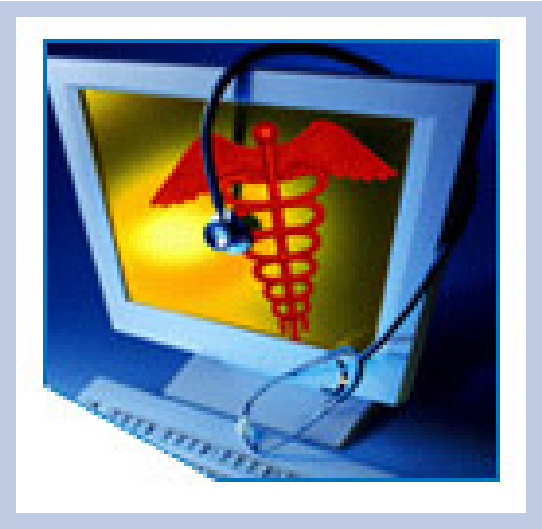
March 27, 2008
Version 1.0

HITSP Medication Management Interoperability Specification

HITSP/IS07



Submitted to:

Healthcare Information Technology Standards Panel

Submitted by:

Care Delivery Technical Committee

DOCUMENT CHANGE HISTORY

Version Number	Description of Change	Name of Author	Date Published
0.0.1	Review Copy	Care Delivery Technical Committee	December 7, 2007
0.0.2	Review Copy	Care Delivery Technical Committee	March 19, 2008
1.0	Released for Implementation	Care Delivery Technical Committee	March 27, 2008

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1.0 INTRODUCTION

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

1.1 INTEROPERABILITY SPECIFICATION OVERVIEW

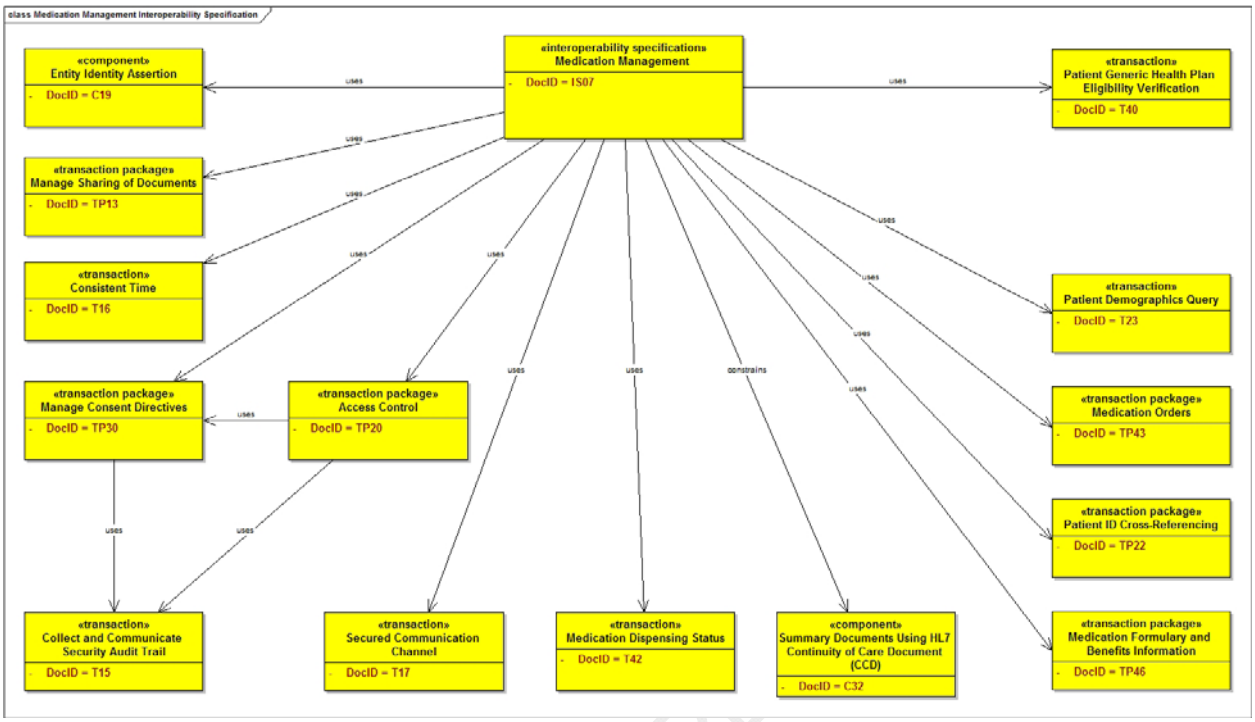
This section provides a high level definition of this Interoperability Specification and background information about the underlying Use Case that it is based upon.

The HITSP Medication Management Interoperability Specification describes the information flows, issues and system capabilities that apply to the multiple organizations participating in medication management. It is intended to facilitate access to necessary medication and allergy information for consumers, clinicians, pharmacists, health insurance agencies, inpatient and ambulatory care, etc.

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. This IS groups specific actions and actors to describe the relevant context(s) for the use of HITSP constructs that further identify and constrain standards where necessary. In addition to ISs, there are three other types of HITSP constructs called Transaction Packages (TP), Transactions (T) and Components (C). The document map 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 'Released for Implementation' versions of the specifications.

Table 1.2.1-1 List of Constructs

Construct	Description
HITSP/TP13	HITSP Manage Sharing of Documents Transaction Package
HITSP/T15	HITSP Collect and Communicate Security Audit Trail Transaction
HITSP/T16	HITSP Consistent Time Transaction
HITSP/T17	HITSP Secured Communication Channel Transaction
HITSP/C19	HITSP Entity Identity Assertion Component
HITSP/TP20	HITSP Access Control Transaction Package
HITSP/TP22	HITSP Patient ID Cross-Referencing Transaction Package
HITSP/T23	HITSP Patient Demographics Query Transaction
HITSP/TP30	HITSP Manage Consent Directives Transaction Package
HITSP/C32	HITSP Summary Documents Using HL7 Continuity of Care Document (CCD) Component
HITSP/T40	HITSP Patient Generic Health Plan Eligibility Verification Transaction

Construct	Description
HITSP/T42	HITSP Medication Dispensing Status Transaction
HITSP/TP43	HITSP Medication Orders Transaction Package
HITSP/TP46	HITSP Medication Formulary and Benefits Information Transaction Package

1.3 COPYRIGHT PERMISSIONS

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1.4 REFERENCE DOCUMENTS

This section contains links to key reference documents and background material.

The HITSP Interoperability Specification Overview provides the 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.

The conventions that are used to convey the full descriptions and usage of standards in the HITSP specifications are contained in the HITSP Conventions List.

The acronyms used in this document are contained in the HITSP Acronyms List.

The HITSP Glossary provides definitions for relevant terms used by HITSP documents.

The HITSP Harmonization Framework describes the current framework within which the Interoperability Specifications are built.

This document references the Medication Management Detailed Use Case, June 18, 2007.

A Technical Note, TN900 - Security and Privacy, has been developed as a reference document to provide the overall context for use of the HITSP Security and Privacy constructs. It includes the following:

- The scope, reference policy background, and Security and Privacy principles used in the development of the constructs
- A detailed description and schematics of the conceptual relationship between the Security and Privacy constructs
- A mapping of existing standards and constructs to be used in meeting the stated requirements of the AHIC Use Cases
- A list of identified gaps and the recommended approaches to resolving those gaps
- A roadmap for how the Security and Privacy constructs will evolve and eventually align with other HITSP Interoperability Specifications
- A conceptual framework for Security and Privacy management, including reference information on privacy policies, risk assessment and risk management
- A glossary of terms used in all the Security and Privacy construct documents
- 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

HITSP will periodically update this Technical Note as required by the introduction of new contexts for use.

2.0 INTEROPERABILITY REQUIREMENTS

This section provides a high level description of the Medication Management 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 Business 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 business 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 UML Interaction (Business Sequence) Diagrams - these diagrams are used to describe the interaction between business actors, and the data involved in each scenario that is documented

2.1 USE CASE SYNOPSIS

This section provides a synopsis of the AHIC Medication Management Use Case, including any applicable scenarios that are part of the Use Case.

A key goal of the Medication Management Use Case is improving medication management to promote patient safety and support relevant aspects of the medication management cycle with better interoperability and efficiency. To support this, the Medication Management Use Case focuses on patient medication and allergies information exchange and the sharing of that information between consumers, clinicians (in multiple sites and settings of care), pharmacists (dispensers) and organizations that provide health insurance and provide pharmacy benefits (payers).

This Use Case describes medication management in two scenarios. The first scenario, inpatient setting, includes medication reconciliation and ordering, along with other supporting interactions in the hospital. The second scenario, ambulatory setting, addresses access to current medication and allergy information and support for electronic prescribing. Many needs within these two scenarios overlap, but this separation of scenarios was useful in emphasizing some aspects that are particular to each.

This Use Case also recognizes the uniqueness and complexity of medication management and other activities in the long term care setting. While not all long term care needs can be addressed explicitly in this Use Case, medication management areas are highlighted where the existing considerations may also be appropriate for long term care.

This Use Case assumes the developing presence of electronic systems such as Electronic Health Records (EHRs), ePrescribing tools, Personal Health Records (PHRs) and other local or Web-based solutions supporting consumers and clinicians, while recognizing the issues and obstacles associated with these assumptions. This approach provides a foundation for the development of longer-term efforts.

A key component of the Medication Management Use Case is its relationship to an existing federal initiative on ePrescribing undertaken by the Centers for Medicare & Medicaid Services (CMS). Demonstration projects for this initiative have been implemented in multiple environments and they are governed by existing government regulations. The ePrescribing initiative requires that the following transactions conform to the foundation standards required for implementation by January 1, 2006 for all electronic prescribing under Part D of the Medicare Modernization Act (MMA):

- Transactions between prescribers (who write prescriptions) and dispensers (who fill prescriptions) for:
  - new prescriptions
  - refill requests and responses
  - prescription change requests and responses
  - prescription cancellation, request and response and
  - related messaging and administrative transactions
- Eligibility and benefits queries and responses between prescribers and Part D sponsors
- Eligibility queries between dispensers and Part D sponsors

MMA required CMS to implement pilot projects to test additional standards. These additional standards apply to transactions involving:

- Formulary and benefit information
- Medication history
- Fill status notification
- Structured and Codified Sig
- Clinical drug terminology (RxNorm and other terminology systems)
- Prior authorization

The ePrescribing transactions have been included in the Medication Management Use Case in order to:

- Demonstrate the need for compatibility between the standards adopted for the ePrescribing transactions and other medication-related information exchange transactions
- Provide a context for identifying the types of information being exchanged in the workflow steps leading up to, and following, the ePrescribing transactions
- Provide a context for complementary standards harmonization, architecture, policy development and certification activities

To support these requirements, the following standards pertinent to this document, have been named in the MMA:

- ASC X12N ASC) X12N 270/271 - Health Care Eligibility Benefit Inquiry and Response, Version 4010, May 2000, Washington Publishing Company, 004010X092 and Addenda to Health Care Eligibility

Benefit Inquiry and Response, Version 4010A1, October 2002, Washington Publishing Company.004010X092A1

- NCPDP SCRIPT Standard Implementation Guide Version 8.1
- NCPDP Telecommunication Standard Implementation Guide Version 5.1

The standards continue to evolve; the industry has already requested more current versions be named for the MMA. In this specification, NCPDP SCRIPT Standard Implementation Guide Version 8.1 and 10.1 are cited. The only difference between the two versions that is relevant to this Management Interoperability Specification and the related set of HITSP constructs is that SCRIPT Standard Implementation Guide Version 10.1 is needed to support long-term care needs. That is, SCRIPT Standard Implementation Guide Version 8.1 does not provide the data elements needed for long-term care but for all other uses in this IS set of constructs, NCPDP SCRIPT Standard Implementation Guide Version 8.1 and version 10.1 have no differences and could be used interchangeably. The MMA exempted long-term care, so they are not bound by the requirement of SCRIPT Standard Implementation Guide Version 8.1 and, therefore, use SCRIPT Standard Implementation Guide Version 10.1. When CMS names SCRIPT Standard Implementation Guide Version 10.1, SCRIPT Version 10.1 should be used in this specification.

Note on medication history information sharing:
In the context of medication history, NCPDP SCRIPT is often used by prescriber, payer and dispenser business actors to share medication history detail records. However, when a prescriber obtains a patient's medication history from another of these business actors, the medication history is often part of a broader patient summary that includes all medications and also includes allergies, problem lists, etc. A common means is needed to produce and receive such a summary document when entities are communicating with PHRs, EHRs and other entities under the interoperable NHIN paradigm. HITSP specifications use the C32 Component (Summary Documents using HL7 Continuity of Care Document or CCD) as the common structure for all summary documents with CCD as the selected standard for the sharing of summary documents. This approach has the advantage of flexibility for future enhancement and the ability to map from other existing standards. In particular, C32 includes an Appendix with mapping information to NCPDP SCRIPT.[1]

Because of the aforementioned need, this specification describes the broader summary that includes medication history as being communicated between business actors using the C32 summary document. It is expected that prescriber organizations will always use this summary document form when communicating with each other. Payers and dispensers will also use the C32 summary document if they wish to communicate medication history summary information together with other health summary information. However, if only medication history detail is to be communicated and a payer or dispenser is

[1] Since the last publication of C32, it has been noted that the C32-NCPDP SCRIPT Medication History mapping is not complete - there is a scope mismatch. C32 is broader than NCPDP SCRIPT Medication History, but also lacks some specific elements of Medication History. This gap has been noted and will be addressed in the next iteration of C32.

either a sending or receiving business actor, one business practice today is to communicate the medication history detail via NCPDP SCRIPT (CMS has defined this as a regulation under Part D of the Medicare Modernization Act).

In the public comment version of this IS, C32 was selected to communicate health summary information that included medication history. This choice does not account for the NCPDP SCRIPT medication history detail (as discussed above). It is expected to be included in future versions.

2.2 USE CASE REQUIREMENTS

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

The Medication Management Use Case focuses on two scenarios: inpatient medication reconciliation and ambulatory care medication management. In these scenarios, availability and exchange of complete information on patient medication and allergies would improve patient safety and care efficiency.

NOTE: Inpatient scenarios and perspectives are indicated throughout this document as 6.X Use Case Events and Actions and ambulatory scenarios are referenced as 7.X Use Case Event and Actions.

1. INPATIENT MEDICATION RECONCILIATION

The inpatient medication reconciliation scenario is focused on aspects of inpatient medication management including the formal process of medication reconciliation. Patients are at risk during transitions in care across settings, services, providers or levels of care. Medication reconciliation documents the efforts made to assemble and consider information on current medications and patient allergies during these transitions. Briefly stated, medication reconciliation occurs at patient admission, discharge and transfer (e.g., to another level of care in the hospital or to another hospital). The requirements include:

- Gathering and documenting information on current medications, allergies and medication intolerances
- Deciding and documenting, which medications are to be continued or discontinued
- Ordering new medications or considering modifications to existing medications that are to be continued (with consideration of the patient's outpatient medication list)
- Communicating information to the next provider(s) of care at each transition within the hospital (e.g., change of setting, service, level of care or provider)
- Communicating information at discharge to the next provider(s) of care
- Communicating discharge information to the patient

This scenario includes several additional medication management events in addition to medication reconciliation.

2. AMBULATORY MEDICATION MANAGEMENT

The ambulatory medication management scenario addresses access to current medication and allergy information and support for electronic prescribing in the ambulatory environment. The scenario includes the following requirements:

- Gathering and documenting information on current medications, allergies and medication intolerances
- Performing eligibility and benefits checking
- Communicating the current medication list, prescriptions, allergy information, medication information and care instructions to the patient

It also focuses on prescription management, prescription writing, prescription transmittal to a pharmacy and consumer-generated request for prescription refills and renewals. This scenario focuses on providing clinicians and pharmacists with information about each patient's medications and allergies, not just from local documentation, but also from the following sources:

- Other ambulatory clinicians
- Hospitals, long-term care facilities or other care settings from which the patient has been previously discharged
- Organizations that manage prescription or insurance-related information
- Patients whose self-reported information may be recorded in PHRs or other electronic sources

2.2.1 MAPPING OF USE CASE REQUIREMENTS TO BUSINESS REQUIREMENTS

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

Six tables are provided, one for each scenario perspective. The tables describe the following list of scenario perspectives:

- 6.1 Inpatient Medication Reconciliation, Clinician Perspective (Table 2.2.1-1)
- 6.2 Inpatient Medication Reconciliation, Pharmacist Perspective (Table 2.2.1-2)
- 6.3 Inpatient Medication Reconciliation, Consumer Perspective (Table 2.2.1-3)
- 7.1 Ambulatory Medication Management, Clinician Perspective (Table 2.2.1-4)
- 7.2 Ambulatory Medication Management, Pharmacist Perspective (Table 2.2.1-5)
- 7.3 Ambulatory Medication Management, Consumer Perspective (Table 2.2.1-6)

Table 2.2.1-1 illustrates the mapping between the business actors and their Use Case requirements for the scenario 6.1, Inpatient Medication Reconciliation from a Clinician Perspective.

NOTE: Internal interactions may be shown in UML but are not shown in this table.

Table 2.2.1-1 Mapping of Use Case Requirements to Business Requirements - Inpatient Medication Reconciliation, Clinician Perspective

Use Case	Business Actor	Event	Action	Interoperability Requirement(s) (includes security requirements)	Data Requirement Number
Medication Management	Drug Knowledge Suppliers (Clinicians, Clinicians Other, Pharmacists, Consumers)	Event: 6.1.1 Configure medication decision support	Action: 6.1.1.1 Receive information from drug knowledge supplier	Vendors and other sources provide data tables and reference information to support medication screening for contraindications and other decision support capabilities. These act in conjunction with and are integrated into the hospital EHR. These tools can also be used in a long term care setting.	14,16
	EHR - Hospitals	Event: 6.1.2 Gather medication and allergy information at admission	Action: 6.1.2.1 Request available medications and allergy information in interoperable electronic form	Upon admission to the Emergency Department or the hospital, the clinician gathers information about the patient's current medication and allergies from several sources. Consumer self-reported prescription, over-the-counter (OTC) medication, vitamins, implanted medication infusion devices, and herbal and other supplements may also be available from the patient's PHR, as well as information about allergies, intolerances, side effects, sensitivity responses, adverse effects and similar reactions in addition to accompanying information (e.g., nature of reaction, severity of reaction and source of information). Additional available information could be gathered electronically via health information exchange, from hospital EHRs, ambulatory EHRs (such as from a Primary Care Physician (PCP)), long term care EHRs and other sources (such as pharmacy systems, PNIs, PBMs, Payers, etc.) that hold information about the patient. Ideally, this information should be provided in an integrated view without duplications. It can then be used during the stay and communicated at discharge. In each case, the information source (e.g., authoritative clinical source, administrative source or patient) should also be captured.	1, 2, 4, 13,18, 22
			Alternative Action: 6.1.2.1a Request available medication and allergy information in viewable electronic form	Alternative Action 6.1.2.1a Upon admission, the clinician views summary medication information from external sources.	
			Alternative Action: 6.1.2.1b Request available medication and allergy information via interview	Alternative Action 6.1.2.1b Upon admission, the clinician and support staff gather medication and allergy information by interviewing the patient, patient's family, significant others and/or caregivers - and in some instances, by contacting the patient's Primary Care Physician (PCP).	

Use Case	Business Actor	Event	Action	Interoperability Requirement(s) (includes security requirements)	Data Requirement Number
		Event: 6.1.4 Write medication order	Action: 6.1.4.4 Send order to integrated pharmacy system	After the medication order is written and signed, it is electronically transmitted to the inpatient pharmacy system, which is frequently closely integrated with the CPOE and other applications of the inpatient EHR.	2, 14, 15, 21
			Alternative Action: 6.1.4.4a Send order to separate, in-house hospital pharmacy system	Alternative Action 6.1.4.4a The medication order is communicated to a hospital pharmacy system that may exist as a separate application, but is directly interoperable with the hospital EHR.	
			Alternative Action: 6.1.4.4b Send order to external pharmacy system	Alternative Action 6.1.4.4b The medication order is communicated to an external pharmacy that is completely separate from the organization's EHR.	
		Event: 6.1.8 Write new discharge prescriptions	Action: 6.1.8.1 Prescribe new medications at discharge	The clinician writes any new prescriptions required following the hospital stay. This process could be supported by clinical decision support for recommended indications, dosing and access to reference information. The clinician could benefit from the ability to verify patient eligibility, formulary access and pharmacy benefits coverage to minimize overall medication costs. Clinicians could use an electronic prescribing function (e.g., an ePrescribing tool, an ambulatory EHR, or a hospital or long term care EHR with ambulatory prescribing functionality) to write these prescriptions electronically. These prescriptions immediately update the information being compiled on discharge medications for medication reconciliation.	1, 2, 3, 4, 5, 7, 14, 18
	EHRs-Hospital and Long term care	Event: 6.1.8 Write new discharge prescriptions	Action: 6.1.8.1 Prescribe new medications at discharge	The clinician writes any new prescriptions required following the hospital stay. This process could be supported by clinical decision support for recommended indications, dosing and access to reference information. The clinician could benefit from the ability to verify patient eligibility, formulary access and pharmacy benefits coverage to minimize overall medication costs. Clinicians could use an electronic prescribing function (e.g., an ePrescribing tool, an ambulatory EHR or a hospital or long term care EHR with ambulatory prescribing functionality) to write these prescriptions electronically. These prescriptions immediately update the information being compiled on discharge medications for medication reconciliation.	1, 2, 3, 4, 5, 7, 14, 18

Use Case	Business Actor	Event	Action	Interoperability Requirement(s) (includes security requirements)	Data Requirement Number
		Event: 6.1.9 Provide information to the next provider of care and patient	Action: 6.1.9.2 Communicate medication and allergy information to the patient	Along with other discharge instructions, the patient could be given the outpatient medication list captured at admission, annotated as to which ones are to be resumed or discontinued, as well as any new discharge prescriptions. The information could also include up-to-date information about the patient's documented allergies. Typically, the information would be hand-written or printed out from the hospital EHR. It could also be communicated to the patient's PHR. The patient may also be provided with relevant medication guides or patient information sheets.	1, 2, 18
	Pharmacy Systems, Hospital - Integrated			Receives Data Only for: 6.1.1.1 6.1.4.4	2, 14, 15, 16, 21
	Pharmacy Systems, Hospital - Non-Integrated			Receives Data Only for: 6.1.1.1 6.1.4.4a	2, 14, 15, 16
	Pharmacy Systems - External			Receives Data Only for: 6.1.4.4b	2, 14, 15, 21
	PHRs			Receives Data Only for: 6.1.9.2	1, 2,18
	EHRs			Receives Data Only for: 6.1.2.1	1, 2, 4, 13, 18
	PBM / Payers			Receives Data Only for: 6.1.2.1 6.1.8.1	1, 2, 3, 4, 5, 7, 13, 14, 18
	Health Information Exchange (HIE)			Receives Data Only for: Can be the intermediary for almost all actions of this scenario.	

Table 2.2.1-2 illustrates the mapping between the business actors and their Use Case requirements for the scenario, Inpatient Medication Reconciliation from a Pharmacist Perspective.

Table 2.2.1-2 Mapping of Use Case Requirements to Business Requirements - Inpatient Medication Reconciliation, Pharmacist Perspective

Use Case	Business Actor	Event	Action	Interoperability Requirement(s) (includes security requirements)	Data Requirement Number
Medication Management	Pharmacy Systems - External	Event: 6.2.1 Verify medication order	Action: 6.2.1.4 Return information on verification status and any order changes	After a medication order is verified, information on verification status and any order modifications could be incorporated into the EHR for access by clinicians involved in the patient's care. Information could include medication lot number, expiration date, and quantity dispensed. NOTE: This action is relevant to Pharmacy System-External.	6, 17
	EHRsHospital and EHR LTC			Receives Data Only for: 6.2.1.4	6, 17

Table 2.2.1-3 illustrates the mapping between the business actors and their Use Case requirements for the scenario, Inpatient Medication Reconciliation from a Consumer Perspective.

Table 2.2.1-3 Mapping of Use Case Requirements to Business Requirements - Inpatient Medication Reconciliation, Consumer Perspective

Use Case	Business Actor	Event	Action	Interoperability Requirement(s) (includes security requirements)	Data Requirement Number
Medication Management	PHRs	Event: 6.3.2 Request and view medication and allergy information	Action: 6.3.2.1 Request available medication and allergy information	The consumer requests available medication and allergy information via their PHR. This information may have been self-reported earlier or may be derived from their clinicians' EHR systems, a PBM system, a pharmacy system, Payers, other authoritative clinical sources and/or administrative data sources. Information obtained from some sources may be obtained at the time of the consumer request or may have been previously "pushed" to the patient's PHR. Consumers would additionally benefit from the ability to permit designated clinicians, pharmacists and other individuals (e.g., family members) to request and view information in their PHR (a.k.a., proxy access).	1, 2, 13, 18
	EHRs			Receives Data Only for: 6.3.2.1	1, 2, 13, 18
	EHR - Hospital			Receives Data Only for: 6.3.2.1	1, 2, 13, 18
	Pharmacy Systems			Receives Data Only for: 6.3.2.1	1, 2, 13, 18
	Other Clinical or Admin Data Sources			Receives Data Only for: 6.3.2.1	1, 2, 13, 18
	PBM/Payers			Receives Data Only for: 6.3.2.1	1, 2, 13, 18

Table 2.2.1-4 illustrates the mapping between the business actors and their Use Case requirements for the scenario, 7.1 Ambulatory Medication Management from a Clinician Perspective

Table 2.2.1-4 Mapping of Use Case Requirements to Business Requirements - Ambulatory Medication Management, Clinician Perspective

Use Case	Business Actor	Event	Action	Interoperability Requirement(s) (includes security requirements)	Data Requirement Number
Medication Management	Drug Knowledge Suppliers	Event: 7.1.1 Configure medication decision support	Action: 7.1.1.1 Receive information from drug knowledge suppliers	Vendors and other sources provide data tables and reference information to support medication screening for contraindications and other decision support capabilities. These act in conjunction with and are integrated into, the ambulatory EHR. These tools may also support pharmacists in their roles.	14, 16
	EHR-Ambulatory	Event: 7.1.2 Perform eligibility and benefits checking	Action: 7.1.2.1 Check Patient Eligibility	The patient's eligibility for services, including pharmacy benefits, needs to be confirmed. Direct query for eligibility and pharmacy benefits information from a PBM, or Payer directly, and/or through health information exchange or a Medication Network Intermediary may exist. This event may also support the long term care setting.	4, 22
			Action: 7.1.2.2 Check pharmacy benefits information	Information on the patient's pharmacy benefits and formulary obtained during this step may be useful for prescribing. Similarly, patient and condition specific formulary information may be obtained during prescription writing.	3, 4, 7, 15, 22
		Event: 7.1.3 Gather medication and allergy information	Action: 7.1.3.1 Request available medication and allergy information in interoperable electronic form	To make decisions about care, the clinician would benefit from a complete view of the patient's current medications and allergies as well as past access to a medication. A patient may have a PCP, as well as one or more specialists, all of whom may be writing medication prescriptions for the patient.	1, 2, 4, 13, 18, 22
			Action: 7.1.3.1a Request available medication and allergy information in viewable electronic form	The clinician views summary medication information from multiple sources.	1, 2, 4, 13, 18, 22
			Alternative Action: 7.1.3.1b Request available medication and allergy information via interview	In today's environment, clinicians frequently ask the patient, patient's family, significant others and/or caregivers about medications that are not documented locally. This action could be beneficial even if medication information is obtained through alternate means as another data source for clinicians to consider.	1, 2, 4, 13, 18, 22

