

HITSP EHR-Centric Interoperability Specification

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TABLE OF CONTENTS

1.0	INTRODUCTION	8
1.1	HITSP EHR-Centric Interoperability Specification Overview	8
1.2	Copyright Permissions.....	8
2.0	EHR-CENTRIC INTEROPERABILITY REQUIREMENTS	9
2.1	Introduction	9
2.2	List of Capabilities	9
2.3	ARRA Requirements	13
2.4	Security and Privacy Functions	23
3.0	CAPABILITY SPECIFICATIONS.....	26
3.1	Capabilities Overview	26
3.2	HITSP/CAP117 – Communicate Ambulatory and Long Term Care Prescription Specification	31
3.3	HITSP/CAP118 – Communicate Hospital Prescription Specification.....	34
3.4	HITSP/CAP119 – Communicate Structured Document Specification.....	36
3.5	HITSP/CAP120 – Communicate Unstructured Document Specification.....	47
3.6	HITSP/CAP121 – Communicate Clinical Referral Request Specification.....	50
3.7	HITSP/CAP122 – Retrieve Medical Knowledge Specification	52
3.8	HITSP/CAP123 – Retrieve existing data Specification	54
3.9	HITSP/CAP124 – Establish Secure web access Specification	56
3.10	HITSP/CAP125 – Retrieve Genomic Decision Support Specification.....	58
3.11	HITSP/CAP126 – Communicate Lab Results Message Specification	60
3.12	HITSP/CAP127 – Communicate Lab Results Document Specification	64
3.13	HITSP/CAP128 – Communicate Imaging Information Specification.....	68
3.14	HITSP/CAP129 – Communicate Quality Measure Data Specification.....	71
3.15	HITSP/CAP130 – Communicate Quality Measure Specification	75
3.16	HITSP/CAP131 – Update Immunization Registry Specification.....	78
3.17	HITSP/CAP132 – Retrieve Immunization Registry Information Specification.....	81
3.18	HITSP/CAP133 – Communicate Immunization Summary Specification.....	84
3.19	HITSP/CAP135 – Retrieve and Populate Form Specification	87
3.20	HITSP/CAP136 – Communicate Emergency Alert Specification	91
3.21	HITSP/CAP137 – Communicate Encounter Information Message Specification	93
3.22	HITSP/CAP138 – Retrieve Pseudonym Specification	96
3.23	HITSP/CAP139 – Communicate Resource Utilization Specification.....	99
3.24	HITSP/CAP140 – Communicate Benefits and Eligibility specification	100
3.25	HITSP/CAP141 – Communicate Referral Authorization Specification.....	103
3.26	HITSP/CAP142- Retrieve Communications Recipient Specification	106
3.27	HITSP/CAP143 – Manage Consumer Preference and Consents Specification	108
4.0	CONFORMANCE STATEMENT.....	112
5.0	APPENDIX	113
5.1	HITSP Capabilities Mapped to the HITSP Provider, Population and Consumer Interoperability Specifications	113



FIGURES AND TABLES

Figure 3-1 Typical Network Topologies	27
Figure 3-2 HITSP/CAP117 – Communicate Ambulatory and Long Term Care Prescription Visual Overview	33
Figure 3-3 HITSP/CAP118 – Communicate Hospital Prescription Visual Overview	36
Figure 3-4 HITSP/CAP119 – Communicate Structured Document Visual Overview	42
Figure 3-5 HITSP/CAP120 – Communicate Unstructured Document Visual Overview	50
Figure 3-6 HITSP/CAP121 – Communicate Clinical Referral Request Visual Overview	52
Figure 3-7 HITSP/CAP122 – Retrieve Medical Knowledge Visual Overview	54
Figure 3-8 HITSP/CAP123 – Retrieve Existing Data Visual Overview	56
Figure 3-9 HITSP/CAP124 – Establish Secure Web Access Visual Overview	58
Figure 3-10 HITSP/CAP125 – Retrieve Genomic Decision Support Visual Overview	60
Figure 3-11 HITSP/CAP126 – Communicate Lab Results Message Visual Overview	63
Figure 3-12 HITSP/CAP127 – Communicate Lab Results Document Visual Overview	67
Figure 3-13 HITSP/CAP128 – Communicate Imaging Information Visual Overview	71
Figure 3-14 HITSP/CAP129 – Communicate Quality Measure Data Visual Overview	75
Figure 3-15 HITSP/CAP130 – Communicate Quality Measure Specification Visual Overview	78
Figure 3-16 HITSP/CAP131 – Update Immunization Registry Visual Overview	81
Figure 3-17 HITSP/CAP132 – Retrieve Immunization Registry Information Visual Overview	84
Figure 3-18 HITSP/CAP133 – Communicate Immunization Summary Visual Overview	87
Figure 3-19 HITSP/CAP135 – Retrieve and Populate Form Visual Overview	91
Figure 3-20 HITSP/CAP136 – Communicate Emergency Alert Visual Overview	93
Figure 3-21 HITSP/CAP137 – Communicate Encounter Information Message Visual Overview	96
Figure 3-22 HITSP/CAP138 – Retrieve Pseudonym Visual Overview	98
Figure 3-23 HITSP/CAP139 – Communicate Resource Utilization Visual Overview	100
Figure 3-24 HITSP/CAP140 – Communicate Benefits and Eligibility Visual Overview	103
Figure 3-25 HITSP/CAP141 – Communicate Referral Authorization Visual Overview	106
Figure 3-26 HITSP/CAP142 – Retrieve Communications Recipient Visual Overview	108
Figure 3-27 HITSP/CAP143 – Manage Consumer Preference and Consents Visual Overview	111
Table 2-1 HITSP Information Exchange Capabilities	9
Table 2-2 Map of Requirements to Capabilities	14
Table 2-3 ARRA Gap Analysis and Resolution Recommendations	17
Table 2-4 Security and Privacy Functions Mapped to Capabilities	24
Table 2-5 Service Collaborations – Definitions	25
Table 3-1 Information Exchange Topologies Mapped to Capabilities	28
Table 3-2 Network Topologies Mapped to Service Collaborations	29
Table 3-3 Service Collaborations Mapped to HITSP Constructs	29
Table 3-4 Global Constraints and Assumptions	30
Table 3-5 Interacting Systems	31
Table 3-6 Constraints and Assumptions	32
Table 3-7 List of Constructs	32
Table 3-8 HITSP/CAP117 – Communicate Ambulatory and Long Term Care Prescription Specified Interfaces	32
Table 3-9 Interface Conditions and T/TP/SC/Content Optionality	33
Table 3-10 Interacting Systems	34
Table 3-11 Constraints and Assumptions	34
Table 3-12 List of Constructs	35
Table 3-13 HITSP/CAP118 – Communicate Hospital Prescription Specified Interfaces	35
Table 3-14 Interface Conditions and T/TP/SC/Content Optionality	36
Table 3-15 Interacting Systems	37
Table 3-16 Constraints and Assumptions	37
Table 3-17 List of Constructs	38



Table 3-18 HITSP/CAP119 – Communicate Structured Document Specified Interfaces	39
Table 3-19 Interface Conditions and T/TP/SC/Content Optionality	40
Table 3-20 Creator Registration Subset Content Modules	43
Table 3-21 Creator Medication and Immunization History Subset Content Modules	43
Table 3-22 Creator Conditions and Allergy Subset Content Modules	44
Table 3-23 Creator Laboratory Subset Content Modules	44
Table 3-24 Creator Medication and Allergies Information Subset Content Modules	45
Table 3-25 Structured Family History Creator-Structured Family History Subset Content Modules	45
Table 3-26 Structured Family History – Content Creator Subset Content Modules	46
Table 3-27 Interacting Systems	48
Table 3-28 Constraints and Assumptions	48
Table 3-29 List of Constructs	48
Table 3-30 HITSP/CAP120 – Communicate Unstructured Document Specified Interfaces	49
Table 3-31 Interface Conditions and T/TP/SC/Content Optionality	49
Table 3-32 Interacting Systems	50
Table 3-33 Constraints and Assumptions	51
Table 3-34 List of Constructs	51
Table 3-35 HITSP/CAP121 – Communicate Clinical Referral Request Specified Interfaces	51
Table 3-36 Interface Conditions and T/TP/SC/Content Optionality	51
Table 3-37 Interacting Systems	52
Table 3-38 Constraints and Assumptions	53
Table 3-39 List of Constructs	53
Table 3-40 HITSP/CAP122 – Retrieve Medical Knowledge Specified Interfaces	53
Table 3-41 Interface Conditions and T/TP/SC/Content Optionality	53
Table 3-42 Interacting Systems	54
Table 3-43 Constraints and Assumptions	55
Table 3-44 List of Constructs	55
Table 3-45 HITSP/CAP123 – Retrieve Existing Data Specified Interfaces	55
Table 3-46 Interface Conditions and T/TP/SC/Content Optionality	55
Table 3-47 Interacting Systems	56
Table 3-48 Constraints and Assumptions	57
Table 3-49 List of Constructs	57
Table 3-50 HITSP/CAP124 – Establish Secure Web Access Specified Interfaces	57
Table 3-51 Interface Conditions and T/TP/SC/Content Optionality	57
Table 3-52 Interacting Systems	58
Table 3-53 Constraints and Assumptions	59
Table 3-54 List of Constructs	59
Table 3-55 HITSP/CAP125 – Retrieve Genomic Decision Support Specified Interfaces	59
Table 3-56 Interface Conditions and T/TP/SC/Content Optionality	59
Table 3-57 Interacting Systems	60
Table 3-58 Constraints and Assumptions	61
Table 3-59 List of Constructs	61
Table 3-60 HITSP/CAP126 – Communicate Lab Results Message Specified Interfaces	62
Table 3-61 Interface Conditions and T/TP/SC/Content Optionality	62
Table 3-62 Interacting Systems	64
Table 3-63 Constraints and Assumptions	64
Table 3-64 List of Constructs	65
Table 3-65 HITSP/CAP127 – Communicate Lab Results Document Specified Interfaces	65
Table 3-66 Interface Conditions and T/TP/SC/Content Optionality	66
Table 3-67 Interacting Systems	69
Table 3-68 Constraints and Assumptions	69
Table 3-69 List of Constructs	69
Table 3-70 HITSP/CAP128 – Communicate Imaging Information Specified Interfaces	70
Table 3-71 Interface Conditions and T/TP/SC/Content Optionality	70



Table 3-72 Interacting Systems	72
Table 3-73 Constraints and Assumptions	72
Table 3-74 List of Constructs	72
Table 3-75 HITSP/CAP129 – Communicate Quality Measure Data Specified Interfaces.....	73
Table 3-76 Interface Conditions and T/TP/SC/Content Optionality	74
Table 3-77 Interacting Systems	76
Table 3-78 Constraints and Assumptions	76
Table 3-79 List of Constructs	76
Table 3-80 HITSP/CAP130 – Communicate Quality Measure Specified Interfaces	77
Table 3-81 Interface Conditions and T/TP/SC/Content Optionality	77
Table 3-82 Interacting Systems	79
Table 3-83 Constraints and Assumptions	79
Table 3-84 List of Constructs	79
Table 3-85 HITSP/CAP131 – Update Immunization Registry Specified Interfaces.....	80
Table 3-86 Interface Conditions and T/TP/SC/Content Optionality	80
Table 3-87 Interacting Systems	82
Table 3-88 Constraints and Assumptions	82
Table 3-89 List of Constructs	82
Table 3-90 HITSP/CAP132 – Retrieve Immunization Registry Information Specified Interfaces.....	83
Table 3-91 Interface Conditions and T/TP/SC/Content Optionality	83
Table 3-92 Interacting Systems	85
Table 3-93 Constraints and Assumptions	85
Table 3-94 List of Constructs	85
Table 3-95 HITSP/CAP133 – Communicate Immunization Summary Specified Interfaces.....	86
Table 3-96 Interface Conditions and T/TP/SC/Content Optionality	86
Table 3-97 Interacting Systems	88
Table 3-98 Constraints and Assumptions	88
Table 3-99 List of Constructs	89
Table 3-100 HITSP/CAP135 – Retrieve and Populate Form Specified Interfaces.....	89
Table 3-101 Interface Conditions and T/TP/SC/Content Optionality	90
Table 3-102 Interacting Systems	91
Table 3-103 Constraints and Assumptions	92
Table 3-104 List of Constructs	92
Table 3-105 HITSP/CAP136 – Communicate Emergency Alert Specified Interfaces.....	92
Table 3-106 Interface Conditions and T/TP/SC/Content Optionality	92
Table 3-107 Interacting Systems	94
Table 3-108 Constraints and Assumptions	94
Table 3-109 List of Constructs	94
Table 3-110 HITSP/CAP137 – Communicate Encounter Information Message Specified Interfaces	95
Table 3-111 Interface Conditions and T/TP/SC/Content Optionality	95
Table 3-112 Interacting Systems	97
Table 3-113 Constraints and Assumptions	97
Table 3-114 List of Constructs	97
Table 3-115 HITSP/CAP138 – Retrieve Pseudonym Specified Interfaces	98
Table 3-116 Interface Conditions and T/TP/SC/Content Optionality	98
Table 3-117 Interacting Systems	99
Table 3-118 Constraints and Assumptions	99
Table 3-119 List of Constructs	99
Table 3-120 HITSP/CAP139 – Communicate Resource Utilization Specified Interfaces	99
Table 3-121 Interface Conditions and T/TP/SC/Content Optionality	100
Table 3-122 Interacting Systems	101
Table 3-123 Constraints and Assumptions	101
Table 3-124 List of Constructs	101
Table 3-125 HITSP/CAP140 – Communicate Benefits and Eligibility Specified Interfaces	102



Table 3-126 Interface Conditions and T/TP/SC/Content Optionality	102
Table 3-127 Interacting Systems	104
Table 3-128 Constraints and Assumptions	104
Table 3-129 List of Constructs	104
Table 3-130 HITSP/CAP141 – Communicate Referral Authorization Specified Interfaces.....	105
Table 3-131 Interface Conditions and T/TP/SC/Content Optionality	105
Table 3-132 Interacting Systems	107
Table 3-133 Constraints and Assumptions	107
Table 3-134 List of Constructs	107
Table 3-135 HITSP/CAP142 – Retrieve Communications Recipient Specified Interfaces	107
Table 3-136 Interface Conditions and T/TP/SC/Content Optionality	108
Table 3-137 Interacting Systems	109
Table 3-138 Constraints and Assumptions	109
Table 3-139 List of Constructs	110
Table 3-140 HITSP/CAP143 – Manage Consumer Preference and Consents Specified Interfaces	110
Table 3-141 Interface Conditions and T/TP/SC/Content Optionality	110
Table 5-1 HITSP Capabilities Mapped to Interoperability Specifications	114



1.0 INTRODUCTION

1.1 HITSP EHR-CENTRIC INTEROPERABILITY SPECIFICATION OVERVIEW

This Interoperability Specification consolidates all information exchanges that involve an Electronic Health Record (EHR) System within any of the thirteen HITSP Interoperability Specifications existing as of February 13, 2009, the enactment date of the American Recovery and Reinvestment Act (ARRA). This EHR-Centric Interoperability Specification also documents how these consolidated information exchanges address EHR System requirements documented in the ARRA, notably in Title XIII (HITECH) Section 3000 Definitions (13) Qualified Electronic Health Record, Section 3002 Required Areas for Consideration; and Medicare and Medicaid Incentives defined in ARRA Title IV (Division B) – Subtitle A and B.

This Interoperability Specification is organized as a set of HITSP Capabilities. Each Capability specifies a business service that an EHR system addresses (e.g., the HITSP Communicate Hospital Prescriptions Capability supports electronic prescribing for inpatient prescription orders) in one or more of the existing HITSP Interoperability Specifications. Greater detail on these Capabilities is provided in the remainder of this document. Each HITSP Capability is based on existing HITSP constructs (e.g., Transactions, Transactions Packages, and Components) to specify the interoperable information exchanges and standards that support the workflow, information content, infrastructure, security and privacy requirements. Note that for secure infrastructure, the Capabilities Identify Secure Infrastructure Service Collaboration(s) that specify how the requirements are met. Each Secure Infrastructure Service Collaboration summarizes the HITSP constructs, their sequence of use and any constraints needed to realize a service. However, while Capabilities specify the contents and secure infrastructure needed for a business service, Service Collaborations only specify a secure infrastructure service for use by many business services, regardless of content.

1.2 COPYRIGHT PERMISSIONS

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2.0 EHR-CENTRIC INTEROPERABILITY REQUIREMENTS

2.1 INTRODUCTION

This section summarizes the ARRA requirements that can be addressed by EHR systems. It then lists and describes the set of HITSP Capabilities that define business services that support information exchanges that involve an EHR system – information exchanges that are specified in one or more of the thirteen HITSP Interoperability Specifications (IS) accepted or recognized as of the enactment date. Following is a mapping between the EHR system Capabilities and the ARRA requirements that they address. Finally this Section describes security and privacy functions as outlined in ARRA and how they are addressed and integrated within infrastructure Service Collaborations.

2.2 LIST OF CAPABILITIES

The following table lists the HITSP Capabilities, their ID number, and a short description of each. A Capability specifies a business service (e.g., the HITSP Communicate Hospital Prescriptions Capability supports electronic prescribing for inpatient prescription orders). Each HITSP Capability is based on HITSP constructs (e.g., Transactions, Transactions Packages, and Components) and secure Infrastructure Service Collaborations. It is expected that further policy decisions may identify proper subsets of this overall specification for implementation – e.g., for definition of Meaningful Use for 2011. It is the intention of this specification that each capability could be used as part or all of an independent subset and that definition of such a proper subset could identify additional constraints to be placed on the capability(s) included in the subset.

Note that capabilities may be combined by an Interoperability Specification to address more inclusive requirements – for example, support for the formal process of medication reconciliation can be addressed when HITSP/CAP118 Communicate Hospital Prescription is associated with HITSP/CAP 119 Communicate Structured Document (medications and allergies).

In this IS, the capabilities are limited to those information exchanges that involve an EHR in one or more of the existing HITSP Interoperability Specifications (Table 5-1 in the Appendix portrays what ISs each Capability is derived from). The Design specifications for each Capability are provided in Section 3.0.

Table 2-1 HITSP Information Exchange Capabilities

Capability ID	Capability Name	Capability Description
HITSP/CAP117	Communicate Ambulatory and Long Term Care Prescription	This capability addresses interoperability requirements that support electronic prescribing in the ambulatory and long term care environment. The capability supports: 1. The transmittal of new or modified prescriptions 2. Transmittal of prescription refills and renewals 3. Communication of dispensing status 4. Access to formulary and benefit information
HITSP/CAP118	Communicate Hospital Prescription	This capability addresses interoperability requirements that support electronic prescribing for inpatient orders that can occur within an organization or between organizations. The capability supports the transmittal of a new or modified prescription from a Hospital to an internal or external pharmacy. It also includes the optionality to access formulary and benefit information.



Capability ID	Capability Name	Capability Description
HITSP/CAP119	Communicate Structured Document	<p>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:</p> <ol style="list-style-type: none"> 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 <p>Document creators shall support a number of the HITSP specified coded terminologies as defined by specific content subsets specified in this capability.</p>
HITSP/CAP120	Communicate Unstructured Document	<p>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:</p> <ol style="list-style-type: none"> 1. PDF-A supporting long-term archival 2. UTF-8 text
HITSP/CAP121	Communicate Clinical Referral Request	<p>This capability addresses interoperability requirements that support provider-to-provider (clinical) referral request interaction. It allows the bundling of the referral request document with other relevant clinical documents of interest by referencing such documents as shared by other capabilities such as: CAP119 Communicate Structured Document; CAP120 Communicate Unstructured Document; or CAP133 Communicate Immunization Summary.</p>
HITSP/CAP122	Retrieve Medical Knowledge	<p>This capability addresses the requirements to retrieve medical knowledge that is not patient-specific based on context parameters. The actual content delivered is not constrained by this capability; this capability focuses on providing the mechanism to ask for (query) and receive the medical knowledge.</p>
HITSP/CAP123	Retrieve Existing Data	<p>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).</p>
HITSP/CAP124	Establish Secure Web Access	<p>This capability is focused on providing a secured method to access information available from document repositories (e.g., Laboratory Report) in order to view them locally on a system. The chosen method for viewing the document content is through a web browser.</p>
HITSP/CAP125	Retrieve Genomic Decision Support	<p>This capability addresses interoperability requirements that support the communication of genetic and family history information and an assessment of genetic risk of disease for a patient.</p>
HITSP/CAP126	Communicate Lab Results Message	<p>This capability addresses interoperability requirements that support the sending of a set of laboratory test results. Ordering Providers of Care receive results as a laboratory results message. The communication of the order is out of scope for this capability.</p> <p>The content of these test results may be either or both: General Laboratory Test Results; Microbiology Test Results</p> <p>This capability may use content anonymization.</p>



Capability ID	Capability Name	Capability Description
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.
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.
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. Quality measures may include: 1. Patient-level clinical detail from which to compute quality measures. Patient level clinical data is compiled from both the local systems and from longitudinal data available through other sources such as a Health Information Exchange (HIE). 2. Patient-level quality data based upon clinical detail. The "patient-level quality data reports" are exported from EHRs or quality-monitoring applications at the point of care This capability may use content anonymization. Pseudonymization, if needed, is supported by the Capability 138 Retrieve Pseudonym. This capability may use Value Set Sharing.
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.
HITSP/CAP131	Update Immunization Registry	This capability addresses interoperability requirements that enable electronic communication of immunization data among clinicians, with patients, and with immunization registries as unsolicited structured patient immunization data. This capability may use content anonymization.
HITSP/CAP132	Retrieve Immunization Registry Information	This capability addresses interoperability requirements that support the query and retrieval of structured immunization data related to a patient's vaccination. The capability may use one of the following: 1. HL7V2 query with implicit Patient Identity resolution 2. HL7V2 query with explicitly Patient Identity resolution prior to query 3. HL7V3 Query for Existing Data The query for immunization documents from Capability 133 - Communicate Immunization Summary may also be used.
HITSP/CAP133	Communicate Immunization Summary	This capability addresses interoperability requirements to support the communication of structured health data related to a patient's vaccination history. This immunization document contains a history of administered vaccines with details such as lot number, who administered it, as well as other information related to the patient's care such as medical history, medications, allergies, vital signs.



Capability ID	Capability Name	Capability Description
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>
HITSP/CAP136	Communicate Emergency Alert	<p>This capability addresses interoperability requirements to support multicast of non-patient specific notification messages about emergencies events, alerts concerning incidence of communicable diseases, alerts concerning population needs for vaccines and other generic alerts sent to an identified channel. The intended recipients are populations such as "all emergency departments in XXX county", "within a geographic area", etc. Note that this capability is not used to communicate patient-specific or identifiable data.</p>
HITSP/CAP137	Communicate Encounter Information Message	<p>This capability addresses interoperability requirements to send specific clinical encounter data among multiple systems.</p> <p>The content may be either or both:</p> <ol style="list-style-type: none"> 1. Encounter Data Message 2. Radiology Results Message <p>It may be used in conjunction with other capabilities such as those related to the communication of laboratory data. This capability includes optional anonymization of content.</p>
HITSP/CAP138	Retrieve Pseudonym	<p>This capability addresses interoperability requirements to support a particular type of anonymization that both removes the association with a data subject, and adds an association between a particular set of characteristics relating to the data subject and one or more pseudonyms. This enables a process of supplying an alternative identifier, which permits a patient to be referred to by a key that suppresses his/her actual identification information. The purpose of this capability is to offer a pseudonymization framework for situations that require the use of specific data without disclosing the specific identity of patients or providers. Pseudo-identifiers are intended to allow accessibility to clinical information, while safeguarding any information that may compromise the privacy of the individual patient or provider. However, unlike anonymization, the alternative identifier key can be used to re-identify the individuals whose data was used.</p>
HITSP/CAP139	Communicate Resource Utilization	<p>This capability specifies the message and content necessary to report utilization and status of health provider resources to systems supporting emergency management officials at local, state or national levels who have a need to know the availability of hospital and other healthcare resources. The resource utilization information may be provided routinely or in response to a request.</p>
HITSP/CAP140	Communicate Benefits and Eligibility	<p>This capability addresses interoperability requirements that support electronic inquiry and response from a patient's eligibility for health insurance benefits. The information exchanged includes the following:</p> <ol style="list-style-type: none"> 1. A patient's identification (i.e., name, date of birth, and the health plan's member identification number) 2. Communication of a member's status of coverage and benefit information and financial liability 3. Access to information about types of services, benefits and coverage for various medical care and medications <p>It provides clinicians with information about each member's health insurance coverage and benefits.</p>



Capability ID	Capability Name	Capability Description
HITSP/CAP141	Communicate Referral Authorization	<p>This capability addresses interoperability requirements that support electronic inquiry and response to authorizing a patient (health plan member) to be referred for service by another provider or to receive a type of service or medication under the patient's health insurance benefits.</p> <p>The capability supports the transmittal of a patient's name and insurance identification number with the request for the type of service. It also includes the following optional requirements:</p> <ol style="list-style-type: none"> 1. Identification of the type of service or medication requested for benefit coverage (does not guarantee payment by insurance provider) 2. Communication of a referral notification number or authorization number from the Payer System to the Provider System. It provides clinicians and pharmacists with information about each patient's medical insurance coverage and benefits. It may include information on referral or authorization permission.
HITSP/CAP142	Retrieve Communications Recipient	<p>This capability addresses interoperability requirements that support access to a directory to identify one or more communication recipients in order to deliver alerts and bi-directional communications (e.g., public health agencies notifying a specific group of service providers about an event). The method and criteria by which individuals are added to a directory is a policy decision, which is out of scope for this construct.</p>
HITSP/CAP143	Manage Consumer Preference and Consents	<p>This capability addresses management of consumer preferences and consents as an acknowledgement of a privacy policy. This capability is used to capture a patient or consumer agreement to one or more privacy policies; where examples of a privacy policy may represent a consent, dissent, authorization for data use, authorization for organizational access, or authorization for a specific clinical trial. This capability also supports the recording of changes to prior privacy policies such as when a patient changes their level of participation or requests that data no-longer be made available because they have left the region.</p>

2.3 ARRA REQUIREMENTS

The American Recovery and Reinvestment Act (ARRA), notably in Title XIII (HITECH) Section 3000 Definitions (13) Qualified Electronic Health Record, Section 3002 Required Areas for Consideration; and Medicare and Medicaid Incentives defined in ARRA Title IV (Division B) – Subtitle A and B have been identified as the source of specific HIT requirements. These ARRA requirements are described in varying degrees of granularity from high-level objectives to explicit HIT functionalities. In the interim since the announcement of this Act, there have been numerous discussions and presentations regarding this set of requirements in various flavors of aggregation in order to simplify the discussion and target the objectives of these requirements around some key priorities. In discussion with the Office of the National Coordinator for Health Information Technology (ONC), it was concluded that the most consistent set of objectives is grounded in the requirements identified in ARRA Section 3002(b)(2)(B)(i)-(viii). As a result, this HITSP EHR-Centric Interoperability Specification has established these requirements as the target to which the HITSP Capabilities are to be associated. The results of identifying which HITSP Capability addresses which ARRA requirement are shown in the Table 2-2 Map of Requirements to Capabilities.

In addition to this identified set of requirements, a recent meeting by the ONC HIT Policy Committee has identified a high-level set of Health Outcomes Priorities that are associated with achieving “meaningful use” of an EHR. In the interest of harmonization of this latest discussion with this HITSP EHR-centric document, these high-level Priorities have also been included in Table 2-2 for informational purposes.



Table 2-2 Map of Requirements to Capabilities¹

Capability #	Capability Name	ARRA 3002(b)(2)(B)								Meaningful Use: Health Outcomes Priorities				
		(i) Protect Security & Privacy	(ii) Exchange & Integrate Health Information	(iii) Certified EHR by 2014	(iv) Disclosure Audit (per HIPAA for covered entities)	(v) Improve Quality and Population Health	(vi) PHI Rendered Unusable by Unauthorized Individual	(vii) Patient Demographic Data	(viii) Needs of Children and Vulnerable	Quality Safety, Efficiency, Reduce Health Disparities	Engage Patients & Families	Coordination of Care	Population and Public Health	Security and Privacy
CAP117	Communicate Ambulatory and Long Term Care Prescription	X		X	X	X	X			X				X
CAP118	Communicate Hospital Prescription	X		X	X	X	X			X				X
CAP119	Communicate Structured Document	X	X	X	X	X	X	X	X	X	X	X	X	X
CAP120	Communicate Unstructured Document	X	X	X	X	X	X	X	X	X	X	X	X	X
CAP121	Communicate Clinical Referral Request	X	X	X	X	X	X			X		X		X
CAP122	Retrieve Medical Knowledge			X		X				X	X			
CAP123	Retrieve Existing Data	X	X	X	X	X	X			X		X		X
CAP124	Establish Secure Web Access	X	X	X		X			X	X		X		X
CAP125	Retrieve Genomic Decision Support	X			X	X	X	X	X	X	X			X
CAP126	Communicate Lab Results Message	X	X	X	X	X	X					X	X	X
CAP127	Communicate Lab Results Document	X	X	X	X	X	X			X	X	X		X
CAP128	Communicate Imaging Information	X	X	X	X	X	X			X		X		X
CAP129	Communicate Quality Measure Data	X		X	X	X	X			X				X
CAP130	Communicate Quality Measure Specification			X		X				X				
CAP131	Update Immunization Registry	X		X	X	X	X		X				X	X
CAP132	Retrieve Immunization Registry Information	X		X	X	X	X		X	X			X	X
CAP133	Communicate Immunization Summary	X	X	X	X	X	X		X	X		X	X	X

¹ For additional information, see ONC/HIT Policy Committee Meaningful Use Matrix at:

http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_11113_872719_0_0_18/Meaningful%20Use%20Matrix.pdf



Capability #	Capability Name	ARRA 3002(b)(2)(B)								Meaningful Use: Health Outcomes Priorities				
		(i) Protect Security & Privacy	(ii) Exchange & Integrate Health Information	(iii) Certified EHR by 2014	(iv) Disclosure Audit (per HIPAA for covered entities)	(v) Improve Quality and Population Health	(vi) PHI Rendered Unusable by Unauthorized Individual	(vii) Patient Demographic Data	(viii) Needs of Children and Vulnerable	Quality Safety, Efficiency, Reduce Health Disparities	Engage Patients & Families	Coordination of Care	Population and Public Health	Security and Privacy
CAP135	Retrieve and Populate Form	X		X	X	X	X		X	X			X	X
CAP136	Communicate Emergency Alert			X		X				X			X	
CAP137	Communicate – Encounter Information Message	X		X	X	X	X						X	X
CAP138	Retrieve Pseudonym	X		X	X	X	X						X	X
CAP139	Communicate Resource Utilization		X	X		X				X		X	X	
CAP140	Communicate Benefits and Eligibility	X	X	X	X	X	X	X	X	X		X		X
CAP141	Communicate Referral Authorization	X	X	X	X	X	X	X	X	X		X		X
CAP142	Retrieve Communications Recipient		X	X		X				X	X	X		
CAP143	Manage Consumer Preference and Consents	X		X	X	X	X		X	X	X	X		X



The work of associating HITSP Capabilities to the ARRA requirements has resulted in every targeted objective having a number of Capabilities that have addressed them in some degree as depicted in Table 2-2. This HITSP work has also included an opportunity to conduct a gap analysis of the HITSP deliverables to the ARRA requirements in order to identify and document areas of these requirements where pending or future HITSP work would enhance the solution for a specific ARRA requirement. The results of this gap analysis is shown in the Table 2-3.



Table 2-3 ARRA Gap Analysis and Resolution Recommendations²

ARRA Requirement [3002(b)(2)(B)...]	ARRA Text	Gap in constructs	Recommended Resolution
(i) Protect Security & Privacy	3001(b) Purpose- The National Coordinator shall perform the duties under subsection (c) in a manner consistent with the development of a nationwide health information technology infrastructure that allows for the electronic use and exchange of information and that...	Once law is promulgated against this overall scoping section, this list will need to be revisited to identify additional gaps and validate existing gaps.	Defer, pending publication of regulations.
(i) Protect Security & Privacy	Technologies that protect the privacy of health information and promote security in a qualified electronic health record, including for the segmentation and protection from disclosure of specific and sensitive individually identifiable health information with the goal of minimizing the reluctance of patients to seek care (or disclose information about a condition) because of privacy concerns, in accordance with applicable law, and for the use and disclosure of limited data sets of such information.	Of the four data states specified in the NIST 800-66 document the following gaps exist: <ul style="list-style-type: none"> • Data at Rest • Data in Use • Data Disposed Data in motion is covered by HITSP/T17 and HITSP/C44, but the other three data states are not currently addressed by HITSP.	The HITSP SPI Tiger Team will forward to the SPI Technical Committee the gaps of data at rest, data in use, and data disposal for consideration in a revised Technical Committee 2009-2010 SOW. This includes identification and selection of appropriate standards and referring any residual gaps to standards development organizations for resolution.
(i) Protect Security & Privacy	3002(b)(2)(C)(viii) Methods to facilitate secure access by an individual to such individual's protected health information.	Possible gap: Mobile devices are not specifically covered by existing constructs. This may be a gap. Some additional language may need to be added as to which types of devices are supported and to what degree. (E.g.: Inclusion of portable computing devices.)	The HITSP SPI Tiger Team will determine if revisions to the constructs to add clarity and explicitly include portable computing devices can be an integral part of the next maintenance release. If not, the SPI TT will identify the gaps so they can revise the HITSP SPI TC 2009-2010 SOW. Note: The recommended resolution is to provide additional language as to which types of mobile devices are supported and to what degree, e.g., portable computing devices, and address confidentiality protections when data leaves the secured perimeter.

² If the explicit text cited is different than the actual text associated with the Section 3002(b)(2)(B) to which it is associated then the specific ARRA section reference is also noted.



ARRA Requirement [3002(b)(2)(B)...]	ARRA Text	Gap in constructs	Recommended Resolution
(ii) Exchange & Integrate Health Information [Meaningful Use Health Outcomes Priority / Coordination of Care]	A nationwide health information technology infrastructure that allows for the electronic use and accurate exchange of health information.	Standardized terminology for allergies to medication, drug intolerances and other allergies is needed as well as the elements or accompanying information (e.g. nature of reaction, severity or reaction, and source of info) In addition agreement is needed on distinctions among allergies, intolerances, side-effects, sensitivity responses, adverse effects and other similar reactions, tolerance, adverse events, side effects, sensitivity reaction	ISO TS Adverse events pending Some SNOMED mapping for some adverse event/side effect terminologies under way Tolerance definitions not available (for quality typically medication allergen for exclusion) International Harmonization Committee (MedDRA) WHO terminology Recommend harmonization and development of coded terminology
		Standards are able to manage the death indicator, but there is a gap in the process to reliably collect and transmit this data element. Hospital outpatient clinics and Emergency Departments may use ADT A^03 to indicate death of outpatients. In the ambulatory setting there is usually no clear standard electronic record of death. The HL7 death indicator exists but is not currently part of workflow in the ambulatory setting	This will be a matter of training. If there is a demographic resource (e.g. IHE PIX - could be an IHE PDQ message); If Vital Health Statistics resource is available; IHE QED might be used against this resource to access the reason(problem) for death. Vital Health Statistics could be instantiated as a Patient Demographic Supplier
(ii) Exchange & Integrate Health Information [Meaningful Use Health Outcomes Priority / Coordination of Care]	3001(b) (6) improves the coordination of care and information among hospitals, laboratories, physician offices, and other entities through an effective infrastructure for the secure and authorized exchange of health care information;	Gaps may be identified when the definition of "meaningful use" is available. Revisit to validate when the definition of meaningful use is available	Defer, pending publication definition for "meaningful use"
(ii) Exchange & Integrate Health Information [Meaningful Use Health Outcomes Priority / Coordination of Care]	3002(b)(2)(C)(vi) Technologies that facilitate the continuity of care among health settings.	Long term care (LTC) is referenced only as it relates to the inpatient and ambulatory settings. This capability does not define the LTC environment fully with LTC workflow, participants, needs and activities. It is expected that once an LTC medication management scenario is defined, LTC requirements will be fully addressed.	The extension of the Medication Management IS for LTC is currently part of the 2009 HITSP work. This will result in the Long Term Care setting requirements being discussed and documented in greater detail.



