Medication Handling and Accountability Policy

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1. Background

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

This Policy outlines the requirements for storage, ordering or requesting, recording, reporting discrepancies and accountability structures for medication management in WA Country Health Service (WACHS). The requirements of this Policy are in addition to the legal requirements of the Medicines and Poisons Act 2014, the Medicines and Poisons Regulations 2016 and the WA Heath Medicines Handling Policy MP 0139/20.

2. Policy Statement

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

2.1 Medication Storage

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

Access to medication should be limited to staff members who have the authority to handle medications. Unregulated health care workers required to have handling of medications as part of their position need to have this listed in the Job Description Form (JDF) associated with the position. Swipe card access should be used for medication rooms and must be limited to staff who are required to handle medication as part of their position. In circumstances where it is not appropriate for staff authorised to handle medications to supervise access to medication rooms, WACHS cleaning and maintenance staff are permitted access.

Pharmacy stores, where present, in integrated district hospitals, should have access limited and granting of access, particularly after hours, through a clear approval process. This system should be audited every six months to ensure all staff permitted access still require access as part of their position.

Where access is granted to a medication room for staff members not authorised to handle medications, that region needs to risk assess, consider any methods available to mitigate the risk and record the risk in the enterprise risk management system.

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 every 6 months to ensure all staff permitted access still require access as part of their position.

2.1.1 Storage of high risk medications

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

- High concentration intravenous potassium products must be stored separately from other ampoules in a sealed clearly marked container in clinical areas.
- Opioids have additional storage requirements due to risk of diversion defined by legislation and mandatory policy.

2.1.2 Storage of recordable medications

Schedule 8 Medications

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

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

Any existing S8 cupboards made from medium-density fibreboard (MDF) have an ongoing exemption from the Department of Health. Any newly installed cupboards must be compliant (metal or hardwood).

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

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

Schedule 4 Restricted Medications

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

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

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

2.1.3 Control of keys

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

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

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

2.2 Medication Ordering

2.2.1 Purchasing medications

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

There are a small number of exemptions where it is acceptable for medications to be purchased by other systems:

- Medical gases (nitrous oxide) where there are specialised storage requirements unable to be met by the pharmacy department.
- Individual patient medication dispensed to a patient from a prescription via a community pharmacy such as community mental health patient programs or medications for residential patients in multipurpose sites.
- Service charges related to packing of medications into a dose administration aid.

Pharmacy departments must have processes that prevent the same staff member ordering and receipting medication into the iPharmacy system. A monthly report of all medications ordered and received by the same staff member is scrutinised, reviewed, signed and filed for 2 years by the Regional Chief Pharmacist (or their delegate). In the instances of breach, the documented reason must be recorded on the monthly report. The WACHS Chief Pharmacist (or their delegate) will perform an annual audit of these receipts to ensure they are being conducted.

Pharmacy departments must have processed for at least an annual stocktake of purchased medications. The WACHS Chief Pharmacist (or their delegate) will perform an annual audit of this process.

2.2.2 Ordering for clinical areas

Ordering of medications in clinical areas is via three systems:

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

Imprest orders

Imprest orders are the regular medication maintained in each clinical area. Imprest lists should be reviewed annually by clinicians (nursing and medical) and clinical pharmacists to ensure wastage is reduced and medications onsite support contemporary practice. A clear process is required for each region to enable clinical areas to request additions to imprest, removal of items no longer required and notification of changes. Ordering of imprest items should be done at regular intervals according to local delivery schedules. Maximum quantities on imprest should not be exceeded when ordering unless required for a current inpatient.

Non-imprest patient specific supplies

Medication required for patients not on the imprest may be obtained via three systems depending on local practices:

- Requisition to the pharmacy including the name of the patient who has used or requires the medication.
- Via the medication chart.
- Via a prescription (such as for day admitted patient supply for administration in the hospital).

Items not required for a specific patient and not on imprest should be reviewed by the Regional Chief Pharmacist prior to supply.

Recordable medication requisitions

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

Opioid Substitution Therapy (methadone, buprenorphine) supply should follow the WA Health clinical policies and the Schedule 8 Medicines Prescribing Code.

Sites without a pharmacy department must send the requisition form via fax or electronic systems to the pharmacy department.

