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Electronic Prescribing

Participating Software Conformance Profile

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Council of Australian Governments

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Electronic Prescriptions Project Technical Working Group

The Electronic Prescriptions Technical Working Group (TWG) was established by the Australian Digital Health Agency to co-develop the solution architecture and conformance framework for the Electronic Prescriptions Project. Over 30 members representing the medical software industry, medical practitioners, pharmacists, consumers, Department of Health and jurisdictional members made up the TWG and provided their time and expertise to the successful delivery of this Conformance Profile document.

Department of Health Electronic Prescribing Project Team

The Department of Health has overall accountability for the Electronic Prescriptions Project, and the Department's Electronic Prescribing Project Team provided valuable guidance and feedback on the draft versions of this Conformance Profile document.

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1 Introduction

1.1 Purpose

This document summarises the functional and non-functional requirements for software that supports participation in electronic prescribing. This includes software used by:

- Authorised prescribers
- Authorised dispensers
- Prescription Delivery Services
- Subjects of Care (SoC), or their Agents, using mobile devices to access their prescriptions through URIs sent to them via SMS/email, or using prescription management applications that access electronic prescriptions

This document lists the specific conformance requirements that must or should be met to support participation in electronic prescribing. These requirements build on those that have already been implemented to support ETP.

1.2 Intended audience

The intended audience includes the following organisations:

- Software vendors; and
- Developers of health software systems.

2 Scope

- Systems able to participate in electronic prescribing may include prescribing, Prescription Delivery Services, dispensing, consumer mobile applications, and mobile application intermediaries.
- This document is limited to discussing functional and non-functional requirements related to electronic prescribing of systems that participate in prescription exchange for the purpose of electronic prescribing.
- Functional and non-functional requirements of those systems unrelated to electronic prescribing are out of scope.
- This document does not cover usability or commercial aspects of those systems or their participation in electronic prescribing.

2.1 Conformance Requirements Approach

Conformance requirements have been developed against detailed use cases. The use cases are detailed in the Electronic Prescribing Solution Architecture.

The use cases are grouped into four broad areas covering the activities performed by:

- The Prescriber
- The Dispenser
- The Subject of Care (or their Agent)
- The Prescription Delivery Service

Vendors should consider those use cases relevant to the functionality and purpose of their solution.

Requirements follow a standard form, utilising the following language:

Shall: When appearing in a conformance requirement, the verb SHALL indicates a mandatory requirement. Its negative form SHALL NOT indicates a prohibition.

Should: When appearing in a conformance requirement, the verb SHOULD indicates a recommendation. Its negative form SHOULD NOT indicate an option that should not be supported.

May: When appearing in a conformance requirement, the verb MAY indicates an optional requirement.

3 Conformance requirements for Electronic Prescribing

This section describes conformance requirements specific for electronic prescribing.

Prescription Delivery Service Applicability

An electronic prescribing or dispensing system may connect to or act as a Prescription Delivery Service (PDS) to enable end to end electronic prescription transactions. Conformance requirements are classified as "Open PDS applicable" and "Direct PDS applicable".

Vendors connecting to an open PDS, are required to consider conformance requirements relevant to their system functionality (e.g. prescribing, delivery, or dispensing) marked with "yes" in the "open PDS applicable" column.

Vendors implementing with a direct PDS system, are required to consider conformance requirements relevant to their system functionality (e.g. prescribing, delivery, and dispensing) marked with "yes" in the "direct PDS applicable" column.

Where "No" appears in either the "Open PDS applicable" column or in the "Direct PDS applicable" column, it means that that requirement is not applicable in that context.

3.1 Prescribing Systems

This section describes conformance requirements specific to electronic prescribing - prescribing systems. A prescribing system is that which is capable of authoring a prescription on behalf of an authorised prescriber. This software is often also a Clinical Information System (CIS) such as a GP desktop product.

Authentication and authorisation

Reference	Requirement	Open PDS	Direct PDS
PRES-1	The system **SHALL** provide single factor, multi-stage, or multi-factor authentication on all user accounts.	Yes	Yes
PRES-2	The system **SHALL** allow access to electronic prescribing capability only to designated user accounts. *Note: Only users designated by the healthcare organisation as having prescribing rights may access the electronic prescribing capability.*	Yes	Yes
PRES-3	The system **SHOULD** provide multi-factor authentication on user accounts with electronic prescribing capability. *Note: As per Australian Cyber Security Centre (ACSC) recommendations.*	Yes	Yes
PRES-4	User accounts with electronic prescribing capability **SHALL** contain the user's: • Full Name; • Title; • PBS Prescriber Number, where they have one; • AHPRA Number; and • Healthcare Provider Identifier - Individual (HPI-I).	Yes	No

Authentication and authorisation

Reference	Requirement	Open PDS	Direct PDS
PRES-4A	User accounts with electronic prescribing capability **SHALL** contain the user's: • Full Name; • Title; • PBS Prescriber Number, where they have one; • AHPRA Number; and User accounts with electronic prescribing capability **SHOULD** contain the user's: • Healthcare Provider Identifier - Individual (HPI-I).	No	Yes
PRES-5	Where only single factor or multi-stage authentication is provided, the system **SHALL** allow healthcare organisations the ability to establish authentication parameters. Including, but not limited to: • Minimum password length; • Password composition; • Password retry limit (before lockout); • Password refresh interval (frequency with which new password must be created); and • Password reuse interval (period which must expire before a password may be reused). *Note: Healthcare organisations shall have the support of the system in the implementation of access control policies.*	Yes	Yes
PRES-6	The system **SHALL** automatically log off an account, or require re-authentication, after a period of inactivity defined by the healthcare organisation. *Note: Healthcare organisations shall be able to define a period of inactivity after which the prescriber's terminal may be considered unattended and vulnerable to misuse.*	Yes	Yes

Authentication and authorisation

Reference	Requirement	Open PDS	Direct PDS
PRES-7	The system **SHALL** require the user to re-authenticate as and when required under state and territory regulations when prescribing controlled medicines (or attain an additional stage where multi-stage authentication is used). *Note: Prescriptions for Controlled Drugs warrant additional measures to ensure that the prescription is being created by an authorised prescriber.*	Yes	Yes
PRES-8	The system **MAY** automatically disable an account that has been inactive for a period defined by the healthcare organisation. *Note: This measure is a "backstop". Healthcare organisations should implement de-provisioning or account disablement where the user leaves on a permanent or temporary basis.*	Yes	Yes

Audit

Reference	Requirement	Open PDS	Direct PDS
PRES-10	The system **SHALL** maintain an audit log of logon, logoff, stage-change and credential change activity for all user accounts. *Note: Stage-change is where an additional credential is required - for example a PIN is required to undertake a particular function. Credential change would be the change of the form of the credential or a change to the value (for example, password change).*	Yes	Yes

Audit

Reference	Requirement	Open PDS	Direct PDS
PRES-38	The system **SHALL** record each electronic prescription generated in an audit log. The details of the record shall include: • Date and time of prescription creation (UTC Time); • The Globally Unique Prescription Identifier; • The Delivery Service Prescription Identifier (DSPID); • Date and time receipt acknowledged by the PDS (UTC Time); and • All information fields (including metadata) contained in the electronic prescription.	Yes	Yes
PRES-39	The system **SHALL** record each electronic prescription cancellation request in the audit log. The details of the record shall include: • Date and time of cancellation (UTC Time); • The Globally Unique Prescription Identifier; • The Delivery Service Prescription Identifier (DSPID); • Date and time of acknowledgement (UTC Time); and • The success (or otherwise) of the cancellation.	Yes	Yes

