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Version 2.5

HITSP Summary Documents Using HL7 Continuity of Care Document (CCD) Component

HITSP/C32

Submitted to:

Healthcare Information Technology Standards Panel

Submitted by:

Care Management and Health Records Domain Technical Committee

DOCUMENT CHANGE HISTORY

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NOTE: HITSP/C32 has been revised to remove specification of Content Module data element constraints. These constraints now appear in HITSP/C83 CDA Content Modules.

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FIGURES AND TABLES

1.0 INTRODUCTION

1.1 OVERVIEW

The HITSP Summary Documents Using HL7 Continuity of Care Document (CCD) Component describes the document content summarizing a consumer's medical status for the purpose of information exchange. The content may include administrative (e.g., registration, demographics, insurance, etc.) and clinical (problem list, medication list, allergies, test results, etc) information. Any specific use of this Component by another HITSP specification may constrain the content further based upon the requirements and context of the document exchange. This specification defines content in order to promote interoperability between participating systems. Any given system creating or consuming the document may contain much more information than conveyed by this specification. Such systems may include Personal Health Record Systems (.1.s), Electronic Health Record Systems (EHRs), Practice Management Applications and other persons and systems as identified and permitted.

This Component is essentially a subset of the healthcare data that has been developed for specific business Use Cases. This subset contains the minimum critical or pertinent medical information sections as specified by the business case. Information conveyed according to the Component Construct is a representative extract of the information available on the creating system. The information in the HITSP Summary Documents Using HL7 Continuity of Care Document (CCD) Component and the creating systems must be consistent. Furthermore there should be no data elsewhere in the creating systemthat would contradict the meaning of any data in this construct. The expectation is that consuming systems will be able to use this specification as a source of information to input and/or update information in their instantiation of the healthcare record. This specification does not define the policies applicable to the import of this information.

It is anticipated and desirable that some implementers of the HITSP Summary Documents Using HL7 Continuity of Care Document (CCD) Component will want to add data and sections to permit greater communication between systems. The underlying standards (primarily HL7 CCD – Continuity of Care Document) have additional modules that may serve such purposes. This practice is beyond the scope of this HITSP Component. Implementers should be aware that they must assume that receivers of the document may only be able to view or process content modules as described in this specification, and may not be able to use the additional modules in the document. This means that the HITSP Summary Documents Using HL7 Continuity of Care Document (CCD) Component must be able to stand-alone. Applications may wish to display the document in two different user-selected views, one of which is restricted to the minimal dataset contents of this component. Adding optional sections and data elements should not generate errors. Optional data should be used if understood by the receiving system, but must not change the meaning of the document.

This Component refers to the HITSP 2008 work cycle. It expands upon the prior version of the specification for a consumer's registration/medication history information to include content to support the consumer's access to clinical information, medication management activities and supportive information for quality of care assessment.

1.2 COPYRIGHT PERMISSIONS

1.3 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. These documents can be retrieved from www.hitsp.org.

Table 1-1 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
TN901 - Clinical Documents	TN901 is a reference document that provides the overall context for use of the HITSP Care Management and Health Records constructs

1.4 CONFORMANCE

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

1.4.1 CONFORMANCE CRITERIA

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 implement all of the required interfaces 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 or Capability with which this construct is associated.

1.4.2 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 interface 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.

2.0 COMPONENT DEFINITION

2.1 CONTEXT OVERVIEW

This Component describes the document content that summarizes a consumer's medical status for the purpose of health information exchange. While an EHR or PHR system can contain much more information, this Component only deals with the summary information to be exchanged between such systems as established as requirements described in AHIC Use Cases.

HITSP Summary Documents Using HL7 Continuity of Care Document (CCD) Component is essentially a subset of the data in an EHR or PHR system that has been developed for interoperability purposes for specific business Use Cases. This subset contains the minimum critical or pertinent medical information of sections and data elements used in those business cases. The information in the subset of data to be exchanged and the EHR or PHR system must be consistent. Furthermore there should be no data elsewhere in the EHR or PHR system that would contradict the meaning of any data in the summary. The expectation is that consuming systems will be able to use the information received as appropriate information to input and/or update information in their instantiation of the healthcare record. This specification does not define the policies applicable to the import of this information.