Use Case	Business Actor	Event	Action	Interoperability Requirement(s) (includes security requirements)	Data Requirement Number
		Event: 7.1.4 Write Prescription	Action: 7.1.4.1 Consider formulary	Clinicians would benefit from the ability to access and consider patient-specific pharmacy benefit information for pharmacy benefits, Medicare part D, and formulary information as they make prescribing decisions to minimize overall medication costs. [This information may have been obtained previously based on an earlier eligibility request.] This information may be provided by, PBMs or Payers and may be provided directly or through the use of a Medication Network Intermediary. Formulary considerations are also relevant in the long term care setting.	7
			Action: 7.1.4.5 Communicate information to pharmacy	An ePrescribing tool or an ambulatory EHR could communicate electronic prescriptions to the patient's preferred pharmacy. A pharmacy may also be affiliated with a clinician's ambulatory office (with integrated prescribing and pharmacy functions). Prescription changes and cancellations could also be transmitted to the pharmacy in a similar manner. Clinician prescribers (and clinics) may also give patients access to no-cost (free) medications that would need to be correctly captured in the EHR medication prescription record.	4, 9, 15, 21, 22
		Event: 7.1.6 Provide information to patient	Action: 7.1.6.1 Communicate current medication list, prescriptions, allergy information, and care instructions to the patient	The medication list, new prescriptions, allergy information and instructions should be communicated to the patient. This information could also be communicated to their PHRs from the ambulatory EHR. The patient may also be provided with relevant medication guides or patient information sheets. Note: Care instructions are given using paper copies and not part of the electronic record.	1, 2, 6, 11, 18
	Heath Care Entities (Long Term Care)	Event: 7.1.2 Perform eligibility and benefits checking	Action: 7.1.2.1 Check Patient Eligibility	The patient's eligibility for services, including pharmacy benefits, needs to be confirmed. Direct query for eligibility and pharmacy benefits information from a PBM, or Payer directly and/or through health information exchange or a Medication Network Intermediary may exist. This event may also support the long term care setting.	4, 22
			Action: 7.1.2.2 Check pharmacy benefits information	Information on the patient's pharmacy benefits and formulary obtained during this step may be useful for prescribing. Similarly, patient and condition specific formulary information may be obtained during prescription writing.	3, 4, 7, 15, 22
		Event: 7.1.4 Write Prescription	Action: 7.1.4.1 Review to determine formulary	Clinicians would benefit from the ability to access and consider patient-specific pharmacy benefit information for pharmacy benefits, Medicare Part D, and formulary information as they make prescribing decisions to minimize overall medication costs. [This information may have been obtained previously based on an earlier eligibility request]. This information may be provided by pharmacy systems, PBMs or Payers and may be provided directly or through the use of a Medication Network Intermediary. Formulary considerations are also relevant in the long term care setting.	7

Use Case	Business Actor	Event	Action	Interoperability Requirement(s) (includes security requirements)	Data Requirement Number
	Pharmacy Systems			Receives Data Only for: 7.1.1.1 7.1.2.1 7.1.2.2 7.1.3.1 7.1.3.1a 7.1.4.1 7.1.4.5	1, 2, 3, 4, 7, 9, 13, 14, 15, 16, 18, 21, 22
	PBM/Payers			Receives Data Only for: 7.1.2.1 7.1.2.2 7.1.3.1 7.1.3.1a 7.1.4.1	1, 2, 3, 4, 7, 13, 15, 18, 22
	EHRs			Receives Data Only for: 7.1.3.1 7.1.3.1a 7.1.4.1	1, 2, 4, 7, 13, 18, 22
	PHRs			Receives Data Only for: 7.1.3.1 7.1.3.1a 7.1.6.1	1, 2, 4, 6, 7, 13, 18, 22

Table 2.2.1-5 illustrates the mapping between the business actors and their Use Case requirements for the scenario, Ambulatory Medication Management from a Pharmacist Perspective

Table 2.2.1-5 Mapping of Use Case Requirements to Business Requirements - Ambulatory Medication Management, Pharmacist Perspective

Use Case	Business Actor	Event	Action	Interoperability Requirement(s) (includes security requirements)	Data Requirement Number
Medication Management	PHRs	Event: 7.2.1 Verify prescription	Action: 7.2.1.1 Notification	The prescription is processed in a series of steps including receipt of order, checking for possible contraindications using medication decision support tools and prescription verification. The pharmacist may also communicate with the prescribing clinician where questions exist and prescription changes are appropriate. An electronic request for a prescription refill could also be initiated by a consumer via their PHR. Note: Pharmacist also might communicate with the consumer.	1, 2, 7, 9, 14, 15

Use Case	Business Actor	Event	Action	Interoperability Requirement(s) (includes security requirements)	Data Requirement Number
	Pharmacy Systems	Event: 7.2.1 Verify prescription	Action: 7.2.1.1 Notify pharmacist Action: 7.2.1.1 Communicate prescription changes and questions Action: 7.2.1.1 Request for renewal	The prescription is processed in a series of steps including receipt of order, checking for possible contraindications using medication decision support tools and prescription verification. The pharmacist may also communicate with the prescribing clinician where questions exist and prescription changes are appropriate. An electronic request for a prescription refill could also be initiated by a consumer via their PHR. Note: Pharmacist also might communicate with the consumer.	1, 2, 7, 9, 14, 15
		Event: 7.2.2 Request and view medication and allergy information	Action: 7.2.2.1 Request medication and allergy information from PHR Action: 7.2.2.1 Request medication and allergy information from EHRs-ambulatory Action: 7.2.2.1 Request medication and allergy information from Pharmacy Benefit Managers	The pharmacist requests available medication and allergy information. This information may be derived from sources such as a PBM system, payer and/or a pharmacy system.	1, 2, 4, 13, 18, 22
		Event: 7.2.3 Perform eligibility and benefits checking	Action: 7.2.3.1 Check patient eligibility from Pharmacy Benefit Managers Action: 7.2.3.1 Check patient eligibility from Healthcare Payers	In the pharmacy, the consumer's eligibility for pharmacy benefits is confirmed, along with information about patient financial responsibility and formulary. A patient's eligibility for service could be confirmed by communicating identifying patient information to a Payer. This communication could be accomplished through an HIE, PBM or Medication Network Intermediary. Drug utilization review could also be accomplished during this event. This activity is also relevant for the long term care setting. NOTE: Could be eligibility only check.	4, 22

Use Case	Business Actor	Event	Action	Interoperability Requirement(s) (includes security requirements)	Data Requirement Number
			Action: 7.2.3.2 Check pharmacy benefits information from Pharmacy Benefit Managers Action: 7.2.3.2 Check pharmacy benefits information from Healthcare Payers	Once patient eligibility is confirmed, the patient's pharmacy benefits information can be viewed and considered during dispensing. In some situations, medication claims processing may be intertwined with benefits and eligibility checking prior to medication dispensing. NOTE: Claims never submitted in this Use Case.	3, 4, 6, 7, 22
		Event: 7.2.4 Dispense prescription	Action: 7.2.4.2 PHR Update Action: 7.2.4.2 EHR Update Action: 7.2.4.2 Notify Public Health agency	The pharmacy system records the dispensing status (or "fill status notification") of each medication for future consideration. Clinicians would benefit from knowing the dispensing status as a partial indicator of patient compliance with the recommended treatment. The information communicated should include the dispensing date, the date the prescription was picked up from the pharmacy, medication lot number, expiration date and quantity dispensed.	6, 15, 23
	EHR - Ambulatory	Event: 7.2.1 Verify prescription	Action: 7.2.1.1 Communicate prescription changes and questions	The prescription is processed in a series of steps including receipt of order, checking for possible contraindications using medication decision support tools and prescription verification. The pharmacist may also communicate with the prescribing clinician where questions exist and prescription changes are appropriate. An electronic request for a prescription refill could also be initiated by a consumer via their PHR. Note: Pharmacist also might communicate with the consumer.	1, 2, 7, 9, 14, 15
		Event: 7.2.4 Dispense prescription	Action: 7.2.4.2 Provide medication dispensing status	The pharmacy system records the dispensing status (or "fill status notification") of each medication for future consideration. Clinicians would benefit from knowing the dispensing status as a partial indicator of patient compliance with the recommended treatment. The information communicated should include the dispensing date, the date the prescription was picked up from the pharmacy, medication lot number, expiration date and quantity dispensed.	6, 15, 23
	PBM/Payers			Receives Data Only for: 7.2.2.1 7.2.3.1 7.2.3.2	1, 2, 3, 4, 6, 7, 13, 18, 22
	Public Health Entity			Receives Data Only for: 7.2.4.2	6, 15, 23

Table 2.2.1-6 illustrates the mapping between the business actors and their Use Case requirements for the scenario, Ambulatory Medication Management from a Consumer Perspective

Table 2.2.1-6 Mapping of Use Case Requirements to Business Requirements - Ambulatory Medication Management, Consumer Perspective

Use Case	Business Actor	Event	Action	Interoperability Requirement(s) (includes security requirements)	Data Requirement Number
Medication Management	PHRs	Event: 7.3.1 Self-report medication and allergy information	Action: 7.3.1.1 PHR update	The consumer could use their PHR to record information about other prescribed medications, their use of over-the-counter medication, vitamins, herbal and other supplements, and other medication information. The consumer could likewise self-report allergies, including allergies to medications as well as any environmental and food allergens, intolerances, side effects, sensitivity responses, adverse effects and similar reactions, in addition to accompanying information (e.g., nature of reaction, severity of reaction, and source of information). This information could be available to a clinician via retrieval from the consumer's PHR or provided automatically to the clinician based on the consumer's preferences.	1, 2, 4, 18
		Event: 7.3.2 Request Refills	Action: 7.3.2.1 Request Refill	A consumer could send prescription refill requests via their PHR to a pharmacy of choice. If no refills remain on the original prescription, the consumer could contact the original prescribing clinician for a prescription renewal. Alternatively, the pharmacist may notify the prescribing clinician if a refill is requested by a consumer and no more are available. Some EHRs and Medication Network Intermediaries may offer this capability in addition to PHRs. Additionally Payers may need to be included in this action for approval of some refills.	4, 15, 21
		Event: 7.3.3 Request renewals	Action: 7.3.3.1 Renewal request to Pharmacy System	A consumer could request prescription renewals using their PHR. The PHR would transmit renewal requests directly to the consumer's clinician or pharmacist. As noted above, the renewal request may also be initiated by a pharmacist when no more refills are allowed by the prescription.	4, 15, 21, 23
		Event: 7.3.4 Request and view available medication and allergy information	Action: 7.3.4.1 Request available medication and allergy information	The consumer requests available medication and allergy information via their PHR. This information might have been self-reported earlier, or may be derived from external sources such as their clinicians' EHR systems, a PBM system, payer systems and/or a pharmacy system. Information obtained from some sources may be obtained at the time of the consumer request or may have been previously "pushed" to the patient's PHR. The consumer may benefit from the ability to permit designated clinicians, pharmacists and other individuals (e.g., family members) to view information in their PHR (a.k.a., proxy access).	1, 2, 4, 13, 18, 22
	Pharmacy Systems	Event: 7.3.2 Request Refills	Action: 7.3.2.1 Refill notification	A consumer could send prescription refill requests via their PHR to a pharmacy of choice. If no refills remain on the original prescription, the consumer could contact the original prescribing clinician for a prescription renewal. Alternatively, the pharmacist may notify the prescribing clinician if a refill is requested by a consumer and no more are available. Some EHRs and Medication Network Intermediaries may offer this capability in addition to PHRs. Additionally Payers may need to be included in this action for approval of some refills.	4, 15, 21
		Event: 7.3.3 Request Renewals	Action: 7.3.3.1 Notify pharmacist	A consumer could request prescription renewals using their PHR. The PHR would transmit renewal requests directly to the consumer's clinician or pharmacist. As noted above, the renewal request may also be initiated by a pharmacist when no more refills are allowed by the prescription.	4, 15, 21, 23

Use Case	Business Actor	Event	Action	Interoperability Requirement(s) (includes security requirements)	Data Requirement Number
	EHRs - Ambulatory	Event: 7.3.3 Request Renewals	Action: 7.3.3.1 Notify Clinician	A consumer could request prescription renewals using their PHR. The PHR would transmit renewal requests directly to the consumer's clinician or pharmacist. As noted above, the renewal request may also be initiated by a pharmacist when no more refills are allowed by the prescription.	4, 15, 21, 23
	PBM/Payer			Receives Data Only for: 7.3.2.1 7.3.4.1	1, 2, 4, 13, 15, 18, 21, 22

2.2.2 DATA AND INFORMATION REQUIREMENTS MATRIX

This section contains an extraction of data and information requirements that are referenced from Table 2.2.1-1 to 2.2.1-6, with a listing of the actual data elements and information that meet the described data requirements.

Table 2.2.2-1 Data Element and Information Requirements

Data Requirement Number	Description
1	Allergies/Medication Intolerances are provided including (but not limited to): • Intolerances • Sensitivity Responses • Side Effects • Adverse Effects • Allergies
2	Current Medication information is provided including (but not limited to): • Herbal Medications • Implanted Medication Infusion Devices • Over the Counter (OTC) Medications • Active Prescriptions • Medication Fill Status • Vitamins • Other Supplements
3	Defined Benefit information is provided including (but not limited to): • Patient responsibility • Medication Therapy Management
4	Demographics information is provided including (but not limited to): • Name • Date of Birth (DOB) • Address • Gender • Member ID Number
5	Discharge Prescription information is provided including (but not limited to): • Drug • Dose • Route • Sig • Quantity • Frequency
6	Dispensed Product information is provided including (but not limited to):

Data Requirement Number	Description
	• Medication Lot Number • Expiration Data • Quantity Dispensed • Package Type • Dispensed Data and Time • Released/Delivered Date and Time
7	Formularies information is provided including (but not limited to): • Status • Co-Pay • Alternative • Coverage
9	Healthcare Provider Information is provided including (but not limited to): • Privileges • ID/NPI • Credentials • Licensing • Phone Number • DEA Number
10 (Further analysis required)	Medication Decision Support information is provided including (but not limited to): *<to be provided after further analysis>* *<to be provided after further analysis>*
11	Medication Guides/Patient Information Sheets are provided including (but not limited to): • Name • Description • Contraindications • Precautions • Chemical substances
12	Reserved (not used)
13	Medication History information is provided including (but not limited to): • Patient • Drug • Pharmacy • Doctor
14	Medication Reference information is provided including (but not limited to): • Therapeutic Class • Contraindications • Ingredients • Order Information
15	Medication Orders/Prescriptions information is provided including (but not limited to): • Dispense As Written • Dose • Frequency • Name • Route
16	Medication Screening Data Tables information is provided including (but not limited to): • Contraindications • Decision Support • Allergen Reference Information/Structures
17	Medication Verification Status and Order Modification information is provided including (but not limited to): • Fill Status • Change Status
18	Nature of Reaction information is provided including (but not limited to): • Severity of Reaction • Source of Information

Data Requirement Number	Description
20	Patient Clinical information is provided including (but not limited to): • Diagnosis • Problems • Conditions • Weight
21	Destination Pharmacy information is provided including (but not limited to): • Pharmacy Number
22	Plan information is provided including (but not limited to): • Payer • Plan Name • Plan ID • PCN • RX BIN
23	Destination Clinician is provided including (but not limited to): • Clinician Name • Clinician Address • Routing Information • NPI

2.2.3 IDENTIFICATION OF BUSINESS ACTORS AND SCENARIOS

This section describes the business actors that need to be integrated in order to meet the interoperability requirements for each scenario. 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. The table below describes the optionality of the actors involved and a description of the actor.

Table 2.2.3-1 Business Actors

Business Actor	Description	Use Case Scenario
Clinicians (Prescribers)	Healthcare providers with patient care responsibilities, including physicians, advanced practice nurses, physician assistants, nurses and other credentialed personnel, involved in treating patients	6.1, 6.2, 6.3, 7.1, 7.2, 7.3
Clinicians - other	Other clinicians that do not have primary responsibility (see above for Clinicians description).	6.1
Pharmacists (Dispensers)	Health professionals and clinicians who are licensed to prepare and dispense medication pursuant to the request of authorized prescribers. The practice of pharmacy includes, but is not limited to, the assessment, monitoring and modification of medication and the compounding or dispensing of medication. Direct care activities that pharmacists can perform include patient education, patient assessment, consultation and support for medication use.	6.1, 6.2, 7.1, 7.2, 7.3
Consumers	Members of the public who may receive healthcare services. These individuals may include: caregivers, patient advocates, surrogates, family members and other parties who may be acting for or in support of a patient in the activities of receiving healthcare.	6.1, 6.3, 7.1, 7.2, 7.3

Business Actor	Description	Use Case Scenario
Drug Knowledge Suppliers	Organizations that maintain and provide reference information on drugs that is used to provide clinical content in pharmacy systems and EHRs. Drug reference information provides the clinical content for medication screening for possible contraindications such as drug-drug, drug-allergy or drug-diagnosis interactions and inappropriate dosing. It also can provide assistance in selecting appropriate medications and quick access to monographs and other reference information. Drug Knowledge Suppliers can also provide new warnings, prescribing limitations, similar communications and patient education information.	6.1, 7.1
Electronic Health Record (EHR)	The Electronic Health Record (EHR) is a longitudinal electronic record of patient health information generated in one or more encounters in any care delivery setting. This information may include patient demographics, progress notes, problems, medications, vital signs, past medical history, immunizations, laboratory information and radiology reports.	6.1, 6.3, 7.1, 7.2, 7.3
EHRs - Hospital	An EHR in a hospital setting (see above for EHR definition).	6.1, 6.2, 6.3, 7.3
EHRs Hospital and EHR LTC	An EHR in a hospital or an EHR in a long term care (LTC) setting (see above for EHR definition).	6.1, 6.2
EHRs - Ambulatory	An EHR in an ambulatory setting (see above for EHR definition).	7.1, 7.2, 7.3
Computerized Provider Order Entry	Computerized systems that allow providers to enter orders for medications, labs, etc.	6.1
Pharmacy Systems-hospital, Integrated	Electronic systems that support pharmacists in their role for dispensing medications and performing professional services that are closely integrated with the inpatient EHR. This includes systems that may provide consumers' medication histories.	6.1, 6.2, 6.3, 7.1, 7.2, 7.3
Pharmacy Systems - Hospital, Non-integrated	Electronic systems that support pharmacists in their role for dispensing medications and performing professional services that exist as a separate application from the inpatient EHR. This includes systems that may be able to provide useful information on consumers' past medication histories.	6.1, 6.2
Pharmacy Systems - External	Electronic systems that support pharmacists in their role for dispensing medications. This includes systems that may be able to provide useful information on consumers' past medication histories. These systems exist outside of an organization.	6.1, 6.2, 7.2, 7.3
Clinical Decision Support Systems	Systems that help clinicians avoid adverse drug events through prompts and advisory messages about potential drug interactions, drug-diagnosis considerations, drug-renal function contraindications, patient allergies, potential errors in dosing and other issues that may lead to adverse drug events. The clinician may also have access to relevant reference information.	6.3, 7.1
Pharmacy Benefit Managers	These entities manage pharmacy benefits on behalf of Payers, interacting with pharmacies and providers via a Medication Network Intermediary. As part of this role, they can provide information on pharmacy benefits available to an individual consumer and an individual consumer's medication history.	6.1, 6.3, 7.1, 7.2, 7.3
Healthcare Payers	Insurers, including health plans, self-insured employer plans, and third party administrators, providing healthcare benefits to enrolled members and reimbursing provider organizations. As part of this role, they provide information on eligibility and coverage for individual consumers, as well as claims-based information on consumer medication history. Case management or disease management may also be supported.	6.1, 6.3, 7.1, 7.2, 7.3
PBM/Payers	This actor combines the Pharmacy Benefit Manager and Healthcare Payer. Note: The actors are two different entities (as shown above,) but for the use case this version of IS07 is based upon, they have the same interoperability requirements. In order to simplify tables and diagrams a combined Business Actor has been created.	6.1, 6.3, 7.1, 7.2, 7.3

Business Actor	Description	Use Case Scenario
Personal Health Record (PHR)	A healthcare record that can be created, reviewed, annotated and maintained by the patient or the caregiver for a patient. The PHR may include any aspect(s) of the health condition, medications, medical problems, allergies, vaccination history, visit history or communications with healthcare providers.	6.1, 6.3, 7.1, 7.2, 7.3
Other clinical or Admin Data Sources	Other authoritative clinical sources or administrative data source, which are able to provide medication and allergy information for a patient's PHR.	6.3, 7.3
Health Information Exchange (HIE)	An entity that enables the movement of health-related data within state, regional or non-jurisdictional participant groups.	6.1, 6.2, 6.3, 7.1, 7.2, 7.3
Public Health Agencies	Local, state and federal government organizations and personnel that exist to help protect and improve the health of their respective constituents.	7.2
Heath Care Entities	Organizations that are engaged in or support the delivery of healthcare. These organizations could include hospitals, ambulatory clinics, long term care facilities, community-based healthcare organizations, employers/occupational health, school health, dental clinics, psychology clinics, care delivery organizations and other healthcare facilities.	6.1, 7.1, 7.2

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 Business Sequence Diagram - 6.1.1

