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Clinical Documents
Common Conformance Profile

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[1] https://www.digitalhealth.gov.au/implementation-resources/clinical-documents/EP-2563-2017/DH-2564-2017

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1 Introduction

1.1 Purpose

This document summarises the common requirements for software systems that producing systems and consuming systems of clinical documents.

Clinical document producing systems author clinical documents for distribution to clinical document consuming systems.

Clinical document consuming systems obtain clinical documents created by clinical document producing systems and provide the content to healthcare providers.

This document does not list the requirements for the distribution of clinical documents between producing systems and consuming systems. 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 My Health Record 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 My Health Record 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;
- Developers and vendors of digital health systems; and
- Software test laboratories.

2 Common conformance requirements for clinical documents

2.1 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.

2.2 Objects of conformance

The conformance profile for clinical documents applies to the objects described below:

- Producing system; and
- Consuming system

The producing system and consuming system roles for clinical documents may have different behavioural requirements when undertaken in certain digital health contexts. These differences, if any, are documented in the separate clinical document conformance profiles.

2.3 Relevant specifications

The specifications listed below provide the common software conformance requirements that support the behaviour of clinical documents:

- the Structured Content Specification (SCS) for each clinical document type;
- the CDA Implementation Guide (CDA IG) for each clinical document type;
- the My Health Record Conformance Profile for each clinical document type;
- Use of Healthcare Identifiers in Health Software Systems, Software Conformance Requirements [NEHTA2014b];
- Clinical Terminology – Guidance for Use in Healthcare Software [NEHTA2014c];
- Clinical Terminology - Use of Medical Nomenclatures in Information Exchange [NEHTA2014d].

Additionally, the following specification provides the common use cases that support the behaviour of clinical documents:

- Use of Healthcare Identifiers in Health Software Systems, Business Use Cases [NEHTA2014a].

2.4 Conformance requirements for producing systems

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 producing system SHALL conform to the requirements in the relevant structured content specification, the CDA IG, 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. Similarly, requirements in the Common Conformance Profile take precedence over requirements in the structured content specification, and the CDA IG.

Additional Notes

a CDA IGs include a conformance clause stating that a software system must also conform to a number of other listed specifications. These include the HL7 Version 3 Standard: Data Types - Abstract Specification [HL72004], the HL7 Clinical Document Architecture, Release 2 specification [HL72005], the HL7 Reference Implementation Model, Release 2 [HL72010] specification, and the CDA Rendering Specification: Clinical Documentation [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 IG. For example, the requirements for conformance levels 1A, 1B and 2 each modify the mandatory requirements for structured data in a clinical document.

2.4.1 Header

The header is mandatory for all clinical documents.

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**

Any encoded content in the header SHALL support the terminology specified in the "Vocab" column of the CDA IGs.

2.4.2 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 1 (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 definitions of the conformance levels do not affect the mandatory elements in a CDA header.

Table 1 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; and ii. a CDA body that only includes attachment references in the narrative block.	The body SHALL contain only one section <section>. 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; and ii. a CDA body that includes at least one section containing a narrative block.	*The body SHALL contain at least one section <section> with a section label <title> and a narrative block <text>.* The narrative block SHALL contain human-readable mark-up content.
2	With level 2 conformance a clinical document SHALL consist of: i. a CDA header; ii. a CDA body 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 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.

CDA level	Minimum conformance requirements	Requirements
3A	With level 3A conformance a clinical document SHALL consist of: i. a CDA header; ii. a CDA body 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 those for 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; ii. a CDA body that contains mandatory sections; iii. mandatory sections, each containing a section label, a narrative block and encoded content for mandatory elements; and iv. encoded contents use codes from terminology sets specified in the CDA IG.	Requirements are the same as those for 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.

2.4.3 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 producing system MAY include additional data elements in a clinical document's structured data or narrative, but these data elements SHALL NOT qualify or negate any of the data elements defined in the CDA IGs.

