

HITSP Notification of Document Availability Transaction

HITSP/T29



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Submitted by:

**Population Health Technical Committee
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TABLE OF CONTENTS

1.0	FOREWORD	5
2.0	INTRODUCTION	8
2.1	Overview	8
2.2	Technical Assumptions and Scope	9
2.2.1	Interoperability Specifications Not Functional Specifications	9
2.2.2	Architectural Neutrality	9
2.2.3	The Use of Messages and Documents as Appropriate.....	9
2.2.4	Implementation Testing	10
2.2.5	Security and Privacy	10
2.3	Audience	11
2.4	Copyright Permissions.....	11
2.5	Acronyms.....	11
2.6	Conventions.....	11
3.0	REFERENCED STANDARDS.....	12
3.1	List of Standards.....	12
3.2	Dependencies.....	13
3.3	Constraints.....	13
4.0	TRANSACTIONS.....	14
4.1	Context Overview	14
4.1.1	Contextual Constraints	14
4.1.2	Technical Actors	14
4.1.3	Actor Interactions.....	14
4.2	Process Flows	14
4.2.1	Process Pre-Conditions.....	14
4.2.2	Process Post-Conditions	14
4.3	Data Flows.....	14
5.0	CONSTRAINTS FOR REUSE	15
6.0	CHANGE HISTORY	16
6.1	May 11, 2007	16



FIGURES AND TABLES

Figure 1.0-1 HITSP Harmonization Process Steps	7
Table 2.1-1 Related Documents	8
Table 3.1-1 List of Standards.....	13



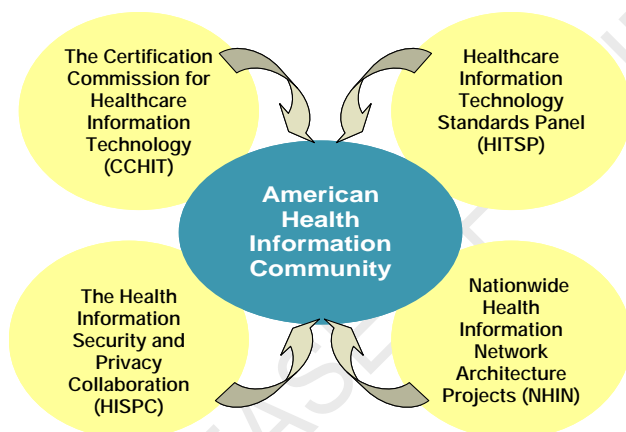
1.0 FOREWORD

This document is referred to as a Transaction and is an artifact of the Healthcare Information Technology Standards Panel (HITSP).

The following paragraphs provide background information about the HITSP and its role in the overall U.S. efforts to realize large scale interoperability of health information. It also describes the HITSP process for healthcare standards harmonization and explains how to use this document and other related documents to inform your health IT product development or product refinement. If you are familiar with HITSP and HITSP artifacts, please proceed to Section 2.0.

U.S. Nationwide Health Information Interoperability

Studies published by the Institute of Medicine and others have raised awareness of the extent to which the fragmented nature of clinical information adversely impacts the quality of care across the U.S. Health Information Technology (IT) can be used to enable better integration of clinical information. However, as of 2007, only a small number of U.S. healthcare providers have fully adopted health IT due, in part, to technical barriers associated with a lack of unambiguous and nationally recognized interoperability standards.



The American Health Information Community¹ (AHIC), a 2005 federally-chartered commission made up of leaders from public and private health sectors, was formed to provide recommendations on how to make health records digital and interoperable, and assure that the privacy and security of those records are protected, in a smooth, market-led way. At the same time, The Department of Health and Human Services, through the Office of the National Coordinator for Health IT (ONC) awarded contracts to 1) identify Interoperability Standards to facilitate the exchange of patient data

(HITSP), 2) define a process for certifying that health IT products comply with appropriate standards through the Certification Commission for Healthcare Information Technology (CCHIT), and 3) develop a series of prototypes to establish the requirements of a nationwide health information network (NHIN). Under a renewed second year contract, HITSP scheduled activities will include identifying and constraining the standards needed for a standards-based security framework that provides the mechanisms needed to protect patient privacy and maintain confidentiality of information about the patient, as well as further work in additional Use Case priority areas recommended by AHIC. This year, CCHIT is expanding its certification efforts to inpatient, or hospital, electronic health record products. In

¹ <http://www.hhs.gov/healthit/ahic.html>



January 2007, four NHIN prototypes were delivered based on the requirements for health information exchange. The next phase will be to connect the prototypes and state and regional health information exchange efforts in trial implementations. These activities share the goal of widespread adoption of interoperable electronic health records within 10 years through public-private collaboration.

