

HITSP Medical Home Requirements and Design

HITSP/RDSS157



Healthcare Information Technology Standards Panel

Submitted to:

Healthcare Information Technology Standards Panel

Submitted by:

Consumer Perspective Technical Committee



DOCUMENT CHANGE HISTORY

Version Number	Description of Change	Name of Author	Date Published
1.0	Review Copy	Consumer Perspective Technical Committee	November 9, 2009



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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 refer to this document to review 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 RDSS as a source of requirements for interoperable information exchange.

The following table details sections of this RDSS template and how sections of this document are targeted to specific readers. Each of the stakeholders listed in this table is more fully defined in a separate Appendix. This table is provided as an aid to readers to assist them in identifying sections to focus on. Readers are encouraged to review all sections of this document to further their understanding of HITSP's work.

Table 1-1 RDSS Reader's Guide

Document Section	Sub Section	Intended Audience	Information Contained
Section 2.0 Requirements	2.1	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 RDSS is built to meet
	2.2 – 2.3	Program Managers Policy Analysts Executive Leadership	Each of the scenarios specific to the RDSS are outlined and described using a HITSP concept known as an Information Exchange Requirement (IER). HITSP uses IER's to outline requirements for HITSP work products to meet
	2.4	Architects Business Analysts Policy Analysts Program Managers	The systems assigned to the system roles (as defined in the HITSP Capabilities used by this RDSS) are identified and described here. Readers can learn which systems have been included as part of this HITSP RDSS
Section 3.0 Design Specification	3.1	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 Capabilities meet information exchange needs. A diagram is also provided to show the interchange of data among systems identified in this RDSS
	3.2	Architects Development Team	The core of the design in the HITSP RDSS is documented here. This solution shows orchestration of HITSP 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	Business Analysts Development Team Architects	Gaps specific to Capabilities used as part of this RDSS are reviewed in this section to determine why specific Information Exchange Requirements may not yet be met or defined. Readers should review this section to track the progress of gap resolution
Section 5.0 Appendix	5.1	Architects Business Analysts	A complete mapping of HITSP Information Exchange Requirements to functional requirements is provided in this section. Readers can trace IER's to underlying Use Case events and actions (in those instances where a Use Case exists) or to functional requirements defined as part of an official standards Harmonization Request
	5.2	Architects	Supporting information is provided for HITSP exchange actions that have been identified as provisional due to gaps identified in the Section 4.0
	5.3	Architects	Supporting information is provided for any new HITSP exchange contents that have been identified as provisional due to gaps identified in the Section 4.0
	5.4	Architects	Supporting information is provided for any new HITSP data requirements that have been identified as provisional (due to gaps identified in the Section 4.0



Document Section	Sub Section	Intended Audience	Information Contained
	5.5	Architects	Supporting information is provided for any new HITSP Capabilities or constructs (or extensions to existing ones) that will be needed to close gaps indentified in Section 4.0

1.1 RDSS 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. Typically, a patient's medical home (MH) includes a team of healthcare providers lead by a clinician, the 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 their 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 Harmonization Request. However, the concept of the MH is still evolving including the definition, functionality, and even the certification and some of these evolving concepts might not be reflect in this document. We invite comments from the public addressing these issues.

This RDSS focuses on 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 IS but to identify those standards that support the exchange of information related to certain aspects unique to the PCMH. In addition, where appropriate, this RDSS leverages existing, and ongoing HITSP work, to identify those aspects that are pertinent to the MH.

The 2009 Medical Home: Problem Lists & Practice-Based Registries Extension/Gap Harmonization Request 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 Uses Cases 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 either to query or to receive directly, documents 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 a number of other clinical data that might 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.

