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Event Summary
PCEHR Conformance Profile v1.4

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Key information

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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.
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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* [NEHTA2015c]. 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.

2 Glossary

Term	Meaning
AMT	Australian Medicines Terminology
approver	A person responsible for approving the contents of a clinical document [NEHTA2011a]. The approver cannot be a device or organisation.
atomic attachment	An atomic attachment is a single byte stream. For example, a JPEG image (c.f. the definition of an atomic packaged attachment defined in the *CDA® Package* specification [NEHTA2011a]).
Clinical Document Architecture (CDA®)	An XML-based markup standard intended to specify the encoding, structure and semantics of clinical documents exchanged between health software systems. Specifications for clinical documents are based on *Clinical Document Architecture, Release 2* [HL72005].
CDA® IG	clinical document architecture implementation guide
CIS	clinical information system
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 [SA5021]. 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 clinical documents.
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 to the PCEHR system. (Section 5 *PCEHR Act 2012* [COM2012].)
CSP	contracted service provider
CSP system	A software system operated by a CSP that deals with information pertaining to subjects of care [SA5021]. May comprise one or more applications or components. May perform some or all of the functions of a CIS.
CSP registration number	A number that uniquely identifies a CSP. The number has 16 digits, commences with '800363', and ends with a check digit derived using the Luhn algorithm [ISO7812-1], [NEHTA2014a].
custodian	The custodian of a clinical document is the organisation that is responsible for maintaining the information in the clinical document. The information maintained by the custodian may be in a propriety format, rather than CDA® [HL72005].

Term	Meaning
diagnostic report	A generic term used to describe an eHealth Diagnostic Imaging Report or an eHealth Pathology Report. In a healthcare environment other types of documents may be regarded as diagnostic report but uses other than eHealth Diagnostic Imaging Report or eHealth Pathology Report are out of scope in the context of this conformance profile.
digital signature	Signs the clinical document inside a signed CDA® package. The digital signature is contained within the eSignature.
eSignature	An eSignature is included in a signed CDA® package to attest to the contents of the clinical document (and indirectly its packaged attachments) [NEHTA2011a]. An eSignature contains a digital signature, identifies the approver and signing time so in addition to the attestation it is also a mechanism to prevent forgery and to detect tampering of that assertion, and/or of the data being asserted.
external atomic attachment	An atomic attachment that is external to the CDA® package.
healthcare individual	A person who is the subject of care.
healthcare provider organisation	An enterprise that provides healthcare (including healthcare provided free of charge) [COM2012].
HI	Healthcare identifier: an identifier assigned to a healthcare provider (individual or organisation) or a healthcare recipient.
HL7	HL7 is a trademark of Health Level Seven International.
HPI-I	A national identifier that uniquely identifies a healthcare provider individual. The identifier has 16 digits, commences with '800361' and ends with a check digit derived using the Luhn algorithm [ISO7812-1], [NEHTA2014a].
HPI-O	A national identifier that uniquely identifies a healthcare provider organisation. The identifier has 16 digits, commences with '800362' and ends with a check digit derived using the Luhn algorithm [ISO7812-1], [NEHTA2014a].
IHI	A national identifier that uniquely identifies a healthcare recipient. The identifier has 16 digits, commences with '800360' and ends with a check digit derived using the Luhn algorithm [ISO7812-1], [NEHTA2014a].
legal authenticator	An approver who legally authenticates the accuracy of an act. For example, a staff physician who sees a patient and dictates a note, then signs it [HL72005]. A legal authenticator provides a signature.
MAY	When appearing in a conformance requirement, the verb **MAY** indicates an optional requirement.
NASH	National Authentication Service for Health
OID	object identifier

