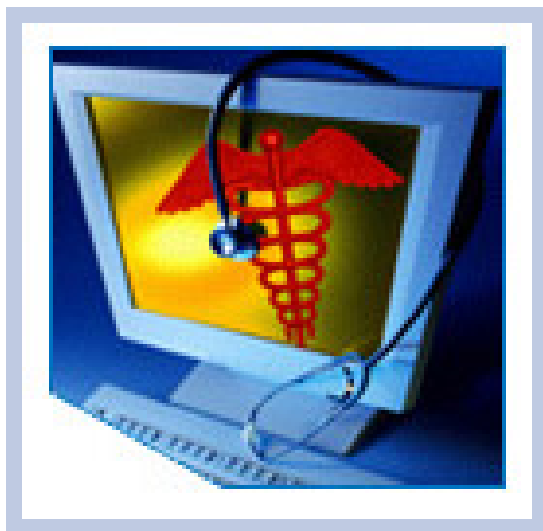


# HITSP Consumer Empowerment and Access to Clinical Information via Media Interoperability Specification

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HITSP/IS05



*Submitted to:*

**Healthcare Information Technology Standards Panel**

*Submitted by:*

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



## DOCUMENT CHANGE HISTORY

Version Number	Description of Change	Name of Author	Date Published
0.0.1	Review Copy	Consumer Empowerment Technical Committee	September 18, 2007
0.0.2	Review Copy	Consumer Empowerment Technical Committee	December 5, 2007
1.0	Released for Implementation	Consumer Empowerment Technical Committee	December 13, 2007
1.0.1	Review Copy	Consumer Perspective Technical Committee	August 20, 2008
1.1	Released for Implementation	Consumer Perspective Technical Committee	August 27, 2008

RELEASED FOR IMPLEMENTATION



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## 1.0 INTRODUCTION

As an introduction to the HITSP Consumer Empowerment and Access to Clinical Information via Media Interoperability Specification, this section provides a high level overview of an information sharing scenario enabled by following this specification, provides a document map of the construct relationships for the Interoperability Specification, acknowledges the copyright protections that pertain, and provides a list of key reference documents and background material. If you are already familiar with this information, proceed to Section 2.0 Interoperability Requirements.

### 1.1 INTEROPERABILITY SPECIFICATION OVERVIEW

This section provides a high level definition of this Interoperability Specification and background information about the underlying Use Cases 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 system to track patient and insurance information, family history, medications, and other special conditions.

As part of a personal health record (PHR), this specification addresses several key areas: the patient's registration data and a healthcare summary including medication history, allergies, encounters, problems and conditions, immunizations, and key laboratory tests results.

This 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

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.

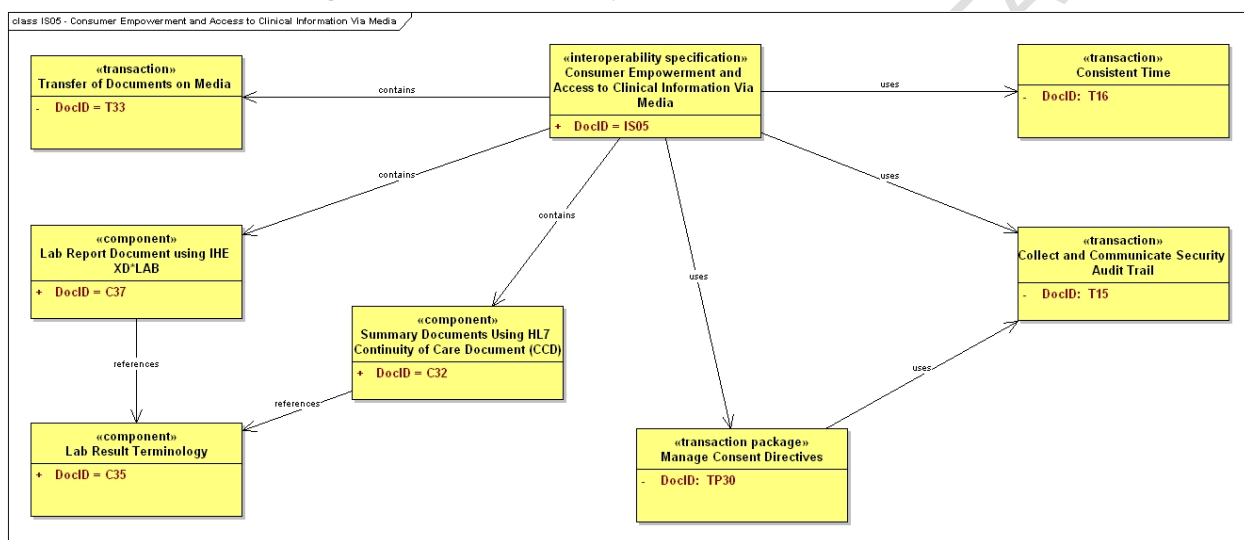




## 1.2 INTEROPERABILITY SPECIFICATION DOCUMENT MAP

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 roadmap depicted in Figure 1.2-1 identifies the HITSP constructs used to meet the IS requirements. Implementers should read the documents that describe the constructs depicted in the diagram for their details and specific uses.

Figure 1.2-1 Interoperability Specification Document Map



### 1.2.1 LIST OF CONSTRUCTS

The following table lists and describes the HITSP constructs that are shown in the Unified Modeling Language (UML) diagram above and are used by the Interoperability Specification. All references to HITSP specifications are to the current and Panel approved versions of the specifications.

Table 1.2.1-1 List of Constructs

Construct	Description
HITSP/T33	HITSP Transfer of Documents on Media Transaction
HITSP/TP22	HITSP Patient ID Cross-Referencing Transaction Package
HITSP/T23	HITSP Patient Demographics Query Transaction
HITSP/C32	HITSP Summary Documents Using HL7 Continuity of Care Document (CCD) Component
HITSP/C37	HITSP Lab Report Document Component
HITSP/C35	HITSP Lab Result Terminology Component



Construct	Description
HITSP/T15	HITSP Collect and Communicate Security Audit Trail Transaction
HITSP/T16	HITSP Consistent Time Transaction
HITSP/C19	HITSP Entity Identity Assertion Component
HITSP/TP20	HITSP Access Control Transaction Package
HITSP/TP30	HITSP Manage Consent Directives Transaction Package

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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.

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

**Table 1.4-1 Reference Documents**

Reference Document	Document Description
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 product development or product refinement
HITSP Conventions List	Describes the conventions that are used to convey the full descriptions and usage of standards in the HITSP specifications
HITSP Acronyms List	Lists and defines the acronyms used in this document
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
Consumer Empowerment-Consumer Access to Clinical Information Detailed Use Case, June 18, 2007	AHIC Use Case that is the basis of this Interoperability Specification



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



## 2.0 INTEROPERABILITY REQUIREMENTS

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

- Mapping from the Use Case Requirements to the Derived Interoperability Requirements – this table lists the requirements grouped by actor for each event and related action
- Data Element Requirements – this table further describes the data requirements for each specified interoperability requirement and the business actor that is responsible for the data
- Business Actors – this table defines the business actors that are included for the Interoperability Specification
- High Level Unified Modeling Language (UML) Business Sequence 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: Consumer Access to Clinical Information Use Cases, 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: 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 this Use Case, the linking of a consumer's registration summary to the healthcare summary includes: (1) identity matching, (2) linkages between the data, (3) and the ability to incorporate both types of data simultaneously into a system (although they may come from different systems themselves). This linkage applies to 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, 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

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 IS, HITSP IS03 Consumer Empowerment and Access to Clinical Information via Media) 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 the Use Case has been preserved as well as is 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 the 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 EHR systems back to the consumer PHR. Such an extension to the Consumer Empowerment Use Case is simply supported by recommending that at the end of a healthcare encounter, the new registration/healthcare summary data are communicated to the PHR system (e.g. via a document repository/registry). The importance of such an extension is illustrated in this example:

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 the Use Case has been preserved as well as possible.

#### 2.2.1 MAPPING OF USE CASE REQUIREMENTS TO INTEROPERABILITY REQUIREMENTS

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

#### Consumer Empowerment and Access to Clinical Information Use Cases – Scenario 1: Consumer Creates Account to Host and Access Registration Summary and Clinical Information

**Table 2.2.1-1 Mapping of Use Case Requirements to Interoperability Requirements**

Use Case	Perspective/ Business Actor	Event	Action	Interoperability Requirement(s)	Data Requirement Number
Consumer Empowerment and Access to Clinical Information	Consumer and PHR Service Provider	Event 6.1.1 Identify PHR of Choice Event 2.1.1 Select a provider of PHR Services	Action 6.1.1.1 Identify and communicate PHR of choice Action 2.1.1.1 Provide identification data	Identification of PHR Service / PHR instance (PHR Location-Gap) Identification of Consumer (Target of PHR) {Registry Patient Id/Id Domain OID} Authentication of Consumer-to-PHR-Service-Provider / Information Exchange-Leverage Entity Identity Assertion HITSP/C19 {Authenticate Consumers-Partial Gap} Identification of providers -Leverage Entity Identity Assertion HITSP/C19 {Partial Gap} Identification of Information Sources	9, 10, 11





Use Case	Perspective/ Business Actor	Event	Action	Interoperability Requirement(s)	Data Requirement Number
		Event 2.2.1 Create account	Action 2.2.1.1 Confirm consumer's identity	Policies and internal PHR systems operation	
			Action 2.2.1.2 Create consumer's account	Internal PHR systems operation	
			Action 2.2.1.3 Maintain consumer's permissions for system access	Internal PHR systems operation. Manage Consent Directives	
		Event 2.2.2 Gather registration and/or medication data	Action 2.2.2.1 Receive consumer request	Internal PHR systems operation	
		Event 6.1.3 PHR(s) receive available information from other sources	Action 2.2.2.2 Confirm consumer identity	Internal PHR systems operation plus policies	
			Action 2.2.2.3 Transmit request for registration/ medication data to data or network system	Request for relevant records/documents/information	3
			Action 6.1.3.1 Receive Information	Standardized information {direct reuse of HITSP/C32 – Summary Documents Using HL7 Continuity of Care Document (CCD) and HITSP/C37 – Lab Report Document, HITSP/C35 – Lab Result Terminology}	1, 2, 4, 9,
			Action 2.2.2.4 Receive registration/medic ation data		
			Action 2.2.2.5 Acknowledge receipt of registration/ medication data	Request/response	



Use Case	Perspective/ Business Actor	Event	Action	Interoperability Requirement(s)	Data Requirement Number
			Action 6.1.3.2 Information is automatically populated for viewing using appropriate translations or transformations	Structured information { reuse of HITSP/C32 – Summary Documents Using HL7 Continuity of Care Document (CCD) and HITSP/C37 – Lab Report Document. Translate to lay person terminology (Consumer-friendly sub task)  The consumer receives personal information about his or her health from a healthcare provider. The information could be in the form of a laboratory test result, for example. The information may contain a term with which the consumer is not familiar, or about which the consumer wishes to learn more. The PHR application may provide a mechanism where the consumer clicks a button in the interface to request more information about a term. A multi-term query is created and transmitted to one or more Health Information Resource providers, with which the PHR Service Provider or the consumer may have a business relationship	1, 2, 4, 5, 10, 12
			Action 2.2.2.6 Log interaction	Collect and communicate secured audit trail	
		Event 2.1.4 View registration/medication data	Action 2.1.4.1 Authenticate to system	(PHR application functionality) plus policies	
		Event 6.1.4 Access available information	Action 6.1.4.1 Request information Action 2.1.4.2 Request data Action 2.1.4.3 Receive data	Structured communication request from consumer/PHR to Information Source; one-time-request  Allergies, Conditions, Health Problems and Diagnosis Codes are to be accessed. There needs to be both free text and controlled vocabulary data elements for each Condition/Problem/Diagnosis. Clinical status should be included (e.g. active, chronic, resolved, etc.) Date/time is needed for beginning and ending of the Condition/Problem/Diagnosis  A key pre-condition needs to be documented involving consumer access via the PHR system to the document locator service (see pre-condition section)	1, 2, 4, 5, 11
			Action 6.1.4.2 View information	Translate to lay person terminology (Consumer-friendly sub task)	5



Use Case	Perspective/ Business Actor	Event	Action	Interoperability Requirement(s)	Data Requirement Number
		Event 6.1.5 Select and incorporate information	Action 6.1.5.1 Select information	(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	7
			Action 6.1.5.2 Incorporate selected information into the PHR	(PHR user interface activity) Metadata to identify original source/context of information	
		Event 6.1.6 Annotate information or request change	Action 6.1.6.1 Annotate information	(PHR user interface activity) (PHR application functionality) The HITSP/C32 – Summary Documents Using HL7 Continuity of Care Document (CCD) Comment Module is already defined to describe annotation and target information being annotated. Need to request its explicit addition to IHE XD* Lab. For extending HITSP/C37 – Lab Report Document	1, 2, 3, 4, 7, 9,10
			Action 6.1.6.2 Request change	Request must be interpretable (structured information, structured interaction)  This requires a new HITSP construct (See Section 3.1)	1, 2, 3, 4, 7, 9,
Consumer Empowerment	Consumer and PHR Service Provider	Event 2.1.2 Establish/ Change Permissions	Action 2.1.2.1 Authenticate to system	(PHR application functionality)	
			Action 2.1.2.2 Establish / Modify permissions for access to the system	(PHR application functionality) May also imply change in Consent Directives	
Consumer Access to Clinical Information	Consumer and PHR Service Provider	Event 6.1.2 Receive Notification	Action 6.1.2.1 Receive notification	Standardized notification pursuant to "subscription". {Gap-reuse and expand existing constructs (HITSP/TP13 – Manage Sharing of Documents, HITSP/T29- Notification of Document Availability)}  Upon Notification receipt retrieve information interactions as defined by Events 6.1.3, 6.1.4, 6.1.5, and 6.1.6 above may be automatically triggered	12
Consumer Empowerment	Consumer and	Event 2.1.5 Modify registration and	Action 2.1.5.1 Authenticate to system	(PHR application functionality)	



Use Case	Perspective/ Business Actor	Event	Action	Interoperability Requirement(s)	Data Requirement Number
	PHR Service Provider	Medication data	Action 2.1.5.2 Request data	(PHR application functionality) or may require query and retrieve info from HIE	
			Action 2.1.5.3 Receive data	Query/retrieve information	
			Action 2.1.5.4 Modify data	(PHR application functionality)	
			Action 2.1.5.4a Annotate data	(PHR application functionality)	
			Action 2.1.5.5 Transmit modified and/or annotated data	Register/Make available for query/retrieve annotated information If policy permit may "replace/Flag deprecated" previous version of information	
			Action 2.1.5.5a Transmit request to modify and/or correct data	Standardized notification pursuant to "subscription" (Gap-reuse and expand existing constructs (HITSP/TP13 – Manage Sharing of Documents, HITSP/T29- Notification of Document Availability))	5
Consumer Empowerment and Access to Clinical Information	Health Information Source(s) EHR Systems Health Plans /Intermediaries PBM/Pharmacies	Event 2.4.1 Process request for registration /medication data	Action 2.4.1.1 Receive and validate the query request	Query for Information/Documents against a registry (may be supported by HIE)	
			Action 2.4.1.2 Authenticate and verify authorization of requestor	Validate Assertion in Query	
			Action 2.4.1.3 Authorize release of registration /medication information	(Application access control functionality)	
			Action 2.4.1.4 Transmit registration /medication information to an authorized system	Query response/Retrieve Information	
		Event 6.1.3 PHR(s) receive available information from other sources	Action 6.1.3.1 Receive information		
		Event 2.4.1 Process request for registration /medication data	Action 2.4.1.5 Log interaction	Collect and communicate secured audit trail	



Use Case	Perspective/ Business Actor	Event	Action	Interoperability Requirement(s)	Data Requirement Number
Consumer Empowerment and Access to Clinical Information	Information Exchange Data or Network System (RHIO/HIE)	Event 6.1.1 Identify PHR(s) of choice	Action 6.1.1.1 Identify and communicate PHR(s) of choice	Identification of PHR Service / PHR instance {PHR Location-Gap} Identification of Consumer (Target of PHR) {Registry Patient Id/Id Domain OID} Authentication of Consumer-to-PHR-Service-Provider / Information Exchange-Leverage HITSP/C19 – Entity Identity Assertion {Authenticate Consumers-Partial Gap} Identification of providers Leverage HITSP/C19 Entity Identity Assertion {Partial Gap} Identification of Information Sources	9, 10,11
		Event 2.4.1 Process Request for Registration and/or Medication Data	Action 2.4.1.1 Receive and validate the query request Action: 6.1.4.1 Request information	Structured communicating request: from consumer/PHR to Information Source	7, 9, 11
		Event 6.1.4 Access available information	Action 2.4.1.2 Authenticate and verify the authorization of the requestor	Validate Assertion in Query	
			Action 2.4.1.3 Authorize release of registration/medication data	(Application access control functionality)	
			Action 2.4.1.4 Transmit registration/medication data to an authorized system	Query response/Retrieve Information	
			Action 2.4.1.5 Log interaction	Collect and communicate secured audit trail	
		Event 6.1.2 PHR(s) receive available information from other sources	Action 6.1.2.1 Receive information	Information-Source-to-PHR/ Information Exchange	1,2,4
			Action 6.1.2.2 Information is automatically populated for viewing using appropriate translations or transformations	Structured information {direct reuse of HITSP/C32 – Summary Documents Using HL7 Continuity of Care Document (CCD) and HITSP/C37 – Lab Report Document translate to lay terminology {Consumer-friendly sub task}	1, 2, 4, 5



Use Case	Perspective/ Business Actor	Event	Action	Interoperability Requirement(s)	Data Requirement Number
		Event 6.1.3 Receive Notification	Action 6.1.3.1 Receive notification	Standardized notification pursuant to "subscription". {Gap-reuse and expand existing constructs (HITSP/TP13 – Manage Sharing of Documents, HITSP/T29- Notification of Document Availability)}	12
		Event 6.1.6 Annotate information or request change	Action 6.1.6.1 Annotate information	PHR application functionality Metadata to describe annotation and target information being annotated	7
			Action 6.1.6.2 Request change	Request must be interpretable (structured information, structured interaction) This requires a new HITSP construct (See Section 3.1)	3, 7, 9, 11,
Consumer Empowerment	Consumer	Event 2.1.6 Close Account	Action 2.1.6.1 Request to close PHR account	(PHR application functionality)	
			Action 2.1.6.1a Request registration/medic ation data sent to another provider of PHR service	To be addressed by Scenario 3 in the future	
			Action 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.	

