nehta

Clinical Documents
Common Conformance Profile v1.6

10 April 2015

Approved for external use

Document ID: NEHTA-1850:2015

National E-Health Transition Authority

National E-Health Transition Authority Ltd
Level 25, 56 Pitt Street
Sydney, NSW 2000
Australia
www.nehta.gov.au

Acknowledgements

Council of Australian Governments

The National E-Health Transition Authority is jointly funded by the Australian Government and all State and Territory Governments.

Document information

Key information

Owner Head of Product Delivery

Contact for enquiries NEHTA Help Centre
t: 1300 901 001
e: help@nehta.gov.au

Product version history

Product version	Date	Release comments
1.0	28 Nov 2011	First published version
1.1	7 Mar 2012	See Change Log in Appendix A.
1.2	19 Mar 2012	
1.3	17 May 2012	
1.4	9 Oct 2013	
1.5	25 Sept 2014	
1.6	10 April 2015	

Table of contents

1 Introduction

1.1 Purpose

This document summarises the common requirements for software systems that are producers and consumers of clinical documents (i.e. 'producers' and 'consumers' respectively).

Clinical document producers author clinical documents for distribution to clinical document consumers.

Clinical document consumers obtain clinical documents created by clinical document producers and provide the content to healthcare providers.

This document does not list the requirements for the distribution of clinical documents between producers and consumers. There are a number of mechanisms to achieve this, such as direct exchanges between healthcare providers, and indirect exchanges, mediated by local and national shared repositories, such as the PCEHR system.

This document lists the common conformance requirements for clinical documents, which include the relevant requirements for healthcare identifiers and clinical terminology used in clinical documents.

1.2 Scope

The scope of this conformance profile is the production and consumption of clinical documents.

Types of clinical documents include, but are not limited to:

- Documents sent from one healthcare provider to another, i.e. sent provider-to-provider (P2P);
- Documents created specifically to be sent to the PCEHR system by clinical information systems, contracted service provider (CSP) systems, or consumer portals; and
- Documents produced by the Department of Human Services – Medicare.

1.3 Intended audience

The intended audience includes the following organisations:

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

2 Glossary

Term	Meaning
AMT	Australian Medicines Terminology
approver	A person responsible for approving the contents of a clinical document [NEHTA2011a]. The approver cannot be a device or organisation.
atomic attachment	An atomic attachment is a single byte stream. For example, a JPEG image (c.f. the definition of an atomic packaged attachment defined in the *CDA Package* specification [NEHTA2011a]).
Clinical Document Architecture (CDA®[1])	An XML-based markup standard intended to specify the encoding, structure and semantics of clinical documents exchanged between health software systems. Specifications for clinical documents are based on *Clinical Document Architecture, Release 2* [HL72005].
CDA® IG	Clinical Document Architecture implementation guide
CIS	clinical information system
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 [AS5021-2005]. 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 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 to the PCEHR system. (Section 5 *PCEHR Act 2012* [COM2012].)
CSP	contracted service provider
CSP system	A software system operated by a CSP that deals with information pertaining to subjects of care [AS5021-2005]. May comprise one or more applications or components. May perform some or all of the functions of a CIS.
CSP registration number	A number that uniquely identifies a CSP. The number has 16 digits, commences with '800363', and ends with a check digit derived using the Luhn algorithm [ISO7812-1], [NEHTA2014b].

[1] CDA® and HL7® are registered trademarks of Health Level Seven International.

Term	Meaning
custodian	The custodian of a clinical document is the organisation responsible for maintaining the information in the clinical document. The information maintained by the custodian may be in a propriety format, rather than CDA [HL72005].
diagnostic report	A generic term used to describe an eHealth Diagnostic Imaging Report or an eHealth Pathology Report. In a healthcare environment other types of documents may be regarded as diagnostic report but uses other than eHealth Diagnostic Imaging Report or eHealth Pathology Report are out of scope in the context of this conformance profile.
eSignature	An eSignature is included in a signed CDA® package to attest to the contents of the clinical document (and indirectly its packaged attachments) [NEHTA2011a]. An eSignature contains a digital signature and identifies the approver and signing time. In addition to the attestation it is also a mechanism to prevent forgery and to detect tampering of that assertion, or of the data being asserted.
external atomic attachment	An atomic attachment that is external to the CDA® package.
healthcare individual	A person who is the subject of care.
healthcare provider organisation	An enterprise that provides healthcare (including healthcare provided free of charge) [COM2012].
HI	Healthcare identifier: an identifier assigned to a healthcare provider (individual or organisation) or a healthcare recipient.
HL7	Health Level 7.
HPI-I	A national identifier that uniquely identifies a healthcare provider individual. The identifier has 16 digits, commences with '800361' and ends with a check digit derived using the Luhn algorithm [ISO7812-1], [NEHTA2014b].
HPI-O	A national identifier that uniquely identifies a healthcare provider organisation. The identifier has 16 digits, commences with '800362' and ends with a check digit derived using the Luhn algorithm [ISO7812-1], [NEHTA2014b].
IHI	A national identifier that uniquely identifies a healthcare recipient. The identifier has 16 digits, commences with '800360' and ends with a check digit derived using the Luhn algorithm [ISO7812-1], [NEHTA2014b].
legal authenticator	An approver who legally authenticates the accuracy of an act, for example, a staff physician who sees a patient and dictates a note, then signs it [HL72005]. A legal authenticator provides a signature.
MAY	When appearing in a conformance requirement, the verb **MAY** indicates an optional requirement.
NASH	National Authentication Service for Health
OID	Object Identifier
object identifier	An ordered list of primary integer values from the root of the international object identifier tree to a node, which unambiguously identifies that node.

