PCEHR Conformance Profile for Event Summary Clinical Documents

Version 1.3 - 9 October 2013

Approved for external use

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Key information

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Version history

Version	Date	Comments
1.0	28 Nov 2011	Published version
1.01	21 Dec 2011	Clarification on extensibility was added
1.1	16 Mar 2012	See Change Log in Appendix A
1.2	10 July 2012	See Change Log in Appendix A
1.3	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 Event Summary clinical document that connects to the national PCEHR system.

This document lists the specific conformance requirements for the Event 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 Event Summary Clinical Document.

1.2 Scope

The scope of this conformance profile is the use of Event 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 event 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 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	Healthcare Level 7
MAY	When appearing in a conformance requirement, the verb **MAY** indicates an optional requirement.
PCEHR	Personally Controlled Electronic Health Record.
Producer	In this document 'Producer' refers to a software system that creates Event 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 portal used by healthcare providers to access information on the PCEHR system.
registered repository	A third-party repository used to store clinical documents and other clinical data that connects to the PCEHR system. A repository may either store clinical documents in a proprietary format or a CDA 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.

[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.

3 Conformance requirements for Event Summary

3.1 Introduction

This section describes the conformance requirements specific to the Event 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 1.

Specification	Notes
Event Summary Structured Content Specification [NEHTA2011]	Specifies the data elements and constrained values for a clinical document at a logical level.
Event Summary CDA Implementation Guide [NEHTA2012]	Specifies the mapping from the structured content specification into a clinical document using an HL7 CDA structure.

Table 1 Specifications for event summary

3.3 Conformance requirements for Producers

3.3.1 Objects of conformance

The objects of conformance are subject to the following requirements:

1. Event Summary clinical documents **MAY** be produced by:
   - Clinical information systems; and
   - CSP systems.
2. Event Summary clinical documents **SHALL NOT** be produced by:
   - Registered repositories;
   - Registered consumer portals; or
   - Registered provider portals.

3.3.2 Conformance levels

An Event 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].

3.3.3 Temporary relaxation of inclusion of HPI-I

The *Event Summary Structured Content Specification* [NEHTA2011] and the *Event Summary CDA Implementation Guide* [NEHTA2012] include 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 data elements:

- Document Author > Participant > Entity Identifier; and
- Diagnostic Investigations > Requested Service > Service Provider > Participant > Entity Identifier.

The mandatory requirements for an HPI-I for these data elements are temporarily modified.

1. The value of one Document Author > Participant > Entity Identifier **SHALL** be an HPI-I if one is present in the Event Summary Producer, otherwise it **SHALL** have a value that identifies the document author and the value **SHALL NOT** be a NullFlavor.
2. If Diagnostic Investigations > Requested Service > Service Provider is present in an Event Summary, the value of one Diagnostic Investigations > Requested Service > Service Provider > Participant > Entity Identifier **SHALL** be an HPI-I if one is present in the Event Summary Producer, otherwise it **SHALL** have a value that identifies the diagnostic investigations service provider (person) 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 for a document author.*

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.

3.4 Conformance requirements for consumers

3.4.1 Objects of conformance

The objects of conformance requirements include:

1. Event 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 1.01 (21 Dec 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	3.1.4.3	The minimum conformance level was changed from 3A to 1B.	An event summary containing unstructured text in the document body is acceptable.
5	3.1.4.4	Added new section to includes reference to approves attachment types and file size limit	To support PCEHR requirements
6	3.1.5.1	Added new section to constrain clinical document to certain PCEHR conformance contexts	See ID#1
7	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 (10 July 2012)

ID	Section	Change Detail	Rationale
1	2	The types of systems able to connect to the PCEHR System were added.	This allowed requirements to be included for each type of connecting system.
2	3.1.2	This section was removed	The information was moved to section 2.
3	3.1.3.2	The requirement on the minimum conformance level was updated.	The minimum conformance level is now level 3A.
4	3.1.3.3	This section was added.	This reflects the PCEHR requirements for signing documents.
5	3.1.4.2, 3.1.4.4, 3.1.5.2	These sections were removed	The information is now in the Common Conformance Profile for Clinical Documents

Changes from Version 1.2 (10 July 2012) to Version 1.3 (9 Oct 2013)

ID	Section	Change Detail	Rationale
1	3.3.3	This section has been added.	The requirement in the Event Summary SCS and CDA IG for mandatory inclusion of an HPI-I has been relaxed.
2		The digital signature requirement was removed	Digital signature requirements are now in the Common Conformance Profile for Clinical Documents
3	References	References were updated	

References

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

[NEHTA2011] *Event Summary Structured Content Specification*, Version 1.1, NEHTA, 30 Nov 2011**Error! Hyperlink reference not valid.**

[NEHTA2012] *Summary CDA Implementation Guide*, NEHTA, Version 1.2, 7 Mar 2012, http://www.nehta.gov.au/implementation-resources/clinical-documents/EP-0939-2012/NEHTA-0989-2012

[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