Government of **Western Australia**
Department of **Health**

Risk based requirements for medicines handling

Including requirements for Schedule 4 Restricted medicines

health.wa.gov.au

Contents

1. Introduction

This document provides details of controls and information which must be included in policies and procedures developed by public health service facilities, to comply with the requirements of MP 0139/20 *Medicines Handling Policy*.

These requirements are in addition to the regulatory controls over scheduled medicines. The additional requirements are considered necessary because public health service facilities, particularly larger hospitals, are complex organisations, where multiple staff handle significant quantities of medicines. This means the controls mandated by the *Medicines and Poisons Act 2014* and the Medicines and Poisons Regulations 2016 alone are not considered sufficient to minimise risks of misappropriation and diversion of scheduled medicines in this setting.

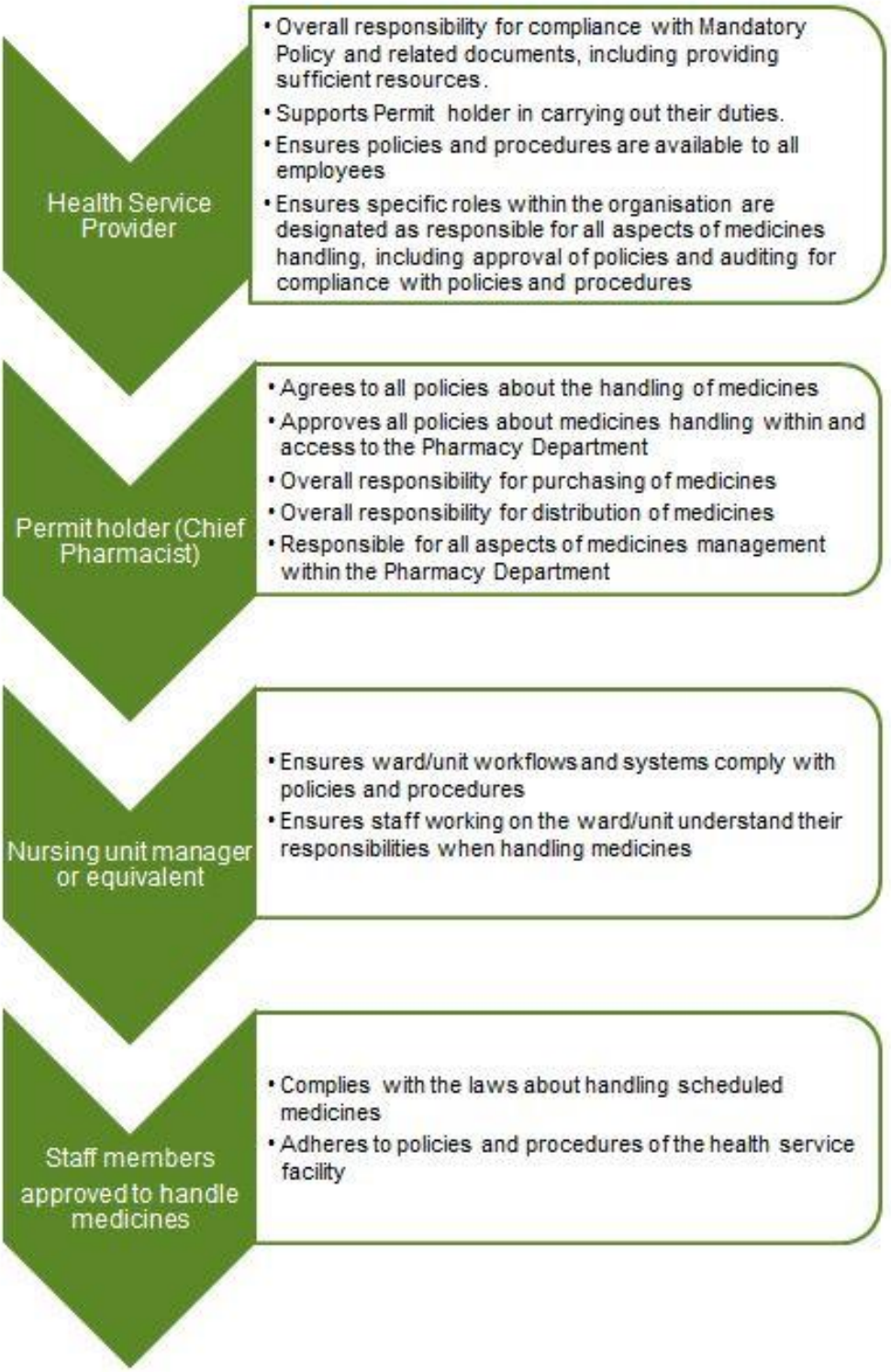
This document does not cover all requirements for the handling of medicines, as many of the requirements are already covered by the Medicines and Poisons Legislation or directly included in MP 0139/20 *Medicines Handling Policy*. Cross-references to the relevant section of MP 0139/20 *Medicines Handling Policy* are included for clarity.

The requirements about medicines handling are applicable regardless of whether the scheduled medicine is a formulary item, a medicine compounded by the Pharmacy Department, a clinical trial drug, a high cost drug subject to individual patient approval, an unregistered therapeutic good obtained via a scheme such as the Therapeutic Goods Administration's (TGA) Special Access Scheme (SAS) or the patient's own medicines.

No system used for medicines handling, regardless of whether the system is a contemporary technology based solution or a manual system, completely eliminates the risk of misappropriation and diversion. However, it is acknowledged that technology based medicines handling systems, such as automated dispensing cabinets (ADCs), controlled substances cabinets and unit dose packaging equipment, are superior to paper-based systems for medicines tracking and record-keeping to monitor inventory and deter drug diversion.

