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Shared Health Summary My Health Record Conformance Profile

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Transition of terms

Certain terms used within the context of this document have changed. The table provides a clear comparison of the historical terms used in text and their current equivalents for your reference.

Historical term	Current term
Personally controlled electronic health record (PCEHR)	My Health Record (MHR)
National eHealth Transition Authority (NEHTA)	The Australian Digital Health Agency (ADHA)

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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 My Health Record 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 [NEHTA2015c]. 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 My Health Record 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 Conformance requirements for shared health summary

2.1 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 My Health record system.

2.2 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 *Shared Health Summary Structured Content Specification* [NEHTA2015a] - Specifies the data elements and constrained values for a clinical document at a logical level.
- 3 *Shared Health Summary CDA® Implementation Guide* [NEHTA2015b] - Specifies the mapping from the structured content specification into a clinical document using an HL7® CDA® structure.

2.3 Conformance requirements for producers

2.3.1 Objects of conformance

The objects of conformance are subject to the following requirements:

- | | |
|---------------|--|
| 023762 | <p>Shared health summary clinical documents MAY be produced by</p> <p>Shared health summary clinical documents MAY be produced by:</p> <ul style="list-style-type: none"> • clinical information systems (CIS); and • contracted service provider (CSP) systems. |
| 023763 | <p>Shared health summary clinical documents SHALL NOT be produced by</p> <p>Shared health summary clinical documents SHALL NOT be produced by:</p> <ul style="list-style-type: none"> • registered consumer portals; • registered provider portals; or • registered repositories. |

2.3.2 Superseding a shared health summary

- | | |
|-------------------------|---|
| 023764 | Upload shared health summary as a new clinical document <ul style="list-style-type: none">A shared health summary SHALL be uploaded to the My Health Record system as a new clinical document and SHALL NOT be uploaded as a new version to supersede a previously-uploaded version. |
| Additional Notes | <ul style="list-style-type: none">The <i>Common Conformance Profile for Clinical Documents</i> [NEHTA2015c] 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 My Health Record system does not allow a shared health summary to be superseded.The My Health Record system regards only the most recently-uploaded shared health summary in a My Health 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 always upload shared health summaries to the My Health Record system as a new document. |

2.3.3 Conformance levels

- | | |
|---------------|--|
| 023765 | Conformance levels <ul style="list-style-type: none">A shared health summary sent to the My Health Record system SHALL conform to the requirements for one, and only one, of the following conformance levels: 3A, or 3B, as defined in the <i>Common Conformance Profile for Clinical Documents</i> [NEHTA2015c]. |
|---------------|--|

2.3.4 Clinical document authoring requirements

CDA Rendering Specification – Clinical Documentation [NEHTA2012a] 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 My Health Record system to create the overview of a person's healthcare.

For shared health summaries, requirement CDA-RS 3 in the *CDA Rendering Specification* [NEHTA2012a] is replaced with the following attestation requirement:

- | | |
|-------------------------|---|
| 023766 | Attesting the content of the shared health summary <p>A shared health summary producer SHALL display the final version of a shared health summary to the author and prompt the author to attest:</p> <ul style="list-style-type: none">to the content of the shared health summary before the shared health summary producer uploads the shared health summary to the My Health Record system; andthat the healthcare provider individual (i.e. the author of the shared health summary) is a nominated healthcare provider as defined by the <i>My Health Records Act 2012</i> [COM2012]. |
| Additional Notes | <p>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 attest that I am a Nominated Health Care Provider for this patient as defined by the <i>My Health Records Act 2012</i>", with the name of the Act in italics (including the year).</p> |

2.3.5 Temporary relaxation of inclusion of HPI-I

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

Notes:

- The Common Conformance Profile for Clinical Documents [NEHTA2015c] provides requirements for the inclusion of a local identifier for a document author.
- The relaxation is only available to specific healthcare provider organisations, at the discretion of the My Health Record System Operator. The relaxation is provided to allow time for large healthcare provider organisations to incorporate HPI-Is for the personnel in their systems.

023767

Mandatory requirement for an HPI-I temporarily modified

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.

Additional Notes

The *Common Conformance Profile for Clinical Documents* [NEHTA2015c] provides requirements for the inclusion of a local identifier.

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

2.3.6 Exclusion statement requirements

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 in the specifications to:

- *None known*
- *None supplied.*

023761

Using an exclusion statement

Where the Shared Health Summary Structured Content Specification [NEHTA2015a] 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 **SHALL** be recorded in the shared health summary produced.

024979	"None known" exclusion statement The software SHALL NOT record a "none known" exclusion statement unless a healthcare provider has explicitly indicated so by making an entry either before or during the clinical document authoring process.
Additional Notes	"None known" is only to be used when the user has made a positive statement that there are no known items. This is equivalent to the "no clinically significant items known" flag that appears in some applications.

