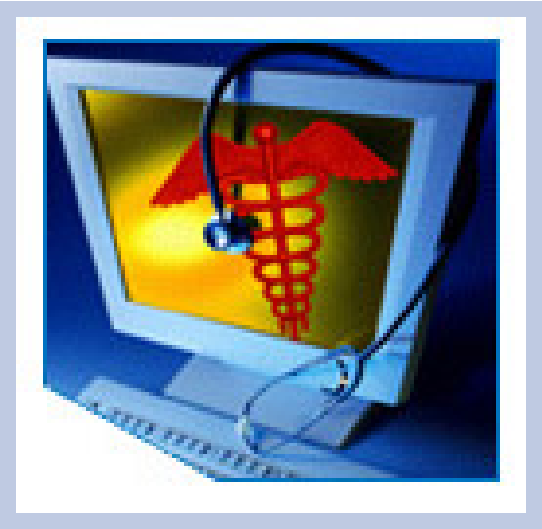
December 13, 2007
Version 2.1

HITSP Consumer Empowerment Interoperability Specification

HITSP/IS03



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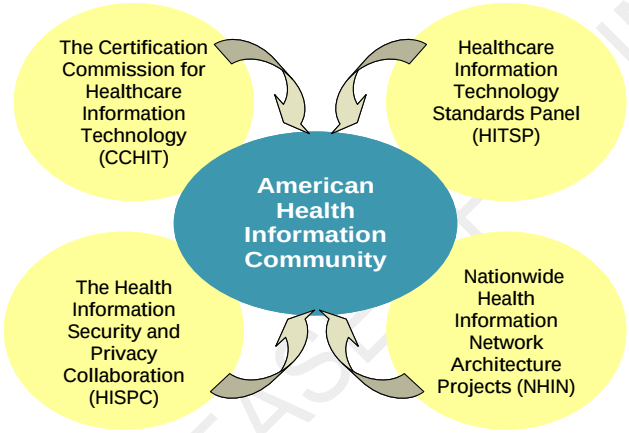
1.0 FOREWORD

This document is referred to as an Interoperability Specification 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.html

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. 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 the HITSP is conducted through formally chartered Technical Committees 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.

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

[2] www.hitsp.org

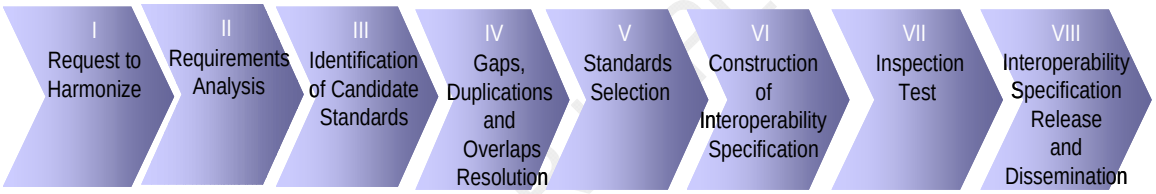
Use Case	Specific Scope of this Use Case
Consumer Empowerment	Allow consumers to establish and manage permissions access, rights, and informed consent for authorized and secure exchange, viewing, and querying of their linked patient registration summaries and medication histories between designated caregivers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

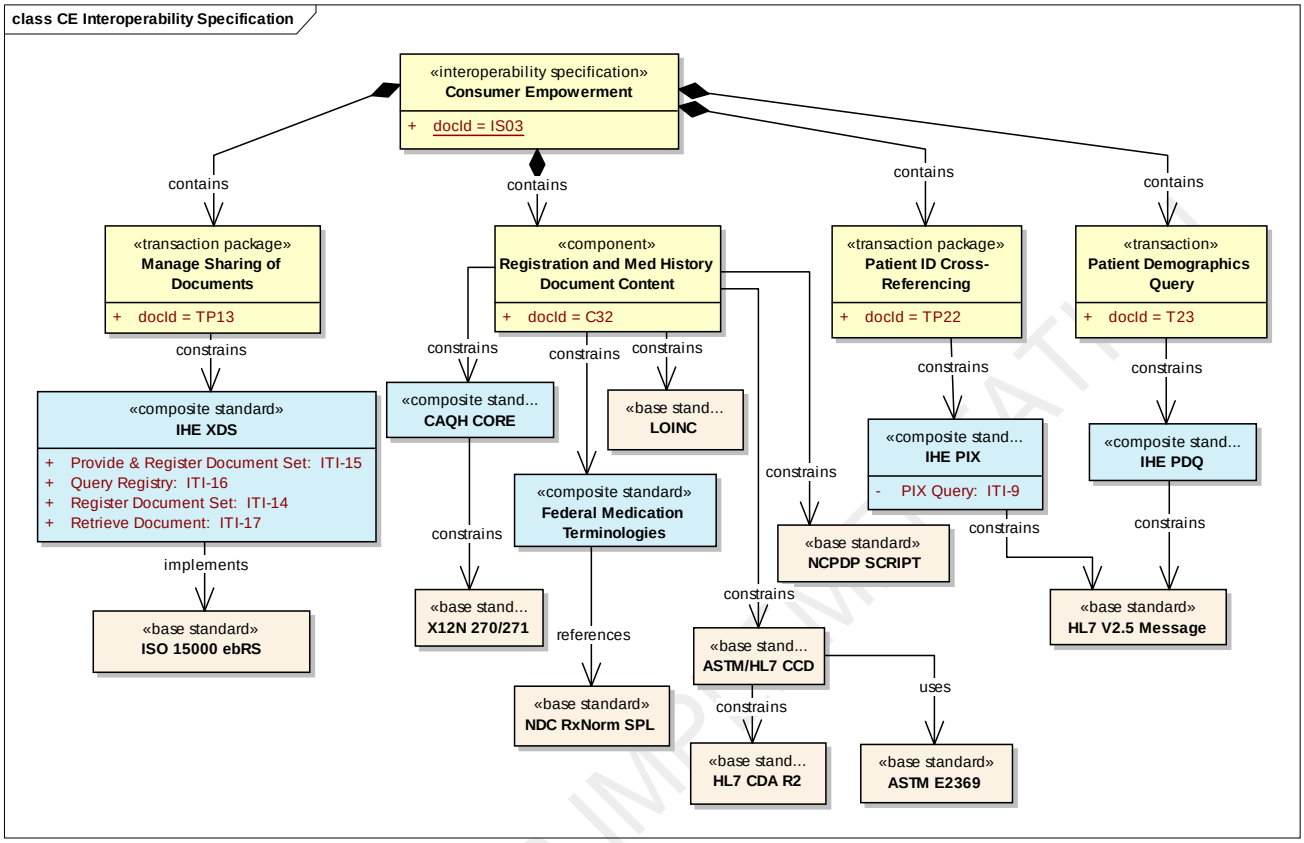
Figure 1.0-1 HITSP Harmonization Process Steps



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 depicted in the diagram below. The most effective way to use any Interoperability Specification is to begin with the document indicated at the top of the diagram.

Figure 1.0-2 Interoperability Specification Roadmap



2.0 INTRODUCTION

As an introduction to the HITSP Consumer Empowerment Interoperability Specification, 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 HITSP Consumer Empowerment Interoperability Specification identifies a subset of the functional components of the healthcare enterprises and health information networks called HITSP actors and specifies their interactions in terms of a set of coordinated, standards-based transactions. This document, the HITSP Consumer Empowerment Interoperability Specification, defines specific implementations of established standards intended to achieve integration goals that promote appropriate exchange of a consumer's personal health record information.

Consumer Empowerment is the active involvement of consumers (i.e., individuals) in managing their healthcare and gaining the benefits of having their health information in a format easily accessible to them. This includes having a personal health record to track patient information, insurance, family history, medications, and other special conditions.

As part of a personal health record, this specification addresses two key areas: the patient's registration data and medication history.

A vital part of a personal health record is registration information. Going to the doctor or hospital frequently requires filling out multiple forms. These forms collect information such as name, address, insurance, medications, allergies, etc. Then, when an individual requires laboratory work or other testing, the same information has to be collected again. A single electronic registration will make it easier for individuals to give their information and for clinicians to use it. Additionally, the consumer could update the information once and share it with all healthcare providers.

An electronic medication history provides the consumer with an updated list of all pertinent medications and allergies in an easily accessible format. Most individuals do not know the specific medications and exact dosages that have been prescribed to them, and often do not know their allergies. In addition, clinicians do not always have consistent prescription information about the same individual nor do they have easy access to medication information directly from the patient. Too often, this results in errors or unnecessary treatments. An electronic medication history would have all the current data available to the individual and to each authorized healthcare provider. The need for an electronic medication history was

highlighted by the high interest in the KatrinaHealth.org web tool. Having a complete electronic medication list would also prevent drug-to-drug or allergic reactions when subsequent prescriptions are written.

Traditionally, registration is viewed from the healthcare provider's perspective and consists of patient registration with the healthcare provider and the patient giving their information to the healthcare provider. The dawn of consumer empowerment creates a new perspective of healthcare providers and healthcare organizations not only registering patients but also providing the healthcare provider's contact and identification information to the consumer. This process of reciprocal registration and sharing of data should be encouraged and facilitated by the Use Case. It is desired, but not required or essential, that healthcare providers who register a patient should also enter their information in the patient's registration summary. Ideally that would include contact information, the identifier, such as a medical record number, that the healthcare provider assigned to that patient. This will facilitate the Personal Health Record (PHR) to serve as a "Regional Health Information Organization (RHIO) of one" having all essential master patient index data and record locator data for a single patient.

This Interoperability Specification defines an interoperable registration and medication history document; one means of which to share this type of document is by registering them in a record locator and retrieving them from the referenced document repository. Some of the other HITSP Use Cases define other types of documents (e.g., a laboratory report in the EHR Use Case) which may also be used as part of information exchange to and from a consumer PHR. Other types of interoperable documents may be defined by HITSP in the future for radiology reports, images, electrocardiogram (ECG) reports, etc. These other types of documents are out of scope of this Use Case.

The interoperability requirements are based upon three well-defined scenarios related to a consumer's personal health record. This is the first document of a series of documents that need to be understood and implemented in order to conform to this initiative. Table 2.1-1 specifies the documents needed in order to conform to this specification.

Table 2.1-1 Related Documents

Related Documents	Document Description
HITSP/TP13	HITSP Manage Sharing of Documents Transaction Package
HITSP/TP22	HITSP Patient ID Cross-Referencing Transaction Package
HITSP/T23	HITSP Patient Demographics Query Transaction
HITSP/C32	HITSP Registration and Medication History Document Content Component

2.2 TECHNICAL ASSUMPTIONS AND SCOPE

The Interoperability Specification focuses on a set of constrained standards for information interchange that address the core requirements of the Use Case described herein. 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 the CE Interoperability Specification. This precondition will be established using Interoperability Specifications related to privacy 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

may be copied or reproduced in any form outside of the Interoperability Specification documents, including an electronic retrieval system, or made available on the Internet without the prior written permission of Health Level Seven, Inc. Copies of standards included in this Interoperability Specification may be purchased from the Health Level Seven, Inc. Material drawn from these standards is credited where used.

IHE materials used in this document have been extracted from relevant copyrighted materials with permission of Integrating the Healthcare Enterprise (IHE). Copies of this standard may be retrieved from the IHE at www.ihe.net.

NCPDP materials used in this document have been extracted from relevant copyrighted materials with permission of the National Council for Prescription Drug Programs (NCPDP). Copies of this standard are available from the NCPDP Web Site at www.ncpdp.org.

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 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 roadmapped 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.

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 table lists the standards required to implement the entire Use Case for Consumer Empowerment.

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
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.

