Government of Western Australia
Department of Health

Policy Frameworks
MP 0139/20
Effective from: 31 May 2021

Medicines Handling Policy

1. Purpose

This Policy outlines requirements for Health Service Providers to promote accountable approaches to the handling of medicines in order to maintain the integrity of the supply chain. Whilst medicines must be available to ensure timely patient care, there is also a need to protect public health and, in particular, mitigate the risk of diversion, misuse and theft. Handling of medicines refers to the acquisition, distribution, storage, authorisation of prescribing, administration, supply, dispensing and disposal of medicines.

The Policy seeks to ensure hospitals, nursing posts and other public health service facilities operated by Health Service Providers handle medicines in a consistent manner and, where applicable, meet relevant standards. The Policy promotes a risk-based approach when developing policies and procedures about the handling of medicines.

The Policy focuses on Schedule 8 (S8) medicines and a group of higher risk Schedule 4 (S4) medicines, termed Schedule 4 Restricted (S4R) medicines. The Policy also includes requirements relating to more general aspects of medicines handling, including the role of health practitioner students, health practitioner initiation of non-prescription medicines, supply of medicines to patients by staff other than pharmacists, and security of prescription stationery.

The requirements of this Policy are in addition to the legal requirements of the *Medicines and Poisons Act 2014* and the Medicines and Poisons Regulations 2016 (Medicines and Poisons Legislation). This Policy recognises public health service facilities are often large organisations and the minimum requirements of the Medicines and Poisons Legislation may not be sufficient to ensure safe and accountable handling of medicines.

Individual S4 and S8 medicines may be designated as a 'voluntary assisted dying substance' (VAD substance), under the *Voluntary Assisted Dying Act 2019* (VAD Act). Unless a VAD substance is prescribed and supplied in accordance with the VAD Act, it cannot legally be used for the purpose of voluntary assisted dying.

When a VAD substance is prescribed under the VAD Act, it becomes a 'prescribed substance'. The possession, supply, use and disposal of a 'prescribed substance' is not subject to the Medicines Handling Policy and any related documents.

VAD substances supplied to a patient, including VAD substances brought into a public healthcare facility by a patient and VAD substances returned for disposal, are subject to the VAD Act and *MP0154/21 Managing Voluntary Assisted Dying Policy*.

The *Clinical Governance, Safety and Quality Policy Framework* deals with aspects of medicines management relating to clinical decisions and overall quality use of medicines (QUM).

This Policy is a mandatory requirement under the *Public Health Policy Framework* pursuant to section 26(2)(d) of the *Health Services Act 2016*.

This Policy supersedes:

- OD 0142/08 *Administration of Schedule 8 medicines to patients attending for emergencies*
- MP 0039/16 *Cannabis-based Products for Medicinal Use*
- OD 0141/08 *Code of practice for the handling of Schedule 8 medicines (drugs of addiction) in hospitals and nursing posts*
- OD 0598/15 *Management of Community Program for Opioid Pharmacotherapy (CPOP) patients in a hospital setting*
- OD 0492/14 *Management of Schedule 8 and Restricted Schedule 4 oral liquid medicines*
- OD 0529/14 *Storage and recording of propofol*
- OD 0528/14 *Storage and recording of Restricted Schedule 4 (S4R) medicines.*

2. Applicability

This Policy is applicable to all Health Service Providers.

To the extent that the requirements contained within this Policy are applicable to the services purchased from contracted health entities, Health Service Providers are responsible for ensuring these requirements are accurately reflected in the relevant contract and managed accordingly.

3. Policy requirements

3.1 Roles and responsibilities

Health Service Providers must:

- Have governance structures that support safe and effective medicines handling within all public health service facilities
- Have policies and procedures on the handling of medicines that:
  - are consistent with the requirements of relevant legislation and Mandatory Policies
  - use a risk management approach
  - include clear direction on the roles responsible for all aspects of the handling of scheduled medicines
  - include agreement of the ‘health service permit’ holder at the relevant public health service facility as part of the approval process
- Allocate adequate material, human and financial resources to ensure the requirements of this Policy are met
- Make policies and procedures on the handling of medicines available to all relevant staff members.

Chief Pharmacists (or equivalent positions) within public health service facilities are responsible for approving policies and procedures about the handling of medicines within the Pharmacy Department, including about access to the Pharmacy Department.

Within each discrete patient care area (ward or unit), the nurse unit manager or equivalent role is responsible for ensuring workflows and systems used by the area are consistent with Health Service Provider policies and procedures for the handling of scheduled medicines.

Staff members must comply with:

- regulatory controls over scheduled medicines
- policies and procedures about the handling of medicines applicable to the public health service facility at which they work.