ARRA Requirement [3002(b)(2)(B)...]	ARRA Text	Gap in constructs	Recommended Resolution
		A standard enabling law enforcement to securely hand over crash victim ID/ECON information to crash scene EMS providers in an automated and streamlined format	The IHE PCC Technical Committee, in collaboration with various Emergency Responder SME organizations, including the National Association of State EMS Officials, International Association of Chiefs of Police, and International Association of Fire Chiefs, are responsible for resolving the ECON Gap as part of IHE's development of the 2009 'EMS Transfer of Care' Technical Framework Supplement
		There is a need for a CDA implementation guide for the exchange of assessment instruments that include functional status.	HITSP has sent a request to SDOs for consideration. HL7 has embraced this requirement and incorporated this into its 2009 work.
		Nursing documentation, such as nurse's notes are a gap in the current standards	HITSP will send a request to SDOs to create an implementation guide to fill this gap, including: Nursing Summary Component Document that contains notes and observations from the nursing staff and to make sure that CDA will work for all nursing documentation
(ii) Exchange & Integrate Health Information [Meaningful Use Health Outcomes Priority / Coordination of Care]	13101; 3000 Def. (13) QUALIFIED ELECTRONIC HEALTH RECORD.—The term 'qualified electronic health record' means an electronic record of health related information on an individual that— (B) has the capacity— (ii) to support physician order entry;	Orders are ill-defined for both lab and procedure ordered. Need a standard model so that each vendor can map to standardized mechanism to capture the procedure ordered data element.	Recommend to LOINC, SNOMED CT, and CPT to develop AND harmonize a suitable coded value set to express order test name and code values
		Gap for electronic capture of "consult ordered"; there are many ways to determine this information, but no good standard identified. For instance Consult result with appropriate components (e.g. an eye exam with appropriate components – retinopathy; provides a dx DX ICD can help, but may not be sufficient). Procedures may be an indication of consultation. Need to manage the status of all referrals and orders	The consultation and communication process is too granular to be measurable Explore incorporation of communication transaction notification



ARRA Requirement [3002(b)(2)(B)...]	ARRA Text	Gap in constructs	Recommended Resolution
(iii) Certified EHR by 2014	3002(b)(2)(A) IN GENERAL- The HIT Policy Committee shall recommend the areas in which standards, implementation specifications, and certification criteria are needed for the electronic exchange and use of health information for purposes of adoption under section 3004 and shall recommend an order of priority for the development, harmonization, and recognition of such standards, specifications, and certification criteria among the areas so recommended. Such standards and implementation specifications shall include named standards, architectures, and software schemes for the authentication and security of individually identifiable health information and other information as needed to ensure the reproducible development of common solutions across disparate entities.	Gaps may be identified when the definition of "meaningful use" is available. Revisit to validate when the definition of meaningful use is available	Defer, pending publication definition for "meaningful use"
(iii) Certified EHR by 2014	3002(b)(2)(C)(i) (i) The appropriate uses of a nationwide health information infrastructure, including for purposes of--	Gaps may be identified as we perform a detailed analysis on the Common Data Transport (CDT) Use Case and identify the requirements listed in CDT.	The HITSP SPI Tiger Team will identify the gaps so they can revise the HITSP SPI TC 2009-2010 SOW accordingly. This includes identification and selection of appropriate standards and referring any residual gaps to standards development organizations for resolution.



ARRA Requirement [3002(b)(2)(B)...]	ARRA Text	Gap in constructs	Recommended Resolution
(iv) Disclosure Audit (per HIPAA for covered entities)	Technologies that as a part of a qualified electronic health record allow for an accounting of disclosures made by a covered entity (as defined for purposes of regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996) for purposes of treatment, payment, and health care operations (as such terms are defined for purposes of such regulations).	<p>There is a gap. HITSP/T15 can support accounting of disclosures but is just one component.</p> <p>HITSP does not have an accounting of disclosures constructs. While HITSP/T15 employs the use of security logs, accounting of disclosures is more akin to event logs.</p> <p>The purpose of disclosure and other criteria need to be recorded in the Disclosure log.</p>	<p>If needed, HITSP can look to develop an "accounting of disclosures" construct, recognizing that there may be a gap in underlying standards. HITSP would need guidance on the level of specificity within the disclosure log (e.g. limited to specific system behavior, or does the system have to capture all disclosures whether generated by the system itself or otherwise (e.g. verbal)).</p> <p>The HITSP SPI Tiger Team will identify the gaps so HITSP can seek guidance from ONC for what HITSP needs to deliver, and revise HITSP SPI TC 2009-2010 SOW accordingly.</p> <p>This includes identification and selection of appropriate standards and referring any residual gaps to standards development organizations for resolution.</p>
(iv) Disclosure Audit (per HIPAA for covered entities)	<p>13405(C) ACCOUNTING OF CERTAIN PROTECTED HEALTH INFORMATION DISCLOSURES REQUIRED IF COVERED ENTITY USES ELECTRONIC HEALTH RECORD</p> <p>IN GENERAL</p>	<p>There is a gap. HITSP/T15 can support accounting of disclosures but is just one piece of the puzzle.</p> <p>HITSP does not have an accounting of disclosures constructs. While HITSP/T15 employs the use of security logs, accounting of disclosures is more akin to event logs.</p> <p>The purpose of disclosure and other criteria need to be recorded in the Disclosure log.</p>	<p>The HITSP SPI Tiger Team will identify the gaps so HITSP can seek guidance from ONC for what HITSP needs to deliver, and revise HITSP SPI TC 2009-2010 SOW accordingly.</p> <p>This includes identification and selection of appropriate standards and referring any residual gaps to standards development organizations for resolution.</p>



ARRA Requirement [3002(b)(2)(B)...]	ARRA Text	Gap in constructs	Recommended Resolution
(v) Improve Quality and Population Health [Meaningful Use Health Outcomes Priority / Quality Safety , Efficiency, Reduce Health Disparities]	3002(b)(2)(C)(x) Any other technology that the HIT Policy Committee finds to be among the technologies with the greatest potential to improve the quality and efficiency of health care.	The following topics have not yet been covered by HITSP constructs and are not discussed elsewhere in this document: 1. Nonrepudiation of receipt 2. Common vocabulary to represent NIST level of assurance 3. Cross-Enterprise Security and Privacy Authorization (XSPA) 4. Common vocabulary for Patient Consent Directives 5. Gaps in the use of HITSP/TP13 and HITSP/TP30 may exist in terms of managing the consent, or document, in an exchange environment where an IHE XDS registry or repository may not exist. This situation has been identified in the NHIN trial implementations.	Item 1 is not clearly called-for in ARRA, so we need clarification from ONC as to whether a need for nonrepudiation of receipt may be forthcoming (e.g. in a value case). Items 2, 3 and 4 exist in the current HITSP SPI TC 2009 SOW. A known set of prioritized, business relationship privacy policies and consumer privacy policies would be of great benefit to the TC in closing the identified gaps. Item 5 will be referred to the SPI Technical Committee to address.
(v) Improve Quality and Population Health [Meaningful Use Health Outcomes Priority /Engage Patients and Families]	3002(b)(2)(C)(ii) Self-service technologies that facilitate the use and exchange of patient information and reduce wait times.	HITSP/C44 enables the use of public terminals for secure access of data. There may be other self-service technologies to facilitate the use of exchange of patient information and reduce wait times that HITSP has not yet considered.	Seek guidance from ONC on the types of other self-service technologies that we may need to support. Note: Since HITSP/C44 supports the use of "uncertified" user browsers, this supports the notion of self serving technologies (no gap).
(vi) PHI Rendered Unusable by Unauthorized Individual	Technologies that allow individually identifiable health information to be rendered unusable, unreadable, or indecipherable to unauthorized individuals when such information is transmitted in the nationwide health information network or physical transport.	HITSP/T17 supports encryption of data during transmission. For physically transporting IHH outside of the secured perimeter there is a gap: Encrypting physical media, e.g., encryption for HITSP/T33. There is no construct for encrypting media at rest. Furthermore, HITSP needs to expand our definition for portable media to include portable computing devices.	The HITSP SPI Tiger Team will identify the gaps of data at rest, data in use, and data disposal for consideration in a revised 2009-2010 SOW. This includes identification and selection of appropriate standards and referring any residual gaps to standards development organizations for resolution.



ARRA Requirement [3002(b)(2)(B)...]	ARRA Text	Gap in constructs	Recommended Resolution
(vi) PHI Rendered Unusable by Unauthorized Individual	13402(h) Unsecured Protected Health Information. (1) DEFINITION. (A) IN GENERAL.--Subject to subparagraph (B), for purposes of this section, the term "unsecured protected health information" means protected health information that is not secured through the use of a technology or methodology specified by the Secretary in the guidance issued under paragraph (2).	Gap in encryption of removable media and portable devices. Encryption of data on removable media and portable devices would provide support for "Safe Harbor" breach notification requirement. See previous gap statement on this topic.	The HITSP SPI Tiger Team will identify the gaps of data at rest, data in use, and data disposal for consideration in a revised 2009-2010 SOW. This includes identification and selection of appropriate standards and referring any residual gaps to standards development organizations for resolution. Seek guidance from the HIT Standards Committee on how to proceed.
(viii) Needs of Children and Vulnerable [Meaningful Use Health Outcomes Priority / Quality Safety , Efficiency, Reduce Health Disparities]	Technologies that address the needs of children and other vulnerable populations.	No way to receive a Risk Analysis report into an EHR.	The HITSP Care Management and Health Records Domain TC will investigate current standards The resulting Risk Analysis report should use standard Interoperable Clinician/Nursing Terminology with the following local/Interoperable language agreed to by HITSP: This Interoperability Specification will use the CHI recommended SNOMED CT as a reference terminology to communicate interoperable information among and between systems, with the HITSP Interoperability Specification Pre-condition that the sending and using systems must use formal coded nursing terminologies such as the Clinical Care Classification (CCC) System and the Omaha System that are integrated in SNOMED CT

2.4 SECURITY AND PRIVACY FUNCTIONS

2.4.1 MAP TO CAPABILITIES

The following matrix portrays what key security and privacy related functions are integrated within each Capability. Details regarding specific underlying constructs can be found in each Capability. Furthermore, the HITSP Security and Privacy Technical Note (HITSP/TN900) provides a detailed discussion of these constructs, including consideration and context for any security and privacy related policy decisions. Within each cell, a "Y" indicates an integrated function, an "O" represents an optionally integrated function, and a blank cell indicates the function is not supported/not necessary.



Table 2-4 Security and Privacy Functions Mapped to Capabilities

Security and Privacy Functions	CAP 117	CAP 118	CAP 119	CAP 120	CAP 121	CAP 122	CAP 123	CAP 124	CAP 125	CAP 126	CAP 127	CAP 128	CAP 129	CAP 130	CAP 131	CAP 132	CAP 133	CAP 135	CAP 136	CAP 137	CAP 138	CAP 139	CAP 140	CAP 141	CAP 142	CAP 143
Manage Consent Directives	Y	Y	Y	Y	Y		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Access Control	Y	Y	Y	Y	Y		Y	0	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Secured Communication Channel	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Security Audit	Y	Y	Y	Y	Y		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Entity Identity Assertion	Y	Y	Y	Y	0		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Document Integrity	0	0	0	0	0				0		0	0	0				0								0	0
Non-Repudiation of Origin		0											0	0			Y					0			0	
De-identification	0	0	0	0	0		0		0		0	0	0		Y		0			Y		0	0		0	0



2.4.2 SERVICE COLLABORATIONS

A Service Collaboration is the composition of HITSP Transaction and or Transaction Package constructs into a reusable workflow, primarily at the infrastructure level. Service Collaborations do not contain content, i.e., Components. Service Collaborations are organized into an external view, i.e., outward facing interfaces, and an internal view that includes inward facing interfaces and HITSP Transactions and Transaction Packages. Security and privacy constructs are incorporated into the infrastructure Service Collaborations.

2.4.2.1 SERVICE COLLABORATIONS – DEFINITIONS

Table 2-5 Service Collaborations – Definitions

SC #	Service Collaboration Name	Definition
SC108	Access Control	The HITSP Access Control Service Collaboration provides the mechanism for security authorizations which control the enforcement of security policies including: role-based access control, entity based access control, context based access control, and the execution of consent directives.
SC109	Security Audit	The HITSP Security Audit Service Collaboration describes the mechanism to record security relevant events in support of policy, regulation, or risk analysis. It also provides the mechanism to determine the record format to support analytical reports that are needed.
SC110	Patient Identification Management	The HITSP Patient Identification Management Service Collaboration provides the ability to lookup and/or cross-reference patient identities.
SC111	Knowledge and Vocabulary	The HITSP Knowledge and Vocabulary Service Collaboration provides the ability to retrieve medical knowledge and terminology.
SC112	Healthcare Document Management	The HITSP Healthcare Document Management Service Collaboration provides the ability to share healthcare documents using a set of topologies, such as Media, e-Mail, Point-to-Point, Shared within a Health Information Exchange, and Shared within a larger community (made up of potentially diverse Health Information Exchanges).
SC113	Query for Existing Data	The HITSP Query for Existing Data Service collaboration provides the capability to query and retrieve data from another clinical system, and the capability to respond to same queries. It applies the necessary Security and Privacy constructs and supports all the queries found in HITSP/TP21.
SC114	Administrative Transport to Health Plan	The HITSP Administrative Transport to Health Plan Service Collaboration provides the transport mechanism for conducting administrative transactions with health plans.
SC115	HL7 Messaging	The HITSP HL7 Messaging Service Collaboration provides the capability to send and receive HL7 messages. This Service Collaboration applies the necessary Security and Privacy constructs.
SC116	Emergency Message Distribution	The HITSP Emergency Message Distribution Service Collaboration performs a multicast notification to specifically identified populations, such as emergency departments.



3.0 CAPABILITY SPECIFICATIONS

3.1 CAPABILITIES OVERVIEW

This section provides an overview of Capabilities including typical topologies, descriptions of Service Collaborations used in Capabilities and global constraints applied to all Capabilities.

3.1.1 INTRODUCTION

This section provides guidance and specifications for implementing Capabilities and underlying Service Collaborations that are supported by EHR systems. In addition there is a brief description of network topologies that can be supported by Capabilities.

Capability Specifications can be implemented by EHR systems to fulfill business requirements, such as those described in the ARRA. Capabilities are implementable business services that specify interoperable information exchanges using HITSP constructs. Capabilities may be combined by an Interoperability Specification to address more inclusive requirements – for example, support for the formal process of medication reconciliation can be addressed when HITSP/CAP118 Communicate Hospital Prescription is associated with HITSP/CAP119 Communicate Structured Document (medications and allergies).

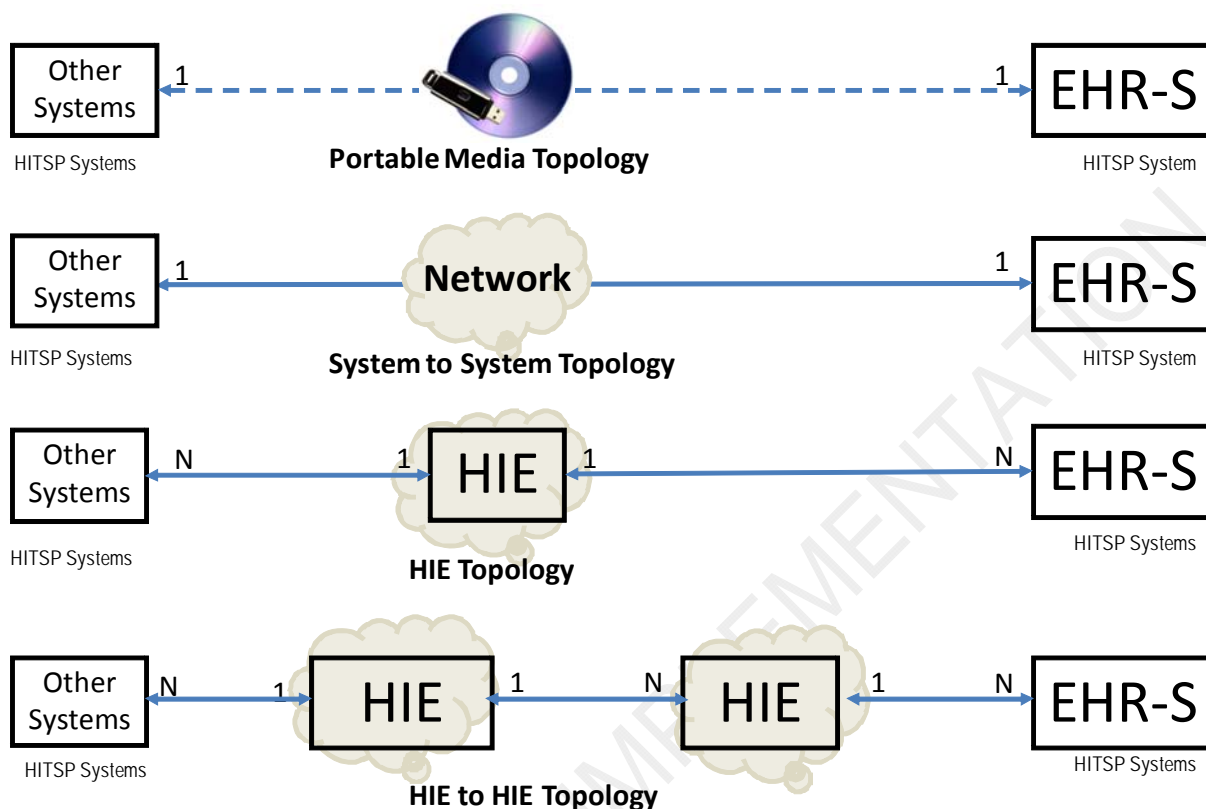
Each Capability section defined later in this section contains an overview, the participating systems, a list of the HITSP constructs used and a detailed design section including constraints and interfaces. All Capabilities are based on EHR system information exchanges that are defined in the existing HITSP Interoperability Specifications.

3.1.2 TYPICAL TOPOLOGIES SUPPORTED BY CAPABILITIES

Topology is the arrangement or mapping of networked Systems, especially the physical (real) and logical (virtual) interconnections between Systems. A Health Information Exchange (HIE) is a special network system that provides intermediary services, such as directories, registries or translations. Networks exhibit both a physical topology and a logical topology. Figure 3-1 Typical Network Topologies illustrates possible interconnections between systems employing HITSP Specifications.



Figure 3-1 Typical Network Topologies



NOTE: HITSP Interoperability Specifications apply across business boundaries. An associated business agreement defines the business boundaries of EHRs, other systems and HIEs. HITSP ISs apply to information exchanges indicated by the arrows in the figure.

The following matrix portrays which of the typical network topologies in the U.S. are addressed within each Capability. Within each cell, a “Y” indicates that the topology is addressed while an “N” indicates that the topology is not supported/not necessary.



Table 3-1 Information Exchange Topologies Mapped to Capabilities

Information Exchange Topologies	CAP 117	CAP 118	CAP 119	CAP 120	CAP 121	CAP 122	CAP 123	CAP 124	CAP 125	CAP 126	CAP 127	CAP 128	CAP 129	CAP 130	CAP 131	CAP 132	CAP 133	CAP 135	CAP 136	CAP 137	CAP 138	CAP 139	CAP 140	CAP 141	CAP 142	CAP 143
System-to-System (e.g., EHR System-to-Lab System)	Y	Y	Y	Y	Y ³	Y	Y	Y	Y	Y	Y	Y	Y		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
System-to-HIE	Y	Y	Y	Y	Y ⁴	Y	Y	N	Y	Y	Y	Y	Y		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
HIE-to-HIE	N	N	Y ⁵	Y	Y ⁶	N	Y	N	N	N	Y ⁷	Y	Y		N	N	Y ⁸	N	N	N	N	N	N	N	Y	Y
Portable Media	N	N	Y	Y	Y ⁹	N	N	N	N	N	Y	N ¹⁰	Y		N	N	Y	N	N	N	N	N	N	N	N	Y

³ See Capabilities 119, 120, 127, 128, 131: These are all the Capabilities that do document interchange.

⁴ See Capabilities 119, 120, 127, 128, 131: These are all the Capabilities that do document interchange.

⁵ Partial support. HITSP Construct on Cross-community Patient Discovery needed.

⁶ See Capabilities 119, 120, 127, 128, 131: These are all the Capabilities that do document interchange.

⁷ Partial support. HITSP construct on Cross-community Patient Discovery needed.

⁸ Partial support by HITSP/T33. HITSP construct on Portable Data for Imaging is needed. Gap has been addressed by the IHE PDI Profile

⁹ See Capabilities 119, 120, 127, 128, 131: These are all the Capabilities that do document interchange.

¹⁰ Partial support by HITSP/T33. HITSP construct on Portable Data for Imaging is needed. Gap has been addressed by the IHE PDI Profile



The following matrix identifies which Service Collaborations can be used in typical topology variants found in the US. Within each cell, a “Y” indicates a supported topology and a blank or null cell indicates the topology is not supported or a need for support has not yet been identified within the scope of HITSP activities to date.

Table 3-2 Network Topologies Mapped to Service Collaborations

Topology	SC108 Access Control	SC109 Security Audit	SC110 Patient Identification Management	SC111 Knowledge and Vocabulary	SC112 Healthcare Document Management	SC113 Query for Existing Data	SC114 Administrative Transport to Health Plan	SC115 HL7 Messaging	SC116 Emergency Message Distribution
System-to-System (e.g., EHR System-to-Lab System)	Y	Y	Y	Y	Y	Y	Y	Y	Y
System-to-HIE	Y	Y	Y	Y	Y	Y	Y	Y	Y
HIE-to-HIE	Y	Y	Y	Y	Y	Y		Y	Y
Portable Media	Y	Y			Y				

3.1.3 SERVICE COLLABORATIONS MAPPED TO HITSP CONSTRUCTS

A Service Collaboration is the composition of HITSP Transaction and or Transaction Package constructs into a reusable workflow, primarily at the infrastructure level. Table 3-3 Service Collaborations mapped to HITSP Constructs shows how each Service Collaboration is composed from other constructs. Security and privacy constructs are incorporated into the infrastructure Service Collaborations.

Table 3-3 Service Collaborations Mapped to HITSP Constructs

Service Collaboration Title	Interfaces	SC #	Primary Associated Constructs	Integrated S&P Constructs/SCs
Access Control	Request Access Control	HITSP/SC108	HITSP/TP20, HITSP/TP30, HITSP/C19, HITSP/T17	
Knowledge and Vocabulary	Request Medical Knowledge Respond Medical Knowledge Request Value-Set Respond Value-Set	HITSP/SC111	HITSP/T81, HITSP/T66	HITSP/T17
Patient Identification Management	Request Patient Identification	HITSP/SC110	HITSP/T23, HITSP/TP22, HITSP/T24	HITSP/SC108, HITSP/SC109, HITSP/T17
Query for Existing Data	Request Existing Patient Data Respond Existing Patient Data	HITSP/SC113	HITSP/TP21	HITSP/SC108, HITSP/SC110, HITSP/SC109, HITSP/T17
Security Audit	Send Security Audit Event	HITSP/SC109	HITSP/T15, HITSP/T16	



Service Collaboration Title	Interfaces	SC #	Primary Associated Constructs	Integrated S&P Constructs/SCs
Healthcare Document Management	Send Documents (dynamically choose method) Send Documents Directly Send Documents through email Publish Documents through Media Send Documents through Share Publish Documents through Share Receive Documents (dynamically choose method) Receive Documents Directly Receive Documents through email Consume Documents through Media Receive Documents through Share Consume Documents through Share	HITSP/SC112	HITSP/TP13, HITSP/T31, HITSP/T33, HITSP/T29	HITSP/SC108, HITSP/SC110, HITSP/SC109, HITSP/T17, HITSP/T64
Emergency Message Distribution Element	Send Emergency Message Distribution Element	HITSP/SC116	HITSP/T63	HITSP/SC108, HITSP/SC109, HITSP/T17
Administrative Transport to Health Plan	Request Administrative Response to Health Plan Respond to Administrative Response to Health Plan	HITSP/SC114	HITSP/T85	HITSP/SC108, HITSP/SC110, HITSP/SC109, HITSP/T17
HL7 Messaging	Request HL7 Message Respond to HL7 Message	HITSP/SC115	HL7 v2.x MLLP	HITSP/SC108, HITSP/SC109, HITSP/T17

3.1.4 EHR-CENTRIC CONSTRAINTS AND ASSUMPTIONS FOR ALL CAPABILITIES

The following table defines the constraints, which include assumptions, pre and post conditions and constraints that apply to all Capabilities used by EHR systems within this Interoperability Specification.

Table 3-4 Global Constraints and Assumptions

Constraint	Type of Constraint
Appropriate protocols, patient identification methodology, consent, Security and Privacy procedures are agreed to by all relevant participants in Business Agreements that address relevant statutory, regulatory, and policy requirements for security and privacy. Security and Privacy policies, procedures and practices are implemented to support appropriate levels of consumer/patient privacy and security. Legal and governance issues regarding data access authorizations, data ownership, and data use are in effect. Organizations handling data address statutory, regulatory, and policy requirements (e.g., HIPAA policy compliance) in their policy, agreements, and/or processes.	Pre-Condition
This specification provides the needed capabilities that organizations could use to address relevant statutory, regulatory, and policy requirements. These capabilities use established standards for trust management, risk assessment and cross-jurisdiction information exchange.	Assumption
Unless precluded by statute, the consumer shall be informed of the existence and unavailability of the document per statute. Consumer escalation procedures should be available, at minimum, by reference	Assumption
There is no regulatory roadblock to the transmission of personal health information between systems and that all exchanges between systems are properly handled by the appropriate business rules by the system provider.	Assumption
Process and places where portable media would be created or read in healthcare delivery organization is consistent with policy restrictions (e.g., to protect from malicious data or unauthorized release of Individual Identifiable Health Information). It is assumed the import/export to and from portable media to be restricted to specific locations and/or staff	Assumption



Constraint	Type of Constraint
Network infrastructures enable secure, appropriate, and accurate information exchange across data sources and systems to view the data. This includes, but is not limited to: methods to: identify and authenticate users; identify and determine providers of care; enforce data access authorization policies correctly match consumers/patients across systems. To identify and determine health insurers; identify and determine pharmacy benefits managers (NOTE: Pharmacy benefit information obtained through NCPDP transactions); identify data sources including but not limited to provider EHR systems	Pre-Condition
Support the technical measures to ensure Security and Privacy of consumer/patient health information	Pre-Condition
Support the technical measures to ensure Security and Privacy of consumer/patient health information	Pre-Condition
Security and Privacy policies, procedures and practices are commonly implemented to support acceptable levels of consumer/patient privacy and security Legal and governance issues regarding data access authorizations, data ownership, and data use are in effect	Pre-Condition
A user's access or disclosure of PHR information is successfully logged	Post-Condition
Access and disclosure logs for PHR are available for Consumer review	Post-Condition
Health Information Exchange (HIE) can serve as intermediary for data in many implementation variants.	Assumption
Appropriate patient consent is obtained and recorded for treatment, payment and healthcare operations.	Pre-condition
Either (1) Providers can't limit a consumer's access to clinical information directly related to that consumer, or; (2) The specification, interoperability requirements, and policy considerations of such restrictions are outside the scope of this document	Assumption
A user-friendly error message is displayed in the event of retrieval failure	Post-Condition
Policies exist authorizing registries to exchange information	Pre-condition
Augmentation of electronic data with manual input or query to other systems require appropriate authorizations	Assumption

3.2 HITSP/CAP117 – COMMUNICATE AMBULATORY AND LONG TERM CARE PRESCRIPTION SPECIFICATION

3.2.1 OVERVIEW

This capability addresses interoperability requirements that support electronic prescribing in the ambulatory and long term care environment. The capability supports:

1. The transmittal of new or modified prescriptions
2. Transmittal of prescription refills and renewals
3. Communication of dispensing status
4. Access to formulary and benefit information

3.2.2 DESIGN SPECIFICATION

3.2.2.1 INTERACTING SYSTEMS

Table 3-5 Interacting Systems

Interacting Systems
Electronic Health Record (EHR)
Electronic Health Record (EHR) Hospital & EHR LTC
Pharmacy Systems
Pharmacy Systems – Hospital and Pharmacy Systems – External
Clinical Decision Support and Other Clinical or Admin Data Sources
Health Care Entities (for LTC)
Health Information Exchange (HIE)
PBM/Payers System



3.2.2.2 CONSTRAINTS AND ASSUMPTIONS

This section provides an overview of the constraints (i.e., Assumptions, Pre-conditions, Post-conditions, Triggers) associated with the Capability.

Table 3-6 Constraints and Assumptions

Constraint	Type of Constraint
Health Information Exchange (HIE) can serve as intermediary for data in many implementation variants. The various alternative options are not shown	Assumption
Patient consent for treatment, payment and healthcare operations	Pre-condition
Entities have pre-established a business relationship to exchange information	Pre-condition
Authentication service to authenticate requestors and/or data submissions from various locations	Pre-condition
Security and privacy policies, procedures and practices are commonly implemented to support acceptable levels of consumer/patient security and privacy	Pre-condition
Medication has been dispensed to a patient, or the reason why it was not is provided to the prescribing clinician	Post-condition

3.2.2.3 LIST OF CONSTRUCTS

Table 3-7 List of Constructs

Construct	Description
HITSP/SC114 – Administrative Transport to Health Plan	The Administrative Transport to Health Plan service collaboration provides the transport mechanism for conducting administrative transactions with health plans
HITSP/T40 – Patient Health Plan Eligibility Verification	The Patient Health Plan Eligibility Verification Transaction is intended to provide the status of a health plan covering the individual, along with details regarding patient liability for deductible, co-pay and co-insurance amounts for a defined base set of generic benefits or services. The base set of benefits includes, but is not limited to, coverage status and patient liability for medical, chiropractic, dental, hospital inpatient, hospital outpatient, emergency, physician office visit, pharmacy and vision services that are included in the patient's generic health plan benefit
HITSP/T42 – Medication Dispensing Status	This Medication Dispensing Status Transaction provides a medication prescriber the dispensing status of an ordered prescription (dispensed, partially dispensed, not dispensed). This Transaction is used for original prescriptions, refills and renewals. It uses the NCPDP SCRIPT Standard Implementation Guide Version 10.1 RXFILL message to provide the status
HITSP/TP43 – Medication Orders	The Medication Orders Transaction Package is used to define transactions between prescribers (who write prescriptions) and dispensers (who fill prescriptions). It is used for new prescriptions, refill requests, prescription change requests and prescription cancellations. Orders/prescriptions may occur in many different real world settings, such as inpatient, long term care and ambulatory settings
HITSP/TP46 – Medication Formulary and Benefits Information	The Medication Formulary and Benefits Information Transaction Package addresses two tasks. The first task is to perform an eligibility check for a specific patient's pharmacy benefits. The second task is to obtain the medication formulary and benefit information

3.2.2.4 SPECIFIED INTERFACES

Table 3-8 HITSP/CAP117 – Communicate Ambulatory and Long Term Care Prescription Specified Interfaces

Interface (Initiating or Responding)	Interface number	Interface Condition	T/TP/SC or Content	T/TP/SC/Content Optionality ¹¹
Medication Order Prescriber	1	R	Medication Order Request (HITSP/TP43)	CAP117-[201]
Medication Dispensing Status Receiver	2	O*	Medication Dispensing Status Query (HITSP/T42)	R
Medication Order Filler	3	R	Medication Order Request (HITSP/TP43)	R

¹¹ Optionality = "R" for Required, "R2" for Required if known, "O" for Optional, or "C" for Conditional. If applicable, conditional footnotes are further described below.



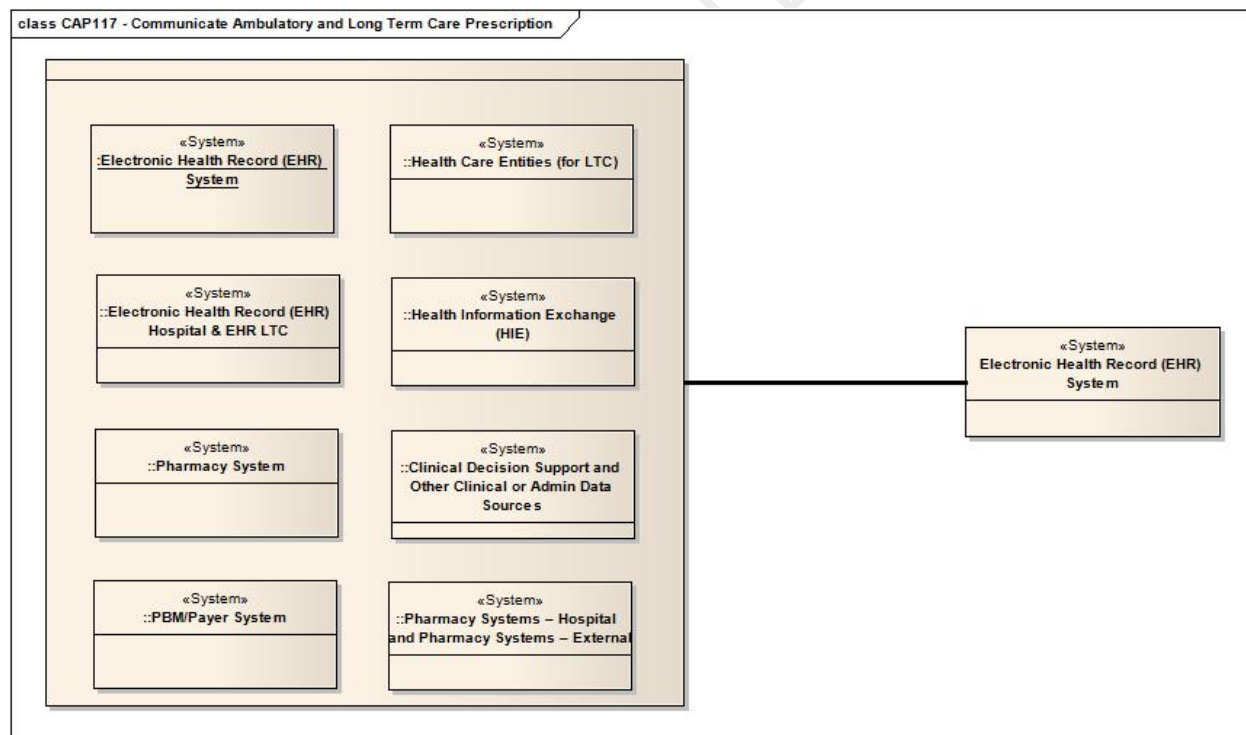
Interface (Initiating or Responding)	Interface number	Interface Condition	T/TP/SC or Content	T/TP/SC/Content Optionality ¹¹
Eligibility Information Receiver	4	R	Patient Generic Health Plan Eligibility Verification (HITSP/T40)	R
Medication Formulary and Benefits Retriever	5	R	Medication Formulary and Benefits Request (HITSP/TP46)	R
Request Administrative Transport to Health Plan	6	R	Administrative Transport (HITSP/SC114)	R
Respond to Administrative Request to Health Plan	7	R	Administrative Transport (HITSP/SC114)	R

Table 3-9 Interface Conditions and T/TP/SC/Content Optionality

Condition Code	Condition Description
CAP117-[201]	The NCPDP transaction method shall be used

The following diagram shows a visual overview of the Capability using UML notation. The visual overview outlines how the interacting systems work together as part of implementing the Capability. The thick arrow in the middle of the diagram outlines how sets of systems can interact together, and represent the information exchange requirement (IER) inherent to the Capability. An IER is not explicitly noted as part of this diagram.

Figure 3-2 HITSP/CAP117 – Communicate Ambulatory and Long Term Care Prescription Visual Overview



3.2.2.5 CAPABILITY OPTIONS

Note that subsets of the data content can be sent as appropriate for the application; but the system must be able to address the entire data content. Note that transport options can be addressed.



3.3 HITSP/CAP118 – COMMUNICATE HOSPITAL PRESCRIPTION SPECIFICATION

3.3.1 OVERVIEW

This capability addresses interoperability requirements that support electronic prescribing for inpatient orders that can occur within an organization or between organizations. The capability supports the transmittal of a new or modified prescription from a Hospital to an internal or external pharmacy. It also includes the optionality to access formulary and benefit information.

Note that support for the formal process of medication reconciliation can be addressed when this Capability is associated with Capability 119 Communicate Structured Document (medications and allergies).

3.3.2 DESIGN SPECIFICATION

3.3.2.1 INTERACTING SYSTEMS

Table 3-10 Interacting Systems

Interacting Systems
Electronic Health Record (EHR)
Electronic Health Record (EHR) – Hospital
Electronic Health Record (EHR) Hospital and EHR LTC
Pharmacy Systems
Pharmacy Systems – Hospital and Pharmacy Systems – External
Clinical Decision Support and Other Clinical or Admin Data Sources
Health Information Exchange (HIE)
PBM/Payers System

3.3.2.2 CONSTRAINTS AND ASSUMPTIONS

This section provides an overview of the constraints (i.e., Assumptions, Pre-conditions, Post-conditions, Triggers) associated with the Capability.

