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Australian Digital Health Agency

Electronic Prescribing Conformance Assessment Scheme

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1 Introduction

1.1 Purpose

This document describes the scheme for assessing the conformance of software involved in the electronic prescribing process.

1.2 Intended audience

This document is intended for:

- Vendors of software systems participating in electronic prescribing
- Health jurisdictions, healthcare providers and system integrators that implement software systems that participate or interact in electronic prescribing
- Federal, 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 systems that participate in electronic prescribing, specifically those systems identified in section 2.

This Conformance Assessment Scheme (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 PBS Claiming Service (PBS Online). Where interaction with those systems is required by software systems participating in electronic prescriptions, software systems will be expected to comply with the certification requirements specific to the use of those systems.

Technical integration requirements will be met using the technical specifications developed, supplied and maintained by existing Prescription Exchange Services.

1.4 Development Approach

The Electronic Prescriptions Project Technical Working Group has been established by the Agency to co-design the solution architecture and conformance framework for electronic prescriptions. In support of this activity, the Agency prepares draft material for consultation and discussion with the Technical Working Group and incorporates suggestions and changes as agreed.

The Electronic Prescriptions Working Group (EPWG), comprised of members from the Commonwealth, States and Territories, has been formed under the Australian Health Ministers Advisory Council (AHMAC) to consider these matters and will provide final endorsement on the solution architecture, conformance requirements and conformance assessment scheme.

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 and Human Services (Tasmania)
- 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
- Services Australia
- Australian Digital Health Agency

1.6 Scheme Objectives

The objectives of the Scheme, together with Commonwealth, State and Territory Regulations, are to provide users and regulators with an acceptable level of assurance that the electronic prescribing system is safe to use.

1.7 Overview

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

Electronic Prescribing by means of an eligible electronic communication is recognised in the *National Health (Pharmaceutical Benefits) Amendment (Electronic Prescriptions) Regulations 2019* (Cth) and is expected to be similarly recognised in applicable State and Territory regulations.

The National Health (Pharmaceutical Benefit) Regulations stipulates that electronic prescriptions must meet approved information technology requirements in relation to their:

a) Preparation and submission

b) Authorisation

c) Presentation to an approved supplier

d) Lodging an order with an approved pharmacist

e) Submitting a receipt for a pharmaceutical benefit

f) Acknowledging receipt of a pharmaceutical benefit

g) Doing any other thing that is required or permitted under the Regulations.

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

The Electronic Prescribing Conformance Assessment Scheme is the process by which software systems are identified as meeting the approved information technology requirements.

2 Software System Roles

Software Systems may perform one or more roles within the electronic prescribing space.

Software System Role	Definition	Example
Electronic Prescribing System	A Prescribing System is 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.	Software systems used in primary care and private specialist settings such as Medical Director, Best Practice, Zedmed, Genie, etc. Software systems used in acute and residential care settings such as Cerner, Medchart, BESTmed, etc.
Electronic Dispensing System	A dispensing system capable of facilitating the dispensing of medications.	Community pharmacy software systems such as FRED NXT, Minfos, Corum, Aquarius, etc. Hospital pharmacy software systems such as iPharmacy, Merlin, etc.
Prescription Delivery Service	A service that supports defined interfaces and services to facilitate the transfer of electronic prescriptions and related information between participating systems.	Services such as eRx Script Exchange and MediSecure ETP.
Mobile Intermediary System	A system which manages communication between an Open Prescription Delivery Service and mobile applications.	
Mobile Application	A mobile application 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.	

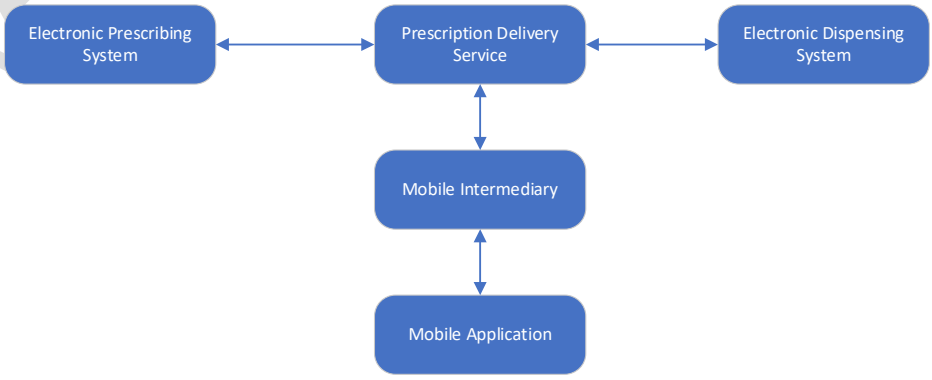

Figure 1 - Software System Participants (Logical View)

