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Electronic Prescribing Conformance Profile

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Product or document version	Date	Release comments
DRAFT for information 1.0	23 September 2019	Preliminary document released for external information
2.0	31 October 2019	Final document for external use
2.1	16 March 2020	Revised document superseding v2.0
2.2	5 June 2020	ASLR relaxed, Jurisdictional requirements added, and other minor adjustments
2.3	2 October 2020	Included ASLR requirements
3.0	16 April 2021	Included ASLR, Mobile Intermediary, Mobile App and security requirements and other amendments

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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
- Providers of Active Script List Registry 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 (mobile or web-based) that access information about electronic prescriptions and Active Script Lists.

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 Electronic Transfer of Prescription (ETP).

1.2 Intended audience

The intended audience includes the following organisations:

- The Department of Health;
- Services Australia;
- The Australian Commission on Safety and Quality in Healthcare;
- Software developers;
- Mobile intermediary developers;
- Mobile application developers;
- Medication chart e-medication management developers;
- Active Script List Registry developers;
- Prescription Delivery Service Software Developers; and
- State and Territory Jurisdiction Representatives.

2 Scope

- Systems able to participate in electronic prescribing may include prescribing systems including prescribing systems for electronic medication charts, Prescription Delivery Services, Active Script List Registry Services, dispensing systems and consumer (mobile/web) applications.
- 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 Services
- The Active Script List Registry Services

Software 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 specifically 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 for prescribing, delivery and dispensing systems 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 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.

Medication chart software

Vendors connecting to an open medication chart PDS, are required to consider conformance requirements relevant to their system functionality marked with “yes” in the “Med charts Open PDS applicable” column.

Vendors implementing with a direct medication chart PDS are required to consider conformance requirements relevant to their system functionality marked with “yes” in the “Med charts direct PDS applicable” column.

3.1 Prescribing Systems

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

Note: The vendors of prescribing systems for medication charts are required to consider the last two columns (Med charts Open PDS and Med charts Direct PDS).

Authentication and authorisation

Reference	Requirement	Open PDS	Direct PDS	Med charts Open PDS	Med charts Direct PDS
PRES-1	The system SHALL provide single factor, multi-stage, or multi-factor authentication on all user accounts.	Yes	Yes	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	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	Yes	Yes
PRES-4	User accounts with electronic prescribing capability SHALL contain the user's: • Full Name; • PBS Prescriber Number, where they have one; and • Healthcare Provider Identifier - Individual (HPI-I).	Yes	No	Yes	No

Reference	Requirement	Open PDS	Direct PDS	Med charts Open PDS	Med charts Direct PDS
PRES-4A	User accounts with electronic prescribing capability SHALL contain the user's: • Full Name; • PBS Prescriber Number, where they have one; • AHPRA Number (if known); and User accounts with electronic prescribing capability SHOULD contain the user's: • Healthcare Provider Identifier - Individual (HPI-I).	No	Yes	No	Yes

Reference	Requirement	Open PDS	Direct PDS	Med charts Open PDS	Med charts Direct PDS
PRES-5	Where only single factor or multi-stage authentication is provided, the system SHALL use strong authentication for users who have the permission to author an ePrescription or view the patient's Active Script List. This is to be done by at least one of the following 3 approaches: 1. Give the 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). 2. Require all users to have a strong password which permits the use of special characters with a minimum of: • Eight characters; • One letter; and • One number. 3. Require all users to have passwords aligned to ISM Security Control 0417 and ISM Security Control 0421. *Note: Healthcare organisations shall have the support of the system in the implementation of access control policies.* *Note: Some Software-As-A-Service software are not able to adopt password policy at an organisational level and as such must ensure users have a strong password.*	Yes	Yes	Yes	Yes

Reference	Requirement	Open PDS	Direct PDS	Med charts Open PDS	Med charts Direct PDS
PRES-6	The system SHALL automatically log off an account, or require re-authentication, after a period of inactivity. The period of inactivity SHALL be either: 1. configurable by the healthcare organisation AND the default SHOULD be no longer than 15min OR 2. a time period set by the software vendor no longer than 15 minutes. *Note: Healthcare organisations need to be able to define a period of inactivity after which the prescriber's terminal may be considered unattended and vulnerable to misuse.* *Note: Software-as-a-Service providers may not be able to set time period for each organisation and as such may select a time period no longer than 15 minutes for all users.*	Yes	Yes	Yes	Yes
PRES-7	The system SHALL require the user to re-authenticate prior to submitting a Schedule 8 medicine. *Note: Prescriptions for Controlled Drugs warrant additional measures to ensure that the prescription is being created by an authorised prescriber.*	Yes	Yes	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	Yes	Yes
PRES-955	If the system is integrated to the healthcare provider organisation's Single-Sign-On service the system MAY allow the healthcare provider organisations to disable application level authentication.	Yes	Yes	Yes	Yes

Reference	Requirement	Open PDS	Direct PDS	Med charts Open PDS	Med charts Direct PDS
PRES-95	If the system is comprised of multiple products with different branding, or optional installation configurations, that are providing functionality that is tested as a part of conformance, to this conformance profile, then all of the products associated with the specific function need to be operating when transacting with a PDS and ASLR. If one or more of the products associated with the specific function is not operating then the system SHALL NOT interact with the PDS or ASLR. *Note: a system that is designed to work in a specific configuration is conformant only when implemented in that configuration. Exchanging Conformance IDs when it is in an alternate configuration or operating in isolation is a breach of the Conformance Assessment Scheme and the Electronic Prescribing legislation.* *Note: 'operating' means it must be integrated into the system and active. Simply installing the product in an inactive state is not sufficient.* *Note: the system will be tested with different configurations to ensure that interactions with PDS and ASLR are permitted only when all products are operating and active.*	Yes	Yes	Yes	Yes
PRES-931	If the system stores passwords it SHALL ensure that the passwords are stored securely in line with ISM Security Control 1252. This is to be done by: • not storing passwords as plain text; • passwords stored using an ASD approved Cryptography hash and password salt.	Yes	Yes	Yes	Yes
PRES-937	The system SHOULD check users' credentials with a known breached credentials service to ensure the credentials haven't been used in a previous data breach. *Note: a known breached credentials service is a service which provides either an API to check if a password has been included in a known data breach or a list of all known passwords included in known data breaches.*	Yes	Yes	Yes	Yes

Reference	Requirement	Open PDS	Direct PDS	Med charts Open PDS	Med charts Direct PDS
PRES-940	Where the system is hosted and accessible over the public internet (see note) and the system is only using single factor or multi-stage authentication the system SHALL check the users' credentials with a known breached credentials service or against a known breached password list. The system shall perform this check at the time the password is set by the user and on the first login after the known breached credentials service or password list has been updated. If the password was found in a past breach the user shall be required to update their password before authenticating into the system. *Note: a known breached credentials service is a service which provides either an application programming interface (API) to check if a password has been included in a known data breach or a list of all known passwords included in known data breaches.* *Note: This requirement applies to software-as-a-service accessible over the public internet. Software which is deployed within a healthcare provider organisation's infrastructure does not need to meet this requirement.*	Yes	Yes	Yes	Yes

Audit

Reference	Requirement	Open PDS	Direct PDS	Med charts Open PDS	Med charts Direct PDS
PRES-9	The system SHALL, on request, generate a file or files that contain the information captured in the audit logs in human readable format. *Note: this requirement permits the generation of a file or files that can be shared or sent to relevant regulatory bodies on request. "Human readable formats" include text files, PDF files, log files or any other format that presents the required information "in the clear".*	Yes	Yes	Yes	Yes
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	Yes	Yes

Reference	Requirement	Open PDS	Direct PDS	Med charts Open PDS	Med charts 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 (time and time zone); • The Globally Unique Prescription Identifier; • The Delivery Service Prescription Identifier (DSPID); • Date and time receipt acknowledged by the PDS (time and time zone) if applicable; and • All information related to the electronic prescription. *Note: Some direct PDS may not have an acknowledgement. This will be determined by the architecture and technical solution.* *Note: storing the audit log in a location that is NOT the main system would assist data recovery efforts if the main system is compromised or unavailable.*	Yes	Yes	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 (time and time zone); • The Globally Unique Prescription Identifier; • The Delivery Service Prescription Identifier (DSPID); • Date and time of acknowledgement (time and time zone) if applicable; and • The success (or otherwise) of the cancellation. *Note: Cancellation is used to reflect that the prescription was created in error, not that it has been ceased or has expired.* *Note: Some direct PDS may not have an acknowledgement. This will be determined by the architecture and technical solution.*	Yes	Yes	Yes	Yes

Reference	Requirement	Open PDS	Direct PDS	Med charts Open PDS	Med charts Direct PDS
PRES-405	If the system provides ASL viewing capability, then the system SHALL maintain an audit log of access to Active Script Lists. The audit log SHALL include at least: • Date and time of access (time and time zone); • Subject of Care's IHI number; • Organisation or site ID, or User ID (from the prescribing system) or both.	Yes	No	Yes	No
PRES-705A	When printing the evidence of prescription for the medication chart the prescribing system SHOULD capture the printing event in an audit log.	No	No	Yes	No

Cryptography

Reference	Requirement	Open PDS	Direct PDS	Med charts Open PDS	Med charts Direct PDS
PRES-81	The meta-data component of every electronic prescription SHALL be: a) Unencrypted when at rest and; b) Encrypted when in transit; *Note: the meta-data is designed to be available to electronic prescribing and dispensing systems to assist those systems in the delivery of electronic prescriptions.* *Note: this requirement does not impact other requirements around the presentation of electronic prescriptions. The inclusion of information in meta-data or otherwise doesn't imply this information must or can be hidden from healthcare providers.*	Yes	No	Yes	No
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	No	Yes	No

Reference	Requirement	Open PDS	Direct PDS	Med charts Open PDS	Med charts Direct PDS
PRES-26	When connecting to a PDS over a public network, the system SHALL assert the identity of the organisation operating the system to the PDS. *Note: The Conformance Requirements will be updated if the approved authentication methods change.*	Yes	No	Yes	No
PRES-27	All transmissions of electronic prescription information over public networks SHALL be encrypted using Australian Signals Directorate (ASD) approved cryptographic algorithms.	Yes	Yes	Yes	Yes
PRES-938	The system SHOULD validate digital certificates. *Note: See Appendix B Implementation Advice for further implementation guidance.*	Yes	No	Yes	No
PRES-939	The system SHOULD encrypt information assets (excluding meta-data) at rest using Australian Signals Directorate (ASD) approved cryptographic algorithms	Yes	No	Yes	No

User Selection

Reference	Requirement	Open PDS	Direct PDS	Med charts Open PDS	Med charts 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	Yes	Yes
PRES-12	When creating a prescription, 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	Yes	No

Reference	Requirement	Open PDS	Direct PDS	Med charts Open PDS	Med charts Direct PDS
PRES-13	When creating a prescription, the system SHALL allow the prescriber to select between creation of an electronic or paper prescription (but not both). *Note: Supports Subject of Care's choice. Furthermore, under Regulations, the medicines prescribed may require a paper prescription.*	Yes	No	No	No
PRES-15	When generating an Electronic Prescription, the system SHALL NOT issue an Electronic Transfer of Prescription (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 prescription.*	Yes	No	Yes	No
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 must not be sent at all to an open PDS. This is to avoid duplication of the prescription.*	Yes	Yes	Yes	Yes

Patient records

Reference	Requirement	Open PDS	Direct PDS	Med charts Open PDS	Med charts Direct PDS
PRES-70	The system SHALL conform to the following requirements for Healthcare Identifiers use cases UC.010 (Register patient) and UC.015 (Update patient health record): 1. All mandatory and applicable conditional conformance requirements. 2. Recommended conformance requirements 005812, 005813, 005814 and 005818. *Note: Conformance to requirements 005812, 005813, 005814 and 005818 is mandated for Prescribing Systems. That is, Prescribing Systems need to be able to query the HI Service using an IHI, Medicare card number or DVA file number and be able to resubmit a query using modified search criteria (such as a person's maiden name or alternative given names).* *The requirements are stated in Use of Healthcare Identifiers in Health Software Systems Software Conformance Requirements* [AGENCY2020].	Yes	Yes	Yes	Yes

Composition

Reference	Requirement	Open PDS	Direct PDS	Med charts Open PDS	Med charts Direct PDS
PRES-17	The system SHALL include, within the electronic prescription, all data fields as required by Jurisdictional Regulations. *Note: Jurisdictional Regulations may change periodically.*	Yes	Yes	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 (Including both the clinical content and the metadata).	Yes	Yes	Yes	Yes
PRES-80	When transmitting an electronic prescription, the software SHALL ensure sure that the transmission includes: a) A meta-data component and b) A prescription component	Yes	No	Yes	No

	Note: The meta-data component is a wrapper/container that allows for the identifying and indexing of the prescription component. The prescription component is often called 'the payload'.				
PRES-83	The meta-data component of every electronic prescription SHALL contain at least: a) The unique prescription number for that prescription (Globally Unique Prescription ID) and; b) The Conformance ID for each information system used to generate, send, receive, store or otherwise process the electronic prescription and; c) Subject of Care Individual Healthcare Identifier - (IHI)	Yes	No	Yes	No
PRES-72	The system SHALL include an IHI in an electronic prescription only if its status is "active" and "verified" in the prescribing system. *Note: This disallows a Prescribing System from using an IHI with another status such as "deceased".*	Yes	No	Yes	No
PRES-84	Where a system is required to include a HPI-O or HPI-I, the system SHALL include those identifiers inside the prescription component of the transmission only (i.e. the payload). *Note: these identifiers are to be stored in the payload and eventually encrypted if sent externally (see PRES-81).*	Yes	No	Yes	No
PRES-18	The system SHALL also include, within an electronic prescription, at least the following information: • Healthcare Provider Identifier - Organisation (HPI-O) of the prescribing organisation; • Hospital Provider Number (HPN), if it exists; • Residential Aged Care Facility ID (RACFID), if it exists; • Subject of Care Date of Birth; • Subject of Care's address; • The medicine name; • The medicine strength; Either: • Maximum quantity authorised to dispense Or for chart-based electronic prescriptions: • the medicine dose, • frequency for use, and	Yes	Yes	Yes	Yes

	• the duration of use or cessation date (as an alternative to the quantity. • Directions for use; • medicine form; • Route of administration; • Number of repeats (if applicable); • Closing the Gap code (if applicable); • Prescription notes to record unusual dose, staged supply etc; • Either the privacy notice or a reference to the privacy notice, but not both *Note: The data fields listed in the requirement are in addition to the mandatory fields as per the legislation and do not form the complete data set.* *Note: a reference to the privacy notice might be a clickable hyperlink, a url or some other means to locate the privacy notice. The privacy notice can be provided by Services Australia.* *Note: unusual doses can be emphasised either in the dosage instructions, the prescriptions notes or by emphasising the dose at the point of rendering.* *Note: where the patient is attending a public hospital, private hospital, correctional health facility, children and youth services facility or residential care facility the address (subject of care address attribute) of the hospital or facility must be provided to ensure supply if in Tasmania. An additional address attribute is not required.* *Note: Maximum quantity authorised can be provided in words in the notes.* *Note: Route can be provided in the directions.* *Note: DISP-50 requires dispensing systems to display the information in this requirement.* *Note: each line item in a chart represents a prescription and relevant attributes stored at a chart level need to be repeated for each line item when submitted to a PDS/dispensing system.*				
PRES-18A	The system SHALL also support and include (if applicable) in the electronic prescription: • Authorisation reference number (up to 25 characters alpha/numeric); • Prescriber specialist qualification (if not in the ACT); • Prescriber qualification (if in Qld, ACT); • The name of the pharmacy the prescription is to be dispensed (if required by NSW).	Yes	Yes	Yes	Yes

	The system SHALL present the Authorisation reference number as: • "Authorisation number" in NSW and NT; • "Authority number" in WA and TAS; • "Approval number" in QLD and ACT; • "Permit number" in SA; and • "Warrant number" in VIC. *Note: all states and territories use the same authority number concept and the authority number performs the same function across states and territories. Systems and databases may utilise the same field/attribute, but it must be presented according to this requirement.* *Note: DISP-50 requires dispensing systems to display the information in this requirement.*				
PRES-18B	The system SHALL include or display, the following text into or with the electronic prescription as appropriate: • 'for dental treatment only' • 'for midwifery use only' • 'for optometry use only' • 'for podiatric treatment only' • 'for treatment of foot conditions only' • 'for ocular treatment only' *Note: software is to insert/display text as appropriate.* *Note: this can be texted entered/provided by the local user creating the prescription and may appear in the prescription notes.* *Note: DISP-50 requires dispensing systems to display the information in this requirement.*	Yes	Yes	Yes	Yes