3.2 Accountability principles

- A risk management approach is to be used when developing policies about the acquisition, storage, distribution, use and disposal of medicines, where these policies aim to mitigate the risk of diversion, misuse and theft of medicines.
- All records of the acquisition, distribution, prescribing, administration, dispensing, supply and disposal of scheduled medicines must be kept in a manner which allows subsequent auditing. Records must be available for auditing by an investigator appointed under the *Medicines and Poisons Act 2014*, for at least the periods prescribed by the Medicines and Poisons Legislation. Health Service Providers must retain records in accordance with the *State Records Act 2000* and the requirements of the *Information Management Policy Framework,* which may include different time periods for records retention.
- A chain of custody must be maintained for all S4R and S8 medicines, such that the transfer of responsibility is clear at each transaction point.

3.3 General requirements for scheduled medicines

The following requirements relate to scheduled medicines in general. There are more specific requirements for S4R and S8 medicines, detailed in section 3.4.

The related document *Risk-based requirements for medicines handling* includes further detail about developing policies and procedures relating to scheduled medicines.

Health Service Providers must have policies, and if appropriate, procedures that address the requirements detailed in this Policy.

3.3.1 Purchasing medicines

Under the *Medicines and Poisons Act 2014*, public health service facilities must hold a current permit to have authority to purchase scheduled medicines. For public health service facilities serviced by a Pharmacy Department, it is consistent with the job description of the Chief Pharmacist (or equivalent position) for the permit to be issued to the Chief Pharmacist (or equivalent position).

The permit holder has overall responsibility for purchasing scheduled medicines.

Scheduled medicines to treat patients of the public health service facility must be purchased through the Pharmacy Department, unless there is a documented alternative acquisition system which has been approved by the permit holder. This includes public

health service facilities where the Pharmacy Department is located within a different public health service facility within the same region.

See also section 4 of the *Risk based* requirements *for medicines handling*.

3.3.2 Distribution

Public health service facilities must identify risks associated with the distribution of medicines within and by the organisation, and implement strategies aimed at mitigating these risks, as medicines are a high cost, high risk item. It is therefore important for the integrity of the supply chain to be maintained. In particular, distribution policies and procedures for scheduled medicines must maintain availability of medicines to treat patients whilst including requirements which aim to minimise opportunities for misappropriation of medicines during distribution.

See also section 6 of the *Risk based requirements for medicines handling*.

3.3.3 Storage

Specific storage requirements for S4R and S8 medicines are detailed in Section 3.4.3.

All scheduled medicines must be stored in a manner that precludes access by unauthorised persons, unless under the direct supervision of an authorised person.

These storage requirements are applicable to medicines:

- awaiting distribution
- in use
- brought into the public health service facility by patients and their carers
- dispensed for outpatients and awaiting collection
- dispensed for patients being discharged (awaiting final delivery to the patient).

When determining storage requirements for scheduled medicines, both the need for access to allow timely patient care and the risk of diversion must be considered.

See also section 5 of *Risk based requirements for medicines handling*.

3.3.4 Prescribing

The Medicines and Poisons Regulations 2016 detail which registered health practitioners have authority to write prescriptions, such as at discharge and for non-admitted patients. Authorised prescribers also have authority to issue directions to administer doses of scheduled medicines to patients (see Section 3.3.5).

When prescribing S8 medicines for a patient to use outside a public health service facility, compliance with the Schedule 8 Medicines Prescribing Code is mandatory.

Public health service facilities can place additional restrictions on which medicines particular classes of registered health practitioners can prescribe, according to scope of practice and credentialing considerations. Additional restrictions may also be put in place due to cost, formulary considerations, or clinical safety, such as risk of antibiotic resistance, high risk of adverse effects or need for specialised monitoring during use.

Public health service facilities intending to limit prescribing must have policies which:

- detail local governance processes
- clearly identify any restrictions.

When developing policies about issuing prescriptions, MP 0077/18 *Statewide Medicines Formulary Policy* and MP 0084/18 *Credentialing and Defining Scope of Clinical Practice Policy* are also applicable.

The Medicines and Poisons Regulations 2016 include requirements in relation to the issuing of covering prescriptions where a pharmacist has been directed to supply a S4 or S8 medicine urgently, such as by telephone or via a faxed or emailed copy of a prescription. The Regulations may be relevant when telehealth services are offered, where the authorised prescriber and the patient being treated are not at the same location.

Public health service facilities providing care via telehealth consultations must have a policy and/or procedure in relation to the dispatch of covering prescriptions to the pharmacy which has supplied the medicine to the patient.

