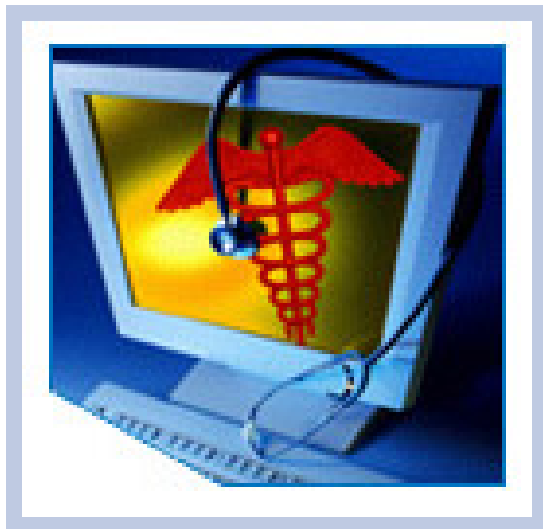


HITSP Consumer Empowerment and Access to Clinical Information via Media Interoperability Specification

HITSP/IS05



Submitted to:

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Submitted by:

**Consumer Perspective Technical Committee
(Formerly Consumer Empowerment Technical Committee)**



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1.0 INTRODUCTION

As an introduction to the Healthcare Information Technology Standards Panel (HITSP) Consumer Empowerment and Access to Clinical Information via Media 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 links to key reference documents and background material.

This update to the HITSP Consumer Empowerment and Access to Clinical Information via Media Interoperability Specification introduces two new constructs, both of which address specific gaps identified in the previous version of this specification. 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 Interoperability Specification, 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 lay-person 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 Media 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 and Access to Clinical Information via Media Interoperability Specification contributes to Consumer Empowerment, defined as the active involvement of consumers (i.e., individuals) in managing their healthcare and gaining the benefits of having their healthcare information in a form easily accessible to them. This includes having a Personal Health Record (PHR) system to track patient and insurance information, family history, medications, and other special conditions.

As part of a PHR, this Interoperability 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.



This Interoperability Specification addresses the recording of an individual's healthcare information on portable media such as, a CD or a USB key, to achieve portability between the consumer's PHR Systems and other information systems. These other systems might include an Electronic Health Record (EHR), another PHR to which the consumer wishes to transfer healthcare information or other IT systems such as, those of public health agencies. A consumer may also use the media to convey healthcare information to and from selected caregivers and other healthcare professionals.

This Interoperability Specification is closely related to the HITSP Consumer Empowerment and Access to Clinical Information via Networks Interoperability Specification. These two specifications support the same patient registration, medication history, and clinical summary information content; however, the present specification is addressing its transfer on portable media, thus making this information portable by the consumer.

The concept of consumer empowerment creates a new perspective on how healthcare providers and healthcare organizations can share information with patients. Storing healthcare information about the consumer on portable media is one of the ways to move healthcare information in an electronic form. For example, this may allow providers to obtain more reliable and complete registration, medication or clinical information in a form more suitable for import and export from computer based health applications, such as those supported by PHR systems, EHR systems and other health IT systems.

The HITSP Consumer Empowerment and Access to Clinical Information via Media Interoperability Specification defines broadly available standardized physical media technologies and the technical details for how information should be stored to ensure effective portability across different implementations. It also defines how information should be structured and represented so that it can be easily imported and exported from healthcare information applications. In particular, this Interoperability Specification supports interchange of the following interoperable electronic documents:

- Registration and healthcare summary information (e.g. medication history, allergies, conditions, laboratory results, and immunizations): This allows consumers to create and track summaries of their current and past health status
- Laboratory results: This allows a complete set of test results ordered by a provider to be recorded as a laboratory report document
- Unstructured documents: This allows consumers to use and store documents, which are in an unstructured format such as a scanned document, a PDF, etc.

Other types of documents may be defined by HITSP in the future (e.g. radiology reports, images, electrocardiogram (ECG) reports, etc.). These other types of documents are beyond the current scope of this Interoperability Specification.

The HITSP Consumer Empowerment and Access to Clinical Information via Media Interoperability Specification supports a broad range of requirements such as:



1. The transfer by consumers of their healthcare information on portable media from an existing PHR system (A) to another PHR system (B). This may include the transfer of provider lists and permissions
2. The use of portable media by a provider will give patients a snapshot of key elements from the EHR system. This allows consumers to import this information into their PHR system(s) or to hand the media to other providers
3. The means for consumers to extract healthcare information from their PHR system(s), and to transfer this information on portable media to selected providers

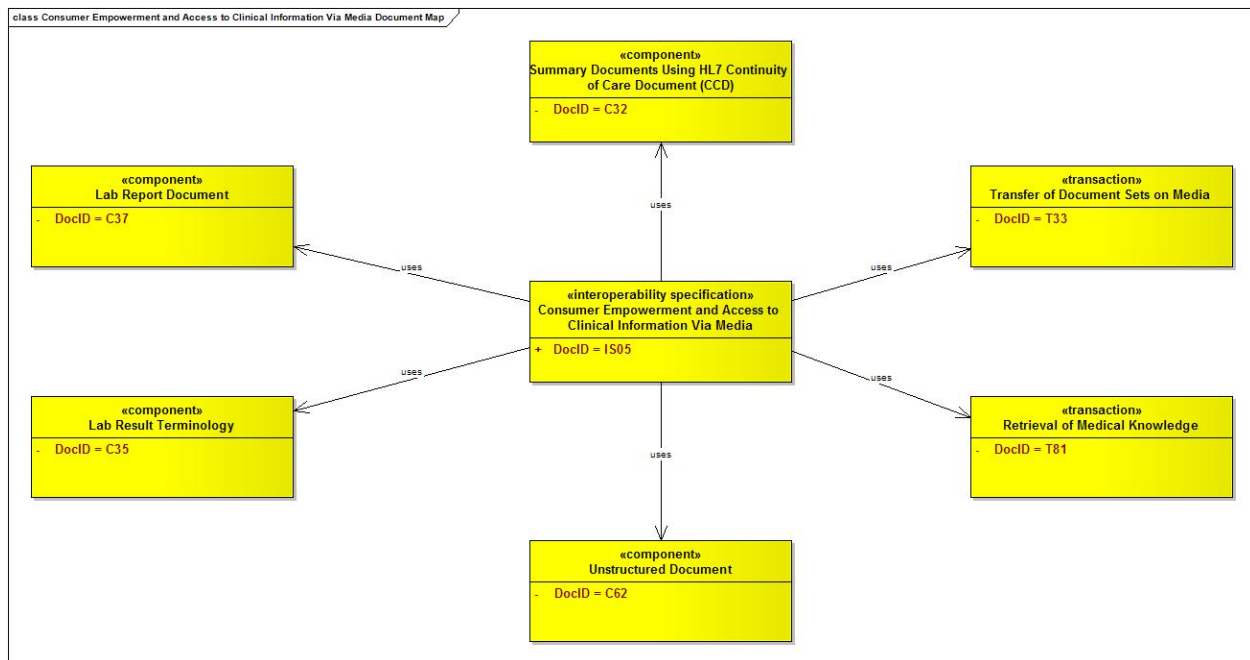
The interoperability requirements are based upon six well-defined scenarios related to a consumer's personal health record. This is the first document in a series of documents that need to be understood and implemented in order to conform to this specification.

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 Document Map



1.2.1 LIST OF CONSTRUCTS

The following table lists and describes the HITSP constructs that 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.

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).

Table 1.2.1-1 List of Constructs

Construct	Description
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



Construct	Description
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
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/T33 - Transfer of Documents on Media	The Transfer of Documents on Media Transaction describes both the type of media (CD-ROM, USB Memory, and e-Mail) that may be used to write the documents and provides a directory structure that must be followed in order for the contents to be successfully accessed and processed by systems. An example might be to transport data from one healthcare provider to another healthcare provider, or a healthcare consumer may wish to move the contents of a Personal Health Record (PHR) using physical media or e-Mail. This Transaction uses the IHE Cross-Enterprise Document Media Interchange Integration Profile developed by Integrating the Healthcare Enterprise (IHE), a companion to the IHE Cross-Enterprise Document Sharing (XDS) 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/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/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

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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.

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-Consumer Access to Clinical Information Detailed Use Case, June 18, 2007	AHIC Use Case that is the basis of this Interoperability Specification



<p>TN900 - Security and Privacy Technical Note</p>	<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"> • The scope, reference policy background, and Security and Privacy principles used in the development of the constructs • A detailed description and schematics of the conceptual relationship between the Security and Privacy constructs • A mapping of existing standards and constructs to be used in meeting the stated requirements of the AHIC Use Cases • A list of identified gaps and the recommended approaches to resolving those gaps • A roadmap for how the Security and Privacy constructs will evolve and eventually align with other HITSP Interoperability Specifications • A conceptual framework for Security and Privacy management, including reference information on privacy policies, risk assessment, and risk management • 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 <p>HITSP will periodically update this Technical Note as required by the introduction of new contexts for use.</p>
<p>TN901 – Technical Note for Clinical Documents</p>	<p>Developed as a reference document to provide the overall context for use of the HITSP Care Management and Health Records constructs. It includes the following:</p> <ul style="list-style-type: none"> • The scope, background, and principles for use in the development of the CMHR constructs • A detailed description and schematics of the relationship between CMHR constructs • A conceptual framework for the construction of clinical documents • An overview of Clinical Document concepts • An overview of Vocabulary concepts



2.0 REQUIREMENTS

This section provides a high level description of the Consumer Empowerment and the Consumer Access to Clinical Information Use Case, 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 Consumer Access to Clinical Information Use Case, including any applicable scenarios that are part of the Use Case.

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
 - lists of diagnosis codes
- 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 consumer's 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 decision by using information which can be communicated among systems involved in information exchange

Based on the charge from the American Health Information Community (AHIC), 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) ability to incorporate both types of data simultaneously into a system (although they may come from different systems themselves)

This linkage applies to laboratory results in the healthcare summary or to sharing one or more laboratory reports as separate documents.

Certain parts of the most recent Use Case: Consumer Access to Clinical Information via Media, 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 IS 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 Media, which would be in the scope of this IS, from the transfer of PHR Information via Networks which is addressed by a companion IS, HITSP/IS03 Consumer Empowerment and Access to Clinical Information via Networks

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.

2.2 USE CASE REQUIREMENTS

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

The tables and diagrams in this section describe the Use Case requirements and outline all the given scenarios at a high level. As noted in Section 2.1, two of the scenarios contain events/actions which



require the availability of standards under development and as such are included in this IS as gaps (see Section 4.2.1).

This document (and its companion, HITSP/IS03 Consumer Empowerment and Access to Clinical Information via Networks Interoperability Specification) specifies a design to address the following three scenario flows from the 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); 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 and 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 Actions 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 or via media). The importance of such an extension is illustrated in this example:

A patient is seen in the emergency department at a local hospital the night before a visit to her physician. The physician submits a new medication history request query, but there is an interval when a multi-State Rx Plan has not yet processed the new medication (e.g. the night before) and published it to an available resource that can be accessed by multiple care providers. If the emergency department did not send the information to this shared resource, the patient's physician would not have access to that information unless the patient enters the data into their PHR. The patient's physician 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 their registration summary, clinical and laboratory data, and 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 well as possible.

2.2.1 MAPPING OF USE CASE REQUIREMENTS 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 3.0.



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 6.2-1 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):	
	<ul style="list-style-type: none"> Name Unique identifier Race Ethnicity Occupation 	<ul style="list-style-type: none"> 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"> Advance Directive Allergy/Drug Sensitivity Comment Condition Encounter Healthcare Provider Immunization Information Source Insurance Provider 	<ul style="list-style-type: none"> Insurance Provider Language Spoken Medication – Prescription and Non-Prescription Person Information Pregnancy Procedure Support Vital Sign
DR03	Clinical History: Patient clinical history is provided Including (but not limited to):	
	<ul style="list-style-type: none"> History of specific disorder Environmental exposure data Any prior treatment for specific disorders 	<ul style="list-style-type: none"> Relevant non-genetic laboratory test and pathology data Other clinical data such as radiology study results Family history information
DR04	Personal Genetic/Genomic Information: Personal Genetic/genomic information including (but not limited to):	
	<ul style="list-style-type: none"> Prior genetic/genomic laboratory test results Full genome scan: deoxyribonucleic acid (DNA) 	<ul style="list-style-type: none"> Prior genetic status for specific disease Risk Analysis relative to family history
DR05	Family Genetic/Genomic Information: Family Genetic/genomic information including (but not limited to):	



Data Requirement Number (DR)	Description	
	<ul style="list-style-type: none"> Genetic/genomic data of family members Pedigree in structured form when appropriate 	<ul style="list-style-type: none"> History of consanguinity Consent/access allowance information
DR08	Unstructured Data: Unstructured data, including (but not limited to):	
	<ul style="list-style-type: none"> Unstructured Documents (see HITSP/C62 - Unstructured Document) Entry-level support of advance directive documents 	
DR27	Message Routing and Content/Envelope/Metadata of the secure message: Metadata should include (but are not limited to):	
	<ul style="list-style-type: none"> Patient ID and basic demographics Class of Document Document Type Source Care-Setting/Specialty Date/time Format/MIME Type 	<ul style="list-style-type: none"> Source identifier Entry identifier Date of original datum Last update date Updated by identifier(s)
DR66	Diagnosis Codes: Diagnosis Codes are provided, data elements include (but are not limited to):	
	<ul style="list-style-type: none"> Patient Class (outpatient, inpatient, and ER (UHDDS)) Diagnosis/Injury Code (ICD 9/10) Diagnosis Type (UHDDS) Diagnosis Date and Time (UHDDS) Date/time of first symptoms 	<ul style="list-style-type: none"> Discharge Disposition (UHDDS) Chief Complaint (ICD9/10) Date/time of first symptoms of illness (UHDDS) Identity of diagnosing provider or institution Diagnostic procedure(s) HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD) Section 4.2.3.1.7
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"> Allergy type Date/time of first symptoms 	<ul style="list-style-type: none"> HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD) Section 4.2.3.1.6
DR68	Structured information request	
	<ul style="list-style-type: none"> Information Service Identifier Requested information type Patient (target) identification Requested information parameters (date range, limiting criteria) Requestor authentication and authorization information 	<ul style="list-style-type: none"> Type of request: One time request, notification request, subscription request Request active dates (how long to continue request)



