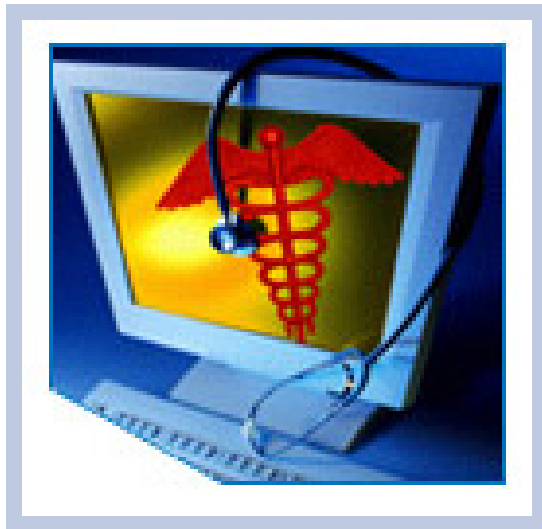


# HITSP Consumer Empowerment and Access to Clinical Information via Networks Interoperability Specification

---

HITSP/IS03



*Submitted to:*

**Healthcare Information Technology Standards Panel**

*Submitted by:*

**Consumer Perspective Technical Committee  
(Formerly 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 | September 7, 2006  |
| 1.1            | Ready for Public Comment         | Consumer Empowerment Technical Committee | September 12, 2006 |
| 1.2            | Ready for Implementation Testing | Consumer Empowerment Technical Committee | October 20, 2006   |
| 2.0            | Released for Implementation      | Consumer Empowerment Technical Committee | May 11, 2007       |
| 2.0.1          | Review Copy                      | Consumer Empowerment Technical Committee | September 18, 2007 |
| 2.0.2          | Review Copy                      | Consumer Empowerment Technical Committee | December 5, 2007   |
| 3.0            | Released for Implementation      | Consumer Empowerment Technical Committee | December 13, 2007  |
|                | Template Update to V2.4          | Project Team                             | July 31, 2008      |
| 3.0.1          | Review Copy                      | Consumer Perspective Technical Committee | August 20, 2008    |
| 3.1            | Released for Implementation      | Consumer Perspective Technical Committee | August 28, 2008    |
| 3.1.1          | Review Copy                      | Consumer Perspective Technical Committee | September 26, 2008 |
| 3.1.2          | Review Copy                      | Consumer Perspective Technical Committee | December 10, 2008  |
| 4.0            | Released for Implementation      | Consumer Perspective Technical Committee | December 18, 2008  |



# TABLE OF CONTENTS

|            |  |           |
|------------|--|-----------|
| <b>1.0</b> | <b>INTRODUCTION .....</b>  | <b>8</b>  |
| 1.1        | Interoperability Specification Overview .....  | 8         |
| 1.2        | Interoperability Specification Document Map .....  | 10        |
| 1.2.1      | List of Constructs .....   | 11        |
| 1.3        | Copyright Permissions .....  | 13        |
| 1.4        | Reference Documents .....  | 13        |
| <b>2.0</b> | <b>REQUIREMENTS .....</b>  | <b>15</b> |
| 2.1        | Use Case Synopsis .....  | 15        |
| 2.2        | Use Case Requirements .....  | 16        |
| 2.2.1      | Mapping of Use Case Actions to Information Exchange Requirements .....   | 18        |
| 2.2.2      | Data and Information Exchange Requirements .....   | 18        |
|            | Table 2.2.2-1 Table and Information Requirements Matrix .....  | 18        |
|            | Table 2.2.2-2 Information Exchange Requirements (IER) .....  | 22        |
| 2.2.3      | Identification of Business Actors, Mapped to Requirements .....  | 22        |
|            | Table 2.2.3-1 Business Actors .....  | 23        |
| 2.2.4      | High-Level Diagrams .....  | 28        |
| <b>3.0</b> | <b>DESIGN .....</b>  | <b>31</b> |
| 3.1        | Scope of Design .....  | 31        |
| 3.1.1      | Assumptions .....  | 32        |
| 3.1.2      | Constraints .....  | 32        |
| 3.1.3      | Pre-conditions .....   | 33        |
| 3.1.4      | Post-conditions .....  | 35        |
| 3.1.5      | Process Triggers .....   | 35        |
| 3.2        | Detailed Design .....  | 35        |
| 3.2.1      | Technical Actors Role Descriptions .....   | 36        |
| 3.2.2      | Construct Requirements .....   | 39        |
| 3.2.2.1    | Consumer Creates Account to Host Health Information Scenario Actor Interactions .....  | 42        |
|            | 3.2.2.1.1 Transaction Descriptions .....   | 43        |
| 3.2.2.2    | Consumer Visits Healthcare Provider and Provides Registration and Medication History and/or Laboratory Information Scenario Actor Interactions ..... | 44        |
|            | 3.2.2.2.1 Transaction Descriptions .....   | 45        |
| 3.2.2.3    | Authorized Healthcare Provider Reviews Registration and Medication History Scenario Actor Interactions .....   | 46        |
|            | 3.2.2.3.1 Transaction Descriptions .....   | 47        |
| 3.2.2.4    | Implementation and Architecture Variants .....   | 49        |



|            |   |           |
|------------|---|-----------|
| 3.2.3      | Mapping of Business Actors to Technical Actors and Constructs with Optionality ....     | 54        |
| 3.2.3.1    | C32 “Creator-Registration Subset” .....   | 63        |
| 3.2.3.2    | C32 “Creator-Registration-Coded Subset” .....   | 63        |
| 3.2.3.3    | C32 “Creator-Medication and Immunization History Subset” .....                          | 63        |
| 3.2.3.4    | C32 “Creator-Medication and Immunization History-Coded Subset” .....                    | 64        |
| 3.2.3.5    | C32 “Creator-Conditions and Allergy Subset” .....                                       | 64        |
| 3.2.3.6    | C32 “Creator-Conditions and Allergy-Coded Subset” .....                                 | 65        |
| 3.2.3.7    | C32 “Creator-Laboratory Section Subset” .....   | 65        |
| 3.2.3.8    | C32 “Creator-Laboratory Section-Coded Subset” .....                                     | 65        |
| 3.2.3.9    | Consumer-Document Display Subset .....  | 65        |
| 3.2.3.10   | Consumer-Document Import Subset.....  | 66        |
| 3.2.3.11   | C32 “Consumer-Registration Discrete Data Import Subset” .....                           | 66        |
| 3.2.3.12   | C32 “Consumer-Medication and Immunization History Discrete Data<br>Import Subset” ..... | 66        |
| 3.2.3.13   | C32 “Consumer-Conditions and Allergy Discrete Data Import Subset” .....                 | 66        |
| 3.2.3.14   | C32 “Consumer-Laboratory Discrete Data Import Subset” .....                             | 66        |
| 3.2.3.15   | C37 “Consumer-Lab Report Discrete Data Import Subset” .....                             | 66        |
| 3.2.4      | Construct Dependencies .....  | 66        |
| 3.2.5      | Additional Constraints on Required Constructs.....                                      | 67        |
| <b>4.0</b> | <b>STANDARDS SELECTION .....</b>  | <b>68</b> |
| 4.1        | Standards .....   | 69        |
| 4.1.1      | Regulatory Guidance.....  | 69        |
| 4.1.2      | Selected Standards .....  | 70        |
| 4.1.3      | Informative Reference Standards.....  | 73        |
| 4.2        | Gaps Where There Are No Standards .....   | 77        |
|            | Table 4.2-1 Use Case Events and Associated Gaps .....                                   | 78        |
| 4.3        | Standard Overlaps.....  | 81        |
|            | Table 4.3-1 Use Case Requirements and Associated Standard Overlaps .....                | 82        |
| <b>5.0</b> | <b>CONFORMANCE.....</b>   | <b>83</b> |
| 5.1        | Conformance Criteria .....  | 83        |
| 5.2        | Conformance Scoping, Subsetting and Options .....                                       | 83        |
| 5.3        | Test Methods .....  | 84        |
| <b>6.0</b> | <b>APPENDIX .....</b>   | <b>85</b> |
| 6.1        | Description of Standards .....  | 85        |
| 6.2        | Use Case to Information Exchange and Data Requirements .....                            | 92        |
| 6.3        | Use Case Sequence Diagrams .....  | 106       |
| 6.4        | Mapping of Constructs to Information Exchange and Data Requirements .....               | 115       |
|            | Table 6.4-1 Mapping of HITSP Constructs to Requirements .....                           | 115       |



|            |                               |            |
|------------|-------------------------------|------------|
| <b>7.0</b> | <b>DOCUMENT UPDATES .....</b> | <b>118</b> |
| 7.1        | May 11, 2007 .....            | 118        |
| 7.2        | September 18, 2007 .....      | 118        |
| 7.3        | December 5, 2007 .....        | 119        |
| 7.4        | December 13, 2007 .....       | 120        |
| 7.5        | August 20, 2008 .....         | 120        |
| 7.6        | August 27, 2008 .....         | 120        |
| 7.7        | December 10, 2008 .....       | 120        |
| 7.8        | December 18, 2008 .....       | 121        |



## FIGURES AND TABLES

|   |     |
|---|-----|
| Figure 1.2-1 Interoperability Specification Construct Roadmap .....   | 10  |
| Figure 2.2.4-1 Legend for Component Diagrams .....  | 29  |
| Figure 2.2.4-2 Consumer Access to Clinical Information Component Data Flow Diagram .....  | 30  |
| Figure 3.2.2.1-1 Customer Creates Accounts to Host Registration and Medication History .....  | 43  |
| Figure 3.2.2.2-1 Consumer Visits Healthcare Provider and Provides Registration and Medication<br>History Information .....  | 45  |
| Figure 3.2.2.3-1 Authorized Healthcare Provider Views Registration and Medication History .....   | 47  |
| Figure 3.2.2.4-1 RHIO/HIE Functionality Assumed by PHR Service Provider .....   | 50  |
| Figure 3.2.2.4-2 Payer assumes RHIO/HIE functionality and PHR Service Provider .....  | 51  |
| Figure 3.2.2.4-3 RHIO/HIE is Only Registry, No Central Repository .....   | 52  |
| Figure 3.2.2.4-4 EHR System or Health Plan Assumes RHIO/HIE Functionality .....   | 53  |
| Figure 3.2.2.4-5 Intermediary between Health Plans and PHR Service Provider .....   | 54  |
| Figure 6.3-1 Scenario 1: Consumer Creates Account to Host and Access Registration Summary<br>and Clinical Information High-Level Business Sequence Diagram - Part A .....                     | 107 |
| Figure 6.3-2 Scenario 1: Consumer Creates Account to Host and Access Registration Summary<br>and Clinical Information High-Level Business Sequence Diagram - Part B .....                     | 108 |
| Figure 6.3-3 Scenario 1: Consumer Creates Account to Host and Access Registration Summary<br>and Clinical Information High-Level Business Sequence Diagram - Part C .....                     | 109 |
| Figure 6.3-4 Scenario 1: Consumer Creates Account to Host and Access Registration Summary<br>and Clinical Information High-Level Business Sequence Diagram - Part D .....                     | 110 |
| Figure 6.3-5 Scenario 2: Consumer Visits Healthcare Provider and Provides Registration<br>Summary Information and Clinical Information High-Level Business Sequence Diagram –<br>Part A ..... | 111 |
| Figure 6.3-6 Scenario 2: Consumer Visits Healthcare Provider and Provides Registration<br>Summary Information and Clinical Information High-Level Business Sequence Diagram –<br>Part B ..... | 112 |
| Figure 6.3-7 Scenario 3: Authorized Healthcare Provider Reviews Registration Summary and<br>Other Clinical Information High-Level Business Sequence Diagram – Part A .....                    | 113 |
| Figure 6.3-8 Scenario 3: Authorized Healthcare Provider Reviews Registration Summary and<br>Other Clinical Information High-Level Business Sequence Diagram – Part B .....                    | 114 |
| Table 1.2.1-1 List of Constructs .....  | 11  |
| Table 1.4-1 Reference Documents .....   | 13  |
| Table 2.2.2-1 Table and Information Requirements Matrix .....   | 18  |
| Table 2.2.2-2 Information Exchange Requirements (IER) .....   | 22  |
| Table 2.2.3-1 Business Actors .....   | 23  |
| Table 3.1-1 Scoping .....   | 31  |
| Table 3.1.1-1 Assumptions .....   | 32  |
| Table 3.1.2-1 Constraints .....   | 33  |



|  |     |
|--|-----|
| Table 3.1.3-1 Pre-conditions .....   | 33  |
| Table 3.1.4-1 Post-conditions .....  | 35  |
| Table 3.1.5-1 Process Triggers.....  | 35  |
| Table 3.2.1-1 Technical Actor Role Descriptions.....   | 36  |
| Table 3.2.2-1 HITSP/C32 Content Modules in this IS .....   | 41  |
| Table 3.2.3-1 Business-Technical Actor Mapping to Transaction and/or Content .....   | 55  |
| Table 3.2.3-2 Implementation Conditions/Constraints.....   | 62  |
| Table 3.2.3.1-1 Creator Registration Subset Content Modules.....   | 63  |
| Table 3.2.3.3-1 Creator Medication and Immunization History Subset Content Modules.....  | 64  |
| Table 3.2.3.5-1 Creator Conditions and Allergy Subset Content Modules .....  | 64  |
| Table 3.2.3.7-1 Creator Laboratory Subset Content Modules .....  | 65  |
| Table 3.2.4-1 Construct Dependencies .....   | 67  |
| Table 3.2.5-1 Additional Constraints on Required Constructs.....   | 67  |
| Table 4.1.1-1 Regulatory Guidance .....  | 69  |
| Table 4.1.2-1 Selected Standards Linked to HITSP Constructs.....   | 70  |
| Table 4.1.3-1 Informative Reference Standards.....   | 73  |
| Table 4.2-1 Use Case Events and Associated Gaps.....   | 78  |
| Table 4.3-1 Use Case Requirements and Associated Standard Overlaps.....  | 82  |
| Table 6.1-1 Description of Standards .....   | 85  |
| Table 6.2-1 Mapping of Use Case Actions to Information Exchange Requirements – Consumer<br>Empowerment Use Case – Scenario 1 .....                   | 92  |
| Table 6.2-2 Mapping of Use Case Actions to Information Exchange Requirements - Consumer<br>Empowerment Use Case – Scenario 2.....                    | 98  |
| Table 6.2-3 Mapping of Use Case Actions to Information Exchange Requirements - Consumer<br>Empowerment Use Case – Scenario 3.....                    | 101 |
| Table 6.2-4 Mapping of Use Case Actions to Information Exchange Requirements – Consumer<br>Access to Clinical Information Use Case – Scenario 2..... | 105 |
| Table 6.2-5 Mapping of Use Case Actions to Information Exchange Requirements – Consumer<br>Access to Clinical Information Use Case – Scenario 3..... | 106 |
| Table 6.4-1 Mapping of HITSP Constructs to Requirements.....   | 115 |



## 1.0 INTRODUCTION

As an introduction to the Healthcare Information Technology Standards Panel (HITSP) Consumer Empowerment and Access to Clinical Information via Networks Interoperability Specification, this section provides a high level overview of the information sharing scenario enabled by following this specification, provides a document map of the construct relationships for the Interoperability Specification, acknowledges the copyright protections that pertain, and provides a list of key reference documents and background material.

This update to the HITSP Consumer Empowerment and Access to Clinical Information via Networks Interoperability Specification (IS) introduces two new constructs, which address specific gaps identified in previous versions of this IS. This update uses HITSP/C62 Unstructured Document, which allows the user to use documents such as PDF, scanned documents etc. For the purposes of this IS HITSP/C62 is used to provide support for an entry-level advance directive document. The other new construct included in this update is HITSP/T81 Retrieval of Medical Knowledge, which provides a mechanism for the query and receipt of medical knowledge. HITSP/T81 addresses the need to allow users the ability to obtain additional knowledge about a clinical concept including translating concepts into layperson language.

### 1.1 INTEROPERABILITY SPECIFICATION OVERVIEW

This section provides a high level definition of this Interoperability Specification and background information about the underlying Use Case that it is based upon.

The HITSP Consumer Empowerment and Access to Clinical Information via Networks 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 defines specific implementations of established standards intended to achieve integration goals that promote appropriate exchange of a consumer's personal health record information.

The HITSP Consumer Empowerment Use Case describes 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 (PHR) system to track healthcare information, insurance, family history, medications, and other special conditions.

As part of a PHR, this specification addresses several key areas: The patient's registration data and a healthcare summary including medication history, allergies, encounters, problems and conditions, immunizations, advance directives, and key laboratory tests results.

A vital part of a PHR is the registration information. A visit to the doctor or hospital frequently requires filling out multiple forms. These forms collect information such as name, address, insurance, medications,





allergies, etc. 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 healthcare summary provides a set of key health related information at a point in time. It includes a medication history which 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 own 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 consumer. 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. A complete electronic medication list would also prevent drug-to-drug or allergic reactions when subsequent prescriptions are written. The consumer's healthcare summary should also include a list of allergies, encounters, identified conditions and problems diagnosed, the current list of immunizations, and laboratory test results as indications of the consumer's health status.

Traditionally, registration is viewed from the healthcare provider's perspective and consists of patient registration with the healthcare provider organization and the consumer giving their information to the healthcare provider. The concept of consumer empowerment creates a new perspective of healthcare providers and healthcare organizations that goes beyond traditional registration to provide the healthcare provider's contact and identification information to the consumer. This process of reciprocal registration and sharing of data are 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 own information into the patient's registration summary. Ideally that would include contact information and the identifier, such as a medical record number, that the healthcare provider assigned to that patient. This will facilitate the PHR system 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 three types of interoperable documents. The first is a registration and healthcare summary document; the second, a laboratory report document (also used for the HITSP/IS01 Electronic Health Records Laboratory Results Reporting); and finally, the third is an unstructured document which can be used for scanned documents (such as advance directives). One means to share these documents is by registering them in a record locator and retrieving them from the referenced document repository. Other types of interoperable documents may be defined by HITSP in the future such as radiology reports, images, electrocardiogram (ECG) reports, etc. These other types of documents are out of scope of the Use Cases presented to HITSP for consideration at this time.

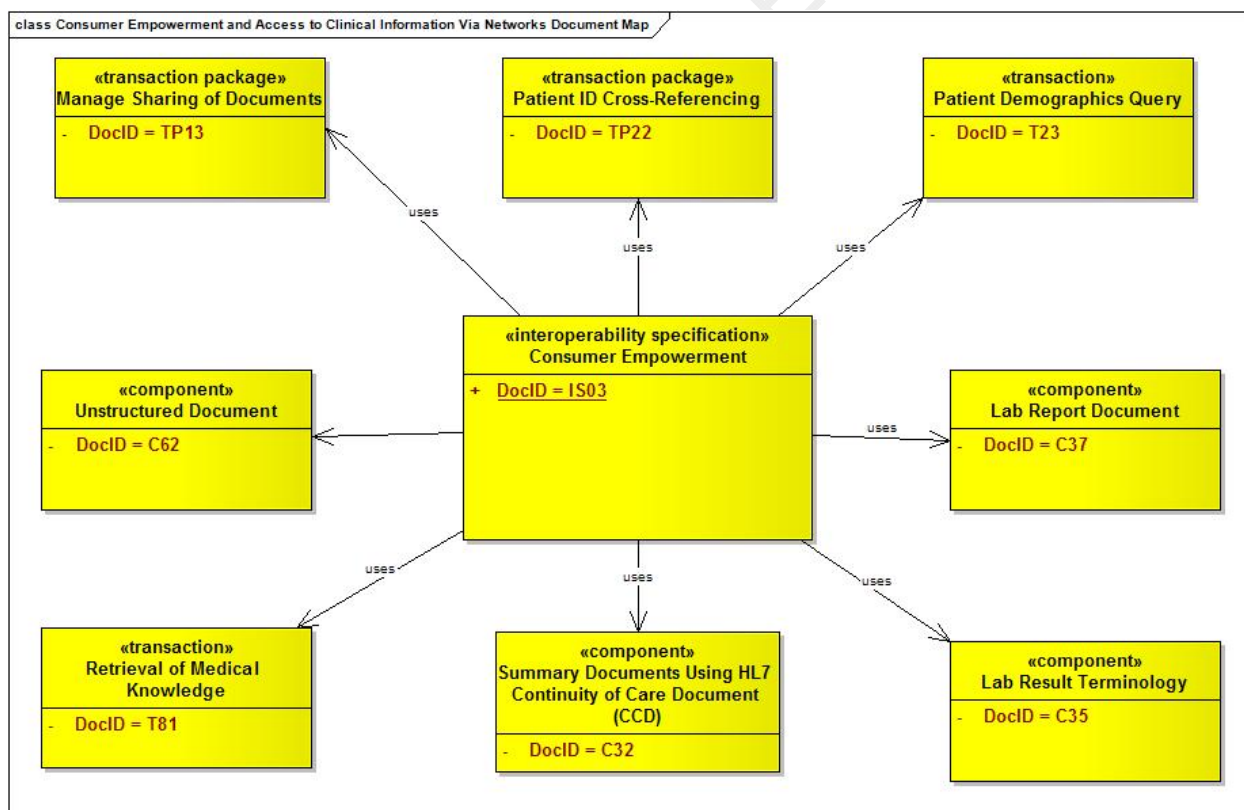


The interoperability requirements are based upon six well-defined scenarios related to a consumer's personal health record. This is the first document in a series of documents that need to be understood and implemented in order to conform to this specification.

## 1.2 INTEROPERABILITY SPECIFICATION DOCUMENT MAP

Each HITSP Interoperability Specification (IS) is comprised of a suite of constructs that, taken as a whole, define how to integrate and constrain existing standards and specifications to satisfy the requirements imposed by a given Use Case. The IS groups specific actions and actors to describe the relevant context(s) for the use of HITSP constructs that further identify and constrain standards where necessary. In addition to ISs, there are three other types of HITSP constructs called Transaction Packages (TP), Transactions (T), and Components (C). The document map in Figure 1.2-1 depicts how this IS integrates and constrains HITSP constructs to support the information exchange, within the defined context of the Use Case. Implementers should read the documents that describe the constructs depicted in the diagram for their details and specific uses. Note that the baseline Security and Privacy constructs are not shown in the diagram, however, they are described in Table 1.2.1-1.

**Figure 1.2-1 Interoperability Specification Construct Roadmap**



### 1.2.1 LIST OF CONSTRUCTS

The following table lists and describes the HITSP constructs that are used by the Interoperability Specification. All references to HITSP specifications are to the current, and Panel approved 'Released for Implementation' versions of the specifications retrieved from [www.hitsp.org](http://www.hitsp.org).

Where HITSP has adopted HL7 V3.0 CDA/CCD for conveying information between Electronic Health Record (EHR) and Personal Health Record (PHR) applications and in other healthcare scenarios, it has consolidated common constraints applied against the Content Modules in HITSP/C83 CDA Content Modules. Likewise, HITSP/C80 Clinical Document and Message Terminology maintains commonly applied terminology constraints. Readers should refer to HITSP/TN901 Technical Note for Clinical Documents to better understand how HITSP/C83 and HITSP/C80 are used by other constructs that are based upon HL7 V3.0 CDA/CCD (e.g., HITSP/C32 Summary Documents Using HL7 Continuity of Care Document (CCD), HITSP/C48 Encounter Document Using IHE Medical Summary (XDS-MS) and HITSP/C84 Consult and History & Physical Note Document).

**Table 1.2.1-1 List of Constructs**

| Construct  | Description   |
|--|---|
| HITSP/ C19 - Entity Identity Assertion                                     | The Entity Identity Assertion Component provides the mechanisms to ensure that an entity is the person or application that claims the identity provided. An example of this Component is the validation and assertion of a consumer logging on to a Personal Health Record (PHR) system   |
| HITSP/ C26 - Nonrepudiation of Origin                                      | The Nonrepudiation of Origin Component provides the mechanisms to support Nonrepudiation of Origin, which refers to both the proof of the integrity and origin of documents in a high-assurance manner, which can be verified by any party. This Component does not provide Nonrepudiation of Receipt   |
| HITSP/ C32 - Summary Documents Using HL7 Continuity of Care Document (CCD) | The Summary Documents Using HL7 Continuity of Care Document (CCD) Component describes the document content summarizing a consumer's medical status for the purpose of information exchange. The content may include administrative (e.g., registration, demographics, insurance, etc.) and clinical (problem list, medication list, allergies, test results, etc) information. This Component defines content in order to promote interoperability between participating systems such as Personal Health Record Systems (PHRs), Electronic Health Record Systems (EHRs), Practice Management Applications and others  |
| HITSP/ C35 - Lab Result Terminology  | The Lab Result Terminology Component defines the vocabulary for either message-based or document-based laboratory results reporting   |
| HITSP/ C37 - Lab Report Document   | The Lab Report Document Component prescribes the use of the standard Clinical Document Architecture Release 2 (CDA R2), as in the HL7 V3 2006 normative edition profiled by IHE LAB TF-3 for: transmission of complete, preliminary, final and updated laboratory results to the EHR system (local or remote) of the ordering clinician; transmission of complete, preliminary, final and updated (or notification) to the EHR system (local or remote) or other clinical data system of designated providers of care (with respect to a specific patient); transmission of laboratory result data from electronically enabled healthcare delivery and public health systems in standardized and anonymized format to authorized Public Health Agencies with less than one day lag time |



| Construct   | Description   |
|---|---|
| HITSP/C62 - Unstructured Document                         | The Unstructured Document Component is provided for the capture and storage of patient identifiable, unstructured document content, such as text, PDF, and images rendered in PDF. It is based on the Cross-Enterprise Sharing of Scanned Documents (XDS-SD) profile from the Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF)  |
| HITSP/ T15 - Collect and Communicate Security Audit Trail | The Collect and Communicate Security Audit Trail Transaction is a means to provide assurance that security policies are being followed or enforced and that risks are being mitigated. This document describes the mechanisms to define and identify security relevant events and the data to be collected and communicated as determined by policy, regulation or risk analysis. It also provides the mechanism to determine the record format to support analytical reports that are needed   |
| HITSP/ T16 - Consistent Time                              | The Consistent Time Transaction provides a mechanism to ensure that all of the entities that are communicating within the network have synchronized system clocks   |
| HITSP/ T17 - Secured Communication Channel                | The Secured Communication Channel Transaction provides the mechanisms to ensure the authenticity, integrity, and confidentiality of transmissions, and the mutual trust between communicating parties. Its objectives include providing: mutual node authentication to assure each node of the others' identity; transmission integrity to guard against improper information modification or destruction while in transit; and transmission confidentiality to ensure that information in transit is not disclosed to unauthorized individuals, entities, or processes   |
| HITSP/ T23 - Patient Demographics Query                   | The Patient Demographics Query Transaction is intended to provide a 'list patients and their demographics' query/'patient(s) and their demographics identified' response message pair (QBP^K22, RSP^K22) for use wherever such needs exist. This Transaction document extracts the Health Level Seven (HL7) version 2.5 Query and Response data mapping. The underlying basis for this extraction can be found in the Integrating the Healthcare Enterprise IT Infrastructure Technical Framework, Patient Demographics Query integration profile   |
| HITSP/ T81 - Retrieval of Medical Knowledge               | The Retrieval of Medical Knowledge Transaction enables the request and receipt of additional knowledge about a medical concept based on specific context parameters. This transaction does not prescribe the knowledge content of the message returned but provides the specifications for the query for and receipt of additional knowledge. It uses the Health Level 7 (HL7) Context-Aware Information Retrieval (Infobutton) Specification: URL Implementation Guide as the base standard for implementation   |
| HITSP/ TP13 - Manage Sharing of Documents                 | The Manage Sharing of Documents Transaction Package supports the sharing of patient records in the form of source attested objects called documents. A healthcare document is a composite of structured and coded health information, both narrative and tabular, that describes acts, observations and services for the purpose of exchange. No assumption is made by this construct in terms of the format and structure of the content of documents shared   |
| HITSP/TP20 - Access Control                               | The Access Control Transaction Package provides the mechanism for security authorizations which control the enforcement of security policies including: role-based access control; entity based access control; context based access control; and the execution of consent directives. An example of this is a functional role that has the permission to perform an act (e.g., consumer updating a Personal Health Record (PHR). In an emergency, this construct must support the capability to alter access privileges to the appropriate level (failsafe/emergency access), which may include override of non-emergency consents |



| Construct                                 | Description  |
|---|--|
| HITSP/TP22 - Patient ID Cross-Referencing | The Patient ID Cross-Referencing Transaction Package is used for identifying and cross-referencing different attributes for the same patient. It contains a query for cross-reference and patient identity feed transactions. These transactions are used to identify patients from a list of potentials, and/or to communicate patient demographic data   |
| HITSP/TP30 - Manage Consent Directives    | The Manage Consent Directives Transaction Package describes the messages needed to capture, manage, and communicate rights granted or withheld by a consumer to one or more identified entities in a defined role to access, collect, use or disclose individually identifiable health information (IIHI), and also supports the delegation of the patient's right to consent. The transactions described in this construct are intended to be carried out by HITSP/TP13 - Manage Sharing of Documents |

### 1.3 COPYRIGHT PERMISSIONS

#### COPYRIGHT NOTICE

© 2007 ANSI. This material may be copied without permission from ANSI only if and to the extent that the text is not altered in any fashion and ANSI's copyright is clearly noted.

### 1.4 REFERENCE DOCUMENTS

This section provides a list of key reference documents and background material. If you are already familiar with this information, proceed to Section 2.0.

A list of key reference documents and background material is provided in the table below. These documents can be retrieved from [www.hitsp.org](http://www.hitsp.org).

**Table 1.4-1 Reference Documents**

| Reference Document  | Document Description   |
|---|--|
| HITSP Acronyms List   | Lists and defines the acronyms used in this document   |
| HITSP Conventions List  | Describes the conventions that are used to convey the full descriptions and usage of standards in the HITSP specifications   |
| HITSP Glossary  | Provides definitions for relevant terms used by HITSP documents  |
| HITSP Harmonization Framework   | Describes the current framework within which the Interoperability Specifications are built   |
| HITSP Interoperability Specification Overview   | Provides background information about the HITSP and its role in the overall U.S. efforts to realize large scale interoperability of health information. The document also provides a description of the HITSP process for healthcare standards harmonization and explains how to use the Interoperability Specifications and other related documents to inform your health IT system development or refinement |
| The Consumer Empowerment Use Case (Registration and Medication History), March 19, 2006 and the Consumer Access to Clinical Information Detailed Use Case, June 18, 2007, the Harmonized Use Case | AHIC Use Case that is the basis of this HITSP Interoperability Specification   |



|   |  |
|---|--|
| TN900 - Security and Privacy Technical Note | <p>Developed as a reference document to provide the overall context for use of the HITSP Security and Privacy constructs. It includes the following:</p> <ul style="list-style-type: none"> <li>• The scope, reference policy background, and Security and Privacy principles used in the development of the constructs</li> <li>• A detailed description and schematics of the conceptual relationship between the Security and Privacy constructs</li> <li>• A mapping of existing standards and constructs to be used in meeting the stated requirements of the AHIC Use Cases</li> <li>• A list of identified gaps and the recommended approaches to resolving those gaps</li> <li>• A roadmap for how the Security and Privacy constructs will evolve and eventually align with other HITSP Interoperability Specifications</li> <li>• A conceptual framework for Security and Privacy management, including reference information on privacy policies, risk assessment, and risk management</li> <li>• A description of the application of the Security and Privacy constructs to the HITSP Interoperability Specifications for the three initial AHIC Use Cases – Biosurveillance, Electronic Health Records - Laboratory Results Reporting, and Consumer Empowerment</li> </ul> <p>HITSP will periodically update this Technical Note as required by the introduction of new contexts for use.</p> |
|---|--|





## 2.0 REQUIREMENTS

This section provides a high level description of the Consumer Empowerment and the Consumer Access to Clinical Information Use Cases, as well as the specific information exchange and data requirements that are extracted from the Use Case. It includes the following information:

- Mapping from the Use Case actions and events, to the derived information exchange and data requirements – this table lists the requirements grouped by actor for each event and related action
- Data requirements – this table further describes the data requirements for each specified information exchange requirement
- Information exchange requirements – this table further describes the information exchange requirements for each applicable Use Case action
- Business Actors – this table defines the business actors that are included for the Interoperability Specification, and maps them to the applicable scenario, information exchange, and data requirements
- High Level Diagrams – these diagrams are used to describe the interaction between the business actors, and the data involved in each scenario that is documented

### 2.1 USE CASE SYNOPSIS

This section provides a synopsis of the Consumer Empowerment and the Consumer Access to Clinical Information Use Cases, including any applicable scenarios that are part of the Use Cases.

The Consumer Empowerment and the Consumer Access to Clinical Information Use Cases identify the principal stakeholders and flow of events for the authorized and secure exchange of consumers' registration and healthcare summaries as well as laboratory reports. The Use Cases are not intended to define all system features; they identify and describe interactions between key systems and stakeholders and serve as a guide that leads to further development of functional requirements and other products. The Consumer Empowerment and the Consumer Access to Clinical Information Use Cases include:

- 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
- Ability for the consumer to retrieve, store, graph and share laboratory test results
- Ability for consumers to retrieve and store
  - lists of current and previous health conditions
  - lists of current medications, current environment, dietary, medication or medical supply allergies
  - a list of diagnosis codes
- The ability to access results, conditions, allergies, and diagnosis codes in layperson terms



- Ability to identify and maintain a list of all providers involved in the care of a specific patient, to use the provider list to communicate information about the patient to all or selected providers and forward the list of providers to another provider or entity
- Ability for a consumer to identify those providers which are permitted to access information in the consumers' PHR, and which of those data they are permitted to access and to communicate the consumer's decisions to other entities which also hold data about the consumer
- Ability for a consumer to request, consolidate, and access audit log information from multiple sources to create logical views of access to their information
- Ability to describe a consumer's access decisions using information which can be communicated among systems involved in information exchange

Based on the charge from the American Health Information Community, these Use Cases presume some level of linkage between a consumer's registration summary and their healthcare summary. (e.g., medication history, allergies, encounters, and immunizations). This linkage is an important consideration for identifying and locating individual consumers and their available healthcare information across network systems. For the purposes of these Use Cases, the linking of a consumer's registration summary to the healthcare summary 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 linkage applies to including laboratory results in the healthcare summary or to sharing one or more laboratory reports as separate documents.

Certain parts of the Consumer Access to Clinical Information, have not yet been addressed by this Interoperability Specification. These gaps relate mostly to:

- Scenario 2: Provider Lists and permissions. It is important to note that this Interoperability Specification provides a level of Security and Privacy but not with the detailed control as expected in Scenario 2
- Scenario 3: Transfer of PHR Information. It is important to distinguish the transfer of PHR information on Networks, which is within the scope of this Interoperability Specification, from the transfer of PHR Information on portable Media which is addresses by a companion Interoperability Specification, HITSP/IS05 Consumer Empowerment and Access to Clinical Information via Media

These gaps relate to a number of more advanced interoperability capabilities that require the availability of standards under development. For a detailed discussion of these gaps, see Section 4.2.1.

## 2.2 USE CASE REQUIREMENTS

This section describes the Use Case requirements and outlines all the given scenarios at a high level.

This document specifies three scenarios flows to satisfy the harmonized Use Cases:

### 1. Consumer creates account to host and access registration summary and clinical information





This first scenario defines the flow for a consumer to create their account; obtain registration summary and healthcare summary data (including medication and other clinical data) and laboratory reports; access, view and generate new data through a PHR system.

**Important Note:** *This Scenario combines:*

- *Scenario 1: Consumer creates account to host registration summary & medication history from the Consumer Empowerment Use Case (Events and Action starting with a number “2”)*
- *Parts of Scenario 1: Consumers Receive and Access Clinical Information from the Consumer Access to Clinical Information Use Case (Events and Action starting with a number “6”)*

Events and Actions as well as Perspectives from the two Use Cases have been matched as closely as possible, but as the two Use Cases are not aligned in their conventions and vocabulary, the “intent” of each Use Case has been preserved as well as possible.

## **2. Consumer visits healthcare provider and provides registration summary and clinical information**

This second scenario defines the flow for a consumer to log onto their account, obtain registration summary and clinical data, allow a healthcare provider to review this data and update their EHR system.

