Medication Handling and Accountability Policy

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1. Background

Medications, particularly Schedule 8 (S8) and Schedule 4 Restricted (S4R) medications may be targeted for diversion or abuse. Theft, unauthorised use or unaccountable loss of any medication can be due to inadequate security, storage, record keeping and general controls.

This Policy outlines the requirements for purchasing, ordering, transporting, recording, and return and disposal of medicines in WA Country Health Service (WACHS).
The requirements of this Policy are in addition to the legal requirements of the *Medicines and Poisons Act 2014*, the *Medicines and Poisons Regulations 2016* and the WA Heath Medicines Handling Policy MP 0139/20.

2. Policy Statement

- There are minimum standards required by legislation for the storage of medication and additional requirements provided by WA Health policy.
- Where the word “must” has been used in this policy the requirement is a minimum standard to achieve safety of medications and meet legislative requirements.
- Where the word “should” has been used in this policy it is the recommended standard for the storage of medications in this situation. Any deviation from the recommended standard requires the region to complete a risk assessment and document the acceptance of the risk by the regional executive.
- A chain of custody must be maintained for all S4R and S8 medications, such that the transfer of responsibility is clear at each transaction point.

2.1 Medication Purchasing and Receiving

All medications, including medication sample packs, must be procured by the Pharmacy Department.

There are a small number of exceptions where medications are to be purchased by other systems:

- Medical gases (nitrous oxide) where there are specialised storage requirements unable to be met by the pharmacy department.
- Individual patient medication dispensed to a patient from a prescription via a community pharmacy such as community mental health patient programs or medications for residential patients in multipurpose sites.
- Dosage administration aids in aged care facilities or as a part of the Indigenous Dose Administration Aids Program.
- Medications from community pharmacies as a part of the Indigenous Health Services Pharmacy Support Program (Including but not limited to regional arrangements for the supply of S100 RAAHS medicines).

The Regional Chief Pharmacist of each region is the Poison Permit holder and can delegate the duties involved in purchasing medications to appropriate positions within the pharmacy department. Medications must be purchased on a purchase order using the iPharmacy application. Authorisation for purchases of medications are required to comply with the WACHS Authorisation Schedule including processes for approval outside the iPharmacy system for high cost orders. Any suspected breaches of this policy should be immediately reported to the Regional Chief Pharmacist for action.

Medication must not be ordered and receipted into the iPharmacy system by the same staff member. The Regional Chief Pharmacist (or their delegate) is responsible for auditing this monthly. In the instance of a breach, the documented reason must be recorded on the monthly report. These reports must be signed and filed for 2 years. The WACHS Chief Pharmacist (or their delegate) will perform an annual audit of this process.

In accordance with the WA Health Financial Management Manual, Pharmacy departments must perform a stocktake of all medication in the pharmacy annually at a minimum. The WACHS Chief Pharmacist (or their delegate) will perform an annual audit of this process.

2.2 Medication Ordering and Supply for Clinical Areas

Ordering of medications in clinical areas is via three systems:

- Imprest items.
- Non-imprest patient specific supplies.
- Recordable medication requisitions.

2.2.1 Imprest orders

Imprest medicines are the regular medicines maintained in each clinical area and allow for quick access to high-volume but low-cost medicines and/or clinically urgent medicines where safety concerns can be mitigated. Imprest on Formulary One allows a search of ward imprest lists to see where specific medicines can be found across WACHS.

Regular review of imprest lists should be facilitated by clinical pharmacists and include input by clinicians (nursing and medical) to ensure wastage is reduced, and medications available reflect contemporary practice. It is recommended that high risk or

high turn-over imprest locations are reviewed annually, with the Regional Chief Pharmacist to perform a risk-based assessment on the remaining imprest locations. Changes, additions, amendments of quantities or removal of medications from the imprest should be approved by the Chief Pharmacist, and senior nursing and medical staff. A risk management approach should be taken to these changes and consideration should be given to the risks associated with having the medication on imprest versus not having it immediately available. Imprest changes should be notified to staff in writing. Evidence of imprest review must be clearly documented and archived for 2 years.

Imprest items should be ordered at regular intervals according to local delivery schedules. Maximum quantities on imprest should be adhered to unless clinical need temporarily requires these quantities to be exceeded.

2.2.2 Non-imprest patient specific supplies

Medication not on imprest required for patients should be obtained through non-imprest supply mechanisms. Non-imprest supply gives an opportunity for the prescription to be clinically reviewed for appropriateness, including dose, allergies, interaction, duplication, length of treatment if not done so already. Non-imprest supply should occur after a clinical review however it is recognised that this is not always possible, and the medication may be supplied in the following circumstances depending on local practices by a:

- medication chart (scanned/faxed, physical or telehealth)
- requisition form including the details of the patient who requires the medication
- prescription for day admitted patient supply for administration in the hospital.

2.2.3 Recordable medication requisitions

Recordable medications must be requested using a numbered duplicate requisition booklet designed for use with S4R or S8 medications. The requisition slip must be signed and have the requestors full name printed and legible. Authorisation of a recordable order may only be completed by a staff member authorised to handle the medication.

Substitution Therapy (methadone, buprenorphine etc) supply should follow the FSFHG Management of Community Program for Opioid Pharmacotherapy (CPOP) for Inpatients Policy.
Sites without a pharmacy department must scan and send or fax the requisition form to the pharmacy department.

2.2.4 Use of Patient's Own Medications

Patients are encouraged to bring their own medications to the hospital to facilitate an accurate medication reconciliation and subsequent prescribing.

It may be appropriate to use a patient's own medication to continue therapy where the medication is not available on site and the treatment is not part of their admission diagnosis.

Where a patient's own medications are in use, the original manufacturers or pharmacy dispensed packaging must be labelled with the patient's name and clinical staff must be confident the product has been stored in an appropriate manner by the patient prior to admission. The expiry date on the medication must be visible and it must not be beyond its expiry date.

Medication packed in either commercially or self-prepared dose administration aids are unable to be used to administer regular medications to acute admissions due to the risk of administering medications ceased on admission. The community pharmacist who supplies the pack locally may be able to provide the original packaged medication from the patient's own supply as an alternative. Where a medication is only available from a patient's dose administration aid and the medication can be clearly identified it may be used but must be removed from the aid and the remaining tablets discarded.

There are specific considerations for the self-administered voluntary assisted dying substance which is to remain with the patient at all times. Refer to the WACHS Voluntary Assisted Dying Policy for details.

2.2.5 After hours ordering of medications

Regional pharmacy departments have limited to no after-hours cover. In most areas, pharmacy departments or an afterhours cupboard can be accessed for non-controlled medications by the hospital after-hours nurse manager (or site equivalent authorised person). All medication must be requested in writing and recorded appropriately when removed from the pharmacy. Controlled medications are not available from the pharmacy afterhours unless the pharmacy has an on-call arrangement. Only the hospital after-hours nurse manager (or site equivalent authorised person) is permitted to contact the pharmacist afterhours where an emergency after hours service is available. Patients may need to use their own medications or have alternative agents prescribed if an on-call service is not available.

2.2.6 Medication Storage

All medications must be stored in an area that is not accessible to the public as per the *Medicines and Poisons Regulations 2016*. Medication should be locked in a trolley, cupboard, patient medication drawer or storage room when not in use.
Mobile storage products such as medication and resus trolleys should be kept in an area inaccessible to the public if the area is not a 24-hour staffed location.

Access to medication should be limited to staff members who have the authority to handle medications. Unregulated health care workers required to have handling of medications as part of their position need to have this listed in the Job Description Form (JDF) associated with the position. Swipe card access should be used for medication rooms and must be limited to staff who are required to handle medication as part of their position. In circumstances where it is not appropriate for staff authorised to handle medications to supervise access to medication rooms, WACHS cleaning and maintenance staff may be permitted with supervised access. Where access is granted to a medication room for staff members not authorised to handle medications, that region needs to risk assess, consider any methods available to mitigate the risk and record the risk in the enterprise risk management system.

Pharmacy stores, where present, in integrated district hospitals, should have access limited and granting of access, particularly after hours, through a clear approval process. The Regional Chief Pharmacist responsible for the remote location, is responsible for auditing this every six months to ensure all staff permitted access still require access as part of their position.