2.3 Medication Transport / Transfer

Medication prepared for transport to a ward or packed to be sent to another hospital must be stored in a way that prevents access by the general public and diversion within the pharmacy. After hours transport of medications is covered in section 2.8 of this policy.

In hospitals with a pharmacy department, non-recordable medications may be transported via a pneumatic tube (refer to WACHS Delivery of Pharmaceutical Products via the Pneumatic Tube System Procedure), delivery by the pharmacy staff or collection by a staff member from the ward area. Other support workers may be used where their JDF includes the transport of supplies including pharmaceuticals.

Large orders and heavy items must be transported using equipment appropriate for the load to prevent injury to the staff member transporting the products.

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. Where traceable recording systems are not available, a risk assessment must be completed and strategies aimed at mitigating these risks must be implemented.

2.3.1 Recordable medications

Where there is an onsite pharmacy department, S4R and S8 medications must be transported to a clinical area by a pharmacy staff member. A pharmacist or pharmacy support staff approved by the Regional Chief Pharmacist must be involved in the delivery of S8 medications. Urgent requests can be collected by two authorised nurses who must present to the pharmacy with the register to record the medication.

Controlled substances transported to sites without a pharmacy department must be packed with tamper evident packaging plus any other requirements defined by the regional chief pharmacist. All controlled substances transported in this way must be accompanied by an S4R or S8 Requisition and a Delivery Docket that have been signed by the staff member/s preparing the order.

On receipt of the stock, the authorised person/s must sign both documents and immediately fax or email the completed documents to the pharmacy department. If the original paper requisitions/dockets are not requested back to the pharmacy department by mail, they must be stored with all other controlled substance paperwork.

If the regional pharmacy department has not received notice of receipt within 7 days of the expected arrival, the manager of the receiving site will be contacted to investigate immediately. If the stock is not identified, the manager is to proceed with a discrepancy investigation as per section 2.9 of this policy.

2.3.2 After hours transfer of medications between pharmacy, wards or sites

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

There is limited capability to transfer medications between sites afterhours. Emergency replacement stock may be transferred where local stock is limited if WACHS department staff have accompanied a patient to the larger hospital (e.g. nurse escort) or where other authorised health service staff are available to transport.

Transfer of recordable medication

The movement of controlled medications between wards within a hospital requires the same requisition documentation as ordering from the pharmacy department. The process of requesting, transferring and receiving must be completed by at least three different authorised staff members.

If a single dose is required, the medication chart can be used to remove the medication from the safe or cupboard without the need for a requisition form, but the register must include an annotation of the ward the patient has been admitted to.

Transfer of recordable medication to other hospitals after hours should be avoided and only occur where no other alternative is available to manage a specific patient. Requisition forms must be completed. Transport may only be done by an authorised professional and the quantity limited to what is required to manage the patient until access from pharmacy can be arranged.

2.4 Medication Recording

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

2.4.1 Recordable medications

Registers

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 in clinical areas and aged care facilities and HA176 for pharmacy departments). A separate register must be kept for each separate location where controlled substances are stored. Where possible, a single register must be used for multiple medications.

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

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

- full name of the patient,
- UMRN of the patient (if available),
- date administered,
- time removed from the safe or cupboard,
- dose administered to the patient,
- amount removed,
- amount discarded,
- balance in the safe or cupboard,
- name of the prescribing doctor,
- signature of the authorised person administering the medication

- signature of the authorised person checking the medication
- The names of both authorised staff printed.

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

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

Patients' own medications, where there may be multiple products not required to be used during admission, can be recorded on a single page if sealed in a bag for security. The list of the medication must be on the page but checking only requires confirmation the seal is intact and confirmation of the bag number. Patients own products being used by the patient during their admission must be recorded on a separate page.

2.4.2 Receipt of orders

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

2.4.3 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 confirm the current stock holdings and sign the register

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

2.4.4 Storage of registers

All registers should be numbered to ensure the register in use and completed registers can be tracked for audit purposes. Once a register is completed the register must be stored away from the ward area in a secure location. Any register stored off site in an

archiving facility must be recorded in a traceable system managed by the pharmacy department to ensure it can be retrieved in a timely manner if required. Registers must be available for inspection for a period of five years from the date of the last recorded transaction. Each region must have a procedure for the management of controlled substance registers so that they are readily available in the event of an audit or investigation.