Data Requirement Number (DR)	Description	
DR69	Context-aware Information Retrieval Message. Data elements include:	
	InformationEventNotification Relationships <ul style="list-style-type: none"> MainSearchCriteria <ul style="list-style-type: none"> SeverityObservation class: SubTopic TaskContext PerformerChoice Relationship <ul style="list-style-type: none"> LanguageCommunication InformationEventNotification class <ul style="list-style-type: none"> InfobuttonEventNotification.id InfobuttonEventNotification.effectiveTime	InformationEventNotification Participants <ul style="list-style-type: none"> AssignedEntity <ul style="list-style-type: none"> Username CertificateText Organization Organization.id AuthorizedPerson PatientContext <ul style="list-style-type: none"> PatientPerson.administrativeGenderCode PerformerChoice: Patient or HealthCareProvider Age AgeGroup
DR70	Information Source identification data: These include (but are not limited to):	
	<ul style="list-style-type: none"> URL Service Provider 	<ul style="list-style-type: none"> Service Type (e.g., laboratory, pharmacy, healthcare entity, etc)
DR71	Change request data: Send request to change data including (but not limited to):	
	<ul style="list-style-type: none"> Information source identifier Consumer identifier Original entry identifier Data enterer identification/authorization information 	<ul style="list-style-type: none"> Annotation/change request information (relate to standard clinical content structures) Rational for change request (free text?) Requestor contact information
DR73	Provider Identification: Provider identification, location, details including (but not limited to):	
	<ul style="list-style-type: none"> Provider demographic data (Name, Location, Specialty, Location, Contact Information) Superset of HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD) & C37 - Lab Report Document provider identification, and additional elements as needed for entity resolution 	
DR74	Access Control Lists: Data elements include (but are not limited to):	
	<ul style="list-style-type: none"> Identification of entity being authorized Identification of entity granting authorization/test results, etc. 	<ul style="list-style-type: none"> Type of authorization (read/no-read, write/no-write, etc) Criteria defining the application of the authorization (e.g., document type, procedure)
DR75	Access log summary	
	<ul style="list-style-type: none"> Access log information, available in both summary and detail format: What information was accessed Who accessed the information 	<ul style="list-style-type: none"> When was the information accessed Stated purpose for the access Override criteria, if applicable (e.g., "break-glass")



Data Requirement Number (DR)	Description
DR100	Lab Report Document
	<ul style="list-style-type: none"> • Uses IHE-Lab TF • Alternatively to LOINC, other coding schemes, national or international (like SNOMED) may also be used • LOINC codification for laboratory tests • 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

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
IER01	Provide authorization and consent: System authenticates user and verifies authorization
IER03	Create audit log entry: The secure message system will log that the message was sent, received or viewed. Provides assurance that security policies are being followed or enforced and that risks are being mitigated
IER11	Identify provider based on patient preference: Identify/Select a consulting clinician or next setting of care, based on patient preference
IER18	Send/Receive clinical document: Supports the sharing of patient records in the form of source attested objects called documents, using physical media and email to transport clinical document information from a source to a destination, or communicate a clinical document to a recipient through direct communication conveying a set of medical documents in a point-to-point network-based communication
IER21	Receive updated clinical information: Patient receives newly validated and updated personal and family health history information and pedigree, if appropriate, via an interoperable PHR
IER23	Send/Receive additional test results: Send/receive a request for additional information, or send/receive additional information in unstructured format
IER28	Download historical health data: Download historical health information from EHR's, PHR, health record banks, etc
IER42	Request/Receive medical concept knowledge: Supports the query and receipt of ancillary medical knowledge
IER43	Send/Receive accept patient: Send/Receive query/response if the patient can be accepted
IER68	Identify PHR location: Identification of PHR Service/PHR instance (PHR Location-Gap)
IER69	Authorize release of information
IER72	Send/Receive audit log: The system sends/receives a log of all actions and event logged
IER76	Request modification of clinical data
IER77	Identify information sources



2.2.3 IDENTIFICATION OF BUSINESS ACTORS, INTERACTIONS AND SCENARIOS

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) 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	Consumer Empowerment Consumer Access to Clinical Information Scenarios: (1) Consumer Creates Account to Host and Access Registration Summary and Clinical Information (2) Consumer visits Healthcare Provider and Provides Registration Summary information and Clinical Information Provider Permissions and Lists (3) Authorized Healthcare Provider Reviews Registration Summary and Other Clinical Information	IER1 Provide authorization and consent IER3 Create audit log entry IER5 Verify entity identity IER8 Generate a delivery receipt IER10 Identify patient IER18 Send/receive clinical document IER21 Receive updated clinical information IER23 Request/provide additional information IER28 Download historical health data IER42 Request/receive medical concept knowledge IER43 Send/receive accept patient IER63 Request additional patient data	DR01 Demographic data DR02 Patient clinical information DR03 Clinical History DR04 Personal Genetic/Genomic Information DR05 Family Genetic/Genomic Information DR08 Unstructured Data DR27 Message Routing and Content/Envelope/Metadata of the secure message DR29 Read/Delivery Receipt DR38 Health plan authorization




Business Actor	Description	Supported Stakeholders	Use Case Scenario	Information Exchange Requirement Numbers (IER)	Data Requirement Numbers (DR)
				IER72 Send/receive audit log IER68 Identify PHR Location IER76 Request modification to clinical data	DR66 Diagnosis Codes DR67 Allergies/Medication Allergies DR68 Structured information request DR70 Information Source identification data DR71 Change request data DR100 Lab Report Document
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 Payers Health Plans	Consumer Empowerment Consumer Access to Clinical Information Scenarios: (1) Consumer Creates Account to Host and Access Registration Summary and Clinical Information	IER1 Provide authorization and consent IER3 Create audit log entry IER5 Verify entity identity IER10 Identify patient IER23 Send/receive additional test results IER18 Send/receive clinical document IER31 Provide message routing/description information IER33 Send/receive message IER42 Request/receive medical concept knowledge IER43 Send/receive accept patient IER72 Send/receive audit log IER68 Identify PHR Location	DR01 Demographic data DR02 Patient clinical information DR03 Clinical History DR04 Personal Genetic/Genomic Information DR05 Family Genetic/Genomic Information DR08 Unstructured Data DR27 Message Routing and Content/Envelope/Metadata of the secure message DR29 Read/Delivery Receipt DR66 Diagnosis Codes DR67 Allergies/Medication Allergies DR68 Structured information request DR70 Information Source identification data DR71 Change request data



Business Actor	Description	Supported Stakeholders	Use Case Scenario	Information Exchange Requirement Numbers (IER)	Data Requirement Numbers (DR)
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 Pharmacist	Consumer Empowerment Consumer Access to Clinical Information Scenarios: (1) Consumer Creates Account to Host and Access Registration Summary and Clinical Information	IER42 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>IER3 Create audit log entry</p> <p>IER8 Generate a delivery receipt</p> <p>IER10 Identify patient</p> <p>IER11 Identify provider based on patient preference</p> <p>IER18 Send/receive clinical document</p> <p>IER21 Receive updated clinical information</p> <p>IER23 Request/provide additional information</p> <p>IER28 Download historical health data</p> <p>IER38 Query/retrieve document set</p> <p>IER42 Request/receive medical concept knowledge</p> <p>IER43 Send/receive accept patient</p> <p>IER61 Provide and register document set</p> <p>IER68 Identify PHR Location</p> <p>IER72 Send/receive audit log</p> <p>IER73 Request/receive provider information</p> <p>IER74 Access/Select provider information</p> <p>IER75 Designate provider permissions</p> <p>IER76 Request modification to clinical</p> <p>IER77 Identify information sources data</p>	<p>DR01 Demographic data</p> <p>DR02 Patient clinical information</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 Receipt</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>
 HITSP Consumer Empowerment and Access to Clinical Information via Media Interoperability Specification Released for Implementation 20081218 V2.0					

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 Consumer Access to Clinical Information Scenarios: (1) Consumer Creates Account to Host and Access Registration Summary and Clinical Information	IER1 Provide authorization and consent IER3 Create audit log entry IER5 Verify entity identity IER10 Identify patient IERR 23 Send/receive additional test results IER18 Send/receive clinical document IER43 Send/receive accept patient IER68 Identify PHR Location IER72 Send/receive audit log	DR01 Demographic data DR02 Patient clinical information DR03 Clinical History DR04 Personal Genetic/Genomic Information DR05 Family Genetic/Genomic Information DR08 Unstructured Data DR29 Read/Delivery Receipt DR66 Diagnosis Codes DR67 Allergies/Medication Allergies DR68 Structured information request DR70 Information Source identification data 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 Consumer Access to Clinical Information Scenarios: (1) Consumer Creates Account to Host and Access Registration Summary and Clinical Information	IER1 Provide authorization and consent IER3 Create audit log entry IER5 Verify entity identity IER10 Identify patient IER23 Request/provide additional information IER18 Send/receive clinical document IER43 Send/Receive accept patient IER68 Identify PHR Location IER72 Send/receive audit log	DR01 Demographic data DR02 Patient clinical information DR03 Clinical History DR04 Personal Genetic/Genomic Information DR05 Family Genetic/Genomic Information DR08 Unstructured Data DR29 Read/Delivery Receipt DR66 Diagnosis Codes DR67 Allergies/Medication Allergies DR68 Structured information request DR70 Information Source identification data DR71 Change request data

These business actors are identified as separate actors in the various scenario actor transactions descriptions below, in this section and Sections 3.2.2 and 3.2.3. 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 3.2.3, to illustrate in part the architecture flexibility provided by this Interoperability Specification.

2.2.4 HIGH-LEVEL UML INTERACTION (BUSINESS SEQUENCE) DIAGRAM

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.

Section 6.3 provides High Level Sequence Diagrams to illustrate each Use Case scenario with a representation of a normal sequence of exchange between the primary actors



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

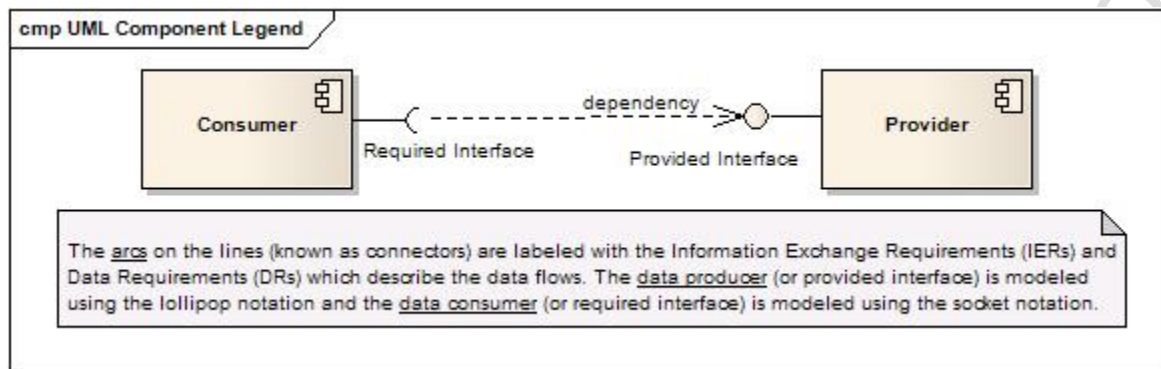
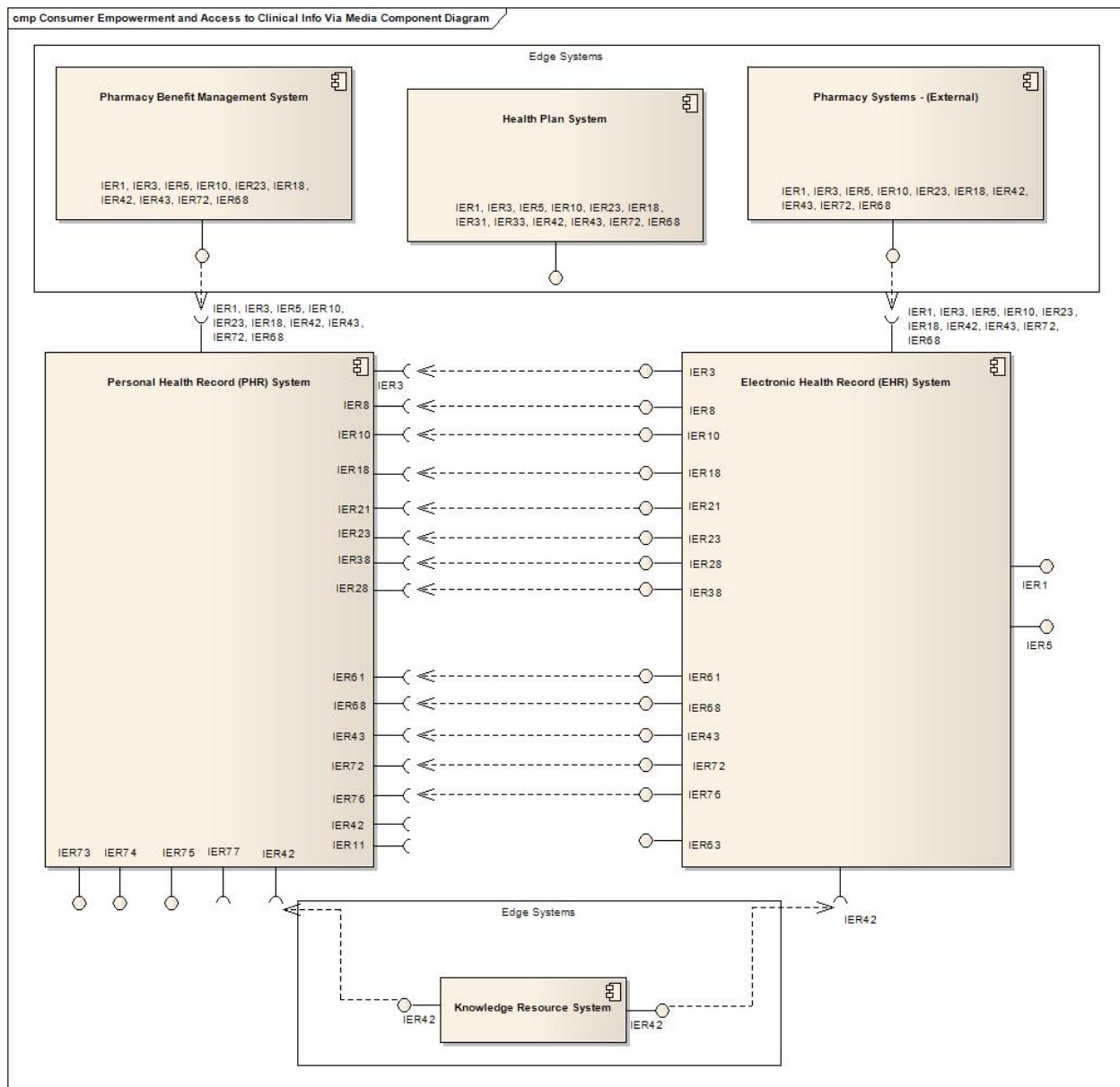