PRES-19	The system SHALL also include, within an electronic prescription, the following information:
	• Healthcare Provider Identifier - Individual (HPI-I) of the Prescriber
	• Unusual dose indicator (if applicable)
	• Minimum interval between repeats (if applicable) as per
	  ○ Schedule 4D and Schedule 8 in NSW
	  ○ Schedule 8 in ACT, WA, Qld and NT
		Yes	No	Yes	No

	○ Schedule 8 and 4D in TAS *Note: see PRES-84.*				
PRES-19A	The system SHALL include, within an electronic prescription, the following information: • Healthcare Provider Identifier - Individual (HPI-I) of the Prescriber (if available); *Note: also see PRES-84.*	No	Yes	No	Yes
PRES-20	The system SHOULD include Medicine Name as a SNOMED CT-AU (which includes the Australian Medicines Terminology) Codable Value if a SNOMED code is available for that medicine.	Yes	Yes	Yes	Yes
PRES-21	The system SHOULD allow for the inclusion of Reason for prescribe (clinical indication) as a SNOMED CT-AU Codeable Value. *Note: support for the inclusion of a SNOMED code is encouraged noting the clinician sometimes doesn't provide a Reason for prescribe or the reason has no SNOMED code. If the clinician provides a Reason for prescribe, and that reason has a SNOMED code, the system is expected to include it in the prescription.* *Note: Contact the NCTS for guidance on the appropriate SNOMED value set for Reason for Prescribe.*	Yes	Yes	Yes	Yes
PRES-21A	The system SHALL NOT require Reason for prescribe (clinical indication) as a SNOMED CT-AU Codeable Value. *Note: The system should 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	Yes	Yes
PRES-22	Irrespective of the inclusion of any codeable 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	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	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.	Yes	Yes	Yes	Yes

	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.*				
PRES-56	The system SHALL capture an indication from the prescriber if the electronic prescription is confirmation of a verbal authority for an urgent case/supply. *NOTE: a 'verbal authority' prescription is issued in confirmation of the prescriber's direction to the pharmacist given orally in person or by phone, or fax or email. The common term for this is "script owing". If the prescription generated should be provided to a particular pharmacy because they have already provided urgent supply with authorisation from the prescriber, a flag or check box should be set by the prescriber within the prescribing system.* *NOTE: This requirement may not be applicable in a hospital setting.*	Yes	No	No	No
PRES-56A	If the prescription is a confirmation of a verbal authority for urgent case/ supply, the system SHALL NOT generate a token that is passed to the Subject of Care (electronically).	Yes	No	No	No
PRES-62	The system SHALL include one and only one prescription line item within each electronic prescription. *Note: Whilst it is common for paper prescriptions to contain up to three line items, electronic prescriptions must have one and only one line item.*	Yes	No	Yes	Yes
PRES-705	The prescribing system SHALL be able to print: • chart identifiers and; • evidence of electronic prescriptions included in the medication chart by showing tokens for each line item so that the tokens can be scanned and prescriptions can be downloaded by a dispensing system from an Open PDS. *Note: This requirement caters for the scenario when the pharmacy cannot receive an electronic medication chart and will need to receive a printed copy of the chart to scan the code and dispense the medication.*	No	No	Yes	No
PRES-706	If a medication chart containing tokens is printed in New South Wales, the system SHALL ensure the name of the person who printed that medication chart appears on that medication chart.	No	No	Yes	Yes

Finalisation

Reference	Requirement	Open PDS	Direct PDS	Med charts Open PDS	Med charts Direct PDS
PRES-42	After submitting 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 (e.g. SMS, email), in electronic form. *Note: Electronic prescriptions are limited to one line item, and it is required that an Evidence of Prescription is produced for each Electronic Prescription.* *Note: Requirements PRES-42, PRES-48 and PRES-50 apply only where Evidence of Prescription is to be provided to the Subject of Care (i.e. where the SoC should leave the consultation with a valid prescription).*	Yes	No	No	No
PRES-43	If the Evidence of Prescription is printed, the Token SHALL be printed as a Barcode/QR Code.	Yes	No	Yes	No
PRES-43A	The system SHALL be able to reprint an Evidence of Prescription should the prescriber need to do so. *Note: The system is not expected to reprint an Evidence of Prescription that originated from a different system. That is, the CIS needs to only reprint an Evidence of Prescription if it was created in that system.*	Yes	No	Yes	No
PRES-44	If the Evidence of Prescription is printed, 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/QR Code 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	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	No	No

Reference	Requirement	Open PDS	Direct PDS	Med charts Open PDS	Med charts Direct PDS
PRES-46	Where Evidence of Prescription is provided in electronic form (e.g. SMS, email), the system SHALL transmit at least: • The electronic token or URI (e.g. URL) linking to the electronic token; • The initials of the Name of the Subject of Care; and • Medicine name. Note: see pres-48A for more information	Yes	No	Yes	No
PRES-46A	Where an Evidence of Prescription is provided in electronic form and that Evidence of Prescription includes a link to an electronic token (URI), then any information provided by that link SHALL also conform to PRES-46 and PRES-48A. *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	Yes	No
PRES-46B	Where Evidence of Prescription is provided 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	Yes	No

Reference	Requirement	Open PDS	Direct PDS	Med charts Open PDS	Med charts Direct PDS
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/QR Code 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. *Note: The privacy notice can be provided by Services Australia.* *Note: Medication Charts carry tokens (not EoP's) so need not conform to this requirement when printing charts (see requirement PRES-705). See glossary for "Evidence of Prescription".* *Note: Charting software that prints individual EoP's WILL need to conform to this requirement.*	Yes	No	Yes	No

Reference	Requirement	Open PDS	Direct PDS	Med charts Open PDS	Med charts 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 date of birth; • Subject of Care sex; • PBS Prescriber number; • Authority number; • Form; • Dose (directions); or • Reason for prescribe. There SHALL NOT be a place for the prescriber to sign. *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.* *Note: If Form is incorporated into the Medicine Name, it may be included. There is no requirement to strip the form out of the medicine name.*	Yes	No	Yes	No

Reference	Requirement	Open PDS	Direct PDS	Med charts Open PDS	Med charts Direct PDS
PRES-48A	Where Evidence of Prescription is provided in electronic form, the system SHALL NOT include the following details: • Subject of Care name • Subject of Care age • Subject of Care date of birth; • Subject of Care sex; • PBS Prescriber number; • Authority number; • Form; • Dose (directions); or • Reason for prescribe. There SHALL NOT be a place for the prescriber to sign. *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.* *Note: If Form is incorporated into the Medicine Name, it may be included. There is no requirement to strip the form out of the medicine name.* *Note: PRES-46 requires the subject of care's initials (not full 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	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	Yes	No

Modification

Reference	Requirement	Open PDS	Direct PDS	Med charts Open PDS	Med charts 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	Yes	Yes
PRES-41	Post finalisation, where an electronic prescription has been sent to the PDS as an electronic prescription, the system SHALL provide a mechanism for the prescriber to correct a prescription if the prescriber needs to. *Note: an "amend" operation or a "cancel prescription" operation followed by a "create prescription" operation is an acceptable mechanism. Vendors will need to understand what operations the PDS will support.* *Note: A prescription that has been dispensed cannot be corrected or cancelled. Outstanding repeats can still be cancelled – depending on PDS functionality.* *Note: If the correction request fails, the outcome will include the cause of the failure e.g. already dispensed, locked, disabled see DS-11B.*	Yes	Yes	Yes	Yes

Submission

Reference	Requirement	Open PDS	Direct PDS	Med charts Open PDS	Med charts 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 *Note: NSW regulations require prescription details to be retained for at least two years.*	Yes	Yes	Yes	Yes

Reference	Requirement	Open PDS	Direct PDS	Med charts Open PDS	Med charts Direct PDS
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 including all data fields that will be submitted to the PDS, 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.* *Note: An action by the prescriber to "send" the electronic prescription is considered adequate confirmation of final approval.* *Note: It is recommended software conforms with National Guidelines for On-Screen Display of Medicines Information [ACSQHC2017] where practical.* *Note: "All data fields" includes any automatic data mapping or translations that may occur due to active ingredient prescribing but does not include system data like GUID's, OIDS, P*BS codes, *serial numbers, datetime stamps etc.*	Yes	Yes	Yes	Yes
PRES-70A	The system SHALL conform to mandatory requirements 021561, 016832, 016813 and 016815 in Healthcare Identifiers use case UC.330 (Send patient health information electronically) when sending an electronic prescription. If a failure to validate a known IHI can be attributed to the unavailability of the HI Service then a Prescribing System is permitted to include the IHI in an electronic prescription (without positively validating it). *Note: UC.330 conformance requirements not listed above are optional for Prescribing Systems.*	Yes	No	Yes	No

Reference	Requirement	Open PDS	Direct PDS	Med charts Open PDS	Med charts Direct PDS
PRES-71	The system SHOULD conform to mandatory requirements 021561, 016832, 016813 and 016815 in Healthcare Identifiers use case UC.330 (Send patient health information electronically) when sending an electronic prescription. If a failure to validate a known IHI can be attributed to the unavailability of the HI Service then a Prescribing System is permitted to include the IHI in an electronic prescription (without positively validating it). *Note: UC.330 conformance requirements not listed above are optional for Prescribing Systems.*	No	Yes	No	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: it might be useful to include the SoC electronic address to assist in delivery. The header is sent 'in the clear' hence this should only be done with consumer consent.*	Yes	No	Yes	No
PRES-30	On submission to a PDS, the system SHALL capture and retain the provided DSPID in the local system so that it can be recalled if required.	Yes	No	Yes	No
PRES-31	The system SHALL record the date and time (time and time zone) that the PDS acknowledged receipt of the electronic prescription. *Note: Some direct PDS may not have an acknowledgement. This will be determined by the architecture and technical solution.*	Yes	Yes	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: Tokens may not be activated by the PDS unless the PDS acknowledges receipt of the electronic prescription.*	Yes	No	Yes	No

Reference	Requirement	Open PDS	Direct PDS	Med charts Open PDS	Med charts Direct PDS
PRES-33	When creating an electronic prescription, 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 removing the "create" transaction from the queue or some other technique that results in no electronic prescription in the PDS.* *Note: an "abort" request is not a "cancel" request (see PRES-34).* *Note: the user initiated "abort" is in addition to the system initiated AORT described in PRES-36.*	Yes	No	No	No
PRES-34	The system SHALL allow the user to issue a cancellation request for 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.* *Note: Some direct PDS may not have an acknowledgement. This will be determined by the architecture and technical solution.* *Note: If the cancellation request fails, the outcome will include the cause of the failure e.g. already dispensed, locked, disabled see DS-11B.*	Yes	Yes	Yes	Yes
PRES-35	When the user issues a cancellation request the system SHALL issue a cancellation message to the PDS. *Note: this is a cancel request. The request will fail if the prescription has already been dispensed or is locked for dispensing.*	Yes	Yes	Yes	Yes

Reference	Requirement	Open PDS	Direct PDS	Med charts Open PDS	Med charts Direct PDS
PRES-36	When creating an electronic prescription, 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". *Note: if the system uses a cloud-based system or similar where there is no single organisation, then it is acceptable for this AORT setting to be specified by the vendor supporting those organisations. This setting must be configurable through a GUI, configuration file or similar and must not be a hard-coded value.*	Yes	No	Yes	No
PRES-37	In the event of an AORT, the system SHALL automatically: 1 alert the user, and 2 cancel the electronic prescription, and 3 proceed with printing a paper prescription.	Yes	No	No	No
PRES-37A	When creating an electronic prescription that is chart-based AND that same electronic prescription is to be provided to the Subject of care (SoC), the system, in the event of an Acknowledgement of Receipt – Timeout (AORT), SHALL automatically: 1. alert the user, and 2. cancel the electronic prescription, and 3. notify the user that they need to issue a paper prescription. *Note: this requirement applies when the prescriber intends to provide the SoC with a valid prescription for the SoC to fill as a community pharmacy prescription, on hospital discharge or in outpatient settings.*	Yes	No	Yes	Yes
PRES-710	When a medication chart is ceased, the system SHALL send a notification to the prescription delivery service that each electronic prescription is no longer active for each active electronic prescription on that chart.	No	No	Yes	Yes
PRES-715	When uploading a prescription that has been written on a medication chart, the system SHOULD provide the unique identifier for the chart in the metadata of the prescription so that all the active prescriptions on a medication chart can be easily retrieved when required.	No	No	Yes	Yes

ASLR Assisted registration

Software that does not support ASLR Assisted Registration will need to mark the relevant test case as "N/A".

Reference	Requirement	Open PDS	Direct PDS	Med charts Open PDS	Med charts Direct PDS
PRES-205	The prescribing system SHOULD provide assisted registration functionality to support Subject of Care registration for an Active Script List.	Yes	No	Yes	No
PRES-73	The system SHALL conform to mandatory requirements 016832 and 016813 in Healthcare Identifiers use case UC.330 (Send patient health information electronically) if accessing an Active Script List Registry Service to register a SoC for an Active Script List, update registration details, or to establish whether a SoC has registered for participation or to retrieve an Active Script List. The system SHALL include an IHI in communication with the Active Script List Registry Service only if its status "active" and "verified". *Note: This conformance requirement makes the Prescribing System responsible for checking that an IHI in the local system is valid and belongs to the SoC.*	Yes	No	Yes	No

Reference	Requirement	Open PDS	Direct PDS	Med charts Open PDS	Med charts Direct PDS
PRES-210	If the system supports assisted registration, the prescribing system SHALL only allow pre-population of the SoC's locally stored personal information in the assisted registration form, and only send the following SoC's information to the ASLR: • IHI number • Family name • Given names (if available) • Date of birth • Gender • Medicare card number and IRN (if available) • DVA number (if available) • Residential address (optional for software to support) *Note: The above attributes align to the attributes used by the HI Service when there is a need to discover or validate an IHI.* *Note: It is important that the ASLR is populated with the same data that is in the CIS so that those systems are consistent. If, for example, the date of birth requires correction, then this must be corrected in the patient record first so it can be correctly reflected in the assisted registration form.* *Note: Vendors should refer to ASLR interface specifications to understand if the transmission of the residential address is supported.* *Note: See also PRES-225 and PRES-230 for carers and agents.*	Yes	No	Yes	No
PRES-215	If the system supports assisted registration, and the SoC wishes to add a carer or an agent to the SoC's ASL, the prescribing system SHALL provide a checkbox (or similar) to indicate that the SoC and the agent/carer consents to those details being added to the ASL. The checkbox SHALL default to 'off', meaning, an explicit action is required to acknowledge consent. *Note: The SoC is responsible for getting consent from the Carer/Agent and communicating this to the healthcare provider.* *Note: A healthcare provider can consent on behalf of a SoC if the healthcare provider is satisfied that the SoC can't provide consent (e.g. incapacitated).*	Yes	No	Yes	No

Reference	Requirement	Open PDS	Direct PDS	Med charts Open PDS	Med charts Direct PDS
PRES-220	If the system supports assisted registration and the SoC wishes to register a carer or agent, the prescribing system SHALL allow the healthcare provider to nominate which role that person supports (Carer or Agent). *Note: A 'carer' and 'agent' are different concepts and must be captured separately.*	Yes	No	Yes	No
PRES-225	If the system supports assisted registration, the prescribing system SHALL allow at least one carer to be registered in the SoC's ASL, and only send the following carer information to the ASLR: • Family name, and • Given names (optional if the carer has only one name), and • Address (optional for the carer to provide), and • Relationship to SoC (optional for the carer to provide) and SHALL NOT capture any other information for ASLR purposes. *Note: Capturing a carer is optional but the software must support this function.* *Note: The CIS can store additional information about carers that are not sent to the ASLR (e.g. notes for administration purposes or identity management).* *Note: If the carer has a given name then that given name must be recorded.* *Note: If the carer is an organisation (e.g. residential aged care facility) then PRES-235 applies.* *Note: It is recommended that the system captures the above attributes as separate attributes (i.e. not as a single text field) as future architecture may require this information to be discrete and ready to be validated for identity management purposes.*	Yes	No	Yes	No

