

Electronic Prescribing Participating Software Conformance Profile

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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 ETP.

1.2 Intended audience

The intended audience includes the following organisations:

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

2 Scope

- Systems able to participate in electronic prescribing may include prescribing systems, 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 Service
- The Active Script List Registry Services

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.

This profile intentionally removes conformance requirements (by using strike-through) that are not applicable to this version of the conformance profile. Some conformance requirements in this document contain strike-through to indicate that software is not expected to satisfy that requirement. Those requirements, or similar, will be re-introduced at a later date.

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.

3.1 Prescribing Systems

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

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

Authentication and authorisation

Reference	Requirement	Open PDS	Direct PDS
PRES-5	Where only single factor or multi-stage authentication is provided, the system SHALL allow healthcare organisations the ability to establish authentication parameters. Including, but not limited to:	Yes	Yes
	Minimum password length;		
	Password composition;		
	 Password retry limit (before lockout); 		
	 Password refresh interval (frequency with which new password must be created); and 		
	 Password reuse interval (period which must expire before a password may be reused). 		
	Note: Healthcare organisations shall have the support of the system in the implementation of access control policies.		
PRES-6	The system SHALL automatically log off an account, or require re-authentication, after a period of inactivity defined by the healthcare organisation.	Yes	Yes
	The default inactivity period SHOULD NOT be longer than 10 minutes.		
	Note: Healthcare organisations shall be able to define a period of inactivity after which the prescriber's terminal may be considered unattended and vulnerable to misuse.		
PRES-7	The system SHALL require the user to re- authenticate prior to submitting a Schedule 8 medicine.	Yes	Yes
	Note: Prescriptions for Controlled Drugs warrant additional measures to ensure that the prescription is being created by an authorised prescriber.		
PRES-8	The system MAY automatically disable an account that has been inactive for a period defined by the healthcare organisation.	Yes	Yes
	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.		

Reference	Requirement	Open PDS	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 thos products need to be operating when transacting with a PDS.		Yes
	If one or more of those products is not operating then th system SHALL NOT interact with the PDS.	e	
	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 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 are permitted only when all products are operating and activ	е.	

Audit

Reference	Requirement	Open PDS	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.	Yes	Yes
	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".		
PRES-10	The system SHALL maintain an audit log of logon, logoff, stage-change and credential change activity for all user accounts.	Yes	Yes
	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).		

Reference	Requirement	Open PDS	Direct PDS
PRES-38	The system SHALL record each electronic prescription generated in an audit log. The details of the record shall include:	Yes	Yes
	 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.		
PRES-39	The system SHALL record each electronic prescription cancellation request in the audit log. The details of the record shall include:	Yes	Yes
	• 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.		

User Selection

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

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

Composition

Reference	Requirement	Open PDS	Direct PDS
PRES-17	The system SHALL include, within the electronic prescription, all data fields as required by Jurisdictional Regulations.	Yes	Yes
PRES-17A	For PBS and RPBS prescriptions, the system SHALL also include within the electronic prescription, all data fields as required by the National Health Act.	Yes	Yes

Reference	Requirement	Open PDS	Direct PDS
PRES-80	When transmitting an electronic prescription, the software SHALL ensure sure that the transmission includes:	Yes	Yes
	a) A meta-data component andb) A prescription component		
	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-81	The meta-data component of every electronic prescription SHALL be:	Yes	Yes
	a) Unencrypted when at rest and;b) Encrypted when in transit;		
	Note: the meta-data is designed to be available to electronic prescribing 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.		
PRES-83	The meta-data component of every electronic prescription SHALL contain at least:	Yes	Yes
	 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)		
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).	Yes	Yes
	Note: these identifiers are to be stored in the encrypted payload.		

Reference	Requirement	Open PDS	Direct PDS
PRES-18	The system SHALL also include, within an electronic prescription, at least the following information:	Yes	Yes
	 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;		
	 Maximum quantity authorised to dispense (in numbers and words if a controlled drug); 		
	• Directions for use;		
	medicine form;		
	Route of administration;		
	 Number of repeats (if applicable); 		
	 Closing the Gap code (if applicable); 		
	 Prescriber specialist qualification (if not in the ACT); 		
	 Prescriber qualification (if in Qld, ACT); 		
	 Prescription notes to record unusual dose, staged supply etc; 		
	• Either the privacy notice or a reference to the privacy notice, but not both.		
	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.		

