

HITSP Medical Home Interoperability Specification

HITSP/IS98



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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	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	Each of the scenarios specific to the Interoperability Specification are outlined and described using a HITSP concept known as an Information Exchange Requirement (IER). HITSP uses IERs to outline requirements for HITSP work products
	2.40 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 Interoperability Specification) are identified and described here. Readers can learn which systems have been included as part of this HITSP Interoperability Specification
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 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 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 (IER) 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 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
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 IERs 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 Patient-Centered Medical Home (PCMH) represents a shifting paradigm in the practice of medicine characterized by care that is “accessible, comprehensive and coordinated and delivered in the context of



family and community.”¹ Typically, a patient’s Medical Home (MH) includes a team of healthcare providers led by a MH provider or designee. The MH provider is the central point of planning, coordination, and management of the patient’s health promotion, acute illness care, and chronic condition management. Integral to the MH is communication between the MH provider and the patient to enable the patient’s active participation in his/her care.

This document seeks to respond to a specific instance of the MH as described in the 2009 Medical Home: Problem Lists & Practice-Based Registries Extension/Gap document. However, the concept of the MH is still evolving, including the definition, functionality, and even the certification of medical homes;² some of these evolving concepts might not be reflected in this document.

This Interoperability Specification (IS) focuses on the information received by the MH for care coordination and the manner in which this information supports individual patient needs and co-morbidity management. It is important to note that HITSP’s current suite of Interoperability Specifications (ISs) describe specific provider functionalities related to the exchange of information between healthcare providers and organizations, for example: HITSP/IS09 Consultations and Transfers of Care, HITSP/IS06 Quality etc. The goal of this effort is not to replicate the work of previous ISs but to identify those standards that support the exchange of information related to certain aspects unique to the PCMH. In addition, where appropriate, this IS leverages existing and ongoing HITSP work to identify those aspects that are pertinent to the PCMH.

The American Health Information Community’s (AHIC’s) 2009 Medical Home: Problem Lists & Practice-Based Registries Extension/Gap describes two main requirements:

- The ability to manage patient problem lists and provider information (from intra-organizational and inter-organizational sources) within the medical home to support co-morbidity management
- The ability to utilize information to perform practice-based, patient population management and registry functions within the medical home for care coordination to support individual patient needs

Prior Harmonization Requests and HITSP ISs describe the ability for individual providers to create or use a problem list derived from a summary document. The additional requirement for the MH is the ability to either query or to receive documents directly with specific modules, e.g., problems, conditions, diagnoses, plan of care etc. across a number of care settings, created by a number of healthcare providers. In addition, though not explicitly stated, there are other clinical data that may be relevant to the MH, (e.g., allergies, laboratory results) derived from the care provided by other providers who may or may not be part of the MH team, which the MH provider may receive.

The PCMH industry activities suggest that the MH provider should be able to provide practice-based population management via patient or condition-specific registries that are updated by the MH provider. Disease-specific registries from federal, state, and local agencies may be available to Medical Home provider. The MH Extension/Gap Document requirements call for the MH’s “effective use of a patient registry to increase its ability to track delivery of evidence based care, and monitor results across the practice population.” Specifically, practice-based population management involves information exchange with the MH provider and other members of the team and the ability to provide a population view of and report on a group of patients based on specific criteria. Data queries and reports could be performed

¹ Medical Home: Problem Lists & Practice-Based Registries Extension/Gap:
http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_10731_848122_0_0_18/MedHomeFinalExtGap.pdf (last accessed Dec 2009)

² National Committee for Quality Assurance Patient-Centered Medical Home webpage:
<http://www.ncqa.org/tabid/631/Default.aspx>



against a practice-based or an external registry including identifying patient populations and reporting quality measures.

The 2009 Medical Home: Problem Lists & Practice-Based Registries Extension/Gap describes two main requirements. The IS describes the information exchanges for these requirements in the following scenarios:

- Scenario 1: Document Sharing Functionality: Problem Lists and Medical Home Designation (Section 2.2)
- Scenario 2: Practice-based Registry Functionality (Section 2.3)

1.2 DOCUMENT SCOPE

The following are in scope for the Medical Home IS:

- The aggregation of the patient's problem list from multiple sources
- The management of provider information originating from both intra-organizational and inter-organizational sources
- Standards-based information to support practice-based registry Capabilities external to the MH designee's EHR system (disease-specific and specialty-specific)

The following Transactions are described in other HITSP ISs and are part of primary care provider processes and as such will not be included as part of the MH interfaces for this effort:

- Administrative information exchanges conducted by the primary care provider workflows [e.g., Patient Generic Health Plan Eligibility Verification (HITSP/T40), Patient Health Plan Authorization Request and Response (HITSP/T68)]
- Public health alerts and notifications [e.g. Identify Communication Recipients (HITSP/T64)]
- Information exchanges conducted using a message vs. a document format [e.g. Laboratory Report Message (HITSP/C36), Radiology Report Message (HITSP/C41)]. Currently, there are regulations that specify how and to whom laboratories report medical results; in some States, there are provisions that allow State-sponsored entities to receive results in addition to the ordering provider

The following Transactions are considered out-of-scope for the MH requirements.

- Reconciliation of data documents received from different sources (e.g. the same radiology report received from two different systems) that might need a clinical determination about the clinical content e.g., similar diagnoses
- Standards-based Information to support practice-based registry capabilities within an EHR system

1.3 COPYRIGHT PERMISSIONS

COPYRIGHT NOTICE

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1.4 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
HITSP Acronyms List	Lists and defines the acronyms used in this document
HITSP Glossary	Provides definitions for relevant terms used by HITSP documents
TN900 – Security and Privacy	TN900 is a reference document that provides the overall context for use of the HITSP Security and Privacy constructs
TN901 - Clinical Documents	TN901 is a reference document that provides the overall context for use of the HITSP Care Management and Health Records constructs
TN903 – Data Architecture	TN903 is a reference document that provides the overall context for use of the HITSP Data Architecture constructs
TN904 – Harmonization Framework and Exchange Architecture	TN904 is a reference document that provides the overall context for use of the HITSP Harmonization Framework and Exchange Architecture constructs

1.5 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.