Reference	Requirement	Open PDS	Direct PDS	Med charts Open PDS	Med charts Direct PDS
PRES-230	If the system supports assisted registration, the prescribing system SHALL allow at least one agent to be registered in the SoC's ASL, and send the following agent information to the ASLR: • Family name, and • Given names (optional if agent has only one name), and • Address (optional for the agent to provide), and • Relationship to SoC (optional for the agent to provide) *Note: Capturing an agent is optional but the software must support this function.* *Note: Agents are not authorised to receive notifications from healthcare providers so capturing their electronic details is not necessary and prevents software systems sending the notification to the agent by mistake (unless the Agent is also the nominated ASL Primary Contact).* *Note: The CIS can store additional information about the agents that are not sent to the ASLR (e.g. notes for administration purposes or identity management).* *Note: If the agent has a given name then that given name must be recorded.*	Yes	No	Yes	No
PRES-235	If the system supports assisted registration, the prescribing system SHALL support the capture of an organisation name as a carer for the SoC. *Note: It is likely that the RACF for a resident patient will, with permission, nominate themselves as a carer so they can receive electronic notifications and provide site-consent.* *Note: The attributes specified in PRES-225 do not apply to organisations as a carer.*	Yes	No	Yes	No
PRES-240	If the systems supports assisted registration, the prescribing system SHALL record and send one and only one primary contact for the SoC's ASL. *Note: The patient or primary carer will nominate primary contact details for ASL notifications. Having a single contact avoids conflicting notifications and consent messages being sent from multiple carers.*	Yes	No	Yes	No
PRES-245	If the software supports assisted registration then the system SHALL NOT permit the user to delete, remove or erase the primary contact details registered against an ASL. *Note: the system can permit the editing/updating of primary contact information but the removal of that information is not permitted.*	Yes	NO	Yes	NO

Reference	Requirement	Open PDS	Direct PDS	Med charts Open PDS	Med charts Direct PDS
PRES-250	If the prescribing system supports assisted registration, the prescribing system SHALL support the subsequent update of the SoC, carer and agent's personal information that is in the ASL, in accordance with PRES-210, PRES-225 and PRES-230. *Note: The term "update" includes add, remove and modify operations.* *Note: If it is known that the SoC's IHI has changed then the ASLR operator must be notified via the ASLR support phone number. The ASLR operator will take steps to move prescription information from the de-activated ASL to the new ASL.*	Yes	No	Yes	No
PRES-255	If the prescribing system supports assisted registration, the prescribing system SHALL ensure SoC's IHI has a record status of "Active" and status of "Verified" before displaying the assisted registration form. *Note: It is best practice to refresh the IHI against the HI Service immediately before satisfying this requirement but a check against the HI Service is not required.*	Yes	No	Yes	No

ASLR Viewing

Software that does not support ASLR Viewing will need to mark the relevant test case as "N/A".

Reference	Requirement	Open PDS	Direct PDS	Med charts Open PDS	Med charts Direct PDS
PRES-275	When viewing a patient record, the prescribing system MAY display a visual indication if the SoC has an Active Script List.	Yes	No	Yes	No
PRES-280	The prescribing system MAY allow the healthcare provider to view the SoC's Active Script List, if and only if: • the SoC has an Active Script List (refer to PRES-275), and • the healthcare provider has site consent for the SoC's ASL (refer to PRES-295). *Note: The prescriber has the patient's prescription history in their local patient record. The viewing of the ASL might help with clinical decision making but it is optional for prescribing software vendors to provide this function.*	Yes	No	Yes	No

Reference	Requirement	Open PDS	Direct PDS	Med charts Open PDS	Med charts Direct PDS
PRES-290	If the SoC has an Active Script List, the prescribing system MAY display the name of that ASLR in the patient record.	Yes	No	Yes	No
PRES-295	If the SoC has an Active Script List and the system can determine this, the prescribing system MAY indicate whether the healthcare provider organisation has been given site consent to access the SoC's ASL.	Yes	No	Yes	No
PRES-305	If a healthcare provider organisation does not have site access to the SoC's ASL, the prescribing system SHALL allow the healthcare provider to request site consent.	Yes	No	Yes	No

Reference	Requirement	Open PDS	Direct PDS	Med charts Open PDS	Med charts Direct PDS
PRES-315	If displaying a patient's ASL the prescribing system SHALL display at least the following information: For carers & agents: • Family name, and • Given name, and • Address (optional), and • Relationship to SoC. For medicines: • Name of the Subject of Care • Medicine(s) name, strength; • Date prescribed; • Number of repeats available; • Indication that the token is not available (if applicable – for paper prescriptions). The system MAY display: • Name of the prescriber; • Name of the prescriber organisation; • Contact details of the prescriber and / or prescribing organisation; *Note: Prescribers wanting to view the complete prescription from other prescribers (i.e. not in their local system) will need to enquire directly with that prescriber or the prescriber's organisation.* *Note: The ASL intentionally contains limited information to prevent a dispense from the ASL. Dispensers are required to download the full legal prescription before dispensing. See ASLR-315.*	Yes	No	Yes	No

ASLR Prescribing

Reference	Requirement	Open PDS	Direct PDS	Med charts Open PDS	Med charts Direct PDS
PRES-345	The prescribing system SHALL display a checkbox (or similar) for the prescriber to describe the following event (for electronic and paper prescriptions): • Patient has exercised their choice to keep the information away from their ASL. This SHOULD default to 'off' meaning SoC intends the prescription to be added to their ASL. *Note: The prescriber needs to consider the dispensing expectation for each prescription and use the checkboxes (or similar) to influence the prescription information in the ASL.*	Yes	No	Yes	No
PRES-345A	The prescribing system SHALL display a checkbox (or similar) for the prescriber to describe the following event (for electronic and paper prescriptions): • the prescription will be retained by the pharmacy for legal purposes and must not be sent to an ASL. This SHOULD default to 'off' meaning the prescription will not be retained by the pharmacy. *Note: This profile does not describe how a token is to be sent directly to a pharmacy. The checkbox only captures that that action will be done via fax, email, SMS, secure message delivery etc. Each developer needs to decide if this is done within their system or is dependent on an external process.* *Note: also see PRES-365* *Note: Prescribing to dosing points is a reason to send directly to that pharmacy and keep the token from an ASL.*	Yes	No	No	No
PRES-360	The prescribing system SHALL include the status (or similar) of the following item in the prescription meta-data: • the patient consents to the prescription being added to the ASL, or, the absence of any objection to the prescription being added to the ASL; *Note: Including this information in the transmission permits the PDS and dispensing system to make intelligent decisions around the treatment of ASL's and repeat authorisations.* *Note: The patient consent status (or absence of objection) reflects the patient's intention to include the prescription in the ASL i.e. patient choice.*	Yes	No	Yes	No

Reference	Requirement	Open PDS	Direct PDS	Med charts Open PDS	Med charts Direct PDS
PRES-362	The prescribing system SHALL include the status (or similar) of the following item in the prescription meta-data: • the prescription will be sent directly to a dispenser and must not be sent to an ASL. *Note: This profile does not describe how a token is to be sent directly to a dispenser. The status only captures that that action will be done via fax, email, SMS, secure message delivery etc. Each developer needs to decide if this is done within their system or is dependent on an external process.* *Note: Including this information in the transmission permits the PDS and dispensing system to make intelligent decisions around the treatment of ASL's and repeat authorisations.*	Yes	No	No	No
PRES-365	If the system has the capability to send notifications to the subject of care, then the system SHALL NOT send an electronic EoP (token) to the SoC if the token will be sent directly to a dispenser (also see PRES- 345a). *Note: Some CIS's delegate the sending of the communication to the PDS.* *Note: Prescribers should not give printed EoP's to the SoC if the token is to be given directly to the dispenser (i.e. a dosing point).*	Yes	No	No	No
PRES-390	When creating a prescription, the prescribing system SHALL be able to create an Evidence of Prescription regardless of the presence of an active script list. *Note: Sending prescription information to an ASL does not remove the onus of providing an EoP to the subject of care. All relevant conformant requirements apply when there is a need for an EoP.* *Note: The SoC can give instructions to not receive an EoP thereby removing that obligation on the healthcare provider and/or the system.*	Yes	No	No	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-2	The system SHALL allow access to electronic prescribing capability (including dispensing capability) only to designated user accounts. *Note: Only users designated by the healthcare organisation as having dispensing rights may access the electronic prescribing capability.*	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
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. Creating and uploading a dispense record under a guest account or any other anonymous account is disallowed.*	Yes	Yes
DISP-6	The system SHALL record the following information with each account: • Full Name; • AHPRA Number (if any); • User Class: Pharmacist, Supervising Pharmacist, Pharmacy Technician, etc; and • HPI-I (if any). *Note:* The *user classes available in* the *system is a* software *design decision and should reflect real world occupations/business practices.*	Yes	No

Reference	Requirement	Open PDS	Direct PDS
DISP-6A	The system SHALL record the following information with each account: • Full Name; • 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). *Note: The user classes available in the system is a software design decision and should reflect real world occupations/business practices.*	No	Yes
DISP-7	Where only single factor or multi-stage authentication is provided, the system SHALL use strong authentication. This is to be done by at least one of the following 3 approaches: 1. allow either 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). 2. require all users to have a strong password which permits the use of special characters with a minimum of: • Eight characters; • One letter; and • One number. 3. Require all users to have passwords aligned to ISM Security Control 0417 and ISM Security Control 0421. *Note: Healthcare organisations shall have the support of the system in the implementation of access control policies.* *Note: Some Software-As-A-Service software are not able to adopt password policy at an organisational level and as such must ensure users have a strong password.*	Yes	Yes
DISP-8	The system SHALL facilitate the identification and recording of the identity of each user involved with dispensing activity.	Yes	Yes

Reference	Requirement	Open PDS	Direct PDS
DISP-9	The system SHALL facilitate the identification and recording of the identity of the dispenser authorising the dispensing activity. *Note: the person authorising the dispense record to be submitted to the PDS needs to be identified and details captured.*	Yes	Yes
DISP-10	The system SHALL automatically log off an account, or require re-authentication, after a period of inactivity. The period of inactivity SHALL be either: 1. configurable by the healthcare organisation AND the default SHOULD be no longer than 15min OR 2. a time period set by the software vendor no longer than 15 minutes. *Note: Healthcare organisations need to be able to define a period of inactivity after which the dispenser's terminal may be considered unattended and vulnerable to misuse.* *Note: Software-as-a-Service providers may not be able to set time period for each organisation and as such may select a time period no longer than 15 minutes for all users.*	Yes	No
DISP-53	If the authorised dispenser identification is not present, the system SHALL NOT execute the dispense function.	Yes	Yes
DISP-95	If the system is comprised of multiple products with different branding, or optional installation configurations, that are providing functionality that is tested as a part of conformance, to this conformance profile, then all of the products associated with the specific function need to be operating when transacting with a PDS and ASLR. If one or more of the products associated with the specific function is not operating, then the system SHALL NOT interact with the PDS and ASLR. *Note: a system that is designed to work in a specific configuration is conformant only when implemented in that configuration. Exchanging Conformance IDs when it is in an alternate configuration or operating in isolation is a breach of the Conformance Assessment Scheme and the Electronic Prescribing legislation.* *Note: 'operating' means it must be integrated into the system and active. Simply installing the product in an inactive state is not sufficient.* *Note: the system will be tested with different configurations to ensure that interactions with PDS and ASLR are permitted only when all products associated with the specific function are operating and active.*	Yes	Yes

Reference	Requirement	Open PDS	Direct PDS
DISP-931	If the system stores passwords it SHALL ensure that the passwords are stored securely inline with ISM Security Control 1252. This is to be done by: • not storing passwords as plain text; • passwords stored using an ASD approved cryptographic hash and password salt.	Yes	yes
DISP-955	If the system is integrated to the healthcare provider organisation's Single-Sign-On service the system MAY allow the healthcare provider organisations to disable application level authentication.	Yes	Yes
DISP-940	Where the system is hosted and accessible over the public internet and the system is only using single factor or multi-stage authentication the system SHALL check the users' credentials with a known breached credentials service or against a known breached password list. The system shall perform this check at the time the password is set by the user and on the first login after the known breached credentials service or password list has been updated. If the password was found in a past breach the user shall be required to update their password before authenticating into the system. *Note: a known breached credentials service is a service which provides either an application programming interface (API) to check if a password has been included in a known data breach or a list of all known passwords included in known data breaches.* *Note: This requirement applies to software-as-a-service accessible over the public internet. Software which is deployed within a healthcare provider organisation's infrastructure does not need to meet this requirement.* *Note: This requirement applies to software-as-a-service accessible over the public internet. Software which is deployed within a healthcare provider organisation's infrastructure odes not need to meet this requirement.*	Yes	Yes
DISP-937	The system SHOULD check users' credentials with a known breached credentials service to ensure the credentials haven't been used in a previous data breach. *Note: a known breached credentials service is a service which provides either an API to check if a password has been included in a known data breach or a list of all known passwords included in known data breaches.*	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. *Note: NSW regulations require audit logs to be retained for at least two years.* *Note: storing the audit log in a location that is NOT the main system would assist data recovery efforts if the main system is compromised or unavailable.*	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 record creation (time and time zone); • The Globally Unique Prescription Identifier; • The Delivery Service Prescription Identifier (DSPID); • Date and time receipt acknowledged by the Delivery Service (time and time zone); and • All information fields relevant to the dispense record. • All information fields relevant to the prescription record. *Note: At a minimum, all elements required by State/Territory legislation in a dispensing record must be included.* *Note: storing the audit log in a location that is NOT the main system would assist data recovery efforts if the main system is compromised or unavailable.*	Yes	No
DISP-37	The system SHALL record each dispense record reversal request in the audit log. The details of the record SHALL include: • Date and time of Dispense reversal (time and time zone); • The Globally Unique Prescription Identifier; • The Delivery Service Prescription Identifier (DSPID); • Date and time of acknowledgement from the Delivery Service (time and time zone); and • The success (or otherwise) of the reversal request. *Note: reversal is used to reflect that the dispense record was created in error, not that it has been ceased or has expired.* *Note: Some direct PDS may not have an acknowledgement. This will be determined by the architecture and technical solution.*	Yes	No

Reference	Requirement	Open PDS	Direct PDS
DISP-51	The system SHALL, on request, generate a file or files that contain at least the following information in human readable format: • The information in the original electronic prescription • The date and time the electronic prescription was retrieved from the PDS • The information in electronic repeat authorisations (including non-PBS) • All information in associated annotations • All information about token(s) associated to the prescription and its repeat authorisations *Note: this requirement permits the generation of a file or files that can be shared or sent to relevant regulatory bodies on request. "Human readable formats" include text files, PDF files, log files or any other format that presents the required information "in the clear".* *Note*: *dispensing software must include the functionality to produce required information on demand without the pharmacist needing assistance from a third party.*	Yes	Yes
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. N*ote: Vendors may consider inclusion of a watermark.*	Yes	Yes
DISP-405	The system SHALL maintain an audit log of access to Active Script Lists. The audit log SHALL include at least: • Date and time of access (time and time zone); • Subject of Care's IHI number; • Organisation or site ID, or User ID (from the dispensing system) or both.	Yes	No

Cryptography

Reference	Requirement	Open PDS	Direct PDS
DISP-81	The meta-data component of every electronic prescription SHALL be: a) Unencrypted when at rest and; b) Encrypted when in transit; *Note: the meta-data is designed to be available to electronic prescribing and dispensing systems to assist those systems in the delivery of electronic prescriptions.* *Note: this requirement does not impact other requirements around the presentation of electronic prescriptions. The inclusion of information in meta-data or otherwise doesn't imply this information must or can be hidden from healthcare providers.*	Yes	No
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: The Conformance Requirements will be updated if the approved authentication methods change.*	Yes	Yes
DISP-26	When connecting to a PDS over a public network, the system SHALL assert its identity to the PDS using Public Key Infrastructure (PKI).	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-938	The system SHOULD validate digital certificates. *Note: See Appendix B Implementation Advice for further implementation guidance.*	Yes	No
DISP-939	The system SHOULD encrypt information assets (excluding meta-data) at rest using an Australian Signals Directorate (ASD) approved cryptographic algorithms.	Yes	Yes