Access to the pharmacy department must be via approval of the Regional Chief Pharmacist. Pharmacy departments are to be fitted with a working intruder alarm system to alert unauthorised access afterhours. Local processes are required to determine when the alarm is to be active, who can deactivate the alarm and who is able to acknowledge and deactivate the alarm. The list of approved staff, as well as a report of staff members who accessed the pharmacy department, should be audited by the regional chief pharmacist every 6 months to ensure all staff permitted access still require access as part of their position.

2.2.7 Storage of High Risk Medications

High risk medications are described in MP 0131/20 High Risk Medication Policy and the WACHS High Risk Medication Procedure. Some high risk medications have specific storage requirements including:

- High concentration intravenous potassium products must be stored separately from other ampoules in a sealed clearly marked container or dedicated locked cupboard in clinical areas.
- Opioids have additional storage requirements due to risk of diversion defined by legislation and mandatory policy.
- Voluntary assisted dying substance – refer to the WACHS Voluntary Assisted Dying Policy for more details.

2.2.8 Storage of Schedule 8 Medications

S8 medications must always be kept secured (refer to the WA Health Medications and Poison Regulation Branch website for full requirements and details).

In clinical areas with 24-hour nursing coverage, S8 medications must be stored in a locked cupboard or safe secured to the wall or floor. In accordance with the *Medicines and Poisons Regulations 2016*, the cupboard must be made of hardwood or metal with a deadbolt pin and tumbler style locking mechanism. The key must not be the same as other keys available on site.

Any existing S8 cupboards made from medium-density fibreboard (MDF) have an ongoing exemption from the Department of Health. Any newly installed cupboards must be compliant (metal or hardwood) and involve consultation with the Regional Chief Pharmacist prior to installation.

Areas without 24-hour nursing coverage must have a drug safe made from solid steel plate that is fixed to the building structure with bolts. Areas without 24-hour nursing coverage must keep the contents of the safe below 250 dose units (see Medication and Poison Regulation Branch website for calculation method). If more than 250 dose units are stored in the safe, the area must be covered by continuously monitored movement detectors. This may apply to pharmacy store areas in integrated district sites with bulk S8 medication storage areas.

Schedule 8 medications are not permitted to be stored on a resuscitation trolley or anaesthetic trolley if unattended by an authorised person.

2.2.9 Storage of Schedule 4 Restricted Medications

S4R medications must be stored in a locked cupboard or safe separate from other medications. In the case of a cupboard it must be secured to the wall or floor. The lock must be sturdy (deadbolt pin and tumbler style). The key must not be the same as any other key on site.

In situations where space is limited and there are minimal S4R medications such as theatre or resuscitation bays, the S4R medications may be stored in the schedule 8 safe. Approval from the Poison Permit holder is required and would include a risk assessment. Where this occurs the S4R medications should be treated as schedule 8 medications for the purpose of recording and checking.

S4R medications may be stored in an emergency or resuscitation trolley, with the approval of the poison permit holder. Quantities in a trolley should be limited to the amount required to treat a single patient. The trolley must be locked or secured with a security tag or similar tamper evident seal. Daily checking of the contents of the locked trolley or integrity of the tag is required. As part of the approval process the poison permit holder will need to define the register recording and restocking requirements.

2.2.10 Control of keys

Keys for accessing S4R and S8 safes and cupboards must be maintained under the control of an authorised person. Records should be maintained for all keys relating to medication to enable tracking of keys between shifts and a list of staff with access during a shift. Recordable medication keys should only be in the possession of health professionals with the authority to administer or supply scheduled medication. Within theatres, keys may be in the possession of an anaesthetic technician when they are assisting an anaesthetist with medication administration.

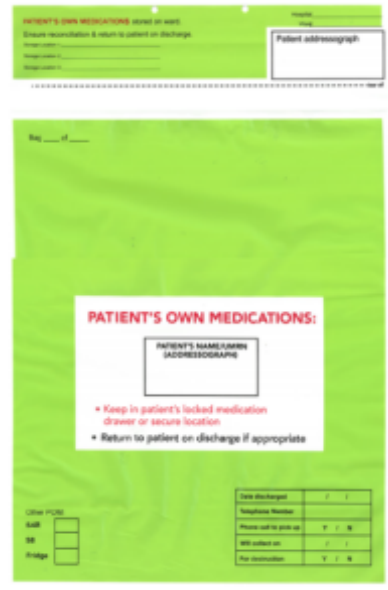
In order to report who had access to medications at any one time, allocation and handover of medication keys should be recorded on a specific key register, the daily roster sheet, the shift handover sheet or via an alternate mechanism approved by the Regional Chief Pharmacist. A common example of this in the ward environment is where a shift coordinator hands the S8/S4R keys over to the next shift coordinator. The date and time of this handover, with signatures of the two coordinators are recorded on the daily roster sheet as well as the names of all nursing staff who might access these keys.

Where the keys are maintained on site outside of working hours, they must be maintained in a way that prevents access by unauthorised staff (such a coded key safe). Storage must be in a manner that enables any staff member accessing the keys to be identified (such as swipe card access to the room or area). Where additional security of a coded key safe is used, access codes should be changed regularly at least annually.

Only one copy of the key is able to be in use at any time. A maximum of two copies of the key are able to be made, one to be in use and one to be stored in an appropriate key safe within the pharmacy department.

2.2.11 Storage of Patient's Own Non-Recordable Medication

Patient's own medications not required during their admission should be stored in the appropriate patients' own medication bag.



Patient's own non-recordable medications should be stored in a green bag either locked in the patient's bedside locker or in a specified area in the medication room. Record the receipt and storage of patient's own medication in the patient integrated notes.

The medication bag has a tear off tab that should be placed in the patient records for reference e.g. in the patient's bedside folder or alternatively attached to the patient's discharge checklist.

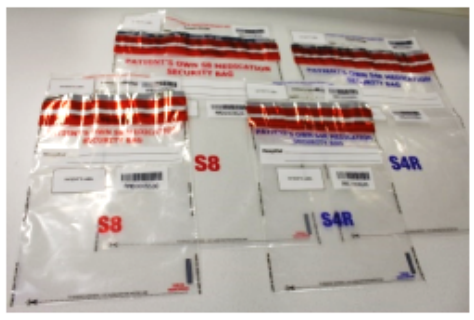
Patient's Own Non-Recordable Medication Bag (Prod ID 5648)

2.2.12 Storage of Patient's Own Recordable Medications

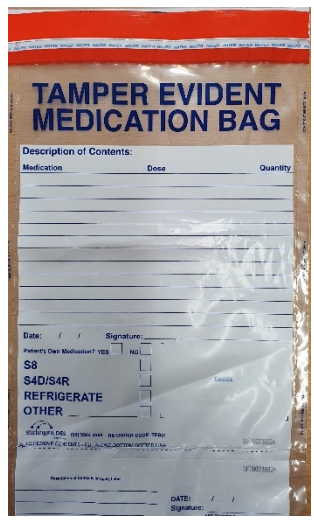
Patient's own recordable medications must be kept with the same level of security as other recordable medication. All recordable medication must be counted and recorded on admission by two authorised persons. Oral liquid S4R and S8 medications present particular challenges. Measuring should be avoided, but estimation is required and ideally should be agreed to by the patient as well.

If the medication is not required during the admission, it should be counted and sealed in a tamper evident bag. Multiple patient's own recordable medicines can be store in the one bag. The unique security bag number should be recorded on a dedicated page in the appropriate register (S4R or S8) along with the full details of each medication (including generic medication name, strength and individual quantities) After this initial entry daily checks must then be recorded and signed as balance check, correct and confirmation that the security bag is still sealed and intact. Patient's own medicines that present in a DAA are to be stored in accordance with the highest scheduled item it contains.

Patient's Own Recordable (S4R and S8) Medication Security Bags and Tamper Evident Medication Bag



S4R Small (A5) bag – 154413B
S4R Large (A4) bag – 154412A
S8 Small (A5) bag – 154414C
S8 Large (A4) bag – 154411Y



Product Code: TEB01

Both medication bags have a tear off tab that should be placed in the patient records for reference e.g. in the patient's bedside folder or alternatively attached to the patient's discharge checklist.