Table 3-11 Constraints and Assumptions

Constraint	Type of Constraint
Health Information Exchange (HIE) can serve as intermediary for data in many implementation variants. The various alternative options are not shown	Assumption
Patient consent for treatment, payment and healthcare operations	Pre-condition
Entities have pre-established a business relationship to exchange information	Pre-condition
Authentication service to authenticate requestors and/or data submissions from various locations	Pre-condition
Security and privacy policies, procedures and practices are commonly implemented to support acceptable levels of consumer/patient security and privacy	Pre-condition
Medication has been dispensed to a patient, or the reason why it was not is provided to the prescribing clinician	Post-Condition



3.3.2.3 LIST OF CONSTRUCTS

Table 3-12 List of Constructs

Construct	Description
HITSP/TP43 Medication Orders	The HITSP Medication Orders Transaction Package is used to define transactions between prescribers (who write prescriptions) and dispensers (who fill prescriptions). It is used for new prescriptions, refill requests, prescription change requests and prescription cancellations. Orders/prescriptions may occur in many different real world settings, such as inpatient, long term care and ambulatory settings
HITSP/T42 Medication Dispensing Status	The HITSP Medication Dispensing Status Transaction provides a medication prescriber the dispensing status of an ordered prescription (dispensed, partially dispensed, not dispensed). This Transaction is used for original prescriptions, refills and renewals. It uses the NCPDP SCRIPT Standard Implementation Guide Version 10.1 RXFILL message to provide the status
HITSP/T40 Patient Health Plan Eligibility Verification	The HITSP Patient Health Plan Eligibility Verification Transaction is intended to provide the status of a health plan covering the individual, along with details regarding patient liability for deductible, co-pay and co-insurance amounts for a defined base set of generic benefits or services. The base set of benefits includes, but is not limited to, coverage status and patient liability for medical, chiropractic, dental, hospital inpatient, hospital outpatient, emergency, physician office visit, pharmacy and vision services that are included in the patient's generic health plan benefit
HITSP/TP46 – Medication Formulary and Benefits Information	The HITSP Medication Formulary and Benefits Information Transaction Package addresses two tasks. The first task is to perform an eligibility check for a specific patient's pharmacy benefits. The second task is to obtain the medication formulary and benefit information
HITSP/SC114 – Administrative Transport to Health Plan	The HITSP Administrative Transport to Health Plan Service Collaboration provides the transport mechanism for conducting administrative transactions with health plans
HITSP/SC115 – HL7 Messaging	The HITSP HL7 Messaging Service Collaboration provides the Capability to send and receive HL7 messages. The Service Collaboration applies the necessary Security and Privacy constructs

3.3.2.4 SPECIFIED INTERFACES

Table 3-13 HITSP/CAP118 – Communicate Hospital Prescription Specified Interfaces

Interface (Initiating or Responding)	Interface number	Interface Condition	T/TP/SC or Content	T/TP/SC/Content Optionality ¹²
Medication Order Prescriber	1	R	Medication Order Request (HITSP/TP43)	CAP118-[201]
Medication Dispensing Status Receiver	2	R	Medication Dispensing Status Query (HITSP/T42)	R
Medication Order Filler	3	R	Medication Order Request (HITSP/TP43)	R
Eligibility Information Receiver	4	R	Patient Generic Health Plan Eligibility Verification (HITSP/T40)	R
Medication Formulary and Benefits Retriever	5	R	Medication Formulary and Benefits Request (HITSP/TP46)	R
Request Administrative Transport to Health Plan	6	R	Administrative Transport to Health Plan (HITSP/SC114)	R
Respond to Administrative Request to Health Plan	7	R	Administrative Transport to Health Plan (HITSP/SC114)	R
Request HL7 Message	8	R	HL7 Messaging (HITSP/SC115)	R
Respond to HL7 Message	9	R	HL7 Messaging (HITSP/SC115)	R

¹² Optionality = "R" for Required, "R2" for Required if known, "O" for Optional, or "C" for Conditional. If applicable, conditional footnotes are further described below.

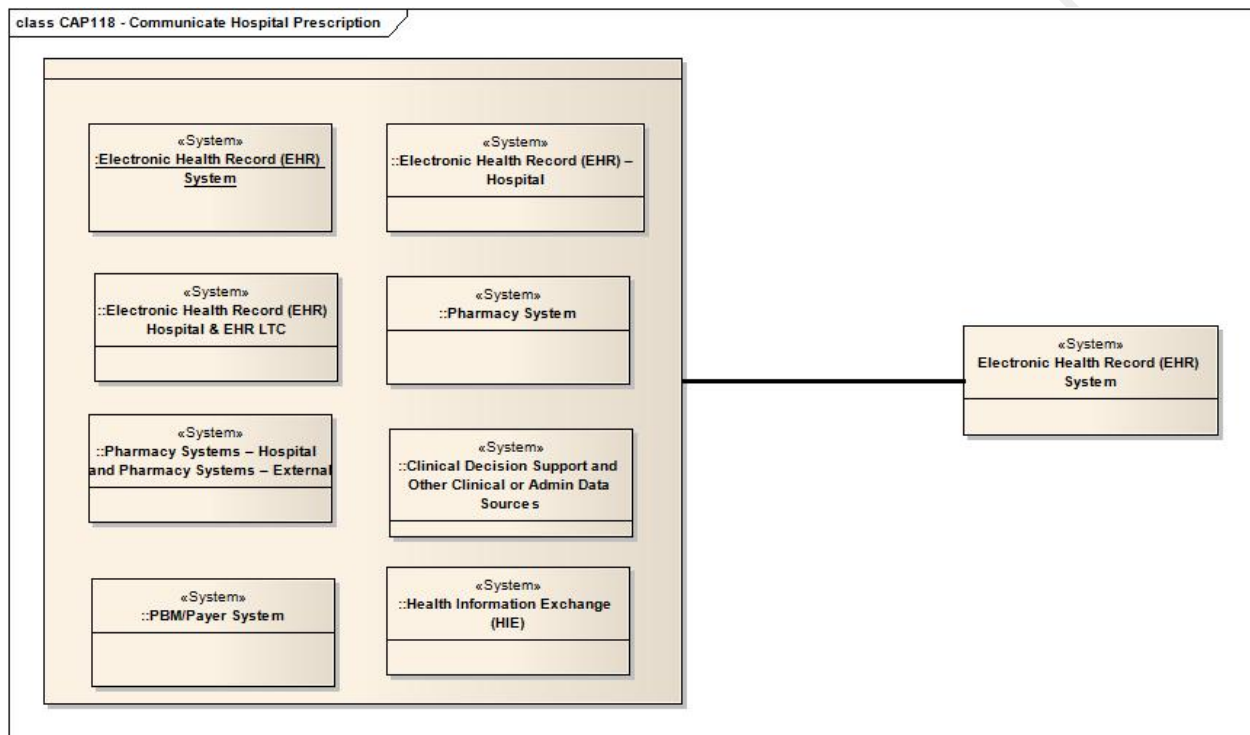


Table 3-14 Interface Conditions and T/TP/SC/Content Optionality

Condition Code	Condition Description
CAP118-[201]	The HL7 transaction method shall be used within the hospital, and the NCPDP transaction method shall be used when communicating with external systems

The following diagram shows a visual overview of the Capability using UML notation. The visual overview outlines how the interacting systems work together as part of implementing the Capability. The thick arrow in the middle of the diagram outlines how sets of systems can interact together, and represent the information exchange requirement (IER) inherent to the Capability. An IER is not explicitly noted as part of this diagram.

Figure 3-3 HITSP/CAP118 – Communicate Hospital Prescription Visual Overview



3.3.2.5 CAPABILITY OPTIONS

Note that subsets of the data content can be sent as appropriate for the application; but the system must be able to address the entire data content. Note that transport options can be addressed.

3.4 HITSP/CAP119 – COMMUNICATE STRUCTURED DOCUMENT SPECIFICATION

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:

- Continuity of Care Document (CCD)
- Emergency Department Encounter Summary
- Discharge Summary (In-patient encounter and/or episodes of care)
- Referral Summary Ambulatory encounter and/or episodes of care
- Consultation Notes



- History and Physical
- Personal Health Device Monitoring Document
- 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.

3.4.1 DESIGN SPECIFICATION

3.4.1.1 INTERACTING SYSTEMS

Table 3-15 Interacting Systems

Interacting Systems
Electronic Health Record (EHR) Systems
Personal Health Record (PHR) Systems
Public Health Information System
Health Information Exchange (HIE) / Regional Health Information Organizations (RHIO)
Laboratory Information Systems
Emergency Communications System
Immunization Information System
Clinical Decision Support System
Quality Measure Processing Entity

3.4.1.2 CONSTRAINTS AND ASSUMPTIONS

This section provides an overview of the constraints (i.e., Assumptions, Pre-conditions, Post-conditions, Triggers) associated with the Capability.

Table 3-16 Constraints and Assumptions

Constraint	Type of Constraint
Systems store patient data as an encounter. A patient has one to many encounters linked into episodes of care. Each encounter holds documents. Each document holds data. This is analogous to each encounter being a report holding many paper document sections and each document section containing many data elements. An episode of care contains many reports on the same incident. The file folder also contains incident information on the same topic (e.g., patient). We assume data are communicated in both document and message forms	Assumption
Ability to identify and request corrections to errors is available	Pre-Condition
Ability to apply notes, corrections and comments on original entries is available	Pre-Condition
Appropriate standards are developed, approved, and widely adopted supporting data content and structure, allowing universal access by compliant systems	Pre-Condition
Core datasets are defined and adhered to	Pre-Condition
Method to query other organizations for data and matching to the consumer is available	Pre-Condition
If physical media is used for the transport, when the media is read the consent directives stored on the portable media need to be enforced by the portable media importer. The validity of these content directives may need to be checked	Post-Condition



3.4.1.3 LIST OF CONSTRUCTS

Table 3-17 List of Constructs

Construct	Description
HITSP/C28 – Emergency Care Summary Document Using IHE Emergency Department Encounter Summary (EDES)	The HITSP Emergency Care Summary Document Using IHE Emergency Department Encounter Summary (EDES) Component is the collection of data from multiple sources (such as physicians, nurses, technologists, etc.) recording the assessments and care delivered by the ED team in response to an ED visit. It is a summary of the patient's current health status and care tendered in the ED between arrival and ED departure. This Component specifies the use of the IHE Emergency Department Encounter Summary (EDES), Technical Framework Supplement, Volume I, Revision 3.0, 2007-2008
HITSP/C32 – Summary Documents Using HL7 Continuity of Care Document (CCD)	The HITSP Summary Documents Using HL7 Continuity of Care Document (CCD) Component describes the document content summarizing a consumer's medical status for the purpose of information exchange. The content may include administrative (e.g., registration, demographics, insurance, etc.) and clinical (problem list, medication list, allergies, test results, etc) information. This Component defines content in order to enable interoperability between participating systems such as Personal Health Record Systems (PHRs), Electronic Health Record Systems (EHRs), Practice Management Applications and others
HITSP/C39 – Encounter Message	The HITSP Encounter Message Component supports the process of sending patient encounter data (excluding laboratory, radiology) from a Biosurveillance Message Sender to a Biosurveillance Message Receiver
HITSP/C48 – Encounter Document Using IHE Medical Summary (XDS-MS)	The HITSP Encounter Document Using IHE Medical Summary (XDS-MS) Component supports the process of sending patient encounter data (excluding laboratory and radiology) in a document sharing functional flow scenario. Patient encounter data are captured as part of the normal process of care performed by healthcare providers, such as hospitals, emergency departments and outpatient clinics
HITSP/C74 – Remote Monitoring Observation Document	The HITSP Remote Monitoring Observation Document Component describes the document content to convey medical information collected by remote monitoring management systems from monitoring devices and/or device intermediaries for the purpose of information exchange. The content may include administrative (e.g., registration, demographics, insurance, etc.) and clinical (results, vital signs, etc) information. This specification defines content in order to promote interoperability between participating systems. Such systems may include Remote Monitoring Management Systems, Personal Health Record Systems (PHRs), Electronic Health Record Systems (EHRs), Health Information Exchange infrastructure services and other persons and systems as identified and permitted
HITSP/C75 – Healthcare Associated Infection (HAI) Report	The HITSP Healthcare Associated Infection (HAI) Report Component specifies a standard for electronic submission of Healthcare Associated Infection (HAI) Reports to the National Healthcare Safety Network (NHSN) of the Centers for Disease Control and Prevention (CDC). HITSP has adopted the HL7 Implementation Guide for CDA Release 2: NHSN Healthcare Associated Infection (HAI) Reports, Release 1 for this construct
HITSP/C78 – Immunization Document	The HITSP Immunization Document Component defines the immunization data content to be exchanged between healthcare entities such as immunization information systems, electronic medical records systems, personal healthcare record systems and other stakeholders. It is based upon the IHE Patient Care Coordination (PCC) Technical Framework Supplement 2008-2009, Immunization Content (IC), Trial Implementation Version 1.0
HITSP/C80 – Clinical Document and Message Terminology	The HITSP Clinical Document and Message Terminology Component defines the vocabularies and terminologies utilized by HITSP specifications for Clinical Documents and Messages used to support the interoperable transmission of information
HITSP/C83 – CDA Content Modules	The HITSP CDA Content Modules Component defines the content modules for document based HITSP constructs utilizing clinical information. These Content modules are based on IHE PCC Technical Framework Volume II, Release 4. That technical framework contains specifications for document sections that are consistent with all implementation guides for clinical documents currently selected for HITSP constructs
HITSP/C84 – Consult and History & Physical Note	The HITSP Consult and History & Physical Note Component supports two types of commonly used clinical notes, a consult note, and a history and physical note. It is intended for use to support the exchange of information from a consulting provider to a referring provider; and may also be used to provide background information from a referring provider to a consulting provider (e.g., prior reports)
HITSP/SC112 – Healthcare Document Management	The HITSP Healthcare Document Management Service Collaboration provides the ability to share healthcare documents using a set of topologies, such as Media, e-Mail, Point-to-Point, Shared within a Health Information Exchange, and Shared within a larger community (made up of potentially diverse Health Information Exchanges)



3.4.1.4 SPECIFIED INTERFACES

Table 3-18 HITSP/CAP119 – Communicate Structured Document Specified Interfaces

Interface (Initiating or Responding)	Interface number	Interface Condition	T/TP/SC or Content	T/TP/SC/Content Optionality ¹³
Content Creator	1	R	Creator-Registration Subset (see Section 3.4.1.5.1)(HITSP/C32)	CAP119-[201]
			Creator-Registration-Coded Subset (see Section 3.4.1.5.2)(HITSP/C32)	CAP119-[201]
			Creator-Medication and Immunization History Subset (see Section 3.4.1.5.3)(HITSP/C32)	CAP119-[201]
			Creator-Medication and Immunization History – Coded Subset (see Section 3.4.1.5.4)(HITSP/C32)	CAP119-[201]
			Creator-Conditions and Allergy Subset (see Section 3.4.1.5.5)(HITSP/C32)	CAP119-[201]
			Creator-Conditions and Allergy -Coded Subset (see Section 3.4.1.5.6)(HITSP/C32)	CAP119-[201]
			Creator-Laboratory Section Subset (see Section 3.4.1.5.7)(HITSP/C32)	CAP119-[201]
			Creator-Laboratory Section -Coded Subset (see Section 3.4.1.5.8)(HITSP/C32)	CAP119-[201]
			Creator-Medication and Allergies Subset (See Section 3.4.1.5.9) (HITSP/C32)	CAP119-[201]
			Encounter Document Using IHE Medical Summary (XDS-MS) Component(HITSP/C48)	CAP119 -[201]
			Structured Family History Creator-Structured Family History subset (see Section 3.4.1.5.10)(HITSP/C48)	CAP119-[201]
			Emergency Department Encounter(HITSP/C28)	CAP119-[201], [202]
			Consult and History & Physical Note(HITSP/C84)	CAP119-[201]
			Structured Family History – Content Creator (See Section 3.4.1.5.11)(HITSP/C84)	CAP119-[201]
			Remote Monitoring Observation Document(HITSP/C74)	CAP119-[201]
			Adverse Event Reports: CDC – Healthcare Associated Infection Reporting (HITSP/C75)	CAP119-[201]
Content Consumer	2	R	Clinical Document and Message Terminology(HITSP/C80)	R
			CDA Content Modules (HITSP/C83)	R
			Consumer-Document Display)(HITSP/C32)	R
			Consumer-Document Import (HITSP/C32)	CAP119-[203]
			Consumer-Registration Discrete Data Import (HITSP/C32)	CAP119-[203]
			Consumer-Medication and Immunization History Discrete Data Import Subset (see Section 3.4.1.5.12)(HITSP/C32)	O
			Consumer-Conditions and Allergy Discrete Data Import Subset (see Section 3.4.1.5.13)(HITSP/C32)	O
			Consumer-Medication and Allergies Information Import Subset (See Section 3.4.1.5.14)(HITSP/C32)	O
			Structured Family History Consumer-Document Import Subset (see Section 3.4.1.5.15)(HITSP/C32)	O

¹³ Optionality = “R” for Required, “R2” for Required if known, “O” for Optional, or “C” for Conditional. If applicable, conditional footnotes are further described below.



Interface (Initiating or Responding)	Interface number	Interface Condition	T/TP/SC or Content	T/TP/SC/Content Optionality ¹³
			Structured Family History Consumer-Document Discrete Data Import (see Section 3.4.1.5.16)(HITSP/C32)	O
			Consumer-Document Display (HITSP/C28)	R
			Consumer-Document Import (HITSP/C28)	CAP119-[203]
			Consumer-Document Discrete Data Import HITSP/C28)	CAP119-[203]
			Consumer-Document Display (HITSP/C48)	R
			Consumer-Document Import (HITSP/C48)	CAP119-[203]
			Consumer-Document Discrete Data Import(HITSP/C48)	CAP119-[203]
			Structured Family History Consumer-Document Import (see Section 3.4.1.5.17)(HITSP/C48)	O
			Structured Family History Consumer-Document Discrete Data Import Subset (See Section 3.4.1.5.18)(HITSP/C48)	O
			Consumer-Document Display(HITSP/C84)	R
			Consumer-Document Import(HITSP/C84)	CAP119-[203]
			Consumer-Document Discrete Data Import(HITSP/C84)	CAP119-[203]
			Structured Family History Consumer-Document Import Subset (see Section 3.4.1.5.19)(HITSP/C84)	O
			Structured Family History Consumer-Document Discrete Data Import Subset (see Section 3.4.1.5.20)(HITSP/C84)	O
			Consumer-Document Display (HITSP/C74)	R
			Consumer-Document Import (HITSP/C74)	CAP119-[203]
			Consumer-Document Discrete Data Import (HITSP/C74)	CAP119-[203]
			Consumer-Document Display (HITSP/C78)	R
			Consumer-Document Import (HITSP/C78)	CAP119-[203]
			Consumer-Document Discrete Data Import (HITSP/C78)	CAP119-[203]
Send Documents	3	CAP119-[101], [102]	Healthcare Document Management (HITSP/SC112)	R
Receive Documents	4	CAP119-[101]	Healthcare Document Management (HITSP/SC112)	R

Table 3-19 Interface Conditions and T/TP/SC/Content Optionality

Condition Code	Condition Description
CAP119-[101]	An implementation shall choose amongst one of the interfaces defined in HITSP/SC112 Healthcare Document Management. This choice is dependent on the topology chosen (See Table 3-1 Information Exchange Topologies Mapped to Capabilities above), the physical limitations, policies and processes of the implementation
CAP119-[102]	The EHR System may optionally choose to implement a Document Repository or use an external repository for the Send Documents through Share option of HITSP/SC112 Healthcare Document Management

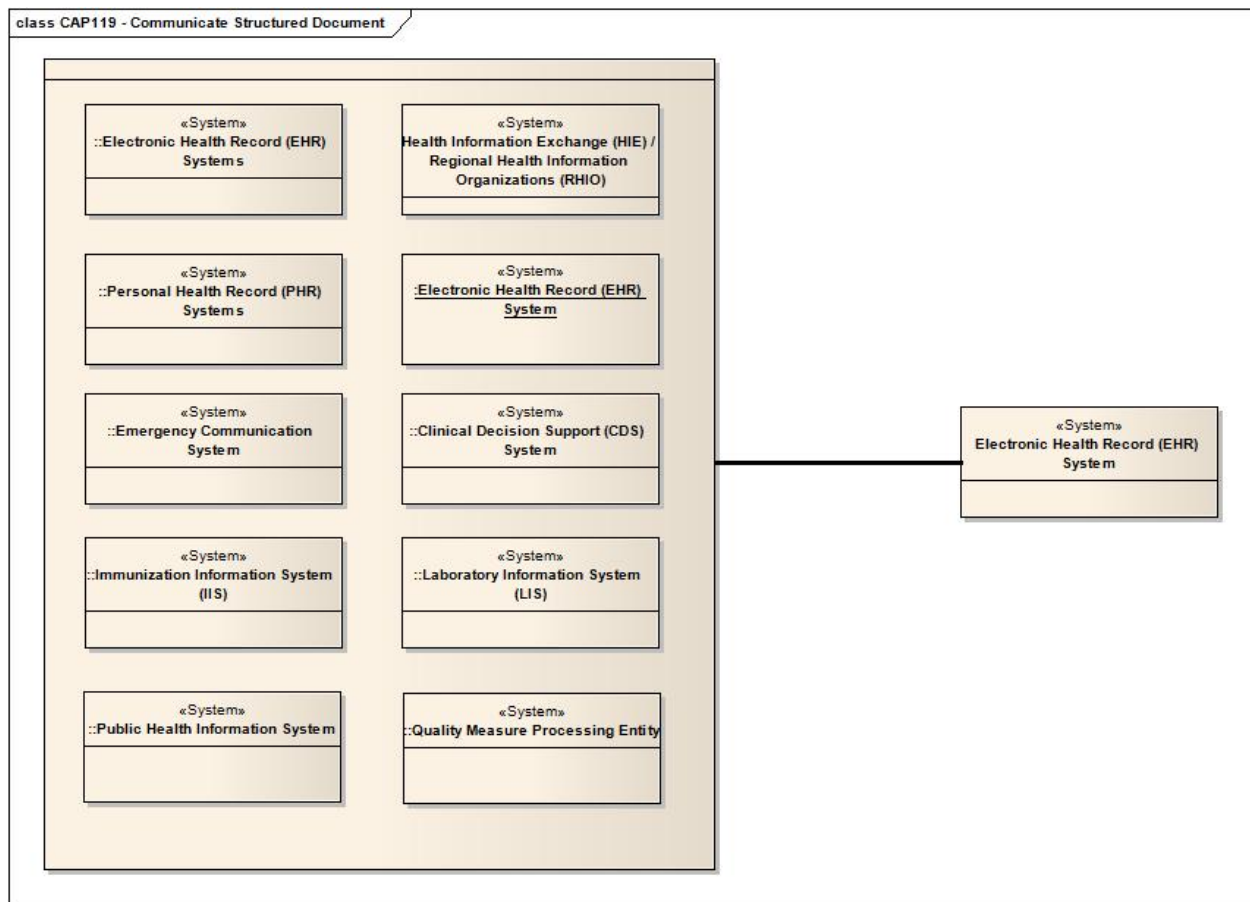


Condition Code	Condition Description
CAP119-[201]	Shall support either at least one of the subsets of the HITSP/C32 – Summary Documents Using HL7 Continuity of Care Document (CCD), HITSP/C37 – Lab Report Document, the entire document or at least one of the subsets of HITSP/C48 – Encounter Document Using IHE Medical Summary (XDS-MS), HITSP/C28 – Emergency Department Encounter, the entire document or at least one of the subsets of HITSP/C84 – Consult and History & Physical Note, HITSP/C74 – Remote Monitoring Observation Document, HITSP/C75 – Adverse Event Reports: CDC – Healthcare Associated Infection Reporting Document, or any combination of the these constructs
CAP119-[202]	Shall be supported if the EHR is used by an emergency department
CAP119-[203]	<p>The Content Consumer should minimally Display the content received in the specified CDA document (i.e. HITSP/C32, HITSP/C28, HITSP/C48, HITSP/C74, HITSP/C78, and HITSP/C84). Optionally, the Content Consumer may support one or both of the following functions:</p> <ul style="list-style-type: none"> • Consumer-Document Import [Requires the Content Consumer to have the ability to import the CDA document into the patient record as a whole and display it as requested] • Consumer-Discrete Data Import [Requires the Content Consumer to have the ability to import the discrete data from one or more of the data section entries in a structured form into the patient record. Coded values shall be maintained.] <p>The specific data sections which have been described in HITSP documents which can be optionally supported have been identified as Discrete Data Import subsets.</p>

The following diagram shows a visual overview of the Capability using UML notation. The visual overview outlines how the interacting systems work together as part of implementing the Capability. The thick arrow in the middle of the diagram outlines how sets of systems can interact together, and represent the information exchange requirement (IER) inherent to the Capability. An IER is not explicitly noted as part of this diagram.



Figure 3-4 HITSP/CAP119 – Communicate Structured Document Visual Overview



3.4.1.5 CAPABILITY OPTIONS

Note that subsets of the data content can be sent as appropriate for the application; but the system must be able to address the entire data content. Note that transport options can be addressed.

3.4.1.5.1 HITSP/C32 “Creator-Registration Subset”

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



Table 3-20 Creator Registration Subset Content Modules

Content Modules	Optionality ¹⁴
Advance Directive	R2
Comments	R2
Healthcare Provider	R2
Information Source	R2
Insurance Provider	R2
Language Spoken	R2
Person Information	R
Pregnancy	R2
Support	R2

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

The Support content module includes emergency contact information when available.

The type of payer and type of payer entries contain the concepts but without the HITSP/C32 specified code set.

3.4.1.5.2 HITSP/C32 "Creator-Registration-Coded Subset"

This subset is identical to the Creator-Registration Subset but requires the creation of type of payer and type of payer entries with the HITSP/C32 specified code set.

3.4.1.5.3 HITSP/C32 "Creator-Medication and Immunization History Subset"

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

Table 3-21 Creator Medication and Immunization History Subset Content Modules

Content Modules	Optionality ¹⁵
Comments	R2
Healthcare Provider	R2
Immunization	R2
Information Source	R2
Medications – Prescription and Non-Prescription	R2
Person Information	R

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

¹⁴ Optionality = "R" for Required, "R2" for Required if known, "O" for Optional, or "C" for Conditional. If applicable, conditional footnotes are further described below.

¹⁵ Optionality = "R" for Required, "R2" for Required if known, "O" for Optional, or "C" for Conditional. If applicable, conditional footnotes are further described below.



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

3.4.1.5.4 HITSP/C32 “Creator-Medication and Immunization History-Coded Subset”

This subset is identical to the Creator-Medication Subset but requires the creation of medication entries with the HITSP/C32 specified code sets.

3.4.1.5.5 HITSP/C32 “Creator-Conditions and Allergy Subset”

This subset impacts the content of the HITSP/C32 Summary Documents Using HL7 Continuity of Care Document (CCD) document produced by a Content Creator Interface. It requires the Content Creator to have the ability to create the content for the purpose of exchange as specified in the HITSP/C32 construct:

Table 3-22 Creator Conditions and Allergy Subset Content Modules

Content Modules	Optionality ¹⁶
Allergies and Drug Sensitivity	R2
Comments	R2
Condition	R2
Healthcare Provider	R2
Information Source	R2
Person Information	R

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

The Condition and Allergy entries contain the concepts but without the HITSP/C32 specified code set.

3.4.1.5.6 HITSP/C32 “Creator-Conditions and Allergy-Coded Subset”

This subset is identical to the Creator-Registration Subset but requires the creation of conditions and allergies entries with the HITSP/C32 specified code set.

3.4.1.5.7 HITSP/C32 “Creator-Laboratory Section Subset”

This subset impacts the content of the HITSP/C32 Summary Documents Using HL7 Continuity of Care Document (CCD) document produced by a Content Creator Interface. It requires the Content Creator to have the ability to create the content for the purpose of exchange as specified in the HITSP/C32 construct:

Table 3-23 Creator Laboratory Subset Content Modules

Content Modules	Optionality ¹⁷
Comments	R2
Healthcare Provider	R2
Information Source	R2
Person Information	R
Result	R2

¹⁶ Optionality = “R” for Required, “R2” for Required if known, “O” for Optional, or “C” for Conditional. If applicable, conditional footnotes are further described below.

¹⁷ Optionality = “R” for Required, “R2” for Required if known, “O” for Optional, or “C” for Conditional. If applicable, conditional footnotes are further described below.



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

The Result entries contain the concepts but without the HITSP/C32 specified code set.

3.4.1.5.8 HITSP/C32 "Creator-Laboratory Section-Coded Subset"

This subset is identical to the Creator-Laboratory Section Subset but requires the creation of laboratory results entries with the HITSP/C32 specified code set.

3.4.1.5.9 HITSP/C32 "Creator-Medication and Allergies Information Coded Subset"

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

Table 3-24 Creator Medication and Allergies Information Subset Content Modules

Content Modules	Optionality ¹⁸
Person Information	R
Medications – Prescription and Non-Prescription	R
Allergies and Drug Sensitivity	R
Healthcare Provider	R2
Insurance Provider	R2
Information Source	R2
Conditions	R2
Comments	R2

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

3.4.1.5.10 HITSP/C48 "Structured Family History Creator-Structured Family History Subset"

These documents **shall** contain data sections conforming to the requirements specified for the following CDA content modules in HITSP/C83 CDA Content Modules:

Table 3-25 Structured Family History Creator-Structured Family History Subset Content Modules

Content Modules	Optionality ¹⁹
Family History	R
Allergies and Adverse Reactions	R
Active Problems	R
History of Past Illness	R
Diagnostic Results	R

¹⁸ Optionality = "R" for Required, "R2" for Required if known, "O" for Optional, or "C" for Conditional. If applicable, conditional footnotes are further described below.

¹⁹ Optionality = "R" for Required, "R2" for Required if known, "O" for Optional, or "C" for Conditional. If applicable, conditional footnotes are further described below.



3.4.1.5.11 HITSP/C84 “Structured Family History – Content Creator Subset”

These documents **shall** contain data sections conforming to the requirements specified for the following CDA content modules in HITSP/C83 CDA Content Modules:

Table 3-26 Structured Family History – Content Creator Subset Content Modules

Content Modules	Optionality ²⁰
Family History	R
Allergies and Adverse Reactions	R
Active Problems	R
History of Past Illness	R
Diagnostic Results	R

3.4.1.5.12 HITSP/C32 “Consumer-Medication and Immunization History Discrete Data Import Subset”

This subset impacts the import of the HITSP/C32 Summary Documents Using HL7 Continuity of Care Document (CCD) document processed by a Content Consumer Interface. It requires the Document Consumer to have the ability to import the discrete data from one or more of the medication and immunization history entries in a structured form into the patient record. Coded values shall be maintained.

3.4.1.5.13 HITSP/C32 “Consumer-Conditions and Allergy Discrete Data Import Subset”

This subset impacts the import of the HITSP/C32 Summary Documents using HL7 Continuity of Care Document (CCD) document processed by a Content Consumer Interface. It requires the Document Consumer to have the ability to import the discrete data from one or more of the conditions and allergy entries in a structured form into the patient record. Coded values shall be maintained.

3.4.1.5.14 HITSP/C32 “Consumer-Medication and Allergies Import Subset”

This subset impacts the import of Documents processed by a Content Consumer Interface. It requires the Document Consumer to have the ability to import into the patient record the medication and allergies modules of HITSP/C32 as a whole and display it as requested.

3.4.1.5.15 HITSP/C32 “Structured Family History Consumer-Document Import Subset”

This subset impacts the import of Documents processed by a Content Consumer Interface. It requires the Document Consumer to have the ability to import into patient record the HITSP/C32 containing structured family history as a whole and display it as requested.

3.4.1.5.16 HITSP/C32 “Structured Family History Consumer-Document Discrete Data Import Subset”

This subset impacts the import of the HITSP/C32 Summary Documents Using HL7 Continuity of Care Document (CCD) document processed by a Content Consumer Interface. It requires the Document Consumer to have the ability to import the discrete data from one or more of the structured family history entries in a structured form into the patient record. Coded values shall be maintained.

²⁰ Optionality = “R” for Required, “R2” for Required if known, “O” for Optional, or “C” for Conditional. If applicable, conditional footnotes are further described below.



3.4.1.5.17 HITSP/C48 “Structured Family History Consumer-Document Import Subset”

This subset impacts the import of Documents processed by a Content Consumer Interface. It requires the Document Consumer to have the ability to import into patient record the HITSP/C48 Encounter Document Using IHE Medical Summary (XDS-MS) containing structured family history as a whole and display it as requested.

3.4.1.5.18 HITSP/C48 “Structured Family History Consumer-Document Discrete Data Import Subset”

This subset impacts the import of the HITSP/C48 – Encounter Document Using IHE Medical Summary (XDS-MS) document processed by a Content Consumer Interface. It requires the Document Consumer to have the ability to import the discrete data from one or more of the structured family history entries in a structured form into the patient record. Coded values shall be maintained.

3.4.1.5.19 HITSP/C84 “Structured Family History Consumer-Document Import Subset”

This subset impacts the import of Documents processed by a Content Consumer Interface. It requires the Document Consumer to have the ability to import into patient record the HITSP/C84 Consult and History & Physical Note containing structured family history as a whole and display it as requested.

3.4.1.5.20 HITSP/C84 “Structured Family History Consumer-Document Discrete Data Import Subset”

This subset impacts the import of the HITSP/C84 Consult and History & Physical Note document processed by a Content Consumer Interface. It requires the Document Consumer to have the ability to import the discrete data from one or more of the structured family history entries in a structured form into the patient record. Coded values shall be maintained.

Document Consumer only have the ability to display HITSP/C74 Remote Monitoring Observation Document, as requested (it may not be able to locally import it in the patient record).

3.5 HITSP/CAP120 – COMMUNICATE UNSTRUCTURED DOCUMENT SPECIFICATION

3.5.1 OVERVIEW

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



3.5.2 DESIGN SPECIFICATION

3.5.2.1 INTERACTING SYSTEMS

Table 3-27 Interacting Systems

Interacting Systems
Electronic Health Record (EHR) Systems
Personal Health Record (PHR) Systems
Patient Identifier Service
Public Health Information System
Health Information Exchange (HIE)
Immunization Information System (IIS)
Laboratory Information Systems
Emergency Communications System

3.5.2.2 CONSTRAINTS AND ASSUMPTIONS

This section provides an overview of the constraints (i.e., Assumptions, Pre-conditions, Post-conditions, Triggers) associated with the Capability.

