PCEHR Conformance Profile for PCEHR Dispense Record Clinical Documents

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Approved for external use

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Version history

Version	Date	Comments
1.0	23 Jan 2013	Approved for external release.
1.1	9 May 2013	The requirements for digital signatures were modified.
1.2	9 Oct 2013	See Change Log in Appendix A.

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1 Introduction

1.1 Purpose

This document summarises the requirements for Producers and Consumers of PCEHR Dispense Record clinical documents.

As well as listing requirements for clinical information systems that connect directly to the PCEHR system, this document includes requirements for clinical information systems that upload dispense records to the PCEHR via an intermediary system such as a contracted service provider or registered repository.

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

1.2 Scope

The scope of this conformance profile is the use of PCEHR Dispense Record clinical documents in the context of the national infrastructure of the PCEHR System.

1.3 Derivation

This conformance profile has been strictly derived from the following sources:

- The structured content specification and CDA implementation guides for PCEHR Dispense Record.

1.4 Intended audience

The intended audience includes the following organisations:

- Healthcare providers;
- Software vendors;
- Developers of health software systems; and
- Software test laboratories.

1.5 Contact details

Any comments or feedback should be sent to: help@nehta.gov.au.

2 Abbreviations and terminology

AMT	Australian Medicines Terminology
CDA	Clinical Document Architecture; an XML-based markup 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 PCEHR Dispense Records.
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 *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.
HL7	Health Level 7
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 PCEHR 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.
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].
PCEHR	personally controlled electronic health record
PCEHR participant	A healthcare provider organisation, repository operator, portal operator, or contract service provider that has been registered with the PCEHR system operator as a participant in the PCEHR system [COM2012].

PBS	Pharmaceutical Benefits Scheme
Producer	In this document, 'producer' refers to a software system that creates PCEHR Dispense Records in CDA format.
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 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
SHOULD	When appearing in a conformance requirement, the verb **SHOULD** indicates a recommendation. Its negative form **SHOULD NOT** indicates an option that is not recommended.

[1] 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 the national PCEHR system are not registered consumer or registered provider portals.

3 Conformance requirements for PCEHR Dispense Record

This section describes conformance requirements specific to PCEHR 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 a PCEHR 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 PCEHR 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. PCEHR Dispense Records **MAY** be produced by:
   - Clinical information systems;
   - CSP systems; and
   - Registered repositories.
2. PCEHR Dispense Records **SHALL NOT** be produced by:
   - Registered consumer portals;
   - Registered provider portals; or
   - The PCEHR system.

3.2.2 Conformance levels

1. A PCEHR Dispense Record sent to the PCEHR 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].
2. If conformance to level 3B requirements is claimed, the Therapeutic Good Identification field **SHALL** contain either PBS Item codes, or AMT version 2 codes, or both.

Note: Both PBS and AMT codes are included in the *Therapeutic Good Identification field when the software supports mapping between PBS and AMT. In this case the 'translation' attribute is present.*

3.2.3 Clinical terminology

1. If a code and code system is used as the primary value of the Therapeutic Good Identification field, the software **SHALL** only use PBS Code (from the PBS Schedule), or AMT version 2.
2. In a PCEHR Dispense Record, 'Dispense Item > Therapeutic Good Identification' **SHALL** include the originalText.

3.2.4 Clinical information system uploading to the PCEHR 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 PCEHR Dispense Records, or removal of a PCEHR 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 [NEHTA2012c] as follows:
    a. UC.CIS.001 (check if an advertised PCEHR 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 [NEHTA2012c] states they apply to clinical information systems accessing the PCEHR system, they are extended here to also apply to clinical information systems sending proprietary dispense records to an intermediary system for transformation into PCEHR 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 PCEHR 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.

    Note: a) Requirements for the validation of healthcare identifiers are stated in the requirements for clinical information systems [NEHTA2012c], including those making the validation of an IHI mandatory. Validation of HPI-I and HPI-O is mandatory only if they are manually entered into the clinical information system [NEHTA2012d, requirements 10038 and 10040], otherwise validation of HPI-I and HPI-O prior to creating a dispense record is optional.

    b) An intermediary system may not validate healthcare identifiers, so this validation must be performed by clinical information systems accessing the intermediary system.

