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Electronic Prescribing Conformance Assessment Scheme

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1 Introduction

1.1 Purpose

This document is the Conformance Assessment Scheme (the Scheme) developed by the Australian Digital Health Agency (the Agency), which describes the process for assessing the conformance of software and systems involved in electronic prescribing.

1.2 Intended audience

This document is intended for:

- Vendors of software and systems participating in electronic prescribing.
- Health jurisdictions, healthcare providers and system integrators that implement software or systems that participate or interact in electronic prescribing.
- Commonwealth, State and Territory regulators responsible for legislation relating to the writing and dispensing of prescriptions in Australia.

1.3 Scope

The scope of this Scheme is for establishing the conformance of software and systems that participate in electronic prescribing, specifically those identified in section 2.

The Scheme does not describe any conformance activities in relation to the My Health Record System, the Healthcare Identifier (HI) Service, the National Authentication Service for Health (NASH), Secure Messaging or the Pharmaceutical Benefits Scheme (PBS) Claiming Service (PBS Online). Where interaction with those systems is required by other software or systems participating in electronic prescribing, the software or systems will be expected to comply with the certification requirements specific to the use of those systems.

Technical integration requirements for integration with a Prescription Delivery Service (PDS) will be met using the technical specifications developed, supplied and maintained by existing Prescription Exchange Service (PES) providers.

1.4 Development approach

The Electronic Prescriptions Project Technical Working Group has been established by the Agency to co-design the Conformance Framework for electronic prescriptions, which includes the Scheme in addition to the Solution Architecture and the Conformance Profile. In support of this co-design activity, the Agency has prepared draft material for consultation and discussion with the Technical Working Group and has incorporated suggestions and changes as agreed.

The Electronic Prescribing Working Group (EPWG), chaired by the Commonwealth and comprised of States and Territory representatives, has been formed under the Australian Health Ministers' Advisory Council (AHMAC) to consider development and implementation of electronic prescribing, and will provide final endorsement on the Conformance Framework.

The Scheme will be subject to ongoing review (at least annually), to ensure any conformance related issues arising during the Scheme's operation are addressed.

1.5 Contributions

This document has been developed through co-design and consultation with the Electronic Prescriptions Project Technical Working Group.

The Group is comprised of members from the following bodies and organisations:

- Australian Medical Association
- The Royal Australian College of General Practitioners
- Pharmaceutical Society of Australia
- The Pharmacy Guild of Australia
- Medical Software Industry Association
- Queensland Health
- Department of Health, Tasmanian Government
- FRED IT Group
- MediSecure
- Cerner
- Chemist Warehouse
- Medical Director
- Best Practice Software
- Minfos
- Corum Health
- MedAdvisor
- DXC Technology
- Best Health Solutions
- Consumer representatives
- Commonwealth Department of Health
- Commonwealth Department of Human Services
- Australian Digital Health Agency

1.6 Scheme objectives

The objectives of the Scheme, together with the relevant Commonwealth and state or territory regulations, are to provide users and regulators with an acceptable level of assurance that the software and systems used for electronic prescribing are secure and safe to use.

1.7 Overview

Electronic prescribing is the preparation, transmission and receipt of a prescription in accordance with approved information technology requirements and by means of an eligible electronic communication. The electronic prescription carries the same legal status as a paper prescription and from which supply of medicines may be provided.

Electronic prescribing is supported in Commonwealth legislation under the *National Health (Pharmaceutical Benefits) Regulations 2017* and subordinate legislation and is expected to be similarly recognised in applicable state and territory regulations.

Under the PBS legislative framework, an electronic prescription must include a valid conformance identifier for all software and systems that handle the prescription. Software and systems must be self-assessed against the Conformance Framework in order to assert a valid conformance identifier.

Electronic prescribing conformance testing is a process to establish that the software or system under test against the Conformance Framework meets the approved information technology requirements.

The Scheme is the process by which systems are identified as meeting the approved information technology requirements.

2 System Roles

A number of systems will be used in electronic prescribing and may perform one or more roles within the electronic prescribing space.

