Schedule 8 and Restricted Schedule 4 Medicines PPHC NT Health Guideline

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Purpose

To provide guidelines for Primary and Public Health Care Central Australia and Barkly Regions and Population and Primary Health Care Big Rivers, East Arnhem and Top End Regions, (hereafter referred to collectively as PPHC) Health Practitioners regarding the legislative and PPHC requirements related to the management of Schedule 8 and Restricted Schedule 4 Medicines.

Guideline

This document provides guidelines for the management of schedule 8 (S8) and restricted schedule 4 (RS4) medicines by PPHC health practitioners, including:

- Storage of S8 and RS4 Medicines in the Health Centre
- Schedule 8 and Restricted Schedule 4 Drug Register
- Obtaining Supplies of Schedule 8 and Restricted Schedule 4 Medicines
- Packaging, Delivery and Receipt of Schedule 8 and Restricted Schedule 4 Medicines
- Prescribing, Supplying or Administering Schedule 8 and Restricted Schedule 4 Medicines
- Self-Medication of Schedule 8 and Restricted Schedule 4 Medicines
- Quality Assurance
- Unwanted or Expired Schedule 8 and Restricted Schedule 4 Medicines
- Retention of Pharmaceutical Records

The Northern Territory (NT) adopts the nationally recommended schedules for drugs and poisons into the NT *Medicines, Poisons and Therapeutic Goods Act (MPTGA) 2012* and the Medicines, Poisons and

Therapeutic Goods Regulations 2014. These schedules are published in the Poisons Standard, which is published under the *Australian Government Therapeutic Goods Act 1989*.

All health practitioners must be aware of legislated responsibilities under the NT MPTGA and regulations according to their scope of practice.

PPHC directs that certain schedule 4 medicines are subject to further restriction of supply, distribution, possession and use to reduce abuse, misuse and physical or psychological dependence. PPHC classifies these as RS4 medicines which include:

Benzodiazepine Medicines: (including but not limited to the following Medicines)		**Other Medicines:**	
Clobazam	Midazolam *	Paracetamol 500mgs / Codeine 30 mg *	Chloral Hydrate
Clonazepam	Nitrazepam		Methoxyflurane
Diazepam *	Oxazepam	Pseudoephedrine *	Phenobarbitone
Lorazepam	Temazepam	Tramadol	Propofol
** denotes RS4 Medicines listed on the Standard Drug List*			

1 Storage of Schedule 8 and Restricted Schedule 4 Medicines in the Health Centre

Schedule 8 and RS4 medicines must be stored in an area and in such a manner as to prevent unauthorised access.

The S8 drug safe or an RS4 dedicated lockable cupboard must only be unlocked for the purposes of: the storage of medicines; supply, administration or destruction of a medicine; the examination and counting of medicines for audit and record keeping purposes. The safe or RS4 dedicated lockable cupboard must be re-locked immediately after use.

1.1 Schedule 8 Medicines

S8 Medicines must be placed in a securely locked storage cabinet that meets the requirements of the Australia/New Zealand Standard for Safes and Strongrooms (AS/NZS 3809:1998) Resistance Grade 1.

Schedule 8 Medicines must be locked in the S8 Drug Safe. It is recommended the safe be located within the Drug Storage Room of the health centre whenever possible.

1.2 Restricted Schedule 4 Medicines

Restricted S4 Medicines (with the exception of midazolam held in Emergency Kits, see 2.1) must be locked in the S8 Drug Safe or a RS4 dedicated lockable cupboard. It is recommended the S8 drug safe and dedicated lockable cupboard be located within the drug storage room of the health centre when ever possible.

1.3 Schedule 8 Drug Safe and Restricted Schedule 4 Dedicated Lockable Cupboard Keys

Access to S8 Drug Safe and RS4 dedicated lockable cupboard keys is limited to a nurse, midwife, ATSIHP, medical officer, pharmacist or dentist . One key to the S8 drug safe and RS4 dedicated lockable cupboard is to be kept with the 'on-call' keys in the possession of the responsible nurse, midwife or ATSIHP. A second key to the S8 drug safe and RS4 dedicated lockable cupboard is to be held by the PHCM or delegate. 'Possession' is defined as held on the person and not stored in another location.

In the event that the person on-call is required to leave the community e.g. an ambulance transfer, arrangements are to be made to hand the 'on-call' keys to the next nurse or ATSIHP on call or ensure that the key is stored in a secure key safe located in the drug storage room.

1.4 Schedule 8 Drug Safe – Combination / PIN

Where the key is a combination or PIN it must not be further divulged by the person to whom the combination or PIN was given. Combinations must be changed at regular intervals, including when a health practitioners ceases to work at the health centre. PINs must be deactivated when the health practitioner ceases to work at the health centre. The PIN must not be on display in the health centre.

