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Medication Handling and Accountability Policy

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1. Purpose

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 <u>Medicines and Poisons Act 2014</u> (WA), the <u>Medicines and Poisons Regulations 2016</u> (WA) and the WA Health MP 0139/20 <u>Medicines Handling Policy</u>.

Additional requirements apply for Schedule 8 (S8) and Schedule 4 Restricted (S4R) medications which may be targeted for diversion or abuse. Inadequate security, storage, record keeping, and controls can contribute to theft, unauthorised use, or unaccountable loss.

2. Policy

There are minimum standards required by legislation for the storage and handling of medication and additional requirements provided by WA Health policy.

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 Medicines Governance

The WACHS Medicines and Therapeutics Committees (MTC) is the peak medicines governance body for WACHS and governs all aspects of medicines management which includes high risk medicines, medicines defects and recalls, medicines shortages, and clinical incident management. Figures 1 and 2 reflect the WACHS Medicines Governance and Regional Medicines Governance Structures.

Subcommittees of the WACHS MTC facilitate the functions of the WACHS MTC. These subcommittees are the:

- WACHS Medication Safety Committee
- WACHS Antimicrobial Stewardship Forum
- WACHS Pharmacy Advisory and Leadership Group.

Regional MTCs govern medicine within each region and are responsible for escalating risks to the WACHS MTC, where required.

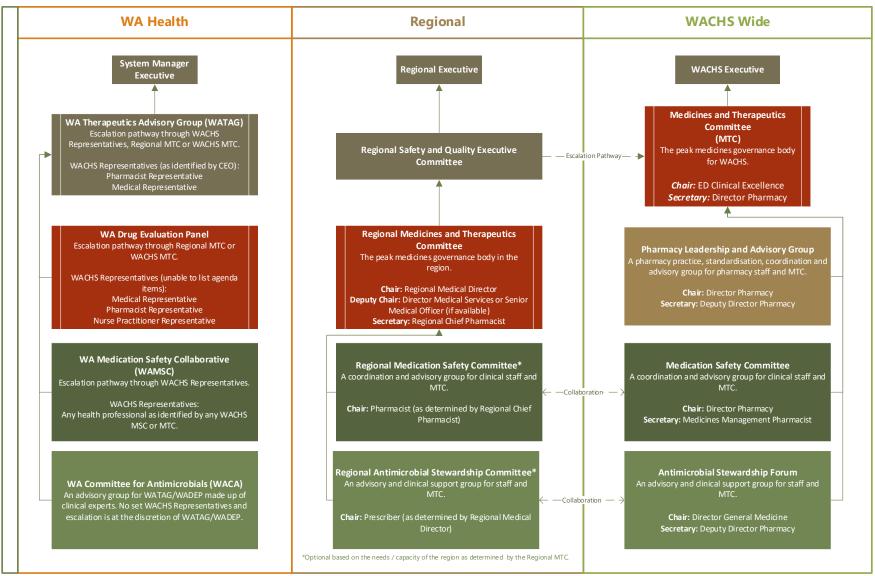


Figure 1: WACHS Medicines Governance Structure

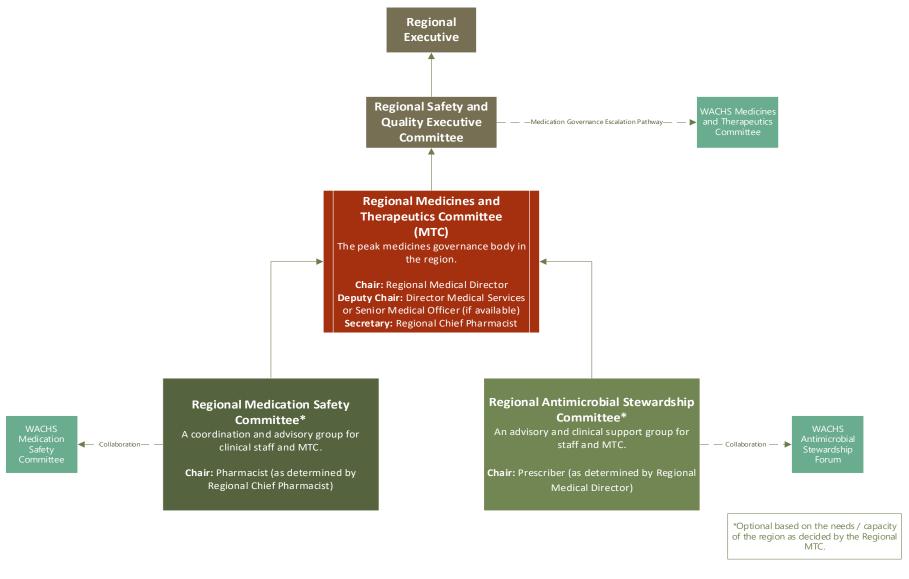


Figure 2: Regional Medicines Governance Overview

2.2 Medication Purchasing and Receiving

All medications (including sample packs and free or subsidised medications via access programs), must be procured (purchased and received) by pharmacy and align with:

- the Standardised Catalogue Definitions for WA Public Hospitals (Appendix A); and
- the Pharmaceutical Products HCNS119914 Contract.

Exceptions include:

- documented endorsement by the Department of Health or by the Health Service Medicines and Poisons Act Permit Holders (i.e., the Regional Chief Pharmacist) for acquisition and management of scheduled medications by another unit of the public health service (i.e., not pharmacy). Examples include:
- scheduled medical gases (e.g., nitrous oxide, nitric oxide) see <u>WACHS Nitrous Oxide</u>
 <u>Policy.</u>
- programs supplied by community pharmacies:
 - Community mental health
 - Community palliative care
 - Residential aged care (multipurpose sites)
 - Dosage administration aids in aged care facilities or as a part of the Indigenous Dose Administration Aids Program
 - o Indigenous Health Services Pharmacy Support Program (Including but not limited to regional arrangements for the supply of S100 RAAHS medicines).

Purchasing

Purchasing requirements within WACHS include:

- medications purchased within pharmacy must be purchased on a purchase order via the iPharmacy application.
- authorisation for purchases of medications must comply with the WACHS Authorisation Schedule.
- S8 and S4R medicines must be on separate purchase orders, not containing general medicines (i.e., a purchase order for S8s and a purchase order for S4Rs). This is to increase the transparency relating to the handling of S8 and S4R medicines.

Receiving

Receiving requirements within WACHS include:

- medication must be purchased and received into iPharmacy by different staff members, as per the Treasurer's Instruction 304 Authorisation of Payments.
- 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 7 years. The WACHS Chief
 Pharmacist (or their delegate) will perform an annual audit of this process.

2.3 Medication Ordering and Supply for Clinical Areas

Ordering of medications in clinical areas is via three systems:

- Imprest
- non-Imprest patient-specific distribution or dispensing
- S8 and S4R medication requisitions.

Imprest orders

Imprest medicines are the medicines which are routinely stocked in each clinical area. Imprest systems are to be designed for safety and to balance the need for timely access for patient care. The Imprest tabs on <u>Formulary One</u> 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 pharmacists and include input by clinicians (nursing and medical) to ensure medications available reflect contemporary practice, Imprests are designed for safety, and to ensure minimal wastage. Imprest lists should be reviewed annually. Changes, additions, amendments of quantities or removal of medications from the Imprest should be approved by the Regional Chief Pharmacist, and senior nursing and medical staff. Some high-risk medications on Imprest should be approved by the regional Medicines and Therapeutics Committee (see WACHS High Risk Medications Procedure). 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.

