My Health Record

Conformance Vendor Declaration Form

11 March 2020 v20200311

Approved for external use

Document ID: DH-3119:2020

|  |
| --- |
| This Vendor Declaration Form is a declaration that states software products comply with all applicable My Health Record technical specifications and conformance points and have undergone the necessary internal testing. Submitting this form is one of the requirements for software developed by vendors to be granted connection to the My Health Record system. For further information, refer to the *Conformance Vendor Declaration form* *instructions* and the *Software Vendor Guide to the connection process*. |
| **Vendor instructions** |
| If you are **connecting for the first time, adding a new function, changing a function, or changing a conformance level**:* Please complete all sections of the form and sign the Vendor Deed Poll.
* The Vendor Deed Poll must be signed by a person with authority to legally bind the vendor in the presence of a witness.
* Send a copy of the completed form (including the Vendor Deed Poll) to myhealthrecord.operations@digitalhealth.gov.au

 |
| **SECTION 1 - Vendor, contact and software details** |
| **1.1 Vendor details**  |
| Vendor name |        |
| Contact number |        |
| Address |        |
| Suburb:       | State:       | Postcode:       |
| **1.2 Contact details – *please provide direct contact numbers for each contact person.***  |
| Primary contact | Secondary contact |
| Name:      Position:      Email:      Telephone:       | Name:      Position:      Email:      Telephone:       |
| **1.3 Software product details *(please specify below )*** |
| Type of software product  | Clinical Information System (CIS)[ ]  | Contracted Service Provider (CSP)[ ]  |
| Description of software product or changes to the software |                           |
| Type of request | New software product[ ]  | Add new function[ ]  | Update to function or conformance level[ ]  |
| Software component name | Version number | Function |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |
| ***Please insert extract of SOAP message as per the following example***<productType>               <vendor>Software Pty Ltd</vendor>               <productName>New Health Software</productName>               <productVersion>1.1</productVersion>               <platform>Windows</platform></productType> |
| *Is the software product approved for connection to the Healthcare Identifiers (HI) Service? (HI Service connection is a prerequisite to My Health Record Production access)* | [ ]  YES [ ]  NO |
| **1.4 Terminology in clinical documents** |
| *Does the software product include clinical terminology in clinical documents?* | [ ]  YES (please specify below)[ ]  N/A (Go to next question) |
| Terminology Used | Version Number |
| [ ]  Clinical Terminology Guidance for Use in Healthcare Software (AMT & SNOMED CT-AU) |       |
| [ ]  Clinical Terminology Guidance for Use of Medical Nomenclature in Information Exchange |       |
| [ ]  Other terminology (please specify below) |
| Additional Information about the scope of inclusion of terminology           |
| **1.5 Special conditions** |
| *Are there any special conditions that your organisation would like considered when applying for production access to the My Health Record system?(Include exemptions from mandatory requirements here: title, date approved and date of exemption expiry)* | [ ]  YES (please specify below)[ ]  N/A (Go to next question) |
| Description |                           |
| **SECTION 2 Software compliance areas** |
| **2.1 Software compliance – My Health Record National Repository** |
| *2.1.1 Are the following use cases supported by the software product?* | [ ]  YES (please specify below)[ ]  N/A (Go to next question) |
