Australian Government
Australian Digital Health Agency

Electronic Prescribing
Medication Chart Prescribing Systems Conformance Profile

6 August 2024 v3.0.1

Approved for external use
Document ID: DH-3941:2024

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Acknowledgements
The Australian Digital Health Agency is jointly funded by the Australian Government and all state and territory governments.

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Product or document version history

Product or document version	Date	Release comments
V3.0.1	06/08/2024	Derived from Electronic Prescribing Connecting Systems Conformance Profile v3.0.1

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1 Introduction

1.1 Purpose

This document summarises the functional and non-functional requirements for medication chart prescribing software systems that is used by authorised prescribers and supports participation in electronic prescribing by connecting to the National Prescription Delivery Service (NPDS).

This document lists the specific conformance requirements for medication chart prescribing systems that must or should be met to support participation in electronic prescribing by connecting to the NPDS. These requirements build on those that have already been implemented to support Electronic Transfer of Prescription (ETP).

1.2 Intended audience

The intended audience includes:

- Software developers:
    - Medication chart prescribing system developers
    - National Prescription Delivery Service and Active Script List Registry (ASLR) software developer
- Australian Government Department of Health and Aged Care
- State and territory government health departments and agencies
- Services Australia
- Australian Commission on Safety and Quality in Healthcare.

2 Scope

- Systems able to participate in electronic prescribing may include prescribing systems for general electronic prescriptions and medication chart-based electronic prescriptions, the NPDS and ASLR Service, Direct Prescription Delivery Services (Direct PDS), dispensing systems, and consumer (mobile/web) applications.
    - *Medication chart-based (chart-based) electronic prescription:* A chart-based electronic prescription is generated from an active electronic medication chart via the conformant electronic medication chart prescribing system. The chart-based electronic prescriptions will have chart identifier which is used to group one or more chart-based electronic prescriptions from the same medication chart.
    - *General electronic prescription:* A general electronic prescription is generated from a conformant electronic prescribing system and does not have a chart identifier. These electronic prescriptions are also referred as 'non-chart-based' electronic prescriptions.
- This document is limited to discussing functional and non-functional requirements related to medication chart prescribing systems that have the capability to generate medication chart-based electronic prescriptions to participate in prescription exchange for the purpose of electronic prescribing by connecting to the NPDS.
- The medication chart prescribing systems that have the capability to generate general electronic prescriptions should refer to functional and non-functional requirements listed in the *Electronic Prescribing - General Prescribing Systems and Other Connecting Systems Conformance Profile v3.0.1*
- Functional and non-functional requirements related to other electronic prescribing connecting systems participating in electronic prescription are detailed in *Electronic Prescribing - General Prescribing Systems and Other Connecting Systems Conformance Profile v3.0.1*
- Functional and non-functional requirements related to National Prescription Delivery Service and Active Script List Registry Service are detailed in *Electronic Prescribing – National Prescription Delivery Service and Active Script List Registry Service Conformance Profile v3.1*
- 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 5 broad areas covering the activities performed by a:

- Prescriber
- Dispenser
- Subject of Care (or their Agents)
- Prescription Delivery Service
- Active Script List Registry Service.

Software developers 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.

Compliance with Commonwealth and State legislation and regulation

The prescribing of medicines under the Pharmaceutical Benefits Scheme is governed by a range of Commonwealth laws (such as the National Health Act 1953, the National Health (Pharmaceutical Benefits) Regulations 2017 and subordinate legislation and instruments) which define requirements for electronic prescriptions, electronic medication charts, and electronic medication chart prescriptions. Relevant legislation is outlined in section 4.3 of the Electronic Prescribing Solution Architecture v3.0 document.

Additionally, state and territory regulations also outline requirements for the electronic prescribing of medicines that must also be complied with. The indicative state and territory laws are listed at *https://www.health.gov.au/initiatives-and-programs/electronic-prescribing#state-and-territory-requirements.*

Further to the legislation that governs electronic prescribing systems and processes, the Australian Commission on Quality and Safety in Health Care define medicine safety and clinical safety standards that are to be considered for electronic prescribing systems and processes. Information on these standards can be found at: *Electronic medication management | Australian Commission on Safety and Quality in Health Care* and *Electronic medication charts | Australian Commission on Safety and Quality in Health Care*

3 Conformance requirements for Electronic Prescribing – Medication Chart Prescribing Systems

This section describes conformance requirements specifically for medication chart electronic prescribing systems that have the capability to generate chart-based electronic prescription and connect to the NPDS to participate in prescription exchange for the purpose of electronic prescribing.

National Prescription Delivery Service

A medication chart prescribing system will connect to the NPDS to enable end to end electronic prescription transactions for chart-based electronic prescriptions

3.1 Medication Chart Prescribing Systems

This section describes conformance requirements specific to medication chart prescribing systems that connect to the NPDS. A medication chart prescribing system is that which is capable of authoring a chart-based electronic prescription on behalf of an authorised prescriber. This software is often also a Clinical Information System (CIS) such as an Electronic Medication Management (EMM) system.

Authentication and authorisation

Reference	Requirement
PRES-1	The system SHALL provide single factor, multi-stage, or multi-factor authentication on all user accounts.
PRES-2	The system SHALL allow access to electronic prescribing capability only to designated user accounts. *Note: only users designated by the healthcare organisation as having prescribing rights may access the electronic prescribing capability.*
PRES-3	The system SHOULD provide multi-factor authentication on user accounts with electronic prescribing capability. *Note: as per Australian Cyber Security Centre (ACSC) recommendations.*
PRES-4	User accounts with electronic prescribing capability SHALL contain the user's: • Full Name • PBS Prescriber Number, where they have one • Healthcare Provider Identifier - Individual (HPI-I).

Reference	Requirement
PRES-5	Where only single factor or multi-stage authentication is provided, the system SHALL use strong authentication for users who have the permission to author an electronic prescription or view the patient's Active Script List. This is to be done by at least one of the following 3 approaches: 1. Give the healthcare organisations the ability to establish authentication parameters. Including, but not limited to: • Minimum password length • Password composition • Password retry limit (before lockout) • Password refresh interval (frequency with which new password must be created) • Password reuse interval (period which must expire before a password may be reused). 2. Require all users to have a strong password which permits the use of special characters with a minimum of: • Eight characters • One letter • One number. 3. Require all users to have passwords aligned to ISM Security Control 0417 and ISM Security Control 0421. *Note: healthcare organisations shall have the support of the system in the implementation of access control policies.* *Note: some Software-As-A-Service software are not able to adopt password policy at an organisational level and as such must ensure users have a strong password.*
PRES-6	The system SHALL automatically log off an account, or require re-authentication, after a period of inactivity. The period of inactivity SHALL be either: • configurable by the healthcare organisation AND the default SHOULD be no longer than 15min; or • a time period set by the software vendor no longer than 15 minutes. *Note: healthcare organisations need to be able to define a period of inactivity after which the prescriber's terminal may be considered unattended and vulnerable to misuse.* *Note: Software-as-a-Service providers may not be able to set time period for each organisation and as such may select a time period no longer than 15 minutes for all users.* *Note: healthcare organisation may choose not to enable this functionality where their corporate system addresses this requirement.*
PRES-7	The system SHALL require the user to re-authenticate prior to submitting a Schedule 8 medicine. *Note: prescriptions for Controlled Drugs warrant additional measures to ensure that the prescription is being created by an authorised prescriber. See also PRES-7A.*
PRES-7A	When the system requests re-authentication for a Schedule 8 medicine, the system SHOULD indicate the authentication is for a Schedule 8 medicine.

