May 11, 2007
Version 2.0

HITSP Registration and Medication History Document Content Component

HITSP/C32

Submitted to:

Healthcare Information Technology Standards Panel

Submitted by:

Consumer Empowerment Technical Committee

DOCUMENT CHANGE HISTORY

Version Number	Description of Change	Name of Author	Date Published
1.0	Final Draft	Consumer Empowerment Technical Committee	August 18, 2006
1.1	Ready for Public Comment	Consumer Empowerment Technical Committee	September 12, 2006
1.2	TC Working Document	Consumer Empowerment Technical Committee	October 20, 2006
1.2.1	Review Draft - Released to TC for internal review	Consumer Empowerment Technical Committee	March 16, 2007
1.2.2	Review Draft – Revised based on Panel Comments	Consumer Empowerment Technical Committee	April 17, 2007
1.3	Review Copy	Consumer Empowerment Technical Committee	April 27, 2007
2.0	Released for Implementation	Consumer Empowerment Technical Committee	May 11, 2007

TABLE OF CONTENTS

FIGURES AND TABLES

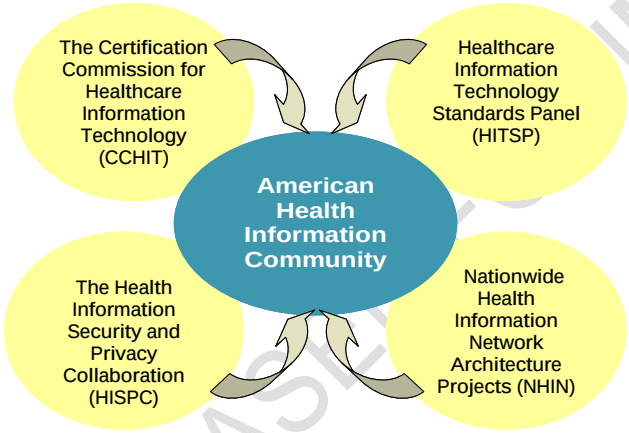
1.0 FOREWORD

This document is referred to as a Component and is an artifact of the Healthcare Information Technology Standards Panel (HITSP).

The following paragraphs provide background information about the HITSP and its role in the overall U.S. efforts to realize large scale interoperability of health information. It also describes the HITSP process for healthcare standards harmonization and explains how to use this document and other related documents to inform your health IT product development or product refinement. If you are familiar with HITSP and HITSP artifacts, please proceed to Section 2.0.

U.S. Nationwide Health Information Interoperability

Studies published by the Institute of Medicine and others have raised awareness of the extent to which the fragmented nature of clinical information adversely impacts the quality of care across the U.S. Health Information Technology (IT) can be used to enable better integration of clinical information. However, as of 2007, only a small number of U.S. healthcare providers have fully adopted health IT due, in part, to technical barriers associated with a lack of unambiguous and nationally recognized Interoperability Standards.



The American Health Information Community[1] (AHIC), a 2005 federally-chartered commission made up of leaders from public and private health sectors, was formed to provide recommendations on how to make health records digital and interoperable, and assure that the privacy and security of those records are protected, in a smooth, market-led way. At the same time, the Department of Health and Human Services, through the Office of the National Coordinator for Health IT (ONC) awarded contracts to 1) identify Interoperability Standards to facilitate the exchange of patient data (HITSP), 2) define a process for certifying that health IT products comply with appropriate standards through the Certification Commission for Healthcare Information Technology (CCHIT), and 3) develop a series of prototypes to establish the requirements of a Nationwide Health Information Network (NHIN). Under a renewed second year contract, HITSP scheduled activities will include identifying and constraining the standards needed for a standards-based security framework that provides the mechanisms needed to protect patient privacy and maintain confidentiality of information about the patient, as well as further work in additional Use Case priority areas recommended by AHIC. This year, CCHIT is expanding its certification efforts to inpatient, or hospital, electronic health record products. In

[1] www.hhs.gov/healthit/ahic

January 2007, four NHIN prototypes were delivered based on the requirements for health information exchange. The next phase will be to connect the prototypes and state and regional health information exchange efforts in trial implementations. These activities share the goal of widespread adoption of interoperable electronic health records within 10 years through public-private collaboration.

HITSP's Role within Nationwide Interoperability Efforts

The HITSP[2] is a multi-stakeholder coordinating body designed to provide the process within which affected parties can identify, select, and harmonize standards for communicating healthcare information throughout the healthcare spectrum. As used by HITSP, the term "standard" refers, but is not limited to Specifications, Implementation Guides, Code Sets, Terminologies, and Integration Profiles. A standard should be produced through a well-defined approach that supports a business process and

1. has been agreed upon by a group of experts
2. has been publicly vetted
3. provides rules, guidelines, or characteristics
4. helps to ensure that materials, products, processes, and services are fit for their intended purpose
5. is available in an accessible format
6. is subject to an ongoing review and revision process

HITSP functions as a partnership of the public and private sectors and operates with a neutral and inclusive governance model administered by the American National Standards Institute (ANSI). The goal of the Panel is to:

- Facilitate the development of harmonized Interoperability Specifications and information policies, including Standards Development Organization (SDO) work products (e.g. standards, technical reports). These policies, profiles and work products are essential for establishing privacy, security and Interoperability among healthcare software applications
- Coordinate, as appropriate, with other national, regional and international groups addressing healthcare information to ensure that the resulting standards are globally relevant
- Be Use Case driven, using information from stakeholders and basing decisions on industry needs

The work of HITSP is conducted through formally chartered Technical Committees (TC) and Work Groups. The artifact of the Technical Committee and Work Group activities is an Interoperability Specification (IS) and related constructs referred to as Transaction Packages, Transactions, or Components. For additional information on these constructs, please refer to the HITSP Harmonization Framework.

[2] www.hitsp.org

This HITSP document pertains to the Interoperability Specification for the following:

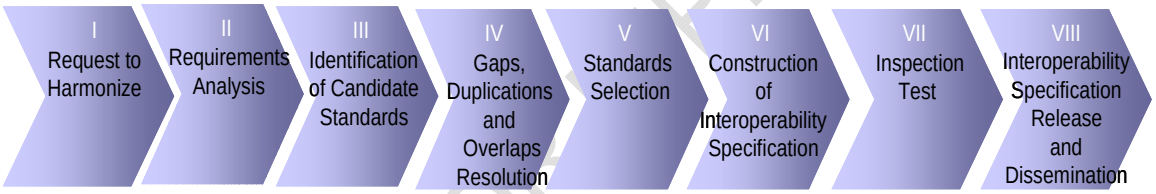
Use Case	Specific Scope of this Use Case
Consumer Empowerment	Allow consumers to establish and manage permissions access, rights, and informed consent for authorized and secure exchange, viewing, and querying of their linked patient registration summaries and medication histories between designated caregivers and other health professionals.

In its final state, this Interoperability Specification provides unambiguous instructions for how two or more systems should exchange information within the specific context of the Use Case.

How Use Cases and HITSP Interoperability Specifications are Developed

The American Health Information Community, as the representative of public and private health sector stakeholders, identified the three Use Cases (available at www.hitsp.org) that drove the initial efforts of the HITSP. Nationwide public and private health sector priorities continue to focus the efforts of the HITSP. The Use Case driven HITSP harmonization process is implemented by formally chartered Technical Committees. The volunteers that comprise a Technical Committee followed an 8 step process, depicted below.

Figure 1.0-1 HITSP Harmonization Process Steps



How to Read this Interoperability Specification

Each Interoperability Specification (IS) is actually a suite of documents that, taken as a whole, provide a detailed map to existing standards and specifications that will satisfy the requirements imposed by a given Use Case. It identifies and constrains standards where necessary, and creates groupings of specific actions and actors to further describe the relevant contexts. Where gaps and overlaps are identified, the Interoperability Specification provides recommendations and a roadmap for corrections to be made. This Interoperability Specification includes the Transaction Packages, Transactions, and Components.

2.0 INTRODUCTION

As an introduction to the Registration and Medication History Document Content Component, this section provides a high level overview of an information sharing scenario enabled by following this specification, outlines the technical scope of the specification, describes the intended audience for the technical content of the document, acknowledges the copyright protections that pertain, provides Internet links to the HITSP Acronyms List and an explanation of the conventions used to convey the full descriptions and usage of standards. If you are already familiar with this information, proceed to Section 3.0 Referenced Standards.

2.1 OVERVIEW

The Registration and Medication History Document Content Component describes the document content that summarizes a consumer's registration and medication data information contained within a Personal Health Record (PHR) for the purpose of information exchange. While a PHR can contain much more information, this component only deals with the exchange of summary information to and from the PHR.

The registration summary is restricted to the information consumers generally need to provide when visiting a physician, hospital, or pharmacy, such as:

1. Demographic information sufficient to help identify the consumer
2. Financial information sufficient for insurance eligibility checking and claims submission
3. Basic clinical information including allergies

The registration summary is essentially a subset of the data in a PHR that has been developed for the specific business Use Case of registration. This subset contains the minimum critical medical information of sections and data elements in a PHR used in that business case. A registration summary may be prepared using information technology standards developed for a PHR, for example, by creating a view of specific items from the full PHR data set. The resulting registration summary must be a representative extract of the PHR. The information in the registration summary and the full PHR must be consistent. Furthermore there should be no data elsewhere in a PHR that would contradict the meaning of any data in the registration summary. The expectation is that consuming systems will be able use the registration/medication as source of info to input and/or update information in the patient record. This specification does not define the policies applicable to the import of this information.

It is anticipated and desirable that some implementers of the registration summary will want to add data and sections to permit greater communication between a PHR and EHR systems. This practice is beyond the scope of this HITSP component. Implementers must be aware that they must assume that receivers of the document may only be able to view this data, but may not be able to use the additional data in the registration Use Case. This means that the registration summary must be able to stand-alone. Applications may wish to display the document in two different user-selected views, one of which is restricted to the minimal dataset contents of a registration summary. Adding additional optional sections

and data elements should not generate errors. Optional data should be used if understood, but must not change the meaning of the basic registration summary.

With respect to medication history, the summary information about consumers' medications is intended to enable the following activities:

1. Create medication history
2. Update medication history
3. View medication history
4. Enable physician's review of medication history with consumer
5. Differentiate current medications from relevant past medications

The medication history (i.e., prescriptions and over-the-counter products) is the first clinical data section added to the core registration summary and illustrates a modular path to a broader PHR information exchange. A core medication summary that answers the question of "what medications are you currently taking" is actually part of the HITSP registration and medication history document component summary. A more complete medication history provides additional data to support transfer of clinical care and more complete consumer education and medication management opportunities. Asking a patient about their medications and allergies should be a basic part of all clinical encounters and including this step in an interoperable registration summary is an important tool for improving patient safety and quality of care as well as facilitating electronic prescribing. Making the patient's pharmacies, insurance, and demographics part of the registration summary also allows the registration to facilitate implementation of electronic prescribing by eliminating the need to ask for and enter data needed to drive electronic prescribing systems or electronic prescribing functions of an EHR.

Other types of historical medication information, especially those needed to analyze medication compliance and deliver patient education, are important, but are out of scope of this Use Case.

This document refers to the 2006 cycle of the HITSP Consumer Empowerment initiative. It defines the component specification that provides document content specifications for a consumers' registration and medication history information.

2.2 TECHNICAL ASSUMPTIONS AND SCOPE

This Interoperability Specification focuses on a set of constrained standards for information interchange that address the core requirements of the Use Case described above. It may not define all functions, constructs and standards necessary to implement a conforming system in a real world environment. In particular, an implementer must provide the technical infrastructure and security framework necessary to support operations in accordance with law, regulation, best practices and business agreements. The following paragraphs provide the HITSP principles with regard to several critical topics to ensure consistent interpretation of the Interoperability Specifications.

2.2.1 INTEROPERABILITY SPECIFICATIONS NOT FUNCTIONAL SPECIFICATIONS

The HITSP Interoperability Specification defines how two or more systems exchange standard data content in a standardized manner. Interoperability Specifications define the necessary business and technical actors, the transactions between them including the message, content and terminology standards for the actual information exchange. Interoperability Specifications do not specify the functional requirements or behaviors of the systems or applications.

2.2.2 ARCHITECTURAL NEUTRALITY

HITSP Interoperability Specifications, unless otherwise noted, are not intended to define or prescribe any system architecture or implementation. At the most basic level, the Interoperability Specifications define specific information exchange standards that are to be used by any two systems. Information exchange must be placed within the context of a transaction between defined technical actors which fulfill higher level business requirements derived from the Use Case. In some cases the necessary technical actors may require some architectural structure or make some assumptions involving synchronous or asynchronous data exchanges, or require specific type of exchange, such as a message or document. These requirements may constrain to some degree the total range of choices regarding system architectures. When constraints are necessary to meet the Use Case requirements, the Interoperability Specification will note this and will retain as much architectural neutrality as possible. When appropriate, the Interoperability Specifications may provide architectural examples and discuss considerations of such examples.

2.2.3 THE USE OF MESSAGES AND DOCUMENTS AS APPROPRIATE

Within healthcare information there is an ongoing debate concerning the proper role of messages and documents as methods of exchanging data. Messages are typically non-persistent encapsulations of highly structured data that require external context. Documents are persistent encapsulations of both data and context which may be authenticated to insure non-repudiation. Persistence as defined by Health Level Seven (HL7) means that a clinical document continues to exist in an unaltered state for a time period defined by local and regulatory requirements. Non-repudiation, as defined by ISO adapted from ASTM E31, means a service that provides proof of the integrity and origin of data, which can be verified by any party. HITSP recognizes that requirements for both messages and documents exist and where consistent with harmonization will support both. For example, depending on specific phases of the workflow, a laboratory result might be exchanged as a message, as a document, or both. Business requirements may define which format is more effective.

2.2.4 IMPLEMENTATION TESTING

The 2006 set of Interoperability Specifications were evaluated by inspection testers (desktop review) and reviewed by HITSP members prior to HITSP approval. Although the Interoperability Specifications are based on approved standards, when published, they represent combinations and constraints that have not been tested in actual implementations. HITSP enlisted partners to develop test plans, data and suites to test the implementation and then to support a program for progressive testing, feedback and

deployment of implementations. Feedback from test implementers has been used in the revisions in Version 2.0.

2.2.5 SECURITY AND PRIVACY

The Health Insurance Portability and Accountability Act (HIPAA) and its Administrative Simplification sections establish the minimum federal requirements for security and privacy of individually identifiable health information (IIHI). HIPAA requires that "covered entities" establish and maintain secure systems that protect IIHI from unauthorized disclosures while ensuring its availability for authorized uses. Most providers, health plans and intermediaries, and by contract their business associates, are covered by HIPAA regulation. However, HIPAA does not cover personal health records unless they are held by a covered entity, nor an individual's use of their own health information.

Currently, HITSP is charged by ONC to harmonize standards based on Use Cases derived from AHIC requirements and priorities. Implicitly and in some cases explicitly, the Use Cases require a secure infrastructure and certain security or privacy functions. Because of time and resource constraints and the need for further information as described below, HITSP has decided to defer specifying most security requirements, instead treating these as a pre-condition for implementing the core information exchanges. The underlying premise is that HITSP**,** based upon prioritization by AHIC and ONC, will in the future identify and constrain the standards needed for a standards-based security framework that provides the mechanisms needed to protect patient privacy and maintain confidentiality of information about the patient. This standards-based security framework will need to accommodate federal, state, local, and healthcare enterprise security and privacy policies and processes. Exceptions to the deferred requirements that are addressed in this first release are secure web-based messaging, pseudonymization and anonymization.

There is a special case for the Consumer Empowerment (CE) Use Case. In the first year of HITSP's work, the Consumer Empowerment TC is to provide an Interoperability Specification for sharing of demographic data, medication lists, and allergies *based on patient consent*. Patient consent is clearly within the scope of the CE Use Case. However, HITSP requires further guidance on patient consent, particularly since patient consent is not addressed by HIPAA in the case of a personal health record (PHR) nor is it established within widely accepted PHR standards. Therefore HITSP identifies patient consent as a necessary pre-condition for successful implementation of a PHR that contains personal demographic data and medication histories. Patient consent has been documented as a pre-condition in CE Interoperability Specification. This pre-condition will be established using HITSP work products being developed in 2007.

2.3 AUDIENCE

The Interoperability Specification is designed to be used by analysts who need to understand the Interoperability requirements for the described Use Case, and by implementers working to develop interoperable applications. Understanding and using the relevant set of Interoperability Specifications is a key requirement for establishing interoperability compliance.

2.4 COPYRIGHT PERMISSIONS

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2.5 ACRONYMS

The acronyms used in this document are contained in the HITSP Acronyms List.

2.6 CONVENTIONS

Conventions are used to convey the full descriptions and usage of standards in the Interoperability Specification and are contained in the HITSP Conventions List.

3.0 REFERENCED STANDARDS

It is HITSP's policy to incorporate only standards that have been approved according to the formal policy of the standards organization, as defined by HITSP, which publishes the standard. HITSP interprets approval to include Draft Standards for Trial Use. The objective is to incorporate only standards that are managed within a formal life cycle process as defined by the standards organization. In some cases, where we believe a standard that is not yet approved may best meet the requirements of an Interoperability Specification, HITSP may provide a roadmap of its future intent conditional on future actions by either or both the standards organizations and the HITSP Technical Committee. Thus there are four classes of HITSP-committed standards.

- Approved for Use – standards included for unconditional use within a HITSP construct
- Interim – standards included for use now within a HITSP construct but for a defined time period or conditional on future actions, e.g., "Intended for Use" standard is available
- Provisional - standards that are not yet but are expected to be approved by the Standards Organization by the time the Interoperability Specification is released by HITSP. A "Provisional" standard becomes an "Approved for Use" standard only if:
  - It is approved by the Standards Organization by the time that the Interoperability Specification is released by HITSP and
  - It is substantially the same as it was when it was provisionally used and
  - It requires no further action by the Technical Committee
- Intended for Use – proposed standards that are road mapped for future use pending actions by the TC and/or the standards organization. Therefore a standard is defined as "Intended for Use" because it will not be approved by the time that the HITSP construct is released but is sufficiently defined to enable detailed evaluation of how well it will meet technical and business requirements

HITSP may continue to use "Provisional" or "Interim" standards as they existed when incorporated into the HITSP construct if the expected conditions are not satisfied until such time as HITSP can replace it with a more suitable standard. In this circumstance, the Standards Organization would have no responsibility to maintain or correct this artifact. If a standard "Intended for Use" is not developed and approved in terms of time frame or content as expected by the TC at the time of its initial selection, it may be replaced. All standards used by HITSP must meet the HITSP selection criteria. The use of "Interim" and "Intended for Use" standards will be weighed against the alternative of simply declaring a gap for HITSP and the Standards Organizations to resolve.

The Consumer Empowerment Technical Committee (CE TC) has been charged with introducing the consumer, and the PHR, as an integral partner of the healthcare information flow representing a new paradigm in healthcare interoperability. This paradigm establishes the consumer as the active participant in health information exchange that touches all segments of the industry: providers/care facilities, health plans, pharmacies/prescription benefit managers (PBM), and others. This challenge is exacerbated by the current information technology situation wherein providers, health plans, pharmacies, and pharmacy

benefit managers (PBMs) segments, each have created different standards based on differing business needs and timing, with shared and overlapping data elements via three different standards developers: Health Level Seven (HL7), Accredited Standards Committee (ASC) X12, and National Council for Prescription Drug Programs (NCPDP).

In addition to these aforementioned standards, a fourth standard initiative from American Society for Testing Materials Standards (ASTM) targeting the provider-provider and provider-consumer Interoperability space, entitled the Continuity of Care (CCR), passed favorable ballot in October 2005. In the latter phase of the successful CCR balloting process, ASTM and HL7 initiated a formal harmonization effort regarding their respective efforts addressing the same interoperability space. This harmonization initiative resulted in the joint development of the Continuity of Care Document (CCD) that was approved by HL7 ballot in January 2007.

The Consumer Empowerment TC has determined that it is in the best interest of HITSP harmonization efforts to wholeheartedly support the HL7-ASTM harmonization initiative and leverage its deliverables to the highest degree possible. To this end, the approach taken by the CE TC is to align its Interoperability Specification to the harmonized HL7-ASTM CCD. This CE Interoperability Specification artifact is therefore intended to facilitate the transition from the current disparate standards environment to a harmonized state.

As noted in the initial paragraph, the CE TC has also recognized the need to ensure consistency of its specified data elements across all the standards deployed by the business actors of the Use Case which are potential sources of data in the PHR. For example, ASC X12 is used to describe health plan information that is relevant for updating a consumer's PHR. To this end, this HITSP Interoperability Specification and the Registration / Medication History Document Content Component includes appendices for informative data element cross-mapping tables between the CCD elements and the ASTM CCR, ASC X12, and NCPDP SCRIPT data elements for all common content areas. These element mapping tables will serve as guidance to the SDOs and/or application system vendors using these base standards as to how to adapt these standards and their implementations to the HITSP Interoperability Specification.