The MP 0006/16 *Risk Management Policy*, and its related document *Risk Assessment Tables for the WA Health System*, are relevant to governance and decision making about the handling of medicines.

2. Summary of roles and responsibilities



3. Schedule 4 Restricted medicines

See also Section 3.4.1 in MP 0139/20 *Medicines Handling Policy*.

The following medicines in all brands, formulations and strengths are designated as Schedule 4 Restricted (S4R) medicines[1]

Bromazepam	Lorazepam	Temazepam
Clobazam	Midazolam	Tramadol
Clonazepam	Nitrazepam	Zolpidem
Codeine containing preparations in S4	Oxazepam	Zopiclone
Diazepam	Propofol	

4. Medicines acquisition

See also section 3.3.1 in MP 0139/20 *Medicines Handling Policy*.

Scheduled medicines must be ordered by the 'health service permit' holder or by persons in positions delegated by the permit holder.

Where acquisition of scheduled medicines will not be directly managed by the Pharmacy Department, two pathways are applicable:

- acquisition of inventory stock by another unit of the public health service facility

or

- supply of scheduled medicines to the public health service facility for a named patient.

Where supply to the facility is for a named patient, applicable systems include, but are not limited to:

- medicines dispensed at community pharmacies for aged care residents in Multi Purpose Services (MPS)
- S100 Remote Area Aboriginal Health Services Program supplies from community pharmacies to remote clinics operated by Health Service Providers
- funded community based supply systems, such as for mental health patients.

If acquisition of inventory stock of particular scheduled medicines (such as nitrous oxide or blood products in S4) is to be managed by another unit of the public health service facility, this must be approved by the permit holder. The reasons for the decision to order and manage stock of scheduled medicines other than via the Pharmacy Department must be documented.

Scheduled medicines must be ordered from suppliers licensed or otherwise approved under the Medicines and Poisons Legislation or suppliers approved to supply scheduled medicines under legislation in other jurisdictions.

5. Storage of medicines, including control of access to storage

See also section 3.3.3 in MP 0139/20 *Medicines Handling Policy*.

Public health service facilities must have policies describing the required attributes of storage areas for scheduled medicines for each part of the facility.

Applicable parts of the facility include, but are not limited to:

- the Pharmacy Department

[1] Dextropropoxyphene and triazolam were previously classified as S4R medicines. As these medicines are no longer marketed in Australia, they have been deleted from the Schedule 4 Restricted list.

- wards
- other patient care areas, including areas that are not operational 24 hours a day, 7 days a week, such as operating theatres and wards associated with day procedures
- other areas where scheduled medicines are stored such as storage areas for cylinders of Schedule 4 (S4) anaesthetic gases (such as nitrous oxide).

Storage areas for scheduled medicines must:

- ensure the medicines are not accessible to unauthorised persons
- ensure patients, visitors and other members of the public cannot enter medicines storage areas
- preferably be located such that entry to the storage area or the storage receptacle can be observed by authorised persons when the area is in operation
- use additional security measures commensurate with the risk level for diversion of the medicines stored.

Consideration of security measures other than the physical attributes of the storage receptacle itself are particularly relevant where S4R and Schedule 8 (S8) medicines are being stored. Additional security measures include:

- closed circuit television (CCTV), which may contribute information in the event of an investigation of a medicines discrepancy
- monitored alarm systems, which may allow detection of unauthorised entry in a timely manner where medicines storage is in locations that are not open 24 hours a day, 7 days a week.

See also MP 0103/19 *Reporting of Schedule 4 Restricted and Schedule 8 Medicines Discrepancies Policy* and the Guidelines for Dealing with a S4R or S8 Medicine Discrepancy.

5.1. Staff access to medicines storage areas

Public health service facility policies and/or procedures about staff members who may access medicines storage areas must include details of:

- governance over the granting of access to medicines storage areas
- dealing with access breaches, including if keys, entry codes or proximity cards are lost, stolen, provided to, or accessed by, an unauthorised person
- maintaining ongoing security of the medicines storage areas when a potential security breach is identified.

Pharmacy Department staff, that are not pharmacists and whose job description includes tasks relating to the distribution and delivery of medicines within a public health service facility, are permitted to access relevant storage areas/receptacles outside the Pharmacy Department without the direct supervision of an authorised person, provided the storage receptacle is not a S8 cupboard or safe.

The involvement of those responsible for facilities management and security within the public health service facility is recommended to ensure appropriate planning, implementation and monitoring of controls over access to storage areas for scheduled medicines.

5.2. Storage of S4R medicines

See also section 3.3.3 and 3.4.3 in MP 0139/20 *Medicines Handling Policy*.

S4R medicines must be stored separately to other medicines, including other S4 medicines. The storage receptacle or storage area must be kept locked when not in use.

If a cupboard is used for storage of S4R medicines, the cupboard must be securely attached to a floor or wall.

There may be operational circumstances, particularly in interventional treatment areas or areas where anaesthesia is administered, where public health service facilities wish to use alternative storage provisions for S4R medicines. Propofol is an example of a S4R medicine for which alternative storage arrangements may be considered necessary in certain clinical settings. Similarly, alternative storage arrangements may need to be considered for S4R products requiring refrigeration. Where this is the case, public health service facilities must:

- conduct a documented risk assessment
- document any deviations from the standard storage provisions for S4R medicines and describe how these deviations will mitigate identified risks
- obtain approval from the public health service facility executive for the proposed alternative storage arrangements.

