Clinical Data Source supporting the Vital Signs option. When careProvisionCode is set to COBSCAT from the HL7 ActCode vocabulary domain, a Clinical Data Source supporting shall respond by returning all matching observations that correspond to the LOINC code values from the table in [Vital Signs Observation](#). It shall also respond to any of the individual LOINC codes found in that table to return specific kinds of vital signs measurements. The observations returned shall conform the the PCC [Vital Signs Observation](#) entry template.

2280 A Clinical Data Source Actor may respond to requests using other LOINC codes to return other common observations. These observations shall conform to the [Simple Observations](#) entry template. For example, a Clinical Data Source Actor may respond to a query request where the LOINC code matches any individual LOINC code found in the table in the [Pregnancy Observations](#) with clinical statements conforming to that entry template.

#### 3.1.8.2 Problems and Allergies

2290 The following rules applied to a Clinical Data Source supporting the Problems and Allergies option. The clinical statements that are returned for codes specified in the table above in the section on [careProvisionCode](#) shall conform to the template identifiers shown therein.

A Clinical Data Source actor may respond to query requests using other codes to return information about specific problem, allergy or risk observations. These observations shall conform to the [Problem Entry](#) or [Allergy and Intolerance Entry](#)

#### 3.1.8.3 Medications

2295 The following rules applied to a Clinical Data Source supporting the Medications option. Clinical statements representing medications that are returned by this transaction shall conform to the [Medications](#) template.

**3.1.8.4 Immunizations**

2300 The following rules applied to a Clinical Data Source supporting the Immunizations option. Clinical statements representing medications that are returned by this transaction shall conform to the [Immunizations](#) template.

**3.1.8.5 Professional Services**

2305 A Clinical Data Source Actor shall respond to a query request for Professional Services by returning clinical statements matching the query parameter returned within <pertinentInformation3> data elements. The clinical statements containing Professional Services shall conform to the templates shown above.

**3.1.9 WSDL Declarations**

The following WSDL naming conventions SHALL apply for this transaction:

| WSDL Item                                | Value   |
|--|---|
| wsdl:definitions/@name                   | ClinicalDataSource                            |
| Get Care Record Profile Query            | QUPC_IN043100UV_Message                       |
| Get Care Record Profile Response         | QUPC_IN043200UV_Message                       |
| General Query Activate Continue / Cancel | QUQI_IN000003UV01_Message                     |
| portType                                 | ClinicalDataSource_PortType                   |
| Query Operation                          | ClinicalDataSource_QUPC_IN043100UV            |
| Continue Operation                       | ClinicalDataSource_QUQI_IN000003UV01_Continue |
| Cancel Operation                         | ClinicalDataSource_QUQI_IN000003UV01_Cancel   |
| SOAP 1.1 binding                         | ClinicalDataSource_Binding_Soap11             |
| SOAP 1.1 port                            | ClinicalDataSource_Port_Soap11                |
| SOAP 1.2 binding                         | ClinicalDataSource_Binding_Soap12             |
| SOAP 1.2 port                            | ClinicalDataSource_Port_Soap12                |

2310 The following WSDL snippets specify the Port Type and Binding definitions, according to the requirements specified in ITI TF-2: Appendix V. A full WSDL example for the Clinical Data Source actor can be found at [ftp://ftp.ihe.net/TF\\_Implementation\\_Material/PCC/ClinicalDataSource.wsdl](ftp://ftp.ihe.net/TF_Implementation_Material/PCC/ClinicalDataSource.wsdl).

2315 For a general description of the WSDLs for PCC see the Appendix of the same name in this volume.

### 3.1.9.1 Port Type

```

2320 <portType name="ClinicalDataSource_PortType">
  <operation name="ClinicalDataSource_QUPC_IN043100UV">
    <input message="tns:QUPC_IN043100UV_Message"
      wsaw:Action="urn:hl7-org:v3:QUPC_IN043100UV"/>
    <output message="tns:QUPC_IN043200UV_Message"
      wsaw:Action="urn:hl7-org:v3:QUPC_IN043200UV"/>
  </operation>
2325 <operation name="ClinicalDataSource_QUQI_IN000003UV01_Continue">
  <input message="tns:QUQI_IN000003UV01_Message"
    wsaw:Action="urn:hl7-org:v3:QUQI_IN000003UV01"/>
  <output message="tns:QUPC_IN043200UV_Message"
    wsaw:Action="urn:hl7-org:v3:QUPC_IN043200UV"/>
2330 </operation>
  <operation name="ClinicalDataSource_QUQI_IN000003UV01_Cancel">
  <input message="tns:QUQI_IN000003UV01_Message"
    wsaw:Action="urn:hl7-org:v3:QUQI_IN000003UV01"/>
  <output message="tns:QUPC_IN043200UV_Message"
    wsaw:Action="urn:hl7-org:v3:QUPC_IN043200UV"/>
2335 </operation>
</portType>

```

### 3.1.9.2 Bindings

```

2340 <binding name="ClinicalDataSource_Binding_Soap12"
  type="ClinicalDataSource_PortType">
  <wssoap12:binding style="document"
    transport="http://schemas.xmlsoap.org/soap/http"/>
2345 <operation name="ClinicalDataSource_QUPC_IN043100UV">
  <wssoap12:operation soapAction="urn:hl7-org:v3:QUPC_IN043100UV"/>
  <input>
    <wssoap12:body use="literal"/>
  </input>
  <output>
    <wssoap12:body use="literal"/>
  </output>
  </operation>
</binding>
2355 <binding name="ClinicalDataSource_Binding_Soap11"
  type="ClinicalDataSource_PortType">
  <wssoap11:binding style="document"
    transport="http://schemas.xmlsoap.org/soap/http"/>
2360 <operation name="ClinicalDataSource_QUPC_IN043100UV">
  <wssoap11:operation soapAction="urn:hl7-org:v3:QUPC_IN043100UV"/>
  <input>
    <wssoap11:body use="literal"/>
  </input>
  <output>
    <wssoap11:body use="literal"/>
2365 </output>
  </operation>
</binding>

```

## 3.2 PCC-2

The functionality of this transaction was incorporated into [PCC-1](#) as a result of a Change Proposal. This transaction is now reserved.

### **3.3 PCC-3**

2375 The functionality of this transaction was incorporated into [PCC-1](#) as a result of a Change Proposal. This transaction is now reserved.

### **3.4 PCC-4**

The functionality of this transaction was incorporated into [PCC-1](#) as a result of a Change Proposal. This transaction is now reserved.

### **3.5 PCC-5**

2380 The functionality of this transaction was incorporated into [PCC-1](#) as a result of a Change Proposal. This transaction is now reserved.

### **3.6 PCC-6**

The functionality of this transaction was incorporated into [PCC-1](#) as a result of a Change Proposal. This transaction is now reserved.

2385 **4 Namespaces and Vocabularies**

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

2390

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

## 4.1 IHE Format Codes

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

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



|  |   |          |  |
|--|---|----------|--|
| Scanned Documents                                    | urn:ihe:iti:xds-sd:text:2008<br>urn:ihe:iti:xds-sd:pdf:2008 | text/xml |  |
| Basic Patient Privacy Consents                       | urn:ihe:iti:bppc:2007                                       | text/xml |  |
| Basic Patient Privacy Consents with Scanned Document | urn:ihe:iti:bppc-sd:2007                                    | text/xml |  |
| <b>LAB Profiles</b>                                  |   |          |  |
| CDA Laboratory Report                                | urn:ihe:lab:?:?:2007  | text/xml |  |

2395 **4.2 IHEActCode Vocabulary**

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

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

2400

| Code      | Description  |
|-----------|--|
| COMMENT   | This is the act of commenting on another act.  |
| PINSTRUCT | This is the act of providing instructions to a patient regarding the use of medication.  |
| FINSTRUCT | This is the act of providing instructions to the supplier regarding the fulfillment of the medication order.   |
| IMMUNIZ   | The act of immunization of a patient using a particular substance or class of substances identified using a specified vocabulary. Use of this vocabulary term requires the use of either the SUBSTANCE or SUBSTCLASS qualifier described below, along with an identified substance or class of substances.                       |
| DRUG      | The act of treating a patient with a particular substance or class of substances identified using a specified vocabulary. Use of this vocabulary term requires the use of either the SUBSTANCE or SUBSTCLASS qualifier described below, along with an identified substance or class of substances.                               |
| INTOL     | An observation that a patient is somehow intollerant of (e.g., allergic to) a particular substance or class of substances using a specified vocabulary. Use of this vocabulary term requires the use of either the SUBSTANCE or SUBSTCLASS qualifier described below, along with an identified substance or class of substances. |
| SUBSTANCE | A qualifier that identifies the substance used to treat a patient in an immunization or drug   |

|   |  |
|---|--|
|   | treatment act. The substance is expected to be identified using a vocabulary such as RxNORM, SNOMED CT or other similar vocabulary and should be specific enough to identify the ingredients of the substance used.  |
| SUBSTCLASS  | A qualifier that identifies the class of substance used to treat a patient in an immunization or drug treatment act. The class of substances is expected to be identified using a vocabulary such as NDF-RT, SNOMED CT or other similar vocabulary, and should be broad enough to classify substances by mechanism of action (e.g., Beta Blocker), intended effect (Diuretic, antibiotic) or ... |
| <b>For Public Comment</b> What else needs to appear above for SUBSTCLASS? |  |

### 4.3 IHERoleCode Vocabulary

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

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

2405 **5 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.

**5.1 CDA and HL7 Version 3 Entry Content Modules**

**5.1.1 Authors and Informants**

- 2410 Each clinical statement that can be made in a CDA Document or HL7 Version 3 message shall be attributable to one or more authors. These are found in <author> elements, either directly within the clinical statement, or in one of its ancestors in the XML document or message. Each clinical statement may also contain information from zero or more informants. These are found in <informant> elements, again, either directly within the
- 2415 clinical statement, or in one of its ancestors in the XML document or message.

**5.1.1.1 <author>**

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

**5.1.1.2 <time value=' '/>**

- 2420 The time of authorship shall be recorded in the <time> element.

**5.1.1.3 <assignedAuthor> -OR- <assignedEntity1>**

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

- 2425 In a CDA document details about the author are provided in the <assignedAuthor> element. In Version 3 messages, they are provided in the <assignedEntity1> element. The semantics are identical even though the element names differ. The identifier of the author, and their address and telephone number shall be present inside the <id>, <addr> and <telecom> elements.

- 2430 **5.1.1.4 <assignedPerson><name></name></assignedPerson>  
<representedOrganization><name></name></representedOrganization>**

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

2435 **5.1.2 Linking Narrative and Coded Entries**

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

**5.1.2.1 Standards**

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

**5.1.2.2 Constraints for CDA**

2440 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:

- 2445
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.
- 2450

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

2455

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

**Table 5.1-1 Example Uses of ID**

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

2460 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)])
```

2465

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

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

2470 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:

```
2475 //cda:reference[@URI=concat('#',$theID)]
```

### 5.1.2.3 Constraints for HL7 Version 3 Messages

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

### 2480 5.1.3 Severity 1.3.6.1.4.1.19376.1.5.3.1.4.1

Any condition or allergy may be the subject of a severity observation. This structure is included in the target act using the <entryRelationship> element defined in the CDA Schema. The example below shows the recording the condition or allergy severity, and is used as the context for the following sections.

### 2485 5.1.3.1 Standards

**PatCareStruct** HL7 Care Provision Domain (DSTU)

**CCD** ASTM/HL7 Continuity of Care Document

### 5.1.3.2 Specification

```

2490 <observation classCode='COND' moodCode='EVN'>
    <entryRelationship typeCode='SUBJ' inversionInd='true'>
2495     <observation classCode='OBS' moodCode='EVN'>
        <templateId root='2.16.840.1.113883.10.20.1.55' />
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.1' />
        <code code='SEV' displayName='Severity'
2500         codeSystem='2.16.840.1.113883.5.4' codeSystemName='ActCode' />
        <text><reference value='#severity-2' /></text>
        <statusCode code='completed' />
        <value xsi:type='CD' code='H|M|L'
2505         codeSystem='2.16.840.1.113883.5.1063'
            codeSystemName='ObservationValue' />
        </observation>
    </entryRelationship>
2510 </observation>

```

2510 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
2515 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.

#### 5.1.3.2.1 <entryRelationship typeCode='SUBJ' inversionInd='true'>

2520 The related statement is made about the severity of the condition (or allergy). For CDA, this observation is recorded inside an <entryRelationship> element occurring in the condition, allergy or medication entry. The containing <entry> is the subject (typeCode='SUBJ') of this new observation, which is the inverse of the normal containment structure, thus inversionInd='true'. For HL7 Version 3 Messages this relationship is represented with a <sourceOf> element, however the semantics, typeCode,
2525 and inversionInd is unchanged.

#### 5.1.3.2.2 <observation moodCode='EVN' classCode='OBS'>

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

2530 **5.1.3.2.3 <templateId root='2.16.840.1.113883.10.20.1.55'/>**  
**<templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.1'/>**

2535 The <templateId> elements identifies this <observation> as a severity observation, allowing for validation of the content. As a side effect, readers of the CDA can quickly locate and identify severity observations. The templateId elements shown above must be present.

**5.1.3.2.4 <code code='SEV' codeSystem='2.16.840.1.113883.5.4'**  
**displayName='Severity' codeSystemName='ActionCode' />**

2540 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.

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

2545 The <observation> element shall contain a <text> element. For CDA, the <text> elements shall contain a <reference> element pointing to the narrative where the severity is recorded, rather than duplicate text to avoid ambiguity. For HL7 Version 3 Messages, the <text> element should contain the full narrative text.

**5.1.3.2.6 <statusCode code='completed'/>**

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

2550 **5.1.3.2.7 <value xsi:type='CD' code='H|M|L'**  
**codeSystem='2.16.840.1.113883.5.1063'**  
**codeSystemName='SeverityObservation'/>**

2555 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 affect the situation of the subject.

2560 **5.1.4 Problem Status Observation 1.3.6.1.4.1.19376.1.5.3.1.4.1.1**

2565 Any problem or allergy observation may reference a problem status observation. This structure is included in the target observation using the <entryRelationship> element defined in the CDA Schema. The clinical status observation records information about the current status of the problem or allergy, for example, whether it is active, in remission, resolved, et cetera. The example below shows the recording of clinical status of a condition or allergy, and is used as the context for the following sections.

**5.1.4.1 Standards**

CCD ASTM/HL7 Continuity of Care Document

**5.1.4.2 Specification**

2570

