Australian Government
Australian Digital Health Agency

Electronic Prescribing
National Prescription Delivery Service and Active Script List Registry Conformance Profile

6 August 2024 v3.1

Approved for external use

Document ID: DH-3939:2024

Australian Digital Health Agency ABN 84 425 496 912, Level 25, 175 Liverpool Street, Sydney, NSW 2000
Telephone 1300 901 001 or email help@digitalhealth.gov.au
www.digitalhealth.gov.au

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

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Owner	Chief Digital Officer
Contact for enquiries	Australian Digital Health Agency Help Centre Phone 1300 901 001 Email help@digitalhealth.gov.au

Product or document version history

Product or document version	Date	Release comments
V3.1	06/08/2024	Derived from Electronic Prescribing PDS and ASLR Conformance Profile v3.1

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1 Introduction

1.1 Purpose

This document summarises the functional and non-functional requirements for software that acts as national infrastructure in electronic prescribing.

This document lists the specific conformance requirements for the National Prescription Delivery Service (NPDS) and Active Script List Registry (ASLR) that must, or should, be met to support participation in electronic prescribing. These requirements build on those that have already been implemented to support Electronic Transfer of Prescription (ETP).

1.2 Intended audience

The intended audience includes:

- National Prescription Delivery Service and Active Script List Registry 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, 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 doesn't have 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 the NPDS and ASLR systems that participate in prescription exchange for the purpose of electronic prescribing for both chart-based and general electronic prescriptions.
- Functional and non-functional requirements related to other electronic prescribing systems participating in electronic prescription are detailed in *Electronic Prescribing - General Prescribing Systems and Other Connecting Systems Conformance Profile v3.0.1* and *Electronic Prescribing – Medication Chart Prescribing Systems Conformance Profile v3.0.1*
- 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

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.

Where there is a reference to connecting systems requirements (e.g. PRES or DISP), the NPDS and ASLR operator should refer to relevant electronic prescribing connecting systems conformance profiles (*Electronic Prescribing - General Prescribing Systems and Other Connecting Systems Conformance Profile v3.0.1 or Electronic Prescribing – Medication Chart Prescribing Systems Conformance Profile v3.0.1) to gain full understanding of the requirements.*

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 – NPDS and ASLR

This section describes conformance requirements specifically for the NPDS and ASLR participating in electronic prescribing.

3.1 National Prescription Delivery Service System

This section describes conformance requirements specific to electronic prescribing – NPDS. An electronic prescribing or dispensing system may connect to the NPDS to enable end to end electronic prescription transactions. The NPDS system is the mechanism through which an electronic prescription is communicated from a prescriber to a dispenser.

Authentication and authorisation

Reference	Requirement
DS-1	The system SHALL NOT accept electronic prescriptions or dispense notifications from non-conforming systems.
DS-2	The system SHALL NOT provide electronic prescription information or dispense information to a non-conforming system. *Note: every communication received by the system must contain a conformance ID and the system must verify that conformance ID is active. This may be done by comparing the conformance ID against an internal whitelist of active conformance IDs.*
DS-3	The system SHALL verify the authenticity of the requestor for all connection requests over public networks using Public Key Infrastructure (PKI) and PKI certificates SHALL be obtained from publicly trusted Certificate Authorities (CAs). *Note: the system will not accept connections from unknown participants.*

Audit

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

Reference	Requirement
DS-22A	The system SHALL, on request, generate a file or files that contain the information captured in the audit logs in human readable format. *Note: this requirement permits the generation of a file or files that can be shared or sent to relevant regulatory bodies on request. 'Human readable formats' include text files, PDF files, log files or any other format that presents the required information 'in the clear'.*
DS-405	The system SHALL retain, for auditing purposes, all electronic requests for information, including requests that were rejected. Audit logs SHALL include at least: • the date and time of each request for information • the DSPID submitted (if available) • the conformance ID(s) submitted (if available).