| [ ]  UC.CIS.001 – Check if an advertised PCEHR exists | [ ]  UC.CIS.401 – Search for a template package |
| [ ]  UC.CIS.002 – Gain access to PCEHR | [ ]  UC.CIS 402 – Retrieve a template package |
| [ ]  UC.CIS.201 – Upload a clinical document | [ ]  UC.CIS 403 – Store template metadata/template package |
| [ ]  UC.CIS.202 – Supersede a clinical document | [ ]  UC.CIS.501 – Assisted PCEHR Registration (adult) |
| [ ]  UC.CIS.203 – Remove a clinical document | [ ]  UC.CIS.502 – Assisted PCEHR Registration (child) |
| [ ]  UC.CIS.204 – Download a clinical document | [ ]  UC.CIStoNPP.001 – CIS to NPP direct access MHR from National Provider using web-browsers component |
| [ ]  UC.CIS.301 – Access a view service | [ ]  UC.CIStoNPP.002 – CIS to NPP direct access MHR from National Provider using system browsers  |
|  | [ ]  UC.CIStoNPP.003 – CIS to NPP user configuration of vendor's CIS |
| *2.1.2 Does the software product use the following web services to access the My Health Record National Repository?* | [ ]  YES (please specify below)[ ]  N/A (Go to next question) |
| [ ]  doesPCEHRExist – v1.1 | [ ]  getChangeHistoryView – v1.1 |
| [ ]  gainPCEHRAccess – v1.1 | [ ]  getAuditView – v 1.1 |
| [ ]  ITI – 41 Provide & Register Document Set-b - v1.1 | [ ]  getRepresentativeListView – v1.1 |
| [ ]  RemoveDocument/DeregisterDocument – v1.1 | [ ]  getIndividualDetailsView – v2.0 |
| [ ]  ITI – 43 Retrieve Document Set – v1.1 | [ ]  getView – v1.0 |
| [ ]  ITI – 18 Registry Stored Query – v1.1 | [ ]  searchTemplate – v1.1 |
| [ ]  RegisterPCEHR – v2.0 | [ ]  getTemplate – v1.1 |
| [ ]  CIStoNPP |  |
| **2.2 Software compliance – clinical documents created by software** |
| *Does the software product produce clinical documents in Clinical Document Architecture (CDA) ® format?* | [ ]  YES (specify below the template package ID’s for each document type)[ ]  N/A (Go to next question) |
| **Discharge Summary** | **eHealth Diagnostic Imaging Report** |
| *1A* | 1.2.36.1.2001.1006.1.      | *3A* | 1.2.36.1.2001.1006.1.      |
| 1.2.36.1.2001.1006.1.      | 1.2.36.1.2001.1006.1.      |
| *1B* | 1.2.36.1.2001.1006.1.      | **eHealth Dispense Record** |
| 1.2.36.1.2001.1006.1.       | *3A* | 1.2.36.1.2001.1006.1.      |
| *2* | 1.2.36.1.2001.1006.1.      | 1.2.36.1.2001.1006.1.      |
| 1.2.36.1.2001.1006.1.      | **eHealth Prescription Record** |
| *3A* | 1.2.36.1.2001.1006.1.      | *3A* | 1.2.36.1.2001.1006.1.      |
| 1.2.36.1.2001.1006.1.       | 1.2.36.1.2001.1006.1.      |
| *3B* | 1.2.36.1.2001.1006.1.      | **eHealth Pathology Report** |
| 1.2.36.1.2001.1006.1.      | *3A* | 1.2.36.1.2001.1006.1.      |
| 1.2.36.1.2001.1006.1.      | 1.2.36.1.2001.1006.1.      |
| **Shared Health Summary** | **Event Summary** |
| *3A* | 1.2.36.1.2001.1006.1.      | *3A* | 1.2.36.1.2001.1006.1.      |
| 1.2.36.1.2001.1006.1.      | 1.2.36.1.2001.1006.1.      |
| 1.2.36.1.2001.1006.1.      | 1.2.36.1.2001.1006.1.      |
| *3B* | 1.2.36.1.2001.1006.1.      | *3B* | 1.2.36.1.2001.1006.1.      |
| 1.2.36.1.2001.1006.1.      | 1.2.36.1.2001.1006.1.      |
| 1.2.36.1.2001.1006.1.      | 1.2.36.1.2001.1006.1.      |
| **Specialist Letter** | **eReferral**  |
| *1A* | 1.2.36.1.2001.1006.1.      | *1A* | 1.2.36.1.2001.1006.1.      |
| 1.2.36.1.2001.1006.1.      | 1.2.36.1.2001.1006.1.      |
| *1B* | 1.2.36.1.2001.1006.1.      | *1B* | 1.2.36.1.2001.1006.1.      |
| 1.2.36.1.2001.1006.1.      | 1.2.36.1.2001.1006.1.      |
| *2* | 1.2.36.1.2001.1006.1.      | *2* | 1.2.36.1.2001.1006.1.      |
| 1.2.36.1.2001.1006.1.      | 1.2.36.1.2001.1006.1.      |
| *3A* | 1.2.36.1.2001.1006.1.      | *3A* | 1.2.36.1.2001.1006.1.      |
| 1.2.36.1.2001.1006.1.      | 1.2.36.1.2001.1006.1.      |