Figure 2.2.4-2 Component Data Flow Diagram



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 Interoperability Specification HITSP/IS05 Consumer Empowerment and Access to Clinical Information via Media and updates to HITSP/IS03 Consumer Empowerment and Access to Clinical Information via Networks shown in table below
- Gaps to be addressed during 2009 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 IS (IS05) and update to IS03	Reference existing HITSP Construct developed by Provider Perspective TC 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 IS (IS05) and update to IS03	Extend HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD) Component 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 IS (IS05) and update to IS03	Extend HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD) Component artifact with relevant sections
PHR Portability—using portable media	Addressed by this IS (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 (1) Providers do not have the option of limiting the consumer's access to clinical information that directly relates to that consumer, or (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
It is assumed that the media will be carried by the patient to ensure that the confidentiality and security of the health information contained is preserved. Support of other methods of physical transport may be possible as further extensions to this Use Case with appropriate security mechanisms	Consumer Access to Clinical Information/3 (media)
The media must be structured to ensure integrity (at the byte storage level) of the information stored (e.g. support a file system)	Consumer Access to Clinical Information/3 (media)
Regarding statutory limitations on a consumer's access to clinical information: (1) Statutory and policy considerations are beyond the scope of this Use Case (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
The HITSP Consumer Empowerment and Access to Clinical Information via Media Interoperability Specification requires that sharing of personal demographic data and medical summaries is based on consumer control and management of the media created and when in transit. In particular, given the lack of a HITSP construct for strong confidentiality on media, media usage may be restricted by policy to single consumer health information or specific dependents in some environments. Digital signatures may be applied where strong source attestation and integrity are desired	Consumer Access to Clinical Information/All
Process and places where such media would be created or read in healthcare delivery organization is often restricted by policy for multiple reasons (e.g. protect from malicious data, protect from unauthorized release of Individual Identifiable Health Information, etc.). It is expected the import/export to and from interchange media to be restricted to specific locations and/or staff	Consumer Access to Clinical Information/All



Assumption	Use Case Scenario
This Use Case has been designed for use by specific consumers that accept responsibility for the Security and Privacy of the interchange media and of its content. When an instance of an interchange media is being presented by the consumer that has accepted responsibility for its protection, it implies consent for use of the entire content is being granted to the recipient. Therefore the media need not be encrypted for protection and validation of the hash (Document Integrity) is not necessary. Reuse of this Interoperability Specification for other purposes would require a new risk assessment	Consumer Access to Clinical Information/All
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
The portable media used to store the consumer's PHR may have the ability to connect to a network or the internet to facilitate the retrieval of medical knowledge	Consumer Access to Clinical Information/2
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), and 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	Scenario
Available HITSP constructs (i.e., HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD) Component, 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	Scenario
The Consumer has access to a PHR System with the means to write to or read health information selected by the consumer from interchange media. This includes, but is not limited to: a. methods to identify and authenticate users b. methods to enforce data access authorization policies c. methods to ensure that the data are true copies of the data as attested by the source d. methods to correctly match patients across systems e. methods to log transactions and provide an audit trail f. methods to identify data sources including but not limited to provider EHR systems	All
Appropriate standards are developed, approved, and widely adopted supporting media formats, data content and structure, allowing universal access by compliant systems	All
Core datasets are defined and adhered to	All
Appropriate consumer-friendly medical knowledge (e.g., translation or additional references) is available for the consumer to view.	All
Security and Privacy policies, procedures and practices are commonly implemented to support acceptable levels of consumer Security and Privacy. In particular, the consent directives related to the documents to be stored on the media have been retrieved and placed as documents on the portable media	Consumer Access to Clinical Information/All
Appropriate standards protocols, patient identification methodology, consent, Security and Privacy procedures, will be agreed to by all relevant participants	All
Support the technical measures to ensure Security and Privacy of consumer/patient health information	All
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 privacy and security	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: HITSP/T16 - Consistent Time HITSP/T17 - Secured Communication Channel HITSP/T15 - Collect and Communicate Security Audit Trail HITSP/TP30 - Manage Consent Directives HITSP/TP20 - Access Control	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 an environment that insures 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 Media Interoperability Specification requires that sharing of personal demographic data and medical summaries is based on consumer control and management of the media created and when in transit. In particular, given the lack of a HITSP construct for strong confidentiality on media, media usage may be restricted by policy to single consumer health information or specific dependents in some environments. Digital signatures may be applied where strong source attestation and integrity are desired.

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 3.1.5-1 Post-conditions

Post-Condition	Use Case Scenario
New information from an Information Source is incorporated into the PHR	1
When the media is read the consent directives stored on the portable media need to be enforced by the portable media importer. The validity of these content directives may need to be checked	1, 2, 3
Provider information is successfully incorporated into the PHR as specified by the Consumer	2
A user's access or disclosure of PHR information is successfully logged	2
Access and disclosure logs are available for Consumer review	2
The consumer's PHR or a provider's EHR have been updated with the selected health information	2
PHR information, or the specified sub-set, is successfully incorporated into the receiving system	3
The extract from the consumer's PHR is available to the health professional and any healthcare provider staff that have been given the portable media by the consumer	3
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 3.1.4-1 Process Triggers

Trigger	Use Case Scenario
The consumer decides to create a PHR	Consumer Empowerment (Registration and Medication History)/1
Consumer elects to import health information into own PHR	Consumer Empowerment (Registration and Medication History)/1
The consumer decides to create a piece of portable media from health information accessed through a PHR system	Consumer Access to Clinical Information/1
Patient selects Providers to retain or be incorporated into their PHR	Consumer Access to Clinical Information/2
Provider selects PHR information to incorporate into local system	Consumer Empowerment (Registration and Medication History)/3
The consumer and/or the physician needs to store health information on a piece of media	Consumer Access to Clinical Information/2
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	Constructs
Access Control Service	The enterprise security service that supports and implements user-side and/or service side access control capabilities. This service would be utilized by the Service User, and/or Service Provider	HITSP/TP20
Audit Record Source	Creates and communicates an Audit Record to the Audit Record Repository on behalf of another actor that performs an action requiring logging	HITSP/T15
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
Content Consumer	Responsible for viewing, import, or other processing of content created by a Content Creator actor	HITSP/C32, HITSP/C37, HITSP/C62
Content Creator	Responsible for the creation of content and transmission to a Content Consumer	HITSP/C32, HITSP/C37, HITSP/C62
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
Portable Media Creator	The Portable Media Creator writes the selected information to media (CD-ROM, USB-Memory, e-Mail) following the directory structure outlined by XDM	HITSP/T33
Portable Media Importer	Media Importer reads the selected information from media (CD-ROM, USB-Memory, e-Mail) following the directory structure outlined by XDM	HITSP/T33
Service User	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 transactions	HITSP/TP20,
Time Client	Establishes time synchronization with one or more Time Servers using 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



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> = Personal Health Record System (PHRS)

<Primary Provider> = Dr. Doctor

<EHR> = Physician's Choice Office-base Electronic Health Record System (OfficeEHR) used by Dr. Doctor

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 a free-standing PHR solution which gives him maximum opportunity for untethered information exchange with his Primary Provider's EHR (<EHR>) and other PHRs. Mr. Everyperson decided that the most expedient method to exchange his health information with these other parties is via portable media such as a USB key or a CD [see HITSP/T33 Transfer of Documents on Media for detailed specifications]. In this way, he can forego the more complex technical requirements of cross-referencing his identification information with that of the receiving parties since him, or someone he has approved, will physically transport the portable media to the other party. The receiving party would then interact with himself or this designated individual to ensure that the health information is related, and imported, into the correct system record. For information that his Dr. Doctor (<Primary Provider>) might select to share with him, Mr. Everyperson would similarly conduct this exchange via a portable media.



The level of detail for data exchanged between two PHRs or between PHR and EHR systems depends upon information contained in these systems. The specification of the format and the content of the information to be exchanged are as specified in HITSP Components for content summarized below. Despite this detailed specification of data elements, some information exchanged may still require the personal assessment of the individuals conducting this information exchange which is pertinent to achieve semantic interoperability but is out of scope of this IS, e.g. 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, he can both begin the entry of his personal demographics and share that with Dr. Doctor or request information from Dr. Doctor which he can then import into his PHR from the portable media. Due to the breadth of the healthcare information for Mr. Everyperson, he may choose to establish multiple PHRs for different purposes. These may be from different PHR service providers. The exchange between any of Mr. Everyperson's PHRs would be accomplished via the same portable media-based process as accomplished with Dr. Doctor's EHR.

3.2.2.1 Summary Document Using HL7 Continuity of Care Document (CCD) Component

The HITSP/C32 Summary Documents Using HL7 Continuity of Care Document (CCD) Component 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 3.2.2.1-1. Subsequent sections indicate those content modules which are required in particular transaction/content subsets.

Table 3.2.2.1-1 HITSP/C32 Content Modules in this Interoperability Specification

Content Module
Advance Directive
Allergies and Drug Sensitivity
Comments
Condition
Encounter
Healthcare Provider
Immunization
Information Source
Insurance Provider
Language Spoken



Content Module
Medications – Prescription and Non-Prescription
Person Information
Pregnancy
Procedure
Result
Support
Vital Sign

The HITSP Summary Document Using HL7 Continuity of Care Document (CCD) Component, 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.

3.2.2.2 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 of a laboratory report in a source attested manner (laboratory or EHR system where the report was created). The laboratory results section in the HITSP/32 Summary Documents Using HL7 Continuity of Care (CCD) serves a complementary purpose in allowing the patient's healthcare summary to include selected lab results relevant in the context of the summary (e.g., abnormal results that resulted in a specific diagnosis or in medication being prescribed).

3.2.2.3 Unstructured Document Component

HITSP/C62 Unstructured Document Component 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/T81 Retrieval of Medical Knowledge should only be used to transport documents that are not natively structured.

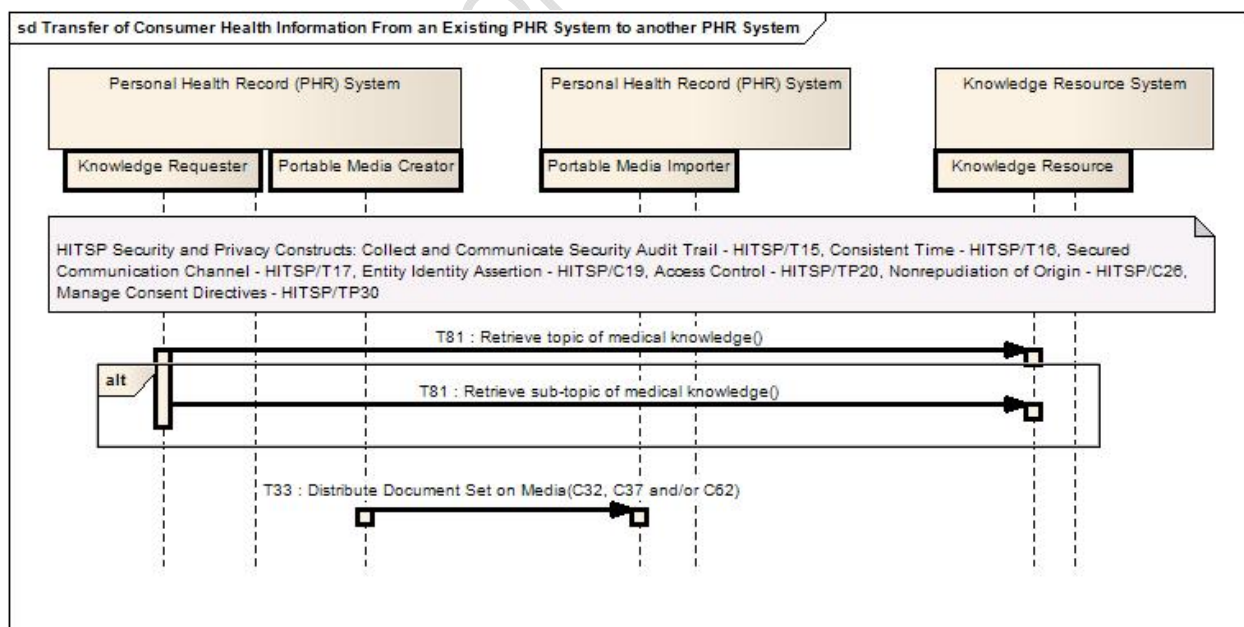
It produces output as a CDA document - with the attributes of a document, such as persistence, authenticity, wholeness, etc. Examples of documents that would be embedded in the CDA document include plain text notes to the patient, notes from the patient, or a presentation preserved document such as a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

3.2.2.4 Transfer of Consumer Health Information from an Existing PHR System to another PHR System Scenario Actor Interactions

Adam Everyperson has decided that he wishes to transfer all or part of the information retained in his PHR system to another PHR system. This scenario pertains to both the desire to maintain multiple PHR systems for different purposes as well as the transfer of an entire PHR system content to another PHR system completely.