1.5.1 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.

1.5.2 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.

1.5.3 TEST METHODS

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

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.



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	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	Each of the scenarios specific to the Interoperability Specification are outlined and described using a HITSP concept known as an Information Exchange Requirement (IER). HITSP uses IERs 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 Interoperability Specification) are identified and described here. Readers can learn which systems have been included as part of this Interoperability Specification

2.1 SYNOPSIS OF REQUIREMENTS

This IS describes two specific requirements for the 2009 Medical Home: Problem Lists & Practice-Based Registries Extension/Gap:

1. The first requirement is the ability to manage patient problem lists and provider information (from intra- and inter-organizational sources) within the medical home to support co-morbidity management. For the purposes of the IS this represents the interoperability requirements for sharing documents with the designated MH provider, so that he can obtain the problem list and other clinical information. The first scenario below describes and outlines the information exchange requirements necessary to facilitate problem list management.
2. The second requirement is the ability to perform practice-based, patient population management and registry functions within the medical home for care coordination. This may also trigger clinical decision support and/or reporting.

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 (IER) Number	Description
IER01	Designate Medical Home Provider via PHR
IER02	Designate Medical Home Provider via EHR
IER03	Send and Receive Clinical Information
IER04	Request & Receive Patient-level Registry Data – PBR
IER05	Request & Receive Patient-level Registry Data - EHR



Information Exchange Requirement (IER) Number	Description
IER06	Request & Receive Registry Criteria Definition
IER07	Request & Receive Consent Document
IER08	Request & Receive Patient Demographics
IER09	Request & Receive Clinical Data

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
Document Sharing Functionality: Problem Lists and Medical Home Designation	This scenario describes the ability to manage patient problem lists and provider information (from intra- and inter-organizational sources) within the medical home to support co-morbidity management
Practice-Based Registry Functionality	This scenario describes the ability to utilize standards-based information to perform practice-based, patient population management and registry functions within the medical home for care coordination to support individual patient needs, clinical decision support, and quality reporting

2.2 DOCUMENT SHARING FUNCTIONALITY: PROBLEM LISTS AND MEDICAL HOME DESIGNATION

This scenario describes the interoperability requirements for sharing documents with the designated MH provider to facilitate the management of a problem list. Many of the summary documents available for interchange (e.g., HITSP/C32, HITSP/C48) have content modules that support the specification of problems, conditions, diagnoses source, etc. Access to these summary documents in the context of the MH may represent either a “push” of information to the MH provider vs. a “pull” of information by the MH provider. This IS also supports the MH provider’s ability to query and/or receive just a problem list and not the entire document.

Although the MH extension/gap and this IS specifies the creation and management of a problem list, the same functionality described here also holds for the management of other content modules of summary documents (e.g., plan of care module, advance directives).

Finally, it is important to emphasize that although this IS describes the MH provider’s access to specific documents, this does not preclude the provider from accessing any other document or message that may be generated or available to them as part of their role as the patient’s healthcare provider as described in other HITSP ISs.

This first scenario describes and outlines the interoperable information exchange requirements (IERs) necessary for document and message sharing from multiple sources to create the patient’s problem list.

2.2.1 INFORMATION EXCHANGE REQUIREMENTS FOR DOCUMENT SHARING FUNCTIONALITY: PROBLEM LISTS AND MEDICAL HOME DESIGNATION

Table 2-4 summarizes the relationship between the Exchange Action, Exchange Content, and the Initiating and Responding System(s) along with Exchange Attributes.



Table 2-4 Document Sharing Functionality: Problem Lists and Medical Home Designation Information Exchange Requirements

IER Number	Exchange Action	Exchange Content	Initiating System	Responding System(s)	Exchange Attribute
IER01	Designate Medical Home Provider via PHR	HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD)	Personal Health Record (PHR) System	Health Information Exchange (HIE) Electronic Health Record (EHR) System	Capture the patient's MH provider
IER02	Designate Medical Home Provider via EHR	HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD)	Electronic Health Record (EHR) System	Health Information Exchange (HIE) Electronic Health Record (EHR) System	Capture the patient's MH provider
IER03	Send and Receive Clinical Information	HITSP/C28 - Emergency Care Summary Document Using IHE Emergency Department Encounter Summary (EDES) HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD) HITSP/C37 - Lab Report Document HITSP/C48 - Encounter Document Using IHE Medical Summary (XDS-MS) HITSP/C62 - Unstructured Document HITSP/C74 - Remote Monitoring Observation Document HITSP/C84 - Consult and History & Physical Note HITSP/C168 - Long Term Care and Post Acute Assessments HITSP/TP89 – Sharing Imaging Results	Electronic Health Record (EHR) System	Health Information Exchange (HIE) Electronic Health Record (EHR) System	Will support at a minimum the condition module of the CDA

2.3 PRACTICE-BASED REGISTRY (PBR) FUNCTIONALITY

This second scenario describes the ability to utilize standards-based information to perform practice-based, population management and registry functions within the MH for care coordination. The practice-based registry (PBR) system facilitates the collection, storage, retrieval, analysis, and dissemination of information to support health needs of patients and populations within a clinician practice or organization. In the best-case scenario, the PBR functions are part of the workflow of the MH provider and allow the provider to recognize gaps in care at a population and individual patient level with the appropriate clinical decision support tools.