Note: An Australian and New Zealand College of Anaesthetists *Advisory Statement on the Storage of Propofol in Clinical Settings* (March 2019) is available.

5.3. Storage of S4R medicines for medical emergencies

Where S4R medicines are kept as part of dedicated stock in a clinical area specifically for the purpose of treating patients during a medical emergency, the above described storage requirements do not apply.

Storage of S4R medicines for use in a medical emergency must:

- be in a designated resuscitation box or trolley, which contains an appropriate amount of S4R stock for treating a patient in an emergency
- be in a storage system designed to provide clear evidence of tampering or opening (including when opened for legitimate use)
- be located in an area which can be routinely observed by authorised persons or is subject to additional security measures to enhance detection of interference by unauthorised persons
- be subject to regular checking for tampering, including documentation of those checks.

5.4. Access to storage for S4R and S8 medicines

See also section 3.4.4 in MP 0139/20 *Medicines Handling Policy*.

Access to storage for S4R and S8 medicines includes storage of access mechanisms, including spare keys or access cards, when areas are closed (such as after hours or when maintenance is being undertaken). These policies and procedures must include details of how access breaches, including lost keys and access codes being divulged to other persons, will be managed.

During times of operation, all keys in use, access codes or other mechanisms to unlock S4R or S8 storage receptacles or storage areas must remain in the personal possession of an authorised person.

Any spare keys or other mechanisms to unlock S4R and S8 storage receptacles and storage areas must be stored in a manner that provides at least an equivalent level of security as the

storage receptacle for the medicines themselves. For example, spare keys for a drug safe in a patient care area could be stored in a drug safe within the Pharmacy Department.

Public health service facilities must have an accountability system for the issue and return of keys or other mechanisms to unlock S4R and S8 storage receptacles and storage locations.

The involvement of those responsible for facilities management and security within the public health service facility is recommended to ensure appropriate planning, implementation and monitoring of controls over access to storage areas for S4R and S8 medicines.

5.5. Pharmacy Department access, including after hours

See also section 3.5.1 in MP 0139/20 *Medicines Handling Policy*.

Physical security applicable to the Pharmacy Department includes consideration of:

- electronic access to control and monitor entry on all external doors
- camera surveillance in areas where higher risk medicines are being handled
- ensuring stored medicines are not easily visible to the general public
- documentation of distribution of keys/access codes.

During usual operating hours, unsupervised access to the Pharmacy Department must be limited to pharmacy staff. The only exception to this is during an emergency code activation, in circumstances where pharmacy staff are not able to supervise access (such as due to evacuation requirements).

Access to the Pharmacy Department must be controlled by the Chief Pharmacist for the public health service facility.

Public health service facilities must have a policy detailing:

- when and why access to the Pharmacy Department by staff members, other than pharmacy staff, is authorised
- which staff members are authorised to access the Pharmacy Department.

When the Pharmacy Department is entered outside the usual operating hours:

- the identity of the person entering and their entry (and ideally exit) times/dates must be recorded and those records must be available for up to five years from when the record was made
- the records must be regularly reviewed by the Chief Pharmacist (or their delegate)
- if the reason for after-hours entry is not readily apparent when the records are reviewed, the reasons for the after-hours entry must be investigated and action taken in accordance with the requirements of the *Integrity Policy Framework*, if applicable.

5.6. After-hours access to S8 medicines in the Pharmacy Department

See also section 3.4.4.1 in MP 0139/20 *Medicines Handling Policy*.

The public health service facility policy and/or procedures relating to after-hours access to S8 medicines within the Pharmacy Department must include:

- details of the role responsible for approving access to S8 medicines within the Pharmacy Department outside usual operating hours
- mechanisms to ensure after hours supply/dispensing is recorded in an auditable manner

- requirements for regular audits of after-hours supply/dispensing to be undertaken by a nominated role.

Further information is available in the *Guideline on Pharmacy Department access*.

5.7. Storage of nitrous oxide

See also section 3.3.3 in MP 0139/20 *Medicines Handling Policy*.

Nitrous oxide (including in cylinders combined with oxygen), for therapeutic use, is classified as a S4 substance.

Nitrous oxide presents different risks to most other S4 medicines due to:

- the inherent hazards of compressed gas cylinders
- the oxidising nature of nitrous oxide
- risk of diversion and misuse, with inhalation resulting in euphoria and relaxation.

The storage risks are applicable to nitrous oxide in all forms: in stored cylinders, in cylinders attached to anaesthetic machines and when piped to theatre and other procedural areas.

Public health service facility policies and/or procedures about the storage of nitrous oxide must include:

- information about storage of both large and small cylinders
- details of how the risk of unauthorised access to piped nitrous oxide and cylinders attached to anaesthetic machines will be minimised
- a process for monitoring the amount of nitrous oxide procured to detect any unusual or unexpected changes
- action to be taken where monitoring detects unusual or unexpected changes in the amount of nitrous oxide being procured.

5.8. Management of patients' own medicines

See also section 3.3.8 and 3.4.9 in MP 0139/20 *Medicines Handling Policy*.

Scheduled medicines which belong to patients may have been purchased over the counter at a pharmacy (Schedule 2 and Schedule 3 medicines) or dispensed to the patient by a pharmacist (S4 and S8 medicines). These medicines are the property of the patient and are not subject to the controls of the Medicines and Poisons Legislation. This legislation has already been applied to its fullest extent when the medicine was supplied to the patient by their community pharmacy.