User Selection

Reference	Requirement	Open PDS	Direct PDS
PRES-11	The system **MAY** provide for an option to enable / disable electronic prescribing capability on a per user account basis. *Note: Some prescribers may elect not to participate in electronic prescribing and may not wish to be presented with electronic prescribing options.*	Yes	No

User Selection

Reference	Requirement	Open PDS	Direct PDS
PRES-12	The system **SHOULD** disable electronic prescribing functionality if it is aware that the Open Prescription Delivery Service is unavailable or unreachable. *Note: For prescriber workflow efficiency. The intent is that the system should support early detection that the electronic prescribing process will not succeed.*	Yes	No
PRES-13	The system **SHALL** allow the prescriber to select between creation of an electronic or paper prescription. *Note: Supports Subject of Care's choice. Furthermore, under Regulations, the medicines prescribed may require a paper prescription.*	Yes	No
PRES-14	When generating a paper prescription the system **SHOULD** support the generation of an ETP message. *Note: To maintain the efficiencies in pharmacy workflow and improved data quality enabled through the current use of ETP in support of paper prescriptions.*	Yes	No
PRES-15	When generating an Electronic Prescription, the system **SHALL NOT** issue an ETP message. *Note: An ETP Message may be sent if a Paper Prescription is created. An Electronic Prescription will be sent to the PDS only if there is no paper prescription. There should never be a paper prescription and an electronic prescription at the same time for the same medicine order.*	Yes	Yes
PRES-16	The system **SHALL NOT** send the electronic prescription to more than one (1) PDS. *Note: If an "Open" electronic prescription is generated it must be sent to only one PDS. If a "Direct" electronic prescription is generated it should not be sent at all to an open PDS. This is to avoid duplication of the prescription.*	Yes	Yes

Composition

Reference	Requirement	Open PDS	Direct PDS
PRES-17	The system **SHALL** include, within the electronic prescription, all data fields as required by Jurisdictional Regulations.	Yes	Yes
PRES-17A	For PBS and RPBS prescriptions, the system **SHALL** also include within the electronic prescription, all data fields as required by the National Health Act.	Yes	Yes
PRES-18	The system **SHALL** also include, within an electronic prescription, the following data elements: • Prescription Software Conformance ID; • Globally Unique Prescription ID; • Healthcare Provider Identifier - Organisation (HPI-O) of the prescribing organisation; • Subject of Care Date of Birth; and • Privacy notice.	Yes	Yes
PRES-19	The system **SHALL** also include, within an electronic prescription, the following data elements: • Healthcare Provider Identifier - Individual (HPI-I) of the Prescriber; • Subject of Care Individual Healthcare Identifier - (IHI); and • Privacy notice.	Yes	No
PRES-19A	The system **SHALL** also include, within an electronic prescription, the following data elements: • Healthcare Provider Identifier - Individual (HPI-I) of the Prescriber (if available); and • Subject of Care Individual Healthcare Identifier - (IHI) (if available).	No	Yes

Composition

Reference	Requirement	Open PDS	Direct PDS
PRES-20	The system **SHOULD** include Medicine Name as a SNOMED CT-AU (which includes the Australian Medicines Terminology) Codable Value.	Yes	Yes
PRES-21	The system **SHALL** allow for the inclusion of Reason for prescribe (clinical indication) as a SNOMED CT-AU Coded Value.	Yes	Yes
PRES-21A	The system **SHALL NOT** require Reason for prescribe (clinical indication) as a SNOMED CT-AU Coded Value. *Note: The system must allow, but not demand, that Reason for Prescribe be populated. Where it is populated, it should also be represented as a SNOMED CT-AU Coded Value.* *Related requirements: PRES-21, PRES-22, PRES-49, PRES-53.*	Yes	Yes
PRES-22	Irrespective of the inclusion of any coded values, the system **SHALL** include all information fields presented to the prescriber in "Original Text". *Note: The clinical/supervising pharmacist sees the instructions as displayed to the prescriber when the prescriber wrote the prescription.* *"Original Text" is defined as the text "exactly as presented to the prescriber or dispenser".*	Yes	Yes
PRES-49	Where the Reason for prescribe (clinical indication) is included as a coded value, the system **SHALL** also include Reason for prescribe as a text (human readable) field.	Yes	Yes
PRES-53	The system **SHALL** allow capture of Reason for prescribe (clinical indication) as a text field if no coded value is provided. *Note: Reason for prescribe may not be easily defined or may cover more than one drop down menu option.* *Related requirements: PRES-21, PRES-21A.*	Yes	Yes

Finalisation

Reference	Requirement	Open PDS	Direct PDS
PRES-42	Having submitted an electronic prescription to an Open PDS, the system **SHALL**: • Print Evidence of Prescription (including the Token) in paper form; and/or • Facilitate the transmission of Evidence of Prescription (including the Token) to an electronic address in electronic form.	Yes	No
PRES-43	If printed, the Token **SHALL** be printed as a 1D Barcode.	Yes	No
PRES-44	The DSPID **SHALL** be printed in alphanumeric form in a position associated with the barcode on the Evidence of Prescription. If it is not directly below the barcode it should be labelled DSPID. *Note: In the event that the Token is unable to be scanned, a user may enter the DSPID manually.*	Yes	No
PRES-45	Where Evidence of Prescription is requested electronically, the system **SHALL** allow the user to select an electronic address for a particular Subject of Care (SoC) on a per prescription basis. *Note: Prescribers may have a default electronic address on file for the SoC. This may be for appointment reminders or other types of communication. The SoC may wish to use a different address to receive their prescription Token.*	Yes	No
PRES-46	Where Evidence of Prescription is sent in electronic form (e.g. SMS, email), the system **SHALL** transmit: • URI (e.g. URL); • Name of the Subject of Care; and • Medicine(s) name. *Note: In the event that the electronic address was incorrectly recorded, this limits the potential for exposing personal information to an unknown party.*	Yes	No

Finalisation

Reference	Requirement	Open PDS	Direct PDS
PRES-46A	Where Evidence of Prescription is sent in electronic form, the system **SHALL** support confirmation of the electronic address to be used by the prescriber with the Subject of Care. *Note: The address that will be used should be conveniently displayed so the prescriber can confirm this verbally or by display.*	Yes	No
PRES-47	Where Evidence of Prescription is provided in paper form, the system **SHALL** include the following details: • Indication that this is an Evidence of Prescription (e.g. Not a dispensable prescription); • Token (Barcode and DSPID); • Name of the Subject of Care; • Name of the prescriber; • Name of the prescriber organisation; • Contact details of the prescriber and / or prescribing organisation; • Medicine(s) name, strength; • Date prescribed; • Number of repeats available; and • Privacy notice.	Yes	No