Reference	Requirement
PRES-8	The system MAY automatically disable an account that has been inactive for a period defined by the healthcare organisation. *Note: this measure is a 'backstop'. Healthcare organisations should implement de-provisioning or account disablement where the user leaves on a permanent or temporary basis.*
PRES-955	If the system is intended to integrate with the healthcare provider organisation's Authorisation Service (e.g. Single-Sign-On service), then the system SHOULD provide the capability for the healthcare provider organisation to disable application-level authentication. *Note: PRES-7 still applies when application-level authentication has been disabled.*
PRES-95	If the system is comprised of multiple products with different branding, or optional installation configurations, that are providing functionality that is tested as a part of conformance, to this conformance profile, then all of the products associated with the specific function need to be operating when transacting with NPDS and ASLR. If one or more of the products associated with the specific function is not operating, then the system SHALL NOT interact with the NPDS or ASLR. *Note: a system that is designed to work in a specific configuration is conformant only when implemented in that configuration. Exchanging Conformance IDs when it is in an alternate configuration or operating in isolation is a breach of the Conformance Assessment Scheme and the Electronic Prescribing legislation.* *Note: 'operating' means it must be integrated into the system and active. Simply installing the product in an inactive state is not sufficient.* *Note: the system will be tested with different configurations to ensure that interactions with NPDS and ASLR are permitted only when all products are operating and active.*
PRES-931	If the system stores passwords in any form, it SHALL ensure that the passwords are stored securely. This is to be done by: • not storing passwords as plain text • ensuring that passwords are stored with salt added and encrypted using an ASD approved hashing algorithm. *Note: it is recommended that salt is unique randomly generated.*
PRES-937	The system SHOULD check users' credentials with a known breached credentials service to ensure the credentials haven't been used in a previous data breach. *Note: a known breached credentials service is a service which provides either an API to check if a password has been included in a known data breach or a list of all known passwords included in known data breaches.*

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

Audit

Reference	Requirement
PRES-9	The system SHALL, on request, generate a file or files that contain the information captured in the audit logs in human readable format. *Note: this requirement permits the generation of a file or files that can be shared or sent to relevant regulatory bodies on request. 'Human readable formats' include text files, PDF files, log files or any other format that presents the required information 'in the clear'.*
PRES-10	The system SHALL maintain an audit log of logon, logoff, stage-change and credential change activity for all user accounts. *Note: stage-change is where an additional credential is required - for example a PIN is required to undertake a particular function. Credential change would be the change of the form of the credential or a change to the value (for example, password change).*
PRES-38	The system SHALL record each electronic prescription generated in an audit log. The details of the record shall include: • Date and time of prescription creation (time and time zone) • Globally Unique Prescription Identifier • Delivery Service Prescription Identifier (DSPID) • Date and time receipt acknowledged by the NPDS (time and time zone) if applicable • All information related to the electronic prescription. *Note: storing the audit log in a location that is NOT the main system would assist data recovery efforts if the main system is compromised or unavailable.*
PRES-39	The system SHALL record each electronic prescription cancellation request in the audit log. The details of the record shall include: • Date and time of cancellation (time and time zone) • Globally Unique Prescription Identifier • Delivery Service Prescription Identifier (DSPID) • Date and time of acknowledgement (time and time zone) if applicable • The success (or otherwise) of the cancellation.

Reference	Requirement
PRES-405	If the system provides ASL viewing capability, then the system SHALL maintain an audit log of access to Active Script Lists. The audit log SHALL include at least: • Date and time of access (time and time zone) • Subject of Care's IHI number • Organisation or site ID, or User ID (from the prescribing system) or both.

Cryptography

Reference	Requirement
PRES-81	Personal and sensitive information SHALL be encrypted when in transit.
PRES-25	When connecting to the NPDS over a public network, the system SHALL authenticate the identity of the NPDS using Public Key Infrastructure (PKI). *Note: the Conformance Requirements will be updated if the approved authentication methods change.*
PRES-26	When connecting to the NPDS over a public network, the system SHALL assert the identity of the organisation connecting the system to the NPDS. *Note: the Conformance Requirements will be updated if the approved authentication methods change.*
PRES-27	All transmissions of electronic prescription information over public networks SHALL be encrypted using Australian Signals Directorate (ASD) approved cryptographic algorithms.
PRES-938	The system SHOULD validate digital certificates. *Note: see Appendix B Implementation Advice for further implementation guidance.*
PRES-939	The system SHOULD encrypt information assets at rest using Australian Signals Directorate (ASD) approved cryptographic algorithms.

User Selection

Reference	Requirement
PRES-11	The system MAY provide for an option to enable / disable electronic prescribing capability on a per user account basis. *Note: some prescribers may elect not to participate in electronic prescribing and may not wish to be presented with electronic prescribing options.*
PRES-12	When creating a chart-based electronic prescription, the system SHOULD alert the user when it is aware that the National Prescription Delivery Service is unavailable or unreachable. *Note: for prescriber workflow efficiency. The intent is that the system should support early detection that the creation of electronic prescription process will not succeed immediately.*

Reference	Requirement
PRES-15	When generating a chart-based electronic prescription, the system SHALL NOT issue a paper prescription for the same chart item. *Note: A chart-based electronic prescription will be sent to the NPDS 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 chart item.*
PRES-16	The system SHALL NOT send the electronic prescription to both NPDS and directly to another system for dispensing. *Note: If an electronic prescription is sent to the NPDS, it must not be sent directly to a dispensing system via a closed system for dispensing and vice versa.*

Patient records

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

Composition

Reference	Requirement
PRES-17	The system SHALL include, within the electronic prescription, all data fields as required by Jurisdictional Regulations. *Note: Jurisdictional Regulations may change periodically.*
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.
PRES-72	The system SHALL include an IHI in an electronic prescription only if its status is 'active' and 'verified' in the prescribing system. *Note: this disallows a Prescribing System from using an IHI with another status such as 'deceased'.*
PRES-18	The system SHALL also include, within an electronic prescription, at least the following information: • Healthcare Provider Identifier - Organisation (HPI-O) of the prescribing organisation • Hospital Provider Number (HPN), if it exists • Residential Aged Care Facility ID (RACFID) or equivalent, if it exists • Subject of Care's Date of Birth • Subject of Care's address

