

# HITSP Medication Management Interoperability Specification

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HITSP/IS07



Healthcare Information Technology Standards Panel

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*Submitted by:*

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## 1.0 INTRODUCTION

This Healthcare Information Technology Standards Panel (HITSP) document is divided into Requirements, Design and Capabilities sections which may be used by analysts, architects and implementers. Analysts might use this document to refer to the requirements of a particular Harmonization Request. Architects and system implementers might refer to this document as the top level architectural specification for a system design while software developers will use the Interoperability Specification as a source of requirements for interoperable information exchange.

The following table details specific sections of this Interoperability Specification (IS) and how specific sections of this document are targeted to specific readers. Each of the stakeholders listed in this table are more fully defined in a separate appendix. This table is provided as an aid to readers to assist with identifying specific areas of focus. Readers are encouraged to review all sections of this document to further their understanding of HITSP's work.

**Table 1-1 Reader's Guide for Interoperability Specification**

Document Section	Section Number	Intended Audience	Information Contained
Section 2.0 Requirements	2.1 Synopsis of Requirements	Policy Managers Policy Analysts Executive Leadership End-users (e.g., clinicians)	Used to provide an overview (using a scenario-based approach) of the requirements applicable to this document. Readers should start here to learn more about what specific requirements this IS is intended to address
	2.2 – 2.3 Scenarios	Program Managers Policy Analysts Executive Leadership	Each of the scenarios specific to the IS are outlined and described using a HITSP concept known as an Information Exchange Requirement (or IER). HITSP uses IER's to outline requirements for HITSP work products
	2.4 System Description	Architects Business Analysts Policy Analysts Program Managers	The systems assigned to the system roles (as defined in the HITSP Capabilities used by this IS) are identified and described here. Readers can learn which systems have been included as part of this HITSP IS
Section 3.0 Design Specification	3.1 Capabilities Used	Architects Business Analysts Development Team	For each HITSP Information Exchange Requirement (IER) identified in Section 2.0, a corresponding HITSP Capability is associated and mapped. A reader can review how specific HITSP Capabilities meet information exchange needs. A diagram is also provided to show the interchange of data among systems identified in this IS
	3.2 Capability Orchestration	Architects Development Team	The core of the design in the IS is documented here. This solution shows orchestration of Capabilities to meet the specific HITSP information exchange requirements in Section 3.1. The design also identifies conditions and constraints, as well as any content subsets specific to the solution
Section 4.0 Capability Gaps	4.0 Capability Gaps	Business Analysts Development Team Architects	Gaps specific to Capabilities used as part of this IS are reviewed in this section to determine why specific information exchange requirements may not yet be met or defined. Readers should check this section to track the progress of gap resolution
Section 5.0 Appendix	5.1 Harmonization Request Traceability	Architects Business Analysts	A complete mapping of information exchange requirements to functional requirements is provided in this section. Readers can trace IER's to underlying Harmonization Request events and actions (in those instances where a Use Case exists) or to functional requirements defined as part of an official standards Harmonization Request

### 1.1 INTEROPERABILITY SPECIFICATION OVERVIEW

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 DOCUMENT SCOPE

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), entities that manage care (e.g., Long Term Care (LTC) and post-acute care (PAC) facilities) and organizations that provide health insurance and provide pharmacy benefits (payers).

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

A key component of the Medication Management Use Case is its relationship to federal regulations by the Centers for Medicare & Medicaid Services (CMS). The regulation, the Medicare Modernization Act (MMA), contains requirements on ePrescribing (<http://www.cms.hhs.gov/EPrescribing/>):

- 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
- Provides prescribers information about which drugs are covered by a Medicare beneficiary's prescription drug benefit plan
- Provides prescribers with information about medications a beneficiary is already taking, including those prescribed by other providers, to help reduce the number of adverse drug events
- Allows prescribers to receive an electronic notice from the pharmacy telling them that a patient's prescription has been picked up, not picked up, or has been partially filled, to help monitor medication adherence in patients with chronic conditions

Additional pilots are underway to test the following standards and their application in transactions:

- Structured and Codified Sig
- Clinical drug terminology (RxNorm)

Industry work is continuing in the area of standards and piloting for:

- 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
- NCPDP Formulary and Benefit Standard Implementation Guide Version 1.0

The standards continue to evolve; the regulatory process has been invoked to name more current versions 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 Medication 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 this specification was written, NCPDP SCRIPT Standard Implementation Guide Version 10.1 was the most recently approved. However since that time, the versions have evolved further. The regulatory process is expected to name the NCPDP SCRIPT Standard Implementation Guide Version 10.6, and the ASC X12N 270/271 Version 5010. This IS will need to be updated to support these versions.

Note on medication history information sharing:

In the context of medication history, NCPDP SCRIPT Medication History transactions are used by prescriber, payer and dispenser System to share medication history detail records.

A prescriber or a dispenser may also receive medication history which is part of a broader patient summary – in the form of a document which may include allergies, problem lists, etc in addition to medications. To establish a common means to produce and exchange such a summary document when entities are communicating with PHRs, EHRs and other entities under the interoperable NHIN paradigm, the HITSP specifications use HL7 Clinical Document Architecture (CDA) Continuity of Care Document (CCD) as the common structure for all summary documents.

Because of the aforementioned need, this specification describes the broader patient summary that includes medication history as being communicated between Systems. It is expected that prescriber organizations will use the summary document form when communicating with each other. Payers and dispensers will also use the summary document form 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 either a sending or receiving System, 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).

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## **1.4 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.

### **1.4.1 CONFORMANCE CRITERIA**

For an implementation to claim conformance to a HITSP Interoperability Specification, it must be implemented in its entirety or within a limited scope or subset as defined within the 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 this





Interoperability Specification, and implement all of the required interfaces within the scope, subset or implementation options as described.

#### 1.4.2 CONFORMANCE SCOPING, SUBSETTING AND OPTIONS

HITSP may define the permissibility for system scoping, subsetting or implementation options by which the specification may be implemented in a limited manner. The selected scope, subset or options shall specifically be stated, and implementations must include all requirements within the selected scope, subset or options to claim conformance.

For this Interoperability Specification, conformance may be declared by a participating system for any Capability provided that all declared constraints, conditions and requirements imposed by the Capability and its referenced HITSP constructs are satisfied.

#### 1.4.3 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 and Support](#) Web Site has been developed in collaboration with HITSP, the National Institute of Standards and Testing (NIST), the Certification Commission for Healthcare Information Technology (CCHIT), and the Office of the National Coordinator for Health Information Technology (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.