| *3B* | 1.2.36.1.2001.1006.1.      | *3B* | 1.2.36.1.2001.1006.1.      |
| 1.2.36.1.2001.1006.1.      | 1.2.36.1.2001.1006.1.      |
| **Advance Care Planning** | **Pharmacist Shared Medicines List** |
| *3A* | 1.2.36.1.2001.1006.1.      | *1A* | 1.2.36.1.2001.1006.1.      |
| 1.2.36.1.2001.1006.1.      | 1.2.36.1.2001.1006.1.      |
| **Goals of Care** |  |
| *3A* | 1.2.36.1.2001.1006.1.       |  |  |
| 1.2.36.1.2001.1006.1.       |  |  |
| **2.3 Software compliance – clinical document authoring** |
| *Does the software product conform to the mandatory and relevant conditional requirements for CDA ® document producers listed in the following Conformance profiles?* | [ ]  YES (please specify below)[ ]  N/A (Go to next question) |
| My Health Record Conformance Profile | Version Number |
| Discharge Summary |       |
| Shared Health Summary |        |
| Specialist Letter |       |
| Advance Care Planning |       |
| eHealth Diagnostic Imaging Report |       |
| eHealth Dispense Record |       |
| eHealth Prescription Record |       |
| eHealth Pathology Report |        |
| Event Summary |        |
| eReferral  |       |
| Pharmacist Shared Medicines List |       |
| Goals of Care |       |
| **2.4 Software compliance – My Health Record views** |  |  |  |
| *Does the software product present My Health Record views?* | [ ]  YES (please specify below)[ ]  N/A (Go to next question) |
| 2.4.1 Does the software product access the following My Health Record views? |
| [ ]  Health Record Overview | [ ]  Medicare Overview |
| [ ]  Prescription and Dispense View | [ ]  Health Check Schedule View |
| [ ]  Observations View | [ ]  Diagnostic Imaging Report View |
| [ ]  Pathology Report View |  |
|       |
| 2.4.2 According to which version/s of Conformance Profile does this software product display information? |
| My Health Record Conformance Profile | Version Number |
| Health Record Overview  |       |
| Prescription and Dispense View  |       |
| Observations View |       |
| Pathology Report View |       |
| Medicare Overview  |       |
| Health Check Schedule View |       |
| Diagnostic Imaging Report View  |       |
| **2.5 Software compliance – CDA document presentation** |
| *Does the software product conform to the specification for downloading and rendering CDA documents?* | [ ]  YES (please specify below)[ ]  N/A (Go to next question) |
| Conformance Profile | Version Number |
| Clinical Documents – Common Conformance Profile |       |
| **2.6 My Health Record Usability Recommendations** |
| *Is the software product compliant with the My Health Record usability recommendations?* | [ ]  YES (please specify below)[ ]  N/A (Go to next question) |
| My Health Record Usability Recommendation | Version Number |
| [ ]  Clinical Documents  |       |
| [ ]  Shared Health Summary  |       |
| [ ]  Event Summary  |       |
| **2.7 Software compliance – Assisted Registration** |
| *Does the software product conform to the specification for registering a digital health record for an adult or child?* | [ ]  YES (please specify below)[ ]  N/A (Go to next question) |
| Conformance Requirements | Version Number |
| Assisted Registration |       |
| **SECTION 3 Promotion of product**  |
| **3.1 Register of Conformity** |
| *Would you like your software product to be listed in the Register of Conformity?* | [ ]  YES (please specify below)[ ]  N/A (Go to Vendor Deed Poll) |
| [ ]  I have read and agree with the Vendor Terms and Conditions on the Register of Conformity webpage: (<https://www.myhealthrecord.gov.au/for-healthcare-professionals/conformant-clinical-software-products>) |
| [ ]  The primary and secondary contacts nominated in Section 1.2 consent to their details being made publicly available on the Register of Conformity. |