**Consumer Empowerment – Scenario 2: Consumer Visits Healthcare Provider and Provides  
Registration Summary Information and Clinical Information  
[Including Operationally Equivalent Events/Actions from the Consumer Access Use Case]**

**Table 2.2.1-2 Mapping of Use Case Requirements to Business Requirements**

Use Case	Perspective/ Business Actor	Event	Action	Interoperability Requirement(s)	Data Requirement Number
Consumer Empowerment	Consumer	Event 2.1.3 Log on to system	Action 2.1.3.1 Authenticate to system	(PHR application functionality) plus policies	



Use Case	Perspective/ Business Actor	Event	Action	Interoperability Requirement(s)	Data Requirement Number
Consumer Empowerment and Access to Clinical Information	PHR Service Provider	Event 2.2.3 Process registration/medication data	Actor 2.2.3.1 Receive and validate query	Query for Information/Documents against a registry (may be supported by PHR service provider or via RHIO/HIE)	
			Actor 2.2.3.2 Authenticate and verify the authorization of the requestor	Validate Assertion in Query	
			Action 2.2.3.3 Transmit requested registration/medication information to authorized system	Query response/Retrieve Information	
			Actor 2.2.3.4 Log interaction	Collect and communicate secured audit trail	
		Event 2.2.2 Gather registration and/or medication data Event 6.1.3 PHR(s) or EHR(s) receive available information from other sources	Action 2.2.2.1 Receive consumer request	Internal PHR systems operation	
			Action 2.2.2.2 Confirm consumer identity	Internal PHR systems operation plus policies	
			Action 2.2.2.3 Transmit request for registration/medication data to data or network system	Request for relevant records/documents/information	3
			Action 2.2.2.4 Receive registration/medication data Action: 6.1.3.1 Receive information	Standardized information {direct reuse of HITSP/C32 – Summary Documents Using HL7 Continuity of Care Document (CCD) and HITSP/C37 – Lab Report Document, HITSP/C35 – Lab Result Terminology}	1, 2, 4, 9
			Action 2.2.2.5 Acknowledge receipt of registration/medication data	Request/response	



Use Case	Perspective/ Business Actor	Event	Action	Interoperability Requirement(s)	Data Requirement Number
			Action 6.1.3.2 Information is automatically populated for viewing using appropriate translations or transformations	Structured information (reuse of HITSP/C32 – Summary Documents Using HL7 Continuity of Care Document (CCD) and HITSP/C37 – Lab Report Document. Translate to lay person terminology (Consumer-friendly sub task)  The consumer receives personal information about his or her health from a healthcare provider. The information could be in the form of a laboratory test result, for example. The information may contain a term with which the consumer is not familiar, or about which the consumer wishes to learn more. The PHR application may provide a mechanism where the consumer clicks a button in the interface to request more information about a term. A multi-term query is created and transmitted to one or more Health Information Resource providers, with which the PHR Service Provider or the consumer may have a business relationship	1, 2, 4, 5, 10, 12
			Action 2.2.2.6 Log interaction	Collect and communicate secured audit trail	
		Event 2.2.3 Process request for registration and/or medication data	Action 2.2.3.1 Receive and validate the query process	Query for Information/Documents against a registry (may be supported by PHR service provider or via RHIO/HIE)	
			Action 2.2.3.2 Authenticate and verify the authorization of the requestor	Validate Assertion in Query	
			Action 2.2.3.3 Transmit registration/medication data to an authorized system	Query response/Retrieve Information	
			Action 2.2.3.4 Log interaction	Collect and communicate secured audit trail	





Use Case	Perspective/ Business Actor	Event	Action	Interoperability Requirement(s)	Data Requirement Number
Consumer Empowerment  Consumer Empowerment and Access to Clinical Information	Healthcare Provider	Event 2.3.1 View registration and/or medication data  Event 6.1.3 PHR(s) or EHR(s) receive available information from other sources	Action 2.3.1.1 Submit authentication information to PHR	Validate Assertion in Query	
			Action 2.3.1.2 Receive registration/medication data  Action: 6.1.3.1 Receive information	Standardized information {direct use or reuse of HITSP/C32 – Summary Documents Using HL7 Continuity of Care Document (CCD) and HITSP/C37 – Lab Report Document, HITSP/C35 – Lab Result Terminology (Lab)}	1, 2, 4, 9
Consumer Empowerment	Provider	Event 2.3.2 Integrate registration data into EHR or other care system	Action 2.3.2.1 Transmit request for registration/medication data to provider of PHR service	Query for Information/Documents against a registry (may be supported by PHR service provider or via RHIO/HIE)	
			Action 2.3.2.2 Accept data into EHR system	(EHR application functionality)	
			Action 2.3.2.3 Confirm data integrity	(EHR application functionality)	
			Action 2.3.2.3a Produce exception list of errors	(EHR application functionality)	
			Action 2.3.2.4 Parse and validate results content	(EHR application functionality)	
			Action 2.3.2.5 Acknowledge receipt of registration/medication data	Request/response	
			Action 2.3.2.6 Log interaction	Collect and communicate secured audit trail	



Use Case	Perspective/ Business Actor	Event	Action	Interoperability Requirement(s)	Data Requirement Number
Consumer Empowerment  Consumer Empowerment and Access to Clinical Information	Data or Network System Health Information Source(s)	Event 2.4.1 Process Request for Registration and/or Medication Data  Event 6.1.3 PHR(s) or EHR(s) receive available information from other sources	Action 2.4.1.1 Receive and validate the query request  Action 6.1.3.1 Receive information	Query for Information/Documents against a registry (may be supported by HIE)  Standardized information {direct use or reuse of HITSP/C32 – Summary Documents Using HL7 Continuity of Care Document (CCD) and HITSP/C37 – Lab Report Document, HITSP/C35 – Lab Result Terminology}	1, 2, 4, 9
			Action 2.4.1.2 Authenticate and verify the authorization of the requestor	Validate Assertion in Query	
			Action 2.4.1.3 Authorize release of registration/ medication data	Application access control functionality	
			Action 2.4.1.4 Transmit registration/medication data to an authorized system	Query response/Retrieve Information	
			Action 2.4.1.5 Log interaction	Collect and communicate secured audit trail	

**Consumer Empowerment – Scenario 3: Authorized Healthcare Provider Reviews Registration Summary and Other Clinical Information**  
**[Including Operationally Equivalent Events/Actions from the Consumer Access Use Case]**

**Table 2.2.1-3 Mapping of Use Case Requirements to Business Requirements**

Use Case	Perspective/ Business Actor	Event	Action	Interoperability Requirement(s)	Data Requirement Number
Consumer Empowerment	Consumer	Event 2.1.3 Log on to system	Action 2.1.3.1 Authenticate to system	PHR application functionality plus policies	
Consumer Empowerment	PHR Service Provider	Event 2.2.2 Gather registration	Action 2.2.2.1 Receive consumer request	Internal PHR systems operation	



Use Case	Perspective/ Business Actor	Event	Action	Interoperability Requirement(s)	Data Requirement Number
Consumer Empowerment and Access to Clinical Information		and/or medication data Event 6.1.3 PHR(s) (or EHRs) receive available information from other sources	Action 2.2.2.2 Confirm consumer identity	Internal PHR systems operation plus policies	
			Action 2.2.2.3 Transmit request for registration/ medication data to data or network system	Request for relevant records/documents/information	3
			Action 2.2.2.4 Receive registration / medication data Action 6.1.3.1 Receive Information	Standardized information {direct reuse of HITSP/C32 – Summary Documents Using HL7 Continuity of Care Document (CCD) and HITSP/C37 – Lab Report Document, HITSP/C35 – Lab Result Terminology}	1, 2, 4, 9
			Action 2.2.2.5 Acknowledge receipt of registration / medication data	Request/response	
			Action 6.1.3.2 Information is automatically populated for viewing using appropriate translations or transformations	Structured information {reuse of HITSP/C32 – Summary Documents Using HL7 Continuity of Care Document (CCD) and HITSP/C37 – Lab Report Document. Translate to lay terminology (Consumer-friendly sub task)  The consumer receives personal information about his or her health from a healthcare provider. The information could be in the form of a laboratory test result, for example. The information may contain a term with which the consumer is not familiar, or about which the consumer wishes to learn more. The PHR application may provide a mechanism where the consumer clicks a button in the interface to request more information about a term. A multi-term query is created and transmitted to one or more Health Information Resource providers, with which the PHR Service Provider or the Consumer may have a business relationship	1, 2, 4, 5, 10, 12
			Action 2.2.2.6 Log interaction	Collect and communicate secured audit trail	



Use Case	Perspective/ Business Actor	Event	Action	Interoperability Requirement(s)	Data Requirement Number
Consumer Empowerment	PHR Service Provider	Event 2.2.3 Process request for registration and/or medication data	Action 2.2.3.1 Receive and validate the query process	Query for Information/Documents against a registry (may be supported by PHR service provider or via HIE)	
			Action 2.2.3.2 Authenticate and verify the authorization of the requestor	Validate Assertion in Query	
			Action 2.2.3.3 Transmit registration/medication data to an authorized system	Query response/Retrieve Information	
			Action 2.2.3.4 Log interaction	Collect and communicate secured audit trail	
Consumer Empowerment	Healthcare Provider	Event 2.3.1 View registration and/or medication data	Action 2.3.1.1 Submit authentication information to PHR	Validate Assertion in Query	
			Action 2.3.1.2 Receive registration/medication data	Standardized information {direct use or reuse of HITSP/C32 – Summary Documents Using HL7 Continuity of Care Document (CCD) and HITSP/C37 – Lab Report Document, HITSP/C35 – Lab Result Terminology}	1, 2, 4, 9
Consumer Empowerment	Healthcare Provider	Event 2.3.2 Integrate registration data into EHR or other care system	Action 2.3.2.1 Transmit request for registration / medication data to provider of PHR service	Query for Information/Documents against a registry (may be supported by PHR service provider or via RHIO/HIE)	
			Action 2.3.2.2 Accept data into EHR system	(EHR application functionality)	
			Action 2.3.2.3 Confirm data integrity	(EHR application functionality)	
			Action 2.3.2.3a Produce exception list of errors	(EHR application functionality)	
			Action 2.3.2.4 Parse and validate results content	(EHR application functionality)	



Use Case	Perspective/ Business Actor	Event	Action	Interoperability Requirement(s)	Data Requirement Number
			Action 2.3.2.5 Acknowledge receipt of registration/medic ation data	Request/response	
			Action 2.3.2.6 Log interaction	Collect and communicate secured audit trail	
Consumer Empowerment  Consumer Empowerment and Access to Clinical Information	Data or Network System Health Information Source(s)	Event 2.4.1 Process Request for Registration and/or Medication Data  Event 6.1.3 PHR(s) or EHR(s) receive available information from other sources	Action 2.4.1.1 Receive and validate the query request  Action 6.1.3.1 Receive Information	Query for Information/Documents against a registry (may be supported by HIE)  Standardized information {direct use or reuse of HITSP/C32 – Summary Documents Using HL7 Continuity of Care Document (CCD) and HITSP/C37 – Lab Report Document, HITSP/C35 – Lab Result Terminology}	1, 2, 4, 9
			Action 2.4.1.2 Authenticate and verify the authorization of the requestor	Validate Assertion in Query	
			Action 2.4.1.3 Authorize release of registration/medic ation data	(Application access control functionality)	
			Action 2.4.1.4 Transmit registration/medic ation data to an authorized system	Query response/Retrieve Information	
			Action 2.4.1.5 Log interaction	Collect and communicate secured audit trail	

### Consumer Access Use Case – Scenario 2: Provider Lists and Permissions



**Table 2.2.1-4 Mapping of Use Case Requirements to Business Requirements**

Use Case	Perspective/ Business Actor	Event	Action	Interoperability Requirement(s)	Data Requirement Number
Consumer Empowerment and Access to Clinical Information	Consumer	Event 7.1.1 Request and access provider information	Action 7.1.1.2 Request provider information	Using the PHR, consumers request information about providers who they may wish to add to their provider list. Providers may include individuals, practices, and/or organizations. The PHR retrieves provider information from an HIE registry, EHRs, or payors, etc	13
			Action 7.1.1.4 Access provider information	Consumers access the requested provider identifying information. Identifying information may include: services, place of practice, etc	13
		Event 7.1.2 Create/update provider lists	Action 7.1.2.1 Select and incorporate provider information	Consumers select the desired provider information and create and/or update their lists of providers in their PHR	13
		Event 7.1.3 Designate provider permissions	Action 7.1.3.1 Designate provider permissions	Consumers designate which information in their PHR can be accessed by which providers. Methods for designating the consumer's decisions could include designating access for individual providers, designating access based on roles assigned to providers, designating access for provider practices or organizations, designating access by type of health information or some other criteria. In addition, the models may need to accommodate various approaches or a combination of approaches for designating permissions. These approaches may include, an inclusive model, an exclusive model, and/or the utilization of pre-determined defaults. A generalized process for access control is described in Appendix A: Create and Maintain Access Control Lists. Consumers may have the ability to allow (or not allow) providers to override the permissions in necessary situations. Reasons for "breaking the glass" are recorded in a consistent manner and incorporated into access and disclosure logs	13, 14



Use Case	Perspective/ Business Actor	Event	Action	Interoperability Requirement(s)	Data Requirement Number
		Event 7.1.4 Review access and disclosure logs	Action 7.1.4.1 Review access and disclosure logs	Consumers review information describing who has viewed their health information. The ability to merge or integrate this information from multiple sources into a time-sequence or other logical view may also be important for consumers. Information describing access to and disclosure of PHR information, "break the glass" access, HIE information exchange information access, and, at times, may include access to information in EHRs, etc	15
Consumer Empowerment and Access to Clinical Information	Provider	Event 7.2.1 Request and access available clinical information	Action 7.2.1.1 Request and access information	Providers request and are able to access information from the consumers' PHR and other sources based upon access permissions established by the consumer. Providers may be informed that some information is not accessible as a result of the consumers' access decisions. Providers are able to identify the original source of the data as well as whether the information has been subsequently modified. If modification has occurred, the identity of the source of the modification is also available to providers. A generalized process for access control is described in Appendix A: Create and Maintain Access Control Lists. A generalized process for matching patients is described in Appendix A: Arbitrating Identities	10, 11, 15
		Event 7.2.2 Select and incorporate clinical information	Action 7.2.2.1 Select information	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
			Action 7.2.2.2 Incorporate data into EHRs	The providers' EHR incorporates the selected information. The original source of the data are also incorporated into the EHR	None



Use Case	Perspective/ Business Actor	Event	Action	Interoperability Requirement(s)	Data Requirement Number
		Event 7.2.3 Systems log the activity	Action 7.2.3.1 Log access to information	The consumers' PHR and data intermediaries create logs of the information exchanges. The logs identify who has accessed the consumers' information. The access and disclosure logs could be reviewable by the consumers. It may be helpful to combine log information from several systems in order to establish a complete view of who has accessed the consumers' information over a period of time	15

### Consumer Access Use Case – Scenario 3: Transfer of PHR Information

**Table 2.2.1-5 Mapping of Use Case Requirements to Business Requirements**

Use Case	Perspective/ Business Actor	Event	Action	Interoperability Requirement(s)	Data Requirement Number
Consumer Empowerment and Access to Clinical Information	Consumer	Event 8.1.1 Access PHR(A)	Action 8.1.1.1 Access PHR(A)		
		Event 8.1.2 Request and access available information in PHR(A)	Action 8.1.2.1 Review PHR(A) Information	Consumers request and are able to access information in their PHR. Consumers are able to identify the original source of the data as well as whether the information has been subsequently modified. If modification has occurred, the identity of the source of the modification is also available	10, 11, 15
		Event 8.1.3 Select Information to send PHR(B)	Action 8.1.3.1 Select data elements and/or data sets	Standardized information {direct use or reuse of HITSP/C32 – Summary Documents Using HL7 Continuity of Care Document (CCD) and HITSP/C37 – Lab Report Document, HITSP/C35 – Lab Result Terminology}	1, 2, 4, 9
			Action 8.1.3.2 Select providers and permissions		
		Event 8.1.4 Identify PHR(B) which is to receive the information	Action 8.1.4.1 Identify PHR(B) which is to receive the information		





Use Case	Perspective/ Business Actor	Event	Action	Interoperability Requirement(s)	Data Requirement Number
		Event 8.1.5 PHR(A) sends information to PHR(B)	Action 8.1.5.1 Forward information to PHR (B)	Write selected information on device/interchange media. Ensure consistent management of organization on media	
			Action 8.1.5.2 Confirm delivery of information to PHR (B)	Confirm delivery of information not applicable for media interchange as media is provided to consumer who will be responsible for delivery to other PHR or EHR Action: Consider this to be the confirmation of reading of media as acceptable to consumers. May review media content and select documents of interest and import content.	



