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## **eHealth Prescription Record My Health Record Conformance Profile**

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## Document information

### Key information

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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 eHealth Prescription Record clinical documents. The document also lists requirements for clinical information systems (CIS) sending proprietary prescription information to an intermediary system. As well as listing requirements for clinical information systems that connect directly to the My Health Record system, this document includes requirements for clinical information systems that upload prescription records to the My Health Record system via an intermediary system such as a contracted service provider (CSP) or registered repository.

This document lists the specific conformance requirements for eHealth Prescription Record clinical documents that are in addition to the Common Conformance Profile for Clinical Documents [NEHTA2013].

## 1.2 Intended audience

The intended audience includes the following organisations:

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

## 2 Scope

The scope of this conformance profile is the use of eHealth Prescription Record clinical documents in the context of the national infrastructure of the My Health Record system.

## 3 Conformance requirements for eHealth Prescription Record

This section describes conformance requirements specific to eHealth Prescription Records.

### 3.1 Relevant specifications

Relevant specifications are listed in Table 1.

| Specification  | Notes  |
|--|--|
| <i>PCEHR Prescription Record Structured Content Specification</i> [NEHTA2012a] | Specifies the data elements and constrained values for an eHealth Record Prescription Record at a logical level. |
| <i>PCEHR Prescription Record CDA Implementation Guide</i> [NEHTA2012b]         | Specifies the mapping from the structured content specification into a document using an HL7 CDA structure.      |

*Table 1 Specifications for the eHealth Record Prescription Record*

### 3.2 Conformance requirements for Producers

#### 3.2.1 Objects of conformance

The objects of conformance are subject to the following requirements:

- 1 eHealth Prescription Records **MAY** be produced by:
  - a clinical information systems;
  - b contracted service provider (CSP) systems; and
  - c registered repositories.
- 2 eHealth Prescription Records **SHALL NOT** be produced by:
  - a registered consumer portals; or
  - b registered provider portals; or
  - c the My Health Record system.

#### 3.2.2 Conformance levels

An eHealth Prescription Record 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 Common Conformance Profile for Clinical Documents [NEHTA2013].

#### 3.2.3 Clinical terminology

In an eHealth Prescription Record, 'Prescription Item (MEDICATION INSTRUCTION) > Therapeutic Good Identification' **SHALL** include the originalText.

### 3.2.4 Clinical information system uploading to the My Health Record via an intermediary system

The following conformance requirements apply to a clinical information system that sends proprietary prescription information to an intermediary system for transformation into eHealth Prescription Records, or for the removal of an eHealth Prescription Record.

*Note: Specific implementation details must be sought from the operator of an intermediary system.*

- 1 The clinical information system **SHALL** conform to mandatory requirements for the role of a CIS Producer [NEHTA2012e] as follows:
  - a UC.CIS.001 (check if an advertised My Health Record exists): 019100;
  - b UC.CIS.201 (upload a clinical document): 017841, 017842, 019100;
  - c UC.CIS.202 (supersede a clinical document): 017841, 017842, 019100, 018338; and
  - d UC.CIS.203 (remove a clinical document): 017887, 019377, 019100.

*Note: Although the specification of these requirements [NEHTA2012e] states that they apply to clinical information systems accessing the My Health Record system, they are extended here to also apply to clinical information systems sending proprietary prescription records to an intermediary system for transformation into eHealth Prescription Records.*

- 2 The clinical information system **SHALL** set the default consent for each prescription item to 'Consent Not Indicated' and **SHALL NOT** allow any subsequent changes to the prescription item consent settings if:
  - a The prescribing organisation is not a My Health Record Participant; or
  - b The prescriber's HPI-I is determined to be invalid; or
  - c The prescribing organisation's HPI-O is determined to be invalid; or
  - d The healthcare consumer's IHI is determined to be invalid.

In all other cases, the clinical information system **SHALL** call doesPCEHRExist prior to setting the default consent settings.