System Role	Description	Example
Active Script List Registry	The system and services that allows: • a Subject of Care to register for an active script list; • Prescribing and dispensing systems to add prescriptions/dispense records to a Subject of Care's active script list; and • mobile application vendor to provide mobile applications to allow Subjects of Care to view and manage access to their active script lists.	
API Gateway	Programming that sits in front of a set of application programming interfaces (APIs) and acts as a single point of entry for subscribing software systems.	
Electronic Prescribing System	Software or a system which facilitates authoring an electronic prescription by an approved Prescriber. This software is often also a Clinical Information System such as a General Practice desktop product.	Systems used in primary care and private specialist settings. Systems used in acute and residential care settings.
Electronic Dispensing System	Software or a system which is capable of retrieving an electronic prescription and facilitating the dispensing of medications.	Community pharmacy systems. Hospital pharmacy systems.
Mobile Intermediary System	A system which manages communication between an Open Prescription Delivery Service and an elected Mobile Application.	
Mobile Application	Software that may be used by the Subject of Care to manage their prescriptions as well as provide the capability to present the prescription token (see below) to the pharmacy.	

System Role	Description	Example
Prescription Delivery Service (PDS)	A system that supports defined interfaces and services to facilitate the transfer of electronic prescriptions and related information between participating systems. A PDS may be Open or Direct.	A Prescription Exchange Service (PES) is a type of Open PDS. A Direct PDS is typically enabled through point to point integration between prescribing and dispensing systems.

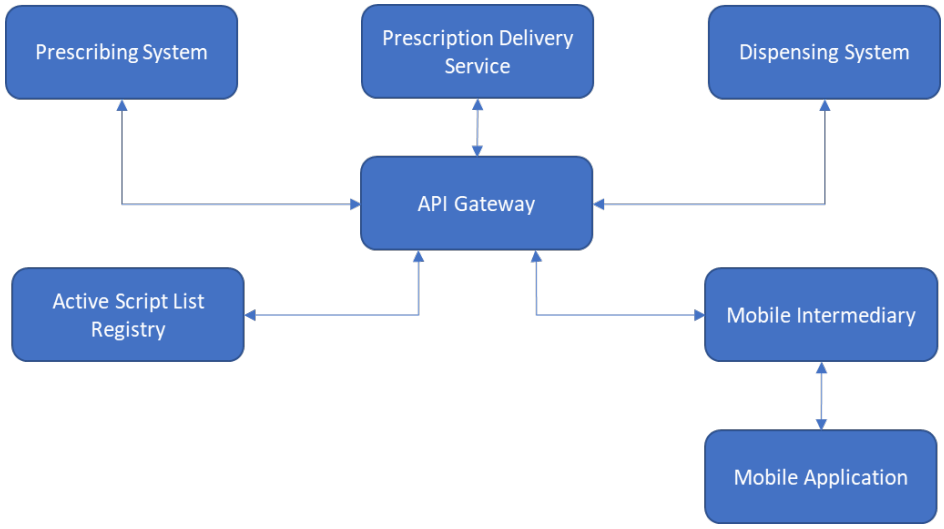

Figure 1 - System Participants (Logical View)

3 General Approach

The general approach is for all participating software and system vendors/implementers to declare their conformance with a published statement of system requirements (the Electronic Prescribing Conformance Profile) and any other requirements as defined by applicable Commonwealth, State or Territory regulators.

There are multiple system participants for electronic prescribing and participants are expected to work cooperatively to help manage system safety, effectiveness, reliability and efficiency.

Where systems are identified as non-conformant, mechanisms exist through which their participation in electronic prescribing could be denied.

3.1 Services provided by the Agency

The Agency provides a number of services to electronic prescribing systems:

1 Publication of the Electronic Prescribing Solution Architecture and Conformance Profile.

These documents are published on the Agency's Developer Centre Website (https://developer.digitalhealth.gov.au/). Interested parties may register their interest on the website and receive notifications as the documents are updated.

2 Introductory Program.

Prior to inclusion in the Register of Conformance (the Register) all vendors must access the Agency's Electronic Prescribing Introductory Program. The program is designed to inform prospective vendors of the electronic prescribing system architecture, conformance elements and its component service providers. As part of vendor support, participants are encouraged to solicit information which clarifies the requirements for them, in the context of their own offerings.

3 Testing process.

The Agency will provide details of how software vendors will test against the Conformance Profile and meet any other requirements to make the declaration to the Agency that their software is conformant.

Further support will include:

- Supply of test cases and test data to software vendors.
- Observational verification and audit log verification.

4 Support for vendors and implementers wishing to declare their conformance with the requirements expressed in the Conformance Profile.

The Agency acknowledges that vendors and implementers operate in many different parts of the health sector. The Agency can provide advice to vendors regarding their interpretation of the requirements in the context of their environment however it is the responsibility of the individual vendor to confirm their conformance with the requirements.

