Common - Clinical Document
Release Note v1.4.1

29 January 2016

Approved for external information

EP-2231:2016 Common – Clinical Document v1.4.1

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™[1] 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[2] Usability Recommendations v1.2;* and
- *Event Summary PCEHR Usability Recommendations v1.1*.

Package inclusions

New

None

Updated (supersedes previous version)

Identifier	Name
NEHTA-2210:2016	*Clinical Documents - My Health Record Usability Recommendations v1.3*
NEHTA-2064:2016	*Clinical Documents - Conformance Test Specification for CDA Rendering v1.4*
NEHTA-2230:2016	*Common – Clinical Document - Release Note v1.4.1* (this document)

[1] CDA is a trademark of Health Level Seven International and is registered with the United States Patent and Trademark Office.
[2] Disclaimer: PCEHR means the My Health Record, formally 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).

No change

Identifier	Name
NEHTA-2189:2015	*Clinical Documents - Conformance Test Specification for PCEHR Views v1.0*
NEHTA-1096:2011	*Clinical Documents - FAQ OIDs For HL7 v1.0*
NEHTA-1097:2011	*Clinical Documents - Implementation Guidance - Representing Coding in CDA Documents v1.0*
NEHTA-1229:2011	*Clinical Documents - CDA Package v1.0*
NEHTA-1226:2011	*Clinical Documents - Clinical Package v1.0*
NEHTA-1850:2015	*Clinical Documents - Common Conformance Profile v1.6*
NEHTA-1199:2012	*Clinical Documents - CDA Rendering Specification v1.0*
NEHTA-1329:2012	*Clinical Documents - Conformance Test Specification for Clinical Documents v1.2*
NEHTA-2063:2015	*Clinical Documents - Conformance Test Specification for PCEHR Usability v3.0*
NEHTA-1270:2013	*Clinical Documents - FAQ - Clarification on Messaging and CDA Packaging v1.4*
NEHTA-1255:2012	*Clinical Documents - FAQ Appropriate use of date and date-time values in Clinical Documents v1.0*
NEHTA-1276:2013	*Clinical Documents - FAQ Hash value verification v1.0*
NEHTA-1328:2013	*Clinical Documents - Supplementary Notes for Implementers Relating to Clinical Document Presentation v1.0*
NEHTA-2065:2015	*Clinical Documents - Conformance Test Specification for CDA Packaging v1.5*
NEHTA-2004:2015	*Clinical Documents - Template Package Directory v1.5*

Capabilities

Updated Conformance Test Specification for CDA Rendering

Version 1.4 of the *Conformance Test Specification for CDA Rendering* supports the currently published *CDA Rendering Specification*, the My Health Record clinical document specifications and their conformance requirements.

The specification now applies only to the rendering of documents, with the authoring of documents tested within a separate specification. The format of the specification has been amended to align with other NEHTA conformance specifications, with explicit test steps and outcomes, and additional commentary to describe the operation of the worksheets, including the acceptability of "partial conformance" under certain conditions.

New tests have been applied which relate to medical nomenclature and areas of common conformance. Tests that relate to specific contexts or document types, and may not be applicable to all users, have been separated into distinct worksheets.

The worksheets, which define a suite of test cases covering eHealth conformance requirements, have been organised as follows:

1. CDA Rendering Systems;
2. CDA Rendering Details Fields;
3. CDA Rendering P2P Context;
4. CDA Rendering Pathology Report; and
5. CDA Rendering Diagnostic Imaging Report;

Additional worksheets have been included for the minimum test data required to execute each of these test suites.

Conformance test specification document use

The intended audience of this document are healthcare providers, software vendors developing My Health Record-enabled system products, and other implementers of clinical systems producing or consuming eHealth clinical documents. The *Conformance Test Specification for CDA™ Rendering* is a test case management document, which help users design and execute quality control measures for their software products.

Clinical Documents – My Health Record Usability Recommendations

Updates to version 1.3 include:

- Renaming from PCEHR to My Health Record;
- New section with recommendations on recording adverse reactions;
- New recommendations on recording immunisation sequence number;
- Miscellaneous additional recommendations and amendments for additional clarity and usability in existing areas;
- New recommendations have a status of **NEW in v1.3** (CLD.107 to CLD.140) while recommendations that have been revised for clarity have a status of *Revised for v1.3*;
- Additional clarifications and corrections that are not considered to have any potential impact on clinical information system behaviour.

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.

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 as follows:

- the 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 known

Support

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

Previous releases

Date	Version
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.
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.

Date	Version
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.
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.

Date	Version
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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Contact for enquiries
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