2 Schedule 8 and Restricted Schedule 4 Drug Register

Under the NT MPTGA 2012 the management of all S8 medicines must be documented in a register maintained in each health centre. The primary health care manager (PHCM) must ensure that an S8 and RS4 drug register is kept for the purpose of documenting all S8 medicines supplied to the health centre. The S8 and RS4 drug register is kept in the drug storage room near the S8 drug safe. While it is not legislated the same principles apply to RS4 Medicines in PPHC.

The principles for maintaining an S8 and RS4 drug register are:

- Entries in the S8 and RS4 drug register must be legible and written indelibly in English.
- One page of the register is to be used per medicine. The generic name / strength / form of the medicine is to be recorded at the top of the page.
- Completed S8 and RS4 drug registers are to be kept at the health centre (see Section 9 Retention of Pharmceutical Records). An Authorised Officer may request a register at any time under the NT MPTGA (Chapter 4 Enforcement, Section 185).
- If a mistake is made, the entry must be left as it is, and marked with an asterisk, rewritten and corrected on the next line, with a note explaining the error eg *written in error, wrong client, see client X on pg145*. Both entries must be countersigned and dated by a second health practitioner (NT Medicines Management Framework, p 16).

Under the NT MPTGA it is an offence to cancel, change or obliterate an entry in the S8 / RS4 Drug Register.

Note: for a single practitioner, countersigning must be completed as soon as possible after the mistake.

2.1 Details to be Recorded in the Schedule 8 and Restricted Schedule Drug Register

The following information must be documented by Health Practitioners in the S8 and RS4 drug register:

- All S8 and RS4 medicines supplied to the health centre, including those provided through client prescriptions.
- Every occasion on which an S8 or RS4 medicine is administered or supplied to a client.
- Regular checks of the S8 and RS4 medicines stock count. For details see Section 7.
- Unwanted or expired S8 or RS4 medicines returned or destroyed per the guidelines in the information sheet - Return or Disposal of Unwanted or Expired S8 / RS4 Medicines.
- Every occasion on which midazolam is transferred to the Emergency Outreach Drug Box and Fit Kit. The contents lists provide stock level of midazolam to be maintained in the box / kit. Documentation and restocking requirements are provided in the Information Sheet Midazolam for Emergency Kits.
- A clinician may take possession of Morphine ampoules (x 2) from the Drug Safe to place in the Emergency Outreach Drug Box to attend an emergency without making an entry in the Drug Register. Following return to the health centre if Morphine is used for a client, a full record of use must be documented in the S8 & RS4 Drug Register as soon as practicable. Further documentation requirements are provided in the Information Sheet Morphine for Emergency Outreach Drug Box.

Note: Client-held S8 or RS4 Medicine in a Dose Administration Aid (DAA) is exempt from being counted or recorded in the S8 and RS4 Drug Register.

When administering or supplying S8 or RS4 Medicines to a client, Health Practitioners must include the following details in S8 and RS4 Drug Register documentation:

- Date and time the S8 or RS4 Medicine is administered or supplied.
- Surname and given name of the client and HRN where available or Date of Birth only if there is no HRN.
- Name of the prescriber (person authorising treatment). Note administration under a Scheduled Substance Treatment Protocol (SSTP) eg CARPA STM, should be noted in the comments column.
- Amount (dose) administered or supplied.

- The running balance of the medicine left in the S8 drug safe or RS4 dedicated locakable cupboard.
- Printed name and signature of person administrating or supplying the substance.
- Printed name and signature of the person witnessing[1] the administration or supply of the S8 or RS4 medicine.
- Comment (if necessary). For example, placing drugs into the emergency kits, destruction of expired stock, etc.
- Amount of any S8 or RS4 medicine unused and destroyed, when the full ampoule is not required for the prescribed dose.
- Names and signatures of health practitioners who destroyed and witnessed destruction of unused S8 or RS4 Medicine.
- Where there is no witness available to co-sign the S8 and RS4 Drug Register and/or when a drug count is unable to be performed prior to administering or supplying an S8 or RS4 Medicine, a check of stock levels by two health practitioners registered under the *Health Practitioner Regulation (National Uniform Legislation) Act 2010*, is to be undertaken at the next available opportunity.

See Schedule 8 and Restricted Schedule 4 Drug Register Example.

2.1.1 S8 and RS4 Drug Count

A daily count must be done for each drug in the safe. Once completed the shift change check must be signed to acknowledge this. See Schedule 8 and RS4 drug register example.

A Weekly "Checked and Correct" must be completed on the dedicated medication pages of the drug register, this counts as the daily check for that day.