HITSP's Role within Nationwide Interoperability Efforts

The HITSP² is a multi-stakeholder coordinating body designed to provide the process within which affected parties can identify, select, and harmonize standards for communicating healthcare information throughout the healthcare spectrum. As used by HITSP, the term "standard" refers, but is not limited to Specifications, Implementation Guides, Code Sets, Terminologies, and Integration Profiles. A standard should be produced through a well defined approach that supports a business process and

1. has been agreed upon by a group of experts
2. has been publicly vetted
3. provides rules, guidelines, or characteristics
4. helps to ensure that materials, products, processes, and services are fit for their intended purpose
5. is available in an accessible format
6. is subject to an ongoing review and revision process

HITSP functions as a partnership of the public and private sectors and operates with a neutral and inclusive governance model administered by the American National Standards Institute (ANSI). The goal of the Panel is to:

- Facilitate the development of harmonized Interoperability Specifications and information policies, including Standards Development Organization (SDO) work products (e.g. standards, technical reports). These policies, profiles and work products are essential for establishing privacy, security and interoperability among healthcare software applications
- Coordinate, as appropriate, with other national, regional and international groups addressing healthcare information to ensure that the resulting standards are globally relevant
- Be Use Case driven, using information from stakeholders and basing decisions on industry needs

The work of the HITSP is conducted through formally chartered Technical Committees and Work Groups. The artifact of the Technical Committee and Work Group activities is an Interoperability Specification (IS) and related constructs referred to as Transaction Packages, Transactions, or Components. For additional information on these constructs, please refer to the HITSP Harmonization Framework.

This HITSP document pertains to the Interoperability Specification for the following:

² www.hitsp.org



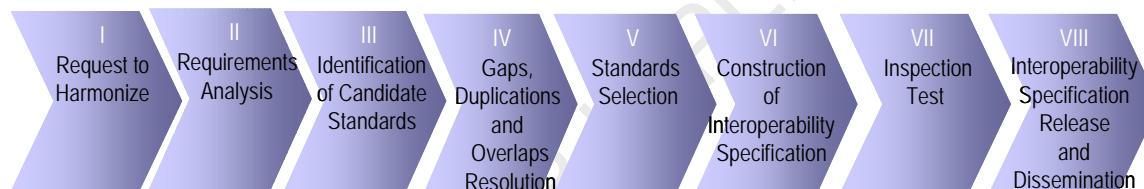
Use Case	Specific Scope of this Use Case
Biosurveillance	Transmit essential ambulatory care and emergency department visit, utilization, and lab result data from electronically enabled healthcare delivery and public health systems in standardized and anonymized format to authorized Public Health Agencies with less than one day lag time.
Electronic Health Record	Allow ordering clinicians to electronically access laboratory results, and allow non-ordering authorized clinicians to electronically access historical and other laboratory results for clinical care.

In its final state, this Interoperability Specification provides unambiguous instructions for how two or more systems should exchange information within this specific context of the Use Case.

How Use Cases and HITSP Interoperability Specifications are Developed

The American Health Information Community, as the representative of public and private health sector stakeholders, identified the three initial Use Cases (available at hitsp.org) that drove the initial efforts of the HITSP. Nationwide public and private health sector priorities continue to focus the efforts of the HITSP. The Use Case driven HITSP harmonization process is implemented by formally chartered Technical Committees. The volunteers that comprise a Technical Committee followed an 8 step process, depicted below.

