

HITSP Communicate Structured Document Capability

HITSP/CAP119



Healthcare Information Technology Standards Panel

Submitted to:

Healthcare Information Technology Standards Panel

Submitted by:

Capabilities Team



DOCUMENT CHANGE HISTORY

Version Number	Description of Change	Name of Author	Date Published
0.0.1	Populate Template	Capabilities Team	September 30, 2009
0.0.2	Review Copy	Selected Perspective, Domain and/or Tiger Team reviewers	November 9, 2009
0.0.3	Review Copy	Selected Perspective, Domain and/or Tiger Team reviewers	January 18, 2010
1.0	Released for Implementation	Selected Perspective, Domain and/or Tiger Team reviewers	January 25, 2010



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1.0 INTRODUCTION

This Healthcare Information Technology Standards Panel (HITSP) Capability document is divided into five sections: Requirements Analysis, External Capability Options, Design Specification, Standards and the Appendix. All sections may be useful to analysts and architects. However as shown in Table 1-1, different readers may find specific sections of greater interest and utility. This table is provided as an aid to readers to assist them in identifying sections to focus on. Readers are encouraged to review all sections of this document to further their understanding of HITSP's work.

Table 1-1 Reader's Guide for Capability

Document Section	Number	Intended Audience	Contained Information
Section 2.0 Requirements	2.0	Policy Managers Policy Analysts Executive Leadership	Provides an overview of the requirements which this Capability addresses. It lists, describes and diagrams the external interfaces and relates these to the system roles supported by the Capability. It shows how these roles can be assigned at a higher level to real world systems, such as an Electronic Health Record (EHR)
	2.1	Program Managers Policy Analysts Executive Leadership Architects Business Analysts	Defines the actual information exchanges supported by the Capability in terms of exchange actions, exchange content, constraints mapped to the initiating and responding system roles that participate in these exchanges
Section 3.0 External Capability Options	3.1	Policy Analysts Architects Business Analysts Developers	Defines the integrated and optional Security and Privacy functions supported by the Capability
	3.2	Architects Business Analysts Developers	Describes the external information exchange options associated with topology, or message and document content as applicable
Section 4.0 Design Specification	4.1	Program Managers Architects Business Analysts Developers	Maps the information exchanges developed in requirements to the actual HITSP construct used by the Capability to support the exchange
	4.2	Business Analysts Developers	Lists the context that is necessary to use the Capability, including assumptions, pre-conditions, post-conditions and triggers
	4.3	Business Analysts Developers	Identifies the constructs and their interfaces assigned to each system role. It also lists the implementation conditions for use
Section 5.0 Standards	5.1	Program Managers Policy Analysts Architects Business Analysts Developers	Lists regulatory guidance, selected standards and informative references used by the Capability and all its supporting constructs
	5.2	Program Managers Policy Analysts Architects Business Analysts Developers	Identifies gaps or overlaps in standards to implement the Capability including a plan to resolve issues

1.1 CAPABILITY OVERVIEW

HITSP/CAP119 Communicate Structured Document addresses interoperability requirements that support the communication of structured health data related to a patient in a context determined by the author of the document. This Capability supports the exchange of a broad range of CDA documents related to clinical patient care. The following are examples of the type of CDA structured data that are supported:

- 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
- Labor and Delivery Record
- Antepartum Record
- Operative Notes
- Procedure Notes

1.2 SCOPE

A Capability provides the ability for two or more systems to address a business need for interoperable information exchange. The objective of a Capability is to provide the bridge between the business, policy and implementation disciplines by defining a set of information exchanges at a level relevant to policy and business decisions and specifying the use of HITSP constructs sufficiently for implementation. A Capability supports stakeholder requirements and business processes and includes information content, infrastructure, security and privacy. The design of Capabilities leverages existing HITSP constructs and communication methodologies. As new constructs become available, the scope of this Capability may be extended.

The scope of this Capability is to support the exchange of clinical notes and other clinical documents containing structured information, e.g. remote monitoring data. Example authors would be clinicians, patients or patient representatives documenting clinical care. These clinical notes document a patient encounter, visit or service. Clinicians treating patients as part of a consultation transfer of care, or providing care management, or continuity of care may use this Capability to access structured clinical notes to gain a more comprehensive understanding of a patient's history, or to create and share clinical notes with other providers to better support transfers of care.

Documents that are not typically authored by a clinician or not generated for clinical purposes (e.g., patient forms, consents, administrative documents) and do not constitute clinical documentation of a patient encounter or service are not in scope for this Capability. In addition, items that may accompany or support clinical notes, such as images and waveforms, are not in the scope of this Capability.

1.3 COPYRIGHT PERMISSIONS

COPYRIGHT NOTICE

© 2010 ANSI. This material may be copied without permission from ANSI only if and to the extent that the text is not altered in any fashion and ANSI's copyright is clearly noted.

1.4 REFERENCE DOCUMENTS

This section provides a list of key reference documents and background material.

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

Table 1-2 Reference Documents

Reference Document	Document Description
HITSP Acronyms List	Lists and defines the acronyms used in this document
HITSP Glossary	Provides definitions for relevant terms used by HITSP documents



TN900 – Security and Privacy	HITSP/TN900 is a reference document that provides the overall context for use of the HITSP Security and Privacy constructs
TN901 – Clinical Documents	HITSP/TN901 is a reference document that provides the overall context for use of the HITSP Care Management and Health Records constructs
TN903 – Data Architecture	HITSP/TN903 is a reference document that provides the overall context for use of the HITSP Data Architecture constructs
TN904 – Harmonization Framework and Exchange Architecture	HITSP/TN904 is a reference document that provides the overall context for use of the HITSP Harmonization Framework and Exchange Architecture
CDA Quick Start Guide (v1.5)	The CDA Quick Start Guide was created by Alschuler Associates, LLC. The guide helps implementers create a simple CDA document and then as they increase their knowledge of CDA, go on to create more complex versions using the resources cited in this QSG and their own experience.
Continuity of Care Document (CCD) Quick Start Guide	This CCD Quick Start Guide was created by the Healthcare Information and Management Systems Society Electronic Health Record Vendors Association (EHRVA). This guide was developed to support CCD implementers. The scope is “just enough” to get started – it is not a standalone or complete guide or reference.
National Institute of Standards and Technology (NIST) Validator	NIST in collaboration with Alschuler Associates, LLC, Integrating the Healthcare Enterprise (IHE) and the CCHIT Health IT Collaboration Effort “LAIKA”, is working on a series of testing tools for promoting the adoption of standards-based interoperability by vendors and users of healthcare information systems.
Schematron Home Page	This Schematron is owned by ISO. It allows you to develop and mix two kinds of schemas: <ul style="list-style-type: none"> Report elements allow you to diagnose which variant of a language you are dealing with Assert elements allow you to confirm that the document conforms to a particular schema
Schematron Standard	

1.5 GUIDANCE FOR USE OF A CAPABILITY

NOTE: For questions related to details on HITSP Capabilities and HITSP System Roles, please refer to HITSP/TN904 Harmonization Framework and Exchange Architecture Technical Note.

To use a HITSP Capability, a HITSP Interoperability Specification or an implementation conformance statement must assign specific systems to one or more HITSP Capability System Roles and identify how the HITSP Capability Options are to be addressed. In order to assign systems to HITSP System Roles, the reader uses Table 2-3 Supported Information Exchanges to determine what systems can support the specific information exchanges required. For an example of how HITSP System Roles and systems are mapped, readers can consult a HITSP Interoperability Specification Table 3-3 Orchestration of Capabilities by System. In the case of an Implementation Guide, systems can be assigned to HITSP System Roles using a similar methodology.

The use of a HITSP Capability implies that these specific rules will be followed:

- For each HITSP Capability System Role listed in Table 2-2 Capability System Roles, the defined responsibilities of that HITSP Capability System Role are supported. Responsibilities for the HITSP Capability System Role are defined as support for the HITSP Construct interfaces listed in Section 4.3 Specified Interfaces by System Role. Support implies that the system assigned to the HITSP Capability System Role makes the associated HITSP construct interfaces available for use by other systems. For those HITSP construct interfaces in Section 4.3 that have associated content optionality, the HITSP Capability System Role must comply with the optionality condition listed in Table 4-7 Implementation Conditions.
- Responsibilities also include the constraints and assumptions associated with use of a Capability, as outlined in Table 4-3 Context. For those Capabilities with Section 3.2 options, the following additional rules apply:
 - Each topology option listed in Table 3-2 Topology Related Options should be supported by the implementation



2. Each content import option listed in Table 3-3 Content Import Options should be supported by the implementation
3. Each document content option listed in Table 3-4 Document Content Options should be supported by the implementation



2.0 REQUIREMENTS ANALYSIS

The following table is provided as an aid to readers to assist them in identifying the parts of this section to focus on. Readers are encouraged to review all sections of this document to further their understanding of HITSP's work.