Finalisation

Reference	Requirement	Open PDS	Direct PDS
PRES-48	Where Evidence of Prescription is provided in paper form, the system **SHALL NOT** include the following details: • Subject of Care age; • Subject of Care sex; • PBS Prescriber number; • Authority number; • Dose; or • Reason for prescribe. *Note: The dispenser will have the SoC's age and gender available to them, and may use this information to achieve a degree of certainty that the person presenting the Token is entitled to receive the medicines. The information on the Evidence of Prescription is not a definitive (legal) representation of the prescription.* *Not providing the PBS prescriber number, any PBS or state authority or permit number and dose mitigates the risk of the dispenser dispensing against Evidence of Prescription rather than the electronic prescription.*	Yes	No
PRES-50	Where the Evidence of Prescription is provided in paper form, the system **SHALL** provide a clear indication that it is *not* to be signed. *Note: Evidence of Prescription must not be misconstrued by a dispenser as a legal prescription.*	Yes	No

Modification

Reference	Requirement	Open PDS	Direct PDS
PRES-40	The system **SHALL** allow the user to make changes to a prescription prior to finalising. If the prescription has been sent to the PDS, PRES-41 applies. *Note: Supports current primary care workflow where the prescriber may review prescription details onscreen and want to make corrections prior to finalising.*	Yes	Yes

Modification

Reference	Requirement	Open PDS	Direct PDS
PRES-41	Post finalisation, where an electronic prescription has been sent to the PDS as an electronic prescription, the system **SHALL** issue a cancellation for the original prescription and issue a new prescription if a prescriber makes any changes to the prescription. *Note: This supports the existing front end "correction" process, where a prescriber may make alterations and re-issue the prescription to the SoC. The original prescription must be cancelled and reissued.*	Yes	Yes

Submission

Reference	Requirement	Open PDS	Direct PDS
PRES-23	The system **SHALL** store, in a permanent and non-alterable manner within the clinical or medicines record of the person for whom the electronic prescription was generated, the particulars of any electronic prescription generated, consistent with and as required by any applicable regulations	Yes	Yes
PRES-24	The system **SHALL** display the electronic prescription in a format that meets the requirements of the National Regulations and relevant state and territory legislation to the prescriber and obtain a final approval from the prescriber prior to finalising the prescription for transmission. *Note: Through this display, prescribers will be provided a step in their workflow to review the prescription prior to issuing. This offers an opportunity to review and amend the prescription as required to ensure patient safety.* *How the particulars of the prescription are displayed may vary between software products and jurisdiction. It's intended that a prescription should be displayed in a manner similar to a paper prescription.*	Yes	Yes

Submission

Reference	Requirement	Open PDS	Direct PDS
PRES-25	When connecting to a PDS over a public network, the system **SHALL** authenticate the identity of the PDS using Public Key Infrastructure (PKI). *Note: The Conformance Requirements will be updated if the approved authentication methods change.*	Yes	Yes
PRES-26	When connecting to a PDS over a public network, the system **SHALL** assert its identity to the PDS using Public Key Infrastructure (PKI). *Note: The Conformance Requirements will be updated if the approved authentication methods change.*	Yes	Yes
PRES-27	All transmission of electronic prescription information over public networks **SHALL** be encrypted using Australian Signals Directorate (ASD) approved cryptographic algorithms.	Yes	Yes
PRES-28	On submission to an Open PDS, the system **MAY** include in the electronic prescription header, the electronic address to which the PDS may send the Evidence of Prescription to the Subject of Care or their Agent. *Note: Subject to SoC consent.*	Yes	No
PRES-29	On submission to an Open PDS, the system **SHALL NOT** include in the electronic prescription header, the Subject of Care's Individual Healthcare Identifier (IHI). *Note: To be reviewed at any point in time that the use of an Active Script List model[1] is determined to be no less secure, private, equitable and accessible to a Token-only model.*	Yes	No

[1] In previous development versions of the Solution Architecture and Conformance Profile, the Active Script List model was originally referred to as 'Lookup' model.

Submission

Reference	Requirement	Open PDS	Direct PDS
PRES-30	On submission to a PDS, the system **SHALL** record the DSPID which references the electronic prescription in the PDS.	Yes	No
PRES-31	The system **SHALL** record the date and time (UTC) that the PDS acknowledged receipt of the electronic prescription.	Yes	Yes
PRES-32	The system **SHALL** provide the user with an indication as to whether the PDS has acknowledged receipt of the electronic prescription. *Note: Until the PDS acknowledges receipt, the SoC may not have a valid prescription in their possession.*	Yes	No
PRES-33	The system **SHALL** allow the user to abort submission of the electronic prescription prior to acknowledgement of receipt. *Note: The context is that the prescriber attempted to send an electronic prescription, but has had no acknowledgement of receipt from the PDS and decides to revert to a paper prescription.* *The required outcome is that there should be no electronic prescription in the PDS if the prescriber elects to stop the electronic prescribing process and revert to paper. This should be achieved by queuing and sending a cancellation to PDS.*	Yes	No
PRES-34	The system **SHALL** allow the user to issue a cancellation of an electronic prescription after acknowledgement of receipt by the PDS. *Note: It is understood that the cancellation may not take effect if the electronic prescription has already been filled or transferred to another PDS.* *Cancellation is not the same as ceasing a medicine on a medication chart.*	Yes	Yes

Submission

Reference	Requirement	Open PDS	Direct PDS
PRES-35	Upon cancellation, the system **SHALL** issue a cancellation message to the PDS.	Yes	Yes
PRES-36	The system **SHALL** allow the organisation to set the (seconds) duration of an "acknowledgement of receipt - timeout" (AORT), including a value which represents "no timeout".	Yes	No
PRES-37	The system, in the event of an AORT, **MAY** automatically: 1) alert the user, and 2) cancel the electronic prescription, and 3) proceed with printing a paper prescription.	Yes	No

3.2 Dispensing Systems

This section describes conformance requirements specific to electronic prescribing - dispensing systems. A dispensing system is that which is capable of facilitating the dispensing of medications. This system may be used by a dispenser in order to retrieve prescriptions from a Prescription Delivery Service (PDS).

Authentication and authorisation

Reference	Requirement	Open PDS	Direct PDS
DISP-1	When connecting to a PDS over a public network, the system **SHALL** authenticate the identity of the PDS using Public Key Infrastructure (PKI). *Note: Conformance requirements will be updated if the approved authentication methods change.*	Yes	Yes
DISP-3	Where the system interacts with the PDS over a public network, the system **SHALL** ensure that all information sent over the public network is encrypted using Australian Signals Directorate (ASD) approved cryptographic algorithms.	Yes	Yes
DISP-4	The system **SHALL** provide single factor, multi-stage, or multi-factor authentication on all user accounts. *Note: Dispensing systems provide an account for each user. Users are identified in relation to a dispense event by entering their initials. Dispensing systems then associate the initials entered with the account. There is no requirement to "login" (e.g. enter username and password) for each dispenser for each dispense transaction. Existing arrangements in dispensing software and practice may meet the requirement, if the requirement for single factor authentication is met (i.e. password may be required if different initials from last transaction are used).*	Yes	Yes