3.1 LIST OF STANDARDS

It is important to understand that the standards selected here are within the context of the specific Use Case requirements and do not necessarily reflect selection in other contexts. The following standards are used to implement this Interoperability Specification:

Table 3.1-1 List of Standards

Standard	Description
Accredited Standards Committee (ASC) X12 Insurance Subcommittee (X12N) Implementation Guides Version 004010 plus Addenda 004010A1	Detailed Implementation Guides based on release 004010 of the X12 standards. These Implementation Guides provide details on the use of X12 standards to accomplish specific transaction functions. Some of the version 004010 Implementation Guides, but not all, have been adopted as Implementation Specifications under HIPAA. Many of the version 004010 Implementation Guides, including all of those adopted under HIPAA, have Addenda that contain updates -- only -- to the original Implementation Guides. These Addenda are identified as version 004010A1. Implementation Guides 004010X092 and 004010X092A1 describe transactions for Health Care Eligibility Benefit Inquiry and Response. Implementation Guides are published by Washington Publishing Company. Visit www.wpc-edi.com for more information.
Accredited Standards Committee (ASC) X12 Standards Release 004010	Release (version) 004010 of the Accredited Standards Committee (ASC) X12 standards including the X12.5 Interchange Control, X12.6 Application Control Structure, 270 Eligibility, Coverage or Benefit Inquiry, 271 Eligibility, Coverage or Benefit Information and other control standards for the uniform electronic interchange of business transactions. Published by the Data Interchange Standards Association (DISA). Visit www.x12.org for more information.
American Society for Testing and Materials (ASTM) Standard Specification for Coded Values Used in the Electronic Health Record: # E1633-02	Identifies the lexicons to be used for the data elements identified in ASTM's Standard Guide for Content and Structure of the Electronic Health Record (EHR): # E1384-02. E1633-02 "is intended to unify the representations for: (1) primary record of care data elements, (2) the data elements identified in other standard statistical data sets, (3) data elements used in other healthcare data message exchange format standards, or (4) in data gathering forms for this purpose, and (5) in data derived from these elements in order that data recorded in the course of patient care be exchangeable and be the source of accurate statistical and resource management data." {Source: ASTM E1633-02a, 2006} Visit www.astm.org for more information.
American Society for Testing and Materials (ASTM) Standard Specification for Continuity of Care Record (CCR): # E2369-05	A core data set of the most relevant and timely facts about a patient's healthcare. It is to be prepared by a practitioner at the conclusion of a healthcare encounter in order to enable the next practitioner to readily access such information. It includes a summary of the patient's health status (e.g., problems, medications, allergies) and basic information about insurance, advance directives, care documentation, and care plan recommendations. An XML version of the CCR, known as the Continuity of Care Document (CCD), prepared by Health Level Seven (HL7) in collaboration with ASTM, also exists and described under Health Level Seven standards. Visit www.astm.org for more information.
CDC Race and Ethnicity Code Sets	The U.S. Centers for Disease Control and Prevention (CDC) has prepared a code set for use in coding race and ethnicity data. This code set is based on current federal standards for classifying data on race and ethnicity, specifically the minimum race and ethnicity categories defined by the U.S. Office of Management and Budget (OMB) and a more detailed set of race and ethnicity categories maintained by the U.S. Bureau of the Census (BC). The main purpose of the code set is to facilitate use of federal standards for classifying data on race and ethnicity when these data are exchanged, stored, retrieved, or analyzed in electronic form. At the same time, the code set can be applied to paper-based record systems to the extent that these systems are used to collect, maintain, and report data on race and ethnicity in accordance with current federal standards. More information is available from www.cdc.gov/nedss/DataModels

Standard	Description
Council for Affordable Quality Health Care (CAQH) Committee on Operating Rules for Information Exchange (CORE) Phase I Operating Rules	Provide agreed-upon business rules and guidelines for using and processing eligibility inquiry and response transactions between providers and health plans; in particular those that have been adopted under HIPAA. Visit www.caqh.org for more information.
Federal Medication Terminologies	A set of controlled terminologies and code sets developed and maintained as part of a collaboration between the Food and Drug Administration, National Library of Medicine, Veterans Health Administration, National Cancer Institute and Agency for Healthcare Research and Quality related to medications, including medication proprietary and nonproprietary names, clinical drug code (RxNorm); ingredient names and Unique Ingredient Identifiers (UNII); routes of administration, dosage forms, and units of presentation from the NCI Thesaurus (NCIt); and certain pharmacological drug classes from the National Drug File Reference Terminology (NDF-RT) . The Federal Medication Terminology leverages medication models maintained by the Food and Drug Administration (ex. UNII, NDC Codes), National Library of Medicine (RxNorm), the Veterans Health Administration (NDF-RT), and the National Cancer Institute (NCIt). Information on the Federal Medication Terminologies may be found and downloaded from the NCI Web portal terminology resources page at www.cancer.gov/cancertopics/terminologyresources/FMT
Health Care Provider Taxonomy	The Health Care Provider Taxonomy code set is a collection of unique alphanumeric codes, ten characters in length. The Health Care Provider Taxonomy code set includes specialty categories for individuals, Groups of individuals, and non-individuals. The National Uniform Claims Committee maintains this code set. The complete code set is available from the Washington Publishing Company at www.wpc-edi.com/taxonomy/more_information
Health Level Seven (HL7) Version 3.0	The HL7 Version 3.0 Messaging Standard is an application protocol for electronic data exchange in healthcare. Version 3.0 is based on a Reference Information Model (RIM); which is used to instantiate various message formats. Value sets / code tables are contained in the standard. Visit www.hl7.org for more information.
Health Level Seven (HL7) Version 3.0 Clinical Document Architecture (CDA/CDA R2)	The HL7 Clinical Document Architecture is an XML-based document markup standard that specifies the structure and semantics of clinical documents for the purpose of exchange. CDA is one instantiation of HL7's Version 3.0 Reference Information Model (RIM) into a specific message format. Of particular focus for HITSP Interoperability Specifications are message formats for Laboratory Results and Continuity of Care (CCD) documents. Release 2 of the HL7 Clinical Document Architecture (CDA) is an extension to the original CDA document markup standard that specifies the structure and semantics of clinical documents for the purpose of exchange. CDA R2 includes a prose document in HTML, XML schemas, data dictionary, and sample CDA documents. CDA R2 further builds upon other HL7 standards beyond just the Version 3.0 Reference Information Model (RIM) and incorporates Version 3.0 Data Structures, Vocabulary, and the XML Implementation Technology Specifications for Data Types and Structures. Visit www.hl7.org for more information.

Standard	Description
HL7 Implementation Guide: CDA Release 2 – Continuity of Care Document (CCD), Release 1.0, April 01, 2007	The Continuity of Care Document implementation guide describes constraints on the HL7 Clinical Document Architecture, Release 2 (CDA) specification in accordance with requirements set forward in ASTM E2369-05 Standard Specification for Continuity of Care Record (CCR). The resulting specification, known as the Continuity of Care Document (CCD), is developed as a collaborative effort between ASTM and HL7. It is intended as an alternate implementation to the one specified in ASTM ADJE2369 for those institutions or organizations committed to implementation of the HL7 Clinical Document Architecture.
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 3.0	The IHE IT Infrastructure Technical Framework defines specific implementations of established standards to achieve integration goals that promote appropriate sharing of health information to support optimal patient care. IHE Integration Profiles, offer a common language that healthcare professionals and vendors may use in communicating requirements for the integration of products. The current version of the ITI-TF, rev. 3.0 for Final Text, specifies the IHE transactions defined and implemented as of December 9, 2006. The latest version of the IHE Technical Framework is available at www.ihe.net.
National Council for Prescription Drug Programs (NCPDP) SCRIPT Standard Version 8.1	Provides for the realtime electronic transfer of prescription data between pharmacies and providers. Functions supported include communication of new prescriptions, prescription changes, refill requests, prescription fill status notifications, and prescription cancellations. Visit www.ncpdp.org for more information.
Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity	This classification provides a minimum standard for maintaining, collecting, and presenting data on race and ethnicity for all Federal-reporting purposes. The categories in this classification are social-political constructs and should not be interpreted as being scientific or anthropological in nature. The standards have been developed to provide a common language for uniformity and comparability in the collection and use of data on race and ethnicity by Federal agencies. Visit www.census.gov/population/www/socdemo/race/Ombdir15.html for more information.

4.0 COMPONENTS

Components define atomic constructs used to support an information exchange or to meet an infrastructure requirement (e.g., security, logging/audit). This is accomplished by:

(a) Referencing one or more underlying standards, and
(b) Specifying constraints and other rules for using the standards

4.1 CONTEXT OVERVIEW

The Registration and Medication History Document Content Component describes the document content that summarizes a consumer's registration and medication data information contained within a PHR. While a PHR can contain much more information, this component only deals with the summary information coming from and returning to the PHR.

4.1.1 CONTEXTUAL CONSTRAINTS

All constraints to this component are defined in the Data Mapping sections beginning with 4.2.3.1.

4.1.2 TECHNICAL ACTORS

No technical actors are contained in this document. Application technical actors are described in higher-level specifications that incorporate this component.

When this component is combined with HITSP TP13 Manage Sharing of Documents, the XDS Registry Entry Meta-Data to be used when registering any instance of a document specified by this HITSP C32 construct shall follow the specification defined in the IHE Patient Care Coordination Technical Framework Revision 1.0 (IHE PCC TF Rev 1.0) Section 4.1 of volume 2.

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

4.2 INFORMATION INTERCHANGE COMPONENTS: RULES FOR IMPLEMENTING

The following sections document the content of the Registration and Medication History component. It provides the basic elements and secondary standards that are supported by this component and the constraints that are being placed on those standards.

4.2.1 PROCESS PRE-CONDITIONS AND TRIGGERS

No process pre-conditions or triggers are contained in this document. Application process pre-conditions and triggers are described in higher-level specifications that incorporate this component.

4.2.2 PROCESS POST-CONDITIONS AND OUTPUTS

No process post-conditions or outputs are contained in this document. Application process post-conditions and outputs are described in higher-level specifications that incorporate this component.

4.2.3 DATA STRUCTURE

This component uses tables to provide the content of the Registration/Medication History summary. Requirement types are defined for various entries in the tables. The convention for this is defined below.

Table 4.2.3-1 Table Conventions

Data Elem. ID	Data Element	HITSP Opt / Repeat	CCD Name	HITSP Additional Specification for Component
1.01	Name xxx	R/Y	cda:recordTarget/cda:patientRole/ cda:patient/cda:name	None
1.02	…..	…..	…..	…..

- Table Headings:
  - Data Elem. ID –a numeric identification of the data element, can be used for referencing this data element in this document only
  - Data Element – the name of the data element being defined
  - Opt/Repeat – two fields where the first defines the Requirement Type and the second a Repeating Definition
  - CCD Name –The CCD name is expressed as an XPath expression identifying the CCD data element that contains the content (see www.w3.org/TR/xpath.html for more information on XPath). These expressions assume that the namespace prefix "cda:" has been mapped to the CDA specified namespace "urn:hl7-org:v3", and the namespace prefix "sdtc:" has been mapped to the namespace "urn:ansi-org:sdtc".
  - Additional Specification Registration and Medication History Document – specifies HITSP requirements and restriction, if needed
- Requirement Type Definitions: Adapted from IHE
  - R = Required
    Required data elements must always be sent. Data elements that are required may under exceptional circumstances have an unknown value (e.g., the name of an unconscious patient). In these cases the sending application is required to indicate the reason that the data are not available
  - R2 = Required if known
    Data elements that are marked required if known (R2) must be sent when the sending application has that data available. The sending application must be able to demonstrate that it can send all

required if known elements, unless it does not in fact gather that data. When the information is not available, the sending application may indicate the reason that the data are not available

– O = Optional
  Data elements that are marked optional (O) may be sent at the choice of the sending application. An optional element need not be sent, but when it is sent, the content module defines the meaning of that data element, and a receiver can always be assured of what that data element represents when it is present. Senders should not send an optional data element with an unknown value. If the value is not known, simply do not send the data element

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

If a data element coded value may be derived from another data element coded value, the creator of this component shall ensure the accuracy and consistency between the two data elements. If the receiver detects an inconsistency it shall not correct the value without human intervention.

Whether a module or element may be repeated is defined for various entries in the tables. The convention for this is defined as Y = Yes, N = No.

4.2.3.1 DATA MAPPING

Table 4.2.3.1-1 defines the Content Modules used by this component. Below Table 4.2.3.1-1 is a set of two related tables. The tables are based upon the ASTM/HL7 Continuity of Care Document (CCD) specification. The first table specifies the data elements within each Content Module and their definitions. The second table specifies the same data elements and defines their optionality, repeatability, the CCD name and a reference to the section that specifies any HITSP additional requirements and/or restrictions (if needed).

C32-[#] Specific constraints imposed by this specification are numbered as shown in this example.

Many constraints appearing below reference external vocabularies. Where vocabularies have been referenced, implementers are advised to obtain them from the authoritative sources described in the list of standards above. Links to the authoritative sources are provided within these additional specifications for the component.

Examples have been included in the sections below. These examples assume that the default namespace has been set to "urn:hl7-org:v3" to simplify reading, and the namespace prefix "sdtc:" has been mapped to the namespace "urn:ansi-org:sdtc". Some of the examples below have been elided for brevity using the symbol … to represent the elisions.

The template identifier for the Registration Medication History is 2.16.840.1.113883.3.88.11.32.1.

C32-[1] A CDA Document shall declare conformance to this specification by including a **<templateId>** element with the **root** attribute set to the value 2.16.840.1.113883.3.88.11.32.1.

Figure 4.2-1 Conformance Declaration Example

```
<ClinicalDocument xmlns='urn:hl7-org:v3'>
  <typeId extension='POCD_HD000040' root='2.16.840.1.113883.1.3'/>
  <templateId root='2.16.840.1.113883.10.20.1'/>
  <templateId root='2.16.840.1.113883.3.88.11.32.1'/>
```

Table 4.2.3.1-1 Registration and Medication History Document Content Component Modules

Content Modules		HITSP Opt	HITSP Repeat	Specification Reference	Additional Specification for Component
Person Information		R	N	See CCD: 2.5	See section 4.2.3.1.1
Language Spoken		R2	Y	See HL7 RIM 3.2.2	See section 4.2.3.1.2
Support		R2	Y	See CCD: 3.3	See section 4.2.3.1.3
Healthcare Provider		R	Y	See CCD: 3.17	See section 4.2.3.1.4
Insurance Provider		R	Y	See CCD: 3.1	See section 4.2.3.1.5
Allergies and Drug Sensitivity		R	Y	See CCD: 3.8	See section 4.2.3.1.6
Condition		R	Y	See CCD: 3.5	See section 4.2.3.1.7
Medications – Prescription and Non-Prescription		R	Y	See CCD: 3.9	See section 4.2.3.1.8
Pregnancy		O	N	See CCD: 3.5	See section 4.2.3.1.9
Information Source		R	N	See CCD: 5.2	See section 4.2.3.1.10
Comments		O	Y	See CCD: 4.3 HL7 CDAR2: 4.3.7.1 and 4.3.8.5	See section 4.2.3.1.11
Advance Directives		O	Y	See CCD 3.2	See section 4.2.3.1.12

4.2.3.1.1 Person Information Module

This module provides the name, address, contact information, personal identification information; ethnic and racial affiliation, and marital status of the person who is the subject of this Registration / Medication

History Document Content Component. See the HL7 Continuity of Care Document section 2.5 for constraints applicable to this module.

Table 4.2.3.1.1-1 Person Information Data Element Definitions

Data Elem. ID	Data Element	Definition
1.01	Document Timestamp	The date and time that this Registration Summary and Medication History Document has been created.
1.02	Person ID	An identifier that uniquely identifies the individual to which the Registration and Medication History Document refers, and connects that document to the individual's personal health record. Potential security risks associated with use of SSN or driver's license for this element suggest that these should not be used routinely.
1.03	Person Address	The current address of the individual to which the Registration and Medication History Document refers. Multiple addresses are allowed and the work address may be a method of disclosing the employer.
1.04	Person Phone/Email/URL	A telephone number (voice or fax), e-mail address, or other locator for a resource mediated by telecommunication equipment. One object class is used to describe phone numbers, pagers, Email addresses, and URLs. The patient may designate one of more of these contact numbers as the preferred methods of contact and temporary items can be entered for use on specific effective dates.
1.05	Person Name	The individual to whom the Registration and Medication History Document refers. Multiple names are allowed to retain birth name, maiden name, legal names, and aliases as required.
1.06	Gender	Gender is used to refer to administrative sex rather than biological sex and therefore should easily be classified into female and male. It is included in the registration summary for purposes of linking to insurance information and other patient identification linkages and the value chosen by the patient should reflect the information under which any insurance or financial information will be files as well as the same information given to other healthcare providers, institutions, or health data exchange networks.
1.07	Person Date of Birth	The date and time of the birth of the individual to which this Registration and Medication History Document refers. The date of birth is typically a key patient identifier variable and used to enable computation of age at the effective date of any other data element. It is assumed to be unique and fixed throughout the patient's lifetime.
1.08	Marital Status	A value representing the domestic partnership status of a person. Marital status is important in determining insurance eligibility and other legal arrangements surrounding care. Marital status often changes during a patient's lifetime so the data should relate to the effective date of the patient data object and not entered with multiple values like an address or contact number. This element should only have one instance reflecting the current status of the individual at the time the Registration and Medication History Document is produced. Former values might be part of the personal and social history in a full PHR but are not to be included for registration summary purposes.
1.09	Religious Affiliation	Religious affiliation is the religious preference of the person.
1.10	Race	Race is usually a single valued term that may be constant over that patient's lifetime. The coding of race is aligned with public health and other Federal reporting standards of the CDC and the Census bureau. Typically the patient is the source of the content of this element. However, the individual may opt to omit race from the Registration and Medication History Document. In this event, some healthcare organizations who receive the summary may choose to enter an observed race as may be their current practice for manual registration. Such organization observed race data should be differentiated from a patient sourced in the patient's registration summary.
1.11	Ethnicity	Ethnicity is a term that extends the concept of race. The coding of ethnicity is aligned with public health and other Federal reporting standards of the CDC and the Census bureau.

Table 4.2.3.1.1-2 Person Information Data Element Requirements

Data Elem. ID	Data Element	Opt / Repeat	CCD Name	Additional Specification for Component
1.01	Document Timestamp	R/N	/cda:ClinicalDocument/cda:effectiveTime	None
	Patient Information	R/N	/cda:ClinicalDocument/cda:recordTarget/ cda:patientRole	
1.02	Person ID	R/Y	cda:id	None
1.03	Person Address	R/Y	cda:addr	See section 4.2.3.1.1.2
1.04	Person Phone/Email/URL	R/Y	cda:telecom	See section 4.2.3.1.1.3
	Personal Information		cda:patient	
1.05	Person Name	R/Y	cda:name	See section 4.2.3.1.1.1
1.06	Gender	R/N	cda:administrativeGenderCode	See section 4.2.3.1.1.4
1.07	Person Date of Birth	R/N	cda:birthTime	None
1.08	Marital Status	R2/N	cda:maritalStatusCode	See section 4.2.3.1.1.5
1.09	Religious Affiliation	O/N	cda:religiousAffiliationCode	See section 4.2.3.1.1.8
1.10	Race	O/Y	cda:raceCode sdtc:raceCode	See section 4.2.3.1.1.6
1.11	Ethnicity	O/N	cda:ethnicityCode	See section 4.2.3.1.1.7

4.2.3.1.1.1 Person Name Constraints

The HL7 Clinical Document Architecture indicates how names are to be represented. A person's name appears in a **<name>** element, as a collection of name parts. See example 1 below in Figure 4.2-2 below.

C32-[2] Each name part shall be identified using one of the tags **<given>**, **<family>**, **<prefix>** or **<suffix>**.

C32-[3] The "first" name of the patient shall appear in the first **<given>** tag. In example 1 given below, "Margaret" is the patient's first name.

C32-[4] The "middle" name of the patient if it exists shall appear in the second **<given>** tag. In example 1 given below, "Ross" is the patient's middle name.

C32-[5] Name parts within a **<name>** tag shall be ordered in proper display order.

C32-[6] At most one **<name>** tag shall have a **use** attribute containing the value "L", indicating that it is the legal name of the patient.

C32-[7] More than one **<name>** tag may be present to retain birth name, maiden name and aliases.

C32-[8] An alias or former name may be identified by the inclusion of a **use** attribute containing the value "P".

C32-[9] Name parts may be identified as being a name given at birth or adoption by the inclusion of a **qualifier** attribute containing the value "BR" for birth or "AD" for adoption.

C32-[10] A name part shall be identified as the patient's preferred name by the inclusion of a **`qualifier`** attribute containing the value "CL" on the name part.

C32-[11] A prefix or suffix that is an academic title or credential shall be identified by the inclusion of a **`qualifier`** attribute containing the value "AC" on the name part.

Figure 4.2-2 Name Example

```
<!-- These examples assumes the default namespace is 'urn:hl7-org:v3' -->
<!-- example 1 -->
<name use="L">
    <prefix qualifier="AC">Dr.</prefix>
    <given>Margaret</given>
    <given>Ross</given>
    <family>Ellen</family>
</name>
<!-- example 2 -->
<name use="P">
    <given qualifier="CL">Meg</given>
    <family>Ellen</family>
</name>
<!-- example 3 -->
<name use="P">
    <given>Margaret</given>
    <given qualifier="BR">Josephine</given>
    <family qualifier ="BR">Ross</family>
</name>
<!-- example 4 -->
<name use="P">
    <prefix use="AC">Dr.</prefix>
    <given>Margaret</given>
    <given>Josephine</given>
    <family qualifier="BR">Ross</family>
</name>
```

4.2.3.1.1.2 Address Constraints

The HL7 Clinical Document Architecture indicates how addresses are to be represented. An address appears in a **<addr>** element, as a collection of address parts. See example 1 below in Figure 4.2-3 below.

Figure 4.2-3 Address Example

```
<!-- These examples assumes the default namespace is 'urn:hl7-org:v3' -->
<!-- example 1 -->
<addr use="HP">
    <streetAddressLine>17 Daws Road</streetAddressLine>
    <city>Blue Bell</city> <state>MA</state> <postalCode>00000</postalCode>
    <country>US</country>
</addr>
<!-- example 2 -->
<addr use="HV">
    <streetAddressLine>41 IDX Dr </streetAddressLine>
    <city>South Burlington </city> <state>VT</state> <postalCode>05403</postalCode>
    <country>US</country>
</addr>
<!-- example 3 -->
<addr use="WP">
    <streetAddressLine>116 Huntington Ave</streetAddressLine>
    <streetAddressLine>2nd Floor</streetAddressLine>
    <city>Boston</city> <state>MA</state> <postalCode>02116</postalCode>
    <country>US</country>
</addr>
```

C32-[12] Each address part shall be identified using the **<streetAddressLine>**, **<city>**, **<state>**, **<postalCode>** and **<country>** tags.

C32-[13] More than one **<streetAddressLine>** may be present.

C32-[14] No more than four **<streetAddressLine>** elements may be present.[3]

C32-[15] The **<country>** element shall be present for addresses outside of the United States.

C32-[16] At most one address for a person shall have a **use** attribute with a value containing "HP" (See example 1 in Figure 4.2-3 above).

C32-[17] At least one address for a patient should have a **use** attribute with a value containing "HP".

C32-[18] One or more vacation addresses may be present for a person.

C32-[19] A vacation address shall be recorded with a **use** attribute containing the value "HV" (See example 2 in Figure 4.2-3 above).

C32-[20] One or more work addresses may be present.

C32-[21] A work address shall be recorded with a **use** attribute containing the value "WP" (See example 3 in Figure 4.2-3 above).

C32-[22] The **<country>** shall be recorded using ISO-3166-1, using the two letter country codes.

[3] X12 and NCPDP standards only support two address lines. Implementations should not expect more than two address lines to be retained.

4.2.3.1.1.3 Person Phone/Email/URL

The HL7 Clinical Document Architecture indicates how telecommunications addresses are to be represented. A telecommunications address appears in a **<telecom>** element.