### 1.5 REFERENCE DOCUMENTS

A list of key reference documents and background material is provided in the table below. HITSP-maintained reference documents can be retrieved from the [HITSP Web Site](#).

**Table 1-2 Reference Documents**

Reference Documents	Document Description
<a href="#">HITSP Acronyms List</a>	Lists and defines the acronyms used in this document
<a href="#">HITSP Glossary</a>	Provides definitions for relevant terms used by HITSP documents
<a href="#">TN900 - Security and Privacy</a>	TN900 is a reference document that provides the overall context for use of the HITSP Security and Privacy constructs
<a href="#">TN903 – Data Architecture</a>	TN903 is a reference document that provides the overall context for use of the HITSP Data Architecture constructs
<a href="#">TN904 – Harmonization Framework and Exchange Architecture</a>	TN904 is a reference document that provides the overall context for use of the HITSP Harmonization Framework and Exchange Architecture



## 2.0 REQUIREMENTS

Section 2.0 identifies the requirements from the Harmonization Request for which information exchanges are necessary. The following table details how this section and other sections of the document are targeted to specific readers. Each of the stakeholders listed in this table are more fully defined in a separate appendix. This table is provided as an aid to readers to assist with identifying specific areas of focus. Readers are encouraged to review all sections of this document to further their understanding of HITSP's work.

**Table 2-1 Reader's Guide for Section 2.0**

Document Section	Section Number	Intended Audience	Information Contained
Section 2.0 Requirements	2.1 Synopsis of Requirements	Policy Managers Policy Analysts Executive Leadership End-users (e.g., clinicians)	Used to provide an overview (using a scenario-based approach) of the requirements applicable to this document. Readers should start here to learn more about what specific requirements this Interoperability Specification is intended to address
	2.2 – 2.3 Scenarios	Program Managers Policy Analysts Executive Leadership End-users (e.g., clinicians)	Each of the scenarios specific to the Interoperability Specification are outlined and described using a HITSP concept known as an Information Exchange Requirement (or IER). HITSP uses IER's to outline requirements for HITSP work products
	2.4 System Description	Architects Business Analysts Policy Analysts Program Managers	The systems assigned to the system roles (as defined in the Capabilities used by this IS) are identified and described here. Readers can learn which systems have been included as part of this Interoperability Specification

### 2.1 SYNOPSIS OF REQUIREMENTS

The following table describes the Information Exchange Requirements needed to accomplish the Harmonization Request for which information exchange is necessary.

**Table 2-2 Description of Information Exchange Requirements**

Information Exchange Requirement Number (IER)	Description
IER1	Patient Health Plan Eligibility Verification (Pharmacy Benefit) – Ambulatory and LTC
IER2	Patient Health Plan Eligibility Verification (Medical Benefit) – Ambulatory and LTC
IER3	Medication Orders– Ambulatory and LTC
IER4	Medication Formulary and Benefits Information– Ambulatory and LTC
IER5	Medication Dispensing Status– Ambulatory and LTC
IER6	Patient Health Plan Eligibility Verification (Pharmacy Benefit) – Hospital
IER7	Patient Health Plan Eligibility Verification (Medical Benefit) - Hospital
IER8	Medication Orders – Hospital
IER9	Medication Formulary and Benefits Information – Hospital
IER10	Medication Dispensing Status – Hospital
IER11	Request (structured/unstructured) information (HITSP/CAP119/HITSP/CAP120)

Table 2-3 lists and describes the major subdivisions of a Harmonization Request, called Scenarios.

**Table 2-3 Description of Scenarios**

Scenario Name	Scenario Description
Communicate Ambulatory and Long-Term Care Prescription	This scenario addresses interoperability requirements that support electronic prescribing in the ambulatory and long term care environment such as transmittal of new or modified prescriptions, transmittal of prescription refills and renewals, communication of dispensing status, request for benefit eligibility determination, exchange of formulary and benefit information



Communicate Hospital Prescription	This scenario addresses interoperability requirements that support electronic prescribing for inpatient orders that can occur within an organization or between organizations such as the transmittal of a new or modified prescription from a Hospital to an internal or external pharmacy. It also includes the option to access formulary and benefit information
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## 2.2 AMBULATORY AND LONG-TERM CARE PRESCRIPTION

### Ambulatory Medication Management

The ambulatory medication management scenario addresses access to current medication and allergy information and support for electronic prescribing in the ambulatory and LTC environments. 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 INFORMATION EXCHANGE REQUIREMENTS FOR AMBULATORY AND LONG-TERM CARE PRESCRIPTION

The following Information Exchange Requirements Table summarizes the relationship between the Exchange Action, Exchange Content, and the Initiating and Responding Systems.

**Table 2-4 Communicate Ambulatory and Long-Term Care Prescription Information Exchange Requirements**

IER Number	Exchange Action	Exchange Content	Initiating System	Responding System(s)	Exchange Attribute
IER1	Request & Response	Patient Health Plan Eligibility Verification (Pharmacy Benefit)	Pharmacy Systems – External	Healthcare Payer System Or Pharmacy Benefit Manager System	When a pharmacy system in a hospital (e.g. outpatient pharmacy functionality) or LTC environment verifies pharmacy benefits, they function as an ambulatory pharmacy system
IER2	Request & Response	Patient Health Plan Eligibility Verification (Medical Benefit)	Computerized Provider Order Entry Or Electronic Health Record (EHR) System Or EHRs – Ambulatory Or Health Care Entity Systems	Healthcare Payer System	



IER Number	Exchange Action	Exchange Content	Initiating System	Responding System(s)	Exchange Attribute
IER3	Request & Response	Medication Orders	Computerized Provider Order Entry Or Electronic Health Record (EHR) System Or EHRs – Ambulatory Or Health Care Entity Systems Or Pharmacy Systems – External	Computerized Provider Order Entry Or Electronic Health Record (EHR) System Or EHRs – Ambulatory Or Health Care Entity Systems Or Pharmacy Systems – External	Medication Orders supports exchanges FROM prescribing systems TO pharmacy systems, and FROM pharmacy systems TO prescribing systems for new prescriptions, refills/renewals, changes, cancellations, etc.
IER4	Request & Response	Medication Formulary and Benefits Information	Computerized Provider Order Entry Or Electronic Health Record (EHR) System Or EHRs – Ambulatory Or Health Care Entity Systems Or Pharmacy Systems – External	Healthcare Payer System Or Pharmacy Benefit Manager System Or Health Information Exchange (HIE) System	When a pharmacy system in a hospital (e.g. outpatient pharmacy functionality) or LTC environment verifies pharmacy benefits, they function as an ambulatory pharmacy system.
IER5	Notification	Medication Dispensing Status	Pharmacy Systems – External	Computerized Provider Order Entry Or Electronic Health Record (EHR) System Or EHRs – Ambulatory Or Health Care Entity Systems	When a pharmacy system in a hospital (e.g. outpatient pharmacy functionality) or LTC environment verifies pharmacy benefits, they function as an ambulatory pharmacy system.