Table 2-1 Reader's Guide for Section 2.0

Document Section	Section Number	Intended Audience	Information Contained
Section 2.0 Requirements Analysis	2.1	Policy Managers Policy Analysts Executive Leadership	Provides an overview of the requirements which this Capability addresses, and identifies the system roles supported by the Capability
	2.2	Program Managers Policy Analysts Executive Leadership Architects Business Analysts	Defines the actual information exchanges supported by the Capability in terms of exchange actions, exchange content, constraints mapped to the initiating and responding system roles that participate in these exchanges

2.1 INTRODUCTION

Table 2-2 summarizes the system roles of the Capability. Section 2.2 identifies how these system roles participate in the set of information exchanges.

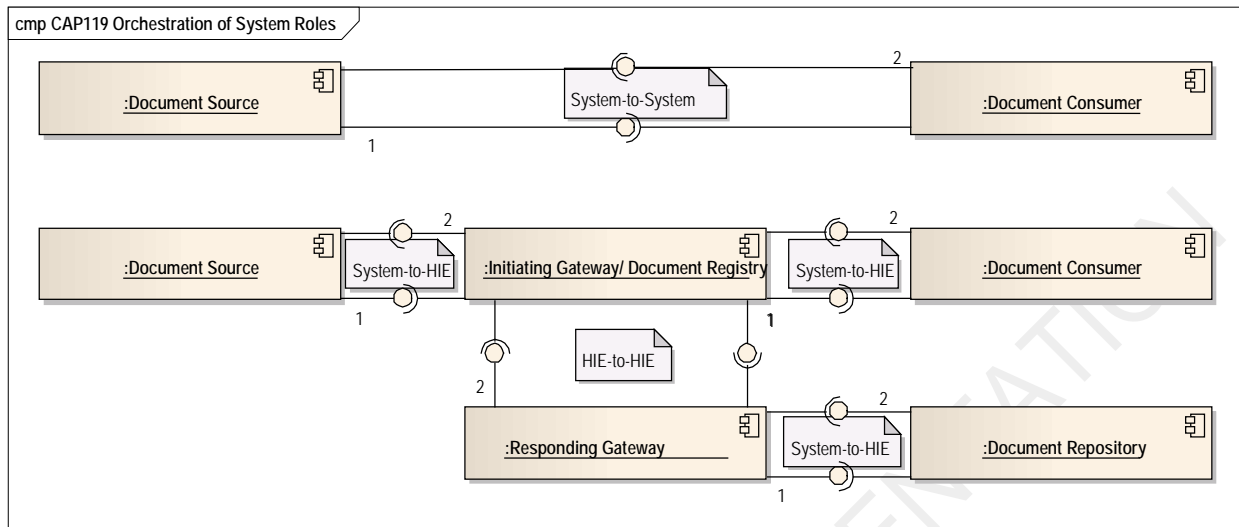
Table 2-2 Capability System Roles

System Role	System Role Definition
Document Sender	The system which sends the document
Document Consumer	The system which receives the document and which initiates a query for documents in an HIE
Document Registry	The system which registers the document within a repository and which responds to a query for documents
Document Repository	The system which stores a copy of the document and forwards the document upon request

Table 2-3 and Figure 2-1 describe how this Capability is intended to support various system roles within multiple system architectures (e.g., an Electronic Health Record (EHR) system or a Health Information Exchange (HIE) could serve the role of document repository system). In an implementation architecture, system roles may be aggregated locally (e.g., Hospital EHR System) and in others, the system roles may be provided by multiple-distributed trusted third parties (e.g., pharmacies within an HIE). A system is deemed to be conformant to this Capability if, for each system role which a system claims to address, that system supports all required interfaces for the defining system role.



Figure 2-1 System Role Interface Diagram



2.2 REQUIREMENTS

2.2.1 INFORMATION EXCHANGES

Table 2-3 defines each of the Information Exchanges supported by this Capability in terms of the Exchange Action (EA) or Exchange Content (EC) used.

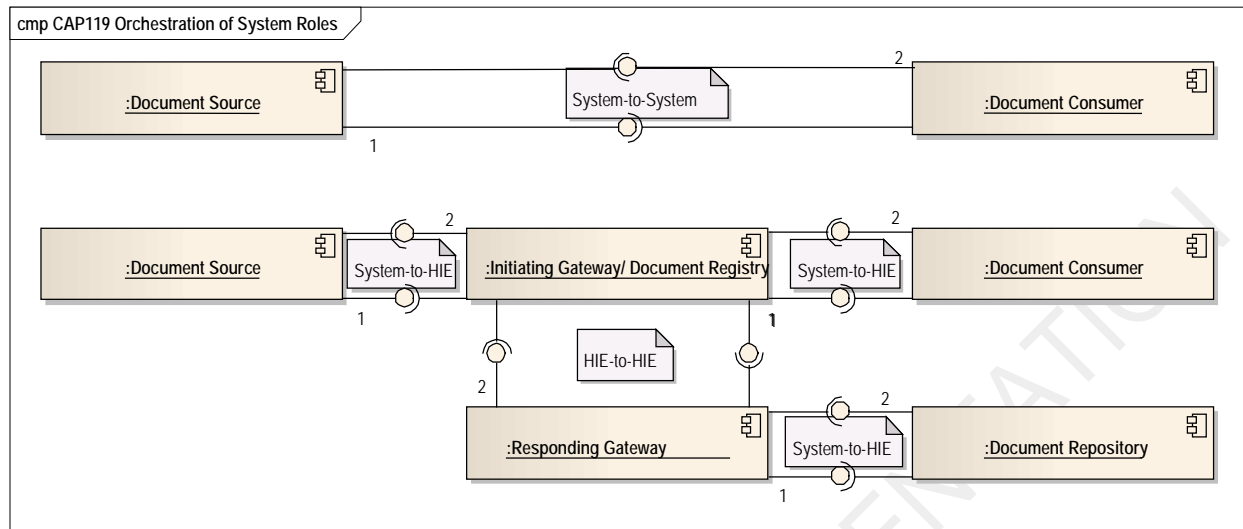
Table 2-3 Supported Information Exchanges

Information Exchange Identifier	Exchange Action	Exchange Content
A	Send and Receive	Clinical Document
A	Send and Receive	Clinical Document Metadata

Figure 2-2 identifies how this Capability supports various system roles within multiple system architectures. For example, either an Electronic Health Record (EHR) system or a Health Information Exchange (HIE) might fill a document repository system role in an information exchange). In an implementation architecture, system roles may be combined locally (e.g., Hospital EHR System) and in others, the system roles may be provided by multiple-distributed trusted third parties (e.g., pharmacies within an HIE).



Figure 2-2 Information Exchanges Between System Roles



3.0 EXTERNAL CAPABILITY OPTIONS

The following table is provided as an aid to readers to assist them in identifying the parts of this section to focus on. Readers are encouraged to review all sections of this document to further their understanding of HITSP's work.

Table 3-1 Reader's Guide for Section 3.0

Document Section	Section Number	Intended Audience	Information Contained
Section 3.0 External Capability Options	3.1 Security and Privacy	Policy Analysts Architects Business Analysts Developers	Defines the integrated and optional Security and Privacy functions supported by the Capability
	3.2 Information Exchange Options	Architects Business Analysts Developers	Describes the external information exchange options associated with topology and message and document content as applicable

This section is primarily for architects, engineers and analysts. It allows those who consider using this Capability to evaluate and/or constrain the options that are externally made available for the Capability implementers.

Interoperability among system roles defined by this Capability often requires the selection of consistent options.

3.1 SECURITY AND PRIVACY

The application of Security and Privacy is highly influenced by the security and privacy policies. The HITSP Security and Privacy Technical Note (HITSP/TN900) provides a detailed discussion of the security and privacy constructs, including consideration and appropriate context for needed security and privacy related policy decisions. Security and privacy constructs are integrated comprehensively into the Service Collaborations. The actual constructs used and the way in which the constructs are used is dependent on the policies and physical setting. Conformance claims are against the security and privacy constructs that are chosen to enforce the policies.

3.2 INFORMATION EXCHANGE OPTIONS

Three types of information exchange options are externally offered by this Capability:

- Topology Related Options
- Content Import Options
- Document Content Options

The HITSP Exchange Architecture adds topology to the HITSP Harmonization Framework. Topology is the arrangement or mapping of networked Systems, especially the physical (real) and logical (virtual) interconnections between Systems. A Health Information Exchange¹ (HIE) is a special network system that provides intermediary services, such as directories, registries or translations. HITSP supports the following topologies.