Non-Imprest patient specific supplies

Medication required for patients but that are not in Imprest should be obtained through non-Imprest supply mechanisms. Non-Imprest supply gives an opportunity for the prescription/medication order to be clinically reviewed for appropriateness, including dose, allergies, interaction, duplication, length of treatment, etc. If a pharmacist is available, a review of a non-Imprest supply should occur and should utilise, where applicable:

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

For locations where a pharmacist does not review non-Imprest medication supply, the Regional Chief Pharmacist must have performed a documented risk assessment.

S8 and S4R medication requisitions

Staff who are authorised to handle S8 and S4R medicines are authorised to order, supply and receive these medicines.

S8 and S4R medications must be requested using a numbered duplicate requisition booklet designed for use with S8 or S4R medications. The requisition slip must be completed by a staff member authorised to handle S8/S4R medicines, must be signed and have the requestor's full name printed and legible. Sites without a pharmacy department on-site must email/fax the requisition form to the regional pharmacy department.

On receipt of S8 or S4R medications, an authorised staff member must sign the requisition slip to confirm the stock has been received in the clinical area. The completed requisition

slip must have signatures from three different staff members. The staff member who ordered the medication, must never be the staff member to accept receipt in the clinical area. An approved exception to this is if a pharmacist orders an S4R or S8 medication, they can also supply the medication, however, a separate authorised staff member must be responsible for receiving the medication and signing the requisition slip.

If after hours S4R or S8 medication transfer between clinical areas is facilitated without a pharmacist, three separate signatures are required. An authorised staff member from the requesting site orders the medication/s, an authorised staff member from the supplying site must sign to confirm supply and a second authorised staff member from the requesting site must sign to confirm receipt. This signed slip must be received back in the pharmacy department by the next business day for on-site supplies and within 5 business days for supplies to non-pharmacy sites.

Opioid Substitution Therapy (methadone, buprenorphine, etc.) supply must follow the Fiona Stanley Fremantle Hospitals Group <u>Inpatient Management of Community Program for Opioid Pharmacotherapy (CPOP) Policy</u>. Where minor deviations to this policy exist (i.e. to facilitate after-hours supply), a risk assessment must have been performed and documented by the Regional Medicines and Therapeutics Committee.

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 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 department or after-hours cupboard. S8 and S4R medicines 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 medications prescribed if unable to obtain supply.

2.4 Medication Storage

All medications must be stored in an area that is not accessible to the public as per the <u>Medicines and Poisons Regulations 2016</u> (WA). Medication should be secured/locked in a trolley, cupboard, patient medication drawer or storage room when not in use. Exceptions are permitted to allow rapid access to medications required in emergency situations (e.g., neonatal resus medication kits) however these kits must:

- have tamper-evident seals which are checked daily on days when the clinical area is operational.
- not contain any S4R or S8 medicines (unless endorsed by the regional Medicines and Therapeutics Committee).

Mobile storage such as medication and resuscitation 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 are authorised to handle medications. Unregulated health care workers required to handle medications as part of their role need to have this listed in the Job Description Form (JDF) associated with the role. 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. Authorised staff who provide temporary access to medication rooms to other staff (e.g., cleaning and maintenance staff) are responsible for supervising that staff member until they leave the medication room. Where access to medications is granted to unregulated health care workers the region is required to perform a risk assessment, consider any methods available to mitigate the risk and record the risk in the enterprise risk management system.

Access to pharmacy stores in integrated district hospitals should be limited (particularly after-hours). There must be a clear approval process for granting access. The Regional Chief Pharmacist responsible for the remote location is responsible for auditing access every six months to ensure that access is only granted to staff who require it.

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.

All medication should be stored at the required temperature range recommended by the manufacturer. The requirement to store medications below 25 degrees Celsius (°C) can usually be satisfied by room temperature storage. If there is any doubt about the temperature in a room where medication is stored, temperature monitoring should be carried out to ascertain if the temperature is above 25 °C. Contact the Pharmacy Department for advice if the room temperature is found to be above 25 °C. See also Cold Chain Storage section.

Storage of High-Risk Medications

High risk medications are described in MP 0131/20 <u>High Risk Medication Policy</u> and the WACHS <u>High Risk Medication Procedure</u> and should be stored according to these documents.

Storage of Schedule 8 Medications

S8 medications must always be kept secured (refer to the <u>WA Health Medications and Poison Regulation Branch</u> page on HealthPoint for full requirements and details on S8 storage safes and cupboards).

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 <u>Medicines and Poisons Regulations 2016</u> (WA), the cupboard must be made of hardwood or metal with a deadbolt pin and tumbler style locking mechanism. A unique key to each site must be used and the key must not be the same as other keys used at the same site.

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 safe made from solid steel plate that is fixed to the building structure with bolts. If more than 250 dose units are stored in the safe (see WA Health Medications and Poison Regulation Branch page on HealthPoint for calculation method) of an area without 24-hour nursing coverage, the area must have continuously monitored movement detectors operational. This may apply to pharmacy store areas in integrated district sites with bulk S8 medication storage areas. S8 medications are not permitted to be stored in a resuscitation trolley or anaesthetic trolley.

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). A key unique to the site must be used and the key must not be the same as any other key used at the same site.

In situations where space is limited and there are minimal S4R medications stored, such as theatre or resuscitation bays, the S4R medications may be stored in the S8 safe. Approval from the Regional Chief Pharmacist and the regional MTC are required, and a risk assessment must be completed. Where this occurs the S4R medications must be treated as S8 medications for the purpose of recording and checking.

For S4R medicines requiring refrigeration (i.e., Lorazepam ampoules) in pharmacy, these must be stored in a metal locked box cable tied to the fridge shelves. The keys to this locked box must be managed in an accountable manner approved by the Regional Chief Pharmacist. S4R medicines requiring refrigeration may be temporarily stored on a ward for a specific patient. They must be returned to pharmacy when that patient has been discharged or transferred from the clinical area. For temporary storage on the ward, a second metal locked managed by pharmacy can be deployed to the clinical area. When based on the ward, the locked box must be cable tied to the fridge shelves, the keys are to be managed in accordance with the Control of keys section and contain the smallest amount of medication appropriate to manage a patient's immediate clinical requirements.

S4R medications may be stored in an emergency or resuscitation trolley, with the approval of the Regional Chief Pharmacist and the regional MTC. Quantities in a trolley should be limited to the amount required to treat a single patient (refer to Resuscitation trolley recommended minimum equipment lists). 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 Regional Chief Pharmacist and the regional MTC will need to define the register recording and restocking requirements.

Control of keys

Individuals authorised to handle S4R/S8 medications within their scope of practice are authorised to handle S4R/S8 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 storage areas to enable tracking of keys between shifts, and a list of staff with access during a shift. S8 and S4R keys should only be in the possession of authorised staff members. 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 permissible to be in use at any time. A maximum of two copies of the key may be made if approved by the regional Medicines and Therapeutics Committee and the WACHS Regional Chief Pharmacist, one to be in use and one to be stored in an appropriate key safe within the pharmacy department. For sites without an onsite pharmacy department, a spare key can be kept in an approved area to be determined by the regional Medicines and Therapeutics Committee and the WACHS Regional Chief Pharmacist.

