PCEHR Conformance Profile for Shared Health Summary Clinical Documents

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Approved for external use

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Document information

Key information

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Version history

Version	Date	Comments
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 A
1.2	19 Mar 2012	See Change Log in Appendix A
1.3	17 May 2012	See Change Log in Appendix A
1.4	03 Aug 2012	See Change Log in Appendix A
1.5	9 Oct 2013	See Change Log in Appendix A

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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* [NEHTA2013]. These 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.

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: help@nehta.gov.au.

2 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 document	A digital file containing personal health information about an individual, containing unstructured (narrative) information and optionally structured (atomic) information.
clinical information system (CIS)	A system that deals with the collection, storage, retrieval, communication, and use of health related data, information and knowledge pertaining to subjects of care [AS5021]. The system may comprise one or more applications or components.
conformance	A measurement (by testing) of the adherence of an implementation to a specification or standard.
consumer	In this document 'Consumer' refers to a software system that has the role of being a consumer of Shared Health Summaries.
contracted service provider (CSP)	An entity that may offer health software as a service, and support access to the PCEHR system on behalf of healthcare organisations. A CSP provides under a contract with the healthcare provider organisation: a) information technology services relating to the PCEHR system; or b) health information management services relating the PCEHR system. (Section 5 *PCEHR Act 2012*.)
CSP	contracted service provider
CSP system	A software system operated by a CSP that deals information and knowledge pertaining to subjects of care [AS5021]. The system may comprise one or more applications or components. A CSP system may perform some or all of the functions of a CIS.
healthcare consumer	A person who is the subject of care. (For the software system, see 'Consumer'.)
HL7	Health Level 7
MAY	When appearing in a conformance requirement, the verb **MAY** indicates an optional requirement.
nominated healthcare provider	See the *PCEHR Act 2012* [COM2012] for the definition of 'nominated healthcare provider'. One requirement for a nominated healthcare provider is to be a medical practitioner, a registered nurse or an Aboriginal and/or Torres Strait Islander health practitioner.
PCEHR	personally controlled electronic health record
Producer	In this document 'Producer' refers to a software system that creates shared health summaries.
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. A repository may store clinical documents in a proprietary format or a CDA

[1] Third-party refers to a software system developed independently of the national PCEHR System and intended to connect to the national PCEHR System. The portals provided the national PCEHR System are not Registered Consumer or Registered Provider Portals.

	format.
SHALL	When appearing in a conformance requirement, the verb **SHALL** indicates a mandatory requirement. Its negative form **SHALL NOT** indicates a prohibition.
SHOULD	When appearing in a conformance requirement, the verb **SHOULD** indicates a recommendation. Its negative form **SHOULD NOT** indicates an option that is not recommended.

3 Conformance requirements for Shared Health Summary

3.1 Introduction

This section describes the conformance requirements specific to the Shared Health Summary clinical document type when it is used in communication with the national PCEHR system.

3.2 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 1: Specifications for Shared Health Summary

3.3 Conformance requirements for Producers

3.3.1 Objects of conformance

The objects of conformance are subject to the following requirements:

1. Shared Health Summary clinical documents **MAY** be produced by:
   - clinical information systems (CIS); and
   - CSP systems.
2. Shared Health Summary clinical documents **SHALL NOT** be produced by:
   - registered consumer portals;
   - registered provider portals; or
   - registered repositories.

3.3.2 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* [NEHTA2013] lists the use cases that a CIS Producer must support. UC.CIS.202 'Supersede a Clinical Document' is not relevant for a 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.

3.3.3 Conformance levels

A Shared Health Summary sent to the PCEHR system **SHALL** conform to the requirements for one, and only one, of the following conformance levels: 3A, or 3B, as defined in the *Common Conformance Profile for Clinical Documents* [NEHTA2013].

3.3.4 Clinical document authoring requirements

CDA Rendering Specification – Clinical Documentation [NEHTA2012b] 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* [NEHTA2012b] is replaced with the following attestation requirement:

1. A Shared Health Summary Producer **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 Shared Health Summary Producer uploads the Shared Health Summary to the PCEHR system and to attest 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:

a. One option for meeting this requirement is for a clinical information system to display the Shared Health Summary along with a user interface button including 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).*

3.3.5 Temporary relaxation of inclusion of HPI-I

The *Shared Health Summary Structured Content Specification* [NEHTA2011] and the *Shared Health CDA Implementation Guide* [NEHTA2012a] contain mandatory conformance requirements for the inclusion of HPI-Is. These specifications state the conformance requirement:

"The value of one Entity Identifier SHALL be an Australian HPI-I"

This applies to the mandatory data element:

- Document Author > Participant > Entity Identifier.