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 PCEHR is determined during the episode of care (i.e. during the healthcare consumer 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 PCEHR participant.

4. The clinical information system **SHALL** set the default dispense item consent information by obtaining from the intermediary system the consent settings for the most recent dispense item, or the prescription item if the last dispense item is not available. Information about the prescription item, last dispense item, and the doesPCEHRExist call **SHALL** be used as follows:

   a. If a previous dispense item for the prescription has been obtained from the intermediary system and if the consent setting for the most recent dispense item is not 'Consent Not Indicated', then the clinical information system **SHALL** set the default consent setting for the new dispense item to be the same as the consent setting for the most recent dispense item.

   b. If the clinical information system could not obtain a previous dispense item from the intermediary system then the clinical information system **SHALL** obtain the corresponding prescription item. If the consent setting for the prescription item is not 'Consent Not Indicated', then then the clinical information system **SHALL** set the default consent setting for the dispense item to be the same as the consent setting for the prescription item.

   c. If the prescription item or a previous dispense item could not be obtained from the intermediary system or if the consent setting for both was 'Consent Not Indicated', then the clinical information system **SHALL** determine the default dispense item consent setting based on the returned status of the doesPCEHRExist call:

      i. If the PCEHR is found to exist, the default dispense item consent **SHALL** be set to 'Consent Indicated'; or

      ii. If the PCEHR is not found, the default dispense item consent status **SHALL** be 'Consent Not Indicated'; or

      iii. If the attempt to find the PCEHR returns an error state, the default dispense item consent status **SHALL** be 'Consent Not Indicated'.

   Note: If the healthcare consumer has a non-advertised PCEHR, the doesPCEHRExist will indicate the PCEHR does not exist.

5. When sending a record of a new dispense 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 PCEHR, in which case the dispense item consent status **SHALL** be set to 'Consent Indicated'; or

b. The healthcare consumer or healthcare provider withdraws consent for a dispense item being uploaded to the PCEHR, in which case the dispense item consent status **SHALL** be '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 PCEHR, and **SHALL NOT** allow these to be changed by the user.

3.2.5 Uploading a PCEHR Dispense Record to a PCEHR

1. If the dispensing organisation is a PCEHR participant and consent has not been withdrawn, the PCEHR Dispense Record **SHALL** be uploaded to a PCEHR. Otherwise, the PCEHR Dispense Record **SHALL NOT** be uploaded to a PCEHR.

   Notes: a) Consent may be withdrawn either because the healthcare consumer has withdrawn their consent or because the healthcare provider has chosen to not upload the PCEHR Dispense Record to the PCEHR.

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

2. If the PCEHR Dispense Record Producer transforms a proprietary dispense record into a PCEHR Dispense Record, the Producer **SHALL** upload the new PCEHR Dispense Record to a PCEHR if the dispense item consent status is 'Consent Indicated' and the dispensing organisation is a PCEHR participant. Otherwise, the PCEHR Dispense Record Producer **SHALL NOT** upload the PCEHR Dispense Record to any PCEHR.

3.2.6 Revision to a PCEHR Dispense Record

1. A PCEHR Dispense Record Producer **SHALL** supersede a previously-uploaded PCEHR Dispense Record when there is a change or error in the data used to create the originally-uploaded PCEHR Dispense Record.
2. If the supersede operation fails, the PCEHR Dispense Record Producer **SHALL** remove the previously-uploaded PCEHR Dispense Record.

   Note: This requirement overrides requirements 017839 and 019042 listed in the Conformance Requirements for Clinical Information Systems Connecting to the PCEHR System *[NEHTA2012c].*

3.2.7 Temporary relaxation of 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 Dispenser > Participant > Entity Identifier **SHALL** be an HPI-I if one is present in the PCEHR 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 a PCEHR Dispense Record the document author is the dispenser.*

b) The relaxation is only available to specific healthcare provider organisations, at the discretion of the PCEHR 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 a PCEHR Dispense Record is used by the PCEHR 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 PCEHR Dispense Record unique instance identifier, setId and version number

The *PCEHR Dispense Record CDA Implementation Guide* [NEHTA2012b] provides information about the document identifiers without mandating the type of identifiers to be used. The identifier type is specified here.