Term	Meaning
packaged attachment	A packaged attachment is defined as an attachment that is external to the CDA® XML document, included in the same CDA® package as the CDA® XML document; and it is referenced appropriately (*CDA Package* specification [NEHTA2011a]).
P2P	Provider-to-provider: documents sent from one healthcare provider to another.
PCEHR	personally controlled electronic health record
PCEHR system	National eHealth infrastructure for managing records in eHealth records. The PCEHR system includes the PCEHR repository, and the national prescription and dispense repository.
PKI	Public-key infrastructure: a set of hardware, software, people, policies, and procedures to create, manage, distribute, use, store, and revoke digital certificates.
PKI certificate	A string that mathematically combines a PKI private key with the content of a message to cryptographically bind the message content to the PKI certificate associated with the private key. The PKI certificates used with clinical documents are NASH PKI certificates [DHS2013].
Producer	In this document 'producer' refers to a software system that has the role of generating and issuing conformant clinical documents suitable for use by other participants in the eHealth.
registered consumer portal	A third-party portal used by healthcare recipients to access information on the PCEHR system.
registered portal operator	A person who is the operator of an electronic interface that facilitates access to the PCEHR system; and is registered as a portal operator under section 49 of the *PCEHR Act 2012* [COM2012].
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. May store clinical documents in either a proprietary format or a CDA® format.
registered repository operator	A person who holds, or can hold, records of information included in personally controlled electronic health records for the purposes of the PCEHR system, and is registered as a repository operator under section 49 of the *PCEHR Act 2012* [COM2012].
request	A request to create a diagnostic report, initiated and generated by a healthcare provider such as a GP or a specialist.
requester	The healthcare provider individual that issued a request.
SCS	structured content specification
SHALL	When appearing in a conformance requirement, this 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** indicate an option that should not be supported.

Term	Meaning
signed CDA® package	A single compressed digital file archive containing a clinical document, optional packaged attachments and one or more eSignatures [NEHTA2011a].
SNOMED CT-AU	Systematized nomenclature of medicine clinical terms – Australia.
Standing consent	The consent provided by a healthcare individual when they agree to the creation of an eHealth record in the PCEHR system. Standing consent allows any participating healthcare provider to upload health information to a healthcare individual's eHealth record. Standing consent continues to apply unless the healthcare individual explicitly withdraws their consent.
supporting organisation	An organisation that assists in the delivery of healthcare, but is not a healthcare provider organisation. Examples are registered repository operators, and registered portal operators.
supporting organisation registration number	A number that uniquely identifies a supporting organisation. The number has 16 digits, commences with '800364', and ends with a check digit derived using the Luhn algorithm [ISO7812-1], [NEHTA2014b].
Third-party	Third-party refers to a software system developed independently of the national PCEHR system and intended to connect to the national PCEHR system.

3 Common conformance requirements for clinical documents

3.1 Introduction

Due to the similarity in structure, content and processes related to clinical documents, a number of common conformance requirements are outlined in this section that apply to all clinical documents.

Differences and additional requirements that are specific to a particular type of clinical document are expressed in separate clinical document conformance profiles.

The common conformance requirements, together with each clinical document conformance profile, are required to ensure all the conformance requirements are addressed for each clinical document.

3.2 Objects of conformance

The conformance profile for clinical documents applies to the objects in Table 1.

Table 1 Objects of conformance

Object of conformance	Examples/Description
Producer	A software system that has the role of being a producer of clinical documents.
Consumer	A software system that has the role of being a consumer of clinical documents.

The two producer and consumer roles for clinical documents may have different behavioural requirements when undertaken in certain eHealth contexts. These differences, if any, are documented in the separate clinical document conformance profiles.

3.3 Relevant specifications

The specifications listed in Table 2 provide the common software conformance requirements that support the behaviour of clinical documents.

Table 2 Relevant specifications for clinical documents

Specification	Notes
Clinical document structured content specification	Specifies the data elements and constrained values for a clinical document at a logical level. There is a structured content specification and a CDA® implementation guide for each type of clinical document.

Specification	Notes
Clinical document CDA® implementation guide	Specifies the mapping from the structured content specification into a clinical document using an HL7® CDA® structure. There is a structured content specification and a CDA® implementation guide for each type of clinical document.
PCEHR conformance profile	Specifies additional requirements for software systems related to a type of clinical document supported by the PCEHR system. There is a PCEHR conformance profile for every type of clinical document supported by the PCEHR system.
Use of Healthcare Identifiers in Health Software Systems, Software Conformance Requirements v3.1 [NEHTA2014b]	The requirements for the management and use of national healthcare identifiers.
Clinical Terminology – Guidance for Use in Healthcare Software v1.0 [NEHTA2014c]	Guidance for managing risks when implementing AMT or SNOMED CT AU in healthcare software. This guidance complements the software requirements provided by other eHealth specifications.
Clinical Terminology - Use of Medical Nomenclatures in Information Exchange v1.0 [NEHTA2014d]	Guidance for healthcare software systems that produce and consume clinical messages containing medical nomenclatures. This guidance helps software developers manage risks when developing healthcare software systems using medical nomenclatures for the purpose of supporting healthcare delivery through the exchange of clinical information.

The specifications listed in Table 3 provide the common use cases that support the behaviour of clinical documents.

Table 3 Use case specifications for clinical documents

Specification	Notes
Use of Healthcare Identifiers in Health Software Systems, Business Use Cases [NEHTA2014a]	The use cases for the management and use of national healthcare identifiers.

3.4 Conformance requirements for producers

The overall structure of a CDA-based clinical document includes a header and a body.