**Important Note:** *This Scenario combines:*

- *Scenario 2: (Consumer visits healthcare provider and provides registration summary information from the Consumer Empowerment Use Case (Events and Action starting with a number “2”)*
- *Parts of Scenario 1: Consumers Receive and Access Clinical Information from the Consumer Access to Clinical Information Use Case (Events and Action starting with a number “6”)*

Events and Actions as well as Perspectives from the two Use Cases have been matched as closely as possible, but as the two Use Cases are not aligned in their conventions and vocabulary, the “intent” of each Use Case has been preserved as well as possible.

In addressing this second scenario, HITSP has ensured that the most up-to-date and complete information may be provided from the provider electronic health record (EHR) systems back to the consumer PHR. Such an extension to the Consumer Empowerment Use Case is simply supported by recommending that at the end of a healthcare encounter the new registration/healthcare summary data are communicated to the PHR system (e.g. via a document repository/registry). The importance of such an extension is illustrated in this example:

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 has not yet processed the new medication (e.g. the night before) and published it to GM-HIN. If the emergency department did not send 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 display 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 (or other clinical and laboratory data) summary but it is not guaranteed by this specification (policies and appropriate applications are needed).

### 3. Authorized Healthcare Provider reviews registration summary and clinical information

This third scenario defines the flow for a consumer to log onto their account, obtain registration summary and clinical and laboratory data, allow a healthcare provider to review this data.

Important Note: This Scenario combines:

- Scenario 3: Authorized Healthcare Provider reviews medication history from the Consumer Empowerment Use Case (Events and Action starting with a number “2.”)
- Parts of Scenario 1: Consumers Receive and Access Clinical Information from the Consumer Access to Clinical Information Use Case (Events and Action starting with a number “6.”).

Events and Actions as well as Perspectives from the two Use Cases have been matched as closely as possible, but as the two Use Cases are not aligned in their conventions and vocabulary, the “intent” of each Use Case has been preserved as best as possible.

#### 2.2.1 MAPPING OF USE CASE ACTIONS TO INFORMATION EXCHANGE REQUIREMENTS

Section 6.2 contains the perspectives, scenarios, and events from the Use Case. This section maps these events and actions to extracted Information Exchange Requirements (IER), and Data Requirements (DR) that are described in Section 2.2.2. An Information Exchange Requirements (IER) describes a requirement for information exchange between HITSP Business Actors. Data Requirements (DR) define requirements for part, or all, of the data exchanged by one or more IERs. The DR's are defined as a set of information attributes with specific details for each attribute. IER's and DR's form the basis for the construct requirements of the Interoperability Specification that are described in Section 3.

#### 2.2.2 DATA AND INFORMATION EXCHANGE REQUIREMENTS

This section contains an extraction of data and information requirements (Table 2.2.2-1) and information exchange requirements (Table 2.2.2-2).

Table 2.2.2-1 provides the data requirement numbers, requirement descriptions, and a listing of the actual data elements and information that meet the data requirements. These requirements are referenced from the Data Requirements column of the Use Case Mapping Table 2.2.1-1 provided in Section 6.2.

**Table 2.2.2-1 Table and Information Requirements Matrix**

| Data Requirement Number (DR) | Description  |
|------------------------------|--|
| DR01                         | Demographic data: Consumer identification data including (but not limited to): |



| Data Requirement Number (DR) | Description   |  |
|------------------------------|---|--|
|                              | <ul style="list-style-type: none"> <li>Name</li> <li>Unique identifier</li> <li>Race</li> <li>Ethnicity</li> <li>Occupation</li> </ul>  | Consumer Demographic Information (DOB, age, gender, resident zip code, state of residence)   |
| DR02                         | Patient clinical information: Patient clinical summary, including (but not limited to):   |  |
|                              | <ul style="list-style-type: none"> <li>Advance Directive</li> <li>Allergy/Drug Sensitivity</li> <li>Comment</li> <li>Condition</li> <li>Encounter</li> <li>Healthcare Provider</li> <li>Immunization</li> <li>Information Source</li> <li>Insurance Provider</li> </ul> | <ul style="list-style-type: none"> <li>Insurance Provider</li> <li>Language Spoken</li> <li>Medication – Prescription and Non-Prescription</li> <li>Person Information</li> <li>Pregnancy</li> <li>Procedure</li> <li>Support</li> <li>Vital Sign</li> </ul> |
| DR03                         | Clinical History: Patient clinical history is provided Including (but not limited to):  |  |
|                              | <ul style="list-style-type: none"> <li>History of specific disorder</li> <li>Environmental exposure data</li> <li>Any prior treatment for specific disorders</li> </ul>   | <ul style="list-style-type: none"> <li>Relevant non-genetic laboratory test and pathology data</li> <li>Other clinical data such as radiology study results</li> <li>Family history information</li> </ul>   |
| DR04                         | Personal Genetic/Genomic Information. Personal Genetic/genomic information including (but not limited to):  |  |
|                              | <ul style="list-style-type: none"> <li>Prior genetic/genomic laboratory test results</li> <li>Full genome scan: deoxyribonucleic acid (DNA)</li> </ul>  | <ul style="list-style-type: none"> <li>Prior genetic status for specific disease</li> <li>Risk Analysis relative to family history</li> </ul>  |
| DR05                         | Family Genetic/Genomic Information: Family Genetic/genomic information including (but not limited to):  |  |
|                              | <ul style="list-style-type: none"> <li>Genetic/genomic data of family members</li> <li>Pedigree in structured form when appropriate</li> </ul>  | <ul style="list-style-type: none"> <li>History of consanguinity</li> <li>Consent/access allowance information</li> </ul>   |
| DR08                         | Unstructured Data: Unstructured data, including (but not limited to):   |  |
|                              | <ul style="list-style-type: none"> <li>Unstructured Documents (see HITSP/C62 - Unstructured Document)</li> <li>Entry-level support of advance directive documents.</li> </ul>   |  |
| DR27                         | Message Routing and Content/Envelope/Metadata of the secure message: Metadata should include (but are not limited to):  |  |



| Data Requirement Number (DR) | Description   |  |
|------------------------------|---|--|
|                              | <ul style="list-style-type: none"> <li>• Patient ID and basic demographics</li> <li>• Class of Document</li> <li>• Document Type</li> <li>• Source Care-Setting/Specialty</li> <li>• Date/time</li> <li>• Format/MIME Type</li> </ul>   | <ul style="list-style-type: none"> <li>• Source identifier</li> <li>• Entry identifier</li> <li>• Date of original datum</li> <li>• Last update date</li> <li>• Updated by identifier(s)</li> </ul>  |
| DR29                         | Read/delivery confirmation: Read and/delivery receipt data are provided, including (but not limited to):  |  |
|                              | <ul style="list-style-type: none"> <li>• Read Receipt Request</li> <li>• Delivery Receipt Request</li> <li>• Read/Delivery Date/Time</li> </ul>   |  |
| DR66                         | Diagnosis Codes: Diagnosis Codes are provided, data elements include (but are not limited to):  |  |
|                              | <ul style="list-style-type: none"> <li>• Patient Class (outpatient, inpatient, and ER (UHDDS))</li> <li>• Diagnosis/Injury Code (ICD 9/10)</li> <li>• Diagnosis Type (UHDDS)</li> <li>• Diagnosis Date and Time (UHDDS)</li> <li>• Date/time of first symptoms</li> </ul>   | <ul style="list-style-type: none"> <li>• Discharge Disposition (UHDDS)</li> <li>• Chief Complaint (ICD9/10)</li> <li>• Date/time of first symptoms of illness (UHDDS)</li> <li>• Identity of diagnosing provider or institution</li> <li>• Diagnostic procedure(s)</li> <li>• HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD) Section 4.2.3.1.7</li> </ul> |
| DR67                         | Allergies/Medication Allergies: Ability for consumer to retrieve and store lists of current medication, environmental, dietary or medical supply allergies. Data elements include (but are not limited to):   |  |
|                              | <ul style="list-style-type: none"> <li>• Allergy type</li> <li>• Date/time of first symptoms</li> </ul>   | <ul style="list-style-type: none"> <li>• HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD) Section 4.2.3.1.6</li> </ul>  |
| DR68                         | Structured information request  |  |
|                              | <ul style="list-style-type: none"> <li>• Information Service Identifier</li> <li>• Requested information type</li> <li>• Patient (target) identification</li> <li>• Requested information parameters (date range, limiting criteria)</li> <li>• Requestor authentication and authorization information</li> </ul> | <ul style="list-style-type: none"> <li>• Type of request: One time request, notification request, subscription request</li> <li>• Request active dates (how long to continue request)</li> </ul>   |
| DR69                         | Context-aware Information Retrieval Message. Data elements include:   |  |



| Data Requirement Number (DR) | Description   |  |
|------------------------------|---|--|
|                              | <p>InformationEventNotification Relationships</p> <ul style="list-style-type: none"> <li>MainSearchCriteria <ul style="list-style-type: none"> <li>SeverityObservation class:</li> </ul> </li> <li>SubTopic</li> <li>TaskContext</li> </ul> <p>PerformerChoice Relationship</p> <ul style="list-style-type: none"> <li>LanguageCommunication</li> </ul> <p>InformationEventNotification class</p> <ul style="list-style-type: none"> <li>InfobuttonEventNotification.id</li> </ul> <p>InfobuttonEventNotification.effectiveTime</p> | <p>InformationEventNotification Participants</p> <ul style="list-style-type: none"> <li>AssignedEntity <ul style="list-style-type: none"> <li>username</li> <li>certificateText</li> <li>Organization</li> <li>Organization.id</li> <li>AuthorizedPerson</li> </ul> </li> <li>PatientContext <ul style="list-style-type: none"> <li>PatientPerson.administrativeGenderCode</li> </ul> </li> <li>PerformerChoice: Patient or HealthCareProvider</li> <li>Age</li> <li>AgeGroup</li> </ul> |
| DR70                         | Information Source identification data: These include (but are not limited to):   |  |
|                              | <ul style="list-style-type: none"> <li>URL</li> <li>Service Provider</li> </ul>   | <ul style="list-style-type: none"> <li>Service Type (e.g., laboratory, pharmacy, healthcare entity, etc)</li> </ul>  |
| DR71                         | Change request data: Send request to change data including (but not limited to):  |  |
|                              | <ul style="list-style-type: none"> <li>Information source identifier</li> <li>Consumer identifier</li> <li>Original entry identifier</li> <li>Data enterer identification/authorization information</li> </ul>  | <ul style="list-style-type: none"> <li>Annotation/change request information (relate to standard clinical content structures)</li> <li>Rational for change request (free text?)</li> <li>Requestor contact information</li> </ul>  |
| DR73                         | Provider Identification: Provider identification, location, details including (but not limited to):   |  |
|                              | <ul style="list-style-type: none"> <li>Provider demographic data (Name, Location, Specialty, Location, Contact Information)</li> <li>Superset of HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD) &amp; C37 - Lab Report Document provider identification, and additional elements as needed for entity resolution</li> </ul>  |  |
| DR74                         | Access Control Lists: Data elements include (but are not limited to):   |  |
|                              | <ul style="list-style-type: none"> <li>Identification of entity being authorized</li> <li>Identification of entity granting authorization/test results, etc.)</li> </ul>  | <ul style="list-style-type: none"> <li>Type of authorization (read/no-read, write/no-write, etc)</li> <li>Criteria defining the application of the authorization (e.g., document type, procedure)</li> </ul>   |
| DR75                         | Access log summary  |  |
|                              | <ul style="list-style-type: none"> <li>Access log information, available in both summary and detail format:</li> <li>What information was accessed</li> <li>Who accessed the information</li> </ul>   | <ul style="list-style-type: none"> <li>When was the information accessed</li> <li>Stated purpose for the access</li> <li>Override criteria, if applicable (e.g., "break-glass")</li> </ul>   |
| DR100                        | Lab Report Document   |  |
|                              | <ul style="list-style-type: none"> <li>Uses IHE-Lab TF</li> </ul>   | <ul style="list-style-type: none"> <li>LOINC codification for laboratory tests</li> </ul>  |
|                              | <ul style="list-style-type: none"> <li>Alternatively to LOINC, other coding schemes, national or international (like SNOMED) may also be used</li> </ul>  | <ul style="list-style-type: none"> <li>Tests on in-vitro specimens, including microbiology and blood bank testing (e.g. ABO group) [Note: Anatomic Pathology reports are not included at this time]</li> </ul>   |



Table 2.2.2-2 below contains an extraction of the Information Exchange Requirements from the Use Case. These requirements are referenced from the Information Exchange Requirements column of the Use Case Mapping Table 2.2.1-1 provided in Section 6.2.

**Table 2.2.2-2 Information Exchange Requirements (IER)**

| Information Exchange Requirement Number (IER) | Description   |
|---|---|
| IER 1   | <b>Provide authorization and consent</b> System authenticates user and verifies authorization.  |
| IER 3   | <b>Create audit log entry</b> The system creates log of actions and events  |
| IER 5   | <b>Verify entity identity</b>   |
| IER 8   | <b>Generate a delivery--receipt</b> On request the system generates a message that document/message was delivered   |
| IER 10  | <b>Identify patient</b> Identification of Patient (Registry Patient Id/Id Domain OID) -Leverage Entity Identity Assertion HITSP/C19 {Authenticate Consumers-Partial Gap} Patient  |
| IER 11  | <b>Identify provider based on patient preference</b> Provider Demographics Query  |
| IER 21  | <b>Receive updated clinical information</b> The PHR system receives updated clinical information once available   |
| IER 23  | <b>Request/provide additional information</b> Send/receive a request for additional information, or send/receive additional information in unstructured format.   |
| IER 28  | <b>Download historical health data</b> The system receives and stores any historical data that are now available  |
| IER 38  | <b>Query/retrieve document set</b> The system queries and retrieves patient's clinical/health data including health records, documents etc. Standardized information {direct reuse of HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD) and HITSP/C37 - Lab Report Document, HITSP/C35 - Lab Result Terminology |
| IER 42  | <b>Request/receive medical concept knowledge</b>  |
| IER 43  | <b>Send/Receive accept patient</b> Send/Receive query/response if the patient can be accepted.  |
| IER 61  | <b>Provide and Register Document Set</b> A global unique document ID must be included. Must be able to update a previously submitted record. A unique patient ID must be associated with the summary data.  |
| IER 63  | <b>Request additional patient data</b> Request for additional patient information   |
| IER 68  | <b>Identify PHR Location</b> Identification of PHR Service/PHR instance   |
| IER 69  | <b>Authorize release of information</b>   |
| IER 72  | <b>Send/receive audit log</b> The system sends/receives a log of all actions and event logged.  |
| IER 73  | <b>Request/receive provider information</b>   |
| IER 74  | <b>Access/Select provider information</b>   |
| IER 75  | <b>Designate provider permissions</b> Identify those providers who will have access to the consumer's PHR   |
| IER 76  | <b>Request modification to clinical data</b>  |
| IER 77  | <b>Identification of information sources</b>  |

### 2.2.3 IDENTIFICATION OF BUSINESS ACTORS, MAPPED TO REQUIREMENTS

This section describes the Business Actors that impact information exchange requirements for each scenario. A Business Actor is an abstraction that is instantiated as an IT system application that a



Stakeholder uses in the exchange of data needed to complete Use Case action(s); a Business Actor is not a Stakeholder. A HITSP Stakeholder is a person, organization or “personified system” that performs actions in a Use Case. Only Business Actors as an IT system are directly engaged and benefit from the real world information exchange defined within a business Use Case action. Only Business Actors are associated with Technical Actors, which support the data exchanges of the Business Actors (see Section 3.2 for Technical Actors). The table below identifies the significant Use Case Business Actors, their descriptions, the Stakeholders they support, the Use Case scenarios, and the information exchange or data requirements for which they are used. Refer to the Use Case for a more detailed description of the listed stakeholders.

Other business actors not explicitly mentioned may be able to benefit from this Interoperability Specification. NOTE: While Pharmacies and Pharmacy Benefits Managers (PBMs) systems 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 2.2.3-1 Business Actors**

| Business Actor                        | Description  | Supported Stakeholders | Use Case Scenario   | Information Exchange Requirement Numbers (IER)  | Data Requirement Numbers (DR)   |
|---------------------------------------|--|------------------------|---|---|---|
| Electronic Health Record (EHR) System | The Electronic Health Record (EHR) System is a secure, real-time, point-of-care, patient-centric information resource for clinicians | Providers              | <p>Consumer Empowerment</p> <p>Consumer Access to Clinical Information</p> <p>Scenarios:</p> <p>(1) Consumer Creates Account to Host and Access Registration Summary and Clinical Information</p> <p>(2): Consumer visits Healthcare Provider and Provides Registration Summary information and Clinical Information</p> <p>Provider Permissions and Lists</p> <p>(3): Authorized Healthcare Provider Reviews Registration Summary and Other Clinical Information</p> | <p>IER 1 Provide authorization and consent</p> <p>IER 3 Create audit log entry</p> <p>IER 5 Verify entity identity</p> <p>IER 8 Generate a delivery receipt</p> <p>IER 10 Identify patient</p> <p>IER 21 Receive updated clinical information</p> <p>IER 23 Request/provide additional information</p> <p>IER 28 Download historical health data</p> <p>IER 38 Query/retrieve document set</p> <p>IER 42 Request/receive medical concept knowledge</p> <p>IER 43 Send/Receive accept patient</p> <p>IER 61 Provide and register document set</p> <p>IER 63 Request additional patient data</p> <p>IER 72 Send/receive audit log</p> | <p>DR01 Demographic data</p> <p>DR02 Patient clinical summary</p> <p>DR03 Clinical History</p> <p>DR04 Personal Genetic/Genomic Information</p> <p>DR05 Family Genetic/Genomic Information</p> <p>DR08 Unstructured Data</p> <p>DR27 Message Routing and Content/Envelope/Metadata of the secure message</p> <p>DR29 Read/delivery confirmation</p> <p>DR38 Health plan authorization</p> <p>DR66 Diagnosis Codes</p> <p>DR67 Allergies/Medication Allergies</p> <p>DR68 Structured</p> |





| Business Actor          | Description  | Supported Stakeholders            | Use Case Scenario  | Information Exchange Requirement Numbers (IER)   | Data Requirement Numbers (DR)  |
|-------------------------|--|-----------------------------------|--|--|--|
|                         |  |                                   |  | IER 68 Identify PHR Location<br>IER 76 Request modification to clinical data   | information request<br>DR70 Information Source identification data<br>DR71 Change request data<br>DR100 Lab Report Document  |
| Infrastructure Services | Infrastructure Services is a multi-stakeholder system 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 | Health Information Exchange (HIE) | Consumer Empowerment<br>Consumer Access to Clinical Information<br>Scenarios:<br>(1) Consumer Creates Account to Host and Access Registration Summary and Clinical Information<br><br>(2): Consumer visits Healthcare Provider and Provides Registration Summary information and Clinical Information<br><br>(3): Authorized Healthcare Provider Reviews Registration Summary and Other Clinical Information | IER 1 Provide authorization and consent<br>IER 3 Create audit log entry<br>IER 5 Verify entity identity<br>IER 10 Identify patient<br>IER 23 Request/provide additional information<br>IER 38 Query/retrieve document set<br>IER 42 Request/receive medical concept knowledge<br>IER 43 Send/Receive accept patient<br>IER 61 Provide and register document set<br>IER 72 Send/receive audit log<br>IER 68 Identify PHR Location | DR01 Demographic data<br>DR02 Patient clinical summary<br>DR03 Clinical History<br>DR04 Personal Genetic/Genomic Information<br>DR05 Family Genetic/Genomic Information<br>DR08 Unstructured Data<br>DR27 Message Routing and Content/Envelope/Metadata of the secure message<br>DR29 Read/delivery confirmation<br>DR66 Diagnosis Codes<br>DR67 Allergies/Medication Allergies<br>DR68 Structured information request<br>DR70 Information Source identification data<br>DR71 Change request data<br>DR100 Lab Report Document |





| Business Actor            | Description  | Supported Stakeholders            | Use Case Scenario  | Information Exchange Requirement Numbers (IER)  | Data Requirement Numbers (DR)   |
|---------------------------|--|-----------------------------------|--|---|---|
| Health Plan System        | Systems used by health plans that include administrative and financial functions associated with the coverage and financing of healthcare for the health plan's enrolled members. These functions include information regarding the individual's enrollment, eligibility, coverage and benefits, authorizations, claims, care coordination and other information related to the member | Healthcare Payors<br>Health Plans | Consumer Empowerment<br>Consumer Access to Clinical Information<br>Scenarios:<br>(1) Consumer Creates Account to Host and Access Registration Summary and Clinical Information | IER 1 Provide authorization and consent<br>IER 3 Create audit log entry<br>IER 5 Verify entity identity<br>IER 10 Identify patient<br>IER 23 Send/receive additional test results<br>IER 31 Provide message routing/description information<br>IER 33 Send/receive message<br>IER 42 Request/receive medical concept knowledge<br>IER 43 Send/Receive accept patient<br>IER 72 Send/receive audit log<br>IER 68 Identify PHR Location | DR01 Demographic data<br>DR02 Patient clinical summary<br>DR03 Clinical History<br>DR04 Personal Genetic/Genomic Information<br>DR05 Family Genetic/Genomic Information<br>DR08 Unstructured Data<br>DR27 Message Routing and Content/Envelope/Metadata of the secure message<br>DR29 Read/delivery confirmation<br>DR66 Diagnosis Codes<br>DR67 Allergies/Medication Allergies<br>DR68 Structured information request<br>DR70 Information Source identification data<br>DR71 Change request data |
| Knowledge Resource System | The consumer knowledge resource system is a resource that is capable of providing consumer friendly medical knowledge to the PHR system on request   | Consumer Providers<br>Pharmacist  | Consumer Empowerment<br>Consumer Access to Clinical Information<br>Scenarios:<br>(1) Consumer Creates Account to Host and Access Registration Summary and Clinical Information | IER 42 Request/receive medical concept knowledge  | DR69 Context-aware Information Retrieval Message  |



| Business Actor                       | Description  | Supported Stakeholders | Use Case Scenario   | Information Exchange Requirement Numbers (IER)   | Data Requirement Numbers (DR)  |
|--------------------------------------|--|------------------------|---|--|--|
| Personal Health Record (PHR) Systems | A healthcare record system used to create, review, annotate and maintain records by the patient or the caregiver for a patient. The PHR may include any aspect(s) of the health condition, medications, medical problems, allergies, vaccination history, visit history or communications with healthcare providers. | Consumer               | <p>Consumer Empowerment</p> <p>Consumer Access to Clinical Information</p> <p>Scenarios:</p> <p>(1) Consumer Creates Account to Host and Access Registration Summary and Clinical Information</p> <p>(2) Consumer visits Healthcare Provider and Provides Registration Summary information and Clinical Information</p> <p>Provider Permissions and Lists</p> <p>(3) Authorized Healthcare Provider Reviews Registration Summary and Other Clinical Information</p> | <p>IER 3 Create audit log entry</p> <p>IER 8 Generate a delivery receipt</p> <p>IER 10 Identify patient</p> <p>IER 11 Identify provider based on patient preference</p> <p>IER 21 Receive updated clinical information</p> <p>IER 23 Request/provide additional information</p> <p>IER 28 Download historical health data</p> <p>IER 38 Query/retrieve document set</p> <p>IER 42 Request/receive medical concept knowledge</p> <p>IER 43 Send/Receive accept patient</p> <p>IER 61 Provide and register document set</p> <p>IER 68 Identify PHR Location</p> <p>IER 72 Send/receive audit log</p> <p>IER 73 Request/receive provider information</p> <p>IER 74 Access/Select provider information</p> <p>IER 75 Designate provider permissions</p> <p>IER 76 Request modification to clinical</p> <p>IER 77 Identify information sources data</p> | <p>DR01 Demographic data</p> <p>DR02 Patient clinical summary</p> <p>DR03 Clinical History</p> <p>DR04 Personal Genetic/Genomic Information</p> <p>DR05 Family Genetic/Genomic Information</p> <p>DR08 Unstructured Data</p> <p>DR27 Message Routing and Content/Envelope/Metadata of the secure message</p> <p>DR29 Read/delivery confirmation</p> <p>DR66 Diagnosis Codes</p> <p>DR67 Allergies/Medication Allergies</p> <p>DR68 Structured information request</p> <p>DR69 Context-aware Information Retrieval Message</p> <p>DR70 Information Source identification data</p> <p>DR71 Change request data</p> <p>DR73 Provider identification</p> <p>DR74 Access Control Lists</p> <p>DR75 Access log summary</p> |



| Business Actor                     | Description  | Supported Stakeholders    | Use Case Scenario  | Information Exchange Requirement Numbers (IER)  | Data Requirement Numbers (DR)   |
|------------------------------------|--|---------------------------|--|---|---|
| Pharmacy Benefit Management System | Systems used by entities that manage pharmacy benefits on behalf of Payers via a Medication Network Intermediary. They can provide information on pharmacy benefits available for an individual consumer, as well as the individual consumer's | Pharmacy Benefit Managers | Consumer Empowerment<br>Consumer Access to Clinical Information<br>Scenarios:<br>(1) Consumer Creates Account to Host and Access Registration Summary and Clinical Information | IER 1 Provide authorization and consent<br>IER 3 Create audit log entry<br>IER 5 Verify entity identity<br>IER 10 Identify patient<br>IERR 23 Send/receive additional test results<br>IER 43 Send/Receive accept patient<br>IER 68 Identify PHR Location<br>IER 72 Send/receive audit log | DR01 Demographic data<br>DR02 Patient clinical summary<br>DR03 Clinical History<br>DR04 Personal Genetic/Genomic Information<br>DR05 Family Genetic/Genomic Information<br>DR08 Unstructured Data<br>DR29 Read/delivery confirmation<br>DR66 Diagnosis Codes<br>DR67 Allergies/Medication Allergies<br>DR68 Structured information request<br>DR70 Information Source identification data<br>DR71 Change request data |



| Business Actor                | Description   | Supported Stakeholders | Use Case Scenario  | Information Exchange Requirement Numbers (IER)   | Data Requirement Numbers (DR)   |
|-------------------------------|---|------------------------|--|--|---|
| Pharmacy Systems - (External) | Electronic systems that support pharmacists in their role for dispensing medications. This includes systems that may be able to provide useful information on consumers' past medication histories. These systems exist outside of an organization. | Pharmacists            | Consumer Empowerment<br>Consumer Access to Clinical Information<br>Scenarios:<br>(1) Consumer Creates Account to Host and Access Registration Summary and Clinical Information | IER 1 Provide authorization and consent<br>IER 3 Create audit log entry<br>IER 5 Verify entity identity<br>IER 10 Identify patient<br>IER 23 Request/provide additional information<br>IER 43 Send/Receive accept patient<br>IER 68 Identify PHR Location<br>IER 72 Send/receive audit log | DR01 Demographic data<br>DR02 Patient clinical summary<br>DR03 Clinical History<br>DR04 Personal Genetic/Genomic Information<br>DR05 Family Genetic/Genomic Information<br>DR08 Unstructured Data<br>DR29 Read/delivery confirmation<br>DR66 Diagnosis Codes<br>DR67 Allergies/Medication Allergies<br>DR68 Structured information request<br>DR70 Information Source identification data<br>DR71 Change request data |

These business actors are identified as separate actors in the various scenario actor Transactions descriptions below in Section 3.2.1 and 3.2.2. This descriptive approach does not prevent business actors from being grouped in a variety of ways. A number of such implementation variants are depicted in Sections 3.2.2 to illustrate in part the architecture flexibility provided by this Interoperability Specification.

#### 2.2.4 HIGH-LEVEL DIAGRAMS

This section contains diagrams that describe the relationships and data interactions between the primary and alternative business actors and stakeholders for each Use Case scenario.

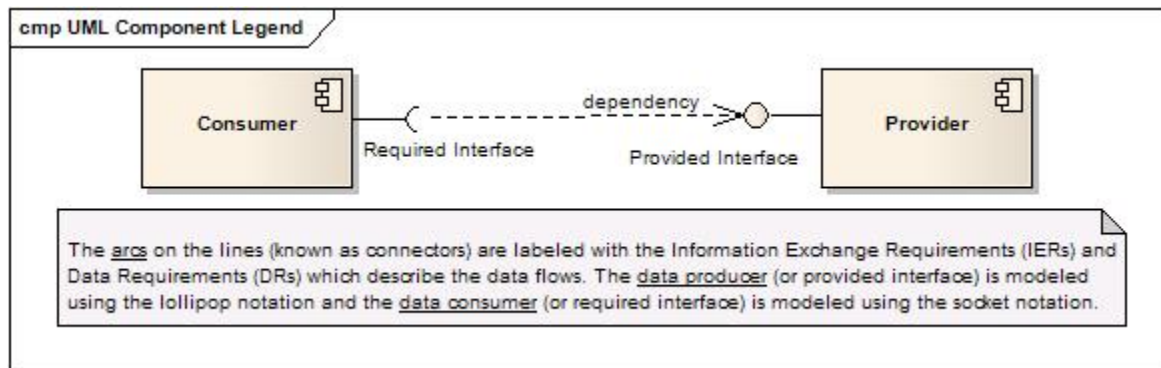
High level Sequence diagrams are provided in Section 6.3 that illustrate each Use Case scenario with a representation of a normal sequence of exchange between the primary actors. The interactions are supported by the various constructs which will be introduced in Section 3 of this Interoperability Specification.

The figures below are Component Data Flow diagrams that illustrate the data flow and information exchanges between the primary HITSP Business Actors. The information exchange and data requirement



numbers from tables in Section 2.2.2 are annotated on the diagrams to show how the requirements relate to the primary actors. The in-scope requirements are supported by constructs which will be introduced in Section 3 of this Interoperability Specification. Figure 2.2.4-1 is a legend for reading the Component Data Flow diagrams.

**Figure 2.2.4-1 Legend for Component Diagrams**



The diagram illustrates the Consumer Empowerment and Access to Clinical Information via Networks Component Diagram. It shows the flow of information between various systems:

- Health Plan System** (Left): Contains IERs 1, 3, 5, 10, 23, 18, 31, 33, 42, 43, 72, 68. It connects to the HIE via IERs 1, 3, 5, 10, 23, 18, 31, 33, 42, 43, 72, 68.
- Health Information Exchange (HIE)** (Center): Acts as a central hub, connecting to all other systems. It contains IERs 1, 3, 5, 10, 23, 18, 31, 33, 42, 43, 72, 68.
- Infrastructure Services** (Center): Provides underlying services to the HIE. It contains IERs 1, 3, 5, 10, 23, 18, 31, 33, 42, 43, 72, 68.
- Electronic Health Record (EHR) System** (Right): Contains IERs 1, 3, 5, 8, 10, 18, 21, 23, 28, 38, 42, 43, 61, 63, 72, 68, 76. It connects to the HIE via IERs 1, 3, 5, 8, 10, 18, 21, 23, 28, 38, 42, 43, 61, 63, 72, 68, 76.
- Pharmacy Benefit Management System** (Left): Contains IERs 1, 3, 5, 10, 23, 18, 43, 68, 72. It connects to the HIE via IERs 1, 3, 5, 10, 23, 18, 43, 68, 72.
- Personal Health Record (PHR) System** (Left): Contains IERs 8, 10, 11, 18, 21, 23, 28, 38, 42, 43, 61, 68, 72, 73, 74, 75, 76, 77, 3. It connects to the HIE via IERs 8, 10, 11, 18, 21, 23, 28, 38, 42, 43, 61, 68, 72, 73, 74, 75, 76, 77, 3.
- Pharmacy Systems - (External)** (Right): Contains IERs 1, 3, 5, 10, 23, 18, 43, 68, 72. It connects to the HIE via IERs 1, 3, 5, 10, 23, 18, 43, 68, 72.
- Knowledge Resource System** (Right): Contains IERs 42. It connects to the HIE via IER 42.

The diagram uses various symbols (circles, triangles, rectangles) to represent different types of information exchange (IER) and data flow.



## 3.0 DESIGN

The design for the Interoperability Specification is the result of the requirements analysis and iterative standards selection process. This section describes the design based on the specified Business Actors and their Information Exchange and Data Requirements. It provides a detailed mapping of the specified requirements to HITSP constructs and their Technical Actors, groupings of specific Technical Actors which support Business Actors are specified to further describe the relevant interactions from existing or new HITSP constructs required for interoperability.

### 3.1 SCOPE OF DESIGN

This section describes the scope of the design as it relates to the requirements for this Use Case that were identified in Section 2.2 above. The scope identifies the assumptions that provide the boundaries for the specification and the constraints that limit the use of the specification. In addition, any pre-conditions, post-conditions and triggers that underlie the interactions between the various actors, data and transactions are provided.

Considering the relationship to previous constructs, known gaps, potential activities by standards development organizations (SDOs), and other initiatives that are either in-progress or pending results that might impact the Interoperability Specification development, the Use Cases were broken down in high-level Work Items to one of two Work Sets.

- Addressed by this update to this Interoperability Specification HITSP/IS03 Consumer Empowerment and Access to Clinical Information via Networks and the new HITSP/IS05 Consumer Empowerment and Access to Clinical Information via Media shown in table below
- Gaps to be addressed during next year's HITSP cycle shown in Table 4.2.1

**Table 3.1-1 Scoping**

| Work Items  | Work Set  | Reason for Classification Result   |
|---|---|--|
| LAB/Results-to-PHR-to-other using lab report document   | Addressed by this update to IS03 and the new IS05 | Reference existing HITSP/C37 - Lab Report Document for inclusion of complete lab reports into a PHR  |
| LAB/Results-to-PHR-to-other using structured elements in registration/medication history document | Addressed by this update to IS03 and the new IS05 | Extend HITSP/C32 artifact with a lab results section for inclusion of selected lab results extracts. Subset of CDA structure in HITSP/C37 - Lab Report Document  |
| Allergies, Conditions, Immunizations, Health Problems and Diagnosis Codes                         | Addressed by this update to IS03 and the new IS05 | Extend HITSP/C32 artifact with relevant sections.  |
| PHR Portability – using portable media  | Addressed by this update to IS03 and the new IS05 | Given lack of a strong source attestation on media construct, media usage may be restricted by policy to single consumer health information in a number of environments. In some environments consumer and dependents health information may be allowed on the same portable media (up to a certain age) |





### 3.1.1 ASSUMPTIONS

This section provides an overview of the assumptions, including the circumstances, actors, policies and/or technologies that need to be in place for the design to be completed as specified. Assumptions are different from constraints which are specifically used to narrow the definition, or indicate limitations of the specified interactions.

**Table 3.1.1-1 Assumptions**

| Assumption  | Use Case Scenario                            |
|---|--|
| Regarding provider-specified restrictions to clinical information, either<br>(1) Providers do not have the option of limiting the consumer's access to clinical information that directly relates to that consumer, or,<br>(2) The specification, interoperability requirements, and policy considerations of such restrictions are outside the scope of this Use Case                          | Consumer Access to Clinical Information/1    |
| Although the Use Case is focused on the Information Transfer from one PHR to another, HITSP has opted to ensure that the constructs produced not only support the Use Case but other Use Cases where the interchange takes place between a PHR and an EHR or between two EHRs   | Consumer Access to Clinical Information/3    |
| Regarding statutory limitations on a consumer's access to clinical information:<br>(1) Statutory and policy considerations are beyond the scope of this Use Case<br>(2) Unless precluded by statute, the consumer shall be informed (via the PHR) of the existence and unavailability of the document per statute. Consumer escalation procedures should be available, at minimum, by reference | Consumer Access to Clinical Information/1    |
| Consumers have access to appropriate identification information for Information Sources and Recipients, and Providers   | Consumer Access to Clinical Information/1, 2 |
| If an advance directive document is stored in a PHR (or in a document repository used by a PHR), it is assumed that the appropriate measures are taken to ensure persistence and non-repudiation  | Consumer Access to Clinical Information/2, 3 |
| There is no regulatory roadblock to the transmission of personal health information from the PHR to other entities and that all exchanges between the PHR and clinical entities are properly handled by the appropriate business rules by the PHR provider.   | Consumer Access to Clinical Information/2    |
| The present scope limits the translation of clinical information using coded concepts only. Free-text queries are not supported at this time.   | Consumer Access to Clinical Information/2    |
| The system is agnostic to the medical knowledge returned/displayed. The system does not prescribe the knowledge content of the message returned but provides the query for, and receipt of, requested knowledge.  | Consumer Access to Clinical Information/2    |
| The context-specific parameters regarding the request for medical knowledge may include consumer knowledge level, preferred language, consumer demographics (gender, age), document type (laboratory results, radiology reports). If these parameters are known, these could be used to tailor the response and the medical knowledge returned.   | Consumer Access to Clinical Information/2    |

### 3.1.2 CONSTRAINTS

This section describes the constraints that limit the context in which the Interoperability Specification may be used. A constraint describes a rule that limits the use of the actors, actions or data within the given context, or to which the interactions must conform to be used within the described context. It is a





description of the limits and scope of the interactions and can describe actions or events that are not part of the initial definition for the context.