Standard	Description
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) EHR System Functional Model Draft Standard for Trial Use (DSTU)	The HL7 EHR System Functional Model and Standard documents key functions of Electronic Health Record Systems (EHR-S) to enable consistent expression of system functionality. The functions are organized in two ways: as a hierarchy within the broad headings of care delivery and infrastructure functions; and as a list of functions that are deemed essential or desirable within four common care settings. Visit www.hl7.org for more information
Health Level Seven (HL7) Version 2.5[3]	The HL7 Version 2.5 Messaging Standard is an application protocol for electronic data exchange in healthcare. It and prior versions have widespread use in the U.S. and internationally. Both message formats and value sets / code tables (e.g., diagnosis type, gender, patient class, result status, specimen collection method, abnormal flags, observation result status codes interpretation, timestamp format) are contained in the standard. Of particular focus for HITSP Interoperability Specifications are message formats described in Chapters 2, 3, 5, and 7 including patient demographic (ADT) and lab result reporting. These are also used within composite standards from IHE for Patient Identity Cross-Referencing and Feed (PIX), Patient Demographics Query (PDQ), and Acknowledgements. Visit www.hl7.org for more information.
Health Level Seven (HL7) Version 2.5/2.5.1	The HL7 Version 2.5 and 2.5.1 Messaging Standard is an application protocol for electronic data exchange in healthcare. It and prior versions have widespread use in the U.S. and internationally. Both message formats and value sets / code tables (e.g., diagnosis type, gender, patient class, result status, specimen collection method, abnormal flags, observation result status codes interpretation, timestamp format) are contained in the standard. Of particular focus for HITSP Interoperability Specifications are message formats described in Chapters 2, 3, 4, 5, and 7 including patient demographic (ADT), Pharmacy/Treatment Orders and lab result reporting. These are also used within composite standards from IHE for Patient Identity Cross-Referencing and Feed (PIX), Patient Demographics Query (PDQ), and Acknowledgements. They are also used in HL7 order messages such as Visit www.hl7.org for more information.

[3] HITSP references HL7 2.5.1 messaging for lab results reporting and HL7 2.5 for other messages. Future maintenance work will move toward referencing a single HL7 version across HITSP documents.

Standard	Description
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.
Health Level Seven (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.
International Organization for Standardization (ISO) Electronic business eXtensible Markup Language (ebXML), Technical Specification # 15000 -- Part 4: Registry services specification (ebRS), May, 2004	Describes eXtensible Markup Language (XML) and its usage characteristics. Consists of 4 parts: ebCPP, ebMS, ebRIM, and ebRS. Part 4 ebRS defines the interface between the registry and the registry clients, as well as the interaction protocols, message definitions and XML schema. Visit www.iso.org for more information.
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.
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0	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. 4.0 for Final Text, specifies the IHE transactions defined and implemented as of August 22, 2007. The latest version of the IHE Technical Framework is available at www.ihe.net

Standard	Description
Integrating the Healthcare Enterprise (IHE) Patient Care Coordination (PCC) Technical Framework Revision 3.0	The IHE Patient Care Coordination Technical Framework (PCC TF) defines specific implementations (called Integration Profiles) of established standards to deal with integration issues that cross providers, patient problems or time. The Cross Enterprise Document Sharing of Medical Summaries (XDS-MS) Integration Profile enables sharing of health information between enterprises of a regional health network, and further describes how to map content in a CDA medical document into registry metadata. In the registry, healthcare providers publish pointers to documents stored in distributed repositories. Other healthcare providers may search and retrieve these and other documents. Visit www.ihe.net for more information.
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0 - Registry Stored Query Transaction for XDS Profile Supplement	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 Registry Stored Query Transaction Trial Implementation Supplement specifies an IHE transaction that provides optimization and implementation simplification. This supplement is available at www.ihe.net.
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0 XCA Supplement	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 trial implementation version of the XCA Supplement to the ITI-TF, rev. 4.0 Final Text, specifies the IHE transactions that support access between communities in a manner compatible with the XDS Integration profile. This supplement is available at www.ihe.net.
Logical Observation Identifiers Names and Codes (LOINC®)	A database of universal identifiers for laboratory and other clinical observations. The laboratory portion of the LOINC database contains the usual categories of chemistry, hematology, serology, microbiology (including parasitology and virology), and toxicology; as well as categories for drugs and the cell counts typically reported on a complete blood count or a cerebrospinal fluid cell count. Antibiotic susceptibilities are a separate category. The clinical portion of the LOINC database includes entries for vital signs, hemodynamics, intake/output, EKG, obstetric ultrasound, cardiac echo, urologic imaging, gastroendoscopic procedures, pulmonary ventilator management, selected survey instruments, and other clinical observations. Visit www.loinc.org for more information.
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.

3.2 STANDARDS GAPS AND OVERLAPS

This section describes the gaps defined in this Interoperability Specification. Gaps are shown in two cases:

- Identify requirements derived from the context that have no standards that meet all tiers of HITSP criteria to merit endorsement for that context
- Identify a single standard that encompasses and singly fulfills a set of tightly-coupled standards from the given context, yet is lacking in fulfilling one or more of the tightly-coupled requirements

Table 3.2-1 Identifies the Use Case events and known associated gaps.

Table 3.2-1 Use Case Events and Associated Gaps

Event Code	Event Description	Identified Gaps	Recommended Resolution
2.1.5.0	Modify registration and medication data	The Use Case states: Consumers may have the following options for modifying, updating, and correcting various data elements: (1) some data fields will permit unrestricted modifications. (2) some data fields may not permit consumers to edit data, but could allow annotations to be made by the consumer. (3) some data fields will not permit changes and consumers would need to submit requests for modifications and corrections directly to the Providers of PHR Services and/or the Data Systems and Networks that are the original source of the data. Requirements (1) and (2) are met by preventing all fields from any information modules for the Registration/medication history not authored by the document creator to be modified, but allowing any author to create new modules in the documents it makes available. Requirement (3) is a precondition for the Use Case, but is a gap that would eventually need to be addressed.	Consider a future extension to the Use Case to explicitly include a means for the consumer to submit an electronic request for modifications and corrections directly to the original source of data.
2.1.5.0	Modify registration and medication data	A robust terminology that allows consumers to qualify the role of their healthcare providers in their registration summary is lacking. The Use Case was addressed without such a terminology, but further extensions will likely require its definition.	A consumer oriented terminology for healthcare provider type role (e.g., primary care physician, ob/gyn, pharmacy, cardiologist). Consider use of X12 and consider leaving roles as an uncoded entry because consumer use does not fit existing coding systems.
2.1.4.3	Receive data	The Use Case states: The consumer receives data for review. This data may be obtained through various mechanisms to include a web portal, automatic fax service, hardware token, smart card, a print out from a URL, automated login software, etc. The receipt of the data via a network interface (e.g. Internet) is met. Other requirements such as media (e.g. hardware token, smart card) are not yet specified.	A media interchange transaction needs to be specified. IHE XDM (Cross-Enterprise Document Media Interchange) is a candidate to be evaluated.

Event Code	Event Description	Identified Gaps	Recommended Resolution
2.1.5.0	Modify registration and medication data	There is no recognized standard or vocabulary in the industry regarding how the dose calculation is to be explicitly expressed.	The medication history needs to include an entry for dose calculation including weight dosing. We should monitor and encourage standards progress in both NCPDP and HL7 in this regard.

Table 3.2-2 Identifies overlaps known for this Interoperability Specification.

Table 3.2-2 Overlaps

Event Description	Standard Duplication/ Overlap	Recommended Resolution
View registration and medication data	Standard terminology used to describe providers used in the U.S. are almost all driven by, based on, or have been source material for the HIPAA Healthcare Provider Taxonomy, which leads to a large number of overlaps. Since the HIPAA provider taxonomy is the logical successor to many of these standards, this overlap is not hard to understand. However, harmonization of the HIPAA provider taxonomy with other working going on in ISO, should be undertaken. The HIPAA provider taxonomy is used to describe providers by their specialty, and is often related to licensure, accreditation, and/or certification, a "structural role," based on who they are and what they know. However, what is needed from a Consumer Empowerment perspective is a way to describe providers by their function role according to the consumer, not provider viewpoint. Consumers think in terms of Cardiologist, Gynecologist, et cetera. Often the consumer "functional role" and the provider "structural role" will match, but this is not always the case.	The CE TC recommends that a standardized terminology be developed that might be used in future releases of this component. The HL7 Security Technical Committee is presently working with the VHA Role Based Access Control Task Force (RBAC-TF) to develop materials describing the roles of providers, for the purposes of supporting access controls. The present work nearly met the needs of the CE TC, lacking only coded terms to describe the roles.
View registration and medication data	For the Registration Summary and Medication History Document, two base standards may be used: HL7 CDA Rel 2 and ASTM CCR. For PHR information exchange “on the wire”, this specification selected the use of the CCD implementation guide resulting from the harmonization work performed by ASTM and HL7.	See Section 3.2.1

3.2.1 STANDARDS OVERLAP RECOMMENDED RESOLUTION

The CE 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, and others. This challenge is exacerbated by the current information technology situation wherein providers, health plans, and pharmacies, and pharmacy benefit managers (PBMs) industry segments each have created different standards based on differing business needs and timing, with shared and overlapping data elements via three different standards developers: HL7, ASC X12, and NCPDP.

In addition to these aforementioned standards, a fourth standard initiative from 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) which 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 this 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 and require its sole use for provider-consumer information exchange. 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 also recognizes 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, 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.

Resolution Plan

Table 3.2.1-1 Resolution Plan

Date	Task to be Accomplished/Who is involved
January 2007	HL7 and ASTM have released and achieved a successful ballot of the HL7 CCD standard and implementation guide.

4.0 INTEROPERABILITY REQUIREMENTS

4.1 USE CASE OVERVIEW

The Consumer Empowerment Use Case identifies the principal stakeholders and flow of events for the authorized and secure exchange of consumers' registration summaries and medication histories. The Use Case is not intended to define all system features; it identifies and describes interactions between key systems and stakeholders and serves as a guide that leads to further development of functional requirements and other products. The Consumer Empowerment Use Case includes:

- Enabling consumers to establish permissions and access rights for viewing their data
- Authenticating consumers, designated caregivers, and health professionals
- Querying other organizations for data and matching to the consumer
- Accepting "batch" data from other organizations and matching to the appropriate consumers
- Accessing, viewing, and sharing registration summaries and medication histories
- Recording of interactions to enable access and viewing tracking and generation of system logs

Based on the charge from the American Health Information Community, the Consumer Empowerment Use Case presumes some level of linkage between a consumer's registration summary and their medication history. This linkage is an important consideration for identifying and locating individual consumers and their available medication information across network systems. For the purposes of this Use Case, the linking of a consumer's registration summary to the medication history includes: (1) identity matching, (2) linkages between the data, (3) and the ability to incorporate both types of data simultaneously into a system (although they may come from different systems themselves).

This document specifies three scenarios flows to satisfy the harmonized Use Cases defined by ONC. They are:

- Consumer creates account to host registration summary & medication history
- Consumer visits Healthcare Provider and provides registration summary information
- Authorized Healthcare Provider reviews medication history

4.1.1 SCENARIO OVERVIEW: CONSUMER CREATES ACCOUNT TO HOST REGISTRATION SUMMARY & MEDICATION HISTORY

The first scenario is "Consumer Creates Account to Host Registration Summary & Medication History." It defines the flow for a consumer to create their account, obtain registration summary and medication data, view and modify that data and provide to the PHR.

4.1.1.1 SCENARIO CONSTRAINTS

The scenario constraints are defined in the pre-conditions section.

4.1.1.2 SCENARIO PRE-CONDITIONS

Pre-conditions are the conditions that must be in place before the start of the scenario. This includes, but is not limited to, the state of a Business Actor, data that must be available somewhere, or an action that must have occurred. Following are pre-conditions for this scenario.