```

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

```

2575

2580

2585

2590

This CCD models a problem status observation as a separate observation from the problem, allergy or medication observation. While this model is different from work presently underway by various organizations (i.e., SNOMED, HL7, TermInfo), it is not wholly incompatible with that work. In that work, qualifiers may be used to identify problem status in the coded condition observation, and a separate clinical status

2595

observation is no longer necessary. The use of qualifiers in the problem observation is not precluded by this specification or by CCD. However, to support semantic interoperability between EMR systems using different vocabularies, this specification does require that problem status information also be provided in a separate observation. This ensures that all EMR systems have equal access to the information, regardless of the vocabularies they support.

2600

**5.1.4.3 <entryRelationship typeCode='REFR' inversionInd='false'>**

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

2605

**5.1.4.4 <observation moodCode='EVN' classCode='OBS'>**

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

2610



**5.1.4.5** `<templateId root='2.16.840.1.113883.10.20.1.57'/>`  
`<templateId root='2.16.840.1.113883.10.20.1.50'/>`  
`<templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.1.1'/>`

2615 These `<templateId>` elements identify this `<observation>` as a problem status observation, allowing for validation of the content.

**5.1.4.6** `<code code='33999-4' codeSystem='2.16.840.1.113883.6.1' displayName='Status' codeSystemName='LOINC' />`

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

2620 **5.1.4.7** `<text><reference value='#cstatus-2'/></text>`

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

2625

**5.1.4.8** `<statusCode code='completed'/>`

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

2630 **5.1.4.9** `<value xsi:type='CE' code=' ' displayName=' ' codeSystem='2.16.840.1.113883.6.96' codeSystemName='SNOMED CT'/>`

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

2635

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

### 5.1.5 Health Status 1.3.6.1.4.1.19376.1.5.3.1.4.1.2

2640 A problem observation may reference a health status observation. This structure is included in the target observation using the <entryRelationship> element defined in the CDA Schema. The health status observation records information about the current health status of the patient. The example below shows the recording the health status, and is used as the context for the following sections.

#### 5.1.5.1 Specification

```

2645 <entry>
      <observation classCode='OBS' moodCode='EVN'>
          <entryRelationship typeCode='REFR' inversionInd='false'>
              <observation classCode='OBS' moodCode='EVN'>
                  <templateId root='2.16.840.1.113883.10.20.1.57' />
2650                 <templateId root='2.16.840.1.113883.10.20.1.51' />
                  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.1.2' />
                  <code code='11323-3' displayName='Health Status'
                      codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC' />
2655                 <text><reference value='#hstatus-2' /></text>
                  <statusCode code='completed' />
                  </value>
                  <value xsi:type='CE' code=' ' codeSystem='2.16.840.1.113883.6.96'
                      codeSystemName='SNOMED CT' />
2660                 </observation>
              </entryRelationship>
          </observation>
      </entry>

```

2665 This specification models a health status observation as a separate observation about the patient.

#### 5.1.5.2 <entryRelationship typeCode='REFR'>

2670 The related statement is made about the health status of the patient. For CDA, this observation is recorded inside an <entryRelationship> element occurring in the observation. The contained observation is referenced (typeCode='REFR') by the observation entry. For HL7 Version 3 Messages, the entryRelationship tagName is sourceOf, though the typeCode and inversionInd attributes and other semantics remain the same.

#### 5.1.5.3 <observation moodCode='EVN' classCode='OBS'>

2675 The related statement is another event (moodCode='EVN') observing (<observation classCode='OBS'>) the health status of the patient.

**5.1.5.4** `<templateId root='2.16.840.1.113883.10.20.1.57'/>`  
`<templateId root='2.16.840.1.113883.10.20.1.51'/>`  
`<templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.1.2'/>`

2680 The `<templateId>` element identifies this `<observation>` as a health status observation, allowing for validation of the content.

**5.1.5.5** `<code code='11323-3'`  
`displayName='Health Status'`  
`codeSystem='2.16.840.1.113883.6.1'`  
`codeSystemName='LOINC' />`

2685

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

**5.1.5.6** `<text><reference value='#hstatus-2'/></text>`

2690 The `<observation>` element shall contain a `<text>` element that contains the narrative text describing the clinical status. For CDA, the `<text>` elements shall contain a `<reference>` element pointing to the narrative section (see [Linking Narrative and Coded Entries](#), rather than duplicate text to avoid ambiguity. For HL7 Version 3 Messages, the `<text>` element shall contain the full narrative text.

2695 **5.1.5.7** `<statusCode code='completed'/>`

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

**5.1.5.8** `<value xsi:type='CE' code=' ' displayName=' '`  
`codeSystem='2.16.840.1.113883.6.96' codeSystemName='SNOMED`  
`CT'/>`

2700

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

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

419099009 Deceased

**5.1.6 Comments 1.3.6.1.4.1.19376.1.5.3.1.4.2**

2705 This entry allows for a comment to be supplied with each entry. For CDA this structure is included in the target act using the <entryRelationship> element defined in the CDA Schema. The example below shows recording a comment for an <entry>, and is used as context for the following sections. For HL7 Version 3 Messages, this relationship is represented with the element <sourceOf>, although the remainder of the typecodes and semantics are unchanged. Any condition or allergy may be the subject of a comment.

2710

**5.1.6.1 Standards**

**CareStruct** [HL7 Care Provision Care Structures \(DSTU\)](#)

**CCD** [ASTM/HL7 Continuity of Care Document](#)

**5.1.6.2 Specification**

```

2715 <entry>
      <observation classCode='OBS' moodCode='EVN'>
        <entryRelationship typeCode='SUBJ' inversionInd='true'>
          <act classCode='ACT' moodCode='EVN'>
            <templateId root='2.16.840.1.113883.10.20.1.40' />
            <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.2' />
            <code code='48767-8' displayName='Annotation Comment'
              codeSystem='2.16.840.1.113883.6.1'
              codeSystemName='LOINC' />
            <text><reference value='#comment-2' /></text>
            <statusCode code='completed' />
            <author>
              <time value='' />
              <assignedAuthor>
                <id root='' extension='' />
                <addr></addr>
                <telecom value='' use='' />
                <assignedPerson><name></name></assignedPerson>
                <representedOrganization><name></name></representedOrganization>
              </assignedAuthor>
            </author>
          </act>
        </entryRelationship>
      </observation>
    </entry>
2740
```

**5.1.6.3 <entryRelationship typeCode='SUBJ' inversionInd='true'>**

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

2745

relationship element is <sourceOf>, however the typeCode and inversionInd remain the same.

**5.1.6.4 <act classCode='ACT' moodCode='EVN'>**

2750 The related statement is an event (moodCode='EVN') describing the act (classCode='ACT') of making an arbitrary comment or providing instruction on the related entry.

**5.1.6.5 <templateId root='2.16.840.1.113883.10.20.1.40' />  
<templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.2' />**

2755 These <templateId> elements identify this <act> as a comment, allowing for validation of the content.

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

2760 The <code> element indicates that this is a comment and shall be recorded as shown above. The codeSystem and code attributes shall use the values specified above.

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

2765 The <text> element provides a way to represent the <reference> to the text of the comment in the narrative portion of the document. For CDA, this SHALL be represented as a <reference> element that points to the narrative text section of the CDA. The comment itself is not the act being coded, so it appears in the <text> of the <observation>, not as part of the <code>. For HL7 Version 3 Messages, the <text> element SHALL contain the full narrative text.

**5.1.6.8 <statusCode code='completed' />**

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

2770 **5.1.6.9 <author>**

The comment may have an author.

**5.1.6.10 <time value=' ' />**

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

2775 **5.1.6.11 <assignedAuthor>  
<id root=' ' extension=' ' />  
<addr></addr>  
<telecom value=' ' use=' ' />**

2780 The identifier of the author, and their address and telephone number must be present inside the <id>, <addr> and <telecom> elements when the <author> element is present.

---

### 5.1.6.12 <assignedPerson><name></name></assignedPerson> <representedOrganization><name></name></representedOrganization>

2785 The author's and/or the organization's name must be present when the <author> element is present.

### 5.1.7 Patient Medication Instructions 1.3.6.1.4.1.19376.1.5.3.1.4.3

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

2790 This structure is included in the target substance administration or supply act using the <entryRelationship> element defined in the CDA Schema. The example below shows the recording of patient medication instruction for an <entry>, and is used as context for the following section.

#### 5.1.7.1 Standards

Pharmacy HL7 Pharmacy Domain (Normative)

#### 5.1.7.2 Specification

2795

```

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

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

```

2800

2805

2810

#### 5.1.7.3 <entryRelationship typeCode='SUBJ' inversionInd='true'>

2815 Again, a related statement is made about the medication or immunization. This observation is recorded inside an <entryRelationship> element occurring at the end of the substance administration or supply entry. The containing <entry> is the subject (typeCode='SUBJ') of this new observation, which is the inverse of the normal containment structure, thus inversionInd='true'.

#### 5.1.7.4 <act classCode='ACT' moodCode='INT'>

2820 The related statement is the intent (moodCode='INT') on how the related entry is to be performed. .

**5.1.7.5 <templateId root='2.16.840.1.113883.10.20.1.49'/>  
<templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.3'/>**

2825 These <templateId> elements identify this <act> as a medication instruction, allowing for validation of the content. As a side effect, readers of the CDA can quickly locate and identify medication instructions.

**5.1.7.6 <code code='PINSTRUCT' codeSystem='1.3.6.1.4.1.19376.1.5.3.2' codeSystemName='IHEActCode' />**

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

2830 Note: These values will be sent to HL7 for harmonization with the HL7 Act Vocabulary.

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

2835 The <text> element indicates the text of the comment. For CDA, this SHALL be represented as a <reference> element that points at the narrative portion of the document. The comment itself is not the act being coded, so it appears in the <text> of the <observation>, not as part of the <code>. For HL7 Version 3 Messages, the full text SHALL be represented here.

**5.1.7.8 <statusCode code='completed' />**

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

**5.1.8 Medication Fulfillment Instructions 1.3.6.1.4.1.19376.1.5.3.1.4.3.1**

2840 Any medication may be the subject of further instructions to the pharmacist, for example to indicate that it should be labeled in Spanish, et cetera.

2845 This structure is included in the target substance administration or supply act using the <entryRelationship> element defined in the CDA Schema. The figure below is an example of recording an instruction for an <entry>, and is used as context for the following sections.

**5.1.8.1 Standards**

**Pharmacy** HL7 Pharmacy Domain (Normative)

**5.1.8.2 Specification**

2850

```

<entry>
  <supply classCode='SPLY' moodCode='EVN'>
2855     <entryRelationship typeCode='SUBJ' inversionInd='true'>
       <act classCode='ACT' moodCode='INT'>
         <templateId root='2.16.840.1.113883.10.20.1.43' />
         <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.3.1' />
2860         <code code='FINSTRUCT' codeSystem='1.3.6.1.4.1.19376.1.5.3.2'
              codeSystemName='IHEActCode' />
         <text><reference value='#comment-2' /></text>
         <statusCode code='completed' />
       </act>
     </entryRelationship>
2865   </supply>
</entry>

```

### 5.1.8.3 <entryRelationship typeCode='SUBJ' inversionInd='true'>

2870 Again, a related statement is made about the medication or immunization. In CDA, this observation is recorded inside an <entryRelationship> element occurring at the end of the substance administration or supply entry. The containing <act> is the subject (typeCode='SUBJ') of this new observation, which is the inverse of the normal containment structure, thus inversionInd='true'. For HL7 Version 3 Messages, this relationship is represented with the <sourceOf> element however the semantics, 2875 typeCode, and inversionInd remain the same.

### 5.1.8.4 <act classCode='ACT' moodCode='INT'>

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

### 5.1.8.5 <templateId root='2.16.840.1.113883.10.20.1.43' /> <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.3.1' />

2880

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

### 5.1.8.6 <code code='FINSTRUCT' codeSystem='1.3.6.1.4.1.19376.1.5.3.2' codeSystemName='IHEActCode' />

2885

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

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

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

2890

The <text> element contains a free text representation of the instruction. For CDA this SHALL contain a <reference> element 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>. For HL7 Version 3 Messages, the full text SHALL be represented here.

2895 **5.1.8.8 <statusCode code='completed' />**

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

**5.1.9 External References 1.3.6.1.4.1.19376.1.5.3.1.4.4**

2900 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.

- 2905
1. The identity of a document does not change, but the URLs used to access it may vary depending upon location, implementation, or other factors.
  2. Referencing clinical documents by identity does not impose any implementation specific constraints on the mechanism used to resolve these references, allowing the content to be implementation neutral. For example, in the context of an XDS Affinity domain the clinical system used to access documents would be an XDS Registry and one or more XDS Repositories where documents are stored. In other contexts, access might be through a Clinical Data Repository (CDR), or Document Content Management System (DCMS). Each of these may have different mechanisms to resolve a document identifier to the document resource.
  - 2910
  - 2915 3. The identity of a document is known before the document is published (e.g., in an XDS Repository, Clinical Data Repository, or Document Content Management System), but its URL is often not known. Using the document identity allows references to existing documents to be created before those documents have been published to a URL. This is important to document creators, as it does not impose workflow restrictions on how links are created during the authoring process.
  - 2920

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

**5.1.9.1 Specification**