The mandatory requirement for an HPI-I for this data element is temporarily modified.

1. The value of one Document Author > Participant > Entity Identifier **SHALL** be an HPI-I if one is present in the Shared Health Summary Producer, otherwise it **SHALL** have a value that identifies the document author and the value **SHALL NOT** be a NullFlavor.

Notes: a) The Common Conformance Profile for Clinical Documents *[NEHTA2013] provides requirements for the inclusion of a local identifier.*

b) The relaxation is only available to specific healthcare provider organisations, at the discretion of the PCEHR system operator. The relaxation is provided to allow time for large healthcare provider organisations to incorporate HPI-Is for their personnel in their systems.

3.3.6 Restriction on exclusion statements

The *Shared Health Summary Structured Content Specification* [NEHTA2011] lists three allowed values for exclusion statements for *Adverse Reactions*:

- *Medications (Medication Orders)*;
- *Past and Current Medical History (Medical History)*;and
- *Immunisations*.

The values are *not asked*, *none known* and *none supplied*. However the intention of a Shared Health Summary is for the healthcare provider to explicitly determine the *Adverse Reactions*, *Medications*, *Past and Current Medical History* and *Immunisations.* Therefore the allowed values for exclusion statements are restricted here. Furthermore it is expected that where the Shared Health Summary SCS states information or an exclusion statement may be included in a Shared Health Summary, that a Shared Health Summary Producer will allow a user to enter information or an exclusion statement.

1. Any exclusion statement in a Shared Health Summary **SHALL** either have the value *none known* or *none supplied*.
2. Where the Shared Health Summary Structured Content Specification allows an exclusion statement to be provided as an alternative to providing information, a Shared Health Summary Producer **SHALL** allow the user to enter information or select an exclusion statement, but not both, depending on whichever is relevant for an episode of care. The information or exclusion statement entered into the Shared Health Summary Producer **SHALL** be recorded in the Shared Health Summary produced.

3.4 Conformance requirements for Consumers

3.4.1 Objects of conformance

The objects of conformance requirements include:

1. Shared Health Summary clinical documents **MAY** be consumed by:
   - clinical information systems;
   - CSP systems;
   - registered consumer portals;
   - registered provider portals; and
   - registered repositories.

Appendix A: Change log

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

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

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 1.1 (7 Mar 2012) to Version 1.2 (19 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 1.2 (19 Mar 2012) to Version 1.3 (17 May 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.

ID	Section	Change Detail	Rationale
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 1.3 (17 May 2012) to Version 1.4 (03 Aug 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	App A	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 1.4 (03 Aug 2012) to Version 1.5 (9 Oct 2013)

ID	Section	Change Detail	Rationale
1	3.3.5	This section has been added.	The requirement in the Shared Health Summary SCS and CDA IG for mandatory inclusion of an HPI-I has been relaxed.
2	3.3.6	This section has been added.	To include restrictions on the use of exclusion statements.
3		The digital signature requirement was removed	Digital signature requirements are now in the Common Conformance Profile for Clinical Documents
4	App A	References were updated	

References

[AS5021] *AS 5021:2005 - The language of health concept representation*, Standards Australia, 2005.

[COM2012] *Personally Controlled Electronic Health Records Act 2012*, http://www.comlaw.gov.au/Details/C2012A00063

[NEHTA2011] *Shared Health Summary Structured Content Specification*, Version 1.1, NEHTA, 30 Nov 2011http://www.nehta.gov.au/implementation-resources/clinical-documents/EP-1074-2012/NEHTA-0997-2011

[NEHTA2012a] *Shared Health Summary CDA Implementation Guide*, NEHTA, Version 1.3, 7 Mar 2012

http://www.nehta.gov.au/implementation-resources/clinical-documents/EP-1074-2012/NEHTA-0988-2012

[NEHTA2012b] *CDA Rendering Specification – Clinical Documentation*, NEHTA, Version 1.0, 7 March 2012

http://www.nehta.gov.au/implementation-resources/clinical-documents/EP-1094-2011/NEHTA-1199-2012

[NEHTA2013] *Common Conformance Profile for Clinical Documents*, Version 1.4, NEHTA, 2013

http://www.nehta.gov.au/implementation-resources/clinical-documents/EP-1094-2011/NEHTA-1446-2013