1. Network infrastructures that enable secure, appropriate, and accurate information exchange across data sources and systems to view the data. This includes, but is not limited to:
    a. methods to identify and authenticate users
    b. methods to identify and determine providers of care
    c. methods to enforce data access authorization policies
    d. methods to ensure that the data are true copies of the data as attested by the source
    e. methods to correctly match patients across systems
    f. methods to identify and determine health insurers
    g. methods to identify and determine pharmacy benefits managers (NOTE: pharmacy benefit information is obtained through NCPDP transactions)
    h. methods to log transactions and provide an audit trail
    i. methods to identify data sources including but not limited to provider EHR systems

    Many of these pre-conditions will be established using HITSP work products being developed by the Security and Privacy Technical Committee in 2007

2. Ability to identify and request corrections to errors is available

3. Ability to apply notes, corrections and comments on original entries is available

4. Appropriate standards are developed, approved, and widely adopted supporting data content and structure, allowing universal access by compliant systems

5. Core datasets are defined and adhered to

6. Authenticate consumers, designated caregivers, and health professionals for access to the consumer's PHR service providers

7. Query other organizations for data and matching to the consumer

8. Support the technical measures to ensure privacy and security of patient health information

9. System transactions will be logged

10. Authentication service to authenticate requestors and/or data submissions from various locations

11. Security and privacy policies, procedures and practices are commonly implemented to support acceptable levels of patient privacy and security

12. Appropriate standards protocols, patient identification methodology, consent, privacy and security procedures, will be agreed to by all relevant participants

13. Legal and governance issues regarding data access authorizations, data ownership, and data use are in effect

In order to implement the information interchange conforming to this Interoperability Specification and its constructs in a real world environment, the implementer must insure that the implementing systems operate within a secure infrastructure that insures the privacy, integrity and availability of all individually identifiable health information as prescribed by the Health Insurance Portability and Accountability Act, all other applicable laws and regulations and terms of any contracts and agreements. The information interchange standards may also assume that certain information technology infrastructure and functions are in place. These assumptions collectively are the general pre-conditions for conforming to this Interoperability Specification and its constructs.

The Consumer Empowerment Interoperability Specification requires that sharing of personal demographic data and medication lists and allergies is *based on patient consent*. Patient consent is clearly within the scope of the CE Use Case but is deferred in order to gather further input to inform its work particularly to the extent it is not addressed by HIPAA nor based on widely accepted PHR standards. Patient consent is thus designated a necessary pre-condition for a successful implementation of a system conforming to the CE Interoperability Specification.

As a pre-condition of the Use Case, appropriate security and privacy controls must be in place to implement role based access. The registration summary and medication history document has been designed to provide a clear separation between demographic and financial data that are not restricted and clinical data (advance directives, conditions, allergies, and medications) that must be restricted. It is also acknowledged that some demographic or financial data may justify fine grained access control in special situations. For example, some consumers may wish to conceal some contact information (such as a cell phone number), some healthcare provider information (such as a same sex spouse or partner), or a condition specific health plan (that might reveal a medical diagnosis) from some individuals.

4.1.1.3 SCENARIO TRIGGERS

The consumer decides to create a PHR.

4.1.1.4 SCENARIO POST-CONDITIONS

The consumer's PHR is available to be accessed by the consumer and any persons/organizations that have been given consent by the consumer.

4.1.1.5 SCENARIO OUTPUTS

The consumer's PHR has been updated with the current patient registration and medication history information.

4.1.1.6 SCENARIO BUSINESS ACTORS

Table 4.1.1.6-1 defines the business actors for this scenario. Other business actors not explicitly mentioned may be able to benefit from this Interoperability Specification. NOTE: While Pharmacies and PBMs are distinct and different entities, within this Use Case they perform the same functions: either or both may provide demographic information and/or medication history. For simplicity of discussion and diagrams, they are described together.

Table 4.1.1.6-1 Business Actors

Actor	Description
Consumer	The individual who receives healthcare services and selects a provider of PHR services to maintain their personal health record consisting of registration data and medication history. This individual determines which Business Actors are authorized to review, access, and update their personal health record.
Personal Health Record (PHR) Service Provider	The organization that supplies the Personal Health Record (PHR), a secure, real-time, point-of-care, person-centric information resource, for consumers.
Regional Health Information Organizations (RHIO)	A Regional Health Information Organization (RHIO) is a multi-stakeholder organization that enables the exchange and use of health information, in a secure manner, for the purpose of promoting the improvement of health quality, safety and efficiency.
Electronic Health Record (EHR) System	The Electronic Health Record (EHR) is a secure, real-time, point-of-care, patient-centric information resource for clinicians.
Health Plan/Intermediary	The organization or its designated intermediary that pays for healthcare, may participate as a data or network system of registration summary information, and can act as a provider of PHR services.
Pharmacy Benefit Manager (PBM)/Pharmacy	The organization that has been delegated authority from the payer to process pharmaceutical claims, intermediary, pharmacy or sub network to provide data for medication history, and can act as a provider of PHR services.

These business actors are identified as separate actors in the various scenario actor transactions descriptions below in this section and sections 4.1.2, and 4.1.3. This descriptive approach does not prevent that such business actors may be grouped in a variety of ways. A number of such implementation variants are depicted in sections 4.1.4 to illustrate in part the architecture flexibility provided by this Interoperability Specification.

4.1.1.7 SCENARIO TECHNICAL ACTORS

Table 4.1.1.7-1 defines the Technical Actors used for this scenario.

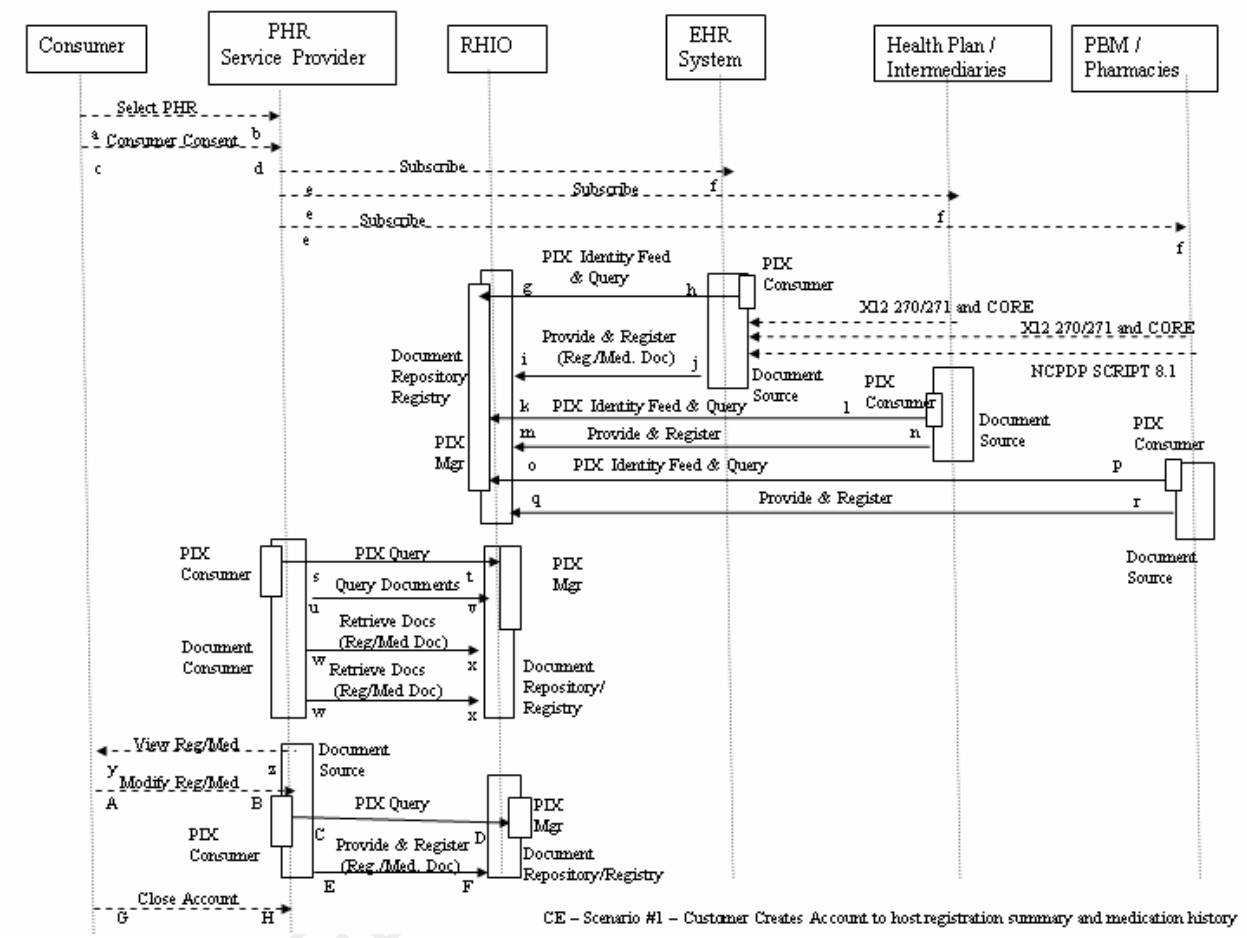
Table 4.1.1.7-1 Technical Actors

Actor	Description
Document Consumer	The Document Consumer queries a Document Registry for documents meeting certain criteria, and retrieves selected documents from one or more Document Repository actors.
Document Source	The Document Source is the producer and publisher of documents and information. It is responsible for sending documents to a Document Repository. It also supplies metadata to the Document Repository for subsequent registration of the documents with the Document Registry Actor.
Document Repository/Registry	The Document Repository is responsible for both the persistent storage of documents as well as for their registration with the appropriate Document Registry. It assigns a URI to documents for subsequent retrieval by a Document Consumer. The Document Registry maintains metadata about each registered document in a document entry. This includes a link to the Document in the Repository where it is stored. The Document Registry responds to queries from Document Consumer actors about documents meeting specific criteria. It also enforces some healthcare specific technical policies at the time of document registration.
PIX Manager	The Patient Identifier Cross-Reference Manager Actor is responsible for creating, maintaining and providing lists of identifiers that are aliases of one another across different Patient Identifier Domains.
PIX Consumer	The Patient Identifier Cross-Reference Consumer either queries for sets of cross-reference patient identifiers. It may also receive notifications about cross-reference changes.
Patient Demographics Supplier	The Patient Demographics Supplier receives patient registration and update messages from other systems in the enterprise (e.g., ADT Patient Registration or Health Plan Membership Management systems), which may or may not represent different Patient ID Domains. It responds to queries for information.
Patient Demographics Consumer	The Patient Demographics Consumer queries the Patient Demographics Supplier to obtain patient demographic data. It may receive matches for one or more patients that enable the selection of the desired patient.

4.1.1.8 SCENARIO ACTOR INTERACTIONS

The sequence diagram for this scenario is shown in Figure 4.1.1.8-1.

Figure 4.1.1.8-1 Customer Creates Accounts to Host Summary and Medication History



Health Plans/Intermediary and PBM/Pharmacy have two approaches for conveying information to their member's/enrollee's PHRs:

- They may choose to act as a direct source of information as a Document Source by using the X12 270/271 and CORE or NCPDP SCRIPT mapping defined in Registration and Med History Document Content Component, section 6
- Alternatively, a provider may act as an intermediary for its patients in retrieving their information from Health Plans/Intermediary and PBM/Pharmacy through the use of X12 270/271 and CORE or NCPDP SCRIPT transactions and convey it to their PHR as defined by this Interoperability Specification (see EHR as Document Source)

Health Plans/Intermediary and PBM/Pharmacy may in addition provide PHR services. This is simply the grouping of the technical actors (and collapse of the transactions) defined for the combined business actors (See Section 4.1.4).

4.1.1.9 TRANSACTIONS DESCRIPTIONS

The transactions shown with dotted lines, are either out of scope (not specified in this Interoperability Specification) because they do not pose specific interoperability issues (e.g. web browsing) to support the Use Case, or are handled at this time through non-electronic communication (e.g. subscribe transaction).