```

2925 <entry>
      <act classCode='ACT' moodCode='EVN'>
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.4' />
        <id root='' extension='' />
2930 <code nullFlavor='NA' />
        <text><reference value='#study-1' /></text>
        <!-- For CDA -->
        <reference typeCode='REFR|SPRT'>
          <externalDocument classCode='DOC' moodCode='EVN'>
2935 <id extension='' root='' />
          <text><reference value='http://foo..' /></text>
          </externalDocument>
        </reference>
        <!-- For HL7 Version 3 Messages -->
2940 <sourceOf typeCode='REFR|SPRT'>
          <act classCode='DOC' moodCode='EVN'>
            <id extension='' root='' />
            <text><reference value='http://foo..' /></text>
          </act>
2945 </sourceOf>
        <!--
      </act>
    </entry>

```

**5.1.9.2 <act classCode='ACT' moodCode='EVN'>**

2950 The external reference is an act that refers to documentation of an <act> (classCode='ACT'), that previously occurred (moodCode='EVN').

**5.1.9.3 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.4' />**

2955 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'.

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

2960 The reference is an act of itself, and must be uniquely identified. If there is no explicit identifier for this act in the source EMR system, a GUID may be used for the root attribute, and the extension may be omitted. Although HL7 allows for multiple identifiers, this profile requires that one and only one be used.

**5.1.9.5 <code nullFlavor='NA' />**

The reference act has no code associated with it.

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

2965 In order to connect this external reference to the narrative text which it refers, the value of the <reference> element in the <text> element is a URI to an element in the CDA narrative of this document.

---

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

2970 External references are listed as either supporting documentation (typeCode='SPRT') or  
simply reference material (typeCode='REFR') for the reader. If this distinction is not  
supported by the source EMR system, the value of typeCode should be REFR. For CDA,  
the reference is indicated by a <reference> element containing an <externalDocument>  
2975 element which documents (classCode='DOC') the event (moodCode='EVN'). For HL7  
Version 3 Messages, the reference is represented with the element <sourceOf> and the  
external document is represented with a <act> element, however semantics, and  
attributes remain otherwise without change.

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

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

### 5.1.9.9 <text><reference value=' '/></text>

2980 A link to the original document may be provided here. This shall be a URL where the  
referenced document can be located. For CDA, the link should also be present in the  
narrative inside the CDA Narrative in a <linkHTML> element.

### 5.1.10 Internal References 1.3.6.1.4.1.19376.1.5.3.1.4.4.1

2985 CDA and HL7 Version 3 Entries may reference (point to) information contained in other  
entries within the same document or message as shown below.

#### 5.1.10.1 Specification

```
2990 <entryRelationship typeCode='' inversionInd='true|false'>
      <act classCode='' moodCode=''>
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.4.1' />
        <id root='' extension='' />
        <code code='' displayName='' codeSystem='' codeSystemName='' />
      </act>
    </entryRelationship>
```

2995

#### 5.1.10.2 <entryRelationship typeCode=' ' inversionInd='true|false'>

3000 For CDA the act being referenced appears inside a related entryRelationship. The type  
(typeCode) and direction (inversionInd) attributes will be specified in the entry content  
module that contains the reference. For HL7 Version 3 Messages, the relationship is  
indicated with a <sourceOf> element, however typeCodes and semantics remain  
unchanged.

#### 5.1.10.3 <act classCode=' ' moodCode=' '>

The act being referred to can be any CDA Clinical Statement element type (act,  
procedure, observation, substanceAdministration, supply, et cetera). For compatibility

3005 with the Clinical Statement model the internal reference shall always use the <act> class, regardless of the XML element type of the act it refers to.

**5.1.10.4 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.4.1' />**

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

3010 **5.1.10.5 <id root=' ' extension=' ' />**

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

**5.1.10.6 <code code=' ' displayName=' ' codeSystem=' ' codeSystemName=' ' />**

3015 This element shall be present. It shall be valued when the internal reference is to element that has a <code> element, and shall have the same attributes as the <code> element in the act it references. If the element it references does not have a <code> element, then the nullFlavor attribute should be set to "NA".

**5.1.11 Concern Entry 1.3.6.1.4.1.19376.1.5.3.1.4.5.1**

3020 This event (moodCode='EVN') represents an act (<act classCode='ACT') of being concerned about a problem, allergy or other issue. The <effectiveTime> element describes the period of concern. The subject of concern is one or more observations about related problems (see [1.3.6.1.4.1.19376.1.5.3.1.4.5.2](#)) or allergies and intolerances (see [1.3.6.1.4.1.19376.1.5.3.1.4.5.3](#)). Additional references can be provided having additional

3025 information related to the concern. The concern entry allows related acts to be grouped. This allows representing the history of a problem as a series of observation over time, for example.

**5.1.11.1 Standards**

|                   |   |
|-------------------|---|
| <b>CCD</b>        | <a href="#">ASTM/HL7 Continuity of Care Document</a>      |
| <b>CareStruct</b> | <a href="#">HL7 Care Provision Care Structures (DSTU)</a> |
| <b>ClinStat</b>   | ClinStat HL7 Clinical Statement (DRAFT)                   |

**5.1.11.2 Specification**

3030

3035

3040

3045

3050

3055

3060

```

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

```

**5.1.11.3 <act classCode='ACT' moodCode='EVN'>**

3065

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.

**5.1.11.4 <templateId root='2.16.840.1.113883.10.20.1.27' />  
<templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.1' />**

3070

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

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

This required element identifies the concern.

**5.1.11.6 <code nullFlavor='NA' />**

3075

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

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

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

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

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

Table 5.1-2

**5.1.11.8 <effectiveTime><low value=' '/><high value=' '/></effectiveTime>**

3080 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.

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

3085 Each concern is about one or more related problems or allergies. This entry shall contain one or more problem or allergy entries that conform to the specification in section [Problem Entry](#) or [Allergies and Intolerances](#). This is how a series of related observations can be grouped as a single concern.

3090 For CDA this SHALL be represented with the <entryRelationship> element. For HL7 Version 3 Messages, this SHALL be represented as a <sourceOf> element. The typeCode SHALL be 'SUBJ' for both HL7 Version 3 and CDA. HL7 Version 3 additionally requires that inversionInd SHALL be 'false'.

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

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

3095 Each concern may have 0 or more related references. These may be used to represent related statements such related visits. This may be any valid CDA clinical statement, and SHOULD be an IHE entry template. For CDA this SHALL be represented with the <entryRelationship> element. For HL7 Version 3 Messages, this SHALL be represented

3100

as a <subjectOf> element. The typeCode SHALL be ‘SUBJ’ and inversionInd SHALL be ‘false’

### 5.1.12 Problem Concern Entry 1.3.6.1.4.1.19376.1.5.3.1.4.5.2

3105 This entry is a specialization of the Concern Entry, wherein the subject of the concern is focused on a problem. Elements shown in the example below in gray are explained in the [Concern Entry](#).

#### 5.1.12.1 Standards

|                   |   |
|-------------------|---|
| <b>CCD</b>        | <a href="#">ASTM/HL7 Continuity of Care Document</a>      |
| <b>CareStruct</b> | <a href="#">HL7 Care Provision Care Structures (DSTU)</a> |
| <b>ClinStat</b>   | <a href="#">HL7 Clinical Statement Pattern (Draft)</a>    |

#### 5.1.12.2 Parent Template

3110 The parent of this template is [Concern Entry](#). This template is compatible with the ASTM/HL7 Continuity of Care Document template: 2.16.840.1.113883.10.20.1.27

#### 5.1.12.3 Specification

```

3115 <act classCode='ACT' moodCode='EVN'>
  <templateId root='2.16.840.1.113883.10.20.1.27' />
  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.1' />
  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.2' />
  <id root=' ' extension=' ' />
  <code nullFlavor='NA' />
  <statusCode code='active|suspended|aborted|completed' />
3120 <effectiveTime>
  <low value=' ' />
  <high value=' ' />
</effectiveTime>
  <!-- 1..* entry relationships identifying problems of concern -->
3125 <entryRelationship type='SUBJ'>
  <observation classCode='OBS' moodCode='EVN' />
  <templateID root='1.3.6.1.4.1.19376.1.5.3.1.4.5'>
  :
  </observation>
  </entryRelationship>
3130 <!-- optional entry relationship providing more information about the concern
-->
  <entryRelationship type='REFR'>
  </entryRelationship>
</act>

```

3135

#### 5.1.12.4 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.1' /> <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.2' />

This entry has a template identifier of 1.3.6.1.4.1.19376.1.5.3.1.4.5.2, and is a subtype of the [Concern Entry](#), and so must also conform to that specification, with the template

3140 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.

**5.1.12.5 <!-- 1..\* entry relationships identifying problems of concern -->**

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

**<templateID root=' 1.3.6.1.4.1.19376.1.5.3.1.4.5'/'>**

3145

...

**</observation>**

**<entryRelationship type='SUBJ'>**

3150 This entry shall contain one or more problem entries that conform to the [Problem Entry](#) template 1.3.6.1.4.1.19376.1.5.3.1.4.5. For CDA this SHALL be represented with the <entryRelationship> element. For HL7 Version 3 Messages, this SHALL be represented as a <subjectOf> element. The typeCode SHALL be 'SUBJ' and inversionInd SHALL be 'false'

**5.1.13 Allergy and Intolerance Concern 1.3.6.1.4.1.19376.1.5.3.1.4.5.3**

3155 This entry is a specialization of the [Concern Entry](#), wherein the subject of the concern is focused on an allergy or intolerance. Elements shown in the example below in gray are explained in that entry.

**5.1.13.1 Standards**

CCD [ASTM/HL7 Continuity of Care Document](#)

CareStruct [HL7 Care Provision Care Structures \(DSTU\)](#)

ClinStat [HL7 Clinical Statement Pattern \(Draft\)](#)

**5.1.13.2 Parent Template**

3160 The parent of this template is [Concern Entry](#). This template is compatible with the ASTM/HL7 Continuity of Care Document template: 2.16.840.1.113883.10.20.1.27



**5.1.13.3 Specification**

```

3165 <act classCode='ACT' moodCode='EVN'>
    <templateId root='2.16.840.1.113883.10.20.1.27' />
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.1' />
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.3' />
    <id root=' ' extension=' ' />
    <code nullFlavor='NA' />
3170 <statusCode code='active|suspended|aborted|completed' />
    <effectiveTime>
        <low value=' ' />
        <high value=' ' />
    </effectiveTime>
3175 <!-- 1..* entry relationships identifying allergies of concern -->
    <entryRelationship type='SUBJ'>
        <observation classCode='OBS' moodCode='EVN' />
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.6' />
        :
    </observation>
3180 </entryRelationship>
    <!-- optional entry relationship providing more information about the concern
    -->
    <entryRelationship type='REFR'>
    </entryRelationship>
3185 </act>

```

**5.1.13.4 <templateId root='2.16.840.1.113883.10.20.1.27' />  
 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.1' />  
 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5.3' />**

3190 This entry has a template identifier of 1.3.6.1.4.1.19376.1.5.3.1.4.5.3, and is a subtype of the Concern entry, and so must also conform to the rules of the [Concern Entry](#). These elements are required and shall be recorded exactly as shown above.

**5.1.13.5 <!-- 1..\* entry relationships identifying allergies of concern -->**

```

3195 <observation classCode='OBS' moodCode='EVN' />
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.6' />
    :
    </observation>
    <entryRelationship type='SUBJ'>

```

3200 This entry shall contain one or more allergy or intolerance entries that conform to the [Allergy and Intolerance Entry](#). For CDA this SHALL be represented with the <entryRelationship> element. For HL7 Version 3 Messages, this SHALL be represented as a <sourceOf> element. The typeCode SHALL be 'SUBJ' and inversionInd SHALL be 'false'

**5.1.14 Problem Entry 1.3.6.1.4.1.19376.1.5.3.1.4.5**

3205 This section makes use of the linking, severity, clinical status and comment content specifications defined elsewhere in the technical framework. In HL7 RIM parlance, observations about a problem, complaint, symptom, finding, diagnosis, or functional

3210 limitation of a patient is the event (moodCode='EVN') of observing (<observation classCode='OBS'>) that problem. The <value> of the observation comes from a controlled vocabulary representing such things. The <code> contained within the <observation> describes the method of determination from yet another controlled vocabulary. An example appears below in the figure below.

#### 5.1.14.1 Standards

|            |   |
|------------|---|
| CCD        | <a href="#">ASTM/HL7 Continuity of Care Document</a>      |
| CareStruct | <a href="#">HL7 Care Provision Care Structures (DSTU)</a> |
| ClinStat   | <a href="#">HL7 Clinical Statement Pattern (Draft)</a>    |

#### 5.1.14.2 Parent Template

3215 This template is compatible with the ASTM/HL7 Continuity of Care Document template: 2.16.840.1.113883.10.20.1.28

#### 5.1.14.3 Specification