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

A level 1B, 2, or 3A clinical document MAY include structured data with a higher level of conformance that is specified in the SCS and CDA IG. If such data is included, it SHALL conform to the relevant requirements in the SCS and CDA IGs.

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

If a producing system includes additional data in a clinical document that is not specified in the SCS or CDA IG, the data SHALL conform to the HL7 CDA R2 specification [HL72005].

023725 **No obligation for any consuming system to handle additional elements**

If the producing system includes additional elements, they SHALL be included so that the consuming system is able to safely ignore any additional elements that are not specified in the CDA IGs and their associated schema.

2.4.4 Limitations

In some digital health 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.

2.4.5 Clinical terminology

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

Clinical document producing systems that insert AMT or SNOMED CT-AU terminology into a clinical document SHALL conform to the clinical terminology requirements in the relevant CDA IG.

027734 **Guidance for use of clinical terminology in Healthcare Software**

The requirements in Clinical Terminology - Guidance for Use in Healthcare Software [NEHTA2014c] SHOULD be adopted.

027735 **Clinical terminology guidance for use of medical nomenclatures in information exchange**

The requirements in Clinical Terminology Guidance for use of Medical Nomenclatures in Information Exchange [NEHTA2014d] SHOULD be adopted.

2.4.6 Clinical document authoring requirements

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

Clinical document producing systems 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.

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

Clinical document producing systems 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 mandatory conformance requirements in the CDA Rendering Specification are context-specific. If that context does not apply then the corresponding mandatory requirement does not apply either. 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 containing data within the document body.

027732 **Inclusion of optional elements in clinical document**

If the software has information in a form that may be used to populate an optional data component then the software SHALL allow the inclusion of that data component in a clinical document.

Additional Notes

The data component may be omitted from a clinical document if at least one of the following conditions is true:

- The software does not have information for an optional data component;
- The information is not in a form that may be used for the data component;
- There is a clinical reason why supplying the data would be unsafe, misleading, or otherwise clinically inappropriate.

2.4.7 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.