Term	Meaning
object identifier	An ordered list of primary integer values from the root of the international object identifier tree to a node, which unambiguously identifies that node.
packaged attachment	A packaged attachment is defined as an attachment that is external to the CDA® XML document, included in the same CDA® package as the CDA® XML document, and is referenced appropriately (*CDA® package specification* [NEHTA2011a]).
P2P	Provider-to-provider: documents sent from one healthcare provider to another.
PCEHR	personally controlled electronic health record
PCEHR system	National eHealth infrastructure for managing records in eHealth records. The PCEHR system includes the PCEHR repository, and the national prescription and dispense repository.
PKI	Public-key infrastructure: a set of hardware, software, people, policies, and procedures to create, manage, distribute, use, store, and revoke digital certificates.
PKI certificate	A string that mathematically combines a PKI private key with the content of a message to cryptographically bind the message content to the PKI certificate associated with the private key. The PKI certificates used with clinical documents are NASH PKI certificates [DHS2013].
Producer	In this document 'producer' refers to a software system that has the role of generating and issuing conformant clinical documents suitable for use by other eHealth participants.
registered consumer portal	A third-party portal used by healthcare recipients to access information on the PCEHR system.
registered portal operator	A person who is the operator of an electronic interface that facilitates access to the PCEHR system; and who is registered as a portal operator under section 49 of the *PCEHR Act 2012* [COM2012].
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. May store clinical documents in either a proprietary format or a CDA® format.
registered repository operator	A person who holds, or can hold, records of information included in personally controlled electronic health records for the purposes of the PCEHR system, and who is registered as a repository operator under section 49 of the *PCEHR Act 2012* [COM2012].
request	A request to create a diagnostic report, initiated and generated by a healthcare provider such as a GP or a specialist.
requester	The healthcare provider individual that issued a request.
SCS	structured content specification

Term	Meaning
SHALL	When appearing in a conformance requirement, this 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** indicate an option that should not be supported.
signed CDA® package	A single compressed digital file archive containing a clinical document, optional packaged attachments and one or more eSignatures [NEHTA2011a].
SNOMED CT-AU	Systematized nomenclature of medicine clinical terms – Australia. SNOMED® and SNOMED CT® are registered trademarks of the International Health Terminology Standards Development Organisation.
standing consent	The consent provided by a healthcare individual when they agree to the creation of an eHealth record in the PCEHR system. Standing consent allows any participating healthcare provider to upload health information to a healthcare individual's eHealth record. Standing consent continues to apply unless the healthcare individual explicitly withdraws their consent.
supporting organisation	An organisation that assists in the delivery of healthcare, but is not a healthcare provider organisation. Examples are registered repository operators, and registered portal operators.
supporting organisation registration number	A number that uniquely identifies a supporting organisation. The number has 16 digits, commences with '800364', and ends with a check digit derived using the Luhn algorithm [ISO7812-1], [NEHTA2014a].
third-party	Third-party refers to a software system developed independently of the national PCEHR system and intended to connect to the national PCEHR system.

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 below:

1. *Common Conformance Profile for Clinical Documents* [NEHTA2015c] - provides common Conformance Requirements which must be adhered to unless specifically contradicted in this document.
2. *Event Summary Structured Content Specification* [NEHTA2015a] - Specifies the data elements and constrained values for a clinical document at a logical level.
3. *Event Summary CDA® Implementation Guide* [NEHTA2015b] - Specifies the mapping from the structured content specification into a clinical document using an HL7® CDA® structure.

3.3 Conformance requirements for producers

The objects of conformance are subject to the following requirements:

3.3.1 Objects of conformance

023756 **Systems that MAY produce event summary clinical documents**

Event Summary clinical documents **MAY** be produced by:

- clinical information systems; and
- contracted service provider (CSP) systems.

023757 **Entities that SHALL NOT produce event summary clinical documents**

Event summary clinical documents **SHALL NOT** be produced by:

- registered repositories;
- registered consumer portals; or
- registered provider portals.

3.3.2 Conformance levels

023857 Levels of conformance

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* [NEHTA2015c].

3.3.3 Temporary relaxation of inclusion of HPI-I

The *Event Summary Structured Content Specification* [NEHTA2015a] and the *Event Summary CDA® Implementation Guide* [NEHTA2015b] 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.

Notes:

a) The Common Conformance Profile for Clinical Documents [NEHTA2015c] 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.

023858 Document Author Entity Identifier value

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 NO**T be a nullFlavor.

023859 **Diagnostic Investigations Service Provider Entity Identifier value**

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.

3.3.4 Displaying medicine instructions

In systems that create medicine items, there is a need to ensure appropriate and consistent presentation when these entries are viewed in the PCEHR system, or when downloaded and displayed via other clinical information systems.