Reference	Requirement
	• The medicine name • The medicine strength Either: • Maximum quantity authorised to dispense Or • The medicine dose, and • Frequency for use, and • The duration of use or cessation date (as an alternative to the quantity). • Directions for use • Medicine form • Route of administration • Closing the Gap code (if applicable) • Prescription notes to record unusual dose, staged supply etc • Either the privacy notice or a reference to the privacy notice, but not both. *Note: the data fields listed in the requirement are in addition to the mandatory fields as per the legislation and do not form the complete data set.* *Note: a reference to the privacy notice might be a clickable hyperlink, a URL or some other means to locate the privacy notice. The privacy notice can be provided by Services Australia.* *Note: unusual doses can be emphasised either in the dosage instructions, the prescriptions notes or by emphasising the dose at the point of rendering.* *Note: where the patient is attending a public hospital, private hospital, correctional health facility, children and youth services facility or residential care facility the address (subject of care address attribute) of the hospital or facility must be provided to ensure supply if in Tasmania. An additional address attribute is not required.* *Note: maximum quantity authorised can be provided in words in the notes.* *Note: Route can be provided in the directions.* *Note: DISP-50 requires dispensing systems to display the information in this requirement. Refer to Electronic Prescribing - General Prescribing Systems and Other Connecting Systems Conformance Profile v3.0.1 to gain full understanding of the requirement.* *Note: each line item in a chart represents a prescription and relevant attributes stored at a chart level need to be repeated for each line item when submitted to the NPDS/dispensing system.*
PRES-18A	The system SHALL also support and include (if applicable) in the electronic prescription: • Authorisation reference number (up to 25 characters alpha/numeric) • Prescriber specialist qualification (if not in the ACT) • Prescriber qualification (if in Qld, ACT) • The name of the pharmacy the prescription is to be dispensed (if required by NSW). The system SHALL present the Authorisation reference number as: • 'Authorisation number' in NSW and NT • 'Authority number' in WA and TAS • 'Approval number' in QLD and ACT

Reference	Requirement
	• 'Permit number' in SA • '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.* *Refer to Electronic Prescribing - General Prescribing Systems and Other Connecting Systems Conformance Profile v3.0.1to gain full understanding of the requirement.*
PRES-18B	The system SHALL include or display, the following text into or with the electronic prescription as appropriate: • 'for dental treatment only' • 'for midwifery use only' • 'for optometry use only' • 'for podiatric treatment only' • 'for treatment of foot conditions only' • 'for ocular treatment only' *Note: software is to insert/display text as appropriate.* *Note: this can be texted entered/provided by the local user creating the prescription and may appear in the prescription notes.* *Note: DISP-50 requires dispensing systems to display the information in this requirement.* *Refer to Electronic Prescribing - General Prescribing Systems and Other Connecting Systems Conformance Profile v3.0.1 to gain full understanding of the requirement.*

PRES-19	The system SHALL also include, within an electronic prescription, the following information:
	• Healthcare Provider Identifier - Individual (HPI-I) of the Prescriber
	• Unusual dose indicator (if applicable)
	• Minimum interval between repeats (if applicable) as per
	  • Schedule 4 Appendix B and Schedule 8 in NSW
	  • Schedule 8 in ACT, WA, Qld and NT
	  • Schedule 8 and 4D in TAS.
	Note: Schedule 4 Appendix B refers to the NSW Poisons and Therapeutic Goods Regulation 2008.

PRES-20	The system SHOULD include Medicine Name as a SNOMED CT-AU (which includes the Australian Medicines Terminology) Codable Value if a SNOMED code is available for that medicine.
PRES-21	The system SHOULD allow for the inclusion of Reason for prescribe (clinical indication) as a SNOMED CT-AU Codeable Value. *Note: support for the inclusion of a SNOMED code is encouraged noting the clinician sometimes doesn't provide a Reason for prescribe or the reason has no SNOMED code. If the clinician provides a Reason for prescribe, and that reason has a SNOMED code, the system is expected to include it in the prescription.* *Note: contact the NCTS for guidance on the appropriate SNOMED value set for Reason for Prescribe.*

Reference	Requirement
PRES-21A	The system SHALL NOT require Reason for prescribe (clinical indication) as a SNOMED CT-AU Codeable Value. *Note: the system should allow, but not demand, that Reason for Prescribe be populated. Where it is populated, it should also be represented as a SNOMED CT-AU Coded Value.* *Related requirements: PRES-21, PRES-22, PRES-49, PRES-53.*
PRES-22	Irrespective of the inclusion of any codeable values, the system SHALL include all information fields presented to the prescriber in 'Original Text'. *Note: the clinical/supervising pharmacist sees the instructions as displayed to the prescriber when the prescriber wrote the prescription.* *'Original Text' is defined as the text 'exactly as presented to the prescriber or dispenser'.*
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.
PRES-53	The system SHALL allow capture of Reason for prescribe (clinical indication) as a text field if no coded value is provided. *Note: Reason for prescribe may not be easily defined or may cover more than one drop down menu option.* *Related requirements: PRES-21, PRES-21A.*
PRES-56	The system SHALL capture an indication from the prescriber if the electronic prescription is confirmation of a verbal authority for an urgent case/supply. *NOTE: a 'verbal authority' prescription is issued in confirmation of the prescriber's direction to the pharmacist given orally in person or by phone, or fax or email. The common term for this is 'script owing'. When generating an electronic prescription for which an urgent supply has already been provided, the prescriber should be able to indicate (a flag or checkbox) that the prescription is an 'owing script' and it should be sent to the pharmacy that provided the urgent supply with authorisation from the prescriber.*
PRES-56A	If the prescription is a confirmation of a verbal authority for urgent case/ supply, the system SHALL NOT generate a token that is passed to the Subject of Care (electronically).
PRES-705	The prescribing system SHALL be able to make available in a medication chart: • the chart identifier • tokens for each prescription line item in line with the medication chart. *Note: providing the chart identifier and/or tokens permits the dispenser to download prescriptions from the NPDS.*

Finalisation

Reference	Requirement
PRES-42	After submitting an electronic prescription to the NPDS, the system SHALL have the ability to: • facilitate the transmission of Evidence of Prescription (including the Token) to an electronic address (e.g. SMS, email), in electronic form; and • print Evidence of Prescription (including the Token) in paper form. *Note: requirements PRES-42 and PRES-48 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).*