Provision

Reference	Requirement
DS-10	When a dispensing system retrieves an electronic prescription, the system SHALL be able to compile and provide all the relevant information including: • original electronic prescription • most recent dispense record • all annotations.
DS-11	When a dispensing system retrieves an electronic prescription, the system SHALL lock that electronic prescription while the transaction is in progress to prevent multiple concurrent transactions.
DS-11A	When a dispensing system attempts to retrieve an electronic prescription that is not available (locked/cancelled/disabled/does not exist), the system SHALL withhold that prescription from the dispensing system and clearly indicate the cause of the failure to the CIS. *Note: the system that disabled the prescription is permitted to retrieve and view that prescription for auditing, investigation, review and for re-instating if appropriate.*
DS-11B	When a prescribing system attempts to amend or cancel an electronic prescription that is cancelled, disabled, locked or does not exist, the system SHALL clearly indicate the cause of the failure to the CIS.
DS-12	The system SHALL NOT aggregate and make available prescription information based on an IHI number *Note: an IHI number shall be included in the electronic prescription provided by the prescriber.*
DS-410	When a technical error prevents the provision of prescription information then the system SHALL return an error message to the requesting system that indicates the presence of a technical issue. *Note: technical failure is not to be confused with the absence of data or the rejection of a request. Systems need to be unambiguously clear when information cannot be discovered due to technical faults, so tokens are not misconstrued as 'not active' and incorrectly removed from the local system.*

Submission

Reference	Requirement
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.
DS-4A	The system SHALL accept and support every data item specified in connecting systems profile *i*ncluding codes for data items if the prescribing/dispensing systems provide those codes. *Reference – The NPDS operator should refer to the relevant electronic prescribing connecting systems conformance profile (Electronic Prescribing - General Prescribing Systems and Other Connecting Systems Conformance Profile v3.0.1 or Electronic Prescribing – Medication Chart Prescribing Systems Conformance Profile v3.0.1) to gain full understanding of the requirements.* *Note: PRES-18, PRES-20, DISP-19 and other requirements specify data items those systems are expected to support. It is important that the NPDS receiving those prescription/dispense records also support those data items.* *Note: text values for Medicine identifier, medicine form and medicine route might also have codes provided by the originating system. The NPDS receiving those codes are expected to capture and retain those codes.*
DS-5	The system SHALL provide an acknowledgement of receipt of an electronic prescription to the prescribing system.
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.
DS-7	The system SHALL accept and process a request for cancellation of an electronic prescription.
DS-8	The system SHALL provide an acknowledgement of receipt and the outcome of an electronic prescription cancellation request to the prescribing system. *Note: if the cancellation request fails, the outcome must include the cause of the failure e.g. already dispensed, locked, disabled. (refer to DS-11B)*
DS-9	The system MAY support the delivery of the electronic Token to a nominated electronic address in accordance with DS-9A. *Note: an electronic token may be sent or re-sent to a nominated electronic address should there be a need to do so. The system is not expected to send or re-send an electronic token that originated from a different system.*
DS-9A	The system SHALL NOT send an electronic token to a nominated address (i.e. the patient/carer) for prescriptions or repeat authorities where that prescription or repeat authorisation will be sent directly to a dispenser. *Note: tokens to be controlled by healthcare providers for legal reasons (e.g. dosing points) must not be provided to the subject of care/carers – including the ASL if one is active.*
DS-13	The system SHALL accept a notification of dispense against an electronic prescription.
DS-14	The system SHALL provide an acknowledgement of a Dispense Record to the dispensing system.
DS-15	The system SHALL accept an annotation made by a dispenser against an electronic prescription during a dispense event.