Patient records

Reference	Requirement	Open PDS	Direct PDS
DISP-70	The system SHALL conform to the following requirements for Healthcare Identifiers use cases UC.010 (Register patient) and UC.015 (Update patient health record): 1. All mandatory and applicable conditional conformance requirements. 2. Recommended conformance requirements 005812, 005813, 005814 and 005818. *Note: UC.010 and UC.015 are initiated by the receipt of an electronic prescription but may also be initiated by the operator of a Dispensing System. That is, Dispensing Systems need to be able to query the HI Service using an IHI, Medicare card number or DVA file number and be able to resubmit a query using modified search criteria (such as a person's maiden name or alternative given names).* *The requirements are stated in Use of Healthcare Identifiers in Health Software Systems Software Conformance Requirements* [AGENCY2020].	Yes	Yes

Retrieval

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 a lookup service 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.*	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
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.	Yes	No

	Note: Electronic prescriptions are only considered valid if they assert a Conformance ID.		
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
DISP-70A	The system SHALL conform to mandatory requirements 023942, 023943 and 023944 in Healthcare Identifiers use case UC.325 (Receive patient health information electronically) when receiving an electronic prescription. If a failure to validate a known IHI can be attributed to the unavailability of the HI Service then a Dispensing System is permitted to include the IHI (without positively validating it) in a Dispense Notice but SHALL NOT record the electronic prescription in a local patient record. *Note: UC.325 includes requirements for matching an electronic prescription to the correct local record in the Dispensing System. UC.325 conformance requirements not listed above are optional for Dispensing Systems. This mitigates the clinical risk that a dispenser associates an electronic prescription to a local patient profile of another individual. The mandatory inclusion of the IHI in the prescription payload and subsequent repeats means dispensing systems should be validating the IHI against the locally assigned patient profile for patient safety.*	Yes	No
DISP-71	The system SHOULD conform to mandatory requirements 023942, 023943 and 023944 in Healthcare Identifiers use case UC.325 (Receive patient health information electronically) when receiving an electronic prescription. If a failure to validate a known IHI can be attributed to the unavailability of the HI Service then a Dispensing System is permitted to include the IHI in a Dispense Notice (without positively validating it). *Note: UC.325 includes requirements for matching an electronic prescription to the correct local record in the Dispensing System. UC.325 conformance requirements not listed above are optional for Dispensing Systems.*	No	Yes
DISP-715	The system SHOULD provide the ability for a dispensing system to provide a chart identifier to the prescription delivery service so that all prescriptions available for dispensing on that chart can be easily downloaded.	Yes	No

Presentation

Reference	Requirement	Open PDS	Direct PDS
DISP-16	For a valid electronic prescription that has a status of 'active' (i.e. not dispensed, not cancelled, not expired, not disabled), the system SHALL have the ability to display: • All information related to the prescription provided by the PDS; • The prescription status (i.e active); • All previous dispenses (if any); and • The details of any annotations in relation to the prescription recorded during previous dispenses (if any). *Note: The above requirement details the minimum system requirements. Vendors may choose to display additional details.* *Note: Displaying the original prescription supports the dispenser checking process.* *Note: Annotations, or the presence of annotations, need to be clearly displayed when the prescription is first opened/rendered.* *Note: "all information" does not include system data like GUID's, OIDS, serial numbers, datetime stamps etc.*	Yes	Yes
DISP-16A	The system SHALL have the ability to display all the information related to the prescription and the repeat authorisation (if applicable) after it has been dispensed. The system SHALL make it clear that the prescription has been dispensed and if the prescription is not a chart based prescription then the system SHALL prevent a double dispense against that prescription. *Note: this is to allow pharmacies to complete the dispensing process but to allow a double check against the prescription at a later date, especially where medicines are collected sometime after the dispensing event.* *Note: tokens associated with chart based prescriptions can persist for the life of the chart and multiple dispenses against that single token is expected.* *Note: "all information" does not include system data like GUID's, OIDS, serial numbers, datetime stamps etc.*	Yes	Yes
DISP-17	The system SHALL display all data elements in 'original text' to the dispenser, 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.*	Yes	Yes

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 SHALL 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
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 electronic address and select a different electronic address for a Subject of Care on a per prescription basis.	Yes	No

Finalisation

Reference	Requirement	Open PDS	Direct PDS
DISP-30	The system SHALL be able to print, or reprint, an Evidence of Prescription for the Subject of Care that details the medicine(s) prescribed where there are remaining repeats. The system SHALL include the following details: • Indication that this is an Evidence of Prescription (e.g. Not for Dispense); • DSPID (as a Barcode/QR Code); • 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. *Note: The system is not expected to reprint an Evidence of Prescription that originated from a different system. That is, the CIS can only reprint an Evidence of Prescription if it was created in that system.*	Yes	No

Reference	Requirement	Open PDS	Direct PDS
DISP-90	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; • Form; • Dose (directions); or • Reason for prescribe. There SHALL NOT be a place for the prescriber to sign. *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.* *Note: If Form is incorporated into the Medicine Name, it may be included. There is no requirement to strip the form out of the medicine name.*	Yes	No
DISP-31	For a repeat authorisation (for PBS and non-PBS), 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 at least: • URI (e.g. URL) linking to the electronic token; • The initials of the Name of the Subject of Care; • The Subject of Care's date of birth (optional); and Medicine name. *Note: there might be a need for the Pharmacy to retain the Evidence of Prescription (e.g. scripts on file). The software can permit the Pharmacy to print and retain the Evidence of Prescription for repeat authorisations without sending the Evidence of Prescription for repeat authorisations electronically.*	Yes	No

Reference	Requirement	Open PDS	Direct PDS
DISP-91	Where Evidence of Prescription is provided in electronic form, the system SHALL NOT include the following details: • Subject of Care name • Subject of Care age; • Subject of Care sex; • PBS Prescriber number; • Authority number; • Form; • Dose (directions); or • Reason for prescribe. There SHALL NOT be a signature box. *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.* *Note: If Form is incorporated into the Medicine Name, it may be included. There is no requirement to strip the form out of the medicine name.* *Note: DISP-31 requires the subject of care's initials (not full name).*	Yes	No
DISP-31A	Where an Evidence of Prescription is sent in electronic form and that Evidence of Prescription includes a link to an electronic token (URI), then any information provided by that link SHALL also conform to DISP-31 and DISP-91. *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
DISP-31B	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

Reference	Requirement	Open PDS	Direct PDS
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. If the PDS is unavailable, the Dispense Record 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-59	Post finalisation, where a dispense record has been sent to the PDS, the system SHALL provide a mechanism for the dispenser to correct a dispense record if the dispenser needs to. *Note: the dispense record might be against the prescription or subsequent repeat authorisations. The dispenser must have the option to correct a dispense record under both scenarios.* *Note: a "r*eversal*" operation followed by a "create" operation is an acceptable mechanism provided the system automatically and instantly creates the subsequent "create" request. It is unacceptable for the onus for the subsequent "create" request to fall on the local user.* *Vendors will need to understand what operations the PDS will support.*	Yes	Yes
DISP-86	The system SHALL provide the ability to disable an electronic prescription, including all repeats, rendering the prescription unavailable by other dispensing systems. *Note: "Disable" means the prescription will not be accessible by another pharmacy.* *Note: This is to support the situation where there are concerns regarding patient safety, fraud or excessive supply of high-risk medication in line with legislative requirements.*	Yes	No

Reference	Requirement	Open PDS	Direct PDS
DISP-82	The system SHALL provide the ability to annotate a disabled prescription during the 'disable' event. *Note: annotations should be used, whilst disabling a prescription, to explain why that prescription is being disabled.*	Yes	No
DISP-83	The system SHALL provide the ability to re-enable (i.e. enable) a previously disabled electronic prescription. The system can then either dispense or release the token so it can be accessed by other dispensing systems. *Note: This is to support the situation where the user has confirmed the validity of the prescription with the prescriber.*	Yes	No
DISP-84	The system SHALL save all "Disable Prescription" and "Re-enable prescription" events in an event log. The details of the record shall include: • Date and time of the disable/re-enable event (time and time zone); • The user that disabled/ re-enabled the prescription; and • All information related to the electronic prescription along with all the prescription information. *Note: This is to support monitoring trends and reporting incidents.*	Yes	No
DISP-85	The system SHALL NOT automatically send a new EoP for a disabled prescription to the SoC. *Note: The EoP can be printed and retained at the Pharmacy but it should not be given to the patient, especially if there is concerns regarding patient safety, fraud or excessive supply of high-risk medication in line with legislative requirements.*	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 (including non-PBS) together with at least: • Dispense software conformance identifier; • Globally Unique Prescription ID recorded in the original prescription; • Date of the dispense • Name of the pharmacy • Address of the pharmacy • Pharmacist name • HPI-O of the dispensing organisation • Medicine generic name dispensed (if known) • Medicine brand name dispensed (if known) • Unique identifier for the medicine dispensed if known (i.e. AMT, PBS code, or both) • Form, strength and quantity dispensed • Subject of Care Date of Birth as recorded in the original prescription • Subject of Care address (if in South Australia) • The total number of repeats dispensed (if dispensing against a repeat authorisation) • Closing the Gap code (if applicable)	Yes	No
DISP-19A	If there is a repeat authorisation then the system SHALL NOT generate, display, print, render or make available the token of the repeat authority, in barcode or plain text format, until the dispense record is finalised and is, or will, be transmitted (where applicable) to the PDS. *Note: The 'final check' process might detect an error with a dispense or dispense record resulting in a reversal of the dispense record. The subject of care must not have access to the token for the repeat authorisation until the original dispense is final sent to the PDS (or queued to be sent to the PDS).*	Yes	Yes
DISP-20	The system SHOULD include 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) number; and • Subject of Care electronic communication address. The SoC electronic communication address SHOULD default to the address stored in the original prescription. *Note: The dispense record might contain a different address if the SoC prefers.*	Yes	No

Reference	Requirement	Open PDS	Direct PDS
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-21A	The system SHALL NOT upload a dispense record for a prescription that has expired.	Yes	Yes
DISP-22	The system SHALL be able to send a message reflecting an annotation to the PDS.	Yes	No
DISP-23	The system MAY determine that the PDS is unavailable and alert the dispenser.	Yes	Yes
DISP-24	If an item is not involved in a dispense event, the system SHALL ensure the electronic prescription in the Open PDS is not locked (i.e. able to be dispensed). *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.*	Yes	No
DISP-25	The system SHALL be able to 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 record 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-17.*	Yes	No
DISP-27	The system SHALL record the date and time (time and time zone) that the PDS acknowledged receipt of the dispense record.	Yes	No
DISP-28	The system SHALL record the date and time (time and time zone) that the PDS acknowledged receipt of the dispense reversal (when applicable).	Yes	No
DISP-29	If the PDS is unavailable / unresponsive, the system SHALL queue messages and retry until the PDS acknowledges receipt.	Yes	No

Reference	Requirement	Open PDS	Direct PDS
DISP-50	Prior to submitting a dispense record, the system SHALL display to the dispenser at least the information defined in PRES-18, PRES-18A and PRES-18B. *Note: a system can auto-populate a dispense record based on information stored in a prescription but this population and submission must not be automatic without the dispenser viewing the dispense record for accuracy.*	Yes	Yes
DISP-57	On submission to an Open PDS, the system MAY include, in the dispense record header, the electronic address to which the Open PDS may send the Evidence of Prescription to the Subject of Care or their Agent. *Note: After SoC consents.*	Yes	No

Reconciliation[1]

Reference	Requirement	Open PDS	Direct PDS
DISP-38	The system SHALL allow a DSPID to be manually entered into an electronic dispense record where applicable. *Note: Medicines might be dispensed without the dispenser having access to a token or evidence of prescription (e.g when dispensing under verbal authority). Allowing the dispenser to manually enter a DSPID provided by phone or email etc allows that dispense to be reconciled to the matching prescription at a later date.*	Yes	Yes
DISP-38A	Where a prescription has been dispensed under a verbal authority from the prescriber for an urgent case/supply, and the DSPID of the electronic prescription has been entered at the time of dispense, the System SHALL attempt to reconcile the Dispense Record with the electronic prescription retrieved from the PDS with that DSPID when the PDS becomes available where applicable.	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 where applicable.	Yes	Yes
DISP-42	In attempting to reconcile a manually entered dispense record with an electronic prescription, the system SHOULD identify and display any discrepancies where applicable.	Yes	Yes

[1] 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.

Reference	Requirement	Open PDS	Direct PDS
DISP-43	Once the electronic prescription has been retrieved, the system SHALL allow the Dispenser to mark the Dispense Record as: • Reconciled where applicable. *Note:* *A dispense record that is reconciled is not prohibited from having annotations in-line with normal dispensing processes.*	Yes	Yes
DISP-46	Should the electronic prescription to be reconciled be identified as "already filled", the system SHOULD be able to provide an indication on the dispense record that the electronic prescription was already filled. *Note:* *This will support discussions with the prescriber and the prescriber can be made aware that the SoC has had the prescription filled more than once.*	Yes	No

ASLR Assisted registration

Reference	Requirement	Open PDS	Direct PDS
DISP-200	The dispensing system SHALL integrate with only one ASLR for supporting electronic prescriptions. *Note: The ASLR will act like a broker for the CIS and present ASL activity and scripts to the CIS through a single point. The ASLR will search for other ASLRs as required.*	Yes	No
DISP-205	The dispensing system SHALL provide assisted registration functionality to support Subject of Care registration for an Active Script List.	Yes	No
DISP-73	The system SHALL conform to mandatory conformance requirements 016832 and 016813 in Healthcare Identifiers use case UC.330 (Send patient health information electronically) when accessing an Active Script List Registry Service to register a SoC for an Active Script List, update registration details, to establish whether a SoC has registered for participation or to retrieve an Active Script List. An IHI SHALL NOT be used for communication with the Active Script List Registry Service unless it is “active” and “verified”. *Note: This conformance requirement makes the Dispensing System responsible for checking that an IHI in the local system is valid and belongs to the SoC.*	Yes	No

Reference	Requirement	Open PDS	Direct PDS
DISP-210	When the healthcare provider performs assisted registration for a SoC wanting an Active Script List, the dispensing system SHALL only allow pre-population of the SoC's locally stored personal information in the assisted registration form, and only send the following SoC's information to the ASLR: • IHI number • Family name • Given name (if available) • Date of birth • Gender • Medicare card number and IRN (if available) • DVA number (if available) • Residential address (optional for software to support) *Note: The above attributes align to the attributes used by the HI Service when there is a need to discover or validate an IHI.* *Note: It is important that the ASLR is populated with the same data that is in the CIS so that those systems are consistent. If, for example, the date of birth requires correction, then this must be corrected in the patient record first so it can be correctly reflected in the assisted registration form.* *Note: Vendors should refer to ASLR interface specifications to understand if the transmission of the residential address is supported.* *Note: See also DISP-225 and DISP-230 for carers and agents.*	Yes	No
DISP-215	When adding a carer or an agent to the SoC's ASL, the dispensing system SHALL provide a checkbox (or similar) to indicate that the SoC and the agent/carer consents to those details being added to the ASL. The checkbox SHALL default to 'off', meaning, an explicit action is required to acknowledge consent. *Note: The SoC is responsible for getting consent from the Carer/Agent and communicating this to the healthcare provider.* *Note: A healthcare provider can consent on behalf of a SoC if the healthcare provider is satisfied that the SoC can't provide consent (e.g. incapacitated).*	Yes	No
DISP-220	If the patient has a registered carer or agent, the dispensing system SHALL allow the healthcare provider to nominate which role that person supports (Carer or Agent). *Note: A 'carer' and 'agent' are different concepts and must be captured separately.*	Yes	No