5 Registration of Conformance.

The Agency will provide a service through which it may receive declarations of conformance from software vendors and implementers. Upon receipt of the Declaration, the Agency shall:

a Ensure that all necessary information is contained within the declaration; and

b Ensure that the declaration is from an identifiable source.

Having satisfied itself as to these matters, the Agency shall, within 1 business day of receipt, include the details within the Register of Conformance, publish the Register on their public website and send the Register directly the Department of Human Services.

6 Electronic Prescribing Help Line.

The Agency will operate a vendor support line to provide assistance and a point of contact for vendors to notify the Agency of suspected or confirmed non-conformance to the requirements expressed in the Conformance Profile.

7 Solution Architecture, Conformance Profile and Conformance Assessment Scheme Maintenance.

The Agency may determine that an update to one or more of the elements in these documents would enhance the safety, privacy, efficiency or efficacy of electronic prescribing. Such modifications would be undertaken in consultation with the relevant organisations and peak bodies and timeframes for conformance agreed.

8 Quality Assurance.

The Agency will provide ongoing quality assurance processes to assist software and system vendors to remain conformant and to ensure the safety, privacy, efficiency and efficacy of the electronic prescribing Conformance Framework.

The Agency will act on advice received regarding potential or confirmed non-conformance and work with software vendors to address non-conformance within agreed timeframes and to an agreed management plan.

The Agency will have the ability to remove non-conformant systems from the Register.

4 Scheme Operation

4.1 Software development

Developers of systems designated for participation in electronic prescribing are required to observe all mandatory obligations identified in the Electronic Prescribing Conformance Profile (the Profile) as published by the Agency.

4.2 Conformance assessment

Organisations which develop systems designated for participation in electronic prescribing are to test that their system does, in fact, comply with all mandatory obligations identified in the Profile as published by the Agency.

4.3 Declaration

Having established that the system they have developed is conformant with the current version of the Profile, and prior to its release to market, organisations are required to notify the Agency, in an Agency approved form, of their Declaration that the system they are releasing is conformant together with the details of the product.

Product details are to include Vendor Name, Product Name and Product Version, together with its Conformance ID.

The Conformance ID is a text string of no more than 36 printable characters containing a text string representing the Product Name, a single character delimiter ("|") and an alpha-numeric string representing the Software Product Version.

Noting that the Conformance ID may assist with issue identification and is used to manage participation, declaration of accurate version information is strongly advised. It is, however, recognised that some software products update version information on a regular basis and in response to changes which do not impact electronic prescribing functionality. For this reason, software vendors may ascertain for themselves the granularity of version information declared in the Conformance ID and the occasions at which it is declared.

Note: Developers SHALL NOT release software to the market with electronic prescribing capability until the Agency has acknowledged receipt of the Declaration of Conformance. This prohibition applies to all software versions and revisions that impact electronic prescribing capability (major and minor).

Prescription Delivery Services SHALL NOT commence operations with connecting electronic prescribing systems until the Agency has acknowledged receipt of their Declaration of Conformance.

4.4 Registration

Upon receipt of the Declaration of Conformance, the Agency shall enter the details of the software product or system into the Register, together with the version of the Profile, and it shall pass the details to the Department of Human Services within 1 Business Day. The Agency may make the Register available to other interested parties.

Note: A vendor's initial inclusion in the Register is contingent upon them having accessed and read the Electronic Prescribing Introductory Program provided by the Agency.

4.5 Assertion

The system shall assert its Conformance ID in all electronic prescription messages. In all PBS claims, a dispensing system shall assert its Conformance ID, together with that of the PDS that the prescription was uploaded to, the PDS from which they downloaded the electronic prescription (if different) and of the prescribing system which generated the electronic prescription.

4.6 Verification

PDS providers assess and certify integration between the participating system and the PDS as per current arrangements. This does not constitute a verification of conformance with the Scheme but is, as per Section 1.3, an element of Scheme conformance.

Note: PDS Operators SHALL NOT exchange electronic prescription messages between systems which are not listed on the Register as provided by the Agency. This prohibition extends to the exchange of electronic prescriptions with other PDS Operators and Mobile Intermediary systems.

Note: Vendor systems will be required to undergo further conformance assessment if software version changes impact electronic prescribing functionality.

4.7 Profile version maintenance

Due to the identification of issues that may arise from time to time, the Agency retains the discretion to revise the Profile.