Authentication and authorisation

Reference	Requirement	Open PDS	Direct PDS
DISP-5	The system **SHALL** allow access to the capability for dispensing against electronic prescriptions only to designated user accounts. *Note: Only users designated by the healthcare organisation as having dispensing rights may access electronic prescribing capability.*	Yes	Yes
DISP-6	The system **SHALL** record the following information with each account: • Full Name; • Title; • AHPRA Number (if any); • HPI-I (if any); and • User Class: Pharmacist, Supervising Pharmacist, Pharmacy Technician, etc.	Yes	No
DISP-6A	The system **SHALL** record the following information with each account: • Full Name; • Title; • AHPRA Number (if any); and • User Class: Pharmacist, Supervising Pharmacist, Pharmacy Technician, etc. The system **SHOULD** record the following information with each account: • HPI-I (if any).	No	Yes

Authentication and authorisation

Reference	Requirement	Open PDS	Direct PDS
DISP-7	Where only single factor or multi-stage authentication is provided, the system **SHALL** allow healthcare organisations the ability to establish authentication parameters. Including, but not limited to: • Minimum password length; • Password composition; • Password retry limit (before lockout); • Password refresh interval (frequency with which new password must be created); and • Password reuse interval (period which must expire before a password may be reused). *Note: Healthcare organisations shall have the support of the system in the implementation of their access control policies.*	Yes	Yes
DISP-8	The system **SHALL** facilitate the identification and recording of the identity of each user involved with dispensing activity.	Yes	Yes
DISP-9	The system **SHALL** facilitate the identification and recording of the identity of the dispenser authorising the dispensing activity.	Yes	Yes
DISP-10	The system **SHALL** automatically log off an account, or require re-authentication, after a period of inactivity defined by the healthcare organisation. *Note: Healthcare organisations shall be able to define a period of inactivity after which the dispenser's terminal may be considered unattended and vulnerable to misuse.*	Yes	Yes
DISP-53	If the authorised dispenser identification is not present, the system **SHALL NOT** execute the dispense function.	Yes	Yes

Audit

Reference	Requirement	Open PDS	Direct PDS
DISP-34	The system **SHALL** maintain audit logs associated with electronic prescription dispense events in accordance with relevant legislation and regulation.	Yes	Yes
DISP-35	The system **SHALL** maintain an audit log of logon, logoff, stage-change and credential change activity for all user accounts.	Yes	Yes
DISP-36	The system **SHALL** record each dispense record generated in an audit log. The details of the record **SHALL** include: • Date and time of dispense creation (UTC Time); • The Globally Unique Prescription Identifier; • The Delivery Service Prescription Identifier (DSPID); • Date and time receipt acknowledged by the Delivery Service (UTC Time); and • All information fields (including Metadata) contained in the dispense record. *Note: At a minimum, all elements required by State/Territory legislation in a dispensing record should be included.*	Yes	Yes

Audit

Reference	Requirement	Open PDS	Direct PDS
DISP-37	The system **SHALL** record each dispense record cancellation request in the audit log. The details of the record **SHALL** include: • Date and time of Dispense cancellation (UTC Time); • The Globally Unique Prescription Identifier; • The Delivery Service Prescription Identifier (DSPID); • Date and time of acknowledgement from the Delivery Service (UTC time); and • The success (or otherwise) of the cancellation.	Yes	No
DISP-51	The system **SHALL** allow generation of a prescription file able to be transmitted to a regulatory body. This file **SHALL** include: • The original electronic prescription; • Any subsequent repeat authorisations; • Any associated annotations; • Any details about when the electronic prescription was downloaded from the PDS; • Date and time of dispense; • Date and time of PDS acceptance; and • Copies of any relevant Token(s) (DSPID) provided to the Subject of Care (SoC) / Agent. *Note: Electronic Prescribing shall allow for prescription information to be sent to relevant regulatory bodies, displayed appropriately, as required. The information to be made available to the regulator shall be equivalent to existing paper prescriptions (Original, repeats, and annotations). This should be able to be transmitted by print or digital methods.*	Yes	Yes

Audit

Reference	Requirement	Open PDS	Direct PDS
DISP-52	When the system is used to generate a file for submission to a regulatory body, the file **SHALL** clearly indicate that it cannot be used as a prescription. *Note: Vendors may consider inclusion of a watermark.*	Yes	Yes

Retrieval

Reference	Requirement	Open PDS	Direct PDS
DISP-11	The system **SHALL** support scanning (or other methods) of an electronic prescription Token from paper or a mobile device.	Yes	No
DISP-11A	The system **SHALL** support manual entry of an electronic prescription Token (i.e. entry of the DSPID). *Note: The DSPID may be represented as a barcode and / or the corresponding alpha numerical value. Should the barcode be corrupt, a dispenser may manually enter the alpha numerical value.* *Note: To be reviewed at any point in time that the use of an Active Script List model is determined to be no less secure, private, equitable and accessible to a Token-only model.*	Yes	No
DISP-12	The system **SHOULD** support accepting an electronic prescription Token electronically. *Note: Some dispensing systems may allow a SoC to submit a Token electronically in advance of presentation to the dispenser. This supports sending prescriptions from an eNRMC and other electronic medication charts to a contracted pharmacy.*	Yes	No
DISP-13	The system **SHALL** provide visual indication to the user if it detects that the PDS is unreachable or unavailable.	Yes	No

Retrieval

Reference	Requirement	Open PDS	Direct PDS
DISP-14	The system **SHALL NOT** accept as an electronic prescription a message or transaction that does not include the: • Prescribing software conformance identifier; • originalRepositorySoftUniqueID; and, • RepositorySoftUniqueID (if any). *Note: Electronic prescriptions are only considered valid if they assert a Conformance ID.*	Yes	Yes
DISP-15	The system **SHALL** accept all information relevant to an electronic prescription, including: • The original electronic prescription; • The most recent dispense (if any); and • All annotations (if any).	Yes	Yes

Presentation

Reference	Requirement	Open PDS	Direct PDS
DISP-16	For an electronic prescription, the system **SHALL** display: • Details of the original prescription; • The prescription status (e.g. fully dispensed, expired, cancelled, active etc.); • Details of the previous dispense (if any); and • The details of any annotations in relation to the prescription recorded by previous dispensers (if any). *Note: The above requirement details the minimum system requirements. Vendors may choose to display additional details.*	Yes	Yes
DISP-17	The system **SHALL** display all data elements as displayed to the prescriber, irrespective of the presence or otherwise of coded information fields.	Yes	Yes

Presentation

Reference	Requirement	Open PDS	Direct PDS
DISP-18	The system **SHALL** provide a clear visual indication to the user that the prescription is an electronic prescription. *Note: It must be made clear to the dispenser that this information represents the legal form.*	Yes	Yes
DISP-60	The system **SHOULD** clearly indicate to the user if the prescriber has specified that brand substitution not allowed. *Note: This is easily distinguished on an existing paper prescription. The dispenser should be directed to this value on an electronic prescription.*	Yes	Yes

Finalisation

Reference	Requirement	Open PDS	Direct PDS
DISP-30	The system **SHALL** be able to print an Evidence of Prescription for the Subject of Care that details the medicine(s) prescribed where there are remaining repeats or it is deferred supply. The system **SHALL** include the following details: • Indication that this is an Evidence of Prescription (e.g. Not for Dispense); • DSPID (as a 1D Barcode); • DSPID (as a number); • Name of the Subject of Care; • Name of the prescriber; • Name of the prescriber organisation; • Contact details of the prescriber / organisation; • Date prescribed; • Dispenser (pharmacy) contact; • Medicine(s) name and strength; • Date dispensed; and • Number of repeats available.	Yes	No