IER Number	Exchange Action	Exchange Content	Initiating System	Responding System(s)	Exchange Attribute
IER11		Information gathering	Computerized Provider Order Entry Or Electronic Health Record (EHR) System Or EHRs – Ambulatory Or Heath Care Entity Systems Or Pharmacy Systems – External Or Pharmacy Systems – External	PHRs Or Electronic Health Record (EHR) System Or EHRs – Ambulatory Or Heath Care Entity Systems Or Pharmacy Systems – External Or Health Information Exchange (HIE) System	

## 2.3 HOSPITAL PRESCRIPTION

### 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.

#### 2.3.1 INFORMATION EXCHANGE REQUIREMENTS FOR HOSPITAL PRESCRIPTION

The following Information Exchange Requirements Table summarizes the relationship between the Exchange Action, Exchange Content, and the Initiating and Responding Systems.



**Table 2-5 Communicate Hospital Prescription Information Exchange Requirements**

Information Exchange Requirement Number	Exchange Action	Exchange Content	Initiating System	Responding System(s)	Exchange Attribute
IER6	Request & Response	Patient Health Plan Eligibility Verification (Pharmacy Benefit)	Pharmacy Systems - Hospital, Integrated Or Pharmacy Systems - Hospital, Non-integrated	Healthcare Payer System Or Pharmacy Benefit Manager System	When a pharmacy system in a hospital (e.g. outpatient pharmacy functionality) or LTC environment verifies pharmacy benefits, they function as an ambulatory pharmacy system
IER7	Request & Response	Patient Health Plan Eligibility Verification (Medical Benefit)	EHRs – Hospital Or EHRs Hospital and EHR LTC	Healthcare Payer System	
IER8	Request & Response	Medication Orders	EHRs – Hospital Or EHRs Hospital and EHR LTC	Pharmacy Systems - Hospital, Integrated Or Pharmacy Systems - Hospital, Non-integrated	Medication Orders supports exchanges FROM prescribing systems TO pharmacy systems, and FROM pharmacy systems TO prescribing systems for new prescriptions, refills/renewals, changes, cancellations, etc.  HITSP/CAP118 is used
IER9	Request & Response	Medication Formulary and Benefits Information	EHRs – Hospital Or EHRs Hospital and EHR LTC Or Pharmacy Systems - Hospital, Integrated Or Pharmacy Systems - Hospital, Non-integrated	Healthcare Payer System Or Pharmacy Benefit Manager System Or Health Information Exchange (HIE) System	When a pharmacy system in a hospital (e.g. outpatient pharmacy functionality) or LTC environment verifies pharmacy benefits, they function as an ambulatory pharmacy system
IS07-IER10	Notification	Medication Dispensing Status	Pharmacy Systems - Hospital, Integrated Or Pharmacy Systems - Hospital, Non-integrated	EHRs – Hospital Or EHRs Hospital and EHR LTC	When a pharmacy system in a hospital (e.g. outpatient pharmacy functionality) or LTC environment verifies pharmacy benefits, they function as an ambulatory pharmacy system



IS07-IER11		Information gathering	Computerized Provider Order Entry Or Electronic Health Record (EHR) System Or EHRs – Ambulatory Or Heath Care Entity Systems Or Pharmacy Systems – External	PHRs Or Electronic Health Record (EHR) System Or EHRs – Ambulatory Or Heath Care Entity Systems Or Pharmacy Systems – External Or Health Information Exchange (HIE) System	
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## 2.4 SYSTEM DESCRIPTION

The following table lists Systems involved in the above listed scenarios, and identifies the stakeholders served by those involved systems.

**Table 2-6 System Names and Descriptions**

System Name	System Description	Stakeholders
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	Clinicians (prescribers, others), Drug Knowledge Suppliers, Healthcare Entities, Pharmacists (dispensers, others)
Computerized Provider Order Entry	Computerized systems that allow providers to enter orders for medications, labs, etc.	Clinicians (prescribers, others), Drug Knowledge Suppliers, Healthcare Entities
Drug Knowledge Database Repository	System that maintains and provides 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	
Electronic Health Record (EHR) System	The Electronic Health Record (EHR) System is a secure, real-time, point-of-care, patient-centric information resource for clinicians and pharmacists. EHR systems contain Electronic Health Records (EHR) which 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	Healthcare Delivery Organizations, Ancillary Entities, Clinicians, Pharmacists, Health Information Exchanges, Healthcare Entities





System Name	System Description	Stakeholders
EHRs - Hospital	An EHR in a hospital setting (see above for EHR definition)	See above for EHR stakeholders
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)	See above for EHR stakeholders
EHRs - Ambulatory	An EHR in an ambulatory setting (see above for EHR definition)	See above for EHR stakeholders
Health Care Entity Systems	Organizations that are engaged in or support the delivery of healthcare, such as a "health authority"	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
Health Information Exchange (HIE) System	Health Information Exchange (HIE) System is a multi-stakeholder system that enables the exchange and use of health information, in a secure manner, for the purpose of promoting the improvement of health quality, safety and efficiency	Health Information Exchanges, Clinicians, Pharmacists, Healthcare Payers, Pharmacy Benefit Managers, PHRs, Public Health Agencies
Healthcare Payer System	Systems to provide 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	Insurers, including health plans, self-insured employer plans, and third party administrators
Other clinical or Admin Data Source Systems	Systems of other authoritative clinical sources or administrative data source, which are able to provide medication and allergy information for a patient's PHR	Consumers, Clinicians, Pharmacists, Drug Knowledge Suppliers
Personal Health Record (PHR) System	A healthcare system containing records 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	Consumers, Clinicians, Pharmacists
Pharmacy Benefit Manager System	System used by entities that 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	Insurers, including health plans, self-insured employer plans, and third party administrators
Pharmacy Systems - External	Electronic systems that support pharmacists in their role for dispensing medications. This includes systems that may be able to provide useful information on consumers' past medication histories. These systems exist outside of an organization	Pharmacists (dispensers, others), Drug Knowledge Suppliers, Healthcare Entities
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	Pharmacists (dispensers, others), Drug Knowledge Suppliers, Healthcare Entities
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	Pharmacists (dispensers, others), Drug Knowledge Suppliers, Healthcare Entities