However, within public health service facilities, the risks that flow from inappropriate access to patients' own medicines are the same as the risks with medicines more generally. These relate to the schedule of the medicine rather than its status as a previously supplied item. This means patients' own medicines must be stored with an equivalent level of security to other scheduled medicines.

Public health service facilities must have policies and/or procedures about the handling of all patients' own medicines which:

- recognise that although these medicines are the property of the patient, risks of diversion and theft exist whilst these medicines are within the public health service facility

- include specific requirements for the transport, use, documentation, storage, return to the patient and disposal of patients' own S4R and S8 medicines which ensure the security of these medicines throughout the time the patient is at the facility
- use 'chain of custody' handling for patient's own S4R and S8 medicines, with auditable record keeping of the movement of the medicines from the patient's arrival up to and including the return of the medicines to the patient (or their family/carers) or disposal of the medicines.

6. Distribution of medicines

See also section 3.3.2 in MP 0139/20 *Medicines Handling Policy*.

Distribution of medicines within and between public health service facilities must be managed by the Pharmacy Department. The exception to this is where there is an approval in place in accordance with Section 4 of this document which allows particular medicines to be managed by another unit of the public health service facility.

Public health service facilities must have policies and procedures about the distribution of scheduled medicines throughout the public health service facility, including to sites located separately to the Pharmacy Department or sites located separately to the initial delivery point for scheduled medicines.

Distribution of scheduled medicines within the public health service facility, such as from the Pharmacy Department to the wards, must be undertaken in a manner which allows later audit.

Technology based medicines distribution (and storage) systems, such as ADCs have advantages over paper-based systems. However, the benefits of these systems in improving safety and reducing risk will only be fully realised where both design and use are carefully planned and implemented.

In circumstances where:

- a medicine required for patient care is not available within the public health service facility, either from the Pharmacy Department or from elsewhere in the facility
- stock of the medicine cannot be obtained from a wholesaler in a timely manner
- not obtaining the medicine would compromise patient care,

the public health service facility may obtain an appropriate quantity of the required medicine from another public health service facility.

Obtaining stock from another public health service facility includes transferring stock from the originating facility to the destination facility, when a patient is transferred from one facility to another.

Public health service facilities must have a policy and, if necessary, procedures about obtaining stock from other public health service facilities under the above described circumstances, which ensures the Pharmacy Department of each of the public health service facilities is involved in the decision to transfer the stock and the transfer is documented in a manner that allows later audit to be performed.

Further information is available in the *Guideline on distribution of medicines*.

6.1. Distribution outside Pharmacy Department operating hours

Public health service facilities must have a policy on patient care areas obtaining medicines outside the usual operating hours of the Pharmacy Department. This includes obtaining medicines from the Pharmacy Department itself, such as through an on-call pharmacist service, as well as other mechanisms, such as use of an 'after-hours' stock cupboard and transfer of medicines from one patient care area to another.

Public health service facility policies about the distribution of medicines at times when the Pharmacy Department is closed must:

- include mechanisms to ensure the correct medicine is obtained
- ensure all stock transferred to patient care areas is packaged and labelled in a manner that allows the person administering the medicine to fully identify the name, strength and dosage form of the medicine
- ensure documentation of ordering, supply and receipt, such that auditing after the event can occur
- maintain separation of duties, if possible
- if separation of duties is not possible, include other security measures and monitoring to reduce the opportunity for misappropriation of higher risk medicines and increase the probability that misappropriation will be detected
- where medicines are not obtained from the Pharmacy Department via a pharmacist on-call service, consider whether mechanisms to notify the Pharmacy Department of the details of the stock movement are required.

Further information is available in the *Guideline on distribution of medicines*.

6.2. Distribution of S4R and S8 medicines

See also section 3.4.2 in MP 0139/20 *Medicines Handling Policy*.

Distribution systems for S4R and S8 medicines must ensure the 'chain of custody' is maintained at all times. 'Chain of custody' controls rely on the ability to audit at all points where transfer of S4R and S8 medicines occurs between individuals, whether within the Pharmacy Department, within a single public health service facility location or from one public health service facility location to a separate public health service facility location (such as from a hub hospital Pharmacy Department in a regional or remote area to a smaller hospital or nursing post).

The distribution of S4R and S8 medicines must:

- incorporate auditable verification of delivery to provide certainty that the medicines reached the intended area of the public health service facility
- ensure distribution records, including hard copy orders and requisitions, picking slips and delivery receipts as well as electronic versions of these documents, are made and retained in a manner that allows both internal and independent audits to be conducted
- wherever possible, require separation between ordering, order processing and order delivery, such that different persons complete each part of the distribution process
- where separation of duties is not possible, public health service facilities are to undertake a risk assessment of the distribution process and implement measures to reduce the risks of misappropriation and diversion.

Measures that may reduce misappropriation and diversion risks during distribution, where separation of duties is not possible include, but are not limited to:

- minimising the range and quantity of S4R and S8 medicines distributed to particular sites
- additional physical security such as CCTV
- additional inventory checks or audits.

Public health service facilities must have a policy about distribution of S4R and S8 medicines which includes:

- clear direction on the roles responsible for each stage of the distribution process
- details of risk mitigation measures where task separation cannot be achieved
- details of the required documentation for each stage of the distribution process.

Further information is available in the *Guideline on distribution of medicines*.