Finalisation

Reference	Requirement	Open PDS	Direct PDS
DISP-31	The system **SHALL** be able to provide an Evidence of Prescription, used to access the electronic prescription, to the Subject of Care. Where an Evidence of Prescription is sent in electronic form (e.g. SMS, email), the system **SHALL** transmit: • URI (e.g. URL); • Name of the Subject of Care; and • Medicine(s) name.	Yes	No
DISP-31A	Where an Evidence of Prescription is sent in electronic form, the system **SHALL** default delivery to the electronic address specified in the electronic prescription. *Note: The address to be used should be displayed to enable dispenser to confirm verbally, or by display, with the SoC. For a contracted pharmacy, this may be treated as a standing confirmation.*	Yes	No
DISP-32	The system **SHALL** produce an Evidence of Prescription in paper or electronic form for the Subject of Care without acknowledgement of successful lodgement from the PDS. *Note: If the PDS is unavailable, the Dispense Notice shall be queued and repeatedly retried until successfully delivered.*	Yes	No
DISP-33	The system **SHALL** be able to record receipt of supply. *Note: The system may provide a simple method of recording that receipt of supply has been acknowledged by the recipient. Any processes or tools dispensers may employ in order meet any State, Territory or Commonwealth Regulation are independent of these conformance requirements.*	Yes	Yes

Modification

Reference	Requirement	Open PDS	Direct PDS
DISP-56	The system **SHALL** provide a mechanism to support a dispense final check-off process in the absence of a paper prescription. *Note: Traditionally the final checking process is supported by comparing the paper prescription to the medicines to be dispensed. The system needs to provide an onscreen or printed mechanism to support check-off for electronic prescriptions.*	Yes	Yes
DISP-58	The system **SHALL** allow the user to override the default and select a different electronic address for a Subject of Care on a per prescription basis.	Yes	No
DISP-59	Post finalisation, where a dispense record has been sent to the PDS, the system **SHALL** issue a cancellation for the original dispense notice and issue a new dispense notice if a dispenser makes any changes. *Note: Achieved through cancellation of the original dispense record and submission of a new dispense record. This shall occur without changing the DSPID as this may have been provided to the SoC.*	Yes	Yes

Submission

Reference	Requirement	Open PDS	Direct PDS
DISP-19	The system **SHALL** send a dispense record to the PDS with all the data fields required for a Repeat Authorisation or Deferred Supply together with: • Dispense software conformance identifier; • Globally Unique Prescription ID *; • HPI-O of the dispensing organisation; and • Subject of Care Date of Birth *. *Note: * As per Original Prescription.*	Yes	No

Submission

Reference	Requirement	Open PDS	Direct PDS
DISP-20	The system **SHOULD** include any and all of the following fields in a dispense record to the PDS: • HPI-I of the authorising dispenser; • AMT coded value of medicine supplied; • Subject of Care Individual Healthcare Identifier (IHI) if available *; and • Subject of Care electronic communication address *. *Note: * As per Original Prescription.*	Yes	No
DISP-21	The system **SHALL NOT** allow an electronic prescription dispense record to be submitted to the PDS without the existence of the original electronic prescription. *Note: This avoids "orphan" dispense records in the PDS.* *Note: Supply under continued dispensing provisions will not be notified to the PDS using an Electronic Dispense Record.*	Yes	No
DISP-22	The system **SHALL** be able to send a message reflecting an annotation to the PDS as part of the dispense activity.	Yes	No
DISP-23	The system **MAY** determine that the PDS is unavailable and alert the dispenser.	Yes	Yes

Submission

Reference	Requirement	Open PDS	Direct PDS
DISP-24	If an item is not dispensed, the system **SHALL** restore the state of the electronic prescription in the Open PDS. *Note: The electronic prescription is locked in the Open PDS when retrieved by a dispensing system. If the dispense does not proceed, it shall be unlocked.* *There may be instances where a dispenser is required to abandon a dispense event prior to a dispense notice being posted to the PDS (for example, the dispenser is out of stock). In this instance, following the dispense event ceasing, the electronic prescription record should be returned to an unlocked state. The outcome is that the prescription is valid for dispense.* *Related requirement: DS-17.*	Yes	No
DISP-25	The system **SHALL** communicate a dispense reversal to the Open PDS. *Note: There may be instances where a dispenser is required to reverse a dispense event after a dispense notice has been posted to the Open PDS (for example, SoC declines supply). In this instance, following the dispense event, the dispenser is required to reverse the dispense event and return the electronic prescription record to an unlocked state. The outcome is that the prescription is valid for dispense.* *Related requirement DS-19.*	Yes	No
DISP-27	The system **SHALL** record the date and time (UTC) that the PDS acknowledged receipt of the dispense record.	Yes	No
DISP-28	The system **SHALL** record the date and time (UTC) that the PDS acknowledged receipt of the dispense cancellation or reversal.	Yes	No
DISP-29	If the PDS is unavailable / unresponsive, the system **SHALL** queue messages and retry until the PDS acknowledges receipt.	Yes	No

Submission

Reference	Requirement	Open PDS	Direct PDS
DISP-50	The system **SHALL** display the particulars of the prescription repeat required by state and territory legislation to the dispenser and obtain a final approval from the dispenser prior to finalising the prescription repeat.	Yes	Yes
DISP-57	On submission to an Open PDS, the system **MAY** include, in the dispense notice header, the electronic address to which the Open PDS may send the Evidence of Prescription to the Subject of Care or their Agent. *Note: Subject to SoC consent*	Yes	No

Reconciliation[2]

Reference	Requirement	Open PDS	Direct PDS
DISP-38	When a Dispense Record with a DSPID is manually entered, the System **SHALL** attempt to reconcile it against an electronic prescription retrieved from the PDS with that DSPID when the PDS becomes available.	Yes	Yes
DISP-39	The system **SHOULD** allow a user to request reconciliation of a manually entered dispense record with the electronic prescription retrieved from the PDS.	Yes	Yes
DISP-40	The system **SHALL** allow a user to review all dispense records pending reconciliation. *Note: Electronic prescriptions shall be a part of any existing reconciliation process(es). This may be achieved through a report, or an actionable on-screen list, or other mechanism.*	Yes	Yes

[2] There may arise a scenario to manually enter information to the dispensing system to allow a medicine to be dispensed. For example, a prescriber creates an electronic prescription which is stored in the PDS awaiting dispense. Upon request for dispense by the SoC, should the dispenser's internet connection be faulty, a dispenser may enter the details of the medicine to be dispensed (as obtained from the prescriber) into the dispensing system. These details shall include the DSPID. This will enable reconciliation processes to be enacted upon restoration of connectivity. The manually entered information will be reconciled with the electronic prescription based on the DSPID.