System Name	System Description	Stakeholders
Public Health Agency Systems	Systems that exist to help protect and improve the health of their respective constituents	Local, state and federal government organizations and personnel



## 3.0 DESIGN SPECIFICATION

Section 3.0 identifies the Capabilities used to meet the requirements identified in Section 2.0 Requirements and describes how to orchestrate this set of Capabilities to meet those requirements. The following table details how this section of the document is targeted to specific readers. Each of the stakeholders listed in this table are more fully defined in a separate appendix. This table is provided as an aid to readers to assist with identifying specific areas of focus. Readers are encouraged to review all sections of this document to further their understanding of HITSP's work.

**Table 3-1 Reader's Guide for Section 3.0**

Document Section	Section Number	Intended Audience	Information Contained
Section 3.0 Design Specification	3.1 Capabilities Used	Architects Business Analysts Development Team	For each Information Exchange Requirement (IER) identified in Section 2.0, a corresponding Capability is associated and mapped. A reader can review how specific Capabilities meet information exchange needs. A diagram is also provided to show the interchange of data among systems identified in this Interoperability Specification
	3.2 Capability Orchestration	Architects Development Team	The core of the design in the Interoperability Specification is documented here. This solution shows orchestration of Capabilities to meet the specific information exchange requirements in Section 3.1. The design also identifies conditions and constraints, as well as any content subsets specific to the solution

### 3.1 CAPABILITIES USED

The table below lists the Capabilities used in this Interoperability Specification, and relates them to the Information Exchange Requirements from Table 2-2 that the Capability satisfies.

**Table 3-2 Capabilities Used**

Capability	Capability Summary	Capability IE Used	IERs satisfied
HITSP/CAP117 – Communicate Ambulatory and Long-Term Care Prescription	This Capability addresses interoperability requirements that support electronic prescribing in the ambulatory and long term care environment such as transmittal of new or modified prescriptions, transmittal of prescription refills and renewals, communication of dispensing status, request for benefit eligibility determination, exchange of formulary and benefit information		IER1 IER2 IER3 IER4 IER5
HITSP/CAP118 – Communicate Hospital Prescription	This Capability addresses interoperability requirements that support electronic prescribing for inpatient orders that can occur within an organization or between organizations such as the transmittal of a new or modified prescription from a Hospital to an internal or external pharmacy. It also includes the option to access formulary and benefit information		IER6 IER7 IER8 IER9 IER10
HITSP/CAP119 - Communicate Structured	This Capability addresses interoperability requirements that support the communication of structured health data related		IER11



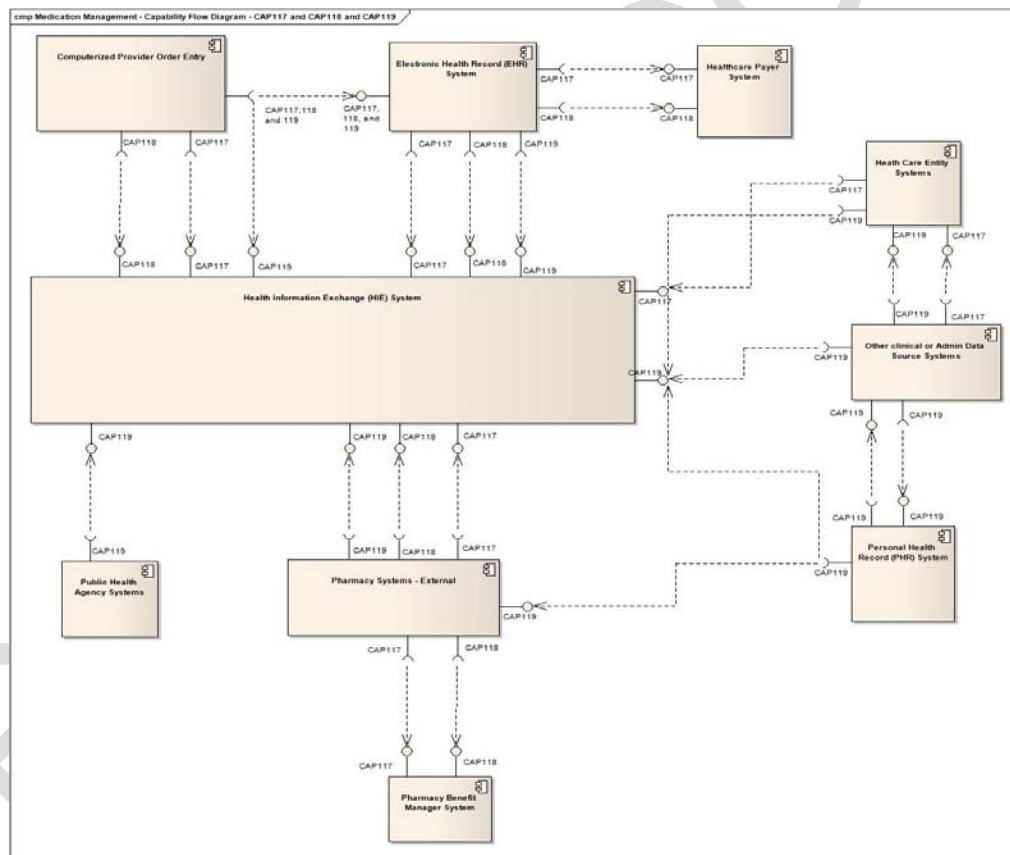
Capability	Capability Summary	Capability IE Used	IEs satisfied
Document	<p>to a patient in a context set by the source of the document who is attesting to its content. Several document content subsets, structured according to the HL7 CDA standard, are supported by this Capability. The following are examples of the type of structured data that may be used:</p> <p>Continuity of Care Document (CCD) HITSP/C32  Emergency Department Encounter Summary HITSP/C28  Discharge Summary (In-patient encounter and/or episodes of care) HITSP/C48  Referral Summary Ambulatory (encounter and/or episodes of care) HITSP/C48  Consultation Notes &amp; History and Physical HITSP/C84  Personal Health Device Monitoring Document HITSP/C74  Healthcare Associated Infection (HAI) Report Document HITSP/C75</p> <p>Document creators shall support a number of the HITSP specified coded terminologies as defined by specific content subsets specified in this Capability</p>		IER11
HITSP/CAP120 - Communicate Unstructured Document	<p>The Communicate Unstructured Document Capability addresses interoperability requirements that support the communication of a set of unstructured health data related to a patient in a context set by the source of the document who is attesting to its content. Two types of specific unstructured content are supported, both with a structured CDA header: • PDF-A supporting long-term archival • UTF-8 text</p>		IER11
HITSP/CAP140 - Communicate Benefits and Eligibility	<p>This Capability addresses interoperability requirements that support electronic inquiry and response about a patient's eligibility for health insurance benefits. The information exchanged includes the following: • A patient's identification (e.g., name, date of birth, and the health plan's member identification number) • Communication of a member's status of coverage and benefit information and financial liability • Access to information about types of services, benefits and coverage for various medical care and medications This Capability provides clinicians and healthcare providers with information about their patient's health insurance coverage and benefits</p>		IER6 IER7
HITSP/CAP141 - Communicate Referral Authorization	<p>This Capability addresses interoperability requirements that support electronic inquiry and response to authorizing a patient (health plan member) to be referred for service by another provider or to receive a type of service or medication under the patient's health insurance benefits. The Capability supports the transmittal of a patient's name and insurance identification number with the request for the type of service. It also includes the following optional requirements: • Identification of the type of service or medication requested for benefit coverage (does not guarantee payment by insurance provider) • Communication of a referral notification number or authorization number from the Payer System to the Provider System It provides clinicians and pharmacists with information about each patient's medical insurance coverage and benefits. It may include information on referral or authorization permission</p>		



