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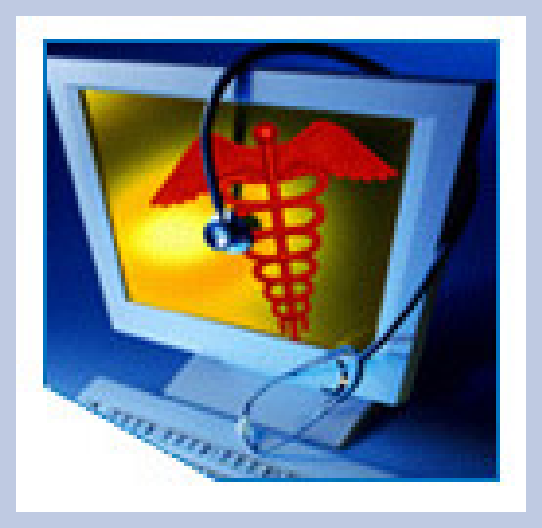
Version 2.3

HITSP Encounter Document Using IHE Medical Summary (XDS-MS) Component

HITSP/C48



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Care Management and Health Records Domain Technical Committee

DOCUMENT CHANGE HISTORY

Version Number	Description of Change	Name of Author	Date Published
1.0	Initial draft	Biosurveillance Technical Committee	August 9, 2006
1.1	Ready for Public Comment	Biosurveillance Technical Committee	September 12, 2006
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2.2.1	Review Copy	Care Management and Health Records Domain Technical Committee	August 20, 2008
2.3	Released for Implementation	Care Management and Health Records Domain Technical Committee	August 27, 2008

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FIGURES AND TABLES

1.0 INTRODUCTION

As an introduction to the HITSP Encounter Document Using IHE Medical Summary (XDS-MS) Component, this section provides a high level overview of the information sharing scenario enabled by following this specification, provides a document map of the construct relationships for this specification, acknowledges the copyright protections that pertain, and provides a list of key reference documents and background material. If you are already familiar with this information, proceed to Section 2.0 Component Definition.

1.1 OVERVIEW

This section describes the contents of this specification and provides a high level definition of this Component and background information about the underlying standards that the Component is based on.

This Component supports the process of sending patient encounter data (excluding laboratory and radiology) in a document sharing functional flow scenario. Patient encounter data are captured as part of the normal process of care performed by healthcare providers, such as hospitals, emergency departments and outpatient clinics.

1.2 COMPONENT DOCUMENT MAP

Each HITSP specification describes how to integrate and constrain existing standards and specifications that will satisfy the requirements for the HITSP construct. There are four types of HITSP constructs called Interoperability Specifications (IS), Transaction Packages (TP), Transactions (T), and Components (C). Interoperability Specifications define the context(s) in which any other HITSP construct may be used. The current Encounter Document Using IHE Medical Summary (XDS-MS) Component specification does not depend on any other HITSP constructs, however, it is used with other constructs to meet the requirements of one or more ISs. Review Section 1.2 Interoperability Specification Document Map from the relevant IS to better understand the context, dependencies, and relationships between the constructs used to meet the IS requirements.

1.3 COPYRIGHT PERMISSIONS

Seven, Inc. Copies of standards included in this Interoperability Specification may be purchased from the Health Level Seven, Inc. Material drawn from these standards is credited where used.

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 Web Site at www.ihe.net.

1.4 REFERENCE DOCUMENTS

This section provides a list of key reference documents and background material. If you are already familiar with this information, proceed to Section 2.

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

Table 1.4-1 Reference Documents

Reference Document	Document Description
HITSP Interoperability Specification Overview	Provides background information about the HITSP and its role in the overall U.S. efforts to realize large scale interoperability of health information. The document also provides a description of the HITSP process for healthcare standards harmonization and explains how to use the Interoperability Specifications and other related documents to inform your health IT product development or product refinement.
HITSP Conventions List	Describes the conventions that are used to convey the full descriptions and usage of standards in the HITSP specifications
HITSP Acronyms List	Lists and defines the acronyms used in this document
HITSP Glossary	Provides definitions for relevant terms used by HITSP documents
HITSP Harmonization Framework	Describes the current framework within which the Interoperability Specifications are built