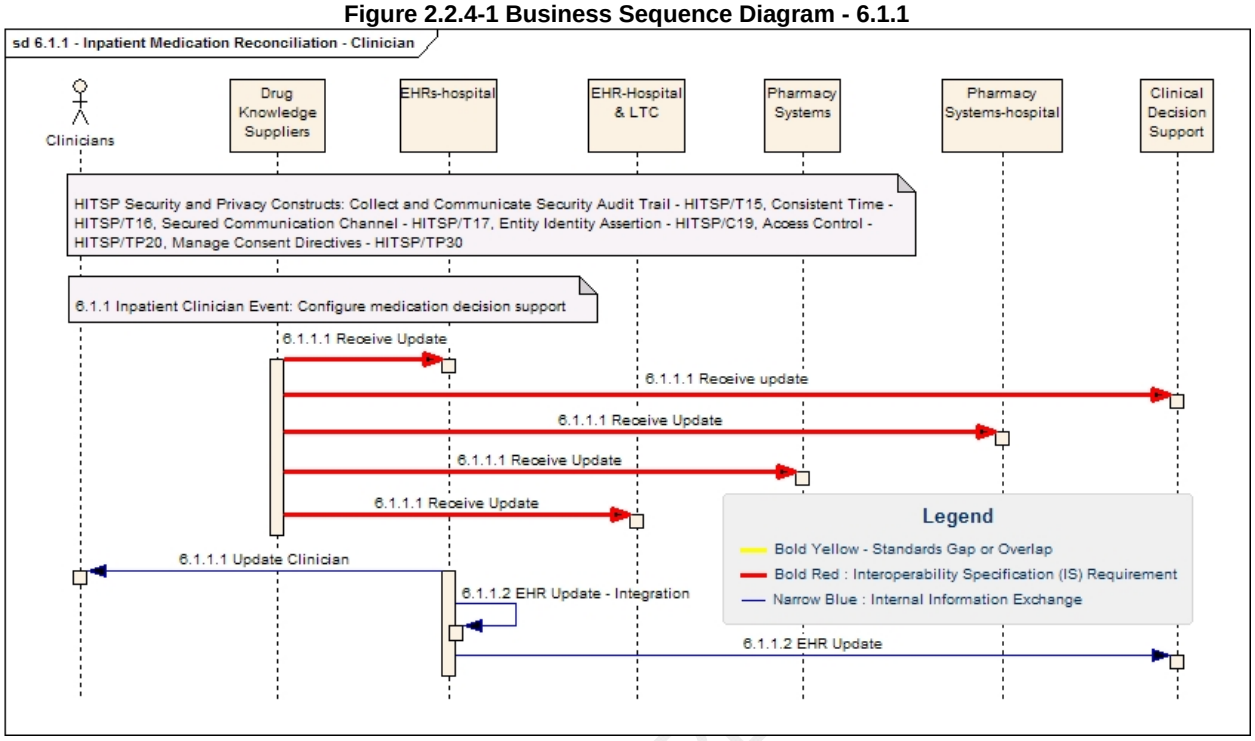


Figure 2.2.4-2 Business Sequence Diagram - 6.1.2

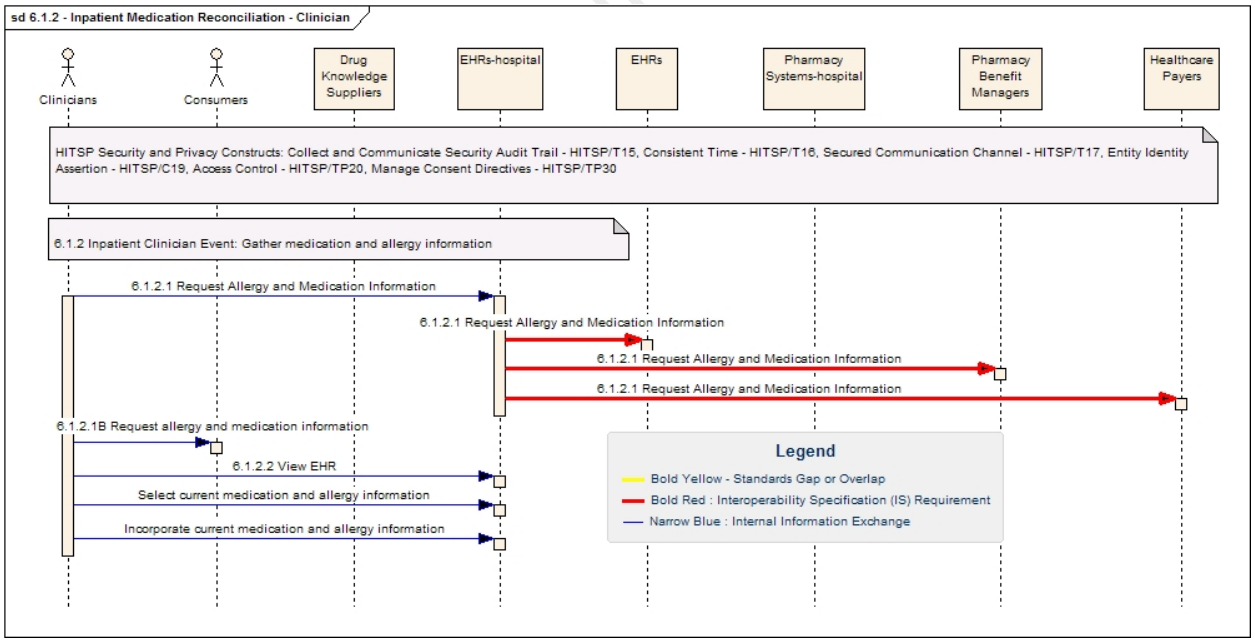


Figure 2.2.4-3 Business Sequence Diagram - 6.1.3 and 6.1.4

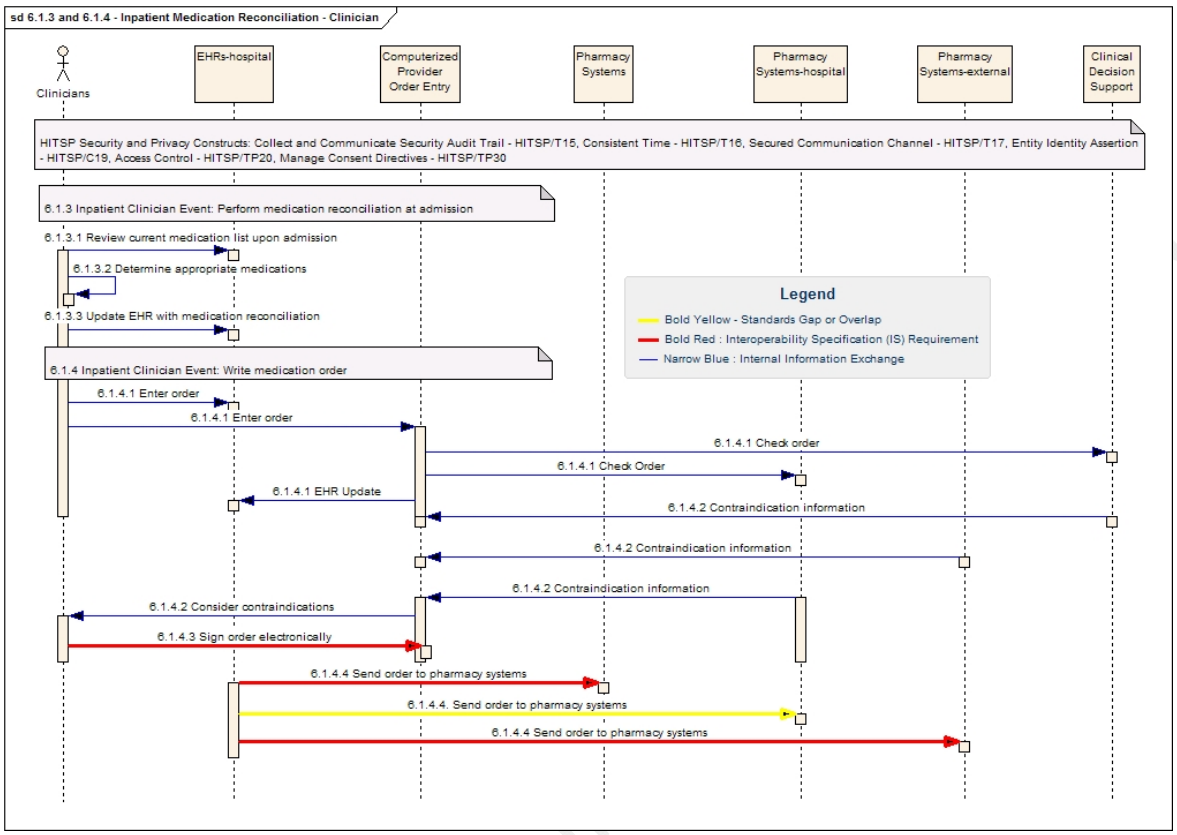


Figure 2.2.4-4 Business Sequence Diagram - 6.1.5, 6.1.6, and 6.1.7

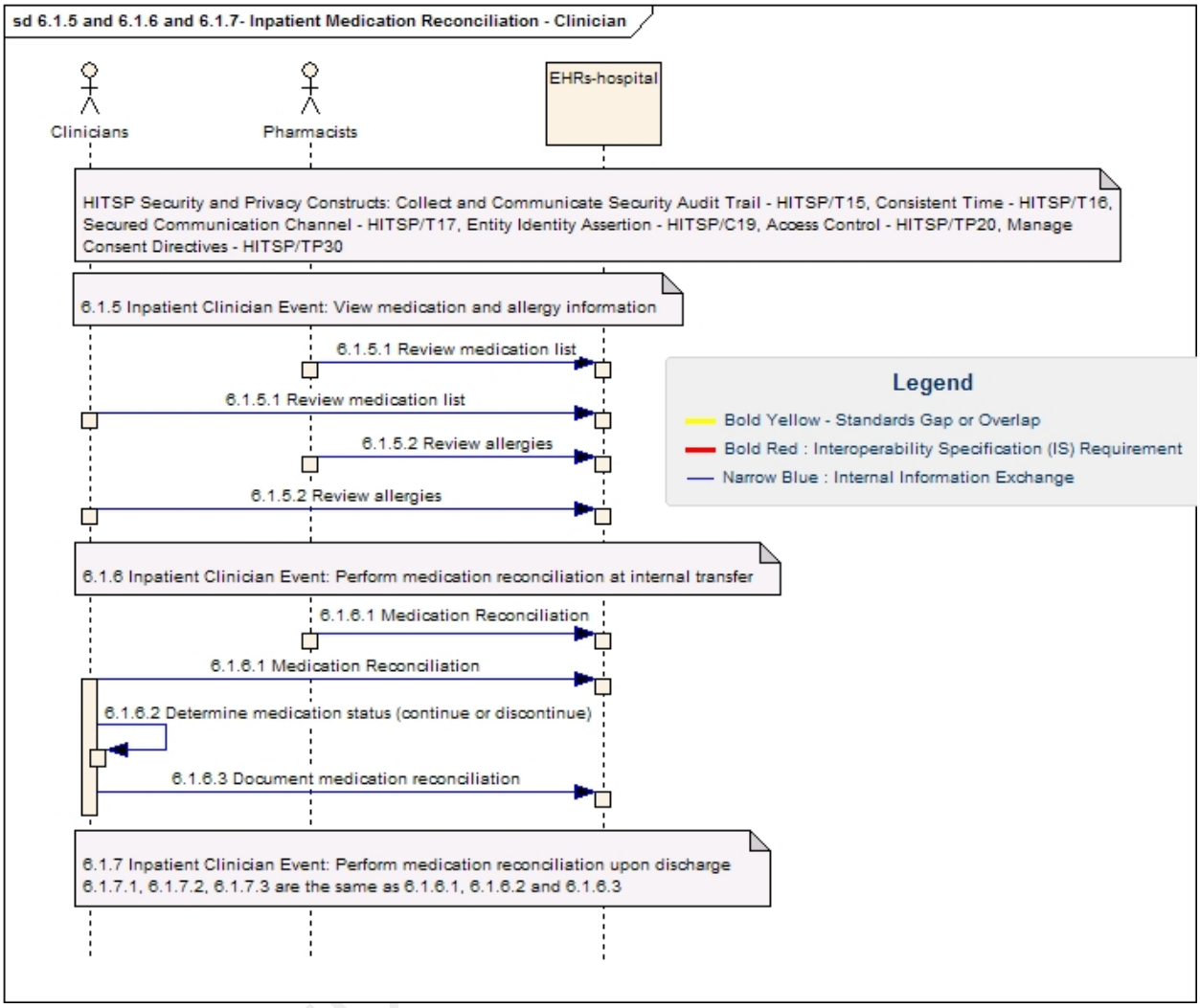


Figure 2.2.4-5 Business Sequence Diagram - 6.1.8

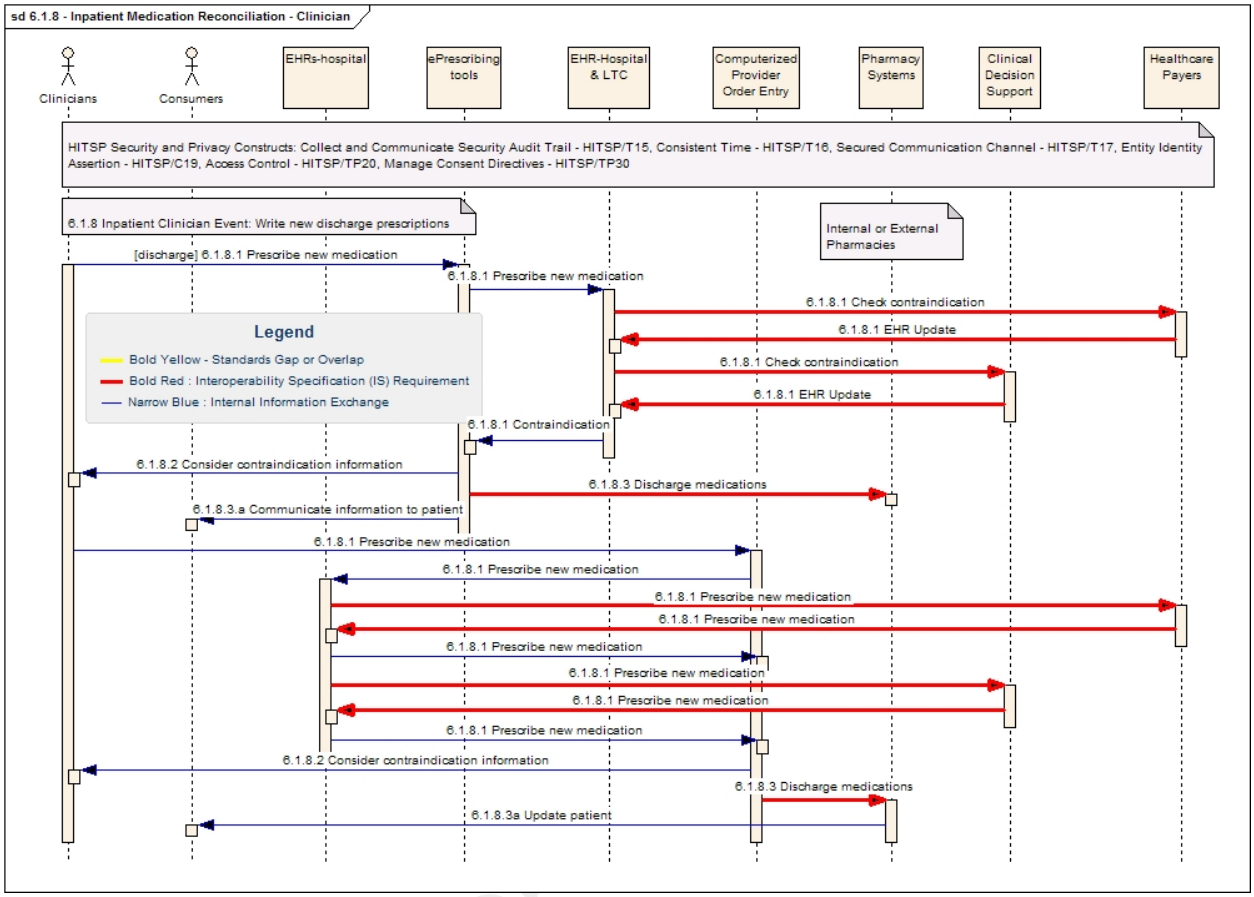


Figure 2.2.4-6 Business Sequence Diagram - 6.1.9

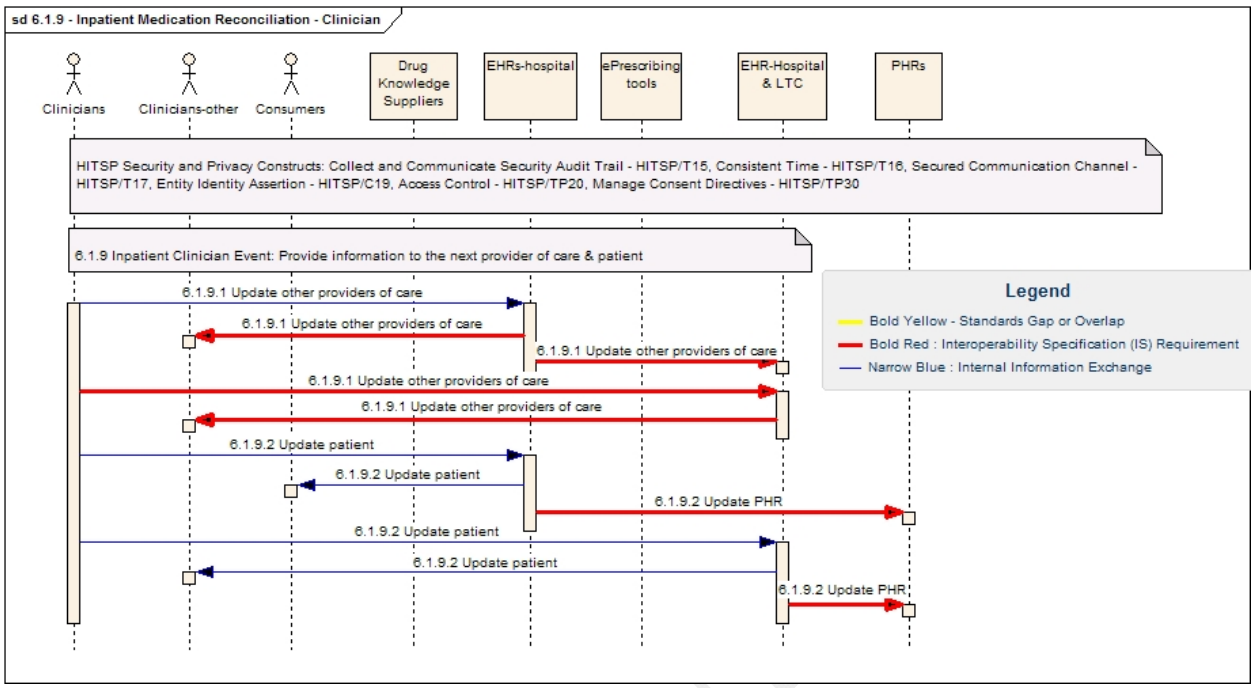


Figure 2.2.4-7 Business Sequence Diagram - 6.2

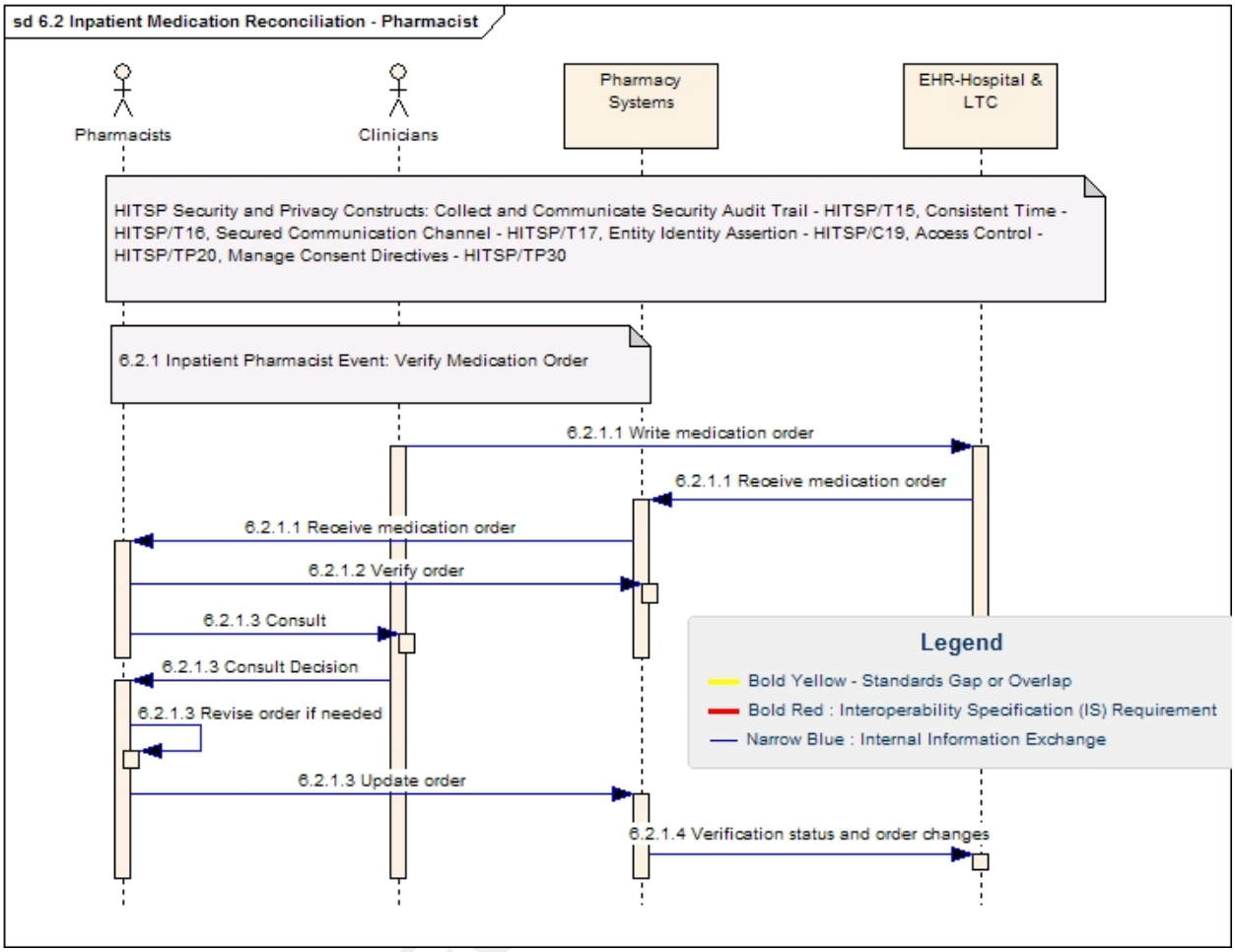


Figure 2.2.4-8 Business Sequence Diagram - 6.3

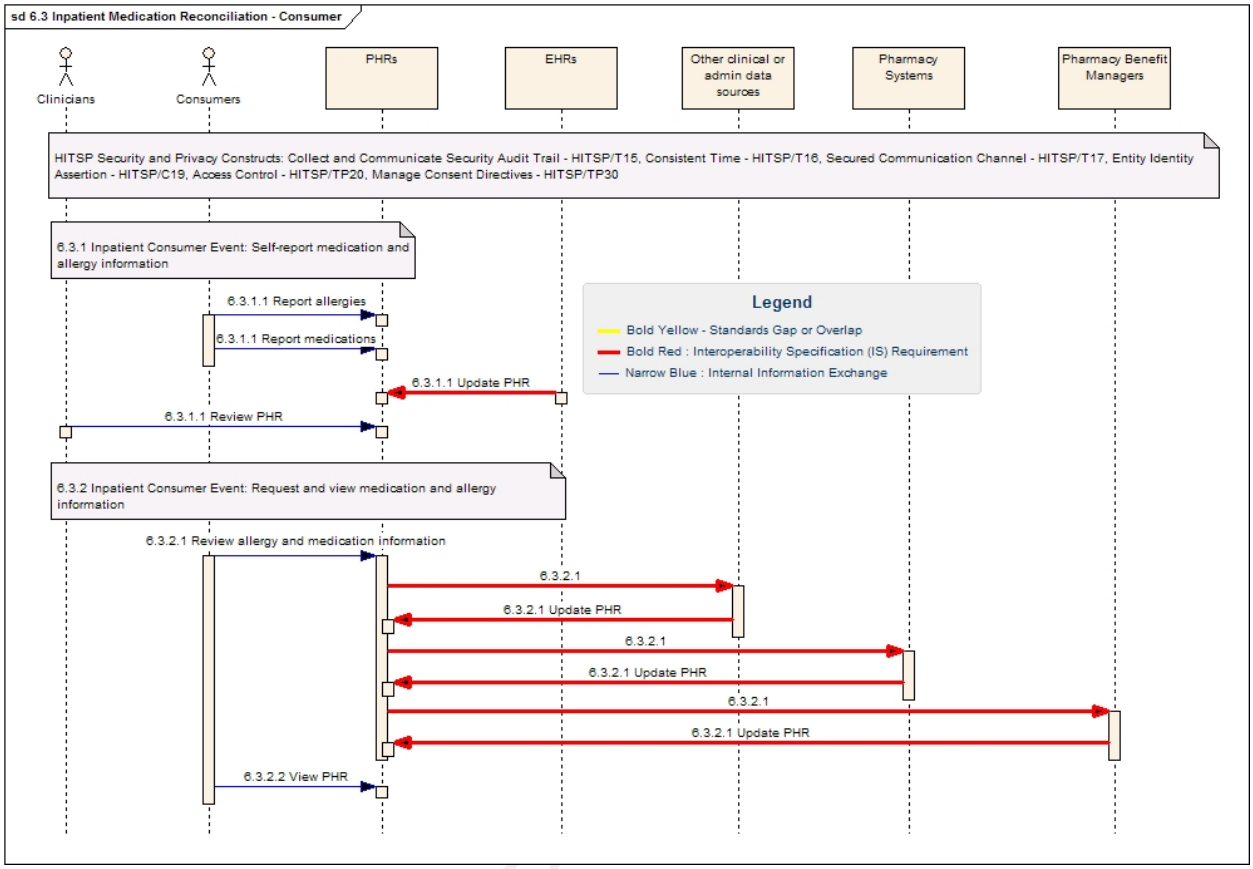


Figure 2.2.4-9 Business Sequence Diagram - 7.1.1 and 7.1.2

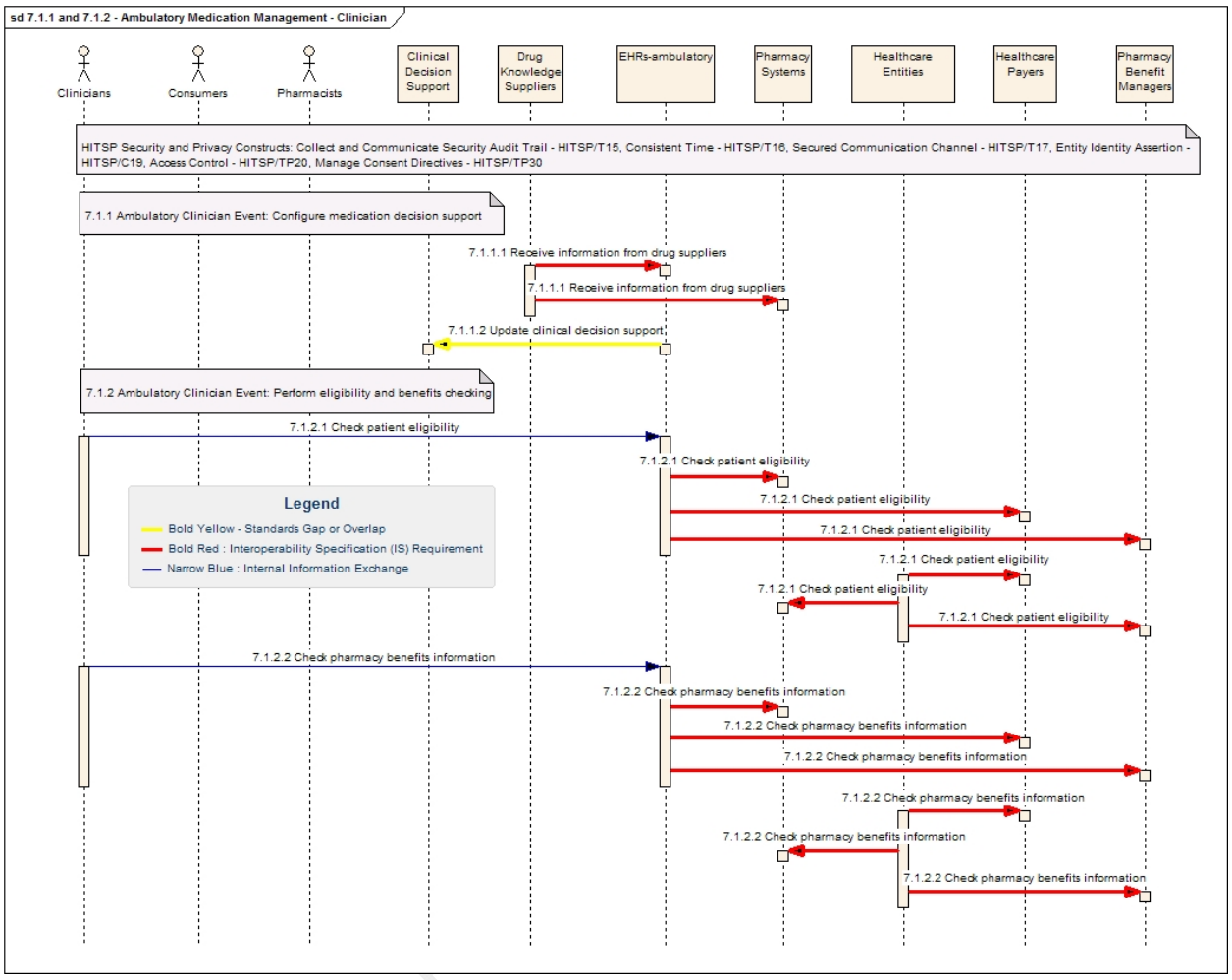


Figure 2.2.4-10 Business Sequence Diagram - 7.1.3 and 7.1.4

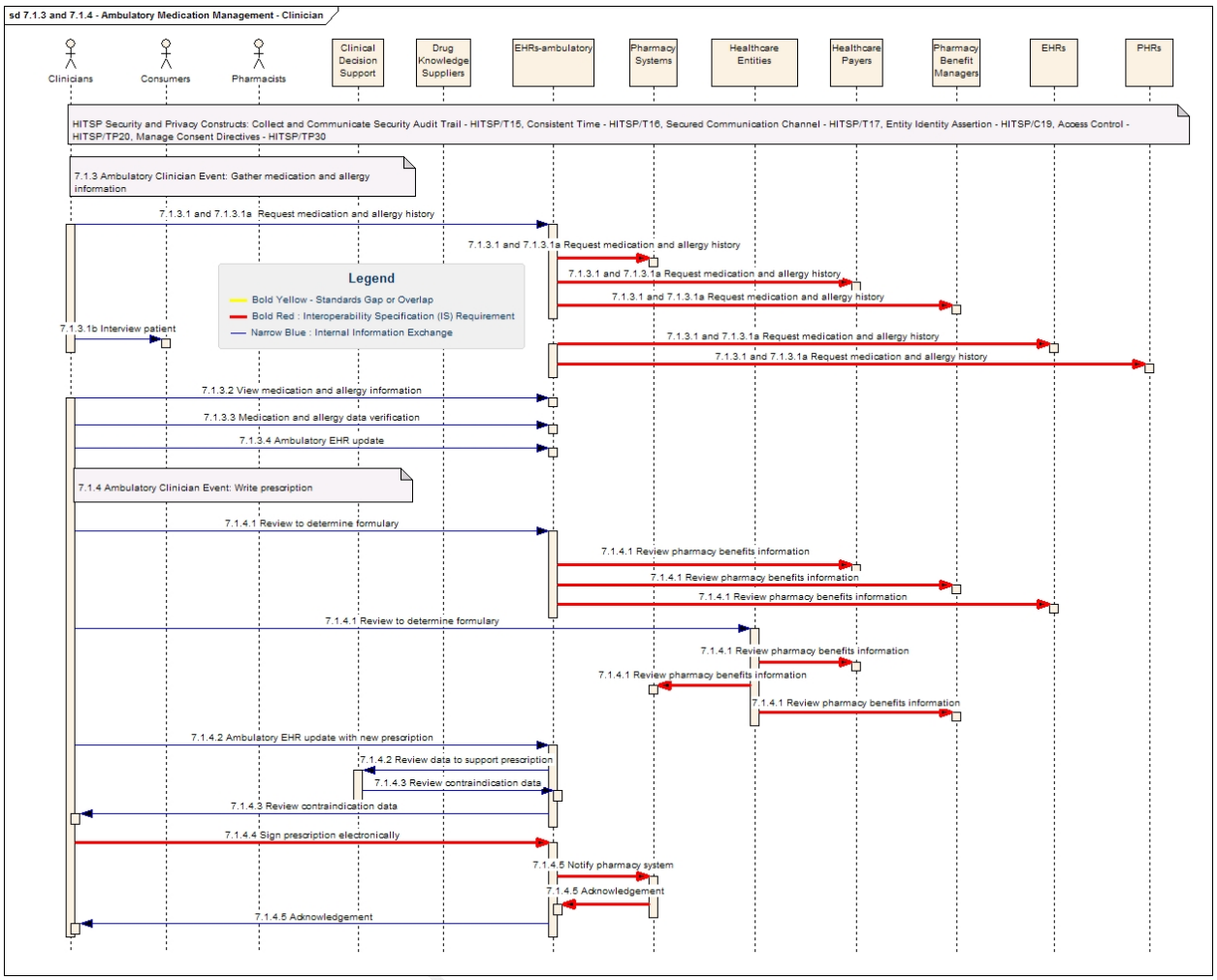


Figure 2.2.4-11 Business Sequence Diagram - 7.1.5 and 7.1.6

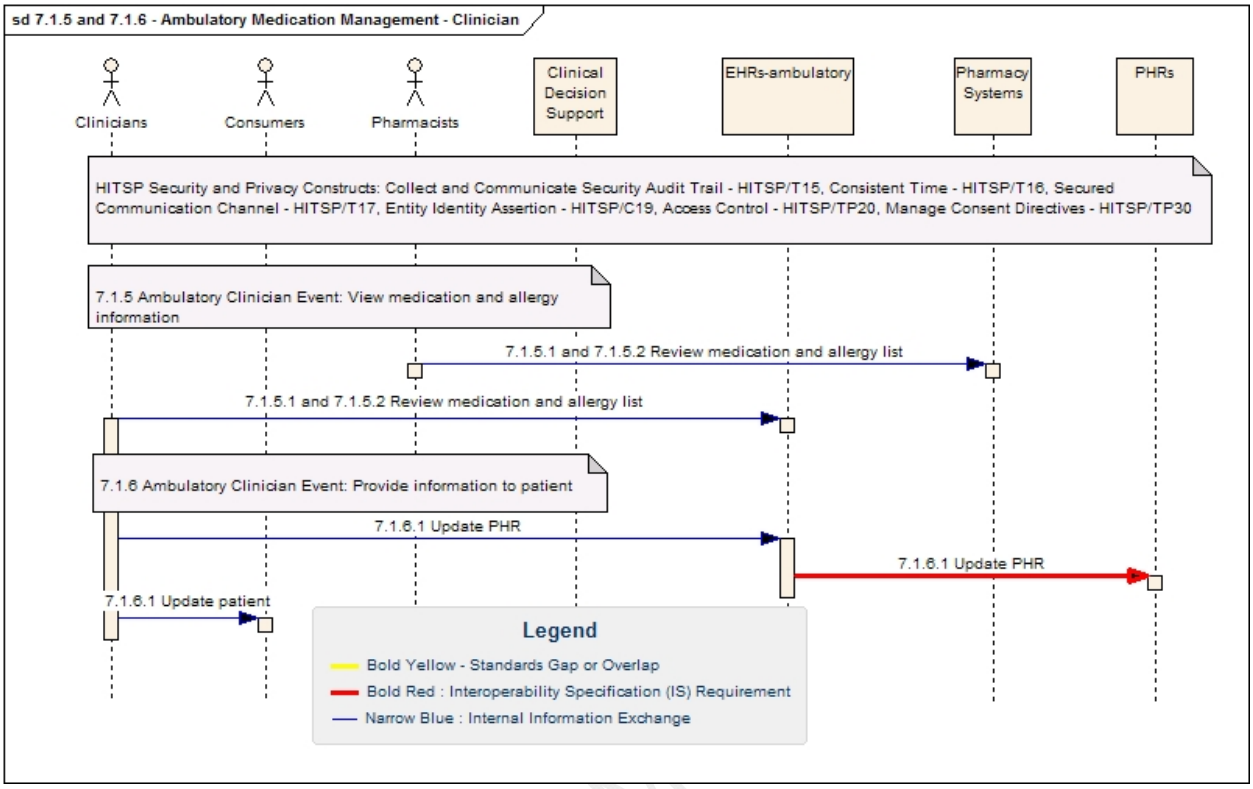


Figure 2.2.4-12 Business Sequence Diagram - 7.2.1 and 7.2.2

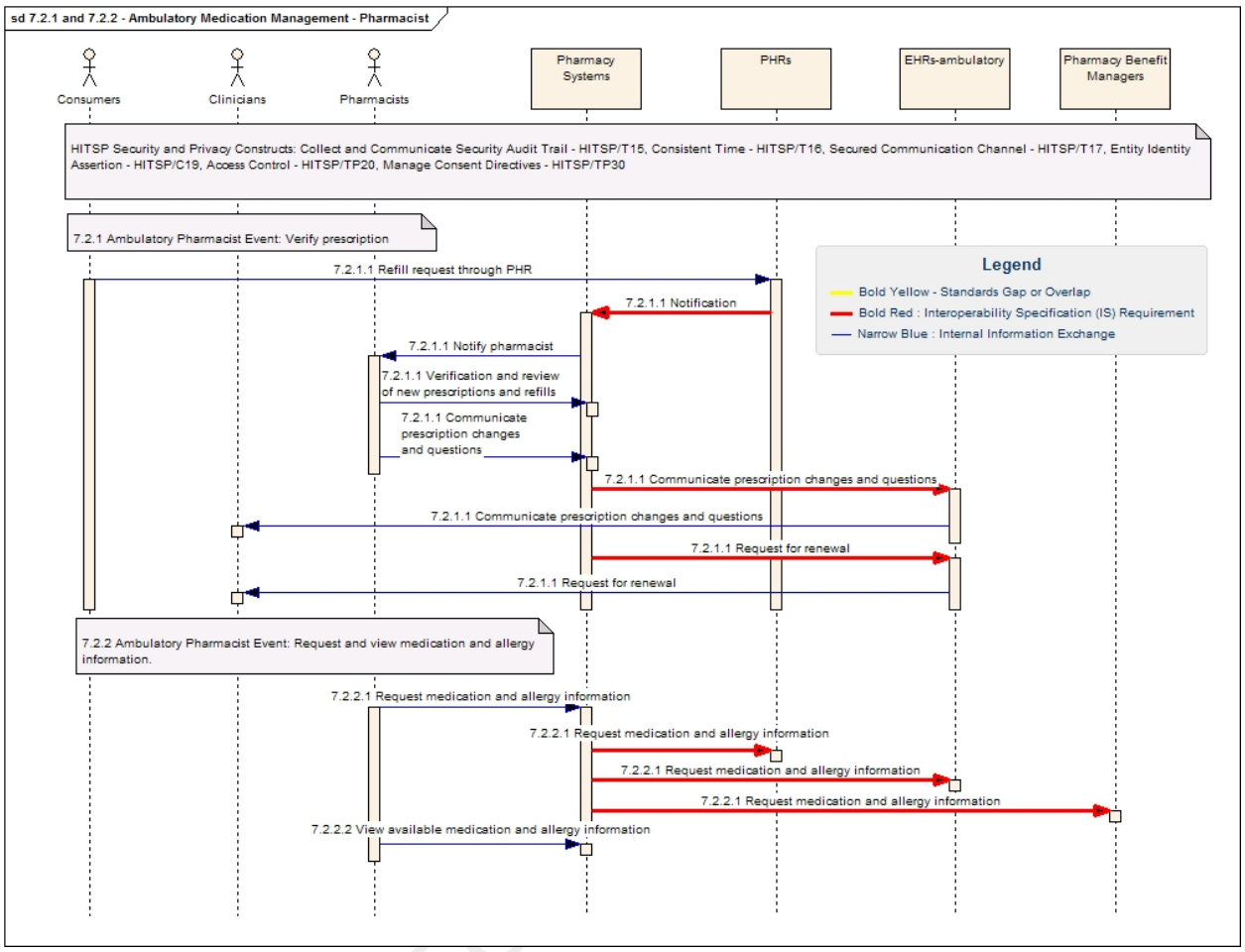


Figure 2.2.4-13 Business Sequence Diagram - 7.2.3 and 7.2.4

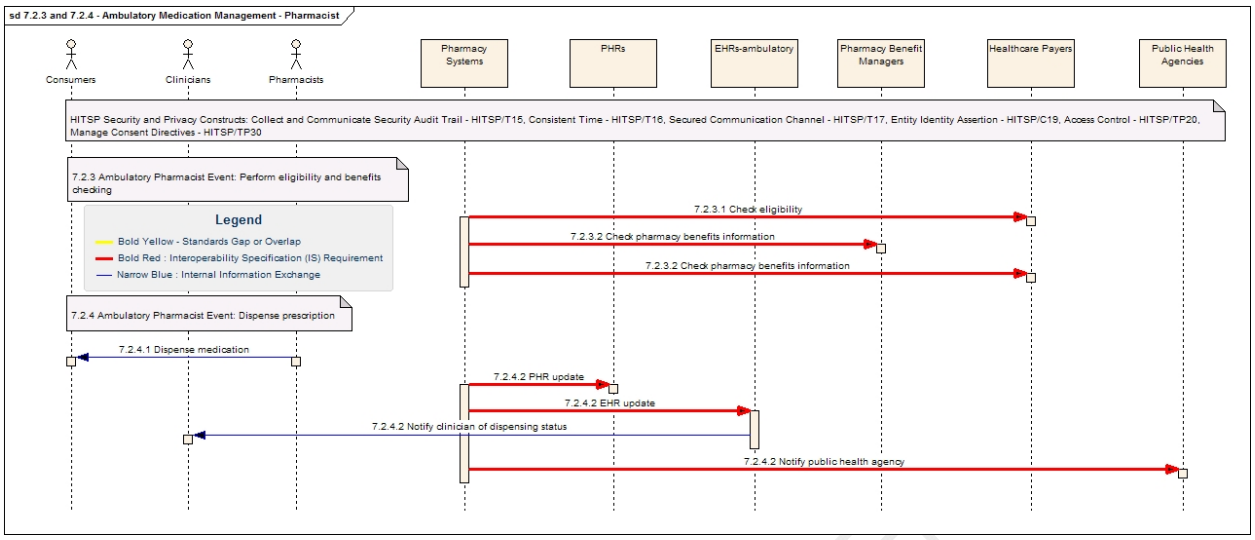


Figure 2.2.4-14 Business Sequence Diagram - 7.3.1 and 7.3.2

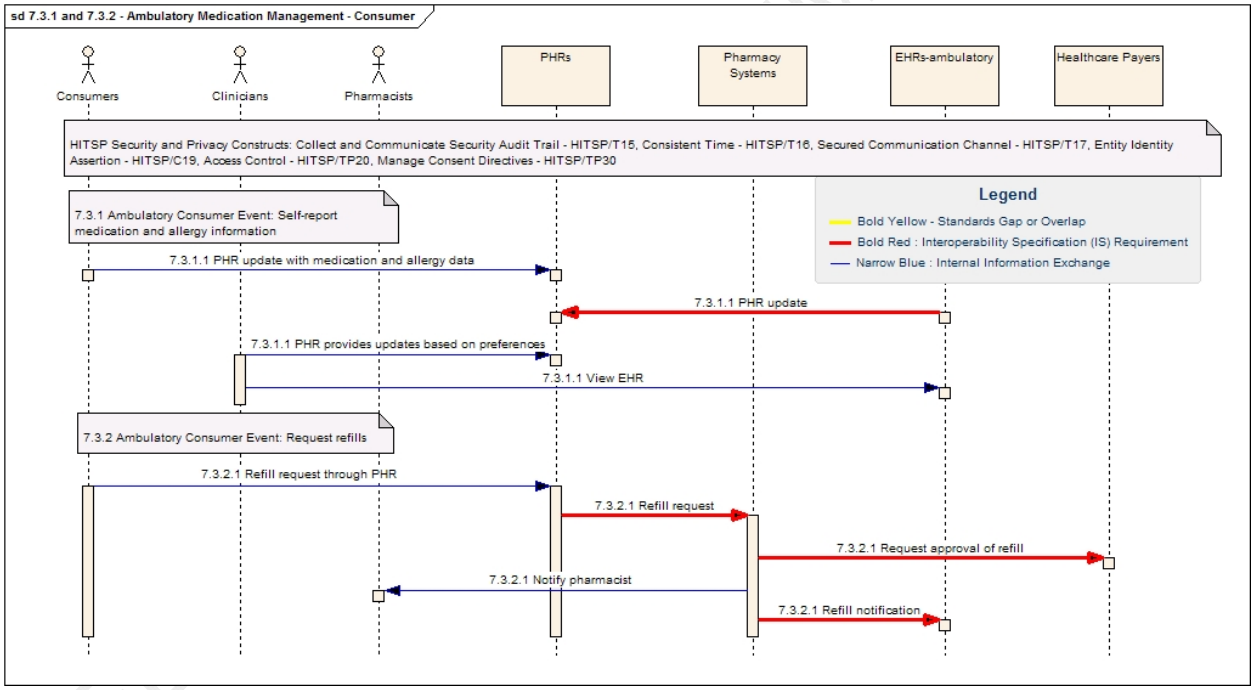
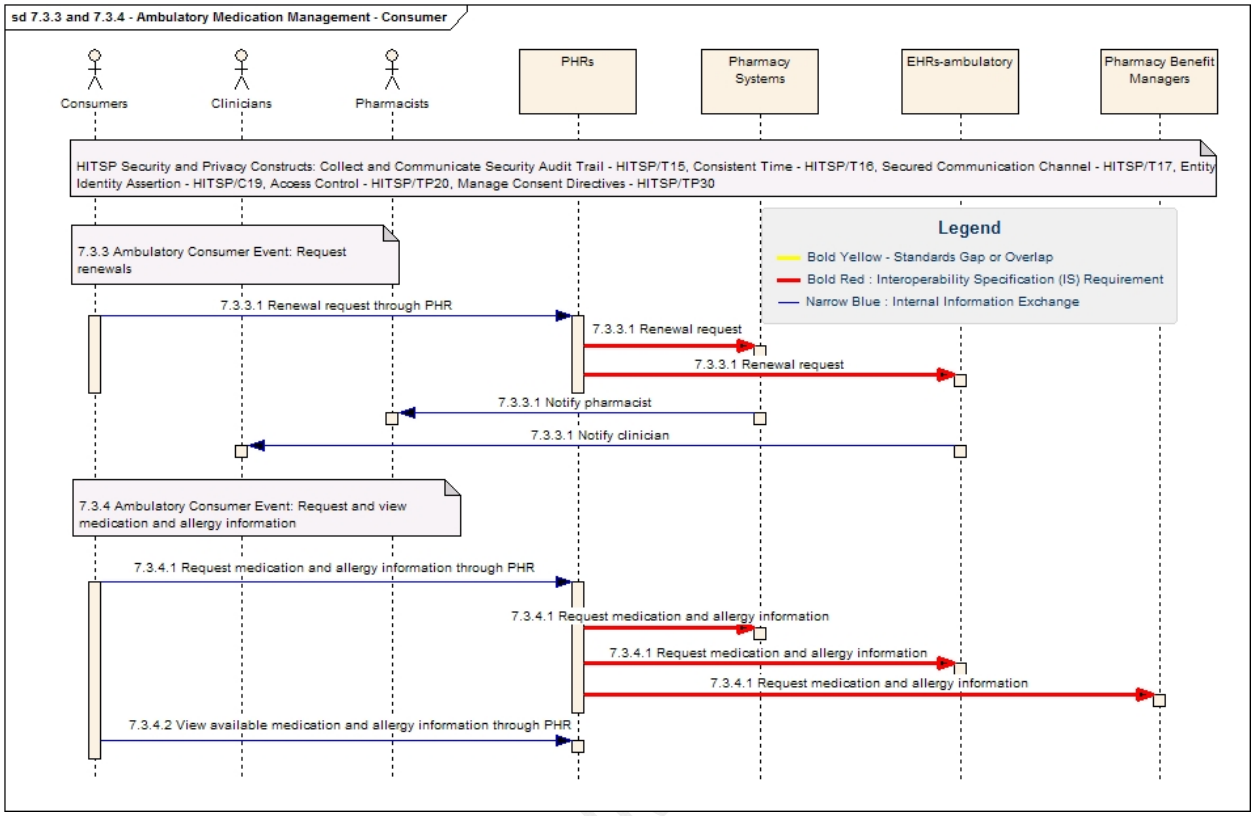


Figure 2.2.4-15 Business Sequence Diagram - 7.3.3 and 7.3.4



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

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
7.2.4.2 - Patient signs for, and receives prescription at this step. Long term care is different in relation to this step; it is assumed that long term care is NOT covered in this action.	7.2
Health Information Exchange (HIE) can serve as intermediary for data in many different scenarios in this Use Case and it is assumed that it may exist in real world implementations. The various alternative options are not shown.	All
Long term care (LTC) is referenced in some of the event/actions of the Use Case only as it relates to the inpatient and ambulatory settings. LTC requirements are only partially defined in the Use Case. The Medication Management Use Case does not define the LTC environment fully with LTC workflow, participants, needs and activities. It is expected that once an LTC medication management scenario is defined, LTC requirements will be fully addressed.	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	Use Case Scenario
Constraints are defined in the HITSP constructs referenced in this Interoperability Specification.	All

3.1.3 PRE-CONDITIONS

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

Table 3.1.3-1 Pre-conditions

Pre-condition	Use Case Scenario
Patient consent for treatment, payment and healthcare operations.	All
Entities have pre-established a business relationship to exchange information.	All
Appropriate standards are developed, approved, and widely adopted supporting data content and structure, allowing universal access by compliant systems.	All
Core datasets are defined and adhered to.	All
Authentication service to authenticate requestors and/or data submissions from various locations.	All
Security and privacy policies, procedures and practices are commonly implemented to support acceptable levels of consumer/patient security and privacy.	All
HITSP/T16-Consistent Time is implemented for each grouping of actors to ensure that all of the entities that are communicating within the network have synchronized system clocks.	All
HITSP/TP30-Manage Consent Directives is implemented to capture, manage and communicate rights granted or withheld by a consumer to one or more identified entities in a defined role to access, collect, use or disclose Individually Identifiable Health Information (IIHI).	All

3.1.4 POST-CONDITIONS

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

Table 3.1.4-1 Post-conditions

Post-condition	Use Case Scenario
Medication has been prescribed to a patient or the reason why it is not given.	All

3.1.5 PROCESS TRIGGERS

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

Table 3.1.5-1 Process Triggers

Process Trigger	Use Case Scenario
Patient has a condition for which clinician wishes to prescribe medication.	7.1, 7.2, 7.3
Patient is admitted to inpatient or long term care setting and requires medication.	6.1, 6.2, 6.3

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 this Use Case. Any variances in the Security and Privacy implementation are also described here.

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

3.2.1 TECHNICAL ACTOR 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
Any actor grouped with a Secure Node	Any actor from the HITSP Interoperability Specification that is grouped with a Secure Node.
Access Control Service	The Access Control Service is the enterprise security service that supports and implements user-side and service side access control capabilities. This service would be utilized by the Service User, and/or Service Provider.

Technical Actor(s)	Actor Role
Audit Record Repository	This actor provides a repository for audit events.
Audit Record Source	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.
Consent Directive Requestor	The Consent Directive Requester accesses Consent Directives located through a Consent Registry from Consent Repositories.
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.
Consent Registry	The Consent Registry is responsible for providing location information and sender notification regarding consent directives. The Consent Registry receives *a Manage Consent Directive Metadata Request.*
Consent Repository	The Consent Repository is responsible for both the persistent storage of consent directives as well as for their registration with the appropriate Consent Registry. It assigns a Uniform Resource Identifier (URI) and Metadata such as confidentiality codes to the consent directive for subsequent retrieval by an authorized consumer, e.g., for association with published personal health information or for evaluation at a policy decision point.
Consenter	The Consenter is an individual consumer of healthcare services or a consumer delegate that selects a Consent Originator to capture and manage the consumer's consent directives so that these can be associated with personal health information. The Consenter receives a *Resolve Consent Directive Request* from the Consent Directive Originator to resolve an apparent conflict between a proposed consent directive and a current consent directive. The Consenter sends a *Resolve Consent Directive Response* either modifying the consent directive or confirming that the conflict is an intended update of a current consent directive.
Content Creator	The Content Creator is responsible for the creation of content and transmission to a Content Consumer.
Content Consumer	A Content Consumer is responsible for viewing, import or other processing of content created by a Content Creator.
Document Consumer	The Document Consumer Actor queries a Document Registry Actor for documents meeting certain criteria and retrieves selected documents from one or more Document Repository actors.
Document Registry	The Document Registry Actor maintains metadata about each registered document in a document entry. This includes a link to the Document in the Repository where it is stored. The Document Registry responds to queries from Document Consumer Actors about documents meeting specific criteria. It also enforces some healthcare specific technical policies at the time of document registration.
Document Repository	The Document Repository is responsible for both the persistent storage of these documents as well as for their registration with the appropriate Document Registry. It assigns a Uniform Resource Identifier to documents for subsequent retrieval by a Document Consumer.