7. Administration of medicines to patients

7.1. Self-administration of scheduled medicines by patients

Public health service facility policies and/or procedures about self-administration of scheduled medicines by patients:

- must include:
  - the circumstances where self-administration is authorised
  - how self-administration by patients will be safely managed, including managing any risks of misappropriation and diversion of the medicines
  - details of how access to storage by unauthorised persons will be precluded whilst simultaneously allowing the patient access to the medicines
  - the roles and responsibilities of non-regulated healthcare workers, such as patient care assistants and assistants in nursing, in assisting patients with self-administration of scheduled medicines
  - how self-administration will be recorded.
- must not allow self-administration of S4R or S8 medicines unless:
  - the S4R or S8 medicine is contained within a patient controlled analgesia (PCA) infusion and the patient is self-administering via a PCA pump
  - the patient is an aged care resident at a MPS
    or
  - there is a documented clinical reason to allow self-administration of all medicines, such as where self-administration is an integral part of the patient's rehabilitation process.

All directions relating to administration of scheduled medicines must be documented on the patient's medication chart, regardless of whether administration is by a staff member or the patient.

The MP 0078/18 *Medication Chart Policy* requires documentation about whether doses of charted medicines have been administered and includes a specific code to record self-administration. This means self-administration supervised by appropriate staff is the most appropriate form of self-administration of medicines by patients in public health service facilities.

7.2. Administration of S8 medicines

See also section 3.4.6 in MP 0139/20 *Medicines Handling Policy*

Wherever possible, S8 medicines are to be retrieved from storage immediately prior to administration. Where maintaining best practice clinical care means S8 medicines need to

be removed from storage at other times, such as in procedural areas or emergency care situations, public health service facilities must have procedures in place to minimise risks of misappropriation and diversion.

Any unusable amounts of S8 medicines remaining after the administration of a dose, such as a part ampoule, must be discarded in a manner that results in the discarded S8 being unrecognisable, unusable and irretrievable.

Public health service facility policies and/or procedures about administration of S8 medicines must include details of:

- the classes of health professionals who can administer doses of S8 medicines
- any restrictions on who can administer doses
- any restrictions on the circumstances under which particular health professionals can administer doses
- any additional checks to be performed before administration (such as whether two authorised persons must be involved in preparing and administering S8 medicines)
- any additional risk mitigation measures to be used when administering infusions of S8 medicines, such as use of infusion pumps with security features that minimise opportunities for diversion
- the recording of administration, both in the patient's clinical record and in the S8 register, including recording and witnessing of any discarded amounts
- any specific requirements for procedural areas or emergency care situations, where clinical care could be compromised if S8 medicines are not immediately available.

Where public health service facilities require a second person to check any aspect of the administration of a S8 medicine (including making a record), the second person must be an authorised person.

Further information is available in the *Guideline on administration and record keeping for Schedule 4 Restricted and Schedule 8 medicines*.

8. Supply of medicines to patients

8.1. Supply of scheduled medicines to patients by health professionals other than pharmacists

See also section 3.3.7 in MP 0139/20 *Medicines Handling Policy*.

Examples of where it may be appropriate for supply of medicines to be made by an authorised person, other than through dispensing of a prescription by a pharmacist, include:

- provision of doses of medicines for use prior to a booked procedure (for example, prior to a colonoscopy)
- supply of medicines by an investigator as part of a clinical trial.

Public health service facility policies about supply by authorised persons must be consistent with the requirements of the Medicines and Poisons Legislation, which allows:

- a pharmacist to dispense a prescription for a S4 or S8 medicine and supply a schedule 2 (S2) or schedule 3 (S3) medicine
- an authorised prescriber to supply a S2, S3, S4 or S8 medicine
- a SASA to allow supply of a S2, S3 or S4 medicine by an authorised person, who is not an authorised prescriber, to treat an acute health condition or for a public health program.

This means, unless a relevant SASA is in place, S4 medicines must only be supplied to non-admitted patients or patients being discharged, by an authorised prescriber or by a pharmacist (following receipt of a prescription). S8 medicines must only be supplied by an authorised prescriber or a pharmacist (following receipt of a prescription).

Supply by an authorised prescriber includes supply made during a telehealth consultation utilising video, where the authorised prescriber visually supervises the supply of the medicine. In this circumstance, the authorised prescriber remains responsible for the supply of the medicine. The authorised prescriber must undertake all the checks they would ordinarily take if physically present including that:

- the correct medicine is selected from stock
- the correct labelling applied
- records are made in accordance with both the regulatory requirements and any local policy (including any records in S4R or S8 registers).

9. Record keeping

9.1. General record keeping requirements for S4R medicines

See also section 3.4.5.2 in MP 0139/20 *Medicines Handling Policy*.

The movements of S4R medicines must be recorded in a register or software approved by the public health service facility executive or by the permit holder. Any recording system must ensure a running balance of stock on hand can be kept and records cannot be deleted, amended or removed, without this action being evident.

The minimum information to be recorded about transactions involving S4R medicines is:

- date and time,
- information identifying medicine – substance, dosage form, strength
- quantity of medicine used (dose administered, amount discarded, and, if applicable, amount supplied to the patient e.g. at discharge)
- patient name if administered or dispensed/supplied
- receiving or supplying area if applicable
- invoice or requisition number if applicable
- signature and name (or electronic equivalent) of authorised person recording the transaction.

Where hardcopy registers are used, information identifying the medicine is not required to be recorded for each transaction provided the information is included on each page and a single medicine is recorded on that page.

Public health service facilities must have a policy about the recording of S4R transactions which includes information about:

- the type of recording system(s) to be used (hard copy or electronic) and where each system will be used
- any requirements for more than one authorised person being involved in S4R transactions
- any requirements for taking an inventory of S4R medicines (see also section 6).

