

CLINICAL POLICIES, PROCEDURES & GUIDELINES

Approved by Quality & Patient Care Committee 4 February 2016

MEDICATION- SCHEDULE 4 (D) AND SCHEDULE 8

Storage

- Principles for the safe storage of accountable medications is detailed in Section 6.4 of PD2013 043- Medication Handling in NSW Public Health Facilities.
- The nurse/midwife in charge of a ward (i.e. Nursing/Midwifery Unit Manager (N/MUM) or Nursing/Midwifery Manager (N/MM) or Registered Nurse/Midwife (RN/RM) is responsible for the storage of all S4D and S8 drugs in that ward.
- All Schedule 4D (S4D) and Schedule 8 (S8) Drugs must be stored in the designated Dangerous Drug (DD) cupboard.
- The only exception where S4D drugs may be stored outside of the DD cupboard is if stored on a
 designated trolley used for anaesthetic purposes in operating theatres. Drugs stored on
 designated trolleys must be kept to a minimum and left in the manufacturers packaging where
 possible.
- The DD cupboard is a separate locked cupboard securely attached to the structure of the building (i.e. wall or floor) and must only contain S4D and S8 medications or additional accountable medication as determined by the Drug and Therapeutics Committee. All medication stored in the DD cupboard must accounted for in a DD register.
- Medications which may be prone to mix-up must be stored on separate shelf location e.g. morphine and hydromorphone.
- Discharge medications containing S8 drugs must be collected from Pharmacy by a RN/MW or delivered to the ward by Pharmacy. The medication(s) must be recorded on a separate page in the DD Register and stored in the DD cupboard until the patient is discharged.

Supply

Schedule 4D and Schedule 8 medication ordered from the Pharmacy Service may be collected by a registered nurse or midwife from the patient care area.

The RN/RM who receives the medication must present their RHW identification and sign and date the requisition book as proof of receipt confirming the quantity of the medication supplied. Alternatively S4D and S 8 medication may be delivered to the ward by a Pharmacist. In both cases the RN/RM receiving the medication must check the order, sign for receipt, enter the supply into the drug register and lock the medication in the DD cupboard with a witness. Due to safety issues, methadone syrup will be supplied to patient care areas as unit doses for each individual patient. For use after hours a small emergency stock of methadone may be obtained from Delivery Suite, Postnatal wards and Antenatal ward.

DD Key Management

- A nurse/ midwife, employed in a permanent RN/ RM capacity, must always carry the DD keys. Ideally this should be the responsibility of the N/MUM or the nurse in charge of the shift.
- Casual Pool RN/RM may NOT carry the DD keys.
- The key to the DD cupboard must be kept separate from all other keys except the S4D key and PCA key.
- ENs must NEVER have custody of the DD cupboard keys.
- DD keys from wards that close overnight or at weekends must be stored in a secure area
 overnight such as with the After Hours Nurse Managers (AHNM), and not in the DD cupboard
 of another ward. When areas are closed for longer periods, S8 and S4D drugs should be
 removed to another secure safe in the hospital, such as the Pharmacy Department.
- Investigate immediately any reported loss of DD keys. Loss of the DD key is to be immediately notified to the RN/RM in Charge or AHNM



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- In the event that keys:
 - are unable to be located after discussion with all parties concerned OR
 - have left the premises and are not returned in a timely manner the RN/RM in Charge must notify RHW Management Executive and Pharmacy (during business hours) or the AHNM (after hours) who will arrange to have the lock, barrel and keys changed as soon as possible.

After Hours Emergency Drug Room

The After Hours Emergency Drug Cupboard must not contain S4D or S8 drugs.