The directions of the arrows are based upon the initiator of the transaction, not the primary flow of data or document. For example, when a Document Consumer wishes to obtain documents from a Document Repository, the arrow flows from the Document Consumer to the Document Repository (i.e. the arrow shows the Retrieve request). The transactions actually include the request, response and acknowledgements.

Each transaction is labeled using letters (a, b, c, etc). These letters are used to map the transactions in each scenario to events defined in the Use Case. See Table 6.1-1 for this mapping.

The Subscribe Transaction is intended to represent the necessary establishment of a business relationship between a consumer's PHR service Provider and a source of data for the consumer such as a provider, health plan/intermediary or PBM/pharmacy. In a future version of this Interoperability Specification one may envision the need to specify a standards-based Subscribe transaction for the consumer to establish a reciprocal information path into the consumer's PHR.

All gaps and standards overlaps for each scenario are identified in section 3.2.

The detailed technical requirements for the transactions shown in Figure 4.1.1.8-1 are specified in section 5.1.

The following narrative provides a high level walk though of the flow in the context of a fictitious scenario. The legend used to read the fictitious scenario is shown below. This legend is used for all scenarios.

<Consumer> = Adam Everyperson
<PHR> = WebExcellent Personal Health Record (WebPHR)
<RHIO> = Greater Metropolitan Health Information Network (GM-HIN)
<Primary Provider> = Dr. Doctor
<EHR> = Physician's Choice Office-base Electronic Health Record (OfficeEHR) used by Dr. Doctor
<Health Plan> = Evergreen Health
<PBM> = MultiState Rx Plan
<Pharmacy> = SmallTown Pharmacy

Adam Everyperson has decided to exert greater control over his health and healthcare. As part of his self-reliant approach, Mr. Everyperson decides that he will maintain his own Personal Health Record. After examining various options, Mr. Everyperson decides to use the web-based Personal Health Record available from WebExcellent (WebPHR). Mr. Everyperson provides basic demographic information to identify himself to WebPHR and establishes an account [Select PHR (a,b)]. Mr. Everyperson also establishes that his spouse, Mary Everyperson, and primary physician, Dr. Doctor, can view the information in his PHR and that his PHR can be accessible, on an emergency basis, via the Greater Metropolitan Health Information Network (GM-HIN) [Consumer Consent (c,d)].

Based upon information provided by Mr. Everyperson, WebPHR establishes relationships [Subscribe (e,f)] with GM-HIN, Dr. Doctor's Electronic Health Record (OfficeEHR), Evergreen Health (Mr. Everyperson's Health Plan), MultiState Rx Plan (a Pharmacy Benefit Manager), SmallTown Pharmacy (Pharmacy) and other similarly related applications as Mr. Everyperson's PHR.

In the course of its operation, GM-HIN receives documents from a number of participating organizations, including Dr. Doctor's OfficeEHR. This requires that patient identities must be matched [PIX Query (g,h)] and documents must be appropriately indexed and stored [Provide & Register (Reg/MedHx), (i,j, and m,n, and q,r)]. GM-HIN may interact with additional information sources, such as Evergreen Health, SmallTown Pharmacy and MultiState Rx Plan. Alternatively, these additional sources can send information into WebPHR directly or through another application. The level of detail of data exchanged between PHR and EHR systems depends upon information contained in these systems. The definition of problems as major medical conditions depends upon the clinical judgment of the consumer's trusted healthcare providers.

In order to initially populate Mr. Everyperson's PHR, WebPHR requests information from GM-HIN on behalf of Mr. Everyperson. This requires first matching that WebPHR and GM-HIN both recognize Mr. Everyperson [PIX Query (s,t)] and determining what relevant documents are contained in GM-HIN [Query Documents (u,v)]. Once the documents are identified, WebPHR retrieves particular documents of interest [Retrieve Documents, this may happen multiple times because of multiple documents (w,x)].

WebPHR consolidates the information provided by Mr. Everyperson and the documents that have been retrieved and presents that information to Mr. Everyperson [View Reg/Med (y,z)]. The nature of this consolidation and, in particular the reconciliation of duplicates, is outside the scope of this document. Mr. Everyperson reviews the information and realizes that some of the information is out of date and other information is not correct from his recollection. Mr. Everyperson updates the information as it is stored in WebPHR [Modify Reg/Med (A,B)]. WebPHR passes updated documentation along to GM-HIN, as allowed by the access and consents set up by Mr. Everyperson.

Registration History/Medication History Document Content Component

The Registration and Medication (Reg/Med) History Document Content Component (HITSP/C32) describes the document content that summarizes a consumer's registration and medication data

information for the purpose of information exchange with a Personal Health Record (PHR).

NOTE: that we are not describing the content of the PHR, but the exchange of information with a PHR.

The document consists of Content Modules that contain multiple data elements. The list of content modules is:

Table 4.1.1.9-1 HITSP/C32 Content Modules and Optionality in this IS

Content Module	Optional
Person Information	Required
Language Spoken	Required if known (R2)[4]
Support	Required if known (R2)[4]
Healthcare Provider	Required
Insurance Provider	Required
Allergies and Drug Sensitivity	Required
Condition	Required
Medications – Prescription and Non-Prescription	Required
Pregnancy	Optional
Information Source	Required
Comments	Optional
Advance Directives	Optional

The Reg/Med document, as a whole, contains a designated author that is the consumer and/or their designated agent, such as the parent of a minor child. Every content module; such as a medication, allergy, or problem; contains an author that defaults to the document author or authors unless otherwise specified. When data are copied from another source, such as medication history information from a PBM, the original source and author (such as the prescribing healthcare provider) shall be retained. A consumer shall only edit data that they entered themselves, but they may add a comment (for which they will be the author) to specific content modules in the record or delete any data element they wish to remove from their record. Users should be aware that changing consumer demographics or financial data may cause future consumer linkages and queries to fail. Requesting changes to data in external systems, such as a health plan system that would correct errors in a field such as name or indicate changes in address or phone number is not addressed by this specification and has been identified as a gap.

4 Data elements that are marked required if known (R2) must be sent when the content creator technical actor has that data available. The content creator technical actor 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 content creator technical actor may indicate as reason that the data is not available.

4.1.2 SCENARIO OVERVIEW: CONSUMER VISITS HEALTHCARE PROVIDER AND PROVIDES REGISTRATION SUMMARY INFORMATION

The second scenario is named “Consumer Visits Healthcare Provider and Provides Registration Summary Information.” It defines the flow for a consumer to log onto their account, obtain registration summary and medication data, allow a healthcare provider to review the registration data and update their EHR.

For the most up to date and complete information, it is recommended that at the end of a healthcare encounter the new registration/medication data are pushed to the document registry. For example, a Mr. Everyperson is seen in the emergency department at a local hospital the night before a visit to Dr. Doctor. Dr. Doctor submits a new medication history request query, but there is an interval when MultiState Rx Plan had not yet processed the new medication (e.g. the night before) and published it to GM-HIN. If the emergency department did not push the information to the repository, Dr. Doctor would not have access to that information unless Mr. Everyperson enters the data into their WebPHR. Dr. Doctor’s query would also not return any medications administered by the emergency department.

It is the intent of this specification to allow for a complete, up to date, relevant registration and/or medication summary but it is not guaranteed by this specification.

4.1.2.1 SCENARIO CONSTRAINTS

The consumer has already established their PHR.

4.1.2.2 SCENARIO PRE-CONDITIONS

The pre-conditions for this scenario are defined in section 4.1.1.2.

4.1.2.3 SCENARIO TRIGGERS

The consumer has already established their PHR.

4.1.2.4 SCENARIO POST-CONDITIONS

The consumer’s PHR is available to be accessed by the consumer and any healthcare provider staff that have been given consent by the consumer.

4.1.2.5 SCENARIO OUTPUTS

The consumer’s PHR has been updated with the current patient registration and medication history information and the consumer’s EHR has been updated with the consumer’s registration summary data. The Registration/Medication History entries integrated into the healthcare provider EHR have their source identified, thus allowing the healthcare provider to distinguish between Consumer-provided information and information provided by other healthcare entities.

4.1.2.6 SCENARIO BUSINESS ACTORS

The business actors defined for this scenario are defined in section 4.1.1.6.

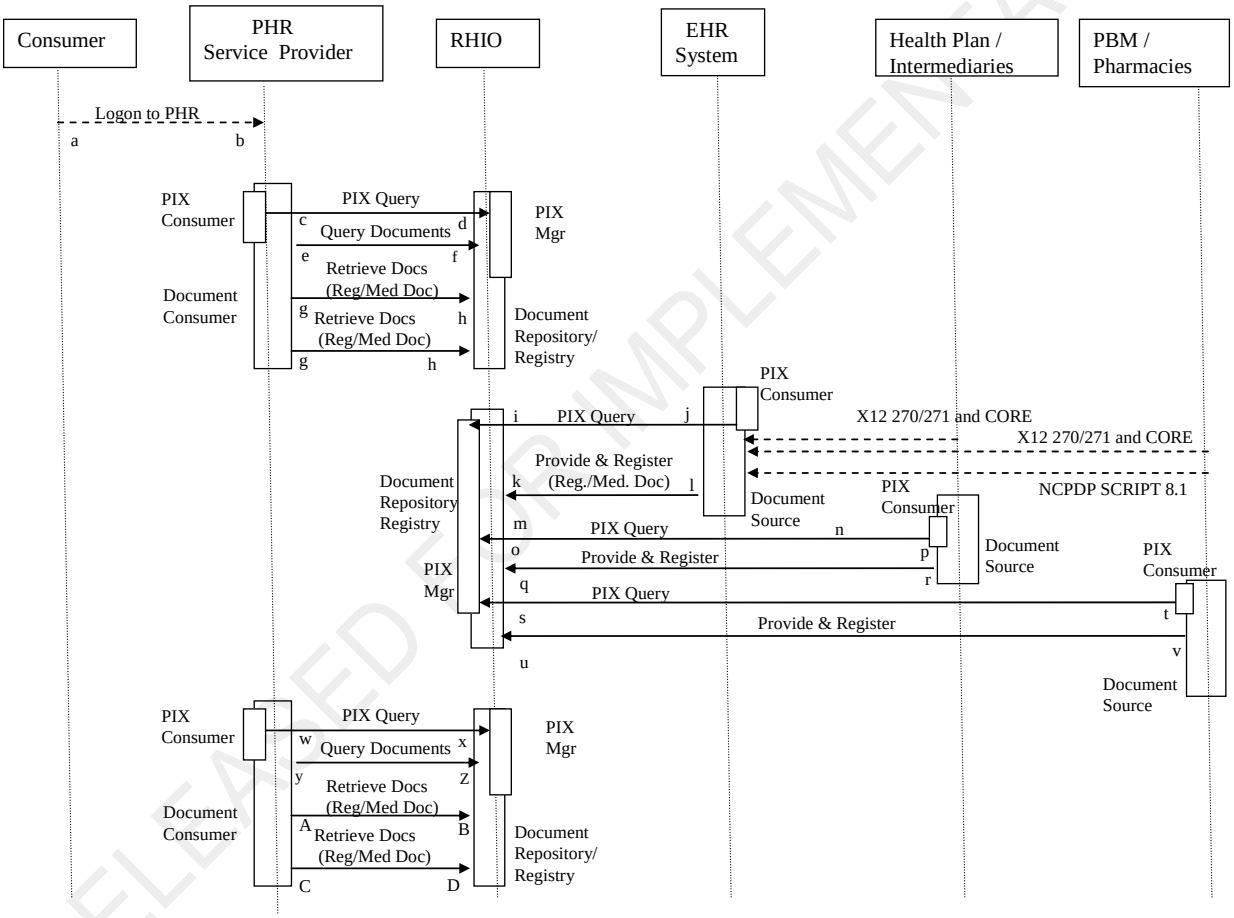
4.1.2.7 SCENARIO TECHNICAL ACTORS

The technical actors defined for this scenario are defined in section 4.1.1.7.