When completing the count, health practitioners need not sight individual S8 or RS4 medicines if commercial clear plastic wrap or tamper evident seals remain intact. If any packaging is open or plastic wrap tampered with, all medicine must be sighted and number / amount checked.

For packaging provided by the manufacturer without a wrap or tamper evident seal, a tamper evident seal will be placed on full packets by the relevant Pharmacy prior to supply to health centres. The tamper evident seal must be able to clearly show breaches in the seal where an attempt has been made to remove it.

2.2 Client-held Schedule 8 and Restricted Schedule 4 Medicines

S8 and RS4 medicines held for clients, such as a palliative care client, are to be stored, recorded, audited and supplied in the same manner as any general health centre S8 and RS4 Medicine stock.

Client-held S8 and RS4 medicines are to be recorded by the name of the drug and name of the client per page in the S8 and RS4 drug register. For an example of how to record client-held S8 and RS4 medicines, see Schedule 8 and Restricted Schedule 4 Drug Register Example.

Every effort should be made to separate client-held S8 and RS4 medicines from health centre stock and other clients' medicines in the S8 Safe or RS4 dedicated lockable cupboard. To facilitate this, client-held medicines should be kept to a working minimum. For some medicines the preferred method is to use health centre imprest supplies, for example panadeine forte, diazepam, etc. This is due to limited storage capacity in health centre drug storage safe / dedicated lockabale cupboard.

Medicines taken from health centre imprest must be labelled prior to issuing to the client.

[1] Note: under the NT MPTGA Section 100, administration of S8 medicines must be witnessed by a third party who is neither the Health Practitioner nor the client. This requirement does not apply if because of the remote location of the place or other special circumstances, another person was not available to witness the administration **and** this is recorded in the client's health record and S8 & RS4 Drug Register. Please note, under PPHC, the same principle applies to RS4 medicines.

If the client does not have a current prescription or has not collected for more than 3 months consider destroying the stock. For more information please refer to the Return or Disposal of Unwanted or Expired S8 and RS4 Medicines PHC Infromation Sheet.

3 Obtaining Supplies of Schedule 8 and Restricted Schedule 4 Medicines

S8 and RS4 medicines are supplied from contracted pharmacies. These may be health centre imprest stock or client-held prescription medicines.

3.1 Obtaining Imprest Stock of Schedule 8 and Restricted Schedule 4 Medicines

The procedure for obtaining supplies of S8 and/or RS4 Medicines is:

- Complete the contracted pharmacy's S8 and RS4 Order Form requesting the required drug/s and amount and send to the relevant Pharmacy.
- File the completed Order Form in the S8 and RS4 Drug Register until receipt of delivery.
- All health centres will be notified of incoming S8 or RS4 deliveries by email or efax of a S8 and RS4 Delivery Notification Form (Delivery Notification Form).

Packaging, delivery and receipt of S8 or RS4 medicines using the delivery notification process and tamper evident bag is detailed in Section 4. Pharmacists providing services to health centres are able to provide advice on the safe and effective management of S8 and RS4 medicines including ordering, supply and storage.

3.2 Obtaining Client-held Schedule 8 and Restricted Schedule 4 Medicines by Prescription

Prescriptions for S8 and RS4 medicines require additional requirements to ensure safe dispensing of potentially addictive medications. Medical officers need to be aware of the voluntary contract notification scheme. Typically this is used for clients on long term S8 or RS4 medicines who may benefit from having an agreement with one medical officer. Participation in the scheme provides an additional safeguard to the medical officer when prescribing S8 and RS4 medicines improves client care and reduces diversion. See Medicines and Poisons Control General Medications Contract.

Distinct from other prescription medicines, health centres will be notified of incoming S8 and/or RS4 medicine deliveries by email or efax of a Delivery Notification Form.

Packaging, delivery and receipt of S8 and/or RS4 medicines using the delivery notification process and tamper evident bag are detailed in Section 4.

RS4 Medicines are obtained using a rural prescription. S8 medicines may have additional requirments. See below.

3.2.1 Obtaining Client-held Schedule 8 Medicines by Prescription

There are additional legislative requirements for the supply of S8 medicines. When prescribing S8 medicines, different requirements exist for a Restricted or UnRestricted S8 Medicine. See Medicines and Poisons Control Medical Practitioners webpage and Information Sheet: Requirements of Prescriptions for S8 Substances for further information.

S8 medicines must be prescribed on both a Pharmaceutical Benefits Scheme (PBS) prescription (for PBS funding) and Rural Prescription (for health centre issuing and administration), observing the PBS requirements for quantities and restrictions.