Figure 4.2-4 Telephone Numbers and E-mail Addresses

```
<!-- These examples assumes the default namespace is 'urn:hl7-org:v3' -->
<!-- example 1 -->
<telecom use="HP" value='tel:+1-999-999-9999'/>
<!-- example 2 -->
<telecom use="WP" value='tel:+1-888-888-8888;ext=9999'/>
<!-- example 3 -->
<telecom use="MC" value='tel:+1-777-777-7777'/>
<!-- example 4 -->
<telecom value='mailto:user@hostname'/>
```

C32-[23] A telephone number shall appear in a **<telecom>** element using the 'tel:' URL scheme (see RFC-3966)

C32-[24] All telephone numbers shall be represented in international form. That means that U.S. telephone numbers appear with a leading +1, and are followed by the 10 digits used to dial the phone number.

C32-[25] A telephone number may include hyphens or parenthesis characters for spacing, but these characters are not considered to be significant in comparisons.

C32-[26] An extension shall be represented by adding the extension dialing digits after the phone number, preceded by ;ext= as represented in example 2 above.

C32-[27] A home phone number shall be represented with a **use** attribute containing the value "HP" (see example 1 above).

C32-[28] A vacation home phone number shall be represented with a **use** attribute containing the value "HV".

C32-[29] A work phone number shall be represented with a **use** attribute containing the value "WP".

C32-[30] A mobile phone number shall be represented with a **use** attribute containing the value "MC".

C32-[31] An e-mail address shall appear in a **<telecom>** element using the 'mailto:' URL scheme (see RFC-2368), and shall encode only a single mailing address, without any headers.

4.2.3.1.1.4 Gender Constraints

C32-[32] Gender shall be coded using the HL7 AdministrativeGenderCode terminology.

The Object Identifier (OID) for this terminology is 2.16.840.1.113883.5.1. Examples are shown below in figure Figure 4.2-5.

Figure 4.2-5 Gender Code Examples

```
<!-- These examples assumes the default namespace is 'urn:hl7-org:v3' -->
<!-- example 1 -->
<genderCode code="M" displayName="Male" codeSystem="2.16.840.1.113883.5.1"
    codeSystemName="AdministrativeGenderCode"/>
<!-- example 2 -->
<genderCode code="F" displayName="Female" codeSystem="2.16.840.1.113883.5.1"
    codeSystemName="AdministrativeGenderCode"/>
```

4.2.3.1.1.5 Marital Status Constraints

C32-[33] Marital Status shall be coded using the vocabulary for marital status defined in ASTM E1633.

The Object Identifier (OID) for this terminology is 2.16.840.1.113883.3.88.6.1633.5.2.2[4].

Figure 4.2-6 Marital Status Example

```
<maritalStatusCode code='M' displayName='Married'
  codeSystem='2.16.840.1.113883.3.88.6.1633.5.2.2'
  codeSystemName='ASTM Marital Status'/>
```

NOTE: At the time of publication, the harmonization of marital status codes between various SDOs was incomplete. A future revision of this publication will likely use that vocabulary when it becomes available.

4.2.3.1.1.6 Race Constraints

C32-[34] Race shall be coded according to Federal Guidelines for reporting race, using the CDC vocabulary for reporting race.

C32-[35] Second and subsequent raceCode elements may be recorded using the sdtc:raceCode extension, as shown in example 2 below.

The Object Identifier (OID) for the CDC Race and Ethnicity terminology is 2.16.840.1.113883.6.238. Figure 4.2-7 shows an example of encoding two races for a patient. Race is reported at the discretion of the patient, according to Federal guidelines for race reporting.

Figure 4.2-7 Race Coding Example

```
<!-- These examples assumes the default namespace is 'urn:hl7-org:v3' -->
<!-- example 1 -->
<raceCode code='1004-1' displayName='American Indian'
  codeSystem='2.16.840.1.113883.6.238' codeSystemName='CDC Race and Ethnicity'/>
<!-- example 2 -->
<sdtc:raceCode code='2058-6' displayName='African American'
  codeSystem='2.16.840.1.113883.6.238' codeSystemName='CDC Race and Ethnicity'/>
```

[4] This OID has been provisionally assigned, and may change before final publication.

4.2.3.1.1.7 Ethnicity Constraints

C32-[36] Ethnicity shall be coded according to Federal Guidelines for reporting ethnicity, using the CDC vocabulary for reporting ethnicity.

The Object Identifier (OID) for the CDC Race and Ethnicity terminology is 2.16.840.1.113883.6.238. Figure 4.2-8 shows an example of encoding the ethnicity of a patient. Ethnicity is reported at the discretion of the patient, according to Federal guidelines for ethnicity reporting.

Figure 4.2-8 Ethnicity Coding Example

```
<!-- These examples assumes the default namespace is 'urn:hl7-org:v3' -->
<!-- example 1 -->
<ethnicityCode code='2178-2' displayName='Latin American'
  codeSystem='2.16.840.1.113883.6.238' codeSystemName='CDC Race and Ethnicity'/>
```

4.2.3.1.1.8 Religious Affiliation

C32-[37] The primary religious affiliation may appear in the **`<religiousAffilliationCode>`** element.

C32-[38] Religious affiliation shall be reported using the HL7 Religious Affiliation vocabulary.

The OID for this vocabulary is 2.16.840.1.113883.5.1076. An example entry for religious affiliation is shown below in Figure 4.2-9. Religious affiliation is recorded at the discretion of the patient.

Figure 4.2-9 Religious Affiliation Example

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

4.2.3.1.2 Language Spoken Module

This module describes the primary and secondary languages of communication for the patient.

Table 4.2.3.1.2-1 Language Spoken Data Element Definition

Data Elem. ID	Data Element	Definition
2.01	Language	Language will be identified as spoken, written, or understood; but no attempt will be made to assess proficiency. The default language is English, but English is to be entered explicitly similar to any other listed language. Languages spoken shall be recorded using the languageCommunication infrastructure class associated with the patient. The languageCommunication element describes the primary and secondary languages of communication for a person.

Table 4.2.3.1.2-2 Language Spoken Data Element Requirements

Data Elem. ID	Data Element	Opt / Repeat	CCD Name	Additional Specification for Component
2.01	Language	R/Y	cda:recordTarget/cda:patientRole/ cda:patient/ cda:languageCommunication	See section 4.2.3.1.2.1

4.2.3.1.2.1 Language

The template identifier for this construct is 2.16.840.1.113883.3.88.11.32.2.

C32-[39] The language of communication shall appear in a **<languageCommunication>** element appearing beneath the **<patient>** element.

C32-[40] This element shall have a **<languageCode>** element that conveys the language of communication.

NOTE: Sign language shall be treated as a separate language for the purpose of this specification.

C32-[41] The **<languageCommunication>** element should have a **<preferenceInd>** element to indicate the patient preference for use of that language for communication.

C32-[42] More than one language preference may be recorded.

C32-[43] To indicate only a specific mode of communication (expressing or receiving written, verbal, or signed communication), a **<modeCode>** element may be included.

C32-[44] The codes for the **<modeCode>** element shall come from the HL7 LanguageAbilityMode vocabulary. Mode codes shall be appropriate to the type of language. Thus English, as spoken in the U.S. should use the code en-US and should only use mode codes for written and verbal communications (see example 2 below). On the other hand, American Sign Language would be represented using the code sgn-US (see example 3 below), and would only use mode codes for signed communication.

C32-[45] While this HL7 CDA allows for the specification of proficiency using the **<proficiencyLevelCode>** element, this element should not be used[5].

Examples are shown below in Figure 4.2-10.

Figure 4.2-10 Language Communication Examples

```
<!-- These examples assumes the default namespace is 'urn:hl7-org:v3' -->
<!-- example 1 -->
<languageCommunication>
  <templateId root='2.16.840.1.113883.3.88.11.32.2'/>
  <languageCode code='fr-CN' displayName='Canadian French' />
  <preferenceInd value='true'/>
</languageCommunication>
<!-- example 2 -->
<languageCommunication>
  <templateId root='2.16.840.1.113883.3.88.11.32.2'/>
  <languageCode code='en-US' displayName='English' />
  <modeCode code='RWR' displayName='Recieve Written'
    codeSystem='2.16.840.1.113883.5.60' codeSystemName='LanguageAbilityMode'/>
  <preferenceInd value='false'/>
</languageCommunication>
<!-- example 3 -->
<languageCommunication>
  <templateId root='2.16.840.1.113883.3.88.11.32.2'/>
  <languageCode code='sgn-US' displayName='American Sign Language' />
  <preferenceInd value='true'/>
</languageCommunication>
```

[5] Judgments about language proficiency are subjective, and could have a negative impact on the desire of consumers to use this construct to exchange registration and medication information.

4.2.3.1.3 Support Module

This module represents the patient's sources of support such as immediate family, relatives, and guardian at the time the summarization is generated. Support information also includes next of kin, caregivers, and support organizations. At a minimum, key support contacts relative to healthcare decisions, including next of kin, should be included. Support providers may include providers of healthcare related services, such as a personally controlled health record, or registry of emergency contacts. If no healthcare providers are supplied, the reason should be supplied as free text in the narrative block (e.g., Unknown, et cetera).
See the HL7 Continuity of Care Document section 3.3 for constraints applicable to this module.

The contact data object is used to store phone numbers, Email, and URL information for contacting the patient or others such as emergency contacts or healthcare providers.

The template identifier for this construct is 2.16.840.1.113883.3.88.11.32.3.

Table 4.2.3.1.3-1 Support Module Data Element Definitions

Data Elem. ID	Data Element	Definition
3.01	Date	The period over which the support is provided.
3.02	Contact Type	This represents the type of support provided, such as immediate emergency contacts, next of kin, family relations, guardians, agents, et cetera.
3.03	Contact Relationship	Identifies the relationship of the contact person to the individual for which this Registration and Medication History Document refers.
3.04	Contact Address	The address of the contact individual or organization providing support to the individual for which this Registration and Medication History Document is produced.
3.05	Contact Phone/Email/URL	A telephone number (voice or fax), e-mail address, or other locator for the contact individual or organization providing support to the individual for which this Registration and Medication History Document is produced. One object class is used to describe phone numbers, pagers, Email addresses, and URLs.
3.06	Contact Name	The name of the individual or organization providing support to the individual for which this Registration and Medication History Document is produced.

Table 4.2.3.1.3-2 Support Module Data Element Requirements

Data Elem. ID	Data Element	Opt / Repeat	CCD Name	Additional Specification for Component
	Support	R2/Y	cda:participant	
3.01	Date	R/N	cda:time	None
	Contact	R2/Y	cda:associatedEntity or cda:patient/cda:guardian	
3.02	Contact Type	R/N	@classCode	See section 4.2.3.1.3.1

Data Elem. ID	Data Element	Opt / Repeat	CCD Name	Additional Specification for Component
3.03	Contact Relationship	R2/N	cda:code	See section 4.2.3.1.3.2
3.04	Contact Address	R2/Y	cda:addr	See also section 4.2.3.1.1.2
3.05	Contact Phone/Email/URL	R2/Y	cda:telecom	See also section 4.2.3.1.1.3
3.06	Contact Name	R/Y	cda:associatedPerson/cda:name or cda:guardianPerson/cda:name	See also section 4.2.3.1.1.1

Examples are given below in Figure 4.2-11 for the **<guardian>** and **<associatedEntity>** elements appearing in the header of the clinical document.

Figure 4.2-11 Support Examples

```
<!-- These examples assumes the default namespace is 'urn:hl7-org:v3' -->
<!-- example 1 -->
<patient>
    …
  <guardian classCode='GUARD'>
    <templateId root='2.16.840.1.113883.3.88.11.32.3'/>
    <code code='GRMTH' displayName='Grandmother'
      codeSystem='2.16.840.1.113883.5.111' codeSystemName='RoleCode'/>
    <addr>…</addr>
    <telecom …/>
    <guardianPerson>
      <name>…</name>
    </guardianPerson>
  </guardian>
</patient>

<!-- example 2 -->
<participant typeCode='IND'>
  <templateId root='2.16.840.1.113883.3.88.11.32.3'/>
  <time value='20070213'/>
  <associatedEntity classCode='AGNT'>
    <code code='STPDAU' displayName='Step-Daughter'
      codeSystem='2.16.840.1.113883.5.111' codeSystemName='RoleCode'/>
    <addr>…</addr>
    <telecom …/>
    <assignedPerson>
      <name>…</name>
    </assignedPerson>
  </associatedEntity>
<participant>
```

4.2.3.1.3.1 Contact Type

C32-[46] With the exception of guardians, supporting persons or organizations shall be represented in the HL7 CDA using the **<participant>** element in the header of the **<ClinicalDocument>**.

C32-[47] Guardians shall be represented using the **<guardian>** element subordinate to the **<patient>** element.

C32-[48] A patient may have more than one guardian.

C32-[49] Contact type shall be expressed by the classCode attribute on the **<guardian>** or **<associatedEntity>**.

The classCode attribute is filled in using HL7 RoleClass vocabulary as shown below in Table 4.2.3.1.3.1-1. For this specification, the following values shall be used to express different types of contacts:

Table 4.2.3.1.3.1-1 Contact Type Additional Specifications

Term	HL7 Definition and Example	Clarification for use in the CE Context

AGNT	An entity that acts or is authorized to act on behalf of another entity (scoper).
	`<assignedEntity classCode='AGNT'>`
	`...`
	`</assignedEntity>`
		Used to record persons that can act on behalf of the patient, e.g., someone holding a healthcare power of attorney, et cetera.

CAREGIVER	A person responsible for the primary care of a patient at home.
	`<assignedEntity classCode='CAREGIVER'>`
	`...`
	`</assignedEntity>`
		None

ECON	An entity to be contacted in the event of an emergency.
	`<assignedEntity classCode='ECON'>`
	`...`
	`</assignedEntity>`
		None

GUARD	Guardian of a ward
	`<patient>`
	`...`
	`<guardian classCode='GUARD'>`
	`...`
	`</guardian>`
	`</patient>`
		The CCD specifies that the guardian relationship shall be encoded using the <cda:guardian> element that appears inside the <cda:patient> element.

NOK	An individual designated for notification as the next of kin for a given entity.
	`<assignedEntity classCode='NOK'>`
	`...`
	`</assignedEntity>`
		None

PRS	Links two people in a personal relationship.
	`<assignedEntity classCode='PRS'>`
	`...`
	`</assignedEntity>`
		Used to describe family members and other persons that have a personal relationship with the patient. When this value is used, the value used for Contact Relationship below is also constrained to the HL7 PersonalRelationshipRoleType vocabulary domain.

4.2.3.1.3.2 Contact Relationship

C32-[50] The contact relationship should be recorded in the **<code>** element beneath the **<assignedEntity>** or **<guardian>** element.

C32-[51] The **<code>** element shall have a code value drawn from the HL7 PersonalRelationshipRoleType vocabulary. The OID for this vocabulary is 2.16.840.1.113883.5.111.

4.2.3.1.4 Healthcare Providers Module

This module represents the healthcare providers involved in the current or pertinent historical care of the patient. See the HL7 Continuity of Care Document section 3.17 for constraints applicable to this module. If no healthcare providers are supplied, the reason shall be supplied as free text in the narrative block (e.g., No providers, Provider Unknown, et cetera).

Providers listed in this module may be referred to by the Conditions Module defined in section 4.2.3.1.7 to link a condition to the treating provider or providers.

The template identifier for this construct is 2.16.840.1.113883.3.88.11.32.4.

Table 4.2.3.1.4-1 Healthcare Providers Data Element Definitions

Data Elem. ID	Data Element	Definition
4.01	Date Range	The period over which this provider has provided healthcare services to the patient.
4.02	Provider Role Coded	Provider role uses a coded value to classify providers according to the role they play in the healthcare of the patient, and comes from a very limited set of values. The purpose of this data element is to express the information often required during patient registration, identifying the patient's primary care provider, the referring physician, or other consultant involved in the care of the patient.
4.03	Provider Role Free Text	This unstructured text classifies providers according to the role they play in the healthcare of the patient.
4.04	Provider Type	Provider type classifies providers according to the type of license or accreditation they hold (e.g. physician, dentist, pharmacist, et cetera) or the service they provide.
4.05	Provider Address	The mailing address to which written correspondence to this provider should be directed.
4.06	Provider Phone/Email/URL	A telephone number (voice or fax), e-mail address, or other locator for a resource mediated by telecommunication equipment. One object class is used to describe phone numbers, pagers, Email addresses, and URLs. One or more of these contact numbers can be designated as the preferred methods of contact; temporary items can be entered for use on specific effective dates.
4.07	Provider Name	The name of the provider.
4.08	Provider's Organization Name	The name of the organization with which the provider is affiliated. While providers may be affiliated with more than one organization, this should be the organization affiliated with this person's care.
4.09	Provider's Patient ID	The identifier used by this provider to identify the patient's medical record.

Table 4.2.3.1.4-2 Healthcare Providers Data Element Requirements

Data Elem. ID	Data Element	Opt / Repeat	CCD Name	Additional Specification for Component
	Provider	R2/Y	/cda:ClinicalDocument/cda:documentationOf/ cda:serviceEvent/cda:performer	
4.01	Date Range	R/N	cda:time	None
4.02	Provider Role Coded	R2/N	cda:functionCode	See section 4.2.3.1.4.2

Data Elem. ID	Data Element	Opt / Repeat	CCD Name	Additional Specification for Component
4.03	Provider Role Free Text	R2/N	cda: functionCode/ cda:originalText	None
	Provider Entity	R/Y	cda:assignedEntity	
4.04	Provider Type	R2/N	cda:code	See section 4.2.3.1.4.3
4.05	Provider Address	R2/Y	cda:addr	See also section 4.2.3.1.1.2
4.06	Provider Phone/Email/URL	R2/Y	cda:telecom	See also section 4.2.3.1.1.3
4.07	Provider Name	R2/N	cda:assignedPerson/cda:name	See also section 4.2.3.1.1.1
4.08	Provider's Organization Name	R2/Y	cda:representedOrganization/ cda:name	None
4.09	Provider's Patient ID	R2/N	sdtc:patient/sdtc:id	None

4.2.3.1.4.1 Provider

Healthcare providers are encoded as shown below in Figure 4.2-12. The registration and medication history document provides documentation of the service event which is the provision of healthcare. This is reflected in the **`<serviceEvent classCode='PCPR'>`** element in the example below. The value PCPR is required, and is a code meaning "provision of care".

Figure 4.2-12 Healthcare Provider Example

```
<!-- These examples assumes the default namespace is 'urn:hl7-org:v3' -->
<documentationOf>
  <serviceEvent classCode="PCPR">    <effectiveTime><low value="19650120"/><high
value="20070209"/></effectiveTime>
    <performer typeCode="PRF">
      <templateId root='2.16.840.1.113883.3.88.11.32.4'/>
      <functionCode code='CP' displayName='Consulting Provider'
        codeSystem='2.16.840.1.113883.12.443' codeSystemName='Provider Role'>
        <orginalText>Consulting Provider</originalText>
      <time>
        <low value=''/>
        <high value=""/>
      </time>
      <assignedEntity>
        <id root='78A150ED-B890-49dc-B716-5EC0027B3982'
          extension="ProviderID"/>
        <code code='200000000X '
          displayName='Allopathic and Osteopathic Physicians'
          codeSystem='2.16.840.1.113883.6.101'
          codeSystemName='ProviderCodes'/>
        <assignedPerson>
          <name>...</name>
        </assignedPerson>
        <sdtc:patient>
          <sdtc:id root='78A150ED-B890-49dc-B716-5EC0027B3983'
            extension='MedicalRecordNumber'/>
        </sdtc:patient>
      </assignedEntity>
    </performer>
  </serviceEvent>
</documentationOf>
```

4.2.3.1.4.2 Provider Role

C32-[52] Provider role shall be taken from a limited subset of the HL7 Version 2 Provider Role vocabulary. The OID for this terminology is 2.16.840.1.113883.12.443.

Table 4.2.3.1.4.1-1 Provider Role Terminology

Term	HL7 Definition
CP	Consulting Provider
PP	Primary Care Provider
RP	Referring Provider

4.2.3.1.4.3 Provider Type

Provider type shall be coded using a subset of the Healthcare Provider Taxonomy. This subset uses only the high-level provider codes, and eliminates a few codes not otherwise needed in the CE Use Case. The OID for this terminology is 2.16.840.1.113883.6.101.

Table 4.2.3.1.4.2-1 Provider Type Additional Specifications

Term	Healthcare Provider Taxonomy
100000000X	Behavioral Health and Social Service Providers
110000000X	Chiropractic Providers
120000000X	Dental Providers
130000000X	Dietary and Nutritional Service Providers
140000000X	Emergency Medical Service Providers
150000000X	Eye and Vision Service Providers
160000000X	Nursing Service Providers
180000000X	Pharmacy Service Providers (Individuals)
200000000X	Allopathic & Osteopathic Physicians
210000000X	Podiatric Medicine and Surgery Providers
220000000X	Respiratory, Rehabilitative and Restorative Service Providers
230000000X	Speech, Language and Hearing Providers
250000000X	Agencies
260000000X	Ambulatory Health Care Facilities
280000000X	Hospitals
290000000X	Laboratories
300000000X	Managed Care Organizations
310000000X	Nursing and Custodial Care Facilities
320000000X	Residential Treatment Facilities
330000000X	Suppliers (including Pharmacies and Durable Medical Equipment)
360000000X	Physician Assistants and Advanced Practice Nursing Providers
370000000X	Nursing Service Related Providers
380000000X	Respite Care Facility

4.2.3.1.5 Insurance Providers Module

This Insurance Providers Module contains data about the entities or other individuals who may pay for a patient's healthcare. Such entities or individuals may be health insurance plans, other payers, guarantors, parties with financial responsibility, some combination of payers, or the patient directly. This module is used to define which entity or combination of entities has any financial responsibility for a patient's care. See the HL7 Continuity of Care Document section 3.1.2.1.2 for constraints applicable to this module. Each unique instance of a payer or party with financial responsibility will include all the pertinent data needed to contact, bill to, and collect from that party. At a minimum, the patient's pertinent current payment sources should be listed. If no payment sources are supplied, the reason shall be supplied as free text in the narrative block (e.g., Not Insured, Payer Unknown, Medicare Pending, et cetera).

The template identifier for this construct is 2.16.840.1.113883.3.88.11.32.5.