Destruction, Breakage and/or Spillage of unusable S4D & S8 Medications

- When an S4D and S8 drug becomes unusable on a ward, the nurse in charge of the ward must immediately, or at least on the next working day, notify the Pharmacy department.
- Two nurses, one of whom must be a RN/RM, must verify that the drug is unusable (eg. Broken ampoule), and adhere to the following procedure:
 - Make the appropriate entry in the Drug Register by the same two nurses. Balance should not be adjusted until Point 2 is completed. The unusable drug is stored in the DD cupboard until the Pharmacist can attend the ward.
 - 2. Contact the Pharmacist who will attend the ward and destroy the unusable drug. A RN/RM must witness the procedure.
 - 3. The drug register entry is signed by the Pharmacist and countersigned by the RN/RM witnessing.
 - 4. In the case of ampoules, where the primary container is broken and/or the liquid contents lost, all parts of the container are handed over to the Pharmacist during pharmacy working hours.
 - After Hours: Notify the AHNM and retain the drug and container in the DD Cupboard until the Pharmacy department is operational
 - 6. If a patient refuses medication after it has been removed from the DD cupboard and entered in the Drug Register, the medication must be discarded (into the sharps container), by the same two RN/RM who removed it and a separate line entry of the discarding entered in the Drug Register.
 - Note: Unusable S8 Drugs **MUST NOT** be sent to the Pharmacy Department for destruction.

Destruction of "Left Over" Drugs

Where an unused portion of a **parenteral** S8 drug remains eg. 25mg remaining from a 100mg ampoule, adhere to the following procedure:-

- Two staff members who "checked out" the dose must discard the "left-over" portion. The unused portion must be removed from the original ampoule, vial or syringe and disposed of in a manner that prevents retrieval and reuse.
- Make a separate line entry to record the disposal of the unused portion of medication in the Drug Register.

Example:

Date	Time	Name of patient	Amount Received	Amount Given	Balance	Signature of nurse 1	Signature of nurse 2	Name of prescriber
3/4/99	1200	Amy Tan		75 mg		M Barry	D Martin	D Nash
3/4/99	1200	Destroyed		25 mg	7	M Barry	D Martin	



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Where an unused portion of a **tablet** remains it must be discarded, in a manner that prevents retrieval, in the presence of a witness, and a separate line entry made to record the destruction of the medication in the DD Register.

- S8 or S4D Drugs remaining from an intravenous or epidural infusion must be discarded on the
 ward in the presence of two people, one of whom is a RN/RM, Medical Officer (MO) or
 Pharmacist, and recorded in the relevant section of PCA/Opioid Infusion/Epidural prescription
 chart.
- Discarding of any unused portions of an S4D or S8 medication following Anaesthetic/Physician led sedation must be recorded in the drug register by the Anaesthetist/Physician and witnessed by an RN/RM.

Used Schedule 8 transdermal patches

Special attention must be applied to the discarding of Schedule 8 (fentanyl, buprenorphine) transdermal patches that have been removed from a patient's skin.

Fentanyl patches, even after being used or when expired, contain sufficient fentanyl to cause life-threatening respiratory depression in an opioid-naïve person if absorbed. If in the disposing of fentanyl patches the active layer come into contact with the skin or other body surface, immediately wash off thoroughly with soap and water. Particular care must be taken to ensure that a Schedule 8 transdermal patch is not left in the patient's clothes/bed linen or dropped onto the floor, thereby providing the opportunity for someone, such as a child, to swallow the patch. The used transdermal patch must be removed in the presence of a witness, even if the patch is not to be replaced. Discarded transdermal patches must be folded in half so that the medication is trapped within the adhesive surface, then disposed of in a 'sharps' container. The time of the discarding must be recorded in the patient's health care record, signed and dated by the registered nurse/midwife and countersigned and dated by the witness to the procedure. Where a Schedule 8 transdermal patch is found to be missing from the patient, this must be treated as a loss and reported immediately.

Partially Used Fentanyl Lozenges

Partially used fentanyl lozenges must be disposed of by a RN/RM in the presence of a witness in a 'sharps' container. The discarding should be recorded in the patient's health care record, signed and dated by the administering RN/RM and countersigned and dated by the witness.

