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eHealth Pathology Report
My Health Record Conformance Profile

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1.0	23 February 2015	Initial release to early implementers
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1.1	10 March 2016	Update consent management and record keeping requirements
2.0	26 Apr 2022	The references to the old SCS & IG has been updated • Potential that the wording on wait times for path reports in the introduction section removed. • Potential that the conformance requirement relating to use of nullFlavor will need to be updated to supporting recording of reporting pathologist (noting that prohibiting use of the original support for nullFlavor for reporting pathologist is a backwards incompatible change) • Section 3.2 wording changed required to clarify that multiple reporting pathologists are allowed, and that there are two locations in the CDA document for this entity • Removal of 025066 so that recording more than one reporting pathologist is handled as per CDA-IG • Amendment of the Logical Paths in 3.2 to cover both locations of reporting pathologist

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1   Introduction

1.1   Purpose

This document summarises the requirements for producers and consumers of eHealth Pathology Reports that connect to the My Health Record[1] system.

This document lists the specific conformance requirements for eHealth Pathology Reports that are in addition to the *Clinical Documents - Common Conformance Profile* [ADHA2015a] and the generic requirements listed in the *Clinical Information Systems Connecting to the PCEHR System - Conformance Requirements* [ADHA2012a]. Together, these documents represent the complete conformance requirements for eHealth Pathology Reports.

1.2   Intended audience

The intended audience includes:

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

1.3   Scope

1.3.1   In scope

An eHealth Pathology Report is created by an authoring pathology provider and contains the pathologist's analysis of one or more test results.

An eHealth Pathology Report is a Clinical Document Architecture (CDA) document that contains a single PDF attachment that may itself contain one or more pathology test results.

The following roles may be performed by software systems:

- *eHealth Pathology Report producer* - A software system used by a pathology provider to create an eHealth Pathology Report.

- *eHealth Pathology Report consumer* - A software system that has the role of being a consumer of an eHealth Pathology Report.

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[1] Previously called the personally controlled electronic health record (PCEHR) system. Please note that referenced documents may still refer to the PCEHR system.

2   Relevant specifications

The detailed conformance requirements are listed below:

1. *Clinical Documents - Common Conformance Profile* [ADHA2015a] provides common conformance requirements that must be adhered to, unless specifically contradicted in this document.

2. *Pathology Report Structured Content Specification* [ADHA2021a] specifies the data elements and constrained values for an eHealth Pathology Report at a logical level.

3. *Pathology Report CDA Implementation Guide* [ADHA2021b] specifies the mapping from the structured content specification into a CDA document using an HL7 CDA structure.

3   Requirements for producers

023456   **Disallowed types of producers**

A producer **SHALL NOT** be a:

- registered consumer portal; or

- registered provider portal.

Priority   Mandatory

023435   **Document conformance levels**

A CDA document sent to the My Health Record system **SHALL** conform to the requirements of one, and only one, of the following conformance levels: either 3A or 3B as defined in the *Clinical Documents - Common Conformance Profile* [ADHA2015a].

Priority   Mandatory

3.1 Requirements for pathology test results

023473   **CDA document has a PDF packaged attachment**

A CDA document **SHALL** reference one, and only one, attachment that is the original diagnostic report. The report **SHALL** be a PDF packaged attachment.

Priority   Mandatory

Additional Notes   The requirement applies only to attachments that include diagnostic test results. Other types of attachments (e.g. a logo) may be included. The original diagnostic report should only be made available in the My Health Record system in PDF format to ensure that the presentation and rendering of the data is as expected by the authoring healthcare provider. The PDF file may contain details of one or more diagnostic examinations or procedures.

The PDF file is expected to be viewable by the healthcare individual and any healthcare provider that is a My Health Record participant. For example, the diagnostic report PDF files should not have any of these features:

- Encryption
- Password protection
- Printing or copying restriction
- Embedded fonts (as not all PDF viewers support them)

023651   **Consistency between information in the CDA document and PDF document**

The values of diagnostic report data elements that are present in both the CDA document and the PDF document **SHALL** be consistent.