The sequence diagram for this scenario is shown in Figure 3.2.2.4-1.

Figure 3.2.2.4-1 Transfer of Consumer Health Information from one PHR System to another PHR System on Media



3.2.2.4.1 Transactions Description

Mr. Everyperson accesses his PHR [Access PHR] and reviews that the information retained in his PHR is accurate. If appropriate, he updates the information retained in his PHR [Annotate Information] before selecting the information to be transferred to another PHR system [Select Information to Send] on the portable media. He extracts the information from his PHR and transfers it to the portable media for transport to the other PHR system [Distribute Document Set on Media (using HITSP/C32, HITSP/C37, HITSP/C62 or any combination of the three constructs)]. Mr. Everyperson's current PHR system generates an audit record of this extraction of health information and storage on the portable media [Generate Audit Log].

At the location of the other PHR system, Mr. Everyperson hands over the portable media to the administrator of the other PHR (or in the case of Mr. Everyperson maintaining two PHRs for different purposes, Mr. Everyperson is the administrator of both PHR systems) for import of information. The PHR system presents the information on the portable media from Mr. Everyperson [Information Presented for Viewing]. Mr. Everyperson (and the administrator, if this is a transfer from one PHR to another PHR entirely) reviews the information presented in the HITSP/C32 Summary Documents Using HL7 Continuity of Care Document (CCD), HITSP/C37 Lab Report Document or HITSP/C62 Unstructured Document and if relevant extracts the data elements for updating the other PHR system [Incorporate Selected Information into PHR]. Mr. Everyperson's new PHR system generates an audit record of this import of health information from the portable media [Generate Audit Log].

[Note: The translation or transformation of the information provided on the portable media into a consumer friendly format is to be addressed in later work cycle as explained in Section 4.2 of this IS]

3.2.2.5 Healthcare Professional Provides Patient with an Extract of Current Health Record on Portable Media for Import into PHR Scenario Actor Interactions

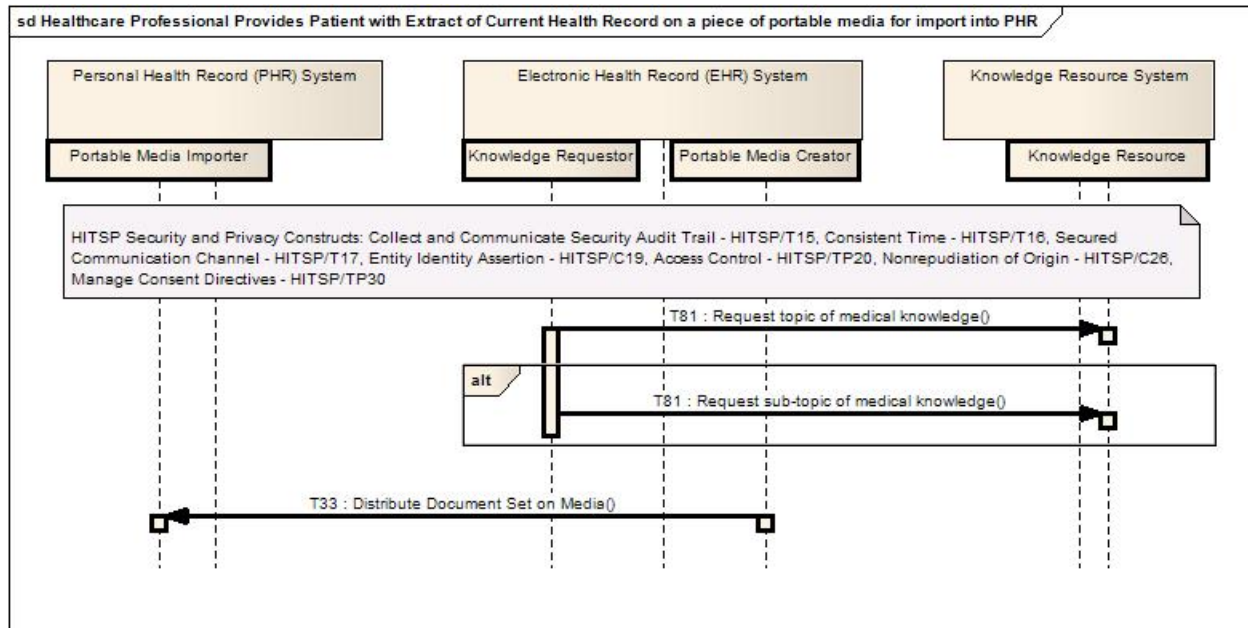
Following an office encounter with Mr. Everyperson, Dr. Doctor selects pertinent information from Mr. Everyperson's record in his EHR system, extracts it from this system (OfficeEHR), formats into the appropriate document format (HITSP/C32, HITSP/C37, or HITSP/C62) and records it on portable media as described in HITSP/T33. Dr. Doctor then provides this portable media (or updated portable media in the case of USB key) to Mr. Everyperson for updating his PHR system.

This second scenario defines the means for a healthcare professional to provide the patient with a snapshot of key current elements of his or her healthcare record and make it available on portable media for import into one's personal health record or handing over to another healthcare professional. For example at the end of a healthcare encounter an updated registration, medication history and other clinical information document, such as a new lab report, may be created and provided to the consumer on portable media. The healthcare professional may also provide the healthcare information associated with a referral on the portable media and ask the patient to convey this to the referring physician

The sequence diagram for this scenario is shown in Figure 3.2.2.5-1.



Figure 3.2.2.5-1 Healthcare Professional Provides Patient with Extract of Current Health Record on Portable Media for Import into PHR



3.2.2.5.1 Transaction Description

The detailed technical requirements for the actors interacting with the transactions shown in Figure 3.2.2.5-1 are specified in section 3.2.1 above.

Adam Everyperson has just completed an encounter with his primary provider, Dr. Doctor. For the most up-to-date and complete information, it is recommended that at the end of every healthcare encounter new registration/medical summary data are provided to the consumer, Mr. Everyperson, for updating his PHR system.

Dr. Doctor accesses his EHR (OfficeEHR) selects the information to be included in a new summary of clinical information [Select information to send], exports the information from the EHR (OfficeEHR) and stores it on portable media [Distribute Document Set on Media (using HITSP/C32, HITSP/C37, or HITSP/C62, or any combination of the three constructs)]. Dr. Doctor then provides this portable media (or updated portable media in the case of USB key) to Mr. Everyperson for updating his PHR system. Dr. Doctor's EHR system generates an audit record of this extraction of health information and storage on the portable media [Generate Audit Log].

Upon returning home, Mr. Everyperson accesses his PHR [Access PHR] inserts or connects the portable media to his PHR system to receive the updated HITSP/C32 Summary Documents Using HL7 Continuity of Care Document (CCD), HITSP/C37 Lab Report Documents, HITSP/C62 Unstructured Document Component, or any combination of all three documents from Dr. Doctor [Receive information]. The PHR system presents the information on the portable media for Mr. Everyperson to review [Information Presented for Viewing]. Mr. Everyperson reviews the information presented and identifies which elements



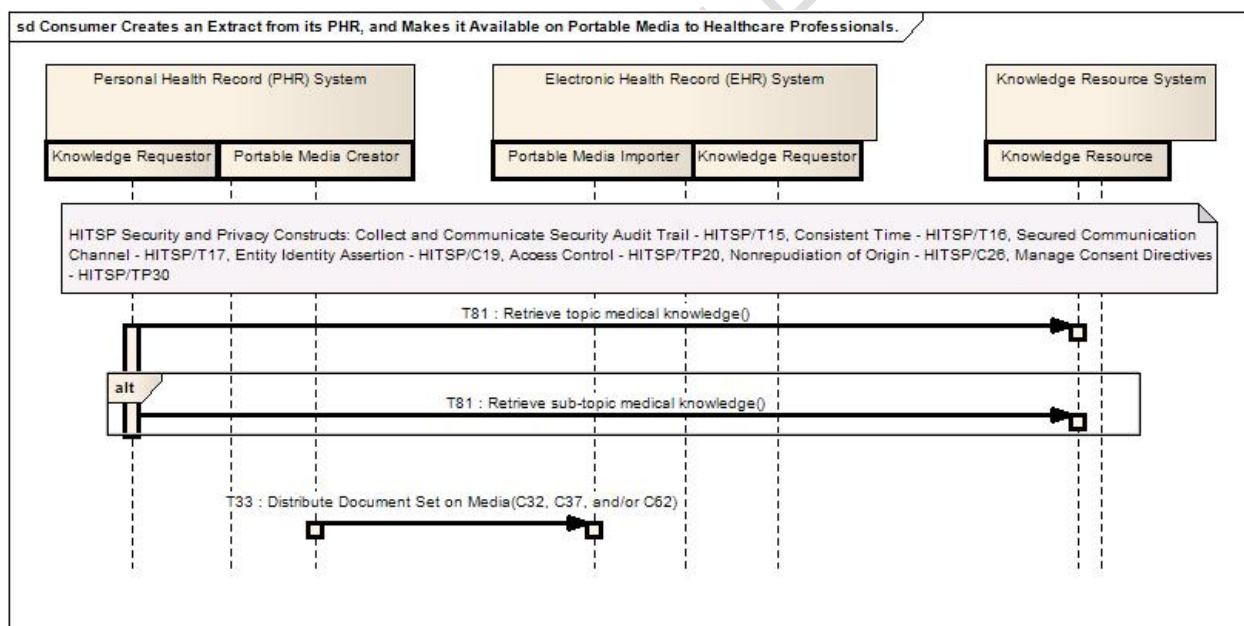
of the new HITSP/C32 Summary Document Using HL7 Continuity of Care Document (CCD), HITSP/C37 Lab Report Document, HITSP/C62 Unstructured Document Component or any combination of all three documents are to be extracted for updating his PHR system [Incorporate Selected Information into PHR]. Mr. Everyperson's PHR system generates an audit record of this import of health information from the portable media [Generate Audit Log].

3.2.2.6 Consumer Creates an Extract from its PHR, and Makes it Available on Portable Media to Healthcare Professionals of its choice

Mr. Everyperson selects pertinent information from his PHR system (<PHR>), extracts it from this system (<PHR>), formats into the appropriate document format (as per HITSP/C32 Summary Documents Using HL7 Continuity of Care Document (CCD), HITSP/C37 Lab Report Document, HITSP/C62 Unstructured Document Component, or any combination of all three documents) and records it on portable media as described in HITSP/T33 Transfer of Documents on Media Transaction.

The sequence diagram is shown in Figure 3.2.2.6-1.

Figure 3.2.2.6-1 Consumer Creates an Extract from its PHR, and makes it available on Portable Media to Healthcare Professionals



3.2.2.6.1 Transaction Description

The detailed technical requirements for the actors interacting with the transactions shown in Figure 3.2.2.6-1 are specified in Section 3.2.1 above.

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 Dr. Doctor's EHR (Office EHR).



Mr. Everyperson accesses his PHR [Access PHR] and reviews that the information retained in his PHR is accurate. If appropriate, he updates the information retained in his PHR [Annotate Information] before selecting the information to be shared with his provider [Select Information to Send] on the portable media. He extracts the information from his PHR and transfers it to the portable media for transport to his Primary Provider [Distribute Document Set on Media (using HITSP/C32 and/or HITSP/C37)]. Mr. Everyperson's PHR system generates an audit record of this extraction of health information and storage on the portable media [Generate Audit Log].

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 on the portable media he has with him. The office staff views the HITSP/C32 Summary Documents Using HL7 Continuity of Care Document (CCD), HITSP/C37 Lab Report Document, HITSP/C62 Unstructured Document Component or any combination of all three documents contained on the media, consults with Dr. Doctor, and selects the information to be transferred to the EHR system (OfficeEHR) [Select Information for Update to the EHR]. The office staff extracts the appropriate elements from the above noted document content provided on the portable media of Mr. Everyperson and imports them into the OfficeEHR [Update EHR with Selected Information].

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 ¹	Construct	Transaction/Content (T/C)	T/C Optionality ¹
Personal Health Record (PHR) Systems	Portable Media Creator	R	HITSP/T33	Distribute Document Set on Media	R
	Portable Media Importer	R	HITSP/T33	Distribute Document Set on Media	R
	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]
		R	HITSP/C37	Lab 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

¹ 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 1
				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 Component	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	C[101]	HITSP/T15	Record Audit Event in Repository	R
	Time Client	R	HITSP/T16	Maintain Time	R
	Time Server	C[101]	HITSP/T16	Maintain Time	R
	Service User	R	HITSP/TP20	Access Control Request	O
	Consent Originator	O	HITSP/TP30	Provide and Register Document Set	R
	Service Provider	R	HITSP/TP20	Access Control Request	O
	Access Control Service	R	HITSP/TP20	Access Control Request	O
Electronic Health Record (EHR) System	Portable Media Creator	R	HITSP/T33	Distribute Document Set on Media	R
	Portable Media Importer	R	HITSP/T33	Distribute Document Set on Media	R
	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]
		R	HITSP/C37	Lab Report Document Component	C[201]
		R	HITSP/C62	Unstructured Document Component	C[201]
		R	HITSP/TP30	Consent Document Component	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



Business Actor	Technical Actor(s)	Actor Optionality^	Construct	Transaction/Content (T/C)	T/C Optionality 1
				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
	Audit Record Repository	C[101]	HITSP/T15	Record Audit Event in Repository	R
	Time Client	R	HITSP/T16	Maintain Time	R
	Time Server	C[101]	HITSP/T16	Maintain Time	R
	Service User	R	HITSP/TP20	Access Control Request	O
	Consent Originator	O	HITSP/TP30	Provide and Register Document Set	R
	Service Provider	R	HITSP/TP20	Access Control Request	O
	Access Control Service	R	HITSP/TP20	Access Control Request	O
Knowledge Resource System	Knowledge Resource	R	HITSP/T81	Retrieval of Medical Knowledge	R
Health Plan/ Intermediary	Portable Media Creator	R	HITSP/T33	Distribute Document Set on Media	R
	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]



Business Actor	Technical Actor(s)	Actor Optionality^	Construct	Transaction/Content (T/C)	T/C Optionality ¹
				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/C62	Unstructured Document	C[201]
	Audit Record Source	R	HITSP/T15	Record Audit Event in Repository	R
	Audit Record Repository	C[101]	HITSP/T15	Record Audit Event in Repository	R
	Time Client	R	HITSP/T16	Maintain Time	R
	Time Server	C[101]	HITSP/T16	Maintain Time	R
	Service User	R	HITSP/TP20	Access Control Request	O
	Service Provider	R	HITSP/TP20	Access Control Request	O
	Access Control Service	R	HITSP/TP20	Access Control Request	O
Pharmacy Benefit Manager (PBM)/Pharmacy	Portable Media Creator	R	HITSP/T33	Distribute Document Set on Media	R
	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]
		R	HITSP/C62	Unstructured Document Component	C[201]
	Audit Record Source	R	HITSP/T15	Record Audit Event in Repository	R
	Audit Record Repository	C[101]	HITSP/T15	Record Audit Event in Repository	R
	Time Client	R	HITSP/T16	Maintain Time	R
	Time Server	C[101]	HITSP/T16	Maintain Time	R
	Service User	R	HITSP/TP20	Access Control Request	O
	Service Provider	R	HITSP/TP20	Access Control Request	O
	Access Control Service	R	HITSP/TP20	Access Control Request	O

* **NOTE:** Optionality = “R” for Required, or “O” for Optional, or “C” for Conditional. If applicable, 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 Creator-Registration Subset Content has an optionality code of C^[201] which represents a conditionally required Actor with the constraint code of 201 described in the table below.

