Australian Government
Australian Digital Health Agency

Pharmaceutical Benefits Report PCEHR Conformance Profile

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Document information

Key information

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Product or document version history

Product or document version	Date	Release comments
1.0	27 October 2014	Initial public release.
1.0	04 June 2025	The document presentation has been enhanced to align with current branding guidelines, however the content has not been changed.

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

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1 Introduction

1.1 Purpose

This document summarises the requirements for producers and consumers of Pharmaceutical Benefits Report clinical documents that connect to the national personally controlled electronic health record (PCEHR) system.

This document lists the specific conformance requirements for the Pharmaceutical Benefits Report clinical documents that are in addition to the *Common Conformance Profile for Clinical Documents* [NEHTA2012]. These documents represent the complete conformance requirements for the Pharmaceutical Benefits Report clinical documents.

1.2 Intended audience

This document is intended for:

- 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 Pharmaceutical Benefits Report clinical documents in the context of the national PCEHR system.

In this document:

- *producer* refers to a software system that creates Pharmaceutical Benefits Report clinical documents.
- *consumer* refers to a software system that has the role of being a consumer of Pharmaceutical Benefits Report clinical documents.

Please refer to the Glossary on page 9 for the meanings of additional terms used in this document.

2 Relevant specifications

The detailed conformance requirements are listed in the specifications below.

Specification	Notes
Pharmaceutical Benefits Report Structured Content Specification [NEHTA2014b]	Specifies the data elements and constrained values for a Pharmaceutical Benefits Report at a logical level.
Pharmaceutical Benefits Report CDA Implementation Guide [NEHTA2014c]	Specifies the mapping from the structured content specification into a document using an HL7 CDA structure.

3 Conformance requirements for producers

3.1 Objects of conformance

The objects of conformance requirements include:

1. Pharmaceutical Benefits Report clinical documents **SHALL** be produced, superseded or removed only by the registered repository operated by the Department of Human Services (DHS) – Medicare.
2. Pharmaceutical Benefits Report clinical documents **SHALL NOT** be produced, superseded or removed by:
    - clinical information systems;
    - CSP systems;
    - registered consumer portals;
    - registered provider portals; or
    - registered repositories other than the DHS-Medicare registered repository.

3.2 Conformance levels

The level of CDA conformance for Pharmaceutical Benefits Report clinical documents **SHALL** be CDA Level 3A, which is defined in the *Common Conformance Profile for Clinical Documents*.

3.3 CDA extensibility

The following variation to the *Common Conformance Profile for Clinical Documents* applies to the production of Pharmaceutical Benefits Report clinical documents by the DHS-Medicare registered repository:

1. Additional data elements **SHALL NOT** be included in the Pharmaceutical Benefits Report clinical documents.

4 Conformance requirements for consumers

4.1 Objects of conformance

The objects of conformance requirements include:

1. Pharmaceutical Benefits Report clinical documents **MAY** be consumed by:
    - clinical information systems;
    - CSP systems;
    - registered consumer portals; and
    - registered provider portals.
2. Pharmaceutical Benefits Report clinical documents **SHALL NOT** be consumed by:
    - registered repositories.

Glossary

Term	Meaning
clinical document	A digital file containing personal health information about an individual, containing unstructured (narrative) information and optionally structured (atomic) information.
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.
clinical information system	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	Conformance is 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 Pharmaceutical Benefits Report 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 the PCEHR system. (Section 5 *Personally Controlled Electronic Health Records Act 2012*.)
contracted service provider 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 clinical information system.
healthcare consumer	A person who is the subject of care. (For the software system, see 'consumer'.)
MAY	When appearing in a conformance requirement, the verb **MAY** indicates an optional requirement.
producer	In this document, *producer* refers to a software system that creates Pharmaceutical Benefits Report clinical documents.
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 store clinical documents in either 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.

[1] In this list of terms, '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 to the national PCEHR system are not registered consumer or registered provider portals.

References

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

[NEHTA2012] *Common Conformance Profile for Clinical Documents*, NEHTA, Version 1.3, 17 May 2012 available from:
https://developer.digitalhealth.gov.au/resources/clinical-documents-common-conformance-profile-v1-3

[NEHTA2014b] *Pharmaceutical Benefits Report Structured Content Specification*, NEHTA, Version 1.1.1, 15 Sept 2014

[NEHTA2014c] *Pharmaceutical Benefits Report CDA Implementation Guide*, NEHTA, Version 1.1.1, 15 Sept 2014