**Table 3.1.2-1 Constraints**

| Constraint   | Use Case Scenario                           |
|--|---|
| Available HITSP constructs (i.e., HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD), HITSP/C35 - Lab Result Terminology and HITSP/C37 - Lab Report Document) do not support the entire range of potential information included in a PHR or clinical information that may be communicated to a PHR. This constrains the information that can be supported in the Interoperability Specification. Further extension to this as written does not address the notification of a change request rejection | Consumer Access to Clinical Information/All |
| The physician has an EHR capable of exporting media.   | Consumer Access to Clinical Information/1   |

### 3.1.3 PRE-CONDITIONS

This section describes the necessary conditions that must be in place prior to the start of each scenario. The pre-conditions are used to convey any conditions that must be true at the outset of a scenario. It describes the context that must be established before the scenario is executed. They are not however the triggers that initiate a Use Case. Where one or more pre-conditions are not met, the behavior of the Use Case should be considered uncertain.

**Table 3.1.3-1 Pre-conditions**

| Pre-condition  | Use Case Scenario |
|--|-------------------|
| 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:<br>methods to identify and authenticate users <ul style="list-style-type: none"> <li>a. Methods to identify and determine providers of care</li> <li>b. Methods to enforce data access authorization policies</li> <li>c. Methods to correctly match consumers/patients across systems</li> <li>d. Methods to identify and determine health insurers</li> <li>e. Methods to identify and determine pharmacy benefits managers (NOTE: pharmacy benefit information is obtained through NCPDP transactions)</li> <li>f. Methods to identify data sources including but not limited to provider EHR systems</li> </ul> | All               |
| Ability to identify and request corrections to errors is available   | All               |
| Ability to apply notes, corrections and comments on original entries is available  | All               |
| Appropriate standards are developed, approved, and widely adopted supporting data content and structure, allowing universal access by compliant systems  | All               |
| Core datasets are defined and adhered to   | All               |
| Authenticate consumers, designated caregivers, and health professionals for access to the consumer's PHR service providers   | All               |
| Method to query other organizations for data and matching to the consumer is available   | All               |
| Support the technical measures to ensure Security and Privacy of consumer/patient health information   | All               |



| Pre-condition  | Use Case Scenario |
|--|-------------------|
| Authentication service to authenticate requestors and/or data submissions from various locations   | All               |
| Security and Privacy policies, procedures and practices are commonly implemented to support acceptable levels of consumer/patient security and privacy   | All               |
| Legal and governance issues regarding data access authorizations, data ownership, and data use are in effect   | All               |
| Support the following HITSP Security and Privacy constructs:<br>HITSP/C19 – Entity Identity Assertion<br>HITSP/T16 - Consistent Time – Maintain time<br>HITSP/T17 - Secured Communication Channel – Authenticate node<br>HITSP/T15 - Collect and Communicate Security Audit Trail – Record audit event in repository<br>HITSP/TP30 - Manage Consent Directives – Capture/Request consent directive<br>HITSP/TP20 - Access Control – Access control request | All               |
| Appropriate consumer-friendly medical knowledge (e.g., translation or additional references) is available for the consumer to view   | All               |

In order to implement the information interchange conforming to this Interoperability Specification and its constructs in a real world environment, the implementer must ensure that the implementing systems operate within a secure infrastructure that ensures the privacy, integrity and availability of all individually identifiable health information as prescribed by the Health Insurance Portability and Accountability Act (HIPAA), 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 HITSP Consumer Empowerment and Access to Clinical Information via Networks Interoperability Specification requires that sharing of personal demographic data, healthcare summary, and laboratory reports is based on patient consent. The management of Patient Consent Directives is supported by this 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 and healthcare summary 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, laboratory results 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.



### 3.1.4 POST-CONDITIONS

This section provides an overview of the conditions or results that must occur at the end of each scenario in order for the scenario to be deemed successfully completed. This includes any required outputs from the scenario, or specific actor states.

**Table 3.1.4-1 Post-conditions**

| Post-condition  | Use Case Scenario |
|---|-------------------|
| The consumer's PHR is available to be accessed by the consumer and any persons/organizations that have been given consent by the consumer | All               |
| A consumer-friendly error message is displayed in the event of query failure  | All               |

### 3.1.5 PROCESS TRIGGERS

This section describes the triggers, including actors and/or processes, which are necessary to start any scenarios, actions or events. It can be an automatic or manual process or result that in turn starts off another scenario, action or event. A trigger is not the same as a pre-condition that describes a context that needs to be in place at the start of the event.

**Table 3.1.5-1 Process Triggers**

| Process Trigger   | Use Case Scenario   |
|---|---|
| The consumer decides to create a PHR  | Consumer Empowerment (Registration and Medication History)/1  |
| The consumer receives information from outside sources  | Consumer Empowerment (Registration and Medication History)/1<br>Consumer Access to Clinical Information/1 |
| The consumer decides to share PHR information with a care provider or another PHR   | Consumer Empowerment (Registration and Medication History)/2<br>Consumer Access to Clinical Information/3 |
| A consumer-authorized user elects to export health information  | Consumer Access to Clinical Information/3   |
| Automatic request: Based upon predefined parameters, the PHR system may initiate, a request for medical knowledge from the Knowledge Resource | Consumer Access to Clinical Information/2   |
| Manual request: The consumer may initiate a request for medical knowledge from the Knowledge Resource   | Consumer Access to Clinical Information/2   |

## 3.2 DETAILED DESIGN

This section provides a detailed description of the technical design, along with an analysis of the main interactions and decisions between all actors, actions and data in support of the specific requirements for each scenario of the Use Case. In addition, this section provides the data element details and an overview of the HITSP constructs used to meet the business and technical requirements for this Use Case. Any variances in the Security and Privacy implementation are also described here.



Note that with respect to Security and Privacy, local implementation policy as determined by risk assessment, including assessment of jurisdictional and regulatory requirements, will determine which assurance level of nonrepudiation of origin is needed. For instance, in document-based transmissions, a low level is offered by the basic use of HITSP/TP13 Manage Sharing of Documents construct. A medium level of assurance is offered by the use of the HITSP/TP13 construct option called "Document Integrity". A high level of assurance is offered by the use of the HITSP/C26 Nonrepudiation of Origin construct which requires the existence of a Public Key Infrastructure (PKI) (See TN900 for a discussion on the challenges with PKI's).

### 3.2.1 TECHNICAL ACTORS ROLE DESCRIPTIONS

This section identifies the Technical Actors used within the Interoperability Specification. Note that a Technical Actor represents an internal software component or IT system, which supports a specific aspect of a real world business information interchange (e.g., set of message exchanges). Technical Actors implement system data exchange transactions, which support real world Business Actor information interchanges (see Section 2.2.3 for Business Actor definitions). The table below identifies the Technical Actors and provides a description of the Technical Actor roles involved in the Interoperability Specification.

**Table 3.2.1-1 Technical Actor Role Descriptions**

| Technical Actor(s)          | Actor Role  | Construct  |
|-----------------------------|---|------------|
| Audit Record Repository     | The Audit Record Repository provides a repository for audit events. IHE does not specify what analysis and reporting features should be implemented for an audit repository   | HITSP/T15  |
| Audit Record Source         | The Audit Record Source is the actor that, on behalf of another actor that performs an action requiring logging, creates and communicates an Audit Record to the Audit Record Repository  | HITSP/T15  |
| Consent Directive Requester | The Consent Directive Requester access consent directive located through a Consent Registry from Consent Repositories. (lack of definition in current public comment version)   | HITSP/TP30 |
| Consent Originator          | The Consent Originator captures consent directives and may publish the consent directive as a document. It is responsible for sending Manage Consent Directive Requests to a Consent Repository. It also supplies Metadata to the Consent Repository for subsequent registration of the Consent within a Consent Registry   | HITSP/TP30 |
| Consent Registry            | The Consent Registry is responsible for providing location information and sender notification regarding consent directives. The Consent Registry receives a <i>Manage</i> Consent Directive Metadata Request   | HITSP/TP30 |
| Consent Repository          | The Consent Repository is responsible for both the persistent storage of consent directives as well as for their registration with the appropriate Consent Registry. It assigns a Uniform Resource Identifier (URI) and Metadata such as confidentiality codes to the consent directive for subsequent retrieval by an authorized consumer, e.g., for association with published personal health information or for evaluation at a policy decision point | HITSP/TP30 |



| Technical Actor(s)            | Actor Role  | Construct               |
|-------------------------------|---|-------------------------|
| Content Consumer              | A Content Consumer is responsible for viewing, import, or other processing of content created by a Content Creator  | HITSP/C32,<br>HITSP/C37 |
| Content Creator               | The Content Creator is responsible for the creation of content and transmission to a Content Consumer   | HITSP/C32,<br>HITSP/C37 |
| 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  | HITSP/TP13              |
| Document Registry             | 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 Consumers about documents meeting specific criteria. It also enforces some healthcare specific technical policies at the time of document registration  | HITSP/TP13              |
| Document Repository           | 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<br><br>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 Consumers about documents meeting specific criteria. It also enforces some healthcare specific technical policies at the time of document registration | HITSP/TP13              |
| 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  | HITSP/TP13              |
| Identity Provider             | The Identity Provider receives the credentials and identifier from the Entity (principal). It may perform authentication at that point or may require additional authentication from another source (the Service Provider)  | HITSP/C19               |
| Knowledge Requestor           | A system that formulates and sends a contextual request for ancillary information about a medical concept. Takes the parameters and sends to the resource available   | HITSP/T81               |
| Knowledge Resource            | The system that holds the information requested and responds to the request from the Knowledge Requestor.   | HITSP/T81               |
| Node                          | The Node is the originating or terminating point of information or signal flow in a telecommunications network. This actor is equivalent to the Secure Node in the IHE ATNA Transaction   | HITSP/T17               |
| Patient Demographics Consumer | The Patient Demographics Consumer queries the Patient Demographics Supplier to obtain patients that match the patient demographic data supplied in order to obtain a patient identification number. It may receive matches for one or more patients that enable the selection of the desired patient  | HITSP/T23               |



| Technical Actor(s)                               | Actor Role   | Construct                |
|--|--|--------------------------|
| 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  | HITSP/T23                |
| Patient Identity Source                          | Sends a patient identification number and demographic information to the Patient Identifier Cross-Reference (PIX) Manager  | HITSP/TP22               |
| PIX Consumer                                     | The Patient Identifier Cross-Reference Consumer queries the Patient Identifier Cross-Reference Manager for a master patient identifier that is a cross-reference to the patient identifiers supplied. It may also receive notifications about cross-reference changes  | HITSP/TP22               |
| PIX Manager                                      | The Patient Identifier Cross-Reference Manager is responsible for creating, maintaining and providing lists of identifiers that are aliases of one another across different Patient Identifier Domains   | HITSP/TP22               |
| Service Provider (SP)                            | The Service Provider represents the system providing a service to all entities that need an assertion or authentication. The service (or assertion) provider is the trusted third party issuer of the trustable identity assertion The SP is the information resource, representing the information repositories and all capabilities that receive, process and fulfill authorized requests. The Service Provider includes any local access decision and enforcement components that are part of the distributed capabilities              | HITSP/TP20<br>HITSP/C19  |
| Service Provider Access Control Service (SP ACS) | The SP ACS service supports and implements the service-side access control capabilities. This is a service provider actor  | HITSP/TP20               |
| Service User                                     | The Service User entity represents any individual entity (such as a clinician or an EHR/PHR system) that needs to make a service request of a Service Provider. The entity may also be known as a principal and/or entity, which represents an end user, an application, a machine, or any other type of entity that may act as a requester in a transaction. A principal is typically represented in a transaction with a digital identity and the principal may have multiple valid digital identities to use with different transaction | HITSP/TP20,<br>HITSP/C19 |
| Time Client                                      | Time Client establishes time synchronization with one or more Time Servers using the NTP protocol and either the Network Time Protocol (NTP) or Simple Network Time Protocol (SNTP) algorithms. Maintains the local computer system clock synchronization with Coordinated Universal Time (UTC) based on synchronization with the Time Servers   | HITSP/T16                |
| Time Server                                      | Time Server provides NTP time services to Time Clients. It is either directly synchronized to a UTC master clock (e.g. satellite time signal) or is synchronized by being grouped with a Time Client to other Time Server(s)   | HITSP/T16                |
| User Access Control Service (UACS)               | The UACS is the enterprise security service that supports and implements user-side access control capabilities. This is an initiator actor   | HITSP/TP20               |



### 3.2.2 CONSTRUCT REQUIREMENTS

This section incorporates the comprehensive business and technical requirements and a detailed specification of the transactions and information content specified to complete the information exchange actions identified in each Use Case scenario.

Table 6.4-1 (see Section 6.0) provides a mapping of the HITSP constructs that will be used in the design of the Interoperability Specification, and the data and information exchange requirements that are being satisfied by the construct. These requirements are limited to those that are deemed within scope for this interoperability specification, which are described in Section 3.1. Further details about the required technical actors, transactions, and content are also provided in the sections below.

The Unified Modeling Language (UML) sequence diagrams used in this section incorporate the detailed data requirements for the selected standards (defined in Section 2.2.2), with the Technical Actors, and their specific and detailed Transactions and content (encapsulated in the HITSP constructs listed above). The detailed actor Transactions described in these diagrams show all common or independent technical actors, data, and the specific transactions from the HITSP constructs that are used for the Interoperability Specification.

The following narrative provides a high level walk through of the flow in the context of a fictitious scenario. The legend used to read the fictitious scenario is shown below. This legend and background explanation applies to 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 (<PHR>). After examining various options, Mr. Everyperson decides to use the web-based PHR 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), 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 [Patient Identity Feed & PIX Query or Patient Demographics Query] and documents must be appropriately indexed and stored [Provide & Register (Registration/MedicationHx)]. 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 [Patient Identity Feed & PIX Query OR Patient Demographics 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, this may happen multiple times because of multiple documents].

WebPHR consolidates the information provided by Mr. Everyperson and the documents that have been retrieved and presents that information to Mr. Everyperson [Retrieve Document Set (using HITSP/C32)]. 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 [Provide and Register Document Set (using HITSP/C32)]. WebPHR passes updated documentation along to GM-HIN, as allowed by the access and consents set up by Mr. Everyperson.

### ***Summary Documents Using HL7 Continuity of Care Document (CCD) Component***

The Summary Documents Using HL7 Continuity of Care Document (CCD) (HITSP/C32) describes the document content that summarizes a consumer's registration and healthcare summary data information for the purpose of information exchange with a PHR system.

NOTE: This does not describe the content of the PHR, but the exchange of information with a PHR system.

The document consists of content modules that contain multiple data elements. The list of content modules is presented in Table 3.2.2-1. Subsequent sections indicate those content modules which are required in particular transaction/content subsets.





**Table 3.2.2-1 HITSP/C32 Content Modules in this IS**

| Content Module                                  |
|---|
| Advance Directive                               |
| Allergies and Drug Sensitivity                  |
| Comments  |
| Condition                                       |
| Encounter                                       |
| Healthcare Provider                             |
| Immunization                                    |
| Information Source                              |
| Insurance Provider                              |
| Language Spoken                                 |
| Medications – Prescription and Non-Prescription |
| Person Information                              |
| Pregnancy                                       |
| Procedure                                       |
| Result  |
| Support   |
| Vital Sign                                      |

The HITSP/C32 Summary Documents Using HL7 Continuity of Care Document (CCD), 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.

#### **Lab Report Document**

HITSP/C37 Lab Report Document describes the document content that summarizes a set of consumer's laboratory test results for the purpose of information exchange with a PHR system.



This document is intended to hold a complete set of laboratory test results (e.g. resulting from one or more orders). It allows the consumer to maintain the structured and coded form in his or her PHR system and a laboratory report in a source attested manner (laboratory or EHR system where the report was created). The laboratory results section in the HITSP/C32 Summary Documents Using HL7 Continuity of Care Document (CCD) serves a complementary purpose in allowing selected lab results relevant in the context of the summary to be included (e.g. abnormal results that resulted in a specific diagnosis or in medication being prescribed).

### ***Unstructured Document***

HITSP/C62 Unstructured Document describes a document that contains “information blocks” which are not limited by format, with the exception that it must be renderable. Sufficient metadata must be present to describe that information.

This document could include an unstructured, presentation-preserved format, such as PDF, which is readily usable by end-users such as consumers and providers.

This construct relates to patient identifiable documents and will be supported by HITSP constructs for sharing of documents (HITSP/TP13 Manage Sharing of Documents, HITSP/T31 Document Reliable Interchange, or HITSP/T33 Transfer of Documents on Media). HITSP/T31 should only be used to transport documents that are not natively structured.

It produces output as a CDA document - with the attributes of a document, such as persistence, authenticity, wholeness, etc. Examples of documents that would be embedded in the CDA document include plain text notes to the patient, notes from the patient, or a presentation preserved document such as a PDF of a scanned image of a legacy immunization card.

#### **3.2.2.1 Consumer Creates Account to Host Health Information Scenario Actor Interactions**

Health Plans/Intermediary and PBM/Pharmacy have two approaches for conveying information to their members'/enrollees' PHRs:

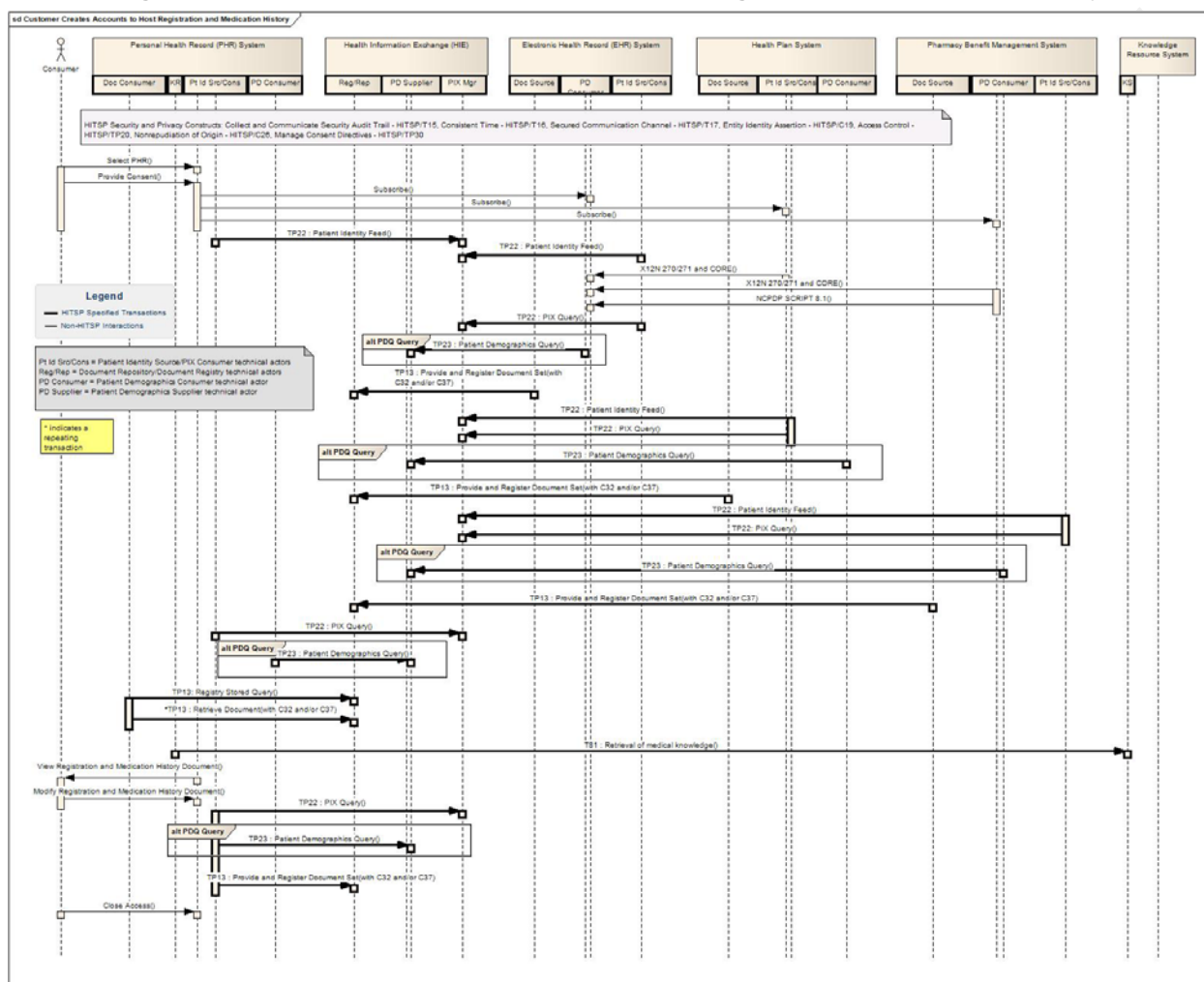
- They may choose to act as a direct source of information as a Document Source by using the X12 270/271 and CORE or NCPDP SCRIPT mapping defined in Section 6.2 and Section 6.1 of the HITSP/C32 Summary Documents Using HL7 Continuity of Care Document (CCD) respectively.
- Alternatively, a provider may act as an intermediary for its consumers 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 system 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.



The sequence diagram for this scenario is shown in Figure 3.2.2.1-1. For simplification, please note that Security and Privacy transactions may not be reflected in the following detailed technical design UML diagram.

**Figure 3.2.2.1-1 Customer Creates Accounts to Host Registration and Medication History**



#### 3.2.2.1.1 Transaction Descriptions

The transactions shown with thin 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.

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 can 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 4.2 and Section 4.3.

The detailed technical requirements for the transactions shown in Figure 3.2.2.1-1 are specified further in Section 3.2.3.

### 3.2.2.2 Consumer Visits Healthcare Provider and Provides Registration and Medication History and/or Laboratory Information Scenario Actor Interactions

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 selects pertinent information from his PHR system (<PHR>), extracts it from this system (<PHR>), formats it into the appropriate document format (HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD), HITSP/C37 Lab Report Document HITSP/C62 Unstructured Document or any combination of the three formats) and transfers it to WebPHR for sharing with his provider as described in HITSP/T13 Manage Sharing of Documents. WebPHR has established relationships to GM-HIN (or other systems). Prior to sending any documents to be shared WebPHR ensures that the patient identity of the documents being submitted for transfer is cross-referenced to the patient identity that the GM-HIN will recognize.

The sequence diagram for this scenario is shown in Figure 3.2.2.2-1. For simplification, please note that Security and Privacy transactions may not be reflected in the following detailed technical design UML diagram.



**Legend**

- HITSP Specified Transactions
- Non-HITSP Interactions

**Participant Roles:**

- Consumer
- Personal Health Record (PHR) System: PI ID Src/Cons, PD Consumer, PI, Doc Consumer
- Health Information Exchange (HIE): Reg/Rep, PI, Mgr, PD Supplier
- Electronic Health Record (EHR) System: Doc Consumer, PD Consumer, HR, PI ID Src/Cons
- Health Plan System: PI ID Src/Cons, PD Consumer, Doc Source
- Pharmacy Benefit Management System: PI ID Src/Cons, PD Consumer, Doc Source
- Knowledge Resource System: KS

**Key Transactions:**

- TP22: Patient Identity Feed()
- TP13: Registry Stored Query()
- TP13: Retrieve Document()
- TS1: Retrieval of medical knowledge()
- TP22: PI(X Query())
- all PDQ Query / TP23: Patient Demographics Query()
- X12N 270/271 and CORE
- X12N 270/271 and CORE
- NCPDP 8.1 SCRIPTg
- TP13: Provide and Register Document Set(w/ C32 and/or C37)
- TP22: PI(X Query())
- all PDQ Query / TP23: Patient Demographics Query()
- TP13: Provide and Register Document Set(w/ C32 and/or C37)
- TP22: PI(X Query())
- all PDQ Query / TP23: Patient Demographics Query()
- TP13: Provide and Register Document Set(w/ C32 and/or C37)
- TP22: PI(X Query())
- all PDQ Query / TP23: Patient Demographics Query()
- TP13: Registry Stored Query()
- TP13: Retrieve Document()
- TP22: PI(X Query())
- all PDQ Query / TP23: Patient Demographics Query()
- TP13: Registry Stored Query()
- TP13: Retrieve Document()
- TS1: Retrieval of medical knowledge()
- View and Integrate Registration Data into EHR()

**Notes:**

- PI ID Src/Cons = Patient Identity Source/PI Consumer technical actors
- Reg/Rep = Document Repository/Document Registry technical actors
- PD Consumer = Patient Demographics Consumer technical actor
- PD Supplier = Patient Demographics Supplier technical actor
- \* Indicates a repeating transaction

The detailed technical requirements for the transactions shown in Figure 3.2.2.2-1 are specified in Section 3.2.3. The follow narrative provides a high level walk though of the flow in the context of a fictitious scenario.

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 [Patient Identity Feed & PIX Query OR Patient Demographics Query] and determining what relevant documents are contained in GM-HIN [Registry Stored Query]. Once the documents are identified, WebPHR retrieves particular documents of interest [Retrieve Documents Set, this may happen multiple times because of multiple 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 [Patient Identity Feed & PIX Query OR Patient Demographics Query] and documents must be appropriately indexed and stored [Provide & Register Document Set].

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 [Patient Identity Feed & PIX Query OR Patient Demographics Query] and determine what relevant documents are contained in GM-HIN [Registry Stored Query]. Once the documents are identified, WebPHR retrieves particular documents of interest [Retrieve Documents Set (using HITSP/C32 Summary Documents Using HL7 Continuity of Care Document (CCD), HITSP/C37 Lab Report Document, HITSP/C62 Unstructured Document or any combination of the three constructs)].

Upon arriving for his appointment with Dr. Doctor, Mr. Everyperson is handed the standard visit forms to complete. 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 ensure that OfficeEHR and GM-HIN both recognized Mr. Everyperson [Patient Identity Feed & PIX Query OR Patient Demographics Query]. OfficeEHR requests information on relevant documents contained in GM-HIN [Registry Stored Query], and retrieves the current Registration and Medication History, Laboratory Reports document(s) as well as any available unstructured document(s) [Retrieve Documents Set (using HITSP/C32 HITSP/C37, HITSP/C62 or any combination of the three constructs)],

OfficeEHR presents the Summary Document Using the HL7 CCD to the office staff and Dr. Doctor, who then determine if the information should be posted into the OfficeEHR record for Mr. Everyperson [Document Consumer (with Content Consumer/Document Import Option)].

### 3.2.2.3 Authorized Healthcare Provider Reviews Registration and Medication History Scenario Actor Interactions

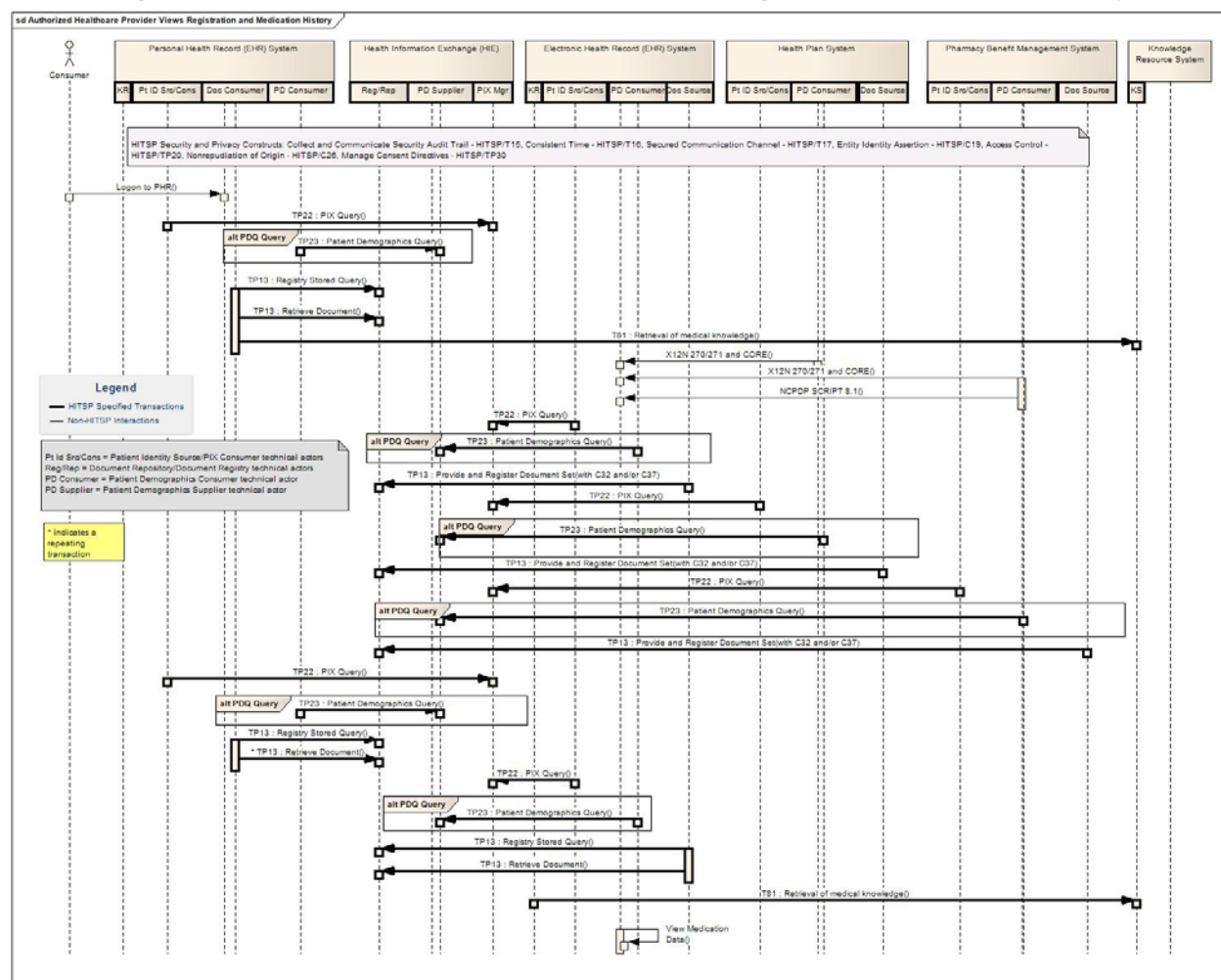
Upon arriving for his appointment with Dr. Doctor, Mr. Everyperson advises the office staff that his information is available via WebPHR. The office staff enters the appropriate information (e.g. patient identification, authorization, etc) into OfficeEHR to retrieve Mr. Everyperson's information from WebPHR (via GM-HIN). OfficeEHR queries GM-HIN to ensure that OfficeEHR and GM-HIN both recognized Mr. Everyperson. OfficeEHR requests information on relevant documents contained in GM-HIN, and retrieves the current Registration Summary and Medication History document(s). OfficeEHR presents the retrieved documents to the office staff and Dr. Doctor, who then determine if the information should be posted into the OfficeEHR record for Mr. Everyperson.





The sequence diagram is shown in Figure 3.2.2.3-1. For simplification, please note that Security and Privacy transactions may not be reflected in the following detailed technical design UML diagram.

**Figure 3.2.2.3-1 Authorized Healthcare Provider Views Registration and Medication History**



### 3.2.2.3.1 Transaction Descriptions

The detailed technical requirements for the transactions shown in Figure 3.2.2.3-1 are specified in Section 3.2.3. The following narrative provides a high level walk through 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]. 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 [Patient Identity Feed & PIX Query OR Patient Demographics Query] and determining what relevant documents are contained in GM-HIN [Registry Stored Query]. Once the documents are identified, WebPHR retrieves particular documents of interest [Retrieve Documents Set (using HITSP/C32 Summary Documents Using HL7 Continuity of Care Document (CCD), HITSP/C37 Lab Report Document, HITSP/C63 Unstructured Document or any combination of the three constructs)].

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 [Patient Identity Feed & PIX Query OR Patient Demographics Query] and documents must be appropriately indexed and stored [Provide & Register Document Set]. 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 [Patient Identity Feed & PIX Query OR Patient Demographics Query] and determines what relevant documents are contained in GM-HIN [Registry Stored Query]. Once the documents are identified, WebPHR retrieves particular documents of interest [Retrieve Documents Set (using HITSP/C32 Summary Documents Using HL7 Continuity of Care Document (CCD), HITSP/C37 Lab Report Document, HITSP/C62 Unstructured Document or any combination of the three constructs)].

Upon arriving for his appointment with Dr. Doctor, Mr. Everyperson is handed a current medication form to complete. 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 ensure that OfficeEHR and GM-HIN both recognized Mr. Everyperson [Patient Identity Feed & PIX Query OR Patient Demographics Query]. OfficeEHR requests information on relevant documents contained in GM-HIN [Registry Stored Query], and retrieves the current Registration and Medication History document(s) [Retrieve Documents Set (using HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD), HITSP/C37 Lab Report Document , HITSP/C62 Unstructured Document or any combination of the three constructs)].

OfficeEHR presents the Summary Document Using the HL7 CCD to the office staff and Dr. Doctor, who then determine if the information should be posted into the OfficeEHR record for Mr. Everyperson [Document Consumer (with Content Consumer/Document Import Option)].

For the most up-to-date and complete information, it is recommended that at the end of a healthcare encounter the new registration/medication history data are pushed to the document repository/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 (or other clinical and laboratory data) history but it is not guaranteed by this specification.

#### 3.2.2.4 Implementation and Architecture Variants

The three scenarios depicted in Section 3.2.2 assume a specific implementation architecture which is just one of the possible architectural variants that are supported for this HITSP/IS03 - Consumer Empowerment and Access to Clinical Information via Networks Interoperability Specification. Such flexibility is necessary to support environments where:

- No RHIO/HIE 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 and Medication History Documents, and Laboratory Report Documents, others being shared as part of the RHIO/HIE infrastructure

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

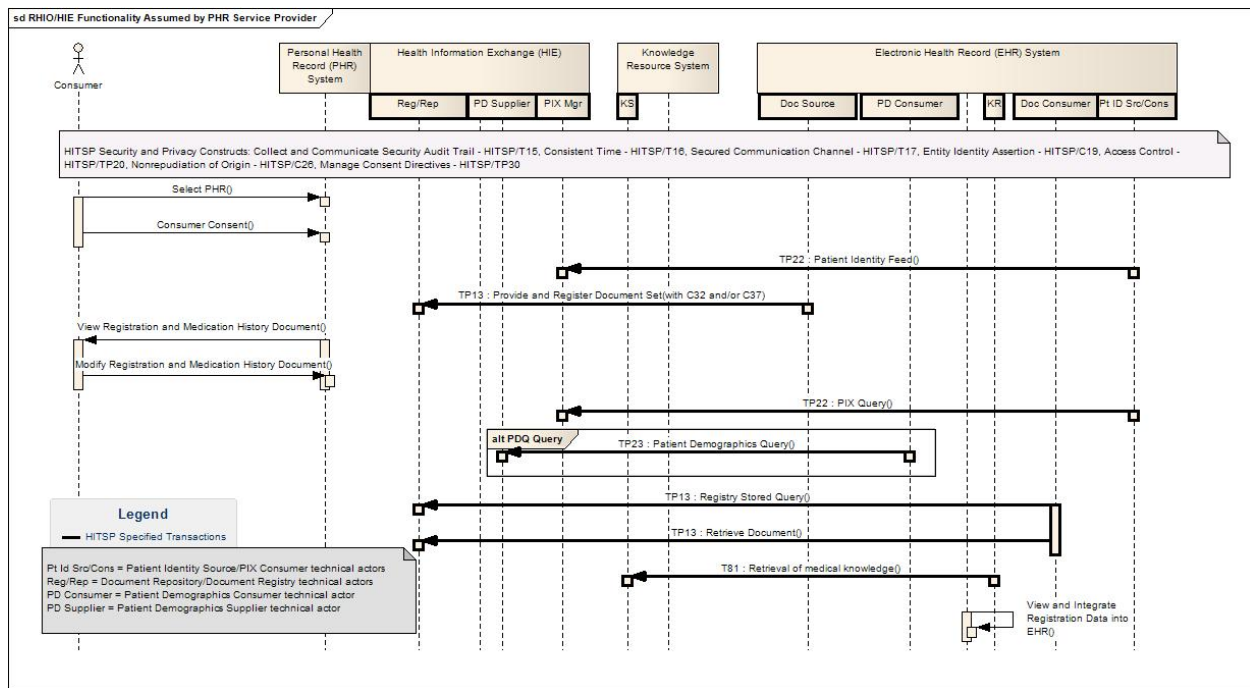
Five examples are provided to illustrate these many possible variants. This is a fluid and evolving area of healthcare technology and, as such, the examples shown are only a small subset of all possible variants. They leverage a subset of the transactions and business actors defined for the Use Cases, 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. For simplification, please note that Security and Privacy transactions may not be reflected in the following detailed technical design UML diagrams.