Reference Document	Document Description
TN900 - Security and Privacy Technical Note	Developed as a reference document to provide the overall context for use of the HITSP Security and Privacy constructs. It includes the following: • The scope, reference policy background, and Security and Privacy principles used in the development of the constructs • A detailed description and schematics of the conceptual relationship between the Security and Privacy constructs • A mapping of existing standards and constructs to be used in meeting the stated requirements of the AHIC Use Cases • A list of identified gaps and the recommended approaches to resolving those gaps • A roadmap for how the Security and Privacy constructs will evolve and eventually align with other HITSP Interoperability Specifications • A conceptual framework for Security and Privacy management, including reference information on privacy policies, risk assessment, and risk management • A glossary of terms used in all the Security and Privacy construct documents • A description of the application of the Security and Privacy constructs to the HITSP Interoperability Specifications for the three initial AHIC Use Cases – Biosurveillance, Electronic Health Records - Laboratory Results Reporting, and Consumer Empowerment HITSP will periodically update this Technical Note as required by the introduction of new contexts for use.

2.0 COMPONENT DEFINITION

A Component defines atomic constructs used to support an information exchange or to meet an infrastructure requirement. This is accomplished by:

(a) Referencing one or more underlying standards
(b) Specifying constraints and other rules for using the standards

2.1 CONTEXT OVERVIEW

This section provides a general description of the Component. It includes a detailed definition of the Component and the reason for its use. It also provides all the necessary background information that further describes the context in which the Component is needed, and the base or composite standard that the Component is based on.

As stated in IHE PCC-Technical Framework (TF):

The text for the PCC-TF specification begins here:

> Patient, clinician, industry and governmental demands for improved healthcare quality have created increased focus to make patient healthcare information interoperability across disparate systems a reality.
>
> The challenge is to identify the clinically relevant documents (and data elements those documents contain) that are used in typical “transfer of care” scenarios and then to provide interoperability standards to promote ease in transmission of those documents (and data elements). The Cross-Enterprise Sharing of Medical Summary (XDS-MS) Integration Profile facilitates this by defining the appropriate standards for document transmission and a minimum set of “record entries” that should be forwarded or made available to subsequent care provider(s) during specific transfer of care scenarios. In addition, this Integration Profile needs to define the utilization requirements/options for the receiving entity in order to ensure that the “care context” of the sending entity is appropriately maintained following the information transfer.

The text for the PCC-TF specification ends here.

2.1.1 COMPONENT CONSTRAINTS

This section describes the constraints that limit the context in which the Component may be used. A constraint describes a rule that limits the use of the actors, actions or data within the given context, or to which the interactions must conform to be used within the described context. It is a description of the limits and scope of the interactions and can describe actions or events that are not part of the initial definition for the context.

Table 2.1.1-1 Component Constraints

Constraint	Constraint Section
No applicable constraints	

2.1.2 COMPONENT DEPENDENCIES

This section describes any specific mapping criteria for the standards underlying the Component. It elaborates on the relationships between different standards used by this Component, and how they map to each other. Additional required mapping criteria not currently enforced by the underlying standards, and any specific elements that are required for this mapping to succeed, are also provided.

Table 2.1.2-1 Component Dependencies

Standard/HITSP Component	Depends On (Name of standard/HITSP Component that it depends on)	Dependency Type (Pre-condition, Post-condition, General)	Purpose (Reason for this dependency)
No applicable dependencies			

2.2 RULES FOR IMPLEMENTING

The following section documents the content of the Component. It provides the basic elements and secondary standards that are supported by this Component and the constraints that are being placed on those standards. Specifically, it describes the subset or constraints that are required for this Component, and the minimum attributes of the Component as it relates to the base or composite standards on which it is based.

All process flows associated with this Component can be found in Section 3.2 of IHE PCC-TF, Volume 1.

2.2.1 DATA MAPPING

This section describes the specific data elements used by this Component. Due to the potentially large number of data elements in a particular standard, only the fields that HITSP is constraining differently from the standard will be described here.

The following table shows how AHIC data elements are mapped to the XDS-MS elements specified in IHE-PCC-TF, which specifies constraints to HL7 CDA-2:

Table 2.2.1-1 Data Mapping of Patient Data Elements

Data Element	Description	Limit/Range of values	Data Source	Destination	Requirements/ Pre-conditions
Randomized Data Linker	A unique, randomly generated, encoded number that links to patient-level information (i.e., name and address) retained at the facility	Alphanumeric		ClinicalDocument/recordTarget/patientRole/id	Required in every document where pseudonymization is used
Encounter Date / Time	Time of the patient presentation for care: ED arrival time (initial triage time) or the registration time for inpatients or check-in time for ambulatory settings	HL7 Timestamp		ClinicalDocument/componentOf/encompassingEncounter/effectiveTime	
Date of Birth	Date of birth	HL7 Timestamp		ClinicalDocument/recordTarget/patientRole/patient/birthTime	
Age	Patient sex / gender	LOINC / UCUM		ClinicalDocument/recordTarget/patientRole/patient/birthTime (Calculate from this info)	
Gender	Electronic medical records billing codes	HL7 V3 AdministrativeGender (M, F, UN) corresponding to HL7 V2.X M,F,O Use nullFlavor for Unknown		ClinicalDocument/recordTarget/patientRole/patient/administrativeGenderCode	
Zip Code	General type of patient, e.g., Inpatient, Outpatient, Emergency	USPS		ClinicalDocument/recordTarget/patientRole/addr/postalCode	
State	This field indicates where the patient was admitted	HL7 ADDR		ClinicalDocument/recordTarget/patientRole/addr/state	
Date / Time of Message		HL7 Timestamp		Clinical Document / EffectiveTime (This timestamp presides over the whole document, unless it is overridden at a more granular level)	

Table 2.2.1-2 Data Mapping Clinical Data Elements

Data Element	Description	Limit/Range of values	Data Source	Destination	Requirements/Pre-conditions
Patient Identification	A unique, randomly generated, encoded number that links to patient-level information (i.e., name and address) retained at the facility	N/A		ClinicalDocument/recordTarget/patient/id	Required in every document where pseudonymization is used
Admit Date / Time		N/A		/ClinicalDocument/componentOf/encompassingEncounter/effectiveTime or /ClinicalDocument/componentOf/encompassingEncounter/effectiveTime/low	
Discharge Date / Time		N/A		/ClinicalDocument/componentOf/encompassingEncounter/effectiveTime or /ClinicalDocument/componentOf/encompassingEncounter/effectiveTime/high	
Diagnosis / Injury Code		ICD-9-CM ICD-10-CM or SNOMED CT		ClinicalDocument/component/structuredBody/component/section (PROBLEMS LIST 11450-4, HOSPITAL DISCHARGE DX 11535-2, HOSPITAL ADMISSION DX X-HAD-X)/entry/act/entryRelationship/observation/value	
Diagnosis type (Problem Code)	Preliminary, Interim, final.	Can be derived from the section code For Vocabulary, use Section Code (LOINC)		ClinicalDocument/component/structuredBody/component/section (PROBLEMS LIST 11450-4, HOSPITAL DISCHARGE DX 11535-2, HOSPITAL ADMISSION DX X-HAD-X)/entry/act/entryRelationship/observation/code	
Diagnosis Date / Time	*[System time stamp of data entry likely to be only associated date and time+E94]*	N/A		ClinicalDocument/component/structuredBody/component/section (PROBLEMS LIST 11450-4, HOSPITAL DISCHARGE DX 11535-2, HOSPITAL ADMISSION DX X-HAD-X)/entry/act/effectiveTime	
Discharge Disposition	If discharged, place to which patient was released	Use Universal Billing codes (UB-04/NUBC Current UB Data Specifications Manual)		ClinicalDocument/componentOf/encompassingEncounter/dischargeDispositionCode NOTE: Only required where patient has been discharged (E.g., not usually relevant to ambulatory care)	

Data Element	Description	Limit/Range of values	Data Source	Destination	Requirements/Pre-conditions
Patient class (Outpatient, Inpatient, ER)	General type of patient, *e.g.*, Inpatient, Outpatient, Emergency	ActEncounterCode subset of HL7 V3.0 CDA/CDA R2, ActCode, constrained to IMP, AMB, EMER, corresponding to HL7 V2.X I, O, E		ClinicalDocument/componentOf/encompassingEncounter/code	
Date and Time Onset of Illness	Recorded by triage or clinician *[May not be coded value]*	N/A		ClinicalDocument/component/structuredBody/component/section (HISTORY OF PRESENT ILLNESS 10164-2, PROBLEMS LIST 11450-4, HOSPITAL DISCHARGE DX 11535-2, HOSPITAL ADMISSION DX X-HAD-X)/entry/act/entryRelationship/observation/effectiveTime	For hospital stays, effectiveTime/high should be used to represent the discharge time; for very brief encounters, a single time could be used to represent the start and end of the encounter
Chief Complaint	Short description, recorded during triage, for seeking care *[May have text string or coded (e.g., ICD-9) values]*	This component will use the CHI recommended SNOMED CT as a reference terminology to communicate inter-operable information among and between systems, with the HITSP Interoperab-ility Specification Pre-condition that the sending and using systems must use formal coded nursing terminologies such as the Clinical Care Classification (CCC) System and the Omaha System that are integrated in SNOMED CT		ClinicalDocument/component/structuredBody/component/section (REASON FOR VISIT 29299-5, CHIEF COMPLAINT 10154-3)	Expected for hospital encounters when the encounter is complete
Temperature	Recorded temperature during triage	temperature units: either 'Cel^Cel – degree Celsius – temperature ^UCUM' or '[degF]^[degF] – degree Fahrenheit – temperature^UCUM'		ClinicalDocument/component/structuredBody/component/section (VITAL SIGNS 8716-3)/text	