3.3.5 Administration of doses

The Medicines and Poisons Legislation requires doses of S4 and S8 medicines to only be administered to patients following a direction by an authorised prescriber. Except in an emergency, a direction to administer a S4 or S8 medicine must be provided in writing before a dose is administered. In an emergency, an authorised prescriber can provide a direction verbally, including by telephone, or by other electronic means.

Part 7 of the Medicines and Poisons Regulations 2016 details which health professionals are authorised to administer S4 and S8 medicines. These Regulations do not preclude public health service facilities from further limiting which staff are authorised to administer doses, based on scope of practice and health professional credentialing.

Public health service facility policies and procedures about directions to administer medicines must:

- consider the risks associated with emergency directions, such as:
  - potential for misinterpretation of verbal orders
  - the need for patient review by an authorised prescriber in a clinically appropriate timeframe
- cover the management of directions given during telehealth consultations, where applicable
- include details of governance over any limitations on administration
- clearly identify any limitations on administration applicable within the public health service facility.

Public health service facilities that allow patients to self-administer scheduled medicines must have a policy and/or procedures to minimise the risk of medicines misappropriation and ensure documentation requirements are maintained.

Other mandatory requirements under the *Clinical Governance, Safety and Quality Policy Framework* will also be applicable to policies about administration of medicines.

See also section 7 of *Risk based requirements for medicines handling*.

3.3.6 Use of Structured Administration and Supply Arrangements (SASAs)

SASAs are described in Part 6 of the Medicines and Poisons Regulations 2016. SASAs allow a health professional without prescribing rights to initiate administration or supply of a medicine in the circumstances described in the SASA. There are strict regulatory rules about the governance and authorisation process for SASAs.

Health Service Providers or public health service facilities that intend to issue SASAs must:

- designate their Drug and Therapeutics Committee (or equivalent committee) as the 'clinical governance committee' for the purpose of Regulation 34 of the Medicines and Poisons Regulations 2016
- have a policy, and if necessary, procedure which includes details of the governance and authorisation process for issuing SASAs, including clear role responsibilities
- not issue a SASA that is inconsistent with a CEO of Health issued SASA, where a relevant CEO of Health issued SASA exists
- send a copy of any SASA issued to the CEO of Health, by emailing the copy to MPRB@health.wa.gov.au as soon as reasonably practicable.

When developing SASAs, MP 0077/18 *Statewide Medicines Formulary Policy* and MP 0084/18 *Credentialing and Defining Scope of Clinical Practice Policy* are also applicable.

3.3.7 Dispensing and supply to non-admitted patients and at discharge

The Medicines and Poisons Regulations 2016 include specific requirements for the packaging and labelling of S4 and S8 medicines supplied to patients, including that a detailed record of supply be kept. These requirements are applicable regardless of whether the S4 or S8 medicine is dispensed by a pharmacist, supplied by a prescriber, or supplied by a health professional authorised by a SASA.

Where the public health service facility will supply medicines to patients being discharged or to non-admitted patients:

- scheduled medicines must be dispensed by the Pharmacy Department unless clinical, cultural or logistical reasons mean this is not practicable
- where supply to the patient will be by the prescriber themselves, the public health service facility must have a policy which includes:
  - details of the circumstances where direct supply by prescribers is allowable, including any limitations on supply
  - packaging and labelling requirements
  - documentation requirements.
- where supply of S2, S3 or S4 medicines by staff, other than a pharmacist or a prescriber, will be authorised by using SASAs, the requirements of Section 3.3.6 must be met.

See also section 8 of *Risk based requirements for medicines handling*.

3.3.8 Medicines no longer in use and disposal

Public health service facilities must have a policy about management of medicines which have been distributed to patient care areas that are no longer required for the treatment of patients. The policy needs to balance having medicines available for patient care in a timely manner against the risks associated with storing medicines no longer in use or unlikely to be immediately required for patient treatment.

When disposing of a patients' own medicines, it must be recognised that these medicines are the property of the patient and, where appropriate, steps must be taken to ensure the patient and/or their family/carer agree to and are aware of the disposal of the patient's own medicines. Return of a patient's own medicines may not be appropriate in all circumstances. Where this is the case, the reason(s) the medicines were not returned must be documented, in accordance with local policy.

Note: The Code of practice for clinical and related waste management describes how pharmaceutical waste must be managed.

3.4 Handling Schedule 4 Restricted and Schedule 8 medicines

3.4.1 Designation of Schedule 4 Restricted (S4R) medicines

Some S4 medicines are more liable to abuse and may cause dependence. This includes benzodiazepines and other hypnotic sedatives as well as opioid and opioid-like analgesics such as compound analgesics containing codeine and tramadol.

