PCEHR Conformance Profile

PCEHR Prescription Record and PCEHR Dispense Record

Version 1.1

9 May 2013

Approved for External Release

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Document information

Version	Date	Comments
1.0	23 Jan 2013	Approved for external release.
1.1	9 May 2013	Modified requirements for digital signatures.

1 Introduction

1.1 Purpose

This document summarises the requirements for producers and consumers of the PCEHR Prescription Record and PCEHR Dispense Record clinical documents.

This document lists the specific conformance requirements for the PCEHR Prescription Record and PCEHR Dispense Record clinical documents that are in addition to the Common Conformance Profile for Clinical Documents [NEHTA2012a].

1.2 Scope

The scope of this conformance profile is the use of the PCEHR Prescription Record and PCEHR Dispense Record clinical documents in the context of the National infrastructure of the PCEHR System, that is, in a "point-to-share" environment.

1.3 Derivation

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

1. The structured content specification and CDA implementation guides for PCEHR Prescription Record and PCEHR Dispense Record;
2. Agreement on conformance levels;
3. Any agreed variations to the structured content specification and CDA implementation guides.

1.4 Intended audience

The intended audience includes the following organisations:

- Healthcare providers;
- Vendors and developers of connecting systems; and
- Software test laboratories.

1.5 Contact details

Any comments or feedback should be sent to: nehtasupport@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 information system	Within the context of the PCEHR programme, a clinical information system (CIS) is defined as a system that may deal with the collection, storage, retrieval, communication, or 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 PCEHR Prescription Records or PCEHR Dispense Records.
CSP	contracted service provider
HL7	Healthcare Level 7
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
PBS	Pharmaceutical Benefits Scheme
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[1] portal used by healthcare providers to access information on the PCEHR System.
registered repository	A third-party[1] repository used to store clinical documents and other clinical data that connects to the PCEHR System.
may	This verb **may** when appearing in a conformance requirement indicates an optional requirement.
producer	In this document 'producer' refers to a software system that has the role of being a producer of PCEHR Prescription Records or PCEHR Dispense Records.
shall	This verb **shall** when appearing in a conformance requirement indicates a mandatory requirement. Its negative form **shall not** indicates a prohibition
should	The verb **should** when appearing in a conformance requirement indicates a recommendation. Its negative form **should not** indicates an option that should not be supported.

[1] Third-party refers to a software system developed independently of the national PCEHR System and intended to connect to the national PCEHR System.

3 Conformance requirements

This section describes conformance requirements specific to PCEHR Prescription Record and PCEHR Dispense Record.

3.1 Relevant specifications

Relevant specifications are listed in Table 3.1.

Table 3.1: Specifications for the PCEHR Prescription Record and PCEHR Dispense Record

Specification	Notes
PCEHR Prescription Record Structured Content Specification [NEHTA2013b]	Specifies the data elements and constrained values for a PCEHR Prescription Record at a logical level.
PCEHR Prescription Record CDA Implementation Guide [NEHTA2013c]	Specifies the mapping from the structured content specification into a document using an HL7 CDA structure.
PCEHR Dispense Record Structured Content Specification [NEHTA2013d]	Specifies the data elements and constrained values for a PCEHR Dispense Record at a logical level.
PCEHR Dispense Record CDA Implementation Guide [NEHTA2013e]	Specifies the mapping from the structured content specification into a document using an HL7 CDA structure.

3.2 Conformance requirements for producers

3.2.1 Objects of conformance

The objects of conformance requirements include:

1. PCEHR Prescription Records and PCEHR Dispense Records **may** be produced by clinical information systems or software operated by a registered repository provider to provide services for healthcare provider organisations.

   Note: It is expected the registered repository providers that produce PCEHR Prescription Records and PCEHR Dispense Records will be operators of Prescription Exchange Services.

2. PCEHR Prescription Records and PCEHR Dispense Records **shall not** be produced by:
   - registered consumer portals;
   - registered provider portals;
   - contracted service providers or
   - the PCEHR System.
3. Software that produces PCEHR Prescription Records or PCEHR Dispense Records **shall** conform to the mandatory requirements for clinical document producers listed in the Common Conformance Profile for Clinical Documents [NEHTA2012a], including the common PCEHR conformance requirements.

4. If the software producing PCEHR Prescription Records or PCEHR Dispense Records is a clinical information system (CIS), the software **shall** conform to the mandatory requirements for the role of a CIS Producer, described in the conformance requirements for clinical information systems accessing the PCEHR System [NEHTA2012f].