Reference	Requirement
DS-16	The system SHALL provide an acknowledgement of receipt of an annotation to the dispensing system.
DS-17	The system SHALL accept and process a notification of dispense reversal. *Note: there may be instances where a dispenser is required to reverse a dispense prior to supply to a SoC (for example, the pharmacy is out of stock). In this instance, following the submission of the dispense reversal, the electronic prescription record should be returned to an unlocked state. The outcome is that the prescription is valid for dispense.*
DS-20	The system SHALL provide an acknowledgement of receipt of a dispense reversal to the dispensing system. *Note: the system will reverse the dispense event and return the electronic prescription to its previous state.*
DS-21	The system SHALL unlock an electronic prescription when the dispensing system releases it (unchanged). *Note: where an electronic prescription is released by the dispensing system without a dispense record (i.e. not dispensed), the prescription shall be unlocked. That prescription shall be unchanged from that which was originally drawn down by the dispenser.*
DS-715	The system SHALL provide the ability to retrieve all active prescriptions on a chart when a chart identifier is provided.
DS-50	The system SHALL prevent a token for a disabled prescription from being sent directly to the Subject of Care/Carer and the Subject of Care's Active Script List. *Note: 'Disabled' means the prescription is not accessible by another pharmacy.*
DS-51	The system SHALL ensure a re-enabled prescription token can be sent directly to the Subject of Care/Carer and is added to the Subject of Care's Active Script List (if applicable).

Data Integrity

Reference	Requirement
DS-26	The system and the NPDS Operator SHALL NOT change or manipulate the semantic content of any prescription.
DS-595	In response to a request for information for an item that has expired, been cancelled, been disabled or dispensed, the system SHALL provide at least the following information: • The status of the item (i.e. expired, cancelled, disabled, dispensed) *Reference –The NPDS operator should refer to the relevant electronic prescribing connecting systems conformance profile (Electronic Prescribing - General Prescribing Systems and Other Connecting Systems Conformance Profile v3.0.1 or Electronic Prescribing – Medication Chart Prescribing Systems Conformance Profile v3.0.1) to gain full understanding of the requirements.* *Note: providing this information to the requester enables rich information to be provided to the SoC.*

Reference	Requirement
DS-597	In response to a request for information for a prescription that is active, the system SHALL provide all the information the prescribers and dispensers have provided on that prescription (if requested). *Note: other requirements in this conformance profile that conflict with this requirement, take precedence. e.g. The need to withhold some information for privacy reasons.*

Privacy

Reference	Requirement
DS-25	The system SHALL NOT expose the unencrypted payload to the operator or user of the NPDS system when in normal operations. *Note: under normal circumstances, the system will prohibit access to the unencrypted payload to staff or technicians via a user interface, remote connection, data export or via any other means. The technical inability to access unencrypted data protects patient privacy.* *The system may need to expose unencrypted payloads internally for maintenance, fault finding, authorised investigations or by legal order.*
DS-25A	The system SHALL NOT share personal and sensitive information with other internal or external systems unless: • those recipient systems are covered by legal regulatory frameworks (e.g. EP, MHR, RTPM) and/or • under a legal order/direction and/or • there is explicit patient consent for read-only access to their personal and health data for healthcare reasons
DS-81	Personal and sensitive information SHALL be: a) Encrypted when at rest b) Encrypted when in transit EXCEPT when a conformant dispensing or consumer facing system requires this to be decrypted or when it needs to be decrypted to meet legal obligations
DS-924	When encrypting information at rest the system SHALL utilise cryptography that consists of: • an algorithm that is approved by the ASD for encrypting information at rest.
DS-925	When encrypting information for transport the system SHALL utilise cryptography that consists of: • an algorithm that is approved by the ASD for encrypting information for transit.

Security

Reference	Requirement
DS-23	If the service operates as a Commonwealth Government Service, the system SHALL put in place necessary controls for managing 'OFFICIAL' data with a Protective Marking of 'OFFICIAL: Sensitive'.
DS-938	The system SHALL validate digital certificates. *Note: see Appendix B for further implementation guidance.*

ASLR Integration

Reference	Requirement
DS-200	The system SHALL facilitate the exchange of prescription information between the NPDS and the ASLR.