To obtain a prescription of S8 medicine, it is important to note that while a signed copy of the PBS prescription and rural prescription for S8 medicines may be sent electronically or via efax to obtain the S8 medicine for urgent supplies, **the original signed copy of the PBS prescription must be sent to the Contracted Pharmacy as soon as possible and definitely within seven (7) days.**

Under the NT MPTGA the authorised prescriber must notify the Chief Health Officer of the supply of unrestricted S8 substances under certain circumstances, eg if supply exceeds 8 weeks, if certain dosage levels of increments are exceeded or if they have any concerns for the safety of the client, or concerns about circumstances surrounding the client and the client/s need for or use of the substance. The Medicines and Poisons Control Medical Practitioners webpage information and related notification forms (scroll down webpage) for S8 restricted, unrestricted and psychostimulant medicines requirements. Also see the Code of Practice – Schedule 8 Substances Volume 1 - Issuing Prescriptions Supplying Schedule 8 Substances.

4 Packaging, Delivery and Receipt of Schedule 8 and Restricted Schedule 4 Medicines

The Contracted Pharmacy has a standard process in place to monitor return documentation of previous S8 and/or RS4 medicine dispatches. When return documentation is not received the health centre will be contacted to follow up any outstanding returns prior to dispatching further orders.

4.1 Packaging for Delivery

The person packing the S8 and/or RS4 medicines for delivery between a pharmacy and a health centre must:

- Obtain a copy of the Delivery Notification Form.
- Select a tamper evident bag and record the bag's unique identifier number on the delivery notification form.
- Complete the label on the tamper evident bag and the 'tear off' receipt.
- With another staff member, check the S8 and/or RS4 medicines for delivery and complete the delivery notification form.
- Email or fax the completed delivery notification form to the recipient and make a copy of the form for inclusion in the delivery.
- Enclose the S8 and/or RS4 medicines and a copy of the completed delivery notification form in the tamper evident bag ensuring that the bag does not contain any other goods.
- Seal the tamper evident bag according to the instructions on the bag and staple the 'tear off' receipt to the original of the delivery notification form.
- Place the tamper evident bag in a carton or opaque packaging addressed to the person authorised to receive it. No indication that it contains an S8 and/or RS4 medicine is to be on this outer package.

4.2 Delivery of Schedule 8 and Restricted Schedule 4 Medicines

S8 and/or RS4 medicine parcels must be consigned to a particular person for delivery. Delivery may be organised through:

- Regular freight mechanisms utilised by the pharmacy for deliveries to health centres. Deliveries and pick-ups are timed for S8 and/or RS4 medicine parcels to spend as little time as possible in transit. For example the parcel would not be dispatched on a Friday only to remain in the freight company's premises over the weekend.
- Deliveries coordinated via the PPHC Office is not a routine practice. In exceptional circumstances where no other delivery mechanism is available or for urgent orders, the PHCM and or contracted pharmacy may arrange for delivery via the PPHC office with health staff travelling to the health centre.

4.3 Receipt of Schedule 8 and Restricted Schedule 4 Medicines

All health centres will be notified of incoming S8 and/or RS4 medicine deliveries by email or efax of a Delivery Notification Form. On receipt of delivery at the health centre, a registered health practitioner in conjunction with another health practitioner (where possible) must:

- Check that the tamper evident bag is intact with no evidence of tampering.
- Check that medicines received are correct against the delivery notification form.

Note: contact the sender immediately if the tamper-evident bag shows evidence of tampering or if the medicines do not match the delivery note and complete a RiskMan report.

- Complete and sign the bottom section of the delivery notification form and email or efax back to the dispatching pharmacy to acknowledge receipt of delivery

  Note: Failure to return documentation to the dispatching Pharmacy may result in the pharmacy being unable to supply future orders for S8 and RS4 Medicines.
- Attach the completed delivery notification form to the S8 and RS4 order form; file in the back of the pharmacy manual for a period of two years.
- For S8 and RS4 medicines dispensed from a client prescription, the delivery notification form alone is filed in the pharmacy manual.
- Complete S8 and RS4 drug register documentation as detailed below:
  - New stock must be documented in the S8 and RS4 Drug Register as 'received stock'. Supplies must be rechecked and retotalled with the existing S8 or RS4 stock of that medicine in the drug safe or RS4 dedicated lockable cupboard when appropriate and a record commenced for a new drug or client-held S8 or RS4 medicine.
  - All S8 and/or RS4 incoming stock must be checked by two health practitioners whenever possible. Where two health practitioners are not available, the receiver must take the next possible opportunity to check the medicines with another health practitioner.
- When unpacking medicines, check the expiry date and complete stock rotation so that the soonest to expire is placed at the front to be used first.

