nehta

Common Conformance Profile for Clinical Documents

Version 1.3 - 17 May 2012

Approved for Release

National E-Health Transition Authority Ltd
Level 25
56 Pitt Street
Sydney, NSW, 2000
Australia.
www.nehta.gov.au

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Document information

Version	Date	Comments
0.1	04 Nov 2011	First draft – For structure comments only
0.2	11 Nov 2011	Updated to recognise point-2-share and point-2-point clinical documents
0.3	15 Nov 2011	Added SHS, eDischarge, eReferral, Specialist Letter Added "Ongoing validity of conformance" section
0.4	15 Nov 2011	Updated Extensibility conformance for clinical documents
0.5	24 Nov 2011	Removed all Clinical Documents - now appear in separate documents Added "UC.PCEHR.168 - Withdraw Clinical Document Pending Authorisation for Amendment" use case Removed "Ongoing validity of conformance" section
1.0	28 Nov 2011	Final Version
1.1	7 Mar 2012	See Change Log in Appendix B
1.2	19 Mar 2012	See Change Log in Appendix B
1.3	17 May 2012	See Change Log in Appendix B

1 Introduction

1.1 Purpose

This document summarises the common requirements for producers and consumers of Clinical Documents. Producers typically author Clinical Documents and create CDA conformant content for distribution to consumers. Consumers typically obtain Clinical Documents from Producers and provide the content for consumption.

This document does not list the requirements for the distribution of Clinical Documents between Producers and Consumers. There are a number of mechanisms to achieve this, such as directly between Healthcare Providers and/or via local and national shared repositories, such as the PCEHR System.

This document lists the common conformance requirements for Clinical Documents which include any requirements for Healthcare Identifiers and Clinical Terminology used in Clinical Documents.

1.2 Scope

The scope of this Conformance Profile is the production and consumption of Clinical Documents.

Clinical Document types include, but are not limited to:

- Documents sent from one healthcare provider to another, i.e. sent point-to-point (P2P):
  - Discharge Summary
  - Electronic Referral
  - Specialist Letter
- Documents created specifically for the PCEHR System:
  - Shared Health Summary
  - Event Summary
  - Consumer Entered Notes
  - Consumer Entered Health Summary
  - Advance Care Directive Custodian Record
- Documents for the electronic transfer of prescriptions:
  - Electronic Prescription
  - Dispense Record
  - Prescription Request
- Documents produced by the Department of Human Services – Medicare:
  - Medicare/DVA Benefits Report
  - Australian Childhood Immunisation Register
  - Australian Organ Donor Register
  - Pharmaceutical Benefits Report.

1.3 Intended audience

The intended audience includes the following organisations:

- Healthcare Providers;

- Vendors and developers of eHealth systems; and
- Software test laboratories.

1.4 Contact details

Any comments or feedback should be sent to NEHTA at: nehtasupport@nehta.gov.au.

2 Abbreviations and Terminology

AMT	Australian Medicines Terminology
CDA	Clinical Document Architecture; an XML-based markup standard intended to specify the encoding, structure and semantics of clinical documents exchanged between health software systems.
Conformance	Conformance is a measurement (by testing) of the adherence of an implementation to a specification or standard.
HI	Healthcare Identifier: an identifier assigned to a healthcare provider (individual or organisation) or a healthcare recipient.
HL7	Healthcare Level 7.
May	This verb may when appearing in a conformance requirement indicates an optional requirement.
P2P	Point-to-point. That is, documents sent from one healthcare provider to another healthcare provider.
PCEHR	Personally Controlled Electronic Health Record
Shall	This verb **shall** when appearing in a conformance requirement indicates a mandatory requirement. Its negative form **shall not** indicates a prohibition
Should	The verb **should** when appearing in a conformance requirement indicates a recommendation. Its negative form **should not** indicate an option that should not be supported.
SNOMED CT-AU	Systematized Nomenclature of Medicine Clinical Terms – Australia.

3 Common Conformance Requirements

3.1 Introduction

Due to the similarity in structure, content and processes related to Clinical Documents, a number of common conformance requirements are outlined in this section which applies to all Clinical Documents.