Traditionally, EHRs facilitate the collection of data for individual patients in a physician's practice and allow the physician to see aggregated information for each individual patient, whereas the PBR systems provide the ability to aggregate data across many patients to facilitate a practice-based population view within a physician's practice. These roles are not mutually exclusive as there may be EHRs that have built-in PBR functionality.

There are two possible system configurations:



1. An EHR system may communicate with a PBR system (directly or via hubs) to facilitate the population view of a MH provider's panel of patients
2. The EHR system and the PBR system are integrated to perform the registry functions

In the first configuration, the PBR system is populated with patient data based on specific criteria determined by the population metrics the MH provider is tracking. The definition of the specific criteria may be provided by the PBR system to the EHR system and on receipt of the data the PBR system computes the results. The PBR system makes these results available to the MH provider (how this happens is out of scope for this IS).

In the second configuration, the PBR and the EHR systems are the same and therefore the criteria definitions and the computation functionality reside in the one system. This allows the MH provider to view the results directly and drill down to individual patients as a part of his regular workflow.

For example, the MH provider may want to target all of his patients with diabetes and kidney disease to ensure that they are on the appropriate medications. This would require specific denominator inclusion criteria: give me all my diabetic patients who have kidney disease and specific exclusion criteria, remove those patients with an allergy to the appropriate medication, since they would not be targeted for the intervention. The numerator criteria would analyze the resulting population for those patients on the appropriate medications.

There are HITSP constructs that facilitate standardized clinical definitions based on specific requirements: HITSP/IS06: Quality Measures describes the definition and the reporting of findings. It is possible to extend the constructs from the quality domain for the purposes of data aggregation within a PBR system and the computation of a metric. This functionality should be part of the MH provider's workflow, to identify patients at a population and individual level who may need specific interventions. This section describes the information exchange requirement necessary for the definition of criteria for select populations and the data required. If the MH provider exchanges patient data with an external registry there may be a need to manage consent directives.

Finally it is possible to facilitate the aggregation of data without applying specific criteria as described above. In this variant the PBR system queries the EHR for existing data, which are aggregated in the PBR system. (See Implementation Variant Section 3.2.2 below)

2.3.1 INFORMATION EXCHANGE REQUIREMENTS FOR PRACTICE-BASED REGISTRY FUNCTIONALITY

Table 2-5 Practice-Based Registry Functionality Information Exchange Requirements summarizes the relationship between the Exchange Action, Exchange Content, and the Initiating and Responding Systems along with Exchange Attributes.

Table 2-5 Practice-Based Registry Functionality Information Exchange Requirements

Information Exchange Requirement (IER) Number	Exchange Action	Exchange Content	Initiating System	Responding System(s)	Exchange Attribute
IER04	Request and Receive Patient-Level Registry Data - PBR	HITSP/C105 Patient-Level Quality Data	Practice-Based Registry(PBR) System	Electronic Health Record (EHR) System Health Information Exchange (HIE)	The PBR system collects patient-level data and computes the results
IER05	Request and Receive Patient-Level Registry Data - EHR	HITSP/C105 Patient-Level Quality Data	Electronic Health Record (EHR) System	Practice-Based Registry System Health Information Exchange (HIE)	The EHR system collects patient-level data and computes the results



IER06	Request & Receive Registry Criteria Definition	HITSP/C106 Measurement Criteria Component	Electronic Health Record (EHR) System	Practice-Based Registry (PBR) System	Used to define the criteria for the practice-based population aggregation of data including the denominator and numerator definitions
IER07	Request & Receive Consent Document	HITSP/TP30 - Manage Consent Directives	Electronic Health Record (EHR) System	Practice-Based Registry (PBR) System	If an external PBR system is used then consent may be necessary as dictated by local jurisdictions
IER08	Request & Receive Patient Demographics	HITSP/T23 - Patient Demographics Query	Electronic Health Record (EHR) System	Health Information Exchange (HIE) Practice-Based Registry (PBR) System	
IER09	Request & Receive Clinical Data	HITSP/TP21 Query for Existing data	Practice-Based Registry(PBR) System	Electronic Health Record (EHR) System	

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
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	Healthcare Delivery Organizations, Ancillary Entities, Clinicians, Care Delivery Interface
Health Information Exchange (HIE)	A Health Information Exchange (HIE) is a multi-stakeholder system that enables the exchange and use of health information, in a secure manner, for the purpose of promoting the improvement of health quality, safety and efficiency	Health Information Exchange
Personal Health Record (PHR) Systems	A healthcare record system used to create, review, annotate and maintain records by the patient or the caregiver for a patient. The PHR may include any aspect(s) of the health condition, medications, medical problems, allergies, vaccination history, visit history or communications with healthcare providers	Healthcare Delivery Organizations, Ancillary Entities, Clinicians, Practice-based Registry System Suppliers
Practice - Based Registry (PBR) System	A system for the collection, storage, retrieval, analysis, and dissemination of information to support healthcare needs of patients and populations within a clinician's practice or organization. While EHRs may contain functionalities to manage populations of patients, they are primarily focused on managing the individual patient. For example, a physician using his EHR can manage his individual diabetic patient with elevated HbA1c, while his PBR system will allow him to view all of his patients in his practice with elevated HbA1cs	Healthcare Delivery Organizations, Ancillary Entities, Clinicians, Practice-based Registry System Suppliers



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 (IER) 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. The information exchanges listed are the relevant information exchanges from the underlying Capability.