Table 4.2.3.1.5-1 Insurance Providers Data Element Definitions

Data Elem. ID	Data Element	Definition
5.01	Group Number	The policy or group contract number identifying the contract between a health plan sponsor and the health plan. This is not a number that uniquely identifies either the subscriber or person covered by the health insurance.
5.02	Health Insurance Type	The type of health plan covering the individual, e.g., an HMO, PPO, POS, Medicare Part A/B, etc.
5.03	Health Plan Insurance Information Source ID	The coded identifier of the payer corresponding to the Health Plan Information Source Name. It is important to note that Health Plan Information Source Name and ID are NOT synonymous with Health Plan Name or the health plan identifier (when/if health plans are enumerated under HIPAA).
5.04	Health Plan Insurance Information Source Address	The official mailing address to which written correspondence is to be directed.
5.05	Health Plan Insurance Information Source Phone/Email/URL	A telephone number (voice or fax), e-mail address, or other locator for a resource mediated by telecommunication equipment. One object class is used to describe phone numbers, pagers, Email addresses, and URLs. One or more of these contact numbers can be designated as the preferred methods of contact; temporary items can be entered for use on specific effective dates.
5.06	Health Plan Insurance Information Source Name	The name of the entity that is the source of information about the health insurance. This name is not synonymous with a Health Plan Name or a health plan identifier (when/if health plans are enumerated under HIPAA). In the context of the X12N 271 transaction, an information source could be the payer, a third party administrator (TPA), a health plan sponsor, or a gateway provider.
5.07	Health Plan Coverage Dates	The begin and end dates the health plan coverage of the individual. These dates may not apply equally to all benefits included in the health plan coverage. Some benefits may have waiting periods for coverage to be effective which results in a different benefit begin date. The purpose of providing this information in the registration / medication summary is to better inform patients about their health coverage. Providers should use the applicable standard transactions required under regulation to determine patient eligibility for benefits.

Data Elem. ID	Data Element	Definition
5.08	Member ID	The identifier assigned by the health plan to the patient who is covered by the health plan. When the patient is the actual member or health plan contract holder (the true subscriber) and not a dependent of the subscriber, it is the same as the Subscriber ID. A related spouse, child, or dependent may not have a unique identification number of their own.
5.09	Patient Relationship to Subscriber	Specifies only if patient is the subscriber or dependent within the context of the specified health plan.
5.10	Patient Address	The mailing address of the patient who is a member or enrollee of health plan as recorded by the health plan. This address may be the same as or different from the true subscriber of the health plan. The mailing address used by the health plan may also differ from any other address otherwise used by the patient. See section 4.2.3.1.5.5
5.11	Patient Phone/Email/URL	A telephone number (voice or fax), e-mail address, or other locator for a resource mediated by telecommunication equipment. One object class is used to describe phone numbers, pagers, Email addresses, and URLs. One or more of these contact numbers can be designated as the preferred methods of contact; temporary items can be entered for use on specific effective dates.
5.12	Patient Name	The name of the actual patient who is a member or enrollee of health plan as entered into the eligibility system of the health plan. The patient may be the true subscriber or any related spouse, child, or dependent. See section 4.2.3.1.5.3
5.13	Patient Date of Birth	The date of birth of the patient as entered into the eligibility system of the health plan. See section 4.2.3.1.5.4
5.14	Financial Responsibility Party Type	The type of party that has responsibility for all or a portion of the patient's healthcare; includes health insurance, the patient directly, a guardian or other guarantor, or other third party that is not a health insurance plan.
5.15	Subscriber ID	The identifier assigned by the health plan to the actual member or health plan contract holder (the true subscriber) entered into the eligibility system of the health plan.
5.16	Subscriber Address	The official mailing address of the actual member or health plan contract holder (the true subscriber) as entered into the eligibility system of the health plan to which written correspondence is to be directed.
5.17	Subscriber Phone/Email/URL	A telephone number (voice or fax), e-mail address, or other locator for a resource mediated by telecommunication equipment. One object class is used to describe phone numbers, pagers, Email addresses, and URLs. One or more of these contact numbers can be designated as the preferred methods of contact; temporary items can be entered for use on specific effective dates.
5.18	Subscriber Name	The name of the actual member or health plan contract holder (the true subscriber) as entered into the eligibility system of the health plan. This is not the name of a related spouse, child, or dependent. See section 4.2.3.1.5.1
5.19	Subscriber Date of Birth	The date of birth of the actual member or health plan contract holder (the true subscriber) as entered into the eligibility system of the health plan. See section 4.2.3.1.5.2
5.20	Effective Date of Financial Responsibility	The time span over which the Financial Responsibility Party is responsible for the payment of the patient's healthcare.
5.21	Financial Responsibility Party Address	The official mailing address of the Financial Responsibility Party to which written correspondence is to be directed.

Data Elem. ID	Data Element	Definition
5.22	Financial Responsibility Party Phone/Email/URL	A telephone number (voice or fax), e-mail address, or other locator for a resource mediated by telecommunication equipment. One object class is used to describe phone numbers, pagers, Email addresses, and URLs. One or more of these contact numbers can be designated as the preferred methods of contact; temporary items can be entered for use on specific effective dates.
5.23	Financial Responsibility Party Name	The name of the financially responsible party.
5.24	Health Plan Name	The name of the specific health insurance product as specified by the insurance company offering the healthcare insurance. The HIPAA legislation requires the Secretary of HHS to establish unique health plan identifiers. To date regulations specifying the enumeration and identification of health plans have not been promulgated by the Secretary of HHS.

Table 4.2.3.1.5-2 Insurance Providers Data Element Requirements

Data Elem. ID	Data Element	Opt / Repeat	CCD Name	Additional Specification for Component
	Payment Providers	R2/Y	cda:act[cda:templateId/@root= '2.16.840.1.113883.10.20.1.26']	See section 4.2.3.1.5.1
5.01	Group Number	O/N	cda:id	See section 4.2.3.1.5.2
5.02	Health Insurance Type	R2/N	cda:code	See section 4.2.3.1.5.3
	Payer	R/N	cda:performer/cda:assignedEntity	
5.03	Health Plan Insurance Information Source ID	O/Y	cda:id	See section 4.2.3.1.5.4
5.04	Health Plan Insurance Information Source Address	O/Y	cda:addr	See also section 4.2.3.1.1.2
5.05	Health Plan Insurance Information Source Phone/Email/URL	O/Y	cda:telecom	See also section 4.2.3.1.1.3
5.06	Health Plan Insurance Information Source Name	R2/N	cda:representedOrganization/ cda:name	None
	Patient Information	R2/N	cda:participant[@typeCode='COV']	See section 4.2.3.1.5.5
5.07	Health Plan Covererage Dates	R2/N	cda:time	See section 4.2.3.1.5.6
	Patient	R/N	cda:participantRole [@classCode='PAT']	
5.08	Member ID	R2/N	cda:id	See section 4.2.3.1.5.7
5.09	Relationship to Subscriber	R/N	cda:code	See section 4.2.3.1.5.8
5.10	Patient Address	R2/Y	cda:addr	See also section 4.2.3.1.1.2
5.11	Patient Phone/Email/URL	R2/Y	cda:telecom	See also section 4.2.3.1.1.3
5.12	Patient Name	R/N	cda:playingEntity/cda:name	See section 4.2.3.1.5.9 See also section 4.2.3.1.1.1

Data Elem. ID	Data Element	Opt / Repeat	CCD Name	Additional Specification for Component
5.13	Patient Date of Birth	R/N	cda:playingEntity/sdtc:birthTime	See section 4.2.3.1.5.10
5.14	Financial Responsibilty Party Type	R/N	cda:performer/cda:assignedEntity/cda:code	See section 4.2.3.1.5.11
	Subscriber Information	R2/N	cda:participant[@typeCode='HLD']/ cda:participantRole	See section 4.2.3.1.5.12
5.15	Subscriber ID	R/N	cda:id	See section 4.2.3.1.5.13
5.16	Subscriber Address	R/N	cda:addr	See also section 4.2.3.1.1.2
5.17	Subscriber Phone/Email/URL	R2/Y	cda:telecom	See also section 4.2.3.1.1.3
5.18	Subscriber Name	R/N	cda:playingEntity/cda:name	See also section 4.2.3.1.1.1
5.19	Subscriber Date of Birth	R/N	cda:playingEntity/sdtc:birthTime	See section 4.2.3.1.5.14
	Guarantor Information	R2/Y	cda:performer[cda:assignedEntity/cda:code[@code='' and @codeSystem='']]	
5.20	Effective Date of Financial Responsibility	R2/N	cda:time	None
5.21	Financial Responsibility Party Address	R2/Y	cda:assignedEntity/cda:addr	See also section 4.2.3.1.1.2
5.22	Financial Responsibility Party Phone/Email/URL	R2/Y	cda:assignedEntity/cda:telecom	See also section 4.2.3.1.1.3
5.23	Financial Responsibility Party Name	R2/N	cda:assignedEntity/cda:assignedPerson/ cda:name - AND/OR - cda:assignedEntity/ cda:representedOrganization/cda:name	See also section 4.2.3.1.1.1
	Health Plan	R2/N	cda:entryRelationship[@typeCode='REFR']/ cda:act[@classCode='ACT' and @moodCode='DEF']	
5.24	Health Plan Name	R2/N	cda:text	See section 4.2.3.1.5.16

4.2.3.1.5.1 Payment Providers

Information for payment providers shall be recorded as a policy act inside the coverage act as described in section 3.1 of the Continuity of Care Document Implementation Guide. Examples are shown below in Figure 4.2-13.

Figure 4.2-13 Insurance Provider Examples

```
<!-- These examples assumes the default namespace is 'urn:hl7-org:v3' -->
<!-- example 1 -->
<act classCode='ACT' moodCode='DEF'>
  <templateId root='2.16.840.1.113883.10.20.1.20'/>
  <id root=''/>
  <code code='48768-6' displayName='Payment Sources'
    codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
  <statusCode code='completed'/>

  <!-- Example 1, A health plan -->
  <entryRelationship typeCode='COMP'>
    <sequenceNumber value='1'/>
    <act classCode='ACT' moodCode='EVN'>
      <templateId root='2.16.840.1.113883.10.20.1.26'/>
      <templateId root='2.16.840.1.113883.3.88.11.32.5'/>
      <id root='2844AF96-37D5-42a8-9FE3-3995C110B4F8'
        extension='GroupOrContract#'/>
      <code code='' displayName=''
        codeSystem='2.16.840.1.113883.6.255.1336' codeSystemName='X12N-1336'/>
      <statusCode code='completed'/>
      <performer typeCode='PRF'>…</performer>
      <participant typeCode='COV'>…</participant>
      <participant typeCode='HLD'>…</participant>
      <entryRelationship typeCode='REFR'>
        <act classCode='ACT' moodCode='DEF'>…</act>
      </entryRelationship>
    </act>
  </entryRelationship>

  <!-- Example 2, A guarantor -->
  <entryRelationship typeCode='COMP'>
    <sequenceNumber value='2'/>
    <act classCode='ACT' moodCode='EVN'>
      <templateId root='2.16.840.1.113883.10.20.1.26'/>
      <templateId root='2.16.840.1.113883.3.88.11.32.5'/>
      <id root='2844AF96-37D5-42a8-9FE3-3995C110B4F9'/>
      <code code='PP' displayName='Personal Payment'
        codeSystem='2.16.840.1.113883.6.255.1336' codeSystemName='X12N-1336'/>
      <statusCode code='completed'/>
      <performer typeCode='PRF'>
        <time value='…'/>
        <assignedEntity>
          <id …/>
          <code code='GUAR' displayName='Guarantor'
            codeSystem='2.16.840.1.113883.5.110' codeSystemName='RoleClass'/>
          <assignedPerson><name>…</name></assignedPerson>
        </assignedEntity>
      </performer>
    </act>
  </entryRelationship>
</act>
```

4.2.3.1.5.2 Group Number

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

C32-[53] The group or contract number shall be recorded in the **`extension`** attribute of the **`<id>`** element found in the **`<act>`**.

C32-[54] The value of the **`root`** attribute of the **`<id>`** element shall be present.

C32-[55] The **`root`** attribute should be the OID of the assigning authority for the identifier, however, determining the assigning authority is not feasible in all settings.

C32-[56] A GUID may be used in place of the OID of the assigning authority.

C32-[57] Implementers should use the same GUID for each instance of the same group or contract number.

Figure 4.2-14 Group Number Example

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

4.2.3.1.5.3 Health Insurance Type

C32-[58] The health insurance type should be recorded in the **`<code>`** element beneath the act representing the policy.

C32-[59] The **`code`** attribute value shall come from the X12 vocabulary for Insurance Type Code (X12 Data Element 1336), as restricted by the X12N 271 Transaction. The OID for this vocabulary is 2.16.840.1.113883.6.255.1336.

C32-[60] The **`code`** attribute shall use the value PP to indicate self-pay or payment by a guarantor.

Figure 4.2-15 Health Insurance Type Example

```
<!-- These examples assumes the default namespace is 'urn:hl7-org:v3' -->
    <act classCode='ACT' moodCode='EVN'>
    <templateId root='2.16.840.1.113883.10.20.1.26'/>
      ...
    <code code='IP' displayName='Individual Policy'
      codeSystem='2.16.840.1.113883.6.255.1336' codeSystemName='X12N-1336'/>
      ...
  </act>
```

4.2.3.1.5.4 Health Plan Insurance Information Source ID

The information source identifier corresponds to the RxBIN and RxPCN fields found on pharmacy benefit cards. When a national payer identifier is standardized, it would also go in this field.

The OID for RxBIN is 2.16.840.1.113883.3.88.3.1[6]
The OID for an RxPCN is 2.16.840.1.113883.3.88.3.1 plus the numeric identifier used in the RxBIN.

Figure 4.2-16 Payer Example

```
<!-- These examples assumes the default namespace is 'urn:hl7-org:v3' -->
<performer typeCode='PRF'>
  <assignedEntity classCode='ASSIGNED'>
    <id root='OID for RxBIN' extension='#RxBIN'/>
    <id root='OID for RxPCN' extension='#RxPCN'/>
    <addr>…</addr>
    <telecom value='…'/>
    <representedOrganization classCode='ORG'>
      <name>…</name>
    </representedOrganization>
  </assignedEntity>
</performer>
```


[6] This OID has been provisionally assigned and may change before final publication.

4.2.3.1.5.5 Member Information

The data elements described below identify the member (patient) to the health plan for eligibility and/or claims processing. For various reasons, the health plan may not have the member's name, address or data of birth recorded in the same way as the provider has recorded the patient information. Using the member information as recorded by the health plan will improve the healthcare provider's ability to determine eligibility for benefits, and reduce rejections of claims. Two examples are provided below in Figure 4.2-17.

C32-[61] Member information shall be recorded in a **<participant>** element with the typeCode attribute set to "COV".

Figure 4.2-17 Member Information Examples

```
<!-- These examples assumes the default namespace is 'urn:hl7-org:v3' -->
<!-- Example 1, The patient is the subscriber -->
<participant typeCode='COV'>
  <time>
    <low value='20070101'/>
  </time>
  <participantRole classCode='PAT'>
    <id root='' extension=''/>
    <code code='SUBSCR' displayName='subscriber'
      codeSystem='2.16.840.1.113883.5.111' codeSystemName='RoleCode'/>
    <playingEntity>
      <name>…</name>
      <sdtc:birthTime value='…'/>
    </playingEntity>
  </participant>
</participant>

<!-- Example 2, The patient is a dependent of the subscriber -->
<participant typeCode='COV'>
  <time>
    <low value='20070209'/>
  </time>
  <participantRole classCode='PAT'>
    <id root='' extension=''/>
    <code code='DEPEND' displayName='dependent'
      codeSystem='2.16.840.1.113883.5.111' codeSystemName='RoleCode'/>
    <playingEntity>
      <name><given>Baby</given><family>Ross</family></name>
      <sdtc:birthTime value='20070209'/>
    </playingEntity>
  </participant>
</participant>
```

4.2.3.1.5.6 Health Plan Coverage Dates

C32-[62] The date when the plan began covering the member should be recorded in the **<low>** element of the **<time>** element beneath the **<participant>** element.

C32-[63] The date when the plan stops covering the member should be recorded in the **<high>** element of the **<time>** element beneath the **<participant>** element.

4.2.3.1.5.7 Member ID

C32-[64] The member identifier number shall be recorded in the **`extension`** attribute of the **`<id>`** element found in the **`<participantRole>`** element.

C32-[65] The value of the **`root`** attribute of the **`<id>`** element shall be present.

C32-[66] The **`root`** attribute should be the OID of the assigning authority for the identifier, however, determining the assigning authority is not feasible in all settings.

C32-[67] A GUID may be used in place of the OID of the assigning authority.

C32-[68] Implementers should use the same GUID for each instance of a member identifier from the same health plan.

4.2.3.1.5.8 Relationship to Subscriber

C32-[69] The relationship to the subscriber shall be recorded in the **`<code>`** element underneath the **`<participantRole>`** element recording the member information.

C32-[70] The **`code`** attribute shall be present, and shall contain a value from the HL7 CoverageRoleType vocabulary domain. The OID for this vocabulary is 2.16.841.1.113883.5.111.

4.2.3.1.5.9 Patient Name

C32-[71] If the member name as recorded by the health plan differs from the patient name as recorded in the registration medication summary (e.g., due to marriage or for other reasons), then the member name shall be recorded in the **`<name>`** element of the **`<playingEntity>`** element beneath the **`<participantRole>`** element.

C32-[72] Otherwise, the name shall be assumed to be the same as recorded for the patient, as described for data element 1.05 above.

4.2.3.1.5.10 Patient Date of Birth

C32-[73] If the member date of birth as recorded by the health plan differs from the patient date of birth as recorded in the registration medication summary, then the member date of birth shall be recorded in the **`<sdtc:birthTime>`** element of the **`<playingEntity>`** element beneath the **`<participantRole>`** element.

C32-[74] Otherwise, the date of birth of the member shall be assumed to be the same as recorded for the patient, as described for data element 1.07 above.

The **`<sdtc:birthTime>`** element represents an extension to the HL7 CDA Release 2.0.

4.2.3.1.5.11 Financial Responsibility Party Type

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

C32-[75] The type of financially responsible party shall be recorded in the **<code>** element beneath the **<assignedEntity>** element of the **<performer>**.

C32-[76] The code attribute shall contain a value from the HL7 RoleClassRelationshipFormal vocabulary. The OID for this vocabulary is 2.16.840.1.113883.5.110.

C32-[77] When the **code** of the encompassing act is PP, the **code** attribute value shall be set to GUAR or PAT to represent a guarantor or self-paying patient respectively.

C32-[78] The **code** attribute shall be set to PAYOR when the **code** of the encompassing act is other than PP.

4.2.3.1.5.12 Subscriber

These data elements identify the subscriber to the health plan for eligibility and/or claims processing. For various reasons, the health plan's eligibility system may not have the subscriber's name, address or data of birth recorded in the same way as the provider records it. Using the subscriber information as recorded by the eligibility system will improve the healthcare provider's ability to determine eligibility for benefits, and reduce rejections of claims.

C32-[79] When the Subscriber is other than the patient, subscriber information shall be recorded in a **<participant>** element with the typeCode attribute set to "HLD".

C32-[80] When the Subscriber is the patient, no **<participant>** element describing the subscriber shall be present. This information will be recorded instead in the data elements used to record member information. See sections 4.2.3.1.5.5 through 4.2.3.1.5.10.

Figure 4.2-18 Subscriber Information Example

```
<!-- These examples assumes the default namespace is 'urn:hl7-org:v3' -->
<participant typeCode='HLD'>
  <participantRole classCode='IND'>
    <id root='...' extension='...'/>
    <playingEntity>
      <name><given>Meg</given><family>Ellen</family></name>
      <sdtc:birthTime value='19600127'/>
    </playingEntity>
  </participant>
</participant>
```

4.2.3.1.5.13 Subscriber ID

C32-[81] The subscriber identifier number shall be recorded in the **`extension`** attribute of the **`<id>`** element found in the **`<participantRole>`** element.

C32-[82] The value of the **`root`** attribute of the **`<id>`** element shall be present.

C32-[83] The **`root`** attribute should be the OID of the assigning authority for the identifier, however, determining the assigning authority is not feasible in all settings.

C32-[84] A GUID may be used in place of the OID of the assigning authority. Implementers should use the same GUID for each instance of a subscriber identifier from the same health plan.

4.2.3.1.5.14 Subscriber Date of Birth

C32-[85] The subscriber date of birth shall be recorded in the **`<sdtc:birthTime>`** element of the **`<playingEntity>`** element beneath the **`<participantRole>`** element.

The **`<sdtc:birthTime>`** element represents an extension to the HL7 CDA Release 2.0.

4.2.3.1.5.15 Health Plan

The health plan description is recorded as specified by the Policy Activity Section of the HL7 Continuity of Care Document Implementation Guide.

Figure 4.2-19 Health Plan Example

```
<!-- These examples assumes the default namespace is 'urn:hl7-org:v3' -->
  <entryRelationship typeCode='REFR'>
      <act classCode='ACT' moodCode='DEF'>
        <id root='2844AF96-37D5-42a8-9FE3-3995C110B4FA' extension='PlanCode'/>
        <code code='HMO' displayName='health maintenance organization policy'
        codeSystem='2.16.840.1.113883.5.4' codeSystemName='ActCode'/>
        <text>Health Plan Name</text>
      </act>
    </entryRelationship>
```

4.2.3.1.5.16 Health Plan Name

C32-[86] The name of the health plan shall be recorded in the **`<text>`** element of **`<act>`** element identifying the plan.

C32-[87] The plan or group code[7] may be recorded in the **`<id>`** element of the **`<act>`** element identifying the plan.

[7] For pharmacy benefits, the group code is the RxGRP value.

4.2.3.1.6 Allergies and Drug Sensitivities Module

This module contains the allergy or intolerance conditions and the associated adverse reactions suffered by the patient. At a minimum, currently active and any relevant historical allergies and adverse reactions shall be listed. See the HL7 Continuity of Care Document section 3.8 for constraints applicable to this module.

The template identifier for this construct is 2.16.840.1.113883.3.88.11.32.6.

Table 4.2.3.1.6-1 Allergies and Drug Sensitivities Data Element Definitions

Data Elem. ID	Data Element	Definition
6.01	Adverse Event Date	This is a date that expresses when this particular allergy or intolerance was known to be active for the patient.
6.02	Adverse Event Type	Describes the type of product and intolerance suffered by the patient. The type of product shall be classified with respect to whether the adverse event occurs in relationship with a medication, food, or environmental or other product. The adverse event should also be classified more specifically as an allergy, non-allergy intolerance, or just adverse reaction if that level of detail is not known.
6.03	Product Free-Text	This is the name or other description of the product or agent that causes the intolerance.
6.04	Product Coded	This value is a code describing the product.
6.05	Reaction Free-Text	This is the reaction that may be caused by the product or agent.
6.06	Reaction Coded	This value is a code describing the reaction.
6.07	Severity Free-Text	This is a description of the level of severity of the allergy or intolerance.
6.08	Severity Coded	This value is a code describing the level severity of the allergy or intolerance.