Priority   Mandatory

Additional Notes   This is to reduce the risk that CDA data items conflict with data within the diagnostic report PDF document.

024692 **Pathology Report information which must be present and not null**

The value of the following data elements **SHALL NOT** be a nullFlavor:

- Document Author > Participant > Person or Organisation or Device > Person > Employment Detail > Employer Organisation > Organisation > Organisation Name

- Order Details > Requester > Participant > Person or Organisation of Device > Person > Person Name > Family Name

- Pathology > Pathology Test Result > Test Result Name

- Pathology > Pathology Test Result > Test Specimen Detail > Handling and Processing > Collection Datetime

- Pathology > Pathology Test Result > Diagnostic Service

- Pathology > Pathology Test Result > Overall Pathology Test Result Status

- Pathology > Related Document > Document Details > Report Identifier

- Pathology > Related Document > Document Details > Report DateTime

Priority Mandatory

Additional Notes These data elements are presented in the eHealth Pathology Report View created by the My Health Record system, so they must have an actual value rather than a nullFlavor.

Including the time in Date and Time data elements is optional. The time should only be included if it is known.

024798 **Order test results in CDA document and PDF attachment consistently**

The diagnostic report provider software **SHOULD** order the test result details in the CDA document in the same order as displayed in the report PDF document.

Priority Recommended

Additional Notes Inconsistent ordering of results within a report may confuse the user, reduce the user experience, cause results and result updates to be missed and, in extreme cases, may impact clinical decision making.

026615	**Omission of the Pathology Test Result section title**
	If a narrative is not included in a Pathology Test Result section, then the section title **SHALL NOT** be included.
Priority	Conditional
Additional Notes	The purpose of this requirement is to state that when there is no narrative block then the title for the narrative block must not be present.
	Each pathology test result is recorded in a section within the Pathology Report section of the CDA document. The *Pathology Report CDA Implementation Guide* [ADHA2014d] specifies the inclusion of a narrative block for each pathology test result section but that may be omitted using requirement 025052 in the *Clinical Document - Common Conformance Profile* [ADHA2015a].
026832	Identify the laterality using a SNOMED CT-AU code
	If the software includes a SNOMED CT-AU code to identify the anatomical location name and provides laterality information then the software SHALL include a SNOMED CT-AU code for the laterality and SHALL NOT use a nullFlavor.
Additional Notes	The code for the anatomical location is recorded in Pathology > Pathology Test Result > Specimen > Anatomical Location > Specific Location > Anatomical Location Name.
	The code for laterality is recorded in Pathology > Pathology Test Result > Specimen > Anatomical Location > Specific Location > Side.
	As the laterality code qualifies the code for the anatomical location name then if laterality information is provided the laterality information must include a SNOMED CT-AU code.
	The eHealth Pathology Report CDA Implementation Guide [ADHA2022b] states the SNOMED CT-AU reference sets that may be used for these codes.

3.2 Document author and reporting pathologist

The document author is responsible for composing the pathology report, whereas a reporting pathologist is responsible for one or more pathology test results. Therefore it is possible that the reporting pathologist may also be the document author. When there is more than one reporting pathologist, it is possible that one of them may also be named as the document author.

The information model described in the *Pathology Report Structured Content Specification* [ADHA2021a] has the following constraints:

1. It does allow multiple reporting pathologists to be recorded in the CDA document and the pathology report level

   Pathology > Reporting Pathologist

2. It allows a single reporting pathologist to be recorded for each pathology test in the pathology report

   Pathology > Pathology Test Result > Reporting Pathologist

3. It requires the composer of the document (i.e. the document author) to be one person and one person only.

Requirements are defined here to resolve these constraints.

In addition, the My Health Record System Operator has relaxed the mandatory requirement for inclusion of an HPI-I, with the relaxation being available to specific healthcare provider organisations.