Differences and additional requirements that are specific to a particular Clinical Document type are expressed in separate Clinical Document Conformance Profiles.

The Common Conformance Requirements together with each Clinical Document Conformance Profile are required to ensure all the conformance requirements are addressed for each Clinical Document.

3.2 Objects of Conformance

The Conformance Profile for Clinical Documents applies to the objects described in Table 3.1.

Object of conformance	Examples/Description
Producer	eHealth software that creates a Clinical Document intended for distribution to Consumers (directly and/or via shared repositories)
Consumer	eHealth software that receives a Clinical Document from a Producer (directly and/or via shared repositories).

Table 3.1: Objects of Conformance

The two Producer and Consumer roles for Clinical Documents may have different behavioural requirements when undertaken in certain eHealth contexts. These differences, if any, will be documented in the separate Clinical Document Conformance Profiles.

3.3 Relevant Specifications

The specifications listed in Table 3.2 provide the common software conformance requirements that support the behaviour of Clinical Documents.

Specification	Notes
Use of healthcare identifiers in health software systems [NEHTA2011a]	The requirements for the management and use of national healthcare identifiers.
Requirements for the use of Australian Medicines Terminology [NEHTA2011b]	The requirements for the use of Australian Medicines Terminology including requirements for mapping propriety terminology sets to AMT.
Requirements for the use of SNOMED CT-AU [NEHTA2011c]	The requirements for the use of SNOMED CT-AU including requirements for mapping propriety terminology sets to SNOMED CT-AU.

Table 3.2: Requirement Specifications for Clinical Documents

The specifications listed in Table 3.3 provide the common use cases that support the behaviour of Clinical Documents.

Specification	Notes
Healthcare Identifiers use cases [NEHTA2011a]	The use cases for the management and use of national healthcare identifiers.

Table 3.3: Use Case Specifications for Clinical Documents

3.4 Common Conformance Requirements for Producers

3.4.1 Conformance Levels

3.4.1.1 CDA-based Specification

Each Clinical Document CDA Implementation Guide (CDA IG) specifies how to implement the Clinical Document in an XML format in accordance to the HL7 clinical document architecture.

The overall structure of a CDA-based Clinical Document includes a Header and a Body. The Header is mandatory for all Clinical Documents and:

1. The format **shall** be XML; and
2. All mandatory elements **shall** be present; and
3. All logical Header elements coded in the Body **shall** be present; and
4. Each section's encoded content **shall** support the specified terminology in the "Vocab" column of the CDA IGs;

In addition to the CDA Header, a number of levels of CDA conformance are defined for clinical documents in Table 3.4 (that apply to the CDA Body, not including logical header components). The appropriate conformance levels and other requirements that apply to each Clinical Document type are specified in the separate Clinical Document Conformance Profiles.

CDA Level	Minimum Conformance Requirements	CDA IG Guide
1A	With level 1A conformance a clinical document **shall** consist of: i. A CDA body in XML format; and ii. A CDA body that only includes attachment references in the narrative block.	The body **shall** contain one section <section> with a section label <title> and a narrative block <text>. The narrative block **shall** contain only <renderMultimedia> elements which reference attachments contained in <observationMedia> entry elements which are contained in the same section. The <observationMedia> element **shall** only reference local attachments that are part of the same CDA package. The attachment **shall** be any of the approved file types (e.g. Adobe PDF format). Multiple attachments **shall** be different formats of the same document.