Figure 1.0-1 HITSP Harmonization Process Steps



How to Read this Interoperability Specification

Each Interoperability Specification (IS) is actually a suite of documents that, taken as a whole, provide a detailed map to existing standards and specifications that will satisfy the requirements imposed by a given Use Case. It identifies and constrains standards where necessary, and creates groupings of specific actions and actors to further describe the relevant contexts. Where gaps and overlaps are identified, the Interoperability Specification provides recommendations and a roadmap for corrections to be made. This Interoperability Specification includes the Transaction Packages, Transactions, and Components.



2.0 INTRODUCTION

This Transaction notifies its recipient that a document is available and provides the information needed to retrieve the document. As an introduction to the Notification of Document Availability Transaction, this section provides a high level overview of an information sharing scenario enabled by following this specification, outlines the technical scope of the specification, describes the intended audience for the technical content of the document, acknowledges the copyright protections that pertain, provides Internet links to the HITSP Acronym List and an explanation of the conventions we use to convey the full descriptions and usage of standards. If you are already familiar with this information, proceed to Section 3.0 Referenced Standards.

2.1 OVERVIEW

This Notification of Document Availability (NAV) Transaction references the structures and the work that is accomplished by implementing this Transaction. Source material was predominantly from the Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (TF) Supplement ITI-25 Notification of Document Availability (NAV). This IHE Integration Profile supports the HITSP Notification of Document Availability Transaction.

The NAV Integration Profile introduces a mechanism allowing notifications to be sent point-to-point to systems within a Cross-Enterprise Document Sharing Affinity Domain (See “IHE IT Infrastructure Cross-Enterprise Document Sharing (XDS) Integration Profile”), eliminating the need for manual steps or polling mechanisms for a Document Consumer to be aware that documents of interest have been registered with an XDS Document Registry Actor.

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.

This basic mechanism is 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.

Table 2.1-1 Related Documents

Related Documents	Document Description
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 3.0	Volume 1 (ITI TF-1) Integration Profiles Revision 2 August 15, 2005
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 3.0	Volume 2, (ITI TF-2) Transactions Revision 2 August 15, 2005



Related Documents	Document Description
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (TF) Supplement	Supplement (ITI TF-Supplement) ITI-25 Notification of Document Availability (NAV), IHE TF Jun 28, 2005

2.2 TECHNICAL ASSUMPTIONS AND SCOPE

This Interoperability Specification focuses on a set of constrained standards for information interchange that address the core requirements of the Use Case described above. It may not define all functions, constructs and standards necessary to implement a conforming system in a real world environment. The following paragraphs provide the HITSP principles with regard to several critical topics to ensure consistent interpretation of the Interoperability Specifications.

2.2.1 INTEROPERABILITY SPECIFICATIONS NOT FUNCTIONAL SPECIFICATIONS

The HITSP Interoperability Specification defines how two or more systems exchange standard data content in a standardized manner. Interoperability Specifications define the necessary business and technical actors, the transactions between them including the message, content and terminology standards for the actual information exchange. Interoperability Specifications do not specify the functional requirements or behaviors of the systems or applications.

2.2.2 ARCHITECTURAL NEUTRALITY

HITSP Interoperability Specifications, unless otherwise noted, are not intended to define or prescribe any system architecture or implementation. At the most basic level, the Interoperability Specifications define specific information exchange standards that are to be used by any two systems. Information exchange must be placed within the context of a transaction between defined technical actors which fulfill higher level business requirements derived from the Use Case. In some cases the necessary technical actors may require some architectural structure or make some assumptions involving synchronous or asynchronous data exchanges, or require specific type of exchange, such as a message or document. These requirements may constrain to some degree the total range of choices regarding system architectures. When constraints are necessary to meet the Use Case requirements, the Interoperability Specification will note this and will retain as much architectural neutrality as possible. When appropriate, the Interoperability Specifications may provide architectural examples and discuss considerations of such examples.

2.2.3 THE USE OF MESSAGES AND DOCUMENTS AS APPROPRIATE

Within healthcare information there is an ongoing debate concerning the proper role of messages and documents as methods of exchanging data. Messages are typically non-persistent encapsulations of highly structured data that require external context. Documents are persistent encapsulations of both data and context which may be authenticated to insure non-repudiation. Persistence as defined by Health Level Seven (HL7), means that a clinical document continues to exist in an unaltered state for a



time period defined by local and regulatory requirements. Non-repudiation, as defined by ISO adapted from ASTM E31, means a service that provides proof of the integrity and origin of data, which can be verified by any party. HITSP recognizes that requirements for both messages and documents exist and where consistent with harmonization will support both. For example, depending on specific phases of the workflow, a laboratory result might be exchanged as a message, as a document, or both. Business requirements may define which format is more effective.