Document Source	The Document Source Actor is the producer and publisher of documents. It is responsible for sending documents to a Document Repository Actor. It also supplies metadata to the Document Repository Actor for subsequent registration of the documents with the Document Registry Actor.
Eligibility Information Receiver	The entity that is asking about an individual's health plan insurance eligibility, coverage and benefits. It initiates queries to the Eligibility Information Source.
Eligibility Information Source	The entity that holds and maintains the information regarding the patient's insurance eligibility, coverage and benefits. It responds to queries from the Eligibility Information Receiver.
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).
Initiating Gateway Actor	The Initiating Gateway Actor, support a community, queries one or more Responding Gateway Actor each serving one or more communities for documents meeting certain criteria, and retrieves selected documents from the respective Responding Gateway Actors.
Medication Formulary and Benefits Retriever	The entity that is asking about an individual's formulary and benefits information. It initiates queries to the Medication Formulary and Benefits Source.

Technical Actor(s)	Actor Role
Medication Formulary and Benefits Source	The entity who maintains individual's formulary and benefits information. It responds to queries from the Medication Formulary and Benefits Retriever.
Medication Order Filler	The Medication Order Filler responds to the requests for medication orders/prescriptions. This includes the ability to respond to: New orders, refill orders, change orders and cancel orders. These responses are sent to the Medication Order Prescriber.
Medication Order Prescriber	The Medication Order Prescriber initiates requests for medication orders/prescriptions. This includes the ability to create: New orders, refill orders, change orders and cancel orders. These requests are sent to the Medication Order Filler.
Medication Status Dispenser	The Medication Status Dispenser provides a dispensing status (RXFILL message) to a Medication Status Receiver about a preciously performed medication order/prescription.
Medication Status Receiver	The Medication Status Receiver receives a dispensing status (RXFILL message) from a Medication Status Dispenser about a previously performed medication order/prescription.
Node	The originating or terminating point of information or signal flow in a telecommunications network. This actor is equivalent to the *Secure Node* in the IHE-ITI-TF ATNA Transaction.
Patient Demographics Consumer	The entity that queries the Patient Demographics Supplier for a list of patient demographic information, if any, and receives a list of corresponding patient demographic information from the Patient Demographics Supplier.
Patient Demographics Supplier	The entity that receives the query for a list of corresponding patient demographics from the Patient Demographics Consumer, sends a list of corresponding patient demographic information to the Patient Demographics Consumer, and maintains one or more Patient Information Sources of patient demographics data.
Patient Identifier Cross-reference (PIX) Manager	System that maintains a cross-domain patient index including all known identifiers (real and pseudo) for each patient within all domains with which it communicates.
Patient Identity Consumer	System that wishes to know alternate identifiers (real and pseudo) for patients within its domain or pseudo-identifiers for patients outside its domain.
Patient Identity Source	The Patient Identity Source Actor assigns a provider-unique identifier for each patient and maintains a domain patient index including all known identifiers (real and pseudo) for each patient within its domain. Each Patient Identifier Domain requires this Actor to assign patient identities and to notify other Actors (e.g. a Patient Identifier Cross-Reference Manager or a Registry Actor) of all events related to patient identification (creation, update, merge, etc.). Also a Patient Identity Consumer for the purpose of receiving pseudo-identifiers for patients within its domain.
Responding Gateway Actor	The Responding Gateway Actor, supporting one or more communities, receives queries and documents or retrieves requests from remote Initiating Gateways and responds to these requests.
Service Provider	The Service Provider represents the system providing a protected resource and relies on the provided security service.
Service User	The 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. Any Service User may also be a Service Provider.
Time Client	The text for the IHE ITI-TF-1 V4.0 begins here: 'Establishes time synchronization with one or more Time Servers using the NTP protocol and either the NTP or SNTP algorithms. Maintains the local computer system clock synchronization with UTC based on synchronization with the Time Servers.' The text for the IHE ITI-TF-1 V4.0 ends here.
Time Server	The text for the IHE ITI-TF-1 V4.0 begins here: 'Provides NTP time services to Time Clients. It is either directly synchronized to a UTC master clock (e.g. satellite time signal) or is synchronized by being grouped with a Time Client to other Time Server(s).' The text for the IHE ITI-TF-1 V4.0 ends here.

3.2.2 SEQUENCE DIAGRAM FOR PROCESS FLOW

This section 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 (defined in Section 2.2.2) with the technical actors and their specific and detailed interactions (encapsulated in HITSP constructs). The detailed actor interactions described in these diagrams show all common or independent actors, data, and the actual transactions from the HITSP constructs that are used for the Interoperability Specification.

Diagrams show all common or independent actors, data, actions and groupings of actions around common actors.

Six UMLs are provided, one for each scenario perspective. These UMLs are examples only but highlight possible workflows. The actual transactions required for all business actors are specified in Table 3.2.3-1. The scenario perspectives are:

- 6.1 Inpatient Medication Reconciliation, Clinician Perspective
- 6.2 Inpatient Medication Reconciliation, Pharmacist Perspective
- 6.3 Inpatient Medication Reconciliation, Consumer Perspective
- 7.1 Ambulatory Medication Management, Clinician Perspective
- 7.2 Ambulatory Medication Management, Pharmacist Perspective
- 7.3 Ambulatory Medication Management, Consumer Perspective

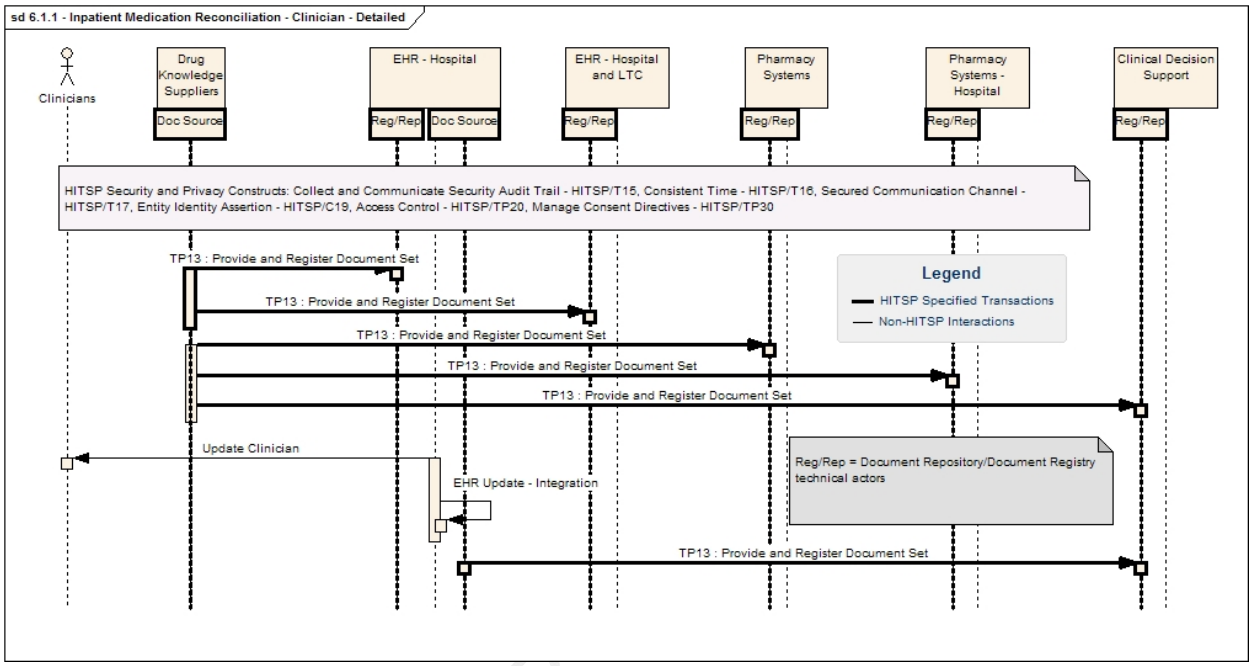
In order to obtain patient identifiers from various Business Actors, two HITSP constructs are used. These two constructs are HITSP/T23 - Patient Demographics Query and HITSP/TP22 - Patient ID Cross-Referencing. There are many scenarios in this Interoperability Specification when it is needed to obtain patient identifiers and either solution may be used.

HITSP/T23 - Patient Demographics Query is used to obtain identifiers from other domains for workflows that do not have the local domain patient identifier. The Patient Demographic Supplier receives a Patient Demographics Query from the Patient Demographics Consumer with information such as name, sex, address, date of birth, etc. The Patient Demographic Supplier returns demographics information and the associated identifier for the domain and/or domain(s) supported by the supplier.

HITSP/TP22 - Patient ID Cross-Referencing supports the cross-referencing of patient identifiers from multiple Patient Identifier Domains. It is used to obtain identifiers from other domains for workflows that do have the local domain patient identifier. The PIX Consumer queries the PIX Manager with the known local domain identifier and the PIX Manager returns the identifier of the requested domain.

In order to simplify the UML diagrams only the HITSP/T23 and HITSP/TP22 construct is shown. Both HITSP/T23 and HITSP/TP22 may be used for the various perspectives and showing one example does not exclude supporting the other construct.