There are some situations where it is necessary to use the patient's own recordable medications. In these situations, each item needs to be recorded on a separate page and should be treated in the same manner as other recordable medications. Refer to section 2.2.22 Medication Recording for documentation requirements.

Refer to Section 2.2.28 Medicinal Cannabis Products (MCP) for more specific information.

2.2.13 Storage of Medication in the Residential Aged Care setting

In WACHS Residential Aged Care settings, oral medications (including S4R and S8's) are permitted to be packed into dose administration aids, as their stability dictates, for administration by appropriately trained staff or self-administration in accordance with the WACHS Medication Prescribing and Administration Policy.

Recordable medication other than regular oral medications, in a dose administration aid must be stored in a safe or locked cupboard and recorded in a register in the manner as other controlled medications. All residents' medications, apart from those approved to be self-administered by the patient, must be stored in a manner that prevents access other than by authorised staff. Authorised staff may include unregulated health care workers where they are permitted by their JDF to assist patients in medication assistance/prompting/administration and have completed appropriate training in accordance with the WACHS Medication Assistance by Unregulated Health Workers Policy.

2.2.14 Cold Chain Storage

It is strongly recommended for medicines to be stored in purpose-built vaccine fridges and to have them connected to an essential power supply. Existing general purpose refrigerators storing medicines, must be replaced with a purpose built vaccine refrigerator when it is at the end of its useful life. The fridges must only store medications and diagnostic items as approved by the regional chief pharmacist.

Data loggers should be used in medication fridges that are not connected to a reliable Building Management System (BMS), and these fridges must have recorded daily temperature checks (minimum, maximum and actual) at the site of the fridge of the fridge and then archived. If the fridge contains vaccines, there must be documentation of twice daily temperature checks, in-line with National Vaccine Storage Guidelines 'Strive for 5'.

If the facility does have fridge temperature monitoring facilitated via a BMS, it is up to the individual site as to whether manual recording is required but nurses/midwives/ pharmacy must always remain aware of fridge temperatures when removing stock and act as appropriate.

Wards – Nursing/Midwifery staff are responsible for the review and archiving of weekly data logger readings or BMS records. This may also be provided to the Pharmacy department based on regional / local requirements.

Pharmacy – Pharmacy staff are responsible for ensuring the review and archiving of weekly data logger readings or BMS records for fridges with the Pharmacy department.

Documentation should be archived for 2 years and in-line with the WACHS Records Management Policy.

If transporting temperature sensitive medications between areas, the use of eskies, ice bricks and a temperature monitoring device is required if the product is going to be out the fridge for greater than 15 minutes. If transport time is less than 15 minutes, no additional packaging is required.

The unit manager must ensure cleaning of the medication fridge in-line with the WA Health Safe Use of Medication Refrigerators Policy (3 monthly – purpose built vaccine fridges and monthly when using a domestic refrigerator).

Regions must have documented and auditable evidence of the following for all sites:
- A routine maintenance schedule and work completed (essential).
- A current fridge asset list (essential).
- A fridge asset replacement plan (highly recommended).
- Annual audit of refrigeration temperature recording system for all fridges.

2.2.15 Cold Chain Breaches

A cold chain breach (CCB) occurs when storage temperatures are outside the recommended temperature range (generally 2-8 degrees Celsius) for longer than 15 minutes (or if temperatures reach 0 degrees C or below).

If the alarm on the temperature monitoring device sounds, attending staff (or delegate) are to:
- check the medication fridge door is closed
- monitor the temperature to ensure the temperature is returning to within the appropriate temperature range then reset the fridge alarm
- relocate stock as appropriate to avoid a cold chain breach (as outlined below)
- initiate the cold chain breach process if temperature and duration of excursion warrants it. Refer to Medication Fridge / Cold Chain Action Plan (Appendix 7 and Appendix 8*).*

2.2.16 Prohibited Substances

Prohibited substances within a WACHS facility, whether on the person or within their property include prohibited drugs as defined in the *Misuse of Drugs Act 1981;* and unidentifiable substances in any form including, but not limited to:
- tablets
- pastes
- plant materials
- liquids
- powders
- crystalline.

Note: Staff are not required to establish what the substance is. A brief description of the substance will be required to be documented.

If it is the clinical decision of the most senior authorised person that the prohibited item is to be confiscated, the following actions should be undertaken:

Prohibited items categories	Actions to be taken
Prohibited drugs as defined in the *Misuse of Drugs Act 1981,* OR, Unidentifiable substances, including liquids.	Should be confiscated and placed into a tamper-proof bag and placed in a dedicated and approved secure storage until collection by the WA Police, in accordance with site specific procedures. Liquids should be handled with extreme caution and placed in a pre-determined designated area. They are NOT to be stored with any other item or substance and WA Police must be notified for collection of liquids immediately.

The patient must be issued with a property sheet / receipt confirming that the prohibited substance(s) have been removed from them for safety reasons and may be claimed from WA Police where appropriate. All confiscated items must be appropriately documented and placed in a dedicated and approved secure storage for collection by the WA Police.

A Register must be kept in a secure location by all WACHS sites to document all confiscated items. Patient details must not be documented on confiscated items, instead, a unique identifier must be assigned to enable future tracking of items if required.

Details to be written in the Register and property sheet / receipt:
- Name of person.
- Date and time the substance was found.
- Description of item found.
- Circumstances of confiscation.
- Location of secure and safe storage where substance is placed awaiting WA Police collection.
- Unique identifier (refer to site specific procedures).

Details to be written on the confiscated item(s):
- Unique identifier only.

Once a substance has been confiscated, it is recommended to be stored in a secure storage (consider the availability of monitoring by 24/7 CCTV cameras where appropriate).

The operational management of prohibited substances may require unique region or site-based responses following these principles.

2.2.17 Medication Transport / Transfer

Inter and intra hospital transport and transfer of medications should occur in a way that maintains accountability, prevents access to the general public and maintains the integrity of the product. Persons involved in transport and transfer of large orders must have access to appropriate equipment to enable them to work safely and avoid injury.

2.2.18 Intra-hospital movement of medication

Medication movement within a hospital must only be conducted by authorised person or unregulated health care workers where their JDF includes the transport of supplies including pharmaceuticals.

In the case of S4R and S8 medications, they must be transported to a clinical area by a pharmacy staff member, registered nurse or registered midwife. A pharmacist or pharmacy support staff approved by the Regional Chief Pharmacist must be involved in the delivery of S8 medications for ward stock. Urgent requests can be collected by two authorised nurses who must present to the pharmacy with the register to record the medication.

2.2.19 Pneumatic Tube

A pneumatic tube is available in some sites and is used to convey specific items in a fast, safe and efficient manner. Medications are to be packed into the canister with adequate packing to prevent breakage and sealed according to the manufacturer's instruction.

Not all medications are suitable to send via the pneumatic tube. Appendix 6a and Appendix 6b outlines a standard list of items not suitable to be sent in the pneumatic tube however regional variation might warrant additional items to be added according to local processes.

2.2.20 Inter-hospital Transportation of Medications

Transportation of medications to sites without a pharmacy department must be undertaken using systems that provide evidence of receipt on delivery. External courier services with traceable recording systems are preferred and must be used where available. Stock is not to be sent via any other method without specific approval from the regional chief pharmacist. Where traceable recording systems are not available, a risk assessment must be completed, and strategies aimed at mitigating these risks must be implemented.

Controlled substances, in addition to the above, must be transported to sites packed with tamper evident packaging plus any other requirements defined by the regional chief pharmacist. All controlled substances transported in this way must be accompanied by an S4R or S8 Requisition and a Delivery Docket that have both been signed by the staff member/s preparing the order. When returning S4R or S8 medications it is recommended that the Pharmacy is contacted to inform them that the stock is being sent. This can be done via phone, fax or email.

