Australian Government
Australian Digital Health Agency

Clinical Package Validator
Release Note

12 January 2021 v3.2
Approved for external information
Document ID: DH-3352:2020

Related end product identifier: EP-3408:2020

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.

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-3354:2020	*Clinical Package Validator – Installation Guide v3.2*
DH-3353:2020	*Clinical Package Validator – Product Data Sheet v3.2*
DH-3352:2020	*Clinical Package Validator – Release Note v3.2* (this document)
DH-3351:2020	*Clinical Package Validator – Software Package v3.2*
DH-3350:2020	*Clinical Package Validator – User and Configuration Guide v3.2*

No change

None

Removed (archived or withdrawn)

None

Change details

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

Configuration documentation

Documentation about the configuration of the Validator is now included in the *User and Configuration Guide* (previously *User Guide*). It has been removed from the *Installation Guide* (previously *Installation and Configuration Guide*).

Changes to CDA validation

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

Type	ID	Change
Enhancement	CCTT-885	The Validator no longer validates Australian Vaccine Codes. Updates for the code system for Australian Vaccine Codes are published by Services Australia independently of the lifecycle of the Validator. This created a risk that the Validator performed validations of vaccine codes against outdated versions of the Australian Vaccine Codes code set. Australian Vaccine Codes are published by Services Australia and not available through NCTS and Ontoserver.
Enhancement	CCTT-886	The Validator no longer validates ANZSCO codes. This change eliminates potential issues resulting from the Validator's inability to determine the correct ANZSCO version for a CDA document.
Enhancement	CCTT-940	Validator now uses tab separators instead of comma separators for its reports. The new file names for these reports are: • analysis.tsv • report.tsv
Enhancement	CCTT-949 CCTT-967	analysis.tsv now includes priority ratings for each reported error. Available ratings are: HIGH, MEDIUM, LOW, TRIVIAL. The ratings were provided by the Agency's Clinical Governance team.
Enhancement	CCTT-950	The Validator's report (PDF format) now contains improved wording about the limitations of the Validator's ability to comprehensively assess the conformance.
Enhancement	CCTT-951	The User and Configuration now also covers the configuration of the Validator for integration with the Ontoserver, particularly the Ontoserver's address.
Enhancement	CCTT-962	Validator now comes with a set of pre-loaded template packages. Refer to the Product Data Sheet for a comprehensive list of all pre-loaded template packages.
Enhancement	CCTT-963	The error pane is now expandable for improved usability.
Enhancement	CCTT-968	Legacy tabs for reference sets and terminology removed from Validator user interface.
Enhancement	CCTT-976	Error logs for Ontoserver (terminology) validations (TSlog) and Schematron validations (EFlog) can now turned on or off separately. Previously, turning off TSlog also turned off EFlog.

Type	ID	Change
Enhancement	CCTT-977	The Validator now supports the validation of collections of documents (bulk validation).
Enhancement	CCTT-978	The Validator's error log (EFlog) now states the timestamp for each detected error.
Enhancement	CCTT-979	Recoverable errors are now also reported in the Validator's user interface (in addition to the EFlog file).
Enhancement	CCTT-981	TSlog now contains more details for calls to Ontoserver.
Enhancement	CCTT-982	Expanded validation of XDS.b header fields: Document IDs and document replacement IDs are not checked for correct formatting and for alignment with corresponding fields in the CDA document.
Bug	CCTT-942	Issue resolved with the validation of UCUMs, which could lead to an infinite loop.
Bug	CCTT-952	Issue resolved that led to some messages being displayed on the user interface but missing from analysis.csv.
Bug	CCTT-980	SNOMED/AMT load errors are now reported without truncation of the error message.

Changes to HL7 v2 validation

This release of the Validator provides the following changes to the HL7 v2 validation functionality:

Type	ID	Change
Enhancement	N/A	Introduce new HL7 v2 validation tab to support conformance testing and validation of HL7 v2 clinical messages

Deprecation of SMIO testing capabilities

Testing capabilities in support of the Agency's Secure Messaging Industry Offer (SMIO), first made available in the v3.0 limited release of the Validator, have been deprecated and disabled in this release. They can be re-enabled in the Validator's configuration settings here:

CPV-install-directory/CPValidator.exe.config

In this file, change `showSmioButton` to `true`:

```
<add key="showSmioButton" value="true"/>
```

and restart the application.

The SMIO button will appear on the CDA validation tab of the CPV tool.

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
2.9 - 3.1	-	Controlled releases only
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.

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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

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