Excess/Expired Stock

- 1. Ward staff must not return excess / expired S4D and S8 stock to Pharmacy.
- 2. Contact the pharmacist who will attend the Ward/Unit and either destroy the drugs in the presence of the registered nurse or return them to the Pharmacy Department.
- 3. Record the details in the DD register.

Management of liquid S8 - loss or excess stock

- Liquid S8 medications may contain an excess of the stated volume in the original bottle when supplied by the manufacturer. At times this volume will need to be adjusted in the Ward's DD Register.
- 2. DO NOT adjust the recorded volume in the Drug Register without a pharmacist present
- 3. If the register states that a bottle should be empty (or nearly empty), QUARANTINE the remaining liquid.
- 4. Start a new bottle and wait for the pharmacist to correct the volume in the DD Register when the excess stock is destroyed.
- 5. If the liquid count is below the expected amount, i.e. a loss, **DO NOT** adjust the recorded volume in the DD Register. Notify the pharmacist who will investigate.



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Recording and Checking

- Schedule 8 medication: At least once every shift (ideally at the change of shift), two people, one of whom is employed in a RN/RM capacity, must count the quantity of stock on hand and record it in red ink in the drug register, which is then signed by the two people counting. Any discrepancies should be treated as loss or theft of a drug and reported and investigated immediately
- **Schedule 4D medication**: At least once every 24 hours two people, one of whom is employed in a RN/RM capacity, must count the quantity of stock on hand and record it in red ink in the drug register, which is then signed by the two people counting. Any discrepancies should be treated as loss or theft of a drug and reported and investigated immediately.
- An Enrolled Nurse may check the balance of S4 and S8 medication in the presence of an RN/MW
- A check of the balance of all Schedule 8 drugs held in Pharmacy must be made during March and September each year as a minimum and at other times as deemed necessary by the Director of Pharmacy.
- A Pharmacist who assumes control over the S8 stock in Pharmacy for one month or more must, immediately on assuming control, perform a full balance check.

Drug Register

- Signatures in the drug register must be full signatures so that the person signing can be identified.
- The RN/RM in charge is responsible for ensuring that a record is kept of all S4D & S8 drugs in a ward register.
- S4D and S8 drugs must have separate registers.
- When a new DD Register is acquired, the balance transferred from the completed book must be witnessed and countersigned by two people one of whom is a RN/RM.
- When transferring the balance, some form of identifying notation from the register from which
 the balance is being transferred must be entered, such as a number or date. The same form
 of notation identifying the new register to which the balance is being transferred must be
 recorded in the old register.
- It is the responsibility of the senior nurse (N/MUM /N/MM) to archive the old DD Register for a period of seven years.
- Loss or theft of a DD Register must be reported to the Director of Pharmacy or delegate who
 must then notify the NSW Ministry of Health at Pharmaceutical Services Unit in writing.
- When the balance of a drug is transferred to a new section in the same Drug Register, the
 page number to which it has been transferred is recorded on the old page and the index. The
 page number from which the balance has been transferred is recorded on the new page. This
 must be witnessed and countersigned by two people one of whom is a RN/RM.

Refer to PD2013_043- Medication Handling in NSW Public Health Facilities for further details.

Recording in the Dangerous Drug Register

All entries are to be in ink. The following colour scheme for entries in the register is to be adopted:

- Recording administration of a drug- Black
- Shift to shift check-Red
- Stock received-Red
- Monthly check by Nurse Manager, Administration-Red
- Footnotes-Red
- Blue pen is not to be used.



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Drug Register Alterations

When alterations to the DD Register are required (due to error or unresolved discrepancy in count) the following must be adhered to:

- 1. Do not CROSS or WHITE OUT entries in the Drug Register.
- 2. Numerals MUST NOT be altered.
- 3. Amendments are to be written sequentially as a footnote on the lines at the bottom of the page.
- 4. Do not write in the margins.
- 5. All alterations/incorrect entries are to be marked with an asterix (*) and numbered sequentially as they occur.
- 6. Enter the sequential number with the date (dd/mm/yy), comments (including IIMS number) and signatures in the footnote.
- 7. When transferring entries onto a new page, rule through all blank lines in the footnote.