Storage of Patient's Own Medications (POMs)

POMs **required** for inpatient administration:

- Patients' Own Medications (POMs) are frequently required for use in the healthcare setting.
- Unscheduled, S2, S3 and S4 POMs in use are to be stored with other patient specific medicines- For POM for self-administration, see the WACHS <u>Medication Prescribing</u> and <u>Administration Policy</u>.
- When using patient's own S8 and S4R medications, each item needs to be recorded on a separate register page and must be managed as S8 and S4R medications. Refer to <u>Medication Recording section</u> for documentation requirements.
- There is no evidence supporting the safe administration of inhaled cannabis in an
 enclosed space. If no clinical alternative is available for the treatment of the patient,
 the treating team can consider alternate therapy locations that mitigate the risk to staff,
 other patients and visitors. See POMs not required for inpatient administration section
 for storage.

POMs **not required** for inpatient administration:

- POMs not required for administration must be stored in a POM bag (Figure 3 - Patient's Own Medication Storage Bag (Prod ID 5648) or Figure 4 - Patient's Own S8 and S4R Medication Security Bags and Tamper Evident Medication Bag) and must be secured in the patient's bedside locker or in a specified area in the medication room (or S8/S4R cupboard).
- Medications that require refrigeration are to be placed in a separate POM bag and placed in the fridge.
- S4R/S8 POM must be kept with the same level of security as other S8 and S4R medication. They must be counted, recorded, and sealed in a tamper evident bag on admission by two authorised persons. For inhaled (e.g., flowers or metered dose inhalers etc) and oral liquid S4R and S8 medications estimation via visual inspection/check is required ideally with agreement of the patient (do not measure). The unique security bag number must be recorded on a dedicated page in the appropriate register (S4R or S8) along with the full Figure 3: Example of POM storage bag details of each medication (including generic medication



- name, strength, and individual quantities) included in that security bag. After this initial entry, daily checks must then be recorded by way of confirmation that the security bag is present and is sealed and intact.
- POMs that are present in a DAA are to be stored in accordance with the highest scheduled item it contains (i.e., S4, S4R and S8). Clearly mark bags when multiple POM bags are required e.g., Bag 1 of 3 – bag 2 in S4R/S8 cupboard, bag 3 in fridge. Record the receipt and storage of POM in the healthcare record, e.g. MR 170.1 WACHS Medication History and Management Plan, including:
 - the number of POM bags and where they are stored.
 - placing the tear off tab in the healthcare records.





Figure 4: Example POM S4R and S8 storage bags with relevant order codes

Refer to Section Cannabis Based Products (CBP) for more specific information.

Storage of Medication in the Residential Aged Care setting

In WACHS Residential Aged Care settings, oral medications (including S4R and S8s) packed in dose administration aids are permitted to be administered to patients by appropriately trained staff or self-administration in accordance with the WACHS Medication Prescribing and Administration Policy.

S8 and S4R medication in a dose administration aid must be stored in a safe or locked cupboard. They must be recorded in a register in the same manner as other S8 and S4Rmedications. 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 Care Workers Policy.

Cold Chain Storage

Medicines should be stored in purpose-built vaccine refrigerators which are connected to an essential power supply. Existing general purpose (domestic) refrigerators used for storing medicines must be replaced with a purpose-built vaccine refrigerator when it is at the end of its useful life. Refrigerators for medicines must only store medicines, and diagnostic items as approved by the Regional Chief Pharmacist.

Where a clinical area has only one fridge to use for both blood and other items (e.g. medicines and diagnostic agents), a risk assessment shall be undertaken and if needed to be stored together, blood products must be segregated from medicines.

Where a reliable Building Management Service (BMS) is in place, the site may choose to document manual temperatures checks also. Where there is no reliable BMS in place, data loggers must be used (data reviewed weekly, as a minimum), and manual temperature checks must be documented. Manual temperature checks involve documentation of the actual, minimum and maximum temperatures.

For all medicines requiring cold chain storage (vaccines and non-vaccines), follow all requirements outlined in the <u>National Vaccine Storage Guidelines Strive for 5</u>, including temperature monitoring and actions required for cold chain breaches. Refer to <u>Appendix L: Medication Refrigerator Cold Chain Action Plan</u> for detailed parameters.

Clinical areas – where data loggers are used, nursing and midwifery staff are responsible for manual temperature checks. Nursing and midwifery staff are responsible for the review (minimum once weekly) and archiving of data logger readings or BMS records. Regional procedures may require these records to be provided to the regional pharmacy department.

Pharmacy – where data loggers are used, pharmacy staff are responsible for manual temperature checks. Pharmacy staff are responsible for ensuring the review (minimum once weekly) and archiving of data logger readings or BMS records for fridges with the pharmacy department.

Documentation must be kept for 2 years in-line with the WACHS <u>Records Management Policy</u>.

If transporting temperature sensitive medications between areas, the use of eskies, ice bricks and a temperature monitoring device is required if transport time is 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 (3 monthly – purpose-built vaccine fridges and monthly when using a general purpose (domestic) refrigerator).

Regions must have documented and auditable evidence of the following for all sites:

- a routine fridge maintenance schedule and record of work completed
- a current fridge asset list
- a fridge asset replacement plan
- annual audit of refrigeration temperature recording system for all fridges.

Cold Chain Breaches

Management of cold chain breaches (CCB) are outlined in the <u>National Strive for 5</u> <u>Guidelines</u>. See <u>Appendix L</u> on how to respond to a cold chain breach.

Where vaccines are involved, all exposures outside the allowable limits contained within the Strive for 5 Guidelines, must be reported to the regional Immunisation Co-ordinator. For other medicines, report to the regional pharmacy department.

See Appendix L for documentation requirements in the event of a breach.

2.5 Prohibited Substances

Prohibited substances within a WACHS facility, whether on the person or within their property include prohibited drugs as defined in the <u>Misuse of Drugs Act 1981</u> (WA); 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 <u>Misuse</u> of <u>Drugs Act 1981</u> (WA), 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 closed circuit television (CCTV) cameras where appropriate).

The operational management of prohibited substances may require unique region or sitebased responses following the above principles.

2.6 Medication Transport/Transfer

Inter-hospital and intra-hospital transport and transfer of medications should occur only when clinically essential and 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.

When a patient is transferred from one ward/area/hospital to another, staff must ensure that their admission medications are transferred with them and that adequate supplies of medication are sent with the patient or receive assurance that the receiving location has adequate supplies of required medications, until they can be sourced locally on their own accord. See also section "Interhospital transportation of medicines".

For information in regard to medications requiring temperature monitoring, refer to the Cold Chain Storage section.

Intra-hospital movement of medication

Medication movement within a hospital must only be conducted by authorised persons or unregulated health care workers where their JDF includes undertaking deliveries as a regular part of their role.

In the case of S4R and S8 medications, if being transported by one authorised person from pharmacy to a clinical location, they must be enclosed in a tamper-evident bag in accordance with regional Pharmacy Department procedures.