¹ The terms "RHIO" and "Health Information Exchange" or "HIE" are often used interchangeably. An HIE is a more general instance of a RHIO (Regional Health Information Organization). Both are groupings of organizations with a business stake in improving the quality, safety and efficiency of healthcare delivery. NHIEs are HIEs that support the building blocks of the Nationwide Health Information Network (NHIN) initiative proposed by the Office of the National Coordinator (ONC) for Health Information Technology (HIT). To build a nationwide network of interoperable health records, the effort must first develop at the local and state levels. The concept of NHIN requires extensive collaboration by a diverse set of stakeholders. The challenges are many to achieve success for an HIE or a RHIO.



- Portable Media (non-connected)
- System to System (point-to-point)
- System to HIE
- HIE to HIE

The following matrix portrays which of the typical network topologies (see HITSP/TN904 Harmonization Framework and Exchange Architecture for details on topologies) are addressed within the Capability. Within each cell, “Available” indicates that the topology is supported while “Not Available” indicates that the topology is not supported.

Table 3-2 Topology Related Options

Topology	Availability
Point-to-Point	Available
E-mail	Available
Portable Media	Available
Document Share/Community	Available

In addition to providing topology options, a Capability may provide Information Content Import Options (see Table 2-3). Note that subsets of the data content can be sent as appropriate for the Capability; but the responding system must be able to address the entire data content corresponding to the Exchange Content supported. Content subsets should be specified in the document that uses this Capability – either an Interoperability Specification or an implementation design document.

Table 3-3 Content Import Options

Document Display	Document Import	Document Discrete Data Import
Integrated	Option	Option

Two content import options are offered:

- Document Import Option impacts the import of Documents processed by an application Content Consumer. It requires the Document Consumer to have the ability to import into the health record one or more of the received documents as a whole and display it as requested
- Discrete Data Import Option impacts the import of the HL7 CDA Documents 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 data modules in a structured form into the health record. Coded values shall be maintained

This Capability supports the HITSP/C83 Clinical Document Architecture (CDA) Modules document profiles listed in Table 3-4. Any use of this Capability by either an Initiating or a Responding System MUST support at least one of the HITSP CDA documents listed below.

Table 3-4 Document Content Options

Optionality	Supported Document Types
O	Emergency Care Summary Document Using IHE Emergency Department Encounter (EDES) (HITSP/C28)
O	Summary Documents Using HL7 Continuity of Care Document (CCD) (HITSP/C32)
O	Encounter Document Using IHE Medical Summary (XDS-MS) (HITSP/C48)
O	Remote Monitoring Observation Document (HITSP/C74)
O	Healthcare Associated Infection (HAI) Report (HITSP/C75)
O	Immunization Document (HITSP/C78)
O	Consult and History & Physical Note (HITSP/C84)
O	Labor and Delivery Record (HITSP/C152)



O	Antepartum Record (HITSP/C161)
---	--------------------------------

Optionality Legend: "R" for Required, "O" for Optional, or "C" for Conditional

Please note that at least one of the options shall be supported either by the Initiating System or the Responding System.



4.0 DESIGN SPECIFICATION

The following table is provided as an aid to readers to assist them in identifying the parts of this section to focus on. Readers are encouraged to review all sections of this document to further their understanding of HITSP's work.

Table 4-1 Reader's Guide for Section 4.0

Document Section	Section Number	Intended Audience	Information Contained
Section 4.0 Design Specification	4.1 Requirements Mapped to Constructs	Program Managers Architects Business Analysts Developers	Maps the information exchanges developed in requirements to the actual HITSP construct used by the Capability to support the exchange
	4.2 Constraints and Assumptions	Business Analysts Developers	Lists the context that is necessary to use the Capability, including assumptions, pre-conditions, post-conditions and triggers
	4.3 Specified Interfaces by System Role	Business Analysts Developers	Identifies the constructs and their interfaces assigned to each system role. It also lists the implementation conditions for use

4.1 REQUIREMENTS MAPPED TO CONSTRUCTS

4.1.1 CONSTRUCTS

Table 4-2 defines the mapping of the Information Exchanges supported by this Capability in terms of the Exchange Action (EA) or Exchange Content (EC) and any constraints applied to the Information Exchange with specific initiating and/or responding system interfaces. This provides the traceability of constructs to the information exchanges identified in Section 2.0 above. Content modules and terminology Components are not listed here because they are referenced by other constructs, but do not provide an interface. HITSP/TN903 Data Architecture discusses how content modules and terminology Components are referenced by other constructs.

Table 4-2 Information Exchanges Mapped to Constructs

Information Exchange Identifier	Exchange Type	Construct Identifier	Description
A – Send/Receive Clinical Document	Content	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.
A – Send/Receive Clinical Document	Content	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.
A – Send/Receive Clinical Document	Action	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)



4.2 CONSTRAINTS AND ASSUMPTIONS

Table 4-3 specifies the context that must be provided in order to use the Capability, identifying any assumptions, pre-conditions, post-conditions, and triggers relevant for use of the Capability.

Table 4-3 Context

Assumptions, Pre-conditions, Post-conditions, and Triggers	Type of Context
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

4.3 SPECIFIED INTERFACES BY SYSTEM ROLE

This section specifies the HITSP Capability interfaces in terms of the System Roles identified in Table 2-2 Capability's System Roles. Table 4-4 specifies interfaces for document sender system roles as defined in Table 2-2.

Table 4-4 Document Sender System Role Mapped to HITSP Construct Interfaces

Construct Interface	Interface Type	T/TP/SC or Content	T/SC/Content Optionality
Send Documents Directly	Initiating	HITSP/SC112 - Healthcare Document Management	C[101]
Send Document through email	Initiating	HITSP/SC112 - Healthcare Document Management	C[101]
Publish Document Through Media	Initiating	HITSP/SC112 - Healthcare Document Management	C[101]
Send Document Through Share	Initiating	HITSP/SC112 - Healthcare Document Management	C[101]
Publish Document Through Share	Initiating	HITSP/SC112 - Healthcare Document Management	C[101]
N/A	Initiating	Any CDA document using HITSP/C83 - CDA Content Modules	R

Optionality Legend: "R" for Required, "O" for Optional, or "C" for Conditional

Table 4-5 specifies interfaces for document consumer system roles as defined in Table 2-2.

Table 4-5 Specified Interfaces for Document Consumer System Role

Interface	Interface Type	T/TP/SC or Content	T/SC/Content Optionality
Receive Documents Directly	Responding	Any CDA document using HITSP/C83 - CDA Content Modules + HITSP/SC112 - Healthcare Document Management	C[102]
Receive Document through email	Responding	HITSP/SC112 - Healthcare Document Management	C[102]



Interface	Interface Type	T/TP/SC or Content	T/SC/Content Optionality
Publish Document Through Media	Responding	HITSP/SC112 - Healthcare Document Management	C[102]
Receive Document Through Share	Responding	HITSP/SC112 - Healthcare Document Management	C[102]
Publish Document Through Share	Responding	HITSP/SC112 - Healthcare Document Management	C[102]
N/A	Responding	Any CDA document using HITSP/C83 - CDA Content Modules	R

Optionality Legend: "R" for Required, "O" for Optional, or "C" for Conditional

Table 4-6 specifies interfaces for registry and repository system roles as defined in Table 2-2.

Table 4-6 Specified Interfaces for Registry and Repository System Role²

Interface	Interface Type	T/TP/SC or Content	T/SC/Content Optionality
Send Document Through Share	Initiating	HITSP/SC112 - Healthcare Document Management	C[103]
N/A	Initiating	Any CDA document using HITSP/C83 - CDA Content Modules	R
Receive Document Through Share	Responding	HITSP/SC112 - Healthcare Document Management	C[103]
Publish Document Through Share	Responding	HITSP/SC112 - Healthcare Document Management	C[103]
N/A	Responding	Any CDA document using HITSP/C83 - CDA Content Modules	R

Optionality Legend: "R" for Required, "O" for Optional, or "C" for Conditional

Table 4-7 specifies optionality conditions referenced in Table 4-4 through Table 4-6 above

Table 4-7 Implementation Conditions

Condition ID	Condition Description
C [101]	The implementation SHALL support the appropriate specializations of the Send Document interface for each topology supported
C [102]	The implementation SHALL support the appropriate specializations of the Receive Document interface for each topology supported
C[103]	This system role and interface is required if the information exchange topology utilized deploys one or more HIE's which SHALL support the Send/Consume Documents via Share interface described in HITSP/SC112

² Any system may optionally choose to implement a document registry and/or document repository or use an external registry and/or repository for the Send Documents through Share options of HITSP/SC112 Healthcare Document Management.