Table 4.2.3.1.6-2 Allergies and Drug Sensitivities Data Element Requirements

Data Elem. ID	Data Element	Opt / Repeat	CCD Name	Additional Specification for Component
	Adverse Event Entry	R2/Y	cda:act[cda:templateId/@root= '2.16.840.1.113883.10.20.1.27']/ cda:entryRelationship[@typeCode='SUBJ']/ cda:observation[cda:templateId/@root= '2.16.840.1.113883.10.20.1.18']	See CCD section 3.8.2.1.2
6.01	Adverse Event Date	R2/N	cda:effectiveTime	None
6.02	Adverse Event Type	R/N	cda:code	See section 4.2.3.1.6.1
	Product	R2/Y	cda:participant[@typeCode='CSM']/ cda:participantRole[@classCode='MANU']/ cda:playingEntity[@classCode='MMAT']/	See CCD section 3.8.2.3
6.03	Product Free-Text	R/N	cda:name	None
6.04	Product Coded	R2/N	cda:code	See section 4.2.3.1.6.2

Data Elem. ID	Data Element	Opt / Repeat	CCD Name	Additional Specification for Component
	Reaction	O/Y	cda:entryRelationship[@typeCode='MFST']/ cda:observation[templateId/@root= '2.16.840.1.113883.10.20.1.54']	See CCD section 3.8.2.4
6.05	Reaction Free-Text	R2/N	cda:text	
6.06	Reaction Coded	R2/N	cda:value	See section 4.2.3.1.6.3
	Severity	R2/N	cda:entryRelationship [@typeCode='SUBJ']/ cda:observation[templateId/@root= '2.16.840.1.113883.10.20.1.55']	See CCD section 3.8.2.4.1.2
6.07	Severity Free-Text	R2/N	cda:text	None
6.08	Severity Coded	R2/N	cda:value	See section 4.2.3.1.6.4

An example of an allergy is shown below in Figure 4.2-20.

Figure 4.2-20 Alert Example

```
<!-- These examples assumes the default namespace is 'urn:hl7-org:v3' -->
<text>
  Penicillin Allergy on February 2, 2001
  <content ID='severity-1'>Severe</content> <content ID='reaction-1'>Hives</content>
</text>
<entry>
  <act classCode='ACT' moodCode='EVN'>
    <templateId root='2.16.840.1.113883.10.20.1.27'/>
    <templateId root='2.16.840.1.113883.3.88.11.32.6'/>
    <id root='2C748172-7CC2-4902-8AF0-23A105C4401B'/>
    <code nullFlavor='NA'/>
    <entryRelationship typeCode='SUBJ'>
      <observation classCode='OBS' moodCode='EVN'>
        <templateId root='2.16.840.1.113883.10.20.1.18'/>
        <code code='416098002' displayName='drug allergy'
          codeSystem='2.16.840.1.113883.6.96' codeSystemName='SNOMED CT'/>
        <effectiveTime>
          <low value='20010209'/>
        </effectiveTime>
        <participant typeCode='CSM'>
          <participantRole classCode='MANU'>
            <playingEntity classCode='MMAT'>
              <code code='70618' displayName='Penicillin'
                codeSystem='2.16.840.1.113883.6.88'
                 codeSystemName='RxNorm'/>
              <name>Penicillin</name>
            </playingEntity>
          </participantRole>
        </participant>
        <entryRelationship typeCode='MFST' inversionInd='true'>
          <templateId root='2.16.840.1.113883.10.20.1.54'/>
          <text><reference value='#reaction-1'/></text>
          <value xsi:type='CD' code='247472004' displayName='Weal'
              codeSystem='2.16.840.1.113883.6.96'
              codeSystemName='SNOMED CT' />
          <entryRelationship  typeCode='SUBJ' inversionInd='true'>
            <observation classCode='OBS' moodCode='EVN'>
              <templateId root='2.16.840.1.113883.10.20.1.55'/>
              <code code='SEV' displayName='Severity'
                codeSystem='2.16.840.1.113883.5.4'
                codeSystemName='ActCode' />
              <text><reference value='#severity-1'/></text>
              <statusCode code='completed'/>
              <value xsi:type='CD' code='24484000' displayName='Severe'
                codeSystem='2.16.840.1.113883.6.96'
                codeSystemName='SNOMED CT' />
            </observation>
          </entryRelationship>
        </entryRelationship>
      </observation>
    </entryRelationship>
  </act>
</entry>
```

4.2.3.1.6.1 Adverse Event Type Vocabulary

C32-[88] The vocabulary used for adverse event types shall come from the limited set of values of SNOMED CT shown in Table 4.2.3.1.6.1-1. The OID for this terminology is 2.16.840.1.113883.6.96.

Table 4.2.3.1.6.1-1 Adverse Event Type Vocabulary

SNOMED CT Preferred Terms for Adverse Event Type	SNOMED CT Code	Usage
propensity to adverse reactions	420134006	Used to record an adverse reaction.
propensity to adverse reactions to substance	418038007	Used to record an adverse reaction to an environmental agent.
propensity to adverse reactions to drug	419511003	Used to record an adverse reaction to a drug.
propensity to adverse reactions to food	418471000	Used to record an adverse reaction to a food.
allergy to substance	419199007	Used to record an allergy to an environmental agent.
drug allergy	416098002	Used to record an allergy to a drug.
food allergy	414285001	Used to record an allergy to a food.
drug intolerance	59037007	Used to record intolerance to a drug.
food intolerance	235719002	Used to record intolerance to a food.

4.2.3.1.6.2 Product Coded Vocabulary

C32-[89] The product causing the adverse event shall be coded to UNII for Food and substance allergies, or RxNorm when to medications, or NDF-RT when to classes of medications.

4.2.3.1.6.3 Reaction Coded

C32-[90] The reaction shall be coded using the VA/KP Problem List Subset of SNOMED CT, and shall be terms that descend from the clinical finding (404684003) concept. The OID for this vocabulary is 2.16.840.1.113883.6.96. The problem list subset can be obtained from www.cancer.gov/cancertopics/terminologyresources/FDA

4.2.3.1.6.4 Severity Coded

C32-[91] The terminology used for severity of the adverse event shall be coded to SNOMED CT, and shall be terms that descend from the severities (272141005) concept.

Table 4.2.3.1.6.4-1 SNOMED CT Preferred Terms for Severity

SNOMED CT Preferred Terms for Severity	SNOMED CT Code
mild	255604002
mild to moderate	371923003
moderate	6736007
moderate to severe	371924009
severe	24484000
fatal	399166001

4.2.3.1.7 Conditions Module

This module lists and describes all relevant clinical problems at the time the summary is generated. At a minimum, all pertinent current and historical problems should be listed. See the HL7 Continuity of Care Document section 3.5 for constraints applicable to this module.

A registration summary is normally limited to a brief list of serious major medical conditions that should always be disclosed even in many ancillary service department settings. Because there is a difference between a full problem list and a brief check list of major conditions, it should be apparent to the provider that this is a brief registration summary list.

The template identifier for this construct is 2.16.840.1.113883.3.88.11.32.7.

Table 4.2.3.1.7-1 Conditions Data Element Definitions

Data Elem. ID	Data Element	Definition
7.01	Problem Date	This is the range of time of which the problem was active for the patient.
7.02	Problem Type	This is a fixed value indicating the level of medical judgment used to determine the existence of a problem.
7.03	Problem Name	This is a text description of the problem suffered.
7.04	Problem Code	This value is a code describing the problem according to a specific vocabulary of problems.
7.05	Treating Provider	The provider or providers treating the patient for this condition.

Table 4.2.3.1.7-2 Conditions Data Element Requirements

Data Elem. ID	Data Element	Opt / Repeat	CCD Name	Additional Specification for Component
	Problem Entry	R2/Y	cda:act[cda:templateId/@root='2.16.840.1.113883.10.20.1.27']/ cda:entryRelationship[@typeCode='SUBJ']/ cda:observation[cda:templateId/@root= '2.16.840.1.113883.10.20.1.28']	See CCD section 3.5.2.1.2
7.01	Problem Date	R2/N	cda:effectiveTime	See section 4.2.3.1.7.1
7.02	Problem Type	R2/N	cda:code	See section 4.2.3.1.7.2
7.03	Problem Name	R/N	cda:text	See section 4.2.3.1.7.3
7.04	Problem Code	O/N	cda:value	See section 4.2.3.1.7.4
7.05	Treating Provider	O/Y	cda:act[cda:templateId/@root='2.16.840.1.113883.10.20.1.27']/ cda:performer	See section 4.2.3.1.7.5

4.2.3.1.7.1 Problem Date

The problem date include the onset and resolution dates for the problem. The onset date shall be recorded in the **<low>** element of the **<effectiveTime>** element when known (see example 1 below). The resolution data shall be recorded in the **<high>** element of the **<effectiveTime>** element when known (see example 1 below).

If the problem is known to be resolved, but the date of resolution is not known, then the **<high>** element shall be present, and the nullFlavor attribute shall be set to 'UNK' (see example 2 below). Therefore, the existence of a **<high>** element within a problem does indicate that the problem has been resolved.

> *NOTE: The date of resolution is the date that the consumer is no longer concerned with the problem. This information may come from a provider, but the consumer should have control over whether they accept that judgment within their PHR.*

Figure 4.2-21 Problem Date Examples

```
<!-- These examples assumes the default namespace is 'urn:hl7-org:v3' -->
<!-- example 1 -->
<effectiveTime>
  <low value='20070209'/>
  <high value='20070210'/>
</effectiveTime>
<!-- example 2 -->
<effectiveTime>
  <low value='20070209'/>
  <high nullFlavor='UNK'/>
</effectiveTime>
```

4.2.3.1.7.2 Problem Type

C32-[92] The type of problem shall be recorded in the **<code>** element of the **<observation>**.

C32-[93] The problem type shall be recorded using the subset of SNOMED CT shown in Table 4.2.3.1.7.2-1. The OID for this vocabulary is 2.16.840.1.113883.6.96.

Figure 4.2-22 Problem Type Example

```
<!-- These examples assumes the default namespace is 'urn:hl7-org:v3' -->
<observation classCode='OBS' moodCode='EVN'>
  <templateId root='2.16.840.1.113883.10.20.1.28'/>
    ...
  <code code='404684003' displayName='Finding'
      codeSystem='2.16.840.1.113883.96' codeSystemName='SNOMED CT'/>
    ...
</observation>
```

Table 4.2.3.1.7.2-1 Problem Type Vocabulary

SNOMED CT Terms for Problem Type	SNOMED CT Code
Finding	404684003
Symptom	418799008
Problem	55607006
Complaint	409586006
Condition	64572001
Diagnosis	282291009
Functional limitation	248536006

4.2.3.1.7.3 Problem Name

The problem name shall be recorded in the entry by recording a **<reference>** where the **value** attribute points to the narrative text containing the name of the problem. Figure 4.2-23 shows an example recording the problem name.

Figure 4.2-23 Problem Name Example

```
<!-- These examples assumes the default namespace is 'urn:hl7-org:v3' -->
<text><p ID='problem-1'>Migrane</p><text>
<entry>
  <act classCode='ACT' moodCode='EVN'>
    <templateId root='2.16.840.1.113883.10.20.1.27'/>
    <templateId root='2.16.840.1.113883.3.88.11.32.7'/>
    <id root='...'/>
    <code nullFlavor='NA'/>
    <entryRelationship typeCode='SUBJ'>
        <observation classCode='OBS' moodCode='EVN'>
        <templateId root='2.16.840.1.113883.10.20.1.28'/>
          ...
        <text><reference value='#problem-1'/></text>
        </observation>
      </entryRelationship>
  </act>
</entry>
```

4.2.3.1.7.4 Problem Code

C32-[94] The problem shall be coded using the VA/KP Problem List Subset of SNOMED CT, and shall be terms that descend from the clinical finding (404684003) concept. The OID for this vocabulary is 2.16.840.1.113883.6.96. The problem list subset can be obtained from www.cancer.gov/cancertopics/terminologyresources/FDA

C32-[95] The problem shall be recorded in the **<value>** element using the CD data type.

NOTE: SNOMED CT provides crosswalks to ICD-9-CM covering more than 18,000 SNOMED CT concepts to over 10,000 ICD-9-CM codes. In addition, a large number of ICD-9-CM concepts are already incorporated into SNOMED CT.

Figure 4.2-24 Problem Code Example

```
<!-- These examples assumes the default namespace is 'urn:hl7-org:v3' -->
<observation classCode='OBS' moodCode='EVN'>
  <templateId root='2.16.840.1.113883.10.20.1.28'/>
    ...
  <value xsi:type='CD' code='37796009' displayName='Migraine'
    codeSystem='2.16.840.1.113883.96' codeSystemName='SNOMED CT'/>
</observation>
```

4.2.3.1.7.5 Treating Provider

C32-[96] The treating provider or providers shall be recorded in a **<performer>** element under the **<act>** that describes the condition of concern.

C32-[97] The time over which this provider treated the condition may be recorded in the **<time>** element beneath the **<performer>** element.

C32-[98] The identifier of the treating provider shall be present in the **<id>** element beneath the **<assignedEntity>**. This identifier shall be the identifier of one of the providers listed in the healthcare providers module described in section 4.2.3.1.4.

Figure 4.2-25 Treating Provider Example

```
<!-- These examples assumes the default namespace is 'urn:hl7-org:v3' -->
<text><p ID='problem-1'>Migrane</p><text>
<entry>
  <act classCode='ACT' moodCode='EVN'>
    <templateId root='2.16.840.1.113883.10.20.1.27'/>
    <id root='...'/>
    <code nullFlavor='NA'/>
    <performer typeCode='PRF'>
      <time><low value='...'/><high value='...'/></time>
      <assignedEntity>
        <id root='...' extension='...'/>
      </assignedEntity>
    </performer>
      ...
  </act>
</entry>
```

4.2.3.1.8 Medications – Prescription and Non-Prescription Module

This module defines a patient's current medications and pertinent medication history. At a minimum, the currently active medications should be listed. See the HL7 Continuity of Care Document section 3.9 for constraints applicable to this module.

The template identifier for this construct is 2.16.840.1.113883.3.88.11.32.8.

Table 4.2.3.1.8-1 Medications – Prescription and Non-Prescription Data Element Definitions

Data Elem. ID	Data Element	Definition
8.01	Free Text Sig	The instructions, typically from the ordering provider, to the patient on the proper means and timing for the use of the product. This information is free-text but can also be represented as a series of Sig components.
8.02	Indicate Medication Stopped	A Sig component: Used to express a "hard stop", such as the last Sig sequence in a tapering dose, where the last sequence is 'then D/C' or where the therapy/drug is used to treat a condition and that treatment is for a fixed duration with a hard stop, such as antibiotic treatment, etc.
8.03	Administration Timing	A Sig component: defines a specific administration or use time. Can be a text string (Morning, Evening, Before Meals, 1 Hour After Meals, 3 Hours After Meals, Before Bed) or an exact time.
8.04	Frequency	A Sig component: defines how often the medication is to be administered as events per unit of time. Often expressed as the number of times per day (e.g., four times a day), but may also include event-related information (e.g., 1 hour before meals, in the morning, at bedtime). Complimentary to Interval, although equivalent expressions may have different implications (e.g., every 8 hours versus 3 times a day).
8.05	Interval	A Sig component: defines how the product is to be administered as an interval of time. For example, every 8 hours. Complimentary to Frequency, although equivalent expressions may have different implications (e.g., every 8 hours versus 3 times a day).

Data Elem. ID	Data Element	Definition
8.06	Duration	A Sig component: for non-instantaneous administrations, indicates the length of time the administration should be continued. For example, (infuse) over 30 minutes.
8.07	Route	A Sig component: indicates how the medication is received by the patient (e.g., by mouth, intravenously, topically, et cetera).
8.08	Dose	A Sig component: the amount of the product to be given. This may be a known, measurable unit (e.g., milliliters), an administration unit (e.g., tablet), or an amount of active ingredient (e.g., 250 mg). May define a variable dose, dose range or dose options based upon identified criteria (see Dose Indicator).
8.09	Site	A Sig component: The anatomic site where the medication is administered. Usually applicable to injected or topical products
8.10	Dose Restriction	A Sig component: defines a maximum or dose limit. This segment can repeat for more than one dose restriction.
8.11	Product Form	The physical form of the product as presented to the patient. For example: tablet, capsule, liquid, ointment.
8.12	Delivery Method	A Sig component: A description of how the product is administered/consumed.
8.13	Coded Product Name	A code describing the product from a controlled vocabulary
8.14	Coded Brand Name	A code describing the product as a branded or trademarked entity from a controlled vocabulary
8.15	Free Text Product Name	The name of the substance or product without reference to a specific vendor (e.g., generic or other non-proprietary name). If a Coded Product Name is present, this is the text associated with the coded concept. This should be sufficient for a provider to identify a medication, and may include additional information such as strength, dose form, etc. If the name of the product is unknown, the type, purpose or other description may be supplied.
8.16	Free Text Brand Name	The branded or trademarked name of the substance or product. If a Coded Brand Name is present, this is the text associated with the coded concept. This may include additional information such as strength, dose form, etc.
8.17	Drug Manufacturer	The manufacturer of the substance or product as ordered or supplied. The distributor may be supplied if the manufacturer is not known.
8.18	Product Concentration	The amount of active ingredient, or substance of interest, in a specified product dosage unit, mass or volume. For example 250 mg per 5 ml. Note: "product dosage unit" provides for describing the "concentration" of a physical form. For example, 800 mg per 1 tablet. In this manner, this data element may also be known as Product Strength. This may be implicit in the product as named or as a codified product.
8.19	Type of Medication	A classification based on how the medication is marketed (e.g., prescription, over the counter drug).
8.20	Status of Medication	If the medication is Active, D/C'd, Chronic, Acute, etc.
8.21	Indication	A Sig component: The medical condition or problem intended to be addressed by the ordered product. For example: for chest pain, for pain, for high blood pressure.
8.22	Patient Instructions	Instructions to the patient that are not traditionally part of the Sig. For example, "keep in the refrigerator".

Data Elem. ID	Data Element	Definition
8.23	Reaction	Any noted intended or unintended effects of the product. For example: full body rash, nausea, rash resolved.
8.24	Vehicle	A Sig component: Non-active ingredient(s), or substances not of therapeutic interest, in which the active ingredients are dispersed. Most often applied to liquid products where the major fluid component is considered the vehicle. For example: Normal Saline is the vehicle in “Ampicllin 150mg in 50ml NS”; Aquaphor is the vehicle in “10% LCD in Aquaphor”.
8.25	Dose Indicator	A Sig component: A criteria that specifies when an action is, or is not, to be taken. For example, “if blood sugar is above 250 mg/dl”.
8.26	Fills	The number of times that the ordering provider has authorized the pharmacy to dispense this medication.
8.27	Quantity Ordered	The amount of product indicated by the ordering provider to be dispensed. For example, number of dosage units or volume of a liquid substance. Note: this is comprised of both a numeric value and a unit of measure.
8.28	Order Date/Time	The date, including time if available, when the ordering provider wrote the order
8.29	Ordering Provider	The person that wrote this order (may include both a name and an identifier)
8.30	Fulfillment Instructions	Instructions to the dispensing pharmacist or nurse that are not traditionally part of the Sig. For example, “instruct patient on the use of occlusive dressing”.
8.31	Fulfillment History	History of dispenses for this order. Comprised of Fulfillment History components.
8.32	Prescription Number	Fulfillment History component: The prescription identifier assigned by the pharmacy.
8.33	Provider	Fulfillment History component: The pharmacy that performed this dispense (may include both a name and an identifier)
8.34	Location	Fulfillment History component: The pharmacy’s location
8.35	Dispense Date	Fulfillment History component: The date of this dispense
8.36	Quantity Dispensed	Fulfillment History component: The actual quantity of product supplied in this dispense. Note: this is comprised of both a numeric value and a unit of measure.

Table 4.2.3.1.8-2 Medications – Prescription and Non-Prescription Data Element Requirements

Data Elem. ID	Data Element	Opt / Repeat	CCD Name	Additional Specification for Component
	Administration Information	R2/Y	cda:substanceAdministration[templateId/@root = '2.16.840.1.113883.10.20.1.24']	See CCD Section 3.9.2.1.1
8.01	Free Text Sig	O/N	cda:text	See section 0
8.02	Indicate Medication Stopped	O/N	cda:effectiveTime[1]/cda:high	See section 4.2.3.1.8.2
8.03	Administration Timing	O/Y	cda:effectiveTime[2]	See section 4.2.3.1.8.3
8.04	Frequency	O/Y		
8.05	Interval	O/Y		
8.06	Duration	O/Y		

Data Elem. ID	Data Element	Opt / Repeat	CCD Name	Additional Specification for Component
8.07	Route	O/Y	cda:routeCode	See section 4.2.3.1.8.4
8.08	Dose	O/Y	cda:doseQuantity	See section 4.2.3.1.8.5
8.09	Site	O/Y	cda:approachSiteCode	See section 4.2.3.1.8.6
8.10	Dose Restriction	O/Y	cda:maxDoseQuantity	None
8.11	Product Form	O/N	cda:administrationUnitCode	See section 4.2.3.1.8.7
8.12	Delivery Method	O/Y	cda:code	See section 4.2.3.1.8.8
	Medication Information	R/Y	cda:consumable/cda:manufacturedProduct	See section 4.2.3.1.8.9
8.13	Coded Product Name	R2/Y	cda:manufacturedMaterial/cda:code	
8.14	Coded Brand Name	R2/Y	cda:manufacturedMaterial/cda:code/cda:translation	
8.15	Free Text Product Name	R/N	cda:manufacturedMaterial/cda:code/cda:orginalText	
8.16	Free Text Brand Name	R2/N	cda:manufacturedMaterial/cda:name	
8.17	Drug Manufacturer	O/N	cda:manufacturerOrganization	None
8.18	Product Concentration	R2/N	No mapping, See section 4.2.3.1.8.10	
8.19	Type of Medication	R2/N	cda:entryRelationship[@typeCode='SUBJ']/ cda:observation[cda:templateId/@root= '2.16.840.1.113883.3.88.11.32.10']/ cda:value/@code	See section 4.2.3.1.8.11
8.20	Status of Medication	R2/N	cda:entryRelationship[@typeCode='REFR']/ cda:observation[cda:templateId/@root= '2.16.840.1.113883.10.20.1.47']/ cda:value/@code	See CCD Section 3.9.2.3 See section 4.2.3.1.8.12
8.21	Indication	O/Y	cda:entryRelationship[@typeCode='RSON']/ cda:observation[cda:templateId/@root= '2.16.840.1.113883.10.20.1.28']	See CCD Section 3.9.2.3 See section 4.2.3.1.8.13
8.22	Patient Instructions	O/N	cda:entryRelationship/cda:act[cda:templateId/@root='2.16.840.1.113883.10.20.1.49']/cda:text	See CCD Section 3.9.2.2.2 See section 4.2.3.1.8.14
8.23	Reaction	O/N	cda:entryRelationship [@typeCode='CAUS']/ cda:observation	See CCD Section 3.9.2.2.5
8.24	Vehicle	O/Y	cda:participant/cda:participantRole[cda:code/@code = '412307009' and cda:code/@codeSystem= '2.16.840.1.113883.6.96']	See section 4.2.3.1.8.15
8.25	Dose Indicator	O/Y	cda:precondition/cda:criteria	See CCD section 3.9.2.2.1
	Order Information	R2/Y	cda:entryRelationship[@typeCode='REFR']/ cda:supply[moodCode='RQO']	See section 4.2.3.1.8.16
8.26	Fills	O/N	cda:repeatNumber	See section 4.2.3.1.8.17
8.27	Quantity Ordered	R2/N	cda:quantity	See section 4.2.3.1.8.18
8.28	Order Date/Time	O/N	cda:author/cda:time	None

Data Elem. ID	Data Element	Opt / Repeat	CCD Name	Additional Specification for Component
8.29	Ordering Provider	O/N	cda:author/cda:assignedEntity/ cda:assignedPerson/cda:name	See also section 4.2.3.1.10
8.30	Fulfillment Instructions	O/N	cda:entryRelationship/ cda:act [cda:templateId/@root='2.16.840.1.113883.10.20.1.43']/cda:text	See CCD section 3.9.2.2.3 See section 4.2.3.1.8.19
8.31	Fulfillment History	O/Y	cda:supply[@moodCode='EVN']	See CCD section 3.9.2.1.2
8.32	Prescription Number	R2/N	cda:id	See section 4.2.3.1.8.20
8.33	Provider	O/N	cda:performer/cda:assignedEntity	See 4.2.3.1.8.21
8.34	Location	O/N	cda:performer/cda:assignedEntity/ cda:addr	See also 4.2.3.1.1.2
8.35	Dispense Date	O/N	cda:effectiveTime	None
8.36	Quantity Dispensed	R2/N	cda:quantity	See section 4.2.3.1.8.22

4.2.3.1.8.1 Free Text Sig

C32-[99] The **<text>** element of the free text sig shall contain a **<reference>** element whose **value** attribute points to the text of the free text sig in the narrative portion of the CCD.