Requirement	Open PDS	Direct PDS
The system SHALL also support and include (if applicable) in the electronic prescription:	Yes	Yes
 Authorisation reference number (up to 25 characters alpha/numeric) 		
The system SHALL present this 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.		
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
 The system SHALL also include, within an electronic prescription, the following information: Healthcare Provider Identifier - Individual (HPI-I) of the Prescriber Minimum interval between repeats (if applicable) as per Schedule 4B and 8 in NSW Schedule 8 in ACT, WA, Qld and NT Schedule 8 and 4D in TAS Unusual dose indicator (if applicable) 	Yes	No
	The system SHALL also support and include (if applicable) in the electronic prescription: Authorisation reference number (up to 25 characters alpha/numeric) The system SHALL present this number as: "Authoristion number" in NSW and NT; "Authority number" in WA and TAS; "Authority number" in QLD and ACT; "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. The system SHALL include or display, the following text into or with the electronic prescription as appropriate: 'for dental treatment only' 'for optometry use only' 'for podiatric treatment only' 'for ocular treatment only' 'for ocular treatment only' Note: software is to insert/display text as appropriate. Note: DISP-50 requires dispensing systems to display the information in this requirement. Note: software is to insert/display text as appropriate. Note: bis 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. The system SHALL also include, within an electronic prescription, the following information: Healthcare Provider Identifier - Individual (HPI-I) of the Prescriber Minimum interval between repeats (if applicable) as per Schedule 4B and 8 in NSW Schedule 8 and 4D in TAS	The system SHALL also support and include (if applicable) in the electronic prescription: Yes in the electronic prescription: Authorisation reference number (up to 25 characters alpha/numeric) The system SHALL present this number as: "Authorisation number" in NSW and NT; . "Authority number" in WA and TAS; "Authority number" in QLD and ACT; . "Authority 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. Yes The system SHALL include or display, the following text into or with the electronic prescription as appropriate: Yes . 'for optometry use only' 'for optometry use only' Yes . 'for occular treatment only' 'for cocular treatment only' Yes Note: software is to insert/display text as appropriate. Note: DISP-50 requires dispensing systems to display the information in this requirement. Note: software is to insert/display text as appropriate. Note: Software is to insert/display text as appropriate. Note: DISP-50 requires dispensing systems to display the information in this requirement. Yes Note: D

Reference	Requirement	Open PDS	Direct PDS
PRES-19A	The system SHALL include, within an electronic prescription, the following information:	No	Yes
	 Healthcare Provider Identifier - Individual (HPI-I) of the Prescriber (if available); 		
	Note: also see PRES-84.		
PRES-20	The system SHALL 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
	Note: PBS claimable items will require a PBS code. Including an AMT code does not remove the need to also include a PBS code.		
PRES-21	The system SHALL allow for the inclusion of Reason for prescribe (clinical indication) as a SNOMED CT-AU Codeable Value.	Yes	Yes
PRES-21A	The system SHALL NOT require Reason for prescribe (clinical indication) as a SNOMED CT-AU Codeable Value.	Yes	Yes
	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.		
PRES-22	Irrespective of the inclusion of any codeable values, the system SHALL include all information fields presented to the prescriber in "Original Text".	Yes	Yes
	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".		
PRES-49	Where the Reason for prescribe (clinical indication) is included as a coded value, the system SHALL also include Reason for prescribe as a text (human readable) field.	Yes	Yes
PRES-53	The system SHALL allow capture of Reason for prescribe (clinical indication) as a text field if no coded value is provided.	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.		

Reference	Requirement	Open PDS	Direct PDS
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.	Yes	No
	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: The three day supply that a pharmacist may provide as emergency supply is out of scope for electronic prescriptions.		
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
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

Finalisation

Reference	Requirement	Open PDS	Direct PDS
PRES-42	After submitting an electronic prescription to an Open PDS, the system SHALL:	Yes	No
	 Print Evidence of Prescription (including the Token) in paper form; and/or 		
	 Facilitate the transmission of Evidence of Prescription (including the Token) to an electronic address in electronic form. 		
	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)		
PRES-43	If the Evidence of Prescription is printed, the Token SHALL be printed as a Barcode/QR Code.	Yes	No

Reference	Requirement	Open PDS	Direct PDS
PRES-43A	The system SHALL be able to reprint an Evidence of Prescription should the prescriber need to do so.	Yes	No
	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.		
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.	Yes	No
	Note: In the event that the Token is unable to be scanned, a user may enter the DSPID manually.		
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.	Yes	No
	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.		
PRES-46	Where Evidence of Prescription is sent in electronic form (e.g. SMS, email), the system SHALL transmit at least:	Yes	No
	 The electronic token or 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: In the event that the electronic address was incorrectly recorded, this limits the potential for exposing personal information to an unknown party.		
PRES-46A	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 PRES-46 and PRES-48A.	Yes	Yes
	Note: In the event that the electronic address was incorrectly recorded, this limits the potential for exposing personal information to an unknown party.		
PRES-46B	Where Evidence of Prescription is sent in electronic form, the system SHALL support confirmation of the electronic address to be used by the prescriber with the Subject of Care.	Yes	No
	Note: The address that will be used should be conveniently displayed so the prescriber can confirm this verbally or by display.		

Reference	Requirement	Open PDS	Direct PDS
PRES-47	Where Evidence of Prescription is provided in paper form, the system SHALL include the following details:	Yes	No
	 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.		
PRES-48	Where Evidence of Prescription is provided in paper form, the system SHALL NOT include the following details:	Yes	No
	• 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.		

Reference	Requirement	Open PDS	Direct PDS
PRES-48A	Where Evidence of Prescription is provided in electronic form, the system SHALL NOT include the following details:	Yes	No
	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).		
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.	Yes	No
	Note: Evidence of Prescription must not be misconstrued by a dispenser as a legal prescription.		

Modification

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

Reference	Requirement	Open PDS	Direct PDS
PRES-41	Post finalisation, where an electronic prescription has been sent to the PDS as an electronic prescription, the system SHALL provide a mechanism for the prescriber to correct a prescription if the prescriber needs to.	Yes	Yes
	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.		