#### ***Implementation/Architecture Variant A***

In this variant, the PHR Service provider cannot rely on a RHIO/HIE. The tasks of the RHIO/HIE 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 system) use the very same transactions as when the RHIO/HIE exists as a separate business actor. Figure 3.2.2.4-1 is an example of this variant.



**Figure 3.2.2.4-1 RHIO/HIE Functionality Assumed by PHR Service Provider**

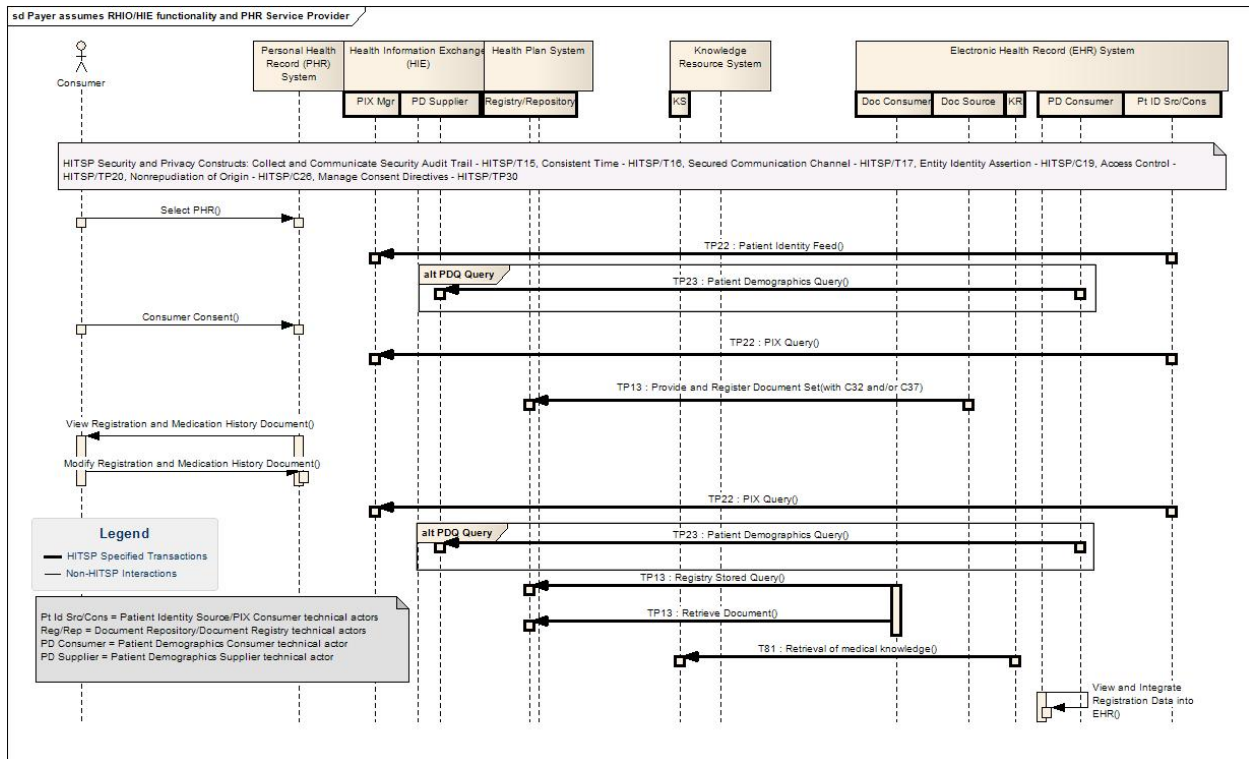


### Implementation/Architecture Variant B

In this variant, the PHR Service provider cannot rely on a RHIO/HIE similar to as shown in variant A, and the PHR service is being offered by a payer. By combining 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 system) use the very same transactions as when the business actors exist as separate entities. Figure 3.2.2.4-2 is an example of this variant.



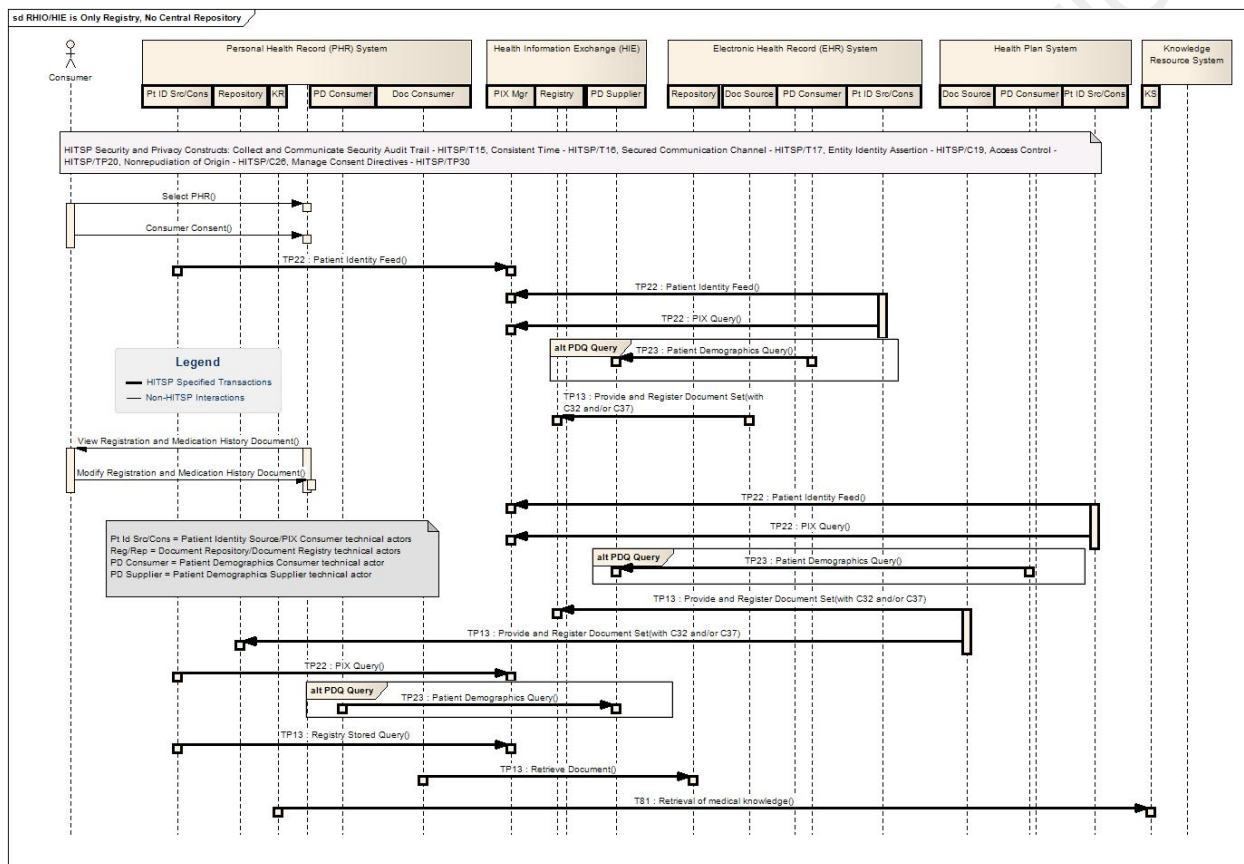
Figure 3.2.2.4-2 Payer assumes RHIO/HIE functionality and PHR Service Provider



### Implementation/Architecture Variant C

In this variant, the RHIO/HIE does not offer a centralized document repository. Repositories are supported by the PHR for the Registration/Medication History, Laboratory Report, and unstructured documents the consumer creates and by the EHR system for the documents it creates. In this architecture, the RHIO/HIE 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 3.2.2.4-3 is an example of this variant.

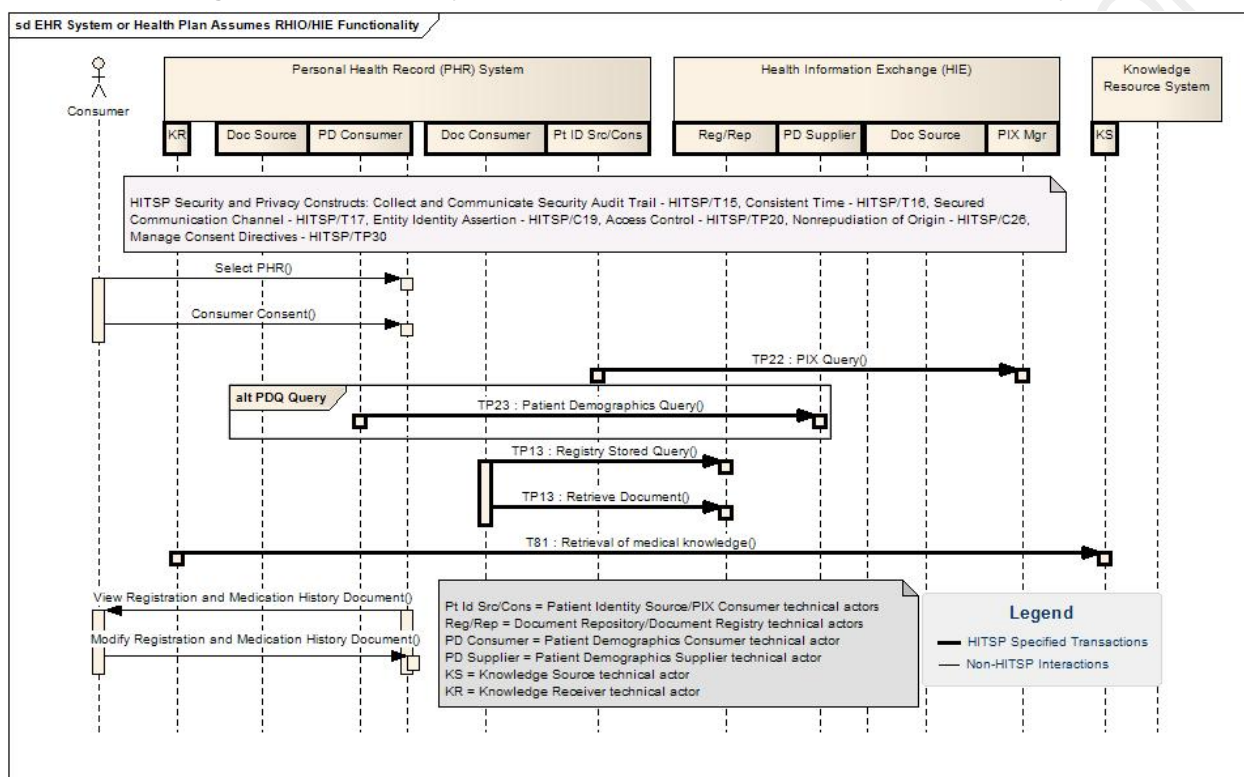
Figure 3.2.2.4-3 RHIO/HIE is Only Registry, No Central Repository



### Implementation/Architecture Variant D

In this variant, the EHR system, PBM, Pharmacy or Health Plan is shown acting as a RHIO/HIE 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 3.2.2.4-4 is an example of this variant.

**Figure 3.2.2.4-4 EHR System or Health Plan Assumes RHIO/HIE Functionality**

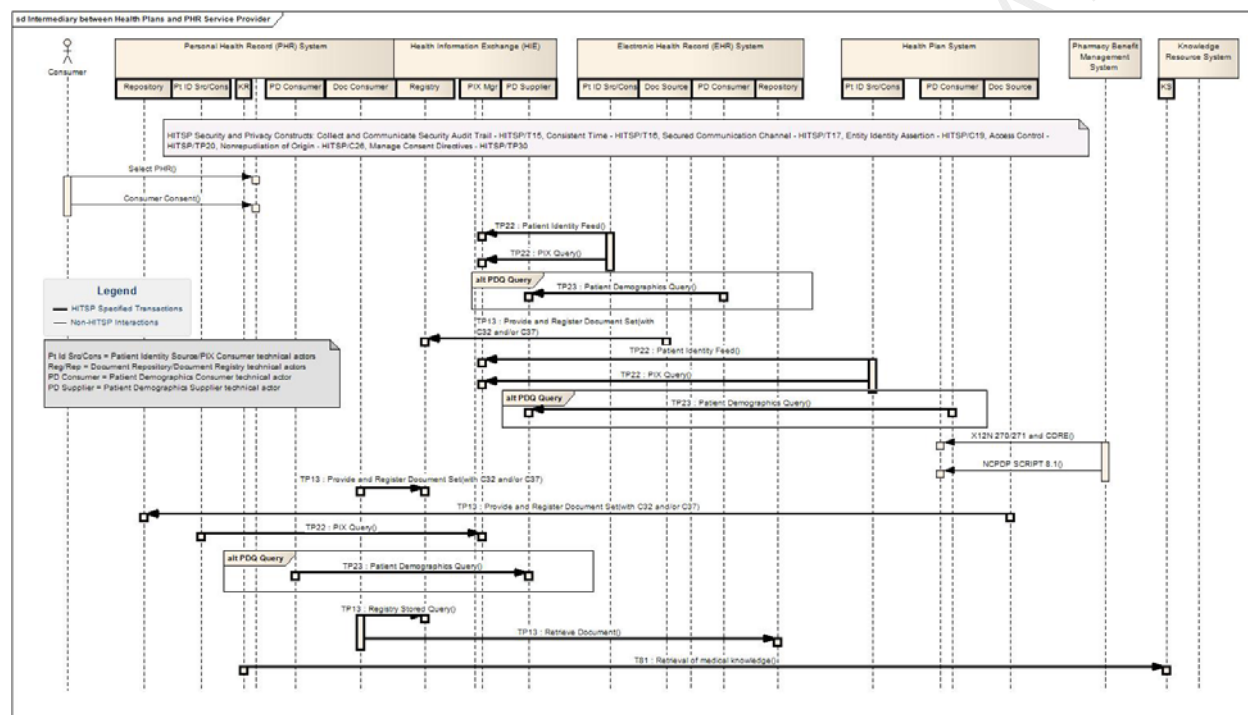




## Implementation/Architecture Variant E

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 3.2.2.4-5 is an example of this variant. It should be noted, that the Documents need not be persisted by the source (e.g. Health Plan, Pharmacy/Intermediaries). It may either provide an X270/X271 to another party (e.g., EHR system 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/HIE, PHR system such as variant A, B, C).

**Figure 3.2.2.4-5 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.

### 3.2.3 MAPPING OF BUSINESS ACTORS TO TECHNICAL ACTORS AND CONSTRUCTS WITH OPTIONALITY

The table below maps the individual business actors to the technical actors defined in the Interoperability Specification and depicted in the above detailed UML sequence diagram. Table 3.2.3-1 below specifies the requirements associated with each business actor in the Interoperability Specification. For each implemented business actor, the table specifies the following:

1. All Required or Conditionally Required technical actors listed for the business actor shall be supported as specified in the associated construct





2. Optional technical actors listed for the business actor may be supported as specified in the associated construct
3. All Required or Conditionally Required transactions and content subsets listed for each implemented technical actor assigned to the business actor shall be supported as specified in the associated construct
4. Optional transactions and content subsets listed for each implemented technical actor assigned to the business actor may be supported as specified in the associated construct

This table also includes the corresponding technical actors associated with the relevant Security and Privacy constructs that are used for this Interoperability Specification. Section 1.2 provides a summary description of all the referenced HITSP constructs. Note that this table only shows the business and technical actors that are implemented by the specification. Business actors that are out of scope, or gaps are not included in this section, however, they are discussed in Section 3.1 if they are out of scope, or in Section 4.2 if they are found to be gaps where there are no standards.

**Table 3.2.3-1 Business-Technical Actor Mapping to Transaction and/or Content**

| Business Actor                                | Technical Actor(s)            | Actor Optionality | Construct  | Transaction/Content (T/C)                         | T/C Optionality <sup>1</sup> |
|---|-------------------------------|-------------------|------------|---|------------------------------|
| Personal Health Record (PHR) Service Provider | Patient Identity Source       | C [101]           | HITSP/TP22 | Patient Identity Feed                             | R                            |
|   | PIX Consumer                  | C [101]           | HITSP/TP22 | PIX Query   | R                            |
|   |                               |                   |            | PIX Update Notification                           | O                            |
|   | Patient Demographics Consumer | C [101]           | HITSP/T23  | Patient Demographics Query                        | R                            |
|   | Document Source               | R                 | HITSP/TP13 | Provide & Register Document Set-b                 | R                            |
|   |                               | C[103]            | HITSP/C19  | Convey Assertion                                  | O                            |
|   | Document Consumer             | R                 | HITSP/TP13 | Registry Stored Query                             | R                            |
|   |                               |                   |            | Retrieve Document Set                             | R                            |
|   |                               |                   |            | Convey Assertion                                  | O                            |
|   | Document Repository           | O                 | HITSP/TP13 | Retrieve Document Set                             | R                            |
|   |                               |                   |            | Register Document Set-b                           | R                            |
|   |                               |                   |            | Provide & Register Document Set-b                 | R                            |
|   |                               | C[103]            | HITSP/C19  | Convey Assertion                                  | O                            |
|   | Document Registry             | O                 | HITSP/TP13 | Patient Identity Feed                             | R                            |
|   |                               |                   |            | Registry Stored Query                             | R                            |
|   |                               |                   |            | Provide and Register Document Set-b               | R                            |
|   | Content Creator               | R                 | HITSP/C32  | Creator-Registration Subset (see Section 3.2.3.1) | C[201]                       |

<sup>1</sup> Optionality = "R" for Required, "O" for Optional, or "C" for Conditional



| Business Actor | Technical Actor(s)  | Actor Optionality | Construct  | Transaction/Content (T/C)   | T/C Optionality <sup>1</sup> |
|----------------|---------------------|-------------------|------------|---|------------------------------|
|                |                     |                   |            | Creator-Registration-Coded Subset (see Section 3.2.3.2)   | C[201]                       |
|                |                     |                   |            | Creator-Medication and Immunization History Subset (see Section 3.2.3.3)                        | C[201]                       |
|                |                     |                   |            | Creator-Medication and Immunization History - Coded Subset (see Section 3.2.3.4)                | C[201]                       |
|                |                     |                   |            | Creator-Conditions and Allergy Subset (see Section 3.2.3.5)                                     | C[201]                       |
|                |                     |                   |            | Creator-Conditions and Allergy-Coded Subset (see Section 3.2.3.6)                               | C[201]                       |
|                |                     |                   |            | Creator-Laboratory Section Subset (see Section 3.2.3.7)   | C[201]                       |
|                |                     |                   |            | Creator-Laboratory Section -Coded Subset (see Section 3.2.3.8)                                  | C[201]                       |
|                |                     | R                 | HITSP/C37  | Laboratory Report Document  | C[201]                       |
|                |                     | R                 | HITSP/C62  | Unstructured Document   | C[201]                       |
|                |                     | R                 | HITSP/TP30 | Consent Document  | R                            |
|                | Content Consumer    | R                 | HITSP/C32  | Consumer-Document Display Subset (see Section 3.2.3.9)  | R                            |
|                |                     |                   |            | Consumer-Document Import Subset (see Section 3.2.3.10)  | O                            |
|                |                     |                   |            | Consumer-Registration Discrete Data Import Subset (see Section 3.2.3.11)                        | O                            |
|                |                     |                   |            | Consumer-Medication and Immunization History Discrete Data Import Subset (see Section 3.2.3.12) | O                            |
|                |                     |                   |            | Consumer-Conditions and Allergy Discrete Data Import Subset (see Section 3.2.3.13)              | O                            |
|                |                     |                   |            | Consumer-Laboratory Discrete Data Import Subset (see Section 3.2.3.14)                          | O                            |
|                |                     | R                 | HITSP/C37  | Consumer-Document Display Subset (see Section 3.2.3.9)  | R                            |
|                |                     |                   |            | Consumer-Document Import Subset (see Section 3.2.3.10)  | O                            |
|                |                     |                   |            | Consumer-Lab Report Discrete Data Import Subset (see Section 3.2.3.15)                          | O                            |
|                |                     | R                 | HITSP/C62  | Consumer-Document Display Subset (see Section 3.2.3.9)  | R                            |
|                |                     |                   |            | Consumer-Document Import Subset (see Section 3.2.3.10)  | O                            |
|                |                     | R                 | HITSP/TP30 | Consent Document  | R                            |
|                | Knowledge Requester | O                 | HITSP/T81  | Retrieval of Medical Knowledge  | R                            |
|                | Audit Record Source | R                 | HITSP/T15  | Record Audit Event in Repository  | R                            |



| Business Actor          | Technical Actor(s)                               | Actor Optionality  | Construct  | Transaction/Content (T/C)         | T/C Optionality <sup>1</sup> |
|-------------------------|--|--------------------|------------|-----------------------------------|------------------------------|
|                         | Audit Record Repository                          | O                  | HITSP/T15  | Record Audit Event in Repository  | R                            |
|                         | Time Client                                      | R                  | HITSP/T16  | Maintain Time                     | R                            |
|                         | Time Server                                      | O                  | HITSP/T16  | Maintain Time                     | R                            |
|                         | Node   | R                  | HITSP/T17  | Secured Communication Channel     | R                            |
|                         | Identity provider                                | C[104]             | HITSP/C19  | Provide Assertion                 | R                            |
|                         |  |                    |            | Verify Assertion                  | O                            |
|                         | Consent Originator                               | O                  | HITSP/TP30 | Provide and Register Document Set | R                            |
|                         | Consent Registry                                 | O                  | HITSP/TP30 | Register Document Set             | R                            |
|                         |  |                    |            | Stored Query                      | R                            |
|                         | Consent Repository                               | O                  | HITSP/TP30 | Provide and Register Document Set | R                            |
|                         |  |                    |            | Register Document Set             | R                            |
|                         | Consent Directive Requester                      | R                  | HITSP/TP30 | Stored Query                      | R                            |
|                         |  |                    |            | Retrieve Document Set             | R                            |
|                         | Service User                                     | R                  | HITSP/TP20 | Access Control Request            | O                            |
|                         | User Access Control Service (UACS)               | R                  | HITSP/TP20 | Access Control Request            | O                            |
|                         | Service Provider                                 | C [102]<br>C [103] | HITSP/TP20 | Access Control Request            | O                            |
|                         | Service Provider Access Control Service (SP ACS) | C [102]            | HITSP/TP20 | Access Control Request            | O                            |
| Infrastructure Services | PIX Manager                                      | C[105]             | HITSP/TP22 | Patient Identity Feed             | R                            |
|                         |  |                    |            | PIX Query                         | R                            |
|                         |  |                    |            | PIX Update Notification           | R                            |
|                         | Patient Demographics Supplier                    | C[105]             | HITSP/T23  | Patient Demographics Query        | R                            |
|                         | Document Registry                                | C[105]             | HITSP/TP13 | PIX Identity Feed                 | R                            |
|                         |  |                    |            | Registry Stored Query             | R                            |
|                         |  |                    |            | Register Document Set-b           | R                            |
|                         | Document Repository                              | O                  | HITSP/TP13 | Retrieve Document                 | R                            |
|                         |  |                    |            | Retrieve Document Set-b           | R                            |
|                         |  |                    |            | Provide & Register Document Set-b | R                            |
|                         |  | C[103]             | HITSP/C19  | Convey Assertion                  | O                            |
|                         | Initiating Gateway                               | O                  | HITSP/TP13 | Cross Gateway Query               | R                            |
|                         |  |                    |            | Cross Gateway Retrieve            | R                            |
|                         | Responding Gateway                               | O                  | HITSP/TP13 | Cross Gateway Query               | R                            |
|                         |  |                    |            | Cross Gateway Retrieve            | R                            |
|                         | Audit Record Source                              | R                  | HITSP/T15  | Record Audit Event in Repository  | R                            |
|                         | Audit Record Repository                          | R                  | HITSP/T15  | Record Audit Event in Repository  | R                            |



| Business Actor                        | Technical Actor(s)                               | Actor Optionality | Construct  | Transaction/Content (T/C)  | T/C Optionality <sup>1</sup> |
|---------------------------------------|--|-------------------|------------|--|------------------------------|
|                                       | Time Client                                      | R                 | HITSP/TP16 | Maintain Time  | R                            |
|                                       | Time Server                                      | R                 | HITSP/TP16 | Maintain Time  | R                            |
|                                       | Node   | R                 | HITSP/TP17 | Secured Communication Channel  | R                            |
|                                       | Identity provider                                | C[104]            | HITSP/C19  | Provide Assertion  | R                            |
|                                       |  |                   |            | Verify Assertion   | O                            |
|                                       | Consent Registry                                 | R                 | HITSP/TP30 | Register Document Set  | R                            |
|                                       |  |                   |            | Stored Query   | R                            |
|                                       | Consent Repository                               | R                 | HITSP/TP30 | Provide and Register Document Set  | R                            |
|                                       |  |                   |            | Register Document Set  | R                            |
|                                       | Consent Directive Requester                      | O                 | HITSP/TP30 | Stored Query   | R                            |
|                                       |  |                   |            | Retrieve Document Set  | R                            |
|                                       | User   | R                 | HITSP/TP20 | Access Control Request   | O                            |
|                                       | User Access Control Service (UACS)               | R                 | HITSP/TP20 | Access Control Request   | O                            |
|                                       | Service Provider                                 | R                 | HITSP/TP20 | Access Control Request   | O                            |
|                                       | Service Provider Access Control Service (SP ACS) | R                 | HITSP/TP20 | Access Control Request   | O                            |
| Electronic Health Record (EHR) System | Patient Identity Source                          | C [101]           | HITSP/TP22 | Patient Identity Feed  | R                            |
|                                       | PIX Consumer                                     | C [101]           | HITSP/TP22 | PIX Query  | R                            |
|                                       |  |                   |            | PIX Update Notification  | O                            |
|                                       | Patient Demographics Consumer                    | C [101]           | HITSP/TP23 | Patient Demographics Query   | R                            |
|                                       | Document Source                                  | R                 | HITSP/TP13 | Provide & Register Document Set-b  | R                            |
|                                       |  | C[103]            | HITSP/C19  | Convey Assertion   | O                            |
|                                       | Document Consumer                                | R                 | HITSP/TP13 | Registry Stored Query  | R                            |
|                                       |  |                   |            | Retrieve Documents   | R                            |
|                                       |  |                   |            | Convey Assertion   | O                            |
|                                       | Document Repository                              | O                 | HITSP/TP13 | Retrieve Document  | R                            |
|                                       |  |                   |            | Retrieve Documents Set-b   | R                            |
|                                       |  |                   |            | Provide & Register Document Set-b  | R                            |
|                                       |  |                   |            | Convey Assertion   | O                            |
|                                       | Content Creator                                  | R                 | HITSP/C32  | Creator-Registration Subset (see Section 3.2.3.1)                        | C[201]                       |
|                                       |  |                   |            | Creator-Registration-Coded Subset (see Section 3.2.3.2)                  | C[201]                       |
|                                       |  |                   |            | Creator-Medication and Immunization History Subset (see Section 3.2.3.3) | C[201]                       |



| Business Actor | Technical Actor(s)      | Actor Optionality | Construct  | Transaction/Content (T/C)   | T/C Optionality <sup>1</sup> |
|----------------|-------------------------|-------------------|------------|---|------------------------------|
|                |                         |                   |            | Creator-Medication and Immunization History - Coded Subset (see Section 3.2.3.4)                | C[201]                       |
|                |                         |                   |            | Creator-Conditions and Allergy Subset (see Section 3.2.3.5)                                     | C[201]                       |
|                |                         |                   |            | Creator-Conditions and Allergy -Coded Subset (see Section 3.2.3.6)                              | C[201]                       |
|                |                         |                   |            | Creator-Laboratory Section Subset (see Section 3.2.3.7)   | C[201]                       |
|                |                         |                   |            | Creator-Laboratory Section -Coded Subset (see Section 3.2.3.8)                                  | C[201]                       |
|                |                         |                   | HITSP/C62  | Unstructured Document   | C[201]                       |
|                |                         |                   | HITSP/C37  | Laboratory Report Document  | C[201]                       |
|                |                         |                   | HITSP/TP30 | Consent Document  | R                            |
|                | Content Consumer        | R                 | HITSP/C32  | Consumer-Document Display Subset (see Section 3.2.3.9)  | R                            |
|                |                         |                   |            | Consumer-Document Import Subset (see Section 3.2.3.10)  | O                            |
|                |                         |                   |            | Consumer-Registration Discrete Data Import Subset (see Section 3.2.3.11)                        | O                            |
|                |                         |                   |            | Consumer-Medication and Immunization History Discrete Data Import Subset (see Section 3.2.3.12) | O                            |
|                |                         |                   |            | Consumer-Conditions and Allergy Discrete Data Import Subset (see Section 3.2.3.13)              | O                            |
|                |                         |                   |            | Consumer-Laboratory Discrete Data Import Subset (see Section 3.2.3.14)                          | O                            |
|                |                         |                   | HITSP/C37  | Consumer-Document Display Subset (see Section 3.2.3.9)  | R                            |
|                |                         |                   |            | Consumer-Document Import Subset (see Section 3.2.3.10)  | O                            |
|                |                         |                   |            | Consumer-Lab Report Discrete Data Import Subset (see Section 3.2.3.15)                          | O                            |
|                |                         |                   | HITSP/C62  | Consumer-Document Display Subset (see Section 3.2.3.9)  | R                            |
|                |                         |                   |            | Consumer-Document Import Subset (see Section 3.2.3.10)  | O                            |
|                |                         |                   | HITSP/TP30 | Consent Document  | R                            |
|                | Knowledge Requester     | O                 | HITSP/T81  | Retrieval of Medical Knowledge  | R                            |
|                | Audit Record Source     | R                 | HITSP/T15  | Record Audit Event in Repository  | R                            |
|                | Audit Record Repository | O                 | HITSP/T15  | Record Audit Event in Repository  | R                            |
|                | Time Client             | R                 | HITSP/T16  | Maintain Time   | R                            |
|                | Time Server             | O                 | HITSP/T16  | Maintain Time   | R                            |



| Business Actor                      | Technical Actor(s)                               | Actor Optionality | Construct  | Transaction/Content (T/C)  | T/C Optionality <sup>1</sup> |
|-------------------------------------|--|-------------------|------------|--|------------------------------|
|                                     | Node   | R                 | HITSP/TP17 | Secured Communication Channel  | R                            |
|                                     | Identity provider                                | C[104]            | HITSP/C19  | Provide Assertion  | R                            |
|                                     |  |                   |            | Verify Assertion   | O                            |
|                                     | Consent Originator                               | O                 | HITSP/TP30 | Provide and Register Document Set  | R                            |
|                                     | Consent Repository                               | O                 | HITSP/TP30 | Register Document Set  | R                            |
|                                     |  |                   |            | Stored Query   | R                            |
|                                     | Consent Registry                                 | O                 | HITSP/TP30 | Provide and Register Document Set  | R                            |
|                                     |  |                   |            | Register Document Set  | R                            |
|                                     | Consent Directive Requester                      | O                 | HITSP/TP30 | Stored Query   | R                            |
|                                     |  |                   |            | Retrieve Document Set  | R                            |
|                                     | Service User                                     | R                 | HITSP/TP20 | Access Control Request   | O                            |
|                                     | User Access Control Service (UACS)               | R                 | HITSP/TP20 | Access Control Request   | O                            |
|                                     | Service Provider                                 | R                 | HITSP/TP20 | Access Control Request   | O                            |
|                                     | Service Provider Access Control Service (SP ACS) | R                 | HITSP/TP20 | Access Control Request   | O                            |
| Knowledge Resource Service Provider | Knowledge Resource                               | R                 | HITSP/T81  | Retrieval of Medical Knowledge   | R                            |
| Health Plan/Intermediary            | Patient Identity Source                          | C [101]           | HITSP/TP22 | Patient Identity Feed  | R                            |
|                                     | PIX Consumer                                     | C [101]           | HITSP/TP22 | PIX Query  | R                            |
|                                     | Patient Demographics Consumer                    | C [101]           | HITSP/T23  | Patient Demographics Query   | R                            |
|                                     | Document Source                                  | R                 | HITSP/TP13 | Provide & Register Document Set-b  | R                            |
|                                     |  | C[103]            | HITSP/C19  | Convey Assertion   | O                            |
|                                     | Content Creator                                  | R                 | HITSP/C32  | Creator-Registration Subset (see Section 3.2.3.1)                                | C[201]                       |
|                                     |  |                   |            | Creator-Registration-Coded Subset (see Section 3.2.3.2)                          | C[201]                       |
|                                     |  |                   |            | Creator-Medication and Immunization History Subset (see Section 3.2.3.3)         | C[201]                       |
|                                     |  |                   |            | Creator-Medication and Immunization History - Coded Subset (see Section 3.2.3.4) | C[201]                       |
|                                     |  |                   |            | Creator-Conditions and Allergy Subset (see Section 3.2.3.5)                      | C[201]                       |
|                                     |  |                   |            | Creator-Conditions and Allergy -Coded Subset (see Section 3.2.3.6)               | C[201]                       |
|                                     |  |                   |            | Creator-Laboratory Section Subset (see Section 3.2.3.7)                          | C[201]                       |
|                                     |  |                   |            | Creator-Laboratory Section -Coded Subset (see Section 3.2.3.8)                   | C[201]                       |



| Business Actor                          | Technical Actor(s)                 | Actor Optionality | Construct  | Transaction/Content (T/C)  | T/C Optionality <sup>1</sup> |
|---|------------------------------------|-------------------|------------|--|------------------------------|
|   | Audit Record Source                | R                 | HITSP/T15  | Record Audit Event in Repository   | R                            |
|   | Audit Record Repository            | O                 | HITSP/T15  | Record Audit Event in Repository   | R                            |
|   | Time Client                        | R                 | HITSP/T16  | Maintain Time  | R                            |
|   | Time Server                        | O                 | HITSP/T16  | Maintain Time  | R                            |
|   | Node                               | R                 | HITSP/T17  | Secured Communication Channel  | R                            |
|   | Identity provider                  | C[104]            | HITSP/C19  | Provide Assertion  | R                            |
|   |                                    |                   |            | Verify Assertion   | O                            |
|   | Service provider                   | C [103]           | HITSP/TP20 | Access Control Request   | R                            |
|   | Consent Repository                 | O                 | HITSP/TP30 | Register Document Set  | R                            |
|   |                                    |                   |            | Stored Query   | R                            |
|   | Consent Registry                   | O                 | HITSP/TP30 | Provide and Register Document Set  | R                            |
|   |                                    |                   |            | Register Document Set  | R                            |
|   | Consent Directive Requester        | O                 | HITSP/TP30 | Stored Query   | R                            |
|   |                                    |                   |            | Retrieve Document Set  | R                            |
|   | Service User                       | R                 | HITSP/TP20 | Access Control Request   | O                            |
|   | User Access Control Service (UACS) | R                 | HITSP/TP20 | Access Control Request   | O                            |
| Pharmacy Benefit Manager (PBM)/Pharmacy | Patient Identity Source            | C [101]           | HITSP/TP22 | Patient Identity Feed  | R                            |
|   | PIX Consumer                       | C [101]           | HITSP/TP22 | PIX Query  | R                            |
|   | Patient Demographics Consumer      | C [101]           | HITSP/T23  | Patient Demographics Query   | R                            |
|   | Document Source                    | R                 | HITSP/TP13 | Provide & Register Document Set-b  | R                            |
|   |                                    | C[103]            | HITSP/C19  | Convey Assertion   | O                            |
|   | Content Creator                    | R                 | HITSP/C32  | Creator-Registration Subset (see Section 3.2.3.1)                                | C[201]                       |
|   |                                    |                   |            | Creator-Registration-Coded Subset (see Section 3.2.3.2)                          | C[201]                       |
|   |                                    |                   |            | Creator-Medication and Immunization History Subset (see Section 3.2.3.3)         | C[201]                       |
|   |                                    |                   |            | Creator-Medication and Immunization History - Coded Subset (see Section 3.2.3.4) | C[201]                       |
|   |                                    |                   |            | Creator-Conditions and Allergy Subset (see Section 3.2.3.5)                      | C[201]                       |
|   |                                    |                   |            | Creator-Conditions and Allergy -Coded Subset (see Section 3.2.3.6)               | C[201]                       |
|   |                                    |                   |            | Creator-Laboratory Section Subset (see Section 3.2.3.7)                          | C[201]                       |
|   |                                    |                   |            | Creator-Laboratory Section -Coded Subset (see Section 3.2.3.8)                   | C[201]                       |
|   | Audit Record Source                | R                 | HITSP/T15  | Record Audit Event in Repository   | R                            |





| Business Actor | Technical Actor(s)                 | Actor Optionality | Construct  | Transaction/Content (T/C)         | T/C Optionality <sup>1</sup> |
|----------------|------------------------------------|-------------------|------------|-----------------------------------|------------------------------|
|                | Audit Record Repository            | O                 | HITSP/T15  | Record Audit Event in Repository  | R                            |
|                | Time Client                        | R                 | HITSP/T16  | Maintain Time                     | R                            |
|                | Time Server                        | O                 | HITSP/T16  | Maintain Time                     | R                            |
|                | Node                               | R                 | HITSP/T17  | Secured Communication Channel     | R                            |
|                | Identity Provider                  | C[104]            | HITSP/C19  | Provide Assertion                 | R                            |
|                |                                    |                   |            | Verify Assertion                  | O                            |
|                | Service Provider                   | C [103]           | HITSP/TP20 | Access Control Request            | R                            |
|                | Consent Repository                 | O                 | HITSP/TP30 | Register Document Set             | R                            |
|                |                                    |                   |            | Stored Query                      | R                            |
|                | Consent Registry                   | O                 | HITSP/TP30 | Provide and Register Document Set | R                            |
|                |                                    |                   |            | Register Document Set             | R                            |
|                | Consent Directive Requester        | O                 | HITSP/TP30 | Stored Query                      | R                            |
|                |                                    |                   |            | Retrieve Document Set             | R                            |
|                | Service User                       | R                 | HITSP/TP20 | Access Control Request            | O                            |
|                | User Access Control Service (UACS) | R                 | HITSP/TP20 | Access Control Request            | O                            |

**NOTE:** Optionality = “R” for Required, “R2” for Required if known, “O” for Optional, or “C” for Conditional. Conditional footnotes are further described below.

