Australian Government
Australian Digital Health Agency

Common – Clinical Document Release Note

21 December 2017 v1.5
Approved for external use
Document ID: DH-2564:2017

Related end product identifier: EP-2563:2017

Release rationale

This release of the Common - Clinical Document end product provides developers of systems generating CDA documents with important updates of:

- Clinical Documents -Common Conformance Profile;
- Conformance Test Specification for Authoring Systems.

It also introduces a new FAQ document providing important guidance for the usage of qualifiers in structured parts of CDA™[1] documents.

Common Conformance Profile v1.7

The Common Conformance Profile has been updated to resolve a number of issues.

Conformance Test Specification for Authoring Systems v1.1

This update of the *Conformance Test Specification for Authoring Systems* includes updates to feature sets, improves the readability of the document, and addresses multiple issues raised during internal agency reviews.

FAQ Qualifiers for Clinical Information v1.0

This document provides guidance to determine whether clinical information system includes qualifiers as expected (or stated or conform to HL7 Clinical Document Architecture Release 2.0).

Template Package Directory v1.9

The updated Template Package Directory contains entries for new or updated template packages for the following document types:

- Advance Care Planning (first release)
- Australian Immunisation Register (first release)
- eHealth Diagnostic Imaging Report (replacements)
- eHealth Pathology Report (replacements)

[1] CDA is a trademark of Health Level Seven International and is registered with the United States Patent and Trademark Office.

Please refer to the Change Details section below for further details of the changes.

Package inclusions

New

Identifier	Name
DH-2594:2017	*Clinical Documents – FAQ Qualifiers for Clinical Information v1.0*

Updated (supersedes previous version)

Identifier	Name
DH-2481:2017	*Clinical Documents – Common Conformance Profile v1.7*
DH-2587:2017	*Clinical Documents - Conformance Test Specification for Authoring Systems v1.1*
DH-2564:2017	*Common – Clinical Document - Release Note v1.5 (this document)*
DH-2565:2017	*Clinical Documents – Template Package Directory v1.9*

No change

Identifier	Name
NEHTA-1229:2011	*Clinical Documents - CDA Package v1.0*
NEHTA-1199:2012	*Clinical Documents - CDA Rendering Specification v1.0*
NEHTA-1226:2011	*Clinical Documents - Clinical Package v1.0*
NEHTA-2064:2016	*Clinical Documents - Conformance Test Specification for CDA Rendering v1.4*
NEHTA-2065:2015	*Clinical Documents - Conformance Test Specification for CDA Packaging v1.5*
NEHTA-2063:2015	*Clinical Documents - Conformance Test Specification for PCEHR[2] Usability v3.0*
NEHTA-2189:2015	*Clinical Documents - Conformance Test Specification for PCEHR Views v1.0*
NEHTA-1255:2012	*Clinical Documents - FAQ Appropriate use of date and date-time values in Clinical Documents v1.0*
NEHTA-1270:2013	*Clinical Documents - FAQ Clarification on Messaging and CDA Packaging v1.4*
NEHTA-1274:2013	*Clinical Documents - FAQ Global Statements None Known v1.1*
NEHTA-1276:2013	*Clinical Documents - FAQ Hash value verification v1.0*
NEHTA-2336:2016	*Clinical Documents - FAQ OIDs for HL7 v1.1*
NEHTA-1459:2013	*Clinical Documents – FAQ Undifferentiated Pathology and Radiology Results v1.3*
NEHTA-1097:2011	*Clinical Documents - Implementation Guidance - Representing Coding in CDA Documents v1.0*

[2] Clarification: PCEHR means the My Health Record, formerly the "Personally Controlled Electronic Health Record", within the meaning of the *My Health Records Act 2012* (Cth), formerly called the *Personally Controlled Electronic Health Records Act 2012* (Cth).

Identifier	Name
DH-2267:2017	*Clinical Documents - My Health Record Usability Recommendations v1.4*
NEHTA-1328:2013	*Clinical Documents - Supplementary Notes for Implementers Relating to Clinical Document Presentation v1.0*

Removed

Identifier	Name
NEHTA-1329:2012	*Clinical Documents - Conformance Test Specification for Clinical Documents v1.2*
NEHTA-1273:2013	*Clinical Documents - FAQ Nullable Fields Guidance v1.1*

Change details

Conformance Test Specification for Authoring Systems v1.1

This version of test specification contains updates to the feature sets *Authoring Systems* (*FS-Auth*), *Narratives* (*FS-Narr*), *Data types and data groups* (*FS-Types*) and *Clinical Documents* (*FS-Doc*).

