nehta

PCEHR Conformance Profile for Shared Health Summary Clinical Documents

Version 1.4 - 3 August 2012

Approved for Release

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Document information

Version	Date	Comments
0.5	24 Nov 2011	First draft (as separate document)
1.0	28 Nov 2011	Published version
1.05	29 Nov 2011	Updated to only allow creation by CIS
1.06	22 Dec 2011	Clarification on extensibility was added
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
1.4	03 Aug 2012	See Change Log in Appendix B

1 Introduction

1.1 Purpose

This document summarises the requirements for producers and consumers of the Shared Health Summary Clinical Document that connect to the National PCEHR System.

This document lists the specific conformance requirements for the Shared Health Summary Clinical Document that are in addition to the Common Conformance Profile for Clinical Documents [NEHTA2012b]. Both documents represent the complete conformance requirements for the Shared Health Summary Clinical Document.

1.2 Scope

The scope of this Conformance Profile is the use of Shared Health Summary Clinical Documents in the context of the National PCEHR System, that is, in a "point-to-share" environment.

1.3 Intended audience

The intended audience includes the following organisations:

- Healthcare Providers;
- Vendors and developers of connecting systems; and
- Software test laboratories.

1.4 Contact details

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

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Abbreviations and 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.		
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 National PCEHR System		
Conformance	Conformance is a measurement (by testing) of the adherence of an implementation to a specification or standard.		
HL7	Healthcare Level 7		
PCEHR	Personally controlled electronic health record.		
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.		
Мау	This verb may when appearing in a conformance requirement indicates an optional requirement.		
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 indicates an option that should not be supported.		

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

3 Shared Health Summary

3.1.1 Introduction

This section describes the conformance requirements specific to the Shared Health Summary Clinical Document type when it is used in a point-to-share communication with the National PCEHR System.

3.1.2 Relevant Specifications

The detailed conformance requirements are listed in Table 3.1.

Specification	Notes
Shared Health Summary structured content specification [NEHTA2011]	Specifies the data elements and constrained values for a clinical document at a logical level.
Shared Health Summary CDA implementation guide [NEHTA2012a]	Specifies the mapping from the structured content specification into a clinical document using an HL7 CDA structure.

Table 3.1	Specifications	for Shared	Health	Summary
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3.1.3 Conformance Requirements for Producers

3.1.3.1 Objects of Conformance

The Objects of Conformance requirements include:

- 1. Shared Health Summary clinical documents **may** be produced by:
 - Clinical Information Systems (CIS).
- 2. Shared Health Summary clinical documents **shall not** be produced by:
 - Registered Consumer Portals;
 - Registered Provider Portals; and
 - Registered Repositories.

3.1.3.2 Superseding a Shared Health Summary

A Shared Health Summary **shall** be uploaded to the PCEHR System as a new clinical document and **shall not** be uploaded as a new version to supersede a previously uploaded version.

The Common Conformance Profile for Clinical Documents [NEHTA2012b] lists the use cases that a CIS Producer must support. UC.CIS.202 'Supersede a Clinical Document' is not relevant for Shared Health Summary as the PCEHR System does not allow a Shared Health Summary to be superseded.

The PCEHR System regards only the most recently uploaded Shared Health Summary in a PCEHR record as the only active Shared Health Summary for that record. Any previously uploaded Shared Health Summaries are treated as historical versions. Therefore the CIS is to upload Shared Health Summaries to the PCEHR System always as a new document.

3.1.3.3 Conformance Levels

The minimum level of CDA Conformance for Shared Health Summary clinical document **shall** be CDA Level 3A [NEHTA2012b].

3.1.3.4 Clinical Document Authoring Requirements

The CDA Rendering Specification [NEHTA2012c] contains authoring requirements that apply to general clinical document types. However specific authoring requirements apply to Shared Health Summary clinical documents as they are used by the PCEHR System to create the overview of a person's healthcare.