Submission

Reference	Requirement	Open PDS	Direct PDS
PRES-23	The system SHALL store, in a permanent and non-alterable manner within the clinical or medicines record of the person for whom the electronic prescription was generated, the particulars of any electronic prescription generated, consistent with and as required by any applicable regulations <i>Note: NSW regulations require prescription details to be</i> <i>retained for at least two years.</i>	Yes	Yes
PRES-24	The system SHALL display the electronic prescription in a format that meets the requirements of the National Regulations and relevant state and territory legislation to the prescriber and obtain a final approval from the prescriber prior to finalising the prescription for transmission.	Yes	Yes
	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.		

Reference	Requirement	Open PDS	Direct PDS
PRES-25	When connecting to a PDS over a public network, the system SHALL authenticate the identity of the PDS using Public Key Infrastructure (PKI).	Yes	Yes
	Note: The Conformance Requirements will be updated if the approved authentication methods change.		
PRES-26	When connecting to a PDS over a public network, the system SHALL assert its identity to the PDS using Public Key Infrastructure (PKI).	Yes	Yes
	Note: The Conformance Requirements will be updated if the approved authentication methods change.		
PRES-27	All transmission of electronic prescription information over public networks SHALL be encrypted using Australian Signals Directorate (ASD) approved cryptographic algorithms.	Yes	Yes
PRES-28	On submission to an Open PDS, the system MAY include in the electronic prescription header, the electronic address to which the PDS may send the Evidence of Prescription to the Subject of Care or their Agent.	Yes	No
	Note: Only if SoC consents.		
PRES-30	On submission to a PDS, the system SHALL record the DSPID which references the electronic prescription in the PDS.	Yes	No
PRES-31	The system SHALL record the date and time (time and time zone) that the PDS acknowledged receipt of the electronic prescription. <i>Note: Some direct PDS may not have an</i> <i>acknowledgement. This will be determined by the</i> <i>architecture and technical solution.</i>	Yes	Yes
PRES-32	The system SHALL provide the user with an indication as to whether the PDS has acknowledged receipt of the electronic prescription. Note: Until the PDS acknowledges receipt, the SoC may not have a valid prescription in their possession.	Yes	No
PRES-33	 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 queuing and sending a cancellation 	Yes	No

Reference	Requirement	Open PDS	Direct PDS
PRES-34	The system SHALL allow the user to issue a cancellation of an electronic prescription after acknowledgement of receipt by the PDS.	Yes	Yes
	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.		
PRES-35	Upon cancellation, the system SHALL issue a cancellation message to the PDS.	Yes	Yes
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".	Yes	No
	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.		
PRES-37	The system, in the event of an AORT, SHALL automatically:	Yes	No
	1 alert the user, and		
	2 cancel the electronic prescription, and		
	3 proceed with printing a paper prescription.		

ASLR Assisted registration

Reference	Requirement	Open PDS	Direct PDS
PRES-200	The prescribing system SHALL integrate with only one ASLR for supporting electronic prescriptions.	Yes	No
	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.		
PRES-205	The prescribing system SHOULD provide assisted registration functionality to support Subject of Care registration for an Active Script List.	Yes	No

Reference	Requirement	Open PDS	Direct PDS
PRES-210	When the healthcare provider performs assisted registration for a SoC wanting an Active Script List, 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:	Yes	No
	• 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 PRES-225 and PRES-230 for carers and agents.		
PRES-215	When the healthcare provider performs assisted registration for a SoC and adds 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.	Yes	No
	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).		

Reference	Requirement	Open PDS	Direct PDS
PRES-220	When the healthcare provider performs assisted registration for a SoC and the patient registers a carer or agent, the prescribing system SHALL allow the healthcare provider to nominate which role that person supports (Carer or Agent).	Yes	No
	Note: A 'carer' and 'agent' are different concepts and must be captured separately.		
PRES-225	When the healthcare provider performs assisted registration for a SoC, 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:	Yes	No
	• 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 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.		

Reference	Requirement	Open PDS	Direct PDS
PRES-230	When the healthcare provider performs assisted registration for a SoC, 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:	Yes	No
	• Family name, and		
	 Given name (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.		
	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.		
PRES-235	When the healthcare provider performs assisted registration for a SoC, the prescribing system SHALL support the capture of an organisation name as a carer for the SoC.	Yes	No
	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.		
PRES-240	When the healthcare provider performs assisted registration for a SoC, the prescribing system SHALL record and send one and only one primary contact for the SoC's ASL.	Yes	No
	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.		

Reference	Requirement	Open PDS	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.	Yes	No
	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.		
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.	Yes	No
	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.		

ASLR Viewing

Reference	Requirement	Open PDS	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
PRES-280	The prescribing system MAY allow the healthcare provider to view the SoC's Active Script List, if and only if:	Yes	No
	 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.		
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
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

Reference	Requirement	Open PDS	Direct PDS
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
PRES-315	If displaying a patient's ASL the prescribing system SHALL display at least the following information:	Yes	No
	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.		

ASLR Prescribing

Reference	Requirement	Open PDS	Direct PDS
PRES-345	The prescribing system SHALL display a checkbox (or similar) for the prescriber to describe each of the following events (for electronic and paper prescriptions):	Yes	No
	 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.		
	and		
	 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: 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.		
	Note: Prescribing to dosing points is a reason to send directly to that pharmacy and keep the token from an ASL.		