### Implementation Conditions/Constraints

The following table describes the implementation conditions or constraints placed on the technical actors, transactions, or content. The constraint codes listed below correspond to the codes placed in the Actor and Transaction/Content optionality column in Table 3.2.3-1 above. For example, the Patient Demographics Consumer Technical Actor has an optionality code of C<sup>[105]</sup> <sup>[106]</sup> which represents a conditionally required Actor with the constraint codes of 105 and 106 described in the table below.

**Table 3.2.3-2 Implementation Conditions/Constraints**

| Constraint Code | Constraint Description  |
|-----------------|---|
| 101             | Shall support (Patient Identity Source plus PIX Consumer) and/or Patient Demographics Consumer  |
| 102             | Required if Access Control Request transaction is not supported.  |
| 103             | Required when a Document Repository and/or a Document Registry is supported.  |
| 104             | There must be at least one in a group of business actors  |
| 105             | There can be ONLY one in a group of business actors   |
| 201             | Shall support either at least one of the subsets of the HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD), the HITSP/C37 - Lab Report Document , the HITSP/C62 – Unstructured Document, or any combination of the three constructs. |



The following sections describe the implementation subset options by which the specification may be implemented in a limited manner. These implementation subsets are focused on delivering specific content. Any dependencies between subsets, and business actors are also described. Conformance considerations for implementing this Interoperability Specification and any of its subsets are described in detail in Section 5.0

### 3.2.3.1 C32 “Creator-Registration Subset”

This subset impacts the content of the HITSP/C32 Summary Document Using HL7 Continuity of Care Document (CCD) document produced by a Content Creator Technical Actor. It requires the Content Creator to have the **ability to create the content** of the following content modules for the purpose of exchange, with variants as specified in the HITSP/C32 construct:

**Table 3.2.3.1-1 Creator Registration Subset Content Modules**

| Content Modules     | Optionality |
|---------------------|-------------|
| Advance Directive   | R2          |
| Comments            | R2          |
| Healthcare Provider | R2          |
| Information Source  | R2          |
| Insurance Provider  | R2          |
| Language Spoken     | R2          |
| Person Information  | R           |
| Pregnancy           | R2          |
| Support             | R2          |

**NOTE:** Optionality = “R” for Required, “R2” for Required if known, “O” for Optional, or “C” for Conditional.

Additional HITSP/C32 content modules may be present, but are not required in this subset. Within the context of this subset, the content consumer is not required to recognize or process such "additional" content modules.

The type of payer and type of payer entries contain the concepts but without the HITSP/C32 specified code set.

### 3.2.3.2 C32 “Creator-Registration-Coded Subset”

This subset is identical to the Creator-Registration Subset but requires the creation of type of payer and type of payer entries with the HITSP/C32 specified code set.

### 3.2.3.3 C32 “Creator-Medication and Immunization History Subset”

This subset impacts the content of the HITSP/C32 Summary Document Using HL7 Continuity of Care Document (CCD) document produced by a Content Creator Technical Actor. It requires the Content



Creator to have the ability to create the content of the following content module for the purpose of exchange, with variants as specified in the HITSP/C32 construct:

**Table 3.2.3.3-1 Creator Medication and Immunization History Subset Content Modules**

| Content Modules                                 | Optionality |
|---|-------------|
| Comments  | R2          |
| Healthcare Provider                             | R2          |
| Immunization                                    | R2          |
| Information Source                              | R2          |
| Medications – Prescription and Non-Prescription | R2          |
| Person Information                              | R           |

**NOTE:** Optionality = “R” for Required, “R2” for Required if known, “O” for Optional, or “C” for Conditional.

Additional HITSP/C32 content modules may be present, but are not required in this subset. Within the context of this subset, the content consumer is not required to recognize or process such "additional" content modules.

The Medication entry may contain the concepts but without an associated code.

#### 3.2.3.4 C32 “Creator-Medication and Immunization History-Coded Subset”

This subset is identical to the Creator-Medication Subset but requires the creation of medication entries with the HITSP/C32 specified code sets.

#### 3.2.3.5 C32 “Creator-Conditions and Allergy Subset”

This subset impacts the content of the HITSP/C32 Summary Documents Using HL7 Continuity of Care Document (CCD) document produced by a Content Creator Technical Actor. It requires the Content Creator to have the ability to create the content for the purpose of exchange as specified in the HITSP/C32 construct:

**Table 3.2.3.5-1 Creator Conditions and Allergy Subset Content Modules**

| Content Modules                | Optionality |
|--------------------------------|-------------|
| Allergies and Drug Sensitivity | R2          |
| Comments                       | R2          |
| Condition                      | R2          |
| Healthcare Provider            | R2          |
| Information Source             | R2          |
| Person Information             | R           |

**NOTE:** Optionality = “R” for Required, “R2” for Required if known, “O” for Optional, or “C” for Conditional.



Additional HITSP/C32 content modules may be present, but are not required in this subset. Within the context of this subset, the content consumer is not required to recognize or process such "additional" content modules.

The Condition and Allergy entries contain the concepts but without the HITSP/C32 specified code set.

#### 3.2.3.6 C32 "Creator-Conditions and Allergy-Coded Subset"

This subset is identical to the Creator-Registration Subset but requires the creation of conditions and allergies entries with the HITSP/C32 specified code set.

#### 3.2.3.7 C32 "Creator-Laboratory Section Subset"

This subset impacts the content of the HITSP/C32 Summary Documents Using HL7 Continuity of Care Document (CCD) document produced by a Content Creator Technical Actor. It requires the Content Creator to have the ability to create the content for the purpose of exchange as specified in the HITSP/C32 construct:

**Table 3.2.3.7-1 Creator Laboratory Subset Content Modules**

| Content Modules     | Optionality |
|---------------------|-------------|
| Comments            | R2          |
| Healthcare Provider | R2          |
| Information Source  | R2          |
| Person Information  | R           |
| Result              | R2          |

**NOTE:** Optionality = "R" for Required, "R2" for Required if known, "O" for Optional, or "C" for Conditional.

Additional HITSP/C32 content modules may be present, but are not required in this subset. Within the context of this subset, the content consumer is not required to recognize or process such "additional" content modules.

The Result entries contain the concepts but without the HITSP/C32 specified code set.

#### 3.2.3.8 C32 "Creator-Laboratory Section-Coded Subset"

This subset is identical to the Creator-Laboratory Section Subset but requires the creation of laboratory results entries with the HITSP/C32 specified code set.

#### 3.2.3.9 Consumer-Document Display Subset

This subset impacts the import of Documents processed by a Content Consumer Technical Actor. It requires the Document Consumer only to have the ability to display one or more of the required documents (e.g., HITSP/C32, HITSP/C37, HITSP/C62) as requested (it may not be able to locally import it in the patient record).



#### 3.2.3.10 Consumer-Document Import Subset

This subset impacts the import of Documents processed by a Content Consumer Technical Actor. It requires the Document Consumer to have the ability to import into the patient record one or more of the required documents (e.g., HITSP/C32, HITSP/C37, HITSP/C62) as a whole and display it as requested.

#### 3.2.3.11 C32 “Consumer-Registration Discrete Data Import Subset”

This subset impacts the import of the HITSP/C32 Summary Documents Using HL7 Continuity of Care Document (CCD) document processed by a Content Consumer Technical Actor. It requires the Document Consumer to have the ability to import the discrete data from one or more of the registration entries in a structured form into the patient record. Coded values shall be maintained.

#### 3.2.3.12 C32 “Consumer-Medication and Immunization History Discrete Data Import Subset”

This subset impacts the import of the HITSP/C32 Summary Documents Using HL7 Continuity of Care Document (CCD) document processed by a Content Consumer Technical Actor. It requires the Document Consumer to have the ability to import the discrete data from one or more of the medication and immunization history entries in a structured form into the patient record. Coded values shall be maintained.

#### 3.2.3.13 C32 “Consumer-Conditions and Allergy Discrete Data Import Subset”

This subset impacts the import of the HITSP/C32 Summary Documents using HL7 Continuity of Care Document (CCD) document processed by a Content Consumer Technical Actor. It requires the Document Consumer to have the ability to import the discrete data from one or more of the conditions and allergy entries in a structured form into the patient record. Coded values shall be maintained.

#### 3.2.3.14 C32 “Consumer-Laboratory Discrete Data Import Subset”

This subset impacts the import of the HITSP/C32 Summary Documents using HL7 Continuity of Care Document (CCD) document processed by a Content Consumer Technical Actor. It requires the Document Consumer to have the ability to import the discrete data from one or more of the laboratory entries in a structured form into the patient record. Coded values shall be maintained.

#### 3.2.3.15 C37 “Consumer-Lab Report Discrete Data Import Subset”

This subset impacts the import of HITSP/C37 Lab Report Document processed by a Content Consumer Technical Actor. It requires the Document Consumer to have the ability to import the discrete data from one or more of the entries in a structured form into the patient record. Coded values shall be maintained.

### 3.2.4 CONSTRUCT DEPENDENCIES

The following table shows a list of constructs with their existing dependencies. Dependencies usually exist when there are some additional pre-requisites for a specific construct. To support a dependent



construct, a technical actor must implement all the required actions in the pre-requisite construct, or be grouped together with another construct as specified in the table below:

**Table 3.2.4-1 Construct Dependencies**

| Construct   | Depends On<br>(Name of construct that it depends on) | Dependency Type<br>(Pre-condition, post-condition, general) | Purpose<br>(Reason for this dependency)                                       |
|---|--|---|---|
| HITSP/T15 - Collect and Communicate Audit Trail                           | HITSP/T16 - Consistent Time                          | Pre-condition   | Pre-requisites for Use Cases  |
| HITSP/TP13 - Manage Sharing of Documents                                  | HITSP/T15 - Collect and Communicate Audit Trail      | Pre-condition   | Pre-requisites for Use Cases  |
| HITSP/T17 - Secured Communication Channel                                 | HITSP/T15 - Collect and Communicate Audit Trail      | General   | Identification and management of audit trigger events and audit event outputs |
| HITSP/TP30 - Manage Consent Directives                                    | HITSP/T17 - Secured Communication Channel            | Pre-condition   | Pre-requisites for Use Cases  |
| HITSP/TP30 - Manage Consent Directives                                    | HITSP/T16 - Consistent Time                          | Pre-condition   | Pre-requisites for Use Cases  |
| HITSP/TP30 - Manage Consent Directives                                    | HITSP/T15 - Collect and Communicate Audit Trail      | Pre-condition   | Pre-requisites for Use Cases  |
| HITSP/TP30 - Manage Consent Directives                                    | HITSP/C19 - Entity Identity Assertion                | General   | Pre-requisites for Use Cases  |
| HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD) | HITSP/ C35 - Lab Result Terminology                  | General   | Describes the vocabulary to be used for discrete lab results data elements    |
| HITSP/C37 - Lab Report Document   | HITSP/ C35 - Lab Result Terminology                  | General   | Describes the vocabulary to be used for discrete lab results data elements    |

### 3.2.5 ADDITIONAL CONSTRAINTS ON REQUIRED CONSTRUCTS

This section describes the constraints that further limit the constructs that are used by this Interoperability Specification.

**Table 3.2.5-1 Additional Constraints on Required Constructs**

| Data Element                         | Construct | Constraint | Constraint Type<br>(Pre-condition, post-condition, general) | Purpose<br>(Reason for this constraint) |
|--------------------------------------|-----------|------------|---|---|
| No applicable additional constraints |           |            |   |   |



## 4.0 STANDARDS SELECTION

This section presents the standards required to support each major Use Case event. Standards selection is based on the following process:

- **Evaluation:** The Technical Committee evaluates the standards using the Tier 2 Readiness Criteria.
- **Selection:** Based on the Tier 2 evaluations, named standards are selected and listed in the table of selected standards below. 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
- **Gap and Overlap Analysis and Recommendations:** The Technical Committee also identifies and analyzes gaps and overlaps within the standards industry as they relate to the specific Use Case. The Technical Committee provides a description of the gaps, including missing or incomplete standards, a description of all overlaps, or competition among standards for the relevant Use Cases, and recommendations for resolving these gaps and overlaps

It is HITSP's policy to incorporate only standards that have been approved according to the formal policy of the standards organization, as defined by HITSP, which publishes the standard. HITSP interprets approval to include Draft Standards for Trial Use. The objective is to incorporate only standards that are managed within a formal life cycle process as defined by the standards organization. In some cases, where we believe a standard that is not yet approved may best meet the requirements of an Interoperability Specification, HITSP may provide a roadmap of its future intent conditional on future actions by either or both the standards organization 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 at 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 Technical Committee and/or the standards organization. Therefore a standard is defined as "Intended for Use" if it will not be approved by the standard organization at the time that the HITSP construct is released, but is sufficiently defined to enable detailed evaluation of how well it will meet technical and information exchange 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 Technical Committee 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.

## 4.1 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. In addition, adherence to the selected standards alone is not sufficient to ensure interoperability. In order to ensure interoperability for the Use Case, and to claim conformance to the specification, an implementation must satisfy all the requirements and mandatory statements listed in the HITSP Interoperability Specification, its associated construct specifications, as well as conformance criteria from the selected base and composite standards. A conformant system must also be constrained as specified in Table 3.1.2-1, and implement all of the required technical actors from Table 3.2.3-1, within the scope and implementation subset that is selected.

The standards used by this Interoperability Specification fall into the following categories:

- Regulatory guidance is a legal or other authoritative declaration that HITSP must abide by in standards selection (see Section 4.1.1)
- Selected standards are necessary for interoperability. These are standards that are used to meet information exchange requirements of associated constructs. For example, they are used to realize direct information exchange, to provide the transport mechanism, to specify the content, or to address security (see Section 4.1.2)
- Informative reference standards provide additional background information or guidance, and are not required for interoperability. These standards are not required to implement the Interoperability Specification (see Section 4.1.3)

### 4.1.1 REGULATORY GUIDANCE

The following table provides a list of legal or other authoritative guidelines that HITSP must abide by, or has agreed to use as guidance in the selection of standards. Note that only the referenced sections of the regulations are relevant to this Interoperability Specification.

**Table 4.1.1-1 Regulatory Guidance**

| Standard  | Description   |
|---|---|
| Clinical Laboratory Improvement Amendments (CLIA) of 1988 | Establishes quality standards for all laboratory testing to ensure the accuracy, reliability, and timeliness of patient test results regardless of where the test is performed. The Centers for Medicare and Medicaid Services (CMS) regulates all laboratory testing (except research) performed on humans in the U.S. based on CLIA. For more information visit <a href="http://www.fda.gov">www.fda.gov</a> and <a href="http://www.cms.hhs.gov">www.cms.hhs.gov</a> . |



#### 4.1.2 SELECTED STANDARDS

The following table provides a list of standards that are used to meet information exchange requirements of the Interoperability Specification, and the HITSP constructs that use each standard. A detailed description of each standard is also provided in the Appendix.

Note that the standards selected for this Interoperability Specification are approved for use as defined in Section 4.0 above.

**Table 4.1.2-1 Selected Standards Linked to HITSP Constructs**

| Standard Name   | HITSP Construct   | Remarks/ Minor Gaps                    |
|---|---|--|
| Accredited Standards Committee (ASC) X12 Standards Release 004010   | HITSP/C80 - Clinical Document and Message Terminology                     | Vocabularies are enabled via HITSP/C32 |
| American Medical Association (AMA) Current Procedural Terminology (CPT®) Fourth Edition (CPT-4); CPT Evaluation and Management Codes  | HITSP/C80 - Clinical Document and Message Terminology                     | Vocabularies are enabled via HITSP/C32 |
| American Society for Testing and Materials (ASTM) Standard Guide for Electronic Authentication of Health Care Information: # E1762-95(2003)   | HITSP/C26 - Nonrepudiation of Origin                                      |  |
| CDC Race and Ethnicity Code Sets  | HITSP/C80 - Clinical Document and Message Terminology                     | Vocabularies are enabled via HITSP/C32 |
| European Telecommunications Standards Institute (ETSI) Technical Specification TS 101 903: XML Advanced Electronic Signatures (XadES)   | HITSP/C26 - Nonrepudiation of Origin                                      |  |
| Federal Information Processing Standards (FIPS) Codes for the Identification of the States, the District of Columbia and the Outlying Areas of the United States, and Associated Areas Publication # 5-2, May, 1987 | HITSP/C80 - Clinical Document and Message Terminology                     | Vocabularies are enabled via HITSP/C32 |
| Food and Drug Administration (FDA) - Unique Ingredient Identifier (UNII)  | HITSP/C80 - Clinical Document and Message Terminology                     | Vocabularies are enabled via HITSP/C32 |
| Food and Drug Administration (FDA) - National Drug Code (NDC)   | HITSP/C80 - Clinical Document and Message Terminology                     | Vocabularies are enabled via HITSP/C32 |
| Health Level Seven (HL7) HL7 Version 3 Standard: Clinical Document Architecture (CDA), Release 2  | HITSP/C37 - Lab Report Document   |  |
| Health Level Seven (HL7) Implementation Guide: CDA Release 2.0 – Continuity of Care Document (CCD), April 01, 2007  | HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD) |  |
| Health Level Seven (HL7) Standard Code Set CVX - Vaccines Administered  | HITSP/C80 - Clinical Document and Message Terminology                     | Vocabularies are enabled via HITSP/C32 |
| Health Level Seven (HL7) Standard Code Set MVX - Manufacturers of Vaccines  | HITSP/C80 - Clinical Document and Message Terminology                     | Vocabularies are enabled via HITSP/C32 |
| Health Level Seven (HL7) V3 RBAC, R1-2008, HL7 Version 3 Standard: Role Based Access Control (RBAC) Healthcare Permissions Catalog, Release 1, February 2008  | HITSP/TP20 – Access Control   |  |



| Standard Name  | HITSP Construct   | Remarks/ Minor Gaps                    |
|--|---|--|
| Health Level Seven (HL7) Version 2.5, Chapter 2 – Control, Chapter 3 – Patient Administration, Chapter 5 - Query   | HITSP/TP22 - Patient ID Cross-Referencing<br>HITSP/T23 - Patient Demographics Query |  |
| Health Level Seven (HL7) Version 2.5.1 - Vocabularies and Value Sets   | HITSP/C35 - Lab Result Terminology  |  |
| Health Level Seven (HL7) Version 3.0 – Vocabularies and Value Sets   | HITSP/C80 - Clinical Document and Message Terminology                               | Vocabularies are enabled via HITSP/C32 |
| Health Level Seven (HL7) Version 3.0 Context-Aware Information Retrieval Specification: URL Implementation Guide   | HITSP/T81 – Retrieval of Medical Knowledge  |  |
| Health Level Seven (HL7) Version 3.0 Privacy Consent related specifications<br>RCMR_RM010001 - Data Consent  | HITSP/TP30 - Manage Consent Directives  |  |
| Integrating the Healthcare Enterprise (IHE) Exchange of Personal Health Record Content (XPHR) Integration Profile  | HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD)           |  |
| Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0, Section 10 Cross-Enterprise Document Sharing (XDS.a) Integration Profile                            | HITSP/TP13 - Manage Sharing of Documents<br>HITSP/TP30 - Manage Consent Directives  |  |
| Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Volume 2 Supplement 2007 – 2008 Cross-Enterprise Document Sharing-B (XDS.b) Integration Profile                   | HITSP/TP13 - Manage Sharing of Documents<br>HITSP/TP30 - Manage Consent Directives  |  |
| Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0 - Registry Stored Query Transaction for XDS Profile Supplement [ITI-18]                              | HITSP/TP13 - Manage Sharing of Documents<br>HITSP/TP30 - Manage Consent Directives  |  |
| Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0 XCA Supplement   | HITSP/TP30 - Manage Consent Directives  |  |
| Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Supplement 2008-2009, Cross-Community Access (XCA), Trial Implementation, October 10, 2008                        | HITSP/TP13 - Manage Sharing of Documents  |  |
| Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0 or later, Patient Identifier Cross-Referencing Integration Profile (PIX)                             | HITSP/TP22 - Patient ID Cross-Referencing   |  |
| Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0 or later, Audit Trail and Node Authentication (ATNA) Integration Profile, Section 9.1 Authentication | HITSP/T17 - Secured Communication Channel   |  |
| Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0 or later, Audit Trail and Node Authentication Integration Profile (ATNA)                             | HITSP/T15 - Collect and Communicate Security Audit Trail                            |  |



| Standard Name  | HITSP Construct   | Remarks/ Minor Gaps                              |
|--|---|--|
| Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0 or later, Consistent Time (CT) Integration Profile   | HITSP/T16 - Consistent Time   |  |
| Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Supplement 2007 - 2008 Basic Patient Privacy Consents (BPPC) – Trial Implementation Integration Profile | HITSP/TP30 - Manage Consent Directives  |  |
| Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Volume 2 Supplement 2007 – 2008 Cross-Enterprise User Assertion (XUA) Integration Profile               | HITSP/C19 - Entity Identity Assertion   |  |
| Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Supplement Volume 3 – Document Digital Signature (DSG) Content Profile                                  | HITSP/C26 - Nonrepudiation of Origin  |  |
| Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 5.0 or later, Patient Demographics Query (PDQ) Integration Profile                             | HITSP/T23 - Patient Demographics Query  |  |
| Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Supplement 2008 - 2009, Pediatric Demographics, Draft for Trial Implementation (August 22, 2008)        | HITSP/TP22 - Patient ID Cross-Referencing<br>HITSP/T23 - Patient Demographics Query         |  |
| Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) – Revision 5.0 or later, Cross Enterprise Sharing of Scanned Documents (XDS-SD) Integration Profile     | HITSP/C62 – Unstructured Document   |  |
| Integrating the Healthcare Enterprise (IHE) Laboratory Technical Framework Volume 3 (LAB TF-3) Document-based Transactions, Revision 2.0 - For Trial Implementation, August 16, 2007               | HITSP/C37 - Lab Report Document   |  |
| International Health Terminology Standards Development Organisation (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®)   | HITSP/C80 - Clinical Document and Message Terminology<br>HITSP/C35 - Lab Result Terminology | HITSP/C80 vocabularies are enabled via HITSP/C32 |
| International Organization for Standardization (ISO) ISO 3166-1  | HITSP/C80 - Clinical Document and Message Terminology                                       | Vocabularies are enabled via HITSP/C32           |
| International Organization for Standardization (ISO) PDF/A ISO 19005-1b. Document management - Electronic document file format for long-term preservation - Part 1: Use of PDF (PDF/A)             | HITSP/C62 – Unstructured Document   |  |
| Internet Engineering Task Force (IETF) Network Time Protocol (Version 3) Specification, Implementation and Analysis, "Request for Comment" (RFC) #1305, March, 1992                                | HITSP/T16 - Consistent Time   |  |
| Internet Engineering Task Force (IETF) Simple Network Time Protocol (SNTP) Version 4, "Request for Comment" (RFC) #2030, October, 1996   | HITSP/T16 - Consistent Time   |  |



| Standard Name  | HITSP Construct   | Remarks/ Minor Gaps                              |
|--|---|--|
| Internet Engineering Task Force (IETF) Tags for Identifying Languages, "Request for Comment" (RFC) # 4646, September, 2006   | HITSP/C80 - Clinical Document and Message Terminology                                       | Vocabularies are enabled via HITSP/C32           |
| Logical Observation Identifiers Names and Codes (LOINC®)   | HITSP/C80 - Clinical Document and Message Terminology<br>HITSP/C35 - Lab Result Terminology | Vocabularies are enabled via HITSP/C32           |
| National Cancer Institute (NCI) Thesaurus  | HITSP/C80 - Clinical Document and Message Terminology                                       | Vocabularies are enabled via HITSP/C32           |
| National Library of Medicine (NLM) Unified Medical Language System (UMLS) RxNorm   | HITSP/C80 - Clinical Document and Message Terminology                                       | Vocabularies are enabled via HITSP/C32           |
| Organization for the Advancement of Structured Information Standards (OASIS) Security Assertion Markup Language (SAML) Core V2.0 OASIS Standard; ITU-T X.1141              | HITSP/TP20 - Access Control   |  |
| Organization for the Advancement of Structured Information Standards (OASIS) WS-Trust Version 1.3, March 2007  | HITSP/TP20 - Access Control   |  |
| Organization for the Advancement of Structured Information Standards (OASIS) eXtensible Access Control Markup Language (XACML), ITU-T Recommendation X.1142, February 2005 | HITSP/TP20 - Access Control   |  |
| U.S. National Uniform Claims Committee Health Care Provider Taxonomy Code Set  | HITSP/C80 - Clinical Document and Message Terminology                                       | Vocabularies are enabled via HITSP/C32           |
| Unified Code for Units of Measure (UCUM)   | HITSP/C80 - Clinical Document and Message Terminology<br>HITSP/C35 - Lab Result Terminology | HITSP/C80 vocabularies are enabled via HITSP/C32 |
| United States Postal Service (USPS) – Postal Codes   | HITSP/C80 - Clinical Document and Message Terminology                                       | Vocabularies are enabled via HITSP/C32           |
| VHA National Drug File Reference Terminology (NDF-RT) Formulary  | HITSP/C80 - Clinical Document and Message Terminology                                       | Vocabularies are enabled via HITSP/C32           |

#### 4.1.3 INFORMATIVE REFERENCE STANDARDS

The following table lists standards that provide additional background information or guidance; however, they are not required for the implementation of the Interoperability Specification.

**Table 4.1.3-1 Informative Reference Standards**

| Standard Name   | Description/Reason for Use   |
|---|--|
| American National Standards Institute (ANSI) International Committee for Information Technology Standards (INCITS), #359-2004 | This standard describes RBAC features that have achieved acceptance in the commercial marketplace. It includes a reference model and functional specifications for the RBAC features defined in the reference model. It is intended for (1) software engineers and product development managers who design products incorporating access control features; and (2) managers and procurement officials who seek to acquire computer security products with features that provide access control capabilities in accordance with commonly known and understood terminology and functional. For more information visit <a href="http://www.ansi.org">www.ansi.org</a> . |



| Standard Name  | Description/Reason for Use   |
|--|--|
| ASTM International Standard Guide for Privilege Management Infrastructure (PMI) Guidelines: #E2595-07                                  | <p>Defines interoperable mechanisms to manage privileges in a distributed environment. This standard is oriented towards support of a distributed or service-oriented architecture (SOA) where security services are themselves distributed and applications are consumers of distributed services. This standard incorporates privilege management mechanisms alluded to in a number of existing standards (e.g., E1986, E2084). The privilege mechanisms in this standard support policy-based access control (including role, entity and contextual-based access control) including the application of policy constraints, patient requested restrictions and delegation. Finally, the standard supports hierarchical, enterprise-wide privilege management.</p> <p>The mechanisms defined in this standard may be used to support a privilege management infrastructure (PMI) using existing public key infrastructure (PKI) technology. This standard does not specifically support mechanisms based on secret-key cryptography. Mechanisms involving privilege credentials are specified in International Organization for Standardization (ISO) 9594-8:2000 (attribute certificates), and Organization for the Advancement of Structured Information Standards (OASIS) Security Assertion Markup Language (SAML) (attribute assertions); however, this standard does not mandate or assume the use of such standards.</p> <p>Many current systems require only local privilege management functionality (on a single computer system). Such systems frequently use proprietary mechanisms. This standard does not address this type of functionality; rather, it addresses an environment where privileges and capabilities (authorizations) must be managed between computer systems across the enterprise, and with business partners. For more information visit <a href="http://www.astm.org">www.astm.org</a>.</p> |
| ASTM International Standard Specification for Audit and Disclosure Logs for Use in Health Information Systems: # E2147-01              | <p>E2147-01 "is for the development and implementation of security audit/disclosure logs for health information. It specifies how to design an access audit log to record all access to patient identifiable information maintained in computer systems and includes principles for developing policies, procedures, and functions of health information logs to document all disclosure of health information to external users for use in manual and computer systems. The process of information disclosure and auditing should conform, where relevant, with the Privacy Act of 1974 (1)." For more information visit <a href="http://www.astm.org">www.astm.org</a>.</p>  |
| Council for Affordable Quality Health Care (CAQH) Committee on Operating Rules for Information Exchange (CORE) Phase I Operating Rules | <p>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. For more information visit <a href="http://www.caqh.org">www.caqh.org</a>.</p>   |
| Federal Medication Terminologies   | <p>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) .</p> <p>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).</p> <p>Information on the Federal Medication Terminologies may be found and downloaded from the NCI Web portal terminology resources page at <a href="http://www.cancer.gov/cancertopics/terminologyresources/FMT">www.cancer.gov/cancertopics/terminologyresources/FMT</a></p>  |





| Standard Name  | Description/Reason for Use  |
|--|---|
| Health Level Seven (HL7) Consent related vocabulary including Confidentiality Codes  | HL7 concept domains, including ConfidentialityCodes, ActInformationCategoryCode, ActInformationAccessType, ActInformationAccessContextCode, AuthorizedParticipationFunctionCode, ActPolicyType, ActConsentType, and ActMaskableCode For more information visit <a href="http://www.hl7.org">www.hl7.org</a> .   |
| 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. For more information visit <a href="http://www.hl7.org">www.hl7.org</a> .  |
| 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. For more information visit <a href="http://www.ihe.net">www.ihe.net</a> .  |
| 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 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. For more information visit <a href="http://www.ihe.net">www.ihe.net</a> . |
| Integrating the Healthcare Enterprise (IHE) Patient Care Coordination (PCC), Revision 3.0, 2007 - 2008   | 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. For more information visit <a href="http://www.ihe.net">www.ihe.net</a> . |
| International Organization for Standardization (ISO) Health Informatics -- Information technology -- Open Systems Interconnection -- Systems Management: Security alarm reporting function, Technical Specification #10164-- Part 7: Security Alarm Reporting Function, 1992   | Establishes user requirements for the service definition needed to support the security alarm reporting function, defines the service provided by the security alarm reporting function, specifies the protocol that is necessary in order to provide the service, defines the relationship between the service and management notifications, defines relationships with other systems management functions, specifies conformance requirements. The security alarm reporting function is a systems management function which may be used by an application process in a centralized or decentralized management environment to exchange information for the purpose of systems management. For more information visit <a href="http://www.iso.org">www.iso.org</a> .             |
| International Organization for Standardization (ISO) Health Informatics -- Information technology -- Text and office systems - Office Document Architecture (ODA) and interchange format, Technical Report on ISO 8613 implementation testing, Technical Specification # ISO/IEC CD 10183 -- Part 3: Testing procedure | Specifies a general framework for the provision of access control. The purpose of access control is to counter the threat of unauthorized operations involving a computer or communication system. For more information visit <a href="http://www.iso.org">www.iso.org</a> .  |





| Standard Name   | Description/Reason for Use  |
|---|---|
| International Organization for Standardization (ISO) Health Informatics -- Privilege management and access control (PMAC), Technical Specification #22600 – Part 1: Overview and policy management, July 2006 | Supports the needs of healthcare information sharing across unaffiliated providers of healthcare, healthcare organizations, health insurance companies, their patients, staff members and trading partners. It is also intended to support inquiries from both individuals and application systems. For more information visit <a href="http://www.iso.org">www.iso.org</a> .   |
| International Organization for Standardization (ISO) Health Informatics – Functional and Structural Roles (ISO SF Roles), Technical Specification #21298, Draft May, 2007                                     | <p>This document contains a specification for encoding information related to roles for health professionals and consumers. At least four areas have been identified where a model for encoding role information is needed.</p> <ol style="list-style-type: none"> <li>1. Privilege management and access control: role-based access control is not possible without an effective means of recording role information for healthcare actors.</li> <li>2. Directory services: structural roles are usefully recorded within directories of healthcare providers (see for example, ISO TS 21091 Health Informatics – Directory services for security, communications, and identification of professionals and patients).</li> <li>3. Audit trails: functional roles are usefully recorded within audit trails for health information applications.</li> <li>4. Public key infrastructure (PKI): The three part ISO standard 17090 Health Informatics – Public Key Infrastructure (PKI) allows for the encoding of healthcare roles in certificate extensions, but no structured vocabulary for such roles is specified. This technical specification identifies such a coded vocabulary.</li> </ol> <p>For more information visit <a href="http://www.iso.org">www.iso.org</a>.</p> |
| Internet Engineering Task Force (IETF) The application/pdf Media Type (RFC 3778)  | PDF, the 'Portable Document Format', is a general document representation language that has been in use for document exchange on the Internet since 1993. This document provides an overview of the PDF format, explains the mechanisms for digital signatures and encryption within PDF files, and updates the media type registration of 'application/pdf'. For more information visit <a href="http://www.ietf.org">www.ietf.org</a> .   |
| Internet Engineering Task Force (IETF) Tags for the Identification of Languages, "Request for Comment" (RFC) #3066, January, 2001   | Describes a language tag for use in cases where it is desired to indicate the language used in an information object, how to register values for use in this language tag, and a construct for matching such language tags. For more information visit <a href="http://www.ietf.org">www.ietf.org</a> .   |
| National Cancer Institute (NCI) Thesaurus: Route of Administration  | Route of Administration is the path by which a particular drug product is introduced on or into the body. The medication terminology is maintained by the NCI Thesaurus, a reference terminology and biomedical ontology used in a growing number of NCI and other systems. It covers vocabulary for clinical care, translational and basic research, and public information and administrative activities. The NCI Thesaurus provides definitions, synonyms, and other information on nearly 10,000 cancers and related diseases, 8,000 single agents and combination therapies, and a wide range of other topics related to cancer and biomedical research. It is part of the Federal Medication Terminologies. For more information visit <a href="http://www.cancer.gov">www.cancer.gov</a> .   |
| Organization for the Advancement of Structured Information Standards (OASIS) Web Services Security SOAP Message Security Version 1.0  | Describes enhancements to SOAP messaging to provide message integrity and confidentiality. The specified mechanisms can be used to accommodate a wide variety of security models and encryption technologies. This specification also provides a general-purpose mechanism for associating security tokens with message content. No specific type of security token is required, the specification is designed to be extensible (i.e., support multiple security token formats. Additionally, this specification describes how to encode binary security tokens, a framework for XML-based tokens, and how to include opaque encrypted keys. It also includes extensibility mechanisms that can be used to further describe the characteristics of the tokens that are included with a message. For more information visit <a href="http://www.oasis-open.org">www.oasis-open.org</a> .   |



| Standard Name   | Description/Reason for Use  |
|---|---|
| Organization for the Advancement of Structured Information Standards (OASIS) Simple Object Access Protocol (SOAP) Version 1.1 | SOAP is a protocol specification for invoking methods on servers, services, components and objects. SOAP codifies the existing practice of using XML and HTTP as a method invocation mechanism. The SOAP specification mandates a small number of HTTP headers that facilitate firewall/proxy filtering plus an XML vocabulary that is used for representing method parameters, return values, and exceptions." {DevelopMentor} SOAP consists of three parts: an envelope that defines a framework for describing what is in a message and how to process it, a set of encoding rules for expressing instances of application-defined data types, and a convention for representing remote procedure calls and responses. For more information visit <a href="http://www.oasis-open.org">www.oasis-open.org</a> . |
| Organization for the Advancement of Structured Information Standards (OASIS) – ebXML Registry Information Model (3.0)         | The Registry Information Model provides a blueprint or high-level schema for the ebXML Registry. Its primary value is for implementers of ebXML Registries. It provides these implementers with information on the type of metadata that is stored in the Registry as well as the relationships among metadata Classes. The Registry information model: a) Defines what types of objects are stored in the Registry; b) Defines how stored objects are organized in the Registry. For more information visit <a href="http://www.oasis-open.org">www.oasis-open.org</a> .   |
| Organization for the Advancement of Structured Information Standards (OASIS) – ebXML Registry Services Specification (3.0)    | The ebXML Registry provides a set of services that enable sharing of information between interested parties for the purpose of enabling business process integration between such parties based on the ebXML specifications. The shared information is maintained as objects in a repository and managed by the ebXML Registry Services defined in this document. For more information visit <a href="http://www.oasis-open.org">www.oasis-open.org</a> .   |
| 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. For more information visit <a href="http://www.census.gov">www.census.gov</a> .   |

## 4.2 GAPS WHERE THERE ARE NO STANDARDS

This section describes gaps in standards. Gaps occur in the following two cases, where HITSP has:

- Identified requirements derived from the context that have no standards that meet all tiers of HITSP criteria to merit selection for that context
- Identified 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

The gap is only relative to the specific Use Case requirement. Recommended resolutions were developed through a series of steps including the Technical Committee's initial recommendations, cross Technical Committee validation of the gap, provisional recommendations and peer review by the Technical Committee.