On receipt of the stock, the authorised person/s must sign both documents and immediately fax or email the completed documents to the pharmacy department. If the original paper requisitions/dockets are not requested back to the pharmacy department by mail, they must be stored with all other controlled substance paperwork.
If the regional pharmacy department has not received notice of receipt within 7 days of the expected arrival, the manager of the receiving site will be contacted to investigate immediately. If the stock is not identified, the manager is to proceed with a discrepancy investigation

Transfer of recordable medication, between WACHS hospitals within a region, after hours should be avoided and only occur where no other alternative is available and when required for a specific patient. Transport may only be done by an authorised person and the quantity limited to what is required to manage the patient until access from pharmacy can be arranged. Appropriate requisition forms must be completed for the transfer, and a copy of the completed form sent to the regional pharmacy department. Emergency replacement stock may be transferred where local stock is limited if WACHS staff are accompanying a patient to another hospital (e.g. nurse escort) or where other authorised persons are available to transport.

2.2.21 S4R / S8 Transport Bags (Blue Bags)

S4R / S8 Transport Bags (blue bags) are used by some regions to transport S4R and S8 medications to sites. In these sites all S4R or S8 stock being returned are to be packaged into the appropriate blue bag for transport and sealed using a tamper evident seal. An empty bag and additional tamper evident seals may be requested to be sent to a site to allow return of stock if that site is not anticipating a S4R or S8 order within a suitable time period. To avoid any attention being drawn to the blue bag, it is then to be placed inside a sealed and de-identified cardboard box for transport with the courier.

2.2.22 Medication Recording

Administration and supply of medications to patients in clinical areas must be recorded on a medical record– Refer to WACHS Medication Prescribing and Administration Policy.

2.2.23 Recordable medications

All medications must be recorded in an appropriate register. Each cupboard / location requires a separate register. Schedule 8 medications must be recorded in an approved register (HA14 / HA176). A separate register must be kept for each separate location where controlled substances are stored. Where possible, a single register must be used for multiple medications.

Each product requires a separate page and the page description must include the generic name, strength and form (e.g. Midazolam 5mg/ml ampoule or Oxycodone 10mg SR tablets). Each product should be included in the index page. Brand names may be included in brackets to ensure correct product selection.

On administration of the medications, two authorised staff members are required to complete all components of the entry including:

- Full name of the patient.
- UMRN of the patient (if available).
- Date administered.
- Time removed from the safe or cupboard.
- Dose administered to the patient.
- Amount removed.
- Amount discarded.
- Balance in the safe or cupboard.
- Name of the prescribing doctor.
- Signature of the authorised person administering the medication.
- Signature of the authorised person checking the medication.
- The names of both authorised staff printed.

Where the balance is discarded at a later stage, such as with patient controlled analgesics (PCA) the discarded amount must be recorded on the appropriate medication record (such as MR170.5).

Locations where 2 authorised staff members are not available, a single staff member may complete the transactions however other risk management strategies such as limited quantities, CCTV monitoring and more frequent audits should be used to reduce the risk of diversion.

For recordable patient's own medications refer to section 2.2.12 Storage of Patient's Own Recordable Medications.

There are specific considerations for the self-administered voluntary assisted dying substance which is to remain with the patient at all times. Refer to the WACHS Voluntary Assisted Dying Policy for details.

2.2.24 Receipt of recordable medication ward orders

On receipt of the medications, two authorised staff members are required to sign in the medications. The date, requisitions number and quantity received must be recorded in the receipt columns of the register. Where two authorised staff members are not available on site a single staff member may complete the transaction. The balance of the register must be reconciled each time an entry is recorded.

2.2.25 Daily register balance checks

The balance of the register must be checked at least once per day in all 24 hours clinical areas. In non-24hour clinical areas, the balance must be checked each day the clinical area is in use. Ideally a balance check should occur at the end of a working day as members who have handled the medications are available to respond to any queries.

Non-clinical areas where there is stock stored and access is restricted, such as pharmacy department or pharmacy store areas in smaller hospitals, the balance must be checked monthly as a minimum. More frequent checking is appropriate where multiple staff members have access to the storage areas and as determined by the unit manager or Regional Chief Pharmacist.

Balance check must be completed by two authorised staff members, where both staff members confirm the current stock holdings and sign the register.

In locations with a single authorised staff member in control of the keys, the check must be completed on arrival to the service, prior to departure and at least monthly during the period of work.

2.2.26 Storage of registers, requisition books and prescribing stationery

Registers, prescribing stationery (pads and paper), and requisition books must all be supplied in a manner that increases traceability and minimises the risk of theft. There must be a clear process for the control and custody of stationery addressing

purchasing, storage and supply.

All unused registers stored in the pharmacy department should be stored in a locked cupboard. Where this cannot be achieved, the unused registers must be included in a quarterly stocktake. All registers should be uniquely numbered when supplied. The unique number / number range of all registers and requisition books must be documented within pharmacy prior to being supplied to clinical locations. This is to ensure the registers and requisition books in use, and completed registers, can be tracked for audit purposes. Once a register or requisition book is completed it must be stored away from the ward area in a secure location. Archiving processes may vary between regions, but all must be approved by the Regional Chief Pharmacist. Return of completed registers and requisition books to pharmacy for archiving may be required. Any register or requisition book stored off site in an archiving facility must be recorded in a traceable system to ensure it can be retrieved in a timely manner if required.

Registers and requisition books must be available for inspection for a period of five years from the date of the last recorded transaction. Each region must have a procedure for the management of controlled substance registers so that they are readily available in the event of an audit or investigation.

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

All prescription stationery must be stored in a manner that reduces general access. Within clinical areas, in-use stationery should be kept away from public access and spare stationery should be reduced to a minimum and with access controlled by ward coordinators (or equivalent authorised person).

2.2.27 Oral liquid recordable medications

Oral liquid recordable medications require individualised measurement for each dose and are therefore subject to minor unavoidable errors. Oral liquid pods are available for many products and enable oral liquid formulations to be managed in a similar way to ampoules (where remaining volumes can be easily discarded). This may be a preferred method particularly where the product is not in high use.

Repackaging is not encouraged, and unit dose pods should be used where possible. Where the product is repacked by the pharmacy, a maximum expiry date of one month is to be used.

Methadone for opioid substitution should either be provided in pods or dispensed to the ward in prepared doses for administration.

Where a multiuse bottle is in use, it is not possible to confirm the volume present at each medication check. The following processes are used to manage oral liquid:

- Stock holding kept to a minimum with unused product returned to pharmacy when no longer in use.
- Oral dosing syringes and bungs are used except where the product is supplied with a dropper dose system. Bungs must be kept in situ during the use of the product. Drawing up cannula must not be used in recordable oral liquid as these always result in unacceptable volume discrepancies.
- Writable tape or similar is applied to the side of the bottle to enable marking the remaining volume at regular intervals. Pre-printed marking on some bottles are useful but are not calibrated.
- Bottle are not measured via transfer, decanting or physical measurement during stock checks as any measurement of the product leads to further loss.

Oral liquids must be reconciled at the end of every bottle and the balance adjusted. The maximum allowable discrepancy is based on the number of measurements (doses) and should not exceed 0.2mL/dose measured. A discrepancy report is not required for balance variations within this range, but the number of doses must be recorded in the register.

Where a discrepancy is suspected pharmacy staff must be involved in the measurement of the bottle.

2.2.28 Medicinal Cannabis Products (MCP)

MCPs are not listed on the WA State-wide Medications Formulary. Patients must supply their own MCP for continued treatment whilst an inpatient.

Before prescribing and administering a patient's own cannabis based medication for continuation of treatment, it must be established that the product was legally prescribed and supplied to the patient.

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

All patient's own MCP must be stored and managed according to legislative requirements and hospital policy. Specific requirements are determined according to

the Schedule classification for the particular MCP. Examples of MCPs and their schedules include:

- MCPs containing predominantly cannabidiol (at least 98% of the total cannabinoid content): classified as S4.
- Tetrahydrocannabinol (THC), nabiximols, nabilone, dronabinol and products prepared or packaged for human therapeutic use that are not otherwise scheduled (i.e. a product purchased online rather than through a registered prescriber or pharmacy): classified as S8.

2.2.29 Return of Medications to Pharmacy

Where medications cannot be disposed of in clinical areas as per this policy (see section 2.2.31 Medication Disposal) then medications should be returned to pharmacy for disposal.