Pneumatic Tube

A pneumatic tube is available in some sites and is used to transport items in a fast and efficient manner. Pack medications into canisters with adequate packing material to prevent damage.

Not all medications are suitable for transport via the pneumatic tube. <u>Appendix J</u> and <u>Appendix K</u> outlines items **not** suitable to be sent in the pneumatic tube. The list is a minimum list, therefore regions may choose to add items to the list (i.e. not for transport).

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.

S8 and S4R medicines 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 S8 and S4R medicines 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 required that the pharmacy is contacted to inform them that the stock is being sent.

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 S8 and S4R medicines paperwork.

If the regional pharmacy department has not received notice of receipt within 5 business days, 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 S8 and S4R 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 within 5 business days. 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.

S4R/S8 Transport Bags

S4R/S8 transport Bags are used by some regions to transport S4R and S8 medications to sites. For sites returning S4R or S8 stock to pharmacy, the stock must be packaged into the appropriate 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 bag, it is then to be placed inside a sealed and deidentified cardboard box for transport with the courier. Alternatively, S8 or S4R tamper evident security bags may be used for the same purpose and documented as per region specific processes.

2.7 Medication Recording

Administration and supply of medications to patients in clinical areas must be recorded on a healthcare record – refer to the WACHS <u>Medication Prescribing and Administration Policy</u>.

S8 and S4R medications

Tasks involving S4R and S8 medicines require a second check by an authorised person. Two authorised persons must be involved when supplying medicines, preparing medicines for administration and when taking an inventory, as well as when processing orders, receiving stock and when discarding unusable portions (in conjunction with administering doses) or destroying unusable medicines.

In locations where 2 authorised staff members are not available, a single staff member may complete the tasks and 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.

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 S8 and S4R medicines are stored. Where possible, a single register should 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 5 mg/mL ampoule or oxycodone 10 mg SR tablets). Each product should be included in the index page. Brand names may be included in brackets to enhance 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 WACHS PCIA-IV Opioid Infusion Prescription and Additional Observation Chart).

For S8 and S4R patient's own medications refer to the <u>Storage of Patient's Own Medications section</u>.

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 <u>Voluntary</u> Assisted Dying Policy for details.

Receipt of S8 and S4R 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.

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-24-hour 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 independently 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.

Storage of registers, requisition books and prescribing stationery

Registers, and requisition books must 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 S8 and S4R medicines 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: <a href="mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto:mpressed-mailto

All prescription stationery must be stored securely to minimise risk of theft. 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).

Oral liquid S8 and S4R medications

Oral liquid S8 and S4R 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) and must be used in preference to multi-dose bottles, where clinically appropriate.

Repackaging must only be conducted by a pharmacist upon approval of the Regional Chief Pharmacist and unit dose pods should be used where possible. Where the product is repacked, 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 clinical area as prepared doses for administration. Where a multi-dose 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
- 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
- volumes are not to be physically measured (e.g., via transfer, decanting or drawing up in syringes) during stock checks, as any measurement of the product leads to further loss
- drawing up cannulas must not be used with S8 and S4R oral liquids as these can result in unacceptable volume discrepancies. Oral/enteral dosing syringes and bungs are to be used except where the product is supplied with a dropper dose system
- bungs must be kept in situ during the use of the bottle
- when the bottle is opened for the first time, insert the bung into the bottle opening
 ensuring it sits tightly in place. Make sure a tight seal is formed between the bung and
 the bottle opening. When a bung is in use the usual cap/lid cannot be attached and
 should be kept aside. Use the bung cover to close the bottle when not in use
- at each dispensing of liquid medication, open the bung cover and insert tip of the
 purple oral/enteral syringe firmly into the bung. While the oral/enteral syringe and bung
 are attached, turn the entire unit upside down. Withdraw required volume into the
 oral/enteral syringe while firmly holding the bung in place. Turn the entire unit back into
 the upright position, remove oral/enteral syringe and close bung cover.
- bungs should be sourced via iProc. (Example subject to change: Universal Bottle Adaptor BX-42000).

Oral liquids must be reconciled at the end of every bottle (prior to opening the new bottle) and the balance adjusted. The maximum allowable discrepancy is based on the number of measurements (doses) and should not exceed 0.2 mL/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 should be involved in the measurement of the bottle. The measurement should occur on the ward/at the site of discrepancy, prior to being returned to pharmacy.

2.8 Cannabis Based Products (CBP)

Recreational cannabis is illegal. Any cannabis-based product that is not legally prescribed and dispensed and/or not being used for legitimate medical or research purposes is classified as a S9 prohibited substance. Refer to section <u>Prohibited Substances</u>.

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, and thus must be TGA registered or imported via the TGA Special Access Scheme (SAS).

Due to variability in timely access between WACHS hospitals, patients should be encouraged to supply their own CBP for continued treatment whilst an inpatient. All patient's own CBP must be stored and managed according to legislative requirements and WACHS policy. Specific requirements are determined according to the Schedule classification for the particular CBP. There are no CBPs that are considered S4R. Examples of CBPs and their schedules include:

- CBPs 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.

The CBP remains the property of the patient and is to be returned to the patient or, with the patient's permission, the next of kin when discharged from hospital. If a clinical decision is made to cease the CBP, the patient may:

- keep the medicine if deemed clinically appropriate, or
- provide the hospital with permission to destroy the medicine.

2.9 Unregistered Medications for Clinical Trials

A clinical trial medication which is not registered or listed on the Australian Register of Therapeutic Goods must be labelled, stored, prescribed, administered and recorded either:

- where the substance or a similar substance is currently included in (or is exempt from) the Poisons Standard- in accordance with that Schedule (or exemption)
- where there is no similar substance on the <u>Poisons Standard</u>, as a Schedule 4 substance.

If uncertain, please contact your pharmacist.

2.10 Return of Medications to Pharmacy

Where medications cannot be disposed of in clinical areas as per <u>Medication Disposal</u>, 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
- physical address of the pharmacy department address in the receiver's box
- number of parcels (number of boxes/eskies)
- description "medical goods"
- weight of the parcel estimation (minimum of 1 kg)
- 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.

Return of Refrigerated Medications

Cold chain management outlined in sections <u>Cold Chain Storage</u> and <u>Cold Chain Breaches</u> must be applied to all medication returns.

2.11 Medication Disposal



Medications must 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).
 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.
- 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.

Expired General Stock

Regions are expected to have a documented process relating to the disposal of expired medicines, however they may choose to either:

- allow medicines (which are not S4R or S8 medications) to be disposed on the ward into a pharmaceutical waste bin for removal and incineration; or
- return medicines to the Pharmacy Department for disposal.

When disposing medicines in clinical areas, **before** putting stock into the bin, record on the "Stock Disposal Record" (see <u>Appendix N</u>), this information will then be processed by the pharmacy department into iPharmacy via the 'non-stock' disposal process.

Expired S4R/S8 Medication

There are three options available for the destruction of S8/S4R medications. The option utilised must be in-line with regional procedures:

- destroy with a pharmacist and a nurse
- send the stock to pharmacy for destruction (notify the pharmacy department before transporting the returning medicines)
- seek written approval from the regional chief pharmacist for two authorised persons to destroy on site.

