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eHealth Dispense Record
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 eHealth Dispense Record clinical documents. The document also lists requirements for clinical information systems (CIS) sending proprietary dispense 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 Dispense 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 Dispense 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 Dispense Record clinical documents in the context of the national infrastructure of the My Health Record system.

3 Conformance requirements for eHealth Dispense Record

This section describes conformance requirements specific to eHealth Dispense Records.

3.1 Relevant specifications

Relevant specifications are listed in Table 1.

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

Table 1 Specifications for the eHealth Record Dispense 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 Dispense Records MAY be produced by:

- a clinical information systems;
- b CSP systems; and
- c registered repositories.

2 eHealth Dispense Records **SHALL NOT** be produced by:

- a registered consumer portals;
- b registered provider portals; or
- c the My Health Record system.

3.2.2 Conformance levels

1 An eHealth Dispense 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

1 In an eHealth Dispense Record, 'Dispense Item > 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 dispense information to an intermediary system for transformation into eHealth Dispense Records, or for the removal of an eHealth Dispense 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

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 Dispense Records to an intermediary system for transformation into eHealth Dispense Records.

2 The clinical information system **SHALL** set the default consent for each Dispense Item to 'Consent Not Indicated' and **SHALL NOT** allow any subsequent changes to the Dispense Item consent settings if:

a the dispensing organisation is not a My Health Record Participant; or

b the dispenser's HPI-I is determined to be invalid; or

c the dispensing 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.

Notes:

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 Dispense 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

Dispense 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 dispensing 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 Dispense Item to 'Consent Not Indicated' and **SHALL NOT** allow any subsequent changes to the Dispense Item consent settings.

Note: The doesPCEHRExist service will return an error of PCEHR_ERROR_0004 if the healthcare provider organisation (i.e. the dispensing 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 Dispense Item consent settings such that one of the following is selected:

a If the My Health Record is found to exist, the Dispense Item consent **SHALL** be set to indicate 'Consent Indicated';

b If the My Health Record is not found, the Dispense 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 Dispense 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 Dispense Record to an intermediary system, the clinical information system **SHALL** allow the user to override the default Dispense Item consent settings if:

a The healthcare consumer indicates they consent to a Dispense Item being uploaded to the My Health Record, in which case the Dispense Item consent **SHALL** be set to 'Consent Indicated'; or

b The healthcare consumer or healthcare provider withdraws consent for a Dispense Item to be uploaded to the My Health Record system, in which case the Dispense Item consent **SHALL** be changed to 'Consent Withdrawn'.

6 The clinical information system **SHALL** retain existing Dispense Item consent settings as previously recorded when superseding or removing a Dispense 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 Dispense Record to the My Health Record

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

Otherwise the eHealth Dispense Record **SHALL NOT** be uploaded to a My Health Record.

Notes:

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 Dispense 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 Dispense Record Producer transforms a proprietary Dispense Record into a eHealth Dispense Record, the Producer **SHALL** upload the new eHealth Dispense Record to a My Health Record if the Dispense Item consent setting indicates 'Consent Indicated' and the dispensing organisation is a My Health Record participant. Otherwise, the eHealth Dispense Record Producer **SHALL NOT** upload the eHealth Dispense Record to the My Health Record system

3.2.6 Revision to a eHealth Dispense Record

1 An eHealth Dispense Record Producer **SHALL** supersede (UC.CIS.202 [NEHTA2012e]) or replace (UC.CIS.203 and UC.CIS.201 [NEHTA2012e]) a previously uploaded eHealth Dispense Record when there is a change or error in the data used to create the originally uploaded eHealth Dispense Record.

2 If the attempt to supersede or replace the document fails, the eHealth Dispense Record Producer **SHALL** remove (UC.CIS.203 [NEHTA2012e] the previously uploaded eHealth Dispense 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 Dispense Record Structured Content Specification* [NEHTA2012a] and the *PCEHR Dispense 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:

- Dispenser > 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, Dispenser > Participant > Entity Identifier **SHALL** be an HPI-I if one is present in the eHealth Dispense Record Producer, otherwise it **SHALL** have a value that identifies the dispenser (person) and the value **SHALL NOT** be a nullFlavor.

Notes:

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 Dispense Record, the document author is the dispenser.

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 Dispense Item narrative block

Conformance to the PCEHR Dispense 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 Dispense 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 Dispense Items not included in the corresponding encoded entry.

1 Information in a narrative block **SHALL NOT** contain information about a Dispense Item not listed in the corresponding encoded section.

3.2.9 My Health Record version number

The *PCEHR Dispense 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 Dispense Record setId **SHALL** be present.

2 The eHealth Dispense Record version number **SHALL** be provided in the /ClinicalDocument/versionNumber header element.

3.2.10 Superseded document typeCode

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

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

1 If the eHealth Dispense Record supersedes a previously created eHealth Dispense Record, the eHealth Dispense 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 Dispense 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 Dispense Item > 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 Dispense Records.

1 An eHealth Dispense Record Producer **SHALL NOT** include clinical information in eHealth Dispense 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 Dispense 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 Dispense 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

The objects of conformance requirements include:

1 eHealth Dispense Records MAY be consumed by:

- a clinical information systems;
- b CSP systems;
- c registered consumer portals;
- d registered provider portals;
- e registered repositories; and
- f the My Health Record system.

3.3.2 Clinical terminology

1 If a clinical term from an eHealth Dispense 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
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 Dispense 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 *My Health Record 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.
MAY	When appearing in a conformance requirement, the verb **MAY** indicates an optional requirement.
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].
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].

Term	Meaning
producer	In this document, 'producer' refers to a software system that creates eHealth Dispense Records in CDA format.
registered consumer Portal	A third-party[1] 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.
SHALL	When appearing in a conformance requirement, the verb **SHALL** indicates a mandatory requirement. Its negative form **SHALL NOT** indicates a prohibition.

[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

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

[COM2012] *My Health Records Act 2012*, Australian Government ComLaw, 2012

[HL72010] Health Level Seven, Inc., January 2010, HL7 V3 RIM, *Data types and Vocabulary*

[NEHTA2012a] *PCEHR Dispense Record Structured Content Specification*, version 1.0, NEHTA, 9 May 2013

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https://developer.digitalhealth.gov.au/resources/pcehr-dispense-record-cda-implementation-guide-v1-0

[NEHTA2012e] *Conformance Requirements for Clinical Information Systems Connecting to the PCEHR System*, Version 1.5, NEHTA, 6 September 2012

[NEHTA2013] *Common Conformance Profile for Clinical Documents*, Version 1.4, NEHTA, 2013

[NEHTA2014] *Use of Healthcare Identifiers in Health Software Systems – Software Conformance Requirements*, Version 3.1, NEHTA, 31 October 2014