5 Prescribing, Supplying or Administering Schedule 8 and Restricted Schedule 4 Medicines

5.1 Authorised Prescriber (see Definition)

Authorised prescribers need to familiarise themselves with all relevant provisions the *NT MPTGA 2012* and the Code of Practice – Schedule 8 Substances: Volume 1 - Issuing Prescriptions Supplying Schedule 8 Substances in order to provide an effective clinical service that meets the terms of the legislation. For details regarding S8 and RS4 prescriptions and supply see Section 3.2 for details.

5.2 Nurse, Midwife or ATSIHP

This guideline does not compel a nurse, midwife or ATSIHP to administer the medicine or authorise a nurse, midwife or ATSIHP to provide treatments she/he is not competent to provide.

5.2.1 Schedule 8 Medicines

A nurse, midwife or ATSIHP should only administer S8 Medicines to clients following prescription by a authorised prescriber, either via a written prescription or a verbal order [2] as part of a telephone consultation. Morphine is approved under Section 250 of the NT MPTGA and may be administered in accordance with an approved SSTP without the personal attendance or advice of an authorised prescriber, only if the clinician is satisfied on reasonable grounds that its administration is required without delay. After administration of morphine the clinician must bring the matter to the attention of an authorised prescriber as soon as practicable. See Section 250 NT MPTGA for further details.

5.2.2 Restricted Schedule 4 Medicines

Under Section 250 of the NT MPTGA 2012, a nurse, midwife or ATSIHP may supply and administer paracetamol 500mgs/codeine 30 mg, diazepam and midazolam in accordance with an approved SSTP without the direction of an authorised prescriber. PPHC recommends however that authorised prescriber

[2] When receiving a telephone order for an S8 Medicine from an authorised prescriber, the Nurse, Midwive and ATSIHP must repeat the medicine order back to the authorised prescriber to confirm the order. Whenever a second Nurse or ATSIHP is present, this person must also verify the order. All telephone or verbal orders must be confirmed in writing by the authorised prescriber as soon as possible and definitely within 24 hours. See Issuing and Administering Medicines for further details.

instruction should be obtained prior to use whenever possible.

Other RS4 medicines held as health centre stock are not classified under Section 250 and a nurse, midwife or ATSIHP may only administer these RS4 medicines to a client following a medicine order from an authorised prescriber.

5.3 Requirements for Administering and Supplying Schedule 8 and Restricted Schedule 4 Medicines

Health Practitioners must apply the 'Seven Rights' whenever medicines are administered or issued: the **right medicine** must be administered to the **right person** in the **right dose** at the **right time** via the **right route**, with the **right documentation**, and the client has the **right to refuse** treatment (NT Medicines Management Framework). For details see Information Sheet: Medicines - The Seven Rights.

Under the NT MPTGA 2012, administration of an S8 or RS4 medicine must involve two people whenever possible. Witnessing the administration or supply of S8 or RS4 medicine to a client will depend on whether a health practitioner is available. See table below for details:

Witness who is a Health Practitioner	• Checking the medicine (right medicine) against the authorised prescriber's order:
	  ○ Written order if available – in the client's EHR, rural prescription, etc.
	  ○ A phone order for the medicine should be recorded in the client's EHR immediately, whenever possible, and verified with the authorised prescriber on the phone. This provides the written order for checking the drug prior to administration.
	• Checking the removal of the S8 or RS4 Medicine from the S8 Drug Safe or RS4 dedicated lockable cupboard.
	• Documenting S8 and RS4 Drug Register requirements (see guidelines in Section 2).
	• The same two people checking the medicine during preparation and before administration, ie ensuring the 'seven rights' are observed.

Witness who is **not** a Health Practitioner	When a witness is available who is not a Health Practitioner (eg second responder) they are able to check the S8 or RS4 medicine for administration purposes only and comment should be made in the S8 & RS4 Drug Register to this effect and the witness is not required to undertake a count of the S8 or RS4 stock. Entry to the Drug Storage Room is restricted to Health Practitioners only.
No Witness available [3]	In the event another Health Practitioner / person is not available to witness administration or supply, comment should be made in the client's EHR and S8 and RS4 Drug Register to this effect.

5.4 Home or Residential Care Visits

Where a clinician visits a client at home (or other residential setting) and administers an S8 or RS4 medicine that has been brought from the health centre, a record must be made in the S8 and RS4 drug register at the health centre showing the amount issued to the client. It is acknowledged that it is usually not possible for a second person to be present at the client's home to witness the administration and therefore, in this case, the countersignature in the register reflects only that the second person witnessed removal of the S8 or RS4 medicine from the S8 drug safe or RS4 dedicated lockable cupboard. The amount administered and amount discarded if any, must be recorded in the client's EHR by the administering clinician. All due care must be taken by the clinician administering the S8 or RS4 medicine in applying the 'Seven Rights'.