The PCMH industry activities indicate 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 designees. Use Case 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 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 Harmonization Request describes two main requirements. The RDSS 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

In scope for the Medical Home RDSS is:

- Management and reconciliation of Patient Problem Lists
- 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/T60)]
- Public health alerts and notifications [e.g. Identify Communication Recipients (HITSP/T64)]
- Information exchanges conducted using a message vs. document format [e.g. Lab Result Message (HITSP/C36), Radiology Result Message (HITSP/C41)]. Currently, there are regulations that specify how and to whom laboratories report test 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)
- Standards-based Information to support practice-based registry capabilities within an EHR system

1.3 COPYRIGHT PERMISSIONS

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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 or Capability, it must be implemented in its entirety or within a limited scope or subset as defined within the IS or Capability, 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 RDSS, 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 RDSS and the subsequent associated IS, 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, NIST, CCHIT, and ONC to advance conformance and interoperability testing Capabilities. This Web Site provides HIT implementers with the necessary resources to support and test their implementation of standards-based health systems.

1.5 REFERENCE DOCUMENTS

A list of key reference documents and background material is provided in the table below. These documents can be retrieved from www.hitsp.org.

Table 1-2 Reference Documents

Reference Document	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



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 is more fully defined in a separate Appendix. This table is provided as an aid to readers to assist them in identifying sections to focus on. Readers are encouraged to review all sections of this document to further their understanding of HITSP's work.

Table 2-1 Section 2.0 Reader's Guide

Document Section	Sub Section	Intended Audience	Information Contained
Section 2.0 Requirements	2.1	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 RDSS is built to meet
	2.2 – 2.3	Program Managers Policy Analysts Executive Leadership	Each of the scenarios specific to the RDSS are outlined and described using a HITSP concept known as an Information Exchange Requirement (IER). HITSP uses IER's to outline requirements for HITSP work products to meet
	2.4	Architects Business Analysts Policy Analysts Program Managers	The systems assigned to the system roles (as defined in the Capabilities used by this RDSS) are identified and described here. Readers can learn which systems have been included as part of this RDSS

2.1 SYNOPSIS OF REQUIREMENTS

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

1. The first requirement is 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. For the purposes of the RDSS this represents the interoperability requirements for sharing documents with the designated medical home provider. The first scenario below describes and outlines the Information Exchange Requirements necessary for document sharing
2. The second requirement is 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. The standards-based information may trigger clinical decision support and / reporting

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

Table 2-2 Description of Information Exchange Requirements

Information Exchange Requirement Number (IER)	Description
IER01	Designate Medical Home Provider
IER02	Send and Receive Clinical Information
IER03	Request & Receive Patient-level Registry Data
IER04	Request & Receive Registry Criteria Definition
IER05	Request & Receive Consent Document
IER06	Request & Receive Patient Demographics

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 Capability: Problem Lists	This scenario describes 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.
Practice-Based Registry Capability	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

This scenario describes the ability to manage patient problem lists and provider information (from intra-organizational and inter-organizational sources) within the MH to support co-morbidity management. This represents the interoperability requirements for sharing documents with the designated MH provider to manage 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 designee vs. a “pull” of information by the MH designee.

Although the MH extension / gap and this RDSS calls out the creation and management of a problem list, the same functionality described here will also hold true for the management of other elements of summary documents (e.g., plan of care module, advance directives).

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

This first scenario describes and outlines the interoperable Information Exchange Requirements necessary for document and message sharing.

2.2.1 INFORMATION EXCHANGE REQUIREMENTS FOR DOCUMENT SHARING FUNCTIONALITY: PROBLEM LISTS

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

Table 2-4 Document Sharing Functionality: Problem Lists 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 MH provider / designee for the patient
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 MH provider / designee for the patient



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/C84 - Consult and History & Physical Note HITSP/C168 - Long Term Care Assessment	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
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2.3 PRACTICE-BASED REGISTRY 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 the 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 them to recognize gaps in care at a population level and with the appropriate clinical decision support tools allows the MH provider to address specific issues for the individual patient.

There are two possible system configurations:

- An EHR system may communicate with a PBR system (directly or via hubs) to facilitate the population view of an MH provider's panel of patients
- 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 definition 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 RDSS).