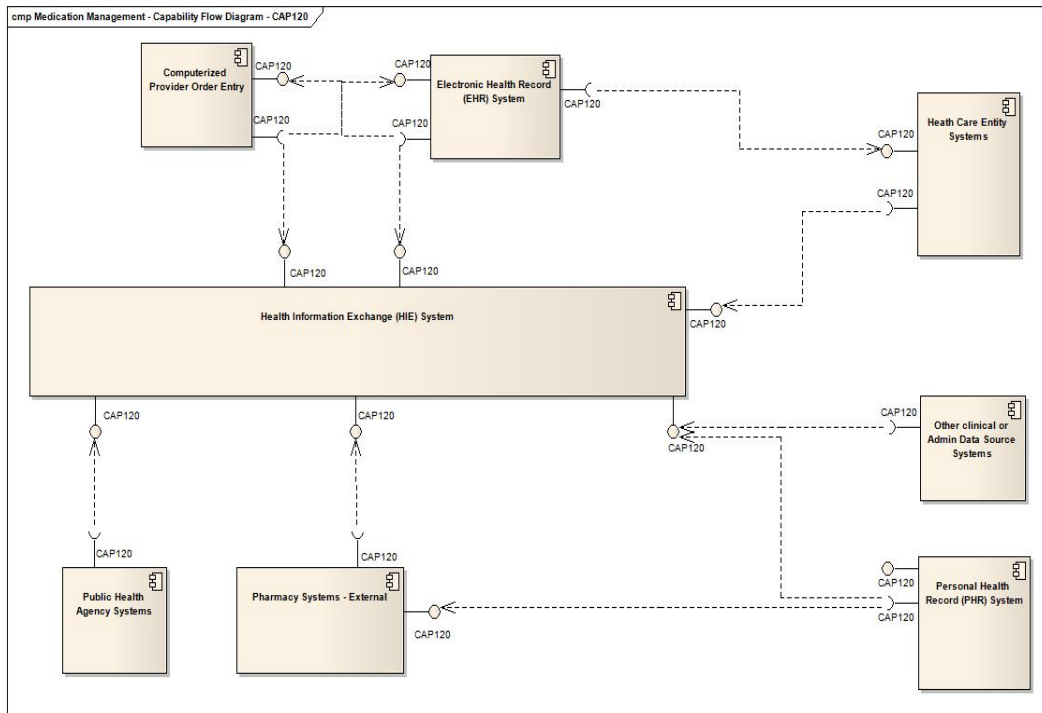
Capability	Capability Summary	Capability IE Used	IEs satisfied
HITSP/CAP143 - Manage Consumer Preference and Consents	This Capability addresses management of consumer preferences and consents as an acknowledgement of a privacy policy. This Capability is used to capture a patient or consumer agreement to one or more privacy policies; where examples of a privacy policy may represent a consent, dissent, authorization for data use, authorization for organizational access, or authorization for a specific clinical trial. This Capability also supports the recording of changes to prior privacy policies such as when a patient changes their level of participation or requests that data no-longer be made available because they have left the region		

The following diagram shows how systems use Capabilities to complete the full IS. The diagram is purposely created to be architecturally neutral. In some settings a given system role within a Capability will be filled by more than one system in the IS. In many settings, one system may implement multiple Capabilities as shown in the diagram. There are many potential combinations of systems using these Capabilities in different architectures as discussed in Section 3.2.2 Implementation Variants. The diagram therefore uses one example that includes all systems.