4.1.2.8 SCENARIO ACTOR INTERACTIONS

The sequence diagram for this scenario is shown in Figure 4.1.2.8-1.

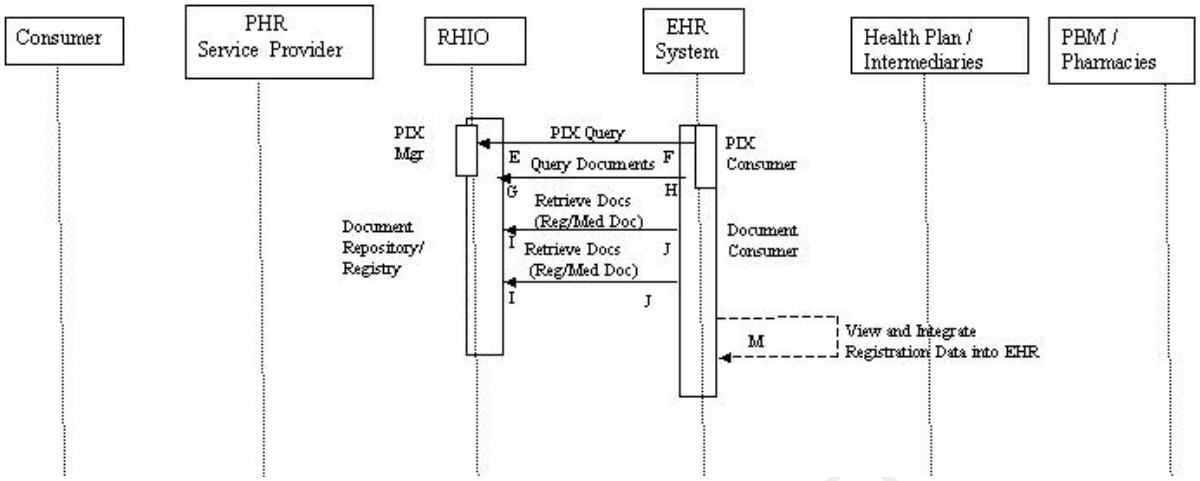
Figure 4.1.2.8-1 Consumer Visits Healthcare Provider and Provides Registration Summary Information



CE – Scenario #2 – Customer Visits Health Care Provider and provides registration summary information

Continue Sequence Diagram

Figure 4.1.2.8-1 Consumer Visits Healthcare Provider and Provides Registration Summary Information (continued)



4.1.2.9 TRANSACTION DESCRIPTIONS

The detailed technical requirements for the transactions shown in Figure 4.1.2.8-1 are specified in section 5.1. The follow narrative provides a high level walk though of the flow in the context of a fictitious scenario.

Adam Everyperson has an appointment coming up with his primary provider, Dr. Doctor. He wants to make sure that his address, insurance and other similar information is up to date in his PHR and, thus, available to Dr. Doctor.

Mr. Everyperson connects to WebPHR and identifies himself [Logon to PHR (a,b)]. For external information, WebPHR requests documents from GM-HIN on behalf of Mr. Everyperson. This requires first matching that WebPHR and GM-HIN both recognize Mr. Everyperson [PIX Query (c,d)] and determining what relevant documents are contained in GM-HIN [Query Documents (e,f)]. Once the documents are identified, WebPHR retrieves particular documents of interest [Retrieve Documents, this may happen multiple times because of multiple documents (g,h)].

In the course of its operation, GM-HIN receives documents from a number of participating organizations, including Dr. Doctor's OfficeEHR. Patient identities must be matched [PIX Query (i,j, & m,n, & s,t)] and documents must be appropriately indexed and stored [Provide & Register (Reg/MedHx)]. *GM-HIN may interact with additional information sources, such as Evergreen Health, SmallTown Pharmacy and MultiState Rx Plan. Alternatively, these additional sources can send information into GM-HIN through another application, such as OfficeEHR, that consolidates the information into a common format*.

Mr. Everyperson requests an update of the external information in his PHR. WebPHR requests updated information from GM-HIN, and other information sources, on behalf of Mr. Everyperson. This requires

that WebPHR has established relationships to GM-HIN (or other system) [subscribe], and then match that WebPHR and GM-HIN both recognize Mr. Everyperson [PIX Query (w,x)] and determining what relevant documents are contained in GM-HIN [Query Documents, (y,z)]. Once the documents are identified, WebPHR retrieves particular documents of interest [Retrieve Documents (A,B)].

Upon arriving for his appointment with Dr. Doctor, Mr. Everyperson is handed the standard visit forms to fill out. He advises the office staff that his information is available via WebPHR. The office staff enters the appropriate information (e.g. patient identification, authorization, etc) into OfficeEHR to retrieve Mr. Everyperson's information from WebPHR via GM-HIN. OfficeEHR queries GM-HIN to match that OfficeEHR and GM-HIN both recognized Mr. Everyperson [PIX Query (E,F)]. OfficeEHR requests information on relevant documents contained in GM-HIN [Query Documents (G,H)], and retrieves the current Registration Summary document(s) [Retrieve Documents (I,J)].

OfficeEHR presents the Registration Summary to the office staff and Dr. Doctor, who then determine if the information should be posted into the OfficeEHR record for Mr. Everyperson [View and Integrate Information into EHR (M)].

4.1.3 SCENARIO OVERVIEW: AUTHORIZED HEALTHCARE PROVIDER REVIEWS MEDICATION HISTORY

The third scenario is named "Authorized Healthcare Provider Reviews Medication History." It defines the flow for a consumer to log onto their account, obtain registration summary and medication data, allow a healthcare provider to review the medication data.

4.1.3.1 SCENARIO CONSTRAINTS

The scenario constraints are defined in the pre-conditions section.

4.1.3.2 SCENARIO PRE-CONDITIONS

The pre-conditions for this scenario are defined in section 4.1.1.2.

4.1.3.3 SCENARIO TRIGGERS

The consumer has already established their PHR.

4.1.3.4 SCENARIO POST-CONDITIONS

The consumer's PHR is available to be accessed by the consumer and any healthcare provider staff that have been given consent by the consumer.

4.1.3.5 SCENARIO OUTPUTS

The consumer's PHR has been updated with the current patient registration and medication history information and an authorized healthcare provider is able to view and if needed update and EHR with the consumer's medication history.

4.1.3.6 SCENARIO BUSINESS ACTORS

The business actors for this scenario are defined in section 4.1.1.6.

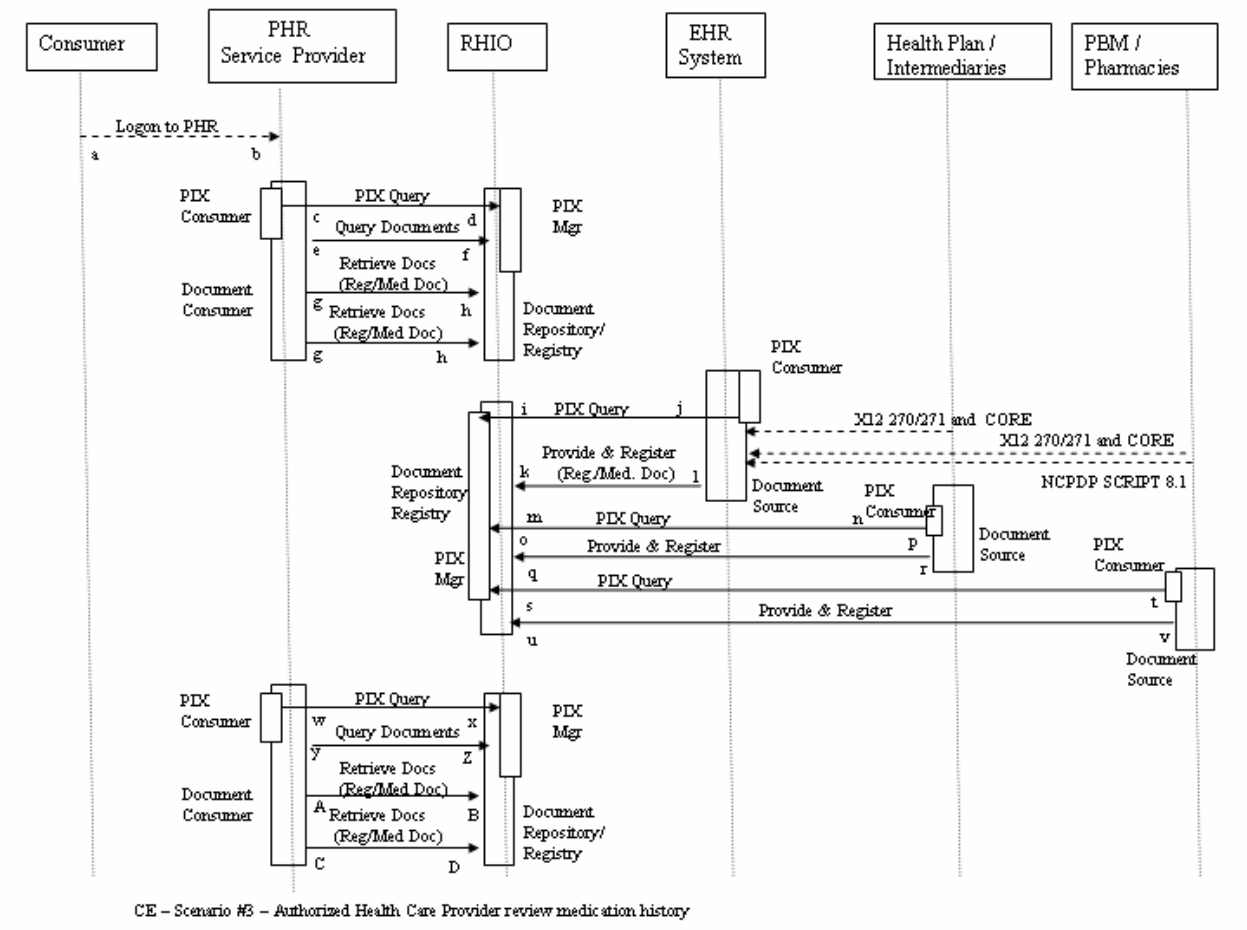
4.1.3.7 SCENARIO TECHNICAL ACTORS

The technical actors for this scenario are defined in section 4.1.1.7.

4.1.3.8 SCENARIO ACTOR INTERACTIONS

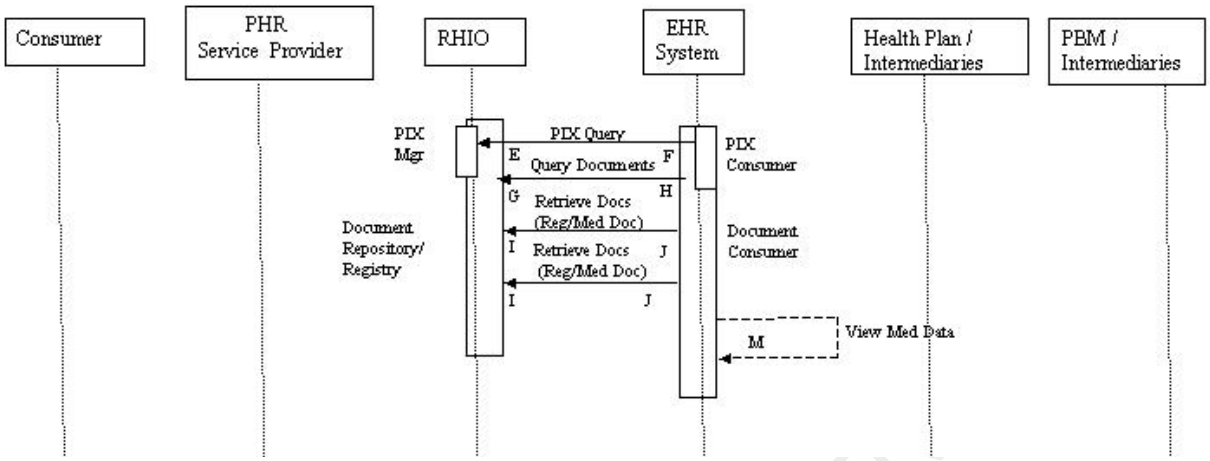
The sequence diagram is shown in Figure 4.1.3.8-1.