2.1.1 COMPONENT CONSTRAINTS

An Interoperability Specification (IS) may constrain this Component to satisfy the requirements of an information exchange scenario. An Interoperability Specification describes the specific context of exchange and may declare additional constraints, e.g., by requiring the presence of information modules that are otherwise described in this Component as optional. Thus, to satisfy the Use Case of a consumer updating their registration information and medication history, the IS may impose requirements on the exchange to always contain the Person Information and Medications modules.

This Component should not be used outside the context of an Interoperability Specification as this may result in loss of interoperability.

However, the modules defined in this Component are intended for use and reuse whenever summary information such as a consumer's patient registration, medical history, immunizations, or other information modules defined in this Component are needed. Individual modules defined in this specification may be reused in other defined document types, such as operative notes, to convey similar information in other Use Cases. HITSP has assigned template identifiers to the reusable information modules to facilitate this reuse and provide a method for implementers to declare conformance to the templates within this Component.

Specific constraints related to each of the modules are defined in HITSP/C83 CDA Content Modules. Vocabulary constraints on Content Modules data are specified in HITSP/C80 Clinical Document and Message Terminology.

Table 2-1 Component Constraints

Constraint	Constraint Section
No applicable constraints	

2.1.2 COMPONENT DEPENDENCIES

Although no component dependencies exist, it is important to note the following dependencies that are specific to HITSP constructs:

Table 2-2 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)
HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD)	HITSP/C83 - CDA Content Modules	General	Constraints on Content Module fields
HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD)	HITSP/C/80 - Clinical Document and Message Terminology	General	Vocabulary constraints on Content Modules data defined in HITSPC/83

2.2 RULES FOR IMPLEMENTING

Note: We have added template identifiers to the document specifications that follow. These template identifiers are recommended to be used in exchanges, but are not required to restrictions on major change. It is possible that these identifiers could be required in future editions of this specification.

2.2.1 DATA MAPPING

This section describes the specific Content Modules used by this Component. Implementers will need to refer to HITSP/C83 CDA Content Modules, to see the fields that HITSP is constraining differently from the standard.

Table 2-3 defines the Content Modules used by the HITSP Summary Documents Using HL7 Continuity of Care Document (CCD) Component.

NOTE: Content Modules in this document map to the CCD Entry elements. The CCD sections themselves are not repeatable.

Table 2-3 Content Modules

Constraint ID	Content Module	HITSP Optional Entry[1]	HITSP Repeatable Entry[2]	Specification Reference
C32-[CT1--1]	Advance Directive	O	N	See HITSP/C83 Section 2.2.2.12 Advance Directives Section
C32-[CT1--2]	Allergy / Drug Sensitivity	O	N	See HITSP/C83 Section 2.2.1.2 Allergies and Other Adverse Reactions Section
C32-[CT1--3]	Comment	O	Y	See HITSP/C83 Section 2.2.2.11 Comment
C32-[CT1--4]	Condition	O	N	See HITSP/C83 Section 2.2.1.3 Problem List Section
C32-[CT1--5]	Encounter	O	N	See HITSP/C83 Section 2.2.1.27 Encounters Section
C32-[CT1--6]	Healthcare Provider	O	Y	See HITSP/C83 Section 2.2.2.4 Healthcare Provider
C32-[CT1--7]	Immunization	O	N	See HITSP/C83 Section 2.2.1.17 Immunizations Section
C32-[CT1--8]	Information Source	R	Y	See HITSP/C83 Section 2.2.2.10 Information Source
C32-[CT1--9]	Insurance Provider	O	N	See HITSP/C83 Section 2.2.1.1 Payers Section
C32-[CT1--10]	Language Spoken	R2	Y	See HITSP/C83 Section 2.2.2.2 Language Spoken
C32-[CT1--11]	Medication – Prescription and Non-Prescription	O	N	See HITSP/C83 Section 2.2.1.12 Medications Section
C32-[CT1--12]	Person Information	R	N	See HITSP/C83 Section 2.2.2.1 Personal Information