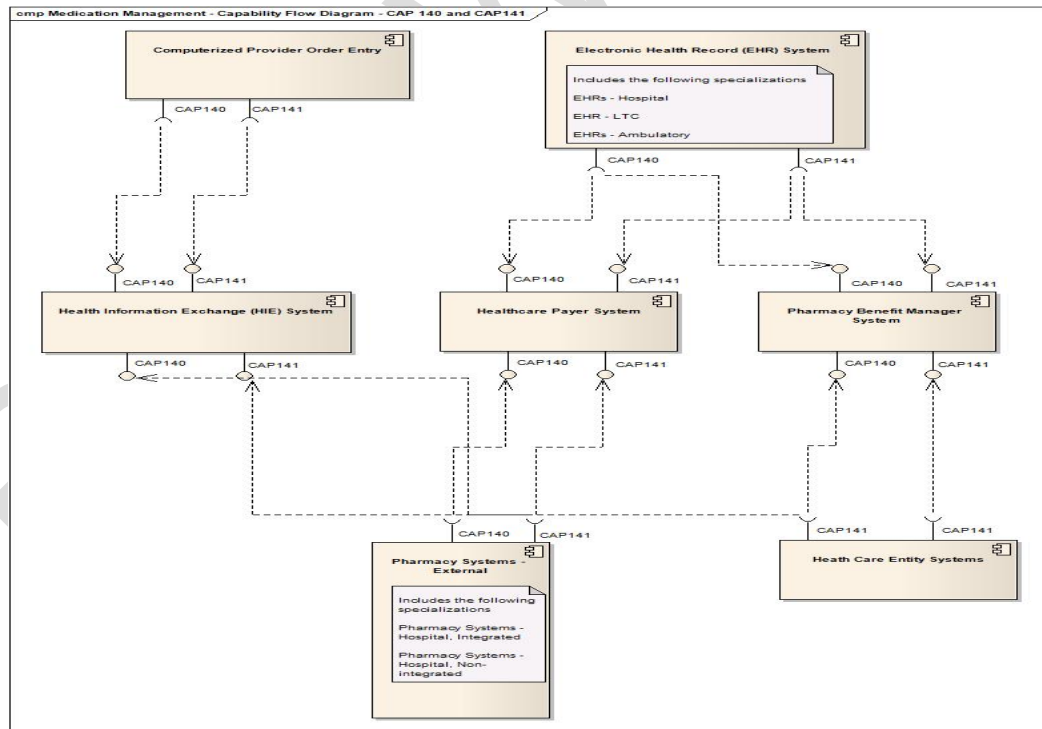
**Figure 3-1 Capabilities Used Between Systems- HITSP/CAP117, HITSP/CAP118 and HITSP/CAP119**



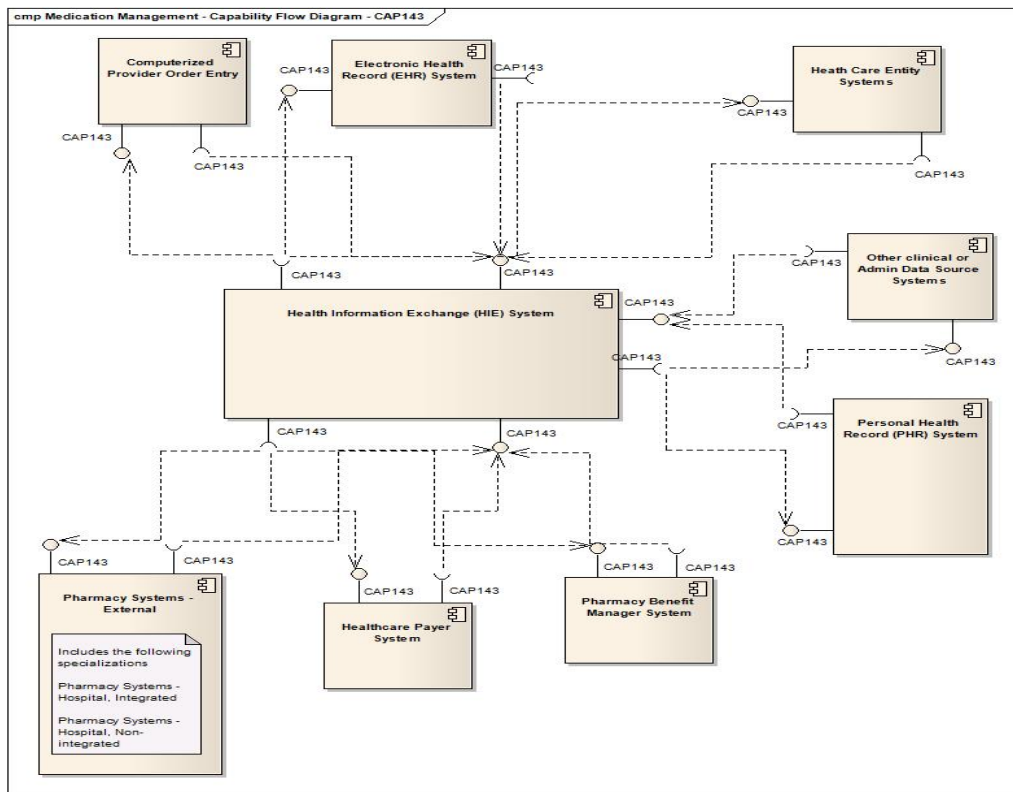
**Figure 3-2 Capabilities Used Between Systems - HITSP/CAP120**



**Figure 3-3 Capabilities Used Between Systems - HITSP/CAP140 and HITSP/CAP141**



**Figure 3-4 Capabilities Used Between Systems- HITSP/CAP143**



### 3.2 CAPABILITY ORCHESTRATION

This section describes how the Capabilities identified above are orchestrated to achieve the aims of the Harmonization Request (such as a Use Case) addressed by this Interoperability Specification. The orchestration identifies, Systems that fill the System roles in the Capabilities to achieve the desired data flows.

Table 3-3 lists the orchestration of Capabilities to meet the information exchange requirements described in Section 2.0. Subsets of these Systems perform information exchanges according to one or more of the Capabilities identified in this Specification. The Capabilities are annotated on the diagrams. The in-scope requirements are supported by Capabilities either previously specified by HITSP or new Capabilities introduced in this section. Optionality is expressed as Required (R), Optional (O) or Conditional (C). If the optionality is Conditional, the applicable conditions are given in Table 3-4 below.





**Table 3-3 Orchestration of Capabilities by System**

System	Capability	System Role(s)	System Role Option	System Role Optionality
Clinical Decision Support Systems			O	Interfaces for CDS Systems include messaging for clinical requests and interactions manage information content. These interactions are noted as gaps in Section 4.0. Clinical Decision Support Systems may be integral to other Systems in this Document. In these cases, only the information management functions are subject to interoperability considerations
Computerized Provider Order Entry	HITSP/CAP117 – Communicate Ambulatory and Long-Term Care Prescription	Initiator Responder	C	IS07- [101]
	HITSP/CAP118 – Communicate Hospital Prescription	Initiator	C	IS07- [101]
	HITSP/CAP119 - Communicate Structured Document	Initiator Responder		
	HITSP/CAP120 - Communicate Unstructured Document	Initiator Responder	O	IS07- [102]
	HITSP/CAP140 - Communicate Benefits and Eligibility	Initiator	O	
	HITSP/CAP141 - Communicate Referral Authorization	Initiator	O	
	HITSP/CAP143 - Manage Consumer Preference and Consents	Initiator Responder		
Drug Knowledge Database Repository	The exchange of information with Drug Knowledge Database Repositories employs proprietary processes. Standardization of these exchanges is noted as a gap			
Electronic Health Record (EHR) System  Includes the following specializations  EHRs - Hospital  EHR - LTC  EHRs - Ambulatory	HITSP/CAP117 – Communicate Ambulatory and Long-Term Care Prescription	Initiator Responder	C	IS07- [103] IS07- [104]
	HITSP/CAP118 – Communicate Hospital Prescription	Initiator	C	IS07- [103] IS07- [105]
	HITSP/CAP119 - Communicate Structured Document	Initiator Responder		
	HITSP/CAP120 - Communicate Unstructured Document	Initiator Responder	O	IS07- [102]
	HITSP/CAP140 - Communicate Benefits and Eligibility	Initiator	O	