Figure 4.2-26 Free Text Sig Example

```
<!-- These examples assumes the default namespace is 'urn:hl7-org:v3' -->
<section>
    ...
  <text>
      ...
    <content ID='sig-1'> Acetaminophen 325 mg tablet tid po prn</content>
      ...
  </text>
    ...
  <entry>
    <substanceAdministration classCode='SBADM' moodCode='INT'>
      <templateId root='2.16.840.1.113883.10.20.1.24'/>
      <templateId root='2.16.840.1.113883.3.88.11.32.8'/>
        ...
      <text><reference value='#sig-1'/></text>
        ...
    </substanceAdministration>
  </entry>
</section>
```

4.2.3.1.8.2 Indicate Medication Stopped

See the section below on administration timing for more detail. The time at which the medication was stopped is determined based on the first **<effectiveTime>** element.

C32-[100] The stop date of the medication shall be recorded in the **<high>** element of the first **<effectiveTime>** element in the **<substanceAdministration>** element.

4.2.3.1.8.3 Administration Timing

C32-[101] The timing of the medication administration shall be recorded in one or two **<effectiveTime>** elements beneath the **<substanceAdministration>** element.

C32-[102] The first **<effectiveTime>** element shall record the range of time over which the medication is to be administered, i.e., the start and stop dates for administration of the medication, or for a single administration, the time of that administration.

C32-[103] The first **<effectiveTime>** shall use the IVL_TS data type unless for a single administration, in which case, it shall use the TS data type.

C32-[104] The second **<effectiveTime>** element shall record the details about frequency, interval and duration when more than one administration is to occur.

C32-[105] The second **<effectiveTime>** element shall include the **operator** attribute, set to the value "A".

C32-[106] Medications that are administered at a specified interval shall record interval between doses in the **<period>** element beneath an **<effectiveTime>** element of type PIVL_TS. The **<effectiveTime>** element shall have an institutionSpecified attribute value of "false".

NOTE: The HL7 data type for PIVL_TS uses the institutionSpecified attribute to indicate whether it is the interval (time between dosing), or frequency (number of doses in a time period) that is important. If instititutionSpecified is not present, or is set to false, then the time between dosing is important (every 8 hours). If true, then the frequency of administration is important (e.g., 3 times per day).

C32-[107] Medications that are administered at a specified frequency shall record the expected interval between doses in the **<period>** element beneath an **<effectiveTime>** of type PIVL_TS. The **<effectiveTime>** element shall have an institutionSpecified attribute value of "true".

C32-[108] Medications that are administered based on activities of daily living shall identify the events which trigger administration in the **<event>** element beneath the **<effectiveTime>** element. The **<effectiveTime>** element shall be of type EIVL.

Several examples of Administration timing are shown below in Figure 4.2-27.

Figure 4.2-27 Administration Timing Examples

```
<!-- These examples assumes the default namespace is 'urn:hl7-org:v3' -->
<!-- twice a day for 10 days from 2/1/07 to 2/10/07 -->
<effectiveTime xsi:type='IVL_TS'>
  <low value='20070201'/>
  <high value='20070210'/>
</effeciveTime>
<effectiveTime xsi:type='PIVL_TS' institutionSpecified='true'  operator='A'>
  <period value='12' unit='h' />
</effectiveTime>

<!-- every 12 hours for 10 days from 2/1/07 to 2/10/07 -->
<effectiveTime xsi:type='IVL_TS'>
  <low value='20070201'/>
  <high value='20070210'/>
</effeciveTime>
<effectiveTime xsi:type='PIVL_TS' institutionSpecified='false' operator='A'>
  <period value='12' unit='h' />
</effectiveTime>

<!-- Once, on 2005-09-01 at 1:18am. -->
<effectiveTime xsi:type='TS' value='200509010118'/>

<!-- Three times a day, for 10 days from 2/1/07 to 2/10/07 -->
<effectiveTime xsi:type='IVL_TS'>
  <low value='20070201'/>
  <high value='20070210'/>
</effeciveTime>
<effectiveTime xsi:type='PIVL_TS' institutionSpecified='true' operator='A'>
  <period value='8' unit='h' />
</effectiveTime>

<!-- every 8 hours for 10 days from 2/1/07 to 2/10/07 -->
<effectiveTime xsi:type='IVL_TS'>
  <low value='20070201'/>
  <high value='20070210'/>
</effeciveTime>
<effectiveTime xsi:type='PIVL_TS' institutionSpecified='false' operator='A'>
  <period value='8' unit='h' />
</effectiveTime>

<!-- in the morning for 10 days from 2/1/07 to 2/10/07 -->
<effectiveTime xsi:type='IVL_TS'>
  <low value='20070201'/>
  <high value='20070210'/>
</effeciveTime>
<effectiveTime xsi:type='EIVL' operator='A'>
  <event code='ACM'/>
</effectiveTime>

<!-- Every day at 8 in the morning for 10 minutes for 10 days from 2/1/07 to 2/10/07 -->
<effectiveTime xsi:type='IVL_TS'>
  <low value='20070201'/>
  <high value='20070210'/>
</effeciveTime>
<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>
```

4.2.3.1.8.4 Route of Administration

C32-[109] Shall have a value drawn from FDA route of administration. The OID for this vocabulary is 2.16.840.1.113883.3.26.1.1.

See www.fda.gov/oc/datacouncil/splncicodes.html - route.

Figure 4.2-28 Route Code Example

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

4.2.3.1.8.5 Dose

C32-[110] Dose shall be recorded in a **<doseQuantity>** element beneath the substance administration element, and have a **value** attribute.

C32-[111] The **unit** attribute may be present when needed. If present it shall be coded using Unified Code for Units of Measures (UCUM).

C32-[112] When the coded product or brand name describes the strength or concentration of the medication, and the dosing is in administration units (e.g., 1 tablet, 2 capsules), the **unit** attribute should contain the preferred name of the presentation units within braces { } using the units of presentation from the NCI Thesaurus.

The units of presentation can be found www.fda.gov/oc/datacouncil/splncicodes.html#potency, and include only those terms which have not been mapped to UCUM. Terms with mappings to UCUM are units of administration.

Figure 4.2-29 Dose Examples

```
<!-- These examples assumes the default namespace is 'urn:hl7-org:v3' -->
<!-- example 1, dose is in units of tablets -->
<code code='' displayName='Acetaminophen 325 mg tablet'
  codeSystem='2.16.840.1.113883.6.88' codeSystemName='RxNorm'/>
  ...
<doseQuantity value='1' unit='{TABLET}'/>

<!-- example 2, dose is in measurable units -->
<code code='' displayName='Tylenol'
  codeSystem='2.16.840.1.113883.6.88' codeSystemName='RxNorm'/>
  ...
<doseQuantity value='325' unit='mg'/>
```

4.2.3.1.8.6 Site

C32-[113] The site of the medication administration shall be recorded in the **<administrationSiteCode>** element.

C32-[114] The **code** attribute shall contain a value descending from the SNOMED CT Anatomical Structure (91723000) hierarchy.

4.2.3.1.8.7 Product Form

C32-[115] Shall have a value drawn from dosage form - FDA dosage form – source NCI Thesaurus. The OID for this vocabulary is 2.16.840.1.113883.3.26.1.1

See www.fda.gov/oc/datacouncil/splncicodes.html - dosage.

Figure 4.2-30 Product Form Example

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

4.2.3.1.8.8 Delivery Method

C32-[116] The Delivery Method may be recorded in the **<cda:code>** element.

C32-[117] The free text description of the delivery method may be included within a **<cda:orginalText>** element beneath the **<cda:code>** element.

An example of the delivery method is shown below in Figure 4.2-31.

Figure 4.2-31 Delivery Method

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

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

4.2.3.1.8.9 Medication Information

The name and code for the medication are recorded in the **<consumable>** element, as shown below in Figure 4.2-32. The template identifier for this construct is 2.16.840.1.113883.3.88.11.32.9.

Figure 4.2-32 Medication Information Example

```
<!-- These examples assumes the default namespace is 'urn:hl7-org:v3' -->
<substanceAdministration classCode='SBADM' moodCode='INT'>
    ...
  <consumable>
    <templateId root='2.16.840.1.113883.10.20.1.53'/>
    <templateId root='2.16.840.1.113883.3.88.11.32.9'/>
    <manafacturedProduct classCode='MANU'>
      <manufacturedMaterial classCode='MMAT' determinerCode='KIND'>
        <code code='161' displayName='Acetaminophen'
          codeSystem='2.16.840.1.113883.6.88' codeSystemName='RxNorm'>
          <originalText>Acetaminophen</originalText>
          <translation code='202433' displayName='Tylenol'
            codeSystem='2.16.840.1.113883.6.88' codeSystemName='RxNorm'/>
        </code>
        <name>Tylenol</name>
      </manufacturedMaterial>
    </manufacturedProduct>
  </consumable>
    ...
</substanceAdministration>
```

C32-[118] The product name or brand name shall be coded using RxNorm, or NDC. The code shall appear in the **code** attribute of the **<code>** or **<translation>** element.

C32-[119] When only the class of the drug is known (e.g., Beta Blocker or Sulfa Drug), it shall be coded using NDF-RT.

C32-[120] FDA Unique Ingredient Identifier codes (UNII) codes may be used when there are no suitable codes in the other vocabularies to identify the medication.

C32-[121] The code for the product (generic) name shall appear in **code** attribute of the **<code>** element. If the code for the generic product is unknown, the **code** and **codeSystem** attributes may be omitted.

C32-[122] The product (generic) name shall appear in the **<originalText>** element beneath the **<code>** element.

C32-[123] The code for the specific brand of product shall appear in a **<translation>** element

C32-[124] The brand name shall appear in the **<name>** element of the **<manufacturedMaterial>**.

Table 4.2.3.1.8.10-1 Product/Brand Name Vocabulary

Vocabulary	OID	Used for	Example
RxNorm	2.16.840.1.113883.6.88	Brand Names	Tylenol
		Clinical Drugs	Acetaminophen 325 mg tablet
NDC	2.16.840.1.113883.6.69	Packaged Product	Tylenol 325 mg tablet bottle of 100
FDA Unique Ingredient Identifier (UNIII)	2.16.840.1.113883.4.9	Ingredient Name	gentian violet
NDF-RT	2.16.840.1.113883.4.209	Drug Class	cephalosporins

4.2.3.1.8.10 Product Concentration

The product concentration is determined from the coded product or brand name using knowledge base information in the vocabularies specified for these fields, and therefore this information is not explicitly included in the medication / registration summary.

4.2.3.1.8.11 Type of Medication

The template identifier for the type of medication construct is 2.16.840.1.113883.3.88.11.32.10.

C32-[125] Each **<supply>** or **<substanceAdministration>** act may reference an **<observation>** element that describes the type of medication, by including an **<entryRelationship typeCode='REFR'/>** element.

C32-[126] The type of a medication shall be represented with an **<observation>** element in the **<entryRelationship>**.

C32-[127] The **<observation>** element shall have a **<templateId>** with a **root** attribute set to 2.16.840.1.113883.3.88.11.32.10

C32-[128] The **<observation>** shall have a **<code>** element that represents the kind of medication actually or intended to be administered or supplied.

C32-[129] The **code** attribute shall contain a code derived from a limited set of values SNOMED CT. The OID for this terminology is 2.16.840.1.113883.6.96.

Table 4.2.3.1.8.12-1 Type of Medication Vocabulary

SNOMED CT Preferred Terms for Type of Medication Vocabulary	SNOMED CT Code
Over the counter products	329505003
Prescription Drug	73639000

Figure 4.2-33 Type Of Medication

```
<!-- These examples assumes the default namespace is 'urn:hl7-org:v3' -->
<substanceAdministration classCode='SBADM' moodCode='INT'>
    ...
  <entryRelationship typeCode='REFR'>
    <observation classCode='OBS' moodCode='EVN'>
      <templateId root='2.16.840.1.113883.3.88.1.11.32.10'/>
      <code code='73639000' displayName='Prescription Drug'
        codeSystem='2.16.840.1.113883.6.96' codeSystemName='SNOMED CT'/>
      <statusCode code='completed'/>
    </observation>
  </entryRelationship>
    ...
</substanceAdministration>
```

4.2.3.1.8.12 Status of Medication

C32-[130] The medication status may be recorded using the CCD Medication Status observation. The vocabulary is defined by CCD.

See sections 3.9.2.3 and 5.1 of the HL7 Continuity of Care Document Implementation Guide for additional requirements for this data element.

Figure 4.2-34 Medication Status Example

```
<!-- These examples assumes the default namespace is 'urn:hl7-org:v3' -->
<substanceAdministration classCode='SBADM' moodCode='INT'>
    ...
  <entryRelationship typeCode='REFR'>
    <observation classCode='OBS' moodCode='EVN'>
      <code code='33999-4' displayName='Status'
        codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
      <statusCode code='completed'/>
      <value xsi:type='CE' code='55561003' displayName='Active'
        codeSystem='2.16.840.1.113883.6.96' codeSystemName='SNOMED CT'/>
    </observation>
  </entryRelationship>
    ...
</substanceAdministration>
```

4.2.3.1.8.13 Indication

C32-[131] The indication shall be recorded using the Indication **<observation>** described in section 3.9.2.1.1 of the HL7 Continuity of Care Document Implementation Guide.

C32-[132] The indication **<observation>** shall contain a **<text>** element that includes a **<reference>** element whose **value** attribute points to the narrative text that is the indication for the medication.

C32-[133] The indication shall be coded using the VA/KP Problem List Subset of SNOMED CT, and shall be terms that descend from the clinical finding (404684003) concept. The OID for this vocabulary is 2.16.840.1.113883.6.96. The problem list subset can be obtained at www.cancer.gov/cancertopics/terminologyresources/FDA

Figure 4.2-35 Indication Example

```
<!-- These examples assumes the default namespace is 'urn:hl7-org:v3' -->
<substanceAdministration classCode='SBADM' moodCode='INT'>
    ...
  <entryRelationship typeCode="RSON">
    <observation classCode="OBS" moodCode="EVN">
      <templateId root="2.16.840.1.113883.10.20.1.28"/>
          <code code='' displayName=''
        codeSystem='2.16.840.1.113883.6.96' codeSystemName='SNOMED CT'/>
      <text><reference value="#indication-1"/></text>
      <statusCode code="completed"/>
      <effectiveTime value="…"/>
    </observation>
  </entryRelationship>
    ...
</substanceAdministration>
```

4.2.3.1.8.14 Patient Instructions

C32-[134] Patient instructions shall be recorded as described in section 3.9.2.2.2 of the HL7 Continuity of Care Document.

C32-[135] The **<act>** containing the instructions shall contain a **<text>** element that includes a **<reference>** element whose **value** attribute points to the narrative text that contains the instructions.

An example of a patient instruction is shown below in Figure 4.2-36.

Figure 4.2-36 Patient Instructions Example

```
<!-- These examples assumes the default namespace is 'urn:hl7-org:v3' -->
<text>
    ...
  <content ID='patient-instruction'>Take with food</content>
    ...
</text>
<entry>
  <substanceAdministration>
      ...
      <entryRelationship typeCode='SUBJ' inversionInd='true'>
        <act classCode='ACT' moodCode='INT'>
          <templateId root='2.16.840.1.113883.10.20.1.49'/>
          <text><reference value='#patient-instruction'/></text>
        </act>
    </entryRelationship>
  </substanceAdministration>
</entry>
  ...
```

4.2.3.1.8.15 Vehicle

C32-[136] The vehicle for administering a medication may be recorded in a **<participantRole>** element inside a **<participant>** element in the **<substanceAdministration>** element.

C32-[137] The typeCode attribute of the **<participant>** element shall be CSM.

C32-[138] The classCode of the **<participantRole>** shall be MANU.

C32-[139] A **<code>** element for the **<participant>** shall be present, using the code 412307009 from SNOMED CT. The OID for SNOMED CT is 2.16.840.1.113883.6.96.

C32-[140] The **<name>** element in the **<playingEntity>** element shall record the name of the drug vehicle.

C32-[141] The **<code>** element in the **<playingEntity>** element may be used to supply a coded term for the drug vehicle. The codes for drug vehicles are the same as those used for the coded product or brand name found in section 4.2.3.1.8.9 above.

Figure 4.2-37 Vehicle Example

```
<!-- These examples assumes the default namespace is 'urn:hl7-org:v3' -->
<substanceAdministration classCode='SBADM' moodCode='...'>
    ...
  <participant typeCode='CSM'>
    <participantRole classCode='MANU'>
      <code code='412307009' displayName='drug vehicle'
        codeSystem='2.16.840.1.113883.6.96' codeSystemName='SNOMED CT'/>
      <playingEntity classCode='MMAT'>
        <code .../>
        <name>...</name>
      </playingEntity>
    </participantRole>
  </participant>
</substanceAdministration>
```

4.2.3.1.8.16 Order Information

Order information may be recorded as part of the fulfillment history, or as part of the administration information. Examples are shown below in Figure 4.2-38. The template identifier for this construct is 2.16.840.1.113883.3.88.1.11.32.11.

Figure 4.2-38 Order Information Examples

```
<!-- These examples assume the default namespace is 'urn:hl7-org:v3' -->
<!-- example 1, recording order information with substance administration event or intent -->
<substanceAdministration classCode='SBADM' moodCode='…'>
    …
  <entryRelationship typeCode='REFR'>
    <supply classCode='SPLY' moodCode='RQO'>
      <templateId root='2.16.840.1.113883.3.88.1.11.32.11'/>
      <id root='14ED7742-2428-4e2c-9446-A9B0D0075272' extension='SCRIP#'/>
      <repeatNumber value='1'/>
      <quantity value='30'/>
      <author>
        <time value='20070210'/>
        <assignedAuthor>
          <id …/>
          <assignedPerson>
            <name>…</name>
          </assignedPerson>
        </assignedAuthor>
      </author>
    </supply>
  </entryRelationship>
</substanceAdministration>

<!-- example 2, recording order information with supply event -->
<supply classCode='SPLY' moodCode='EVN'>
    …
  <entryRelationship typeCode='REFR'>
    <supply classCode='SPLY' moodCode='RQO'>
      <templateId root='2.16.840.1.113883.3.88.1.11.32.11'/>
      <id root='14ED7742-2428-4e2c-9446-A9B0D0075272' extension='SCRIP#'/>
      <repeatNumber value='3'/>
      <quantity value='30'/>
      <author>
        <time value='20070210'/>
        <assignedAuthor>
          <id …/>
          <assignedPerson><name>…</name></assignedPerson>
        </assignedAuthor>
      </author>
    </supply>
  </entryRelationship>
</supply>
```

4.2.3.1.8.17 Fills

NOTE: The number of fills requested is what is recorded in the document, not the number of refills. The number of refills is simply one less than the number of fills.

C32-[142] The number of fills may be recorded in the **<repeatNumber>** element within the **<supply>** element used to record order information.

Figure 4.2-39 Fills Example

```
<!-- These examples assumes the default namespace is 'urn:hl7-org:v3' -->
<!-- Example 1, 1 fill, no refills -->
<repeatNumber value='1'/>

<!-- Example 2, 3 fills = 1 initial fill + 2 refills -->
<repeatNumber value='3'/>

<!—Example 3, unbounded number of fills -->
<repeatNumber nullFlavor='PINF'/>
```

4.2.3.1.8.18 Quantity Ordered

C32-[143] The quantity ordered shall be recorded in the **value** attribute of **<quantity>** element inside a **<supply>** element used to record order information.

C32-[144] The **unit** attribute shall be present.

C32-[145] When the quantity ordered is in other than administration units (e.g., when the quantity ordered is a volume of liquid or mass of substance) units shall be recorded using the Unified Code for Units of Measure.

C32-[146] Otherwise, the **unit** attribute should contain the preferred name of the presentation units within braces { } using the units of presentation from the NCI Thesaurus.

The units of presentation can be found www.fda.gov/oc/datacouncil/splncicodes.html#potency, and include only those terms which have not been mapped to UCUM. Terms with mappings to UCUM are units of administration, rather than units of presentation.

Figure 4.2-40 Quantity Ordered Examples

```
<!-- These examples assumes the default namespace is 'urn:hl7-org:v3' -->
<!-- Example 1, 100 tablets -->
<quantity value='100' unit='{TABLET}'/>

<!-- Example 2, 0.5 liters -->
<quantity value='0.5' unit='l'/>
```

4.2.3.1.8.19 Fulfillment Instructions

C32-[147] The **<act>** containing the instructions shall contain a **<text>** element that includes a **<reference>** element whose **value** attribute points to the narrative text that contains the instructions.