In Aged Care Services in multipurpose sites, expired S8 and S4R medications or S8 and 7S4R medications no longer required by a resident can also be returned to the dispensing or local community pharmacy and the requisition form signed by the receiving community pharmacist.

Return of S8 and S4R medications must comply with the requirements for transportation of medications as above including completion of a requisition form marked clearly as returned expired medicines (or other reason for return such as unwanted patient's own) in a sealed tamper evident bag. Notify the pharmacy department before transporting the returned medicines. When received by the pharmacy department, the sealed bag must be entered into an appropriate register immediately.

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.

For the destruction of pharmacy S4R and S8 medication, transfer to the destruction register and complete an accompanying S4R/S8 requisition form clearly marking medications for destruction.

Part Tablets or Doses

Part tablets or ampoules/vials of medications (excluding S8 and S4R 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 S8 and S4R medications (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 one of the following and vessels and subsequently deemed unusable, unrecognisable, or irretrievable:

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

Where larger volumes of S8 and S4R medications in liquid form are routinely being discarded (such as PCA products) an area should consider using specific medication disposal tubs to render the product unsuitable for diversion before discarding.

Disposal of Patient's Own Medication

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.

In Aged Care Services in multipurpose sites, medications or dose administration aids for residents with medication changes should be returned to the community pharmacy. Expired medications and medications no longer required by a resident can be returned to the dispensing or local community pharmacy. If the medicines are S4R or S8 medicines they must be accompanied by a requisition stating the medication name, form, strength and quantity.

For the transfer and disposal of Voluntary Assisted Dying Substances please refer to the WACHS Voluntary Assisted Dying Policy.

2.12 Reporting Discrepancies

MP 0103/19 Reporting of Schedule 4 Restricted and Schedule 8 Medicines Discrepancies Policy 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 S8 and S4R 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 <u>Guidelines for dealing with a S4R or S8 medication discrepancy</u>.

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 Medicines Discrepancy Report (MDR) Form must be completed. The 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), Regional Chief Pharmacist and Regional Director of Nursing and Midwifery 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 Case 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 for ensuring 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, Regional Director of Nursing and Midwifery 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 (or delegate). The WACHS Chief Pharmacist (or delegate) 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 B.

2.13 Monitoring and Audit Requirements

The seven audits described below are required, and example audit tools are provided in the appendices (except for stocktake). Regions may choose to customise audits by adding additional fields.

Ward Based Audits:

Environmental/storage audit		
Description	Audit of the storage of medications	
Frequency	Annually	
Sample size	All areas	
Example audit tool	Appendix C	

S4R and S8 administration documentation audit		
Description	Crosscheck administration documentation in the S4R or S8 register with the medication chart	
Frequency	Every 3 months	

Sample size	If less than 10 occupied beds: a minimum of 5 entries spread between S4R and S8 transactions (or all entries if there are less than 5 entries in total)
Campic Size	If more than 10 occupied beds: a minimum of 10 entries equally spread between S4R and S8 (or all entries if there are less than 10 entries)
Example audit tool	Appendix D

S4R and S8 return to pharmacy audit		
Description	Crosscheck details of return to pharmacy transactions (ward register and requisition details) with documentation in the pharmacy register.	
Frequency	Every 3 months	
Sample size	Minimum 1 entry of either a S4R or S8 transaction	
Example audit tool	Appendix E	

S4R and S8 requisition audit		
Description	Compare S4R and S8 order requisition details documented in the pharmacy department register with information in the ward register.	
Frequency	3 monthly	
Sample size	Minimum 5 entries for S4R and 5 entries for S8 transactions	
Example audit tool	Appendix F	

Pharmacy Based Audits:

S4R and S8 pharmacy destruction audit		
Description	Within pharmacy, compare details of 'for destruction' requisitions and physical stock with the details recorded in the	
	Pharmacy Destruction Register, and ward register.	
Frequency	3 monthly	
Sample size	Minimum 5 entries of either S4R or S8 transactions	
Example audit tool	Appendix G	

S4R and S8 register movement audit		
Description	Maintain and audit annually a database to record and reconcile regional S8 and S4R medicines register movement	
Frequency	Annually	
Sample size	10% of clinical areas.	
Example audit tool	Appendix H	

Medication stocktake process audit		
Description	In accordance with the <u>WA Health Financial Management</u> <u>Manual</u> , 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.	
Frequency	Annually	
Sample size	All inventory within pharmacy	
Example audit tool	As per iPharmacy procedures.	

Audit reports must be tabled at the regional Medicines and Therapeutics Committee 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 Pharmacist Advisory and Leadership Group via the Regional Medicines and Therapeutics Committee as soon as possible.

2.14 Compliance

This policy is a mandatory requirement under the *Medicines and Poisons 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 <u>Integrity Policy Framework</u> issued pursuant to section 26 of the <u>Health Services Act 2016</u> (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.

3. Roles and Responsibilities

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 medicines specifically 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 (e.g., 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 Health Service Medicines and Poisons Act 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 0139/20 <u>Medicine Handling Policy</u>.

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

- reviewing any breaches of the policy or legislation identified by the regional evaluations outlined in the <u>Monitoring and Evaluation Section</u>
- ensuring a system of regular audit reporting between the regions, WACHS-wide 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 Health Service Medicines and Poisons Act Permit or approval to delegate 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 S8 and S4R medications, is managed to limit the risk of diversion
- ensuring medications are procured and distributed as per this policy
- supporting legislative/WA Health policy compliance related to medicines and medicines stewardship and escalate non-compliance as needed through medicine governance channels
- maintaining and auditing annually a database to record and reconcile regional S8 and S4R medicines register movement
- ensuring the regional Medicines and Therapeutics Committee or equivalent, reports all medication audits as outlined in the <u>Monitoring and Evaluation Section</u>, to the Pharmacist Advisory and Leadership Group.
- supporting the execution of audits in accordance with requirements set out in this policy and escalate issues via established medicine governance channels.

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

- developing workflows and systems used in the area to ensure they are consistent with policies and procedures for handling medications
- conducting 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 this policy
- handling and control of medications at a ward level, this includes but is not limited to the management of medication expiry where a direct pharmacy Imprest service is not currently servicing the clinical location.

All staff are required to comply with the directions in WACHS policies and procedures as per their roles and responsibilities. If staff are unsure which policies procedures and guidelines apply to their role or scope of practice, and/or are unsure of the application of directions they should consult their manager in the first instance.

4. Monitoring and Evaluation

Monitoring and evaluation of this policy is to be carried out by the unit managers and Regional Chief Pharmacists, or their delegate. Where possible, an independent staff member who does not work in the area should conduct the evaluation (i.e. WACHS-wide Pharmacist or a Registered Nurse from another clinical area).

5. References

Medicines and Poisons Regulations 2016. Medicines and Poisons Regulations 2016. Available from:

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6. Definitions

Term	Definition
Authorised person	An Authorised 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. 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.
Building Management System	A Building Management System (BMS) 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.

