



**Australian Government**  
**Australian Digital Health Agency**



## **Electronic Prescribing Participating Software Conformance Profile**

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## Document information

### Key information

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### Product or document version history

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Product or document version	Date	Release comments
DRAFT for information 1.0	23 September 2019	Preliminary document released for external information
2.0	31 October 2019	Final document for external use
2.1	16 March 2020	Revised document superseding v2.0
2.2	5 June 2020	ASLR relaxed, Jurisdictional requirements added, and other minor adjustments
2.2.1	11 August 2020	Adjusted DS-22 and MI-4 to be backwards compatible with previous profiles

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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.

<b>Authentication and authorisation</b>			
<b>Reference</b>	<b>Requirement</b>	<b>Open PDS</b>	<b>Direct PDS</b>
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. <i>Note: Only users designated by the healthcare organisation as having prescribing rights may access the electronic prescribing capability.</i>	Yes	Yes
PRES-3	The system SHOULD provide multi-factor authentication on user accounts with electronic prescribing capability. <i>Note: As per Australian Cyber Security Centre (ACSC) recommendations.</i>	Yes	Yes
PRES-4	User accounts with electronic prescribing capability SHALL contain the user's: <ul style="list-style-type: none"> <li>• Full Name;</li> <li>• PBS Prescriber Number, where they have one; and</li> <li>• Healthcare Provider Identifier - Individual (HPI-I).</li> </ul>	Yes	No
PRES-4A	User accounts with electronic prescribing capability SHALL contain the user's: <ul style="list-style-type: none"> <li>• Full Name;</li> <li>• PBS Prescriber Number, where they have one;</li> <li>• AHPRA Number (if known); and</li> </ul> User accounts with electronic prescribing capability SHOULD contain the user's: <ul style="list-style-type: none"> <li>• Healthcare Provider Identifier - Individual (HPI-I).</li> </ul>	No	Yes



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**Authentication and authorisation**

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PRES-5	<p>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:</p> <ul style="list-style-type: none"> <li>• Minimum password length;</li> <li>• Password composition;</li> <li>• Password retry limit (before lockout);</li> <li>• Password refresh interval (frequency with which new password must be created); and</li> <li>• Password reuse interval (period which must expire before a password may be reused).</li> </ul> <p><i>Note: Healthcare organisations shall have the support of the system in the implementation of access control policies.</i></p>	Yes	Yes
PRES-6	<p>The system SHALL automatically log off an account, or require re-authentication, after a period of inactivity defined by the healthcare organisation. The default inactivity period SHOULD NOT be longer than 10 minutes.</p> <p><i>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.</i></p>	Yes	Yes
PRES-7	<p>The system SHALL require the user to re-authenticate prior to submitting a Schedule 8 medicine.</p> <p><i>Note: Prescriptions for Controlled Drugs warrant additional measures to ensure that the prescription is being created by an authorised prescriber.</i></p>	Yes	Yes
PRES-8	<p>The system MAY automatically disable an account that has been inactive for a period defined by the healthcare organisation.</p> <p><i>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.</i></p>	Yes	Yes

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**Authentication and authorisation**

PRES-95	<p>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.</p> <p>If one or more of those products is not operating then the system SHALL NOT interact with the PDS.</p>	Yes	Yes
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*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
PRES-9	<p>The system SHALL, on request, generate a file or files that contain the information captured in the audit logs in human readable format.</p> <p><i>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".</i></p>	Yes	Yes
PRES-10	<p>The system SHALL maintain an audit log of logon, logoff, stage-change and credential change activity for all user accounts.</p> <p><i>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).</i></p>	Yes	Yes

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**Audit**

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PRES-38	<p>The system SHALL record each electronic prescription generated in an audit log. The details of the record shall include:</p> <ul style="list-style-type: none"> <li>• Date and time of prescription creation (time and time zone);</li> <li>• The Globally Unique Prescription Identifier;</li> <li>• The Delivery Service Prescription Identifier (DSPID);</li> <li>• Date and time receipt acknowledged by the PDS (time and time zone) if applicable; and</li> <li>• All information related to the electronic prescription.</li> </ul> <p><i>Note: Some direct PDS may not have an acknowledgement. This will be determined by the architecture and technical solution.</i></p>	Yes	Yes
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PRES-39	<p>The system SHALL record each electronic prescription cancellation request in the audit log. The details of the record shall include:</p> <ul style="list-style-type: none"> <li>• Date and time of cancellation (time and time zone);</li> <li>• The Globally Unique Prescription Identifier;</li> <li>• The Delivery Service Prescription Identifier (DSPID);</li> <li>• Date and time of acknowledgement (time and time zone) if applicable; and</li> <li>• The success (or otherwise) of the cancellation.</li> </ul> <p><i>Note: Cancellation is used to reflect that the prescription was created in error, not that it has been ceased or has expired.</i></p> <p><i>Note: Some direct PDS may not have an acknowledgement. This will be determined by the architecture and technical solution.</i></p>	Yes	Yes
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**User Selection**

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

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<b>User Selection</b>			
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.  <i>Note: For prescriber workflow efficiency. The intent is that the system should support early detection that the electronic prescribing process will not succeed.</i>	Yes	No
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).  <i>Note: Supports Subject of Care's choice. Furthermore, under Regulations, the medicines prescribed may require a paper prescription.</i>	Yes	No
PRES-14	When generating a paper prescription, the system SHOULD support the generation of an ETP message.  <i>Note: To maintain the efficiencies in pharmacy workflow and improved data quality enabled through the current use of ETP in support of paper prescriptions.</i>	Yes	No
PRES-15	When generating an Electronic Prescription, the system SHALL NOT issue an ETP message.  <i>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.</i>	Yes	Yes
PRES-16	The system SHALL NOT send the electronic prescription to more than one (1) PDS.  <i>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.</i>	Yes	Yes
<b>Composition</b>			
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

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**Composition**

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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
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PRES-80	When transmitting an electronic prescription, the software SHALL ensure sure that the transmission includes: <ul style="list-style-type: none"> <li>a) A meta-data component and</li> <li>b) A prescription component</li> </ul>	Yes	Yes
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*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: <ul style="list-style-type: none"> <li>a) Unencrypted when at rest and;</li> <li>b) Encrypted when in transit;</li> </ul>	Yes	Yes
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*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: <ul style="list-style-type: none"> <li>a) The unique prescription number for that prescription (Globally Unique Prescription ID) and;</li> <li>b) The Conformance ID for each information system used to generate, send, receive, store or otherwise process the electronic prescription and;</li> <li>c) Subject of Care Individual Healthcare Identifier - (IHI)</li> </ul>	Yes	Yes
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**Composition**

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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
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*Note: these identifiers are to be stored in the encrypted payload.*

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PRES-18	<p>The system SHALL also include, within an electronic prescription, at least the following information:</p> <ul style="list-style-type: none"> <li>• Healthcare Provider Identifier - Organisation (HPI-O) of the prescribing organisation;</li> <li>• Hospital Provider Number (HPN), if it exists;</li> <li>• Residential Aged Care Facility ID (RACFID), if it exists;</li> <li>• Subject of Care Date of Birth;</li> <li>• Subject of Care's address</li> <li>• The medicine name</li> <li>• The medicine strength</li> <li>• Maximum quantity authorised to dispense (in numbers and words if a controlled drug)</li> <li>• Directions for use</li> <li>• medicine form</li> <li>• Route of administration</li> <li>• Number of repeats (if applicable)</li> <li>• Minimum interval between repeats (if applicable) as per <ul style="list-style-type: none"> <li>○ Schedule 4B and 8 in NSW</li> <li>○ Schedule 8 in ACT, WA and NT</li> <li>○ Schedule 8 and 4D in TAS</li> </ul> </li> <li>• Prescriber specialist qualification (if not in the ACT)</li> <li>• Prescriber qualification (if in the ACT)</li> <li>• Prescription notes to record unusual dose, staged supply etc</li> <li>• Either the privacy notice or a reference to the privacy notice, but not both</li> </ul>	Yes	Yes
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*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.*

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**Composition**

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PRES-18A	The system SHALL also support and include (if applicable) in the electronic prescription:	Yes	Yes
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- 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.*

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PRES-18B	The system SHALL include or display, the following text into or with the electronic prescription as appropriate:	Yes	Yes
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- ‘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.*

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PRES-19	The system SHALL also include, within an electronic prescription, the following information:	Yes	No
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- Healthcare Provider Identifier - Individual (HPI-I) of the Prescriber.

