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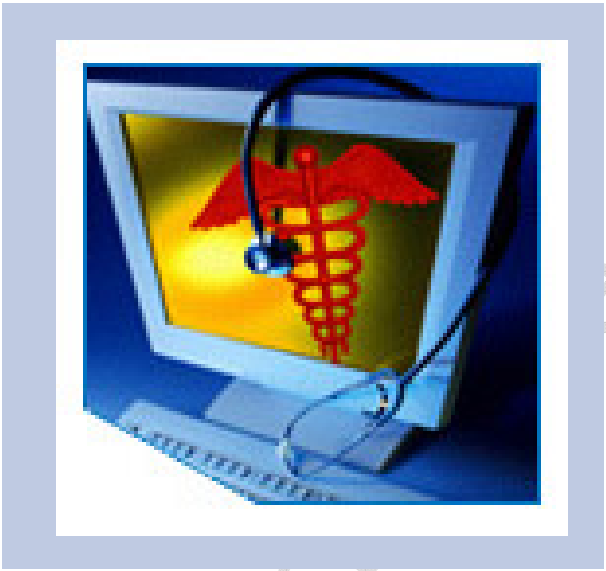
HITSP Interoperability Specification Consumer Empowerment (Registration and Medication History)

HITSP/IS-03



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Healthcare Information Technology Standards Panel

Submitted by:

Consumer Empowerment Technical Committee

DOCUMENT CHANGE HISTORY

Version Number	Description of Change	Name of Author	Date Published
1.0	Final Draft	Consumer Empowerment Technical Committee	8/18/2006

1.0 FOREWORD

Healthcare Information Technology Standards Panel (HITSP) 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. 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 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 informatics to ensure that the resulting standards are globally relevant.
- Be use-case driven, utilize information from stakeholders and base its decisions on industry needs.

The HITSP shall serve the public good by working to ensure that the combined work of various healthcare information standards organizations supports interoperability, accurate use, access, privacy and security of shared health information.

In order to advance the goal of expanding harmonized interoperability specifications and information policies, HITSP was tasked with developing interoperability specifications for three main use case "breakthroughs areas" in which specific, near term value to the health care consumer could be realized. The harmonized use case areas are:

1.	Biosurveillance	Transmit essential ambulatory care and emergency department visit, utilization, and lab result data from electronically enabled health care delivery and public health systems in standardized and anonymized format to authorized Public Health Agencies with less than one day lag time.
2.	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.
3.	Electronic Health Record	Allow ordering clinicians to electronically access laboratory results, and allow non-ordering authorized clinicians to electronically access historical and other laboratory results for clinical care.

The interoperability specification provides a detailed mapping of existing standards and specifications such as implementation guides, integration profiles to actions and actors that satisfy the requirements imposed by the relevant use cases. 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.

2.0 INTRODUCTION

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.

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

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 often requires filling out multiple forms. These forms collect information such as name, address, insurance, medications, allergies, etc. Then, when an individual requires lab work or other testing, the same information has to be collected again. A single electronic health 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 providers.

A medication history provides the consumer with an updated list of all medications pertinent 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. Too often, this results in errors or unnecessary treatments. A medication history would have all the current data in one location, available to the individual and to each authorized healthcare provider. The need for 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 provider and the patient giving their information to the provider. The dawn of consumer empowerment creates a new perspective of providers and healthcare institutions registering with patients and providing the 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 providers who register a patient should also help

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 provider assigned to that consumer, and also a basic entry in the list or encounters or procedures for the date of service. Encounters include office visits, emergency room visits, hospitalizations, and other healthcare events. Procedures should log major diagnostic or imaging procedures or surgical procedures. This will facilitate the PHR to serve as a RHIO of one having all essential master patient index data and record locator data for a single patient.

The other domains within the HITSP initiative also produce Interoperability Specifications within their respective areas that together form the HITSP Interoperability Specification. These areas include:

- HITSP Electronic Health Record
- HITSP Consumer Empowerment
- HITSP Biosurveillance
- HITSP Chronic Care

This Interoperability Specification defines an interoperable registration and medication history document and the means to share this type of document 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 in the future by HITSP for radiology reports, images, ECG reports, etc. These other types of documents are out of scope of this use case.

2.1 OVERVIEW

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 does 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 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 specifies the documents needed in order to conform to this specification.

Related Documents	Document Description	Document Name and Location
HITSP/ISTP-13	HITSP Interoperability Specification: Manage Sharing of Docs Transaction Package	ISTP_HITSP_13_v1.0_2006
HITSP/IST-11	HITSP Interoperability Specification: Consumer/Patient ID Cross-reference Transaction	IST_HITSP_11_v1.0_2006

HITSP/IST-22	HITSP Interoperability Specification: Patient ID Cross Referencing Transaction	IST_HITSP_22_v1.0_2006
HITSP/IST-23	HITSP Interoperability Specification: Patient Demographics Query Transaction	IST_HITSP_23_v1.0_2006
HITSP/ISC-32	HITSP Interoperability Specification: Registration and Med History Document(s) Content Component	ISC_HITSP_32_v1.0_2006

Table 2.1 HITSP Documents Specified

2.2 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 interoperability set of specifications is a key requirement for establishing interoperability compliance.

2.3 TERMS AND DEFINITIONS

The definitions used for the purposes of this document can be found in the glossary. Refer to appendix 6.3 for the Common Terms and Definitions Document.

2.4 CONVENTIONS

This specification uses the following to convey the full descriptions and usage of standards:

UML sequence and activity diagrams

In these diagrams, the actors and transactions are highlighted within the framework of the specific scenario or context. The actors involved in the specified use-scenario or context are mapped out, and the interactions between each action and actor for a particular context, and the flow of data are provided through the use of arrows. Diagrams are named according to the section in which they reside, and will use the following naming convention:

Figure <section number>-<consecutive number for the diagram, e.g. 1, 2, 3, etc.>. <Short name/description of diagram>. For example, a diagram residing in section 3.1.3 showing the Actor Interactions for the Send Lab Results transaction package is named:

Figure 3.1.3-1. Send Lab Results Transaction Package

Tables

Tables are used to indicate standards categorizations, as well as dependencies and constraints between constructs. Tables are named according to the section in which they reside, and will use the following naming convention:

Table <section number>-<consecutive number for the table, e.g. 1, 2, 3, etc.>. <Short name/description of table>. For example, a table residing in section 2.7.1 showing the Dependencies between the transactions for the Send Lab Results transaction package is named:

Table 2.7.1-1. Send Lab Results Transaction Package dependencies

References

When references are made to another section within an Interoperability Specification a section number is used by itself. When references are made to other constructs that are related to the Interoperability Specification, such as Transaction Packages, Components or Composite Standards, the HITSP document short name and section number are displayed as follows:

<HITSP Document short name or Composite Standard Short Name>-<Volume Number>: <section number>

where:

<HITSP document short name> is a short designator for the construct (e.g. HITSP/ISTP-13)

<Composite Standard Short Name> is a short designator for the composite standard (e.g. IHE-ITI TF)

<Volume Number> is the applicable volume within the given composite standard (e.g. 1)

<section number> is the applicable section number (e.g. 3.1)

For example: HITSP/ISTP-13: 3.1 refers to Section 3.1 in the Interoperability Specification for a Transaction Package, IHE-ITI TF-2: 4.33 refers to Section 4.33 in volume 2 of the IHE IT Infrastructure Technical Framework.

Reproductions

Where large sections of composite standards or base standards are reproduced within a HITSP specification, the reproduced sections are cited with introductory text containing the reference information for the composite or base standard. In addition, the beginning and ending of the reproduced text are respectively shown using a beginning statement:

The text for the <composite or base standard name> specification begins here:

And an ending statement:

The text for the <composite or base standard name> ends here.

2.5 COMMENTS

To submit comments for this interoperability specification, please download the Comment Submission sheet from the HITSP site at www.hitsp.org and provide all relevant information, and then email the completed document to hitspcomments@ansi.org. Comments are consolidated periodically and sent to the Technical Committees for review.

2.6 COPYRIGHT PERMISSIONS

HL7 materials used in this document have been extracted from relevant copyrighted materials with permission of Health Level Seven (HL7). Copies of this standard may be purchased from the Health Level 7 website at www.hl7.org.

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 website at www.ihe.net.

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3.0 STANDARDS REFERENCES

It is HITSP's policy to only incorporate standards that have been approved according to the formal policy of the standards development organization that publishes the standard. HITSP interprets approval to include standards for trial use. The objective is to incorporate only standards that are managed within a formal life cycle process as defined by the SDO. In some cases, where we believe a not yet approved standard best meets the requirements of an Interoperability Specification, HITSP may provisionally select and conditionally use such standard subject to the following:

- The standard is approved by the time that the Interoperability Specification is released by HITSP.
- The standard approved is substantially the same as it was when provisionally used.

If either condition is not met at the date of the HITSP Interoperability Specification release, HITSP may continue to use the "standard" as it was in its provisional state until such time as HITSP can replace it with a more suitable artifact. In this circumstance, the SDO would have no responsibility to maintain or correct this artifact.

3.1 LIST OF BASE STANDARDS

Table 3.1-1 documents the base standards needed to conform to this interoperability specification.