```

3220 <observation classCode='OBS' moodCode='EVN' negationInd=' false|true '>
    <templateId root='2.16.840.1.113883.10.20.1.28' />
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5' />
    <id root=' ' extension=' ' />
    <code code=' ' displayName=' '
3225     codeSystem='2.16.840.1.113883.6.96' codeSystemName='SNOMED CT' />
    <statusCode code='completed' />
    <effectiveTime><low value=' ' /><high value=' ' /></effectiveTime>
    <value xsi:type='CD' code=' '
3230     codeSystem=' ' displayName=' ' codeSystemName=' '
        <originalText><reference value=' ' /></originalText>
    </value>
    <
3235     <!-- zero or one <entryRelationship typeCode='REFR' inversionInd='false'>
        elements
            identifying the health status of concern -->
     <!-- zero or one <entryRelationship typeCode='REFR' inversionInd='false'>
        elements
            containing clinical status -->
3240     <!-- zero to many <entryRelationship typeCode='REFR' inversionInd='true'>
        elements
            containing comments -->
    </observation>

```

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

3245 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

3250 is "no prior history of chicken pox", one would use a coded value indicated exactly that. However, it is not always possible to record problems in this manner, especially if using a controlled vocabulary that does not supply pre-coordinated negations, or which do not allow the negation to be recorded with post-coordinated coded terminology.

3255 **5.1.14.5 <templateId root='2.16.840.1.113883.10.20.1.28'/>  
<templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5'/>**

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

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

3260 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 HL7 Version 3 allows for more than one identifier element to be provided, this profile requires that only one be used.

3265 **5.1.14.7 <code code=' ' displayName=' '  
codeSystem='2.16.840.1.113883.6.96' codeSystemName='SNOMED  
CT'/>**

3270 The <code> describes the process of establishing a problem. The code element should be used, as the process of determining the value is important to clinicians (e.g., a diagnosis is a more advanced statement than a symptom). The recommended vocabulary for describing problems is shown in the table below. Subclasses of this content module may specify other vocabularies. When the list below is used, the codeSystem is '2.16.840.1.113883.6.96' and codeSystemName is SNOMED CT.

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

---

**3275 5.1.14.8 <statusCode code='completed'/>**

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

**5.1.14.9 <effectiveTime><low value=' '/><high value=' '/></effectiveTime>**

3280 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 HL7 Version 3 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 this to use only the low/high  
3285 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  
3290 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  
3295 present. There are exceptions, such as for the case where the patient may be able to report  
that they had chicken pox, but are unsure when. In this case, the <effectiveTime> element  
shall have a <low> element with a nullFlavor attribute set to 'UNK'. The <high> value  
need not be present when the observation is about a state of the patient that is unlikely to  
change (e.g., the diagnosis of an incurable disease).

**3300 5.1.14.10 <confidentialityCode code=' '/>**

While CDA allows for a condition to specify a <confidentialityCode> 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  
3305 should be negotiated within the affinity domain.

**5.1.14.11 <uncertaintyCode code=' '/>**

CDA allows a condition to be specified with an <uncertaintyCode>. Such conditions can  
also be recorded as a possible condition (e.g. possible ear infection). There is no present  
consensus on the best use of this element; therefore, it is recommended that this element  
3310 not be sent.

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

3315 The <value> is the condition that was found. This element is required. While the value may be a coded or an un-coded string, the type is always a coded value (xsi:type='CD'). If coded, the code and codeSystem attributes shall be present. The codeSystem should reference a controlled vocabulary describing problems, complaints, symptoms, findings, diagnoses, or functional limitations, e.g., ICD-9, SNOMED-CT or MEDCIN, or others. The table below is an incomplete listing of acceptable values for the codeSystem attribute, along with the codeSystemName.

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

3320 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.

**5.1.14.13 <originalText><reference value=' ' /></originalText>**

3325 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.

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

3330 An optional <entryRelationship> element may be present indicating the severity of the problem. When present, this <entryRelationship> element shall contain a severity observation conforming to the [Severity](#) entry template (1.3.6.1.4.1.19376.1.5.3.1.4.1).

3335 For CDA this SHALL be represented with the <entryRelationship> element. For HL7 Version 3 Messages, this SHALL be represented as a <subjectOf> element. The typeCode SHALL be 'SUBJ' and inversionInd SHALL be 'true'.

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

3340 An optional <entryRelationship> may be present indicating the clinical status of the problem, e.g., resolved, in remission, active. When present, this <entryRelationship> element shall contain a clinical status observation conforming to the Problem Status Observation template (1.3.6.1.4.1.19376.1.5.3.1.4.1.1).

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

3345 **5.1.14.16 <!-- zero or one <entryRelationship typeCode='REFR' inversionInd='false'> elements identifying the health status of concern -->**

3350 An optional <entryRelationship> may be present referencing the health status of the patient, e.g., resolved, in remission, active. When present, this <entryRelationship> element shall contain a clinical status observation conforming to the [Health Status Observation](#) template (1.3.6.1.4.1.19376.1.5.3.1.4.1.1). The typeCode SHALL be 'REFR' and inversionInd SHALL be 'false'. For CDA this SHALL be represented with the <entryRelationship> element. For HL7 Version 3 Messages, this SHALL be represented as a <sourceOf> element.

3355 **5.1.14.17 <!-- zero to many <entryRelationship typeCode='SUBJ' inversionInd='true'> element containing comments -->**

3360 One or more optional <entryRelationship> elements may be present providing an additional comments (annotations) for the condition. When present, this <entryRelationship> element shall contain a comment observation conforming to the [Comment](#) entry template (1.3.6.1.4.1.19376.1.5.3.1.4.2). The typeCode SHALL be 'SUBJ' and inversionInd SHALL be 'true'. For CDA this SHALL be represented with the <entryRelationship> element. For HL7 Version 3 Messages, this SHALL be represented as a <sourceOf> element.

**5.1.15 Allergies and Intolerances 1.3.6.1.4.1.19376.1.5.3.1.4.6**

3365 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.

**5.1.15.1 Standards**

|                   |   |
|-------------------|---|
| <b>CCD</b>        | <a href="#">ASTM/HL7 Continuity of Care Document</a>      |
| <b>CareStruct</b> | <a href="#">HL7 Care Provision Care Structures (DSTU)</a> |
| <b>ClinStat</b>   | <a href="#">HL7 Clinical Statement Pattern (Draft)</a>    |

**5.1.15.2 Specification**

```

3370 <observation classCode='OBS' moodCode='EVN' negationInd='false'>
      <templateId root='2.16.840.1.113883.10.20.1.18' />
      <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.6' />
3375 <id root=' ' extension=' ' />
      <code
        code='ALG|OINT|DALG|EALG|FALG|DINT|EINT|FINT|DNAINT|ENAIN|FNAINT'
        codeSystem='2.16.840.1.113883.5.4'
        codeSystemName='ObservationIntoleranceType' />
3380 <statusCode code='completed' />
      <effectiveTime>
        <low value=' ' />
        <high value=' ' />
      </effectiveTime>
3385 <value xsi:type='CD' code=' ' codeSystem=' ' displayName=' ' codeSystemName='
      ' />
      <participant typeCode='CSM'>
        <participantRole classCode='MANU'>
          <playingEntity classCode='MMAT'>
3390 <code code=' ' codeSystem=' '>
            <originalText><reference value='#substance' /></originalText>
            </code>
            <name></name>
          </playingEntity>
        </participantRole>
3395 </participant>
      <!-- zero to many <entryRelationship> elements containing reactions -->
      <!-- zero or one <entryRelationship> elements containing severity -->
      <!-- zero or one <entryRelationship> elements containing clinical status -->
3400 <!-- zero to many <entryRelationship> elements containing comments -->
    </observation>

```

**5.1.15.3 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5' />  
 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.6' />**

3405 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.

**5.1.15.4 <code**

```

3410 <code='ALG|OINT|DINT|EINT|FINT|DALG|EALG|FALG|DNAINT|ENAIN
      T|FNAINT' displayName=' ' codeSystem='2.16.840.1.113883.5.4'
      codeSystemName='ObservationIntoleranceType' />

```

3415 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.

3420 **5.1.15.5 <value xsi:type='CD' code=' ' codeSystem=' ' codeSystemName=' ' displayName=' ' >**

3425 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. 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.

3430 **5.1.15.6 <participant typeCode='CSM'>  
<participantRole classCode='MANU'>  
<playingEntity classCode='MMAT'>**

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

3435 **5.1.15.7 <code code=' ' codeSystem=' ' >  
<originalText><reference value=' ' /></originalText>  
</code>**

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

3440 **5.1.15.8 <!-- zero to many <entryRelationship> elements containing reactions -->**

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

3445

```

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

```

3450

3455 **5.1.15.9 <entryRelationship typeCode='MFST'>**

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



3460 **5.1.15.10 <observation classCode='OBS' moodCode='EVN'>**  
**<templateId root='2.16.840.1.113883.10.20.1.54'/>**  
**<templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.5'/>**  
**</observation>**

3465 The entry contained with this entry relationship is some sort of problem that is a manifestation of the allergy. It is recorded using the [Problem Entry](#) structure, with the additional template identifier (2.16.840.1.113883.10.20.1.54) indicating that this problem is a reaction.

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

3470 An optional <entryRelationship> element may be present indicating the severity of the problem. When present, this <entryRelationship> element shall contain a severity observation conforming to the [Severity](#) entry template (1.3.6.1.4.1.19376.1.5.3.1.4.1). For CDA this SHALL be represented with the <entryRelationship> element. For HL7  
 3475 Version 3 Messages, this SHALL be represented as a <sourceOf> element. The typeCode SHALL be 'SUBJ' and inversionInd SHALL be 'true'.

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

3480 An optional <entryRelationship> may be present indicating the clinical status of the allergy, e.g., resolved, in remission, active. When present, this <entryRelationship> element shall contain a clinical status observation conforming to the [Problem Status Observation](#) template (1.3.6.1.4.1.19376.1.5.3.1.4.1.1). The typeCode SHALL be 'REFR' and inversionInd SHALL be 'false'. For CDA this SHALL be represented with the <entryRelationship> element. For HL7 Version 3 Messages, this SHALL be represented as a <sourceOf> element.

3485 **5.1.15.13 <!-- zero to many <entryRelationship typeCode='SUBJ' inversionInd='true'> element containing comments -->**

One or more optional <entryRelationship> elements may be present providing an additional comments (annotations) for the allergy. When present, this  
 3490 <entryRelationship> element shall contain an entry conforming to the [Comment](#) entry template (1.3.6.1.4.1.19376.1.5.3.1.4.2). The typeCode SHALL be 'SUBJ' and inversionInd SHALL be 'true'. For CDA this SHALL be represented with the <entryRelationship> element. For HL7 Version 3 Messages, this SHALL be represented as a <sourceOf> element.

**5.1.16 Medications 1.3.6.1.4.1.19376.1.5.3.1.4.7**

3495 This content module describes the general structure for a medication. All medication administration acts will be derived from this content module.

**5.1.16.1 Standards**

Pharmacy HL7 Pharmacy Domain (Normative)

CCD [ASTM/HL7 Continuity of Care Document](#)**5.1.16.2 Specification**