5.0 STANDARDS

The following table is provided as an aid to readers to assist them in identifying the parts of this section to focus on. Readers are encouraged to review all sections of this document to further their understanding of HITSP's work.

Table 5-1 Reader's Guide for Section 5.0

Document Section	Section Number	Intended Audience	Information Contained
Section 5.0 Standards	5.1 Standards Used	Program Managers Policy Analysts Architects Business Analysts Developers	List regulatory guidance, selected standards and informative references used by the Capability and all its supporting constructs
	5.2 Standards Gaps and Overlaps	Program Managers Policy Analysts Architects Business Analysts Developers	Identifies gaps or overlaps in standards to implement the Capability including a plan to resolve issues

5.1 STANDARDS USED

5.1.1 REGULATORY GUIDANCE

Table 5-2 lists any regulatory guidance that determines or constrains use of standards.

Table 5-2 Regulatory Guidance

Regulation	Description
No applicable regulatory guidance	

5.1.2 SELECTED STANDARDS

Table 5-3 lists the standards selected as relevant to this Capability.

Table 5-3 Selected Standards

Standard	Description
American National Standards Institute (ANSI) International Committee for Information Technology Standards (INCITS), #359-2004	This standard describes RBAC features that have achieved acceptance in the commercial marketplace. It includes a reference model and functional specifications for the RBAC features defined in the reference model. It is intended for (1) software engineers and product development managers who design products incorporating access control features; and (2) managers and procurement officials who seek to acquire computer security products with features that provide access control capabilities in accordance with commonly known and understood terminology and functional. For more information visit www.ansi.org
ASTM International Standard Guide for Electronic Authentication of Health Care Information: # E1762-95(2003)	Defines a document structure for use by electronic signature mechanisms, describes the characteristics of an electronic signature process. Defines minimum requirements for different electronic signature mechanisms, defines signature attributes for use with electronic signature mechanisms, describes acceptable electronic signature mechanisms and technologies, defines minimum requirements for user identification, access control, and other security requirements for electronic signatures, and outlines technical details for all electronic signature mechanisms in sufficient detail to allow interoperability between systems supporting the same signature mechanism. For more information visit www.astm.org
ASTM International #E1986 -98 (2005) Standard Guide for Information Access Privileges to Health Information	The guide covers the process of granting and maintaining access privileges to health information. In particular, Table 2 Healthcare Personnel that Warrant Differing Levels of Access Control provides the necessary content for structural roles per ASTM International E2595 and for user-based access controls enforcing patient consent directives



Standard	Description
ASTM International Standard Guide for Privilege Management Infrastructure (PMI) Guidelines: #E2595-07 (2003)	Defines interoperable mechanisms to manage privileges in a distributed environment. This standard is oriented towards support of a distributed or service-oriented architecture (SOA) where security services are themselves distributed and applications are consumers of distributed services. This standard incorporates privilege management mechanisms alluded to in a number of existing standards (e.g., E1986, E2084). The privilege mechanisms in this standard support policy-based access control (including role, entity and contextual-based access control) including the application of policy constraints, patient requested restrictions and delegation. Finally, the standard supports hierarchical, enterprise-wide privilege management The mechanisms defined in this standard may be used to support a privilege management infrastructure (PMI) using existing public key infrastructure (PKI) technology. This standard does not specifically support mechanisms based on secret-key cryptography. Mechanisms involving privilege credentials are specified in International Organization for Standardization (ISO) 9594-8:2000 (attribute certificates), and Organization for the Advancement of Structured Information Standards (OASIS) Security Assertion Markup Language (SAML) (attribute assertions); however, this standard does not mandate or assume the use of such standards Many current systems require only local privilege management functionality (on a single computer system). Such systems frequently use proprietary mechanisms. This standard does not address this type of functionality; rather, it addresses an environment where privileges and capabilities (authorizations) must be managed between computer systems across the enterprise, and with business partners. For more information visit www.astm.org
ASTM International Standard Specification for Audit and Disclosure Logs for Use in Health Information Systems: # E2147-01	E2147-01 "is for the development and implementation of security audit/disclosure logs for health information. It specifies how to design an access audit log to record all access to patient identifiable information maintained in computer systems and includes principles for developing policies, procedures, and functions of health information logs to document all disclosure of health information to external users for use in manual and computer systems. The process of information disclosure and auditing should conform, where relevant, with the Privacy Act of 1974 (1)." For more information visit www.astm.org
European Telecommunications Standards Institute (ETSI) Technical Specification TS 101 903: XML Advanced Electronic Signatures (XadES)	Extends the IETF/W3CXML-Signature Syntax and Processing specification [XMLDSIG] into the domain of nonrepudiation by defining XML formats for advanced electronic signatures that remain valid over long periods and are compliant with the European Directive. This includes evidence as to its validity even if the signer or verifying party later attempts to deny (repudiates) the validity of the signature. An advanced electronic signature aligned with this document can, in consequence, be used for arbitration in case of a dispute between the signer and verifier, which may occur at some later time, even years later. For more information visit www.etsi.org
Health Level Seven (HL7) Consent related vocabulary including Confidentiality Codes	HL7 concept domains, including ConfidentialityCodes, ActInformationCategoryCode, ActInformationAccessType, ActInformationAccessContextCode, AuthorizedParticipationFunctionCode, ActPolicyType, ActConsentType, and ActMaskableCode For more information visit www.hl7.org
Health Level Seven (HL7) Implementation Guide: CDA Release 2.0 – Continuity of Care Document (CCD), April 01, 2007	The Continuity of Care Document Implementation Guide describes constraints on the HL7 Clinical Document Architecture, Release 2 (CDA) specification in accordance with requirements set forward in ASTM International E2369-05 Standard Specification for Continuity of Care Record (CCR). The resulting specification, known as the Continuity of Care Document (CCD), is developed as a collaborative effort between ASTM International and HL7. It is intended as an alternate implementation to the one specified in ASTM International ADJE2369 for those institutions or organizations committed to implementation of the HL7 Clinical Document Architecture. For more information visit www.hl7.org
Health Level Seven (HL7) V3 RBAC, R1-2008, HL7 Version 3 Standard: Role Based Access Control (RBAC) Healthcare Permissions Catalog, Release 1, February 2008	The Healthcare Permission Catalog provides the necessary content for creating interoperable roles facilitating inter-organizational communications and information sharing among healthcare organizations and their business partners. For more information visit www.hl7.org
Health Level Seven (HL7) Version 2.3.1	The HL7 Version 2.3.1 Messaging Standard is an application protocol for electronic data exchange in healthcare. It and prior versions have widespread use in the U.S. and internationally. Both message formats and value sets/code tables are contained in the standard. For more information visit www.hl7.org



Standard	Description
Health Level Seven (HL7) Version 2.5	The HL7 Version 2.5 Messaging Standard is an application protocol for electronic data exchange in healthcare. It and prior versions have widespread use in the U.S. and internationally. Both message formats and value sets/code tables (e.g., diagnosis type, gender, patient class, result status, specimen collection method, abnormal flags, observation result status codes interpretation, timestamp format) are contained in the standard. Of particular focus for HITSP Interoperability Specifications are message formats described in Chapters 2, 3, 5, and 7 including patient demographic (ADT) and lab result reporting. These are also used within composite standards from IHE for Patient Identity Cross-Referencing and Feed (PIX), Patient Demographics Query (PDQ), and Acknowledgements. For more information visit www.hl7.org .
Health Level Seven (HL7) Version 3.0 Clinical Document Architecture (CDA) Release 2.0	The HL7 Clinical Document Architecture is an XML-based document markup standard that specifies the structure and semantics of clinical documents for the purpose of exchange. CDA is one instantiation of HL7's Version 3.0 Reference Information Model (RIM) into a specific message format. Of particular focus for HITSP Interoperability Specifications are message formats for Laboratory Results and Continuity of Care (CCD) documents. Release 2 of the HL7 Clinical Document Architecture (CDA) is an extension to the original CDA document markup standard that specifies the structure and semantics of clinical documents for the purpose of exchange. CDA R2 includes a prose document in HTML, XML schemas, data dictionary, and sample CDA documents. CDA R2 further builds upon other HL7 standards beyond just the Version 3.0 Reference Information Model (RIM) and incorporates Version 3.0 Data Structures, Vocabulary, and the XML Implementation Technology Specifications for Data Types and Structures. For more information visit www.hl7.org .
Health Level Seven (HL7) Version 3.0 Privacy Consent related specifications RCMR_RM010001 - Data Consent	The Data Consent RMIM captures the data and associations needed to (1) record or report a consumer's consent or dissent to authorize the access, collection, use, or disclosure of personally identifiable information; (2) convey a provider's request or intent to override a patient's recorded consent or dissent; (3) convey a type of consent directive associated with a privacy policy; or (4) to record or report a consumer's consent directive, which is to be applied to future access, collection, use or disclosure of personally identifiable information. For more information visit www.hl7.org .
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0 or later, Patient Identifier Cross-Referencing (PIX) Integration Profile	The Patient Identifier Cross-referencing (PIX) Integration Profile is targeted at healthcare enterprises of a broad range of sizes (hospital, a clinic, a physician office, etc.). It supports the cross-referencing of patient identifiers from multiple Patient Identifier Domains via the following interactions: 1) The transmission of patient identity information from an identity source to the Patient Identifier Cross-reference Manager. 2) The ability to access the list(s) of cross-referenced patient identifiers either via a query/response or via update notification. By specifying the above transactions among specific actors, this integration profile does not define any specific enterprise policies or cross-referencing algorithms. By encapsulating these behaviors in a single actor, this integration profile provides the necessary interoperability while maintaining the flexibility to be used with any cross-referencing policy and algorithm as deemed adequate by the enterprise. For more information visit www.ihe.net .
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 5.0 or later, Patient Demographics Query (PDQ) Integration Profile	Provides ways for multiple distributed applications to query a central patient information server for a list of patients, based on user-defined search criteria, and retrieve a patient's demographic (and, optionally, visit or visit-related) information directly into the application. For more information visit www.ihe.net .
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0, Section 10 Cross-Enterprise Document Sharing (XDS.a) Integration Profile	The IHE IT Infrastructure Technical Framework defines specific implementations of established standards to achieve integration goals that promote appropriate sharing of health information to support optimal patient care. Section 10, Cross-Enterprise Document Sharing facilitates the registration, distribution and access across health enterprises of patient electronic health records. IHE Integration Profiles offer a common language that healthcare professionals and vendors may use in communicating requirements for the integration of products. The current version of the ITI-TF, rev. 4.0 for Final Text, specifies the IHE Transactions defined and implemented as of August 22, 2007. For more information visit www.ihe.net .