Table 3-28 Constraints and Assumptions

Constraint	Type of Constraint
Systems store patient data as an encounter. A patient has one to many encounters linked into episodes of care. Each encounter holds documents. Each document holds data. This is analogous to each encounter being a report holding many paper document sections and each document section containing many data pieces. An episode of care contains many reports on the same incident. The file folder also contains incident information on the same topic (e.g., patient). We assume data are communicated in both document and message forms	Assumption
Ability to identify and request corrections to errors is available	Pre-Condition
Ability to apply notes, corrections and comments on original entries is available	Pre-Condition
Appropriate standards are developed, approved, and widely adopted supporting data content and structure, allowing universal access by compliant systems	Pre-Condition
Core datasets are defined and adhered to	Pre-Condition
Method to query other organizations for data and matching to the consumer is available	Pre-Condition
If physical media is used for the transport, when the media is read the consent directives stored on the portable media need to be enforced by the portable media importer. The validity of these content directives may need to be checked	Post-Condition

3.5.2.3 LIST OF CONSTRUCTS

Table 3-29 List of Constructs

Construct	Description
HITSP/C62 – Unstructured Document	The HITSP Unstructured Document Component is provided for the capture and storage of patient identifiable, unstructured document content, such as text, PDF, and images rendered in PDF. It is based on the Cross-Enterprise Sharing of Scanned Documents (XDS-SD) profile from the Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF)
HITSP/SC112 – Healthcare Document Management	The HITSP Healthcare Document Management Service Collaboration provides the ability to share healthcare documents using a set of topologies, such as Media, e-Mail, Point-to-Point, Shared within a Health Information Exchange, and Shared within a larger community (made up of potentially diverse Health Information Exchanges)



3.5.2.4 SPECIFIED INTERFACES

Table 3-30 HITSP/CAP120 – Communicate Unstructured Document Specified Interfaces

Interface (Initiating or Responding)	Interface number	Interface Condition	T/TP/SC or Content	T/TP/SC/Content Optionality ²¹
Content Creator	1	R	Unstructured Document(HITSP/C62)	R
Content Consumer	2	R	Consumer-Document Display (HITSP/C62)	R
			Consumer-Document Import(HITSP/C62)	CAP120-[201]
Send Documents	3	CAP120- [101],[102]	Healthcare Document Management (HITSP/SC112)	R
Receive Documents	4	CAP120- [101]	Healthcare Document Management (HITSP/SC112)	R

Table 3-31 Interface Conditions and T/TP/SC/Content Optionality

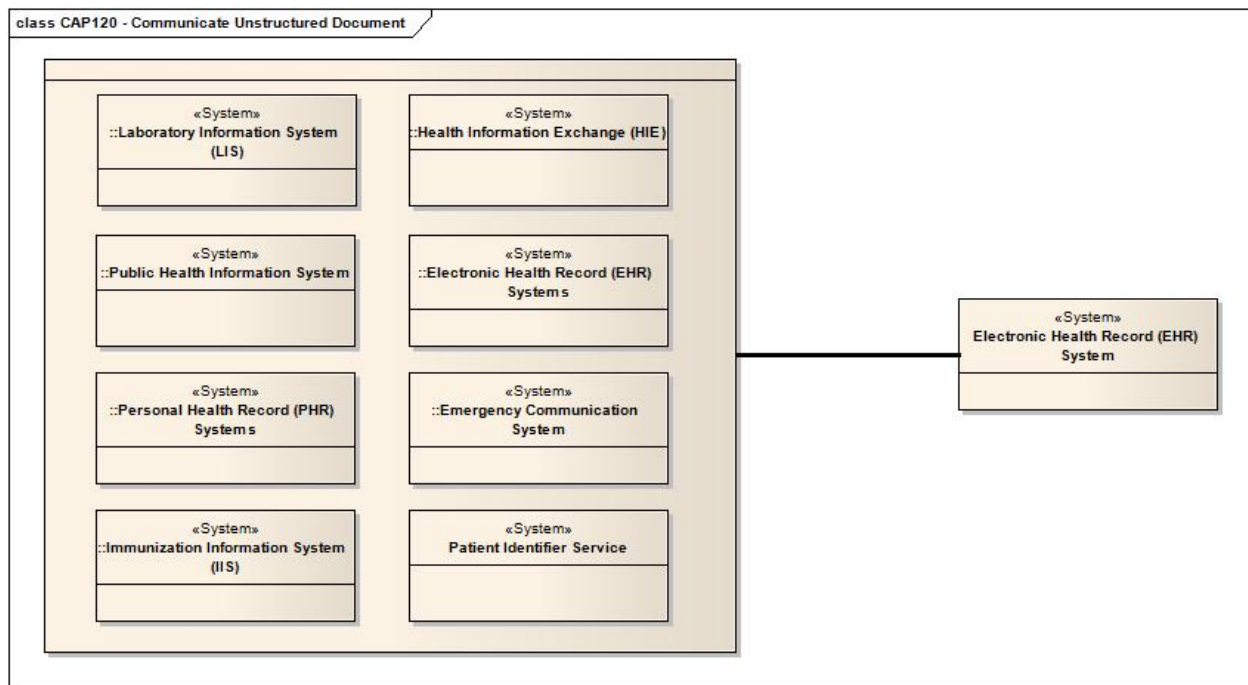
Condition Code	Condition Description
CAP120-[101]	An implementation shall choose amongst one of the interfaces defined HITSP/SC112 Healthcare Document Management. This choice is dependent on the topology chosen (See Table 3-1 Information Exchange Topologies Mapped to Capabilities above), the physical limitations, policies and processes of the implementation
CAP120-[102]	The EHR System may optionally choose to implement a Document Repository or use an external repository for the Send Documents through Share option of HITSP/SC112 Healthcare Document Management
CAP120-[201]	The Content Consumer should minimally Display the content received in the specified CDA document (i.e. HITSP/C62). Optionally, the Content Consumer may the following function: <ul style="list-style-type: none"> Consumer-Document Import [Requires the Content Consumer to have the ability to import the CDA document into the patient record as a whole and display it as requested]

The following diagram shows a visual overview of the Capability using UML notation. The visual overview outlines how the interacting systems work together as part of implementing the Capability. The thick arrow in the middle of the diagram outlines how sets of systems can interact together, and represent the information exchange requirement (IER) inherent to the Capability. An IER is not explicitly noted as part of this diagram.

²¹ Optionality = “R” for Required, “R2” for Required if known, “O” for Optional, or “C” for Conditional. If applicable, conditional footnotes are further described below.



Figure 3-5 HITSP/CAP120 – Communicate Unstructured Document Visual Overview



3.5.2.5 CAPABILITY OPTIONS

Note that subsets of the data content can be sent as appropriate for the application; but the system must be able to address the entire data content. Note that transport options can be addressed.

3.6 HITSP/CAP121 – COMMUNICATE CLINICAL REFERRAL REQUEST SPECIFICATION

3.6.1 OVERVIEW

This Capability addresses interoperability requirements that support provider-to-provider (clinical) referral request interaction. It allows the bundling of the referral request document with other relevant clinical documents of interest by referencing such documents as shared by other capabilities such as:

HITSP/CAP119 Communicate Structured Document; HITSP/CAP120 Communicate Unstructured Document; or HITSP/CAP133 Communicate Immunization Summary.

3.6.2 DESIGN SPECIFICATION

3.6.2.1 INTERACTING SYSTEMS

Table 3-32 Interacting Systems

Interacting Systems
Electronic Health Record System
Health Information Exchange(HIE)

3.6.2.2 CONSTRAINTS AND ASSUMPTIONS

This section provides an overview of the constraints (i.e., Assumptions, Pre-conditions, Post-conditions, Triggers) associated with the Capability.



Table 3-33 Constraints and Assumptions

Constraint	Type of Constraint
No Applicable Constraints	

3.6.2.3 LIST OF CONSTRUCTS

Table 3-34 List of Constructs

Construct	Description
HITSP/SC112 – Healthcare Document Management	The HITSP Healthcare Document Management Service Collaboration provides the ability to share healthcare documents using a set of topologies, such as Media, e-Mail, Point-to-Point, Shared within a Health Information Exchange, and Shared within a larger community (made up of potentially diverse Health Information Exchanges)
HITSP/SC115 – HL7 Messaging	The HITSP HL7 Messaging Service Collaboration provides the Capability to send and receive HL7 messages. The Service Collaboration applies the necessary Security and Privacy constructs
HITSP/T67 – Clinical Referral Request Transport	The HITSP Clinical Referral Request Transport Transaction will be used to transport the provider to provider (clinical) referral request interaction. It is based on the IHE Document-based Referral Request (DRR) profile which is used to bundle a referral request document with other relevant clinical documents of interest and optionally to send a trigger message to the receiving provider system

3.6.2.4 SPECIFIED INTERFACES

Table 3-35 HITSP/CAP121 – Communicate Clinical Referral Request Specified Interfaces

Interface (Initiating or Responding)	Interface number	Interface Condition	T/TP/SC or Content	T/TP/SC/Content Optionality ²²
Receive Documents	1	R	Healthcare Document Management (HITSP/SC112)	R
Referral Dispatcher	2	R	Convey/Request Referral (HITSP/T67)	R
Referral Requestor	3	R	Convey/Request Referral (HITSP/T67)	R
Request HL7 Message	4	R	HL7 Messaging (HITSP/SC115)	R
Respond to HL7 Message	5	R	HL7 Messaging (HITSP/SC115)	R
Send Documents	6	CAP121-[101], [102]	Healthcare Document Management (HITSP/SC112)	R

Table 3-36 Interface Conditions and T/TP/SC/Content Optionality

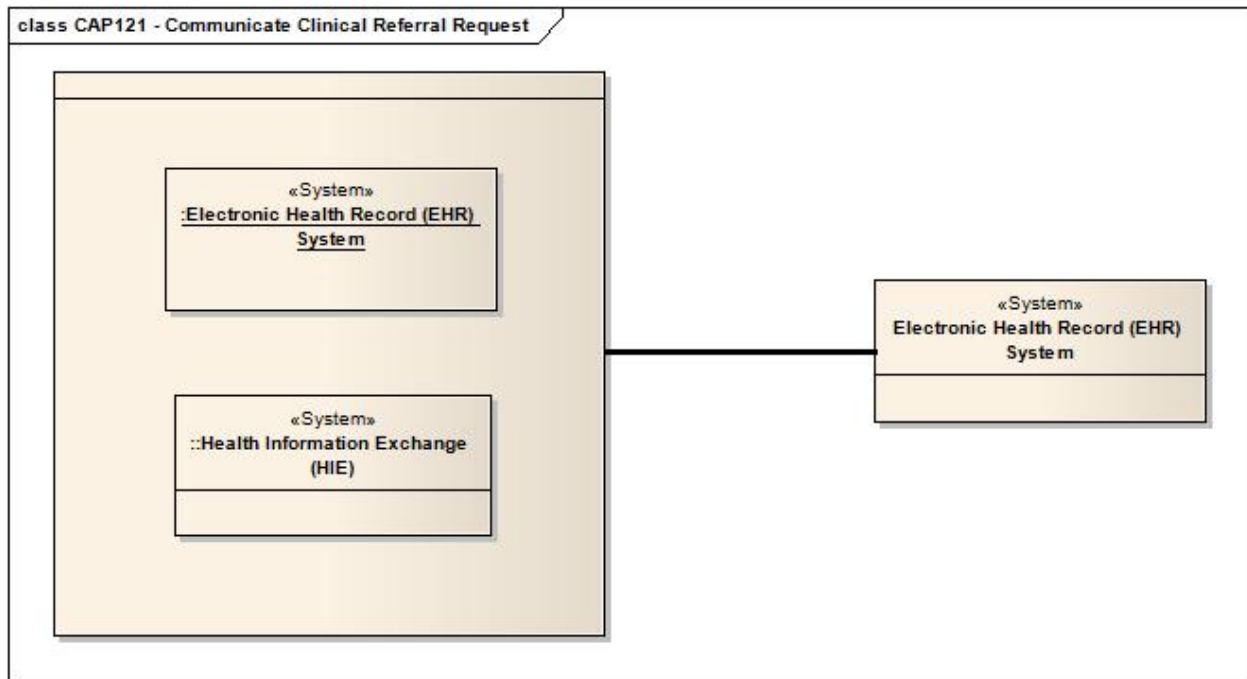
Condition Code	Condition Description
CAP121-[101]	An implementation shall choose amongst one of the interfaces defined in HITSP/SC112 Healthcare Document Management. This choice is dependent on the topology chosen (See Table 3-1 Information Exchange Topologies Mapped to Capabilities above), the physical limitations, policies and processes of the implementation
CAP121-[102]	The EHR System may optionally choose to implement a Document Repository or use an external repository for the Send Documents through Share option of HITSP/SC112 Healthcare Document Management

The following diagram shows a visual overview of the Capability using UML notation. The visual overview outlines how the interacting systems work together as part of implementing the Capability. The thick arrow in the middle of the diagram outlines how sets of systems can interact together, and represent the information exchange requirement (IER) inherent to the Capability. An IER is not explicitly noted as part of this diagram.

²² Optionality = “R” for Required, “R2” for Required if known, “O” for Optional, or “C” for Conditional. If applicable, conditional footnotes are further described below.



Figure 3-6 HITSP/CAP121 – Communicate Clinical Referral Request Visual Overview



3.6.2.5 CAPABILITY OPTIONS

Note that subsets of the data content can be sent as appropriate for the application; but the system must be able to address the entire data content. Note that transport options can be addressed.

3.7 HITSP/CAP122 – RETRIEVE MEDICAL KNOWLEDGE SPECIFICATION

3.7.1 OVERVIEW

This Capability addresses the requirements to retrieve medical knowledge that is not patient-specific based on context parameters. The actual content delivered is not constrained by this Capability; this Capability focuses on providing the mechanism to ask for (query) and receive the medical knowledge.

3.7.2 DESIGN SPECIFICATION

3.7.2.1 INTERACTING SYSTEMS

Table 3-37 Interacting Systems

Interacting Systems
Clinical Information System
Laboratory Information System
Radiology Information System
Personal Health Record (PHR) Service Provider
Knowledge Resource System
Electronic Health Record (EHR) System
Health Information Exchange (HIE) (Knowledge Resource System)
Quality Measure Processing Entity
Performance Measurement Information Resource (Knowledge Resource System)



3.7.2.2 CONSTRAINTS AND ASSUMPTIONS

This section provides an overview of the constraints (i.e., Assumptions, Pre-conditions, Post-conditions, Triggers) associated with the Capability.

Table 3-38 Constraints and Assumptions

Constraint	Type of Constraint
The context-specific parameters regarding the request for medical knowledge may include consumer knowledge level, preferred language, consumer demographics (gender, age), document type (laboratory results, radiology reports). If these parameters are known, these could be used to tailor the response and the medical knowledge returned	Assumption
A user-friendly error message is displayed in the event of query failure	Post-Condition
Automatic request: Based upon predefined parameters, the requesting system may initiate, a request for medical knowledge from the Knowledge Resource	Process Trigger
Manual request: The user may initiate a request for medical knowledge from the Knowledge Resource	Process Trigger

3.7.2.3 LIST OF CONSTRUCTS

Table 3-39 List of Constructs

Construct	Description
HITSP/SC111 – Knowledge and Vocabulary	The HITSP Knowledge and Vocabulary Service Collaboration provides the ability to retrieve medical knowledge and terminology

3.7.2.4 SPECIFIED INTERFACES

Table 3-40 HITSP/CAP122 – Retrieve Medical Knowledge Specified Interfaces

Interface (Initiating or Responding)	Interface number	Interface Condition	T/TP/SC or Content	T/TP/SC/Content Optionality ²³
Request Medical Knowledge	1	R	Knowledge and Vocabulary (HITSP/SC111)	R
Respond Medical Knowledge	2	R	Knowledge and Vocabulary (HITSP/SC111)	R
Request Value Set	3	R	Knowledge and Vocabulary (HITSP/SC111)	R
Respond Value Set	4	O	Knowledge and Vocabulary (HITSP/SC111)	R

Table 3-41 Interface Conditions and T/TP/SC/Content Optionality

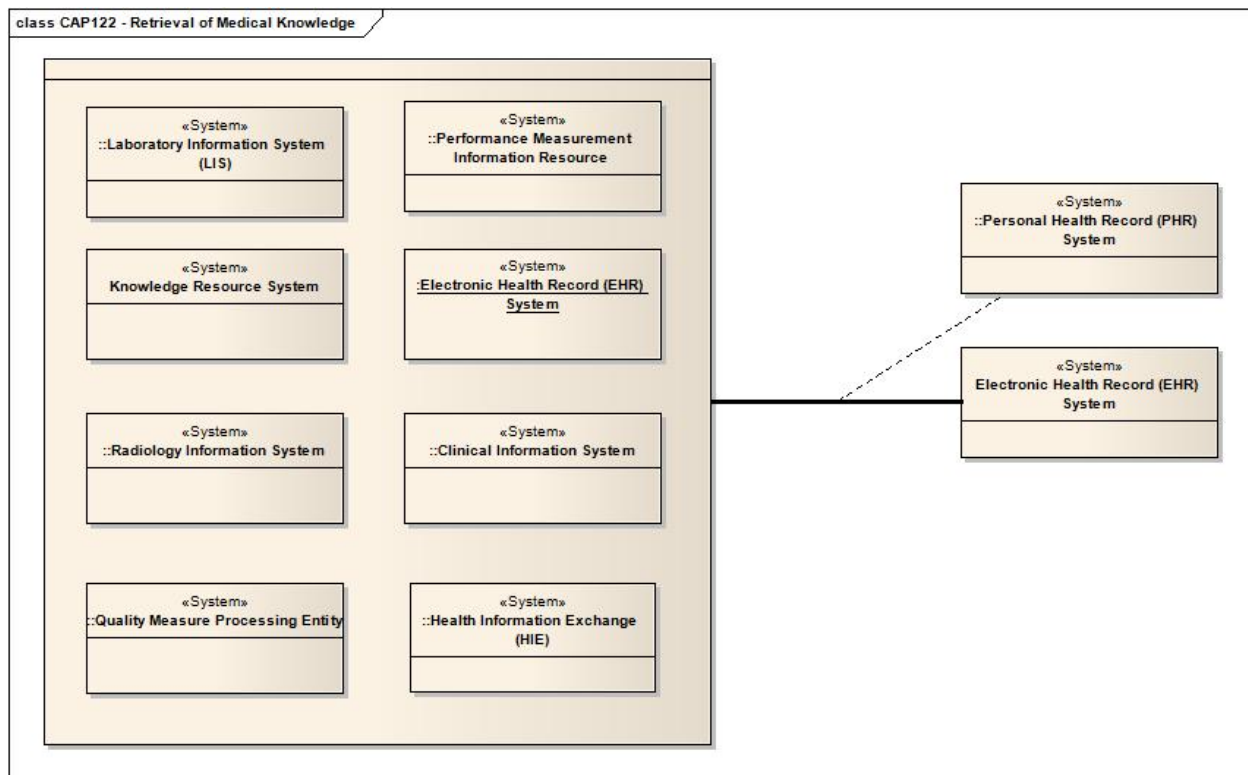
Condition Code	Condition Description
No Applicable Condition Codes	

The following diagram shows a visual overview of the Capability using UML notation. The visual overview outlines how the interacting systems work together as part of implementing the Capability. The thick arrow in the middle of the diagram outlines how sets of systems can interact together, and represent the information exchange requirement (IER) inherent to the Capability. An IER is not explicitly noted as part of this diagram.

²³ Optionality = “R” for Required, “R2” for Required if known, “O” for Optional, or “C” for Conditional. If applicable, conditional footnotes are further described below.



Figure 3-7 HITSP/CAP122 – Retrieve Medical Knowledge Visual Overview



3.7.2.5 CAPABILITY OPTIONS

Note that subsets of the data content can be sent as appropriate for the application; but the system must be able to address the entire data content. Note that transport options can be addressed.

3.8 HITSP/CAP123 – RETRIEVE EXISTING DATA SPECIFICATION

3.8.1 OVERVIEW

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).

3.8.2 DESIGN SPECIFICATION

3.8.2.1 INTERACTING SYSTEMS

Table 3-42 Interacting Systems

Interacting Systems
Electronic Health Record (EHR) System
Immunization Information System (IIS)
Quality Measure Processing Entity

3.8.2.2 CONSTRAINTS AND ASSUMPTIONS

This section provides an overview of the constraints (i.e., Assumptions, Pre-conditions, Post-conditions, Triggers) associated with a Capability.



Table 3-43 Constraints and Assumptions

Constraint	Type of Constraint
No Applicable Constraints	

3.8.2.3 LIST OF CONSTRUCTS**Table 3-44 List of Constructs**

Construct	Description
HITSP/C19 – Entity Identity Assertion	The HITSP Entity Identity Assertion Component ensures that an entity is the person or application that claims the identity provided
HITSP/SC113 – Query for Existing Data	The HITSP Query for Existing Data Service Collaboration provides the Capability to query and retrieve data from another clinical system, and the Capability to respond to same queries. It applies the necessary Security and Privacy constructs and supports all the queries found in HITSP/TP21
HITSP/TP21- Query for Existing Data	The HITSP Query for Existing Data Transaction Package supports retrieval of patient level quality data from source repositories to compile the required patient level data submission

3.8.2.4 SPECIFIED INTERFACES**Table 3-45 HITSP/CAP123 – Retrieve Existing Data Specified Interfaces**

Interface (Initiating or Responding)	Interface number	Interface Condition	T/TP/SC or Content	T/TP/SC/Content Optionality ²⁴
Request Existing Patient Data	1	R	Query for Existing Data (HITSP/SC113)	CAP123-[201]
Respond to Existing Patient Data	2	R	Query for Existing Data (HITSP/SC113)	R

Table 3-46 Interface Conditions and T/TP/SC/Content Optionality

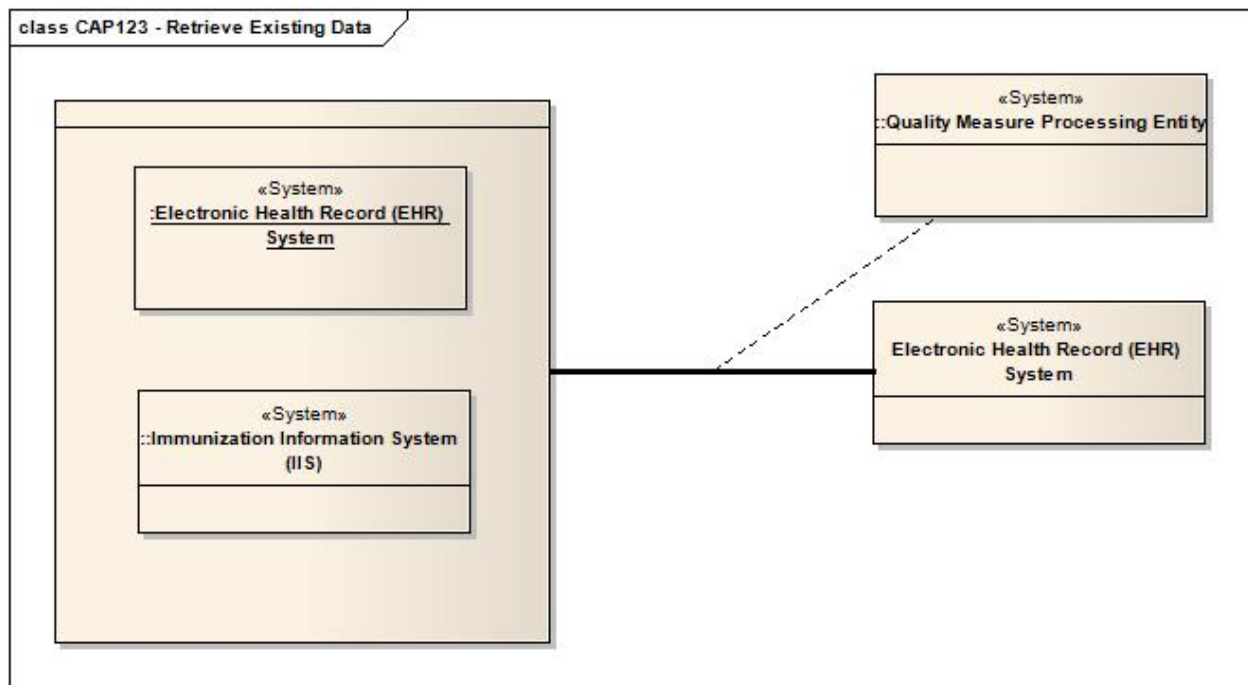
Condition Code	Condition Description
CAP123-[201]	Shall be applied where identity assertion is required by the jurisdiction or information sharing agreements

The following diagram shows a visual overview of the Capability using UML notation. The visual overview outlines how the interacting systems work together as part of implementing the Capability. The thick arrow in the middle of the diagram outlines how sets of systems can interact together, and represent the information exchange requirement (IER) inherent to the Capability. An IER is not explicitly noted as part of this diagram.

²⁴ Optionality = “R” for Required, “R2” for Required if known, “O” for Optional, or “C” for Conditional. If applicable, conditional footnotes are further described below.



Figure 3-8 HITSP/CAP123 – Retrieve Existing Data Visual Overview



3.8.2.5 CAPABILITY OPTIONS

Note that subsets of the data content can be sent as appropriate for the application; but the system must be able to address the entire data content. Note that transport options can be addressed.

3.9 HITSP/CAP124 – ESTABLISH SECURE WEB ACCESS SPECIFICATION

3.9.1 OVERVIEW

This Capability is focused on providing a secured method to access information available from document repositories (e.g., Laboratory Report) in order to view them locally on a system. The chosen method for viewing the document content is through a web browser.

3.9.2 DESIGN SPECIFICATION

3.9.2.1 INTERACTING SYSTEMS

Table 3-47 Interacting Systems

Interacting Systems
Repository
Electronic Health Record (EHR) System

3.9.2.2 CONSTRAINTS AND ASSUMPTIONS

This section provides an overview of the constraints (i.e., Assumptions, Pre-conditions, Post-conditions, Triggers) associated with the Capability.



Table 3-48 Constraints and Assumptions

Constraint	Type of Constraint
The Laboratory has registered the laboratory result document in the Repository, and the Repository has notified the Locator Service of the document location	Pre-Condition
Result is received and is viewable or can be processed	Post-Condition

3.9.2.3 LIST OF CONSTRUCTS

Table 3-49 List of Constructs

Construct	Description
HITSP/C44 – Secure Web Connection	The HITSP Secure Web Connection Component provides the Capability to access documents through a secure web browser
HITSP/SC108 – Access Control	The HITSP Access Control Service Collaboration provides the mechanism for security authorizations which control the enforcement of security policies including: role-based access control, entity based access control, context based access control, and the execution of consent directives
HITSP/SC109 – Security Audit	The HITSP Security Audit Service Collaboration describes the mechanism to record security relevant events in support of policy, regulation, or risk analysis. It also provides the mechanism to determine the record format to support analytical reports that are needed
HITSP/T17 – Secured Communication Channel	The HITSP Secured Communication Channel Transaction provides the mechanisms to ensure the authenticity, integrity, and confidentiality of transmissions, and the mutual trust between communicating parties. Its objectives include providing: mutual node authentication to assure each node of the others' identity; transmission integrity to guard against improper information modification or destruction while in transit; and transmission confidentiality to ensure that information in transit is not disclosed to unauthorized individuals, entities, or processes
HITSP/T18 – View Laboratory Results from a Web Application	The HITSP View Laboratory Results from a Web Application Transaction allows a user to view a laboratory report through a secure browser. This Transaction uses the HITSP/C44 – Secure Web Connection Component. It may not define all functions, constructs and standards necessary to implement a conforming system in a real world environment. In particular, an implementer must provide the technical infrastructure and security framework necessary to support operations in accordance with law, regulation, best practices and business agreements

3.9.2.4 SPECIFIED INTERFACES

Table 3-50 HITSP/CAP124 – Establish Secure Web Access Specified Interfaces

Interface (Initiating or Responding)	Interface number	Interface Condition	T/TP/SC or Content	T/TP/SC/Content Optionality ²⁵
Web Server	1	R	View Laboratory Results (HITSP/T18) Secure Web Connection (HITSP/C44)	R R
Node	2	R	Secured Communication Channel (HITSP/T17)	R
Request access control decision	3	R	Access Control (HITSP/SC108)	R
Send Security Audit Event	4	R	Security Audit (HITSP/SC109)	R

Table 3-51 Interface Conditions and T/TP/SC/Content Optionality

Condition Code	Condition Description
No Applicable Condition Codes	

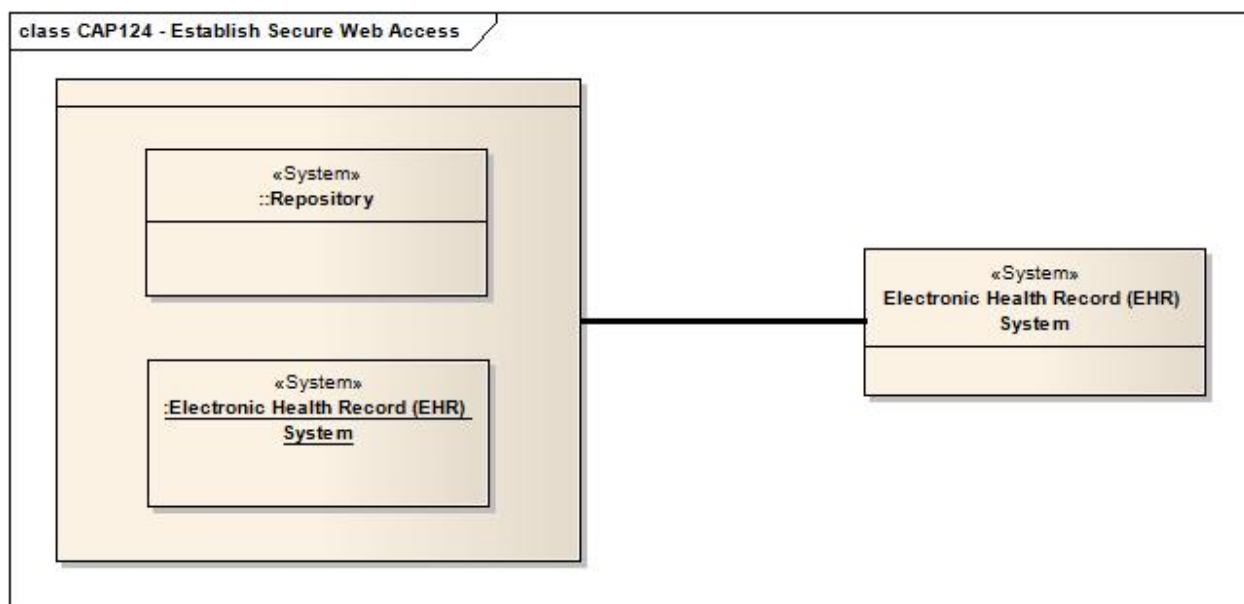
The following diagram shows a visual overview of the Capability using UML notation. The visual overview outlines how the interacting systems work together as part of implementing the Capability. The thick arrow

²⁵ Optionality = "R" for Required, "R2" for Required if known, "O" for Optional, or "C" for Conditional. If applicable, conditional footnotes are further described below.



in the middle of the diagram outlines how sets of systems can interact together, and represent the information exchange requirement (IER) inherent to the Capability. An IER is not explicitly noted as part of this diagram.

Figure 3-9 HITSP/CAP124 – Establish Secure Web Access Visual Overview



3.9.2.5 CAPABILITY OPTIONS

Note that subsets of the data content can be sent as appropriate for the application; but the system must be able to address the entire data content. Note that transport options can be addressed.

3.10 HITSP/CAP125 – RETRIEVE GENOMIC DECISION SUPPORT SPECIFICATION

3.10.1 OVERVIEW

This Capability addresses interoperability requirements that support the communication of genetic and family history information and an assessment of genetic risk of disease for a patient.

3.10.2 DESIGN SPECIFICATION

3.10.2.1 INTERACTING SYSTEMS

Table 3-52 Interacting Systems

Interacting Systems
Genetic Clinical Decision Support System
Electronic Health Record (EHR) System

3.10.2.2 CONSTRAINTS AND ASSUMPTIONS

This section provides an overview of the constraints (i.e., Assumptions, Pre-conditions, Post-conditions, Triggers) associated with the Capability.



Table 3-53 Constraints and Assumptions

Constraint	Type of Constraint
No Applicable Constraints	

3.10.2.3 LIST OF CONSTRUCTS

Table 3-54 List of Constructs

Construct	Description
HITSP/C90 – Clinical Genomic Decision Support	The HITSP Family History Decision Support for Genetic Risk Analysis Component is used to communicate genetic and family history information from healthcare IT applications to a clinical decision support system that provides an assessment of genetic risk of disease for a patient. It uses the HL7 Version 3 Standard: Clinical Genomics; Pedigree, Release 1 to support the communication of genetic and family history information to the clinical decision support system, and to support the communication of risk information from that system back to the originator
HITSP/SC112 – Healthcare Document Management	The HITSP Healthcare Document Management Service Collaboration provides the ability to share healthcare documents using a set of topologies, such as Media, e-Mail, Point-to-Point, Shared within a Health Information Exchange, and Shared within a larger community (made up of potentially diverse Health Information Exchanges)

3.10.2.4 SPECIFIED INTERFACES

Table 3-55 HITSP/CAP125 – Retrieve Genomic Decision Support Specified Interfaces

Interface (Initiating or Responding)	Interface number	Interface Condition	T/TP/SC or Content	T/TP/SC/Content Optionality ²⁶
Content Creator	1	CAP125-[101]	Content Creator-Family History (HITSP/C90)	R
Content Consumer	2	R	Content Consumer Genetic Risk Analysis (HITSP/C90)	CAP125-[101]
Send Documents	3	CAP125-[102], [103]	Healthcare Document Management (HITSP/SC112)	R
Receive Documents	4	CAP125-[102]	Healthcare Document Management (HITSP/SC112)	R

Table 3-56 Interface Conditions and T/TP/SC/Content Optionality

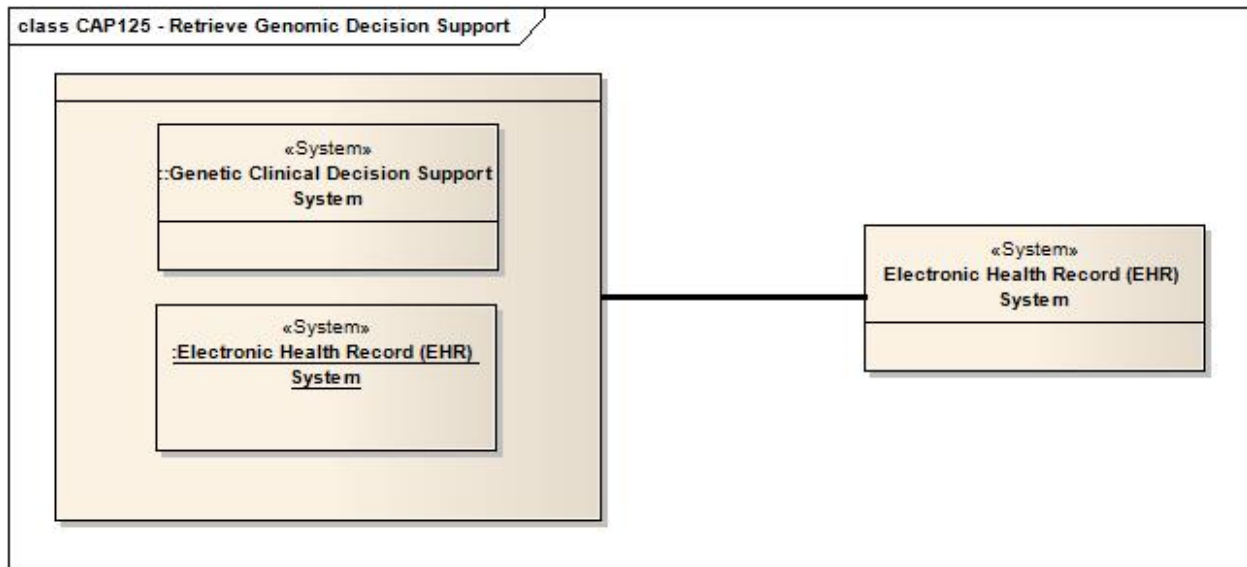
Condition Code	Condition Description
CAP125-[101]	Shall be supported if this system is being used to provide genetic counseling
CAP125-[102]	An implementation shall choose amongst one of the interfaces defined in HITSP/SC112 Healthcare Document Management. This choice is dependent on the topology chosen (See Table 3-1 Information Exchange Topologies Mapped to Capabilities above), the physical limitations, policies and processes of the implementation
CAP125-[103]	The EHR System may optionally choose to implement a Document Repository or use an external repository for the Send Documents through Share option of HITSP/SC112 Healthcare Document Management

The following diagram shows a visual overview of the Capability using UML notation. The visual overview outlines how the interacting systems work together as part of implementing the Capability. The thick arrow in the middle of the diagram outlines how sets of systems can interact together, and represent the information exchange requirement (IER) inherent to the Capability. An IER is not explicitly noted as part of this diagram.

²⁶ Optionality = “R” for Required, “R2” for Required if known, “O” for Optional, or “C” for Conditional. If applicable, conditional footnotes are further described below.



Figure 3-10 HITSP/CAP125 – Retrieve Genomic Decision Support Visual Overview



3.10.2.5 CAPABILITY OPTIONS

Note that subsets of the data content can be sent as appropriate for the application; but the system must be able to address the entire data content. Note that transport options can be addressed.

3.11 HITSP/CAP126 – COMMUNICATE LAB RESULTS MESSAGE SPECIFICATION

3.11.1 OVERVIEW

This Capability addresses interoperability requirements that support the sending of a set of laboratory test results. Ordering Providers of Care receive results as a laboratory results message. The communication of the order is out of scope for this Capability.

The content of these test results may be either or both: General Laboratory Test Results; Microbiology Test Results

This Capability may use content anonymization.

3.11.2 DESIGN SPECIFICATION

3.11.2.1 INTERACTING SYSTEMS

Table 3-57 Interacting Systems

Interacting Systems
Electronic Health Record (EHR) System
Infrastructure Services
Laboratory Information System
Health Information Exchange (HIE)
Public Health Information System
Clinical Information System
Diagnostic Imaging Information System



3.11.2.2 CONSTRAINTS AND ASSUMPTIONS

This section provides an overview of the constraints (i.e., Assumptions, Pre-conditions, Post-conditions, Triggers) associated with the Capability.