Reference	Requirement
PRES-43	If generating a Token in any format (e.g. paper, electronic or on a medication chart), the Token SHALL be displayed as a barcode or QR code. The DSPID SHALL be displayed in alphanumeric form in a position associated with the barcode/QR code. (e.g. directly below) or the DSPID SHALL be labelled DSPID. *Note: in the event that the Token is unable to be scanned, a user may enter the DSPID manually.*
PRES-43A	The system SHALL be able to reprint an Evidence of Prescription when the prescriber needs to do so. *Note: the system is not expected to reprint an Evidence of Prescription that originated from a different system. That is, the CIS needs to only reprint an Evidence of Prescription if it was created in that system.*
PRES-43B	If the system has the capacity to send an EoP to the subject of care electronically, the system SHOULD be able to re-send an electronic EoP should there be a need to do so. *Note: the system is not expected to re-send an electronic EoP that originated from a different system. That is, the CIS needs to only re-send an electronic EoP if it was created in that system.*
PRES-45	Where Evidence of Prescription is provided electronically, the system SHALL allow the user to select an electronic address for a particular Subject of Care (SoC) on a per prescription basis. *Note: Prescribers may have a default electronic address on file for the SoC. This may be for appointment reminders or other types of communication. The SoC may wish to use a different address to receive their prescription Token.*
PRES-46	Where Evidence of Prescription is provided in electronic form (e.g. SMS, email), the system SHALL transmit at least: • the electronic token or URI (e.g. URL) linking to the electronic token • the initials of the Name of the Subject of Care • Medicine name. *Note:* see pres-48A for more information
PRES-46A	Where an Evidence of Prescription is provided in electronic form and that Evidence of Prescription includes a link to an electronic token (URI), then any information provided by that link SHALL also conform to PRES-46 and PRES-48A. *Note: in the event that the electronic address was incorrectly recorded, this limits the potential for exposing personal information to an unknown party.*
PRES-46B	Where Evidence of Prescription is provided in electronic form, the system SHALL support confirmation of the electronic address to be used by the prescriber with the Subject of Care. *Note: the address that will be used should be conveniently displayed so the prescriber can confirm this verbally or by display.*

Reference	Requirement
PRES-47	Where Evidence of Prescription is provided in paper form, the system SHALL include the following details: • Indication that this is an Evidence of Prescription (e.g. Not a dispensable prescription): • Token (Barcode/QR Code and DSPID) • Name of the Subject of Care • Name of the prescriber • Name of the prescriber organisation • Medicine(s) name, strength • Date prescribed • Contact details of the prescriber and / or prescribing organisation • Privacy notice. *Note: the privacy notice can be provided by Services Australia.* *Note: an individual EoP printed by charting software needs to conform to this requirement.*
PRES-47A	An Evidence of Prescription (in any form) for a chart-based electronic prescription SHALL include text to indicate that it is a chart-based electronic prescription. *Note: indicating the prescription originates from a medication chart alerts the dispenser to the need to sight the entire medication chart before dispensing to satisfy their legal obligations and improves patient safety.*
PRES-48	When generating an Evidence of Prescription in any format, the EoP SHALL NOT include the following details: • Subject of Care age • Subject of Care date of birth • Subject of Care sex • PBS Prescriber number • Authority number • Medicine form • Medicine dose or directions • Reason for prescribe. There SHALL NOT be a place for the prescriber to sign. *Note: the dispenser will have the SoC's age and gender available to them and may use this information to achieve a degree of certainty that the person presenting the Token is entitled to receive the medicines. The information on the Evidence of Prescription is not a definitive (legal) representation of the prescription.* *Not providing the PBS prescriber number, any PBS or state authority or permit number and dose mitigates the risk of the dispenser dispensing against Evidence of Prescription rather than the electronic prescription.* *Note: If Form is incorporated into the Medicine Name, it may be included. There is no requirement to strip the form out of the medicine name.*
PRES-48A	When generating an Evidence of Prescription in electronic format, the EoP SHALL NOT include the following details • Subject of Care name

Reference	Requirement
PRES-55	An Evidence of Prescription (in any format) SHALL have one and only one DSPID. *Note: the system may provide multiple EoP's on a page or screen, but the system must print or repeat all the details (i.e SoC/prescriber details) for each DSPID. This allows the SoC to separate and manage their EoPs and reduces the chance of unintended barcode scanning incidences.*

Modification

Reference	Requirement
PRES-40	The system SHALL allow the user to make changes to a prescription prior to finalising. If the prescription has been sent to the NPDS, PRES-41 applies. *Note: supports workflow where the prescriber may review prescription details onscreen and want to make corrections prior to finalising.*
PRES-41	Post finalisation, where an electronic prescription has been sent to the NPDS as an electronic prescription, the system SHALL provide a mechanism for the prescriber to correct a prescription if the prescriber needs to. *Note: an 'amend' operation or a 'cancel prescription' operation followed by a 'create prescription' operation is an acceptable mechanism. Vendors will need to understand what operations the NPDS will support.* *Note: an electronic prescription that has been supplied at least once, or exhausted, or ceased, or disabled, or cancelled cannot corrected or cancelled.* *Note: if the correction request fails, the outcome will include the cause of the failure e.g. already extinguished, locked, disabled.*

Submission

Reference	Requirement
PRES-23	The system SHALL store, in a permanent and non-alterable manner within the clinical or medicines record of the person for whom the electronic prescription was generated, the particulars of any electronic prescription generated, consistent with and as required by any applicable regulations.

Reference	Requirement
PRES-24	The system SHALL display the electronic prescription in a format that meets the requirements of the National Regulations and relevant state and territory legislation including all data fields that will be submitted to the NPDS, to the prescriber and obtain a final approval from the prescriber prior to finalising the prescription for transmission. *Note: through this display, prescribers will be provided a step in their workflow to review the prescription prior to issuing. This offers an opportunity to review and amend the prescription as required to ensure patient safety.* *How the particulars of the prescription are displayed may vary between software products and jurisdiction. It's intended that a prescription should be displayed in a manner similar to a paper prescription.* *Note: an action by the prescriber to 'send' the electronic prescription is considered adequate confirmation of final approval.* *Note: it is recommended software conforms with National Guidelines for On-Screen Display of Medicines Information [ACSQHC2017] where practical.* *Note: 'All data fields' includes any automatic data mapping or translations that may occur due to active ingredient prescribing but does not include system data like GUID's, OIDS, P*BS codes, *serial numbers, datetime stamps etc.*
PRES-70A	The system SHALL conform to mandatory requirements 021561, 016832, 016813 and 016815 in Healthcare Identifiers use case UC.330 (Send patient health information electronically [AGENCY2020]) when sending an electronic prescription. If a failure to validate a known IHI can be attributed to the unavailability of the HI Service, then a Prescribing System MAY include the IHI in an electronic prescription (without validating it). *Note: UC.330 conformance requirements not listed above are optional for Prescribing Systems.*
PRES-30	On submission to the NPDS, the system SHALL capture and retain the provided DSPID in the local system so that it can be recalled if required.
PRES-32	The system SHALL provide the user with an indication as to whether the NPDS has acknowledged receipt of the electronic prescription. *Note: Tokens may not be activated by the NPDS unless the NPDS acknowledges receipt of the electronic prescription.*
PRES-33	When creating an electronic prescription for an item in the medication chart, the system SHALL allow the user to proceed with the submission of the electronic prescription for an item prior to establishing successful connection with the NPDS. Note: the context is that the prescriber submitted an electronic prescription for an item via the medication chart prescribing system, but the prescribing system is unable to reach NPDS and has had no acknowledgement of receipt from the NPDS and decides to queue up the requests. The required outcome is that the prescribing system should attempt to re-send electronic prescription message to the NPDS as soon as it is able to connect to the NPDS.
PRES-34	The system SHALL allow the user to issue a cancellation request for an electronic prescription after acknowledgement of receipt by the NPDS. *Note: it is understood that the cancellation may not take effect if the electronic prescription has already been extinguished* *Note: if the cancellation request fails, the outcome will include the cause of the failure e.g. already extinguished, locked, disabled.*