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 look at the resulting population for those patients on the appropriate medications.

There are HITSP constructs that facilitate standardized clinical definitions for specific requirements. It is possible to extend these constructs for the purposes of data aggregation within a practice-based registry and the computation of a metric. This section describes the Information Exchange Requirements necessary for the definition of criteria for select populations and the data required. If the MH provider is exchanging patient data with an external registry there is a need to manage consent directives.



2.3.1 INFORMATION EXCHANGE REQUIREMENTS FOR PRACTICE-BASED REGISTRY FUNCTIONALITY

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

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

Information Exchange Requirement Number	Exchange Action	Exchange Content	Initiating System	Responding System(s)	Exchange Attribute
IER04	Request and Receive Patient-level Registry Data in Separate PBR	HITSP/C105 – Patient Level Quality Data	Practice-Based Registry System	Electronic Health Record (EHR) System, Health Information Exchange (HIE)	The EHR system is collects patient level data and computes the results
IER05	Request and Receive Patient-level Registry Data in EHR	HITSP/C105 – Patient Level Quality Data	Electronic Health Record (EHR) System	Practice-Based Registry System, Health Information Exchange (HIE)	The PBR system collects patient level data and computes the results
IER06	Request & Receive Registry Criteria Definition	HITSP/C106 – Measure Criteria Document	Electronic Health Record (EHR) System	Practice-Based Registry System	Use 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	Health Information Exchange (HIE)	
IER08	Request & Receive Patient Demographics	HITSP/C23 – Patient Demographics Query	Electronic Health Record (EHR) System	Health Information Exchange (HIE)	

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



System Name	System Description	Stakeholders
Practice - Based Registry (PBR) System (NEW)	A system for the collection, storage, retrieval, analysis, and dissemination of information to support health needs of patients and populations within a clinician practice, or organization.	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 HITSP 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 is more fully defined in a separate Appendix. This table is provided as an aid to readers to assist them in identifying sections to focus on. Readers are encouraged to review all sections of this document to further their understanding of HITSP's work.

Table 3-1 Section 3.0 Reader's Guide

Document Section	Section Number	Intended Audience	Information Contained
Section 3.0 Design Specification	3.1	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 RDSS
	3.2	Architects Development Team	The core of the design in the HITSP RDSS is documented here. This solution shows orchestration of HITSP 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

3.1 CAPABILITIES USED

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

Table 3-2 Capabilities Used

Capability	Capability Summary	IERs satisfied
HITSP/CAP119 – 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	IER01 IER02 IER03
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	IER03



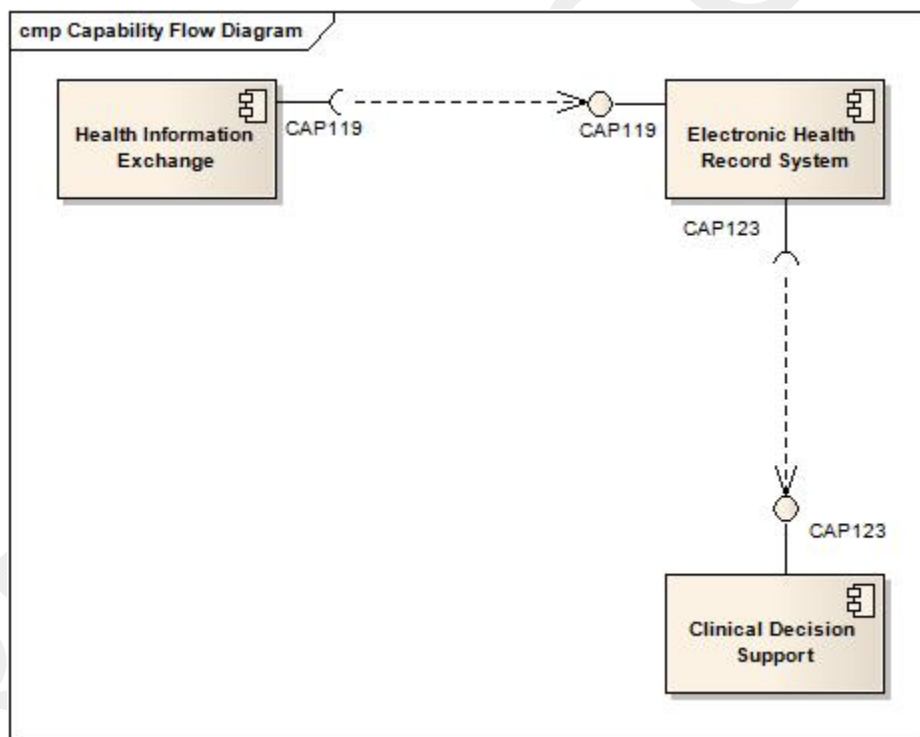
Capability	Capability Summary	IERs satisfied
HITSP/CAP123 – Retrieve Existing Data	This Capability supports queries for clinical data (e.g., common observations, vital signs, problems, medications, allergies, immunizations, diagnostic results, professional services, procedures and visit history)	IER03
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	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 RDSS will call on the document component of this Capability	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	IER04 IER05
HITSP/CAP130 – Communicate Quality Measure Specification	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	IER06
HITSP/CAP135 – Retrieve and Populate Form	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: 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 Systems may optionally support the means to retrieve request for clarifications.	IER04 IER05



