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SA Health

Policy

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

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Government
of South Australia

SA Health

1. Name of Policy

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

2. Policy statement

This policy provides the mandatory requirements in relation to the storage and recording of certain Schedule 4 medicines that are associated with a heightened risk of misuse, diversion, and misappropriation, ensuring patient safety, greater accountability and quality use of medicines. The Schedule 4 medicines which are subject to these policy requirements are known as 'restricted' Schedule 4 medicines.

3. Applicability

This policy applies to all employees and contracted staff of SA Health; that is all employees and contracted staff of the Department for Health and Wellbeing (DHW), Local Health Networks (LHNs) including state-wide services aligned with those Networks and SA Ambulance Service (SAAS).

In particular, this policy applies to all health practitioners (and staff with delegated responsibility for) handling medicines in SA Health, and those authorised under the *Controlled Substances Act 1984* (SA) and associated regulations to obtain or possess Schedule 4 medicines.

4. Policy principles

SA Health's approach to this policy is underpinned by the following principles:

- > We ensure a standardised and consistent approach to the storage and recording processes for restricted Schedule 4 medicines in LHNs, hospitals and health services.
- > We support the clinical workforce by providing governance around restricted Schedule 4 medicines, to reduce risk to patients and staff associated with diversion, abuse or misappropriation.
- > We ensure emergency medicines are available when required.

5. Policy requirements

Restricted Schedule 4 Medicines

LHNs and statewide services must:

- > Manage all restricted Schedule 4 medicines in accordance with this policy and in line with LHN procedures.
- > At a minimum apply this policy for the following restricted Schedule 4 medicines of all strengths, brands and formulations:
 - benzodiazepines in Schedule 4
 - codeine containing preparations in Schedule 4
 - tramadol
 - zolpidem
 - zopiclone, and
 - any other medicine included by LHNs or health services in local lists, due to known risk of diversion or misuse.

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- > Have systems in place to manage new or additional medicines in accordance with legislation.
- > Monitor for potential misuse, diversion, and misappropriation, and consider implementation of local risk management strategies where appropriate.

Ordering

- > The ordering and receipt of restricted Schedule 4 medicines must be in accordance with LHN or health services procedures for Schedule 8 medicines.

Storage

- > Restricted Schedule 4 medicines must be stored 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, or
 - 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 [Patients' Own Medications \(POMs\) Policy](#).
- > The secure storage area or lockable cupboard must not be left open or unsecured in all areas where restricted Schedule 4 medicines are stored and/or administered.

Access

LHNs and statewide services must:

- > Ensure restricted Schedule 4 medicines storage areas are only accessed by authorised persons.
- > Have a local procedure (or equivalent document) in place to ensure accountability of all keys or other access devices used to access restricted Schedule 4 medicines such as swipe cards.
- > Ensure the access keys are uniquely keyed for each secure storage location where restricted Schedule 4 medicines are:
 - stored in a separate lockable cupboard, or
 - in a secure storage area used for storage of Schedule 8 medications.
- > Consider swipe card access or automated storage solutions which allow identification of individuals accessing the system for all restricted Schedule 4 medicine storage areas.
- > Ensure access to restricted Schedule 4 medicines if required for emergency or resuscitation use is not impeded (see [Exemption – Medicines for Emergency or Resuscitation](#)).

Recording/Accountability

LHNs and statewide services must:

- > Record restricted Schedule 4 medicines in accordance with procedures and requirements for recording Schedule 8 medications. Record all stock transactions of a restricted Schedule 4 medicine in a register approved by the SA Health hospital or health service, including transactions

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involving receiving restricted Schedule 4 medications from a pharmacy, patient or wholesaler and returning (to patient or pharmacy) or destroying restricted Schedule 4 medicines.

