Australian Government
Australian Digital Health Agency

Event Summary
My Health Record Conformance Profile

8 September 2022 v1.5

Approved for external use

Document ID: DH-3418:2022

Australian Digital Health Agency ABN 84 425 496 912, Level 25, 175 Liverpool Street, Sydney, NSW 2000
Telephone 1300 901 001 or email help@digitalhealth.gov.au
www.digitalhealth.gov.au

Acknowledgements
The Australian Digital Health Agency is jointly funded by the Australian Government and all state and territory governments.

Document information

Key information

Owner	Chief Digital Officer
Contact for enquiries	Australian Digital Health Agency Help Centre Phone 1300 901 001 Email help@digitalhealth.gov.au

Product or document version history

Document version	Date	Release comments
1.0.1	21/12/2011	Initial version
1.1	07/03/2012	Minimum conformance level set to 1B; requirements for attachments
1.2	10/07/2012	Minimum conformance level set to 3A; digital signature requirement added; sections 3.1.4.2, 3.1.4.4, 3.1.5.2 moved to Common Conformance Profile
1.3	09/10/2013	Added section 3.3.3; digital signature requirement moved to Common Conformance Profile
1.4	10/04/2015	Added sections 3.3.4, 3.3.5
1.5	08/09/2022	Added support for document subtyping

Table of contents

1 Introduction

1.1 Purpose

This document summarises the requirements for producing and consuming systems of the Event Summary clinical document that connects to the national My Health Record (MHR) 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 [AGENCY2015c]. These documents represent the complete conformance requirements for the Event Summary clinical document.

1.2 Intended audience

The intended audience includes the following organisations:

- healthcare providers;
- vendors and developers of connecting systems; and
- software test laboratories.

1.3 Scope

The scope of this conformance profile is the use of Event Summary clinical documents in the context of the national MHR system.

2 Conformance requirements for Event Summary

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

2.1 Relevant specifications

The detailed conformance requirements are listed below:

- *Common Conformance Profile for Clinical Documents* [AGENCY2015c] - provides common Conformance Requirements which must be adhered to unless specifically contradicted in this document.
- *Event Summary Structured Content Specification* [AGENCY2015a] - Specifies the data elements and constrained values for a clinical document at a logical level.
- *Event Summary CDA® Implementation Guide* [AGENCY2015b] - Specifies the mapping from the structured content specification into a clinical document using an HL7® CDA® structure.

2.2 Conformance requirements for producing systems

The objects of conformance are subject to the following requirements:

2.2.3 Objects of conformance

50060 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.

Type Conformance **Status** Proposed **Priority** Optional

50061 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.

Type Conformance **Status** Proposed **Priority** Mandatory

2.2.4 Conformance levels

50062 Levels of conformance

An Event Summary sent to the MHR 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* [AGENCY2015c].

Type Conformance **Status** Proposed **Priority** Mandatory

2.2.5 Temporary relaxation of inclusion of HPI-I

The Event Summary Structured Content Specification [AGENCY2015a] and the Event Summary CDA® Implementation Guide [AGENCY2015b] 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 [AGENCY2015c] 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 MHR System Operator. The relaxation is provided to allow time for large healthcare provider organisations to incorporate HPI-Is for their personnel in their systems.

50063 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 producing system, otherwise it SHALL have a value that identifies the document author and the value SHALL NOT be a nullFlavor.

Type Conformance **Status** Proposed **Priority** Mandatory

50064 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 producing system, otherwise it SHALL have a value that identifies the diagnostic investigations service provider (person) and the value SHALL NOT be a nullFlavor.

Type Conformance **Status** Proposed **Priority** Conditional

2.2.6 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 MHR 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.

50065 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 semicolon " ; " 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.

Type Conformance **Status** Proposed **Priority** Conditional

50066 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’.

Type Conformance **Status** Proposed **Priority** Conditional

2.2.7 Document author 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 MHR.

Note: *Providers who have elected not to have their software automatically include any individual electronic contact details or address may still include these details where required in the narrative part of the document.*

50067 Confirm author's personal electronic communication details to be included

If the producing system captures the personal electronic communication details (e.g. email address, phone number or fax number) of the document author, the author's personal electronic communication details SHALL NOT be automatically included unless stated otherwise.