Common Conformance Profile v1.7

The Common Conformance Profile has been updated with the following inclusions:

- Provision of advice for the adoption of terminology is included;
- Producing systems now need to provide optional data if that optional data is known/available;
- Clarity around the construction of some XML has been provided;
- Complex requirements have been replaced with simpler requirements;
- Editorial corrections.

Note for implementers:

The introduction of requirement 27732 will impact software that collects and stores optional data but does not include that optional data in clinical documents at the time of authoring. Requirement 27732 stipulates that if that optional data is available, then it must be included in the clinical document and there is no option to omit that clinical data from the clinical document. Refer to requirement 27732 in the conformance profile for details.

The following changes have been implemented:

ID	Change description	Requirements affected
CCP-295	Disallow the compression of attachments within CDA packages	New: 27766
CCP-354	Clarification of CDA elements that could refer to attachments	Updated: 23741
CCP-502	Missing words added in additional notes for requirement 23877	Updated: 23877
CCP-504	Revised requirement for inclusion of elements of higher conformance levels	Updated: 23723

ID	Change description	Requirements affected
CCP-514 CCP-629 CCP-635	Convert conformance points from requirement 23876 into discrete requirements	New: 27736; 27737; 27738; 27789; 27790; 27791; 27792 Removed: 23876
CCP-518	Editorial updates	none
CCP-523	Remove redundant requirement 23707	Removed: 23707
CCP-524	Rephrased requirement for terminology usage in level 3B CDA documents	Updated: 24482
CCP-542	Modify description notes of CDA-IG	none
CCP-543	Remove redundant XML references in CDA Level 1A requirements	Updated: 24482
CCP-545	Broadening of terminology requirement to all sections of a CDA document	Updated: 23710
CCP-546	Clarification of prohibition of inline attachments	Updated: 24631
CCP-550	Revise statement re producer obligations for additional elements	Updated: 23725
CCP-559	Add requirement for personId URIs	New: 27765
CCP-560	Add constraints for attached PDF documents	New: 27730
CCP-563	Add requirement to omit section title if no section narrative provided	New: 27731
CCP-566	Remove redundant requirement 023747	Removed: 23747
CCP-584	Add requirement prohibiting the upload of unapproved documents	New: 27745
CCP-585	Add requirement mandating inclusion of optional information items if available in the software	New: 27732
CCP-617	Add reference to "Clinical Terminology Guidance for Use in Healthcare Software v1.0"	New: 27734
CCP-618	Integration of *Clinical Terminology Guidance for Use of Medical Nomenclatures in Information Exchange v1.0*	New: 27735
CCP-630	Require section title only if section text is provided	Updated: 25054

Template Package Directory v1.9

The updated Template Package Directory incorporates entries for the following new or updated template package libraries:

Document type	End product version	Template Package Library version	MHR Conformance Profile version
Advance Care Planning	1.0	1.0	1.0
Australian Immunisation Register	1.0	1.0	1.0
eHealth Diagnostic Imaging Report	1.2.2	1.1.3 (replacement)	1.1

Document type	End product version	Template Package Library version	MHR Conformance Profile version
eHealth Pathology Report	1.2.2	1.1.3 (replacement)	1.1

Template packages for eHealth Diagnostic Imaging Report and eHealth Pathology Report document types are replacements providing backwards compatible defect fixes. The template package IDs of these template packages remain unchanged.

Stakeholders

The stakeholders for this release are:

- Implementers of clinical information systems and contracted service provider systems consuming one or more of the My Health Record views generated by the My Health Record system;
- Commonwealth Department of Health; and
- National Infrastructure Operator.

Audience

The audiences for this release are:

- Implementers of clinical information systems and contracted service provider systems; and
- Senior managers and policy makers, clinical experts, health information managers, IT operations and support teams, and system integrators.

Known issues

None

Support

For further support or to provide feedback, please email help@digitalhealth.gov.au.

Future releases

Further changes may occur from time to time in accordance with customer feedback or changes to source information. Supplementary guidance may also be provided from time to time based on implementation experience from vendors.