Where pharmacy is not on site, any medication for transport is to be packaged into a carton and the sending site is required to contact the courier to arrange a pickup and complete the courier consignment note including:

- the name and address of your hospital in the sender's box
- the physical address of the pharmacy department address in the receiver's box
- the number of parcels (number of boxes/eskies)
- the description – “Medical goods”
- the weight of the parcel – estimation (minimum of 1kg)
- the signature and date.

Where pharmacy is on site, medications can be returned by the most efficient and locally accepted method (i.e. Non-imprest returns tub in imprest room, or directly by an authorised person etc.)

Returns of both general, refrigerated and S4R / S8 medications will only be accepted for a financial credit from the cost centre if there is greater than 3 months expiry remaining on the stock, it is the current brand held within the pharmacy and it will be able to be used upon return (based on stock usage reports). If clinical and/or diversion risk warrants the return of medicines to pharmacy with less than 3 months expiry, the regional chief pharmacist should be contacted for advice. Prior to all returns, contact must be made with a pharmacy staff member to ensure appropriate site procedures are followed (i.e. Cold chain management, chain of custody, imprest and non-imprest).

When returning in-date S4R or S8 medications to Pharmacy, in addition to placing them into a tamper evident bag, a correctly completed requisition form (including reason for return) must accompany any stock to clearly document the transfer. The requisition form used must only specify the stock being returned (either S4R or S8) and not include any other orders of stock or return of expired stock (which are to be written onto their own separate requisition forms). All stock being returned is to be written out of the appropriate registers with reference to the requisition form number clearly marked in the entry. Both the register and the requisition are to be signed by two nurses.

2.2.30 Refrigerated Medication (Non-Recordable)

Cold chain management outlined in sections 2.2.14 and 2.2.15 must be applied to all medication returns.

2.2.31 Medication Disposal

Medications shall not be discarded down the sink or into general waste bins.

Pharmaceutical waste is to be separated from other clinical waste and disposed of by high temperature incineration.

- All sites are to utilise suitable Pharmaceutical specific waste bins (i.e. Pharmasmart P22 or P64 pharmaceutical waste containers or the Drug Waste Bins or equivalent).
- All cytotoxic waste must be kept separate and placed in a purple disposable plastic container labelled “Cytotoxic Waste”.
- Intravenous fluids without additive may be discarded into the sink or general waste. This includes electrolyte infusions such as potassium chloride and total parenteral nutrition.

2.2.32 Expired General Stock

Medications (which are not S4R or S8 medications) can be appropriately disposed on the ward into a pharmaceutical waste bin for removal and incineration if expired. **Before** putting stock into the bin, record on the “Stock Disposal Record” (see Appendix 9).

2.2.33 Expired S4R/S8 Medication

Regional procedures for the destruction of expired recordable medications are stipulated by the Regional Chief Pharmacist and must be:

- disposed on site with a clinical pharmacist and the most senior nurse on site; or
- returned to the pharmacy department for destruction by the pharmacists.

Return of recordable medications must comply with the requirements for transportation of medications as above including completion of a requisition form marked clearly as returned expired goods in a sealed tamper evident bag.

If returning S4R or S8 oral liquid medication bottles it is important to ensure that the bottle is suitably sealed, preferably with the original lid.

2.2.34 Part Tablets or Doses

Part tablets or ampoules of non-recordable medications may be disposed into a sharps container at a patient bedside where workflows may otherwise be impeded by the use of specific pharmaceutical waste bins.
Part doses of recordable medication (balance of a syringe or tablet, part ampoule, balance of a liquid medication pod) must be recorded in the appropriate register and may be discarded into a:

- sharps container
- drug waste bin (for injectable / oral liquids); or
- pharmaceutical waste bin.

Where larger volumes of recordable medication in liquid form are routinely being discarded (such as Patient Controlled Analgesia (PCA) products) an area should consider using specific medication disposal tubs to render the product unsuitable for diversion before discarding.

2.2.35 Disposal of Patient's Own Mediation

Patient's Own medications are the property of the patient and should be returned to the patient on discharge from the hospital if there is no clinical risk to the patient. Every effort should be made to return patient's own medications to the patient. Any patient's own medications that are unable to be returned to the patient are to be treated as per expired medications. When recording on the "Stock Disposal Record" they must be clearly noted as patient's own stock

If a medication has been ceased this may be removed from the patient's own medication, with the patient's permission, to prevent medications errors / misadventure post discharge. This should be documented in the patient's medical records.

If a patient is considered by medical staff to be at risk of harm if patient's own medication is returned to them, medications should be retained with this clearly documented in the patient's medical records.

Consider WACHS and regional recycling procedures when disposing of pharmaceutical waste.

2.2.36 Reporting Discrepancies

The Report of Schedule 4 Restricted and Schedule 8 Medicines Discrepancies Policy (MP 0103/19) requires WACHS to maintain policies and systems to support the identification of discrepancies and the investigation and documentation of medication loss or theft.

Medication discrepancies generally relate to excess or missing recordable medications, but the process can also be used for other medications if they are known to be missing.

Prompt action is required in response to a discrepancy. Guidelines for the initial response to a discrepancy can be found in the Guidelines for dealing with a S4R or S8 medication discrepancy.

The staff member(s) who discover the discrepancy must act immediately on identifying the discrepancy. Where a discrepancy is identified, an initial review should be conducted by the staff member(s) who discovered the discrepancy during the current shift where possible but always within 24 hours of the discovery.

If the discrepancy is resolved during the initial review, no further action is required.

Any suspected theft of a medication requires immediate escalation to the Regional Chief Pharmacist for consideration of WACHS obligations under the MP 0125/19 Notifiable and Reportable Conduct Policy and/or MP0127/20 Discipline Policy.

Where the reason for the discrepancy is not able to be found during the initial review, the Medications Discrepancy Report (MDR) Form must be completed Form must be completed by the staff member(s) who discovered the discrepancy. The completed Part 1 of the MDR form must be sent to the Unit manager, WACHS Integrity Unit (WACHSIntegrity@health.wa.gov.au) WACHS Chief Pharmacist (WACHSChiefPharmacist@health.wa.gov.au) and the Regional Chief Pharmacist within 24 hours of the discovery of the discrepancy.

Upon receipt of the completed Part 1 of the MDR, it is to be entered into the approved database by the WACHS Chief Pharmacist. For WACHS, the approved database is the Conduct Management System (CMS).

An Inquiry into the unexplained discrepancy is then to be conducted by an appropriate staff member (the manager of the unit or department of the hospital). This person

should be appropriately qualified and independent of the initial review into the loss. This person is responsible to ensure the discrepancy is further investigated which may include a review of all medication charts in use during the time, confirming who had access to the safe, searching the safe and surrounding areas and/or reviewing CCTV footage. The appropriate person must complete Part 2 of the MDR Form, detailing the inquiries undertaken, and the completed MDR Form sent to the WACHS Chief Pharmacist, Regional Chief Pharmacist and WACHS Integrity Unit, within seven days of the initial discovery.

Additional guidance on conducting the investigation may be obtained from the WACHS Chief Pharmacist or WACHS Integrity Unit.

Upon receipt of the completed MDR Form, the relevant record in CMS should be updated by the WACHS Chief Pharmacist. The WACHS Chief Pharmacist will assess the available information in accordance with Step 1 of the WACHS Discipline Guide to determine if the information may concern a Breach of Discipline; the matter should be referred as appropriate to the WACHS Integrity Unit. This assessment will also consider if any risk mitigation action is necessary to prevent re-occurrence.

A flowchart for managing discrepancies is available in Appendix 1.