Table 3-2 Capabilities Used

Capability	Capability Summary	Capability IE Used	IERs Satisfied
HITSP/CAP 119 – Communicate Structured Document	This Capability addresses interoperability requirements that support the communication of structured health data related 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: 1. Continuity of Care Document (CCD) 2. Emergency Department Encounter Summary 3. Discharge Summary (In-patient encounter and/or episodes of care) 4. Referral Summary Ambulatory (encounter and/or episodes of care) 5. Consultation Notes 6. History and Physical 7. Personal Health Device Monitoring Document 8. Healthcare Associated Infection (HAI) Report Document Document creators shall support a number of the HITSP specified coded terminologies as defined by specific content subsets specified in this Capability	A – Send/Receive Clinical Document	IS98-IER01 IS98-IER02 IS98-IER03



Capability	Capability Summary	Capability IE Used	IEs Satisfied
HITSP/CAP120 – Communicate Unstructured Document	This 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: 1. PDF-A supporting long-term archival 2. UTF-8 text	A – Send/Receive Unstructured Document	IER03
HITSP/CAP123 – Retrieve Existing Data	This Capability supports queries for clinical data (e.g., common observations, vital signs, problems, medications, allergies, immunizations, diagnostic results, professional services, procedures and visit history)	A – Request and Respond Query for Existing Data	IER09
HITSP/CAP127 – Communicate Lab Results Document	This Capability addresses interoperability requirements that support the communication of a set of structured laboratory results related to a patient in a context set by the source of the document who is attesting to its content. Non-ordering Providers of Care access historical laboratory results as documents and "copy-to" Providers of Care may receive document availability notifications to retrieve such lab report documents. Lab Report content creators shall support HITSP specified coded terminologies as defined by specific content subsets specified in this Capability for: General Laboratory Test Results; Microbiology Test Results This Capability may use content anonymization	A – Send and Receive Laboratory Report Document	IER03
HITSP/CAP128 – Communicate Imaging Information	This Capability addresses interoperability requirements that support the communication of a set of imaging results (i.e., reports, image series from imaging studies) related to a patient in a context set. This is done by an Imaging System acting as the information source attesting to its content. This Capability may use content anonymization. For the purposes of this IS will call on the document component of this Capability	A – Send and Receive Medical Image Result	IER03
HITSP/CAP129 – Communicate Quality Measure Data	This Capability addresses interoperability to support hospital and clinician collection and communication of patient encounter data to support the analysis needed to identify a clinician or hospital's results relative to an EHR-compatible, standards-based quality measure	B – Send Patient Level Quality Data	IER04 IER05
HITSP/CAP130 – Communicate Quality Measure	This Capability addresses interoperability requirements for an EHR-compatible, standards-based quality measure. In the measure specification, needed patient encounter data elements are identified so they can be extracted from local systems and from longitudinal data available through other sources such as a Health Information Exchange (HIE). The measure specification also includes various sets of exclusion/inclusion criteria to identify which patients to include in calculation of the measure. This Capability may use Value Set Sharing	B – Send Measurement Criteria	IER06