System	Capability	System Role(s)	System Role Option	System Role Optionality
	HITSP/CAP141 - Communicate Referral Authorization	Initiator	0	
	HITSP/CAP143 - Manage Consumer Preference and Consents	Initiator Responder		
Heath Care Entity Systems	HITSP/CAP117 – Communicate Ambulatory and Long-Term Care Prescription	Initiator Responder		
	HITSP/CAP119 - Communicate Structured Document	Initiator Responder		
	HITSP/CAP120 - Communicate Unstructured Document	Initiator Responder		
	HITSP/CAP140 - Communicate Benefits and Eligibility	Initiator		
	HITSP/CAP141 - Communicate Referral Authorization	Initiator		
	HITSP/CAP143 - Manage Consumer Preference and Consents	Initiator Responder		
Health Information Exchange (HIE) System	HITSP/CAP117 – Communicate Ambulatory and Long-Term Care Prescription	Gateway/Common Services		
	HITSP/CAP118 – Communicate Hospital Prescription	Gateway/Common Services		
	HITSP/CAP119 - Communicate Structured Document	Gateway/Common Services		
	HITSP/CAP120 - Communicate Unstructured Document	Gateway/Common Services		
	HITSP/CAP140 - Communicate Benefits and Eligibility	Gateway/Common Services		
	HITSP/CAP141 - Communicate Referral Authorization	Gateway/Common Services		
	HITSP/CAP143 - Manage Consumer Preference and Consents	Gateway/Common Services		
Healthcare Payer System	HITSP/CAP117 – Communicate Ambulatory and Long-Term Care Prescription	Responder		
	HITSP/CAP118 – Communicate Hospital Prescription	Responder		
	HITSP/CAP140 - Communicate Benefits and Eligibility	Responder		
	HITSP/CAP141 - Communicate Referral Authorization	Responder		
	HITSP/CAP143 - Manage Consumer Preference and Consents	Initiator Responder		



System	Capability	System Role(s)	System Role Option	System Role Optionality
Other clinical or Admin Data Source Systems	HITSP/CAP119 - Communicate Structured Document	Initiator Responder		
	HITSP/CAP120 - Communicate Unstructured Document	Initiator Responder		
	HITSP/CAP143 - Manage Consumer Preference and Consents	Initiator Responder		
Personal Health Record (PHR) System	HITSP/CAP119 - Communicate Structured Document	Initiator Responder		
	HITSP/CAP120 - Communicate Unstructured Document	Initiator Responder		
	HITSP/CAP143 - Manage Consumer Preference and Consents	Initiator Responder		
Pharmacy Benefit Manager System	HITSP/CAP117 – Communicate Ambulatory and Long-Term Care Prescription	Responder		
	HITSP/CAP118 – Communicate Hospital Prescription	Responder		
	HITSP/CAP140 - Communicate Benefits and Eligibility	Responder		
	HITSP/CAP141 - Communicate Referral Authorization	Responder		
	HITSP/CAP143 - Manage Consumer Preference and Consents	Initiator Responder		
Pharmacy Systems – External  Includes the following specializations  Pharmacy Systems - Hospital, Integrated  Pharmacy Systems - Hospital, Non-integrated	HITSP/CAP117 – Communicate Ambulatory and Long-Term Care Prescription	Initiator Responder	C	[101] [106]
	HITSP/CAP118 – Communicate Hospital Prescription	Initiator Responder	C	[101] [107]
	HITSP/CAP119 - Communicate Structured Document	Initiator Responder		
	HITSP/CAP120 - Communicate Unstructured Document	Initiator Responder		[102]
	HITSP/CAP140 - Communicate Benefits and Eligibility	Initiator	C	[108]
	HITSP/CAP141 - Communicate Referral Authorization	Initiator	C	[109]
	HITSP/CAP143 - Manage Consumer Preference and Consents	Initiator Responder		
Public Health Agency Systems	HITSP/CAP119 - Communicate Structured Document	Initiator Responder		
	HITSP/CAP120 - Communicate Unstructured Document	Initiator Responder		

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

Table 3-4 below lists the conditions applicable to the orchestration (see above table) of the Capabilities engaged in this Interoperability Specification.



**Table 3-4 Conditions**

Condition ID	Condition Description
[101]	At least one of HITSP/CAP117 or HITSP/CAP118 SHALL be implemented
[102]	Within the context of this Interoperability Specification, support for Unstructured documents is limited to inpatient settings
[103]	At least one of HITSP/CAP117 or HITSP/CAP118 SHALL be implemented, UNLESS implemented as a separate, distinct CPOE
[104]	If prescriptions will be sent to ambulatory or LTC pharmacies, then HITSP/CAP117 SHALL be implemented
[105]	If prescriptions will be sent to inpatient pharmacies, then HITSP/CAP118 SHALL be implemented
[106]	If the pharmacy is engaged in ambulatory medication dispensing, then HITSP/CAP117 SHALL be implemented
[107]	If the pharmacy is engaged in inpatient medication dispensing then HITSP/CAP118 SHALL be implemented
[108]	If the pharmacy is engaged in ambulatory medication dispensing, then HITSP/CAP140 SHALL be implemented
[109]	If the pharmacy is engaged in ambulatory medication dispensing, then HITSP/CAP141 SHALL be implemented

### 3.2.1 CONTENT SUBSETS

Content subsets are appropriate subsets of the data content supported by the Capability that may be sent by the system and/or received in a specific information exchange. There may be no relevant subsets identified.