Example:

Date	Time	Name of patient	Amount Received	Amount Given	Balance	Signature of nurse 1	Signature of nurse 2	Name of prescriber
7/3/99	1100	Mary Jones		10 mg	7	J Blythe	M Smith	Dr Jones
*8/3/99	1615	Mary Jones		10 mg	5	J Sara	A Sole	Dr Jones
8/3/99	1620	Balance Checked			6	J Sara	A Sole	

*8/3/99 Balance incorrect. Should read 6. J Sara A Sole

Discrepancies in the Drug Count

Refer to PD2013_043- Medication Handling in NSW Public Health Facilities for further details.

Note: This includes S4D and S8 medications <u>AND</u> non Appendix D Schedule 4 medications also stored in the DD cupboard.

Investigate immediately any discrepancy between the ward stock and the Drug Register If it remains unresolved, the discrepancy must be recorded in IIMS by the RN/RM, and reported in succession, as follows:

Business Hours

- The N/MUM / N/MM who notifies...
- The Nursing/ Midwifery Clinical Co Director and the RHW Management Executive.
- The RHW Senior Pharmacist who notifies...
- The Director General of Health, by submitting the required <u>notification form</u> to the pharmacist on duty, Pharmaceutical Service Unit.



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After Hours

- The Nurse in Charge who notifies...
- The AHNM who informs the Nursing/ Midwifery Clinical Co Director and the RHW Management Executive by email and notifies the Executive On Call...
- The On-call Pharmacist who notifies....
- The RHW Senior Pharmacist, who notifies...
- The Director General of Health, by submitting the required <u>notification form</u> to the pharmacist on duty, Pharmaceutical Service Unit on the next working day.

Notification Form

- Prior to submission by the RHW Senior Pharmacist, all available information is to be documented on the notification form by the manager (or delegate) of the area responsible for the loss. (E.g. N/MUM or Pharmacist). This must include the relevant IIMS number.
- The notification form is accessible via the following link: http://www.health.nsw.gov.au/pharmaceutical/Documents/loststolen.pdf
- Do not select 'Submit Form' as this is the responsibility of the Director of Pharmacy. Use
 the 'Save as' option from the File menu to save an electronic copy of the completed PDF
 form to a local drive and attach the copy to an email.
- The email with attached notification form is then sent to the RHW Management Executive for approval.
- The RHW Management Executive then sends the approved notification form by email to the RHW Senior Pharmacist.
- The approved notification form is submitted by RHW Senior Pharmacist to the Pharmaceutical Service, Legal and Regulatory Services Branch by either:
 - using the 'Submit Form' button (visible at the top of the form) or
 - emailing the form to pharmserv@doh.health.nsw.gov.au
- Notification must occur without delay and soon as the facts are known. This is to be
 marked on the form as an 'initial' notification. If further notifiable details become available,
 an additional notification form should be submitted, including all further details of the
 incident, with the form marked as a 'follow-up' notification.
- The RHW Senior Pharmacist (or delegate) must retain a copy of the submitted form (in electronic or hard copy format) for 10 years in accordance with <u>PD2009 057 Records</u> <u>Management</u> and the State Records Authority of NSW

Misappropriation

- Where there is no apparent loss of drugs, but concern exists of possible or admitted misappropriation of drugs by a staff member, this must be similarly reported to the N/MUM of the ward who will notify the RHW Management Executive.
- Staff can proactively prevent misappropriation of S8 and S4D drugs by ensuring adherence to Ministerial and Hospital policies and procedures.