Reconciliation[2]

Reference	Requirement	Open PDS	Direct PDS
DISP-42	In attempting to reconcile a manually entered dispense record with an electronic prescription, the system **SHOULD** identify and display any reportable discrepancies.	Yes	Yes
DISP-43	Once the electronic prescription has been retrieved, the system **SHALL** allow the Dispenser to mark the Dispense Record as: • Reconciled; or • Reconciled with Annotations; or • Dispensing Exception. *Note: A Dispensing Exception occurs where there is a failure to reconcile substantial elements of the prescription beyond those acceptable by the State Regulator.*	Yes	Yes
DISP-44	Where marked as "Reconciled with Annotations" the system **SHALL** allow the recording of annotations. *Note: This allows an annotation to be made once the electronic prescription has been received (noting that this is an "urgent case"/"script owing" scenario).* *Annotations may be made where there is a failure to reconcile minor elements of the prescription; those acceptable by the State or Territory Regulator. This is likely to be agreed between the prescriber and dispenser.*	Yes	Yes
DISP-44A	Where marked as "Reconciled with Annotations", the system **SHALL** post the annotation(s) to the PDS to be available to subsequent dispensers.	Yes	No

Reconciliation[2]

Reference	Requirement	Open PDS	Direct PDS
DISP-46	Should the electronic prescription to be reconciled be identified as "already filled", the system **SHALL** be able to provide an indication on the dispense record that the electronic prescription was already filled. *Note: This is an exception condition related to "urgent case"/"script owing". If, when the electronic prescription is retrieved, it has already been dispensed against, the local dispense record should be updated to reflect this.*	Yes	No
DISP-47	Should the electronic prescription to be reconciled be determined "not present", the system **SHALL** include this event in a report. The local dispense record **SHALL** be marked as "Prescription Owing". *Note: Where the urgent case/script owing scenario was due to PDS unavailability and the medicines have been dispensed under "Script owing - PDS unavailable" conditions. Once the PDS becomes available, and it is revealed that the prescription is not residing in the PDS the script becomes "Script owing".* *(1) There should be a report to show a dispenser all "script owing - PDS unavailable" prescriptions. This is as the dispenser (or system) will trigger the activity to reconcile (rather than triggered on receipt of script in existing script owing scenarios). "Script owing - PDS unavailable" status may allow quicker processing where a dispenser (or system) may do this as scheduled / once connection is re-established.* *(2) After the reconcile process is completed and if no electronic prescription was found in the PDS, "script owing - PDS unavailable" status would then move to "script owing" status. It's expected that a dispenser would have noted the circumstances on the local dispense record. Any follow on processes (e.g. reporting) should be followed as usual.*	Yes	Yes

3.3 Prescription Delivery Service Systems

This section describes conformance requirements specific to electronic prescribing – Prescription Delivery Service systems. A Prescription Delivery Service (PDS) system is the mechanism through which an electronic prescription is communicated from a prescriber to a dispenser.

Authentication and authorisation

Reference	Requirement	Open PDS	Direct PDS
DS-1	The system **SHALL NOT** accept electronic prescriptions or dispense notifications from non-conforming systems.	Yes	Yes
DS-2	The system **SHALL NOT** provide electronic prescription information or dispense information to a non-conforming system.	Yes	Yes
DS-3	The system **SHALL** verify the authenticity of the requestor for all connection requests over public networks using Public Key Infrastructure (PKI). *Note: The system will not accept connections from unknown participants.* *Conformance requirements will be updated if the approved authentication methods change.*	Yes	Yes

Audit

Reference	Requirement	Open PDS	Direct PDS
DS-22	The system **SHALL** record each transaction in an audit log. The details of the record **SHALL** include: • Date and Time of creation (UTC Time); • Transaction type; • Transaction status (for example, "Accepted", "Rejected"); • Reason for rejection (if rejected); • Identifier of submitting system; • The Globally Unique Prescription Identifier; • The Delivery Service Prescription Identifier (DSPID); • Date and time receipt acknowledged (UTC Time); and • All information fields contained in the message metadata. *Note: Security Information and Event Management (SIEM) should be used to identify attempts at unauthorised access. This should raise an incident for investigation when a threshold number of attempts is identified.*	Yes	Yes

Provision

Reference	Requirement	Open PDS	Direct PDS
DS-10	When a dispensing system retrieves an electronic prescription, the system **SHALL** be able to compile and provide all the relevant information including: • Original electronic prescription; • Most recent dispense record; and • All annotations.	Yes	No
DS-11	When a dispensing system retrieves an electronic prescription, the system **SHALL** lock that electronic prescription while the transaction is in progress to prevent multiple concurrent transactions.	Yes	No

Provision

Reference	Requirement	Open PDS	Direct PDS
DS-12	The system **SHALL NOT** aggregate and make available prescription information based on an IHI. *Note: An IHI shall be included in the metadata of the electronic prescription provided by the prescriber.* *To be reviewed at any point in time that the use of an Active Script List model is determined to be no less secure, private, equitable and accessible to a Token-only model.*	Yes	No

Submission

Reference	Requirement	Open PDS	Direct PDS
DS-4	The system **SHALL** accept electronic prescriptions from prescribing systems that provide a valid conformance id from an organisation with which they have a contractual agreement.	Yes	Yes
DS-5	The system **SHALL** provide an acknowledgement of receipt of an electronic prescription to the prescribing system.	Yes	Yes
DS-6	The system **SHALL** define and use a Delivery Service prescription identifier (DSPID) format that will result in globally unique and distinguishable delivery service prescription identifiers.	Yes	No
DS-6A	The system **SHALL** define and use a DSPID format that will result in organisationally unique and distinguishable prescription identifiers.	No	Yes
DS-7	The system **SHALL** accept and process a request for cancellation of an electronic prescription.	Yes	Yes

Submission

Reference	Requirement	Open PDS	Direct PDS
DS-8	The system **SHALL** provide an acknowledgement of receipt of an electronic prescription cancellation request and the outcome of that request to the prescribing system.	Yes	Yes
DS-9	The system **MAY** support the delivery of the electronic Token to a nominated electronic address (which would be included in the metadata of the electronic prescription by the prescriber).	Yes	No
DS-13	The system **SHALL** accept a notification of dispense against an electronic prescription.	Yes	No
DS-14	The system **SHALL** provide an acknowledgement of a Dispense Record to the dispensing system.	Yes	No
DS-15	The system **SHALL** accept an annotation made by a dispenser against an electronic prescription.	Yes	No
DS-16	The system **SHALL** provide an acknowledgement of receipt of an annotation to the dispensing system.	Yes	No
DS-17	The system **SHALL** accept and process a notification of dispense cancellation. *Note: There may be instances where a dispenser is required to abandon a dispense event prior to a dispense notice being posted to the PDS (for example, the pharmacy is out of stock). In this instance, following dispense event ceasing, the electronic prescription record should be returned to an unlocked state. The outcome is that the prescription is valid for dispense.* *Related requirement: DISP-24.*	Yes	No