*Note: see PRES-84.*

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<b>Composition</b>			
PRES-19A	The system SHALL include, within an electronic prescription, the following information:  <ul style="list-style-type: none"> <li>Healthcare Provider Identifier - Individual (HPI-I) of the Prescriber (if available);</li> </ul> <p><i>Note: also see PRES-84.</i></p>	No	Yes
<del>PRES-20</del>	<del>The system SHALL include Medicine Name as a SNOMED CT-AU (which includes the Australian Medicines Terminology) Codeable Value if a SNOMED code is available for that medicine.</del>  <p><del><i>Note: PBS claimable items will require a PBS code. Including an AMT code does not remove the need to also include a PBS code.</i></del></p>	<del>Yes</del>	<del>Yes</del>
<del>PRES-21</del>	<del>The system SHALL allow for the inclusion of Reason for prescribe (clinical indication) as a SNOMED CT-AU Codeable Value.</del>	<del>Yes</del>	<del>Yes</del>
PRES-21A	The system SHALL NOT require Reason for prescribe (clinical indication) as a SNOMED CT-AU Codeable Value.  <p><i>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.</i></p> <p><i>Related requirements: PRES-21, PRES-22, PRES-49, PRES-53.</i></p>	Yes	Yes
PRES-22	Irrespective of the inclusion of any codeable values, the system SHALL include all information fields presented to the prescriber in "Original Text".  <p><i>Note: The clinical/supervising pharmacist sees the instructions as displayed to the prescriber when the prescriber wrote the prescription.</i></p> <p><i>"Original Text" is defined as the text "exactly as presented to the prescriber or dispenser".</i></p>	Yes	Yes
PRES-49	Where the Reason for prescribe (clinical indication) is included as a coded value, the system SHALL also include Reason for prescribe as a text (human readable) field.	Yes	Yes

<b>Composition</b>			
PRES-53	<p>The system SHALL allow capture of Reason for prescribe (clinical indication) as a text field if no coded value is provided.</p> <p><i>Note: Reason for prescribe may not be easily defined or may cover more than one drop down menu option.</i></p> <p><i>Related requirements: PRES-21, PRES-21A.</i></p>	Yes	Yes
PRES-54	<p><del>When creating an electronic prescription that is not chart-based, the system SHALL establish whether the SoC has registered for participation in an Active Script List by polling the ASL Registry Services using the SoC's IHI number, given name and family name.</del></p>	Yes	No
PRES-55	<p><del>If the SoC is registered with an Active Script List Registry, the system MAY allow the prescriber to indicate, following conversation with the SoC, whether the electronic prescription is to be included on the SoC's Active Script List.</del></p>	Yes	No
PRES-56	<p>The system SHALL capture an indication from the prescriber if the electronic prescription is confirmation of a verbal authority for an urgent case/supply.</p> <p><i>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.</i></p> <p><i>NOTE: The three day supply that a pharmacist may provide as emergency supply is out of scope for electronic prescriptions.</i></p>	Yes	No
PRES-56A	<p>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).</p>	Yes	No

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**Composition**

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PRES-57	<p>The system <del>SHOULD</del> also include, within an electronic prescription, the following data element(s):</p> <ul style="list-style-type: none"> <li><del>• ASL Consent Indicator</del></li> <li><del>• ASLR Identifier</del></li> </ul> <p>If:</p> <ul style="list-style-type: none"> <li><del>• the SoC is registered with an Active Script List Registry;</del></li> <li><del>AND</del></li> <li><del>• the prescriber and SoC have not determined that the electronic prescription should not be added to the SoC's Active Script List; AND</del></li> <li><del>• the prescription is NOT a confirmation of a verbal authority for urgent or emergency supply;</del></li> </ul> <p><i>NOTE: That is, the prescription SHOULD BE added to the ASL.</i></p>	Yes	No
PRES-62	<p>The system SHALL include one and only one prescription line item within each electronic prescription.</p> <p><i>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.</i></p>	Yes	No

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**Finalisation**

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Reference	Requirement	Open PDS	Direct PDS
PRES-42	<p>After submitting an electronic prescription to an Open PDS, the system SHALL:</p> <ul style="list-style-type: none"> <li>• Print Evidence of Prescription (including the Token) in paper form; and/or</li> <li>• Facilitate the transmission of Evidence of Prescription (including the Token) to an electronic address in electronic form.</li> </ul> <p><i>Note: Electronic prescriptions are limited to one line item, and it is required that an Evidence of Prescription is produced for each Electronic Prescription.</i></p> <p><i>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)</i></p>	Yes	No
PRES-43	<p>If the Evidence of Prescription is printed, the Token SHALL be printed as a Barcode/QR Code.</p>	Yes	No

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<b>Finalisation</b>			
PRES-44	<p>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.</p> <p><i>Note: In the event that the Token is unable to be scanned, a user may enter the DSPID manually.</i></p>	Yes	No
PRES-45	<p>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.</p> <p><i>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.</i></p>	Yes	No
PRES-46	<p>Where Evidence of Prescription is sent in electronic form (e.g. SMS, email), the system SHALL transmit at least:</p> <ul style="list-style-type: none"> <li>• The electronic token or URI (e.g. URL) linking to the electronic token;</li> <li>• The initials of the Name of the Subject of Care;</li> <li>• The Subject of Care’s date of birth (optional); and</li> <li>• Medicine name.</li> </ul> <p><i>Note: In the event that the electronic address was incorrectly recorded, this limits the potential for exposing personal information to an unknown party.</i></p>	Yes	No
PRES-46A	<p>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.</p> <p><i>Note: In the event that the electronic address was incorrectly recorded, this limits the potential for exposing personal information to an unknown party.</i></p>	Yes	Yes
PRES-46B	<p>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.</p> <p><i>Note: The address that will be used should be conveniently displayed so the prescriber can confirm this verbally or by display.</i></p>	Yes	No

