Australian Government
Australian Digital Health Agency

Clinical Package Validator
Release Note

27 June 2024 v3.4
Approved for external use
Document ID: DH-3864:2024

Related end product identifier: EP-3927:2024

Release rationale

Version 3.4 of the Clinical Package Validator (the Validator) addresses a couple of bug fixes and enhancements to support the latest version of 'Ontoserver v6.2.0' and the Agency's Information Quality Rule (IQ Rules) tool.

For other changes and defect fixes included in this release, please refer to the Change details section below.

Before formally declaring conformity to the System Operator of the My Health Record system, developers need to perform additional tests to ensure full coverage of all requirements.

Please refer to the *Clinical Package Validator Product Data Sheet* for more detailed information about the Validator's coverage of requirements and conformance test cases.

Package inclusions

New

None

Updated (supersedes previous version)

Identifier	Name and version
DH-3865:2024	*Clinical Package Validator – Product Data Sheet v3.4*
DH-3864:2024	*Clinical Package Validator – Release Note v3.4* (this document)
DH-3863:2024	*Clinical Package Validator – Software Package v3.4*

No change

Identifier	Name and version
DH-3354:2020	*Clinical Package Validator – Installation Guide v3.2*
DH-3350:2020	*Clinical Package Validator – User and Configuration Guide v3.2*

Removed (archived or withdrawn)

None

Change details

The following subsections provide additional details about the changes included in this release.

Changes to CDA validation

This release of the Validator provides the following changes to the CDA validation functionality:

Type	ID	Change
Enhancement		Updated HL7 v2.4 Coding table to align with the latest conformance profiles
Enhancement	CCTT-1111	Added improvements to queries made to Ontoserver for IQ rules
Enhancement	CCTT-1127	Added random number generator in Schematron rules
Enhancement	CCTT-1130	Added check box to clear our Zip files in collection folder
Bug	CCTT-1125	Fixed orderDate where timezones involved for IQ rules
Enhancement		Support for additional document types for Residential and Aged care

Audience

This document is intended for:

- developers and implementers of clinical information systems
- the System Operator of the My Health Record system
- the National Infrastructure Operator.

Licence

The Agency provides the Clinical Package Validator end product subject to the Software Licence Terms and Conditions contained in the Software Package product component.

Support

For further support or to provide feedback, please email the Agency Help Centre at help@digitalhealth.gov.au or phone 1300 901 001.

Previous releases

Version	Date	Comment
3.3	16 June 2023	EP-3352:2020 Clinical Package Validator v3.3 Release Note **Release rationale** Version 3.3 of the Clinical Package Validator (the Validator) introduces enhancements to the terminology searching and bug fixes as listed in the previous release notes.
3.2	12 January 2021	EP-3352:2020 Clinical Package Validator v3.2 Release Note **Release rationale** Version 3.2 of the Clinical Package Validator (the Validator) introduces validation capabilities for messages in addition to clinical packages: **Validation of HL7 v2 messages** • Referral messages (REF_I12) • Order messages (ORM_O01) • Observation result messages (ORU_R01) • MDM messages (MDM_T02) • Referral acknowledgement messages (ACK_I12) • Referral response messages (RRI_I12) • Order acknowledgement messages (ACK_O01) • Order response messages (ORR_O02) • Observation result acknowledgement messages (ACK_R01) • MDM acknowledgement messages (ACK_T02) Details about all supported HL7 v2 messages and the validations performed on them are listed in the *Product Data Sheet*. **For other changes and defect fixes included in this release, please refer to the Change details section below.**
2.9 - 3.1	-	Controlled releases only