Standard	Description
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0 - Registry Stored Query Transaction for XDS Profile Supplement [ITI-18]	The IHE IT Infrastructure Technical Framework defines specific implementations of established standards to achieve integration goals that promote appropriate sharing of health information to support optimal patient care. IHE Integration Profiles offer a common language that healthcare professionals and vendors may use in communicating requirements for the integration of products. The Registry Stored Query Transaction Trial Implementation Supplement specifies an IHE Transaction that provides optimization and implementation simplification. For more information visit www.ihe.net
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Supplement 2008-2009, Cross-Community Access (XCA), Trial Implementation, October 10, 2008	The IHE IT Infrastructure Technical Framework defines specific implementations of established standards to achieve integration goals that promote appropriate sharing of health information to support optimal patient care. IHE Integration Profiles offer a common language that healthcare professionals and vendors may use in communicating requirements for the integration of products. The trial implementation version of the XCA Supplement to the ITI-Technical Framework, specifies the IHE Transactions that support access between communities in a manner compatible with the XDS Integration profile. For more information visit www.ihe.net
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0 or later, Audit Trail and Node Authentication (ATNA) Integration Profile	The Audit Trail and Node Authentication (ATNA) Integration Profile establishes the characteristics of a Basic Secure Node. It describes the security environment (user identification, authentication, authorization, access control, etc.) assumed for the node so that security reviewers may decide whether this matches their environments. It defines basic auditing requirements for the node. It defines basic security requirements for the communications of the node using TLS or equivalent functionality. It establishes the characteristics of the communication of audit messages between the Basic Secure Nodes and Audit Repository nodes that collect audit information. This integration profile has been designed so that specific domain frameworks may extend it through an option defined in the domain specific technical framework. Extensions are used to define additional audit event reporting requirements, especially actor specific requirements. The latest version of the IHE Technical Framework is available at www.ihe.net
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Supplement 2007 - 2008 Basic Patient Privacy Consents (BPPC) Integration Profile – Trial Implementation	The Basic Patient Privacy Consents (BPPC) Integration Profile provides a mechanism to record the patient privacy consent(s), a method to mark documents published to XDS with the patient privacy consent that was used to authorize the publication, and a method for XDS Consumers to use to enforce the privacy consent appropriate to the use. This profile complements XDS by describing a mechanism whereby an XDS Affinity Domain can develop and implement multiple privacy policies, and describes how that mechanism can be integrated with the access control mechanisms supported by the XDS Actors (e.g. systems). There are two key parts of the profile: 1) It provides a document content specification for capturing a patient acknowledgement of a privacy consent policy or policies. 2) It describes the method by which XD* Actors can enforce the privacy policies determined by the document confidentiality Code related to the patient privacy consents. For more information visit www.ihe.net
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 2.0 XDM Supplement	This Supplement to the IHE IT Infrastructure Technical Framework defines the means to store and interchange personal medical documents on portable media. The current version of the XDM is specified in the XDM Trial Implementation Supplement to the ITI-TF, rev. 2.0, which is consistent with IHE XDS.b Supplement in term of document entry metadata. For more information visit www.ihe.net
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Supplement Volume 3 – Document Digital Signature (DSG) Content Profile	Specifies the use of digital signatures for documents that are shared between organizations. For more information visit www.ihe.net
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Supplement - ITI-25 Notification of Document Availability (NAV) Jun 28, 2005	The Capability for automation of critical workflows used in healthcare has been greatly advanced by the introduction of the Cross-Enterprise Document Sharing Integration Profile. However, without point-to-point notification of document availability, these workflows still require manual interactions between parties using document sharing. The Notification of Document Availability Integration Profile (NAV) introduces a mechanism allowing notifications to be sent point-to-point to systems and users within an affinity domain, eliminating the need for manual steps or polling mechanisms. This basic mechanism is only intended to facilitate the common part of a large range of workflows related to notifying a remote party (user or system) that one or more documents have been registered in an XDS Registry and may be retrieved if the notified party wishes. For further information visit www.ihe.net



Standard	Description
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Volume 2 Supplement 2007 – 2008 Cross-Enterprise Document Sharing-B (XDS.b) Integration Profile	The Cross-Enterprise Document Sharing-B (XDS.b) Integration Profile supplement provides a new implementation choice for the Cross-Enterprise Document Sharing (XDS) Integration Profile based on use of the Web Services and ebXML Reg/Rep standards that is consistent with current developments and best practices in the industry. For more information visit www.ihe.net
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) 2007-2008 Trial Implementation Supplement Cross-enterprise Document Reliable Interchange (XDR) Release 3	This Supplement to the IHE IT Infrastructure Technical Framework provides a generic, standards based mechanism for conveying a set of medical documents in a point-to-point networked based communication. The current version of the XDR is specified in the XDR Trial Implementation Supplement to the ITI-TF, rev. 4.0, which is consistent with IHE XDS.b Supplement in term of document entry metadata. For more information visit www.ihe.net NOTE: Off-line mode transaction expected to be updated once standards are available for Web Services Off-line
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0 or later, Consistent Time (CT) Integration Profile	The Consistent Time Integration Profile (CT) provides a means to ensure that the system clocks and time stamps of the many computers in a network are well synchronized. This profile specifies synchronization with a median error less than 1 second. This is sufficient for most purposes. The current version of the ITI-TF Final Text, specifies the IHE CT Integration Profile, and other transactions defined and implemented as of October 10, 2008. The latest version of the IHE Technical Framework is available at www.ihe.net
Integrating the Healthcare Enterprise (IHE) Patient Care Coordination (PCC), Revision 5.0	The IHE Patient Care Coordination Technical Framework (PCC TF) defines specific implementations (called Integration Profiles) of established standards to deal with integration issues that cross providers, patient problems or time. For more information visit www.ihe.net
International Health Terminology Standards Development Organisation (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®)	SNOMED CT consists of a technical design, core content architecture, and Core content. SNOMED CT Core content includes the technical specification of SNOMED CT and fully integrated multi-specialty clinical content. The Core content also includes a concepts table, description table, relationships table, history table, ICD-9-CM mapping, and Technical Reference Guide. Additionally, SNOMED CT provides a framework to manage language dialects, clinically relevant subsets, qualifiers and extensions, as well as concepts and terms unique to particular organizations or localities. For more information visit www.ihtsdo.com
International Organization for Standardization (ISO) Electronic business eXtensible Markup Language (ebXML), Technical Specification # 15000 -- Part 4: Registry services specification (ebRS), May, 2004	Describes eXtensible Markup Language (XML) and its usage characteristics. Consists of 4 parts: ebCPP, ebMS, ebRIM, and ebRS. Part 4 ebRS defines the interface between the registry and the registry clients, as well as the interaction protocols, message definitions and XML schema. For more information visit www.iso.org
International Organization for Standardization (ISO) Health Informatics – Functional and Structural Roles (ISO SF Roles), Technical Specification #21298, Draft May, 2007	This document contains a specification for encoding information related to roles for health professionals and consumers. At least four areas have been identified where a model for encoding role information is needed: <ul style="list-style-type: none"> • Privilege management and access control: role-based access control is not possible without an effective means of recording role information for healthcare actors • Directory services: structural roles are usefully recorded within directories of healthcare providers (see for example, ISO TS 21091 Health Informatics – Directory services for security, communications, and identification of professionals and patients) • Audit trails: functional roles are usefully recorded within audit trails for health information applications • Public key infrastructure (PKI): The three part ISO standard 17090 Health Informatics – Public Key Infrastructure (PKI) allows for the encoding of healthcare roles in certificate extensions, but no structured vocabulary for such roles is specified. This technical specification identifies such a coded vocabulary For more information visit http://www.iso.org/
International Organization for Standardization (ISO) Health Informatics - Privilege management and access control (PMAC), Technical Specification #22600 -- Part 1: Overview and policy management, July 2006	Supports the needs of healthcare information sharing across unaffiliated providers of healthcare, healthcare organizations, health insurance companies, their patients, staff members and trading partners. It is also intended to support inquiries from both individuals and application systems. For more information visit www.iso.org