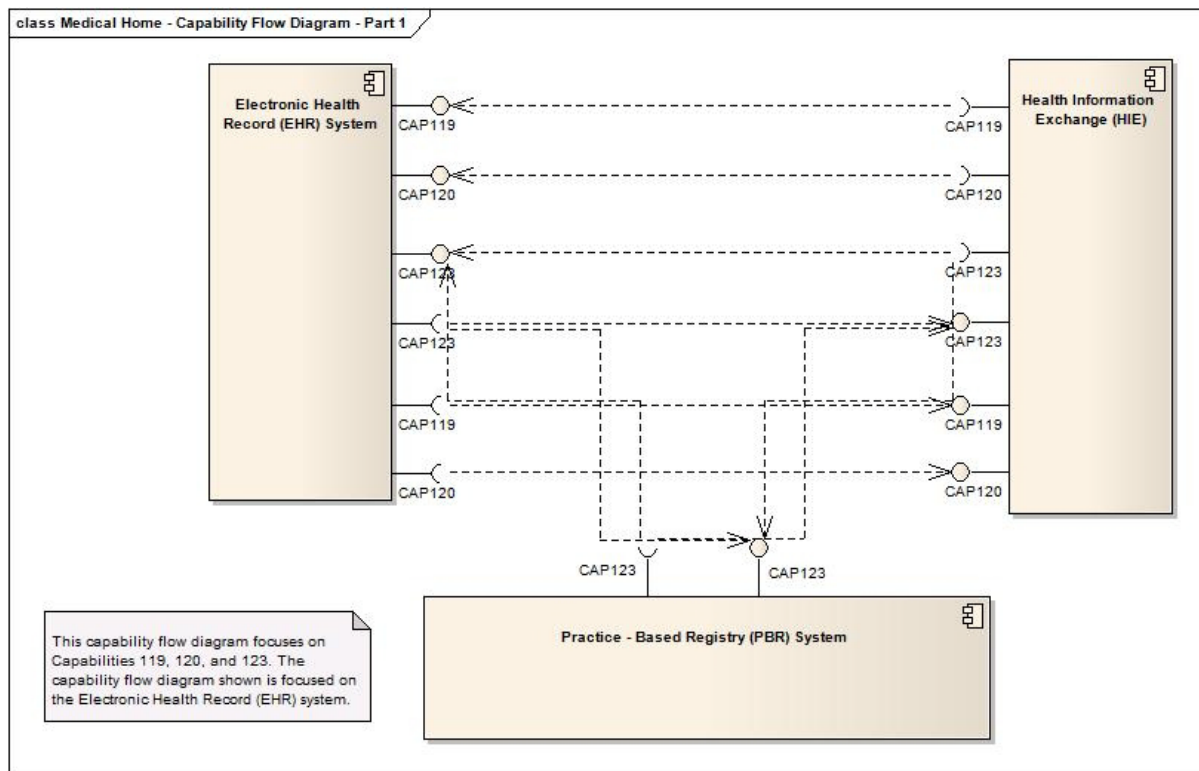


Capability	Capability Summary	Capability IE Used	IEs Satisfied
HITSP/CAP135 - Retrieve and Populate Form	<p>This Capability addresses interoperability requirements to support the upload of specific captured data (e.g. public health surveillance reportable conditions, healthcare associated infection reporting) to Public Health Monitoring Systems and Quality Organizations Systems. The forms presented may be pre-populated by information provided by the clinical or laboratory information systems to avoid manual re-entry. A number of supplemental information variables may be captured from within the user's clinical information system to improve the workflow and timeliness of required reporting. One or more types of form content may be supported:</p> <ol style="list-style-type: none"> 1. Pre-population for Public Health Case Reports from Structured Documents using CDA 2. Pre-population for Quality Data from Structured Documents using CDA 3. No pre-population content <p>Systems may optionally support the means to retrieve request for clarifications</p>	B – Receive Pre-population Data	IER04 IER05
HITSP/CAP143 – Manage Consumer Preference and Consents	<p>This Capability addresses management of consumer preferences and consent 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 mind on participation or requests that data no-longer be made available because they have left the region. Systems that act as sources or consumers/receivers of privacy policy acknowledgement documents include EHR, PHR, or a dedicated consent management system</p>	<p>A - Management of Consumer Preference for their MH</p> <p>B - Management of sharing of data with other entities i.e. PBR</p>	<p>IER01 IER02</p> <p>IER03 IER04 IER05 IER08 IER09</p>

The following diagram shows how systems use Capabilities to complete the full Interoperability Specification. 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 Interoperability Specification. 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 Diagram Showing Capabilities Used Between Systems: HITSP/CAPs 119, 120, 123



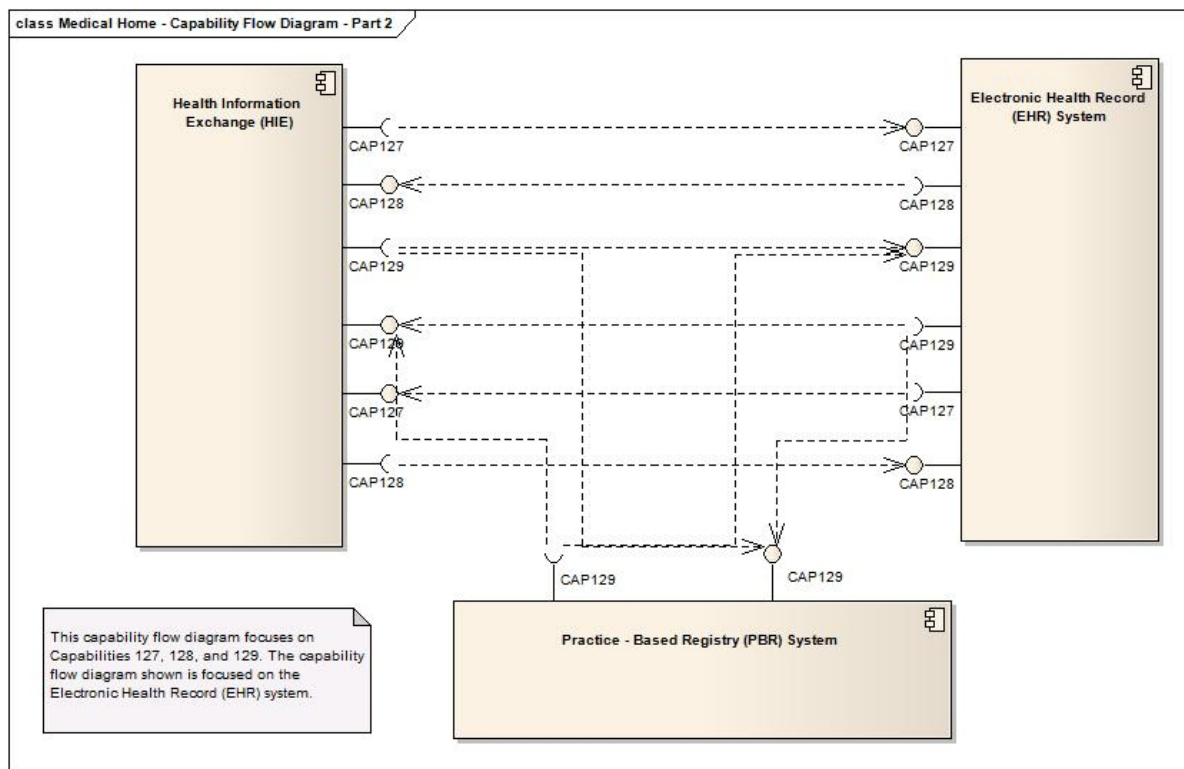
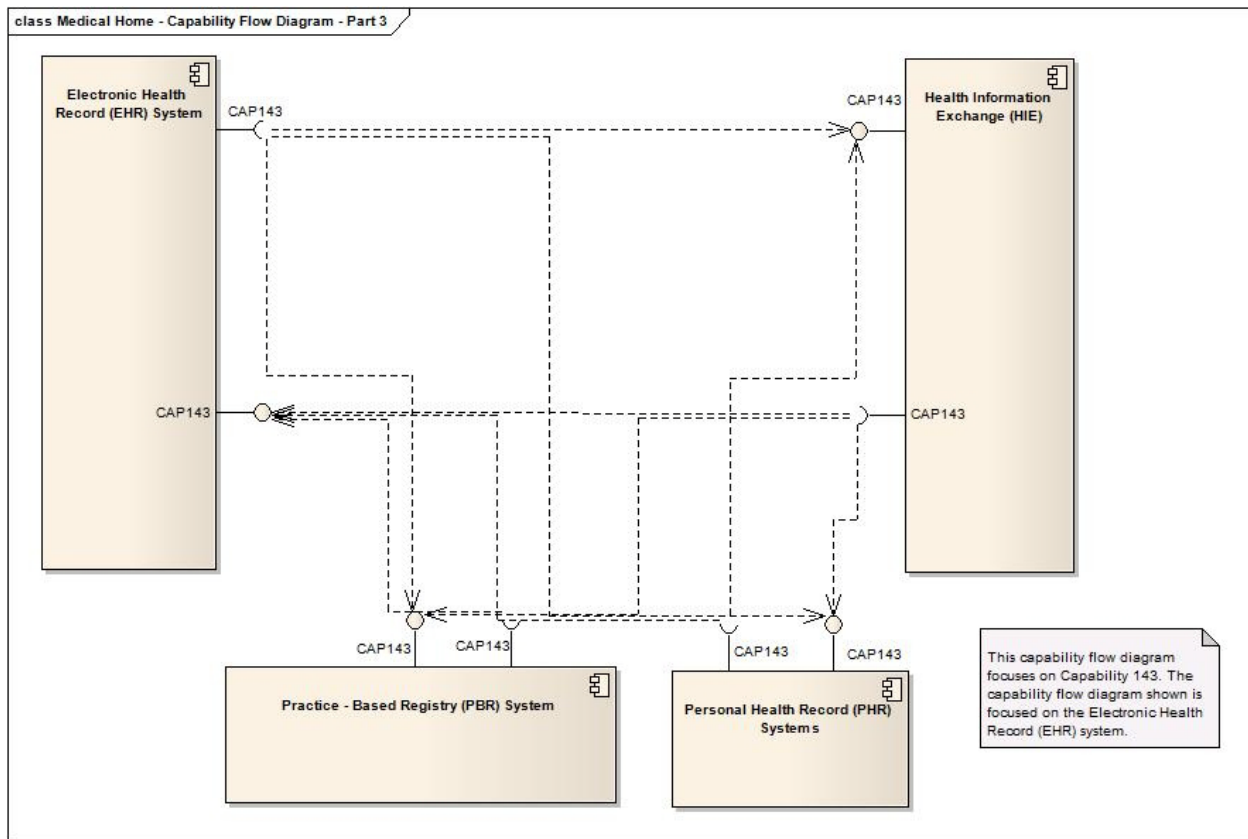