Version	Date	Comment
2.8	7 January 2020	EP-2903:2020 Clinical Package Validator v2.8 Release Note **Release rationale** Version 2.8 of the Clinical Package Validator (the Validator) provides important enhancements to external functions used by the Agency's Information Quality Rules (IQ Rules). Developers and implementers of clinical information systems planning to use the Agency's IQ Rules for the validation of their clinical documents should upgrade to this version of the Validator. This version is required for the execution of IQ Rules from version 1.6. IQ Rules can be used to perform an in-depth analysis of clinical documents. This complements the structural analysis performed by My Health Record template packages. The Validator supports the parallel execution of IQ Rules and My Health Record template packages. The Agency publishes IQ Rules separately. For a comprehensive list of all changes and defect fixes, please refer to Change details, below. Before formally declaring conformity to the System Operator of the My Health Record system, developers need to perform additional tests to ensure full coverage of all requirements. Please refer to the *Clinical Package Validator Product Data Sheet* for more detailed information about the Validator's coverage of requirements and conformance test cases.
2.7	1 June 2018	EP-2684:2018 Clinical Package Validator v2.7 Release Note **Release rationale** Version 2.7 of the Clinical Package Validator (i.e., Validator) enables software developers to improve the depth and automation of clinical document conformance testing. The new release includes a number of defect fixes and enhancements which will improve the Validator's ability to effectively support implementers in their conformance assessment activities. Additional updates have been added to the Validator's documentation. The Validator introduces call back functions required by advanced Information Quality Rules (IQ Rules). Developers can perform more thorough conformance tests of clinical documents using the latest version of the Agency's IQ Rules. IQ Rules enable developers to perform in-depth analysis of clinical documents that complements the structural analysis performed by standard template packages. The Validator supports the parallel execution of IQ Rules and standard template packages. IQ Rules are published separately by the Agency.

Version	Date	Comment
2.6.1	-	Not released. EP-2489:2017 Clinical Package Validator v2.6.1 Release Note **Release rationale** Version 2.6.1 of the Clinical Package Validator (Validator) introduces call back functions required by advanced Information Quality Rules (IQ Rules). Developers can perform more thorough conformance tests of clinical documents using the latest version of the Agency's IQ Rules. IQ Rules enable developers to perform in-depth analysis of clinical documents that complements the structural analysis performed by standard template packages. The Validator supports the parallel execution of IQ Rules and standard template packages. IQ Rules are published separately by the Agency.
2.5	20 May 2016	EP-2489:2017 Clinical Package Validator v2.5 Release Note **Release rationale** Version 2.5 of the Clinical Package Validator (Validator) provides software developers with enhanced capabilities to achieve a greater degree of automation and depth of their conformance tests of clinical documents. The new release helps developers reduce efforts for manual conformance testing and increase their confidence about their targeted test coverage when declaring conformance. This is achieved through new types of validation checks, greater depth of document inspections and improved automation features. The new Validator supports: • More powerful validations through additional validation languages: ○ ISO Schematron ○ XSLT v2.0 ○ XPath v2.0 ○ XQuery v1.0 • Improved batch operation and reporting. • Australian Immunisation Register (AIR) documents. For a comprehensive list of all changes and defect fixes, please refer to release note. Before formally declaring conformance of a software product to the System Operator of the My Health Record system, developers need to perform additional tests to ensure full coverage of all requirements. Please refer to the *Product Data Sheet* for more detailed information about the Validator's coverage of requirements and conformance test cases.