[1] **NOTE:** Optionality = “R” for Required, “R2” for Required if Known or “O” for Optional, or “C” for Conditional. Conditional footnotes are further described below. Repeatable = “Y” for yes, “N” for No

[2] **NOTE:** See HITSP/C83 for information regarding the repeatability of Data Elements with a Section

Constraint ID	Content Module	HITSP Optional Entry[1]	HITSP Repeatable Entry[2]	Specification Reference
C32-[CT1--13]	Plan of Care	O	N	See HITSP/C83 Section 2.2.1.24 Plan of Care
C32-[CT1--14]	Pregnancy	O	N	See HITSP/C83 Section 2.2.2.9 Pregnancy
C32-[CT1--15]	Procedure	O	N	See HITSP/C83 Section 2.2.1.8 List of Surgeries Section
C32-[CT1--16]	Support	R2	Y	See HITSP/C83 Section 2.2.2.3 Support
C32-[CT1--17]	Vital Sign	O	N	See HITSP/C83 Section 2.2.1.19 Vital Signs Section
C32-[CT1-18]	Results	O	N	See HITSP/C83 Section 2.2.1.22 Diagnostic Results Section

2.2.1.1 CONFORMANCE STATEMENTS, TEMPLATES, AND IDENTIFIERS

Conformance statements are used to provide explicit guidance, or rules, on the structure or content of a CDA document. These are identified as numbered statements, the format for the identifier is [docId]-[###] where docId is the mnemonic of the defining document, and the number is any numbering scheme. Note that conformance statement identifiers may not be stable over time; references in validation error reports or other specifications should also cite the specific version and date of publication of the Component where the conformance statement is located.

2.2.1.2 CDA DOCUMENT

At the clinical document level, template identifiers are employed to assert which template(s) the document conforms to. A document may assert conformance to more than one template. Template identifiers for context specific documents are declared in the Interoperability Specifications where the context is defined.

C32-[CT1-19] A CDA Document **SHALL** declare conformance to this specification by including a <templateID> element with the root attribute set to the value 2.16.840.1.113883.3.88.11.32.1.

Asserting conformance to this specification via the inclusion of the Summary Document templateID indicates that additional constraints from this specification are followed when applicable.

- Required modules from this specification shall be present and follow the associated constraints
- Modules that have been explicitly prohibited shall not be included
- Optional modules, when present, will follow the associated constraints if that module also asserts conformance to this document, i.e., includes the associated templates
- Additional CCD entry elements (the equivalent to modules in this specification) may be present. The consumer of the document may choose to accept or exclude the additional content, but shall not reject the document solely based upon the presence of the additional content

2.2.2 ADDITIONAL GUIDELINES AND EXAMPLES

Additional guidelines and examples that support the underlying base or composite standards for the HITSP Summary Documents Using HL7 Continuity of Care Document (CCD) Component may be included in this section if appropriate in the future to help describe how this specification differs from the underlying standards.

2.3 STANDARDS

2.3.1 REGULATORY GUIDANCE

Table 2-4 Regulatory Guidance

Standard	Description
No applicable regulatory guidance	

2.3.2 SELECTED STANDARDS

Table 2-5 Selected Standards

Standard	Description
Health Level Seven (HL7) Implementation Guide: CDA Release 2 – 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 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 and HL7. It is intended as an alternate implementation to the one specified in ASTM ADJE2369 for those institutions or organizations committed to implementation of the HL7 Clinical Document Architecture. For more information visit www.hl7.org
Integrating the Healthcare Enterprise (IHE) Exchange of Personal Health Record Content (XPHR)	The Exchange of Personal Health Record Content (XPHR) integration profile describes the content and format of summary information extracted from a PHR system used by a patient for import into healthcare provider information systems, and visa versa. The purpose of this profile is to support interoperability between PHR systems used by patients and the information systems used by healthcare providers. This profile does not address all the data exchange requirements of PHR systems. For more information visit www.ihe.org

2.3.3 INFORMATIVE REFERENCE STANDARDS

Table 2-6 Informative Reference Standards

Standard	Description
Health Level Seven (HL7) HL7 Version 3 Standard: Clinical Document Architecture (CDA), Release 2	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

3.0 APPENDIX

The following sections include relevant materials referenced throughout this document.