Figure 3-2 Diagram Showing Capabilities Used Between Systems: HITSP/CAPs 127, 128, 129



Figure 3-3 Diagram Showing 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 by system 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	System Role Option	Condition
Electronic Health Record (EHR) System	HITSP/CAP119 – Communicate Structured Document	Document Sender	R	C[101] C[102]
	HITSP/CAP119 – Communicate Structured Document	Document Consumer	R	C[101] C[102]
	HITSP/CAP119 – Communicate Structured Document	Registry/Repository	O	C[101] C[102]



System	Capability	System Role	System Role Option	Condition
	HITSP/CAP120 – Communicate Unstructured Document	Document Sender	R	C[101] C[102]
	HITSP/CAP120 – Communicate Unstructured Document	Document Consumer	R	C[101] C[102]
	HITSP/CAP120 – Communicate Unstructured Document	Registry/Repository	O	C[101] C[102]
	HITSP/CAP123 – Retrieve Existing Data	Clinical Data Source	R	C[101] C[102]
	HITSP/CAP123 – Retrieve Existing Data	Clinical Data Consumer	R	C[101] C[102]
	HITSP/CAP127 – Communicate Lab Results Document	Document Sender	R	C[101] C[102]
	HITSP/CAP127 – Communicate Lab Results Document	Document Consumer	R	C[101] C[102]
	HITSP/CAP127 – Communicate Lab Results Document	Registry/Repository	O	C[101] C[102]
	HITSP/CAP128 – Communicate Imaging Information	Document Sender	R	C[101] C[102] C[103]
	HITSP/CAP128 – Communicate Imaging Information	Document Consumer	R	C[101] C[102] C[103]
	HITSP/CAP128 – Communicate Imaging Information	Registry/Repository	O	C[101] C[102]
	HITSP/CAP129 – Communicate Quality Measure Data	Document Sender	R	C[101] C[102] C[104]
	HITSP/CAP130 – Communicate Quality Measure	Document Consumer	R	C[101] C[102]
	HITSP/CAP135 - Retrieve and Populate Form	Form Filler	R	C[101] C[102]
	HITSP/CAP143 – Manage Consumer Preference and Consents	Document Sender	R	C[101] C[102]
	HITSP/CAP143 – Manage Consumer Preference and Consents	Document Consumer	R	C[101] C[102]
	HITSP/CAP143 – Manage Consumer Preference and Consents	Registry/Repository	O	C[101] C[102]
Health Information Exchange (HIE)	HITSP/CAP119 – Communicate Structured Document	Registry/Repository	O	C[101] C[102]
	HITSP/CAP120 – Communicate Unstructured Document	Registry/Repository	O	C[101] C[102]
	HITSP/CAP127 – Communicate Lab Results Document	Registry/Repository	O	C[101] C[102]
	HITSP/CAP128 – Communicate Imaging Information	Registry/Repository	O	C[101] C[102]
	HITSP/CAP128 – Communicate Imaging Information	Document Consumer	R	C[101] C[102] C[103]
	HITSP/CAP128 – Communicate Imaging Information	Registry/Repository	O	C[101] C[102] C[103]