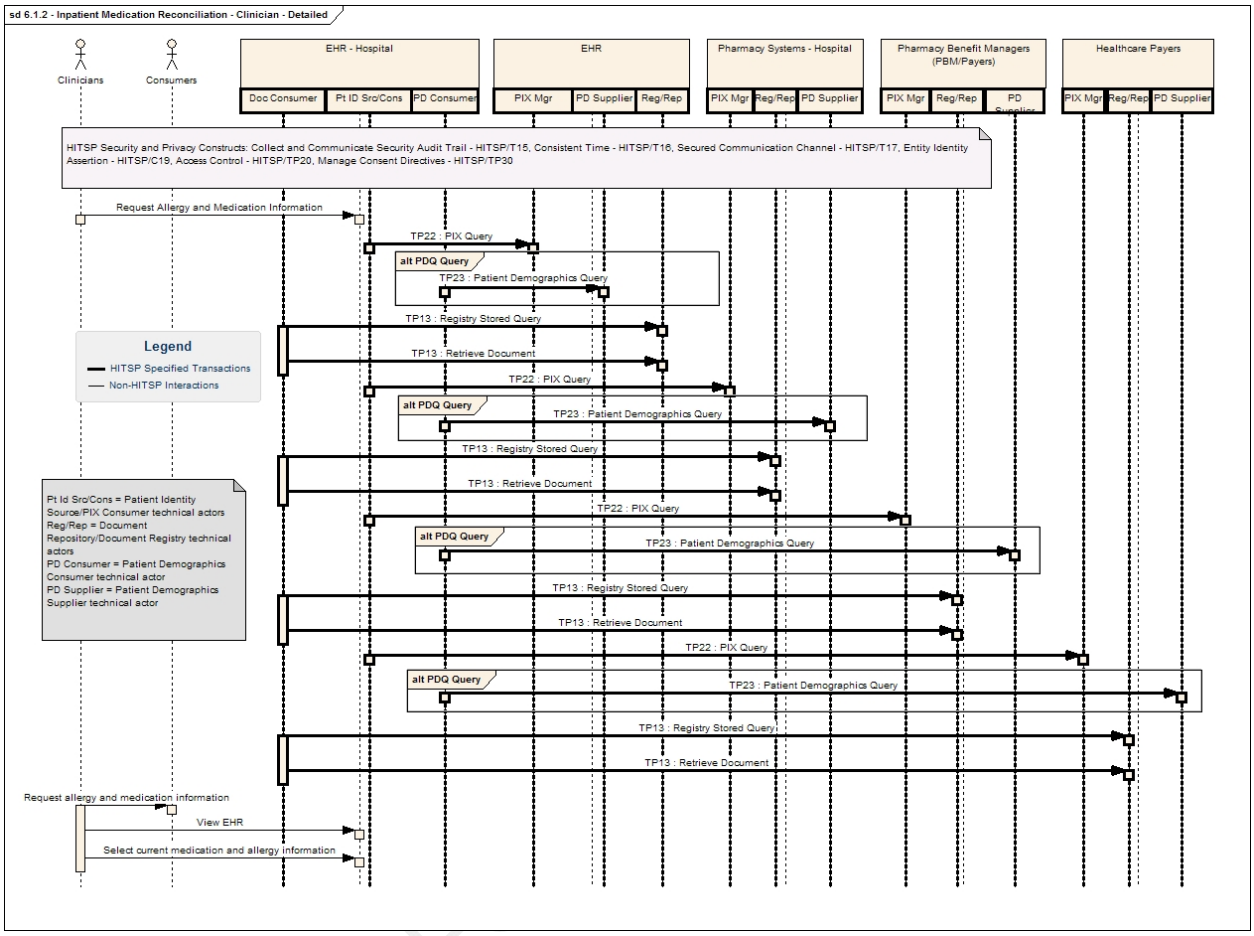
Figure 3.2.2-1 Detailed Sequence Diagram Inpatient Medication Reconciliation from a Clinician Perspective - 6.1.1



The Drug Knowledge Supplier sends updated drug knowledge information to each of the sources listed [Provide and Register Document Set].

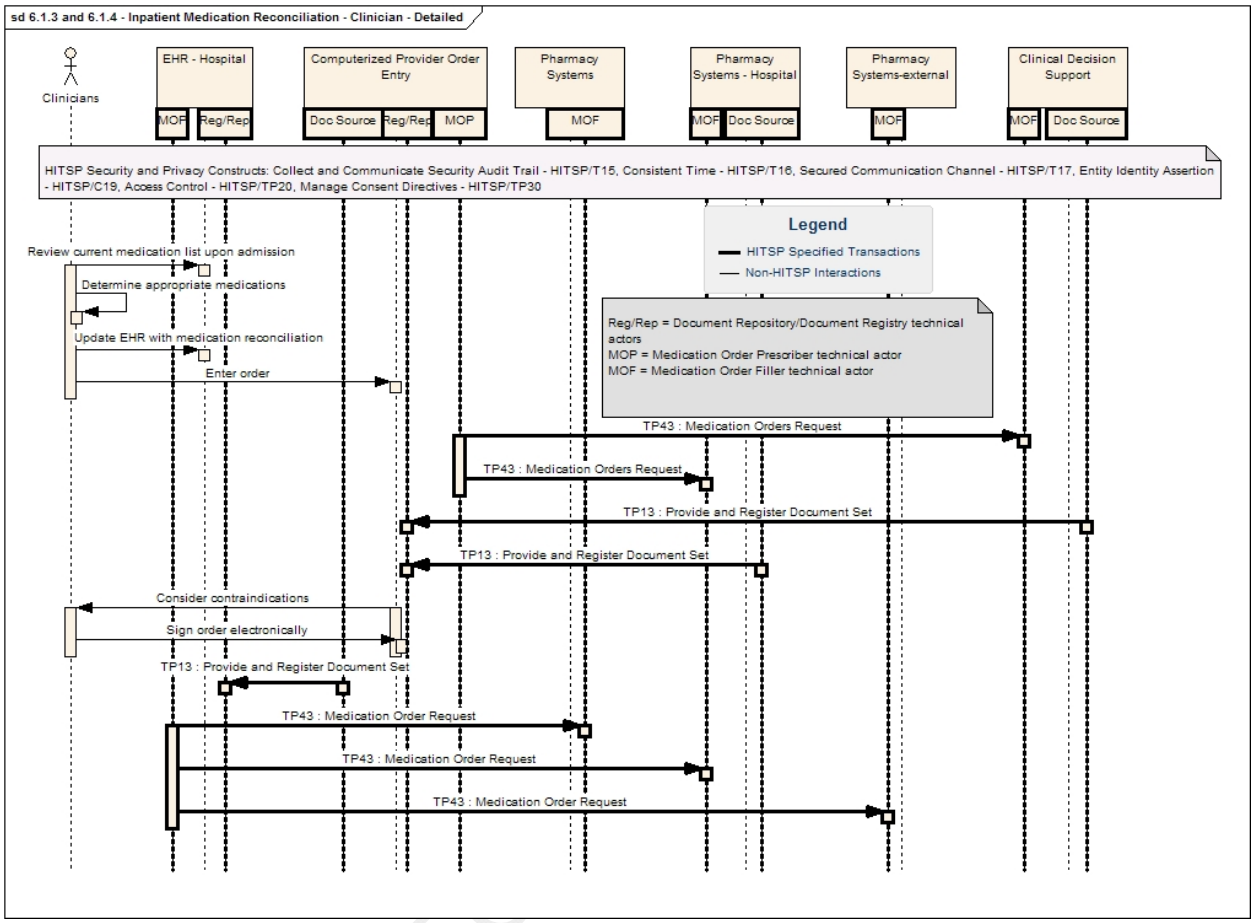
The clinician is then updated on all changes and the information is incorporated into the hospital EHR and sent to the clinical decision support system.

Figure 3.2.2-2 Detailed Sequence Diagram Inpatient Medication Reconciliation from a Clinician Perspective - 6.1.2



A request for medication and allergy information is received by a hospital EHR from a clinician. The hospital EHR retrieves registration and medication history information from each of the sources listed, using a [PIX Query and/or PDQ Query] to identify the patient, a [Registry Stored Query] to locate the data and a [Retrieve Document] transaction to gather the information. The clinician may also request information directly from the consumer. Once the information is collected in the hospital EHR, the clinician views the EHR and selects the current medication and allergy information.

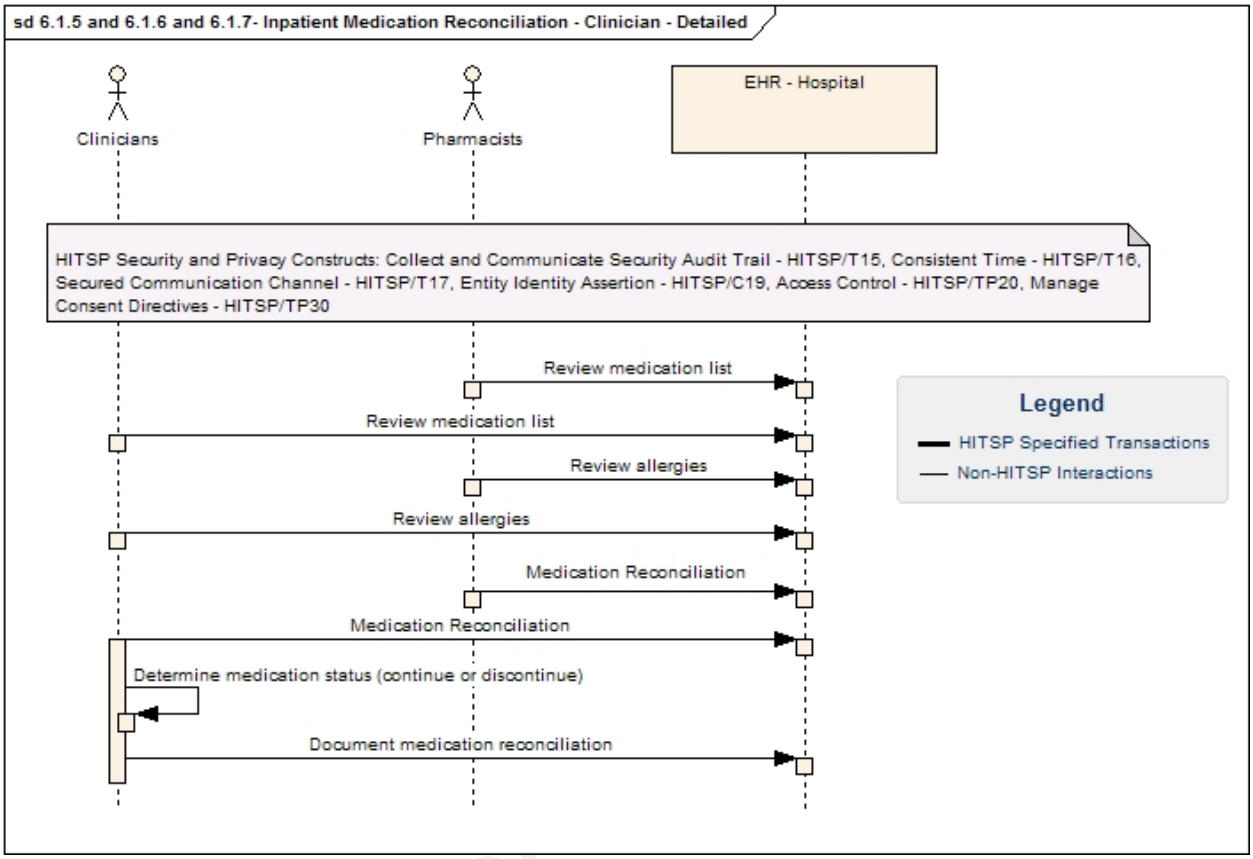
Figure 3.2.2-3 Detailed Sequence Diagram Inpatient Medication Reconciliation from a Clinician Perspective - 6.1.3 and 6.1.4



A clinician reviews the hospital EHR upon admission of a patient. The clinician determines appropriate medications and updates the EHR with the appropriate list of medications. The clinician then enters the medication order into the Computerized Provider Order Entry (CPOE) system of the hospital EHR.

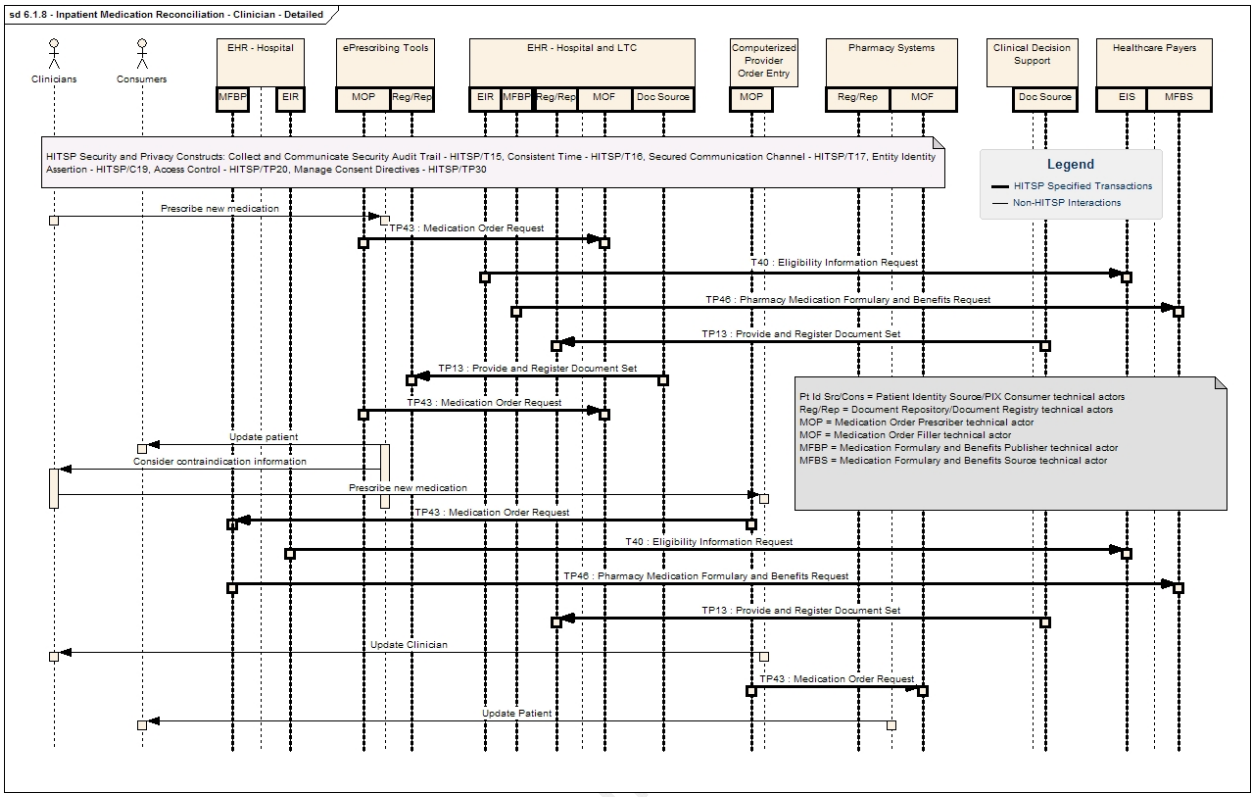
Once the order is entered into the CPOE system, the system uses the [Medication Order Request] transaction to submit the order to the clinical decision support system and then the hospital pharmacy system for the purpose of contraindications and interaction checking. The CPOE is updated using the [Provide and Register Document Set] transaction, from the clinical decision support and hospital pharmacy systems, providing contraindication data to the clinician to view in the CPOE.
Once the contraindications are reviewed, the clinician signs the order electronically and then the [Provide and Register Document Set] is sent to the EHR system. The [Medication Order Request] transaction is sent out from the hospital EHR to the pharmacy systems at the hospital and external to the hospital.

Figure 3.2.2-4 Detailed Sequence Diagram Inpatient Medication Reconciliation from a Clinician Perspective - 6.1.5, 6.1.6, and 6.1.7



Clinicians and pharmacists review the hospital EHR and reconcile medications depending on medications and allergy information in the system. This is an internal information exchange. This reconciliation is documented.

Figure 3.2.2-5 Detailed Sequence Diagram Inpatient Medication Reconciliation from a Clinician Perspective - 6.1.8



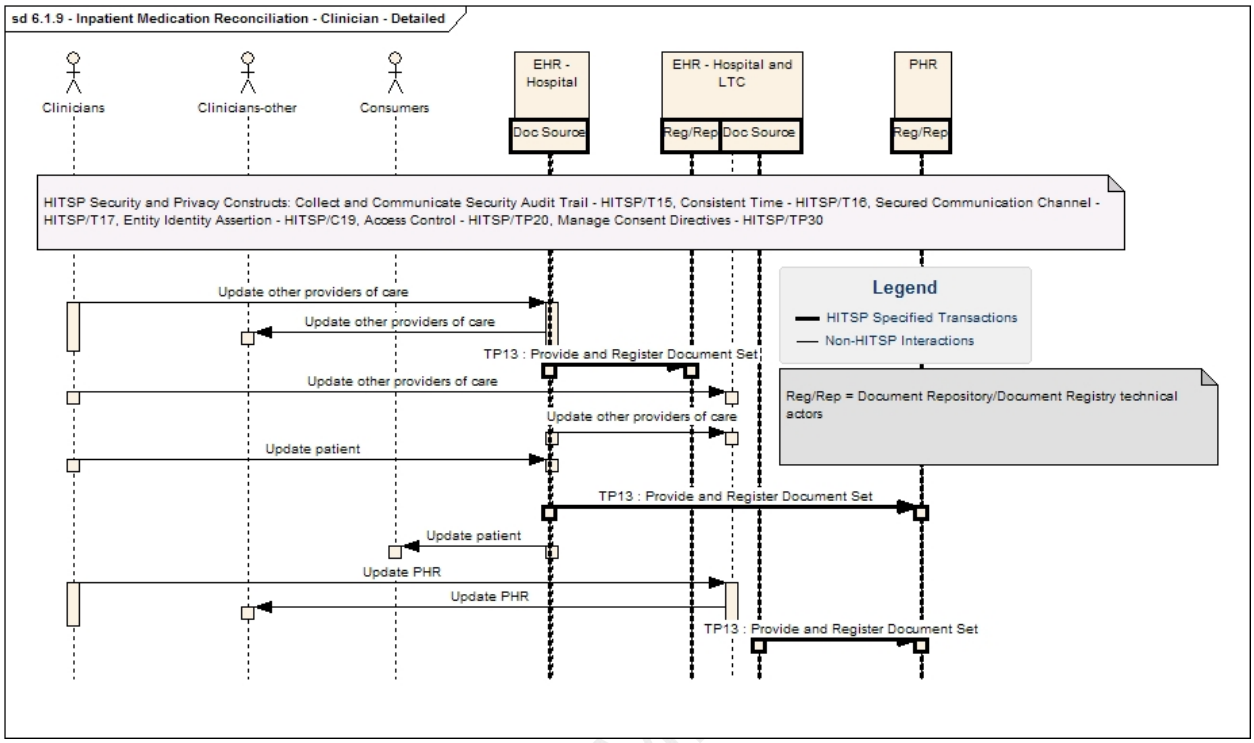
A clinician prescribes a new medication using an ePrescribing tool. The [Medication Order Request] is sent to an EHR at a hospital and/or an EHR at a long term care (LTC) facility. A [Eligibility Information Request] and if it is a LTC facility a [Pharmacy Medication Formulary and Benefits Request] is sent to a healthcare payer system.

The clinical decision support system also returns contraindication information for clinician consideration using the [Provide and Register Document Set] transaction, which loads the contraindication information into the hospital and/or long term care facility EHR.

The [Medication Order Request] information is provided by the ePrescribing Tool to the hospital/LTC EHR, which then processes the request.

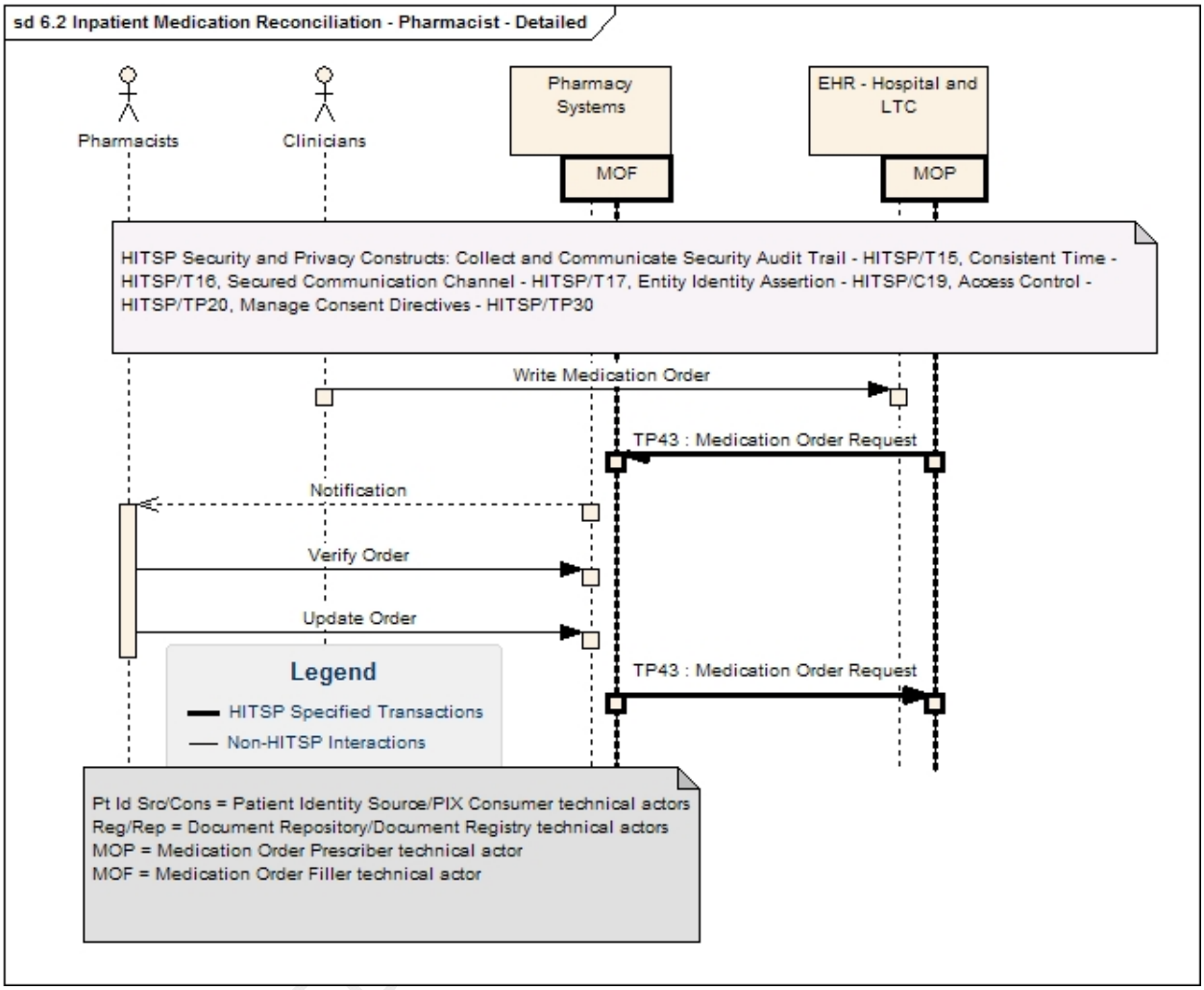
In an alternative scenario, the clinician prescribes a new medication order through a CPOE system. The [Medication Order Request] is sent from the CPOE system to the hospital EHR. The hospital EHR sends an [Eligibility Information Request] and a [Pharmacy Medication Formulary and Benefits Request] to the healthcare payer, and the clinical decision support system provides contraindication data for analysis by the clinician. The order is then sent by the CPOE to the pharmacy system through a [Medication Order Request]. The pharmacy system updates the patient on the status of the order.

Figure 3.2.2-6 Detailed Sequence Diagram Inpatient Medication Reconciliation from a Clinician Perspective - 6.1.9



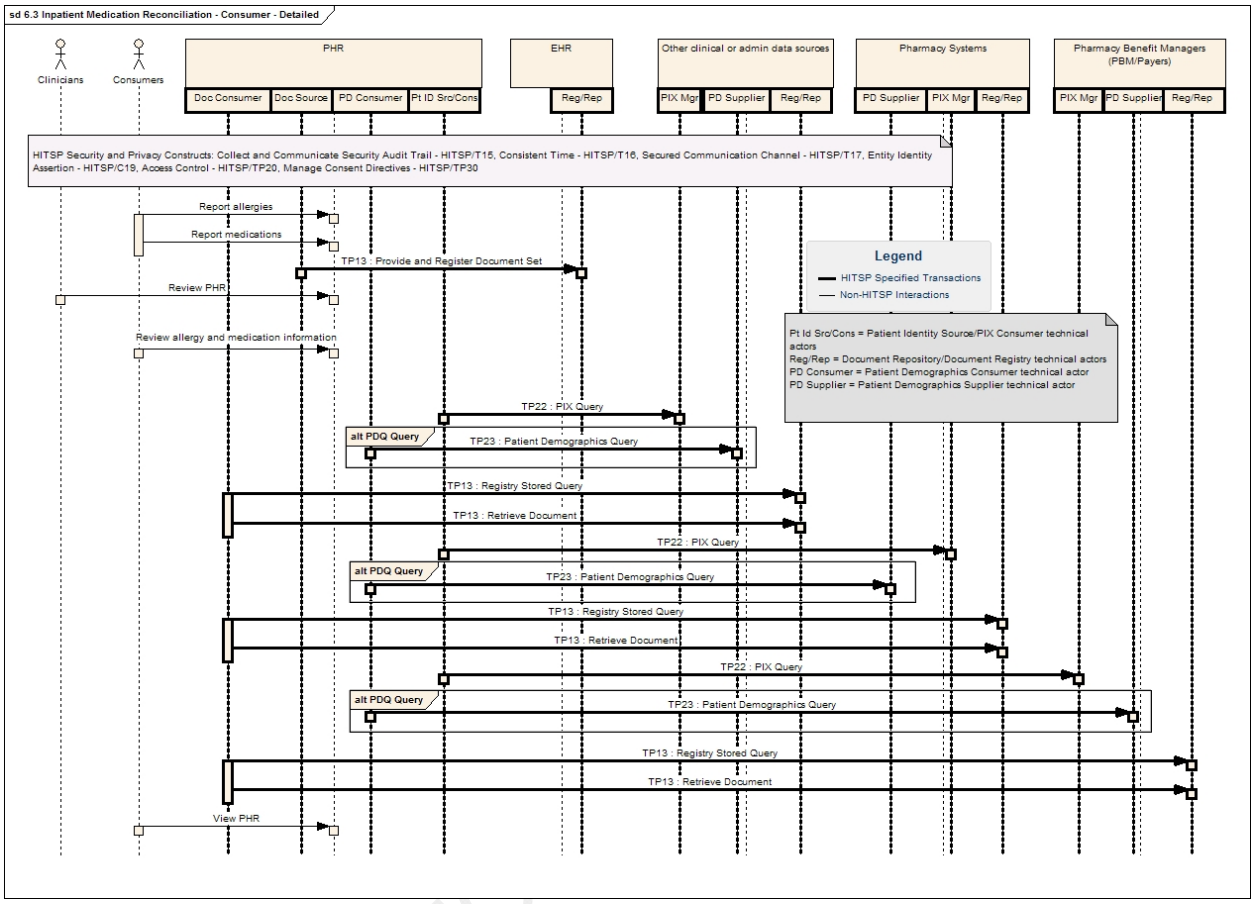
In this scenario, providers of care are updated from the hospital EHR. The hospital EHR is updated by both clinicians and the consumer and these updates are propagated to other systems using the [Provide and Register Document Set] transaction.

Figure 3.2.2-7 Detailed Sequence Diagram Inpatient Medication Reconciliation from a Pharmacist Perspective - 6.2



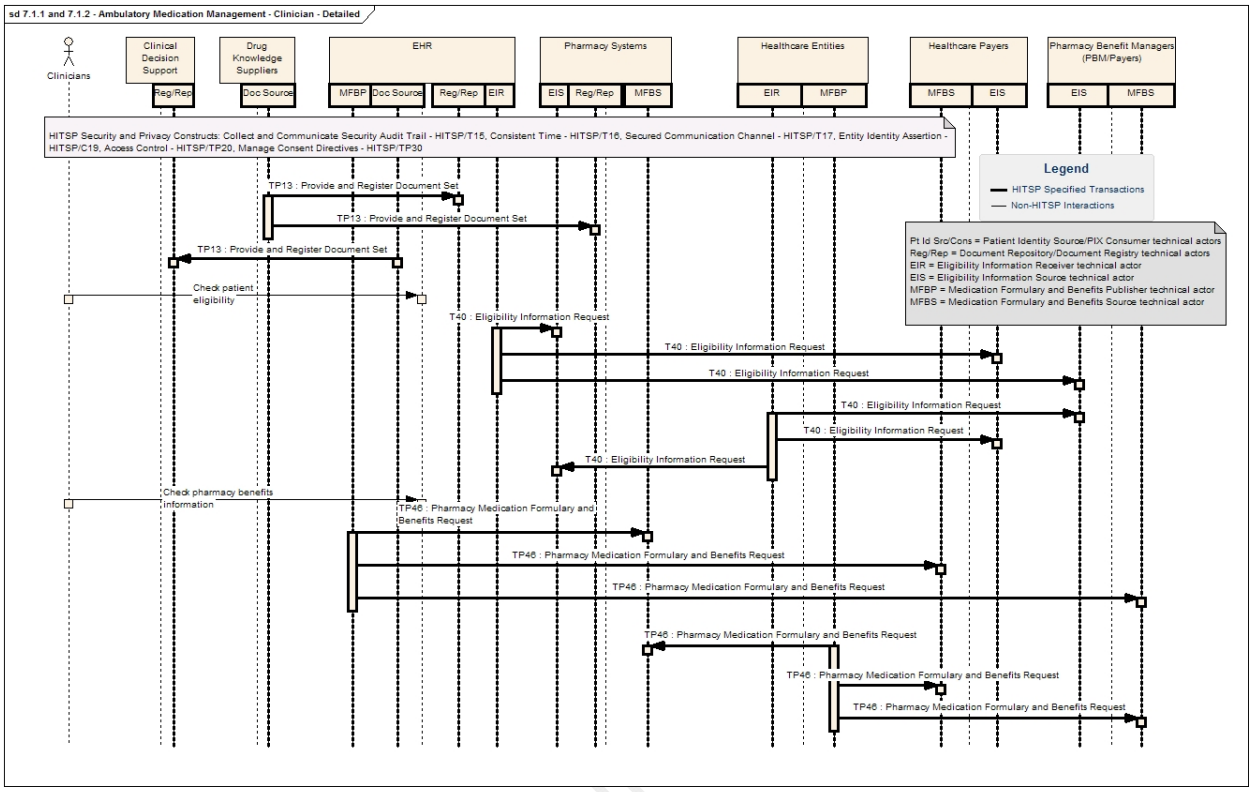
In this scenario, the clinician enters a medication order into the hospital EHR or a long term facility EHR. The [Medication Order Request] is transferred from the hospital EHR or the long term facility EHR to the pharmacy system. The pharmacy system sends a notification to the clinician, asking for verification and updates to the medication order. The pharmacy system uses the [Medication Order Request] transaction to send a response to the hospital or long term care facility EHR with the current order contents.