023706 **Conformance to requirements specific for the type of clinical document**

A clinical document producer **SHALL** conform to the requirements in the relevant structured content specification, the CDA® implementation guide, the *Common Conformance Profile for Clinical Documents*, and any specific conformance profile for the type of clinical document. Requirements in the specific conformance profile take precedence over requirements in the *Common Conformance Profile*. Requirements in the *Common Conformance Profile* take precedence over requirements in the structured content specification, and the CDA® implementation guide.

Additional Notes

a) CDA® implementation guides include a conformance clause stating that a software system must also conform to a number of other listed specifications. These include the HL7® data types specification [HL72004], the HL7® CDA® R2 specification [HL72005], the HL7® Reference Implementation Model, Release 2 [HL72010] and the *CDA Rendering Specification* [NEHTA2012a].

b) Structured content specifications (also called structured document templates) include conformance requirements in clauses titled 'Conditions of Use' and refer to other specifications, such as the *Participation Data Specification* [NEHTA2011b], that also contain conformance requirements.

c) Requirements in this document may override the requirements in the CDA® implementation guide. This is stated in the CDA® implementation guides. For example, the requirements for conformance levels 1A, 1B and 2, modify the mandatory requirements for structured data in a clinical document.

3.4.1 Header

The header is mandatory for all clinical documents.

023707 **Header format for all clinical documents**

The format of a header **SHALL** be XML.

023708 **Contain all mandatory elements**

All mandatory elements **SHALL** be present in a header.

023709 Contain all logical header elements coded in the body

All logical header elements coded in the body **SHALL** be present.

023710 Support CDA® IGs specified terminology

Each section's encoded content **SHALL** support the specified terminology in the "Vocab" column of the CDA® IGs.

3.4.2 Conformance levels

024482 Conformance levels

In addition to the CDA® header, a number of levels of CDA® conformance are defined for clinical documents in Table 4 (i.e. those that apply to the CDA® body, not including logical header components). The appropriate conformance levels and other requirements that apply to each clinical document type are specified in the separate clinical document conformance profiles.

Note: The definition of the conformance levels does not affect the mandatory elements in a CDA® header.

Table 4 Levels of CDA® conformance

CDA® level	Minimum conformance requirements	Requirements
1A	With level 1A conformance a clinical document **SHALL** consist of: i. A CDA® header in XML format; ii. A CDA® body in XML format that only includes attachment references in the narrative block.	The body **SHALL** contain only one section <section>. The section **SHALL** include a section label <title> and one narrative block <text>. The narrative block **SHALL** contain only <renderMultimedia> elements which reference attachments contained in <observationMedia> entry elements that are contained in the same section. The <observationMedia> element **SHALL** only reference local attachments that are part of the same CDA® package. The attachment **SHALL** be any of the approved file types (e.g. Adobe PDF format). The same document **MAY** be included as multiple attachments with each of a different file type.
1B	With level 1B conformance a clinical document **SHALL** consist of: i. A CDA® header in XML format; ii. A CDA® body in XML format that includes at least one section which contains a narrative block.	The body **SHALL** contain only one section <section> with a section label <title> and a narrative block <text>. The narrative block **SHALL** contain human-readable markup content.
2	With level 2 conformance a clinical document **SHALL** consist of: i. A CDA® header in XML format; ii. A CDA® body in XML format that contains mandatory sections; and iii. Mandatory sections, each containing a section label and a narrative block.	The body **SHALL** contain all sections that contain mandatory data elements (represented as narrative) as specified in the SCS and CDA® IG. Each mandatory section in the body **SHALL** contain all mandatory elements specified as "CDA Body Level 2 Data Elements" in the CDA® IG.
3A	With level 3A conformance a clinical document **SHALL** consist of: i. A CDA® header in XML format; ii. A CDA® body in XML format that contains mandatory sections; and iii. Mandatory sections, each containing a section label, a narrative block and encoded content for mandatory elements.	Requirements are the same as Level 2. In addition, each section in the body **SHALL** contain all mandatory elements specified as "CDA Body Level 3 Data Elements" in the CDA® IGs.

CDA® level	Minimum conformance requirements	Requirements
3B	With level 3B conformance a clinical document **SHALL** consist of: i. A CDA® header in XML format; ii. A CDA® body in XML format that contains mandatory sections; iii. Mandatory sections, each containing a section label, a narrative block and encoded content for mandatory elements; and iv. Specified terminologies.	Requirements are the same as Level 3A. In addition, each section's encoded content **SHALL** use the clinical terminology (e.g. AMT and SNOMED CT-AU) and codes from the Pharmaceutical Benefits Schedule and the Medicare Benefits Schedule, as specified in the "Vocab" column of the CDA® IGs.

3.4.3 Extensibility

The specifications for clinical documents define the minimum set of data elements to be supported in the clinical documents.

023722 MAY include additional data elements

A producer **MAY** include additional data elements in a clinical document structured data or narrative, but these data elements **SHALL NOT** qualify or negate any of the data elements defined in the CDA® implementation guides.

023723 Conform to the relevant requirements in the SCS and CDA® IG for structured data

The body of a level 1B, 2 or 3A clinical document **MAY** include structured data specified in the SCS and CDA® implementation guide that is mandatory for a higher level of conformance. If such data is included, it **SHALL** conform to the relevant requirements in the SCS and CDA® IG.

023724 Conform to the HL7® CDA® R2 specification for additional data

If a producer includes additional data in a clinical document which is not specified in the SCS or CDA® implementation guide, the data **SHALL** conform to the HL7® CDA® R2 specification [HL72005].