- A listing of all HITSP Constraints defined within this document.

3.1 HITSP CONSTRAINTS DEFINED IN THIS DOCUMENT

C32-[CT1-19]	A CDA Document **SHALL** declare conformance to this specification by including a <templateID> element with the root attribute set to the value 2.16.840.1.113883.3.88.11.32.1.
[C84-[CT2-15]	See HITSP/C83 Section 2.2.1.26 Social History Section
C32-[CT1--1]	See HITSP/C83 Section 2.2.2.12 Advance Directives Section
C32-[CT1--2]	See HITSP/C83 Section 2.2.1.2 Allergies and Other Adverse Reactions Section
C32-[CT1--3]	See HITSP/C83 Section 2.2.2.11 Comment
C32-[CT1--4]	See HITSP/C83 Section 2.2.1.3 Problem List Section
C32-[CT1--5]	See HITSP/C83 Section 2.2.1.27 Encounters Section
C32-[CT1--6]	See HITSP/C83 Section 2.2.2.4 Healthcare Provider
C32-[CT1--7]	See HITSP/C83 Section 2.2.1.17 Immunizations Section
C32-[CT1--8]	See HITSP/C83 Section 2.2.2.10 Information Source
C32-[CT1--9]	See HITSP/C83 Section 2.2.1.1 Payers Section
C32-[CT1--10]	See HITSP/C83 Section 2.2.2.2 Language Spoken
C32-[CT1--11]	See HITSP/C83 Section 2.2.1.12 Medications Section
C32-[CT1--12]	See HITSP/C83 Section 2.2.2.1 Personal Information
C32-[CT1--13]	See HITSP/C83 Section 2.2.1.24 Plan of Care
C32-[CT1--14]	See HITSP/C83 Section 2.2.2.9 Pregnancy
C32-[CT1--15]	See HITSP/C83 Section 2.2.1.8 List of Surgeries Section
C32-[CT1--16]	See HITSP/C83 Section 2.2.2.3 Support
C32-[CT1--17]	See HITSP/C83 Section 2.2.1.19 Vital Signs Section
C32-[CT1-18]	See HITSP/C83 Section 2.2.1.22 Diagnostic Results Section

4.0 DOCUMENT UPDATES

The following sections provide the history of all changes made to this document since the last publication.

4.1 DECEMBER 13, 2007

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

4.2 MARCH 19, 2008

The following changes have been made to the construct:

- Removed the standards below from Table 2.3.1-1 and Figure 1.2-1 because they were only included in the construct for mapping purposes:
  - Accredited Standards Committee (ASC) X12 Insurance Subcommittee (X12N) Implementation Guides Version 004010 plus Addenda 004010A1
  - Accredited Standards Committee (ASC) X12 Standards Release 004010
  - American Society for Testing and Materials (ASTM) Standard Specification for Coded Values Used in the Electronic Health Record: # E1633-02
  - American Society for Testing and Materials (ASTM) Standard Specification for Continuity of Care Record (CCR): # E2369-05
  - National Council for Prescription Drug Programs (NCPDP) SCRIPT Standard Version 8.1

4.3 MARCH 27, 2008

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

4.4 APRIL 18, 2008

Correction to Table 4.4.1.18-2 Procedure Data Mapping Table – Requirements to change 17.1 from Optional to Required per the descriptive text for this section.

4.5 JULY 11, 2008

Editorial Changes

- Applied formatting to keywords in conformance statements
- Applied formatting to xpath statements for clarity
- Clarification of R2 designation; inserted source definition (IHE)
- Moved the templateID constraints statements into constraint statement tables, applied numbering for consistency (all constraints are numbered, use keywords, etc.)
- Added a map of module/statement name to template ID (OID)

4.6 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.