System	Capability	System Role	System Role Option	Condition
	HITSP/CAP129 – Communicate Quality Measure Data	Registry/Repository	R	C[101] C[102] C[104]
	HITSP/CAP130 – Communicate Quality Measure	Registry/Repository	O	C[101] C[102]
	HITSP/CAP143 – Manage Consumer Preference and Consents	Registry/Repository	O	C[101] C[102]
Personal Health Record (PHR) System	HITSP/CAP143 – Manage Consumer Preference and Consents	Document Sender	R	C[101] C[102]
	HITSP/CAP143 – Manage Consumer Preference and Consents	Document Consumer	O	C[101] C[102]
	HITSP/CAP143 – Manage Consumer Preference and Consents	Registry/Repository	O	C[101] C[102]
Practice – Based Registry (PBR) System	HITSP/CAP123 – Retrieve Existing Data	Document Consumer	R	C[101] C[102]
	HITSP/CAP129 – Communicate Quality Measure Data	Document Consumer	R	C[101] C[102] C[104]
	HITSP/CAP130 – Communicate Quality Measure	Document Sender	R	C[101] C[102]
	HITSP/CAP135 - Retrieve and Populate Form	Form Receiver	R	C[101] C[102]
	HITSP/CAP143 – Manage Consumer Preference and Consents	Document Sender	R	C[101] C[102]
	HITSP/CAP143 – Manage Consumer Preference and Consents	Document Consumer	R	C[101] C[102]
	HITSP/CAP143 – Manage Consumer Preference and Consents	Registry/Repository	O	C[101] C[102]

Optionality Legend: “R” for Required, “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 Code	Condition Description
[101]	Content-related options from the Capability are not further constrained
[102]	Topology-related options from the Capability used are not further constrained
[103]	Constrained to reports and evidence documents
[104]	Constrained to the collection of patient level data

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 IMMUNIZATION HISTORY SUBSET”

Table 3-5 Creator Medication and Immunization History Subset Content Modules

Content Modules	Optionality
Conditions	R
Information Source	R
Healthcare Provider	R
Personal Information	R
Advance Directives	RE
Allergies	RE
Encounter	RE
Immunization	RE
Medications – Prescription and Non-Prescription	RE
Plan of Care	RE
Support	RE
Test Results	RE
Vital signs	RE

Optionality Legend: “R” for Required, “RE” for Required if Known, “O” for Optional, or “C” for Conditional

3.2.2 IMPLEMENTATION VARIANTS

This specification is intended to support multiple implementation architectures. Described below are four likely scenarios, all leveraging one or more of the information exchange requirements identified above in Table 2-2. In some environments, information may be analyzed and aggregated locally and in others, the service may be provided by a trusted third party. The following list of example environments is not an exhaustive list:

Table 3-6 Document Sharing (HIE): Implementation Variant 1

Implementation Variant 1: Document Sharing (HIE)
<p>In this variant, the Medical Home designee is on a health information exchange (HIE) and has access to clinical documents from one or more providers. This variant leverages the MH designation as part of access control to facilitate the sharing of documents with the designee. As part of his role as the MH designee, the healthcare provider is now capable of making a call to the HIE for all relevant summary documents that the MH designee is permitted to view. The MH designee leverages HITSP/CAP119, HITSP/CAP120, HITSP/CAP127 and HITSP/CAP128 to facilitate the query for clinical data (e.g., problems and information source modules) from other systems.</p> <p>In this variant, other healthcare providers do not need to know who the MH designee is but once they share documents or the location of their documents on the HIE this is accessible by the MH designee. This variant allows for serial MH designation and the access of documents by each subsequent designee on or via the HIE. It does not need each subsequent designee to obtain documents from an earlier designee</p>

Table 3-7 Document Sharing (Point-to-Point): Implementation Variant 2

Implementation Variant 2: Document Sharing (Point-to-Point)
<p>In this Implementation Variant, the MH designee's EHR has document repository and/or document registry capabilities. Other healthcare providers once they know who the MH designee is, they can push documents or the document location to the MH designee. The patient using his PHR may also designate his MH provider.</p> <p>In this variant, the healthcare provider is designated as the MH provider and the MH designee's EHR has the capability of accepting or maintaining a registry of documents. Other healthcare providers involved in the care of the patient “push” documents to the MH designee. This variation requires that the other providers know who the patient's MH designee is. In this configuration, the current MH designee will be responsible for pushing documents to a subsequent designee</p>

Table 3-8 Practice-Based Data Aggregation for Population Management, Internal to the EHR: Implementation Variant 3

Implementation Variant 3: Practice-Based Data Aggregation for Population Management, internal to the EHR
<p>In this variant, the PBR system functionality is available in the MH designee's EHR system.</p> <p>The EHR system:</p> <ul style="list-style-type: none"> • Uses eMeasure criteria available to the EHR system • Assembles data using HITSP/CAP119, HITSP/CAP123, HITSP/CAP127, HITSP/CAP128, HITSP/CAP129, and/or HITSP/CAP135 • Produces the HITSP/C105 Patient Level Quality Data Document Using HITSP/CAP130



Table 3-9 Practice-Based Data Aggregation for Population Management, External to the EHR: Implementation Variant 4

Implementation Variant 4: Practice-Based Data Aggregation for Population Management, external to the EHR
<p>In this variant, the PBR and the EHR systems are distinct.</p> <p>The EHR system:</p> <ul style="list-style-type: none"> • Receives the eMeasure directly from the PBR system using HITSP/CAP130 for exchanging the HITSP/C106 Measurement Criteria Component • Assembles data using HITSP/CAP119, HITSP/CAP123, HITSP/CAP127, HITSP/CAP128, HITSP/CAP129, and/or HITSP/CAP135 • Produces the HITSP/C105 Patient Level Quality Data Document Using HITSP/CAP130 • Sends the QRDA to the PBR system to compute the results <p>The PBR system:</p> <ul style="list-style-type: none"> • Sends the eMeasure to the EHR system • Receives the QRDA from the EHR and assembles and aggregates the data for the MH designee's patients • Computes the results of the measure • Makes the results visible to the provider (Out of scope)

Table 3-10 Practice-Based Data Aggregation for Population Management: Implementation Variant 5

Implementation Variant 5: Practice-Based Data Aggregation for Population Management
<p>In this variant, the PBR and the EHR systems may or may not be distinct. The difference in this variant is that the implementers may choose to aggregate the patient population data without using specifically defined criteria as outlined in Implementation Variants 3 and 4. Therefore, the PBR system:</p> <ul style="list-style-type: none"> • Receives and aggregates data using HITSP/CAP119, HITSP/CAP123, HITSP/CAP127, HITSP/CAP128, HITSP/CAP129, and/or HITSP/CAP135 • Makes the results visible to the provider (Out of scope)

Table 3-11 lists a number of general constraints applicable to this specification. They include assumptions, a number of pre-conditions and post-conditions as well as external trigger events that play a critical role in implementing this specification.

