Common Conformance Profile for Clinical Documents

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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, 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.

1.4 Contact details

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

2 Abbreviations and terminology

Term	Meaning
AMT	Australian Medicines Terminology
approver	A person that is responsible for approving the contents of a clinical document [NEHTA2011a]. The approver cannot be a device or organisation.
Clinical Document Architecture (CDA)	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]. 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*.)
CSP	contracted service provider
CSP system	A software system operated by a CSP that deals with information pertaining to subjects of care [AS5021]. 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], [NEHTA2012d].
custodian	The custodian of a clinical document is the organisation that is 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].
digital signature	Signs the clinical document inside a signed CDA package. The digital signature is contained within the eSignature.

Term	Meaning
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, identifies the approver and signing time, so in addition to the attestation it is also a mechanism to prevent forgery and to detect tampering of that assertion, and/or of the data being asserted.
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], [NEHTA2012d].
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], [NEHTA2012d].
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], [NEHTA2012d].
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.
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].

Term	Meaning
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[1] portal used by healthcare recipients to access information on the PCEHR system.
registered portal operator	A person that 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[1] 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 that 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].
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.
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.
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], [NEHTA2012d].

[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 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 described in Table 1.

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.

Table 1 Objects of conformance

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.

Specification	Notes
Clinical document structured content specification[2]	Specifies the data elements and constrained values for a clinical document at a logical level.
Clinical document CDA implementation guide[2]	Specifies the mapping from the structured content specification into a clinical document using an HL7 CDA structure.
PCEHR conformance profile[3]	Specifies additional requirements for software systems related to a type of clinical document supported by the PCEHR system.
Use of Healthcare Identifiers in Health Software Systems, Software Conformance Requirements [NEHTA2012d]	The requirements for the management and use of national healthcare identifiers.
Software Conformance Requirements for Terminology [NEHTA2013a]	The requirements for the use of terminology including Australian medicines terminology and SNOMED CT AU, including requirements for mapping propriety terminology sets to AMT or SNOMED CT-AU.

Table 2 Relevant specifications for clinical documents

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

Specification	Notes
Use of Healthcare Identifiers in Health Software Systems, Business Use Cases [NEHTA2012c]	The use cases for the management and use of national healthcare identifiers.

Table 3 Use case specifications for clinical documents

3.4 Conformance requirements for Producers

The overall structure of a CDA-based clinical document includes a Header and a Body.

1. 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.

   Notes: a) CDA implementation guides include a conformance clause stating that a software system must also conform to a number

[2] There is a structured content specification and a CDA implementation guide for each type of clinical document.

[3] There is a PCEHR conformance profile for every type of clinical document supported by the PCEHR system.

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 the Common Conformance Profile for Clinical Documents *or in a PCEHR conformance profile 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 and:

1. The format of a Header **SHALL** be XML;
2. All mandatory elements **SHALL** be present in a Header;
3. All logical Header elements coded in the Body **SHALL** be present; and
4. Each section's encoded content **SHALL** support the specified terminology in the "Vocab" column of the CDA IGs.

3.4.2 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.

CDA level	Minimum conformance requirements	Relationship to the CDA IG
1A	With level 1A conformance a clinical document **SHALL** consist of: i. A CDA body in XML format; and ii. A CDA body 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.

CDA level	Minimum conformance requirements	Relationship to the CDA IG
1B	With level 1B conformance a clinical document **SHALL** consist of: i. A CDA body in XML format; and ii. A CDA body 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; iii. A CDA body that contains mandatory sections; and iv. 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; iii. A CDA body that contains mandatory sections; and iv. 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.
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; iii. A CDA body that contains mandatory sections; iv. Mandatory sections, each containing a section label, a narrative block and encoded content for mandatory elements; and v. 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.

Table 4 Levels of CDA conformance

3.4.3 Extensibility

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

1. A Producer **MAY** include additional data elements in a clinical document structured data or narrative, but such **SHALL NOT** qualify or negate any of the data elements defined in the CDA implementation guides.
2. 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.
3. 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].
4. 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 and/or file size limits.

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

3.4.5 Clinical terminology

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

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

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.*

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.

1. 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.

1. The approver **MAY** be recorded in the eSignature.
2. 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 an identifier that is valid for the domain namespace.

   Note: 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>
```

3. 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.

   Note: 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>
```

4. 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.

   Note: 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.

5. 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.

   Note: 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 users of clinical information can determine which organisation is the custodian of a clinical document.

1. 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.

   Note: 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, and a legal authenticator.

1. 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.

Note: The root/extension combination must be unique within the organisation. For example, if the organisation maintains more than one index of healthcare consumers and an identifier in one index may be the same as an identifier within another index, then they must have different root values.

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>
```

5. 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.

Note: 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>
```

3.5 Conformance requirements for Consumers

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:

1. Clinical document Consumers **SHALL** conform to the rendering requirements from the *CDA Rendering Specification* [NEHTA2012a] for the display of the clinical document.
2. The Consumer **SHALL** have the capability to render all CDA levels of clinical documents of the type supported by the Consumer.
3. 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.

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]. 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]. 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[4] 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.

Table 5 Objects of conformance

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

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.

Table 6 PCEHR use case specifications

Note: Use cases applying to registered portals and registered repositories are under development and may be referenced in a later version of this document. 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:

1. 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 [NEHTA2012e].
2. 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 [NEHTA2012e] that are relevant for the scope of the CSP system.
3. A clinical document Producer uploading a clinical document to the PCEHR system **SHALL** conform to the requirements in the relevant PCEHR conformance profile.

   Note: 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:

1. 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
2. Documents of other MIME types **SHALL NOT** be attached to a clinical document.

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

4.4.3 PKI certificate

Clinical documents sent to the PCEHR system are sent as a signed CDA package [NEHTA2013b], which includes a PKI certificate. Requirements for the PKI certificate are as follows.

1. 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].

   Note: 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

1. 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 [NEHTA2012e].
2. 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 [NEHTA2012e] that are relevant for the scope of the CSP system.
3. 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.

Note: 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.

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 described in Table 7.

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]. 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]. The system may comprise one or more applications or components. A CSP system may perform some or all of the functions of a CIS.

Table 7 Objects of conformance

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.

1. A signed CDA package produced in the P2P context **SHALL** contain an eSignature with a valid NASH PKI Certificate for Healthcare Provider Organisations [DHS2013].

   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.

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

	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

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

	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.

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.	

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

	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 subsections 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.

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