As these higher risk S4 medicines may be targeted for unauthorised use and diversion into illicit activities, suitable controls are required to minimise the risk of misappropriation and theft. These controls are in addition to the requirements of the Medicines and Poisons Legislation.

Section 3 of the Related document *Risk based requirements for medicines handling* lists the medicines designated as S4R medicines and provides additional information about how S4R medicines are to be managed in public health service facilities.

3.4.2 Distribution of Schedule 4 Restricted and Schedule 8 medicines

When distributing S4R and S8 medicines, public health service facilities must:

- ensure the 'chain of custody' is maintained at all times
  - including S4R and S8 medicines dispensed in the Pharmacy Department for patients being discharged, up until the point the dispensed medicines are handed to the patient (or their carer/relative), immediately prior to them leaving the public health service facility
- have a policy that:
  - mitigates against any risks identified during any risk assessment process
  - includes controls designed to minimise the risk of diversion.

See also section 6 of *Risk based requirements for medicines handling*.

3.4.3 Storage of Schedule 8 and Schedule 4 Restricted medicines

See also section 5 of *Risk based requirements for medicines handling*.

It is acceptable to store S4R and S8 medicines, which have been dispensed by the Pharmacy Department for a patient being discharged, with any other medicines dispensed for that patient in a secure receptacle other than the receptacles usually used for S4R or S8 medicines. Dispensed S4R and S8 medicines must be stored in a manner which:

- precludes access by unauthorised persons
- ensures any tampering with the package containing the dispensed medicines can be detected.

3.4.3.1 Storage of Schedule 4 Restricted medicines

S4R medicines must be stored in accordance with the related document *Risk based requirements for medicines handling.*

3.4.3.2 Storage of Schedule 8 medicines

The Medicines and Poisons Regulations 2016 include specific storage requirements for S8 medicines within public health service facilities, with particular requirements for Pharmacy Departments. The Regulations include clauses which allow the CEO of Health to approve alternative storage arrangements for S8 medicines.

Where alternative storage of S8 medicines is considered desirable, the 'health service permit' holder for the relevant public health service facility must:

- ensure a risk assessment is undertaken to determine whether a request for approval of alternative storage arrangements will be made to the CEO of Health
- be responsible for submitting any requests for alternative storage of S8 medicines to the CEO of Health.

Note: The Medicines and Poisons Regulations 2016 do not oblige the CEO of Health to approve requests for alternative storage arrangements. Wherever possible public health service facilities should comply with the standard S8 storage requirements as detailed in the Regulations.

3.4.4 Access to storage for Schedule 4 Restricted and Schedule 8 medicines

Public health service facilities must have a policy and if necessary, procedures which must:

- detail which classes of authorised persons are allowed access to S4R and S8 medicines within the public health service facility
- include specific requirements for the Pharmacy Department, where larger quantities of S4R and S8 medicines will usually be stored
- describe how keys, access codes or other mechanisms to unlock S4R and S8 storage receptacles and storage areas will be managed.

3.4.4.1 After hours access to Schedule 8 storage in the Pharmacy Department

Public health service facilities must have a policy about access to S8 medicines stored within the Pharmacy Department outside the usual operating hours of the department. A range of access levels may be appropriate, based on a risk assessment of each S8 storage location within the department.

Public health service facility policies about after hours access to S8 medicines storage must:

- balance any need for access to ensure safe and timely patient care against the risk of misappropriation, misuse and theft
- include requirements for regular audit of:
  - details of staff who accessed the Pharmacy Department S8 storage after hours
  - why access to S8 medicines was necessary.

3.4.5 Records about Schedule 4 Restricted and Schedule 8 medicines

See also section 9 of *Risk based requirements for medicines handling*.

3.4.5.1 Use and archiving of Schedule 8 Registers

The Medicines and Poisons Regulations 2016 require transactions involving S8 medicines to be recorded in an approved register. Registers must be available for inspection for a period of five years from the date of the last recorded transaction.

Public health service facilities must have a policy and/or procedure for the distribution of hard copy S8 registers and the management of registers no longer in use. Such records must be readily accessible in the event of an audit or investigation.

If a public health service facility uses an approved electronic register, the facility must have policy and/or procedure for:

- managing access to the electronic register
- dealing with known or suspected security or data breaches.

If a register cannot be located within 24 hours of being detected as missing, a report must be made immediately to the Department of Health via email: MPRB.Compliance@health.wa.gov.au

If a security or data breach occurs in relation to an approved electronic register, a report must be made to the Department of Health via email: MPRB.Compliance@health.wa.gov.au within 24 hours of the security or data breach being detected.