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

2.5 Medication Disposal

Non-recordable expired medications in clinical areas should be disposed into an appropriate medication disposal bin for removal and incineration. Part tablets or ampoules of non-recordable medications should be disposed into a sharps container if a medication disposal unit is not available at the preparation location.

Expired recordable medication must be either disposed on site with a clinical pharmacist and the most senior nurse on site or returned to the pharmacy department for destruction by the pharmacists. Return of recordable medications must comply with the requirements for transportation of medications as above including completion of a requisition form marked clearly as returned goods.

Part doses of recordable medication (balance of a syringe, part ampoule, balance of a liquid medication pod) may be discarded into a sharps container or tamperproof pharmaceutical waste bin (refer to the Medicine and Poison Regulation Branch Medicine Disposal S8 Recommendations). Where larger volumes of liquid are being discarded (such as Patient Controlled Analgesia (PCA) products) an area should consider using specific medication disposal tubs to render the product unsuitable for diversion before discarding.

2.6 Oral liquid recordable medications

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

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

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

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

- Stock holding kept to a minimum with unused product returned to pharmacy when no longer in use.
- Oral dosing syringes and bungs are used except where the product is supplied with a dropper dose system. Bungs must be kept in situ during the use of the product. Drawing up cannula must not be used in recordable oral liquid as these always result in unacceptable volume discrepancies.
- Writable tape or similar is applied to the side of the bottle to enable marking the remaining volume at regular intervals. Pre-printed marking on some bottles are useful but are not calibrated.
- Bottle are not measured via transfer, decanting or physical measurement during stock checks as any measurement of the product leads to further loss.
- Oral liquids must be reconciled at the end of every bottle and the balance adjusted. The maximum allowable discrepancy is based on the number of measurements (doses) and should not exceed 0.2ml/dose measured. A discrepancy report is not required for balance variations within this range but the number of doses must be recorded in the register.

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

Patients' own recordable liquid medications, particularly viscous formulations, are not able to be measured accurately on admission in clinical areas. An estimation of the volume, preferably confirmed with the patient or carer, should be recorded.

2.7 Patients' own medications

Patients' own medications are the property of the patient and must be stored in a way that prevents access by the general public and inappropriate administration by the patient.

Patients' own medications not required during their admission should be stored in a specific patients' own medication bag.

It is appropriate to use a patient's own medication to continue therapy where the medication is not available on site and the treatment is not part of their admission diagnosis. Where patients' own medications are in use the packaging must be labelled with the patients name and staff members must be confident the product has been stored in an appropriate manner by the patient prior to admission. Expiry dates must be visible and checked. Medication packed in dose administration aids are unable to be used to administer regular medications to acute admissions due to the risk of administering medications ceased on admission. The community pharmacist who supplies the pack locally may be able to provide the original packaged medication from the patient's own supply as an alternative. Where a medication is only available from a patient's dose administration aid and the medication can be clearly identified it may be used but must be removed from the aid and the remaining tablets discarded.

Where a patient is self-medicating under the direction of the prescriber, the medication must be maintained in a manner that prevents access by visitors and other members of the public. Refer to WACHS Medication Prescribing and Administration Policy.

2.7.1 Recordable patients' own medications

Patients own S4R and S8 medications must be kept with the same level of security as other S4R and S8 medication. All medication must be counted and recorded on admission. If the medication is not required during the admission it should be sealed in a security bag and the bag checked for integrity daily.

Oral liquid controlled medications present particular challenges. Measuring should be avoided, but estimation is required and ideally should be agreed to by the patient as well.

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

2.7.2 Patients' own medications in Multipurpose Facilities

Patients who are residents in multipurpose facilities are able to source medication via community pharmacy. The requirements for storage of these medications may be different due to different processes and staff levels in age care environments.
All medication including regular oral solid recordable medications (tablets / caps) are permitted to be packed into dose administration aids (Webster packs® or similar) for administration by appropriately trained staff.

All patient's medications 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.