Additional Notes

Software that does not provide this option can conform to this requirement by not automatically inserting author's personal electronic communication details into the document as appropriate.

The software can also demonstrate conformance by not capturing the author's personal electronic communication details in the CIS.

Type Conformance **Status** Proposed **Priority** Conditional

50068 Confirm author's personal address to be included

If the producing system captures the personal address of the document author, the author's personal address SHALL NOT be automatically included unless stated otherwise.

Additional Notes

Software that does not provide this option can conform to this requirement by not automatically inserting author's personal address details into the document as appropriate.

The software can also demonstrate conformance by not capturing the author's personal address details in the CIS.

Type Conformance **Status** Proposed **Priority** Conditional

2.2.8 Address of the individual

50069 Address of the individual

When authoring the individual's address, the document SHALL contain one of the followings:

- an address, or
- a nullflavor, or
- both, BUT NOT
- an address AND an MSK nullflavor.

Rationale The address of the healthcare individual can be masked due to privacy or safety concerns.

Additional Notes The document author is permitted to suppress or not include the individual's residential address through the use of nullflavor. If the address is known, but not included in the document, then it is preferred the "MSK" nullflavor is used. The masking of the address may be used when there are patient privacy or safety concerns.

It is prohibited to include a MSK nullflavor AND an address because a masked address should not be available in the CDA/XML document.

Other nullflavors are also permitted.

Type Conformance **Status** Proposed **Priority** Mandatory

2.2.9 Document subtype

To support clinical document discoverability, the producing system is encouraged to include a document subtype in the clinical document. The document subtype is intended to assist healthcare providers and individuals to discover the most relevant clinical documents and identify the clinically relevant content easily in the healthcare individual's MHR.

The Document Type Register is a comprehensive list of all document types and its associated subtypes supported by the MHR system. Each document type and subtype will be supplemented with a description to inform implementers about the intention of the subtypes. Implementers should refer to the Agency's Developer Centre (https://developer.digitalhealth.gov.au) for information on how to access the Document Type Register.

The national Document Type Register will be maintained by the Agency and it may change over time for additional or to update subtypes. Because the locally stored list of subtypes provided by the CIS is sourced from the national Document Type Register and cached periodically it is expected the local list of subtypes will not perfectly align to the national Document Type Register.

This is acceptable provided that the update of the local Document Type Register will be performed by the CIS within a reasonable timeframe. See requirement 50073 for detail.

The conformance requirements in this section refer to the local version of Document Type Register that is implemented within the local CIS at the time of authoring. See requirements 50070, 50071, 50130, 50072 and 50073 for the inclusion of subtypes known to the local CIS.

50070 Document subtype name

If instantiating the document subtype, the producing system SHALL instantiate the following XPaths with the same subtype name:

- ClinicalDocument/code/originalText
- ClinicalDocument/title

This SHALL be one of the subtypes in the local Document Type Register for the document type.

Rationale To differentiate the document with a subtype and reflect the document subtype name in the MHR document title.

Additional Notes The local Document Type Register contains the list of document types and its subtypes for the My Health Record. Implementers should refer to the Agency's Developer Centre for information about how to access and sync with the national Document Type Register.

Type Conformance **Status** Proposed **Priority** Conditional

50071 Authoring a document with subtype

When authoring the first version of a subtyped document, the document SHALL only contain a subtype that is "active" in the local system.

Rationale To ensure CIS's local document type register is updated regularly and transition to the new subtypes where appropriate. To prevent document rejection by the MHR system when the subtype becomes retired.

Additional Notes The first version of the document is a newly authored document that is authored at the first instance (i.e., new document set ID), and not a superseding document.

The local Document Type Register stored in the CIS may not be up-to-date with the version in the MHR system. Once the CIS has updated to a newer version of the national Document Type Register, the CIS must incorporate any new "active" subtypes for authoring

Type Conformance **Status** Proposed **Priority** Mandatory

50130 Superseding a document with the same subtype

When superseding a subtyped document, the subtype of the superseding document SHOULD be the same as the subtype of the preceding document and that subtype MAY be deprecated or retired.