- > Ensure a stock count for each item is performed at the end of each shift, with the names and signatures of two authorised personnel, as per local procedure (or equivalent document) and requirements for Schedule 8 medications.
- > Ensure, in pharmacy areas, a stock check process is in place that allows for accountability of all transactions to and from the pharmacy area.
 - Pharmacy areas must complete a routine stock take at least monthly of all items stored in the restricted Schedule 4 lockable cupboard or secure storage area. Stocktake of restricted Schedule 4 medicines must be undertaken more frequently if required by local procedure (or equivalent document).
- > Ensure, in patient care areas, stock holdings of restricted Schedule 4 medicines are reviewed and maintained at the minimum required level required for safe patient care.

Reporting

Any breaches of this Policy must be reported in:

- > Accordance with the institutional reporting lines of delegation, such as line managers and shift supervisors.
- > The Safety Learning System (SLS).

Exemption – Medicines for Emergency or Resuscitation

- > Where restricted Schedule 4 medicines are required for emergency and/or resuscitation use, the medicines must be readily available for the management of the patient, such as midazolam for the emergency treatment of seizures.
- > LHN Clinical units must develop a plan for the storage and recording of supplies of restricted Schedule 4 medicines required for emergency and/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.
- > Consideration must 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 must 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 stock level, and
 - 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 (see [Recording/Accountability](#)).

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- > Exemptions to this policy must comply with the following 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.
 - The plan must be documented and clearly identify the alternative safety controls that will be implemented to minimise the risk to patient, public and staff safety.
 - Any exemption to the conditions of this policy must be authorised by the Chief Executive Officer (CEO) or approved delegate of the LHN.
 - A review date for any approved exemption(s) must be assigned by the CEO (or approved delegate).
 - When approved by the CEO (or approved delegate), alternative requirements commensurate with the level of risk must be implemented for restricted Schedule 4 medicines, as identified in the management plan. These must 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*.

6. Mandatory related documents

The following documents must be complied with under this Policy, to the extent that they are relevant:

- > [Controlled Substances Act 1984](#)
- > [Controlled Substances Act 1984 Pharmacists' obligations](#)
- > [Controlled Substances \(Poisons\) Regulations 2011](#)
- > [Code of Practice for the Storage and Transport of Drugs of Dependence](#)
- > [Patients' Own Medications Policy](#)
- > [High Risk Medicines Management Policy](#)
- > [Staff Access to Medicines for Personal Use Policy](#)
- > 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](#).

7. Supporting information

- > The scheduling of medicines is outlined in the current Poisons Standard also known as the [Standard for the Uniform Scheduling of Medicines and Poisons \(SUSMP\)](#).

8. Definitions

- > **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.

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- > **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*.
- > **Restricted Schedule 4:** means Schedule 4 medicines which are liable to abuse, diversion or dependence, as defined by SA Health, LHNs, hospitals and/or health services, and require additional controls to minimise risk of misappropriation.

9. Compliance

This policy is binding on those to whom it applies or relates. Implementation at a local level may be subject to audit/assessment. The Domain Custodian must work towards the establishment of systems which demonstrate compliance with this policy, in accordance with the requirements of the [Risk Management, Integrated Compliance and Internal Audit Policy](#).

Any instance of non-compliance with this policy should be reported to the Domain Custodian for the Clinical Governance, Safety and Quality Policy Domain and the Domain Custodian for the Risk, Compliance and Audit Policy Domain.

10. Document ownership

Policy owner: Domain Custodian for the Clinical Governance, Safety and Quality Policy Domain

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

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11. Document history

Version	Date approved	Approved by	Amendment notes
V.1	04/05/2017	SA Health Policy Committee	Original approved version
V.1.1	05/07/2017	Acting Deputy Chief, Executive, Transforming Health	Addition of medicines to the SA Health restricted Schedule 4 medicines list
V2	12/12/2024	Chief Executive, Department for Health and Wellbeing	Update to new Policy Framework template and requirements. Updates to restricted Schedule 4 medicines list.

12. Appendices

Nil