2.2.4 IMPLEMENTATION TESTING

The 2006 set of Interoperability Specifications were evaluated by inspection testers (desktop review) and reviewed by HITSP members prior to HITSP approval. Although the Interoperability Specifications are based on approved standards, when published, they represent combinations and constraints that have not been tested in actual implementations. HITSP enlisted partners to develop test plans, data and suites to test the implementation and then to support a program for progressive testing, feedback and deployment of implementations. Feedback from test implementers has been used in the revisions in Version 2.0.

2.2.5 SECURITY AND PRIVACY

The Health Insurance Portability and Accountability Act (HIPAA) and its Administrative Simplification sections establish the minimum federal requirements for security and privacy of individually identifiable health information (IIHI). HIPAA requires that “covered entities” establish and maintain secure systems that protect IIHI from unauthorized disclosures while ensuring its availability for authorized uses. Most providers, health plans and intermediaries, and by contract their business associates, are covered by HIPAA regulation. However, HIPAA does not cover personal health records unless they are held by a covered entity, nor an individual’s use of their own health information.

Currently, HITSP is charged by ONC to harmonize standards based on Use Cases derived from AHIC requirements and priorities. Implicitly and in some cases explicitly, the Use Cases require a secure infrastructure and certain security or privacy functions. Because of time and resource constraints and the need for further information as described below, HITSP has decided to defer specifying most security requirements, instead treating these as a pre-condition for implementing the core information exchanges. The underlying premise is that HITSP, based upon prioritization by AHIC and ONC, will in the future identify and constrain the standards needed for a standards-based security framework that provides the mechanisms needed to protect patient privacy and maintain confidentiality of information about the patient. This standards-based security framework will need to accommodate federal, state, local, and healthcare enterprise security and privacy policies and processes. Exceptions to the deferred requirements that are addressed in this first release are secure web-based messaging, pseudonymization and anonymization.

There is a special case for the Consumer Empowerment (CE) Use Case. In the first year of HITSP’s work, the Consumer Empowerment TC is to provide an Interoperability Specification for sharing of demographic data, medication lists, and allergies *based on patient consent*. Patient consent is clearly within the scope of the CE Use Case. However, HITSP requires further guidance on patient consent,



particularly since patient consent is not addressed by HIPAA in the case of a personal health record (PHR) nor is it established within widely accepted PHR standards. Therefore HITSP identifies patient consent as a necessary pre-condition for successful implementation of a PHR that contains personal demographic data and medication histories. Patient consent will be documented as a pre-condition in the CE Interoperability Specification. Work on patient consent has been deferred until the second year of HITSP work.

2.3 AUDIENCE

The Interoperability Specification is designed to be used by analysts who need to understand the interoperability requirements for the described Use Case, and by implementers working to develop interoperable applications. Understanding and using the relevant interoperability set of specifications is a key requirement for establishing interoperability compliance.

2.4 COPYRIGHT PERMISSIONS

COPYRIGHT NOTICE

© 2007 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.

IHE materials used in this document have been extracted from relevant copyrighted materials with permission of Integrating the Healthcare Enterprise (IHE). Copies of this standard may be retrieved from the IHE at www.ihe.net.

2.5 ACRONYMS

The acronyms used in this document are contained in the HITSP Acronyms List.

2.6 CONVENTIONS

Conventions are used to convey the full descriptions and usage of standards in the Interoperability Specification and are contained in the HITSP Conventions List.



3.0 REFERENCED STANDARDS

It is HITSP's policy to incorporate only standards that have been approved according to the formal policy of standards organization, as defined by HITSP, which publishes the standard. HITSP interprets approval to include Draft Standards for Trial Use. The objective is to incorporate only standards that are managed within a formal life cycle process as defined by the standards organization. In some cases, where we believe a standard that is not yet approved may best meet the requirements of an Interoperability Specification, HITSP may provide a roadmap of its future intent conditional on future actions by either or both the standards organizations and the HITSP Technical Committee. Thus there are four classes of HITSP-committed standards.