Reference	Requirement	Open PDS	Direct PDS
DISP-225	The dispensing system SHALL allow at least one carer to be registered in the SoC's ASL, and only send the following care information to the ASLR: • Family name, and • Given name (optional if carer has only one name), and • Address (optional for the carer to provide), and • Relationship to SoC (optional for the carer to provide) and SHALL NOT capture any other information for ASLR purposes. *Note: Capturing a carer is optional but the software must support this function.* *Note: The CIS can store additional information about carers that are not sent to the ASLR (e.g. notes for administration purposes or identity management).* *Note: If the carer has a given name then that given name must be recorded.* *Note: If the carer is an organisation (e.g. residential aged care facility) then DISP-235 applies.* *Note: It is recommended that the system captures the above attributes as separate attributes (i.e. not as a single text field) as future architecture may require this information to be discrete and ready to be validated for identity management purposes.*	Yes	No
DISP-230	The dispensing system SHALL allow at least one agent to be registered in the SoC's ASL, and send the following agent information to the ASLR: • Family name, and • Given name (optional if the agent has only one name), and • Address (optional for the agent to provide), and • Relationship to SoC (optional for the agent to provide) *Note: Capturing an agent is optional but the software must support this function.* *Note: Agents are not authorised to receive notifications from healthcare providers so capturing their electronic details is not necessary and prevents software systems sending the notification to the agent by mistake.* *Note: The CIS can store additional information about the agents that are not sent to the ASLR (e.g. notes for administration purposes or identity management).* *Note: If the agent has a given name then that given name must be recorded.*	Yes	No

Reference	Requirement	Open PDS	Direct PDS
DISP-235	The dispensing system SHALL support the capture of an organisation name as a carer for the SoC. *Note: It is likely that the RACF for a resident patient will, with permission, nominate themselves as a carer so they can receive electronic notifications and provide site-consent.* *Note: The attributes specified in DISP-225 do not apply to organisations as a carer.*	Yes	No
DISP-240	The dispensing system SHALL record and send one and only one primary contact for the SoC's ASL. *Note: The patient or primary carer will nominate primary contact details for ASL notifications. Having a single contact avoids conflicting notifications and consent messages being sent from multiple carers.*	Yes	No
DISP-250	The dispensing system SHALL support the subsequent update of the SoC, carer and agent's personal information that is in the ASL, in accordance with DISP-210, DISP-225 and DISP-230. *Note: The term "update" includes add, remove and modify operations.* *Note: If it is known that the SoC's IHI has changed then the ASLR operator must be notified via the ASLR support phone number. The ASLR operator will take steps to move prescription information from the de-activated ASL to the new ASL.*	Yes	No
DISP-255	Before displaying the assisted registration form, the dispensing system SHALL ensure the SoC's IHI has been validated as "active" and "verified" against the HI Service within the last 24 hours and not display the assisted registration form if the IHI has not, or cannot be validated, or is not "active" and "verified".	Yes	No

ASLR Viewing

Reference	Requirement	Open PDS	Direct PDS
DISP-275	When viewing a patient record, the dispensing system SHALL display a visual indication if the SoC has an Active Script List.	Yes	No
DISP-280	The dispensing system SHALL allow the healthcare provider to view the SoC's Active Script List, if and only if: • the SoC has an Active Script List (refer to DISP-275), and • the healthcare provider has site consent for the SoC's ASL (refer to DISP-295).	Yes	No

Reference	Requirement	Open PDS	Direct PDS
DISP-290	If the SoC has an Active Script List, the dispensing system MAY display the name of the ASLR in the patient record. *Note: The ASLR will act like a broker for the CIS and present ASL activity and scripts to the CIS through a single point. The ASLR will search for other ASLRs as required.*	Yes	No
DISP-295	If the SoC has an Active Script List, the dispensing system SHALL indicate whether the healthcare provider organisation has been given site consent to access the SoC's ASL.	Yes	No
DISP-305	If a healthcare provider organisation does not have site access to the SoC's ASL, the dispensing system SHALL allow the healthcare provider to request site consent.	Yes	No

Reference	Requirement	Open PDS	Direct PDS
DISP-315	When displaying a patient's ASL the dispensing system SHALL display at least the following information: For carers & agents: • Family name, and • Given name, and • Address (optional for the carer/agent to provide), and • Relationship to SoC For medicines: • Name of the Subject of Care • Medicine(s) name, strength; • Date prescribed; • Number of repeats available • Indication that the token is not available (if applicable - for paper prescriptions); • Token (Barcode/QR code and DSPID) (if applicable). The system MAY display: • Name of the prescriber; • Name of the prescriber organisation; • Contact details of the prescriber and / or prescribing organisation; *Note: A QR code for a DSPID may or may not be rendered in the ASL.* *Note: The ASL intentionally contains limited information to prevent a dispense from the ASL. Dispensers are required to download the full legal prescription before dispensing. See ASLR-315.*	Yes	No

ASLR Dispensing

Reference	Requirement	Open PDS	Direct PDS
DISP-345	The dispensing system SHALL display a checkbox (or similar) for the dispenser to describe each of the following events (for electronic and paper prescriptions): • Patient has exercised their choice to keep the information away from their ASL; and • the prescription will be retained by the pharmacy (or another pharmacy) for legal purposes and must not be sent to an ASL. *Note: The checkboxes (or similar) are only relevant if there is a repeat authorisation.* *Note: This profile does not describe how a token is to be sent directly to, or retained by, a pharmacy. The checkbox only captures that that action will be done via fax, email, SMS, secure message delivery etc. Each developer needs to decide if this is done within their system or is dependent on an external process.* *Note: The dispenser needs to consider the dispensing expectation for each repeat authorisation and use the checkboxes (or similar) to influence the prescription in the ASL.* *Note: Prescribing to dosing points is a reason to send directly to (or retain by) that pharmacy and keep the token from an ASL.* *Note: DISP-350 identifies default behaviour for these checkboxes.*	Yes	No
DISP-350	For repeat authorisations, if the original prescription or most recent repeat authorisation indicates the patient has exercised their choice to keep the information away from their ASL, then the repeat authorisation SHALL default to the same for that repeat authorisation. *Note: The healthcare provider, with instructions from the subject of care, must be able to change this setting before submitting a repeat authorisation to the PDS.*	Yes	No

Reference	Requirement	Open PDS	Direct PDS
DISP-360	The dispensing system SHALL include the status of the following items in the repeat authorisation meta-data: • the patient consents to the prescription being added to the ASL, or, the absence of any objection to the prescription being added to the ASL; • the prescription will be sent directly to a dispenser and must not be sent to an ASL. *Note: This profile does not describe how a token is to be sent directly to, or retained by, a dispenser. The status only captures that that action will be done via fax, email, SMS, secure message delivery etc. Each developer needs to decide if this is done within their system or is dependent on an external process.* *Note: Including this information in the transmission permits the PDS and subsequent dispensing system to make intelligent decisions around the treatment of ASL's and repeat authorisations.*	Yes	No
DISP-365	If the system has the capability to send notifications to the subject of care, then the system SHALL NOT send an electronic EoP (token) to the SoC if the token will be sent directly to a dispenser. *Note: Some CIS's delegate the sending of the communication to the PDS.* *Note: Dispensers should not give printed EoPs to the SoC if the token is to be retained by the dispenser (or provided to a different dispenser).* *Note: The SoC cannot receive an EoP for a repeat authorisation until the current dispense is completely supplied (i.e. staged supply arrangement).*	Yes	No
DISP-370	The dispensing system SHALL NOT pre-populate the dispense record with the information provided by the ASLR. *Note: It is important that the CIS retrieves the legal prescription from the PDS and then (optionally) pre-populate the dispense record from the legal prescription.*	Yes	No

Reference	Requirement	Open PDS	Direct PDS
DISP-390	When a repeat authorisation is available, the dispensing system SHALL be able to create an Evidence of Prescription regardless of the presence of an active script list. *Note: Sending prescription information to an ASL does not remove the onus of providing an EoP to the subject of care. All relevant conformant requirements (DISP-30 etc) apply when there are repeat authorisations.* *Note: The SoC can give instructions to not receive an EoP thereby removing that obligation on the healthcare provider and/or the system.*	Yes	No

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. *Note: Every communication received by the system must contain a conformance ID and the system must verify that conformance ID is active. This may be done by comparing the conformance ID against an internal white list of active conformance ID's.*	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 (and time zone) of creation; • Transaction type; • Transaction status (for example, "Accepted", "Rejected"); • Reason for rejection (if rejected); • Identifier of submitting/requesting system; • The Globally Unique Prescription Identifier; • The Delivery Service Prescription Identifier (DSPID); • Date and time of acknowledged (time and time zone) if applicable; 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.* *Note: Some direct PDS may not have an acknowledgement. This will determined by the architecture and technical solution.*	Yes	Yes
DS-22A	The system SHALL, on request, generate a file or files that contain the information captured in the audit logs in human readable format. *Note: this requirement permits the generation of a file or files that can be shared or sent to relevant regulatory bodies on request. "Human readable formats" include text files, PDF files, log files or any other format that presents the required information "in the clear".*	Yes	Yes
DS-405	The system SHALL retain, for auditing purposes, all electronic requests for information, including requests that were rejected. Audit logs SHALL include at least: • the date and time of each request for information; • the DSPID submitted; the conformance ID(s) submitted.	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
DS-11A	When a dispensing system attempts to retrieve an electronic prescription that is not available (locked/cancelled/disabled/does not exist), the system SHALL withhold that prescription from the dispensing system and clearly indicate the cause of the failure to the CIS. *Note: the system that disabled the prescription is permitted to retrieve and view that prescription for auditing, investigation, review and for re-instating if appropriate.*	Yes	Yes
DS-11B	When a prescribing system attempts to amend or cancel an electronic prescription that is cancelled, disabled, locked or does not exist, the system SHALL clearly indicate the cause of the failure to the CIS.	Yes	Yes
DS-12	The system SHALL NOT aggregate and make available prescription information based on an IHI number *Note: An IHI number shall be included in the metadata of the electronic prescription provided by the prescriber.*	Yes	No
DS-410	When a technical error prevents the provision of prescription information (e.g. system outage) then the system SHALL return an error message to the requesting system that indicates the presence of a technical issue. *Note: a technical failure is not to be confused with the absence of data or the rejection of a request. Systems need to be unambiguously clear when information cannot be discovered due to technical faults so tokens are not misconstrued as 'not active' and incorrectly removed from the local system.*	Yes	Yes

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	NO
DS-4A	The system SHALL accept and support every data item specified in this profile including codes for data items if the prescribing/dispensing systems provide those codes. *Note: PRES-18, PRES-20, DISP-19 and other requirements specify data items those systems are expected to support. It is important that the PDS's receiving those prescription/dispense records also support those data items.* *Note: text values for Medicine identifier, medicine form and medicine route might also have codes provided by the originating system. The PDS's receiving those codes are expected to capture and retain those codes.*	Yes	Yes
DS-5	The system SHALL provide an acknowledgement of receipt of an electronic prescription to the prescribing system.	Yes	No
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
DS-8	The system SHALL provide an acknowledgement of receipt and the outcome of an electronic prescription cancellation request to the prescribing system. *Note: If the cancellation request fails, the outcome must include the cause of the failure e.g. already dispensed, locked, disabled. (refer to DS-11B)*	Yes	No
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), in accordance with DS-9A	Yes	No
DS-9A	The system SHALL NOT send an electronic token to a nominated address (i.e. the patient/carer) for prescriptions or repeat authorities where that prescription or repeat authorisation will be sent directly to a dispenser. *Note: tokens to be controlled by healthcare providers for legal reasons (e.g. dosing points) must not be provided to the subject of care/carers – including the ASL if one is active.*	Yes	Yes

Reference	Requirement	Open PDS	Direct PDS
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 during a dispense event.	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 reversal. *Note: There may be instances where a dispenser is required to reverse a dispense prior to supply to a SoC (for example, the pharmacy is out of stock). In this instance, following the submission of the dispense reversal, the electronic prescription record should be returned 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 reverse 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 record (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
DS-715	The system SHALL provide the ability to retrieve all active prescriptions on a chart when a chart identifier is provided.	Yes	No
DS-50	The system SHALL prevent a token for a disabled prescription from being sent directly to the Subject of Care/Carer and the Subject of Care's Active Script List. *Note: "Disabled" means the prescription is not accessible by another pharmacy.*	Yes	No
DS-51	The system SHALL ensure a re-enabled prescription token can be sent directly to the Subject of Care/Carer and is added to the Subject of Care's Active Script List (if applicable).	Yes	No

PDS Connections

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

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
DS-595	In response to a request for information for an item that has expired, been cancelled, been disabled or dispensed, the system SHALL provide at least the following information: • The status of the item (i.e. expired, cancelled, disabled, dispensed) *Note: providing this information to the requester enables rich information to be provided to the SoC. See MA-595.*	Yes	No
DS-597	In response to a request for information for a prescription that is active, the system SHALL provide all the information the prescribers and dispensers have provided on that prescription (if requested). *Note: Other requirements in this conformance profile that conflict with this requirement, take precedence. Eg The need to withhold some information for privacy reasons.*	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 system SHALL NOT expose the unencrypted payload to the operator or user of the PDS system when in normal operations. *Note: under normal circumstances, the system will prohibit access to the unencrypted payload to staff or technicians via a user interface, remote connection, data export or via any other means. The technical inability to access unencrypted data protects patient privacy.* *The system may need to expose unencrypted payloads internally for maintenance, fault finding, authorised investigations or by legal order.*	Yes	Yes
DS-25A	The system SHALL NOT share the payload with other internal or external systems unless: • Those recipient systems are covered by legal regulatory frameworks (e.g. EP, MHR, RTPM) and/or; • Under a legal order/direction and/or; • There is explicit patient consent for read-only access to their personal and health data for healthcare reasons	Yes	Yes
DS-81	The meta-data component of every electronic prescription SHALL be: • Unencrypted when at rest and; • Encrypted when in transit; *Note: the meta-data is designed to be available to electronic prescribing and dispensing systems to assist those systems in the delivery of electronic prescriptions.* *Note: this requirement does not impact other requirements around the presentation of electronic prescriptions. The inclusion of information in meta-data or otherwise doesn't imply this information must or can be hidden from healthcare providers.*	Yes	Yes

Reference	Requirement	Open PDS	Direct PDS
DS-82	The prescription component (the payload) of the transmission SHALL be: a) Encrypted when at rest and b) Encrypted when in transit; EXCEPT when a conformant dispensing system requires the payload to be decrypted at rest for the purposes of dispensing that prescription. *Note: Prescription information (the payload) is only available to dispensing systems for dispensing activities.*	Yes	Yes
DS-924	When encrypting information at rest the system SHALL utilise cryptography that consists of: • an implementation that has been approved for the protection of information assets at rest; • an algorithm that is approved by the ASD for encrypting information at rest; and • a supporting key management infrastructure	Yes	No
DS-925	When encrypting information for transport the system SHALL utilise validated cryptography that consists of: • an implementation that has been approved for the protection of information assets for transit; • an algorithm that is approved by the ASD for encrypting information for transit; and • a supporting key management infrastructure	Yes	No

Security

Reference	Requirement	Open PDS	Direct PDS
DS-23	If the service operates as a Commonwealth Government Service, the system SHALL put in place necessary controls for managing "Unclassified" data with a Dissemination Limiting Marker of "Sensitive: Personal".	Yes	Yes
DS-938	The system SHALL validate digital certificates. Note: See Appendix B Implementation Advice for further implementation guidance.	Yes	No

ASLR Assisted Registration

Reference	Requirement	Open PDS	Direct PDS
DS-200	The system SHALL facilitate the exchange of prescription information between the PDS and all conformant ASLRs. *Note: The ASLR will act like a broker for the CIS and present ASL activity and scripts to the CIS through a single point. The ASLR will search for other ASLRs as required.*	Yes	No

ASLR Prescribing and Dispensing

Reference	Requirement	Open PDS	Direct PDS
DS-344	When activating an ASL, the PDS SHALL share with the ASL prescription information (and tokens) for all known prescriptions for that SoC if: • The SoC consents to the pre-population of their SoC; and • The SoC, at the time of prescription creation, did not exercise their choice to keep the prescription information away from the ASLR (even if the ASL was not active at the time) (according to the payload); and • The prescription is active (i.e. not cancelled, not expired, not disabled or not dispensed).	Yes	No
DS-345	On receipt of a new electronic prescription (i.e. not during an assisted registration event), the system SHALL send the prescription information and the token (if applicable) to the ASLR only when: • The prescription is active (i.e. not cancelled, not expired, not disabled or not dispensed); and • It is known the SoC has an active ASL. *Note: Prescription information can be shared with the ASLR if the patient consents, that is, the ASL is active, and exception conditions are absent.*	Yes	No
DS-85	The system SHALL ensure a disabled prescription is not visible in the patients Active Script List.	Yes	No
DS-365	If the system has the capability to send an electronic EoP (token) to the subject of care, then the system SHALL NOT send an electronic EoP (token) to the SoC if the token will be sent directly to a dispenser. *Note: Some CIS's delegate the sending of the communication to the PDS.*	Yes	No
DS-380	The system SHALL NOT generate a token for a paper prescription. *Note: The prescription information can be displayed in the ASL without the token. However, there must not be a dispense without the paper prescription.*	Yes	No

3.4 Active Script List and Registers

There is an expectation for PDS's and ASLR's to interoperate and exchange information in a non-disruptive and harmonious manner and the degree of co-operation between systems is a routine aspect of conformance testing. It is acknowledged that early adopters and early entrants may not have other systems to interoperate with and demonstrations in this space can be technically challenging. This is especially true for the first production ready ASLR.