023725 No consumer obligation to handle additional elements

If the producer includes additional elements, they **SHALL** be included so that the consumer is not obliged to interpret or take any action with regard to these elements beyond that identified in the normative specifications.

3.4.4 Limitations

In some eHealth contexts, additional requirements may be applied for CDA® conformance levels. For example, the attachments to a clinical document may be restricted to a defined set of file types or file size limits, or both.

Any such limitations will be defined in the separate clinical document conformance profiles.

3.4.5 Clinical terminology

023726 **Conform to the relevant clinical terminology requirements**

Clinical document producers that insert AMT or SNOMED CT-AU terminology into a clinical document **SHALL** conform to the clinical terminology requirements in the relevant CDA® implementation guide.

3.4.6 Clinical document authoring requirements

023727 **Conform to the authoring requirements from the CDA Rendering Specification**

Clinical document producers **SHALL** conform to the authoring requirements from the *CDA Rendering Specification* [NEHTA2012a] for the creation of the clinical document.

Additional Notes

Note that some of the conformance requirements in the *CDA Rendering Specification* that are stated to be mandatory are in fact mandatory within a specific context. If that context does not apply then the requirement does not apply. For example:

- Mandatory requirements that apply to automatically generated narratives do not apply to software that does not automatically generate narratives; and
- Some mandatory requirements that apply to a document body do not apply to software that generates clinical documents with an attachment rather than data in the document body.

025254 **Prohibit specific rendering of CDA® content.**

Clinical document producers **SHALL NOT** include any content that instructs or implies a specific rendering of the CDA® content.

Additional Notes

This explicitly includes the 'xml-stylesheet' processing instruction in CDA® document XML content.

3.4.7 Legal authenticator

In the CDA® implementation guides, the name, identifier, contact details and address of the legal authenticator are optional attributes. A requirement is defined here as mandating the inclusion of the legal authenticator's name and identifier, if a legal authenticator is recorded.

023728 **Include the person's name and an entity identifier in the legalAuthenticator element**

If the clinical document legalAuthenticator element is used in the clinical document, the person's name and an entity identifier **SHALL** be included in the legalAuthenticator element, and the legalAuthenticator entity identifier value **SHALL NOT** be a nullFlavor.

3.4.8 Approver

The CDA® packaging specification [NEHTA2011a] mandates that the eSignature be used to record the name and identifier of a person that is the approver. That requirement is modified here to make it optional to record the approver in the eSignature.

023729 **Record approver in the eSignature**

The approver **MAY** be recorded in the eSignature.

023730 **The value of the personId to identify a person in the eSignature**

If an approver is to be recorded in the eSignature, the value of the personId attribute **SHALL** identify a person and the value **SHALL** consist of a domain namespace followed by an identifier that is valid for the domain namespace.

Additional Notes The following XML fragment for personId is an example when a national healthcare provider individual identifier is used:

```
<q1:personId>
http://ns.electronichealth.net.au/id/hi/hpii/1.0/8003619166667441
</q1:personId>
```

023731 **The value of the personId if approver is not recorded in the eSignature**

If the approver is not recorded in the eSignature the value of personId **SHALL** be http://ns.electronichealth.net.au/id/null/person/1.0 and the value of familyName **SHALL** be NA.

Additional Notes

The following shows 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>
```

023732 **Authenticate the person identified as the approver recorded in the eSignature**

If an approver is to be recorded in the eSignature, prior to recording the approver in the eSignature, the producer **SHALL** authenticate the person identified as the approver. The approver **SHALL NOT** be recorded in the eSignature if they cannot be authenticated.

Additional Notes

The software developer shall choose an appropriate method of authenticating the approver. An example of a suitable method may be the validation of a local username and password.

023733 **Record approver's approval of the contents of the clinical document**

If an approver is to be recorded in the eSignature, the producer **SHALL** have previously received an indication of the approver’s approval of the contents of the clinical document. If an authenticated person has not indicated their approval of the content of the clinical document, the approver **SHALL NOT** be recorded in the eSignature.

Additional Notes

As an example, the producer may render the clinical document and request the approver to select a user interface button to indicate their approval. The date and time of their approval, and the approver’s name and identifier, may be recorded in a log. Other methods of recording the act of approval may also be applied.

3.4.9 Custodian

The custodian is the organisation that is responsible for maintaining the information included in a clinical document. Custodians may be healthcare provider organisations or supporting organisations (i.e. registered repository operators, or registered portal operators).

CDA® implementation guides mandate the inclusion of a custodian, and state the name, identifier, contact details, and address as optional attributes. A requirement is defined here to mandate the inclusion of the custodian name and identifier so that users of clinical information can determine which organisation is the custodian of a clinical document.

023734 **Clinical document must include custodian organisation's name and entity identifier**

The name and entity identifier of the custodian organisation **SHALL** be recorded in the clinical document and the custodian entity identifier value **SHALL NOT** be a nullFlavor.

Additional Notes Information maintained by the custodian may be in a propriety or CDA® format. The custodian may or may not be the organisation operating a software system that produces documents in the CDA® format [HL72005].

3.4.10 Local identifier of a person

The following conformance requirements apply when a person's local identifier is included in an entity identifier element of a clinical document. The requirement applies to any type of person, such as an individual healthcare provider, a healthcare consumer, or a legal authenticator.

The following requirements apply to local identifiers that are assigned by a healthcare provider organisation. That is, a local identifier is an identifier which is not guaranteed to be globally unique. For example:

- Global identifiers include: IHI, HPI-I and HPI-O
- Local identifiers include: Medical Record Number (MRN), Medicare Number, Provider Number or The Australian Health Practitioner Regulation Agency number (AHPRA).

023876 **Local identifier details for a person in an entity identifier element**

If an entity identifier element in a clinical document includes a local identifier for a person:

a. The name of the organisation that maintains the local identifier **SHALL** be recorded as the assigningAuthorityName.

b. The root attribute of the id element **SHALL** identify the organisation that maintains the local identifier using an OID registered with the HL7 OID registry. The OID in the root attribute of the id element **SHALL** either be the registered OID or derived from an OID registered for an organisation that owns or has authority over the organisation that maintains the local identifier.

Note: the web address for the HL7 OID registry is www.hl7.org/oid/index.cfm.

c. If the person being identified is a healthcare consumer, the root attribute of the id element **SHALL** either be the OID 1.2.36.1.2001.1005.29 followed by the national healthcare identifier of the organisation that maintains the local identifier, or an OID that identifies the organisation.

d. If the person being identified is a healthcare consumer, the entity identifier element **SHALL** include a code element with attributes codeSystem="2.16.840.1.113883.12.203" and codeSystemName="Identifier Type (HL7)", and the code **SHALL** be a valid HL7 Identifier Type code that does not indicate an employee (i.e. to indicate the identifier is a local identifier rather than a national identifier).

e. If the person being identified is an individual healthcare provider or a legal authenticator, the root attribute of the id element **SHALL** either be the OID 1.2.36.1.2001.1005.41 followed by the national healthcare identifier of the organisation that maintains the local identifier, or an OID that identifies the organisation.

f. If the person being identified is an individual healthcare provider or a legal authenticator, the entity identifier element **SHALL** include a code element with attributes code="EI", codeSystem="2.16.840.1.113883.12.203" and codeSystemName="Identifier Type (HL7)", to indicate the identifier is a local employee identifier rather than a national identifier.

g. The local identifier **SHALL** be recorded as the value of the id extension attribute.

Additional Notes

Note: Examples are listed below. In the first example, the fictitious OID 2.999 is used to indicate the organisation that maintains the local identifier. In both examples the local identifier is ‘localID’.