## 2.2.2 DATA AND INFORMATION REQUIREMENTS MATRIX

This section contains an extraction of data and information requirements with a listing of the actual data elements and information that meet the described data requirements.

**Table 2.2.2-1 Requirements Matrix**

Data Requirement Number	Description	Data Element(s)	Scenario
1	Diagnosis Codes	<p>"Ability for a consumer to retrieve and store a list of diagnosis codes."</p> <p>Patient Class (outpatient, inpatient, and ER (UHDDS))</p> <p>Diagnosis/Injury Code (ICD 9/10)</p> <p>Diagnosis Type (UHDDS)</p> <p>Diagnosis Date and Time (UHDDS)</p> <p>Date/time of first symptoms</p> <p>Discharge Disposition (UHDDS)</p> <p>Chief Complaint (ICD9/10)</p> <p>Date/time of first symptoms of illness (UHDDS)</p> <p>Identity of diagnosing provider or institution</p> <p>Diagnostic procedure(s)</p> <p>HITSP/C32 – Summary Documents Using HL7 Continuity of Care Document (CCD) Section 4.2.3.1.7</p>	1
2	Allergies / Medication Allergies	<p>"Ability for consumer to retrieve and store lists of current environment, dietary, or medical supply allergies"</p> <p>"Ability for consumer to retrieve and store lists of current medication allergies"</p> <p>Allergy type</p> <p>Date/time of first symptoms</p> <p>HITSP/C32 – Summary Documents Using HL7 Continuity of Care Document (CCD) Section 4.2.3.1.6</p>	1
3	Change request	<p>Information source identifier</p> <p>Consumer identifier</p> <p>Original entry identifier</p> <p>Data enterer identification/authorization information</p> <p>Annotation / change request information (relate to standard clinical content structures)</p> <p>Rationale for change request (free text?)</p> <p>Requestor contact information</p>	1
4	Clinical data are provided, including (but not limited to)	<p>Laboratory test results (see HITSP/C35 – Lab Result Terminology, HITSP/C37 – Lab Report Document)</p> <p>Medication History (see HITSP/C32 – Summary Documents Using HL7 Continuity of Care Document (CCD))</p>	1



Data Requirement Number	Description	Data Element(s)	Scenario
5	Context-aware Information Retrieval Message Model	<p>A query to an information resource will contain at least one Main Search Criteria as described below. In addition, the query may contain any of the other classes listed below (Using a subset of the criteria defined by HL7 v3 InfoButton):</p> <p>MainSearchCriteria  SeverityObservation class:  SubTopic  TaskContext  Encounter type  DeliveryLocation / id  AssignedEntity  username  certificateTex  Organization  Organization.id  AuthorizedPerson:  PatientContext  PatientPerson.administrativeGenderCode  PerformerChoice: Patient or HealthCareProvider  Age  AgeGroup  LanguageCommunication:  InfobuttonEventNotification.id  InfobuttonEventNotification.effectiveTime</p>	



Data Requirement Number	Description	Data Element(s)	Scenario
7	Document metadata/ Source/context metadata	<p>One or more sets of documents.</p> <p>Documents should be of any format, structure and content. This is critical to support any currently defined documents by HITSP as well as future documents.</p> <p>Selected metadata about each document, forming the entries of a media table of content. One entry per document stored on the media. Metadata should contain information such as:</p> <p>Patient ID and basic demographics</p> <p>Class of Document</p> <p>Document Type</p> <p>Source Care-Setting/Specialty</p> <p>Date/time</p> <p>Format/MIME Type</p> <p>Source identifier</p> <p>Entry identifier</p> <p>Date of original datum</p> <p>Last update date</p> <p>Updated by identifier(s)</p> <p>(look at document metadata in HITSP/C32 -- Summary Documents Using HL7 Continuity of Care Document (CCD), HITSP/C37 -- Lab Report Document)</p>	3 (Consumer Empowerment and Consumer Access)
9	Information Source identification data	<p>URL</p> <p>Service Provider</p> <p>Service Type (e.g., laboratory, pharmacy, healthcare entity, etc)</p>	1, 3 (Consumer Empowerment and Consumer Access)
10	Secure consumer identification data	<p>Consumer Demographic Information (DOB, age, gender, resident zip code, state of residence)</p> <p>Consumer identifiers (identifier and authority)</p>	1, 3 (Consumer Access)
11	Structured information request	<p>Information Service Identifier</p> <p>Requested information type</p> <p>Patient (target) identification</p> <p>Requested information parameters (date range, limiting criteria)</p> <p>Requestor authentication and authorization information</p> <p>Type of request: One time request, notification request, subscription request</p> <p>Request active dates (how long to continue request)</p> <p>Per HITSP/IS03 – Consumer Empowerment and Access to Clinical Information via Networks, the current HITSP/TP13 – Manage Sharing of Documents, query and retrieve transactions provide the same service to both EHR and PHR service providers. This should remain in place to support this Use Case</p>	1, 3 (Consumer Access)



Data Requirement Number	Description	Data Element(s)	Scenario
12	Structured Notification	Information Source identification Consumer (target) identification Information type (e.g., laboratory, pharmacy, etc) Notification Identifier or Record reference identifier	1
13	Provider identification, details, location	Superset of HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD) & HITSP/C37 – Lab Report Document, provider identification and additional elements as needed for entity resolution  Consistent representation of practice sites, nature of practice, all alternatively presented in lay person friendly terms	2 (Consumer Access)
14	Access Control Lists	Identification of entity being authorized Identification of entity granting authorization Type of authorization (read/no-read, write/no-write, etc) Criteria defining the application of the authorization (e.g., document type, procedure/test results, etc.)	2 (Consumer Access)
15	Access log summary/detail: what was accessed, when, by whom, stated purpose	Access log information, available in both summary and detail format: What information was accessed? Who accessed the information? When was the information accessed? Stated purpose for the access? Override criteria, if applicable (e.g., "break-glass") Is the access log all-event or exception-event-only?	2 (Consumer Empowerment and Consumer Access)

### 2.2.3 IDENTIFICATION OF BUSINESS ACTORS, INTERACTIONS AND SCENARIOS

This section describes the business actors that impact interoperability requirements for each scenario. A HITSP business actor should generally be an IT system that is directly engaged, and benefits from the real world information interchange defined within a business Use Case action. A business actor may also be a person or organization, however, only IT systems have associated technical actors (see Section 3.2 for technical actors). The table below identifies the significant Use Case business actors, their descriptions and the Use Case scenarios in which they are used.

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	Scenario
Consumer	The individual who receives healthcare services and selects a provider of PHR services to maintain their personal health record consisting of registration data and medication history. This individual determines which business actors are authorized to review, access, and update their personal health record.	1, 2, 3
Personal Health Record (PHR) Service Provider	The organization that supplies the Personal Health Record (PHR), a secure, real-time, point-of-care, person-centric information resource, for consumers	1, 2, 3
Regional Health Information Organizations (RHIO)/Health Information Exchange (HIE)	A Regional Health Information Organization (RHIO)/Health Information Exchange (HIE) is a multi-stakeholder organization that enables the exchange and use of health information, in a secure manner, for the purpose of promoting the improvement of health quality, safety and efficiency	1, 2, 3
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	1, 2, 3
Health Plan/Intermediary	The organization or its designated intermediary that pays for healthcare, may participate as a data or network system of registration summary information, and can act as a provider of PHR services	1, 2, 3
Pharmacy Benefit Manager (PBM)/Pharmacy	The organization that has been delegated authority from the payer to process pharmaceutical claims, intermediary, pharmacy or sub network to provide data for medication history, and can act as a provider of PHR services	1, 2, 3

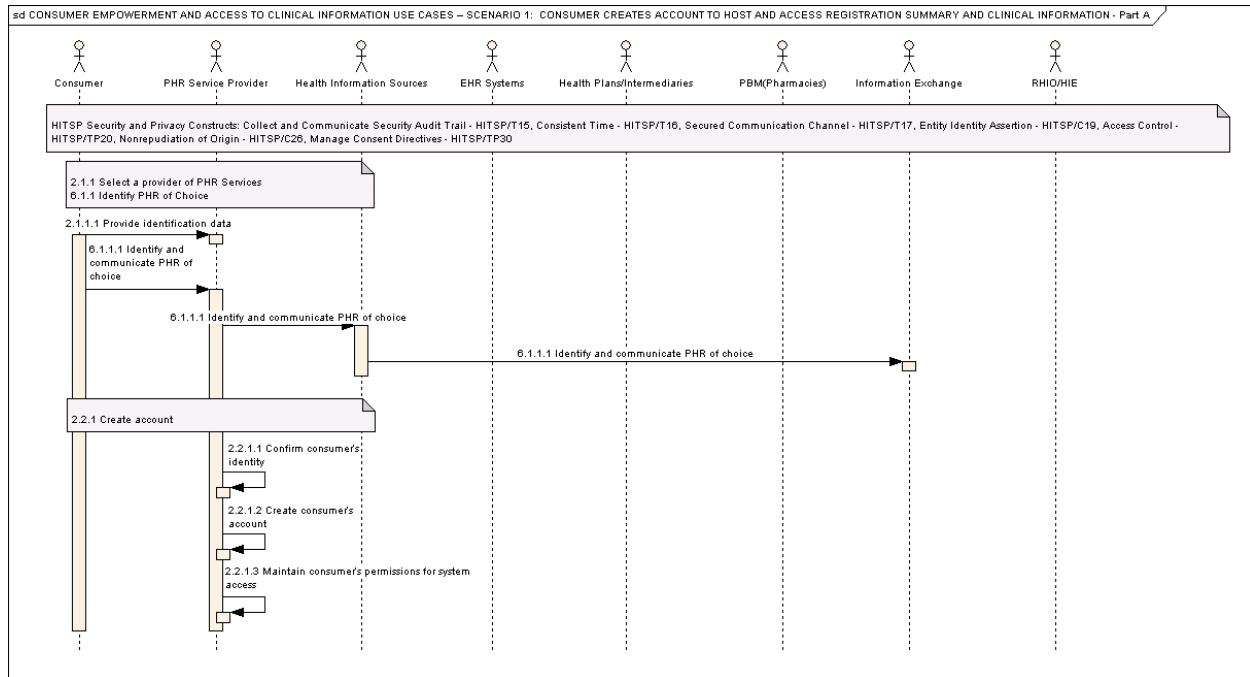
These business actors are identified as separate actors in the various scenario actor transactions descriptions below, in this section and sections 3.2.2 and 3.2.3. This descriptive approach does not prevent business actors from being grouped in a variety of ways. A number of such implementation variants 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 an explanation of the relationship between the business actors and data interactions between the primary actors and alternative actors for each Use Case scenario. The diagrams that follow illustrate each scenario with a representation of a normal sequence of exchange between the primary actors.



**Figure 2.2.4-1 Scenario 1: Consumer Creates Account to Host and Access Registration Summary and Clinical Information High-Level UML Business Sequence Diagram - Part A**