Transfer of Drugs between Units/Wards

Supply of Schedule 8 and Schedule 4D medication should only occur from Pharmacy. The ward to ward transfer of S8/S4D medication should only occur out of hours (after consultation with the AHNM). When a drug is borrowed from another ward adhere to the following procedure:-

- 1. The AHNM must take the ward requisition book for the 'borrowing' ward to the ward from whom they are obtaining the medication.
- Medication packaging must be maintained intact so that the drug name, dose and expiry date
 can be identified. If this is not possible both the 'supplying' RN/RM and the AHNM supervising
 the transfer must witness administration of the drug immediately after taking it from the DD
 cupboard.



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3. Both the 'supplying' RN/RM and the AHNM supervising the transfer must sign and date the requisition. The receipt (white copy) must be retained in the patient care area supplying the medication, and the pink copy retained at the patient care area obtaining the medication. The corresponding drug register entries detailing the transaction must be completed for both patient care areas. Arrangements should be made as soon as is practical to obtain subsequent supplies of the medication from the pharmacy.

Patient's Own Medications

Whenever possible S4D and S8 medications brought into hospital by the patient should be given to the relatives to take home. If this is not possible the following procedure must be adhered to:

- 1. Count the medications and store in Ward/Unit DD Cupboard. Medications should be stored in original pharmacy packing (e. g. Blister pack, manufacturers packaging).
- 2. Record in the drug register designated for this purpose, or separate page of the DD register. One page may be used for each patient's own supply. The drug is signed out of the drug register by two RN/RM, one of whom is an RN/RM, and the balance altered on return of the drugs to the patient, or pharmacy if destroyed by pharmacy.
- 3. Stock is counted at least once every 24 hours
- 4. If the patient's own supply of S4D or S8 medications are to be administered to the patient during their hospital stay this must be recorded on a separate page of the drug register designated for that drug and that patient only. The medication must be checked for correct labelling and integrity, and must not be administered to any other patient.

Administration of S4D and S8 Medications in Operating Suite (for anaesthetic use) For the administration, recording, witnessing and checking of S4D and S8 medications used in

Operating Theatres- please refer to : Operating Theatres Procedure: Handling Schedule 4 and Schedule 8 Medications

Administration of S4D and S8 Medications in an Outpatients setting

If a patient requires an S4D/S8 medication to be administered during the outpatient consultation, it will need to be prescribed on a prescription form (complying with S8/S4D legal requirements). Pharmacy will supply the medication to the medical officer or nurse. The order will also need to be prescribed on the national inpatient medication chart so that a record of the medication being administered is

If a patient requires an S8/S4D medication to be administered following an outpatient appointment, the medical officer will be required to write an external prescription to be filled by the community

Prescriptions

S4D and S8 medications can only be administered from a legal medication order provided that the order complies with NSW Ministry of Health legal requirements.

The prescription must be documented in the form of:

- A prior written medical order on the patient's medication chart or anaesthetic record, or
- A standing order- Clauses 57, 119, Poisons and Therapeutic Goods Regulation 2002

Telephone orders for S8 are **NOT** permitted. The National Inpatient Medication Chart (NIMC) must be used unless using approved specialty charts. When using 'PRN' in dosage directions, state the dosage interval, the 24 hour maximum and the reason for administration e.g. morphine 10 mg (ten), subcut every 4 hours PRN for pain x 10 (ten) doses maximum 3 doses in 24 hours.

If the dosage interval is not stated, ONE DOSE ONLY may be given.

Administration, recording, witnessing and checking procedure in Patient Care Areas

A 'signature register' should be maintained by the N/MUM (in charge of the patient care area) with the names and signatures of the authorised persons eligible to access the DD cupboard. The signature register should be kept under the control of N/MUM /N/MM in charge of the patient care area, and apart from the Schedule 8 drug register.



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Authorised persons could include a RN/RM or authorised prescriber assigned to the patient care area or a registered pharmacist.

It is the N/MUM's responsibility to select appropriate staff to be included on the register and to ensure that the 'signature register' is current.

Medications must only be administered by the route which they are prescribed and medication for one patient must be administered prior to signing out other drugs from the cupboard.