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**Finalisation**

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PRES-47	<p>Where Evidence of Prescription is provided in paper form, the system SHALL include the following details:</p> <ul style="list-style-type: none"> <li>• Indication that this is an Evidence of Prescription (e.g. Not a dispensable prescription);</li> <li>• Token (Barcode/QR Code and DSPID);</li> <li>• Name of the Subject of Care;</li> <li>• Name of the prescriber;</li> <li>• Name of the prescriber organisation;</li> <li>• Contact details of the prescriber and / or prescribing organisation;</li> <li>• Medicine(s) name, strength;</li> <li>• Date prescribed;</li> <li>• Number of repeats available; and</li> <li>• Privacy notice.</li> </ul> <p><i>Note: The privacy notice can be provided by Services Australia.</i></p>	Yes	No
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PRES-48	<p>Where Evidence of Prescription is provided in paper form, the system SHALL NOT include the following details:</p> <ul style="list-style-type: none"> <li>• Subject of Care age;</li> <li>• Subject of Care sex;</li> <li>• PBS Prescriber number;</li> <li>• Authority number;</li> <li>• Form;</li> <li>• Dose (directions); or</li> <li>• Reason for prescribe.</li> </ul> <p>There SHALL NOT be a place for the prescriber to sign.</p> <p><i>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.</i></p> <p><i>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.</i></p> <p><i>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.</i></p>	Yes	No
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**Finalisation**

PRES-48A	<p>Where Evidence of Prescription is provided in electronic form, the system SHALL NOT include the following details:</p> <ul style="list-style-type: none"> <li>• Subject of Care name</li> <li>• Subject of Care age;</li> <li>• Subject of Care sex;</li> <li>• PBS Prescriber number;</li> <li>• Authority number;</li> <li>• Form;</li> <li>• Dose (directions); or</li> <li>• Reason for prescribe.</li> </ul> <p>There SHALL NOT be a place for the prescriber to sign.</p> <p><i>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.</i></p> <p><i>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.</i></p> <p><i>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.</i></p> <p><i>Note: PRES-46 requires the subject of care's initials (not full name).</i></p>	Yes	No
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PRES-50	<p>Where the Evidence of Prescription is provided in paper form, the system SHALL provide a clear indication that it is not to be signed.</p> <p><i>Note: Evidence of Prescription must not be misconstrued by a dispenser as a legal prescription.</i></p>	Yes	No
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**Modification**

Reference	Requirement	Open PDS	Direct PDS
PRES-40	<p>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.</p> <p><i>Note: Supports current primary care workflow where the prescriber may review prescription details onscreen and want to make corrections prior to finalising.</i></p>	Yes	Yes

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**Modification**

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PRES-41	<p>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.</p> <p><i>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.</i></p> <p><i>Note: A prescription that has been dispensed cannot be corrected or cancelled. Outstanding repeats can still be cancelled – depending on PDS functionality.</i></p>	Yes	Yes
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**Submission**

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Reference	Requirement	Open PDS	Direct PDS
PRES-23	<p>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</p> <p><i>Note: NSW regulations require prescription details to be retained for at least two years.</i></p>	Yes	Yes
PRES-24	<p>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.</p> <p><i>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.</i></p> <p><i>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.</i></p> <p><i>Note: An action by the prescriber to “send” the electronic prescription is considered adequate confirmation of final approval.</i></p> <p><i>Note: It is recommended software conforms with National Guidelines for On-Screen Display of Medicines Information [ACSQHC2017] where practical.</i></p>	Yes	Yes

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<b>Submission</b>			
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). <i>Note: The Conformance Requirements will be updated if the approved authentication methods change.</i>	Yes	Yes
PRES-26	When connecting to a PDS over a public network, the system SHALL assert its identity to the PDS using Public Key Infrastructure (PKI). <i>Note: The Conformance Requirements will be updated if the approved authentication methods change.</i>	Yes	Yes
PRES-27	All transmission of electronic prescription information over public networks SHALL be encrypted using Australian Signals Directorate (ASD) approved cryptographic algorithms.	Yes	Yes
PRES-28	On submission to an Open PDS, the system MAY include in the electronic prescription header, the electronic address to which the PDS may send the Evidence of Prescription to the Subject of Care or their Agent. <i>Note: Subject to SoC consent.</i>	Yes	No
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 acknowledgement. This will be determined by the 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. <i>Note: Until the PDS acknowledges receipt, the SoC may not have a valid prescription in their possession.</i>	Yes	No



<b>Submission</b>			
PRES-33	<p>When creating an electronic prescription, the system SHALL allow the user to abort submission of the electronic prescription prior to acknowledgement of receipt.</p> <p><i>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.</i></p> <p><i>The required outcome is that there should be no electronic prescription in the PDS if the prescriber elects to stop the electronic prescribing process and revert to paper. This should be achieved by queuing and sending a cancellation to PDS.</i></p>	Yes	No
PRES-34	<p>The system SHALL allow the user to issue a cancellation of an electronic prescription after acknowledgement of receipt by the PDS.</p> <p><i>Note: It is understood that the cancellation may not take effect if the electronic prescription has already been filled or transferred to another PDS.</i></p> <p><i>Note: Some direct PDS may not have an acknowledgement. This will be determined by the architecture and technical solution.</i></p>	Yes	Yes
PRES-35	<p>Upon cancellation, the system SHALL issue a cancellation message to the PDS.</p>	Yes	Yes
PRES-36	<p>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".</p>	Yes	No
PRES-37	<p>The system, in the event of an AORT, SHALL automatically:</p> <ol style="list-style-type: none"> <li>1 alert the user, and</li> <li>2 cancel the electronic prescription, and</li> <li>3 proceed with printing a paper prescription.</li> </ol>	Yes	No
<b>Active Script List Assisted Registration</b>			
Reference	Requirement	Open PDS	Direct PDS
PRES-58	<p>The system MAY provide assisted registration functionality to support a Subject of Care register for an Active Script List.</p>	Yes	No

**Active Script List Assisted Registration**

PRES-59	<p>If the system provides assisted registration functionality, when the prescriber or dispenser clicks the Active Script List registration icon within the patient record in their Clinical Information System, the prescribing system SHALL launch a registration screen, pre-populated with the Subject of Care's locally stored personal information, including (where available):</p> <ul style="list-style-type: none"> <li>● IHI number (which must be "verified" and "active")</li> <li>● Family name</li> <li>● Given name</li> <li>● Date of birth</li> <li>● Sex<sup>1</sup></li> <li>● Address</li> <li>● Mobile phone number</li> <li>● Email address</li> <li>● DVA file number</li> <li>● Medicare number</li> <li>● Medicare IRN (if Medicare card number provided)</li> </ul>	Yes	No
PRES-60	<p>If the system provides assisted registration functionality, the prescribing system SHALL launch a screen that captures details of individuals that the Subject of Care authorises to collect electronic prescriptions on their behalf. Information captured should include:</p> <ul style="list-style-type: none"> <li>● Family name</li> <li>● Given name</li> <li>● Address</li> <li>● Telephone number (if available)</li> <li>● Email address (if available)</li> </ul>	Yes	No

<sup>1</sup> The Conformance Profile has aligned to the HI service requirement to use the term Sex, to avoid potential confusion should a system be able to hold both Sex and Gender.

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**Active Script List Viewing**

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Reference	Requirement	Open PDS	Direct PDS
<del>PRES-61</del>	<p>The system MAY provide the ability for the prescriber to view the Subject of Care's Active Script List. If the SoC has registered for participation in an Active Script List (refer to PRES-54), and the prescriber details are associated with the Subject of Care's active script list and their access status is current and active, the prescriber is authorised to view the Subject of Care's active script list.</p> <p><i>Note: Related requirement ASLR-18</i></p>	Yes	No
PRES-61A	<p>If the system does provide the ability for the prescriber to view the Subject of Care's Active Script List, the system SHALL display details of the SoC's active prescriptions, including:</p> <ul style="list-style-type: none"> <li>• Medicine(s) name, strength;</li> <li>• Date prescribed;</li> <li>• Number of repeats available</li> <li>• The system MAY display additional details such as: <ul style="list-style-type: none"> <li>• Name of the prescriber;</li> <li>• Name of the prescriber organisation;</li> <li>• Contact details of the prescriber and / or prescribing organisation;</li> </ul> </li> </ul>	Yes	No

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## 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).

