Electronic Prescribing

Conformance Vendor Declaration Form

31 July 2020 v1.1

Approved for external use

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| This form facilitates a vendor’s declaration that their software product conforms to the mandatory and relevant conditional requirements for the Electronic Prescribing Participating Software Conformance Profile stated in section 2.2.  This declaration form and Vendor Deed Poll cannot be accepted until the software has been subjected to a successful observed conformance testing session. | | | | | | | | | | | | |
| **Vendor instructions** | | | | | | | | | | | | |
| * Please complete all sections of the declaration form and sign the Vendor Deed Poll. * The Vendor Deed Poll must be signed by a person with legal authority in the presence of a witness. * Send a copy of the completed declaration form (including the Vendor Deed Poll) to [help@digitalhealth.gov.au](mailto:help@digitalhealth.gov.au) | | | | | | | | | | | | |
| **SECTION 1 – Organisation contact and software details** | | | | | | | | | | | | |
| **1.1 Vendor details** | | | | | | | | | | | | |
| Organisation name | |  | | | | | | | | | | |
| Contact number | |  | | | | | | | | | | |
| Address | |  | | | | | | | | | | |
| Suburb: | | | | | | | State: | | Postcode: | |
| **1.2 Contact details – *please provide direct contact numbers for each contact person.***  ***These details may be published in association with the Electronic Prescribing Conformance Register with your consent.*** | | | | | | | | | | | | |
| Primary contact | | | | | | | | Secondary contact | | | | |
| Name:  Position:  Email:  Telephone: | | | | | | | | Name:  Position:  Email:  Telephone: | | | | |
| **1.3 Software product details *(please specify below )*** | | | | | | | | | | | | |
| Type of software product | Prescribing System Provider | | Dispensing System Provider | | | Prescription Delivery Service (PDS) | | | | Active Script List Registry Service | Mobile Application Provider | Mobile Intermediary Provider |
| General description of software product or changes to the software |  | | | | | | | | | | | |
| Reason for this declaration | New software product | | | | Added new functions to previously registered product | | | | | | Updated functions or delivery service type to previously registered product | |
| Software or component name | | | | Version number | | | | | | | Conformance ID | |
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| **IMPORTANT**: The software must be configured to use the EXACT conformance ID nominated on this form. The conformance ID is **case-sensitive**. | | | | | | | | | | | | |
| **SECTION 2 Software compliance areas** | | | | | | | | | | | | |
| **2.1 Software compliance – use cases** | | | | | | | | | | | | |
| *2.1.1 Tick the use cases supported by the software product?* | | | | | | | | | | | | |
| Prescribing System connecting to an Open PDS | | | | | | | Direct Prescription Delivery Service System | | | | | |
| Prescribing System participating in Direct PDS | | | | | | | Active Script List Registry | | | | | |
| Dispensing System connecting to an Open PDS | | | | | | | Mobile Intermediary System | | | | | |
| Dispensing System participating in Direct PDS | | | | | | | Mobile Application | | | | | |
| Open Prescription Delivery Service System | | | | | | |  | | | | | |
| **2.2 Software compliance – electronic prescribing transaction** | | | | | | | | | | | | |
| This form records your declaration that the software product conforms to the mandatory and relevant conditional requirements of the Electronic Prescribing Participating Software Conformance Profile. Nominate below the version of the Conformance Profile this declaration pertains to: | | | | | | | | | | | | |
| Electronic Prescribing Participating Software Conformance Profile version: | | | | | | | | | | |  | |

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| Notes: |  |

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| **SECTION 3 Promotion of product** |
| **3.1 Electronic Prescribing Conformance Register** |
| The conformance register includes the software product details and conformance identifier (Conformance ID), and will be published on the Australian Digital Health Agency’s [Electronic Prescribing Conformance Register](https://www.digitalhealth.gov.au/get-started-with-digital-health/set-up/electronic-prescribing-overview-and-conformance-register/electronic-prescribing-conformance-register) website. |
| The primary and secondary contacts nominated in Section 1.2 consent to their contact details being made publicly available in association with the Electronic Prescribing Conformance Register. |