#### 3.2.1.1 HITSP/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 Interface. It requires the Content Creator to have the ability to create the content of the following content module for the purpose of exchange, with variants as specified in the HITSP/C32 construct:

**Table 3-5 Creator Medication and Allergies Information Coded 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

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

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

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

#### 3.2.1.2 CONSUMER-MEDICATION AND ALLERGIES DISPLAY SUBSET

This subset impacts the import of Documents processed by a Content Consumer Interface. It requires the Document Consumer only to have the ability to display either document (e.g., HITSP/C32, HITSP/C37) as requested. The Document Consumer is not required to import it into the local patient record.

#### 3.2.1.3 CONSUMER-MEDICATION AND ALLERGIES IMPORT SUBSET

This subset impacts the import of Documents processed by a Content Consumer Interface. 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.



### 3.2.2 IMPLEMENTATION VARIANTS

This specification is intended to support multiple implementation architectures. For example, Health Information Exchange (HIE) can serve as intermediary for data in many different scenarios in this Harmonization Request and it is assumed that it may exist in real world implementations. The various alternative options are not explicitly described in this document.

Table 3-6 lists a number of general constraints applicable to this specification. They include assumptions, pre-conditions and post-conditions as well as external trigger events that play a critical role in implementing this specification.

**Table 3-6 Orchestration Constraints**

Number	Constraint	Type of Constraint
1	Patient has a condition for which clinician wishes to prescribe medication.	Trigger
2	Patient is admitted to inpatient or long term care setting and requires medication.	Trigger
3	Where Ambulatory/Long Term Care workflows do not precisely align, "missing" actions in either Ambulatory or LTC workflows SHALL NOT be assessed as an error. For Example, when a prescription is "received" by the patient, the Ambulatory work flow had the patient (or patient's agent) taking possession of the medication. In LTC, this would entail sending a supply to the LTC facility.	Assumption
4	Medication has been prescribed to a patient or the reason why the medication is not given is known.	Post Condition



## 4.0 CAPABILITY GAPS

Section 4.0 identifies gaps not met by existing Capabilities but needed to achieve the aims of the Harmonization Request for which this Interoperability Specification is written. This includes overlaps in Capabilities as well. The following table details how this section of the document is targeted to specific readers. Each of the stakeholders listed in this table are more fully defined in a separate appendix. This table is provided as an aid to readers to assist with identifying specific areas of focus. Readers are encouraged to review all sections of this document to further their understanding of HITSP's work.

**Table 4-1 Reader's Guide for Section 4.0**

Document Section	Section Number	Intended Audience	Information Contained
Section 4.0	4.0	Business Analysts Development Team Architects	Gaps specific to Capabilities used as part of this Interoperability Specification are reviewed in this section to determine why specific information exchange requirements may not yet be met or defined. Readers should check this section to track the progress of gap resolution

The following table identifies gaps not met by or overlapping with existing Capabilities as described above.

**Table 4-2 Capability Gaps**

Requirement Number	Summary Description	Identified Gap	Recommended Resolution
1	Receive information from drug knowledge supplier	No standard exists for this information exchange. Only exists in proprietary formats	Identify the business need for this gap. Identify the entities exchanging this information. Drug knowledge suppliers to work with named terminology sources for common concepts that are to be exchanged. Then perhaps identify and work with appropriate SDO to defined standard for the exchange of drug knowledge supplier information
2	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
3	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 or terminology organization to define terminology for receiving implanted medication infusion devices
4	Events which communicate medication orders/prescriptions	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	Industry pilots are completing which are testing the use of the RxNorm codes in electronic prescribing functions. 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 incorporating recommendations from the industry,



Requirement Number	Summary Description	Identified Gap	Recommended Resolution
		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	from the pilots, into standards guidance for the use of RxNorm and current identifiers
5	Events to determine Medication Formulary and Benefit Eligibility and Information	<p>The information required by the NCPDP standard allows optional data elements and/or lists about coverage, without requiring the details of the coverage</p> <p>The mechanisms to determine the routing of the ASC X12 270/271 messages are not clearly understood and currently performed using proprietary solutions</p>	There have been pilots researching this issue by the Medicare Modernization ACT (MMA). NCPDP WG11 is actively discussing industry implementation findings and will be bringing forward recommendation for enhancements to future versions of the Formulary and Benefit Standard
6	Events which require Medication and Allergy information using the HITSP/C32 Subset (Medication and Allergies Information Subset)	Information about Medication Expiration Date of the medication is not included in the HL7 Continuity of Care Document (CCD)	HITSP recommends updating HL7 CCD, HITSP/C83, HITSP/C154, and HITSP/C32 to include Medication Expiration Date for the dispensed medication
7	Events which require Medication Fill Status	HITSP/C32 needs to describe how the sources of Fill Status will use HITSP/C32 Fill Status vocabulary	HITSP recommends updating HITSP/C83, HITSP/C154, and HITSP/C32 to include this description





## 5.0 APPENDIX

The following sections include relevant materials referenced throughout this document. The following table details how this section of the document is targeted to specific readers. Each of the stakeholders listed in this table are more fully defined in a separate appendix. This table is provided as an aid to readers to assist with identifying specific areas of focus. Readers are encouraged to review all sections of this document to further their understanding of HITSP's work.

**Table 5-1 Reader's Guide for Section 5.0**

Document Section	Section Number	Intended Audience	Information Contained
Section 5.0	5.1 Harmonization Request Traceability	Architects Business Analysts	A complete mapping of information exchange requirements to functional requirements is provided in this section. Readers can trace IER's to underlying Harmonization Request events and actions (in those instances where a Use Case exists) or to functional requirements defined as part of an official standards Harmonization Request

### 5.1 HARMONIZATION REQUEST TRACEABILITY

This section describes the traceability to the Harmonization Request for which this IS is written. The Traceability may be described in terms of events and actions, or in terms of functional requirements.

As this document updates IS07v1.0 with the requirements specified by the 2009 Medication Gaps Extension, the Harmonization Request traceability has been purposely omitted.



## 6.0 DOCUMENT UPDATES

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

### 6.1 MARCH 27, 2008

No changes. This is the first published version of V1.0 of this document.

### 6.2 JANUARY 31, 2010

This document has been re-published to meet the requirements of the 2009 Template for Interoperability Specifications Version 2.0, and has been updated to include the requirements outlined in the 2009 Medication Gaps Extension published by the Office of the National Coordinator. Document scope has been harmonized as a single Interoperability Specification, and illustrated by two Use Cases covering Ambulatory/Long Term Care and Inpatient Hospital environments.