3. Definitions

Authorised person	Authorised person is a person authorised to possess, administer, prescribe or supply as defined within the *Medicines and Poisons Regulations 2016.* In the case of Anaesthetic technicians, they may possess and administer Schedule 4 and Schedule 8 medications if required within their JDF under the direction of a medical practitioner.
Bung	Device fitted to the bottle neck of an oral liquid container to allow connection of an oral dosing syringe
Control of the keys	Keys for a safe or cupboard are considered under the control of the unit manager, Director of nursing or Regional Chief Pharmacist as long as a key register or other mechanism is in place to enable tracing of any staff members who may have possession of the key at any point in time.
Imprest Medication	Predefined list of medications and quantities stored for use in patients where the requirement is unable to be predicted and the medication has not been supplied for a specific patient.
Medication	Medication defined as Schedule 2, Schedule 3, Schedule 4 or Schedule 8 in the Poison Standard (SUSMP)
Medication Room	Area in a clinical room where medications are stored. These are defined as clean utilities in some facilities.
Pharmacy Department	Non-Clinical storage area managed by pharmacist and/or pharmacy technicians. Includes areas where there is storage of medication not allocated to clinical areas and usually has the capability to order medications direct from wholesalers.
Pharmacy Stores	Storage area for medications outside of clinical areas of a health service which may or may not be staffed by pharmacists. Generally applied to integrated district hospitals.
Recordable Medications (medications)	Schedule 8 (S8) medications and Schedule 4 Restricted (S4R) as defined by the Poison Standard (SUSMP) or Section 3 Risk based requirements for medicines handling
Schedule 4 Restricted (S4R)	Medications defined by Mandatory Policy Risk based requirements for medicine handling as requiring additional controls due to the risk of abuse, dependence or diversion. Additional medications may be designated Restricted by regions where additional operational controls are needed to prevent diversion or inappropriate use under the authority of the Regional Chief Pharmacist. For the full list refer to the Appendix 5.
Schedule 8 Medication	Controlled medication according to the Poison Standard. The packaging will have the descriptor “controlled medication”
Swipe Cards	Individual issued access cards linked to a reportable system able to identify the person who gained access to the area or cupboard.
Continuously monitored movement detectors	As per the Medicines and Poisons Regulations 2016, this is a system: a) to detect the presence of a person who interferes, or attempts to interfere, with a safe or strongroom or any security measures associated with the safe or strongroom; and

	b) that complies with the requirements in AS 2201.3 1991 Intruder alarm systems, Part 3: Detection devices for internal use published by Standards Australia.
Pharmaceutical Waste Container	Pharmasmart P22 Specific pharmaceutical waste container (or equivalent) to be utilised for disposal of pharmaceutical waste. The lid should not be closed before the full indicator appears. Once closed the lid should be locked into place, so that it cannot be reopened. Even while the lid is open the contents remain secure and inaccessible.
Pharmaceutical Waste Container - Pharmaceutical Waste Container - Pharmasmart P64	Specific pharmaceutical waste container to be utilised for disposal of pharmaceutical waste. Once closed the lid should be locked into place, so that it cannot be reopened. These are to be stored in a secure, restricted access area.
Drug Waste Bin (for Injectable / Oral liquid drugs)	Specific pharmaceutical waste container to be utilised for disposal of liquid pharmaceutical waste. Ordered via iProcurement.
Purpose-built vaccine fridge	Specifically designed to store vaccines, and are the best-practice storage option for temperature-sensitive medicines and vaccines
Building Management System (BMS)	A centralised electronic system, usually maintained by the Engineering Department that can potentially be used to monitor refrigeration networks. A suitable substitute to a BMS is a web-based platform specifically designed for environmentally monitoring that has integrated alarms and has been approved for use by the Regional Chief Pharmacist.
Data logger	An electronic temperature recording device that can be downloaded to a computer to interrogate and store recorded temperature data. Data loggers should undergo routine maintenance as per National Vaccine Storage Guidelines – Strive for 5
Temperature monitoring device	Any proprietary device that can be utilised to indicate to the ambient temperature within a defined period. Often used during transport to ensure the recipient of a package can confirm the contents have remained within the specified temperature range.

4. Roles and Responsibilities

All Staff are required to work within policies and guidelines to make sure that WACHS is a safe, equitable and positive place.

Authorised persons possessing medication, to be administered to a patient, assume full responsibility for that medication and its handling. The responsibility for the handling of controlled substances transfers to the authorised person as soon as they possess the controlled substance until there is a recorded point where the chain of custody changes and is documented (i.e. administration record on a medication chart, return of stock to a register).

The **WACHS Board and Regional Executive teams** are responsible under the MP 0139/20 Medicine Handling Policy to ensure:

- Governance structures support safe and effective medications handling in all WACHS facilities.
- Policies are in place and risk management approach is taken to the management of medications.
- The Regional Chief Pharmacist, who is the regional *Medicines and Poisons Act 2014* permit holder, is part of the approval process for any mitigation strategies to manage risks around medication handling.
- Adequate material, human and financial resources are made available to comply with the requirements of MP 0319/20 Medication Handling Policy.

The **WACHS Chief Pharmacist** is responsible for:

- Reviewing any breaches of the policy or relevant legislation identified by the regional evaluations outlined in the Evaluation Section.
- Ensuring a system of regular audit reporting between the regions, central office and where required, the board.

The **Regional Chief Pharmacists** are responsible for:

- Approval of all medication handling policies in the region and to ensure they are endorsed by an appropriate governance group.
- Purchasing of scheduled medications as per the poison permit or approve the delegate of purchases as appropriate.
- The initial review and any subsequent inquiry into medication discrepancies within the pharmacy department being conducted, documented and appropriately referred within seven days.
- Management of medication stored within the pharmacy department, including access to recordable medications, is managed to limit the risk of diversion.

- Ensuring medications are procured and distributed as per this policy.
- Maintaining and auditing annually a database to record and reconcile regional controlled substance register movement.
- Ensuring the Regional Drugs and Therapeutics Committee or equivalent, reports all medication audits as outlined in the Evaluation Section, to the WACHS Chief Pharmacist.
- Ensure audits are conducted and archived in accordance with requirements set out in this policy.

The **Nurse Unit Manager, Nurse Manager of a small hospital or equivalent position** is responsible for:

- Workflows and systems used in the area to ensure they are consistent with policies and procedures for handling medications.
- The initial review and any subsequent inquiry into medication discrepancies within the unit or hospital being conducted and finalised within seven days.
- Undertaking medication audits as outlined in-line with this policy.
- Handling and control of mediations at a ward level. This includes but is not limited to the management of medication expiry whereby a direct pharmacy imprest service is not currently servicing the clinical location.

5. Compliance

This policy is a mandatory requirement under the *Medication and Poison Act 2014.* Failure to comply with this policy may constitute a breach of the WA Health Code of Conduct Policy (Code). The Code is part of the Integrity Policy Framework issued pursuant to section 26 of the *Health Services Act 2016* (WA) and is binding on all WACHS staff which for this purpose includes trainees, students, volunteers, researchers, contractors for service (including all visiting health professionals and agency staff) and persons delivering training or education within WACHS.

WACHS staff are reminded that compliance with all WA health system and WACHS policies is mandatory.

6. Records Management

All WACHS corporate records must be stored in the approved Electronic Documents and Records Management System in accordance with the Health Record Management Policy and the WACHS Records Management Policy.

7. Evaluation

Evaluation of this policy is to be carried out by the unit managers and regional chief pharmacists. Where possible, an independent staff member who does not work in the area should conduct the evaluation (i.e. Safety and Quality team or a Registered Nurse from another clinical area). The following frequency and assessments are to be followed:

- Audit of the storage of medications annually as defined in Appendix 2.
- Audit of the requisition, supply, inventory assessment and administration of recordable medications at an interval not more than 3 months.
- For administration records the number of entries examined should be:
- A minimum of 10 entries for areas with less than 10 occupied beds (or all entries if less than 10).
    - A minimum of 20 entries for areas with greater than 10 occupied beds.
- For pharmacy destruction records, no less than 5 entries should be examined every 3 months.

Appendix 3 has an example of an audit form for administration records however regions may customise this audit by including additional fields.

Audit reports must be tabled at the Regional Drugs and Therapeutics Committee or equivalent as evidence of adherence to this policy and to NSQHS Medication Safety Standard- Actions 4.01 and 4.14. If an audit identifies a breach of the policy:

- The details of the breach must be escalated to the regional executive team.
- The audit and the region's response must be reported to the WACHS Chief Pharmacist via the Regional Drugs and Therapeutics Committee or equivalent as soon as possible.