```

3500 <substanceAdministration classCode='SBADM' moodCode='INT|EVN'>
      <templateId root='2.16.840.1.113883.10.20.1.24' />
      <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7' />
3505 <templateId root='' />
      <id root='' extension='' />
      <code code='' codeSystem='' displayName='' codeSystemName='' />
      <text><reference value='#med-1' /></text>
      <statusCode code='completed' />
      <effectiveTime xsi:type='IVL_TS'>
3510   <low value='' />
   <high value='' />
      </effectiveTime>
      <effectiveTime operator='A'
3515   xsi:type='TS|PIVL_TS|EIVL_TS|PIVL_PPD_TS|SXPR_TS'>
      :
      </effectiveTime>
      <routeCode code='' codeSystem='' displayName='' codeSystemName=''>
      <doseQuantity value='' unit='' />
3520 <approachSiteCode code='' codeSystem='' displayName='' codeSystemName=''>
      <rateQuantity value='' unit='' />
      <consumable>
      :
      .
      </consumable>
3525 <!-- 0..* entries describing the components -->
      <entryRelationship typeCode='COMP' >
        <sequenceNumber value='' />
      </entryRelationship>
      <!-- An optional entry relationship that indicates the the reason for use -->
3530 <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='' />
3535 </act>
      </entryRelationship>
      <!-- An optional entry relationship that provides prescription activity -->
      <entryRelationship typeCode='REFR'>
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7.3' />
3540 :
      .
      </entryRelationship>
      <precondition>
        <criterion>
3545   <text><reference value=''></text>
        </criterion>
      </precondition>
    </substanceAdministation>

```

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

3550 Medications are perhaps the most difficult data elements to model due to variations in the ways that medications are prescribed. This profile identifies the following relevant fields of a medication as being important to be able to generate in a medical summary. The table below identifies and describes these fields, and indicates the constraints on whether or not they are required to be sent. The fields are listed in the order that they appear in the CDA XML content.

3555

### 5.1.16.2.1 Medication Fields

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

### 5.1.16.3 <substanceAdministration classCode='SBADM' moodCode='INT|EVN'>

3560 The general model is to record each prescribed medication in a <substanceAdministration> intent (moodCode='INT'). Medications that have been reported by the patient or administered (instead of prescribed), are recorded in the same element, except that this is now an event (moodCode='EVN'). The <substanceAdministration> element may contain subordinate <substanceAdministration> elements in a related component entry to deal with special cases (see the section below on

3565 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.

3570 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.

#### 5.1.16.3.1 Normal Dosing 1.3.6.1.4.1.19376.1.5.3.1.4.7.1

3575 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 <substanceAdministration> acts.

#### 5.1.16.3.2 Tapered Doses 1.3.6.1.4.1.19376.1.5.3.1.4.8

3580 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.

- 3585 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  
3590 created for each distinct dosage.

#### **5.1.16.3.3 Split Dosing 1.3.6.1.4.1.19376.1.5.3.1.4.9**

This template identifier is used to identify medication administration events that require special processing to handle split dosing. The parent template is  
3595 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).

- 3600 In this case a subordinate <substanceAdministration> entry is required for each separate dosage.

#### **5.1.16.3.4 Conditional Dosing 1.3.6.1.4.1.19376.1.5.3.1.4.10**

This template identifier is used to identify medication administration events that require special processing to handle conditional dosing. The parent template is  
3605 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.

#### **5.1.16.3.5 Combination Medications 1.3.6.1.4.1.19376.1.5.3.1.4.11**

- 3610 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.

- 3615 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 <substanceAdministration> entry. The dosing information should then be recorded as simply a count of administration units.

- 3620 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.

**5.1.16.4 <templateId root='2.16.840.1.113883.10.20.1.24'/>  
<templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7' />**

3625 All medication entries use the <templateId> elements specified above to indicate that they are medication acts. This element is required. In addition, a medication entry shall further identify itself using one of the template identifiers detailed in the next section.

**5.1.16.5 <templateId root=' ' />**

3630 The <templateId> element identifies this <entry> as a particular type of medication event, allowing for validation of the content. As a side effect, readers of the CDA can quickly locate and identify medication events. The templateId must use one of the values in the table below for the root attribute.

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

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

3635 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.

**5.1.16.7 <code code=' ' displayName=' ' codeSystem=' '  
codeSystemName=' ' />**

3640 Do NOT code the medication here. This <code> element is used to supply a code that describes the <substanceAdministration> act, not the medication being administered or prescribed. This may be a procedure code, such as those found in CPT-4 (and often used for billing), or may describe the method of medication administration, such as by  
3645 intravenous injection. This element is optional.

**5.1.16.8 <text><reference value=' '/></text>**

3650 The URI given in the value attribute of the <reference> element points to an element in the narrative content that contains the complete text describing the medication. In a CDA document, the URI given in the value attribute of the <reference> element points to an element in the narrative content that contains the complete text describing the medication. In an HL7 message, the content of the text element shall contain the complete text describing the medication.

**5.1.16.9 <statusCode code='completed'/>**

3655 The status of all <substanceAdministration> elements must be "completed". The act has either occurred, or the request or order has been placed.

**5.1.16.10 <effectiveTime xsi:type='IVL\_TS'>**

3660 The first <effectiveTime> element encodes the start and stop time of the medication regimen. This is 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.

**5.1.16.11 <low value=' '/><high value=' '/>**

3665 The <low> and <high> values of the first <effectiveTime> element represent the start and stop times for the medication. The <low> value represents the start time, and the <high> value represents the stop time. If either the <low> or the <high> value is unknown, this shall be recorded by setting the nullFlavor attribute to UNK. The <high> value records the end of the medication regime according to the information provided in the prescription or order. For example, if the prescription is for enough medication to last 30 days, then the high value should contain a date that is 30 days later than 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.

3670

**5.1.16.12 <effectiveTime operator='A' xsi:type='TS|PIVL\_TS|EIVL\_TS|PIVL\_PPD\_TS|SXPR\_TS' />**

3675 The second <effectiveTime> element records the frequency of administration. This <effectiveTime> element must be intersected with the previous time specification (operator='A'), producing the bounded set containing only those time specifications that fall within the start and stop time of the medication regimen. Several common frequency expressions appear in the table below, along with their XML representations.

### 5.1.16.12.1 Specifying Medication Frequency

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

- 3680 The last frequency specification is about as bad as it gets, but can still be represented accurately within the HL7 V3 datatypes. The mean (average) of the low and high values is specified for the period. The mean of 4 and 6 is 5. The standard deviation is recorded as one half the difference between the high and low values, with an unspecified distribution. The type attribute of the <effectiveTime> element describes the kind of
- 3685 frequency specification it contains. More detail is given for each type in the table below.

### 5.1.16.12.2 Data types used in Frequency Specifications

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



|             |   |
|-------------|---|
|             | from the specified event (e.g., <offset><low value='-1' unit='h'/><width value='10' unit='min'/></offset> means 1 hour before the event. In that same example, the <width> element indicates the duration for the dose to be given.   |
| PIVL_PPD_TS | An xsi:type of PIVL_PPD_TS represents an probabilistic time interval and is used to represent dosing frequencies like q4-6h. This profile requires that the distributionType of this interval be left unspecified. The <period> element specifies the average of the time interval, and the value of the <standardDeviation> shall be computed as half the width of the interval. The unit attributes of the <period> and <standardDeviation> elements shall be the same. |
| SXPR_TS     | An xsi:type of SXPR_TS represents a parenthetical set of time expressions. This type is used when the frequency varies over time (e.g., for some cases of tapered dosing, or to handle split dosing). The <comp> elements of this <effectiveTime> element are themselves time expressions (using any of the types listed above). Each <comp> element may specify an operator (e.g. to intersect or form the union of two sets).   |

**5.1.16.13 <routeCode code=' ' displayName=' ' codeSystem='2.16.840.1.113883.5.112' codeSystemName='RouteOfAdministration'>**

3690 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.

**5.1.16.14 <approachSiteCode code=' ' codeSystem=' ' originalText><reference value=' '/></originalText></approachSiteCode>**

3695

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

3700

**5.1.16.15 <doseQuantity> <low value=' ' unit=' '/><high value=' ' unit=' '/></doseQuantity>**

3705 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 .

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

3710

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

3715 elements used for <doseQuantity> or <rateQuantity> should contain a <translation>  
element that provides a <reference> to the <originalText> found in the narrative body of  
the document. In a message, the <originalText> may contain the original text used to  
describe dose quantity.

3720 **5.1.16.17 <rateQuantity><low value=' ' unit=' '/><high value=' '  
unit=' '/></rateQuantity>**

The rate is specified in the <rateQuantity> element. The rate is given in units that have  
measure over time. In this case, the units should be specified as a string made up of a unit  
of measure (see doseQuantity above), followed by a slash (/), followed by a time unit (s,  
min, h or d). Again, if a range is given, then the <low> and <high> elements contain the  
3725 lower and upper bound of the range, otherwise, they contain the same value.

**5.1.16.18 <consumable>**

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

3730 **5.1.16.19 <entryRelationship typeCode='REFR'>  
&nbsp;   <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7.3'>**

The top level <substanceAdministration> element may contain a reference  
(typeCode='REFR') to related prescription activity as described in section 5.1.18 below.

**5.1.16.20 <entryRelationship typeCode='COMP'>  
    <sequenceNumber value=' '>**

3735 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  
3740 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.

**5.1.16.21 <entryRelationship typeCode='SUBJ' inversionInd='true'>**

3745 At most one instruction may be provided for each <substanceAdministration> entry. If  
provided, it shall conform to the requirements listed above under section 5.1.7 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).

3750 **5.1.16.22 <entryRelationship typeCode='RSON'>  
    <act classCode='ACT' moodCode='EVN'>**

---

```

    <templated root='1.3.6.1.4.1.19376.1.5.3.1.4.4.1' />
    <id root=' ' extension=' ' />
    </act>
3755 </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 5.1.10.

3760 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.

```

5.1.16.23 <precondition><critereion>
    <text><reference value=' ' /></text>
3765 </critereion></precondition>

```

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

```

5.1.16.24 <condition typeCode='PRCN'>
3770   <critereion>
    <text></text>
    <value nullFlavor='UNK' />
    <interpretationCode nullFlavor='UNK' />
    </critereion>
3775 </condition>

```

3780 In a message, the preconditions for use of the medication are recorded in the <condition> element. The typeCode shall be PRCN. The <text> element of the critereion shall contain a text description of the precondition. The <value> element is required, and may be recorded in a structured data type if known, and if not, may be recorded using a nullFlavor as shown above. The same is true for <interpretationCode>.

### **5.1.17 Immunizations 1.3.6.1.4.1.19376.1.5.3.1.4.12**

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

## 5.1.17.1 Specification

```

3785 <substanceAdministration typeCode='SBADM' moodCode='EVN'
negationInd='true{{!}}false'>
  <templateId root='2.16.840.1.113883.10.20.1.24' />
  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.12' />
3790
  <id root='' extension='' />
  <code code='IMMUNIZ' codeSystem='2.16.840.1.113883.5.4'
codeSystemName='ActCode' />
  <text><reference value='#xxx' /><text>
3795  <statusCode code='completed' />
  <effectiveTime value='' />
  <!-- The reasonCode would normally provide a reason why the immunization was
not performed. It isn't supported by CDA R2, and so comments will have to
suffice.
3800  <reasonCode code='' codeSystem=''
codeSystemName='ActNoImmunizationReasonIndicator' />
  -->
  <routeCode code='' codeSystem='' codeSystemName='RouteOfAdministration' />
  <approachSiteCode code='' codeSystem=''
codeSystemName='HumanSubstanceAdministrationSite' />
3805  <doseQuantity value='' units='' />
  <consumable typeCode='CSM'>
    <manufacturedProduct classCode='MANU'>
      <manufacturedLabeledDrug classCode='MMAT' determinerCode='KIND'>
3810        <code code='' codeSystem='' codeSystemName=''>
          <originalText><reference value='#yyy' /></originalText>
        </code>
      </manufacturedLabeledDrug>
    </manufacturedProduct>
  </consumable>
3815  <!-- An optional entry relationship that provides prescription activity -->
  <entryRelationship typeCode='REFR'>
    <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7.3' />
    :
    .
3820  </entryRelationship>
  <!-- An optional entry relationship that identifies the immunization series
number -->
  <entryRelationship typeCode='SUBJ'>
    <observation typeCode='OBS' moodCode='EVN'>
3825    <templateId root='2.16.840.1.113883.10.20.1.46' />
    <code code='30973-2' displayName='Dose Number'
codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC' />
    <statusCode code='completed' />
    <value xsi:type='INT' value='' />
3830    </observation>
  </entryRelationship>

  <entryRelationship inversionInd='true' typeCode='CAUS'>
    <observation typeCode='OBS' moodCode='EVN'>
3835    <id root='' extension='' />
    </observation>
  </entryRelationship>
  <!-- Optional <entryRelationship> element containing comments -->
</substanceAdministration>
3840

```

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

3845 An immunization is a substance administration event. An immunization entry may be a record of why a specific immunization was not performed. In this case, negationInd shall be set to "true", otherwise, it shall be false.

**5.1.17.3 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.12'>**

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

3850 **5.1.17.4 <id root=' ' extension=' ' />**

This shall be the identifier for the immunization event.

**5.1.17.5 <code code='IMMUNIZ' codeSystem='2.16.840.1.113883.5.4' codeSystemName='ActCode' />**

3855 This required element records that the act was an immunization. The substance administration act must have a <code> element with code and codeSystem attributes present. If no coding system is used by the source, then simply record the code exactly as shown above. Another coding system that may be used for codes for immunizations are the CPT-4 codes for immunization procedures. This <code> element shall not be used to record the type of vaccine used from a vocabulary of drug names.

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

3860 **5.1.17.6 <text><reference value='#xxx' /><text>**

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

3865 **5.1.17.7 <statusCode code='completed' />**

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

**5.1.17.8 <effectiveTime value=' ' />**

3870 The effectiveTime element shall be present and should contain a time value that indicates the date of the substance administration. If the date is unknown, this shall be recorded using the nullFlavor attribute, with the reason that the information is unknown being specified. Otherwise, the date shall be recorded, and should have precision of at least the day.

**5.1.17.9 <routeCode code=' ' codeSystem=' '  
codeSystemName='RouteOfAdministration'/>**

3875 See [routeCode](#) under Medications.

**5.1.17.10 <approachSiteCode code=' ' codeSystem=' '  
codeSystemName='HumanSubstanceAdministrationSite'/>**

See [approachSiteCode](#) under Medications.

**5.1.17.11 <doseQuantity value=' ' units=' '/>**

3880 See [doseQuantity](#) under Medications.

**5.1.17.12 <consumable typeCode='CSM'/>**

See [consumable](#) under Medications.

**5.1.17.13 <entryRelationship typeCode='REFR'>  
<templated root='1.3.6.1.4.1.19376.1.5.3.1.4.7.3'/>**

3885 The top level <substanceAdministration> element may contain a reference (typeCode='REFR') to related [Supply entry](#)

**5.1.17.14 <entryRelationship typeCode='SUBJ'>  
<observation classCode='OBS' moodCode='EVN'>  
<templated root='2.16.840.1.113883.10.20.1.46'/>**

3890 This optional entry relationship may be present to indicate that position of this immunization in a series of immunizations.

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

3895 The <code> element shall be present and must be recorded with the code and codeSystem attributes shown above. This element indicates that the observation describes the dose number for the immunization.

**5.1.17.16 <statusCode code='completed'/>**

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

3900 **5.1.17.17 <value xsi:type='INT' value=' '/>**

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

**5.1.17.18 <entryRelationship inversionInd='true' typeCode='CAUS'>**

3905 This repeatable element should be used to identify adverse reactions caused by the immunization.

**5.1.17.19 <observation typeCode='OBS' moodCode='EVN'>**

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

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

3910 This element is required, and gives the identifier of the adverse reaction. The adverse reaction pointed to by this element shall be described in more detail using the Allergies entry, elsewhere in the document where this element was found.

**5.1.17.21 <!-- Optional <entryRelationship> element containing comments -->**

3915 An immunization entry can have negationInd set to true to indicate that an immunization did not occur. In this case, it shall have at least one comment that provides an explanation for why the immunization did not take place . Other comments may also be present.

**5.1.18 Supply Entry 1.3.6.1.4.1.19376.1.5.3.1.4.7.3**

3920 The supply entry describes a prescription activity.

**5.1.18.1 Specification**

```

3925 <substanceAdministration classCode='SBADM' moodCode='INT|EVN'>
      :
      .
      <entryRelationship type='REFR' inversionInd='false'>
3930 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7.3' />
      <sequenceNumber value='' />
      <supply classCode='SPLY' moodCode='INT|EVN'>
3935 <templateId root='2.16.840.1.113883.10.20.1.34' />
      <id root='' extension='' />
      <repeatNumber value='' />
      <quantity value='' unit='' />
      <author>
        <time value='' />
        <assignedAuthor>
          <id root='' extension='' />
          <addr></addr>
3940 <telecom use='' value='' />
          <assignedPerson><name></name></assignedPerson>
          <representedOrganization><name></name></representedOrganization>
        </assignedAuthor>
      </author>
3945 <performer typeCode='PRF'>
      <time value='' />
      <assignedEntity>
        <id root='' extension='' />
        <addr></addr>
3950 <telecom use='' value='' />
        <assignedPerson><name></name></assignedPerson>
        <representedOrganization><name></name></representedOrganization>
      </assignedEntity>
      </performer>
3955 <!-- Optional Fulfillment instructions -->
      <entryRelationship typeCode='SUBJ'>
      </entryRelationship>
    </supply>
  </entryRelationship>
3960 </substanceAdministration>

```

**5.1.18.2 <entryRelationship typeCode='REFR' inversionInd='false'>**

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

**5.1.18.3 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7.3' />**

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

**5.1.18.4 <sequenceNumber value=' '/>**

The prescription activity may have a <sequenceNumber> element to indicate the fill number. A value of 1, 2 or N indicates that it is the first, second, or Nth fill respectively



of a specific prescription. This element should be present when the embedded <supply> element has a moodCode attribute of EVN.

