

Policy Directive: compliance is mandatory

Storage and Recording of Restricted Schedule 4 (Prescription Only) Medicines Policy Directive

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Summary The Storage and Recording of Restricted Schedule 4 (Prescription Only) Medicines Policy Directive provides increased governance to reduce the risks to patients, staff and the public from Schedule 4 (prescription only) medicines that are liable to abuse and diversion. The policy includes storage and recording processes that will provide greater accountability for the restricted Schedule 4 medicines.

Keywords Schedule 4 medicines, S4 medicines, restricted, medicines, prescription only medicines, policy directive, storage, storing, recording, handling, secure, diversion, abuse, Storage and Recording of Restricted Schedule 4 (Prescription Only) Medicines Policy Directive

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 Does this policy amend or update an existing policy? *Y v1.0*
 Does this policy replace an existing policy? *N*

Applies to All SA Health Portfolio

Staff impacted All Staff, Management, Admin, Students; Volunteers

EPAS compatible Yes

Registered with Divisional Policy Contact Officer *No*

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Version control and change history

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| 1.0 | 04/05/2017 | 04/05/2022 | Original version |
| 1.1 | 05/07/2017 | Current | Addition of medicines to the SA Health restricted Schedule 4 medicines list |
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Storage and Recording of
Restricted Schedule 4
(Prescription Only)
Medicines
Policy Directive

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Government
of South Australia

SA Health

Document control information

| | |
|----------------------------|--|
| Document owner | Director, Medicines and Technology Programs and Out of Hospital Pharmacy Services, Transforming Health/SA Pharmacy |
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Document history

| Date | Version | Who approved New/Revised Version | Reason for Change |
|------------|---------|---|---|
| 05/07/2017 | V.1.1 | Lynne Cowan, Acting Deputy Chief Executive, Transforming Health | Addition of medicines to the SA Health restricted Schedule 4 medicines list |
| 04/05/2017 | V.1 | SA Health Policy Committee | Original approved version |

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Storage and Recording of Restricted Schedule 4 (Prescription Only) Medicines Policy Directive

1. Objective

The Storage and Recording of Restricted Schedule 4 (Prescription Only) Medicines Policy Directive supports enhanced patient safety and quality use of medicines by providing additional management requirements of certain Schedule 4 medicines. These storage and recording requirements provide greater accountability for these medicines which are associated with a heightened risk of misuse and misappropriation.

The Storage and Recording of Restricted Schedule 4 (Prescription Only) Medicines Policy Directive aims to:

- reduce the risks to patients and staff associated with the diversion or misappropriation of restricted Schedule 4 medicines
- provide greater accountability for the storage and recording of restricted Schedule 4 medicines.

The policy:

- contains the list of Schedule 4 medicines governed by this policy
- ensures a standardised and consistent approach to the storage and recording processes for restricted Schedule 4 medicines in South Australian Local Health Networks, hospitals and health services
- ensures emergency medicines are available when required
- supports the clinical workforce by providing governance around restricted Schedule 4 medicines
- outlines individual and health service responsibilities in storage and recording of restricted Schedule 4 medicines.

Implementation of this policy will:

- ensure greater accountability to this class of medicines which are associated with a risk of abuse and misappropriation
- provide evidence of organisational leadership and governance around storage and recording of restricted Schedule 4 medicines.

2. Scope

This policy applies to all SA Health hospitals and health services, including Local Health Networks (LHNs), statewide clinical services and emergency services (SA Ambulance Service (SAAS) and SAAS MedSTAR). All health practitioners (and staff delegated responsibility for) handling medicines in SA Health, and authorised under the *Controlled Substances Act (SA)1984* and associated regulations to obtain or possess Schedule 4 medicines, are required to adhere to the Storage and Recording of Restricted Schedule 4 (Prescription Only) Medicines Policy Directive (Policy Directive).

3. Principles

The following principles apply to all SA Health hospitals and health services.