Table 3-58 Constraints and Assumptions

Constraint	Type of Constraint
Laboratory results are only sent to the prescribing physician; all others receive notification, due to HIPAA regulation	Assumption
An order for a laboratory test has been created and accepted by the performing laboratory	Pre-condition
The order contains an electronic address of all authorized electronic recipients	Pre-condition
Result is received and is viewable or can be processed	Post-condition

3.11.2.3 LIST OF CONSTRUCTS

Table 3-59 List of Constructs

Construct	Description
HITSP/C35 – Lab Result Terminology	The HITSP Lab Result Terminology Component defines the vocabulary for either message-based or document-based laboratory results reporting
HITSP/C36 – Lab Result Message	The HITSP Lab Result Message Component describes the use of a constrained Health Level Seven (HL7) Version 2.5.1 ORU – Unsolicited Observation Message for electronic laboratory results reporting
HITSP/C87 – Anonymize Public Health Case Reporting Data	The HITSP Anonymize Public Health Case Reporting Data Component provides specific instructions for anonymizing data that was created as part of routine clinical care data delivery in preparation for repurposing data for public health case reporting. This construct defines the Component specification that provides the ability to anonymize patient identifiable information. Anonymization, according to the International Organization for Standardization (ISO), is the process that removes the association between the identifying data set and the data subject
HITSP/SC115 – HL7 Messaging	The HITSP HL7 Messaging Service Collaboration provides the Capability to send and receive HL7 messages. The Service Collaboration applies the necessary Security and Privacy constructs
HITSP/T14 – Send Laboratory Result Message	The HITSP Send Laboratory Result Message Transaction supports: Transmission of complete, preliminary, final and updated laboratory results to the EHR system (local or remote) of the ordering clinician; and transmission of complete, preliminary, final and updated laboratory results (or notification of the availability of laboratory results) to the EHR system (local or remote) or other clinical data system of designated providers of care (with respect to a specific patient)
HITSP/T24 – Pseudonymize	The HITSP Pseudonymize Transaction describes a framework for including Pseudonymization Services where the use of “dummy” or pseudo references to specific patients or providers is required. Pseudo-identifiers are intended to allow accessibility to clinical information, while safeguarding any information that may compromise the privacy of the individual patient or provider. Using pseudo-identifiers can assist in compliance with HIPAA regulations regarding suppression of patient identification information



3.11.2.4 SPECIFIED INTERFACES

Table 3-60 HITSP/CAP126 – Communicate Lab Results Message Specified Interfaces

Interface (Initiating or Responding)	Interface number	Interface Condition	T/TP/SC or Content	T/TP/SC/Content Optionality ²⁷
Content Creator	1	R	Lab Result Terminology (HITSP/C35)	R
		O	Lab Result Message (HITSP/C36)	R
		CAP126-[101]	Pseudonymization Request (HITSP/T24)	R
		CAP126-[102]	Anonymize (HITSP/C87)	R
Content Consumer	2	R	Laboratory Result – General Laboratory Subset (See Section 3.11.2.5.1)(HITSP/C36)	R
			Laboratory Result – Microbiology Subset (See section 3.11.2.5.2)(HITSP/C36)	R
			Laboratory Result Terminology – General Laboratory Subset (See section 3.11.2.5.1)(HITSP/C35)	R
			Laboratory Result Terminology – Microbiology Subset (See section 3.11.2.5.2)(HITSP/C35)	R
Laboratory Result Message Sender	3	R	Send Lab Result Message (HITSP/T14)	R
			Lab Result Terminology (HITSP/C35)	R
			Lab Result Message (HITSP/C36)	R
Laboratory Result Message Receiver	4	R	Send Lab Result Message (HITSP/T14)	R
			Lab Result Terminology (HITSP/C35)	R
			Lab Result Message (HITSP/C36)	R
Request HL7 Message	5	R	HL7 Messaging (HITSP/SC115)	R
Respond to HL7 Message	6	R	HL7 Messaging (HITSP/SC115)	R

Table 3-61 Interface Conditions and T/TP/SC/Content Optionality

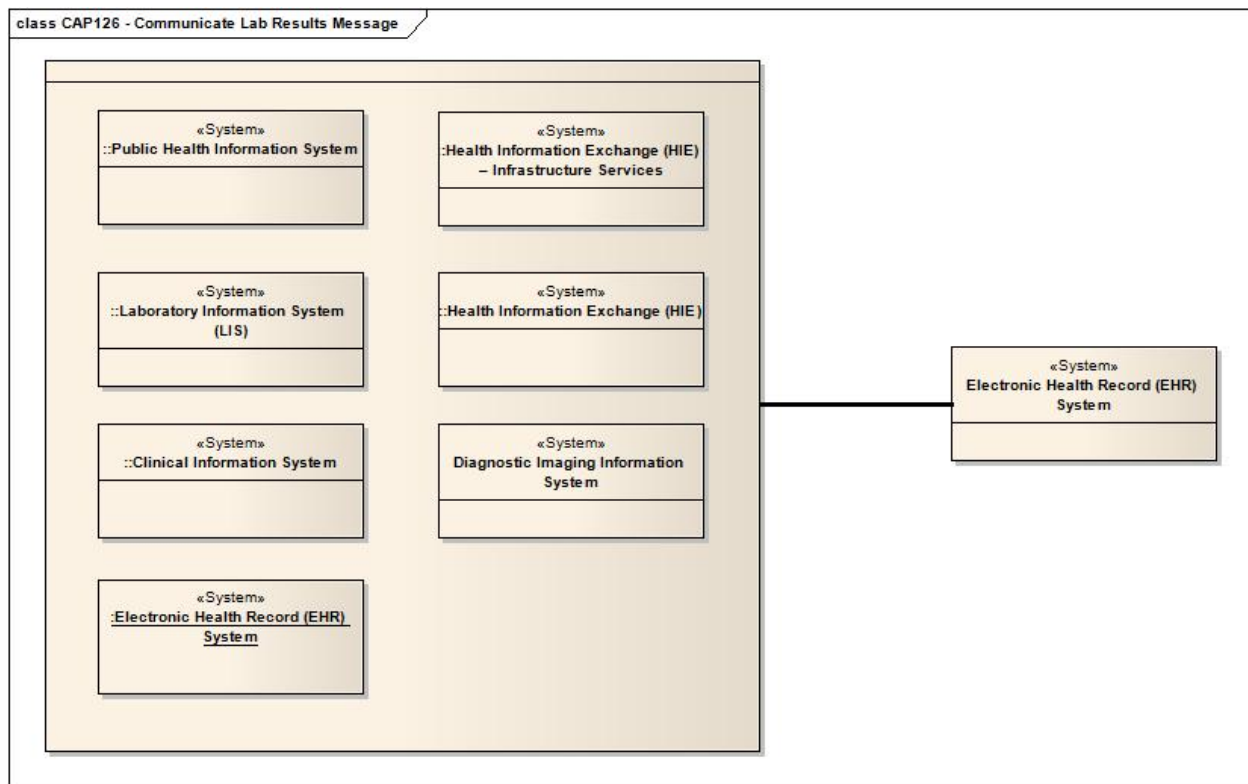
Condition Code	Condition Description
CAP126-[101]	Shall be applied where pseudonymization is required by the jurisdiction or information sharing agreements or selected by PHR
CAP126-[102]	Shall be applied where anonymization is required by the jurisdiction or information sharing agreements or selected by PHR

The following diagram shows a visual overview of the Capability using UML notation. The visual overview outlines how the interacting systems work together as part of implementing the Capability. The thick arrow in the middle of the diagram outlines how sets of systems can interact together, and represent the information exchange requirement (IER) inherent to the Capability. An IER is not explicitly noted as part of this diagram.

²⁷ Optionality = “R” for Required, “R2” for Required if known, “O” for Optional, or “C” for Conditional. If applicable, conditional footnotes are further described below.



Figure 3-11 HITSP/CAP126 – Communicate Lab Results Message Visual Overview



3.11.2.5 CAPABILITY OPTIONS

Note that subsets of the data content can be sent as appropriate for the application; but the system must be able to address the entire data content. Note that transport options can be addressed.

3.11.2.5.1 HITSP/C36 and HITSP/C35 “Laboratory Result-General Laboratory Subset”

The General Laboratory subset as defined by this Interoperability Specification includes the following specialties (The LOINC codes are provided in parenthesis):

- Hematology (HM, 18723-7, 18768-2)
- Blood banks (BLB, 18717-9, 18724-5 HLA studies) (excluding transfusion workflow and blood products distribution)
- Coagulation studies, clotting factors (18720-3)
- Immunology (IMM) and Serology (SR, 18727-8)
- Chemistry (CH, 18719-5)
- Urinalysis (18729-4)
- Blood gas (BG, 18767-4)
- Dynamic function tests (26437-4 challenge studies)
- Spermiology (18722-9 fertility studies)
- Hormonology
- Enzymology
- Proteins, tumor markers (18718-7 cell marker studies), vitamins
- Toxicology (TX, 18728-6) and pharmacology (18721-1 therapeutic drug monitoring)



3.11.2.5.2 HITSP/C36 and HITSP/C35 “Laboratory Result-Microbiology Subset”

The Microbiology subset, as defined in this Interoperability Subset, includes the following specialties (LOINC codes are provided in parenthesis):

- Microbiology including bacteriology (MB, 18725-2)
- Mycology (MCB, MYC)
- Parasitology
- Microbial susceptibility tests (18769-0)
- Virology (VR)

3.12 HITSP/CAP127 – COMMUNICATE LAB RESULTS DOCUMENT SPECIFICATION

3.12.1 OVERVIEW

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.

3.12.2 DESIGN SPECIFICATION

3.12.2.1 INTERACTING SYSTEMS

Table 3-62 Interacting Systems

Interacting Systems
Electronic Health Record (EHR) System
Laboratory Information System
Health Information Exchange (HIE)
Infrastructure Services
Public Health Information System
Clinical Information System
Diagnostic Imaging Information System
Personal Health Record (PHR) System
Emergency Communications System

3.12.2.2 CONSTRAINTS AND ASSUMPTIONS

This section provides an overview of the constraints (i.e., Assumptions, Pre-conditions, Post-conditions, Triggers) associated with the Capability.

Table 3-63 Constraints and Assumptions

Constraint	Type of Constraint
No Applicable Constraints	



3.12.2.3 LIST OF CONSTRUCTS

Table 3-64 List of Constructs

Construct	Description
HITSP/C25 – Anonymize	The HITSP Anonymize Component provides specific instruction for anonymizing data that are prepared for repurposing data created as part of routine clinical care delivery. This construct defines the Component specification that provides the ability to anonymize patient identifiable information
HITSP/C35 – Lab Result Terminology	The HITSP Lab Result Terminology Component defines the vocabulary for either message-based or document-based laboratory results reporting
HITSP/C37 – Lab Report Document	The HITSP Lab Report Document Component prescribes the use of the standard Clinical Document Architecture Release 2 (CDA R2), as in the HL7 V3 2006 normative edition profiled by IHE LAB TF-3 for: transmission of complete, preliminary, final and updated laboratory results to the EHR system (local or remote) of the ordering clinician; transmission of complete, preliminary, final and updated (or notification) to the EHR system (local or remote) or other clinical data system of designated providers of care (with respect to a specific patient); transmission of laboratory result data from electronically enabled healthcare delivery and public health systems in standardized and anonymized format to authorized Public Health Agencies with less than one day lag time
HITSP/C87 – Anonymize Public Health Case Reporting Data	The HITSP Anonymize Public Health Case Reporting Data Component provides specific instructions for anonymizing data that was created as part of routine clinical care data delivery in preparation for repurposing data for public health case reporting. This construct defines the Component specification that provides the ability to anonymize patient identifiable information. Anonymization, according to the International Organization for Standardization (ISO), is the process that removes the association between the identifying data set and the data subject
HITSP/SC111 – Knowledge and Vocabulary	The HITSP Knowledge and Vocabulary Service Collaboration provides the ability to retrieve medical knowledge and terminology
HITSP/SC112 – Healthcare Document Management	The HITSP Healthcare Document Management Service Collaboration provides the ability to share healthcare documents using a set of topologies, such as Media, e-Mail, Point-to-Point, Shared within a Health Information Exchange, and Shared within a larger community (made up of potentially diverse Health Information Exchanges)

3.12.2.4 SPECIFIED INTERFACES

Table 3-65 HITSP/CAP127 – Communicate Lab Results Document Specified Interfaces

Interface (Initiating or Responding)	Interface number	Interface Condition	T/TP/SC or Content	T/TP/SC/Content Optionality ²⁸
Content Consumer	1	R	Consumer-Document Display Subset(See section 3.12.2.5.1) (HITSP/C37)	R
			Consumer-Document Import Subset(See section 3.12.2.5.2) (HITSP/C37)	R
			Consumer-Lab Report Discrete Data – General Laboratory Import Subset(See section 3.12.2.5.3) (HITSP/C37)	R
			Consumer-Lab Report Discrete Data – Microbiology Import Subset (See section 3.12.2.5.4)(HITSP/C37)	CAP127 –[201]
			Laboratory Result Terminology – General Laboratory Subset (See section3.12.2.5.5)(HITSP/C35)	R
			Laboratory Result Terminology – Microbiology Subset (See section 3.12.2.5.6)(HITSP/C35)	R
Content Creator	2	R	Lab Report Document (HITSP/C37)	R
			Anonymize (HITSP/C25)	R
		R	Anonymize (HITSP/C87)	R

²⁸ Optionality = “R” for Required, “R2” for Required if known, “O” for Optional, or “C” for Conditional. If applicable, conditional footnotes are further described below.



Interface (Initiating or Responding)	Interface number	Interface Condition	T/TP/SC or Content	T/TP/SC/Content Optionality ²⁸
Send Documents	3	CAP127- [101], [102]	Healthcare Document Management (HITSP/SC112)	R
Receive Documents	4	CAP127- [101]	Healthcare Document Management (HITSP/SC112)	R
Request Value Set	5	R	Knowledge and Vocabulary (HITSP/SC111)	R

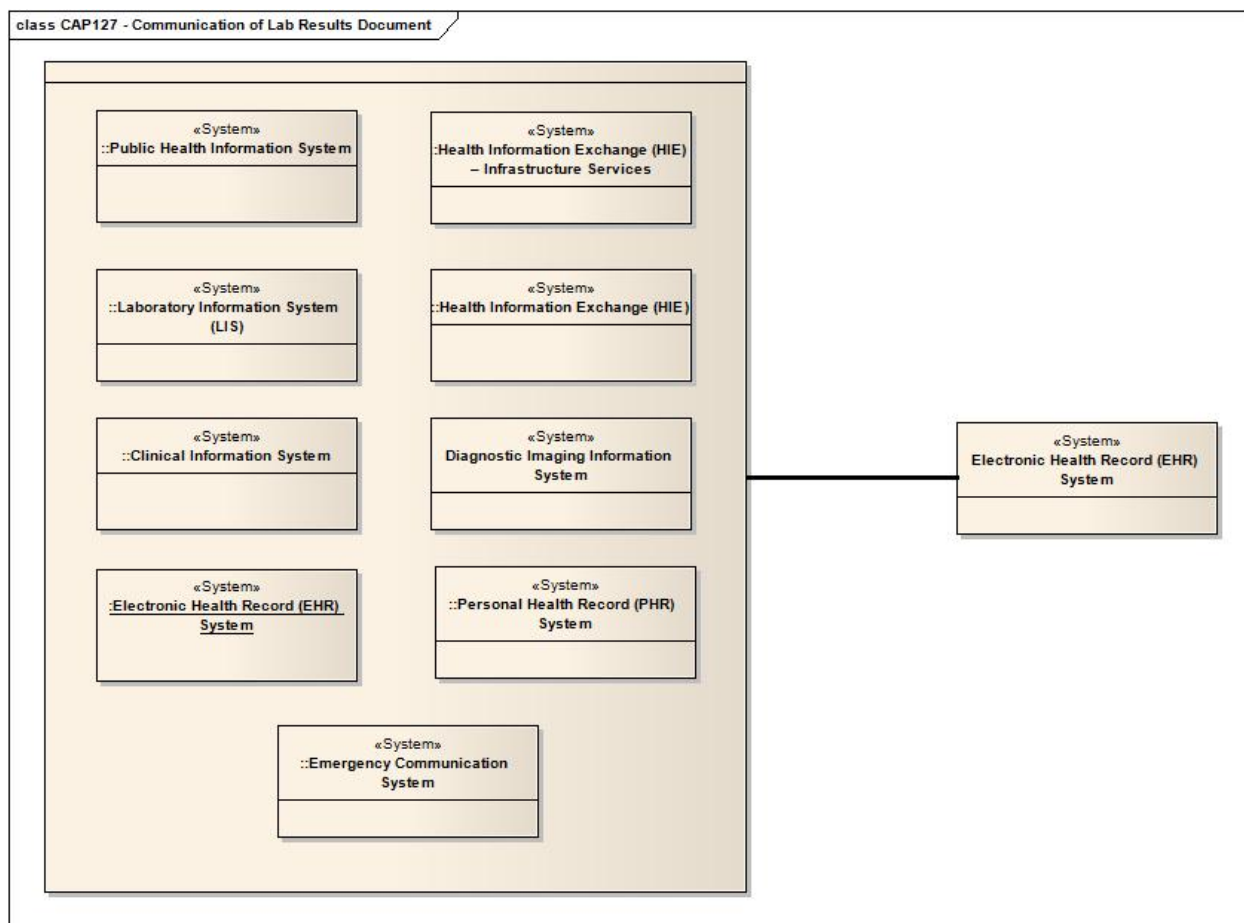
Table 3-66 Interface Conditions and T/TP/SC/Content Optionality

Condition Code	Condition Description
CAP127-[101]	An implementation shall choose amongst one of the interfaces defined in HITSP/SC112 Healthcare Document Management. This choice is dependent on the topology chosen (See Table 3-1 Information Exchange Topologies Mapped to Capabilities above), the physical limitations, policies and processes of the implementation
CAP127-[102]	The EHR System may optionally choose to implement a Document Repository or use an external repository for the Send Documents through Share option of HITSP/SC112 Healthcare Document Management
CAP127-[201]	If an implementation claims to manage microbiology data, it must support this subset

The following diagram shows a visual overview of the Capability using UML notation. The visual overview outlines how the interacting systems work together as part of implementing the Capability. The thick arrow in the middle of the diagram outlines how sets of systems can interact together, and represent the information exchange requirement (IER) inherent to the Capability. An IER is not explicitly noted as part of this diagram.



Figure 3-12 HITSP/CAP127 – Communicate Lab Results Document Visual Overview



3.12.2.5 CAPABILITY OPTIONS

Note that subsets of the data content can be sent as appropriate for the application; but the system must be able to address the entire data content. Note that transport options can be addressed.

3.12.2.5.1 HITSP/C37 “Consumer - Document Display Subset”

This subset impacts the import of Documents processed by a Content Consumer Technical Actor. It requires the Document Consumer only to have the ability to display the HITSP/C37 - Lab Report Document as requested (it may not be able to locally import the lab report document into the patient record).

3.12.2.5.2 HITSP/C37 “Consumer - Document Import Subset”

This subset impacts the import of Documents processed by a Content Consumer Technical Actor. It requires the Document Consumer to have the ability to import into the patient record the HITSP/C37 - Lab Report Document as a whole and display it as requested.

3.12.2.5.3 HITSP/C37 “Consumer-Lab Report Discrete Data – General Laboratory Import Subset”

This subset impacts the import of HITSP/C37 - Lab Report Document processed by a Content Consumer Technical Actor. It requires the Document Consumer to have the ability to import General Laboratory discrete data (See **Error! Reference source not found.** for the definition of the corresponding laboratory



specialties) from one or more of the entries in a structured form into the patient record. Coded values shall be maintained.

3.12.2.5.4 HITSP/C37 “Consumer-Lab Report Discrete Data – Microbiology Import Subset”

This subset impacts the import of HITSP/C37 - Lab Report Document processed by a Content Consumer Technical Actor. It requires the Document Consumer to have the ability to import *Microbiology* discrete data (See Section **Error! Reference source not found.** for the definition of the corresponding microbiology specialties) from one or more of the entries in a structured form into the patient record. Coded values shall be maintained.

3.12.2.5.5 HITSP/C35 “Laboratory Result Terminology-General Laboratory Subset”

The General Laboratory subset as defined by this Interoperability Specification includes the following specialties (The LOINC codes are provided in parenthesis):

- Hematology (HM, 18723-7, 18768-2)
- Blood banks (BLB, 18717-9, 18724-5 HLA studies) (excluding transfusion workflow and blood products distribution)
- Coagulation studies, clotting factors (18720-3)
- Immunology (IMM) and Serology (SR, 18727-8)
- Chemistry (CH, 18719-5)
- Urinalysis (18729-4)
- Blood gas (BG, 18767-4)
- Dynamic function tests (26437-4 challenge studies)
- Spermiology (18722-9 fertility studies)
- Hormonology
- Enzymology
- Proteins, tumor markers (18718-7 cell marker studies), vitamins
- Toxicology (TX, 18728-6) and pharmacology (18721-1 therapeutic drug monitoring)

3.12.2.5.6 HITSP/C35 “Laboratory Result Terminology-Microbiology Subset”

The Microbiology subset, as defined in this Interoperability Subset, includes the following specialties (LOINC codes are provided in parenthesis):

- Microbiology including bacteriology (MB, 18725-2)
- Mycology (MCB, MYC)
- Parasitology
- Microbial susceptibility tests (18769-0)
- Virology (VR)

3.13 HITSP/CAP128 – COMMUNICATE IMAGING INFORMATION SPECIFICATION

3.13.1 OVERVIEW

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.



3.13.2 DESIGN SPECIFICATION

3.13.2.1 INTERACTING SYSTEMS

Table 3-67 Interacting Systems

Interacting Systems
Electronic Health Record (EHR) System
Laboratory Information Systems
Infrastructure Services
Health Information Exchange (HIE)
Public Health Information System
Clinical Information System
Diagnostic Imaging Information System
Personal Health Record (PHR) System
Emergency Communications System

3.13.2.2 CONSTRAINTS AND ASSUMPTIONS

This section provides an overview of the constraints (i.e., Assumptions, Pre-conditions, Post-conditions, Triggers) associated with the Capability.

Table 3-68 Constraints and Assumptions

Constraint	Type of Constraint
No Applicable Constraints	

3.13.2.3 LIST OF CONSTRUCTS

Table 3-69 List of Constructs

Construct	Description
HITSP/SC111 – Knowledge and Vocabulary	The HITSP Knowledge and Vocabulary Service Collaboration provides the ability to retrieve medical knowledge and terminology
HITSP/SC112 – Healthcare Document Management	The HITSP Healthcare Document Management Service Collaboration provides the ability to share healthcare documents using a set of topologies, such as Media, e-Mail, Point-to-Point, Shared within a Health Information Exchange, and Shared within a larger community (made up of potentially diverse Health Information Exchanges)
HITSP/TP89 - Sharing Imaging Results	The Sharing Imaging Results Transaction Package supports the process of sharing medical imaging results data. Imaging results data are captured as part of the normal process of care performed by healthcare providers. This data can be made available through document sharing for both clinical care and public health purposes



3.13.2.4 SPECIFIED INTERFACES

Table 3-70 HITSP/CAP128 – Communicate Imaging Information Specified Interfaces

Interface (Initiating or Responding)	Interface number	Interface Condition	T/TP/SC or Content	T/TP/SC/Content Optionality ²⁹
Imaging Document Consumer	1	R	Retrieve Images [RAD-16] (HITSP/TP89)	CAP128-[201]
			WADO Retrieve [RAD-55] (HITSP/TP89)	CAP128-[201]
Receive Documents	2	CAP128-[101]	Healthcare Document Management (HITSP/SC112)	R
Send Documents	3	CAP128-[101], [102]	Healthcare Document Management (HITSP/SC112)	R
Request Value Set	4	R	Knowledge and Vocabulary (HITSP/SC111)	R
Request Medical Knowledge	5	R	Knowledge and Vocabulary (HITSP/SC111)	R
Respond Medical Knowledge	6	R	Knowledge and Vocabulary (HITSP/SC111)	R

Table 3-71 Interface Conditions and T/TP/SC/Content Optionality

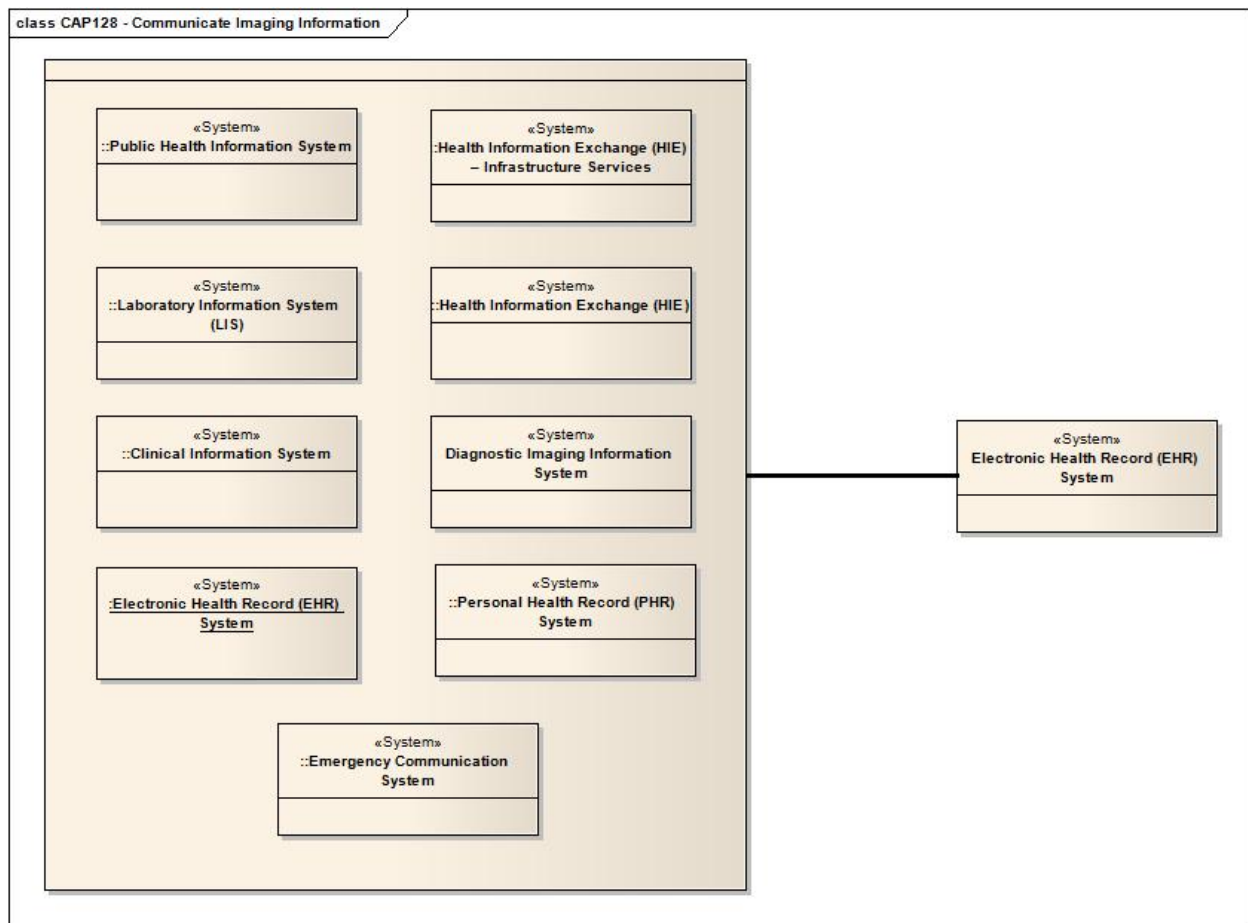
Condition Code	Condition Description
CAP128-[101]	An implementation shall choose amongst one of the interfaces defined in HITSP/SC112 Healthcare Document Management. This choice is dependent on the topology chosen (See Table 3-1 Information Exchange Topologies Mapped to Capabilities above), the physical limitations, policies and processes of the implementation
CAP128-[102]	The EHR System may optionally choose to implement a Document Repository or use an external repository for the Send Documents through Share option of HITSP/SC112 Healthcare Document Management
CAP128-[201]	System shall support at least one of these interfaces to communicate image content

The following diagram shows a visual overview of the Capability using UML notation. The visual overview outlines how the interacting systems work together as part of implementing the Capability. The thick arrow in the middle of the diagram outlines how sets of systems can interact together, and represent the information exchange requirement (IER) inherent to the Capability. An IER is not explicitly noted as part of this diagram.

²⁹ Optionality = “R” for Required, “R2” for Required if known, “O” for Optional, or “C” for Conditional. If applicable, conditional footnotes are further described below.



Figure 3-13 HITSP/CAP128 – Communicate Imaging Information Visual Overview



3.13.2.5 CAPABILITY OPTIONS

Note that subsets of the data content can be sent as appropriate for the application; but the system must be able to address the entire data content. Note that transport options can be addressed.

3.14 HITSP/CAP129 – COMMUNICATE QUALITY MEASURE DATA SPECIFICATION

3.14.1 OVERVIEW

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.

Quality measures may include:

1. Patient-level clinical detail from which to compute quality measures. Patient level clinical data is compiled from both the local systems and from longitudinal data available through other sources such as a Health Information Exchange (HIE).
2. Patient-level quality data based upon clinical detail. The "patient-level quality data reports" are exported from EHRs or quality-monitoring applications at the point of care.

This Capability may use content Anonymization. Pseudonymization, if needed, is supported by the Capability 138 Retrieve Pseudonym.



This Capability may use Value Set Sharing.

3.14.2 DESIGN SPECIFICATION

3.14.2.1 INTERACTING SYSTEMS

Table 3-72 Interacting Systems

Interacting Systems
Electronic Health Record (EHR) System
Health Information Exchange (HIE)
Quality Measure and Reporting Enterprise
Quality Measure Processing Entity

3.14.2.2 CONSTRAINTS AND ASSUMPTIONS

This section provides an overview of the constraints (i.e., Assumptions, Pre-conditions, Post-conditions, Triggers) associated with the Capability.

Table 3-73 Constraints and Assumptions

Constraint	Type of Constraint
Pre-implementation certification/audit of the process (e.g., integrator/vendor certification)	Pre-condition
This specification will assume clearly defined measures as a Pre-condition. (See AQA for Heart Failure set of measures as an example of a clearly defined measure)	Pre-condition
The 'EHR' referenced may include any information system contained in any clinical and/or financial system supporting patient care and may be used for quality analysis; Augmentation is information that does not exist in an electronic form in the described systems	Assumptions
Claims data are available to CIS during compilation of historical and supplemental information retrieval	Assumptions
Clinical care documentation is available in an electronic format so that measure data can be provided in electronic form	Assumptions
Assume that there may be a statistician encoding the rules, and that the implementation of the mathematical formula is not specified in the Interoperability Specification and is left to product innovation	Assumptions
For each measure, wherever analyzed, the calculation algorithm is the same	Assumptions
Changes in measures can be tracked over time (NOTE: a likely solution is versioning)	Assumptions
Minimum dataset requirements for quality measurement are established	Pre-condition
There is policy surrounding sharing of this data, refuting data pre and post publication, and release of risk-adjusted public dissemination. Internal risk management policies surrounding public disclosures will be defined by organizational and public policy	Assumptions
Measures are available for quality improvement feedback and for measurement developer	Post-Conditions
An audit is performed to ensure the integrity and accuracy of the measurement and reporting program	Post-Conditions
The information recipient MAY further translate from the standard format to a local format at the system edge	Post-Conditions
Patient level data are ready for submission for measurement calculation	Trigger

3.14.2.3 LIST OF CONSTRUCTS

Table 3-74 List of Constructs

Construct	Description
HITPS/SC111 - Knowledge and Vocabulary	The HITSP Knowledge and Vocabulary Service Collaboration provides the ability to retrieve medical knowledge and terminology



Construct	Description
HITSP/C105 – Patient Level Quality Data Document Using HL7 Quality Reporting Document Architecture (QRDA)	The HITSP Patient Level Quality Data Document Using HL7 Quality Reporting Document Architecture Component supports the communication of patient level quality data for quality measurement in a document sharing environment. Patient encounter data are compiled from both the local systems and from longitudinal data available through a Health Information Exchange (HIE) prior to communicating the retrieved data described in this construct for analysis
HITSP/C25 – Anonymize	The HITSP Anonymize Component provides specific instruction for anonymizing data that are prepared for repurposing data created as part of routine clinical care delivery. This construct defines the Component specification that provides the ability to anonymize patient identifiable information
HITSP/C34 – Patient Level Quality Data Message	The HITSP Patient Level Quality Data Message Component supports the process of sending patient data from a Quality Message Sender to a Quality Message Receiver for further analysis and aggregation. Patient data are captured as part of the normal process of care performed by healthcare providers such as hospitals, emergency departments and outpatient clinics
HITSP/SC112 – Healthcare Document Management	The HITSP Healthcare Document Management Service Collaboration provides the ability to share healthcare documents using a set of topologies, such as Media, e-Mail, Point-to-Point, Shared within a Health Information Exchange, and Shared within a larger community (made up of potentially diverse Health Information Exchanges)
HITSP/SC115 – HL7 Messaging	The HL7 Messaging service collaboration provides the capability to send and receive HL7 messages. The Service Collaboration applies the necessary Security and Privacy constructs
HITSP/C26 - Nonrepudiation of Origin	The Nonrepudiation of Origin Component provides the mechanisms to support Nonrepudiation of Origin, which refers to both the proof of the integrity and origin of documents in a high-assurance manner, which can be verified by any party. This Component does not provide Nonrepudiation of Receipt

3.14.2.4 SPECIFIED INTERFACES

Table 3-75 HITSP/CAP129 – Communicate Quality Measure Data Specified Interfaces

Interface (Initiating or Responding)	Interface number	Interface Condition	T/TP/SC or Content	T/TP/SC/Content Optionality ³⁰
Request HL7 Message	1	CAP129-[103], [104]	HL7 Messaging (HITSP/SC115)	R
Respond to HL7 Message	2	CAP129-[103], [104]	HL7 Messaging (HITSP/SC115)	R
Content Creator	3	R	Patient Level Quality Data Message Component (HITSP/C34)	CAP129-[201]
		R	Patient Level Quality Document Component (HITSP/C105)	CAP129-[201]
		<u>R</u>	Anonymize (HITSP/C25)	CAP129-[202]
		R	Nonrepudiation of Origin (HITSP/C26)	CAP129-[205]
Content Consumer	4	R	Patient Level Quality Data Message Component (HITSP/C34)	CAP129-[201]
		R	Patient Level Quality Document Component (HITSP/C105)	CAP129-[201]
		R	Nonrepudiation of Origin (HITSP/C26)	CAP129-[205]
Send Documents	5	CAP129-[101], [102]	Healthcare Document Management (HITSP/SC112)	R
Receive Documents	6	CAP129-[101] [105]	Healthcare Document Management (HITSP/SC112)	CAP129-[204], [203]

³⁰ Optionality = “R” for Required, “R2” for Required if known, “O” for Optional, or “C” for Conditional. If applicable, conditional footnotes are further described below.