Recordable medication, other than regular oral medications in a dose aid must be stored in a safe or locked cupboard and recorded in a register in the manner as other controlled medications.

2.7.3 Medicinal Cannabis Products (MCP)

- MCPs are not listed on the WA State-wide Medications Formulary. Patients must supply their own MCP for continued treatment whilst an inpatient.
- Before prescribing and administering a patient's own cannabis based medication for continuation of treatment, it must be established that the product was legally prescribed and supplied to the patient.
- Cannabis based products intended for therapeutic use are subject to the same regulatory controls through the Medicines and Poisons regulations as other S4 and S8 medications.
- All patients' own MCP must be stored and managed according to legislative requirements and hospital policy. Specific requirements are determined according to the Schedule classification for the particular MCP. Examples of MCPs and their schedules include:
    - MCPs containing predominantly cannabidiol (at least 98% of the total cannabinoid content): classified as S4.
    - Tetrahydrocannabinol (THC), nabiximols, nabilone, dronabinol and products prepared or packaged for human therapeutic use that are not otherwise

scheduled (i.e. a product purchased on line rather than through a registered prescriber or pharmacy): classified as S8.

2.8 Reporting Discrepancies

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

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

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

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

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

Any suspected theft of a medication requires immediate escalation to the Regional Chief Pharmacist for consideration of WACHS obligations under the *Notifiable and Reportable Conduct Policy* (MP0125/19) and/or *Discipline Policy* (MP0127/20).

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

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

An Inquiry into the unexplained discrepancy is then to be conducted by an appropriate staff member (the manager of the unit or department of the hospital). This person should be appropriately qualified and independent of the initial review into the loss. This person is responsible to ensure the discrepancy is further investigated which may include a review of all medication charts in use during the time, confirming who had access to the safe, searching the safe and surrounding areas and/or reviewing CCTV footage. The appropriate person must complete Part 2 of the MDR Form, detailing the inquiries undertaken, and the completed MDR Form sent to the WACHS Chief

Pharmacist, Regional Chief Pharmacist and WACHS Integrity Unit, within seven days of the initial discovery.

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

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

A flowchart for managing discrepancies is available in appendix 1.

3. Definitions

Authorised person	Authorised person is a person authorised to possess, administer, prescribe or supply as defined within the *Medicines and Poisons Regulations 2016.* In the case of Anaesthetic technicians, they may possess and administer Schedule 4 and Schedule 8 medications if required within their JDF under the direction of a medical practitioner.
Bung	Device fitted to the bottle neck of an oral liquid container to allow connection of an oral dosing syringe
Control of the keys	Keys for a safe or cupboard are considered under the control of the unit manager, Director of nursing or Regional Chief Pharmacist as long as a key register or other mechanism is in place to enable tracing of any staff members who may have possession of the key at any point in time.
Imprest Medication	Predefined list of medications and quantities stored for use in patients where the requirement is unable to be predicted and the medication has not been supplied for a specific patient.
Medication	Medication defined as Schedule 2, Schedule 3, Schedule 4 or Schedule 8 in the Poison Standard (SUSMP)
Medication Room	Area in a clinical room where medications are stored. These are defined as clean utilities in some facilities.
Pharmacy Department	Non-Clinical storage area managed by pharmacist and/or pharmacy technicians. Includes areas where there is storage of medication not allocated to clinical areas and usually has the capability to order medications direct from wholesalers.
Pharmacy Stores	Storage area for medications outside of clinical areas of a health service which may or may not be staffed by pharmacists. Generally applied to integrated district hospitals.

Recordable Medications (medications)	Schedule 8 (S8) medications and Schedule 4 Restricted (S4R) as defined by the Poison Standard (SUSMP) or Section 3 *Risk based requirements for medicines handling*
Schedule 4 Restricted (S4R)	Medications defined by Mandatory Policy *Risk based requirements for medicine handling* as requiring additional controls due to the risk of abuse, dependence or diversion. Additional medications may be designated Restricted by regions where additional operational controls are needed to prevent diversion or inappropriate use under the authority of the Regional Chief Pharmacist. For the full list refer to the Appendix 5.
Schedule 8 Medication	Controlled medication according to the Poison Standard. The packaging will have the descriptor "controlled medication"
Swipe Cards	Individual issued access cards linked to a reportable system able to identify the person who gained access to the area or cupboard.
Continuously monitored movement detectors	As per the Medicines and Poisons Regulations 2016, this is a system: a) to detect the presence of a person who interferes, or attempts to interfere, with a safe or strongroom or any security measures associated with the safe or strongroom; and b) that complies with the requirements in AS 2201.3 1991 Intruder alarm systems, Part 3: Detection devices for internal use published by Standards Australia;