Context Standards	
Standard	Description
ASTM E 2369-05 – Standard Specification for Continuity of Care Record (CCR)	The Continuity of Care Record (CCR) is 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.
ASC X12 Standards Release 004010	Release (version) 004010 of the ANSI-chartered 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.
Health Level Seven (HL7) CDA R2	The HL7 Clinical Document Architecture (CDA) is a document markup standard that specifies the structure and semantics of "clinical documents" for the purpose of exchange. The CDA Release 2.0 distribution includes a prose document in HTML, XML schemas, data dictionary, and sample CDA documents. The HL7 CDA Release 2.0 standards builds upon other HL7 standards, including the HL7 Version 3 Reference Information Model (RIM), Data Structures, Vocabulary, and the XML Implementation Technology Specifications for Data Types and V3 Structures.
Health Level Seven (HL7) CCD	The purpose of this document is to constrain the HL7 Clinical Document Architecture, Release 2 (CDA) specification in accordance with requirements set forward by the in ASTM E 2369-05 – 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 E2369-05 for those institutions or organizations committed to implementation of the HL7 Clinical Document Architecture.
Health Level Seven (HL7) version 2.5	HL7 Version 2.5 introduces a number of new events, segments and messages, as well as a significantly expanded chapter on Control. Version 2.5 is more consistent and supports more functionality than any of the previous versions.
National Council for Prescription Drug Programs SCRIPT Standard V 8.1	The NCPDP SCRIPT Standard provides for the exchange of new prescriptions, changes, renewals, cancellations, and fill status notifications. Each function has varying degrees of industry experience. The NCPDP SCRIPT new prescription function is most widely used. The renewal function has good industry acceptance, represents an easy transition, and provides the most immediately apparent return on investment. The NCPDP SCRIPT Standard cancellation and change functions are currently underutilized.

Information Interchange Standards	
Standard	Description
ASTM E 2369-05 – Standard Specification for Continuity of Care Record (CCR)	The Continuity of Care Record (CCR) is 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.
ASC X12 Standards Release 004010	Release (version) 004010 of the ANSI-chartered 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.
Health Level Seven (HL7) CDA R2	The HL7 Clinical Document Architecture (CDA) is a document markup standard that specifies the structure and semantics of "clinical documents" for the purpose of exchange. The CDA Release 2.0 distribution includes a prose document in HTML, XML schemas, data dictionary, and sample CDA documents. The HL7 CDA Release 2.0 standards builds upon other HL7 standards, including the HL7 Version 3 Reference Information Model (RIM), Data Structures, Vocabulary, and the XML Implementation Technology Specifications for Data Types and V3 Structures.
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Terminology Standards	
Standard	Description
ASTM E 2369-05 – Standard Specification for Continuity of Care Record (CCR)	The Continuity of Care Record (CCR) is 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.
ASC X12 Standards Release 004010	Release (version) 004010 of the ANSI-chartered 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.
Health Level Seven (HL7) CDA R2	The HL7 Clinical Document Architecture (CDA) is a document markup standard that specifies the structure and semantics of "clinical documents" for the purpose of exchange. The CDA Release 2.0 distribution includes a prose document in HTML, XML schemas, data dictionary, and sample CDA documents. Note: The HL7 CDA Release 2.0 standards builds upon other HL7 standards, including the HL7 Version 3 Reference Information Model (RIM), Data Structures, Vocabulary, and the XML Implementation Technology Specifications for Data Types and V3 Structures
Health Level Seven (HL7) CCD	The purpose of this document is to constraints on the HL7 Clinical Document Architecture, Release 2 (CDA) specification in accordance with requirements set forward by the in ASTM E 2369-05 – 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.
LOINC	The LOINC database provides a set of universal names and ID codes for identifying laboratory and clinical test results, and document types and sections. The purpose of these codes is to facilitate the exchange and pooling of information for clinical care, outcomes management, and research.
Security Standards	
Standard	Description
	Security is considered a pre-conditions, therefore are not listed in this specification.
Identifier Standards	
Standard	Description

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Functionality and Process/Process and Workflow Standards	
Standard	Description
CORE Phase I Operating Rules	The Committee on Operating on Rules for Information Exchange (CORE) Phase 1 Operating Rules provide operating rules and guidelines for giving providers access to eligibility and benefits information before or at the time of service using the electronic system of their choice for any patient or health plan.
HL7 EHR System Functional Model	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.
Legislative Standards	
Standard	Description
	Security is consider a pre-conditions, therefore are not listed in this specification.
Other Standards	
Standard	Description

Table 3.1-1 List of Base Standards

3.2 LIST OF COMPOSITE STANDARDS

260 Table 3.2-1 lists and describes the composite standards needed to conform to this interoperability specification.

Composite Standard	Description
CORE Phase I Operating Rules	The Committee on Operating on Rules for Information Exchange (CORE) Phase 1 Operating Rules provide operating rules and guidelines for giving providers access to eligibility and benefits information before or at the time of service using the electronic system of their choice for any patient or health plan.
Federal Medication Terminologies	A set of federal terminologies related to medications, including the Food and Drug Administration's names and codes for ingredients, manufactured dosage forms, drug products and medication packages, the National Library of Medicine's RxNORM for describing clinical drugs, and the Veterans Administration's National Drug File Reference Terminology (NDF-RT) for specific drug classifications. This leverages the controlled terminology from three medication models that are

Composite Standard	Description
	maintained by the federal government: National Drug File Reference Terminology (NDF-RT) • Veterans Health Administration Structured Product Labeling (SPL) • Food and Drug Administration RxNorm • National Library of Medicine
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework V2.0– Cross Document Sharing (XDS)	IHE is an initiative by healthcare professionals and industry to improve the way computer systems in healthcare share information. IHE promotes the coordinated use of established standards such as DICOM and HL7 to address specific clinical needs in support of optimal patient care. Cross Enterprise Clinical Document Sharing (XDS) Patient Demographic Query.
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework V2.0– Patient Identifier Cross-referencing (PIX)	The Patient Identifier Cross-referencing Integration Profile (PIX) is targeted at a broad range of healthcare enterprises. It supports the cross-referencing of patient identifiers from multiple Patient Identifier Comains via: The transmission of patient identity information from an identity source to the Patient Identifier Cross-reference manager The ability to access the list(s) of cross-reference patient identifiers either via a query/response or via update notification.
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework Revision 2.0– Patient Demographics Query (PDQ)	The Patient Demographics Query (PDQ) receives patient registration and update messages from other systems in the enterprise (*e.g.*, ADT Patient Registration systems), which may or may not represent different Patient ID Domains.
Integrating the Healthcare Enterprise (IHE) Patient Care Coordination (PCC) Technical Framework Revision 1.0	The IHE Patient Care Coordination Technical Framework (PCC TF) defines specific implementations (called profiles) of established standards to deal with integration issues that cross providers, patient problems or time.
Integrating the Healthcare Enterprise (IHE) Patient Care Coordination (PCC) - Exchange of Personal Health Record Content (XPHR) Profile Supplement for Trial Implementation	The Exchange of Personal Health Record Content (XPHR) integration profile describes the content and format of summary information extracted from a PHR system for import into an EHR system, and visa versa. The purpose of this profile is to support interoperability between PHR systems used by patients and EHR systems used by healthcare providers.
X12N 270/271 Version 004010A1 Implementation Guide	The HIPAA-named implementation guides to be used for healthcare eligibility and benefits data exchange between healthcare providers (e.g.,dentists, professionals, institutions), health plans, PBMs, and healthcare clearinghouses.

Table 3.2-1 List of Composite Standards

3.3 BASE 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 3.3-1 identifies the use case events and known 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. Requirement (1) and (2) are met by preventing all fields from any information modules for the Registry/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 needs 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.	A consumer oriented terminology for healthcare provider type role (e.g. primary care physician, ob/gyn, pharmacy, cardiologist).
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.
2.1.4.3	Receive data	During review and subsequent addition of data elements in the Insurance Providers Module of the Registration and Med History Document(s) Content Component, several data fields were found not to be	The CDA does not provide explicit support for reporting multiple race and ethnicity. The HITSP CETC will provide

Event Code	Event Description	Identified Gaps	Recommended Resolution
		explicitly supported in the base standards (CDA, CCD) nor in the composite standard (XPHR). For the interim period, CETC closed this gap by providing an extension based on the based and composite standards. The HITSP CETC will provide to the related organizations in the hope that these organizations will close these gaps in subsequent releases of their artifacts	feedback to HL7 on the CCD and CDA in the hope that HL7 will close this gap in subsequent releases of their artifacts.
2.1.5.0	Modify registration and medication data	A robust terminology that allows consumers to manage their allergies along with their providers is lacking.	CHI is conducting the development of a composite standard including a coherent set of terminologies. It is proposed to adopt these terminologies as soon as available.

Table 3.3-1 Use Case Events and Associated Gaps

Table 3.3-2 identifies Standard Overlaps known for this interoperability specification.

Event Description	Standard Duplication/ Overlap	Recommended Resolution
View registration and medication data	Standard terminology used to describe providers used in the US 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 CETC 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 CETC, lacking only coded terms to desribe the roles.
View registration and medication data	For the Registration Summary and Medication History Document, two based standards may be used: HL7 CDA Rel 2 and ASTM CCR.	See Section 3.3.1

Table 3.3-2 Standards Overlaps

3.3.1 STANDARD'S DUPLICATION/OVERLAP RECOMMENDED RESOLUTION

The CETC 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/PBMs industry segments each have independently selected different standards with overlapping data elements from 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 issued as an HL7 ballot in August 2006.