Table 3.2.3-2 Implementation Conditions/Constraints

Constraint Code	Constraint Description
101	Shall serve as its own Audit Record Repository and Time Server in the event that this business actor has no network connectivity without access to these services
201	Shall support either HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD), 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 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 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 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 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 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 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, and 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 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 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 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 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 (Name of construct that it depends on)	Dependency Type (Pre-condition, post-condition, general)	Purpose (Reason for this dependency)
HITSP/T15 - Collect and Communicate Security Audit Trail	HITSP/T16 - Consistent Time	Pre-condition	Pre-requisites for Use Cases
HITSP/T33 - Transfer of Documents on Media	HITSP/T15 - Collect and Communicate Security Audit Trail	Pre-condition	Pre-requisites for Use Cases

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 (Pre-condition, post-condition, general)	Purpose (Reason for this constraint)
No additional applicable 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 www.fda.gov and www.cms.hhs.gov .



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
CDC Race and Ethnicity Code Sets	HITSP/C80 - Clinical Document and Message Terminology)	Vocabularies are enabled via HITSP/C32
Digital Imaging and Communications in Medicine (DICOM) Part 3.12: Media Formats and Physical Media for Media Interchange	HITSP/T33 - Transfer of Documents on Media	
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 – Continuity of Care Document (CCD), April 01, 2007	HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD)	
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	
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



Standard Name	HITSP Construct	Remarks/Minor Gaps
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 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 RCMR_RM010001 - Data Consent	HITSP/TP30 - Manage Consent Directives	
Integrating the Healthcare Enterprise (IHE) Exchange of Personal Health Record Content (XPHR)	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 or later, Audit Trail and Node Authentication Profile (ATNA)	HITSP/T15 - Collect and Communicate Security Audit Trail	
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) Revision 4.0, Section 10 Cross-Enterprise Document Sharing (XDS.a)	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)	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/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) Revision 5.0 or later, Cross-Enterprise Document Media Interchange (XDM) Integration Profile	HITSP/T33 - Transfer of Documents on Media	



Standard Name	HITSP Construct	Remarks/Minor Gaps
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Supplement 2007 - 2008 Basic Patient Privacy Consents (BPPC) – Trial Implementation	HITSP/TP30 - Manage Consent Directives	
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 Organization (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®)	HITSP/C80 - Clinical Document and Message Terminology HITSP/C35 - Lab Result Terminology	HITSP/C80 vocabularies are enabled via HITSP/C32
International Organization for Standardization (ISO) Health Informatics - 9660 Level 1	HITSP/T33 - Transfer of Documents on Media	
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	
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 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



Standard Name	HITSP Construct	Remarks/Minor Gaps
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 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
USB Removable Device Type 2.0 (USB Implementers Forum)	HITSP/T33 - Transfer of Documents on Media	
VHA National Drug File Reference Terminology (NDF-RT) Formulary	HITSP/C80 - Clinical Document and Message Terminology)	Vocabularies are enabled via HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD)

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 www.ansi.org .



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 www.astm.org.</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 www.astm.org.</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 www.caqh.org.</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 www.cancer.gov/cancertopics/terminologyresources/FMT</p>
Health Level Seven (HL7) Consent related vocabulary including Confidentiality Codes	<p>HL7 concept domains, including ConfidentialityCodes, ActInformationCategoryCode, ActInformationAccessType, ActInformationAccessContextCode, AuthorizedParticipationFunctionCode, ActPolicyType, ActConsentType, and ActMaskableCode For more information visit www.hl7.org.</p>



Standard Name	Description/Reason for Use
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 www.hl7.org .
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 www.hl7.org .
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 www.ihe.net .
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0 or later, Audit Trail and Node Authentication (ATNA) Integration Profile	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 www.ihe.net .
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 www.ihe.net .
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 www.iso.org .
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 www.iso.org .



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 www.iso.org .
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> <p>Privilege management and access control: role-based access control is not possible without an effective means of recording role information for healthcare actors.</p> <p>Directory services: structural roles are usefully recorded within directories of health care providers (see for example, ISO TS 21091 Health Informatics -- Directory services for security, communications, and identification of professionals and patients).</p> <p>Audit trails: functional roles are usefully recorded within audit trails for health information applications.</p> <p>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.</p> <p>For more information visit http://www.iso.org/www.iso.org.</p>
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 www.cancer.gov .
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 www.oasis-open.org .
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 www.oasis-open.org .



Standard Name	Description/Reason for Use
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 www.oasis-open.org .
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 www.oasis-open.org .
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 www.census.gov .

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
IER76 DR71	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
IER63 DR68	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
DR73	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>
DR02	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
DR02	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.</p> <p>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>
IER68	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 [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>	<p>Monitor and encourage standards development organizations noted to address in 2009 cycle</p>
DR74	Access control lists	<p>Distributed Management of Access Control:</p> <p>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"> 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) 2. Data level access controls to the elements within a PHR <p>Leverage and extend HITSP Security Privacy Infrastructure DTC work regarding the definition of an HIE-level access control technical actor</p>	<p>To be handled by HITSP SPIDTC in its entirety</p>
DR75	Access log summary	<p>Audit Logs/Disclosure Logs :There is existing work re audit logs (EHRSFM 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>	<p>The definition of a standard format and the content for an interoperable disclosure log is to be addressed by the HITSP SPIDTC</p>



Requirement Number	Summary Description	Identified Gaps	Recommended Resolution
IER68	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"> 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) 2. Data level access controls to the elements within a PHR (better managed by the PHR itself when the query is received) <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 information, also how do we specify this content to be used for the different types of information 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 SDO's, 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 Interoperability Specification (HITSP/IS05) and updates to HITSP/IS03 Consumer Empowerment and Access to Clinical Information via Networks. Shown in Table 3.1-1
- Gaps or results of works-in-progress initiatives to be addressed during the 2008 HITSP cycle 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.

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
DR73	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 Consumer Empowerment Perspective Technical Committee recommends that a standardized terminology be developed that might be used in future releases of this Component. The HL7 Security Technical Committee is presently working with the VHA Role Based Access Control Task Force (RBAC-TF) to develop materials describing the roles of providers, for the purposes of supporting access controls. The present work nearly met the needs of the HITSP Consumer Empowerment Perspective Technical Committee 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 Media Interoperability Specification, available at 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 Healthcare Information Technology Standards Panel (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.



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:

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

Table 6.1-1 Descriptions 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 www.x12.org .
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 www.ama-assn.org .
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 www.cdc.gov .
Digital Imaging and Communications in Medicine (DICOM) Part 3.12: Media Formats and Physical Media for Media Interchange	This DICOM Standard describes the services and the data necessary for the interchange of information between digital imaging computer systems found in health care settings. PS 3.12 of the DICOM Standard articulates the structure between the Media Storage Model and specific media. Media physical characteristics are also covered. For more information visit medical.nema.org .
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 www.itl.nist.gov . 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.



Standard Name	Description
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 www.fda.gov/oc/datacouncil/SRS.htm
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 www.fda.gov/cder/ndc/database/default.htm
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 http://www.cdc.gov/vaccines/programs/iis/stds/cvx.htm .
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 http://www.cdc.gov/vaccines/programs/iis/stds/mvx.htm .
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 www.hl7.org .
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 www.hl7.org .
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 www.hl7.org .
Health Level Seven (HL7) Version 2.3.1 Chapter 2 – Control, Chapter 3 – Patient Administration	The HL7 Version 2.3.1 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 are contained in the standard. For more information visit www.hl7.org .



Standard Name	Description
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 www.hl7.org .
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 www.hl7.org .
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 www.hl7.org .
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.
Health Level Seven (HL7) Version 3.0 Privacy Consent related specifications 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 www.hl7.org .
Integrating the Healthcare Enterprise (IHE) Exchange of Personal Health Record Content (XPHR)	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.
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 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. For more information visit www.ihe.net to retrieve Volume 1, and Volume 2 of the framework



Standard Name	Description
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0 or later, Audit Trail and Node Authentication Profile (ATNA)	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. For more information visit www.ihe.net .
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 www.ihe.net .
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 www.ihe.net .
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Supplement 2007 - 2008 Basic Patient Privacy Consents (BPPC) – Trial Implementation	The Basic Patient Privacy Consents (BPPC) 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 www.ihe.net .
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 5.0 or later, Cross-Enterprise Document Media Interchange (XDM) Integration Profile	Provides document interchange using a common file and directory structure over several standard media types. This permits the patient to use physical media to carry medical documents. This also permits the use of person-to-person email to convey medical documents. XDM supports the transfer of data about multiple patients within one data exchange. For more information visit www.ihe.net .
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 www.ihe.net .



Standard Name	Description
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 www.ihtsdo.com .
International Organization for Standardization (ISO) Health Informatics - 9660 Level 1	Defines a common logical format for files and directories so discs written to ISO 9660 specifications can be read by a wide array of computer operating systems. For more information visit www.iso.org .
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 www.iso.org .
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 www.ietf.org .
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 www.ietf.org .
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 www.ietf.org/rfc/rfc4646.txt .
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 www.loinc.org .



Standard Name	Description
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 www.cancer.gov .
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 www.nlm.nih.gov
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 www.oasis-open.org .
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 www.oasis-open.org .
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 www.oasis-open.org .
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 www.wpc-edi.com .
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 aurora.regenstrief.org .
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 www.usps.com .
USB Removable Device Type 2.0 (USB Implementers Forum)	The USB-IF was formed to provide a support organization and forum for the advancement and adoption of Universal Serial Bus technology. The Forum facilitates the development of high-quality compatible USB peripherals (devices), and promotes the benefits of USB and the quality of products that have passed compliance testing. For more information visit www.usb.org .
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 www.cancer.gov/cancertopics/terminologyresources/page5



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 table below provides the mapping from the Consumer Empowerment and Consumer Access to Clinical Information Use Cases – Scenario 1 - Consumer Creates Account to Host and Access Registration Summary and Clinical Information, to the derived information exchange and data requirements.

Table 6.2-1 Mapping of Use Case Actions to Information Exchange Requirements: Consumer Empowerment and Consumer Access to Clinical Information Use Cases – Scenario 1 - Consumer Creates Account to Host and Access Registration Summary and Clinical Information

Event	Action	Information Exchange Requirement(s) (includes security requirements)	Data Requirements
Personal Health Record (PHR) Systems			
CACI 6.1.1 Identify PHR of Choice CE 2.1.1 Select a provider of PHR Services	6.1.1.1 Identify and communicate PHR of choice 2.1.1.1 Provide identification data	IER68 Identify PHR Location IER43 Send/receive accept patient IER77 Identify of information sources	DR01 DR68 DR70
CE 2.2.1 Create account	2.2.1.1 Confirm consumer's identity	Out-of-scope Policies and internal PHR systems operation	
	2.2.1.2 Create consumer's account	Out-of-scope Internal PHR systems operation	
	2.2.1.3 Maintain consumer's permissions for system access	Out-of-scope Internal PHR systems operation The PHR Service provider manages Consent Directives	
CE 2.2.2 Gather registration and/or medication data CACI Event 6.1.3 PHR(s) receive available information from other sources	2.2.2.1 Receive consumer request	Out-of-scope (Internal PHR systems operation)	
	2.2.2.2 Confirm consumer identity	Out-of-scope (Internal PHR systems operation plus policies)	
	2.2.2.3 Transmit request for registration/medication data to data or network system	IER63 Request additional patient data	DR68



Event	Action	Information Exchange Requirement(s) (includes security requirements)	Data Requirements
	6.1.3.1 Receive Information	IER18 Send/receive clinical document IER21 Receive updated clinical information IER28 Download historical health data	DR01 DR02 DR03 DR04 DR05 DR08 DR66 DR67 DR70 DR100
	2.2.2.4 Receive registration/medication data		
	2.2.2.5 Acknowledge receipt of registration/medication data	Out-of-scope	
	6.1.3.2 Information is automatically populated for viewing using appropriate translations or transformations	IER42 Request/receive medical concept knowledge	DR69
	2.2.2.6 Log interaction	IER3 Create audit log entry IER72 Send/receive audit log	DR75
CE 2.1.4 View registration/medication data	2.1.4.1 Authenticate to system	Out-of-scope Internal PHR application functionality plus policies)	
CACI 6.1.4 Access available information	6.1.4.1 Request information 2.1.4.2 Request data 2.1.4.3 Receive data	IER18 Send/receive clinical document IER21 Receive updated clinical information	DR01 DR02 DR03 DR04 DR05 DR08 DR66 DR67 DR68 DR70 DR100
	6.1.4.2 View Information	IER42 Request/receive medical concept knowledge	DR69
CACI 6.1.5 Select and incorporate information	6.1.5.1 Select Information	Out-of-scope 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	