General principles

- All restricted Schedule 4 medicines are to be handled in accordance with procedures and requirements for Schedule 8 medicines.
- The storage and recording requirements are applicable in all areas where restricted Schedule 4 medicines are stored and administered.
- SA Health hospitals and health services must develop and implement a plan, including relevant local procedures (or equivalent documents), for the management of restricted Schedule 4 medicines.
- In patient care areas, stock holdings of restricted Schedule 4 medicines must be reviewed and maintained at the minimum required level required for safe patient care.
- In all areas where restricted Schedule 4 medicines are stored and administered, the secure storage area or lockable cupboard must not be left open or unsecured.
- To ensure access to restricted Schedule 4 medicines required for emergency or resuscitation use is not impeded, implementation plans may need to include specific requirements for storing and recording of these medicines (for further information refer to section 7 of this policy).

4. Detail

For the purpose of this document the minimum list of medicines to be subject to additional storage and recording requirements and classified as restricted Schedule 4 medicines are all strengths, brands and formulations of the following medicines:

- > benzodiazepines in Schedule 4
- > cannabidiol containing preparations in Schedule 4
- > codeine containing preparations in Schedule 4
- > dextropropoxyphene
- > tramadol
- > zolpidem
- > zopiclone

It is noted that SA Health hospitals and health services may require greater accountability for some Schedule 4 medicines not included on this list. Consequently, these additional storage and recording requirements may be extended where appropriate to other Schedule 4 medicines.

Other medicines where there is a known risk of diversion and misuse may be considered for inclusion in local lists, for example anaesthetic agents such as propofol. Propofol is known to be diverted and misused, nationally and internationally there have been reported deaths, the causes of which have been linked to misappropriated propofol.

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4.1 Ordering

The ordering and receipt of restricted Schedule 4 medicines must be in accordance with procedures for Schedule 8 medicines.

4.2 Storage

The storage of restricted Schedule 4 medicines is to be in a separate lockable cupboard or secure storage area apart from other Schedule 4 medicines. Automated dispensing cabinets and other storage solutions approved for Schedule 8 medicines can be used to store restricted Schedule 4 medicines. Restricted Schedule 4 medicines may be stored in the same storage cupboard (or other approved storage area) currently used for storing Schedule 8 medicines.

Any restricted Schedule 4 medicines brought into the hospital or healthcare facility by a patient (patient's own medications) must be managed in accordance with the requirements for Schedule 8 medicines outlined in the SA Health Patients' Own Medications (POMs) Policy Directive and Patients' Own Medications Guideline.

Implementation of tamper proof systems as additional security for storage of restricted Schedule 4 POMs may also be considered.

4.3 Access

Only authorised persons are to have access to restricted Schedule 4 medicines storage areas. A local procedure (or equivalent document) must be in place to ensure accountability of all keys or other access devices used, e.g. swipe cards. Where restricted Schedule 4 items are stored in a separate lockable cupboard or secure storage area used for storage of Schedule 8 medications, the access keys are required to be uniquely keyed for each secure storage location.

Swipe card access or automated storage solutions which allow identification of individuals accessing the system are encouraged.

4.4 Recording/Accountability

The recording of restricted Schedule 4 medicines must be in accordance with procedures for recording Schedule 8 medications. As with Schedule 8 items, all stock transactions of a restricted Schedule 4 medicine are to be recorded in a register approved by the SA Health hospital or health service. This includes transactions involving receiving restricted Schedule 4 medications from a pharmacy, patient or wholesaler and returning (to patient or pharmacy) or destroying restricted Schedule 4 medicines.

A stock count for each item is required, with the names and signatures of two authorised personnel at the end of each shift as per local procedure (or equivalent document) and requirements for Schedule 8 medications.

In pharmacy areas, a stock check process must be in place that allows for accountability of all transactions to and from the pharmacy area. Pharmacy areas should complete a routine stock take on at least a monthly basis of all items stored in the restricted Schedule 4 lockable cupboard or secure storage area. Stocktake of restricted Schedule 4 medicines may be undertaken more frequently if required by local procedure (or equivalent document).