Previous releases

Date	Version
16 June 2017	EP-2395:2017 Common – Clinical Document v1.4.4 Release note **Release rationale** This incremental release of the Common - Clinical Document end product (EP-2395:2017) introduces the new *Conformance Test Specification for Authoring Systems* and provides updates to *Clinical Documents – My Health Record Usability Recommendations*. ***Clinical Documents – Conformance Test Specification for Authoring Systems v1.0*** This conformance test specification is a significant expansion of the authoring test cases previously available to developers in the *Conformance Test Specification for CDA Rendering v1.3*, which contained test cases for authoring and rendering. This v1.3 document has been superseded by the *Conformance Test Specification for CDA Rendering v1.4* (published in January 2016) and this new *Conformance Test Specification for Authoring Systems v1.0*. The rationale for the expansion of test cases is an analysis of over 600 conformance errors found by the NEHTA CCA team between 2012 and 2015, which covered approximately 50 software development organisations. This new conformance test specification seeks to address those issues. ***Clinical Documents – My Health Record Usability Recommendations v1.4*** This document provides usability recommendations for clinical information systems authoring or rendering information contained in clinical documents and views exchanged with the My Health Record system.
19 May 2016	EP-2320:2016 Common – Clinical Document v1.4.3 Release note **Release rationale** This incremental release of the Common – Clinical Document end product provides updates to the *Clinical Documents – Template Package Directory* to include references to the following product components: • *Advance Care Document Custodian – Conformance Profile v1.0* • *Personal Health Summary – Conformance Profile v1.0* The *FAQ OIDs for HL7* has been revised to correctly show how a Medicare number may be used for an entity identifier for a subject of care. Three FAQs have been moved into this end product from the Common – Continuity of Care end product (which has been archived): • *FAQ Nullable Fields Guidance* (This FAQ answers the question: What are the nullable fields in clinical documents conformant to the CDA implementation guides?) • *FAQ Global Statements None Known* (This FAQ answers the question: What is the proper use of none known in global exclusion statements?) • *FAQ Undifferentiated Pathology and Radiology Results* (This FAQ answers the question: What should we do if our system cannot distinguish between pathology and radiology reports?) The content of these three FAQs has not changed.

Date	Version
10 Mar 2016	EP-2241:2016 Common – Clinical Document v1.4.2 Release note **Release rationale** This incremental release of the Common – Clinical Document end product provides updates to the Clinical Documents – Template Package Directory to include references to updated: • eHealth Diagnostic Imaging Report – Conformance Profile v1.1 • eHealth Pathology Report – Conformance Profile v1.1 This release of the Common – Clinical Document end product aligns with approved change request CCB-0469.
29 Jan 2016	EP-2231:2016 Common - Clinical Document v1.4.1 Release note **Release rationale** This incremental release of the Common - Clinical Document end product provides updates of the following product components: • Clinical Documents – Conformance Test Specification for CDA Rendering; • Clinical Documents – My Health Record Usability Recommendations. Version 1.4 of the *Conformance Test Specification for CDA Rendering* provides clarifications for many of the test cases, improves the readability of the document, and adds a number of test cases in support of recently published Pathology Report and Diagnostic Imaging Report conformance profiles. Details of the changes are listed in the *Capabilities* section of this release note. Version 1.3 of *Clinical Documents – My Health Record Usability Recommendations* provides usability recommendations for clinical information systems authoring or rendering information contained in clinical documents and views exchanged with the My Health Record system. It is focused on recommendations applicable to *all* types of clinical documents. Additional usability recommendations have been published as follows: • *Shared Health Summary PCEHR Usability Recommendations v1.2;* and • *Event Summary PCEHR Usability Recommendations v1.1*.
3 Dec 2015	EP-2198:2015 Common – Clinical Document v1.4 Release note **Release rationale** This release of the Common - Clinical Document end product provides a new product component, *Conformance Test Specification for PCEHR Views v1.0*, which provides a targeted set of test cases, managed using a Microsoft Excel workbook. This conformance test specification supports the currently published PCEHR views specifications and their conformance requirements. Details of the document are listed in the Capabilities section of the release note. Additionally, four FAQs have been archived and are no longer included in this end product release.