ASLR Prescribing and Dispensing

Reference	Requirement
DS-344	When activating an ASL, the NPDS SHALL share with the ASLR prescription information (and tokens) for all known prescriptions for that SoC if: • the SoC consents to the pre-population of their ASL • the SoC, at the time of prescription creation, did not exercise their choice to keep the prescription information away from the ASLR (even if the ASL was not active at the time) • the prescription is active (i.e. not cancelled, not expired, not disabled or not dispensed).
DS-345	On receipt of a new electronic prescription (i.e. not during an assisted ASL registration event), the system SHALL send the prescription information and the token (if applicable) to the ASLR only when: • the prescription is active (i.e. not cancelled, not expired, not disabled or not dispensed) • it is known the SoC has an active ASL. *Note: prescription information can be shared with the ASLR if the patient consents, that is, the ASL is active, and exception conditions are absent.*
DS-85	The system SHALL ensure a disabled prescription is not visible in the patients Active Script List.
DS-365	If the system has the capability to send an electronic EoP (token) to the subject of care, then the system SHALL NOT send an electronic EoP (token) to the SoC if the token will be sent directly to a dispenser. *Note: some CISs delegate the sending of the communication to the NPDS.*
DS-380	The system SHALL NOT generate a token for a paper prescription. *Note: the prescription information can be displayed in the ASL without the token. However, there must not be a dispense without the paper prescription.*

3.2 Active Script List Registry

There is an expectation for the National Prescription Delivery Service (NPDS) and Active Script List Registry (ASLR) to interoperate and exchange information in a non-disruptive and harmonious manner and the degree of co-operation between systems is a routine aspect of conformance testing.

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

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

The ASLR vendor will need to understand the NPDS technical interface specifications to understand how to implement these concepts in a conformant manner.

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

This profile refers to the following concepts:

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

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

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

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

ASL Assisted Registration

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

Reference	Requirement
ASLR-225	The system SHALL allow at least one carer to be registered in the SoC's ASL, and only store the following carer information in the ASLR: • Family name • Given name (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 MAY capture the carer contact details for administrative purposes, including: • Telephone number • Email address. *Note: capturing a carer is optional but the software must support this function.* *Note: the CIS can store additional information about the carers that are not sent to the ASLR (e.g. notes for administration purposes or identity management).* *Note: if the carer has a given name, then that given name must be recorded.* *Note: if the carer is an organisation (e.g. residential aged care facility) then ASLR-235 applies)* *Note: it is recommended that the system captures the above attributes as separate attributes (i.e. not as a single text field) as future architecture may require this information to be discrete and ready to be validated for identity management purposes.*
ASLR-230	The system SHALL allow at least one agent to be registered in the SoC's ASL, and only store the following agent information in the ASLR: • Family name • Given name (optional if the 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 notifications from healthcare providers so capturing their electronic details is not necessary and prevents software systems sending the notification to the agent by mistake.* *Note: the system can store additional information about the agents for administration purposes or identity management.* *Note: if the agent has a given name, then that given name must be recorded.*
ASLR-235	The system SHALL allow the capture of an organisation name as a carer for the SoC. *Note: it is likely that the RACF for a resident patient will, with permission, nominate themselves as a carer so they can receive electronic notifications and provide site-consent.*
ASLR-240	The system SHALL support the capture of one and only one primary contact for an ASL. *Note: the patient needs to nominate, through the ASL assisted registration process, a primary contact point that can receive ASLR notifications.*