The CETC 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, in the absence of having a balloted CCD standard to reference, the approach taken by the CETC is to align its Interoperability Specification to the expected technical design characteristics of the CCD. This CE Interoperability Specification artifact is therefore intended to facilitate the transition from the current disparate standards environment to a harmonized state through use of an interim specification that is on the convergence path of the promised HL7-ASTM harmonization. HITSP is committed to migrate this interim specification to the final balloted result of this HL7-ASTM harmonization work as soon as it's officially available.

As an interim specification, the CETC has chosen the Integrating the Healthcare Enterprise (IHE) Technical Framework (TF) for the Exchange Personal Health Record (XPHR) profile as its primary source of data element specifications. The XPHR TF itself is a reconciliation of current industry activities for describing the PHR elements and their use in a registration and medication history information exchange. Contributing standards/publications to this TF include AHIMA PHR Common Data Elements, CDAr2, and the current CCD ballot, whereby the CCD has been recognized as a CDA instance of the CCR standard. Where necessary, this CE interim specification has constrained the published XPHR TF to appropriately satisfy the interoperability requirements of the CE Use Case. Such data element constraints provide relevant feedback to the HL7 and ASTM SDOs for their joint standards development activities.

As noted in the initial paragraph, the CETC has also recognized the need to ensure consistency of its specified data elements across all the standards deployed by the business actors of the Use Case which are potential sources of data in the PHR. For example, ASC X12 is used to describe health plan information that is relevant for updating a consumer's PHR. To this end, this HITSP Interoperability Specification Registration / Medication History Content Component includes appendices for informative data element cross-mapping tables between its own elements and the ASTM CCR, ASC X12, and NCPDP Script 8.1 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:

Date	Task to be Accomplished/Who is involved
August 2006	HL7 and ASTM should work towards the completion and approval process for the CCD Implementation Guide as soon as possible.

Table 3.3.1-1 Resolution Plan

4.0 INTEROPERABILITY REQUIREMENTS

4.1 USE CASE OVERVIEW

The Consumer Empowerment Harmonized Use Case identifies the principle 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 Harmonized Use Case includes:

1. enabling consumers to establish permissions and access rights for viewing their data;
2. authenticating consumers, designated caregivers, and health professionals;
3. querying other organizations for data and matching to the consumer;
4. accepting "batch" data from other organizations and matching to the appropriate consumers;
5. accessing, viewing, and sharing registration summaries and medication histories; and
6. 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 Harmonized Use Case presumes some level of linkage between 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 Use Cases defined by ONC. They are:

- Consumer creates account to host registration summary & medication history
- Consumer visits Health Care Provider and provides registration summary information
- Authorized Health Care 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 Actors, data that must be available somewhere, or an action that must have occurred. Following are pre-conditions for this scenario.

1. Network infrastructures 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 the veracity of data; and
    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
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.
7. Query other organizations for data and matching to the consumer.
8. Support 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.

14. 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 personally 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.

4.1.1.2.1 SCENARIO TRIGGERS

The consumer decides to create a PHR.

4.1.1.3 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.

4.1.1.3.1 SCENARIO OUTPUTS

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

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4.1.1.4 SCENARIO BUSINESS ACTORS

Table 4.1.1.4-1 defines the business actors for this scenario. Other business actors not explicitly mentioned may be able to benefit from this interoperability specification.

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	A set of consumer health related information used by the consumer and any other care or service providers as appropriate. This may include information generated by care or service provider systems (e.g., pharmacy information systems, health plan systems, physicians' and hospitals' electronic health record systems, etc.) as well as patient generated information.
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	A repository of information managing health care information for the consumer. Whose primary purpose is the support of continuing, efficient and quality integrated healthcare.
Authorized Third Party Consumer	An entity authorized by the patient to access the PHR. This includes, but is not limited to, disability insurers, schools, relatives, etc. and entities who request medical information for purposes other than for providing health care services or payment for healthcare services.
Health Plan/Intermediary	The organization or its designated intermediary that pays for health care, 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 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.

455 Table 4.1.1.4-1 Business Actors

4.1.1.5 SCENARIO TECHNICAL ACTORS

Table 4.1.1.5-1 defines the Technical Actors used for this scenario.

460

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 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.

Table 4.1.1.5-1 Technical Actors

4.1.1.6 SCENARIO ACTOR INTERACTIONS

465 The sequence diagram for this scenario is shown in Figure 4.1.1.6-1.

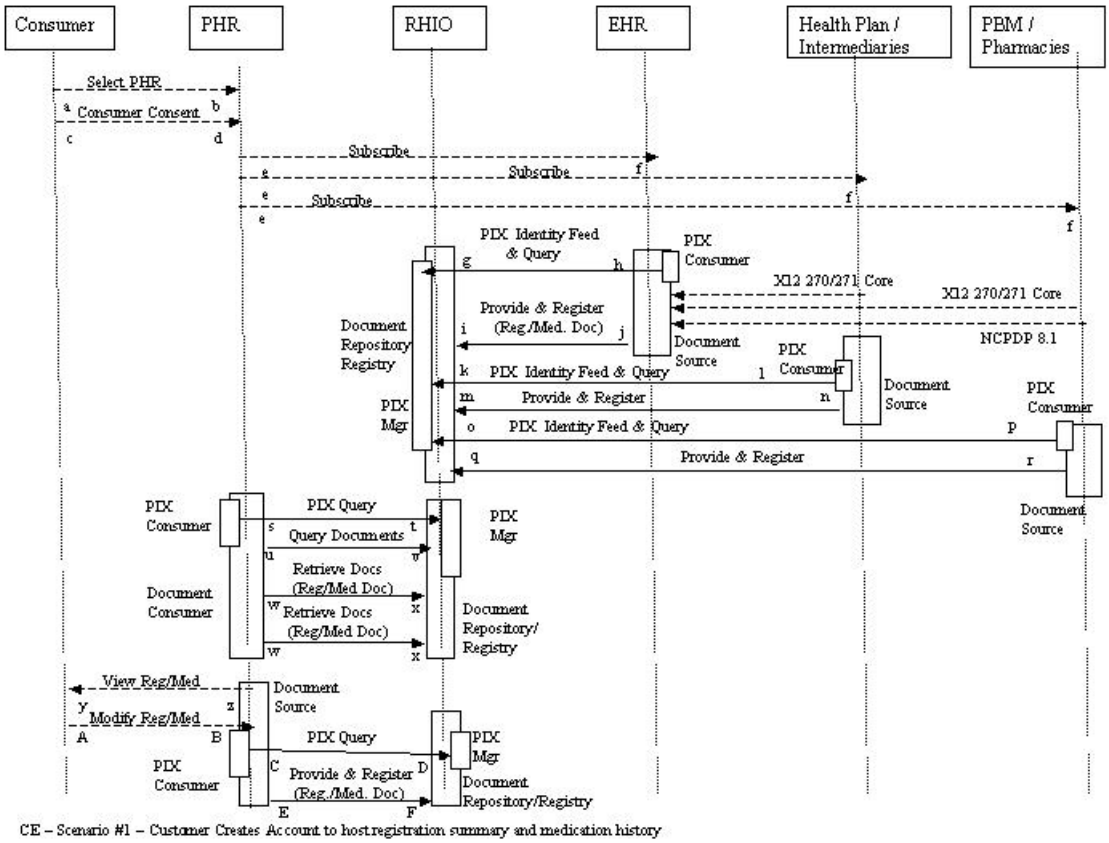


Figure 4.1.1.6-1 Customer Creates Accounts to Host Summary and Medication History

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

- They may chose to act as a direct source of information as a Document Source by using the X12 X271/CORE or NCPDP 8.1 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 X270/X271/CORE or NCPDP 8.1 transactions (specified by HIPAA and ePrescribing Rule) 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 4.14).

4.1.1.6.1 TRANSACTIONS DESCRIPTIONS

The detailed technical requirements for the transactions shown in Figure 4.1.1.6-1 are specified in section 5.1.

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 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 one of his provider, health plan/intermediary or PBM/pharmacy. In a future version of this Interoperability Specification one may envision to specify a standards-based Subscribe transaction for the consumer to establish a reciprocals information path into the consumer's PHR.

The follow narrative provides a high level walk though of the flow in the context of a fictitious scenario.

<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 health care. 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]. 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].

Based upon information provided by Mr Everyperson, WebPHR establishes relationships [Subscribe] with GM-HIN, Dr Doctor's Electronic Health Record (OfficeEHR), Evergreen Health (Mr Everyperson's Health Plan), MultiState Rx Plan (a Pharmacy Benefit Manager) 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] and documents must be appropriately indexed and stored [Provide & Register (Reg/MedHx)]. GM-HIN may interact with additional information sources, such as Evergreen Health 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.

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] and determining what relevant documents are contained in GM-HIN [Query Documents]. Once the documents are identified, WebPHR retrieves particular documents of interest [Retrieve Documents].

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]. 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]. WebPHR passes updated documentation along to GM-HIN, as allowed by the access and consents set up by Mr Everyperson.

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

The second scenario is named "Consumer visits Health Care 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 health care provider to review the registration data and update their EHR.

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.

4.1.2.2.1 SCENARIO TRIGGERS

The consumer has already established their PHR.

4.1.2.3 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.

4.1.2.3.1 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.

4.1.2.4 SCENARIO BUSINESS ACTORS

The business actors defined for this scenario are defined in section 4.1.1.4.