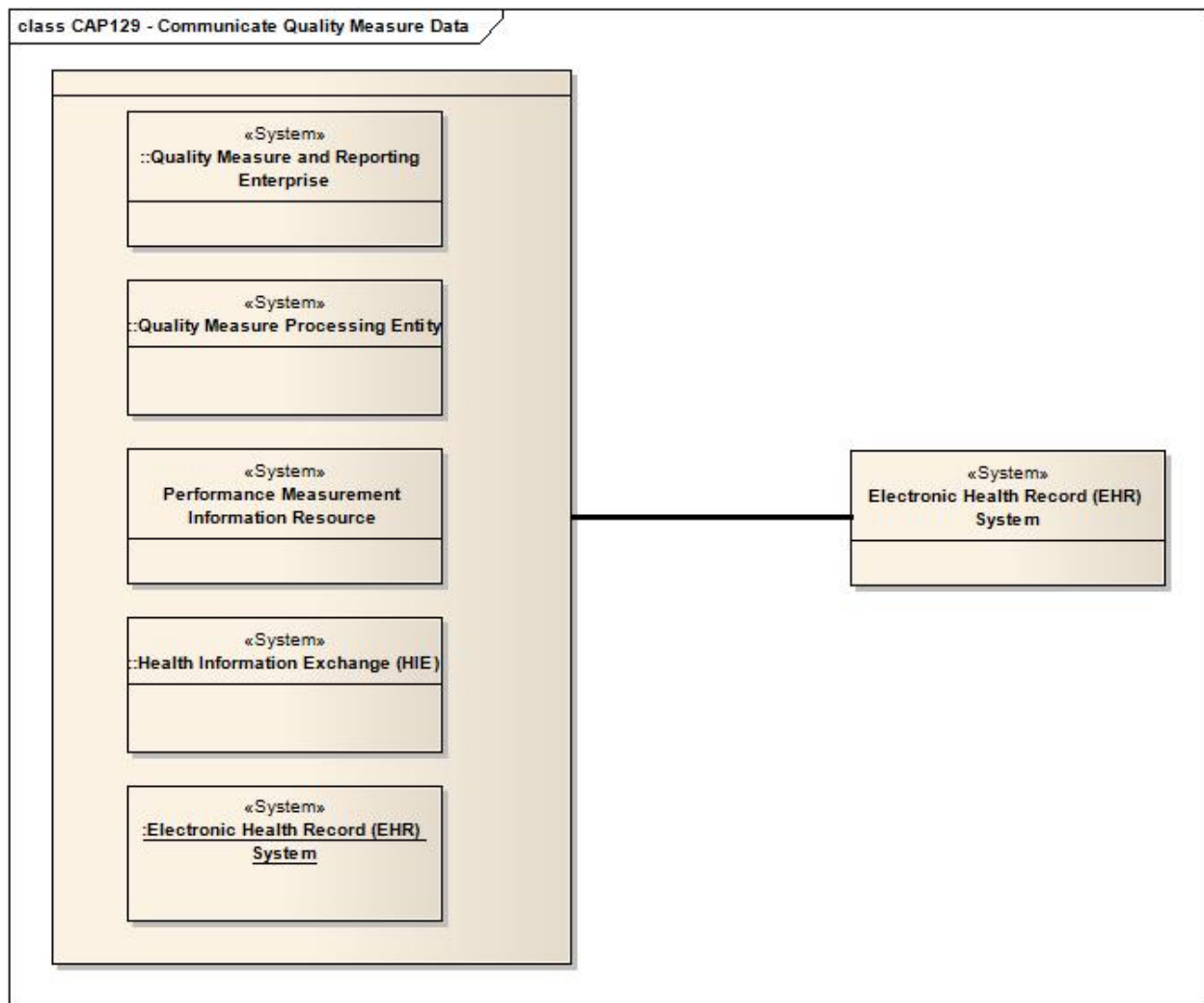
Table 3-76 Interface Conditions and T/TP/SC/Content Optionality

Condition Code	Condition Description
CAP129-[101]	An implementation shall choose amongst one of the interfaces defined in HITSP/SC112 Healthcare Document Management. This choice is dependent on the topology chosen (See Table 3-1 Information Exchange Topologies Mapped to Capabilities above), the physical limitations, policies and processes of the implementation
CAP129-[102]	The EHR System may optionally choose to implement a Document Repository or use an external repository for the Send Documents through Share option of HITSP/SC112 Healthcare document Management
CAP129-[103]	Shall be applied for message-based functional flow
CAP129-[104]	System shall support at least one of these interfaces
CAP129-[105]	NAV may be required by implementation to support notification of document availability
CAP129-[201]	Shall support either HITSP Patient level Quality Message Component or HITSP Patient level Quality Document Component, or both
CAP129-[202]	Shall be applied where anonymization is required by the jurisdiction or information sharing agreements
CAP129-[203]	Shall support Multi-Patient Stored Query
CAP129-[204]	Shall support Document Metadata Subscription
CAP129-[205]	Shall be applied where non-repudiation is required by the jurisdiction or information sharing agreements

The following diagram shows a visual overview of the Capability using UML notation. The visual overview outlines how the interacting systems work together as part of implementing the Capability. The thick arrow in the middle of the diagram outlines how sets of systems can interact together, and represent the information exchange requirement (IER) inherent to the Capability. An IER is not explicitly noted as part of this diagram.



Figure 3-14 HITSP/CAP129 = Communicate Quality Measure Data Visual Overview



3.14.2.5 CAPABILITY OPTIONS

Note that subsets of the data content can be sent as appropriate for the application; but the system must be able to address the entire data content. Note that transport options can be addressed.

3.15 HITSP/CAP130 – COMMUNICATE QUALITY MEASURE SPECIFICATION

3.15.1 OVERVIEW

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.



3.15.2 DESIGN SPECIFICATION

3.15.2.1 INTERACTING SYSTEMS

Table 3-77 Interacting Systems

Interacting Systems
Electronic Health Record (EHR) System
Health Information Exchange (HIE)
Quality Measure and Reporting Enterprise
Quality Measure Processing Entity
Performance Measurement Information Resource

3.15.2.2 CONSTRAINTS AND ASSUMPTIONS

This section provides an overview of the constraints (i.e., Assumptions, Pre-conditions, Post-conditions, Triggers) associated with the Capability.

Table 3-78 Constraints and Assumptions

Constraint	Type of Constraint
Hospitals and clinicians will only receive measures applicable to their population	Pre-condition
New measure or updated measure is ready to be communicated – to publish, record, send, or review	Trigger
Quality measures are provided with sufficient specification to enable the electronic upload and processing of queries without the need for local interpretation. Limitation on potentially ambiguous criteria should be part of the measurement endorsement process. Measures are unambiguous, well-defined	Assumptions

3.15.2.3 LIST OF CONSTRUCTS

Table 3-79 List of Constructs

Construct	Description
HITSP/C26 - Nonrepudiation of Origin	The Nonrepudiation of Origin Component provides the mechanisms to support Nonrepudiation of Origin, which refers to both the proof of the integrity and origin of documents in a high-assurance manner, which can be verified by any party. This Component does not provide Nonrepudiation of Receipt
HITSP/C106 – Measurement Criteria Document	This Component supports communication of a quality measure (aka an "eMeasure"). Clinical concepts (e.g. "atrial fibrillation", "coronary artery disease") and parameters (e.g. "numerator", "denominator") in an eMeasure are formally defined to support consistent and unambiguous interpretation. The eMeasure is standardized as a structured document, where one can capture the complete narrative of the measure and a formalized computable representation of statements
HITSP/SC108 – Access Control	The HITSP Access Control Service Collaboration provides the mechanism for security authorizations which control the enforcement of security policies including: role-based access control, entity based access control, context based access control, and the execution of consent directives
HITSP/SC109 – Security Audit	The HITSP Security Audit Service Collaboration describes the mechanism to record security relevant events in support of policy, regulation, or risk analysis. It also provides the mechanism to determine the record format to support analytical reports that are needed
HITSP/SC111 – Knowledge and Vocabulary	The HITSP Knowledge and Vocabulary Service Collaboration provides the ability to retrieve medical knowledge and terminology
HITSP/T17 – Secured Communication Channel	The HITSP Secured Communication Channel Transaction provides the mechanisms to ensure the authenticity, integrity, and confidentiality of transmissions, and the mutual trust between communicating parties. Its objectives include providing: mutual node authentication to assure each node of the others' identity; transmission integrity to guard against improper information modification or destruction while in transit; and transmission confidentiality to ensure that information in transit is not disclosed to unauthorized individuals, entities, or processes



3.15.2.4 SPECIFIED INTERFACES

Table 3-80 HITSP/CAP130 – Communicate Quality Measure Specified Interfaces

Interface (Initiating or Responding)	Interface number	Interface Condition	T/TP/SC or Content	T/TP/SC/Content Optionality
MEASURE Message Receiver	1	CAP130-[101]	Receive Message (PUBLIC COMMENT INPUT WELCOME)	R
			Send Ack (PUBLIC COMMENT INPUT WELCOME)	R
Content Consumer	2	R	Measurement Criteria Document (HITSP/C106)	R
		R	Nonrepudiation of Origin (HITSP/C26)	CAP130-[201]
Query Measures	3	CAP130-[101]	Measurement Criteria (HITSP/C106) (PUBLIC COMMENT INPUT WELCOME)	R
Node	4	R	Secured Communication Channel (HITSP/T17)	R
Request Access Control Decision	5	R	Access Control (HITSP/SC108)	R
Send Security Audit Event	6	R	Security Audit (HITSP/SC109)	R
Request Medical Knowledge	7	CAP130-[102]	Knowledge and Vocabulary (HITSP/SC111)	R

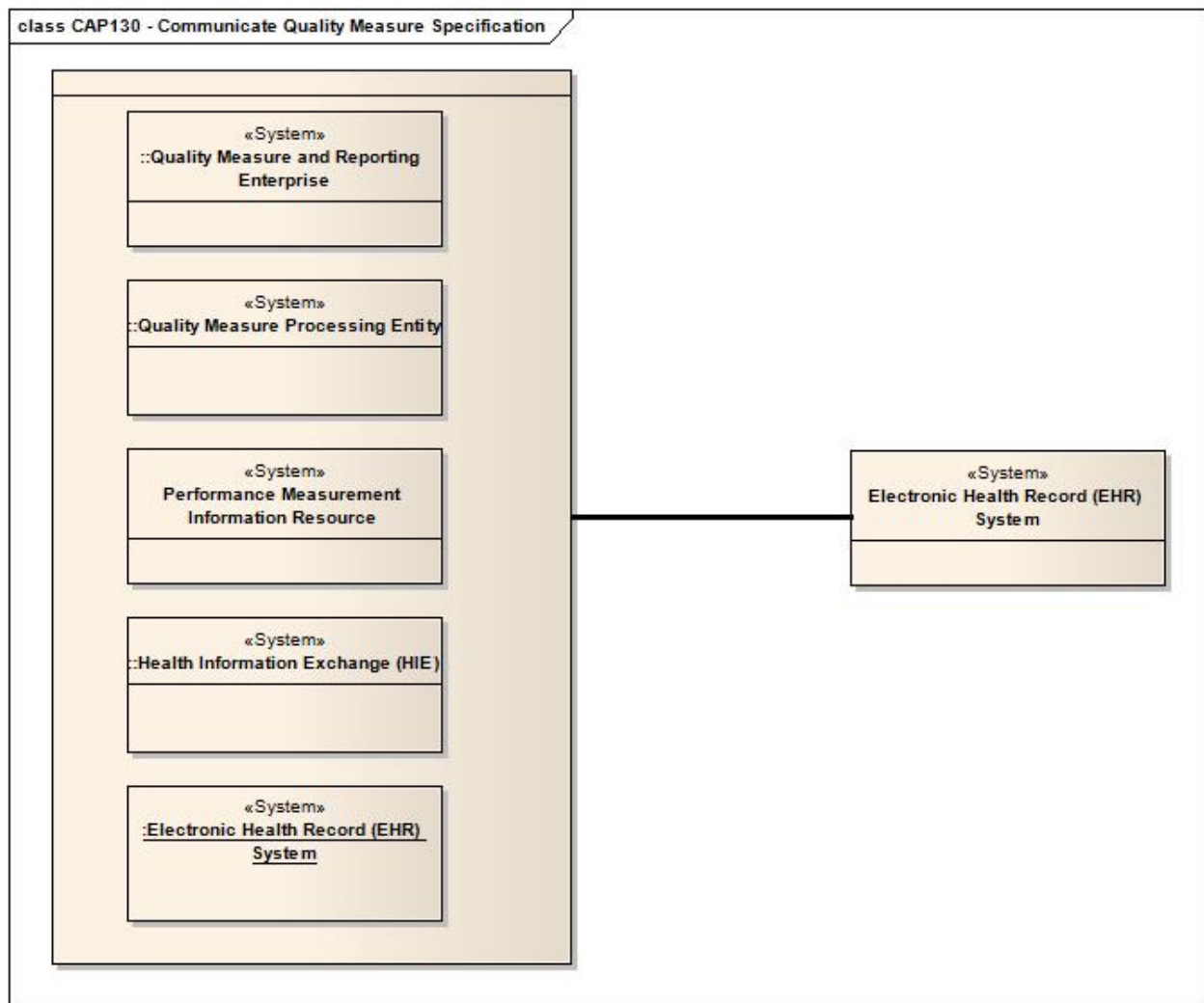
Table 3-81 Interface Conditions and T/TP/SC/Content Optionality

Condition Code	Condition Description
CAP130-[101]	System shall support at least one of these interfaces
CAP 130-[102]	This may be optionally used to deliver HITSP/C106 content. Other ways of transmitting HITSP/C106 are permissible (e.g. email) as this is not patient-specific content
CAP 130-[201]	Shall be applied where non-repudiation required by policy

The following diagram shows a visual overview of the Capability using UML notation. The visual overview outlines how the interacting systems work together as part of implementing the Capability. The thick arrow in the middle of the diagram outlines how sets of systems can interact together, and represent the information exchange requirement (IER) inherent to the Capability. An IER is not explicitly noted as part of this diagram.



Figure 3-15 HITSP/CAP130 – Communicate Quality Measure Specification Visual Overview



3.15.2.5 CAPABILITY OPTIONS

Note that subsets of the data content can be sent as appropriate for the application; but the system must be able to address the entire data content. Note that transport options can be addressed.

3.16 HITSP/CAP131 – UPDATE IMMUNIZATION REGISTRY SPECIFICATION

3.16.1 OVERVIEW

This Capability addresses interoperability requirements that enable electronic communication of immunization data among clinicians, with patients, and with immunization registries as unsolicited structured patient immunization data.

This Capability may use content anonymization.



3.16.2 DESIGN SPECIFICATION

3.16.2.1 INTERACTING SYSTEMS

Table 3-82 Interacting Systems

Interacting Systems
Health Information Exchange (HIE)
Immunization Information System (IIS)
Electronic Health Record System (EHR)

3.16.2.2 CONSTRAINTS AND ASSUMPTIONS

This section provides an overview of the constraints (i.e., Assumptions, Pre-conditions, Post-conditions, Triggers) associated with the Capability.

Table 3-83 Constraints and Assumptions

Constraint	Type of Constraint
Public Health system or stakeholder has a number of related components, including IIS. Most IIS are under state (or regional) Public Health Jurisdiction. In addition, Public Health has national, state and regional components	Assumption
Registries may or may not choose to receive data from PHRs or HIE connection	Assumption
Adult immunization handling may be different (e.g., some immunization registries will not accept adult immunizations)	Assumption
The registry may or may not be the same system for routine vs. emergency reporting	Assumption
Legal and governance issues regarding data access authorizations, data ownership, and data use are in effect	Pre-condition
Policies exist authorizing registries to exchange information	Pre-condition
Immunization knowledge providers distribute immunization schedules for incorporation into IIS, other registries, EHR systems and possibly health information exchange New immunization schedule is announced and received	Trigger
Registries, including IISs, gather vaccine or drug administration information from clinicians, consumers, other registries and other organizations A vaccine has been administered <ul style="list-style-type: none">• Consumer or provider needs/wants to send information to registry (e.g., new patient, an encounter, PHR)• Registries have negotiated an exchange of immunization information, and there is new data since the last exchange (for periodic exchange agreements) A vaccine has been administered to a patient from another IIS Registry jurisdiction	Trigger
A vaccine is given	Trigger

3.16.2.3 LIST OF CONSTRUCTS

Table 3-84 List of Constructs

Construct	Description
HITSP/C72 – Immunization Message	The HITSP Immunization Message Component provides the Capability to communicate an update to a patient's vaccination record. It is based upon the Centers for Disease Control and Prevention Implementation Guide for Immunizations Data Transaction using Version 2.3.1 of the Health Level Seven (HL7) Standard Protocol Implementation Guide Version 2.2 June 2006
HITSP/SC110 – Patient Identification Management	The HITSP Patient Identification Management Service Collaboration provides the ability to lookup and/or cross-reference patient identities.
HITSP/SC115 – HL7 Messaging	The HITSP HL7 Messaging Service Collaboration provides the Capability to send and receive HL7 messages. The Service Collaboration applies the necessary Security and Privacy constructs



Construct	Description
HITSP/T24 – Pseudonymization Request	The HITSP Pseudonymize Transaction describes a framework for including Pseudonymization Services where the use of “dummy” or pseudo references to specific patients or providers is required. Pseudo-identifiers are intended to allow accessibility to clinical information, while safeguarding any information that may compromise the privacy of the individual patient or provider. Using pseudo-identifiers can assist in compliance with HIPAA regulations regarding suppression of patient identification information

3.16.2.4 SPECIFIED INTERFACES

Table 3-85 HITSP/CAP131 – Update Immunization Registry Specified Interfaces

Interface (Initiating or Responding)	Interface number	Interface Condition	T/TP/SC or Content	T/TP/SC/Content Optionality ³¹
Content Consumer	1	O	Vaccination Message (HITSP/C72)	R
Content Creator	2	R	Vaccination Message (HITSP/C72)	R
		CAP131-[102]	Pseudonymization Request(T24)	R
Message Receiver	3	CAP131-[100], [101]	Vaccination Message(HITSP/C72)	R
Message Sender	4	CAP131-[100]	Vaccination Message(HITSP/C72)	R
Request Patient Identification	5	R	Patient Identification Management (HITSP/SC110)	R
Request HL7 Message	6	R	HL7 Messaging (HITSP/SC115)	R
Respond to HL7 Message	7	R	HL7 Messaging (HITSP/SC115)	R

Table 3-86 Interface Conditions and T/TP/SC/Content Optionality

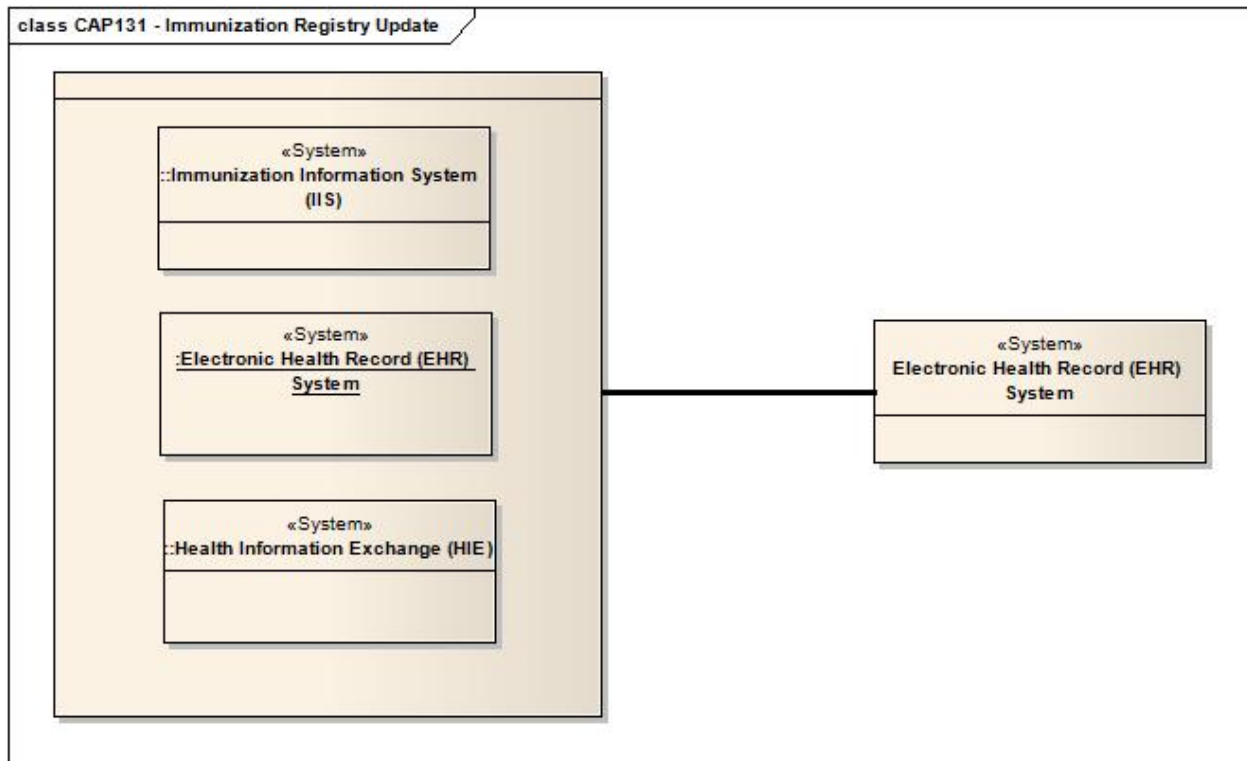
Condition Code	Condition Description
CAP131-[100]	Shall be applied for message-based vaccination query/response (VXQ/VXR) or submissions (VXU)
CAP131-[101]	System shall support at least one of these interfaces to receive or retrieve inbound content
CAP131-[102]	Shall be applied where pseudonymization is required by the jurisdiction or information sharing agreements or selected by PHR

The following diagram shows a visual overview of the Capability using UML notation. The visual overview outlines how the interacting systems work together as part of implementing the Capability. The thick arrow in the middle of the diagram outlines how sets of systems can interact together, and represent the information exchange requirement (IER) inherent to the Capability. An IER is not explicitly noted as part of this diagram.

³¹ Optionality = “R” for Required, “R2” for Required if known, “O” for Optional, or “C” for Conditional. If applicable, conditional footnotes are further described below.



Figure 3-16 HITSP/CAP131 – Update Immunization Registry Visual Overview



3.16.2.5 CAPABILITY OPTIONS

Note that subsets of the data content can be sent as appropriate for the application; but the system must be able to address the entire data content. Note that transport options can be addressed.

3.17 HITSP/CAP132 – RETRIEVE IMMUNIZATION REGISTRY INFORMATION SPECIFICATION

3.17.1 OVERVIEW

This Capability addresses interoperability requirements that support the query and retrieval of structured immunization data related to a patient's vaccination.

The Capability may use one of the following:

- HL7V2 query with implicit Patient Identity resolution
- HL7V2 query with explicitly Patient Identity resolution prior to query
- HL7V3 Query for Existing Data

The query for immunization documents from HITSP/CAP 133 - Communicate Immunization Summary may also be used.

3.17.2 DESIGN SPECIFICATION

This Capability addresses interoperability requirements that support the query and retrieval of structured immunization data related to a patient's vaccination.

The Capability may use one of the following:



- HL7V2 query with implicit Patient Identity resolution
- HL7V2 query with explicitly Patient Identity resolution prior to query
- HL7V3 Query for Existing Data

The query for immunization documents from HITSP/CAP133 - Communicate Immunization Summary may also be used.

3.17.3 DESIGN SPECIFICATION

3.17.3.1 INTERACTING SYSTEMS

Table 3-87 Interacting Systems

Interacting Systems
Health Information Exchange (HIE)
Immunization Information System (IIS)
Electronic Health Record (EHR) System
Personal Health Record (PHR) System

3.17.3.2 CONSTRAINTS AND ASSUMPTIONS

This section provides an overview of the constraints (i.e., Assumptions, Pre-conditions, Post-conditions, Triggers) associated with the Capability.

Table 3-88 Constraints and Assumptions

Constraint	Type of Constraint
A separate registry may be used for routine or emergency reporting	Assumption

3.17.3.3 LIST OF CONSTRUCTS

Table 3-89 List of Constructs

Construct	Description
HITSP/C70 – Immunization Query and Response	The HITSP Immunization Query and Response Component is used for a message based exchange of immunization information. It specifies the use of HL7 Version 2.3.1 Query for Vaccination Record (VXQ), to send a query from the message sender (clinician system, schools, IIS) to the message receiver (immunization registry)
HITSP/C88 – Anonymize Immunizations and Response Management Data	The HITSP Anonymize Immunizations and Response Management Data Component provides the ability to anonymize patient identifiable information for Immunization and Response Management. It provides specific instruction for anonymizing data that was created as part of routine clinical care delivery in preparation for repurposing the data. Anonymization, according to the International Organization for Standardization (ISO), is the process that removes the association between the identifying data set and the data subject
HITSP/SC110 – Patient Identification Management	The HITSP Patient Identification Management Service Collaboration provides the ability to lookup and/or cross-reference patient identities
HITSP/SC115 – HL7 Messaging	The HITSP HL7 Messaging Service Collaboration provides the capability to send and receive HL7 messages. This Service Collaboration applies the necessary Security and Privacy constructs



3.17.3.4 SPECIFIED INTERFACES

Table 3-90 HITSP/CAP132 – Retrieve Immunization Registry Information Specified Interfaces

Interface (Initiating or Responding)	Interface number	Interface Condition	T/TP/SC or Content	T/TP/SC/Content Optionality ³²
Message Sender	1	CAP132-[100], [101]	Vaccination Query Message(HITSP/C70)	R
			Vaccination Response Message(HITSP/C70)	O
Message Receiver	2	CAP132-[100], [102]	Vaccination Query Message(HITSP/C70)	O
			Vaccination Response Message(HITSP/C70)	R
Content Creator	3	CAP132-[103]	Vaccination Query Message (VXQ/VXR) (Query)(HITSP/C70)	R
			Vaccination Query Message (VXQ/VXR) (Response) (HITSP/C70)	O
		CAP132-[104]	Anonymize for IRM (HITSP/C88)	R
Content Consumer	4	CAP132-[103]	Vaccination Query Message (VXQ/VXR) (Query)(HITSP/C70)	O
			Vaccination Query Message (VXQ/VXR) (Response) (HITSP/C70)	R
Request HL7 Message	6	R	HL7 Messaging (HITSP/SC115)	R
Respond to HL7 Message	7	R	HL7 Messaging (HITSP/SC115)	R
Request Patient Identification	8	R	Patient Identification Management (HITSP/SC110)	R

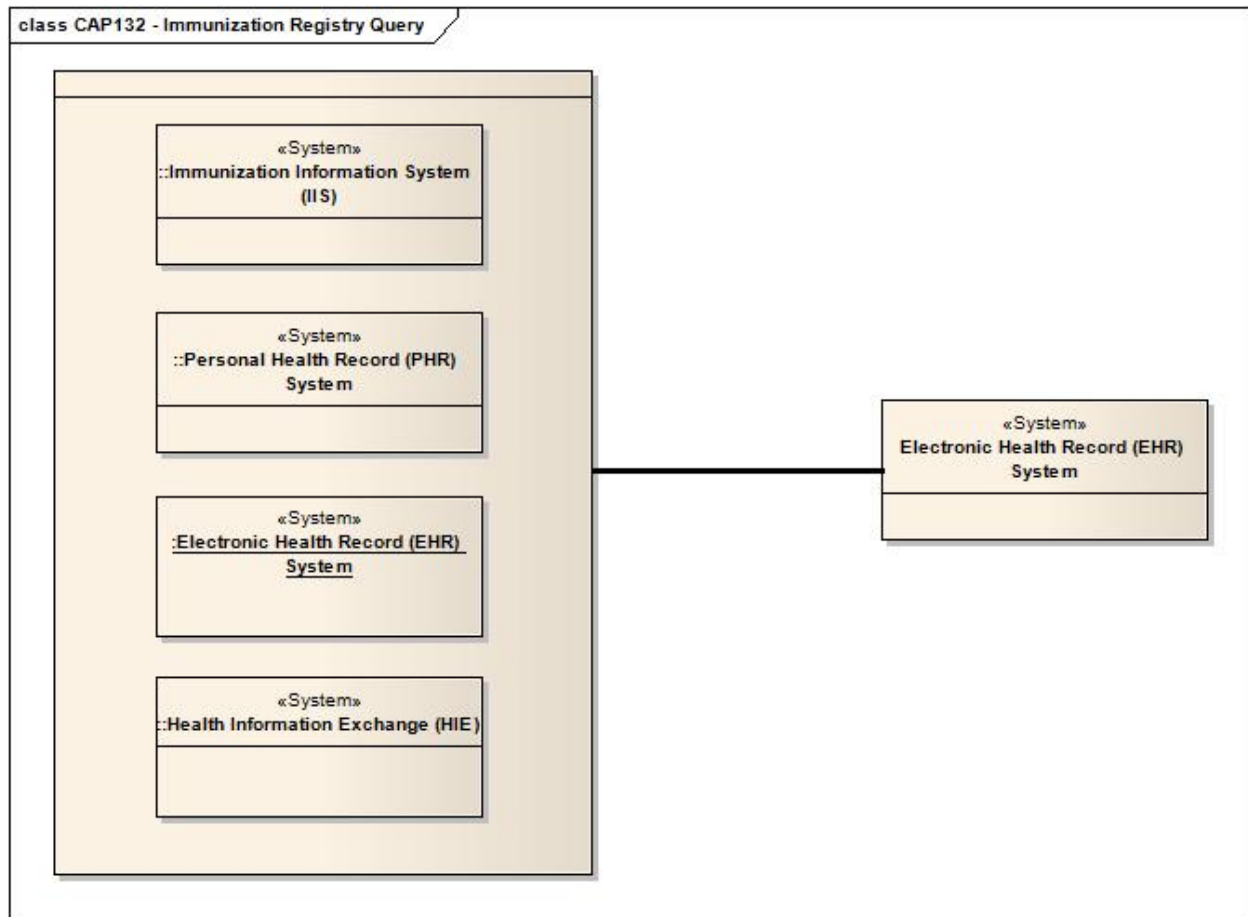
Table 3-91 Interface Conditions and T/TP/SC/Content Optionality

Condition Code	Condition Description
CAP132-[100]	Shall be applied for message-based vaccination query/response (VXQ/VXR) or submissions (VXU)
CAP132-[101]	System shall support at least one of these interfaces to communicate outbound content
CAP132-[102]	System shall support at least one of these interfaces to receive or retrieve inbound content
CAP132-[103]	One or both of these shall be applied for vaccination query/response
CAP132-[104]	Shall be applied where anonymization is required by the jurisdiction or information sharing agreements or selected by PH

³² Optionality = “R” for Required, “R2” for Required if known, “O” for Optional, or “C” for Conditional. If applicable, conditional footnotes are further described below.



Figure 3-17 HITSP/CAP132 – Retrieve Immunization Registry Information Visual Overview



3.17.3.5 CAPABILITY OPTIONS

Note that subsets of the data content can be sent as appropriate for the application; but the system must be able to address the entire data content. Note that transport options can be addressed.

3.18 HITSP/CAP133 – COMMUNICATE IMMUNIZATION SUMMARY SPECIFICATION

3.18.1 OVERVIEW

This Capability addresses interoperability requirements to support the communication of structured health data related to a patient's vaccination history. This immunization document contains a history of administered vaccines with details such as lot number, who administered it, as well as other information related to the patient's care such as medical history, medications, allergies, vital signs.



3.18.2 DESIGN SPECIFICATION

3.18.2.1 INTERACTING SYSTEMS

Table 3-92 Interacting Systems

Interacting Systems
Electronic Health Record (EHR) System
Personal Health Record (PHR) System
Health Information Exchange (HIE)
Immunization Information System (IIS)

3.18.2.2 CONSTRAINTS AND ASSUMPTIONS

This section provides an overview of the constraints (i.e., Assumptions, Pre-conditions, Post-conditions, Triggers) associated with the Capability.

Table 3-93 Constraints and Assumptions

Constraint	Type of Constraint
Immunization Information Systems may choose to not receive data from PHRs or HIE connection	Assumption
Adult immunization handling may be different (e.g., some immunization registries will not accept adult immunizations)	Assumption
The IIS may not be the same system for routine vs. emergency reporting	Assumption
Legal and governance issues regarding data access authorizations, data ownership, and data use are in effect	Pre-condition
Registries, including IISs, gather vaccine or drug administration information from clinicians, consumers, other registries and other organizations <ul style="list-style-type: none">• A vaccine has been administered• Consumer or provider needs/wants to send information to registry (e.g., new patient, an encounter, PHR)• Registries have negotiated an exchange of immunization information, and there is new data since the last exchange (for periodic exchange agreements)• A vaccine has been administered to a patient from another IIS Registry jurisdiction	Trigger
Content of the immunization documentation from the PHR may not be the same content as the Immunization Information System. Patients typically have all this detail. There may need to be more information given/reported. The consumer vaccination view limits the information provided to improve the clarity to the consumer so as to make the content consumer-friendly– e.g., remove duplicative doses)	Assumption
Document sharing can support sources of vaccine information from schools, or other entities as well as providers (e.g., camps, daycare), or from other immunization registries/jurisdictions	Assumption

3.18.2.3 LIST OF CONSTRUCTS

Table 3-94 List of Constructs

Construct	Description
HITSP/C26 – Nonrepudiation of Origin	The HITSP Nonrepudiation of Origin Component provides the mechanisms to support Nonrepudiation of Origin, which refers to both the proof of the integrity and origin of documents in a high-assurance manner, which can be verified by any party. This Component does not provide Nonrepudiation of Receipt
HITSP/C78 – Immunization Document	The HITSP Immunization Document Component defines the immunization data content to be exchanged between healthcare entities such as immunization information systems, electronic medical records systems, personal healthcare record systems and other stakeholders. It is based upon the IHE Patient Care Coordination (PCC) Technical Framework Supplement 2008-2009, Immunization Content (IC), Trial Implementation Version 1.0



Construct	Description
HITSP/C88 – Anonymize Immunizations and Response Management Data	The HITSP Anonymize Immunizations and Response Management Data Component provides the ability to anonymize patient identifiable information for Immunization and Response Management. It provides specific instruction for anonymizing data that was created as part of routine clinical care delivery in preparation for repurposing the data. Anonymization, according to the International Organization for Standardization (ISO), is the process that removes the association between the identifying data set and the data subject
HITSP/SC112 – Healthcare Document Management	The HITSP Healthcare Document Management Service Collaboration provides the ability to share healthcare documents using a set of topologies, such as Media, e-Mail, Point-to-Point, Shared within a Health Information Exchange, and Shared within a larger community (made up of potentially diverse Health Information Exchanges)

3.18.2.4 SPECIFIED INTERFACES

Table 3-95 HITSP/CAP133 – Communicate Immunization Summary Specified Interfaces

Interface (Initiating or Responding)	Interface number	Interface Condition	T/TP/SC or Content	T/TP/SC/Content Optionality ³³
Content Creator	1	R	Immunization Content (HITSP/C78)	R
	2	CAP133-[103]	Anonymize for IRM (HITSP/C88)	R
	3	O	Nonrepudiation (HITSP/C26)	R
Content Consumer	4	R	Immunization Content (HITSP/C78)	R
Receive Documents	5	CAP133-101]	Healthcare Document Management (HITSP/SC112)	R
Send Documents	6	CAP133-[101], [102]	Healthcare Document Management (HITSP/SC112)	R

Table 3-96 Interface Conditions and T/TP/SC/Content Optionality

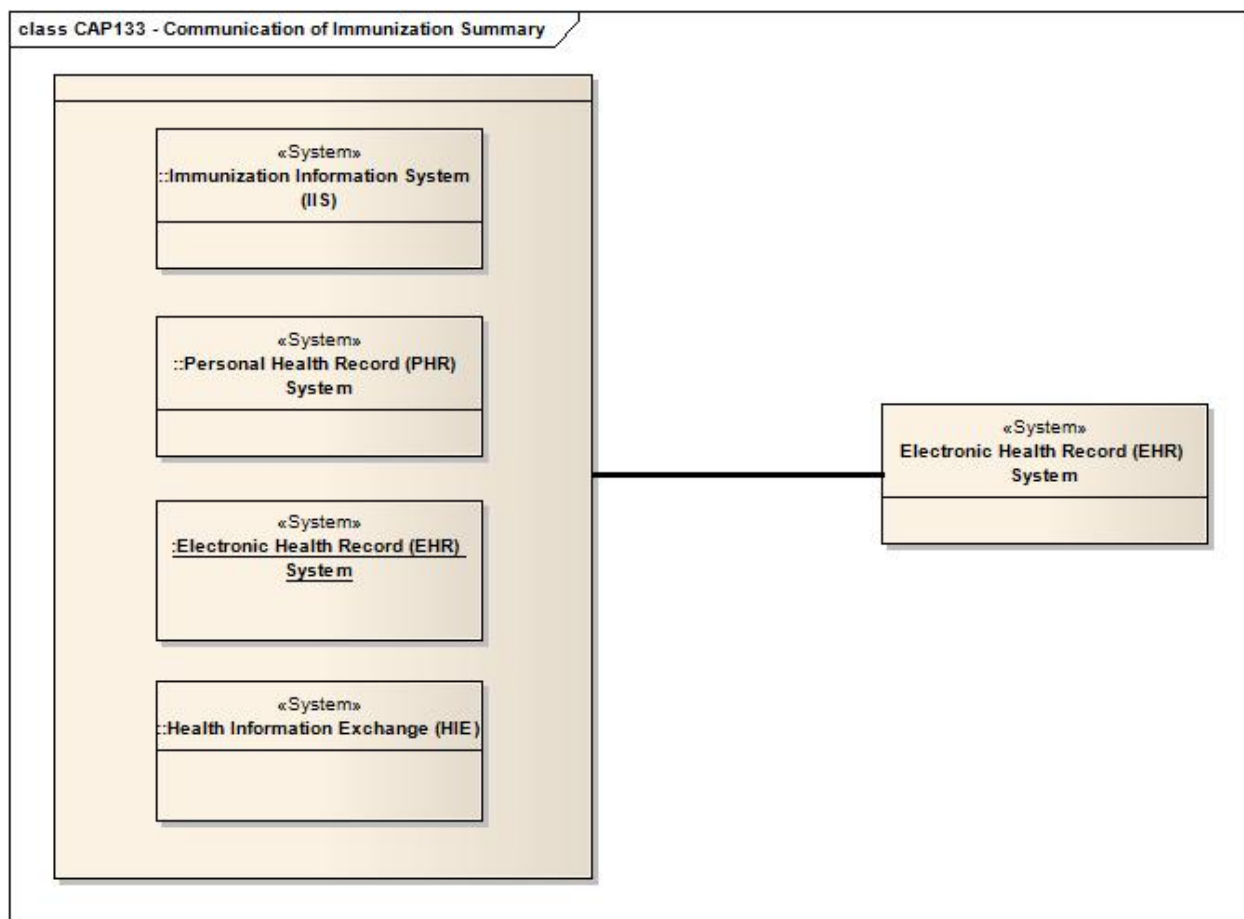
Condition Code	Condition Description
CAP133-[101]	An implementation shall choose amongst one of the interfaces defined in HITSP/SC112 Healthcare Document Management. This choice is dependent on the topology chosen (See Table 3-1 Information Exchange Topologies Mapped to Capabilities above), the physical limitations, policies and processes of the implementation
CAP133-[102]	The EHR System may optionally choose to implement a Document Repository or use an external repository for the Send Documents through Share option of HITSP/SC112 Healthcare document Management
CAP133-[103]	Shall be applied where anonymization is required by the jurisdiction or information sharing agreements or selected by PH

The following diagram shows a visual overview of the Capability using UML notation. The visual overview outlines how the interacting systems work together as part of implementing the Capability. The thick arrow in the middle of the diagram outlines how sets of systems can interact together, and represent the information exchange requirement (IER) inherent to the Capability. An IER is not explicitly noted as part of this diagram.