5. Roles and Responsibilities

- **SA Health Chief Executive**
 - Ensures services across SA Health operate in accordance with this policy.

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- **Director of Medicines and Technology Programs and Out of Hospital Pharmacy Services**
 - Establishes this policy
 - Ensures this policy is maintained and periodically reviewed to ensure consistency with current evidence and nationally agreed best practice.
- **Chief Executive Officers**
 - Ensure there is a plan developed for implementing this policy, including access to restricted Schedule 4 medicines required for emergency or resuscitation use. The plan must be implemented within 12 months of this policy's approval date.
 - Ensure employees, contractors and consultants are aware of, have access to, and comply with this policy.
 - Ensure breaches of this policy are handled appropriately in accordance with SA Health policy.
 - Delegate the day-to-day responsibility for complying with this policy to the relevant senior managers.
- **Executive Directors, Directors, Heads of Service/Department and other senior managers**
 - Develop, implement and monitor local processes that support the operation of this policy.
 - Ensure local protocols/procedures are implemented for appropriate storage and recording of restricted Schedule 4 medicines. This should also include ensuring access to restricted Schedule 4 medicines required for emergency or resuscitation use is not impeded (refer to section 8 of this policy).
 - Ensure incidents involving storage and recording of restricted Schedule 4 medicines are reported into the Safety Learning System (SLS) and via other appropriate pathways.
- **All SA Health employees, consultants, students and contractors**
 - Adhere to the principals and aims of this policy.
 - Adhere to local processes established to support the operation of this policy.
 - Ensure they are familiar with the list of restricted Schedule 4 medicines for their SA Health hospital or health service.
 - Ensure they are familiar with and adhere to the requirements for storage and recording of restricted Schedule 4 medicines.
 - Report medication incidents involving the storage and recording of restricted Schedule 4 medicines via appropriate pathways including through SLS in accordance with the SA Health Incident Management Policy.

6. Reporting

Any breaches of the Storage and Recording of Restricted Schedule 4 (Prescription Only) Medicines Policy Directive are to be reported in accordance with the institutional reporting lines of delegation.

7. Exemption

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7.1 Exemption Scope

Restricted Schedule 4 medicines required for emergency or resuscitation use

It is noted that some restricted Schedule 4 medicines may be required for emergency or resuscitation use. This Policy Directive should not impede access to restricted Schedule 4 medicines required for management of a patient in an emergency situation, for example midazolam for the emergency treatment of seizures.

Clinical units must develop a plan for the storage and recording of supplies of restricted Schedule 4 medicines required for emergency or resuscitation use. The plan must align with the principles of increased storage and accountability in this policy, but not prevent timely access to the medicines. Any plans which include exemptions to any part of this policy must be approved according to the SA Health hospital or health service exemption process (refer to section 7.2 of this policy).

Consideration should be given to using tamper evident seals or storage systems which provide clear evidence of tampering or use for emergency or resuscitation supplies of restricted Schedule 4 medicines.

Emergency or resuscitation supplies of restricted Schedule 4 medicines should be accessible as per Schedule 8 medicines used in this setting. This includes:

- > Storing in a manner such that general public access is not permitted
- > Maintaining a minimum of stock
- > Regular stock checks, with a record of the name and date of the person completing the check. The frequency of stock checks of restricted Schedule 4 medicines for emergency or resuscitation must be in line with the requirements outlined for all other restricted Schedule 4 and Schedule 8 medicines.

7.2 Exemption Process

Where an exemption to any of the conditions of this policy is considered necessary, a plan must be developed to manage the restricted Schedule 4 medicines in such a way that the principles of greater accountability and restricted access are still taken into account. This plan should be documented and clearly identify the alternative safety controls that will be implemented to minimise the risk to patient, public and staff safety.

Exemption Authority:











Any exemption to the conditions of this policy must be authorised by the Chief Executive (or delegate) of the SA Health hospital or health service

A review date for any approved exemption(s) must be assigned by the Chief Executive (or delegate).