3.4.5.2 Recording Schedule 4 Restricted transactions

To reduce the risk of misappropriation, S4R medicines require specific mandatory controls which are in addition to the regulatory controls required for all S4 medicines. Storage controls and additional record keeping requirements are required for S4R medicines, in accordance with the Related document *Risk based requirements for medicines handling*.

Where hard copy S4R registers are in use, public health service facilities must have a policy and/or procedure for distribution of hard copy registers and for the management of registers no longer in use, to ensure archived S4R registers are readily available in the event of an audit or investigation.

3.4.5.3 Inventories of Schedule 4 Restricted and Schedule 8 medicines

The Medicines and Poisons Regulations 2016 require monthly inventories of S8 medicines. Monthly inventories of S4R medicines are not required under the Regulations, however S4R inventories must be completed on a regular basis.

The frequency of inventories of S8 and S4R medicines must be:

- at a frequency sufficient to detect discrepancies in a timely manner
- consistent with any risk assessment conducted by the public health service facility.

Any discrepancies found at inventory must be dealt with in accordance with the MP 0103/19 Reporting *of Schedule 4 Restricted and Schedule 8 Medicines Discrepancies Policy*.

3.4.6 Administration of Schedule 8 medicines

Part 7 of the Medicines and Poisons Regulations 2016 details which health professionals are authorised to administer S8 medicines. Authorised health professionals applicable to public health service facilities include: authorised prescribers, registered nurses, enrolled nurses[1], midwives and anaesthetic technicians.

Public health service facilities must have a policy about the administration of S8 medicines to patients which seeks to manage risks of diversion whilst maintaining access to achieve safe and timely patient care.

3.4.7 Destruction, discards and disposal of Schedule 4 Restricted and Schedule 8 medicines

The Medicines and Poisons Regulations 2016 requires documentation of the destruction of S8 medicines and permits certain classes of health professionals to undertake destruction and witness destruction.

Destruction is a separate activity to discarding of unusable amounts (such as a part ampoule) when a dose is being administered to a patient. Destruction relates to S8 medicines that cannot be used for patient treatment such as medicines that are expired, have not been correctly stored, are contaminated, damaged or otherwise unfit for use.

Public health service facilities must have a policy and/or procedure about the destruction, discarding and disposal of S4R and S8 medicines applicable to all areas to which these medicines are distributed, including within the Pharmacy Department.

See also section 10 of *Risk based requirements for medicines handling*.

3.4.8 Management of oral liquid Schedule 4 Restricted and Schedule 8 medicines

Public health service facilities must have a policy about the management of oral liquid S4R and S8 medicines which:

- aims to reduce measurement errors
- aims to detect discrepancies in a timely manner
- support the correct medicine being selected from the storage receptacle
- ensures any manipulation of the contents of containers is undertaken in a manner that minimises loss and contamination.

See also section 11 of *Risk based requirements for medicines handling*.

3.4.9 Patients' own Schedule 4 Restricted and Schedule 8 medicines

Patient's own S8 and S4R medicines must be stored with an equivalent level of security as other medicines in these categories.

For patients' own S4R and S8 medicines the chain of custody must be maintained from the patient's arrival through to when the medicines are either returned to the patient or disposal is completed.

See also section 5.8 of *Risk based requirements for medicines handling*.

[1] Provided the enrolled nurse does not have the notation "Does not hold Board-approved qualifications in administration of medicines" on their registration.

3.4.10 Requirements for cannabis-based products for medicinal use

Cannabis based products, intended for therapeutic use, are subject to the same regulatory controls, through the Medicines and Poisons Legislation, as other S4 and S8 medicines.

Before using a patient's own cannabis based medicine, the public health service facility must be satisfied that the product was legally prescribed for and supplied to the patient.

Public health service facilities must consider how continued treatment will be managed in the event that the patient's own supply of cannabis based medicine is exhausted whilst the patient is under the care of the public health service facility.

See also section 12 of *Risk based requirements for medicines handling*.

3.4.11 Management of opioid pharmacotherapy

If a person currently 'in treatment' on the Community Program for Opioid Pharmacotherapy (CPOP) becomes an admitted patient, treatment can be continued by public health service facility prescribers whilst the patient is admitted.

'In treatment' means:

- a prescriber is authorised to treat the person
- the person has received their doses in accordance with their prescription
- the person has a current opioid substitution therapy (OST) prescription.

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 facilities treating inpatients must have policy and/or procedure about continuation of opioid substitution therapy which:

- includes mechanisms to reduce the risk of overdose
- considers the risk of diversion of OST doses, including diversion by the patient during dosing.

See also section 13 of *Risk based requirements for medicines handling*.

3.4.12 Management of opioid detoxification

The Schedule 8 Medicines Prescribing Code includes detailed regulatory requirements in relation to opioid detoxification, including specific requirements for public hospitals.