**5.1.18.5 <supply classCode='SPLY' moodCode='INT|EVN'>**

3975 The <supply> element shall be present. The moodCode attribute shall be INT to reflect that a medication has been prescribed, or EVN to indicate that the prescription has been filled.

**5.1.18.6 <templateId root='2.16.840.1.113883.10.20.1.34' />  
<templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7.3' />**

3980 The <templateId> elements shown above shall be present, and identify this supply act as a Supply Entry.

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

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

**5.1.18.8 <repeatNumber value=' ' />**

3985 Each supply entry should have a <repeatNumber> element that indicates the number of times the prescription can be filled.

**5.1.18.9 <quantity value=' ' unit=' ' />**

3990 The supply entry should indicate the quantity supplied. The value attribute shall be present and indicates the quantity of medication supplied. If the medication is supplied in dosing units (tablets or capsules), then the unit attribute need not be present (and should be set to 1 if present). Otherwise, the unit element shall be present to indicate the quantity (e.g., volume or mass) of medication supplied.

**5.1.18.10 <author>**

3995 A supply entry that describes an intent (<supply classCode='SPLY' moodCode='INT'>) may include an <author> element to identify the prescribing provider.

**5.1.18.11 <time value=' ' />**

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

4000 **5.1.18.12 <assignedAuthor>**

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

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

4005 One or more <id> elements should be present. These identifiers identify the author of the act. When the author is the prescribing physician they may include local identifiers or regional identifiers necessary for prescribing.

**5.1.18.14 <assignedPerson><name/></assignedPerson>  
<representedOrganization><name/></ representedOrganization>**

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

4010 **5.1.18.15 <performer typeCode='PRF'>**

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

**5.1.18.16 <time value=' '/>**

4015 The <time> element shall be present to indicate when the prescription was filled (moodCode='EVN'). If this information is unknown, it shall be recorded by setting the nullFlavor attribute to UNK.

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

**5.1.18.17 <assignedEntity>**

4020 The < assignedEntity> element shall be present, and identifies the filler of the prescription.

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

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

**5.1.18.19 <assignedPerson><name/></assignedPerson>  
<representedOrganization><name/></ representedOrganization>**

4025 An <assignedPerson> and/or <representedOrganization> element shall be present. This element shall contain a <name> element to identify the filler or their organization.

**5.1.18.20 <!-- Optional Fulfillment instructions -->  
<entryRelationship typeCode='SUBJ'>  
</entryRelationship>**

4030 An entry relationship may be present to provide the fulfillment instructions. When present, this entry relationship shall contain a [Medication Fulfillment Instructions](#) entry.

**5.1.19 Product Entry 1.3.6.1.4.1.19376.1.5.3.1.4.7.2**

4035 The product entry describes a medication or immunization used in a  
 <substanceAdministration> or <supply> act. It adopts the constraints of the ASTM/HL7  
 Continuity of Care Document.

**5.1.19.1 Specification**

```

4040 <!-- Within a CDA Document -->
      <manufacturedProduct>
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7.2' />
        <templateId root='2.16.840.1.113883.10.20.1.53' />
        <manufacturedMaterial>
4045   <code code='' displayName='' codeSystem='' codeSystemName=''>
     <originalText><reference value=''/></originalText>
     </code>
     <name></name>
   </manufacturedMaterial>
</manufacturedProduct>
4050 <!-- Within a message -->
      <administerableMaterial>
        <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7.2' />
        <templateId root='2.16.840.1.113883.10.20.1.53' />
4055   <administerableMaterial>
     <code></code>
     <desc></desc>
   </administerableMaterial>
</administerableMaterial>

```

4060 **5.1.19.2 <manufacturedProduct> -OR- <administerableMaterial>**  
**<templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.7.2' />**  
**<templateId root='2.16.840.1.113883.10.20.1.53' />**  
**<manufacturedMaterial> -OR- <administerableMaterial>**

4065 In a CDA document, the name and strength of the medication are specified in the  
 elements under the <manufacturedMaterial> element. In a message, they are contained  
 within the <administeredMaterial> element, inside another <administerableMaterial>  
 element<sup>1</sup>. The templateId elements are required and identify this as a product entry.

Note: This duplication of element names is an artifact of the standard.

4070 **5.1.19.3 <code code=' ' displayName=' ' codeSystem=' '**  
**codeSystemName=' ' >**  
**<originalText><reference value=' '/></originalText>**  
**</code>**

4075 The <code> element of the <manufacturedMaterial> describes the medication. This may  
 be coded using a controlled vocabulary, such as RxNorm, First Databank, or other  
 vocabulary system for medications, and should be the code that represents the generic  
 medication name and strength (e.g., acetaminophen and oxycodone -5/325), or just the  
 generic medication name alone if strength is not relevant (Acetaminophen).

4080 In a CDA document, the <originalText> shall contain a <reference> whose URI value points to the generic name and strength of the medication, or just the generic name alone if strength is not relevant. Inside a message, the <originalText> may contain the actual text that describes the medication in similar fashion.

4085 Note: When the text is supplied from the narrative, the implication is that if you supply the components of a combination medication in an entry, you must also display these in the narrative text, otherwise you would not be able to break the combination medication down into its component parts. This is entirely consistent with the CDA Release 2.0 requirements that the narrative supply the necessary and relevant human readable information content.

4090 The <code> element is also used to support coding of the medication. If coded, it must provide a code and codeSystem attribute using a controlled vocabulary for medications. The displayName for the code and codeSystemName should be provided as well for diagnostic and human readability purposes, but are not required. The table below provides the codeSystem and codeSystemName for several controlled terminologies that may be used to encode medications and/or immunizations.

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

4095 The code used for an immunization may use code systems other than what might be used for other medications, such as the CDC maintained CVX codes. Code systems that describe vaccination *procedures* (such as CPT-4) shall not be used to describe the vaccine entry.

#### 5.1.19.4 <name> -OR- <desc>

4100 In a CDA document, the <name> element should contain the brand name of the medication (or active ingredient in the case of subordinate <substanceAdministration> elements used to record components of a medication). Within a message, this information shall be provided in the <desc> element.

#### 5.1.20 Simple Observations 1.3.6.1.4.1.19376.1.5.3.1.4.13

4105 The simple observation entry is meant to be an abstract representation of many of the observations used in this specification. It can be made concrete by the specification of a few additional constraints, namely the vocabulary used for codes, and the value representation. A simple observation may also inherit constraints from other specifications (e.g., ASTM/HL7 Continuity of Care Document).

4110 **5.1.20.1 Specification**

```

4115 <observation typeCode='OBS' moodCode='EVN'>
  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13' />
  <id root='' extension='' />
  <code code='' displayName='' codeSystem='' codeSystemName='' />
  <!-- for CDA -->
  <text><reference value='#xxx' /></text>
  <!-- For HL7 Version 3 Messages
4120 <text>text</text>
  -->
  <statusCode code='completed' />
  <effectiveTime value='' />
  <repeatNumber value='' />
  <value xsi:type='' ... />
4125 <interpretationCode code='' codeSystem='' codeSystemName='' />
  <methodCode code='' codeSystem='' codeSystemName='' />
  <targetSiteCode code='' codeSystem='' codeSystemName='' />
  <author typeCode='AUT'>
    <assignedAuthor typeCode='ASSIGNED'><id></assignedAuthor> <!-- for CDA -->
4130 <!-- For HL7 Version 3 Messages
    <assignedEntity typeCode='ASSIGNED'>
      <Person classCode='PSN'>
        <determinerCode root=''>
4135 <name>...</name>
      </Person>
      <assignedEntity>
        -->
    </author>
  </observation>
4140

```

**5.1.20.2 <observation typeCode='OBS' moodCode='EVN'>**

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

**5.1.20.3 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13' />**

4145 The <templateId> element identifies this <observation> as a simple observation, allowing for validation of the content. The templateId must appear as shown above.

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

Each observation shall have an identifier.

4150 **5.1.20.5 <code code='' displayName='' codeSystem='' codeSystemName='' />**

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

4155 **5.1.20.6 <text><reference value='#xxx'/></text> -OR- <text>text</text>**

Each observation measurement entry may contain a <text> element providing the free text that provides the same information as the observation within the narrative portion of the document with a <text> element. For CDA based uses of Simple Observations, this element SHALL be present, and SHALL contain a <reference> element that points to the related string in the narrative portion of the document. For HL7 Version 3 based uses, the <text> element MAY be included.

4160 **5.1.20.7 <statusCode code='completed'/>**

The status code of all observations shall be completed.

**5.1.20.8 <effectiveTime value=' '/>**

4165 The <effectiveTime> element shall be present in standalone observations , and shall record the date and time when the measurement was taken. This element should be precise to the day. If the date and time is unknown, this element should record that using the nullFlavor attribute.

**5.1.20.9 <value xsi:type=' ' .../>**

4170 The value of the observation shall be recording using a data type appropriate to the observation. Content modules derived from the Simple Observation content module may restrict the allowable data types used for the observation.

**5.1.20.10 <interpretationCode code=' ' codeSystem=' ' codeSystemName=' '/>**

4175 If there is an interpretation that can be performed using an observation result (e.g., high, borderline, normal, low), these may be recorded within the interpretationCode element.

**5.1.20.11 <methodCode code=' ' codeSystem=' ' codeSystemName=' '/>**

4180 The methodCode element may be used to record the specific method used to make an observation when this information is not already pre-coordinated with the observation code .

**5.1.20.12 <targetSiteCode code=' ' codeSystem=' ' codeSystemName=' '/>**

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

4185 **5.1.20.13 <author><assignedAuthor classCode='ASSIGNED'>...<assignedAuthor></author>**

In CDA uses, SimpleObservaions are assumed to be authored by the same author as the document through context conduction. However specific authorship of observation may be represented by listing the author in the header and referencing the author in a <author> relationship. If authors are explicitly listed in documents, an <id> element SHOULD

4190 reference the ID of the author in the header through an assignedAuthor Role. If the author of the observation is not an author of the document the <person> object including a name and ID SHALL be included.

For HL7 Version 3 purposes, the <author> element SHOULD be present unless it can be determined by conduction from organizers or higher level structures. When used for HL7  
4195 Version 3 the role element name is <assignedEntity> and the author is represented a <assignedPerson> element.

### 5.1.21 Vital Signs Organizer 1.3.6.1.4.1.19376.1.5.3.1.4.13.1

A vital signs organizer collects vital signs observations.

#### 5.1.21.1 Specification

4200

```

<organizer classCode='CLUSTER' moodCode='EVN'>
  <templateId root='2.16.840.1.113883.10.20.1.32' />
  <templateId root='2.16.840.1.113883.10.20.1.35' />
  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13.1' />
4205 <id root='' extension='' />
  <code code='46680005' displayName='Vital signs'
    codeSystem='2.16.840.1.113883.6.96' codeSystemName='SNOMED CT' />
  <statusCode code='completed' />
  <effectiveTime value='' />
4210 <!-- For HL7 Version 3 Messages
  <author classCode='AUT'>
    <assignedEntity1 typeCode='ASSIGNED'>
      :
    <assignedEntity1>
4215 </author>
  -->
  <!-- one or more vital signs observations -->
  <component typeCode='COMP'>
    <observation classCode='OBS' moodCode='EVN'>
4220     <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13.2' />
      :
    </observation>
  </component>
</organizer>

```

4225

#### 5.1.21.2 <organizer classCode='CLUSTER' moodCode='EVN'>

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

#### 5.1.21.3 <templateId root='2.16.840.1.113883.10.20.1.32' /> <templateId root='2.16.840.1.113883.10.20.1.35' /> <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13.1' />

4230

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

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

The organizer shall have an <id> element.

4235 **5.1.21.5 <code code='46680005' displayName='Vital signs'  
codeSystem='2.16.840.1.113883.6.96'  
codeSystemName='SNOMED CT'/>**

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

4240 **5.1.21.6 <statusCode code='completed'/>**

The observations have all been completed.

**5.1.21.7 <effectiveTime value=' '/>**

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

4245 **5.1.21.8 <author typeCode='AUT'><assignedEntity1  
typeCode='ASSIGNED'>...</assignedEntity1></author>**

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

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

4250 The organizer shall have one or more <component> elements that are <observation> elements using the [Vital Signs Observation](#) template.