³³ Optionality = “R” for Required, “R2” for Required if known, “O” for Optional, or “C” for Conditional. If applicable, conditional footnotes are further described below.



Figure 3-18 HITSP/CAP133 – Communicate Immunization Summary Visual Overview



3.18.2.5 CAPABILITY OPTIONS

Note that subsets of the data content can be sent as appropriate for the application; but the system must be able to address the entire data content. Note that transport options can be addressed.

3.19 HITSP/CAP135 – RETRIEVE AND POPULATE FORM SPECIFICATION

3.19.1 OVERVIEW

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:

- Pre-population for Public Health Case Reports from Structured Documents using CDA
- Pre-population for Quality Data from Structured Documents using CDA
- No pre-population content

Systems may optionally support the means to retrieve request for clarifications.



3.19.2 DESIGN SPECIFICATION

3.19.2.1 INTERACTING SYSTEMS

Table 3-97 Interacting Systems

Interacting Systems
Electronic Health Record (EHR) System
Health Information Exchange (HIE)
Public Health Information System
Clinical Information System
Laboratory Information System
Radiology Information System
Quality Measure and Reporting System
Quality Measure Processing Entities

3.19.2.2 CONSTRAINTS AND ASSUMPTIONS

This section provides an overview of the constraints (i.e., Assumptions, Pre-conditions, Post-conditions, Triggers) associated with the Capability.

Table 3-98 Constraints and Assumptions

Constraint	Type of Constraint
Medical judgment may need attestation from the clinician; post-marketing situations may have certain tracking/PH response or severity-based decisions (clinician may look at this and determine other potential reasons for a false positive – and rules out a case). May need clinician validation/human judgment to kick off a next step. There may be a cascade of trigger events – there may be limited knowledge as to how to respond to a trigger event	Assumption
Forms is a very ambiguous word – we may have assumptions surrounding the interpretations. The common aspect is XML	Assumption
Need to consider reporting workflow: ID, review, report	Assumption
Need to consider workflow management: Optionality for human review; review /comment/ modification option before sending	Assumption
Need to support various reporting users: User may be clinician or office staff/hospital staff (e.g. stand-alone infection control applications, clinical registries, etc.)	Assumption
Authorizations for capture of supplemental data are defined by jurisdiction	Assumption
Augmentation mechanisms require appropriate authorizations: Not just PH agencies, but clinicians that may be reaching out in various ways to capture data that may not have been available in original data source	Assumption
Assume that confirm means that clinician confirms transmission in that point in time. Clinician may be able to gather info from a PHR	Assumption
The entity that needs to receive/file the report is determined by jurisdiction or domain policy agreements	Assumption
Trans-border communication expectations/specifications and mutual reporting are specified by policy	Assumption
Security/communications policies between institutions are established using established standards for trust management, risk assessment and cross-jurisdiction information exchange	Assumption
Secure communications are in place, and all policy, compliance, and authorization issues are addressed through automated or manual means	Pre-conditions
The receiving Information System has received the submitted data	Post-conditions
<ul style="list-style-type: none">• Terminology mapping is required• Assume that there may be a statistician encoding the rules• Transformation mapping• Assume that the implementation of the mathematical formula is not specified in the Interoperability Specification and is left to product innovation	Assumption



Constraint	Type of Constraint
The EHR is a resource for structured data	Assumption
Whether or not data are manually entered, the transaction must use the standards	Assumption
Data augmentation may be accomplished through additional electronic queries	Assumption
Data are ready for submission to recipient	Process Trigger

3.19.2.3 LIST OF CONSTRUCTS

Table 3-99 List of Constructs

Construct	Description
HITSP/C105 – Patient Level Quality Data Document Using HL7 Quality Reporting Document Architecture (QRDA)	The HITSP Patient level Quality Data Document Using HL7 Quality Reporting Document Architecture (QRDA) iComponent supports the communication of patient level quality data for quality measurement in a document sharing environment. Patient encounter data are compiled from both the local systems and from longitudinal data available through a Health Information Exchange (HIE) prior to communicating the retrieved data described in this construct for analysis.
HITSP/C26 - Nonrepudiation of Origin	The Nonrepudiation of Origin Component provides the mechanisms to support Nonrepudiation of Origin, which refers to both the proof of the integrity and origin of documents in a high-assurance manner, which can be verified by any party. This Component does not provide Nonrepudiation of Receipt
HITSP/C76 – Case Report Pre-Populate	The HITSP Case Report Pre-Populate Component supports the Data Mapping needed for Public Health Case Reports. Initially the Component supports only those data attributes that are universal or pertain to Drug Safety reporting. For those attributes that are universal in case reporting, this component may be used in support of pre-populating the remaining report types. However, other public health specific attributes will be addressed in subsequent releases
HITSP/SC108 – Access Control	The HITSP Access Control Service Collaboration provides the mechanism for security authorizations which control the enforcement of security policies including: role-based access control, entity based access control, context based access control, and the execution of consent directives
HITSP/SC109 – Security Audit	The HITSP Security Audit Service Collaboration describes the mechanism to record security relevant events in support of policy, regulation, or risk analysis. It also provides the mechanism to determine the record format to support analytical reports that are needed
HITSP/TP50 – Retrieve Form for Data Capture	The HITSP Retrieve Form for Data Capture Transaction Package enables capture of supplemental data variables not typically maintained in an electronic health record or laboratory information system through a more seamless integration with the local information system. This allows for the local system to retrieve a form specific to the identified potential public health threat. In the context of quality, it allows for the local system to capture supplemental data elements required for quality reporting that may not be available to the electronic health record

3.19.2.4 SPECIFIED INTERFACES

Table 3-100 HITSP/CAP135 – Retrieve and Populate Form Specified Interfaces

Interface (Initiating or Responding)	Interface number	Interface Condition	T/TP/SC or Content	T/TP/SC/Content Optionality
Form Filler	1	CAP135-[101]	Retrieve Form (HITSP/TP50)	R
			Submit Form (HITSP/TP50)	R
			Archive Form (HITSP/TP50)	O
			Retrieve Clarifications (HITSP/TP50)	O
			Patient Level Quality Data (HITSP/C105)	O
			Healthcare Associated Infection Report (HITSP/C75)	O
			Case Report Pre-Populate (HITSP/C76)	O
			Nonrepudiation of Origin (HITSP/C26)	CAP135-[202]
Form Manager (Option for CIS)	2	CAP135-[101]	Retrieve Form (HITSP/TP50)	R



Interface (Initiating or Responding)	Interface number	Interface Condition	T/TP/SC or Content	T/TP/SC/Content Optionality
supporting form management locally)			Retrieve clarifications (HITSP/TP50)	R
			Patient-Level Quality Data (HITSP/C105)	O
			Case Report Pre-Populate (HITSP/C76)	O
			Healthcare Associated Infection Report (HITSP/C75)	O
			Nonrepudiation of Origin (HITSP/C26)	CAP135-[202]
Form Receiver (Option for CIS supporting form management locally)	3	CAP135-[101]	Submit Form (HITSP/TP50)	R
			Patient Level Quality Data (HITSP/C105)	O
			Case Report Pre-Populate (HITSP/C76)	O
			Healthcare Associated Infection Report (HITSP/C75)	O
			Nonrepudiation of Origin (HITSP/C26)	CAP135-[202]
Form Archiver (Option for CIS supporting form management locally)	4	CAP135-[101]	Archive Form (HITSP/TP50)	R
			Patient Level Quality Data (HITSP/C105)	O
			Case Report Pre-Populate (HITSP/C76)	O
			Healthcare Associated Infection Report (HITSP/C75)	O
			Nonrepudiation of Origin (HITSP/C26)	CAP135-[202]
Node	5	R	Secured Communication Channel (HITSP/T17)	R
Request Access Control Decision	6	R	Access Control (HITSP/SC108)	CAP135-[201]
Send Security Audit Event	7	R	Security Audit (HITSP/SC109)	R

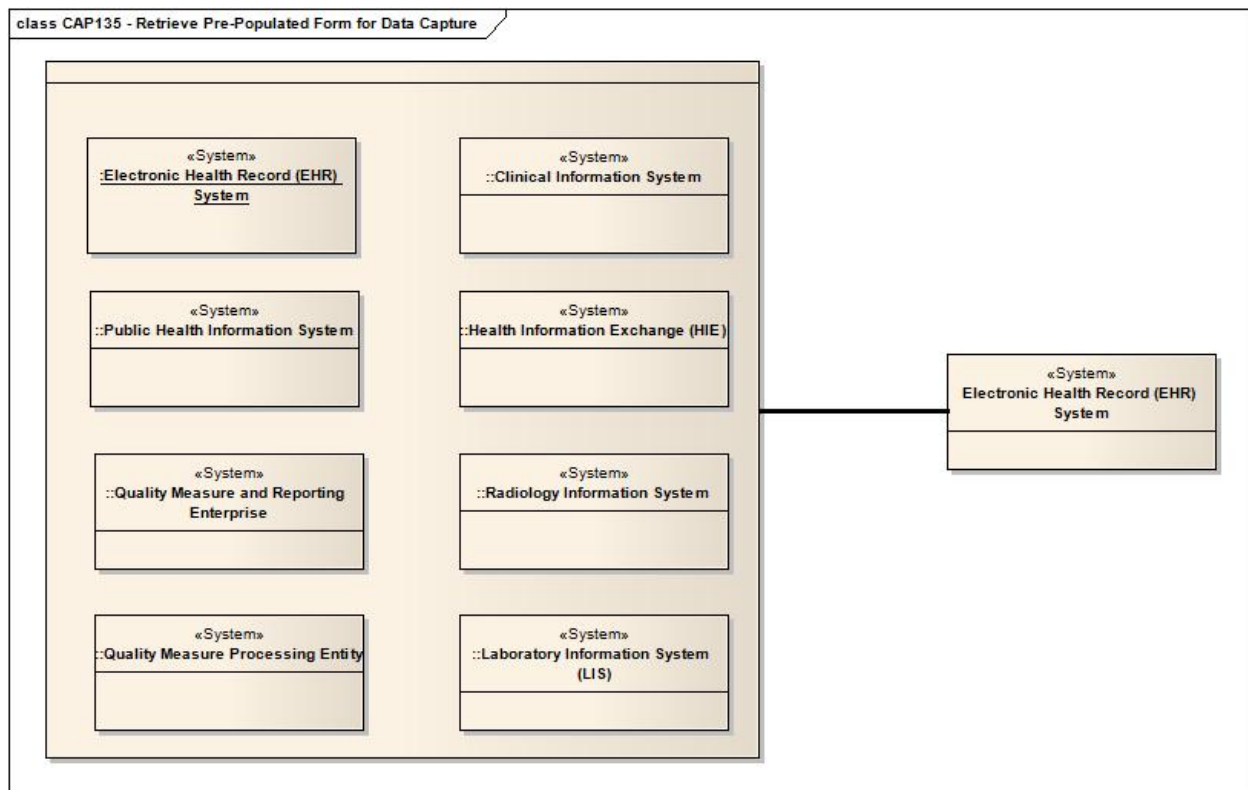
Table 3-101 Interface Conditions and T/TP/SC/Content Optionality

Condition Code	Condition Description
CAP135-C[101]	An implementation shall choose amongst one or more of the interfaces. This choice is dependent on the topology chosen, the physical limitations, policies and processes of the implementation
CAP135-C[201]	HITSP/C19 shall be applied where Entity Identity Assertion is required by the jurisdiction or information sharing agreements
CAP135-C[202]	Shall be applied where nonrepudiation is required by the jurisdiction or information sharing agreements

The following diagram shows a visual overview of the Capability using UML notation. The visual overview outlines how the interacting systems work together as part of implementing the Capability. The thick arrow in the middle of the diagram outlines how sets of systems can interact together, and represent the information exchange requirement (IER) inherent to the Capability. An IER is not explicitly noted as part of this diagram.



Figure 3-19 HITSP/CAP135 – Retrieve and Populate Form Visual Overview



3.19.2.5 CAPABILITY OPTIONS

Note that subsets of the data content can be sent as appropriate for the application; but the system must be able to address the entire data content. Note that transport options can be addressed.

3.20 HITSP/CAP136 – COMMUNICATE EMERGENCY ALERT SPECIFICATION

3.20.1 OVERVIEW

This Capability addresses interoperability requirements to support multicast of non-patient specific notification messages about emergencies events, alerts concerning incidence of communicable diseases, alerts concerning population needs for vaccines and other generic alerts sent to an identified channel. The intended recipients are populations such as “all emergency departments in XXX county”, “within a geographic area”, etc. In the event that patient specific emergency alerting is required, other Capabilities such as HITSP/CAP120 Communicate Unstructured Document or HITSP/CAP122 Retrieval of Medical Knowledge Capability may be used (See HITSP/IS10 Section 3.2.2).

3.20.2 DESIGN SPECIFICATION

3.20.2.1 INTERACTING SYSTEMS

Table 3-102 Interacting Systems

Interacting Systems
Electronic Health Record (EHR) System
Emergency Communications System



3.20.2.2 CONSTRAINTS AND ASSUMPTIONS

This section provides an overview of the constraints (i.e., Assumptions, Pre-conditions, Post-conditions, Triggers) associated with the Capability.

Table 3-103 Constraints and Assumptions

Constraint	Type of Constraint
Behavior and Policy of PSO is defined by jurisdiction	Assumption
Authorizations for capture of supplemental data are defined by jurisdiction	Assumption
The entity that needs to receive/file the report is determined by jurisdiction or domain policy agreements	Assumption
Trans-border communication expectations/specifications and mutual reporting are specified by policy	Assumption
Case count is not the priority/purpose here – goal is to manage/contain event not to produce a case count	Assumption
Assume that the perspective addresses both National and local jurisdiction; Local PH jurisdiction perspective may differ from CDC perspective	Assumption
Policy considerations apply to exposure notifications and IRB/research authorization	Assumption
Jurisdiction or HIE Policy may impose information exchange restrictions for some of these communications if electronic	Assumption
Authentication service to authenticate requestors and/or data submissions from various locations	Pre-condition

3.20.2.3 LIST OF CONSTRUCTS

Table 3-104 List of Constructs

Construct	Description
HITSP/C82 – Emergency Common Alerting Protocol	The HITSP Emergency Common Alerting Protocol Component selects the OASIS Common Alerting Protocol (CAP) v1.1 standard, and is used as a multicast notification message sent to an identified channel. The intended recipients are populations such as “all emergency departments in XXX county”, “within a geographic area”, etc
HITSP/SC116 – Emergency Message Distribution Element	The HITSP Emergency Message Distribution Service Collaboration performs a multicast notification to specifically identified populations, such as emergency departments

3.20.2.4 SPECIFIED INTERFACES

Table 3-105 HITSP/CAP136 – Communicate Emergency Alert Specified Interfaces

Interface (Initiating or Responding)	Interface number	Interface Condition	T/TP/SC or Content	T/TP/SC/Content Optionality ³⁴
Alert Message Transmitter	1	R	Send Message (HITSP/C82)	R
Alert Message Receiver	2	R	Receive Message (HITSP/C82)	R
Send Emergency Message Distribution Element	3	R	Emergency Message Distribution Element (HITSP/SC116)	R

Table 3-106 Interface Conditions and T/TP/SC/Content Optionality

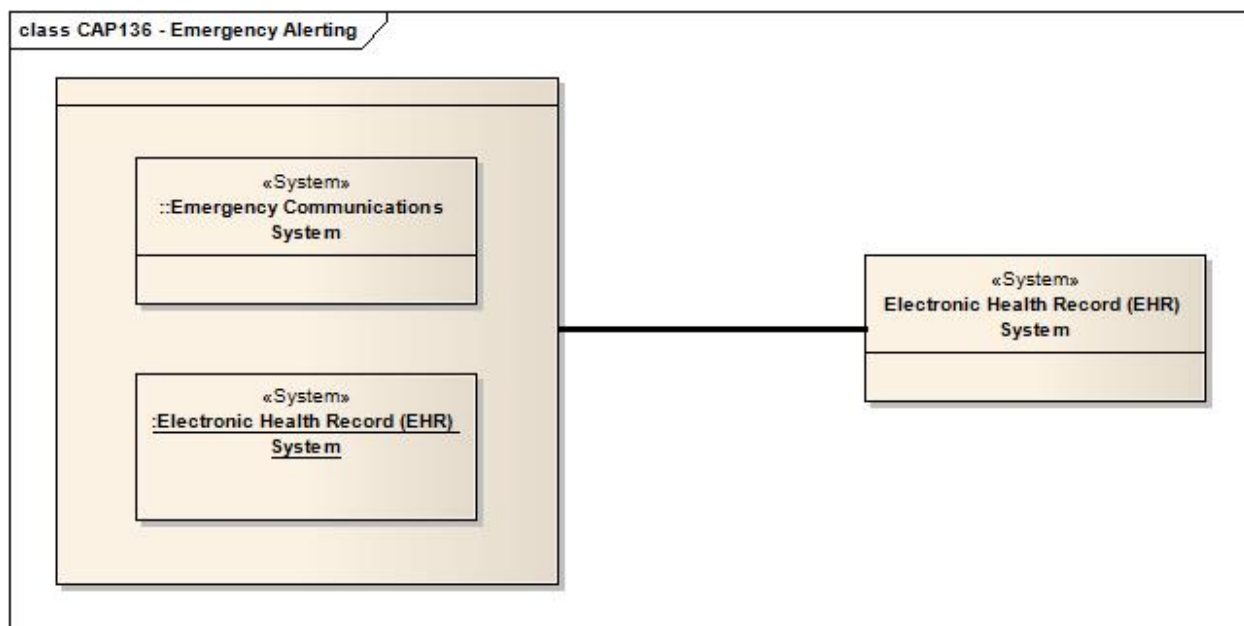
Condition Code	Condition Description
No Applicable Condition Codes	

³⁴ Optionality = “R” for Required, “R2” for Required if known, “O” for Optional, or “C” for Conditional. If applicable, conditional footnotes are further described below.



The following diagram shows a visual overview of the Capability using UML notation. The visual overview outlines how the interacting systems work together as part of implementing the Capability. The thick arrow in the middle of the diagram outlines how sets of systems can interact together, and represent the information exchange requirement (IER) inherent to the Capability. An IER is not explicitly noted as part of this diagram.

Figure 3-20 HITSP/CAP136 – Communicate Emergency Alert Visual Overview



3.20.2.5 CAPABILITY OPTIONS

Note that subsets of the data content can be sent as appropriate for the application; but the system must be able to address the entire data content. Note that transport options can be addressed.

3.21 HITSP/CAP137 – COMMUNICATE ENCOUNTER INFORMATION MESSAGE SPECIFICATION

3.21.1 OVERVIEW

This Capability addresses interoperability requirements to send specific clinical encounter data among multiple systems.

The content may be either or both:

1. Encounter Data Message
2. Radiology Results Message

It may be used in conjunction with other capabilities such as those related to the communication of laboratory data. This Capability includes optional anonymization of content.



3.21.2 DESIGN SPECIFICATION

3.21.2.1 INTERACTING SYSTEMS

Table 3-107 Interacting Systems

Interacting Systems
Electronic Health Record (EHR) System
Clinical Information System, Laboratory Information System, Radiology Information System
Diagnostic Imaging Information System
Health Information Exchange
Personal Health Record (PHR) System
Public Health Agencies (includes Local/State/Federal)
Emergency Operations Center (EOC)
Emergency Communications System
Healthcare Delivery Organization, Regional Health Information Organizations (RHIO))

3.21.2.2 CONSTRAINTS AND ASSUMPTIONS

This section provides an overview of the constraints (i.e., Assumptions, Pre-conditions, Post-conditions, Triggers) associated with the Capability.

Table 3-108 Constraints and Assumptions

Constraint	Type of Constraint
Machine-generated Radiology Results are included in data requirements for Lab Results	Assumption
Visit data are likely to be supplied through the admitting/registration system	Assumption
Radiology and laboratory clinical orders are available electronically, may be used, and contain information describing patients and the types of clinical tests requested	Pre-conditions
Legal and governance issues regarding data access authorizations, data ownership, and data use are in effect	Pre-conditions
The receiving system has received the submitted data	Post-conditions

3.21.2.3 LIST OF CONSTRUCTS

Table 3-109 List of Constructs

Construct	Description
HITSP/C25 – Anonymize	The HITSP Anonymize Component provides specific instruction for anonymizing data that are prepared for repurposing data created as part of routine clinical care delivery. This construct defines the Component specification that provides the ability to anonymize patient identifiable information
HITSP/C39 – Encounter Message	The HITSP Encounter Message Component supports the process of sending patient encounter data (excluding laboratory results and radiology reports) from a Biosurveillance Message Sender to a Biosurveillance Message Receiver. Patient encounter data are captured as part of the normal process of care performed by healthcare providers such as hospitals, emergency departments and outpatient clinics
HITSP/C41 – Radiology Result Message	The HITSP Radiology Result Message Component supports the process of sending radiology result data from a Biosurveillance Message Sender to a Biosurveillance Message Receiver. Radiology result data are captured as part of the normal process of care performed by healthcare providers
HITSP/SC115 – HL7 Messaging	The HITSP HL7 Messaging Service Collaboration provides the Capability to send and receive HL7 messages. The Service Collaboration applies the necessary Security and Privacy constructs



3.21.2.4 SPECIFIED INTERFACES

Table 3-110 HITSP/CAP137 – Communicate Encounter Information Message Specified Interfaces

Interface (Initiating or Responding)	Interface number	Interface Condition	T/TP/SC or Content	T/SC/Content Optionality ³⁵
Message Sender	1	CAP137-[101]	Send Message (HL7)	R
			Receive Ack (HL7)	R
Message Receiver	2	CAP137-[101]	Receive Message (HL7)	R
			Send Ack (HL7)	R
Content Creator	3	R	Encounter message Component (HITSP/C39)	CAP137-[201]
			Radiology Result Message (HITSP/C41)	CAP137-[201]
			Anonymize (HITSP/C25)	CAP137-[202]
Request HL7 Message	4	R	HL7 Messaging (HITSP/SC115)	R
Respond to HL7 Message	5	R	HL7 Messaging (HITSP/SC115)	R

Table 3-111 Interface Conditions and T/TP/SC/Content Optionality

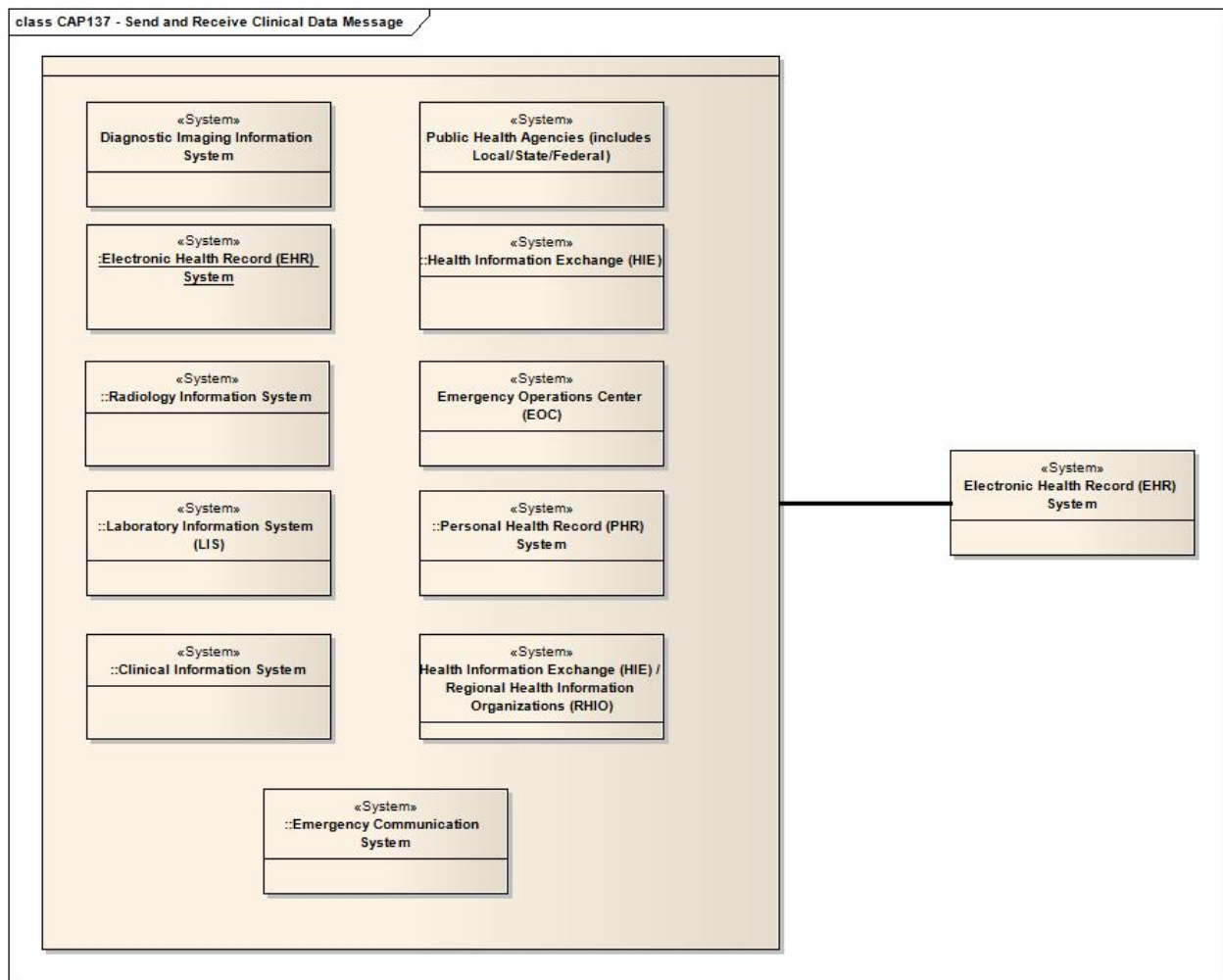
Condition Code	Condition Description
CAP137-[101]	The system shall support at least one of these interfaces
CAP137-[201]	At least one of these constructs shall be supported
CAP137-[202]	Shall be applied where anonymization is required by the jurisdiction or information sharing agreements

The following diagram shows a visual overview of the Capability using UML notation. The visual overview outlines how the interacting systems work together as part of implementing the Capability. The thick arrow in the middle of the diagram outlines how sets of systems can interact together, and represent the information exchange requirement (IER) inherent to the Capability. An IER is not explicitly noted as part of this diagram.

³⁵ Optionality = “R” for Required, “R2” for Required if known, “O” for Optional, or “C” for Conditional. If applicable, conditional footnotes are further described below.



Figure 3-21 HITSP/CAP137 – Communicate Encounter Information Message Visual Overview



3.21.2.5 CAPABILITY OPTIONS

Note that subsets of the data content can be sent as appropriate for the application; but the system must be able to address the entire data content. Note that transport options can be addressed.

3.22 HITSP/CAP138 – RETRIEVE PSEUDONYM SPECIFICATION

3.22.1 OVERVIEW

This Capability addresses interoperability requirements to support a particular type of anonymization that both removes the association with a data subject, and adds an association between a particular set of characteristics relating to the data subject and one or more pseudonyms. This enables a process of supplying an alternative identifier, which permits a patient to be referred to by a key that suppresses his/her actual identification information. The purpose of this Capability is to offer a pseudonymization framework for situations that require the use of specific data without disclosing the specific identity of patients or providers. Pseudo-identifiers are intended to allow accessibility to clinical information, while safeguarding any information that may compromise the privacy of the individual patient or provider. However, unlike anonymization, the alternative identifier key can be used to re-identify the individuals whose data was used.



3.22.2 DESIGN SPECIFICATION

3.22.2.1 INTERACTING SYSTEMS

Table 3-112 Interacting Systems

Interacting Systems
Electronic Health Record (EHR) System
Health Information Exchange (HIE)
Emergency Communications System (ECS)
Public Health Information System
Quality Measure Processing Entities
Personal Health Record (PHR) Systems
Immunization Information System (IIS)
Laboratory Information Systems

3.22.2.2 CONSTRAINTS AND ASSUMPTIONS

This section provides an overview of the constraints (i.e., Assumptions, Pre-conditions, Post-conditions, Triggers) associated with the Capability.

Table 3-113 Constraints and Assumptions

Constraint	Type of Constraint
Security/communications policies between institutions are established using established standards for trust management, risk assessment and cross-jurisdiction information exchange	Assumption
Re-identification of pseudonymized data as needed is authorized	Assumption
Security standard selection must be done in accordance with HIPAA and based upon the risk assessment for the selected architecture	Assumption
Data to be pseudonymized is not anonymized	Pre-condition
Security and Privacy policies, procedures and practices are commonly implemented to support acceptable levels of consumer/patient privacy and security	Pre-condition
Legal and governance issues regarding data access authorizations, data ownership, and data use are in effect and Secure communications are in place, and all policy, compliance, and authorization issues are addressed through automated or manual means	Pre-condition
All re-identification events for Pseudonymized quality data shall record the re-identification purpose from the list provided in section 5.3.1 of ISO TS25237 Health Informatics: Pseudonymization	Pre-condition
Policy for re-linking is defined	Pre-condition
Patient level data requires pseudonymization by policy	Trigger

3.22.2.3 LIST OF CONSTRUCTS

Table 3-114 List of Constructs

Construct	Description
HITSP/T24 – Pseudonymize	The HITSP Pseudonymize Transaction describes a framework for including Pseudonymization Services where the use of “dummy” or pseudo references to specific patients or providers is required. Pseudo-identifiers are intended to allow accessibility to clinical information, while safeguarding any information that may compromise the privacy of the individual patient or provider. Using pseudo-identifiers can assist in compliance with HIPAA regulations regarding suppression of patient identification information



3.22.2.4 SPECIFIED INTERFACES

Table 3-115 HITSP/CAP138 – Retrieve Pseudonym Specified Interfaces

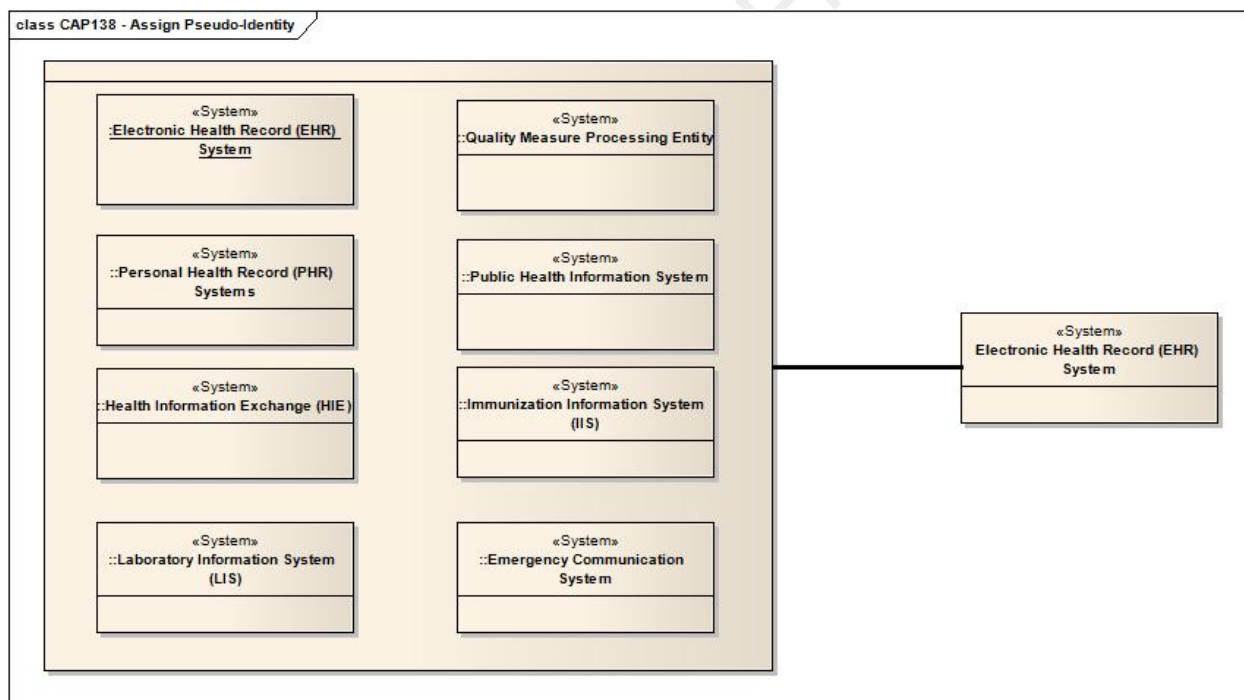
Interface (Initiating or Responding)	Interface number	Interface Condition	T/TP/SC or Content	T/TP/SC/Content Optionality ³⁶
Pseudonymization Service	1	CAP138-[101]	Pseudonymization Request (HITSP/T24)	R
Person Identification Service	2	CAP138-[101]	Person Identity Feed (HITSP/T24)	R
Content Creator	3	CAP138-[101]	Pseudonymization Request (HITSP/T24)	R

Table 3-116 Interface Conditions and T/TP/SC/Content Optionality

Condition Code	Condition Description
CAP138-[101]	Shall be applied where pseudonymization is required by the jurisdiction or information sharing agreements

The following diagram shows a visual overview of the Capability using UML notation. The visual overview outlines how the interacting systems work together as part of implementing the Capability. The thick arrow in the middle of the diagram outlines how sets of systems can interact together, and represent the information exchange requirement (IER) inherent to the Capability. An IER is not explicitly noted as part of this diagram.

Figure 3-22 HITSP/CAP138 – Retrieve Pseudonym Visual Overview



3.22.2.5 CAPABILITY OPTIONS

Note that subsets of the data content can be sent as appropriate for the application; but the system must be able to address the entire data content. Note that transport options can be addressed.

³⁶ Optionality = “R” for Required, “R2” for Required if known, “O” for Optional, or “C” for Conditional. If applicable, conditional footnotes are further described below.



3.23 HITSP/CAP139 – COMMUNICATE RESOURCE UTILIZATION SPECIFICATION

3.23.1 OVERVIEW

This Capability specifies the message and content necessary to report utilization and status of health provider resources to systems supporting emergency management officials at local, state or national levels who have a need to know the availability of hospital and other healthcare resources. The resource utilization information may be provided routinely or in response to a request.

3.23.2 DESIGN SPECIFICATION

3.23.2.1 INTERACTING SYSTEMS

Table 3-117 Interacting Systems

Interacting Systems
Electronic Health Record (EHR) System
Emergency Communications System

3.23.2.2 CONSTRAINTS AND ASSUMPTIONS

This section provides an overview of the constraints (i.e., Assumptions, Pre-conditions, Post-conditions, Triggers) associated with the Capability.