Figure 4.1.3.8-1 Authorized Healthcare Provider Views Medication History



Continue Sequence Diagram

Figure 4.1.3.8-1 Authorized Healthcare Provider Views Medication History (continued)



4.1.3.9 TRANSACTION DESCRIPTIONS

The detailed technical requirements for the transactions shown in Figure 4.1.3.8-1 are specified in Section 5.1. The following narrative provides a high level walk though of the flow in the context of a fictitious scenario.

Adam Everyperson has an appointment coming up with his primary provider, Dr. Doctor. He wants to make sure that his latest medications, including over-the-counter and herbals, are appropriately listed in his PHR and, thus, available to Dr. Doctor.

Mr. Everyperson connects to WebPHR and identifies himself [Logon to PHR (a,b)]. For external information, WebPHR requests documents from GM-HIN on behalf of Mr. Everyperson. This requires first matching that WebPHR and GM-HIN both recognize Mr. Everyperson [PIX Query (c,d)] and determining what relevant documents are contained in GM-HIN [Query Documents (e,f)]. Once the documents are identified, WebPHR retrieves particular documents of interest [Retrieve Documents (g,h)].

In the course of its operation, GM-HIN receives documents from a number of participating organizations, including Dr. Doctor's OfficeEHR. Patient identities must be matched [PIX Query (i,j, & m,n, s,t)] and documents must be appropriately indexed and stored [Provide & Register (Reg/MedHx) (k,l, & o,p, & u,v)]. GM-HIN may interact with additional information sources, such as Evergreen Health, SmallTown Pharmacy, and MultiState Rx Plan. Alternatively, these additional sources can send information into GM-HIN through another application, such as OfficeEHR, that consolidates the information into a common format.

Mr. Everyperson requests an update of the external information in his PHR. WebPHR requests updated information from GM-HIN, and other information sources, on behalf of Mr. Everyperson. This requires

that WebPHR has established relationships to GM-HIN (or other system) [subscribe], and then ensures that WebPHR and GM-HIN both recognize Mr. Everyperson [PIX Query (w,x)] and determines what relevant documents are contained in GM-HIN [Query Documents (y,z)]. Once the documents are identified, WebPHR retrieves particular documents of interest [Retrieve Documents (A,B)].

Upon arriving for his appointment with Dr. Doctor, Mr. Everyperson is handed a current medication form to fill out. He advises the office staff that his information is available via WebPHR. The office staff enters the appropriate information (e.g. patient identification, authorization, etc) into OfficeEHR to retrieve Mr. Everyperson's information from WebPHR (via GM-HIN). OfficeEHR queries GM-HIN to match that OfficeEHR and GM-HIN both recognized Mr. Everyperson [PIX Query (E,F)]. OfficeEHR requests information on relevant documents contained in GM-HIN [Query Documents (G,H)], and retrieves the current Medication History document(s) [Retrieve Documents (I,J)].

OfficeEHR presents the Medication History to the office staff and Dr. Doctor, who then determine if the information should be posted into the OfficeEHR record for Mr. Everyperson [View and Integrate Information into EHR (M)].

4.1.4 IMPLEMENTATION AND ARCHITECTURE VARIANTS

The three scenarios depicted in sections 4.1.1, 4.1.2, 4.1.3 assume a specific implementation architecture which is just one of the possible architectural variants that are supported for this Consumer Empowerment Registration and Medication History Interoperability Specification. Such flexibility is necessary to support environments where:

- No RHIO is established
- Data are stored in a centralized way or distributed among several repositories
- Some of the repositories are grouped with the source of Registration & Medication Documents, others being shared as part of the RHIO infrastructure

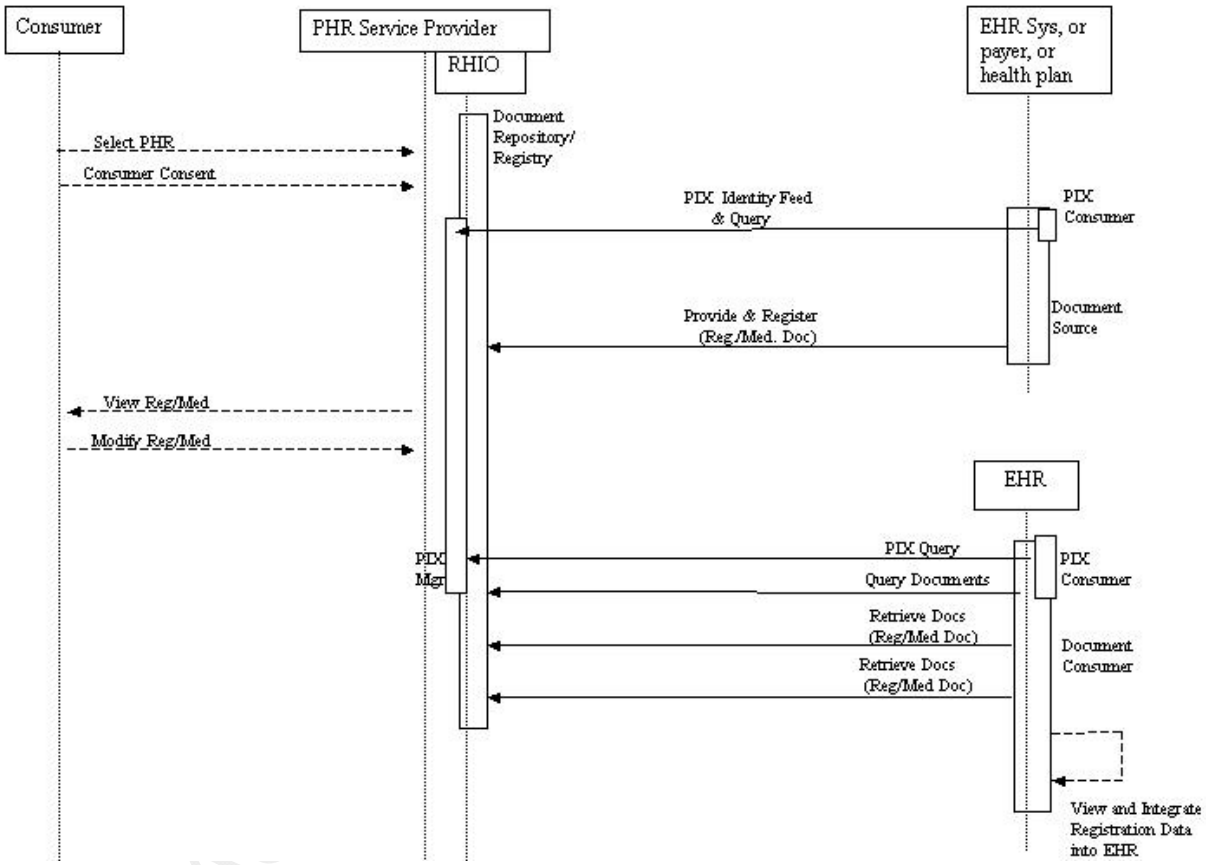
In some situations, some business actors may be grouped to support cases such as: a PHR Service is provided by a Healthcare Provider or a Payer, etc.; or the functionality of a RHIO may be subsumed by the PHR Service Provider,

Five examples are provided to illustrate these many possible variants. This is a fluid and evolving area of healthcare technology and, as such, the examples shown are only a small subset of all possible variants. They leverage a subset of the transactions and business actors defined for the Use Case, but do not attempt to present all business actors or transactions. Note that these examples include "actors" subsumed by other actors. This is intended to point out where functionality is consolidated, not to imply that those actors are separate and distinct.

Implementation/Architecture Variant A

In this variant, the PHR Service provider cannot rely on a RHIO. The tasks of the RHIO are performed by the PHR Service Provider and a number of transactions disappear and technical actors are combined. One should note that the other business actors (e.g. the Health Plan or the EHR) use the very same transactions as when the RHIO exists as a separate business actor. Figure 4.1.4-1 is an example of this variant.

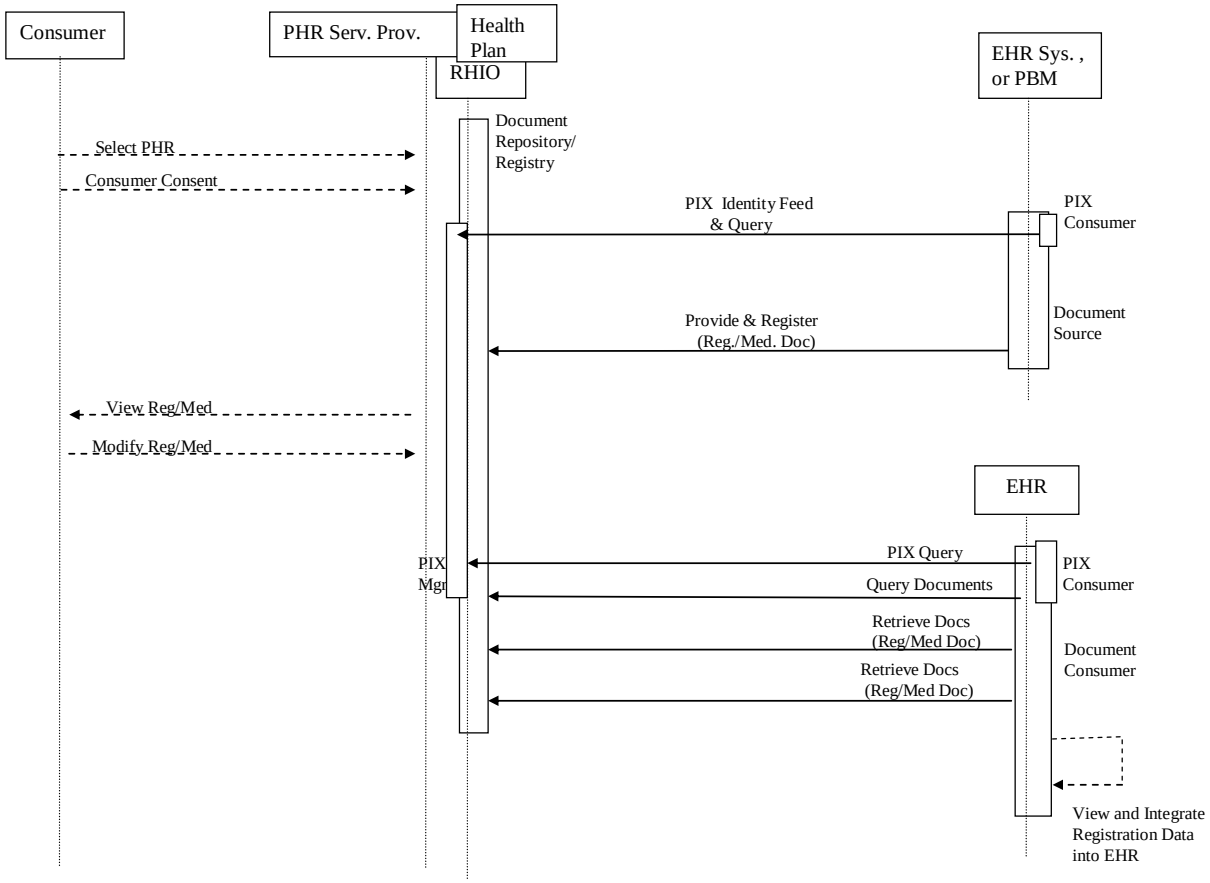
Figure 4.1.4-1 RHIO Functionality Assumed by PHR Service Provider



Implementation/Architecture Variant B

In this variant, the PHR Service provider cannot rely on a RHIO similar to as shown in variant A, and the PHR service is being offered by a payer. By combining now three business actors, a number of transactions further disappear and technical actors are combined. One should note that the other business actors (e.g. the PBM, Pharmacy or the EHR) use the very same transactions than when the business actors exist as separate entities. Figure 4.1.4-2 is an example of this variant.