Capability	Capability Summary	IERs satisfied
HITSP/CAP143 – Manage Consumer Preference and Consents	This Capability addresses management of consumer preferences and consent as an <i>acknowledgement of a privacy policy</i> . 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	IER01 IER02 IER04 IER05

The following diagram shows how systems use Capabilities to complete the full RDSS. 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 RDSS. 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



3.2 CAPABILITY ORCHESTRATION

This section describes how the Capabilities identified above are orchestrated to achieve the aims of the Harmonization Request (such as Use Case) addressed by this RDSS. 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 HITSP 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	System Role(s)	System Role Option	Capability	Optionality
Electronic Health Record (EHR) System	Initiator	R	HITSP/CAP119 – Communicate Structured Document	C[101] C[102]
	Responder	R	HITSP/CAP119 – Communicate Structured Document	C[101] C[102]
	Gateway/Common Services	O	HITSP/CAP119 – Communicate Structured Document	C[101] C[102]
	Initiator	R	HITSP/CAP120 – Communicate Unstructured Document	C[101] C[102]
	Responder	O	HITSP/CAP120 – Communicate Unstructured Document	C[101] C[102]
	Gateway/Common Services	O	HITSP/CAP120 – Communicate Unstructured Document	C[101] C[102]
	Initiator	R	HITSP/CAP123 – Retrieve Existing Data	C[101] C[102]
	Responder	O	HITSP/CAP123 – Retrieve Existing Data	C[101] C[102]
	Gateway/Common Services	O	HITSP/CAP123 – Retrieve Existing Data	C[101] C[102]
	Initiator	R	HITSP/CAP127 – Communicate Lab Results Document	C[101] C[102]
	Responder	O	HITSP/CAP127 – Communicate Lab Results Document	C[101] C[102]
	Gateway/Common Services	O	HITSP/CAP127 – Communicate Lab Results Document	C[101] C[102]
	Initiator	R	HITSP/CAP128 – Communicate Imaging Information	C[101] C[102]
	Responder	O	HITSP/CAP128 – Communicate Imaging Information	C[101] C[102]
	Gateway/Common Services	O	HITSP/CAP128 – Communicate Imaging Information	C[101] C[102]
	Initiator	R	HITSP/CAP129 – Communicate Quality Measure Data	C[101] C[102] C[103]
	Responder	R	HITSP/CAP129 – Communicate Quality Measure Data	C[101] C[102] C[103]
	Gateway/Common Services	O	HITSP/CAP129 – Communicate Quality Measure Data	C[101] C[102] C[103]
	Initiator	R	HITSP/CAP130 – Communicate Quality Measure Specification	C[101] C[102]
	Responder	R	HITSP/CAP130 – Communicate Quality Measure Specification	C[101] C[102]
	Gateway/Common Services	O	HITSP/CAP130 – Communicate Quality Measure Specification	C[101] C[102]
	Initiator	R	HITSP/CAP135 – Retrieve and Populate Form	C[101] C[102] C[103]