1B	With level 1B conformance a clinical document **shall** consist of: i. A CDA body in XML format; and ii. A CDA body that includes at least one section which contains a narrative block.	The body **shall** contain at least one section <section> with a section label <title> and a narrative block <text>. The narrative block **shall** contain human-readable markup content.
2	With level 2 conformance a clinical document **shall** consist of: i. A CDA header in XML format; ii. A CDA body in XML format; iii. A CDA body that contains mandatory sections; and iv. Mandatory sections, each containing a section label and a narrative block.	The body **shall** contain all sections which contain mandatory data elements (represented as narrative) as specified in the CDA IGs. Each mandatory section in the body **shall** contain all mandatory elements specified as "CDA Body Level 2 Data Elements" in the CDA IGs.
3A	With level 3A conformance a clinical document **shall** consist of: i. A CDA header in XML format; ii. A CDA body in XML format; iii. A CDA body that contains mandatory sections; iv. Mandatory sections, each containing a section label, a narrative block and encoded content for mandatory elements.	Requirements are the same as Level 2. In addition, each section in the body **shall** contain all mandatory elements specified as "CDA Body Level 3 Data Elements" in the CDA IGs.
3B	With level 3B conformance a clinical document **shall** consist of: i. A CDA header in XML format; and ii. A CDA body in XML format; and iii. A CDA body that contains mandatory sections; iv. Mandatory sections, each containing a section label, a narrative block and encoded content for mandatory elements; and v. Specified terminologies.	Requirements are the same as Level 3A. In addition, each section's encoded content **shall** use the Clinical Terminology (e.g. AMT and SNOMED CT-AU) and codes from the Pharmaceutical Benefits Schedule and the Medicare Benefits Schedule if specified in "Vocab" column of the CDA IGs.

Table 3.4: Levels of CDA Conformance

3.4.1.2 CDA Extensibility

The specifications for Clinical Documents define the minimum set of data elements that are to be supported in the Clinical Documents. Producers **may** also:

1. Include additional data elements in a Clinical Document which **shall not** qualify or negate any of the data elements defined in the CDA implementation guides.

If the Producer includes additional elements, they **shall** be aware that:

2. The Consumer is not obliged to interpret or take any action with regard to these elements defined in addition to those identified in the normative specifications.

3.4.1.3 CDA Limitations

In some eHealth contexts, additional requirements may be applied for CDA conformance levels. For example, the attachments to a Clinical Document may be restricted to a defined set of file types and/or file size limits.

Any such limitations will be defined in the separate Clinical Document Conformance Profiles.

3.4.2 Clinical Terminology

The common Clinical Terminology requirements for Clinical Documents include:

1. Clinical Document producers that insert AMT terminology into a Clinical Document **shall** conform to the AMT requirements [NEHTA2011b] regardless of the level of conformance of the producer's clinical documents.
2. Clinical Document producers that insert SNOMED CT-AU terminology into a Clinical Document **shall** conform to the SNOMED CT-AU requirements [NEHTA2011c] regardless of the level of conformance of the producer's clinical documents.

3.4.3 Clinical Document Authoring Requirements

The common Clinical Document Authoring requirements include:

1. Clinical Document Producers **shall** conform to the authoring requirements from the CDA Rendering Specification [NEHTA2012a] for the creation of the Clinical Document.
2. If the Producer has included any valid additional elements (beyond the normative CDA IG specification, but consistent with the HL7 CDA, Release 2.0 data elements [HL72005]), they **shall** be aware that the Consumer is not be obliged to interpret or take any action with regard to these elements.

Note that some of the conformance requirements in the CDA Rendering Specification that are stated to be mandatory are in fact mandatory within a specific context. If that context does not apply then the requirement does not apply. For example:

- *Mandatory requirements that apply to automatically generated narratives do not apply to software that does not automatically generate narratives.*
- *Some mandatory requirements that apply to a document body do not apply to software that generates clinical documents with an attachment rather than data in the document body.*

3.5 Conformance Requirements for Consumers

3.5.1 Clinical Document Rendering Requirements

The common Clinical Document Rendering requirements include:

1. Clinical Document consumers **shall** conform to the rendering requirements from the CDA Rendering Specification [NEHTA2012a] for the display of the Clinical Document.
2. The Consumer **shall** have the capability to render all CDA Levels of Clinical Documents.
3. If the Producer has included any valid additional elements (beyond the normative CDA IG specification, but consistent with the HL7 CDA, Release 2.0 data elements [HL72005]), then the Consumer **shall** render these elements. The Consumer **shall not** be obliged to interpret or take any action with regard to these additional elements.

3.6 Guidance on Data Element Cardinalities

This section provides guidance on the support of data elements in health software which may be a Clinical Document producer or consumer. Developers of health software should note that this is guidance and not a conformance requirement.