It is recognised that vendors may be a considerable way into their development cycle when a new version of the Profile becomes available.

The date required for compliance with a new profile shall be nominated at the time of publication. The date specified shall afford all participating vendors reasonable time with which to achieve conformance and reasonable time for healthcare facilities to upgrade to the new version.

If there are specific clinical safety or security aspects that require immediate redress, the Agency shall negotiate the required date of conformance with participating vendors.

It is recognised that healthcare facilities may be operating versions of vendor software which are not the most current. Where the Profile is updated, vendors may be requested by the Agency to advise whether the prior versions in use are conformant or non-conformant with the new profile. Where it is identified that facilities are operating non-conformant software or systems, a grace period shall be identified after which time the old versions shall be removed from the Register of Conformance.

4.8 Issue detection

Participating systems which submit malformed messages to a PDS will be notified of rejections. Where a PDS submits a malformed message to a participating system, there will be similar notifications raised and issues addressed.

System participants would, as per current practice, identify issues through operation of the system.

4.9 Issue remediation

As per current practice, issues identified between participating systems are cooperatively resolved between participating software vendors.

4.10 Issue escalation

Advice regarding the interpretation of the Profile may be obtained from the Agency. The Agency does not warrant the conformance of vendor software. If an issue cannot be satisfactorily resolved in a timely manner by participating software vendors, system participants are required to escalate the matter to the appropriate Commonwealth, state or territory regulator. Management of the Register of Conformance rests with the Agency.

5 Compliance Monitoring

The Agency's role in publishing the Electronic Prescribing Solution Architecture, Conformance Profile and Conformance Assessment Scheme on its public web site; providing an Introductory Program for electronic prescribing vendors; developing test cases and test data; and providing independent testing oversight, ensures a level of confidence that the software systems included on the Register distributed by the Agency were compliant with the Electronic Prescribing Conformance Profile at the time of registration.

The inclusion of the Conformance IDs of the prescribing system, the upload PDS, the download PDS and the dispensing system in PBS claim messages provides PBS Online with visibility of all systems participating in electronic prescribing for a particular electronic prescription. The Conformance IDs asserted in all PBS claim transactions are verified against the Register distributed to the Department of Human Services by the Agency as the claims are processed.

The Agency will have the ability to remove non-conformant systems from the Register, if warranted, in accordance with this process.

Acronyms

Acronym	Description
Agency	Australian Digital Health Agency
ETP	Electronic Transfer of Prescriptions data
PDS	Prescription Delivery Service
PES	Prescription Exchange Service (a type of PDS)

Glossary

Term	Meaning
Dispenser	An individual who dispenses medically prescribed drugs and medicines after providing instruction and counsel on the proper use and adverse effects of those drugs and medications in accordance with all relevant legislative, regulatory and professional requirements.
Electronic prescribing	Electronic prescribing is the preparation, transmission and receipt of a prescription in accordance with approved information technology requirements and by means of an eligible electronic communication. The electronic prescription carries the same legal status as a paper prescription and from which supply of medicines may be provided.
Electronic prescription	Electronic clinical documents that contain all information relating to an order to supply medicine to an individual. An electronic prescription is generated electronically by a prescriber, authenticated, securely transmitted (either directly or indirectly) for dispensing and supply, integrated into the pharmacy dispensing software and, in the case of Pharmaceutical Benefits Scheme (PBS) prescriptions, available to be sent electronically to the Department of Human Services for claiming purposes. Note: This definition does not preclude the use of other processes or artefacts to support electronic prescribing.
Electronic Transfer of Prescriptions (ETP)	The current process whereby prescribing systems pass a copy of prescription data to a PES, which is available for download by dispensing systems to support dispensing of a paper prescription.
Participating system	Software or a system that participates in electronic prescribing. Participating systems include any system which facilitates generation of an electronic prescription, retrieval of and dispensing from an electronic prescription, facilitates the transfer of an electronic prescription, or management of an electronic prescription.
Prescriber	An individual who provides healthcare and who creates prescriptions in accordance with all relevant legislative, regulatory and professional requirements.
Prescription	A written direction from a registered health provider to a supplier for preparing and dispensing a drug [Oxford Medical Dictionary] [HIM].
Prescription Delivery Service (PDS)	A service that supports defined interfaces and services to facilitate electronic prescribing, that is the transfer of electronic prescriptions and related information between participating systems.