The table below identifies the Use Case requirements and known associated gaps, along with the recommended resolutions.



**Table 4.2-1 Use Case Events and Associated Gaps**

| Requirement Number | Summary Description                   | Identified Gaps  | Recommended Resolution   |
|--------------------|---------------------------------------|--|--|
| IER 76<br>DR 71    | Request modification of clinical data | <p>The Use Case states:</p> <p>Consumers may have the following options for modifying, updating, and correcting various data elements:</p> <p>(1) some data fields will permit unrestricted modifications</p> <p>(2) some data fields may not permit consumers to edit data, but could allow annotations to be made by the consumer</p> <p>(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</p> <p>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</p> <p>Requirement (3) is a pre-condition for the Use Case, but is a gap that would eventually need to be addressed</p> | 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   |
| IER 63<br>DR 68    | Request additional patient data       | The Use Case states in action 2.2.2.3 that the system needs to "Transmit request for registration/medication data to data or network system." At this time, there is no known standards-based query transaction to satisfy this requirement  | Monitor and encourage standards development organizations noted to address in 2009 cycle   |
| DR 73              | Provider identification               | 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  | <p>A consumer oriented terminology for healthcare provider type role (e.g., primary care physician, ob/gyn, pharmacy, cardiologist).</p> <p>Consider use of X12 and consider leaving roles as an uncoded entry because consumer use does not fit existing coding systems</p> |
| DR 2               | Patient clinical summary              | 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   |



| Requirement Number | Summary Description                                 | Identified Gaps  | Recommended Resolution  |
|--------------------|---|--|---|
| DR 2               | Patient clinical summary                            | <p>May need additional vocabulary re: types of AD, location of it, currency of it, as well as nonrepudiation issue specification work. The AD is packaged with the rest of the HITSP/C32 message</p> <p>Encourage State Health Alliance work to address this topic</p> <p>Acknowledge the gap that exists in the industry to do something better in this regard, however, this is not work that is currently requested in the current Use Case. Since we're modifying HITSP/C32 we will add this to the Gap table. Awaiting HISPC to address the X-State disjointed solution in terms of policy as a prerequisite.</p> <p>Address in 2009 cycle</p>  | <p>Encourage State Health Alliance work to address this topic</p> <p>Until this gap is specifically resolved, the use of the unstructured document component (HITSP/C62) will allow consumers to save a scanned version of their advance directives with the appropriate metadata</p> |
| IER 68             | PHR Portability – via a data network-based exchange | <p>Scope issue. It is critical that the “payload” specification be independent of the transport/packaging utilized and that consistency be ensured for information continuity with the current Interoperability Specification IS03. It is logical that current documents described in HITSP/C32, the additional lab documents (see candidate above), and other documents (HITSP defined or not), be supported</p> <p>Want to do a “copy” function w/o any implication of why this is being accomplished. The management of intent is a pre-condition. Be content agnostic, multi-document capable, adequate wrapper and select transport to affect interoperability</p> <p>[Wrapper/Transport Standard Selection options: X12 plan-to-plan PHR transfer, IHE XDR (reuse of existing of TP13 transaction), EDIFACT (e.g. for NCPDP Medication content only transfer), other transport standards</p> | Monitor and encourage standards development organizations noted to address in 2009 cycle  |
| IER 75             | Designate provider permissions                      | <p>Permission Lists for PHR Portability : HL7 is currently balloting a “permissions catalogue.” Need definition of provider roles (static &amp; dynamic)...some of this may be available but may vary State-to-State</p> <p>The Use Case includes the access to pharmacy information at PBMs by providers (7.2.1) It needs to be determined if this mandates different query/response solutions for different types of information (e.g. NCPDP-based message exchange)</p>   | Monitor and encourage standards progress in HL7 in this regard to address in 2009 cycle   |



| Requirement Number | Summary Description   | Identified Gaps  | Recommended Resolution   |
|--------------------|---|--|--|
| DR 74              | Access Control Lists  | <p>Distributed Management of Access Control:<br/>The HIE is described as enforcing the permissions/access controls from the consumer (9.2). We might need to consider two tiers of access control:</p> <ol style="list-style-type: none"> <li>1. High-level access control to a consumer's PHR location (a consumer may have different PHRs for different purposes and may desire that different sets of users have different access controls to one or more of them)</li> <li>2. Data level access controls to the elements within a PHR</li> </ol> <p>Leverage and extend HITSP SP TC work regarding the definition of an HIE-level access control technical actor</p>   | To be handled by HITSP Security and Privacy Technical Committee (SPTC) in its entirety                                       |
| IER 73<br>IER 74   | <p>Request/receive provider information</p> <p>Access/Select provider information</p> | <p>Provider List(s): Major gap in the specification of a provider registry (if using the HIE variant); its content, privacy issues, organization-provider relationship(s), and organization-organization relationship(s). Also, if this is related to addressing the permissions issue then are there other organizations/individuals that we need to cover as well. This provider list is required for inclusion in/association to the permissions/access control entries</p> <ol style="list-style-type: none"> <li>1. Need to do query/retrieve access with a provider registry (assumes that one exists and is maintained) or do pt-to-pt request (in-person, phone) to a healthcare entity. The entity pushes this info to the consumer (using HITSP/C32).</li> <li>2. Consumer creates and is capable of communicating this list to others (method for building the relationship to permissions?)</li> </ol> <p>Consider payor-provided portals to provider lists for its members as a source of provider list content</p> | Monitor and encourage standards development organizations noted to address in 2009 cycle                                     |
| DR 75              | Access log summary  | <p>Audit Logs/Disclosure Logs :There is existing work re: audit logs (EHRSM IN 2.2, RFC 3881, IHE ATNA, ), and some use of the term "disclosure logs" exists in HIPAA (Section 164.528), but nothing standards-based regarding Disclosure Logs as described in the Use Case.</p> <p>If the PHR contains a pointer to information, how does this get reflected in the audit/disclosure logs?</p>  | The definition of a standard format and the content for an interoperable disclosure log is to be addressed by the HITSP SPTC |



| Requirement Number | Summary Description   | Identified Gaps  | Recommended Resolution  |
|--------------------|-----------------------|--|---|
| IER 68             | Identify PHR location | <p>There is no known standard for expressing the “address” for information destined for someone’s PHR.</p> <p>[Also noted in the Access Controls entry] The HIE is described as enforcing the permissions/access controls from the consumer (9.2). We might need to consider two tiers of access control:</p> <ol style="list-style-type: none"> <li>1. High-level access control to a consumer’s PHR location (a consumer may have different PHRs for different purposes and may desire that different sets of users have different access controls to one or more of them)</li> <li>2. Data level access controls to the elements within a PHR (better managed by the PHR itself when the query is received)</li> </ol> <p>Is there any work regarding the definition of an HIE-level access control technical actor (e.g. from HITSP SPTC)?</p> | Address in 2009 cycle to identify if there is an element in the HITSP/C32 currently for retaining this info, also how do we specify this content to be used for the different types of info exchange? Also, solicit input from SDO’s and consumer-focused other healthcare organizations for input in this regard |

Considering the relationship to previous constructs, known gaps, potential activities by SDOs, and other initiatives that are either in-progress or pending results that might impact the Interoperability Specification development, the Use Case was broken down in high-level Work Items to one of two Work Sets.

- Addressed by this update to this Interoperability Specification (HITSP/IS03) and HITSP/IS05 Consumer Empowerment and Access to Clinical Information via Media shown in Table 3.1-1
- Gaps or results of works-in-progress initiatives to be addressed during next year’s HITSP cycle are shown below

A detailed analysis of work items marked as “2008 Cycle” has not been conducted by the HITSP Technical Committees. They are included here as a reflection that the requirement standards to satisfy them are not available or that a more in-depth review is required to make this determination definitively.

### 4.3 STANDARD OVERLAPS

This section describes the instances where there are overlaps among standards for the Use Case requirements. The overlap is only relative to the specific Use Case requirement. Overlaps refer to instances wherein some of the requirements are met by multiple standards. Recommended resolutions were developed through a series of steps including the Technical Committee’s initial recommendations, cross Technical Committee validation of the overlap, provisional recommendations and peer review by the Technical Committee’s.

The table below presents the identified overlaps and the respective resolution plans.



**Table 4.3-1 Use Case Requirements and Associated Standard Overlaps**

| Requirement Number | Summary Description     | Standard Overlap  | Recommended Resolution  |
|--------------------|-------------------------|---|---|
| DR 73              | Provider Identification | <p>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</p> <p>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</p> | <p>The HITSP 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 HITSP lacking only coded terms to describe the roles</p> |





## 5.0 CONFORMANCE

This section describes the conformance criteria, which are objective statements of requirements that can be used to determine if a specific behavior, function, interface, or code set has been implemented correctly.

### 5.1 CONFORMANCE CRITERIA

In order to claim conformance to the specification, an implementation must satisfy all the requirements and mandatory statements listed in the HITSP Interoperability Specification, its associated construct specifications, as well as conformance criteria from the selected base and composite standards. A conformant system must be constrained as specified in Table 3.1.2-1, and implement all of the required actors from Table 3.2.3-1, within the scope, subset or implementation option that is selected from Section 5.2 below.

Claims of conformance to this specification must be made using the following language:

This product conforms to HITSP's Consumer Empowerment and Access to Clinical Information via Networks Interoperability Specification, available at [www.hitsp.org](http://www.hitsp.org).

### 5.2 CONFORMANCE SCOPING, SUBSETTING AND OPTIONS

A HITSP Interoperability Specification can be implemented for individual business actors defined in the Interoperability Specification. An implementation claiming conformance to a specific business actor from the Interoperability Specification shall support all of the requirements associated to that business actor as described in Table 3.2.3-1.

This means that **for each implemented business actor:**

1. All Required or Conditionally Required technical actors listed for the business actor shall be supported as specified in the associated construct
2. Optional technical actors listed for the business actor may be supported as specified in the associated construct
3. All Required or Conditionally Required transactions and content subsets listed for each implemented technical actor assigned to the business actor shall be supported as specified in the associated construct
4. Optional transactions and content subsets listed for each implemented technical actor assigned to the business actor may be supported as specified in the associated construct

Implementers of this Interoperability Specification who follow the principles listed above are being provided a level of implementation flexibility, while maintaining interoperability.



### 5.3 TEST METHODS

HITSP relies on the conformance test methods, test tools and other test-related material produced by, or under the auspices, of standards developers, profiling organizations and implementation guide producers as part of its collaborative implementation testing effort. Efforts to produce conformance test methods, tools, etc. may be internal to the organization, or provided by an external organization.

A Health Information Technology (HIT) Implementation Testing website has been developed in collaboration with HITSP, the National Institute of Standards and Technology (NIST), the Certification Commission for Healthcare Information Technology (CCHIT), and the Office of the National Coordinator (ONC) to advance conformance and interoperability testing capabilities. This website provides HIT implementers with the necessary resources to support and test their implementation of standards-based health systems. For more information, visit NIST at [www.nist.gov](http://www.nist.gov).



## 6.0 APPENDIX

The following sections include relevant materials referenced throughout this document.

### 6.1 DESCRIPTION OF STANDARDS

The following table contains descriptions of the selected standards from Section 4.1.2 above:

**Table 6.1-1 Description of Standards**

| Standard Name   | Description  |
|---|--|
| 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). For more information visit <a href="http://www.x12.org">www.x12.org</a> .   |
| American Medical Association (AMA) Current Procedural Terminology (CPT®) Fourth Edition (CPT-4); CPT Evaluation and Management Codes        | A uniform coding system used primarily to identify medical services and procedures furnished by physicians and other healthcare professionals. For more information visit <a href="http://www.ama-assn.org">www.ama-assn.org</a> .   |
| American Society for Testing and Materials (ASTM) Standard Guide for Electronic Authentication of Health Care Information: # E1762-95(2003) | Defines a document structure for use by electronic signature mechanisms, describes the characteristics of an electronic signature process. Defines minimum requirements for different electronic signature mechanisms, defines signature attributes for use with electronic signature mechanisms, describes acceptable electronic signature mechanisms and technologies, defines minimum requirements for user identification, access control, and other security requirements for electronic signatures, and outlines technical details for all electronic signature mechanisms in sufficient detail to allow interoperability between systems supporting the same signature mechanism. For more information visit <a href="http://www.astm.org">www.astm.org</a> .   |
| 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. For more information visit <a href="http://www.cdc.gov">www.cdc.gov</a> . |
| European Telecommunications Standards Institute (ETSI) Technical Specification TS 101 903: XML Advanced Electronic Signatures (XadES)       | Extends the IETF/W3CXML-Signature Syntax and Processing specification [XMLDSIG] into the domain of non-repudiation by defining XML formats for advanced electronic signatures that remain valid over long periods and are compliant with the European Directive. This includes evidence as to its validity even if the signer or verifying party later attempts to deny (repudiates) the validity of the signature. An advanced electronic signature aligned with this document can, in consequence, be used for arbitration in case of a dispute between the signer and verifier, which may occur at some later time, even years later. For more information visit <a href="http://www.etsi.org">www.etsi.org</a> .   |



| Standard Name   | Description  |
|---|--|
| Federal Information Processing Standards (FIPS) Codes for the Identification of the States, the District of Columbia and the Outlying Areas of the United States, and Associated Areas Publication # 5-2, May, 1987 | A set of two-digit numeric codes and a set of two-letter alphabetic codes for representing the 50 states, the District of Columbia and the outlying areas of the United States, and associated areas. The standard covers all land areas under the sovereignty of the United States, the freely associated states of Federated States of Micronesia and Marshall Islands, and the trust territory of Palau. For more information visit <a href="http://www.itl.nist.gov">www.itl.nist.gov</a> .<br><br>NOTE: ASC X12 transactions and ASC X12N Implementation Guides do not allow use of this standard; instead they require use of the U.S. Postal Service's National Zip Code and Post Office Directory -- which provides similar alphabetic code values.  |
| Food and Drug Administration (FDA) - Unique Ingredient Identifier (UNII)  | Provides codes developed by FDA to uniquely identify all ingredients used in marketed medications in the United States. Each UNII is assigned based on molecular structure, manufacturing process, or other characteristics. UNII is part of the Federal Medication Terminologies. For more information visit <a href="http://www.fda.gov/oc/datacouncil/SRS.htm">www.fda.gov/oc/datacouncil/SRS.htm</a>   |
| Food and Drug Administration (FDA) - National Drug Code (NDC)   | Provides drug codes for prescription medicine and insulin products. NDC is managed by the FDA and is part of the Federal Medication Terminologies. For more information visit <a href="http://www.fda.gov/cder/ndc/database/default.htm">www.fda.gov/cder/ndc/database/default.htm</a> .   |
| Health Level Seven (HL7) HL7 Version 3 Standard: Clinical Document Architecture (CDA), Release 2  | 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. For more information visit <a href="http://www.hl7.org">www.hl7.org</a> . |
| Health Level Seven (HL7) Implementation Guide: CDA Release 2 – Continuity of Care Document (CCD), 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. For more information visit <a href="http://www.hl7.org">www.hl7.org</a> .  |
| Health Level Seven (HL7) Standard Code Set CVX - Vaccines Administered  | The CDC's National Center of Immunization and Respiratory Diseases (NCIRD) maintains the HL7 external code set CVX. The implementation of the HL7 standard for immunization data exchange is described in Chapter 4 of the HL7 standard. The codes in HL7 Version 2.3 table 0292, represented the initial content of the external CVX code set. Since vaccines have to be added to this table more quickly than new versions of HL7 are released, this document represents the most up-to-date version of the CVX code set. Items have been added. Others have been added for planning purposes, pending FDA approval. For more information visit <a href="http://www.cdc.gov/vaccines/programs/iis/stds/cvx.htm">http://www.cdc.gov/vaccines/programs/iis/stds/cvx.htm</a> .  |
| Health Level Seven (HL7) Standard Code Set MVX - Manufacturers of Vaccines  | The CDC's National Center for Immunization and Respiratory Diseases (NCIRD) maintains the HL7 external code set MVX. The implementation of the HL7 standard for immunization data exchange is described in Chapter 4 of the HL7 standard. The codes in HL7 Version 2.3 table 0227 represent the initial content of the external MVX code set. This document represents the most up-to-date version of the MVX code set. For more information visit <a href="http://www.cdc.gov/vaccines/programs/iis/stds/mvx.htm">http://www.cdc.gov/vaccines/programs/iis/stds/mvx.htm</a> .   |



| Standard Name  | Description   |
|--|---|
| Health Level Seven (HL7) V3 RBAC, R1-2008, HL7 Version 3 Standard: Role Based Access Control (RBAC) Healthcare Permissions Catalog, Release 1, February 2008 | The Healthcare Permission Catalog provides the necessary content for creating interoperable roles facilitating inter-organizational communications and information sharing among healthcare organizations and their business partners. For more information visit <a href="http://www.hl7.org">www.hl7.org</a> .  |
| Health Level Seven (HL7) Version 2.5, Chapter 2 – Control, Chapter 3 – Patient Administration, Chapter 5 - Query   | 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. For more information visit <a href="http://www.hl7.org">www.hl7.org</a> .  |
| Health Level Seven (HL7) Version 2.5.1 – Vocabulary and Value Sets   | The HL7 Version 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), 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. For more information visit <a href="http://www.hl7.org">www.hl7.org</a> . |
| Health Level Seven (HL7) Version 3.0 – Vocabularies and Value Sets   | 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. For more information visit <a href="http://www.hl7.org">www.hl7.org</a> .  |
| Health Level Seven (HL7) Version 3.0 Context-Aware Information Retrieval Specification: URL Implementation Guide   | Informative implementation guide for URL-based implementations of the context-aware information retrieval ("infobutton") The goal of this infobutton implementation guide is to recommend a URL-based implementation of the context-aware information retrieval ("infobutton") domain. The intent is to provide a simple way to implement infobuttons that is compatible with the current state of the market in this area. Most infobutton implementations to date, especially on the side of on-line information resources, rely on URL-based APIs. For more information visit <a href="http://www.hl7.org">www.hl7.org</a> .   |
| Health Level Seven (HL7) Version 3.0 Privacy Consent related specifications<br>RCMR_RM010001 - Data Consent  | The Data Consent RMIM captures the data and associations needed to (1) record or report a consumer's consent or dissent to authorize the access, collection, use, or disclosure of personally identifiable information; (2) convey a provider's request or intent to override a patient's recorded consent or dissent; (3) convey a type of consent directive associated with a privacy policy; or (4) to record or report a consumer's consent directive, which is to be applied to future access, collection, use or disclosure of personally identifiable information. For more information visit <a href="http://www.hl7.org">www.hl7.org</a> .   |
| Integrating the Healthcare Enterprise (IHE) Exchange of Personal Health Record Content (XPHR) Integration Profile  | The Exchange of Personal Health Record Content (XPHR) Integration Profile describes the content and format of summary information extracted from a PHR system used by a patient for import into healthcare provider information systems, and visa versa. The purpose of this profile is to support interoperability between PHR systems used by patients and the information systems used by healthcare providers. This profile does not address all the data exchange requirements of PHR systems.   |



| Standard Name  | Description   |
|--|---|
| Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Volume 2 Supplement 2007 – 2008 Cross-Enterprise User Assertion (XUA) Integration Profile                         | The Cross-Enterprise User Assertion Profile (XUA) Integration Profile provides a means to communicate claims about the user identity of an authenticated principal (user, application, system...) in transactions that cross enterprise boundaries. To provide accountability in these cross enterprise transactions there is a need to identify the requesting user in a way that the receiver can make access decisions and proper audit entries. The XUA Profile supports enterprises that have chosen to have their own user directory with their own unique method of authenticating the entities, and others that may have chosen to use a third party to perform the authentication. For more information visit <a href="http://www.ihe.net">www.ihe.net</a> .   |
| Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Supplement Volume 3 – Document Digital Signature (DSG) Content Profile  | Specifies the use of digital signatures for documents that are shared between organizations. For more information visit <a href="http://www.ihe.net">www.ihe.net</a> .  |
| Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) – Revision 5.0 or later, Cross Enterprise Sharing of Scanned Documents (XDS-SD) Integration Profile               | This Integration Profile defines how to store healthcare metadata in clinical documents, including patient identifiers, demographics, encounter, order or service information, represented within a structured HL7 CDA R2 header, with a PDF or plaintext formatted document containing clinical information within a nonXML Body. For more information visit <a href="http://www.ihe.net">www.ihe.net</a> to retrieve Volume 1, and Volume 2 of the framework  |
| Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0 or later, Audit Trail and Node Authentication (ATNA) n Integration Profile                           | The Audit Trail and Node Authentication (ATNA) Integration Profile establishes the characteristics of a Basic Secure Node. It describes the security environment (user identification, authentication, authorization, access control, etc.) assumed for the node so that security reviewers may decide whether this matches their environments. It defines basic auditing requirements for the node. It defines basic security requirements for the communications of the node using TLS or equivalent functionality. It establishes the characteristics of the communication of audit messages between the Basic Secure Nodes and Audit Repository nodes that collect audit information. This integration profile has been designed so that specific domain frameworks may extend it through an option defined in the domain specific technical framework. Extensions are used to define additional audit event reporting requirements, especially actor specific requirements. For more information visit <a href="http://www.ihe.net">www.ihe.net</a> .                |
| Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0 or later, Consistent Time (CT) Integration Profile   | The Consistent Time Integration Profile (CT) provides a means to ensure that the system clocks and time stamps of the many computers in a network are well synchronized. This profile specifies synchronization with a median error less than 1 second. This is sufficient for most purposes. The current version of the ITI-TF Final Text, specifies the IHE CT Integration Profile, and other transactions defined and implemented as of October 10, 2008. The latest version of the IHE Technical Framework is available at <a href="http://www.ihe.net">www.ihe.net</a> .   |
| Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0 or later, Audit Trail and Node Authentication (ATNA) Integration Profile, Section 9.1 Authentication | Audit Trail and Node Authentication (ATNA) establishes the characteristics of a Basic Secure Node. It describes the security environment (user identification, authentication, authorization, access control, etc.) assumed for the node so that security reviewers may decide whether this matches their environments. It defines basic auditing requirements for the node. It defines basic security requirements for the communications of the node using TLS or equivalent functionality. It establishes the characteristics of the communication of audit messages between the Basic Secure Nodes and Audit Repository nodes that collect audit information. This integration profile has been designed so that specific domain frameworks may extend it through an option defined in the domain specific technical framework. Extensions are used to define additional audit event reporting requirements, especially actor specific requirements. The latest version of the IHE Technical Framework is available at <a href="http://www.ihe.net">www.ihe.net</a> . |





| Standard Name   | Description  |
|---|--|
| Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 5.0 or later, Patient Demographics Query (PDQ) Integration Profile                      | Provides ways for multiple distributed applications to query a central patient information server for a list of patients, based on user-defined search criteria, and retrieve a patient's demographic (and, optionally, visit or visit-related) information directly into the application. For more information visit <a href="http://www.ihe.net">www.ihe.net</a> .   |
| Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Supplement 2008 - 2009, Pediatric Demographics, Draft for Trial Implementation (August 22, 2008) | The experience of immunization registries and other public health population databases has shown that matching and linking patient records from different sources for the same individual person in environments with large proportions of pediatric records requires additional demographic data. Pediatric Demographics makes use of the following six additional demographic fields to aid record matching in databases with many pediatric records. The latest version of the IHE Technical Framework is available at <a href="http://www.ihe.net">www.ihe.net</a> .   |
| Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0, Section 10 Cross-Enterprise Document Sharing (XDS.a) Integration Profile           | 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. Section 10, Cross-Enterprise Document Sharing facilitates the registration, distribution and access across health enterprises of patient electronic health records. 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. For more information visit <a href="http://www.ihe.net">www.ihe.net</a> . |
| Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0 - Registry Stored Query Transaction for XDS Profile Supplement [ITI-18]             | 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. For more information visit <a href="http://www.ihe.net">www.ihe.net</a> .  |
| Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Supplement 2008-2009, Cross-Community Access (XCA), Trial Implementation, October 10, 2008       | 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-Technical Framework, specifies the IHE transactions that support access between communities in a manner compatible with the XDS Integration profile. For more information visit <a href="http://www.ihe.net">www.ihe.net</a> .  |
| Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Volume 2 Supplement 2007 - 2008 Cross-Enterprise Document Sharing-B (XDS.b) Integration Profile  | The Cross-Enterprise Document Sharing-B Integration Profile (XDS.b) supplement provides a new implementation choice for the Cross-Enterprise Document Sharing (XDS) Integration Profile based on use of the Web Services and ebXML Reg/Rep standards that is consistent with current developments and best practices in the industry. For more information visit <a href="http://www.ihe.net">www.ihe.net</a> .  |
| 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. For more information visit <a href="http://www.ihe.net">www.ihe.net</a> .  |





| Standard Name  | Description  |
|--|--|
| Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Supplement 2007 - 2008 Basic Patient Privacy Consents (BPPC) – Trial Implementation Integration Profile | The Basic Patient Privacy Consents (BPPC) Integration Profile provides a mechanism to record the patient privacy consent(s), a method to mark documents published to XDS with the patient privacy consent that was used to authorize the publication, and a method for XDS Consumers to use to enforce the privacy consent appropriate to the use. This profile complements XDS by describing a mechanism whereby an XDS Affinity Domain can develop and implement multiple privacy policies, and describes how that mechanism can be integrated with the access control mechanisms supported by the XDS Actors (e.g. systems). There are two key parts of the profile: 1) It provides a document content specification for capturing a patient acknowledgement of a privacy consent policy or policies. 2) It describes the method by which XD* Actors can enforce the privacy policies determined by the document confidentialityCode related to the patient privacy consents. For more information visit <a href="http://www.ihe.net">www.ihe.net</a> .   |
| Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0 or later, Patient Identifier Cross-Referencing (PIX) Integration Profile                   | The Patient Identifier Cross-referencing (PIX) Integration Profile is targeted at healthcare enterprises of a broad range of sizes (hospital, a clinic, a physician office, etc.). It supports the cross-referencing of patient identifiers from multiple Patient Identifier Domains via the following interactions: 1) The transmission of patient identity information from an identity source to the Patient Identifier Cross-reference Manager. 2) The ability to access the list(s) of cross-referenced patient identifiers either via a query/ response or via update notification. By specifying the above transactions among specific actors, this Integration Profile does not define any specific enterprise policies or cross-referencing algorithms. By encapsulating these behaviors in a single actor, this integration profile provides the necessary interoperability while maintaining the flexibility to be used with any cross-referencing policy and algorithm as deemed adequate by the enterprise. For more information visit <a href="http://www.ihe.net">www.ihe.net</a> . |
| Integrating the Healthcare Enterprise (IHE) Laboratory Technical Framework Volume 3 (LAB TF-3) Document-based Transactions, Revision 2.0 - For Trial Implementation, August 16, 2007               | The IHE Laboratory Technical Framework introduces a content Integration Profile Sharing Laboratory Reports (LAB TF-3) that describes a clinical laboratory report as a human-readable electronic document. This document, which may also contain data in a machine-readable format and contains the complete set of final results produced by a clinical laboratory in fulfillment of one or more test orders for a patient. This document is focused on the sharing of sets of laboratory results in the form of a laboratory report structured document, and is not intended to address ordering or return of laboratory results to the ordering provider. For more information visit <a href="http://www.ihe.net">www.ihe.net</a> .   |
| International Health Terminology Standards Development Organisation (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®)   | SNOMED CT consists of a technical design, core content architecture, and Core content. SNOMED CT Core content includes the technical specification of SNOMED CT and fully integrated multi-specialty clinical content. The Core content also includes a concepts table, description table, relationships table, history table, ICD-9-CM mapping, and Technical Reference Guide. Additionally, SNOMED CT provides a framework to manage language dialects, clinically relevant subsets, qualifiers and extensions, as well as concepts and terms unique to particular organizations or localities. For more information visit <a href="http://www.ihtsdo.com">www.ihtsdo.com</a> .  |
| International Organization for Standardization (ISO) ISO 3166-1  | The International Standard for country codes. The purpose of ISO 3166 is to establish codes for the representation of names of countries, territories or areas of geographical interest, and their subdivisions.   |
| International Organization for Standardization (ISO) PDF/A ISO 19005-1b. Document management - Electronic document file format for long-term preservation - Part 1: Use of PDF (PDF/A)             | Specifies how to use the Portable Document Format (PDF) 1.4 for long-term preservation of electronic documents. It is applicable to documents containing combinations of character, raster and vector data. For more information visit <a href="http://www.iso.org">www.iso.org</a> .  |



| Standard Name   | Description  |
|---|--|
| Internet Engineering Task Force (IETF) Network Time Protocol (Version 3) Specification, Implementation and Analysis, "Request for Comment" (RFC) #1305, March, 1992 | Describes the Network Time Protocol (NTP): the mechanisms to synchronize time and coordinate time distribution in a large, diverse internet operating at rates from mundane to lightwave. For more information visit <a href="http://www.ietf.org">www.ietf.org</a> .  |
| Internet Engineering Task Force (IETF) Simple Network Time Protocol (SNTP) Version 4, "Request for Comment" (RFC) #2030, October, 1996                              | Describes the Simple Network Time Protocol (SNTP) Version 4, which is an adaptation of the Network Time Protocol (NTP). SNTP can be used when the ultimate performance of the full NTP implementation is not needed or justified. When operating with current and previous NTP and SNTP versions, SNTP Version 4 involves no changes to the NTP specification or known implementations, but is rather a clarification of certain design features of NTP. For more information visit <a href="http://www.ietf.org">www.ietf.org</a> .   |
| Internet Engineering Task Force (IETF) Tags for Identifying Languages, "Request for Comment" (RFC) # 4646, September, 2006  | This document describes the structure, content, construction, and semantics of language tags for use in cases where it is desirable to indicate the language used in an information object. It also describes how to register values for use in language tags and the creation of user-defined extensions for private interchange. This document, in combination with RFC 4647, replaces RFC 3066, which replaced RFC 1766. For more information visit <a href="http://www.ietf.org/rfc/rfc4646.txt">www.ietf.org/rfc/rfc4646.txt</a> .  |
| 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. For more information visit <a href="http://www.loinc.org">www.loinc.org</a> . |
| National Cancer Institute (NCI) Thesaurus   | The NCI Thesaurus is a reference terminology and biomedical ontology used in a growing number of NCI and other systems. It covers vocabulary for clinical care, translational and basic research, and public information and administrative activities. The NCI Thesaurus provides definitions, synonyms, and other information on nearly 10,000 cancers and related diseases, 8,000 single agents and combination therapies, and a wide range of other topics related to cancer and biomedical research. It is part of the Federal Medication Terminologies. For more information visit <a href="http://www.cancer.gov">www.cancer.gov</a> .  |
| National Library of Medicine (NLM) Unified Medical Language System (UMLS) RxNorm  | Provides standard names for (1) clinical drugs and (2) drug dose forms as administered to a patient. Also provides links from clinical drugs, both branded and generic, to their active ingredients, drug components (active ingredient + strength), and related brand names. Food and Drug Administration (FDA) National Drug Codes (NDCs) for specific drug products and many of the drug vocabularies commonly used in pharmacy management and drug interaction software are additionally linked to RxNorm. RxNorm is a part of the Federal Medication Terminologies. For more information visit <a href="http://www.nlm.nih.gov">www.nlm.nih.gov</a>   |
| Organization for the Advancement of Structured Information Standards (OASIS) Security Assertion Markup Language (SAML) Core V2.0 OASIS Standard; ITU-T X.1141       | SAML, developed by the Security Services Technical Committee of OASIS, is an XML-based framework for communicating user authentication, entitlement, and attribute information. As its name suggests, SAML allows business entities to make assertions regarding the identity, attributes, and entitlements of a subject (an entity that is often a human user) to other entities, such as a partner company or another enterprise application. For more information visit <a href="http://www.oasis-open.org">www.oasis-open.org</a> .  |
| Organization for the Advancement of Structured Information Standards (OASIS) WS-Trust Version 1.3, March 2007   | Defines extensions that build on [WS-Security] to provide a framework for requesting and issuing security tokens, and to broker trust relationships. Defines Security Token Service (STS) model for security tokens including requesting, issuing, renewing, canceling and validating. For more information visit <a href="http://www.oasis-open.org">www.oasis-open.org</a> .   |



| Standard Name  | Description  |
|--|--|
| Organization for the Advancement of Structured Information Standards (OASIS) eXtensible Access Control Markup Language (XACML), ITU-T Recommendation X.1142, February 2005 | The Organization for the Advancement of Structured Information Standards (OASIS) standards group developed the eXtensible Access Control Markup Language (XACML) as a language to express and evaluate access decisions. The XACML technical specification includes a profile for RBAC using XACML that complies with the ANSI RBAC standard. The HL7 RBAC Permission Catalog provides a standard vocabulary that can be used for cross-enterprise access control. For more information visit <a href="http://www.oasis-open.org">www.oasis-open.org</a> . |
| U.S. National Uniform Claims Committee Health Care Provider Taxonomy Code Set  | 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 <a href="http://www.wpc-edi.com">www.wpc-edi.com</a> .  |
| Unified Code for Units of Measure (UCUM)   | A code system intended to include all units of measures being contemporarily used in international science, engineering, and business. The purpose is to facilitate unambiguous electronic communication of quantities together with their units. The focus is on electronic communication, as opposed to communication between humans. For more information visit <a href="http://aurora.regenstrief.org">aurora.regenstrief.org</a> .  |
| United States Postal Service (USPS) – Postal Codes   | List of United States postal codes (known in various countries as a post code, postcode, or ZIP code) appended to a postal address for the purpose of sorting mail. For more information visit <a href="http://www.usps.com">www.usps.com</a> .  |
| VHA National Drug File Reference Terminology (NDF-RT) Formulary  | Provides standard names for (1) mechanism of action, (2) Physiologic Effect and (3) Structural Class. NDF-RT is part of the Federal Medication Terminologies. For more information visit <a href="http://www.cancer.gov/cancertopics/terminologyresources/page5">www.cancer.gov/cancertopics/terminologyresources/page5</a>  |

## 6.2 USE CASE TO INFORMATION EXCHANGE AND DATA REQUIREMENTS

This section contains an extraction of business actors, required interactions and conditions/scenarios from the Use Case into a matrix/table.