```
<ext:asEntityIdentifier classCode="IDENT">
<ext:id root="2.999"
extension="localID" assigningAuthorityName="State Hospital" />
<ext:code code="EI" codeSystem="2.16.840.1.113883.12.203"
codeSystemName="Identifier Type (HL7)" />
</ext:asEntityIdentifier>
```

and

```
<ext:asEntityIdentifier classCode="IDENT">
<ext:id root="1.2.36.1.2001.1005.41.8003621566684455"
extension="localID" assigningAuthorityName="Good Hospital" />
<ext:code code="EI" codeSystem="2.16.840.1.113883.12.203"
codeSystemName="Identifier Type (HL7)" />
</ext:asEntityIdentifier>
```

023877 **PersonId details if a local identifier is used for the eSignature approver**

If a local identifier is used for the eSignature approver personId, the personId **SHALL** include the domain namespace of the organisation that manages the approver's local identifier, followed by the value of the local identifier.

Additional Notes

The following XML fragment for personId is an example when the local identifier is 'localID' and the organisation domain name.

```
<q1:personId>
    http://goodhospital.com.au/id/cda/userid/1.0/localID
</q1:personId>
```

3.4.11 Requirements for narrative sections

Appendix A of the CDA® implementation guides requires that all sections in a CDA® document have a text element (i.e. a narrative block). The *CDA Rendering Specification* requires that all sections in a CDA® document have a title [NEHTA2012a, requirement CDA-RS 42].

The following conformance points override and clarify the constraints for title and narrative.

025052 **Nested sections**

A section **SHALL** contain narrative unless:

- it contains sub-sections and only sub-sections; OR
- the information that would otherwise be contained in that narrative is contained in the narrative of an ancestor section.

025053 **Sections with no requirement for narrative**

The narrative for the following sections **MAY** be omitted:

- Administrative Observations; and
- a section containing a logo only.

025054 **Requirements for title element**

Sections that have either narrative or sub-sections **SHALL** have a title element, with content as fixed by the CDA® implementation guides.

Sections that have neither narrative nor sub-sections **SHOULD NOT** have a title.

3.5 Conformance requirements for consumers

024688 **Clinical document consumer conforms to Common Conformance Profile**

A clinical document consumer **SHALL** conform to the requirements in the *Common Conformance Profile for Clinical Documents*, and any specific conformance profile for the relevant type of clinical document. Requirements in the specific conformance profile take precedence over requirements in the *Common Conformance Profile*.

3.5.1 Clinical document rendering requirements

The common clinical document rendering requirements are as follows:

023738 **Conform to rendering requirements for the display of the clinical document**

Clinical document consumers **SHALL** conform to the rendering requirements from the *CDA Rendering Specification* [NEHTA2012a] for the display of the clinical document.

023739 **Capability to render all supported CDA® levels of clinical documents**

The consumer **SHALL** have the capability to render all CDA® levels of clinical documents of the type supported by the consumer.

023740 Obligation for valid additional narrative elements

If the producer has included any valid additional narrative elements (beyond the normative CDA® IG specification, but consistent with the HL7 CDA, Release 2.0 data elements [HL72005]), then the consumer **SHALL** render these narrative elements. The consumer **SHALL NOT** be obliged to interpret or take any action with regard to these additional narrative elements.

3.6 Guidance on data element cardinalities

Note: This section provides guidance on the support of data elements in health software that may be a clinical document producer or consumer. Developers of health software should note that this is guidance and not a conformance requirement.

Each data element and data group in a CDA® implementation guide and structured content specification are attributed a cardinality that falls under one of the following categories:

- Optional data elements - "0..1" or "0..Many" (also notated as "0..*"); or
- Mandatory data elements – "1..1" or "1..*".

Mandatory data elements are the minimum set of data elements that an implementation under test is expected to source or maintain and include in a clinical document.

Optional data elements are those that are not required to be included in a clinical document. For example, in some clinical circumstances, it is not required that a clinical document contains diagnostic investigations. Therefore, data elements with a cardinality "0..1" or "0..*" are those that may be optionally included by the user. A specific conformance profile may state some cases where these are mandatory for support by a producer.

Not all data elements are required to be displayed to users, and their labels may be different from those data elements used in the information requirements specification. Not all data elements require a value in each and every clinical document (e.g. items that are categorised with "0..1" or "0..*").

4 Common PCEHR conformance requirements

4.1 Introduction

Due to the similarities in structure, content, and processes related to the exchange of clinical documents with the PCEHR system, common conformance requirements are listed in this section that apply to all clinical documents sent to, and retrieved from, the PCEHR system. These conformance requirements are additional to the common conformance requirements in Section 3. That is, the common conformance requirements in Section 3 also apply to the exchange of clinical documents with the PCEHR system.