Event	Action	Information Exchange Requirement(s) (includes security requirements)	Data Requirements
	6.1.5.2 Incorporate selected information into the PHR	Out-of-scope (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	IIER76 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	IER18 Send/receive clinical document	DR01 DR02 DR03 DR04 DR05 DR08 DR66 DR67 DR68 DR69 DR70 DR100
	2.1.5.4 Modify data	IER76 Request modification to clinical data	DR71
	2.1.5.4a Annotate data	Out-of-scope	



Event	Action	Information Exchange Requirement(s) (includes security requirements)	Data Requirements
	2.1.5.5 Transmit modified and/or annotated data	IIE18 Send/receive clinical document	DR01 DR02 DR03 DR04 DR05 DR08 DR66 DR67 DR68 DR69 DR70 DR100
	2.1.5.5a Transmit request to modify and/or correct data	IIE76 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	IIE76 Request modification to clinical data	DR71
	2.4.1.2 Authenticate and verify authorization of requestor	IIE1 Provide authorization and consent IIE5 Verify entity identity	DR74
	2.4.1.3 Authorize release of registration/medication information	Out-of-scope (Application access control functionality)	
	2.4.1.4 Transmit registration/medication information to an authorized system	IIE18 Send/receive clinical document	DR01 DR02 DR03 DR04 DR05 DR08 DR66 DR67 DR70
CACI 6.1.3 PHR(s) receive available information from other sources	6.1.3.1 Receive Information	IIE18 Send/receive clinical document IIE28 Download historical health data	DR01 DR02 DR03 DR04 DR05 DR08 DR66 DR67 DR70 DR100



Event	Action	Information Exchange Requirement(s) (includes security requirements)	Data Requirements
CE 2.4.1 Process request for registration/medication data	2.4.1.5 Log interaction	IER3 Create audit log entry IER72 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	IER68 Identify PHR location IER43 Send/Receive accept patient	DR70 DR01 DR68
CE 2.4.1 Process Request for Registration and/or Medication Data CACI 6.1.4 Access available information	2.4.1.1 Receive and validate the query request 6.1.4.1 Request information	IER76 Request modification to clinical data	DR71
	2.4.1.2 Authenticate and verify the authorization of the requestor	IER1 Provide authorization and consent	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	IER18 Send/receive clinical document IER23 Request/provide additional information	DR01 DR02 DR03 DR04 DR05 DR08 DR66 DR67 DR68 DR70 DR100
	2.4.1.5 Log interaction	IER3 Create audit log entry IER72 Send/receive audit log	DR75
CACI 6.1.2 PHR(s) receive available information from other sources	6.1.2.1 Receive Information	IER18 Send/receive clinical document IER23 Request/provide additional information	DR01 DR02 DR03 DR04 DR05 DR08 DR66 DR67 DR68 DR70 DR100
	6.1.2.2 Information is automatically populated for viewing using appropriate translations or transformations	IER42 Request/receive medical concept knowledge	DR69



Event	Action	Information Exchange Requirement(s) (includes security requirements)	Data Requirements
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	IER76 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 (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 table below provides the mapping from the Consumer Empowerment Use Case, Scenario 2 - Consumer Visits Healthcare Provider and Provides Registration Summary Information and Clinical Information, to the derived information exchange and data requirements. This includes operationally equivalent events/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 – Scenario 2: Consumer Visits Healthcare Provider and Provides Registration Summary Information and Clinical Information

Event	Action	Information Exchange Requirement(s) (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 (PHR application functionality) plus policies	
CE 2.2.3 Process registration/medication data	2.2.3.1 Receive and validate query	IER18 Send/receive clinical document IER21 Receive updated clinical information	DR01 DR02 DR03 DR04 DR05 DR08 DR66 DR67 DR70



Event	Action	Information Exchange Requirement(s) (includes security requirements)	Data Requirements
	2.2.3.2 Authenticate and verify the authorization of the requestor	IER1 Provide authorization and consent	DR74
	2.2.3.3 Transmit requested registration/medication information to authorized system	IER18 Send/receive clinical document IER23 Request/provide additional information	DR01 DR02 DR03 DR04 DR05 DR08 DR66 DR67 DR68 DR70 DR100
	2.2.3.4 Log interaction	IER3 Create audit log entry IER72 Send/receive audit log	DR75
CE 2.2.2 Gather registration and/or medication data CACI 6.1.3 PHR(s) (or EHRs) receive available information from other sources	2.2.2.1 Receive consumer request	Out of Scope Internal PHR systems operation	
	2.2.2.2 Confirm consumer identity	Out of Scope Internal PHR systems operation plus policies	
	2.2.2.3 Transmit request for registration/medication data to data or network system	IER63 Request additional patient data	DR68
	2.2.2.4 Receive registration/medication data 6.1.3.1 Receive Information	IER18 Send/receive clinical document IER21 Receive updated clinical information IER23 Request/provide additional information IER28 Download historical health data	DR01 DR02 DR03 DR04 DR05 DR08 DR66 DR67 DR70 DR100
	2.2.2.5 Acknowledge receipt of registration/medication data	Out-of-scope	
	6.1.3.2 Information is automatically populated for viewing using appropriate translations or transformations	IER42 Request/receive medical concept knowledge	DR69
	2.2.2.6 Log interaction	IER3 Create audit log entry IER72 Send/receive audit log	DR75



Event	Action	Information Exchange Requirement(s) (includes security requirements)	Data Requirements
CE 2.2.3 Process request for registration and/or medication data	2.2.3.1 Receive and validate the query process	IER18 Send/receive clinical document	DR01 DR02 DR03 DR04 DR05
	2.2.3.2 Authenticate and verify the authorization of the requestor	IER1 Provide authorization and consent	DR74
	2.2.3.3 Transmit registration/medication data to an authorized system	IER18 Send/receive clinical document	DR01 DR02 DR03 DR04 DR05 DR08
	2.2.3.4 Log interaction	IER3 Create audit log entry IER72 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	IER1 Provide authorization and consent	
CACI 6.1.3 PHR(s) (or EHRs) receive available information from other sources	2.3.1.2 Receive registration/medication data 6.1.3.1 Receive Information	IER18 Send/receive clinical document IER21 Receive updated clinical information IER23 Request/provide additional information IER28 Download historical health data	DR01 DR02 DR03 DR04 DR05 DR08 DR66 DR67 DR70 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	IER18 Send/receive clinical document	DR01 DR02 DR03 DR04 DR05 DR08
	2.3.2.2 Accept data into EHR system	Out of scope (EHR application functionality)	
	2.3.2.3 Confirm data integrity	Out of scope (EHR application functionality)	
	2.3.2.3a Produce exception list of errors	Out of scope (EHR application functionality)	



Event	Action	Information Exchange Requirement(s) (includes security requirements)	Data Requirements
	2.3.2.4 Parse and validate results content	Out of scope (EHR application functionality)	
	2.3.2.5 Acknowledge receipt of registration/medication data	Out-of-scope	
	2.3.2.6 Log interaction	IER3 Create audit log entry IER72 Send/receive audit log	DR75
Health Information Exchange (HIE)			
CE 2.4.1 Process Request for Registration and/or Medication Data CACI 6.1.3 PHR(s) (or EHRs) receive available information from other sources	2.4.1.1 Receive and validate the query request	IER18 Send/receive clinical document IER21 Receive updated clinical information	DR01 DR02 DR03 DR04 DR05 DR08 DR66 DR67 DR70 DR100
	6.1.3.1 Receive Information		
	2.4.1.2 Authenticate and verify the authorization of the requestor	IER1 Provide authorization and consent IER5 Verify entity identity	DR74
	2.4.1.3 Authorize release of registration/medication data	IER69 Authorize release of information	
	2.4.1.4 Transmit registration/medication data to an authorized system	IER18 Send/receive clinical document IER23 Request/provide additional information	DR01 DR02 DR03 DR04 DR05 DR08 DR66 DR67 DR70 DR100
	2.4.1.5 Log interaction	IER3 Create audit log entry IER72 Send/receive audit log	DR75

The table below provides the mapping from the Consumer Empowerment Use Case, Scenario 3 - Authorized Healthcare Provider Reviews Registration Summary and Other Clinical Information, to the derived information exchange and data requirements. This includes operationally equivalent events/actions from the Consumer Access to Clinical Information Use Case.



Table 6.2-3 Mapping of Use Case Actions to Information Exchange Requirements: Consumer Empowerment – Scenario 3: Authorized Healthcare Provider Reviews Registration Summary and Other Clinical Information

Event	Action	Information Exchange Requirement(s) (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 PHR application functionality plus policies	
CE 2.2.2 Gather registration and/or medication data CACI 6.1.3 PHR(s) (or EHRs) receive available information from other sources	2.2.2.1 Receive consumer request	Out-of-scope Internal PHR systems operation	
	2.2.2.2 Confirm consumer identity	Out-of-scope (Internal PHR systems operation plus policies)	
	2.2.2.3 Transmit request for registration/medication data to data or network system	IER23 Request/provide additional information IER63 Request additional patient data	DR68
	2.2.2.4 Receive registration/medication data 6.1.3.1 Receive Information	IER18 Send/receive clinical document IER21 Receive updated clinical information IER23 Request/provide additional information IER28 Download historical health data	DR01 DR02 DR03 DR04 DR05 DR08 DR66 DR67 DR70 DR100
	2.2.2.5 Acknowledge receipt of registration/medication data	Out-of-scope	
	6.1.3.2 Information is automatically populated for viewing using appropriate translations or transformations	IER42 Request/receive medical concept knowledge	DR69
	2.2.2.6 Log interaction	IER3 Create audit log entry IER72 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	IER18 Send/receive clinical document	DR01 DR02 DR03 DR04 DR05
	2.2.3.2 Authenticate and verify the authorization of the requestor	IER1 Provide authorization and consent	DR74



Event	Action	Information Exchange Requirement(s) (includes security requirements)	Data Requirements
	2.2.3.3 Transmit registration/medication data to an authorized system	IER18 Send/receive clinical document	DR01 DR02 DR03 DR04 DR05
	2.2.3.4 Log interaction	IER3 Create audit log entry IER72 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	IER1 Provide authorization and consent	DR74
	2.3.1.2 Receive registration/medication data	IER18 Send/receive clinical document IER21 Receive updated clinical information IER23 Request/provide additional information IER28 Download historical health data	DR01 DR02 DR03 DR04 DR05 DR08 DR66 DR67 DR70 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	IER23 Request/provide additional information IER63 Request additional patient data	DR68
	2.3.2.2 Accept data into EHR system	Out of Scope (EHR application functionality)	
	2.3.2.3 Confirm data integrity	Out of Scope (EHR application functionality)	
	2.3.2.3a Produce exception list of errors	Out of Scope (EHR application functionality)	
	2.3.2.4 Parse and validate results content	Out of Scope (EHR application functionality)	
	2.3.2.5 Acknowledge receipt of registration/medication data	Out-of-scope	
	2.3.2.6 Log interaction	IER3 Create audit log entry IER72 Send/receive audit log	DR75



Event	Action	Information Exchange Requirement(s) (includes security requirements)	Data Requirements
Health Information Exchange (HIE)			
CE 2.4.1 Process Request for Registration and/or Medication Data CACI 6.1.3 PHR(s) (or EHRs) receive available information from other sources	2.4.1.1 Receive and validate the query request 6.1.3.1 Receive Information	IER18 Send/receive clinical document IER21 Receive updated clinical information IER23 Request/provide additional information IER28 Download historical health data	DR01 DR02 DR03 DR04 DR05 DR08 DR66 DR67 DR70 DR100
	2.4.1.2 Authenticate and verify the authorization of the requestor	IER1 Provide authorization and consent	DR74
	2.4.1.3 Authorize release of registration/medication data	IER69 Authorize release of information (Application access control functionality)	
	2.4.1.4 Transmit registration/medication data to an authorized system	IER18 Send/receive clinical document IER23 Request/provide additional information	DR01 DR02 DR03 DR04 DR05 DR08 DR66 DR67 DR70 DR100
	2.4.1.5 Log interaction	IER3 Create audit log entry IER72 Send/receive audit log	DR75

The table below provides the mapping of the Use Case events and actions from the Consumer Access to Clinical Information Use Case, Scenario 2 – Provider Lists and Permissions, to the derived information exchange and data requirements.

Table 6.2-4 Mapping of Use Case Actions to Information Exchange Requirements: Consumer Access Use Case – Scenario 2: Provider Lists and Permissions

Event	Action	Information Exchange Requirement(s) (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	IER11 Identify provider based on patient preference IER73 Request/receive provider information	DR73



Event	Action	Information Exchange Requirement(s) (includes security requirements)	Data Requirements
	7.1.1.4 Access provider information	IER74 Access/Select provider information	DR73
CACI 7.1.2 Create/update provider lists	7.1.2.1 Select and incorporate provider information	IER74 Access/Select provider information	DR73
CACI 7.1.3 Designate provider permissions	7.1.3.1 Designate provider permissions	IER75 Designate provider permissions	DR73 DR74
CACI 7.1.4 Review access and disclosure logs	7.1.4.1 Review access and disclosure logs	IER3 Create audit log entry IER72 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	IER18 Send/receive clinical document	DR01 DR68 DR75
CACI 7.2.2 Select and incorporate clinical information	7.2.2.1 Select information	Out of Scope (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 (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	IER3 Create audit log entry IER72 Send/receive audit log	DR75

The table below provides the mapping of the Use Case events and actions from the Consumer Access Use Case – Scenario 3 - Transfer of PHR Information, to the derived information exchange and data requirements.