|  |
| --- |
| **VENDOR DEED POLL** |
| This Deed Poll is made by, <**vendor legal name and ABN/ACN**> (the Vendor), in favour of the System Operator (as defined in the *My Health Records Act 2012* (Cth)).**Background:**1. The System Operator requiresvendors, whose software is used to connect to the My Health Record system,to implement software products that conform to all applicable My Health Record system Conformance Profiles and the specifications they reference and the Conformance Requirements for My Health Record Connecting Systems (Specifications), prior to their software being granted connection to the My Health Record system, and to maintain compliance. These Specifications can be found at <http://www.digitalhealth.gov.au/>
2. The Vendor has successfully and fully completed testing of conformance for the software product(s) described in this Vendor Declaration Form without error against applicable mandatory conformance points for the functions they are implementing.
3. The Vendor has completed My Health Record Notice of Connection (NOC) testing for the Software.
4. The Vendor submits this Vendor Declaration Form, of which this Deed Poll forms a part, as attestation that the Software fully complies with all applicable Specifications and has undergone HI Service testing and connection and internal conformance testing.

**Operative provisions:**1. In accordance with AS ISO/IEC 17050.1-2005, the Vendor declares that the contents of this Vendor Declaration Form, of which this Deed Poll forms a part, are true and correct and that the Software fully complies with all applicable Specifications. The Vendor acknowledges that the giving of false or misleading information to the Commonwealth is a serious offence under section 137.1 of the schedule to the *Criminal Code Act 1995* (Cth).
2. The Vendor warrants that they have successfully completed conformance testing without error against applicable mandatory Specifications for the functions that are implemented in the Software.
3. The Vendor acknowledges that the System Operator will conduct quality assurance analysis of the Software’s conformance and compliance with the relevant Specifications from time to time (Quality Assurance Analysis), and will comply with clause 9 in respect of any such analysis. For the avoidance of doubt, the Vendor agrees that the System Operator or its representatives is not obligated to treat information in connection with the Quality Assurance Analysis as confidential information.
4. The Vendor must notify the System Operator promptly if there is an error or other issue in the Software that will or has the potential to impact on the operation, security, integrity, clinical safety or reputation of the My Health Record system.
5. The Vendor must promptly notify the System Operator when:
	1. there are changes or upgrades to the Software including, without limitation, when the Software introduces new My Health Record system functions, to permit completion of a risk assessment;
	2. there is a material change in the Vendor’s legal structure, or the Vendor is involved in a merger or acquisition; or
	3. the Vendor’s nominated contact person(s), or their contact details, change.
6. The Vendor must retain copies of test reports that demonstrate conformance and compliance with Specifications for the term of this Deed Poll and for a period of seven years following termination and, without limiting clause 9, must provide a copy of the test report(s) to the System Operator within 14 days on request.
7. The Vendor agrees that the Software will not introduce any virus, disabling or malicious device or code, worm, Trojan, time bomb or other harmful or destructive code (Harmful Code) when connecting to or accessing the My Health Record system. The Vendor must, as soon as it becomes aware that Harmful Code has or might have been introduced into the My Health Record system, immediately notify the System Operator, giving details of the circumstances, in which case clause 8 will apply.
8. If:
	1. the Vendor notifies the System Operator of an error or other issues in the Software in accordance with clause 4;
	2. a Quality Assurance Analysis of the Software in accordance with clause 3 reveals conformance issues with the Software;
	3. the Software has or may have introduced Harmful Code into the My Health Record system; or
	4. the System Operator becomes aware of errors or issues, or potential errors or issues, in the Software, or conformance issues with the Software,

the Vendor must:* 1. (to the extent the error, issue or introduction of Harmful Code has not been confirmed) promptly confirm whether or not the error, issue or introduction of Harmful Code has occurred and inform the System Operator;
	2. negotiate remediation actions and timeframes to address the error, issue or conformance issue in good faith with the System Operator; and
	3. implement at the Vendor’s own cost the agreed remediation actions in the agreed timeframes.