Differences and additional requirements that are specific to a particular clinical document type are expressed in separate PCEHR clinical document conformance profiles.

The common conformance requirements, together with each clinical document conformance profile, are required to ensure all the conformance requirements are addressed for each type of clinical document.

4.2 Objects of conformance

The common PCEHR conformance requirements apply to the objects described in Table 5.

Table 5 Objects of conformance

Object of conformance	Examples/Description
Clinical information system (CIS)	A system that deals with the collection, storage, retrieval, communication, or use of health-related data and information pertaining to subjects of care [AS5021-2005]. The system may comprise one or more applications or components.
CSP system	A software system operated by a contracted service provider (CSP) that deals information and knowledge pertaining to subjects of care [AS5021-2005]. The system may comprise one or more applications or components. A CSP system may perform some or all of the functions of a CIS.
Registered consumer portal	A third-party 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.

4.3 Relevant specifications

The specifications listed in Table 6 provide the common use cases that support the behaviour of clinical documents exchanged with the PCEHR system.

Table 6 PCEHR use case specifications

Specification	Notes
Clinical Information Systems Connecting to the PCEHR system: Use Cases [NEHTA2012b].	The use cases for the uploading, downloading, and removal of clinical documents from the PCEHR system, by clinical information systems.

Note: The use cases for clinical information systems also apply to CSP systems, as a CSP system provides a subset or all of the functionality of a CIS.

4.4 Conformance requirements for producers

4.4.1 Objects of conformance

The objects of conformance requirements include the following:

023873 **CIS to conform to the mandatory requirements for the role of a CIS producer**

If the software producing a clinical document is a clinical information system, the software **SHALL** conform to the mandatory requirements for the role of a CIS producer [NEHTA2012c].

023874 **CSP to conform to the mandatory requirements relevant for the scope of the CSP system**

If the software producing a clinical document is a CSP system, the software **SHALL** conform to the mandatory requirements for the role of a CIS producer [NEHTA2012c] that are relevant for the scope of the CSP system.

023875 **Conformance for uploading a clinical document to the PCEHR system**

A clinical document producer uploading a clinical document to the PCEHR system **SHALL** conform to the requirements in the relevant PCEHR conformance profile.

Additional Notes The generic requirements for a software system in the role of a producer may need to be varied for specific types of clinical documents. In this case, the PCEHR conformance profile for a type of clinical document may override the generic requirements.

4.4.2 Limitations

The clinical document's limitations requirements include the following:

023741 **MIME types allowed as attachments**

A clinical document producer **MAY** include documents of the following MIME types as attachments:

a. .gif image/gif

b. .jpg image/jpeg

c. .jpeg image/jpeg

d. .pdf application/pdf

e. .png image/png

f. .tif image/tiff

g. .tiff image/tiff

024629 **Supported filename extensions**

Only the listed filename extensions in requirements number 023741 **SHALL** be supported for attachments within CDA® packages.

024630 **Matching filename extensions**

An attachment's filename extension **SHALL** match its MIME type.

023742 **MIME types not allowed as attachments**

Documents of other MIME types **SHALL NOT** be attached to a clinical document.

023743 **Maximum size of the CDA® package**

The size of the CDA® package **SHALL NOT** be greater than 10MB.

024631 **Only text SHALL be attached inline**

Attachments referenced in the CDA® document **SHALL** reference an external package attachment file in the same CDA® package as the CDA® document. Attachments **SHALL NOT** be inlined in the CDA® document's XML content (i.e. by including base64 encoded binary data in the CDA® document).

4.4.3 PKI certificate

Clinical documents sent to the PCEHR system are sent as a signed CDA® package [NEHTA2014e], which includes a PKI certificate. Requirements for the PKI certificate are as follows.

023744 Valid NASH PKI certificate for a signed CDA® package

A signed CDA® package sent to the PCEHR system **SHALL** either contain an eSignature with a valid NASH PKI certificate for healthcare provider organisations, or contain an eSignature with a valid NASH PKI certificate for supporting organisations [DHS2013].

Additional Notes

The policy identifier within the PKI certificate identifies the certificate as a NASH PKI certificate for healthcare provider organisations or a NASH PKI certificate for supporting organisations [DHS2013]. The policy identifier for NASH PKI certificates for healthcare provider organisations is 1.2.36.174030967.1.10.1.1. The policy identifier for NASH PKI certificates for supporting organisations is 1.2.36.174030967.1.12.1.1.

4.5 Conformance requirements for consumers

The generic requirements for a software system in the role of a document consumer may need to be varied for specific types of clinical documents. In this case the PCEHR conformance profile for a type of clinical document may override the generic requirements.

023745 Software consuming a clinical document is a clinical information system