System	System Role(s)	System Role Option	Capability	Optionality
	Responder	R	HITSP/CAP135 – Retrieve and Populate Form	C[101] C[102]
	Gateway/Common Services	O	HITSP/CAP135 – Retrieve and Populate Form	C[101] C[102]
	Initiator	R	HITSP/CAP143 – Manage Consumer Preference and Consents	C[101] C[102]
	Responder	O	HITSP/CAP143 – Manage Consumer Preference and Consents	C[101] C[102]
	Gateway/Common Services	O	HITSP/CAP143 – Manage Consumer Preference and Consents	C[101] C[102]
Health Information Exchange (HIE)	Initiator	O	HITSP/CAP119 – Communicate Structured Document	C[101] C[102]
	Responder	R	HITSP/CAP119 – Communicate Structured Document	C[101] C[102]
	Gateway/Common Services	O	HITSP/CAP119 – Communicate Structured Document	C[101] C[102]
	Initiator	O	HITSP/CAP120 – Communicate Unstructured Document	C[101] C[102]
	Responder	R	HITSP/CAP120 – Communicate Unstructured Document	C[101] C[102]
	Gateway/Common Services	O	HITSP/CAP120 – Communicate Unstructured Document	C[101] C[102]
	Initiator	O	HITSP/CAP123 – Retrieve Existing Data	C[101] C[102]
	Responder	R	HITSP/CAP123 – Retrieve Existing Data	C[101] C[102]
	Gateway/Common Services	O	HITSP/CAP123 – Retrieve Existing Data	C[101] C[102]
	Initiator	O	HITSP/CAP127 – Communicate Lab Results Document	C[101] C[102]
	Responder	R	HITSP/CAP127 – Communicate Lab Results Document	C[101] C[102]
	Gateway/Common Services	O	HITSP/CAP127 – Communicate Lab Results Document	C[101] C[102]
	Initiator	O	HITSP/CAP128 – Communicate Imaging Information	C[101] C[102]
	Responder	R	HITSP/CAP128 – Communicate Imaging Information	C[101] C[102]
	Gateway/Common Services	O	HITSP/CAP128 – Communicate Imaging Information	C[101] C[102]
	Initiator	O	HITSP/CAP129 – Communicate Quality Measure Data	C[101] C[102]
	Responder	R	HITSP/CAP129 – Communicate Quality Measure Data	C[101] C[102]
	Gateway/Common Services	O	HITSP/CAP129 – Communicate Quality Measure Data	C[101] C[102]
	Initiator	O	HITSP/CAP135 – Retrieve and Populate Form	C[101] C[102]
	Responder	R	HITSP/CAP135 – Retrieve and Populate Form	C[101] C[102]