**5.1.22 Vital Signs Observation 1.3.6.1.4.1.19376.1.5.3.1.4.13.2**

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



4255

**5.1.22.1 Specification**

4260

```

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

4265

4270

**5.1.22.2 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13' />  
 <templateId root='2.16.840.1.113883.10.20.1.31' />  
 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13.2' />**

4275

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

**5.1.22.3 <code code=' ' codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC' />**

4280

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

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

**5.1.22.4 <value xsi:type='PQ' value=' ' unit=' '/>**

4285 The <value> element shall be present, and shall be of the appropriate data type specified for measure in the table above.

**5.1.22.5 <interpretationCode code=' ' codeSystem=' ' codeSystemName=' '/>**

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

4290 **5.1.22.6 <methodCode code=' ' codeSystem=' ' codeSystemName=' '/>**

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

**5.1.22.7 <targetSiteCode code=' ' codeSystem=' ' codeSystemName=' '/>**

4295 The target site of the measure may be identified in the <targetSiteCode> element (e.g., Left arm [blood pressure], oral [temperature], et cetera).

**5.1.23 Family History Organizer 1.3.6.1.4.1.19376.1.5.3.1.4.15**

The family history organizer collects the problems of a patient's family member.

**5.1.23.1 Specification**

```

4300 <entry>
      <organizer classCode='CLUSTER' moodCode='EVN'>
        <templateId root='2.16.840.1.113883.10.20.1.23' />
4305 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.15' />
      <subject typeCode='SUBJ'>
        <relatedSubject classCode='PRS'>
          <code code='' displayName=''
4310         codeSystem='2.16.840.1.113883.5.111' codeSystemName='RoleCode' />
          <subject>
            <sdtc:id root='' extension='' />
            <administrativeGenderCode code='' displayName=''
4315         codeSystem='' codeSystemName='' />
          </subject>
        </relatedSubject>
      </subject>
      <!-- zero or more participants linking to other relations -->
      <participant typeCode='PART'>
        <participantRole classCode='PRS'>
4320       <code code='' displayName=''
          codeSystem='2.16.840.1.113883.5.111' codeSystemName='RoleCode' />
        <playingEntity classCode='PSN'>
          <sdtc:id root='' extension='' />
4325       </playingEntity>
        </participantRole>
      </participant>
      <!-- one or more entry relationships for family history observations -->
      <entryRelationship typeCode='COMP'>
        <observation classCode='OBS' moodCode='EVN'>
4330       <templateId root='2.16.840.1.113883.10.20.1.22' />
        </observation>
      </entryRelationship>
    </organizer>
  </entry>

```

**4335 5.1.23.2 <organizer classCode='CLUSTER' moodCode='EVN'>**

Each family history entry is organized (classCode='CLUSTER') into a group of observations about a family member.

**5.1.23.3 <templateId root='2.16.840.1.113883.10.20.1.23' />  
<templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.15' />**

4340 The organizer is identified by the <templateId> elements, which shall be present as shown above.

**5.1.23.4 <subject typeCode='SUBJ'>  
<relatedSubject classCode='PRS'>**

4345 The <subject> element shall be present and relates the subject of the observations to the patient. It shall contain a <relatedSubject> element that is a personal relation of the patient (classCode='PRS').

**5.1.23.5 <code code=' ' displayName=' ' codeSystem='2.16.840.1.113883.5.111' codeSystemName='RoleCode' />**

4350 The <code> element shall be present, and give the relationship of the subject to the patient. The code attribute shall be present, and shall contain a value from the HL7 FamilyMember vocabulary. The codeSystem attribute shall be present and shall use the value shown above.

**5.1.23.6 <subject>**

4355 The <subject> element contains information about the relation.

**5.1.23.7 <sdctc:id root=' ' extension=' ' />**

The <sdctc:id> element should be present. It is used to identify the patient relation to create a pedigree graph.

**5.1.23.8 <administrativeGenderCode code=' ' />**

4360 The <administrativeGenderCode> element should be present. It gives the gender of the relation.

**5.1.23.9 <participant typeCode='PART'>  
<participantRole classCode='PRS'>**

4365 The <participant> element may be present to record the relationship of the subject to other family members to create a pedigree graph. It shall contain a <participantRole> element showing the relationship of the subject to other family members (classCode='PRS').

**5.1.23.10 <code code=' ' displayName=' ' codeSystem=' ' codeSystemName=' ' />**

4370 The <code> element shall be present, and gives the relationship of the participant to the subject. The code attribute shall be present, and shall contain a value from the HL7 FamilyMember vocabulary. The codeSystem attribute shall be present and shall use the value shown above.

**5.1.23.11 <playingEntity classCode='PSN'>**

4375 The <playingEntity> element identifies the related person. It shall be recorded as shown above.

**5.1.23.12 <sdctc:id root=' ' extension=' ' />**

The <sdctc:id> element shall be present. It must have the same root and extension attributes of the <subject> of a separate family history organizer.

4380 **5.1.23.13 <entryRelationship typeCode='COMP'>**  
**<observation classCode='OBS' moodCode='EVN'>**  
**<templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13.3' />**

The family history organizer shall contain one or more components using the <entryRelationship> element shown above. These components must conform to the  
 4385 [Family History Observation](#) template.

### 5.1.24 Family History Observation 1.3.6.1.4.1.19376.1.5.3.1.4.13.3

A family history observation is a [Simple Observation](#) that uses a specific vocabulary, and inherits constraints from CCD. Family history observations are found inside [Family History Organizers](#).

#### 4390 5.1.24.1 Standards

CCD [ASTM/HL7 Continuity of Care Document](#)

#### 5.1.24.2 Parent Template

The parent of this template is [Simple Observation](#). This template is compatible with the ASTM/HL7 Continuity of Care Document template: 2.16.840.1.113883.10.20.1.22

#### 5.1.24.3 Specification

4395 

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

```
<templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13' />
```

```
<templateId root='2.16.840.1.113883.10.20.1.22' />
```

```
<templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13.3' />
```

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

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

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

```
<statusCode code='completed' />
```

```
<effectiveTime value=' ' />
```

```
<repeatNumber value=' ' />
```

```
<value xsi:type='CD' ... />
```

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

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

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

```
</observation>
```

4400

4405

4410

**5.1.24.4 <templateId root='2.16.840.1.113883.10.20.1.22' />**  
**<templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13.3' />**

The <templateId> elements identify this observation as a family history observation, and shall be present as shown above.  
 4415

---

**5.1.24.5 <code code=' ' displayName=' ' codeSystem=' ' codeSystemName=' '/>**

The <code> indicates the type of observation made (e.g., Diagnosis, et cetera). See the [code](#) element in the Problem Entry entry for suggested values.

**4420 5.1.24.6 <value xsi:type='CD' code=' ' displayName=' ' codeSystem=' ' codeSystemName=' '/>**

The <value> element indicates the information (e.g., diagnosis) of the family member. See the [value](#) element in the Problem Entry for suggested values.

**5.1.25 Social History Observation 1.3.6.1.4.1.19376.1.5.3.1.4.13.4**

4425 A social history observation is a simple observation that uses a specific vocabulary, and inherits constraints from CCD.

**5.1.25.1 Standards**

CCD [ASTM/HL7 Continuity of Care Document](#)

**5.1.25.2 Parent Template**

4430 The parent of this template is [Simple Observation](#). This template is compatible with the ASTM/HL7 Continuity of Care Document template: 2.16.840.1.113883.10.20.1.33

**5.1.25.3 Specification**

```

4435 <observation typeCode='OBS' moodCode='EVN'>
  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13' />
  <templateId root='2.16.840.1.113883.10.20.1.33' />
  <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13.4' />
  <id root=' ' extension=' ' />
  <code code=' ' displayName=' ' codeSystem=' ' codeSystemName=' '/>
  <text><reference value='#xxx' /></text>
4440 <statusCode code='completed' />
  <effectiveTime value=' ' />
  <repeatNumber value=' ' />
  <value xsi:type=' ' />
4445 <interpretationCode code=' ' codeSystem=' ' codeSystemName=' ' />
  <methodCode code=' ' codeSystem=' ' codeSystemName=' ' />
  <targetSiteCode code=' ' codeSystem=' ' codeSystemName=' ' />
</observation>

```

**5.1.25.4 <templateId root='2.16.840.1.113883.10.20.1.33' />  
<templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.13.4' />**

4450 These <templateId> elements identify this as a Social History observation.

**5.1.25.5 <code code=' ' displayName=' ' codeSystem=' ' codeSystemName=' '/>**

The <code> element identifies the type social history observation.

Code	Description	Data Type	Units
229819007	Smoking	PQ	{pack}/d or {pack}/wk or {pack}/a
256235009	Exercise		{times}/wk
160573003	ETOH (Alcohol) Use		{drink}/d or {drink}/wk
364393001	Diet	CD	N/A
364703007	Employment		
425400000	Toxic Exposure		
363908000	Drug Use		
228272008	Other Social History	ANY	

#### 5.1.25.6 <repeatNumber value='1' />

4455 The <repeatNumber> element should not be used in a social history observation.

#### 5.1.25.7 <value xsi:type=' ' ... />

The <value> element reports the value associated with the social history observation. The data type to use for each observation shall be drawn from the table above.

4460 Observations in the table above using the PQ data type have a unit in the form {xxx}/d, {xxx}/wk or {xxx}/a represent the number of items per day, week or year respectively. The value attribute indicates the number of times of the act performed, and the units represent the frequency. The example below shows how to represent 1 drink per day.

```

4465   :
      <code code='160573003' displayName='ETOH Use'
         codeSystem='2.16.840.1.113883.6.96'
         codeSystemName='SNOMED CT' />
      :
4470   <value xsi:type='PQ' value='1' unit='{drink}/d' />
      :

```

Observations in the table using the CD data type should include coded values from an appropriate vocabulary to represent the social history item. The example below shows the encoding to indicate drug use of cannabis.

4475

```
:  
<code code='363908000' displayName='Drug Use'  
      codeSystem='2.16.840.1.113883.6.96'  
      codeSystemName='SNOMED CT' />
```

4480

```
:  
<value xsi:type='CD' code='398705004' displayName='cannabis'  
       codeSystem='2.16.840.1.113883.6.96'  
       codeSystemName='SNOMED CT' />  
:
```

4485 Other social history observations may use any appropriate data type.

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

4490 The <interpretationCode>, <methodCode>, and <targetSiteCode> elements should not be used in a social history observation.

### 5.1.26 Procedure Entry 1.3.6.1.4.1.19376.1.5.3.1.4.19

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

#### 5.1.26.1 Standards

CCD [ASTM/HL7 Continuity of Care Document](#)



4495 **5.1.26.2 Specification**

```

4500 <procedure classCode='PROC' moodCode='EVN|INT'>
      <templateId root='1.3.6.1.4.1.19376.1.5.3.1.1.19' />
      <templateId root='2.16.840.1.113883.10.20.1.29' /><!-- see text of section 0 -
->
      <templateId root='2.16.840.1.113883.10.20.1.25' /><!-- see text of section 0 -
->
      <id root='' extension='' />
      <code code='' codeSystem='2.16.840.1.113883.5.4' codeSystemName='ActCode' />
4505 <text><reference value='#xxx' /></text>
      <statusCode code='completed|active|aborted|cancelled' />
      <effectiveTime>
        <low value='' />
4510 <high value='' />
      </effectiveTime>
      <priorityCode code='' />
      <approachSiteCode code='' displayName='' codeSystem='' codeSystemName='' />
      <targetSiteCode code='' displayName='' codeSystem='' codeSystemName='' />
      <author />
4515 <informant />
      <entryRelationship typeCode='REFR'>
        <encounter classCode='ENC' moodCode=''>
          <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.4.1' />
4520 <id root='' extension='' />
        </encounter>
      </entryRelationship>
      <entryRelationship typeCode='RSON'>
        <act classCode='ACT' moodCode='EVN'>
          <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.4.1' />
4525 <id root='' extension='' />
        </act>
      </entryRelationship>
    </procedure>

```

**5.1.26.3 <procedure classCode='PROC' moodCode='EVN|INT'>**

4530 This element is a procedure. The classCode shall be 'PROC'. The moodCode may be INT to indicated a planned procedure or EVN, to describe a procedure that has already occurred.

**5.1.26.4 <templateId root='1.3.6.1.4.1.19376.1.5.3.1.4.19' />**

4535 The templateId indicates that this <procedure> entry conforms to the constraints of this content module. NOTE: When the procedure is in event mood (moodCode='EVN'), this entry conforms to the CCD template 2.16.840.1.113883.10.20.1.29, and when in intent mood, this entry conforms to the CCD template 2.16.840.1.113883.10.20.1.25.

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

4540 This required element shall contain an identifier for the procedure. More than one procedure identifier may be present.

**5.1.26.6 <code code=' ' displayName=' ' codeSystem=' ' codeSystemName=' ' />**

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

**5.1.26.7 <text><reference value='#xxx' /></text>**

4545 The <text> element shall contain a reference to the narrative text describing the procedure.

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

4550 The <statusCode> element shall be present when used to describe a procedure event. It shall have the value 'completed' for procedures that have been completed, and 'active' for procedures that are still in progress. Procedures that were stopped prior to completion shall use the value 'aborted', and procedures that were cancelled before being started shall use the value 'cancelled'.

**5.1.26.9 <effectiveTime><low value=' ' /><high value=' ' /></effectiveTime>**

4555 This element should be present, and records the time at which the procedure occurred (in EVN mood), or the desired time of the procedure in INT mood.

**5.1.26.10 <priorityCode code=' ' />**

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

**5.1.26.11 <approachSiteCode code=' ' displayName=' ' codeSystem=' ' codeSystemName=' ' />**

4560 This element may be present to indicate the procedure approach.

**5.1.26.12 <targetSiteCode code=' ' displayName=' ' codeSystem=' ' codeSystemName=' ' />**

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

**5.1.26.13 <entryRelationship typeCode='COMP' inversionInd='true'>**

4565 This element may be present to point the encounter in which the procedure was performed, and shall contain an internal reference to the encounter. See section 1.3.6.1.4.1.19376.1.5.3.1.4.4.1 for more details.

**5.1.26.14 <entryRelationship typeCode='RSON'>**

4570 A <procedure> act may indicate one or more reasons for the procedure. These reasons identify the concern that was the reason for use via the Internal Reference entry content module specified in section 1.3.6.1.4.1.19376.1.5.3.1.4.4.1. The extension and root of each observation present must match the identifier of a concern entry contained elsewhere within the CDA document.

## 4575 **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:

```
4590 <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'>
4595   <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>
```

### **A.3 Validating Documents**

4600 For document content modules, the pattern can be extended to support common document content module constraints as shown below:

```

4605 <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
4610 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. -->
4615 <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 -->
4620 <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"]'>
4625 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 -->
4630 <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"]'>
4635 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"]'>
4640 Note: This referral summary does not contain the pertinent review of
        systems.
      </assert>
    </rule>
  </pattern>
</schema>

```

## A.4 Validating Sections

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

```

4645 <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'>
4650   <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'>
4655       Error: The coded reason for referral module can only be used on a
section.
     </assert>
     <assert test='false'>
4660       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"]'>
4665       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"]'>
4670       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"]'>
4675       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"]'>
4680     <!-- 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"]'>
4685       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 -->
4690     <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 -->
4695   </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.