Normative note: where a system under test is expected to inter-operate with systems that are not commercially available then those systems under test are not expected to demonstrate that specific level of inter-operability. When other production systems do become production ready and inter-operability is possible and required then those inter-operability tests become relevant and need to be satisfied.

Some requirements refer to the capturing of different status (or states). This is a conceptual status and can be equally represented as the inverse of that state. The requirements are not intending to enforce the status precisely as described, but instead to describe the concept and the desired outcome. Software designers are free to implement as described, or the inverse (as a negative value), provided the intent of the requirement is supported and demonstrated. For example[2], both concepts are acceptable:

- Send to ASL = true
- Do not send to ASL = false or absent/null

Vendors will need to understand the PDS technical interface specifications to understand how to implement these concepts in a conformant manner.

Normative note: where a system is expected to implement a boolean status (true/false) the system can implement the status exactly as described, or, at the developers discretion, implement the inverse of that status (as a negative value), to achieve the same outcome, unless expressly stated otherwise in the requirement. A 'true' value asserts the item being represented (e.g. consent). A 'false' or 'absent' value asserts an absence of the item being represented.

This profile refers to the following concepts:

- A Subject of care (SoC or patient)
- A carer – a pre-registered person who has the same ASL rights and access as the SoC
- An agent – a pre-registered persons whom the SoC has authorised to collect supplied medicines (i.e. to receive a dispense on behalf of the SoC)

In addition to the above, this profile refers to a primary (and single) contact point (for example mobile or email). This primary contact point might be associated with the SoC, or the carer, or the agent, or somebody else. The SoC (or carer) needs to decide who the contact point will be and there is no requirement for that contact point to be the SoC or the carer. There is no pre-defined way to manage this information and it is incumbent on software developers to determine the best way to provide this functionality. Being a pre-registered carer or agent does not give them automatic access to ASL notifications.

Normative note: systems will capture a single contact point for ASL purposes, and this profile makes no implication this contact point is explicitly associated with a SoC, a carer or an agent. Software design decisions will be required to ensure the requirements are satisfied.

Some requirements relate to prescribing systems performing assisted registration. If the software system does not implement assisted registration then the requirements relating to that do not apply, noting that assisted registration is mandatory for dispensing systems to implement.

[2] Example only – does not appear in any requirement.

ASLR Assisted Registration

Reference	Requirement	Open PDS
ASLR-200	The system SHALL have the capability to receive prescription information from every conformant PDS. *Note: A patient's complete set of active prescriptions might be stored across multiple PDSs. The ASLR needs to collate and display prescriptions from multiple PDSs.*	Yes
ASLR-7	The system SHALL be able to receive registration information from a CIS, activate the ASL and register patient, carer and agent details.	Yes
ASLR-210	The system SHALL support an Assisted Registration function provided by CIS's, and only store the following SoC's information in ASLR: • IHI number • Family name • Given name (if available) • Date of birth • Gender • Medicare card number and IRN (if available) • DVA number (if available) • Residential address (optional for software to support) *Note: The above attributes align to the attributes used by the HI Service when there is a need to discover or validate an IHI.* *Note: It is important that the ASLR is populated with the same data that is in the CIS so that those systems are consistent.* *Note: See also ASLR-225 and ASLR-230 for carers and agents.*	Yes
ASLR-215	The system SHALL capture the agent/carer and SoC consent prior to storing the agent/carer's details in the SoC's ASL. *Note: The consent flag must be sent to ASLR when agent/carer's details are provided to the ASLR.*	Yes
ASLR-220	When storing an agent/carer's details, the system SHALL record whether an individual is a carer or an agent of the SoC. *Note: A 'carer' and 'agent' are different concepts and must be captured separately.*	Yes

Reference	Requirement	Open PDS
ASLR-225	The system SHALL allow at least one carer to be registered in the SoC's ASL, and only store the following carer information in the ASLR: • Family name, and • Given name (optional if the carer has only one name), and • Address (optional for the carer to provide), and • Relationship to SoC (optional for the carer to provide) And MAY capture the carer contact details for administrative purposes, including: • Telephone number, and • Email address *Note: Capturing a carer is optional but the software must support this function.* *Note: The CIS can store additional information about the carers that are not sent to the ASLR (e.g. notes for administration purposes or identity management).* *Note: If the carer has a given name then that given name must be recorded.* *Note: If the carer is an organisation (e.g. residential aged care facility) then ASLR-235 applies)* *Note: It is recommended that the system captures the above attributes as separate attributes (i.e. not as a single text field) as future architecture may require this information to be discrete and ready to be validated for identity management purposes.*	Yes

Reference	Requirement	Open PDS
ASLR-230	The system SHALL allow at least one agent to be registered in the SoC's ASL, and only store the following agent information in the ASLR: • Family name, and • Given name (optional if the agent has only one name), and • Address (optional for the agent to provide), and • Relationship to SoC (optional for the agent to provide) *Note: Capturing an agent is optional but the software must support this function.* *Note: Agents are not authorised to receive notifications from healthcare providers so capturing their electronic details is not necessary and prevents software systems sending the notification to the agent by mistake.* *Note: The system can store additional information about the agents for administration purposes or identity management.* *Note: If the agent has a given name then that given name must be recorded.*	Yes
ASLR-235	The system SHALL allow the capture of an organisation name as a carer for the SoC. *Note: It is likely that the RACF for a resident patient will, with permission, nominate themselves as a carer so they can receive electronic notifications and provide site-consent.*	Yes
ASLR-240	The system SHALL support the capture of one and only one primary contact for an ASL. *Note: The patient needs to nominate, through the assisted registration process, a primary contact point that can receive ASLR notifications.*	Yes
ASLR-250	The system SHALL support the subsequent update of the SoC, carer and agent's personal information that is registered in the ASL. *Note: The term "update" includes add, remove and modify operations.* *Note: If it is known that the SoC's IHI has changed then the ASLR operator will take steps to move prescription information from the de-activated ASL to the new ASL.*	Yes

Reference	Requirement	Open PDS
ASLR-265	Prior to completing the registration process, the system SHALL send an electronic notification (e.g. SMS or email) to the registered primary ASLR contact to confirm that they wish to register. The electronic notification SHALL include a link to the Terms & Conditions and privacy policy in the electronic notification that is sent to the registered contact. *Note: The notification intends to obtain consent from the SoC/carer for the electronic prescriptions to be accessed by the Registry Operator (and any other parties as allowed by the Registry Operator).*	Yes
ASLR-266	When the registered carer details on an ASL are changed, the system SHALL send a confirmation message containing the new details to the primary contact so the primary contact knows the details have been changed and are correct.	Yes
ASLR-267	When activating and pre-populating the ASL, the ASLR SHALL NOT display any electronic prescription information in the ASL if the electronic prescription information comes from a legacy system that doesn't allow the prescriber the option to indicate the prescription will be sent directly to a dispenser.	Yes
ASLR-270	The system SHALL receive prescription information if and only if the SoC's ASL has been activated. *Note: The ASLR must not be in possession of SoC's prescription information unless the SoC consents by activating their ASL.* *Note: Prescription information received for an ASL that is NOT activated must be discarded and not retained.*	Yes
ASLR-355	The system SHALL NOT permit the user to delete, remove or erase the primary contact details registered against an ASL. *Note: the ASLR can permit the editing/updating of primary contact information but the removal of that information is not permitted.*	Yes
ASLR-395	If the system receives a request to activate an ASL via the self-registration method (i.e. not assisted registration) then the system SHALL confirm it has the correct IHI for that person by validating or discovering that IHI via the HI Service B2B webservice and not activate the ASL if that process fails.	Yes
ASLR-416	When the primary contact details on an ASL are changed, the system SHALL attempt to send a confirmation message containing the new details to the previous primary contact.	Yes

Reference	Requirement	Open PDS
ASLR-938	The system SHALL validate digital certificates. Note: See Appendix B *Implementation Advice* for further implementation guidance.	Yes

ASLR Viewing

Reference	Requirement	Open PDS
ASLR-272	The ASLR SHALL NOT display prescription information in an ASL for prescriptions that were sent directly to a dispenser (e.g. dosing points). *Note: because there is patient consent during the activation of the ASL, the ASLR can receive prescriptions that are sent directly to a dispenser (if the architecture supports that) but are prohibited from displaying those prescriptions in the ASL.*	Yes
ASLR-273	On receipt of a new electronic prescription (i.e. not during an assisted registration event), the system SHALL NOT display any prescription information on an ASL if the prescription information comes from a legacy system that doesn't provide the SoC the option to withhold that prescription information from their ASL. *Note: This requirement applies to information pertaining to electronic and paper prescriptions.*	Yes
ASLR-275	The system SHALL provide a means for the CIS to determine if the SoC has an active ASL.	Yes
ASLR-280	The system SHALL provide a means to share a patient's ASL to a CIS if and only if: • the SoC has an Active Script List, and • the healthcare provider has site consent for the SoC's ASL.	Yes
ASLR-290	If the SoC has an Active Script List, the system MAY provide a means for the CIS to determine the name of the ASLR that the SoC is registered for. *Note: The ASLR will act like a broker for the CIS and present ASL activity and scripts to the CIS through a single point. The ASLR will search for other ASLRs as required.*	Yes

Reference	Requirement	Open PDS
ASLR-295	If the SoC has an Active Script List, the system SHALL provide a means for the CIS to determine whether the healthcare provider organisation has been given site consent to access the SoC's ASL. *Note: The ASLR will act like a broker for the CIS and present ASL site consent to the CIS through a single point.*	Yes
ASLR-305	When access to view an Active Script List is requested by a provider and that provider has no site-consent, the system SHALL send a direct communication (for example, SMS or email) to the registered primary ASLR contact requesting authorisation for the provider. This communication SHALL provide: • organisation or pharmacy or clinic name who is requesting the view access (mandatory); and • the name of healthcare provider individual (optional) *Note: The organisation or pharmacy, or clinic name that appears in the notification is intentionally open to interpretation (within reason) and is subject to software design, architecture and data availability. The intent is that the ASL primary contact can ascertain which business is making the request.* *Note: It is acceptable for this requirement to be satisfied by another system if that other system is responsible for sending electronic communications (e.g. email/SMS). This will be determined by the solution design but the need to demonstrate conformance remains.*	Yes

Reference	Requirement	Open PDS
ASLR-315	When the prescribing or dispensing system requests an Active Script List, the system SHALL provide at least the following to a CIS: For carers & agents (if applicable): • Family name, and • Given name, and • Address (optional for the carer/agent to provide), and • Relationship to SoC. For medicines: • Name of the Subject of Care • Medicine(s) name, strength; • Date prescribed; • Number of repeats available; • Indication that the token is not available (if applicable – for paper prescriptions); • Token (Barcode/QR code and DSPID) (if applicable). The system SHALL NOT provide: • Medicine(s) direction; or • Prescriber number. The system MAY provide: • Name of the prescriber; • Name of the prescriber organisation; • Contact details of the prescriber and / or prescribing organisation. *Note: The ASL intentionally contains limited information to prevent a dispense from the ASL. Dispensers are required to download the full legal prescription before dispensing.*	Yes
ASLR-320	The system SHALL NOT make available any prescription information for prescriptions that are expired, cancelled, disabled, hidden or when the patient has exercised their choice to keep the information away from their ASL.	Yes

Reference	Requirement	Open PDS
ASLR-340	The ASLR SHALL indicate to systems downloading the ASL which line item is being shared without a token. *Note: The prescription meta-data will contain information that will enable systems to determine if the prescription has a token available for dispensing.*	Yes

ASLR Prescribing and Dispensing

Reference	Requirement	Open PDS
ASLR-342	The system SHALL NOT accept electronic prescription information about electronic prescriptions from non-conformant systems. *Note: Every communication received by the ASLR about electronic prescriptions must contain a conformance ID and the ASLR must verify that conformance ID is active. This may be done by comparing the conformance ID against an internal white list of active conformance ID's.* *Note: The ASLR can accept prescription information about paper prescriptions from non-conformant systems. These systems won't have a conformance ID and the ASLR can still accept those communications.*	Yes
ASLR-343	The system SHALL NOT provide prescription information to non-conformant systems. *Note: Every communication received by the system must contain a conformance ID and the system must verify that conformance ID is active. This may be done by comparing the conformance ID against an internal white list of active conformance ID's.*	Yes

ASLR Audit Log

Reference	Requirement	Open PDS
ASLR-405	The system SHALL provide a mechanism to present the audit log to review access events against an Active Script List. *Note: This functionality might eventually be available to a SoC through a mobile application or other user interface.*	Yes
ASLR-410	The system SHALL record the date and time (including time zone) of the registration and deregistration of an ASLR, and the provided consent from the SoC in the audit log.	Yes
ASLR-415	The system SHALL maintain a record of carers that the SoC has authorised to view their ASL.	Yes

3.5 Requirements for Mobile Intermediaries and Mobile applications

These requirements apply to mobile applications (MA) and mobile intermediaries (MI) participating in the EP mobile channel. Some requirements are conditional and only apply if the software meets that condition.

Common requirements for all Mobile Intermediaries and Mobile Applications

Reference	Requirement
MC-16	The system SHALL support approved authentication methods of connection requests between mobile implementations (regardless of device or platform), intermediaries, PDS's, ASLR's and CIS's.
MC-615	If the system supports the creation of a profile or user account (or similar) then the system SHALL allow the user to de-activate that account. The de-activation process SHALL provide the user the option to remove all personal and prescription items held by the system and associated systems. The de-activate process SHOULD warn the user that their personal and prescription items will be removed (if that is applicable) at the completion of the de-activation process. *Note: the system can retain local stored digital passport or digital identity files/tokens/settings etc in case it becomes important at a later date (e.g the system is re-installed).* *Note: also see MA-585 for mobile apps.*
MC-545	The system SHALL provide a valid conformance ID when requesting information. *Note: non-conformant systems are not permitted to engage PDS's and ASLR's.*

3.6 Requirements for Mobile Applications

These requirements apply to mobile applications noting that, depending on the architecture and solution design, the requirements may be satisfied by a mobile intermediary system (e.g. a cloud-based service or mobile gateway) on behalf of the mobile application. Regardless of the architecture, the intent and objective of the requirement needs to be satisfied when under test conditions.

Common requirements for all Mobile Applications

The following requirements describe how personal information and prescription items are to be managed in the mobile device. These requirements apply to mobile apps (and web pages) connecting to a mobile intermediary or sourcing information from a PDS/ASLR.