Reference	Requirement	Open PDS	Direct PD
PRES-360	The prescribing system SHALL include the status (or similar) of the following items in the prescription meta- data:	Yes	No
	 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 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.		
	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.		
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.	Yes	No
	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).		
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.	Yes	No
	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.		

ASLR Audit log

Reference	Requirement	Open PDS	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.	Yes	No
	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 prescribin system) or both. 	g	

3.2 Dispensing Systems

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

Authentication and authorisation

Reference	Requirement	Open PDS	Direct PDS
DISP-1	When connecting to a PDS over a public network, the system SHALL authenticate the identity of the PDS using Public Key Infrastructure (PKI).	Yes	Yes
	Note: Conformance requirements will be updated if the approved authentication methods change.		
DISP-3	Where the system interacts with the PDS over a public network, the system SHALL ensure that all information sent over the public network is encrypted using Australian Signals Directorate (ASD) approved cryptographic algorithms.	Yes	Yes
DISP-4	The system SHALL provide single factor, multi-stage, or multi-factor authentication on all user accounts.	Yes	Yes
	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).		
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

Reference	Requirement	Open PDS	Direct PDS
DISP-6	The system SHALL record the following information with each account:	Yes	No
	Full Name;		
	AHPRA Number (if any);		
	• HPI-I (if any); and		
	 User Class: Pharmacist, Supervising Pharmacist, Pharmacy Technician, etc. 		
	Note: The user classes available in the system is a software design decision and should reflect real world occupations/business practices.		
DISP-6A	The system SHALL record the following information with each account:	No	Yes
	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.		
DISP-7	Where only single factor or multi-stage authentication is provided, the system SHALL allow healthcare organisations the ability to establish authentication parameters. Including, but not limited to:	Yes	Yes
	 Minimum password length; 		
	Password composition;		
	 Password retry limit (before lockout); 		
	 Password refresh interval (frequency with which new password must be created); and 		
	 Password reuse interval (period which must expire before a password may be reused). 		
	Note: Healthcare organisations shall have the support of the system in the implementation of their access control policies.		
DISP-8	The system SHALL facilitate the identification and recording of the identity of each user involved with dispensing activity.	Yes	Yes
DISP-9	The system SHALL facilitate the identification and recording of the identity of the dispenser authorising the dispensing activity.	Yes	Yes
	Note: the person authorising the dispense record to be submitted to the PDS needs to be identified and details captured.		

Reference	Requirement	Open PDS	Direct PDS
DISP-10	The system SHALL automatically log off an account, or require re-authentication, after a period of inactivity defined by the healthcare organisation.	Yes	Yes
	The default inactivity period SHOULD NOT be longer than 10 minutes.		
	Note: Healthcare organisations shall be able to define a period of inactivity after which the dispenser's terminal may be considered unattended and vulnerable to misuse.		
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 those products need to be operating when transacting with a PDS.	Yes	Yes
	If one or more of those products is not operating then the system SHALL NOT interact with the PDS.		
	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 are permitted only when all products are operating and active.		

Audit

Reference	Requirement	Open PDS	Direct PDS
DISP-34	The system SHALL maintain audit logs associated with electronic prescription dispense events in accordance with relevant legislation and regulation.	Yes	Yes
	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.		
DISP-35	The system SHALL maintain an audit log of logon, logoff, stage-change and credential change activity for all user accounts.	Yes	Yes

Reference	Requirement	Open PDS	Direct PDS
DISP-36	The system SHALL record each dispense record generated in an audit log. The details of the record SHALL include:	Yes	No
	 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.		
DISP-37	The system SHALL record each dispense record cancellation request in the audit log. The details of the record SHALL include:	Yes	No
	 Date and time of Dispense cancellation (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 cancellation.		
DISP-51	The system SHALL, on request, generate a file or files that contain at least the following information in human readable format:	Yes	Yes
	• 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.		

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

Retrieval

Reference	Requirement	Open PDS	Direct PDS
DISP-11	The system SHALL support scanning (or other methods) of an electronic prescription Token from paper or a mobile device.	Yes	No
DISP-11A	The system SHALL support manual entry of an electronic prescription Token (i.e. entry of the DSPID).	Yes	No
	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.		
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:	Yes	Yes
	 Prescribing software conformance identifier; 		
	 originalRepositorySoftUniqueID; and, 		
	RepositorySoftUniqueID.		
	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:	Yes	Yes
	The original electronic prescription;		
	 The most recent dispense (if any); and 		
	All annotations (if any).		
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), the system SHALL have the ability to display:	Yes	Yes
	 Details of the original prescription; 		
	 The prescription status (i.e active); 		
	 Details of the previous dispense (if any); and 		
	 The details of any annotations in relation to the prescription recorded by previous dispensers (if any). 		
	Note: The above requirement details the minimum system requirements. Vendors may choose to display additional details.		
	Note: Displaying the original prescription supports the dispenser checking process.		
DISP-16A	The system SHALL have the ability to display the original 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 the system SHALL prevent a double dispense against that prescription.	Yes	Yes
	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.		
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.	Yes	Yes
	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.		
DISP-18	The system SHALL provide a clear visual indication to the user that the prescription is an electronic prescription. Note: It must be made clear to the dispenser that this information represents the legal form.	Yes	Yes
DISP-60	The system SHOULD clearly indicate to the user if the prescriber has specified that brand substitution not allowed. Note: This is easily distinguished on an existing paper prescription. The dispenser should be directed to this value on an electronic prescription.	Yes	Yes

Reference	Requirement	Open PDS	Direct PDS
DISP-56	The system SHALL provide a mechanism to support a dispense final check-off process in the absence of a paper prescription.	Yes	Yes
	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.		
DISP-58	The system SHALL allow the user to override the default and select a different electronic address for a Subject of Care on a per prescription basis.	Yes	No

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.	Yes	No
	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.		