An example of a fulfillment instruction is shown below in Figure 4.2-36.

Figure 4.2-41 Fulfillment Instructions Example

```
<!-- These examples assumes the default namespace is 'urn:hl7-org:v3' -->
<text>
    ...
  <content ID='fulfillment-instruction'>Prepare with distilled water.</content>
    ...
</text>
<entry>
  <substanceAdministration moodCode='INT'>
      ...
      <entryRelationship typeCode='SUBJ' inversionInd='true'>
        <act classCode='ACT' moodCode='INT'>
          <templateId root='2.16.840.1.113883.10.20.1.43'/>
          <text><reference '#fulfillment-instruction'/></text>
        </act>
    </entryRelationship>
  </substanceAdministration>
</entry>
  ...
```

4.2.3.1.8.20 Prescription Number

C32-[148] The prescription number shall be recorded in the **`extension`** attribute of the **`<id>`** element within a **`<supply>`** element having a moodCode attribute of EVN.

C32-[149] The **`root`** attribute of the **`<id>`** element should be the OID of the assigning authority for the identifier, however, determining the assigning authority is not feasible in all settings.

C32-[150] A GUID may be used in place of the OID of the assigning authority.

Figure 4.2-42 Prescription Number Example

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

4.2.3.1.8.21 Provider

C32-[151] The provider shall be recorded in the **`<assignedEntity>`** element.

C32-[152] At least one of **`<assignedPerson>`** or **`<representedOrganization>`** elements shall appear inside the **`<assignedEntity>`** to indicate the name of the person or the organization fulfilling the prescription.

C32-[153] The name of the person shall appear in the **`<name>`** element of the **`<assignedPerson>`** element beneath the **`<assignedEntity>`** element.

C32-[154] The name of the organization shall appear in the **`<name>`** element of the **`<representedOrganization>`** element beneath the **`<assignedEntity>`** element.

4.2.3.1.8.22 Quantity Dispensed

C32-[155] The quantity dispensed shall be recorded in the **`value`** attribute of **`<quantity>`** element inside a **`<supply>`** element with a **`moodCode`** attribute set to EVN.

C32-[156] When the quantity dispensed is in other than administration units (e.g., when the quantity ordered is a volume of liquid or mass of substance) units shall be recorded using the Unified Code for Units of Measure.

C32-[157] Otherwise, the **`unit`** attribute should contain the preferred name of the presentation units within braces { } using the units of presentation from the NCI Thesaurus.

The units of presentation can be found at www.fda.gov/oc/datacouncil/splncicodes.html#potency, and include only those terms which have not been mapped to UCUM. Terms with mappings to UCUM are units of administration, rather than units of presentation.
See Figure 4.2-40 for an example.

4.2.3.1.9 Pregnancy Module

This module contains a coded entry indicating whether the patient is currently pregnant.

Table 4.2.3.1.9-1 Pregnancy Data Element Definitions

Data Elem. ID	Data Element	Definition
9.01	Pregnancy	This is a simple observation that records whether the patient is currently pregnant.

Table 4.2.3.1.9-2 Pregnancy Data Element Requirements

Data Elem. ID	Data Element	Opt / Repeat	CCD Name	Additional Specification for Component
9.01	Pregnancy	O/N	cda:observation[cda:code[@code='77386006' and @codeSystem='2.16.840.1.113883.6.96']]/cda:value	Use the SNOMED-CT code for patient currently pregnant (77386006)

Figure 4.2-43 Pregnancy Coding Example

```
<!-- These examples assumes the default namespace is 'urn:hl7-org:v3' -->
<observation classCode='OBS' moodCode='EVN'>
  <value xsi:type='CD' code='77386006' displayName='patient currently pregnant'
    codeSystem='2.16.840.1.113883.6.96' codeSystemName='SNOMED CT'/>
</observation>
```

4.2.3.1.10 Information Source Module

This module allows for information about the original author to be supplied and for a reference to the original document to be provided. This module may be applied to all other modules 4.2.3.1.1 through 4.1.3.1.12. See the HL7 Continuity of Care Document section 5.5 for constraints applicable to this module.

Table 4.2.3.1.10-1 Information Source Data Element Definitions

Data Elem. ID	Data Element	Definition
10.01	Author Time	The time at which this information was created.
10.02	Author Name	The name of the person who created the information content.
10.03	Reference	A reference to the original document from which this information was obtained.

Data Elem. ID	Data Element	Definition
10.04	Reference Document ID	Identifier of the external document that was referenced.
10.05	Reference Document URL	A URL from which this document may be retrieved. Note: Depending on the architectural variant applied, only references to documents which have been registered, so as to ensure that the registry / repository / PHR access control mechanisms are used to access these documents.
10.06	Information Source Name	The name of the person or organization that provided the information.

Table 4.2.3.1.10-2 Information Source Data Element Requirements

Data Elem. ID	Data Element	Opt / Repeat	CCD Name	Additional Specification for Component
	Author	R/N	ancestor-or-self::./cda:author[1]	None
10.01	Author Time	R/N	cda:time	None
10.02	Author Name	R/N	cda:assignedAuthor/ cda:name	See also 4.2.3.1.1.1
10.03	Reference	R2/Y	cda:reference/cda:externalDocument	None
10.04	Reference Document ID	R/N	cda:id	None
10.05	Reference Document URL	O/N	cda:text/cda:reference/@value	None
	Information Source	O/Y	ancestor-or-self::./cda:informant	
10.06	Information Source Name	R/N	.//cda:name	See 4.2.3.1.10.1 See also 4.2.3.1.1.1

Note: Each content module described above in subsection 5 through 9 above and in subsections 11 and 12 below may have one author. The author is the person who created the information content. The **<author>** element may be included in the **<observation>**, **<substanceAdministration>** or **<supply>** element hosting the information described in the content modules defined above to indicate who created this information and when it was created.
Each content module described above in subsection 5 through 9 and in subsections 11 and 12 may have one **<reference>** element that describes the document that was the original source of the information. The **<reference>** element may be included in the **<observation>**, **<substanceAdministration>** or **<supply>** element hosting the information described in the content modules defined above to indicate what document the information came from.

4.2.3.1.10.1 Information Source Name

C32-[158] The name of the information source shall be provided in the <name> element.

C32-[159] The <name> element shall appear within an <assignedPerson> element within an <assignedEntity>, an within a <relatedPerson> element within a <relatedEntity> element beneath the <informant> element.

4.2.3.1.11 Comments Module

This module allows for a comment to be supplied for any other module listed in subsections 5 through 9 above and 12 below. Data elements defined elsewhere in the specification shall not be recorded using the Comments Module. See the HL7 Continuity of Care Document section 4.3 for constraints applicable to this module. The template identifier for this construct is 2.16.840.1.113883.3.88.11.32.12.

Note: Each content module described in subsection 5 through 9 above and in subsection 12 below may include one or more comments.

Table 4.2.3.1.11-1 Comments Data Element Definitions

Data Elem. ID	Data Element	Definition
11.01	Free Text Comment	A free text comment.

Table 4.2.3.1.11-2 Comments Data Element Requirements

Data Elem. ID	Data Element	Opt / Repeat	CCD Name	Additional Specification for Component
	Comment		cda:act[cda:templateId/@root = '2.16.840.1.113883.10.20.1.40']	
	Author		ancestor-or-self::../cda:author[1]	See section 4.2.3.1.10
11.01	Free Text Comment	R/N	cda:text/cda:reference/@value	See 4.2.3.1.11.1

4.2.3.1.11.1 Free Text Comment

Comments are free text data that cannot otherwise be recorded using data elements already defined by this specification. They are not to be used to record information that can be recorded elsewhere. For example, a free text description of the severity of an allergic reaction would not be recorded in a comment. Instead, it would be recorded using data element 6.07 defined above.

C32-[160] Comments shall be included in entries using an **`<entryRelationship>`** element.

C32-[161] The typeCode attribute of the **`<entryRelationship>`** element shall be SUBJ.

C32-[162] The inversionInd attribute of the **`<entryRelationship>`** element shall be true[8]

C32-[163] The **`<text>`** element of a comment shall contain a **`<reference>`** element whose **`value`** attribute points to the text of the comment in the narrative portion of the CCD.

C32-[164] The author of a comment shall be recorded as specified for authors in the Information Source module. See section 4.2.3.1.10 above.

An example of a comment is shown below in Figure 4.2-44.

[8] Setting inversionInd='true' tells us that the subject of the comment is the act (observation, substanceAdministration, supply, et cetera) that it is contained within, rather than the reverse.

Figure 4.2-44 Comment Example

```
<!-- These examples assumes the default namespace is 'urn:hl7-org:v3' -->
<entry>
  <act><!-- could also be observation, substanceAdministration, supply, et cetera -->
      …
    <entryRelationship typeCode='SUBJ' inversionInd='true'>
      <act classCode='ACT' moodCode='EVN'>
        <templateId root='2.16.840.1.113883.10.20.1.40'/>
        <templateId root='2.16.840.1.113883.3.88.11.32.12'/>
        <code code='' displayName='Annotation Comment'
          codeSystem='2.16.840.1.113883.6.1' codeSystemName='LOINC'/>
        <text><reference value='#comment-1'/></text>
        <author>
          <assignedAuthor>
            <assignedPerson>
              <name>…</name>
            </assignedPerson>
          </assignedAuthor>
        </author>
      </act>
    </entryRelationship>
  </act>
</entry>
```

4.2.3.1.12 Advance Directives

This module contains data describing the patient's advance directives and any reference to supporting documentation. This section contains data such as the existence of living wills, healthcare proxies, and CPR and resuscitation status. The custodian of these documents may be described. See the HL7 Continuity of Care Document section 3.2 for constraints applicable to this module. The template identifier for this construct is 2.16.840.1.113883.3.88.11.32.13.

Table 4.2.3.1.12-1 Advance Directives Data Element Definitions

Data Elem. ID	Data Element	Definition
12.01	Advance Directive Type	This is a coded value describing the type of the advance directive.
12.02	Advance Directive Free Text Type	Free text comment to describe the Advance Directive Type.
12.03	Effective Date	The effective date for the advance directive.
12.04	Custodian of the Document	Name, address or other contact information for the person or organization that can provide a copy of the document.

Table 4.2.3.1.12-2 Advance Directives Data Element Requirements

Data Elem. ID	Data Element	Opt / Repeat	CCD Name	Additional Specification for Component
	Advance Directive		cda:observation[cda:templateId/@root = '2.16.840.1.113883.10.20.1.17']	See CCD section 3.2.2.1
12.01	Advance Directive Coded Type	R2/N	cda:code	See 4.2.3.1.12.1
12.02	Advance Directive Free Text Type	R/N	cda:originalText/ cda:reference/@value	See 4.2.3.1.12.2

Data Elem. ID	Data Element	Opt / Repeat	CCD Name	Additional Specification for Component
12.03	Effective Date	R/N	cda:effectiveTime	See 4.2.3.1.12.3
12.04	Custodian of the Document	R/N	cda:participant[@typeCode='CST']/ cda:participantRole[@classCode='AGNT']	See also 4.2.3.1.1.1, 4.2.3.1.1.2 and 4.2.3.1.1.3

NOTE: The existence of an advance directive of a particular type (e.g., intubation) is a signal to the provider that such a directive exists. When determining how to care for a patient, the provider is advised to review the advance directive directly, rather than relying upon summary information contained within the Registration and Medication Summary

Figure 4.2-45 Advanced Directive Example

```
<!-- These examples assumes the default namespace is 'urn:hl7-org:v3' -->
<observation classCode='OBS' moodCode='EVN'>
  <templateId root='2.16.840.1.113883.10.20.1.17'/>
  <templateId root='2.16.840.1.113883.3.88.11.32.13'/>
  <code code='...' displayName='...'
    codeSystem='2.16.840.1.113883.6.96' codeSystemName='SNOMED CT'>
    <originalText><reference value='#directive-1'/></originalText>
  </code>
  <effectiveTime>
    <low value='...'/>
    <high value='...'/>
  </effectiveTime>
  <participant typeCode='CST'>
    <participantRole classCode='AGNT'>
      <addr>…</addr>
      <telecom>…</telecom>
      <playingEntity>
        <name>…</name>
      </playingEntity>
    </participantRole>
  </participant>
</observtion>
```

4.2.3.1.12.1 Advance Directive Coded Type

C32-[165] The code shall appear in the **<code>** element, and shall use the AdvanceDirectiveTypeCode vocabulary defined by CCD. The OID for this vocabulary is 2.16.840.1.113883.6.96 (SNOMED CT).

C32-[166] The type of advanced directive should be coded.

4.2.3.1.12.2 Advance Directive Free Text Type

C32-[167] The human readable description of the type of advance directive shall appear in the narrative text, and shall be pointed to by the **value** attribute of the **<reference>** element inside the **<originalText>** element of the **<code>**.

4.2.3.1.12.3 Effective Date

C32-[168] The starting time of the advance directive shall be recorded in the **<low>** element of the **<effectiveTime>** element in the Advance Directive **<observation>**.

C32-[169] If the starting time is unknown, the **<low>** element shall have the nullFlavor attribute set to UNK.

C32-[170] The ending time of the advance directive shall be recorded in the **<high>** element of the **<effectiveTime>** element in the Advance Directive **<observation>**.

C32-[171] If the ending time is unknown, the **<high>** element shall have the nullFlavor attribute set to UNK.

C32-[172] If the advance directive does not have a specified ending time, the **<high>** element shall have the nullFlavor attribute set to NA.

4.2.3.1.12.4 Custodian of the Document

C32-[173] Information required to obtain a copy of the advance directive shall be recorded in a **<participantRole>** element within a **<participant>** element of the Advance Directive **<observation>**.

C32-[174] The typeCode attribute of the **<participant>** element shall be CST.

C32-[175] The classCode of the **<participantRole>** element shall be AGNT.

C32-[176] The address of the agent shall be recorded in an **<addr>** element when known.

C32-[177] The telephone number or other electronic communications address for the agent shall be recorded in a **<telecom>** element when known.

C32-[178] The name of the agent who can provide a copy of the advance directive shall be recorded in the **<name>** element inside the **<playingEntity>** element.

5.0 CONSTRAINTS FOR REUSE

There are no constraints regarding use or reuse of this component. It is intended for use and reuse whenever a consumer's patient registration and medical history information is needed. Individual components of this specification may be reused where appropriate to convey similar information for other Use Cases. HITSP has assigned template identifiers to the reusable components to facilitate this reuse.

6.0 APPENDIX

This appendix provides additional detail not included in the other parts of the specification, but that are supportive of the specification. It also provides example mappings into this component specification. Three mappings of the Registration/Medication History Document Component elements are provided at this time, namely to NCPDP SCRIPT element names, X12N 271 Implementation Guide element names and ASTM E2369-5 CCR element names. A mapping of these same elements to HL7 v2.x segments and elements is not currently included but may be provided in a future version of this Component document.

6.1 MAPPING OF NCPDP SCRIPT MEDICATION ATTRIBUTES INTO THE REGISTRATION AND MEDICATION HISTORY DOCUMENT CONTENT COMPONENT

This section illustrates a mapping of the NCPDP SCRIPT standard into the Medications – Prescription and Non-Prescription Module of the Registration and Medication History Document Content Component.[9] This is informative text only and is not a normative part of this document.

The XML Companion Guide for NCPDP SCRIPT provides details and guidelines for developers to exchange electronic prescription messages utilizing an XML implementation of NCPDP SCRIPT. The document describes the XML Message standard, the set of supported messages, and other variables related to the use of an XML implementation of SCRIPT. The XML Message standard supports the same featured message sets as EDIFACT implementations of NCPDP SCRIPT a one-to-one correspondence for their respective data elements.

6.1.1 MEDICATIONS – PRESCRIPTION AND NON-PRESCRIPTION MODULE

Table 6.1.1-1 Medications – Prescription and Non-Prescription Data Element Mappings

Data Elem. ID	Data Element	NCPDP SCRIPT Name
8.01	Free Text Sig	DRU Ø3Ø-IØ14-Ø2, -Ø3 Dosage (Sig instructions. Dosage free text.)
8.02	Indicate Medication Stopped	Not Currently Mapped Sig fields will be available in new Sig Segment in future version of SCRIPT after eprescribing pilots. Sig 13Ø Stop (Indicator, Text, Code, System, Version).
8.03	Administration Timing	Not Currently Mapped Sig fields will be available in new Sig Segment in future version of SCRIPT after eprescribing pilots. Sig Ø8Ø Administration Timing (Text, Code, System, Version, Multiple Modifier).

[9] Other modules do not map to NCPDP.

Data Elem. ID	Data Element	NCPDP SCRIPT Name
8.04	Frequency	Not Currently Mapped Sig fields will be available in new Sig Segment in future version of SCRIPT after eprescribing pilots. Sig Ø7Ø Frequency (Frequency, Units, Code, System, Version, Multiple Modifier).
8.05	Interval	Not Currently Mapped Sig fields will be available in new Sig Segment in future version of SCRIPT after eprescribing pilots. Sig Ø9Ø Interval (Value, Text, Code, System, Version, Variable Interval Modifier).
8.06	Duration	Not Currently Mapped Sig fields will be available in new Sig Segment in future version of SCRIPT after eprescribing pilots. Sig Ø9Ø Interval (Value, Text, Code, System, Version, Variable Interval Modifier).
8.07	Route	Not Currently Mapped Sig fields will be available in new Sig Segment in future version of SCRIPT after eprescribing pilots. Sig Ø5Ø Route (Route, Code, System, Version, Multiple Modifier).
8.08	Dose	Not Currently Mapped Sig fields will be available in new Sig Segment in future version of SCRIPT after eprescribing pilots. Sig Ø2Ø-1Ø Dose as text. Can also express Dose Units Text, Code, Code System, Code System Version.
8.09	Site	Not Currently Mapped Sig fields will be available in new Sig Segment in future version of SCRIPT after eprescribing pilots. Sig Ø6Ø Site (Site, Code, System, Version, Multiple Modifier).
8.10	Dose Restriction	Not Currently Mapped Sig fields will be available in new Sig Segment in future version of SCRIPT after eprescribing pilots. Sig 11Ø Dose Restriction (Maximum Value, Units Text, Code, System, Version, Maximum Variable Value, Units Text, Code, System, Version, Maximum Calculation Equation Code, System, Version, Modifier).
8.11	Product Form	DRU Ø1Ø-IØ13-Ø5-1131 Code List Qualifier Drug form, in a code.
8.12	Delivery Method	Not Currently Mapped Sig fields will be available in new Sig Segment in future version of SCRIPT after eprescribing pilots.Sig Ø2Ø-Ø2 Dose Delivery Method (Text, Code, Version, and System)
8.13	Coded Product Name	DRU Ø1Ø-IØ13-Ø3-714Ø Drug Number, Ø1Ø-IØ13-Ø4-3Ø55 Code List Responsibility Agency
8.14	Coded Brand Name	Not Used

Data Elem. ID	Data Element	NCPDP SCRIPT Name
8.15	Free Text Product Name	DRU Ø1Ø-IØ13-Ø2-7ØØ8, Ø1Ø-IØ13-1Ø-7ØØ8, Ø1Ø-IØ13-11-7ØØ8, Ø1Ø-IØ13-12-7ØØ8 Item Description
8.16	Free Text Brand Name	Not Used
8.17	Drug Manufacturer	Not Used
8.18	Product Concentration	Not Used
8.19	Type of Medication	Not Used
8.20	Status of Medication	Not Used
8.21	Indication	Not Currently Mapped Sig fields will be available in new Sig Segment in future version of SCRIPT after eprescribing pilots. Sig 12Ø Indication (Timing Text, Code, System, Version, Text, Code, System, Version, Value, Value Units, Code, System, Version, Modifier).
8.22	Patient Instructions	DRU-Ø9Ø Free Text . Sig fields will be available in new Sig Segment in future version of SCRIPT after eprescribing pilots. Sig 14Ø Free Text
8.23	Reaction	
8.24	Vehicle	Not Currently Mapped Sig fields will be available in new Sig Segment in future version of SCRIPT after eprescribing pilots. Sig Ø4Ø Vehicle (Name, Name Code, Name Code System, Name Code System Version). Also Vehicle Volume, Multiple Vehicle Modifier.
8.25	Dose Indicator	Sig fields will be available in new Sig Segment in future version of SCRIPT after eprescribing pilots.Sig Ø2Ø-Ø1 Dose Indicator
8.26	Fills	DRU - If number of Refills - Ø6Ø-IØØ9 Quantity Composite (Ø6Ø-IØØ9-Ø1-6Ø63 Quantity Qualifier (R = Number of Refills), Ø6Ø-IØØ9-Ø2-6Ø6Ø Quantity)
8.27	Quantity Ordered	DRU Ø2Ø-IØØ9 Quantity Composite (Ø2Ø-IØØ9-Ø1-6Ø63 Quantity Qualifier - Unit of Measure X-12 DE 355. Ø2Ø-IØØ9-Ø2-6Ø6Ø Quantity. Ø2Ø-IØØ9-Ø3-1131 Code List Qualifier (38 = Original Quantity))
8.28	Order Date/Time	DRU Ø4Ø-IØØ6 Date Composite (Qualifier, Date, Format) SCRIPT value 85 = Date Issued (Written Date) for original order date. CCYYMMDD
8.29	Ordering Provider	NCPDP SCRIPT PVD Segment
8.30	Fulfillment Instructions	DRU-Ø9Ø Free Text . Sig fields will be available in new Sig Segment in future version of SCRIPT after eprescribing pilots. Sig 14Ø Free Text
8.31	Fulfillment History	Loops of PVD (Prescriber), PVD (Pharmacy) and DRU (Drug) Segments to relay up to 300 history occurrences, within Medication History Response.
8.32	Prescription Number	NCPDP SCRIPT DRU- Ø8Ø-Ø1
8.33	Provider	Loops of PVD (Prescriber), PVD (Pharmacy) and DRU (Drug) Segments to relay up to 300 history occurrences, within Medication History Response.
8.34	Location	If provider location, contained in PVD Segment, within Medication History Response.

Data Elem. ID	Data Element	NCPDP SCRIPT Name
8.35	Dispense Date	DRU Ø4Ø-IØØ6 Date Composite (Qualifier, Date, Format) SCRIPT value LD = Last Demand (Last Fill) for original order date. CCYYMMDD. Within Medication History Response.
8.36	Quantity Dispensed	DRU Ø2Ø-IØØ9 Quantity Composite (Ø2Ø-IØØ9-Ø1-6Ø63 Quantity Qualifier - Unit of Measure X-12 DE 355. Ø2Ø-IØØ9-Ø2-6Ø6Ø Quantity. Ø2Ø-IØØ9-Ø3-1131 Code List Qualifier (38 = Original Quantity)) within Medication History Response.