Data Element	Description	Limit/Range of values	Data Source	Destination	Requirements/Pre-conditions
Blood Pressure	Systolic / Diastolic blood pressure measurement and the date / time that it was performed. The BP done on initial assessment / triage is the vital sign of interest	UCUM Blood Pressure Unit Code		ClinicalDocument/component/structuredBody/component/section (VITAL SIGNS 8716-3)/text	
Pulse / Heart rate		Not restricted		ClinicalDocument/component/structuredBody/component/section (VITAL SIGNS 8716-3)/text	
Extended Triage Notes		This component will use the CHI recommended SNOMED CT as a reference terminology to communicate inter-operable information among and between systems, with the HITSP Interoperab-ility Specification Pre-condition that the sending and using systems must use formal coded nursing terminologies such as the Clinical Care Classification (CCC) System and the Omaha System that are integrated in SNOMED CT		For text representation: ClinicalDocument/component/structuredBody/component/section/text For Coded representation: /ClinicalDocument/componet/structuredBody/section[code/@code='']/entry/act/entryRelationship/observation	

2.3 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. The following standards are used to implement this Component specification:

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. The standards used by this Component specification fall into the following categories:

- Regulatory guidance is a legal or other authoritative declaration that HITSP must abide by in standards selection (see Section 2.3.1)
- Selected standards are necessary for interoperability. These are standards that are used to meet information exchange requirements of associated constructs. For example, they are used to realize direct information exchange, to provide the transport mechanism, to specify the content, or to address security (see Section 2.3.2)
- Informative reference standards provide additional background information or guidance, and are not required for interoperability. These standards are not required to implement the Component specification (see Section 2.3.3)

2.3.1 REGULATORY GUIDANCE

The following table provides a list of legal or other authoritative guidelines that HITSP must abide by, or has agreed to use as guidance in the selection of standards. Note that only the referenced sections of the regulations are relevant to this Component specification.

Table 2.3.1-1 Regulatory Guidance

Standard	Description
No applicable regulatory and guidance standards	

2.3.2 SELECTED STANDARDS

The following table provides a list of standards that are used to meet information exchange requirements of this Component specification, and a detailed description of each standard.

Table 2.3.2-1 Selected Standards

Standard	Description
Health Level Seven (HL7) Version 3.0 Clinical Document Architecture (CDA/CDA R2)	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

Standard	Description
Integrating the Healthcare Enterprise (IHE) Patient Care Coordination (PCC), Revision 3.0, 2007 - 2008, Cross-Enterprise Sharing of Medical Summaries (XDS-MS) Integration Profile	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. The Cross Enterprise Document Sharing of Medical Summaries (XDS-MS) Integration Profile enables sharing of health information between enterprises of a regional health network, and further describes how to map content in a CDA medical document into registry metadata. In the registry, healthcare providers publish pointers to documents stored in distributed repositories. Other healthcare providers may search and retrieve these and other documents. For more information visit www.ihe.net
International Classification of Diseases, 10th Revision, Related Health Problems (ICD-10-CM)	The International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM), describes the classification of morbidity information for statistical purposes and for the indexing of healthcare records by diseases. The National Center for Health Statistics (NCHS), the Federal agency responsible for use of the International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) in the United States, developed a clinical modification of the classification for morbidity purposes. For more information visit www.cdc.gov/nchs Note: While ICD-10 is not deployed in US installations, we recognize the need to move toward new releases of coded values
International Classification of Diseases, 9th Revision, Clinical Modifications (ICD-9-CM)	The International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM), Volumes I, II (diagnoses) and III (procedures) describes the classification of morbidity information for statistical purposes and for the indexing of healthcare records by diseases and procedures. For more information visit www.cdc.gov/nchs
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
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
National Uniform Billing Committee (NUBC) Uniform Bill Version 2007 (UB-04) Current UB Data Specification Manual Field 22, Patient Discharge Status, Codes	A code set identifying status of patient discharge on an institutional claim (e.g., inpatient, outpatient, hospice, home care). For more information visit www.nubc.org
Unified Code for Units of Measure (UCUM)	A code system intended to include all units of measures being contemporarily used in international science, engineering, and business. The purpose is to facilitate unambiguous electronic communication of quantities together with their units. The focus is on electronic communication, as opposed to communication between humans. For more information visit aurora.regenstrief.org

2.3.3 INFORMATIVE REFERENCE STANDARDS

The following table lists standards that provide additional background information or guidance; however, they are not required for the implementation of this Component specification.