The following table provides the mapping of use case actions from the Consumer Empowerment and Access to Clinical Information Use Cases – Scenario 1: Consumer Creates Account to Host and Access Registration Summary and Clinical Information.

**Table 6.2-1 Mapping of Use Case Actions to Information Exchange Requirements – Consumer Empowerment Use Case – Scenario 1**

| Event                                      | Action   | Information Exchange Requirement(s)<br>(includes security requirements)      | Data Requirements |
|--|--|--|-------------------|
| Personal Health Record (PHR) Systems       |  |  |                   |
| CACI 6.1.1 Identify PHR of Choice          | 6.1.1.1 Identify and communicate PHR of choice | IER 68 Identify PHR Location<br>IER 10 Identify patient                      | DR01<br>DR68      |
| CE 2.1.1 Select a provider of PHR Services | 2.1.1.1 Provide identification data            | IER 43 Send/Receive accept patient<br>IER 77 Identify of information sources | DR70              |
| CE 2.2.1 Create account                    | 2.2.1.1 Confirm consumer's identity            | Out of scope<br><br>Policies and internal PHR systems operation              |                   |



| Event   | Action   | Information Exchange Requirement(s)<br>(includes security requirements)   | Data Requirements   |
|---|--|---|---|
|   | 2.2.1.2 Create consumer's account  | Out of scope<br><br>Internal PHR systems operation  |   |
|   | 2.2.1.3 Maintain consumer's permissions for system access  | Out of scope<br><br>Internal PHR systems operation The PHR Service provider manages Consent Directives                      |   |
| CE 2.2.2 Gather registration and/or medication data<br><br>CACI Event 6.1.3 PHR(s) receive available information from other sources | 2.2.2.1 Receive consumer request   | Out of scope<br><br>(Internal PHR systems operation)  |   |
|   | 2.2.2.2 Confirm consumer identity  | Out of scope<br><br>(Internal PHR systems operation plus policies)  |   |
|   | 2.2.2.3 Transmit request for registration/medication data to data or network system                          | IER 63 Request additional patient data  | DR68  |
|   | 6.1.3.1 Receive Information<br><br>2.2.2.4 Receive registration/medication data                              | IER 21 Receive updated clinical information<br>IER 28 Download historical health data<br>IER 38 Query/retrieve document set | DR01<br>DR02<br>DR03<br>DR04<br>DR05<br>DR08<br>DR27<br>DR66<br>DR67<br>DR70<br>DR100 |
|   | 2.2.2.5 Acknowledge receipt of registration/medication data  | IER 8 Generate a delivery receipt   | DR29  |
|   | 6.1.3.2 Information is automatically populated for viewing using appropriate translations or transformations | IER 42 Request/receive medical concept knowledge  | DR69  |
|   | 2.2.2.6 Log interaction  | IER 3 Create audit log entry<br>IER 72 Send/receive audit log   | DR75  |
| CE 2.1.4 View registration/medication data  | 2.1.4.1 Authenticate to system   | Out of scope<br><br>(Internal PHR application functionality plus policies)  |   |
| CACI 6.1.4 Access available information   | 6.1.4.1 Request information  | IER 21 Receive updated clinical information   | DR01  |



| Event   | Action  | Information Exchange Requirement(s)<br>(includes security requirements)   | Data Requirements   |
|---|---|---|---|
|   | 2.1.4.2 Request data<br>2.1.4.3 Receive data                  | IER 38 Query/retrieve document set  | DR02<br>DR03<br>DR04<br>DR05<br>DR08<br>DR27<br>DR66<br>DR67<br>DR68<br>DR70<br>DR100 |
|   | 6.1.4.2 View Information                                      | IER 42 Request/receive medical concept knowledge  | DR69  |
| CACI 6.1.5 Select and incorporate information     | 6.1.5.1 Select Information                                    | Out of scope<br><br>Internal PHR application functionality. Source information comes minimally from the document/record header and will be used as needed to facilitate the incorporation of Allergies/Condition/Problem/Diagnosis into the PHR |   |
|   | 6.1.5.2 Incorporate selected information into the PHR         | Out of scope<br>(PHR user interface activity) Metadata to identify original source/context of information   |   |
| CACI 6.1.6 Annotate information or request change | 6.1.6.1 Annotate Information                                  | Out of scope  |   |
|   | 6.1.6.2 Request Change  | IIER 76 Request modification to clinical data   | DR71  |
| CE 2.1.2 Establish/Change Permissions             | 2.1.2.1 Authenticate to system                                | Out of scope  |   |
|   | 2.1.2.2 Establish/Modify permissions for access to the system | Out of scope  |   |
| CACI 6.1.2 Receive Notification                   | 6.1.2.1 Receive Notification                                  | Out of scope  |   |
| CE 2.1.5 Modify registration/medication data      | 2.1.5.1 Authenticate to system                                | Out of scope  |   |
|   | 2.1.5.2 Request data  | Out of scope  |   |
|   | 2.1.5.3 Receive data  | IER 38 Query/retrieve document set  | DR01<br>DR02<br>DR03<br>DR04<br>DR05  |



| Event   | Action   | Information Exchange Requirement(s)<br>(includes security requirements) | Data Requirements   |
|---|--|---|---|
|   |  |   | DR08<br>DR27<br>DR66<br>DR67<br>DR68<br>DR69<br>DR70<br>DR100   |
|   | 2.1.5.4 Modify data  | IER 76 Request modification to clinical data                            | DR71  |
|   | 2.1.5.4a Annotate data   | Out of scope  |   |
|   | 2.1.5.5 Transmit modified and/or annotated data                              | IIER 61 Provide and register document set                               | DR01<br>DR02<br>DR03<br>DR04<br>DR05<br>DR08<br>DR27<br>DR66<br>DR67<br>DR68<br>DR69<br>DR70<br>DR100 |
|   | 2.1.5.5a Transmit request to modify and/or correct data                      | IER 76 Request modification to clinical data                            | DR71  |
| Electronic Health Record (EHR) System, Health Plan System, Pharmacy Benefit Management System/Pharmacy Systems - (External) |  |   |   |
| CE 2.4.1 Process request for registration/medication data   | 2.4.1.1 Receive and validate the query request                               | IER 76 Request modification to clinical data                            | DR71  |
|   | 2.4.1.2 Authenticate and verify authorization of requestor                   | IER 1 Provide authorization and consent<br>IER 5 Verify entity identity | DR74  |
|   | 2.4.1.3 Authorize release of registration/medication information             | Out of scope<br>(Application access control functionality)              |   |
|   | 2.4.1.4 Transmit registration/medication information to an authorized system | IER 61 Provider and register document set                               | DR01<br>DR02<br>DR03<br>DR04<br>DR05<br>DR08<br>DR27  |



| Event   | Action  | Information Exchange Requirement(s)<br>(includes security requirements)                       | Data Requirements   |
|---|---|---|---|
|   |   |   | DR66<br>DR67<br>DR70  |
| CACI 6.1.3 PHR(s) receive available information from other sources  | 6.1.3.1 Receive Information   | IER 28 Download historical health data<br>IER 38 Query/retrieve document set                  | DR01<br>DR02<br>DR03<br>DR04<br>DR05<br>DR08<br>DR27<br>DR66<br>DR67<br>DR70<br>DR100         |
| CE 2.4.1 Process request for registration/medication data   | 2.4.1.5 Log interaction   | IER 3 Create audit log entry<br>IER 72 Send/receive audit log                                 | DR75  |
| Health Information Exchange (HIE)   |   |   |   |
| CACI 6.1.1 Identify PHR(s) of choice  | 6.1.1.1 Identify and communicate PHR(s) of choice                             | IER 68 Identify PHR location<br>IER 10 Identify patient<br>IER 43 Send/Receive accept patient | DR70<br>DR01<br>DR68  |
| CE 2.4.1 Process Request for Registration and/or Medication Data<br>CACI 6.1.4 Access available information | 2.4.1.1 Receive and validate the query request<br>6.1.4.1 Request information | IER 76 Request modification to clinical data  | DR71  |
|   | 2.4.1.2 Authenticate and verify the authorization of the requestor            | IER 1 Provide authorization and consent<br>IER 5 Verify entity identity                       | DR74  |
|   | 2.4.1.3 Authorize release of registration/medication data                     | Out of scope  |   |
|   | 2.4.1.4 Transmit registration/medication data to an authorized system         | IER 23 Request/provide additional information<br>IER 61 Provide and register document set     | DR01<br>DR02<br>DR03<br>DR04<br>DR05<br>DR08<br>DR27<br>DR66<br>DR67<br>DR68<br>DR70<br>DR100 |





| Event  | Action   | Information Exchange Requirement(s)<br>(includes security requirements)             | Data Requirements   |
|--|--|---|---|
|  | 2.4.1.5 Log interaction  | IER 3 Create audit log entry<br>IER 72 Send/receive audit log                       | DR75  |
| CACI 6.1.2 PHR(s) receive available information from other sources | 6.1.2.1 Receive Information  | IER 23 Request/provide additional information<br>IER 38 Query/retrieve document set | DR01<br>DR02<br>DR03<br>DR04<br>DR05<br>DR08<br>DR27<br>DR66<br>DR67<br>DR68<br>DR70<br>DR100 |
|  | 6.1.2.2 Information is automatically populated for viewing using appropriate translations or transformations | IER 42 Request/receive medical concept knowledge                                    | DR69  |
| CACI 6.1.3 Receive Notification                                    | 6.1.3.1 Receive Notification   | Out of scope  |   |
| CACI 6.1.6 Annotate information or request change                  | 6.1.6.1 Annotate information   |   |   |
|  | 6.1.6.2 Request Change   | IER 76 Request modification to clinical data  | DR71  |
| Personal Health Record (PHR) Systems                               |  |   |   |
| CE 2.1.6 Close Account   | 2.1.6.1 Request to close PHR account   | Out of scope<br><br>(PHR application functionality)                                 |   |
|  | 2.1.6.1a Request registration/medication data sent to another provider of PHR service                        | To be addressed by Scenario 3 in the future   |   |
|  | 2.1.6.2 Receive confirmation of account closure  | To be addressed by Scenario 3 in the future   |   |
|  | Action 2.1.6.2a Receive confirmation of account transfer   | To be addressed by Scenario 3 in the future   |   |

The following table provides the mapping of use case actions from the Consumer Empowerment Use Case – Scenario 2: Consumer visits Healthcare Provider and Provides Registration Summary information and Clinical Information. This includes operationally equivalent events and actions from the Consumer Access to Clinical Information Use Case.



**Table 6.2-2 Mapping of Use Case Actions to Information Exchange Requirements - Consumer Empowerment  
Use Case – Scenario 2**

| Event  | Action  | Information Exchange Requirement(s)<br>(includes security requirements)                   | Data Requirements   |
|--|---|---|---|
| Personal Health Record (PHR) Systems                                 |   |   |   |
| CE 2.1.3 Log on to system  | 2.1.3.1 Authenticate to system  | Out of scope<br><br>(PHR application functionality) plus policies                         |   |
| CE 2.2.3 Process registration/medication data                        | 2.2.3.1 Receive and validate query  | IER 21 Receive updated clinical information<br>IER 38 Query/retrieve document set         | DR01<br>DR02<br>DR03<br>DR04<br>DR05<br>DR08<br>DR27<br>DR66<br>DR67<br>DR70                  |
|  | 2.2.3.2 Authenticate and verify the authorization of the requestor                  | IER 1 Provide authorization and consent<br>IER 5 Verify entity identity                   | DR74  |
|  | 2.2.3.3 Transmit requested registration/medication information to authorized system | IER 23 Request/provide additional information<br>IER 61 Provide and register document set | DR01<br>DR02<br>DR03<br>DR04<br>DR05<br>DR08<br>DR27<br>DR66<br>DR67<br>DR68<br>DR70<br>DR100 |
|  | 2.2.3.4 Log interaction   | IER 3 Create audit log entry<br>IER 72 Send/receive audit log                             | DR75  |
| CE 2.2.2 Gather registration and/or medication data                  | 2.2.2.1 Receive consumer request  | Out of scope<br><br>Internal PHR systems operation  |   |
| CACI 6.1.3 PHR(s) (or EHRs) receive available information from other | 2.2.2.2 Confirm consumer identity   | Out of scope<br><br>Internal PHR systems operation plus policies                          |   |



| Event  | Action   | Information Exchange Requirement(s)<br>(includes security requirements)  | Data Requirements   |
|--|--|--|---|
| sources  | 2.2.2.3 Transmit request for registration/ medication data to data or network system                         | IER 63 Request additional patient data   | DR68  |
|  | 2.2.2.4 Receive registration/medication data<br><br>6.1.3.1 Receive Information                              | IER 21 Receive updated clinical information<br>IER 23 Request/provide additional information<br>IER 28 Download historical health data<br>IER 38 Query/retrieve document set | DR01<br>DR02<br>DR03<br>DR04<br>DR05<br>DR08<br>DR27<br>DR66<br>DR67<br>DR70<br>DR100 |
|  | 2.2.2.5 Acknowledge receipt of registration/medication data  | IER 8 Generate a delivery receipt  | DR29  |
|  | 6.1.3.2 Information is automatically populated for viewing using appropriate translations or transformations | IER 42 Request/receive medical concept knowledge   | DR69  |
|  | 2.2.2.6 Log interaction  | IER 3 Create audit log entry<br>IER 72 Send/receive audit log  | DR75  |
| CE 2.2.3 Process request for registration and/or medication data | 2.2.3.1 Receive and validate the query process   | IER 38 Query/retrieve document set   | DR01<br>DR02<br>DR03<br>DR04<br>DR05<br>DR27  |
|  | 2.2.3.2 Authenticate and verify the authorization of the requestor   | IER 1 Provide authorization and consent<br>IER 5 Verify entity identity  | DR74  |
|  | 2.2.3.3 Transmit registration/medication data to an authorized system  | IER 61 Provide and register document set   | DR01<br>DR02<br>DR03<br>DR04<br>DR05<br>DR027   |
|  | 2.2.3.4 Log interaction  | IER 3 Create audit log entry<br>IER 72 Send/receive audit log  | DR75  |



| Event  | Action   | Information Exchange Requirement(s)<br>(includes security requirements)  | Data Requirements   |
|--|--|--|---|
| Electronic Health Record (EHR) System  |  |  |   |
| CE 2.3.1 View registration and/or medication data                            | 2.3.1.1 Submit authentication information to PHR                                     | IER 1 Provide authorization and consent<br>IER 5 Verify entity identity  |   |
| CACI 6.1.3 PHR(s) (or EHRs) receive available information from other sources | 2.3.1.2 Receive registration/medication data<br><br>6.1.3.1 Receive Information      | IER 21 Receive updated clinical information<br>IER 23 Request/provide additional information<br>IER 28 Download historical health data<br>IER 38 Query/retrieve document set | DR01<br>DR02<br>DR03<br>DR04<br>DR05<br>DR08<br>DR27<br>DR66<br>DR67<br>DR70<br>DR100 |
| CE 2.3.2 Integrate registration data into EHR or other care system           | 2.3.2.1 Transmit request for registration/medication data to provider of PHR service | IER 23 Request/provide additional information  | DR01<br>DR02<br>DR03<br>DR04<br>DR05<br>DR08<br>DR27                                  |
|  | 2.3.2.2 Accept data into EHR system  | Out of scope<br>(EHR application functionality)  |   |
|  | 2.3.2.3 Confirm data integrity   | Out of scope<br>(EHR application functionality)  |   |
|  | 2.3.2.3a Produce exception list of errors  | Out of scope<br>(EHR application functionality)  |   |
|  | 2.3.2.4 Parse and validate results content   | Out of scope<br>(EHR application functionality)  |   |
|  | 2.3.2.5 Acknowledge receipt of registration/medication data                          | IER 8 Generate a delivery receipt  | DR029   |
|  | 2.3.2.6 Log interaction  | IER 3 Create audit log entry<br>IER 72 Send/receive audit log  | DR75  |
| Health Information Exchange (HIE)  |  |  |   |



| Event  | Action  | Information Exchange Requirement(s)<br>(includes security requirements)                   | Data Requirements   |
|--|---|---|---|
| CE 2.4.1 Process Request for Registration and/or Medication Data<br><br>CACI 6.1.3 PHR(s) (or EHRs) receive available information from other sources | 2.4.1.1 Receive and validate the query request                        | IER 21 Receive updated clinical information<br>IER 38 Query/retrieve document set         | DR01<br>DR02<br>DR03<br>DR04<br>DR05<br>DR08<br>DR27<br>DR66<br>DR67<br>DR70<br>DR100 |
|  | 6.1.3.1 Receive Information   |   |   |
|  | 2.4.1.2 Authenticate and verify the authorization of the requestor    | IER 1 Provide authorization and consent<br>IER 5 Verify entity identity                   | DR74  |
|  | 2.4.1.3 Authorize release of registration/medication data             | IER 69 Authorize release of information   |   |
|  | 2.4.1.4 Transmit registration/medication data to an authorized system | IER 23 Request/provide additional information<br>IER 61 Provide and register document set | DR01<br>DR02<br>DR03<br>DR04<br>DR05<br>DR08<br>DR27<br>DR66<br>DR67<br>DR70<br>DR100 |
|  | 2.4.1.5 Log interaction   | IER 3 Create audit log entry<br>IER 72 Send/receive audit log                             | DR75  |

The following table provides the mapping of use case actions from the Consumer Empowerment Use Case – Scenario 3: Authorized Healthcare Provider Reviews Registration Summary and Other Clinical Information. This includes operationally equivalent events and actions from the Consumer Access Use Case.

**Table 6.2-3 Mapping of Use Case Actions to Information Exchange Requirements - Consumer Empowerment Use Case – Scenario 3**

| Event                                | Action | Information Exchange Requirement(s)<br>(includes security requirements) | Data Requirements |
|--------------------------------------|--------|---|-------------------|
| Personal Health Record (PHR) Systems |        |   |                   |



| Event   | Action   | Information Exchange Requirement(s)<br>(includes security requirements)  | Data Requirements   |
|---|--|--|---|
| CE 2.1.3 Log on to system   | 2.1.3.1 Authenticate to system   | Out of scope<br><br>PHR application functionality plus policies  |   |
| CE 2.2.2 Gather registration and/or medication data<br><br>CACI 6.1.3 PHR(s) (or EHRs) receive available information from other sources | 2.2.2.1 Receive consumer request   | Out of scope<br><br>Internal PHR systems operation   |   |
|   | 2.2.2.2 Confirm consumer identity  | Out of scope<br><br>(Internal PHR systems operation plus policies)   |   |
|   | 2.2.2.3 Transmit request for registration/ medication data to data or network system                         | IER 23 Request/provide additional information<br>IER 63 Request additional patient data  | DR68  |
|   | 2.2.2.4 Receive registration/medication data<br><br>6.1.3.1 Receive Information                              | IER 21 Receive updated clinical information<br>IER 23 Request/provide additional information<br>IER 28 Download historical health data<br>IER 38 Query/retrieve document set | DR01<br>DR02<br>DR03<br>DR04<br>DR05<br>DR08<br>DR27<br>DR66<br>DR67<br>DR70<br>DR100 |
|   | 2.2.2.5 Acknowledge receipt of registration/ medication data   | IER 8 Generate a delivery receipt  | DR29  |
|   | 6.1.3.2 Information is automatically populated for viewing using appropriate translations or transformations | IER 42 Request/receive medical concept knowledge   | DR69  |
|   | 2.2.2.6 Log interaction  | IER 3 Create audit log entry<br>IER 72 Send/receive audit log  | DR75  |
| CE 2.2.3 Process request for registration and/or medication data  | 2.2.3.1 Receive and validate the query process   | IER 38 Query/retrieve document set   | DR01<br>DR02<br>DR03<br>DR04<br>DR05<br>DR27  |



| Event  | Action   | Information Exchange Requirement(s)<br>(includes security requirements)  | Data Requirements   |
|--|--|--|---|
|  | 2.2.3.2 Authenticate and verify the authorization of the requestor                   | IER 1 Provide authorization and consent<br>IER 5 Verify entity identity  | DR74  |
|  | 2.2.3.3 Transmit registration/medication data to an authorized system                | IER 61 Provide and register document set   | DR01<br>DR02<br>DR03<br>DR04<br>DR05<br>DR27  |
|  | 2.2.3.4 Log interaction  | IER 3 Create audit log entry<br>IER 72 Send/receive audit log  | DR75  |
| Electronic Health Record (EHR) System                              |  |  |   |
| CE 2.3.1 View registration and/or medication data                  | 2.3.1.1 Submit authentication information to PHR                                     | IER 1 Provide authorization and consent<br>IER 5 Verify entity identity  | DR74  |
|  | 2.3.1.2 Receive registration/medication data   | IER 21 Receive updated clinical information<br>IER 23 Request/provide additional information<br>IER 28 Download historical health data<br>IER 38 Query/retrieve document set | DR01<br>DR02<br>DR03<br>DR04<br>DR05<br>DR08<br>DR27<br>DR66<br>DR67<br>DR70<br>DR100 |
| CE 2.3.2 Integrate registration data into EHR or other care system | 2.3.2.1 Transmit request for registration/medication data to provider of PHR service | IER 23 Request/provide additional information<br>IER 63 Request additional patient data  | DR68  |
|  | 2.3.2.2 Accept data into EHR system  | Out of scope<br>(EHR application functionality)  |   |
|  | 2.3.2.3 Confirm data integrity   | Out of scope<br>(EHR application functionality)  |   |
|  | 2.3.2.3a Produce exception list of errors  | Out of scope<br>(EHR application functionality)  |   |
|  | 2.3.2.4 Parse and validate results content   | Out of scope<br>(EHR application functionality)  |   |
|  | 2.3.2.5 Acknowledge receipt of registration/medication data                          | IER 8 Generate a delivery receipt  | DR29  |





| Event  | Action  | Information Exchange Requirement(s)<br>(includes security requirements)  | Data Requirements   |
|--|---|--|---|
|  | 2.3.2.6 Log interaction   | IER 3 Create audit log entry<br>IER 72 Send/receive audit log  | DR75  |
| Health Information Exchange (HIE)  |   |  |   |
| CE 2.4.1 Process Request for Registration and/or Medication Data<br><br>CACI 6.1.3 PHR(s) (or EHRs) receive available information from other sources | 2.4.1.1 Receive and validate the query request<br>6.1.3.1 Receive Information | IER 21 Receive updated clinical information<br>IER 23 Request/provide additional information<br>IER 28 Download historical health data<br>IER 38 Query/retrieve document set | DR01<br>DR02<br>DR03<br>DR04<br>DR05<br>DR08<br>DR27<br>DR66<br>DR67<br>DR70<br>DR100 |
|  | 2.4.1.2 Authenticate and verify the authorization of the requestor            | IER 1 Provide authorization and consent<br>IER 5 Verify entity identity  | DR74  |
|  | 2.4.1.3 Authorize release of registration/medication data                     | IER 69 Authorize release of information<br>(Application access control functionality)  |   |
|  | 2.4.1.4 Transmit registration/medication data to an authorized system         | IER 23 Request/provide additional information<br>IER 61 Provide and register document set  | DR01<br>DR02<br>DR03<br>DR04<br>DR05<br>DR08<br>DR27<br>DR66<br>DR67<br>DR70<br>DR100 |
|  | 2.4.1.5 Log interaction   | IER 3 Create audit log entry<br>IER 72 Send/receive audit log  | DR75  |

The following table provides the mapping of use case actions from the Consumer Access to Clinical Information Use Case – Scenario 2: Provider Lists and Permissions.



**Table 6.2-4 Mapping of Use Case Actions to Information Exchange Requirements – Consumer Access to Clinical Information Use Case – Scenario 2**

| Event  | Action  | Information Exchange Requirement(s)<br>(includes security requirements)  | Data Requirements    |
|--|---|--|----------------------|
| Personal Health Record (PHR) Systems                         |   |  |                      |
| CACI 7.1.1: Request and access provider information          | 7.1.1.2 Request provider information                | IER 11 Identify provider based on patient preference<br><br>IER 73 Request/receive provider information  | DR73                 |
|  | 7.1.1.4 Access provider information                 | IER 74 Access/Select provider information  | DR73                 |
| CACI 7.1.2 Create/update provider lists                      | 7.1.2.1 Select and incorporate provider information | IER 74 Access/Select provider information  | DR73                 |
| CACI 7.1.3 Designate provider permissions                    | 7.1.3.1 Designate provider permissions              | IER 75 Designate provider permissions  | DR73<br>DR74         |
| CACI 7.1.4 Review access and disclosure logs                 | 7.1.4.1 Review access and disclosure logs           | IER 3 Create audit log entry<br>IER 72 Send/receive audit log  | DR75                 |
| Electronic Health Record (EHR) System                        |   |  |                      |
| CACI 7.2.1 Request and access available clinical information | 7.2.1.1 Request and access information              | IER 38 Query/retrieve document set   | DR01<br>DR68<br>DR75 |
| CACI 7.2.2 Select and incorporate clinical information       | 7.2.2.1 Select information                          | Out of scope<br><br>(Internal EHR system functionality: After accessing the available consumer information based upon permissions set by consumers, providers may choose to incorporate selected information into EHRs. This information may be selected at various levels of specificity, such as discrete pieces of information and/or groups of information (e.g. data sets)) | None                 |
|  | 7.2.2.2 Incorporate data into EHRs                  | Out of scope<br><br>(Internal EHR system functionality: The providers' EHR incorporates the selected information. The original source of the data are also incorporated into the EHR )   | None                 |
| CACI 7.2.3 Systems log the activity                          | 7.2.3.1 Log access to information                   | IER 3 Create audit log entry<br>IER 72 Send/receive audit log  | DR75                 |



The following table provides the mapping of use case actions from the Consumer Access to Clinical Information Use Case – Scenario 3: Transfer of PHR Information.

**Table 6.2-5 Mapping of Use Case Actions to Information Exchange Requirements – Consumer Access to Clinical Information Use Case – Scenario 3**

| Event  | Action  | Information Exchange Requirement(s)<br>(includes security requirements)  | Data Requirements   |
|--|---|--|---|
| Personal Health Record (PHR) Systems                           |   |  |   |
| CACI 8.1.1 Access PHR(A)                                       | 8.1.1.1 Access PHR(A)                                       | Out of scope<br>(Internal PHR system function)   |   |
| CACI 8.1.2 Request and access available information in PHR(A)  | 8.1.2.1 Review PHR(A) Information                           | Out of scope<br>(Internal PHR system function)   |   |
| CACI 8.1.3 Select Information to send PHR(B)                   |   | Out of scope<br>(Internal PHR system function – the ability to select is an internal system function but what they are able to select is dictated by standardized information exchange documents.) |   |
|  | 8.1.3.2 Select providers and permissions                    | IER 74 Access/Select provider information  |   |
| CACI 8.1.4 Identify PHR(B) which is to receive the information | 8.1.4.1 Identify PHR(B) which is to receive the information | IER 68 Identify PHR Location (gap)   |   |
| CACI 8.1.5 PHR(A) sends information to PHR(B)                  | 8.1.5.1 Forward information to PHR B)                       | IER 23 Request/provide additional information<br>IER 61 Provide and register document set  | DR01<br>DR02<br>DR03<br>DR04<br>DR05<br>DR08<br>DR27<br>DR66<br>DR67<br>DR70<br>DR100 |
|  | 8.1.5.2 Confirm delivery of information to PHR(B)           | IER 8 Generate a delivery receipt  | DR29  |

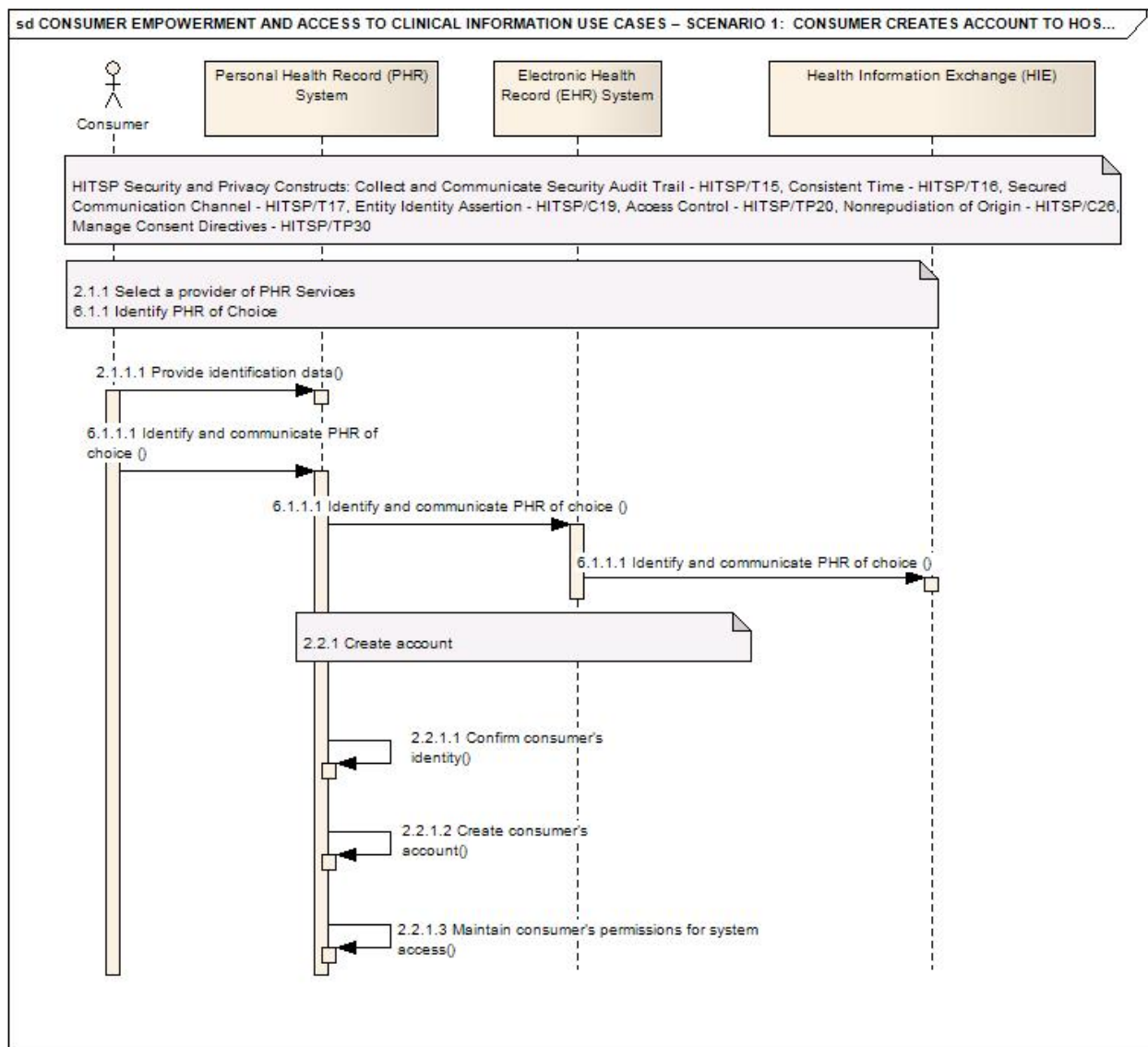
### 6.3 USE CASE SEQUENCE DIAGRAMS

The Use Case sequence diagrams illustrate each Use Case scenario with a representation of a normal sequence of exchange between the primary actors. The event codes from the Use Case are annotated



on the diagrams to show how the interactions relate to the Use Case. The interactions are supported by the various constructs which are introduced in Section 3.0 of this Interoperability Specification.

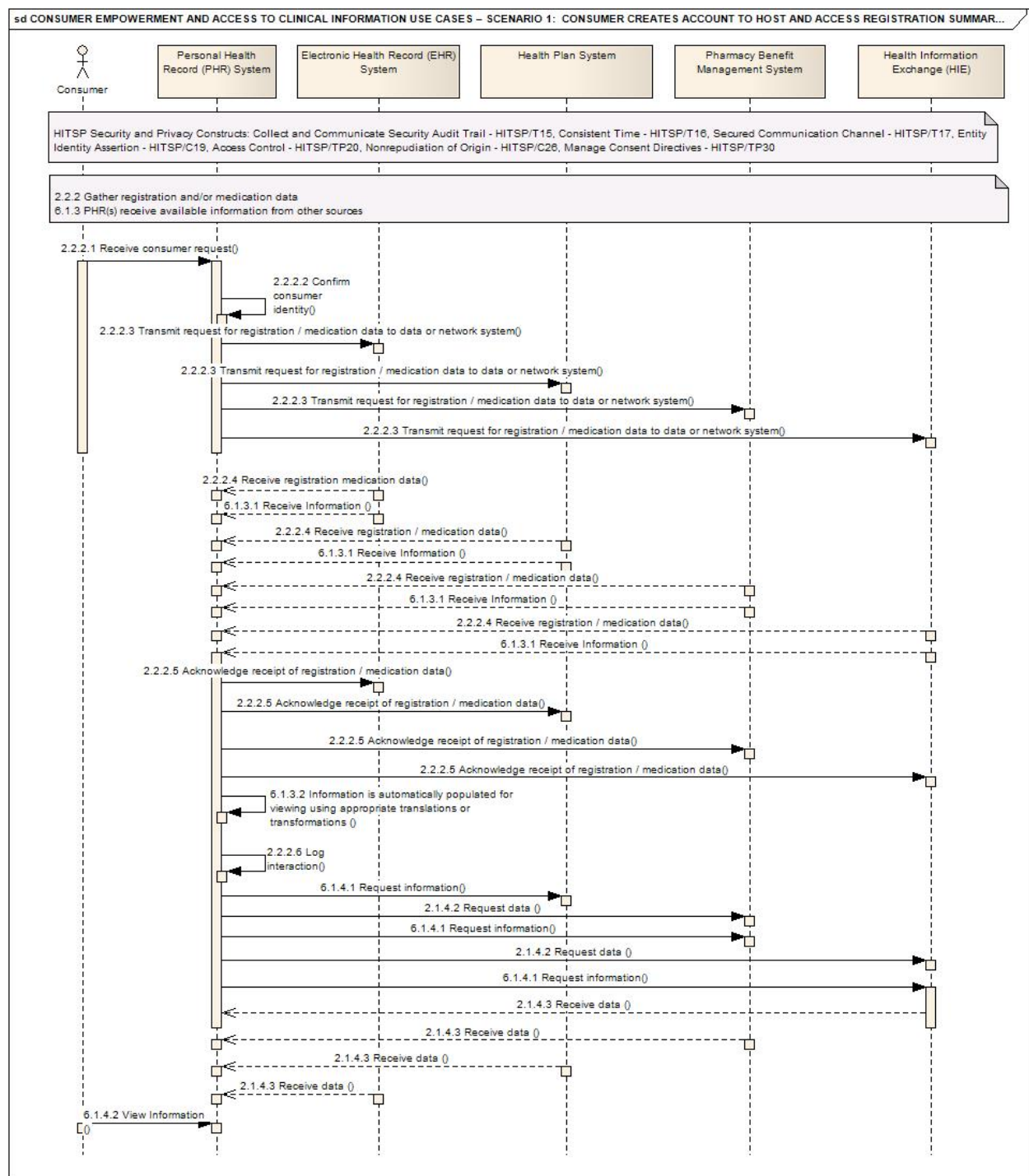
**Figure 6.3-1 Scenario 1: Consumer Creates Account to Host and Access Registration Summary and Clinical Information High-Level Business Sequence Diagram - Part A**



The following diagram represents Part B of the sequence of exchange for Scenario 1 of the Use Case, in which a Consumer creates account to host and access registration summary and clinical information.