8. Standards

National Safety and Quality Health Service Standards (NSQHS) – 1.7, 4.1, 4.14
Australian Aged Care Quality Agency Accreditation Standards – 1 (3) (c)I, 2.3d, 3.3b

9. Legislation

Medicines and Poisons Act 2014
Medicines and Poisons Regulations 2016

10. References

- *Medicines and Poisons Regulations 2016*.
- Mandatory Standard for Intravenous Potassium, Feb 2020.
- WA Health Disposal of Medications
- Approved Schedule 8 Registers
- The WA Health Schedule 8 Medications Prescribing Code
- Medicine and Poison Regulation Branch Medicine Disposal S8 Recommendations.
- Department of Health Cold Chain Management Guidance
- National Vaccine Storage Guidelines – Strive for 5
- WA Health Safe Use of Medication Refrigerators Policy

11. Related Forms

WA Health Medication Discrepancy Report Form

12. Related Policy Documents

FSFHG Management of Community Program for Opioid Pharmacotherapy (CPOP) for Inpatients Policy.
WACHS Discipline Guide
WACHS Health Record Management Policy
WACHS High Risk Medication Procedure
WACHS Medication Assistance by Unregulated Health Workers Policy.
WACHS Medication Prescribing and Administration Policy
WACHS Record Management Policy
WACHS Waste Management Policy
WACHS Voluntary Assisted Dying Policy

13. Related WA Health System Policies

Code of Practice for Clinical and Related Waste Management
MP 0124/19 Code of Conduct Policy
MP 0127/20 Discipline Policy
MP 0139/20 Medicine Handling Policy
MP 0125/19 Notifiable and Reportable Conduct Policy
MP 0103/19 Reporting of Schedule 4 Restricted and Schedule 8 Medicines Discrepancies Policy

WA Health Supporting Documentation

WA Health Disposal of Medications Recommendations
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 medications
Guideline on Pharmacy Department access
Guideline on administration and record keeping for Schedule 4 Restricted and Schedule 8 medications
Guideline on oral liquid Schedule 4 Restricted and Schedule 8 medications
Guideline on patient's own medications
Guideline on continuation of opioid substitution treatment in hospitals
Guideline on health practitioner initiated non-prescription medications

14. Policy Framework

Clinical Governance, Safety and Quality

15. Appendices

Appendix 1: WACHS Medication Discrepancy Flow Chart
Appendix 2: Environmental / Storage Audit
Appendix 3: Controlled Substance Documentation Audit
Appendix 4: Destruction Register Audit
Appendix 5: Schedule 4 Recordable Medications
Appendix 6a: Medication unable to be sent via Pneumatic Tube
Appendix 6b: Some Medications Don't Mix with a Pneumatic Tube Poster
Appendix 7: Medication Refrigerator Cold Chain Action Plan
Appendix 8: Cold Chain Breach – Documentation
Appendix 9: Stock Disposal Record

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

Contact:	WACHS Chief Pharmacist		
Directorate:	Medical Services	**EDRMS Record #**	ED-CO-21-62062
Version:	2.00	**Date Published:**	9 November 2021

Appendix 1: WACHS Medication Discrepancy Flow Chart

Government of **Western Australia**
WA Country Health Service

Medication Discrepancy Flowchart

1 Discrepancy Identified

Where a discrepancy is identified, an initial review should be conducted by the staff member(s) who discovered the discrepancy during the current shift where possible but always within 24 hours of the discovery.

2 Discrepancy Resolved

If the discrepancy is resolved during the initial review, no further action is required.

3 MDR Form

Where the reason for a discrepancy is unable to be found during the review, a Medicine Discrepancy Report (MDR) form must be completed by the staff who discovered the discrepancy. The completed Part 1 of the MDR Form must be sent to the Unit Manager, Integrity Unit, WACHS Chief Pharmacist, Regional Chief Pharmacist and Regional Director Nursing & Midwifery within 24 hours of the discovery.

4 Initial Assessment

Upon receipt of the completed Part 1 of the MDR, it is entered by the WACHS Chief Pharmacist into the Conduct Management System (CMS) and assessed.

5 Inquiry

Within seven days of the initial discovery, an Inquiry into the discrepancy is to be conducted by an appropriate staff member (the manager of the unit or department of the hospital). The appropriate person must complete Part 2 of the MDR Form, detailing the inquiries undertaken. The form should be sent to the Integrity Unit, WACHS Chief Pharmacist, Regional Chief Pharmacist and Regional Director Nursing & Midwifery.

6 Final Assessment

Upon receipt of the completed Part 2 of the MDR, CMS is updated by the WACHS Chief Pharmacist. The WACHS Chief Pharmacist will assess the available information to determine if the matter may concern a suspected breach of discipline.

Any suspected theft of a medicine requires immediate escalation to the Regional Chief Pharmacist for consideration of WACHS obligations under the Notifiable and Reportable Conduct Policy and/or Discipline Policy.

Appendix 2: Environmental / Storage Audit

Demographics	
Region / Hospital	
Area / Ward	
Surveyor name/ designation	
Date	

Safe Medication Storage	Yes	No	NA
Is the door to the Medication Room, for areas with swipe card access, securely closed?			
Are all the Medication Imprest Cupboard doors closed and locked, for areas without swipe card access into a secure room?			

Medication Storage	Yes	No
Does the S4R cupboard /safe meet the standards required by this policy? (i.e. deadbolt pin, secured to wall/floor etc.)		
Does the S8 cupboard /safe meet the standards required by this policy? (i.e. hardwood, solid steel, deadbolt pin and tumbler, motion sensors etc.)		
Are the S4R cupboards / safe doors closed and locked?		
Are the S8 cupboards / safe doors closed and locked?		
Are the Schedule 8 (S 8) medication keys being carried by the Shift Coordinator (a RN / Registered Midwife)?		
If Yes: Is the Shift Coordinator currently on the ward?		
Are the Schedule 4 Restricted (S4R) medication keys being carried by a RN, Midwife or Medication Competent Enrolled Nurse?		
If YES: are they currently on the ward?		
Has the allocation of medication keys been documented in a specific key register or on the daily roster sheet or on the shift handover sheet by the shift coordinator?		
Is the allocation of medication keys recorded on - A specific key register		
Is the allocation of medication keys recorded on - The daily roster sheet		
Is the allocation of medication keys recorded on - the shift handover sheet		
Does the document where allocation of medication keys has been recorded include the date and time?		
Does the document where allocation of medication keys has been recorded include the printed name of the staff member accepting responsibility for the keys?		
Does the document where allocation of medication keys has been recorded include the signature of the staff member accepting responsibility for the keys?		
Does the document where allocation of medication keys has been recorded include the details of the keys?		
Were all medication keys accounted for at the end of the last shift?		

Emergency / Resus Trolley	yes	no	NA
Are S4R medications stored on the Emergency / Resus Trolley			
Has the trolley been checked each day for the last 7 days?			

Environmental / Storage Audit page 2

Registers	yes	no
Have balance checks been performed on all S4R medications at least daily for the past 7 days?		
Have balance checks been performed on all S8 medications at least daily for the past 7 days?		
Have all entries in the S4R registers in the last 7 days been signed by 2 authorised staff members? (NA □)		
Have all entries in the S8 registers in the last 7 days been signed by 2 authorised staff members? (NA □)		
Have all entries in the S4R registers in the last 7 days for administration included full name and UMRN for the patient?		
Have all entries in the S8 registers in the last 7 days for administration included full name and UMRN for the patient?		
Have all entries in the S4R registers in the last 7 days for administration included the prescriber's legal name?		
Have all entries in the S8 registers in the last 7 days for administration included the prescriber's legal name?		

Comments
Audit results must be tabled at the Regional Drugs and Therapeutics Committee or equivalent. If an audit identifies a breach of the policy, the audit and the region's response to rectify the breach must be reported to the WACHS Chief Pharmacist via the Regional Drugs and Therapeutics Committee or equivalent.