Public health service facilities wishing to undertake opioid detoxification must have a policy which:

- maximises patient safety
- minimises the risk of diversion of the medicines used for detoxification, including diversion by the patient during dosing.

See also section 14 of *Risk based requirements for medicines handling*.

3.5 Other matters related to the handling of medicines

3.5.1 Access to the Pharmacy Department

Access to the Pharmacy Department must be controlled by the Chief Pharmacist (or equivalent position) of the public health service facility.

Public health service facilities must have a policy on Pharmacy Department access which:

- permits sufficient access to ensure medicines are available for patient treatment in a timely manner
- limits access to minimise the risk of diversion of medicines
- considers any access required for management of emergencies, such as fire or other threats to staff members
- includes methods for monitoring access to the Pharmacy Department
- requires regular review of entries to the Pharmacy Department, including entries occurring outside normal operating hours.

See also sections 5.5 and 5.6 of *Risk based requirements for medicines handling*.

3.5.2 Management of prescription stationery

Only prescriptions are regulated by the Medicines and Poisons Legislation. However, prescription stationery, without a prescription written on it, is an item susceptible to theft and misappropriation, which may result in presentation of forged 'prescriptions' to pharmacies.

Public health service facilities must have systems in place to reduce the risk of prescription stationery being stolen or misappropriated from any area of the facility, including, but not limited to, wards, outpatient clinics, the emergency department and areas where quantities of prescription stationery awaiting distribution are stored.

Theft or unexplained loss of prescription stationery is to be reported to the Department of Health via email: MPRB.Compliance@health.wa.gov.au

3.5.3 Health practitioner initiated non-prescription medicines

Public health service facilities that allow health practitioner initiated non-prescription medicines must have a policy detailing the governance, safe use and documentation requirements for these medicines.

3.5.4 Medicines handling by health practitioner students

The Medicines and Poisons Legislation does not permit health practitioner students to independently handle scheduled medicines. Health practitioner students must be under the direct supervision of an authorised person where handling of scheduled medicines is required as part of their training.

Public health service facilities that host health practitioner students on clinical placements or other visits, must have a policy which ensures any handling of scheduled medicines by students is only under the direct supervision of an authorised person.

See also section 15 of *Risk based requirements for medicines handling*.

4. Compliance monitoring

Health Service Providers must conduct an audit of compliance with this Policy on an annual basis. At a minimum, this audit must determine whether:

- all public health service facilities operated by the Health Service Provider have policies and/or procedures in place consistent with the requirements of this Policy (including any requirements detailed in the related document)
- public health service facility policies and/or procedures required by this Policy are available to relevant staff members
- any audit or compliance review requirements included within specific public health service facility policies about medicines handling have been completed.

If requested by the System Manager, Health Service Providers must supply a report of their annual audit of compliance and copies of any public health service facility policies required by this Policy (including any policies required by the related documents).

The System Manager will undertake reviews of compliance with this Policy by Health Service Providers. This may take various forms, including:

- reviews of reports to the Department of Health of loss of registers, security or data breaches involving electronic registers and theft or unexplained loss of prescription stationery
- review of public health service facility policies for inclusion of required risk based measures
- audits of compliance by public health service facilities with other aspects of this Policy.

5. Related documents

The following document is mandatory pursuant to this Policy:

- Risk based requirements for medicines handling

6. Supporting information

The following information is not mandatory but informs and/or supports the implementation of this Policy:

- Documentation and policies required by the *Medicines Handling Policy*
- Requirements of the Medicines and Poisons Legislation: a summary for public health service facilities
- Guideline on distribution of medicines
- Guideline on Pharmacy Department access
- Guideline on administration and record keeping for Schedule 4 Restricted and Schedule 8 medicines
- Guideline on oral liquid Schedule 4 Restricted and Schedule 8 medicines
- Guideline on patients' own medicines
- Guideline on continuation of opioid substitution treatment in hospitals
- Guideline on health practitioner initiated non-prescription medicines

7. Definitions

The following definition(s) are relevant to this Policy.