Reference	Requirement
MA-500	If the system collects personal information regardless of the source of that information, then the system SHALL: • Display or provide a means to read the privacy statement used by the system • Ensure the SoC takes some action to consent (i.e. tick a box or press a button or some other action that indicates consent) The privacy statement SHALL disclose how the personal information will be used. The system SHALL NOT collect, store or share personal information until the SoC has actively provided consent. *Note: demographic data, contact information and prescription information is considered personal information.* *Note: sources for personal information includes, but is not limited to:* • *A paper or electronic EoP* • *A CIS* • *A PDS* • *Manual data entry* *Note: the privacy statement must be sufficient to satisfy the Privacy Act 1988.*
MA-505	The system SHALL NOT intentionally manipulate the device, operating system or other software settings in such a way that the system becomes the default system for the discovery and management of electronic prescribing tokens without user knowledge. The system MAY provide options or settings within the device, operating system or software settings that enable the system to become the default system when discovering or managing electronic prescribing tokens. *Note: systems are not to 'take over' a device in such a way that the system automatically becomes the default device for electronic prescribing. EP systems must be designed to co-exist with other EP systems so that patient choice and preferences are maintained.*
MA-510	The system SHALL provide application level security that requires the SoC to enter a password, PIN, biometric input or similar before the system provides any functionality to the SoC. *Note: app level security is applicable once per session and is in addition to device level security. This prevents the abuse of tokens if the mobile device is lost or stolen.* *Note: the definition of 'session' used by this document is described in the glossary.*
MA-513	The system SHALL enforce the user to satisfy application level security (see MA-510) when the system detects system inactivity for 15 minutes or more. *Note: if the app hasn't been used for 15 minutes or more then the app must present the password/PIN etc to the user before the app becomes activated.*
MA-515	The system SHALL include the system's device ID in every request for prescription information. *Note: a device ID might be a MAC address or some hardware identifier (e.g. IMEI number). Providing a device ID empowers systems to identify and block nefarious end-points suspected of exploiting the EP infrastructure (e.g. unusual patterns of web service requests that align with known patterns of abuse etc).*

Reference	Requirement
MA-520	The system MAY receive and store a token from the following sources: • A PDS • A CIS • An SMS/email (or hyperlink) • Paper (e.g. a printed EoP) • Manual entry by a user (i.e. user enters a DSPID) • An ASLR • Some other source *Note: See MA-525 about sources of information for prescription information.*
MA-525	The system MAY receive and store prescription information from the following sources: • A PDS • A CIS • An SMS/email (or hyperlink) • An ASLR • Some other source, subject to MA-530.
MA-530	The system SHALL NOT receive prescription information by scanning paper sources (i.e. a printed EoP) and determining prescription information via OCR or similar. *Note: OCR scanning of a printed EoP is unreliable and not trusted. The mobile device can retrieve prescription information from a PDS or ASLR (via scanning a token) but trying to determine medicine information from a printed EoP is not permitted.* *Note: the token (DSPID) CAN be determined by scanning a printed EoP. See MA-520 and MA-535.*
MA-535	If the system stores tokens sourced from a paper EoP (i.e. scans QR codes or consumes paper EoP's by any method), the system SHALL provide instructions to the SoC to keep their EoP in a secure location or to destroy the EoP when discarding it. This instruction SHALL appear either: a) Each time the system is activated or launched (i.e. after successful login); or b) After each successful scan of a token into the system. *Note: the SoC might import a token into the system and then discard or fail to protect the paper token without understanding the paper token could still be acquired and dispensed without the SoC's knowledge.* *Note: The SoC needs to acknowledge the instruction by clicking a button, closing a window, swiping on the device etc and will persist until it is dismissed by the user. The instruction does NOT need to interrupt the system or prevent the system from functioning. The instruction may be incorporated into other screens or functions that also require an action from the SoC (e.g. can be displayed on a log in screen).*

Reference	Requirement
MA-14	The system SHALL ensure locally stored electronic prescription information is read only. *Note: Any information retrieved from a source system (e.g. a PDS), including the barcode itself, needs to be read only to ensure the mobile app reflects that source system.* *Note: user-provided information augmenting the prescription information is not bound by this requirement. See MA-550 for more information.*
MA-550	The system MAY allow the user to augment prescription information with the user's own notes or medical information if the user chooses to do so. *Note: the user may wish to add notes against an item, via manual entry or other means, that assists them in the management of their prescription information. For example, they may wish to add clinical indications; notes provided by the prescriber; brand/generic names etc.*
MA-12	The system MAY provide indication to the user if it detects the PDS/ASLR/MI (as appropriate) is unreachable or unavailable. *Note: if the system relies on a mobile intermediary and that is unavailable then the PDS/ASLR is also unavailable.*
MA-555	The system SHALL permit the user to select and view prescription information and tokens for every token stored by the system. The tokens SHALL be rendered as QR codes. *Note: the app must be able to view stored prescription information and tokens for management and dispensing purposes.* *Note: an app fetching an ASL from an ASLR is storing tokens – even if briefly and only for the purposes of rendering the ASL to the user.*
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-560	If the system supports notifications (via email/SMS/phone alert etc) when the system discovers a prescription has been dispensed, cancelled or has expired then the system SHALL provide the SoC the option to turn off those notifications. *Note: the cancellation of a prescription is initiated by the prescriber or dispenser. The user should have the option to be informed of this event so they proactively manage their prescriptions but need to be able to disable that option.*
MA-562	If the system sends notifications (see MA-560) then the system SHOULD NOT send those notifications exclusively to the same mobile device (e.g. the notification should be able to be sent via email or other electronic address). *Note: allowing the SoC the option of being notified about each dispense via a channel that is not the same mobile device presents an opportunity for the SoC to detect abuse, especially if a phone containing tokens is lost or stolen.* *Note: this requirement implies a robust means of collecting and verifying an electronic address should be designed into the solution.*

Reference	Requirement
MA-575	The system SHALL allow an item to be transmitted to an electronic address via email, SMS, or other 3rd party channel. The mechanism used to do this (e.g. email/SMS) SHALL be initiated or launched by the system and not rely on native device functions. *Note: For example, if the system is designed to use SMS then the system must create/start a SMS message with prescription information provided in that SMS message.* *Note: the SoC might want to send an item to a carer, agent, dispenser or someone else for the purposes of managing or dispensing a prescription.* *Note: acceptable mechanisms are SMS, email or other non-proprietary mechanism.* *Note: there is no implication that that token must be removed from the first device. The token can co-exist on multiple devices.* *Note: transfer via proprietary channels is permitted in addition to this requirement.*
MA-577	When transmitting an item to another electronic address (e.g. another device or email address), the system SHALL transmit the following information, and only the following information: • The electronic token or original URI (e.g. URL) provided that links to the electronic token; • The initials of the Name of the Subject of Care; and • Medicine name. *Note: this safeguards patient privacy if the item is transferred to an incorrect address. The receipt, after receiving the transmission, can retrieve more information from the PDS as required.*
MA-580	The system MAY display historical information for prescriptions that are no longer active. This historical information SHALL clearly indicate the item is not active, and it SHALL NOT contain a token (i.e. barcode). *Note: systems may, for user convenience or to assist in medication management, display historical prescribing information to the user. The system must be clear that that information is historical, does not constitute legal prescriptions and those items are not available for dispense.*
MA-585	When the system is uninstalled or removed from the mobile device, the system SHOULD warn the SoC that locally stored and active tokens need to be transferred, backed up or dispensed prior to uninstalling the system and to provide the option to abort the uninstalling process until those tokens are preserved. *Note: device settings, operating systems and technologies can make this requirement technically difficult to satisfy. Vendors should make best efforts to ensure tokens are not lost when their software is uninstalled by the SoC.* *Note: also see MC-615.*

Reference	Requirement
MA-590	The system SHALL query the status of locally stored tokens: • By user-request; and/or • Automatically at the start of each session (or more frequently). *Note: the system will need to routinely or on request (design decision) check the validity of tokens to ensure they have not been cancelled, expired or dispensed.* *Note: if the system does not support a 'refresh on user request' option then an automatic refresh at the start of the session is required.* *Note: the definition of 'session' used by this document is described in the glossary.*
MA-595	The system SHALL clearly indicate items that have expired, been disabled, been cancelled or dispensed. *Note: legal prescriptions have an expiry date and can't be dispensed beyond that date. The user needs to be able to see if a prescription has expired.* *Note: expired items are not to be automatically removed from the app or local device. See MA-570.*
MA-600	The system MAY provide a notification to the user when the system discovers a prescription has expired or is about to expire. *Note: the notification might be via the mobile device (i.e. phone notification), SMS, email, or some other method (design decision).*
MA-606	The system SHOULD apply the principles of WCAG level AA. *Note: WCAG v2.1 level AA is the recommended minimum when designing webpages. Mobile app users can apply many WCAG principles despite the app not being, or using, webpages.*
MA-607	If the system stores or presents ETP information then the system SHALL present ETP information in a way that is visually different to EP's and the system will provide information, via on-screen text, a help screen, a link to a web page or similar, that explains that ETP information that appears in the system requires the paper prescription when dispensing.
MA-608	The system SHALL validate input fields to ensure they are of the correct data type before submitting that data to a PDS or ASLR. *Note: the system needs to ensure date fields contain dates, integer fields contain integers etc to protect infrastructure from unnecessary traffic and potential malicious activity.*

Mobile Application Connected to a PDS (via a mobile intermediary)

If the mobile application connects to a PDS via a mobile intermediary:

Reference	Requirement
MA-565	The system SHALL permit the user to permanently delete individual items from the local system at the user's discretion. *Note: a user must be able to remove items from the local system if those items have expired or they have no intention to have dispensed.* *Note: the term "item" refers to the prescription information and the token.*
MA-570	The system SHALL NOT automatically remove from the local system, without user intervention, a prescription item that has been dispensed, cancelled or expired (e.g. "Confirm removing this cancelled prescription (yes/no)?" *Note: the prescription item must not be silently removed from the system without intentional action or confirmation from the user.* *Note: a phone notification, SMS or email that does NOT require an action and can be ignored/deleted is NOT considered "user intervention".*

Mobile Application Connected to ASLR (via a mobile intermediary)

If the mobile application connects to a ASLR via a mobile intermediary:

Reference	Requirement
MA-8	If the system permits self-registration via a mobile device, that system SHALL validate the SoC's identity via an Agency approved Identity Management Service.
MA-9	The system SHALL present prescription information as provided by the prescription author and not present prescription information that has been translated, mapped or substituted with other data sources or information. *Note: AMT or PBS code mapping or translations are not to be presented to the user. The medicine that was provided by the prescription author needs to be displayed at the point of rendering/displaying.* *Note: This requirement is compatible with "active ingredient prescription" legislation which allows a medicine name (not active ingredient) to be prescribed under some conditions.*
MA-620	If the system permits the user to de-activate their ASL then the system SHALL display a prompt that needs to be actively acknowledged and that prompt will state that prescriptions will become unavailable to the SoC and HCPs unless the SoC has access to the original EoP and prescription data sourced from the Active Script List will be deleted and can't be restored. *Note: De-activating an ASL makes all tokens stored in the ASL inaccessible.*

MA-630	The system SHALL provide a means for the user to hide and unhide prescription items that are in the ASL and active. *Note: hiding an item in the ASL prevents healthcare providers from seeing that item in the ASL. The user will need to make a copy of the token, or ensure their mobile device is available, if they wish to have that hidden item dispensed, or, unhide those items before dispense.* *Note: the system will need to allow the user to view hidden items in the system so those items can be selected by the user and 'unhidden' should they choose to.*
MA-635	When the system is about to hide an item in the ASL (see MA-630) the system SHALL display a prompt that needs to be actively acknowledged and that prompt will state that hiding an item prevents healthcare providers from seeing that item and the user will need to keep a copy of the token either in the app or a copy stored elsewhere if they wish to have that hidden item dispensed.
MA-640	When the system is about to unhide an item in the ASL then the system SHALL warn the user that unhiding the item will permit other healthcare providers to see that item.
MA-645	The system SHALL NOT permit the user to delete, remove or erase the primary contact details registered against an ASL. *Note: the app can permit the editing/updating of primary contact information but the removal of that information is not permitted.*
MA-650	When displaying an active script list, the system SHALL display every item in the Active Script List. Note: the mobile application needs to show every ASL item – including hidden items – so the SoC can see and manage those items or have them dispensed. *Note: providers won't be able to see hidden items in the CIS but the consumer can see those via a mobile app.* *Note: the system is not permitted to filter, or arbitrarily hide prescription that are on the active script list.* *Note: "display every item" does not mean display every possible attribute and meta-data. It means that prescriptions can not be selectively suppressed.*

Security requirements for Mobile Application Systems

Reference	Requirement
MA-16	For software running on a mobile device, the system SHALL support authentication of connection requests using a unique identifier tied to the mobile device hardware. *Note: See Appendix B implementation advice.*
MA-960	The system MAY offer single-factor authentication for users.
MA-944	The app SHALL NOT use PINs as the sole method of the initial authentication such as when the user first uses the application on the device.
MA-946	The system SHALL automatically log off an account or require re-authentication after a period of inactivity. The inactivity period SHOULD NOT be longer than 15 minutes.

Reference	Requirement
MA-965	If the user has authenticated into the application and reopens or resumes the application after it has been closed, placed in the background or paused the app SHALL: • Confirm the phone has device level authentication enabled; or • Use the operating system level passcode or password; or • Reauthenticate the user using at least one of the following: o Pin; o Password; o One-time SMS codes; o One-time password applications; o Universal 2nd Factor security keys; o physical one-time password tokens; o biometrics (such as finger print or face identification); or o smartcards. • Or both. *Note: to reduce the likelihood of patient data being exposed by a lost or stolen phone the app must ensure the device requires a pin, password or biometric authentication to unlock or require the user to reauthenticate.*
MA-942	The system SHALL enforce a strong password where a password is used. At a minimum the password: • must contain at least seven characters • must contain at least one letter • must contain at least one number • must not be the same as one of your last four passwords • must not use the same character repeatedly or have any sequential characters (for example, AAAA or 1234) • may contain any of the following characters: ! @ # $ % ^ & * *Note: The password complexity rules above reflect the minimum requirement for apps. It is strongly recommended that stronger passwords should be supported where possible (so that users may select longer/more complex passwords if they wish).*
MA-931	If the system stores passwords it SHALL ensure that the passwords are stored securely in line with ISM Security Control 1252. This is to be done by: • not storing passwords as plain text; • passwords stored using an ASD approved cryptographic hash and password salt.

Reference	Requirement
MA-943	The app SHALL enforce a strong PIN where a PIN code is used. Either by: 1. Using the device level pin provided by the operating system; or 2. Implementing a Pin within the application which at a minimum: • contains a minimum of four digits; • contains non-consecutive digits; and • contains no more than two repeated digits. *Note: The PIN complexity rules above reflect the minimum requirement for apps. It is strongly recommended that stronger PINs should be supported where possible (so that users may select longer/more complex PINs if they wish).* *Note: where usability challenges arise associated with a long and complex PIN code, alternative solutions are also supported (such as strong passwords or biometric authentication).*
MA-937	The system SHOULD check users' credentials with a known breached credentials service to ensure the credentials haven't been used in a previous data breach. *Note: a known breached credentials service is a service which provides either an API to check if a password has been included in a known data breach or a list of all known passwords included in known data breaches.*

3.7 Requirements for Mobile Intermediary

These requirements apply to mobile intermediary systems connected to a PDS.

Authentication and authorisation

Reference	Requirement
MI-610	The system SHALL NOT provide prescription information to non-conformant systems. *Note: Every communication received by the system must contain a conformance ID and the system must verify that conformance ID is active. This may be done by comparing the conformance ID against an internal white list of active conformance ID's.*

Common requirements for all Mobile Intermediaries

The following requirements describe how personal information and prescription items are to be managed in the mobile device.

Reference	Requirement
MI-10	The system SHALL maintain audit logs associated with electronic prescription retrieval events in accordance with relevant legislation and regulation. *Note: For example, current NSW regulations require prescription details to be retained for at least two years.*

Reference	Requirement
MI-10A	The system SHALL, on request, generate a file or files that contain the information captured in the audit logs in human readable format. *Note: this requirement permits the generation of a file or files that can be shared or sent to relevant regulatory bodies on request. "Human readable formats" include text files, PDF files, log files or any other format that presents the required information "in the clear".*
MI-9	The system SHALL NOT change or manipulate the content (metadata or encrypted payload) of any message.
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*.
MI-8	The mobile intermediary (or operator) SHALL NOT access the encrypted payload of any message without explicit patient consent. *Note: In this scenario, "consent" may be from the patient. 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.*
MI-13	The system SHALL NOT aggregate data across SoCs or provide data to any entity for secondary use unless explicit consent from the SoC has been obtained.