Reference	Requirement
ASLR-250	The system SHALL support the subsequent update of the SoC, carer and agent's personal information that is registered in the ASL. *Note: the term 'update' includes add, remove and modify operations.* *Note: if it is known that the SoC's IHI has changed then the ASLR operator will take steps to move prescription information from the de-activated ASL to the new ASL.*
ASLR-265	Prior to completing the registration process, the system SHALL send an electronic notification (e.g. SMS or email) to the registered primary ASLR contact to confirm that they wish to register. The electronic notification SHALL include a link to the Terms & Conditions and privacy policy in the electronic notification that is sent to the registered contact. *Note: the notification intends to obtain consent from the SoC/carer for the electronic prescriptions to be accessed by the Registry Operator (and any other parties as allowed by the Registry Operator).*
ASLR-266	When the registered carer details on an ASL are changed, the system SHALL send a confirmation message containing the new details to the primary contact, so the primary contact knows the details have been changed and are correct.
ASLR-267	When activating and pre-populating the ASL, the ASLR SHALL NOT display any electronic prescription information in the ASL if the electronic prescription information comes from a legacy system that doesn't allow the prescriber the option to indicate the prescription will be sent directly to a dispenser.
ASLR-270	The system SHALL receive prescription information if and only if the SoC's ASL has been activated. *Note: the ASLR must not be in possession of SoC's prescription information unless the SoC consents by activating their ASL.* *Note: prescription information received for an ASL that is NOT activated must be discarded and not retained.*
ASLR-355	The system SHALL NOT permit the user to delete, remove or erase the primary contact details registered against an ASL. *Note: the ASLR can permit the editing/updating of primary contact information, but the removal of that information is not permitted.*
ASLR-395	If the system receives a request to activate an ASL via the self-registration method (i.e. not assisted registration) then the system SHALL confirm it has the correct IHI for that person by validating or discovering that IHI via the HI Service B2B webservice and not activate the ASL if that process fails.
ASLR-416	When the primary contact details on an ASL are changed, the system SHALL attempt to send a confirmation message containing the new details to the previous primary contact.
ASLR-938	The system SHALL validate digital certificates. *Note: See Appendix B*Implementation Advice *for further implementation guidance.*

ASLR Viewing

Reference	Requirement
ASLR-272	The ASLR SHALL NOT display prescription information in an ASL for prescriptions that were sent directly to a dispenser (e.g. dosing points). *Note: because there is patient consent during the activation of the ASL, the ASLR can receive prescriptions that are sent directly to a dispenser (if the architecture supports that) but are prohibited from displaying those prescriptions in the ASL.*
ASLR-273	On receipt of a new electronic prescription (i.e. not during an ASL assisted registration event), the system SHALL NOT display any prescription information on an ASL if the prescription information comes from a legacy system that doesn't provide the SoC the option to withhold that prescription information from their ASL. *Note: this requirement applies to information pertaining to electronic and paper prescriptions.*
ASLR-275	The system SHALL provide a means for the CIS to determine if the SoC has an active ASL.
ASLR-280	The system SHALL provide a means to share a patient's ASL to a CIS if and only if: • the SoC has an Active Script List, and • the healthcare provider has site consent for the SoC's ASL.
ASLR-290	If the SoC has an Active Script List, the system MAY provide a means for the CIS to determine the name of the ASLR that the SoC is registered for.
ASLR-295	If the SoC has an Active Script List, the system SHALL provide a means for the CIS to determine whether the healthcare provider organisation has been given site consent to access the SoC's ASL. *Note: the ASLR will act like a broker for the CIS and present ASL site consent to the CIS through a single point.*
ASLR-305	When access to view an Active Script List is requested by a provider and that provider has no site-consent, the system SHALL send a direct communication (for example, SMS or email) to the registered primary ASLR contact requesting authorisation for the provider. This communication SHALL provide: • organisation or pharmacy or clinic name who is requesting the view access (mandatory) • the name of healthcare provider individual (optional). *Note: the organisation or pharmacy, or clinic name that appears in the notification is intentionally open to interpretation (within reason) and is subject to software design, architecture and data availability. The intent is that the ASL primary contact can ascertain which business is making the request.* *Note: it is acceptable for this requirement to be satisfied by another system if that other system is responsible for sending electronic communications (e.g. email/SMS). This will be determined by the solution design but the need to demonstrate conformance remains.*