Term	Definition
administer or administration	To give a dose of a medicine to a patient, usually for the patient to take immediately. All doses of medicines administered to patients must be documented, on the patient's medication chart or equivalent, such as on the anaesthetic record.
authorised person	Person defined in the Medicines and Poisons Regulations 2016 as a person permitted to be in possession of scheduled medicines and perform particular activities in relation to those medicines, such as prescribe, dispense, administer or supply depending on their role.
authorised prescriber	A class of registered health practitioner for whom the Medicines and Poisons Regulations 2016 include prescribing as a professional authority. Includes: medical practitioners, dentists, nurse practitioners, endorsed optometrists, endorsed podiatrists and endorsed midwives. The Regulations limit prescribing by some types of authorised prescribers to specific lists of medicines. The Regulations require authorised prescribers prescribe "in the lawful practice of their profession", in other words, consistent with both their personal scope of practice and the scope of practice for their type of health practitioner.
CEO of Health	Director General of the Department of Health or their delegate.
chain of custody	In relation to medicines, the chronological documentation that records the transfer of a medicine from one individual to another. Sometimes described as the 'paper trail', even though the records may be electronically made and stored. A critical element of maintaining the chain of custody is that the records must be robust and auditable.
Chief Pharmacist	The position responsible for managing the Pharmacy Department of a public health service facility and providing leadership in relation to the management of medicines at the facility. Sometimes termed Director of Pharmacy or Head of Department – Pharmacy. Standard practice is for the Chief Pharmacist to hold the Health Service Permit for the public health service facility as this role is consistent with job descriptions for Chief Pharmacist positions.
Community Program for Opioid Pharmacotherapy	Framework developed to regulate the prescribing of opioid pharmacotherapy medicines for the treatment of opioid dependence in Western Australia. Regulatory controls are via the Medicines and Poisons Regulations 2016.

destruction	The process of removing an unusable S8 medicine from storage and recording this action in the S8 register in accordance with the Medicines and Poisons Regulations 2016. Also refers to the process of removing an unusable S4R medicine from storage and recording this action in accordance with local policy. Destruction of a S8 or S4R medicine will be followed by disposal of the same medicine.
direct supervision	Supervision which requires the actual presence of the authorised person, such that the actions of the person being supervised can be monitored.
discards	Any unusable amounts of S4R and S8 medicines remaining after the administration of a dose, such as a part ampoule, which are discarded in a manner that results in the S4R or S8 substance being irretrievable and unusable.
discrepancy	Any difference in balance between the physical stock of a medicine and the balance recorded in the register for the medicine.
dispense	To provide a patient with a medicine (usually for the patient to take home), in accordance with a prescription. Only a pharmacist is authorised to dispense prescriptions. When a prescriber provides a patient with a medicine to take home, they are performing the act of 'supply' rather than 'dispensing'.
disposal	The act of rendering a S4R or S8 medicine, for which destruction has been recorded, unusable and irretrievable. Also refers to activities relating to transfer of medicines to waste management contractors for incineration.
health practitioner	As defined in Section 5 of the *Health Practitioner Regulation National Law (WA) Act 2010*.
health practitioner student	A student registered with the National Board for their respective health practitioner profession and who is undertaking a clinical placement within a public health service facility.
health practitioner initiated non-prescription medicines	Medicines which may be initiated by a registered health practitioner with supply and/or administration rights, without a prior written or verbal/telephone direction from an authorised prescriber. Traditionally, these medicines have been termed 'nurse/midwife initiated medicines' indicating the medicine may be administered by a registered nurse or midwife or delegated to an enrolled nurse. The Medicines and Poisons Legislation also provides authority for certain other registered health practitioners to initiate administration and supply of non-prescription medicines under specific circumstances.

Health Service Permit	A type of permit issued under the Medicines and Poisons Regulations 2016, which provides authority to purchase the scheduled medicines listed on the permit. Where the public health service facility has a Pharmacy Department, the permit will be issued to the person in charge of the Pharmacy Department. Note: under the previous legislation, this type of permit was commonly termed a 'poisons permit'.
in treatment (in the Community Program for Opioid Pharmacotherapy)	To be considered 'in treatment' all of the following must be met: • a prescriber is authorised to treat the person • the person has received their doses in accordance with their prescription • the person has a current opioid substitution therapy (OST) prescription
inventory	Checking and recording of stock on hand of S8 or S4R medicines.
medicines access programs	Programs offered by pharmaceutical sponsors to facilitate cost-free, subsidised or deferred cost access to medicines for public health service facility patients before the implementation of relevant funding arrangements. See also: https://ww2.health.wa.gov.au/Articles/U_Z/Western-Australian-Therapeutics-Advisory-Group-WATAG (Guidelines and principles issued by the WA Therapeutic Advisory Group).
Medicines and Poisons Legislation	The *Medicines and Poisons Act 2014* and the Medicines and Poisons Regulations 2016 and any Notices or Codes issued in accordance with the Act and the Regulations, such as the Schedule 8 Medicines Prescribing Code.
non-prescription medicines	Medicines in Schedule 2 (pharmacy only), Schedule 3 (pharmacist only). Also includes medicines which are 'unscheduled' and 'exempt from scheduling' i.e. medicines over which there are no controls through the Medicines and Poisons Legislation.
patient care area	Any area of a public health service facility where treatment or care of a patient occurs, includes wards, outpatient clinics, community mental health centres, emergency departments, operating theatres/recovery rooms and specialised treatment units such as haemodialysis, oncology and radiology.
patients' own medicines	Refers to medicines brought into the public health service facility by the patient or their family or carers. Medicines which have been dispensed at the public health service facility but not yet given to the patient are not considered to be 'patients' own medicines'.