Date	Version
15 Jul 2015	EP-2085:2015 Common - Clinical Document v1.3.1 Release note **Release rationale** This incremental release of the Common - Clinical Document end product provides updates of the following product components: • *Clinical Documents - Conformance Test Specification for CDA Packaging v1.5*; and • *Clinical Documents - Template Package Directory v1.5*. Version 1.5 of the *Conformance Test Specification for CDA Packaging* provides clarifications for many of the test cases, improves the readability of the document, and adds a number of test cases in support of recently published CDA packaging-related conformance requirements. Details of the changes are listed in the Capabilities section of this release note. Version 1.5 of the *Template Package Directory* includes references to updated template packages for: • *eHealth Diagnostic Imaging Report v1.1*; and • *eHealth Pathology Report v1.1*. The FAQ Patient Medications has been archived and is no longer included in this end product release. Its contents have been superseded by updates to the latest versions of the CDA Implementation Guides for Event Summary and Specialist Letter document types. This release of the Common – Clinical Document end product aligns with the following approved change requests: CCB-0418; CCB-0419; and CCB-0431.
10 Apr 2015	EP-1818:2015 Common - Clinical Document v1.3 Release note **Release rationale** This release of the Common - Clinical Document end product introduces the Conformance Test Specification for PCEHR Usability and provides updates of the *Common Conformance Profile for Clinical Documents* and the *Template Package Directory*. The *Conformance Test Specification for PCEHR Usability v3.0* provides test cases for the assessment of clinical information systems for conformance with the following PCEHR usability recommendations published as part of the Clinical Usability Programme (CUP) Release 3: • *Clinical Documents – PCEHR Usability Recommendations v1.2*; • *Event Summary – PCEHR Usability Recommendations v1.1*; • *Shared Health Summary – PCEHR Usability Recommendations v1.2*. The updated version of the Common Conformance Profile for Clinical Documents: • clarifies requirements for narrative sections; and • explicitly disallows direct references to XSL stylesheets for all CDA documents. The updated version of the *Template Package Directory* includes references to updated template packages for: • *Event Summary v1.4*; and • *Shared Health Summary v1.5.* This release of the Common – Clinical Document end product aligns with the following approved change requests: CCB-0202; CCB-0309; CCB-0345; CCB-0357; CCB-0380; CCB 0388.

Date	Version
17 Feb 2015	EP-2024:2015 Common - Clinical Document v1.2.2 Release note **Release rationale** This incremental release of the Common - Clinical Document end product introduces an updated version of the *Template Package Directory*. It includes references to updated template packages for: • *eHealth Dispense Record v1.2*; and • *eHealth Prescription Record v1.2*. These updated template packages now support the inclusion of codes from the Australian Medicines Terminology (AMT) version 3. The changes applied to the template package libraries for these document types are aligned with approved change request CCB-0409.
31 Dec 2014	EP-1962:2014 Common - Clinical Document v1.2.1 Release note **Release rationale** This release of the Common – Clinical Documents end product introduces an updated version of the *Common – Clinical Documents - PCEHR Usability Recommendations* document and provides an update of the *Template Package Directory*. *Updated PCEHR Usability Recommendations* This version of the PCEHR Usability Recommendations introduces the concept of a "PCEHR Page" for general practice clinical information systems. The PCEHR Page expands on the Document List concept included in previous CUP releases. In addition, the PCEHR Indicator has been enhanced to provide users with a notification of any new documents available on a patient's PCEHR. For more details, please refer to the Capabilities section of this release note. The updated Common – Clinical Documents - PCEHR Usability Recommendations aligns with updated versions of the Event Summary - PCEHR Usability Recommendations and Shared Health Summary - PCEHR Usability Recommendations. Together, these three documents represent the result of the Clinical Usability Programme (CUP) Release 3. The PCEHR Usability Recommendations have been developed by NEHTA in consultation with key general practice peak bodies to improve the user experience of general practice software products. Vendors of clinical information systems used outside of general practice settings are encouraged to consider the extent to which these recommendations are applicable to their software products. **Updated Template Package Directory** The *Template Package Directory* has been updated to include references to template package libraries published for the following end products: • *eHealth Pathology Report v1.0*; • *eHealth Diagnostic Imaging Report v1.0*; • *Event Summary v1.3.3*; and • *Medicare Overview v1.2*. Support for eHealth Pathology Report and eHealth Diagnostic Imaging Report by the PCEHR system was introduced with PCEHR Release 5 (29 November 2014). The changes applied to the template package libraries for Event Summary and Medicare Overview are aligned with approved change requests CCB-0378 and CCB-0244, respectively.