Figure 3.2.2-8 Detailed Sequence Diagram Inpatient Medication Reconciliation from a Clinician Perspective - 6.3



The consumer reports allergies and medications to their PHR. These allergies and medications are transferred by the PHR to an EHR (hospital, ambulatory, etc.) using the [Provide and Register Document Set] transaction. The clinician then reviews the PHR to validate these allergies and medications, and the consumer again checks to ensure all information is correct. Following this verification, the updated allergy and medication information is sent to pharmacy systems and pharmacy benefit managers, as well as any other clinical or administrative data sources.

Figure 3.2.2-9 Detailed Sequence Diagram Ambulatory Medication Management From a Clinician Perspective - 7.1.1 and 7.1.2

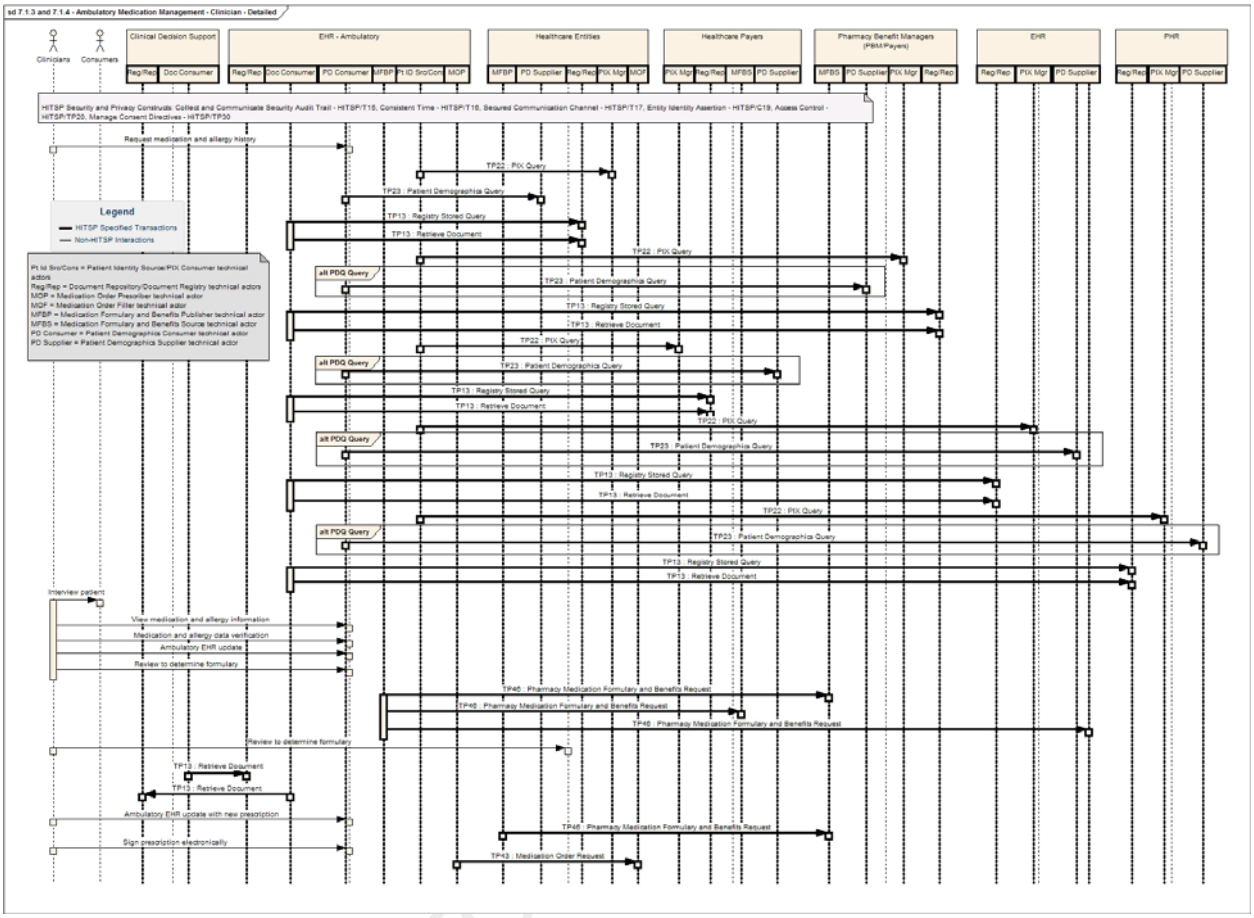


The drug knowledge supplier sends updated drug knowledge information to each of the sources listed. The information is provided using the [Provide and Register Document Set] transaction.

An update from the EHR is also provided to clinical decision support systems.

The clinician then checks patient eligibility and patient pharmacy benefits information, using the [Eligibility Information Request] transaction and [Pharmacy Medication Formulary and Benefits] request.

Figure 3.2.2-10 Detailed Sequence Diagram Ambulatory Medication Management from a Clinician Perspective - 7.1.3 and 7.1.4



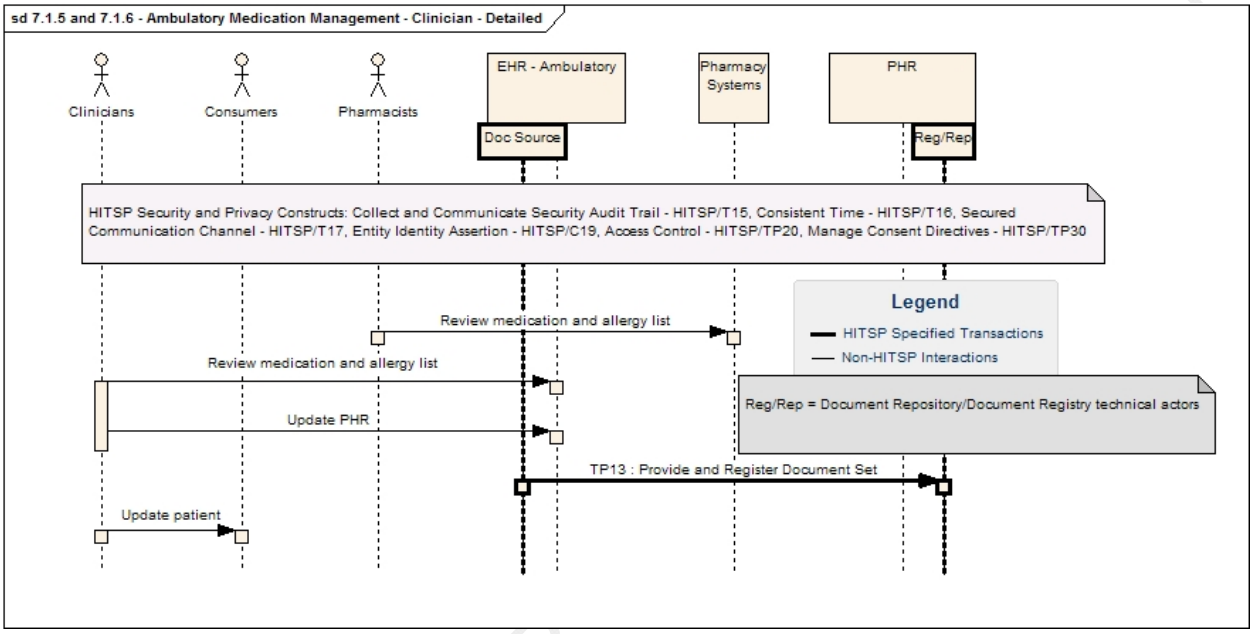
The clinician requests allergy and medication history from the ambulatory EHR. The ambulatory EHR uses a [PIX Query] to locate the patient ID, performs a [Registry Stored Query] to locate specific allergy and medication documentation, and then, once that is located, retrieves the allergy and medication history data using a [Retrieve Document] transaction and consolidated within the ambulatory EHR. This process occurs through multiple sources.

Once the data has been collected and consolidated, the clinician views the medication and allergy information and verifies its accuracy. The ambulatory EHR is then updated by the clinician with any new or changed information.

The clinician then reviews the formulary information. A request is sent from the ambulatory EHR to multiple sources of formulary information using the [Pharmacy Medication Formulary and Benefits Request]. The clinician also might contact other healthcare entities to review formulary information. In addition, clinical decision support systems might request additional data from the ambulatory EHR to check for contraindication data and the ambulatory EHR might request data from the clinician decision support system to check formulary information.

Once all the formulary data has been gathered and analyzed, the ambulatory EHR is then updated with new prescription data and signed electronically. The order is then transmitted by the ambulatory EHR to the pharmacy system using the [Medication Order Request] transaction.

Figure 3.2.2-11 Detailed Sequence Diagram Ambulatory Medication Management from a Clinician Perspective -7.1.5 and 7.1.6

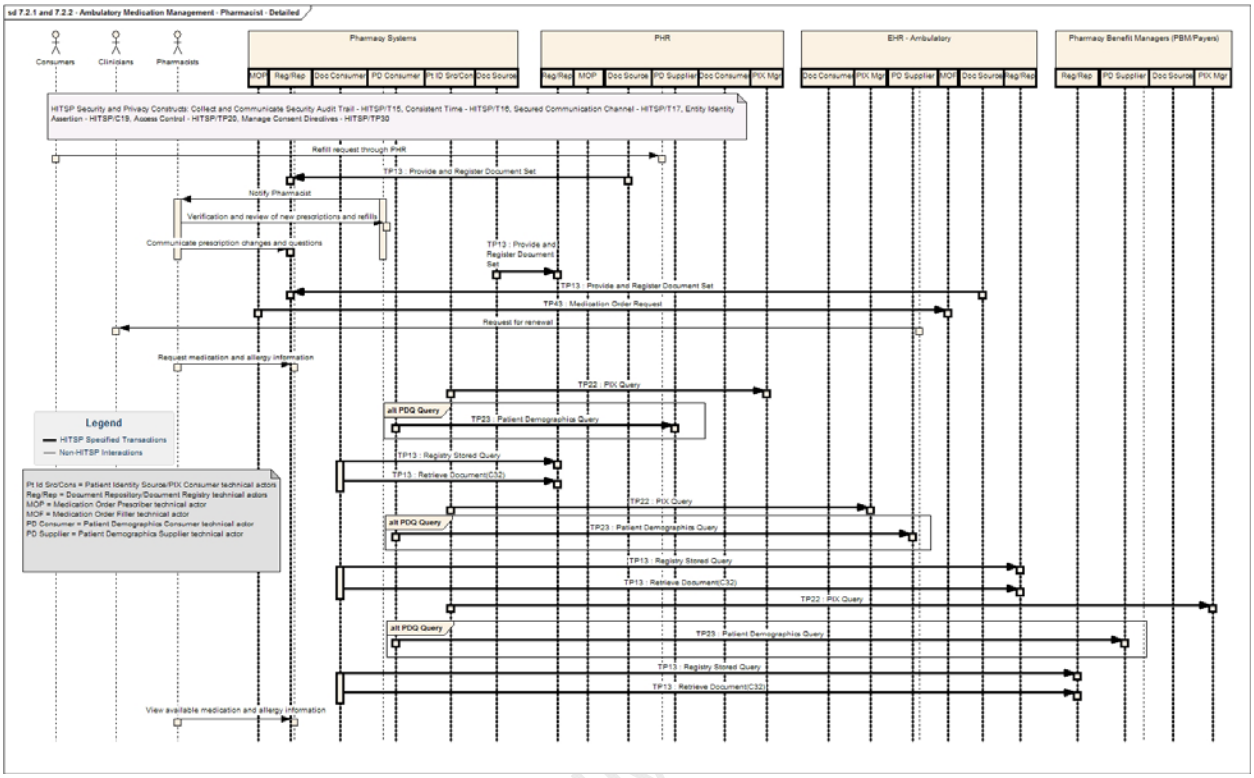


The pharmacist reviews medication and allergy information in the pharmacy system. In addition, the clinician may also review this information and provide updates.

These updates are collected in the ambulatory EHR and transferred to the PHR using the [Provide and Register Document Set] transaction.

The patient is updated by the clinician regarding the review of medication and allergy information.

Figure 3.2.2-12 Detailed Sequence Diagram Ambulatory Medication Management from a Pharmacist Perspective - 7.2.1 and 7.2.2



A refill request is placed by the consumer through their PHR. The request is transferred to the pharmacy system using the [Provide and Register Document Set] transaction. The pharmacist is notified by the pharmacy system and the pharmacy system also asks for a verification and review of the new prescription/refill request. Any changes to the order are communicated from the pharmacist to the pharmacy system.

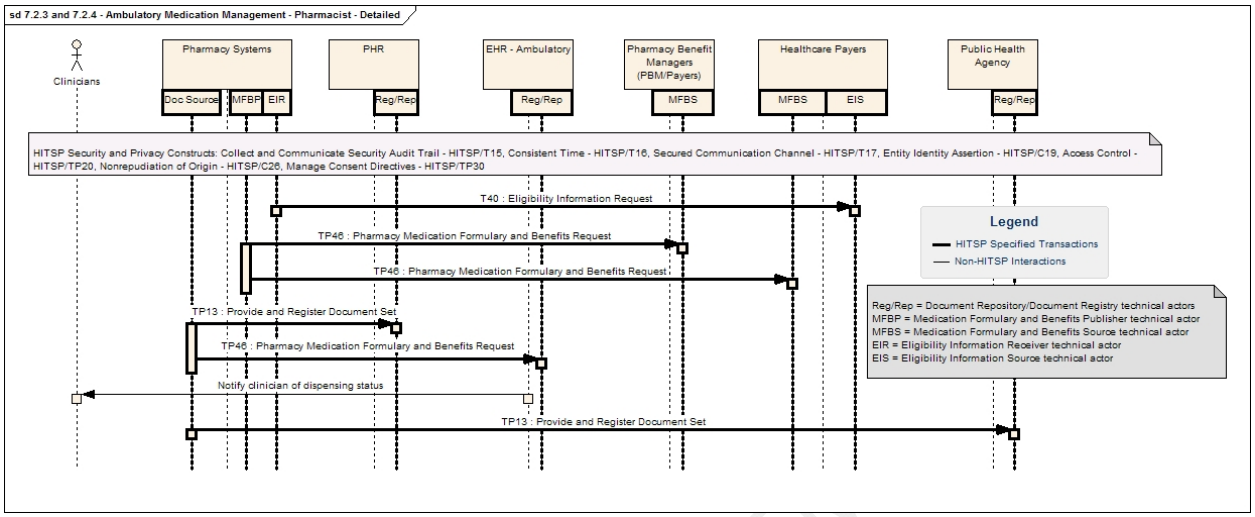
These updates are transferred from the pharmacy system to the PHR. The ambulatory EHR might also provide updates to the order if specific information is needed. Once the updates are collected, a medication order request is placed by the pharmacy system through the ambulatory EHR.

The pharmacist might also request medication and allergy information. The pharmacy system will send a request to the PHR requesting this information, first by locating the patient information through a [PIX Query], then querying the registry through a [Registry Stored Query] to locate the information and then retrieving the document using the [Retrieve Document] transaction.

Additional allergy and medication information might be requested from the ambulatory EHR and the pharmacy benefit system (PBM). This information is collected in the same technical process as that used to collect data from the PHR; a [PIX query and/or PDQ Query] to locate the patient, a [Registry Stored Query] to locate the document and a [Retrieve Document] transaction to collect the document.

Once all information is collected, the pharmacist views all available allergy and medication information.

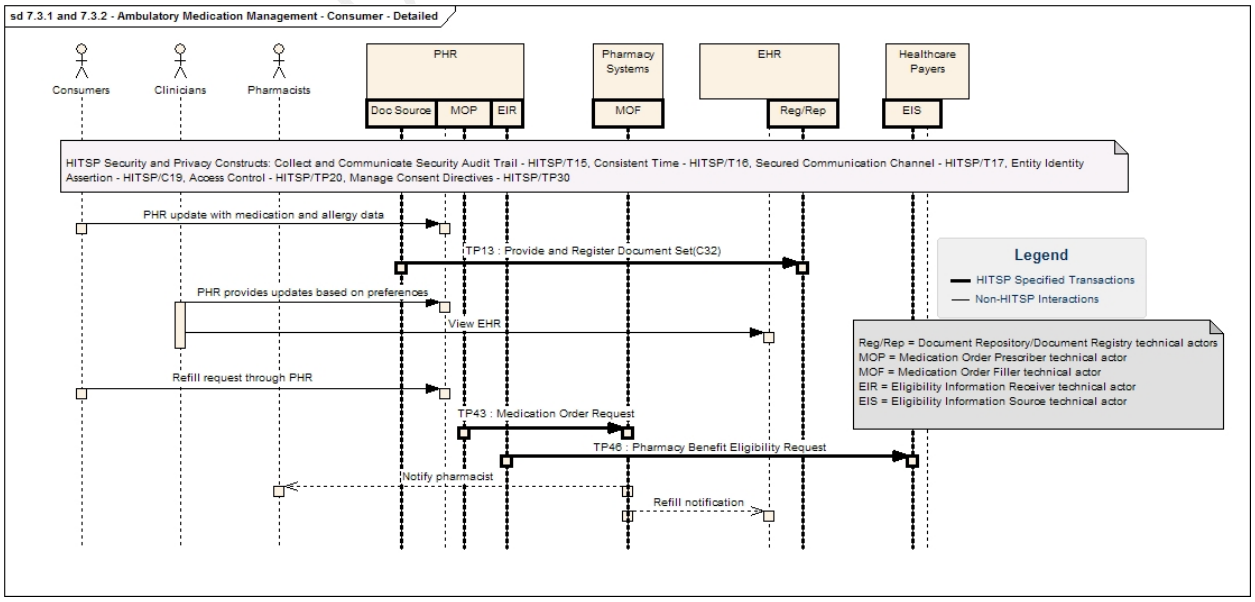
Figure 3.2.2-13 Detailed Sequence Diagram Ambulatory Medication Management from a Pharmacist Perspective - 7.2.3 and 7.2.4



A pharmacist verifies the eligibility and pharmacy benefits of a patient, using the [Eligibility Information Request] to the healthcare payer and a [Pharmacy Medication Formulary and Benefits Request] to the healthcare payer and pharmacy benefit manager (PBM).

A pharmacist also may request additional data from the PHR and additional pharmacy benefit information from the ambulatory EHR. The clinician is notified of the dispensing status and the pharmacy system also sends an update to a public health agency system with specific biosurveillance information.

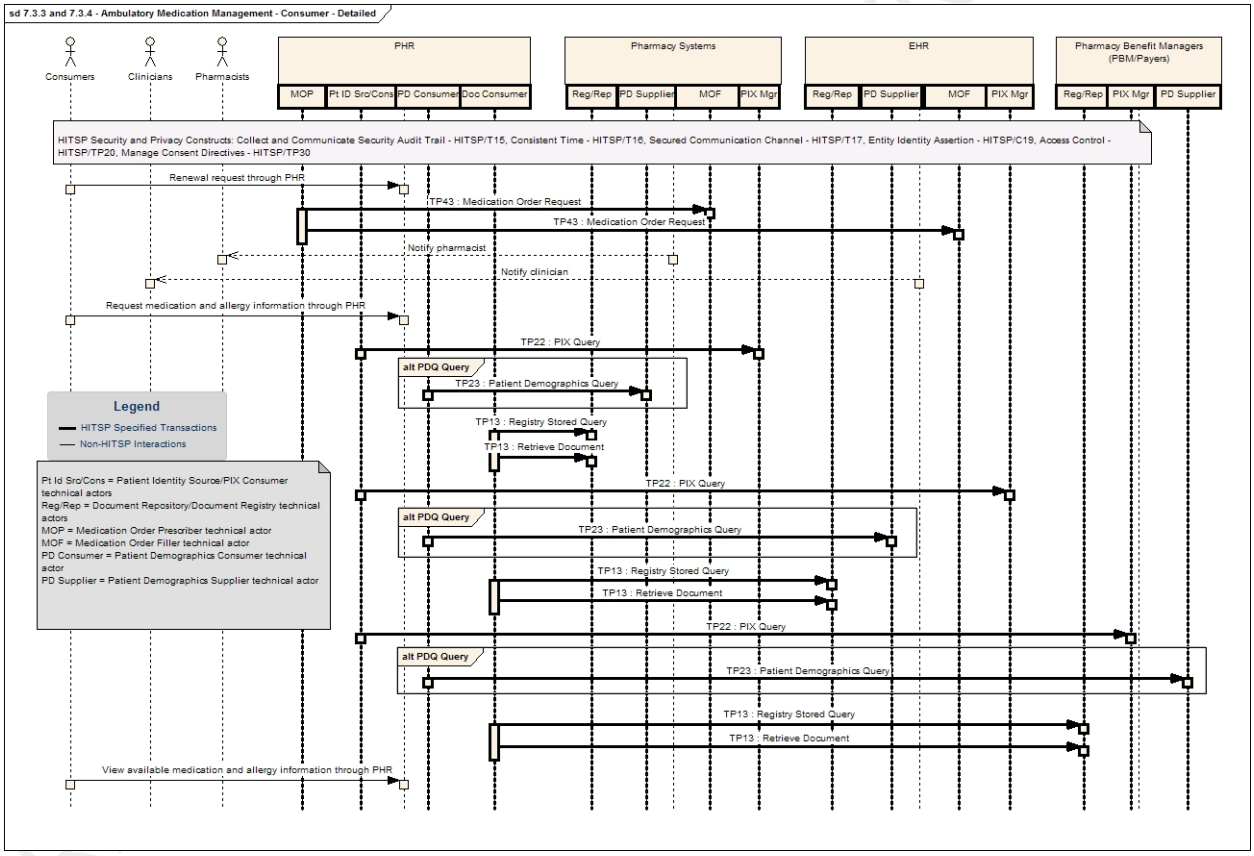
Figure 3.2.2-14 Detailed Sequence Diagram Ambulatory Medication Management from a Consumer Perspective - 7.3.1 and 7.3.2



The consumer wishes to update the PHR with medication and allergy data. Once the data is added to the PHR, an update is also sent to EHR systems that have the patient's medication and allergy data, using a [Provide and Register Document Set] transaction. Additional updates might come from the clinician depending on consumer PHR preferences. The clinician will also review the EHR to ensure that the data updates are correct.

The consumer may also wish to send a refill request through their PHR. A [Medication Order Request] is sent from the PHR to the pharmacy system. An additional [Pharmacy Benefits Eligibility Request] is sent to the healthcare payer to confirm eligibility for benefits on the refill request. The pharmacist is also notified of this request, as well as the EHR.

Figure 3.2.2-15 Detailed Sequence Diagram Ambulatory Medication Management from a Consumer Perspective - 7.3.3 and 7.3.4



A request to renew a prescription is sent by the consumer through their PHR. The [Medication Order Request] is typically sent from the PHR to the pharmacy system or if no refills remain it would be sent to the EHR.

The consumer may also request to review medication and allergy information through the PHR. The PHR will execute a [PIX Query and/or PDQ Query] to locate the patient data, run a [Registry Stored Query] to

locate the medication and allergy data and then run a [Retrieve Document] transaction to collect the medication and allergy information.

The consumer then views the medication and allergy information through the PHR.

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 Unified Modeling Language (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.

Transaction names may be shared by multiple HITSP constructs. The actual construct defines how the transactions are to be implemented. For example, the constructs HITSP/T40 - Patient Generic Health Plan Eligibility Verification Transaction and HITSP/TP46 - Medication Formulary and Benefits Information Transaction Package, use the same Technical Actor and Transaction names but the details of the actual transactions performed are defined in the constructs.

This Interoperability Specification uses HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD) Component in many of its workflows. HITSP has created a new ability to “subset” HITSP/C32 specific to each Interoperability Specification’s requirements. The Care Delivery Technical Committee plans to investigate this feature for the next release of this specification. Some examples of how HITSP has chosen to subset HITSP/C32 are available in HITSP/IS03 - Consumer Empowerment and Access to Clinical Information via Networks.

Health Information Exchange (HIE) Systems can serve as intermediary for data in many different scenarios in this Use Case and it is assumed that it may exist in real world implementations. The various alternative options are not shown.