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| **VENDOR DEED POLL** |
| This Deed Poll is made by, <**vendor legal name and ABN/ACN**> (the Vendor), in favour of the Australian Digital Health Agency as the administrator of the Electronic Prescribing Conformance Assessment Scheme, on behalf of the Commonwealth Department of Health.  **Operative provisions:**   1. In accordance with AS ISO/IEC 17050.1-2005, the Vendor submits this Vendor Declaration Form, of which this Deed Poll forms a part, as attestation that the Software conforms to all applicable conformance requirements in the Electronic Prescribing Participating Software Conformance Profile and has undergone an observed conformance testing session with an approved organisation. 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. From time to time the Australian Digital Health Agency or its representatives may conduct, handle or facilitate quality assurance analysis, administrative or statutory reviews, inquiries, investigations, audits or complaints in connection with electronic prescribing systems (including data related issues). At the Australian Digital Health Agency’s request, and on reasonable notice, the Vendor must at its own 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. 3. The Vendor must promptly notify the Australian Digital Health Agency when:    1. there are changes or upgrades to the Software including, without limitation, when the Software introduces new electronic prescribing 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;    3. the Vendor’s nominated contact person(s), or their contact details, change; or    4. 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 electronic prescribing. 4. If:    1. the Vendor notifies the Australian Digital Health Agency of an error or other issues in the Software in accordance with clause 3;    2. a quality assurance analysis of the Software in accordance with clause 2 reveals conformance issues with the Software;    3. the Software has or may have introduced harmful code into electronic prescribing systems; or    4. the Australian Digital Health Agency 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 Australian Digital Health Agency;   2. negotiate remediation actions and timeframes to address the error, issue or conformance issue in good faith with the Australian Digital Health Agency; and   3. implement at the Vendor’s own cost the agreed remediation actions in the agreed timeframes.   The Vendor acknowledges that if:   * 1. the Australian Digital Health Agency and Vendor cannot agree on remediation actions; or   2. the Vendor fails to implement the agreed remediation actions in the agreed timeframes,   3. the Australian Digital Health Agency may take any action it considers necessary including, without limitation, preventing the Software participating in electronic prescribing. The Australian Digital Health Agency will provide the Vendor with reasonable assistance to assist with resolving problems pertaining to electronic prescribing.  1. The Vendor must remain compliant with the Electronic Prescribing Conformance Assessment Scheme and retain copies of test reports that demonstrate conformance to the published statement of system requirements in the Electronic Prescribing Participating Software Conformance Profile, for the term of this Deed Poll and for a period of seven years following termination. Without limiting clause 9, the Vendor must provide a copy of the test report(s) to the Australian Digital Health Agency within 14 days on request. 2. 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 participating in electronic prescribing. The Vendor must, as soon as it becomes aware that harmful code has or might have been introduced, immediately notify the Australian Digital Health Agency, giving details of the circumstances, in which case clause 8 will apply. 3. Electronic prescribing and its functionality will change over time. As such, the Electronic Prescribing Participating Software Conformance Profile and other associated technical framework documents may be updated or replaced from time to time, and the Australian Digital Health Agency may withdraw support for previous versions. Although the Australian Digital Health Agency will endeavour to consult with affected parties about any such changes, it is impossible to guarantee that the Australian Digital Health Agency will consult individually with every participant. Vendors are encouraged to register at <https://developer.digitalhealth.gov.au/home> to be kept informed of latest news and events. The Vendor acknowledges that it may be required to complete conformance testing against new/updated conformance requirements and that failure to do so may result in the Software no longer participating in electronic prescribing. 4. The Australian Digital Health Agency 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 participation in electronic prescribing which includes, without limitation, any decision of the Australian Digital Health Agency to prevent the Software’s connection. 5. The Vendor indemnifies the Australian Digital Health Agency and its representatives against all liability, expense, loss, damage or cost reasonably sustained or incurred by the Australian Digital Health Agency (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 threatened, or action taken, by a third party arising out of or in connection with: 6. any negligent, unlawful or willfully wrong act or omission of the Vendor; 7. an allegation that the Software infringes the intellectual property rights or moral rights of the third party; or 8. the Vendor’s breach of one or more terms of this Deed Poll. 9. The Vendor may terminate this Deed Poll by giving the Australian Digital Health Agency at least seven days written notice, in which case the Australian Digital Health Agency may immediately take any action it considers necessary including, without limitation, preventing the Software’s participation in electronic prescribing. 10. This Deed Poll will terminate immediately upon cancellation of the Software’s participation in electronic prescribing. 11. Nothing in this Deed Poll limits or restricts any function, power, right or entitlement of the Australian Digital Health Agency. 12. Any notice required to be given to the Australian Digital Health Agency under this Deed Poll should be in writing to: [help@digitalhealth.gov.au](mailto:eprescribing.conformance@digitalhealth.gov.au?subject=Observed%20conformance%20assessment%20session%20booking) . 13. This Deed Poll is governed by and will be construed according to the laws of the state of New South Wales.   Executed as a deed poll.   |  |  |  | | --- | --- | --- | | **SIGNED** **SEALED AND DELIVERED** for and on behalf of:    Vendor legal name and ABN/ACN  in 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 | |