023436	Identifier for document author
	The value of at least one Document Author > Participant > Entity Identifier **SHALL** be an HPI-I if one is present or can be obtained from the Healthcare Identifiers Service; otherwise at least one document author identifier **SHALL** have a value that uniquely identifies the document author, and the value **SHALL NOT** be a nullFlavor.
	The relaxation of the mandatory requirement to include an HPI-I is only available to specific healthcare provider organisations, at the discretion of the My Health Record System Operator.
Priority	Mandatory
Additional Notes	The structured content specifications and CDA implementation guides require the inclusion of an HPI-I for every document author. This requirement overrides those specifications.
	The *Clinical Documents - Common Conformance Profile* [ADHA2015a] provides requirements for the local identifiers of the type that are managed by a healthcare provider. Examples of other types of local identifiers are provided by the *Healthcare Identifier HL7 Implementation Guide* [SA2012].

025065	**When the document author is not one person**

The following values **SHALL** be used for mandatory Document Author data elements when it is not possible to name one person as the document author:

- Document Author > Role **SHALL** have the value nullFlavor="NI"

- Document Author > Participant > Entity Identifier **SHALL** be a local identifier with the value "NI" for the extension attribute

- Document Author > Participant > Person or Organisation or Device > Person > Person Name > Family Name **SHALL** have the value nullFlavor="NI".

Priority Mandatory

Additional Notes The structured content specification and CDA implementation guide require that one person is named as the document author. This modification of the specifications will not be needed when the specifications are revised to cater for the scenario where there is no single person in the role of document author.

The *Clinical Documents - Common Conformance Profile* [ADHA2015a] provides requirements for the inclusion of local identifiers.

The nullFlavor "NI" is an abbreviation for "no information" and means that no information whatsoever can be inferred.

Note that even though a person is not being named and identified as the document author, the mandatory inclusion of Employment Detail still applies. The required information in the Employment Detail includes the name and identifier of the organisation that created the CDA document. See the CDA implementation guide for a description of information that must be included in the author's Employment Detail. The mandatory inclusion of the Participation Period still applies.

023648	**Identifier for reporting pathologist**
	The value of at least one reporting pathologist entity identifier **SHALL** be an HPI-I if one is present or can be obtained from the Healthcare Identifiers Service; otherwise at least one reporting pathologist identifier **SHALL** have a value that identifies the reporting pathologist and the value **SHALL NOT** be a nullFlavor.
	This requirement does not impact any relaxation to the mandatory requirement to include an HPI-I that is available to specific healthcare provider organisations, at the discretion of the My Health Record System Operator.
Priority	Mandatory
Additional Notes	Reporting pathologists may be stored in:
	Pathology Report > Pathology > Pathology Test Result > Reporting pathologist; or
	Pathology Report > Pathology > Reporting Pathologist
	The eHealth Pathology Report structured content specification and CDA implementation guide require the inclusion of an HPI-I for every reporting pathologist. This requirement overrides those specifications
	The *Clinical Documents - Common Conformance Profile* [ADHA2015a] provides requirements for the local identifiers of the type that are managed by a healthcare provider. Examples of other types of local identifiers are provided by the *Healthcare Identifier HL7 Implementation Guide* [SA2012].

3.3 Healthcare identifier validation requirements

The My Health Record system relies on healthcare software to ensure that an IHI is correct for a healthcare individual. Therefore the default requirements applying to healthcare software accessing the My Health Record system [ADHA2012a] mandate that the software has access to the Healthcare Identifiers Service, and that the software uses an IHI only if it has been obtained or validated within a configurable period (see requirement 019100[2] in the *Clinical Information Systems Connecting to the PCEHR System - Conformance Requirements* [ADHA2012a]).

The default requirements are modified here so that software used by a diagnostic services provider need not have access to the Healthcare Identifiers Service if the software only ever

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[2] The wording of requirement 019100 states that the software must be connected to the Healthcare Identifiers Service or else obtain an IHI from another software application connected to the Healthcare Identifiers Service. That allows an IT environment to have multiple applications where one accesses the My Health Record system and another application accesses the Healthcare Identifiers Service. However, the IT environment operates within the boundary of a healthcare provider organisation.

receives electronic requests for diagnostic services. The default requirements still apply for software that may receive paper requests for diagnostic services.