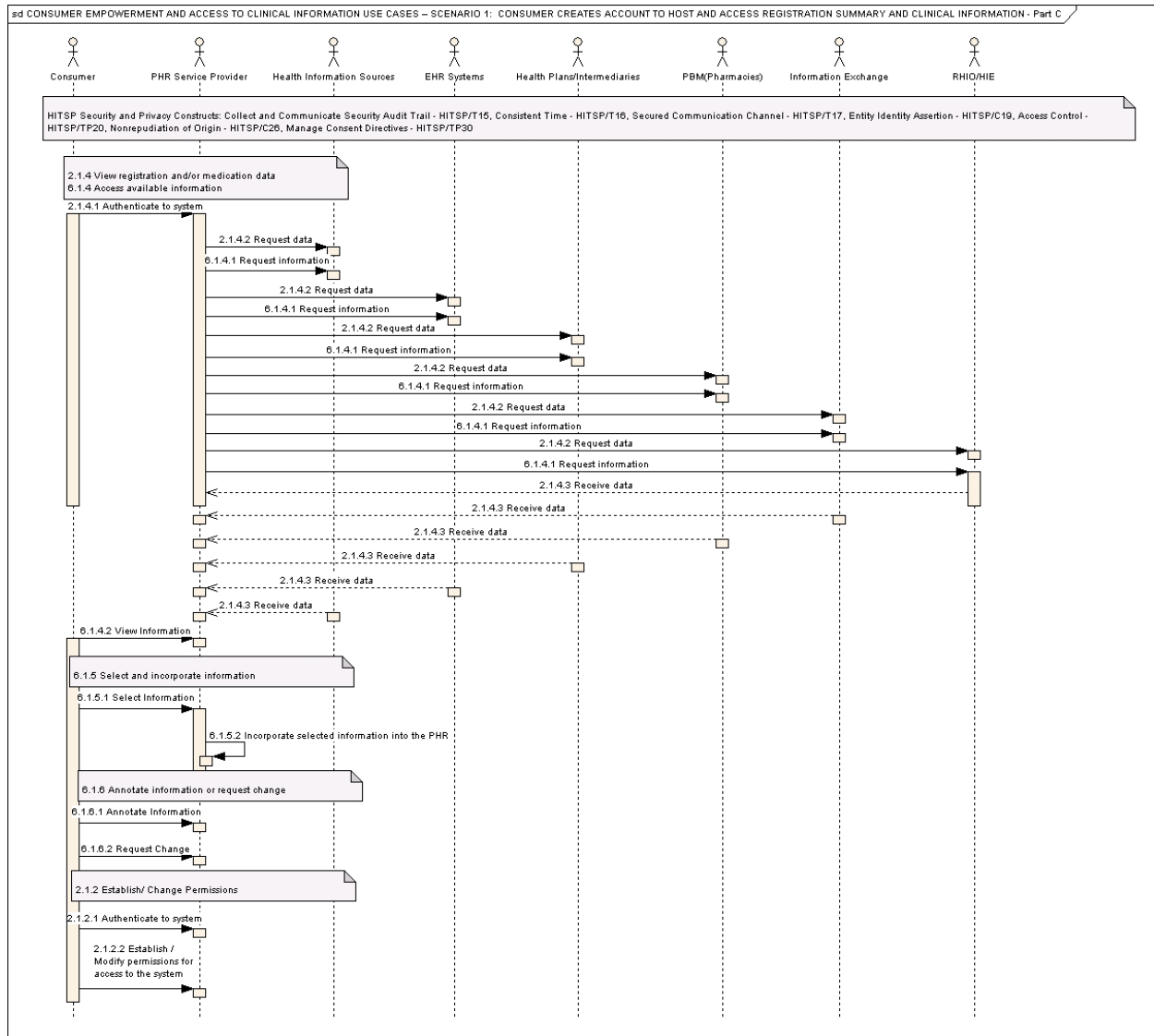
**sd CONSUMER EMPOWERMENT AND ACCESS TO CLINICAL INFORMATION USE CASES – SCENARIO 1: CONSUMER CREATES ACCOUNT TO HOST AND ACCESS REGISTRATION SUMMARY AND CLINICAL INFORMATION - Part B**

```
sequenceDiagram\n    actor C as Consumer\n    participant PSP as PHR Service Provider\n    participant HIS as Health Information Sources\n    participant EHR as EHR Systems\n    participant HPI as Health Plans/Intermediaries\n    participant PBM as PBM(Pharmacies)\n    participant IE as Information Exchange\n    participant RHIO as RHIO/HIE\n\n    Note over C,PSP,HIS,EHR,HPI,PBM,IE,RHIO: HITSP Security and Privacy Constructs: Collect and Communicate Security Audit Trail - HITSP/T15, Consistent Time - HITSP/T16, Secured Communication Channel - HITSP/T17, Entity Identity Assertion - HITSP/C19, Access Control - HITSP/TP20, Nonrepudiation of Origin - HITSP/C26, Manage Consent Directives - HITSP/TP30\n\n    Note left of C: 2.2.2 Gather registration and/or medication data  
6.1.3 PHR(s) receive available information from other sources\n\n    Note left of C: 2.2.2.1 Receive consumer request\n    C->>PSP: 2.2.2.2 Confirm consumer identity\n    PSP-->>C: \n\n    Note left of C: 2.2.2.3 Transmit request for registration / medication data to data or network system\n    PSP->>HIS: 2.2.2.3 Transmit request for registration / medication data to data or network system\n    PSP->>EHR: 2.2.2.3 Transmit request for registration / medication data to data or network system\n    PSP->>HPI: 2.2.2.3 Transmit request for registration / medication data to data or network system\n    PSP->>PBM: 2.2.2.3 Transmit request for registration / medication data to data or network system\n    PSP->>IE: 2.2.2.3 Transmit request for registration / medication data to data or network system\n    PSP->>RHIO: 2.2.2.3 Transmit request for registration / medication data to data or network system\n\n    Note left of C: 2.2.2.4 Receive registration medication data\n    HIS->>PSP: 2.2.2.4 Receive registration medication data\n    EHR->>PSP: 2.2.2.4 Receive registration medication data\n    HPI->>PSP: 2.2.2.4 Receive registration medication data\n    PBM->>PSP: 2.2.2.4 Receive registration medication data\n    IE->>PSP: 2.2.2.4 Receive registration medication data\n    RHIO->>PSP: 2.2.2.4 Receive registration medication data\n\n    Note left of C: 6.1.3.1 Receive Information\n    PSP->>C: 6.1.3.1 Receive Information\n\n    Note left of C: 2.2.2.4 Receive registration / medication data\n    PSP->>HIS: 2.2.2.4 Receive registration / medication data\n    PSP->>EHR: 2.2.2.4 Receive registration / medication data\n    PSP->>HPI: 2.2.2.4 Receive registration / medication data\n    PSP->>PBM: 2.2.2.4 Receive registration / medication data\n    PSP->>IE: 2.2.2.4 Receive registration / medication data\n    PSP->>RHIO: 2.2.2.4 Receive registration / medication data\n\n    Note left of C: 6.1.3.1 Receive Information\n    HIS->>PSP: 6.1.3.1 Receive Information\n    EHR->>PSP: 6.1.3.1 Receive Information\n    HPI->>PSP: 6.1.3.1 Receive Information\n    PBM->>PSP: 6.1.3.1 Receive Information\n    IE->>PSP: 6.1.3.1 Receive Information\n    RHIO->>PSP: 6.1.3.1 Receive Information\n\n    Note left of C: 2.2.2.5 Acknowledge receipt of registration / medication data\n    PSP->>HIS: 2.2.2.5 Acknowledge receipt of registration / medication data\n    PSP->>EHR: 2.2.2.5 Acknowledge receipt of registration / medication data\n    PSP->>HPI: 2.2.2.5 Acknowledge receipt of registration / medication data\n    PSP->>PBM: 2.2.2.5 Acknowledge receipt of registration / medication data\n    PSP->>IE: 2.2.2.5 Acknowledge receipt of registration / medication data\n    PSP->>RHIO: 2.2.2.5 Acknowledge receipt of registration / medication data\n\n    Note left of C: 6.1.3.2 Information is automatically populated for viewing using appropriate translations or transformations\n    Note left of C: 2.2.2.6 Log interaction\n    PSP->>C: 6.1.3.2 Information is automatically populated for viewing using appropriate translations or transformations\n    C->>PSP: 2.2.2.6 Log interaction\n\n    Note left of C: 6.1.4.1 Request information\n    PSP->>HIS: 6.1.4.1 Request information\n    PSP->>EHR: 6.1.4.1 Request information\n    PSP->>HPI: 6.1.4.1 Request information\n    PSP->>PBM: 6.1.4.1 Request information\n    PSP->>IE: 6.1.4.1 Request information\n    PSP->>RHIO: 6.1.4.1 Request information\n\n    Note left of C: 2.1.4.2 Request data\n    HIS->>PSP: 2.1.4.2 Request data\n    EHR->>PSP: 2.1.4.2 Request data\n    HPI->>PSP: 2.1.4.2 Request data\n    PBM->>PSP: 2.1.4.2 Request data\n    IE->>PSP: 2.1.4.2 Request data\n    RHIO->>PSP: 2.1.4.2 Request data\n\n    Note left of C: 6.1.4.1 Request information\n    PSP->>HIS: 6.1.4.1 Request information\n    PSP->>EHR: 6.1.4.1 Request information\n    PSP->>HPI: 6.1.4.1 Request information\n    PSP->>PBM: 6.1.4.1 Request information\n    PSP->>IE: 6.1.4.1 Request information\n    PSP->>RHIO: 6.1.4.1 Request information\n\n    Note left of C: 2.1.4.3 Receive data\n    HIS->>PSP: 2.1.4.3 Receive data\n    EHR->>PSP: 2.1.4.3 Receive data\n    HPI->>PSP: 2.1.4.3 Receive data\n    PBM->>PSP: 2.1.4.3 Receive data\n    IE->>PSP: 2.1.4.3 Receive data\n    RHIO->>PSP: 2.1.4.3 Receive data\n\n    Note left of C: 6.1.4.2 View Information\n    PSP->>C: 6.1.4.2 View Information
```

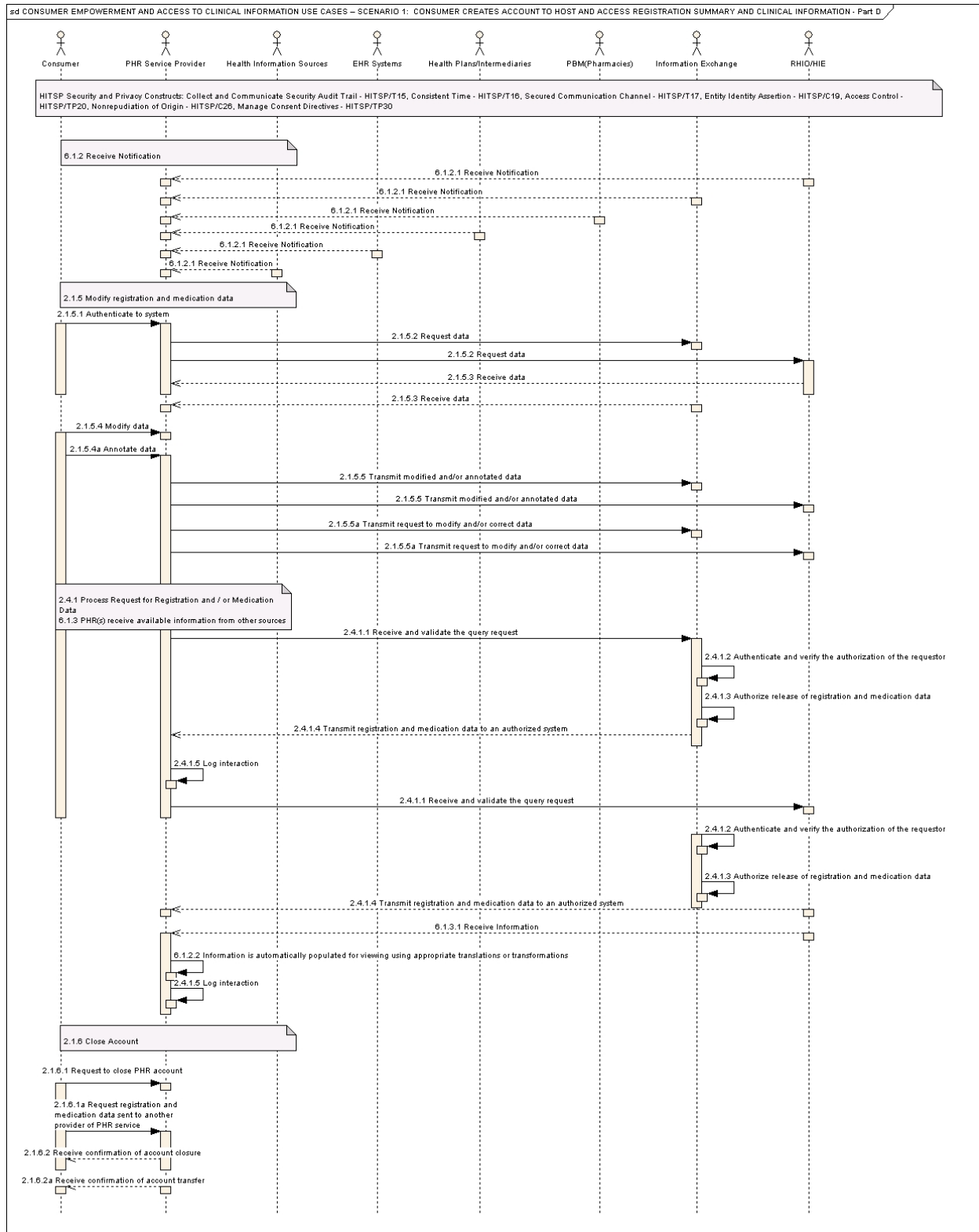




**Figure 2.2.4-1 Scenario 1: Consumer Creates Account to Host and Access Registration Summary and Clinical Information High-Level UML Business Sequence Diagram - Part C**



**Figure 2.2.4-1 Scenario 1: Consumer Creates Account to Host and Access Registration Summary and Clinical Information High-Level UML Business Sequence Diagram - Part D**



CONSUMER EMPOWERMENT AND ACCESS TO CLINICAL INFORMATION USE CASES – SCENARIO 2: CONSUMER VISITS HEALTHCARE PROVIDER AND PROVIDES REGISTRATION SUMMARY INFORMATION AND CLINICAL INFORMATION

```
sequenceDiagram
    participant Consumer
    participant PHR as PHR Service Provider
    participant HP as Healthcare Provider
    participant DNS as Data or Network System
    participant HIS as Health Information Sources

    Note over Consumer, PHR, HP, DNS, HIS: HITSP Security and Privacy Constructs: Collect and Communicate Security Audit Trail - HITSP/T15, Consistent Time - HITSP/T16, Secured Communication Channel - HITSP/T17, Entity Identity Assertion - HITSP/C19, Access Control - HITSP/T20, Nonrepudiation of Origin - HITSP/C26, Manage Consent Directives - HITSP/T30

    Consumer->>PHR: 2.1.3.1 Authenticate to System
    Note over Consumer: Event 2.1.3 Log on to system

    Note over Consumer, PHR: Event 2.2.2 Gather registration and/or medication data  
Event 6.1.3 PHR(s) receive available information from other sources
    PHR->>Consumer: 2.2.2.1 Receive consumer request
    PHR->>PHR: 2.2.2.2 Confirm Consumer Identity
    PHR->>DNS: 2.2.2.3 Transmit request for registration / medication data to data or network system
    DNS-->>PHR: 2.2.2.4 Receive registration / medication data
    PHR->>HIS: 6.1.3.1 Receive Information
    HIS-->>PHR: 2.2.2.5 Acknowledge receipt of registration / medication data
    PHR->>PHR: 6.1.3.2 Information is automatically populated for viewing using appropriate translations or transformations
    PHR->>DNS: 2.2.2.6 Log Interaction
    PHR->>PHR: 2.2.2.6 Log Interaction

    Note over Consumer, PHR, HP, DNS, HIS: Event 2.2.3 Process request for registration and/or medication data
    PHR->>PHR: 2.2.3.1 Receive and validate the query process
    PHR->>PHR: 2.2.3.2 Authenticate and verify the authorization of the requestor
    PHR->>DNS: 2.2.3.3 Transmit registration and medication data to an authorized system
    DNS-->>PHR: 2.2.3.4 Log interaction

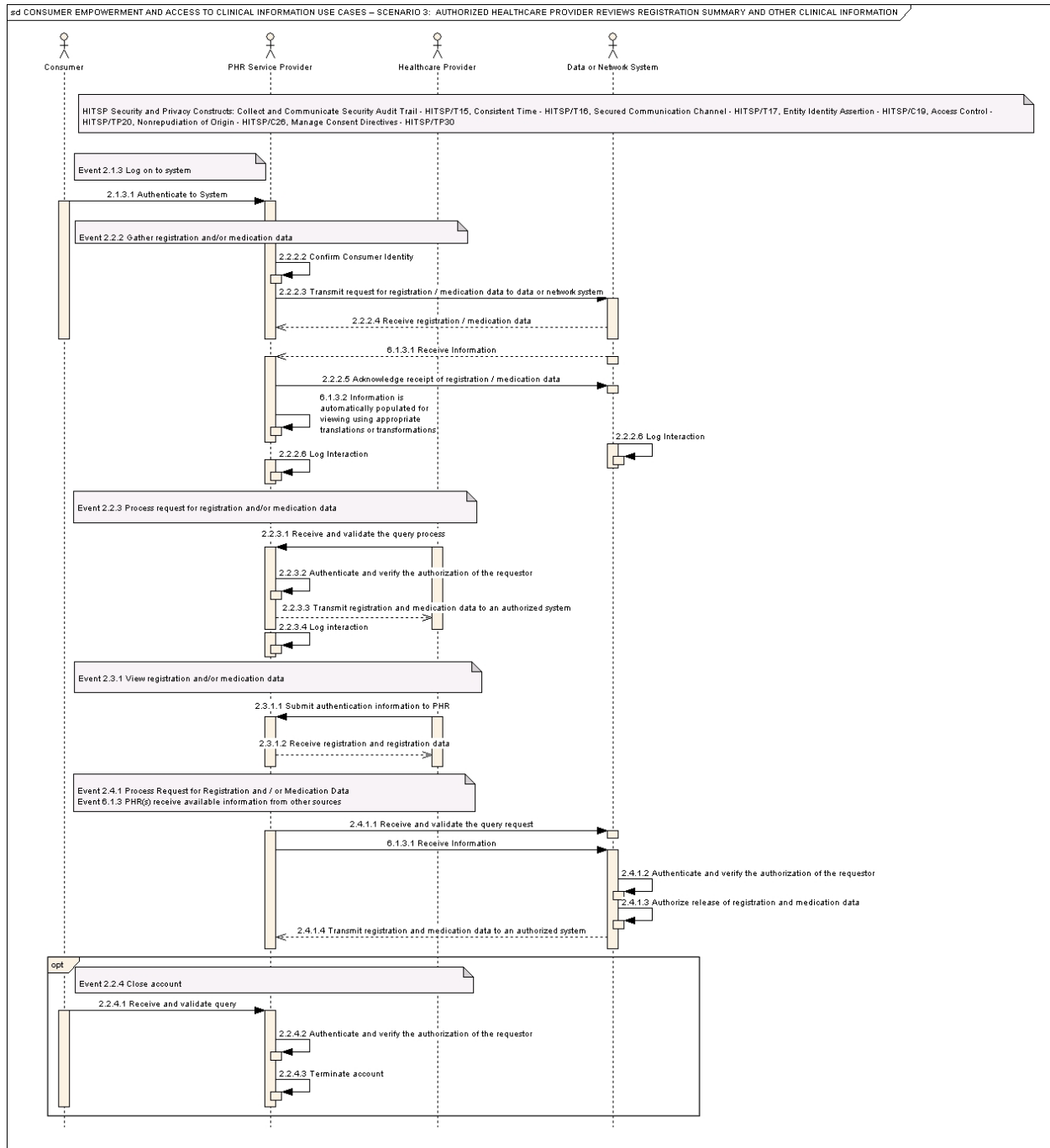
    Note over Consumer, PHR, HP, DNS, HIS: Event 2.3.1 View registration and/or medication data
    PHR->>PHR: 2.3.1.1 Submit authentication information to PHR
    PHR->>DNS: 2.3.1.2 Receive registration and medication data
    DNS-->>PHR: 6.1.3.1 Receive Information

    Note over Consumer, PHR, HP, DNS, HIS: Event 2.3.2 Integrate registration data into EHR or other care system
    PHR->>HP: 2.3.2.1 Transmit request for registration / medication data to provider of PHR service
    HP->>HP: 2.3.2.2 Accept data into EHR system
    HP->>HP: 2.3.2.3 Confirm data integrity
    HP->>HP: 2.3.2.3a Produce exception list of errors
    HP->>HP: 2.3.2.4 Parse and validate results content
    HP-->>PHR: 2.3.2.5 Acknowledge receipt of registration and medication data
    PHR->>PHR: 2.3.2.6 Log interaction
    HP->>HP: 2.3.2.6 Log interaction

    Note over Consumer, PHR, HP, DNS, HIS: Event 2.4.1 Process Request for Registration and / or Medication Data  
Event 6.1.3 PHR(s) receive available information from other sources
    PHR->>DNS: 2.4.1.1 Receive and validate the query request
    PHR->>HIS: 6.1.3.1 Receive Information
    DNS->>PHR: 2.4.1.2 Authenticate and verify the authorization of the requestor
    PHR->>HIS: 2.4.1.3 Authorize release of registration and medication data
    HIS-->>PHR: 2.4.1.4 Transmit registration and medication data to an authorized system
```