Bung	A bung is a daying fitted to the hattle ready of an arely		
Bung	A bung is a device fitted to the bottle neck of an oral liquid container to allow connection of an oral dosing syringe.		
Continuously Monitored Movement Detector	A continuously monitored movement detector is defined by the Medicines and Poisons Regulations 2016, as 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. 		
Control of keys	Keys for a S8 or S4R 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.		
Data logger	A data logger is 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.		
Dose administration aid	A dose administration aid (DAA) is a device that allows individual medicine doses to be organised according to a patient's dose schedule. May be packed in a pharmacy (blister packs, Webster Paks®) or self-packed (dosette boxes).		
Drug waste bin	A drug waste bin is a specific pharmaceutical waste container to be utilised for disposal of injectable or oral liquid pharmaceutical waste. Ordered via iProcurement.		
Health Service Medicines and Poisons Act Permit & holder	A Health Service Medicines and Poisons Act Permit is 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' holder.		
Medicine/medication	A medicine/medication is, any registered or listed drug on the Australian Register of Therapeutic Goods (ARTG) or overseas equivalent, regardless of schedule status.		

Medication room	A medication room is an area in a clinical room where
	medications are stored. These are defined as clean utilities in some facilities.
Medicine schedule (Poisons Standard)	Medicines can be unscheduled, Schedule 2 (pharmacy medicine), Schedule 3 (pharmacist only medicine), Schedule 4 (prescription only medicine) or Schedule 8 (controlled medicine). The Schedules are published in the Poisons Standard and are given legal effect through state and territory legislation. The Poisons Standard is also referred to as the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).
Pharmacy Department	A Pharmacy Department is a 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	Pharmacy stores is an area for storage of medications outside of clinical areas of a health service which may or may not be staffed by pharmacists. Generally applied to integrated district hospitals.
Pharmaceutical waste container	A pharmaceutical waste container is a specific pharmaceutical waste container (or equivalent) to be utilised for disposal of pharmaceutical waste. E.g. Pharmasmart P22/P64.
Purpose-built vaccine fridge	A purpose-built vaccine fridge is specifically designed to store vaccines and are the best-practice storage option for temperature-sensitive medicines and vaccines.
Schedule 4 Restricted (S4R) medication	Schedule 4 Restricted (S4R) medications are defined by Mandatory Policy Risk based requirements for medicine handling as requiring additional controls due to the risk of abuse, dependence or diversion. For the full list refer to Appendix I.
Schedule 8 (S8) medication	A Schedule 8 (S8) medication is a controlled medication according to the Poison Standard. The packaging will have the descriptor "controlled medication".
Special Access Scheme	Generally, medicines must be registered on the Australian Register of Therapeutic Goods (ARTG). In certain circumstances prescribers can access unapproved medicines for individual patients via the TGA Special Access Scheme.
Swipe cards	A swipe card is a staff access card, issued by Security and linked to a reportable system able to identify the person who gained access to the area or cupboard.

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Temperature monitoring device	A temperature monitoring device is 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.
Unauthorised persons	An unauthorised person in the context of this policy 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.
Unregulated health care worker	An unregulated healthcare worker in the context of this policy includes Patient Care Assistant (PCA), Community Care Worker; Support Worker and Aboriginal Health Care Worker

7. Document Summary

Coverage	WACHS-wide		
Audience	Medical, nursing, midwifery, pharmacy, and any staff who work with medicines		
Records Management	Clinical: Health Record Management Policy		
Related Legislation	Medicines and Poisons Act 2014 (WA) Medicines and Poisons Regulations 2016 (WA)		
Related Mandatory Policies/Frameworks	 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 0109/19 Reporting of Schedule 4 Restricted and Schedule 8 Medicines Discrepancies Policy Clinical Governance, Safety and Quality Framework 		
Related WACHS Policy Documents	 Discipline Guide High Risk Medication Procedure Medication Assistance by Unregulated WACHS Health Care Workers Policy. Medication Prescribing and Administration Policy Waste Management Policy Voluntary Assisted Dying Policy 		
Other Related Documents	 Code of Practice for Clinical and Related Waste Management DoH Documentation and policies required by the Medicines Handling Policy DoH Guideline on administration and record keeping for Schedule 4 Restricted and Schedule 8 medications DoH Guideline on continuation of opioid substitution treatment in hospitals DoH Guideline on distribution of medications DoH Guideline on health practitioner initiated non-prescription medications DoH Guideline on oral liquid Schedule 4 Restricted and Schedule 8 medications DoH Guideline on patient's own medications DoH Guideline on Pharmacy Department access DoH Requirements of the Medicines and Poisons Legislation: a summary for public health service facilities FSFHG Inpatient Management of Community Program for Opioid Pharmacotherapy (CPOP) for Inpatients Policy WA Health Disposal of Medications Recommendations WACHS Audit and Reporting Framework WACHS Authorisation Schedule 		

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Related Forms	WA Health <u>Medicines Discrepancy Report Form</u>
Related Training	 Available from MyLearning: High Risk Medications: High Risk Medications: Introduction (HRMINT EL2) Medication Safety (MDSWA EL2)
Aboriginal Health Impact Statement Declaration (ISD)	ISD Record ID: 3649
National Safety and Quality Health Service (NSQHS) Standards	1.7, 4.1, 4.14
Aged Care Quality Standards	1 (3) (c)I, 2.3d, 3.3b
Chief Psychiatrist's Standards for Clinical Care	Nil
Other Standards	Nil

8. Document Control

Version	Published date	Current from	Summary of changes
3.00	18 November 2024	18 November 2024	 added clarity around the audits required and optimised the required audit tools and recording tools for improved usability. terminology change: "Recordable Medicine"/"Controlled drug" - now S8 and S4R medicines and all cold chain medicines to be treated as vaccines. added new section for medicines governance across WACHS and clinical trial medicines. additional information relating to medicinal cannabis products. Storage, handling, accountability aspects included.
3.01	02 December 2024	18 November 2024	 Monitoring and Audit Requirements updated to show S4R and S8 Requisition Audit as a Ward Based Audit. Appendices updated to reflect this change.

9. Approval

Policy Owner	Executive Director Clinical Excellence	
Co-approver	Executive Director Nursing and Midwifery	
Contact	WACHS Chief Pharmacist	
Business Unit	Pharmacy Services	
EDRMS#	ED-CO-21-62062	

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This document can be made available in alternative formats on request.