Reference	Requirement
PRES-35	When the user issues a cancellation request the system SHALL issue a cancellation message to the NPDS. *Note: this is a cancel request. The request will fail if the prescription has already been extinguished is locked for dispensing.*
PRES-36	When creating an electronic prescription, the system SHALL allow the organisation to set the (seconds) duration of an 'acknowledgement of receipt - timeout' (AORT), including a value which represents 'no timeout'. *Note: if the system uses a cloud-based system or similar where there is no single organisation, then it is acceptable for this AORT setting to be specified by the vendor supporting those organisations. This setting must be configurable through a GUI, configuration file or similar and must not be a hard-coded value.*
PRES-37	When creating an electronic prescription, in the event of an Acknowledgement of Receipt – Timeout (AORT), the system SHALL automatically: 1. Cancel the electronic prescription 2. Alert the user the transmission to the NPDS has failed 3. Suggest the user resends the electronic prescription to the NPDS or issues a paper prescription. *Note: item 2 and 3 could appear on the same pop-up/alert/message.*
PRES-710	When a medication chart is ceased, the system SHALL send a notification to the prescription delivery service that each electronic prescription is no longer active for each active electronic prescription on that chart.
PRES-715	When uploading a prescription that has been written on a medication chart, the system SHOULD provide the unique identifier for the chart in the prescription so that all the active prescriptions on a medication chart can be easily retrieved when required.

ASL Assisted registration

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

Reference	Requirement
PRES-205	The prescribing system SHOULD provide assisted registration functionality to support Subject of Care registration for an Active Script List.
PRES-73	The system SHALL conform to mandatory requirements 016832 and 016813 in Healthcare Identifiers use case UC.330 (Send patient health information electronically [AGENCY2020]) if accessing an Active Script List Registry Service to register a SoC for an Active Script List, update registration details, or to establish whether a SoC has registered for participation or to retrieve an Active Script List. The system SHALL include an IHI in communication with the Active Script List Registry Service only if its status 'active' and 'verified'. *Note: this conformance requirement makes the Prescribing System responsible for checking that an IHI in the local system is valid and belongs to the SoC.*
PRES-210	If the system supports assisted registration, the prescribing system SHALL only allow pre-population of the SoC's locally stored personal information in the assisted registration form, and only send the following SoC's information to the ASLR: • IHI number • Family name • Given names (if available) • Date of birth • Gender • Medicare card number and IRN (if available) • DVA number (if available) • Residential address (optional for software to support) *Note: the above attributes align to the attributes used by the HI Service when there is a need to discover or validate an IHI.* *Note: it is important that the ASLR is populated with the same data that is in the CIS so that those systems are consistent. If, for example, the date of birth requires correction, then this must be corrected in the patient record first so it can be correctly reflected in the assisted registration form.* *Note: Vendors should refer to ASLR interface specifications to understand if the transmission of the residential address is supported.* *Note: see also PRES-225 and PRES-230 for carers and agents.*
PRES-215	If the system supports assisted registration, and the SoC wishes to add a carer or an agent to the SoC's ASL, the prescribing system SHALL provide a checkbox (or similar) to indicate that the SoC and the agent/carer consents to those details being added to the ASL. The checkbox SHALL default to 'off', meaning, an explicit action is required to acknowledge consent. *Note: the SoC is responsible for getting consent from the Carer/Agent and communicating this to the healthcare provider.* *Note: a healthcare provider can consent on behalf of a SoC if the healthcare provider is satisfied that the SoC can't provide consent (e.g. incapacitated).*

Reference	Requirement
PRES-220	If the system supports assisted registration and the SoC wishes to register a carer or agent, the prescribing system SHALL allow the healthcare provider to nominate which role that person supports (Carer or Agent). *Note: a 'carer' and 'agent' are different concepts and must be captured separately.*
PRES-225	If the system supports assisted registration, the prescribing system SHALL allow at least one carer to be registered in the SoC's ASL, and only send the following carer information to the ASLR: • Family name • Given names (optional if the carer has only one name) • Address (optional for the carer to provide) • Relationship to SoC (optional for the carer to provide) and SHALL NOT capture any other information for ASLR purposes. *Note: capturing a carer is optional but the software must support this function.* *Note: the CIS can store additional information about carers that are not sent to the ASLR (e.g. notes for administration purposes or identity management).* *Note: if the carer has a given name, then that given name must be recorded.* *Note: if the carer is an organisation (e.g. residential aged care facility) then PRES-235 applies.* *Note: it is recommended that the system captures the above attributes as separate attributes (i.e. not as a single text field) as future architecture may require this information to be discrete and ready to be validated for identity management purposes.*
PRES-230	If the system supports assisted registration, the prescribing system SHALL allow at least one agent to be registered in the SoC's ASL, and send the following agent information to the ASLR: • Family name • Given names (optional if agent has only one name) • Address (optional for the agent to provide) • Relationship to SoC (optional for the agent to provide) *Note: capturing an agent is optional but the software must support this function.* *Note: agents are not authorised to receive ASLR notifications from healthcare providers so capturing their electronic details is not necessary and prevents software systems sending the notification to the agent by mistake (unless the Agent is also the nominated ASL Primary Contact).* *Note: the CIS can store additional information about the agents that are not sent to the ASLR (e.g. notes for administration purposes or identity management).* *Note: if the agent has a given name, then that given name must be recorded.*
PRES-235	If the system supports assisted registration, the prescribing system SHALL support the capture of an organisation name as a carer for the SoC. *Note: it is likely that the RACF for a resident patient will, with permission, nominate themselves as a carer so they can receive electronic notifications and provide site-consent.* *Note: the attributes specified in PRES-225 do not apply to organisations as a carer.*