4.1.2.5 SCENARIO TECHNICAL ACTORS

The technical actors defined for this scenario are defined in section 4.1.1.5.

4.1.2.6 SCENARIO ACTOR INTERACTIONS

The sequence diagram for this scenario is shown in Figure 4.1.2.6-1.

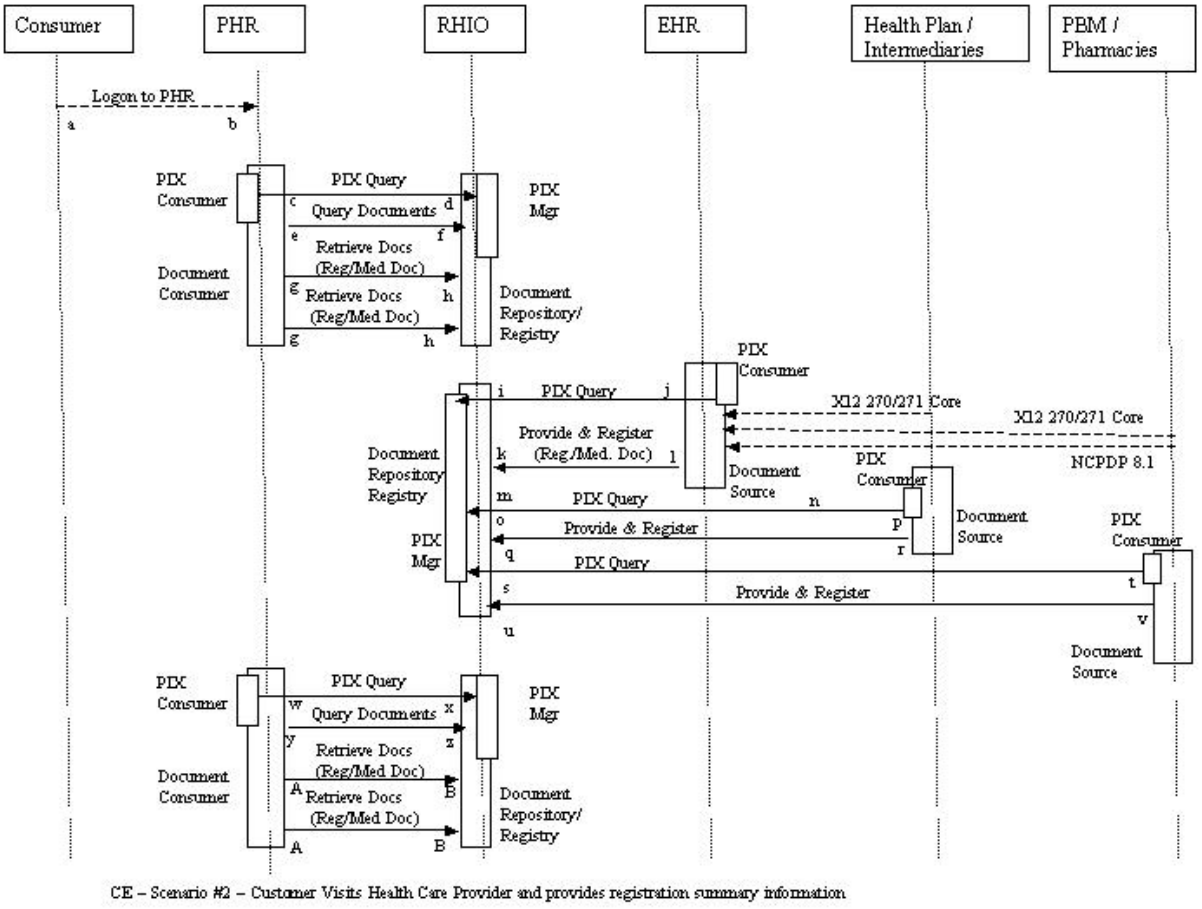


Figure 4.1.2.6-1 Consumer Visits Health Care Provider and Provides Registration Summary Information.

Continue Sequence Diagram

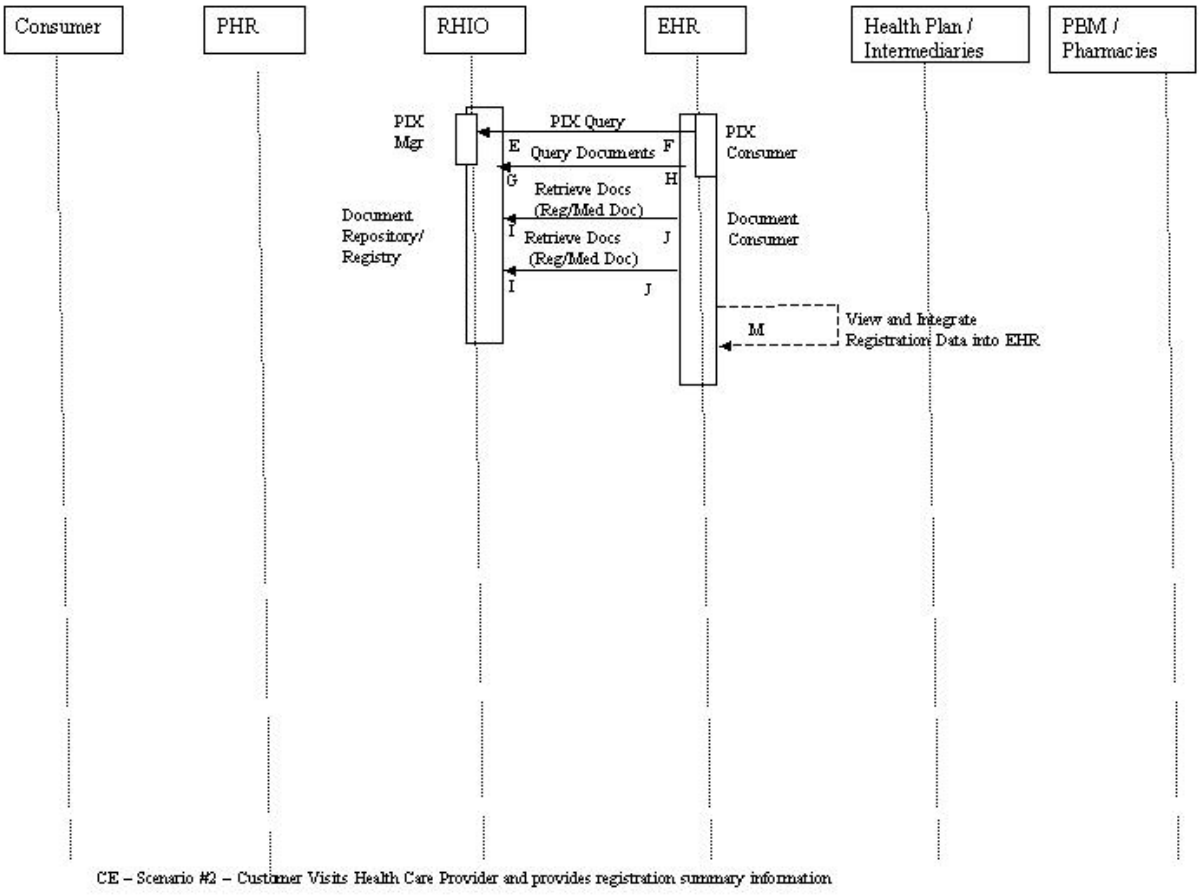
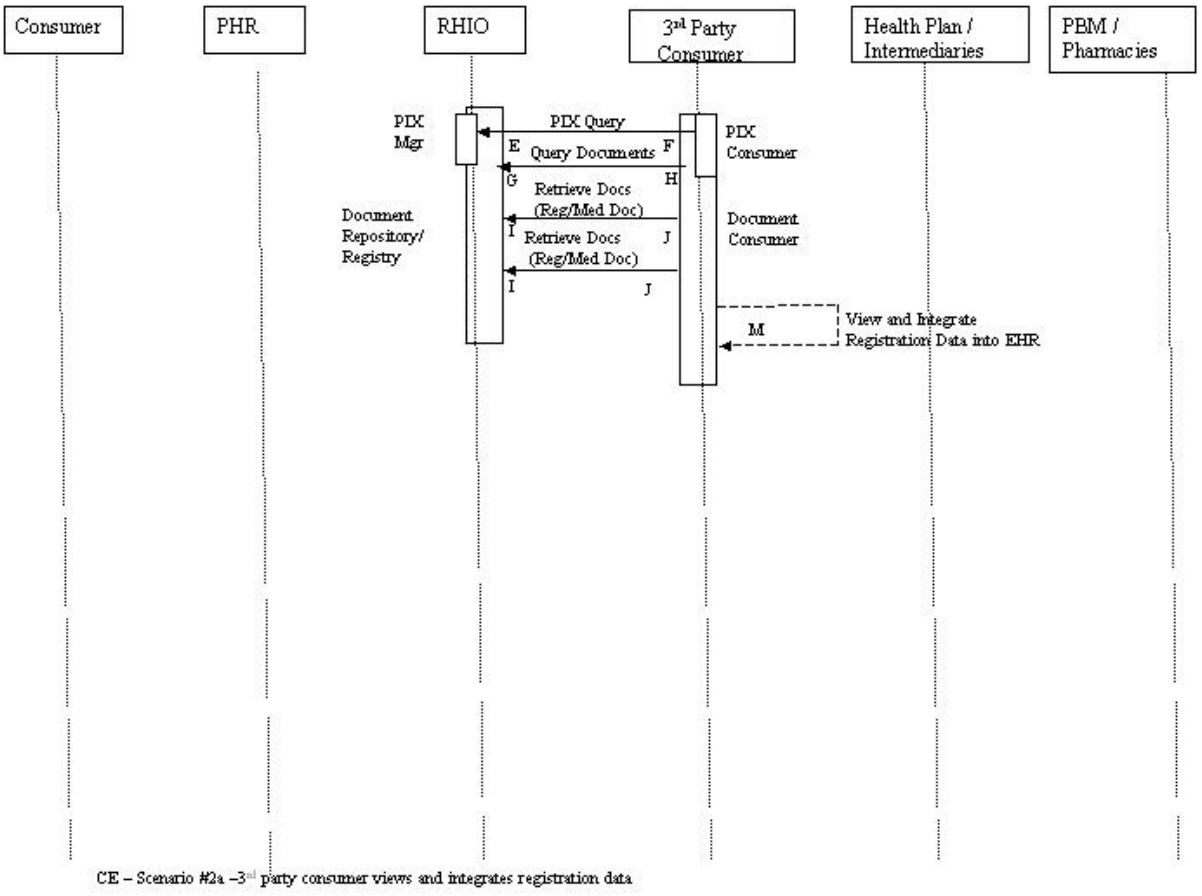