*Note:*

*a) Requirements for the validation of healthcare identifiers are stated in the requirements for clinical information systems [NEHTA2012e], which state that the validation of an IHI is mandatory. Validation of an HPI-I and HPI-O is mandatory if they are manually entered into the clinical information system [NEHTA2014], requirements 10038 and 10040, otherwise validation of HPI-I and HPI-O prior to creating a prescription record is optional.*

*b) Validation of healthcare identifiers must be performed by a clinical information system that is accessing the intermediary system. The intermediary system may validate healthcare identifiers, but that is more properly the role of participating clinical information systems.*

*c) Requirements in this document refer to three consent states: 'Consent Not Indicated', 'Consent Indicated', and 'Consent Withdrawn'. The method of indicating the consent states will depend on the format of the proprietary prescription record.*



d) *The phrase 'prior to' means the existence of the My Health Record is determined during the episode of care (i.e. during the healthcare consumer's presence at the prescribing organisation).*

- 3 If the doesPCEHRExist service returns an error of PCEHR\_ERROR\_0004 the clinical information system **SHALL** set the default consent setting for each prescription item to 'Consent Not Indicated' and **SHALL NOT** allow any subsequent changes to the prescription item consent settings.

*Note: The doesPCEHRExist service will return an error of PCEHR\_ERROR\_0004 if the healthcare provider organisation (i.e. the prescribing organisation) is not a My Health Record participant.*

- 4 The clinical information system **SHALL** use the returned status of the doesPCEHRExist call prior to setting default prescription item consent settings such that one of the following is selected:
  - a If the My Health Record is found to exist, the prescription item consent **SHALL** be set to indicate 'Consent Indicated'; or
  - b If the My Health Record is not found, the prescription item consent **SHALL** be set to 'Consent Not Indicated'; or
  - c If the attempt to find the My Health Record returns an error state, the prescription item consent **SHALL** be set to 'Consent Not Indicated'.

*Note: If the healthcare consumer has a non-advertised My Health Record the doesPCEHRExist will indicate the My Health Record does not exist.*

- 5 When sending a record of a new prescription to an intermediary system, the clinical information system **SHALL** allow the user to override the default prescription item consent settings if:
  - a The healthcare consumer indicates they consent to a prescription item being uploaded to the My Health Record, in which case the prescription item consent **SHALL** be set to 'Consent Indicated'; or
  - b The healthcare consumer or healthcare provider withdraws consent for a prescription item to be uploaded to the My Health Record system, in which case the prescription item consent **SHALL** be changed to 'Consent Withdrawn'.
- 6 The clinical information system **SHALL** retain existing prescription item consent settings as previously recorded when superseding or removing a prescription item that has already been uploaded to the My Health Record system, and **SHALL NOT** allow these to be changed by the user.

### 3.2.5 Uploading an eHealth Prescription Record to the My Health Record

- 1 If the eHealth Prescription Record Producer is a clinical information system, CSP system or registered repository, the eHealth Prescription Record **SHALL** be uploaded to a My Health Record if consent has not been withdrawn and the prescribing organisation is a My Health Record participant. Otherwise the eHealth Prescription Record **SHALL NOT** be uploaded to a My Health Record.

*Note:*

*a) Consent may be withdrawn either because the healthcare consumer has withdrawn their consent, or because the healthcare provider has chosen not to upload the eHealth Prescription Record to the My Health Record system.*

*b) Consent management may be based on the healthcare provider's policy. For example it could be episodic.*

- 2 If the eHealth Prescription Record Producer transforms a proprietary prescription record into a eHealth Prescription Record, the Producer **SHALL** upload the new eHealth Prescription Record to a My Health Record if the prescription item consent setting indicates 'Consent Indicated' and the prescribing organisation is a My Health Record participant. Otherwise, the eHealth Prescription Record Producer **SHALL NOT** upload the eHealth Prescription Record to the My Health Record system.

### 3.2.6 Revision to a eHealth Prescription Record

- 1 An eHealth Prescription Record Producer **SHALL** supersede (UC.CIS.202 [NEHTA2012e]) or replace (UC.CIS.203 and UC.CIS.201 [NEHTA2012e]) a previously uploaded eHealth Prescription Record when there is a change or error in the data used to create the originally uploaded eHealth Prescription Record.
- 2 If the attempt to supersede or replace the document fails, the eHealth Prescription Record Producer **SHALL** remove (UC.CIS.203 [NEHTA2012e]) the previously uploaded eHealth Prescription Record.