1. The PCEHR Dispense Record unique instance identifier **SHALL** be provided as a universally unique identifier (UUID) value.
2. The PCEHR Dispense Record unique instance identifier UUID **SHALL** be encoded in canonical form2 as the value of the root attribute of the /ClinicalDocument/id header element with no extension attribute.
3. The PCEHR Dispense Record setId **SHALL** be present and provided as a UUID value.
4. The PCEHR Dispense Record setId UUID value **SHALL** be encoded in canonical form2 as the value of the root attribute in the /ClinicalDocument/setId header element, and with no extension attribute.
5. The PCEHR Dispense Record version number **SHALL** be provided in the /ClinicalDocument/versionNumber header element.

[2] The UUID canonical form has 32 alphanumeric characters and four hyphens using lower case alphabetic characters, in the form 8-4-4-4-12 for a total of 36 characters. For example, f81d4fae-7dec-11d0-a765-00a0c91e6bf6.

3.2.10 Superseded document typeCode

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

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

3.2.11 PBS item codes

The PCEHR system uses the atomic data in the PCEHR Dispense Record to construct a PCEHR Prescription and Dispense View. This requires the Therapeutic Good Identification values coded as PBS item codes to have at least six characters. Also:

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 notes that, by default, clinical documents may include additional data elements. A requirement is included here to disallow additional data elements in the structured data for PCEHR Dispense Records.

1. A PCEHR Dispense Record Producer **SHALL NOT** include data elements in PCEHR Dispense Record structured data that are not listed in the CDA implementation guide.
2. A PCEHR Dispense Record Producer **MAY** include additional data elements which are not specified in the CDA implementation guide in the narrative block for the Dispense Item section of a PCEHR Dispense Record.

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 *PCEHR Dispense Record Structured Content Specification*, or *PCEHR Dispense Record CDA Implementation Guide*, **SHALL** be present without any nullFlavor attribute. Additionally, a value **SHALL** be provided with the exception of data elements for which the *PCEHR Dispense Record Structured Content Specification*, the *PCEHR Dispense Record CDA Implementation Guide*, or the conformance profile explicitly state that a nullFlavour is allowed.

3.3 Conformance requirements for Consumers

3.3.1 Objects of conformance

The objects of conformance requirements include:

1. PCEHR Dispense Records **MAY** be consumed by:
   - Clinical information systems;
   - CSP systems;
   - Registered consumer portals;
   - Registered provider portals;
   - Registered repositories; and
   - The PCEHR system.

3.3.2 Clinical terminology

1. If a clinical term from a PCEHR Dispense Record is transferred into some other form or document, the value of the originalText attribute **SHALL** be maintained.

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

Appendix A: Change log

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

Changes from Version 1.1 (9 May 2013) to Version 1.2 (9 Oct 2013)

ID	Section	Change detail	Rationale
1	all	Requirements for dispense record have been moved from the conformance profile for PCEHR Prescription Record and PCEHR Dispense Record into this document.	Separating the prescription record and dispense record requirements improves the clarity of the conformance profile.
2		The digital signature requirement was removed	Digital signature requirements are now in the *Common Conformance Profile for Clinical Documents*.

References

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[COM2012] *Personally Controlled Electronic Health Records Act 2012*, Australian Government ComLaw, 2012.

[HL72010] Health Level Seven, Inc., January 2010, HL7 V3 RIM, *Data types and Vocabulary*, http://www.hl7.org/memonly/downloads/v3edition.cfm

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http://www.nehta.gov.au/implementation-resources/clinical-documents/EP-1323-2013/NEHTA-0928-2013

[NEHTA2012b] *PCEHR Dispense Record CDA Implementation Guide*, NEHTA, 2012

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[NEHTA2012d] *Use of Healthcare Identifiers in Health Software Systems, Software Conformance Requirements*, Version 2.0, NEHTA, 22 October 2012

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

http://www.nehta.gov.au/implementation-resources/clinical-documents/EP-1094-2011/NEHTA-1446-2013