024885	**Healthcare identifier received via electronic request does not require revalidation**
	If the software has no access to the Healthcare Identifiers Service, the software **MAY** use a healthcare identifier received via an electronic request without needing to revalidate the healthcare identifier.
Priority	Optional
Additional Notes	This means that conformance to requirement 019100 in the *Clinical Information Systems Connecting to the PCEHR System - Conformance Requirements* [ADHA2012a] is now optional for software that produces diagnostic reports when a healthcare identifier is contained within an electronic request.

024972	**Access to the Healthcare Identifiers Service**
	The software **MAY** have no access to the Healthcare Identifiers Service if the software only uses healthcare identifiers received via electronic requests.
Priority	Optional
Additional Notes	A standard mandatory requirement for software that accesses the My Health Record system is for the software to use the Healthcare Identifiers Service to ensure the validity of an IHI (see requirement 019100 in *Clinical Information Systems Connecting to the PCEHR System - Conformance Requirements* [ADHA2012a]).
	This requirement means that requirement 019100 is optional if the software only ever uses IHIs received via electronic requests. Software uploading a diagnostic report following the receipt of a paper request must use the Healthcare Identifiers Service for validation, as stated in requirement 019100.

3.4 Withdrawal of consent

When registering for a digital health record, the healthcare individual agrees to provide "standing consent" to information being uploaded to their digital health record by any healthcare provider participating in the My Health Record system. However, the healthcare individual may wish to withdraw consent for specific documents being uploaded to the My Health Record system. Tracking the healthcare individual's withdrawal of consent and the management of uploading documents to the My Health Record system requires the storage of some information items.

Information related to each request, report, or encounter
The following information is to be recorded in the diagnostic service provider's software for each request received, each report produced, or each healthcare encounter:

- an indication that the healthcare individual has withdrawn consent (or not) for the request, report, or healthcare encounter.

If the above information is provided to the diagnostic service provider, then the diagnostic service provider's software is required to capture that information so that withdrawn consent can be determined before uploading reports.

Information about withdrawn consent may be conveyed by a requester to a diagnostic service provider in various ways, including a paper or electronic request, or after the request is issued (e.g. over the telephone, or via electronic communication). The requirements make no assumptions about the format or content of this communication.

Information about the upload of the document
The software needs to record the following information related to each report:

- an indication that the report has been uploaded (or not) to the My Health Record system.

The diagnostic service provider may choose to prevent a report from being uploaded to the My Health Record system even when consent has been determined. The decision to not upload a report does not change the healthcare individual's withdrawal of consent status.

026757	**"Withdrawn consent" indicator**
	The software **SHALL** store a "withdrawn consent" indicator against a request, report, or healthcare encounter if the healthcare individual's consent to upload reports to their digital health record has been withdrawn.
	In the absence of any instruction or indication, the software **SHALL** indicate that consent was not withdrawn.
Priority	Mandatory
Additional Notes	The diagnostic service may be informed of withdrawn consent via an instruction included with the request or received from the healthcare individual directly. The instruction need not travel with the request and may be communicated after the request is received by the diagnostic service provider.
	The indicator may be implemented in the software via different means, including a check box on the screen, selectable code, plain text message, etc.
	This indicator defaults to "No withdrawn consent" (or equivalent) and retains that value unless the healthcare individual explicitly withdraws consent at, or after, the point of request.

026760   **"Document uploaded" indicator**

The software **SHALL** store a "document uploaded" indicator for each report to indicate documents that have been uploaded to the digital health record.

Priority   Mandatory

Additional Notes   It is important to track documents that have been uploaded to prevent a healthcare individual from withdrawing consent to a document that is already in the My Health Record system.

The indicator may be implemented in the software via different means, including a check box on the screen, selectable code, plain text message etc.

This indicator defaults to "document not uploaded" (or equivalent) and retains that value unless the report has been uploaded to the My Health Record system successfully.

026761   **Preventing uploading when consent is withdrawn**

The software **SHALL** prevent a report from being uploaded where "withdrawn consent" is indicated on the request, report, or the healthcare encounter.