System	System Role(s)	System Role Option	Capability	Optionality
	Gateway/Common Services	O	HITSP/CAP135 – Retrieve and Populate Form	C[101] C[102]
	Initiator	O	HITSP/CAP143 – Manage Consumer Preference and Consents	C[101] C[102]
	Responder	R	HITSP/CAP143 – Manage Consumer Preference and Consents	C[101] C[102]
	Gateway/Common Services	O	HITSP/CAP143 – Manage Consumer Preference and Consents	C[101] C[102]
Personal Health Record (PHR) System	Initiator	O	HITSP/CAP143 – Manage Consumer Preference and Consents	C[101] C[102]
	Responder	R	HITSP/CAP143 – Manage Consumer Preference and Consents	C[101] C[102]
	Gateway/Common Services	O	HITSP/CAP143 – Manage Consumer Preference and Consents	C[101] C[102]
Practice – Based Registry (PBR) System (NEW)	Initiator	R	HITSP/CAP123 – Retrieve Existing Data	C[101] C[102]
	Responder	R	HITSP/CAP123 – Retrieve Existing Data	C[101] C[102]
	Gateway/Common Services	O	HITSP/CAP123 – Retrieve Existing Data	C[101] C[102]
	Initiator	R	HITSP/CAP129 – Communicate Quality Measure Data	C[101] C[102]
	Responder	R	HITSP/CAP129 – Communicate Quality Measure Data	C[101] C[102]
	Gateway/Common Services	O	HITSP/CAP129 – Communicate Quality Measure Data	C[101] C[102]
	Initiator	R	HITSP/CAP130 – Communicate Quality Measure Specification	C[101] C[102]
	Responder	R	HITSP/CAP130 – Communicate Quality Measure Specification	C[101] C[102]
	Gateway/Common Services	O	HITSP/CAP130 – Communicate Quality Measure Specification	C[101] C[102]
	Initiator	R	HITSP/CAP135 – Retrieve and Populate Form	C[101] C[102]
	Responder	R	HITSP/CAP135 – Retrieve and Populate Form	C[101] C[102]
	Gateway/Common Services	O	HITSP/CAP135 – Retrieve and Populate Form	C[101] C[102]
	Initiator		HITSP/CAP143 – Manage Consumer Preference and Consents	C[101] C[102]
	Responder		HITSP/CAP143 – Manage Consumer Preference and Consents	C[101] C[102]
	Gateway/Common Services	O	HITSP/CAP143 – Manage Consumer Preference and Consents	C[101] C[102]

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

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



Condition Code	Condition Description
[103]	Constrained to the collection of patient 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 C32 “CREATOR-MEDICATION AND IMMUNIZATION HISTORY SUBSET”

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

Content Modules	Optionality ¹
Conditions	R
Information Source	R
Healthcare Provider	R
Plan of Care	R
Personal Information	R
Advance Directives	R2
Allergies	R2
Encounter	R2
Immunization	R2
Medications – Prescription and Non-Prescription	R2
Support	R2
Test Results	R2
Vital signs	R2

3.2.1.2 C32 “CREATOR-MEDICATION AND IMMUNIZATION HISTORY-CODED SUBSET”

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 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 support the two scenarios described previously namely:

- How to send documents to the MH
- How to facilitate practice-based aggregation of data to facilitate the MH providers population view of his patients

The following list of example environments is not an exhaustive list:

Table 3-6 Implementation Variant 1

Implementation Variant 1: Document Sharing “Pull” Publish /Subscribe functionality
<p>In this variant, the Medical Home designee on a health information exchange (HIE) is able to access documents using the “publish and subscribe” functionality. The variant leverages the MH designation as part of access control to facilitate the sharing of documents with the designee.</p> <p>The healthcare provider is designated as the MH provider and subscribes to the HIE. As part of his role as the MH provider, the healthcare provider is now capable of making a call to the HIE for all relevant summary documents that the MH provider is permitted to view. The MH designee leverages all the documents using HITSP/CAP119 to facilitate the query for clinical data (problems and information source modules primarily) 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 provider. 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>

¹ Optionality = “R” for Required, “R2” for Required if Known or “O” for Optional, or “C” for Conditional. Repeatable = “Y” for Yes, “N” for No



The constructs that support this variant include HITSP/CAP119, HITSP/SC112 (Healthcare Document Management) with HITSP/T13, HITSP/T29 and HITSP/SC108 (Access Control) with HITSP/TP20