Table 2.3.3-1 Informative Reference Standards

Standard Name	Description/Reason for Use
International Classification of Diseases, 10th Revision, Procedure Coding System (ICD-10-PCS)	The International Classification of Diseases, 10th Revision, Procedure Coding System (ICD-10-PCS), describes the classification of inpatient procedures for statistical purposes and for the indexing of healthcare records by procedures. ICD-10-PCS is a procedural coding system managed by the Centers for Medicare and Medicaid Services (CMS). For more information visit www.cms.hhs.gov Note: While ICD-10 is not deployed in US installations, we recognize the need to move toward new releases of coded values

3.0 TECHNICAL IMPLEMENTATION

3.1 CONFORMANCE

This section describes the conformance criteria, which are objective statements of requirements that can be used to determine if a specific behavior, function, interface or code set has been implemented correctly.

3.1.1 CONFORMANCE CRITERIA

In order to claim conformance to this construct specification, an implementation must satisfy all the requirements and mandatory statements listed in this specification, the associated HITSP Interoperability Specification, its associated construct specifications, as well as conformance criteria from the selected base and composite standards. A conformant system must also be constrained as specified in table 2.1.1-1 and implement all of the required actors, where defined within the scope, subset or implementation option that is selected from the associated Interoperability Specification.

Claims of conformance may only be made for the overall HITSP Interoperability Specification with which this construct is associated.

3.1.2 CONFORMANCE SCOPING, SUBSETTING AND OPTIONS

A HITSP Interoperability Specification must be implemented in its entirety for an implementation to claim conformance to the specification. HITSP may define the permissibility for actor scoping, subsetting or implementation options by which the specification may be implemented in a limited manner. Such scoping, subsetting and options may extend to associated constructs, such as this construct. This construct must implement all requirements within the selected scope, subset or options as defined in the associated Interoperability Specification to claim conformance.

4.0 APPENDIX

The following sections include relevant materials referenced throughout this document.

No additional information at this time.

5.0 CHANGE HISTORY

The following sections provide the history of changes made to this document.

5.1 DECEMBER 13, 2007

Upon approval by the HITSP Panel on December 13, 2007, this document is now Released for Implementation.

5.2 MARCH 19, 2008

The following changes have been made to the construct:

- Updated Nursing Terminology references to reflect HITSP standards harmonization
- Replaced HL7 V3.0 reference with reference to HL7 V3.0 CDA/CDA R2
- Updated Figure 1.2-1
- Added ICD10 statement
- Removed the Clinical Care Classification (CCC) Version 2.0 standard because it is an example that satisfied the preconditions and therefore should not be in the list of standards

5.3 MARCH 27, 2008

Upon approval by the HITSP Panel on March 27, 2008, this document is now Released for Implementation.

The following changes have been made to this construct:

- Updated PCC Revision 3.0 standard to include XDS-MS
- Removed RxNorm and ITI-TF Rev. 4 from Table 2.3-1 due to the new HITSP standards referencing approach
- Added FIPS 5-2 to Table 2.3-1 to indicate State Code

5.4 AUGUST 20, 2008

This document has been modified to reflect the updated HITSP approach to categorizing standards as Regulatory Guidance, Selected Standards, and Informative References.

Deleted the following standards from the standards table:

- American Medical Association (AMA) Current Procedural Terminology (CPT®) Fourth Edition (CPT-4)
- Federal Information Processing Standards (FIPS) Codes for the Identification of the States, the District of Columbia and the Outlying Areas of the United States, and Associated Areas Publication # 5-2, May, 1987
- Healthcare Common Procedure Coding System (HCPCS) Level II Code Set

Moved the following standard from the standards table to the Informative Reference table:

- International Classification of Diseases, 10th Revision, Procedure Coding System (ICD-10-PCS) to informative

5.5 AUGUST 27, 2008

Upon approval by the HITSP Panel on August 27, 2008, this document is now Released for Implementation.