The Vendor acknowledges that if: * 1. the System Operator and Vendor cannot agree on remediation actions; or
	2. the Vendor fails to implement the agreed remediation actions in the agreed timeframes, the System Operator may take any action it considers necessary including, without limitation, preventing the Software from connecting to or accessing the My Health Record system. The System Operator will provide the Vendor with reasonable assistance to assist with resolving problems pertaining to the My Health Record system.
1. From time to time the System Operator or its representatives may conduct, handle or facilitate Quality Assurance Analysis, administrative or statutory reviews, inquiries, investigations, audits or complaints in connection with the My Health Record system (including data related issues). At the System Operator’s request, and on reasonable notice, the Vendor must at its cost provide reasonable assistance in relation to any such activities. This may include, but is not limited to, providing access to material, records, personnel and computer hardware, software and equipment associated with the Software and when requested, copies of the Software.
2. The My Health Record system and its functionality will change over time. As such, the Specifications will be updated or replaced from time to time, and the System Operator may withdraw support for previous versions. Although the System Operator will endeavour to consult with affected parties about any such changes, it is impossible to guarantee that the System Operator will consult individually with every participant. The Vendor acknowledges that it may be required to complete internal conformance testing against new/updated Specifications and that failure to do so may result in the Software no longer having a connection or access to the My Health Record system.
3. The System Operator has no liability to the Vendor, or to any other party claiming via or through the Vendor, in respect of any loss the Vendor might incur or suffer (including as a result of negligence) that is directly or indirectly related to the Software’s connection or access to the My Health Record system which includes, without limitation, any decision of the System Operator to prevent the Software’s connection or access.
4. The Vendor indemnifies the System Operator and its representatives against all liability, expense, loss, damage or cost reasonably sustained or incurred by the System Operator (or its representatives) as a result of:
	1. the Vendor’s breach of one or more terms of this Deed Poll; or
	2. a claim made, or action taken, by a third party arising out of or in connection with:
5. any negligent, unlawful or willfully wrong act or omission of the Vendor;
6. an allegation that the Software infringes the intellectual property rights or moral rights of the third party; or
7. the Vendor’s breach of one or more terms of this Deed Poll.

The Vendor’s liability under the indemnity in this clause will be reduced proportionately to the extent that any negligent or other tortious act or omission of the System Operator or its representatives contributed to the relevant liability, expense, cost, loss or damage.1. The Vendor may terminate this Deed Poll by giving the System Operator at least seven days written notice, in which case the System Operator may immediately take any action it considers necessary including, without limitation, preventing the Software’s connection or access to the My Health Record system.
2. This Deed Poll will terminate immediately upon cancellation of the Software’s connection or access to the My Health Record system.
3. Clauses 3 (but only for a period of seven years following termination), 6, 9 (but only for a period of seven years following termination), 10, 11, 14 and 17, and any definitions or other provisions necessary to give effect to these clauses, will survive termination of this Deed Poll.
4. Nothing in this Deed Poll limits or restricts any function, power, right or entitlement of the System Operator under the *My Health Records Act 2012* (Cth) or My Health Records Rule.
5. Any notice required to be given to the System Operator under this Deed Poll should be in writing to: myhealthrecord.operations@digitalhealth.gov.au
6. This Deed Poll is governed by and will be construed according to the law of the Australian Capital Territory.

Executed as a deed poll.

|  |  |  |
| --- | --- | --- |
| **SIGNED** **SEALED AND DELIVERED** for and on behalf of:  Vendor legal name and ABN/ACNin the presence of: Signature of witness Full name and designation of witness Date | **))****) ))****)****))****)****))****)****))****)****))** |  Signature of representative who by executing this Deed Poll warrants that they have the authority to bind the vendor in this regard Full name and position of representative |

 |

**Publication date:** 11 March 2020 This date should be the latest approval date. If the document has been through multiple approvals/releases, include a version history table as the last section above.

**Australian Digital Health Agency** ABN 84 425 496 912, Level 25, 175 Liverpool Street, Sydney, NSW 2000 [digitalhealth.gov.au](http://www.digitalhealth.gov.au/)

Telephone 1300 901 001 or email help@digitalhealth.gov.au

Disclaimer

The Australian Digital Health Agency (“the Agency”) makes the information and other material (“Information”) in this document available in good faith but without any representation or warranty as to its accuracy or completeness. The Agency cannot accept any responsibility for the consequences of any use of the Information. As the Information is of a general nature only, it is up to any person using or relying on the Information to ensure that it is accurate, complete and suitable for the circumstances of its use.

Document control

This document is maintained in electronic form and is uncontrolled in printed form. It is the responsibility of the user to verify that this copy is the latest revision.

Copyright © 2019 Australian Digital Health Agency

This document contains information which is protected by copyright. All Rights Reserved. No part of this work may be reproduced or used in any form or by any means – graphic, electronic, or mechanical, including photocopying, recording, taping, or information storage and retrieval systems – without the permission of the Australian Digital Health Agency. All copies of this document must include the copyright and other information contained on this page.

Official

Acknowledgements

Council of Australian Governments

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