<b>Authentication and authorisation</b>			
<b>Reference</b>	<b>Requirement</b>	<b>Open PDS</b>	<b>Direct PDS</b>
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).  <i>Note: Conformance requirements will be updated if the approved authentication methods change.</i>	Yes	Yes
DISP-3	Where the system interacts with the PDS over a public network, the system SHALL ensure that all information sent over the public network is encrypted using Australian Signals Directorate (ASD) approved cryptographic algorithms.	Yes	Yes
DISP-4	The system SHALL provide single factor, multi-stage, or multi-factor authentication on all user accounts.  <i>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).</i>	Yes	Yes
DISP-5	The system SHALL allow access to the capability for dispensing against electronic prescriptions only to designated user accounts.  <i>Note: Only users designated by the healthcare organisation as having dispensing rights may access electronic prescribing capability.</i>	Yes	Yes

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**Authentication and authorisation**

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DISP-6	<p>The system SHALL record the following information with each account:</p> <ul style="list-style-type: none"> <li>• Full Name;</li> <li>• AHPRA Number (if any);</li> <li>• HPI-I (if any); and</li> <li>• User Class: Pharmacist, Supervising Pharmacist, Pharmacy Technician, etc.</li> </ul> <p><i>Note: The user classes available in the system is a software design decision and should reflect real world occupations/business practices.</i></p>	Yes	No
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DISP-6A	<p>The system SHALL record the following information with each account:</p> <ul style="list-style-type: none"> <li>• Full Name;</li> <li>• AHPRA Number (if any); and</li> <li>• User Class: Pharmacist, Supervising Pharmacist, Pharmacy Technician, etc.</li> <li>• The system SHOULD record the following information with each account:</li> <li>• HPI-I (if any).</li> </ul> <p><i>Note: The user classes available in the system is a software design decision and should reflect real world occupations/business practices.</i></p>	No	Yes
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DISP-7	<p>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:</p> <ul style="list-style-type: none"> <li>• Minimum password length;</li> <li>• Password composition;</li> <li>• Password retry limit (before lockout);</li> <li>• Password refresh interval (frequency with which new password must be created); and</li> <li>• Password reuse interval (period which must expire before a password may be reused).</li> </ul> <p><i>Note: Healthcare organisations shall have the support of the system in the implementation of their access control policies.</i></p>	Yes	Yes
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DISP-8	<p>The system SHALL facilitate the identification and recording of the identity of each user involved with dispensing activity.</p>	Yes	Yes
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<b>Authentication and authorisation</b>			
DISP-9	<p>The system SHALL facilitate the identification and recording of the identity of the dispenser authorising the dispensing activity.</p> <p><i>Note: the person authorising the dispense record to be submitted to the PDS needs to be identified and details captured.</i></p>	Yes	Yes
DISP-10	<p>The system SHALL automatically log off an account, or require re-authentication, after a period of inactivity defined by the healthcare organisation.</p> <p>The default inactivity period SHOULD NOT be longer than 10 minutes.</p> <p><i>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.</i></p>	Yes	Yes
DISP-53	<p>If the authorised dispenser identification is not present, the system SHALL NOT execute the dispense function.</p>	Yes	Yes
DISP-95	<p>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.</p> <p>If one or more of those products is not operating then the system SHALL NOT interact with the PDS.</p> <p><i>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.</i></p> <p><i>Note: 'operating' means it must be integrated into the system and active. Simply installing the product in an inactive state is not sufficient.</i></p> <p><i>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.</i></p>	Yes	Yes

<b>Audit</b>			
<b>Reference</b>	<b>Requirement</b>	<b>Open PDS</b>	<b>Direct PDS</b>
DISP-34	<p>The system SHALL maintain audit logs associated with electronic prescription dispense events in accordance with relevant legislation and regulation.</p> <p><i>Note: NSW regulations require audit logs to be retained for at least two years.</i></p>	Yes	Yes
DISP-35	<p>The system SHALL maintain an audit log of logon, logoff, stage-change and credential change activity for all user accounts.</p>	Yes	Yes
DISP-36	<p>The system SHALL record each dispense record generated in an audit log. The details of the record SHALL include:</p> <ul style="list-style-type: none"> <li>• Date and time of dispense record creation (time and time zone);</li> <li>• The Globally Unique Prescription Identifier;</li> <li>• The Delivery Service Prescription Identifier (DSPID);</li> <li>• Date and time receipt acknowledged by the Delivery Service (time and time zone); and</li> <li>• All information fields relevant to the dispense record.</li> <li>• All information fields relevant to the prescription record.</li> </ul> <p><i>Note: At a minimum, all elements required by State/Territory legislation in a dispensing record must be included.</i></p>	Yes	No
DISP-37	<p>The system SHALL record each dispense record cancellation request in the audit log. The details of the record SHALL include:</p> <ul style="list-style-type: none"> <li>• Date and time of Dispense cancellation (time and time zone);</li> <li>• The Globally Unique Prescription Identifier;</li> <li>• The Delivery Service Prescription Identifier (DSPID);</li> <li>• Date and time of acknowledgement from the Delivery Service (time and time zone); and</li> <li>• The success (or otherwise) of the cancellation.</li> </ul>	Yes	No

<b>Audit</b>			
DISP-51	<p>The system SHALL, on request, generate a file or files that contain at least the following information in human readable format:</p> <ul style="list-style-type: none"> <li>• The information in the original electronic prescription</li> <li>• The date and time the electronic prescription was retrieved from the PDS</li> <li>• The information in electronic repeat authorisations (including non-PBS)</li> <li>• All information in associated annotations</li> <li>• All information about token(s) associated to the prescription and its repeat authorisations</li> </ul> <p><i>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".</i></p>	Yes	Yes
DISP-52	<p>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.</p> <p><i>Note: Vendors may consider inclusion of a watermark.</i></p>	Yes	Yes
<del>DISP-61</del>	<p><del>The system SHALL maintain an audit log of access to Active Script Lists.</del></p> <p><del>This file SHALL include:</del></p> <ul style="list-style-type: none"> <li><del>• Date and time of access (time and time zone);</del></li> <li><del>• Subject of Care's IHI number;</del></li> <li><del>• User ID (from the dispensing system).</del></li> </ul>	<del>Yes</del>	<del>No</del>
<b>Retrieval</b>			
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