The following standards have been added as selected:

- Internet Engineering Task Force (IETF), The tel URI (Uniform Resource Identifier) for Telephone Numbers (RFC 3966) Proposed Standard

- Internet Engineering Task Force (IETF), The mailto URL (Uniform Resource Locators) scheme (RFC 2368) Proposed Standard
- Unified Code for Units of Measure (UCUM)

The following standards have been designated as informative references:

- Council for Affordable Quality Health Care (CAQH) Committee on Operating Rules for Information Exchange (CORE) Phase I Operating Rules
- Health Level Seven (HL7) Version 3.0
- Integrating the Healthcare Enterprise (IHE) Patient Care Coordination (PCC) Technical Framework Revision 1.0
- Integrating the Healthcare Enterprise (IHE) Patient Care Coordination (PCC), Revision 3.0, 2007 - 2008
- National Cancer Institute (NCI) Thesaurus: Route of Administration
- Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity

4.7 SEPTEMBER 26, 2008

This document has been modified to:

- Remove all specification of Content Module data element constraints. These are now specified in HITSP/C83 CDA Content Modules.
- The Appendix material showing mappings of the HITSP/C32 Summary Documents Using HL7 Continuity of Care Document (CCD) Document Component elements to NCPDP SCRIPT element names, X12N 271 Implementation Guide element names and ASTM E2369-5 CCR element names have been removed.

4.8 DECEMBER 10, 2008

The changes in this construct address the following comments received during the Public Comment and Inspection Testing period (September 29 – October 24, 2008).

- 5641, 5642

The full text of the comments along with the Technical Committee's disposition can be reviewed on the HITSP Public Web Site.

- Section 2.1.2 Component Dependencies
  - Corrected the table numbering for Table 2.1.2-1 Content Modules
  - Removed the explanation regarding the use of XDS Registry Entry Metadata when registering any instance of HITSP/C32 Summary Documents Using HL7 Continuity of Care Document (CCD). This explanation had broader application since it applies to all HITSP constructs that use CDA, thus it was moved to HITSP/TN901 Technical Note for Clinical Documents.
- Section 2.2.1 Data Mapping
  - Removed explanation that other data elements not defined in HITSP/C83 CDA Content Modules may be included in an instance of a Content Module. This wording has now been incorporated into HITSP/C83 CDA Content Modules Component.
- Section 2.2.1.1 Conformance Statements, Templates, and Identifiers
  - Removed explanation regarding use of templates. This explanation is now included in HITSP/C83 CDA Content Modules and HITSP/TN901 Technical Note for Clinical Documents.
- Section 2.2.1.2 CDA Document
  - Removed constraint the "exclude modules shall not be present."
- Section 2.3.2.2 Selected Standards

  - Added Integrating the Healthcare Enterprise (IHE) Exchange of Personal Health Record Content (XPHR) as a selected standard.
- Section 5.7 September 26, 2008
  - Updated to indicate that the HITSP/C32 Summary Documents Using HL7 Continuity of Care Document (CCD) Appendix material was removed. It originally indicated this Appendix material was moved to HITSP/C83 CDA Content Modules but a decision was made to exclude it from HITSP/C83 CDA Content Modules Component also.

Minor editorial changes were made to this construct.

4.9 DECEMBER 18, 2008

Upon approval by the HITSP Panel on December 18, 2008, this document is now Released for Implementation.

4.10 JUNE 30, 2009

Revised the document based on HITSP/TN903 Data Architecture

General Updates:

- Section 2.2 Rules for Implementing
  - Addition of Note on usage of HITSP Constraints
  - Section 2.2.1 Data Mapping
    Added Constraint IDs to identify all HITSP Constraints
- Appendix 4.0
  - Addition of links to all C32 CCD Data Element and Constraints
- Changes based upon Public Comment:
  - 7059
  - The full text of the comments along with the Technical Committee's disposition can be reviewed on the HITSP Public Web Site.

Minor editorial changes were made to this document. Removed boilerplate text for simplification. The term "actor" was replaced with "interface".

4.11 JULY 8, 2009

Upon approval by the HITSP Panel on July 8, 2009, this document is now Released for Implementation.