Reference	Requirement
PRES-240	If the system supports assisted registration, the prescribing system SHALL record and send one and only one primary contact for the SoC's ASL. *Note: the patient or primary carer will nominate primary contact details for ASL notifications. Having a single contact avoids conflicting notifications and consent messages being sent from multiple carers.*
PRES-245	If the software supports assisted registration, then the system SHALL NOT permit the user to delete, remove or erase the primary contact details registered against an ASL. *Note: the system can permit the editing/updating of primary contact information, but the removal of that information is not permitted.*
PRES-250	If the prescribing system supports assisted registration, the prescribing system SHALL support the subsequent update of the SoC, carer and agent's personal information that is in the ASL, in accordance with PRES-210, PRES-225 and PRES-230. *Note: the term 'update' includes add, remove and modify operations.* *Note: if it is known that the SoC's IHI has changed then the ASLR operator must be notified via the ASLR support phone number. The ASLR operator will take steps to move prescription information from the de-activated ASL to the new ASL.*
PRES-255	If the prescribing system supports assisted registration, the prescribing system SHALL ensure SoC's IHI has a record status of 'Active' and status of 'Verified' before displaying the assisted registration form. *Note: it is best practice to refresh the IHI against the HI Service immediately before satisfying this requirement but a check against the HI Service is not required.*

ASLR Viewing

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

Reference	Requirement
PRES-275	When viewing a patient record, the prescribing system MAY display a visual indication if the SoC has an Active Script List.
PRES-280	The prescribing system MAY allow the healthcare provider to view the SoC's Active Script List, if and only if: • the SoC has an Active Script List (refer to PRES-275), and • the healthcare provider has site consent for the SoC's ASL (refer to PRES-295). *Note: the prescriber has the patient's prescription history in their local patient record. The viewing of the ASL might help with clinical decision making but it is optional for prescribing software vendors to provide this function.*
PRES-290	If the SoC has an Active Script List, the prescribing system MAY display the name of that ASLR in the patient record.
PRES-295	If the SoC has an Active Script List and the system can determine this, the prescribing system MAY indicate whether the healthcare provider organisation has been given site consent to access the SoC's ASL.
PRES-305	If a healthcare provider organisation does not have site access to the SoC's ASL, the prescribing system SHALL allow the healthcare provider to request site consent.

Reference	Requirement
PRES-315	If displaying a patient's ASL the prescribing system SHALL display at least the following information: For carers & agents: • Family name • Given name • Address (optional) • Relationship to SoC. For medicines: • Name of the Subject of Care • Medicine(s) name, strength • Date prescribed • Number of repeats available(if applicable) • Indication that the token is not available (if applicable – for paper prescriptions). The system MAY display: • Name of the prescriber • Name of the prescriber organisation • Contact details of the prescriber and / or prescribing organization. *Note: Prescribers wanting to view the complete prescription from other prescribers (i.e. not in their local system) will need to enquire directly with that prescriber or the prescriber's organisation.* *Note: the ASL intentionally contains limited information to prevent a dispense from the ASL. Dispensers are required to download the full legal prescription before dispensing.*

ASLR Prescribing

Reference	Requirement
PRES-345	The prescribing system SHALL display a checkbox (or similar) for the prescriber to describe the following event chart-based electronic prescriptions: • Patient has exercised their choice to keep the information away from their ASL. This SHALL default to 'on' meaning SoC does not intend the prescription to be added to their ASL. *Note: the prescriber needs to consider the dispensing expectation for each prescription and use the checkboxes (or similar) to influence the prescription information in the ASL.*

Reference	Requirement
PRES-345A	The prescribing system SHALL display a checkbox (or similar) for the prescriber to describe the following event for chart-based electronic prescriptions: • the prescription will be retained by the pharmacy for legal or other clinical safety purposes and must not be sent to an ASL. This SHALL default to 'off' meaning the prescription will not be retained by the pharmacy. *Note: this profile does not describe how a token is to be sent directly to a pharmacy. The checkbox only captures that that action will be done via fax, email, SMS, secure message delivery etc. Each developer needs to decide if this is done within their system or is dependent on an external process.* *Note: see PRES-365* *Note: prescribing to dosing points is a reason to send directly to that pharmacy and keep the token from an ASL*
PRES-360	The prescribing system SHALL include the status (or similar) of the following item in the transmission of the prescription: • the patient consents to the prescription being added to the ASL or the absence of any objection to the prescription being added to the ASL. *Note: including this information in the transmission permits the NPDS and dispensing system to make intelligent decisions around the treatment of ASL's and repeat authorisations.* *Note: the patient consent status (or absence of objection) reflects the patient's intention to include the prescription in the ASL i.e. patient choice.*
PRES-362	The prescribing system SHALL include the status (or similar) of the following item in the prescription: • the prescription will be sent directly to a dispenser and must not be sent to an ASL. *Note: this profile does not describe how a token is to be sent directly to a dispenser. The status only captures that that action will be done via fax, email, SMS, secure message delivery etc. Each developer needs to decide if this is done within their system or is dependent on an external process.* *Note: including this information in the prescription permits the NPDS and dispensing system to make intelligent decisions around the treatment of ASL's and repeat authorisations*
PRES-365	If the system has the capability to send notifications to the subject of care, then the system SHALL NOT send an electronic EoP (token) to the SoC if the token will be sent directly to a dispenser (see PRES- 345A). *Note: some CIS's delegate the sending of the communication to the NPDS.* *Note: prescribers should not give printed EoPs to the SoC if the token is to be given directly to the dispenser (i.e. a dosing point).*
PRES-390	When creating a prescription, the prescribing system SHALL be able to create an Evidence of Prescription regardless of the presence of an active script list. *Note: sending prescription information to an ASL does not remove the onus of providing an EoP to the subject of care. All relevant conformant requirements apply when there is a need for an EoP.* *Note: the SoC can give instructions to not receive an EoP thereby removing that obligation on the healthcare provider.*

4 Acronyms

Acronym	Description
1D	One Dimensional
ACSC	Australian Cyber Security Centre
ADHA	Australian Digital Health Agency
AHPRA	Australian Health Practitioner Regulation Agency
AMT	Australian Medicines Terminology
AORT	Acknowledgement Of Receipt - Timeout
ASD	Australian Signals Directorate
ASL	Active Script List
ASLR	Active Script List Registry
CIS	Clinical Information System
CRL	Certificate Revocation List
CWE	Common Weakness Enumeration
DLM	Dissemination Limiting Marker
DoB	Date of Birth
DSPID	Delivery Service Prescription Identifier
eNRMC	electronic National Residential Medication Chart
eMM	Electronic Medication Management
EP	Electronic Prescribing
ETP	Electronic Transfer of Prescriptions
HCP	Healthcare provider
HI Service	Healthcare Identifiers Service operated by Services Australia
HPN	Hospital Provider Number
HPI-I	Healthcare Provider Identifier - Individual
HPI-O	Healthcare Provider Identifier - Organisation
HTTPS	Hyper Text Transfer Protocol Secure
IHI	Individual Healthcare Identifier
IMEI	International Mobile Equipment Identity
ISM	Information Security Manual