Pharmacy Department	The area from which a pharmacy service operates. The primary point for receival of medicines from wholesalers (unless approved exceptions exist). In many public health service facilities, the main stock of medicines will be stored within the Pharmacy Department and distributed to other areas of the facility from this Department. Other medication storage locations, regardless of whether these storage locations are in patient care areas or in non-clinical areas of the facility, are not considered to be the Pharmacy Department.
public health service facility	As defined in Section 6 of the *Health Services Act 2016*. Such facilities include, but are not limited to, a hospital, nursing post, remote area clinic, community mental health clinic, health centre or similar facility operated by a Health Service Provider.
purchase (of medicines)	Includes scheduled medicines that are both purchased and provided 'free of charge'. Examples include medicines for use in clinical trials, sample packs provided by pharmaceutical companies, or medicines to be used in medicines access programs
register	For S8 medicines: records of transactions involving S8 medicines, kept in a written or electronic form in accordance with the Medicines and Poisons Regulations 2016. For S4R medicines: records of transactions involving S4R medicines, kept in a written or electronic form to comply with this Policy and kept in accordance with any policy issued by the public health service facility.
registered health practitioner	As defined in Section 5 of the *Health Practitioner Regulation National Law (WA) Act 2010*. Health practitioner students are not classified as 'registered health practitioners'.
SASA	Structured Administration and Supply Arrangement, as defined in Part 6 of the Medicines and Poisons Regulations 2016.
Schedule 4 (S4) medicine	All substances included in S4 of the *Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)*. Also termed prescription only medicines.
Schedule 4 Restricted (S4R)medicine	A list of S4 medicines, for the purpose of this Policy, which are considered to be at higher risk of diversion and misuse. Individual medicines designated as S4R are listed in the related document: Risk based requirements for medicines handling. Note: S4R medicines are not designated through legislation.

Schedule 8 (S8) medicine	All substances included in S 8 of the *Standard for the Uniform Scheduling of Medicines and Poisons (*SUSMP*)*. Also termed controlled drugs, drugs of dependence and drugs of addiction. Includes opiate medicines such as morphine, oxycodone, methadone and fentanyl, stimulant medicines such as dexamphetamine and methylphenidate, medicinal cannabis and two benzodiazepines (alprazolam and flunitrazepam).
Schedule 8 Medicines Prescribing Code	A Code published under the Medicines and Poisons Regulations 2016. The *S8 Medicines Prescribing Code* is published on the Department of Health website.
scheduled medicine	A medicine included in Schedule 2, 3, 4 or 8 of the SUSMP.
staff member	As defined in Section 6 of the *Health Services Act 2016*. This term includes, but is not limited to, staff employed permanently, on fixed-term contracts, on other contracts and casual staff, such as agency nurses.
supply	To provide a patient with medicines to take away from the public health service facility, such as for the patient to use at home. A prescriber is authorised to supply a patient with a quantity of a scheduled medicine.
unauthorised persons	Includes patients (except where the patient is self-administering their medicines in accordance with local policy), visitors and other members of the public as well as staff members who have no requirement to handle medicines as part of their job.

8. Policy contact

Enquiries relating to this Policy may be directed to:

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9. Document control

Version	Published date	Effective from	Review date	Effective to	Amendment(s)
MP0139/20	15 July 2020	01 December 2020	December 2023	31 May 2021	Original version
MP0139/20 v.2.0	31 May 2021	31 May 2021	December 2023	23 August 2021	Major Amendments to: 1. Support implementation of the *Voluntary Assisted Dying Act 2019* 2. Refer to the Code of Practice for Clinical and Related Waste Management.
MP0139/20 v.2.1	23 August 2021	23 August 2021	December 2023	Current	Amendment to Supporting Information - *Guideline of Continuation of Opioid Substitution Treatment in Hospitals*. The Guideline has had input from experienced specialist clinicians working with CPOP and by staff within the Medicines and Poisons Regulation Branch

10. Approval

Initial approval	Nicole O'Keefe, Assistant Director General - Strategy and Governance Division, Department of Health
	07 July 2020
Current version approved	Denise Sullivan, A/Assistant Director General, Public and Aboriginal Health Division, Department of Health
	26 May 2021

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