Figure 4.1.2.6-2 Consumer Visits Health Care Provider and Provides Registration Summary Information (continued)

Apart from the entities that provide healthcare services and pay for healthcare services, there are health information systems that are authorized by the patient to connect to personal health record. The Use case refers to them as other health related entities and other health information systems. These entities are Authorized Third Party Consumers of health records. Some examples of such entities are Disability Insurers and Social Security Administration. Because these entities do not provide healthcare services or pay for health care, they cannot be grouped with health care providers or health plans. Figure 4.1.2.6-2 illustrates this scenario.



600 Figure 4.1.2.6-2 3rd Party View and Integrates Registration Data

4.1.2.6.1 Transaction Descriptions

605 The detailed technical requirements for the transactions shown in Figure 4.1.2.6-1 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.

<Consumer> = Adam Everyperson
610 <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
615 <PBM> = MultiState Rx Plan
<Pharmacy> = SmallTown Pharmacy

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]. 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] and determining what relevant documents are contained in GM-HIN [Query Documents]. Once the documents are identified, WebPHR retrieves particular documents of interest [Retrieve Documents].

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] and documents must be appropriately indexed and stored [Provide & Register (Reg/MedHx)]. *GM-HIN may interact with additional information sources, such as Evergreen Health 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] and determining what relevant documents are contained in GM-HIN [Query Documents]. Once the documents are identified, WebPHR retrieves particular documents of interest [Retrieve Documents].

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 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]. OfficeEHR requests information on relevant documents contained in GM-HIN [Query Documents], and retrieves the current Registration Summary document(s) [Retrieve Documents].

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].

4.1.3 SCENARIO OVERVIEW: AUTHORIZED HEALTH CARE PROVIDER REVIEWS MEDICATION HISTORY

The third scenario is named "Authorized Health Care Provider Reviews medication history". It defines the flow for a consumer to log onto their account, obtain registration summary and medication data, allow a health care 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.

4.1.3.2.1 SCENARIO TRIGGERS

The consumer has already established their PHR.

4.1.3.3 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.

4.1.3.3.1 SCENARIO OUTPUTS

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

4.1.3.4 SCENARIO BUSINESS ACTORS

The business actors for this scenario are defined in section 4.1.1.4.

4.1.3.5 SCENARIO TECHNICAL ACTORS

The technical actors for this scenario are defined in section 4.1.1.5.

4.1.3.6 SCENARIO ACTOR INTERACTIONS

The sequence diagram is shown in Figure 4.1.3.6-1.

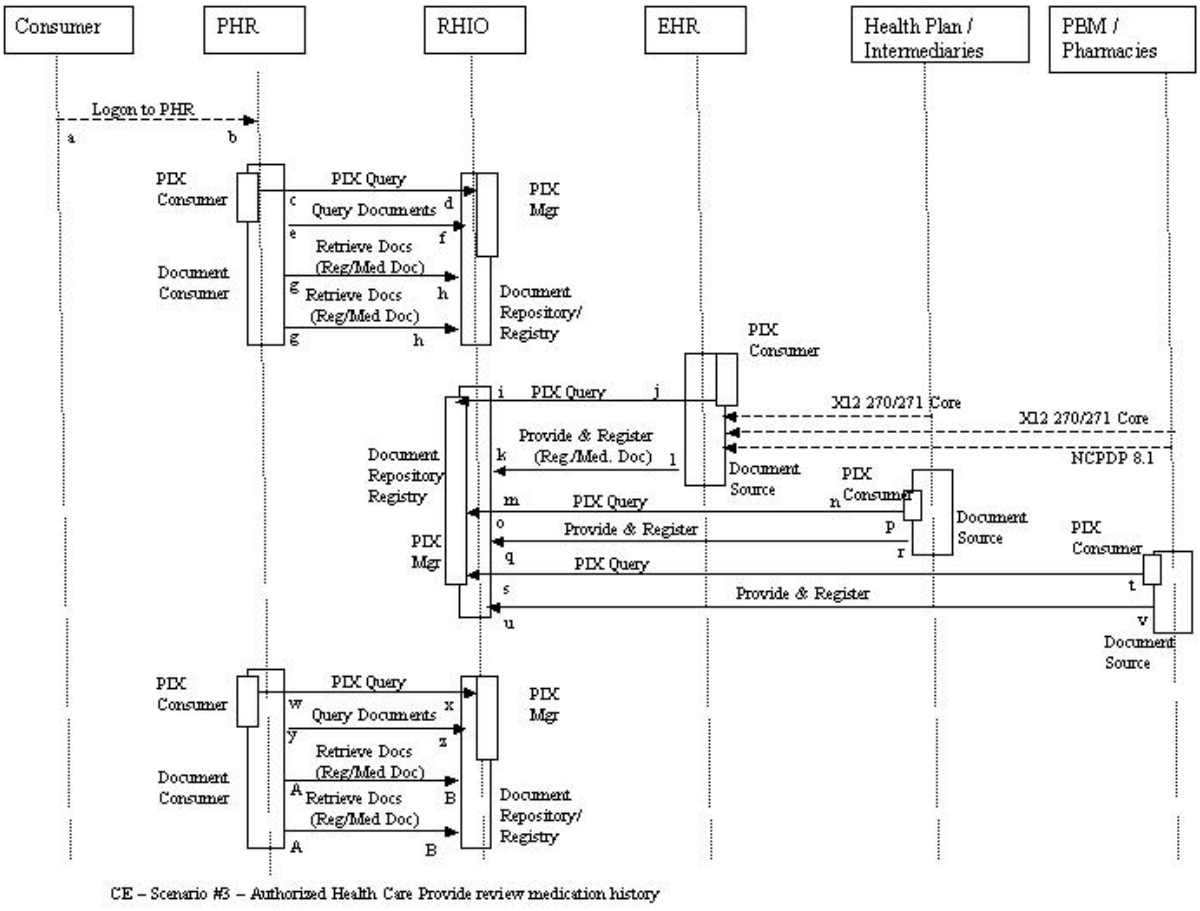


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Figure 4.1.3.6-1 - Authorized Health Care Provider Views Medication History