Priority   Mandatory

Additional Notes   The document uploader must not upload a document when it is known that the healthcare individual has withdrawn consent.

026762	**Uploading when a digital health record exists**

The software **SHALL** permit a report to be uploaded where:

- there is no indication of withdrawn consent for the request, report, or encounter; and

- it is known that the healthcare individual has a digital health record.

Priority	Mandatory

Additional Notes	The document uploader must take steps to determine the existence of a digital health record before uploading, because attempting to upload a document to a non-existent digital health record may result in a breach of privacy. Knowledge of the digital health record can be determined via a PCEHR web service call, or the existence of the individual's digital health record may have been confirmed during a previous event and that knowledge retained in the local software.
	A document uploader is not obliged to upload every report that meets this criteria. It may be inappropriate to upload some test results and the final decision to upload to the My Health Record system is with the document uploader.

026763	**Invoking doesPCEHRexist web service**

The software **SHOULD** have the capability to determine the existence and visibility of an individual's digital health record via a doesPCEHRexist web service call.

Priority	Recommended

Additional Notes	The local software should be capable of determining the existence of the digital health record before uploading a document. Undertaking a doesPCEHRexist web service call, and receiving a response that an advertised digital health record exists, provides evidence of the existence of the record and therefore the healthcare individual's standing consent to the uploading of records to their digital health record.

026766   **Changing "Withdrawn consent" indicator**

The software **SHALL** permit the "Withdrawn consent" indicator to be updated to reflect new knowledge provided to the diagnostic service provider that the individual has withdrawn consent prior to the upload of the document.

Priority   Mandatory

Additional Notes   Indicators may need to change due to new instructions being received from the requester, the healthcare individual or other source. The indicators may also be set in error. The software must be able to update the value of the indicators accordingly.

3.5 Record keeping requirements

026625   **Record a failure to upload a diagnostic report**

The software **SHALL** record a failure to upload a diagnostic report to the My Health Record system. The information recorded **SHALL** include the report or document identifier, the error code returned by the My Health Record system and the date and time. The information recorded **SHOULD** include the requester's order identifier.

Priority   Mandatory

Additional Notes   Keeping a record of upload failures will enable the requester to enquire why a report could not be uploaded to the My Health Record system. The record is needed given that the organisation responsible for uploading the diagnostic report is not the healthcare provider organisation in contact with the healthcare individual.

There is also a requirement to keep a record of diagnostic reports successfully uploaded to the My Health Record system (see requirement 017842 in *Clinical Information Systems Connecting to the PCEHR System - Conformance Requirements* [ADHA2012a]).

026626	**Record a failure to create a diagnostic report due to healthcare identifier validation failure**
	If the software uses the Healthcare Identifiers Service to obtain or ensure the validity of an IHI or other healthcare identifier, the software **SHALL** record a failure to create a diagnostic report when the reason for the failure is an inability to obtain or validate one or more healthcare identifiers.
	The information recorded **SHALL** include the report or document identifier, the error code returned by the Healthcare Identifiers Service and the date and time the error occurred.
	The information recorded **SHOULD** include the requester's order identifier.
Priority	Conditional
Additional Notes	The reason for failure can be a predetermined value. That is, there is no requirement for a user to be able to manually enter the reason.
	The requirement applies only when there is an intention to create a diagnostic report, i.e. when the healthcare individual has consented to the report being uploaded to the My Health Record system.

026627	**Record a decision to not upload a diagnostic report**
	The software **SHALL** record a decision to not upload a diagnostic report.
	The information recorded **SHALL** include the report or document identifier, the reason for not uploading the report to the My Health Record system, and the date and time of the decision.
	The information recorded **SHOULD** include the requester's order identifier.
Priority	Mandatory
Additional Notes	A healthcare provider in an organisation that creates diagnostic reports may decide to not upload a diagnostic report to the My Health Record system even though the healthcare individual has consented to its upload (see requirement 017839 in *Clinical Information Systems Connecting to the PCEHR System - Conformance Requirements* [ADHA2012a]).
	Keeping a record of a decision to not upload the report will enable the requester to enquire why a report was not uploaded to the My Health Record system.
	The method of recording and the format of the information are not specified by this requirement. In addition, there is no requirement for a user to be able to manually enter a reason for the decision.