<b>Retrieval</b>			
DISP-11A	<p>The system SHALL support manual entry of an electronic prescription Token (i.e. entry of the DSPID).</p> <p><i>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.</i></p> <p><i>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.</i></p>	Yes	No
DISP-12	<p>The system SHOULD support accepting an electronic prescription Token electronically.</p> <p><i>Note: Some dispensing systems may allow a SoC to submit a Token electronically in advance of presentation to the dispenser.</i></p>	Yes	No
DISP-13	<p>The system SHALL provide visual indication to the user if it detects that the PDS is unreachable or unavailable.</p>	Yes	No
DISP-14	<p>The system SHALL NOT accept as an electronic prescription a message or transaction that does not include the:</p> <ul style="list-style-type: none"> <li>• Prescribing software conformance identifier;</li> <li>• originalRepositorySoftUniqueID; and,</li> <li>• RepositorySoftUniqueID.</li> </ul> <p><i>Note: Electronic prescriptions are only considered valid if they assert a Conformance ID.</i></p>	Yes	Yes
DISP-15	<p>The system SHALL accept all information relevant to an electronic prescription, including:</p> <ul style="list-style-type: none"> <li>• The original electronic prescription;</li> <li>• The most recent dispense (if any); and</li> <li>• All annotations (if any).</li> </ul>	Yes	Yes
DISP-62	<p>The system SHALL establish whether the SoC has registered for participation in an Active Script List by polling the ASL Registry Services using the SoC's IHI number, family name and given name.</p>	Yes	No

**Retrieval**

DISP-63	<p>If the SoC has registered for participation in an Active Script List (refer DISP-62), the system SHALL establish whether the dispenser is authorised to view the Active Script List. If the dispenser’s details are associated with the Subject of Care’s active script list and their access status is current and active, the dispenser is authorised.</p> <p><i>Note: The functionality supporting the granting of access to the dispenser is covered in ASLR-18.</i></p>	Yes	No
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DISP-64	<p>If the dispenser is authorised to view the SoC’s Active Script List, and the SoC wishes to proceed with accessing supply via the Active Script List, the system SHALL allow the dispenser to indicate one or more electronic prescriptions on the Active Script List that are to be dispensed. For each electronic prescription indicated, the system SHALL capture the DSPID of that electronic prescription.</p> <p><i>Note: Dispensing functionality then follows standard flow, using the DSPID captured as equivalent to the token captured in DISP-12.</i></p>	Yes	No
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**Presentation**

Reference	Requirement	Open PDS	Direct PDS
DISP-16	<p>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:</p> <ul style="list-style-type: none"> <li>• Details of the original prescription;</li> <li>• The prescription status (i.e active);</li> <li>• Details of the previous dispense (if any); and</li> <li>• The details of any annotations in relation to the prescription recorded by previous dispensers (if any).</li> </ul> <p><i>Note: The above requirement details the minimum system requirements. Vendors may choose to display additional details.</i></p> <p><i>Note: Displaying the original prescription supports the dispenser checking process.</i></p>	Yes	Yes

<b>Presentation</b>			
DISP-16A	<p>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.</p> <p><i>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.</i></p>	Yes	Yes
DISP-17	<p>The system SHALL display all data elements as displayed to the prescriber, irrespective of the presence or otherwise of coded information fields.</p>	Yes	Yes
DISP-18	<p>The system SHALL provide a clear visual indication to the user that the prescription is an electronic prescription.</p> <p><i>Note: It must be made clear to the dispenser that this information represents the legal form.</i></p>	Yes	Yes
DISP-60	<p>The system SHOULD clearly indicate to the user if the prescriber has specified that brand substitution not allowed.</p> <p><i>Note: This is easily distinguished on an existing paper prescription. The dispenser should be directed to this value on an electronic prescription.</i></p>	Yes	Yes
DISP-56	<p>The system SHALL provide a mechanism to support a dispense final check-off process in the absence of a paper prescription.</p> <p><i>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.</i></p>	Yes	Yes
DISP-58	<p>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.</p>	Yes	No

<b>Finalisation</b>			
<b>Reference</b>	<b>Requirement</b>	<b>Open PDS</b>	<b>Direct PDS</b>
DISP-30	<p>The system SHALL be able to print an Evidence of Prescription for the Subject of Care that details the medicine(s) prescribed where there are remaining repeats.</p> <p>The system SHALL include the following details:</p> <ul style="list-style-type: none"> <li>• Indication that this is an Evidence of Prescription (e.g. Not for Dispense);</li> <li>• DSPID (as a Barcode/QR Code);</li> <li>• DSPID (as a number);</li> <li>• Name of the Subject of Care;</li> <li>• Name of the prescriber;</li> <li>• Name of the prescriber organisation;</li> <li>• Contact details of the prescriber / organisation;</li> <li>• Date prescribed;</li> <li>• Dispenser (pharmacy) contact;</li> <li>• Medicine(s) name and strength;</li> <li>• Date dispensed; and</li> <li>• Number of repeats available.</li> </ul>	Yes	No

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**Finalisation**

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DISP-90	<p>Where Evidence of Prescription is provided in paper form, the system SHALL NOT include the following details:</p> <ul style="list-style-type: none"> <li>• Subject of Care age;</li> <li>• Subject of Care sex;</li> <li>• PBS Prescriber number;</li> <li>• Authority number;</li> <li>• Form;</li> <li>• Dose (directions); or</li> <li>• Reason for prescribe.</li> </ul> <p>There SHALL NOT be a place for the prescriber to sign.</p> <p><i>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.</i></p> <p><i>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.</i></p> <p><i>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.</i></p>	Yes	No
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DISP-31	<p>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.</p> <p>Where an Evidence of Prescription is sent in electronic form (e.g. SMS, email), the system SHALL transmit at least:</p> <ul style="list-style-type: none"> <li>• URI (e.g. URL) linking to the electronic token;</li> <li>• The initials of the Name of the Subject of Care;</li> <li>• The Subject of Care's date of birth (optional); and</li> <li>• Medicine name.</li> </ul> <p><i>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.</i></p>	Yes	No
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Finalisation			
DISP-91	<p>Where Evidence of Prescription is provided in electronic form, the system SHALL NOT include the following details:</p> <ul style="list-style-type: none"> <li>• Subject of Care name</li> <li>• Subject of Care age;</li> <li>• Subject of Care sex;</li> <li>• PBS Prescriber number;</li> <li>• Authority number;</li> <li>• Form;</li> <li>• Dose (directions); or</li> <li>• Reason for prescribe.</li> </ul> <p>There SHALL NOT be a signature box.</p> <p><i>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.</i></p> <p><i>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.</i></p> <p><i>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.</i></p> <p><i>Note: DISP-31 requires the subject of care's initials (not full name).</i></p>	Yes	No
DISP-31A	<p>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.</p> <p><i>Note: In the event that the electronic address was incorrectly recorded, this limits the potential for exposing personal information to an unknown party.</i></p>	Yes	No
DISP-31B	<p>Where an Evidence of Prescription is sent in electronic form, the system SHALL default delivery to the electronic address specified in the electronic prescription.</p> <p><i>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.</i></p>	Yes	No

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**Finalisation**

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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
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If the PDS is unavailable, the Dispense Notice SHALL be queued and repeatedly retried until successfully delivered.