If the software consuming a clinical document is a clinical information system, the software **SHALL** conform to the mandatory requirements for the role of a CIS consumer [NEHTA2012c].

023746 Software consuming a clinical document is a CSP system

If the software consuming a clinical document is a CSP system, the software **SHALL** conform to the mandatory requirements for the role of a CIS consumer [NEHTA2012c] that are relevant for the scope of the CSP system.

023747 Conformance for downloading a clinical document from the PCEHR system

A clinical document consumer downloading a clinical document from the PCEHR system **SHALL** conform to the requirements in the PCEHR conformance profile for that type of document.

5 Common P2P conformance requirements

5.1 Introduction

Common conformance requirements are listed in this section that apply to all clinical documents sent from a software system operated by a healthcare provider or CSP, to a software system operated by another healthcare provider or CSP. This is referred to as the provider-to-provider (P2P) context.

5.2 Objects of conformance

The common P2P conformance requirements apply to the objects in Table 7.

Table 7 Objects of conformance

Object of conformance	Examples/Description
Clinical information system (CIS)	A system that deals with the collection, storage, retrieval, communication, or use of health-related data and information pertaining to subjects of care [AS5021-2005]. The system may comprise one or more applications or components.
CSP system	A software system operated by a contracted service provider (CSP) that deals with health-related data and information pertaining to subjects of care [AS5021-2005]. The system may comprise one or more applications or components. A CSP system may perform some or all of the functions of a CIS.

5.3 Conformance requirements for producers

5.3.1 PKI certificate

Clinical documents sent in the P2P context are sent as a signed CDA® package [NEHTA2011a], which includes a PKI certificate. Requirements for the PKI certificate are provided here.

023748 **Valid NASH PKI certificate for a signed CDA® package in the P2P context**

A signed CDA® package produced in the P2P context **SHALL** contain an eSignature with a valid NASH PKI certificate for healthcare provider organisations [DHS2013].

Additional Notes

a) In the P2P context a signed CDA® package may contain more than one eSignature.

b) The policy identifier within the PKI certificate identifies the certificate as a NASH PKI certificate for healthcare provider organisations [DHS2013]. The policy identifier for NASH PKI certificates for healthcare provider organisations is 1.2.36.174030967.1.10.1.1.

Appendix A Change log

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

A.1 Changes from Version 1.05 (28 Nov 2011) to Version 1.1 (7 Mar 2012)

ID	Section	Change Detail	Rationale
1	1.1	Updated Purpose to remove PCEHR specific focus	To support a wider range of clinical document contexts for use of this conformance profile
2	3.2	Updated Table 3.1 to remove PCEHR specific focus	As per ID#1
3	3.4.1	Updated Table 3.4 to refer to new HI use case	New HI use case more relevant
4	3.4.3.1	Updated Table 3.5 with more details of the CDA® Levels in relation to the CDA® IGs	Greater clarity of the CDA® Levels
5	3.4.3.2	Added additional information support CDA® extensibility for all clinical documents and other expectations	As per ID#1
6	3.4.3.3	Added new section for any additional requirements for CDA® content	As per ID#1
7	3.4.5	Added new section to explicitly refer to the Authoring requirements	As per ID#1
8	3.5.1	Updated Table 3.6 to refer to new HI use cases	New HI use cases more relevant
9	3.5.2	Added new section to explicitly refer to the Rendering requirements	As per ID#1

A.2 Changes from Version 1.1 (7 Mar 2012) to Version 1.2 (19 Mar 2012)

ID	Section	Change Detail	Rationale
1	All	An error in converting the file format MS Word to Adobe PDF affected the appearance of some items in version 1.1. This particularly affected table 3.5 which appeared twice. The format conversion error has been fixed.	No material changes were made to the document.

A.3 Changes from Version 1.2 (19 Mar 2012) to Version 1.3 (17 May 2012)

ID	Section	Change Detail	Rationale
1	1.2	The list of document types was revised	More document types are now specified and supported.
2	2	The table of terminology was updated.	More terms are now defined.
3	3.4.1 & 3.5.1	Sections on healthcare identifiers use case were deleted.	The relevant conformance assessment scheme will be used to list the HI use cases that must be supported.
4	3.4.2	The definition of level 3B was updated.	Level 3B now includes use of PBS and MBS codes when specified in the CDA® IGs.
5	3.4.2.2	The extensibility requirement on modified.	The change reflects the agreement on extensibility.
6	3.4.3	The first requirement was deleted.	The definition of level 3B is included earlier in the document.
7	3.4.4	The second point was replaced with an explanatory note.	The explanatory note provides a more detailed description.
8	3.6	The new section 3.6 was added.	This provides guidance on how to support data elements that are optional in the CDA® IGs but required by the information model stated in the Core Information Components specifications.
9	4.4.1 & 4.5.1	Sections on PCEHR CIS and consumer portal use case were deleted.	The relevant conformance assessment scheme will be used to list the use cases that must be supported.
10	4.4.2	The list of allowed attachment types was updated.	The list is now consistent with the list supported by the PCEHR system.
11	4	The new section 4 was added.	Common PCEHR conformance requirements have been moved from the PCEHR conformance profiles to this document, in section 4.