Each data element and data group in a CDA Implementation Guide and Structured Content Specification are attributed a cardinality that falls under one of the following categories:

- Optional data elements - "0..1" or "0..Many" (also notated as "0..*"); or
- Mandatory data elements – "1..1" or "1..*".

Mandatory data elements are the minimum set of data elements that an implementation under test is expected to source or maintain and include when generating a clinical document.

Optional data elements are optional for inclusion in a clinical document if such elements are not required to be present in the clinical document at the time of creation. For example, in some clinical circumstances, it is not required that a clinical document contains diagnostic investigations. Therefore, optional elements or data groups refer to those elements or data groups, with cardinality "0..1" or "0..*", as being optional for the user or operator to include. In some cases these are mandatory for support by health software, which may be a Clinical Document producer or consumer.

Those elements which are mandatory for health software to support (i.e. must be capable of collecting and transferring and receiving the data elements) are those defined in the information requirements specification. Not all data elements are required to be displayed to users, and their labels may be different from those data elements used in the information requirements specification. Not all data elements require a value in each and every clinical document (e.g. items that are categorised with "0..1" or "0..*").

4 Common PCEHR Conformance Requirements

4.1 Introduction

Due to the similarity in structure, content and processes related to exchanging Clinical Documents with the PCEHR System, common conformance requirements are listed in this section which applies to all Clinical Documents sent to, and retrieved from, the PCEHR System. These conformance requirements are additional to the common conformance requirements in Section 3. That is, the common conformance requirements in Section 3 also apply to the exchange of clinical documents with the PCEHR System.

Differences and additional requirements that are specific to a particular Clinical Document type are expressed in separate PCEHR Clinical Document Conformance Profiles.

The Common Conformance Requirements together with each Clinical Document Conformance Profile are required to ensure all the conformance requirements are addressed for each type of Clinical Document.

4.2 Objects of Conformance

The Common PCEHR Conformance Requirements apply to the additional objects described in Table 4.1.

Object of conformance	Examples/Description
Clinical Information System (CIS)	An information system used in a clinical context to manage a wide range of clinical information functions that connects to the PCEHR System.
Registered Consumer Portal	A third-party[1] portal used by healthcare recipients to access information on the PCEHR System.
Registered Provider Portal	A third-party[1] portal used by healthcare providers to access information on the PCEHR System.
Registered Repository	A third-party[1] repository used to store Clinical Documents and other clinical data that connects to the PCEHR System.

Table 4.1: Objects of Conformance

4.3 Relevant Specifications

The specifications listed in 4.2 provide the common use cases that support the behaviour of Clinical Documents exchanged with the PCEHR System.

Specification	Notes
Use cases for a CIS connecting to the PCEHR System [NEHTA2011b]	The use cases for the uploading, downloading and removal of Clinical Documents from the PCEHR System, by Clinical Information Systems.

[1] Third-party refers to a software system developed independently of the national PCEHR System and intended to connect to the national PCEHR System.

Specification	Notes
Use cases for a Consumer Portal connecting to the PCEHR System [NEHTA2011c]	The use cases for the uploading, downloading and removal of Clinical Documents from the PCEHR System, by Registered Consumer Portals.

Table 4.2: PCEHR Use Case Specifications

Note: use cases applying to Registered Provider Portals and Registered Repositories are under development and will be referenced in a later version of this document.

4.4 Common Conformance Requirements for Producers

4.4.1 CDA Limitations

The Clinical Document's CDA Limitations requirements include:

1. The MIME types to be supported as attachments of Clinical Documents **shall** be as follows:
   a. .gif image/gif
   b. .jpg image/jpeg
   c. .jpeg image/jpeg
   d. .pdf application/pdf
   e. .png image/png
   f. .tif image/tiff
   g. .tiff image/tiff
2. Other MIME types **shall not** be supported.
3. The size of the attachment **shall not** be greater than 10MB.

Appendix A: References

This appendix lists documents that provide information for or about this document. At the time of publication, the document versions listed below were valid. However, as all documents are subject to revision, readers are encouraged to use the most recent versions of these documents.