DISP-33	The system SHALL be able to record receipt of supply. <i>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.</i>	Yes	Yes
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**Modification**

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Reference	Requirement	Open PDS	Direct PDS
DISP-59	Post finalisation, where a dispense record has been sent to the PDS, the system SHALL provide a mechanism for the dispenser to correct a dispense record if the dispenser needs to. <i>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.</i> <i>Note: a "cancel" operation followed by a "create" operation is an acceptable mechanism provided the system automatically and instantly creates the subsequent "create" request. It is unacceptable for the onus for the subsequent "create" request to fall on the local user.</i> <i>Vendors will need to understand what operations the PDS will support.</i>	Yes	Yes

<b>Submission</b>			
<b>Reference</b>	<b>Requirement</b>	<b>Open PDS</b>	<b>Direct PDS</b>
DISP-19	<p>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:</p> <ul style="list-style-type: none"> <li>• Dispense software conformance identifier;</li> <li>• Globally Unique Prescription ID recorded in the original prescription;</li> <li>• Date of the dispense</li> <li>• Name of the pharmacy</li> <li>• Address of the pharmacy</li> <li>• Pharmacist surname</li> <li>• HPI-O of the dispensing organisation</li> <li>• Medicine generic name dispensed (if known)</li> <li>• Medicine brand name dispensed (if known)</li> <li>• Unique identifier for the medicine dispensed if known (i.e. AMT, PBS code, or both)</li> <li>• Form, strength and quantity dispensed</li> <li>• Subject of Care Date of Birth as recorded in the original prescription</li> <li>• Subject of Care address (if in South Australia)</li> <li>• The total number of repeats dispensed (if dispensing against a repeat authorisation)</li> </ul>	Yes	No
DISP-20	<p>The system SHOULD include the following fields in a dispense record to the PDS:</p> <ul style="list-style-type: none"> <li>• HPI-I of the authorising dispenser;</li> <li>• AMT coded value of medicine supplied;</li> <li>• Subject of Care Individual Healthcare Identifier (IHI) number; and</li> <li>• Subject of Care electronic communication address.</li> </ul> <p>The SoC electronic communication address SHOULD default to the address stored in the original prescription.</p> <p><i>Note: The dispense record might contain a different address if the SoC prefers.</i></p>	Yes	No
DISP-21	<p>The system SHALL NOT allow an electronic prescription dispense record to be submitted to the PDS without the existence of the original electronic prescription.</p> <p><i>Note: This avoids "orphan" dispense records in the PDS.</i></p> <p><i>Note: Supply under continued dispensing provisions will not be notified to the PDS using an Electronic Dispense Record.</i></p>	Yes	No



<b>Submission</b>			
DISP-22	The system SHALL be able to send a message reflecting an annotation to the PDS as part of the dispense activity.	Yes	No
DISP-23	The system MAY determine that the PDS is unavailable and alert the dispenser.	Yes	Yes
DISP-24	<p>If an item is not dispensed, the system SHALL restore the state of the electronic prescription in the Open PDS.</p> <p><i>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.</i></p> <p><i>There may be instances where a dispenser is required to abandon a dispense event prior to a dispense notice being posted to the PDS (for example, the dispenser is out of stock). In this instance, following the dispense event ceasing, the electronic prescription record should be returned to an unlocked state. The outcome is that the prescription is valid for dispense.</i></p> <p><i>Related requirement: DS-17.</i></p>	Yes	No
DISP-25	<p>The system SHALL communicate a dispense reversal to the Open PDS.</p> <p><i>Note: There may be instances where a dispenser is required to reverse a dispense event after a dispense notice has been posted to the Open PDS (for example, SoC declines supply). In this instance, following the dispense event, the dispenser is required to reverse the dispense event and return the electronic prescription record to an unlocked state. The outcome is that the prescription is valid for dispense.</i></p> <p><i>Related requirement DS-19.</i></p>	Yes	No
DISP-27	The system SHALL record the date and time (time and time zone) that the PDS acknowledged receipt of the dispense record.	Yes	No
DISP-28	The system SHALL record the date and time (time and time zone) that the PDS acknowledged receipt of the dispense cancellation or reversal.	Yes	No
DISP-29	If the PDS is unavailable / unresponsive, the system SHALL queue messages and retry until the PDS acknowledges receipt.	Yes	No

<b>Submission</b>			
DISP-50	<p>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.</p> <p><i>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.</i></p>	Yes	Yes
DISP-57	<p>On submission to an Open PDS, the system MAY include, in the dispense notice header, the electronic address to which the Open PDS may send the Evidence of Prescription to the Subject of Care or their Agent.</p> <p><i>Note: Subject to SoC consent.</i></p>	Yes	No
<b>Reconciliation<sup>2</sup></b>			
Reference	Requirement	Open PDS	Direct PDS
DISP-38	<p>The system SHALL allow a DSPID to be manually entered into an electronic dispense record.</p> <p><i>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.</i></p>	Yes	Yes
DISP-38A	<p>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.</p>	Yes	Yes
DISP-39	<p>The system SHOULD allow a user to request reconciliation of a manually entered dispense record with the electronic prescription retrieved from the PDS.</p>	Yes	Yes

<sup>2</sup> 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.

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**Reconciliation<sup>2</sup>**

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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
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DISP-43	Once the electronic prescription has been retrieved, the system SHALL allow the Dispenser to mark the Dispense Record as: <ul style="list-style-type: none"> <li>Reconciled.</li> </ul> <p><i>Note:</i> A dispense record that is reconciled is not prohibited from having annotations in-line with normal dispensing processes.</p>	Yes	Yes
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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. <p><i>Note:</i> 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.</p>	Yes	No
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**Active Script List Assisted Registration**

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Reference	Requirement	Open PDS	Direct PDS
DISP-66	The system SHOULD provide assisted registration functionality to support a Subject of Care register for an Active Script List.	Yes	No

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**Active Script List Assisted Registration**

DISP-67	<p>If the system provides assisted registration functionality, when the prescriber or dispenser invokes the Active Script List registration function within the patient record in their Clinical Information System, the dispensing system SHALL launch a registration screen, pre-populated with the Subject of Care's locally stored personal information, including (where available):</p> <ul style="list-style-type: none"> <li>● IHI number (which should be "verified" and "active")</li> <li>● Family name</li> <li>● Given name</li> <li>● Date of birth</li> <li>● Sex</li> <li>● Address</li> <li>● Mobile phone number</li> <li>● Email address</li> <li>● DVA file number</li> <li>● Medicare number</li> <li>● Medicare IRN (if Medicare card number provided)</li> </ul>	Yes	No
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DISP-68	<p>If the system provides assisted registration functionality, the system SHOULD launch a screen that captures details of individuals that the Subject of Care authorises to collect electronic prescriptions on their behalf. Information captured should include:</p> <ul style="list-style-type: none"> <li>● Family name</li> <li>● Given Name</li> <li>● Address</li> <li>● Telephone number (if available)</li> <li>● Email address (if available)</li> </ul>	Yes	No
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### 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.

<b>Authentication and authorisation</b>			
<b>Reference</b>	<b>Requirement</b>	<b>Open PDS</b>	<b>Direct PDS</b>
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). <i>Note: The system will not accept connections from unknown participants.</i> <i>Conformance requirements will be updated if the approved authentication methods change.</i>	Yes	Yes

<b>Audit</b>			
<b>Reference</b>	<b>Requirement</b>	<b>Open PDS</b>	<b>Direct PDS</b>
DS-22	<p>The system SHALL record each transaction in an audit log. The details of the record SHALL include:</p> <ul style="list-style-type: none"> <li>• Date and Time of creation (<del>time and time zone</del>);</li> <li>• Transaction type;</li> <li>• Transaction status (for example, "Accepted", "Rejected");</li> <li>• Reason for rejection (if rejected);</li> <li>• Identifier of submitting/requesting system;</li> <li>• The Globally Unique Prescription Identifier;</li> <li>• The Delivery Service Prescription Identifier (DSPID);</li> <li>• Date and time of acknowledged (<del>time and time zone</del>) if applicable; and</li> <li>• All information fields contained in the message metadata.</li> </ul> <p><i>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.</i></p> <p><i>Note: Some direct PDS may not have an acknowledgement. This will determined by the architecture and technical solution.</i></p> <p><i>Note: this requirement also applies to ASLR-based transactions — that is — when transacting with an ASLR.</i></p>	Yes	Yes
DS-22A	<p>The system SHALL, on request, generate a file or files that contain the information captured in the audit logs in human readable format.</p> <p><i>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".</i></p>	Yes	Yes