Table 6.2-5 Mapping of Use Case Actions to Information Exchange Requirements: Consumer Access Use Case – Scenario 3: Transfer of PHR Information

Event	Action	Information Exchange Requirement(s) (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 (Internal PHR system function)	



Event	Action	Information Exchange Requirement(s) (includes security requirements)	Data Requirements
CACI 8.1.2 Request and access available information in PHR(A)	8.1.2.1 Review PHR(A) Information	Out of scope (Internal PHR system function)	
CACI 8.1.3 Select Information to send PHR(B)		Out of scope (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	IER74 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	IER68 Identify PHR Location (gap)	
CACI 8.1.5 PHR(A) sends information to PHR(B)	8.1.5.1 Forward information to PHR B)	IER18 Send/receive clinical document IER23 Request/provide additional information	DR01 DR02 DR03 DR04 DR05 DR08 DR66 DR67 DR70 DR100
	8.1.5.2 Confirm delivery of information to PHR(B)	Out-of-scope	

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.

The high level 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 will be introduced in Section 3 of this Interoperability Specification.



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

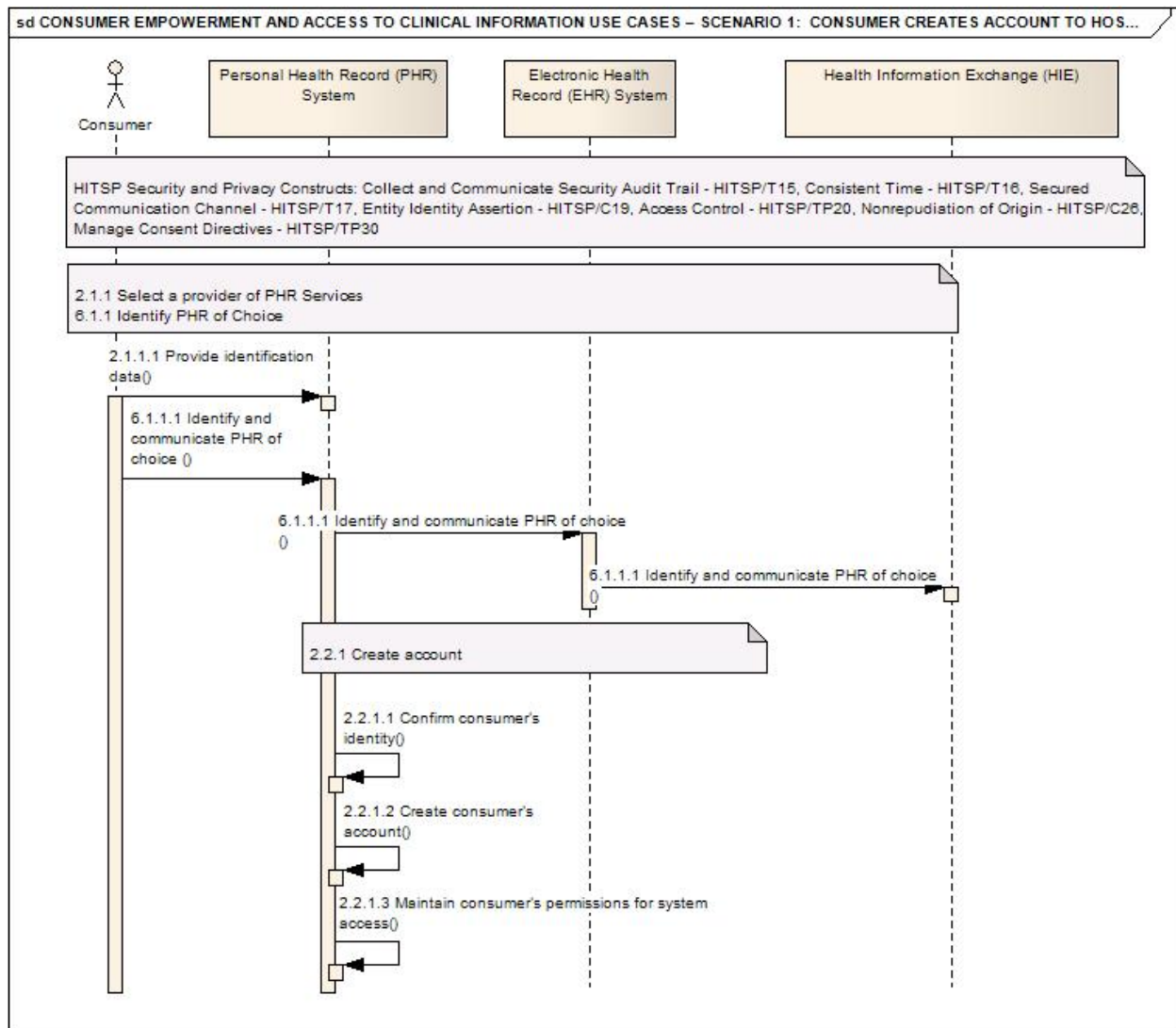


Figure 6.3-2 Scenario 1: Consumer Creates Account to Host and Access Registration Summary and Clinical Information High-Level UML Business Sequence Diagram - Part B

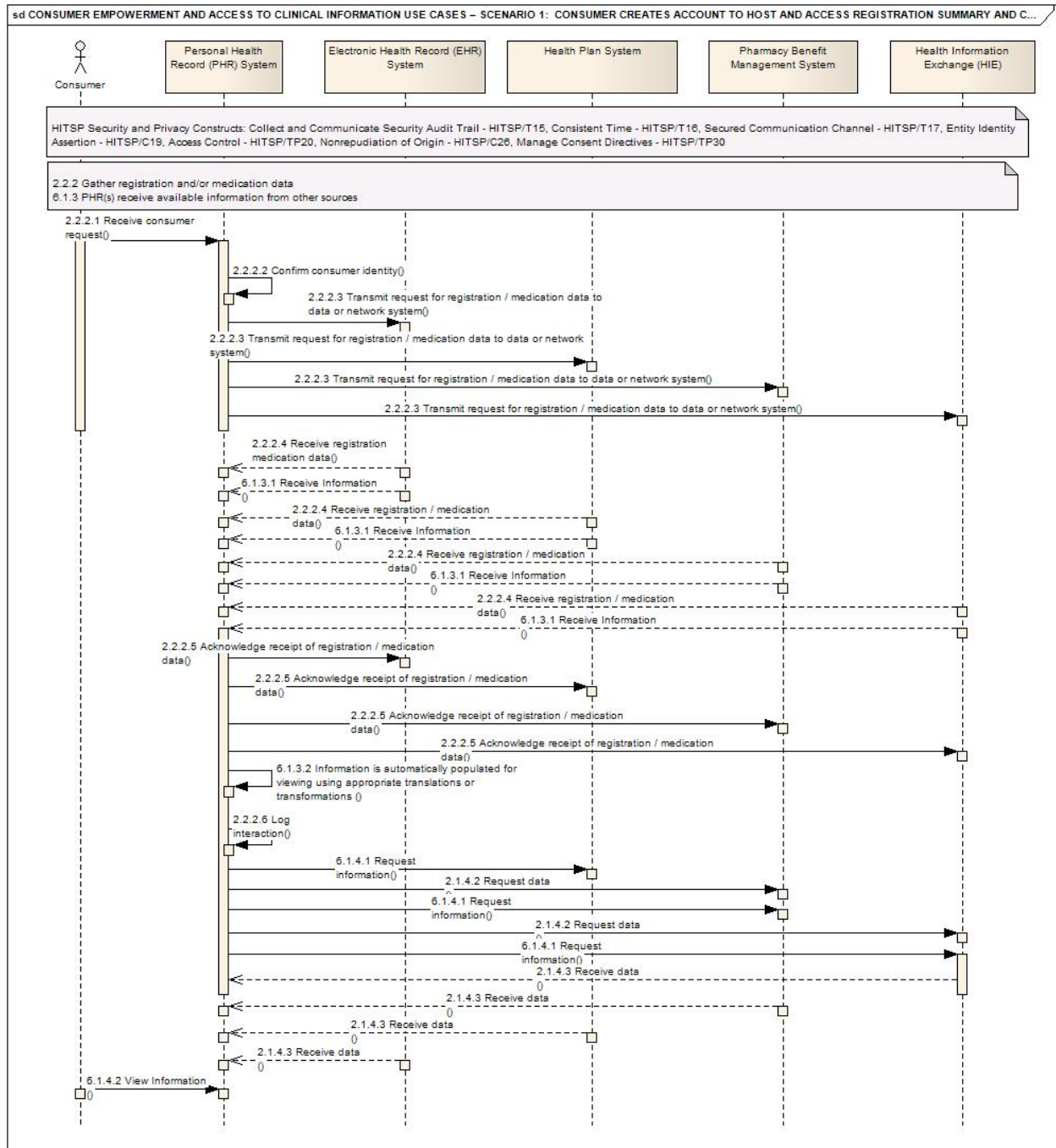


Figure 6.3-3 Scenario 1: Consumer Creates Account to Host and Access Registration Summary and Clinical Information High-Level UML Business Sequence Diagram - Part C

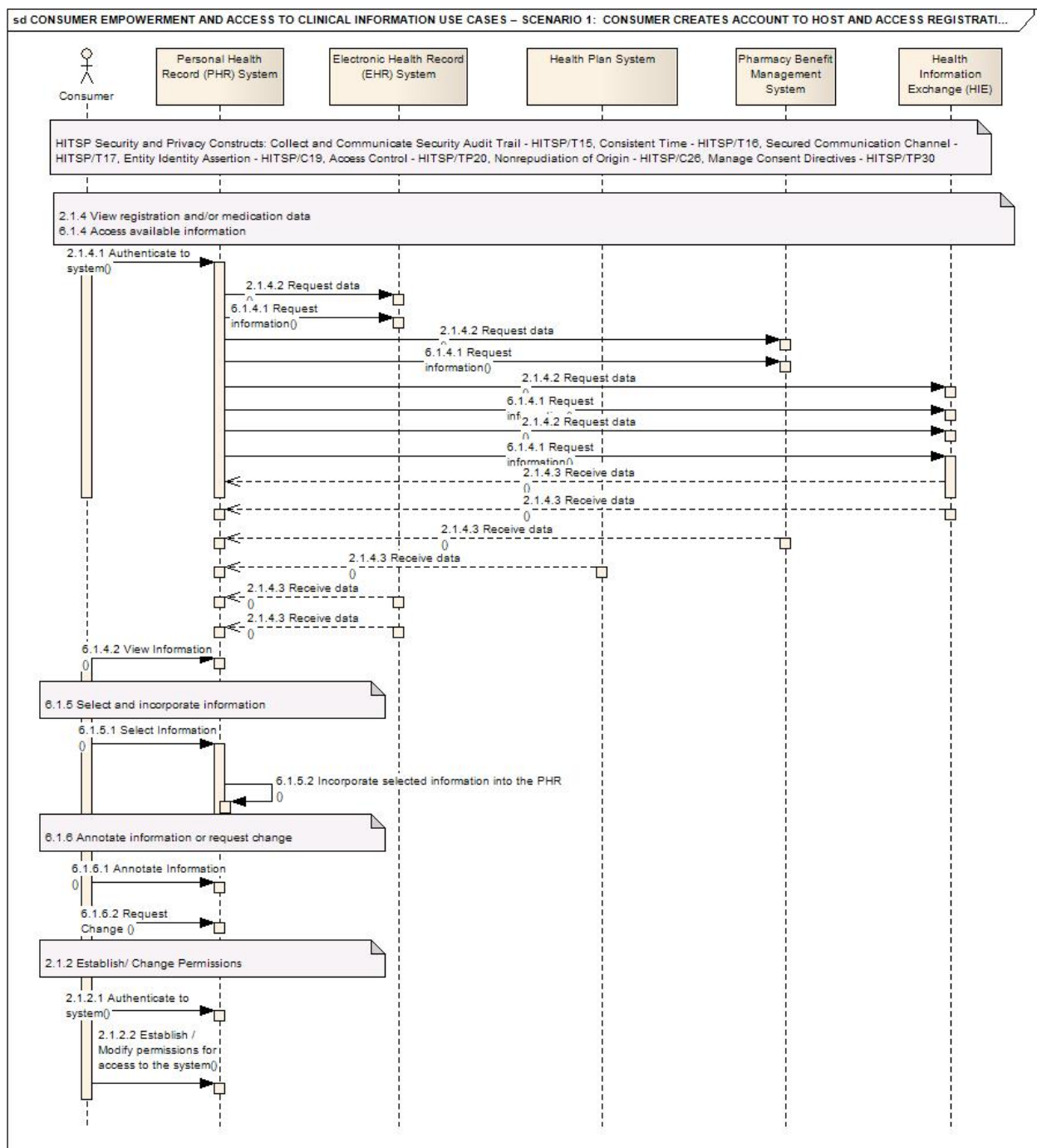


Figure 6.3-4 Scenario 1: Consumer Creates Account to Host and Access Registration Summary and Clinical Information High-Level UML Business Sequence Diagram - Part D