700 Continue Sequence Diagram

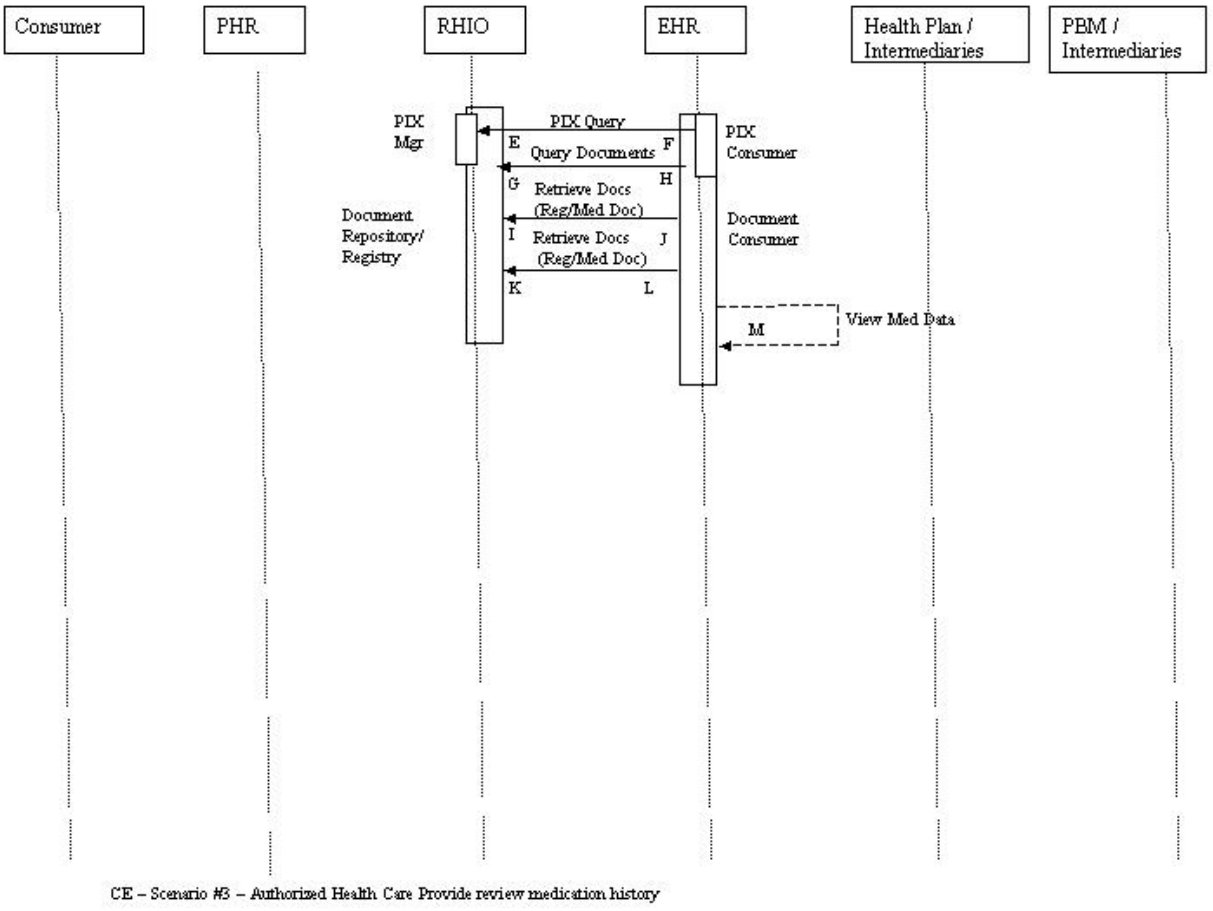

Figure 4.1.3.6-1 - Authorized Health Care Provider Views Medication History (continued)

Apart from the entities that provide healthcare services and pay for healthcare services, there are health information systems which are authorized by the patient to connect to personal health record. The Use case refers to them as other health related entities and other health information systems. These entities are Authorized Third Party Consumers of health records. Some examples of such entities are Disability Insurers and Social Security Administration. Because these entities do not provide healthcare services or pay for health care, they cannot be grouped with health care providers or health plans. Figure 4.1.6.3-2 illustrations this scenario.

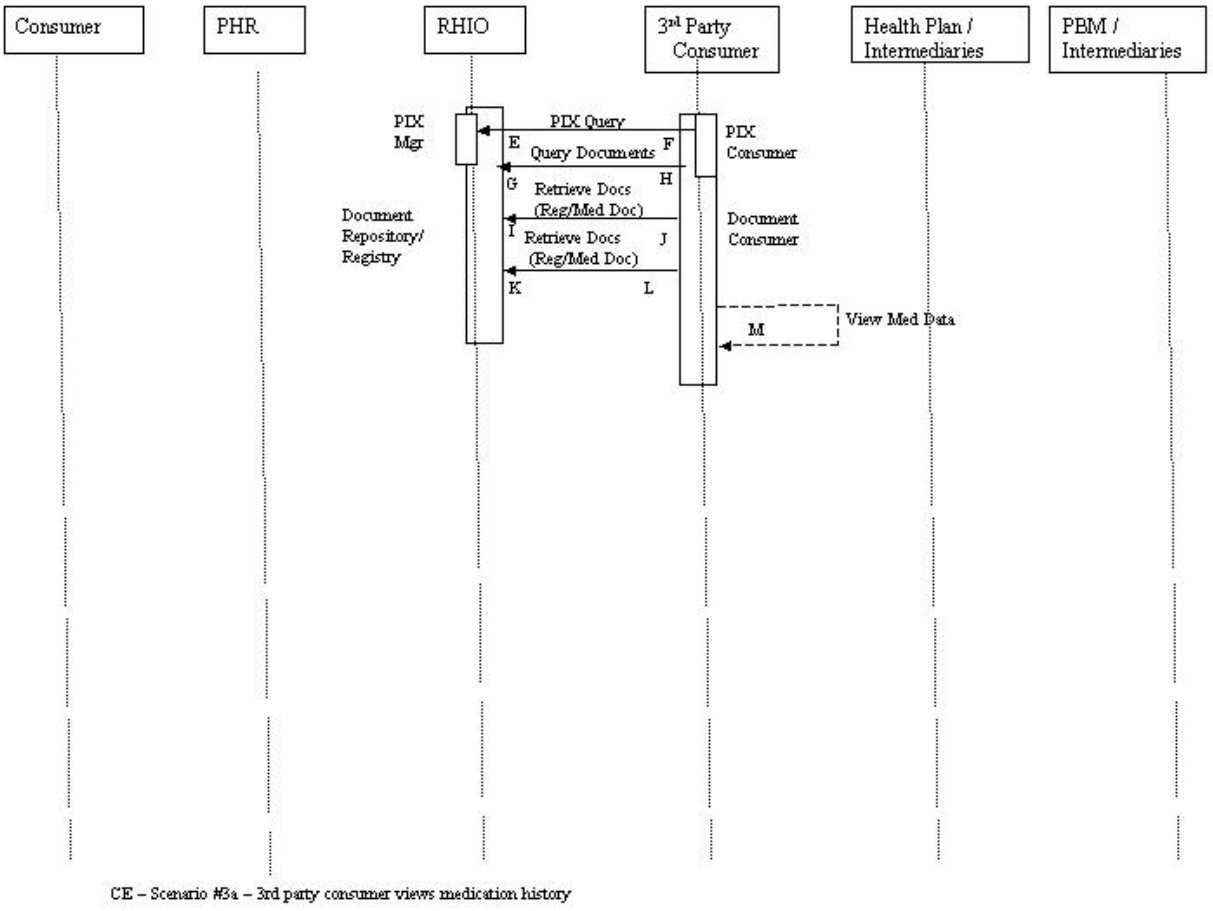

Figure 4.1.6.3-2 - 3rd Party Provider Views Medication History

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4.1.3.6.1 Transaction Descriptions

The detailed technical requirements for the transactions shown in Figure 4.1.6.3-1 are specified in section 5.1. The follow narrative provides a high level walk though of the flow in the context of a fictitious
720 scenario.

<Consumer> = Adam Everyperson
<PHR> = WebExcellent Personal Health Record (WebPHR)
<RHIO> = Greater Metropolitan Health Information Network (GM-HIN)
725 <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
730 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]. 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] and determining what relevant documents are contained in GM-HIN [Query Documents]. Once the documents are identified, WebPHR retrieves particular documents of interest [Retrieve Documents].

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] and documents must be appropriately indexed and stored [Provide & Register (Reg/MedHx)]. GM-HIN may interact with additional information sources, such as Evergreen Health 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] and determining what relevant documents are contained in GM-HIN [Query Documents]. Once the documents are identified, WebPHR retrieves particular documents of interest [Retrieve Documents].

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 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]. OfficeEHR requests information on relevant documents contained in GM-HIN [Query Documents], and retrieves the current Medication History document(s) [Retrieve Documents].

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].

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 the many architectural variants that are supported for this Consumer Empowerment Registration and Medication History Interoperability Specification. Such a flexibility is necessary to support environments where:

- no RHIO is established
- data is stored in a centralized way or distributed among several repositories

- some of the repositories are grouped with the source of Registration & Medication Documents, other being shared as part of the RHIO infrastructure

In some cases some business actors may be grouped to support the case where a PHR Service is provided by a Health Care Provider or a Payer, etc.

Three examples illustrate these 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.

- **Implementation/Architecture Variant A**

In this variant, the PHR Service provider cannot rely on a RHIO. By combining both the PHR and the RHIO business actors, 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.