<b>Provision</b>			
<b>Reference</b>	<b>Requirement</b>	<b>Open PDS</b>	<b>Direct PDS</b>
DS-10	When a dispensing system retrieves an electronic prescription, the system SHALL be able to compile and provide all the relevant information including: <ul style="list-style-type: none"> <li>• Original electronic prescription;</li> <li>• Most recent dispense record; and</li> <li>• All annotations.</li> </ul>	Yes	No
DS-11	When a dispensing system retrieves an electronic prescription, the system SHALL lock that electronic prescription while the transaction is in progress to prevent multiple concurrent transactions.	Yes	No
DS-12	The system SHALL NOT aggregate and make available prescription information based on an IHI number <del>for purposes other than an Active Script List.</del> <i>Note: An IHI number shall be included in the metadata of the electronic prescription provided by the prescriber.</i>	Yes	No
<b>Submission</b>			
<b>Reference</b>	<b>Requirement</b>	<b>Open PDS</b>	<b>Direct PDS</b>
DS-4	The system SHALL accept electronic prescriptions from prescribing systems that provide a valid conformance id from an organisation with which they have a contractual agreement.	Yes	Yes
DS-5	The system SHALL provide an acknowledgement of receipt of an electronic prescription to the prescribing system. <i>Note: Some direct PDS may not have an acknowledgement. This will be determined by the architecture and technical solution.</i>	Yes	Yes
DS-6	The system SHALL define and use a Delivery Service prescription identifier (DSPID) format that will result in globally unique and distinguishable delivery service prescription identifiers.	Yes	No
DS-6A	The system SHALL define and use a DSPID format that will result in organisationally unique and distinguishable prescription identifiers.	No	Yes

<b>Submission</b>			
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).	Yes	No
DS-13	The system SHALL accept a notification of dispense against an electronic prescription.	Yes	No
DS-14	The system SHALL provide an acknowledgement of a Dispense Record to the dispensing system.	Yes	No
DS-15	The system SHALL accept an annotation made by a dispenser against an electronic prescription as part of the dispense event.	Yes	No
DS-16	The system SHALL provide an acknowledgement of receipt of an annotation to the dispensing system.	Yes	No
DS-17	<p>The system SHALL accept and process a notification of dispense cancellation.</p> <p><i>Note: There may be instances where a dispenser is required to abandon a dispense event prior to a dispense notice being posted to the PDS (for example, the pharmacy is out of stock). In this instance, following dispense event ceasing, the electronic prescription record should be returned to an unlocked state. The outcome is that the prescription is valid for dispense.</i></p> <p><i>Related requirement: DISP-24.</i></p>	Yes	No



Submission			
DS-19	<p>The system SHALL accept and process a notification of dispense reversal.</p> <p><i>Note: There may be instances where a dispenser is required to reverse a dispense event after a dispense notice has been posted to the PDS (for example, the SoC declines supply). In this instance, following dispense event, the dispenser is required to reverse the dispense event and return the electronic prescription record to an unlocked state. The outcome is that the prescription is valid for dispense.</i></p> <p><i>Related requirement: DISP-25.</i></p>	Yes	No
DS-20	<p>The system SHALL provide an acknowledgement of receipt of a dispense reversal to the dispensing system.</p> <p><i>Note: The system will cancel the dispense event and return the electronic prescription to its previous state.</i></p> <p><i>Related requirement: DISP-28.</i></p>	Yes	No
DS-21	<p>The system SHALL unlock an electronic prescription when the dispensing system releases it (unchanged).</p> <p><i>Note: Where an electronic prescription is released by the dispensing system without a dispense notice (i.e. not dispensed), the prescription shall be unlocked. That prescription shall be unchanged from that which was originally drawn down by the dispenser.</i></p>	Yes	No
DS-32	<p><del>Where the metadata of the electronic prescription indicates that the SoC has an Active Script List to which the electronic prescription should be added, the system SHALL pass an encrypted copy of the electronic prescription to the relevant Active Script List Registry.</del></p> <p><i>Note: The Active Script List Register does not ever hold the legal electronic prescription. That is retained in the PDS.</i></p>	Yes	No
DS-33	<p><del>Where any transaction received by the PDS relates to an electronic prescription linked to a SoC's Active Script List, the system SHALL pass an encrypted copy of the transaction to the relevant Active Script List Registry.</del></p> <p><i>Note: Other transactions may include dispense records, cancellation of electronic prescriptions or cancellation of dispense records.</i></p>	Yes	No

<b>PDS Connections</b>			
<b>Reference</b>	<b>Requirement</b>	<b>Open PDS</b>	<b>Direct PDS</b>
DS-27	The system SHALL facilitate the exchange of electronic prescriptions between other conformant open PDS operators.	Yes	No
DS-27A	The system MAY facilitate the exchange of electronic prescriptions between other conformant PDS operators.	No	Yes
DS-28	The PDS Operator SHALL have contractual arrangements in place that facilitate the exchange of electronic prescriptions and dispense information with all other conformant Open PDS operators. <i>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.</i>	Yes	No
DS-29	Each system SHALL manage the security process of a connecting PDS to facilitate the receipt and delivery of electronic prescriptions between PDSs.	Yes	No
DS-30	Where the system receives an electronic prescription from another PDS the system SHALL warrant that the privacy controls of the originating PDS are maintained during the delivery process to the requesting dispensing system.	Yes	No
DS-31	Where the system requests an electronic prescription from another PDS the system SHALL warrant that the requesting dispenser or other user is a registered and known end point and the system can assert the validity of the user.	Yes	No
<b>Data Integrity</b>			
<b>Reference</b>	<b>Requirement</b>	<b>Open PDS</b>	<b>Direct PDS</b>
DS-26	The system and the PDS Operator SHALL NOT change or manipulate the semantic content (metadata or encrypted payload) of any message. <i>Note: The format of the message may be changed as the content passes between PDSs.</i>	Yes	Yes

Privacy			
Reference	Requirement	Open PDS	Direct PDS
DS-24	<p>The system SHALL encrypt all electronic prescription data in transit over public network between all authorised end points and at rest.</p> <p><i>Note: End points are any organisation that submits or receives information to/from the PDS that has been authorised to do so.</i></p> <p><i>Note that all data "in transit over a public network" is to be encrypted. This includes both the metadata and electronic prescription payload.</i></p>	Yes	Yes
DS-25	<p>The system SHALL NOT expose the unencrypted payload to the operator or user of the PDS system when in normal operations.</p> <p><i>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.</i></p> <p><i>The system may need to expose unencrypted payloads internally for maintenance, fault finding, authorised investigations or by legal order.</i></p>	Yes	Yes
DS-25A	<p>The system SHALL NOT share the payload with other internal or external systems unless:</p> <ul style="list-style-type: none"> <li>• Those recipient systems are covered by legal regulatory frameworks (e.g. EP, MHR, RTPM) and/or;</li> <li>• Under a legal order/direction and/or;</li> <li>• There is explicit patient consent for read-only access to their personal and health data for healthcare reasons</li> </ul>	Yes	Yes
DS-81	<p>The meta-data component of every electronic prescription SHALL be:</p> <ul style="list-style-type: none"> <li>• Unencrypted when at rest and;</li> <li>• Encrypted when in transit;</li> </ul> <p><i>Note: the meta-data is designed to be available to electronic prescribing systems to assist those systems in the delivery of electronic prescriptions.</i></p> <p><i>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.</i></p>	Yes	Yes