Appendix A: Standardised Catalogue Definitions for WA Public Hospitals

TOPICALS

PRODUCT TYPE	EXAMPLE	MANAGEMENT
Products for use directly on patient	Eg. bath oil, cleanser/body wash,	Supply line
skin with minimal or no therapeutic	lubricating jelly, ultrasound gel,	
use.	sunscreen	
Antiseptics for skin antisepsis	Eg. povidone iodine liquid,	Supply line
	chlorhexidine swabs	
Antiseptics for irrigation	chlorhexidine irrigation	Supply line
Antiseptics for use as hand/body	ABHR, Hand wash	Supply line
wash		
Products for use for disinfecting	Hypochlorite solution	Supply line
instruments and other objects		
Products for irrigation	Water for irrigation, sodium chloride	Supply line
	for irrigation	

ORAL PRODUCTS

PRODUCT TYPE	EXAMPLE	MANAGEMENT
Oral products with therapeutic use	Tablets & capsules, mixtures	Pharmacy line
Enteral feeds – total meal	E.g. Jevity, Optifast	Supply line
replacement		
Enteral feeds – nutritional	E.g. Ensure	Supply line
supplements		
Enteral feeds – infant formula	E.g. S26	Supply line
Enteral feeds - miscellaneous	E.g. guar gum, glucose powder	Supply line
Unscheduled oral products	Mouth wash, saliva substitute	Supply line

FLUIDS

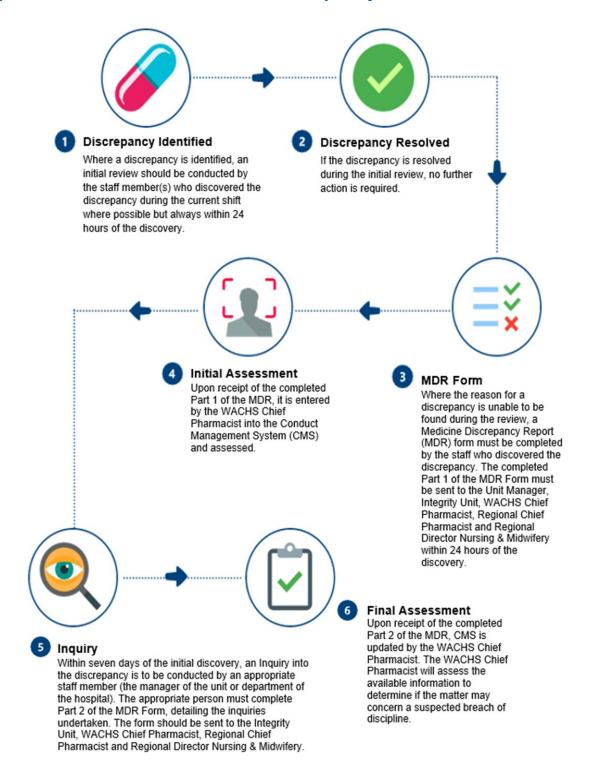
. 20.20		
PRODUCT TYPE	EXAMPLE	MANAGEMENT
High Risk Fluids:	Potassium chloride 10 mmol in	Pharmacy
Potassium chloride premixed	sodium chloride 0.29% 100 mL,	line/Baxter (Total
solutions	Magnesium sulfate 8% (80 mg/mL) in	Fluid Management)
Magnesium sulfate premixed	water for injection 100 mL, sodium	
solution		
Hypertonic saline 3%		
Total Parenteral Nutrition		Pharmacy line
Other fluids for infusion or irrigation	All volumes	Supply line

MISCELLANEOUS

PRODUCT TYPE	EXAMPLE	MANAGEMENT
Contrast media	For therapeutic use (not imaging use)	Pharmacy line
Consumable products associated with inhaled anaesthetic administration	Multi-Absorber (Medisorb®)	Supply line
Diagnostic test strips, kits and solutions	E.g. Multistix, blood glucose machine control solutions, glucose tolerance test, pregnancy tests	Supply line
Dressings, regardless of content (unless S2, S3, S4 or S8)		Supply line
Products to assist with medication administration	Spacers, oral lubricants (Gloup®), spray nozzles	Supply line
Intraocular viscoelastic products	E.g. Healon®, Duovisc®	Supply line
Medication impregnated devices	E.g. stents, bone cement	Supply line

- Any products listed in schedule 2, 3, 4 or 8 of the Poisons Schedules must be
 maintained and managed by pharmacy (except when there is a clear exemption to this
 process endorsed by the Department of Health or when the Health Service Medicines
 and Poisons Permit Holder provides approval for management).
- Scheduled medicines listed on the Pharmaceutical Tender HCNS119914 are to be managed by pharmacy.
- Any product available via the State Distribution Centre for metropolitan hospitals is deemed a non-pharmacy line for all sites.
- Any product registered as a medical device is deemed a non-pharmacy line.

Appendix B: WACHS Medication Discrepancy Flow Chart





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.

Appendix C: Environmental/Storage Audit

Demographics	Demographics				
Frequency	Annually				
Sample size	All areas				
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, secured/closed?			
Are all the medication Imprest cupboard doors 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 locked?		
Are the S8 cupboards/safe doors locked?		
Are the Schedule 8 (S8) medication keys being carried by the		
Designated Nurse/Registered Midwife?		
If Yes: Is the Designated Nurse/Registered Midwife currently		
on the ward?		
Are the Schedule 4 Restricted (S4R) medication keys being carried		
by the Designated Nurse/Registered Midwife?		
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?		

Environmental/Storage Audit page 2

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

Medication fridge(s)	yes	no	NA
Is the temperature of the fridge currently within the correct range?			
Is there a manual log with documented checks at least twice daily for the last 7 days?			
Is there data logger visible in the fridge?			
Has the data logger been downloaded by staff within the last 7 days?			
Is the fridge connected to the BMS?			

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 name?		
Have all entries in the S8 registers in the last 7 days for		
administration included the prescriber's name?		

administration included the prescriber's name?		
Comments		
Audit results must be tabled at the regional Medicines and Theraper		
equivalent. If an audit identifies a breach of the policy, the audit and		
response to rectify the breach must be reported to the WACHS Pha		•
and Leadership Group via the regional Medicines and Therapeutics	Committee	or
equivalent.		

Appendix D: S4R and S8 Administration Documentation Audit

Instructions	Crosscheck administration documentation in the S4R or S8 register with the medication chart
Sample size	If the area has less than 10 occupied beds: audit a minimum of 5 entries spread between S4R and S8 transactions (or all entries if there are less than 5 entries total in the 3-month audit period.)
	If the area has more than 10 occupied beds: audit a minimum of 10 entries equally spread between S4R and S8 (or all entries if there are less than 10 entries total in the 3-month audit period)
Frequency	Every 3 months
Region/Hospital	
Area/Ward	
Surveyor name/	
designation	
Date	

Schedule 4 Restricted (S4R) Register Audit						
Date	Medication	UMRN	Time of administration matches (max 30mins variance)	Dose Administered matches	Initial/register signatures match	Comments

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Sched	Schedule 8 (S8) Register Audit						
Date	Medication	URMN	Time of administration matches (max 30mins variance)	Dose Administered matches	Initial/register signatures match	Comments	

Comments
Audit results must be tabled at the regional Medicines 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 Pharmacist Advisory and Leadership Group via the regional Medicines and Therapeutics
Committee or equivalent.

Appendix E: S4R and S8 Return to Pharmacy Audit

Description	Crosscheck details of return to pharmacy transactions (ward register and requisition details) with documentation in the pharmacy register.	Area/Ward	
Frequency	Every 3 months	Surveyor name	
Sample size	Minimum 1 entry of either a S4R or S8 transaction	Surveyor role	
Region/Hospital		Date	

	S4R and S8 Return to Pharmacy Audit										
Requisition Details (from ward)						Pharmacy Register Details					
Requisition number	Schedule (S8/S4R)	Item description (medication, dose, formulation)	Quantity for return	Signatures and names completed? Y/N	Date	Register number	Requisition number matches (Y/N)	Item description matches (Y/N)	Quantity matches (Y/N)	Reason for return documented (Y/N)	Process as per policy (Y/N)

Audit results must be tabled at the regional Medicines 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 Pharmacist Advisory and Leadership Group via the regional Medicines and Therapeutics Committee or equivalent.