**Figure 2.2.4-3 Scenario 3: Authorized Healthcare Provider Reviews Registration Summary and Other Clinical Information**



## 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 events and actions of the design from the specified requirements. It also provides a detailed mapping of the specified requirements to the business and technical actors, and data elements. Groupings of specific actions and actors are illustrated to further describe the relevant interactions as 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 the Use Cases 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 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 - 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 the 2008 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 Care Delivery-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 environment 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
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



### 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
Support for the technical measures to ensure Security and Privacy of consumer health information	All



Pre-Condition	Scenario
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
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/T15 - Collect and Communicate Security Audit Trail Transaction HITSP/T16 - Consistent Time – Maintain time HITSP/TP30 - Manage Consent Directive – Capture/Request consent directive	All

In order to implement the information interchange conforming to this Interoperability Specification and its constructs in a real world environment, the implementer must insure that the implementing systems operate within 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, 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





Post-Condition	Use Case Scenario
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

### 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

## 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 these Use Cases.

### 3.2.1 TECHNICAL ACTORS ROLE DESCRIPTIONS

This section contains technical actor role descriptions for all scenarios. Note that a business actor is a representation of a person, IT system, organization or any combination that is engaged, and benefits from



the real world information interchange defined by a business Use Case, while a technical actor represents an entity internal to a software application, which is engaged in one or more specific Transactions to support a specific aspect of a real world information interchange (e.g. set of message exchanges). The table below describes the Technical actor roles involved and the correlation between active actors.

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

Technical Actor(s)	Actor Role
Content Creator	The Content Creator Actor is responsible for the creation of content and transmission to a Content Consumer
Content Consumer	A Content Consumer Actor is responsible for viewing, import, or other processing of content created by a Content Creator Actor
Portable Media Creator	The Portable Media Creator writes the selected information from a consumer's PHR to media following the directory structure outlined by XDM
Portable Media Importer	The Portable Media Importer processes all the contents written by a Portable Media Creator on the physical media. The Portable Media Importer must successfully process all documents
Audit Record Source	The Audit Record Source is the actor that, on behalf of another actor that performs an action requiring logging, creates and communicates an Audit Record to the Audit Record Repository
Time Client	The Time Client establishes time synchronization with one or more Time Servers using the NTP protocol and either the Network Time Protocol (NTP) or Simple Network Time Protocol (SNTP) algorithms. Maintains the local computer system clock synchronization with Coordinated Universal Time (UTC) based on synchronization with the Time Servers
Service User	The Service User entity represents any individual entity (such as a clinician or an EHR/PHR system) that needs to make a service request of a Service Provider. The Entity may also be known as a principal and/or entity, which represents an end user, an application, a machine, or any other type of entity that may act as a requester in a transaction. A principal is typically represented in a transaction with a digital identity and the principal may have multiple valid digital identities to use with different transaction
Identity Provider	The Identity Provider receives the credentials and identifier from the Entity (principal). It may perform authentication at that point or may require additional authentication from another source (the Service Provider)
Consent Originator	The Consent Originator captures consent directives and may publish the consent directive as a document. It is responsible for sending Manage Consent Directive Requests to a Consent Repository. It also supplies Metadata to the Consent Repository for subsequent registration of the Consent within a Consent Registry
User	The User is the entity that takes on the actor role of initiator or claimant. This is an initiator actor
User Access Control Service (UACS)	The UACS is the enterprise security service that supports and implements user-side access control capabilities. This is an initiator actor

### 3.2.2 TECHNICAL DESIGN

The technical design incorporates the comprehensive business and technical requirements and a detailed analysis of the interactions and decisions undertaken for the primary actions in each Use Case scenario. The UML sequence diagrams used in this section incorporates the detailed data requirements for the selected standards with the technical actors, and their specific and detailed interactions (encapsulated in HITSP constructs). The detailed actor interactions described in these more detailed diagrams show which HITSP constructs are used for the Interoperability Specification. Diagrams show all common or independent actors, data, actions, and groupings of actions around common actors.



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 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 USB key or a CD [see HITSP/T33 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.



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

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

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

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

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

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

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.

### ***Lab Report Document Using IHE XD\* Lab***

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 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).

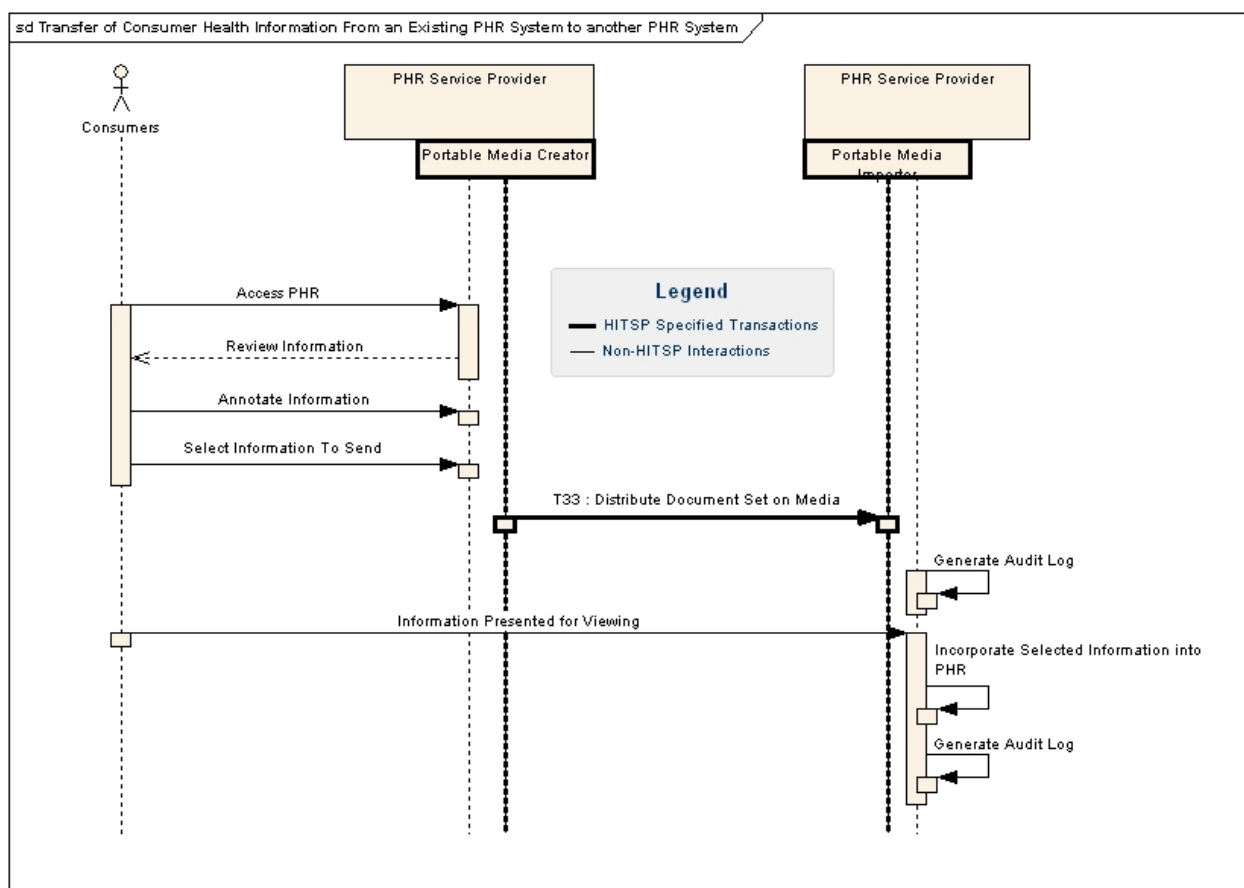
#### **3.2.2.1 Transfer of Consumer Health Information from an Existing PHR System to another PHR System Scenario Actor Interactions**

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 3.2.2.1-1.



**Figure 3.2.2.1-1 Transfer of Consumer Health Information from one PHR System to another PHR System on Media**



### 3.2.2.1.1 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 and/or HITSP/C37)]. 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) and/or HITSP/C37 - Lab Report Document and 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]

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

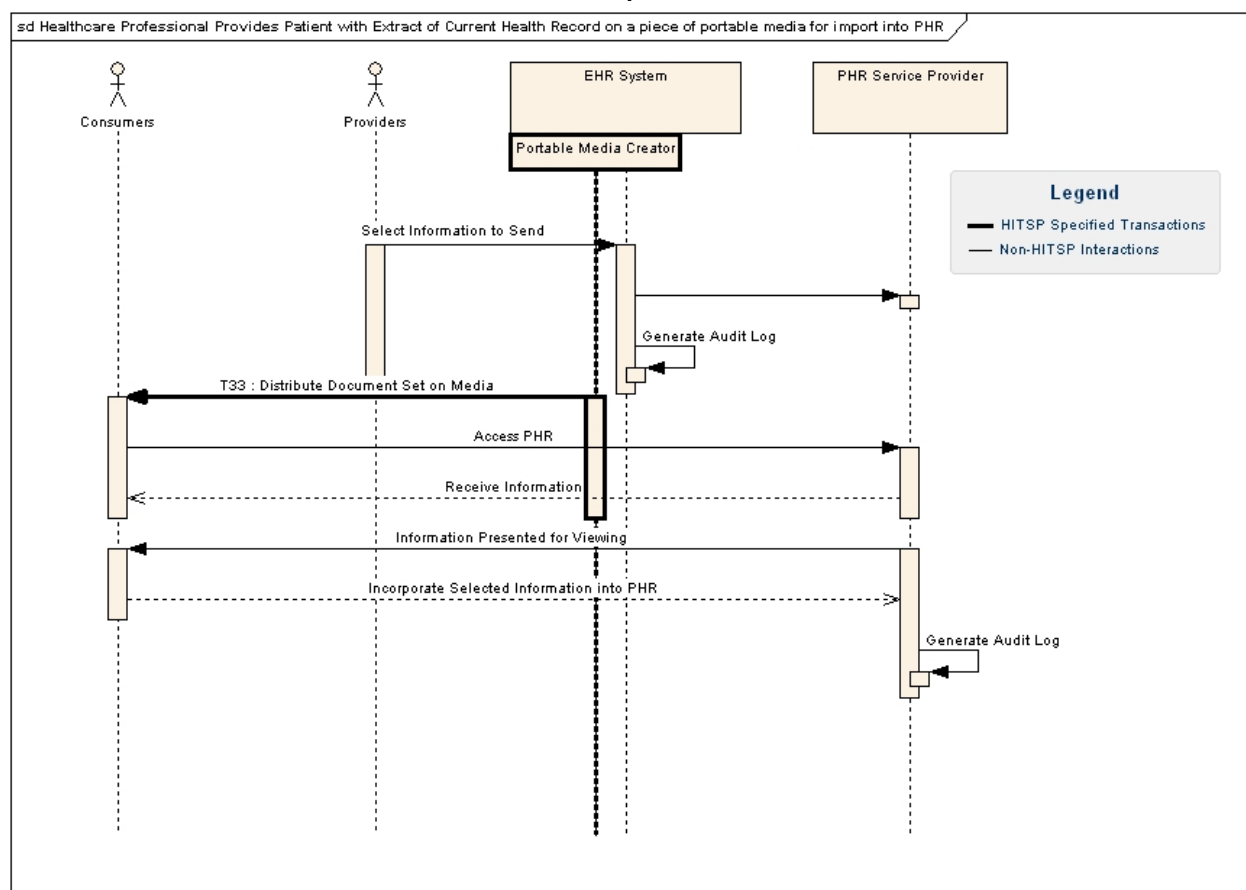
Following an office encounter with Mr. Everyperson, Dr. Doctor selects pertinent information from Mr. Everyperson's record in his EHR system, extracts it from this system (OfficeEHR), formats into the appropriate document format (as per HITSP/C32, HITSP/C37) and records it on portable media as described 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 3.2.2.2-1.



**Figure 3.2.2.2-1 Healthcare Professional Provides Patient with Extract of Current Health Record on Portable Media for Import into PHR**



### 3.2.2.2.1 Transaction Description

The detailed technical requirements for the actors interacting with the transactions shown in Figure 3.2.2.2-1 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 and/or HITSP/C37)]. 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) and/or HITSP/C37 - Lab Report 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) and/or HITSP/C37 - Lab Report Document 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].