<table>
<tr><th>Date</th><th>Version</th></tr>
<tr><td>25 Sep 2014</td><td>EP-1815:2014 Common - Clinical Document v1.2
Release note
Release rationale
This release of the Common – Clinical Documents end product contains updates of the following product components:
Clinical Documents - Common Conformance Profile v1.6; and
Clinical Documents - Template Package Directory v1.5.
The changes to the common conformance profile have been approved as part of change request CCB-0345 and consist of:<table><tr><th>Key</th><th>Category</th><th>Summary of change</th></tr><tr><td>CCP-86</td><td>Addition</td><td>Filenames of attachments now need to match their indicated MIME type.
This decreases the potential for malicious content and provides better rendering support for legitimate attachment content.</td></tr><tr><td>CCP-223</td><td>Addition</td><td>All inline data within XML now needs to be text only.
This ensures that any document that has inline data (such as an exe file) will be rejected by the receiving system.</td></tr><tr><td>CCP-234</td><td>Clarification</td><td>Clarification added that a CDA Header is required for clinical documents at all conformance levels.
This aligns the common conformance profile with the original intent and current practice.</td></tr><tr><td>CCP-238</td><td>Clarification</td><td>Clarification added that conformance points re local identifiers only apply to those local identifiers that are used by healthcare provider organisations.</td></tr></table>The Template Package Directory has been updated to include references to template package libraries published for the following end products:
Specialist Letter v1.3;
Australian Organ Donor Register v1.1; and
Pharmaceutical Benefits Report v1.1.</td></tr>
<tr><td>18 Aug 2014</td><td>EP-1754:2014 Common - Clinical Document v1.1.3
Release note
Release rationale
This incremental release of the Common – Clinical Documents end product introduces the Template Package Directory.
The purpose of this new product component is to provide implementers of clinical document specifications and other stakeholders with a comprehensive overview of available template packages and their current status.
The template package directory also contains hyperlinks referring to the download locations of all template packages. For each template package, the hyperlink refers to the location of the template package library containing the template package. Template package libraries are published for each clinical document type and are contained in the end product for the document type.</td></tr>
</table>

Date	Version
05 May 2014	EP-1589:2014 Common - Clinical Document v1.1.2 Release note **Release rationale** This incremental release of the Common - Clinical Document end product introduces *Clinical Documents – PCEHR Usability Recommendations*. This new product component replaces the *Supplementary Guidance for Implementers* product component introduced with the previous version of this end product. The *PCEHR Usability Recommendations* document contains implementation guidance previously published in *Supplementary Guidance for Implementers*. The new format, "usability recommendations", makes it easier for implementers to assess whether their software conforms to the guidance. PCEHR usability recommendations are not part of PCEHR conformance requirements. Only the latter are used as the basis for conformance assessments performed as a prerequisite to PCEHR system integration. PCEHR usability recommendations can be used by implementers to perform usability assessments on a voluntary basis, for example, with the aim of providing their users with a consistently high level of usability. The *PCEHR Usability Recommendations* document also contains additional guidance for implementers, developed as part of NEHTA's Clinical Usability Program (CUP) Release 2. This release also removes the developer resource product components and related product data sheets. These have been republished in two new end products: • *Clinical Documents Integration Toolkit v1.0*; and • *Secure Messaging Integration Toolkit v1.0*. In addition, the document *Reference Platform - Vendor End 2 End Portal v1.4* has been archived as it is no longer relevant. *eSignature - Java Library v1.1.0* has also been archived since it is included in the libraries in the new integration toolkits
24 Oct 2013	EP-1477:2013 Common - Clinical Document v1.1.1 Release note **Release rationale** This incremental release of the Common Clinical Document end product introduces supplementary guidance for the implementation of clinical documents, representing a key outcome of NEHTA's Clinical Usability Program (CUP) Release 1. Aligning with the sets of template packages supported by PCEHR Releases 3.5 and 4, updated versions of the CDA Document Library sample code have been provided. This release also introduces a number of product data sheets, each containing the description of a type of non-document product associated with this end product.

<table>
<tr><th>Date</th><th>Version</th></tr>
<tr><td>09 Oct 2013</td><td>EP-1457:2013 Common - Clinical Document v1.1
Release note
Release rationale
This release of the Common Clinical Document end product introduces updates to the conformance profile for Common Clinical Documents, as mandated by the following approved change requests.
<table>
<tr><th>Change request ID</th><th>Change request title</th><th>Impact on this release</th></tr>
<tr><td>CCB-0116</td><td>Relaxation of the mandatory use of HPI-Is in uploaded documents</td><td>New conformance requirements added for local identifiers.</td></tr>
<tr><td>CCB-0222</td><td>Support for CSP Certificates in CDA Documents</td><td>Conformance requirements regarding digital signatures previously contained in document-type specific Conformance Profiles have been consolidated and revised in this version of the Common Conformance Profile. New conformance requirements added for Legal Authenticator, Approver and Custodian.</td></tr>
</table>
In addition to these changes, the structure of the document has been modified to improve clarity and readability. This structural change does not affect the contents of any of the conformance requirements.</td></tr>
<tr><td>10 Nov 2011</td><td>EP-1094:2011 Common - Clinical Document v1.0.2
Release note
Release rationale
This incremental release includes:
updated sample code to address a small change in the CDA packaging library; and
updates to three FAQ title prefixes (document content is unchanged).</td></tr>
</table>

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