Public health service facilities must have a policy for storing records about S4R medicines for at least 2 years from when the last record is made. This policy must:

- include information about where archived records will be kept
- ensure storage of archived registers is secure

- include details of which classes of staff member are authorised to access archived records
- provide for an audit trail to be maintained of removal and return of archived records
- include processes for dealing with archived records that cannot be found.

If an 'in use' or archived S4R register cannot be found within 24 hours of being detected as missing, a report must be immediately made to the Medicines and Poisons Regulation Branch via email: MPRB.Compliance@health.wa.gov.au

If a security or data breach in relation to electronic records of S4R transactions occurs, a report must be made to the Medicines and Poisons Regulation Branch via email: MPRB.Compliance@health.wa.gov.au, within 24 hours of the security or data breach being detected.

There may be operational circumstances, particularly in interventional treatment areas, where public health service facilities wish to vary the information recorded for S4R medicines. Where this is the case, public health service facilities must:

- conduct a documented risk assessment
- document any deviations from the standard record keeping requirements for S4R medicines and describe how these deviations will mitigate identified risks
- obtain approval from the public health service facility executive for the proposed alternative record keeping requirements
- as soon as practicable, send a copy of the approved alternative record keeping requirements to the Medicines and Poisons Regulation Branch MPRB@health.wa.gov.au

9.2. Management of the distribution and archiving of S8 registers

See also section 3.4.5.1 in MP 0139/20 *Medicines Handling Policy*.

Public health service facility policies and/or procedures about distribution and management of completed hard copy registers must:

- provide for each hard copy register to be uniquely identified
- ensure records of distribution are maintained
- ensure completed registers are appropriately managed in accordance with the following requirements:
  - information about where archived registers will be kept is documented and available
  - the storage of archived registers is secure
  - details of which classes of staff member are authorised to access archived registers is documented
  - an audit trail is maintained of removal and return of archived registers
- include processes for dealing with registers that cannot be found include investigation in a timely manner and reporting to the Department of Health

9.3. Inventories of S4R medicines

See also section 3.4.5.3 in MP 0139/20 *Medicines Handling Policy*.

Regular inventories must be made of S4R medicines, to reduce the risk of recording errors, other errors (such as choice of the incorrect product for administration), misuse, misappropriation and diversion remaining undetected.

Public health service facilities must have a policy on inventories of S4R medicines which includes:

- prescribed inventory intervals for all areas of the facility where S4R medicines are stored, including when S4R medicines are stored in resuscitation boxes or trolleys
- any requirements for verification by a second authorised person
- clear direction on role responsibilities in relation to making and recording inventories.

9.4. Inventories of S8 medicines

See also section 3.4.5.3 in MP 0139/20 *Medicines Handling Policy*.

As public health service facilities often use significant quantities of S8 medicines at multiple locations across their site, with handling of S8 medicines by multiple staff members, a monthly interval between inventories is unlikely to be sufficient to reduce the risk of recording errors, other errors (such as choice of the incorrect product for administration), misuse, misappropriation and diversion remaining undetected. The longer the interval between physical stock counts, the more difficult it becomes to reconcile any discrepancies due to the volume of transactions to be reviewed and the declining recollection of events that may have contributed to the discrepancy.

Public health service facilities must have a policy about inventories of S8 medicine which includes:

- prescribed intervals for all areas of the facility where S8 medicines are stored
- any requirements for verification by a second authorised person
- clear direction on role responsibilities in relation to making and recording inventories.

Further information is available in the *Guideline on administration and record keeping for Schedule 4 Restricted and Schedule 8 medicines*.

10. Destruction and discards of S4R and S8 medicines

See also section 3.4.7 in MP 0139/20 *Medicines Handling Policy*.

All S8 medicines for which destruction and discarding is undertaken must be rendered unrecognisable, unusable and irretrievable as part of the disposal process.

The misappropriation and diversion risk associated with S4R medicines means these medicines must also be rendered unrecognisable, unusable and irretrievable as part of the disposal process.

When part of a dosage unit, such as a part ampoule, of a S4R or S8 medicine remains after the required amount has been administered to the patient, the remaining part of the dosage unit (commonly referred to as a ‘discard’) must be rendered unrecognisable, unusable and irretrievable as part of the disposal process.

As with all pharmaceutical waste, final disposal must be by high temperature incineration. OD 0651/16 *Clinical and Related Waste Management Policy* provides further detail about the management of pharmaceutical waste.

Public health service facility policies and procedures about the destruction, discarding and disposal of S8 medicines must:

- ensure the risk of misuse and diversion during destruction, discarding and disposal is minimised

- provide for compliance with the statutory requirements for destruction of S8 medicines, including the requirement for specific record keeping and witnessing of destruction
- ensure S8 medicine discards are documented in the S8 register (in hard copy or electronic form) or in an alternative manner* which maintains the audit trail for these medicines and which would allow later internal and independent audits to be undertaken
- include details of any requirements for two authorised staff to be involved in undertaking and documenting S8 medicine discards
- include information about the destruction and disposal of patients' own S8 medicines, where these medicines are not returned to the patient (or their family/carer)
- provide clear direction on the roles responsible for managing S8 discards, for undertaking S8 destruction and for managing disposal of S8 medicines.

