

HITSP Remote Monitoring Observation Document Component

HITSP/C74



Healthcare Information Technology Standards Panel

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1.0 INTRODUCTION

1.1 OVERVIEW

The HITSP Remote Monitoring Observation Document Component describes the document content to convey medical information collected by remote healthcare monitoring devices for the purpose of information exchange. The content may include administrative (e.g., registration, demographics, insurance, etc.) and clinical (results, vital signs, etc.) information. This specification defines content in order to promote interoperability between participating systems. Such systems may include Personal Health Record (PHRs) systems, Electronic Health Record (EHRs) systems, Practice Management Applications and other persons and systems as identified and permitted. Any given system creating or consuming the document may contain much more information than conveyed by this specification. Thus 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.

Remote Monitoring Observation Documents are 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 of sections and data elements as specified by the business cases. A Remote Monitoring Observation Document must be a representative extract of the creating system. The information in the Remote Monitoring Observation Document and the creating system must be consistent. Furthermore there should be no data elsewhere in the creating system that would contradict the meaning of any data in the construct. The expectation is that consuming systems will be able use this construct as a source of information to input and/or update information in their instantiation of the patient record. This specification does not define the policies applicable to the import of this information.

1.2 COPYRIGHT PERMISSIONS

COPYRIGHT NOTICE

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Certain materials contained in this Interoperability Specification are reproduced from Health Level Seven (HL7) Implementation Guide for CDA Release 2.0 Personal Health Monitoring Report (PHMR) DSTU Release 1 with permission of Health Level Seven, Inc. No part of the material may be copied or reproduced in any form outside of the Interoperability Specification documents, including an electronic retrieval system, or made available on the Internet without the prior written permission of Health Level 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.

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 to provide 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

The purpose of this specification is to provide the context and background for the use of the Health Level 7 (HL7) Implementation Guide for CDA Release 2.0 Personal Health Monitoring Report (PHMR) (International Realm) Draft Standard for Trial Use Release 1 in the construction of Remote Monitoring Observation Documents.

The PHMR standard describes the constraints on the Clinical Document Architecture (CDA) header and body elements for PHMR documents. This construct applies additional constraints to the PHMR standard to conform to HITSP usage of CDA documents.

The text for the HL7 Implementation Guide for CDA Release 2.0 Personal Health Monitoring Report, p. 10 begins here:

The PHMR is a document that carries personal healthcare monitoring data. The data are transmitted either in the form of a summary or as raw data. The summary may be a result of analysis by a disease management service provider. The data has multiple characteristics, including:

- Representation of measurements captured by devices
- Representation of notes, summaries, and other kinds of narrative information that may be added by caregivers or by the users themselves
- Representation of graphs that may be added by intermediary devices that represent trends of users' health

The PHMR chose a CDA-based format to accommodate the wide variety of data characteristics.

Wherever possible, the PHMR reuses templates already set forth by the HL7 Continuity of Care Document (CCD).

The text for the HL7 Implementation Guide for CDA Release 2.0 Personal Health Monitoring Report, ends here.

2.1.1 COMPONENT CONSTRAINTS

Table 2-1 Component Constraints

Constraint	Constraint Section
No applicable constraints	

2.1.2 COMPONENT DEPENDENCIES

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/C74 Remote Monitoring Observation Document Component	HITSP/C83 CDA Content Modules	General	HITSP/C83 defines basic constraints on content modules
HITSP/C83 CDA Content Modules	HITSP/C80 Clinical Document and Message Terminology	General	Vocabulary constraints on content modules defined in HITSP/C83



2.2 RULES FOR IMPLEMENTING

2.2.1 DATA MAPPING

Implementations shall support the “Implementation Guide for CDA Release 2.0 Personal Health Monitoring Report (PHMR) (International Realm) Draft Standard for Trial Use Release 1” and the HITSP constraints defined in Table 2-3.

Table 2-3 Content Modules

Content Module	HITSP Optional Entry ¹	HITSP Repeatable Entry ²	Specification Reference ³
Medical Equipment	R	N	See HITSP/C83 Section 2.2.1.28 Medical Equipment
Medications	O	N	See HITSP/C83 Section 2.2.1.12 Medications
Person Information	R	N	See HITSP/C83 Section 2.2.2.1 Personal Information
Purpose	O	N	See Section 3.4.1 of HL7 PHMR Implementation Guide
Results	C[101] ⁴	N	See HITSP/C83 Section 2.2.1.22 Diagnostic Results Section
Vital Signs	C[101]	N	See HITSP/C83 Section 2.2.1.19 Vital Signs

2.2.2 DATA ELEMENT CONSTRAINTS

The following table represents additional constraints applied to data elements defined in the PHMR Implementation Guide.