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:	Yes	No
	• 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		
risk of the dis Prescription I Note: If Form may be inclue	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.		
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.	Yes	No
	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.		

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:	Yes	No
	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).		
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.	Yes	No
	Note: In the event that the electronic address was incorrectly recorded, this limits the potential for exposing personal information to an unknown party.		
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.	Yes	No
	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.		

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.	Yes	No
	If the PDS is unavailable, the Dispense Record SHALL be queued and repeatedly retried until successfully delivered.		
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	
the PDS, the system SHALL provide a mechanism dispenser to correct a dispense record if the dis needs to. Note: the dispense record might be against the prescription or subsequent repeat authorisation dispenser must have the option to correct a disp	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.	Yes	Yes	
	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 "cancel" operation followed by a "create" operation is an acceptable mechanism provided the system automatically and instantly creates the subsequen "create" request. It is unacceptable for the onus for the subsequent "create" request to fall on the local user.	operation is an acceptable mechanism provided the system automatically and instantly creates the subsequent "create" request. It is unacceptable for the onus for the		
	Vendors will need to understand what operations the PDS will support.			

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:	Yes	No
	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 surname		
	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)		
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 has been transmitted to, and accepted by, the PDS.	Yes	Yes
	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 next repeat authorisation until the original dispense is final and accepted by the PDS.		
DISP-20	The system SHOULD include the following fields in a dispense record to the PDS:	Yes	No
	• 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.		

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.	Yes	No
	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.		
DISP-21A	They 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 dispensed, the system SHALL restore the state of the electronic prescription in the Open PDS.	Yes	No
	Note: The electronic prescription is locked in the Open PDS when retrieved by a dispensing system. If the dispense does not proceed, it shall be unlocked.		
	There may be instances where a dispenser is required to abandon a dispense event prior to a dispense record being posted to the PDS (for example, the dispenser is out of stock). In this instance, following the dispense event ceasing, the electronic prescription record should be returned to an unlocked state. The outcome is that the prescription is valid for dispense. Related requirement: DS-17.		
DISP-25	The system SHALL be able to communicate a dispense reversal to the Open PDS.	Yes	No
	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-19.		
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 cancellation or reversal.	Yes	No

Reference	Requirement	Open PDS	Direct PDS
DISP-29	If the PDS is unavailable / unresponsive, the system SHALL queue messages and retry until the PDS acknowledges receipt.	Yes	No
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.	Yes	Yes
	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.		
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.	Yes	No
	Note: After SoC consents.		

Reconciliation¹

Reference	Requirement	Open PDS	Direct PDS
DISP-38	The system SHALL allow a DSPID to be manually entered into an electronic dispense record.	Yes	Yes
	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.		
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.	Yes	Yes
DISP-39	The system SHOULD allow a user to request reconciliation of a manually entered dispense record with the electronic prescription retrieved from the PDS.	Yes	Yes

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-42	In attempting to reconcile a manually entered dispense record with an electronic prescription, the system SHOULD identify and display any discrepancies.	Yes	Yes
DISP-43	Once the electronic prescription has been retrieved, the system SHALL allow the Dispenser to mark the Dispense Record as:	Yes	Yes
	Reconciled.		
	Note: A dispense record that is reconciled is not prohibited from having annotations in-line with normal dispensing processes.		
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.	Yes	No
	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.		

ASLR Assisted registration

Reference	Requirement	Open PDS	Direct PDS
DISP-200	The dispensing system SHALL integrate with only one ASLR for supporting electronic prescriptions.	Yes	No
	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.		
DISP-205	The dispensing system SHALL provide assisted registration functionality to support Subject of Care registration for an Active Script List.	Yes	No

Reference	Requirement	Open PDS	Direct PDS
DISP-210	 10 When the healthcare provider performs assisted Yes 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) 	Yes	No
	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.		
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.	Yes	No
	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).		
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).	Yes	No
	Note: A 'carer' and 'agent' are different concepts and must be captured separately.		

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:	Yes	No
	• 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.		
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:	Yes	No
	• 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.		

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.	Yes	No
	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.		
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	Yes	No
	primary contact details for ASL notifications. Having a single contact avoids conflicting notifications and consent messages being sent from multiple carers.		
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.	Yes	No
	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.		
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:	Yes	No
	 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). 		

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.	Yes	No
	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.		
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:	Yes	No
	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.		

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):	Yes	No
	 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.		
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.	Yes	No
	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.		

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:	Yes	No
	 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.		
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.	Yes	No
	Note: Some CIS's delegate the sending of the communication to the PDS.		
	Note: Dispensers should not give printed EoP's 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).		
DISP-370	The dispensing system SHALL NOT pre-populate the dispense record with the information provided by the ASLR.	Yes	No
	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.		