026628   **Record the reversal of a diagnostic service provider's decision to not upload a diagnostic report**

The software **SHOULD** record the reversal of a decision by a diagnostic service provider to not upload a diagnostic report.

The information recorded **SHOULD** include the report or document identifier, the requester's order identifier and the date and time of the reversal of the decision.

Priority   Recommended

Additional Notes   A reason for uploading a document should be provided when a document upload was initially delayed and subsequently uploaded at a later date. Recording this reason can assist in later enquiries and provide input to statistical analysis in upload rates.

There is no requirement for a user to be able to manually enter a reason for the decision.

026629   **Record the original and changed withdrawal of consent indicator values**

The software **SHOULD** record the original withdrawal of consent indicator value associated with a request, report, or healthcare encounter for diagnostic services.

The software **SHOULD** also record any change to the withdrawal of consent indicator.

The information recorded **SHOULD** include the report or document identifier, the requester's order identifier, the original and updated value of the withdrawal of consent indicator and the date and time the change of consent was captured.

Priority   Recommended

Additional Notes   Tracking the withdrawal of consent indicator values will help healthcare providers understand any changes to consent over time.

025083   **Retrievable records**

The software **SHOULD** have the capability to retrieve and display the records of:

- a failure to create or upload a diagnostic report;

- a decision, and reversal of a decision, to not upload a diagnostic report; and

- the original and changed withdrawal of consent indicator values.

Priority   Recommended

Additional Notes   Audit information may be used to compile statistical profiles on upload success rates and for other statistical analysis.

3.6   Packaging requirements

Requirements listed here extend the set of packaging requirements listed in the *CDA Package* specification [ADHA2011a] and *CDA Rendering Specification* [ADHA2012c].

024732   **External references are allowed**

A diagnostic report, including the attached PDF file, **MAY** reference an object outside of the CDA package (e.g. an external atomic attachment or a website).

Priority   Optional

Additional Notes   This requirement has the effect of overriding *CDA Rendering Specification* [ADHA2012c] requirements CDA-RS 53(g) and CDA-R5 53(j), which apply to CDA document authoring systems and disallow references to items on a network. This override is needed as a diagnostic report may include a reference to supporting information on a website.

As a diagnostic report uploaded to the My Health Record system will be available to the healthcare individual and all participant healthcare providers for an indefinite period of time, software developers should avoid using references that may become broken after the CDA document is created.

A reference to an object outside of the CDA package may be included in the diagnostic report PDF file, or the CDA document, or both. Objects outside of the CDA package are regarded as "external objects" and may be referenced according to the requirements stated in the HL7 *Clinical Document Architecture, Release 2* specification [HL72005] for external objects. For example, that specification mandates the use of <linkHtml> rather than <renderMultiMedia> to reference an external object from a narrative block.

4 Requirements for consumers

Requirements are listed here for the display and printing of a pathology report. These are additional to the existing requirements stated in the *Clinical Documents - Common Conformance Profile* [ADHA2015a] and *Clinical Information Systems Connecting to the PCEHR System - Conformance Requirements* [ADHA2012a].

The use of a pathology report view to select a pathology report for display is recommended (see the *eHealth Pathology Report View - PCEHR Conformance Profile* [ADHA2014f]).

024858	**Display the requester's order identifiers (if available)**
	The software **SHALL** display the requester's order identifier (if available) when the CDA document is rendered.
Priority	Mandatory
Additional Notes	If the requester's order identifier is known, it is recorded in the extension attribute of the inFulfillmentOf/Order/id data element.
	The effect of this requirement is to add the requester's order identifier (with XPath inFulfillmentOf/Order/id) to the table of CDA document header details that must be rendered (see Table 2 in the *CDA Rendering Specification* [ADHA2012c]).