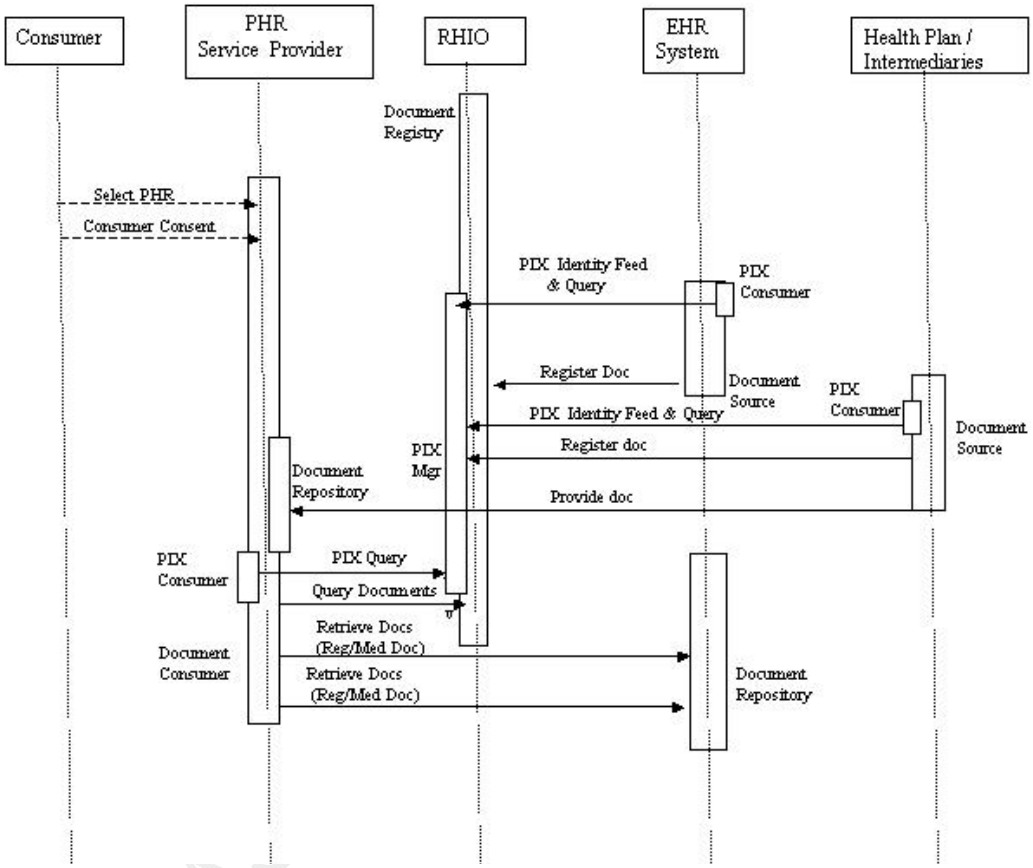
Figure 4.1.4-2 Payer assumes RHIO functionality and PHR Service Provider



Implementation/Architecture Variant C

In this variant, the RHIO does not offer any centralized document repository. Repositories are supported by the PHR for the Registration and Medication History documents the consumer creates and by the EHR for the documents it creates. In this architecture, the RHIO supports only a record locator service (Document Registry technical actor) and an MPI (Patient ID Cross-Reference manager). Again, there is no interoperability impact on the other business actors. Figure 4.1.4-3 is an example of this variant.

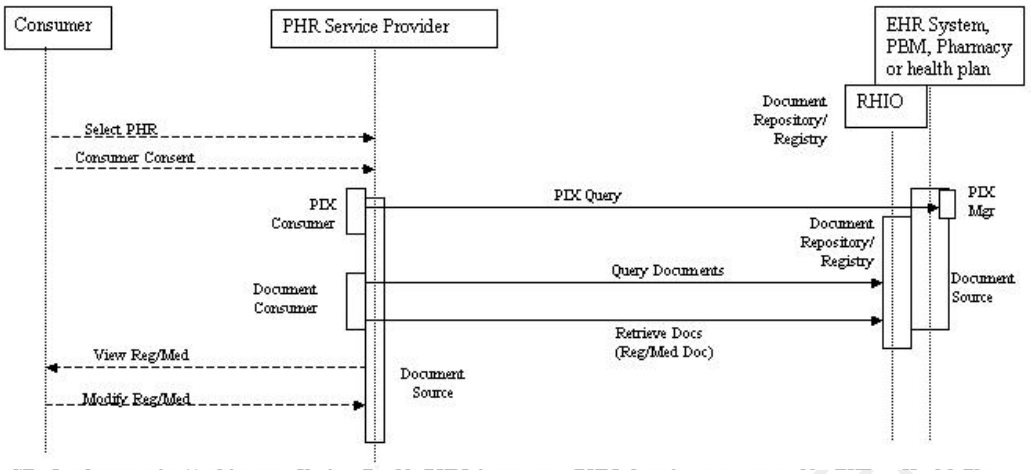
Figure 4.1.4-3 RHIO is Only Registry, No Central Repository



Implementation/Architecture Variant D

In this variant, the EHR, PBM, Pharmacy or Health plan is shown acting as a RHIO to expose access to consumer information stored in these systems. Once again, by combining business actors, a number of transactions have disappeared and technical actors are combined. In this architecture variant, consumer information flows to the PHR using the request/response model. Figure 4.1.4-4 is an example of this variant.

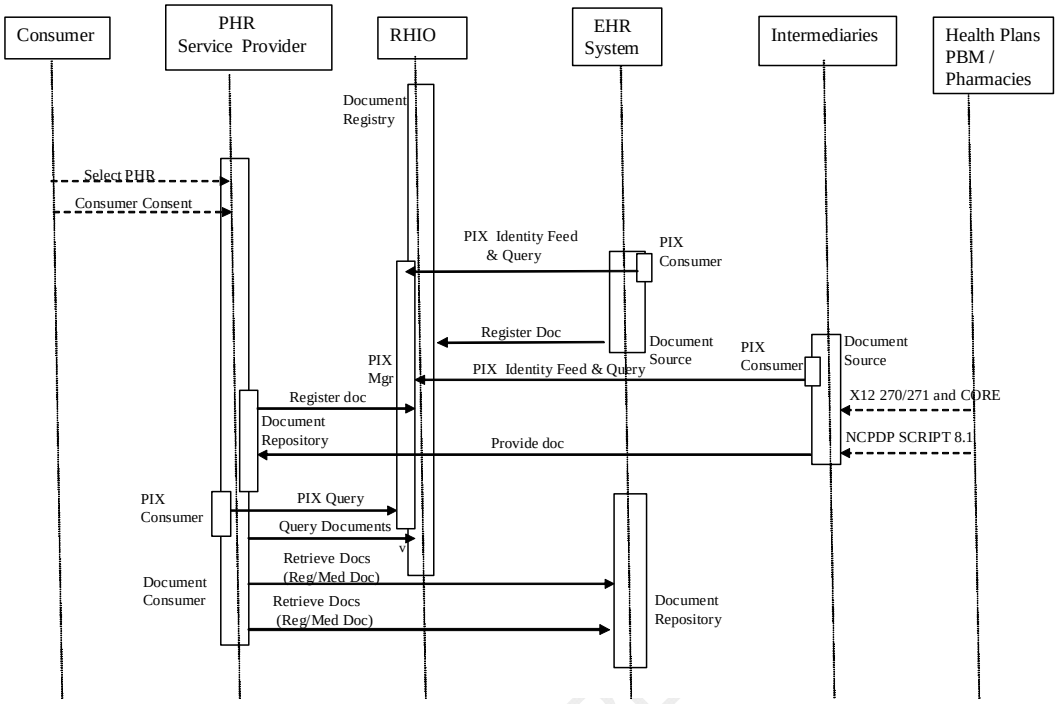
Figure 4.1.4-4 EHR or Health Plan Assumes RHIO Functionality



Implementation/Architecture Variant E

In this variant, there is a Scenario Technical Actor serving as an intermediary acting as the Document Source between the Health Plan/PBM/Pharmacies and the PHR Service Provider (the Document Repository) to perform message translation. Figure 4.1.4-5 is an example of this variant.
It should be noted, that the Document need not be persisted by the source (e.g. Health Plan, Pharmacy/Intermediaries, etc.). It may either provide an X270/X271 to another party (e.g., EHR or intermediary as shown in this variant E) or create and provide the Registration and Medication History documents to an entity where it will be persisted (e.g., RHIO, PHR system such as variant A, B, C).

Figure 4.1.4-5 Intermediary between Health Plans and PHR Service Provider



The architectural flexibilities illustrated in the five variants allow the same edge system implementations to be supported, and a wide range of architectures to be supported.

4.2 LIST OF TRANSACTION PACKAGES AND INDEPENDENT TRANSACTIONS

The following list of transaction packages, independent transactions and their definitions are used by the Interoperability Specification.

Table 4.2-1 Transaction Packages and Transactions in this IS

Transaction Package/ Independent Transaction	Description
HITSP/TP13	HITSP Manage Sharing of Documents Transaction Package
HITSP/TP22	HITSP Patient ID Cross-Referencing Transaction Package
HITSP/T23	HITSP Patient Demographics Query Transaction

4.2.1 DEPENDENCIES

There are no dependencies between the transaction packages and transactions defined in this Interoperability Specification.

4.2.2 CONSTRAINTS

There are no constraints for the transaction packages and transactions defined in this Interoperability Specification.

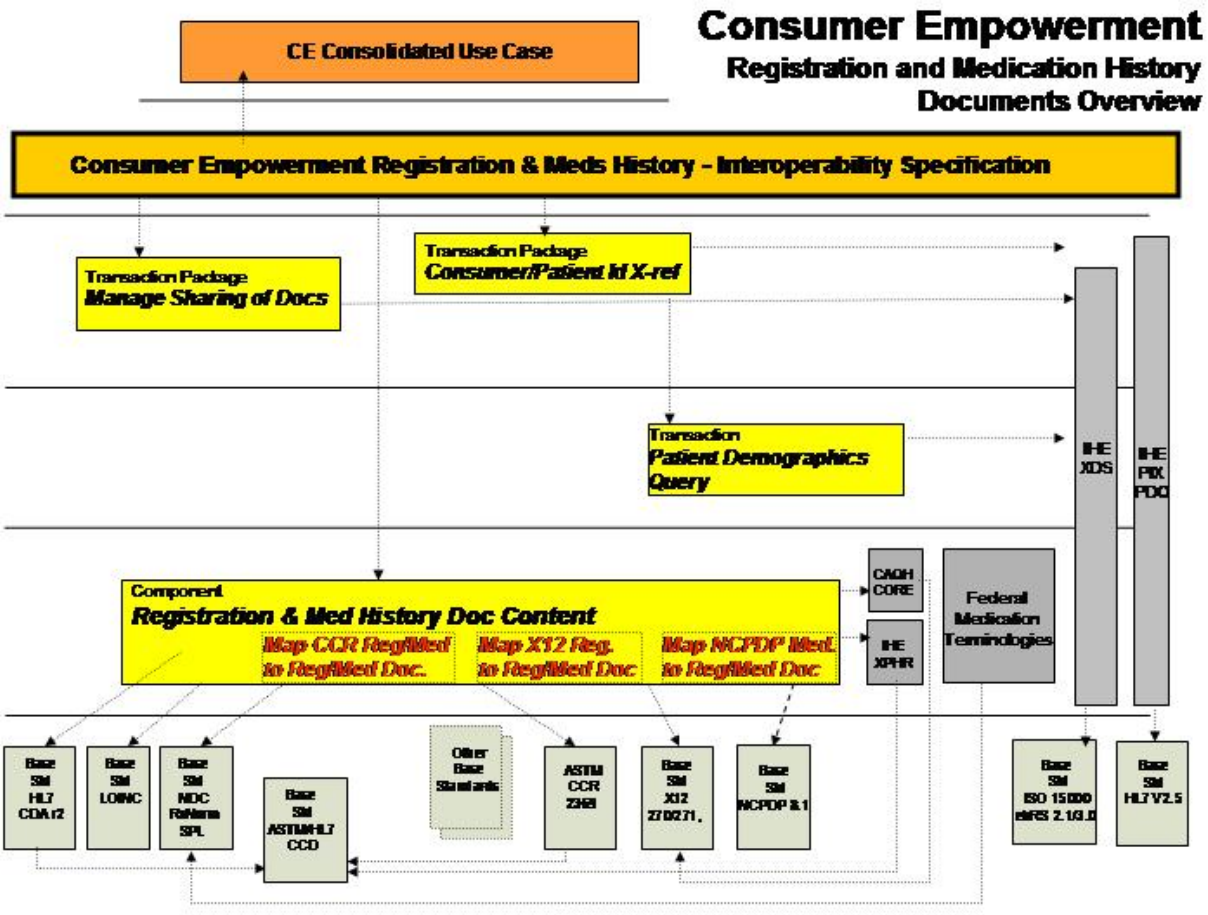
5.0 TECHNICAL IMPLEMENTATION

5.1 CONFORMANCE

A system conforming to this specification for the purposes of representing one or more Business Actors is required to support the Technical Actors as defined in Table 5.1-1. The system specification shall implement this complete specification to include the standards specified (e.g., context standards, information interchange standards, and terminology standards). Conformance also includes implementing the constraints to these standards specified in the component, transaction and transaction package specifications associated with this Interoperability Specification.