<table>
<tr><th>Version</th><th>Date</th><th>Comment</th></tr>
<tr><td>2.4</td><td>20 May 2016</td><td>EP-2257:2016 Clinical Package Validator v2.4
Release Note
Release rationale
Version 2.4 of the Clinical Package Validator (“the Validator”) has been released to provide the following functional improvements:
<table>
<tr><th>ID</th><th>Change</th></tr>
<tr><td>CCTT-704</td><td>Support added for loading combined SNOMED CT-AU and AMT v3 code sets.
AMT v3 and SNOMED CT-AU are now published by the Australian Digital Health Agency as combined code sets. The Validator supports the loading of additional combined SNOMED CT-AU and AMT v3 code sets. This allows users to perform validations against versions of these combined code sets that are released after the publication of this Validator release.</td></tr>
<tr><td>CCTT-703</td><td>Support removed for loading AMT v2 code sets:
AMT v2 has been deprecated more than 18 months ago and no more updates will be published for AMT v2. The Validator continues to support validations against the latest version of the AMT v2 code set, which is preinstalled with the Validator and does not need to be loaded by the user.</td></tr>
<tr><td>CCTT-618</td><td>Improved usability of report tabs for terminology validations:
User feedback suggested that the previous naming of these report tabs could be misleading. Tabs have been renamed and User Guide improved.</td></tr>
<tr><td>CCTT-606</td><td>Improved highlighting of overrides in test reports</td></tr>
</table>
This release contains the following new product component:
• The Product Data Sheet provides all release-independent information about the Clinical Package Validator end product. This information was previously included in this release note, which is now focused on information about this release.</td></tr>
<tr><td>2.3</td><td>17 Jul 2015</td><td>EP-2134:2015 Clinical Package Validator v2.3
Release Note
Release rationale
• Support the validation of eHealth Diagnostic Imaging Reports that reference clinical information outside the clinical package (e.g., a diagnostic image on a website), through the automation of version 1.5 of the Conformance Test Specification for CDA Packaging.
• Provide a platform that enables the automation of conformance test cases and test scenarios, through the application of Schematron rules that are in addition to those in a template package.</td></tr>
<tr><td>2.2</td><td>–</td><td>Not released</td></tr>
</table>

Version	Date	Comment
2.1	20 Jan 2015	New and more consistent user interface with summary screen, drag and drop functionality, better handling of files, user management of terminology database, inclusion of version 1.2.9 of the generic style sheet.
2.0	22 Aug 2014	New package validation function built; Schematron libraries removed; added ability to load template packages for the validation of clinical documents and CDA packages.
1.12.8	08 Jan 2014	Support for both HPI-I relaxation and HPI-I enforcement by Schematron libraries in alignment with PCEHR release 4 (patch for v1.12, to replace v1.12.5a).
1.12.7	08 Jan 2014	Support for HPI-I relaxation by Schematron libraries in alignment with PCEHR release 4 (patch for v1.12, to replace v1.12.5a).
1.12.5a	15 May 2013	Revised validation rules (patch for v1.12, to replace v1.12.5).
1.12.5	20 Mar 2013	Revised validation rules (patch for v1.12).
1.12.2	20 Aug 2012	Validation rules aligned with PCEHR R1c (patch for v1.12).
1.12	15 July 2012	Functionality, validation rules and terminology aligned with PCEHR R1b.
2.1	20 Jan 2015	New and more consistent user interface with summary screen, drag and drop functionality, better handling of files, user management of terminology database, inclusion of version 1.2.9 of the generic style sheet.
2.0	22 Aug 2014	New package validation function built; Schematron libraries removed; added ability to load template packages for the validation of clinical documents and CDA packages.
1.12.8	08 Jan 2014	Support for both HPI-I relaxation and HPI-I enforcement by Schematron libraries in alignment with PCEHR release 4 (patch for v1.12, to replace v1.12.5a).
1.12.7	08 Jan 2014	Support for HPI-I relaxation by Schematron libraries in alignment with PCEHR release 4 (patch for v1.12, to replace v1.12.5a).
1.12.5a	15 May 2013	Revised validation rules (patch for v1.12, to replace v1.12.5).
1.12.5	20 Mar 2013	Revised validation rules (patch for v1.12).
1.12.2	20 Aug 2012	Validation rules aligned with PCEHR R1c (patch for v1.12).
1.12	15 July 2012	Functionality, validation rules and terminology aligned with PCEHR R1b.

Publication date: 27 June 2024

Australian Digital Health Agency ABN 84 425 496 912, Level 25, 175 Liverpool Street, Sydney, NSW 2000 digitalhealth.gov.au
Telephone 1300 901 001 or email help@digitalhealth.gov.au

Acknowledgements
The Australian Digital Health Agency is jointly funded by the Australian Government and all state and territory governments.