Submission

Reference	Requirement	Open PDS	Direct PDS
DS-19	The system **SHALL** accept and process a notification of dispense reversal. *Note: There may be instances where a dispenser is required to reverse a dispense event after a dispense notice has been posted to the PDS (for example, the SoC declines supply). In this instance, following dispense event, the dispenser is required to reverse the dispense event and return the electronic prescription record to an unlocked state. The outcome is that the prescription is valid for dispense.* *Related requirement: DISP-25.*	Yes	No
DS-20	The system **SHALL** provide an acknowledgement of receipt of a dispense reversal to the dispensing system. *Note: The system will cancel the dispense event and return the electronic prescription to its previous state.* *Related requirement: DISP-28.*	Yes	No
DS-21	The system **SHALL** unlock an electronic prescription when the dispensing system releases it (unchanged). *Note: Where an electronic prescription is released by the dispensing system without a dispense notice (i.e. not dispensed), the prescription shall be unlocked. That prescription shall be unchanged from that which was originally drawn down by the dispenser.*	Yes	No

PDS Connections

Reference	Requirement	Open PDS	Direct PDS
DS-27	The system **SHALL** facilitate the exchange of electronic prescriptions between other conformant PDS operators.	Yes	No

PDS Connections

Reference	Requirement	Open PDS	Direct PDS
DS-27A	The system **MAY** facilitate the exchange of electronic prescriptions between other conformant PDS operators.	No	Yes
DS-28	The PDS Operator **SHALL** have contractual arrangements in place that facilitate the exchange of electronic prescriptions and dispense information with all other conformant PDS operators. *Note: This may be achieved through a federated model (i.e. through an intermediary PDS). The intention is that any prescription must be able to be downloaded by any dispensing system regardless of the PDS directly subscribed to. The list of all conformant PDSs will be maintained by the Agency.*	Yes	No
DS-29	Each system **SHALL** manage the security process of a connecting PDS to facilitate the receipt and delivery of electronic prescriptions between PDSs.	Yes	No
DS-30	Where the system receives an electronic prescription from another PDS the system **SHALL** warrant that the privacy controls of the originating PDS are maintained during the delivery process to the requesting dispensing system.	Yes	No
DS-31	Where the system requests an electronic prescription from another PDS the system **SHALL** warrant that the requesting dispenser or other user is a registered and known end point and the system can assert the validity of the user.	Yes	No

Data Integrity

Reference	Requirement	Open PDS	Direct PDS
DS-26	The system and the PDS Operator **SHALL NOT** change or manipulate the semantic content (metadata or encrypted payload) of any message. *Note: The format of the message may be changed as the content passes between PDSs.*	Yes	Yes

Privacy

Reference	Requirement	Open PDS	Direct PDS
DS-24	The system **SHALL** encrypt all electronic prescription data in transit over public network between all authorised end points and at rest. *Note: End points are any organisation that submits or receives information to/from the PDS that has been authorised to do so.* *Note that all data "in transit over a public network" is to be encrypted. This includes both the metadata and electronic prescription payload.*	Yes	Yes
DS-25	The PDS Operator **SHALL NOT** access the payload of any message without explicit consent from the Subject of Care or legal authority. *Note: Consent may be from the patient in the initial instance. However, PDS Operators currently manage this information and would be subject to use and disclosure laws applicable federally (Privacy Act 1988) and any applicable laws in their jurisdiction of registration.*	Yes	Yes

Security

Reference	Requirement	Open PDS	Direct PDS
DS-23	The system **SHALL** put in place necessary controls for managing "Unclassified" data with a Dissemination Limiting Marker of "Sensitive: Personal".	Yes	Yes

3.4 Mobile Intermediary Systems

This section describes conformance requirements specific to electronic prescribing – mobile intermediary systems. A mobile intermediary is a system which manages communication between an Open Prescription Delivery Service and mobile applications. The mobile intermediary's main purpose is to access prescription information contained in one or more PDSs on behalf of mobile applications and provide other functionality such as user authentication and validation. The mobile intermediary may store a Token on behalf of the Subject of Care (SoC). In most cases the mobile intermediary will be the mobile application's server component.

Authentication and authorisation

Reference	Requirement	Open PDS	Direct PDS
MI-1	The system **SHALL NOT** provide electronic prescription information or dispense information to a non-conforming system.	Yes	No
MI-2	The system **SHALL** authenticate all connections with Prescription Delivery Services (PDS) over public networks using Public Key Infrastructure (PKI). *Note: The PDS will not accept connections from unknown participants.* *Conformance requirements will be updated if the approved authentication methods change.*	Yes	No

Audit

Reference	Requirement	Open PDS	Direct PDS
MI-10	The system **SHALL** maintain audit logs associated with electronic prescription retrieval events in accordance with relevant legislation and regulation	Yes	No

Retrieval

Reference	Requirement	Open PDS	Direct PDS
MI-3	The system **SHALL NOT** aggregate and make available electronic prescription information based on an IHI. *Note: An IHI shall be included in the metadata of the electronic prescription provided by the prescriber.* *To be reviewed at any point in time that the use of an Active Script List model is determined to be no less secure, private, equitable and accessible to a Token-only model.*	Yes	No

Audit

Reference	Requirement	Open PDS	Direct PDS
MI-4	The system **SHALL** retrieve all information relevant to an electronic prescription, including the original electronic prescription, and the most recent dispense (if any).	Yes	No

PDS Connections

Reference	Requirement	Open PDS	Direct PDS
MI-5	Where the system receives an electronic prescription from another Delivery Service the system **SHALL** warrant that the privacy controls of the originating PDS are maintained during the delivery process to the requesting application.	Yes	No
MI-6	Where the system requests an electronic prescription from another PDS the system **SHALL** warrant that the requesting application is a registered and known end point and the system can assert the validity of the user.	Yes	No

Data Integrity

Reference	Requirement	Open PDS	Direct PDS
MI-9	The system **SHALL NOT** change or manipulate the content (metadata or encrypted payload) of any message.	Yes	No

Privacy

Reference	Requirement	Open PDS	Direct PDS
MI-7	The system **SHALL** encrypt data in transit between all authorised end points and at rest. *Note: Authorised end points are those defined by PDS operators and mobile intermediary operators. If connecting to a PDS, the PDS is expected to work with the mobile intermediary operators to achieve interoperability.*	Yes	No

Privacy

Reference	Requirement	Open PDS	Direct PDS
MI-8	The mobile intermediary **SHALL NOT** access the encrypted payload of any message without explicit consent. *Note: In this scenario, "consent" may be from the patient in the initial instance. Mobile intermediaries would manage this information and would be subject to use and disclosure laws applicable federally (Privacy Act 1988) and any applicable laws in their jurisdiction of registration.*	Yes	No

Security

Reference	Requirement	Open PDS	Direct PDS
MI-11	The system **SHALL** put in place necessary controls for managing "Unclassified" data with a Delineating Marker of "Sensitive: Personal".	Yes	No
MI-12	The system **SHALL** authenticate all connection requests from mobile devices using a unique identifier tied to the mobile device hardware. *Note: The PDS will not accept connections from unknown participants.* *Examples include Google authenticator or RSA soft token.*	Yes	No

3.5 Mobile Application Systems

This section describes conformance requirements specific to electronic prescribing – mobile application systems. A mobile application is a system used by the Subject of Care (SoC) (or Agent) to manage prescriptions and to provide the capability to present the prescription Token to the dispensary.

Note: Open PDS and Direct PDS columns intentionally removed as they are not applicable.