S8 and S4D DRUGS

Two members of staff, one of whom must be an RN/RM, must check-out and witness administration of all S8 and S4D drugs.

The other person involved in this procedure may be:

- An RN/RM
- An MO or a Pharmacist

Two RN/RM's must check out and witness administration of all S8 and S4D drugs for administration by a student nurse. Three signatures are required in the S8/S4D Drug Register in this instance.

METHOD FOR ADMINISTERING S4D AND S8 MEDICATIONS

- 1. Wash hands.
- 2. Organise equipment.
- 3. Check legality of medication order and check for allergies. Note patient's pain and sedation score, time of last dose and maximum daily dose.
- 4. At the DD cupboard two staff members, one of whom is an RN/RM must:
 - a. Read the medication order and select appropriate drug (1st check).
 - b. Check expiry date.
 - c. Check drug label against medication order (2nd check).
 - d. Calculate the ordered dose.
 - e. Complete the Drug Register.
 - f. Check and verify balance between Drug Register and counted items in cupboard.
 - g. Remove correct dosage hygienically (if oral medication) OR
 - h. Draw up dosage aseptically (if medication for injection) and syringe in accordance with RHW LOP: Labelling of Injectable Medicines, Fluids and Lines
- 5. At the patient's bedside, the persons responsible for administration and witnessing (S8 and medications for injection) will:
 - a. Carry out general preparation, informing patient (or guardian) what the medication is, why you are giving it, and any possible side-effects.
 - b. Identify the patient by checking wrist band and/or asking them their details, and check for allergies.
 - c. Check prepared dose against medication order (3rd check)
 - d. Administer medication appropriately.
 - e. Sign medication order (initials from both MO or RN/RM administering and witness is required for S8 medications and medications for injection)
- 6. If the patient does not take the medication, or refuses too, refusal must be documented on the medication chart and the drug register. Two people must witness and sign for any discarded portion of medication.

Note: The administration of S4 (D) and S8 medications is always by two RN/RM's. When another RN/RM is unavailable to supervise the administration of an S4 (D) or S8, the RN/RM should:

- a) Contact the AHNM on duty to check the drug or
- b) organise an appropriate staff member

A MO may be the second party



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Audit requirements

An objective monthly audit is to be completed by the N/MUM / N/MM to monitor:

- · discrepancies in the amount of stock ordered
- identification of signatures for the purpose of detecting forgeries
- · review of frequency of broken ampoules or discarded portions of ampoules
- compliance with documentation requirements in the ward register as detailed in this business rule

The audit must include the review of a two (2) day consecutive period in the previous month. Audit documentation is to be retained by N/MUM / N/MM and produced as required by internal/external auditor.

S8 and S4D requisition books and registers

Requisition books and registers must be ordered by each ward/department via Salmat.

S8/S4D requisition book order number: NHSIS1076-S1076

S8/S4S registers: NH612005

REFERENCES

Poisons and Therapeutic Goods Regulation 2002 Part 4 Drugs of Addiction

NSW Ministry of Health PD2013_043. Medication Handling in NSW Public Health Facilities. November 2013.

NSW Ministry of Health PD 2012_064 Administration of Medications by Enrolled Nurses. November 2012.

NSW Ministry of Health Safety Notice 003/11. Safe Storage of Accountable Medicines. November 2011

RISK RATING: Low- review in 5 years

NATIONAL STANDARD

Medication Safety- NSQHSS Standard 4

REVISION & APPROVAL HISTORY

Reviewed and endorsed Therapeutic & Drug Utilisation Committee 8/12/15

Approved Quality & Patient Safety Committee 20/11/14

Reviewed and Endorsed Therapeutic & Drug Utilisation Committee 14/10/14

Approved Quality & Patient Safety Committee 19/11/09

Reviewed and Endorsed Therapeutic & Drug Utilisation Committee 20/10/09

Approved Council 27/11/00

FOR REVIEW: FEBRUARY 2021