Table 3-7 Implementation Variant 2

Implementation Variant 1: Document Sharing "Push"
<p>In this implementation variant, the MH designee's EHR has the document repository and/or document registry capabilities. Other healthcare providers once they know who the MH designee is, they can push documents or their location to the MH designee. The patient using his PHR, might designate who is his MH provider.</p> <p>In this variant, the healthcare provider is designated as the MH provider and the MH provider's EHR has the capability of accepting or maintaining a registry of documents. The secondary providers (other healthcare providers involved in the care of the patient) "push" documents to the MH designee. In this configuration, the serial MH designees will be responsible for pushing documents to subsequent MH designees.</p> <p>The advantage of this variant is that it might be more simple compared with the "pull" variant.</p> <p>The constructs that support this variant include HITSP/CAP119, HITSP/SC112 (Healthcare Document Management) with HITSP/T13 and HITSP/SC108 (Access Control) with HITSP/TP20</p>

Table 3-8 Implementation Variant 3

Implementation Variant 1: Practice-Based Data Aggregation for Population Management, internal to the EHR
<p>In this variant, the PBR system functionality is available in the MH provider's EHR system. Therefore, EHR System:</p> <ul style="list-style-type: none">• Receives the eMeasure directly using HITSP/CAP130 for exchanging the HITSP/C106 Measurement Criteria Document• Receives and assembles data using HITSP/CAP119 (pre-populated from HITSP documents HITSP/C28, HITSP/C32, HITSP/C48), HITSP/CAP123, HITSP/CAP135 (pre-populated from HITSP documents HITSP/C28, HITSP/C32, HITSP/C48), or HITSP/CAP129 (messaging using HITSP/C34)• Produces the HITSP/C105 Patient Level Quality Data document Using HL7 Quality Reporting Document Architecture (QRDA)• Uses the QRDA to allow the MH provider via his EHR to review on a population level his patients

Table 3-9 Implementation Variant 4

Implementation Variant 1: Practice-Based Data Aggregation for Population Management, external to the EHR
<p>In this variant, the PBR and the EHR systems are distinct. Therefore, 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 Document• Receives and assembles data using CAP119 (pre-populated from HITSP documents C28, C32, C48), CAP123, CAP135 (pre-populated from HITSP documents C28, C32, C48), or CAP129 (messaging using HITSP/C34)• Produces the HITSP/C105 Patient Level Quality Data document Using HL7 Quality Reporting Document Architecture (QRDA)• Sends the QRDA to allow 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 the data for the MH provider's patients• Computes the results of the measure• Makes the results visible to the provider (out of scope)

Table 3-7 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 3-7 Orchestration Constraints

Number	Constraint	Type of Constraint
None		

3.2.3 CONSTRAINTS ON REQUIRED CAPABILITIES

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



Table 3-8 Additional Constraints on Required Capabilities

Number	Data Element	Capability	Constraint	Constraint Type	Purpose (Reason for this constraint)
None					

Table 3-9 Additional Constraints on XDS Metadata Elements

XDS Metadata Attribute	Optionality	Extended Discussion	Source Type
None			



4.0 CAPABILITY GAPS

Section 4.0 identifies gaps not met by existing HITSP Capabilities but needed to achieve the aims of the Harmonization Request for which this RDSS 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 is more fully defined in a separate Appendix. This table is provided as an aid to readers to assist them in identifying sections to focus on. Readers are encouraged to review all sections of this document to further their understanding of HITSP's work.

Table 4-1 Section 4.0 Reader's Guide

Document Section	Sub Section	Intended Audience	Information Contained
Section 4.0 Capability Gaps	4.0	Business Analysts Development Team Architects	Gaps specific to Capabilities used as part of this RDSS 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 HITSP Capabilities as described above.

Table 4-2 Capability Gaps

Requirement Number	Summary Description	Identified Gap	Recommended Resolution
None			



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 is more fully defined in a separate Appendix. This table is provided as an aid to readers to assist them in identifying sections to focus on. Readers are encouraged to review all sections of this document to further their understanding of HITSP's work.