3.2.2 Conformance levels

The only allowed level of CDA conformance for PCEHR Prescription Records and PCEHR Dispense Records **shall** be CDA level 3A [NEHTA2012a].

3.2.3 Digital signature

1. PCEHR Prescription Records and PCEHR Dispense Records **shall** be digitally signed using the supplying organisation's digital credential issued by a certificate authority identified by the PCEHR System Operator.
2. If PCEHR Prescription Records and PCEHR Dispense Records are produced by software operated by a registered repository provider, the digital signatures of the PCEHR Prescription Records and the PCEHR Dispense Records **shall not** identify an approver.

   Note: This modifies requirement M 29 in the CDA Package specification [NEHTA2011]. The rationale is that software operated by a registered repository provider automatically transforms prescription and dispense records from a proprietary format into HL7 CDA format and there is no individual (person) that approves the product of this transformation.

   The following XML fragment is an example of an approver data element that does not identify an approver:

```
<q1:approver>
    <q1:personId>
        http://ns.electronichealth.net.au/id/null/person/1.0
    </q1:personId>
    <q1:personName>
        <q1:familyName>NA</q1:familyName>
    </q1:personName>
</q1:approver>
```

   This modification to CDA Package requirement M 29 [NEHTA2011] does not apply to PCEHR Prescription Records and PCEHR Dispense Records produced by a clinical information system.

3.2.4 Additional requirements

1. If a code and code system is used as the primary value or a translation 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 Prescription Record, 'Prescription Item (MEDICATION INSTRUCTION) > Therapeutic Good Identification' **shall** include the originalText.
3. In a PCEHR Dispense Record, 'Dispense Item > Therapeutic Good Identification' **shall** include the originalText.

3.3 Conformance requirements for consumers

3.3.1 Objects of conformance

The objects of conformance requirements include:

1. PCEHR Prescription Records and PCEHR Dispense Records **may** be consumed by:
   - clinical information systems;
   - registered consumer portals;
   - registered provider portals and
   - the PCEHR System.
2. PCEHR Prescription Records and PCEHR Dispense Records **shall not** be consumed by Registered Repositories.

   Note: National infrastructure of the PCEHR System will be a consumer of PCEHR Prescription Records and PCEHR Dispense Records.
3. Software that consumes PCEHR Prescription Records or PCEHR Dispense Records **shall** conform to the mandatory requirements for clinical document consumers listed in the Common Conformance Profile for Clinical Documents [NEHTA2012a], including the common PCEHR conformance requirements.
4. If the software that consumes PCEHR Prescription Records or PCEHR Dispense Records is a clinical information system, the software **shall** conform to the mandatory requirements for the role of a CIS Consumer, described in the conformance requirements for clinical information systems accessing the PCEHR System [NEHTA2012f].

3.3.2 Additional requirements

1. If a clinical term from a PCEHR Prescription Record or 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, persisted in a database or patient record.

Appendix A: References

This appendix lists documents that provide information for or about this document. At the time of publication, the document versions listed below were valid. However, as all documents are subject to revision, readers are encouraged to use the most recent versions of these documents.

[AS5021]	AS 5021:2005 - The language of health concept representation, Standards Australia, 2005
[HL72010]	Health Level Seven, Inc., January 2010, HL7 V3 RIM, Data types and Vocabulary, http://www.hl7.org/memonly/downloads/v3edition.cfm accessed 18 November 2009
[NEHTA2011]	CDA Package, Version 1.0, NEHTA, 30 November 2011
[NEHTA2012a]	Common Conformance Profile for Clinical Documents, Version 1.3, NEHTA, 17 May 2012
[NEHTA2013b]	PCEHR Prescription Record Structured Content Specification, v1.0, NEHTA, 9 May 2013
[NEHTA2013c]	PCEHR Prescription Record CDA Implementation Guide, v1.0, NEHTA, 9 May 2013
[NEHTA2013d]	PCEHR Dispense Record Structured Content Specification, v1.0, NEHTA, 9 May 2013
[NEHTA2013e]	PCEHR Dispense Record CDA Implementation Guide, v1.0, NEHTA, 9 May 2013
[NEHTA2012f]	Conformance Requirements for Clinical Information Systems Connecting to the PCEHR System, Version 1.5, NEHTA, 6 September 2012