Rationale To ensure document versions in the My Health Record system contain consistent subtypes.

Additional Notes The system that is superseding a document with the same subtype should acquire the subtype from the superseded document, and not from a source (i.e., Document Type Register) that might encourage an inconsistent subtype.

Type Conformance **Status** Proposed **Priority** Optional

50072 Superseding a document with a different subtype

When superseding a document with a subtype that is different from that of the preceding document, the subtype of the superseding document:

- SHALL NOT be “retired” in the local system, and
- SHALL NOT contradict the content of the clinical document.

Rationale To allow flexibility for CIS to update and correct the document subtype from the preceding document where appropriate.

Additional Notes A superseding document may contain a different subtype from the preceding document. For example, to correct an incorrect subtype; to transition to a more specific subtype; or up-to-date subtype.

The subtype of the subsequent versions of the document must be relevant.

Type Conformance **Status** Proposed **Priority** Mandatory

50073 Document Type Register

The producing system SHALL provide a mechanism to update the local Document Type Register in real time, on a schedule or on request (e.g., manual input).

Rationale To ensure the producing system maintains an up-to-date Document Type Register in the local CIS. Prevent document rejection by the MHR system when subtype becomes retired.

Type Conformance **Status** Proposed **Priority** Mandatory

50115 Automated assignment of subtype

When authoring a subtyped document, the producing system SHOULD support automated assignment of the subtype to the document.

Rationale To promote software usability and conformity when CIS automatically subtypes a document. To mitigate the risk of human errors when document author manually selects a subtype.

Type None Specified **Status** Proposed **Priority** Optional

2.3 Conformance requirements for consuming systems

50074 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.

Type Conformance **Status** Proposed **Priority** Optional

50110 Search or filter subtype

When viewing a subtyped document, the CIS SHOULD provide a mechanism to search or filter a particular subtype(s).

Rationale Allow robust searching or filtering functionality in the CIS to discover the relevant document subtypes easily.

Additional Notes Depending on the software design, the viewing functions may present a long list of subtypes for the healthcare providers to choose from. The CIS should make it easy for healthcare providers to discover the subtyped documents.

Type Conformance **Status** Proposed **Priority** Optional

Acronyms

Acronym	Description
CIS	Clinical information system
CDA® IG	clinical document architecture implementation guide
CSP	contracted service provider
HPI-I	healthcare provider identifier - individual
SCS	structured content specification

Glossary

Term	Meaning
Clinical Document Architecture (CDA®)	An XML-based mark-up 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].
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 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 the functions of a CIS.
healthcare provider organisation	An enterprise that provides healthcare (including healthcare provided free of charge) [COM2012].
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], [AGENCY2014a].
individual	A person who is, or could be, seeking care in Australia. Individual is sometimes referred to as patient, client and consumer. For the purposes of the My Health Record system, an individual must have an IHI.
MAY	When appearing in a conformance requirement, the verb MAY indicates an optional requirement.
MHR	My Health Record
NASH	National Authentication Service for Health
PCEHR	Personally Controlled Electronic Health Record (former name for My Health Record)

Term	Meaning
producing system	A software system that has the role of generating and issuing conformant clinical documents suitable for use by other digital health 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].
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.

References

[COM2012] *Personally Controlled Electronic Health Records Act 2012*

[HL72005] *Clinical Document Architecture, Release 2, ISO/HL7 27932:2008*, Apr 2005

[ISO7812-1] *ISO/IEC 7812-1 Identification cards – Identification of issuers – Part 1: numbering system*, International Organization for Standardization, 2006

[AGENCY2014a] *Use of Healthcare Identifiers in Health Software Systems, Software Conformance Requirements, Version 3.1, Australian Digital Health Agency*, Oct 2014

[AGENCY2015a] Event Summary Structured Content Specification, Version 1.2, Australian Digital Health Agency, Apr 2015

[AGENCY2015b] Event Summary CDA® Implementation Guide, Version 1.3, Australian Digital Health Agency, Apr 2015

[AGENCY2015c] Common Conformance Profile for Clinical Documents, Version 1.6, Australian Digital Health Agency, Apr 2015

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