4700

## A.5 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,
- 4705 • 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.

4710 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.

```

4715 <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">
4720   <active pattern="ReasonForReferralUncoded_Errors"/>
      <active pattern="ReasonForReferralCoded_Errors"/>
      </phase>
      <phase id="manual">
4725   <active pattern="ReasonForReferralUncoded_Manual"/>
      </phase>
      <pattern name='ReasonForReferralUncoded_Errors'>
4730   <rule context='*[templateId/@root="1.3.6.1.4.1.19376.1.5.3.1.3.1"]'>
      <assert test='section'>
4735   Error: The coded reason for referral module can only be used on a
      section.
      </assert>
4740   <assert test='code[@code = "42349-1"]'>
      Error: The section type code of the reason for referral section must be
4745   42349-1
      REASON FOR REFERRAL.
      </assert>
4750   <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>
4755   </rule>
      </pattern>
      <pattern name='ReasonForReferralUncoded_Manual'>
4760   <rule context='*[templateId/@root="1.3.6.1.4.1.19376.1.5.3.1.3.1"]'>
      <assert test='false'>
4765   Manual: Manually verify that this section contains narrative providing
      the
      reason for referral.
      </assert>
      </pattern>
      <pattern name='ReasonForReferralCoded_Errors'>
4770   <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"]'>
4775   Error: The parent template identifier for the reason for referral not
      present.
      </assert>
4780   <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>
4785   </rule>
      </pattern>
4790 </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.

## Extensions to CDA Release 2.0

This section describes extensions to CDA Release 2.0 that are used by the IHE Patient Care Coordination Technical Framework.

### 4770 A.6 IHE PCC Extensions

All Extensions to CDA Release 2.0 created by the IHE PCC Technical Committee are in the namespace urn:ihe:pcc:hl7v3. The approach used to create extension elements created for the PCC Technical Framework is the same as was used for the HL7 Care Record Summary (see Appendix E) and the ASTM/HL7 Continuity of Care Document (see 4775 section 7.2).

#### A.6.1 replacementOf

The <replacementOf> extension element is applied to a section appearing in a PHR Update Document to indicate that that section's content should replace that of a previously existing section. The identifier of the previously existing section is given so that the PHR Manager receiving the Update content will know which section to replace. 4780 The model for this extension is shown below.

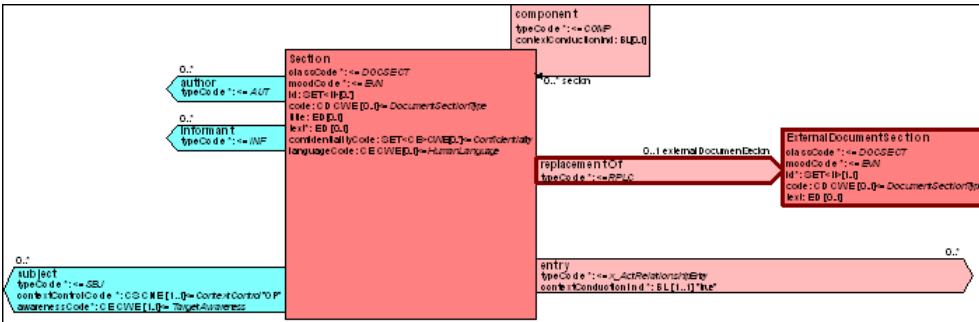


Figure 5.1-1 Model for replacementOf

Use of this extension is shown below. The <replacementOf> element appears after all other elements within the <section> element. The <id> element appearing in the <externalDocumentSection> element shall provide the identifier of the section being replaced in the parent document. 4785



```

4790 <section>
      <id root=' ' extension=' ' />
      <code code=' ' codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC' />
      <title>Name of the Section</title>
      <text>Text of the section</text>
4795 <entry></entry>
      <component></component>
      <pcc:replacementOf xmlns:pcc='urn:ihe:pcc:hl7v3'>
        <pcc:externalDocumentSection>
          <pcc:id root='58FCBE50-D4F2-4bda-BC1C-2105B284BBE3' />
4800 <pcc:externalDocumentSection />
      </pcc:replacementOf>
    </section>

```

## A.7 Extensions Defined Elsewhere used by IHE PCC

### A.7.1 Patient Identifier

4805 There is a need to record the identifier by which a patient is known to another healthcare provider. This extension provides a role link between the assigned, related or associated entity, and the patient role.

Use of this extension to record the identifier under which the patient is known to a provider is shown below.

```

4810 <assignedEntity>
      <id extension='1' root='1.3.6.4.1.4.1.2835.1' />
      <code code='59058001'
4815   codeSystem='2.16.840.1.113883.6.96'
      codeSystemName='SNOMED CT'
      displayName='General Physician' />
      <addr>
        <streetAddressLine>21 North Ave</streetAddressLine>
4820 <city>Burlington</city>
        <state>MA</state>
        <postalCode>01803</postalCode>
        <country>USA</country>
      </addr>
4825 <telecom value='tel:(999)555-1212' use='WP' />
      <assignedPerson>
        <name>
4830 <prefix>Dr.</prefix><given>Bernard</given><family>Wiseman</family><suffix>Sr.</
suffix>
        </name>
      </assignedPerson>
      <sdtc:patient xmlns:sdtc='urn:hl7-org:sdtc' >
        <sdtc:id root='1.3.6.4.1.4.1.2835.2' extension='PatientMRN' />
4835 </sdtc:patient>
    </assignedEntity>

```

The <patient> element records the link between the related, assigned or associated entity and the patient. The <id> element provides the identifier for the patient. The root attribute of the <id> should be the namespace used for patient identifiers by the entity. The

4840 extension attribute of the <id> element shall be the patient's medical record number or other identifier used by the entity to identify the patient.

## Appendix E - WSDLs for PCC

4845 The WSDLs for the transactions in the PCC technical framework represent the interface contracts for the actors in these transactions. Conformance to these contracts is a requirement of each of the transactions. However, the WSDLs representing these contracts are not necessarily the best WSDLs to use when generating application proxies.

4850 Use a generic, non-strongly typed WSDL that is for the purpose of generating the proxy. Use of a strongly typed WSDL forces the generation infrastructure to go through all the XML type definitions. It will then generate classes for each of them, which can result in thousands of generated classes and megabytes of generated code. In addition, the mapping between the schema and object oriented constructs is not straightforward. Because of both the size, and complexity of the schema, proxy generators often run into problems with valid instances of strongly typed WSDLs.

4855 There is a general guideline for generating proxies make application development much easier for complex WSDL/schemas such as the ones included in this technical framework. A commonly used method for creating non-strongly typed WSDL for HL7 Messages used for generating proxies substitutes the ANY data type for the payload of either the message infrastructure or the control act. This results in much smaller proxies. Applications receiving messages using these proxies may want to validate inputs since they are no longer validated by the proxy. A discussion of this method of proxy generation can be found in this article: <http://msdn2.microsoft.com/en-us/library/ms954603.aspx>. See the section on Web Services Code Generation.

4860

```

4865 <?xml version="1.0" encoding="UTF-8"?>
<definitions name="ClinicalDataSource" targetNamespace="urn:ihe:pcc:qed:2007"
  xmlns="http://schemas.xmlsoap.org/wsdl/" xmlns:hl7="urn:hl7-org:v3"
  xmlns:tns="urn:ihe:pcc:qed:2007"
  xmlns:http="http://schemas.xmlsoap.org/wsdl/http/"
4870  xmlns:mime="http://schemas.xmlsoap.org/wsdl/mime/"
  xmlns:wsoap11="http://schemas.xmlsoap.org/wsdl/soap/"
  xmlns:wsoap12="http://schemas.xmlsoap.org/wsdl/soap/"
  xmlns:wsaw="http://schemas.xmlsoap.org/ws/2004/08/addressing"
  xmlns:wSDL="http://schemas.xmlsoap.org/wsdl/"
4875  xmlns:xsd="http://www.w3.org/2001/XMLSchema"
  xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">
  <types>
    <xsd:schema elementFormDefault="qualified" targetNamespace="urn:hl7-
    org:v3">
      <!-- Query Care Record Event Profile Query -->
4880      <xsd:include schemaLocation="QUPC_IN043100UV.xsd" />
      </xsd:schema>
      <xsd:schema elementFormDefault="qualified" targetNamespace="urn:hl7-
    org:v3">
      <!-- Query Care Record Event Profile Query Response -->
4885      <xsd:include schemaLocation="QUPC_IN043200UV.xsd" />
      </xsd:schema>
      <xsd:schema elementFormDefault="qualified" targetNamespace="urn:hl7-
    org:v3">
      <!-- General Query Activate Query Continue / Cancel -->
4890      <xsd:include schemaLocation="QUQI_IN000003UV01.xsd" />
      </xsd:schema>
    </types>
    <message name="QUPC_IN043100UV_Message">
      <part element="hl7:QUPC_IN043100UV" name="Body" />
4895    </message>
    <message name="QUPC_IN043200UV_Message">
      <part element="hl7:QUPC_IN043200UV" name="Body" />
    </message>
    <message name="QUQI_IN000003UV01_Message">
      <part element="hl7:QUQI_IN000003UV01" name="Body" />
4900    </message>
    <portType name="ClinicalDataSource_PortType">
      <operation name="ClinicalDataSource_QUPC_IN043100UV">
        <input message="tns:QUPC_IN043100UV_Message"
4905        wsaw:Action="urn:hl7-org:v3:QUPC_IN043100UV" />
        <output message="tns:QUPC_IN043200UV_Message"
        wsaw:Action="urn:hl7-org:v3:QUPC_IN043200UV" />
      </operation>
      <operation name="ClinicalDataSource_QUQI_IN000003UV01_Continue">
        <input message="tns:QUQI_IN000003UV01_Message"
4910        wsaw:Action="urn:hl7-org:v3:QUQI_IN000003UV01_Continue" />
        <output message="tns:QUPC_IN043200UV_Message"
        wsaw:Action="urn:hl7-org:v3:QUPC_IN043200UV" />
      </operation>
      <operation name="ClinicalDataSource_QUQI_IN000003UV01_Cancel">
        <input message="tns:QUQI_IN000003UV01_Message"
4915        wsaw:Action="urn:hl7-org:v3:QUQI_IN000003UV01_Cancel" />
        <output message="tns:QUPC_IN043200UV_Message"
        wsaw:Action="urn:hl7-org:v3:QUPC_IN043200UV" />
4920      </operation>
    </portType>

```

```

4925 <binding name="ClinicalDataSource_Binding_Soap12"
type="tns:ClinicalDataSource_PortType">
  <wssoap12:binding style="document"
transport="http://schemas.xmlsoap.org/soap/http"/>
  <operation name="ClinicalDataSource_QUPC_IN043100UV">
    <wssoap12:operation soapAction="urn:hl7-org:v3:QUPC_IN043100UV"/>
    <input><wssoap12:body use="literal"/></input>
4930 <output><wssoap12:body use="literal"/></output>
  </operation>
  <operation name="ClinicalDataSource_QUQI_IN000003UV01_Continue">
    <wssoap12:operation soapAction="urn:hl7-org:v3:QUQI_IN000003UV01"/>
    <input><wssoap12:body use="literal"/></input>
4935 <output><wssoap12:body use="literal"/></output>
  </operation>
  <operation name="ClinicalDataSource_QUQI_IN000003UV01_Cancel">
    <wssoap12:operation soapAction="urn:hl7-org:v3:QUQI_IN000003UV01"/>
    <input><wssoap12:body use="literal"/></input>
4940 <output><wssoap12:body use="literal"/></output>
  </operation>
</binding>
  <binding name="ClinicalDataSource_Binding_Soap11"
type="tns:ClinicalDataSource_PortType">
  <wssoap11:binding style="document"
4945 transport="http://schemas.xmlsoap.org/soap/http"/>
  <operation name="ClinicalDataSource_QUPC_IN043100UV">
    <wssoap11:operation soapAction="urn:hl7-org:v3:QUPC_IN043100UV"/>
    <input><wssoap12:body use="literal"/></input>
4950 <output><wssoap12:body use="literal"/></output>
  </operation>
  <operation name="ClinicalDataSource_QUQI_IN000003UV01_Continue">
    <wssoap11:operation soapAction="urn:hl7-org:v3:QUQI_IN000003UV01"/>
    <input><wssoap11:body use="literal"/></input>
4955 <output><wssoap11:body use="literal"/></output>
  </operation>
  <operation name="ClinicalDataSource_QUQI_IN000003UV01_Cancel">
    <wssoap11:operation soapAction="urn:hl7-org:v3:QUQI_IN000003UV01"/>
    <input><wssoap11:body use="literal"/></input>
4960 <output><wssoap11:body use="literal"/></output>
  </operation>
</binding>
  <service name="ClinicalDataSource_Service">
    <port binding="tns:ClinicalDataSource_Binding_Soap11"
4965 name="ClinicalDataSource_Port_Soap11">
      <wssoap11:address location="http://servicelocation/" />
    </port>
    <port binding="tns:ClinicalDataSource_Binding_Soap12"
name="ClinicalDataSource_Port_Soap12">
      <wssoap12:address location="http://servicelocation/" />
4970 </port>
    </service>
  </definitions>

```

This file, along with the necessary HL7 Schemas, and skeletal examples can all be found on the IHE FTP Site at [ftp://ftp.ihe.net/TF\\_Implementation\\_Material/PCC](ftp://ftp.ihe.net/TF_Implementation_Material/PCC).