Figure 5.1-1 provides a visual overview of the Consumer Empowerment written and referenced documents. It is not an exhaustive diagram but provides the relationships between the various HITSP documents, transactions, composite standards, base standards, etc. The actual conformance specifications are defined in Tables 5.1-1 and 5.1-2.

Figure 5.1-1 Consumer Empowerment Registration and Medication History Documents Overview



A system conforming to this specification for the purposes of representing one or more Business Actors is required to support the Technical Actors as defined in Table 5.1-1.

R = Required, O = Optional, C = Conditional

Table 5.1-1 Business Actor to Technical Actor(s) Requirements

Business Actor	Technical Actor(s)	Req/Opt
Consumer	No Technical Actors Defined	
Personal Health Record (PHR) Service Provider	Patient Identity Source	C Shall support (Patient Identity Source plus PIX Consumer) and/or Patient Demographics Consumer
	PIX Consumer	C Shall support (Patient Identity Source plus PIX Consumer) and/or Patient Demographics Consumer
	Patient Demographics Consumer	C Shall support (Patient Identity Source plus PIX Consumer) and/or Patient Demographics Consumer
	Document Repository	O
	Document Source	R
	Document Consumer	R
Regional Health Information Organizations (RHIO)	PIX Manager	R
	Patient Demographics Supplier	R
	Document Registry	R
	Document Repository	O
Electronic Health Record (EHR) System	Patient Identity Source	C Shall support (Patient Identity Source plus PIX Consumer) and/or Patient Demographics Consumer
	PIX Consumer	C Shall support (Patient Identity Source plus PIX Consumer) and/or Patient Demographics Consumer
	Patient Demographics Consumer	C Shall support (Patient Identity Source plus PIX Consumer) and/or Patient Demographics Consumer
	Document Consumer	R
	Document Repository	O
	Document Source	R
Health Plan/Intermediary	Patient Identity Source	C Shall support (Patient Identity Source plus PIX Consumer) and/or Patient Demographics Consumer

Business Actor	Technical Actor(s)	Req/Opt
	PIX Consumer	C Shall support (Patient Identity Source plus PIX Consumer) and/or Patient Demographics Consumer
	Patient Demographics Consumer	C Shall support (Patient Identity Source plus PIX Consumer) and/or Patient Demographics Consumer
	Document Source	R
Pharmacy Benefit Manager (PBM)/Pharmacy	Patient Identity Source	C Shall support (Patient Identity Source plus PIX Consumer) and/or Patient Demographics Consumer
	PIX Consumer	C Shall support (Patient Identity Source plus PIX Consumer) and/or Patient Demographics Consumer
	Patient Demographics Consumer	C Shall support (Patient Identity Source plus PIX Consumer) and/or Patient Demographics Consumer
	Document Source	R

Table 5.1-2 specifies Technical Actors used in this Interoperability Specification and the Transaction Packages, Transactions and Components they shall support.

Table 5.1-2 Technical Actor to Transaction Requirements

Technical Actor	Transaction	Req/ Opt	HITSP Construct
PIX Manager	PIX Identity Feed	R	HITSP Patient ID Cross-Referencing Transaction Package
	PIX Query	R	HITSP Patient ID Cross-Referencing Transaction Package
PIX Consumer	PIX Identity Feed	R	HITSP Patient ID Cross-Referencing Transaction Package
	PIX Query	R	HITSP Patient ID Cross-Referencing Transaction Package
Patient Identity Source	Patient Identity Feed	R	HITSP Patient Demographics Query Transaction
Patient Demographics Supplier	Patient Demographics Query	R	HITSP Patient Demographics Query Transaction
Patient Demographics Consumer	Patient Demographics Query	R	HITSP Patient Demographics Query Transaction
Document Repository	Retrieve Document [with Reg/Med Document History Component]	R	HITSP Manage Sharing of Documents Transaction Package
	Retrieve Documents Set [with Reg/Med Document History Component]	R	HITSP Manage Sharing of Documents Transaction Package
	Provide & Register Document Set [with Reg/Med Document History Component]	R	HITSP Manage Sharing of Documents Transaction Package

Technical Actor	Transaction	Req/ Opt	HITSP Construct
Document Registry	PIX Identity Feed	R	HITSP Manage Sharing of Documents Transaction Package
	Query Registry	R	HITSP Manage Sharing of Documents Transaction Package
	Register Document Set	R	HITSP Manage Sharing of Documents Transaction Package
Document Consumer	Query Registry	R	HITSP Manage Sharing of Documents Transaction Package
	Retrieve Documents [with Reg/Med Document History Component]	R	HITSP Manage Sharing of Documents Transaction Package
Document Source	Provide & Register Document Set [with Reg/Med Document History Component]	R	HITSP Manage Sharing of Documents Transaction Package

5.2 SUPPORTING DOCUMENTS

The following documents were used to support the creation of this Interoperability Specification.

Table 5.2-1 Supporting Documents

Document Title	Relationship
Harmonized Use Case for Consumer Empowerment (Registration and Medication History), March 19, 2006	ONC harmonized Use Case that describes the requirements for the HITSP specifications

6.0 APPENDIX

6.1 USE CASE ACTIONS AND EVENTS

Table 6.1-1 provides the HITSP Consumer Empowerment Use Case Actions and Events, as defined by the HITSP Technical Committees – Consumer Empowerment: Selected Standards, June 29, 2006, Version 2.0. Added to this information are mappings to the 3 scenarios described in this Interoperability Specification. Table 6.1.1 specifically focuses on the HITSP Consumer Empowerment Use Case actions and events that address Interoperability Specifications. Actions and events not listed here (but in the Use Case) have been omitted because they are considered out of scope for interoperability.

Table 6.1-1 Event/Action Code Descriptions and Process Flow References

Event/ Action Code	Description	Scenario #1 Process Flow References	Scenario #2 Process Flow References	Scenario #3 Process Flow References
2.1.2.0	Event: Establish/ change permissions	See Below	Accomplished in Scenario #1	Accomplished in Scenario #1
2.1.2.2	Action: Establish/Modify permissions for access to the system	Pre-Condition c ,d, e, f		
2.1.4.0	Event: View registration and medication data	See Below	Accomplished in Scenario #1	Accomplished in Scenario #1
2.1.4.2	Action: Request data	u		
2.1.4.3	Action: Receive data	w		
2.1.5.0	Event: Modify registration and medication data	See Below	Accomplished in Scenario #1	Accomplished in Scenario #1
2.1.5.1	Action: Authenticate to system	Pre-Condition		
2.1.5.2	Action: Request data	u		
2.1.5.3	Action: Receive data	w		
2.1.5.5	Action: Transmit modified and/or annotated data	E		
2.1.5.5a	Alternate Action: Transmit request to modify and/or correct data	Not Performed		
2.1.6.0	Event: Close account	See Below	See Below	See Below
2.1.6.2a	Alternate Action: Receive confirmation of account transfer	Pre-Condition	Pre-Condition	Pre-Condition
2.2.2.0	Event: Gather registration and/or medication data	See Below	See Below	See Below
2.2.2.3	Action: Transmit request for registration/medication data to data or network system	h	j	j
2.2.2.4	Action: Receive registration/medication data	i, m, q	k, o, u	k, o, u

Event/ Action Code	Description	Scenario #1 Process Flow References	Scenario #2 Process Flow References	Scenario #3 Process Flow References
2.2.2.5	Action: Acknowledge receipt of registration/medication data	i, m, q	k, o, u	k, o, u
2.2.3.0	Event: Process request for registration and/or medication data	Accomplished in Scenario #2& 3	See Below	See Below
2.2.3.1	Action: Receive and validate the query request		e, f, y, z	e, f, y, z
2.2.3.3	Action: Transmit registration and medication data to an authorized system		h, B	h, B
2.2.4.0	Event: Close account [Close portion of 2a.5.8.0]	See Below	See Below	See Below
2.2.4.3a	Alternate Action: Transmit registration and medication data to the new provider of PHR services	Pre-Condition	Pre-Condition	Pre-Condition
2.3.1.0	Event: View registration and/or medication data	Accomplished in Scenario #2& 3	See Below	See Below
2.3.1.2	Action: Receive registration and medication data		J	J
2.3.2.0	Event: Integrate registration data into EHR or other care system	Accomplished in Scenario #2	See Below	Accomplished in Scenario #2
2.3.2.1	Action: Transmit request for registration/medication data to provider of PHR services		G, H	
2.3.2.1a	Receive medication data (probably unintentionally left out of Use Case Event List)		I, J	
2.3.2.2	Action: Accept data into EHR system		J	
2.3.2.3	Action: Confirm data integrity		Pre-Condition	
2.3.2.3a	Alternate Action: Produce exception list of errors		Pre-Condition	
2.3.2.4	Action: Parse and validate results content		Pre-Condition M	
2.3.2.5	Action: Acknowledge receipt of registration and medication data		Pre-Condition M	
2.3.2.6	Action: Log interaction		Pre-Condition M	
2.3.3.0	Event: Process requested data	Has Been Removed from Use Case Although possible to perform with pre-conditions	Has Been Removed from Use Case Although possible to perform with pre-conditions	Has Been Removed from Use Case Although possible to perform with pre-conditions
2.3.3.1	Action: Receive and validate the query request			

Event/ Action Code	Description	Scenario #1 Process Flow References	Scenario #2 Process Flow References	Scenario #3 Process Flow References
2.3.3.2	Action: Authenticate and verify the authorization of the requestor.			
2.3.3.3	Action: Transmit registration and medication data to an authorized system			
2.3.3.4	Action: Log interaction			
2.4.1.0	Event: Process request for registration and/or medication data	See Below	See Below	See Below
2.4.1.1	Action: Receive and validate the query request	g, k, o	i, m, q	i, m, q
2.4.1.4	Action: Transmit registration and medication data to an authorized system	j, n, r	l, p, v	l, p, v

7.0 CHANGE HISTORY

7.1 MAY 11, 2007

This document is now Released for Implementation.

7.2 DECEMBER 13, 2007

Revised list of HITSP/C32 Content Modules to include the optionality associated with each module. This addition matches module optionality information in HITSP/C32 v2.1.