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.	Yes	No
	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.		

ASLR Audit logs

Reference	Requirement	Open PDS	Direct PDS
DISP-405	The system SHALL maintain an audit log of access to Active Script Lists.	Yes	No
	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. 		

3.3 Prescription Delivery Service Systems

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

Authentication and authorisation

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

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:	Yes	Yes
	 Date and Time of creation (time and time zone); 		
	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. 		
shc acc	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.		

Reference	Requirement	Open PDS	Direct PDS
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.	Yes	Yes
	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".		

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:	Yes	No
	Original electronic prescription;		
	 Most recent dispense record; and 		
	All annotations.		
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-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

Submission

Reference	Requirement	Open PDS	Direct PDS
DS-4	The system SHALL accept electronic prescriptions from prescribing systems that provide a valid conformance id from an organisation with which they have a contractual agreement.	Yes	Yes
DS-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.	Yes	Yes
	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.		

Reference	Requirement	Open PDS	Direct PDS
DS-5	The system SHALL provide an acknowledgement of receipt of an electronic prescription to the prescribing system. <i>Note: Some direct PDS may not have an</i>	Yes	Yes
	acknowledgement. This will be determined by the architecture and technical solution.		
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 of an electronic prescription cancellation request and the outcome of that request to the prescribing system.	Yes	Yes
DS-9	The system MAY support the delivery of the electronic Token to a nominated electronic address (which would be included in the metadata of the electronic prescription by the prescriber), 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. <i>Note: tokens to be controlled by healthcare providers for</i>	Yes	Yes
	legal reasons (e.g. dosing points) must not be provided to the subject of care/carers – including the ASL if one is active.		
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

Reference	Requirement	Open PDS	Direct PDS
DS-17	The system SHALL accept and process a notification of dispense cancellation.	Yes	No
	Note: There may be instances where a dispenser is required to abandon a dispense event prior to a dispense record being posted to the PDS (for example, the pharmacy is out of stock). In this instance, following dispense event ceasing, the electronic prescription record should be returned to an unlocked state. The outcome is that the prescription is valid for dispense. Related requirement: DISP-24.		
DS-19	The system SHALL accept and process a notification of dispense reversal.	Yes	No
	Note: There may be instances where a dispenser is required to reverse a dispense event after a dispense record has been posted to the PDS (for example, the SoC declines supply). In this instance, following dispense event, the dispenser is required to reverse the dispense event and return the electronic prescription record to an unlocked state. The outcome is that the prescription is valid for dispense. Related requirement: DISP-25.		
DS-20	The system SHALL provide an acknowledgement of receipt of a dispense reversal to the dispensing system.	Yes	No
	Note: The system will cancel the dispense event and return the electronic prescription to its previous state. Related requirement: DISP-28.		
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

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

Reference	Requirement	Open PDS	Direct PDS
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.	Yes	No
	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.		
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	Yes	Yes
	content passes between PDSs.		

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.	Yes	Yes
	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.		
DS-25	The system SHALL NOT expose the unencrypted payload to the operator or user of the PDS system when in normal operations.	Yes	Yes
	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.		

Reference	Requirement	Open PDS	Direct PDS
DS-25A	The system SHALL NOT share the payload with other internal or external systems unless:	Yes	Yes
	 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 		
DS-81	The meta-data component of every electronic prescription SHALL be:	Yes	Yes
	Unencrypted when at rest and;Encrypted when in transit;		
	Note: the meta-data is designed to be available to electronic prescribing 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.		
DS-82	The prescription component (the payload) of the transmission SHALL be:	Yes	Yes
	a) Encrypted when at rest andb) 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.		

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

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.	Yes	No
	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.		

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:	Yes	No
	 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 or not dispensed). 		
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:	Yes	No
	 The prescription is active (i.e. not cancelled, not expired 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.		
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.	Yes	No
	Note: Some CIS's delegate the sending of the communication to the PDS.		
DS-380	The system SHALL NOT generate a token for a paper prescription.	Yes	No
	Note: The prescription information can be displayed in the ASL without the token. However, there must not be a dispense without the paper prescription.		

3.4 Active Script List and Registers

There is an expectation for PDS's and ASLR's to interoperate and exchange information in a nondisruptive 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, 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 this 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)
- \circ 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.

ASLR Assisted Registration

Reference	Requirement	Open PDS	Direct PDS
ASLR-200	The system SHALL have the capability to receive prescription information from every conformant PDS.	Yes	No
	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.		
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	No
ASLR-210	The system SHALL support an Assisted Registration function provided by CIS's, and only store the following SoC's information in ASLR:	Yes	No
	• 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.		
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.	Yes	No
	Note: The consent flag must be sent to ASLR when agent/carer's details are provided to the ASLR.		

 ASLR-220 When storing an agent/carer's details of the SoC, 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. 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 	No
must be captured separately. 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:	
registered in the SoC's ASL, and only store the following carer information in the ASLR:	
• Family name and	No
i anny hanc, 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	
<i>Note: Capturing a carer is optional but the software must support this function.</i>	
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).	
<i>Note: If the carer has a given name then that given name must be recorded.</i>	
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.	