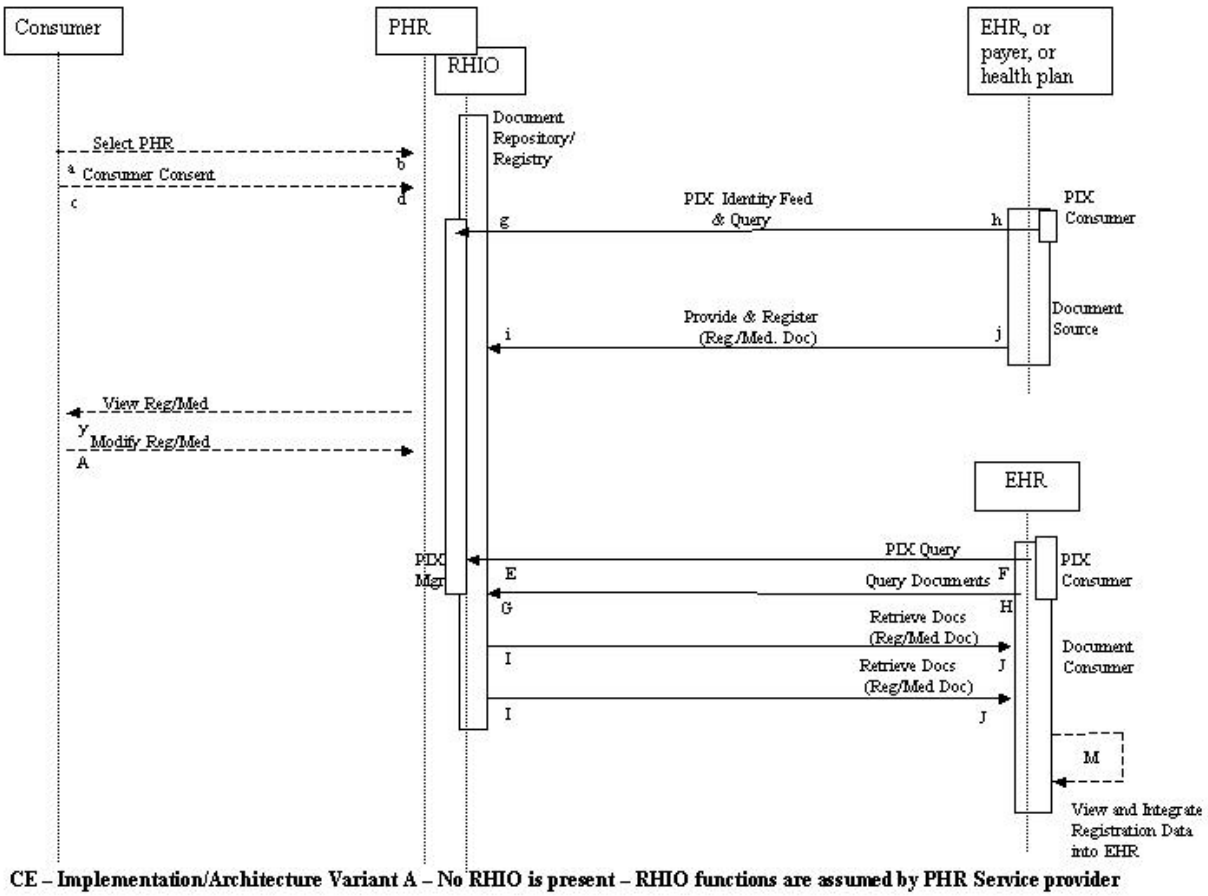

Figure 4.1.4-1 No RHIO is Present – RHIO assumed by PHR Service provider

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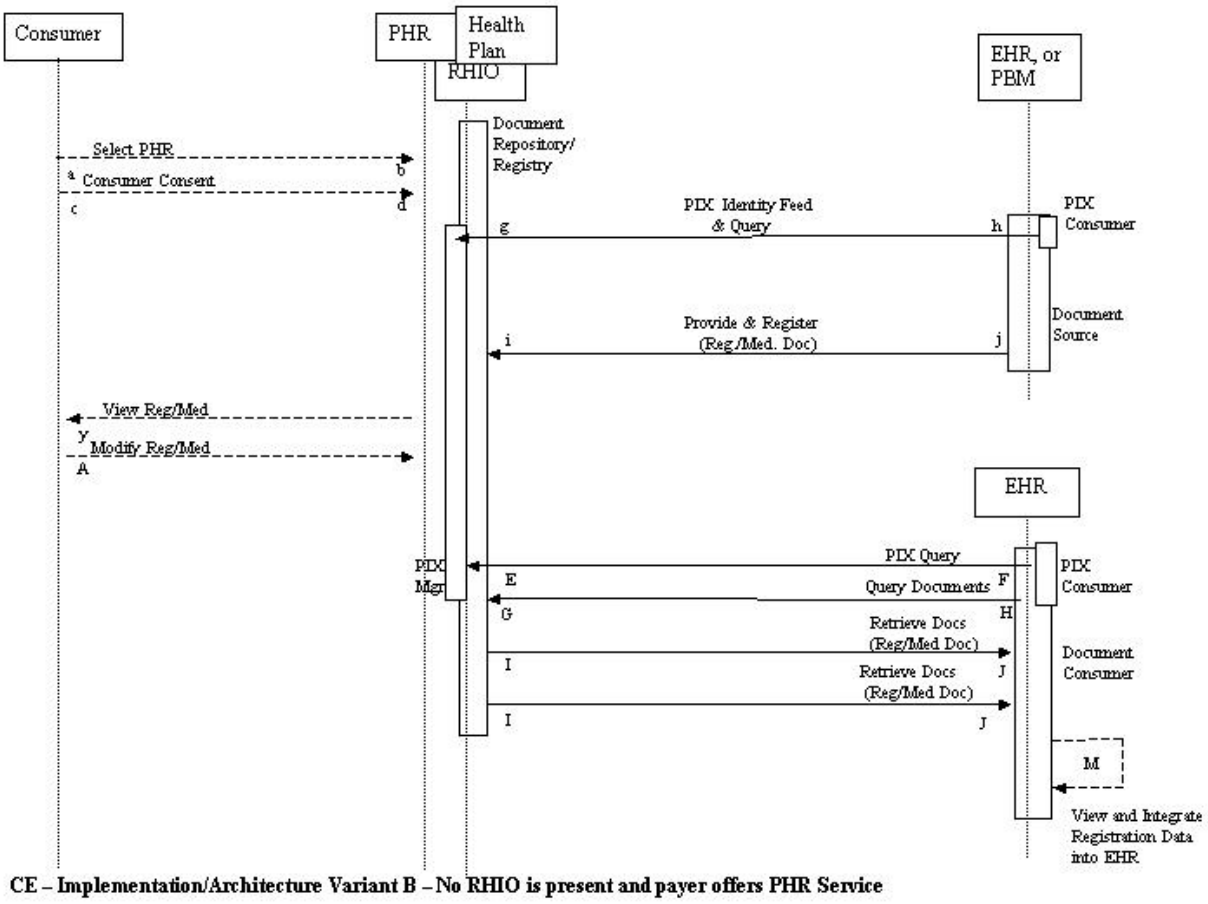
--**Implementation/Architecture Variant B**

In this variant, the PHR Service provider cannot rely on a RHIO 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
800 (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.



CE – Implementation/Architecture Variant B – No RHIO is present and payer offers PHR Service

805 Figure 4.1.4-2 No RHIO is Present and the payer offers 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 the EHR
810 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.

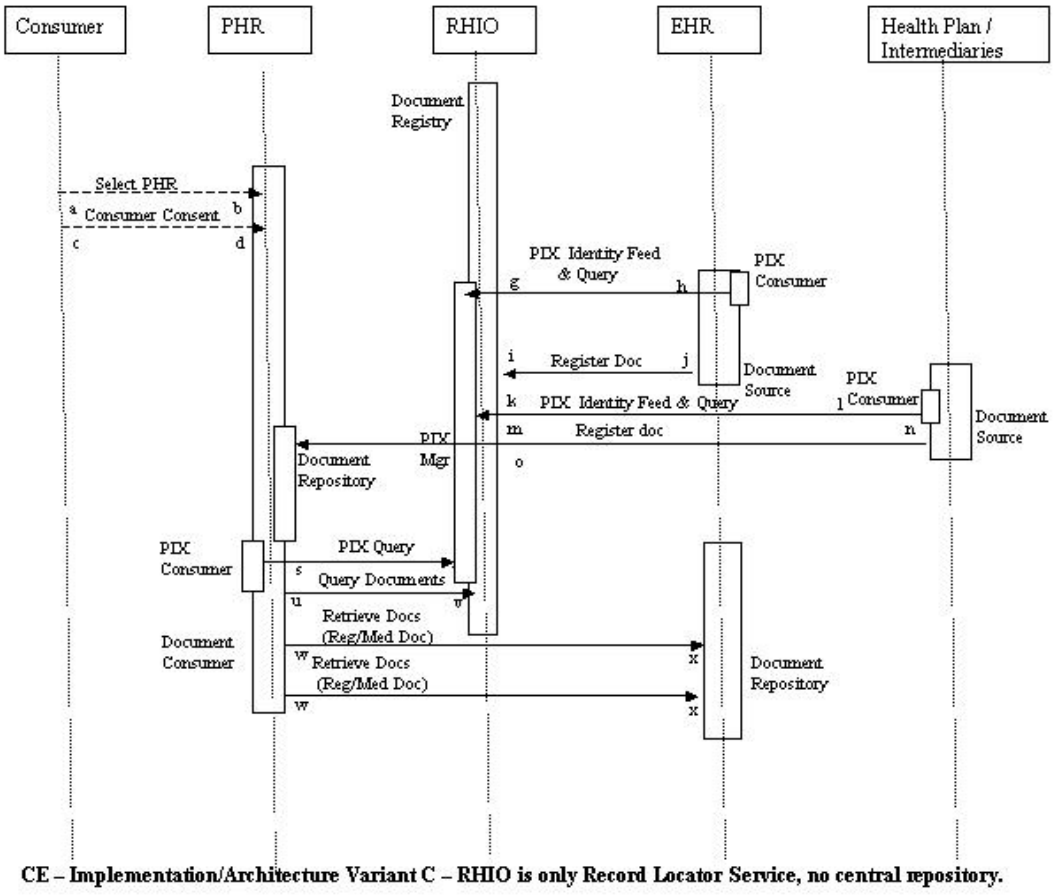


Figure 4.1.4-3 RHIO is Only Registry, No Central Repository

The architectural flexibilities illustrated in the 3 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.