Table 3-11 Orchestration Constraints

Constraint ID	Constraint	Type of Constraint
	N/A	

3.2.3 CONSTRAINTS ON REQUIRED CAPABILITIES

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

Table 3-12 Additional Constraints on Required Capabilities

Constraint ID	Data Element	Capability	Constraint	Constraint Type	Purpose (Reason for this constraint)
1	The data modules listed as required in Table 3-5	HITSP/CAP119 – Communicate Structured Document	Section 3.2.2 in HITSP/CAP119: Content Import Option: The receiver of the information MUST support discrete data import	Pre-condition	Required to ensure the MH designee's EHR system imports the required data modules into its registry



Constraint ID	Data Element	Capability	Constraint	Constraint Type	Purpose (Reason for this constraint)
2	Data sent to the document consumer constrained to RAD 27 and RAD 45	HITSP/CAP128 – Communicate Imaging Information	The imaging document consumer role SHALL support retrieval of reports RAD 27 and RAD 45 and MAY support the other RAD documents as specified in HITSP/TP89 exchange content	Pre-condition	Required to ensure the MH designee only needs to receive the imaging reports and evidence documents and not necessarily the images themselves

Table 3-13 Additional Constraints on XDS Metadata Elements

XDS Metadata Attribute	Optionality	Extended Discussion	Source Type
N/A			

3.2.3.1 XDSDOCUMENTENTRY.EVENTCODELIST

N/A

3.2.3.2 XDSDOCUMENTENTRY.CONFIDENTIALITYCODE

N/A



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 Capability Gaps	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

IER Gap Description	Responsible HITSP TC	Design Approach	Required Standards Now Unavailable for Constructs	SDO Working on Unavailable Standards	Expected Availability
IER03: Problem List Attribute: Disease Course	Care Management and Health Records Domain TC	Update HITSP/CAP119: HITSP/C83: Problem List to include SNOMED "Clinical Course" Value Set	N/A	N/A	2010
IER03: Problem List Attribute: Rule Out	Care Management and Health Records Domain TC	Update HITSP/CAP119:HITSP/C83: Problem List	There are no standards available to describe "rule out"	N/A	N/A
IER03: Problem List Attribute: In Remission	Care Management and Health Records Domain TC	Update HITSP/CAP119:HITSP/C80: Problem Status Value Set	N/A	N/A	2010



5.0 APPENDIX

The following section includes 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 IERs 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 Interoperability Specification is written. The traceability may be described in terms of events and actions, or in terms of functional requirements.

The following table lists functional requirements of the Harmonization Request and relates those to any information exchange requirements.

Table 5-2 Harmonization Request Functional Requirements Analysis Table

Requirement	Description	Information Exchange Requirement(s) (includes security requirements)
7.1.1 Evaluate and manage patient	Out of scope	None
7.1.2 Designate provider as patient's Medical Home	This involves defining the information needed to specify a provider as a patient's medical home provider/designee	IER01: Designate Medical Home Provider via PHR IER02: Designate Medical Home Provider via EHR
7.1.3 Send and receive clinical information	This references the ability to manage patient problem lists and provider information (from intra-organizational and inter-organizational sources) within the medical home to support co-morbidity management	IER03: Send & Receive Clinical Documents
7.1.4 Send and receive information to/from patient	This requirement involves communication of information between patients and providers. Information communicated via patient-provider secure messaging (HITSP/IS12) or remote monitoring (HITSP/IS77) may be utilized by the Medical Home Provider to support patient care. Patients may communicate the list of providers who are involved in their care and the associated information access permissions for information accessible via their PHRs or HIE to the Medical Home Provider. In addition, the patient may use his PHR to designate his MH and communicated this information to all his healthcare providers via his PHR	See Requirement 7.1.2 re the MH designation. As specified by HITSP/IS03, HITSP/IS05, HITSP/IS12, and HITSP/IS77



Requirement	Description	Information Exchange Requirement(s) (includes security requirements)
7.1.5 Reconcile Problem List, Medication List, Allergy List	Out of Scope – Once a list is generated the clinical reconciliation of the specific elements on the list are considered out of scope i.e. if there are two similar clinical diagnoses the clinician will have to determine if these are the same events or different	None
7.1.6 Track and manage patient population	This is the ability of the MD designee to use data in the EHR for the purposes to perform practice-based, patient population management and registry functions within the medical home for care coordination to support individual patient needs. An EHR with a registry capability represents a black box for interoperability purposes. However the ability for a MH EHR to communicate with an external registry (local or otherwise) to facilitate population management is within scope of this design document	IER04: Request & Receive Patient-level Registry Data - PBR IER05: Request & Receive Patient-level Registry Data - EHR IER06: Request & Receive Registry Criteria Definition IER07: Request & Receive Consent Document IER08: Request & Receive Patient Demographics IER09: Request & Receive Clinical Data
7.1.7 Manage patient care	Out of scope	None
7.1.8 Perform Quality Reporting	This is a reference to the HITSP/IS06 Quality document in which the information flow supports the integration of data to support quality measurement, feedback and reporting into EHRs, uses quality measures to support clinical decision making, and allows for the aggregation of quality information across multiple providers and entities to support public reporting of healthcare quality. HITSP/IS06 outlines the requirements to facilitate quality reporting	None except as described by HITSP/IS06



6.0 DOCUMENT UPDATES

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

6.1 JANUARY 31, 2010

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