Reference	Requirement
ASLR-315	When the prescribing or dispensing system requests an Active Script List, the system SHALL provide at least the following to a CIS: For carers & agents (if applicable): • Family name • Given name • Address (optional for the carer/agent to provide) • Relationship to SoC. For medicines: • Name of the Subject of Care • Medicine(s) name, strength • Date prescribed • Number of repeats available • Indication that the token is not available (if applicable – for paper prescriptions) • Token (Barcode/QR code and DSPID) (if applicable). The system SHALL NOT provide: • Medicine(s) direction • Prescriber number. The system MAY provide: • Name of the prescriber • Name of the prescriber organisation • Contact details of the prescriber and / or prescribing organisation. *Note: the ASL intentionally contains limited information to prevent a dispense from the ASL. Dispensers are required to download the full legal prescription before dispensing.*
ASLR-320	The system SHALL NOT make available any prescription information for prescriptions that are expired, cancelled, disabled, hidden or when the patient has exercised their choice to keep the information away from their ASL. *Note: the ASLR is not to make the prescription available but is allowed to share the status of that prescription.*
ASLR-340	The ASLR SHALL indicate to systems downloading the ASL which line item is being shared without a token. *Note: the prescription will contain information that will enable systems to determine if the prescription has a token available for dispensing.*

ASLR Prescribing and Dispensing

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

ASLR Audit Log

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

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
Direct PDS	Direct Prescription Delivery Services
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
NPDS	National Prescription Delivery 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
Active Script List Register	The national e-Health registry service contracted by the Commonwealth or Agency that stores lists of electronic prescriptions for persons and facilitates the transfer of information related to electronic prescriptions for persons between participating systems.
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.
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.
Asset	Anything of value, such as ICT equipment, software or information.
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.

Term	Meaning
Cryptographic Hash	An algorithm (the hash function) which takes as input a string of any length (the message) and generates a fixed length string (the message digest or fingerprint) as output. The algorithm is designed to make it computationally infeasible to find any input which maps to a given digest, or to find two different messages that map to the same digest. https://www.cyber.gov.au/acsc/view-all-content/glossary/c
Cryptographic Salt	A salt is a unique, randomly generated string that is added to each password as part of the hashing process. As the salt is unique for every user, an attacker has to crack hashes one at a time using the respective salt rather than calculating a hash once and comparing it against every stored hash.' – OAWSP https://cheatsheetseries.owasp.org/cheatsheets/Password_Storage_Cheat_Sheet.html#:~:text=A%20salt%20is%20a%20unique,it%20against%20every%20stored%20hash.
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.

Term	Meaning
Electronic transfer of prescription (ETP)	The process whereby prescribing systems pass an electronic representation of a paper prescription to the NPDS, which is available for download by dispensing systems in support of dispensing a paper prescription.
Evidence of Prescription	Provided to the Subject of Care as evidence that an electronic prescription was created for that subject of care. It will contain a token (QR code or URI) to discover and retrieve the electronic prescription. Charts contain tokens (or URIs) but do not contain EoPs. 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
Individual Healthcare Identifier (IHI)	An Individual Healthcare Identifier (IHI) is a unique number used to identify an individual for health care purposes.
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.

Term	Meaning
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/
National Prescription Delivery Service	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 for persons 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

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

Appendix A References

[ACSQHC2017]	*National Guidelines for on-screen display of Medicines Information*, Australian Commission on Safety and Quality in Healthcare, December 2017
[AGENCY2021]	*Electronic Prescribing Solution Architecture,* v3.0, Australian Digital Health Agency, November 2021
[AGENCY2020]	*Use of Healthcare Identifiers in Health Software Systems Software Conformance Profile, v4.0,* Australian Digital Health Agency*, 3 November 2020*
[AGENCY2023]	*Electronic Prescribing Connecting Systems Conformance Profile v3.0.1*, Australian Digital Health Agency*, November 2023*
[AGENCY2024]	*Electronic Prescribing – General Prescribing Systems and Other Connecting Systems Conformance Profile v3.0.1.* Australian Digital Health Agency, September 2024

Appendix B Implementation Advice

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).*