Mobile Intermediaries connected directly to a PDS

If the system connects directly to a PDS:

Reference	Requirement
MI-540	The system SHALL be able to submit a DSPID when requesting information from a PDS then retrieve and store that information or retrieve and pass-through that information. *Note: the system might consume tokens/DSPID's from one source (e.g. a client app) and then use that to fetch prescription information from a PDS.*
MI-2	For systems that connect to a PDS, 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.*
MI-5	Where the system receives information about an electronic prescription from a Prescription Delivery Service the system SHALL warrant that the privacy controls of the originating PDS are maintained during the delivery process to the requesting application and subsequently.

Security requirements for Mobile intermediaries

Reference	Requirement
MI-11	If the service operates as a Commonwealth Government Service, the system SHALL put in place necessary controls for managing "Unclassified" data with a Dissemination Limiting Marker of "Sensitive: Personal".
MI-12	The system SHALL include, in all connection requests from mobile devices, 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.*
MI-939	The system SHOULD encrypt information assets at rest using an Australian Signals Directorate (ASD) approved cryptographic algorithms.

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
ASL	Active Script List
ASLR	Active Script List Registry
CIS	Clinical Information System
CRL	Certificate Revocation List
CWE	Common Weakness Enumeration
DLM	Dissemination Limiting Marker
DoB	Date of Birth
DSPID	Delivery Service Prescription Identifier
eNRMC	electronic National Residential Medication Chart
eMM	Electronic Medication Management
EP	Electronic Prescribing
ETP	Electronic Transfer of Prescriptions
HCP	Healthcare provider
HI Service	Healthcare Identifiers Service operated by Services Australia
HPN	Hospital Provider Number
HPI-I	Healthcare Provider Identifier - Individual
HPI-O	Healthcare Provider Identifier - Organisation
HTTPS	Hyper Text Transfer Protocol Secure
IHI	Individual Healthcare Identifier
IMEI	International Mobile Equipment Identity
ISM	Information Security Manual
MI	Mobile intermediary

Acronym	Description
MHR	My Health Record
MMS	Multimedia Messaging Service
NCTS	National Clinical Terminology Service
NSW	New South Wales
NRMC	National Residential Medication Chart (paper)
OAuth	Open Authorisation
OCR	Optical Character Recognition
OCSP	Online Certificate Status Protocol
OWASP	Open Web Application Security Project
PBS	Pharmaceutical Benefits Scheme
PBS HMC	PBS Hospital Medication Chart (paper)
PDS	Prescription Delivery Service
PKI	Public Key Infrastructure
PRODA	Provider Digital Access
RACFID	Residential Aged Care Facility ID
RPBS	Repatriation Pharmaceutical Benefits Scheme
RSA	An asymmetric cryptosystem invented by Ron Rivest, Adi Shamir and Leonard Adleman
RTPM	Real Time Prescription Monitoring
SaaS	Software as a Service
SIEM	Security Information and Event Management
SoC	Subject of Care (patient or consumer)
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
WAN	Wide Area Network

5 Glossary

Term	Meaning
Agent	A person that acts on behalf of the Subject of Care to collect prescriptions and may be the primary contact for their Active Script List.
Asset	Anything of value, such as ICT equipment, software or information.
ASL Consent Indicator	A Y/N value to indicate whether the Subject of Care has consented for this electronic prescription to be loaded to their Active Script List (ASL).
ASLR Identifier	A value that identifies which Active Script List Register the Subject of Care is registered with.
Australian Government Services	A service provided by the Australian Government
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.
Authority code	Number or code representing any required authority approval from the Services Australia or the Department of Veterans' Affairs for restricted items that require electronic, phone or written authority approval. See also: http://www.pbs.gov.au/info/healthpro/explanatory-notes/section1/Section_1_2_Explanatory_Notes#Authority-PBS
Conformance	A measurement (by testing) of the adherence of an implementation to a specification or standard.
Conformance ID	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. See also: originalRepositorySoftUniqueID, RepositorySoftUniqueID, Prescription Software Conformance ID
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.
Cryptographic Hash	An algorithm (the hash function) which takes as input a string of any length (the message) and generates a fixed length string (the message digest or fingerprint) as output. The algorithm is designed to make it computationally infeasible to find any input which maps to a given digest, or to find two different messages that map to the same digest. https://www.cyber.gov.au/acsc/view-all-content/glossary/c
Cryptographic Salt	A salt is a unique, randomly generated string that is added to each password as part of the hashing process. As the salt is unique for every user, an attacker has to crack hashes one at a time using the respective salt rather than calculating a hash once and comparing it against every stored hash." – OAWSP https://cheatsheetseries.owasp.org/cheatsheets/Password_Storage_Cheat_Sheet.html#:~:text=A%20salt%20is%20a%20unique,it%20against%20every%20stored%20hash.

Term	Meaning
Delivery Service Prescription Identifier (DSPID)	Identifies the particular electronic prescription within the delivery service infrastructure. This identifier may change through the prescription lifecycle (e.g. one that points to original, one that points to repeat authorisation). The Delivery Service Prescription Identifier is allocated managed by the Prescription Delivery Service (and may be referred to as a SCID).
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.
Dispensing Software Conformance ID	The conformance identifier of a software system used to create an electronic dispense record based on an electronic prescription.
Drug	A drug is any substance (with the exception of food and water) which, when taken into the body, alters the body's function either physically and/or psychologically. PBS prescriptions are written for a drug and not for a medicine.
Electronic prescribing	The process by which a prescription is electronically generated by a prescriber, and 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: This definition does not preclude the use of paper processes to support electronic prescribing activity. Repeat 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	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 Services Australia for claiming purposes. Note: This definition does not preclude the use of other processes or artefacts to support e-Prescribing.
Electronic prescription metadata	Each electronic prescription record and dispense record has two sections: • Clinical content - the body of the record containing personal and sensitive information, which remains encrypted within the Open PDS. • Metadata - that is not encrypted within the Open PDS to support the technical operation of the system Together the clinical content and the metadata comprise the Electronic Prescription. The requirements for the prescription metadata are described in Section 8.1 of the Solution Architecture.

Term	Meaning
Electronic transfer of prescription (ETP)	The process whereby prescribing systems pass an electronic representation of a paper prescription to a prescription delivery service (PDS), which is available for download by dispensing systems in support of dispensing a paper prescription.
Evidence of Prescription	Provided to the Subject of Care as evidence that an electronic prescription was created for that subject of care. It will contain a token (QR code or URI) to discover and retrieve the electronic prescription. Charts contain tokens (or URI's) but do not contain EoP's. 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.
Globally Unique Prescription Identifier	A unique identifier that is retained for the life of a prescription and all repeats. This is the number that PBS requires. This value is the consistent thread that binds together an original electronic prescription and its subsequent dispense records / repeat authorisations for the life of the prescriber's order. It is generated at the time of prescription creation and referenced in a dispense notification. This same ID follows through the lifecycle of the electronic prescription. Note: this may be a GUID/UID but need not be.
Hash	See 'Cryptographic Hash'.
Hospital Provider Number (HPN)	Administered by Services Australia
International Mobile Equipment Identity	A number, usually unique, to identify mobile phones. See also: https://en.wikipedia.org/wiki/International_Mobile_Equipment_Identity
Information Asset	An identifiable collection of data stored in any manner and recognised as having value for the purpose of enabling an agency to perform its business functions thereby satisfying a recognised agency requirement."
Item	Prescription information AND a token. This also applies to repeat authorisations.
MAY	When appearing in a conformance requirement, the verb MAY indicates an optional requirement.
Metadata	Metadata is often called 'data about data'. Where data can be defined as a representation of facts, concepts or instructions, metadata can be defined as information about how data are defined, structured and represented. It can provide meaning and context to data by describing how data is captured and the business rules for collecting data. It can also assist in the interpretation of data. https://meteor.aihw.gov.au/content/index.phtml/itemId/268284
Medicine	A substance you take to treat an illness, treatment and prevention of illnesses and injuries. PBS prescriptions are written for a drug and not a medicine.
Mobile Application	An application that provides a user the ability to manage electronic prescriptions via a personal device.

Term	Meaning
Mobile Intermediary	Software used by mobile applications to interact with the electronic prescribing process.
National Clinical Terminology Service (NCTS)	Responsible for managing, developing and distributing national clinical terminologies and related tools and services to support the digital health requirements including being the Australian National Release Centre for SNOMED CT® on behalf of SNOMED International. https://www.healthterminologies.gov.au/
originalRepositorySoftUniqueID	The conformance identifier of the PDS to which the original electronic prescription is loaded from the prescribing system. See also: RepositorySoftUniqueID
Paper prescription	A printed prescription that has been physically signed by a prescriber
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 supplier for preparing and dispensing a drug [Oxford Medical Dictionary] [HIM].
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.
Prescription Software Conformance ID	The conformance identifier of a software system used to create an electronic prescription.
Public network	a type of network wherein anyone, namely the general public, has access and through it can connect to other networks or the Internet.
Registry Operator	An organisation that operates an Active Script List Register.
RepositorySoftUniqueID	The conformance identifier of the PDS from which the electronic prescription is downloaded for dispensing. See also: originalRepositorySoftUniqueID
Residential Aged Care Facility ID (RACFID)	Residential aged care facility identification number, also known as the Residential Aged Care Service ID (RACSId). Required for use of the National Residential Medication Chart (NRMC) and will be available from the facility.
Salt	See 'cryptographic salt'
Session	A session begins when a user successfully provides a password/PIN etc to the application and ends when the application exits through user action or through application timeout based on a period of inactivity. (see MA-513)
SHALL	When appearing in a conformance requirement, this verb SHALL indicates a mandatory requirement. Its negative form SHALL NOT indicates a prohibition.

Term	Meaning
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.
Site consent	The SoC provides consent for a site to view the SoC's ASL. The site might be a pharmacy, clinic, franchise or other organisation that would benefit from viewing the ASL.
Subject of Care	The Subject of Care is the person for whom the medicines described on the prescription are intended.
Token	An electronic prescription Token refers to a representation of the DSPID (in the form of a barcode, QR code or alphanumeric string. A Token may or may not be provided with other prescription information.

Appendix A Example printed Evidence of Prescription

The below diagram is an example presentation of an electronic prescription printed 'Evidence of Prescription'.

Summary[+] of electronic prescription for **John Citizen**

Lipitor 20mg

Details	
Prescribed Date	dd/mm/yyyy
Repeats Authorised	#

[+]This is an electronic prescription token only. The legal prescription must be downloaded for dispensing.

Privacy Notice: Lorem ipsum dolor sit amet, consectetur adipiscing elit. Pellentesque et lectus non risus cursus congue malesuada ut dolor. Sed bibendum venenatis nulla at bibendum. Phasellus vitae consectetur mi. Duis viverra mauris ut vulputate efficitur. Suspendisse fermentum ante ligula, sed dictum lectus tristique sit amet. Quisque metus nunc, ultricies maximus mollis nec, pellentesque quis magna. Nunc sed tempus justo. Integer sapien neque, tempus nec ipsum nec, hendrerit dignissim nunc. Praesent id est augue. Curabitur blandit eleifend dui.

Dr Firstname Lastname
Practice Name
Address line 1
Address line 2
Suburb State Postcode
Phone: ## #### ####

153K4 J1A204 8CD472

NOT TO BE SIGNED

Appendix B Implementation Advice

Breached Password Services	Services exist that allow for the checking of passwords and whether they have been used within a security breach. These services differ from just password checking as they do not just use an algorithm; they use a database of known breach information. These services are highly effective at reducing compromises to systems that only use single factor for authentication such as username/id and password. However, should be used in conjunction with other controls such as Multifactor Authentication mechanisms since breached lists are only updated when the breached lists are discovered by the Breach Password Services operators. Several industries perform this check on their customer accounts on registration and credential change as a good control against password spray and other security attacks. Some useful guidance links include: • https://www.cyber.gov.au/acsc/view-all-content/advisories/2019-130-password-spray-attacks-detection-and-mitigation-strategies • https://www.cyber.gov.au/acsc/view-all-content/publications/creating-strong-passphrases ○ *One way to check your credentials is by going to 'Have I Been Pwned'.* The breach service mentioned by ACSC "Have I Been Pwned" (HIBP) has an API for cloud use or a method for offline use that requires manual syncing to the resource. A risk-based approach should be used as for how often an organisation should update their breached password list if they choose the offline method of use. API: https://haveibeenpwned.com/API/v3 Password Lists: https://haveibeenpwned.com/Passwords **Note:** There may be other services that can be used this is referenced here due to being mentioned by Australian Cyber Security Centre.
Security awareness and support materials	These security awareness and support materials should cover topics such as: • device security (e.g. how to enable the locking/unlocking mechanism and configure a PIN, password, or fingerprint) • password security (e.g. password complexity and confidentiality) • system security (e.g. use of up-to-date web browser and operating system software, potential issues with "jailbroken" devices) • special considerations for using apps and mobile devices in public settings (e.g. "shoulder surfing") • availability of further information through the Stay Smart Online • the ability to revoke access if a mobile device is lost • procedures for reporting suspected security incidents to the developer. The intent of this material is to promote the consumer's awareness of potential risks in relation to electronic prescribing, and the reasonable actions that can be taken to reduce their risk exposure. The following resources are worth consideration:

	*Australian Digital Health Agency, Security practices and policies checklist (*https://www.myhealthrecord.gov.au/for-healthcare-professionals/howtos/security-practices-and-policies-checklist) Australian Cyber Security Centre *(*https://www.cyber.gov.au/) Get smarter with passwords (https://www.cyber.gov.au/acsc/view-all-content/news/get-smarter-passwords).
Certificate validation	Certificate validation should be done by: • ensuring the certificate has not been revoked. This is may be done by using a Certificate Revocation List (CRL), Online Certificate Status Protocol (OCSP) or other method; • checking the certificate was valid and had not expired when the transaction took place; and • the certificate is from a valid Certificate Authority. Certificate pinning should be considered. Which is where, for specific web addresses a certificate is 'pinned' so that only certificates from a specific Certificate Authority are accepted. *Note: Where the network operation to access the CRL or OCSP fails, the certificate validation should not fail as a result.*
Digital Identity	Federal Government has a digital identity framework including accreditation across four roles please see https://www.dta.gov.au/our-projects/digital-identity/trusted-digital-identity-framework for more information. The Agency is investigating the suitability of one or more of these frameworks for electronic prescribing.

General Cyber Security Support Materials for Software Developers	For Advice on Cyber Security For software developers, developers are advised to:
	• Adopt the *Information Security Manual Guidelines for Software Development*;
	• observe platform-specific secure coding guidelines, such as:
	  ○ The iOS and macOS *Secure Coding Guide;*
	  ○ Android Developer *Security tips*;
	  ○ Microsoft .net *Secure coding guidelines*; and
	• implement the mitigation strategies specified in relation to the common risks such as:
	  ○ The Open Web Application Security Project (OWASP) Top 10;
	  ○ The *OWASP Mobile Top 10;* and
	  ○ The *Common Weakness Enumeration Top 25;*
	• complete testing to verify the effectiveness of security controls implemented within their app and associated infrastructure. Using such resources as:
	  ○ The *OWASP based Web Application Security Testing Checklist* should be used for guidance; and
	  ○ The *NIST Mitigating the Risk of Software Vulnerabilities*.
	Unique Hardware Device ID is primarily used for an antifraud control.
	Apple Unique Hardware Device ID:
	• Apple iOS up to 10.3 beta can use Keychain Storage.

	• Apple iOS 11 onwards use DeviceCheck API https://developer.apple.com/documentation/devicecheck Android Unique Hardware Device ID: • *Use APIs that are appropriate for your use case to minimize privacy risk. Use the DRM API for high-value content protection and the SafetyNet APIs for abuse protection. The SafetyNet APIs are the easiest way to determine whether a device is genuine without incurring privacy risk. https://developer.android.com/training/articles/user-data-ids* **NOTE:** The mitigation strategies and coding guidelines above reflect the minimum recommendation for apps interfacing with systems. However, it is strongly recommended that developers should also verify the security of their apps (and associated infrastructure) using penetration testing performed by independent security consultants.

References

[ACSQHC2017] *National Guidelines for on-screen display of Medicines Information*, Australian Commission on Safety and Quality in Healthcare, December 2017

[AGENCY2019] *Electronic Prescribing Solution Architecture,* v2.0, Australian Digital Health Agency, October 2019

[AGENCY2020] *Use of Healthcare Identifiers in Health Software Systems Software Conformance Profile, v4.0,* Australian Digital Health Agency*, 3 November 2020*