2.4.8 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. The approver is a person responsible for approving the contents of a clinical document and cannot be a device or organisation. 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>
```

027765 **The value of the personId conforms to the Secure Message Delivery Qualified Identifiers specification**

The value of the personId attribute SHALL conform to the requirements in the Secure Message Delivery - Qualified Identifiers specification [NEHTA2010a].

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 producing system 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.

2.4.9 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].

2.4.10 Identifiers for a person issued by a Healthcare Provider Organisation

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

027737	**Recording an organisation name** The name of the organisation that maintains the identifier SHALL be recorded as the assigningAuthorityName in id element assigningAuthorityName attribute.

027738	**Organisation OID** The root attribute of the id element SHALL identify the organisation that maintains the identifier using an OID registered with the HL7 OID registry.
Additional Notes	The OID in the root attribute of the id element will either be the registered OID or derived from an OID registered for an organisation that owns or has the authority over the registration that maintains the identifier.

027736	**Value of the id extension attribute** The identifier SHALL be recorded as the value of the id element extension attribute.

023877	**PersonId details if an identifier is used for the eSignature approver** If an identifier is used for the eSignature approver personId, the personId SHALL include the domain namespace of the organisation that manages the approver's identifier, followed by the value of the identifier.

Additional Notes	The following XML fragment for personId is an example when the local identifier is 'localID' and the organisation domain name is goodhospital.com.au:
	`<q1:personId>`
	`  http://goodhospital.com.au/id/cda/userid/1.0/localID`
	`</q1:personId>`

2.4.11 Identifiers for a healthcare individual

The following conformance requirements apply when a healthcare individual identifier, issued by a healthcare provider organisation is included in an entity identifier of a clinical document. The following requirements should be read in conjunction with the requirements listed in section 2.4.10.

027789	**Root attribute for healthcare individual** If the person being identified is a healthcare individual, the root attribute of the id element SHALL either be the OID 1.2.36.1.2001.1005.29 followed by the healthcare identifier of the organisation that maintains the identifier, or an OID that identifies the organisation.
Additional Notes	The healthcare identifier of the organisation is commonly referred to as a healthcare provider identifier - organisation (HPI-O).

027790	**Entity identifier for healthcare individual** If the person being identified is a healthcare individual, the entity identifier 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 differentiate between identifiers).
Additional Notes	The following codes can be used: LR - Local Registry ID; MR - Medical record number; MRT - Temporary medical record number; PE - Living subject enterprise number; PI - Patient internal identifier; PN - Person number; PNT - Temporary living subject number; or PT - Patient external identifier.

2.4.12 Identifiers for a healthcare provider or legal authenticator

The following conformance requirements apply when a healthcare provider or legal authenticator identifier, issued by a healthcare provider organisation, is included in an entity identifier of a clinical document. The following requirements should be read in conjunction with the requirements listed in section 2.4.10.

027791	**Root attribute for individual healthcare provider or legal authenticator** 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 healthcare identifier of the organisation that maintains the identifier, or an OID that identifies the organisation.
Additional Notes	The healthcare identifier of the organisation is commonly referred to as a healthcare provider identifier - organisation (HPI-O).

027792	**Entity identifier for individual healthcare providers or legal authenticators** If the person being identified is an individual healthcare provider or a legal authenticator, the entity identifier 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.

2.4.13 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, discussed in requirement CDA-RS 42 [NEHTA2012a].

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

025052 **Nested sections**

A section SHALL contain narrative unless:

- it does not contain an <author>, <informant>, <ext:coverage2>, <subject> or <entry> element; 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
- any section containing only a logo.

025054 **Requirements for title element**

If a section contains a <text> element then the <title> element SHALL be included.

027731 **Omission of the section title**

If a narrative is not included in a section, then the corresponding section title SHOULD NOT be included.

Additional Notes The purpose of this requirement is to state that when there is no narrative block then the title for the narrative block should not be present.

2.5 Conformance requirements for consuming systems

024688 **Clinical document consuming system conforms to Common Conformance Profile**

A clinical document consuming system 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.

2.5.1 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 consuming systems 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 consuming system SHALL have the capability to render all CDA levels of clinical documents of the type supported by the consuming system.