Standard	Description
International Organization for Standardization (ISO) Health Informatics - 9660 Level 1	Defines a common logical format for files and directories so discs written to ISO 9660 specifications can be read by a wide array of computer operating systems. For more information visit www.iso.org
Internet Engineering Task Force (IETF) Network Time Protocol (Version 3) Specification, Implementation and Analysis, "Request for Comment" (RFC) #1305, March, 1992	Describes the Network Time Protocol (NTP): the mechanisms to synchronize time and coordinate time distribution in a large, diverse internet operating at rates from mundane to lightwave. For more information visit www.ietf.org
Internet Engineering Task Force (IETF) Simple Network Time Protocol (SNTP) Version 4, "Request for Comment" (RFC) #2030, October, 1996	Describes the Simple Network Time Protocol (SNTP) Version 4, which is an adaptation of the Network Time Protocol (NTP). SNTP can be used when the ultimate performance of the full NTP implementation is not needed or justified. When operating with current and previous NTP and SNTP versions, SNTP Version 4 involves no changes to the NTP specification or known implementations, but is rather a clarification of certain design features of NTP. For more information visit www.ietf.org
Logical Observation Identifiers Names and Codes (LOINC®)	A database of universal identifiers for laboratory and other clinical observations. The laboratory portion of the LOINC database contains the usual categories of chemistry, hematology, serology, microbiology (including parasitology and virology), and toxicology; as well as categories for drugs and the cell counts typically reported on a complete blood count or a cerebrospinal fluid cell count. Antibiotic susceptibilities are a separate category. The clinical portion of the LOINC database includes entries for vital signs, hemodynamics, intake/output, EKG, obstetric ultrasound, cardiac echo, urologic imaging, gastroendoscopic procedures, pulmonary ventilator management, selected survey instruments, and other clinical observations. For more information visit www.loinc.org
Organization for the Advancement of Structured Information Standards (OASIS) eXtensible Access Control Markup Language (XACML), ITU-T Recommendation X.1142, February 2005	The Organization for the Advancement of Structured Information Standards (OASIS) standards group developed the eXtensible Access Control Markup Language (XACML) as a language to express and evaluate access decisions. The XACML technical specification includes a profile for RBAC using XACML that complies with the ANSI RBAC standard. The HL7 RBAC Permission Catalog provides a standard vocabulary that can be used for cross-enterprise access control. For more information visit www.oasis-open.org
Organization for the Advancement of Structured Information Standards (OASIS) – ebXML Registry Information Model (3.0)	The Registry Information Model provides a blueprint or high-level schema for the ebXML Registry. Its primary value is for implementers of ebXML Registries. It provides these implementers with information on the type of metadata that is stored in the Registry as well as the relationships among metadata Classes. The Registry information model: a) Defines what types of objects are stored in the Registry; b) Defines how stored objects are organized in the Registry. For more information visit www.oasis-open.org
Organization for the Advancement of Structured Information Standards (OASIS) – ebXML Registry Services Specification (3.0)	The ebXML Registry provides a set of services that enable sharing of information between interested parties for the purpose of enabling business process integration between such parties based on the ebXML specifications. The shared information is maintained as objects in a repository and managed by the ebXML Registry Services defined in this document. For more information visit www.oasis-open.org
Organization for the Advancement of Structured Information Standards (OASIS) Simple Object Access Protocol (SOAP) Version 1.2	SOAP is a protocol specification for invoking methods on servers, services, components and objects. SOAP codifies the existing practice of using XML and HTTP as a method invocation mechanism. The SOAP specification mandates a small number of HTTP headers that facilitate firewall/proxy filtering plus an XML vocabulary that is used for representing method parameters, return values, and exceptions." {DevelopMentor} SOAP consists of three parts: an envelope that defines a framework for describing what is in a message and how to process it, a set of encoding rules for expressing instances of application-defined data types, and a convention for representing remote procedure calls and responses. For more information visit www.oasis-open.org
Organization for the Advancement of Structured Information Standards (OASIS) WS-Federation Web Services Federation Language (WS- Federation), Version 1.2 Committee Draft 01 June 23 2008	Defines mechanisms to allow different security realms to federate, such that authorized access to resources managed in one realm can be provided to security principals whose identities and attributes are managed in other realms. This includes mechanisms for brokering of identity, attribute, authentication and authorization assertions between realms, and privacy of federated claims. For more information visit www.oasis-open.org



Standard	Description
Organization for the Advancement of Structured Information Standards (OASIS) WS-Trust Version 1.3, March 2007	Defines extensions that build on [WS-Security] to provide a framework for requesting and issuing security tokens, and to broker trust relationships. Defines Security Token Service (STS) model for security tokens including requesting, issuing, renewing, canceling and validating. For more information visit www.oasis-open.org
Organization for the Advancement of Structured Information Standards (OASIS) Security Assertion Markup Language (SAML) Core v2.0 OASIS Standard; ITU-T X.1141	SAML, developed by the Security Services Technical Committee of OASIS, is an XML-based framework for communicating user authentication, entitlement, and attribute information. As its name suggests, SAML allows business entities to make assertions regarding the identity, attributes, and entitlements of a subject (an entity that is often a human user) to other entities, such as a partner company or another enterprise application. For more information visit www.oasis-open.org
Organization for the Advancement of Structured Information Standards (OASIS) Cross-Enterprise Security and Privacy Authorization (XSPA) Profile of Security Assertion Markup Language (SAML) for Healthcare, Committee Draft, 13 October 2008	The XSPA SAML profile provides the necessary content for exchange interoperable access control information facilitating inter-organizational communications and information sharing among healthcare organizations and their business partners
Organization for the Advancement of Structured Information Standards (OASIS) Cross-Enterprise Security and Privacy Authorization (XSPA) Profile of WS-Trust for Healthcare, Committee Draft, 14 October 2008	The XSPA WS-Trust profile provides the necessary content for exchange interoperable access control information facilitating inter-organizational communications and information sharing among healthcare organizations and their business partners
Organization for the Advancement of Structured Information Standards (OASIS) Cross-Enterprise Security and Privacy Authorization (XSPA) Profile of eXtensible Access Control Markup Language (XACML) for Healthcare, Committee Draft, 14 October 2008	The XSPA XACML profile provides the necessary content for evaluating principal access control information against established security policy and making access control decisions enforcing established security policy

5.1.3 INFORMATIVE REFERENCE STANDARDS

Table 5-4 includes reference standards that inform the overall semantic interoperability.

Table 5-4 Informative Reference Standards

Standard	Description
Federal Medication Terminologies	A set of controlled terminologies and code sets developed and maintained as part of a collaboration between the Food and Drug Administration, National Library of Medicine, Veterans Health Administration, National Cancer Institute and Agency for Healthcare Research and Quality related to medications, including medication proprietary and nonproprietary names, clinical drug code (RxNorm); ingredient names and Unique Ingredient Identifiers (UNII); routes of administration, dosage forms, and units of presentation from the NCI Thesaurus (NCIt); and certain pharmacological drug classes from the National Drug File Reference Terminology (NDF-RT) The Federal Medication Terminology leverages medication models maintained by the Food and Drug Administration (ex. UNII, NDC Codes), National Library of Medicine (RxNorm), the Veterans Health Administration (NDF-RT), and the National Cancer Institute (NCIt). For more information visit www.cancer.gov/cancertopics/terminologyresources/page4

5.2 STANDARDS GAPS AND OVERLAPS

Table 5-5 identifies the information exchange requirements and known standards gaps, along with the recommended resolutions to the gaps.