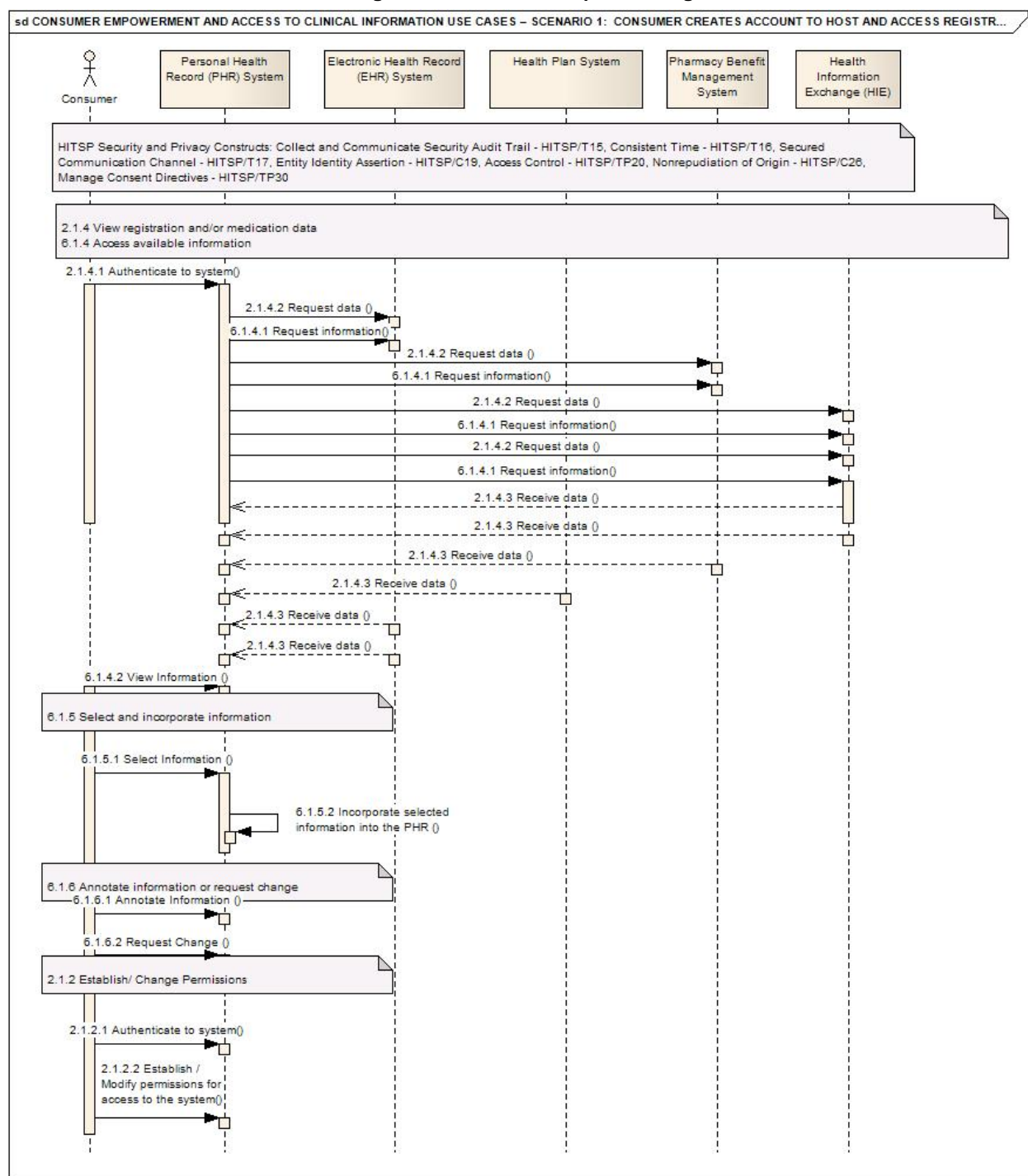
**Figure 6.3-2 Scenario 1: Consumer Creates Account to Host and Access Registration Summary and Clinical Information High-Level Business Sequence Diagram - Part B**



The following diagram represents Part C of the sequence of exchange for Scenario 1 of the Use Case, in which a Consumer creates account to host and access registration summary and clinical information.



**Figure 6.3-3 Scenario 1: Consumer Creates Account to Host and Access Registration Summary and Clinical Information High-Level Business Sequence Diagram - Part C**

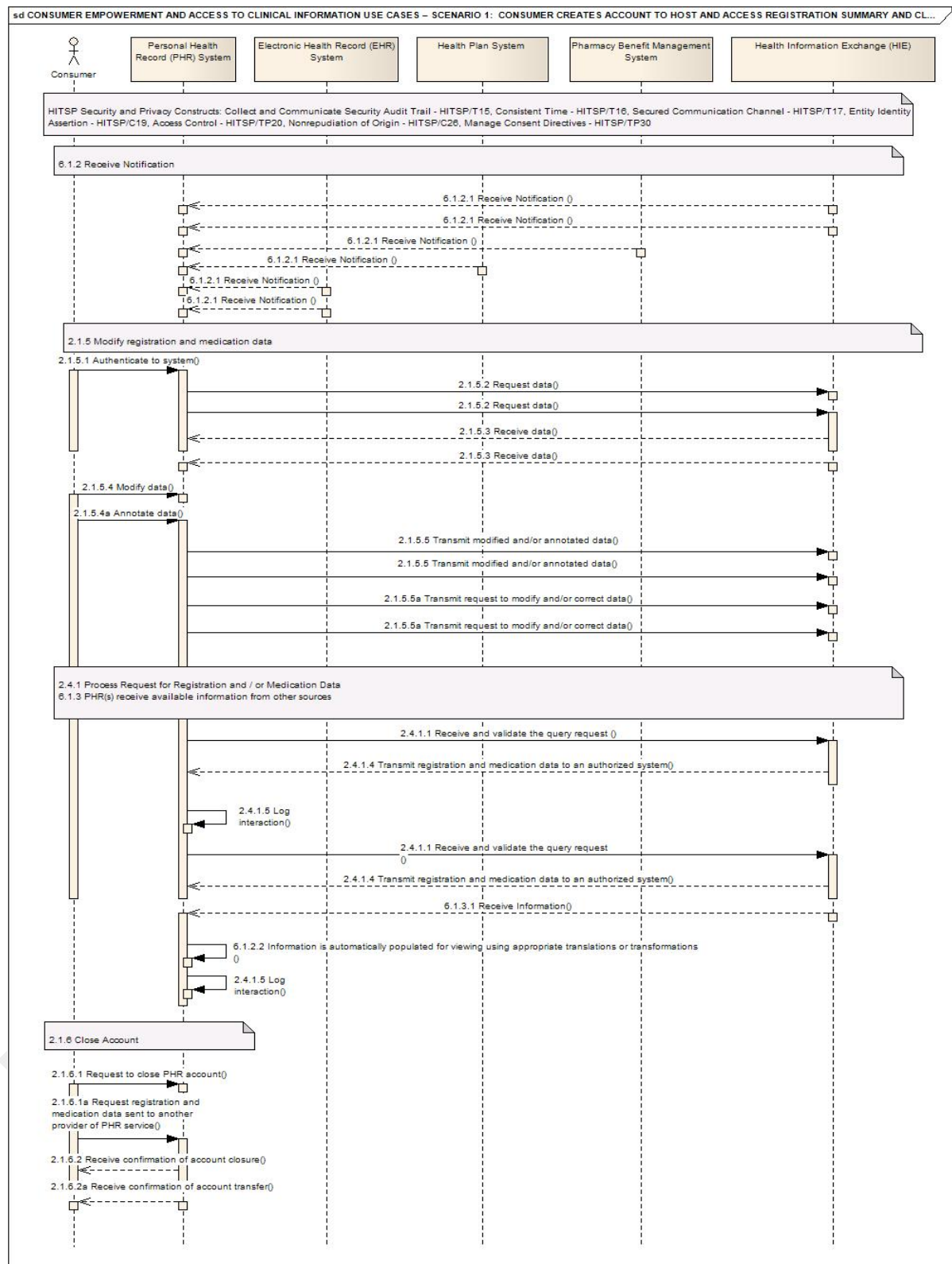


The following diagram represents Part D of the sequence of exchange for Scenario 1 of the Use Case, in which a Consumer creates account to host and access registration summary and clinical information.



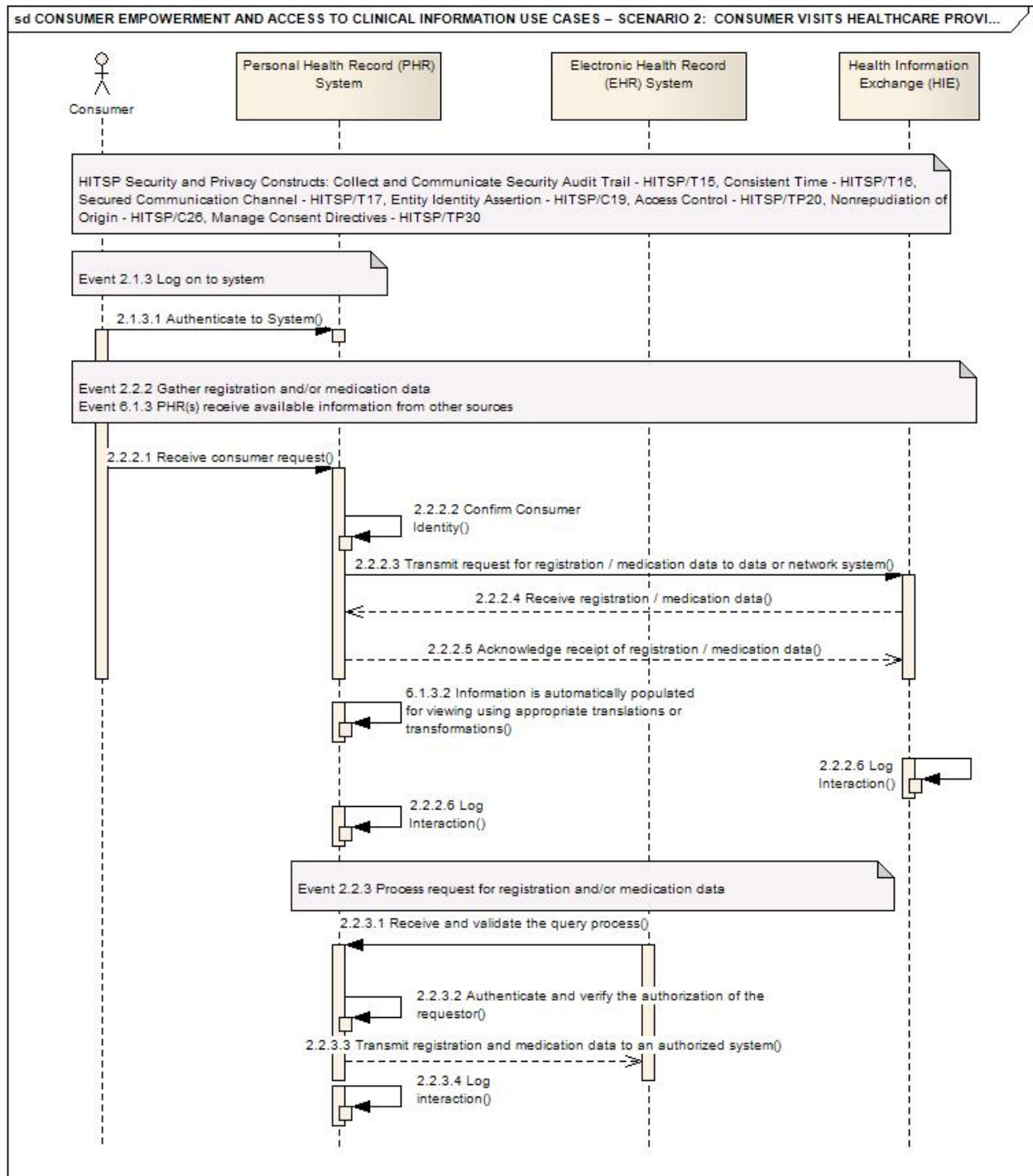


**Figure 6.3-4 Scenario 1: Consumer Creates Account to Host and Access Registration Summary and Clinical Information High-Level Business Sequence Diagram - Part D**

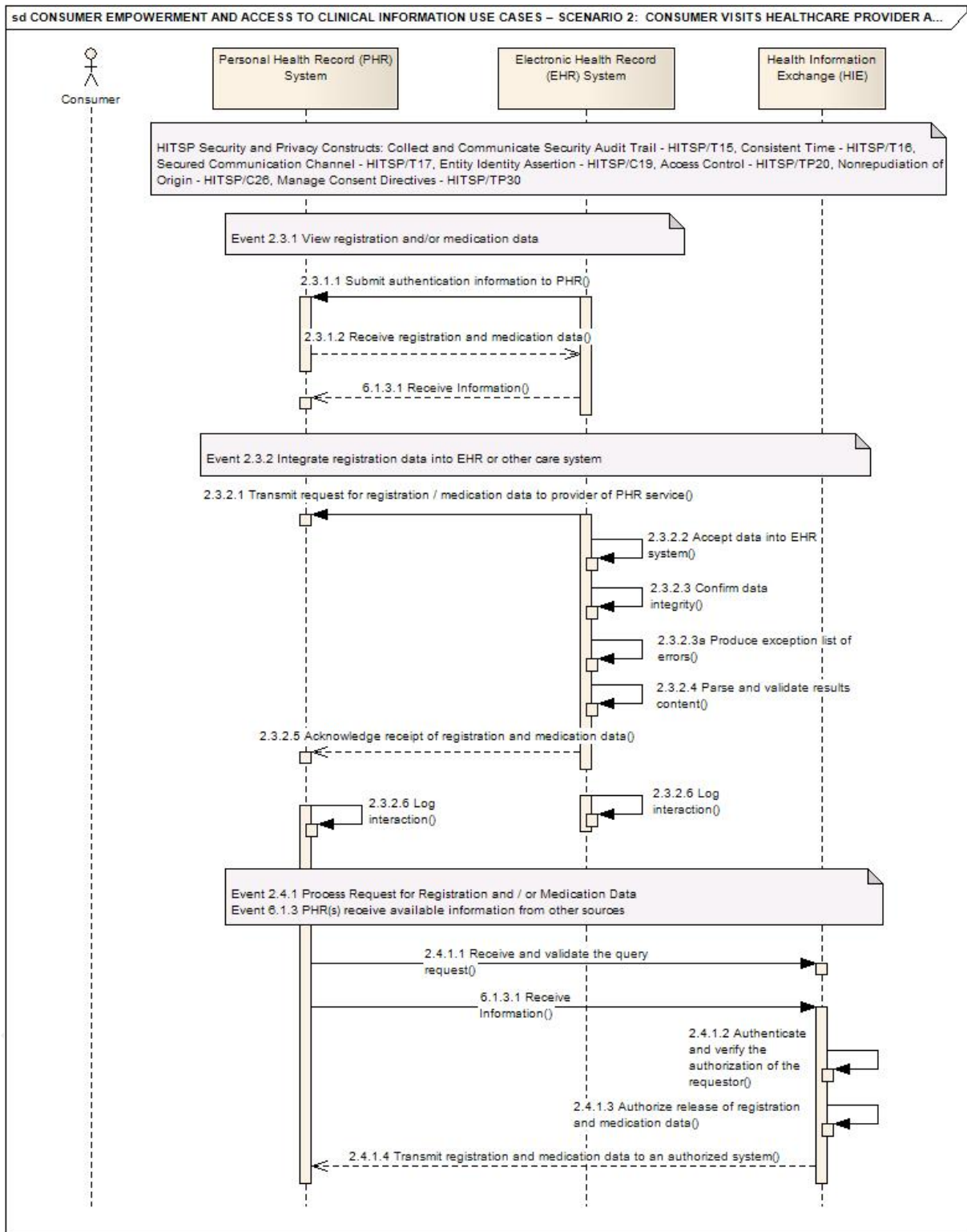




**Figure 6.3-5 Scenario 2: Consumer Visits Healthcare Provider and Provides Registration Summary Information and Clinical Information High-Level Business Sequence Diagram – Part A**

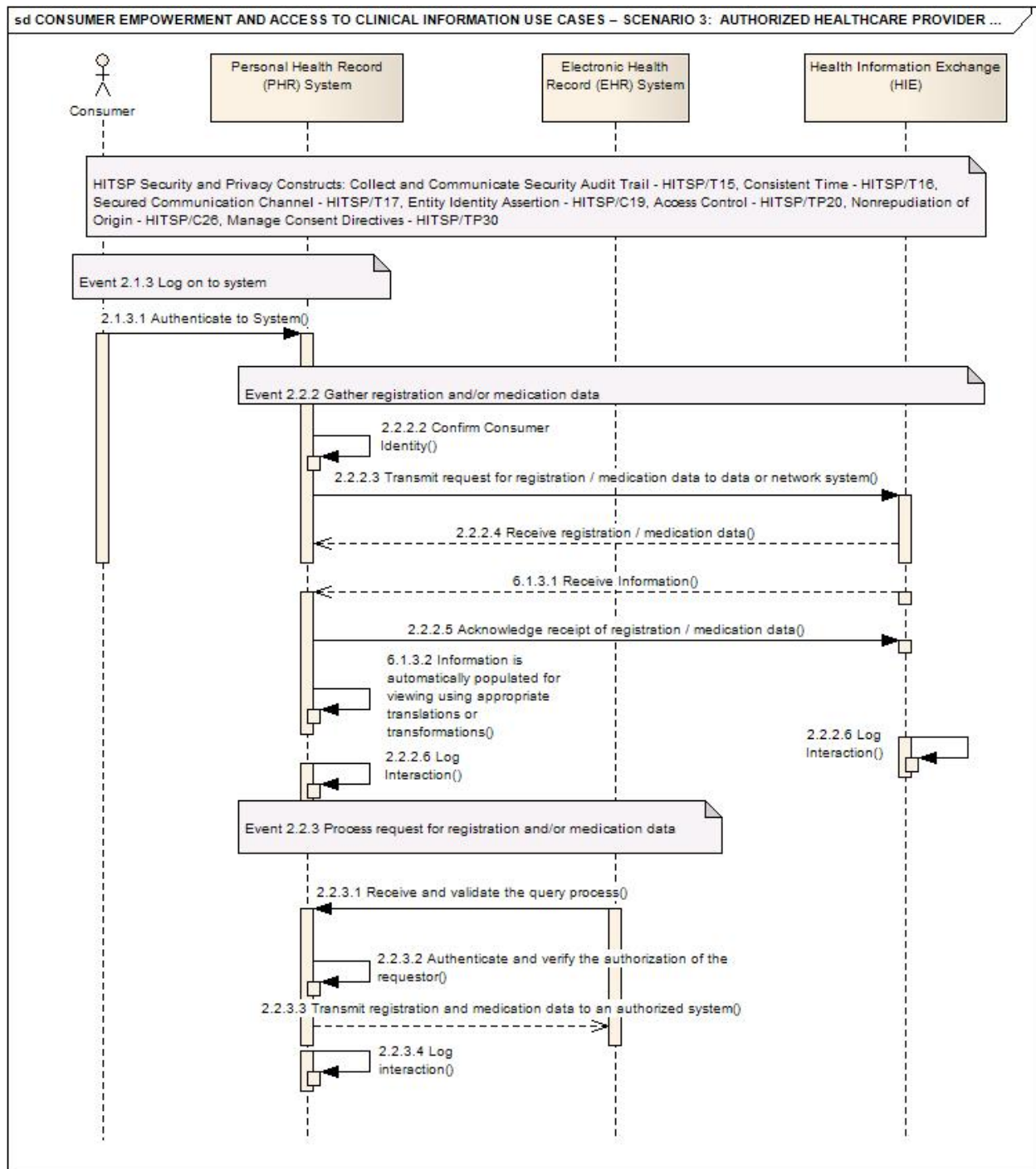


**Figure 6.3-6 Scenario 2: Consumer Visits Healthcare Provider and Provides Registration Summary Information and Clinical Information High-Level Business Sequence Diagram – Part B**

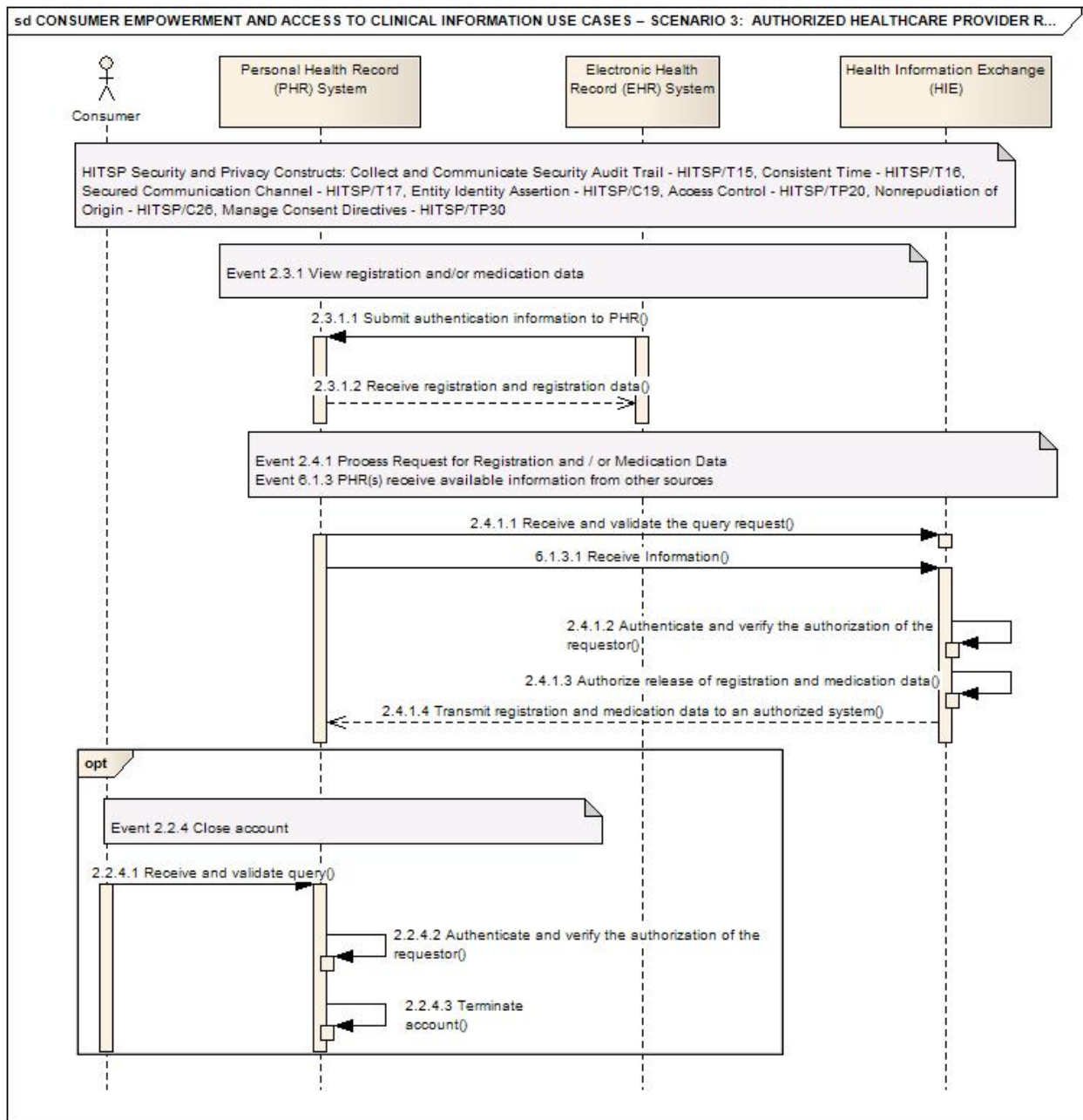


The following diagram represents the sequence of exchange for Scenario 3 of the Use Case, in which an authorized healthcare provider reviews registration summary and other clinical information.

**Figure 6.3-7 Scenario 3: Authorized Healthcare Provider Reviews Registration Summary and Other Clinical Information High-Level Business Sequence Diagram – Part A**



**Figure 6.3-8 Scenario 3: Authorized Healthcare Provider Reviews Registration Summary and Other Clinical Information High-Level Business Sequence Diagram – Part B**



## 6.4 MAPPING OF CONSTRUCTS TO INFORMATION EXCHANGE AND DATA REQUIREMENTS

Table 6.4-1 below provides a mapping of the HITSP constructs that will be used in the design of the Interoperability Specification, and the data and information exchange requirements that are being satisfied by the construct. These requirements are limited to those that are deemed within scope for this interoperability specification, which are described in Section 3.1.

**Table 6.4-1 Mapping of HITSP Constructs to Requirements**

| Construct Name  | Information Exchange Requirement Number (IER#)  | Data Requirement Number (DR#)  |
|---|---|--|
| HITSP/C19 - Entity Identity Assertion                                     | IER 10 Identify Patient<br>IER 1 Provide authentication and consent<br>IER 5 Verify entity identity<br>IER 8 Generate a Delivery Receipt  | DR74 Access Control Lists  |
| HITSP/C26 - Nonrepudiation of Origin                                      | IER 1 Provide authentication and consent<br>IER 5 Verify entity identity  | DR70 Information Source identification data  |
| HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD) | IER 21 Receive updated clinical information<br>IER 28 Download historical health data<br>IER 38 Query/retrieve document set<br>IER 61 Provide and register document set                                   | DR01 Demographic data<br>DR02 Patient clinical summary<br>DR03 Clinical History<br>DR04 Personal Genetic/Genomic Information<br>DR05 Family Genetic/Genomic Information<br>DR66 Diagnosis Codes<br>DR67 Allergies/Medication Allergies |
| HITSP/C35 - Lab Report Terminology  | IER 23 Request/provide additional information<br>IER 38 Query/retrieve document set<br>IER 61 Provide and register document set   | DR100 Lab Report Document  |
| HITSP/C37 - Lab Report Document   | IER 23 Request/provide additional information<br>IER 38 Query/retrieve document set<br>IER 61 Provide and register document set   | DR100 Lab Report Document  |
| HITSP/C62 - Unstructured Document   | IER 23 Request/provide additional information<br>IER 38 Query/retrieve document set<br>IER 61 Provide and register document set   | DR08 Unstructured Data   |
| HITSP/T15 - Collect and Communicate Security Audit Trail                  | IER 10 Identify Patient<br>IER 3 Create Audit Log Entry<br>IER 8 Generate a Delivery Receipt<br>IER 1 Provide authentication and consent<br>IER 5 Verify entity identity<br>IER 72 Send/receive audit log | DR75 Access log summary<br>DR74 Access Control Lists   |





| Construct Name   | Information Exchange Requirement Number (IER#)   | Data Requirement Number (DR#)  |
|--|--|--|
| HITSP/T16 – Consistent Time  | IER 1 Provide authentication and consent<br>IER 5 Verify entity identity<br>IER 3 Create Audit Log Entry<br>IER 8 Generate a Delivery Receipt<br>IER 10 Identify Patient   |  |
| HITSP/T17 - Secured Communication Channel  | IER 1 Provide authorization and consent<br>IER 5 Verify entity identity<br>IER 77 Identify information sources   | DR27 Message Routing and Content/Envelope/Metadata of the secure message   |
| HITSP/T23 - Patient Demographics Query   | IER 1 Provide authentication and consent<br>IER 5 Verify entity identity<br>IER 8 Generate a Delivery Receipt<br>IER 10 Identify Patient<br>IER 43 Send/Receive accept patient   | DR01 Demographic data<br>DR29 Read/delivery confirmation<br>DR70 Information Source identification data  |
| HITSP/T81 - Retrieval of Medical Knowledge   | IER 42 Request/receive medical concept knowledge   | DR 69 Context-aware Information Retrieval Message  |
| HITSP/TP13 V2.0.1 - HITSP Manage Sharing of Documents Transaction Package with Document Integrity Option | IER 21 Receive updated clinical information<br>IER 23 Request/provide additional information<br>IER 28 Download historical health data<br>IER 38 Query/retrieve document set<br>IER 61 Provide and register document set | DR01 Demographic data<br>DR02 Patient clinical summary<br>DR03 Clinical History<br>DR04 Personal Genetic/Genomic Information<br>DR05 Family Genetic/Genomic Information<br>DR08 Unstructured data<br>DR27 Message Routing and Content/Envelope/Metadata of the secure message<br>DR66 Diagnosis Codes<br>DR67 Allergies/Medication Allergies<br>DR70 Information Source identification data<br>DR100 Lab Report document |



| Construct Name                            | Information Exchange Requirement Number (IER#)   | Data Requirement Number (DR#)  |
|---|--|--|
| HITSP/TP13 - Manage Sharing of Documents  | IER 21 Receive updated clinical information<br>IER 23 Request/provide additional information<br>IER 28 Download historical health data<br>IER 38 Query/retrieve document set<br>IER 61 Provide and register document set               | DR01 Demographic data<br>DR02 Patient clinical summary<br>DR03 Clinical History<br>DR 4 Personal Genetic/Genomic Information<br>DR05 Family Genetic/Genomic Information<br>DR08 Unstructured data<br>DR27 Message Routing and Content/Envelope/Metadata of the secure message<br>DR66 Diagnosis Codes<br>DR67 Allergies/Medication Allergies<br>DR70 Information Source identification data<br>DR100 Lab Report document |
| HITSP/TP20 – Access Control               | IER 1 Provide authentication and consent<br>IER 5 Verify entity identity<br>IER 8 Generate a Delivery Receipt<br>IER 10 Identify Patient<br>IER 11 Identify Provider based on Pt Preference<br>IER 69 Authorize release of information | DR74 Access Control Lists<br>DR29 Read/delivery confirmation<br>DR75 Access log summary  |
| HITSP/TP22 - Patient ID Cross-Referencing | IER 1 Provide authentication and consent<br>IER 5 Verify entity identity<br>IER 8 Generate a Delivery Receipt<br>IER 10 Identify Patient<br>IER 43 Send/Receive accept patient   | DR01 Demographic data<br>DR29 Read/delivery confirmation   |
| HITSP/TP30 – Manage Consent Directives    | IER 1 Provide authentication and consent<br>IER 5 Verify entity identity<br>IER 8 Generate a Delivery Receipt<br>IER 10 Identify Patient   | DR74 Access Control Lists<br>DR29 Read/delivery confirmation   |





## 7.0 DOCUMENT UPDATES

The following sections provide the details of updates made to this document.

### 7.1 MAY 11, 2007

This document is now Released for Implementation.

### 7.2 SEPTEMBER 18, 2007

1. Updated Foreword to account for the CACI Use Case description
2. Updated Interoperability Roadmap
3. Rename IS to Consumer Sharing of Health Information via Networks
4. Updated HITSP/C32 Registration and Medication History Document Content Component to include: list of allergies for the consumer, encounters, identified conditions and problems diagnosed, the current list of immunizations received by the consumer, as well as some key laboratory test results indicative of the patient health status
5. Updated HITSP/TP13 with provisional selection of XDS.b to support Entity Identity Assertion (SAML) support
6. Added HITSP/C37 and HITSP/C35 constructs for laboratory reports
7. Added reference to Security and Privacy constructs: HITSP T15, T16, T17, TP20, TP30, C19, C26
8. Add in Section 4.0 reference to SNOMED, CLIA, LOINC, UCUM
9. Add in 3.1 the CACI resolution plan with 2008 work items
10. Add to overview of the CACI Use Case description
11. Re-scope Scenario 3.2.2.1
12. Remove security pre-conditions now explicitly addressed
13. Extend technical actors with Content Creator (to leave Doc Source and Media Creator for infrastructure interchange) and Content Consumer
14. Add Security and Privacy technical actors
15. Add Results – Laboratory, Immunizations, Encounters, Vital Signs in HITSP/C32 summary
16. Add Lab Report Doc description
17. Re-scope Scenario 3.2.2.2
18. Re-scope Scenario 3.2.2.3
19. Extend list of Transaction, Transaction Package and Components
20. Update list of dependencies
21. Remove Overview figure
22. Add for each business actor the extended list of technical actors
23. Extend the mapping from technical actor to Transaction Requirements
24. Add CACI to supporting documents
25. Add Subsetting to the conformance section



### 7.3 DECEMBER 5, 2007

The changes in this cycle address the following comments:

2424, 2444, 2445, 2446, 2456, 246, 2424, 2444, 2445, 2446, 2456, 2461

The full text of the comments along with the Technical Committee's disposition can be reviewed on the HITSP Public Web Site.

1. The Consumer Empowerment IS deliverables represent the joint analysis of both of the Consumer Empowerment (CE) Use Cases (Consumer Empowerment and Clinical Access to Clinical Information). The IS's are differentiated solely by the transport by which the consumer has access to and shares clinical information – via Networks (IS03) and using Media (IS05). As such, Section 2 for each of these IS's is identical. Section 2 Tables and their associated UML's have been completely redone to reflect a concatenation, where appropriate, of the events/actions from both of both CE Use Cases. This integration of the events/actions resulted in scenario one being fully merged into a single scenario entitled "Consumer creates account to host and Access Registration Summary and Clinical Information." Scenario 2 and 3 of the Consumer Empowerment Use Case were likewise edited to include operationally equivalent events/actions from the Consumer Access Use Case. Scenario 2 and 3 of the Consumer Access Use Case remained intact as originally presented.
2. Section 3 has been revised to reflect the new template (effective 11/29/07) which was the result of a cross-TC and project management assessment of the IS readability and usability for implementation and certification purposes. The following changes were made to the document in this regard:
  - Table 3.2.1-1 was revised to only list the technical actor names and their descriptions
  - The UML's in Section 3.2.2 were completely redesigned to improve the segmentation of business actor-to- business actor interactions and technical actor-to technical actor transactions
  - Table 3.2.3-1 was completely redesigned to improve the clarity of the requirements (and optionality) for a business actor in terms of what technical actors need to be supported AND what specific transactions for those technical actors are required, optional, or conditional
  - The conformance subsets previously included in Section 5.1.2 were relocated to Section 3.2.3 as paragraphs 3.2.3.x, where x = the subset number. These subsets were also included in table 3.2.3-1 accordingly
  - The Conformance Section 5.1 was revised to direct the reader to Section 3.2.3 for the mandatory requirements to claim conformance to this specification
3. Transactions and Content were differentiated in Table 3.2.3-1 to clarify how specific technical actors (e.g. Document Source) needed to support both Content Technical Actors (Content Creator and Content Consumer), specified with the detailed subsets of clinical information, and the transaction to transport that information (e.g. TP13).
4. All relevant Security and Privacy constructs, including their applicable transactions, have been included in Section 3, with particular specificity regarding their association to business actors requirements highlighted via Table 3.2.3-1.



5. The results of TC dispositions of public comments received against this IS have been appropriately reflected in the text, tables, and UML diagrams of the IS. Specifically, comment dispositions for the following comment topic categories have been effectively included:
- PHR Data Entry/Quality/Integrity – comments #2424, 2425, 2426, 2427, 2428, 2443, 2450
  - Data Content Specifics – comments #2444, 2446, 2454, 2455, 2456, 2489
  - Data Transport Logistics & Controls – comments #2445, 2453, 2461
  - CFH Initiative General Comments – comment #2495

#### **7.4 DECEMBER 13, 2007**

Upon approval by the HITSP Panel on December 13, 2007, this document is now released for Implementation.

#### **7.5 AUGUST 20, 2008**

This document has been modified to reflect the updated HITSP approach to categorizing standards as Regulatory Guidance, Selected Standards, and Informative References. Please refer to the underlying constructs for specific changes to standards.

#### **7.6 AUGUST 27, 2008**

Upon approval by the HITSP Panel on August 27, 2008, this document is now Released for Implementation.

#### **7.7 DECEMBER 10, 2008**

This document has been modified to address two of the requirements previously identified as gaps in Section 4.2. These were specifically identified as work items targeted for the 2008 publication cycle. The two work items addressed with this update are:

1. Advance Directives (AD)
2. Med/Labs Info in Consumer-friendly Manner

The first work item, Advance Directives, was only partially addressed in the 2008 cycle. The full resolution of this requirement is included as a work item for the 2009 work cycle in that the standards to complete this are still in works-in-progress. In this cycle, the standard for the capture of a scanned document which could include any type of advance directive that has been specified, i.e. HITSP/C62 Unstructured Document.

The second work item, Med Labs Info in Consumer-friendly Manner, has been fully resolved by the creation of a new HITSP construct entitled Retrieval of Medical Knowledge (HITSP/T81). This construct has been fully included and is identified as a construct which can facilitate the translation of clinical terms into consumer-friendly text.



Specific tables modified reflecting the inclusion of these two new constructs are:

Table 2.2.2-1, 2.2.3-1,

Table 3.1.1-1, 3.1.3-1, 3.1.4-1, 3.1.5-1

Table 3.2.1-1, 3.2.3-1, 4.1.2-1, 4.1.3-1

Text in Section 3.2.2

In addition to the inclusion of the above work items to address existing gaps, the document has been converted to the latest template for Interoperability Specification documents.

Minor editorial changes were made to this construct.

## **7.8 DECEMBER 18, 2008**

Upon approval by the HITSP Panel on December 18, 2008, this document is now Released for Implementation.