023740 **Obligation for valid additional narrative elements**

If the producing system 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 consuming system SHALL render these narrative elements. The consuming system SHALL NOT be obliged to interpret or take any action with regard to these additional narrative elements.

2.6 Guidance on data element cardinalities

Note: This section provides guidance on the support of data elements in health software that may function as a clinical document producing system or consuming system. 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 of “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 producing system.

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..*”).

3 Common My Health Record conformance requirements

3.1 Introduction

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

Differences and additional requirements that are specific to a particular clinical document type are expressed in separate My Health Record 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.

3.2 Objects of conformance

The common My Health Record conformance requirements apply to the following objects:

- Clinical information system
- Contracted service provider system
- Registered consumer portal
- Registered provider portal
- Registered repository

3.3 Relevant specifications

The following specification provides the common use cases that support the behaviour of clinical documents exchanged with the My Health Record system.

- Clinical Information Systems Connecting to the My Health Record system: Use Cases [NEHTA2012b].

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.

3.4 Conformance requirements for producing systems

3.4.1 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 producing system**

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 producing system [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 producing system [NEHTA2012c] that are relevant for the scope of the CSP system.

023875 **Conformance for uploading a clinical document to the My Health Record system**

A clinical document producing system uploading a clinical document to the My Health Record system SHALL conform to the requirements in the relevant My Health Record conformance profile.

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

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

If an approver is to be recorded in the eSignature, the producing system 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 producing system may render the clinical document and request that the approver 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.

027745 **Non-approval of the content of a clinical document**

If an approver decided to not approve the content of a clinical document then the clinical document SHALL NOT be uploaded to the My Health Record.

3.4.2 Limitations

The clinical document's limitations requirements include the following:

023741 **MIME types allowed as attachments**

A clinical document producing system MAY include documents of the following MIME types as attachments:

a a. .gif image/gif;

b b. .jpg image/jpeg;
c c. .jpeg image/jpeg;
d d. .pdf application/pdf;
e e. .png image/png;
f f. .tif image/tiff; and
g g. .tiff image/tiff.

Additional Notes The corresponding CDA IG for the clinical document may provide instructions on how to reference attachments, but attachments are usually referenced from within the following elements: observationMedia, observation, externalDocument, externalAct, externalObservation and externalProcedure.

027766 **Compressed attachments**

A clinical document SHALL NOT include any reference to any format of compressed files.

Additional Notes Examples of compression file format are deflate, gzip, zlib, compress, bzip and z7.

027730 **PDF attachment in CDA package**

A PDF file that is an attachment to a clinical document SHOULD NOT have any of these features:

- Encryption;
- Password protection;
- Printing or copying restriction;
- Embedded fonts (as not all PDF viewers support them); or
- Restrictions on changes (i.e. changes are not allowed regardless of whether this PDF flag is set).

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 SHALL NOT be inlined in the CDA document's XML content (e.g. do not include base64 encoded binary data in the CDA document).
Additional Notes	There are internal and external forms of attachments in CDA. In the internal form, the attachment is base64 encoded and included in the CDA XML document. In the external form, the attachment is referenced using elements of the ED datatype elements. The CDA specification does not stipulate the target of the reference; it could be remote (e.g. on a web server, in a networked location, or in local storage) or packaged with the CDA XML document.

3.4.3 PKI certificate

Clinical documents sent to the My Health Record 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 My Health Record 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.

3.5 Conformance requirements for consuming systems

The generic requirements for a software system in the role of a document consuming system may need to be varied for specific types of clinical documents. In this case the My Health Record 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 consuming system [NEHTA2012c].

023746	**Software consuming a clinical document is a CSP system** If the software consuming a clinical document is a contracted service provider system, the software SHALL conform to the mandatory requirements for the role of a consuming system [NEHTA2012c] that are relevant for the scope of the CSP system.

4 Common P2P conformance requirements

4.1 Introduction