*If S8 medicine discards will be recorded other than in the S8 register, the following requirements must be met:

1. The public health service facility must undertake a documented risk assessment which includes consideration of why the S8 register could not be used and how the audit trail will be maintained.
2. Any record keeping system for S8 medicine discards, that is not the S8 register (in hard copy or electronic form), must be approved by the public health service facility executive.
3. The S8 register must be annotated to indicate where the discard is recorded as part of the entry in the S8 register at the time the S8 medicine is issued from the S8 register for the individual patient.
4. If S8 medicine discards will be recorded other than in the S8 register within a particular unit or ward, the method chosen must be used on every occasion that a S8 medicine discard is recorded within that unit or ward.

A risk management approach is required to determine whether a public health service facility will allow destruction of sub-standard S8 stock within patient care areas, within outlying hospitals and nursing posts or require return of stock to the Pharmacy Department for destruction. Consideration of the risks of transportation of S8 medicines (sometimes over large distances and between sites) must be weighed against the benefits of centralised processing of S8 destruction.

Public health service facility policies about destruction and discarding of S4R medicines must:

- ensure the risk of misuse and diversion during destruction, discarding and disposal is minimised
- include information about the destruction and disposal of patients' own S4R medicines, where these medicines are not returned to the patient
- provide clear direction on the roles responsible for the destruction, discarding and disposal of S4R medicines.

Further information is available in the *Guideline on administration and record keeping for Schedule 4 Restricted and Schedule 8 medicines*.

11. Management of oral liquid S4R and S8 medicines

See also section 3.4.8 in MP 0139/20 *Medicines Handling Policy*.

Where multi-dose bottles are in use, discrepancies between the actual volume on hand and the balance recorded in the relevant register can occur. This can present challenges for staff in determining whether the discrepancy is a natural consequence of measuring multiple doses from a bottle or an indicator of misappropriation, misuse or diversion.

Public health service facilities must manage S4R and S8 medicines in oral liquid forms in a manner that:

- minimises the risk of measurement errors
- minimises the risk of balance discrepancies
- minimises the risk of misuse and diversion
- maintains safety for the patient, including with respect to selecting the correct container of medicine when a dose is to be administered.

Public health service facilities policies and procedures for managing S4R and S8 oral liquid medicines must include information about:

- stockholdings and supplies, including when and how repackaging from manufacturers original packs will be undertaken
- dose measurement practices, including use of measuring devices that are distinguishable from equipment used to administer parenteral medicines
- performing inventories of oral liquid medicines
- performing stock reconciliation.

If S4R and S8 oral liquid medicines are repackaged for use in patient care areas, the repackaged medicine must be packaged in such a way that when the pack/container has been opened for use, it is readily distinguishable from other sealed packs/containers.

Repackaging must be undertaken by the Pharmacy Department or by a repackaging facility approved by the TGA.

Further details are available in the *Guideline on oral liquid Schedule 4 Restricted and Schedule 8 medicines*.

12. Cannabis based products

See also section 3.4.10 in MP 0139/20 *Medicines Handling Policy*.

With the exception of inpatient only continuation of treatment using the patient's own cannabis based medicine, prescribing must be compliant with:

- any requirements of the *WA Statewide Formulary*, if the cannabis based medicine is a formulary item
- existing Individual Patient Approval processes for non-formulary medicines consistent with MP 0077/18 *Statewide Medicines Formulary Policy*
- existing compassionate access processes for unregistered medicines

or

- a properly constituted clinical trial, which is consistent with the *Research Policy Framework*.

Prescribing of medicinal cannabis initiated by the public health service facility must also be consistent with relevant Commonwealth and Western Australian regulatory controls.

This means prescribing must be consistent with the TGA processes for prescribing of unapproved medicines (such as the SAS or the TGA Authorised Prescriber Scheme[2]), with the exception of Sativex®.

[2] The TGA Authorised Prescriber Scheme is separate and different to being an authorised prescriber in accordance with the Medicines and Poisons Regulations 2016.

In addition, where it is intended that treatment with the cannabis-based medicine will be continued after discharge or where prescribing is for a non-admitted patient, prescribing must be consistent with the *Schedule 8 Medicines Prescribing Code*, except where the cannabis-based medicine contains cannabidiol only (as cannabidiol only products are classified as S4 medicines).

Medicinal cannabis products supplied by the Pharmacy Department of a public health service facility must:

- comply with the *Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Order 2017 (TGO 93)*
- be purchased from a supplier licensed by the Commonwealth Office of Drug Control (ODC) or by directly imported with appropriate licences and permits issued by the ODC.

13. Management of opioid pharmacotherapy

See also section 3.4.11 in MP 0139/20 *Medicines Handling Policy*.

Methadone, in particular, is associated with a high risk of overdose. Deaths due to overdose have occurred when methadone is used for opioid substitution therapy (OST), including the death of patients in hospital. The complex properties of methadone mean its use is considered 'high-risk' in all settings and for all indications. Methadone must be prescribed under the guidance of an appropriate specialist.

OST is made available to drug dependent individuals through the Community Program for Opioid Pharmacotherapy (CPOP). The Department of Health manages the regulatory aspects of the program and the Mental Health Commission's Community Pharmacotherapy Program (CPP) provides clinical support, advice, training and resources for clients, prescribers and pharmacists.

Medicines used for OST in the CPOP are methadone (oral liquid) and buprenorphine (sublingual tablets, sublingual films and long acting injections).

OST must be provided in accordance with both the *Schedule 8 Medicines Prescribing Code* and the *WA Clinical Policies and Procedures for the Use of Methadone and Buprenorphine in the Treatment of Opioid Dependence* (available from the Mental Health Commission).

Only prescribers who have completed specific CPOP training and have been authorised by the Department of Health as a CPOP prescriber can initiate treatment of a patient within the CPOP.