4. Roles and Responsibilities

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

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

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

- governance structures support safe and effective medications handling in all WACHS facilities
- policies are in place and risk management approach is taken to the management of medications

- the Regional Chief Pharmacist, who is the regional Medicines and Poisons Act 2014 permit holder, is part of the approval process for any mitigation strategies to manage risks around medication handling.
- adequate material, human and financial resources are made available to comply with the requirements of MP 0319/20 Medication Handling Policy.

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

- reviewing any breaches of the policy or relevant legislation identified by the regional evaluations outlined in section 7.
- ensuring a system of regular audit reporting between the regions, central office and where required, the board.

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

- approval of all medication handling policies in the region and to ensure they are endorsed by an appropriate governance group.
- purchasing of scheduled medications as per the poison permit or approve the delegate of purchases as appropriate.
- the initial review and any subsequent inquiry into medication discrepancies within the pharmacy department being conducted, documented and appropriately referred within seven days.
- management of medication stored within the pharmacy department, including access to recordable medications, is managed to limit the risk of diversion.
- ensuring medications are procured and distributed as per this policy.
- ensuring the Regional Drugs and Therapeutics Committee or equivalent, reports all medication audits as outlined in section 7 to the WACHS Chief Pharmacist.

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

- workflows and systems used in the area to ensure they are consistent with policies and procedures for handling medications.
- the initial review and any subsequent inquiry into medication discrepancies within the unit or hospital being conducted and finalised within seven days.
- undertaking medication audits as outlined in section 7.

5. Compliance

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

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

6. Records Management

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

7. Evaluation

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

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

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

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

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

8. Standards

National Safety and Quality Health Service Standards: 4.14

9. Legislation

Medicines and Poisons Regulations 2016

10. References

1. Medicines and Poisons Regulations 2016.
2. Mandatory Standard for Intravenous Potassium, Feb 2020.
3. WA Health Disposal of Medications
4. Approved Schedule 8 Registers
5. The WA Health Schedule 8 Medications Prescribing Code

11. Related Forms

Medication Discrepancy Report Form

12. Related Policy Documents

WACHS High Risk Medication Procedure
WACHS Medication Prescribing and Administration Policy

13. Related WA Health System Policies

MP 0139/20 Medicine Handling Policy
MP 0103/19 Reporting of Schedule 4 Restricted and Schedule 8 Medicines Discrepancies Policy
WA Health Disposal of Medications Recommendations
MP 0125/19 Notifiable and Reportable Conduct Policy
MP 0127/20 Discipline Policy
MP 0124/19 Code of Conduct Policy
WACHS Discipline Guide
Documentation and policies required by the Medicines Handling Policy
Requirements of the Medicines and Poisons Legislation: a summary for public health service facilities
Guideline on distribution of medications
Guideline on Pharmacy Department access
Guideline on administration and record keeping for Schedule 4 Restricted and Schedule 8 medications
Guideline on oral liquid Schedule 4 Restricted and Schedule 8 medications
Guideline on patients' own medications
Guideline on continuation of opioid substitution treatment in hospitals
Guideline on health practitioner initiated non-prescription medications