The common conformance requirements listed in this section apply to all clinical documents sent between software systems operated by any given healthcare provider or CSP. This is referred to as the P2P context.

4.2 Objects of conformance

The common P2P conformance requirements apply to the objects described below:

- Clinical information system; and
- Contracted service provider system

4.3 Conformance requirements for producing systems

4.3.1 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.
Additional Notes	a a) In the P2P context, a signed CDA package may contain more than one eSignature. b 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.

Acronyms

Acronym	Description
AMT	Australian Medicines Terminology
CDA	Clinical Document Architecture
CDA IG	clinical document architecture implementation guide
CIS	clinical information system
CSP	contracted service provider
HI	healthcare identifier
HL7	Health Level Seven
HPI-I	healthcare provider identifier - individual
HPI-O	healthcare provider identifier - organisation
IHI	individual healthcare identifier
NASH	National Authentication Service for Health
OID	object identifier
P2P	provider-to-provider
SCS	structured content specification
SNOMED CT-AU	Systematized Nomenclature of Medicine - Clinical Terms - Australia

Glossary

Term	Meaning
Australian Medicines Terminology (AMT)	AMT is systemised collection of medicines terminology that offers a standard national approach for the identification and naming of medicines which includes: medicinal product, unit of use, product pack, trade product, trade product unit of use, product pack and contains trade product pack information.
clinical document	A clinical document is a document that provides personal health information about an individual. Examples include shared health summary, event summary, discharge summary, referrals and pathology result report.
Clinical Document Architecture (CDA)	An HL7 standard intended to specify the encoding, structure and semantics of clinical documents for exchange.
clinical document architecture implementation guide (CDA IG)	A guide to implementing the logical model detailed in an SCS as an HL7 Clinical Document Architecture (CDA) Release 2 XML document. Each implementation guide contains descriptions of both constraints on the CDA and, where necessary, custom extensions to the CDA, to fulfil the requirements for Australian implementations of the SCS. The resulting CDA document can be used for the electronic exchange of health information.
clinical information system (CIS)	A system that deals with the collection, storage, retrieval, communication and optimal use of health related data, information, and knowledge. A clinical information system may provide access to information contained in an electronic health record, but it may also provide other functions such as workflow, order entry, and results reporting.
conformance	A measurement (by testing) of the adherence of an implementation to a specification or standard.
consuming system	A software system that has the role of being a consumer of clinical documents.
contracted service provider (CSP)	A third-party organisation that supplies health software as a service to healthcare organisations.
contracted service provider system	A software system operated by a contracted service provider (CSP) that deals with information pertaining to subjects of care [AS5021-2005]. The system may comprise one or more applications or components and may perform some or all of the functions of a clinical information system.
custodian	The custodian of a clinical document is the organisation responsible for maintaining the information in the clinical document.
eSignature	An eSignature is included in a signed CDA® package to attest to the contents of the clinical document (and indirectly its packaged attachments). 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.
Health Level Seven (HL7)	HL7 provides standards for the exchange, management and integration of data that supports clinical patient care and the management, delivery and evaluation of healthcare services. Specifically, HL7 creates flexible, cost effective approaches, standards, guidelines, methodologies which enable healthcare information system interoperability and sharing of electronic health records.

Term	Meaning
healthcare identifier (HI)	An identifier assigned to a healthcare provider (individual or organisation) or a healthcare individual.
healthcare individual	An individual who is, or could be, the subject of care in the context of a healthcare event.
healthcare provider identifier - individual (HPI-I)	The healthcare provider identifier for individuals (HPI-I) is a 16-digit unique number used to identify providers who deliver healthcare in the Australian healthcare setting.
healthcare provider identifier - organisation (HPI-O)	A unique 16-digit number used to identify organisations who deliver care in the Australian healthcare setting.
healthcare provider organisation	An entity, or a part of an entity, that has conducted, conducts, or will conduct, an enterprise that provides healthcare (including healthcare provided free of charge). Example: A public hospital, or a corporation that runs a medical centre.
individual healthcare identifier (IHI)	A 16-digit unique number used to identify individuals who receive care in the Australian healthcare system.
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. A legal authenticator provides a signature.