(Adapted from: Guidelines for the handling of palliative care medicines in community services)

5.5 Documentation – Electronic Health Record (EHR)

Administration or supply of the S8 or RS4 Medicine must be documented in the client's EHR using the service item '*Medication: Provide From Script*', providing the following information:

[3] Note: under the NT MPTGA Section 100, administration of S8 medicines must be witnessed by a third party who is neither the Health Practitioner nor the client. This requirement does not apply if because of the remote location of the place or other special circumstances, another person was not available to witness the administration.

- Automatically populated in relevant fields by the EHR:
  - Time and date of administration or supply.
  - Name of the person authorising treatment.
  - The name, electronic signature and qualification of the person administering or supplying the S8 or RS4 medicine (obtained from health practitioner login details).
- Free text content to be entered by the health practitioner:
  - The medicine issued / administered – form, strength, quantity (dose) and route of administration or supply.
- Record in the progress notes:
  - Any notable outcomes of the medicine's effect, if administered.
  - If the S8 or RS4 medicine was administered without first consulting with a medical officer, the reason for not consulting a medical officer must be recorded.

6 Self-Medication of Schedule 8 or Restricted Schedule 4 Substances

It is an offence under the *NT MPTGA 2012* to self-prescribe and/or self-administer S8 medicines. Under the *NT MPTGA 2012* a health practitioner may only self-administer an S8 medicine for genuine therapeutic use in an emergency where there is no access to an authorised person to administer the substance. After administration the health practitioner must seek authorised prescriber assistance as soon as possible. Notice of the administration must also be given to the Chief Health Officer (CHO) within 7 days after the administration.

PPHC applies the same principle to staff self-prescribing and/or self-administering RS4 Medicines. PPHC recommends that staff consult with another clinician for management and administration or supply of medicines. Also see Staff Access to Health Services for further information.

7 Quality Assurance

7.1 Schedule 8 and Restricted Schedule 4 Medicines Check

Health practitioners are required to perform and record counts of S8 and RS4 medicines at regular intervals. S8 and RS4 medicines checks are performed **daily** (on regular business days) as a routine. This includes the:

S8 and RS4 Drug Register	Two health practitioners must verify the S8 and RS4 medicine count* as 'checked and correct' and sign the S8 and RS4 Drug Register. Health practitioners must document the count, sign and date: • **Once a week** on the page which records receipt and use of each medicine in the S8 and RS4 Drug Register (*this counts as the daily 'Shift Change Check' for that day).* and • **Once a day each day of the week** (Monday to Friday) in the 'Shift Change Check' at the end of the register.
**S8/RS4 Medicine count includes: opening the drug safte / dedicated lockable cupboard and physically counting the quantity of medication stored. It also involves checking the expiry date and doing a stock rotation with the earliest expired medicines moved to the front to be used before the later expiring medication.*	
PPHC Remote Essential Checks (daily)	Provides a mechanism to prompt and record checks are performed per S8 and RS4 drug register requirements and recorded on the Essential Quality Checks PPHC Remote Forms – CAHS | TEHS
PPHC Remote Accountable Drugs Quality Return (monthly)	Health centre health practitioners should perform self-auditing through the completion and submission of the monthly Accountable Drugs Check PPHC Remote Form – CAHS | TEHS. See Quality Assurance Overview PHC Remote Guideline for details regarding PPHC processes.

7.2 Drug Storage Room Audit

7.2.1 Contracted Pharmacist

Contracted pharmacists perform Drug Storage Room audits when visiting health centres. This will include a review of S8 and RS4 processes as part of the overall drug storage room audit. See Pharmacy Audits PHC Remote Guideline for further information.

7.2.2 Authorised Officer (formerly Poisons Inspector)

Under the *NT MPTGA 2012*, an authorised officer may visit a health centre at any time, with or without notice for the purpose of auditing:

- The management of S8 and RS4 medicines, including storage and disposal.
- Associated records (eg S8 and RS4 drug register, invoices, receipts, etc.) required to be kept under the *NT MPTGA 2012*.

7.2.3 Visiting Primary Health Care Staff

PPHC staff who are professionally registered under the *Health Practitioner Regulation (National Uniform Legislation) Act 2010* may also perform S8 and RS4 medicine audits when visiting a health centre. Generally this will be the district manager, other manager, PPN, Top End PPHC medication safety nurse or PPHC pharmacist.