3 General Approach

The general approach is for all participating system vendors/implementers to declare their conformance with a published statement of software requirements (the Electronic Prescribing Conformance Profile) and any other requirements as defined by applicable Federal, 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 if and when 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. 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 to Services Australia and the Prescription Delivery Services.

6) Electronic Prescribing Help Line.

The Agency will provide a point of contact for vendors, prescribers, dispensers and members of the public to notify the Agency of suspected issues with electronic prescribing. On receipt of such notification, the Agency shall make a record of the notification and initiate investigation with the relevant parties.

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

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

8) Quality Assurance.

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

The Agency will manage incidents of potential non-conformance from identification through to resolution, working with software vendors and observing software behaviour if required. The Agency will have the ability to remove non-conformant software from the Register.

4 Scheme Operation

4.1 Software Development

Developers of software 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 software designated for participation in electronic prescribing are to test that their software product does, in fact, comply with all mandatory obligations identified in the Profile as published by the Agency.

4.3 Declaration

Having established that the software 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 approved form, of their Declaration that the software 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 are at liberty to 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 (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 into the Register, together with the version of the Profile, and it shall pass the details to Services Australia and the PDS Operators 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 software shall assert its Conformance ID in all electronic prescription messages. Dispensing Software shall assert its Conformance ID, together with that of the PDS from which they downloaded the electronic prescription and the Conformance ID of the system which generated the electronic prescription in all PBS Claims.

4.6 Verification

PDS Operators 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 software may need to undergo further conformance assessment if software version changes impact ePrescribing 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, 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 would 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 assess or 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 regulator.

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 original prescribing system; the PDS which provided the electronic prescription to the dispensing system; and the dispensing system itself, in PBS claim messages provides the PBS Claims System with visibility of all systems participating in electronic prescriptions. The Conformance IDs asserted in all PBS claim transactions are verified against the Register distributed by the Agency before the claims are processed.

Incident management will be in accordance with the Agency's Electronic Prescribing Incident Management Process. The Agency will have the ability to remove non-conformant software from the Register, if warranted, in accordance with this process.

Acronyms

Acronym	Description
ADHA	Australian Digital Health Agency
e-Prescribing	electronic prescribing
e-Prescription	electronic prescription
ETP	electronic transfer of prescription data
PDS	prescription delivery service

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 medicines in accordance with all relevant legislative, regulatory and professional requirements.
electronic prescribing (e-Prescribing)	The process by which a prescription is electronically generated by a prescriber, authenticated with an electronic signature, securely transmitted to a prescription delivery service for dispensing and supply, downloaded by a supplier, seamlessly integrated into the dispensing software and, in the case of Australian government subsidised prescriptions, available to be electronically sent to the Services Australia for claiming purposes. Notes: 1. This definition does not preclude the use of paper-based processes to support electronic prescribing activity. 2. Repeat and deferred supply authorisations that are uploaded to a prescription delivery service by a supplier are not electronic authorisations, unless the original prescription was generated by a prescriber as an electronic prescription.
electronic prescription (e-Prescription)	Electronic clinical documents that contain all information relating to an order to supply medication 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 Services Australia for claiming purposes. Note: This definition does not preclude the use of other processes or artefacts to support e-Prescribing.
electronic transfer of prescription (ETP)	The current process whereby prescribing systems pass data about a prescription to a PDS, which is available for download by dispensing systems is support of dispensing a conventional paper prescription.
participating system	A computer system that participates in electronic prescribing. Participating systems include any system which generates an electronic prescription, retrieves and dispenses from an electronic prescription, facilitates the transfer of an electronic prescription or manages 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 pharmacist for preparing and dispensing a drug [Oxford Medical Dictionary] [HIM].

Term	Meaning
prescription delivery service (PDS)	An e-Health service that supports defined interfaces and services to facilitate the transfer of electronic prescriptions and related information between participating systems.