Acronym	Description
MI	Mobile intermediary
MIS	Mobile Intermediary Services
MHR	My Health Record
MMS	Multimedia Messaging Service
NCTS	National Clinical Terminology Service
NSW	New South Wales
NRMC	National Residential Medication Chart (paper)
OAuth	Open Authorisation
OCR	Optical Character Recognition
OCSP	Online Certificate Status Protocol
OWASP	Open Web Application Security Project
PBS	Pharmaceutical Benefits Scheme
PBS HMC	PBS Hospital Medication Chart (paper)
PDS	Prescription Delivery Service
PKI	Public Key Infrastructure
PRODA	Provider Digital Access
RACFID	Residential Aged Care Facility ID
RPBS	Repatriation Pharmaceutical Benefits Scheme
RSA	An asymmetric cryptosystem invented by Ron Rivest, Adi Shamir and Leonard Adleman
RTPM	Real Time Prescription Monitoring
SaaS	Software as a Service
SIEM	Security Information and Event Management
SoC	Subject of Care (patient or consumer)
SMS	Short Message Service
SNOMED CT-AU	Systematised Nomenclature of Medicine – Clinical Terms - Australia
URI	Uniform Resource Identifier
URL	Uniform Resource Locator
UTC	Coordinated Universal Time
WAN	Wide Area Network

5 Glossary

Term	Meaning
Agent	A person that acts on behalf of the Subject of Care to collect prescriptions and may be the primary contact for their Active Script List.
Asset	Anything of value, such as ICT equipment, software or information.
ASL Consent Indicator	A Y/N value to indicate whether the Subject of Care has consented for this electronic prescription to be loaded to their Active Script List (ASL).
ASLR Identifier	A value that identifies which Active Script List Register the Subject of Care is registered with.
Australian Government Services	A service provided by the Australian Government
Australian Medicines Terminology	The reference set within SNOMED CT-AU that is the national, standards-based approach to the identification and naming of medicines in clinical systems for Australia.
Authority code	Number or code representing any required authority approval from the Services Australia or the Department of Veterans' Affairs for restricted items that require electronic, phone or written authority approval. See also: http://www.pbs.gov.au/info/healthpro/explanatory-notes/section1/Section_1_2_Explanatory_Notes#Authority-PBS
Chart-based electronic prescriptions	A chart-based electronic prescription is generated from an active electronic medication chart via the conformant electronic medication chart prescribing system. The chart-based electronic prescriptions will have chart identifier which is used to group one or more chart-based electronic prescriptions from the same medication chart
Chart Identifier	An identifier that is used to group one or more Electronic Prescriptions from the same medication chart.
Conformance	A measurement (by testing) of the adherence of an implementation to a specification or standard.
Conformance ID	A text string of no more than 36 printable characters containing a text string representing the Product Name, a single character delimiter ('|') and an alpha-numeric string representing the Software Product Version. See also: originalRepositorySoftUniqueID, RepositorySoftUniqueID, Prescription Software Conformance ID
Consumer	In this document 'consumer' refers to a software system that has the role of being a consumer of information about prescription data held by one or more prescription delivery services.
Cryptographic Hash	An algorithm (the hash function) which takes as input a string of any length (the message) and generates a fixed length string (the message digest or fingerprint) as output. The algorithm is designed to make it computationally infeasible to find any input which maps to a given digest, or to find two different messages that map to the same digest. https://www.cyber.gov.au/acsc/view-all-content/glossary/c

Term	Meaning
Cryptographic Salt	A salt is a unique, randomly generated string that is added to each password as part of the hashing process. As the salt is unique for every user, an attacker has to crack hashes one at a time using the respective salt rather than calculating a hash once and comparing it against every stored hash.' – OAWSP https://cheatsheetseries.owasp.org/cheatsheets/Password_Storage_Cheat_Sheet.html#:~:text=A%20salt%20is%20a%20unique,it%20against%20every%20stored%20hash.
Delivery Service Prescription Identifier (DSPID)	Identifies the particular electronic prescription within the delivery service infrastructure. This identifier may change through the prescription lifecycle (e.g. one that points to original, one that points to repeat authorisation). The Delivery Service Prescription Identifier is allocated managed by the Prescription Delivery Service (and may be referred to as a SCID).
Dispenser	An individual who dispenses medically prescribed drugs and medicines after providing instruction and counsel on the proper use and adverse effects of those drugs and medicines in accordance with all relevant legislative, regulatory and professional requirements.
Dispensing Software Conformance ID	The conformance identifier of a software system used to create an electronic dispense record based on an electronic prescription.
Drug	A drug is any substance (with the exception of food and water) which, when taken into the body, alters the body's function either physically and/or psychologically. PBS prescriptions are written for a drug and not for a medicine.
Electronic prescribing	The process by which a prescription is electronically generated by a prescriber, and securely transmitted to a prescription delivery service for dispensing and supply, downloaded by a supplier, seamlessly integrated into the dispensing software and, in the case of Australian government subsidised prescriptions, available to be electronically sent to the Services Australia for claiming purposes. Note: This definition does not preclude the use of paper processes to support electronic prescribing activity. Repeat dispense records that are uploaded to a prescription delivery service by a supplier are not electronic authorisations unless the original prescription was generated by a prescriber as an electronic prescription.
Electronic prescription	Electronic clinical documents that contain all information relating to an order to supply medicine to an individual. An electronic prescription is generated electronically by a prescriber, authenticated, securely transmitted (either directly or indirectly) for dispensing and supply, integrated into dispensing software and, in the case of Pharmaceutical Benefits Scheme (PBS) prescriptions, available to be sent electronically to the Services Australia for claiming purposes. Note: This definition does not preclude the use of other processes or artefacts to support e-Prescribing.
Electronic transfer of prescription (ETP)	The process whereby prescribing systems pass an electronic representation of a paper prescription to a prescription delivery service (PDS), which is available for download by dispensing systems in support of dispensing a paper prescription.