*Note: This requirement overrides requirements 017839 and 019042 listed in the Conformance Requirements for Clinical Information Systems Connecting to the My Health Record system [NEHTA2012e].*

### 3.2.7 Temporary relaxation of the inclusion of HPI-I

The PCEHR Prescription Record Structured Content Specification [NEHTA2012a] and the PCEHR Prescription Record CDA Implementation Guide [NEHTA2012b] 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 mandatory data element:

- Prescriber > Participant > Entity Identifier

However, the mandatory requirement for an HPI-I for this data element is temporarily modified.

- 1 The value of one, and only one, Prescriber > Participant > Entity Identifier **SHALL** be an HPI-I if one is present in the eHealth Prescription Record Producer, otherwise it

**SHALL** have a value that identifies the prescriber (person) and the value **SHALL NOT** be a nullFlavor.

*Note:*

*a) The Common Conformance Profile for Clinical Documents [NEHTA2013] provides requirements for the inclusion of a local identifier for a document author. In the case of an eHealth Prescription Record, the document author is the prescriber.*

*b) This 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.*

### 3.2.8 Prescription item narrative block

Conformance to the PCEHR Prescription Record CDA Implementation Guide [NEHTA2012b] requires all clinical information encoded in a section to also be represented in the corresponding narrative block. The encoded information in an eHealth Prescription Record is used by the My Health Record system to create the Prescription and Dispense View. Therefore it is important that the narrative does not contain prescription items not included in the corresponding encoded entry.

- 1 Information in a narrative block **SHALL NOT** contain information about a prescription item not listed in the corresponding encoded section.

### 3.2.9 My Health Record version number

The PCEHR Prescription Record CDA Implementation Guide [NEHTA2012b] specifies the document version number as optional. This profile overrides the CDA implementation Guide to make the document version number mandatory.

- 1 The eHealth Prescription Record setId **SHALL** be present.
- 2 The eHealth Prescription Record version number **SHALL** be provided in the /ClinicalDocument/versionNumber header element.

### 3.2.10 Superseded document typeCode

Every eHealth Prescription Record has at least one parent document. One instance of a parent document is the source prescription record in its original format prior to transformation into CDA format. This parent document is referenced using the typeCode XFRM (transform).

When an eHealth Prescription Record supersedes a previously created eHealth Prescription Record, the eHealth Prescription Record that is being superseded is referenced using the typeCode RPLC (replace). The following requirement also applies:

- 1 If the eHealth Prescription Record supersedes a previously created eHealth Prescription Record, the eHealth Prescription Record **SHALL** contain a /ClinicalDocument/relatedDocument/parentDocument header element with the typeCode attribute value of 'RPLC'.

### 3.2.11 PBS item codes

The My Health Record system atomic data in the eHealth Prescription Record is used to construct a My Health Record Prescription and Dispense View. This requires the Therapeutic Good Identification values coded as PBS item codes to have at least six characters.

- 1 Any PBS item code used in Prescription Item (MEDICATION INSTRUCTION) > Therapeutic Good Identification **SHALL** be included as a code of at least six characters.
- 2 Any PBS item code that is less than six characters **SHALL** be prepended with leading zeros to create a code of six characters.

*Note: This requirement only applies to the structured data. PBS item codes in the narrative should be included without being prepended with leading zeros.*

### 3.2.12 Extensibility.

The Common Conformance Profile for Clinical Documents [NEHTA2013] notes that, by default, clinical documents may include additional data elements. A requirement is included here to disallow additional clinical information in the structured data for eHealth Prescription Records.

- 1 An eHealth Prescription Record Producer **SHALL NOT** include clinical information in eHealth Prescription Record structured data that is not listed in the structured content specification.

### 3.2.13 Nullable fields

CDA implementation guides specify cardinalities for CDA data elements, but have only been able to provide little information on the proper use of nullFlavor. More information is provided here.