Appendix F: S4R and S8 Requisition Audit

Description	Compare S4R and S8 order requisition details documented in the pharmacy department register with information in the ward register.	Area/Ward	
Frequency	Every 3 months	Surveyor name	
Sample size	Minimum 5 entries for S4R and 5 entries for S8 transactions	Surveyor role	
Region/Hospital		Date	

	Requisition (Req) Details (in pharmacy)							Ward Register			
Date of audit	From site/area	To site/area	Date	Req number	Item description	Quantity match (req, register, ipharm) Y/N	Signatures and names completed?	Req number matches (Y/N)	Product details match (Qty, description) (Y/N)	Signatures and names completed? Y/N	Process as per policy (Y/N) and comments

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Audit results must be tabled at the regional Medicines 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 Pharmacist Advisory and Leadership Group via the regional Medicines and Therapeutics Committee or equivalent.

Appendix G: S4R and S8 Pharmacy Destruction Audits

Description	Within pharmacy, compare details of 'for destruction' requisitions and physical stock with the details recorded in the Pharmacy Destruction Register, and ward register.	Area/Ward	
Frequency	Every 3 months	Surveyor name	
Sample size	Minimum 5 entries of either S4R or S8 transactions	Surveyor role	
Region/Hospital		Date	

Pharmacy Se	Pharmacy S4R and S8 Destruction Audit											
Requisition Details (From Pharmacy Register)						Destruction Register and Ward Register (if applicable) 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)	Reason for destruction documented (Y/N)	Method of destruction documented (Y/N)	Process as per policy (Y/N)
Comment	S											

Audit results must be tabled at the regional Medicines and Therapeutics Committee or equivalent.

Appendix H: S4R and S8 Register Movement Audit

Description	 All regions should maintain a database to record S4R and S8 records. The ID number assigned by the Pharmacy Department Date the register was issued out Where the register was issued to Date the register was returned to pharmacy. The database should be audited annually using the audit tool to the pharmacy.	nt when the register is issued out					
Frequency	Annually	Surveyor name					
Sample size	10% of clinical locations Surveyor role						
Region/Hospital	Date Date						

Instructions

- Contact the Nurse Unit Manager and request they confirm the ID number of each of the S4R and S8 registers in their areas.
- Reconcile this information with the database maintained by the Pharmacy Department.
- Complete the table below.

1a. Were any registers unaccounted for? i.e. issued out from pharmacy but not found to be present in a clinical area?	Yes/No If "No" then there is no need to answer further questions.
1b. How many registers were unaccounted for?	
1c. What actions have been taken to locate the missing registers?	

Comments

Audit results must be tabled at the regional Medicines 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 Pharmacist Advisory and Leadership Group via the regional Medicines and Therapeutics Committee or equivalent.

Appendix I: Schedule 4 Restricted Medications

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

Appendix J: Medication unable to be sent via pneumatic tube

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

- Alteplase
- Botulinium toxin
- Carbonated substances
- Cyclosporin solution
- Cytotoxic agents (all)
- Darbepoetin
- Dyes
- Enoxaparin
- Erythropoetin
- Filgrastim
- Fluids over 250 mL (250 g)
- Glyceryl trinitrate spray
- Hydroxocobalamin (Vitamin B12) injection
- Immunoglobulins
- Inhaled anaesthetics
- Insulins
- Items listed as 'not to be shaken'
- Large glass bottles
- Midodrine (very brittle)
- Monoclonal antibodies (all)
- Mycobacterium bovis (Bacillus Calmette and Guerin (BCG) strain)
- Lipegfigrastim
- S8 and S4R medications
- Tenecteplase
- Refrigerated items
- SAS/IPA/PFP- especially if last remaining stock in hospital
- Vaccines (all)

Appendix K: 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 L: 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, seals not intact). Remain at fridge and monitor temperature to ensure it returns to the acceptable range (2°C – 8°C). If temperature does not return to normal and approaching the limits for a breach, relocate stock as appropriate to avoid a cold chain breach. For fridges not connected to a BMS – review the data logger to determine the duration of temperature excursion (if the alarm 		Current fridge temperature is < 2°C or > 8°C. Refer to Strive for 5 Guideline to determine if Cold Chain Breach is actionable. Complete Appendix M documentation. Quarantine all stock and contact the relevant parties.
				Data logger shows temperature breach as outlined in the Strive for 5 Guideline. Save and print data logger graph. Treat as a Cold Chain Breach, complete Appendix M documentation. Quarantine all stock and contact the relevant parties.
				BMS alarm not triggered OR data logger shows, and allowable temperature excursion as outlined in the Strive for 5 Guideline. Fridge does not return to temperature range. Immediately remove stock to an alternative medication fridge and contact Engineering.
		 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 < 15 minutes and does not exceed 12°C the data logger does not need to be downloaded. 		BMS alarm not triggered OR data logger shows temperature excursion as outlined in the Strive for 5 Guideline. 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.		 First Alarm (≤ 7 minutes) Examine fridge to determine the current fridge temperature. Examine fridge to determine cause of the alarm. 	Fridge does not return to temperature range. Immediately remove stock to an alternative medication fridge and contact Engineering.
The first alarm should be triggered when the fridge temperature has been outside of the pre-set temperature range (min 2°C max 8°C) for < 7 minutes.		 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). 	Reversible cause found and fridge back in temperature range. Reset min/max reading on fridge.
The second alarm should be triggered when the fridge temperature has been outside of the acceptable temperature		Second Alarm (> 15 minutes) • Cold Chain Breach.	Treat as a Cold Chain Breach, complete Appendix M documentation. Quarantine all stock and contact the relevant parties.
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.		'Freeze' Alarm (<0°C) • Cold Chain Breach.	Treat as a Cold Chain Breach, complete Appendix M 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 M documentation	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.		
	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.	Vaccines: Contact the Immunisation Coordinator in your region. Provide Immunisation Coordinator with the data logger graph or BMS graph of the temperature excursion.		
	Inform ward nursing staff including Nurse Unit Manager of Cold Chain Breach. Report the Cold Chain Breach via WACHS Clinical Incident Management System (CIMS) if required.	Provide the Immunisation Coordinator with a list of affected vaccines. Follow advice provided by the Immunisation Coordinator.		

Appendix M: Cold Chain Breach- Documentation

	Date:	D	Details of alarm(s):	S	Staff contacted/informed:		
	Hospital:		□ BMS – First Alarm		☐ Engineering☐ Pharmacy☐ Immunisation Coordinator☐ Nurse Unit Manager		
	Ward/clinical area:	0	☐ Stock moved to alternative fridge	F	Final Outcome:		
Co	ompleted by:						
Na	ame: Signature:		Contact Number:				
Nurse/Midwife/Doctor/Pharmacist (circle)							

Appendix N: Stock Disposal Record

STOCK DISPOSAL RECORD

Site name/ward: Date:	
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PRODUCT DESCRIPTION				QUANTITY DISPOSED	Cost (if known)	Reason for disposal	Was disposal preventable? Y/N
Generic medicine name	Strength	Form (tablets/injection)	Brand	Unit Quantity			
Example – paracetamol	500 mg	Tablets	Sandoz	150 tablets			

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