2.3.7 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 My Health Record 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: <ul style="list-style-type: none">a A spaced semi-colon " ; " with implied dose-form. For example: 1 ; every 3 monthsb Appropriate dose-form text. For example: 1 injection every 3 monthsc 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: <ul style="list-style-type: none"> 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'.

2.3.8 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 My Health Record.

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'.

2.3.9 Disallowing additional data

Currently the CDA® Implementation Guides and the *Common Conformance Profile for Clinical Documents* [NEHTA2015c] allow local extensions to the data model.

However, clinical atomic data will be used in the future within the My Health Record by extracting known elements from the shared health summary to build the Health Record Overview. Any extensions to the shared health summary will therefore be ignored.

024986	Extensibility A shared health summary producer SHALL NOT include data elements in shared health summary structured data that are not listed in the CDA® implementation guide.
Additional Notes	This requirement overrides requirements 023722, 023723, 023724 and 023725 in the <i>Common Conformance Profile for Clinical Documents</i> [NEHTA2015c].

2.4 Conformance requirements for consumers

2.4.1 Objects of conformance

The objects of conformance requirements include:

023759	Allowed consumers of a shared health summary Shared health summary clinical documents MAY be consumed by: <ul style="list-style-type: none">• clinical information systems;• CSP systems;• registered consumer portals;• registered provider portals; and• registered repositories.
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Appendix A Change log

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

A.1 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

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

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

A.3 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.
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.

A.4 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 summary requirement includes this reference.

A.5 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.

ID	Section	Change detail	Rationale
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	

A.6 Changes from version 1.5 (9 Oct 2013) to version 1.6 (10 Apr 2015)

ID	Section	Change detail	Rationale
1	3.3.6	This section has been modified to remove the option for " <i>not asked</i> " as an exclusion statement.	A SHS can only be created with information present about each of the clinical sections.
2	3.3.6	Added new requirement #024979.	To provide clarity when the exclusion statement " <i>none known</i> " may be used.
3	3.3.7	This section has been added.	To provide display requirements for medicine instructions.
4	3.3.8	This section has been added.	To ensure only appropriate contact details for healthcare providers are included in clinical documents.
5	3.3.9	This section has been added.	To disallow additional data not represented in the specifications.

A.7 Changes from version 1.6 (10 Apr 2015) to version 1.6.1 (29 Nov 2019)

ID	Section	Change detail	Rationale
1	3.3.4	Requirement #023766 has been amended with a revised SHS attestation statement.	To provide further clarity to authors of SHS document.

Acronyms

Acronym	Description
AMT	Australian Medicines Terminology
CDA	Clinical Document Architecture
CDA® IG	clinical document architecture implementation guide
CIS	clinical information system
CSP	contracted service provider
HI	healthcare identifier
HL7	Health Level Seven
HPI-I	healthcare provider identifier - individual
HPI-O	healthcare provider identifier - organisation
IHI	individual healthcare identifier
NASH	National Authentication Service for Health
OID	object identifier
PCEHR	personally controlled electronic health record
SCS	structured content specification
SNOMED CT-AU	Systematized Nomenclature of Medicine - Clinical Terms - Australia

Glossary

Term	Meaning
Australian Medicines Terminology (AMT)	AMT is systemised collection of medicines terminology that offers a standard national approach for the identification and naming of medicines which includes: medicinal product, unit of use, product pack, trade product, trade product unit of use, product pack and contains trade product pack information.
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 <i>CDA Package</i> 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 <i>Clinical Document Architecture, Release 2</i> [HL72005].
clinical document architecture implementation guide (CDA IG)	A guide to implementing the logical model detailed in an SCS as an HL7 Clinical Document Architecture (CDA) Release 2 XML document. Each implementation guide contains descriptions of both constraints on the CDA and, where necessary, custom extensions to the CDA, to fulfil the requirements for Australian implementations of the SCS. The resulting CDA document can be used for the electronic exchange of health information.
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 My Health Record system on behalf of healthcare organisations. A CSP provides under a contract with the healthcare provider organisation: a) information technology services relating to the My Health Record system; or b) health information management services relating to the My Health Record system. (Section 5 <i>My Health Records Act 2012</i> [COM2012].)
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.

Term	Meaning
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].
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.

Term	Meaning
MAY	When appearing in a conformance requirement, the verb MAY indicates an optional requirement.
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 (<i>CDA package specification</i> [NEHTA2011a]).
P2P	Provider-to-provider: documents sent from one healthcare provider to another.
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 My Health Record system.
registered portal operator	A person who is the operator of an electronic interface that facilitates access to the My Health Record system; and who is registered as a portal operator under section 49 of the <i>My Health Records Act 2012</i> [COM2012].
registered provider portal	A third-party portal used by healthcare providers to access information on the My Health Record system.
registered repository	A third-party repository used to store clinical documents and other clinical data that connects to the My Health Record 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 My Health Record system, and who is registered as a repository operator under section 49 of the <i>My Health Records Act 2012</i> [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.

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 My Health Record 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 My Health Record system and intended to connect to the national My Health Record system.

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