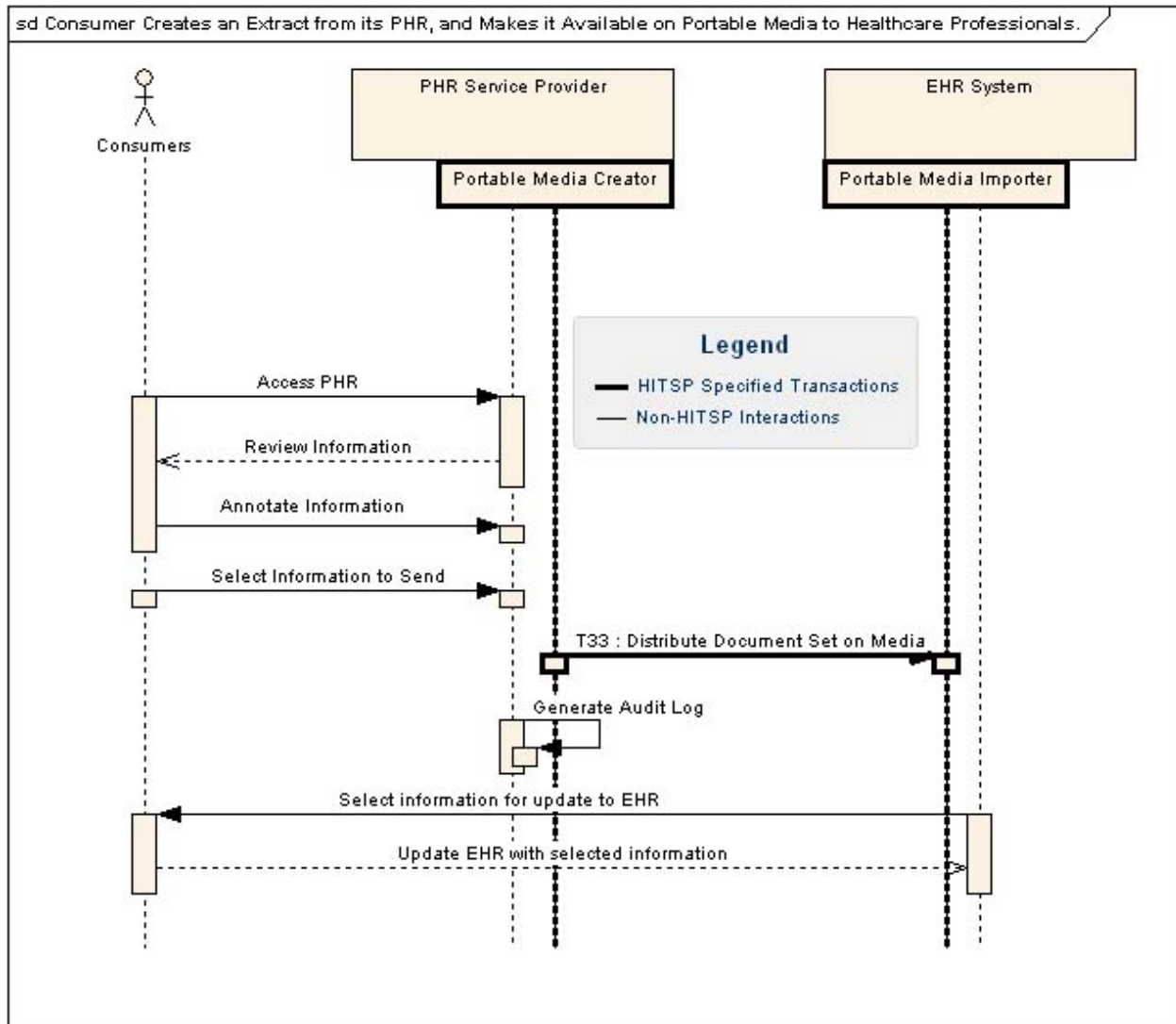
#### 3.2.2.3 Consumer Creates an Extract from its PHR, and Makes it Available on Portable Media to Healthcare Professionals of its choice

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) and/or HITSP/C37 - Lab Report Document) and records it on portable media as described in HITSP/T33 – Transfer of Documents on Media Transaction.

The sequence diagram is shown in Figure 3.2.2.3-1.



**Figure 3.2.2.3-1 Consumer Creates an Extract from its PHR, and makes it available on Portable Media to Healthcare Professionals**



### 3.2.2.3.1 Transaction Description

The detailed technical requirements for the actors interacting with the transactions shown in Figure 3.2.2.3-1 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) and/or HITSP/C37 - Lab Report Document 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 defined in the Interoperability Specification and depicted in the above detailed UML sequence diagram. Table 3.2.3-1 below specifies the requirements associated to each business actor in the Interoperability Specification. For each implemented business actor, the table specifies:

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.

A business actor is a representation of a person, IT system, organization or any combination that is engaged, and benefits from the real world information interchange defined by a business Use Case, while a technical actor represents an entity internal to a software application, which is engaged in one or more specific Transactions to support a specific aspect of a real world information interchange (e.g. set of message exchanges). The table below describes the optionality of the actors involved. It also describes the optionality of the HITSP constructs.



**Table 3.2.3-1 Business-Technical Actor Mapping to Transaction and/or Content with their Respective Optionality**

Business Actor	Technical Actor(s)	Actor Optionality*	Construct	Transaction/Content (T/C)	T/C Optionality*
Personal Health Record (PHR) Service Provider	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/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
				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/TP30	Consent Document Component	R
	Audit Record Source	R	HITSP/T15	Record Audit Event in Repository	R



Business Actor	Technical Actor(s)	Actor Optionality*	Construct	Transaction/Content (T/C)	T/C Optionality*
	Time Client	R	HITSP/T16	Maintain Time	R
	Service User	R	HITSP/C19	Convey Assertion	R
				Provide Assertion	O
	Identity provider	O	HITSP/C19	Provide Assertion	R
				Verify Assertion	O
				Verify Assertion	O
	Consent Originator	O	HITSP/TP30	Provide and Register Document Set	R
	User	R	HITSP/TP20	Access Control Request	O
Electronic Health Record (EHR) System	User Access Control Service (UACS)	R	HITSP/TP20	Access Control Request	O
	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]
			HITSP/C37	Lab Report Document Using IHE XD* Lab Component	C[201]
			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
				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



Business Actor	Technical Actor(s)	Actor Optionality*	Construct	Transaction/Content (T/C)	T/C Optionality*
				Consumer-Laboratory Discrete Data Import Subset (see Section 3.2.3.14)	O
			HITSP/C37	Consumer-Document Display Subset (See Section 3.2.3.9)	R
				Consumer-Document Import Subset (see Section 3.2.3.10)	O
				Consumer-Lab Report Discrete Data Import Subset (see Section 3.2.3.15)	O
			HITSP/TP30	Consent Document Component	R
	Audit Record Source	R	HITSP/T15	Record Audit Event in Repository	R
	Time Client	R	HITSP/T16	Maintain Time	R
	Time Server	O	HITSP/T16	Maintain Time	R
	Service User	R	HITSP/C19	Convey Assertion	R
				Provide Assertion	O
	Identity Provider	O	HITSP/C19	Provide Assertion	R
				Verify Assertion	O
	Consent Originator	O	HITSP/TP30	Provide and Register Document Set	R
	User	R	HITSP/TP20	Access Control Request	O
	User Access Control Service (UACS)	R	HITSP/TP20	Access Control Request	O

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

#### Actor Optionality Conditions

None.

#### Transaction/Content (T/C) Optionality Conditions

C[201] - Shall support either HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD) or HITSP/C37 - Lab Report Document Component, or both.

##### 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
Person Information	R



Content Modules	Optionality
Language Spoken	R2
Support	R2
Healthcare Provider	R2
Insurance Provider	R2
Pregnancy	R2
Information Source	R2
Comments	R2
Advance Directive	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
Person Information	R
Healthcare Provider	R2
Medications – Prescription and Non-Prescription	R2
Information Source	R2
Comments	R2
Immunization	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 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
Person Information	R
Healthcare Provider	R2
Condition	R2
Allergies and Drug Sensitivity	R2
Information Source	R2
Comments	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 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
Person Information	R
Healthcare Provider	R2
Result	R2
Information Source	R2
Comments	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 either document (e.g. HITSP/C32, HITSP/C37 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 either of the documents (e.g. HITSP/C32, HITSP/C37) 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 related 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 standards organization, as defined by HITSP, which publishes the standard. HITSP interprets approval to include Draft Standards for Trial Use. The objective is to incorporate only standards that are managed within a formal life cycle process as defined by the standards organization. In some cases, where we believe a standard that is not yet approved may best meet the requirements of an Interoperability Specification, HITSP may provide a roadmap of its future intent conditional on future actions by either or both the standards organizations and the HITSP Technical Committee. Thus there are four classes of HITSP-committed standards.

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

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

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

### 4.1.1 REGULATORY GUIDANCE

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

**Table 4.1.1-1 Regulatory Guidance**

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

### 4.1.2 SELECTED STANDARDS

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



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

Standard Name	HITSP Construct	Remarks/ Minor Gaps
CDC Race and Ethnicity Code Sets	HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD)	Underlying standard referenced in Health Level Seven (HL7) Version 3.0 Continuity of Care Document (CCD)
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 Medication Terminologies	HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD)	Underlying standard referenced in Health Level Seven (HL7) Version 3.0 Continuity of Care Document (CCD)
Health Level Seven (HL7) Clinical Document Architecture Release 2 (CDA R2)	HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD) HITSP/C37 - Lab Report Document	Re: HITSP/C32 - underlying standard referenced in Health Level Seven (HL7) Version 3.0 Continuity of Care Document (CCD)
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) Version 2.5	HITSP/TP22 - Patient ID Cross-Referencing	Underlying standard referenced in Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0
Health Level Seven (HL7) Version 2.5.1	HITSP/C35 - Lab Result Terminology	
Health Level Seven (HL7) Version 2.5/2.5.1	HITSP/T23 - Patient Demographics Query	
Health Level Seven (HL7) Version 3.0 Privacy Consent related specifications RCMR_RM010001 - Data Consent	HITSP/TP30 - Manage Consent Directives	
Healthcare Provider Taxonomy	HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD)	Underlying standard referenced in Health Level Seven (HL7) Version 3.0 Continuity of Care Document (CCD)
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Volume 2 Supplement 2007 – 2008 Cross-Enterprise User Assertion (XUA)	HITSP/C19 - Entity Identity Assertion	
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 3.0	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, Audit Trail and Node Authentication (ATNA) Integration Profile	HITSP/T15 - Collect and Communicate Security Audit Trail	



Standard Name	HITSP Construct	Remarks/ Minor Gaps
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0, Consistent Time (CT) Integration Profile	HITSP/T16 - Consistent Time	
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0, Patient Demographics Query (PDQ) Integration Profile	HITSP/T23 - Patient Demographics Query	
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0, Patient Identifier Cross-Referencing Integration Profile (PIX)	HITSP/TP22 - Patient ID Cross-Referencing	
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0, 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) Supplement 2007 - 2008 Basic Patient Privacy Consents (BPPC) – Trial Implementation	HITSP/TP30 - Manage Consent Directives	
Integrating the Healthcare Enterprise (IHE) Laboratory Technical Framework Volume 3 (LAB TF-3) Document-based Transactions, Revision 2.0 - For Trial Implementation, August 16, 2007	HITSP/C37 - Lab Report Document	
International Health Terminology Standards Development Organisation (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®)	HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD) HITSP/C35 - Lab Result Terminology	Underlying standard referenced in Health Level Seven (HL7) Version 3.0 Continuity of Care Document (CCD)
International Organization for Standardization (ISO) Health informatics - 9660 Level 1	HITSP/T33 - Transfer of Documents on Media	





Standard Name	HITSP Construct	Remarks/ Minor Gaps
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), The mailto URL (Uniform Resource Locators) scheme (RFC 2368) Proposed Standard	HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD)	
Internet Engineering Task Force (IETF), The tel URI (Uniform Resource Identifier) for Telephone Numbers (RFC 3966) Proposed Standard	HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD)	
Logical Observation Identifiers Names and Codes (LOINC®)	HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD) HITSP/C35 - Lab Result Terminology	Re: HITSP/C32 - underlying standard referenced in Health Level Seven (HL7) Version 3.0 Continuity of Care Document (CCD)
National Library of Medicine (NLM) Unified Medical Language System (UMLS) RxNorm	HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD)	
Organization for the Advancement of Structured Information Standards (OASIS) Security Assertion Markup Language (SAML) 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) WS-Federation Web Services Federation Language (WS- Federation), Version 1.1, December 2006	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	
Unified Code for Units of Measure (UCUM)	HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD) HITSP/C35 - Lab Result Terminology	Underlying standard referenced in Health Level Seven (HL7) Version 3.0 Continuity of Care Document (CCD)
USB Removable Device Type 2.0 (USB Implementers Forum)	HITSP/T33 - Transfer of Documents on Media	
XDM Supplement to the Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF)	HITSP/T33 - Transfer of Documents on Media	





#### 4.1.3 INFORMATIVE REFERENCE STANDARDS

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

**Table 4.1.3-1 Informative Reference Standards**

Standard Name	Description/Reason for Use
American National Standards Institute (ANSI) International Committee for Information Technology Standards (INCITS), #359-2004	This standard describes RBAC features that have achieved acceptance in the commercial marketplace. It includes a reference model and functional specifications for the RBAC features defined in the reference model. It is intended for (1) software engineers and product development managers who design products incorporating access control features; and (2) managers and procurement officials who seek to acquire computer security products with features that provide access control capabilities in accordance with commonly known and understood terminology and functional. For more information visit <a href="http://www.ansi.org">http://www.ansi.org</a>
American Society for Testing and Materials (ASTM) Standard Guide for Privilege Management Infrastructure (PMI) Guidelines: #E2595-07	<p>Defines interoperable mechanisms to manage privileges in a distributed environment. This standard is oriented towards support of a distributed or service-oriented architecture (SOA) where security services are themselves distributed and applications are consumers of distributed services. This standard incorporates privilege management mechanisms alluded to in a number of existing standards (e.g., E1986, E2084). The privilege mechanisms in this standard support policy-based access control (including role, entity and contextual-based access control) including the application of policy constraints, patient requested restrictions and delegation. Finally, the standard supports hierarchical, enterprise-wide privilege management</p> <p>The mechanisms defined in this standard may be used to support a privilege management infrastructure (PMI) using existing public key infrastructure (PKI) technology. This standard does not specifically support mechanisms based on secret-key cryptography. Mechanisms involving privilege credentials are specified in International Organization for Standardization (ISO) 9594-8:2000 (attribute certificates), and Organization for the Advancement of Structured Information Standards (OASIS) Security Assertion Markup Language (SAML) (attribute assertions); however, this standard does not mandate or assume the use of such standards</p> <p>Many current systems require only local privilege management functionality (on a single computer system). Such systems frequently use proprietary mechanisms. This standard does not address this type of functionality; rather, it addresses an environment where privileges and capabilities (authorizations) must be managed between computer systems across the enterprise, and with business partners. For more information visit <a href="http://www.astm.org">www.astm.org</a></p>



Standard Name	Description/Reason for Use
American Society for Testing and Materials (ASTM) Standard Specification for Audit and Disclosure Logs for Use in Health Information Systems: # E2147-01	E2147-01 "is for the development and implementation of security audit/disclosure logs for health information. It specifies how to design an access audit log to record all access to patient identifiable information maintained in computer systems and includes principles for developing policies, procedures, and functions of health information logs to document all disclosure of health information to external users for use in manual and computer systems. The process of information disclosure and auditing should conform, where relevant, with the Privacy Act of 1974 (1)." For more information visit <a href="http://www.astm.org">www.astm.org</a>
Council for Affordable Quality Health Care (CAQH) Committee on Operating Rules for Information Exchange (CORE) Phase I Operating Rules	Provide agreed-upon business rules and guidelines for using and processing eligibility inquiry and response transactions between providers and health plans; in particular those that have been adopted under HIPAA. For more information visit <a href="http://www.caqh.org">www.caqh.org</a>
Health Level Seven (HL7) Consent related vocabulary including Confidentiality Codes	HL7 concept domains, including ConfidentialityCodes, ActInformationCategoryCode, ActInformationAccessType, ActInformationAccessContextCode, AuthorizedParticipationFunctionCode, ActPolicyType, ActConsentType, and ActMaskableCode For more information visit <a href="http://www.hl7.org">www.hl7.org</a>
Health Level Seven (HL7) V3 RBAC, R1-2008, HL7 Version 3 Standard: Role Based Access Control (RBAC) Healthcare Permissions Catalog, Release 1, February 2008	The Healthcare Permission Catalog provides the necessary content for creating interoperable roles facilitating inter-organizational communications and information sharing among healthcare organizations and their business partners. For more information visit <a href="http://www.hl7.org">www.hl7.org</a>
Health Level Seven (HL7) Version 3.0	The HL7 Version 3.0 Messaging Standard is an application protocol for electronic data exchange in healthcare. Version 3.0 is based on a Reference Information Model (RIM); which is used to instantiate various message formats. Value sets / code tables are contained in the standard. For more information visit <a href="http://www.hl7.org">www.hl7.org</a>
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0	The IHE IT Infrastructure Technical Framework defines specific implementations of established standards to achieve integration goals that promote appropriate sharing of health information to support optimal patient care. IHE Integration Profiles offer a common language that healthcare professionals and vendors may use in communicating requirements for the integration of products. The current version of the ITI-TF, rev. 4.0 for Final Text, specifies the IHE transactions defined and implemented as of August 22, 2007. The latest version of the IHE Technical Framework is available at <a href="http://www.ihe.net">www.ihe.net</a>