024874	**Display the request date and time (if available)**
	The software **SHALL** display the request date and time (if available) when the CDA document is rendered.
Priority	Mandatory
Additional Notes	The date and time (if available) of the request is recorded in the ClinicalDocument/participant/time data element.
	The effect of this requirement is to add the request date and time (with XPath ClinicalDocument/participant/time) to the table of CDA document header details that must be rendered (see Table 2 in the *CDA Rendering Specification* [ADHA2012c]).

024886	**Display the diagnostic report PDF document in-line**

The software **SHOULD** display the diagnostic report PDF attachment in-line with the CDA document.

Priority	Recommended

Additional Notes	In-line rendering is a means of rendering, on a screen, an attachment (PDF document) with all or part of the CDA document on the same window or view in such a way that it appears as a single document.

This requirement overrides *CDA Rendering Specification* [ADHA2012c] requirement CDA-RS 60, which applies to CDA document rendering systems and disallows in-line rendering of attachments.

Depending on how a rendering system implements in-line rendering, other risks may need to be considered including:

1   How the PDF document is presented to viewers.

2   How the PDF document prints within the rendered CDA document.

3   How the in-line rendering is displayed on various browsers (if viewed from a web portal).

4   How the in-line rendering is displayed on various devices that may have access, including mobile devices.

5   Security considerations that an organisation may need to assess if a PDF is rendered in-line.

These considerations may result in an inability to implement in-line rendering.

025084	**Printing the PDF document**

If the software supports printing and performs in-line rendering of PDF documents, then the software **SHALL** print both the CDA document and the attached diagnostic report PDF file when the user requests the CDA document to be printed.

Priority	Conditional

Glossary

Term	Meaning
AMT	Australian Medicines Terminology
approver	A person responsible for approving the contents of a clinical document. The approver cannot be a device or organisation.
atomic attachment	An atomic attachment is a single byte stream. For example, a JPEG image.
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.
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. 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 My Health Record system on behalf of healthcare organisations. A CSP provides under a contract with the healthcare provider organisation: a) information technology services relating to the My Health Record system; or b) health information management services relating to the My Health Record system.
CSP	contracted service provider
CSP system	A software system operated by a CSP that deals with information pertaining to subjects of care. 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.
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 proprietary format, rather than CDA.

Term	Meaning
diagnostic report	A generic term used to describe an eHealth Diagnostic Imaging Report or an eHealth Pathology Report. In a healthcare environment, other types of documents may be regarded as diagnostic report, but uses other than eHealth Diagnostic Imaging Report or eHealth Pathology Report are out of scope in the context of this conformance profile.
digital signature	Signs the clinical document inside a signed CDA package. The digital signature is contained within the eSignature.
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.
external atomic attachment	An atomic attachment that is external to the CDA package.
healthcare individual	A person who is the subject of care.
healthcare provider organisation	An organisation that provides healthcare.
HI	Healthcare identifier: an identifier assigned to a healthcare provider (individual or organisation) or a healthcare recipient.
HL7	HL7 is a trademark of Health Level Seven International and is registered with the United States Patent and Trademark Office.
HPI-I	A national identifier that uniquely identifies a healthcare provider individual.
HPI-O	A national identifier that uniquely identifies a healthcare provider organisation.
IHI	A national identifier that uniquely identifies a healthcare recipient.
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	When appearing in a conformance requirement, the verb **MAY** indicates an optional requirement.
My Health Record system	National eHealth infrastructure for managing digital health records.
NASH	National Authentication Service for Health
OID	object identifier
packaged attachment	A packaged attachment is defined as an attachment that is external to the CDA XML document, included in the same CDA package as the CDA XML document, and is referenced appropriately.
P2P	Provider-to-provider: communication sent from one healthcare provider to another.