When approved by the Chief Executive (or delegate), alternative requirements commensurate with the level of risk must be implemented for restricted Schedule 4 medicines, as identified in the management plan. These should be defined in local procedures (or equivalent documents) for the management of restricted Schedule 4 medicines.

Any alternative storage requirements that are implemented for restricted Schedule 4 medicines must be compliant with the conditions of the health service's licence to possess Schedule 4 drugs (if the health service is operating under a licence) or regulation 27 of the Controlled Substances (Poisons) Regulations 2011.

8. National Safety and Quality Health Service Standards

| | | | | | | | | | |
|---|---|--|---|--|---|---|--|---|--|
|  |  |  |  |  |  |  |  |  |  |
| National Standard 1 Governance for Safety and Quality in Health Care | National Standard 2 Partnering with Consumers | National Standard 3 Preventing & Controlling Healthcare associated infections | National Standard 4 Medication Safety | National Standard 5 Patient Identification & Procedure Matching | National Standard 6 Clinical Handover | National Standard 7 Blood and Blood Products | National Standard 8 Preventing & Managing Pressure Injuries | National Standard 9 Recognising & Responding to Clinical Deterioration | National Standard 10 Preventing Falls & Harm from Falls |
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9. Risk Management

Some restricted Schedule 4 medicines are identified as having addictive properties and have a high potential for abuse. Narcotics and other sedatives are also identified as high risk medicines under the APINCH acronym, which has been adopted by the Australian Commission on Safety and Quality in Health Care (ACSQHC).

This Policy Directive has been developed to ensure patient, public and staff safety, staff accountability and to avoid misappropriation of restricted Schedule 4 medicines.

10. Evaluation

SA Health employees, contractors and consultants are required to report breaches of this policy through institutional reporting structures.

Additionally, the South Australian Medicines Advisory Committee (SAMAC) will liaise with SA hospitals and health services regarding the uptake and compliance of this Policy Directive.

11. Definitions

In the context of this document:

SA Health hospitals and health services means: all SA Health hospitals and services, including Local Health Networks (LHNs), statewide clinical services and emergency services (SAAS and MedSTAR).

Schedule 4 means: Prescription Only Medicine – substances, the use or supply of which should be by or on the order of persons permitted by State or Territory legislation to prescribe and should be available from a pharmacist on prescription.

Schedule 8 means: Controlled Drug – substances which should be available for use but require restriction of manufacture, supply, distribution, possession and use to reduce abuse, misuse and physical or psychological dependence. These medicines are regulated by the *Controlled Substances Act 1984*.

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12. Associated Policy Directives / Policy Guidelines

Associated SA Health directives and guidelines:

- > [Code of Practice for the Storage and Transport of Drugs of Dependence](#)
- > [High Risk Medicines Management Policy Directive](#)
- > [High Risk Medicines Management Policy Guideline](#)
- > [Patients' Own Medications Policy Directive](#)
- > [Patients' Own Medications Guideline](#)
- > [Staff Access to Medicines for Personal Use Policy Directive](#)

13. References, Resources and Related Documents

The control and use of restricted Schedule 4 medicines must be in accordance with the *Controlled Substances Act 1984 (SA)* and the Controlled Substances (Poisons) Regulations 2011 (SA), and satisfy the National Safety and Quality Health Service Standard 4 in Medication Safety.

The scheduling of medicines is outlined in the current Poisons Standard also known as the *Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)*.

References:

1. [Australian Commission for Safety and Quality in Health Care \(ACSQHC\) High Risk Medicines webpage](#), including Medication Safety Alerts and Notices
2. *Controlled Substances Act 1984 (SA)*
3. Controlled Substances (Poisons) Regulations 2011 (SA)
4. Government of Western Australia: Department of Health 2013 Storage and recording of restricted Schedule 4 (S4R) medicines.
5. New South Wales (NSW) Government: Ministry of Health, 2013, Medication Handling in NSW Public Health Facilities Policy Directive.
6. The Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) 2013
7. Tasmanian Government: Department of Health and Human Services, 2014, Schedule 8 and Declared Schedule 4 Medicines Management Policy.