Standard Name	Description/Reason for Use
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0, 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 <a href="http://www.ihe.net">www.ihe.net</a>
Integrating the Healthcare Enterprise (IHE) Patient Care Coordination (PCC) Technical Framework Revision 1.0	The IHE Patient Care Coordination Technical Framework (PCC TF) defines specific implementations (called Integration Profiles) of established standards to deal with integration issues that cross providers, patient problems or time. The Cross-Enterprise Document Sharing of Medical Summaries (XDS-MS) Integration Profile enables sharing of health information between enterprises of a regional health network, and further describes how to map content in a CDA medical document into registry metadata. In the registry, healthcare providers publish pointers to documents stored in distributed repositories. Other healthcare providers may search and retrieve these and other documents. For more information visit <a href="http://www.ihe.net">www.ihe.net</a>
Integrating the Healthcare Enterprise (IHE) Patient Care Coordination (PCC), Revision 3.0, 2007 - 2008	The IHE Patient Care Coordination Technical Framework (PCC TF) defines specific implementations (called Integration Profiles) of established standards to deal with integration issues that cross providers, patient problems or time. The Cross-Enterprise Document Sharing of Medical Summaries (XDS-MS) Integration Profile enables sharing of health information between enterprises of a regional health network, and further describes how to map content in a CDA medical document into registry metadata. In the registry, healthcare providers publish pointers to documents stored in distributed repositories. Other healthcare providers may search and retrieve these and other documents. For more information visit <a href="http://www.ihe.net">www.ihe.net</a>
International Organization for Standardization (ISO) Health informatics -- Information technology -- Open Systems Interconnection -- Systems Management: Security alarm reporting function, Technical Specification #10164-- Part 7: Security Alarm Reporting Function, 1992	Establishes user requirements for the service definition needed to support the security alarm reporting function, defines the service provided by the security alarm reporting function, specifies the protocol that is necessary in order to provide the service, defines the relationship between the service and management notifications, defines relationships with other systems management functions, specifies conformance requirements. The security alarm reporting function is a systems management function which may be used by an application process in a centralized or decentralized management environment to exchange information for the purpose of systems management. For more information visit <a href="http://www.iso.org">www.iso.org</a>
International Organization for Standardization (ISO) Health informatics -- Information technology -- Text and office systems - Office Document Architecture (ODA) and interchange format, Technical Report on ISO 8613 implementation testing, Technical Specification # ISO/IEC CD 10183 -- Part 3: Testing procedure.	Specifies a general framework for the provision of access control. The purpose of access control is to counter the threat of unauthorized operations involving a computer or communication system. For more information visit <a href="http://www.iso.org">www.iso.org</a>



Standard Name	Description/Reason for Use
International Organization for Standardization (ISO) Health informatics -- Privilege management and access control(PMAC), Technical Specification #22600 -- Part 1: Overview and policy management, July 2006	Supports the needs of healthcare information sharing across unaffiliated providers of healthcare, healthcare organizations, health insurance companies, their patients, staff members and trading partners. It is also intended to support inquiries from both individuals and application systems. For more information visit <a href="http://www.iso.org">www.iso.org</a>
International Organization for Standardization (ISO) Health informatics – Functional and Structural Roles (ISO SF Roles), Technical Specification #21298 , Draft May, 2007	<p>This document contains a specification for encoding information related to roles for health professionals and consumers. At least four areas have been identified where a model for encoding role information is needed</p> <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. For more information visit <a href="http://www.iso.org">www.iso.org</a></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 <a href="http://www.cancer.gov">www.cancer.gov</a>
Organization for the Advancement of Structured Information Standards (OASIS) Security Assertion Markup Language (SAML) Core v2.0 OASIS Standard; ITU-T X.1141	SAML, developed by the Security Services Technical Committee of OASIS, is an XML-based framework for communicating user authentication, entitlement, and attribute information. As its name suggests, SAML allows business entities to make assertions regarding the identity, attributes, and entitlements of a subject (an entity that is often a human user) to other entities, such as a partner company or another enterprise application. For more information visit <a href="http://www.oasis-open.org">www.oasis-open.org</a>



Standard Name	Description/Reason for Use
Organization for the Advancement of Structured Information Standards (OASIS) Web Services Security SOAP Message Security Version 1.0	Describes enhancements to SOAP messaging to provide message integrity and confidentiality. The specified mechanisms can be used to accommodate a wide variety of security models and encryption technologies. This specification also provides a general-purpose mechanism for associating security tokens with message content. No specific type of security token is required, the specification is designed to be extensible (i.e., support multiple security token formats. Additionally, this specification describes how to encode binary security tokens, a framework for XML-based tokens, and how to include opaque encrypted keys. It also includes extensibility mechanisms that can be used to further describe the characteristics of the tokens that are included with a message. For more information visit <a href="http://www.oasis-open.org">www.oasis-open.org</a>
Organization for the Advancement of Structured Information Standards (OASIS) Simple Object Access Protocol (SOAP) Version 1.1	SOAP is a protocol specification for invoking methods on servers, services, components and objects. SOAP codifies the existing practice of using XML and HTTP as a method invocation mechanism. The SOAP specification mandates a small number of HTTP headers that facilitate firewall/proxy filtering plus an XML vocabulary that is used for representing method parameters, return values, and exceptions." (DevelopMentor) SOAP consists of three parts: an envelope that defines a framework for describing what is in a message and how to process it, a set of encoding rules for expressing instances of application-defined data types, and a convention for representing remote procedure calls and responses. For more information visit <a href="http://www.oasis-open.org">www.oasis-open.org</a>
Organization for the Advancement of Structured Information Standards (OASIS) – ebXML Registry Information Model (3.0)	The Registry Information Model provides a blueprint or high-level schema for the ebXML Registry. Its primary value is for implementers of ebXML Registries. It provides these implementers with information on the type of metadata that is stored in the Registry as well as the relationships among metadata Classes. The Registry information model: a) Defines what types of objects are stored in the Registry; b) Defines how stored objects are organized in the Registry. For more information visit <a href="http://www.oasis-open.org">www.oasis-open.org</a>
Organization for the Advancement of Structured Information Standards (OASIS) – ebXML Registry Services Specification (3.0)	The ebXML Registry provides a set of services that enable sharing of information between interested parties for the purpose of enabling business process integration between such parties based on the ebXML specifications. The shared information is maintained as objects in a repository and managed by the ebXML Registry Services defined in this document. For more information visit <a href="http://www.oasis-open.org">www.oasis-open.org</a>
Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity	This classification provides a minimum standard for maintaining, collecting, and presenting data on race and ethnicity for all Federal-reporting purposes. The categories in this classification are social-political constructs and should not be interpreted as being scientific or anthropological in nature. The standards have been developed to provide a common language for uniformity and comparability in the collection and use of data on race and ethnicity by Federal agencies. For more information visit <a href="http://www.census.gov">www.census.gov</a>

## 4.2 GAPS WHERE THERE ARE NO STANDARDS

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



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

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

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



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

Event Code	Event Description	Identified Gaps	Recommended Resolution
2.1.5.0	Modify registration/medication 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
2.1.5.0	Modify registration/medication data	A robust terminology that allows consumers to qualify the role of their healthcare providers in their registration summary is lacking. The Use Case was addressed without such a terminology, but further extensions will likely require its definition	<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>
2.1.5.0	Modify registration/medication data	There is no recognized standard or vocabulary in the industry regarding how the dose calculation is to be explicitly expressed	The medication history needs to include an entry for dose calculation including weight dosing. We should monitor and encourage standards progress in both NCPDP and HL7 in this regard

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.

**Table 4.2-2 Work Item Analysis and Scoping**

Work Items	Work Set	Reason for Classification Result
Advance Directives (AD)	2008 cycle	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 Encourage State Health Alliance work to address this topic Acknowledge the gap that exists in the industry to do something better in this regard, however, this is not work that is currently requested in the current Use Case. Since we’re modifying HITSP/C32 we will add this to the Gap table. Awaiting HISPC to address the X-State disjointed solution in terms of policy as a prerequisite
Med/Labs Info in Consumer-friendly Manner	2008 cycle	American College of Physicians has worked with HL7 regarding its Context-aware information retrieval activity which can likely be leveraged to query for “consumer friendly” knowledge. Standard expected to be approved by HL7 in 2008
PHR Portability – via a data network-based exchange	2008 cycle	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 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
Permission Lists for PHR Portability	2008 cycle	HL7 is currently balloting a “permissions catalogue.” Need definition of provider roles (static & dynamic)...some of this may be available but may vary State-to-State The Use Case includes the access to pharmacy information at PBMs by providers (7.2.1) It needs to be determined if this mandates different query/response solutions for different types of information (e.g. NCPDP-based message exchange)
Distributed Management of Access Control	2008 cycle	To be handled by HITSP Security and Privacy Technical Committee (SP TC) in its entirety. 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: 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 Leverage and extend HITSP SPTC work regarding the definition of an HIE-level access control technical actor





Work Items	Work Set	Reason for Classification Result
Provider List(s)	2008 cycle	<p>Major gap in the specification of a provider registry (if using the HIE variant); its content, privacy issues, organization-provider relationship(s), and organization-organization relationship(s). Also, if this is related to addressing the permissions issue then are there other organizations/individuals that we need to cover as well. This provider list is required for inclusion in /association to the permissions/access control entries</p> <p>1. Need to do query/retrieve access with a provider registry (assumes that one exists and is maintained) or do pt-to-pt request (in-person, phone) to a healthcare entity. The entity pushes this info to the consumer (using HITSP/C32). 2. Consumer creates and is capable of communicating this list to others (method for building the relationship to permissions?)</p> <p>Consider existing payor-provided portals to provider lists for its members as a source of provider list content</p>
Audit Logs / Disclosure Logs	2008 cycle	<p>There is existing work re audit logs (EHRSM IN 2.2, RFC 3881, IHE ATNA, ), and some use of the term "disclosure logs" exists in HIPAA (Section 164.528), but nothing standards-based regarding Disclosure Logs as described in the Use Case. The definition of a standard format and the content for an interoperable disclosure log is to be addressed by the HITSP SPTC</p> <p>If the PHR contains a pointer to information, how does this get reflected in the audit/disclosure logs?</p>
PHR Location	2008 cycle	<p>There is no known standard for expressing the "address" for information destined for someone's PHR.</p> <p>Need to identify if there is an element in the HITSP/C32 currently for retaining this info, also how do we specify this content to be used for the different types of info exchange?</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> <p>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)</p> <p>2. Data level access controls to the elements within a PHR (better managed by the PHR itself when the query is received)</p> <p>Is there any work regarding the definition of an HIE-level access control technical actor (e.g. from HITSP SPTC)?</p>

### 4.3 STANDARD OVERLAPS

This section describes the instances where there are overlaps among standards for the Use Case. The overlap is only relative to the specific Use Case event. Overlaps refer to instances wherein some of the requirements are met by multiple standards. The overlap is only relative to the specific events for the set of Use Cases for Consumer Empowerment noted in section 1.4. 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 Standard Overlaps**

Event Code	Event Description	Standard Overlap	Recommended Resolution
	View registration/medication data	<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>	HITSP recommends that a standardized terminology be developed that might be used in future releases of this Component. The HL7 Security Technical Committee is presently working with the VHA Role Based Access Control Task Force (RBAC-TF) to develop materials describing the roles of providers, for the purposes of supporting access controls. The present work nearly met the needs of HITSP lacking only coded terms to describe the roles
	View registration/medication data	For the Registration Summary and Medication History Document, two base standards may be used: HL7 CDA Rel 2 and ASTM CCR. For PHR information exchange "on the wire", this specification selected the use of the CCD implementation guide resulting from the harmonization work performed by ASTM and HL7	See Section 4.3.1



## 5.0 TECHNICAL IMPLEMENTATION

### 5.1 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.

#### 5.1.1 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 5.1.2 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 specification, available at [www.hitsp.org](http://www.hitsp.org).

#### 5.1.2 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.



### 5.1.3 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.

An HIT Implementation Testing Web Site has been developed in collaboration with HITSP, NIST, CCHIT, and ONC to advance conformance and interoperability testing capabilities. This Web Site provides HIT implementers with the necessary resources to support and test their implementation of standards-based health systems. A link to the Web Site can be found on [www.hitsp.org](http://www.hitsp.org).



## 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 standards that are referenced by this Interoperability Specification.

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	Description
CDC Race and Ethnicity Code Sets	The U.S. Centers for Disease Control and Prevention (CDC) has prepared a code set for use in coding race and ethnicity data. This code set is based on current federal standards for classifying data on race and ethnicity, specifically the minimum race and ethnicity categories defined by the U.S. Office of Management and Budget (OMB) and a more detailed set of race and ethnicity categories maintained by the U.S. Bureau of the Census (BC). The main purpose of the code set is to facilitate use of federal standards for classifying data on race and ethnicity when these data are exchanged, stored, retrieved, or analyzed in electronic form. At the same time, the code set can be applied to paper-based record systems to the extent that these systems are used to collect, maintain, and report data on race and ethnicity in accordance with current federal standards. For more information visit <a href="http://www.cdc.gov">www.cdc.gov</a>
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 healthcare 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 <a href="http://medical.nema.org">http://medical.nema.org</a>
Federal Medication Terminologies	<p>A set of controlled terminologies and code sets developed and maintained as part of a collaboration between the Food and Drug Administration, National Library of Medicine, Veterans Health Administration, National Cancer Institute and Agency for Healthcare Research and Quality related to medications, including medication proprietary and nonproprietary names, clinical drug code (RxNorm); ingredient names and Unique Ingredient Identifiers (UNII); routes of administration, dosage forms, and units of presentation from the NCI Thesaurus (NCIt); and certain pharmacological drug classes from the National Drug File Reference Terminology (NDF-RT) .</p> <p>The Federal Medication Terminology leverages medication models maintained by the Food and Drug Administration (ex. UNII, NDC Codes), National Library of Medicine (RxNorm), the Veterans Health Administration (NDF-RT), and the National Cancer Institute (NCIt).</p> <p>Information on the Federal Medication Terminologies may be found and downloaded from the NCI Web portal terminology resources page at <a href="http://www.cancer.gov/cancertopics">www.cancer.gov/cancertopics</a></p>



Standard	Description
Health Care Provider Taxonomy	The Health Care Provider Taxonomy code set is a collection of unique alphanumeric codes, ten characters in length. The Health Care Provider Taxonomy code set includes specialty categories for individuals, groups of individuals, and non-individuals. The National Uniform Claims Committee maintains this code set. The complete code set is available from the Washington Publishing Company at <a href="http://www.wpc-edi.com">www.wpc-edi.com</a>
Health Level Seven (HL7) Clinical Document Architecture Release 2 (CDA R2)	The HL7 Clinical Document Architecture is an XML-based document markup standard that specifies the structure and semantics of clinical documents for the purpose of exchange. CDA is one instantiation of HL7's Version 3.0 Reference Information Model (RIM) into a specific message format. Of particular focus for HITSP Interoperability Specifications are message formats for Laboratory Results and Continuity of Care (CCD) documents. Release 2 of the HL7 Clinical Document Architecture (CDA) is an extension to the original CDA document markup standard that specifies the structure and semantics of clinical documents for the purpose of exchange. CDA R2 includes a prose document in HTML, XML schemas, data dictionary, and sample CDA documents. CDA R2 further builds upon other HL7 standards beyond just the Version 3.0 Reference Information Model (RIM) and incorporates Version 3.0 Data Structures, Vocabulary, and the XML Implementation Technology Specifications for Data Types and Structures. For more information visit <a href="http://www.hl7.org">www.hl7.org</a>
Health Level Seven (HL7) Implementation Guide: CDA Release 2 – Continuity of Care Document (CCD), April 01, 2007	The Continuity of Care Document implementation guide describes constraints on the HL7 Clinical Document Architecture, Release 2 (CDA) specification in accordance with requirements set forward in ASTM E2369-05 Standard Specification for Continuity of Care Record (CCR). The resulting specification, known as the Continuity of Care Document (CCD), is developed as a collaborative effort between ASTM and HL7. It is intended as an alternate implementation to the one specified in ASTM ADJE2369 for those institutions or organizations committed to implementation of the HL7 Clinical Document Architecture
Health Level Seven (HL7) V3 RBAC, R1-2008, HL7 Version 3 Standard: Role Based Access Control (RBAC) Healthcare Permissions Catalog, Release 1, February 2008	The Healthcare Permission Catalog provides the necessary content for creating interoperable roles facilitating inter-organizational communications and information sharing among healthcare organizations and their business partners. For more information visit <a href="http://www.hl7.org">www.hl7.org</a>
Health Level Seven (HL7) Version 2.5	The HL7 Version 2.5 Messaging Standard is an application protocol for electronic data exchange in healthcare. It and prior versions have widespread use in the U.S. and internationally. Both message formats and value sets / code tables (e.g., diagnosis type, gender, patient class, result status, specimen collection method, abnormal flags, observation result status codes interpretation, timestamp format) are contained in the standard. Of particular focus for HITSP Interoperability Specifications are message formats described in Chapters 2, 3, 5, and 7 including patient demographic (ADT) and lab result reporting. These are also used within composite standards from IHE for Patient Identity Cross-Referencing and Feed (PIX), Patient Demographics Query (PDQ), and Acknowledgements. For more information visit <a href="http://www.hl7.org">www.hl7.org</a>
Health Level Seven (HL7) Version 2.5.1	The HL7 Version 2.5.1 Messaging Standard is an application protocol for electronic data exchange in healthcare. It and prior versions have widespread use in the U.S. and internationally. Both message formats and value sets / code tables (e.g., diagnosis type, gender, patient class, result status, specimen collection method, abnormal flags, observation result status codes interpretation, timestamp format) are contained in the standard. Of particular focus for HITSP Interoperability Specifications are message formats described in Chapters 2, 3, 4, 5, and 7 including patient demographic (ADT) and lab result reporting. These are also used within composite standards from IHE for Patient Identity Cross-Referencing and Feed (PIX), Patient Demographics Query (PDQ), and Acknowledgements. They are also used in HL7 order messages. For more information visit <a href="http://www.hl7.org">www.hl7.org</a>