In addition, the CPOP prescriber must be authorised, by the Department of Health, to treat each individual patient. The authorisation includes the particular CPOP drug to be used and the location (community pharmacy or Next Step Drug and Alcohol Services) at which the person will receive their doses.

If a person currently 'in treatment' on the CPOP becomes an admitted patient, treatment can be continued by public health service facility prescribers whilst the patient is admitted.

The risk of overdose is considerably higher when:

- a patient on oral maintenance OST, has not received their usual oral OST dose for four or more days or
- a patient in the induction phase of OST, has missed a single oral OST dose.

With the introduction of long acting buprenorphine injections for OST, a person would only be considered ‘in treatment’ if they have received their OST injection within the recommended treatment interval.

In the event that it cannot be conclusively determined whether the patient is ’in treatment’, OST doses must not be administered in the public health service facility. Withdrawal from OST is safer than dosing the patient and risking overdose.

Public health service facility policies and procedures about managing CPOP patients must include requirements for:

- independently determining whether the patient is ‘in treatment’ prior to providing any OST doses
- independently confirming the patient’s current prescription, including OST drug, dose and frequency prior to providing any OST doses
- documenting the most recent OST dose received, including the drug, dose, dosing location and date/time of dosing (including accounting for any ‘take away’ doses provided to the patient by their usual dosing location)
- ensuring the patient’s usual dosing pharmacy is aware of the patient’s admission, discharge and any leave during admission
- where the patient is on the CPOP but not ‘in treatment’, contacting the patient’s CPOP prescriber, or the CPP Clinical Advisory Service (CAS) if the patient’s usual CPOP prescriber is unavailable, for advice prior to prescribing or administering any further doses
- where induction of OST during inpatient admission is contemplated, contacting the CPP or CAS and ensuring prescribing is only by an authorised CPOP prescriber
- ensuring any requirements for analgesia are appropriately managed
- supplying OST drugs to patient care areas in a safe manner, including when the patient presents outside Pharmacy Department opening hours
- supervising dosing to minimise the risk of diversion
- monitoring the patient for signs and symptoms of both overdose and withdrawal
- ensuring appropriate discharge planning occurs
- the roles responsible for each of the tasks and decisions associated with managing a CPOP patient.

‘Takeaway’ doses and discharge prescriptions for OST must not be provided to patients being treated by public health service facilities. Public health service facilities are only authorised to provide supervised doses, not ‘takeaway’ doses. Any ‘takeaway’ doses brought into hospital with the patient must not be used to treat the patient whilst they are in the public health service facility or returned to the patient under any circumstances.

Discharge planning for patients participating in the CPOP must include liaison with the patient’s existing dosing location (pharmacy or Next Step), existing authorised CPOP prescriber (if necessary) and/or CPP to ensure continuity of dosing is maintained at discharge.

Further information is available in the *Guideline on continuation of opioid substitution therapy in public health service facilities*.

14. Management of opioid detoxification

See also section 3.4.12 in MP 0139/20 *Medicines Handling Policy*.

Opioid detoxification is use of the same medicines as are used in the CPOP during medically supervised withdrawal from opioids. The detoxification period must be short-term and limited to no more than 7 days for any single period.

The *Schedule 8 Medicines Prescribing Code* includes specific requirements for opioid detoxification of inpatients at public hospitals.

Policies and procedures issued by public health service facilities about the management of opioid detoxification must:

- provide for compliance with the Schedule 8 Medicines Prescribing Code
- include requirements for supplying OST drugs for detoxification to patient care areas in a safe manner
- include requirements for supervised dosing to minimise the risk of diversion.

Liaison with the Medicines and Poisons Regulation Branch is strongly recommended. The Branch can provide guidance to inform development of public health service facility policies and procedures and information about compliance with regulatory requirements.

15. Health practitioner students

See also section 3.5.4 in MP 0139/20 *Medicines Handling Policy*.

Public health service facility policies and procedures about medicines handling by health practitioner students must include:

- information about which medicines handling tasks can be undertaken by students, under direct supervision of an authorised person
- any restrictions and limitations on activities of health practitioner students in relation to handling scheduled medicines
- clear direction on the roles responsible for providing direct supervision of health practitioner students handling scheduled medicines.

Definitions

Term	Definition
Multi Purpose Service (MPS)	Integrated public health service facilities with both acute care and aged care beds. A joint Commonwealth/state government initiative to improve provision of services in rural and remote communities where standalone hospital or residential aged care services may not be viable. MPS exist in many locations that are part of the WA Country Health Service.
public health service facility executive	The chief executive of the public health service facility or another member of the executive team delegated by the chief executive of the public health service facility.
S100 Remote Area Aboriginal Health Services Program	Commonwealth funded supply arrangement under Section 100 of the *National Health Act 1953*. Program seeks to address barriers experienced by people living in remote areas in accessing Pharmaceutical Benefits Scheme (PBS) medicines.

separation of duties	The concept of having more than one person complete a process. A key part of internal controls in any organisation to protect against fraud and error.
stock reconciliation	Act of comparing the physical balance of stock on hand (inventory) with the recorded balance in the register.
takeaway doses (in the Community Program for Opioid Pharmacotherapy)	Doses of oral opioid pharmacotherapy provided to clients by their dosing pharmacy for use as unsupervised doses. Takeaway doses are described in detail in the *WA Clinical Policies and Procedures for the Use of Methadone and Buprenorphine in the Treatment of Opioid Dependence.*

Document control

Version	Published date	Effective from	Amendment(s)
1.0	15 July 2020	1 December 2020	Original version

This document can be made available in alternative formats on request for a person with disability.