MAY	This word, or the term OPTIONAL, means that an item is truly optional. One implementer may choose to include the item because a particular implementation requires it, or because the implementer determines that it enhances the implementation while another implementer may omit the same item. An implementation which does not include a particular option must be prepared to interoperate with another implementation which does include the option, perhaps with reduced functionality. In the same vein, an implementation which does include a particular option must be prepared to interoperate with another implementation which does not include the option (except of course, for the feature the option provides). Source: Network Working Group, 1997, RFC2119 - Key words for use in RFCs to Indicate Requirement Levels
National Authentication Service for Health (NASH)	A system for verifying the authenticity of patients and professionals for the purpose of ensuring the privacy of a person's electronic health data, while enabling secure access to the data by the person's authorised health providers.
object identifier (OID)	An OID is a globally unique ISO (International Organization for Standardization) identifier.
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.
producing system	A software system that has the role of generating and issuing conformant clinical documents suitable for use by other digital health participants.
provider-to-provider (P2P)	Provider-to-provider: documents sent from one healthcare provider to another.

Term	Meaning
registered consumer portal	A third-party portal used by consumers to access information on the My Health Record system that is registered with the My Health Record system as a registered portal operator.
registered provider portal	A third-party portal used by healthcare providers to access information on the My Health Record system that is registered with the My Health Record system as a registered portal operator.
registered repository	A third-party repository used to store clinical documents and other clinical data that connects to the My Health Record system. A repository may store clinical documents in either a proprietary format or a CDA format.
SHALL	This word, or the term REQUIRED, means that the statement is an absolute requirement of the specification. Source: Network Working Group, 1997, RFC2119 - Key words for use in RFCs to Indicate Requirement Levels.
SHOULD	This word, or the term RECOMMENDED, means that there may exist valid reasons in particular circumstances to ignore a particular item, but the full implications must be understood and carefully weighed before choosing a different course. Source: Network Working Group, 1997, RFC2119 - Key words for use in RFCs to Indicate Requirement Levels.
Signed CDA(c) Package	A single compressed digital file archive containing a clinical document, optional packaged attachments and one or more eSignatures.
structured content specification (SCS)	Describes one or more templates of a structured clinical document, by specifying rigorous business and technical definitions of data that systems may need to share. Each SCS is intended to be a logical specification of the data to be persisted within, or communicated between, systems. They are also the foundation for the compliance, conformance, and declaration process.
supporting organisation	An organisation that assists in the delivery of healthcare, but is not a healthcare provider organisation. Examples are registered repository operators, registered portal operators and registered contracted service providers.
Systematized Nomenclature of Medicine - Clinical Terms - Australia (SNOMED CT-AU)	SNOMED CT-AU is the Australian extension to SNOMED CT; the integrated national release of SNOMED CT for implementation in Australian deployed clinical IT systems. SNOMED CT-AU will be the principal source of clinical coded data Australian clinical IT systems will use to allow clinicians to record, retrieve and process information in an electronic health record at the point of care.

References

[AS5021-2005]	Australian Standard 5021-2005: *The language of health concept representation,* available from http://infostore.saiglobal.com/store/PreviewDoc.aspx?saleItemID=391345.
[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.
[NEHTA2010a]	*Secure Message Delivery - Qualified Identifiers v*2.0, NEHTA, 5 March 2010, available from https://www.digitalhealth.gov.au/implementation-resources/ehealth-foundations/EP-1880-2014/NEHTA-0640-2010.
[NEHTA2011a]	*CDA Package* v1.0, NEHTA, 30 November 2011, available from https://www.digitalhealth.gov.au/implementation-resources/clinical-documents/EP-1962-2014/NEHTA-1229-2011.
[NEHTA2011b]	*Participation Data Specification* v3.2, NEHTA, 20 July 2011, available from https://www.digitalhealth.gov.au/implementation-resources/clinical-documents/EP-1224-2011/NEHTA-0794-2011.
[NEHTA2012a]	*CDA Rendering Specification:* Clinical Documentation v1.0, NEHTA, 7 March 2012, available from https://www.digitalhealth.gov.au/implementation-resources/clinical-documents/EP-1094-2011/NEHTA-1199-2012.
[NEHTA2012b]	*Clinical Information Systems Connecting to the PCEHR system: Use Cases v*1.1, NEHTA, 6 Sep 2012, available from https://www.digitalhealth.gov.au/implementation-resources/national-infrastructure/EP-1521-2013/NEHTA-1298-2012.
[NEHTA2012c]	*Clinical Information Systems Connecting to the PCEHR system, Conformance Requirements* v1.5, NEHTA, 6 September 2012, available from https://www.digitalhealth.gov.au/implementation-resources/national-infrastructure/EP-1482-2013/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.digitalhealth.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.digitalhealth.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.digitalhealth.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 https://www.healthterminologies.gov.au/ncts/#/learn?content=documentlibrary%2FNEHTA-1788-2014.
[NEHTA2014e]	*Technical Service Specification for PCEHR Document Exchange Service Using the IHE XDS.b Platform* v1.5.1, NEHTA, 31 December 2014, available from https://www.digitalhealth.gov.au/implementation-resources/national-infrastructure/EP-1892-2014/NEHTA-1971-2014.