Transaction Package/Independent Transaction	Description	Document References	Date Added
HITSP/ISTP-13	HITSP Interoperability Specification: Manage Sharing of Docs Transaction Package	ISTP_HITSP_13_v1.0_2006	September, 29, 2006

Transaction Package/Independent Transaction	Description	Document References	Date Added
HITSP/IST-11	HITSP Interoperability Specification: Consumer/Patient ID Cross-reference Transaction	IST_HITSP_11_v1.0_2006	September, 29, 2006
HITSP/IST-22	HITSP Interoperability Specification: Patient ID Cross Referencing Transaction	IST_HITSP_22_v1.0_2006	September, 29, 2006
HITSP/IST-23	HITSP Interoperability Specification: Patient Demographics Query Transaction	IST_HITSP_23_v1.0_2006	September, 29, 2006

Table 4.2-1 List of Independent Transactions and Transaction Packages

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 are 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 would also include implementing the constraints to these standards specified in the component, transaction and transaction package specification 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.

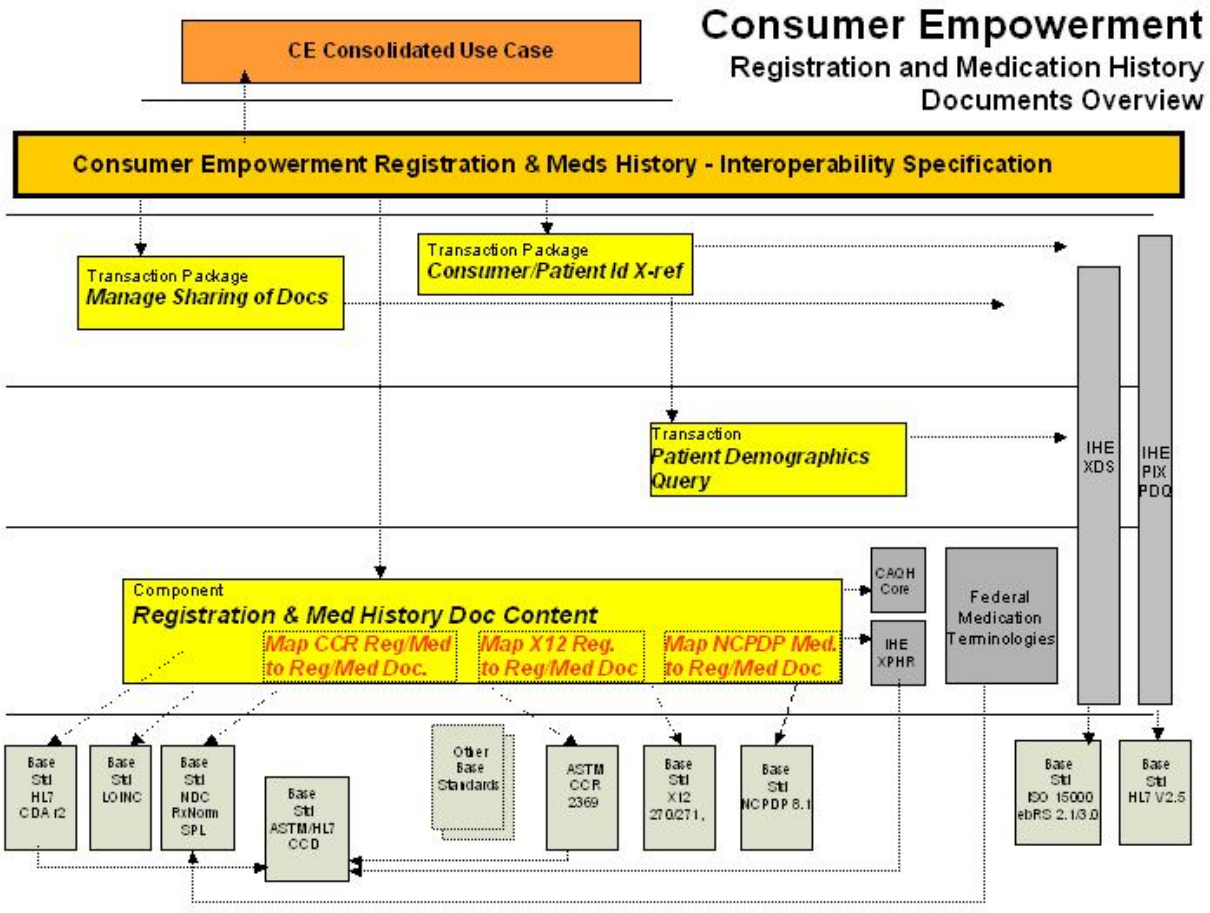


Figure 5.1-1 – Consumer Empowerment Registration and Medication History Documents Overview

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

R = Required, O = Optional, C = Conditional

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

Business Actor	Technical Actor(s)	Req/Opt
	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
Authorized Third Party Consumer	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
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 5.1-1 Business Actor to Technical Actor(s) Requirements

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

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Technical Actor	Transaction	Req/ Opt	HITSP Construct
PIX Manager	PIX Identity Feed	R	HITSP Interoperability Specification: Patient ID Cross Referencing Transaction
	PIX Query	R	HITSP Interoperability Specification: Patient ID Cross Referencing Transaction
PIX Consumer	PIX Identity Feed	R	HITSP Interoperability Specification: Patient ID Cross Referencing Transaction
	PIX Query	R	HITSP Interoperability Specification: Patient ID Cross Referencing Transaction
Patient Identity Source	Patient Identity Feed	R	HITSP Interoperability Specification: Patient Demographics Query Transaction
Patient Demographics Supplier	Patient Demographics Query	R	HITSP Interoperability Specification: Patient Demographics Query Transaction
Patient Demographics Consumer	Patient Demographics Query	R	HITSP Interoperability Specification: Patient Demographics Query Transaction

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

Table 5.1-2 Technical Actor to Transaction Requirements

5.2 SUPPORTING DOCUMENTS

The following documents were used to support the creation of this interoperability specification.

1. Harmonized Use case for Consumer Empowerment (Registration and Medication History) March 19, 2006 - created by the Office of the National Coordinator for Health Information Technology (ONC)

2. HITSP Technical Committees – Consumer Empowerment: Selected Standards June 29, 2006, Version 2.0

3. HITSP Technical Committees – Consumer Empowerment: Standard's Gap and Overlay Analysis, May 30, 2006, Version 3.0

6.0 APPENDIX

This appendix provides additional detail not included in the other parts of the specification, but that are supportive of the specification.

6.1 HITSP HARMONIZATION FRAMEWORK

There are several constructs that are being used to define the interoperability specification, with each level providing more granularity to the standards applicable for fulfillment of the Use Case. The table below describes the current framework within which the interoperability specification is being built, the relationships between each construct, and further illustrative examples.

	CONSTRUCT	DEFINITION	EXAMPLE	RULES
1	Use Case Harmonization Request	Defines business/functional requirements and specifies the relevant context	ONC Harmonized ONC Harmonized EHR Use Case	
2	Interoperability Specification	Models the business/functional requirements, identifies technical/system requirements to meet the specified use-case, and then identifies how to use one or more standards to meet the use-case	HITSP EHR Interoperability Specification	Based on UML diagram to identify actors and actions Sets context Testable functional requirements Identifies transaction(s) or packages of transactions
3	Transaction Package	Defines how two or more transactions are used to support a stand-alone information exchange within a defined context between two or more systems	Record Locator Service, Entity Identification Service	Thin context and functional requirements Testable Based on analysis of like actors, context and content harmonized across the transactions May be fulfilled by one or more complex standards Expresses constraints on how the transactions are used together
4	Transaction	Logical grouping of actions, including necessary content and context, that must all succeed or fail as a group.	Query lab result, Send lab result	Fulfills all actions between two systems that meet one or more functional requirements Testable Expresses constraints on how the components and/or standards are used together
5	Component	An atomic construct used to support an information interchange or to meet an infrastructure requirement (e.g., security, logging/audit)	Lab result message, Lab result context	Typically will use one “primary” standard and may have other “secondary” standards May express constraints on how the standards are used
6	Base Standard	A standard capable of fulfilling a discrete function within a single category produced and maintained by a single standards organization.	Messaging standard, Security standard, Code set.	Per HITSP definition the term “standard” refers to (and is not limited to): –Specifications –Implementation Guides –Code Sets

	CONSTRUCT	DEFINITION	EXAMPLE	RULES
				–Terminologies –Integration Profiles
7	Composite Standard	Grouping of coordinated base standards, often from multiple standards organizations, maintained by a single organization. In HITSP, it can serve as a component, transaction or transaction package functional requirements.	Integration profiles Implementation guides Health transaction services	Per HITSP Definition

Table 6.1-1 HITSP Harmonization Framework

6.2 USE CASE ACTIONS AND EVENTS

Table 6.2-1 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.

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	h	j	j

Event/ Action Code	Description	Scenario #1 Process Flow References	Scenario #2 Process Flow References	Scenario #3 Process Flow References
	data or network system			
2.2.2.4	Action: Receive registration/medication data	i, m, q	k, o, u	k, o, u
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

Event/ Action Code	Description	Scenario #1 Process Flow References	Scenario #2 Process Flow References	Scenario #3 Process Flow References
2.3.3.1	Action: Receive and validate the query request			
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

Table 6.2-1 – Event/Action Code Descriptions and Process Flow References

6.3 GLOSSARY

Included is the common interoperability glossary that is used for all the Use Cases. This is the HITSP glossary that spans all the interoperability specifications, which can be found in the following folder on the HITSP site:
http://publicaa.ansi.org/sites/apdl/Documents/Forms/AllItems.aspx?RootFolder=http%3a%2f%2fpublicaa%2eansi%2eorg%2fsites%2fapdl%2fDocuments%2fStandards%20Activities%2fHealthcare%20Informatics%20Technology%20Standards%20Panel