Reference	Requirement
MA-3	If personal information is to be displayed through the application, the system **SHALL** capture consent at time of registration to expose personal information to the Mobile Intermediary.
MA-4	If personal information is to be displayed through the application, the system **SHALL** capture enough personal information to establish an account with the Mobile Intermediary.
MA-5	The system **SHALL** provide adequate disclosure of terms and conditions. *Note: In line with requirements under the Privacy Act 1988.*
MA-6	The system **SHALL** provide adequate disclosure of use of data.
MA-7	If personal information is to be displayed, the system **SHALL** assure that the end user is authorised to view the personal information on the electronic prescription. *Note: The Mobile Application and Mobile Intermediary shall pay due diligence in assessing the users legitimate right to access electronic prescription information.* *The registered user of the mobile application is considered the end user in this instance.*

Reference	Requirement
MA-8	The system **SHALL** allow a user to de-activate an account with a mobile intermediary.

Reference	Requirement
MA-1	The system **SHALL** support accepting an electronic prescription Token electronically. *Note: Electronically could include but is not limited to HTTPS, SMS, MMS, email, or image capture.*

Reference	Requirement
MA-2	The system vendor **SHALL** have secure and tested connection to a Prescription Delivery Service (PDS) that allows the retrieval of electronic prescriptions and dispense records held by any Prescription Delivery Service. *Note: Applicable to those vendors retrieving electronic prescriptions and dispense records held by any PDS.* *The contractual arrangement allows the parties to be known and appropriate tests and controls to be in place.*

Reference	Requirement
MA-9	For an electronic prescription, the system **SHALL** render, at minimum: • The DSPID as a 1D barcode. *Note: Irrespective of what information the mobile application has about the prescription, as a minimum, it shall render (display) the DSPID as a 1D barcode to be scanned at a dispenser.* *To be reviewed at any point in time that the use of an Active Script List model is determined to be no less secure, private, equitable and accessible to a Token-only model.*
MA-10	The system **MAY** render additional electronic prescription item details including but not limited to: • The details of the original prescription; • The prescription status (e.g. Cancelled, Expired, Exhausted, etc.); • The details of the previous dispense (if any); and • Information communicating available repeats (if any). *Note: Mobile applications are not precluded from displaying information beyond that provided as Evidence of Prescription.*
MA-11	The system **SHALL** display all rendered information in "original text", irrespective of the presence or otherwise of coded information fields. *Note: "Original Text" is defined as the text "exactly as presented to the prescriber or dispenser". This ensures that the content is human readable and facilitates consumer access to information.*
MA-12	The system **SHALL** provide indication to the user if it detects that the Mobile Intermediary service is unreachable or unavailable.
MA-13	The system **MAY** allow an electronic prescription Token to be transmitted to an electronic address.

Reference	Requirement
MA-14	The system **SHALL** make electronic prescription information available read only. *Note: Any information retrieved from a PDS, including the barcode itself, should be read only.*
MA-15	The system **MAY** cache electronic prescription information on a user's account. *Note: Where connection to the PDS is unavailable (e.g. no reception), this would allow the user to view details of prescriptions they have previously retrieved (e.g. when in an area with reception).*

Reference	Requirement
MA-16	The system **SHALL** support authentication of connection requests using a unique identifier tied to the mobile device hardware. *Note: Examples include Google authenticator or RSA soft token.*

4 Acronyms

Acronym	Description
1D	One Dimensional
ACSC	Australian Cyber Security Centre
ADHA	Australian Digital Health Agency
AHPRA	Australian Health Practitioner Regulation Agency
AMT	Australian Medicines Terminology
AORT	Acknowledgement Of Receipt - Timeout
ASD	Australian Signals Directorate
CIS	Clinical Information System
DLM	Dissemination Limiting Marker
DoB	Date of Birth
DSPID	Delivery Service Prescription Identifier
eNRMC	electronic National Residential Medication Chart
ETP	Electronic Transfer of Prescriptions
HI Service	Healthcare Identifiers Service operated by Services Australia
HPI-I	Healthcare Provider Identifier - Individual
HPI-O	Healthcare Provider Identifier - Organisation
HTTPS	Hyper Text Transfer Protocol Secure
IHI	Individual Healthcare Identifier
ISM	Information Security Manual
MMS	Multimedia Messaging Service
OAuth	Open Authorisation
PBS	Pharmaceutical Benefits Scheme
PDS	Prescription Delivery Service
PKI	Public Key Infrastructure
PRODA	Provider Digital Access
RPBS	Repatriation Pharmaceutical Benefits Scheme
RSA	An asymmetric cryptosystem invented by Ron Rivest, Adi Shamir and Leonard Adleman
SIEM	Security Information and Event Management
SoC	Subject of Care (patient or consumer)

Acronym	Description
SMS	Short Message Service
SNOMED-CT-AU	Systematised Nomenclature of Medicine – Clinical Terms - Australia
URI	Uniform Resource Identifier
URL	Uniform Resource Locator
UTC	Coordinated Universal Time

5 Glossary

Term	Meaning
Australian Medicines Terminology	The reference set within SNOMED CT-AU that is the national, standards-based approach to the identification and naming of medicines in clinical systems for Australia.
Conformance	A measurement (by testing) of the adherence of an implementation to a specification or standard.
Consumer	In this document 'consumer' refers to a software system that has the role of being a consumer of information about prescription data held by one or more prescription delivery services.
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 Department of Human Services for claiming purposes. Notes: 1. This definition does not preclude the use of paper processes to support electronic prescribing activity. 2. Repeat and deferred supply dispense records 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 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 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 e-Prescribing.
Electronic transfer of prescription (ETP)	The current process whereby prescribing systems pass data about a prescription to a prescription delivery service (PDS), which is available for download by dispensing systems is support of dispensing a paper prescription.

Term	Meaning
Evidence of Prescription	Evidence of electronic prescription must not resemble a legal paper prescription as it would be illegal to supply a pharmaceutical benefit from only the evidence of the electronic prescription. The Evidence of Prescription should include in human readable format elements such as: • Patient name. • Date on which the prescription was written. • Identification of pharmaceutical benefit with quantity and repeats. • Name and address of PBS prescriber.
MAY	When appearing in a conformance requirement, the verb **MAY** indicates an optional requirement.
Mobile Application	An application that provides a user the ability to manage electronic prescriptions via a personal device.
Mobile Intermediary	Software used by mobile applications to interact with the electronic prescribing process.
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].
Prescription exchange (PE)	A participant in the prescription delivery service that supports defined interfaces and services to facilitate the transfer of electronic prescriptions and related information between prescribers and dispensers.
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.
SHALL	When appearing in a conformance requirement, this verb **SHALL** indicates a mandatory requirement. Its negative form **SHALL NOT** indicates a prohibition.
SHOULD	When appearing in a conformance requirement, the verb **SHOULD** indicates a recommendation. Its negative form **SHOULD NOT** indicate an option that should not be supported.
Subject of Care	The Subject of Care is the person for whom the medicines described on the prescription are intended.

Term	Meaning
Token	An electronic prescription Token refers to the barcode and associated delivery provider service ID. A Token may or may not be provided with other prescription information.

6 References

Related documents are listed in Table 1.

Document	Notes
Electronic Prescribing Solution Architecture [Doc. Code]	Specifies the solution architecture for electronic prescribing including principles, assumptions, key concepts and their usage, data models, and use cases.

Table 1. Related documents