For Shared health Summaries, requirement CDA-RS 3 in the CDA Rendering Specification [NEHTA2012c] is replaced with the following attestation requirement:

A Clinical Information System **shall** display the final version of a Shared Health Summary to the author and prompt the author to attest to the content of the Shared Health Summary before the Clinical Information System uploads the Shared Health Summary to the PCEHR System and to assert the healthcare provider individual (i.e. the author of the Shared Health Summary) is a Nominated Healthcare Provider as defined by the Personally Controlled Electronic Health Records Act 2012.

Notes:

- One option for meeting this requirement is for a Clinical Information System to display the Shared Health Summary along with a user interface button with the statement "By uploading this Shared Health Summary, I acknowledge that I am a Nominated Healthcare Provider for this patient as defined by the Personally Controlled Electronic Health Records Act 2012", with the name of the Act in italics (including the year)
- 3.1.3.5 Digital Signature

Shared Health Summary clinical documents **shall** be digitally signed by the supplying healthcare provider organisation using the healthcare provider organisation's digital credential.

3.1.4 Conformance Requirements for Consumers

3.1.4.1 Objects of Conformance

The Objects of Conformance requirements include:

- 1. Shared Health Summary clinical documents **shall** be consumed by:
 - Clinical Information Systems;
 - Registered Consumer Portals; and
 - Registered Provider Portals.
- 2. Shared Health Summary clinical documents **shall not** be consumed by:
 - Registered Repositories.

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.

Shared Health Summary Structured Content Specification, Version 1.1, NEHTA, 30 Nov 2011
Shared Health Summary CDA Implementation Guide, NEHTA, Version 1.3, 7 Mar 2012
Common Conformance Profile for Clinical Documents, Version 1.3, NEHTA, 17 May 2012
CDA Rendering Specification – Clinical Documentation, NEHTA, Version 1.0, 2 March 2012
Personally Controlled Electronic Health Records Act 2012, http://www.comlaw.gov.au/Details/C2012A00063

Appendix B: Change Log

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

ID	Section	Change Detail	Rationale
1	3.1.2	Added Objects of Conformance specific to the PCEHR context	Support requirements to constrain Clinical Documents to specific PCEHR connecting systems
2	3.1.4.1	Added new section to constrain clinical document to certain PCEHR conformance contexts	See ID#1
3	3.1.4.2	Added new section to include reference to mandatory Clinical Document use cases	Required to support end-system behaviour conformance
4	3.1.4.4	Added new section to includes reference to approves attachment types and file size limit	To support PCEHR requirements
5	3.1.5.1	Added new section to constrain clinical document to certain PCEHR conformance contexts	See ID#1
6	3.1.5.2	Added new section to include reference to mandatory Clinical Document use cases	Required to support end-system behaviour conformance

Changes from Version 1.06 (28 Nov 2011) to Version 1.1 (7 Mar 2012)

ID	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. 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	2 and 3.1.2	The types of systems able to connect to the PCEHR System were added to section 2 and removed from section 3.1.2.	This allowed requirements to be included for each type of connecting system.
2	3.1.3.2	The section on superseding a shared health summary was added.	A shared health summary cannot be superseded. This needed to be stated.
3	3.1.3.4	An authoring requirement was added.	An authoring requirement applies to a shared health summary that does not apply to other document types.

4	3.1.3.5	This section was added.	This reflects the PCEHR requirements for signing documents.
5	3.1.4.2 and 3.1.5.2	The references to PCEHR CIS business use cases were deleted.	These are now included in the Common Conformance Profile for Clinical Documents.
6	3.1.4.4	The CDA limitations section was deleted.	This is now included in the Common Conformance Profile for Clinical Documents.

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

ID	Section	Change Detail	Rationale
1	3.1.3.4	The Shared Health Summary attestation requirement was modified.	This mitigates the risk to a provider of breaching the PCEHR legislation requiring a document author to be a nominated healthcare provider. This will help to ensure that the Shared Health Summary is authored by appropriately qualified practitioners.
2	Арр А	Appendix A was updated to refer to the PCEHR Act.	Information provided with the modified attestation Shared Health Summary requirement includes this reference.

Changes from Version 1.3 (17 May 2012) to Version 1.4 (03 Aug 2012)