The CDA® implementation guides define a "Directions" data element that concatenates dose, frequency and instruction content as part of a medicine item. Australian prescribing systems currently use a variety of data entry fields to capture "*dose*", "*frequency*" and "*instructions*" when entering medicine items into the patient record. When combined into a single "*Directions*" data element, this information may appear as (for example): "*NEO B-12 Solution for Injection 1 2 monthly"* when presented as a narrative within a CDA® document. The proximity of digits "1" and "2" may lead to confusion and potential misinterpretation of the medicine instructions. For example does the above mean "*one (injection) 12 monthly*" or "*12 (injections) each month*"?

The situation is mitigated in some systems where medicine items may include a "Dosage Form" which may also be the administrable dose unit (for example, capsule, tablet, and injection). This, when used explicitly with the dose, clarifies the meaning. For example: "1 2 monthly" becomes "1 injection every 2 months" and "1 in the morning" becomes "1 tablet in the morning". Some drug forms, however, imply the administrable form syrup or liquid; for example "30mL daily".

Similar formatting issues may result if the software allows the clinician to enter the information as free text instead of generating it automatically. Such formatting introduces the potential for clinical safety risks resulting from the misinterpretation of such medication directions.

024984 **Visual separator for direction elements**

If the software allows the user to select dose, frequency, and instructions for using medicine (e.g. via pull down menus) rather than entering the information in a free text field, then a visual separator **SHALL** be used in the "Directions" data element to avoid concatenating combined dose, frequency or instruction values with adjacent numeric digits.

Additional Notes

Acceptable methods include:

a) A spaced semi-colon " ; " with implied dose-form. For example: 1 ; every 3 months

b) Appropriate dose-form text. For example: 1 injection every 3 months

c) Label parts with separating comma "," with implied dose form. For example: Dose: 1, Instructions: every 3 months

Note that the "Directions" data element may have an alternative name.

024985 **Inclusion of dose-form**

If the software allows medicine entries when authoring clinical documents, then it **SHALL** ensure that a "*dose-form*" is included in the entry.

Additional Notes

Acceptable methods include:

a) Drug/product descriptions that include a form that is the dose-form e.g. 'Paracetamol 500mg tablet – 2 times daily'

b) Drug form and dose/directions imply dose-form e.g. 'Benadryl (30mg; 100mg/5mL) Syrup – 30mL daily as required'

c) Through an explicit statement of dose-form in the dose/directions e.g. 'Genteal 0.3% Eye Drops – 3 drops daily'.

3.3.5 Healthcare provider contact details

Clinical documents can support telecommunication and address details for participating healthcare providers. These commonly support entry of address, mobile phone, home phone, pager, fax and email address details as part of the system's healthcare provider record. Inclusion of personal provider contact details is typically supported on an optional basis. However, some clinical information systems automatically populate the relevant fields with personal provider details already stored in the system.

While inclusion of personal provider details may in some cases be useful for documents exchanged point-to-point between providers, this is of concern as this information becomes visible to consumers once they are uploaded to their PCEHR.

Note 1: Providers who have elected not to automatically include any individual electronic contact details or address may do so at any time by writing them in the document's narrative content.

024980 **Confirm individual electronic communication details to be included**

Software **SHALL** afford individual users the ability to confirm which (if any) of their individual electronic communication details (e.g. email address, phone number or fax number) may be automatically included. The default value **SHALL** be 'no'.

024982 **Confirm individual address to be included**

Software **SHALL** afford individual users the ability to confirm which (if any) of their individual addresses may be automatically included. The default value **SHALL** be 'no'.

3.4 Conformance requirements for consumers

3.4.1 Objects of conformance

The objects of conformance requirements include:

023758 **Allowed consumers of an event summary**

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.

A.1 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.

A.2 Changes from version 1.1 (7 Mar 2012) to version 1.2 (19 Mar 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.

A.3 Changes from version 1.2 (17 May 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.	

A.4 Changes from version 1.3 (9 Oct 2013) to version 1.4 (10 Apr 2015)

ID	Section	Change Detail	Rationale
1	3.3.4	This section has been added.	To provide display requirements for medicine instructions.
2	3.3.5	This section has been added.	To ensure only appropriate contact details for healthcare providers are included in clinical documents.

References

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[SA5021] *Australian Standard 5021:2005 - The language of health concept representation*, Standards Australia, 2005