6.2 MAPPING OF X12 PATIENT REGISTRATION ATTRIBUTES INTO THE REGISTRATION AND MEDICATION HISTORY DOCUMENT CONTENT COMPONENT

This section illustrates a mapping of the X12N 271 Implementation Guide into the Insurance Providers Module of the Registration and Medication History Document. This X12N data content is expected to conform to both the HIPAA-Named implementation guide and the CORE Phase I Data Content Rules Version 1.0.0 Rule 154 Section 2 Subsection 2.2 – Health Plan Name and Rule 154 Section 2 Subsection 2.4 – Eligibility Dates. This is informative text only and is not a normative part of this document.

6.2.1 INSURANCE PROVIDERS MODULE

For the purposes of this mapping, the Patient in the X12 270/271 transaction can be located in either the Subscriber Loop (2000C) or Dependent Loop (2000D). The Patient information is considered to be that of the Dependent if Loop 2000D is present, otherwise the Patient information is considered to be that of the Subscriber in Loop 2000C.

Table 6.2.1-1 Insurance Providers Module

Data Elem. ID	Data Element	X12N 271 Name
5.01	Group Number	REF Segment/Loop 2100D if Loop 2000D present ELSE REF Segment/Loop 2100C REF01 = 6P (Group Number) or 1L (Group or Policy Number) REF02 Some plans still use code 1L in REF01 when they are unable to distinguish between the policy or group number.
5.02	Health Insurance Type	EB Segment/Loop 2110D if Loop 2000D present ELSE EB Segment/Loop 2110C EB04
5.03	Health Plan Insurance Information Source ID	NM1 Segment/Loop 2100A NM108 = id/@root NM109 = id/@extension
5.04	Health Plan Insurance Information Source Address	Not Used

Data Elem. ID	Data Element	X12N 271 Name
5.05	Health Plan Insurance Information Source Phone/Email/URL	PER Segment/Loop 2100A PER04, PER06 or PER08, depending upon qualifiers present in PER03, PER05 and PER07. No URL.
5.06	Health Plan Insurance Information Source Name	NM1 Segment/Loop 2100A NM103
5.07	Health Plan Coverage Dates	DTP Segment/Loop 2100D if Loop 2000D present ELSE DTP Segment/Loop 2100C Health plans which operate under CORE rules will provide this information using the eligibility date, which can be found in DTP03 when: DTP01 = 307 DTP03 = date value Other plans may also include this information in DTP03 using different values of DTP01, including 291 (Plan Dates), 346 and 347 (Plan Begin and End Dates), 356 and 357 (Eligibility Begin and End Dates) or 539 and 540 (Policy Effective and Expiration Dates).
5.08	Member ID	NM1 Segment/Loop 2100D if Loop 2000D present ELSE NM1 Segment/Loop 2100C NM108 = MI NM109
5.09	Relationship to Subscriber	INS Segment/Loop 2100D if Loop 2000D present Individual ELSE Self
5.10	Patient Address	N3/N4 Segments/Loop 2100D if Loop 2000D present ELSE N3/N4 Segments/Loop 2100C N301 = cda:addressLine[1] N302 = cda:addressLine[2] N401 = cda:city N402 = cda:state N403 = cda:postalCode N404 = cda:country (if null, US)
5.11	Patient Phone/Email/URL	PER Segment/Loop 2100D if Loop 2000D present ELSE PER Segment/Loop 2100C PER04, PER06 or PER08, depending upon qualifiers present in PER03, PER05 and PER07. No URL.

Data Elem. ID	Data Element	X12N 271 Name
5.12	Patient Name	NM1 Segment/Loop 2100D if Loop 2000D present ELSE NM1 Segment/Loop 2100C NM103 = cda:family NM104 = cda:given[1] NM105 = cda:given[2] NM107 = cda:suffix
5.13	Patient Date of Birth	DMG Segment/Loop 2100D if Loop 2000D present ELSE DMG Segment/Loop 2100C DMG02
5.14	Financial Responsibilty Party Type	Not Used
5.15	Subscriber ID	NM1 Segment/Loop 2100C NM108 = MI NM109
5.16	Subscriber Address	N3/N4 Segments/Loop 2100C N301 = cda:addressLine[1] N302 = cda:addressLine[2] N401 = cda:city N402 = cda:state N403 = cda:postalCode N404 = cda:country (if null, US)
5.17	Subscriber Phone/Email/URL	PER Segment/Loop 2100CPER04, PER06 or PER08, depending upon qualifiers present in PER03, PER05 and PER07. No URL.
5.18	Subscriber Name	NM1 Segment/Loop 2100C NM103 = cda:family NM104 = cda:given[1] NM105 = cda:given[2] NM107 = cda:suffix
5.19	Subscriber Date of Birth	DMG Segment/Loop 2100C DMG02
5.20	Effective Date of Financial Responsibility	Not Used
5.21	Financial Responsibility Party Address	Not Used
5.22	Financial Responsibility Party Phone/Email/URL	Not Used
5.23	Financial Responsibility Party Name	Not Used

Data Elem. ID	Data Element	X12N 271 Name
5.24	Health Plan Name	EB Segment/Loop 2110D if Loop 2000D present ELSE EB Segment/Loop 2110C EB05

6.3 MAPPING OF ASTM E2369 CCR ATTRIBUTES INTO THE REGISTRATION AND MEDICATION HISTORY DOCUMENT CONTENT COMPONENT

This section illustrates a mapping of the ASTM E2369 CCR standard[10] into the Registration and Medication History Document Content Component. This is informative text only and is not a normative part of this document.

6.3.1 PERSON INFORMATION MODULE

Table 6.3.1-1 Person Information Data Element Mappings

Data Elem. ID	Data Element	ASTM E2369-05 CCR Name
1.01	Document Timestamp	/ContinuityOfCareRecord/DateTime
	Person Information	/ContinuityOfCareRecord/Actors/Actor[ActorObjectID = /ContinuityOfCareRecord/Patient/ActorID]
1.02	Person ID	IDs
1.03	Person Address	Address
1.04	Person Phone/Email/URL	Telephone | Email | URL
1.05	Person Name	Person/Name
1.06	Gender	Person/Gender
1.07	Person Date of Birth	Person/DateOfBirth
1.08	Marital Status	/ContinuityOfCareRecord/Body/SocialHistory/SocialHistoryElement/Type[Text = 'Marital Status']/../Description
1.08	Religious Affiliation	/ContinuityOfCareRecord/Body/SocialHistory/SocialHistoryElement/Type[Text = 'Religion']/../Description
1.10	Race	/ContinuityOfCareRecord/Body/SocialHistory/SocialHistoryElement/Type[Text = 'Race']/../Description
1.11	Ethnicity	/ContinuityOfCareRecord/Body/SocialHistory/SocialHistoryElement/Type[Text = 'Ethnicity']/../Description

[10] ASTM International materials used in this document have been extracted, with permission from E-2369-05 Standard Specification for Continuity of Care Record (CCR), copyright ASTM International, 100 Barr Harbor Drive, West Conshohocken, PA 19428. Copies of these standards may be retrieved through the ASTM Web Site at www.astm.org.

6.3.2 LANGUAGE MODULE

Table 6.3.2-1 Language Data Element Mappings

Data Elem. ID	Data Element	ASTM E2369-05 CCR Name
2.01	Language	/ContinuityOfCareRecord/Body/SocialHistory/SocialHistoryElement/Type[Text = 'Language']/../Description

6.3.3 SUPPORT MODULE

Table 6.3.3-1 Support Data Element Mappings

Data Elem. ID	Data Element	ASTM E2369-05 CCR Name
3.01	Date	
3.02	Contact Type	/ContinuityOfCareRecord/Body/Support/SupportProvider/ActorRole
	Contact Information	/ContinuityOfCareRecord/Actors/Actor[ActorObjectID = /ContinuityOfCareRecord/Body/Support/SupportProvider/ActorID]
3.03	Contact Relationship	Relation
3.04	Contact Address	Address
3.05	Contact Phone/Email/URL	Telephone | Email | URL
3.03	Contact Name	Person/Name

6.3.4 HEALTHCARE PROVIDERS MODULE

Table 6.3.4-1 Healthcare Providers Data Element Mappings

Data Elem. ID	Data Element	ASTM E2369-05 CCR Name
4.01	Date	
4.02	Provider Role Coded	/ContinuityOfCareRecord/Body/HealthCareProviders/Provider/ActorRole/Code
4.03	Provider Role Free Text	/ContinuityOfCareRecord/Body/HealthCareProviders/Provider/ActorRole/Text
	Provider Information	/ContinuityOfCareRecord/Actors/Actor[ActorObjectID = /ContinuityOfCareRecord/Body/HealthCareProviders/Provider/ActorID]
4.04	Provider Type	Specialty
4.05	Provider Address	Address
4.06	Provider Phone/Email/URL	Telephone | Email | URL
4.07	Provider Name	Person/Name
4.08	Provider's Organization Name	See 6.3.4.1
4.09	Provider's Patient ID	/ContinuityOfCareRecord/Actors/Actor/IDs[../ActorObjectID = /ContinuityOfCareRecord/Body/HealthCareProviders/Provider /ActorID]/IDs

6.3.4.1 PROVIDER'S ORGANIZATION NAME

The ASTM CCR is patient centric and not provider centric. Those clinics or organizations that the patient is seen would be represented as an Actor. For this reason there is no explicit tagging of a provider's organization. This can be encoded in the CCR though, using the InternalCCRLink.

/ContinuityOfCareRecord/Actors/Actor [ActorObjectID = /ContinuityOfCareRecord/Actors/Actor[ActorObjectID = /ContinuityOfCareRecord/Body/HealthCareProviders/Provider/ActorID]/InternalCCRLink[LinkRelationship = 'Organization']/LinkID]/Organization/Name

6.3.5 INSURANCE PROVIDERS MODULE

Table 6.3.5-1 Insurance Providers Data Element Mappings

Data Elem. ID	Data Element	ASTM E2369-05 CCR Name
5.01	Group Number	/ContinuityOfCareRecord/Body/Payers/Payer/IDs[Type/Text = 'GroupID']/ID
5.02	Health Insurance Type	/ContinuityOfCareRecord/Body/Payers/Payer/Type
	Health Plan Information Source Information	/ContinuityOfCareRecord/Actors/Actor[ActorObjectID = /ContinuityOfCareRecord/Body/Payers/Payer/PaymentProvider/ActorID]/
5.03	Health Plan Information Source ID	IDs
5.04	Health Plan Insurance Information Source Address	Address

Data Elem. ID	Data Element	ASTM E2369-05 CCR Name
5.05	Health Plan Insurance Information Source Phone/Email/URL	Telephone | Email | URL
5.06	Health Plan Insurance Information Source Name	Organization/Name
5.07	Health Plan Coverage Dates	/ContinuityOfCareRecord/Body/Payers/Payer/DateTime
5.08	Member ID	/ContinuityOfCareRecord/Body/Payers/Payer/IDs[Type/Text = 'MemberID']/ID
5.09	Patient Relationship to Subscriber	See 6.3.5.1
	Patient Information	/ContinuityOfCareRecord/Actors/Actor[ActorObjectID = /ContinuityOfCareRecord/Patient/ActorID]/
5.10	Patient Address	Address
5.11	Patient Phone/Email/URL	Telephone Email URL
5.12	Patient Name	Person/Name
5.13	Patient Date of Birth	Person/DateOfBirth
5.14	Financial Responsibilty Party Type	/ContinuityOfCareRecord/Body/Payers/Payer/Type
5.15	Subscriber ID	/ContinuityOfCareRecord/Body/Payers/Payer/IDs[Type/Text = 'SubscriberID']/ID
	Subscriber Information	/ContinuityOfCareRecord/Actors/Actor[ActorObjectID = /ContinuityOfCareRecord/Body/Payers/Payer/Subscriber/ActorID]
5.16	Subscriber Address	Address
5.17	Subscriber Phone/Email/URL	Telephone | Email | URL
5.18	Subscriber Name	Person/Name
5.19	Subscriber Date of Birth	Person/DateOfBirth
5.20	Effective Date of Financial Responsibility	/ContinuityOfCareRecord/Body/Payers/Payer/DateTime[Type = 'Effective Date']
5.21	Financial Responsibility Party Address	Same as 5.04
5.22	Financial Responsibility Party Phone/Email/URL	Same as 5.05
5.24	Financial Responsibility Party Name	Same as 5.06
5.23	Health Plan Name	/ContinuityOfCareRecord/Body/Payers/Payer/Description

6.3.5.1 RELATIONSHIP TO SUBSCRIBER

The ASTM CCR is patient centric not insurance centric, so the relationship to the subscriber is carried in the CCR as the subscriber's relationship to the patient. The mapping to this relationship is:

/ContinuityOfCareRecord/Actors/Actor[ActorObjectID =
/ContinuityOfCareRecord/Body/Payers/Payer/Subscriber/ActorID]/Relation

A logical inversion of the relationship would be required.

6.3.6 ALLERGIES AND DRUG SENSITIVITIES MODULE

Table 6.3.6-1 Allergies and Drug Sensitivities Data Element Mappings

Data Elem. ID	Data Element	ASTM E2369-05 CCR Name
	Alert Information	/ContinuityOfCareRecord/Body/Alerts/Alert/
6.01	Allergy Date	DateTime
6.02	Allergy Type	Type
6.03	Product Free-Text	Agent/Products/Product/Description/Text | Agent/Products/Product/Product/ProductName/Text
6.04	Product Coded	Agent/Products/Product/Description/Code | Agent/Products/Product/Product/ProductName/Code
6.05	Reaction Free-Text	Reaction/Description/Text
6.06	Reaction Coded	Reaction/Description/Code
6.07	Severity Free-Text	Reaction/Severity/Text
6.08	Severity Coded	Reaction/Severity/Code

6.3.7 CONDITIONS MODULE

Table 6.3.7-1 Conditions Data Element Mappings

Data Elem. ID	Data Element	ASTM E2369-05 CCR Name
	Problem	/ContinuityOfCareRecord/Body/Problems/Problem/
7.01	Problem Date	DateTime
7.02	Problem Type	Type
7.03	Problem Name	Description/Text
7.04	Problem Code	Description/Code

6.3.8 MEDICATIONS – PRESCRIPTION AND NON-PRESCRIPTION MODULE

Table 6.3.8-1 Medications – Prescription and Non-Prescription Data Element Mappings

Data Elem. ID	Data Element	ASTM E2369-05 CCR Name
	Medication Information	/ContinuityOfCareRecord/Body/Medications/Medication/
	Directions	Directions/Direction
8.01	Free Text Sig	Description/Text
8.02	Indicate Medication Stopped	StopIndicator
8.03	Administration Timing	AdministrationTiming
8.04	Frequency	Frequency
8.05	Interval	Interval

Data Elem. ID	Data Element	ASTM E2369-05 CCR Name
8.06	Duration	Duration
8.07	Route	Route
8.08	Dose	Dose
8.09	Site	Site
8.10	Dose Restriction	DoseRestriction
8.12	Delivery Method	DeliveryMethod
8.21	Indication	Indication
8.24	Vehicle	Vehicle
8.25	Dose Indicator	DoseIndicator
	Product Information	Product
8.11	Product Form	Form
8.13	Coded Product Name	ProductName/Code
8.14	Coded Brand Name	BrandName/Code
8.15	Free Text Product Name	ProductName/Text
8.16	Free Text Brand Name	BrandName/Text
8.18	Product Concentration	Strength | Concentration
8.17	Drug Manufacturer	/ContinuityOfCareRecord/Actors/Actor[ActorObjectID = Manufacturer/ActorID]/Organization/Name
8.19	Type of Medication	Type
8.20	Status of Medication	Status
8.22	Patient Instructions	PatientInstructions
8.23	Reaction	Reaction
8.26	Fills	Refills
8.27	Quantity Ordered	Quantity
8.28	Ordering Provider	Source[Actor/ActorRole = 'Prescriber']
8.29	Order Date/Time	DateTime[Type = 'Order Date']
8.30	Fullfillment Instructions	FulfillmentInstructions
8.31	Fulfillment History	FulfillmentHistory
8.32	Prescription Number	Fulfillment/IDs
8.33	Provider	Fulfillment/Provider
8.34	Location	Fulfillment/Location
8.35	Dispense Date	Fulfillment/DateTime[Type = 'Dispense Date']
8.36	Quantity Dispensed	Fulfillment/Quantity

6.3.9 PREGNANCY MODULE

Table 6.3.9-1 Pregnancy Data Element Mappings

Data Elem. ID	Data Element	ASTM E2369-05 CCR Name
9.01	Pregnancy	/ContinuityOfCareRecord/Body/Problems/Problem[Description/Code[Value = 'V22.1' & /CodingSystem = 'ICD9-CM']

6.3.10 INFORMATION SOURCE MODULE

Table 6.3.10-1 Information Source Data Element Mappings

Data Elem. ID	Data Element	ASTM E2369-05 CCR Name
10.01	Author Time	/ContinuityOfCareRecord/DateTime
10.02	Author Name	/ContinuityOfCareRecord/Actors/Actor[ActorObjectID = /ContinuityOfCareRecord/From/ActorLink/ActorID]/Person/Name | /ContinuityOfCareRecord/Actors/Actor[ActorObjectID = /ContinuityOfCareRecord/From/ActorLink/ActorID]/Organization/Name
10.03	Reference	/ContinuityOfCareRecord/References/Reference
10.04	Reference Document ID	/ContinuityOfCareRecord/References/Reference/Description/ObjectAttribute[Attribute = 'DocumentID']/AttributeValue
10.05	Reference Document URL	/ContinuityOfCareRecord/Actors/Actor[ActorObjectID = /ContinuityOfCareRecord/References/Reference/Locations/Location/ActorID] /URL

6.3.11 COMMENTS MODULE

Table 6.3.11-1 Comments Data Element Mappings

Data Elem. ID	Data Element	ASTM E2369-05 CCR Name
	Author Name	/ContinuityOfCareRecord/Actors/Actor[ActorObjectID = /ContinuityOfCareRecord/Comments/Comment/Source/ActorID]/Person/Name
	Date	/ContinuityOfCareRecord/Comments/Comment/DateTime
11.01	Free Text Comment	/ContinuityOfCareRecord/Comments/Comment/Description/Text

6.3.12 ADVANCE DIRECTIVES

Table 6.3.12-1 Advance Directives Data Element Mappings

Data Elem. ID	Data Element	ASTM E2369-05 CCR Name
	Advance Directive Information	/ContinuityOfCareRecord/Body/AdvanceDirectives/AdvanceDirective
12.01	Advance Directive Type	Type/Code
12.01	Advance Directive Free Text Type	Type/Text

Data Elem. ID	Data Element	ASTM E2369-05 CCR Name
12.03	Effective Date	DateTime
12.04	Custodian of the Document	InternalCCRLink/LinkID[../LinkRelationship = 'Document Custodian']

7.0 EXTENSIONS

During the development of the C32 specification, it became necessary to extend the HL7 Clinical Document Architecture standard in a few places. The Consumer Empowerment Technical Committee has used the following guidelines in creating extensions:

- An extension is a collection of element or attribute declarations and rules for their application to the applicable HL7 Version 3 standard, in this case HL7 CDA Release 2.0
- A single namespace for all extension elements or attributes defined by HITSP will be defined
- The namespace for these extensions shall be urn:ansi-org:sdtc
- This namespace shall be used as the namespace for any extension elements or attributes that are defined by this implementation guide
- Each extension element shall use the same HL7 vocabularies and data types used by the relevant HL7 Version 3 standard
- Each extension element shall use the same conventions for order and naming as is used by the current HL7 tooling
- An extension element shall appear in XML where the expected RIM element of the same name would have appeared had that element not been otherwise constrained from appearing in the CDA XML schema

These guidelines are very similar to the guideline used by the HL7 Structured Documents Technical Committee in the development of the Continuity of Care Document Implementation Guide. The HL7 Structured Documents Technical Committee has agreed to publish these extensions on the CDA Release 3.0 open issues list, and to be responsible for maintaining them.

7.1 EXTENSIONS TO CDA

7.1.1 sdtc:raceCode

The raceCode extension allows for multiple races to be reported for a patient. Example use of this extension appears below in Figure 7.1-1.

C32-[179] Multiple **<sdtc:raceCode>** extension elements may appear after a CDA **<raceCode>** to report multiple races.

Figure 7.1-1 sdtc:raceCode Extension Example

```
<raceCode code='' displayName='' codeSystem='' codeSystemName=''/>
<sdtc:raceCode code='' displayName='' codeSystem='' codeSystemName=''/>
```

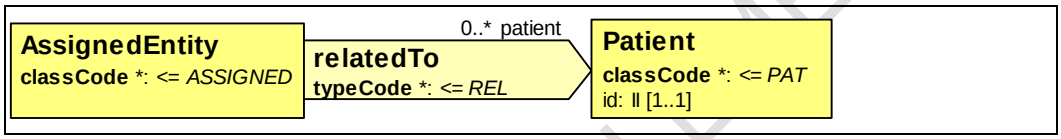
7.1.2 sdtc:patient

The **<sdtc:patient>** extension element allows for the patient identifier used by a given provider to be reported. The provider in their role as an assigned entity is related to the patient.

Figure 7.1-2 sdtc:patient Extension Example

```
<assignedEntity>
  <id root='78A150ED-B890-49dc-B716-5EC0027B3982' extension="ProviderID"/>
  <code code='200000000X '
    displayName='Allopathic and Osteopathic Physicians'
    codeSystem='2.16.840.1.113883.6.101'
    codeSystemName='ProviderCodes'/>
  <assignedPerson>
    <name>...</name>
  </assignedPerson>
  <sdtc:patient>
    <sdtc:id root='78A150ED-B890-49dc-B716-5EC0027B3983' extension='MRN'/>
  </sdtc:patient>
</assignedEntity>
```

Figure 7.1-3 sdtc:patient Extension



7.1.3 sdtc:birthTime

The **<sdtc:birthTime>** element allows for the birth date of any person to be recorded. The purpose of this extension is to allow the recording of the subscriber or member of a health plan in cases where the health plan eligibility system has different information on file than the provider does for the patient. This element appears after the **<name>** of the person.

Figure 7.1-4 sdtc:birthTime Extension Example

```
<playingEntity>
  <name><given>Baby</given><family>Ross</family></name>
  <sdtc:birthTime value='20070209'/>
</playingEntity>
```

8.0 CHANGE HISTORY

8.1 MAY 11, 2007

This document is now Released for Implementation.