**Privacy**

DS-82	<p>The prescription component (the payload) of the transmission SHALL be:</p> <ul style="list-style-type: none"> <li>a) Encrypted when at rest and</li> <li>b) Encrypted when in transit;</li> </ul> <p>EXCEPT when a conformant dispensing system requires the payload to be decrypted at rest for the purposes of dispensing that prescription.</p> <p><i>Note: Prescription information (the payload) is only available to dispensing systems for dispensing activities.</i></p>	Yes	Yes
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**Security**

Reference	Requirement	Open PDS	Direct PDS
DS-23	<p>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".</p>	Yes	Yes

### 3.4 Mobile Intermediary Systems

This section describes conformance requirements specific to electronic prescribing – mobile intermediary systems. A mobile intermediary is a system which manages communication between 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	<p>The system SHALL NOT provide electronic prescription information or dispense information to a non-conforming system.</p>	Yes	No
MI-2	<p>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).</p> <p><i>Note: The PDS will not accept connections from unknown participants.</i></p> <p><i>Conformance requirements will be updated if the approved authentication methods change.</i></p>	Yes	No

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**Authentication and authorisation**

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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
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**Audit**

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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. <i>Note: NSW regulations require prescription details to be retained for at least two years.</i>	Yes	No
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. <i>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".</i>	Yes	No

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**Retrieval**

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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. <i>Note: An IHI number shall be included in the metadata of the electronic prescription provided by the prescriber.</i>	Yes	No
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

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**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	Yes	No
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

**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. <i>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.</i>	Yes	No
MI-8	The mobile intermediary (or operator) SHALL NOT access the encrypted payload of any message without explicit consent. <i>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.</i>	Yes	No

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**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.  <i>Note: The PDS will not accept connections from unknown participants.</i>  <i>Examples include Google authenticator or RSA soft token.</i>	Yes	No

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### 3.5 Mobile Application Systems

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

- manage prescriptions;
- provide the capability to present or send prescription Tokens to a dispensary;
- ~~register for an Active Script List;~~
- manage authorised providers (prescribers and dispensers);
- manage authorised agents;
- manage personal details relevant to the application;
- ~~display active script list;~~
- ~~view audit trail of ASL access by authorised entities;~~
- forward prescription link to online or bricks and mortar pharmacies;
- ~~Pre-populate ASL with active prescriptions held in Open PDSs;~~
- ~~Create an electronic token for an ASL prescription item;~~
- ~~Hide/unhide prescription items on their ASL;~~
- Receive notifications for:
  - ~~ASL registrations;~~
  - Access requests (from prescribers, dispensers, or carers/agents);
  - ~~Electronic prescriptions are added to their ASL;~~
  - ~~Electronic prescriptions held on their ASL are dispensed;~~
  - ~~Their ASL is viewed (by prescribers, dispensers, or carers/agents)~~

*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.*

<b>Account Creation</b>	
<b>Reference</b>	<b>Requirement</b>
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.



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### Account Creation

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MA-5      The system SHALL provide adequate disclosure of terms and conditions.  
Note: In line with requirements under the Privacy Act 1988.

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MA-6      The system SHALL provide adequate disclosure of use of data.

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MA-7      If personal information is to be displayed, the system SHALL assure that the end user is authorised to view the personal information on the electronic prescription.  
*Note: The Mobile Application and Mobile Intermediary shall pay due diligence in assessing the users legitimate right to access electronic prescription information. The registered user of the mobile application is considered the end user in this instance.*

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### Account Deactivation

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

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

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Reference	Requirement
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MA-9	For an electronic prescription, the system SHALL render, at minimum: <ul style="list-style-type: none"><li>• The DSPID as a barcode/QR code.</li></ul> <i>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.</i>
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**Presentation**

- 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
PKI	Public Key Infrastructure

<b>Acronym</b>	<b>Description</b>
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

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## 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 Department of Human Services or the Department of Veterans' Affairs for restricted items that require electronic, phone or written authority approval. See also: <a href="http://www.pbs.gov.au/info/healthpro/explanatory-notes/section1/Section_1_2_Explanatory_Notes#Authority-PBS">http://www.pbs.gov.au/info/healthpro/explanatory-notes/section1/Section_1_2_Explanatory_Notes#Authority-PBS</a>
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 alphanumeric 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	<p>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 Department of Human Services for claiming purposes.</p> <p>Notes:</p> <p>This definition does not preclude the use of paper processes to support electronic prescribing activity.</p> <p>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.</p>
Electronic prescription	<p>Electronic clinical documents that contain all information relating to an order to supply medicine to an individual. An electronic prescription is generated electronically by a prescriber, authenticated, securely transmitted (either directly or indirectly) for dispensing and supply, integrated into dispensing software and, in the case of Pharmaceutical Benefits Scheme (PBS) prescriptions, available to be sent electronically to the Department of Human Services for claiming purposes.</p> <p>Note:</p> <p>This definition does not preclude the use of other processes or artefacts to support e-Prescribing.</p>
Electronic prescription metadata	<p>Each electronic prescription record and dispense record has two sections:</p> <ul style="list-style-type: none"> <li>• Metadata - that is decrypted within the Open PDS to support the technical operation of the system</li> <li>• Clinical content - the body of the record containing personal and sensitive information, which remains encrypted within the Open PDS.</li> </ul> <p>Together the metadata and the clinical content comprise the Electronic Prescription.</p> <p>The requirements for the prescription metadata are described in Section 8.1 of the Solution Architecture.</p>
Electronic transfer of prescription (ETP)	<p>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.</p>
Evidence of Prescription	<p>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.</p>

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Globally Unique Prescription Identifier	<p>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.</p> <p>Note: this may be a GUID/UID but need not be.</p>
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Hospital Provider Number (HPN)	Administered by Services Australia
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MAY	When appearing in a conformance requirement, the verb MAY indicates an optional requirement.
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Mobile Application	An application that provides a user the ability to manage electronic prescriptions via a personal device.
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Mobile Intermediary	Software used by mobile applications to interact with the electronic prescribing process.
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originalRepositorySoftUniqueID	<p>The conformance identifier of the PDS to which the original electronic prescription is loaded from the prescribing system.</p> <p>See also: RepositorySoftUniqueID</p>
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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.
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Prescriber	An individual who provides healthcare and who creates prescriptions in accordance with all relevant legislative, regulatory and professional requirements.
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Prescription	A written direction from a registered health provider to a supplier for preparing and dispensing a drug [Oxford Medical Dictionary] [HIM].
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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.
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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.
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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.
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.

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## Appendix A Example printed Evidence of Prescription

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

### Summary<sup>†</sup> of electronic prescription for **John Citizen**

#### **Lipitor 20mg**

Details	
Prescribed Date	dd/mm/yyyy
Repeats Authorised	#

<sup>†</sup>This is an electronic prescription token only. The legal prescription must be downloaded for dispensing.

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

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



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NOT TO BE SIGNED

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