Reference	Requirement	Open PDS	Direct 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:	Yes	No
	• 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.		
ASLR-235	The system SHALL allow the capture of an organisation name as a carer for the SoC.	Yes	No
	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.		
ASLR-240	The system SHALL support the capture of one and only one primary contact for an ASL.	Yes	No
	Note: The patient needs to nominate, through the assisted registration process, a primary contact point that can receive ASLR notifications.		
ASLR-250	The system SHALL support the subsequent update of the SoC, carer and agent's personal information that is registered in the ASL.	Yes	No
	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.		

Reference	Requirement	Open PDS	Direct 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.	Yes	No
	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).		
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	No
ASLR-270	The system SHALL receive prescription information if and only if the SoC's ASL has been activated.	Yes	No
	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.		

ASLR Viewing

Reference	Requirement	Open PDS	Direct 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.		
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.	Yes	No
	Note: This requirement applies to information pertaining to electronic and paper prescriptions.		

Reference	Requirement	Open PDS	Direct PDS
ASLR-275	The system SHALL provide a means for the CIS to determine if the SoC has an active ASL.	Yes	No
ASLR-280	The system SHALL provide a means to share a patient's ASL to a CIS if and only if:	Yes	No
	 the SoC has an Active Script List, and 		
	• the healthcare provider has site consent for the SoC's ASL.		
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.	Yes	No
	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.		
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.	Yes	No
	Note: The ASLR will act like a broker for the CIS and present ASL site consent to the CIS through a single point.		
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.	Yes	No
	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.		

Reference	Requirement	Open PDS	Direct 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:	Yes	No
	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 SHALL NOT provide:		
	 Medicine(s) direction; or 		
	Prescribing 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.		
ASLR-320	The system SHALL NOT make available, any prescription information for prescriptions that have expired.	Yes	No
	Note: The ASL will only display prescription information for active prescriptions.		

Reference	Requirement	Open PDS	Direct PDS
ASLR-340	The ASLR SHALL indicate to systems downloading the ASL which line item is being shared without a token.	Yes	No
	Note: The prescription meta-data will contain information that will enable systems to determine if the prescription has a token available for dispensing.		

ASLR Prescribing and Dispensing

Reference	Requirement	Open PDS	Direct PDS
ASLR-342	The system SHALL NOT accept electronic prescription information about electronic prescriptions from non-conformant systems.	Yes	No
	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.		
ASLR-343	The system SHALL NOT provide prescription information to non-conformant systems.	Yes	No
	Note: Every communication received by the ASLR 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.		

ASLR Audit Log

Reference	Requirement	Open PDS	Direct PDS
ASLR-405	The system SHALL provide a mechanism to present the audit log to review access events against an Active Script List.	Yes	No
	Note: This functionality might eventually be available to a SoC through a mobile application or other user interface.		
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	No
ASLR-415	The system SHALL maintain a record of carers that the SoC has authorised to view their ASL.	Yes	No

3.5 Mobile Intermediary Systems

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

Authentication and authorisation

Reference	Requirement	Open PDS	Direct PDS
MI-1	The system SHALL NOT provide electronic prescription information or dispense information to a non-conforming system.	Yes	No
MI-2	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).	Yes	No
	Note: The PDS will not accept connections from unknown participants.		
	Conformance requirements will be updated if the approved authentication methods change.		
MI-14	For systems that connect to an ASLR, the system SHALL authenticate all connections with Active Script List Registry services over public networks using OAuth 2.0- based credentials.	Yes	No

Audit

Reference	Requirement	Open PDS	Direct PDS
MI-10	The system SHALL maintain audit logs associated with electronic prescription retrieval events in accordance with relevant legislation and regulation.	Yes	No
	Note: NSW regulations require prescription details to be retained for at least two years.		

Reference	Requirement	Open PDS	Direct PDS
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.	Yes	No
	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".		

Retrieval

Reference	Requirement	Open PDS	Direct PDS
MI-3	The system SHALL NOT aggregate and make available electronic prescription information based on an IHI number unless explicit consent from the SoC has been obtained.	Yes	No
	Note: An IHI number shall be included in the metadata of the electronic prescription provided by the prescriber.		
MI-4	The system SHALL retrieve all information relevant to an electronic prescription, including information about the original electronic prescription, and the most recent dispense (if any).	Yes	No

PDS Connections

Reference	Requirement	Open PDS	Direct PDS
MI-5	Where the system receives 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		No

Data Integrity

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

Privacy

Reference	Requirement	Open PDS	Direct PDS
MI-7	The system SHALL encrypt data in transit between all authorised end points and at rest.	Yes	No
	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 consent.	Yes	No
	Note: In this scenario, "consent" may be from the patient in the initial instance. Mobile intermediaries would manage this information and would be subject to use and disclosure laws applicable federally (Privacy Act 1988) and any applicable laws in their jurisdiction of registration.		
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.	Yes	No

Security

Reference	Requirement	Open PDS	Direct PDS
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".	Yes	No
MI-12	The system SHALL include, in all connection requests from mobile devices, a unique identifier tied to the mobile device hardware.	Yes	No
	Note: The PDS will not accept connections from unknown participants.		
	Examples include Google authenticator or RSA soft token.		