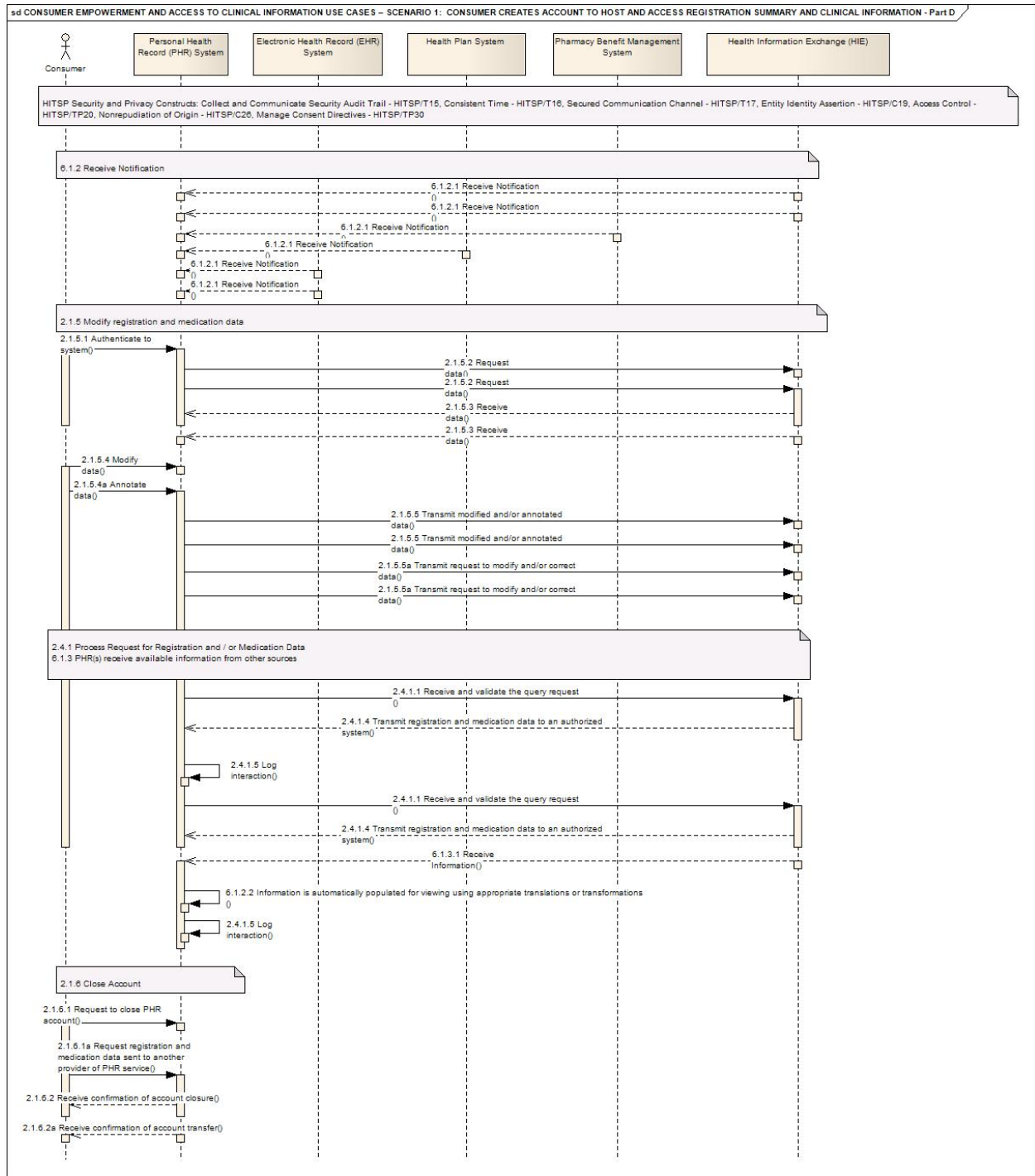


Figure 6.3-5 Scenario 2: Consumer Visits Healthcare Provider and Provides Registration Summary Information and Clinical Information High-Level UML Business Sequence

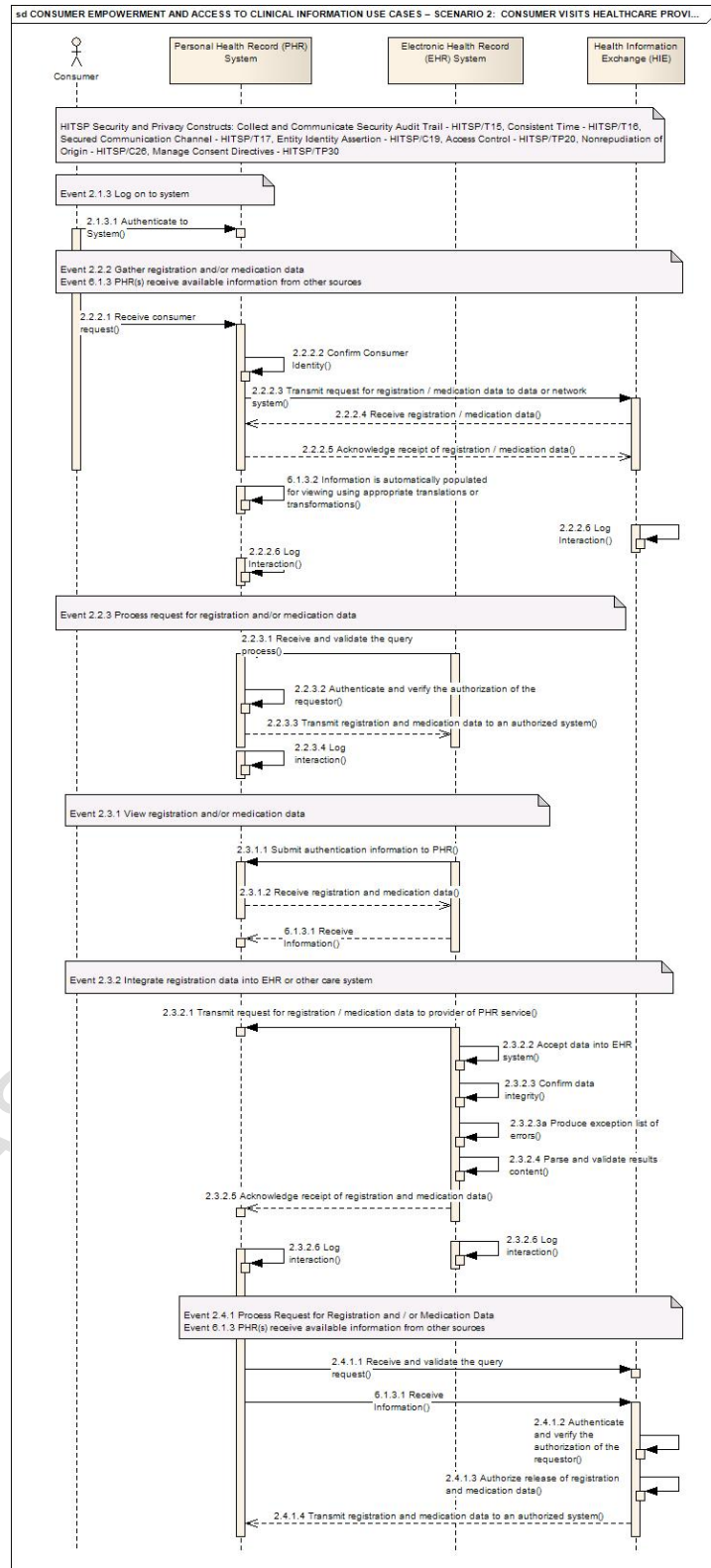
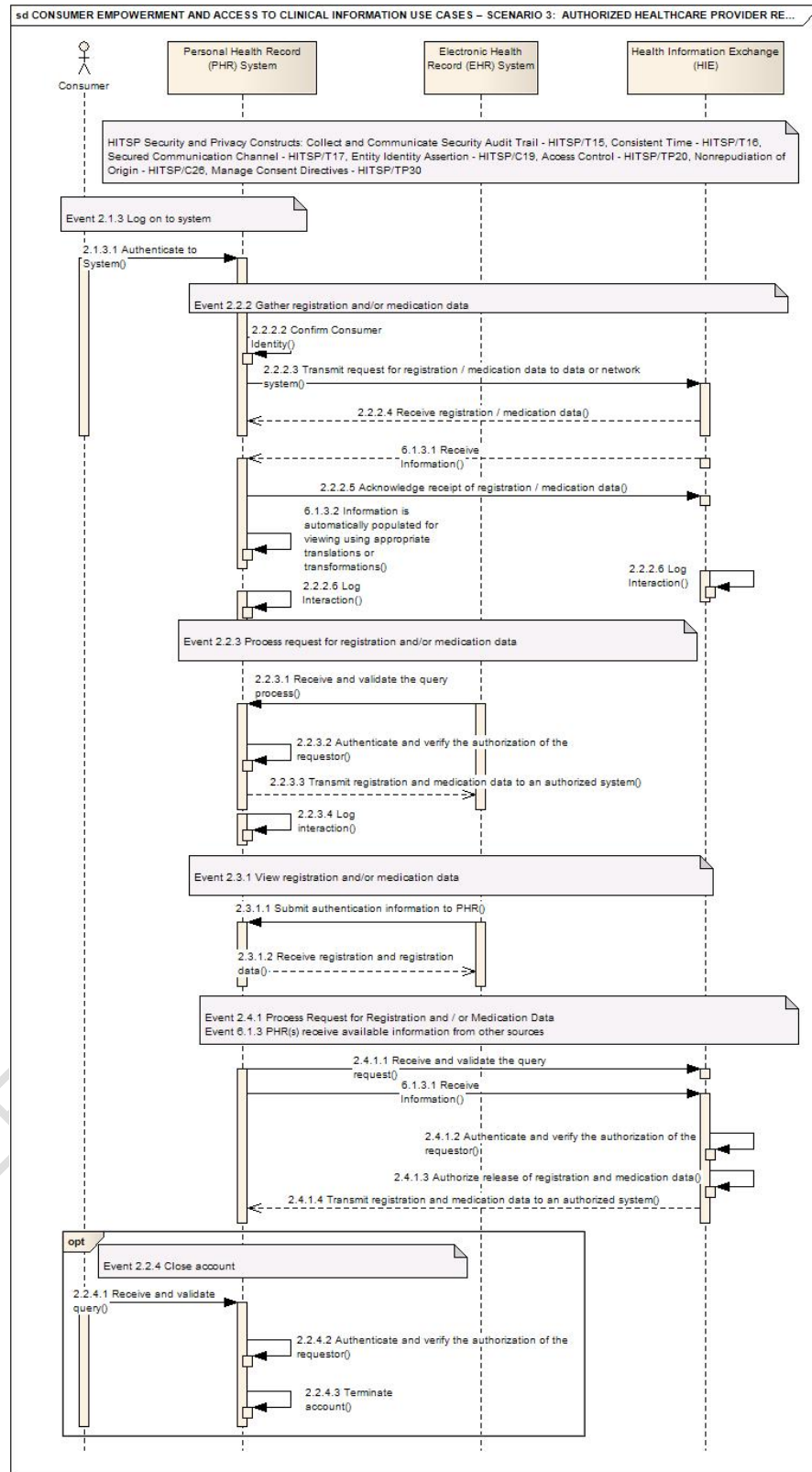


Figure 6.3-6 Scenario 3: Authorized Healthcare Provider Reviews Registration Summary and Other Clinical Information



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 Requirements to HITSP Constructs

Construct Name	Information Exchange Requirement Number (IER#)	Data Requirement Number (DR#)
HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD)	IER18 Send/receive clinical document IER21 Receive updated clinical information IER28 Download historical health data	DR1 Demographic data DR2 Patient clinical summary DR3 Clinical History DR4 Personal Genetic/Genomic Information DR5 Family Genetic/Genomic Information DR66 Diagnosis Codes DR67 Allergies/Medication Allergies DR27 Message Routing and Content/Envelope/Metadata of the secure message
HITSP/C35 - Lab Report Terminology	IER18 Send/receive clinical document	DR2 Patient clinical summary DR27 Message Routing and Content/Envelope/Metadata of the secure message
HITSP/C37 - Lab Report Document	IER18 Send/receive clinical document IER23 Send/receive additional test results	DR2 Patient clinical summary
HITSP/C62 - Unstructured Document	IER33 Send/receive Message IER3 Create Audit Log Entry	DR8 Unstructured Data
HITSP/T15 - Collect and Communicate Security Audit Trail	IER10 Identify Patient IER3 Create Audit Log Entry IER1 Provide authentication and consent IER72 Send/receive audit log	DR75 Access log summary DR74 Access Control Lists
HITSP/T16 - Consistent Time	IER1 Provide authentication and consent IER3 Create Audit Log Entry	



Construct Name	Information Exchange Requirement Number (IER#)	Data Requirement Number (DR#)
HITSP/TP33 - Transfer of Documents on Media	IER18 Send/receive clinical document IER21 Receive updated clinical information IER23 Send/receive additional test results IER28 Download historical health data	DR01 Demographic data DR02 Patient clinical summary DR03 Clinical History DR04 Personal Genetic/Genomic Information DR05 Family Genetic/Genomic Information DR08 Unstructured data DR66 Diagnosis Codes DR67 Allergies/Medication Allergies DR70 Information Source identification data DR100 Lab Report document
HITSP/T81 - Retrieval of Medical Knowledge	IER42 Request/receive medical concept knowledge	DR69 Context-aware Information Retrieval Message
HITSP/TP20 – Access Control	IER1 Provide authentication and consent IER11 Identify Provider based on Pt Preference IER69 Authorize release of information	DR74 Access Control Lists DR29 Read/Delivery Receipt DR75 Access log summary
HITSP/TP30 – Manage Consent Directives	IER1 Provide authentication and consent I	DR74 Access Control Lists DR29 Read/Delivery Receipt



7.0 CHANGE HISTORY

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

7.1 DECEMBER 5, 2007

The changes in this cycle address the following comments:

2365, 2375, 2405, 2407, 2408, 2409, 2410, 2412, 2413

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 Interoperability Specification (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 (HITSP/IS05). As such, Section 2.0 for each of these IS's 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 3.0 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., Portable Media Creator) 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., HITSP/T33 Transfer of Documents on Media).
4. All relevant Security and Privacy constructs, including their applicable transactions, have been included in Section 3.0, 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:
 - Confirmation that known gaps have been identified – comments #2375, 2405, 2407-2413
 - Improvement in Construct format – comment #2374
 - Additional Clinical Info Content – comment #2490

7.2 DECEMBER 13, 2007

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

7.3 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.

Changed all instances of HITSP/C37 to Lab Report Document.

7.4 DECEMBER 10, 2008

The changes in this construct address the following comments received during the Public Comment and Inspection Testing period (September 29 – October 24, 2008).

5387

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

Two major changes have been completed in this version of the IS05 document.

1. The document has been updated to include the specifications to resolve two of the gaps identified in the previous release. Namely,
 - a. Medication/Labs Information in Consumer-friendly Manner
 - b. A partial resolution of the Advance Directives by the specification of an Unstructured Document construct to accommodate a scanned version of an advance directive



2. This document also includes the comment dispositions of any comments received against it in the public comment period of the 2008 cycle, specifically comments #5387 which was related to the harmonization of IERs and DRs across HITSP deliverables.

Minor editorial changes were made to this construct.

7.5 DECEMBER 18, 2008

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