- Approved for Use – standards included for unconditional use within a HITSP construct
- Interim – standards included for use now within a HITSP construct but for a defined time period or conditional on future actions, e.g., "Intended for Use" standard is available
- Provisional - standards that are not yet but are expected to be approved by the Standards Organization by the time that the Interoperability Specification is released by HITSP. A "Provisional" standard becomes an "Approved for Use" standard only if:
 - It is approved by the Standards Organization by the time that the Interoperability Specification is released by HITSP and
 - It is substantially the same as it was when it was provisionally used and
 - It requires no further action by the Technical Committee
- Intended for Use – proposed standards that are roadmapped for future use pending actions by the TC and/or the standards organization. Therefore a standard is defined as "Intended for Use" because it will not be approved by the time that the HITSP construct is released but is sufficiently defined to enable detailed evaluation of how well it will meet technical and business requirements

HITSP may continue to use "Provisional" or "Interim" standards as they existed when incorporated into the HITSP construct if the expected conditions are not satisfied until such time as HITSP can replace it with a more suitable standard. In this circumstance, the Standards Organization would have no responsibility to maintain or correct this artifact. If a standard "Intended for Use" is not developed and approved in terms of time frame or content as expected by the TC at the time of its initial selection, it may be replaced. All standards used by HITSP must meet the HITSP selection criteria. The use of "Interim" and "Intended for Use" standards will be weighed against the alternative of simply declaring a gap for HITSP and the Standards Organizations to resolve.

3.1 LIST OF STANDARDS

It is important to understand that the standards selected here are within the context of the specific Use Case requirements and do not necessarily reflect selection in other contexts.



Table 3.1-1 List of Standards

Composite Standard	Description
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 3.0	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 current version of the ITI-TF, rev. 3.0 for Final Text, specifies the IHE transactions defined and implemented as of December 9, 2006. The latest version of the IHE Technical Framework is available at www.ihe.net .
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (TF) Supplement	Supplement (ITI TF-Supplement) ITI-25 Notification of Document Availability (NAV), IHE TF Jun 28, 2005

3.2 DEPENDENCIES

See IHE ITI-TF Supplement 2005-2006, Notification of Document Availability Integration Profile for this information.

3.3 CONSTRAINTS

See IHE ITI-TF Supplement 2005-2006, Notification of Document Availability Integration Profile for this information.



4.0 TRANSACTIONS

4.1 CONTEXT OVERVIEW

4.1.1 CONTEXTUAL CONSTRAINTS

The NAV operations assume that a suitable security and privacy environment has been established. See IHE ITI-TF NAV supplement for additional information.

4.1.2 TECHNICAL ACTORS

See IHE ITI-TF NAV supplement for this information.

4.1.3 ACTOR INTERACTIONS

See IHE ITI-TF NAV supplement for this information.

4.2 PROCESS FLOWS

See IHE ITI-TF NAV supplement Figure 12.4.1 for this information. Clinical exemplars are also available in the IHE TF specification.

4.2.1 PROCESS PRE-CONDITIONS

See IHE ITI-TF NAV supplement for this information.

Note: This Integration Profile does not address how the recipients of the message are to be selected. This is an administrative function outside of the scope of this Integration Profile. What makes a receiver unique is that they have a unique e-mail address. Whether this is a person or a node is immaterial.

4.2.1.1 PROCESS TRIGGERS

See IHE TF NAV supplement for this information.

4.2.2 PROCESS POST-CONDITIONS

HITSP Acknowledgements component is required for messages, optional for documents.

See IHE ITI-TF NAV supplement for additional information.

4.2.2.1 PROCESS OUTPUTS

None.

4.3 DATA FLOWS

Not applicable.



5.0 CONSTRAINTS FOR REUSE

Not Applicable.

RELEASED FOR IMPLEMENTATION



6.0 CHANGE HISTORY

6.1 MAY 11, 2007

Upon approval by the HITSP Panel on May 11, 2007, this document has been moved to Version 2.0.
This document is now Released for Implementation.

RELEASED FOR IMPLEMENTATION