Table 5-1 Section 5.0 Reader's Guide

Document Section	Sub Section	Intended Audience	Information Contained
Section 5.0 Appendix	5.1	Architects Business Analysts	A complete mapping of HITSP Information Exchange Requirements to functional requirements is provided in this section. Readers can trace IER's to underlying Use Case events and actions (in those instances where a Use Case exists) or to functional requirements defined as part of an official standards Harmonization Request
	5.2	Architects	Supporting information is provided for HITSP exchange actions that have been identified as provisional due to gaps identified in the Section 4.0
	5.3	Architects	Supporting information is provided for any new HITSP exchange contents that have been identified as provisional due to gaps identified in the Section 4.0
	5.4	Architects	Supporting information is provided for any new HITSP data requirements that have been identified as provisional (due to gaps identified in the Section 4.0)
	5.5	Architects	Supporting information is provided for any new HITSP Capabilities or constructs (or extensions to existing ones) that will be needed to close gaps identified in Section 4.0

5.1 HARMONIZATION REQUEST TRACEABILITY

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

The following table relates the events of a Harmonization Request to the actions taken and information exchanges required.

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. MH designation based on access control uses: <ul style="list-style-type: none">Access control: HITSP/TP20 role of MH (Security, Privacy and Infrastructure Domain Technical Committee) Will need: <ul style="list-style-type: none">HITSP/SC108 which supports HITSP/TP20	IER01: Designate Medical Home Provider via PHR IER02: Designate Medical Home Provider via EHR



Requirement	Description	Information Exchange Requirement(s) (includes security requirements)
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 comorbidity management. Implementation variants to facilitate the sending of documents to the MH include the following: <ul style="list-style-type: none"> • Publish and subscribe: HITSP/TP13, HITSP/T29 • Push: HITSP/TP13 HITSP/SC112 which supports HITSP/TP29 and HITSP/TP13 HITSP/SC113	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 above re the MH designation. As specified by IS12, IS77, IS03 & 05
7.1.5 Reconcile Problem List, Medication List, Allergy List	Out of scope	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 in Separate PBR IER05: Request & Receive Patient-level Registry Data in EHR IER06: Request & Receive Registry Criteria Definition IER07: Request & Receive Consent Document IER08 Request & Receive Patient Demographics
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

5.2 NEW EXCHANGE ACTIONS NEEDED

The table below provides a description of the new HITSP Exchange Actions needed for this Harmonization Request.

Table 5-3 New Exchange Actions Needed

New Exchange Action Identifier	New Exchange Action Name	Exchange Action Description	IERs
None			



5.3 NEW EXCHANGE CONTENTS NEEDED

The exchange content descriptions answer one or more data requirements, and map to existing or planned HITSP constructs.

Table 5-4 New Exchange Contents Needed

Exchange Content Identifier	Exchange Content Name	Exchange Content Definition	Data Requirements	IERs
None				

5.4 NEW DATA REQUIREMENTS NEEDED

Table 5-5 New Data Requirements Needed

Data Requirement Number (DR)	Description
None	

5.5 NEW OR UPDATED CAPABILITIES AND CONSTRUCTS

The table below provides a description of the new Capabilities that will be created for this Harmonization Request.

5.5.1 NEW OR UPDATED HITSP CAPABILITIES

Table 5-6 New Capabilities

New Capability	Capability Description	IER
None		

5.5.2 NEW OR UPDATED HITSP SUPPORTING CONSTRUCTS (OPTIONAL)

For the above listed HITSP Capabilities, the table below identifies any, Extensions that might needed to existing HITSP constructs to satisfy this Harmonization Request.

Table 5-7 Constructs and Required Extensions

HITSP Construct	Extension Required	Description
HITSP/C32 – Summary Documents Using HL7 Continuity of Care Document (CCD)		Condition Module: extend to include the following" <ul style="list-style-type: none">• Problem Status• Problem Status Effective Date• Patient Health Status• Problem Source
HITSP/TP20 – Access Control	Include the role of Medical Home provider	Medical Home designation <ul style="list-style-type: none">• Effective date• End date



6.0 DOCUMENT UPDATES

This section provides the history of changes made to this document.

6.1 NOVEMBER 9, 2009

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