[HL72005]	Clinical Document Architecture, Release 2. ISO/HL7 27932:2008, 21 Apr 2005
[NEHTA2011a]	Use of Healthcare Identifiers in Health Software Systems, Business Use Cases, Version 2.2, NEHTA, 15 December 2011
[NEHTA2011b]	Australian Medicines Terminology conformity requirements, NEHTA, Version 1.0, 26 September 2011
[NEHTA2011c]	SNOMED CT-AU conformity requirements, NEHTA, NEHTA, Version 0.5, 18 Nov 2011
[NEHTA2011d]	Use of Healthcare Identifiers in Health Software Systems, Software Conformance Requirements, Version 1.4, NEHTA, 3 May 2011
[NEHTA2012a]	CDA Rendering Specification: Clinical Documentation, NEHTA, Version 1.0, 7 March 2012
[NEHTA2012b]	Clinical Information Systems Connecting to the PCEHR System: Use Cases, NEHTA, 2012
[NEHTA2012c]	Consumer Portals Connecting to the PCEHR System: Use Cases, NEHTA, 2012

Appendix B: Change Log

This appendix lists the major changes and fixes applied to this Document.

	Section	Change Detail	Rationale
1	1.1	Updated Purpose to remove PCEHR specific focus	To support a wider range of clinical document contexts for use of this conformance profile
2	3.2	Updated Table 3.1 to remove PCEHR specific focus	As per ID#1
3	3.4.1	Updated Table 3.4 to refer to new HI use case	New HI use case more relevant
4	3.4.3.1	Updated Table 3.5 with more details of the CDA Levels in relation to the CDA IGs	Greater clarity of the CDA Levels
5	3.4.3.2	Added additional information support CDA extensibility for all clinical documents and other expectations	As per ID#1
6	3.4.3.3	Added new section for any additional requirements for CDA content	As per ID#1
7	3.4.5	Added new section to explicitly refer to the Authoring requirements	As per ID#1
8	3.5.1	Updated Table 3.6 to refer to new HI use cases	New HI use cases more relevant
9	3.5.2	Added new section to explicitly refer to the Rendering requirements	As per ID#1

Changes from Version 1.05 (28 Nov 2011) to Version 1.1 (7 Mar 2012)

	Section	Change Detail	Rationale
1	All	An error in converting the file format MS Word to Adobe PDF affected the appearance of some items in version 1.1. This particularly affected table 3.5 which appeared twice. The format conversion error has been fixed.	No material changes were made to the document.

Changes from Version 1.1 (7 Mar 2012) to Version 1.2 (19 Mar 2012)

ID	Section	Change Detail	Rationale
1	1.2	The list of document types was revised	More document types are now specified and supported.
2	2	The table of terminology was updated.	More terms are now defined.

ID	Section	Change Detail	Rationale
3	3.4.1 & 3.5.1	Sections on healthcare identifiers use case were deleted.	The relevant conformance assessment scheme will be used to list the HI use cases that must be supported.
4	3.4.2	The definition of level 3B was updated.	Level 3B now includes use of PBS and MBS codes when specified in the CDA IGs.
5	3.4.2.2	The extensibility requirement on modified.	The change reflects the agreement on extensibility.
6	3.4.3	The first requirement was deleted.	The definition of level 3B is included earlier in the document.
7	3.4.4	The second point was replaced with an explanatory note.	The explanatory note provides an more detailed description.
8	3.6	The new section 3.6 was added.	This provides guidance on how to support data elements that are optional in the CDA IGs but required by the information model stated in the Core Information Components specifications.
9	4.4.1 & 4.5.1	Sections on PCEHR CIS and consumer portal use case were deleted.	The relevant conformance assessment scheme will be used to list the use cases that must be supported.
10	4.4.2	The list of allowed attachment types was updated.	The list is now consistent with the list supported by the PCEHR System.
11	4	The new section 4 was added.	Common PCEHR conformance requirements have been moved from the PCEHR conformance profiles to this document, in section 4.
12	all	Presentation improvements have been made and typing errors corrected.	

Changes from Version 1.2 (19 Mar 2012) to Version 1.3 (17 May 2012)