Term	Meaning
Evidence of Prescription	Provided to the Subject of Care as evidence that an electronic prescription was created for that subject of care. It will contain a token (QR code or URI) to discover and retrieve the electronic prescription. Charts contain tokens (or URI's) but do not contain EoP's. Evidence of 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.
General electronic prescription	A general electronic prescription is generated from a conformant electronic prescribing system and doesn't have chart identifier. These electronic prescriptions are also referred as 'non-chart-based electronic prescriptions.
Globally Unique Prescription Identifier	A unique identifier that is retained for the life of a prescription and all repeats. This is the number that PBS requires. This value is the consistent thread that binds together an original electronic prescription and its subsequent dispense records / repeat authorisations for the life of the prescriber's order. It is generated at the time of prescription creation and referenced in a dispense notification. This same ID follows through the lifecycle of the electronic prescription. Note: this may be a GUID/UID but need not be.
Hash	See 'Cryptographic Hash'.
Hospital Provider Number (HPN)	Administered by Services Australia
International Mobile Equipment Identity	A number, usually unique, to identify mobile phones. See also: https://en.wikipedia.org/wiki/International_Mobile_Equipment_Identity
Information Asset	An identifiable collection of data stored in any manner and recognised as having value for the purpose of enabling an agency to perform its business functions thereby satisfying a recognised agency requirement.
Item	Prescription information AND a token. This also applies to repeat authorisations.
MAY	When appearing in a conformance requirement, the verb MAY indicates an optional requirement.
Medicine	A substance you take to treat an illness, treatment and prevention of illnesses and injuries. PBS prescriptions are written for a drug and not a medicine.
Mobile Application	An application that provides a user the ability to manage electronic prescriptions via a personal device.
Mobile Intermediary	Software used by mobile applications to interact with the electronic prescribing process.
Mobile Intermediary Service	Mobile Intermediary provides connection services to other software developers' Mobile Applications.
National Clinical Terminology Service (NCTS)	Responsible for managing, developing and distributing national clinical terminologies and related tools and services to support the digital health requirements including being the Australian National Release Centre for SNOMED CT® on behalf of SNOMED International. https://www.healthterminologies.gov.au/

Term	Meaning
National Prescription Delivery Service (NPDS)	The national e-Health service contracted by the Commonwealth or Agency that supports defined interfaces and services to facilitate the transfer of electronic prescriptions for persons and related information between participating systems
originalRepositorySoftUniqueID	The conformance identifier of the NPDS when the original electronic prescription is loaded from the prescribing system. See also: RepositorySoftUniqueID
Paper prescription	A printed prescription that has been physically signed by a prescriber
Participating system	A computer system that participates in electronic prescribing. Participating systems include any system which generates an electronic prescription, retrieves and dispenses from an electronic prescription, facilitates the transfer of an electronic prescription or manages an electronic prescription.
Personal and sensitive information	Personal information is information about an individual. Sensitive information is personal information that has a higher level of privacy protection than other personal information. See https://www.oaic.gov.au/privacy/guidance-and-advice/what-is-personal-information
Prescriber	An individual who provides healthcare and who creates prescriptions in accordance with all relevant legislative, regulatory and professional requirements.
Prescription	A written direction from a registered health provider to a supplier for preparing and dispensing a drug [Oxford Medical Dictionary] [HIM].
Prescription delivery service (PDS)	An e-Health service that supports defined interfaces and services to facilitate the transfer of electronic prescriptions and related information between participating systems.
Prescription Software Conformance ID	The conformance identifier of a software system used to create an electronic prescription.
Public network	A type of network wherein anyone, namely the general public, has access and through it can connect to other networks or the Internet.
Registry Operator	An organisation that operates an Active Script List Register.
RepositorySoftUniqueID	The conformance identifier of the NPDS from when the electronic prescription is downloaded for dispensing. See also: originalRepositorySoftUniqueID
Residential Aged Care Facility ID (RACFID)	Residential aged care facility identification number, also known as the Residential Aged Care Service ID (RACSId). Required for use of the National Residential Medication Chart (NRMC) and will be available from the facility.
Salt	See ‘cryptographic salt’
Session	A session begins when a user successfully provides a password/PIN etc to the application and ends when the application exits through user action or through application timeout based on a period of inactivity.
SHALL	When appearing in a conformance requirement, this verb SHALL indicates a mandatory requirement. Its negative form SHALL NOT indicates a prohibition.

Term	Meaning
SHOULD	When appearing in a conformance requirement, the verb SHOULD indicates a recommendation. Its negative form SHOULD NOT indicate an option that should not be supported.
Site consent	The SoC provides consent for a site to view the SoC's ASL. The site might be a pharmacy, clinic, franchise or other organisation that would benefit from viewing the ASL.
Subject of Care	The Subject of Care is the person for whom the medicines described on the prescription are intended.
Token	An electronic prescription Token refers to a representation of the DSPID (in the form of a barcode, QR code or alphanumeric string. A Token may or may not be provided with other prescription information.

Appendix B Implementation Advice

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

Certificate validation	Implementation advice for the validation of PKI certificates and use of PKI Certificate Authorities (CAs): Certificate validation should be done by: • ensuring the certificate has not been revoked. This may be done by using a Certificate Revocation List (CRL), Online Certificate Status Protocol (OCSP) or other method • checking the certificate was valid and had not expired when the transaction took place • the certificate is from a publicly trusted Certificate Authority. Certificate pinning should be considered. Which is where, for specific web addresses a certificate is 'pinned' so that only certificates from a specific Certificate Authority are accepted. *Note: Where the network operation to access the CRL or OCSP fails, the certificate validation should not fail as a result.* Useful links: • RFC5280: Technical detail for certificate validation (https://www.ietf.org/rfc/rfc5280.txt) • NIST provided resources for testing PKI implementations, including certificate validation and path checking (https://csrc.nist.gov/projects/pki-testing) It is recommended that software developers are using CAs and certificates which implements Certificate Transparency (CT), except when NASH certificates are used. *Note: The National Authentication Service for Health (NASH) is a PKI that was established for healthcare in Australia and is highly recommended as a PKI solution, (refer https://www.servicesaustralia.gov.au/national-authentication-service-for-health).*
Digital Identity	The Australian Government has developed a Trusted Digital Identity Framework (TDIF) which is an accredited framework for Digital Identity services. Refer to https://www.digitalidentity.gov.au/tdif for more information. The Agency is investigating the suitability of one or more of these frameworks for electronic prescribing.

General Cyber Security Support Materials for Software Developers	For Advice on Cyber Security For software developers, developers are advised to:
	
	• Adopt the *Information Security Manual Guidelines for Software Development*;
	
	• observe platform-specific secure coding guidelines, such as:
	
	  ○ The iOS and macOS *Secure Coding Guide*
	
	  ○ Android Developer *Security tips*
	
	  ○ Microsoft .net *Secure coding guidelines*
	
	• implement the mitigation strategies specified in relation to the common risks such as:
	
	  ○ The Open Web Application Security Project (OWASP) Top 10
	
	  ○ The *OWASP Mobile Top 10*
	
	  ○ The *Common Weakness Enumeration Top 2*5
	
	• complete testing to verify the effectiveness of security controls implemented within their app and associated infrastructure. Using such resources as:
	
	  ○ The *OWASP based Web Application Security Testing Checklist* should be used for guidance
	
	  ○ The *NIST Mitigating the Risk of Software Vulnerabilities*.
	
	Unique Hardware Device ID is primarily used for an antifraud control.
	
	Apple Unique Hardware Device ID:
	
	• Apple iOS up to 10.3 beta can use Keychain Storage.

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

Appendix C References

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