Table 5-5 Information Exchange Requirements (IER) and Associated Standards Gaps

IER Gap Description	Responsible HITSP TC	Design Approach	Required Standards Now Unavailable for Constructs	SDO Working on Unavailable Standards	Expected Availability
No Implementation Guides identified yet to exchange clinical note templates	Care Management & Health Records	New/Modified Capability, plus necessary SC, TP, T and/or C to Query/Respond Clinical Templates	Work with HITSP Member SDOs to develop an Implementation Guide for a standards-based clinical note template	HL7	

Table 5-6 lists any standards overlaps and describes plans to resolve each of the overlaps.

Table 5-6 Information Exchange Requirements and Associated Standards Overlaps

Requirement Number	Summary Description	Standard Overlap	Recommended Resolution
None			



6.0 APPENDIX

This section may include additional materials referenced throughout this document, such as requirements analysis tables and figures. If the Capability is yet to be implemented, it may contain the candidate standards, for Tier 2 evaluations.

6.1 SUMMARY OF REQUIREMENTS FOR THE EXCHANGE OF STRUCTURED DOCUMENTS FROM THE CLINICAL NOTES DETAILS EXTENSION³

Table 6-1 Summary of Requirements for the Exchange of Structured Documents

Requirement Source ⁴	Requirement	Exchange Action	Exchange Content
A, B	To create clinical notes based on established templates	Query/Respond	Cnnn Clinical Note Template HITSP/C80 Clinical Document and Message Terminology Metadata
C, D, E	Incorporate established templates into an Electronic Medical Record system	Query/Respond	Cnnn Clinical Note Template
E	Incorporate relevant details into a clinical note through the use of templates	N/A ⁵	Cnnn Clinical Note Template HITSP/C83 Clinical Document and Message Terminology
F	Create and exchange clinical notes with other providers of care	Send/Receive	HITSP/C83 Clinical Document and Message Terminology
F, H, I	To query or access clinical notes created for a patient based on a list of common clinical note types, provider roles, clinical specialty or location, date range, provider name, organization type, and condition/diagnosis	Send/Receive	HITSP/C80 Clinical Document and Message Terminology Metadata
F, J	Compare a patient's progress over time for a specific type of clinical note, or section within clinical notes	N/A ²	HITSP/C83 Clinical Document and Message Terminology
G	Communicate replacement, amended or annotated notes with other providers of care	Send/Receive	HITSP/C83 Clinical Document and Message Terminology
K	Be able to reuse sections or data elements within the clinical note without loss of relevant originating information	N/A ⁴	HITSP/C83 Clinical Document and Message Terminology

6.2 INTEROPERABILITY SPECIFICATION REQUIREMENTS ANALYSIS

The Clinical Notes Extension applied to the Consultations and Transfers of Care and other clinical information exchange Harmonization Requests result in the following table of requirements to be addressed by the information exchanges of this Capability.

³ This document may be found at http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_10731_848116_0_0_18/CNDFinalExtGap.pdf

⁴ See items A-K Section 3.0 Function Needs of the Clinical Note Details Extension found at the URL above.

⁵ This is an internal function of an Electronic Medical Record system that is enabled by the use of templates.



Table 6-2 Interoperability Specification Requirements Analysis Used to Derive Information Exchanges

Functional Requirement	Information Exchange	Data Requirements	Analysis
Medication History <ul style="list-style-type: none"> As part of another document As a distinct document 	A		HITSP/CAP119 references HITSP/C83 and HITSP/C80. Any document based on HITSP/C83 and HITSP/C80 with no other content or specific workflow requirements would be managed by HITSP/CAP119 (see requirements for Clinical Note Detail). No changes required to HITSP/CAP119
Allergy Information <ul style="list-style-type: none"> As part of another document As a distinct document 	A		HITSP/CAP119 references HITSP/C83 and HITSP/C80. Any document based on HITSP/C83 and HITSP/C80 with no other content or specific workflow requirements would be managed by HITSP/CAP119 (see requirements for Clinical Note Detail). No changes required to HITSP/CAP119
Post-Encounter Summary	A		HITSP/CAP119 references HITSP/C83 and HITSP/C80. Any document based on HITSP/C83 and HITSP/C80 with no other content or specific workflow requirements would be managed by HITSP/CAP119 (see requirements for Clinical Note Detail). No changes required to HITSP/CAP119
Care Instructions	A		HITSP/CAP119 references HITSP/C83 and HITSP/C80. Any document based on HITSP/C83 and HITSP/C80 with no other content or specific workflow requirements would be managed by HITSP/CAP119 (see requirements for Clinical Note Detail). No changes required to HITSP/CAP119
Medication Guides	A		HITSP/CAP119 references HITSP/C83 and HITSP/C80. Any document based on HITSP/C83 and HITSP/C80 with no other content or specific workflow requirements would be managed by HITSP/CAP119 (see requirements for Clinical Note Detail). No changes required to HITSP/CAP119
Document Exchange	A		Pharmacy Benefit Managers (PBM's) and Personal Health Records (PHR's) as qualified Systems participating in document exchange
Support for Long Term Care sending patient demographic, clinical and eligibility information to a pharmacy system	A		Outside of patient demographic, clinical and eligibility information contained in various transactions (e.g., medication order, admission notification), LTC facilities may communicate supplemental information in a variety of documents. HITSP/CAP119 references HITSP/C83 and HITSP/C80. Any document based on HITSP/C83 and HITSP/C80 with no other content or specific workflow requirements would be managed by HITSP/CAP119 (see requirements for Clinical Note Detail). No changes required to HITSP/CAP119



Functional Requirement	Information Exchange	Data Requirements	Analysis
Medication Disposal as a structured document	A		HITSP/CAP119 references HITSP/C83 and HITSP/C80. Any document based on HITSP/C83 and HITSP/C80 with no other content or specific workflow requirements would be managed by HITSP/CAP119 (see requirements for Clinical Note Detail). No changes required to HITSP/CAP119 If a new document type with specific associated workflow is required, then a new Capability should be considered
Medication Reconciliation Report (MAR) as a structured document	A		HITSP/CAP119 references HITSP/C83 and HITSP/C80. Any document based on HITSP/C83 and HITSP/C80 with no other content or specific workflow requirements would be managed by HITSP/CAP119 (see requirements for Clinical Note Detail). No changes required to HITSP/CAP119 If a new document type with specific associated workflow is required, then a new Capability should be considered

6.3 DESIGN REQUIREMENTS

The design requirements are specified in the Clinical Note Details Extension. See the references section at the beginning of this document for a link to the original.

Table 6-3 Mapping of Clinical Note Details Functional Requirements to Information Exchange Requirements

Functional Requirements		Information Exchange Requirement(s) (includes security requirements)	Data Requirements
A. Ability to review a listing of available clinical note types	i. When creating a clinical note for a patient, an authoring clinician may need the ability to review a listing of common clinical note types. These listings may be acquired through libraries of commonly used clinical note types and may also include and specify clinical documentation requirements for specific clinical note types. These listings may be grouped by encounter or service type. Examples of these clinical note types may include: History and Physical, Progress/Office Note, Consult Note, Operative Note, Procedure Note, Plan of Care, Triage Note, and Discharge Summary	EHR Function, no interoperability requirements	EHR Function, no interoperability requirements
B. The ability to select a clinical note based upon standardized service, role, clinical condition, diagnosis, specialty, and/or location	i. Using the list of available clinical notes, an authoring clinician may select and complete clinical note documentation within an EHR	EHR Function, no interoperability requirements	EHR Function, no interoperability requirements



Functional Requirements		Information Exchange Requirement(s) (includes security requirements)	Data Requirements
C. The ability to incorporate listings of available clinical note templates provided by external sources into an EHR	i. Listings of available commonly used clinical note templates may be available through libraries. These libraries may also include and specify clinical documentation requirements for specific clinical note types in templates that are human readable or can be processed electronically. These libraries may be made available by clinical specialty organizations and societies, healthcare organizations, external knowledge suppliers, regulatory associations, standards development organizations, and others	IERaa Query/Retrieve Clinical Note Templates	DRmmm Clinical Note Template DR80 Clinical Document Metadata
D. The ability to provide required and optional clinical note details by using templates to facilitate development of a clinical note	i. When creating a clinical note for a patient, an authoring clinician may select templates that provide guidance for structuring and completing the relevant note type. The template may provide required and optional sections or fields to facilitate development of comprehensive and complete documentation that adheres to industry, organizational, and/or coding guidelines for the selected type of note or type of patient encounter	IERaa Query/Retrieve Clinical Note Templates	DRmmm Clinical Note Template
	ii. The use of templates may enable the automated population of patient demographic or clinical information available or documented in other areas of the medical record during the current encounter, or during previous encounters. The use and implementation of this Capability may vary based upon organizational and provider policies and preferences	EHR Function, no interoperability requirements	Clinical Note Template
E. The ability to select from a listing of relevant options for a section within a clinical note to reduce the amount of free text information input for the section	i. The use of templates and standard reference terminologies may reduce the amount of free text information input by the clinician to complete a particular section of a clinical note. The template may provide guidance to enable consistency and completion of documentation that adheres to industry or recommended guidelines for the selected clinical note section	EHR Function, No interoperability requirements	Clinical Note Template