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

Business Actor	Technical Actor(s)	Actor Optionality	Construct	Transaction/Content (T/C)	Optionality*
Electronic Health Record (EHR) - Hospital	Medication Order Prescriber	R	HITSP/TP43	Medication Order Request	R
	Medication Dispensing Status Receiver	R	HITSP/T42	Medication Dispensing Status Query	R
	Medication Order Filler	R	HITSP/TP43	Medication Order Request	R
	Eligibility Information Receiver	R	HITSP/T40	Eligibility Information Request	R
		R	HITSP/TP46	Eligibility Information Request	R
	Medication Formulary and Benefits Retriever	R	HITSP/TP46	Pharmacy Medication Formulary and Benefits Request	R
	Patient Identity Source	C [101]	HITSP/TP22	Patient Identify Feed	R
	PIX Consumer	C [101]	HITSP/TP22	PIX Query	R
				PIX Update Notification	O
	Patient Demographic Consumer	C [101]	HITSP/T23	Patient Demographics Query	R
	Document Source	R	HITSP/TP13	Provide & Register Document Set-b	R
	Document Consumer	R	HITSP/TP13	Registry Stored Query	R
				Retrieve Document Set	R
	Document Repository	O	HITSP/TP13	Retrieve Document Set	R
				Provide & Register Document Set-b	R
				Register Document Set-b	R
	Document Registry	O	HITSP/TP13	Registry Stored Query	R
				Register Document Set-b	R
				Patient Identify Feed	R
	Content Creator	R	HITSP/C32	Creator-Medication and Allergies Subset (See Section 3.2.3.1)	R
		R	HITSP/TP30	Consent Document Component	R
	Content Consumer	R	HITSP/C32	Consumer-Medication and Allergies Information Display Subset (See Section 3.2.3.2)	R

Business Actor	Technical Actor(s)	Actor Optionality	Construct	Transaction/Content (T/C)	Optionality*
				Consumer-Medication and Allergies Information Import Subset (See Section 3.2.3.2)	O
		R	HITSP/TP30	Consent Document Component	R
	Audit Record Source	R	HITSP/T15	Record Audit Event in Repository	R
	Audit Record Repository	O	HITSP/T15	Record Audit Event in Repository	R
	Time Client	R	HITSP/T16	Maintain Time	R
	Time Server	O	HITSP/T16	Maintain Time	R
	Node	R	HITSP/T17	Secured Communication Channel	R
	Service User	R	HITSP/C19	Convey Assertion	R
				Provide Assertion	O
	Identity Provider	O	HITSP/C19	Provide Assertion	R
				Verify Assertion	O
	Service Provider	C [102]	HITSP/C19	Convey Assertion	R
				Verify Assertion	O
	Access Control Consumer	R	HITSP/TP20	Access Control Request	O
	Access Control Service	O	HITSP/TP20	Access Control Request	O
Electronic Health Record (EHR) Hospital & EHR LTC	Medication Order Prescriber	R	HITSP/TP43	Medication Order Request	R
	Medication Order Filler	R	HITSP/TP43	Medication Order Request	R
	Eligibility Information Receiver	R	HITSP/T40	Eligibility Information Request	R
		R	HITSP/TP46	Eligibility Information Request	R
	Medication Formulary and Benefits Retriever	R	HITSP/TP46	Pharmacy Medication Formulary and Benefits Request	R
	Patient Identity Source	C [101]	HITSP/TP22	Patient Identify Feed	R
	PIX Consumer	C [101]	HITSP/TP22	PIX Query	R
				PIX Update Notification	O
	Patient Demographic Consumer	C [101]	HITSP/T23	Patient Demographics Query	R
	Document Source	R	HITSP/TP13	Provide & Register Document Set-b	R
	Document Consumer	R	HITSP/TP13	Registry Stored Query	R
				Retrieve Document Set	R
	Document Repository	O	HITSP/TP13	Retrieve Document Set	R
				Provide & Register Document Set-b	R

Business Actor	Technical Actor(s)	Actor Optionality	Construct	Transaction/Content (T/C)	Optionality*
				Register Document Set-b	R
	Document Registry	O	HITSP/TP13	Registry Stored Query	R
				Register Document Set-b	R
				Patient Identify Feed	R
	Content Creator	R	HITSP/C32	Creator-Medication and Allergies Subset (See Section 3.2.3.1)	R
		R	HITSP/TP30	Consent Document Component	R
	Content Consumer	R	HITSP/C32	Consumer-Medication and Allergies Information Display Subset (See Section 3.2.3.2)	R
				Consumer-Medication and Allergies Information Import Subset (See Section 3.2.3.2)	O
		R	HITSP/TP30	Consent Document Component	R
	Audit Record Source	R	HITSP/T15	Record Audit Event in Repository	R
	Audit Record Repository	O	HITSP/T15	Record Audit Event in Repository	R
	Time Client	R	HITSP/T16	Maintain Time	R
	Time Server	O	HITSP/T16	Maintain Time	R
	Node	R	HITSP/T17	Secured Communication Channel	R
	Service User	R	HITSP/C19	Convey Assertion	R
				Provide Assertion	O
	Identity Provider	O	HITSP/C19	Provide Assertion	R
				Verify Assertion	O
	Service Provider	C [102]	HITSP/C19	Convey Assertion	R
				Verify Assertion	O
	Access Control Consumer	R	HITSP/TP20	Access Control Request	O
	Access Control Service	O	HITSP/TP20	Access Control Request	O
Electronic Health Record (EHR)	Patient Identity Source	C [101]	HITSP/TP22	Patient Identify Feed	R
	PIX Consumer	C [101]	HITSP/TP22	PIX Query	R
				PIX Update Notification	O
	Patient Demographic Consumer	C [101]	HITSP/T23	Patient Demographics Query	R
	PIX Manager	O	HITSP/TP22	Patient Identity Feed	R
				PIX Query	R
				PIX Update Notification	R

Business Actor	Technical Actor(s)	Actor Optionality	Construct	Transaction/Content (T/C)	Optionality*
	Initiating Gateway	O	HITSP/TP13	Cross Gateway Query	R
				Cross Gateway Retrieve	R
	Responding Gateway	O	HITSP/TP13	Cross Gateway Query	R
				Cross Gateway Retrieve	R
	Patient Demographics Supplier	O	HITSP/T23	Patient Demographics Query	R
	Document Source	R	HITSP/TP13	Provide & Register Document Set-b	R
	Document Consumer	O	HITSP/TP13	Registry Stored Query	R
				Retrieve Document Set	R
	Document Repository	O	HITSP/TP13	Retrieve Document Set	R
				Provide & Register Document Set-b	R
				Register Document Set-b	R
	Document Registry	O	HITSP/TP13	Registry Stored Query	R
				Register Document Set-b	R
				Patient Identify Feed	R
	Content Creator	R	HITSP/C32	Creator-Medication and Allergies Subset (See Section 3.2.3.1)	R
		R	HITSP/TP30	Consent Document Component	R
	Content Consumer	C [103]	HITSP/C32	Consumer-Medication and Allergies Information Display Subset (See Section 3.2.3.2)	R
				Consumer-Medication and Allergies Information Import Subset (See Section 3.2.3.2)	O
		C [103]	HITSP/TP30	Consent Document Component	R
	Audit Record Source	R	HITSP/T15	Record Audit Event in Repository	R
	Audit Record Repository	O	HITSP/T15	Record Audit Event in Repository	R
	Time Client	R	HITSP/T16	Maintain Time	R
	Time Server	O	HITSP/T16	Maintain Time	R
	Node	R	HITSP/T17	Secured Communication Channel	R
	Service User	R	HITSP/C19	Convey Assertion	R
				Provide Assertion	O
	Identity Provider	O	HITSP/C19	Provide Assertion	R
				Verify Assertion	O
	Service Provider	C [102]	HITSP/C19	Convey Assertion	R

Business Actor	Technical Actor(s)	Actor Optionality	Construct	Transaction/Content (T/C)	Optionality*
				Verify Assertion	O
	Access Control Consumer	R	HITSP/TP20	Access Control Request	O
	Access Control Service	O	HITSP/TP20	Access Control Request	O
Pharmacy Systems	Medication Order Filler	R	HITSP/TP43	Medication Order Request	R
	Eligibility Information Receiver	R	HITSP/T40	Eligibility Information Request	R
		R	HITSP/TP46	Eligibility Information Request	R
	Medication Formulary and Benefits Retriever	R	HITSP/TP46	Pharmacy Medication Formulary and Benefits Request	R
	Patient Identity Source	C [101]	HITSP/TP22	Patient Identify Feed	R
	PIX Consumer	C [101]	HITSP/TP22	PIX Query	R
				PIX Update Notification	O
	Patient Demographic Consumer	C [101]	HITSP/T23	Patient Demographics Query	R
	Document Source	C [104]	HITSP/TP13	Provide & Register Document Set-b	R
	Content Creator	C [104}	HITSP/C32	Creator-Medication and Allergies Subset (See Section 3.2.3.1)	R
		C [104]	HITSP/TP30	Consent Document Component	R
	Audit Record Source	R	HITSP/T15	Record Audit Event in Repository	R
	Audit Record Repository	O	HITSP/T15	Record Audit Event in Repository	R
	Time Client	R	HITSP/T16	Maintain Time	R
	Time Server	O	HITSP/T16	Maintain Time	R
	Node	R	HITSP/T17	Secured Communication Channel	R
	Service User	R	HITSP/C19	Convey Assertion	R
				Provide Assertion	O
	Identity Provider	O	HITSP/C19	Provide Assertion	R
				Verify Assertion	O
	Service Provider	C [102]	HITSP/C19	Convey Assertion	R
				Verify Assertion	O
	Access Control Consumer	R	HITSP/TP20	Access Control Request	O
	Access Control Service	O	HITSP/TP20	Access Control Request	O
Pharmacy Systems -	Medication Order Filler	R	HITSP/TP43	Medication Order Request	R
	Eligibility Information Receiver	R	HITSP/T40	Eligibility Information Request	R

Business Actor	Technical Actor(s)	Actor Optionality	Construct	Transaction/Content (T/C)	Optionality*
Hospital And Pharmacy Systems - External		O	HITSP/TP46	Eligibility Information Request	R
	Medication Formulary and Benefits Retriever	O	HITSP/TP46	Pharmacy Medication Formulary and Benefits Request	R
	Patient Identity Source	C [101]	HITSP/TP22	Patient Identify Feed	R
	PIX Consumer	C [101]	HITSP/TP22	PIX Query	R
				PIX Update Notification	O
	Patient Demographic Consumer	C [101]	HITSP/T23	Patient Demographics Query	R
	Audit Record Source	R	HITSP/T15	Record Audit Event in Repository	R
	Audit Record Repository	O	HITSP/T15	Record Audit Event in Repository	R
	Time Client	R	HITSP/T16	Maintain Time	R
	Time Server	O	HITSP/T16	Maintain Time	R
	Node	R	HITSP/T17	Secured Communication Channel	R
	Access Control Consumer	R	HITSP/TP20	Access Control Request	O
	Access Control Service	O	HITSP/TP20	Access Control Request	O
Clinical Decision Support And Other Clinical or Admin Data Sources	Patient Identity Source	C [101]	HITSP/TP22	Patient Identify Feed	R
	PIX Consumer	C [101]	HITSP/TP22	PIX Query	R
				PIX Update Notification	O
	Patient Demographic Consumer	C [101]	HITSP/T23	Patient Demographics Query	R
	Document Source	R	HITSP/TP13	Provide & Register Document Set-b	R
	Content Creator	R	HITSP/C32	Creator-Medication and Allergies Subset (See Section 3.2.3.1)	R
		R	HITSP/TP30	Consent Document Component	R
	Audit Record Source	R	HITSP/T15	Record Audit Event in Repository	R
	Audit Record Repository	O	HITSP/T15	Record Audit Event in Repository	R
	Time Client	R	HITSP/T16	Maintain Time	R
	Time Server	O	HITSP/T16	Maintain Time	R
	Node	R	HITSP/T17	Secured Communication Channel	R
	Service User	R	HITSP/C19	Convey Assertion	R
				Provide Assertion	O
	Identity Provider	O	HITSP/C19	Provide Assertion	R
				Verify Assertion	O

Business Actor	Technical Actor(s)	Actor Optionality	Construct	Transaction/Content (T/C)	Optionality*
	Service Provider	C [102]	HITSP/C19	Convey Assertion	R
				Verify Assertion	O
	Access Control Consumer	R	HITSP/TP20	Access Control Request	O
	Access Control Service	O	HITSP/TP20	Access Control Request	O
PBM/Payers	Eligibility Information Source	R	HITSP/T40	Eligibility Information Request	R
		R	HITSP/TP46	Eligibility Information Request	R
	Medication Formulary and Benefits Source	R	HITSP/TP46	Pharmacy Medication Formulary and Benefits Request	R
	Medication Order Filler	R	HITSP/TP43	Medication Order Request Note: this request is sent to the payer for approval of a refill	R
	Patient Identity Source	C [101]	HITSP/TP22	Patient Identify Feed	R
	PIX Consumer	C [101]	HITSP/TP22	PIX Query	R
				PIX Update Notification	O
	Patient Demographic Consumer	C [101]	HITSP/T23	Patient Demographics Query	R
	Document Source	C [104]	HITSP/TP13	Provide & Register Document Set-b	R
	Content Creator	C [104]	HITSP/C32	Creator-Medication and Allergies Subset (See Section 3.2.3.1)	R
		C [104]	HITSP/TP30	Consent Document Component	R
	Document Consumer	O	HITSP/TP13	Registry Stored Query	R
				Retrieve Document Set	R
	Document Repository	O	HITSP/TP13	Retrieve Document Set	R
				Provide & Register Document Set-b	R
				Register Document Set-b	R
	Document Registry	O	HITSP/TP13	Registry Stored Query	R
				Register Document Set-b	R
				Patient Identify Feed	R
	Content Consumer	C [103]	HITSP/C32	Consumer-Medication and Allergies Information Display Subset (See Section 3.2.3.2)	R
				Consumer-Medication and Allergies Information Import Subset (See Section 3.2.3.2)	O
		C [103]	HITSP/TP30	Consent Document Component	R

Business Actor	Technical Actor(s)	Actor Optionality	Construct	Transaction/Content (T/C)	Optionality*
	Audit Record Source	R	HITSP/T15	Record Audit Event in Repository	R
	Audit Record Repository	O	HITSP/T15	Record Audit Event in Repository	R
	Time Client	R	HITSP/T16	Maintain Time	R
	Time Server	O	HITSP/T16	Maintain Time	R
	Node	R	HITSP/T17	Secured Communication Channel	R
	Service User	R	HITSP/C19	Convey Assertion	R
				Provide Assertion	O
	Identity Provider	O	HITSP/C19	Provide Assertion	R
				Verify Assertion	O
	Service Provider	C [102]	HITSP/C19	Convey Assertion	R
				Verify Assertion	O
	Access Control Consumer	R	HITSP/TP20	Access Control Request	O
	Access Control Service	O	HITSP/TP20	Access Control Request	O
Personal Health Record (PHR) Service Provider	Patient Identity Source	C [101]	HITSP/TP22	Patient Identify Feed	R
	PIX Consumer	C [101]	HITSP/TP22	PIX Query	R
				PIX Update Notification	O
	Patient Demographic Consumer	C [101]	HITSP/T23	Patient Demographics Query	R
	Document Source	R	HITSP/TP13	Provide & Register Document Set-b	R
	Document Consumer	R	HITSP/TP13	Registry Stored Query	R
				Retrieve Document Set	R
	Document Repository	O	HITSP/TP13	Retrieve Document Set	R
				Provide & Register Document Set-b	R
				Register Document Set-b	R
	Document Registry	O	HITSP/TP13	Registry Stored Query	R
				Register Document Set-b	R
				Patient Identify Feed	R
	Content Creator	R	HITSP/C32	Creator-Medication and Allergies Subset (See Section 3.2.3.1)	R
		R	HITSP/TP30	Consent Document Component	R
	Content Consumer	R	HITSP/C32	Consumer-Medication and Allergies Information Display Subset (See Section 3.2.3.2)	R

Business Actor	Technical Actor(s)	Actor Optionality	Construct	Transaction/Content (T/C)	Optionality*
				Consumer-Medication and Allergies Information Import Subset (See Section 3.2.3.2)	O
		R	HITSP/TP30	Consent Document Component	R
	Audit Record Source	R	HITSP/T15	Record Audit Event in Repository	R
	Audit Record Repository	O	HITSP/T15	Record Audit Event in Repository	R
	Time Client	R	HITSP/T16	Maintain Time	R
	Time Server	O	HITSP/T16	Maintain Time	R
	Node	R	HITSP/T17	Secured Communication Channel	R
	Service User	R	HITSP/C19	Convey Assertion	R
				Provide Assertion	O
	Identity Provider	O	HITSP/C19	Provide Assertion	R
				Verify Assertion	O
	Service Provider	C [102]	HITSP/C19	Convey Assertion	R
				Verify Assertion	O
	Access Control Consumer	R	HITSP/TP20	Access Control Request	O
	Access Control Service	O	HITSP/TP20	Access Control Request	O
Health Care Entities (for LTC)	Eligibility Information Receiver	R	HITSP/T40	Eligibility Information Request	R
		R	HITSP/TP46	Eligibility Information Request	R
	Medication Formulary and Benefits Retriever	R	HITSP/TP46	Pharmacy Medication Formulary and Benefits Request	R
	Patient Identity Source	C [101]	HITSP/TP22	Patient Identify Feed	R
	PIX Consumer	C [101]	HITSP/TP22	PIX Query	R
				PIX Update Notification	O
	Patient Demographic Consumer	C [101]	HITSP/T23	Patient Demographics Query	R
	Audit Record Source	R	HITSP/T15	Record Audit Event in Repository	R
	Audit Record Repository	O	HITSP/T15	Record Audit Event in Repository	R
	Time Client	R	HITSP/T16	Maintain Time	R
	Time Server	O	HITSP/T16	Maintain Time	R
	Node	R	HITSP/T17	Secured Communication Channel	R
	Access Control Consumer	R	HITSP/TP20	Access Control Request	O
	Access Control Service	O	HITSP/TP20	Access Control Request	O

***NOTE:** Optionality = "R" for Required, or "O" for Optional, or "C" for Conditional. If applicable, conditional footnotes are further described below.

Actor Optionality Conditions

C [101] - Shall support (Patient Identity Source plus PIX Consumer) and/or Patient Demographics Consumer

C [102] - Shall be supported if this Actor is a Document Repository

C [103] - Shall be supported if this Actor is a Document Consumer

C [104] - Shall be supported if providing health and medication history summary information beyond that conveyed by NCPDP SCRIPT

Various technical actors such as the Document Registry, Document Repository, PIX Manager and Patient Demographics Supplier may reside in many different real world business actors. For this table they are shown in the PIX Manager and Patient Demographic Supplier are shown in the EHR, but could reside in other business actors also (such as PHR, RHIO, Other EHRs, Other Facilities, etc). It is not the intent of this document to illustrate all the possible architecture variants. See the HITSP/IS03 - Consumer Empowerment and Access to Clinical Information via Networks Interoperability Specification for real world examples.

3.2.3.1 C32 "Creator-Medication and Allergies Information Coded Subset"

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

Table 3.2.3.1-1 Creator Medication and Allergies Information Subset Content Modules

Content Modules	Optionality*
Person Information	R
Medications - Prescription and Non-Prescription	R
Allergies and Drug Sensitivity	R
Healthcare Provider	R2
Insurance Provider	R2
Information Source	R2
Conditions	R2
Comments	R2

***NOTE:** Optionality = "R" for Required, "R2" for Required if known, "O" for Optional, or "C" for Conditional. If applicable, conditional footnotes are further described below.

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.

3.2.3.2 Consumer-Medication and Allergies 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).

3.2.3.3 Consumer- Medication and Allergies 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.

3.2.4 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)
No applicable construct dependencies			

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 applicable additional constraints				

4.0 STANDARDS SELECTION

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

- Evaluation: The Technical Committee evaluates the standards using the Tier 2 Readiness Criteria. The Tier 2 worksheets used to evaluate the list of standards are provided via links in the Appendix
- 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 roadmapped 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 business requirements

HITSP may continue to use “Provisional” or “Interim” standards as they existed when incorporated into the HITSP construct if the expected conditions are not satisfied until such time as HITSP can replace it with a more suitable standard. In this circumstance, the Standards Organization would have no responsibility to maintain or correct this artifact. If a standard “Intended for Use” is not developed and approved in terms of time frame or content as expected by the 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 LIST OF STANDARDS

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

- Regulatory and guidance standards are legal or other authoritative declarations that HITSP must abide by. These may also be guidelines and recommendations that HITSP has adopted to aid in the selection of standards (see Section 4.1.1)
- Selected standards are those standards that are selected within the context of the specific use case requirements, and are required to be implemented as part of the Interoperability Specification (see Section 4.1.2)

4.1.1 REGULATORY AND GUIDANCE STANDARDS

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 and Guidance Standards

Standard	Description
Health Insurance Portability and Accountability Act (HIPAA) -- Administrative Simplification	A listing of national standards plus rules adopted by federal regulation for electronically communicating specified administrative and financial healthcare transactions, and protecting the security and privacy of healthcare information, as applied to the three types of defined covered entities: health plans, healthcare clearinghouses, and healthcare providers who conduct any of the specified healthcare transactions. See the Code of Federal Regulations, Title 45, Parts 160, et. seq. for more information.
Medicare Prescription Drug Improvement and Modernization Act of 2003 (Pub.L. 108-173, 117 Stat. 2066, also called Medicare Modernization Act or MMA)	The Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA) initiated improvements in the Medicare system. The legislation provided a voluntary program for prescription drug coverage under Medicare. Additionally, the MMA allows a tax deduction to individuals for amounts contributed to health savings security accounts, provides the disposition of unused health benefits in cafeteria plans and flexible spending arrangements. For more information visit www.cms.hhs.gov.

4.1.2 SELECTED STANDARDS

The following table provides a list of standards that are required to implement the 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
Accredited Standards Committee (ASC) X12 Insurance Subcommittee (X12N) Implementation Guides Version 004010 plus Addenda 004010A1	HITSP/T40 - Patient Generic Health Plan Eligibility Verification HITSP/TP46 - Medication Formulary and Benefits Information	
Accredited Standards Committee (ASC) X12 Standards Release 004010	HITSP/T40 - Patient Generic Health Plan Eligibility Verification HITSP/TP46 - Medication Formulary and Benefits Information	Underlying standard for X12N Implementation Guides Version 004010 plus Addenda 004010A1
American National Standards Institute (ANSI) International Committee for Information Technology Standards (INCITS), #359-2004	HITSP/TP20 - Access Control	
American Society for Testing and Materials (ASTM) Privilege Management Infrastructure (PMI) Guidelines	HITSP/TP20 - Access Control	
American Society for Testing and Materials (ASTM) Standard Specification for Audit and Disclosure Logs for Use in Health Information Systems: # E2147-01	HITSP/T15 - Collect and Communicate Security Audit Trail	
CDC Race and Ethnicity Code Sets	HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD)	
Centers for Medicare and Medicaid Services (CMS) National Provider Identifier (NPI)	HITSP/T42 - Medication Dispensing Status HITSP/TP43 - Medication Orders	
Council for Affordable Quality Healthcare (CAQH) Committee on Operating Rules for Information Exchange (CORE) Phase I Operating Rules	HITSP/T40 - Patient Generic Health Plan Eligibility Verification HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD)	
Drug Enforcement Administration (DEA) Prescriber Number	HITSP/T42 - Medication Dispensing Status HITSP/TP43 - Medication Orders	

Standard Name	HITSP Construct	Remarks/ Minor Gaps
Federal Information Processing Standards (FIPS) Codes for the Identification of the States, the District of Columbia and the Outlying Areas of the United States, and Associated Areas Publication # 5-2, May, 1987	HITSP/TP43 - Medication Orders HITSP/T42 - Medication Dispensing Status	
Federal Medication Terminologies	HITSP/T42 - Medication Dispensing Status HITSP/TP43 - Medication Orders HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD)	
Health Care Provider Taxonomy	HITSP/TP43 - Medication Orders HITSP/T42 - Medication Dispensing Status HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD)	
Health Level Seven (HL7) Consent related vocabulary including Confidentiality Codes	HITSP/TP30 - Manage Consent Directives	
Health Level Seven (HL7) Healthcare Permissions Catalogue	HITSP/TP30 - Manage Consent Directives	
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) Version 2.5[2]	HITSP/TP22 - Patient ID Cross-Referencing	
Health Level Seven (HL7) Version 2.5/2.5.1[3]	HITSP/TP22 - Patient ID Cross-Referencing HITSP/T23 - Patient Demographics Query	
Health Level Seven (HL7) Version 2.5/2.5.1 - Pharmacy/Treatment Orders (OMP)	HITSP/TP43 - Medication Orders	
Health Level Seven (HL7) Version 3.0	HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD)	
Health Level Seven (HL7) Version 3.0 Clinical Document Architecture (CDA/CDA R2)	HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD)	
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 3.0	HITSP/T15 - Collect and Communicate Security Audit Trail HITSP/T16 - Consistent Time HITSP/C19 - Entity Identity Assertion HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD)	

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

Standard Name	HITSP Construct	Remarks/ Minor Gaps
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0	HITSP/T16 - Consistent Time HITSP/TP22 - Patient ID Cross-Referencing HITSP/T23 - Patient Demographics Query	
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0, Section 10 Cross-Enterprise Document Sharing (XDS.a)	HITSP/TP13 - Manage Sharing of Documents	
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0 XCA Supplement	HITSP/T13 - Manage Sharing of Documents	
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0 - Registry Stored Query Transaction for XDS Profile Supplement [ITI-18]	HITSP/TP13 - Manage Sharing of Documents	
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Volume 2 Supplement 2007 – 2008 Cross-Enterprise Document Sharing-B (XDS.b)	HITSP/TP13 - Manage Sharing of Documents	
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Supplement 2007 - 2008 Basic Patient Privacy Consents (BPPC) - Trial Implementation	HITSP/TP30 - Manage Consent Directives	
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Volume 2 Supplement 2007 - 2008 Cross-Enterprise User Assertion (XUA)	HITSP/C19 - Entity Identity Assertion	
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (TF) Supplement 2004 - 2005 - Audit Trail and Node Authentication Profile (ATNA)	HITSP/T17 - Secured Communication Channel HITSP/TP20 - Access Control	
Integrating the Healthcare Enterprise (IHE) Patient Care Coordination (PCC), Revision 3.0, 2007 - 2008	HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD)	
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)	
International Organization for Standardization (ISO) Health informatics - Functional and Structural Roles (ISO SF Roles), Technical Specification #21298, Draft May, 2007	HITSP/TP20 - Access Control	

Standard Name	HITSP Construct	Remarks/ Minor Gaps
International Organization for Standardization (ISO) Health informatics -- Information technology -- Open Systems Interconnection -- Systems Management: Security alarm reporting function #10164-- Part 7: Security Alarm Reporting Function, 1992	HITSP/T15 - Collect and Communicate Security Audit Trail	
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.	HITSP/TP20 - Access Control	
International Organization for Standardization (ISO) Health informatics -- Privilege management and access control (PMAC), Technical Specification #22600 -- Part 1: Overview and policy management, July 2006	HITSP/TP20 - Access Control	
Logical Observation Identifiers Names and Codes (LOINC®)	HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD)	
National Council for Prescription Drug Programs (NCPDP) Formulary and Benefits Standard Implementation Guide	HITSP/TP46 - Medication Formulary and Benefits Information	
National Council for Prescription Drug Programs (NCPDP) SCRIPT Standard - 8.1 the currently accepted CMS version (but expected to transition to a version 10.x in the future)	HITSP/T42 - Medication Dispensing Status	For all but Long Term Care
National Council for Prescription Drug Programs (NCPDP) SCRIPT Standard Implementation Guide Version 10.1	HITSP/TP43 - Medication Orders	For Long Term Care only
National Council for Prescription Drug Programs (NCPDP) Telecommunication Standard Implementation Guide	HITSP/TP46 - Medication Formulary and Benefits Information	
National Library of Medicine (NLM) Unified Medical Language System (UMLS) RxNorm	HITSP/TP43 - Medication Orders HITSP/T42 - Medication Dispensing Status	
Organization for the Advancement of Structured Information Standards (OASIS) Security Assertion Markup Language (SAML) v2.0 OASIS Standard; ITU-T X.1141	HITSP/C19 - Entity Identity Assertion HITSP/TP20 - Access Control	

Standard Name	HITSP Construct	Remarks/ Minor Gaps
Organization for the Advancement of Structured Information Standards (OASIS) Web Services Security SOAP Message Security Version 1.0	HITSP/C19 - Entity Identity Assertion	
Organization for the Advancement of Structured Information Standards (OASIS) Simple Object Access Protocol (SOAP) Version 1.1	HITSP/C19 - Entity Identity Assertion	
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	
Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity	HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD)	

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 Medication Management event. 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
6.1.1.1, 7.1.1.1	Receive information from drug knowledge supplier	No standard exists for this information exchange. Only exists in proprietary formats	Identify and work with appropriate SDO to defined standard for receiving drug knowledge supplier information
6.1.8.1, 7.1.2.1 6.1.8.1, 7.2.3.2, 7.1.4.1, 7.1.2.2, 7.2.3.1	Events to determine Patient Eligibility Events to determine Medication Formulary and Benefit Eligibility Information	HITSP/T40 and HITSP/TP46 constructs are used to determine patient and medication formulary/benefit eligibility. These events use the ASC X12 270/271 messages to obtain this information The Interchange Control Header fields ISA05 and ISA07 are used to identify the Sender and Receiver of the messages. Currently, no standard has been selected to identify the Sender and Receiver	The ASC X12 standard identifies various possibilities for this identification, such as US Federal Tax ID, Health Industry Number, Mutually Defined private numbers, etc Most current implementation use privately defined numbers based upon business relationships Recommend assembling topic experts from various organizations (such as ASC X12, CAQH CORE, NCPDP) to research this gap and to determine how to identify the Sender and Receiver of the X12 270/271 messages
6.1.4.4a, 6.1.4.4b, 6.1.8.3, 7.1.4.5, 7.2.1.1, 7.2.3.2, 7.2.4.2, 7.3.2.1, 7.3.3.1	Events which communicate medication orders/prescriptions	The DEA does not allow electronic prescribing for controlled substances. Therefore need to use a paper order	Need to wait until DEA regulations are updated to allow for electronic prescribing for controlled substances
6.1.4.4a, 6.1.4.4b, 6.1.8.3, 7.1.4.5, 7.2.1.1, 7.2.3.2, 7.2.4.2, 7.3.2.1, 7.3.3.1 and 6.1.2.1, 6.1.9,1, 6.1.9.2, 6.3.1.1, 6.3.2.1, 7.1.3.1, 7.1.4.4, 7.1.6.1, 7.2.2.1, 7.3.1.1, 7.3.4.1	Events which communicate medication orders/prescriptions Events which require Medication and Allergy information using the HITSP/C32 Subset (Medication and Allergies Information Subset)	No standard terminology exists for implanted medication infusion device	Identify and work with appropriate SDO to defined terminology for receiving implanted medication infusion devices
6.1.4.4a, 6.1.4.4b, 6.1.8.3, 7.1.4.5, 7.2.1.1, 7.2.3.2, 7.2.4.2, 7.3.2.1, 7.3.3.1 and 7.2.4.2	Events which communicate medication orders/prescriptions Events which notify clinician of dispensing status	Neither NCPDP SCRIPT 8.1 nor 10.1 supports the use of FMT coded fields for Drug Form, Drug Strength and Drug Unit of Measure	NCPDP is developing SCRIPT 10.5 that explicitly identifies conveying the FMT-based required information HITSP recommends researching this version upon completion and possibly updating constructs to support SCRIPT 10.5
7.2.4.2	Events which notify clinician of dispensing status	The National Provider ID (NPI) is used to identity prescribers of medication. Not all medication prescribers are able to obtain a NPI	Work with Centers for Medicare and Medicaid Services (CMS) to enable the ability for any prescriber to obtain an identifier

Event Code	Event Description	Identified Gaps	Recommended Resolution
7.2.4.2	Events which notify clinician of dispensing status	A standard for drug identifiers based on usage (for example, a prescribing system perspective versus a pharmacy system perspective.) In electronic prescribing, the RxNorm Codes may provide standardized identifiers for drugs for the prescribing system perspective, which will provide the dispensing system an identifier in addition to text. The pharmacy system uses the National Drug Code (NDC) for dispensing, but this code is too specific for the prescribing system	Support the industry in exploring pilot tests to pursue the use of the RxNorm codes for prescribers. Many entities in the ePrescribing environment use drug databases and the RxNorm codes can mediate messages between systems that do not use the same vocabulary. Other identifiers may need to be assigned for other than drug products. Until such time as the industry provides recommendations, the specific citing of identifiers will remain a gap The HITSP Foundations Committee has initiated an effort to coordinate the issues identified in this gap NCPDP WG11 is evaluating this gap using RxNorm and representative NDC
6.1.8.1, 7.2.3.2, 7.1.4.1, 7.1.2.2, 7.2.3.1	Events to determine Medication Formulary and Benefit Eligibility and Information	The information required by the NCPDP standard allows optional data elements and/or lists about coverage, without requiring the details of the coverage The mechanisms to determine the routing of the ASC X12 270/271 messages are not clearly understood and currently performed using proprietary solutions	There have been pilots researching this issue by the Medicare Modernization ACT (MMA). Recommend the findings of these pilots be evaluated by NCPDP to propose solutions HITSP recommends discussions with SDO's and other stakeholders to address this gap.
6.1.2.1, 6.1.9,1, 6.1.9.2, 6.3.1.1, 6.3.2.1, 7.1.3.1, 7.1.4.4, 7.1.6.1, 7.2.2.1, 7.3.1.1, 7.3.4.1	Events which require Medication and Allergy information using the HITSP/C32 Subset (Medication and Allergies Information Subset) Events which require Medication Fill Status	Information about Medication Expiration Date of the medication is not included in the HL7 Continuity of Care Document (CCD) C32 needs to describe how the sources of Fill Status will use C32 Fill Status vocabulary	HITSP recommends updating HITSP/C32 to include Medication Expiration Date for the dispensed medication. HITSP recommends updating HITSP/C32 to include this description.