Appendix 3: Controlled Substance Documentation Audit

Demographics	
Region / Hospital	
Area / Ward	
Surveyor name/ designation	
Date	

Schedule 4R Register Audit				
Medication	**UMRN**	**Time of administration matches**	**Dose Administered Matches**	**Initial / register signatures match**

Schedule 8 Register Audit				
Medication	**URMN**	**Time of administration matches**	**Dose Administered Matches**	**Initial / register signatures match**

Appendix 4: Destruction Register Audit

Pharmacy Controlled Substance Destruction Audit											
Requisition Details						Destruction Register Details					
Requisition Number	Schedule (S8/S4R)	Item Description (medication, dose, formulation)	Quantity For Destruction	Signatures and names completed? Y/N	Date	Register Number	Requisition Number matches (Y/N)	Item Description matches (Y/N)	Quantity matches (Y/N)	Destruction as per policy (Y/N)	**Process as per policy (Y/N)**

Appendix 5: Schedule 4 Recordable Medications

Bromazepam	Nitrazepam
Clobazam	Oxazepam
Clonazepam	Propofol
Codeine combination products	Temazepam
Diazepam	Tramadol
Lorazepam	Zolpidem
Midazolam	Zopiclone

Appendix 6a: Medication unable to be sent via Pneumatic Tube

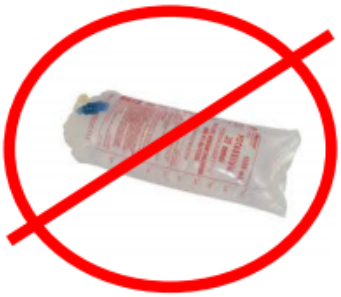
The following medication should never be sent via the pneumatic tube due to its stability/cost/contamination risk:

- All monoclonal antibodies
- All cytotoxic agents
- Alteplase/ tenecteplase
- All vaccines
- BCG
- Botulinium toxin
- Carbonated substances
- Cyclosporin solution
- Darbepoetin
- Dyes
- Enoxaparin
- Erythropoetin
- Filgrastim/pegfilgrastim
- Fluids over 250ml (250g)
- High Risk Medications (ie. Potassium)
- Immunolobulins
- Inhaled anaesthetics
- Insulins
- Items listed as ‘not to be shaken’
- Items with a value greater than $500
- Large glass bottles
- Midodrine (very brittle)
- Recordable medications
- Refrigerated items
- SAS/IPA/PFP- especially if last remaining stock in hospital.

Appendix 6b: Some Medications Don't Mix with a Pneumatic Tube Poster

Some pharmaceuticals don't mix with a pneumatic tube

Products damaged by shaking



Heavy items (more than 250g)

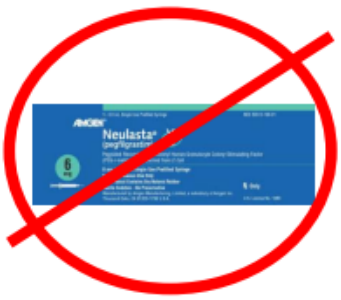
Cold Chain items stored in the fridge

Recordable medications

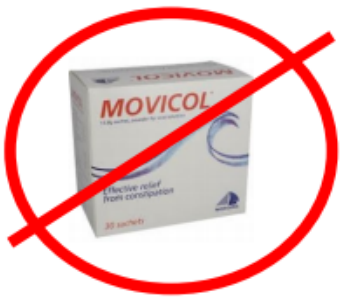
Cytotoxic medications

Protein based products like insulin

Items that break easily



Expensive items



Things too large for the tube

Appendix 7: Medication Refrigerator Cold Chain Action Plan

Fridge	Actions	Outcomes
Audible Alarm Sounds	• Examine fridge to determine the current fridge temperature. • Examine fridge to determine cause of the alarm. • Fix reversible causes (e.g. door open) • Remain at fridge and monitor temperature to ensure it returns to the acceptable range (2°C – 8°C). • For fridges not connected to a BMS – review the data logger to determine the duration of temperature excursion (if the alarm has occurred due to an unwitnessed event of unknown duration). • If the alarm sounds during general, witnessed use – e.g. restocking, and the known duration is < 15minutes the data logger does not need to be downloaded.	Current fridge temperature is 0°C or less. Treat as a Cold Chain Breach, complete Appendix 8 documentation. Quarantine all stock and contact the relevant parties.
		Data logger shows temperature excursion > 15 minutes. Save and print data logger graph. Treat as a Cold Chain Breach, complete Appendix 8 documentation. Quarantine all stock and contact the relevant parties.
		BMS alarm not triggered OR data logger shows temperature excursion < 15 minutes. Fridge does not return to temperature range. Immediately remove stock to an alternative medication fridge and contact Engineering.
		BMS alarm not triggered OR data logger shows temperature excursion < 15 minutes. Reversible cause found and fridge back in temperature range. Reset min/max reading on fridge digital display.

Fridge	Actions	Outcomes
Fridge BMS Alarm Alert It is recommended that all BMS systems are set up with a minimum of two temperature alarms. The first alarm should be triggered when the fridge temperature has been outside of the acceptable temperature range (2°C – 8°C) for ≤ 7 minutes. The second alarm should be triggered when the fridge temperature has been outside of the acceptable temperature range (2°C – 8°C) for 15 minutes – this is a Cold Chain Breach. A third alarm should be considered. The "freeze" alarm should be triggered when the fridge temperature has been below 0°C – this is a Cold Chain Breach.	**First Alarm (≤ 7 minutes)** • Examine fridge to determine the current fridge temperature. • Examine fridge to determine cause of the alarm. • Fix reversible causes (e.g. door open) • Remain at fridge and monitor temperature to ensure it returns to the acceptable range (2°C – 8°C).	Fridge does not return to temperature range. Immediately remove stock to an alternative medication fridge and contact Engineering.
		Reversible cause found and fridge back in temperature range. Reset min/max reading on fridge.
	Second Alarm (> 15 minutes) • Cold Chain Breach.	Treat as a Cold Chain Breach, complete Appendix 8 documentation. Quarantine all stock and contact the relevant parties.
	'Freeze' Alarm (<0°C) • Cold Chain Breach.	Treat as a Cold Chain Breach, complete Appendix 8 documentation. Quarantine all stock and contact the relevant parties.

Fridge	Actions	Outcomes
Cold Chain Breach	**Actions** Quarantine all stock. Remove stock from the affected fridge and place in an alternative medication fridge – maintain at refrigerated temperatures. Complete Appendix 8 documentation Clearly separate quarantined stock and label “DO NOT USE – QUARANTINED. Date: ___/ ___ / ___. By: _____” Do **not** discard any vaccines or medications at this time. Contact the relevant staff for advice. Inform ward nursing staff including Nurse Unit Manager of Cold Chain Breach. Report the Cold Chain Breach via DATIX CIMS.	**Pharmacy Stock:** Contact the Pharmacy Department. Provide Pharmacy with the data logger graph or BMS graph of the temperature excursion. Provide the Pharmacy Department with a list of affected products. Follow advice provided by the Pharmacist. **Vaccines:** Contact the Immunisation Coordinator. Provide Immunisation Coordinator with the data logger graph or BMS graph of the temperature excursion. Provide the Immunisation Coordinator with a list of affected vaccines. Follow advice provided by the Immunisation Coordinator.

Appendix 8: Cold Chain Breach – Documentation

	Date: _____ Hospital: _____ Ward:_____		Details of alarm: ☐ Audible ☐ BMS – First Alarm ☐ BMS – Second Alarm ☐ BMS – "Freeze" Alarm Outcome: ☐ Returned to temperature range ☐ Stock moved to alternative fridge ☐ Cold Chain Breach	Staff Contacted / Informed: ☐ Engineering ☐ Pharmacy ☐ Immunisation Coordinator ☐ Nurse Unit Manager Final Outcome:

Completed by:

Name: _____ Signature: _____ Contact Number:_____

Nurse/ Midwife / Doctor / Pharmacist (circle)

Filed on TRIM: Yes / No

Appendix 9: Stock Disposal Record

STOCK DISPOSAL RECORD

Site name/ward :_____ Date : _____

PRODUCT DESCRIPTION				QUANTITY DISPOSED
Generic drug name	**Strength**	**Form (tablets / injection)**	**Brand**	**Unit Quantity**
Example – paracetamol	500mg	Tablets	Sandoz	150 tablets

Unit Quantity = number of individual tablets / capsules / ampoules / vials / patches