7.3 Discrepancies in Schedule 8 Medicines Count

Health psractitioners must report any discrepancy noted when counting the S8 and RS4 medicines including instances of broken or missing medicines. It must be reported to the PHCM for investigation immediately and an incident report via the RiskMan system completed as soon as practical. The PHCM must report the discrepancy to the district manager immediately and ensure RiskMan incident reporting processes have been followed. RiskMan notification must also include the PPHC Pharmacist and Health Profession Manager in the distribution.

Following investigation, if the discrepancy cannot be reconciled by the PHCM or district manager, the incident must be reported to medicines and poisons branch utilising the Drug Loss Discrepancy Report Form. MPTGA Regulation 71 states that a person commits an offence if they fail to report the loss or discrepancy of a regulated substance as soon as practicable (no later than seven days) after becoming aware of it.

The Police must be notified by the district manager when investigation of the breach suggests criminal activity. The police report identifier must be included in the RiskMan incident report.

8 Unwanted or Expired Schedule 8 and Restricted Schedule 4 Medicines

Whether the medicines are supplied for general health centre stock or stock from client prescriptions, there are two options for managing unwanted or expired S8 or RS4 stock. Details for the appropriate procedure are provided in the information sheet – Return or Disposal of Unwanted or Expired S8 / RS4 Medicines.

Note: Client-held Medicines which no longer have a current prescription or have not been collected for more than three months may be considered as unwanted and discarded even if they are still in date.

9 Retention of Pharmaceutical Records

Under the NT *MPTGA Regulations 2014* (section 76) all records listing pharmaceuticals such as drug registers, prescriptions, orders, invoices, receipts, delivery dockets, etc are required to be retained for 2 years after the date of the last entry in the record. Health facilities must store the records for 2 years on site, after which time records may be transferred to a secondary storage facility such as Iron Mountain or Centralian Records Management for storage and/or destruction per the Records Disposal Schedule Pharmacy Services Department of Health DS2015/22 – October 2015.

S8 and RS4 medicines prescriptions and other S8 and RS4 records should be stored separately to facilitate the period of retention and transfer to secondary storage.

Quality Assurance		
	Method	**Responsibility**
Implementation	Document will be accessible via the Policy Guidelines Centre and Remote Health Atlas	PGC Administrators
Review	Document is to be reviewed within three years, or as changes in practice occur	Atlas Development Officer, Primary Health Care CAHS
Evaluation	Evaluation will be ongoing and informal, based on feedback.	Atlas Development Officer, Primary and Public Health Care
Compliance	Adverse events are entered on RiskMan and managed by the relevant manager or referred for further investigation and management.	Relevant Manager **PPHC CA & Barkly:** Clinical Nurse Manager, Quality and Safety **PPHC Big Rivers; EA & TE:** Safety and Quality Manager
	PPHC CA & Barkly: Monitoring return of Accountable Drugs Quality Return and Essential Quality Checks Form are completed and monitored Follow up issues identified during quality checks	Relevant District Manager Relevant District Manager Clinical Nurse Manager, Quality and Safety PPHC
	PPHC Big Rivers; EA & TE: Monitoring of iAuditor Quality Assurance Checks for the Accountable Drugs Quality Return and Essential Quality Checks Form Follow up issues identified during quality checks	Relevant District Manager Relevant District Manager Medication Safety Nurse Consultant PPHC Safety and Quality Manager PPHC
	Drug Storage Room audits are completed, with any recommendations followed up and monitored	Primary Health Care Manager Relevant District Manager PPHC Senior Pharmacist **PPHC CA & Barkly:** Clinical Nurse Manager, Quality and Safety **PPHC Big Rivers, EA & TE:** Safety and Quality Manager or Medication Safety Nurse

Key Associated Documents	
Key Legislation, By-Laws, Standards, Delegations, Aligned & Supporting Documents	Accountable Drugs Check PHC Remote Form – CAHS | TEHS Essential Quality Checks PHC Remote Forms – CAHS | TEHS S8 and RS4 Medicines Delivery Notification PHC Remote Form Medicines and Poisons Forms:

Key Associated Documents	
	- Application for Authority to Prescribe a Restricted S8 Psychostimulant Medication - Drug Loss Discrepancy Report Form - General Medications Contract - Notification of Supply of a UnRestricted S8 Substance Form RiskMan down time form (ONLY to be used in the event of outages) Dose Administration Aids PHC Remote Guideline Drug Storage Room Standards PHC Remote Guideline Emergency Equipment and Drugs Overview PHC Remote Guideline Issuing and Administering Medicines PHC Remote Guideline Pharmacy Audits PHC Remote Guideline Prescriptions PHC Remote Guideline Quality Assurance Overview PHC Remote Guideline Return of Unwanted Medicines PHC Remote Guideline Section 100 Pharmacy Arrangements PPHC Remote Guideline Section 250 NT MPTGA PPHC NT Health Remote Guideline Staff Access to Health Services PHC Remote Guideline Standard Drug List PHC Remote Guideline Emergency Kit Contents Lists: Emergency Outreach Drug Box Contents PPHC Remote List Fit Kit Contents PPHC Remote List Information Sheets: Medicines – The Seven Rights PHC Remote Information Sheet Midazolam for Emergency Kits PHC Remote Information Morphine for Emergency Outreach Drug Box PHC Remote Restricted Schedule 8 Psychostimulants Medicine Prescriptions PHC Remote Information Sheet Return or Disposal of Unwanted or Expired S8 / RS4 Medicines Information Sheet Schedule 8 and Restricted Schedule 4 Medicine Register Example PPHC Standard Drug List PHC Remote Master Document Unrestricted Schedule 8 Medicine Prescriptions PHC Remote Information Sheet RiskMan intranet site NT Health Staff Identification Policy NT *Medicines, Poisons and Therapeutic Goods Act 2012 (MPTGA) and Regulations 2014* NT *Health Practitioner Regulation (National Uniform Legislation) Act 2010* *Australian Government Therapeutic Goods Act 1989* Poisons Standard NT Medicines Management Framework DoH Medicines and Poisons Control website

Key Associated Documents	
	Medical Practitioners webpage: - Requirements of Prescriptions for S8 Substances - Code of Practice – Schedule 8 Substances: ~ Volume 1 - Issuing Prescriptions Supplying Schedule 8 Substances ~ Volume 2 - Storage & Transportation Pharmaceutical Benefits Scheme (PBS) - PBS-subsidised opiods – steps to prescribing - Revised opiods listings from June 2020 Gazette Notices (Section 250, 252, 254) – *provides links to relevant Gazettal Notices* Government Gazette G37 NT Government Primary Health Care Centres Revocation, Declarations and Approval Notice To access the standard *AS/NZS 3809:1998* go to Australian Standards Online Premium and search by the standard number Remote Primary Health Care Manuals website Guidelines for the handling of palliative care medicines in community services, 2020. Brisbane South Palliative Care Collaborative and NPS MedicineWise. Pharmacy Services DS2015/22 – October 2015 retention and disposal schedule.
References	As Above

Definitions, Acronyms and Alternative Search Terms	
Term	Description
Authorised Officer	For the purpose of this document this is a public sector employee with powers and functions as appointed by the Chief Health Officer (CHO).
Authorised Prescriber	a medical officer, nurse practitioner or other health practitioner (eg Dentist, Optometrist) who is authorised to issue a prescription under the *NT Medicines, Poisons and Therapeutic Goods Act 2012*, and issues the prescription in the course of practicing within their scope of practice.
Drug Storage Room	The dedicated room where medicines are kept in the health centre. (In accordance with the NT MPTGA a 'pharmacy' is defined as the premises or the part of premises in which a pharmacy business is carried on). See clause 1 of Schedule 7 to the NT *Health Practitioners Act 2004.*
Health Profession Manager	For the purpose of this document refers to the Director of Aboriginal and Torres Strait Islander Health Practitioners (ATSIHPs), Director of Nursing and Midwifery and PPHC Director Medical Services.
Possession of S8 Drug Safe and RS4 dedicated lockable cupboard keys	Possession is defined as held on the person and not stored in another location.
Schedule 8 and Restricted Schedule 4 Drug Register	A register required under the NT MPTGA to record the receipt, issue and tally of all Schedule 8 Medicines in a health centre. Note this register also provides a record for Restricted Schedule 4 Medicines.
Schedule 8 (S8) Medicines	S8 Medicines under the Poisons Standard in Australia are defined as: substances that should be available for use but require restrictions relating to manufacture,

Definitions, Acronyms and Alternative Search Terms	
	supply, distribution, possession and use to reduce abuse, misuse and physical or psychological dependence. Schedule 8 Medicines are further classified as UnRestricted or Restricted S8 Medicines. Restricted S8 Medicines are subject to further restrictions as declared by the Chief Health Officer (under section 246 of the NT MPTGA). S8 Medicines may also be referred to as Dangerous Drugs.
Scheduled Substance Treatment Protocol (SSTP)	is a protocol for possessing, supplying or administering a scheduled substance as approved by the Chief Health Officer under Section 254 of the *NT MPTGA 2012*.

National Safety and Quality Health Service Standards							
Clinical Governance	Partnering with Consumers	Preventing and Controlling Healthcare Associated Infection	Medication Safety	Comprehensive Care	Communicating for Safety	Blood Management	Recognising & Responding to Acute Deterioration
☒	☐	☐	☒	☐	☐	☐	☐