12	all	Presentation improvements have been made and typing errors corrected.	

A.4 Changes from Version 1.3 (17 May 2012) to Version 1.4 (9 Oct 2013)

ID	Section	Change Detail	Rationale
1	2	Definitions for more terms have been included.	In the last version terms were used that were not defined.
2	3.4	Section 3.4 was reorganised	The headings of sub-sections were modified for clarity.
3	3.4.2 and 3.4.5	Some text was changed for clarification.	
4	3.4.11 and 4.4.3	These sections were added.	Requirements have been defined for use when a document author is not identified by an HPI-I.
5	3.4.7, 3.4.8, 3.4.9, and 3.4.10	These sections were added.	Requirements for legal authenticator, approver and, custodian, local identifiers were added.
6	4.4.3 and 5.3.1	These sections were added.	Requirements for PKI certificates in the specific conformance profiles have been consolidated and revised.
7	4.4.1 and 4.5.1	Requirements were added stating a clinical information system must conform to the role of a CIS producer or CIS consumer.	The requirements were implied but not explicitly stated in previous versions.
8	5	This section was added.	The section is used to record requirements for the P2P context.
9	References	References were revised	Newer versions of the referenced specifications have been published.

A.5 Changes from Version 1.4 (9 Oct 2013) to Version 1.5 (25 Sep 2014)

ID	Section	Change Detail	Rationale
1	3, 4 and 5	Added requirement numbers and descriptions for all requirements	To conform to NEHTA requirements standards and to support testing.
2	3.4.2	Added missing conformance level description to CDA® level 1A and 1B	To include missing CDA® level description for the header in CDA® level 1A and 1B.
3	3.4.10	Added descriptions of various types of identifiers	To provide clarity on the types of identifiers for better understanding of the requirement.

4	4.4.2	Added requirements number 024629, 024630 and 024631	To further define limits to attachment and content of the CDA® document for security reasons.
5	Appendix B	Added appendix with requirements map to previous version	To support testing and to provide a map of the requirements number to previous versions of the document.

A.6 Changes from Version 1.5 (25 Sep 2014) to Version 1.6 (10 Apr 2015)

ID	Section	Change Detail	Rationale
1	3.4.6	Added a requirement (#025254) to prohibit specific rendering of CDA® content	Reduce the threat from potentially malicious content.
2	3.4.11	Added section 'Requirements for Narrative Sections', with 3 requirements	Allowance to not always need to provide a narrative text.

References

[AS5021-2005] Australian Standard 5021-2005: *The language of health concept representation*

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

[DHS2013] *Human Services eHealth record and NASH PKI Certificates*, 18 April 2013, available from http://www.medicareaustralia.gov.au/provider/vendors/pki/dhs-ehealth-record-and-nash-pki-certificates.jsp

[HL72004] *HL7 Version 3 Standard: Data Types - Abstract Specification*, Release 1, HL7.org, 29 November 2004,

[HL72005] *Clinical Document Architecture, Release 2*, ISO/HL7 27932:2008, 21 Apr 2005,

[HL72010] *HL7 Reference Information Model*, Release 2, HL7.org, 2010,

[ISO7812-1] *ISO/IEC 7812-1 Identification cards – Identification of issuers – Part 1: numbering system*, International Organization for Standardization, 2006,

[NEHTA2011a] *CDA Package*, Version 1.0, NEHTA, 30 November 2011, available from https://www.nehta.gov.au/implementation-resources/clinical-documents/EP-1962-2014/NEHTA-1229-2011

[NEHTA2011b] *Participation Data Specification*, Version 3.2, NEHTA, 20 July 2011, available from http://www.nehta.gov.au/implementation-resources/clinical-documents/EP-1224-2011/NEHTA-0794-2011

[NEHTA2012a] *CDA Rendering Specification: Clinical Documentation*, Version 1.0, NEHTA, 7 March 2012, available from http://www.nehta.gov.au/implementation-resources/clinical-documents/EP-1094-2011/NEHTA-1199-2012

[NEHTA2012b] *Clinical Information Systems Connecting to the PCEHR system: Use Cases,* Version 1.1, NEHTA, 6 Sep 2012, available from https://www.nehta.gov.au/implementation-resources/national-infrastructure/EP-1521-2013/NEHTA-1298-2012

[NEHTA2012c] *Clinical Information Systems Connecting to the PCEHR System, Conformance Requirements*, Version 1.5, NEHTA, 6 September 2012, available from https://www.nehta.gov.au/implementation-resources/national-infrastructure/EP-1481-2012/NEHTA-1297-2012

[NEHTA2014a] *Use of Healthcare Identifiers in Health Software Systems, Business Use Cases*, Version 3.1, NEHTA, 16 October 2014, available from https://www.nehta.gov.au/implementation-resources/national-infrastructure/EP-1826-2014/NEHTA-1733-2014

[NEHTA2014b] Use of Healthcare Identifiers in Health Software Systems, Conformance Requirements, Version 3.1, NEHTA, 31 October 2014, available from https://www.nehta.gov.au/implementation-resources/national-infrastructure/EP-1826-2014/NEHTA-1732-2014

[NEHTA2014c] *Clinical Terminology – Guidance for Use in Healthcare Software*, Version 1.0, NEHTA, 12 August 2014, available from https://www.nehta.gov.au/implementation-resources/ehealth-foundations/EP-1805-2014/NEHTA-1786-2014

[NEHTA2014d] *Clinical Terminology - Use of Medical Nomenclatures in Information Exchange*, Version 1.0, NEHTA, 12 August 2014, available from https://www.nehta.gov.au/implementation-resources/ehealth-foundations/EP-1805-2014/NEHTA-1788-2014

[NEHTA2014e] *Technical Service Specification for PCEHR Document Exchange Service Using the IHE XDS.b Platform*, Version 1.5.1, NEHTA, 31 December 2014, available from https://www.nehta.gov.au/implementation-resources/national-infrastructure/EP-1892-2014/NEHTA-1971-2014