14. Policy Framework

Clinical Governance, Safety and Quality

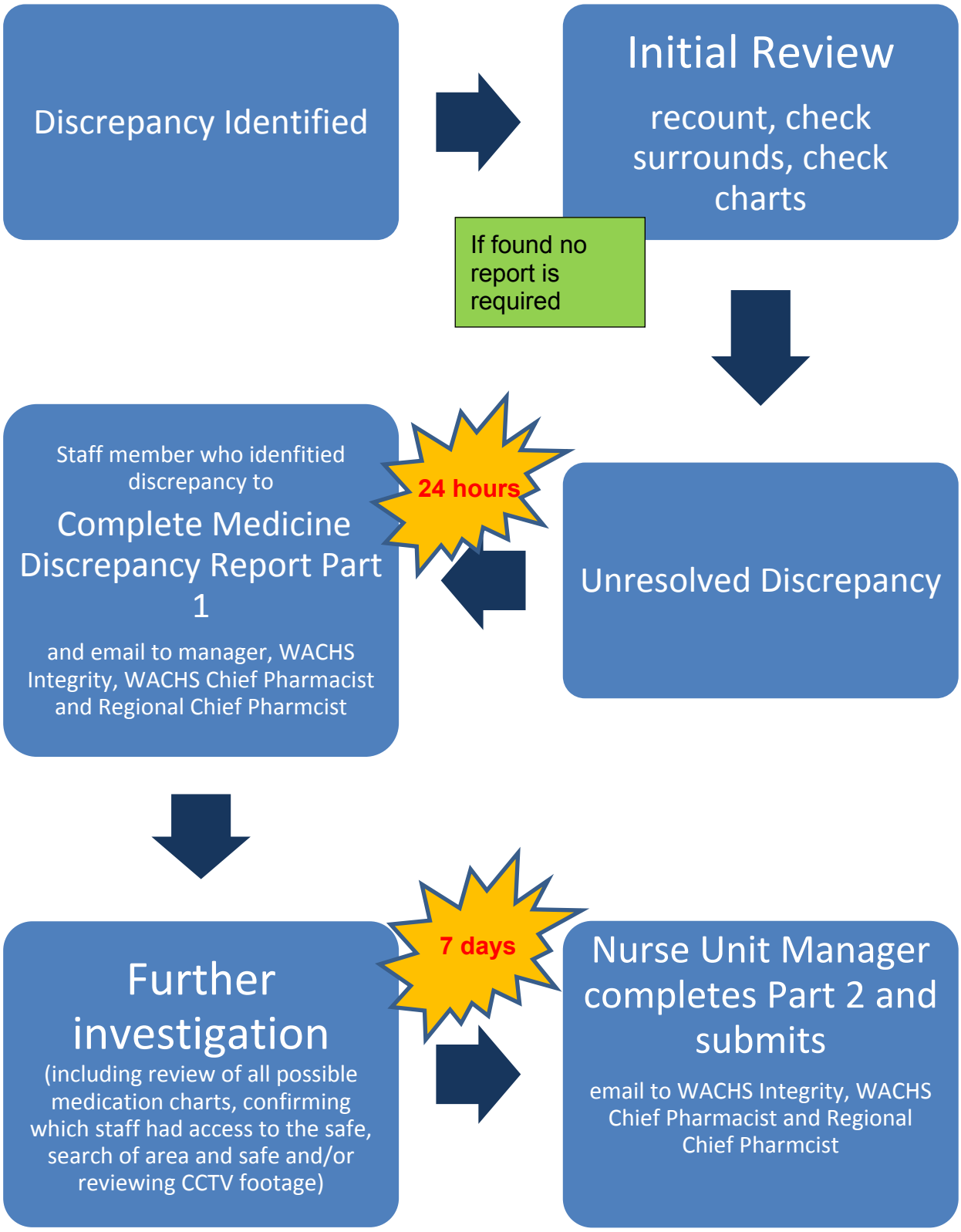
15. Appendices

Appendix 1: WACHS Medication Discrepancy Flow Chart
Appendix 2: Environmental / Storage Audit
Appendix 3: Administration Medication Entry Audit
Appendix 4: Destruction Register Audit
Appendix 5: Schedule 4 Recordable Medications

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

Contact:	WACHS Chief Pharmacist		
Directorate:	Medical Services	**EDRMS Record #**	ED-CO-21-62062
Version:	1.02	**Date Published:**	6 July 2021

Appendix 1 – WACHS Medication Discrepancy Flow Chart



Appendix 2: Environmental / Storage Audit

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

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

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

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

Environmental / Storage Audit page 2

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

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

Appendix 3: Controlled Substance Documentation Audit

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

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

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

Appendix 4: Destruction Register Audit

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

Appendix 5: Schedule 4 Recordable Medications

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