Table 3-118 Constraints and Assumptions

Constraint	Type of Constraint
Legal and governance issues regarding data access authorizations, data ownership, and data use are in effect	Pre-condition

3.23.2.3 LIST OF CONSTRUCTS

Table 3-119 List of Constructs

Construct	Description
HITSP/C47 – Resource Utilization Message	The Resource Utilization Message Component specifies the message and content necessary to report utilization and status of health provider resources to public health agencies. This specification reflects the current status of harmonization efforts between HL7 and OASIS
HITSP/SC116 – Emergency Message Distribution Element	Emergency Message Distribution performs a multicast notification to specifically identified populations, such as emergency departments

3.23.2.4 SPECIFIED INTERFACES

Table 3-120 HITSP/CAP139 – Communicate Resource Utilization Specified Interfaces

Interface (Initiating or Responding)	Interface number	Interface Condition	T/TP/SC or Content	T/SC/Content Optionality ³⁷
Content Creator	1	R	Resource Utilization (HITSP/C47)	CAP139-[201]
Content Consumer	2	R	Resource Utilization (HITSP/C47)	CAP139-[201]
Send Emergency Message Distribution Element	3	R	Emergency Message Distribution Element (HITSP/SC116)	R

³⁷ Optionality = “R” for Required, “R2” for Required if known, “O” for Optional, or “C” for Conditional. If applicable, conditional footnotes are further described below.

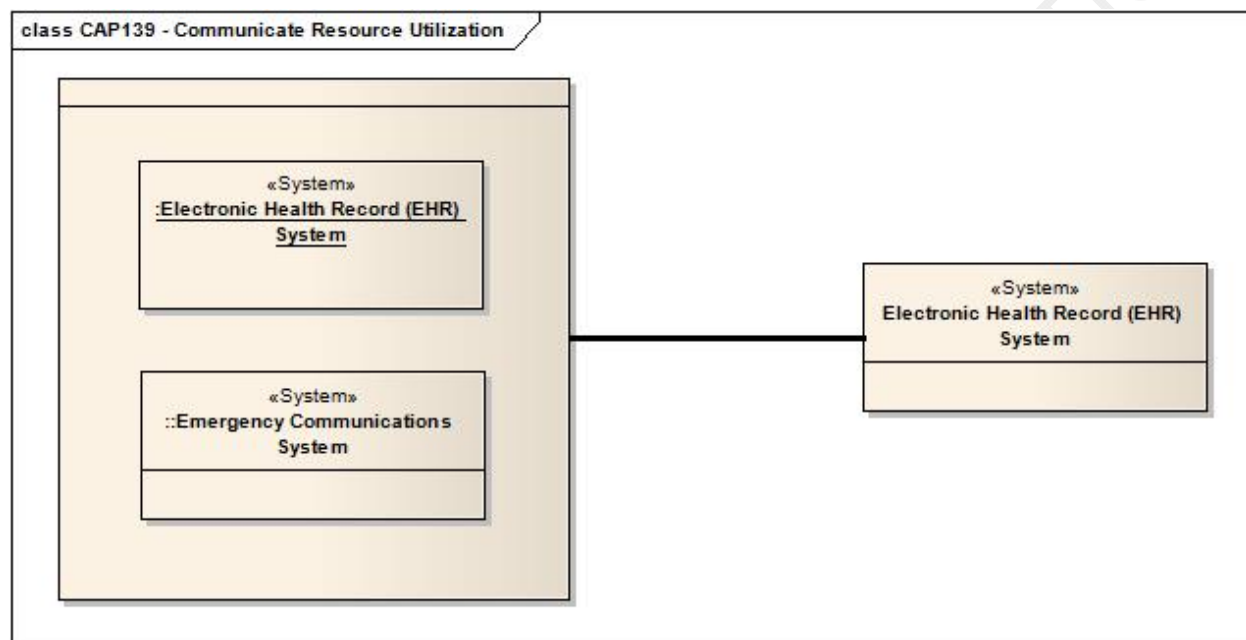


Table 3-121 Interface Conditions and T/TP/SC/Content Optionality

Condition Code	Condition Description
CAP139-[201]	For systems reporting bed availability, system shall support HITSP Resource Utilization Component

The following diagram shows a visual overview of the Capability using UML notation. The visual overview outlines how the interacting systems work together as part of implementing the Capability. The thick arrow in the middle of the diagram outlines how sets of systems can interact together, and represent the information exchange requirement (IER) inherent to the Capability. An IER is not explicitly noted as part of this diagram.

Figure 3-23 HITSP/CAP139 – Communicate Resource Utilization Visual Overview



3.23.2.5 CAPABILITY OPTIONS

Note that subsets of the data content can be sent as appropriate for the application; but the system must be able to address the entire data content. Note that transport options can be addressed.

3.24 HITSP/CAP140 – COMMUNICATE BENEFITS AND ELIGIBILITY SPECIFICATION

3.24.1 OVERVIEW

This Capability addresses interoperability requirements that support electronic inquiry and response from a patient's eligibility for health insurance benefits. The information exchanged includes the following:

1. A patient's identification (i.e., name, date of birth, and the health plan's member identification number)
2. Communication of a member's status of coverage and benefit information and financial liability.
3. Access to information about types of services, benefits and coverage for various medical care and medications.

It provides clinicians with information about each member's health insurance coverage and benefits.



3.24.2 DESIGN SPECIFICATION

3.24.2.1 INTERACTING SYSTEMS

Table 3-122 Interacting Systems

Interacting Systems
Electronic Health Record (EHR) System
Provider Administrative and Financial System
Health Plan System
Electronic Health Record (EHR) – Hospital
Electronic Health Record (EHR) – Hospital and EHR LTC
Pharmacy Systems
Pharmacy Systems – Hospital and Pharmacy Systems – External
Health Care Entities (for LTC)
Health Information Exchange (HIE)
PBM/Payers System

3.24.2.2 CONSTRAINTS AND ASSUMPTIONS

This section provides an overview of the constraints (i.e., Assumptions, Pre-conditions, Post-conditions, Triggers) associated with the Capability.

Table 3-123 Constraints and Assumptions

Constraint	Type of Constraint
Patient Identities (name demographics etc.) are known and are consistent with policies. In this regard, it is expected that the Health Plan's member Id is known and related to the Provider's Finance & Admin System accordingly	Pre-condition
Health Information Exchange (HIE) can serve as intermediary for data in many implementation variants. The various alternative options are not shown	Assumption
Entities have pre-established a business relationship to exchange information	Pre-condition
Authentication service to authenticate requestors and/or data submissions from various locations	Pre-condition
Security and privacy policies, procedures and practices are commonly implemented to support acceptable levels of consumer/patient security and privacy	Pre-condition

3.24.2.3 LIST OF CONSTRUCTS

Table 3-124 List of Constructs

Construct	Description
HITSP/SC114 – Administrative Transport to Health Plan	The HITSP Administrative Transport to Health Plan service collaboration provides the transport mechanism for conducting administrative transactions with health plans
HITSP/T40 – Patient Health Plan Eligibility Verification	The HITSP Patient Health Plan Eligibility Verification Transaction is intended to provide the status of a health plan covering the individual, along with details regarding patient liability for deductible, co-pay and co-insurance amounts for a defined base set of generic benefits or services. The base set of benefits includes, but is not limited to, coverage status and patient liability for medical, chiropractic, dental, hospital inpatient, hospital outpatient, emergency, physician office visit, pharmacy and vision services that are included in the patient's generic health plan benefit
HITSP/TP46 – Medication Formulary and Benefits Information	The HITSP Medication Formulary and Benefits Information Transaction Package addresses two tasks. The first task is to perform an eligibility check for a specific patient's pharmacy benefits. The second task is to obtain the medication formulary and benefit information



3.24.2.4 SPECIFIED INTERFACES

Table 3-125 HITSP/CAP140 – Communicate Benefits and Eligibility Specified Interfaces

Interface (Initiating or Responding)	Interface number	Interface Condition	T/TP/SC or Content	T/TP/SC/Content Optionality ³⁸
Eligibility Information Receiver*	1	R	Eligibility Information Request (HITSP/T40)	R
		R	Eligibility Information Response (HITSP/T40)	R
		R	Medication and Formulary Eligibility Request (HITSP/TP46)	R
		R	Medication and Formulary Eligibility Response (HITSP/TP46)	R
Request Administrative Transport to Health Plan	2	R	Administrative Transport to Health Plan (HITSP/SC114)	R
Respond to Administrative Request to Health Plan	3	R	Administrative Transport to Health Plan (HITSP/SC114)	R

*Note: The Eligibility Information Receiver Interface may be handled via an intermediary Interacting System such as a Provider Administrative and Financial System.

Table 3-126 Interface Conditions and T/TP/SC/Content Optionality

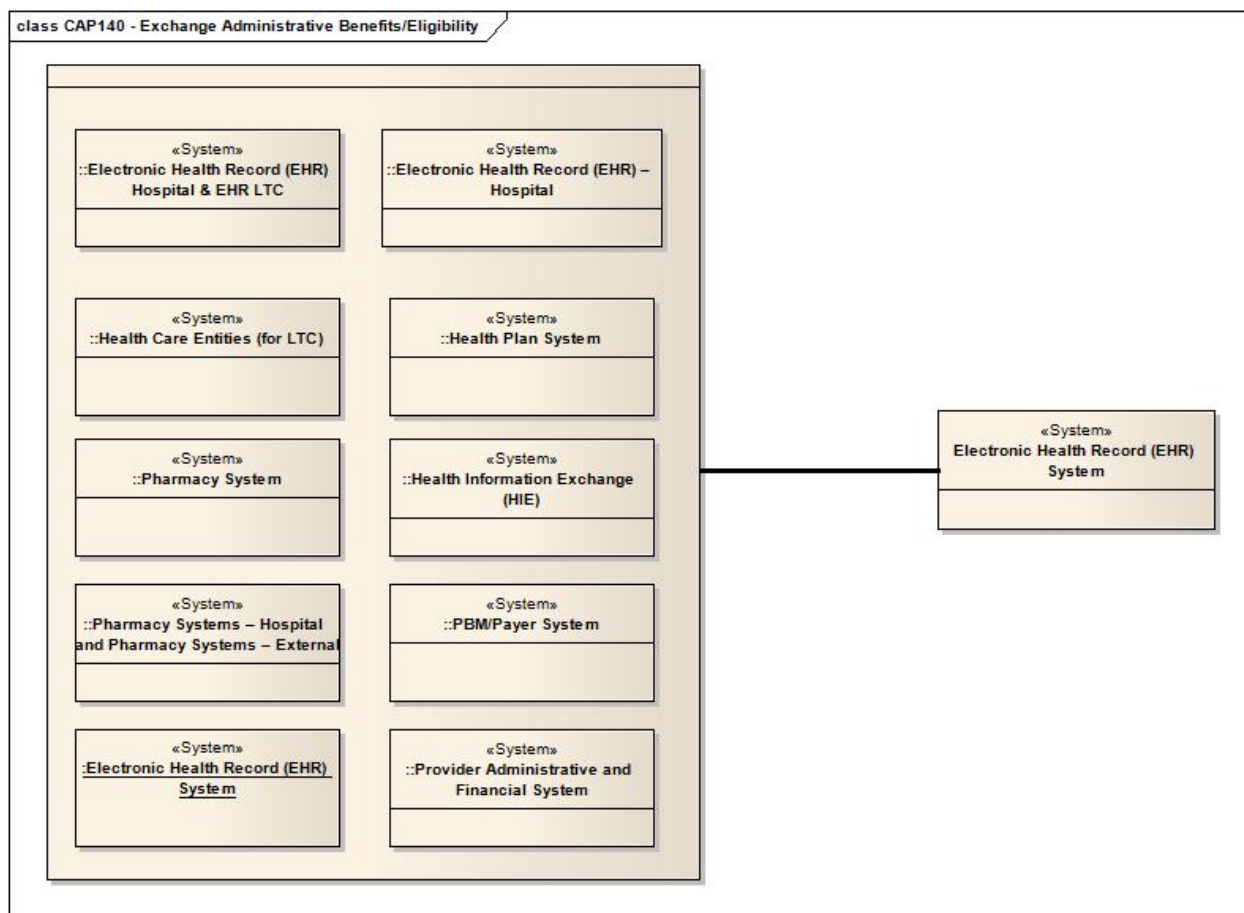
Condition Code	Condition Description
No Applicable Condition Codes	

The following diagram shows a visual overview of the Capability using UML notation. The visual overview outlines how the interacting systems work together as part of implementing the Capability. The thick arrow in the middle of the diagram outlines how sets of systems can interact together, and represent the information exchange requirement (IER) inherent to the Capability. An IER is not explicitly noted as part of this diagram.

³⁸ Optionality = “R” for Required, “R2” for Required if known, “O” for Optional, or “C” for Conditional. If applicable, conditional footnotes are further described below.



Figure 3-24 HITSP/CAP140 – Communicate Benefits and Eligibility Visual Overview



3.24.2.5 CAPABILITY OPTIONS

Note that subsets of the data content can be sent as appropriate for the application; but the system must be able to address the entire data content. Note that transport options can be addressed.

3.25 HITSP/CAP141 – COMMUNICATE REFERRAL AUTHORIZATION SPECIFICATION

3.25.1 OVERVIEW

This Capability addresses interoperability requirements that support electronic inquiry and response to authorizing a patient (health plan member) to be referred for service by another provider or to receive a type of service or medication under the patient's health insurance benefits.

The Capability supports the transmittal of a patient's name and insurance identification number with the request for the type of service. It also includes the following optional requirements:

1. Identification of the type of service or medication requested for benefit coverage (does not guarantee payment by insurance provider)
2. Communication of a referral notification number or authorization number from the Payer System to the Provider System.

It provides clinicians and pharmacists with information about each patient's medical insurance coverage and benefits. It may include information on referral or authorization permission.



3.25.2 DESIGN SPECIFICATION

3.25.2.1 INTERACTING SYSTEMS

Table 3-127 Interacting Systems

Interacting Systems
Electronic Health Record (EHR) System
Provider Administrative and Financial System
Health Plan System
Electronic Health Record (EHR) – Hospital
Electronic Health Record (EHR) – Hospital and EHR LTC
Pharmacy Systems
Pharmacy Systems – Hospital and Pharmacy Systems – External
Health Care Entities (for LTC)
Health Information Exchange (HIE)
PBM/Payers System

3.25.2.2 CONSTRAINTS AND ASSUMPTIONS

This section provides an overview of the constraints (i.e., Assumptions, Pre-conditions, Post-conditions, Triggers) associated with the Capability.

Table 3-128 Constraints and Assumptions

Constraint	Type of Constraint
Patient Identities (name demographics etc.) are known and are consistent with policies. In this regard, it is expected that the Health Plan's Member Id is known and related to the Provider's Finance & Admin System accordingly	Pre-condition
Health Information Exchange (HIE) can serve as intermediary for data in many implementation variants. The various alternative options are not shown.	Assumption
Entities have pre-established a business relationship to exchange information	Pre-condition
Authentication service to authenticate requestors and/or data submissions from various locations	Pre-condition
Security and privacy policies, procedures and practices are commonly implemented to support acceptable levels of consumer/patient security and privacy	Pre-condition

3.25.2.3 LIST OF CONSTRUCTS

Table 3-129 List of Constructs

Construct	Description
HITSP/SC114 – Administrative Transport to Health Plan	The HITSP Administrative Transport to Health Plan service collaboration provides the transport mechanism for conducting administrative transactions with health plans
HITSP/T68 – Patient Health Plan Authorization Request and Response	The HITSP Patient Health Plan Authorization Request and Response Transaction provides a mechanism for a healthcare provider (other than a retail pharmacy) to request approval from a health plan to authorize certain healthcare services, when required by the patient's health plan contract. The information exchanged includes, but is not limited to, approval status for coverage, allowed service provider(s), and certification dates for services that are included in the patient's health plan benefits. The response from the health plan indicates that the health plan has determined that the particular service(s) will or will not be covered, and what is the level of coverage if that information is available from the health plan.



3.25.2.4 SPECIFIED INTERFACES

Table 3-130 HITSP/CAP141 – Communicate Referral Authorization Specified Interfaces

Interface (Initiating or Responding)	Interface number	Interface Condition	T/TP/SC or Content	T/TP/SC/Content Optionality ³⁹
Information Receiver for Health Plan Authorization*	1	R	Health Plan Authorization Information Request (HITSP/T68)	R
		R	Health Plan Authorization Information Response(HITSP/T68)	R
Request Administrative Transport to Health Plan	2	R	Administrative Transport to Health Plan (HITSP/SC114)	R
Respond to Administrative Request to Health Plan	3	R	Administrative Transport to Health Plan (HITSP/SC114)	R

Table 3-131 Interface Conditions and T/TP/SC/Content Optionality

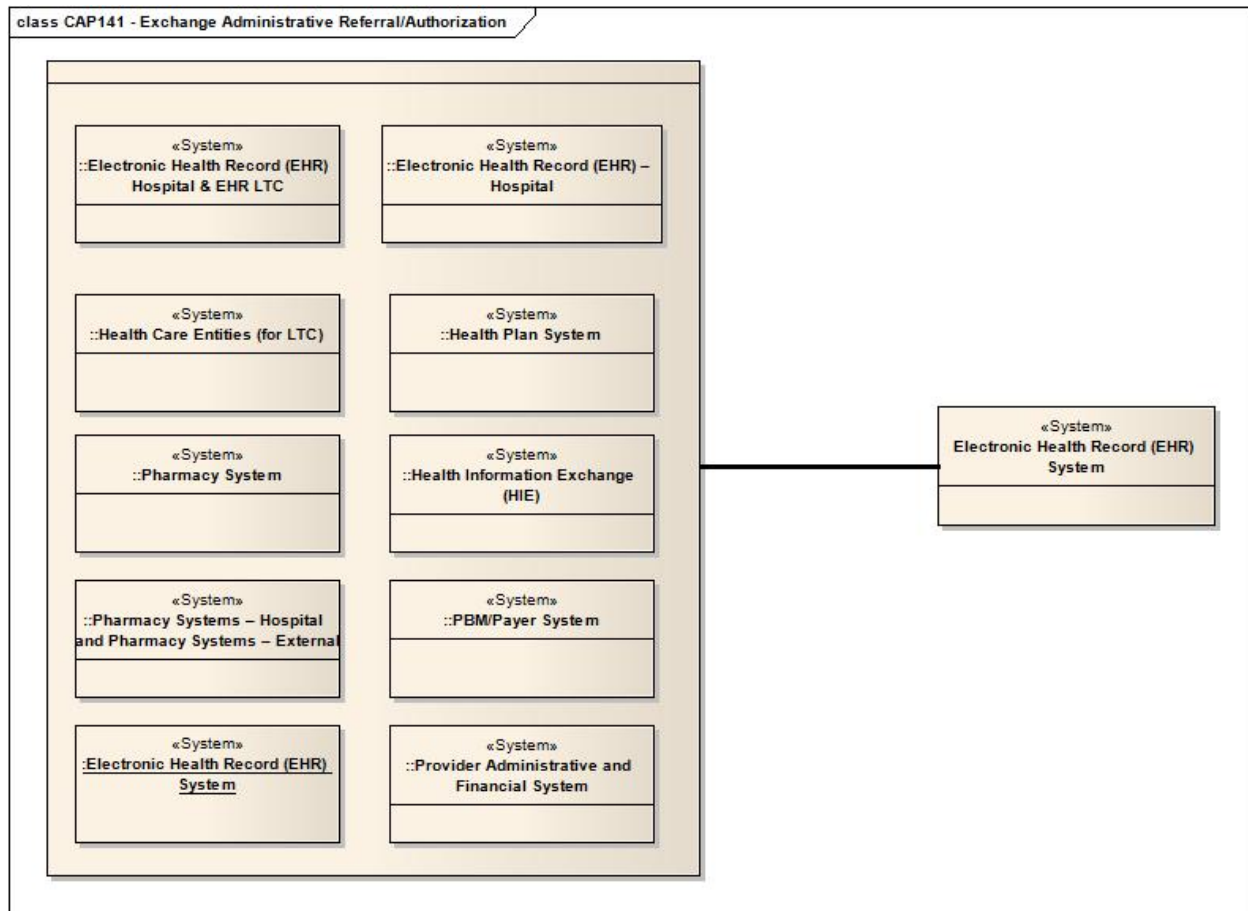
Condition Code	Condition Description
No Applicable Condition Codes	

The following diagram shows a visual overview of the Capability using UML notation. The visual overview outlines how the interacting systems work together as part of implementing the Capability. The thick arrow in the middle of the diagram outlines how sets of systems can interact together, and represent the information exchange requirement (IER) inherent to the Capability. An IER is not explicitly noted as part of this diagram.

³⁹ Optionality = “R” for Required, “R2” for Required if known, “O” for Optional, or “C” for Conditional. If applicable, conditional footnotes are further described below.



Figure 3-25 HITSP/CAP141 – Communicate Referral Authorization Visual Overview



3.25.2.5 CAPABILITY OPTIONS

Note that subsets of the data content can be sent as appropriate for the application; but the system must be able to address the entire data content. Note that transport options can be addressed.

3.26 HITSP/CAP142- RETRIEVE COMMUNICATIONS RECIPIENT SPECIFICATION

3.26.1 OVERVIEW

This Capability addresses interoperability requirements that support access to a directory to identify one or more communication recipients in order to deliver alerts and bi-directional communications (e.g., public health agencies notifying a specific group of service providers about an event). The method and criteria by which individuals are added to a directory is a policy decision, which is out of scope for this construct.



3.26.2 DESIGN SPECIFICATION

3.26.2.1 INTERACTING SYSTEMS

Table 3-132 Interacting Systems

Interacting Systems
Electronic Health Record (EHR) System
Emergency Communications System
Health Information Exchange (HIE) – Infrastructure Services
Clinical Decision Support (CDS) System
Genetic Clinical Decision Support System
Genetic/Genomic Knowledge Repository
Laboratory Information System (LIS)
Public Health Information System
Health Plan System
Personal Health Record (PHR) System

3.26.2.2 CONSTRAINTS AND ASSUMPTIONS

This section provides an overview of the constraints (i.e., Assumptions, Pre-conditions, Post-conditions, Triggers) associated with the Capability.

Table 3-133 Constraints and Assumptions

Constraint	Type of Constraint
No Applicable Constraints	

3.26.2.3 LIST OF CONSTRUCTS

Table 3-134 List of Constructs

Construct	Description
HITSP/T64 – Identify Communication Recipients	The HITSP Identify Communication Recipients Transaction is intended to serve the purpose of identification of communication recipients and the subsequent purpose of delivery of alerts and bi-directional communications (e.g., public health agencies notifying a specific group of service providers about an event.) The method and criteria by which individuals are added to a directory is a policy decision, which is out of scope for this construct. It uses the Integrating the Healthcare Enterprise (IHE) Personnel White Pages profile which provides access to basic directory information for identifying one or more recipients

3.26.2.4 SPECIFIED INTERFACES

Table 3-135 HITSP/CAP142 – Retrieve Communications Recipient Specified Interfaces

Interface (Initiating or Responding)	Interface number	Interface Condition	T/TP/SC or Content	T/TP/SC/Content Optionality ⁴⁰
Personnel White Pages Consumer	1	O	Find Personnel White Pages (HITSP/T64)	O
	2	O	Query Personnel White Pages (HITSP/T64)	R
DNS Server	4	R	Find Personnel White Pages (HITSP/T64)	R
Personnel White Pages Directory	5	R	Query Personnel White Pages (HITSP/T64)	R

⁴⁰ Optionality = “R” for Required, “R2” for Required if known, “O” for Optional, or “C” for Conditional. If applicable, conditional footnotes are further described below.

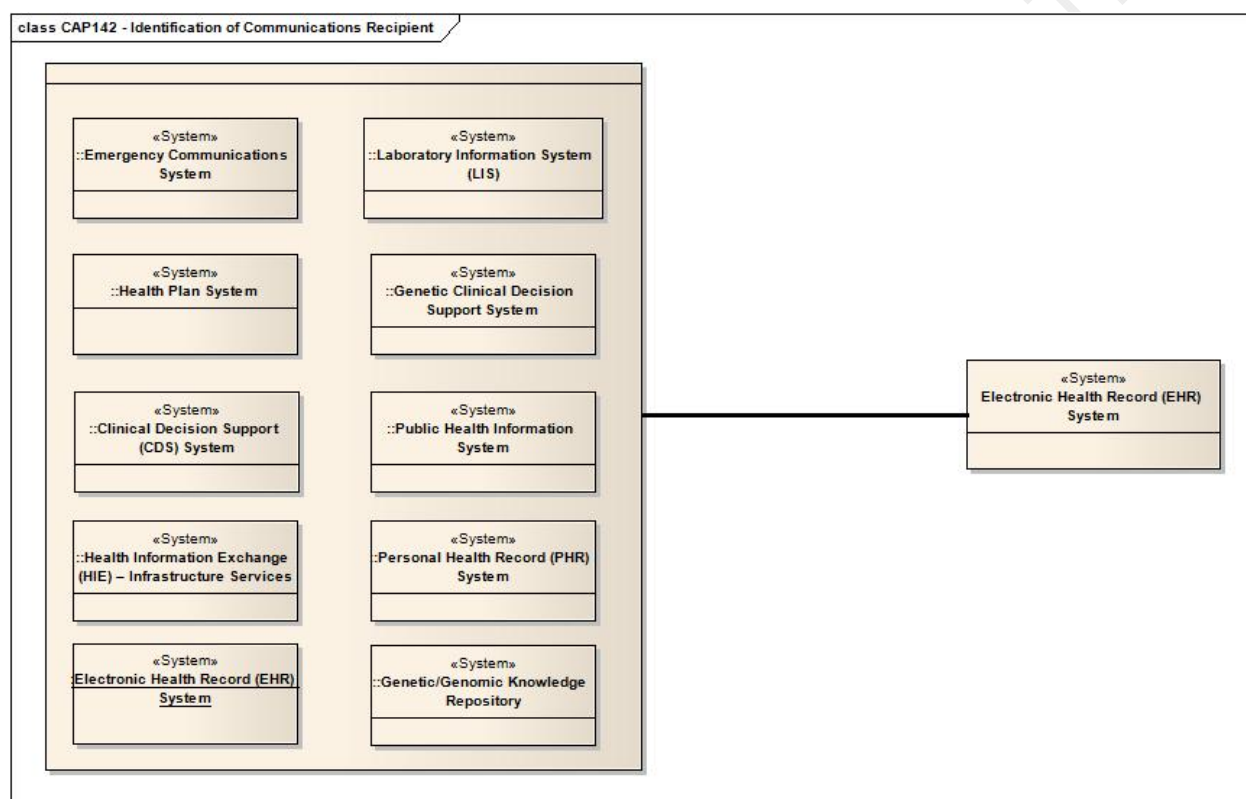


Table 3-136 Interface Conditions and T/TP/SC/Content Optionality

Condition Code	Condition Description
No Applicable Condition Codes	

The following diagram shows a visual overview of the Capability using UML notation. The visual overview outlines how the interacting systems work together as part of implementing the Capability. The thick arrow in the middle of the diagram outlines how sets of systems can interact together, and represent the information exchange requirement (IER) inherent to the Capability. An IER is not explicitly noted as part of this diagram.

Figure 3-26 HITSP/CAP142 – Retrieve Communications Recipient Visual Overview



3.26.2.5 CAPABILITY OPTIONS

Note that subsets of the data content can be sent as appropriate for the application; but the system must be able to address the entire data content. Note that transport options can be addressed.

3.27 HITSP/CAP143 – MANAGE CONSUMER PREFERENCE AND CONSENTS SPECIFICATION

3.27.1 OVERVIEW

This Capability addresses management of consumer preferences and consents as an acknowledgement of a privacy policy. This Capability is used to capture a patient or consumer agreement to one or more privacy policies; where examples of a privacy policy may represent a consent, dissent, authorization for data use, authorization for organizational access, or authorization for a specific clinical trial. This Capability also supports the recording of changes to prior privacy policies such as when a patient



changes their level of participation or requests that data no-longer be made available because they have left the region.

The enforcement of the currently agreed to privacy policies is embedded in HITSP/SC108 Access Control Service Collaboration as enforced by HITSP/TP20 Access Control Construct. Therefore this Capability addresses only the management of the privacy policy acknowledgements.

The acknowledgement to the privacy policy is structured according to the HL7 CDA standard with recording the act of acknowledgement of one or more privacy policies. As the standards develop the content of the privacy policy is expected to be encoded within the same CDA document such that more powerful policies can be expressed.

1. Privacy policy (e.g., Consent) management has the following characteristics as documented in HITSP/TP30:
2. Patient consent directives are captured electronically in a consent repository
3. Patient consent is withdrawn and that withdrawal is captured in a repository
4. Patient consent is revoked and that revocation is captured in a repository
5. Patient consent directives are transmitted to a Requester
6. Processing of patient consent directives is logged in audit trail

3.27.2 DESIGN SPECIFICATION

3.27.2.1 INTERACTING SYSTEMS

Table 3-137 Interacting Systems

Interacting Systems
Electronic Health Record (EHR) Systems
Personal Health Record (PHR) Systems
Consent Management System

3.27.2.2 CONSTRAINTS AND ASSUMPTIONS

This section provides an overview of the constraints (i.e., Assumptions, Pre-conditions, Post-conditions, Triggers) associated with the Capability.

Table 3-138 Constraints and Assumptions

Constraint	Type of Constraint
HIPAA policy compliance is maintained by all organizations handling patient data	Assumption
Network infrastructures that enable secure, appropriate, and accurate information exchange across data sources and systems to view the data. This includes, but is not limited to: methods to identify and authenticate users <ul style="list-style-type: none"> • Methods to identify and determine providers of care • Methods to enforce data access authorization policies • Methods to correctly match consumers/patients across systems • Methods to identify and determine health insurers • Methods to identify and determine pharmacy benefits managers (NOTE: pharmacy benefit information is obtained through NCPDP transactions) • Methods to identify data sources including but not limited to provider EHR systems 	Pre-Condition
Ability to identify and request corrections to errors is available	Pre-Condition
Ability to apply notes, corrections and comments on original entries is available	Pre-Condition
Method to query other organizations for data and matching to the consumer is available	Pre-Condition
Support the technical measures to ensure Security and Privacy of consumer/patient health information	Pre-Condition Pre-Condition



Constraint	Type of Constraint
Legal and governance issues regarding data access authorizations, data ownership, and data use are in effect	Pre-Condition Pre-Condition
Privacy policies are written and identifiers are given to them	Pre-Condition
Appropriate Access Controls are in place specific to the systems and the roles/individuals that are allowed to register acknowledgement of a privacy policy. This is the authorization of the Consent Originator systems	Pre-Condition

3.27.2.3 LIST OF CONSTRUCTS

Table 3-139 List of Constructs

Construct	Description
TP30 – Manage Consent Directives	The HITSP Manage Consent Directives Transaction Package describes the messages needed to capture, manage, and communicate rights granted or withheld by a consumer to one or more identified entities in a defined role to access, collect, use or disclose individually identifiable health information (IIHI), and also supports the delegation of the patient's right to consent. The transactions described in this construct are intended to be carried out by HITSP/TP13 – Manage Sharing of Documents
HITSP/SC112 – Healthcare Document Management	The HITSP Healthcare Document Management Service Collaboration provides the ability to share healthcare documents using a set of topologies, such as Media, e-Mail, Point-to-Point, Shared within a Health Information Exchange, and Shared within a larger community (made up of potentially diverse Health Information Exchanges)

3.27.2.4 SPECIFIED INTERFACES

Table 3-140 HITSP/CAP143 – Manage Consumer Preference and Consents Specified Interfaces

Interface (Initiating or Responding)	Interface number	Interface Condition	T/TP/SC or Content	T/TP/SC/Content Optionality ⁴¹
Content Creator (e.g., Consent Originator and Consenter)	1	R	Consent Document (HITSP/TP30)	R
Content Consumer (e.g., Consent Directive Requestor)	2	R	Consent Document (HITSP/TP30)	R
Send Documents	3	CAP143-[101], [102]	Healthcare Document Management (HITSP/SC112)	R
Receive Documents	4	CAP143-[101]	Healthcare Document Management (HITSP/SC112)	R

Table 3-141 Interface Conditions and T/TP/SC/Content Optionality

Condition Code	Condition Description
CAP143-[101]	An implementation shall choose amongst one of the interfaces defined in Service Collaboration HITSP/SC112 Healthcare document Management. This choice is dependent on the topology chosen (See Table 3-1 Information Exchange Topologies Mapped to Capabilities above), the physical limitations, policies and processes of the implementation
CAP143-[102]	The EHR System may optionally choose to implement a Document Repository or use an external repository for the Send Documents through Share option of HITSP/SC112 Healthcare document Management

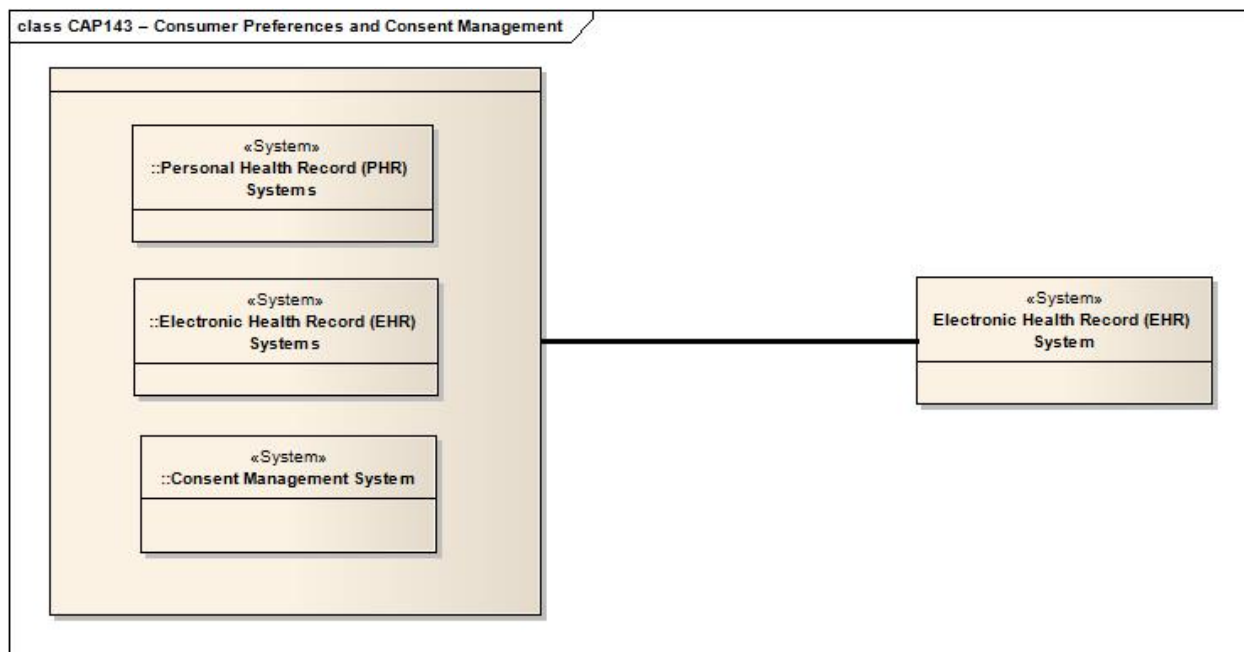
The following diagram shows a visual overview of the Capability using UML notation. The visual overview outlines how the interacting systems work together as part of implementing the Capability. The thick arrow in the middle of the diagram outlines how sets of systems can interact together, and represent the

⁴¹ Optionality = “R” for Required, “R2” for Required if known, “O” for Optional, or “C” for Conditional. If applicable, conditional footnotes are further described below.



information exchange requirement (IER) inherent to the Capability. An IER is not explicitly noted as part of this diagram.

Figure 3-27 HITSP/CAP143 – Manage Consumer Preference and Consents Visual Overview



3.27.2.5 CAPABILITY OPTIONS

Note that subsets of the data content can be sent as appropriate for the application; but the system must be able to address the entire data content. Note that transport options can be addressed.



4.0 CONFORMANCE STATEMENT

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.

4.1.1 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.

4.1.2 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 on the interface are satisfied.

4.1.3 TEST METHODS

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

An [HIT Implementation Testing and Support](#) website has been developed in collaboration with HITSP, NIST, CCHIT, and ONC to advance conformance and interoperability testing capabilities. This website provides HIT implementers with the necessary resources to support and test their implementation of standards-based health systems.



5.0 APPENDIX

The following sections include relevant materials referenced throughout this document.

5.1 HITSP CAPABILITIES MAPPED TO THE HITSP PROVIDER, POPULATION AND CONSUMER INTEROPERABILITY SPECIFICATIONS

The following figure shows the Capabilities used within the EHR-Centric IS mapped to the thirteen HITSP Interoperability Specifications that were approved or recognized as of February 13, the ARRA enactment date. This provides the traceability necessary to fulfill conditions found in Section 3004 of Title XIII (HITECH) of the ARRA.