- 1 Data elements with a minimum cardinality of 1 listed in the eHealth Prescription Record structured content specification, or CDA implementation guide, **SHALL** be present without a nullFlavor attribute. Additionally, a value **SHALL** be provided with the exception of data elements for which the eHealth Prescription Record structured content specification, the CDA implementation guide or the conformance profile explicitly state that a nullFlavor is allowed.

### 3.2.14 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, it is a concern because this information becomes visible to the consumer once the clinical documents are uploaded to the consumer's My Health Record.

- 1 Software **SHALL** allow individual users 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'.
- 2 Software **SHALL** allow individual users to confirm which (if any) of their individual addresses may be automatically included. The default value **SHALL** be 'no'.

### 3.3 Conformance requirements for Consumers

#### 3.3.1 Objects of conformance

- 1 eHealth Prescription Records **MAY** be consumed by:
  - a clinical information systems;
  - b contracted service provider systems;
  - c registered consumer portals;
  - d registered provider portals;
  - e registered repositories; and
  - f the My Health Record system.

#### 3.3.2 Clinical terminology

- 2 If a clinical term from an eHealth Prescription Record is transferred into some other form or document, the value of the originalText attribute **SHALL** be maintained.

*Note: For example, the value of the originalText attribute may be copied to another clinical document, or persisted in a database or patient record.*

## 4 Acronyms

| Acronym | Description                                   |
|---------|---|
| CDA     | Clinical Document Architecture                |
| CIS     | clinical information system                   |
| HL7     | Health Level Seven                            |
| HPI-I   | Healthcare Provider Identifier - Individual   |
| HPI-O   | Healthcare Provider Identifier - Organisation |
| IHI     | individual healthcare identifier              |
| PBS     | Pharmaceutical Benefits Scheme                |
| RPLC    | “replace” typeCode                            |
| XFRM    | “transform” typeCode                          |

## 5 Glossary

| Term                              | Meaning   |
|-----------------------------------|---|
| clinical document architecture    | Clinical Document Architecture; an XML-based mark-up 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 eHealth Prescription Records.  |
| 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 the My Health Record 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.   |
| dispense item                     | An item that is being dispensed. The description of a dispense item includes the identification of the therapeutic good, dispensing information, and other optional information.  |
| healthcare consumer               | A person who is the subject of care. (For the software system, see 'Consumer'.)   |
| intermediary system               | A software system that provides functions to assist a clinical information system to interact with the My Health Record infrastructure. An intermediary system may be a contracted service provider or registered repository.   |
| <b>MAY</b>                        | When appearing in a conformance requirement, the verb <b>MAY</b> indicates an optional requirement.   |
| My Health Record                  | Previously called the personally controlled electronic health record system (PCEHR).  |
| My Health Record participant      | A healthcare provider organisation, repository operator, portal operator, or contract service provider that has been registered with the My Health Record system operator as a participant in the My Health Record system [COM2012].  |

| Term                       | Meaning  |
|----------------------------|--|
| originalText               | The text as seen and/or selected by the user who entered the data which represents the intended meaning of the user. The originalText is an attribute of the Concept Descriptor data type [HL72010].                       |
| producer                   | In this document, 'producer' refers to a software system that creates eHealth Prescription Records in CDA format.  |
| registered consumer Portal | A third-party <sup>1</sup> portal used by healthcare recipients to access information on the My Health Record system.  |
| 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. A repository may either store clinical documents in a proprietary format, or a CDA format. |
| <b>SHALL</b>               | When appearing in a conformance requirement, the verb <b>SHALL</b> indicates a mandatory requirement. Its negative form <b>SHALL NOT</b> indicates a prohibition.  |
| <b>SHOULD</b>              | When appearing in a conformance requirement, the verb <b>SHOULD</b> indicates a recommendation. Its negative form <b>SHOULD NOT</b> indicates an option that is not recommended.   |

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<sup>1</sup> 1 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. The portals provided the national My Health Record system are not registered consumer or registered provider portals.



## 6 References

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