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 Medication Management event. 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 Committees.

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
6.1.4.4a, 6.1.4.4b, 6.1.8.3, 7.1.4.5, 7.2.1.1, 7.2.3.2 , 7.2.4.2, 7.3.2.1, 7.3.3.1	Events which communicate medication orders/prescriptions	NCPDP SCRIPT 8.1 or 10.1 HL7 Version 2.5/2.51 Pharmacy/Treatment Orders Used in HITSP/TP43-Medication Orders	HITSP/TP43 - Medication Orders Transaction Package is used to define transactions between prescribers (who write prescriptions) and dispensers (who fill prescriptions). It is used for new prescriptions, refill requests, prescription change requests, and prescription cancellations Orders/prescriptions may occur in many different real world settings, such as inpatient, long term care and ambulatory settings The interim solution is to use NCPDP SCRIPT 8.1 to support ambulatory and version 10.1 for long-term care orders/prescriptions. HL7 Version 2.5/2.5.1 to support inpatient orders which can occur within an organization or with disparate inpatient organization There are certain ambulatory scenarios where HL7 is used for orders/prescriptions (e.g. centralized mail out pharmacy orders between the VA and DoD) Note: Joint efforts have occurred to provide NCPDP and HL7 messages and workflow mappings. These are described in NCPDP-HL7 Electronic Prescribing Coordination - Mapping Document v1.0 Recommend to work within the HITSP Foundations Committee to discuss harmonizing medication orders to define one solution. Need to assemble topic experts from various SDOs

Event Code	Event Description	Standard Overlap	Recommended Resolution
6.1.8.1, 7.2.3.2, 7.1.4.1, 7.1.2.2, 7.2.3.1	Events to determine Medication Formulary and Benefit Information	ASC X12 Insurance Subcommittee X12N Implementation Guides Version 004010 plus Addenda 004010A1 NCPDP Telecommunication Standard Implementation Guide Version D.Ø Eligibility Verification Transaction	One task of HITSP/TP46 - Medication Formulary and Benefits Information Transaction Package is to perform an eligibility check for a specific patient's pharmacy benefits The interim solution is to use ASC X12 Insurance Subcommittee X12N Implementation Guides if a prescriber is performing the check. NCPDP Telecommunication Standard is used when being performed by a pharmacy Recommend to work within the HITSP Foundations Committee to discuss if this is an overlap that requires harmonization. Need to assemble topic experts from various SDOs
6.1.8.1, 7.1.2.1	Events to determine Patient Eligibility	CAQH CORE Phase 1 Operation Rules HITSP/T17 - Secured Communication Channel	HITSP/T40 is referencing CAQH CORE Phase I Operating Rules which sets HTTPS as a minimum requirement for web connections. Within HITSP we also require T17 that sets TLS as a minimum. This document sets T17 as a constraint to the CAQH CORE Phase I Operating Rules Recommend CAQH coordinate security requirements with the HITSP Security, Privacy and Infrastructure Committee with the purpose of harmonization with HITSP requirements
6.1.2.1, 6.3.2.1, 7.1.3.1, 7.2.2.1, 7.3.4.1	Events which require Medication and Allergy summary information	HITSP/C32 Continuity of Care of Document (CCD) and NCPDP SCRIPT 8.1 or 10.1	The explanation of this overlap is described in detail in Section 2.1 in the note labeled "Note on medication history information sharing"

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 the HITSP Medication Management Interoperability Specification, available at 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.

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:

Table 6.2-1 Description of Standards

Standard Name	Description
Accredited Standards Committee (ASC) X12 Insurance Subcommittee (X12N) Implementation Guides Version 004010 plus Addenda 004010A1	Detailed Implementation Guides based on release 004010 of the X12 standards. These Implementation Guides provide details on the use of X12 standards to accomplish specific transaction functions. Some of the version 004010 Implementation Guides, but not all, have been adopted as Implementation Specifications under HIPAA. Many of the version 004010 Implementation Guides, including all of those adopted under HIPAA, have Addenda that contain updates -- only -- to the original Implementation Guides. These Addenda are identified as version 004010A1. Implementation Guides 004010X092 and 004010X092A1 describe transactions for Health Care Eligibility Benefit Inquiry and Response. Implementation Guides are published by Washington Publishing Company. For more information visit www.wpc-edi.com.
Accredited Standards Committee (ASC) X12 Standards Release 004010	Release (version) 004010 of the Accredited Standards Committee (ASC) X12 standards including the X12.5 Interchange Control, X12.6 Application Control Structure, 270 Eligibility, Coverage or Benefit Inquiry, 271 Eligibility, Coverage or Benefit Information and other control standards for the uniform electronic interchange of business transactions. Published by the Data Interchange Standards Association (DISA). For more information visit www.x12.org.
American National Standards Institute (ANSI) International Committee for Information Technology Standards (INCITS), #359-2004	This standard describes RBAC features that have achieved acceptance in the commercial marketplace. It includes a reference model and functional specifications for the RBAC features defined in the reference model. It is intended for (1) software engineers and product development managers who design products incorporating access control features; and (2) managers and procurement officials who seek to acquire computer security products with features that provide access control capabilities in accordance with commonly known and understood terminology and functional. For more information visit www.ansi.org.
American Society for Testing and Materials (ASTM) Privilege Management Infrastructure (PMI) Guidelines	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. 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. Many current systems require only local privilege management functionality (on a single computer system). Such systems frequently use proprietary mechanisms. This standard does not address this type of functionality; rather, it addresses an environment where privileges and capabilities (authorizations) must be managed between computer systems across the enterprise, and with business partners. For more information visit www.astm.org.

Standard Name	Description
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 www.astm.org.
CDC Race and Ethnicity Code Sets	The U.S. Centers for Disease Control and Prevention (CDC) has prepared a code set for use in coding race and ethnicity data. This code set is based on current federal standards for classifying data on race and ethnicity, specifically the minimum race and ethnicity categories defined by the U.S. Office of Management and Budget (OMB) and a more detailed set of race and ethnicity categories maintained by the U.S. Bureau of the Census (BC). The main purpose of the code set is to facilitate use of federal standards for classifying data on race and ethnicity when these data are exchanged, stored, retrieved, or analyzed in electronic form. At the same time, the code set can be applied to paper-based record systems to the extent that these systems are used to collect, maintain, and report data on race and ethnicity in accordance with current federal standards. For more information visit www.cdc.gov.
Centers for Medicare and Medicaid Services (CMS) National Provider Identifier (NPI)	NPI is a unique 10-digit identification number issued to healthcare providers in the United States by the Centers for Medicare and Medicaid Services (CMS). All individual HIPAA covered healthcare providers (physicians, nurses, dentists, chiropractors, physical therapists, etc.) or organizations (hospitals, home healthcare agencies, nursing homes, residential treatment centers, group practices, laboratories, pharmacies, medical equipment companies, etc.) must obtain an NPI for use in all HIPAA standard transactions, even if a billing agency prepares the transaction. Once assigned, a provider's NPI is permanent and remains with the provider regardless of job or location changes. For more information visit www.cms.gov.
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 www.caqh.org.
Drug Enforcement Administration (DEA) Prescriber Number	The Drug Enforcement Administration (DEA) is a United States Department of Justice law enforcement agency tasked with enforcing the Controlled Substances Act of 1970. It shares concurrent jurisdiction with the Federal Bureau of Investigation in narcotics enforcement matters. A DEA number is a series of numbers assigned to a healthcare provider (such as a dentist, physician, nurse practitioner, or physician assistant) allowing them to write prescriptions for controlled substances. Legally the DEA number is solely to be used for tracking controlled substances. The DEA number, however, is often used by the industry as a general "prescriber" number that is a unique identifier for anyone who can prescribe medication.
Federal Information Processing Standards (FIPS) Codes for the Identification of the States, the District of Columbia and the Outlying Areas of the United States, and Associated Areas Publication # 5-2, May, 1987	A set of two-digit numeric codes and a set of two-letter alphabetic codes for representing the 50 states, the District of Columbia and the outlying areas of the United States, and associated areas. The standard covers all land areas under the sovereignty of the United States, the freely associated states of Federated States of Micronesia and Marshall Islands, and the trust territory of Palau. For more information visit www.itl.nist.gov. NOTE: ASC X12 transactions and ASC X12N Implementation Guides do not allow use of this standard; instead they require use of the U.S. Postal Service's National Zip Code and Post Office Directory -- which provides similar alphabetic code values.

Standard Name	Description
Federal Medication Terminologies	A set of controlled terminologies and code sets developed and maintained as part of a collaboration between the Food and Drug Administration, National Library of Medicine, Veterans Health Administration, National Cancer Institute and Agency for Healthcare Research and Quality related to medications, including medication proprietary and nonproprietary names, clinical drug code (RxNorm); ingredient names and Unique Ingredient Identifiers (UNII); routes of administration, dosage forms, and units of presentation from the NCI Thesaurus (NCIt); and certain pharmacological drug classes from the National Drug File Reference Terminology (NDF-RT). The Federal Medication Terminology leverages medication models maintained by the Food and Drug Administration (ex. UNII, NDC Codes), National Library of Medicine (RxNorm), the Veterans Health Administration (NDF-RT), and the National Cancer Institute (NCIt). Information on the Federal Medication Terminologies may be found and downloaded from the NCI Web portal terminology resources page at www.cancer.gov/cancertopics.
Health Care Provider Taxonomy	The Health Care Provider Taxonomy code set is a collection of unique alphanumeric codes, ten characters in length. The Health Care Provider Taxonomy code set includes specialty categories for individuals, groups of individuals, and non-individuals. The National Uniform Claims Committee maintains this code set. The complete code set is available from the Washington Publishing Company at www.wpc-edi.com.
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 www.hl7.org.
Health Level Seven (HL7) Healthcare Permissions Catalogue	This vocabulary provides access control information supporting access control decision and enforcement functions as defined by ISO 10181.3. For more information visit www.hl7.org
Health Level Seven (HL7) Implementation Guide: CDA Release 2 - Continuity of Care Document (CCD), April 01, 2007	The Continuity of Care Document implementation guide describes constraints on the HL7 Clinical Document Architecture, Release 2 (CDA) specification in accordance with requirements set forward in ASTM E2369-05 Standard Specification for Continuity of Care Record (CCR). The resulting specification, known as the Continuity of Care Document (CCD), is developed as a collaborative effort between ASTM and HL7. It is intended as an alternate implementation to the one specified in ASTM ADJE2369 for those institutions or organizations committed to implementation of the HL7 Clinical Document Architecture. For more information visit www.hl7.org.
Health Level Seven (HL7) 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 www.hl7.org.
Health Level Seven (HL7) Version 2.5/2.5.1	The HL7 Version 2.5 and 2.5.1 Messaging Standard is an application protocol for electronic data exchange in healthcare. It and prior versions have widespread use in the U.S. and internationally. Both message formats and value sets / code tables (e.g., diagnosis type, gender, patient class, result status, specimen collection method, abnormal flags, observation result status codes interpretation, timestamp format) are contained in the standard. Of particular focus for HITSP Interoperability Specifications are message formats described in Chapters 2, 3, 4, 5, and 7 including patient demographic (ADT), Pharmacy/Treatment Orders and lab result reporting. These are also used within composite standards from IHE for Patient Identity Cross-Referencing and Feed (PIX), Patient Demographics Query (PDQ), and Acknowledgements. They are also used in HL7 order messages. For more information visit www.hl7.org.

Standard Name	Description
Health Level Seven (HL7) Version 2.5/2.5.1 - Pharmacy/Treatment Orders (OMP)	The HL7 Version 2.5 and 2.5.1 Messaging Standard is an application protocol for electronic data exchange in healthcare. It and prior versions have widespread use in the U.S. and internationally. Both message formats and value sets / code tables (e.g., diagnosis type, gender, patient class, result status, specimen collection method, abnormal flags, observation result status codes interpretation, timestamp format) are contained in the standard. Of particular focus for HITSP Interoperability Specifications are message formats described in Chapters 2, 3, 4, 5, and 7 including patient demographic (ADT), Pharmacy/Treatment Orders and lab result reporting. These are also used within composite standards from IHE for Patient Identity Cross-Referencing and Feed (PIX), Patient Demographics Query (PDQ), and Acknowledgements. They are also used in HL7 order messages. For more information visit www.hl7.org.
Health Level Seven (HL7) Version 3.0	The HL7 Version 3.0 Messaging Standard is an application protocol for electronic data exchange in healthcare. Version 3.0 is based on a Reference Information Model (RIM); which is used to instantiate various message formats. Value sets / code tables are contained in the standard. For more information visit www.hl7.org.
Health Level Seven (HL7) Version 3.0 Clinical Document Architecture (CDA/CDA R2)	The HL7 Clinical Document Architecture is an XML-based document markup standard that specifies the structure and semantics of clinical documents for the purpose of exchange. CDA is one instantiation of HL7's Version 3.0 Reference Information Model (RIM) into a specific message format. Of particular focus for HITSP Interoperability Specifications are message formats for Laboratory Results and Continuity of Care (CCD) documents. Release 2 of the HL7 Clinical Document Architecture (CDA) is an extension to the original CDA document markup standard that specifies the structure and semantics of clinical documents for the purpose of exchange. CDA R2 includes a prose document in HTML, XML schemas, data dictionary, and sample CDA documents. CDA R2 further builds upon other HL7 standards beyond just the Version 3.0 Reference Information Model (RIM) and incorporates Version 3.0 Data Structures, Vocabulary and the XML Implementation Technology Specifications for Data Types and Structures. For more information visit www.hl7.org.
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 3.0	The IHE IT Infrastructure Technical Framework defines specific implementations of established standards to achieve integration goals that promote appropriate sharing of health information to support optimal patient care. IHE Integration Profiles offer a common language that healthcare professionals and vendors may use in communicating requirements for the integration of products. The current version of the ITI-TF, rev.3.0 for Final Text, specifies the IHE transactions defined and implemented as of December 9, 2006. The latest version of the IHE Technical Framework is available at www.ihe.net.
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) 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 www.ihe.net.
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0	The IHE IT Infrastructure Technical Framework defines specific implementations of established standards to achieve integration goals that promote appropriate sharing of health information to support optimal patient care. IHE Integration Profiles offer a common language that healthcare professionals and vendors may use in communicating requirements for the integration of products. The current version of the ITI-TF, rev. 4.0 for Final Text, specifies the IHE transactions defined and implemented as of August 22, 2007. The latest version of the IHE Technical Framework is available at www.ihe.net.
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 www.ihe.net.

Standard Name	Description
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (TF) Revision 4.0 - Audit Trail and Node Authentication Profile (ATNA)	Audit Trail and Node Authentication (ATNA) establishes the characteristics of a Basic Secure Node. It describes the security environment (user identification, authentication, authorization, access control, etc.) assumed for the node so that security reviewers may decide whether this matches their environments. It defines basic auditing requirements for the node. It defines basic security requirements for the communications of the node using TLS or equivalent functionality. It establishes the characteristics of the communication of audit messages between the Basic Secure Nodes and Audit Repository nodes that collect audit information. This integration profile has been designed so that specific domain frameworks may extend it through an option defined in the domain specific technical framework. Extensions are used to define additional audit event reporting requirements, especially actor specific requirements. The latest version of the IHE Technical Framework is available at www.ihe.net.
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0 - 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 www.ihe.net.
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0 XCA Supplement	The IHE IT Infrastructure Technical Framework defines specific implementations of established standards to achieve integration goals that promote appropriate sharing of health information to support optimal patient care. IHE Integration Profiles offer a common language that healthcare professionals and vendors may use in communicating requirements for the integration of products. The trial implementation version of the XCA Supplement to the ITI-TF, rev. 4.0 Final Text, specifies the IHE transactions that support access between communities in a manner compatible with the XDS Integration profile. This supplement is available at www.ihe.net.
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 www.ihe.net.
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Supplement 2007 - 2008 Basic Patient Privacy Consents (BPPC) - Trial Implementation	The Basic Patient Privacy Consents (BPPC) profile provides a mechanism to record the patient privacy consent(s), a method to mark documents published to XDS with the patient privacy consent that was used to authorize the publication, and a method for XDS Consumers to use to enforce the privacy consent appropriate to the use. This profile complements XDS by describing a mechanism whereby an XDS Affinity Domain can develop and implement multiple privacy policies, and describes how that mechanism can be integrated with the access control mechanisms supported by the XDS Actors (e.g. systems). There are two key parts of the profile: 1) It provides a document content specification for capturing a patient acknowledgement of a privacy consent policy or policies. 2) It describes the method by which XD* Actors can enforce the privacy policies determined by the document confidentialityCode related to the patient privacy consents. The latest version of the IHE Technical Framework is available at www.ihe.net.
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 www.ihe.net.
International Health Terminology Standards Development Organisation (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®)	SNOMED CT consists of a technical design, core content architecture, and Core content. SNOMED CT Core content includes the technical specification of SNOMED CT and fully integrated multi-specialty clinical content. The Core content also includes a concepts table, description table, relationships table, history table, ICD-9-CM mapping, and Technical Reference Guide. Additionally, SNOMED CT provides a framework to manage language dialects, clinically relevant subsets, qualifiers and extensions, as well as concepts and terms unique to particular organizations or localities. For more information visit www.ihtsdo.com.

Standard Name	Description
International Organization for Standardization (ISO) Health informatics -- Information technology -- Open Systems Interconnection -- Systems Management: Security alarm reporting function, Technical Specification #10164-- Part 7: Security Alarm Reporting Function, 1992	Establishes user requirements for the service definition needed to support the security alarm reporting function, defines the service provided by the security alarm reporting function, specifies the protocol that is necessary in order to provide the service, defines the relationship between the service and management notifications, defines relationships with other systems management functions, specifies conformance requirements. The security alarm reporting function is a systems management function which may be used by an application process in a centralized or decentralized management environment to exchange information for the purpose of systems management. For more information visit www.iso.org.
International Organization for Standardization (ISO) Health informatics - Functional and Structural Roles (ISO SF Roles), Technical Specification #21298 , Draft May, 2007	Defines and describes some roles based upon European business models. For more information visit www.iso.org.
International Organization for Standardization (ISO) Health informatics -- Information technology -- Text and office systems - Office Document Architecture (ODA) and interchange format, Technical Report on ISO 8613 implementation testing, Technical Specification # ISO/IEC CD 10183 -- Part 3: Testing procedure	Specifies a general framework for the provision of access control. The purpose of access control is to counter the threat of unauthorized operations involving a computer or communication system. For more information visit www.iso.org.
International Organization for Standardization (ISO) Health informatics -- Privilege management and access control (PMAC), Technical Specification #22600 -- Part 1: Overview and policy management, July 2006	Supports the needs of healthcare information sharing across unaffiliated providers of healthcare, healthcare organizations, health insurance companies, their patients, staff members and trading partners. It is also intended to support inquiries from both individuals and application systems. For more information visit www.iso.org.
Logical Observation Identifiers Names and Codes (LOINC®)	A database of universal identifiers for laboratory and other clinical observations. The laboratory portion of the LOINC database contains the usual categories of chemistry, hematology, serology, microbiology (including parasitology and virology), and toxicology; as well as categories for drugs and the cell counts typically reported on a complete blood count or a cerebrospinal fluid cell count. Antibiotic susceptibilities are a separate category. The clinical portion of the LOINC database includes entries for vital signs, hemodynamics, intake/output, EKG, obstetric ultrasound, cardiac echo, urologic imaging, gastroendoscopic procedures, pulmonary ventilator management, selected survey instruments, and other clinical observations. For more information visit www.loinc.org.
National Council for Prescription Drug Programs (NCPDP) Formulary and Benefits Standard Implementation Guide	Provides a standard means for pharmacy benefit payers (including health plans and Pharmacy Benefit Managers) to communicate formulary and benefit information to prescribers via technology vendor systems. The service enables technology vendors to receive a range of formulary and benefit information through the service: formulary status, preferred alternatives, benefit coverage and copay information. For more information visit www.ncpdp.org.
National Council for Prescription Drug Programs (NCPDP) SCRIPT Standard Implementation Guide Version 8.1 or 10.1	Provides for the realtime electronic transfer of prescription data between pharmacies and providers. Functions supported include communication of new prescriptions, prescription changes, refill requests, prescription fill status notifications, and prescription cancellations. For more information visit www.ncpdp.org.

Standard Name	Description
National Council for Prescription Drug Programs (NCPDP) SCRIPT Standard Implementation Guide Version 10.1	Provides for the realtime electronic transfer of prescription data between pharmacies and providers. Functions supported include communication of new prescriptions, prescription changes, refill requests, prescription fill status notifications, and prescription cancellations. For more information visit www.ncpdp.org.
National Council for Prescription Drug Programs (NCPDP) Telecommunication Standard Implementation Guide	Provides prescription claim transactions between Providers and Adjudicators, and between Adjudicators (a.k.a. Payer-to-Payer). The Telecommunication Standard Implementation Guide supports the following processes: 1. Eligibility Verification 2. Claim 3. Service 4. Information Reporting 5. Prior Authorization 6. Predetermination of Benefits For more information visit www.ncpdp.org.
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. For more information visit www.nlm.nih.gov.
Organization for the Advancement of Structured Information Standards (OASIS) Security Assertion Markup Language (SAML) v2.0 OASIS Standard; ITU-T X.1141	SAML, developed by the Security Services Technical Committee of OASIS, is an XML-based framework for communicating user authentication, entitlement, and attribute information. As its name suggests, SAML allows business entities to make assertions regarding the identity, attributes, and entitlements of a subject (an entity that is often a human user) to other entities, such as a partner company or another enterprise application. For more information visit www.oasis-open.org.
Organization for the Advancement of Structured Information Standards (OASIS) Simple Object Access Protocol (SOAP) Version 1.1	SOAP is a protocol specification for invoking methods on servers, services, components and objects. SOAP codifies the existing practice of using XML and HTTP as a method invocation mechanism. The SOAP specification mandates a small number of HTTP headers that facilitate firewall/proxy filtering plus an XML vocabulary that is used for representing method parameters, return values, and exceptions. {DevelopMentor} SOAP consists of three parts: an envelope that defines a framework for describing what is in a message and how to process it, a set of encoding rules for expressing instances of application-defined data types, and a convention for representing remote procedure calls and responses. For more information visit www.oasis-open.org.
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 Toke Service (STS) model for security tokens including requesting, issuing, renewing, cancelling and validating. For more information visit www.oasis-open.org.
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 www.oasis-open.org.
Organization for the Advancement of Structured Information Standards (OASIS) WS-Trust Version 1.3, March 2007	Defines extensions that build on [WS-Security] to provide a framework for requesting and issuing security tokens, and to broker trust relationships. Defines Security Toke Service (STS) model for security tokens including requesting, issuing, renewing, canceling and validating. For more information visit www.oasis-open.org.

Standard Name	Description
Organization for the Advancement of Structured Information Standards (OASIS) eXtensible Access Control Markup Language (XACML), ITU-T Recommendation X.1142, February 2005	The Organization for the Advancement of Structured Information Standards (OASIS) standards group developed the eXtensible Access Control Markup Language (XACML) as a language to express and evaluate access decisions. The XCML technical specification includes a profile for RBAC using XACML that complies with the ANSI RBAC standard. The HL7 RBAC Permission Catalog provides a standard vocabulary that can be used for cross-enterprise access control. For more information visit www.oasis-open.org.
Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity	This classification provides a minimum standard for maintaining, collecting, and presenting data on race and ethnicity for all Federal-reporting purposes. The categories in this classification are social-political constructs and should not be interpreted as being scientific or anthropological in nature. The standards have been developed to provide a common language for uniformity and comparability in the collection and use of data on race and ethnicity by Federal agencies. For more information visit www.census.gov.

7.0 CHANGE HISTORY

The following sections provide the history of changes made to this document.

7.1 DECEMBER 7, 2007

No changes. This is the first published version of the document.

7.2 MARCH 19, 2008

The changes in this cycle address the following comments:

2999, 3001, 3009, 3010, 3011, 3012, 3013, 3016, 3019, 3020, 3022, 3030, 3031, 3077, 3078, 3087, 3089, 3090, 3091, 3093, 3094, 3096, 3097, 3098, 3102, 3103, 3104, 3105, 3106, 3113, 3124, 3130, 3131, 3133, 3145, 3146, 3150, 3151, 3162, 3163, 3164, 3165, 3166, 3167, 3169, 3170, 3172, 3173, 3174, 3175, 3219, 3241, 3242

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

7.3 MARCH 27, 2008

Upon approval by the HITSP Panel on March 27, 2008, this document is now Released for Implementation with one correction. Per the approved motion, a Standards Gap was added into Table 4.2-1 to document the need to identify the Sender and Receiver of the X12 270/271 messages used by the HITSP/T40 and HITSP/TP46 constructs. In addition, a table of Guiding Regulations has been added to Section 4.1 and the following standard names/descriptions were modified in Table 2.3-1 List of Standards to provide more clarity and specificity for the optionality described in HITSP/TP13:

- Removed high level reference to IHE ITI-TF Revision 4
- Added specific reference to Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0, Section 10 Cross-Enterprise Document Sharing (XDS.a)
- Modified Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Volume 2 Supplement 2007 – 2008 Cross-Enterprise Document Sharing-B (XDS.b) description by moving extraneous content into the narrative of HITSP/TP13
- Modified Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0 - Registry Stored Query Transaction for XDS Profile Supplement standard name by adding [ITI-18] for additional clarity