Standard	Description
Health Level Seven (HL7) Version 2.5/2.5.1	The HL7 Version 2.5 and 2.5.1 Messaging Standard is an application protocol for electronic data exchange in healthcare. It and prior versions have widespread use in the U.S. and internationally. Both message formats and value sets / code tables (e.g., diagnosis type, gender, patient class, result status, specimen collection method, abnormal flags, observation result status codes interpretation, timestamp format) are contained in the standard. Of particular focus for HITSP Interoperability Specifications are message formats described in Chapters 2, 3, 4, 5, and 7 including patient demographic (ADT) and lab result reporting. These are also used within composite standards from IHE for Patient Identity Cross-Referencing and Feed (PIX), Patient Demographics Query (PDQ), and Acknowledgements. They are also used in HL7 order messages. For more information visit <a href="http://www.hl7.org">www.hl7.org</a>
Health Level Seven (HL7) Version 3.0 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 <a href="http://www.hl7.org">www.hl7.org</a>
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Volume 2 Supplement 2007 – 2008 Cross-Enterprise User Assertion (XUA)	The Cross-Enterprise User Assertion Profile (XUA) provides a means to communicate claims about the user identity of an authenticated principal (user, application, system...) in transactions that cross enterprise boundaries. To provide accountability in these cross enterprise transactions there is a need to identify the requesting user in a way that the receiver can make access decisions and proper audit entries. The XUA Profile supports enterprises that have chosen to have their own user directory with their own unique method of authenticating the entities, and others that may have chosen to use a third party to perform the authentication. The latest version of the IHE framework is available at <a href="http://www.ihe.net">www.ihe.net</a>
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 3.0	The IHE IT Infrastructure Technical Framework defines specific implementations of established standards to achieve integration goals that promote appropriate sharing of health information to support optimal patient care. IHE Integration Profiles offer a common language that healthcare professionals and vendors may use in communicating requirements for the integration of products. The current version of the ITI-TF, rev.3.0 for Final Text, specifies the IHE transactions defined and implemented as of December 9, 2006. The latest version of the IHE Technical Framework is available at <a href="http://www.ihe.net">www.ihe.net</a>
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0, 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 <a href="http://www.ihe.net">www.ihe.net</a>
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0, 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, rev. 4.0 for Final Text, specifies the IHE CT Integration Profile, and other transactions defined and implemented as of August 22, 2007. The latest version of the IHE Technical Framework is available at <a href="http://www.ihe.net">www.ihe.net</a>





Standard	Description
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0, Patient Demographics Query (PDQ) Integration Profile	Provides ways for multiple distributed applications to query a central patient information server for a list of patients, based on user-defined search criteria, and retrieve a patient's demographic (and, optionally, visit or visit-related) information directly into the application. The latest version of the IHE Technical Framework is available at <a href="http://www.ihe.net">www.ihe.net</a>
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0, Patient Identifier Cross-Referencing Integration Profile (PIX)	<p>The Patient Identifier Cross-referencing Integration Profile (PIX) is targeted at healthcare enterprises of a broad range of sizes (hospital, a clinic, a physician office, etc.). It supports the cross-referencing of patient identifiers from multiple Patient Identifier Domains via the following interactions: 1) The transmission of patient identity information from an identity source to the Patient Identifier Cross-reference Manager. 2) The ability to access the list(s) of cross-referenced patient identifiers either via a query/ response or via update notification.</p> <p>By specifying the above transactions among specific actors, this integration profile does not define any specific enterprise policies or cross-referencing algorithms. By encapsulating these behaviors in a single actor, this integration profile provides the necessary interoperability while maintaining the flexibility to be used with any cross-referencing policy and algorithm as deemed adequate by the enterprise.. The latest version of the IHE Technical Framework is available at <a href="http://www.ihe.net">www.ihe.net</a></p>
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0, Section 10 Cross-Enterprise Document Sharing (XDS.a)	The IHE IT Infrastructure Technical Framework defines specific implementations of established standards to achieve integration goals that promote appropriate sharing of health information to support optimal patient care. Section 10, Cross-Enterprise Document Sharing facilitates the registration, distribution and access across health enterprises of patient electronic health records. IHE Integration Profiles offer a common language that healthcare professionals and vendors may use in communicating requirements for the integration of products. The current version of the ITI-TF, rev. 4.0 for Final Text, specifies the IHE transactions defined and implemented as of August 22, 2007. The latest version of the IHE Technical Framework is available at <a href="http://www.ihe.net">www.ihe.net</a>
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Volume 2 Supplement 2007 – 2008 Cross-Enterprise Document Sharing-B (XDS.b)	The Cross-Enterprise Document Sharing-B Profile (XDS.b) supplement provides a new implementation choice for the Cross-Enterprise Document Sharing (XDS) Integration Profile based on use of the Web Services and ebXML Reg/Rep standards that is consistent with current developments and best practices in the industry. For more information visit <a href="http://www.ihe.net">www.ihe.net</a>
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0 - Registry Stored Query Transaction for XDS Profile Supplement [ITI-18]	The IHE IT Infrastructure Technical Framework defines specific implementations of established standards to achieve integration goals that promote appropriate sharing of health information to support optimal patient care. IHE Integration Profiles offer a common language that healthcare professionals and vendors may use in communicating requirements for the integration of products. The Registry Stored Query Transaction Trial Implementation Supplement specifies an IHE transaction that provides optimization and implementation simplification. This supplement is available at <a href="http://www.ihe.net">www.ihe.net</a>
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0 XCA Supplement	The IHE IT Infrastructure Technical Framework defines specific implementations of established standards to achieve integration goals that promote appropriate sharing of health information to support optimal patient care. IHE Integration Profiles offer a common language that healthcare professionals and vendors may use in communicating requirements for the integration of products. The trial implementation version of the XCA Supplement to the ITI-TF, rev. 4.0 Final Text, specifies the IHE transactions that support access between communities in a manner compatible with the XDS Integration profile. This supplement is available at <a href="http://www.ihe.net">www.ihe.net</a>





Standard	Description
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. The latest version of specification is available at <a href="http://www.ihe.net">www.ihe.net</a>
Integrating the Healthcare Enterprise (IHE) Laboratory Technical Framework Volume 3 (LAB TF-3) Document-based Transactions, Revision 2.0 - For Trial Implementation, August 16, 2007	The IHE Laboratory Technical Framework introduces a content Integration Profile Sharing Laboratory Reports (LAB TF-3) that describes a clinical laboratory report as a human-readable electronic document. This document, which may also contain data in a machine-readable format and contains the complete set of final results produced by a clinical laboratory in fulfillment of one or more test orders for a patient. This document is focused on the sharing of sets of laboratory results in the form of a laboratory report structured document, and is not intended to address ordering or return of laboratory results to the ordering provider. For more information visit <a href="http://www.ihe.net">www.ihe.net</a>
International Health Terminology Standards Development Organisation (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®)	SNOMED CT consists of a technical design, core content architecture, and Core content. SNOMED CT Core content includes the technical specification of SNOMED CT and fully integrated multi-specialty clinical content. The Core content also includes a concepts table, description table, relationships table, history table, ICD-9-CM mapping, and Technical Reference Guide. Additionally, SNOMED CT provides a framework to manage language dialects, clinically relevant subsets, qualifiers and extensions, as well as concepts and terms unique to particular organizations or localities. For more information visit <a href="http://www.ihtsdo.com">www.ihtsdo.com</a>
International Organization for Standardization (ISO) 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 <a href="http://www.iso.org">www.iso.org</a>
Internet Engineering Task Force (IETF) Network Time Protocol (Version 3) Specification, Implementation and Analysis, "Request for Comment" (RFC) # 1305, March, 1992	Describes the Network Time Protocol (NTP): the mechanisms to synchronize time and coordinate time distribution in a large, diverse internet operating at rates from mundane to lightwave. For more information visit <a href="http://www.ietf.org">www.ietf.org</a>
Internet Engineering Task Force (IETF) Simple Network Time Protocol (SNTP) Version 4, "Request for Comment" (RFC) # 2030, October, 1996	Describes the Simple Network Time Protocol (SNTP) Version 4, which is an adaptation of the Network Time Protocol (NTP). SNTP can be used when the ultimate performance of the full NTP implementation is not needed or justified. When operating with current and previous NTP and SNTP versions, SNTP Version 4 involves no changes to the NTP specification or known implementations, but is rather a clarification of certain design features of NTP. For more information visit <a href="http://www.ietf.org">www.ietf.org</a>
Internet Engineering Task Force (IETF), The mailto URL (Uniform Resource Locators) scheme (RFC 2368) Proposed Standard	This document defines the format of Uniform Resource Locators (URL) for designating electronic mail addresses. It is one of a suite of documents which replace RFC 1738, 'Uniform Resource Locators', and RFC 1808, 'Relative Uniform Resource Locators'. The syntax of 'mailto' URLs from RFC 1738 is extended to allow creation of more RFC 822 messages by allowing the URL to express additional header and body fields. For more information visit <a href="http://www.ietf.org">www.ietf.org</a>
Internet Engineering Task Force (IETF), The tel URI (Uniform Resource Identifier) for Telephone Numbers (RFC 3966) Proposed Standard	This document specifies the URI (Uniform Resource Identifier) scheme "tel". The "tel" URI describes resources identified by telephone numbers. This document obsoletes RFC 2806. For more information visit <a href="http://www.ietf.org">www.ietf.org</a>



Standard	Description
Logical Observation Identifiers Names and Codes (LOINC®)	A database of universal identifiers for laboratory and other clinical observations. The laboratory portion of the LOINC database contains the usual categories of chemistry, hematology, serology, microbiology (including parasitology and virology), and toxicology; as well as categories for drugs and the cell counts typically reported on a complete blood count or a cerebrospinal fluid cell count. Antibiotic susceptibilities are a separate category. The clinical portion of the LOINC database includes entries for vital signs, hemodynamics, intake/output, EKG, obstetric ultrasound, cardiac echo, urologic imaging, gastroendoscopic procedures, pulmonary ventilator management, selected survey instruments, and other clinical observations. For more information visit <a href="http://www.loinc.org">www.loinc.org</a>
National Library of Medicine (NLM) Unified Medical Language System (UMLS) RxNorm	Provides standard names for (1) clinical drugs and (2) drug dose forms as administered to a patient. Also provides links from clinical drugs, both branded and generic, to their active ingredients, drug components (active ingredient + strength), and related brand names. Food and Drug Administration (FDA) National Drug Codes (NDCs) for specific drug products and many of the drug vocabularies commonly used in pharmacy management and drug interaction software are additionally linked to RxNorm. RxNorm is a part of the Federal Medication Terminologies. For more information visit <a href="http://www.nlm.nih.gov">www.nlm.nih.gov</a>
Organization for the Advancement of Structured Information Standards (OASIS) Security Assertion Markup Language (SAML) v2.0 OASIS Standard; ITU-T X.1141	SA SAML, developed by the Security Services Technical Committee of OASIS, is an XML-based framework for communicating user authentication, entitlement, and attribute information. As its name suggests, SAML allows business entities to make assertions regarding the identity, attributes, and entitlements of a subject (an entity that is often a human user) to other entities, such as a partner company or another enterprise application. For more information visit <a href="http://www.oasis-open.org">www.oasis-open.org</a>
Organization for the Advancement of Structured Information Standards (OASIS) WS-Trust Version 1.3, March 2007	Defines extensions that build on [WS-Security] to provide a framework for requesting and issuing security tokens, and to broker trust relationships. Defines Security Token Service (STS) model for security tokens including requesting, issuing, renewing, canceling and validating. For more information visit <a href="http://www.oasis-open.org">www.oasis-open.org</a>
Organization for the Advancement of Structured Information Standards (OASIS) WS-Federation Web Services Federation Language (WS- Federation), Version 1.1, December 2006	Defines mechanisms to allow different security realms to federate, such that authorized access to resources managed in one realm can be provided to security principals whose identities and attributes are managed in other realms. This includes mechanisms for brokering of identity, attribute, authentication and authorization assertions between realms, and privacy of federated claims. For more information visit <a href="http://www.oasis-open.org">www.oasis-open.org</a>
Organization for the Advancement of Structured Information Standards (OASIS) eXtensible Access Control Markup Language (XACML), ITU-T Recommendation X.1142, February 2005	The Organization for the Advancement of Structured Information Standards (OASIS) standards group developed the eXtensible Access Control Markup Language (XACML) as a language to express and evaluate access decisions. The XACML technical specification includes a profile for RBAC using XACML that complies with the ANSI RBAC standard. The HL7 RBAC Permission Catalog provides a standard vocabulary that can be used for cross-enterprise access control. For more information visit <a href="http://www.oasis-open.org">www.oasis-open.org</a>
Unified Code for Units of Measure (UCUM)	A code system intended to include all units of measures being contemporarily used in international science, engineering, and business. The purpose is to facilitate unambiguous electronic communication of quantities together with their units. The focus is on electronic communication, as opposed to communication between humans. For more information visit <a href="http://aurora.regenstrief.org">http://aurora.regenstrief.org</a>
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 <a href="http://www.usb.org">www.usb.org</a>
XDM Supplement to the Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF)	This Supplement to the IHE IT Infrastructure Technical Framework defines the means to store and interchange personal medical documents on portable media. The current version of the XDM is specified in the XDM Trial Implementation Supplement to the ITI-TF, rev. 2.0, which is consistent with IHE XDS.b Supplement in term of document entry metadata. Visit <a href="http://www.ihe.net/technical_framework">http://www.ihe.net/technical_framework</a> for more information



## 7.0 CHANGE HISTORY

The following sections provide the history of all changes made to this document since the last publication.

### 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 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 for each of these IS's is identical. Section 2 Tables and their associated UML's have been completely redone to reflect a concatenation, where appropriate, of the events/actions from both of both CE Use Cases. This integration of the events/actions resulted in scenario one being fully merged into a single scenario entitled "Consumer creates account to host and Access Registration Summary and Clinical Information." Scenario 2 and 3 of the Consumer Empowerment Use Case were likewise edited to include operationally equivalent events/actions from the Consumer Access Use Case. Scenario 2 and 3 of the Consumer Access Use Case remained intact as originally presented.
2. Section 3 has been revised to reflect the new template (effective 11/29/07) which was the result of a cross-TC and project management assessment of the IS readability and usability for implementation and certification purposes. The following changes were made to the document in this regard:
  - Table 3.2.1-1 was revised to only list the technical actor names and their descriptions
  - The UML's in section 3.2.2 were completely redesigned to improve the segmentation of business actor-to-business actor interactions and technical actor-to technical actor transactions
  - Table 3.2.3-1 was completely redesigned to improve the clarity of the requirements (and optionality) for a business actor in terms of what technical actors need to be supported AND what specific transactions for those technical actors are required, optional, or conditional
  - The conformance subsets previously included in Section 5.1.2 were relocated to Section 3.2.3 as paragraphs 3.2.3.x, where x = the subset number. These subsets were also included in table 3.2.3-1 accordingly.
  - The Conformance Section 5.1 was revised to direct the reader to section 3.2.3 for the mandatory requirements to claim conformance to this specification.
3. Transactions and Content were differentiated in table 3.2.3-1 to clarify how specific technical actors (e.g. 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. T33).

4. All relevant Security and Privacy constructs, including their applicable transactions, have been included in Section 3, with particular specificity regarding their association to business actors requirements highlighted via table 3.2.3-1.
5. The results of TC dispositions of public comments received against this IS have been appropriately reflected in the text, tables, and UML diagrams of the IS. Specifically, comment dispositions for the following comment topic categories have been effectively included:
  - 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 AUGUST 27, 2008**

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