Term	Meaning
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.
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 eHealth participants.
registered consumer portal	A third-party portal used by healthcare recipients to access information on the My Health Record system.
registered portal operator	A person who is the operator of an electronic interface that facilitates access to the My Health Record system; and who is registered as a portal operator under the My Health Record *Act 2012*.
registered provider portal	A third-party portal used by healthcare providers to access information on the My Health Record system.
registered repository	A third-party repository used to store clinical documents and other clinical data that connects to the My Health Record system. May store clinical documents in either a proprietary format or a CDA format.
registered repository operator	A person who holds, or can hold, records of information included in digital health records for the purposes of the My Health Record system, and who is registered as a repository operator under the My Health Record *Act 2012*.
SCS	structured content specification
SHALL	When appearing in a conformance requirement, the verb **SHALL** indicates a mandatory requirement. Its negative form **SHALL NOT** indicates a prohibition.
SHOULD	When appearing in a conformance requirement, the verb **SHOULD** indicates a recommendation. Its negative form **SHOULD NOT** 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.
SNOMED CT-AU	Systematized nomenclature of medicine clinical terms – Australia.
	"SNOMED" and "SNOMED CT" are registered trademarks of the International Health Terminology Standards Development Organisation.
standing consent	The consent provided by a healthcare individual when they agree to the creation of a digital record in the My Health Record system. Standing consent allows any participating healthcare provider to upload health information to a healthcare individual's digital health record. Standing consent continues to apply unless the healthcare recipient explicitly withdraws their consent.

Term	Meaning
supporting organisation	An organisation that assists in the delivery of healthcare, but is not a healthcare provider organisation.
supporting organisation registration number	A number that uniquely identifies a supporting organisation.
third-party	Third-party refers to a software system developed independently of the My Health Record system and intended to connect to the national My Health Record system.

References

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

[ADHA2011a]   *CDA Package*, Version 1.0, Agency, 30 November 2011, (available from
              https://developer.digitalhealth.gov.au/specifications/clinical-documents/ep-2563-2017/nehta-
              1229-2011

[ADHA2012a]   *Clinical Information Systems Connecting to the PCEHR System - Conformance Requirements*,
              Version 1.5, Agency, 6 September 2012 (available from
              https://developer.digitalhealth.gov.au/specifications/national-infrastructure/ep-1481-2012/nehta-
              1297-2012

[ADHA2012c]   *CDA Rendering Specification: Clinical Documentation*, Version 1.0, Agency, March 2012, (available
              from https://developer.digitalhealth.gov.au/specifications/clinical-documents/ep-1818-
              2015/nehta-1199-2012).

[ADHA2014a]   *Use of Healthcare Identifiers in Health Software Systems, Software Conformance Requirements*,
              Version 3.1, Agency, 31 Oct 2014, (available from
              https://developer.digitalhealth.gov.au/specifications/national-infrastructure/ep-1826-2014/nehta-
              1732-2014).

[ADHA2014c]   *Pathology Report Structured Content Specification,* Version 1.0, Agency, December 2014 (available
              from https://developer.digitalhealth.gov.au/specifications/clinical-documents/EP-1882-
              2014/NEHTA-1413-2014).

[ADHA2022a]   Pathology Report Structured Content Specification, Version 2.0, Agency, April 2022 (available from
              https://developer.digitalhealth.gov.au/specifications/clinical-documents/ep-3533-2022/dh-3525-
              2022)

[ADHA2022b]   Pathology Report CDA Implementation Guide, Version 2.0, Agency, April 2022 (available from
              https://developer.digitalhealth.gov.au/specifications/clinical-documents/ep-3533-2022/dh-3526-
              2022)

[ADHA2014d]   *Pathology Report CDA Implementation Guide*, Version 1.0, Agency, December 2014 (available from
              https://developer.digitalhealth.gov.au/specifications/clinical-documents/EP-1882-2014/NEHTA-
              1412-2014).

[ADHA2014f]   *eHealth Pathology Report View - PCEHR Conformance Profile*, Version 1.0, Agency, 31 December
              2014 (available from https://developer.digitalhealth.gov.au/specifications/clinical-documents/ep-
              1982-2014/nehta-1973-2014)

[ADHA2015a]   *Clinical Documents - Common Conformance Profile*, Version 1.6, Agency, 2015 (available from
              https://developer.digitalhealth.gov.au/specifications/clinical-documents/ep-2395-2016/nehta-
              1850-2015)

[SA2012]   *Healthcare identifier HL7 implementation guide*, SA HB 234-2012, Standards Australia, 2012.