3.6 Mobile Application Systems

This section describes conformance requirements specific to electronic prescribing – mobile application systems. A mobile application is a system used by the Subject of Care (SoC) (or Agent) to do any or all of the following:

- manage prescriptions;
- provide the capability to present or send prescription Tokens to a dispensary;
- manage personal details relevant to the application;
- forward prescription link to online or bricks and mortar pharmacies;

Note: the functionality does not have to be provided through a mobile device. A web interface providing the user functionality outlined above qualifies as a mobile application for the purposes of this Conformance Profile.

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

Account Creation

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

Account Deactivation

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

Retrieval

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

Presentation

Reference	Requirement
MA-9	For an electronic prescription, the system SHALL render, at minimum:
	• The DSPID as a barcode/QR code.
	Note: Irrespective of what information the mobile application has about the prescription, as a minimum, it shall render (display) the DSPID as a barcode/QR code to be scanned at a dispenser.

Reference	Requirement
MA-10	The system MAY render additional electronic prescription item details including but not limited to:
	The details of the original prescription;
	 The prescription status (e.g. Cancelled, Expired, Exhausted, etc.);
	 The details of the previous dispense (if any); and
	 Information communicating available repeats (if any).
	Note: Mobile applications are not precluded from displaying information beyond that provided as Evidence of Prescription.
MA-11	The system SHALL display all rendered information in "original text", irrespective of the presence or otherwise of coded information fields.
	Note: "Original Text" is defined as the text "exactly as presented to the prescriber or dispenser". This ensures that the content is human readable and facilitates consumer access to information.
MA-12	The system SHALL provide indication to the user if it detects that the Mobile Intermediary service is unreachable or unavailable.
MA-13	The system MAY allow an electronic prescription Token to be transmitted to an electronic address.
MA-14	The system SHALL make electronic prescription information available read only.
	Note: Any information retrieved from a PDS, including the barcode itself, should be read only.
MA-15	The system MAY cache electronic prescription information on a user's account.
	Note: Where connection to the PDS is unavailable (e.g. no reception), this would allow the user to view details of prescriptions they have previously retrieved (e.g. when in an area with reception).

Security

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

4 Acronyms

Acronym	Description
1D	One Dimensional
ACSC	Australian Cyber Security Centre
ADHA	Australian Digital Health Agency
AHPRA	Australian Health Practitioner Regulation Agency
AMT	Australian Medicines Terminology
AORT	Acknowledgement Of Receipt - Timeout
ASD	Australian Signals Directorate
ASL	Active Script List
ASLR	Active Script List Registry
CIS	Clinical Information System
DLM	Dissemination Limiting Marker
DoB	Date of Birth
DSPID	Delivery Service Prescription Identifier
eNRMC	electronic National Residential Medication Chart
EP	Electronic Prescribing
ETP	Electronic Transfer of Prescriptions
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
ISM	Information Security Manual
MHR	My Health Record
MMS	Multimedia Messaging Service
OAuth	Open Authorisation
PBS	Pharmaceutical Benefits Scheme
PDS	Prescription Delivery Service
РКІ	Public Key Infrastructure

Acronym	Description
PRODA	Provider Digital Access
RACFIF	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
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

5 Glossary

Term	Meaning
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 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: <u>http://www.pbs.gov.au/info/healthpro/explanatory-</u> <u>notes/section1/Section 1 2 Explanatory Notes#Authority-PBS</u>
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.
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.

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:
	 Metadata - that is decrypted within the Open PDS to support the technical operation of the system
	 Clinical content - the body of the record containing personal and sensitive information, which remains encrypted within the Open PDS.
	Together the metadata and the clinical content comprise the Electronic Prescription.
	The requirements for the prescription metadata are described in Section 8.1 of the Solution Architecture.
Electronic transfer of prescription (ETP)	The current process whereby prescribing systems pass data about a prescription to a prescription delivery service (PDS), which is available for download by dispensing systems is support of dispensing a paper prescription.
Evidence of Prescription	Evidence of electronic prescription must not resemble a legal paper prescription as it would be illegal to supply a pharmaceutical benefit from only the evidence of the electronic prescription.
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 CLUD/LUD but need not be
Hospital Provider Number (HPN)	Note: this may be a GUID/UID but need not be. Administered by Services Australia

MAY	When appearing in a conformance requirement, the verb MAY indicates an optional requirement.
Mobile Application	An application that provides a user the ability to manage electronic prescriptions via a personal device.
Mobile Intermediary	Software used by mobile applications to interact with the electronic prescribing process.
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 exchange (PE)	A participant in the prescription delivery service that supports defined interfaces and services to facilitate the transfer of electronic prescriptions and related information between prescribers and dispensers.
Prescription delivery service (PDS)	An e-Health service that supports defined interfaces and services to facilitate the transfer of electronic prescriptions and related information between participating systems.
Prescription information	Information sent to and retained by the ASLR.
Prescription Software Conformance ID	The conformance identifier of a software system used to create an electronic prescription.
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.
SHALL	When appearing in a conformance requirement, this verb SHALL indicates a mandatory requirement. Its negative form SHALL NOT indicates a prohibition.
SHOULD	When appearing in a conformance requirement, the verb SHOULD indicates a recommendation. Its negative form SHOULD NOT indicate an option that should not be supported.

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'.

$\mathsf{Summary}^{\scriptscriptstyle +}$ of electronic prescription for $\mathsf{John}\ \mathsf{Citizen}$

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



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