Functional Requirements		Information Exchange Requirement(s) (includes security requirements)	Data Requirements
F. The ability to communicate relevant clinical notes to the next provider of care to support a consultation or transfer of care	i. In support of a request for consultation or patient transfer to another organization, an authorized care provider may provide access to relevant completed clinical notes to the next provider of care. Unique identification of provider organizations and/or individual providers is needed to exchange clinical notes	IER18 Send/Receive Clinical Information	DR83 Clinical Document DR80 Clinical Document Metadata
	ii. Available clinical notes for a patient may be accessed from a list of clinical documents that may be sorted by parameters including but not limited to: note type, date range, reason for encounter/visit, problem/diagnosis, clinician name, clinical specialty, and organization type. The clinician may provide access to clinical notes for the current patient encounter or previous patient encounters	IER18 Send/Receive Clinical Information	DR83 Clinical Document DR80 Clinical Document Metadata
G. The ability to communicate replacement, amended, and annotated notes to the next provider of care	i. An authoring clinician may replace or amend a clinical note that was previously communicated to the next provider of care in support of a request for consultation or patient transfer to another organization. The updated clinical note is communicated to the next provider of care	IER18 Send/Receive Clinical Information	DR83 Clinical Document DR80 Clinical Document Metadata
H. The ability for a clinician to view a list of clinical notes completed for a patient	i. In providing care for a patient, the clinician may require access to additional patient information. The clinician may review a list of available clinical notes for a patient	IER18 Send/Receive Clinical Information	DR83 Clinical Document DR80 Clinical Document Metadata
	ii. The clinician may wish to sort the list of available clinical notes by parameters including but not limited to: clinical note type, date range, reason for encounter/visit, problem/diagnosis, clinician name, clinical specialty, and organization type	EHR Function, No interoperability requirements	EHR Function, No interoperability requirements
I. The ability to view a clinical note for a patient from another organization within the clinician's or facility's electronic health record	i. The clinician is able to access and view prior clinical notes for a patient. The requesting clinician or clinician at the transferring facility has previously granted access to these clinical notes	IER18 Send/Receive Clinical Information	DR83 Clinical Document DR80 Clinical Note Header



Functional Requirements		Information Exchange Requirement(s) (includes security requirements)	Data Requirements
	ii. The consulting clinician or receiving clinician may request access to clinical notes residing in another EHR based upon knowledge or access to a patient's encounter history	Out of scope ⁶	
	iii. The clinical note accessed by the consulting clinician or receiving clinician includes sufficient context to support document management within the clinician's EHR	EHR Function, No interoperability requirements	DR80 Clinical Document Metadata
J. The ability to compare or view a patient's progress over time for a specific type of clinical note or specific section within clinical notes	i. A clinician may view a patient's progress or history over time for a specific type of patient encounter and access desired sections of a note to review progress	EHR Function, No interoperability requirements	EHR Function, No interoperability requirements
K. The ability to reuse sections or data elements within an exchanged clinical note for use in a new note/record without loss of relevant originating information (e.g., author, universal date/time information was documented)	i. A clinician may access and incorporate clinical note information at the section or data element level into new clinical documentation in a manner that includes originating information about the section or data element	EHR Function, No interoperability requirements	EHR Function, No interoperability requirements

6.3.1 DATA AND INFORMATION EXCHANGE REQUIREMENTS

Table 6-4 Data Element and Information Requirements (DR)

Data Requirement Number (DR)	Description
DRmmm Clinical Note Template	Defines the types of information that may be included in a clinical note, and its structure including (but not limited to): <ul style="list-style-type: none"> • Patient Demographics • Vital Signs • Medications • Procedures • Problem Lists • Note Type Date Range • Reason for Encounter/visit • Problem/Diagnosis • Clinician Name • Clinical Specialty • Organization Type
DR80 Clinical Document Metadata	Including (but not limited to): <ul style="list-style-type: none"> • Document ID • Custodian • Author • Universal Date/time • Document Type (e.g. Standardized service, Role, Specialty, Location, Clinical conditions) • Document Class (e.g. History and Physical, Progress/Office Note, Consult Note, Operative Note, etc.)

⁶ This is already covered by existing constructs (e.g., HITSP/TP20 Access Control)



Data Requirement Number (DR)	Description
DR83 Clinical Document	Information included in a clinical note, including (but not limited to): <ul style="list-style-type: none"> • Patient Demographics • Vital Signs • Medications • Procedures • Problem Lists • Note Type • Date Range • Reason for Encounter/visit • Problem/Diagnosis • Clinician Name • Clinical Specialty • Organization Type

Table 6-5 Information Exchange Requirements (IER)

Information Exchange Requirement Number (IER)	Description
IERaa	Query/Respond with clinical note templates
IER18	Send/Receive clinical information

6.3.2 IDENTIFICATION OF SYSTEMS MAPPED TO REQUIREMENTS

Table 6-6 Systems

System	Description	Supported Stakeholders	Harmonization Request Scenario	Information Exchange Requirement Numbers (IER)	Data Requirement Numbers (DR)
Electronic Health Record (EHR) System	The Electronic Health Record (EHR) System is a secure, real-time, point-of-care, patient-centric information resource for clinicians	Clinicians Healthcare Entities	All	All	All
Template Knowledge Repository	Repositories that maintain and provide clinical note templates	Clinicians Knowledge Suppliers	C	IERaa	Clinical Note Template DR80 Clinical Document Metadata

6.4 CHANGES TO OTHER HITSP SPECIFICATIONS

6.4.1 HITSP/C83 CDA CONTENT MODULES

The HITSP/C83 CDA Content Modules construct will be updated to include rules for conformance as follows:

- A document conforming to the HITSP/C83 construct will use at least one section defined within the HITSP/C83 construct
- Documents conforming to the HITSP/C83 construct shall report information using the appropriate HITSP/C83 section unless no applicable HITSP/C83 section exists
- Documents conforming to the HITSP/C83 construct shall use the appropriate entry content modules from HITSP/C83 unless no applicable HITSP/C83 entry module exists
- Documents conforming to the HITSP/C83 construct shall conform to the constraints on the CDA Header found in HITSP/C83 Section 2.2
- Rules will be established for what appears in the header of documents that have been pseudonymized



Additional clinical document templates and sections will be added to HITSP/C83 supporting operative notes, care plans, pre-hospital care, labor and delivery records, antepartum care records, and imaging reports. See Section 6.4.2 below.

6.4.2 HITSP/CAP122 RETRIEVE MEDICAL KNOWLEDGE

The HITSP/CAP122 Retrieve Medical Knowledge construct will be updated to describe retrieval of document templates using HITSP/T81 Retrieval of Medical Knowledge. We note that there is a gap for the content of the template to be retrieved, but believe that the HITSP/T81 construct is appropriate for retrieval of templates by the query criteria.

6.4.3 HITSP/C80 CLINICAL DOCUMENT AND MESSAGE TERMINOLOGY

The HITSP/C80 Clinical Document and Message Terminology construct will be updated to include vocabulary necessary for exchange of templates and query of clinical documents.

6.5 ITEMS FOR PUBLIC COMMENT

HITSP is seeking comments on the relationship of this Capability with results from an ordered service. Should this Capability talk about the use of this Capability to respond to an order (e.g., consult, diagnostic test, et cetera) or should that be dealt with as a separate Capability?



7.0 DOCUMENT UPDATES

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

7.1 SEPTEMBER 30, 2009

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

7.2 NOVEMBER 9, 2009

Updated based on Population Perspective Technical Committee review. Minor editorial changes were made to this document.

- The term “business actor” was replaced with “system”
- Updates have been made to match new Capability template
- Unified Modeling Language (UML) diagrams were updated in Section 2.0

7.3 JANUARY 18, 2010

Conversion of document to the latest Capability Template Version 2.3.

Changes based upon Public Comments:

- 7701, 8135, 8136, 8137, 8476, 8737, 8752, 8908

The full text of the comments along with the Technical Committee’s disposition can be reviewed on the [HITSP Public Web Site](#).

7.4 JANUARY 25, 2010

Upon approval by the HITSP Panel on January 25, 2010, this document is now Released for Implementation.