Table 2-4 Data Element Constraints

Constraint ID	Constraint
C74-[1]	The CDA document SHALL include a /ClinicalDocument/informationRecipient element
C74-[2]	The CDA document SHALL include a /ClinicalDocument/author/assignedAuthor/representedOrganization element
C74-[3]	The CDA document SHOULD identify the originating device in the /ClinicalDocument/author/assignedAuthor/assignedAuthoringDevice element
C74-[4]	The CDA document SHOULD use local coding for device data that do not have identified either MDC or SNOMED CT code
C74-[5]	The CDA document shall conform to the Health Level Seven (HL7) Implementation Guide for CDA Release 2.0 Personal Health Monitoring Report (PHMR) DSTU Release 1

2.3 STANDARDS

2.3.1 REGULATORY GUIDANCE

Table 2-5 Regulatory Guidance

Regulation	Description
No applicable regulatory guidance	

¹ Optionality = “R” for Required, “R2” for Required if Known or “O” for Optional, or “C” for Conditional. Repeatable = “Y” for Yes, “N” for No.

² Optionality = “R” for Required, “R2” for Required if Known or “O” for Optional, or “C” for Conditional. Repeatable = “Y” for Yes, “N” for No.

³ Optionality = “R” for Required, “R2” for Required if Known or “O” for Optional, or “C” for Conditional. Repeatable = “Y” for Yes, “N” for No.

⁴ C[101] - Either Vital Signs and/or Results shall be present



2.3.2 SELECTED STANDARDS

Table 2-6 Selected Standards

Standard	Description
Health Level Seven (HL7) Implementation Guide for CDA Release 2.0 Personal Health Monitoring Report (PHMR) DSTU Release 1	This HL7 profile on the use of CDA R2 has been developed within the HL7 community to define an exchange document in support of the remote health monitoring Use Case. The profile is provisionally selected pending a successful balloting within the HL7 community. The PHMR is a document that carries personal healthcare monitoring data. The data is transmitted either in the form of a summary or as raw data. The summary may be a result of analysis by a disease management service provider. For more information visit www.hl7.org
ISO/IEEE 11073-10101 Health informatics - Point-of-care Medical Device Communication – Nomenclature	<p>Within the context of the ISO/IEEE 11073 family of standards for point-of-care (POC) medical device communication (MCD), this standard provides the nomenclature that supports both the domain information model and service model components of the standards family, as well as the semantic content exchanged with medical devices. The nomenclature is specialized for patient vital signs information representation and medical device informatics, with major areas including concepts for electrocardiograph (ECG), haemodynamics, respiration, blood gas, urine, fluid-related metrics, and neurology, as well as specialized units of measurement, general device events, alarms, and body sites. The standard defines both the architecture and major components of the nomenclature, along with extensive definitions for each conceptual area. Device specific information is defined in:</p> <ul style="list-style-type: none"> • IEEE 11073-10404 - Health Informatics Personal Health Device Communication Device Specialization Pulse Oximeter • IEEE 11073-10407 - Health Informatics Personal Health Device Communication Device Specialization Blood Pressure Monitor • IEEE 11073-10408 - Health Informatics Personal Health Device Communication Device Specialization Thermometer • IEEE 11073-10415 - Health Informatics Personal Health Device Communication Device Specialization Weighing Scale. • IEEE 11073-10417 - Health Informatics Personal Health Device Communication Device Specialization Glucose Meter <p>For more information visit standards.ieee.org</p>

2.3.3 INFORMATIVE REFERENCE STANDARDS

Table 2-7 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
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



3.0 APPENDIX

The following sections include relevant materials referenced throughout this document.

No additional information at this time.



4.0 DOCUMENT UPDATES

The following sections provide the details of updates made to this document.

4.1 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).

5713

4.1.1 GLOBAL

The following changes were applied through-out the document for consistency with the HITSP suite of Interoperability Specifications:

- Removed references to Continua as this specification points to IHE PHMR

4.1.2 SECTION 2.1.2 COMPONENT DEPENDENCIES

- Added component dependencies to table

4.1.3 SECTION 2.2.1 DATA MAPPING

- Added Table 2-3 Content Modules
- Modified text to introduce the table

4.1.4 SECTION 2.2.2 DATA ELEMENT CONSTRAINTS

- Added constraint C74-[5] to conform to HL7 PHMR

4.1.5 SECTION 2.3.2 SELECTED STANDARDS

- Corrected reference to Health Level Seven (HL7) Implementation Guide for CDA Release 2.0 Personal Health Monitoring Report (PHMR) DSTU Release 1

4.2 DECEMBER 18, 2008

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

4.3 JUNE 30, 2009

Minor editorial changes were made to this document. Boilerplate text was removed for simplification. The term “actor” was replaced with “interface”.

4.4 JULY 8, 2009

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

